# Emergency Department Visits for Medical Device-Associated Adverse Events Among Children

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**KEY WORDS**
medical device, adverse events, emergency department

**ABBREVIATIONS**
MDAE—medical device-associated adverse event
NEISS—National Electronic Injury Surveillance System
AIP—All Injury Program
FDA—Food and Drug Administration
CPSC—Consumer Product Safety Commission
ED—emergency department
CI—confidence interval
CDRH—Center for Devices and Radiological Health

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**WHAT'S KNOWN ON THIS SUBJECT:** To our knowledge, national estimates and characterization of MDAEs in the pediatric population have not been reported.

**WHAT THIS STUDY ADDS:** The authors characterized the first national estimates of MDAEs from EDs in the pediatric population. The scope and severity of these MDAEs underscore the need for more-intensive preventive efforts.

## abstract

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**OBJECTIVES:** The purposes of this study were to provide national estimates of emergency department (ED) visits for medical device-associated adverse events (MDAEs) in the pediatric population and to characterize these events further.

**METHODS:** ED medical record reports from the National Electronic Injury Surveillance System All Injury Program database from January 1, 2004, through December 21, 2005, were reviewed. MDAEs among pediatric patients were identified, and data were abstracted. National estimates for pediatric MDAEs were determined according to medical specialty, device category and class, injury diagnosis, and patient characteristics and outcome.

**RESULTS:** The total estimated number of pediatric MDAEs during the 24-month period was 144 799 (95% confidence interval: 113 051–183 903), involving devices from 13 medical specialties. Contact lenses accounted for most MDAEs (23%), followed by hypodermic needles (8%). The distribution of MDAEs according to medical specialty varied according to age subgroup. The most-prevalent types of injuries included contusions/abrasions, foreign-body intrusions, punctures, lacerations, and infections. The most-frequently affected body parts were the eyeball, pubic region, finger, face, and ear. The majority of pediatric MDAEs involved class II (moderate-risk) devices. The incidence of pediatric MDAEs decreased with increasing age from early to late childhood and then spiked after 10 years of age. More girls than boys were affected at older ages (16–21 years) and more boys than girls at younger ages (≤10 years). Hospitalizations were more likely to involve invasive or implanted devices.

**CONCLUSIONS:** This study provides national estimates of pediatric MDAEs resulting in ED visits and highlights the need to develop interventions to prevent pediatric device-related injuries. *Pediatrics* 2010; 126:247–259

The Federal Food, Drug, and Cosmetic Act[1] defines a medical device as an instrument, apparatus, implement, machine, contrivance, implant, or in vitro reagent or similar article that is used to treat, to diagnose, or to prevent a disease or condition. The most important differences between a medical device and other medical products (such as drugs and biological products) are that (1) a device does not achieve any of its primary intended purposes through chemical action within or on the body and (2) a device is not dependent on being metabolized to achieve its primary intended purposes. In the United States, the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA) is responsible for reviewing, approving, and monitoring medical devices, including those used in the pediatric patient population.

The CDRH, in concert with the American Academy of Pediatrics,[2] defines the pediatric population as patients from birth to 21 years of age, including 4 age subgroups, that is, neonates (birth to 28 days), infants (28 days to 2 years), children (2–12 years), and adolescents (12–21 years). To facilitate the development of medical devices that address the needs of the pediatric population, the CDRH issued guidance regarding important considerations in its premarket assessment of medical devices for children.[3] New legislation, the Pediatric Medical Device Safety and Improvement Act of 2007 (part of the FDA Amendments Act of 2007), was introduced to encourage manufacturers to develop innovative medical devices to meet the unmet needs of children.[4] To identify potential areas for pediatric device development, the FDA Amendments Act of 2007 also mandated that manufacturers of higher-risk devices indicated primarily for adults provide a description of any pediatric subpopulations that may suffer from the disease or condition that the device is intended to treat, to diagnose, or to cure, as well as reporting the number of affected pediatric subjects.

Given the age range and dynamic nature of the pediatric population, assessment of the risks associated with the use of medical devices is more complicated in this population than in adults. The risk assessment for medical devices used for pediatric patients should consider both interpopulation and intrapopulation variability, as well as unique characteristics of this population, including anatomic, physiologic, and metabolic changes and difference in growth and development at various stages of life. In addition, there continues to be concern that many devices intended for adults are used in the pediatric population.[5] Concern about the adequacy of postmarket safety surveillance in the pediatric population led to an evaluation by the Institute of Medicine.[6] Among its many recommendations, the Institute of Medicine committee stressed the need for improved methods and tools for epidemiological research on medical device safety in general but most importantly in the pediatric population.

In the United States, injuries represent a major source of medical spending for the pediatric population.[7] To assess the public health burden of a subset of these injuries, namely, those associated with medical devices, the CDRH collaborated with the Consumer Product Safety Commission (CPSC). The CDRH used the National Electronic Injury Surveillance System (NEISS) All Injury Program (AIP) to collect data annually on medical device-associated adverse events (MDAEs) from a nationally representative sample of ~67 hospital emergency departments (EDs).[8] The purposes of this study are to provide national estimates of cases of MDAEs presenting to EDs among the pediatric population and to characterize these events. This should help to identify medical devices that may pose increased risks and patient subgroups that may benefit from certain health interventions.

## METHODS

### Data Source

The study population consisted of all patients who visited a NEISS AIP ED between January 1, 2004, and December 31, 2005, because of a MDAE. The NEISS is a statistical sample of ~100 of the ~5000 US hospital EDs open to the general public in the United States and its territories. The NEISS is stratified into 5 strata, that is, 4 strata based on the size of the ED (measured as the number of visits per year) and a fifth stratum for children's hospitals. On the basis of the sample design, an analysis weight is assigned to each case, which allows for national estimates to be made for any type of injury or group of interest. Weight adjustments are made on a monthly basis, to account for nonresponse of hospitals. A yearly adjustment is made to account for the opening, closing, and consolidation of EDs across the United States. Because estimates from the NEISS are estimates and not census counts, a variability or confidence interval (CI) exists for each estimate. In July 2000, with funding from the Centers for Disease Control and Prevention, the NEISS was expanded to collect data on all trauma-related visits to the ED. This expansion is known as the AIP. Budget constraints limited this expansion to a subsample of two-thirds of the NEISS. The FDA CDRH has provided funding to the CPSC each year to collect data on MDAEs in the NEISS AIP.[9,10] Historically, data from the NEISS have been used for consumer product safety alerts to prevent injuries related to safety issues such as fireworks injuries, infant walker design, drug-related adverse events, bicycle-

related injuries, falls (of children) from shopping carts, and unsafe trampoline use.[10–15] The consistency in methods and the national representativeness of the NEISS have made it an effective public health tool for the past several decades.

### Case Definitions and Measures

A MDAE was defined as an event in which a medical device was considered to have been involved (caused or contributed to the event). This definition includes problems involving not only the physical device itself but also its conditions of use (eg, use error, poor maintenance, or adverse environmental factors associated with use). This study includes data on MDAEs that caused patients to seek medical attention in NEISS AIP EDs.

During the 2-year period, CPSC-trained hospital representatives (NEISS AIP hospital coordinators) at each hospital reviewed clinical records for every ED visit. To facilitate their recognition of MDAE cases during data collection, NEISS AIP hospital coordinators were provided with medical device definitions and an updated list of examples of the wide variety of medical devices regulated by the FDA. For each MDAE case identified, information from ED records was reviewed and abstracted to produce a NEISS AIP case report, which consisted of a brief incident narrative and 13 coded variables (including age, gender, type of device, injury diagnosis, and patient disposition). The narrative statements often provided additional information regarding the injury circumstances.

### Statistical Analyses

According to the type of device involved in the event, each MDAE from the NEISS AIP was assigned to 1 of 15 medical specialties (eg, cardiology, neurology, or orthopedics) used for classification of medical devices by the FDA. Each medical specialty was further classified according to device categories. Because the NEISS AIP involves a probability sample of US hospitals with EDs that are open to the general public, estimated total numbers of MDAEs seen at EDs throughout the nation (referred to as national estimates) can be calculated by assigning each MDAE case a sample weight on the basis of the inverse probability of hospital selection, with adjustments for nonresponse and annual changes in the hospital frame. In this study, national estimates for the number of MDAEs were determined according to medical specialty, device category, and device classification, as well as patient demographic characteristics, injury diagnosis, and patient disposition. Estimates of MDAE incidence rates for the national population were calculated by using data from the 2000 US Census.[16] The proportion of MDAEs requiring hospitalization after ED evaluation was determined according to device category and injury diagnosis for each age subgroup. The national estimates and SEs were calculated by using SAS 9.1 (SAS Institute, Cary, NC) and SUDAAN (Research Triangle Institute, Research Triangle Park, NC), taking into account the weighting and complex survey design; 95% CIs were calculated for each estimate.

## RESULTS

In 2004 and 2005, 4266 MDAEs involving the US pediatric population were reported by the NEISS AIP. This reflected an estimated 144 799 ED visits (95% CI: 113 051–183 903 ED visits) for MDAEs in the pediatric population during the 24-month period. These MDAEs are summarized in Table 1 according to the FDA medical specialty panel and the most-popular device category for each specialty. Overall, devices from 13 of 15 medical specialties defined by the FDA were identified. Ophthalmology contributed the most MDAEs for pediatric patients. Other medical specialties that contributed >10% of MDAEs were general hospital, physical medicine, and obstetrics/gynecology. The device category of contact lenses accounted for the most MDAE cases (23%) among pediatric patients. Other device categories that accounted for >5% of MDAEs in this population were eyeglasses, hypodermic needles, wheelchairs/scooters, and pressure-equalizing tubes. Of note, in accordance with the disease profiles and use of devices among pediatric patients, the distribution of MDAEs according to medical specialty varied for the age subgroups. For children <5 years of age, the most reported MDAEs were from otolaryngology, followed by the gastrointestinal and general hospital categories. Cases related to obstetric/gynecologic devices were primarily seen only for children in the 11- to 15-year and 16- to 21-year subgroups. Ophthalmic devices accounted for 40% of all MDAEs seen among children ≥11 years of age, and a majority of cases were related to contact lenses; for children <11 years of age, most ophthalmic cases were related to eyeglasses.

A wide variety of injury diagnoses were related to pediatric MDAEs. Diagnoses that accounted for ≥1% of all pediatric MDAEs are summarized in Table 2. The most-frequent injury diagnosis was abrasion/contusion, followed by foreign-body intrusion, puncture, laceration, and infection. For each injury diagnosis listed in Table 2, the device category that contributed the most cases is indicated. The majority of poisoning cases were associated with shunts, intravascular or implanted catheters, implanted ports for chemotherapy, or infusion pumps, with MDAEs resulting from overmedication, overinfusion, or actions taken because of device malfunction or user errors.

Overall, the majority of pediatric MDAEs involved class II (moderate-

**TABLE 1** National Estimates of Pediatric MDAEs According to Medical Specialty and Patient Age Group

| Medical Specialty | No. of MDAEs, Estimate [95% CI] (%) | | | | | |
|---|---|---|---|---|---|---|
| | ≤2 y | 3–5 y | 6–10 y | 11–15 y | 16–21 y | Total |
| Ophthalmic | 783 (4) | 1318 (12) | 2698 (16) | 11 131 (39) | 29 884 (42) | 45 791 [33 926–59 594] (31) |
| Contact lenses (corneal abrasion, ulceration, conjunctivitis) | 23 (<1) | 23 (<1) | 186 (1) | 8514 (29) | 25 056 (35) | 33 779 [24 176–45 762] (23) |
| Eyeglasses (laceration to eye or face) | 720 (4) | 1276 (11) | 2483 (15) | 2176 (8) | 1375 (2) | 8031 [5908–10 856] (6) |
| Eye protection devices (corneal abrasion from device earpiece, foreign object in eye, photokeratitis) | 9 (<1) | 0 (0) | 0 (0) | 391 (1) | 3432 (5) | 3832 [1751–8246] (3) |
| General hospital | 2412 (14) | 1758 (15) | 3193 (19) | 2273 (8) | 11 518 (16) | 21 130 [17 442–25 444] (15) |
| Hypodermic needles with/without syringe (puncture) | 556 (3) | 962 (8) | 2194 (13) | 1139 (4) | 7096 (10) | 11 947 [8105–17 380] (8) |
| Intravenous catheters (hemorrhage, infection) | 911 (5) | 546 (5) | 680 (4) | 538 (2) | 1227 (2) | 3902 [1959–7673] (3) |
| Intravenous/infusion pumps (contusion from being struck by device, no analgesia, hypoglycemia/hyperglycemia from device malfunction) | 0 (0) | 72 (1) | 299 (2) | 244 (1) | 1182 (2) | 1796 [1119–2875] (1) |
| Examination tables, stretchers, lifts (contusion or laceration from falling from device, occupational hand/foot trauma) | 506 (3) | 23 (<1) | 0 (0) | 0 (0) | 1055 (1) | 1560 [950–2556] (1) |
| Hospital beds, bed rails (contusion or laceration from falling from, striking, or being struck by device) | 200 (1) | 10 (<1) | 11 (<1) | 9 (<1) | 570 (1) | 799 [329–1933] (1) |
| Equipment carts/stands, intravenous fluid poles (contusion or laceration from being struck by or falling over device) | 115 (1) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 115 [16–829] (<1) |
| Medical sterilizers (thermal/chemical burn) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 116 (<1) | 116 [16–860] (<1) |
| Other devices | 124 (1) | 146 (1) | 9 (<1) | 344 (1) | 273 (<1) | 873 [492–1546] (1) |
| Physical medicine | 2028 (12) | 1176 (10) | 3369 (20) | 5644 (20) | 6767 (10) | 18 961 [16 347–21 921] (13) |
| Wheelchairs, scooters (laceration, contusion, sprain) | 1148 (7) | 593 (5) | 1518 (9) | 2480 (9) | 3536 (5) | 9252 [6822–12 472] (6) |
| Casts, braces (paresthesia, abrasion, swelling from constrictive device) | 692 (4) | 211 (2) | 1109 (7) | 2133 (7) | 1005 (1) | 5149 [3460–7618] (4) |
| Crutches, canes, walkers (laceration, fracture, contusion) | 32 (<1) | 219 (2) | 639 (4) | 880 (3) | 1401 (2) | 3171 [2235–4486] (2) |
| Ice packs (chemical burn to application site) | 22 (<1) | 133 (1) | 0 (0) | 0 (0) | 120 (<1) | 275 [78–970] (<1) |
| Vibrators, massage devices (device as foreign body in perineal orifice) | 10 (<1) | 0 (0) | 85 (<1) | 0 (0) | 0 (0) | 95 [15–580] (<1) |
| Other devices | 125 (1) | 21 (<1) | 17 (<1) | 151 (<1) | 704 (1) | 943 [514–1725] (1) |
| Obstetrics/gynecology | 549 (3) | 108 (1) | 33 (<1) | 1936 (7) | 11 456 (16) | 14 082 [10 662–18 450] (10) |
| Contraceptive devices (potential unintended pregnancy because of tear in condom during coitus) | 85 (<1) | 23 (<1) | 0 (0) | 168 (1) | 3774 (5) | 4050 [2592–6294] (3) |
| Other devices (hymenal laceration from large speculum during pelvic examination) | 464 (3) | 85 (1) | 33 (<1) | 1768 (6) | 7682 (11) | 10 032 [7269–13 742] (7) |
| Dentistry | 956 (5) | 1137 (10) | 2133 (13) | 2683 (9) | 2491 (4) | 9400 [7170–12 262] (6) |
| Orthodontic braces/retainers (oral laceration) | 0 (0) | 330 (3) | 1378 (8) | 1803 (6) | 1428 (2) | 4939 [3689–6594] (3) |
| Toothbrushes (oral laceration) | 896 (5) | 300 (3) | 308 (2) | 156 (1) | 243 (<1) | 1902 [1090–3305] (1) |
| Dental instruments (puncture, laceration) | 20 (<1) | 107 (1) | 238 (1) | 666 (2) | 710 (1) | 1741 [1033–2923] (1) |
| Dental crowns/bridges (ingestion of broken device) | 40 (<1) | 381 (3) | 169 (1) | 19 (<1) | 42 (<1) | 652 [271–1562] (<1) |
| Dental fillings (pain from loss of device) | 0 (0) | 20 (<1) | 30 (<1) | 38 (<1) | 22 (<1) | 110 [33–367] (<1) |
| Otolaryngology | 3947 (22) | 2784 (24) | 1962 (12) | 306 (1) | 352 (<1) | 9350 [4360–19 276] (6) |
| Ear tubes (device-associated otitis media) | 3741 (21) | 2761 (24) | 1704 (10) | 245 (1) | 320 (<1) | 8771 [3854–19 119] (6) |
| Hearing aids (device/part as unretrievable foreign body in ear canal) | 116 (1) | 23 (<1) | 247 (1) | 42 (<1) | 0 (0) | 428 [166–1102] (<1) |
| Other ear/nose/throat devices (tympanic membrane puncture from ear medication dropper) | 89 (1) | 0 (0) | 10 (<1) | 20 (<1) | 32 (<1) | 151 [48–476] (<1) |

**TABLE 1** Continued

| Medical Specialty | No. of MDAEs, Estimate [95% CI] (%) | | | | | |
|---|---|---|---|---|---|---|
| | ≤2 y | 3–5 y | 6–10 y | 11–15 y | 16–21 y | Total |
| General or plastic surgery | 1014 (6) | 923 (8) | 1228 (7) | 1389 (5) | 4092 (6) | 8646 [6122–12 119] (6) |
| Incision/wound retention devices (incision/wound dehiscence from broken sutures, infected suture/staple site) | 808 (5) | 811 (7) | 1151 (7) | 932 (3) | 2362 (3) | 6063 [3620–10 038] (4) |
| Medical/surgical instruments (laceration or puncture from scalpel, lancet, or suture needle) | 32 (<1) | 102 (1) | 0 (0) | 283 (1) | 1203 (2) | 1620 [819–3187] (1) |
| Other devices (swelling or infection from occluded surgical drain) | 175 (1) | 10 (<1) | 77 (<1) | 173 (1) | 526 (1) | 962 [513–1799] (1) |
| Gastroenterology/urology | 3005 (17) | 696 (6) | 688 (4) | 750 (3) | 1603 (2) | 6740 [3180–13 897] (5) |
| Urinary catheters (urinary retention with/without tract infection from occluded device, urinary tract hemorrhage) | 57 (<1) | 139 (1) | 60 (<1) | 49 (<1) | 277 (<1) | 582 [240–1411] (<1) |
| Dialysis blood access devices (hemorrhage or infection at device insertion site) | 10 (<1) | 10 (<1) | 43 (<1) | 85 (<1) | 53 (<1) | 201 [85–473] (<1) |
| Kidney dialysis systems (respiratory distress/chest pain while using device) | 0 (0) | 0 (0) | 0 (0) | 43 (<1) | 23 (<1) | 66 [16–275] (<1) |
| Other devices (severe pain with/without infection after stent placement) | 2928 (17) | 547 (5) | 585 (3) | 573 (2) | 1249 (2) | 5881 [2689–12 533] (4) |
| Neurology | 1267 (7) | 800 (7) | 1052 (6) | 1286 (4) | 1044 (1) | 5449 [1895–14 973] (4) |
| Ventriculoperitoneal shunts (hydrocephalus or symptoms from device malfunction) | 1246 (7) | 800 (7) | 1001 (6) | 1258 (4) | 959 (1) | 5265 [1784–14 838] (4) |
| Other devices | 21 (<1) | 0 (0) | 50 (<1) | 28 (<1) | 85 (<1) | 154 [53–446] (<1) |
| Cardiology | 793 (4) | 333 (3) | 249 (1) | 422 (1) | 142 (<1) | 1940 [765–4858] (1) |
| Pacemakers, internal defibrillators (dyspnea, weakness, or syncope from device malfunction) | 33 (<1) | 20 (<1) | 33 (<1) | 74 (<1) | 27 (<1) | 188 [48–728] (<1) |
| Other cardiovascular devices (chest/groin pain after cardiac catheter use or cardiovascular stent placement) | 760 (4) | 313 (3) | 216 (<1) | 348 (1) | 114 (<1) | 1742 [712–4217] (1) |
| Anesthesiology | 727 (4) | 187 (2) | 130 (1) | 416 (1) | 430 (1) | 1890 [954–3721] (1) |
| Respiratory devices (contusion from striking or being struck by oxygen tube, dyspnea from occluded/displaced tracheostomy tube) | 727 (4) | 177 (2) | 120 (1) | 308 (1) | 280 (<1) | 1612 [728–3543] (1) |
| Other devices | 0 (0) | 10 (<1) | 10 (<1) | 108 (<1) | 150 (<1) | 278 [88–874] (<1) |
| Orthopedics | 10 (<1) | 73 (1) | 184 (1) | 635 (2) | 527 (1) | 1429 [776–2624] (1) |
| Orthopedic fixation devices (pain with/without infection) | 0 (0) | 73 (1) | 184 (1) | 518 (2) | 384 (1) | 1170 [550–2473] (1) |
| Prosthetic devices (dislocation of prosthetic hip) | 10 (<1) | 0 (0) | 0 (0) | 116 (<1) | 0 (0) | 116 [15–890] (<1) |
| Other devices | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 143 (<1) | 120 [17–865] (<1) |
| Radiology | 137 (1) | 120 (1) | 0 (0) | 0 (0) | 388 (1) | 645 [233–1773] (<1) |
| Diagnostic/therapeutic radiation devices (contusion or laceration from striking or being struck by radiograph machine | 137 (1) | 0 (0) | 0 (0) | 0 (0) | 379 (1) | 516 [157–1684] (<1) |
| Other devices | 0 (0) | 120 (1) | 0 (0) | 0 (0) | 9 (<1) | 129 [20–833] (<1) |
| Total | 17 458 (100) | 11 348 (100) | 16 901 (100) | 28 691 (100) | 70 400 (100) | 144 799 [113 051–183 903] (100) |

Estimates of <1200 may be potentially unstable.

risk) devices, and only 1.4% of devices were high-risk class III (Fig 1). In a comparison between age groups, the proportion of cases involving class III devices increased from 0.6% for infants (≤2 years of age) to 1.6% for adolescents (16–21 years of age). Although almost one-half of MDAEs seen for children 6 to 10 years of age were related to low-risk class I devices, only 24% of cases seen for adolescents (16–21 years of age) were.

Overall, the most-frequently affected body part was the eyeball, followed by the pubic region, finger, face, ear, head, and lower trunk (Table 3). In accordance with the use of devices, the distribution of MDAEs differed among age subgroups. For children <2 years of age, the most-affected body parts were the ear, toe, head, pubic region, and upper trunk, which was similar to findings for children 2 to 5 years of

**TABLE 2** National Estimates of Pediatric MDAEs According to Injury Diagnosis, Most Prevalent Device Category, and Age Group

| Injury Diagnosis | ≤2 y | | 3–5 y | | 6–10 y | | 11–15 y | | 16–21 y | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | No. of MDAEs, Estimate (%) | Most Prevalent Device (%) | No. of MDAEs, Estimate (%) | Most Prevalent Device (%) | No. of MDAEs, Estimate (%) | Most Prevalent Device (%) | No. of MDAEs, Estimate (%) | Most Prevalent Device (%) | No. of MDAEs, Estimate (%) | Most Prevalent Device (%) | No. of MDAEs, Estimate [95% CI] (%) | Most Prevalent Device (%) |
| Contusions, abrasion | 1457 (8) | Mechanical wheelchair (22) | 688 (6) | Mechanical wheelchair (40) | 1888 (11) | Mechanical wheelchair (25) | 7997 (28) | Soft contact lenses (58) | 17 700 (25) | Soft contact lenses (70) | 29 729 [22 104–39 146] (21) | Soft contact lenses (57) |
| Foreign-body intrusion | 117 (1) | Tympanostomy tube (28) | 172 (2) | Tympanostomy tube (38) | 562 (3) | Contact lenses (27) | 3050 (11) | Menstrual tampon (53) | 13 953 (20) | Menstrual tampon (50) | 17 855 [13 371–23 573] (12) | Menstrual tampon (48) |
| Puncture | 416 (2) | Hypodermic needle (58) | 929 (8) | Hypodermic needle (77) | 1991 (12) | Hypodermic needle (89) | 929 (3) | Hypodermic needle (90) | 7350 (10) | Hypodermic needle (77) | 11 615 [7960–16 742] (8) | |
| Laceration | 2072 (12) | Mechanical wheelchair (23) | 2065 (18) | Eyeglass frame (44) | 2697 (16) | Eyeglass frame (54) | 2522 (9) | Orthodontic metal bracket (26) | 2212 (3) | Orthodontic metal bracket (18) | 11 568 [8906–14 940] (8) | Eyeglass frame (29) |
| Infection | 3063 (17) | Tympanostomy tube (75) | 2374 (21) | Tympanostomy tube (75) | 2068 (12) | Tympanostomy tube (70) | 1214 (4) | Nonabsorbable suture (35) | 2079 (3) | Nonabsorbable suture (40) | 10 798 [4625–23 812] (7) | Tympanostomy tube (54) |
| Dermatitis/ conjunctivitis | 166 (1) | Bandage cast (31) | 29 (<1) | Coronary stent (37) | 81 (<1) | Soft lenses (29) | 1741 (6) | Soft contact lenses (72) | 6573 (9) | Soft contact lenses (75) | 8590 [6067–12 071] (6) | Soft contact lenses (72) |
| Poisoning | 510 (3) | Intravascular catheter (47) | 604 (5) | Implanted catheter (40) | 687 (4) | Infusion pump (31) | 421 (1) | Implanted catheter (36) | 1509 (2) | Insulin infusion pump (52) | 3731 [1805–7604] (3) | Insulin infusion pump (30) |
| Pain | 339 (2) | Tympanostomy tube (42) | 135 (1) | Tympanostomy tube (35) | 618 (4) | Hearing aid (19) | 742 (3) | Cast bandage (35) | 2121 (3) | Soft contact lenses (30) | 3956 [2431–6394] (3) | Soft contact lenses (16) |
| Strain, sprain | 127 (1) | Stationary radiographic system (100) | 11 (<1) | Traction device (100) | 255 (2) | Mechanical walker (61) | 566 (2) | Crutch (32) | 2471 (4) | Mechanical wheelchair (61) | 3430 [2248–5211] (2) | Mechanical wheelchair (29) |
| Fracture | 447 (3) | Hand splint (34) | 238 (2) | Radiology table (51) | 472 (3) | Eyeglass frame (25) | 1573 (5) | Mechanical wheelchair (31) | 270 (<1) | Cast bandage (31) | 2977 [2219–3987] (2) | Mechanical wheelchair (26) |
| Dental injury | 60 (<1) | Toothbrush (53) | 141 (1) | Preformed crown (78) | 616 (4) | Space maintainer (25) | 372 (1) | Orthodontic wire (42) | 158 (<1) | Orthodontic metal bracket (66) | 1346 [642–2808] (1) | Orthodontic metal bracket (27) |
| Ingestion | 358 (2) | Piston syringe (33) | 497 (4) | Space maintainer (59) | 80 (<1) | Preformed crown (27) | 250 (1) | Screw expansion retainer (57) | 153 (<1) | Screw expansion retainer (79) | 1338 [796–2243] (1) | Space maintainer (23) |
| Internal injury | 348 (2) | Portable liquid-oxygen unit (33) | 44 (<1) | CNS shunt (53) | 100 (1) | Mechanical wheelchair (50) | 107 (<1) | Mechanical wheelchair (26) | 532 (1) | Blood lancet (16) | 1130 [680–1876] (1) | Portable liquid-oxygen unit (10) |
| Radiation | 0 (0) | | 0 (0) | | 0 (0) | | 23 (<1) | Infrared lamp (100) | 1012 (1) | Ophthalmic eye shield (60) | 1035 [472–2262] (1) | Ophthalmic eye shield (58) |
| Hemorrhage | 622 (4) | Eyeglass frame (41) | 57 (<1) | Gastrointestinal tube (19) | 49 (<1) | Intravascular catheter (22) | 208 (1) | Eyeglass frame (61) | 80 (<1) | Soft contact lenses (38) | 1015 [503–2041] (1) | Eyeglass frame (38) |
| Other | 6951 (40) | Gastrointestinal tube (31) | 3312 (29) | Tympanostomy tube (24) | 4232 (25) | CNS shunt (21) | 6312 (22) | Soft contact lenses (18) | 11 326 (16) | Soft contact lenses (28) | 32 088 [22 310–44 593] (22) | CNS shunt (15) |

CNS indicates central nervous system.

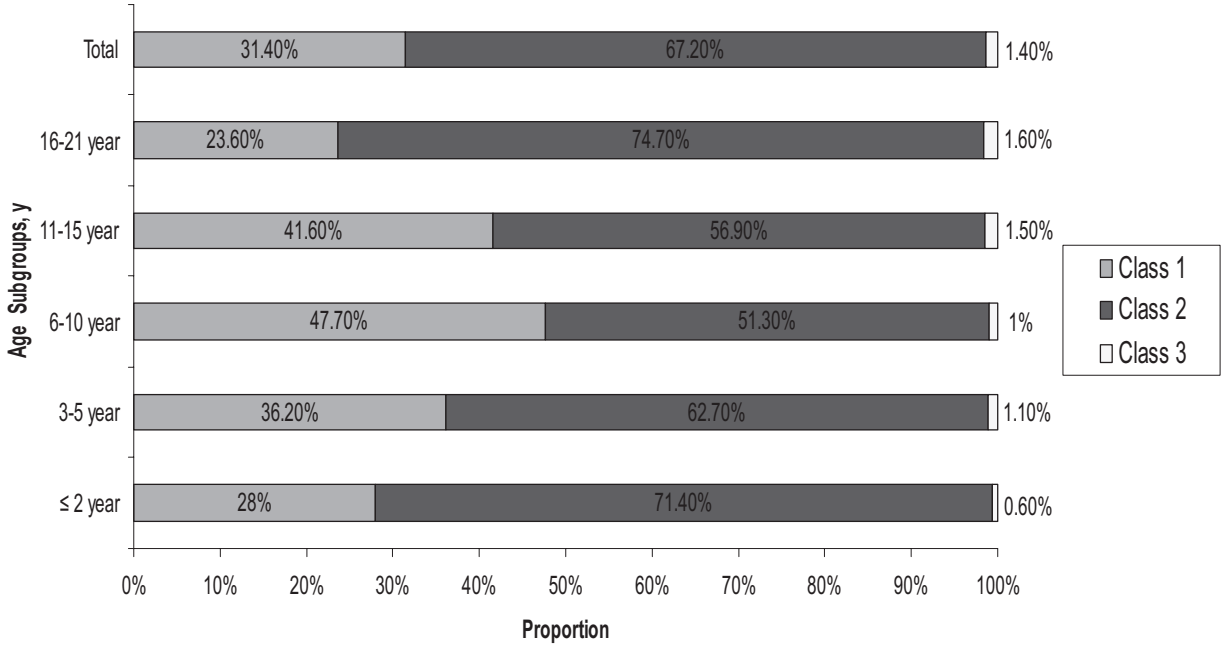


**FIGURE 1**
Pediatric MDAEs according to device class and patient age group.

**TABLE 3** National Estimates of Pediatric MDAEs According to Affected Patient Body Part and Age Group

| Affected Body Part | No. of MDAEs, Estimate [95% CI] (%) | | | | | |
|---|---|---|---|---|---|---|
| | ≤2 y | 3–5 y | 6–10 y | 11–15 y | 16–21 y | Total |
| Eyeball | 1655 (9) | 603 (5) | 705 (4) | 9023 (31) | 27 999 (40) | 38 200 [27 940–50 599] (26) |
| Pubic region | 2075 (12) | 1311 (12) | 206 (1) | 1941 (7) | 10 802 (15) | 13 254 [10 057–17 335] (9) |
| Finger | 27 (<1) | 177 (2) | 1488 (9) | 1426 (5) | 7591 (11) | 11 391 [8097–15 869] (8) |
| Face | 438 (2) | 59 (1) | 2162 (13) | 2189 (8) | 1800 (3) | 9933 [8294–11 868] (7) |
| Ear | 3810 (22) | 2778 (24) | 2254 (13) | 285 (1) | 460 (1) | 9587 [4611–19 196] (7) |
| Head | 2207 (13) | 1575 (14) | 1337 (8) | 1695 (6) | 1869 (3) | 8287 [4884–13 827] (6) |
| Lower trunk | 215 (1) | 43 (<1) | 1055 (6) | 1223 (4) | 3253 (5) | 7790 [5144–11 682] (5) |
| Mouth | 667 (4) | 168 (1) | 1742 (10) | 2361 (8) | 1837 (3) | 7629 [5525–10 473] (5) |
| All body parts | 262 (1) | 415 (4) | 1008 (6) | 1038 (4) | 2034 (3) | 5740 [2761–11 669] (4) |
| Upper trunk | 1713 (10) | 36 (<1) | 515 (3) | 659 (2) | 1144 (2) | 4423 [2302–8385] (3) |
| Lower arm | 85 (<1) | 108 (1) | 522 (3) | 1051 (4) | 2375 (3) | 4312 [3158–5870] (3) |
| Hand | 230 (1) | 151 (1) | 783 (5) | 519 (2) | 1991 (3) | 3752 [2606–5383] (3) |
| Lower leg | 127 (1) | 26 (<1) | 500 (3) | 1072 (4) | 1244 (2) | 3045 [2201–4204] (2) |
| Wrist | 270 (2) | 147 (1) | 17 (<1) | 664 (2) | 1030 (1) | 2090 [1202–3616] (1) |
| Neck | 326 (2) | 560 (5) | 265 (2) | 189 (1) | 766 (1) | 2055 [1261–3337] (1) |
| Foot | 870 (5) | 788 (7) | 271 (2) | 585 (2) | 612 (1) | 1849 [1192–2859] (1) |
| Knee | 204 (1) | 49 (<1) | 185 (1) | 458 (2) | 879 (1) | 1669 [1132–2455] (1) |
| Upper leg | 378 (2) | 81 (1) | 510 (3) | 550 (2) | 164 (<1) | 1649 [1067–2543] (1) |
| Upper arm | 193 (1) | 232 (2) | 276 (2) | 380 (1) | 590 (1) | 1504 [908–2484] (1) |
| Ankle | 294 (2) | 10 (<1) | 329 (2) | 272 (1) | 299 (<1) | 1054 [634–1748] (1) |
| Toe | 3810 (22) | 2778 (24) | 41 (<1) | 170 (1) | 353 (1) | 769 [425–1387] (1) |

age. For children 6 to 10 years of age, the most-frequently affected body parts were the face, ear, mouth, and finger. The profile changed again for children 11 to 15 years and 16 to 21 years of age, with the eyeball, pubic region, and finger being the most-frequently affected body parts.

Of all pediatric MDAEs, 49% occurred among adolescents (16–21 years of age), followed by children 11 to 15 years (20%), ≤2 years (12%), 6 to 10 years (12%), and 3 to 5 years (8%) of age. On the basis of US Census population estimates, the pediatric MDAE incidence trend is shown in Fig 2. The rate decreased with increasing age until 6 to 10 years and then increased abruptly. The incidence rate of MDAEs at 16 to 21 years of age was significantly higher than the rates for all other age subgroups.

Overall, the prevalence of pediatric MDAEs was higher for girls than for

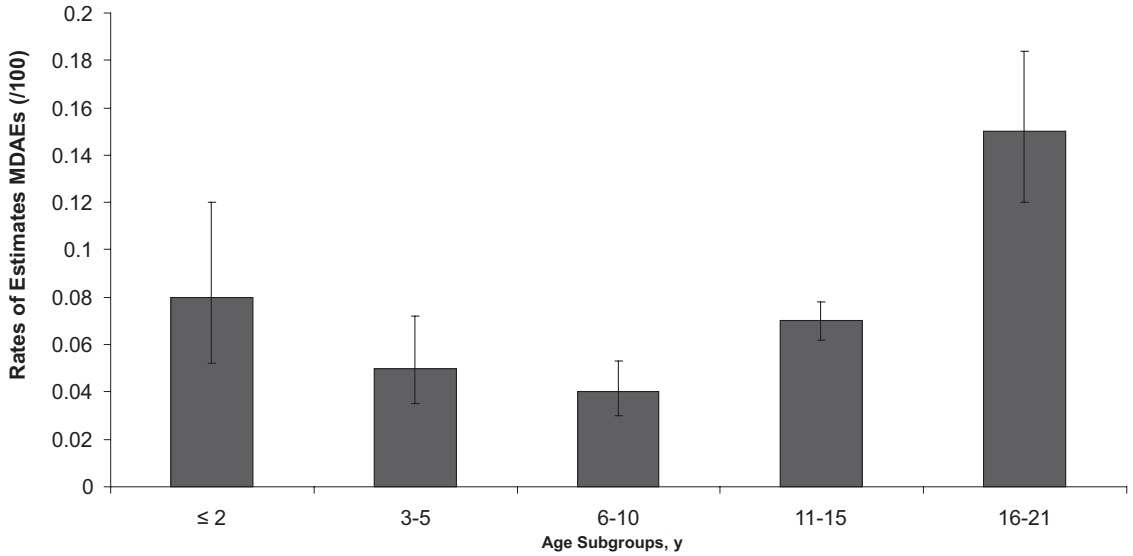


**FIGURE 2**
Incidence rates of pediatric MDAEs according to age group.

boys (Table 4). However, this gender difference was reversed for the youngest groups; more MDAEs were reported for boys than for girls at ≤10 years of age. The numbers of MDAEs were almost equal between genders at 11 to 15 years, and there were significantly more cases for girls than for boys at 16 to 21 years. Among cases for which the location where the event occurred was reported, the majority of MDAEs occurred at home, followed by public property and schools. Interestingly, an estimated 2673 MDAEs occurred at industrial sites, all among persons 16 to 21 years of age, and might be work-related. For >90% of MDAEs seen in EDs, the patients were released after examination and treatment. Overall, 6.3% (95% CI: 2.1%–17.5%) of patients presenting to EDs with MDAEs were hospitalized. With increasing age, the likelihood of being hospitalized decreased. The proportion of hospitalizations decreased from 13% (95% CI: 5.3%–28.0%) for children <2 years of age to 2.5% (95%

**TABLE 4** National Estimates of Pediatric MDAEs According to Patient Demographic and Event Characteristics

| Characteristic | No. of MDAEs, Estimate [95% CI] (%) | | | | | |
|---|---|---|---|---|---|---|
| | ≤2 y | 3–5 y | 6–10 y | 11–15 y | 16–21 y | Total |
| Patient gender | | | | | | |
| Female | 8067 (46) | 4792 (42) | 7345 (43) | 13 938 (49) | 44 222 (63) | 78 294 [72 821–83 701] (54) |
| Male | 9461 (54) | 6556 (58) | 9556 (57) | 14 764 (51) | 26 298 (37) | 66 635 [61 228–72 107] (46) |
| Location of event | | | | | | |
| Unknown | 8325 (47) | 5340 (47) | 7251 (43) | 12 201 (43) | 24 269 (34) | 57 363 [38 475–78 671] (40) |
| Home | 7005 (40) | 4517 (40) | 6010 (36) | 11 500 (40) | 26 727 (38) | 55 758 [40 763–72 434] (38) |
| Public property | 1893 (11) | 730 (6) | 929 (5) | 1386 (5) | 12 958 (18) | 17 851 [12 739–24 632] (12) |
| School | 20 (<1) | 294 (3) | 1296 (8) | 1992 (7) | 1723 (2) | 5325 [4080–6932] (4) |
| Sports | 143 (1) | 208 (2) | 920 (5) | 1051 (4) | 1013 (1) | 3336 [2313–4796] (2) |
| Industrial site | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 2673 (4) | 2673 [1101–6390] (2) |
| Street | 140 (1) | 258 (2) | 495 (3) | 571 (2) | 925 (1) | 2390 [1395–4073] (2) |
| Patient disposition | | | | | | |
| Treated and released or examined and released without treatment | 14 856 (85) | 9639 (85) | 14 871 (88) | 25 738 (90) | 67 387 (96) | 132 444 [118 720–139 321] (91) |
| Treated and admitted for hospitalization | 2254 (13) | 1399 (12) | 1704 (10) | 1977 (7) | 1771 (3) | 9082 [2990–25 373] (6) |
| Left without being seen or left against medical advice | 198 (1) | 216 (2) | 168 (1) | 313 (1) | 1083 (2) | 1979 [1223–3190] (1) |
| Treated and transferred to another hospital | 138 (1) | 10 (<1) | 157 (1) | 399 (1) | 270 (<1) | 974 [494–1913] (1) |
| Held for observation | 72 (<1) | 85 (1) | 0 (0). | 147 (1) | 10 (<1) | 314 [110–895] (<1) |
| Deaths (dead on arrival or died in ED) | 0 (0) | 0 (0) | 0 (0) | 127 (<1) | 0 (0) | 127 [16–988] (<1) |

CI: 1.0%–6.2%) for adolescents 16 to 21 years of age. One death was reported, a suicide in which the patient was found dead at home with a blood pressure cuff around the neck.

A total of 9082 estimated pediatric MDAEs involved hospitalization. As shown in Table 5, the number of cases involving hospitalization tended to be greatest for patients using invasive or implanted devices, such as ventriculoperitoneal shunts (3340 cases [95% CI: 2882–3756 cases]), implanted intravascular catheters (901 cases [95% CI: 439–1243 cases]), gastrointestinal tubes (718 cases [95% CI: 305–1509 cases]), or tracheostomy tubes (315 cases [95% CI: 165–511 cases]). The injury diagnosis associated with the largest proportion of hospitalizations was poisoning. Other types of injuries with ≥10% of patients being hospitalized were anoxia, fractures, hemorrhage, aspiration, and infections.

The profiles of device categories and injury diagnoses associated with large numbers of hospitalizations were similar between age subgroups (Tables 6 and 7). Ventriculoperitoneal shunts contributed to the largest numbers of hospitalizations across all age groups. Intravenous catheters were among the devices associated with the largest proportions of hospitalizations for almost all age groups, except 16 to 21 years. In addition, the devices with the largest proportions of hospitalizations were kidney dialysis devices for children ≥11 years of age and pacemakers and internal defibrillators for children 3 to 10 years of age.

**TABLE 5** Leading Device Categories and Injury Diagnoses for Pediatric MDAEs, According to Proportion of Hospitalizations

| | No. of Hospitalizations | Proportion of Hospitalizations, Estimate (95% CI) |
|---|---|---|
| Device | | |
| Ostomy appliances (infection or inflammation at device insertion site) | 10 | 100 |
| Artificial heart valves (dyspnea after recent device placement) | 10 | 100 |
| Kidney dialysis systems (respiratory distress/chest pain while using device) | 56 | 85 (35–98) |
| Ventriculoperitoneal shunts (hydrocephalus from or symptoms of device malfunction) | 3340 | 63 (55–71) |
| Other cardiovascular devices (chest/groin pain after cardiac catheter use or cardiovascular stent placement) | 899 | 52 (21–81) |
| Pacemakers, internal defibrillators (dyspnea, weakness, syncope from device malfunction) | 73 | 39 (31–47) |
| Intravenous catheters (hemorrhage or infection at device insertion site, phlebitis) | 1480 | 38 (14–69) |
| Respiratory devices (contusion from striking or being struck by oxygen tube, dyspnea from occluded/displaced tracheostomy tube) | 384 | 24 (8–52) |
| Intravenous/infusion pumps (contusion from being struck by device, no analgesia, hypoglycemia/hyperglycemia from device malfunction) | 396 | 22 (9–45) |
| Other gastroenterologic/urologic devices (severe pain with/without infection after stent placement) | 965 | 16 (7–33) |
| Dialysis blood access devices (hemorrhage or infection at device insertion site) | 20 | 10 (1–45) |
| Orthopedic fixation devices (pain with/without infection at pin/screw/wire/rod insertion site) | 114 | 10 (5–17) |
| Injury diagnosis | | |
| Poisoning | 1752 | 47 (17–80) |
| Anoxia | 40 | 23 (3–76) |
| Fracture | 480 | 16 (9–27) |
| Other | 5044 | 16 (6–34) |
| Hemorrhage | 120 | 12 (4–29) |
| Aspiration | 21 | 11 (2–40) |
| Infection | 1019 | 9 (4–21) |
| Internal injury | 55 | 5 (1–15) |
| Pain | 142 | 4 (1–12) |
| Dental injury | 20 | 1 (0–5) |
| Laceration | 135 | 1 (0–4) |
| Puncture | 102 | 1 (0–4) |
| Ingestion | 10 | 1 (0–6) |

## DISCUSSION

The FDA uses various tools to assess medical device safety and effectiveness in the postmarket period. The CDRH Medical Device Reporting System, a passive surveillance system, collects data on MDAEs and product problems from both mandatory reporters (eg, manufacturers and user facilities) and voluntary reporters (eg, health care professionals).[17,18] The CDRH also actively pursues other means of device postmarket surveillance, such as through its postapproval study program (primarily observational studies of the highest-risk devices) and establishment of collaborations with other stakeholders through postmarket registries and population-based observational studies. The collaboration of the FDA with the CPSC to collect MDAEs seen in EDs is part of the effort to monitor and to assess possible associations between adverse events and medical devices.

Injury is currently the number 1 cause of death for children in the United States, being responsible for ~16 000 deaths each year. More than 70% of

**TABLE 6** Leading Device Categories, on the Basis of Proportions of Hospitalizations, According to Age Group

| ≤2 y | | 3–5 y | | 6–10 y | | 11–15 y | | 16–21 y | |
|---|---|---|---|---|---|---|---|---|---|
| Device | Proportion of Hospitalizations, % (*n*) | Device | Proportion of Hospitalizations, % (*n*) | Device | Proportion of Hospitalizations, % (*n*) | Device | Proportion of Hospitalizations, % (*n*) | Device | Proportion of Hospitalizations, % (*n*) |
| Ostomy appliances | 100 (10) | Pacemakers, internal defibrillators | 100 (20) | Pacemakers, internal defibrillators | 70 (23) | Kidney dialysis systems | 77 (33) | Kidney dialysis systems | 100 (23) |
| Orthopedic fixation devices | 100 (10) | Artificial heart valves | 100 (10) | Intravenous catheters | 63 (428) | Ventriculoperitoneal shunts | 63 (795) | Ventriculoperitoneal shunts | 61 (580) |
| Ventriculoperitoneal shunts | 70 (871) | Other cardiovascular devices | 76 (229) | Other cardiovascular devices | 60 (129) | Other neurologic devices | 56 (11) | Other ophthalmic devices | 50 (10) |
| Other cardiovascular devices | 44 (332) | Intravenous catheters | 73 (400) | Ventriculoperitoneal shunts | 60 (598) | Other cardiovascular devices | 52 (181) | Dialysis blood access devices | 38 (20) |
| Pacemakers, internal defibrillators | 30 (10) | Ventriculoperitoneal shunts | 62 (496) | Respiratory devices | 45 (55) | Intravenous catheters | 50 (268) | Pacemakers, internal defibrillators | 37 (10) |
| Intravenous catheters | 29 (268) | Crutches, canes, walkers | 37 (80) | Other surgical devices | 25 (19) | Respiratory devices | 40 (125) | Intravenous/infusion pumps | 26 (306) |
| Respiratory devices | 15 (111) | Respiratory devices | 32 (57) | Other gastroenterologic/ urologic devices | 24 (142) | Other gastroenterologic/ urologic devices | 27 (153) | Other cardiovascular devices | 25 (28) |
| Other gastroenterologic/ urologic devices | 15 (436) | Intravenous/infusion pumps | 28 (20) | Orthopedic fixation devices | 19 (36) | Pacemakers, internal defibrillators | 13 (10) | Other anesthesiologic devices | 15 (23) |
| Other surgical devices | 15 (26) | Other gastroenterologic/ urologic devices | 13 (68) | Urinary catheters | 17 (10) | Crutches, canes, walkers | 12 (103) | Other gastroenterologic/ urologic devices | 13 (165) |
| Toothbrushes | 11 (102) | Incision/wound retention devices | 6 (48) | Intravenous/infusion pumps | 16 (49) | Orthopedic fixation devices | 10 (51) | Respiratory devices | 13 (36) |

**TABLE 7** Leading Injury Diagnoses, on the Basis of Proportions of Hospitalizations, According to Age Group

| ≤2 y | | 3–5 y | | 6–10 y | | 11–15 y | | 16–21 y | |
|---|---|---|---|---|---|---|---|---|---|
| Injury Diagnosis | Proportion of Hospitalizations, % (*n*) | Injury Diagnosis | Proportion of Hospitalizations, % (*n*) | Injury Diagnosis | Proportion of Hospitalizations, % (*n*) | Injury Diagnosis | Proportion of Hospitalizations, % (*n*) | Injury Diagnosis | Proportion of Hospitalizations, % (*n*) |
| Anoxia | 100 (10) | Anoxia | 100 (9) | Poisoning | 36 (247) | Poisoning | 67 (282) | Hemorrhage | 36 (29) |
| Poisoning | 80 (409) | Poisoning | 68 (413) | Hemorrhage | 22 (11) | Aspiration | 66 (21) | Poisoning | 27 (400) |
| Dental injury | 17 (10) | Fracture | 34 (80) | Fracture | 19 (90) | Internal injury | 18 (19) | Infection | 14 (296) |
| Other | 19 (1313) | Hemorrhage | 15 (9) | Other | 25 (1045) | Fracture | 18 (283) | Fracture | 10 (27) |
| Dermatitis/conjunctivitis | 11 (19) | Other | 24 (792) | Internal injury | 17 (17) | Other | 17 (1102) | Other | 7 (793) |
| Infection | 10 (315) | Laceration | <1 (9) | Ingestion | 12 (10) | Anoxia | 15 (22) | Laceration | 2 (46) |
| Hemorrhage | 7 (43) | Infection | 4 (88) | Infection | 8 (156) | Hemorrhage | 14 (29) | Pain | 2 (49) |
| Puncture | 5 (22) | | | Pain | 6 (37) | Infection | 13 (164) | Internal injury | 2 (9) |
| Fracture | 5 (23) | | | Puncture | 4 (80) | Pain | 8 (57) | Contusions, abrasion | 1 (113) |
| Laceration | 4 (80) | | | Dental injury | 2 (10) | | | Dermatitis/conjunctivitis | <1 (10) |
| Internal injury | 3 (10) | | | | | | | | |

these deaths are attributable to unintentional injuries.[19] To date, however, there has been no comprehensive report of medical device-associated injuries among children. Our study estimated that 144 799 medical device-associated injuries in the pediatric population were seen in EDs throughout the nation during this 2 year period, accounting for ~0.7% of the national estimate of unintentional injuries for children 0 to 21 years of age seen in EDs ($n$ = 20 152 184 [95% CI: 17 397 609–22 906 759]).[20] Also, our study showed that the public health burden of pediatric MDAEs treated in EDs is carried primarily by adolescents 16 to 21 years of age, who accounted for almost one-half of the national estimate, followed by children 11 to 15 years of age, who accounted for another 20% of the total national estimate of pediatric MDAEs. Finer division according to age group did not change the MDAE distribution pattern. The risk of MDAEs among adolescents 16 to 21 years of age was twice the risk of MDAEs among children 11 to 15 years of age and 3 times the risk of MDAEs among children 3 to 10 years of age. Interestingly, this is consistent with the general incidence of unintentional injuries among children and adolescents in the United States, for which rates are highest among adolescents 15 to 19 years of age.[21]

We determined that almost one-third of the total pediatric MDAEs involved ophthalmic devices and more than one-fifth of the cases involved 1 device category, namely, contact lenses. In addition, the majority of contact lens-related adverse events occurred among children ≥11 years of age; this is in concert with the current practice of prescribing contact lenses for children. In our study, the most-frequently reported injury diagnoses resulting from contact lenses were corneal contusions/abrasions, conjunctivitis, and hemorrhage, which are well-documented contact lens injuries.[22] These injuries were generally superficial and did not require hospitalization. This information is important in addressing pediatric MDAEs overall, because many eye injuries related to contact lenses can be prevented.[23,24] Common patient factors related to contact lens complications include alteration of the recommended wearing or replacement schedules and noncompliance with recommended contact lens wear and care regimens.[24] Practitioners should review the replacement and cleaning requirements and potential complications at initial lens fitting and follow-up evaluations. The involvement of parents during the entire process of lens-fitting, care, and follow-up monitoring is critical for preventing complications.

Given their continuous development, changing disease risk profiles, and dependence on parents, pediatric populations are unique with respect to medical device safety issues.[25] For example, developmental changes may encompass issues such as infant susceptibility to infections. In our study, the device category with the greatest estimated number of MDAEs for children <5 years of age was tympanostomy tube. Furthermore, children in each age group may have unique illnesses that predispose them to unique MDAEs. For example, infants are more likely to be diagnosed as having and to be treated for evolving cardiac abnormalities, whereas adolescents are more likely to use contact lenses for refraction correction and to be treated with obstetric/gynecologic devices. In our study, >40% of MDAEs among adolescents 16 to 21 years of age involved contact lenses and 16% of MDAEs in this age group involved obstetric/gynecologic devices. In contrast, children <5 years of age had the largest proportion of MDAEs associated with cardiovascular devices.

The patterns of MDAEs among children also may be related to the level and variety of physical activities, which typically increase with age. The provision of many medical devices, such as wheelchairs, scooters, and walkers, to young disabled children gives them the opportunity to participate in activities that were unavailable previously.[26] However, these children are generally at higher risk for injuries because of their physical disorders, even during normal, age-appropriate, exploratory behavior. In our study, injuries related to physical medicine devices (such as wheelchairs, scooters, braces/casts, and crutches/canes/walkers) increased significantly after 5 years of age, to become the second most prevalent medical specialty for injury, after ophthalmology, among children 6 to 21 years of age. Risk factors related to injuries resulting from these types of devices (typically from falls) can be categorized into 4 groups, that is, engineering factors (design of the device), characteristics of the device user (eg, age, gender, and health conditions), physical environment (eg, road conditions and home modifications), and social environment (activities of users, adult oversight, and device use training). Special consideration should be given to modification of these factors to prevent injuries involving physical medicine devices among children, such as improvement of device designs to support pediatric use, better adult supervision, age-appropriate training materials or user guides, and restructuring of the environment, as well as selection of devices on the basis of child development stage and age group.[5,26]

During the process of approval for device marketing, the CDRH categorizes medical devices according to the potential risk posed to patients and de-

vice users. Class I includes the lowest-risk devices and mostly requires only general controls. Class II devices are associated with higher risk and require special controls, including special labeling requirements, mandatory performance standards, and postmarket surveillance. Generally, a 510(k) premarketing submission is required by the FDA to demonstrate that the device is substantially equivalent in safety and effectiveness to a marketed device that is not subject to premarket application. Class III devices generally are life-supporting or life-sustaining, are important in preventing impairment of human health, and/or can present an unreasonable risk of illness or injury. Because of the high level of risk associated with class III devices, these devices require a premarket application for marketing clearance. Overall, the proportion of class III devices involved in pediatric MDAEs is smaller and the proportion of class II devices involved in pediatric MDAEs is larger than the corresponding proportions of class III and II devices involved in all MDAEs seen in EDs. In another study, we determined that ~5% of all MDAEs seen in EDs were related to class III devices and 45% were related to class II devices, which represent the approximate proportions of medical devices approved by the FDA.[27] It should not be interpreted, however, that pediatric patients are less likely to have MDAEs resulting from class III devices, because the majority of class III devices, such as implanted neurologic devices,[28] are indicated for adults and are approved without pediatric data. The smaller proportion of MDAEs resulting from class III devices, therefore, likely reflects less device use by pediatric patients, because of either device indications or physician preferences not to treat pediatric patients with higher-risk devices.

The proportion of pediatric MDAEs requiring hospitalization also was smaller than that of the overall patient population with MDAEs seen in EDs (6% vs 12%). However, younger children (≤5 years of age) had almost 4 times the estimated number of MDAEs requiring hospitalization, compared with adolescents 16 to 21 years of age. This suggests greater vulnerability of younger children to MDAEs, possibly because of their unique health issues and illnesses that may be more acute and more severe in nature; their anatomic, physiologic, and immunologic development status, which may be more susceptible to injury; and their dependence on parents or others because of their limited neurocognitive capacity. In addition, the study results indicated that, across all pediatric age groups, injuries from implanted devices and devices associated with invasive procedures were more likely to be severe, as indicated by hospitalization. Although girls were found to have higher MDAE estimates than boys, there was a reverse trend between genders for numbers of MDAEs with increasing age. The significant increase in MDAEs among girls in the 16- to 21-year age group was attributable primarily to events involving menstrual tampons, daily-wear soft contact lenses, or contraceptive devices such as condoms.

There are several limitations of the NEISS AIP data that should be considered during interpretation of these findings. Firstly, the total estimate for pediatric MDAEs presented here is an underestimate of the actual national total number, because only incidents in which the injured party seeks treatment in an ED are captured in the NEISS AIP data. Treatments received in other settings (eg, primary care offices, military hospitals, or non–hospital-based urgent care centers or through direct admissions to hospitals) were not captured. Secondly, because NEISS AIP MDAE data rely on documentation by the ED physician and medical record abstraction by a hospital coordinator, only MDAEs that are recognized and recorded by the treating physician can be identified, and the information is generally limited regarding the cause of the MDAEs (eg, device failure, user error, packaging error, support system failure, adverse environmental factors, underlying patient disease or comorbid condition, idiosyncratic patient reaction, maintenance error, or adverse device interaction).[8] Thirdly, accurate national estimates of the prevalence of device use in the pediatric population were not available. For long-term implant-related devices, it is possible to obtain national use data; however, this does not provide straightforward estimates of prevalence. For devices designed for short-term use, such as menstrual tampons, there are no readily available national data on rates of purchases and use, much less according to age. Therefore, the incidence rate of pediatric MDAEs, a valid measure of public health burden, is calculated by using national Census data as a surrogate measure of device use in each age group of the pediatric population. We are currently engaging in several efforts (1) to improve the quality of NEISS AIP data (eg, providing additional training for NEISS AIP hospital coordinators and encouraging ED staff members to document targeted information when medical devices are involved); (2) to collect additional information on MDAEs by conducting telephone interviews with patients or their family members; and (3) to use other databases with good national representativeness, such as the Nationwide Inpatient Sample, to estimate nationwide use of identifiable devices and to interpret the incidence of MDAEs from the NEISS AIP data more accurately.

## CONCLUSIONS

As the nation searches for the most cost-effective health care system, preventing injuries related to health care interventions becomes even more important. Our study characterizes the first national ED estimates of MDAEs in the pediatric population. The scope and severity of pediatric MDAEs underscore the need for more-intensive preventive efforts. The public health burden is driven primarily by a few device categories, that is, ophthalmic devices and physical medicine devices. Younger patients, although they are less likely than adults to experience injuries from high-risk devices, are more likely to suffer severe injuries that require hospitalization. Targeted interventions should be developed and resources should be directed to address pediatric MDAEs with the greatest public health impact.

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