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Research Article

Medical Device Injuries and Malfunctions in Non-Clinical Settings: an Analysis of the FDA's Maude Database

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Abstract: The public health burden of adverse events from medical devices that are used in non-clinical settings is not well understood. To describe the frequency and characteristics of medical device events occurring in non-clinical settings. We analyzed 13,739 non-clinical reports occurring between January 2009 and December 2013 and reported in the Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database. In results the majority (85%) of reports in the MAUDE database during this time period were missing an event location. Those reports with a location describe a wide variety of non-clinical settings (home, school, public buildings, public venues, outdoors etc). The current study reveals that deaths 353 (2.6%) and serious injuries 3,494 (25.4) occurred from Class 1, 2 and 3 medical devices over the study period An evaluation of a device implicated in causing harm or malfunction was not conducted by the manufacturer in the majority of events 9077 (66.1%). In conclusion As the use of medical devices in the non clinical setting increases the number of adverse events associated can also be expected to increase. Efforts should be made to encourage the reporting of device-related problems occurring the non-clinical setting through the FDA Med Watch program. The collection of more complete and detailed device data may allow for better public health analyses.
Keywords: public health, burden, Food and Drug Administration, Manufacturer and User Facility Device Experience (MAUDE)

INTRODUCTION

A medical device is an item used for the diagnostic treatment or prevention of a disease, injury, or other condition, that is not a drug or biologic [1]. A medical device can be as simple as a tongue depressor or as sophisticated as an infusion pump [2]. Since 1976, the Food and Drug Administration (FDA) has recognized three classes of medical devices, based on the risk the device poses. Class I devices are devices with the lowest risk and are not intended to support or sustain life and do not require FDA review before they can be marketed. [3]. Devices in this category include elastic bandages, canes, and dental floss [4]. Class II devices are devices that involve some risk to the user. Most devices in this category are non-invasive and include blood pressure cuffs, heating pads, powered wheelchairs, and hearing aids [4]. In contrast to Class III devices, which require pre-market approval to prove safety and effectiveness, most Class l and II devices do not require pre-market 510(k) clearance. Class III devices usually support or sustain human life or present a potential, unreasonable risk of illness or injury [5]. Devices in this category are implantable and include pacemakers and artificial joints [4]. Manufacturers must submit clinical evidence of safety and effectiveness to the FDA prior to marketing [6].

The FDA is responsible for ensuring the safety and effectiveness of medical devices [7]. The FDA monitors medical devices through a passive surveillance system that receives medical device reports (MDRs) of adverse events and malfunctions. An MDR is a report submitted by a manufacturer to the FDA when a marketed device has or may have caused or contributed to a death or serious injury, or has malfunctioned or failed during an incident in which an adverse event did not occur such that the device or a similar device marketed by the manufacturer they have knowledge that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur [7]. Serious injury is any event that is life threatening, results in the permanent impairment of a body function or permanent damage to a body structure, or necessitates a medical or surgical intervention to preclude the permanent impairment of a body function or permanent damage to a body structure [7]. A malfunction is a failure of a device to meet its

performance specifications or otherwise perform as intended [7].

Since the 1980s, medical care has been shifting from the hospital to non-clinical settings [8] [9]. Patients are being released from hospitals to receive medical care for complex medical conditions, permanent disabilities, and palliative care in diverse non-clinical settings. Several factors are driving the shift in patient care from the hospital to a non-clinical setting, including economic forces, patient demographics, and advances in technology [10]. There is significant cost savings associated with treating patients in a non-clinical setting compared with an acute care setting [10]. In addition, the population of the United States is aging rapidly; by 2030, it is projected that approximately 20% of the U.S. population (72 million people) will be over 65 years old [11]. This graying of America will make non-clinical care more common. The majority of the elderly (~80%) will have at least one chronic illness (e.g., hypertension, diabetes, respiratory illness) that will need to be monitored and treated [11] [12]. Each year, an estimated 36 million homes include a family member that provides medical care for another family member [12]. For example, due to advances in technology, many medical devices are now compact and portable [12], which allows devices like infusion pumps, ventilators, and dialysis machines to move into the community setting. The shift of medical devices into non-clinical use not only sustains and supports life but also can improve the overall quality of life, which allows patients greater mobility, independence, and integration with society [13] [12]. As this shift in care continues, the use of medical devices outside of the healthcare setting has been increasing and is expected to increase further in the future [12].

The non-clinical use of a medical device is the use of a device in any setting outside of a professional healthcare facility or clinical laboratory [12]. Patient and/or caregiver capabilities as well as device complexity and environmental conditions present potential safety risks with the non-clinical use of medical devices. Many medical devices are being used in non-clinical settings even though these devices were not designed to be used by lay people and/or outside of a healthcare setting [14]. Manufacturers need FDA approval to sell a medical device directly to a patient over-the-counter; however, a physician can prescribe a medical device that is not specifically designed or labeled for use in a non-clinical setting. Medical devices also enter the non-clinical setting through internet purchases. Medical devices in a non-clinical setting therefore may be used by a lay person who has not received proper training in the operation of the device [12]. In addition, patients and caregivers are a heterogeneous group in terms of age, education, and cognitive abilities [14]. Devices also may be adversely impacted by other elements found in the non-clinical setting, such as pets and children, temperature and humidity, dirt and dust, lightning, and limited space [12, 14].

Despite the lack of data on medical device events in the non-clinical settings [15], it is reasonable to expect that reports occur in this setting. We used a spontaneous adverse event reporting system for medical devices to examine the occurrence of medical device adverse events occurring in non-clinical settings. In addition to analyzing the non-clinical use of medical devices we were also interested in whether such reports were associated with a malfunction alone, serious injury or death. We also examined how medical device events varied by class of medical device, medical specialty and whether an evaluation by the manufacturer was conducted for device described in the medical device reports.

METHODS

Data

The FDA Manufacturer and User Facility Device Experience (MAUDE) database contains all reports submitted by mandatory reporters such as manufacturers, importers, and device user facilities as well as voluntary reporters such as healthcare professionals and consumers [16]. The database contains voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1999 [16]. Manufacturers must file a report when one of their devices has or may have caused or contributed to a death, serious injury, or has malfunctioned such that a similar device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur [7]. Mandatory reports must be submitted using a standard MedWatch form on which the details of the event are described with a combination of codes and narrative text [7]. FDA healthcare professionals review and analyze reports for the purpose of identifying new safety signals [17]. Heightened attention is given to those device reports that involve fire, explosion, anaphylaxis, pediatric deaths, or multiple patient deaths or serious injuries [18]. When appropriate, the FDA may recommend specific actions including public notification about potential health warnings, label changes, a recall of a medical device, and/or education activities aimed at healthcare professionals and consumers [17].

Analytic Methods

We performed a retrospective analysis of reports in non-clinical settings that were received by the FDA and available in the MAUDE database. A subset of MAUDE data from 01 January 2009 through 31 December 2013 was downloaded from the FDA website

as compressed text files, imported into a SAS database, and maintained offline.

The MAUDE data set consists of four records types Master Event Data: Device Data, Patient Data and Narrative Text Data with the records linked via a Medical Device Report key [16]. The Medical Device Report key is new unique number assigned for every new event reported to the MAUDE database. All subsequent reports pertaining to that same event are identified with the same MDR index key. However more than 2 reports can be submitted for the same patient or incident (duplicated reports), and have different Medical Device Report (MDR) report keys if data is misspelled, missing or reported differently [16]. There were no further efforts to remove duplicate reports.

The public dataset does not contain any patient identifiers (birth date, age, weight, or sex). Publicly available information includes: Event Location, Event Type (e.g., death, serious injury, malfunction), Device Name, Medical Specialty, Device Class, and an indication as to whether the device was evaluated by the manufacturer. Reports occurring in the non-clinical setting were retrieved by searching the event location identifier. The following codes were classified as non-clinical: 002 Home, 810 Patient's Home, 830 Public Venue, 831 Outdoors, 832 Park, 833 Playground, 834 Public building, 835 School, and 836 Street. Event locations coded as * Invalid Data, 000 Other, 999 Unknown, NA Not Applicable, NI No Information, and UNK Unknown were classified as unknown and removed from the analysis dataset. All other locations were classified as clinical.

RESULTS

Annual Rate of Medical Device Reports in Non-Clinical Settings

Figure 1 provides the yearly distribution of reports in the non-clinical setting from 2009 through 2013. There were a total of 2.1 million reports received during the study period. The majority of reports 1,745,998 (85%) had an unknown event location. A total of 13,739 reports were classified as non-clinical, accounting for 0.7% of all reports and 4.5% of reports whose location was known. The number of reports in non-clinical settings increased over the study period from 1199 reports in 2009 to over 4500 in the year 2013.

Overall Distribution of Medical Device Reports in Non-Clinical Settings

Table 1 provides an overall distribution of reports occurring in the non-clinical setting according to event location, event type, type of device, device class, and whether a device evaluation was conducted by the Manufacturer. The vast majority (97%) of non-clinical reports for which a location was provided involve a device used in the home. There were also reports from other non-clinical settings, including schools (208; 1.5%) and public buildings (91; 0.7%).

Table 1 provides the distribution of non-clinical incidents by severity. MAUDE event type categories include: malfunction (e.g., device-related problem, user error), serious injury, and death. The majority of non-clinical reports were for device malfunctions (9,082; 66.1%), followed by serious injury (3,494; 25.4%), and death (353; 2.6%); 810 reports (5.9%) were missing the event type or classified as other. The majority (49.9%) of non-clinical reports involved Class II (moderate-risk) devices; however, 13.7% of the Reports involved Class 1 (low-risk) devices. Over 60% of the reported devices were not returned to the manufacturer for evaluation.

The majority of death reports (172; 48.7%) involved Class 3 Ventricular Assist Bypass devices (i.e., mechanical circulatory devices that are used to partially or completely replace the function of a failing heart). There were also 17 (4.8%) death reports associated with Class 1 devices. The types of devices included Manual Beds, Patient Lifts, Mechanical Walkers, and Flotation Therapy Mattress.

Medical devices associated with the highest number of serious injury reports included Invasive Glucose Sensors (1017; 29.2%), Ventricular Assist Bypass devices (624; 17.8%); and Spinal Cord Stimulators Implanted For Pain Relief (564; 16.1%).

The 13,739 non-clinical reports included 293 device types from 16 of 19 medical specialties defined by the FDA, (eg, ophthalmology or orthopedics) Figure 2. The medical specialty clinical hematology accounted for 26.45% of the total reports due primarily to the number of reports associated with Glucose Test Systems (i.e., devices intended to measure glucose quantitatively in blood and body fluids), which accounted for 3,588 (99%) of the clinical hematology reports. Other medical specialties that contributed >10% of reports in the non-clinical setting included the medical specialty general hospital (3,193; 23.5%) and cardiovascular (2889; 21.3%).

The device type that accounted for the most non-clinical reports was Glucose Dehydrogenase Test systems (i.e., devices that are intended to measure glucose quantitatively in blood and body fluids), which accounted for 3,452 (25.1%) of the non-clinical reports. Other devices that accounted for >5% of reports in the non-clinical setting included Ventricular Assist Bypass devices and Blood Lancets. The most common device types reported in the FDA MAUDE database are shown in Figure 3.

Table 1: Characteristics of Non-Clinical Medical Device Reports in the FDA MAUDE Database (2009-2013)

EVENT LOCATION	NUMBER	PERCENTAGE
Home	13,367	97.3
School	208	1.5
Public Building	91	0.7
Public Venue	36	0.3
Outdoors	16	0.1
In Transit	11	0.1
Park	8	0.1
Street	2	0.1
EVENT TYPE		
Malfunction	9,082	66.1
Serious injury	3,494	25.4
Other	591	4.3
Death	353	2.6
Missing: Event Type Not Provided	219	1.6
DEVICE CLASS		
2	6,849	49.9
3	4,957	36.1
1	1,878	13.7
Unclassified	27	0.2
Missing	28	0.2
DEVICE RETURNED FOR EVALUATION		
Device Not Returned to Manufacturer	6,059	44.1
Device Returned to Manufacturer	4,662	33.9
No: Device Not Returned to Manufacturer	1,623	11.8
Missing: No information on whether device Returned or Not Returned to Manufacturer	1,395	10.2

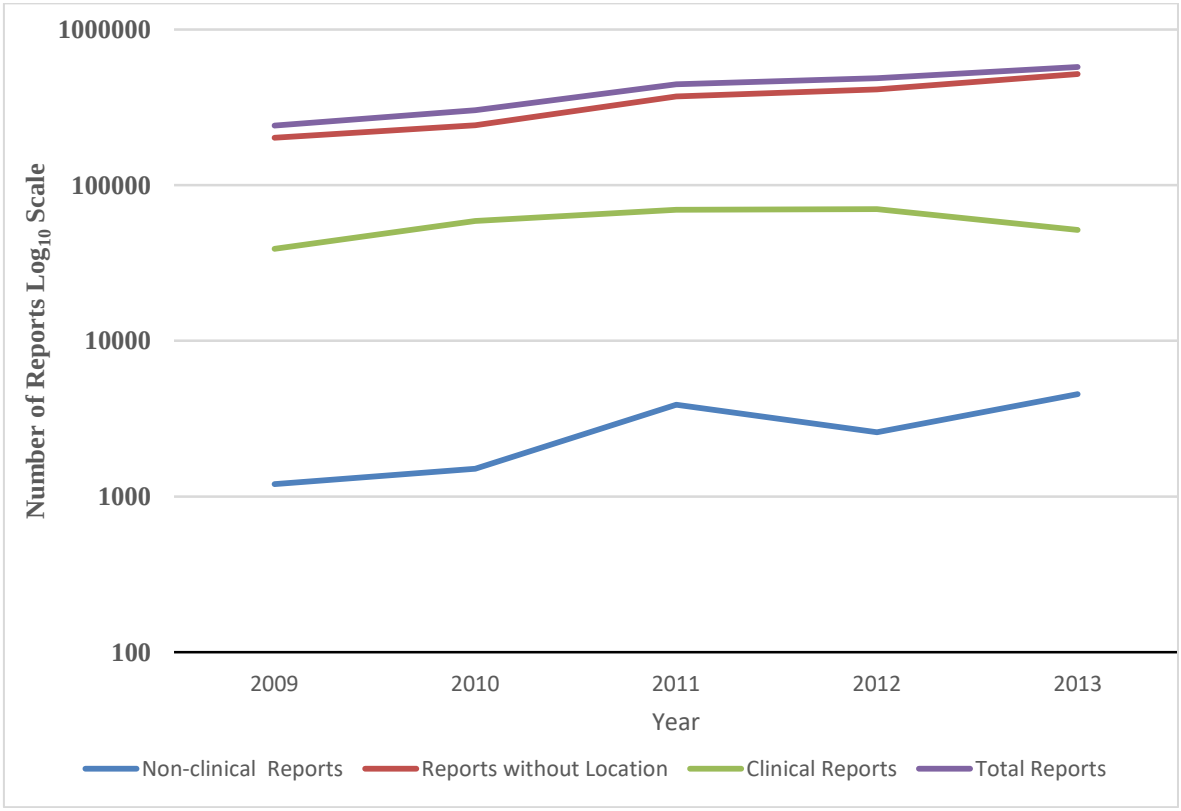

Fig-1: Number of Medical Device Reports in the FDA MAUDE Database by Location for the Years 2009-2013

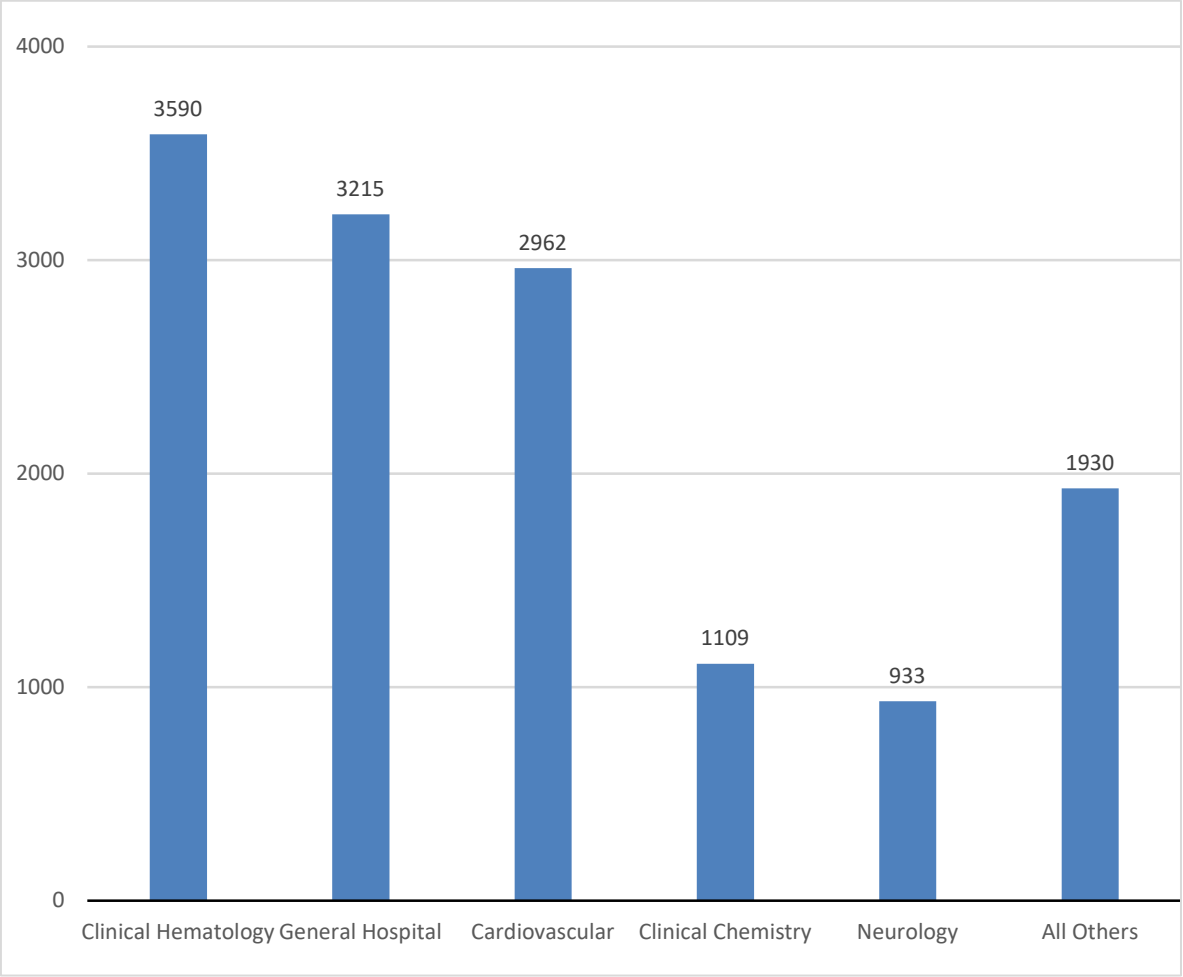

Fig-2: Non-Clinical Medical Device Reports in the FDA MAUDE Database (2009-2013) by Medical Specialty (>10% of Total Non-Clinical Reports)

DISCUSSION

We used the FDA MAUDE spontaneous reporting database to examine non-clinical medical device reporting from 2009 to 2013. We focused on the types of device involved, the location of incidents (e.g., at home or elsewhere), the severity of the injury, the class of medical device, medical specialty and whether an evaluation by the manufacturer was conducted for device described in the medical device reports.. We found several major findings; one is a low number of reports submitted to the FDA MAUDE database and the other was incomplete information provided in the reports. These findings are important becausse as mentioned above the FDA uses individual reports to identify and correct problems with medical devices in a timely manner [17].

The reports we examined occurred in a variety of non-clinical settings and reflect the wide diversity of medical devices used in the non-clinical setting, ranging from heating pads and diagnostic tests to life-sustaining devices and durable medical equipment. Devices in all three classes (I, II and III) contributed to serious injury or death.

There are several implications from this investigation. The number of unique reports found in the FDA MAUDE database that occur in non-clinical settings is small. For example, over 200,000 device-related adverse events are reported annually to the FDA MAUDE database. During the study period, however, the yearly number of non-clinical reports increased but never exceeded 5,000. Despite the fact that the number of reports increased over the study period, the data analysis was hampered by missing event location information for ~85% of the records. This missing data makes it difficult, therefore, to understand whether the proportion of reports in the non-clinical setting increased relative to reports in the clinical setting over the study period.

Given that medical device malfunctions are known to be underreported to the FDA MAUDE database, it is likely that the AEs analyzed in this report

represent only a small fraction of the AEs that occurred over the study period [19] [14]. There are several barriers to knowing when and where to report an event. The low number of reports in the non-clinical setting may reflect difficulty in recognizing device events, a lack of knowledge about what types of events should be reported, and/or difficulty with assigning responsibility to the device for an event [19] [20]. A lack of awareness of the FDA Med Watch reporting system may also contribute to the low numbers of reports, which may indicate a potential need to raise awareness among lay users about recognizing and reporting device problems [19] [20].

Because demographic data such as age, sex, and race is protected under the Freedom of Information Act, there is a limited understanding of the FDA MAUDE data. Although a few devices were responsible for the majority of reports in this study, it is important to understand whether certain subpopulations, such as those with physical, cognitive, demographic, educational, and/or technical literacy differences, might disproportionately contribute to reports in the non-clinical setting [12].

In addition, coding data into standardized terminology using the Medical Dictionary for Regulatory Activities (MedDRA) would support public health efforts and data analysis [21]. The event type selection on the Med Watch form is broad and makes it difficult to analyze harm due to medical devices in a systematic way. To understand the type of injury suffered by a patient, one must review the accompanying narrative text in the MDR, which is not standardized. The narrative text that we reviewed during this study varied in detail, and the majority did not contain sufficient data to gain insight into contributing factors such as environmental factors, user error, comorbid diseases, or medical device problems.

The most prevalent event type was device malfunction (9095; 66.2%), which are events that do not involve an adverse event. Despite this, only a minority of devices (~33.9%) were returned to the manufacturer. A manufacturer's evaluation of a device may be able to determine whether and why a device malfunctioned. A manufacturer's evaluation may also detect user errors which are errors made by a person using a device [22]. A user error may be either the sole cause or a contributing factor to a reportable event. These evaluations are important because they can serve to alert the FDA to device problems that have the potential to lead to adverse events before these events occur and may alert the FDA to the need for improved labeling to prevent future injuries [7].

Our results suggest a need for increased research on the use of medical devices in non-clinical settings. Because devices are more commonly now used in the non-clinical setting; the responsibility for identifying and reporting reports has shifted, to lay people such as patients and care-givers [23]. As noted above, the actual incidence rate of reports experienced by patients in the non-clinical setting is expected to be much higher than what is captured in the MAUDE database [19] [18]. Consequently, measuring the incidence of reports in the non-clinical setting should be considered a priority health policy issue. This research should also evaluate the risks and outcomes for reports in different nonclinical subpopulations), off-label use and in different environmental settings and by patients/care-givers with differing cognitive abilities [12].

The FDA has recognized that medical in the non-clinical setting is important and established The Medical Device Home Use Initiative to develop information and resources to ensure the safe use of medical devices in the non-clinical setting. The FDA developed "Guidance for Industry and Food and Drug Administration Staff: Design Considerations for Devices Intended for Home Use" [24]. The guidance document directs manufacturers on how to design devices for use in the non-clinical setting. As another step, the FDA is building an online database for labeling information, intended to make it easier for consumers to access instructions for use and safety information about devices used in the non-clinical setting. Additionally, the FDA is working to promote more participation in the Med Watch program, by creating a consumer friendly Med Watch form [25]. The new Med Watch form uses lay friendly language with a simplified layout making it easier for consumers to report device problems to the FDA. In conjunction, the FDA developed an online learning program Med Watch Learn, so that consumers can practice submitting a Med Watch form and learn what information is important to the FDA [26].

However, effective policy will require more knowledge and consequently, more research which includes: (1) whether non-clinical reporting of medical device events are different from those that occur in the clinical setting; (2) the impact of increasing awareness about the FDA MAUDE reporting system on the quantity and quality of reports from the non-clinical setting; and (3) how that information can be used for signal generation and analysis.

Our study has several limitations. First, this was a retrospective study that used an existing de-identified dataset of medical device event reports. Data from the FDA MAUDE database cannot be used to estimate the incidence of device events due to the absence of denominator data, that is, the number of patients potentially at risk for adverse events. In

addition, numerator data does not exist due to the underreporting of events. Finally, reports submitted to the FDA are not substantiated for accuracy and completeness.

CONCLUSIONS

This study has added to the evidence base of reports in the non-clinical setting, and has identified several areas of focus for future research. The FDA MAUDE database is a unique resource for understanding medical device events that occur in the non-clinical setting. There is a paucity of published research to evaluate non-clinical device reports. The submission of accurate and complete reports is important for public health efforts. The patient and caregiver are in an opportune position to detect and report device-related issues that occur in the non-clinical setting. Efforts should be made to educate and encourage the reporting of device-related problems through the FDA Med Watch program.

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