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ORIGINAL ARTICLE

An Analysis of the FDA MAUDE Database and the Search for Cobalt Toxicity in Class 3 Johnson & Johnson/DePuy Metal-on-Metal Hip Implants

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Introduction: This study was designed to determine whether systemic cobalt toxicity as an adverse event could be documented using the Food and Drug Administration's (FDA) Manufacturer and User Device Choice Experience (MAUDE) database for adult-onset systemic hip implant recipients. Class 3 Johnson & Johnson (J&J)/DePuy devices were chosen for analysis because of the large number of adverse event reports related to their Pinnacle and ASR XL Acetabular hip replacement systems. A secondary goal was to characterize the reporters who are providing the information in the MAUDE database and to evaluate the quality of the data and information submitted.

Methods: Using FDA MAUDE downloadable data files, 80,323 adverse event medical device incident reports were identified with the product code of KNA (Pinnacle, Hip, Serotomized [Metal Acetabular Component]) for J&J/DePuy (KNA) T&F (T). These are class 3 devices and devices with lower high failure rates. The G&S XL Acetabular hip replacement systems and Pinnacle fall into this category. This group of implants was chosen because acetabular failure is associated with elevated cobalt levels. The additional implants were created from Free Text records in the reports containing key words that indicated a diagnosis of cobalt toxicity and another key words indicating elevated levels of cobalt toxicity. These files were then searched for components of systemic cobalt toxicity with keywords listed using key words pertaining to symptoms, signs, and laboratory test results. The MAUDE database reports are submitted to the FDA at the device component level. It was necessary for multiple reports to be submitted for a single device.

Results: It was not possible to differentiate systemic adverse event reports for adverse event reports in the category category. This category was not included. The number of adverse event reports in the other categories ranged from 17 to 14 for the J&J/DePuy KNA T&F (T) and 19 to 14 for the J&J/DePuy KNA T&F (T) and 19 to 14 for the J&J/DePuy KNA T&F (T).

or toxicity. Cardiac, visual, and auditory conditions were most frequently reported. With the possible exception of cardiomyopathy, the majority of these reports are far below the prevalence reported in the general population of comparable age. The content of the MAUDE database records often contained little objective data. We found less than 4% of 14,714 records, which indicated cobalt elevation or toxicity contained data for quantitative measurement. These records frequently included symptoms, signs, and physical exam findings such as "visual changes," found in 111 (0.75%) Free Text records. Manufacturers submitted more than 99% of the reports and the most common reporter occupation was attorney, found in 42.24% of the 81,508 J&J/DePuy KNA Reporter File records. Physicians were the reporters' occupation in 23.07% of reports but within reported directly to the FDA.

Conclusions: We were not able to find in the FDA MAUDE database meaningful warning signs to support the contention that chromium-cobalt-containing Class 3 J&J and DePuy hip implants caused systemic neurological or thyroid symptoms in patients. The incidence of reported cardiomyopathy was rare but frequent enough to be cause of concern. The reduction of most patient data along with the unstructured nature of data entry would be expected to hinder the identification of warning signs. Further identification of the type of adverse event is not consistently carried out. In addition, the FDA needs to implement a methodology to identify and group all reports from a single device implanted into a patient, so duplication of event counting would not occur. Of 83,550 J&J/DePuy KNA Reporter File records, we found only two physician reports sent directly to the FDA. Almost all reports (99%) are submitted by manufacturers and are most commonly authored by attorneys. A standard of care needs to be set for physicians to report medical device adverse events to the FDA.

Key Words: hip implant, MAUDE, FDA, cobalt poisoning, sensory loss, dementia, depression, cardiomyopathy, hip/neck, cobalt toxicity, event, metal-on-metal.

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The first author, K.T.K., is a medical device manufacturer who manufactures systemic implants with a medical device into his work. He is Board Chairman of Health Watch USA, a patient advocacy organization whose members have been active in raising awareness of the risks of cobalt-containing implants. He has also reported medical conditions, including and receiving support from the U.S. Department of Health and Human Services, National Quality Forum, National Patient Safety Foundation (NPSF), The Leapfrog Group and Consumer Union. He has served on the Centers for Medicare and Medicaid Services Technical Expert Panel for Hip and Acetabular Components, and most recently on the Strategic Working Group for AHRQ for quality indicators and is an Associate Editor for the Journal of Patient Safety for which he receives an honorarium. He also has a long-term relationship with development of pharmaceuticals in a university. Some of the authors have an affiliation with or conflict of interest with Johnson & Johnson. The other authors declare no conflict of interest.

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Currently, the U.S. Food and Drug Administration (FDA) has classified a subgroup subset of hip implant devices as class 3, of highest risk category, which may require that they undergo a premarket approval process, which requires pre-market testing. These devices have an FDA product code of KNA. Other hip implant devices have been placed in a lower risk class 2 category with a product code of LDI and may be brought to market under the 510 k approval process. Products assigned the code KNA are distributed by a few manufacturers, including Johnson & Johnson and its division DePuy (J&J/DePuy), which have also been the focus of numerous legal actions regarding their Metal-on-Metal (MoM) Pinnacle and ASR hip implants.¹⁻³ J&J/DePuy are liable for three to the hundreds of millions of dollars. There are almost ten thousand additional lawsuits pending in the U.S. court system.⁴

Cobalt-containing hip implants have been associated with a myriad of alleged problems, some of the most disturbing reported systemic toxicity.⁵ Cobalt alloys are used in implants to improve corrosion and wear resistance.⁶ However, only a small amount

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The research was unable to find in the FDA MAUDE database meaningful warning signs to support the contention that chromium-cobalt-containing Class 3 J&J and DePuy hip implants caused systemic neurological or thyroid symptoms in patients. The incidence of reported cardiomyopathy was rare but frequent enough to be cause of concern. The reduction of most patient data along with the unstructured nature of data entry would be expected to hinder the identification of warning signs. Even identification of the type of device could not be consistently carried out. In addition, the FDA needs to implement a methodology to identify and group all reports from a single device implanted into a patient, so duplication of event counting would not occur. Of 83,550 J&J/DePuy KNA Reporter File records, we found only two physician reports sent directly to the FDA. Almost all reports (99%) are submitted by manufacturers and are most commonly authored by attorneys. A standard of

care needs to be set for physicians to report medical device adverse events to the FDA.

<https://journals.lww.com/journalpatientsafety/Abstract/publishahead/An-Analysis-of-the-FDA-MAUDE-Database-and-the-99315.aspx>



Catherine Duff, President & Founder of The Fecal Transplant Foundation.

Catherine Duff, tells a harrowing story of how a family administered fecal transplant saved her life and started her down the road of fecal transplant advocacy and FDA policy advisor.

View YouTube Video:

<https://youtu.be/u1c5T3j4OOE>

Finance and Value Based Purchasing

Medicare Eases Readmission Penalties Against Safety-Net Hospitals

"Penalties will total \$566 million for all hospitals. But many that serve a large share of low-income patients will lose less money than they did in previous years."

<https://khn.org/news/medicare-eases-readmissions-penalties-against-safety-net-hospitals/>

As California Hospitals Sweep Up Physician Practices, Patients See Higher Bills

"The percentage of physicians in practices owned by a hospital increased from about 25 percent in 2010 to more than 40 percent in 2016. The estimated impact of the increase in vertical integration from 2013 to 2016 in highly concentrated hospital markets was found to be associated with a 12 percent increase in Marketplace premiums."

<https://californiahealthline.org/news/as-california-hospitals-sweep-up-physician-practices-patients-see-higher-bills/>

Health Affairs: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0472>

American Hospital Association decries CMS' site-neutral payment plan

This proposal would help mitigate the surprise bills that patients receive when their doctor joins a hospital system. The upcharge can be almost double what was previously paid.

FierceHealthcare: "Hospital groups are warning that CMS' plan to institute site-neutral payments could lead to access problems and canceled services—and, they say, the change may not even be within the agency's authority to make." [https://www.fiercehealthcare.com/hospitals-health-systems/american-](https://www.fiercehealthcare.com/hospitals-health-systems/american-hospital-association-cms-site-neutral-payments-opps-rule)

[hospital-association-cms-site-neutral-payments-opps-rule](https://www.fiercehealthcare.com/hospitals-health-systems/american-hospital-association-cms-site-neutral-payments-opps-rule)

Workers' health costs continue to rise, eroding wages, new survey finds

LA Times: "American workers' health insurance premiums and deductibles continued to tick upward in 2018, outpacing wage growth and inflation, according to a new national survey of employers.... The average cost of a family health plan is now \$19,616 a year, with workers contributing \$5,547, or about a quarter of the cost, the survey by the nonprofit Kaiser Family

Foundation found. Employers are picking up the balance of the cost of workers' health benefits."
<http://www.latimes.com/politics/la-na-pol-health-premiums-study-20181003-story.html>

2018 Employer Health Benefits Survey

Kaiser Healthcare News: <https://www.kff.org/health-costs/report/2018-employer-health-benefits-survey/>

Healthcare Quality & Infections

CMS announces plans to ramp up oversight of hospital inspection agencies

FierceHealthcare: "Announced Thursday, CMS officials said they are focusing on watchdog organizations that perform accreditation while also making it easier for patients to look at an organizations' performance online. The changes come following a Wall Street Journal investigation last year which found that some facilities with ongoing problems kept their accreditation. In March, the House Energy and Commerce Committee launched its own investigation into hospital accreditation problems as a result. "

<https://www.fiercehealthcare.com/hospitals-health-systems/cms-announces-plan-to-strengthen-oversight-medicare-s-accreditation>

New Law Makes California First to Require Physicians Tell Patients of Probation Status

Physician News Network: "A bill signed by Gov. Brown on Sept. 19 makes California the first state in the nation to require physicians to inform patients if they're put on probation for certain crimes including sexual misconduct."

http://www.physiciansnewsnetwork.com/ximed/article_7fdd5238-c0ea-11e8-9243-fbd431e6cc55.html

Kentucky lawmakers want a hearing on nursing home staffing. Why it might not happen.

"Several state lawmakers say they want a public hearing this fall addressing the problem of inadequately staffed nursing homes in Kentucky, the subject of a recent Herald-Leader series."

<https://www.kentucky.com/news/politics-government/article219496255.html>

Related Lexington Herald Leader Story: "The facility's persistently inadequate staffing constitutes a "crisis," its administrator warned inspectors in January when he quit. There have been dangerous bedsores, medication errors and residents capable of controlling their bowels who were ordered by stressed nurse's aides to soil themselves and lie in their own feces until someone was free to assist them to the bathroom, according to a state inspection report."

<https://www.kentucky.com/news/local/watchdog/article217065335.html>

Mass Resignation Guts Board of Prestigious Medical Organization - Cochrane Collaboration

Nature: "The board of the Cochrane Collaboration, a prestigious group that reviews health evidence, has been reduced from 13 to 6 members, following a controversial vote to expel a

member for the first time in its 25-year existence." <https://www.nature.com/articles/d41586-018-06727-0>

Infections and Antibiotics

Factors associated with bacteremia due to multidrug-resistant organisms among bacteremia patients with multidrug-resistant organism carriage: a case control study

Study finds the risk of infection from resistant bacteria infections is high.

<https://aricjournal.biomedcentral.com/articles/10.1186/s13756-018-0412-3>

The European Medicine Agency Issues Fluorquinolone Use Restriction Recommendations.

Not To Be Used:

- to treat infections that might get better without treatment or are not severe (such as throat infections);
- or preventing traveler's diarrhea or recurring lower urinary tract infections (urine infections that do not extend beyond the bladder);
- to treat patients who have previously had serious side effects with a fluoroquinolone or quinolone antibiotic;
- to treat mild or moderately severe infections unless other antibacterial medicines commonly recommended for these infections cannot be used;

To be used with caution especially for the elderly, patients with kidney problems, patients who have had an organ transplantation or those who are being treated with a systemic corticosteroid. These patients are at higher risk of tendon injury caused by fluoroquinolone and quinolone antibiotics.

<https://www.ema.europa.eu/en/news/fluoroquinolone-quinolone-antibiotics-prac-recommends-restrictions-use>

Health Watch USA 2018 Fall Conference.



12th Annual Patient Safety Conference in Lexington, Kentucky, held on Oct. 4th.

Catherine Duff, President & Founder of The Fecal Transplant Foundation.

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