Health Watch USA^{sm} Newsletter

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Member of the National Quality Forum and a designated "Community Leader" for Value-Driven Healthcare by the U.S. Dept. of Health and Human Services


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

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

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 redaction of most patient data along with the nonstructured 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 KWA 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-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.

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