



Drug Issues

Miscellaneous Literature

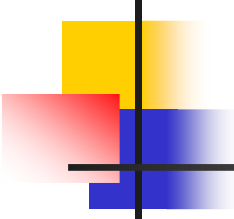


“Medical Errors Make the Headlines Again. New Report Doubles Previous Estimate of Annual Deaths.”

Dynamic Chiropractic 9/27/04

- “According to an analysis released by the health care quality company HealthGrades, up to 195,000 Americans die each year as a result of potentially preventable, in-hospital medical errors.”
- “That figure is nearly twice the number of annual medical errors-related deaths published in a report by the Institute of Medicine (IOM) just five years ago, and make medical mistakes the third-leading cause of death in the US behind heart disease and cancer.”

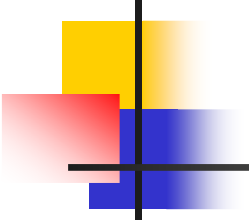
Source: *HealthGrades Quality Study. Patient Safety in American Hospitals.*
Published July 2004



Gurkirpal Singh, George Triadafilopoulos, Epidmiology of NSAID induced gastrointestinal complications. J. Rheumatol 1999, Apr;26 Suppl 56:18-24.

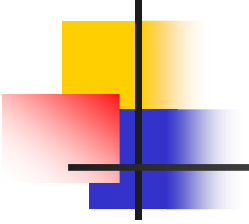
Department of Medicine, Division of Immunology, Stanford University
School of Medicine, Palo Alto, California 94304, USA.

- NSAIDs are one of the most commonly used classes of medications worldwide. 30 million people take NSAIDs daily. GI complications are the most prevalent category of adverse drug reactions. Patients with arthritis are the most frequent users, therefore at greater risk.
- NSAID related deaths among patients with RA and OA are even more startling. **It is conservatively estimated that 16,500 NSAID-related deaths occur in these patients every year in the US.**
- 15th most common cause of death in the US.
- Stats DO NOT include nonarthritis indications.



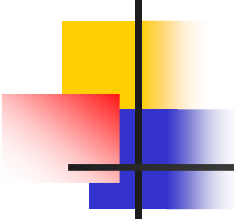
Wolfe, M.D., Lichtenstein, M.D., Singh, M.D.
Gastrointestinal Toxicity of Nonsteroidal Antiinflammatory Drugs. The New
England Journal of Medicine, June 17, 1999, Review Article, Medical
Progress.

- 113 References.
- NSAID agents constitute one of the world's most widely used classes of drugs, with more than 70 million prescriptions and more than 30 billion over-the-counter tablets sold annually in the US.
- *“Although the annual mortality rate is low, it must be emphasized that because a large number of patients are exposed to NSAIDs often for extended periods of time, the risk over a lifetime is substantial.”*
- Hospitalization due to GI complications 103,000/yr. Estimated cost \$15,000 to \$20,000 per hospitalization. Annual cost exceeds \$2 Billion.
- ***“It has been estimated conservatively that 16,500 NSAID-related deaths occur among patients with RA and OA every year in the US.”***



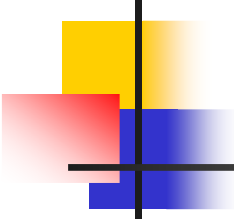
Wolfe, M.D., Lichtenstein, M.D., Singh, M.D.
Gastrointestinal Toxicity of Nonsteroidal Antiinflammatory Drugs. The New
England Journal of Medicine, June 17, 1999, Review Article, Medical
Progress. (cont'd)

- Doses of aspirin as low as 30 mg are sufficient to suppress prostaglandin synthesis in the gastric mucosa initiating gastric-duodenal mucosal injury, resulting in the release of oxygen-derived free radicals.
- Peptic ulcers-gastroduodenal hemorrhage-perforation-death!
- Acetaminophen is nontoxic to the GI mucosa, however, recall that acetaminophen is a leading cause of end-stage renal disease.
- Cox-2 inhibitors will hopefully have a reduced capacity to cause injury to the gastroduodenal mucosa.
- However, Cox-2 inhibitors are also known to cause defects in renal function, alter the regulation of bone resorption, impair female reproductive physiology, and increase the rate of thrombotic events in patients with increase risk for cardiovascular disease.



Dabbs, D.C. and Lauretti, D.C., A Risk Assessment of Cervical Manipulation vs. NSAIDs for the Treatment of Neck Pain. Journal of Manipulative and Physiological Therapeutics. Vol. 18, number 8
Oct. 1995; 18:530-6.

- *“The best evidence indicates that cervical manipulation for neck pain is much safer than the use of NSAIDs, by as much as a factor of several hundred times. There is no evidence that indicates NSAID use is any more effective than cervical manipulation for neck pain.”*
- Death rate for NSAID-associated GI problems at 0.04% per yr among OA patients receiving NSAIDs, or 3,200 deaths in the US per year.
- He (Brandt) also noted that there are several animal studies and human clinical studies that have actually implicated NSAIDs in the acceleration of joint destruction.



The Association of Acetaminophen, aspirin, and ibuprofen with respiratory disease and lung function. McKeever et al. American Journal of Respiratory and Critical Care Medicine. 2005 May 1;171(9).

- Cross-sectional analysis using the Third National Health and Nutrition Examination Survey.
- Conclusion: This study provides further evidence that the use of acetaminophen is associated with an increased risk of asthma and COPD, and with decreased lung function.



FDA MedWatch: Ketek (telithromycin): Reports of Serious Liver Toxicity.

- Annals of Internal Medicine published an article reporting three patients who experienced serious liver toxicity following administration of Ketek (telithromycin). These cases were reported to FDA MedWatch.

Source: MedWatch 2006 Safety Summary:

[http://www.fda.gov/medwatch/safety/2006/safety06.htm#Ketek.](http://www.fda.gov/medwatch/safety/2006/safety06.htm#Ketek)



FDA FedWatch: Cylert and Generic Pemoline Products Withdrawn From the Market Due to Liver Toxicity.

- Cylert, a central nervous system stimulant indicated for the treatment of ADHD is considered second line therapy for ADHD because of its association with life threatening hepatic failure.

- Source:
<http://imageb.epocrates.com/mailbot/links?EdID=20381927&LinkID=2446>



“Antidepressants Get FDA’s “Black Box” Warning. Linked to Suicidal Thoughts/Behavior in Children

Dynamic Chiropractic Nov. 30, 2004

“On October 15, 2004 the Food and Drug Administration (FDA) issued a public health advisory directing manufacturers of all antidepressant drugs to revise their product labeling to include a “black box” warning. The warning is intended to alert health care providers of an increased risk of suicidal thoughts and behavior in children being treated with the drugs.”

Source: *FDA launches a multi-pronged strategy to strengthen safeguards for children treated with antidepressant medications. FDA News, Oct. 15, 2004: www.fda.gov/bbs/topics/news/2004/NEW01124.html.*



“FDA to Probe Antidepressant Risks for Adults...After Planning Warning for Kids, Agency to Re-Examine Evidence Suggesting No Danger of Suicide.”

“It’s unclear why some drugs, including Prozac, Paxil, and Zoloft, could increase suicidal tendencies only in a small subset of young people, and not adults. One theory is that younger people may have less control over their impulses, or less ability to cope with or understand an unexpected drug effect.”

Source: The Wall Street Journal 9/28/04



“Warning Advised on ADHD Drugs.”

“FDA committee urges strongest notification.”

“...8-7 vote...***black box warning***”

“...include Ritalin, Adderall, Focalin, Methylin, Metadate, and Concerta.”

“An FDA report released prior to the meeting said that 25 children and adults had died suddenly from 1999 to 2003 after taking ADHD drugs.”



“Eczema Drug Labels to warn of potential cancer risk”

- FDA...”black box” warning (long-term safety of these drugs has not been established.)
- Elidel and Protopic
- ..animals developed cancer in drug studies.
...should not be used on infants.

Source: USA Today 1/26/06



OxyContin

- U.S. News and World Report, July 2, 2001
- “**Not an appropriate use**”, “*Did the makers of OxyContin push too hard?*”
- Virginia residents filed a \$5.3 billion class action lawsuit that alleges Pharma also failed to disclose the drug’s risks, setting off a wave of OxyContin addiction and abuse.
- Associated deaths jumped 93% between 1997 and 1998.
- DEA reported 291 deaths in just 6 states.



NUTLEY, N.J. (July 15) - Mother's little helper is not so little anymore.

- Valium, the drug that revolutionized the treatment of anxiety and became a cultural icon, is 40 years old this year.
- Invented by chemist Leo Sternbach
- Approved for use in 1963, became the country's most prescribed drug from 1969 to 1982.
- **The Roche Group, Hoffman-La Roche's parent, sold nearly 2.3 billion pills stamped with the trademark ``V'' at its 1978 peak.**



Baycol-Cholesterol drug

- The Columbus Dispatch, August 9, 2001
- **“Bayer pulls medicine tied to 31 U.S.Deaths”**
- Baycol has been linked to significantly more fatal cases than its competitors, Dr. John Jenkins of the FDA
- Other drugs include Lescol, Lipitor, Mevacor, Pravachol, Zocor



Baycol-Cholesterol drug

- “Every statin has been linked to very rare reports of the muscle side effect called rhabdomyolysis.”
- Baycol is the 12th prescription drug taken off the market since 1997.



Allergy Pills Overused

- Study out of OSU, reported in Columbus Dispatch, Monday, April 9, 2001
- Of 246 North Carolina residents taking prescription antihistamines, blood tests showed 65 percent didn't have allergies.
- Skill testing unreliable vs. Blood tests



“Side Effects: As Drug-Sales Teams Multiply, Some Doctors Shut Them Out”

- Wall Street Journal, 6-13-03
- *“’Arms Race’ by Pfizer, Rivals Boost Pill Prices and Ire, But No One Dares Retreat.”*
- *“Free Tacos and Piles of Bextra”*
- 90,000 drug industry reps
- \$12 Billion spent on sales force
- \$2.76 billion on consumer drug ads.
- Result: Prescriptions up 14% to \$161 Billion spent on drugs in 2002!!!!



Antibiotics and Breast Cancer

February 17, 2004 JAMA

The longer that women took the drugs, and the more prescriptions they took, the greater their risk of breast cancer.



Bug Mutates into Medical Mystery. Antibiotics, Heartburn Drugs, Suspected.

- “First came stomach cramps, which left Christina Shultz doubled over and weeping in pain. Then came nausea and fatigue-so overwhelming she couldn’t get out of bed for days. Just when she thought things couldn’t get worse, the nastiest diarrhea of her life hit-repeatedly forcing her into the hospital.”
- Bacterial infection: *Clostridium difficile*
- **“It may, however, be the latest example of a common, relatively benign bug that has mutated because of the overuse of antibiotics.”**

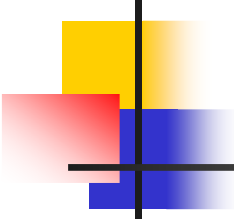
Source: The Washington Post (<http://www.washingtonpost.com/wp-srv/front.htm>)



**Continuous Low-Level Heat Wrap Therapy Provides More Efficacy Than
Ibuprofen and Acetaminophen for Acute Low Back Pain**

Scott F. Nadler, DO, et al. **SPINE 2002;27:1012-1017**

Conclusion. Continuous low-level heat wrap therapy was superior to both acetaminophen and ibuprofen for treating low back pain.



Antibiotics may have affected Milosevic. Took unprescribed drugs, expert says.

- Slobodan Milosevic-died in his jail cell.

“Uges, the Dutch toxicologist, said he discovered traces of rifampicin in Milosevic’s system—a drug that ‘makes the liver extremely active’, and can undermine the effectiveness of other medication.”

Source: USA Today 3/14/06



How did our society get so sick?

- Two industries primarily responsible
 - Food Industry
 - Pharmaceutical Industry
(“*The Next Trillion*” by Paul Zane Pilzer)

Do you really believe either industry is truly interested in your health, versus generating profits by keeping you heavy, unhealthy and drug dependant?



Medical Mistakes: The 3rd Leading Cause of Death

- *JAMA, July 26, 2000 Vol. 284. No. 4*
- 225,000 deaths/yr = 3rd leading cause of death
- 3rd only to heart disease and cancer!!
- Estimates are for death only and do not include adverse effects associated with disability or discomfort.
- Estimates are low!



Epidemiology

- *BMJ March 4, 2000*
- 44,000 to 98,000 unnecessary deaths/yr and 1,000,000 excess injuries.
- Clinicians inexperienced
- New procedures introduced
- Extremes of age, complex care, urgent care, and prolonged hospital stay



Medical Errors

- *JAMA, July 26, 2000 Vol. 284. No. 4*
- 44,000 to 98,000 die/yr - Medical errors
- Of 13 countries, US ranks 12th of 16 indicators (second from the bottom!)
- WHO ranked US 15th of 25 industrialized countries



Medical Errors-Patient Risks

- *“Blunders take 400,000 lives every year, Kaiser head says”*

(By Robert A. Rosenblatt, LOS ANGELES TIMES Oakland Tribune,
July 15, 1999)

- "Mistakes alone kill more people each year than tobacco, alcohol, firearms or automobiles."
- "If passengers were asked to fly with a commercial airline organized like most health care, they wouldn't get on the plane."
- Kaiser is the US's largest HMO. The 400,000 deaths per year caused by medical mistakes is the largest number I have seen in print so far.



JAMA - Hospital Deaths

- *JAMA, July 26, 2000 Vol. 284. No. 4*
- 12,000 deaths/yr - unnecessary surgery
- 7,000 deaths/yr - medication errors in hospitals
- 20,000 deaths/yr - other hospital errors
- 80,000 deaths/yr - nosocomial infections
- 106,000 deaths/yr - adverse rxn, nonerror
- 225,000 deaths/yr - iatrogenic causes



Let's Talk About Error

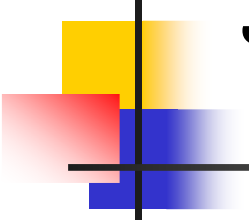
- *BMJ March 2000*
- While reading this article, 8 injured and one will die.
- Likelihood of injury at least 3% in hosp.
- “Reported error rates would go up since we underreport errors and near misses by a factor of 10.”



Shrimp Dodging Injury Blamed for Death

- Jan. 13, 2006 News Bulletin
- Family seeking \$10 million in damages, claiming he died from a neck injury months after ducking to avoid a shrimp tossed by a hibachi chef at a Japanese restaurant.
- Patient, Jerry Colaitis, 43, died from complications (infection) caused by neck surgery he required afterward.

Wall street journal,4/22/03 Page 1, section d
Saying No to the Knife...



- Apparently, research now shows that surgery for back problems, gum disease, hernias, sinus problems, and injured kidneys, to name a few, are not necessary much of the time.
- And the effects of the surgery are apparently often worse than the condition treated.



Antibiotics and Breast Cancer

February 17, 2004 JAMA

The longer that women took the drugs,
and the more prescriptions they took,
the greater their risk of breast cancer.

Aspirin in Gastric Ulcer



- 76 year old women
- *NEJM Levy MD, Vol. 343 Number 12*
- 400 mg. Etodolac 2x/day for RA
- 1 tablet of enteric-coated aspirin / day
- 1 mg. of warfarin sodium per day
- Endoscopy revealed aspirin tablet intact with an ulcer of gastric antrum.



Results of Errors

- *JAMA, July 26, 2000 Vol. 284. No. 4*
- 116 million extra physician visits
- 77 million extra prescriptions
- 17 million emergency department visits
- 8 million hospitalizations
- 3 million long-term admissions
- 199,000 additional deaths
- \$77 billion in extra costs



Error Underreporting

- *BMJ March 4, 2000*
- 100,000 deaths with many more incurring injuries at an annual cost of \$9 billion.
- “Underreporting of adverse events is estimated to range from 50%-96% annually.”



BMJ Statistics

- *BMJ March 2000*
- 100,000 preventable deaths per year in US according to the Institute of Medicine
- Exceeds the combined deaths and injuries from motor and air crashes, suicides, falls, poisonings, and drownings.
- Australia produced even higher rates of error.



President Clinton

- *BMJ March 4, 2000*
- “44,000 to 98,000 Americans die each year from medical mistakes.”
- The President will ask Congress for \$20 million to create a Center for Quality Improvement and Patient Safety.
- Former president of AMA, Dr. Nancy Dickey, opposed to mandatory reporting.



Chiropractic Manipulation...

The Great Flu Pandemic demonstrated that patient receiving Osteopathic spinal manipulation had a greater chance of survival.

According to RAND, Chiropractors perform 94% of all spinal manipulation today.



Muscle Relaxants

“Muscle Relaxants: Overused, Ineffective and Acute LBP”

Bernstein E, Carey TS, Mills Garrett J. The use of muscle relaxant medications in acute low back pain. Spine 2004;29(12):1346-51.

- Cohort of 1600..MC-LBP.
- ...while muscle relaxant use was quite common among patients with acute LBP, the drugs did not help patients return to normal functioning more quickly than patients not taking muscle relaxants, **and in fact, were associated with an increase in the time it took for patients to recover from pain.**”
- Return to functional recovery: 16.2 days vs. 32.4 days (m. relaxants)



“Arthritis drugs may boost risk of blood clotting,
heart attacks” **AP Friday, April 19, 2002**

RE: Vioxx and Celebrex

“New research bolsters the growing suspicion that some popular arthritis drugs could increase certain people’s risk of heart attacks by causing a chemical imbalance that spurs blood clots.”

Based on University of PA study in *Science*



“Merck Recalls Blockbuster Arthritis Drug Vioxx”
AOL News 9/30/04

RE: Vioxx

“The arthritis drug Vioxx, used by two million people around the world, is being pulled off the market after a study confirmed long-standing concerns that it raises the risk of heart attack and stroke, the maker, Merck and Co., said Thursday.”



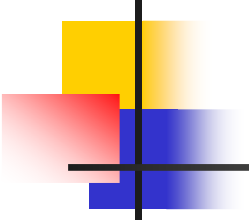
“Another drug for pain off market”
Risk vs. benefit for Bextra cited”

USA Today Fri/Sat/Sun, April 8-10, 2005

RE: ***Bextra***

“The Food and Drug Administration announced Thursday that Pfizer has agreed to stop selling Bextra, a popular arthritis drug, because its risks outweigh its benefits”

Black Box warnings will highlight the drugs’ (***Celebrex, Ibuprofen, naproxen***, etc) risks of heart attacks, strokes, and bleeding of the digestive tract



“Methadone overdose killed activist, coroner reports” Columbus Dispatch 6/12/03

RE: Methadone

“The former grade-school dropout, gang member and ex-con, whose dramatic turnaround inspired a recent TV movie, died May 2 of an accidental overdose of methadone, Franklin County Coroner Brad Lewis ruled this week”

Note: An occurrence so common it doesn't even raise an eyebrow anymore!



“Hormone therapy raises dementia, stroke risk”

Columbus Dispatch 5/28/03

RE: Hormone Replacement Therapy,
estrogen and progestin.

“...new research shows women 65 or older who take the drug face twice the risk of developing dementia, including Alzheimer’s disease....higher risk of stroke in those between 50-79 years old”

Based upon: May 2003 issue of JAMA



“Hormone Therapy is Risky, Study Warns”

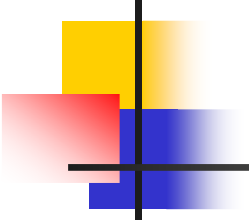
Columbus Dispatch 7/9/02

“Hormone replacement therapy.....should not be taken long-term because it carries more risks than benefits, national researchers...”

“The message is that estrogen plus progestin should not be used for the prevention of heart disease and other chronic diseases.”

The study had been intended to run until March 2005, but the study was suspended.....

“The letter informed study participants that for every 10,000 women taking HRT, experts could predict that 7 additional women would have heart attacks compared to those getting the placebo.”



“Smallpox plan to be unveiled. Vaccine could endanger millions” USA Today 12/13-15/2003

“...some authorities fear mass public vaccinations could put many people at risk, especially those with weakened immune systems who are vulnerable to infection from the live virus used to make smallpox vaccine, say numerous smallpox experts”



Headlines related to Smallpox

USA Today 12/13-15/2003

“Individuals must weigh risks of inoculations”

“Disease symptoms, risk of vaccine and government’s plan”

“For 60 million, the cure may kill”

“States on track to vaccinate public when liability coverage kick in”



Analgesic overuse among subjects with headaches, neck and low back pain.

Zwart et al, *Neurology*, May 11, 2004;62:1540-44

- **Up to 50% of all cases of chronic headaches are attributable to medication overuse.** (Compared to a person who doesn't take them.)

- Taking daily analgesics for more than 6 mns:
 - =20x more likely to suffer ***chronic migraines***.
 - =10x more likely to suffer ***nonmigraine HAs***.
 - =3.5x more likely to suffer ***chronic neck pain***.
 - =3.5x more likely to suffer ***chronic LBP***.

Note: 65,000 persons age 20 and older completed the survey.



“Prescription Drug Use Reaches Epidemic Proportions”

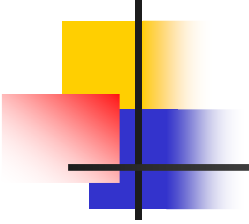
Dynamic Chiropractic Feb 12, 2005

- *Health, United States, 2004, With Chartbook on Trends in the Health of Americans.* National Center for Health Statistics. Hyattsville, Maryland, 2004.
- Citizens taking one drug: 39.1% (1994) to 44.3% (2000)
- Citizens taking 3 or more prescription drugs:
11.8% (1994) to 16.5.% (2000)

Seniors taking more than 1 drug, with 50% taking more than 3 drugs.

Children are becoming major consumers of drugs, on par with parents.

The policy of prescribing multiple drugs simultaneously has become standard practice for most medical doctors and hospitals.



**“Whooping Cough: Vaccines Not Stopping
Global Rise of Disease”** AP, Columbus Dispatch Sunday 4/28/02

“Whooping cough, largely regarded as an infant disease, is making a global comeback in all age groups.”

“Scientists don’t know why, but they suspect that protection from immunization wears off after a few years and that the bug has outsmarted vaccines used to control it for decades.”

“...bacterium may have evolved that are resistant to the vaccines used in some countries”



“Heart Attack risks leads to Vioxx Recall” AP,

Columbus Dispatch Sunday 10/1/04

“Vioxx, the blockbuster arthritis drug heavily promoted on TV and taken by tens of millions of people, was pulled from the market by its maker yesterday after a study found it doubled the risk of heart attacks and strokes.”



“Popular antibiotic increases heart risk”

AP, Columbus Dispatch Sunday 9/9/04

“A widely used antibiotic long considered safe dramatically increases the risk of cardiac arrest, particularly when taken with some popular drugs for infections and high blood pressure, a study found.”

“The drug is erythromycin, which has been on the market for 50 years and is prescribed for everything from strep throat to syphilis.”

Source: NEJM 9/9/04



“Drug-Resistant Germs...Hospital Infections Spread into Community”

AP, Columbus Dispatch Sunday 6/23/02

“Lapses in infection control and overuse of antibiotics are spawning drug-resistant germs that are spreading from hospitals into the community at unprecedented rates.”

“Super Germs”



Thomas Edison...

“The doctor of the future will give no medicine, but will interest his patient in the care of the human frame, in diet, exercise, and in the cause and prevention of disease.”



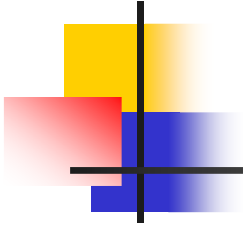
Dorland's Medical Dictionary

Health is state of mental, physical, and social well being, and not merely the absence of disease or infirmity.



Hippocrates..”The Father of Healing”

“Look well to the spine for the cause of disease.”



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