

Adverse Drug Reactions

Adverse drug reactions, (ADRs) usually called side effects, are a long-standing and largely neglected major medical problem. These are not medical errors and occur within the FDA approved dosage and labeling recommendations. The recently reported problems with antidepressant induced teen suicides, the recalls of Vioxx and Baycol and the upgrading of Accutane monitoring by the FDA are the tip of the iceberg.

Incidence of Adverse Drug Reactions

- ADRs are the fourth to sixth greatest killer in US with more than 100,000 deaths per year; and 2.2 million serious adverse reactions per year according to a 1998 Journal of the American Medical Association report. (JAMA 279:1200 1998) This study is a meta analysis of 39 research reports published from 1966 to 1996.
- 21.3% of the 548 most recently FDA approved medications were subsequently withdrawn from the market or given a black box warning. JAMA 287:2215 2002
- The GAO reports that 51% of new drugs have serious, undetected adverse effects at the time of approval.
- Of the best selling prescription drugs, 148 can cause depression, 133 hallucinations or psychoses, 105 constipation, 76 dementia, 27 insomnia and 36 parkinsonism. "Worst Pills Best Pills: A Consumers Guide to Avoiding Drug-Induced Death or Illness," third edition, 1999.

Financial Consequences

- \$1.77 billion in added health care costs per year. J Am Pharm Assoc 41:192 2001
- HMOs spend more treating ADRs than on drugs.
- ADRs are the cost leader for malpractice payouts.
- Up to one-third of drug prescriptions are not needed and therefore wasted.

Potential of Pharmacogenetic DNA Drug Reaction Testing to reduce ADRs and save money.

- More than 50% of Americans have gene based variations that can be tested for and that increase the risk of an ADR.
- The wide use of DNA drug reaction testing has the potential to save tens of thousands of lives, prevent hundreds of thousands of serious events that initiate or extend hospital stays, and save hundreds of millions of dollars in health care costs. Fifty-nine percent of drugs most commonly cited in ADR studies are processed by

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- According to the FDA Vioxx may have contributed to almost 28,000 heart attacks in the US between 1999 and 2003.

Adverse drug reactions in the elderly.

Elderly patients have a decreased capacity to detoxify drugs they are taking. Drug drug interactions are also an important contributor to adverse drug reactions which makes the aging population vulnerable because of the large number of drugs they are taking.

- 90% of all persons 65 or older are taking at least one medication per week, 40% use five or more and 12% ten or more.
- A recent one year study of 30,000 Medicare out-patients showed that in a single year there were 1523 identified adverse drug events, 421 of which were preventable. 578 of these events were serious, life threatening or fatal. The most serious events were also the most preventable. JAMA 289:1107 2003

Adverse drug reactions in children and adolescents.

Few drugs are tested in children prior to release. Many are used off label in pediatric populations. For example, only Prozac (fluoxetine) has been approved for use in children, yet many others are prescribed off label.

- The FDA recently released an analysis of previous studies showing that suicidality doubled in children taking antidepressants compared to placebo resulting in a black box warning being added to antidepressant's required labeling. NEJM 351:16 2004
- While the rate of adverse drug reactions in children is lower than in adults, children with severe medical conditions are the most affected. Drug Safety 27:819 2004

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