



WOMEN'S HEALTH
RESEARCH INSTITUTE
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Science to Care

Sex and Drugs: Do Medications Affect Men and Women Differently? **June 17, 2014**

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Overview: The purpose of this presentation is to articulate how the efficacy and toxicity of drugs varies among men and women, analyze how a new approach to drug development and testing would most likely improve outcomes in both men and women, and examine the need for research about how differences in sex affect the efficacy and toxicity of drug therapy.

The Facts:

- 60% of Adverse Drug Events in emergency rooms occurred in women
- Roughly 80% of drugs withdrawn from the market were due to Adverse Drug Events in women
- Factors such as sex hormones, basal metabolic rate, drug-metabolizing enzymes, renal clearance, and behavior vary among men and women and each of these factors contribute to drug efficacy in the body

The Big Four Drugs: The four most common drugs are caffeine, ethanol, nicotine, and cannabinoids. These drugs produce differing reactions in men and women.

1. Caffeine affects the heart rates of men and women differently; this is due to the differing estrogen levels between men and women. When estrogen interacts with caffeine there are effects on heart rate and blood pressure.
2. Ethanol affects men and women differently. With non-alcoholic women, there's very little difference between intravenous and oral intake of ethanol in regards to blood ethanol level, whereas there is a large difference with non-alcoholic men.
3. Nicotine has a greater head rush effect in women than in men and higher drug strength.
4. Women are more susceptible to the development of abuse and dependence on cannabinoids. Furthermore, women have more severe withdrawal symptoms and are more likely to relapse than men.

Surfacing research indicates that levels of finasteride in pseudohermaphrodites with inherited deficiencies can help with alopecia (hair loss). Research surrounding gemcitabine and lunch injury indicates a disproportionately high fatality rate in women compared to men. These data were gathered from spontaneous reports in FDA AERS (Medwatch) Dataset and must be researched more thoroughly. Opioid dose and pain index data reveal a Simpson's Paradox in that the effect for the whole population is different when broken down by gender.

In conclusion, due to female physiologies, women are more likely than men to experience an Adverse Drug Event (AED). Physiological, hormonal, and genetic differences between males and

females affect each sexes responses to drug therapy. The recent NIH announcement requiring basic science researchers to include both sexes in cell and animal studies in conjunction with studying sex as a variable in drug clinical trials will lead to improved outcomes in both men and women. Sex-related differences in the frequencies of adverse events reporting may be due to pharmacokinetic or pharmacodynamics factors or differences in reporting patterns. Drug development research must acquire data on sex differences in absorption, distribution, metabolism, and elimination to allow exploration of sex differences in disposition and response to chemicals and drugs. There are clinically relevant sex-related differences in the efficacy and safety of drug treatment, therefore requiring the mere inclusion of female subjects will not provide sufficient data for new drug development—sex differences must, therefore, be a research variable. To minimize therapeutic adverse events, clinicians and the pharmaceutical industry must establish clear therapeutic goals for the drugs of choice prior to treatment in women.