DRUG PROMOTION

Prevention of osteoporosis

Gradual bone loss occurs normally with age in both women and men, but osteoporosis provides an excellent example of a process Lyn Payer described as the 'diseasing' of risk factors[13]. In 2000, the manufacturer of a leading osteoporosis drug ran an advertisement in women's magazines in the USA saying, "See how beautiful 60 can look? See how invisible osteoporosis can be?" The advertisement cites a nearly 1 in 2 chance of having osteoporosis, ominously "no matter how healthy you look on the outside." The company urged women to get their bone density tested, saying that osteoporosis can lead to broken bones and disfiguring dowager's hump, which can be prevented if detected early enough.

Bone density does not accurately identify women who will go on to fracture as they age; many more women are misclassified than are accurately classified[14]. Age alone is a better predictor of the risk of hip fracture. Women over 80 with bone mineral densities more than one standard deviation *above* the mean experience more fractures than any group of women aged 70–79, irrespective of their bone mineral density[15]. Bone density testing does predict use of drug therapy, however[16]. For many women, benefits of treatment may not outweigh risks, age-related bone loss is common at age 60, but hip fractures are rare.

Cardio protection: an unfulfilled promise?

Hormone treatments have been widely promoted to prevent heart disease in post-menopausal women, based on changes in lipid levels[17], and less observed heart disease in hormone users than non-users[18]. However, lipid changes do not necessarily reflect lower disease risk, and observational studies may reflect a systematic bias, since hormone users tend to be healthier and wealthier than non-users[19].

The only way to know if hormones prevent heart disease is through well-designed randomized controlled trials. The first randomised controlled trial of hormones and heart disease prevention in post-menopausal women, the HERS trial, was published in 1998[20]. This is the best available evidence, and hormone treatment did not prevent heart disease, shattering previous assumptions.

"The good news is that a woman's risk of heart disease increases dramatically after menopause, but can be significantly reduced by 35 to 50 per cent with hormone replacement therapy (HRT)," said a newspaper article in September 2000, over two years after the HERS trial was published[21]. "Post-menopausal and not taking hormone replacement therapy (HRT)" is the first 'risk factors' for heart disease listed in the article.

Isabelle Savoie and colleagues examined reports on women and heart disease in major US and Canadian women's magazines in 1997 and 1998[22]. They found over 100 articles and advertisements. Three themes predominated: heart disease is the number one killer of women; women must demand equal access to prevention and treatment; and lifestyle changes are likely to be inadequate, drug treatment is needed. A constant theme was that, "one of the most compelling reasons to take replacement hormones is for your heart's sake."

Heart disease risks were frequently exaggerated with messages that after menopause women's risk 'skyrockets' or equals that of men, which is untrue at comparable ages.

Without evidence of fracture or heart disease prevention, and with ongoing concerns about increased breast cancer risks, long-term hormone use may cause more harm than benefit. Drug promotion is not solely responsible, but it clearly contributes.

Overprescribing of psychotropic drugs: a pervasive problem

Women have long been targeted in psychotropic drug advertising, mainly those for benzodiazepine tranquillizers and sleeping pills in the 1970's and 1980's, and antidepressants in the 1990's. These advertisements often convey messages about the position of women in society. A May 2000 advertisement for an anti-anxiety drug features a cartoon drawing of an overwhelmed woman, kneeling under the weight of her anxiety, unable to cope. Unlike earlier images of housewives in benzodiazepine advertisements she is wearing office clothes, but the stereotyped message that women need their 'little helper' remains unchanged.

A 1987 Dutch study of benzodiazepine prescribing found that women were more likely than men to receive benzodiazepines when the diagnosis did not warrant it[23]. Ten years later, a US study of 8,536 physician consultations compared a random sample of visits in which patients received psychotropic drugs to visits in which they did not[24]. With similar diagnoses, health conditions, age, use and payment of clinical services and physician specialty, women were 55% more likely to receive a psychotropic drug than men.

Safety concerns?

Many drugs have been tested primarily or only on men in pre-marketing trials but are used by women – in some cases mainly by women – once they are approved. This includes many psychotropic drugs, such as anti-anxiety drugs, sleeping pills and antidepressants. Although regulatory requirements have improved, a May 2000 review by the US General Accounting Office, the investigative arm of the US Congress, found that numbers are insufficient to allow for separate analysis of drugs' effects in women.

In January 2001, the US General Accounting Office reported that eight of ten drugs withdrawn from the US market for safety reasons from 1997 through to 2000 had caused greater harm to women than men[25]. In half, this was because more women took the drug. The remaining four were due to biological differences. For example, women are more likely than men to suffer a potentially fatal heart arrhythmia from drugs that prolong the interval between the heart muscle's contractions.

Drugs withdrawn for safety reasons represent the tip of the iceberg of drug safety. A UK study combined the experience of over half a million patients: 13 men per thousand experienced suspected adverse drug reactions as compared to 21 women per thousand[26]. Many reactions were dose-related, and the difference may reflect women's smaller average body size.

Promotion of more medicine use in women of child-bearing age increases the risk of accidental exposure in early pregnancy, when women are often unaware they are pregnant. Often little is known about risks of newer drugs in pregnancy and breastfeeding.

Conclusion: what is to be done?

The medicalisation of menopause and the promotion of psychotropic drugs for women are case studies showing that drug promotion can have social as well as health effects, and can affect women differently from men. There is little systematic research on the influence of drug promotion on women.

The risks may be to society as well as to the individual if research and development focuses on 'lifestyle products' for the healthy rather than needed medicines for untreated serious diseases. A largely unexamined risk is to women's equality if individual drug treatment is the only solution offered to distressing life situations or to ill health caused by social inequality.

WHO's Ethical Criteria for Medicinal Drug Promotion stress the principle that drug promotion should be in keeping with national health policies. National governments have been slow to integrate the regulation of drug promotion into broader health and drug policies, or to consider special measures to control promotion of certain classes of drugs or targeting of certain groups. Politically such a move may be difficult, as governments often balance health against economic priorities and face international pressures. Many countries lack adequate resources for effective regulation of drug promotion, and regional or international collaboration may be the answer.

In 2001, the US Government told manufacturers of AIDS drugs to stop showing unrealistic images of treatment success. This was after a San Francisco Public Health Department study had shown that young gay men who saw many drug advertisements were at higher risk for HIV infection because they practiced more unsafe sex and tended to believe that HIV/AIDS was no longer a problem.

This is only one small step, but it shows that regulation of drug promotion can go beyond consistency with approved labelling and also reflect broader health policies. ❑

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