

XY

The gender issue

Sea turtles bury their eggs in sand near the ocean. The sex of the hatchlings is determined by temperature. If the sand is 82° F or lower the hatchlings will emerge as males. If the temperature is 88° F or higher the hatchlings will be female. Temperature between 82° and 88° F will produce a mix of males and females.

For us sex is determined by the XY sex chromosome. Females have a pair of X chromosomes. Males have an X and Y chromosome. If in the mating the male contributes an X chromosome the offspring will be female. If the male contributes a Y chromosome the offspring will be male.

Males and females! We need both, but it is a contentious relationship. The battle of the sexes has gone on since Adam and Eve ate the forbidden fruit in the Garden of Eden.

One of the most watched TV events of all time was the 1973 “Battle of the sexes” tennis match of Billie Jean King and Bobbie Riggs. The match did not turn out so well for Bobbie Riggs.

Years ago I had occasion to go through the Smithsonian displaying the women’s suffrage movement that started before the Civil War and culminated in the 19th amendment to the US Constitution; passed by Congress 4 June 1919 and enacted

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into law 26 August 1920 when Tennessee became the 36th state to ratify, satisfying the requirement of having at least 3/4th of the then 48 states for ratification.

The amendment simply states that a citizen's right to vote "shall not be denied or abridged by the United States or by any State on account of sex."

As I walked through the display you could feel the momentum build. Once the movement gathered strength there was no stopping it. Step aside if you opposed because you were going to get run over.

The women's liberation movement started in the early 1960s. It moved Congress to enact the Equal Rights Amendment that specified:

Equality of rights under the law shall not be denied or abridged by the United States or by any State on account of sex

(Approved 22 March 1972 by both houses of Congress and sent to states for ratification, but failed to get the required 3/4th states by the deadline set by Congress: 22 March 1979.)

By the mid 1980s feminists groups were arguing that women were being denied the benefits of trials because of belief that trials were done predominately in males.

The perception ultimately led to a clause in the National Institutes of Health (NIH) Revitalization Act of 1993:

In the case of any clinical trial in which women or members of minority groups will be included as subjects, the Director of NIH shall ensure that the trial is designed and carried out in a manner sufficient to provide for valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

The legislation requires trials involving conditions common to both gender groups (most conditions) to be large enough to enable researchers to say whether the treatment being tested works differently in women than in men.

Good luck.

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Anybody who knows about trials knows that it is tough enough to find a treatment that works in anybody, let alone whether it work differently in women than in men.

Willie Sutton robbed banks “Because that’s where the money is.” Trialists go where the patients are. They do not care about gender, so long as the gender mix is the same across treatment groups.

Trialists are not like Snow White standing in front of a mirror wanting to know the best treatment in all the land, but only with knowing if the treatment tested is better than the comparison treatment. Relative truth. Not absolute truth.

The issue of who is studied in trials came to the fore in a few high profile male-only trials done in the 70s and 80s:

Physicians Health Study (PHS; N= 22,071)

Multiple Risk Factor Intervention Trial (MRFIT; N= 12,866)

Coronary Drug Project (CDP; N=8,341).

All three were randomized, multicenter, and funded by the NIH. I was involved in the CDP.

The reason for focus on men was because of their high death rates from heart disease, especially in the younger ages of life. Even at 85⁺ deaths in men from heart disease exceed those for women.

The fuss ultimately led to appointment of an Academy of Medicine Committee:
Legal and Ethical Issues Relating to the Inclusion of Women in Clinical Studies

Chairs: Ruth Faden, Ph.D. (Professor, Johns Hopkins University) and Daniel Federman, MD (Professor of Medicine, Dean, Harvard Medical School)

Committee membership: 16

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As a member of the committee I argued against the perception including presentation of data from Hopkins showing more women were involved in trials than men, but I could just as well have been talking to the hand.

Data be damned when it comes to beliefs or perceptions. Perceptions trump data!
