United States General Accounting Office

GAO

Report to Congressional Requesters

May 2000

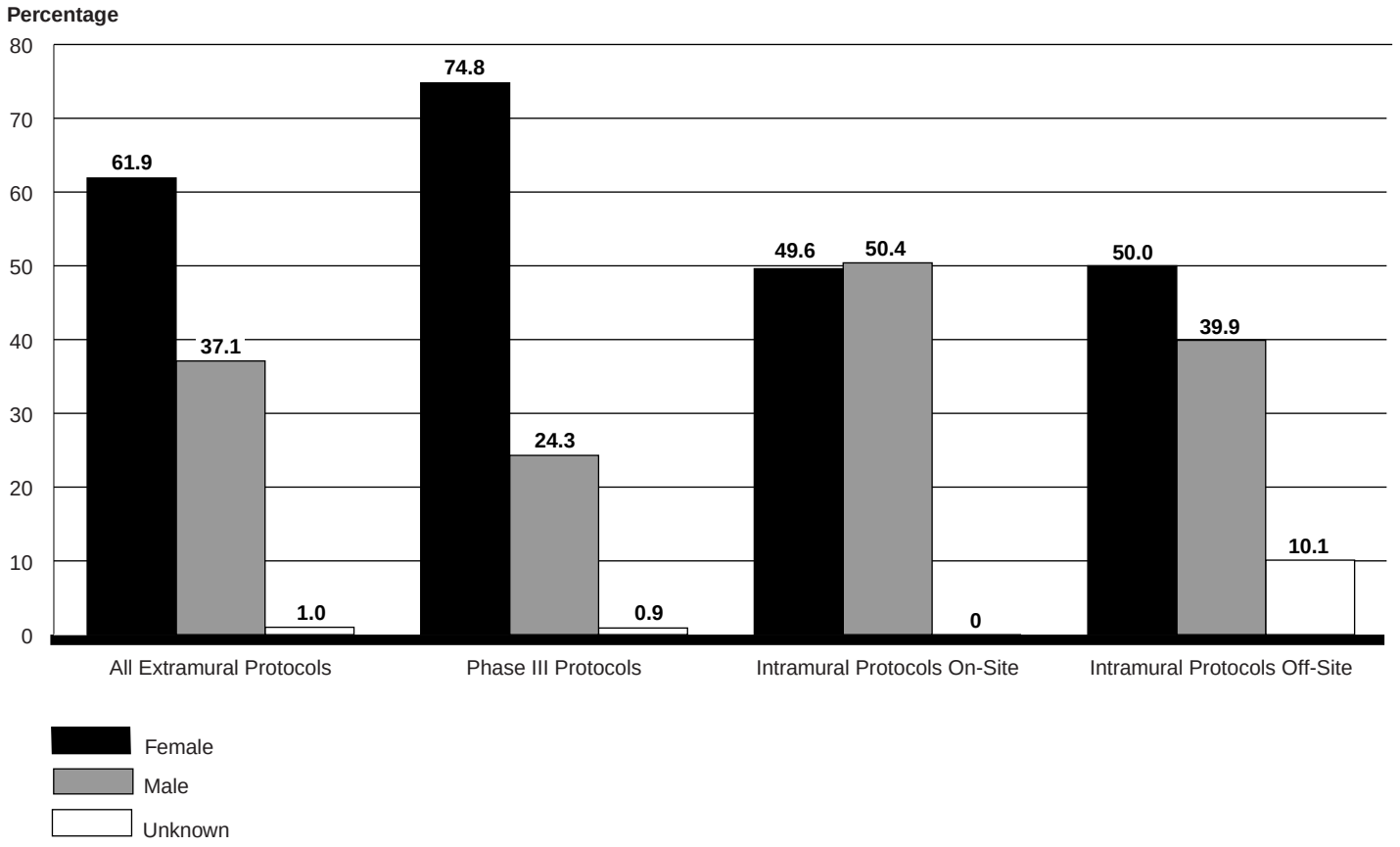
WOMEN'S HEALTH

NIH Has Increased Its Efforts to Include Women in Research

GAO/HEHS-00-96

removed from the aggregate extramural research enrollment data, the proportion of women enrolled was 52.1 percent.[14]

Figure 1: Aggregate Enrollment for NIH Extramural and Intramural Research, Fiscal Year 1997



NIH's data on the enrollment of minority women in extramural research projects indicate that blacks represented the largest proportion of minority women at 17.2 percent. Asians and Pacific Islanders represented 15.4 percent of women enrolled, and Hispanics represented 7.7 percent. (See

[14]Some studies restrict enrollment to women or to men because they focus on reproductive health, on diseases that affect women or men disproportionately or exclusively, or on the action of particular disease processes in only one or the other.

table 1.) These percentages compare favorably with the proportions of black women at 12.4 percent and Asian and Pacific Islander women at 3.6 percent in the general population; however, there is a larger proportion of Hispanic women in the general population, at 10.6 percent, than is represented in extramural research protocols at NIH.

Table 1: Enrollment of Minority Women in NIH Extramural and Intramural Research as a Percentage of Total Female Enrollment, Fiscal Year 1997

Type of research	American Indians and Alaska Natives	Asian and Pacific Islanders	Black, Not Hispanic	Hispanic	White, Not Hispanic	Other and unknown
All extramural	1.1	15.4	17.2	7.7	52.7	5.9
Extramural phase III	1.3	2.0	11.6	4.4	79.5	1.3
Intramural						
On-site	0.1	4.3	12.4	3.6	78.2	1.4
Off-site	0.2	55.3	3.8	0.5	38.4	1.8

NIH officials are cautious, however, about directly comparing enrollment data with national census figures. They believe that the goal of the NIH policy is to conduct biomedical and behavioral research in such a manner that scientific knowledge can be generalized to the entire U.S. population, not to satisfy proportional representation. NIH considers that the appropriate numbers of women or minority subgroups included in a particular study depend on the scientific question addressed in the study and the prevalence among women and minority subpopulations of the disease, disorder, or condition under investigation. Some studies, for example, would require a rate of minority participation higher than a group's presence in the overall population, and others would be sound with lower minority participation.

The Enrollment of Women and the Proportion of Studies Tracked Vary Across Institutes

When we examined the fiscal year 1997 distribution of studies by the percentage of women participating, most (52.5 percent) had enrolled between 30 and 60 percent women participants. Seventy percent of the studies had populations that were at least 40 percent women. (See table 2.) Among the six institutes we reviewed in detail, the range in aggregate enrollment of women in clinical research in fiscal year 1997 ran from the National Cancer Institute's highest at 70.9 percent to the National Institute of Allergy and Infectious Diseases' lowest at 48.1 percent.

Table 2: The Distribution of Fiscal Year 1997 Clinical Studies by the Percentage of Women Participants

Percent of women	Number of studies	Percent of studies
100	740	14.5
90 up to 100	45	0.9
80 up to 90	105	2.1
70 up to 80	196	3.9
60 up to 70	388	7.6
50 up to 60	1,115	21.9
40 up to 50	974	19.1
30 up to 40	586	11.5
20 up to 30	377	7.4
10 up to 20	224	4.4
1 up to 10	95	1.9
0	244	4.8
Total	5,089	100.0

Note: Excludes 74 studies in which it was not known whether the participants were women or men.

ORWH Helps Monitor Implementation of the Inclusion Policy and Develop NIH's Women's Health Research Agenda

ORWH has a mandate to ensure that women and minorities are included in clinical research that NIH funds, and it is specifically responsible for carrying out the guidelines on inclusion and coordinating the data tracking system. It conducted training and education on the inclusion policy when the policy first took effect but has not provided NIH staff with ongoing training on the data tracking system. ORWH took the lead at NIH in developing an agenda for research on women's health, obtaining input from individuals and groups outside NIH through numerous conferences, workshops, and its Advisory Committee for Research on Women's Health. ORWH has provided funding support to institutes and centers for women's health research that it considers important.

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July 2001

WOMEN'S HEALTH

Women Sufficiently Represented in New Drug Testing, but FDA Oversight Needs Improvement

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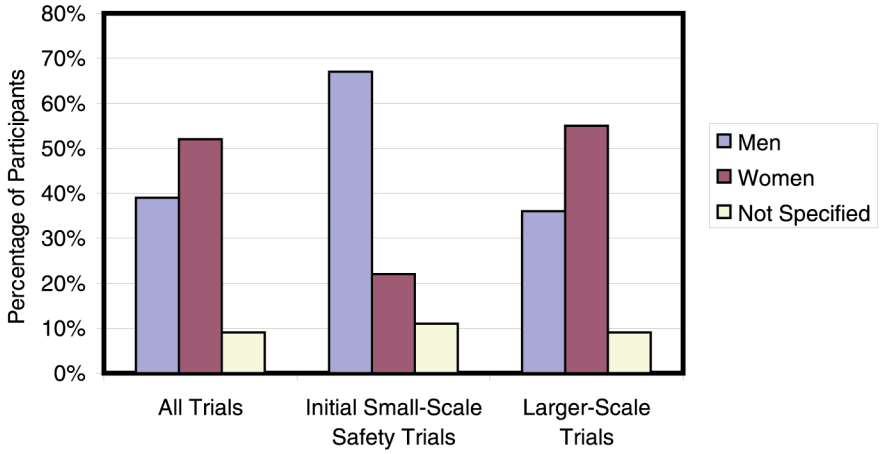
development varied greatly (see figure 1). Women were 22 percent of the participants in the initial, small-scale safety trials used to set the dosing levels for larger-scale trials but were more than one-half of the participants in the subsequent larger trials.

Figure 1: Participants in Clinical Drug Trials by Sex



Source: GAO's review of 36 new drug applications.

FDA has not effectively overseen the presentation and analysis of data related to sex differences in drug development. There is no management system in place to record and track the inclusion of women in clinical drug trials or to monitor compliance with relevant regulations, so FDA is unaware that many new drug application submissions failed to meet standards. The agency also does not routinely review the required tabulation of demographic data by sex in the annual reports for drugs in development. Finally, FDA management has lacked procedures to determine whether the written reviews of new drug applications prepared by its medical officers adequately discuss sex differences. FDA's medical officers have not been required to discuss sex differences in their reviews of new drug applications, and we found that many of them have not done so. Furthermore, even though about one-third of new drug applications specified that the concentrations of the drug in the bloodstream were greater in people who weighed less, such as women, FDA reviewers did not comment in their summaries on the lack of dose adjustments based on sex. Without this documentation FDA management cannot be sure that