

Research Professionals' Experience and Perspectives on Women's Participation in Clinical Research

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Background

Despite continued focus and federal funding requisites, significant gender and racial disparities persist in clinical research participation. Although understanding regarding research professionals’ perspectives about barriers to minority participation has improved, their perspective regarding women’s enrollment remains understudied.

Objective

To identify research professionals’ attitudes, barriers and potential facilitators to enrolling women in clinical research.

Hypothesis

Investigator bias has a tangible effect on female participation in clinical research.

Methods

We conducted an anonymous and voluntary nationwide survey of research professionals whose institution received NIH and/or AHRQ funding in 2013 to conduct clinical research. Research professionals were surveyed regarding factors perceived as barriers deterring women from participation versus factors deterring research professionals from enrolling them (7 questions each) on a 5-point Likert-type scale ranging from “strongly disagree” (score=1) to “strongly agree” (score=5).

Results

Out of 13,541 recipients, only 1,007 (7.4%) responded. After excluding those 374 who were not involved in enrolling patients, 633 surveys were analyzed. Of these, 409 (64.6%) were from investigators, 473 (74.7%) were enrolling in federally funded studies, and 335 (52.9%) were female (Table 1).

Fear of unknown side-effects and unavailability for follow-up visits were the most significant perceived patient barriers to women’s participation, both with a median score of “4” (IQR=1) (Table 2a). Respondents were neither hesitant nor listed any factor as significant barrier to enrolling women (all with a median score of “1,” IQR=1) (Table 2b).

Women over child-bearing age were considered more likely to participate in research (median “3,” IQR=0). A majority indicated that DVDs demonstrating how to approach female candidates might be useful in enrollment training (median “3,” IQR=1) (Table 3).

Table 1: Demographics of the Respondents		
Variables	Coding	N (%)
What is your role in clinical research?	Investigator	409 (64.6)
	Coordinator	92 (14.5)
	Research Nurse	22 (3.5)
	Research Associate	16 (2.5)
	Research Assistant	7 (1.1)
	Other	22 (3.5)
	Combination	64 (10.1)
What type of institution do you currently work at?	Missing	1 (0.2)
	Academic hospital	445 (70.3)
	Community hospital	35 (5.5)
	Academic Community hospital	85 (13.4)
	Government / VA hospital	6 (1)
	Other	34 (5.4)
	Multiple	27 (4.3)
Number of studies you enrolled for within the last 5 years	Missing	1 (0.2)
	None	8 (1.3)
	1-5	371 (58.6)
	6 or more	254 (40.1)
Were any of the studies federally funded?	Yes	473 (74.7)
	No	146 (23.1)
	Don't know	13 (2.1)
	Missing	1 (0.2)
What is your gender?	Female	335 (52.9)
	Male	191 (30.2)
	Missing	107 (16.9)
What is your current employment status?	Full time	498 (78.7)
	Part time	25 (4)
	Per diem	1 (0.2)
	Other	3 (0.5)
	Missing	106 (16.8)

Table 2a. Research Professionals' Opinion on What Discourages Women from Participating?									
	N	Mean	SD	Median (IQR)	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Their distrust in doctors	550	2.7	0.9	3 (1)	37 (6.7)	219 (39.8)	173 (31.4)	110 (20.0)	11 (2.0)
Their fear of unknown side effects	544	3.5	1	4 (1)	19 (3.5)	76 (14.0)	123 (22.6)	273 (50.2)	53 (9.7)
Their fear of unknown pregnancy	549	2.6	0.9	3 (1)	59 (10.8)	178 (32.4)	242 (44.1)	62 (11.3)	8 (1.5)
Their fear of risk to fetus	545	2.9	1.1	3 (2)	56 (10.3)	124 (22.8)	213 (39.1)	110 (20.2)	42 (7.7)
Opposition from their spouse	549	3.1	0.9	3 (2)	25 (4.6)	124 (22.6)	210 (38.3)	170 (31.0)	20 (3.6)
Their unavailability for follow-up visits	549	3.7	0.9	4 (1)	8 (1.5)	61 (11.1)	137 (25.0)	247 (45.0)	96 (17.5)
Their unavailability for follow-up phone calls	548	2.9	0.9	3 (2)	27 (4.9)	172 (31.4)	207 (37.8)	119 (21.7)	23 (4.2)

Table 2b. What Discourages Research Professionals from Enrolling Women?									
	N	Mean	SD	Median (IQR)	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
I hesitate to enroll women	524	1.3	0.6	1(0)	406 (77.5)	89 (17.0)	25 (4.8)	4 (0.8)	0 (0.0)
My religious beliefs	525	1.2	0.5	1(0)	447 (85.1)	56 (10.7)	20 (3.8)	2 (0.4)	0 (0.0)
My fear for their unplanned pregnancy	524	1.4	0.7	1(1)	369 (70.4)	98 (18.7)	50 (9.5)	7 (1.3)	0 (0.0)
My fear that they might withdraw because of unplanned pregnancy	524	1.4	0.7	1(1)	363 (69.3)	104 (19.9)	47 (9.0)	9 (1.7)	1 (0.2)
Their unavailability for follow-up visits	523	1.5	0.9	1(1)	340 (65.0)	112 (21.4)	47 (9.0)	22 (4.2)	2 (0.4)
Their unavailability for follow-up phone calls	525	1.5	0.8	1(1)	349 (66.5)	118 (22.5)	39 (7.4)	17 (3.2)	2 (0.4)
Their dependence on their family's approval	525	1.5	0.7	1(1)	352 (67.1)	120 (22.9)	42 (8.0)	9 (1.7)	2 (0.4)

Table 3. Research Professionals' Observations regarding Female Participants' Age and Recommendations for Helpful Tools to Boost Their Comfort Level in Enrolling Women									
	N	Mean	SD	Median (IQR)	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Women over child-bearing age are more likely to participate.	576	3	0.8	3 (0)	18 (3.1)	113 (19.6)	304 (52.8)	123 (21.4)	18 (3.1)
DVD demonstrating how to approach female candidates would be helpful to me in enrolling women.	528	2.7	1.1	3 (1)	94 (17.8)	119 (22.5)	188 (35.6)	116 (22.0)	11 (2.1)

Conclusion

Research professionals perceive that women over child-bearing age are more likely to participate in clinical research than younger women. Although they expressed no hesitance in approaching women for participation, a majority responded that DVDs demonstrating how to approach women for research might improve their comfort with enrolling women.



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