Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Original article

Gender disparities in coronavirus disease 2019 clinical trial leadership

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ABSTRACT

Objectives: To compare the gender distribution of clinical trial leadership in coronavirus disease 2019 (COVID-19) clinical trials.

Methods: We searched https://clinicaltrials.gov/ and retrieved all clinical trials on COVID-19 from 1 January 2020 to 26 June 2020. As a comparator group, we have chosen two fields that are not related to emerging infections and infectious diseases: and considered not directly affected by the pandemic: breast cancer and type 2 diabetes mellitus (T2DM) and included studies within the aforementioned study period as well as those registered in the preceding year (pre-study period: 1 January 2019 to 31 December 2019). Gender of the investigator was predicted using the genderize.io application programming interface. The repository of the data sets used to collect and analyse the data are available at https://osf.io/k2r57/.

Results: Only 27.8% (430/1548) of principal investigators among COVID-19-related studies were women, which is significantly different compared with 54.9% (156/284) and 42.1% (56/133) for breast cancer ($p < 0.005$) and T2DM ($p < 0.005$) trials over the same period, respectively. During the pre-study period, the proportion of principal investigators who were predicted to be women were 49.7% (245/493) and 44.4% (148/333) for breast cancer and T2DM trials, respectively, and the difference was not statistically significant when compared with results from the study period ($p > 0.05$).

Conclusion: We demonstrate that less than one-third of COVID-19-related clinical trials are led by women, half the proportion observed in non-COVID-19 trials over the same period, which remained similar to the pre-study period. These gender disparities during the pandemic may not only indicate a lack of female leadership in international clinical trials and involvement in new projects but also reveal imbalances in women's access to research activities and funding during health emergencies. **Muge Cevik, Clin Microbiol Infect 2021;27:1007**

Introduction

In addition to the human and financial losses associated with the novel coronavirus disease 2019 (COVID-19) pandemic, COVID-19 has also had a significant impact on both the personal and professional lives of the global workforce, including those of the scientific research community [1–3]. Before COVID-19, women occupied fewer leadership positions, led fewer funded studies, and

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applied for and received less grant funding than men when they did apply [4–7]. The employment gap that occurs when women take parental leave impacts the rate of academic advancement and in turn the receipt of institutional support to apply for and secure funding [6,7]. These imbalances contribute to systemic inequalities that hamper women's access to and progress in science [2,7,8]. A review of the gender distribution of 24 COVID-19 national task forces suggests that many committees comprise less than one-quarter women, indicating that women's voices and expertise have been excluded from decision-making during this unprecedented public health emergency [9].

For example, emerging data suggest that across all disciplines, despite an increased number of peer-reviewed articles submitted to journals during the pandemic, women have published fewer papers than men so far this year [10]. This may indicate a similarly reduced involvement of women in research leadership positions and an imbalanced distribution of grants and funding – important indicators of advancement in a scientist's academic career [4–7,10,11]. Being principal investigator (PI) on a clinical trial is strongly associated with advancement to full professor among female academics in infectious diseases [8].

The COVID-19 pandemic offers numerous opportunities in clinical research. These include trials to assess the safety and efficacy of medical interventions, with protocols in various stages of implementation. Here, we compare the gender distribution of clinical trial leadership in COVID-19 clinical trials.

Materials and methods

We systematically searched https://clinicaltrials.gov/ and retrieved all clinical trials on COVID-19 registered from 1 January 2020 to 26 June 2020 using COVID as a keyword. As a comparator group, we have chosen two fields that are not related to emerging infections and infectious diseases, and considered not directly affected by the pandemic: breast cancer and type 2 diabetes mellitus (T2DM). We retrieved all clinical trials related to these comparator conditions registered at https://clinicaltrials.gov/ within the aforementioned study period as well as those registered in the preceding year (pre-study period: 1 January 2019 and 31 December 2019). We retrieved the names of investigators listed; study director, principal investigator (PI) (the person who is responsible for the scientific and technical direction of the entire clinical study) and study chair (whose role involves toxicity and accrual monitoring). Gender of the investigator was predicted using the genderize.io application programming interface. This tool has been used to predict the gender of first names in studies regarding gender bias [12,13] and achieves a minimum accuracy of 82%, with an F1 score (weighted average of precision and recall) of 90% for women and 86% for men [14]. Clinical trials were excluded if (a) investigator information was not provided; (b) the genderize.io application programming interface could not predict the gender of any of the investigators from their first name; or (c) organization or company names were provided as the investigator. The number of studies that were excluded for the above reasons are reported in the Supplementary material. An exploratory temporal analysis was conducted with the available data. Categorical variables were summarized by frequencies and percentages. We compared groups using χ^2 testing for equality of proportions with continuity correction [15]. The analysis was performed using R (Version 4.0.2). The repository of the data sets used to collect and analyse the data is available at https://osf.io/k2r57/.

Results

We identified 2345 COVID-19-related clinical trials. Of those, 1448 had at least one investigator listed (i.e. PI, study director, or study chair) whose gender could be predicted. In the comparator group, we identified 449 trials on breast cancer and 272 on T2DM that were registered. Of those, 274 breast cancer studies and 139 T2DM studies had at least one investigator whose gender could be predicted.

Overall, 27.8% (430/1548) of PIs among COVID-19-related studies were predicted to be women, which is significantly different compared with 54.9% (156/284) and 42.1% (56/133) for breast cancer ($p < 0.005$) and T2DM ($p < 0.005$) trials over the same period, respectively (Table 1). Although there has been a small increase in the proportion of PIs who were predicted to be women in May 2020, clinical research leadership for COVID-19 among this group was below 25% for the remainder of the study period (see Supplementary material). While 31.4% (76/242) of study chairs were predicted to be women in COVID-19-related studies, 32.1% (9/28) (p 0.7) and 63.6% (7/11) ($p < 0.01$) were predicted to be women in breast cancer and T2DM trials, respectively. The proportion of study chairs was not significantly different across the three fields.

We also reviewed comparator group studies registered before 1 January 2020 to determine whether the pandemic might have affected gender distribution of trial leadership. We identified 839 clinical trials related to breast cancer and 533 on T2DM over a 12-month period before 1 January 2020. Of those, 573 breast cancer studies and 359 T2DM studies yielded at least one investigator whose gender could be predicted. During this pre-study period, the proportion of PIs who were predicted to be women were 49.7% (245/493) and 44.4% (148/333) for breast cancer and T2DM trials, respectively, and the difference was not statistically significant when compared with results from the study period ($p > 0.05$).

Discussion

In this study, we demonstrate that less than one-third of COVID-19-related clinical trials are led by female PIs, half the proportion observed in non-COVID-19 (breast cancer and T2DM) trials over the same period. The proportion of PIs in breast cancer and T2DM studies also remained similar to the pre-study period. These gender disparities during the pandemic may indicate not only a lack of women's leadership in international clinical trials and involvement in new projects, but also may reveal imbalances in women's access to research activities and funding during health emergencies [2,16].

Table 1
Proportion of women in positions of leadership in clinical trials between 1 January 2020 and 26 June 2020 and before 1 January 2020

	1 January 2020 to 26 June 2020					Before 1 January 2020		
	Coronavirus disease 2019	Breast cancer	p value	Type 2 diabetes mellitus	p value	Breast cancer	Type 2 diabetes mellitus	p value
Principal investigator	27.8% (430/1548)	54.9% (156/284)	<0.01	42.1% (56/133)	<0.01	49.7% (245/493)	44.4% (148/333)	0.15
Study director	28.7% (72/251)	48.9% (23/47)	<0.01	22.2% (4/18)	0.75	30.5% (29/95)	47.6% (40/84)	0.02
Study chair	31.4% (76/242)	32.1% (9/28)	1	63.6% (7/11)	0.98	33.3% (26/78)	40.4% (19/47)	0.54

The COVID-19 pandemic offers numerous opportunities for research and leadership that could equalize opportunity in a new field, but our results suggest the opposite. The pandemic has reinforced the prevailing gender norms in which men continue to be allocated a disproportionate share of the funding, as well as leadership and authorship roles [9,10,16]. One potential contributor for this discrepancy is the speed demanded by the research agenda during the pandemic. The sense of urgency in starting clinical trials may lead to an abandonment of any checks and balances around equality and inclusion that would have otherwise encouraged the involvement of female scientists. Many female scientists have already raised concerns about institutional funding distribution lacking gender balance or about being left out of research activities despite their expertise [2,16]. During the COVID-19 pandemic, a UK study showed that women were more than twice as likely to take on childcare and schooling responsibilities of children than men, whereas their male academic counterparts leverage professional relationships and networks more effectively [1,2,16].

As a community, we must recognize that there is a tendency to 'turn to men' in times of crisis both for leadership and scientific expertise [2,3,16,17], highlighting the need to challenge this culture. Research and academia are already competitive; being in the central decision-making group is often challenging due to gender norms, along with roles and rules on how these groups are established and maintained; during health emergencies, these same authoritative circles become more difficult for female scientists to join [2,16]. Our findings suggest that there is a need for transparency in opportunities and funding that requires actively identifying and addressing the structurally implicit and unconscious biases that favour men. For example, in recent years, the campaign against MANELs (Male-only Panels) has already met considerable support in the scientific community and several influential journals have published policies and editorials in support of women in science and medicine.

The evidence, although sparse, indicates that teams that are diverse in terms of gender, ethnicity and social background produce better health science, are more highly cited, generate a broader range of ideas and innovations, and better represent society [2,16,18,19]. Not only can these women drive discovery and innovation, but they can act to address health disparities and provide role models for the next generation of female scientists [2,16,18,19]. Ensuring gender representation would also reflect the commitment of the global community to promoting gender equality in academic medicine and research: inclusion, diversity, representation, progression and success for all. Therefore, the disadvantages not only affect women themselves and their research career but have much more profound implications for wider society, especially given the disproportionate burden of such outbreaks for communities who are marginalized due to their gender, sexuality, class, ethnicity and ability [20–22].

Our analysis has some limitations. We could include only about 50%–75% of trials for which an investigator's gender could be algorithmically predicted because the majority of studies had no investigator information, or the investigator names were not distinguishable (see Supplementary material). Furthermore, although such algorithms allow for the rapid analysis of gender disparities such as those conducted here, they can also be exclusionary to gender non-conforming, non-binary, and trans individuals. Beyond these limitations, although there were several observational studies in our data set, clinicaltrials.gov may be biased towards randomized control trial registration and women may be more likely to be involved in observational studies, which still demonstrates gender disparities in types of trials women lead. Also, we did not consider studies that received private funding, which may not have been registered on clinicaltrials.gov; however, it is worth noting that clinicaltrials.gov is an international database with widespread international representation. Finally, although we attempted to provide a comparison with two other fields, a potential for bias could arise from the difference of gender distributions of researchers working in the fields of infectious diseases, breast cancer and diabetes.

In summary, the COVID-19 pandemic has so far provided many new opportunities for research, with numerous clinical trials initiated worldwide, but a disproportionate number of PIs leading COVID-19-related studies are predicted to be men, despite women accounting for 70% of the global health workforce [16]. Our demonstration of gender differences in trial leadership argue for revised policies and strategies that encourage the participation and leadership of women in pandemic research. This may include setting up review committees that are gender balanced, providing the available funding to equal numbers of PIs, or funding gender-balanced trial teams, and overall ensuring that funding agencies are aware of the lack of female leadership in clinical trials.

Authors' contributions

MC contributed to conceptualization, methodology, investigation, literature review, data curation and writing the original draft. SH and MM contributed to investigation, data curation, formal analysis and to reviewing and editing; JS, KK and PS contributed to methodology, to reviewing and editing, and supervision. CO contributed to conceptualization, methodology, investigation, literature review, writing the original draft and supervision.

Transparency declaration

MC, SH, JS, MM have none to disclose. CO has received honoraria, fees for lectures and advisory boards from Gilead, MSD, Viiv and Janssen. She has also received research grants to her institution from the above-mentioned companies. PES has received honoraria, fees for lectures and advisory boards from Gilead, Merck, Janssen and ViiV; he has also received research grants to his institution from Gilead and ViiV. KK has received personal fees from GSK, outside the submitted work.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cmi.2020.12.025.

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