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INVESTIGACIÓN SANITARIA
Hospital Clínico San Carlos

Investigación bajo la perspectiva de género

Hospital Clínico San Carlos
SaludMadrid

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¿Por qué la perspectiva de género en investigación? Consecuencias negativas

- Limitación de la creatividad, la excelencia y el beneficio a la sociedad (Caprile 2012; Tannenbaum et al. 2019)
- Ciencia basada en estereotipos (de género) = mala ciencia y pérdida de oportunidades
- Ausencia de una mirada crítica que puede aportar un enfoque previamente no contemplado
- Pérdida de validez científica de los resultados
- Necesidades sociales sin respuesta
- Perpetuación de normas y relaciones tradicionales de género vs contribución a su transformación

nature COMMUNICATIONS

ARTICLE

https://doi.org/10.1038/s41467-021-24265-8 OPEN

Lack of consideration of sex and gender in COVID-19 clinical studies

Emer Brady [1], Mathias Wullum Nielsen [2], Jens Peter Andersen [1] & Sabine Oertelt-Prigione [3,4]

Sex and gender differences impact the incidence of SARS-CoV-2 infection and COVID-19 mortality. Furthermore, sex differences influence the frequency and severity of pharmacological side effects. A large number of clinical trials to develop new therapeutic approaches and vaccines for COVID-19 are ongoing. We investigated the inclusion of sex and/or gender in COVID-19 studies on ClinicalTrials.gov, collecting data for the period January 1, 2020 to January 26, 2021. Here, we show that of the 4,420 registered SARS-CoV-2/COVID-19 studies, 935 (21.2%) address sex/gender solely in the context of recruitment, 237 (5.4%) plan sex-matched or representative samples or emphasized sex/gender reporting, and only 178 (4%) explicitly report a plan to include sex/gender as an analytical variable. Just eight (17.8%) of the 45 COVID-19 related clinical trials published in scientific journals until December 15, 2020 report sex-disaggregated results or subgroup analyses.

Women's Health Reports > Vol. 3, No. 1 > Original Article Open Access

Sex Inequalities in Medical Research: A Systematic Scoping Review of the Literature

Lea Merone, Komla Tsey, Darren Russell, and Cate Nagle

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Abstract

Background: Historically, medical studies have excluded female participants and research data have been collected from males and generalized to females. The gender gap in medical research, alongside overarching misogyny, results in real-life disadvantages for female patients. This systematic scoping review of the literature aims to determine the extent of research into the medical research sex and gender gap and to assess the extent of misogyny, if any, in modern medical research.

Methods: Initial literature searches were conducted using PubMed, Science Direct, PsychINFO and Google Scholar. Articles published between January 01, 2009, and December 31, 2019, were included. An article was deemed to display misogyny if it discussed the female aesthetic in terms of health, but did not measure health or could not be utilized to improve clinical practice.

Results: Of the 17 included articles, 12 examined the gender gap in medical research and 5 demonstrated misogyny, assessing female attractiveness for alleged medical reasons. Females remain broadly under-represented in the medical literature, sex and gender are poorly reported and inadequately analyzed in research, and misogynistic perceptions continue to permeate the narrative.

Comment | Published: 24 May 2022

Sex bias in clinical trials in gastroenterology and hepatology

Patrizia Burra, Alberto Zanetto & Giacomo Germani

Nature Reviews Gastroenterology & Hepatology **19**, 413–414 (2022) | Cite this article

1067 Accesses | **1** Citations | **7** Altmetric | Metrics

Biological sex bias in clinical trials is a common issue in various medical fields, including gastroenterology and hepatology. Without sex parity and increased attention to sex-specific analyses, the translation of trial results into real-world clinical practice remains suboptimal with unpredictable consequences for patient care.

ELSEVIER

Contemporary Clinical Trials

Volume 115, April 2022, 106718

Enrollment of female participants in United States drug and device phase 1–3 clinical trials between 2016 and 2019

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Abstract

Background

Historically, females have been underrepresented in clinical trials evaluating the safety and efficacy of investigational drugs and devices. We assessed participation by sex in recent clinical trials.

Methods

We extracted data over a 4-year period (2016–2019) from ClinicalTrials.gov on US-ased, pharmaceutical industry or government-funded Phase 1–3 clinical trials of rugs and devices. We included trials with adult cardiovascular, psychiatric, and ncer endpoints whose protocol planned to enroll both sexes. Average proportions females enrolled per trial were described overall and by disease area.

esults

cross 1433 trials including 302,664 participants in our analysis, on average, 41.2% ere female. Females were underrepresented compared with their proportion of the sease population in cardiovascular disease trials (41.9% female participants vs.)% female population with cardiovascular disease). In psychiatry, where females mprise 60% of patients, the mean participation of females in clinical trials was .0%. Similarly, for cancer trials, where 51% of patients are female, only 41.0% of ncer clinical trial participants were female. For each therapeutic area analyzed, the rticipation of females in clinical trials fell short of the benchmark derived from ational prevalence data.

Conclusions

While the participation of females in clinical trials has improved compared to previous reports, sex-based gaps still persist between trial populations and thc expected to use these drugs/devices based on distributions of diseases in the population. Given potential sex-based differences in treatment responses and toxicities, adequate inclusion of females in clinical trials remains critical.

¿Por qué la perspectiva de género en investigación? Consecuencias positivas I

- Equipos de investigación con equilibrio de género tienden a funcionar mejor porque…
  - … mejora en actividad de los equipos → atracción de personas investigadoras de alto nivel
  - … el mejor equipo posible = mixto*: mayor eficiencia, creatividad, diversidad de puntos de vista, calidad en la toma de decisiones
- **Suficiente representación de mujeres + <u>valores de igualdad</u>**

¿Por qué la perspectiva de género en investigación? Consecuencias positivas II

- Mejores propuestas para proyectos de investigación
  - Inclusión de la perspectiva de género → indicador frecuente para la evaluación en convocatorias autonómicas, estatales e internacionales
  - Mayores oportunidades de financiación
  - Mayor tasa de éxito en convocatorias competitivas

GOBIERNO DE ESPAÑA
MINISTERIO DE CIENCIA E INNOVACIÓN

AGENCIA ESTATAL DE INVESTIGACIÓN

Nota informativa sobre evaluación de la Integración del Análisis de Género en la Investigación (IAGI), en las convocatorias de la Agencia Estatal de Investigación

[Actualizada a noviembre de 2020]

IAGI

- Integrar transversalmente el análisis de sexo y/o género en todas las fases del ciclo de una investigación (sea o no específica de género), siempre que la temática, resultados o aplicaciones del proyecto puedan afectar (in)directamente a seres humanos

- Garantizar mayor rigor científico, basado en la evidencia y en la investigación ética

- Ejemplos: GENDERED INNOVATIONS y GENDERED INNOVATIONS 2

Igualdad e inclusión de género = prioridad transversal

Objetivo: eliminar la desigualdad de género y otras desigualdades (**interseccionalidad**)

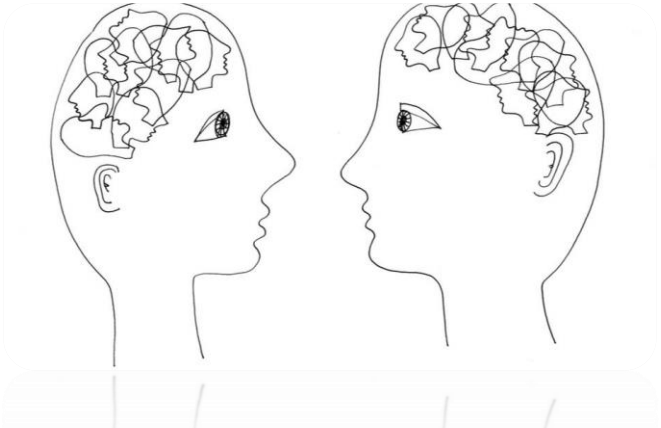
discapacidad, etnia y LGBTIQ+

Sesgos inconscientes y barreras estructurales

+++: salud, cuidado (COVID-19), violencia, IA, robótica, cambio climático

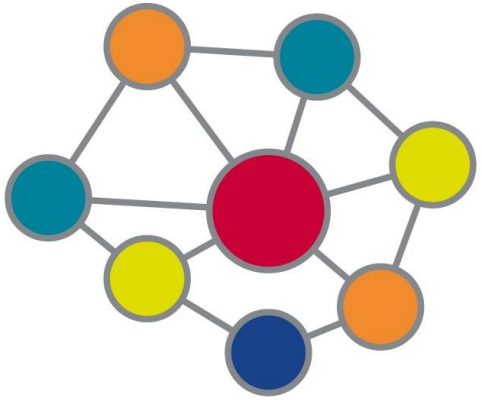
¿Cómo integrar la perspectiva de género en investigación? I

- **Enfoque de investigación →** ¿de qué forma las conclusiones del proyecto se aplicarán a las necesidades específicas de hombres y/o mujeres?
- **Revisión de la literatura →** posibles diferencias y/o semejanzas de sexo/género por las implicaciones en/de los resultados de la investigación en mujeres y/o hombres (o en animales, tejidos y células)
- **Preguntas e hipótesis de la investigación →** análisis riguroso de sexo y/o género sobre posibles diferencias y/o semejanzas que pueda haber entre hombres y mujeres (o en animales, tejidos y células).



¿Cómo integrar la perspectiva de género en investigación? II

- **Cuestiones éticas →** identificación y abordaje adecuado de las implicaciones particulares para hombres y/o mujeres
- **Difusión/transferencia del conocimiento →**
  - Estrategia sólida para la aplicación adecuada de los resultados de la investigación a las necesidades específicas de mujeres y/o hombres
  - Se informará de las diferencias y/o semejanzas que se detecten gracias al proyecto



Heidari *et al. Research Integrity and Peer Review* (2016) 1:2
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Resea

REVIEW

Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use

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Competing interests

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Author Contributions

All authors contributed equally to the drafting, writing, and review of this manuscript.

Review

The Sex and Gender Equity in Research (SAGER) guidelines: Implementation and checklist development

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Table 1. SAGER guidelines checklist
Studies with human participants

Section / topic	Item number	Checklist item	Reported on page number
General			
	1	The terms sex/gender used appropriately	
Title			
	2	Title specifies the sex/gender of participants if only one included	
Abstract			
	3a	Abstract specifies the sex/gender of participants if only one included	
	3b	Study population described with sex/gender breakdown*	

Introduction			
	4a	If relevant, previous studies that show presence or lack of sex/gender differences or similarities are cited	
	4b	Mention of whether sex/gender might be an important variant and if differences might be expected	
	4c	The demographics of the study population with regard to sex/gender (eg, disease prevalence among male/female study participants) are outlined*	
Methods			
	5a	Method of definition of sex/gender (eg, self-report, genetic testing)	
	5b	Description of how sex/gender was considered in the design, whether authors ensured adequate representation of male and female study participants, justification of the reasons for any exclusion of male or female participants, or explanation if not considered. Justification of other sex/gender-specific interventions of study designs (eg, mandating contraception for women).* Explicit reporting of the scientific rationale f	

contraception requirements and exclusions for pregnancy and lactation should be required*

Results			
	6a	Study population description with complete gender/sex breakdown for all categories considered*	
	6b	Where appropriate, data presented disaggregated by sex/gender, and sex/gender differences and similarities are described	
	6c	Sex- and gender-based analyses reported regardless of outcome (in main paper if pre-specified; otherwise in appendix)*	
	6d	For clinical trials, adverse event data disaggregated by sex/gender (in main paper if pre-specified; otherwise in appendix)*	
	6e	Patient-reported outcome data disaggregated by sex/gender (in main paper if pre-specified; otherwise in appendix)*	
	6f	For epidemiological studies, the effects of other exposures on health problems examined for all genders and analysed critically from a gender perspective	
	6g	Table 1 includes separate rows for male sex/gender, female sex/gender and other categories if collected*	
Discussion			
	7a	Potential implications of sex/gender on the study results and analyses, including the extent to which the findings can be generalized to all sexes/genders in a population	
	7b	If a sex/gender analysis not done, a rationale is given and implications of the lack of such analysis on the interpretation of the results are discussed	

Table 2. SAGER guidelines checklist
Other studies (applied sciences, biological sciences)

Section / topic	Item number	Checklist item	Reported on page number
General			
	1	The terms sex/gender used appropriately	
Title			
	2a	Title specifies the sex of animals or any cells, tissues, and other material derived from these	
	2b	In applied sciences (technology, engineering, etc.), the title indicates if the study model was based on one sex/gender or the application was considered for the use of one specific sex/gender	
Abstract			
	3a	Abstract specifies sex of animals or any cells, tissues, and other material derived from these	
	3b	In applied sciences (technology, engineering, etc.), the abstract indicates if the study model was based on one sex/gender or the application was considered for the use of one specific sex/gender	
Introduction			
	4a	If relevant, previous studies that show presence or lack of sex or gender differences or similarities are cited	
	4b	Mention of whether sex/gender might be an important variant and if differences might be expected	

Methods			
	5a	In cell biological, molecular biological, or biochemical experiments, the origin and sex chromosome constitutions of cells or tissue cultures are stated. If unknown, the reasons are stated	
	5b	For studies testing devices or technology, explanation of whether the product will be applied or used by all genders and if it has been tested with a user's gender in mind	
	5c	If relevant, description of how sex/gender was considered in the design	
	5d	For in-vivo and in-vitro studies using primary cultures of cells, or cell lines from humans or animals, or ex-vivo studies with tissues from humans or animals, the sex of the subjects or source donors is stated (except for immortalized cell lines, which are highly transformed)	
Results			
	6	For studies using animal models, present a sex breakdown of the animals*	
Discussion			
	7	If relevant, potential implications of sex/gender on the study results and analyses, including the extent to which the findings can be generalized to all sexes/genders in a population	

Otros recursos

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