Authors: Liz Southey[a], Olivia Kager[b], Elena Mills[a], Laure Nas de Tourris[c], Emma Vitalini[d], Alice Witt[e], Kate Womersley[e]
Affiliations: [a]The Salve Health Ltd, Cheltenham, UK; [b]Kyowa Kirin GmbH, Düsseldorf, Germany; [c]Kyowa Kirin, Marlow, UK; [d]Amgen Ltd, Rotkreuz, Switzerland; [e]The George Institute for Global Health, London, UK

Poster #36



What about sex?

A call to action for **improved sex and gender reporting** in **industry-sponsored clinical research**: Results from a literature review

Conclusions

- The results show that, almost 10 years after publication, the SAGER guidelines are still not being implemented by researchers consistently or adequately in industry-sponsored randomized controlled trials investigating chronic immunological conditions that have known differences in epidemiology and outcomes between the sexes
  - As they are not being implemented consistently within disease areas with known differences between the sexes, it seems reasonable to hypothesize that the SAGER guidelines are also not being implemented consistently or adequately within the wider research landscape
  - Additional research comparing with non-industry sponsored research would help further understand this point
- Routine adoption of sex-/gender-based analyses and reporting could play a significant role in improving health data quality and outcomes in industry-sponsored trials
- There is a requirement for cross-industry dialogue, research, and action to drive the implementation of the SAGER guidelines in clinical research and publications, in order to improve health inequities. We welcome comments and suggestions for further discussion.



Background

- Sex (anatomy, genes and endogenous hormones, e.g., female, male and intersex) and gender (individuals' roles, identities and behaviors in society, e.g., cis and trans women and men, and non-binary people) are known to influence health and wellbeing in multiple ways, including different clinical presentations, disease progression, response to treatment, access to healthcare, health-seeking behavior, and perceived healthcare experience[1–3]

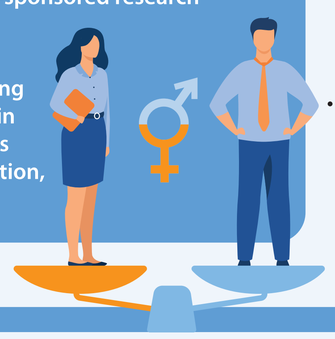


- Health and wellbeing differences in sex and gender are frequently overlooked in scientific research design, execution, and reporting[1,4–6]
- This oversight impacts the generalization of study results and limits their transferability to clinical practice; women are primarily, but not solely, affected[1,5–7]
- The Sex and Gender Equity in Research (SAGER) guidelines were developed to address underrepresentation and inadequate consideration of sex and gender differences in clinical research and publications[1]
- Although many scientific publishers and journals have endorsed the SAGER guidelines,[5,7] awareness of and adherence to the guidelines by researchers in anticipation of submission to these journals is unclear
- The pharmaceutical industry and its suppliers have a collective opportunity and responsibility to lead in this area, with the power to effect change



Objectives

- The aim of this study was to understand the extent to which sex and gender differences in publications are being appropriately represented and considered in clinical research
  - The primary objective was to assess current adoption of SAGER guidelines in industry-sponsored research publications
  - The secondary objective was to identify potential factors affecting adherence to SAGER guidelines in industry-sponsored publications (e.g., sponsoring-company, location, number of women authors)



Research design and methods

- PubMed was used to conduct a literature search, looking at papers published from September 2023 to September 2024* in chronic immunological conditions that show differences in epidemiology and outcomes between biological males and females[3,6]
  - Chronic immunological conditions included:
    - Asthma
    - Atopic dermatitis
    - Axial spondylarthritis
    - Psoriasis
    - Psoriatic arthritis
    - Rheumatoid arthritis
- Eligibility criteria included:
  - Industry-sponsored randomized controlled trials involving a pharmacological therapeutic
    - Industry sponsorship was determined by author affiliations and/or funding statements
  - Open access publications
- Exclusion criteria included:
  - Pharmacokinetic studies
  - Pharmacodynamic studies
  - Phase 2 studies
  - Pooled analyses
  - Post-hoc analyses
- Resulting abstracts and affiliations were screened to identify prospective publications for analysis
- Identified eligible publications were evaluated using the SAGER checklist[4]
  - Author gender was assumed based on information freely available online (e.g., professional profiles) and cross-checked using https://namsor.app/features/gender-name/
  - Journal websites' "instructions to authors" were reviewed for mention of either adherence to the SAGER guidelines specifically, or the need to include sex-/gender-based analyses

*SAGER guidelines were published in 2016; this time frame was chosen to capture studies fully designed and conducted in subsequent years

Results

Screening and selection

- The literature search returned 252 publications
- When screened, 28/252 publications met all eligibility criteria and were included in the analysis set

Therapy areas

- The number of publications per chronic immunological condition is shown in **Table 1**

Journal guidance

- The 28 publications in the analysis set were published across 19 journals; 7/19 (37%) journals mentioned the SAGER guidelines or the need to present sex-/gender-based analyses in their instructions for authors

Presentation/analyses of sex and gender as recommended in the SAGER guidelines

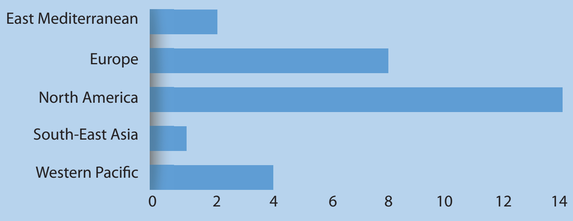
- **0 (0%) publications:**
  - Referenced previous studies in their introduction to highlight the presence or lack of sex/gender differences or similarities
  - Mentioned whether sex/gender might be an important variable and whether differences might be anticipated
  - Defined the terms sex or gender in their methodology; it was therefore unclear if the terms were being used appropriately throughout the manuscript
  - Described how sex/gender was considered in the study design, whether authors ensured adequate representation of male and female study participants, or justified the exclusion of male or female participants (or provided an explanation if not considered)
  - Presented a breakdown of the study population by sex/gender for all categories considered
  - Presented safety data disaggregated by sex/gender
  - Discussed a rationale for not including a sex/gender analysis of results
- **Single (1/28 [4%]) publications*:**
  - Listed a breakdown of the study population by sex in the abstract
  - Presented primary efficacy endpoint data disaggregated by sex/gender
  - Presented patient-reported outcome (primary endpoint) data separated by sex/gender
  - Discussed the need to confirm findings across populations, including sex/gender

*Listed criteria were met by various single publications and not by one sole publication

Table 1. Chronic immunological conditions

Chronic immunological condition investigated, n (%)	Publications (N=28)
Asthma	5 (17.9)
Atopic dermatitis	5 (17.9)
Axial spondylarthritis	1 (3.6)
Psoriasis	9 (32.1)
Psoriatic arthritis	1 (3.6)
Rheumatoid arthritis	7 (25.0)

Figure 1. Geographical location of pharmaceutical sponsors' headquarters



Geographical location determined according to the publication affiliation/funding statement
One publication had pharmaceutical sponsors with headquarters in North America and Europe and has been included in both categories

Figure 2. Proportion of publications with ≥50% women authors

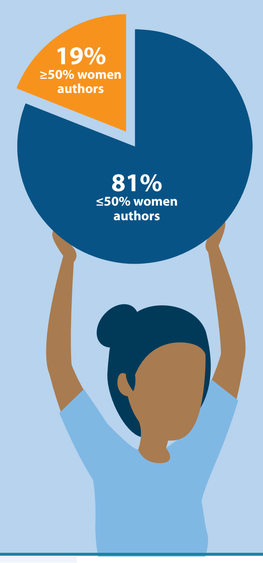
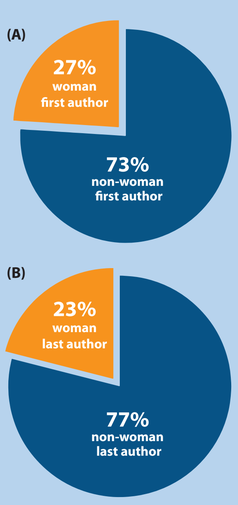


Figure 3. Proportion of publications with **(A)** a woman as the first author, and **(B)** a woman as the last author



- **3 (10%) publications:**
  - Outlined sex/gender disease prevalence information in their introduction
    - Of these publications, one publication's pharmaceutical sponsor was based in Europe (Ukraine) and two publications' pharmaceutical sponsors were based in the Western Pacific (Japan and Korea)
- **5 (18%) publications:**
  - Reported some form of sex/gender-based analysis of results
    - Of these publications, two publications' pharmaceutical sponsors were based in Europe (Finland and Germany), a further two were based in the Western Pacific (China and Japan), and one was based in North America (USA)
- **All publications:**
  - Presented sex/gender data in the patient demographics table (in the supplementary materials in some instances)
    - The language used in the demographics table often appeared incorrect versus the categories listed (e.g., sex: woman/man), although the terms sex or gender were not categorically defined in the methodology of any papers

Publication and authorship demographics

- The geographic location of the pharmaceutical sponsors of the 28 publications is shown in **Figure 1**
- It was possible to assume author gender in 26/28 (93%) publications
  - The mean (range) of women authors was 35% (11–70%)
  - At least 50% of the author group were women in 5/26 (19%) publications **(Figure 2)**
    - For evaluable publications with the pharmaceutical sponsor based in the Western Pacific, Europe, North America, South-East Asia, and the Eastern Mediterranean, the average percentage of female authors was 50%, 39%, 33%, 20%, and 17%, respectively
  - A woman was the first author and last author in 7/26 (27%) publications and 6/26 (23%) publications, respectively **(Figures 3A and 3B)**
    - This included 2/26 (8%) publications that had women as both the first and last authors

Limitations

- This research included open access publications only in the literature search (publications behind a paywall were excluded); this limited the potential pool of results available for analysis
- Another limitation of the study was determining author gender by assumption based on materials freely available online; this may have led to errors in some cases and could have over- or under-estimated the number/proportion of women authors



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Disclosures
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