

What can clinical trial screening logs tell us about sex differences in recruitment pathways?

Laura Hermann¹, Maureen Twiddy¹, Liz Walker², Judith Cohen¹

¹ Institute of Clinical and Applied Health Research, Hull York Medical School, University of Hull, UK

² Faculty of Health Sciences, University of Hull, UK

1. Background

1. Evidence suggests that females continue to be underserved by clinical trials.

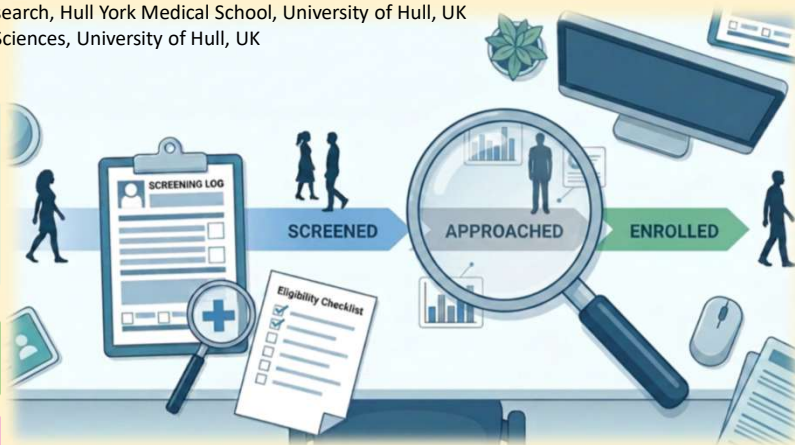
2. Research funders and UK health research regulatory bodies now mandate considerations of inclusivity across the trial lifecycle, including recruitment.

3. Clinical trial screening logs present an opportunity to monitor diversity along the recruitment pathway.

4. Inclusivity is often monitored at recruitment, but monitoring who is approached for participation can reveal threats to inclusivity earlier in the recruitment pathway.

Aim: To quantify female screening and recruitment rates in a sample of UK clinical trials relative to their proportion in the disease population to examine the sources of under-representation of females in clinical trials.

Public partners identified the examination of sex differences in screening log data as a priority research question.



2. Data sources

Screening log case studies:

Identified clinical trial case studies from UK trials units.
Data collected where available: sex, gender, age, ethnicity, approached and recruited status, sex and gender of CI.

Data for comparison with population estimates

Data derived from:

- National registries
- NICE
- The Literature
- Clinical co-applicants.

All data checked for suitability with trial case study teams.

3. Analysis

Comparisons between female proportion of participants eligible, approached and consented in trial case studies to the proportion of females represented in the population of people with the disease / condition under study.

A one sample proportion test will be applied to assess significance level where trial case studies show lower female proportion than population estimates.

4. Emerging findings

Trial	Clinical area	Population comparator data source	N= eligible (F %)	Female approached (%)	Female consented (%)	Female population Comparator (%)
1	Vascular surgery	National Registry	35 (34.3)	37.9	50	27.7
2	Occupational therapy	Published longitudinal study	785 (35)	Data unavailable	64.3	54.1
3	Orthopaedics	National Registry	635 (64.7)	Data unavailable	65.5	Awaiting data
4	Orthopaedics	Published single centre study extrapolated to the UK	778 (18.9)	18.9	17.3	9.3
5	Respiratory	Clinical Practice Research Datalink and linked Hospital Episode Statistics data.	68 (60.3)	60.3	59.6	48
6	Trauma and orthopaedics	Published study retrospective cohort – 18 UK centres	684 (31.6)	31	27.4	44

5. Next steps

Further analysis with population comparator data

Analysis of data from a further 4 x trial case studies

Qualitative analysis of trial protocols, PIS and ICF for future integration with results from this study

Integration with an empirical qualitative study involving female trial decliners, female members of the public, clinical trial staff and trial staff

Emerging findings are mixed, with females both under and overrepresented in trial case studies. Findings should be interpreted with caution, given the small sample of trial case studies and limited comparability of trial populations and available population data

6. Limitations

The trial case studies are drawn from trials units likely already engaged in activities to increase monitoring inclusivity.

Population-level prevalence data did not closely correspond to eligibility criteria of included trials, limiting comparison.

7. Challenges and recommendations

Institutional data sharing rules present challenges to sharing anonymised screening log data for inclusivity monitoring.

Publicly available sex-disaggregated epidemiological data is difficult to obtain, restricting the opportunities for trialists to use these data to plan for inclusive recruitment.

Trial screening logs are heterogeneous and often poorly completed – key variables should be routinely collected across all trials, with specific variables tailored to those at risk of being underserved in individual trials.

To monitor the inclusivity of those offered the opportunity to participate, data on who is approached for participation should be included on screening logs.

FUNDED BY

NIHR | National Institute for Health and Care Research

Laura Hermann is funded by the NIHR for this research project via an NIHR Doctoral Fellowship (NIHR303728). The views expressed in this publication are those of the authors and not necessarily those of the NIHR, NHS or the UK Department of Health and Social Care.

Further details?
We would be delighted to hear from you:
Laura.Hermann@hull.ac.uk