

Incorporating sex and gender considerations into the entire research process

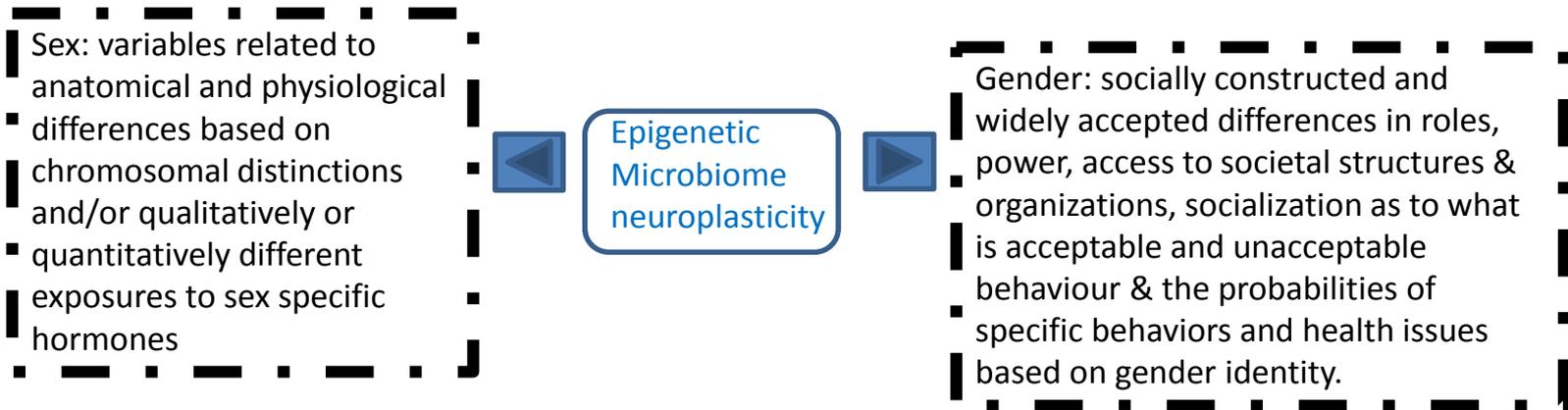
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Incorporating sex and gender considerations into the entire research process



Considering the research question?



- **Human studies:** Is there epidemiological or physiological/pathophysiological evidence of sex or gender differences in the target population or health condition or biological process under study?
- What dimension(s) of human physiology/pathophysiology is the focus?
- **Animal models:** is there evidence that the model can be applied to both sexes or multiple genders?
- **Acknowledgements** – clear information on sources of cell lines, in vitro or ex vivo experimental tissues, project/manuscript titles that specify sex of animals in animal studies.
- **Rationale** stated up front regarding choices & the boundaries of the research purpose and design decisions.
- **Review** of the literature to include sex and gender of the reviewed study populations

Considering the population



- Animal studies: is there evidence that sex & gender specific studies are needed?
- Human studies: who is most appropriate given the research question, should this project be sex and gender-sensitive or specific?
- Is comparing males and females (or genders) appropriate? If both recruited will there be sufficient power to delineate all the relevant and potential confounding variables?
- Acknowledge need but clearly stated that this study will be limited to... & rationale provided for choices. (“we have always done it that way” has become less acceptable)
- Well considered implications of the context of the research question & the population? What are all the relevant variables?
- Discussion of these questions with others reflect the advantages of involving multiple investigators with complementary expertise and skill sets.

Considering recruitment



- Human studies: How important is diversity – in terms of sex & gender to the research question? Based on your decision here, how limited is your ability to interpret and generalize the results.
- Consider potential barriers to broad representation
- Other sources of recruitment – engaging and partnering with community agencies to address diversity & recruiting less accessible patient populations
- Recruitment strategies that consider gender: work schedules, working poor, child care, convenience of site of interviews, use of phone interviews,



Considering demographics

Depending on the research question, sex/gender specific information that may be needed:

- If recruiting both sexes, independent of gender, what sex specific information is needed?
- If recruiting women, acknowledgement of gender role, the multiplicity of roles of E2 in cognitive function & behaviour.
- Less evidence of impact of gender role in what has been considered heterosexual male studies, with exception of the impact of traditional masculinity and psychological well being .
- type of work
- Work schedule
- Menopausal status
- Menstrual phase (confirmed with plasma levels of E2 & progesterone)
- Given birth (role of mothering)
- History of serious stressors
- Gender identity
- SES – inherent assumptions (McArthur scale or sufficiency of income)

Considering data analysis

- In planning the data analysis, does it make more sense to go back and reconsider your decision about the sample size and the inclusion of both sexes and/or multiple genders.
 - Challenging to include multiple genders as the subpopulations are often small unless recruiting only non-heterosexual participants. However, using this strategy raises issues about generalization to both males and females and to the broader population.
 - Is it essential that a best fit model be developed for males and females separately? Will the data likely be incorporated into best practice guidelines?
- Well planned, moving beyond post hoc comparisons that lack the necessary data to address confounds to the simplistic comparison analytic strategies, creates challenges to sample size calculations
 - The drive to personalized healthcare requires a body of knowledge specific to the gender diverse population (beyond the male and female heterosexual population) in terms of the biological and psychosocial underpinnings of their health and their health needs.



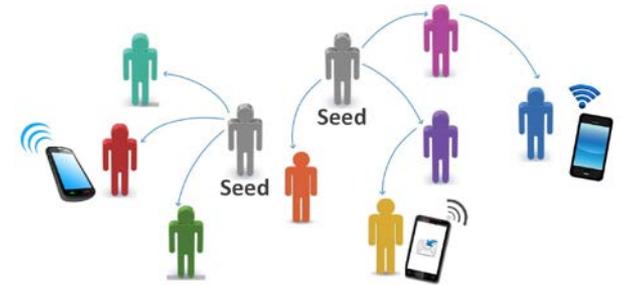


Considering interpretation

Data Interpretation

- What frame of reference or theoretical framework did you use to develop the proposal and will use in which to interpret your findings? Has the chosen frame been specifically applied to both sexes in a way that incorporated relevant sex and gender differences? Answers to these questions can help develop your hypotheses within a given frame.
- The review of those that reported similar or different findings are often superficial and do not take in sex and gender as sources of equivocal data.
- Interpretation often compartmentalized into fields of study.
- Many of our basic physiological models and theories are based on male animal models. There are pragmatic reasons for this.
- In animal studies with females it is also pragmatic to remove the ovaries and add back female sex hormones, but it must be explicitly acknowledged where the similarities and differences to human female menstrual cycling would lay.
- Acknowledgement of the limitations based on sex and gender on interpretation based on your design decisions are important. Here again is where a team of investigators are helpful
- If appropriate, discussion of the relative contribution of your data to complex health issues. Eg: genetic contributions often play a minor role but the conclusions and titles of manuscripts often infer more.

Considering dissemination



- Where to publish data? Highly specific journals perpetuate silos of information that make it hard to integrate across fields of study. Has contributed to the challenges in how to translate research into knowledge that can be used to develop and test new interventions and new standards of practice.
- Personalized health care requires clear bodies of knowledge from which to develop personalized strategies. How can we make ongoing efforts to add to bodies of knowledge not based on field of study but based on the sex and gender of the ultimate end targets of health research.
- Who are your target audiences sometimes is a more important question than what is the IF? There may be reasons to submit to more than one type of journal. Different perspectives from different members of the research team.
- There are increasingly more sex specific and gender specific journals to consider.
- If appropriate, presenting your data and your interpretations to communities of patients (defined in specific ways) for discussion and “face validation”. Can invite participants and non-participants to help ensure anonymity.

Keys to Increase Chances of Success

- Become familiar with CIHR IGH resources
- Encourage research teams to complete the IGH self-learning model.
- Consider including a broader range of co-investigators
- Consider how patient engagement may make a significant contribution to the research process
- Sex/gender consultation, perhaps as a goal offered through the Grant Assist program
- Incorporating discussion and careful consideration of sex and gender issues at the design stage.
- Incorporating a sex and gender lens to reviewing the literature used to support the proposal.
- Clearly stating any boundaries/limitations on your chosen population for study, with clear rationale provided and any implications to these decisions in terms of interpretation of the results.

