FIVE YEARS OUT: PROGRESS REPORT ON THE NIH SABV POLICY

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ORWH Mission

- Enhance and expand women’s health research
- Include women and minority groups in clinical research
- Promote career advancement for women in biomedical careers

NIH Vision

- Sex and gender integrated into biomedical research
- Every woman receives evidence-based care
- Women in science careers reach their full potential
SABV IS GOOD SCIENCE

**Future advances** in biomedical research depend upon the **rigor and reproducibility** of **research conducted today**. Considering SABV in **research design, analysis, and reporting** increases rigor and transparency, which in turn improves the replicability and robustness of findings. In other words, **good science**.
NIH Policy on SABV

“NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies.”

(Eff. 01/25/16)
Early survey shows steady improvement in SABV integration

Survey of NIH Study Section Members was published by Journal of Women’s Health

66% said a majority of applicants adequately addressed incorporation of SABV into their study design, analysis, and reporting

It’s understood. It’s important. It produces better science.*

* I.e., it improves rigor and reproducibility

Woitovich and Woodruff. 2019. JWH. DOI: 10.1089/jwh.2018.7396
2020 follow-up study finds progress in sex-inclusive research over 10 years

Analysis across 9 biological disciplines for papers published in 34 journals in 2019 -- compared to results from 2009

**FINDINGS**

- **Increase in percentage of sex-inclusive articles** with *significant* increases in neurology, immunology, endocrinology and physiology

- **Increase in number of studies** that provided evidence-based rational for single-sex studies -- a requirement of NIH policy
Study also shows more work needs to be done

- % of articles that performed sex-based analysis went down, except for in one field (pharmacology)
Implementation is having far-reaching impact

- NIH peer-reviews over 80,000 applications annually
- Tens of thousands of investigators conducting vertebrate or human studies are required to consider how sex could influence their research.
JWH article highlights SABV’s progress, calls for action

• ORWH and NIH advancing SABV through SCORE, Sex and Gender Administrative Supplements, online courses/training with FDA

• NIH ICs have undertaken initiatives
  National Institute of Diabetes and Digestive and Kidney Diseases workshop
  National Institute on Aging’s Interventions Testing Program studies medication efficacy in male and female mice
  Genotype-Tissue Expression (GTEx) data resource and tissue bank for study of genetic variants and gene expression

• Further integration of SABV depends on stakeholders
  Journal editors
  NIH ICs and NIH’s partners
  Other funding organizations, research and clinical enterprises
  Regulatory agencies
  Academics, clinicians, patients

Another example of “One-Size-Does-Not-Fit-All”

| CURRENT THINKING | Established blood pressure (BP) guidelines state that women and men have the same normal healthy range of BP (i.e., systolic upper limit of 120 mmHg)  
• Above threshold is associated with risk for heart attack, heart failure, stroke |
| RECENT FINDINGS | In fact, women have a lower “normal” systolic BP range (SBP) compared to men (110 v. 120)  
• Researchers observed increasing CVD risk beginning at lower thresholds of SBP for women than for men |
| WHY IS THIS IMPORTANT? | Because guidelines do not account for sex differences, they may be detrimental to a woman’s health. |

Revisit hypertension treatment guidelines that don’t account for sex differences

ORWH advances study of sex/gender and the health of women through collaborations across NIH | FY 2020

**BIRCWH**
Building Interdisciplinary Research Careers in Women’s Health

7 ICOs
Mentored Career Development Program

**SCORE**
Specialized Centers of Research Excellence on Sex Differences

8 ICOs
Disease-Agnostic Research Centers

**Administrative Supplements**
Sex and Gender and Understudied, Underrepresented, and Underreported (U3) admin supps

26 ICOs
Funding Program to Expand Sex & Gender Data

**R01**
Intersection of sex & gender influences on health & disease

11 ICOs
Sex & Gender Influences on Health & Disease

*ICOs that signed on in FY19

RFA-OD-19-029
Implementing a **Maternal health and Pregnancy Outcomes Vision for Everyone**

NIH-wide program funding interdisciplinary research in foundational biology, behavioral, & sociocultural science

- Gain evidence on causes of maternal mortality & morbidity
- Improve health for women before, during, & after delivery
- Reduce preventable causes of maternal deaths

Promote health equity in the U.S.

- Evaluate structural & health care system issues in populations with high rates of maternal deaths & complications
- Develop community partnerships to assess vulnerabilities & implement interventions to improve outcomes

36 projects ($7.5M) in Sept. 2020

- 17 ICOs participating; 12 funding projects

https://www.nih.gov/research-training/medical-research-initiatives/improve-initiative
REMOTE SUPERVISION FOR IMPLEMENTING COLLABORATIVE CARE FOR PERINATAL DEPRESSION

PRENATAL BLOOD PRESSURE PATTERNS TO PREDICT PREGNANCY-RELATED HYPERTENSION & LATER LIFE CVD RISK

ROLE OF HOST-MICROBIAL INTERACTIONS IN ALTERING PRETERM BIRTH RISK AMONG BLACK WOMEN
Small Business Initiatives for Innovative Diagnostic Technology for Improving Outcomes for Maternal Health

- Development of technologies to predict an increased risk for material morbidity and mortality (MMM)
- Identification, phenotyping, subtyping, and stratification of patients at greater risk of MMM.
- Multi-level interventions to address racial disparities in MMM
- Clinical decision-making that considers social and cultural biases
- Wearable, point-of-care, portable, or clinical devices

NOT-EB-21-001
COVID-19 affects males and females differently, yet clinical trials rarely accounted for sex

The “sex gap” in COVID-19 trials: a scoping review

Among 30 studies on pharmacological treatment of COVID-19:

- **ZERO** stratified subjects by sex in their design.
- **ONE** stratified data by sex in an after-the-fact analysis.
- **ZERO** investigated effect size by sex.
- **25%** included twice as many males as females.


Journals and societies are driving change in reporting and SABV implementation.

https://ease.org.uk/communities/gender-policy-committee/the-sager-guidelines/
ORWH’s e-learning educates biomedical community on sex & gender

- **Bench to Bedside: Integrating Sex & Gender to Improve Human Health**
  - Immunology | CVD | Pulmonary Disease | Neurology | Endocrinology | Mental Health

- **Sex as a Biological Variable Primer**
  - With support from [National Institute of General Medical Sciences](#) and the NIH Office of the Director

- **Introduction to the Scientific Basis of Sex- and Gender-Related Differences** | Including facilitator’s guide

[bit.ly/ORWHeLearning](#)
Fifth Annual Vivian Pinn Symposium
Integrating Sex and Gender Into Biomedical Research as a Path for Better Science and Innovation

May 11-12, 2021 | Virtual Meeting

Illustrate the scientific, societal, and economic opportunities of integrating sex and gender into biomedical research and the power of synergistically working together

- Create bridges and capacity across the scientific enterprise to build a broad-based network of government, non-profit, academic, and business organizations
- Develop strategies to integrate sex and gender considerations into research enterprise
- Apply multidimensional perspective to women’s health to advance the integration of sex and gender considerations via transdisciplinary approaches and partnerships

For more information: www.nih.gov/women