

FIVE YEARS OUT: PROGRESS REPORT ON THE NIH SABV POLICY

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**March 2, 2021 – Society for Women's Health Research and
Endocrine Society Congressional Briefing**



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

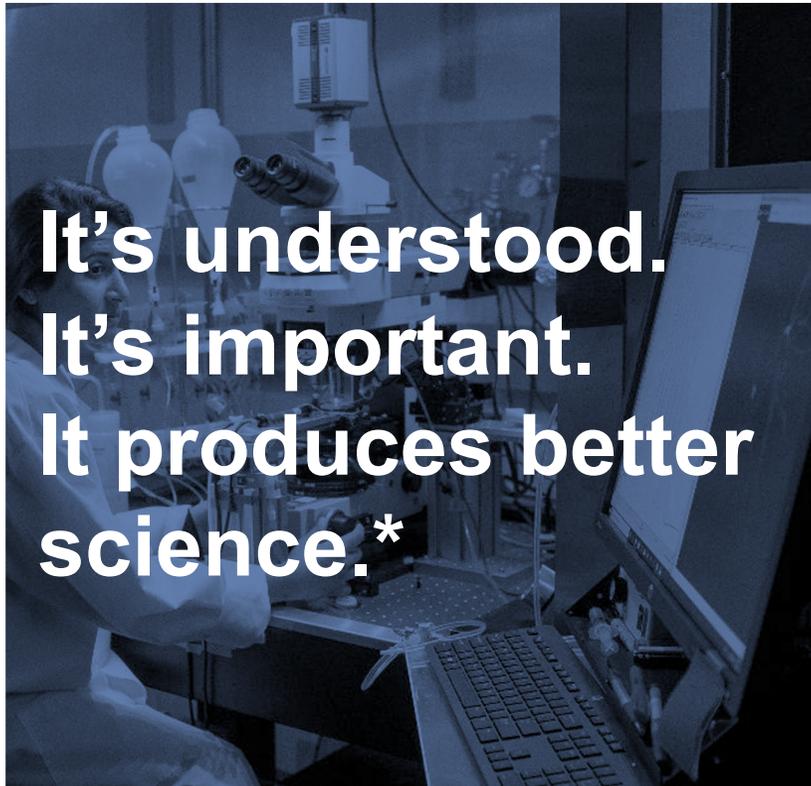
“NIH expects that sex as a biological variable will be factored into research **designs, analyses, and reporting** in vertebrate animal and human studies.”

(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



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

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

* I.e., it improves rigor and reproducibility



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 rationale for single-sex studies – a requirement of NIH policy

eLife FEATURE ARTICLE

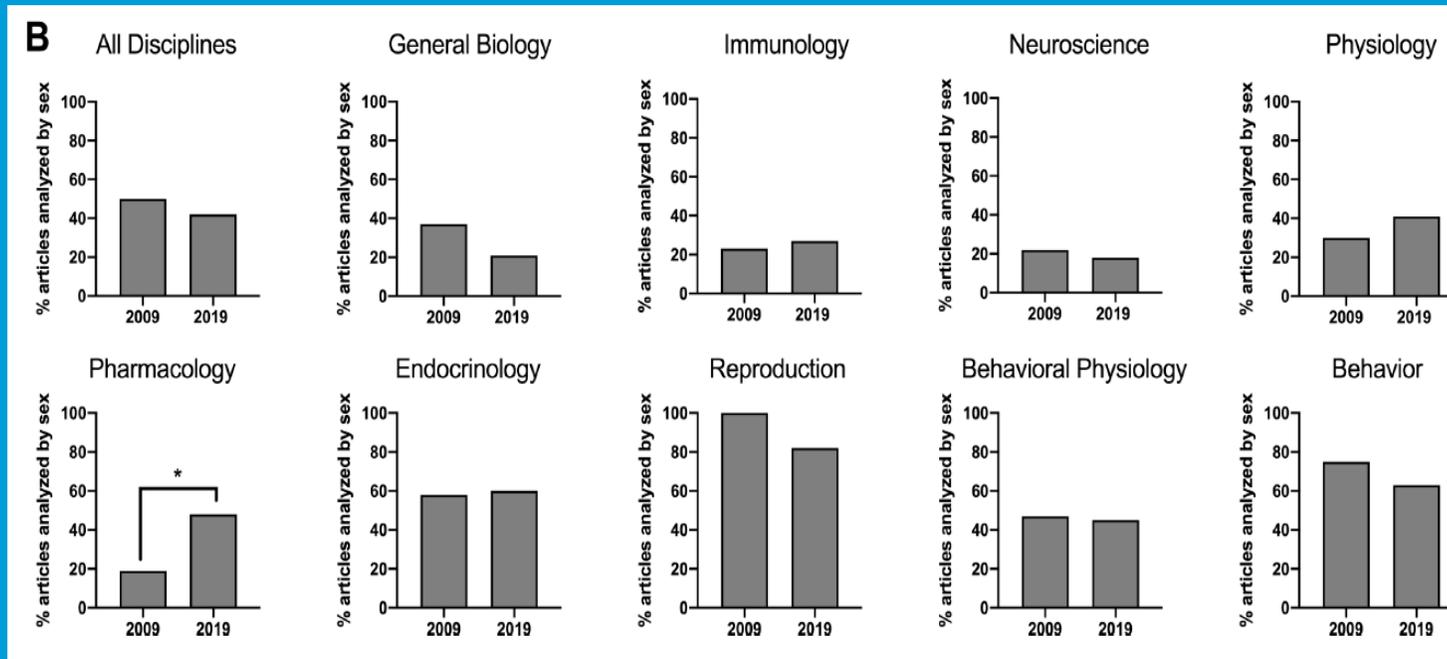
META-RESEARCH

A 10-year follow-up study of sex inclusion in the biological sciences

Abstract In 2016, to address the historical overrepresentation of male subjects in biomedical

Study also shows more work needs to be done

- % of articles that performed sex-based analysis went down, except for in one field (pharmacology)



FEATURE ARTICLE



CC

META-RESEARCH

A 10-year follow-up study of sex inclusion in the biological sciences

Abstract In 2016, to address the historical overrepresentation of male subjects in biomedical

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.



NIH ENHANCING REPRODUCIBILITY GUIDELINES

what you need to know

WHAT ARE THE FOUR ELEMENTS OF RIGOR?

1

RIGOR OF THE PRIOR RESEARCH

2

RIGOR OF THE PROPOSED RESEARCH

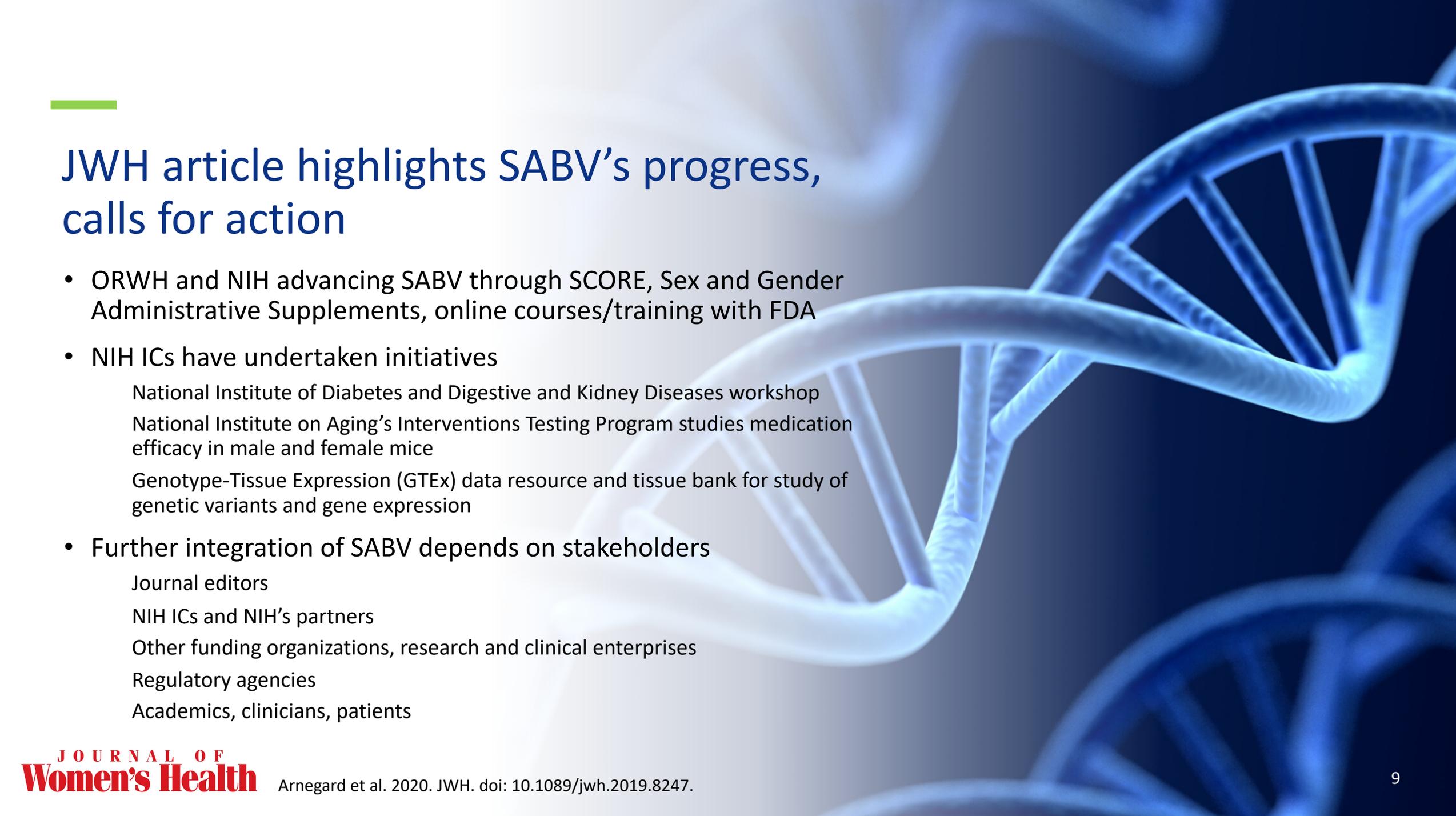
3

BIOLOGICAL VARIABLES

4

AUTHENTICATION





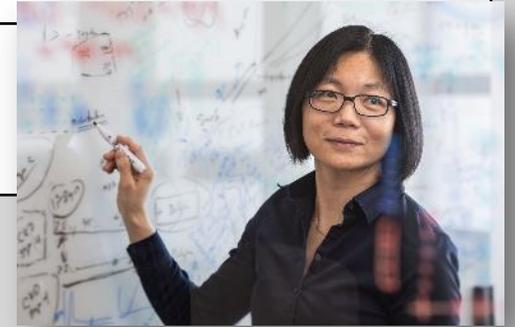
JWH article highlights SABV's progress, calls for action

- 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”



<p>CURRENT THINKING</p>	<p>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)</p> <ul style="list-style-type: none"> • Above threshold is associated with risk for heart attack, heart failure, stroke
<p>RECENT FINDINGS</p>	<p>In fact, women have a lower “normal” systolic BP range (SBP) compared to men (110 v. 120)</p> <ul style="list-style-type: none"> • Researchers observed increasing CVD risk beginning at lower thresholds of SBP for women than for men
<p>WHY IS THIS IMPORTANT?</p>	<p>Because guidelines do not account for sex differences, they may be detrimental to a woman’s health.</p>



Susan Cheng, MD, MPH, MMSc
Smidt Heart Institute, Cedars-Sinai Hospital

Specialized Centers of Research Excellence on Sex Differences



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

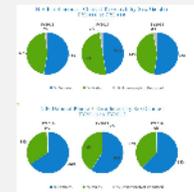


Administrative Supplements

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



Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone

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

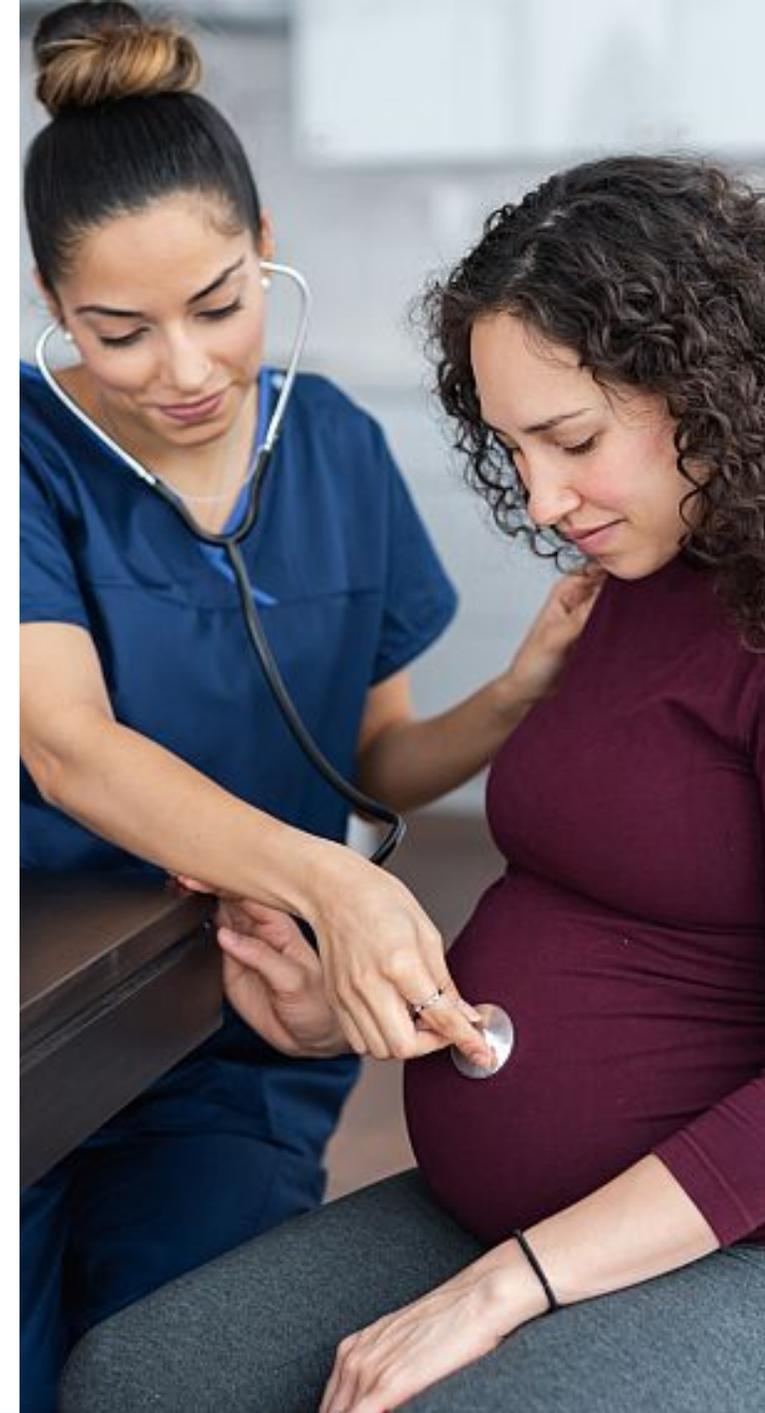
- Gain evidence on causes of maternal mortality & morbidity
- Improve health for women before, during, & after delivery
- Reduce preventable causes of maternal deaths

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



Mental Health



REMOTE SUPERVISION FOR IMPLEMENTING COLLABORATIVE CARE FOR PERINATAL DEPRESSION

Photo by manu mangalassery from Pexels

CVD



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

Photo by Thirdman from Pexels

Immunity



ROLE OF HOST-MICROBIAL INTERACTIONS IN ALTERING PRETERM BIRTH RISK AMONG BLACK WOMEN

Photo by Ketut Subiyanto from Pexels

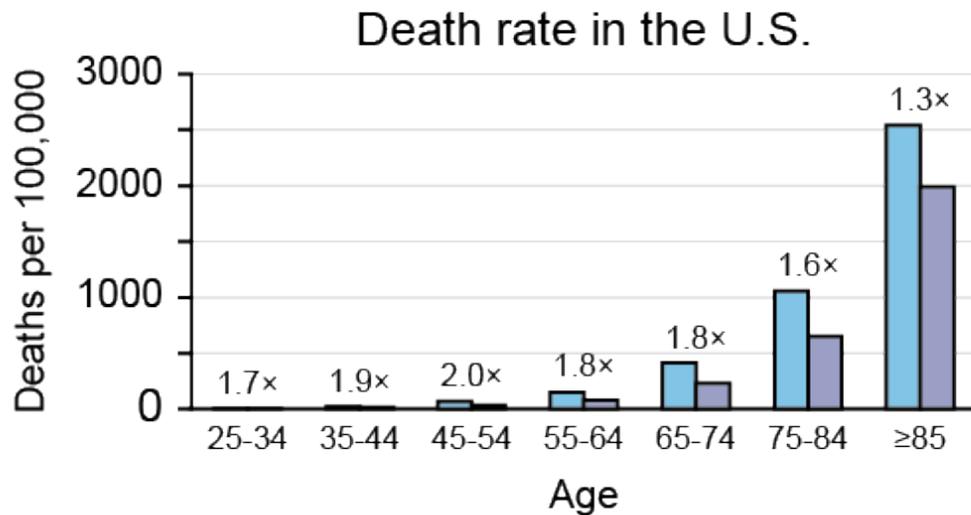
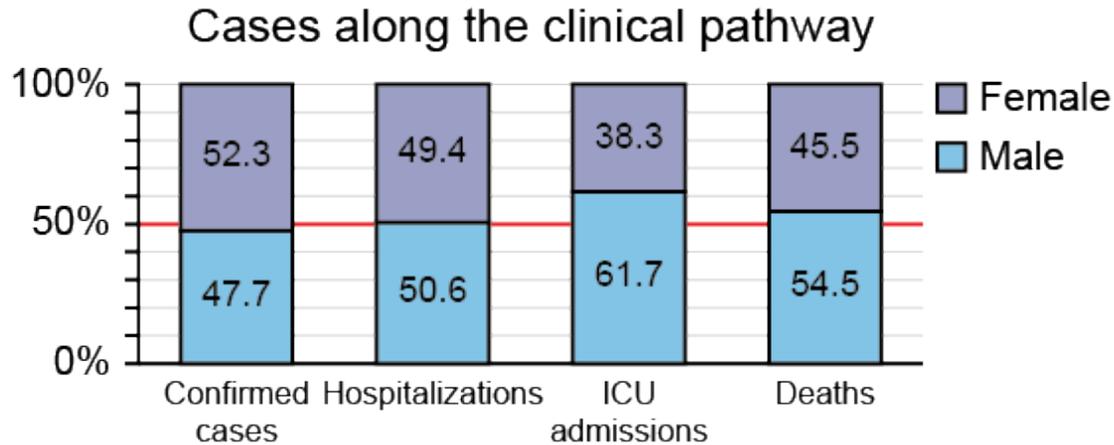
Small Business Initiatives for Innovative Diagnostic Technology for Improving Outcomes for Maternal Health

- 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



EClinicalMedicine
Published by THE LANCET



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

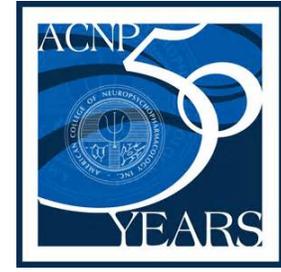
Among 30 studies on pharmacological treatment of COVID-19:

- **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.

Schiffer et al. 2020. *EClinicalMedicine* 100652.

Journals and societies are driving change in reporting and SABV implementation

The collage features several journal covers and a research article snippet. At the top left is the cover of *Journal of Neuroscience Research* (September 2012, Volume 91, Number 9). Below it is the cover of *Journal of Clinical Microbiology*. To the left is the cover of *Journal of Virology*. At the bottom left is the cover of *Molecular and Cellular Biology* (April 2016, Volume 36, Number 7). In the center is a snippet of a research article titled "Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use" by Shirin Heidari¹, Thomas F. Babor^{2*}, Paola De Castro³, Sera Tort⁴ and Mirjam Curno⁵. The snippet includes a "REVIEW" label, "Open Access" text, a CrossMark logo, and a date of "May 3, 2016".



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



Fifth Annual Vivian Pinn Symposium

Integrating Sex and Gender Into Biomedical Research as a Path for Better Science and Innovation



Honoring the first full-time director of ORWH, Vivian Pinn Symposium is held annually during National Women's Health Week

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 trans-disciplinary approaches and partnerships



Vivian Pinn, M.D.



**For more information:
www.nih.gov/women**



Connect with ORWH



30TH ANNIVERSARY ISSUES

quarterly newsletter
bit.ly/ORWHInFocus



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2021

WOMEN'S HEALTH *In Focus* AT NIH
A QUARTERLY PUBLICATION OF THE NIH OFFICE OF RESEARCH ON WOMEN'S HEALTH

The Pulse

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