

Sex Bias in Research

UNC Institutional Review Board
February 2019



Melina R. Kibbe, MD, FACS, FAHA

Colin G. Thomas Jr. Distinguished Professor and Chair, Department of Surgery
Professor, Department of Biomedical Engineering
University of North Carolina School of Medicine
Staff Physician, Durham VAMC

Are These People Similar?



Are These People Similar?



Are These People Similar?

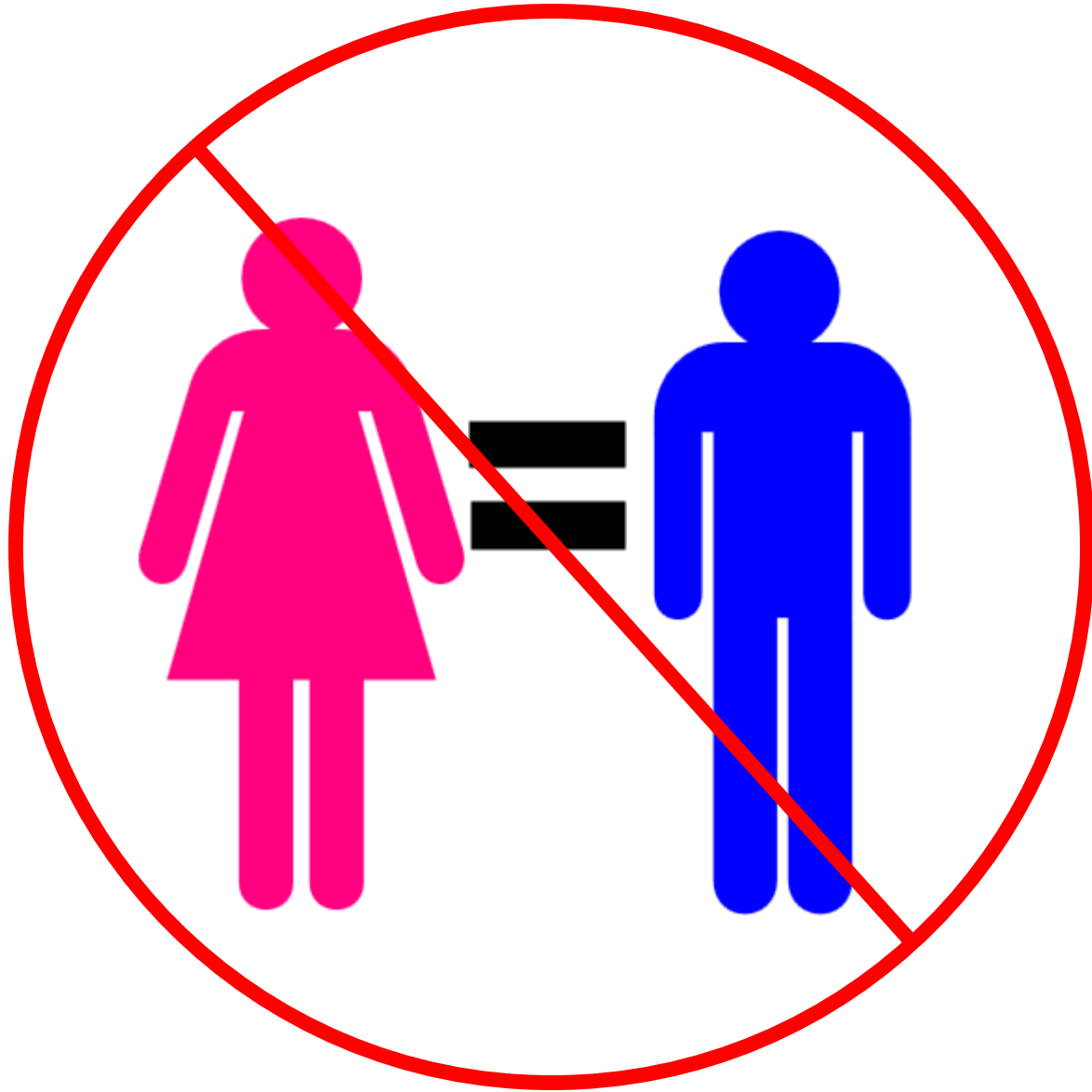


NO!



Why Do Researchers Study *Males* When Developing Therapies for *Both* Sexes?





Sex-Based Differences

- Men and women:
 - Manifest diseases differently
 - Experience illnesses differently
 - Respond to drugs differently
 - Metabolize drugs differently
 - Respond to devices differently
 - Have different outcomes following medical and surgical therapies



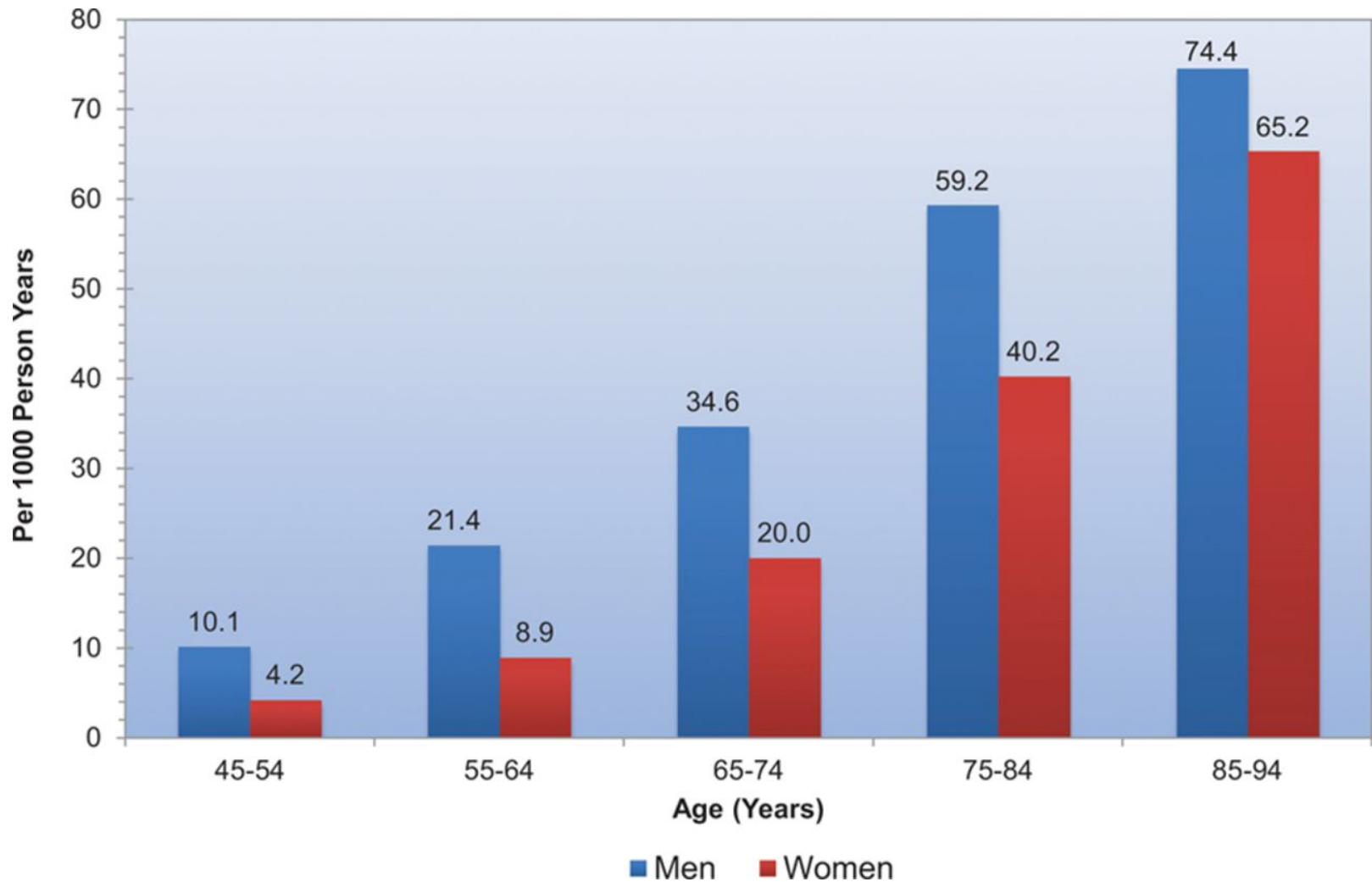
Common Clinical Diseases with Sex and Gender Differences



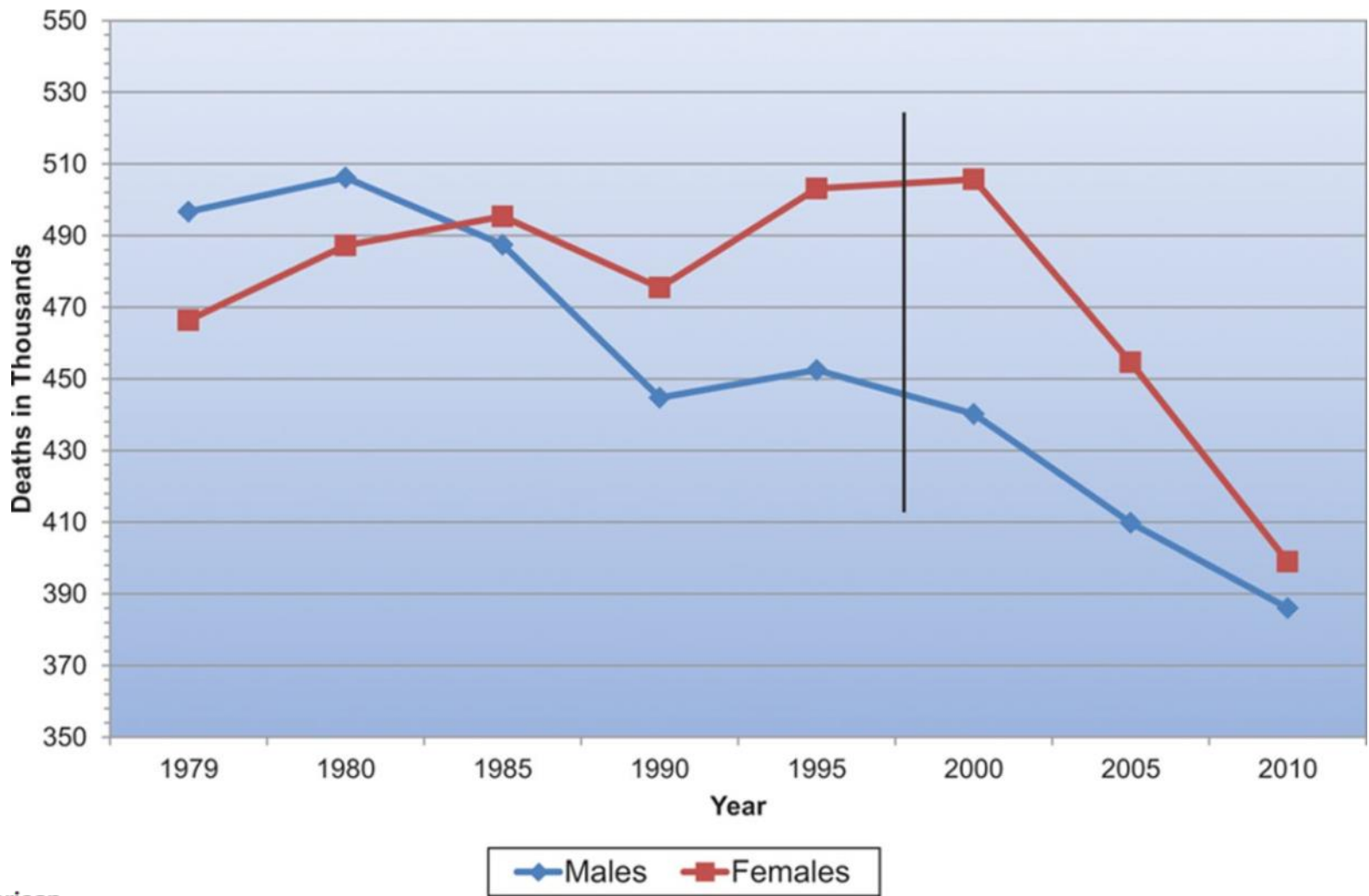
Stroke
Depression
Autism
Dementia
Anxiety disorders
Attention-deficit hyperactivity
Osteoporosis
Autoimmune thyroiditis
Scleroderma
Systemic lupus erythematosus
Rheumatoid arthritis
Multiple sclerosis
Heart disease
Pain
Fat metabolism
Drug metabolism



Incidence of Cardiovascular by Age and Sex



Cardiovascular Disease Mortality Trends by Sex



Sex-Based Differences for Cardiovascular Drugs

- Aspirin
 - More beneficial for men than women
- Statins
 - More beneficial in men for primary prevention
 - Greater risk of adverse reactions in women
- Angiotensin converting enzyme inhibitors
 - Cause more adverse effects in women
- Digoxin
 - Associated with increased mortality in women
- Warfarin
 - Women require lower doses than men

Why Are Men and Women Given the Same Drug?



Why are Men and Women Given the Same Dose of the Drug?



Can You Think of Any Drugs that Are Dosed Based on Sex?





SEARCH

- Home
- Food
- Drugs
- Medical Devices
- Radiation-Emitting Products
- Vaccines, Blood & Biologics
- Animal & Veterinary
- Cosmetics
- Tobacco Products

Drugs

Home > Drugs > Drug Safety and Availability



Drug Safety and Availability

[Drug Alerts and Statements](#)

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FDA Drug Safety Communication: FDA approves new label changes and dosing for zolpidem products and a recommendation to avoid driving the day after using Ambien CR

[en Español](#)

This update is in follow-up to the [FDA Drug Safety Communication: Risk of next-morning impairment after use of insomnia drugs](#); FDA requires lower recommended doses for certain drugs containing zolpidem (Ambien, Ambien CR, Edluar, and Zolpimist) issued on 1/10/2013.

Safety Announcement

[5-14-2013] The U.S. Food and Drug Administration (FDA) is notifying the public that FDA has approved label changes specifying new dosing recommendations for zolpidem products (Ambien, Ambien CR, and Edluar), which are widely prescribed sleep medications. FDA has approved these changes because of the known risk of next-morning impairment with these drugs.

FDA is also warning that patients who take the sleep medication zolpidem extended-release (Ambien CR)—either 6.25 mg or 12.5 mg—should not drive or engage in other activities that require complete mental alertness the day after taking the drug because zolpidem levels can remain high enough the next day to impair these activities. This new recommendation has been added to the *Warnings and Precautions* section of the physician label and to the patient Medication Guide for zolpidem extended-release (Ambien CR).

Also included in the updated label are the dosing recommendations previously stated in FDA's [January 2013 Drug Safety Communication](#): The recommended initial dose of certain immediate-release zolpidem products (Ambien and Edluar) is 5 mg for women and either 5 mg or 10 mg for men. The recommended initial dose of zolpidem extended-release (Ambien CR) is 6.25 mg for women and either 6.25 or 12.5 mg for men. If the lower

EFFECT OF GENDER

A study to determine the effect of gender on zolpidem PK was submitted; however, background and study design was not included. Subjects were healthy males and females (age: 19-45).

RESULTS:

Table. The mean PK parameters of 20 mg zolpidem.

	<u>N</u>	<u>Cmax</u> <u>(ng/ml)</u>	<u>AUC</u> <u>(ng/ml*hr)</u>	<u>tmax</u> <u>(hr)</u>	<u>half-life</u> <u>(hr)</u>
Females	16	340	1264	1.1	2.7
Males	49	234	859	2.0	2.3

COMMENT:

Both Cmax and AUC were approximately 45% higher in females than males with tmax occurring 1 hour sooner in females. The results suggest a gender related difference; however, the lack of specific details such as study design and individual data make it difficult to draw a definite conclusion.

How Did We Get To This Point?

- Women have been poorly represented in clinical trials
- Sex-based differences have not been specifically sought out
- Sex-based differences are often not reported



The Revitalization Act of 1993

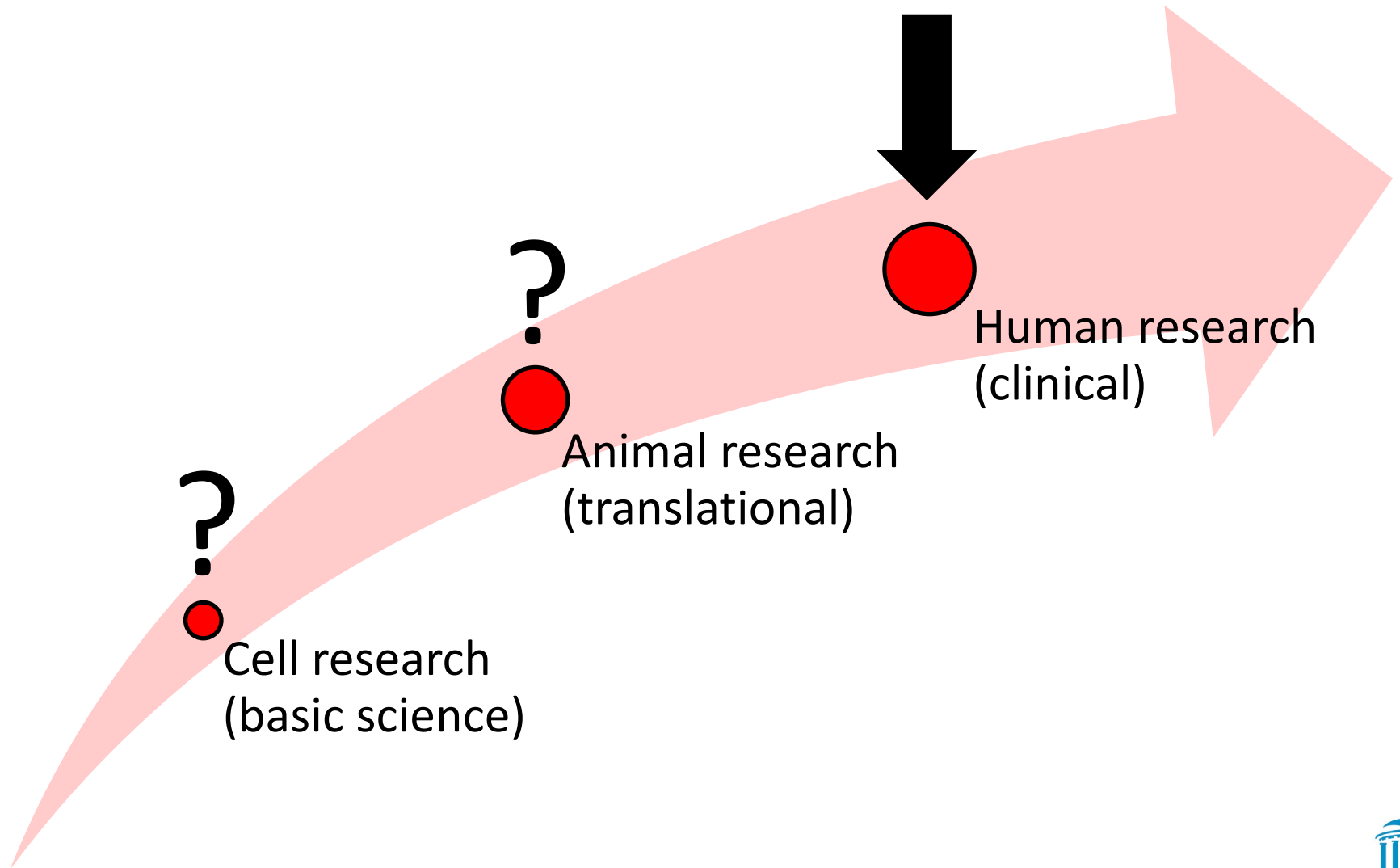
- Signed into law on June 10, 1993 in the US
- Requires that women and minorities be included as subjects in clinical research funded by the National Institutes of Health (NIH)



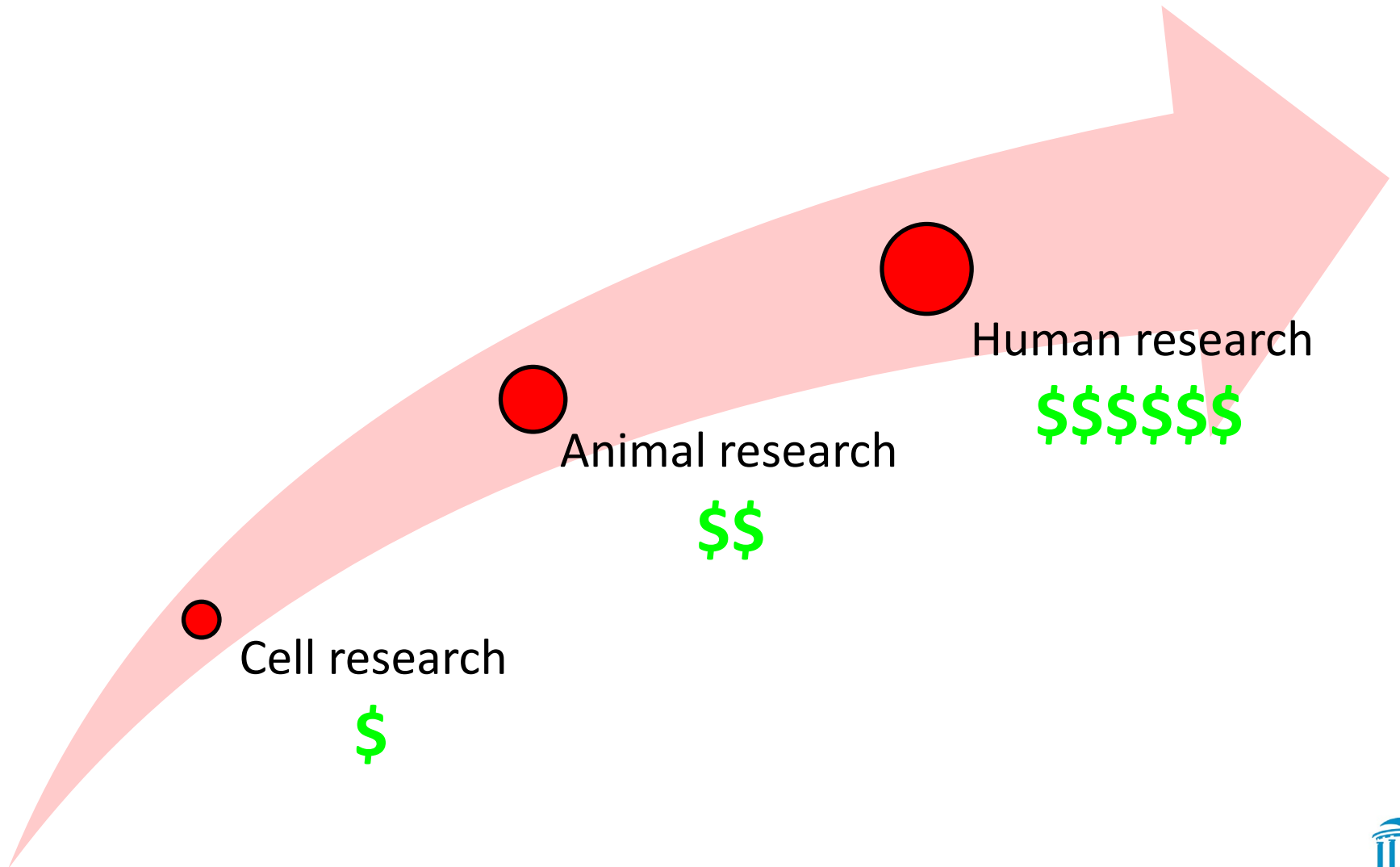
Where Are We At Now?

- Geller et al (2011)
 - Federally funded RCT published in 2009
 - 76% of RCT enrolled both men and women
 - Females represented only 37% of the enrollment
 - 64% of the studies did not specify their results by sex
- Clinical trials on statin use (2014)
 - 1990-2000 – 19% women enrolled
 - 2000-2010 – 31% women enrolled
- Hettrich et al (2015)
 - Showed an increase in sex-specific analysis from 19% to 30% from 2000 to 2010 in orthopedic literature

Root of the Problem



Root of the Problem



Our Study



- Goal
 - To determine if a sex bias exists in basic and translational **surgery** research
- Hypothesis
 - Sex bias exists in surgical biomedical research



Methods

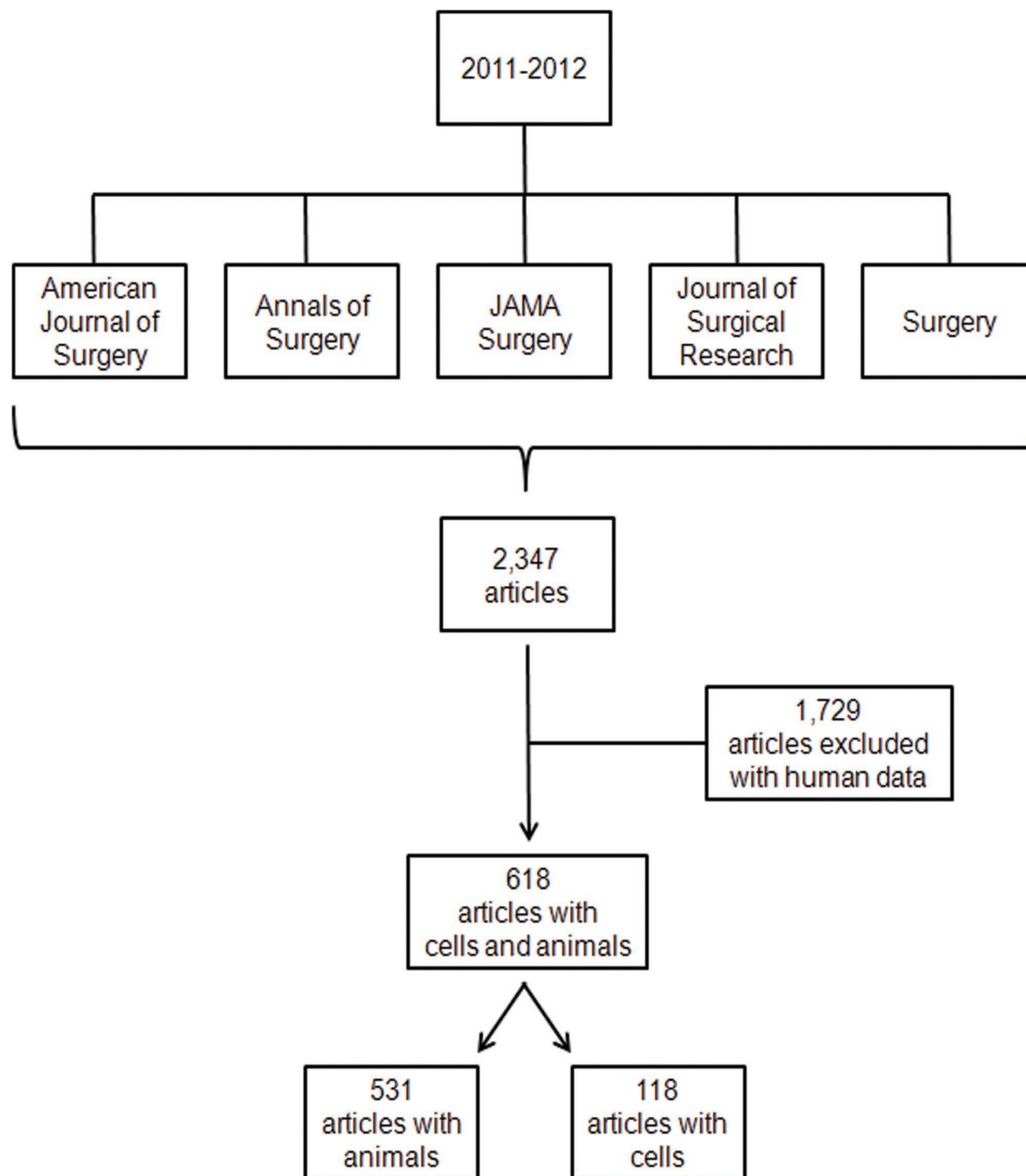
- Evaluated ALL publications in 2011-2012 in:
 - Annals of Surgery
 - American Journal of Surgery
 - JAMA Surgery
 - Journal of Surgical Research
 - Surgery



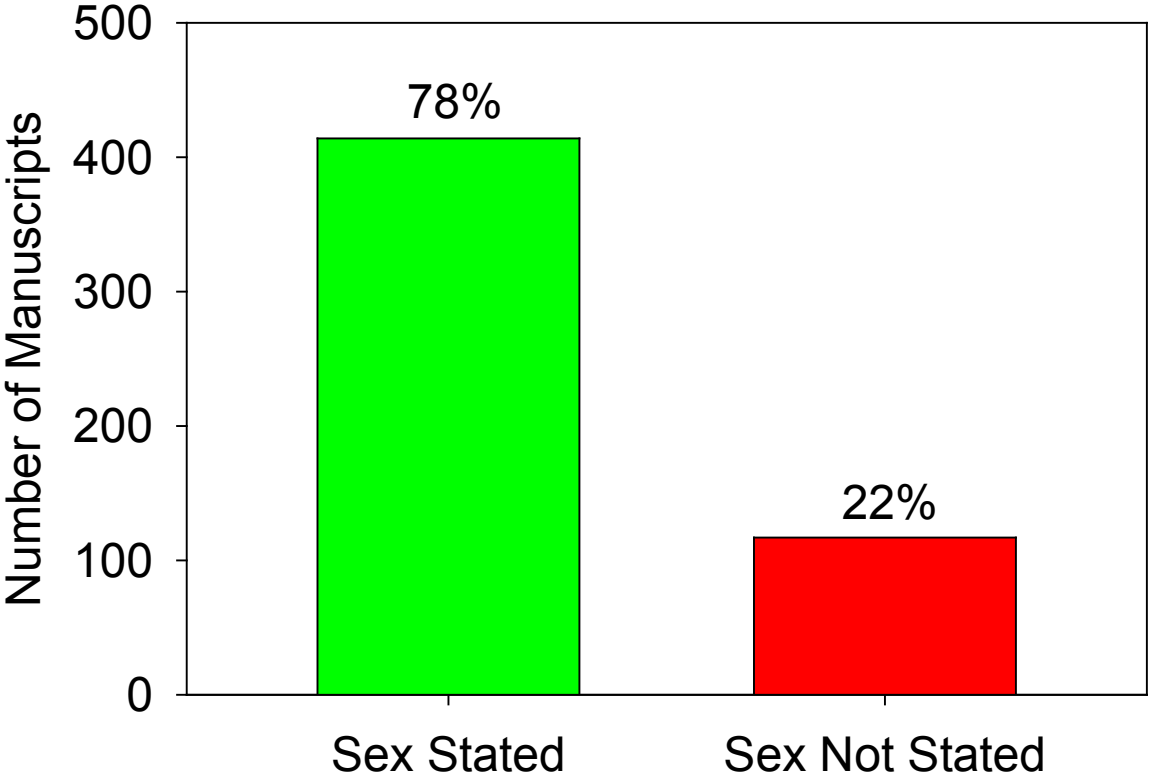
Methods

- Variables abstracted:
 1. Type of study (cells, animals, humans)
 2. First author name
 3. Title
 4. Institution affiliation
 5. Single or multi-center study
 6. National or international
 7. Sex-specific disease (i.e., ovarian, testicular, etc.)
 8. Number of animals used
 9. Sex of the animals and/or cells
 10. Presence of sex-based reporting

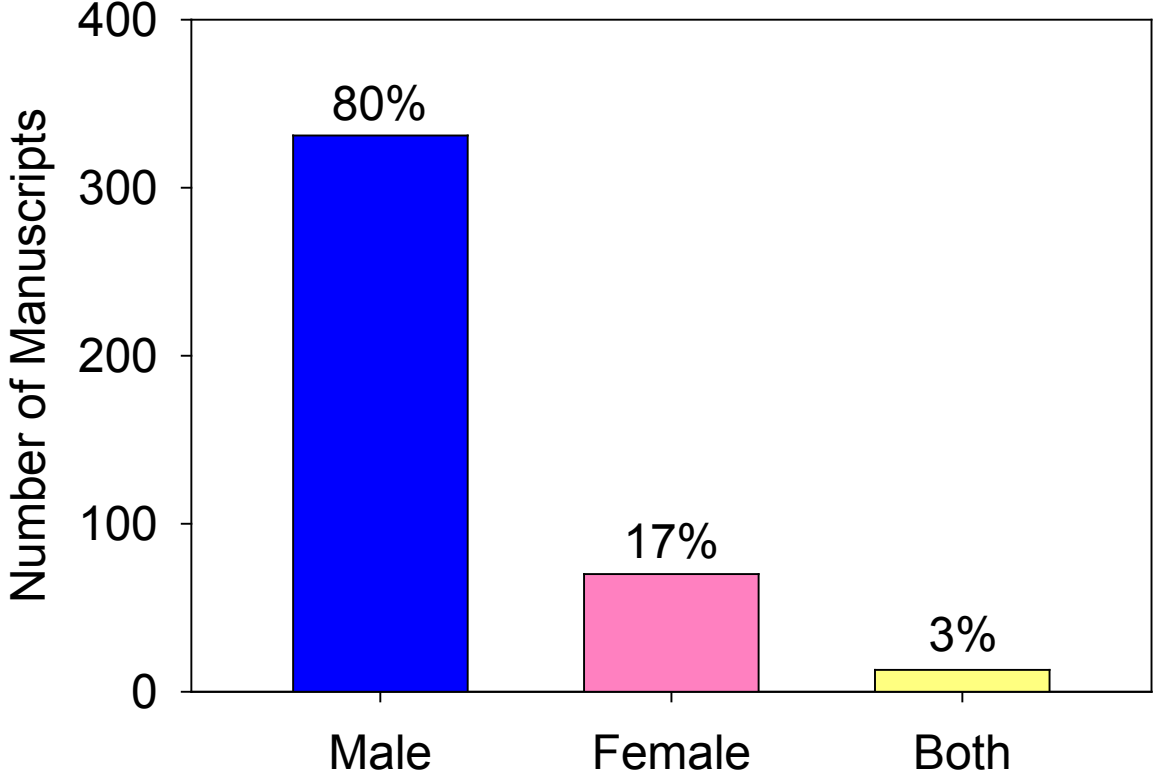




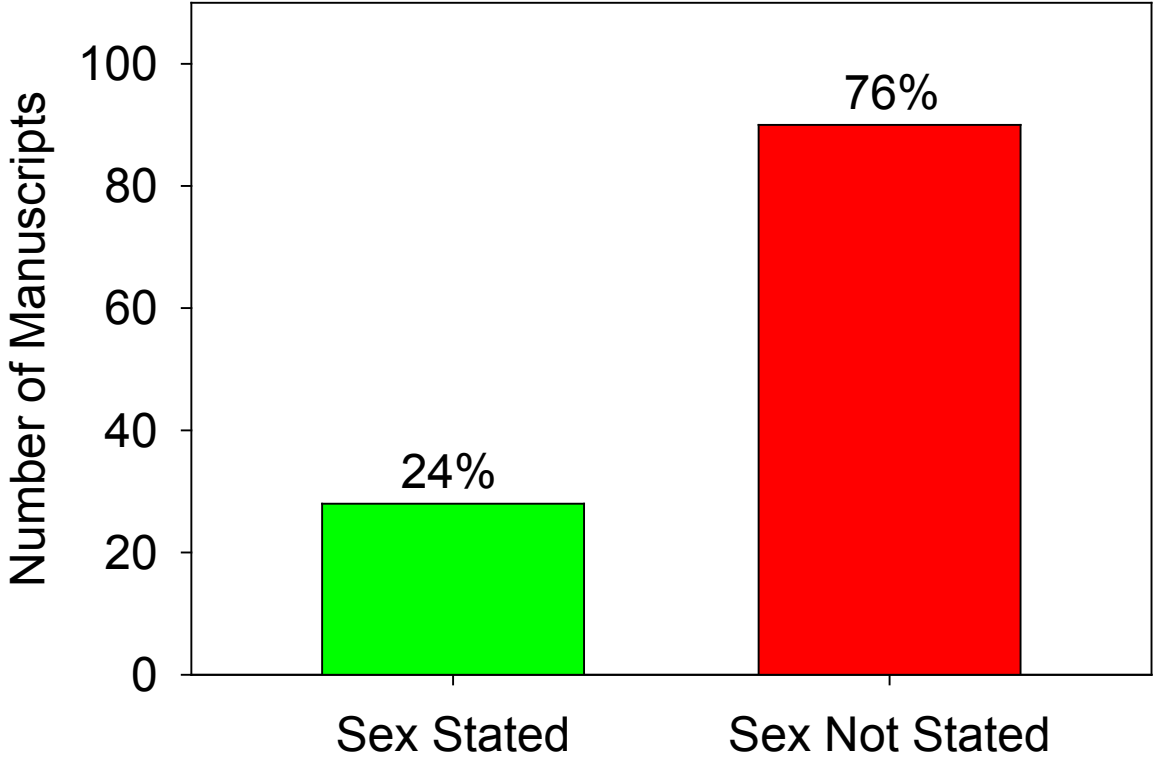
Sex Bias Exists with *Animal* Research



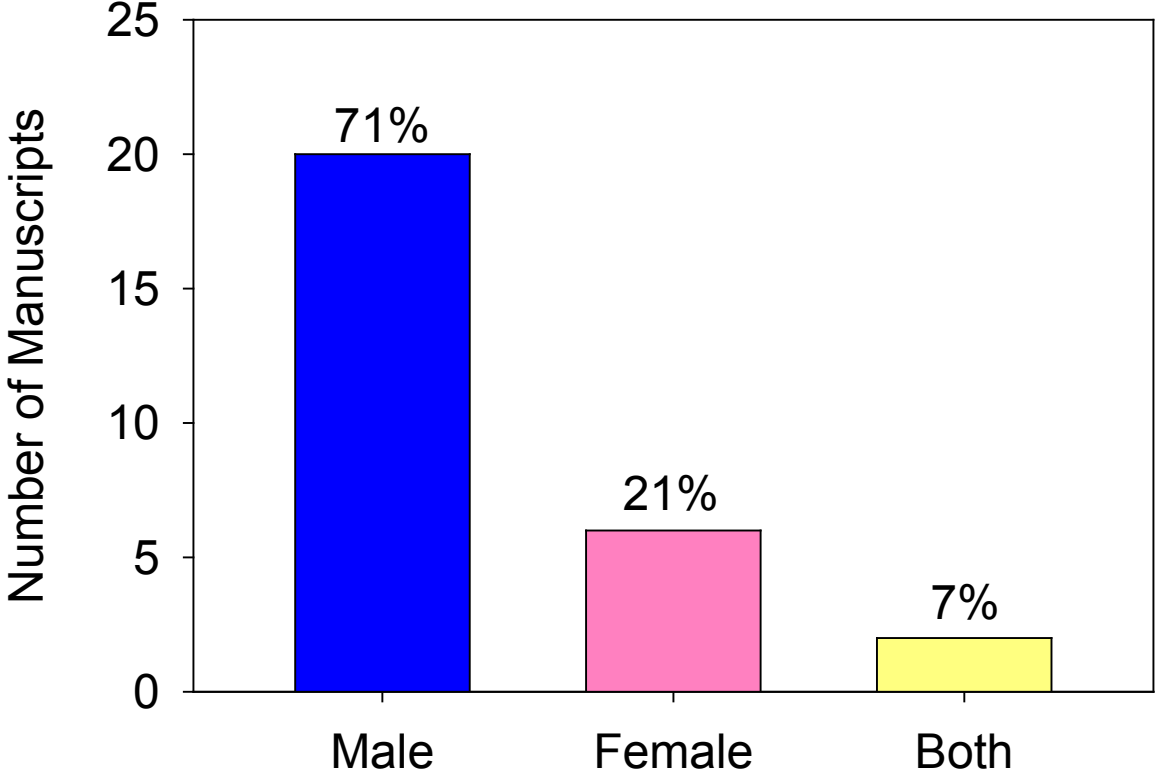
Sex Bias Exists with *Animal* Research



Sex Bias Exists with *Cell* Research



Sex Bias Exists with *Cell* Research



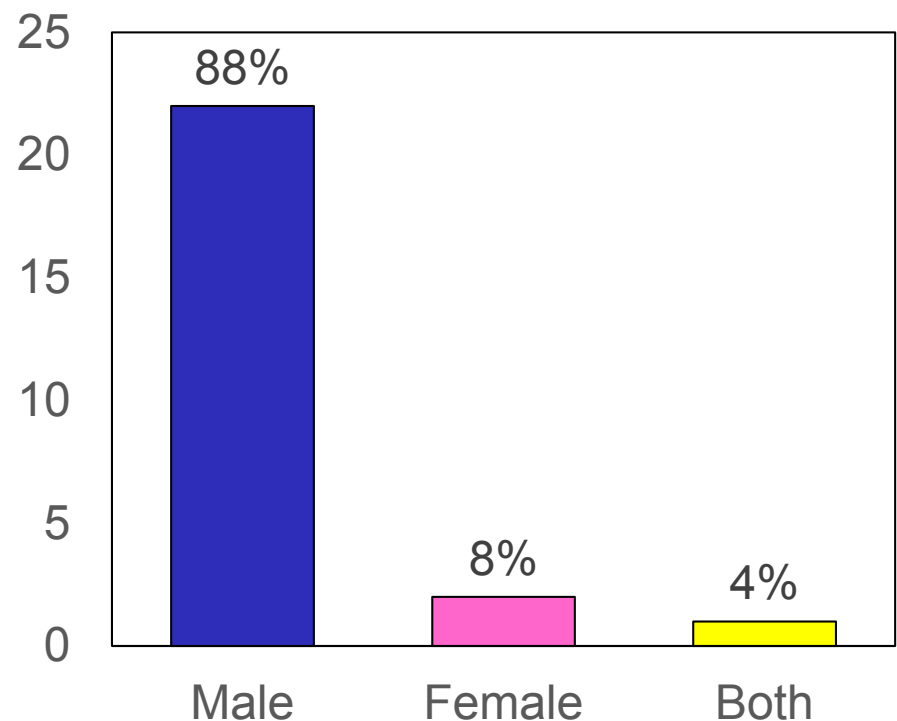
Does Sex Disparity Exist When Studying Diseases Prevalent in Females?

- Diseases prevalent in women:
 - Cardiovascular disease
 - Thyroid disease
 - Obesity
 - Depression
 - Cholelithiasis
 - Migraines
 - Irritable bowel syndrome
 - Multiple sclerosis
 - Rheumatoid arthritis

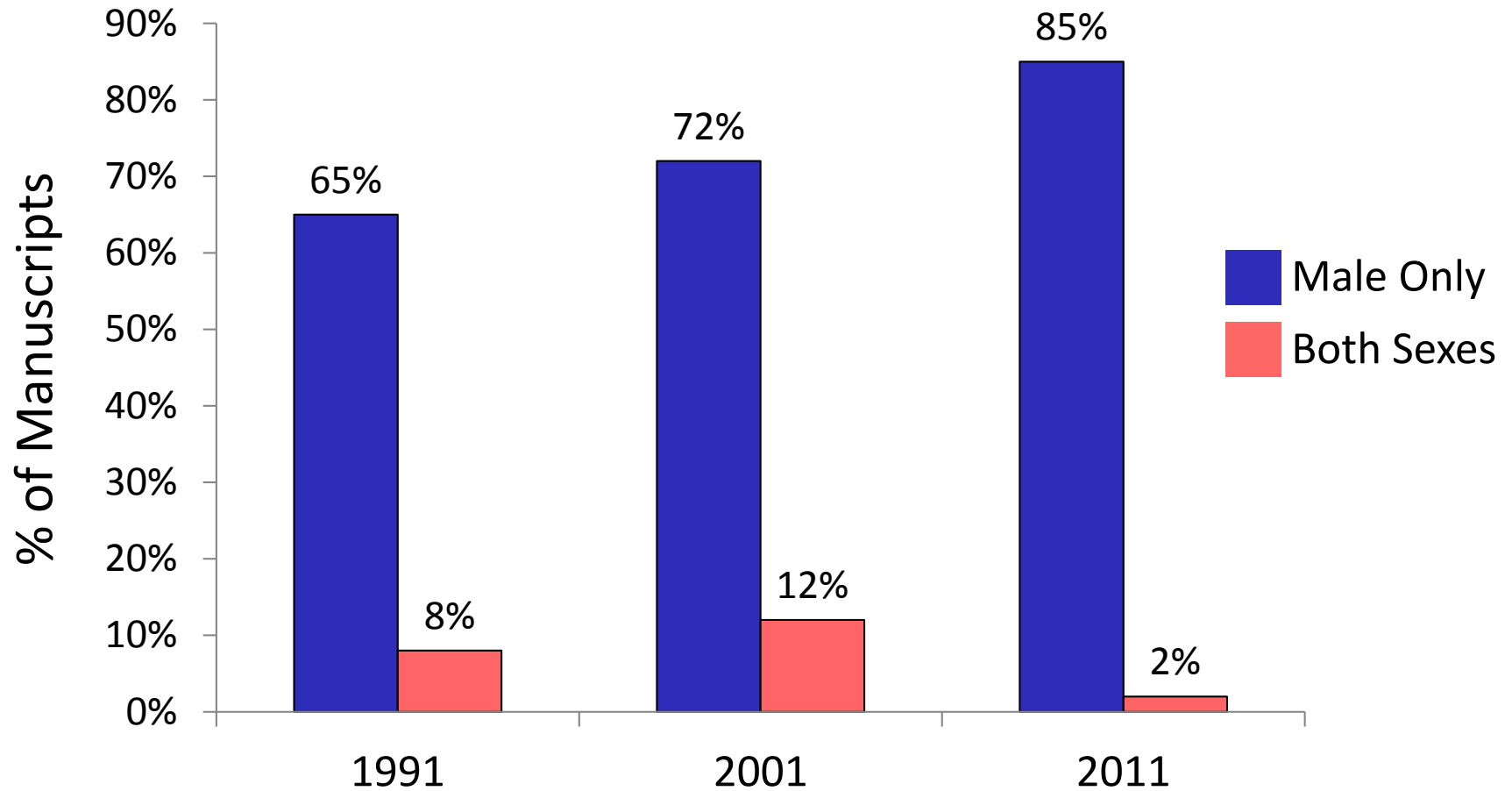


Does Sex Disparity Exist When Studying Diseases Prevalent in Females?

- 45 manuscripts:
 - 29 cardiovascular disease
 - 16 thyroid disease
- 44% did not specify the sex studied (n=20)



Has Sex Disparity in Surgical Research Improved or Worsened Over Time?





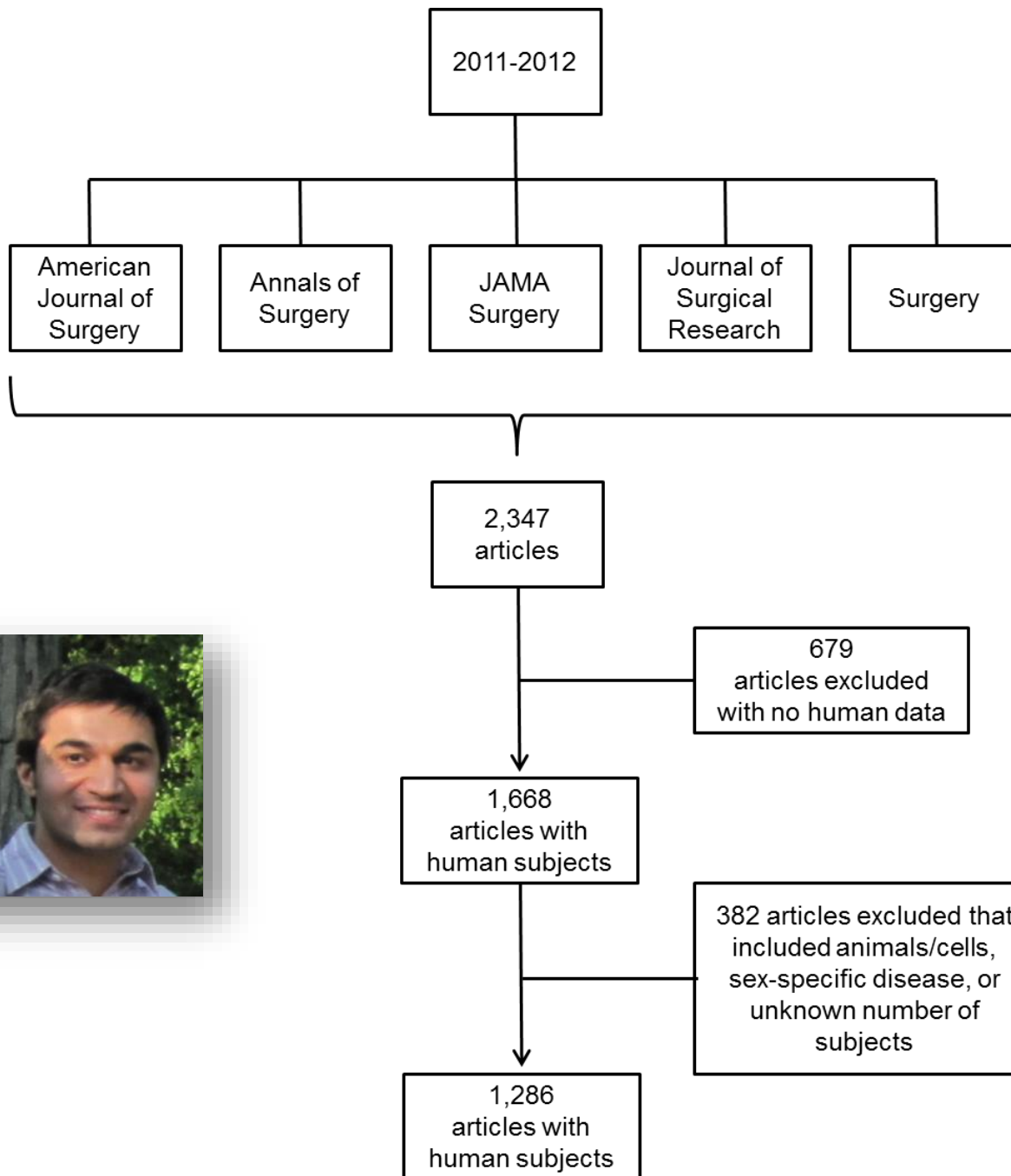
Implications of Sex-Biased Research

- Drugs are developed that may be ineffective for women
- Drugs are developed that may have unidentified side effects in women
- Drugs that show no efficacy in men are not developed further
- Drugs that are studied in both sexes, but with aggregated data, may be more effective in one sex over the other

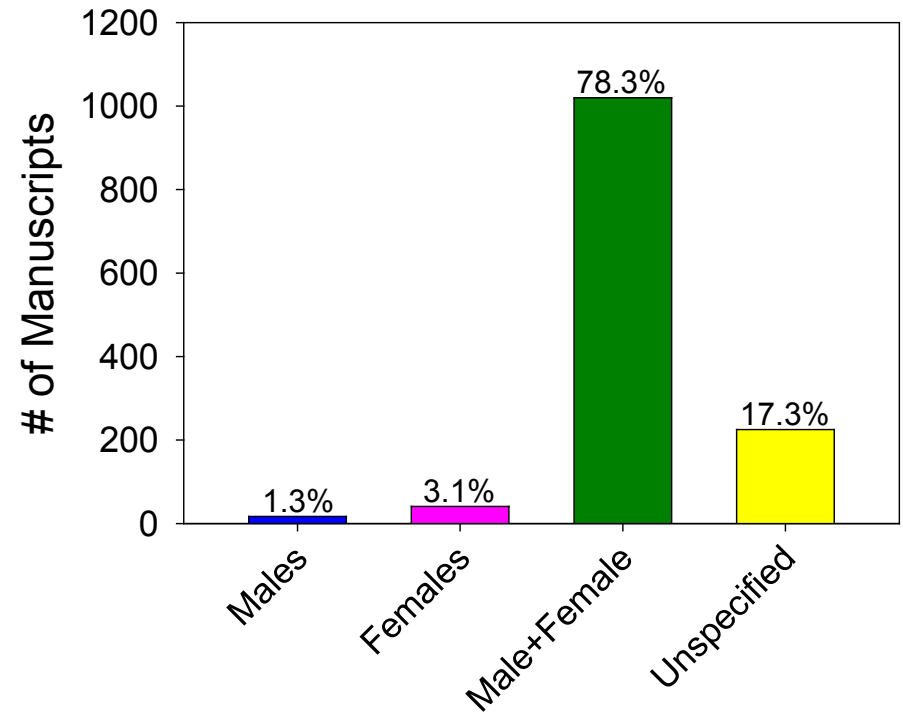
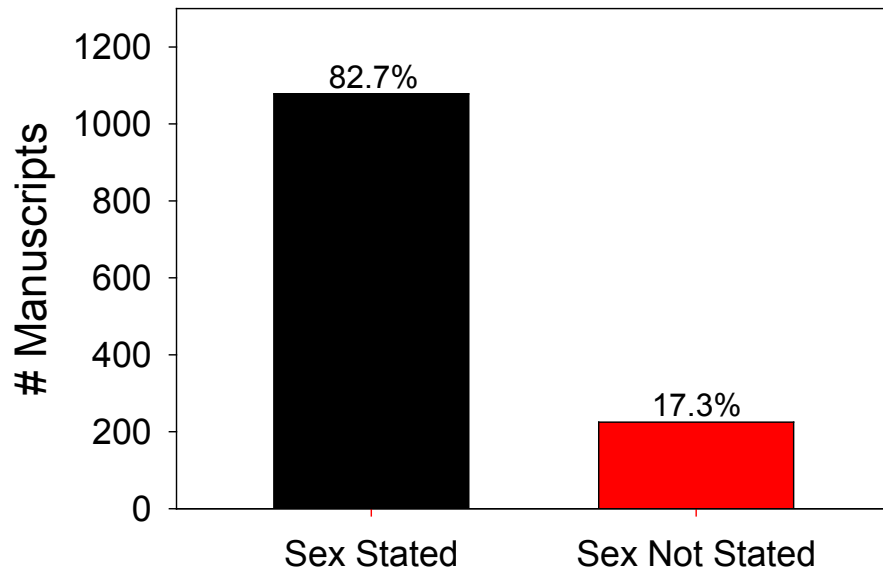


What About **Human** Clinical Research in Surgery?

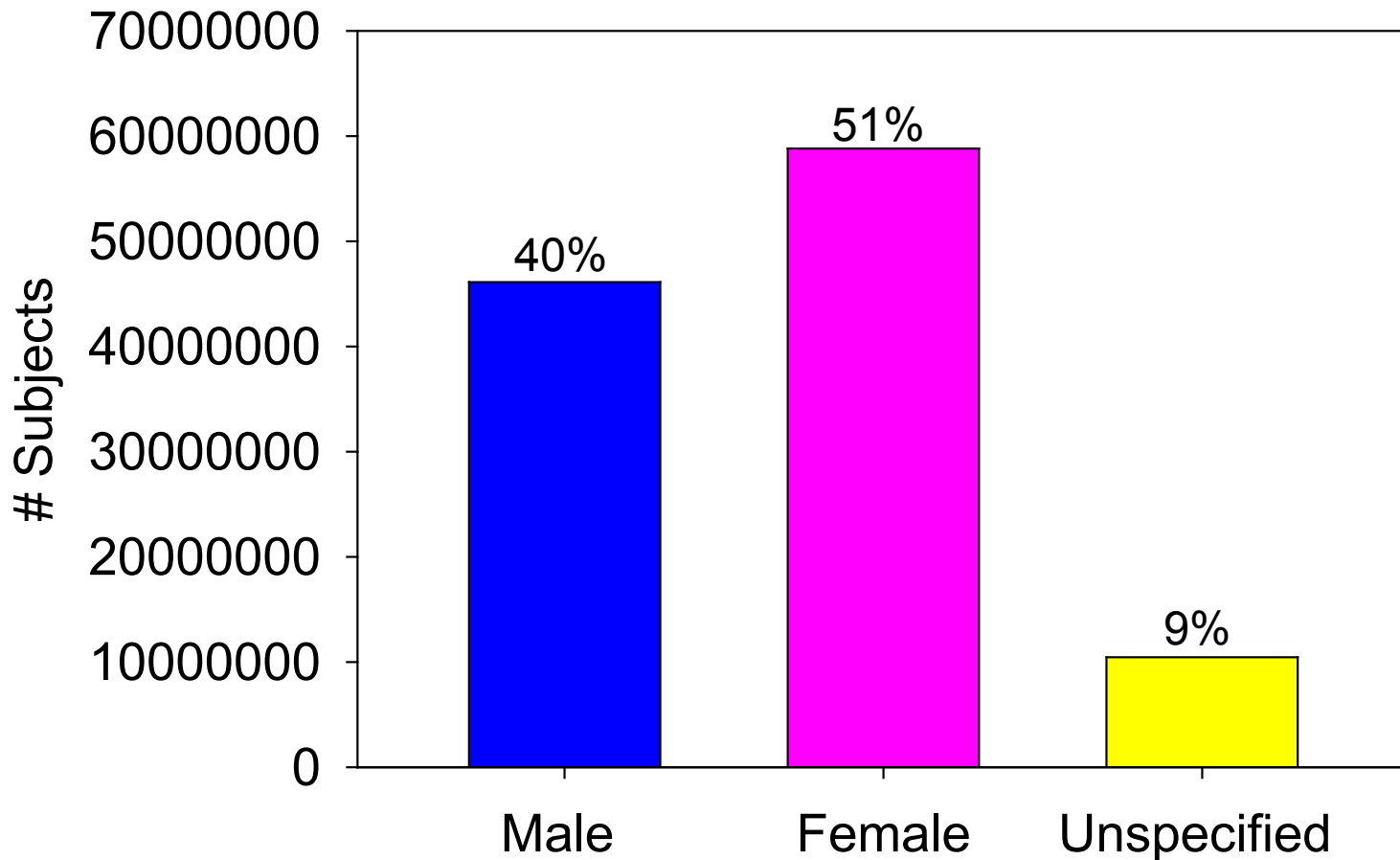




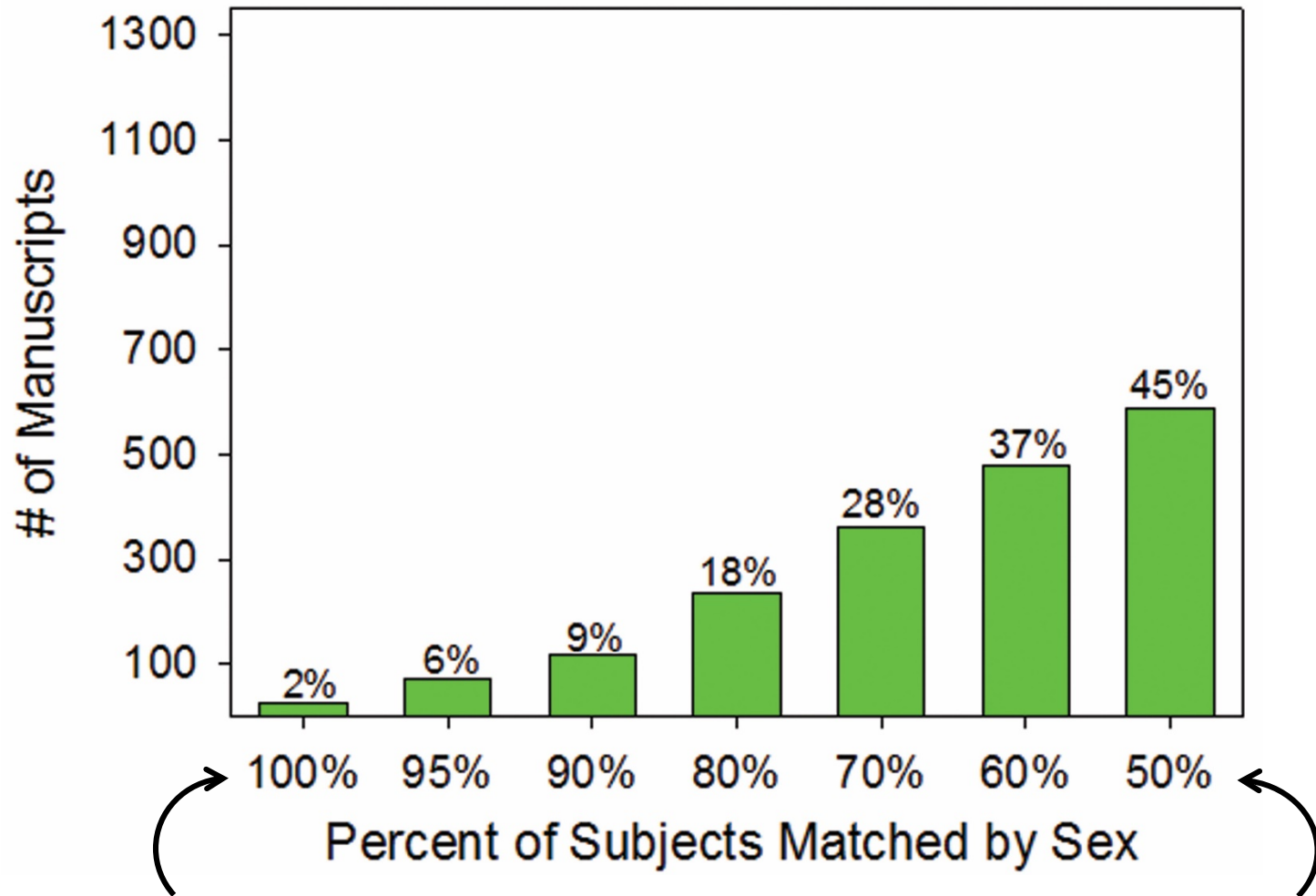
Overall Assessment of the Manuscripts



Inclusion of Both Males and Females



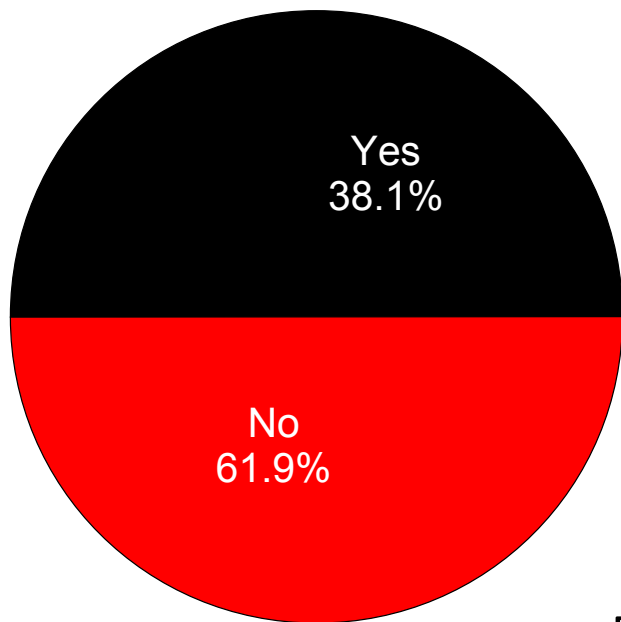
Surgical Research Does Not Match Inclusion of Males and Females Well



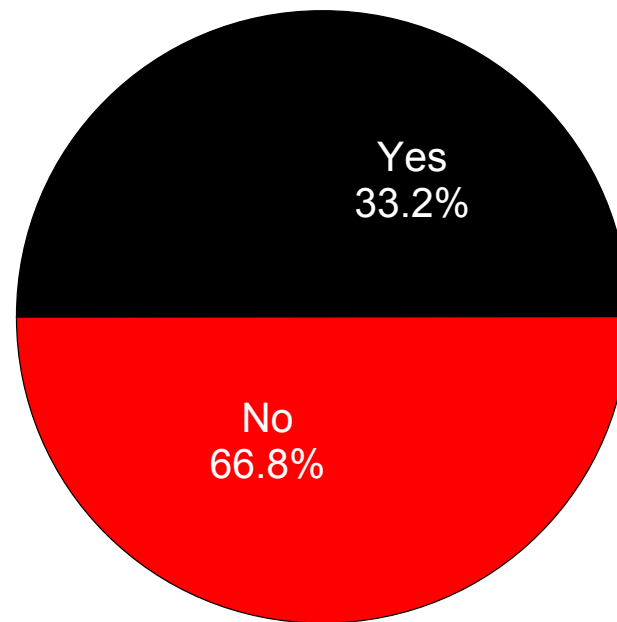
E.g., 100% matching = 50 male + 50 female

E.g., 50% matching = 50 males + 25 females

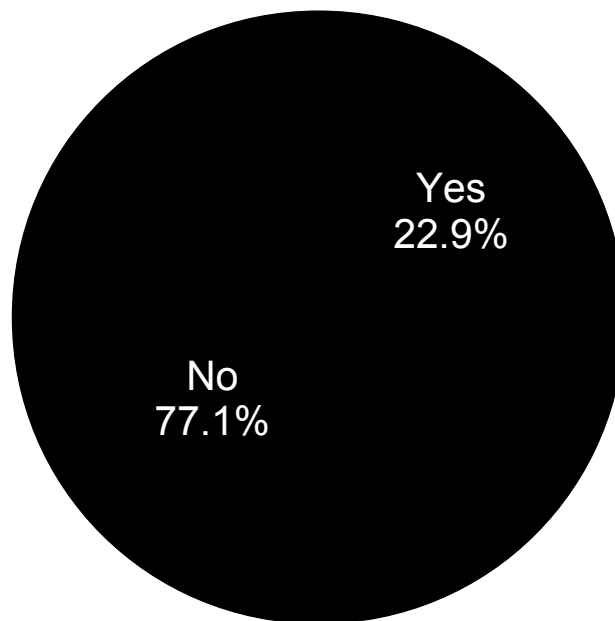
Sex-Based Reporting of Data



Data Analyzed by Sex

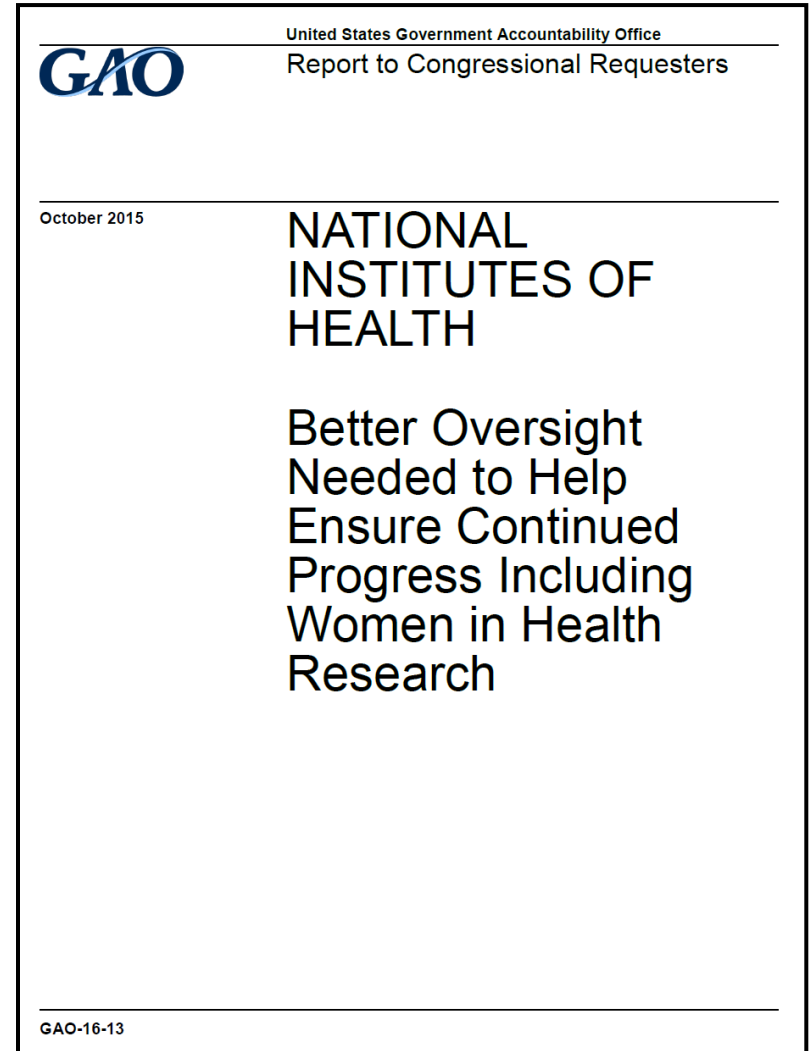


Data Discussed by Sex



GAO 2015 Report

- More females than males were included in NIH-funded clinical research
- But, despite the NIH Revitalization Act of 1993 and increased female enrollment in clinical trials, **sex-based reporting and analysis of results remains an area of disparity**



Drugs Removed From the Market

- 80% of drugs have been removed from the U.S. market due to a greater risk of serious adverse reaction in **women** compared to **men**



Adverse Effects of Drugs in Women

- The odds of an adverse drug reaction in women is **50% greater** than in men
- Women are more likely to be **hospitalized** due to an adverse drug reaction





19:19

+ Queue

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Embed

Transcript



YOUR HEALTH

How 'Bad Medicine' Dismisses And Misdiagnoses Women's Symptoms

March 27, 2018 · 12:15 PM ET

Heard on [Fresh Air](#)

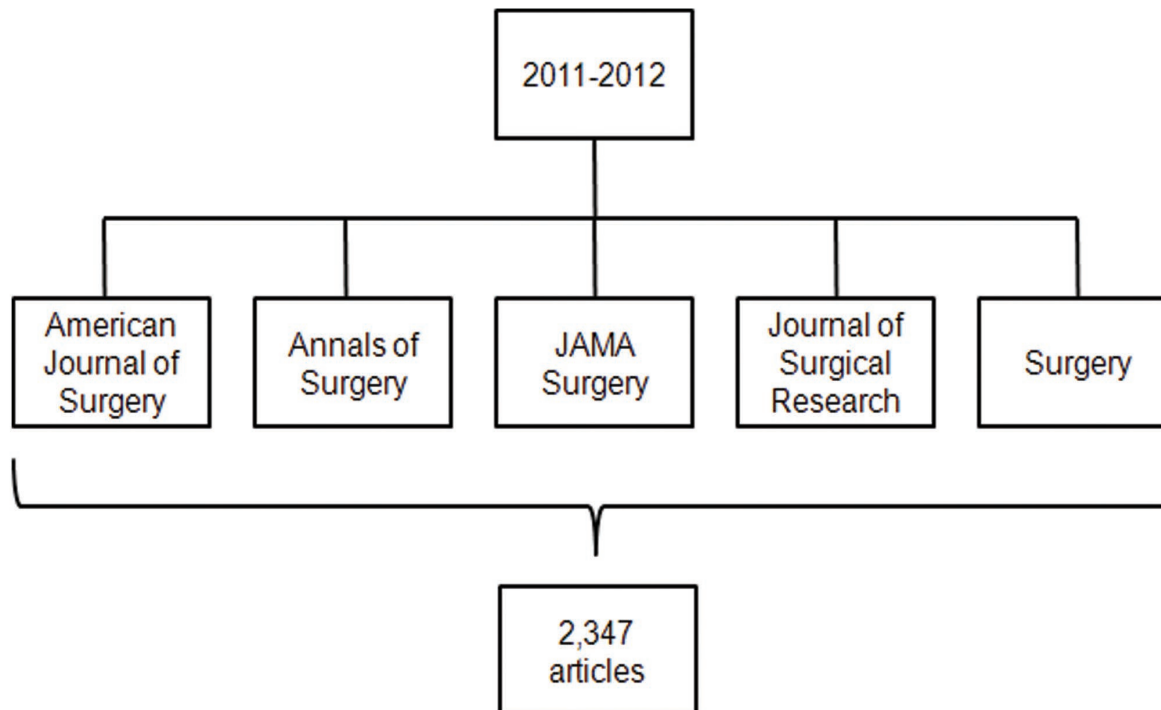


TERRY GROSS



Some Good News....

- We recently examined subsequent citations of the publications from our studies



Sex Inclusive Research Received More Citations

Sex-based reporting

• 2.8 more citations

Sex-based statistical analysis

• 3.5 more citations

Sex-based discussion

• 2.6 more citations

Articles with better sex matching received an increase of **1 citation per 4.8% increase** in percentage of sex matching (95% CI, 2.0%-7.7%, $P = .001$)

How Do We Fix This Problem?



Increased Awareness

Investigators



Physicians



Patients



Increased Awareness

60
MINUTES

Sundays 7/6c

#60Minutes



Increased Awareness

National Institutes of Health

- Announced plans for a new policy in May 2014
- To require investigators “to report their plans for the balance of male and female cells and animals in preclinical studies in all future applications”



Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications

Notice Number: NOT-OD-16-011

Key Dates

Release Date: October 9, 2015

Related Announcements

[NOT-OD-16-034](#)
[NOT-OD-16-011](#)
[NOT-OD-16-031](#)
[NOT-OD-16-012](#)
[NOT-OD-16-005](#)
[NOT-OD-16-004](#)
[NOT-OD-15-103](#)
[NOT-OD-15-102](#)

Issued by

National Institutes of Health (NIH)
Agency for Healthcare Research and Quality (AHRQ)

Purpose

This notice informs the biomedical research community of updates to application instructions and review language intended to enhance the reproducibility of research findings through increased scientific rigor and transparency. These updates will take effect for most* research grant applications (including small business and complex research grant applications) submitted for due dates on or after January 25, 2016. For research contracts, this policy will be effective for proposals received on/after January 25, 2016 and expected to result in contract awards in Fiscal Year 2017 and beyond.

Updates include:

- Revisions to application guide instructions for preparing your research strategy attachment
- Use of a new "Authentication of Key Biological and/or Chemical Resources" attachment
- Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications

These updates focus on four areas deemed important for enhancing rigor and transparency:

- 1) the scientific premise forming the basis of the proposed research,
- 2) rigorous experimental design for robust and unbiased results,
- 3) consideration of relevant biological variables, and
- 4) authentication of key biological and/or chemical resources.

The basic principles of rigor and transparency and the four areas of focus apply to the full spectrum of research, from basic to clinical. Investigators will need to consider how all four areas apply to their proposed research. Likewise, reviewers will assess whether these areas have been appropriately addressed by the applicant through revised language defining the peer review criteria.

NIH Study Sessions

- June 2016 – first NIH study sections with the new requirements
- Consideration of sex as a variable is a **score deriving factor** in the approach!
- Example:
 - “We will attempt to use all male mice since the incidence of aneurysm development is higher in males (80% vs 50%)” –June 2016
 - “Since no known differences have been reported in graft hyperplasia by sex, we will study only males”.
–Feb 2017
 - “We will study male pigs” –June 2018



Publications

Sex bias exists in basic science and translational surgical research

Dustin Y. Yoon, MD, MS,^a Neel A. Mansukhani, MD,^a Vanessa C. Stubbs, MD,^a
Irene B. Helenowski, PhD,^b Teresa K. Woodruff, PhD,^{c,d} and Melina R. Kibbe, MD,^{a,d} Chicago, IL

Background. Although the Revitalization Act was passed in 1993 to increase enrollment of women in clinical trials, there has been little focus on sex disparity in basic and translational research. We hypothesize that sex bias exists in surgical biomedical research.

Methods. Manuscripts from Annals of Surgery, American Journal of Surgery, JAMA Surgery, Journal of Surgical Research, and Surgery from 2011 to 2012 were reviewed. Data abstracted included study type, sex of the animal or cell studied, location, and presence of sex-based reporting of data.

Results. Of 2,347 articles reviewed, 618 included animals and/or cells. For animal research, 22% of the publications did not specify the sex of the animals. Of the reports that did specify the sex, 80% of publications included only males, 17% only females, and 3% both sexes. A greater disparity existed in the number of animals studied: 16,152 (84%) male and 3,173 (16%) female ($P < .0001$). For cell research, 76% of the publications did not specify the sex. Of the papers that did specify the sex, 71% of publications included only males, 21% only females, and 7% both sexes. Only 7 (1%) studies reported sex-based results. For publications on female-prevalent diseases, 44% did not report the sex studied. Of those reports that specified the sex, only 12% studied female animals. More international than national (ie, United States) publications studied only males (85% vs 71%, $P = .004$), whereas more national publications did not specify the sex (47% vs 20%, $P < .0001$). A subanalysis of a single journal showed that across three decades, the number of male-only studies and usage of male animals has become more disparate over time.

Conclusion. Sex bias, be it overt, inadvertent, situational, financial, or ignorant, exists in surgical biomedical research. Because biomedical research serves as the foundation for subsequent clinical research and medical decision-making, it is imperative that this disparity be addressed because conclusions derived from such studies may be specific to only one sex. (*Surgery* 2014;156:508-16.)

From the Departments of Surgery,^a Preventive Medicine,^b and Obstetrics and Gynecology,^c and Women's Health Research Institute,^d Northwestern University, Chicago, IL.





scienze

Melina

QUESTIONE DI SALUTE
Quote rosa nelle ricerche mediche

Quote rosa anche per le cellule utilizzate nella ricerca biomedica. Lo hanno annunciato i National Institutes of Health dopo il polverone sollevato da uno studio del centro Northwestern Medicine di Chicago. Il chirurgo vascolare **Melina R. Kibbe**

è stata analizzata, insieme alla collega Teresa Woodruff, oltre duemila articoli scientifici nel campo della chirurgia e della medicina di base scoprendo che non solo una grossa percentuale di pubblicazioni non specifica il sesso dei soggetti analizzati (il 75 per cento negli studi sulle cellule, il 22 per cento in quelli sugli animali), ma che, quando lo fa, nell'80 per cento dei casi si tratta di quello maschile. E questo avviene nonostante la scienza abbia dimostrato da tempo che gli animali metabolizzano i farmaci in modo diverso a seconda del sesso e che uomini e donne possono reagire diversamente alla stessa malattia o allo stesso tipo di cura. La reazione del Dipartimento della salute Usa è stata immediata: i National Institutes of Health esigeranno dai loro ricercatori lo studio di ambo i sessi nelle ricerche precliniche (quelle in cui non sono ancora coinvolti soggetti umani). «Un provvedimento» ha detto Kibbe «in grado di migliorare sensibilmente la ricerca sulle terapie farmacologiche». (giulia villosesi)



IL SOLARE INVISIBILE FUNZIONA GIÀ CON UN PROTOTIPO A CAPRI. MA IL PROGETTO È DIFFONDERLO IN TUTTA ITALIA

IL FOTOVOLTAICO SI TRAVESTE DA MURETTO E SALVA IL PAESAGGIO

di Alex Saragosa

Fin dal suo esordio il fotovoltaico è stato criticato per la sua bruttezza. In Italia soprattutto, dove il patrimonio architettonico e paesaggistico è sterminato, spesso i pannelli solari suscitano diffidenza. Ora però la tecnologia è riuscita, finalmente, a coniugare funzionalità ed estetica. Lo dimostra il caso della Dyaqua Art Studio, un laboratorio vicentino fondato da Giovanni Battista Quagliato, che, dopo aver inventato pietre luminose dall'aspetto di rocce, ma in realtà fatte di plastica traslucida che si illumina grazie a led, nel 2010 ha avuto l'idea di creare

pannelli fotovoltaici che, attraverso la copertura traslucida incamerano la luce solare, ma imitano perfettamente l'aspetto di roccia, legno o tegole. E così è possibile installarli su costruzioni e in paesaggi di pregio.

Nel maggio scorso un prototipo di «solare invisibile» - perfezionato grazie a studi Enea con il contributo di Lux Italia, Fiamm e Porta Costruzioni - è stato mimetizzato in un muretto di Capri, per illuminare il famoso pino che guarda i Faraglioni. Ora la Dyaqua Art Studio cerca installatori italiani disposti a promuovere coppi, travi e rocce fotovoltaiche in tutta Italia, così da portare l'e-

Il prototipo di pannello fotovoltaico invisibile, mimetizzato in un muretto a Capri per illuminare il pino di Punta Tragara, con vista sui Faraglioni

nergia solare dove finora non aveva osato avventurarsi.

Nel frattempo gli americani hanno reso il fotovoltaico addirittura invisibile. L'ingegner Richard Lunt e suoi colleghi della Michigan State University hanno realizzato un pannello solare trasparente inserendo nella plastica sostanze fluorescenti che trasmettono i raggi Uv e infrarossi del Sole in luce utile per la connessione fotovoltaica, convogliandola verso i bordi della lastra, dove le aspettano strette celle solari. Le case del futuro, quindi, potranno produrre elettricità non solo da muri e tegole, ma anche da finestre e vetrate.

NUMERO VERDE di Cristina Mochi

13 milioni

Sono i turisti (di 119 Paesi) che sono andati a fare whale watching nel 2008 (ultimo anno per il quale sono disponibili dati): un business stimato in 2,1 miliardi di dollari. Nel 1991 erano stati 4 milioni, in 31 Paesi. L'osservazione di balene e delfini a bordo di barche, se praticata su larga scala, potrebbe però mettere in pericolo i cetacei, sia per lo stress che provoca negli animali sia per le ferite che possono riportare dalle collisioni con le imbarcazioni. Lo dice l'Imcc di Glasgow (International Marine Conservation Congress). Una soluzione potrebbe venire dall'imporre più regole a quello che fin qui è stato considerato un turismo ecologico: si possono stabilire per esempio distanze minime da rispettare tra barche e animali, limiti di velocità e aree interdette. Ma anche questo non sembra sufficiente: a Bocas del Toro, Panama, dove queste regole esistono, tra 2012 e 2013 sono morti almeno dieci delfini in una popolazione di circa 250.



Journals

- Should require **all authors** to provide a description of the **sex studied** for cell, animal and human research
- If only one sex is studied, **justification** of a single-sex model should be required
- Would like ALL journals to require this



Surgery Journal Editors Group (SJEG)

Joint Statement by the Surgery Journal Editors Group*

We, the editors of surgery journals, believe that conducting sex-inclusive biomedical and clinical research is imperative to improving health outcomes of men and women. Note that the word “sex” is being used rather than “gender”. Sex is the genotype by which one is born and gender is the phenotype. It is the chromosomal sex of the human, animal, tissue, or cell to which we are referring. Recent studies have shown that the majority of biomedical research in the field of surgery and related topics is conducted on male animals and male cells, even when studying diseases prevalent in women.¹ Human clinical research suffers from a lack of sex-based reporting and sex-based analysis of the results.^{2,3} Given these findings, the National Institutes of Health has now asked that sex be considered as a biologic variable in all National Institutes of Health-funded research.⁴ As such, we support uniform, defined reporting of the sex used for human, animal, tissue, and cell research in ALL manuscripts published in our journals. If only one sex is studied, authors must include a justification statement as to why a single-sex study was conducted. We also will require sex-based reporting and analysis of data for all human, animal, tissue, and cell research. As a group, we will require this among all our collective surgery journals.

*The Surgery Journal Editors Group is comprised of editors from 74 international, surgery-related journals who meet once a year at the annual meeting of the American College of Surgeons and discuss concerns common among surgery journals.

Food & Drug Administration (FDA)

- Should require ALL New Drug Applications to include the study of both sexes **AND** provide sex-based reporting of the data
- Should require ALL **clinical trials** to balance enrollment of men and women, AND conduct sex-based reporting of the data



FDA

FDA Report

FDA ACTION PLAN TO ENHANCE THE COLLECTION AND AVAILABILITY OF DEMOGRAPHIC SUBGROUP DATA

August 2014





Science & Research

Home > Science & Research > Science and Research Special Topics > Women's Health Research

Women's Health Research

[OWH Research and Development Program](#)

[Women's Health Research Roadmap](#)

[OWH Research Initiatives](#)

[OWH Presentations and Publications](#)

[Understanding Sex Differences](#)

[The Inclusion of Women in Clinical Trials](#)

[Pregnancy Registries](#)

Resources for You

- [Women's Health Research](#)
- [Advancing Regulatory Science](#)
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Women's Health Research Roadmap

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A Strategy for Science and Innovation to Improve The Health of Women

Since its inception, the FDA Office of Women's Health (OWH) has worked closely with FDA's centers to expand existing research projects and foster new collaborations related to advancing the science of women's health. OWH has also worked with other governmental agencies, academia, women's research organizations, and other stakeholders to foster and facilitate research projects and scientific forums. These combined efforts have helped to advance our understanding of women's health issues. They have furthered the development of new tools and approaches for informing FDA decisions about the harm or the safety and effectiveness of FDA-regulated products that are used not only by women, but by all Americans.

The Women's Health Research Roadmap (Roadmap), outlined here, builds on knowledge gained from previously funded research and is intended to assist OWH in coordinating future research activities with other FDA research programs and with external partners. The Roadmap outlines priority areas where new or enhanced research is needed. Although many critical women's health issues may warrant further examination, future OWH-funded research should focus on areas where advancements will be directly relevant to FDA as it makes regulatory decisions. The Roadmap creates strategic direction for OWH to help maximize the impact of OWH initiatives and ultimately promote optimal health for women.

Research Priority Areas

- Advance Safety and Efficacy**: Advance the safety and efficacy and reduce the toxicity of FDA-regulated products used by women
- Improve Clinical Study Design and Analyses**: Improve clinical study design and conduct to better identify

7 research priority goals

Industry Funded Research

- Currently, there is no mandate or policy for industry sponsored clinical trials.
- The same guidelines that apply to government funded research and clinical trials should apply to industry sponsored clinical trials, given that these represent the majority (~90%) of clinical trials



Government

- Congressman Jim Cooper has proposed a new bill: “Research for All Act of 2015”
- Requirements for both the FDA and NIH

UNITED STATES CONGRESSMAN
JIM COOPER
Representing Tennessee's 5th District

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Cooper Bill Ensures Equality in Medical Research

Jun 17, 2014 | Press Release

Studying women valuable; new legislation would require it

WASHINGTON – U.S. Rep. Jim Cooper (TN-5) and U.S. Rep. Cynthia Lummis (WY-1) today introduced a bipartisan bill that would require the inclusion and separate analysis of both male and female animals, tissues and cells in basic research conducted and funded by the National Institutes of Health (NIH).

Current law does not require researchers to study female animals when conducting basic medical research.

As researchers at Brigham and Women's Hospital recently said, "Medical research that is either sex- or gender-neutral or skewed to male physiology puts women at risk for missed opportunities for prevention, incorrect diagnoses, misinformed treatments, sickness and even death."

Why do we need The RESEARCH FOR ALL Act?

Most medical research focuses on men. Studying women is suggested, but not required.

Heart disease: the #1 killer of all Americans

Only 1/3 of subjects in cardiac clinical trials are women.

Only 30% of cardiac studies with women report outcomes by sex.

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[All Bill Information](#) (Except Text)

Sponsor: [Rep. Cooper, Jim \[D-TN-5\]](#) | Cosponsor statistics: 10 current - includes 1 original

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Summary

- Sex matters!
- Research is fraught with sex bias
- Of manuscripts that stated the sex of the animal or cell studied, 80% studied only males
- Human surgical research needs better inclusion of both sexes, and data should be reported and analyzed by sex
- Great need for increased awareness
- Need for policy changes



Conclusion