### SYMPOSIUM ANNUEL DU CENTRE CÉRÉBROVASCULAIRE CHUV

## **AVC SEXE ET GENRE: RECHERCHE**

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19.09.2024





Male

Total

P=0.34

Female

442 (5.2%)

80 (4.3%)

522 (5.0%)



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Advance Access Publication Date: 18 May 2022

Critical Care

CRITICAL CARE

Use of tranexamic acid in major trauma: a sex-disaggregated analysis of the Clinical Randomisation of an Antifibrinolytic in Significant Haemorrhage (CRASH-2 and CRASH-3) trials and UK trauma registry (Trauma and Audit Research Network) data

Tim Nutbeam<sup>1,5,\*</sup>, Ian Roberts<sup>2</sup>, Lauren Weekes<sup>3,5</sup>, Haleema Shakur-Still<sup>2</sup>, Amy Francois-Xavier Ageron<sup>4</sup>

<sup>1</sup>Emergency Department, University Hospitals Plymouth NHS Trust, Plymouth, UK, <sup>2</sup>Clinical Trials I Hygiene and Tropical Medicine, London, UK, <sup>3</sup>Department of Anaesthesia, University Hospitals Plymouth, UK, <sup>4</sup>Emergency Department, Lausanne University Hospital, Lausanne, Switzerland and Ambulance Trust, Exeter, UK

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This article is accompanied by an editorial: Sex discrimination after injury: is inequity in tranexamic acid admin iceberg? by Cole et al., Br J Anaesth 2022:129:144–147, doi: 10.1016/j.bja.2022.05.015

#### **Abstract**

Background: Women are less likely than men to receive some emergency treatments. This study e effect of tranexamic acid (TXA) on mortality in trauma patients varies by sex and whether the receipatients varies by sex.

Methods: First, we conducted a sex-disaggregated analysis of data from the Clinical Randomisation

Tranexamic acid Study Placebo RR 95% CI CRASH-2 Male 351 (6.5%) 429 (7.9%) (0.72 - 0.94)Female 59 (5.3%) 84 (8.1%) (0.47 - 0.90)Total 410 (6.3%) 513 (8.0%) (0.70 - 0.90)P=0.20CRASH-3 Male 91 (2.9%) 121 (4.0%) (0.55-0.94)Female 21 (2.8%) 26 (3.5%) (0.46-1.42)Total 112 (2.9%) 147 (3.9%) (0.58 - 0.94)P=0.72Both trials

CRASH-2 trial: June 2010

CRASH-3 trial: October 2019

Fig 2. Forest plot demonstrating the effect of tranexamic acid treatment on relative risk (RR) of death from any cause within 24 h of injury, stratified by sex in the CRASH-2, CRASH-3 trials and both trials pooled. CRASH, Clinical Randomisation of an Antifibrinolytic in Significant Haemorrhage; CI, confidence interval.

0.75

1.0 1.1

0.50

(0.71 - 0.90)

(0.52 - 0.91)

(0.70-0.87)

550 (6.5%)

110 (6.2%)

660 (6.5%)

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UK TARN registry for England and Wales from 2017 to 2020

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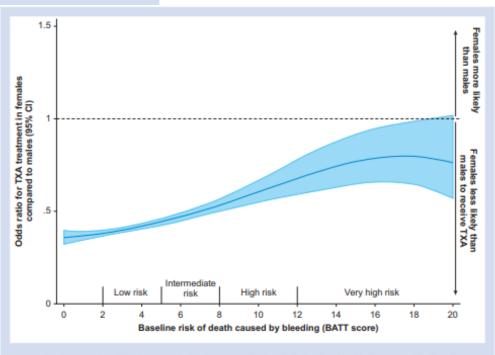


Fig 3. Receipt of tranexamic acid (TXA) treatment in females compared with males by baseline risk of death caused by bleeding adjusted by prehospital time. BATT, Bleeding Audit for Trauma and Triage.

# QUEL EST LE PROBLÈME?

- Biais de connaissance
  - Connaissance médicale construite sur un modèle androcentré
- Biais dans la clinique
  - Stéréotypes de genre/aveuglement face au genre
- Influence complexe du genre sur la santé
  - Influence de facteurs biologiques ET sociaux





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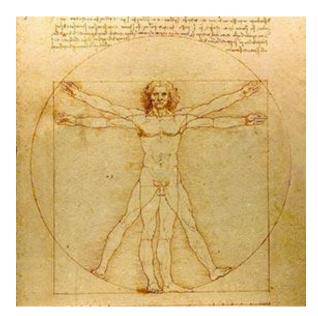




# **ANDROCENTRISME**

Le corps masculin= le corps humain **Standard neutre:** blanc, âge moyen, 70 kg

1977: exclusion des femmes de la recherche médicale (Scandale de la Thalidomide– 1960)



L'Homme de Vitruve (L. De Vinci, 1492): représentation des proportions idéales et parfaites du corps humain inscrit dans un cercle et un carré

# XIX<sup>TH</sup>: PARADIGME NATURALISTE

- Classification des populations: biologie utilisée pour construire 'scientifiquement' un savoir basé sur les différences entre les femmes et les hommes
- Infériorité "naturelle" légitimée par le discours médical
  - Différentation
  - Hiérarchisation

des sexes, de la race

### Notion de savoirs situés

Haraway, Donna. "Situated Knowledges: The Science Question in Feminism and the Privilege of Partial Perspective." *Feminist Studies* 14, no. 3 (1988)

MAY 7, 1892. SEX IN EDUCATION. DES BRITISK 94

### THE ANNUAL ORATION SEX IN EDUCATION.

Delivered before the Medical Society of London.

By Sir JAMES CRICHTON-BROWNE, M.D., LL.D., F.R.S.,
Lord Chancellor's Visitor in Lunacy.

#### [Abbreviated.]

WIRN that eccentric father of a family of geniuses, the late Rev. Mr. Brontă, desiring that his children should spack freely and without timidity, put them behind a mask and questioned them on various subjects, he was told by his son Branwell, then seven years old, in nawer to one of his interrogations, that the best way of knowing the difference between the intellects of men and women is by considering the difference between them as to their bodies. That deliverance of the precoclous boy seemed to his father at the time a wise saying, worthy of being recorded, and I daresay it seems the same to us as medical men to-day; but it is incontestable that there are no largo numbers of cultivated persons to whom it hard the same of the same to the property of the same to the same to the same to a largo numbers of cultivated persons to whom it

There is a growing tendency around us to ignore intellectual distinctions between the sexes, to assimilate the education of girls to that of boys, to throw men and women into industrial competition in every walk of life, and to make them comperes in social intercourse. And as, to my thinking, this tandance is mynhysiological and likely it induced to be de-

average, greater in men than in women. There is, however, as correlation between brain weight and stature, and, laying hold of this fact, the advocates of woman's rights and mights have argued that the deficiency in her brain weight, when for the property of the propert

			Brai	n	We	ight.			
Sexes.	Average Weight of Brain.		Average Height.		Excess of Male over Female Brain Weight.		Excess of Male Brain Weight after Allowance for Height.		
50203	Grams.	Ozs.	Metres.	Feet.	Inches.	Grams.	Ozs.	Grams.	Ozs.
45 Males	1350.54	47.64	1.702	5	7	127.68	4.50	29.71	1.05-
55 Females	1222.86	43.14	1.575	5	2	-	-	-	-

In this table are summed up the brain weights of 1,600 persons: 945 males and 655 females, ranging from 10 to 50 years of age, the weighing of the brain haying been in each case conducted by myself or under my own supervision. The brains of males exceeded those of females in weight by 127,68

"The bodily differences between men and women which underlie their intellectual disparities are universal and intimate, and involve every organ and tissue. I shall not attempt an extensive anatomical survey. My present purpose will be served by directing attention to certain sexual differences in one bodily organ, the brain. [...] Man is more wilful, enterprising, passionate, and energetic, that is to say, more katabolic in the mental sphere, while woman is more receptive, tranquil, affectionate, and constant, that is to say, more anabolic in the mental sphere."



### Perspective

RECOGNIZING HISTORICAL INJUSTICES IN MEDICINE AND THE JOURNAL

### Malicious Midwives, Fruitful Vines, and Bearded Women — Sex, Gender, and Medical Expertise in the *Journal*

Ben Maldonado, B.A., Iamie Marsella, M.A., Abigail Higgins, A.B., and Sarah S. Richardson, Ph.D.

This article is part of an invited series by independent historians, focused on biases and injustice that the Journal has historically helped to perpetuate. We hope it will enable us to learn from our mistakes and prevent new ones.



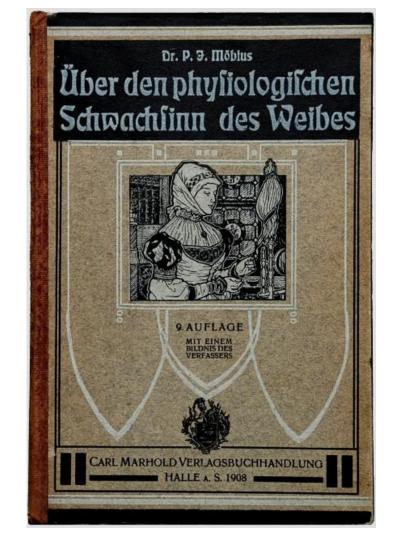
ince its founding in 1812, the Journal has served as a source of medical claims about sex differences, portraying male and female bodies as not only different in terms of physiology, but completely different in nature. Sex was, as one 1844 article put it, "the greatest distinction by far of any which exists among manidu." Early articles in the Journal openly endorsed the superiority of men over women. An 1892 summary of a speech by Scottish physician James Grichton-Browne, for example, argued that differences in brain sizes and thus intelligence were a "fundamental sexual distinction" between men and women."

We analyzed publications in the Journal's archives covering more than 200 years, which we retrieved by means of directed keyword searches, using a snowball approach. The sources we present here are both extraordinary and representative of the Journal's approach to sex in medicine. We structure our discussion using three topic areas, which are neither discrete nor exhaustive, that illustrate the ways in which the Journal has circulated sexis ideas as it has generated authoritative medical discourse about innate sex differences: women in the medical profession, reproductive biology and medicine, and the medical management of interesx conditions. The next article in this series will complement this one, expanding on the theme of sex by addressing sexual and endenf minorities.

### Dr Paul Julius Möbius (1853-1907)

« De l'imbécilité physiologique de la femme», 1900

Sur la base du poids cérébral inférieur des femmes par rapport aux hommes, Möbius conclut que les femmes ne sont pas intellectuellement capables de traiter les problèmes de la vie politique, car elles sont guidées par l'instinct et moins aptes à discerner le bien du mal.



# XX<sup>TH</sup>: SHIFT ÉPISTÉMOLOGIQUE

#### 1960 : mouvements féministes

- Inadéquation des standards normatifs
- Résultats non généralisables
- "Women's health"



#### 1993: NIH Revitalization Act

 Inclusion des femmes et des autres "minorités" dans la recherche

### 2006 : Conseil européen de la recherche :

 Inclusion des dimensions de sexe et de genre dans la recherche



# **QUELLES SONT LES CONSÉQUENCES**





# Putting gender on the agenda

Biomedical research continues to use many more male subjects than females in both animal studies and human clinical trials. The unintended effect is to short-change women's health care.

ifferences in the physiology of males and females, and in their response to disease, have been recognized for decades in many species — not least *Homo sapiens*. The literature on these differences now encompasses everything from variations in gene expression between male and female mice, to a higher susceptibility to adverse drug reactions in women compared with men. Moreover, hormones made by the ovaries are known to influence symptoms in human diseases ranging from multiple sclerosis to epilepsy.

And yet, despite the obvious relevance of these sex differences to experimental outcomes, three articles in this issue (see pages 688–690) document that male research subjects continue to dominate biomedical studies. Some 5.5 male animal models are used for every female in neuroscience, for example. And apart from a few large, all-female projects, such as the Women's Health Study on how aspirin and vitamin E affect cardiovascular disease and cancer, women subjects remain seriously under-represented in clinical cohorts. This is despite reforms undertaken in the 1990s, when sex discrimination in human trials was first widely recomined as a machine.

whether to require the inclusion of such information. Funding agencies should demand that researchers justify sex inequities in grant proposals and, other factors being equal, should favour studies that are more equitable.

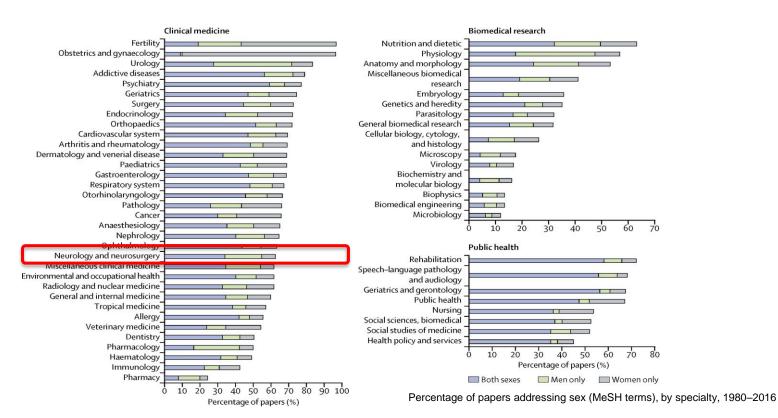
Funding agencies and researchers alike should also start thinking

seriously about how to deal with the most fundamental sex difference: pregnancy. Pregnant women get ill, and sick women get pregnant. They need therapies, too, even though they are carrying a highly vulnerable fetus and their bodies are undergoing massive changes in hormonal balance, immune function

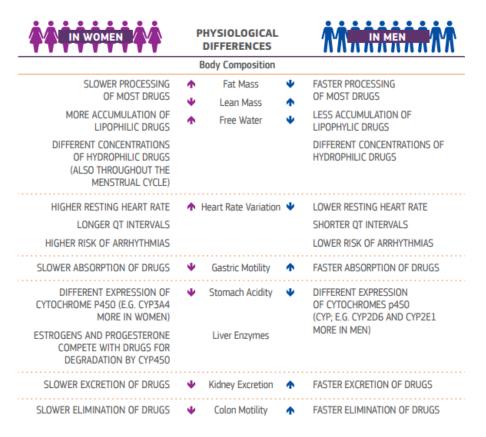
"Medicine as it is currently applied to women is less evidence-based than that being applied to men."

and much else besides. Entering pregnant women in clinical trials is problematic in the extreme, for a host of ethical reasons. But ignoring the problem is not an answer either — the result is that physicians will prescribe drugs whose effects during pregnancy are poorly known.

## LA MÉDECINE RESTE ANDROCENTRÉE



### DIFFÉRENCES DE SEXE EN PHARMACOLOGIE



## LES ÉCHANTILLONS MIXTES NE SUFFISENT PAS

 Besoin de mener des analyses qui prennent en compte le sexe/le genre.





### SEXE ET TRAITEMENTS PHARMACOLOGIQUES

- PETACC-3 clinical trial: teste l'efficacité d'un traitement pour le cancer colorectal stade II et III (2'974 patients, 44% femmes)
  - Treatment A: fluorouracil et leucovorin
  - Treatment B: FOLFIRI (combinaison de leucovorin, fluorouracil et irinotecan hydrochloride)
- Résultats n'ont pas été analysés en fonction du sexe (2009)
- Nouvelles analyses (2018): évaluation de la toxicité des traitements en fonction du sexe

#### Letters

#### RESEARCH LETTER

Association of Patient Sex With Chemotherapy-Related Toxic Effects: A Retrospective Analysis of the PETACC-3 Trial Conducted by the EORTC Gastrointestinal Group

Sex is one of several known factors responsible for the wide interpatient variability in the dose-effect relationship of drugs. It affects both pharmacokinetics and pharmaco-

# **TOXICITÉ PLUS IMPORTANTE CHEZ LES FEMMES**

Table 1. Adverse Events With Statistically Significant Sex Differences in Pooled Treatment Arms in 2974 Patients<sup>a</sup>

	No. (%)		Asymptotic Difference, %		
Characteristic	Female (n = 1318)	Male (n = 1656)	(95% Confidence Limits)	P Value	
Nonhematological Ad	lverse Events				
Diarrhea					
All grade	705 (53.5)	809 (48.9)	4.6 (1.0 to 8.3)	.01	
Grade 3-4	131 (9.9)	122 (7.4)	2.6 (0.5 to 4.6)	.01	
Constipation					
All grade	149 (11.3)	123 (7.4)	3.9 (1.8 to 6.0)	<.001	
Grade 3-4	4 (0.3)	8 (0.5)	-0.2 (-0.6 to 0.3)	.57	
Nausea					
All grade	814 (61.8)	889 (53.7)	8.1 (4.5 to 11.6)	<.001	
Grade 3-4	54 (4.1)	44 (2.7)	1.4 (0.1 to 2.8)	.03	
Vomiting					
All grade	429 (32.5)	405 (24.5)	8.1 (4.8 to 11.4)	<.001	
Grade 3-4	47 (3.6)	42 (2.5)	1.0 (-0.2 to 2.3)	.11	
Cramping					
All grade	251 (19.0)	224 (13.5)	5.5 (2.8 to 8.2)	<.001	
Grade 3-4	16 (1.2)	9 (0.5)	0.7 (0.0 to 1.4)	.07	
Stomatitis					
All grade	480 (36.4)	501 (30.3)	6.2 (2.8 to 9.6)	<.001	
Grade 3-4	34 (2.6)	20 (1.2)	1.4 (0.4 to 2.4)	.01	
Cholinergic syndrome	e				
All grade	123 (9.3)	106 (6.4)	2.9 (1.0 to 4.9)	.004	
Grade 3-4	1 (0.1)	4 (0.2)	-0.2 (-0.4 to 0.1)	.39	
Lethargy					
All grade	556 (42.2)	612 (37.0)	5.2 (1.7 to 8.8)	.004	
Grade 3-4	36 (2.7)	31 (1.9)	0.9 (-0.2 to 2.0)	.14	
Alopecia					
All grade	549 (41.7)	431 (26.0)	15.6 (12.2 to 19.0)	<.001	
Grade 3-4	18 (1.4)	6 (0.4)	1.0 (0.3 to 1.7)	.003	

	No. (%)		— Asymptotic Difference, %		
Characteristic	Female (n = 1318)	Male (n = 1656)	(95% Confidence Limits)	P Value	
Hematological Adver	se Events				
Leukopenia					
All grade	654 (49.6)	645 (38.9)	10.7 (7.1 to 14.3)	<.001	
Grade 3-4	53 (4.0)	40 (2.4)	1.6 (0.3 to 2.9)	.01	
Neutropenia					
All grade	818 (62.1)	886 (53.5)	8.6 (5.0 to 12.1)	<.001	
Grade 3-4	293 (22.2)	215 (13.0)	9.3 (6.5 to 12.0)	<.001	
Anemia					
All grade	1056 (80.1)	820 (49.5)	30.6 (27.4 to 33.8)	<.001	
Grade 3-4	20 (1.5)	8 (0.5)	1.0 (0.3 to 1.8)	.01	

## **BIAIS DE GENRE EN PHARMACOLOIE**



Etudes pré-cliniques 76% cellules mâles 75% animaux mâles





Essais phase I-II 67% études chez les hommes



Dosages mieux adaptés aux hommes



### Pharmacovigilance et postmarketing

~50% de plus d'effets indésirables chez les femmes

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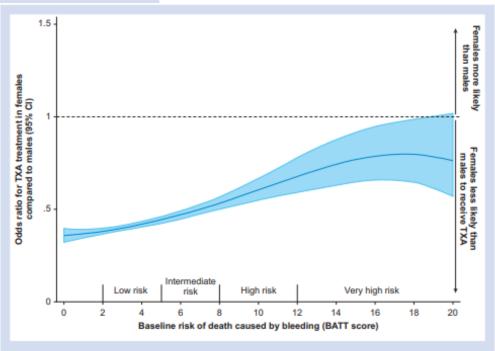
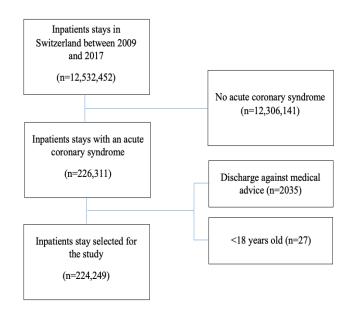


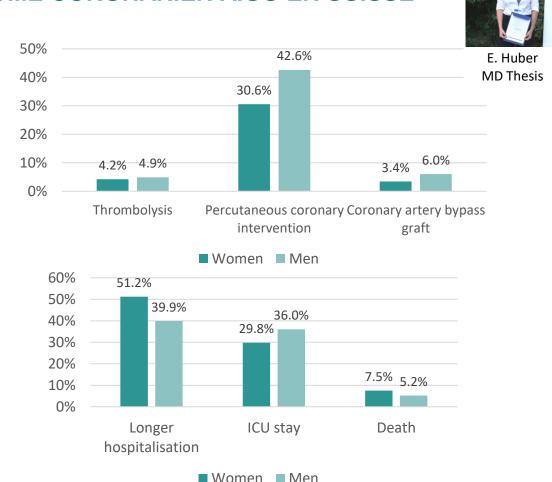
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#### PRISE EN CHARGE DU SYNDROME CORONARIEN AIGU EN SUISSE

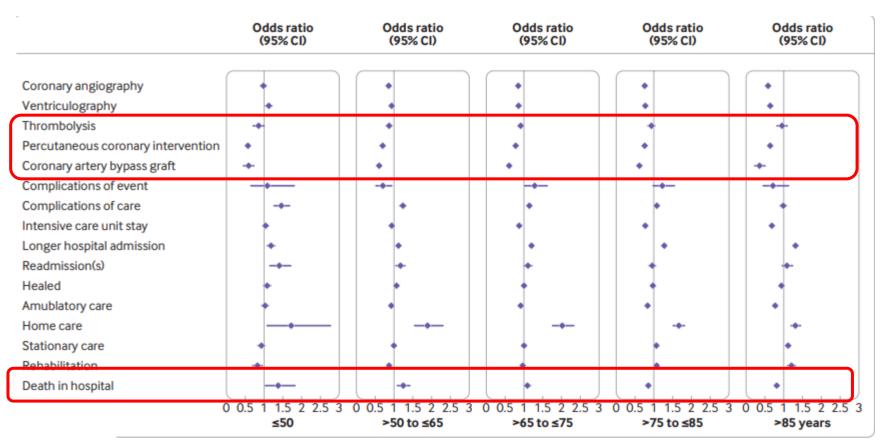
Etude cross-sectionnelle, utilisation des données administratives de santé des hôpitaux suisses, période 2009 to 2017



Huber E, Le Pogam MA, Clair C. *BMJ Med*. 2022 Nov 17;1(1):e000300. doi: 10.1136/bmjmed-2022-000300.



### LES FEMMES JEUNES ONT UN RISQUE DE DÉCÈS AUGMENTÉ



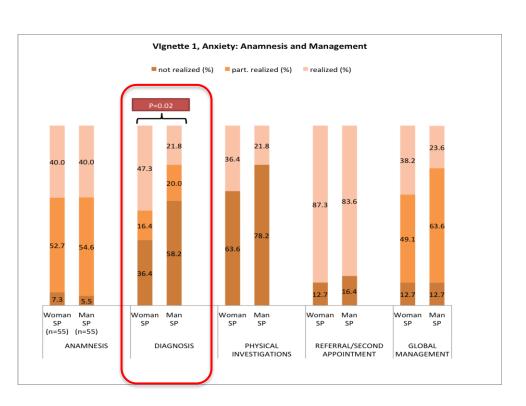
Huber E, Le Pogam M, Clair C BMJ Medicine 2022;1:e000300. doi: 10.1136/bmjmed-2022-000300 \*Adjustment variables: nationality, class of stay, presence of an older acute coronary syndrome event, somatic and psychiatric comorbidities

# BIAIS DE GENRE CHEZ LES ÉTUDIANT.E.S

Examens de compétences cliniques (ECOS) des étudiant.e.s en M1 médecine de Lausanne







Le Boudec J, et al. *Patient Educ Couns*. 2023 Feb 8;110:107655. doi: 10.1016/j.pec.2023.107655.

## BIAIS DE GENRE EN PRATIQUE CLINIQUE

- Il existe des preuves quantitatives de ces biais
- Mais elles n'expliquent pas ce qui se passe
- Besoin d'approches qualitatives pour comprendre les processus de traitements inégaux/injustes
  - Observations (méthodes ethnographiques).





Qualitative Sociology (2020) 43:235–254 https://doi.org/10.1007/s11133-020-09450-3

# The School Form of the Hospital: How Does Social Class Affect Post-Stroke Patients in Rehabilitation Units?



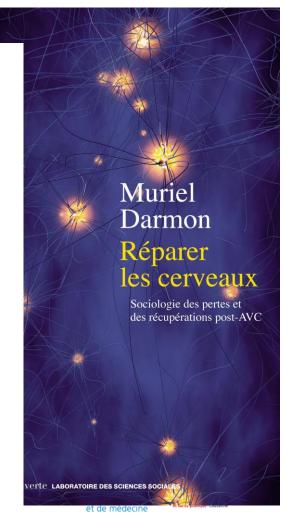
Muriel Darmon 1

Published online: 2 April 2020

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#### Abstract

This paper wishes to explain, using qualitative sociology, an epidemiological finding: that the extent of recovery following stroke is class-based and that patients from the working classes and lower socioeconomic groups are more vulnerable to functional impairments following stroke than those from higher socioeconomic groups. Based on a 15-month ethnographic study of neurology and rehabilitation units, the paper shows that hospital rehabilitation after stroke is shaped by a "school form," and that it therefore proves far

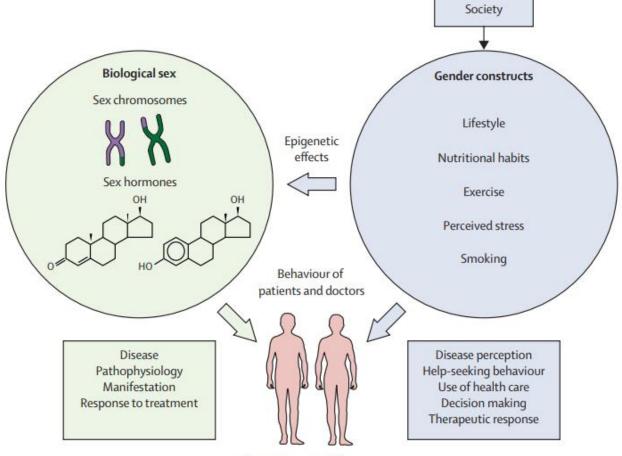


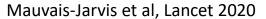
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Sex and gender differences in health, disease, and medicine



# **SEXE OU GENRE?**

Déterminisme biologique

100% biologique 0% social

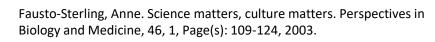
Théorie des systèmes dynamiques

100% biologique 100% social

Relativisme

0% biologique 100% social

Interaction dynamique



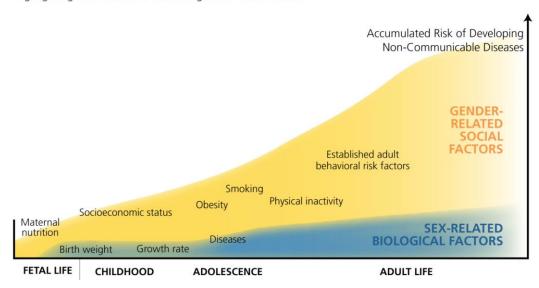




### INFLUENCE DU SEXE ET DU GENRE SUR LA SANTÉ

#### **Cumulative Life Course Risk Factors for Non-Communicable Disease (NCD)**

Highlighting the influence of sex and gender-related factors



Adapted from Darton-Hill et al., 2004





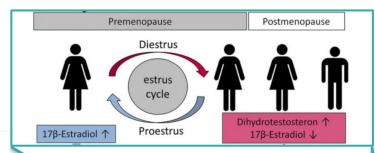
## **ALORS... COMMENT MESURER LE SEXE?**

Sexe: □F □M





### **WHAT ABOUT SEX?**





Richardson, S., (2022) "Sex Contextualism", Philosophy, Theory, and Practice in Biology 14: 2. https://doi.org/10.3998/ptpbio.2096

#### **Perspective**

# Sex contextualism in laboratory research: Enhancing rigor and precision in the study of sex-related variables

Madeleine Pape, 1,\* Mirjam Miyagi, 2 Stacey A, Ritz, 3 Marjon Boulicault, 4 Sarah S, Richardson, 5,8 and Donna L, Maney 7,8

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Department of Philosophy, University of Edinburgh, Edinburgh, Scotland
Department of the History of Science, Harvard University, Cambridge, MA, USA

Committee on Degrees in Studies of Women, Gender, and Sexuality, Harvard University, Cambridge, MA, USA

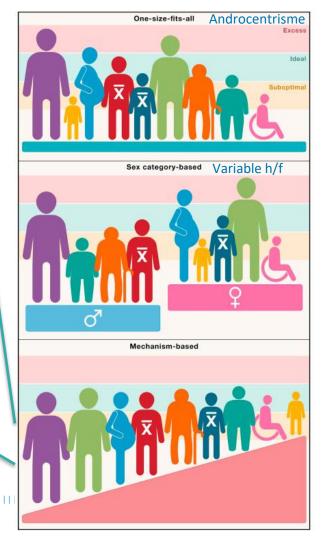
<sup>7</sup>Department of Psychology, Emory University, Atlanta, GA, USA

BHarvard-Radcliffe Institute, Harvard University, Cambridge, MA, USA

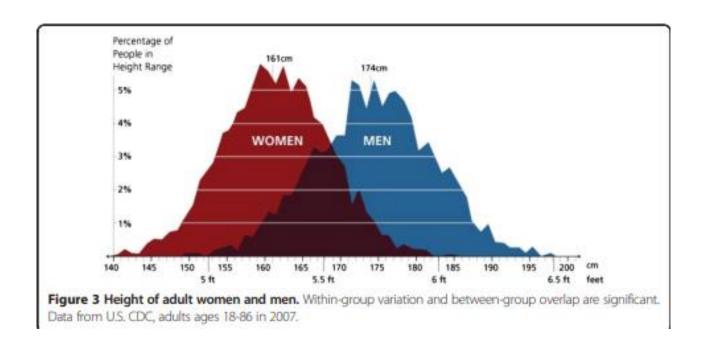
\*Correspondence: madeleine.pape@unil.ch https://doi.org/10.1016/j.cell.2024.02.008

#### SUMMARY

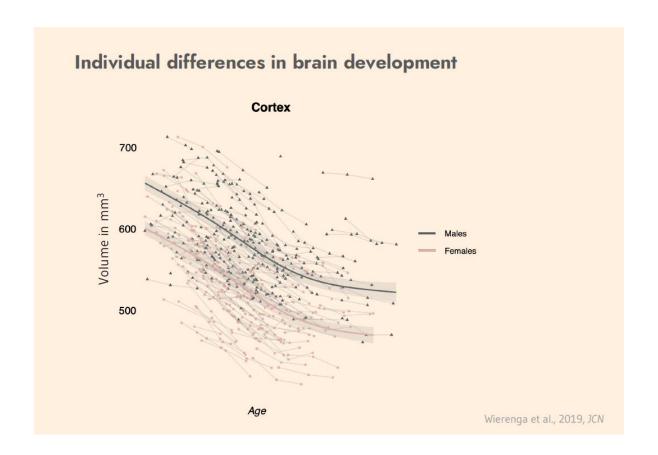
Understanding sex-related variation in health and illness requires rigorous and precise approaches to revealing underlying mechanisms. A first step is to recognize that sex is not in and of itself a causal mechanism; rather, it is a classification system comprising a set of categories, usually assigned according to a range of varying traits. Moving beyond sex as a system of classification to working with concrete and measurable sex-related variables is necessary for precision. Whether and how these sex-related variables matter—and what patterns of difference they contribute to—will vary in context-specific ways. Second, when researchers incorporate these sex-related variables into research designs, rigorous analytical methods are needed to allow strongly supported conclusions. Third, the interpretation and reporting of sex-related variation require care to ensure that basic and preclinical research advance health equity for all.



### **CONTROVERSE: DIMORPHISME SEXUEL?**



Schiebinger, L. Gendered innovations: harnessing the creative power of sex and gender analysis to discover new ideas and develop new technologies. *Triple Helix* **1**, 9 (2014). https://doi.org/10.1186/s40604-014-0009-7



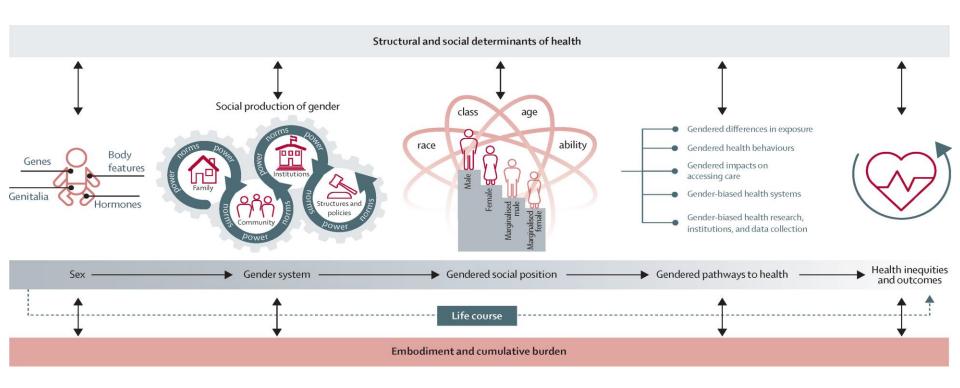
Lara M. Wierenga, Marieke G. N. Bos, Fabienne van Rossenberg, Eveline A. Crone; Sex Effects on Development of Brain Structure and Executive Functions: Greater Variance than Mean Effects. J Cogn Neurosci 2019; 31 (5): 730–753. Figure presented at the Congress of the Organisation of the Study of Sex Differences, Bergen Norway, 08.05.2024.

## **ALORS... COMMENT MESURER LE GENRE?**

Sexe: □F □M







Heise, L., Greene, M. E., Opper, N., Stavropoulou, M., Harper, C., Nascimento, M., ... & Henry, S. (2019). **Gender inequality and restrictive gender norms: framing the challenges to health.** *The Lancet*, *393*(10189), 2440-2454.

et de medecine

# LIENS VERS LA SANTÉ/MALADIE

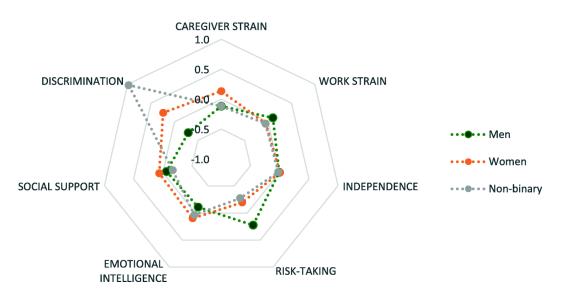
- Différences sociales
  - Différences de genre dans l'exposition :
     Division sexuée du travail (chantiers), lois (militaire), exposition à la violence (dynamiques de pouvoir)
  - Comportements de santé selon le genre :
     Régime alimentaire, activité physique, tabagisme : normes de genre liées à
     l'image corporelle, rôles et comportements attendus
  - Impacts genrés sur l'accès aux soins : Comportements en santé, accès financier (inégalité des retraites)
  - Systèmes de santé biaisés selon le genre :

Biais dans la prise en charge

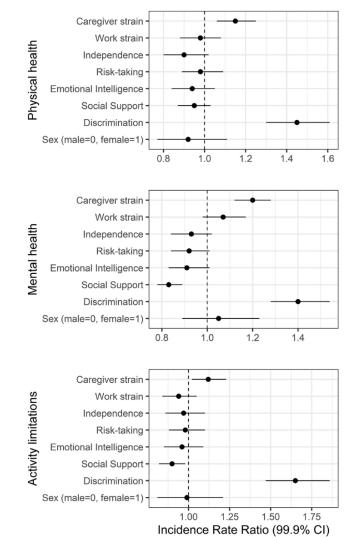




# The Stanford Gender-Related Variables for Health Research



Nielsen et al. Gender-related variables for health research. Biol Sex Differ. 2021 Feb 22;12(1):23. doi: 10.1186/s13293-021-00366-3.

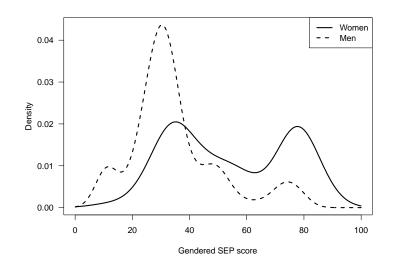


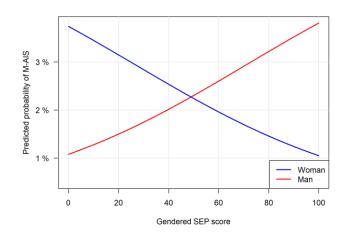
# SCORE DE GENRE POUR ALLER AU-DELÀ DU SEXE



- C. Barras MD thesis
- AVC ischémiques aigus manqués (M-AIS) = 3 %, pas de différences entre les sexes
- Score de position socioéconomique genrée (gendered SEP)
  - État civil, situation de vie, niveau d'éducation, catégories professionnelles, activité professionnelle et avoir des enfants → conformité aux caractéristiques féminines

### La conformité aux normes de genre peut avoir un effet protecteur





### **GENDER TOOLBOX**

### Disponible ici:

https://www.unisante.ch/fr/formationrecherche/recherche/projetsetudes/creation-dun-index-mesure-dugenre-spark



Health and Gender Unit (2021). The Gender Toolbox: Recommendations for Health Researchers. Lausanne, Unisanté – Center for primary care and public health.





Revision date: 19.01.2022

## THE GENDER TOOLBOX: RECOMMENDATIONS FOR HEALTH RESEARCHERS

Diane Auderset, Joana le Boudec, Carole Clair & Joëlle Schwarz

Health and gender Unit - Unisanté, Center for primary care and public health, Lausanne

#### Introduction

The inclusion of both men/males and women/females as study participants/subjects in health research is a prerequisite for good research practice (1). Such inclusion is crucial to understand humans' variability, which is not possible when only male or only female subjects are studied (2). For analysis, the standard variable "female/male", largely used in quantitative health research, is a first step towards inclusion, because it enables exploring variability between the two large categories of women and men. Its use is however often suboptimal for several reasons:

- It is a proxy of potentially different elements such as sex-related biological factors (hormone levels and function, chromosomes, gene expression, reproductive/sexual anatomy) and gendered sociological phenomena (socially constructed roles, behaviors, expressions and identities of girls, women, boys, men, and gender diverse people), and is thus not specific
- It contributes to the widespread confusion around the gender and sex concepts in health research, that tends to focus on sex-related biological explanations for observed differences in women's and men's health
- It excludes certain populations that do not fit into the female or male categories, such as intersex or gender diverse people

In order to support researchers conduct sex/gender analyses as required by some funding programs such as <u>EU Horizon 2000</u>, we developed this toolbox to guide the inclusion of sex/gender in terms of conceptualization and potential indicators to consider. Two sections therefore constitute this working document: a **theoretical framework** linking gender and health; and a **list of indicators** derived from it, to consider before conducting (gender/sex-related) health research. We begin by presenting some questions to address, to guide researchers in identifying relevant sex and gender hypotheses and identify measurement needs.

#### A priori hypotheses and detailed questions

For reliable and useful measures, the effects of sex/gender on the investigated health topic have to be anticipated. Before starting any study, researchers need to ask themselves this fundamental question:

Are gender and/or sex relevant to my research topic?

We recommend formulating hypotheses recogning to the questions:

# LES SAGER GUIDELINES (2016)



- Comprehensive procedure for reporting of sex and gender information in study design, data analysis, results and interpretations of findings
- Primarily designed to guide authors in preparing their manuscripts but they are also useful for editors to integrate assessment of sex and gender in all manuscripts as an integral part of the editorial process
- Convenient list of items to check off when writing, reviewing or editing manuscripts
- One checklist for studies including human participants and one for studies that do not include human participants (animals, cells)

## RECOMMANDATIONS SWISSETHICS

#### swissethics

Schweizerische Vereinigung der Forschungsethikkommissionen Swiss Association of Research Ethics Committees

Home

News

RAPS register

Templates / Checklists ↓↓

BASEC

Topics #

Training ↓↓

https://swissethics.ch/en/themen/gender-sensitive-research







#### swissethics publishes recommendations on research adapted to "sex and gender"

"Sex and gender" equity is a very important topic in medical research and clinical practice. In 2020, swissethics published recommendations on the topic of "sex and gender"-equitable research. A working group has now addressed the topic further and developed instructions on how to implement the aspect of "sex and gender" in research in an ethically appropriate manner

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#### Sex and gender equitable research

Sex and gender differences are often overlooked in research design, study implementation and scientific reporting, as well as in scientific communication in general. This omission limits the possibility to generalize research findings and their applicability to clinical practice, particularly for women but also for men. This section deals with this topic.

#### Recommendations on research adapted to sex and gender

Sex and Gender in research involving humans according to the Human Research Act (HRA): Issues to consider.

This document reflects the swissethics recommendations on sex and gender in research involving humans according to the HRA.



English

1.0 updated: 17.04.2024

Sex and Gender in research involving humans according to the Human Research Act: Recommendation for the ethical review of research projects.

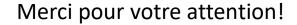


English

1.0 updated: 17.04.2024

## THE SAGER-SWISSETHICS RECOMMENDATIONS

QUESTIONS	YES	NO	Comment for RECs			
1. TOPIC OF THE STUDY			NEO5			
Are sex/gender (S/G), respectively sexual and gender			If the answer is			
diversity (SGD) issues relevant to the topic and aim of the			no. check that it			
study?			is justified			
If sex/gender issues are relevant to the topic/aim, please ch	neck al	I the f				
2. INTRODUCTION						
2.1. Are S/G and SGD dimensions developed (genetic and/or			If no, ask for			
biologic or social mechanisms at play)?			protocol's revision			
,			accordingly			
2.2. If appropriate, do the objectives include the question on			If no, ask for			
S/G and/or SGD?			protocol's revision			
			accordingly			
3. METHODS						
3.1. Is the study population correctly described regarding S/G			If no, ask for			
(including sexual and gender diversity)?			protocol's revision			
, , ,			accordingly			
3.2. Eligibility criteria: does it ensure representativeness of all			If no, ask for			
the S/G and SGD dimensions? Is there a selection bias			protocol's revision			
regarding S/G distribution?			accordingly			
3.3. Recruitment of participants: does the process of			If no, ask for			
obtaining the data ensure an adequate distribution of S/G and			protocol's revision			
SGD?			accordingly			
3.4. Definition of S/G and SGD dimensions: do they capture			If no, ask for			
sex dimensions (hormonal levels, gene expression, etc.)			protocol's revision			
and/or gender dimensions (identities, norms) and/or sexual			accordingly			
orientation dimensions (sexual attraction, romantic						
attraction)?						
<ol><li>Statistics (incl. sample size): if S/G and SGD are of</li></ol>			If no, ask for			
primary interest, does the sample size estimation integrate			protocol's revision			
this aspect? Are the statistical analyses appropriate?			accordingly			
4. INFORMED CONSENT & OTHER DOCUMENTS						
4.1. Informed consent form & other documents: does the			If no, ask for ICF's			
content of information respect the epicene language, or at			revision			
least is written in an inclusive manner?						
4.2. Informed consent form: Does the information cover the			If no, ask for ICF's			
study's aspect related to sex/gender and SGD appropriately?			revision			
4.3. Informed consent form: If applicable, is the issue of			If no, ask for			
contraception and pregnancy fully and clearly presented?			protocol's and			
does the document address the issue of potential extra costs			ICF's revision			
that may deter women/parents to participate in the study, e.g.						
child care and custody						
4.4. In questionnaires, interviews: is the language and content			If no, ask for			
inclusive? is the possibility to cover the sexual and gender			documents'			
diversity open (e.g. in an open box)?			revision			
5. PUBLICATION AND DISSEMINATION POLICY						
Do the publication and dissemination plans include the			If no, ask for			
presentation of disaggregated results by S/G and SGD?			protocol's revision			



www.unisante.ch/fr/formation-recherche/recherche/groupes-recherche/sante-genre

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