LA INCLUSIÓN PERMANENTE DEL GÉNERO EN LA INVESTIGACIÓN Y EN LA PRÁCTICA DE SALUD

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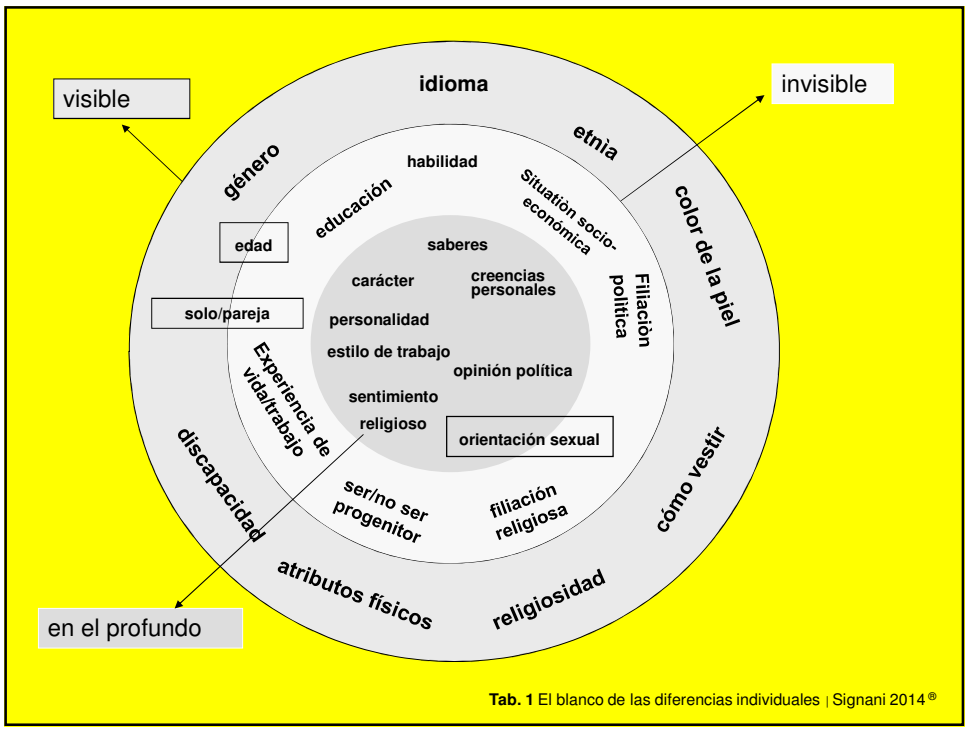
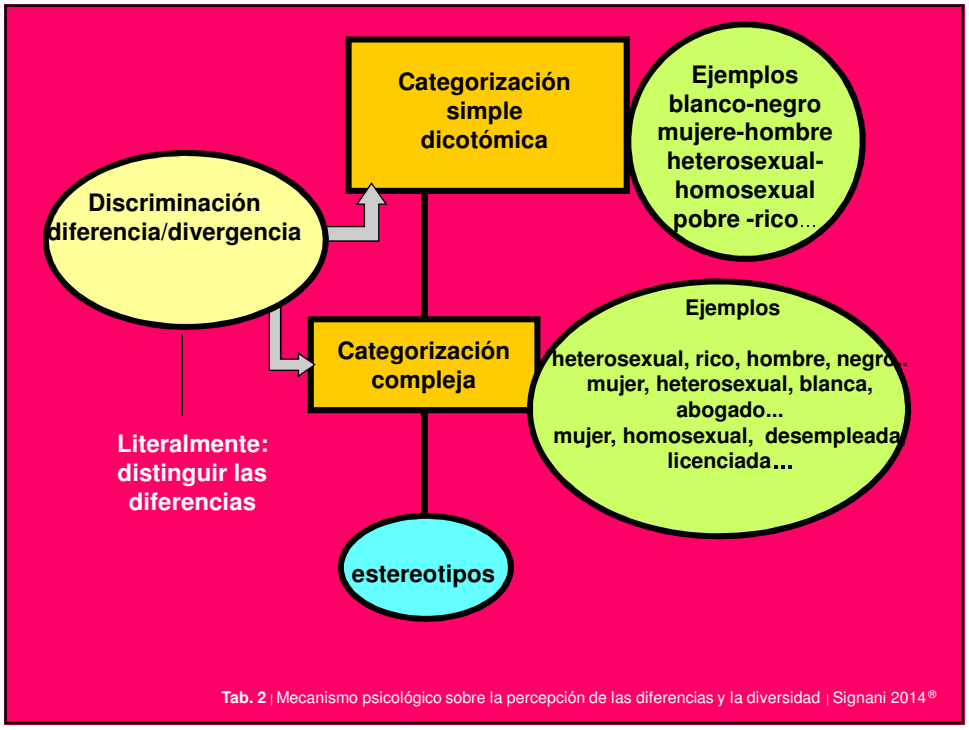
Conferencia de Clausura

28/10/2014

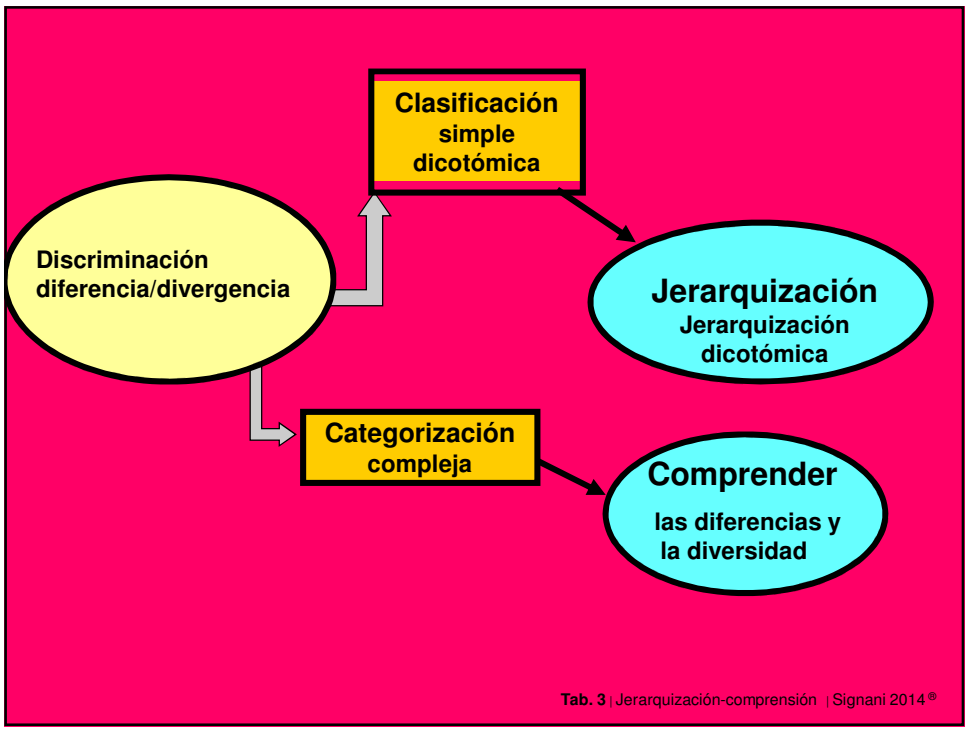
Modelo multinivel para la inclusión del género en la investigación y en la práctica de salud I Signani 2014



Tab. 1 El blanco de las diferencias individuales | Signani 2014®



Tab. 2 | Mecanismo psicológico sobre la percepción de las diferencias y la diversidad | Signani 2014®



Tab. 3 | Jerarquización-comprensión | Signani 2014 ®

Experimentar las diferencias de culturas

" etnocentrismo' '

La incapacidad de experimentar la diferencia cultural

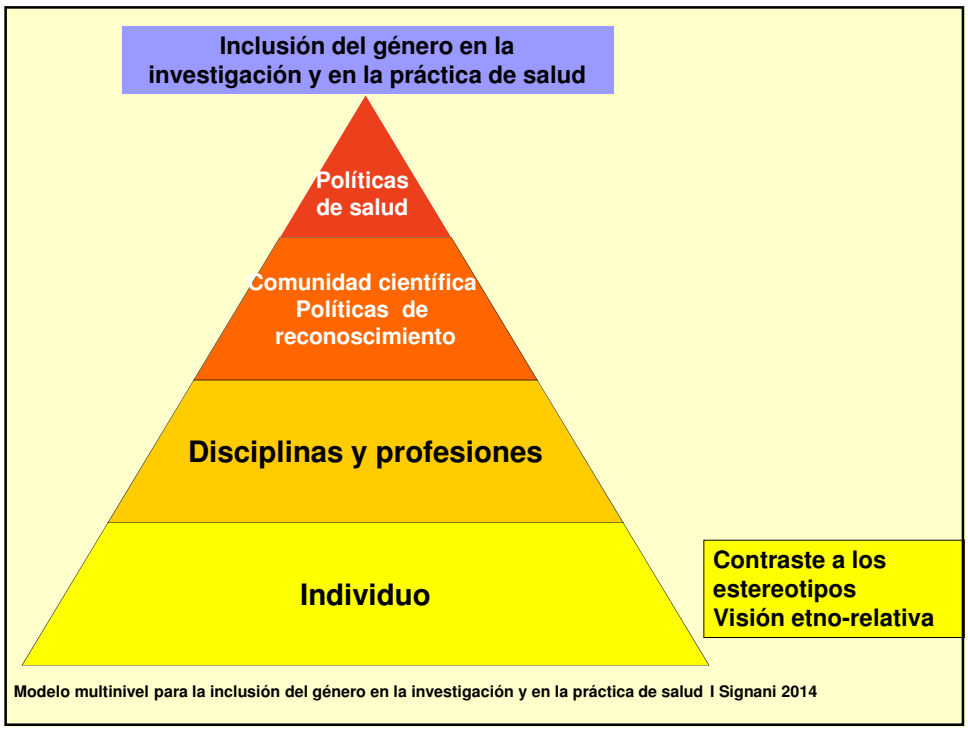
Las otras culturas no existen (negación)
son una amenaza (defensa)
son diferentes superficialmente (minimización)

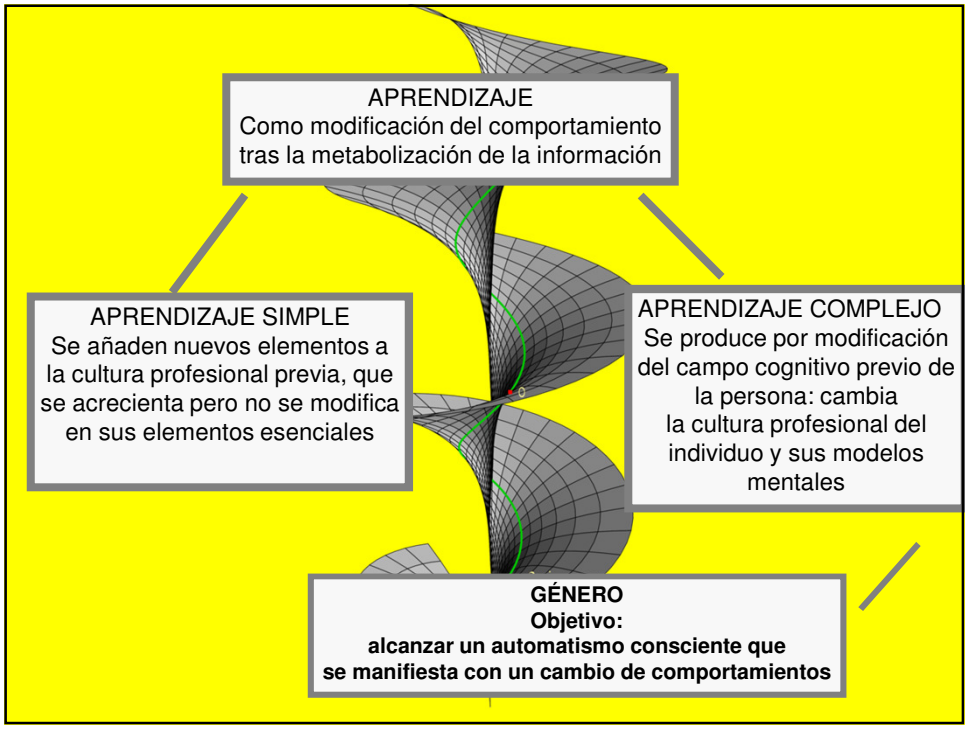
discriminación

"etnorelativismo"

1. **cosmovisión, cambiar la perspectiva**
2. **reconocer el valor de otras culturas (aceptación)**
3. **modificar el comportamiento para tener en cuenta la otra cultura (adaptación)**
4. **incorporar la competencia intercultural en la su propia identidad (integración)**

Tab. 4 | Basada en el modelo dinámico de sensibilidad intercultural (Milton J.Bennet) | Signani 2014 ®


Inclusión del género en la investigación y en la práctica de salud
Políticas de salud
Comunidad científica Políticas de reconoscimiento
Disciplinas y profesiones
Individuo
Contraste a los estereotipos
Visión etno-relativa
Modelo multinivel para la inclusión del género en la investigación y en la práctica de salud I Signani 2014


APRENDIZAJE
Como modificación del comportamiento tras la metabolización de la información
APRENDIZAJE SIMPLE
Se añaden nuevos elementos a la cultura profesional previa, que se acrecienta pero no se modifica en sus elementos esenciales
APRENDIZAJE COMPLEJO
Se produce por modificación del campo cognitivo previo de la persona: cambia la cultura profesional del individuo y sus modelos mentales
GÉNERO
Objetivo:
alcanzar un automatismo consciente que se manifiesta con un cambio de comportamientos

aprendizaje → cambio

- ✓ Preparar la acogida de lo nuevo
- ✓ Promover un aprendizaje
- ✓ Cuidar a lo nuevo

Inclusión del género en la investigación y en la práctica de salud

Un verdadero viaje de descubrimiento no es buscar nuevas tierras, sino mirar con otros ojos
Marcel Proust

No es una nueva disciplina, sino un nuevo enfoque que atraviesa todas las disciplinas médicas

Nadie es maestro de lo nuevo
Proverbio chino

Modelo de conveniencia

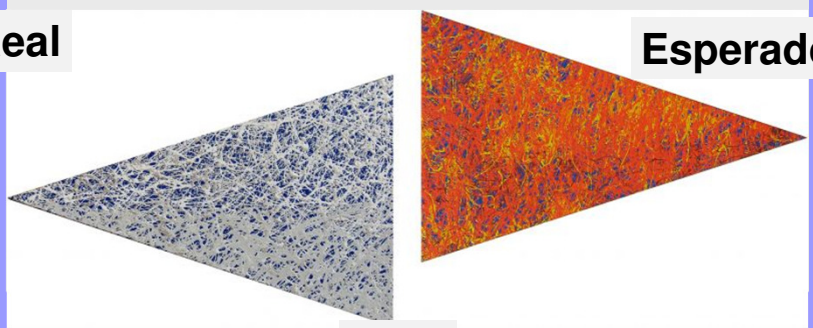
Antiguo comportamiento

Nuevo comportamiento

Beneficios individuales

Profesionalismo

Real



Esperado

Ideal

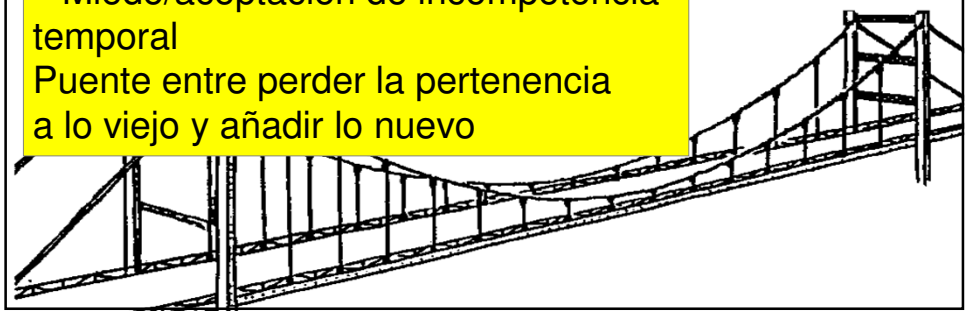
Continuidad de las expectativas
Autoformación
Seguridad psicológica

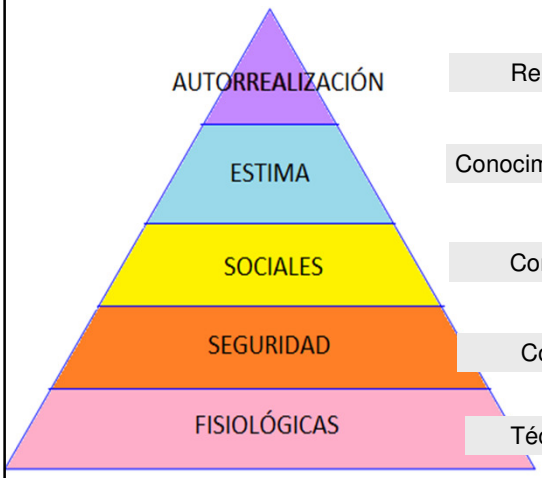
Crear seguridad psicológica

Jerarquía del conocimiento

- ✓ Resistencia al cambio
- ✓Miedo /aceptación de perder la vieja identidad profesional, para construir una nueva identidad profesional
- ✓'Nostalgia por lo viejo'
- ✓Miedo/aceptación de incompetencia temporal

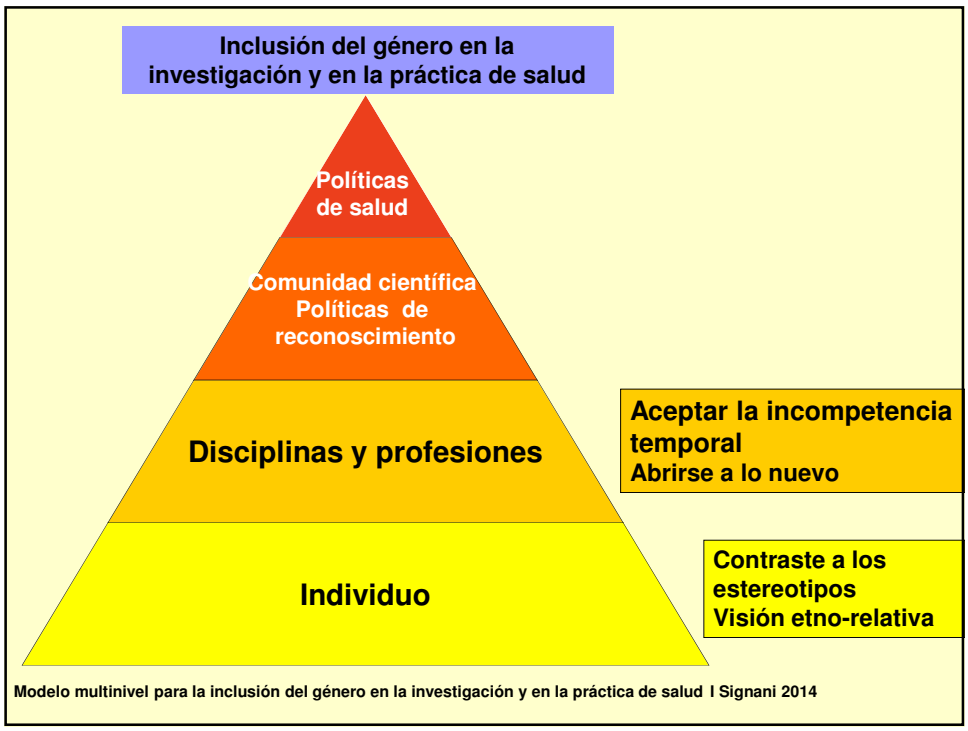
Puente entre perder la pertenencia a lo viejo y añadir lo nuevo





AUTORREALIZACIÓN	Realización, crecimiento y desarrollo
ESTIMA	Conocimientos y ocasiones para distinguirse
SOCIALES	Conocimientos para no ser excluidos
SEGURIDAD	Conocimientos para la vida pacífica
FISIOLÓGICAS	Técnicas de supervivencia profesional

Pirámide de Maslow de necesidades aplicadas a la educación de personas adultas **(Sani, Trombini, 2003)**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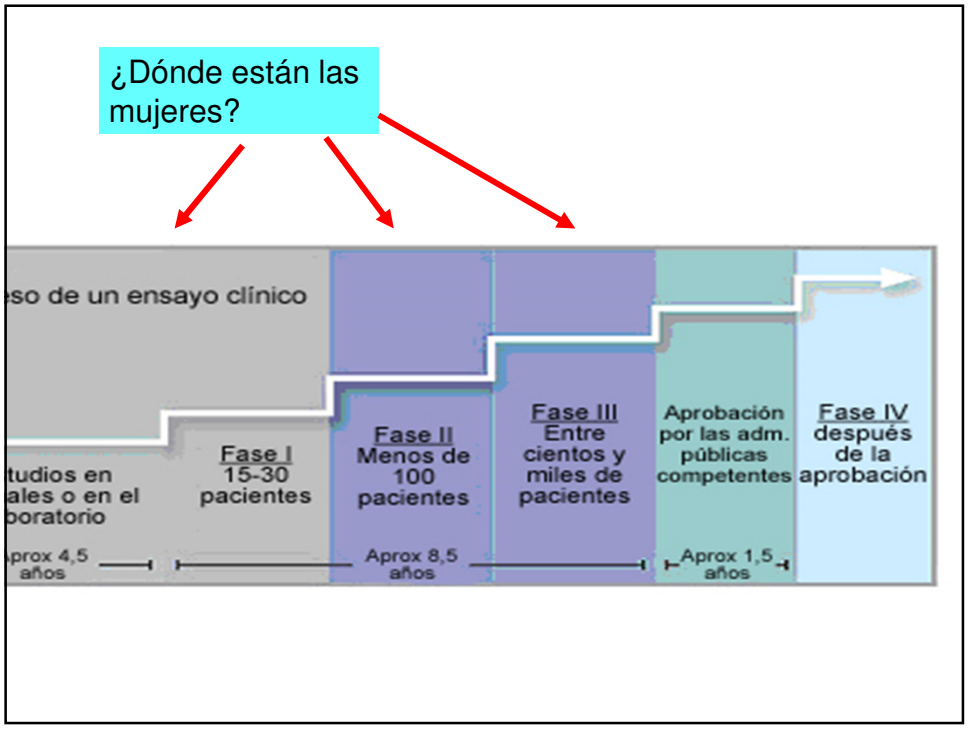
¿Dónde están las mujeres?
so de un ensayo clínico
tudios en ales o en el boratorio
Fase I 15-30 pacientes
Fase II Menos de 100 pacientes
Fase III Entre cientos y miles de pacientes
Aprobación por las adm. públicas competentes
Fase IV después de la aprobación
prox 4,5 años
Aprox 8,5 años
Aprox 1,5 años

Un número creciente de revistas tiene políticas editoriales que requieren informes específicos de sexo o género de la investigación científica y el IOM, el *Istitute of Medicine* americano, ha catalogado una serie de revistas en tal sentido.

IOM (Institute of Medicine), 2012. *Sex-Specific Reporting of Scientific Research: A Workshop Summary*. Washington, D.C. The National Academies Press.

t is Gendered
vations?
GENDER ANALYSIS
nods
ns

Sex and Gender Analysis Policies of Peer-Reviewed Journals

Nature
The Lancet
Journal of the American College of Cardiology- American College of Cardiology (ACC)
American Journal of Physiology (AJP) - Cell Physiology
Endocrinology and Metabolism
Canadian Medical Association
Circulation American Heart Association
Clinical Orhopaedic and related research
Endocrinology
Journal of the International AIDS Society
Journal of the National Cancer Institute
The Journal of Physiology
Plos Biology
Plos Medicine
American Journal of Preventive Medicine
European Journal of Neuroscience

www.nature.com/nature/journal/v465/n7299/pdf/465665a.pdf

nature

www.nature.com/nature

Vol 465 | Issue no. 7299 | 10 June 2010

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.

Differences 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 recognized as a problem.

Admittedly, there can be legitimate reasons to skew the ratios. For instance, researchers may use male models to minimize the variability due to the oestrous cycle, or because males allow them to study the Y chromosome as well as the X. And in studies of conditions such as heart disease, from which female mice are thought to be somewhat protected by their hormones, scientists may choose to concentrate on male mice to maximize the outcome under study.

However justifiable these imbalances may be on a case-by-case 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 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. One possible solution is systematic retrospective data collection from women who have had no choice but to take an unproven drug while they were pregnant.

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

More generally, drug regulators should ensure that physicians and the public alike are aware of sex-based differences in drug reactions and dosages. And medical-school accrediting bodies should impress on their member institutions the importance of training twenty-first-century physicians in how disease symptoms and drug responses can differ by sex. Finally, speeding more women into the senior ranks of

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birth, and children should be involved in the discussions early (as young as 5 years for risks such as smoking).

Yet such advice clearly needs reiteration. For example, a recent analysis of the US National Health and Nutrition Examination Surveys showed that poor diet was rife in the USA. Of 4157 randomly chosen children aged 12–17 years, none was eating a diet classed as ideal in 2003–08 and fewer than 20% met even a less ambitious target. Some of these children will doubtless make up

themselves) should not be discounted in a country with escalating health-care costs (although savings would be made from the US$444 billion per year in associated costs that cardiovascular disease accrues). Nevertheless, the recommendations made by the NHLBI should rightly be promoted to stave off the effects of cardiovascular disease in the expanding ageing population in the USA. ■ *The Lancet*

For the NHLBI report see http://www.nhlbi.nih.gov/guidelines/cvd_ped/

Taking sex into account in medicine

Science Photo Library

Throughout Europe, despite women often forming the majority of students at university, fewer women than men are appointed to high-level jobs in medicine and science. Evidence presented at the first European Gender Summit in Brussels (targets or quotas, it wi reach equality at the and family friendly er allow women to aim high. Moreover, gender-diverse teams have higher team IQs and promote innovation. But the case for equality is not only about who makes it to the top, it is also about medicine itself. What women can do for medicine is one thing; what medicine can do for women is also important.

In medicine too, the common assumption is that men and women experience disease and react to treatment in the same way. Increasingly, though, there is evidence to the contrary. A systematic review published in August online in this journal showed that women who smoke have a higher risk of coronary heart disease than do male smokers. Female smokers also have a higher risk of lung cancer than do male smokers. Overall, in most types of cancer, women have higher 5-year survival than do men. In stroke, atrial fibrillation is one example of a more important risk factor in women than

in some cases the unexpected finding would be if sex had no effect. Body surface area, body mass, and the amount of adipose tissue can all affect response to treatment. Therapeutic drug monitoring is the ideal, but impractical in many settings.

Being male or female might be a more important determinant of health, illness, and response to treatment than is known. To find out, and to aid meta-analysts, *The Lancet* encourages researchers to enrol more women into clinical trials of all phases, and to plan to analyse data by sex, not only when known to be scientifically appropriate, but also as a matter of routine. ■ *The Lancet*

For the European Gender Summit see http://www.gender-summit.eu

For the systematic review on smoking and coronary heart disease see Articles *Lancet* 2011; 378: 1297–305

For more on methods of sex and gender analysis see http://www.genderedinnovations.eu

For more on prescribing see http://www.rpharms.com/blue-pill-pink-pill-does-gender-matter.asp

Tomando en cuenta el sexo en la medicina

The Lancet, 2011

This Week in Medicine

Trial diversity The US Food and Drug Administration (FDA) plans to ensure representation of demographic subgroups (eg, age, ethnic origin, and sex) in clinical trials of drugs and medical products, with an action plan to improve data collection by study funders, identify barriers to subgroup enrolment in trials, and make subgroup data more available.

HIV/AIDs in China Mortality from HIV/AIDS has decreased by 11·3% since 2005 in China as a result of free HIV tests and treatment for poor citizens. However, in 2013, 436 800 people in the country were living with HIV/AIDS and 136 300 had died from the disease. Sex remains the major form of transmission, with 91% of cases resulting from sexual contact.

Health hack A Chinese cyber attack on the US hospital operator Community Health Systems during April to June has compromised patient personal data, including names, dates of birth, addresses, and Social Security numbers. The malware has now been eradicated from the system and

Ensayar la diversidad. El US Food and Drug Administration (FDA) planea garantizar la representación de subgrupos demográficos (por ejemplo, edad, origen étnico y sexo) en los ensayos clínicos de medicamentos y productos médicos, con un plan de acción para mejorar la recopilación de datos por parte de los financiadores de los estudios, para identificar los límites de la incorporación de los subgrupos en los ensayos y para proporcionar más datos inherentes a los subgrupos.

The Lancet Vol.384, No.9945 Aug.30 2014

Inclusión del género en la investigación y en la práctica de salud

Promover investigaciones y publicaciones solo si se ocupan del género

Aceptar la incompetencia temporal
Abrirse a lo nuevo

Contraste a los estereotipos
Visión etno-relativa

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Organismos internacionales se han ocupado hasta ahora del género

- La Organización de las Naciones Unidas (ONU) con la *Convention on the Elimination of All Forms of Discrimination against Women* (*CEDAW*) desde 1981
- La Organización Mundial de la Salud (OMS), con el documento *Health for All in the 21th Century* (1998)
- La Unión Europea

grants.nih.gov/grants/guide/notice-files/NOT-OD-13-092.html

homepage — Unife

Modifications to NIH's Planned and Cumulative Inclusion Enrollmen

Notice Number: NOT-OD-13-092

Update: The following update relating to this announcement has been issued:

- April 30, 2014 - See Notice NOT-OD-14-085 Transition Plans for Reporting Sex/Gender, Race, and Ethnicity Information in Non-Competing NOT-OD-14-086 NIH Launching New System and Procedures for Reporting Sex/Gender, Race, and Ethnicity Information to the NIH.

Key Dates

Release Date: July 26, 2013

Related Announcements
NOT-OD-15-005
NOT-OD-13-091

http://grants.nih.gov/grants/funding/women_min/women_min.htm.#st
qvX.dpuf

Issued by

National Institutes of Health (NIH)

Purpose

The purpose of this Guide Notice is to announce that NIH has modified the forms used to provide information regarding planned enrollment and a individuals involved in clinical research studies on the basis of sex/gender, race, and ethnicity. Using a simplified layout, the modified forms will a a structured format for competing and, eventually, non-competing applications.

The policies for the inclusion of women and minorities in clinical research and the required collection of participants' sex/gender, race, and ethnic

Key changes:

nih.gov/grants/funding/women_min/women_min.htm

U.S. Department of Health & Human Services

NIH National Institutes of Health
Office of Extramural Research

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Glossary & Acronyms

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Grants & Funding

Grants Policy
- Policy & Guidance
- Compliance & Oversight
- Research Involving Human Subjects
- Office of Laboratory Animal Welfare (OLAW)
- Animals in Research
- Peer Review Policies & Practices
- Intellectual Property Policy
- Acknowledging NIH Funding
- Invention Reporting (iEdison)
- NIH Public Access
- Research Integrity

Inclusion of Women and Minorities as Participants in Research Involving Human Subjects - Policy Implementation Page

The NIH is mandated by law (Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2) to ensure the inclusion of women and minority groups in clinical research. The goal is to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study.

News Flash

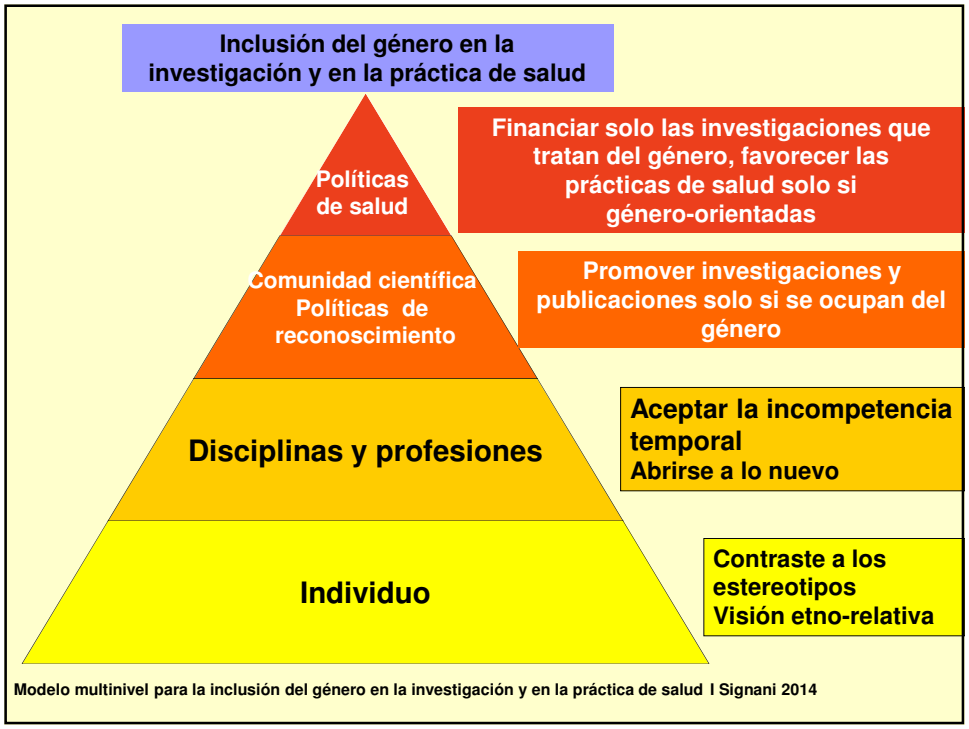
NEW **New System and Procedures for Reporting Sex/Gender, Race, and Ethnicity:** Please see the following NIH Guide Notice for information on this topic: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-086.html

Use of New Inclusion Management System Required as of October 17, 2014: Please see the following NIH Guide Notice for information on this topic: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-005.html

Transition Plans for Reporting Sex/Gender, Race, and Ethnicity

Related Resources
- Inclusion of Women and Minorities (NIH Staff Only)
- Related Archives

El NIH es obligatoria por ley
(ley del servicio sanitario público sec. 492B, 42 U.S.C. sec.289a-2)
para asegurar la inclusión de mujeres y grup os minoritarios en la investigación clínica. El objetivo es asegurar que las personas están incluidas en la investigación clínica de una manera que sea apropiada a la pregunta científica bajo estudio.
Uso de nueva inclusión gestión sistema oblig atoria a partir del 17 de octubre de 2014.
por información sobre este tema:
http://Grants.nih.gov/Grants/Guide/Notice-files/not-OD-15-005.html



Muchas gracias por la atención

sgnflv@unife.it