European roadmap for implementation of sex and gender in biomedicine and health research

FP 7 602050

1.10.2013- 30.9.2015

This project the European Gender Medicine Network (EUGenMed) has received funding from the European Union’s Seventh Framework Programme for research, technological development and demonstration under grant agreement No 602050.
The EUGenMed Project

- ... aims at the introduction of sex and gender aspects into biomedicine and health research
- This approach, focusing on women and men equally will lead to a more efficient use of resources and improve the health of European citizens.
- It will build on existing activities and develop an interdisciplinary, open, inclusive and transparent European Gender Health Network including all stakeholders.
Why do we need gender in biomedical and health care research?

- Women and men have different manifestations of diseases, pathophysiology, response to therapy, response to interventions and drugs, awareness of risk, environmental exposition, expectations, attitudes towards management, communication styles as patients and doctors.

- Gender is an important quality issue in medicine.
- We have to consider these differences to treat women and men in optimal manner.
- Biomedical research must provide optimal treatment tools for both genders.
Sex and Gender Differences

Sex – biological facts,
Genes and Hormones

- X: ca 1500 Genes
- Heart-, Brain-, Immune function

Y: 78 Genes
- Sexual function

Gender –
Socio-cultural facts

- Biological sex affects behaviour

- Environment leads to epigenetic chromatin modifications
France: Myocardial infarction in women: younger, higher mortality than in men

- Data from 4 country-wide registries, in 5 year intervals, 60-80 % of CCU
- 6707 Pat

Percentage of patients < 60 years increases steeper in women

30 Day mortality is higher and decreased less in women than in men

IAMA. 2012;308(10):998-1006
Autoimmune diseases in women and men

Autoimmune diseases have a higher prevalence in women than in men. Research frequently neglects the S&G differences.

<table>
<thead>
<tr>
<th>Disease</th>
<th>Women Ratio</th>
<th>Men Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>RA</td>
<td>10.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Sjögren</td>
<td>9.0</td>
<td>0.5</td>
</tr>
<tr>
<td>SLE</td>
<td>5.0</td>
<td>0.0</td>
</tr>
<tr>
<td>SSc</td>
<td>7.5</td>
<td>0.0</td>
</tr>
<tr>
<td>MS</td>
<td>2.5</td>
<td>0.0</td>
</tr>
<tr>
<td>AS</td>
<td>1.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

RA: rheumatoid arthritis, SLE: lupus erythematoses, SSc: Scleroderma; MS: multiple Sclerosis, AS: Spondylitis ankylosans
Gender differences in psychiatric diseases

Men:
- Antisocial Personality
- Substance abuse
- Completed suicide

Women:
- Anxiety disorders
- Depression
- Attempted Suicide
- Eating disorders
- Posttraumatic syndrome
Sex and Gender differences are common in human diseases

<table>
<thead>
<tr>
<th>Cardiology</th>
<th>Rheumatology/Immunology</th>
<th>Pneumology</th>
<th>Nephrology</th>
<th>Gastro-enterology/Hepatology</th>
<th>Neurology</th>
<th>Endocrinology</th>
<th>Oncology</th>
<th>Haematology</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension (414)</td>
<td>Lupus erythematosus (68)</td>
<td>Asthma (116)</td>
<td>Renal failure (27)</td>
<td>Hepatitis B (22)</td>
<td>Multiple sclerosis (65)</td>
<td>Diabetes mellitus (447)</td>
<td>Skin carcinoma (45)</td>
<td>Anaemia (44)</td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction (275)</td>
<td>Rheumatoid arthritis (41)</td>
<td>Lung cancer (116)</td>
<td>Diabetic nephropathy (11)</td>
<td>Hepatitis C (26)</td>
<td>Stroke (129)</td>
<td>Obesity (349)</td>
<td>Gastric cancer (25)</td>
<td>Leukaemia (49)</td>
<td></td>
</tr>
<tr>
<td>Atrial fibrillation (38)</td>
<td>Fibromyalgia (15)</td>
<td>Pulmonary hypertension (12)</td>
<td>Polycystic kidney disease (12)</td>
<td>Inflammatory bowel disease (13)</td>
<td>Epilepsy (56)</td>
<td>Hypothyroidism (33)</td>
<td>Bladder cancer (22)</td>
<td>Thrombocytopenia (6)</td>
<td></td>
</tr>
<tr>
<td>Coronary heart disease (207)</td>
<td>Sjögren's syndrome</td>
<td>Pulmonary embolism (110)</td>
<td>Renal artery stenosis (0)</td>
<td>Colorectal cancer (24)</td>
<td>Parkinson's disease (69)</td>
<td>Hyperthyroidism (16)</td>
<td>Thyroid carcinoma (16)</td>
<td>Purpura (2)</td>
<td></td>
</tr>
<tr>
<td>Cardiomyopathy (41)</td>
<td>Ankylosing spondylitis (11)</td>
<td>Sarcoidosis (6)</td>
<td>IgA Nephropathy (2)</td>
<td>Autoimmune Hepatitis (2)</td>
<td>Muscular dystrophy (11)</td>
<td>Morbus Addison/Cushing disease (5)</td>
<td>Pancreatic carcinoma (10)</td>
<td>Agranulocytosis (0)</td>
<td></td>
</tr>
</tbody>
</table>

EMBO reports advance online publication XX Month
2012; doi:10.1038/embor.2012.87
Inappropriate medication in the elderly – more frequent in women

Percentage of PRISCUS-patients in % with at least one PRISCUS-prescription

Hofer-Dueckelmann 2012
More and more, scientists are realizing that the differences between the sexes are dangerously understudied.

Earlier this year, the Food and Drug Administration made an unusual and surprising announcement. It cut the recommended dose of the most popular sleep drug in the country, Ambien, in half for women. It turns out men and women metabolize Ambien, known generically as Zolpidem, very differently, leaving women with more of the drug in their bodies the next morning, and therefore at a greater risk of impaired driving.

Basically known since 1992 – Data sheet at FDA describes 40% difference in blood levels

Gender medicine goes beyond personalized medicine

Gender medicine: includes life style, sociocultural and environmental factors

Personalized medicine: based on individualized biological facts, frequently genomic

S&G in adults, women or men
Goals of EUGenMed

- Implementation of S&G in European biomedicine and health care research
- Assembly of all relevant stakeholders
- Inclusion of all biomedical and health care areas where S&G are relevant - to speak with a single voice
- Elaborating a common vision of gender medicine including general hypotheses, research areas, medical applications, teaching, communication and dissemination strategies
Specific aims

1. identify the most relevant S&G topics in different biomedical fields
   - Clinical medicine and pharmacology
   - Public health and prevention
   - Basic research and drug development
   - Medicines regulation and medical education

and bring the stakeholders together!

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II identify target audiences
   Academia
   industry
   Medical societies, NGO‘s, patient organizations
   Regulating bodies
   practioneers, students, lays

III generate strategies for communication and dissemination
   conferences
   journal articles,
   teaching books
   recommendations and guidelines
   Electronic and social media
Structure and Timelines of EUGenMed

Assembly of stakeholders

Kick-off conference

Preparation

WS 1
WS 2
WS 3
WS 4

Generation of materials
Communication with target audiences

Dissemination of results

Planning

1.10.13
7.4.14
Nov 2014 -March 2015
July 15

Nov 2014 -March 2015
Kick-off conference: 6 sessions to prepare 4 workshops in an interdisciplinary approach

- Medicine and pharmacology
- Public health and prevention
- Basic research and drug development
- Medicines regulation and education

- Discuss target audiences
- Discuss communication strategies

- ...we do not intend to answer the suggested questions at the kick-off conference but that we are planning workshops (WS) to answer these questions!