EUGenMed

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

FP 7 602050

1.10.2013- 30.9.2015

Charité – Vera Regitz-Zagrosek,
Maastricht/Charité - Ineke Klinge,
EIWH - Hildrun Sundseth, Peggy Maguire

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.
Sex and Gender are important in medicine

Gender: includes life style, sociocultural and environmental factors

Personalized medicine: based on individualized biological facts, frequently genomic

XX, XY

S&G in adults, women or men

VRZ, EMBO J, 2012
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 a sustainable European Gender Health Network after the end of funding, open to all stakeholders.
NIH statement regarding inclusion of sex in biomedical research  – June 9th, 2015

- Consideration of Sex as a Biological Variable in NIH-funded Research
- Notice Number: NOT-OD-15-102
- Key Dates
  Release Date: June 9, 2015

Accounting for sex as a biological variable begins with the development of research questions and study design. It also includes data collection and analysis of results, as well as reporting of findings. NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex......
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

30 Day mortality is higher and decreased less in women than in men.
Inappropriate medication in the elderly – more frequent in women

Hofer-Dueckelmann 2012
**Sex and Gender differences are common in most human diseases**

<table>
<thead>
<tr>
<th>Cardiology</th>
<th>Rheumatology/Immunology</th>
<th>Pneumology</th>
<th>Nephrology</th>
<th>Gastro-enterology/Hepatopathy</th>
<th>Neurology</th>
<th>Endocrinology</th>
<th>Oncology</th>
<th>Haematology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension (414)</td>
<td>Lupus erythematous (68)</td>
<td>Asthma (140)</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>
</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>
</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>
</tr>
<tr>
<td>Coronary heart disease (207)</td>
<td>Sjögrens 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>
</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>
</tr>
</tbody>
</table>

EMBO reports advance online publication XX Month 2012; doi:10.1038/embor.2012.87
The EUGenMed project

Specific aims

- 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
- Identify potential stakeholders and target audiences: Academia, industry, Medical societies, NGO’s, patient organizations, Regulating bodies, practioneers, students, lays
- Generate strategies for communication and dissemination and implementation of S&G aspects
- Assure sustainability

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.
Structure and Timelines of EUGenMed

- Kick-off conference: 1.10.13
- Preparation: 7.4.14
- Communication with target audiences: June 30
- Network building: Sept 30
- WS 1, WS 2, WS 3, WS 4
- Final conference: End of project
- External conferences, WS
- End of project: Sept 30
Workshop 1 outcomes and further steps towards implementation

Outcomes: (Angela Maas and Karin Schenck-Gustafsson will present)

- Publication: Gender in CVD, V. Regitz-Zagrosek et al, submitted
- Publication: Transdisciplinary criteria for the inclusion of sex and gender into diagnostic algorithms, Oertelt Prigione et al, in prep.
- Contributions to 5 policy briefs on CVD, Stroke, Diabetes, Asthma and Lung Cancer
- Teaching materials, Slide set at EUGenMed homepage

Steps towards implementation

- Contributions to ESC meeting 2015 London; 3 sessions
- Planning sessions at congress of the International Society for Gender Medicine in Berlin, Sept 2015 (www.igmcongress.com/)
- Submitting sessions with cardiovascular gender topics for OSSD 2016, DGK 2016, ESC 2016
- Discussion with guideline committees
- Discussion with pharmaceutical industry
- Discussion with faculties and lays
WS 2 outcomes: Sex and gender in public health and prevention

- Publication: Sex and gender aspects of risk factors for non-communicable diseases across Europe, V. Elisabeth Zemp-Stutz, Ineke Klinge et al, in preparation
- Publication: Doing gender medicine: Reflections on sex and gender in medicine and public health, Lucie Dalibert, in preparation
- Publication: Implementation steps towards gender-sensitive policy and practice, Sabine Oertelt-Prigione, in preparation
- Planning sessions at congress of the International Society for Gender Medicine in Berlin, Sept 2015 (www.igmcongress.com/)
- Submitting abstracts to Gender Summit 2015, EUPHA 2016 and EASST 2016.
WS 2 outcomes: Sex and gender in public health and prevention

- Publication: Sex and gender aspects of risk factors for non-communicable diseases across Europe, V. Elisabeth Zemp-Stutz, Ineke Klinge et al, in preparation
- Publication: Doing gender medicine: Reflections on sex and gender in medicine and public health, Lucie Dalibert, in preparation
- Publication: Implementation steps towards gender-sensitive policy and practice, Sabine Oertelt-Prigione, in preparation
- Submitting abstracts to Gender Summit 2015, EUPHA 2016 and EASST 2016.
WS 3 outcomes and further steps towards implementation - Sex differences in basic research

Outcomes
- Publication: Gender in Basic research, V Regitz-Zagrosek et al, in preparation
- Contributions to policy briefs on CVD, Stroke, Diabetes, Asthma and lung cancer
- Slide set at EUGenMed homepage

Steps towards implementation
- Contributions to ESC meeting 2015 London; a sessions with basic research gender topics
- Planning sessions at congress of the International Society for Gender Medicine in Berlin, Sept 2015 (www.igmcongress.com/): epigenetic mechanisms in sex differences, sex differences in cells,
- Submitting sessions with basic research topics for OSSD 2016, IGM 2017
- Convincing research funders – see NIH
WS 4 : Medical Education and Medicines Regulation

- Details in workshop sessions

- Hold a symposium on sex and gender in medical education (see IGM and gender congress, Sept 2015, Berlin)

- Concept for S&G teaching and training will be presented by U. Seeland
Sustainability - What does it mean?

- Maintaining networks of experts and exchange
- Updating and generating position papers, policy briefs and/or factsheets
- Develop training and teaching books:
  - Participation of all stakeholders
  - Contribution to discussions
EUGenMed Roadmap

**Working phase**
- Assembly of stakeholders:
  - Academic researchers,
  - Industry
  - Medical practitioners
  - Medical societies
  - Teachers & students
  - Regulatory bodies
  - Patients, lays
- Workshops:
  - Clinical Medicine & Pharmacology
  - Public health & Prevention
  - Basic biomedical research
  - Medicines Regulations & Guidelines
  - Medical Education
  - Medicla Edcation
- Generation of materials
  - Reviews
  - Policy briefs
  - Slide sets
  - Reports

**Final conference**
- Presentation of materials,
- Best practice examples
- Strategies for implementation
- Engagement of stakeholders
- Structures for sustainability

**July-Sept 2015**
- Dissemination of results
  - Working structures, networks
- IGM conference, Berlin, Sept 2015

**2016 - 2020**
- Implementation:
  - S&G sensitive clinical studies
  - S&G sensitive public health policies
  - Funding of basic research for sex differences
- Introducing S&G in medical education, medicines regulations

**Consortium & experts and stakeholders Implementation phase**

EUGenMed: project lifetime
Example for implementation

7th Congress of the International Society for Gender Medicine and International Congress Gender Medicine – research excellence

Sessions and workshops on drugs, teaching, gender mainstreaming and gender research in all areas – Junior meets Senior – Networking - Sept 20-23, Berlin,