

European Gender Medicine Network

Charité - Universitätsmedizin Berlin, Germany (Coordinator)

Maastricht University, Maastricht, the Netherlands

European Institute of Women's Health, Dublin, Ireland

Report from WS 1.1

"Sex and Gender Differences in Clinical Medicine and Clinical Pharmacology"

Berlin, December 1st and 2nd, 2014







Sex and Gender Differences in Clinical Medicine and Clinical Pharmacology

On December 1st and 2nd the first EUGenMed workshop took place in Berlin. 28 experts and stakeholders convened to discuss four major topics:

- a) assemble knowledge about sex and gender differences in cardiology that should be considered for future guideline development to compile a white paper
- b) evaluate the levels of evidence on sex and gender specific practice recommendations in a number of co-morbidities
- c) discuss policy briefs for lay persons about sex and gender differences in highly prevalent conditions
- d) design a set of slides for EU policymakers and officials that illustrates the relevance of sex and gender in biomedical research and clinical practice

Day 1 – December 1st

Vera Regitz-Zagrosek, coordinator of the EUGenMed project, opened the workshop and welcomed all participants to an intense one-and-a-half day meeting. The EUGenMed project was briefly introduced in its overall structure and the workshop series explained. The current workshop on "clinical medicine and clinical pharmacology" is to be followed by the following other workshops:

- WS 2 "Sex and Gender in Public Health and Prevention" on Feb. 2-3, 2015 in Maastricht
- WS 3 "Sex and Gender in Basic Biomedical Research and Drug Development" on Feb. 16-17, 2015 in Berlin
- WS 4 "Sex and Gender in Medicines Regulation and Medical Educationn" on March 4th, 2015 in Brussels

The project will culminate in a final conference in early July 2015. The consortium partners then briefly introduced themselves and their institutions: Ineke Klinge and Lucie Dalibert from Maastricht University and Maeve Cusack from the European Insitute of Women's Health (EIWH).

Concept for a white paper

The concept of the white paper and participants' inputs were briefly discussed. The objective of the paper is the assembly of guideline-relevant knowledge to be incorporated in future guideline development processes. The experts briefly debated whether the generation of gender-sensible guidelines, potentially women-specific ones, is preferable to incorporation of information about both sexes in all guidelines. They convene that a – possibly systematic – inclusion of information about sex and gender specificity be included in all guidelines, besides information about pregnancy, which is the current practice. The need for a stronger political mandate from the EU to achieve policy change is also discussed. Although, more challenging to achieve, in the current landscape it appears as a necessary step.

Clinical Cardiology and Comorbidities

Eva Gerdts introduced sex and gender differences in mitral valve disease and aortic stenosis. Angela Maas and Eva Bossano-Prescott described relevant aspects in coronary artery disease and Vera Regitz-Zagrosek illustrated differences in heart failure. After a brief recess, co-morbidities were discussed. The following conditions were introduced and discussed in the group: stroke (Mia van Euler and Christian Nolte), diabetes mellitus (Alexandra Kautzky-Willer), autoimmune diseases (Elena Bartoloni Bocci), chronic

kidney disease (Francesca Colombo) and depression (Karl-Heinz Ladwig). The group convened that besides diabetes and depression, where much evidence-based sex and gender specific knowledge exists, the other specialties are not offering a strong enough evidence base for inclusion into guidelines yet. It was thus decided to generate a review identifying common underlying mechanisms of sex and gender differences in these areas to identify novel research avenues.

Policy Briefs

Next, the policy briefs were discussed. These are brief informative instruments designed for politicians and policymakers. Policy briefs were drafted by the EIWH and presented by Maeve Cusack. Overall, the briefs obtained much positive feedback by the experts. A general discussion on whether the briefs should focus on women's health or gender medicine was conducted. Given the goals of the project, the second option was unanimously accepted. All briefs will include a section on "why gender matters" and address male specificity, whenever distinctly needed. Wording of the policy briefs will be finalized before the next workshop, however, specific recommendations for practice will be formulated in each of the workshops. The policy briefs will, thus, be finalized after the last workshop at the beginning of March.

The editorial perspective

As conclusion of day 1, Ulf Landmesser, one of the editors of the European Heart Journal, gave some input on how a white paper should be structured and which audiences it should address. Overall, it was advised to strengthen the clinical perspective and clearly and transparently define the criteria for inclusion of recommendations.



Figure 1. Discussion round during workshop 1.1

Day 2 – December 2nd

Therapeutic options in cardiology

The next day interventional therapy and pharmacological therapy were discussed. Sex and gender differences in complications and outcomes of transcatheter aortic valve implantation, TAVI (Verena Stangl) and ventricular assist devices were discussed. Also, potential differences in heart transplantation (Vera Regitz-Zagrosek) were introduced. The field of pharmacotherapy offers many examples of sex and gender differences, especially in the area of cardiology. One best practice example to guide physicians in their therapeutic choices is the Janus database (www.janusinfo/genus) a nationally funded Swedish database that analyses all relevant literature on the 250 most prescribed drugs in Sweden to identify relevant sex differences for prescription practice (Karin Schenck-Gustafsson and Mia van Euler).

A slide set for EU policymakers and officials

The slides for EU commissioners were discussed next. The slides are intended as briefing instruments for future EU policy development. Specifically, starting in January 2015 the concept and priorities for the Horizon 2020 phase 2 -2016-17- will be defined and the slides might be used to encourage officials to consider gender as a relevant aspect in grant making and goal setting. The slides will run under the title "Gender Dimensions in the research context"

The perspective of the media

Finally, Elisa Manacorda, an Italian scientific journalist, gave some input on communication strategies. She recommended adequate target group tailoring of all materials. She made the point that "all policymakers are readers and that all readers are (or will be) patients". Hence, the power of lay media and distribution channels beyond specialist knowledge should be taken into account. The cultural context of each EU country might have to be considered in order to optimize uptake and reception. She also advocated for country-based media strategies, since not only the general public but also the medical field might display structural differences which need to be taken into account when developing a communication strategy.

Conclusion and outlook

After this final input, tasks and work assignments were distributed among the participants and a timeline established.

Input into white paper: coordinated by Charité in January, first draft February

Input into policy briefs: from experts Grohé, van Euler, Nolte, Kautzky-Willer, Gerdts, Regitz-Zagrosek until 23.1.2015.

Input into slide set: by all, until end of January

Vera Regitz-Zagrosek and Sabine Oertelt-Prigione thanked all participants for their relevant and insightful comments, which have made this short and intense workshop a great success with relevant outputs to be expected within the next months that will significantly contribute to the roadmap for the implementation of sex and gender in biomedical research and practice.



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