Invitation to contribute:
Evaluation of chronic pain and adherence to treatment among the European population with haemophilia

Herewith we would like to announce a *Europe-wide study* to investigate **chronic pain and adherence to prophylactic treatment in haemophilia patients** and *invite your NMO to participate*.

The objective of this study is to explore potential factors that influence adherence to prophylactic treatment among the European Haemophilia patient population using a self-report questionnaire. The identification of motivators and barriers of treatment adherence would allow to specifically address these issues in patient communication and initiate tailored interventions to support adherence.

**Background:**
Adherence to treatment is essential in haemophilia due to the necessity of lifelong replacement therapy of clotting factor concentrates, especially in case of prophylaxis. As most patients with haemophilia are introduced to self-treatment at home, patients have to accept need for therapy and hold on recommended substitution schedules. Adherence is increasingly recognized as an important factor for health-related quality of life and psychosocial lifestyle. It has been demonstrated that the clinical outcome improves if patients are adherent to treatment\(^1\). On the other hand, reduced adherence can worsen haemophilic arthropathy and chronic pain.

800-1000 patients from all age groups with moderate or severe haemophilia from different European countries should be asked to fulfill the questionnaire anonymously.

To evaluate the adherence to treatment the questionnaire VERITAS Pro (Validated Haemophilia Regimen Treatment adherence Scale for Prophylaxis) has been developed and validated by Duncan et al. from the Indiana Hemophilia and Thrombosis Center (2010)\(^2\). It consists of six sub-scales that examine whether or not the patient infused at the recommended time, used the recommended dose, planned ahead to have adequate factor and supplies on hand, remembered to infuse, skipped infusions and communicated with the haemophilia center. Each item is quantified on a five-point scale ranging from "Always" to "Never." Potential scores range from 24 to 120 with a lower score indicating increased adherence. For studying the chronic pain levels we integrated the revised Faces Pain Scale (FPS-R)\(^3\) in the questionnaire. The FPS-R is a visual scale composed of six faces describing pain intensity. To identify potential impact factors additional data should be captured as sociodemographic data, severity of hemophilia, treatment characteristics (including history of switching or use of longer-acting factor concentrates), clinical variables, kind of medical care and health outcomes. For analysis the VERITAS-Pro total scores, subscale scores and health outcomes will be compared between the different age and population groups, pain levels and the demographics.

In our recently published German survey\(^4\) (see EHC-Newsletter December 2015) we already analyzed answers of nearly 400 Haemophilia patients with regular prophylaxis according to four age groups: 0-14, 15-19, 20-59 and ≥ 60 years of age. The mean total VERITAS-Pro score for the whole sample was 37.3±11.7 (range 24 to 94), well below the defined 57-point-cut-off for non-adherence. Adherence was highest in the youngest patient group < 14 years; one hundred percent of patients up to 19 years were adherent, possibly attributed to a parenteral control of substitution schedules. We could find
several age-specific impact factors influencing adherence to treatment. Patients with severe haemophilia were more adherent than patients with moderate haemophilia in all age groups except for the adolescents (15-19 years). Care in a haemophilia centre significantly improved adherence at least in the middle-aged patients. Limited group sizes did not allow significant observations for the other age groups. Future studies with higher patient numbers have to be conducted to confirm the influence of further age-specific parameters on adherence to prophylactic treatment.

This international study is supported by a HERO research grant from NovoNordisk. It is the first attempt to assess adherence to treatment among paediatric and adult patients in Europe. Considering the rarity of the disease and the small patient population, the collaboration of several patients’ organizations is of great importance and highly appreciated.

Wolfgang Miesbach and Werner Kalnins

Dr. Wolfgang Miesbach is a professor of Internal Medicine/Haemostaseology and director of the Haemophilia Centre at Goethe University Hospital in Frankfurt/Main. Werner Kalnins was the President of the Deutsche Hämostaseologie-Gesellschaft (DHG), the German National Member Organization, from 2004-2016. They recently published an article about adherence to prophylactic treatment in haemophilia patients in Germany. Here they announce the subsequent Europe-wide survey.

If your NMO is interested to participate, please contact Werner Kalnins (werner.kalnins@web.de) or Dr. Miesbach (Tel.: +49/69/63015051, e-Mail: wolfgang.miesbach@kgu.de).

Authorship for publication will be guaranteed. In case your NMO needs financial assistance for conducting the survey, a reimbursement of max. 10€/participant is possible.

References:

4Miesbach W, Kalnins W. Adherence to prophylactic treatment in patients with haemophilia in Germany. Haemophilia 2016, in press.