HAEMOPHILIA EXPERIENCES, RESULTS AND OPPORTUNITIES (HERO)
GUIDELINES FOR THE USE OF QUESTIONNAIRES

BACKGROUND

The HERO questionnaires were first used in the HERO quantitative study conducted in 10 countries during 2011 and 2012. The study methodology and demographic data are published by Forsyth A et al, Haemophilia 2014¹.

ACKNOWLEDGEMENTS

The HERO questionnaires were developed by a subgroup of the HERO International Advisory Board (HERO IAB) and modified with input from the full HERO IAB. Members of the subgroup were:

- Frederica Cassis, psychologist (Brazil), Haemophilia Center, University of São Paulo Faculty of Medicine Clinics Hospital and a member of WFH Psychosocial Committee
- Matt Gregory (UK), Trustee of the UK Haemophilia Society
- Alfonso Iorio, MD, PhD (Canada), Associate Professor of Clinical Epidemiology and Medicine, Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario

The questionnaires were further shared with/reviewed by select members of the World Federation of Haemophilia (WFH) Psychosocial Committee, national patient organizations participating in the recruitment of patients to the study and individual experts in the field acting as external reviewers.

INTRODUCTION

You have chosen to use the materials provided on www.herostudy.org. Whether you decide to use one or both questionnaires, these guidelines provide information designed to ensure you get the best results possible from your research study.

MATERIALS

Two questionnaires are available and intended for self-completion (either pen and paper, or online using fillable PDF):

- Questionnaire for Adult People with Haemophilia (PWH)
- Questionnaire for Parents of a Child below 18 years old with Haemophilia

Please ensure you are using the correct version of the questionnaire for the intended target audience for your research.

Both questionnaires have been uploaded for use with relevant checks to ensure all instructions are easily understood. However, please bear in mind that respondents will be filling in the questionnaires independently; therefore there may be errors in how they complete the document, resulting in potential errors in the data. We advise you recruit about 5% more sample than needed to allow for this.

METHODOLOGY

The questionnaires are designed for self-completion (either pen and paper, or online using fillable PDF). Meaning, respondents will be sent unique files that, once complete will need to be sent to a central point (either team or individual by post and / or email).

It is advised that if conducting pen and paper only, you consider providing a pre-paid addressed return envelope in order to support response rate.

If using a fillable PDF format you will be able to use, for example, Adobe Acrobat Pro to program the information captured either through an on- or off-line method. We advise you consult with an expert on this, or source information through the internet.

Should you wish to use another methodology – such as telephone or Computer Aided Web Interviews (CAWI), it is advised you approach an experienced research agency as routing and file design will require alteration.

COPYRIGHT ON PROPRIETARY INTELLECTUAL PROPERTY

Certain sections of the questionnaires are proprietary intellectual property (IP) and utilise tools that require a valid licence or specific permissions to be obtained prior to commencing your research project:

- Questions E2-E7 in the Questionnaire for Adult People with Haemophilia use EQ-5D. For further information on this, and how to obtain permission to use click: http://www.euroqol.org/eq-5d-products/how-to-obtain-eq-5d.html
- Questions X1-X7 in the Questionnaire for Adult People with Haemophilia use MSHQ. For further information on this, and how to obtain permission to use click: http://www.proqolid.org/instruments/male_sexual_health_questionnaire_mshq?fromSearch=yes&text=yes

The questionnaires available on www.herostudy.org do include the proprietary questions mentioned above for the purpose of providing you with the full questionnaire. It is important that permissions be obtained for each research study and it is advised that materials are submitted for legal approval relative to your company / society / country prior to any research activity.

LEGAL AND ETHICAL CONSIDERATIONS

We are making the questionnaires available for organisations that are interested in conducting research with people living with haemophilia. These organisations could, for example, be patient organisations. Potential users might consider using experienced market research agencies to conduct the study on their behalf. Any use of these
questionnaires to gather information must be done in accordance with all and any relevant codes of conduct pertaining to your organisation.

- We advise you be in contact with the local / national research association, such as MRS, ASOCS, BHBIA, EphMRA, ISPOR, etc. to ensure the process is within protocol and the right guidelines are in place
- Data Protection Legislation MUST be followed at all times
- We advise you be in touch with local DPA (Data Protection Agency), such as ICO, BDSGm CNIL, HIPAA, HITECH, etc. to ensure respondents’ data and personal information are protected, processed, informed and stored according to data protection legislation. Approval from your internal Data Privacy Officer must be sought
- It is important to ensure:
  - Every survey conducted is compliant with protocols set by the industry codes of conduct for each local market included in your research activity
  - Every aspect of the project is considered and planned for – from recruitment methods, data collection strategies, through to data processing, analysis and presentation
  - Every respondent must be protected under international, national and local data protection legislation
- These questionnaires are designed for research purposes only, strictly not to be used for sales and marketing
- Internal legal department review/approval must be sought before execution of final questionnaire, study design, sampling, methodology, ethical review, etc.

LOCAL ADAPTATION AND EXECUTION

The HERO questionnaires were developed by select members of the HERO International Advisory Board and Novo Nordisk, in consultation with Kantar Health.

Questionnaires, and guidelines for use, are only available in English. If you intend to use the questionnaires in another language, we recommend ensuring validation of the translation process:

- Translation advice is not included: it is recommended that a professional healthcare translator / translation agency be employed should translation be required

It is advised that an experienced expert / research agency (e.g. Kantar Health) be commissioned to execute the research activity locally, including but not limited to recruitment, sampling, fieldwork, data collection, data processing and analysis

DATA PRODUCTION AND ANALYSIS

The questionnaires contain a number of multiple choice questions that can be collated using a simple excel spreadsheet. However, there is the additional need to manage ‘open’ and verbatim answers, this requires code frames and coding – you will need to consider consulting an experienced individual or company to support on this.

Furthermore, it is recommended, based on the length of each questionnaire, to develop tables. Production of tables enhances your ability to ‘read’ through the data, they can be set up to deliver data on a question, by question basis, or used to collate data from
several questions or lead from a specific angle (e.g. you may wish to cut data primarily by the haemophilia diagnosis, or age), for this you will need to develop a ‘tabspec’ (document that outlines specific requirements from the tables).

Whether you choose to proceed with the data analysis within your organisation, or consult an expert / company, it is important to establish the story you wish to tell with the data. In doing so, you will identify what tables you require.

**OTHER POINTS FOR CONSIDERATION**

Other issues / areas to be considered include, but are not limited to:

- Respondent inclusion / exclusion criteria
- Sampling / recruitment methodologies
- Respondent interaction
- Data processing methods
- Quality and auditing procedures
- Data analysis techniques
- Data security
- Ethics committee approval
- Publication guidelines, etc.

**FOR FURTHER INFORMATION PLEASE CONTACT**

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