GLANZMANN'S 360

The Lived Experience of People with Glanzmann's Thrombasthenia

Prepared by

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haemnet

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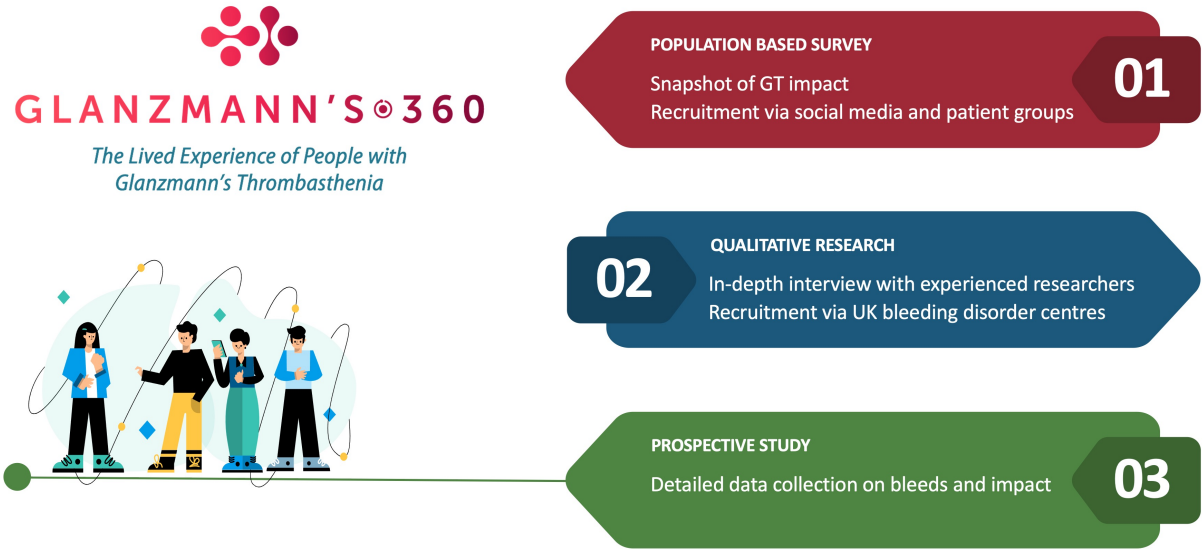
1 Background

Hemab is developing HMB-001 as a subcutaneously administered treatment for the prevention of bleeding in patients with Glanzmann's Thrombasthenia (GT). GT is an extremely rare condition, and little is known about its natural history, or of the impact it has on patients and their families.

Independently of the HMB-001 study, Hemab has commissioned Haemnet in order to gain a greater understanding of GT and its impact on individuals and their families within the UK. The Haemnet Glanzmann's 360 programme is a mixed-methods, three component natural history study comprising both qualitative and quantitative approaches. It is designed to include the perspectives of:

- Individuals diagnosed with GT
- Parents/caregivers of children with diagnosed with GT
- Clinicians who manage people with GT.



The present study protocol covers only the population-based survey and the qualitative research. The prospective study will be the subject of a separate ethics submission.

1.1 Context

Glanzmann's Thrombasthenia (GT) is a rare inherited blood clotting (coagulation) disorder characterized by impaired platelet function due to absent or reduced glycoprotein IIb/IIIa complex which is instrumental in platelet aggregation. Symptoms of GT include bruising and abnormal bleeding, which may be severe. Prolonged untreated or unsuccessfully treated bleeding associated with GT may be life threatening.

GT is characterized by prolonged or spontaneous bleeding from birth. Affected individuals tend to bruise easily, have frequent nosebleeds (epistaxis), and may bleed from the gums. They may also develop red or purple spots on the skin caused by bleeding underneath the skin (petechiae) or swelling caused by bleeding within tissues (hematoma). GT can also cause prolonged bleeding following injury, trauma, or surgery (including dental work).

Women with GT can have prolonged and abnormally heavy menstrual bleeding. They may also have an increased risk of excessive blood loss during pregnancy and childbirth.

About a quarter of individuals with GT have bleeding in the gastrointestinal tract, which often occurs later in life. Rarely, affected individuals have bleeding inside the skull (intracranial haemorrhage) or joints (hemarthrosis).

The severity and frequency of the bleeding episodes in GT can vary greatly among affected individuals, even within the same family. Spontaneous bleeding tends to become less frequent with age in boys/men but menstruation remains a significant challenge for women.

GT affects men and women equally. It is inherited in an autosomal recessive manner: both copies of the gene in each cell have mutations. The parents each carry one copy of the mutated gene, but they typically do not show signs and symptoms of bleeding. Acquired GT can develop as an autoimmune disorder, is extremely rare and will not be part of this study.

GT is estimated to affect 1 in one million individuals worldwide, but may be more prevalent in certain groups, particularly those where consanguineous relationships are common.

Most people with GT are diagnosed early. Patients and families experience considerable psychosocial impact and treatment burden. Patient/family and physician education concerning treatment alternatives and the support of the GT community are critical [1].

There remains a need for a comprehensive understanding of the experience of people with GT in order to identify:

- The nature and range of symptoms that people present with to services
- The variability in pathways through which patients progress to access appropriate care
- The impact of living with GT on the individual's quality of life and that of their family.

2 Aims and Objectives

The Lived Experience of People with Glanzmann's Thrombasthenia (The Glanzmanns 360 study) is an exploration of the lived experience of those affected by GT.

The primary objective of this study is to understand the impact of GT on affected individuals and their families.

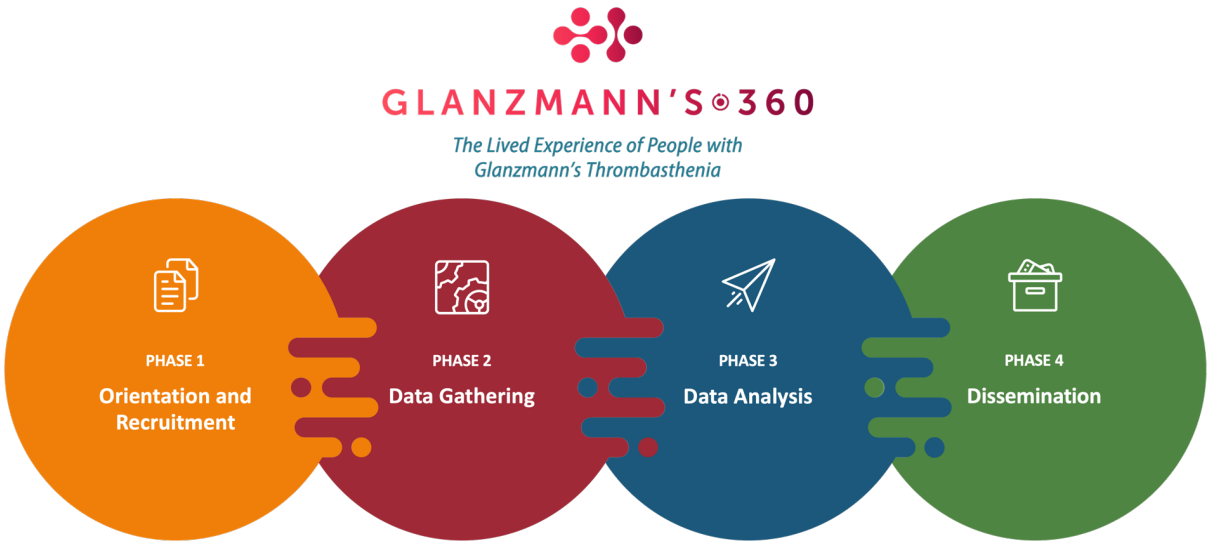
Secondary objectives are to:

- Identify levels of satisfaction with current treatments and management approaches
- Identify areas of unmet need among people with GT.

[1] Duncan A, Kellum A, Peltier S, Cooper DL, Saad H. Disease Burden in Patients with Glanzmann's Thrombasthenia: Perspectives from the Glanzmann's Thrombasthenia Patient/Caregiver Questionnaire. J Blood Med. 2020;11:289-295. doi: 10.2147/JBM.S259904.

3 Methodology

The study programme will encompass the following four-phase process:



3.1 Phase 1: Orientation and Recruitment

We will convene a first steering group meeting. The steering group will manage the overall study approach and confirm the parameters to be analysed in the surveys and focus groups.

The membership includes:

- Kate Khair – chair and Haemnet
- Minette van der Ven – patient advocate
- Amy Owen – patient parent and advocate
- Nicky Curry – clinical
- Suthesh Sivapalaratnam – clinical
- Catherine Rea, Hemab – clinical and Hemab
- Benny Sørensen, Hemab
- Simon Fletcher – Haemnet
- Luke Pembroke, Haemnet
- Mike Holland, Haemnet

We will conduct a roundtable meeting of healthcare professionals (medical and nursing) known to manage people with GT, and patient advocates (from the European Haemophilia Consortium and the UK Haemophilia Society). HCP participants will be drawn from the centres who have agreed to participate in the study from the following geographical areas:

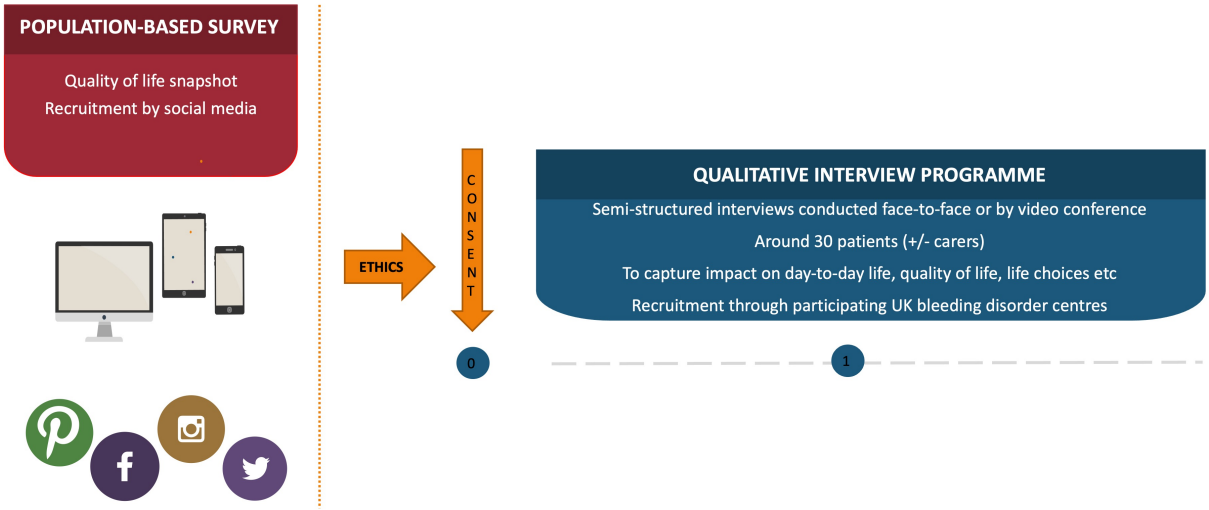
- Birmingham/Stoke/Nottingham
- Leeds/Bradford/Sheffield
- Manchester/Liverpool and the North West
- Basingstoke/ Portsmouth Haemophilia Network
- Oxford
- Bristol and the South West
- London

We will capture details of current service provision for patients with GT and identify potential for improvement for the affected individual, their carers and family members. Importantly, we will also invite these healthcare professionals to disseminate recruitment materials to their GT patients/carers. They will be asked to mail out postcards (in sealed envelopes) to their GT patients.

Each postcard will include a link to a series of study recruitment animations, along with a request that potential participants contact the research team for further study information and consenting.

3.2 Phase 2: Data Gathering

Individuals will be invited to share their experiences of living with GT by completing an online survey to establish quantitative data and participating in one-to-one in-depth qualitative interviews. Through this scheme, we will capture patient experience while also securing a population of patients who may be sufficiently motivated to take part in future clinical trials of new products.



Quantitative data

The online survey which will be completed anonymously via Typeform will be advertised via social media (including the GT Facebook group, the UK Haemophilia Society social media groups and Haemnet) as well as via personal invitation via the PIC sites.

The online survey is designed to collect data on demographics, symptoms, diagnosis, psychosocial impact and treatment history, use of iron and (for women) use of the oral contraceptive pill to ameliorate menstrual bleeding. It includes the following validated questionnaires:

- Generic health related quality of life (EQ-5D) [2] and EQ-5D-Y (for children)
- Self-Efficacy to Manage Chronic Disease Scale (SEMCD) [3]
- Rosenberg's Self-esteem Score [4]
- Psychological health and well-being (PH9[5]),
- Menstrual bleeding questionnaire (MIQ [6])

[2] Brooks R. EuroQol: the current state of play. Health Policy 1996;37:53-72.

[3] Ritter PL, Lorig K. The English and Spanish Self-Efficacy to Manage Chronic Disease Scale measures were validated using multiple studies. J Clin Epidemiol. 2014; 67(11): 1265-1273.

[4] Rosenberg M. Conceiving the Self. New York: Basic Books, 1979.

[5] Kroenke, Kurt, et al. The Patient Health Questionnaire-2: Validity of a Two-Item Depression Screener. *Medical Care*, vol. 41, no. 11, Lippincott Williams & Wilkins, 2003, pp. 1284–92, http://www.jstor.org/stable/3768417.

[6] Bushnell DM, Martin ML, Moore KA, Richter HE, Rubin A, Patrick DL. Menorrhagia Impact Questionnaire: assessing the influence of heavy menstrual bleeding on quality of life. Curr Med Res Opin 2010; 12:2745-55. doi: 10.1185/03007995.2010.532200.

Qualitative data

Interviews give the opportunity to capture the rich detailed data needed for a natural history study. We will conduct face-to-face interviews wherever possible, in different regions of the UK, depending on where we identify patients (this will avoid the findings being skewed by the experience of those attending the London centres). Dependent upon COVID restrictions we may conduct interviews via on-line platforms.

Each interview will be moderated by Dr Kate Khair accompanied by an additional researcher. Each will be structured in order to better understand:

- Impact on quality of life (to identify the holistic impact factors)
- Knowledge in families
- Impact on education
- Impact on career choices
- Societal and cultural issues.

Audio recordings of each interview will be captured and transcribed verbatim by a member of the Haemnet team. Direct quotes may be used in publications – consent to use anonymised quotes will be obtained.

Estimated Patient Numbers

There are ~400 members of the GT Facebook group, we would hope to achieve >100 survey responses.

The UK National Haemophilia Database currently includes 69 males and 85 females with GT. Through contacts with nurses at haemophilia centres, who are keen to participate in this study, we currently know of 60 identified patients at 14 centres in the UK who are predicted to participate in the qualitative interviews. We would aim to recruit around 30 participants to take part in the qualitative interview programme.

Inclusion criteria:	**Exclusion criteria:**
Confirmed diagnosis of inherited GT	Rare patients with acquired GT
Adults aged 16 years and older with GT	Participants unable to read/write/speak English
Parents of children aged <16 years with GT	Those who do not consent
Ability to read/write/speak English for questionnaire and interview completion	
Give informed consent	

3.3 Phase 3: Data Analysis

Quantitative study (survey data)

Descriptive data of socio-demographic characteristics and clinical data will be shown as frequency distribution in per cent or as mean ± standard division SD (range), median and interquartile ranges (IQR). Descriptive statistics of the sociodemographic and clinical data (age, severity, treatment regimen, number of bleeds in last week, anaemia, hospital visits) will be presented to give an overview of the characteristic of the study population.

The impact of bleeds on participants' quality of life (EQ5D), impact of menorrhagia (MIQ) and mental health (PH9, (SEMCD) and Rosenberg's Self-esteem Score will be analysed. The comparison of differences between groups will be examined by Student's test, Mann-Whitney U-test or ANOVA according to distribution. Such analyses will be exploratory in nature.

All data will be tested for normal distribution using the Shapiro Wilk test.

For all analyses, p-values < 0.05 will indicate significance.

Qualitative study (interview data)

The qualitative (interview) data will be analysed using established qualitative research methodologies. We will start with an interview guide developed by the lead researcher and a patient co-researcher. After each of the interviews, the sound files will be transcribed verbatim; the lead investigators will then analyse the transcripts using NVivo software. Direct quotes are analysed into topics, and topics are coded into themes to identify recurring themes seen as important aspects of life with Glanzmann's Thrombasthenia. Each interview is coded as it occurs, following analysis the interview guide may be amended so that emerging themes may be further investigated in later interviews This continues until no new themes are described (data saturation). This is recognised as being a very effective way to gain deep insightful and rich data from study participants.

Qualitative research involves gathering rich data, using a variety of methods, including interviews, ethnography and textual analysis, to identify themes. Data are coded and the themes analysed, and finally theories are developed about the data that has emerged [7]. Such approaches have been used extensively in research with children and families [8] and within haemophilia [9].

Audio-recorded interviews:

- All interviews will be transcribed, verbatim, by a professional transcriptionist unknown to study participants. All data will be anonymised during the transcription process.
- The transcripts will be read and re-read by the research team. The transcribed data will be coded into themes for further analysis using a transformational framework, identifying themes or concepts, summarising and synthesising the data, and using descriptive framework analysis to represent the view expressed [10].
- A table of themes will be produced, characterising recurring ideas and thoughts captured during the interviews. These will form the basis for further analysis.
- Individual quotes may be used – these will be anonymised. Participants will be informed of this in the information sheet(s) and consent.
- Field notes: Immediately after the interviews, the researchers will record any thoughts, reflections or observations made during the interview. In particular, any thoughts or ideas

[7] Charmaz K. *Constructing Grounded Theory*. 2nd edition. Introducing Qualitative Methods series. 2014. London: SAGE Publications.

[8] Neill S. Grounded theory sampling: 'whole' family research. Journal of Research in Nursing 2007; 12; 435-443

[9] Khair K, Pollard D, Harrison C, Hook S, O'Driscoll M, Holland M. HOw Patients view Extended half-life products: impressions from real world experience (The HOPE study). Haemophilia 2019; 25(5): 814-20. doi: 10.1111/hae.13803.

[10] Spencer L, Ritchie J, O'Connor. Analysis: practices, principles and processes. In: Ritchie J, Lewis J (eds). Qualitative Research Practice: A Guide for Social Science Students and Researchers. 2003. London: SAGE Publications.

about emerging themes will be recorded. These notes will be analysed as part of the framework analysis [11 12].

Interview transcripts will be analysed by NVivo (a qualitative data analysis software package that helps qualitative researchers to organize, analyse and find insights in unstructured or qualitative data) and also by a manual thematic analysis [13]. We will thus be able to analyse data at intervals throughout the course of the study.

3.4 Phase 4: Dissemination

Our initial steering group and roundtable panel will be reconvened, and all data gathered and analysed will be presented back to them. This group may be supplemented by external experts. Comments from this meeting will be captured along with the study results in a written report summarising the research process, outputs, findings, and conclusions. The report will include a summary of any policy value messages as well as any additional research questions and suggested solutions for any additional evidence requirements uncovered during the study. It will also identify opportunities for service improvement and development of educational materials.

Outputs from the study that are suitable for wider dissemination in journals or at conferences will be developed for publication in clinical and health economics journals, along with abstracts and posters for use at conferences. The publication plan will be finalised in conjunction with the Steering Committee and other stakeholders. The publication plan will, importantly include materials to be fed back to those affected individuals who have contributed to the study. This is likely to be in the form of animated videos.

[11] Ritchie J, Spencer L, O'Connor W. Carrying out qualitative analysis. In: Ritchie J, Lewis J (eds). Qualitative Research Practice: A Guide for Social Science Students and Researchers. 2003. London: SAGE Publications.

[12] Bowling A. Research Methods in Health: health: investigating health and health services. McGraw Hill 2009; 3rd Edn. Chapter 16 Unstructured interviewing and focus groups.

[13] Creswell JW. Qualitative Inquiry and Research Design, Choosing among Five Approaches. 2nd Edition, Sage Publications Inc., Thousand Oaks, 2007.

4 Ethics and Data

4.1 Risk to participants

There is minimal risk to participants or researchers from participating in this study. Those who choose to do so will be invited to an interview to discuss their hopes, fears, expectations and the realities of living with GT.

In the event that any patient or family member becomes distressed by this, they will be referred (with consent) to the appropriate professionals at the haemophilia centres from which they have been recruited.

4.2 Informed consent

Study participants will be consented prior to taking part in the study. The on-line survey will have a tick box consent to maintain anonymity. This consent can be withdrawn at any stage but entered data will be retained and used. Participants of the survey will be offered an option to enter the prize draw and to join the interview part of the study; this will require an email address.

Written consent will be taken before the interviews take place, this will include consent to use direct quotes in publications. Verbal re-consent will be taken before the interviews for recording.

Finally, there will be an option to 'opt-in' to potential future Hemab studies. Haemnet will seek written consent to maintain email addresses and to contact participants for future GT research on behalf of Hemab (see section 4.8).

4.3 Anonymity/confidentiality

All participants will be assigned a unique study number, that will be known only to the researchers and study participant. The use of interviews raises issues of confidentiality, especially when direct quotes and/or the circumstances of quotes may be used in reports and publications. It is therefore imperative that individuals are anonymised. This will be achieved by the individual reports and quotes using study numbers which are known only to the research team.

4.4 Ethical approval

Ethical approval will be sought from the Health Research Authority using standard IRAS application forms.

The study will be registered with the research and development office at Oxford University Hospitals NHS Foundation Trust.

4.5 Insurance

Haemnet has full public liability insurance cover. All members of staff are fully checked through the UK's Disclosure and Barring Service (DBS).

4.6 Reward for participants

The initial survey will include a prize draw, for which the prize will be three £300 gift vouchers. Those who complete the survey will be offered the opportunity to opt in to the prize draw. Participants who agree to an interview will receive a £100 gift voucher after their interview and will have any travel costs reimbursed. Details of this will be included in the participant information sheet(s).

4.7 Data Protection

Participants in this study will be anonymised and will be known by study number only and managed in line with the EU General Data Protection Regulation (GDPR) (successor to the UK Data Protection Act 1998).

- All audio recordings will be transcribed verbatim by a professional transcriptionist unknown to the study participants. The transcriptionist is a member of staff at Haemnet.

- All data (paper records and audio recordings) will be kept in locked cupboards by Haemnet for the duration of the study.
- Recordings will be deleted by Haemnet once the study has been analysed.
- Any data on computers will be password protected in line with NHS data protection procedures.

Haemnet will act as sponsor to the study and will monitor data quality and undertake site audits as necessary.

4.8 Potential Future Studies

The current study forms part of a portfolio of *potential* future studies about GT that *may* be undertaken in collaboration with Hemab at a future date. These studies would require future ethical approval(s).

To retain *potential* participants from the Glanzmanns 360 study for future research we will seek written consent to hold their contact details and to be able to approach them again in the future when these studies come to fruition. There will be no obligation to participate in these studies.

5 Timelines and deliverables

5.1 Study Timeline

The planned first patient first 'visit' (intervention) date is April 2022. Each participant will be in the study for the time between completion of the survey and the interview (predicted to be a maximum of 12 weeks), recruitment and data collection should be completed by the end of 2022.

5.2 Study Deliverables

These will include:

- Three manuscripts for publication
- Abstracts to international congresses in 2023
- Animation videos for patients/carers

6 About Haemnet

6.1 Project team

Dr Kate Khair

Kate is Director of Research at Haemnet and is Visiting Professor of Health and Social Care London South Bank University. She was formerly Nurse Consultant at Great Ormond Street Hospital for Children NHS Foundation Trust, London. She has extensive knowledge in qualitative research with children and young people with haemophilia and has completed industry-sponsored research in the past, with a good track record of study completion and publication. Kate works very closely with all members of the Haemnet team.

Simon Fletcher

Simon is the Lead Research Nurse at the Haemophilia and Thrombosis Centre at the Churchill Hospital, Oxford. Simon has been in post for eight years and has extensive knowledge of clinical research and the care of people with bleeding disorders. He will oversee the study including ethical approval, study staff training, participant enrolment, study completion including evaluation of all outcome measures used, and ensure timely results presentation and publication.

Luke Pembroke

Luke is Haemnet's Creative Director. From producing and directing video and podcast content to managing our social media presence, Luke's role focuses on communicating Haemnet's work in a creative way through the power of storytelling. He has experience working within the healthcare communications industry and is an active patient advocate having collaborated with a network of patient groups and industry within the UK, Europe and globally. Luke's own experience living with a rare bleeding disorder brings a unique perspective to the work Haemnet does.

Kathryn Jenner

Kathryn is Haemnet's Editorial Manager, charged with maintaining the quality of our written outputs, and has scripted many of our animations. Having previously worked with literary and cultural archives, Kathryn has been a freelance writer, editor and researcher since 2011. Kathryn has a passion for working with words and is co-editor of a long-running literary magazine in her spare time. As well as supporting Haemnet's publishing activities she also works with a range of individuals and organisations across wide range of subject matter – from art to artificial intelligence.

Michelle Huet

Michelle is the Haemnet office manager. As well as organising meetings, keeping the back office and accounts up to date, she is increasingly involved in supporting research projects. Highly personable, she is a former nursing support worker, and is an NVQ level 3 qualified care sector worker.

Mike Holland

Mike Holland is CEO of Haemnet Ltd. After graduating in Physiology and Biochemistry, he began a career in medical and health care writing that has seen him work with numerous academic and news-based publications, professional organisations, pharmaceutical and public relations companies, medical education agencies and charities. He was written materials for healthcare professionals, patients and the media, including books, monographs and articles published in peer-reviewed journals. He formed Haemnet with Kate Khair in 2013 and now leads the team across the full range of Haemnet activities, overseeing all proposals, publications and projects.

6.2 Haemnet

Haemnet works with healthcare professionals, patient communities, industry and other key stakeholders within the area of rare bleeding disorders and other chronic conditions. As a specialist consultancy we offer services across three principal areas: conducting research, designing and delivering education, and producing creative content and media.

The founding shareholders of Haemnet Ltd are Kate Khair, Mike Holland, Luke Pembroke and Jamie O'Hara. Between them they have an unrivalled history of living with, managing and writing about haemophilia and other bleeding disorders. Contributing to improving the lives of people with bleeding disorders is at the core of the work we do.

The operational team comprises:

- Mike Holland – CEO
- Kate Khair – Director of Research
- Luke Pembroke – Creative Director
- Sandra Dodgson – Director of Community Engagement
- Kathryn Jenner – Editorial Manager
- Michelle Huet – Office Manager

The Haemnet team has previously managed and successfully delivered a wide range of studies and projects, the results of which have been published in peer-reviewed journals, informed practice and provided the basis for educational resources that are used by clinical teams with patients. These include:

- Khair K, Pollard D, Steadman L, Jenner K, Chaplin S. The views of women with bleeding disorders: Results from the Cinderella study. Haemophilia. 2022;1–10. https://doi.org/10.1111/hae.14514
- Sanigorska A, Chaplin S, Holland M, Khair K, Pollard D. The lived experience of women with a bleeding disorder: A systematic review. Res Pract Thromb Haemost. 2022;6:e12652. doi:10.1002/rth2.12652
- McLaughlin P, Holland M, Dodgson S, Khair K. Project GYM: A randomized feasibility study investigating effect on motivation of personal trainer-led exercise in young men with hemophilia. Res Pract Thromb Haemost. 2021 Nov 26;5(8):e12613. doi: 10.1002/rth2.12613.
- Khair K, Holland M, Dodgson S, McLaughlin P, Fletcher S, Christie D. Fitness enhances psychosocial well-being and self-confidence in young men with hemophilia: Results from Project GYM. Res Pract Thromb Haemost. 2021 Nov 26;5(8):e12622. doi: 10.1002/rth2.12622.
- Fletcher S, Jenner K, Holland M, Khair K. The lived experience of a novel disruptive therapy in a group of men and boys with haemophilia A with inhibitors: Emi & Me. Health Expect 2021 Dec 8. doi: 10.1111/hex.13404. Online ahead of print.
- Fletcher S, Jenner K, Pembroke L, Holland M, Khair K. The experience of people with haemophilia undergoing gene therapy in a clinical trial setting: Regaining Control, an Exigency Study (manuscript submitted for publication, 2021).
- Fletcher S, Jenner K, Holland M, Chaplin S, Khair K. An exploration of why men with severe haemophilia might not want gene therapy: The exigency study. Haemophilia. 2021;27:760–768. https://doi.org/10.1111/hae.14378
- Khair K, Steadman L, Chaplin S, Holland M, Jenner K, Fletcher S. Parental perspectives on gene therapy for children with haemophilia: the Exigency study. Haemophilia. 2020.
- Khair K, Pollard D, Harrison C, et al. HOw Patients view Extended half-life products: impressions from real world experience (The HOPE study). Haemophilia 2019; 25(5): 814-820. doi: 10.1111/hae.13803.

- Khair K, Holland M. The Kids' immune thrombocytopenia Tool is not suitable for assessing quality of life in children with platelet function disorders. Haemophilia 2018; 24(4): e259-e261. doi: 10.1111/hae.13528.
- Khair K, Klukowska A, Myrin Westesson L, et al. The burden of bleeds and other clinical determinants on caregivers of children with haemophilia (the BBC Study). Haemophilia 2019; 25(3): 416-423. doi: 10.1111/hae.13736.
- von Mackensen S, Myrin Westesson L, Kavakli K, et al. The impact of psychosocial determinants on caregivers' burden of children with haemophilia (results of the BBC study). Haemophilia 2019; 25(3): 424-432. doi: 10.1111/hae.13684.
- Khair K, Holland M, Bladen M, et al; SO-FIT Study Group. Study of physical function in adolescents with haemophilia: The SO-FIT study. Haemophilia 2017; 23(6): 918-925. doi: 10.1111/hae.13323.
- Khair K, Holland M, Pollard D. The experience of girls and young women with inherited bleeding disorders. Haemophilia 2013; 19(5): e276-81. doi: 10.1111/hae.12155.
- Forrester C, Bielby H, Johns S, Efford J, Holland M, Khair K; United Kingdom Haemophilia Nurse's Association. Potential for development of haemophilia link nurse role within UK hospitals. Haemophilia 2013; 19(4): 578-82. doi: 10.1111/hae.12144.
- Khair K, Holland M, Vidler V, Loran C, Harrington C. Why don't haemophilia nurses do research? Haemophilia 2012; 18(4): 540-3. doi: 10.1111/j.1365-2516.2012.02749.x.
- Khair K, Holland M, Carrington S. Social networking for adolescents with severe haemophilia. Haemophilia 2012; 18(3): e290-6. doi: 10.1111/j.1365-2516.2011.02689.x.

7 About Hemab

Hemab Therapeutics is a biotechnology company developing next-generation therapeutics for bleeding and thrombotic disorders. Hemab is developing HMB-001, a novel bispecific antibody with potential for the treatment of Glanzmann's Thrombasthenia (GT) and other rare bleeding disorders.

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