Manual for Nurses leading EBMT studies

EBMT Nurses Group Research Committee

Preface

Thank you for your interest in actively contributing to the EBMT Nurses Group!

Nurses have been taking a leading role in the holistic care of HSCT patients: haematology nurses are involved in the decision-making process about treatment options for their patients and they evidently contribute to an enhancement in their patients' quality of life. Nursing science must therefore be continually improved in order to provide the best patient care possible.

The mission of the EBMT Nurses Group (NG), founded in 1985, is to promote excellence in patient care through international collaboration, education, research and science. Under the guidance of the NG Research Committee, the Nurses Group has become more and more actively involved in conducting research and pursuing its own clinical research agenda.

Activities of the Research Committee include among others:

- developing research protocols within the committee;
- supporting nurse members to develop research protocols;
- collaborating with EBMT scientific working parties (WP) to provide nursing input to their studies and liaise with EBMT WP for relevant NG studies;
- publishing and presenting results of completed work;
- providing research knowledge through education and presentations.

We welcome all EBMT nurse members to contribute to our research mission. This manual provides an overview of the various opportunities, together with instructions, for nurses to contribute to the scientific visibility of the Nurses Group.

How to contribute to the aims of the EBMT NG Research Committee

There are various ways to become actively involved. You can participate in a NG-led study or help in shaping the NG clinical research agenda. Where positions are available, you can apply to become a member of the NG Research Committee, a Working Party Nurse, or you can propose your own research study to the EBMT NG RC.

1. NG Research Committee

The NG Research Committee consists of at least 4 motivated clinical nurses and research specialists, including one chairperson. The chairperson represents the Committee, ensures the Committee functions properly, leads the Committee's meetings, and maintains contact with the NG Board.

Please have a look at the NG Research Committee webpage for additional information on objectives, activities, projects, and publications.

2. Working Party Nurse

The NG Research Committee collaborates and liaises with all other NG Committees, and also with EBMT scientific Working Parties (WP) through the WP Nurses. The WP Nurses have a vitalrole in keeping close contact with the scientific agendas of the WPs.

Within the WP, WP Nurses facilitate both the nursing research activity in collaboration with the Research Committee and nursing education activity in collaboration with the Scientific Committee. As such they contribute to the research and education agenda of the NG and the corresponding WP. In addition, WP Nurses offer support and guidance in the development of research studies and educational initiatives, also promoting opportunities for nursing research within the WP.

While performing this important and responsible position, WP Nurses regularly report on their activities to NG Research Committee, Scientific Committee and the WP Chairperson. WP Nurses are appointed for a 3-year term, with potential for re-nomination for a maximum of 2 terms.

Further information

If you are interested in becoming a NG Research Committee member or a WP Nurse, check the news section of the EBMT website for our current vacancies (under 'The EMBT' >> 'News').

3. Proposing a study to the EBMT NG RC

EBMT nurse members can contribute to the NG Research Committee mission by developing their own nursing research. The Committee offers a range of study support for both novice and experienced researchers.

As members of the inter-professional team (including physicians, social workers, physiotherapists, etcetera), nurses offer a unique role and perspective of patient and family care. Through their reflective way of practicing, nurses are able to make meaning of experience[1], connect theoretical knowledge to the context of clinical practice[2], develop fresh insights, and modify clinical practice[3].

The NG Research Committee has created a Research Proposal Form to guide research design, supporting study development. The most up-to-date Research Proposal Form can be downloaded from the NG Research Committee page of EBMT website ('Nursing' >> 'NG Research Committee'). Try to complete the form as fully as possible (see Appendix I for a brief guide): please contact the NG Study Coordinator at nursesgroup@ebmt.org if you require help.

Once the Proposal Form is completed, please send it to the EBMT Leiden Study Unit (LSU) at nursesgroup@ebmt.org. The NG Study Coordinator will circulate the proposal within the NG Research Committee and will provide you, the Principal Investigator (PI), with progress updates. The approval process entails a feasibility check and a substantive review of the proposal by the Research Committee. The experienced members of the Research Committee will provide necessary feedback. One of the members of the Research Committee will personally link in with the study. During this phase, additional fine-tuning of the proposal by the PI may be required.

Depending on the study topic and/or population (e.g., adults vs. paediatrics), the Research Committee (RC) will assign at least two research nurses (from now on NG RC assigned members) and a Research Coordinator to support your study. If any assigned nurse or the Research Coordinator transitions out of the Committee, the RC will ensure a smooth handover to other team members to maintain study continuity and safeguard against disruptions.

Once approval has been granted by the NG Research Committee and the EBMT NG Board, the NG Study Coordinator from the LSU will initiate the study and invite EBMT members to participate in the study. Data will be collected and checked for quality by the LSU. Statistical data analysis will be performed by an EBMT statistician, although it is possible for the PI to analyse the data upon signing a non-disclosure agreement. In the latter case, the final analysis results require the approval of an EBMT statistician for the data to be published under the banner of EBMT.

The PI will be sent a statistical report from the EBMT statistician featuring the most significant results. Additional analyses can be requested via the EBMT Study Coordinator. The PI is responsible for result interpretation and development of the subsequent abstract/manuscript. It is recommended to start developing and writing at the earliest opportunity to organize information and ideas into an early draft of your research paper. This can also help to generate new ideas. The writing process will reveal 'holes' in the research and helps to gain greater understanding of the project. Please note that the LSU can offer assistance in the writing phase as well.

4. Participating in a NG-led (non-)interventional prospective study

4.1 Interventional prospective study

Interventional prospective studies (IS), also termed clinical trials, are prospective studies that makes requirements that will affect the management of the patient, whether in terms of the treatment itself or the investigations required to obtain the necessary data. Clinical trials are complex to set up and carry with them a series of legal requirements that require expert management. For this reason, clinical trials are coordinated by the EBMT Clinical Study Unit (CSU). EBMT nurse members can request an IS via the Proposal Form (*see section 3: Proposinga study to the EBMT NG RC*) or participate in an ongoing NG-led IS. To see which NG-led IS arecurrently ongoing, please visit the EBMT Studies page (under 'Research' >> 'Current studies list') and filter for the Nurses Group. Once a submitted IS proposal is accepted by the NG RC, the NG Study Coordinator will transfer the proposal to the CSU for coordination.

4.2 Non-interventional prospective study

Non-interventional prospective studies (NIS) are prospective studies which are set up to investigate events that will take place after the study has been initiated. The main and very important difference between a clinical trial and a NIS is that the data collection or patient-participation in the NIS does not interfere with the choice of treatment, sample collection, procedures, and the treatment itself, which should entirely follow standard hospital practices. For the most part, a NIS resembles a retrospective study with regards to study coordination and data management. EBMT nurse members can request a NIS via the Proposal Form (*see section 3:Proposing a study to the EBMT NG RC*) or participate in an ongoing NG-led NIS. To see which NG-led NIS are currently ongoing, please visit the EBMT Studies page (under 'Research' >> 'Current studies list') and filter for the Nurses Group. The EBMT Leiden Study Unit is the point of contact for NG-led NIS, in consultation with the PI. At the start of the NIS, the NG Study Coordinator will send an invitation to all EBMT nurse members from eligible centres to participate in the study. Please consider the following particulars for a NIS:

- For patient data to be collected by the EBMT, patient consent must have been obtained. Its advisable that the protocol includes a section making the hospitals aware that they need to check whether they would need additional patient consent to forward the necessary data.
- Ethical approval may be needed depending on country and on the design of the study. It is beyond the possibility of the EBMT to have expert knowledge about the regulations in each country. It is therefore advisable that the protocol includes a section making the hospitals aware that they may have to apply for ethical approval under their own rules. One option could be to apply at one major centre and use that centre's approval for the entire study. Please note: if sensitive information is being analysed ethical committee application is strongly recommended and it will be obligatory in some countries.
- If a MED-C form is involved, the request to fill in the MED-C form can be sent to the NG Study Coordinator electronically (nursesgroup@ebmt.org), Electronic submission must always be done with password protected files if the documents contain patient data.
- A study can be financed either internally through the WP budget allocated by the EBMT board or through external funding. For a NIS it is not uncommon to provide participating centres with reimbursement for the time invested (a so-called 'per patient fee'). The costs should be calculated early on and should be ready before the protocol is finalised.

Please contact the NG Study Coordinator (nursesgroup@ebmt.org) if you'd like to receive further information concerning (ongoing) NG-led NIS.

Appendix I Brief guide for writing a research proposal

1. **Ask the established 5 W's and H questions**: Who, What, When, Where, Why and How? Initially, a broad description will suffice. You will narrow the topic down further by refining and formulating your research question.

2. **After choosing a topic, enter the reading phase**. Begin by finding secondary literature: texts that others have written and published about the topic or its context. This will provide an overall answer to two questions: What is the topic comprised of? And what is known about it up to this point?
    - Before searching, make a list of keywords, names and topics that are relevant to the research. Make sure the search terms include alternative spellings, translations and synonyms.

    - It is important to use the right search engines to find academic publications. Search engines like Google Scholar, PubMed, Scopus and Web of Science can help to identify articles, books and PhD theses. If there are problems accessing scientific articles, please contact nursesgroup@ebmt.org.

    - After gathering a good amount of literature, make a selection. Determine which publications are the most important or relevant and start by reading these. Take care to write down the title, author, date of publication and publisher of every publication identified in the search, including those considered less important.

    - Through reading, questions will be generated. These questions are the first steps toward the core of the research: the research question. Take notes, both about the contents (facts, places, people) and their location (author, page numbers, etc.). The latter will be of crucial importance to the research at a later stage, when writing footnotes or endnotes and creating a bibliography. A reference manager like Mendeley or Zotero can facilitate this process and help simplify manuscript writing.

3. **Writing the research question**:
    - The research question should showcase the literature research. A good research question has four characteristics: 1) it is bounded in time and space, 2) it requires extensive argumentation, 3) it cannot be answered briefly or descriptively, and 4) it requires a balanced conclusion. (*Tip: Start the research question with the words:'To what extent…', then reformulate to a statement*).

    - Once the main research question is phrased, split up the topic of interest into subquestions. This makes answering the main research question much easier, as subquestions make explicit which questions the research needs to answer.

4. **Choose the method(s) of data collection**. The following study types can be performed using the infrastructure of EBMT:

   - *Survey*: a questionnaire is a very suitable medium to quickly retrieve knowledge and experiences on a large scale. The questionnaire can be addressed to HSCT patients or fellow healthcare professionals (via EBMT members). EBMT uses SurveyMonkey to create online questionnaires. Please have a look at their supportsection on how to write good survey questions and all available options.

   - *Retrospective study*: a retrospective study looks backward in time, usually using medical records and/or interviews with patients who are already known to have a disease. The EBMT Registry can be searched for a specific study group and available data. Please note, because the Registry mainly contains MED-A data, it is regularly necessary to collect more complete (MED-B) or specific data (MED-C) via a targeted request to EBMT members.

   - *Observational or non-interventional prospective study (NIS)*: A NIS is a prospective study that watches for outcomes during the study period, such as the development of a disease, and relates this to other factors such as suspected risk orprotection factor(s). The main advantage of a prospective study is that the selection of patients is done a priori, following certain eligibility criteria, resulting in less bias due to patient selection by unknown circumstances compared with retrospective studies. Collection of MED-C data is also easier than in retrospectivestudies, as the centres do not have to get back to their files.

   For more information on how to conduct studies using the EBMT Registry, please seethe more comprehensive EBMT Guidelines for the Conduct of Registry Based Studies.

5. **Determine the statistical analysis method in advance**: The statistical analysis is critical to the final results and the conclusions drawn. There are many different data analysis methods, depending on the type of research. It must therefore be planned in advance: the EBMT Leiden Study Unit can offer assistance in determining the correct statistical approach for the specific study.

[1] Hartrick, G. (2000). Developing health-promoting practice with families: One pedagogical experience. J Adv Nurs, 31(1), 27-34.
[2] Jenkins, E. (2007). Using cooperative inquiry and clinical supervision to improve practice. Br. J Community Nurs, 12(2), 63-69.
[3] Bailey, M. E., & Graham, M. M. (2007). Introducing guided group reflective practice in an Irish palliative care unit. Int J Palliat Nurs, 13(11), 555-560