Abstract
Nursing research is a systematic inquiry that uses disciplined methods to answer questions or solve problems in order to expand the knowledge base within a given field. There are various issues to address in order to complete a successful study. The aim of this chapter is to provide the reader with an overview of the key topics for consideration and give guidance as to where to go for further information. Providing best care to patients undergoing HSCT is the moral and ethical duty of all nurses. As a consequence, awareness of, and involvement in, research as the vehicle to ensuring best practice is also our moral duty.

Keywords
Nursing research • Audit • Methodology • Quantitative • Qualitative • Mixed methods • Cross-sectional • Longitudinal • Prospective • Retrospective

15.1 Introduction/Background
Nursing research is a systematic inquiry that uses disciplined methods to answer questions or solve problems. It has only been in the last four decades that nurses have had access to knowledge from nursing research to inform their practice. Nowadays nurses are expected to use the best type of evidence to base their nursing care on, so-called evidence-based practice (EBP).

In 1859, Florence Nightingale’s book Notes on Nursing was first published, with the aim of providing guidance to women who have personal charge of the health of others. At this time, there
were no nursing schools and no trained nurses. She was the pioneer of modern nursing. She combined knowledge, her systematic approach, developing instruments, and statistics into an early form of evidence-based practice. Based on her analysis and presentations, she was able to make changes in nursing care with the effect of reducing mortality and morbidity.

In 1997, Molassiotis reported the lack of nursing training in research techniques, problems with funding nursing research, staff shortages, and language barriers as the reasons for the limited contribution of nursing research and the utilization of research findings to the field of bone marrow transplantation (BMT) in Europe. However, he also reported that nursing research was moving forward and starting to be integrated into many European BMT centers.

Currently, huge progress is being made. JACIE accreditation, demonstrating excellence of practice, is a legal requirement for transplant centers in many countries (more information about JACIE in Chap. 1), and as a consequence, nurses have an important role in validating protocols of care. The EBMT nurses group is making it possible to form multi-institutional collaborative models of research. An example of this is the many surveys our nurses have developed looking at current practice in relation to, for example, mouth care, CVCs, isolation, low bacterial diet, nutrition, medication adherence, and patient information. Such surveys are the ideal baseline from which to explore where there is inconsistency in nursing practice across Europe and whether further work is required to clarify what can be seen as best practice. Patient-focused research looking at mouth care, sexuality, and quality of life has been extensively explored and indicates an increasing use of evidence-based practice. Finally, the number of PhDs among registered nurses is growing, which is increasing the capacity of the nursing community to carry out independent research. Nursing research is moving in the right direction.

However, we have been undertaking hematopoietic transplantation for over 60 years with increasing success, and the longer HSCT survivors live, the more long-term effects they report. Much remains to be done. This chapter aims to provide guidance on carrying out research and information about the types of methodology, which can be used in nursing research and what support may be required to complete a successful project.

## 15.2 Service Evaluation: Audit or Research?

Before focusing on research as a topic, it is worth first clarifying the differences between service evaluation, audit, and research. These are all valid methods nurses can use to review, benchmark, or enhance their practice, but there are differences in the way they are performed, and these differences have resource implications (financial, staff, and time). Probably the key difference between the three strategies is the overall aim of the work. Both service evaluation and audit are looking at assessing or confirming the quality of the care being provided to patients, whereas research aims to add new information to the field. It is often the case that a service evaluation or audit will trigger questions, which become the basis of a research study.

### Box 15.1 Definitions of Service Evaluation, Audit and Research

**Service evaluation:** service evaluation seeks to assess how well a service is achieving its intended aims. It is undertaken to benefit the people using a particular healthcare service and is designed and conducted with the sole purpose of defining or judging the current service. The results of service evaluations are mostly used to generate information that can be used to inform local decision-making.

**Audit (clinical):** the English Department of Health states that clinical audit involves systematically looking at the procedures used for diagnosis, care, and treatment, examining how associated resources are used and investigating the effect care has on the outcome and quality of life for the patient. Audit usually involves a quality improvement cycle that measures care against predetermined standards (benchmarking), takes specific actions to improve care, and monitors ongoing sustained improvements to quality against agreed standards or benchmarks.

**Research:** research involves the attempt to extend the available knowledge by means of a systematically defensible process of enquiry.

Adapted from Twycross and Shorten (2014)
Because research may change the care that a patient is currently receiving, there is a significant amount of preparation required and mandatory approvals from statutory bodies (e.g., ethics committee) to be obtained prior to starting a study. This is to ensure the patient is protected from poor study design and unethical research practice. The situation can become confusing as research methodologies are often used for both service evaluation and audit. Equally, there may not always be clear standards available against which to audit practice. However, there are papers offering guidance on how to confidently decide which category a specific project falls into. The following table provides a succinct set of criteria for assessing any new project (Table 15.1):

| Criteria                               | Service evaluation                                                                 | Audit                                                                 | Research                                                                 |
|----------------------------------------|------------------------------------------------------------------------------------|----------------------------------------------------------------------|--------------------------------------------------------------------------|
| Overall aim (intent)                   | To judge the quality of the current service                                        | To measure clinical practice against a standard                      | To generate new knowledge/add to the body of knowledge                   |
| Initiated by                           | Service providers                                                                  | Service providers                                                    | Researchers                                                             |
| Involves a new treatment               | No                                                                                 | No                                                                   | Sometimes                                                               |
| Randomization                          | No                                                                                 | No                                                                   | Sometimes                                                               |
| Allocates patients to treatment groups | No                                                                                 | No                                                                   | Sometimes                                                               |

Adapted from Twycross and Shorten (2014)

15.3 Performing/Undertaking Research

Few people are born as researchers. The majority become researchers through education and training, practical experience, and always hard work. Research is demanding yet rewarding – even when results are not what were expected, as the aim is to learn and increase knowledge in a particular field. When initiating research, it can be challenging to know where to begin. Planning and organization are key concepts in research performance, in order get started and keep focus with the project. For novice researchers, those looking to undertake research in a new field or using a methodology that they may not be familiar with, there is usually help at hand. It is important to build a team to undertake the research, which may begin within the local organization itself; many hospitals have research and development departments (particularly those with links to academic institutions) and/or access to statisticians and support for analysis where necessary. Often difficulties arise when there is a lack of resources or time to undertake research. Getting support from management and senior clinical staff to undertake research can aid in getting some protected time.

Financial support for undertaking research is an important consideration and may be available from a variety of sources. Registration for a personal postgraduate degree (either a master’s or a doctorate) is supported by some institutions and has the added benefit of ongoing training and supervision. Nursing associations/organizations – both national and international such as the European Oncology Nursing Society – provide the possibility of applying for research grants. Information on other available resources can be obtained from, for example, national departments of health and health research boards; however, this will vary from country to country and will need investigation.

Issues of interest for investigation through research and development of the research ques-
tion can be the work of a team. All healthcare professionals will have their own views of what is important and potentially how it can be investigated. By involving other members of staff in the research process, there is a “buy-in” where the project becomes the property and interest of all rather than just one individual. This is important when thinking about the practicalities of undertaking research as it is particularly challenging if one person has to do everything. Research planning can also benefit from user (e.g., patient) involvement in terms of advising on, for example, study design, strategies for recruitment, and data collection methods that may or may not work.

Support can also be sought from a wider field such as via local academic institutions, universities, or other centers for multicenter studies. Knowledge of the literature and contacting those who are the experts in the field can be useful when questions or ideas are unclear. Other professional groups that may be disease or intervention focused such as the EBMT Nurses Group can also be a useful resource. The EBMT NG Research Committee is one such group that promotes collaboration with researchers in order to encourage presentation of ideas and aspirations for research within a wider setting. Please see the website for more details: http://www.ebmt.org/Contents/Nursing/WhoWeAre/NursingCommittees/Pages/default.aspx.

15.4 Interpreting Nursing Research

In order to complete a successful project, regardless of which criteria it comes under (audit, service evaluation, or research), it is important to identify any work that has already been performed within the field of interest. A scoping exercise to identify key relevant research and a critical appraisal of existing literature will facilitate the identification of current knowledge and as such, which studies can be used as a baseline for further work (e.g., to audit against as best practice). It will also identify where gaps in knowledge exist and provide a focus for where research can aid in developing our understanding.

To interpret and evaluate the significance of nursing research, knowledge of the various methodologies is required. This will provide the potential researcher with confidence to know whether the methodology and study design selected were appropriate to answer the research question and, as a consequence, will provide an indicator as to the quality and reliability of the results presented.

Evaluating the quality of existing literature can be complex and time-consuming, but a thorough review can inform future research direction and methodological choices. There are a variety of appraisal checklists available that can facilitate evaluation of research such as the CONSORT statement for randomized controlled trial (RCT) reporting, Critical Appraisal Skills Programme (CASP) tools, and PRISMA Statement. A published paper will usually have a title, abstract, introduction (including study aims), methods (including statement of ethical approval), results, discussion, acknowledgment of funding sources, and a reference section. The abstract is concise while communicating key information and will give the reader an indication of whether the paper is relevant to their field of interest. The main article will provide a more detailed description. The introduction, for example, should provide an overview of previous literature to “set the scene” and state the study rationale and consequent aims/objectives. The methodology and results sections require the reader to undertake a critical appraisal of sampling and recruitment strategies. This includes where appropriate, whether the correct calculation has been made to ensure sufficient subjects were entered, the “power calculation,” to provide meaningful results and data collection methods and analysis of results to inform them of the overall methodological quality and therefore reliability of the study results. The discussion section will provide a summary of the results and their interpretation, often comparing with other pertinent research. It should also describe the limitations of the research and implications for both future research and clinical practice.
It is difficult for a research study to be conducted perfectly; an open and critical reflection of limitations will assist in judging the impact on quality and perhaps generalizability of the results. Equally, suggestions of future studies which may be required and implications for clinical practice can be used as validation of a proposed piece of research. A review of the references may identify recent work and prevent repetition as well as older studies, which are still relevant and can provide a lot of information. If the reference list consists mainly of old or outdated sources, it may be an indicator that the research is based on outdated information or that there is the necessity for more work to be done on the issue in question. Similarly noting the presence of peer-reviewed journals will support evidence of reading around the topic.

15.5 Nursing Research

15.5.1 The Research Question

Once the general topic has been identified, it is important to refine this further to a more specific area of interest. Asking a librarian to assist with finding the appropriate literature as a background reading exercise allows for a greater understanding of the topic. Narrowing the focus may be helped by talking with colleagues about the topic and by working with a team and using sources of support as described earlier. Formulating the research question is about restating your topic as a question. The research question needs to be clear, focused, and ethical – and obviously something that can be researched. The acronym “PICO” is a reminder used to help clarify the clinical question (Box 15.2). It acts as a framework, requiring reflection about different aspects of interest to investigate. Building the PICO requires clarity and specificity, which helps in targeting the right evidence to use in practice. The question must be specific. What type of patient group is of interest? Is there a specific test as an intervention or a broad group? If looking for better outcomes, what are examples of those outcomes?

| Box 15.2 PICO: Worked Example, Aslam and Emmanuel (2010) |
|----------------------------------------------------------|
| P: patient, problem, or population                        | P: allogeneic HSCT recipients |
| I: intervention                                          | I: psychologist               |
| C: comparison                                            | C: no psychologist            |
| O: outcome                                               | O: effect on psychological distress |

Sample question using PICO:
In allogeneic hematopoietic stem cell recipients (P), what is the effect of a psychologist in the multidisciplinary team (I) on psychological distress (O) compared to no psychologist (C)?

15.5.2 Designs for Nursing Research

Once the question has been clearly defined, identifying the appropriate methodology to answer the question most effectively is the next step. The research design has to be pertinent to the question itself, with the nature of the question guiding the choice of approach. Research questions may be exploratory (i.e., with no a priori theory of outcome), wanting to investigate a phenomenon that we know little about and how it is perceived by a group of individuals. This type of question lends itself to in-depth interviews and a qualitative research approach. If a research question is, for example, interested in the efficacy of a novel intervention, perhaps in comparison with to standard care, then a randomized controlled trial may be more appropriate.

Two overarching categories of research are basic research, used to obtain empirical data (e.g., laboratory-based studies), which is unlikely to be immediately translatable to clinical practice, and applied research, which is usually directly relevant to the clinical setting. Nursing research tends to be applied research.

Research can also be categorized into experimental or non-experimental. Although the suggested gold standard of evidence is the experimental approach of an RCT, it is not always possible or appropriate to use this approach, for example, where randomization may be unethical. This does not mean research other than that of an
RCT is not of value; on the contrary, well-conducted research will always add to the knowledge base, and studies using more exploratory methodologies often provide a foundation for clinical trials. Common approaches for nursing research include descriptive or explorative research (e.g., using questionnaires), correlational studies, and both experimental and quasi-experimental approaches.

15.5.3 Literature Reviews

With the ever-increasing amount of research being produced and published, it is possible that answers to research questions already exist, but they sometimes lack the culmination, critical appraisal, and interpretation of individual studies together in one single document. This is where reviews of the literature to identify the evidence base are sources of research in themselves. Systematic reviews have increased in number within the field of nursing care. They use strategies in order to limit bias and systematically critically appraise and synthesize pertinent studies of interest (Greener and Grimshaw 1996). This means having defined objectives for the review, criteria for study inclusion, an organized approach to searching databases, and a clearly defined method for critical appraisal, analysis, and subsequent synthesis of data. Systematic reviews can potentially combine research findings from smaller individual studies, in order to provide a broader overview of findings in which detection of “minor” findings may be amplified or discredited. Box 15.3 describes two examples of systematic reviews within the HSCT setting.

Box 15.3 Systematic Reviews Within the HSCT Setting

In the review by Chaudhry et al. (2016), the incidence and outcomes of oral mucositis (OM) in allogeneic HSCT patients and its association with conditioning regimens were analyzed, reviewing 395 patients in 8 eligible myeloablative regimen studies and 245 patients in 6 eligible reduced-intensity conditioning (RIC) regimen studies. Severe mucositis (defined as either grades 2 to 4 or grades 3 and 4, depending on the studies’ definition of severity) occurred among 79.7% patients treated with myeloablative regimen studies and 71.5% patients treated with reduced-intensity conditioning regimen studies. RIC regimens led to a high incidence of OM similar to that of MA regimens.

Riley et al. (2015) reviewed the effects of oral cryotherapy in patients with cancer receiving treatment. For this they included 14 RCTs analyzing 1280 participants. After high-dose melphalan before HSCT, cryotherapy reduces considerable oral mucositis. However, the size of the reduction could not be detected.

15.5.4 Quantitative, Qualitative, and Mixed Method Research

Research is generally divided into three groups – quantitative, qualitative, and mixed method approaches. Quantitative research is particularly focused on theory testing and relationships between variables (factors which are either changed within an experimental design, such as mouth wash in oral care, or influenced by such changes, e.g., level of oral pain/mucositis), where measurement instruments (e.g., pain scale) provide numerical data which can be subjected to statistical analysis (Creswell 2014). Examples of quantitative designs include those producing numerical data such as experiments or clinical trials (often sponsored by pharmaceutical companies or academic groups that coordinate research projects), observations (looking at frequencies), and surveys with closed questions (using questionnaires, in person, online, or by phone). At the other end of the spectrum, qualitative research is focused on understanding meanings and experiences of human beings, also within a given con-
text (Kielmann et al. 2011). Researchers using these methods do not have any theory on which to base their work; rather they may use their results to develop a theory. Examples of qualitative data include interviews, focus groups, and secondary data (such as written accounts or reports). Both quantitative and qualitative approaches have positive and negative aspects, and a more recent “mixed method” approach to research lies somewhere between these two ends. A combination of qualitative and quantitative data collection methods is aimed to benefit from the advantages of each approach, in order to provide a robust method of validating and investigating findings. Mixed methods may be used within a study or over a program of research, and an example of such is provided in Box 15.4.

15.5.5 Classifications of Research by Time

Research can also be categorized according to the time in/over which it is conducted. This can include retrospective studies, prospective studies, and cross-sectional and longitudinal research.

15.5.6 Cross-Sectional Study Design

A cross-sectional study is an observational study that collects data from a group of similar individuals (cohort) or a representative population at one specific point in time or over a period of time. It may be descriptive and used to assess certain distress of a disease or treatment in a defined population. A cross-sectional study is quick and easy to conduct and good for generating hypotheses, and an example of such is provided in Box 15.5. A weakness is that the onset of the outcome is difficult to determine and that associations may be difficult to interpret.

Box 15.4 Mixed Method Research in the HSCT Setting

Niederbacher et al. (2012) investigated quality of life (QoL) following allogeneic hematopoietic stem cell transplantation (HSCT). Forty-four patients were monitored and followed up for at least 3-month posttransplant. Quality of life was evaluated via the Functional Assessment of Chronic Illness Therapy–Bone Marrow Transplantation (version 4) questionnaire with all patients and semi-structured, problem-oriented interviews with seven subjects. The authors compared results from the quantitative and qualitative parts based on triangulation – a method aimed to increase confidence in findings by use of two or more independent measures (Bryman 2008). Findings suggested <25% were highly satisfied with their QoL, with women scoring lower than men. The results revealed a positive correlation between the post-HSCT period and QOL ($r_s = 0.338$, $P = 0.025$), especially regarding the social/family ($r_s = 0.411$, $P = 0.006$) and emotional well-being ($r_s = 0.306$, $P = 0.043$) aspects. Interviews, however, revealed dependence and inability to work while also acknowledging support from family and healthcare professionals and a shift in priorities. By using mixed method approach, authors were able to say that the comparative quantitative and qualitative parts of the study demonstrated corresponding results.

Box 15.5 Cross-Sectional Studies in the HSCT Setting

Dyer et al. (2016) assessed 421 Australian survivors (57% male, 43% female) of HSCT sexuality and reported sexual inactivity in 12% of both male and female survivors and sexual difficulties in 51% of sexually active male survivors and 66% of sexually active female survivors. Men reported erectile dysfunction (80%) and
15.5.7 Longitudinal Study Design

A longitudinal study is alternative to a cross-sectional study in that data is gathered for the same subjects repeatedly over the study period. As a consequence, longitudinal research can extend over many years or even decades depending on the aims of the study.

Box 15.6 Longitudinal Study in the HSCT Setting
Kupst et al. (2002) undertook a prospective longitudinal study of cognitive and psychosocial functioning in pediatric HSCT patients. They assessed the children on three occasions: pre-HSCT, 1 year post-HSCT, and 2 years post-HSCT. 153 children and adolescents were evaluated pre-HSCT and at 1 year, with 2-year data available for 74 children. Longitudinal analyses of Wechsler IQ data were completed on 100 children (longitudinal exact test) and 52 children (repeated measures analysis of variance). Results of cognitive assessment indicated (1) stability of IQ scores over time and (2) that the strongest predictor was pre-HSCT cognitive functioning. Psychosocial assessment results indicated (1) a low prevalence of behavioral and social problems, (2) stability in functioning over time, and (3) pre-HSCT functioning strongly predictive of later functioning.

Box 15.7 Prospective Studies in the HSCT Setting
Syrjala et al. (2008) reported the most extended longitudinal study in relation to sexual function changes during 5 years after HSCT report that 46% of males and 80% of the female patients have sexual problems 5 years posttransplant. Both men and women declined in average sexual function from before transplantation to 6 months after transplantation. Women did not improve from 6-month posttransplantation levels by 5 years. Men improved significantly by 2 years. A weakness of this study is that the baseline measurement is before transplantation, ideally the baseline measurement would be carried out before induction chemotherapy.

Crooks et al. (2014) determined whether the use of a single-item screening tool and a problem list could monitor patients’ distress and the relations. All consecutive
patients scheduled for an allogeneic transplant between January 15, 2012, and December 17, 2012, who gave informed consent after being informed were handed a packet that included a short demographic sheet, distress thermometer, and problem list. The final sample included 37 patients; they were approximately 54 years of age, range 32–66 years, and had more males (62%) than females (38%). Distress was measured at the transplant talk, discharge, and 3 and 6 months post-discharge. Using the distress cutoff score of 4 as the criterion, 59% had clinically significant distress at time point 1, 58% at discharge, 43% at 3 months, and 19% at 6 months. The results show the use of a one-item screening tool and problem list to monitor psychosocial distress over time as a potential method to coordinate the care to address problems.

15.5.9 Retrospective Study Design

A retrospective study is one which looks backward, often by looking through patients’ notes or registries. It will collate information and examine variables in relation to an outcome (e.g., survival) that is established when the protocol is written at the start of the study. This methodology is useful if the outcome of interest is uncommon, and a prospective investigation would have to be too large to be feasible. Retrospective studies may be carried out prior to commencement of a more targeted prospective study to validate the field of study.

15.6 Ethical Issues in Nursing Research

Throughout the research process, the protection of those participating is paramount. Guidance on the ethical conduct of clinical trials is provided both locally within institutions and nationally and internationally and is based on key documents such as the Nuremberg Code (1947) and the Declaration of Helsinki (2002). Methods to protect human rights include the process of gaining informed consent from each potential subject to participate in a trial, as well as the review of any study and its documentation, by an independent ethics committee.

The process of informed consent is more than a signature on a document. Participants must be aware of the implications of participating in the study, the potential risks and benefits, anonymity and protection of privacy, the voluntariness of their participation, and right to withdraw consent to participate at any time without suffering negative consequences. This information tends to be within a participant information sheet (PIS) and related consent form (CF). These are documents that will also be revised by the independent ethics committee. Potential participants

Box 15.8 Retrospective Study in the HSCT Setting

Aoudjhane et al., on behalf of the Acute Leukemia Working Party of EBMT (2005), compared the results of patients who underwent a reduced intensity conditioning regimen (RIC) prior to HLA identical HSCT, to those after myeloablative (MA) regimen HSCT, in patients with acute myeloblastic leukemia (AML) over 50 years of age. Outcomes of 315 RIC were retrospectively compared with 407 MA HSCT recipients. In multivariate analysis, acute GVHD (II–IV) and transplant-related mortality were significantly decreased ($P = 0.01$ and $P < 10^{-4}$, respectively), and relapse incidence was significantly higher ($P = 0.003$) after RIC transplantation. Leukemia-free survival was not statistically different between the two groups. These results may set the grounds for prospective trials comparing RIC with other strategies of treatment in elderly AML.
should be provided with these documents and have time to both read and assimilate the information, with opportunity to discuss and ask questions so that there is a clear and complete understanding of all aspects of the study. The purpose of ethics committees, however, is to ensure the interests of the participant are accounted for when evaluating studies for approval. This includes evaluating whether the study is ethical, the completeness and appropriateness of documents such as the PIS and CF, and reviewing aspects of the design to ensure its correct conduct.

Ethical considerations in nursing research are sometimes rather complex, and just a simplified overview has been described in this chapter. The requirement for approval to conduct research should be discussed at a local level with research and development units or with the local ethics committee secretary, who will usually be able to provide guidance on the types of approval for the type of research being undertaken. This may also include approval from the national regulatory bodies in some cases. Research should not be undertaken until all necessary approvals have been received and documented. The process of approval may be lengthy if amendments to documents or even research protocols are required in order to address concerns raised by one or more of the approval bodies. This potential for delay should be considered when research is being planned.

**Conclusion**

One of the key factors for nursing research is that we are aiming to produce results and increase our knowledge base in a way that is quickly translatable into clinical practice. In a rapidly developing field such as HSCT, research helps to provide evidence on which to base standards for care, thus helping to ensure the safety and efficacy of our practice with a very vulnerable patient population. Planning a potential study is often the aspect of work which is most time-consuming. It is, however, imperative to get this right to prevent delays further down the line (e.g., with the ethical approval process). For that reason, teamwork is highly recommended as is support from experts/experienced researchers. It is beyond the scope of this chapter to provide specific details for all aspects of the research process, but rather the aim was to provide guidance on the main concepts, which require thought in order to complete a successful project. Research is an integral part of the future of HSCT, and as qualified nurses, we have a duty of care to our patients to become involved in whatever way we can. Finally, it is important to remember that negative results can be just as useful as positive ones, if not more so; please do not let such an outcome, if it should occur, put you off publishing.

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