

When Nursing Care and Clinical Trials Coincide: A Qualitative Study of the Views of Nordic Oncology and Hematology Nurses on Ethical Work Challenges

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Abstract

This study investigated the kinds of ethical challenges experienced by nurses in oncology and hematology when nursing care and research overlap in clinical trials, and how the nurses handle such challenges. Individual interviews with 39 nurses from Sweden, Denmark, and Finland indicated that all nurses were positive about research, considering it essential for developing the best care. Ethical challenges exist, however; the most difficult were associated with the end-of-life patients, no longer responsive to standard therapy, who eagerly volunteer for cutting-edge drug trials in the hope of gaining therapeutic benefit. Many nurses lacked systematic strategies for addressing such challenges but found support from their nursing colleagues and relied on the research protocols to guide them.

Keywords

ethics, cancer/oncology, informed consent, clinical trials, hope, end-of-life, hematology

Introduction

In the Nordic countries, hundreds of clinical trials are run in hospitals every year and thousands of patients volunteer for participation. Through the Nordic Trial Alliance (NTA), all Nordic countries are trying to implement the EU Regulation No. 536/2014. It aims to decrease bureaucracy and accelerate the speed and efficacy of pharmaceutical clinical trials by stimulating, harmonizing, and improving conditions for a common Nordic pharmaceutical industry. A research center in one country cannot always offer the required number of patients, but collaboration allows for larger and more efficient clinical studies.

As the number and complexity of clinical drug trials has increased, so has the number of research nurses employed as key members of the research teams (Catania et al., 2012). Research nurses focus on recruiting patients, coordinating and monitoring trials, and keeping the practice up to date. However, as more staff are needed for research to run efficiently, almost any nurse can be engaged with biomedical research (Hamer, 2015). Nurses in leading roles can be very important for ensuring an adequate research framework in their wards and for educating and supporting the nursing staff (Nurmi, Pietila, Kangasniemi, & Halkoaho, 2015).

However, the nurses do not necessarily share one perspective on the importance of research. Nurses who primarily work with care often do not understand the nature of

clinical research nurses' work; they perceive them as primarily doing "paperwork" and find the research protocols remote from hands-on clinical care (Gordon, 2008). Such differences can possibly extend to ethical issues.

The work of nurses is imbued with moral concerns, as they constantly take part in ethical decision making (Hoglund, Helgesson, & Eriksson, 2010) and are professionally obliged to take action against unethical practices (International Council of Nurses [ICN], 2012). One group of oncology nurses could identify 32 types of ethical issues encountered in their work during 1 year. The most frequent related to pain, costs, decisions about what was in the best interest of the patient, quality-of-life decisions, staff relationships, and truthful disclosure to the patient regarding treatment (Raines, 2000).

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Table I. Interview Guide.

I. Experiences when recruiting
What does it mean for you to work with care and research? (opening question)
Can you describe how you inform patients about a research study?
What factors do you believe affect patients' willingness to participate most?
Do you think patients understand the difference between medical care and research?
II. Ethical issues
Have you felt on occasion that it would be unethical to include a patient, or ethical to exclude a patient?
Do you think there can be conflicts between personnel regarding care and research?
Have you met patients with unrealistic hopes for improvement?
Do you think patients want to participate in anything that they believe offers hope?
III. Strategies for dealing with dilemmas
Do you discuss ethical issues in your workplace?
Do you remember how you or any colleague successfully dealt with one?
Do you feel that there are obstacles in your workplace that make it difficult to act ethically?
Is there something in your workplace that makes it easy to act ethically?

In the nursing literature, there has been growing concern about whether the ability of nurses to act ethically is being compromised (Dierckx de Casterle, Izumi, Godfrey, & Denhaerynck, 2008), a situation which could have dire consequences. Storaker, Naden, and Saeteren (2017) found that newly graduated nurses are committed to everyday ethical concerns, but that they gradually begin to change their ways, mostly as a result of the busyness of daily work and being socialized into a work culture where ethical concerns are not a priority. Time restraints and a heavy workload made them undergo a process resulting in moral blindness and emotional immunization. In the field of oncology, nurses face complex challenges in trying to meet their patients' needs, especially when they encounter patients participating in clinical cancer trials (Beadle, Mengersen, Moynihan, & Yates, 2011). Beadle et al. found that most Australian oncology nurses had dual roles, in that, they were trying to accommodate both nursing and research values. More than 50% of the nurses thought that patients do not always grasp the nature of and risks involved with trials. They also found that some patients harbor unrealistic expectations for potentially very toxic treatments; they can also be quick to consent to research with limited drug efficacy. Although the nurses agreed strongly that clinical trials are a superior way of generating new knowledge, one fourth believed that research has an associated risk of exploiting vulnerable patients.

Little is known about the kinds of ethical challenges nurses might struggle with when caring for oncology and hematology patients who participate in clinical trials. As the pressure to do more Nordic clinical studies with higher efficiency increases, there is a risk that ethical challenges are overlooked and not sufficiently addressed. To our knowledge, no empirical research exists that addresses these questions in a Nordic context. The aims of this study were, therefore, to explore (a) the kinds of ethical challenges nurses in oncology and hematology experience when

nursing care and research overlap and (b) how they handle such ethical challenges.

Method

Because of its flexibility in exploring individual views and experiences, an explorative, qualitative design with semistructured individual interviews was used (Braun & Clarke, 2013). In the interviews, we asked about open concepts such as ethical "problems" and "challenges" to elicit the broadest possible range of experiences and perceptions thought to have an ethical component.

Sampling, Recruitment, and Data Collection

Inclusion criteria for participants were that they should be nurses working with oncology or hematology patients participating in clinical trials. Each hospital department head permitted the study. It was intended to recruit nurses from four Nordic countries, but due to difficulties getting access to departments in Norway, this study included nurses from four hospitals in Finland, Sweden, and Denmark.

A semistructured interview guide was used (Table 1). Three pilot interviews assessed whether questions were appropriate and comprehensible, leading to minor adjustments. The interview guide had three topics: (a) recruitment experiences, (b) ethical issues, and (c) potential strategies.

Interviews were performed by all authors except MM and SE and took place in rooms close to the hospital wards during regular working hours. The interviews lasted approximately 30 to 60 min, were audiotaped, and were transcribed verbatim.

The study includes 39 individual interviews with nurses (Table 2). Most nurses were female (95%) and one third held a master's degree. The main difference among the nurses was in work practice, which ranged from less than a year to almost 40 years of experience. One third were

Table 2. Participant Characteristics.

	Nurses (n = 39)
Gender	
Female	37
Male	2
Age (years)	
Range	<29 to >60 years
<29-39 years	13
40-49 years	10
50 to >60 years	16
Education	
Bachelor's degree	24
Master's degree	15
Working years in oncology/hematology	
Range	3 months to 34 years
Mean/median	11/9 years
Practice setting	
Oncology	27
Hematology	12
Familiar with	
Phase I trials	13
Phase II trials	21
Phase III trials	35
Country	
Denmark	19
Sweden	12
Finland	8

familiar with Phase I trials, slightly less than half were familiar with Phase II trials, and nearly all were familiar with Phase III trials. For detailed characteristics of clinical trial phases, see Table 3.

Data Analysis

Qualitative, inductive content analysis was undertaken (Burnard, Gill, Stewart, Treasure, & Chadwick, 2008). All interview transcripts were treated as one unit, regardless of where the interviews had been carried out, as the Nordic research area is characterized by having research collaborations, similar health care systems, and are planning for a unified Nordic market for clinical trials. The analytical process started during the data collection (Pope, Ziebland, & Mays, 2000). After the first 12 interviews and repeated reading of the transcripts, the study group met, discussed the content of the interviews, and agreed upon the codes to be used. The next three interviews were coded by ZEN and TG and, as a result, more codes were added. The interviews were analyzed and the content and concepts discussed by ZEN and SP for the Danish results, TG and SE for the Swedish results, and AH and MP for the Finnish results. For the Finnish interviews, a summary and list of proposed quotes to use were translated into English. The first author (TG) used ATLAS.ti

8 to analyze the Swedish and Danish interviews and identify all the codes. After having read the transcripts repeatedly, the first analysis was done by TG and MM, and categories were proposed for organizing the content of the interviews. These were then discussed by all the authors. Disagreements of interpretation were solved. When consensus was reached, the content of the interviews was summarized into themes.

A limitation was that the Finnish transcripts could not be read in full by all authors. However, the study groups were uniform regarding views and outlooks. The analysis started with a 2-day workshop, where all researchers met and began the initial analyzing process in consensus, which strengthens the analysis. As with all qualitative research, it is up to the reader to judge whether these results are transferable to other contexts.

Ethical Considerations

This study was performed according to the regulations and guidelines of each country. No ethical approval was required for a noninterventional study without risks or any processing of sensitive personal data taking place. The head of each hospital department gave authorization for approaching the professionals. The study otherwise followed the Declaration of Helsinki (World Medical Association [WMA], 2013). The nurses were informed about the study, about the handling of personal data, and that personal information would be kept confidential. Written informed consent was obtained. To protect the nurses' confidentiality, they were only identified according to country and a designated number (D for Danish, S for Swedish, and F for Finnish interviewees).

Results

The results describe ethical challenges encountered when nursing care and research overlap, as experienced by 39 nurses working in oncology or hematology (four of them not only were working as research nurses but also had work assignments related to care). The results are presented in three overall themes, see Table 4.

It should first be noted that the nurses shared a common, positive view of research. They all said that it is essential that their clinic be intimately connected with research. As best available evidence must underpin health care, clinical trials were seen as a means of offering severely ill patients cutting-edge treatment. Furthermore, they perceived research as important for developing their professional role. Finally, they found supporting patient choice important, and most patients are positive about clinical trial participation.

Patient-Related Challenges

Informed consent. To inform patients when recruiting was often mentioned as challenging: "To inform and to do it

Table 3. Intent and Characteristics of Clinical Trials.

Phase I trials—Safety and dosage
 To determine safe dosage range
 To determine maximum tolerated dose
 To identify short-term side effects
 To identify the absorption, distribution, metabolism, and excretion of the drug, and to evaluate its biochemical and physiological effects
 To determine whether the drug is safe enough to proceed to Phase II tests.

Phase II trials—Efficacy and side effects
 To determine the efficacy of the treatment in patients with specific types of cancer or conditions
 To further assess side effects
 To determine the best dose
 To determine whether the drug works well enough to proceed to Phase III tests

Phase III trials (randomized, controlled trials [RCTs])—Efficacy and monitoring of side effects
 To monitor side effects and identify long-term and/or rare side effects
 To compare the new treatment with standard or other experimental treatments
 To determine the range of standard treatment doses

Phase IV trials—Safety and efficacy
 To be carried out after the drug has been marketed
 To further evaluate safety, efficacy, and best dose in the general population or specific subgroups

Table 4. Themes and Categories From Content Analysis of Narratives About Ethical Challenges Nurses Encounter When Nursing Care and Research Overlap.

Themes	Patient-related challenges	Workplace challenges	Strategies for dealing with challenges
Categories	Informed consent	Nursing workload, competence, and patient safety	Individual responses
	Balance of risks and benefits for individual patients	Being subordinate	Finding support from colleagues
	Hope		Inclusion/exclusion criteria as help

pedagogically . . . so it meets a person’s needs is really difficult, I think . . . ” (D1). Many patients read the consent information and have quite a good understanding of what a clinical trial involves. However, many nurses also said that some patients sign up without adequate understanding: “When I inform a patient, it sometimes feels like the patient is so stuck in a turmoil, that they might not understand and internalise everything” (F3). It was noted that this was also observed when patients consented to standard care.

Not all patients show much interest in the information: “Some are very interested in everything and read articles, and some are not interested at all” (F7). Another nurse stated that “they sign, for their own sake or perhaps for someone else’s. Without them really . . . probably not grasping the content . . . what it really says” (S2). Some nurses found that patients’ circumstances could influence decision making; even when given relevant information, some patients did not acknowledge it: “They are simply not able to accept that the situation is so bad” (F2). Nurses had some concerns regarding patient autonomy and whether the decision-making process is free of pressure or coaxing. As one nurse expressed it, “. . . likely one offers it [in a phase I study] as a drug to keep you alive longer

. . . of course it can also work as a kind of pressure” (S11). Another nurse narrated how she sometimes “can notice how patients are overwhelmed, and that this is something they are pressured to; then I can feel quite a need to state: this is voluntary, and it is up to you . . . ” (D12). Another nurse saw how trust and the will to be complaisant can sometimes determine a decision:

[Many patients want] . . . to please . . . most do trust health care. And they say . . . “What do I know? I trust you to make the right decision for me.” So I think it is very hard for them to understand at all what they are getting themselves into. (S4)

Some nurses reported that they sometimes felt uneasy about information given by physicians. They sometimes felt that the trial protocol was “sold” to patients by being presented as more effective than supported by the evidence:

. . . but maybe sometimes I feel that the physicians are a bit too positive about previous results and what to expect in the trial. While I find us nurses sitting there thinking: “But we do not have anything effective.” Interviewer:—So you feel it is being over-sold?—Yes, a little. Yes, I actually do. (D16)

Several nurses were concerned that this positive attitude toward the protocol could result in patients sometimes being offered treatments with only minor potential benefit; however, that also had the potential for substantial harm: “I don’t believe [side effects and risks] are accentuated when informing. I believe one does it a bit haphazardly, and I do not believe that information is repeated” (S11). Not all nurses agreed on this:

I do not find [information] to be sugar-coated, like “just look what we have for you, it is not very hard” and such. They expect this to be difficult, there are many visits, we cannot guarantee anything, we don’t know the side effects you’ll get, and you should really consider how to spend the time you have left. (D19)

Next of kin were mostly seen as resources for the patients. “Yes, they talk, and probably the relatives are a kind of resource and they talk a lot” (F2). But sometimes their presence and influence could add to the challenge: “. . . rarely the patient just says yes or no to a research protocol, there’s also a whole support team of family and friends . . .” (D19). Nurses mentioned that, in some cases, the relatives maneuver the patient so that patients cannot really make up their own mind about whether to participate or not:

Yes, there was actually a patient where the family was very engaged . . . and once I heard him [the patient] crying and saying “I just want to go back to that beach; we had such a good time watching the sunset.” I believe it was the wife or son beside him who said “well, in a week the treatment starts and this is what we will do.” I just don’t think they heard him, as a matter of fact . . . and I thought: oh, and it was hard . . . I think that is a bit of a problem. (D16)

Balance of risks and benefits for individual patients. Patient choice can rely on trust or information that is made to appear attractive, as per above; and, there is also a risk that patients make decisions that strike the nurses as folly. On one hand, patient involvement in decision making was seen as crucial, and nurses were concerned about not taking over the decision and supporting the patient choice. On the other hand, this supporting role could be demanding, as nurses might disagree with the patients’ decisions: “[One’s own views] should be kept to oneself, and that can be a dilemma” (D3). One nurse gave an example: a patient with a complicated medical history and poor prognosis, eager for enrolment in a Phase I trial even though it involved many visits to the hospital and harsh side effects.

He had great faith that going to the big hospital, this study drug would be beneficial. He drove there himself . . . and he had to stop at every resting place . . . because of persistent diarrhoea . . . to get this treatment that gave him nothing, except a lot of side effects which bothered him greatly. See, I find that difficult, because it intervenes so heavily in his life and daily routines . . . (D8)

Such patient narratives were often reflected upon in the interviews and, for many nurses, patients such as these who are at the end of their lives and in a very poor state of health were of particular concern. The patient eager to enter a trial also illustrates a common trend in the interviews: Patients often want to enroll in all kinds of research to obtain cutting-edge drugs, while they appear not to care about the associated risks and side effects. One nurse said, “I simply believe that some patients hope so much, that the other concerns will be secondary” (D12). Another felt that “if it is a last chance for the patient, they will take it because they have nothing to lose” (F6). Many nurses mentioned this concern as ethically difficult, as some patients “are so desperate” (F2).

Hope. Hope was a source of ethical challenges throughout the interviews. Most nurses narrated how they found patients striving to keep their hope despite serious illness, and how this hope was essential to their lives: “. . . whenever they start on a new drug, there is still a hope that the progression of the disease will be slowed or stopped” (F4). Some patients go further and aim for a full recovery, they “think they ultimately will be cured of the disease, and they will get better in a way, but it’s not necessarily said . . . that the disease will come back after some time” (F4).

Being in an existentially difficult position, with a persistent urge to live, can make patients look uncritically at research protocols. Hope for a potential cure can make patients deaf to the information given, not wishing to hear or acknowledge reality. Sometimes, nurses had watched patients fluctuate between hope and realism in their efforts to sustain a normal everyday life:

. . . basically they [the patients] know, but they hope for something else . . . when living with illness, one has to hope for the best. You cannot function in everyday life if you think you are going to die tomorrow . . . (D10)

When patients appeared to be experiencing seemingly unrealistic hope, many nurses found it ethically challenging to decide whether, or to what extent, they should inform the patients of the realities of their prognoses: “. . . and thus always balancing between neither being the one who dashes hope nor being unrealistic, which I perceive as unethical for us” (D19):

I had a woman, not very old. I don’t know, just over 50 . . . they sort of said she already felt very ill and was quite sick, so this could . . . you sort of could die from the side effects . . . but in that situation there was like no hesitation at all on her part. She just wanted to get well . . . She reacted really negatively, got it again and yet responded like that . . . and you could see it had no effect on the disease and you had to speak your mind. And the total disappointment; she really put all her hope on this. And I have seen this several times . . . one perceives it as a life line. It is like being offered a rope, you know: “Climb this and . . .” (S 11)

This ethical challenge was handled by some nurses by consistently focusing on viewing hope as an individual experience and staying true to their role as decisional support for the patient: “. . . and what is hope then? Is it the hope for a cure? Is it hope for a longer time? Is it hope for a good month? Hope can take so many forms . . . ” (D6). However, nurses narrated how not all patients would let hope control whether they agreed to participate in research. Often the patients who declined were either very fragile with few resources or they had values other than staying alive as long as possible:

Their quality of life is important to them . . . there are also some who would rather have peace and quiet at home during the final time . . . and for others it is important to have hope of living longer . . . (D14)

So, to summarize, ethical challenges were often described by the nurses. The concerns were mostly related to patients with poor prognoses and those where the nurses did not know whether the consent was based on seemingly unrealistic hope or the influence of others. They were also concerned that patients possibly did not understand that a trial was unlikely to give any therapeutic benefit and were not acknowledging that it could cause severe side effects and a loss of quality of life.

Workplace Challenges

Nursing workload, competence, and patient safety. Patient safety was often mentioned as a challenge by the nurses. This was mostly related to high work pressure, lack of time, and not having specific information on the experimental drug they were administering.

A huge workload and insufficient time for research-related work were mentioned as significant challenges. An ongoing protocol results in “extra work and disruptions to clinical practice” (F8), and because trial drugs are not frequently used at the ward, this could be stressful and could affect the quality and safety of the care provided:

Protocols are different as you must, must do a lot of other things, often when you have it hectic . . . we should do it, but if there are ten treatments and protocols and you have a, a study nurse breathing down your neck . . . (D10)

Many nurses reported being uncomfortable in situations where they felt they were unprepared to deal with safety issues (mostly during evenings or night shifts). One gave an example of not having been ready to deal with an adverse event:

We have had patients on the ward where physicians and study nurses have said that “according to protocol this patient should be kept overnight, but we expect nothing to happen,” and then the patient gets . . . very, very ill! . . . What has been administered to this patient? . . . Usually, you know what you have administered and . . . you can read in the medicines compendium

and know what to expect regarding side effects. But this is distressing. (S4)

Although formal training for the specific trials was conducted at the clinic, many nurses experienced not being adequately informed, prepared, or trained for the ongoing trials at the ward. Sometimes, they had not been at work at the time of training and often there were months between the training session and seeing a patient who was receiving the specific protocol. Many nurses requested more routine, experience, and continuity in their work with specific clinical trials.

For me, it’s difficult because I don’t have the same experience with it [research protocols]. Also because you don’t have them very often. Then you have one and then again 10 weeks after, so you don’t get it incorporated and see what’s going on. (D4)

As a result, many nurses were unable to answer questions from patients and next of kin. They could not describe the protocol, the procedures involved, or when the trial would start, for example. Again, being underinformed in this way could be considered an issue of patient safety.

You feel uncertain; you are not used to it [the study drug] and might not have received information, not being present for it, and then a colleague asks “how should this be administered” and such. “What side effects are there?” Yes, you are not fully briefed and have to trust others and some things might easily be missed; a test that should have been taken, and so on. (S12)

Being subordinate. A challenge mentioned by many nurses was the professional discrepancy between nurses’ and physicians’ views on active treatment and treatment withdrawal, where nurses’ values were perceived as being subordinate:

Physicians, they sort of have their oath, and they should cure, you know? Whereas we go much more into quality of life, meaningfulness, and all those things. Sometimes these might very well collide. (D12)

. . . they [physicians] consider the patients, of course, but mostly they think about the trial and the data . . . whereas we nurses, we are on the ground floor, close to the side effects when patients tell, you see? While the doctor . . . well, they note down the side effects, but I do not think they fully appreciate what they do to the everyday life of the patient. For me, that maybe, yes, it is a bit problematic. (D16)

Despite the professional discrepancies experienced, some nurses addressed and discussed ethical questions with the treating physician when a patient issue became apparent. Through such communication, some of the nurses developed a common understanding with the physician, whereas others found that the physician had the opposite opinion, which could lead to ethical conflict:

When I as a nurse don't agree with the decision of the physician, I still have an obligation to be loyal to the decisions being made, and in such a situation my opinion can result in a dilemma, and then I have an ethical conflict. (D5)

Some nurses also described how they often find it challenging to discuss ethical issues with physicians in multidisciplinary forums. "In a way, it takes a lot of courage to bring forth issues with which you disagree" (F4). This was mostly related to differences in perspective, where physicians focused on the treatment itself and its side effects, whereas nurses emphasized the patients' quality of life and aspects of meaning making.

Well, that there is a bit of difference is an old cliché. You know, nurses versus doctors, that we experience how some differences can be difficult. You could say a doctor looks at a patient and orders treatment, while the nurse will perform the actual procedures and administer the medicine to the patient, perhaps while not being completely in accord with the decision taken. Here I think we nurses might see it as being all very well to sit there and make a decision, not being the one having to inject the drug into someone's arm, if you follow me. To be a bit crude. (D12)

When ethical discussions were conducted in multidisciplinary forums, many nurses experienced that, despite the challenges described above, professional discrepancies were replaced with a mutual interdisciplinary understanding. The nurses commonly wished for more opportunities to discuss ethical issues in formal multidisciplinary settings.

Strategies for Dealing With Challenges

Many nurses could not identify any individual or organizational strategy that dealt systematically with the issues discussed in the interviews: "No, I have no strategy, I suppose, but you talk, you talk with all the others about it" (S9). Ethical deliberation was sometimes conceived of as an integral part of the daily work at the clinic. "You have to have good arguments . . . and you need to question, is this really proper . . ." (F6). We found three suggestions for strategies used.

Individual responses. There were some suggestions as to how ethical problems were dealt with. Usually, they were individual responses to a situation or attempts to find support from colleagues. For example, when nurses were asked about how they dealt with ethical challenges such as patients with seemingly unrealistic hope choosing aggressive treatment and then experiencing severe side effects for no therapeutic benefit, one nurse said,

Well, actually I think I am very honest about what I think . . . They should also know it is possible to choose other things that

hold significance for them, having a different quality of life or freedom. It might very well happen that they live a month or half a month less, but they would be better off. This, in my mind, is a very important task for a nurse, not talking people out of it, but informing them about what could happen if you are one of those who get harsh side effects. (D8)

Finding support from colleagues. The nurses had many discussions and meetings among themselves and had no problem talking about ethical issues in those circumstances. However, some nurses said they seldom discuss research ethics. As one nurse put it, "I would almost like to say that we discuss every other problem, except those related to research" (S7). Most nurses emphasized how they gain support from each other, both at hand-over meetings and at ad hoc meetings over breakfast or coffee when needed. They underlined that to deal with ethical challenges, it is essential to have someone to share challenges and difficulties with, in an open, supportive, and accepting setting. As one nurse stated,

Well, you see it is this openness . . . that it is ok to say that this is very hard for me to take part in . . . that it is acceptable, and no one will give someone a belt when you say: this here I find to be quite a challenge. (D12)

Inclusion/exclusion criteria as help. The last item mentioned was that the exclusion and inclusion criteria of the protocol could be of great help when a patient's condition was too bad for him or her to participate in an experimental treatment. Then, the criteria could lend support to a nurse's patient observation. When being asked whether there ever were times where it felt unethical to include a patient, one nurse answered,

Yes, but then the person in question have not been included; again, I find the criteria so strict so we did not . . . or they are expelled later on, as they were unable to make it. (D7)

Discussion

The results showed that all nurses were positive about research, considering it essential and necessary as health care ought to be underpinned by the best available evidence. This positive attitude corresponds to what has been found in other studies (McSherry, Artley, & Holloran, 2006; Oranta, Routasalo, & Hupli, 2002; Timmins, McCabe, & McSherry, 2012). Nonetheless, nurses in Sweden, Denmark, and Finland have encountered ethical challenges, mainly of two kinds (patient related and workplace related).

Patient-Related Difficulties

One of the central challenges highlighted by the nurses was related to patients with progressive disease who were no longer responsive to standard therapy and who eagerly volunteered to participate in cutting-edge drug trials, putting

great hope in some therapeutic benefit. Many nurses were concerned about such seemingly unrealistic hope and saw concerns for well-being becoming secondary to research participation for many patients. They questioned this, pondering whether patients would not gain more from palliative care and by spending their final time prioritizing values other than research. Nonetheless, all the nurses found it very important to support the patients' autonomous decisions. It is interesting that the nurses found that patients who were asked to participate usually volunteered without restrictions and that many potential participants of Phase I trials were eager to enroll. This echoes earlier findings indicating that patients often harbor unrealistic expectations and are prone to participate in research with limited drug efficacy (Beadle et al., 2011; Godskesen, Nygren, Nordin, Hansson, & Kihlbom, 2013; Ulrich et al., 2012). One nurse in our study illustrated these concerns by describing a patient eager to participate in a Phase I trial. From the nurse's point of view, there were no benefits for the patient in taking part; yet, he had to endure the embarrassing burden of dealing with persistent diarrhea when traveling to the hospital. In this context, nurses often struggled with the dilemma of whether it is ethically right to support patient hope when they choose to try aggressive drug trials. They often saw how patients with no other treatment options found renewed hope by enrolment; the trial offered a way to fight their illness. As Phase I trials have a nontherapeutic purpose, the nurses questioned whether, in fact, participation can be seen as always being in line with patient preferences, needs, and values.

Many nurses found that participants lacked knowledge of what participating in a study entails. This has been seen in, for example, Beadle et al. (2011), who found a majority of nurses believed that patients do not always understand the nature and risks of cancer trials. This was also reported by Ulrich et al. (2012); nurses described informed consent as one of the top three ethical challenges in clinical cancer trials.

Patients have also expressed how they often find the consent process vague and ambiguous and have indeed been shown to lack understanding (Cox, 2000; Godskesen et al., 2013; Mangset, Berge, Forde, Nessa, & Wyller, 2009; Sulmasy et al., 2010). Studies have shown that trial information is not very relevant to the patient's decision regarding trial participation; they have often already decided to participate before receiving specific information or a few minutes after the offer of participation (Godskesen et al., 2013; Shannon-Dorcy & Drevdahl, 2011). Many patients admit never having read the specific trial information, and some reported that they deliberately ignored parts of the trial information given to them (Shannon-Dorcy & Drevdahl, 2011).

A possible explanation for this is that patients learn about clinical trials in two specific settings: the clinical

setting, where patients have learned that health care professionals are supposed to deliver personal care in the best interests of the individual patient; and the research setting, where the consent form is often packed with unfamiliar terminology and where important information can easily be overlooked. Some nurses noted the risk of physicians presenting trials in an overly positive light, indicating that clinical trials are state-of-the-art treatment. Studies show that patients often follow the physician's recommendation on trial participation; thus, the physician's attitude toward the trial has a big influence on recruitment (Somkin et al., 2013). This may compromise the informed consent process. Nurses also believed that the media might often shape public attitudes toward experimental research, not least by running "magic bullet" headlines where preclinical research is portrayed as significant treatment breakthroughs. This means that patients may find support for their (desperate) optimism from the clinical setting, from the attitudes of the health care personnel, and from media reporting. Taken together, these influencing factors can be thought of as drivers for the resulting positive attitudes. The understanding that the research process is slow, and that the evaluation and development of a new drug has historically taken about 10 to 15 years, is much harder to reach.

Another explanation could be the cultural setting patients live and act within. According to Sulmasy et al. (2010), patients' high expectations of getting therapeutic benefit from clinical trial participation do not necessarily imply that the patients have misunderstood the facts or have not been accurately informed. In their study, many of the patients participating in early phase oncology trials reported an accurate understanding of the trial purpose even though they simultaneously expressed seemingly unrealistic hope concerning therapeutic benefit. According to Sulmasy et al., this discrepancy can be understood as patients conforming to cultural expectations concerning the maintenance of optimism—and trial participation could be a way for patients to express and confirm such expectations. Moreover, many patients believed that being positive and showing optimism in front of others could improve their chances of benefit from the treatment.

Workplace-Related Difficulties

Nurses often found it challenging to discuss ethical issues with the physicians, an experience commonly related to the position of being subordinate. A typical issue found to split physicians and nurses were end-of-life issues, such as withholding or withdrawing treatment. According to the nurses, physicians are more prone to opt for radical treatment and participation in research with minimal chance of medical benefit. Nurses instead endorse a transition from curative to palliative care and emphasize the quality of life and aspects

of meaning making, a finding that ties in with a study of Oberle and Hughes (2001). The authors hypothesized that this difference has its source in different mandates as caregivers. Doctors have the burden to *make* the decisions and nurses have the burden of *living with the decisions* made by others. This difference in mandates and views also made it difficult to discuss ethical issues in a multidisciplinary setting.

A significant workload and insufficient time for research-related work were highlighted as a significant ethical challenge in this study. This is consistent with, for example, Ulrich et al. (2012), where only one third of nurses concluded that they had sufficient time to explain clinical cancer trials to patients. Nurses in our study suggested that research implies extra work and, sometimes, causes poor compliance with clinical trials, something that has also been shown in other studies (Spilsbury et al., 2008). One study found that clinical research nurses experience pressure regarding recruitment of patients and that industry studies, in contrast to academic studies, can be more business driven. This pressure created a dilemma as nurses, on one side, have a duty of care as patient advocates, whereas, on the other side, they have a mission to recruit participants, as they said, similar to a salesperson (Tinkler, Smith, Yiannakou, & Robinson, 2017). Nurses in our study also indicated that they might lack sufficient knowledge and competence and they, therefore, wanted more information and research training. This echoes the findings of other studies (MacLean, Desy, Juarez, Perhats, & Gacki-Smith, 2006; Ulrich et al., 2012). As in our study, Loh, Butow, Brown, and Boyle (2002) found that professionals often find it stressful when they are not able to answer patients who ask for details about clinical trials and they want more support and education as a consequence (Halkoaho, 2012; Høglund et al., 2010).

Nurses in our study underlined that clinical trials are an important and necessary part of the clinic work; however, due to lack of time and competence, they do not always prioritize research-related work. A high workload and lack of time, competence, and knowledge could have vital consequences for patient safety. Thus, it is very important for sustaining high-quality clinical research that these issues are addressed (Loh et al., 2002). This affected our study as well, as we aimed to interview the same number of nurses in Sweden, Denmark, and Finland. This was not possible, due precisely to the effect of a high workload in Finland and Sweden at the time of the study, which resulted in us getting twice as many informants from Denmark. This might have had an impact on the results discussed above, but we still achieved saturation in each country. A strength of this study is the large sample size ($n = 39$), good representativeness regarding demographic characteristics, and a great variety of both short and long experiences of clinical trials and from all three trial phases.

Best Practices

Faced with the difficulties discussed above, what strategies could be employed to make the situation better? Many facets of the clinical workplace are systematically evaluated and subjected to measures of quality improvement in the Nordic countries, for example, issues of the work environment, employee health, and equal opportunity. However, when it comes to ethical difficulties related to research performed at the clinic, this is not the case. In the daily routine of nursing, ethical issues seem to be discussed a lot among nurses, whereas ethical issues related to research have not been a focus of strategic, systematic discussions. Nurses talk among themselves when pressing issues demand it and they sometimes raise their voices against what is perceived as an ethical problem, but they lack institutional support to develop ethical competence. Lest we forget, it is an essential part of the professional roles of both physicians and nurses to assume ethical responsibility (ICN, 2012; WMA, 2013). Therefore, managers of health care have an overall organizational responsibility to ensure the staff's ability to reflect on ethical aspects of their professional work. We agree with the stated conclusions of Nurmi et al. (2015) that those who lead nurses' work have a duty to ensure good conditions for clinical research at the workplace, by careful planning and managing of, as well as educating, supporting, and motivating, their nursing staff.

Research Agenda

This study indicates a need for subsequent projects to look at the nursing programs in the Nordic countries, asking what would be pedagogically required to facilitate ethical competence and preparation for clinical nursing work that incorporates sound research.

Educational Implications

An important point that emerges from this study is the genuine possibility that nurses perceive themselves as the bearers of ethical, professional obligations, while having a high workload, weighty time restraints, and insufficient information, competence, or understanding of the trials they are involved with, and often not having a say in what is decided for and with the patient. This is potentially a very vulnerable position to be in, if the workplace does not offer enough strategic training and support. It may result in "moral blindness" and "emotional immunization"—something that could affect patient well-being and safety (Storaker et al., 2017). Such ethical challenges could also cause moral stress (Elstad & Vabo, 2008; Glasberg, Eriksson, & Norberg, 2007). We, therefore, conclude with the recommendation that strategic training and support for nurses working with patients in clinical trials be prioritized more strongly, as this

not only is important for the nurses' well-being but also has significant implications for patient safety.

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