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Mapping the risk perception and communication gap between different professions of health care providers in cancer care – A protocol

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Key Words
Direct risk; indirect risk; patient safety; Oncology; Complementary and Alternative Medicine (CAM); cancer care; provider-patient communication

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Abstract

Introduction

In Norway, approximately 50% of all cancer patients use complementary and alternative medicine (CAM) in combination with conventional treatment during their course of disease. Studies show that cancer patients who use CAM have a poorer survival prognosis than those who do not. Part of this increased risk may be due to negative interactions between the two care modalities (direct risk), part may be due to delays in receiving appropriate conventional treatment while the patient is being treated by CAM practitioners (indirect risk) and part may be that patients who turn to CAM have a poorer prognosis at diagnosis. The two former risk-situations are preventable. The global aim of this study is to produce knowledge and interventions that may reduce direct and indirect risk and enhance safety for patients who want to combine conventional treatment with CAM in cancer care.

Methods and analysis

We will delineate, compare, and evaluate perception and clinical experience of communication of risk situations among oncology experts, general practitioners and CAM practitioners. To accomplish this, we will develop a pilot and implement a large-scale survey among the above mentioned health professionals in Norway. Guided by the survey results, we will develop a beta-version of a shared decision making tool for health care providers to use in guiding patients to make safe CAM decisions.

Ethics and dissemination

Participants must give their informed and written consent before inclusion. They will be informed about the opportunity to drop out from the study followed by deletion of all data registered. The study needs no approval from The Regional Committee for Medical and Health Research Ethics, because all participants are health care professionals. Results from this study will be disseminated in medical peer-reviewed journals.

Funding

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Strengths and Limitations of this study

- The methodology of this research project is stronger than previous studies
- There are still some methodological challenges in surveying health care professionals; oncologists and general practitioners are often poor responders, steps must therefore be taken to boost the questionnaire response rate

Introduction

Complementary and alternative medicine (CAM) is a popular treatment modality among cancer patients in Europe [1-4]. In this research project, CAM or alternative treatment is understood as a health-related treatment that is practiced outside the established health services and not practiced by authorized health personnel. However, treatment practiced within the scope of the established health services or by authorized health personnel is also covered by the term alternative treatment when the methods employed are essentially used outside the established health service [5] . Findings from studies suggest that, on average, half of all cancer patients use CAM, and this proportion has increased over the past years [6]. The Norwegian Cancer Society stated that approximately 50% of all Norwegian cancer patients used CAM in 2008 [7] . The majority of cancer patients use CAM because they believe it increases the body's ability to fight the cancer, strengthens the immune system, improves physical and emotional well-being and quality of life or enables the maintenance of hope and control over their cancer care [8, 9]. Although current RCT-based documentation of CAM treatment gives little support to patients' beliefs of CAM's efficacy on tumors [10], a large number of patients still clearly wish to use CAM. The interpretation of this paradox is that either the patients do not give credence to scientific evidence, or they experience some other benefit from the treatment. Objectively, data show that cancer patients who use CAM have a poorer survival prognosis than those who do not use CAM [11, 12]. It remains unclear whether this is due to a priori poorer prognosis, which makes patients turn to CAM, or whether there is a factor associated with CAM use itself that influences the prognosis negatively.

In Norway patients receive conventional medical treatment within the public health care system, while CAM practitioners operate outside this system. The majority of the CAM practitioners are members of professional associations that require professional standards of medical-and CAM-specific skills of their members. However, patients themselves generally cover the costs of visiting a CAM practitioner. Thus, the Norwegian context is comparable to

that of other western settings [13]. Masseurs, acupuncturists, hands on healers and reflexologists are CAM practitioners most used by cancer patients.

Qualitative research into patients' experiences with CAM underlines patient disenchantment with the conventional health care system as an important reason for choosing CAM [14]. Patients emphasize the experience of a fragmented and specialized system, with short consultations in a "production line" approach, which often compromises continuity at the organizational, informational and relational levels [15]. In conventional care the patient's "whole story" may fade and become invisible to the individual practitioner [16]. CAM practitioners claim to have a more holistic approach [17]. They often offer therapy directed at both mind and body [18]. Practicing principles in CAM may include patient-centeredness, empowerment and self-management [19, 20]. Thus, it is plausible that CAM supports continuity in the provider/patient relationship to a greater degree than conventional care.

In this research project, risk will generally be defined as a compound measurement of the probability of an event and the magnitude of the potential negative outcome of that event [21], both operationally and methodologically . Patient safety is understood as the reduction of risk of unnecessary harm associated with health care to an acceptable minimum [22]. Medical science risk can be divided into direct and indirect risk [23, 24] as illustrated in figure 1.

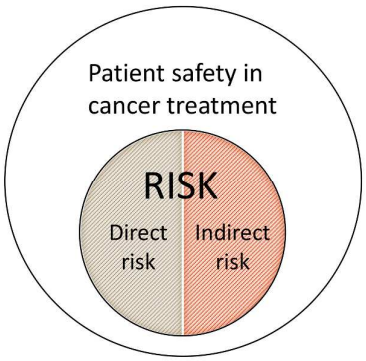

Figure 1: Understanding of patient safety and risk in this research project. Direct risk is caused by the treatment itself and related to the intervention, while indirect risk is related to the treatment context, such as the practitioner more than the medicine.

Direct risk is caused by the treatment itself. This dimension includes traditional adverse effects of an intervention, such as bleeding in response to acupuncture needling, nausea caused by chemotherapeutic medication, or the adverse effect of a herb, as well as risk connected to self-management advice from the practitioner [25]. For example, breast cancer

patients often use herbal supplements, such as ginseng or soy products, in conjunction with conventional cancer treatment [26, 27]. These supplements have phytoestrogen components that may alter estrogen levels or activate estrogen receptors as either pro- or anti-estrogen [28]. High estrogen levels are well-documented risk factors for breast cancer. Studies of these supplements are mixed, showing increased [29], reduced [28] or no association with circulating levels of estrogen [30].

Indirect risk is related to adverse effect of the treatment context, for example, the CAM practitioner, rather than the medicine. A patient may be harmed by a care context, that prevents the patient from receiving the best possible treatment relevant to her or his health needs [31]. A homeopath without appropriate medical training may overlook a serious condition and continue treatment, even in cases where conventional treatment would be an unconditional necessity. This situation may delay meaningful diagnostic procedures and relevant therapeutic interventions. For example, a patient with symptoms of cough, shortness of breath and breast pain might be treated with homeopathy for months without improvement and later diagnosed with lung carcinoma [25]. Another example of indirect risk is care in a conventional or CAM setting, which is experienced as disrespectful and, thus, causes the patient to delay appropriate care [14].

To ensure patient safety and avoid undesired outcomes, conventional care should assist patients in safeguarding their treatment decisions. This can best be achieved through open, transparent, non-judgmental and informed discussions of possible outcomes of combining CAM and conventional treatment for cancer. Cancer patients highly value the input from their physicians about the use of CAM [9, 14]. Patients should feel free to discuss all choices in their care without the fear of being rejected. Research shows, however, that patients fear that health care providers are indifferent or will object to the use of CAM [32]. It is, therefore, important that health care providers initiate this discussion and include this in the history taking [33-35]. However, studies reveal that 38-60% of cancer patients use CAM without informing their health care team [36, 37].

In a Norwegian study, the importance of taking time and effort to learn more about the value of CAM therapies has been emphasized [38]. A qualitative study [39] concludes that physicians have limited knowledge about the occurrence of possible interactions. This study also reports that in Norway no national guidelines exist, and that physicians report absence of frameworks

to address CAM related issues. Breitsameter [40] identifies ethical problems regarding the doctors' inability to inform about the risks of using CAM together with conventional care.

On the other hand, CAM practitioners' beliefs and counseling practices on how to combine the two treatment worlds safely have not been explored. In Norway, the CAM profession is totally unregulated, and CAM practitioners may practice as long as they do no harm. This vague regulation of the CAM profession increases the chance of indirect risk and, thereby, threatens patient safety [25]. However, to become a member of a CAM practitioner organization, a minimum of training in conventional medicine is usually required [41]. It is reasonable to assume that CAM practitioners' knowledge of conventional medicine vary from no formal medical education to being fully trained physicians who have added some CAM modalities to their armamentarium [16, 42].

The current non-communication between CAM and conventional professionals leaves it up to the patients themselves, who are in a vulnerable situation, to choose how to best integrate the two worlds of therapy [4, 14, 27]. As exemplified above, the non-communication may put the patient at increased risk for undesired outcomes. Conventional health care providers may believe that to reduce risk, it is best to advise patients not to use CAM in combination with conventional treatment. However, a study [14] demonstrated that patients may decline conventional medicine, if they feel rejected when they want to discuss possible CAM treatment with their GP or oncology expert. By disregarding the patients' legitimate need for CAM guidance, health professionals may unwittingly cause harm.

It should be possible to support patients in making safe decisions about combining CAM with conventional care [43]. However, the large difference between the two worlds of therapy and the complexity of the issue makes this a challenging task. Conventional and CAM providers differ regarding treatment concepts, philosophies and diagnostic procedures leading to different models of disease causality and treatment practice [18]. These differences are likely to influence the practitioners' conceptualization of benefits and risks, making shared recommendations to patients unlikely.

There is a need to be aware of how practitioners on both sides understand risk, safety and the possible benefits of combining both treatment systems in cancer care [14, 16]. There is little previous knowledge about how health care providers gather and seek information about CAM, and whether the perceptions and assessments of risk are equally understood by oncology experts, general practitioners (GPs), CAM practitioners and patients [39]. The

overarching question is, then, how health care providers in both the conventional and the CAM fields can support patients better in making informed choices about CAM in cancer care. In this study, an interactive shared decision making (SDM) tool [44] will be developed to enable patients and health professionals to make safe health choices.

Aims of the study

The global aim of this research project is to reduce risk and enhance safety for patients who want to combine conventional medicine with CAM in cancer care. To achieve this, we will:

Delineate, compare and evaluate perceptions and clinical experience of communication about direct and indirect risk situations among oncology experts (doctors and nurses), GPs and CAM practitioners (masseurs, acupuncturists, hands on healers and reflexologists/zone therapists)

To accomplish this, we will perform three individual studies:

Study 1: Perform a meta-synthesis of the qualitative and quantitative research literature in the field

Study 2: Develop, pilot and implement a large-scale survey among oncology experts, GPs and CAM practitioners in Norway.

Study 3: Guided by the survey results, design and develop an SDM tool for health care providers to use for guiding patients to make safe CAM decisions that are in line with the patients' health goals. We have qualitative data available from different studies on cancer patients [39, 45]. These data will be incorporated in the tool, so patients can be guided to make safe health decisions.

The following research questions will be addressed in the meta-synthesis, the mixed method survey pilot, and the large-scale survey:

a) Is there a difference among the four professional groups in how they gather information about CAM?

b) Is there a difference among the four professional groups in how they recognize direct and indirect risk situations in clinical practice? What kind of risk assessment tools do they use for this purpose? What procedure is followed when in doubt of medical diagnosis or when to refer to other health care interventions?

c) According to the study participants, what constitutes enough evidence on efficacy and safety to recommend a CAM modality?

d) Is there differences among the four professional groups in how they deal with patients who delay or decline conventional treatment?

e) Is there differences among the four groups in how they experience communication with their patients about CAM? What do practitioners on both sides think about risk and safety and the consequences of combining both treatment systems in cancer care?

Below is the flow chart of the study.

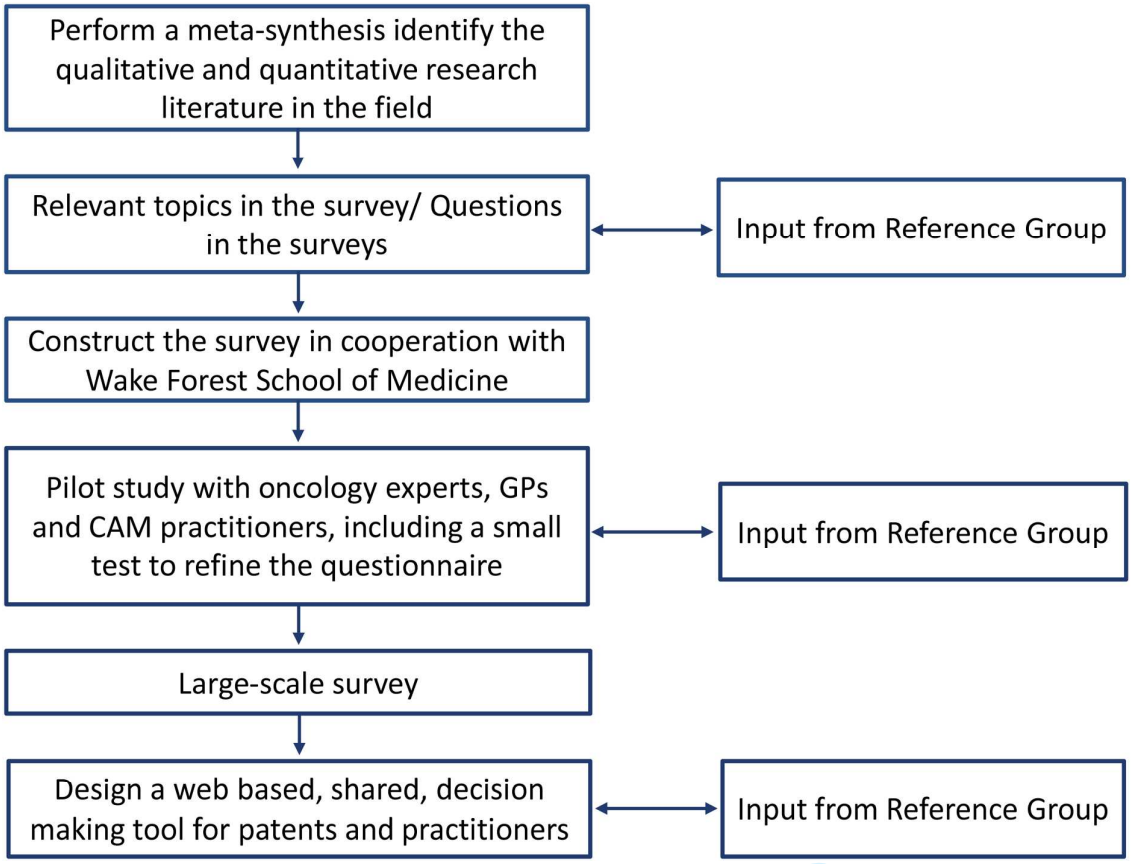

Figure 2: Flow of activities in this research project

Methods and analysis

Study 1: Meta-synthesis

To evaluate the research literature of interest, systematic literature searches in relevant electronic databases will be performed. Relevant databases are AMED, CINAHL, Cochrane Central Register for Controlled Trials (Central) in the Cochrane Library, EMBASE, MEDLINE/ PubMed and PsycINFO. The PEO (Population, Exposure and Outcome) format will be used. PEO is a tool to formulate questions about quantitative research [46], and the search strategy will include keywords, such as *risk perception; risk communication; decision making; cancer care; Complementary and alternative medicine.* MeSH–terms and truncation

symbols will be used, when available. The searches will be combined with manual searches in journals of interest and reference lists, in addition to abstracts and keywords.

Study 2:Pilot survey

Prior to the main large scale study, we plan to conduct a pilot study. The purpose is to test the data collection for face and content validity [47]. Six participants (n=6) including one oncology doctor, one nurse, one GP and three CAM providers will be invited to participate in a *Think-aloud* session [48], which involves participants reporting their thoughts out loud as they complete the questionnaire. They will be asked to say whatever they are thinking, doing or looking at as they perform this task. The think-aloud session will provide us with information regarding whether any items are misunderstood, whether people answer in a meaningful way or whether they get bored or confused part way through. The questionnaire will be revised accordingly.

Then 40 participants (10 oncology doctors, 10 oncology nurses, 10 GPs and 10 CAM providers) will complete the instrument and several other sets of questions to establish construct validity [47]. The results from this questionnaire will be compared to the Holistic Complementary and Alternative Medicine Questionnaire (HCAMQ) and the Complementary and Alternative Medicine Beliefs Inventory (CAMBI) [49, 50]. Both are validated questionnaires including concepts like *CAM beliefs* and *holistic health beliefs*. These two factors represent distinct CAM constructs and will be used to distinguish CAM attitudes from conventional attitudes among the respondents. The oncology experts needed for the pilot study will be recruited through two wards at the University Hospital in North Norway (UNN). The study participants will be contacted by email or postal mail and invited to participate. The CAM providers will be recruited through private clinics in the Troms and Nordland county.

A reference group consisting of one oncology nurse, one GP and two CAM practitioners will assist the research team in testing the validity of the questionnaire. They will complete and comment the instrument before the commencement of the pilot study.

Study 2: Large scale survey

Inclusion criteria

Oncology doctors and nurses, GPs and CAM providers who are currently practicing and members of a professional association and have clinical experience with current or previously diagnosed cancer patients are eligible for the study. Being a member of a professional association ensures high professional standards of medical and/or CAM skills among the

participants. According to a Norwegian study from 2013 [7] , the four most popular CAM modalities used by Norwegian cancer survivors were massage (10,5%), acupuncture (7,6%), hands on healer (4,8%) and reflexology (3,2%). This information was the rationale for choosing these particular CAM participants in the study.

Exclusion criteria

Allopathic and CAM providers who have no clinical experience with current or previously diagnosed cancer patients are ineligible for the study.

Participants

We will include one-hundred oncology doctors and 100 oncology nurses, working at the following four hospitals: *The University Hospital of North-Norway (UNN), Tromso; St. Olav Hospital, Trondheim; Haukeland University Hospital, Bergen;* and *Norwegian Radium Hospital, Oslo.* Furthermore, we will include 100 GPs and 400 CAM providers (100 masseurs, 100 acupuncturists, 100 hands on healers, 100 reflexologists/zone therapists), working in private clinics throughout the country.

Recruitment

The GPs and the oncology doctors will be recruited through *The Norwegian Medical Association* and *The Union for Oncologists.* The oncology nurses and the CAM providers will be recruited through *The Norwegian Nurses organization, The Association for Alternative Provider Organizations (Saborg), The Norwegian Acupuncture Association* and *The Norwegian Healer Association*. We will ask the associations to provide us with a list of their members. The lists will be randomized by the study team. The participants will be offered a gift card as compensation for time spent responding to the study questionnaire. In order to increase the response rate among the GPs and oncology doctors, the gift card incentive will be somewhat higher for them [48].

Data collection

To boost the questionnaire response rate as much as possible, a mixed mode including postal mail and email will be used [48]. A standard introductory letter will be sent to all allopathic and CAM providers identified for inclusion. This letter will inform the recipient that he or she will receive a request to help with an important study. We will use a recognized and respected logo from the Arctic University of Norway and The Northern Norway Regional Health Authority on the stationery and envelopes, and the letters will be co-signed by a well-known physician. One week following the mailing of this letter, emails will be sent to all potential participants with a link to the Internet survey. The survey will be administered through a

secure web application designed for online surveys [51]. We will use a function that enables the research team to identify whether each person completes some or all of the survey, but prevents the research team from seeing any participant's identity, thereby providing anonymity. For those providers who do not have email or limited access to Internet, a questionnaire will be sent by postal mail. After a week, a "thank you" or a reminder email will be sent to the included providers. Finally, one week later a replacement questionnaire and a reminder letter with a link to the survey will be sent to the non-responders, including options to complete the questionnaire either by mail or email. The study participants who have completed the questionnaire will be asked to click on a link at the end of the questionnaire confirming whether they will like to receive a gift card or not. If they wish, a gift card will be sent to them by mail (Table 1).

Table 1: Data implementation procedures for this study

Week	Mail preference	Web preference
1	Standard introducing letter	Standard introducing postal letter
2	Invitation letter including consent statement, mail questionnaire, incentive and return envelope	Invitation email letter including consent statement, link to the survey, incentive and web survey instructions
3	Thank you postcard or reminder postcard	Thank you or reminder email with link to the survey
4	Replacement questionnaire and return envelope with cover letter including link to the survey for web options to the non-responders	Reminder email to the non-responders with link to survey and web survey instructions accompanied by mail questionnaire and return envelope for the mail option

Source: Dillman DA, Smyth JD, Christian LM. Internet, mail and mixed-mode surveys. The Tailored Design Method. 3ed. New Jersey: John Wiley& Sons, Inc.;2009.

Power calculation

In order to identify any possible difference between the two groups of providers (conventional vs. CAM) a power calculation was performed. The four groups to be studied are oncology experts (doctors and nurses), GPs and CAM practitioners. In Norway there are approximately 200 oncologists, 500 oncology nurses, 5.500 GPs and an estimated 2.100 CAM practitioners. Some providers, particularly oncologists and oncology nurses, may practice in the same facility and thereby share beliefs about conventional and CAM cancer treatment. This "clustering" is incorporated into power calculations.

Power calculations are based on the question, "Do you think CAM modalities can interact with conventional cancer treatments?" In our calculations, we presume that CAM providers will be highly likely to respond "no" and that conventional providers will be less likely to

respond "no". We calculate power for several different scenarios of response to the question, with and without clustering taken into account (table 2). With a moderate difference between the two groups (CAM vs. conventional providers) in response to the question (CAM providers with a 70% proportion and Conventional providers with 50%), 124 respondents are needed per group to have 90% power to detect a difference. When clustering is taken into account and a cluster size of 5, with a moderate/high interclass correlation of 0.2 used, 223 per group (conventional and CAM providers) are needed to have 90% power.

Table 2: Scenarios for 90% power to detect a difference between conventional and CAM based on the question: "Do you think CAM modalities can interact with conventional cancer treatments? " Scenarios are based on proportions responding negatively to the question and are presented with no intra class correlation (ICC) and ICC equal 0.2 and a cluster size of 5.

	Proportion 2					
	.7		.8		.9	
Proportion 1	N/Group ICC=0.0	N/Group ICC=0.2	N/Group ICC=0.0	N/Group ICC=0.2	N/Group ICC=0.0	N/-Group ICC=0.2
0.3	31	56	19	34	12	22
0.4	56	101	30	54	17	31
0.5	124	223	52	94	26	47
0.6	477	856	109	196	42	76

However, in order to perform within group comparisons we will include 300 conventional providers (100 oncology doctors, 100 oncology nurses, 100 GPs) and 400 CAM providers (100 masseurs, 100 acupuncturists, 100 hands on healers, 100 reflexologists/zone therapists), a total sample size of 700. Table 3 shows our projections for sample sizes taking into account response screening rates.

Table 3: Targeted response and screening rates for each group of providers and the numbers to be contacted to arrive at the sample sizes

Type of providers	# Available	# Contacted	Response rate	Screened out for not treating cancer patients	Final Sample size
Oncology doctors	200	200	50 %	0%	100
Oncology nurses	500	200	50 %	0%	100
General Practitioners	5.500	200	50 %	0%	100
Acupuncturists	761	400	50 %	50 %	100
Masseurs	687	400	50 %	50 %	100
Reflexologists	290	290	50%	50 %	100
Hands on healers	258	400	50 %	50 %	100

Measurements

Table 4 shows the study measures including the main study concepts and some examples of questions from which these concepts will be constructed. The study measures are based on preliminary analysis from the meta-synthesis and results from the first meeting with the reference group, where the participants were challenged to make questions related to the different concepts in the questionnaire.

Table 4: Study measures

Study concepts	Constructed from the following example questions	Type of variable
Risk perceptions	CAM should only be used as a last resort when conventional medicine has nothing to offer.	Dichotomous
Risk communication	How often do you ask your patients if they use CAM and/or conventional medicine?	Order categories
Direct risk situations	Do you think that CAM modalities can interact with conventional medicines?	Dichotomous
Indirect risk situations	Is the lack of regulation of the CAM profession risky for the patients?	Dichotomous
Information regarding CAM and conventional treatment	Do you seek information regarding CAM cancer treatment? Do you seek information regarding conventional cancer treatment?	Dichotomous Dichotomous

Statistical analyses

The surveys will be a questionnaire based cross-sectional survey. The research questions mentioned above will be explored further in the questionnaire, and both closed and open-ended questions will be used. Responses to the open-ended questions will be categorized into nominal or ordinal scales. The guiding principle of the analyses will be performed by descriptive statistics of the perceptions present overall, and comparisons of the four practitioner groups. Chi-square tests and logistic regression will be used for analyzing binary dependent variables, and analysis of variance will be used analyzing continuous, dependent variables. Quantitative data will be analyzed using the SPSS version 19.0 for Windows.

Study 3: A web-based decision making tool

In cooperation with The Norwegian Centre for Integrated Care and Telemedicine at the University Hospital of North-Norway an SDM tool to support decision making about CAM and conventional care for cancer patients will be developed. The tool will be published on the Internet and ready to use for patients and health care providers. The Norwegian Centre for Integrated Care and Telemedicine will operate the technical version of the SDM tool.

Ethics

The participants will receive a written document describing the purpose and consequences of participating in the study. They will be informed of the possibility to withdraw from the study followed by deletion of all data registered. The returned and completed questionnaire will be considered a consent to participate in the study. The study does not need approval from The Regional Committee for Medical and Health Research Ethics, according to Norwegian legislation, because all participants are health care professionals. All data will be archived according to established procedures and REDCap safety procedures. No information that may be traced back to individuals will be published.

Dissemination

The results of this research project will be disseminated to cancer patients, health care professionals in both conventional care and CAM, the Norwegian Cancer Society, public health associations and various CAM practitioner organizations. The scientific work will be published in peer-reviewed journals, and orally presented at national and international conferences. The published results will be communicated through The National Information Center for Complementary and Alternative Medicine's (NIFAB) web portal. NIFAB is a part of The National Research Center in Complementary and Alternative Medicine (NAFKAM) and its web portal www.nifab.no is frequently visited. The results will be communicated to the relevant organizations through direct contact.

Publication policy

The results of the study will be published in appropriate journals regardless of outcome. The study will be implemented and reported in accordance with the recommendations of the STROBE checklist.

Discussion

This protocol presents three studies designed to delineate, compare and evaluate perceptions and clinical experience of communication with direct and indirect risk situations among different professionals of health care providers in cancer care. The global aim is to reduce risk and enhance safety for patients who want to combine conventional medicine with CAM in cancer care. The project will increase knowledge about how CAM and conventional health providers understand the potential benefits and risks of combining both treatment systems in cancer care. Such information is essential to bridge the communication gap between patients

and their health care providers [35, 52]. Lack of communication and coordination between different parts of the health care system are major threats to patient safety [39]. This general tool can pave the way for more disease-specific tools that highlight the issue of CAM-conventional direct and indirect risks relevant to these patient groups [44]. It is, therefore, innovative and useful for public health authorities, as it will improve patient engagement and the quality of health care.

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Competing interest

The authors declare that they have no conflict of interest.

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Contributors

TS, FM and GB initiated the project. TS, FM, SQ, TA, AS, AK and GB contributed to conceptualisation and design of the study and all revised this manuscript critically for important intellectual content. All authors read and approved the final manuscript.

References

1. Ben-Arye E, Frenkel M, and Stashefsky MR, *Approaching Complementary and Alternative Medicine Use in Patients With Cancer: Questions and Challenges.* The Journal of Ambulatory Care Management, 2004. **27**(1): p. 53-62.
2. Cassileth BR, et al., *Alternative medicine use worldwide.* Cancer, 2001. **91**(7): p. 1390-1393.
3. Yates JS, et al., *Prevalence of complementary and alternative medicine use in cancer patients during treatment.* Support Cancer Care, 2005. **13**(10): p. 806-11.
4. Molassiotis A, Fernandez-Ortega P, and Pud D, *Use of complementary and alternative medicine in cancer patients:a European survey.* Ann Oncol, 2005. **16**(16): p. 655-663.

5. *LOV-2003-06-27-64 Lov om alternativ behandling av sykdom mv; English Act relating to the alternative treatment of disease, illness, etc*. 2003.
6. Horneber M, et al., *How Many Cancer Patients Use Complementary and Alternative Medicine: A Systematic Review and Metaanalysis.* Integrative Cancer Therapies, 2012. **11**(3): p. 187-203.
7. Kristoffersen AE, Norheim AJ, and Fonnebo VM, *Complementary and alternative medicine use among Norwegian cancer survivors: gender-specific prevalence and associations for use.* Evid Based Complement Alternat Med, 2013. **2013**: p. 318781.
8. Molassiotis A, et al., *Complementary and alternative medicine use in breast cancer patients in Europe.* Supportive care in Cancer, 2006. **14**(3): p. 260-267.
9. Verhoef MJ, et al., *Complementary therapies for cancer patients: assessing information use and needs.* Chronic Disease in Canada, 2009. **29**(2).
10. Jacobson JS, Workman SB, and Kronenberg F, *Research on Complementary/Alternative Medicine for Patients With Breast Cancer: A Review of the Biomedical Literature.* Journal of Clinical Oncology, 2000. **18**(3): p. 668.
11. Han E, et al., *Alternative Therapy Used as Primary Treatment for Breast Cancer Negatively Impacts Outcomes.* Annals of Surgical Oncology, 2011. **18**(4): p. 912-916.
12. Risberg, T., et al., *[Does use of alternative medicine aggravate the survival prognosis in cancer?].* Tidsskr Nor Laegeforen, 2003. **123**(5): p. 628-30.
13. Wiesener S, et al., *Legal status and regulation of CAM in Europe.* Forsch Komplementärmed und Klass Naturheilkd, 2012. **19**(suppl 2): p. 29-36.
14. Salamonsen A, *Doctor-patient communication and cancer patients' choice of alternative therapies as supplement or alternative to conventional care.* Scandinavian Journal of Caring Science, 2013. **10.1111/j.1471-6712.2012.01002.x**.
15. Jeannie LH, et al., *Continuity of care: a multidisciplinary review.* BMJ, 2003. **327**(7425): p. 1219-1221.
16. Stub T, Alraek T, and Salamonsen A, *The Red flag! risk assessment among medical homeopaths in Norway: A qualitative study.* BMC Complement. Altern. Med, 2012. **12**(1): p. 150.
17. MacPherson H and Kaptchuk T, *Acupuncture in Practice: Case History Insights from the West*. 1997, Edinburgh: Churchill Livingstone.
18. Singer M and Baer H, *Introducing medical anthropology. A disipline in action*. 2 ed. 2012, Plymouth: AltaMira Press.
19. Maciocia G, *The Practice of Chinese Medicine*. 1994, Edinburgh: Churcill Livingstone.
20. Berger S, Braehler E, and Ernst J, *The health professional–patient-relationship in conventional versus complementary and alternative medicine. A qualitative study comparing the perceived use of medical shared decision-making between two different approaches of medicine.* Patient Education and Counseling, 2012. **88**(1): p. 129-137.
21. Davis EM, *Risky Business: Medical Discourse, Breast Cancer, and Narrative.* Qualitative Health Research, 2008. **18**(1): p. 65-76.
22. Runciman W, et al., *Towards an International Classification for Patient Safety: Key concepts and terms.* Int. Journal for Quality in Health Care, 2009. **21**(1): p. 18-26.
23. Fisher P, Dantas F, and Rampes H, *The safety of homeopathic products* J R Soc Med, 2002. **95**(9): p. 474-476.
24. Ernst E, *Towards a scientific understanding of the placebo effects*, in *Understanding the Placebo Effect in Complementary Medicine*, D. Peters, Editor. 2001, Churchill Livingstone: London. p. 17-29.
25. Stub T, *Safety of Treatment Provided by Homeopaths - Homeopathic Aggravations, Adverse effects and Risk Assessment*, in *Department of Community Medicine.*

NAFKAM - The National Research Center in Complementary and Alternative Medicine. 2013, UiT The Arctic University of Norway, Tromsø NAFKAM skriftserie No.9 Tromsø.

26. Bao P-P, et al., *Ginseng and Ganoderma lucidum Use after Breast Cancer Diagnosis and Quality of Life: A Report from the Shanghai Breast Cancer Survival Study.* PloS ONE, 2012. **7**(6): p. e39343.
27. Ma, H., et al., *Estrogenic botanical supplements, health-related quality of life, fatigue, and hormone-related symptoms in breast cancer survivors: a HEAL study report.* BMC Complementary and Alternative Medicine, 2011. **11**(1): p. 109.
28. Harris, R.M., et al., *Phytoestrogens Are Potent Inhibitors of Estrogen Sulfation: Implications for Breast Cancer Risk and Treatment.* Journal of Clinical Endocrinology & Metabolism, 2004. **89**(4): p. 1779-1787.
29. Wu WH, et al., *Estrogenic Effect of Yam Ingestion in Healthy Postmenopausal Women.* Journal of the American College of Nutrition, 2005. **24**(4): p. 235-243.
30. Wu AH, et al., *A controlled 2-mo dietary fat reduction and soy food supplementation study in postmenopausal women.* The American Journal of Clinical Nutrition, 2005. **81**(5): p. 1133-1141.
31. Wardle J and Adams J, *Indirect risks of complementary and alternative medicine*, in *Traditional, complementary and integrative medicine*, Adams J, et al., Editors. 2012, Palgrave Macmillian: Hampshire. p. 212-219.
32. Tovey P and Broom A, *Oncologists' and specialists cancer nurses' approaches to complementary and alternative medicine and their impact on patient action.* Social Science & Medicine, 2007. **64**: p. 2550-2564.
33. Lindring i nord and Kompetansesenter for lindrende behandling, *Håndbok i lindrende behandling*. 2012, Universitetssykehuset Nord-Norge: Universitetssykehuset Nord-Norge.
34. Verhoef MJ, Boon HS, and Page SA, *Talking to cancer patients about complementary therapies: is it the physicians's responsibility?* Current Oncology, 2008. **15**(2): p. 18-23.
35. Deng GE, et al., *Evidence-Based Clinical Practice Guidelines for Integrative Oncology: Complementary Therapies and Botanicals.* Journal of the Society for Integrative Oncology, 2009. **7**: p. 85-120.
36. Navo MA, et al., *An Assessment of the Utilization of Complementary and Alternative Medication in Women With Gynecologic or Breast Malignancies.* Journal of Clinical Oncology, 2004. **22**(4): p. 671-677.
37. Richardson MA, et al., *Complementary/Alternative Medicine Use in a Comprehensive Cancer Center and the Implications for Oncology.* Journal of Clinical Oncology, 2000. **18**(13): p. 2505-2514.
38. Risberg T, et al., *Knowledge of and attitudes toward complementary and alternative therapies: a national multicentre study of oncology professionals in Norway.* European Journal of Cancer, 2004. **40**: p. 529-535.
39. Salamonsen A, *Mind the Gap! Lay and Medical Perceptions of Risks Associated With the Use of Alternative Treatment and Conventional Medicine.* Forsch Komplementmed,, 2015. **1; DOI 10.1159/000376555**.
40. Breisameter C, *Medical decision-making and communication of risks: an ethical perspective.* J Med Ethics, 2010. **36**: p. 349-352.
41. Norske Homeopaters Landsforbund *Vedtekter for Norske Homeopaters Landsforbund*. 2012.

42. Stub T, Salamonsen A, and Alræk T, *Is it Possible to Distinguish Homeopathic Aggravation from Adverse Effects? A Qualitative Study.* Forsch Komplementärmed und Klass Naturheilkd, 2011. **19**(1): p. 13-19.
43. Gamst, A., et al., *Integrative care and bridge building among health care providers in Norway and Denmark.* J Altern Complement Med, 2006. **12**(2): p. 141-6.
44. Elwyn G, et al., *Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices.* British Journal of General Practice, 2000. **50**(460): p. 892-899.
45. Salamonsen A, Kruse T, and Eriksen SH, *Modes of Embodiment in Breast Cancer Patients Using Complementary and Alternative Medicine.* Qualitative Health Research, 2012. **22**(11): p. 1497-1512.
46. Higgins JPT, *Cochrane Handbook for Systematic Reviews of Interventions 5.1.0.*, ed. Green S. Updated March 2011, Chichester U.K.: Wiley & Sons, Ltd.
47. Peat J, *Health Science Research. A handbook of quantitative methods*. 2002, London: SAGE Publications.
48. Dillman DA, Smuty JD, and Christian LM, *Internet, mail and mixed-mode surveys. The Tailored Design Method.* . 3 ed. 2009, New Jersey: John Wiley & Sons, Inc.
49. Hyland ME, Lewith GT, and Westoby C, *Developing a measure of attitudes: the holistic complementary and alternative medicine questionnaire.* Complementary Therapies in Medicine, 2003. **11**: p. 33-38.
50. Bishop FL, Yardley L, and Lewith G, *Developing a measure ot treatment beliefs: The complementary and alternative medicine beliefs inventory.* Complementary Therapies in Medicine, 2005. **13**: p. 144-149.
51. Harris RA, et al., *Researcg Electronic Data Capture (REDCap) - A meta-driven methodology and workflow process for providing translational research informatics support.* J Biomed Inform, 2009. **42**(2): p. 377-381.
52. Cassileth BR, et al., *Complementary Therapies and Integrative Oncology in Lung Cancer. ACCP Evidence-Based Clinical Practice Guidelines (2nd Edition).* CHEST, 2007. **132**(3): p. 340-354.

Standards for Reporting Qualitative Research: A Synthesis of Recommendations

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Abstract

Purpose
Standards for reporting exist for many types of quantitative research, but currently none exist for the broad spectrum of qualitative research. The purpose of the present study was to formulate and define standards for reporting qualitative research while preserving the requisite flexibility to accommodate various paradigms, approaches, and methods.

Method
The authors identified guidelines, reporting standards, and critical appraisal criteria for qualitative research by searching PubMed, Web of Science, and Google through July 2013; reviewing the reference lists of retrieved sources; and contacting experts. Specifically, two authors reviewed a sample of sources to generate an initial set of items that were potentially important in reporting qualitative research. Through an iterative process of reviewing sources, modifying the set of items, and coding all sources for items, the authors prepared a near-final list of items and descriptions and sent this list to five external reviewers for feedback. The final items and descriptions included in the reporting standards reflect this feedback.

Results
The Standards for Reporting Qualitative Research (SRQR) consists of 21 items. The authors define and explain key elements of each item and provide examples from recently published articles to illustrate ways in which the standards can be met.

Conclusions
The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research. These standards will assist authors during manuscript preparation, editors and reviewers in evaluating a manuscript for potential publication, and readers when critically appraising, applying, and synthesizing study findings.

Qualitative research contributes to the literature in many disciplines by describing, interpreting, and generating theories about social interactions and individual experiences as they occur in natural, rather than experimental, situations.[1–3] Some recent examples include studies of professional dilemmas,[4] medical students' early experiences of workplace learning,[5] patients' experiences of disease and interventions,[6–8] and patients' perspectives about incident disclosures.[9] The purpose of qualitative research is to understand the perspectives/experiences of individuals or groups and the contexts in which these perspectives or experiences are situated.[1,2,10]

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Qualitative research is increasingly common and valued in the medical and medical education literature.[1,10–13] However, the quality of such research can be difficult to evaluate because of incomplete reporting of key elements.[14,15] *Quality* is multifaceted and includes consideration of the importance of the research question, the rigor of the research methods, the appropriateness and salience of the inferences, and the clarity and completeness of reporting.[16,17] Although there is much debate about standards for methodological rigor in qualitative research,[13,14,18–20] there is widespread agreement about the need for clear and complete reporting.[14,21,22] Optimal reporting would enable editors, reviewers, other researchers, and practitioners to critically appraise qualitative studies and apply and synthesize the results. One important step in improving the quality of reporting is to formulate and define clear reporting standards.

Authors have proposed guidelines for the quality of qualitative research, including those in the fields of medical education,[23–25] clinical and health services research,[26–28] and general education research.[29,30] Yet in nearly all cases, the authors do not describe how the guidelines were created, and often fail to distinguish reporting quality from the other facets of quality (e.g., the research question or methods). Several authors suggest standards for reporting qualitative research,[15,20,29–33] but their articles focus on a subset of qualitative data collection methods (e.g., interviews), fail to explain how the authors developed the reporting criteria, narrowly construe qualitative research (e.g., thematic analysis) in ways that may exclude other approaches, and/or lack specific examples to help others see how the standards might be achieved. Thus, there remains a compelling need for defensible and broadly applicable standards for reporting qualitative research.

We designed and carried out the present study to formulate and define standards for reporting qualitative research through a rigorous synthesis of published articles and expert recommendations.

Method

We formulated standards for reporting qualitative research by using a rigorous and systematic approach in which we reviewed previously proposed

recommendations by experts in qualitative methods. Our research team consisted of two PhD researchers and one physician with formal training and experience in qualitative methods, and two physicians with experience, but no formal training, in qualitative methods.

We first identified previously proposed recommendations by searching PubMed, Web of Science, and Google using combinations of terms such as "qualitative methods," "qualitative research," "qualitative guidelines," "qualitative standards," and "critical appraisal" and by reviewing the reference lists of retrieved sources, reviewing the Equator Network,[22] and contacting experts. We conducted our first search in January 2007 and our last search in July 2013. Most recommendations were published in peer-reviewed journals, but some were available only on the Internet, and one was an interim draft from a national organization. We report the full set of the 40 sources reviewed in Supplemental Digital Appendix 1, found at http://links.lww.com/ACADMED/A218.

Two of us (B.O., I.H.) reviewed an initial sample of sources to generate a comprehensive list of items that were potentially important in reporting qualitative research (Draft A). All of us then worked in pairs to review all sources and code the presence or absence of each item in a given source. From Draft A, we then distilled a shorter list (Draft B) by identifying core concepts and combining related items, taking into account the number of times each item appeared in these sources. We then compared the items in Draft B with material in the original sources to check for missing concepts, modify accordingly, and add explanatory definitions to create a prefinal list of items (Draft C).

We circulated Draft C to five experienced qualitative researchers (see the acknowledgments) for review. We asked them to note any omitted or redundant items and to suggest improvements to the wording to enhance clarity and relevance across a broad spectrum of qualitative inquiry. In response to their reviews, we consolidated some items and made minor revisions to the wording of labels and definitions to create the final set of reporting standards—the Standards for Reporting Qualitative Research (SRQR)—summarized in Table 1.

To explicate how the final set of standards reflect the material in the original sources, two of us (B.O., D.A.C.) selected by consensus the 25 most complete sources of recommendations and identified which standards reflected the concepts found in each original source (see Table 2).

Results

The SRQR is a list of 21 items that we consider essential for complete, transparent reporting of qualitative research (see Table 1). As explained above, we developed these items through a rigorous synthesis of prior recommendations and concepts from published sources (see Table 2; see also Supplemental Digital Appendix 1, found at http://links.lww.com/ACADMED/A218) and expert review. These 21 items provide a framework and recommendations for reporting qualitative studies. Given the wide range of qualitative approaches and methodologies, we attempted to select items with broad relevance.

The SRQR includes the article's title and abstract (items 1 and 2); problem formulation and research question (items 3 and 4); research design and methods of data collection and analysis (items 5 through 15); results, interpretation, discussion, and integration (items 16 through 19); and other information (items 20 and 21). Supplemental Digital Appendix 2, found at http://links.lww.com/ACADMED/A218, contains a detailed explanation of each item, along with examples from recently published qualitative studies. Below, we briefly describe the standards, with a particular focus on those unique to qualitative research.

Titles, abstracts, and introductory material. Reporting standards for titles, abstracts, and introductory material (problem formulation, research question) in qualitative research are very similar to those for quantitative research, except that the results reported in the abstract are narrative rather than numerical, and authors rarely present a specific hypothesis.[29,30]

Research design and methods. Reporting on research design and methods of data collection and analysis highlights several distinctive features of qualitative research. Many of the criteria we reviewed focus not only on identifying and describing all aspects of the methods (e.g., approach, researcher characteristics and role, sampling strategy, context, data collection and analysis) but also on justifying each choice.[13,14] This ensures that authors make their assumptions and decisions transparent to readers. This standard is less commonly expected in quantitative research, perhaps because most quantitative researchers share positivist assumptions and generally agree about standards for rigor of various study designs and sampling techniques.[14] Just as quantitative reporting standards encourage authors to describe how they implemented methods such as randomization and measurement validity, several qualitative reporting criteria recommend that authors describe how they implemented a presumably familiar technique in their study rather than simply mentioning the technique.[10,14,32] For example, authors often state that data collection occurred until saturation, with no mention of how they defined and recognized saturation. Similarly, authors often mention an "iterative process," with minimal description of the nature of the iterations. The SRQR emphasizes the importance of explaining and elaborating on these important processes. Nearly all of the original sources recommended describing the characteristics and role of the researcher (i.e., reflexivity). Members of the research team often form relationships with participants, and analytic processes are highly interpretive in most qualitative research. Therefore, reviewers and readers must understand how these relationships and the researchers' perspectives and assumptions influenced data collection and interpretation.[15,23,26,34]

Results. Reporting of qualitative research results should identify the main analytic findings. Often, these findings involve interpretation and contextualization, which represent a departure from the tradition in quantitative studies of objectively reporting results. The presentation of results often varies with the specific qualitative approach and methodology; thus, rigid rules for reporting qualitative findings are inappropriate. However, authors

Table 1
Standards for Reporting Qualitative Research (SRQR)[a]

No.	Topic	Item
	Title and abstract	
S1	Title	Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended
S2	Abstract	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions
	Introduction	
S3	Problem formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement
S4	Purpose or research question	Purpose of the study and specific objectives or questions
	Methods	
S5	Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale[b]
S6	Researcher characteristics and reflexivity	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability
S7	Context	Setting/site and salient contextual factors; rationale[b]
S8	Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale[b]
S9	Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues
S10	Data collection methods	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale[b]
S11	Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study
S12	Units of study	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)
S13	Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts
S14	Data analysis	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale [b]
S15	Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale[b]
	Results/findings	
S16	Synthesis and interpretation	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory
S17	Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings
	Discussion	
S18	Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/ generalizability; identification of unique contribution(s) to scholarship in a discipline or field
S19	Limitations	Trustworthiness and limitations of findings

(*Table continues*)

Table 1
(Continued)

No.	Topic	Item
	Other	
S20	Conflicts of interest	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed
S21	Funding	Sources of funding and other support; role of funders in data collection, interpretation, and reporting

[a]The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.
[b]The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

should provide evidence (e.g., examples, quotes, or text excerpts) to substantiate the main analytic findings.[20,29]

Discussion. The discussion of qualitative results will generally include connections to existing literature and/or theoretical or conceptual frameworks, the scope and boundaries of the results (transferability), and study limitations.[10–12,28] In some qualitative traditions, the results and discussion may not have distinct boundaries; we recommend that authors include the substance of each item regardless of the section in which it appears.

Discussion

The purpose of the SRQR is to improve the quality of reporting of qualitative research studies. We hope that these 21 recommended reporting standards will assist authors during manuscript preparation, editors and reviewers in evaluating a manuscript for potential publication, and readers when critically appraising, applying, and synthesizing study findings. As with other reporting guidelines,[35–37] we anticipate that the SRQR will evolve as it is applied and evaluated in practice. We welcome suggestions for refinement.

Qualitative studies explore "how?" and "why?" questions related to social or human problems or phenomena.[10,38] Purposes of qualitative studies include understanding meaning from participants' perspectives (How do they interpret or make sense of an event, situation, or action?); understanding the nature and influence of the context surrounding events or actions; generating theories about new or poorly understood events, situations, or actions; and understanding the processes that led to a desired (or undesired) outcome.[38] Many different approaches (e.g., ethnography, phenomenology, discourse analysis, case study, grounded theory) and methodologies (e.g., interviews, focus groups, observation, analysis of documents) may be used in qualitative research, each with its own assumptions and traditions.[1,2] A strength of many qualitative approaches and methodologies is the opportunity for flexibility and adaptability throughout the data collection and analysis process. We endeavored to maintain that flexibility by intentionally defining items to avoid favoring one approach or method over others. As such, we trust that the SRQR will support all approaches and methods of qualitative research by making reports more explicit and transparent, while still allowing investigators the flexibility to use the study design and reporting format most appropriate to their study. It may be helpful, in the future, to develop approach-specific extensions of the SRQR, as has been done for guidelines in quantitative research (e.g., the CONSORT extensions).[37]

Limitations, strengths, and boundaries

We deliberately avoided recommendations that define methodological rigor, and therefore it would be inappropriate to use the SRQR to judge the quality of research methods and findings. Many of the original sources from which we derived the SRQR were intended as criteria for methodological rigor or critical appraisal rather than reporting; for these, we inferred the information that would be needed to evaluate the criterion. Occasionally, we found conflicting recommendations in the literature (e.g., recommending specific techniques such as multiple coders or member checking to demonstrate trustworthiness); we resolved these conflicting recommendations through selection of the most frequent recommendations and by consensus among ourselves.

Some qualitative researchers have described the limitations of checklists as a means to improve methodological rigor.[13] We nonetheless believe that a checklist for reporting standards will help to enhance the transparency of qualitative research studies and thereby advance the field.[29,39]

Strengths of this work include the grounding in previously published criteria, the diversity of experience and perspectives among us, and critical review by experts in three countries.

Implications and application

Similar to other reporting guidelines,[35–37] the SRQR may be viewed as a starting point for defining reporting standards in qualitative research. Although our personal experience lies in health professions education, the SRQR is based on sources originating in diverse health care and non-health-care fields. We intentionally crafted the SRQR to include various paradigms, approaches, and methodologies used in qualitative research. The elaborations offered in

Table 2

Alignment of the 21 Standards for Reporting Qualitative Research (SRQR) With Recommendations From 25 Original Sources[a]

		Reference no.[b]																						
No.	Topic	11,12	15[c]	19	20[c]	23	24,25[d]	26	27	29[c,d]	30[c,d]	31[c]	32[c]	33	34	41	42	43	44[c]	45	46	47	48	49	50
S1	Title						*	*		*														*	
S2	Abstract						*			*	*			*											
S3	Problem formulation				*	*	*	*	*	*	*	*		*	*	*	*	*			*			*	*
S4	Purpose or research question	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		*	*	*	*	*	*
S5	Qualitative approach and research paradigm	*	*	*	*	*	*	*		*	*		*	*		*	*	*			*	*	*	*	*
S6	Researcher characteristics, reflexivity	*	*	*	*	*	*	*	*	*		*	*	*		*	*	*	*	*	*	*	*	*	*
S7	Context		*	*	*	*	*	*	*	*	*	*		*		*	*		*	*	*		*		*
S8	Sampling strategy	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		*	*	
S9	Ethical issues pertaining to human subjects	*			*		*			*	*		*	*		*	*	*		*	*	*			*
S10	Data collection methods	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
S11	Data collection instruments/ technologies	*	*				*			*	*	*	*	*		*		*			*				
S12	Units of study	*	*		*		*	*		*	*	*	*	*		*					*			*	
S13	Data processing	*				*	*	*		*	*	*	*				*				*				*
S14	Data analysis	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
S15	Techniques to enhance trustworthiness	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		*	*	*
S16	Synthesis and interpretation	*	*		*	*	*	*	*	*	*	*	*	*		*	*	*			*	*	*	*	*
S17	Links to empirical data	*	*		*	*	*	*	*	*	*	*	*	*		*	*	*	*			*	*			*
S18	Integration with prior work, implications, transferability, and contribution(s)	*		*	*	*	*	*	*	*	*	*	*	*		*	*	*	*	*	*		*	*	*
S19	Limitations	*			*	*	*	*		*				*		*	*	*			*				*
S20	Conflicts of interest						*			*															
S21	Funding									*						*								*	

[a]The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research. In the table, the asterisks indicate which sources mentioned which topics.

[b]The numbers in column headings are the numbers of the citations in the reference list at the end of this report. Those citations are of original sources describing criteria for reporting and/or critical appraisal of qualitative research, which the authors used in creating the SRQR.

[c]Focuses on reporting standards (all other sources focus on quality standards or guidelines for critical review/evaluation).

[d]Addresses quantitative and qualitative research.

Supplemental Digital Appendix 2 (see http://links.lww.com/ACADMED/A218) should provide sufficient description and examples to enable both novice and experienced researchers to use these standards. Thus, the SRQR should apply broadly across disciplines, methodologies, topics, study participants, and users.

The SRQR items reflect information essential for inclusion in a qualitative research report, but should not be viewed as prescribing a rigid format or standardized content. Individual study needs, author preferences, and journal requirements may necessitate a different sequence or organization than that shown in Table 1. Journal word restrictions may prevent a full exposition of each item, and the relative importance of a given item will vary by study. Thus, although all 21 standards would ideally be reflected in any given report, authors should prioritize attention to those items that are most relevant to the given study, findings, context, and readership.

Application of the SRQR need not be limited to the writing phase of a given study. These standards can assist researchers in planning qualitative studies and in the careful documentation of processes and decisions made throughout the study. By considering these recommendations early on, researchers may be more likely to identify the paradigm and approach most appropriate to their research, consider and use strategies for ensuring trustworthiness, and keep track of procedures and decisions.

Journal editors can facilitate the review process by providing the SRQR to reviewers and applying its standards, thus establishing more explicit expectations for qualitative studies. Although the recommendations do not address or advocate specific approaches, methods, or quality standards, they do help reviewers identify information that is missing from manuscripts.

As authors and editors apply the SRQR, readers will have more complete information about a given study, thus facilitating judgments about the trustworthiness, relevance, and transferability of findings to their own context and/or to related literature. Complete reporting will also facilitate meaningful synthesis of qualitative results across studies.[40] We anticipate that such transparency will, over time, help to identify previously unappreciated gaps in the rigor and relevance of research findings. Investigators, editors, and educators can then work to remedy these deficiencies and, thereby, enhance the overall quality of qualitative research.

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References

1 Lingard L, Kennedy TJ. Qualitative research in medical education. In: Swanwick T, ed. Understanding Medical Education: Evidence, Theory and Practice. Oxford, UK: Wiley-Blackwell; 2010:323–335.
2 Harris IB. Qualitative methods. In: Norman GR, van der Vleuten CPM, Newble DI, eds. International Handbook of Research in Medical Education. Dordrecht, Netherlands: Kluwer Academic Publishers; 2002:45–95.
3 Denzin N, Lincoln Y. Introduction: The discipline and practice of qualitative research. In: The Sage Handbook of Qualitative Research. 3rd ed. Thousand Oaks, Calif: Sage Publications, Inc.; 2005:1–32.
4 Ginsburg S, Bernabeo E, Ross KM, Holmboe ES. "It depends": Results of a qualitative study investigating how practicing internists approach professional dilemmas. Acad Med. 2012;87:1685–1693.
5 Yardley S, Brosnan C, Richardson J, Hays R. Authentic early experience in medical education: A socio-cultural analysis identifying important variables in learning interactions within workplaces. Adv Health Sci Educ Theory Pract. 2013;18:873–891.
6 Embuldeniya G, Veinot P, Bell E, et al. The experience and impact of chronic disease peer support interventions: A qualitative synthesis. Patient Educ Couns. 2013;92:3–12.
7 Pinnock H, Kendall M, Murray SA, et al. Living and dying with severe chronic obstructive pulmonary disease: Multi-perspective longitudinal qualitative study. BMJ. 2011;342:d142.
8 Brady MC, Clark AM, Dickson S, Paton G, Barbour RS. Dysarthria following stroke: The patient's perspective on management and rehabilitation. Clin Rehabil. 2011;25:935–952.
9 Iedema R, Allen S, Britton K, et al. Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: The "100 patient stories" qualitative study. BMJ. 2011;343:d4423.
10 Kuper A, Reeves S, Levinson W. An introduction to reading and appraising qualitative research. BMJ. 2008;337:404–407.
11 Giacomini M, Cook, DJ. Users' guides to the medical literature: XXIII. Qualitative research in health care A. Are the results of the study valid? JAMA. 2000;284:357–362.
12 Giacomini M, Cook, DJ. Users' guides to the medical literature: XXIII. Qualitative research in health care B. What are the results and how do they help me care for my patients? JAMA. 2000;284:478–482.
13 Barbour RS. Checklists for improving rigour in qualitative research: A case of the tail wagging the dog? BMJ. 2001;322:1115–1117.
14 Dunt D, McKenzie R. Improving the quality of qualitative studies: Do reporting guidelines have a place? Fam Pract. 2012;29:367–369.
15 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007;19:349–357.
16 Cook DA, Bowen JL, Gerrity MS, et al. Proposed standards for medical education submissions to the Journal of General Internal Medicine. J Gen Intern Med. 2008;23:908–913.
17 Tracy SJ. Qualitative quality: Eight "big-tent" criteria for excellent qualitative research. Qual Inq. 2010;16:837–851.
18 Lincoln YS. Emerging criteria for quality in qualitative and interpretive research. Qual Inq. 1995;1:275–289.
19 Mays N, Pope C. Qualitative research in health care. Assessing quality in qualitative research. BMJ. 2000;320:50–52.
20 Burns N. Standards for qualitative research. Nurs Sci Q. 1989;2:44–52.
21 Ryan GW. What Are Standards of Rigor for Qualitative Research? 2005. http://www.wjh.harvard.edu/nsfqual/Ryan%20Paper.pdf. Accessed April 20, 2014.
22 The EQUATOR Network: Enhancing the quality and transparency of health research. http://www.equator-network.org. Accessed April 6, 2014.
23 Côté L, Turgeon J. Appraising qualitative research articles in medicine and medical education. Med Teach. 2005;27:71–75.
24 Bordage G, Caelleigh AS. A tool for reviewers: "Review criteria for research manuscripts." Acad Med. 2001;76:904–951.
25 Task Force of Academic Medicine and the GEA-RIME Committee. Appendix 1: Checklist of review criteria. Acad Med. 2001;76:958–959.
26 Malterud K. Qualitative research: Standards, challenges, and guidelines. Lancet. 2001;358:483–488.

27 Inui TS, Frankel RM. Evaluating the quality of qualitative research: A proposal pro tem. J Gen Intern Med. 1991;6:485–486.
28 Devers KJ. How will we know" good" qualitative research when we see it? Beginning the dialogue in health services research. Health Serv Res. 1999;34:1153.
29 Duran RP, Eisenhart MA, Erickson FD, et al. Standards for reporting on empirical social science research in AERA publications. Educ Res. 2006;35:33–40.
30 Newman M, Elbourne D. Improving the usability of educational research: Guidelines for the reporting of primary empirical research studies in education (The REPOSE Guidelines). Eval Res Educ. 2004;18:201–212.
31 Knafl KA, Howard MJ. Interpreting and reporting qualitative research. Res Nurs Health. 1984;7:17–24.
32 Kitto SC, Chesters J, Grbich C. Quality in qualitative research. Med J Aust. 2008;188:243–246.
33 Rowan M, Huston P. Qualitative research articles: Information for authors and peer reviewers. CMAJ. 1997;157:1442–1446.
34 Cohen D, Crabtree B. Guidelines for designing, analyzing, and reporting qualitative research. Qualitative Research Guidelines Project, Robert Wood Johnson Foundation. 2006. http://qualres.org/HomeGuid-3868.html. Accessed April 6, 2014.
35 Elm E von, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. Strengthening the reporting of observational studies in epidemiology (STROBE) statement: Guidelines for reporting observational studies. BMJ. 2007;335:806–808.
36 Davidoff F, Batalden P, Stevens D, Ogrinc G, Mooney S; SQUIRE Development Group. Publication guidelines for quality improvement in health care: Evolution of the SQUIRE project. Qual Saf Health Care. 2008;17(suppl 1):i3–i9.
37 Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c332.
38 Maxwell JA. Designing a qualitative study. In: Bickman L, Bog D, eds. The SAGE Handbook of Applied Social Research Methods. 2nd ed. Sage Publications, Inc.; 2009:214–253.
39 Meyrick J. What is good qualitative research? A first step towards a comprehensive approach to judging rigour/quality. J Health Psychol. 2006;11:799–808.
40 Bearman M, Dawson P. Qualitative synthesis and systematic review in health professions education. Med Educ. 2013;47:252–260.

References Cited Only in Table 2

41 Attree P, Milton B. Critically appraising qualitative research for systematic reviews. Evid Policy. 2006;2:109–126.
42 Blaxter M. Criteria for the evaluation of qualitative research. Med Sociol News. 1996;22:34–37.
43 Critical Appraisal Skills Programme (CASP). Qualitative Research Checklist. 2013. http://www.casp-uk.net/wp-content/uploads/2011/11/casp-qualitative-research-checklist-31.05.13.pdf#!casp-tools-checklists/c18f8. Accessed April 6, 2014.
44 Frambach JM, van der Vleuten CP, Durning SJ. AM last page. Quality criteria in qualitative and quantitative research. Acad Med. 2013;88:552.
45 Kuper A, Lingard L, Levinson W. Critically appraising qualitative research. BMJ. 2008;337:687–689.
46 Law M, Stewart D, Letts L, Pollock N, Bosch J, Westmorland M. Guidelines for the critical review of qualitative studies. McMaster University Occupational Therapy Evidence-Based Practice Research Group. 1998. http://www.usc.edu/hsc/ebnet/res/Guidelines.pdf. Accessed April 20, 2014.
47 Pearson A, Field J, Jordan Z. Appendix 2: Critical appraisal tools. In: Evidence-Based Clinical Practice in Nursing and Health Care: Assimilating Research, Experience and Expertise. Oxford, UK: Blackwell Publishing Ltd.; 2009:177–182. http://onlinelibrary.wiley.com/doi/10.1002/9781444316544.app2/summary. Accessed April 13, 2014.
48 Popay J, Rogers A, Williams G. Rationale and standards for the systematic review of qualitative literature in health services research. Qual Health Res. 1998;8:341–351.
49 Sandelowski M, Barroso J. Writing the proposal for a qualitative research methodology project. Qual Health Res. 2003;13:781–820.
50 Stige B, Malterud K, Midtgarden T. Toward an agenda for evaluation of qualitative research. Qual Health Res. 2009;19:1504–1516.

Table 1: Data implementation procedures for this study

Week	Mail preference	Web preference
1	Standard introducing letter	Standard introducing letter
2	Invitation letter including consent statement, mail questionnaire, incentive and return envelope	Invitation email letter including consent statement, link to the survey, incentive and web survey instructions
3	Thank you postcard or reminder postcard	Thank you or reminder email with link to the survey
4	Replacement questionnaire and return envelope with cover letter including link to the survey for web options to the non-responders	Reminder email to the non-responders with link to survey and web survey instructions accompanied by mail questionnaire and return envelope for the mail option

Source: Dillman DA, Smyth JD, Christian LM. Internet, mail and mixed-mode surveys. The Tailored Design Method. 3ed. New Jersey: John Wiley& Sons, Inc.;2009.

Table 2: Scenarios for 90% power to detect a difference between conventional and CAM based on the question: " Do you think CAM modalities can interact with conventional cancer treatments? " Scenarios are based on proportions responding negatively to the question and are presented with no intra class correlation (ICC) and ICC equal 0.2 and a cluster size of 5.

	Proportion 2					
	.7		.8		.9	
Proportion 1	N/Group ICC=0.0	N/Group ICC=0.2	N/Group ICC=0.0	N/Group ICC=0.2	N/Group ICC=0.0	N/-Group ICC=0.2
0.3	31	56	19	34	12	22
0.4	56	101	30	54	17	31
0.5	124	223	52	94	26	47
0.6	477	856	109	196	42	76

Table 3: Targeted response and screening rates for each group of providers					
Type of providers	**# Available**	**# Contacted**	**Response rate**	**Screened out for not treating cancer patients**	**Final sample size**
Oncology doctors	200	200	50 %	0%	100
Oncology nurses	500	200	50 %	0%	100
General Practitioners	5.500	200	50 %	0%	100
Acupuncturists	761	400	50 %	50 %	100
Masseurs	687	400	50 %	50 %	100
Reflexologists	290	290	50%	50 %	100
Hands on healers	258	400	50 %	50 %	100

Table 4: Study measures		
Study concepts	**Constructed from the following example questions**	**Type of variable**
Risk perceptions	CAM should only be used as a last resort when conventional medicine has nothing to offer.	Dichotomous
Risk communication	How often do you ask your patients if they use CAM and/or conventional medicine?	Order categories
Direct risk situations	Do you think that CAM modalities can interact with conventional medicines?	Dichotomous
Indirect risk situations	Is the lack of regulation of the CAM profession risky for the patients?	Dichotomous
Information regarding CAM and conventional treatment	Do you seek information regarding CAM cancer treatment? Do you seek information regarding conventional cancer treatment?	Dichotomous Dichotomous

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Mapping the risk perception and communication gap between different professions of health care providers in cancer care – A cross-sectional protocol

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Mapping the risk perception and communication gap between different professions of health care providers in cancer care – A cross-sectional protocol

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Key Words
Direct risk; indirect risk; patient safety; Oncology; Complementary and Alternative Medicine (CAM); cancer care; provider-patient communication

Word Count: 3974

Abstract

Introduction

Studies show that cancer patients who use Complementary and Alternative Medicine (CAM) have a poorer survival prognosis than those who do not. It remains unclear whether this is due to *a priori* poorer prognosis that makes patients turn to CAM, or whether there is a factor associated with CAM use itself that influences the prognosis negatively. Health care providers should assist patients in safeguarding their treatment decision. However, the current non-communication between CAM and conventional providers leaves it up to the patients themselves to choose how to best integrate the two worlds of therapy. In this study, an interactive shared decision making (SDM) tool will be developed to enable patients and health professionals to make safe health choices.

Methods and analysis

We will delineate, compare, and evaluate perception and clinical experience of communication of risk situations among oncology experts, general practitioners and CAM practitioners. To accomplish this, we will develop a pilot and implement a large-scale survey among the above mentioned health professionals in Norway. Guided by the survey results, we will develop a beta-version of a shared decision making tool for health care providers to use in guiding patients to make safe CAM decisions.

Ethics and dissemination

Participants must give their informed and written consent before inclusion. They will be informed about the opportunity to drop out from the study followed by deletion of all data registered. The study needs no approval from The Regional Committee for Medical and Health Research Ethics because all participants are health care professionals. Results from this study will be disseminated in peer-reviewed medical journals.

Funding

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Strengths and Limitations of this study

- The study plan in this study is strong, as it combines three different strategies (a literature review, a pilot cross-sectional study and a main cross-sectional study) to finally develop a shared decision making tool.
- There are still some methodological challenges in surveying health care professionals; oncologists and general practitioners are often poor responders, so steps must therefore be taken to boost the questionnaire response rate.

Introduction

Complementary and alternative medicine (CAM) is a popular treatment modality among cancer patients in Europe [1-4]. In this research project, CAM, or alternative treatment, is understood as a health-related treatment that is practiced outside the established health services and not practiced by authorized health personnel. However, treatment practiced within the scope of the established health services or by authorized health personnel is also covered by the term alternative treatment when the methods employed are used outside the established health service [5] . Findings from studies suggest that, on average, half of all cancer patients use CAM, and this proportion has increased over the past years [6]. The Norwegian Cancer Society stated that approximately 50% of all Norwegian cancer patients used CAM in 2008 [7] . The majority of cancer patients use CAM because they believe it increases the body's ability to fight the cancer, strengthens the immune system, improves physical and emotional well-being and quality of life or enables the maintenance of hope and control over their cancer care [8, 9]. Although current RCT-based documentation of CAM treatment gives little support to patients' beliefs of CAM's efficacy on tumors [10], a large number of patients still clearly wish to use CAM. The interpretation of this paradox is that either the patients do not give credence to scientific evidence, or they experience some other benefit from the treatment. Objectively, data show that cancer patients who use CAM have a poorer survival prognosis than those who do not use CAM [11, 12]. It remains unclear whether this is due to *a priori* poorer prognosis that makes patients turn to CAM, or whether there is a factor associated with CAM use itself that influences the prognosis negatively.

In Norway patients receive conventional medical treatment within the public health care system, while CAM practitioners operate outside this system. The majority of the CAM practitioners are members of professional associations that require professional standards of medical and CAM-specific skills of their members. However, patients themselves generally

cover the costs of visiting a CAM practitioner. Thus, the Norwegian context is comparable to that of other western settings [13]. Masseurs, acupuncturists, hands on healers and reflexologists are the CAM practitioners most used by cancer patients.

Qualitative research into patients' experiences with CAM underlines patient disenchantment with the conventional health care system as an important reason for choosing CAM [14]. Patients emphasize the experience of a fragmented and specialized system, with short consultations in a "production line" approach, which often compromises continuity at the organizational, informational and relational levels [15]. In conventional care the patient's "whole story" may fade and become invisible to the individual practitioner [16]. CAM practitioners claim to have a more holistic approach [17]. They often offer therapy directed at both mind and body [18]. Practicing principles in CAM may include patient-centeredness, empowerment and self-management [19, 20]. Thus, it is plausible that CAM supports continuity in the provider/patient relationship to a greater degree than conventional care.

In this research project, risk will generally be defined as a compound measurement of the probability of an event and the magnitude of the potential negative outcome of that event [21], both operationally and methodologically. Patient safety is understood as the reduction of risk of unnecessary harm associated with health care to an acceptable minimum [22]. Medical science risk can be divided into direct and indirect risk [23, 24] as illustrated in Figure 1.

Figure 1: Understanding of patient safety and risk in this research project. Direct risk is caused by the treatment itself and related to the intervention, while indirect risk is related to the treatment context, such as the practitioner more than the medicine.

Direct risk is caused by the treatment itself. This dimension includes traditional adverse effects of an intervention, such as bleeding in response to acupuncture needling, nausea caused by chemotherapeutic medication, or the adverse effect of an herb, as well as risk connected to self-management advice from the practitioner [25]. For example, breast cancer patients often use herbal supplements, such as ginseng or soy products, in conjunction with conventional cancer treatment [26, 27]. These supplements have phytoestrogen components that may alter estrogen levels or activate estrogen receptors as either pro- or anti-estrogen [28]. High estrogen levels are well-documented risk factors for breast cancer. Studies of these supplements are mixed, showing increased [29], reduced [28] or no association with circulating levels of estrogen [30].

Indirect risk is related to adverse effects of the treatment context, for example, the CAM practitioner rather than the medicine. A patient may be harmed by a care context that prevents the patient from receiving the best possible treatment relevant to her or his health needs [31]. A homeopath without appropriate medical training may overlook a serious condition and continue treatment, even in cases where conventional treatment would be an unconditional necessity. This situation may delay meaningful diagnostic procedures and relevant therapeutic interventions.

To ensure patient safety and avoid undesired outcomes, conventional care should assist patients in safeguarding their treatment decisions. This can best be achieved through open, transparent, non-judgmental and informed discussions about possible outcomes of combining CAM and conventional treatment for cancer. Cancer patients highly value the input from their physicians about the use of CAM [9, 14]. Patients should feel free to discuss all the options in their care without the fear of being rejected. Research shows, however, that patients fear that health care providers are indifferent or will object to the use of CAM [32]. It is, therefore, important that health care providers initiate this discussion and include this in the history taking [33-35]. However, studies reveal that 38-60% of cancer patients use CAM without informing their health care team [36, 37].

In a Norwegian study, the importance of taking time and effort to learn more about the value of CAM therapies has been emphasized [38]. A qualitative study [39] concludes that physicians have limited knowledge about the occurrence of possible interactions. Breitsameter [40] identifies ethical problems regarding the doctors' inability to provide information about the risks of using CAM together with conventional care.

On the other hand, CAM practitioners' beliefs and counseling practices on how to combine the two treatment worlds safely have not been explored. In Norway, the CAM profession is totally unregulated, and CAM practitioners may practice as long as they do no harm. This vague regulation of the CAM profession increases the chance of indirect risk and thereby threatens patient safety [25]. It is reasonable to assume that CAM practitioners' knowledge of conventional medicine vary from no formal medical education to being fully trained physicians who have added some CAM modalities to their armamentarium [16, 41].

The current non-communication between CAM and conventional professionals leaves it up to the patients themselves, who are in a vulnerable situation, to choose how to best integrate the two worlds of therapy [4, 14, 27]. Conventional health care providers may believe that to reduce

risk, it is best to advise patients not to use CAM in combination with conventional treatment. However, a study [14] demonstrated that patients may decline conventional medicine if they feel rejected when they want to discuss possible CAM treatment with their GP or oncology expert.

It should be possible to support patients in making safe decisions about combining CAM with conventional care [42]. However, the large difference between the two worlds of therapy and the complexity of the issue makes this a challenging task. Conventional and CAM providers differ regarding treatment concepts, philosophies and diagnostic procedures leading to different models of disease causality and treatment practice [18]. These differences likely influence the practitioners' conceptualization of benefits and risks, making shared recommendations to patients unlikely.

There is little previous knowledge about how health care providers gather and seek information about CAM, and whether the perceptions and assessments of risk are equally understood by oncology experts, general practitioners (GPs), CAM practitioners and patients [39]. The overarching question is, then, how health care providers in both the conventional and the CAM fields can better support patients in making informed choices about CAM in cancer care. In this study, an interactive shared decision making (SDM) tool [43] will be developed to enable patients and health professionals to make safe health choices.

Aims of the study

The global aim of this research project is to reduce risk and enhance safety for patients who want to combine conventional medicine with CAM in cancer care. To achieve this, we will:

Delineate, compare and evaluate perceptions and clinical experience of communication about direct and indirect risk situations among oncology experts (doctors and nurses), GPs and CAM practitioners (masseurs, acupuncturists, hands on healers and reflexologists/zone therapists)

To accomplish this, we will perform three individual studies:

Study 1: Perform a literature review of the qualitative research literature in the field

Study 2: Develop, pilot and implement a large-scale survey among oncology experts, GPs and CAM practitioners in Norway.

Study 3: Guided by the survey results, design and develop an SDM tool for health care providers to use for guiding patients to make safe CAM decisions that are in line with the patients' health goals. We have qualitative data available from different studies on cancer patients [39, 44]. These data will be incorporated in the tool, so patients can be guided to make safe health decisions.

The following research questions will be addressed in the literature review, the mixed method survey pilot, and the large-scale survey:

a) Is there a difference among the four professional groups in how they gather information about CAM?

b) Is there a difference among the four professional groups in how they recognize direct and indirect risk situations in clinical practice? What kind of risk assessment tools do they use for this purpose? What procedure is followed when in doubt of medical diagnosis or when to refer to other health care interventions?

c) According to the study participants, what constitutes enough evidence on efficacy and safety to recommend a CAM modality?

d) Are there differences among the four professional groups in how they deal with patients who delay or decline conventional treatment?

e) Are there differences among the four groups in how they experience communication with their patients about CAM? What do practitioners on both sides think about risk and safety and the consequences of combining both treatment systems in cancer care?

Below is the flow chart of the study.

Figure 2: Flow of activities in this research project

Methods and analysis

Study 1: Literature review

The aim of the literature review is to map the qualitative research literature about risk communication and perceptions of complementary therapies among health care providers. We will include qualitative studies in this review as this approach can help researchers to gain access to the view of participants, and it contributes to a deeper understanding and thorough knowledge in health and well-being, especially in situations in which we have limited previous knowledge of our phenomenon of interest [45, 46].

The searches will be performed in databases such as AMED, CINAHL, MBASE, MEDLINE/ PubMed and PsycINFO. The PEO (Population, Exposure and Outcome) format will be used. PEO is a tool used to formulate questions about qualitative research, and the search strategy

will include keywords such as *risk perception; risk communication; decision making; cancer care; Complementary and alternative medicine.* MeSH–terms and truncation symbols will be used when available. The searches will be combined with manual searches in journals of interest and reference lists, in addition to abstracts and keywords. The inclusion will comprise qualitative studies (individual and group interviews, opinion of an expert and literature reviews) investigating communication and perception about risk of complementary therapies among conventional and complementary providers. However, qualitative studies that have an added quantitative component, e.g. a questionnaire in the design (mixed design) will be included in the analysis. Quantitative studies (such as randomized controlled trials and observational studies) and evidence based guidelines will be excluded.

Theoretical framework

We will draw upon theories about risk in health care which, are described in the introduction, and inter-professionals and patient-center communication (PPC). Clear and appropriate communication and interdisciplinary collaboration are critical to the delivery of quality care for the complex patients in today's healthcare settings [47]. Effective communication may contribute to more confidence in the health provider and increased adherence to follow evidence -based recommendations and avoidance of negative interactions between conventional and complementary treatments [48]. Patient-centered communication is the set of skills and behaviours used by health care providers to promote a relationship in which patients actively participate as partners in healthcare decision making and management [48-50]. These theories will assist us in designing and conducting the study phases and interpreting the study findings.

Study 2: Pilot survey

Prior to the main large scale study, we plan to conduct a pilot study. The purpose is to test the data collection for face and content validity [51]. Six participants (n=6), including one oncology doctor, one nurse, one GP and three CAM providers, will be invited to participate in a *Think-aloud* session [52], which involves participants reporting their thoughts out loud as they complete the questionnaire. They will be asked to say whatever they are thinking, doing or looking at as they perform this task. The think-aloud session will provide us with information regarding whether any items are misunderstood, whether people answer in a meaningful way or whether they get bored or confused part way through. The questionnaire will be revised accordingly.

Then, 40 participants (10 oncology doctors, 10 oncology nurses, 10 GPs and 10 CAM providers) will complete the instrument and several other sets of questions to establish construct validity [51]. The results from this questionnaire will be compared to the Holistic Complementary and Alternative Medicine Questionnaire (HCAMQ) and the Complementary and Alternative Medicine Beliefs Inventory (CAMBI) [53, 54]. Both are validated questionnaires including concepts like *CAM beliefs* and *holistic health beliefs*. These two factors represent distinct CAM constructs and will be used to distinguish CAM attitudes from conventional attitudes among the respondents. The oncology experts needed for the pilot study will be recruited through two wards at the University Hospital in North Norway (UNN). The study participants will be contacted by email or postal mail and invited to participate. The CAM providers will be recruited through private clinics in the Troms and Nordland county.

A reference group consisting of one oncology nurse, one GP and two CAM practitioners will assist the research team in testing the validity of the questionnaire. They will complete and comment on the instrument before the commencement of the pilot study.

Study 2: Large scale survey

Inclusion criteria

Oncology doctors and nurses, GPs and CAM providers who are currently practicing and members of a professional association, and have clinical experience with current or previously diagnosed cancer patients are eligible for the study. Being a member of a professional association ensures high professional standards of medical and/or CAM skills among the participants. According to a Norwegian study from 2013 [7], the four most popular CAM modalities used by Norwegian cancer survivors were massage (10,5%), acupuncture (7,6%), hands on healer (4,8%) and reflexology (3,2%). This information was the rationale for choosing these particular CAM participants in the study.

Exclusion criteria

Allopathic and CAM providers who have no clinical experience with current or previously diagnosed cancer patients are ineligible for the study.

Participants

We will include one-hundred oncology doctors and 100 oncology nurses, working at the following four hospitals: *The University Hospital of North-Norway (UNN), Tromso; St. Olav Hospital, Trondheim; Haukeland University Hospital, Bergen;* and *Norwegian Radium Hospital, Oslo.* Furthermore, we will include 100 GPs and 400 CAM providers (100

masseurs, 100 acupuncturists, 100 hands on healers, 100 reflexologists/zone therapists) working in private clinics throughout the country.

Recruitment

The GPs and the oncology doctors will be recruited through *The Norwegian Medical Association* and *The Union for Oncologists.* The oncology nurses and the CAM providers will be recruited through *The Norwegian Nurses Organization, The Association for Alternative Provider Organizations (Saborg), The Norwegian Acupuncture Association* and *The Norwegian Healer Association*. We will ask the associations to provide us with a list of their members. The lists will be randomized by the study team. The participants will be offered a gift card as compensation for time spent responding to the study questionnaire. In order to increase the response rate among the GPs and oncology doctors, the gift card incentive will be somewhat higher for them [52].

Data collection

To boost the questionnaire response rate as much as possible, a mixed mode including postal mail and email will be used [52]. A standard introductory letter will be sent to all allopathic and CAM providers identified for inclusion. This letter will inform the recipient that he or she will receive a request to help with an important study. We will use a recognized and respected logo from the Arctic University of Norway and The Northern Norway Regional Health Authority on the stationery and envelopes, and the letters will be co-signed by a well-known physician. One week following the mailing of this letter, emails will be sent to all potential participants with a link to the Internet survey. The survey will be administered through a secure web application designed for online surveys [55]. We will use a function that enables the research team to identify whether each person completes some or all of the survey, but prevents the research team from seeing any participant's identity, thereby providing anonymity. For those providers who do not have email or have limited access to Internet, a questionnaire will be sent by postal mail. After a week, a "thank you" or a reminder email will be sent to the included providers. Finally, one week later a replacement questionnaire and a reminder letter with a link to the survey will be sent to the non-responders, including options to complete the questionnaire either by mail or email. The study participants who have completed the questionnaire will be asked to click on a link at the end of the questionnaire confirming whether they will like to receive a gift card or not. If they wish, a gift card will be sent to them by mail (Table 1).

Table 1: Data implementation procedures for this study

Week	Mail preference	Web preference
1	Standard introducing letter	Standard introducing postal letter
2	Invitation letter including consent statement, mail questionnaire, incentive and return envelope	Invitation email letter including consent statement, link to the survey, incentive and web survey instructions
3	Thank you postcard or reminder postcard	Thank you or reminder email with link to the survey
4	Replacement questionnaire and return envelope with cover letter including link to the survey for web options to the non-responders	Reminder email to the non-responders with link to survey and web survey instructions accompanied by mail questionnaire and return envelope for the mail option

Source: Dillman DA, Smyth JD, Christian LM. Internet, mail and mixed-mode surveys. The Tailored Design Method. 3ed. New Jersey: John Wiley& Sons, Inc.;2009.

Power calculation

In order to identify any possible difference between the two groups of providers (conventional vs. CAM), a power calculation was performed. The four groups to be studied are oncology experts (doctors and nurses), GPs and CAM practitioners. In Norway there are approximately 200 oncologists, 500 oncology nurses, 5.500 GPs and an estimated 2.100 CAM practitioners. Some providers, particularly oncologists and oncology nurses, may practice in the same facility and thereby share beliefs about conventional and CAM cancer treatment. This "clustering" is incorporated into power calculations.

Power calculations are based on the question, "Do you think CAM modalities can interact with conventional cancer treatments?" In our calculations, we presume that CAM providers will be highly likely to respond "no" and that conventional providers will be less likely to respond "no". We calculate power for several different scenarios of response to the question, with and without clustering taken into account (table 2). With a moderate difference between the two groups (CAM vs. conventional providers) in response to the question (CAM providers with a 70% proportion and Conventional providers with 50%), 124 respondents are needed per group to have 90% power to detect a difference. When clustering is taken into account and a cluster size of 5, with a moderate/high interclass correlation of 0.2 used, 223 per group (conventional and CAM providers) are needed to have 90% power.

Table 2: Scenarios for 90% power to detect a difference between conventional and CAM based on the question: "Do you think CAM modalities can interact with conventional cancer treatments? " Scenarios are based on proportions responding negatively to the question and are presented with no intra class correlation (ICC) and ICC equal 0.2 and a cluster size of 5.

	Proportion 2					
	.7		.8		.9	
Proportion 1	N/Group ICC=0.0	N/Group ICC=0.2	N/Group ICC=0.0	N/Group ICC=0.2	N/Group ICC=0.0	N/-Group ICC=0.2
0.3	31	56	19	34	12	22
0.4	56	101	30	54	17	31
0.5	124	223	52	94	26	47
0.6	477	856	109	196	42	76

However, in order to perform within group comparisons we will include 300 conventional providers (100 oncology doctors, 100 oncology nurses, 100 GPs) and 400 CAM providers (100 masseurs, 100 acupuncturists, 100 hands on healers, 100 reflexologists/zone therapists), a total sample size of 700. Table 3 shows our projections for sample sizes, taking into account response screening rates.

Table 3: Targeted response and screening rates for each group of providers and the numbers to be contacted to arrive at the sample sizes

Type of providers	# Available	# Contacted	Response rate	Screened out for not treating cancer patients	Final Sample size
Oncology doctors	200	200	50 %	0%	100
Oncology nurses	500	200	50 %	0%	100
General Practitioners	5.500	200	50 %	0%	100
Acupuncturists	761	400	50 %	50 %	100
Masseurs	687	400	50 %	50 %	100
Reflexologists	290	290	50%	50 %	100
Hands on healers	258	400	50 %	50 %	100

Measurements

Table 4 shows the study measures including the main study concepts and some examples of questions from which these concepts will be constructed. The study measures are based on preliminary analysis from the meta-synthesis and results from the first meeting with the reference group where the participants were challenged to make questions related to the different concepts in the questionnaire.

Table 4: Study measures		
Study concepts	**Constructed from the following example questions**	**Type of variable**
Risk perceptions	CAM should only be used as a last resort when conventional medicine has nothing to offer.	Dichotomous
Risk communication	How often do you ask your patients if they use CAM and/or conventional medicine?	Order categories
Direct risk situations	Do you think that CAM modalities can interact with conventional medicines?	Dichotomous
Indirect risk situations	Is the lack of regulation of the CAM profession risky for the patients?	Dichotomous
Information regarding CAM and conventional treatment	Do you seek information regarding CAM cancer treatment? Do you seek information regarding conventional cancer treatment?	Dichotomous Dichotomous

Statistical analyses

The surveys will be a questionnaire based cross-sectional survey. The research questions mentioned above will be explored further in the questionnaire, and both closed and open-ended questions will be used. Responses to the open-ended questions will be categorized into nominal or ordinal scales. The guiding principle of the analyses will be performed by descriptive statistics of the perceptions present overall and comparisons of the four practitioner groups. Chi-square tests and logistic regression will be used for analyzing binary dependent variables, and analysis of variance will be used analyzing continuous, dependent variables. Quantitative data will be analyzed using the SPSS version 19.0 for Windows.

Study 3: A web-based decision making tool

In cooperation with The Norwegian Centre for Integrated Care and Telemedicine at the University Hospital of North-Norway, an SDM tool to support decision making about CAM and conventional care for cancer patients will be developed. The tool will be published on the Internet and ready to use for patients and health care providers. The Norwegian Centre for Integrated Care and Telemedicine will operate the technical version of the SDM tool.

Ethics

The participants will receive a written document describing the purpose and consequences of participating in the study. They will be informed of the possibility to withdraw from the study followed by deletion of all data registered. The returned and completed questionnaire will be considered a consent to participate in the study. The study does not need approval from The Regional Committee for Medical and Health Research Ethics, according to Norwegian legislation, because all participants are health care professionals. All data will be archived

according to established procedures and REDCap safety procedures. No information that may be traced back to individuals will be published.

Dissemination

The results of this research project will be disseminated to cancer patients, health care professionals in both conventional care and CAM, the Norwegian Cancer Society, public health associations and various CAM practitioner organizations. The scientific work will be published in peer-reviewed journals, and orally presented at national and international conferences. The published results will be communicated through The National Information Center for Complementary and Alternative Medicine's (NIFAB) web portal. NIFAB is a part of The National Research Center in Complementary and Alternative Medicine (NAFKAM) and its web portal www.nifab.no is frequently visited. The results will be communicated to the relevant organizations through direct contact.

Publication policy

The results of the study will be published in appropriate journals regardless of outcome. The study will be implemented and reported in accordance with the recommendations of the STROBE checklist.

Discussion

This protocol presents three studies designed to delineate, compare and evaluate perceptions and clinical experience of communication with direct and indirect risk situations among different professionals of health care providers in cancer care. The global aim is to reduce risk and enhance safety for patients who want to combine conventional medicine with CAM in cancer care. The project will increase knowledge about how CAM and conventional health providers understand the potential benefits and risks of combining both treatment systems in cancer care. Such information is essential to bridge the communication gap between patients and their health care providers [35, 56]. Lack of communication and coordination between different parts of the health care system are major threats to patient safety [39]. This general tool can pave the way for more disease-specific tools that highlight the issue of CAM-conventional direct and indirect risks relevant to these patient groups [43]. It is, therefore, innovative and useful for public health authorities as it will improve patient engagement and the quality of health care.

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Competing interest

The authors declare that they have no conflict of interest.

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Contributors

TS, FM and GB initiated the project. TS, FM, SQ, TA, AS, AK and GB contributed to conceptualisation and design of the study and all revised this manuscript critically for important intellectual content. All authors read and approved the final manuscript.

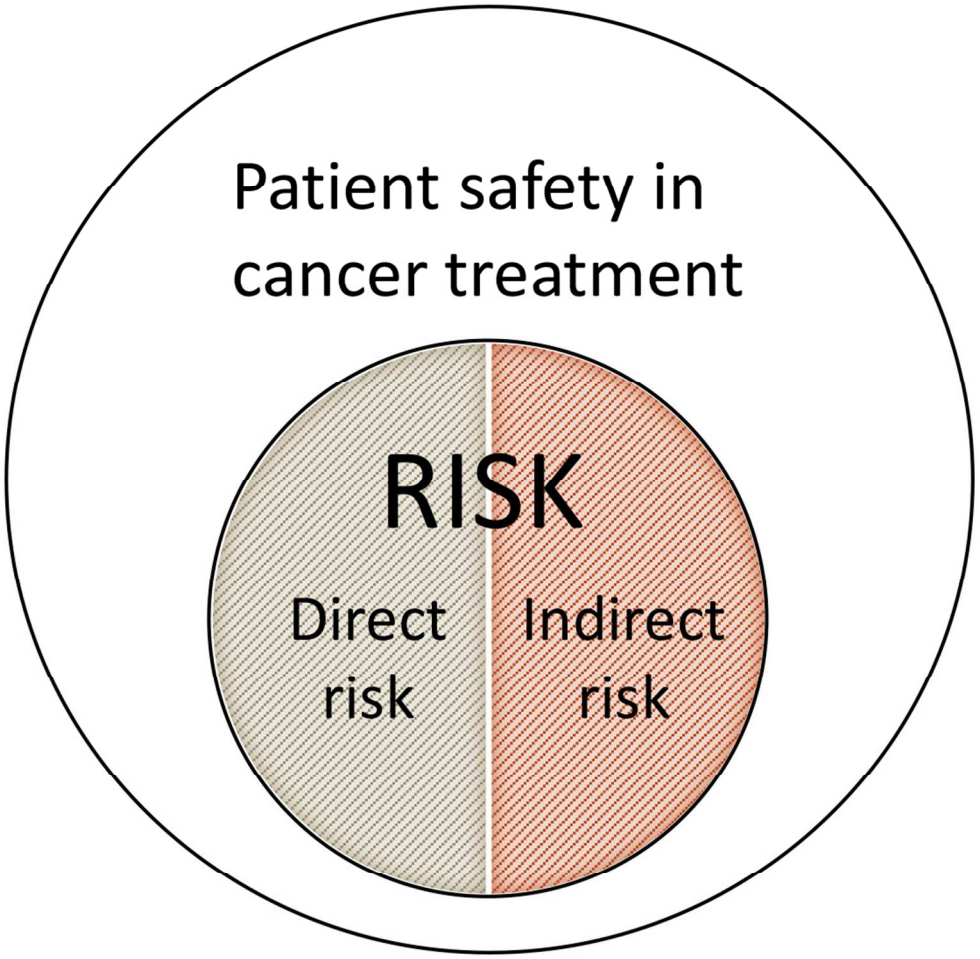
References

1. Ben-Arye E, Frenkel M, and Stashefsky MR, *Approaching Complementary and Alternative Medicine Use in Patients With Cancer: Questions and Challenges.* The Journal of Ambulatory Care Management, 2004. **27**(1): p. 53-62.
2. Cassileth BR, et al., *Alternative medicine use worldwide.* Cancer, 2001. **91**(7): p. 1390-1393.
3. Yates JS, et al., *Prevalence of complementary and alternative medicine use in cancer patients during treatment.* Support Cancer Care, 2005. **13**(10): p. 806-11.
4. Molassiotis A, Fernandez-Ortega P, and Pud D, *Use of complementary and alternative medicine in cancer patients:a European survey.* Ann Oncol, 2005. **16**(16): p. 655-663.
5. *LOV-2003-06-27-64 Lov om alternativ behandling av sykdom mv; English Act relating to the alternative treatment of disease, illness, etc*. 2003.
6. Horneber M, et al., *How Many Cancer Patients Use Complementary and Alternative Medicine: A Systematic Review and Metaanalysis.* Integrative Cancer Therapies, 2012. **11**(3): p. 187-203.
7. Kristoffersen AE, Norheim AJ, and Fonnebo VM, *Complementary and alternative medicine use among Norwegian cancer survivors: gender-specific prevalence and associations for use.* Evid Based Complement Alternat Med, 2013. **2013**: p. 318781.
8. Molassiotis A, et al., *Complementary and alternative medicine use in breast cancer patients in Europe.* Supportive care in Cancer, 2006. **14**(3): p. 260-267.
9. Verhoef MJ, et al., *Complementary therapies for cancer patients: Assessing information use and needs.* Chronic Disease in Canada, 2009. **29**(2).

10. Jacobson JS, Workman SB, and Kronenberg F, *Research on Complementary/Alternative Medicine for Patients With Breast Cancer: A Review of the Biomedical Literature.* Journal of Clinical Oncology, 2000. **18**(3): p. 668.
11. Han E, et al., *Alternative Therapy Used as Primary Treatment for Breast Cancer Negatively Impacts Outcomes.* Annals of Surgical Oncology, 2011. **18**(4): p. 912-916.
12. Risberg, T., et al., *[Does use of alternative medicine aggravate the survival prognosis in cancer?].* Tidsskr Nor Laegeforen, 2003. **123**(5): p. 628-30.
13. Wiesener S, et al., *Legal status and regulation of CAM in Europe.* Forsch Komplementärmed und Klass Naturheilkd, 2012. **19**(suppl 2): p. 29-36.
14. Salamonsen A, *Doctor-patient communication and cancer patient's choice of alternative therapies as supplement or alternative to conventional care.* Scandinavian Journal of Caring Science, 2013. **27**(1): p. 70-76.
15. Jeannie LH, et al., *Continuity of care: a multidisciplinary review.* BMJ, 2003. **327**(7425): p. 1219-1221.
16. Stub T, Alraek T, and Salamonsen A, *The Red flag! risk assessment among medical homeopaths in Norway: A qualitative study.* BMC Complement. Altern. Med, 2012. **12**(1): p. 150.
17. MacPherson H and Kaptchuk T, *Acupuncture in Practice: Case History Insights from the West*. 1997, Edinburgh: Churchill Livingstone.
18. Singer M and Baer H, *Introducing medical anthropology. A disipline in action*. 2 ed. 2012, Plymouth: AltaMira Press.
19. Maciocia G, *The Practice of Chinese Medicine*. 1994, Edinburgh: Churcill Livingstone.
20. Berger S, Braehler E, and Ernst J, *The health professional–patient-relationship in conventional versus complementary and alternative medicine. A qualitative study comparing the perceived use of medical shared decision-making between two different approaches of medicine.* Patient Education and Counseling, 2012. **88**(1): p. 129-137.
21. Davis EM, *Risky Business: Medical Discourse, Breast Cancer, and Narrative.* Qualitative Health Research, 2008. **18**(1): p. 65-76.
22. Runciman W, et al., *Towards an International Classification for Patient Safety: Key concepts and terms.* Int. Journal for Quality in Health Care, 2009. **21**(1): p. 18-26.
23. Fisher P, Dantas F, and Rampes H, *The safety of homeopathic products* J R Soc Med, 2002. **95**(9): p. 474-476.
24. Ernst E, *Towards a scientific understanding of the placebo effects*, in *Understanding the Placebo Effect in Complementary Medicine*, D. Peters, Editor. 2001, Churchill Livingstone: London. p. 17-29.
25. Stub T, *Safety of Treatment Provided by Homeopaths - Homeopathic Aggravations, Adverse effects and Risk Assessment*, in *Department of Community Medicine. NAFKAM - The National Research Center in Complementary and Alternative Medicine*. 2013, UiT The Arctic University of Norway, Tromsø NAFKAM skriftserie No.9 Tromsø.
26. Bao P-P, et al., *Ginseng and Ganoderma lucidum Use after Breast Cancer Diagnosis and Quality of Life: A Report from the Shanghai Breast Cancer Survival Study.* PloS ONE, 2012. **7**(6): p. e39343.
27. Ma, H., et al., *Estrogenic botanical supplements, health-related quality of life, fatigue, and hormone-related symptoms in breast cancer survivors: a HEAL study report.* BMC Complementary and Alternative Medicine, 2011. **11**(1): p. 109.
28. Harris, R.M., et al., *Phytoestrogens Are Potent Inhibitors of Estrogen Sulfation: Implications for Breast Cancer Risk and Treatment.* Journal of Clinical Endocrinology & Metabolism, 2004. **89**(4): p. 1779-1787.

29. Wu WH, et al., *Estrogenic Effect of Yam Ingestion in Healthy Postmenopausal Women.* Journal of the American College of Nutrition, 2005. **24**(4): p. 235-243.
30. Wu AH, et al., *A controlled 2-mo dietary fat reduction and soy food supplementation study in postmenopausal women.* The American Journal of Clinical Nutrition, 2005. **81**(5): p. 1133-1141.
31. Wardle JL and Adams J, *Indirect risks of complementary and alternative medicine*, in *Traditional, complementary and integrative medicine*, Adams J, et al., Editors. 2012, Palgrave Macmillian: Hampshire. p. 212-219.
32. Tovey P and Broom A, *Oncologists' and specialists cancer nurses' approaches to complementary and alternative medicine and their impact on patient action.* Social Science & Medicine, 2007. **64**: p. 2550-2564.
33. Lindring i nord, et al., *Håndbok i lindrende behandling (Handbook for palliative care)*. 2012, Universitetssykehuset Nord-Norge (University Hospital of North Norway): Tromsø.
34. Verhoef MJ, Boon HS, and Page SA, *Talking to cancer patients about complementary therapies: Is it the physicians's responsibility?* Current Oncology, 2008. **15**(2): p. 18-23.
35. Deng GE, et al., *Evidence-Based Clinical Practice Guidelines for Integrative Oncology: Complementary Therapies and Botanicals.* Journal of the Society for Integrative Oncology, 2009. **7**: p. 85-120.
36. Navo MA, et al., *An Assessment of the Utilization of Complementary and Alternative Medication in Women With Gynecologic or Breast Malignancies.* Journal of Clinical Oncology, 2004. **22**(4): p. 671-677.
37. Richardson MA, et al., *Complementary/Alternative Medicine Use in a Comprehensive Cancer Center and the Implications for Oncology.* Journal of Clinical Oncology, 2000. **18**(13): p. 2505-2514.
38. Risberg T, et al., *Knowledge of and attitudes toward complementary and alternative therapies: a national multicentre study of oncology professionals in Norway.* European Journal of Cancer, 2004. **40**: p. 529-535.
39. Salamonsen A, *Mind the Gap! Lay and Medical Perceptions of Risks Associated With the Use of Alternative Treatment and Conventional Medicine.* Forsch Komplementmed,, 2015. **1; DOI 10.1159/000376555**.
40. Breisameter C, *Medical decision-making and communication of risks: an ethical perspective.* J Med Ethics, 2010. **36**: p. 349-352.
41. Stub T, Salamonsen A, and Alræk T, *Is it Possible to Distinguish Homeopathic Aggravation from Adverse Effects? A Qualitative Study.* Forsch Komplementärmed und Klass Naturheilkd, 2011. **19**(1): p. 13-19.
42. Gamst, A., et al., *Integrative care and bridge building among health care providers in Norway and Denmark.* J Altern Complement Med, 2006. **12**(2): p. 141-6.
43. Elwyn G, et al., *Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices.* British Journal of General Practice, 2000. **50**(460): p. 892-899.
44. Salamonsen A, Kruse T, and Eriksen SH, *Modes of Embodiment in Breast Cancer Patients Using Complementary and Alternative Medicine.* Qualitative Health Research, 2012. **22**(11): p. 1497-1512.
45. Kvale, S., *Det kvalitative forskningsintervju*. 2001, Oslo: Gyldendal Norsk Forlag AS.
46. Fontana A and Frey JH, *The Interview from Neutral Stance to Political Involvement*, in *Collecting and Interpreting Qualitative Materials*, V. Knigth, Editor. 2008, SAGE Publications: London. p. 115-159.

47. Rosenstein AH and O'Daniel M, *Original Research: Disruptive Behavior and Clinical Outcomes: Perceptions of Nurses and Physicians: Nurses, physicians, and administrators say that clinicians' disruptive behavior has negative effects on clinical outcomes.* AJN The American Journal of Nursing, 2005. **105**(1): p. 54-64.
48. Saha S and Beach MC, *The impact of patient-centered communication on patients' decision making and evaluations of physicians: A randomized study using video vignettes.* Patient Educ Couns, 2011. **84**(3): p. 386-392.
49. Roter DL and Hall JA, *Doctors Talking with Patients, Patients talking with Doctors*. 1992, Westport: Auburn House.
50. Engel, G.L., *The Need for a New Medical Model: A Challenge for Biomedicine.* Science, 1977. **196**(4286): p. 129-136.
51. Peat J, *Health Science Research. A handbook of quantitative methods*. 2002, London: SAGE Publications.
52. Dillman DA, Smuty JD, and Christian LM, *Internet, mail and mixed-mode surveys. The Tailored Design Method.* . 3 ed. 2009, New Jersey: John Wiley & Sons, Inc.
53. Hyland ME, Lewith GT, and Westoby C, *Developing a measure of attitudes: the holistic complementary and alternative medicine questionnaire.* Complementary Therapies in Medicine, 2003. **11**: p. 33-38.
54. Bishop FL, Yardley L, and Lewith G, *Developing a measure ot treatment beliefs: The complementary and alternative medicine beliefs inventory.* Complementary Therapies in Medicine, 2005. **13**: p. 144-149.
55. Harris RA, et al., *Researcg Electronic Data Capture (REDCap) - A meta-driven methodology and workflow process for providing translational research informatics support.* J Biomed Inform, 2009. **42**(2): p. 377-381.
56. Cassileth BR, et al., *Complementary Therapies and Integrative Oncology in Lung Cancer. ACCP Evidence-Based Clinical Practice Guidelines (2nd Edition).* CHEST, 2007. **132**(3): p. 340-354.



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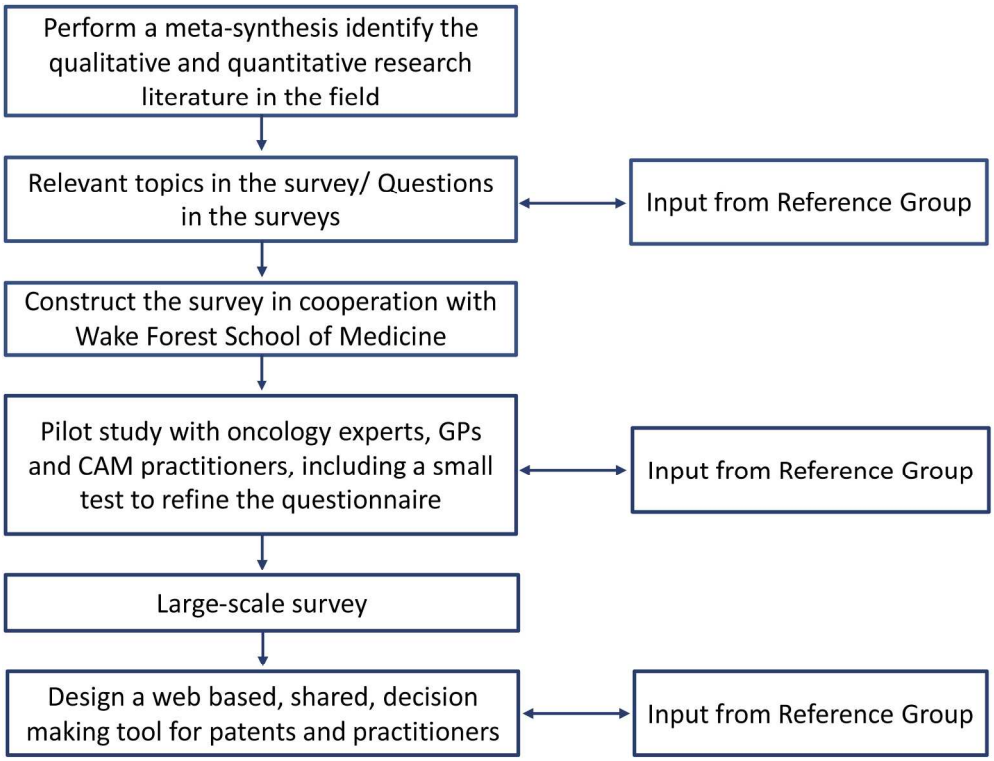

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Standards for Reporting Qualitative Research: A Synthesis of Recommendations

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Abstract

Purpose
Standards for reporting exist for many types of quantitative research, but currently none exist for the broad spectrum of qualitative research. The purpose of the present study was to formulate and define standards for reporting qualitative research while preserving the requisite flexibility to accommodate various paradigms, approaches, and methods.

Method
The authors identified guidelines, reporting standards, and critical appraisal criteria for qualitative research by searching PubMed, Web of Science, and Google through July 2013; reviewing the reference lists of retrieved sources; and contacting experts. Specifically, two authors reviewed a sample of sources to generate an initial set of items that were potentially important in reporting qualitative research. Through an iterative process of reviewing sources, modifying the set of items, and coding all sources for items, the authors prepared a near-final list of items and descriptions and sent this list to five external reviewers for feedback. The final items and descriptions included in the reporting standards reflect this feedback.

Results
The Standards for Reporting Qualitative Research (SRQR) consists of 21 items. The authors define and explain key elements of each item and provide examples from recently published articles to illustrate ways in which the standards can be met.

Conclusions
The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research. These standards will assist authors during manuscript preparation, editors and reviewers in evaluating a manuscript for potential publication, and readers when critically appraising, applying, and synthesizing study findings.

Qualitative research contributes to the literature in many disciplines by describing, interpreting, and generating theories about social interactions and individual experiences as they occur in natural, rather than experimental, situations.[1–3] Some recent examples include studies of professional dilemmas,[4] medical students' early experiences of workplace learning,[5] patients' experiences of disease and interventions,[6–8] and patients' perspectives about incident disclosures.[9] The purpose of qualitative research is to understand the perspectives/experiences of individuals or groups and the contexts in which these perspectives or experiences are situated.[1,2,10]

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Qualitative research is increasingly common and valued in the medical and medical education literature.[1,10–13] However, the quality of such research can be difficult to evaluate because of incomplete reporting of key elements.[14,15] *Quality* is multifaceted and includes consideration of the importance of the research question, the rigor of the research methods, the appropriateness and salience of the inferences, and the clarity and completeness of reporting.[16,17] Although there is much debate about standards for methodological rigor in qualitative research,[13,14,18–20] there is widespread agreement about the need for clear and complete reporting.[14,21,22] Optimal reporting would enable editors, reviewers, other researchers, and practitioners to critically appraise qualitative studies and apply and synthesize the results. One important step in improving the quality of reporting is to formulate and define clear reporting standards.

Authors have proposed guidelines for the quality of qualitative research, including those in the fields of medical education,[23–25] clinical and health services research,[26–28] and general education research.[29,30] Yet in nearly all cases, the authors do not describe how the guidelines were created, and often fail to distinguish reporting quality from the other facets of quality (e.g., the research question or methods). Several authors suggest standards for reporting qualitative research,[15,20,29–33] but their articles focus on a subset of qualitative data collection methods (e.g., interviews), fail to explain how the authors developed the reporting criteria, narrowly construe qualitative research (e.g., thematic analysis) in ways that may exclude other approaches, and/or lack specific examples to help others see how the standards might be achieved. Thus, there remains a compelling need for defensible and broadly applicable standards for reporting qualitative research.

We designed and carried out the present study to formulate and define standards for reporting qualitative research through a rigorous synthesis of published articles and expert recommendations.

Method

We formulated standards for reporting qualitative research by using a rigorous and systematic approach in which we reviewed previously proposed

recommendations by experts in qualitative methods. Our research team consisted of two PhD researchers and one physician with formal training and experience in qualitative methods, and two physicians with experience, but no formal training, in qualitative methods.

We first identified previously proposed recommendations by searching PubMed, Web of Science, and Google using combinations of terms such as "qualitative methods," "qualitative research," "qualitative guidelines," "qualitative standards," and "critical appraisal" and by reviewing the reference lists of retrieved sources, reviewing the Equator Network,[22] and contacting experts. We conducted our first search in January 2007 and our last search in July 2013. Most recommendations were published in peer-reviewed journals, but some were available only on the Internet, and one was an interim draft from a national organization. We report the full set of the 40 sources reviewed in Supplemental Digital Appendix 1, found at http://links.lww.com/ACADMED/A218.

Two of us (B.O., I.H.) reviewed an initial sample of sources to generate a comprehensive list of items that were potentially important in reporting qualitative research (Draft A). All of us then worked in pairs to review all sources and code the presence or absence of each item in a given source. From Draft A, we then distilled a shorter list (Draft B) by identifying core concepts and combining related items, taking into account the number of times each item appeared in these sources. We then compared the items in Draft B with material in the original sources to check for missing concepts, modify accordingly, and add explanatory definitions to create a prefinal list of items (Draft C).

We circulated Draft C to five experienced qualitative researchers (see the acknowledgments) for review. We asked them to note any omitted or redundant items and to suggest improvements to the wording to enhance clarity and relevance across a broad spectrum of qualitative inquiry. In response to their reviews, we consolidated some items and made minor revisions to the wording of labels and definitions to create the final set of reporting standards—the Standards for Reporting Qualitative Research (SRQR)—summarized in Table 1.

To explicate how the final set of standards reflect the material in the original sources, two of us (B.O., D.A.C.) selected by consensus the 25 most complete sources of recommendations and identified which standards reflected the concepts found in each original source (see Table 2).

Results

The SRQR is a list of 21 items that we consider essential for complete, transparent reporting of qualitative research (see Table 1). As explained above, we developed these items through a rigorous synthesis of prior recommendations and concepts from published sources (see Table 2; see also Supplemental Digital Appendix 1, found at http://links.lww.com/ACADMED/A218) and expert review. These 21 items provide a framework and recommendations for reporting qualitative studies. Given the wide range of qualitative approaches and methodologies, we attempted to select items with broad relevance.

The SRQR includes the article's title and abstract (items 1 and 2); problem formulation and research question (items 3 and 4); research design and methods of data collection and analysis (items 5 through 15); results, interpretation, discussion, and integration (items 16 through 19); and other information (items 20 and 21). Supplemental Digital Appendix 2, found at http://links.lww.com/ACADMED/A218, contains a detailed explanation of each item, along with examples from recently published qualitative studies. Below, we briefly describe the standards, with a particular focus on those unique to qualitative research.

Titles, abstracts, and introductory material. Reporting standards for titles, abstracts, and introductory material (problem formulation, research question) in qualitative research are very similar to those for quantitative research, except that the results reported in the abstract are narrative rather than numerical, and authors rarely present a specific hypothesis.[29,30]

Research design and methods. Reporting on research design and methods of data collection and analysis highlights several distinctive features of qualitative research. Many of the criteria we reviewed focus not only on identifying and describing all aspects of the methods (e.g., approach, researcher characteristics and role, sampling strategy, context, data collection and analysis) but also on justifying each choice.[13,14] This ensures that authors make their assumptions and decisions transparent to readers. This standard is less commonly expected in quantitative research, perhaps because most quantitative researchers share positivist assumptions and generally agree about standards for rigor of various study designs and sampling techniques.[14] Just as quantitative reporting standards encourage authors to describe how they implemented methods such as randomization and measurement validity, several qualitative reporting criteria recommend that authors describe how they implemented a presumably familiar technique in their study rather than simply mentioning the technique.[10,14,32] For example, authors often state that data collection occurred until saturation, with no mention of how they defined and recognized saturation. Similarly, authors often mention an "iterative process," with minimal description of the nature of the iterations. The SRQR emphasizes the importance of explaining and elaborating on these important processes. Nearly all of the original sources recommended describing the characteristics and role of the researcher (i.e., reflexivity). Members of the research team often form relationships with participants, and analytic processes are highly interpretive in most qualitative research. Therefore, reviewers and readers must understand how these relationships and the researchers' perspectives and assumptions influenced data collection and interpretation.[15,23,26,34]

Results. Reporting of qualitative research results should identify the main analytic findings. Often, these findings involve interpretation and contextualization, which represent a departure from the tradition in quantitative studies of objectively reporting results. The presentation of results often varies with the specific qualitative approach and methodology; thus, rigid rules for reporting qualitative findings are inappropriate. However, authors

Table 1
Standards for Reporting Qualitative Research (SRQR)[a]

No.	Topic	Item
	Title and abstract	
S1	Title	Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended
S2	Abstract	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions
	Introduction	
S3	Problem formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement
S4	Purpose or research question	Purpose of the study and specific objectives or questions
	Methods	
S5	Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale[b]
S6	Researcher characteristics and reflexivity	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability
S7	Context	Setting/site and salient contextual factors; rationale[b]
S8	Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale[b]
S9	Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues
S10	Data collection methods	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale[b]
S11	Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study
S12	Units of study	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)
S13	Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts
S14	Data analysis	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale [b]
S15	Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale[b]
	Results/findings	
S16	Synthesis and interpretation	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory
S17	Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings
	Discussion	
S18	Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/ generalizability; identification of unique contribution(s) to scholarship in a discipline or field
S19	Limitations	Trustworthiness and limitations of findings

(*Table continues*)

Table 1
(Continued)

No.	Topic	Item
	Other	
S20	Conflicts of interest	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed
S21	Funding	Sources of funding and other support; role of funders in data collection, interpretation, and reporting

[a]The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.
[b]The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

should provide evidence (e.g., examples, quotes, or text excerpts) to substantiate the main analytic findings.[20,29]

Discussion. The discussion of qualitative results will generally include connections to existing literature and/or theoretical or conceptual frameworks, the scope and boundaries of the results (transferability), and study limitations.[10–12,28] In some qualitative traditions, the results and discussion may not have distinct boundaries; we recommend that authors include the substance of each item regardless of the section in which it appears.

Discussion

The purpose of the SRQR is to improve the quality of reporting of qualitative research studies. We hope that these 21 recommended reporting standards will assist authors during manuscript preparation, editors and reviewers in evaluating a manuscript for potential publication, and readers when critically appraising, applying, and synthesizing study findings. As with other reporting guidelines,[35–37] we anticipate that the SRQR will evolve as it is applied and evaluated in practice. We welcome suggestions for refinement.

Qualitative studies explore "how?" and "why?" questions related to social or human problems or phenomena.[10,38] Purposes of qualitative studies include understanding meaning from participants' perspectives (How do they interpret or make sense of an event, situation, or action?); understanding the nature and influence of the context surrounding events or actions; generating theories about new or poorly understood events, situations, or actions; and understanding the processes that led to a desired (or undesired) outcome.[38] Many different approaches (e.g., ethnography, phenomenology, discourse analysis, case study, grounded theory) and methodologies (e.g., interviews, focus groups, observation, analysis of documents) may be used in qualitative research, each with its own assumptions and traditions.[1,2] A strength of many qualitative approaches and methodologies is the opportunity for flexibility and adaptability throughout the data collection and analysis process. We endeavored to maintain that flexibility by intentionally defining items to avoid favoring one approach or method over others. As such, we trust that the SRQR will support all approaches and methods of qualitative research by making reports more explicit and transparent, while still allowing investigators the flexibility to use the study design and reporting format most appropriate to their study. It may be helpful, in the future, to develop approach-specific extensions of the SRQR, as has been done for guidelines in quantitative research (e.g., the CONSORT extensions).[37]

Limitations, strengths, and boundaries

We deliberately avoided recommendations that define methodological rigor, and therefore it would be inappropriate to use the SRQR to judge the quality of research methods and findings. Many of the original sources from which we derived the SRQR were intended as criteria for methodological rigor or critical appraisal rather than reporting; for these, we inferred the information that would be needed to evaluate the criterion. Occasionally, we found conflicting recommendations in the literature (e.g., recommending specific techniques such as multiple coders or member checking to demonstrate trustworthiness); we resolved these conflicting recommendations through selection of the most frequent recommendations and by consensus among ourselves.

Some qualitative researchers have described the limitations of checklists as a means to improve methodological rigor.[13] We nonetheless believe that a checklist for reporting standards will help to enhance the transparency of qualitative research studies and thereby advance the field.[29,39]

Strengths of this work include the grounding in previously published criteria, the diversity of experience and perspectives among us, and critical review by experts in three countries.

Implications and application

Similar to other reporting guidelines,[35–37] the SRQR may be viewed as a starting point for defining reporting standards in qualitative research. Although our personal experience lies in health professions education, the SRQR is based on sources originating in diverse health care and non-health-care fields. We intentionally crafted the SRQR to include various paradigms, approaches, and methodologies used in qualitative research. The elaborations offered in

Table 2

Alignment of the 21 Standards for Reporting Qualitative Research (SRQR) With Recommendations From 25 Original Sources[a]

		Reference no.[b]																						
No.	Topic	11,12	15[c]	19	20[c]	23	24,25[d]	26	27	29[c,d]	30[c,d]	31[c]	32[c]	33	34	41	42	43	44[c]	45	46	47	48	49	50
S1	Title						*	*		*														*	
S2	Abstract						*			*	*			*											
S3	Problem formulation				*	*	*	*	*	*	*	*		*	*	*	*	*			*			*	*
S4	Purpose or research question	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		*	*	*	*	*	*
S5	Qualitative approach and research paradigm	*	*	*	*	*	*	*		*	*		*	*		*	*	*			*	*	*	*	*
S6	Researcher characteristics, reflexivity	*	*	*	*	*	*	*	*	*		*	*	*		*	*	*	*	*	*	*	*	*	*
S7	Context		*	*	*	*	*	*	*	*	*	*		*		*	*		*	*	*		*		*
S8	Sampling strategy	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		*	*	
S9	Ethical issues pertaining to human subjects	*			*		*			*	*		*	*		*	*	*		*	*	*			*
S10	Data collection methods	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
S11	Data collection instruments/ technologies	*	*				*			*	*	*	*	*		*		*			*				
S12	Units of study	*	*		*		*	*		*	*	*	*	*		*					*			*	
S13	Data processing	*				*	*	*		*	*	*	*				*				*				*
S14	Data analysis	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
S15	Techniques to enhance trustworthiness	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		*	*	*
S16	Synthesis and interpretation	*	*		*	*	*	*	*	*	*	*	*	*		*	*	*			*	*	*	*	*
S17	Links to empirical data	*	*		*	*	*	*	*	*	*	*	*	*		*	*	*	*			*	*			*
S18	Integration with prior work, implications, transferability, and contribution(s)	*		*	*	*	*	*	*	*	*	*	*	*		*	*	*	*	*	*		*	*	*
S19	Limitations	*			*	*	*	*		*				*		*	*	*			*				*
S20	Conflicts of interest						*			*															
S21	Funding									*						*								*	

[a]The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research. In the table, the asterisks indicate which sources mentioned which topics.

[b]The numbers in column headings are the numbers of the citations in the reference list at the end of this report. Those citations are of original sources describing criteria for reporting and/or critical appraisal of qualitative research, which the authors used in creating the SRQR.

[c]Focuses on reporting standards (all other sources focus on quality standards or guidelines for critical review/evaluation).

[d]Addresses quantitative and qualitative research.

Supplemental Digital Appendix 2 (see http://links.lww.com/ACADMED/A218) should provide sufficient description and examples to enable both novice and experienced researchers to use these standards. Thus, the SRQR should apply broadly across disciplines, methodologies, topics, study participants, and users.

The SRQR items reflect information essential for inclusion in a qualitative research report, but should not be viewed as prescribing a rigid format or standardized content. Individual study needs, author preferences, and journal requirements may necessitate a different sequence or organization than that shown in Table 1. Journal word restrictions may prevent a full exposition of each item, and the relative importance of a given item will vary by study. Thus, although all 21 standards would ideally be reflected in any given report, authors should prioritize attention to those items that are most relevant to the given study, findings, context, and readership.

Application of the SRQR need not be limited to the writing phase of a given study. These standards can assist researchers in planning qualitative studies and in the careful documentation of processes and decisions made throughout the study. By considering these recommendations early on, researchers may be more likely to identify the paradigm and approach most appropriate to their research, consider and use strategies for ensuring trustworthiness, and keep track of procedures and decisions.

Journal editors can facilitate the review process by providing the SRQR to reviewers and applying its standards, thus establishing more explicit expectations for qualitative studies. Although the recommendations do not address or advocate specific approaches, methods, or quality standards, they do help reviewers identify information that is missing from manuscripts.

As authors and editors apply the SRQR, readers will have more complete information about a given study, thus facilitating judgments about the trustworthiness, relevance, and transferability of findings to their own context and/or to related literature. Complete reporting will also facilitate meaningful synthesis of qualitative results across studies.[40] We anticipate that such transparency will, over time, help to identify previously unappreciated gaps in the rigor and relevance of research findings. Investigators, editors, and educators can then work to remedy these deficiencies and, thereby, enhance the overall quality of qualitative research.

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References

1 Lingard L, Kennedy TJ. Qualitative research in medical education. In: Swanwick T, ed. Understanding Medical Education: Evidence, Theory and Practice. Oxford, UK: Wiley-Blackwell; 2010:323–335.
2 Harris IB. Qualitative methods. In: Norman GR, van der Vleuten CPM, Newble DI, eds. International Handbook of Research in Medical Education. Dordrecht, Netherlands: Kluwer Academic Publishers; 2002:45–95.
3 Denzin N, Lincoln Y. Introduction: The discipline and practice of qualitative research. In: The Sage Handbook of Qualitative Research. 3rd ed. Thousand Oaks, Calif: Sage Publications, Inc.; 2005:1–32.
4 Ginsburg S, Bernabeo E, Ross KM, Holmboe ES. "It depends": Results of a qualitative study investigating how practicing internists approach professional dilemmas. Acad Med. 2012;87:1685–1693.
5 Yardley S, Brosnan C, Richardson J, Hays R. Authentic early experience in medical education: A socio-cultural analysis identifying important variables in learning interactions within workplaces. Adv Health Sci Educ Theory Pract. 2013;18:873–891.
6 Embuldeniya G, Veinot P, Bell E, et al. The experience and impact of chronic disease peer support interventions: A qualitative synthesis. Patient Educ Couns. 2013;92:3–12.
7 Pinnock H, Kendall M, Murray SA, et al. Living and dying with severe chronic obstructive pulmonary disease: Multi-perspective longitudinal qualitative study. BMJ. 2011;342:d142.
8 Brady MC, Clark AM, Dickson S, Paton G, Barbour RS. Dysarthria following stroke: The patient's perspective on management and rehabilitation. Clin Rehabil. 2011;25:935–952.
9 Iedema R, Allen S, Britton K, et al. Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: The "100 patient stories" qualitative study. BMJ. 2011;343:d4423.
10 Kuper A, Reeves S, Levinson W. An introduction to reading and appraising qualitative research. BMJ. 2008;337:404–407.
11 Giacomini M, Cook, DJ. Users' guides to the medical literature: XXIII. Qualitative research in health care A. Are the results of the study valid? JAMA. 2000;284:357–362.
12 Giacomini M, Cook, DJ. Users' guides to the medical literature: XXIII. Qualitative research in health care B. What are the results and how do they help me care for my patients? JAMA. 2000;284:478–482.
13 Barbour RS. Checklists for improving rigour in qualitative research: A case of the tail wagging the dog? BMJ. 2001;322:1115–1117.
14 Dunt D, McKenzie R. Improving the quality of qualitative studies: Do reporting guidelines have a place? Fam Pract. 2012;29:367–369.
15 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007;19:349–357.
16 Cook DA, Bowen JL, Gerrity MS, et al. Proposed standards for medical education submissions to the Journal of General Internal Medicine. J Gen Intern Med. 2008;23:908–913.
17 Tracy SJ. Qualitative quality: Eight "big-tent" criteria for excellent qualitative research. Qual Inq. 2010;16:837–851.
18 Lincoln YS. Emerging criteria for quality in qualitative and interpretive research. Qual Inq. 1995;1:275–289.
19 Mays N, Pope C. Qualitative research in health care. Assessing quality in qualitative research. BMJ. 2000;320:50–52.
20 Burns N. Standards for qualitative research. Nurs Sci Q. 1989;2:44–52.
21 Ryan GW. What Are Standards of Rigor for Qualitative Research? 2005. http://www.wjh.harvard.edu/nsfqual/Ryan%20Paper.pdf. Accessed April 20, 2014.
22 The EQUATOR Network: Enhancing the quality and transparency of health research. http://www.equator-network.org. Accessed April 6, 2014.
23 Côté L, Turgeon J. Appraising qualitative research articles in medicine and medical education. Med Teach. 2005;27:71–75.
24 Bordage G, Caelleigh AS. A tool for reviewers: "Review criteria for research manuscripts." Acad Med. 2001;76:904–951.
25 Task Force of Academic Medicine and the GEA-RIME Committee. Appendix 1: Checklist of review criteria. Acad Med. 2001;76:958–959.
26 Malterud K. Qualitative research: Standards, challenges, and guidelines. Lancet. 2001;358:483–488.

27 Inui TS, Frankel RM. Evaluating the quality of qualitative research: A proposal pro tem. J Gen Intern Med. 1991;6:485–486.
28 Devers KJ. How will we know" good" qualitative research when we see it? Beginning the dialogue in health services research. Health Serv Res. 1999;34:1153.
29 Duran RP, Eisenhart MA, Erickson FD, et al. Standards for reporting on empirical social science research in AERA publications. Educ Res. 2006;35:33–40.
30 Newman M, Elbourne D. Improving the usability of educational research: Guidelines for the reporting of primary empirical research studies in education (The REPOSE Guidelines). Eval Res Educ. 2004;18:201–212.
31 Knafl KA, Howard MJ. Interpreting and reporting qualitative research. Res Nurs Health. 1984;7:17–24.
32 Kitto SC, Chesters J, Grbich C. Quality in qualitative research. Med J Aust. 2008;188:243–246.
33 Rowan M, Huston P. Qualitative research articles: Information for authors and peer reviewers. CMAJ. 1997;157:1442–1446.
34 Cohen D, Crabtree B. Guidelines for designing, analyzing, and reporting qualitative research. Qualitative Research Guidelines Project, Robert Wood Johnson Foundation. 2006. http://qualres.org/HomeGuid-3868.html. Accessed April 6, 2014.
35 Elm E von, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. Strengthening the reporting of observational studies in epidemiology (STROBE) statement: Guidelines for reporting observational studies. BMJ. 2007;335:806–808.
36 Davidoff F, Batalden P, Stevens D, Ogrinc G, Mooney S; SQUIRE Development Group. Publication guidelines for quality improvement in health care: Evolution of the SQUIRE project. Qual Saf Health Care. 2008;17(suppl 1):i3–i9.
37 Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c332.
38 Maxwell JA. Designing a qualitative study. In: Bickman L, Bog D, eds. The SAGE Handbook of Applied Social Research Methods. 2nd ed. Sage Publications, Inc.; 2009:214–253.
39 Meyrick J. What is good qualitative research? A first step towards a comprehensive approach to judging rigour/quality. J Health Psychol. 2006;11:799–808.
40 Bearman M, Dawson P. Qualitative synthesis and systematic review in health professions education. Med Educ. 2013;47:252–260.

References Cited Only in Table 2

41 Attree P, Milton B. Critically appraising qualitative research for systematic reviews. Evid Policy. 2006;2:109–126.
42 Blaxter M. Criteria for the evaluation of qualitative research. Med Sociol News. 1996;22:34–37.
43 Critical Appraisal Skills Programme (CASP). Qualitative Research Checklist. 2013. http://www.casp-uk.net/wp-content/uploads/2011/11/casp-qualitative-research-checklist-31.05.13.pdf#!casp-tools-checklists/c18f8. Accessed April 6, 2014.
44 Frambach JM, van der Vleuten CP, Durning SJ. AM last page. Quality criteria in qualitative and quantitative research. Acad Med. 2013;88:552.
45 Kuper A, Lingard L, Levinson W. Critically appraising qualitative research. BMJ. 2008;337:687–689.
46 Law M, Stewart D, Letts L, Pollock N, Bosch J, Westmorland M. Guidelines for the critical review of qualitative studies. McMaster University Occupational Therapy Evidence-Based Practice Research Group. 1998. http://www.usc.edu/hsc/ebnet/res/Guidelines.pdf. Accessed April 20, 2014.
47 Pearson A, Field J, Jordan Z. Appendix 2: Critical appraisal tools. In: Evidence-Based Clinical Practice in Nursing and Health Care: Assimilating Research, Experience and Expertise. Oxford, UK: Blackwell Publishing Ltd.; 2009:177–182. http://onlinelibrary.wiley.com/doi/10.1002/9781444316544.app2/summary. Accessed April 13, 2014.
48 Popay J, Rogers A, Williams G. Rationale and standards for the systematic review of qualitative literature in health services research. Qual Health Res. 1998;8:341–351.
49 Sandelowski M, Barroso J. Writing the proposal for a qualitative research methodology project. Qual Health Res. 2003;13:781–820.
50 Stige B, Malterud K, Midtgarden T. Toward an agenda for evaluation of qualitative research. Qual Health Res. 2009;19:1504–1516.

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Mapping the risk perception and communication gap between different professions of health care providers in cancer care – A cross-sectional protocol

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Mapping the risk perception and communication gap between different professions of health care providers in cancer care – A cross-sectional protocol

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Key Words
Direct risk; indirect risk; patient safety; Oncology; Complementary and Alternative Medicine (CAM); cancer care; provider-patient communication

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Abstract

Introduction

Studies show that cancer patients who use Complementary and Alternative Medicine (CAM) have a poorer survival prognosis than those who do not. It remains unclear whether this is due to *a priori* poorer prognosis that makes patients turn to CAM, or whether there is a factor associated with CAM use itself that influences the prognosis negatively. Health care providers should assist patients in safeguarding their treatment decision. However, the current non-communication between CAM and conventional providers leaves it up to the patients themselves to choose how to best integrate the two worlds of therapy. In this study, an interactive shared decision making (SDM) tool will be developed to enable patients and health professionals to make safe health choices.

Methods and analysis

We will delineate, compare, and evaluate perception and clinical experience of communication of risk situations among oncology experts, general practitioners and CAM practitioners. To accomplish this, we will develop a pilot and implement a large-scale survey among the above mentioned health professionals in Norway. Guided by the survey results, we will develop a beta-version of a shared decision making tool for health care providers to use in guiding patients to make safe CAM decisions.

Ethics and dissemination

Participants must give their informed and written consent before inclusion. They will be informed about the opportunity to drop out from the study followed by deletion of all data registered. The study needs no approval from The Regional Committee for Medical and Health Research Ethics because all participants are health care professionals. Results from this study will be disseminated in peer-reviewed medical journals.

Funding

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Strengths and Limitations of this study

- The study plan in this study is strong, as it combines three different strategies (a literature review, a pilot cross-sectional study and a main cross-sectional study) to finally develop a shared decision making tool.
- There are still some methodological challenges in surveying health care professionals; oncologists and general practitioners are often poor responders, so steps must therefore be taken to boost the questionnaire response rate.

Introduction

Complementary and alternative medicine (CAM) is a popular treatment modality among cancer patients in Europe [1-4]. In this research project, CAM, or alternative treatment, is understood as a health-related treatment that is practiced outside the established health services and not practiced by authorized health personnel. However, treatment practiced within the scope of the established health services or by authorized health personnel is also covered by the term alternative treatment when the methods employed are used outside the established health service [5] . Findings from studies suggest that, on average, half of all cancer patients use CAM, and this proportion has increased over the past years [6]. The Norwegian Cancer Society stated that approximately 50% of all Norwegian cancer patients used CAM in 2008 [7] . The majority of cancer patients use CAM because they believe it increases the body's ability to fight the cancer, strengthens the immune system, improves physical and emotional well-being and quality of life or enables the maintenance of hope and control over their cancer care [8, 9]. Although current RCT-based documentation of CAM treatment gives little support to patients' beliefs of CAM's efficacy on tumors [10], a large number of patients still clearly wish to use CAM. The interpretation of this paradox is that either the patients do not give credence to scientific evidence, or they experience some other benefit from the treatment. Objectively, data show that cancer patients who use CAM have a poorer survival prognosis than those who do not use CAM [11, 12]. It remains unclear whether this is due to *a priori* poorer prognosis that makes patients turn to CAM, or whether there is a factor associated with CAM use itself that influences the prognosis negatively.

In Norway patients receive conventional medical treatment within the public health care system, while CAM practitioners operate outside this system. The majority of the CAM practitioners are members of professional associations that require professional standards of medical and CAM-specific skills of their members. However, patients themselves generally

cover the costs of visiting a CAM practitioner. Thus, the Norwegian context is comparable to that of other western settings [13]. Masseurs, acupuncturists, hands on healers and reflexologists are the CAM practitioners most used by cancer patients.

Qualitative research into patients' experiences with CAM underlines patient disenchantment with the conventional health care system as an important reason for choosing CAM [14]. Patients emphasize the experience of a fragmented and specialized system, with short consultations in a "production line" approach, which often compromises continuity at the organizational, informational and relational levels [15]. In conventional care the patient's "whole story" may fade and become invisible to the individual practitioner [16]. CAM practitioners claim to have a more holistic approach [17]. They often offer therapy directed at both mind and body [18]. Practicing principles in CAM may include patient-centeredness, empowerment and self-management [19, 20]. Thus, it is plausible that CAM supports continuity in the provider/patient relationship to a greater degree than conventional care.

In this research project, risk will generally be defined as a compound measurement of the probability of an event and the magnitude of the potential negative outcome of that event [21], both operationally and methodologically. Patient safety is understood as the reduction of risk of unnecessary harm associated with health care to an acceptable minimum [22]. Medical science risk can be divided into direct and indirect risk [23, 24] as illustrated in Figure 1.

Figure 1: Understanding of patient safety and risk in this research project. Direct risk is caused by the treatment itself and related to the intervention, while indirect risk is related to the treatment context, such as the practitioner more than the medicine.

Direct risk is caused by the treatment itself. This dimension includes traditional adverse effects of an intervention, such as bleeding in response to acupuncture needling, nausea caused by chemotherapeutic medication, or the adverse effect of an herb, as well as risk connected to self-management advice from the practitioner [25]. For example, breast cancer patients often use herbal supplements, such as ginseng or soy products, in conjunction with conventional cancer treatment [26, 27]. These supplements have phytoestrogen components that may alter estrogen levels or activate estrogen receptors as either pro- or anti-estrogen [28]. High estrogen levels are well-documented risk factors for breast cancer. Studies of these supplements are mixed, showing increased [29], reduced [28] or no association with circulating levels of estrogen [30].

Indirect risk is related to adverse effects of the treatment context, for example, the CAM practitioner rather than the medicine. A patient may be harmed by a care context that prevents the patient from receiving the best possible treatment relevant to her or his health needs [31]. A homeopath without appropriate medical training may overlook a serious condition and continue treatment, even in cases where conventional treatment would be an unconditional necessity. This situation may delay meaningful diagnostic procedures and relevant therapeutic interventions.

To ensure patient safety and avoid undesired outcomes, conventional care should assist patients in safeguarding their treatment decisions. This can best be achieved through open, transparent, non-judgmental and informed discussions about possible outcomes of combining CAM and conventional treatment for cancer. Cancer patients highly value the input from their physicians about the use of CAM [9, 14]. Patients should feel free to discuss all the options in their care without the fear of being rejected. Research shows, however, that patients fear that health care providers are indifferent or will object to the use of CAM [32]. It is, therefore, important that health care providers initiate this discussion and include this in the history taking [33-35]. However, studies reveal that 38-60% of cancer patients use CAM without informing their health care team [36, 37].

In a Norwegian study, the importance of taking time and effort to learn more about the value of CAM therapies has been emphasized [38]. A qualitative study [39] concludes that physicians have limited knowledge about the occurrence of possible interactions. Breitsameter [40] identifies ethical problems regarding the doctors' inability to provide information about the risks of using CAM together with conventional care.

On the other hand, CAM practitioners' beliefs and counseling practices on how to combine the two treatment worlds safely have not been explored. In Norway, the CAM profession is totally unregulated, and CAM practitioners may practice as long as they do no harm. This vague regulation of the CAM profession increases the chance of indirect risk and thereby threatens patient safety [25]. It is reasonable to assume that CAM practitioners' knowledge of conventional medicine vary from no formal medical education to being fully trained physicians who have added some CAM modalities to their armamentarium [16, 41].

The current non-communication between CAM and conventional professionals leaves it up to the patients themselves, who are in a vulnerable situation, to choose how to best integrate the two worlds of therapy [4, 14, 27]. Conventional health care providers may believe that to reduce

risk, it is best to advise patients not to use CAM in combination with conventional treatment. However, a study [14] demonstrated that patients may decline conventional medicine if they feel rejected when they want to discuss possible CAM treatment with their GP or oncology expert.

It should be possible to support patients in making safe decisions about combining CAM with conventional care [42]. However, the large difference between the two worlds of therapy and the complexity of the issue makes this a challenging task. Conventional and CAM providers differ regarding treatment concepts, philosophies and diagnostic procedures leading to different models of disease causality and treatment practice [18]. These differences likely influence the practitioners' conceptualization of benefits and risks, making shared recommendations to patients unlikely.

There is little previous knowledge about how health care providers gather and seek information about CAM, and whether the perceptions and assessments of risk are equally understood by oncology experts, general practitioners (GPs), CAM practitioners and patients [39]. The overarching question is, then, how health care providers in both the conventional and the CAM fields can better support patients in making informed choices about CAM in cancer care. In this study, an interactive shared decision making (SDM) tool [43] will be developed to enable patients and health professionals to make safe health choices.

Aims of the study

The global aim of this research project is to reduce risk and enhance safety for patients who want to combine conventional medicine with CAM in cancer care. To achieve this, we will:

Delineate, compare and evaluate perceptions and clinical experience of communication about direct and indirect risk situations among oncology experts (doctors and nurses), GPs and CAM practitioners (masseurs, acupuncturists, hands on healers and reflexologists/zone therapists)

To accomplish this, we will perform three individual studies:

Study 1: Perform a literature review of the qualitative research literature in the field. In this literature review the aim is to examine the qualitative research literature on the perception of and communication about the risk of complementary therapies among oncology experts

(doctor and nurses), health care physicians and complementary providers who care for cancer patients. The included studies will be summarized into different risk situations.

Study 2: Develop, pilot and implement a large-scale survey among oncology experts, GPs and CAM practitioners in Norway. The following research questions will be addressed in the mixed method survey pilot, and the large-scale survey:

a) Is there a difference among the four professional groups in how they gather information about CAM?

b) Is there a difference among the four professional groups in how they recognize direct and indirect risk situations in clinical practice? What kind of risk assessment tools do they use for this purpose? What procedure is followed when in doubt of medical diagnosis or when to refer to other health care interventions?

c) According to the study participants, what constitutes enough evidence on efficacy and safety to recommend a CAM modality?

d) Are there differences among the four professional groups in how they deal with patients who delay or decline conventional treatment?

e) Are there differences among the four groups in how they experience communication with their patients about CAM? What do practitioners on both sides think about risk and safety and the consequences of combining both treatment systems in cancer care?

Study 3: Guided by the survey results, design and develop an SDM tool for health care providers to use for guiding patients to make safe CAM decisions that are in line with the patients' health goals. We will draw on CAM information available through CAM-Cancer.org and Nifab.no. Both web pages are operated by the National Research Center in Complementary and Alternative Medicine (NAFKAM), the Arctic University of Norway, Tromsø, Norway. We also have qualitative data available from different studies on cancer patients [39, 44]. These data will be incorporated in the tool.When designing the tool, we will cooperate with The Norwegian Centre for Integrated Care and Telemedicine at UNN-HF. They will develop a beta-version of a tool to support decision making. The tool will be published on Internet and will be ready for patients and health care providers to use. Telemedicine will operate the technical version of the SDM tool.

Below is the flow chart of the study.

Figure 2: Flow of activities in this research project

Methods and analysis

Study 1: Literature review

The aim of the literature review is to map the qualitative research literature about risk communication and perceptions of complementary therapies among health care providers. We will include qualitative studies in this review as this approach can help researchers to gain access to the view of participants, and it contributes to a deeper understanding and thorough knowledge in health and well-being, especially in situations in which we have limited previous knowledge of our phenomenon of interest [45, 46].

The searches will be performed in databases such as AMED, CINAHL, MBASE, MEDLINE/ PubMed and PsycINFO. The PEO (Population, Exposure and Outcome) format will be used. PEO is a tool used to formulate questions about qualitative research, and the search strategy will include keywords such as *risk perception; risk communication; decision making; cancer care; Complementary and alternative medicine.* MeSH–terms and truncation symbols will be used when available. The searches will be combined with manual searches in journals of interest and reference lists, in addition to abstracts and keywords. The inclusion will comprise qualitative studies (individual and group interviews, opinion of an expert and literature reviews) investigating communication and perception about risk of complementary therapies among conventional and complementary providers. However, qualitative studies that have an added quantitative component, e.g. a questionnaire in the design (mixed design) will be included in the analysis. Quantitative studies (such as randomized controlled trials and observational studies) and evidence based guidelines will be excluded.

Theoretical framework

We will draw upon theories about risk in health care which, are described in the introduction, and inter-professionals and patient-center communication (PPC). Clear and appropriate communication and interdisciplinary collaboration are critical to the delivery of quality care for the complex patients in today's healthcare settings [47]. Effective communication may contribute to more confidence in the health provider and increased adherence to follow evidence -based recommendations and avoidance of negative interactions between conventional and complementary treatments [48]. Patient-centered communication is the set of skills and behaviours used by health care providers to promote a relationship in which patients actively participate as partners in healthcare decision making and management [48-

50]. These theories will assist us in designing and conducting the study phases and interpreting the study findings.

Study 2: Pilot survey

Prior to the main large scale study, we plan to conduct a pilot study. The purpose is to test the data collection for face and content validity [51]. Six participants (n=6), including one oncology doctor, one nurse, one GP and three CAM providers, will be invited to participate in a *Think-aloud* session [52], which involves participants reporting their thoughts out loud as they complete the questionnaire. They will be asked to say whatever they are thinking, doing or looking at as they perform this task. The think-aloud session will provide us with information regarding whether any items are misunderstood, whether people answer in a meaningful way or whether they get bored or confused part way through. The questionnaire will be revised accordingly.

Then, 40 participants (10 oncology doctors, 10 oncology nurses, 10 GPs and 10 CAM providers) will complete the instrument and several other sets of questions to establish construct validity [51]. The results from this questionnaire will be compared to the Holistic Complementary and Alternative Medicine Questionnaire (HCAMQ) and the Complementary and Alternative Medicine Beliefs Inventory (CAMBI) [53, 54]. Both are validated questionnaires including concepts like *CAM beliefs* and *holistic health beliefs*. These two factors represent distinct CAM constructs and will be used to distinguish CAM attitudes from conventional attitudes among the respondents. The oncology experts needed for the pilot study will be recruited through two wards at the University Hospital in North Norway (UNN). The study participants will be contacted by email or postal mail and invited to participate. The CAM providers will be recruited through private clinics in the Troms and Nordland county.

A reference group consisting of one oncology nurse, one GP and two CAM practitioners will assist the research team in testing the validity of the questionnaire. They will complete and comment on the instrument before the commencement of the pilot study.

Study 2: Large scale survey

Inclusion criteria

Oncology doctors and nurses, GPs and CAM providers who are currently practicing and members of a professional association, and have clinical experience with current or previously diagnosed cancer patients are eligible for the study. Being a member of a professional association ensures high professional standards of medical and/or CAM skills among the

participants. According to a Norwegian study from 2013 [7], the four most popular CAM modalities used by Norwegian cancer survivors were massage (10,5%), acupuncture (7,6%), hands on healer (4,8%) and reflexology (3,2%). This information was the rationale for choosing these particular CAM participants in the study.

Exclusion criteria

Allopathic and CAM providers who have no clinical experience with current or previously diagnosed cancer patients are ineligible for the study.

Participants

We will include one-hundred oncology doctors and 100 oncology nurses, working at the following four hospitals: *The University Hospital of North-Norway (UNN), Tromso; St. Olav Hospital, Trondheim; Haukeland University Hospital, Bergen;* and *Norwegian Radium Hospital, Oslo.* Furthermore, we will include 100 GPs and 400 CAM providers (100 masseurs, 100 acupuncturists, 100 hands on healers, 100 reflexologists/zone therapists) working in private clinics throughout the country.

Recruitment

The GPs and the oncology doctors will be recruited through *The Norwegian Medical Association* and *The Union for Oncologists.* The oncology nurses and the CAM providers will be recruited through *The Norwegian Nurses Organization, The Association for Alternative Provider Organizations (Saborg), The Norwegian Acupuncture Association* and *The Norwegian Healer Association*. We will ask the associations to provide us with a list of their members. The lists will be randomized by the study team. The participants will be offered a gift card as compensation for time spent responding to the study questionnaire. In order to increase the response rate among the GPs and oncology doctors, the gift card incentive will be somewhat higher for them [52].

Data collection

To boost the questionnaire response rate as much as possible, a mixed mode including postal mail and email will be used [52]. A standard introductory letter will be sent to all allopathic and CAM providers identified for inclusion. This letter will inform the recipient that he or she will receive a request to help with an important study. We will use a recognized and respected logo from the Arctic University of Norway and The Northern Norway Regional Health Authority on the stationery and envelopes, and the letters will be co-signed by a well-known physician. One week following the mailing of this letter, emails will be sent to all potential participants with a link to the Internet survey. The survey will be administered through a

secure web application designed for online surveys [55]. We will use a function that enables the research team to identify whether each person completes some or all of the survey, but prevents the research team from seeing any participant's identity, thereby providing anonymity. For those providers who do not have email or have limited access to Internet, a questionnaire will be sent by postal mail. After a week, a "thank you" or a reminder email will be sent to the included providers. Finally, one week later a replacement questionnaire and a reminder letter with a link to the survey will be sent to the non-responders, including options to complete the questionnaire either by mail or email. The study participants who have completed the questionnaire will be asked to click on a link at the end of the questionnaire confirming whether they will like to receive a gift card or not. If they wish, a gift card will be sent to them by mail (Table 1).

Table 1: Data implementation procedures for this study

Week	Mail preference	Web preference
1	Standard introducing letter	Standard introducing postal letter
2	Invitation letter including consent statement, mail questionnaire, incentive and return envelope	Invitation email letter including consent statement, link to the survey, incentive and web survey instructions
3	Thank you postcard or reminder postcard	Thank you or reminder email with link to the survey
4	Replacement questionnaire and return envelope with cover letter including link to the survey for web options to the non-responders	Reminder email to the non-responders with link to survey and web survey instructions accompanied by mail questionnaire and return envelope for the mail option

Source: Dillman DA, Smyth JD, Christian LM. Internet, mail and mixed-mode surveys. The Tailored Design Method. 3ed. New Jersey: John Wiley& Sons, Inc.;2009.

Power calculation

In order to identify any possible difference between the two groups of providers (conventional vs. CAM), a power calculation was performed. The four groups to be studied are oncology experts (doctors and nurses), GPs and CAM practitioners. In Norway there are approximately 200 oncologists, 500 oncology nurses, 5.500 GPs and an estimated 2.100 CAM practitioners. Some providers, particularly oncologists and oncology nurses, may practice in the same facility and thereby share beliefs about conventional and CAM cancer treatment. This "clustering" is incorporated into power calculations.

Power calculations are based on the question, "Do you think CAM modalities can interact with conventional cancer treatments?" In our calculations, we presume that CAM providers will be highly likely to respond "no" and that conventional providers will be less likely to

respond "no". We calculate power for several different scenarios of response to the question, with and without clustering taken into account (table 2). With a moderate difference between the two groups (CAM vs. conventional providers) in response to the question (CAM providers with a 70% proportion and Conventional providers with 50%), 124 respondents are needed per group to have 90% power to detect a difference. When clustering is taken into account and a cluster size of 5, with a moderate/high interclass correlation of 0.2 used, 223 per group (conventional and CAM providers) are needed to have 90% power.

Table 2: Scenarios for 90% power to detect a difference between conventional and CAM based on the question: "Do you think CAM modalities can interact with conventional cancer treatments? " Scenarios are based on proportions responding negatively to the question and are presented with no intra class correlation (ICC) and ICC equal 0.2 and a cluster size of 5.

	Proportion 2					
	.7		.8		.9	
Proportion 1	N/Group ICC=0.0	N/Group ICC=0.2	N/Group ICC=0.0	N/Group ICC=0.2	N/Group ICC=0.0	N/-Group ICC=0.2
0.3	31	56	19	34	12	22
0.4	56	101	30	54	17	31
0.5	124	223	52	94	26	47
0.6	477	856	109	196	42	76

However, in order to perform within group comparisons we will include 300 conventional providers (100 oncology doctors, 100 oncology nurses, 100 GPs) and 400 CAM providers (100 masseurs, 100 acupuncturists, 100 hands on healers, 100 reflexologists/zone therapists), a total sample size of 700. Table 3 shows our projections for sample sizes, taking into account response screening rates.

Table 3: Targeted response and screening rates for each group of providers and the numbers to be contacted to arrive at the sample sizes

Type of providers	# Available	# Contacted	Response rate	Screened out for not treating cancer patients	Final Sample size
Oncology doctors	200	200	50 %	0%	100
Oncology nurses	500	200	50 %	0%	100
General Practitioners	5.500	200	50 %	0%	100
Acupuncturists	761	400	50 %	50 %	100
Masseurs	687	400	50 %	50 %	100
Reflexologists	290	290	50%	50 %	100
Hands on healers	258	400	50 %	50 %	100

Measurements

Table 4 shows the study measures including the main study concepts and some examples of questions from which these concepts will be constructed. The study measures are based on preliminary analysis from the meta-synthesis and results from the first meeting with the reference group where the participants were challenged to make questions related to the different concepts in the questionnaire.

Table 4: Study measures

Study concepts	Constructed from the following example questions	Type of variable
Risk perceptions	CAM should only be used as a last resort when conventional medicine has nothing to offer.	Dichotomous
Risk communication	How often do you ask your patients if they use CAM and/or conventional medicine?	Order categories
Direct risk situations	Do you think that CAM modalities can interact with conventional medicines?	Dichotomous
Indirect risk situations	Is the lack of regulation of the CAM profession risky for the patients?	Dichotomous
Information regarding CAM and conventional treatment	Do you seek information regarding CAM cancer treatment? Do you seek information regarding conventional cancer treatment?	Dichotomous Dichotomous

Statistical analyses

The surveys will be a questionnaire based cross-sectional survey. The research questions mentioned above will be explored further in the questionnaire, and both closed and open-ended questions will be used. Responses to the open-ended questions will be categorized into nominal or ordinal scales. The guiding principle of the analyses will be performed by descriptive statistics of the perceptions present overall and comparisons of the four practitioner groups. Chi-square tests and logistic regression will be used for analyzing binary dependent variables, and analysis of variance will be used analyzing continuous, dependent variables. Quantitative data will be analyzed using the SPSS version 19.0 for Windows.

Study 3: A web-based decision making tool

In cooperation with The Norwegian Centre for Integrated Care and Telemedicine at the University Hospital of North-Norway, an SDM tool to support decision making about CAM and conventional care for cancer patients will be developed. The tool will be published on the Internet and ready to use for patients and health care providers. The Norwegian Centre for Integrated Care and Telemedicine will operate the technical version of the SDM tool.

Ethics

The participants will receive a written document describing the purpose and consequences of participating in the study. They will be informed of the possibility to withdraw from the study followed by deletion of all data registered. The returned and completed questionnaire will be considered consent to participate in the study. The study does not need approval from The Regional Committee for Medical and Health Research Ethics, according to Norwegian legislation, because all participants are health care professionals. All data will be archived according to established procedures and REDCap safety procedures. No information that may be traced back to individuals will be published.

Dissemination

The results of this research project will be disseminated to cancer patients, health care professionals in both conventional care and CAM, the Norwegian Cancer Society, public health associations and various CAM practitioner organizations. The scientific work will be published in peer-reviewed journals, and orally presented at national and international conferences. The published results will be communicated through The National Information Center for Complementary and Alternative Medicine's (NIFAB) web portal. NIFAB is a part of The National Research Center in Complementary and Alternative Medicine (NAFKAM) and its web portal www.nifab.no is frequently visited. The results will be communicated to the relevant organizations through direct contact.

Publication policy

The results of the study will be published in appropriate journals regardless of outcome. The study will be implemented and reported in accordance with the recommendations of the STROBE checklist.

Discussion

This protocol presents three studies designed to delineate, compare and evaluate perceptions and clinical experience of communication with direct and indirect risk situations among different professionals of health care providers in cancer care. The global aim is to reduce risk and enhance safety for patients who want to combine conventional medicine with CAM in cancer care. The project will increase knowledge about how CAM and conventional health providers understand the potential benefits and risks of combining both treatment systems in cancer care. Such information is essential to bridge the communication gap between patients

and their health care providers [35, 56]. Lack of communication and coordination between different parts of the health care system are major threats to patient safety [39]. This general tool can pave the way for more disease-specific tools that highlight the issue of CAM-conventional direct and indirect risks relevant to these patient groups [43]. It is, therefore, innovative and useful for public health authorities as it will improve patient engagement and the quality of health care.

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Competing interest

The authors declare that they have no conflict of interest.

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Contributors

TS, FM and GB initiated the project. TS, FM, SQ, TA, AS, AK and GB contributed to conceptualisation and design of the study and all revised this manuscript critically for important intellectual content. All authors read and approved the final manuscript.

References

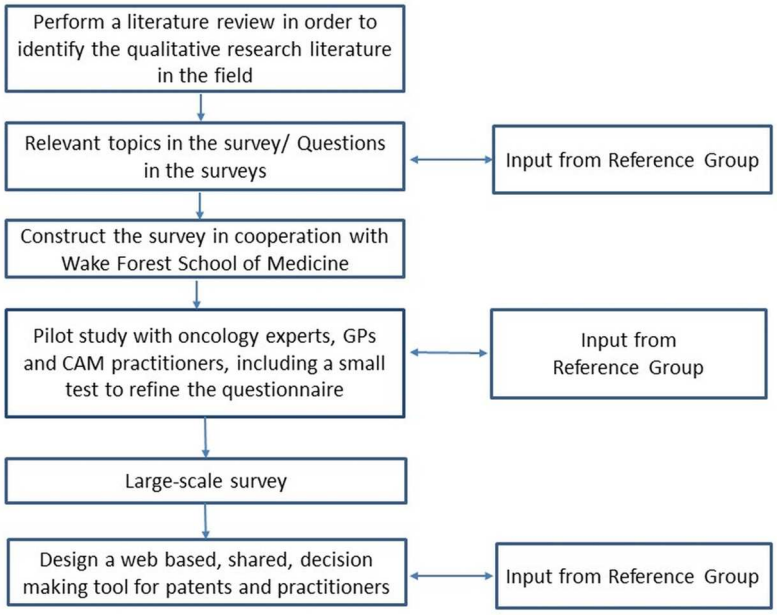
1. Ben-Arye E, Frenkel M, and Stashefsky MR, *Approaching Complementary and Alternative Medicine Use in Patients With Cancer: Questions and Challenges.* The Journal of Ambulatory Care Management, 2004. **27**(1): p. 53-62.
2. Cassileth BR, et al., *Alternative medicine use worldwide.* Cancer, 2001. **91**(7): p. 1390-1393.
3. Yates JS, et al., *Prevalence of complementary and alternative medicine use in cancer patients during treatment.* Support Cancer Care, 2005. **13**(10): p. 806-11.
4. Molassiotis A, Fernandez-Ortega P, and Pud D, *Use of complementary and alternative medicine in cancer patients:a European survey.* Ann Oncol, 2005. **16**(16): p. 655-663.

5. *LOV-2003-06-27-64 Lov om alternativ behandling av sykdom mv; English Act relating to the alternative treatment of disease, illness, etc*. 2003.
6. Horneber M, et al., *How Many Cancer Patients Use Complementary and Alternative Medicine: A Systematic Review and Metaanalysis.* Integrative Cancer Therapies, 2012. **11**(3): p. 187-203.
7. Kristoffersen AE, Norheim AJ, and Fonnebo VM, *Complementary and alternative medicine use among Norwegian cancer survivors: gender-specific prevalence and associations for use.* Evid Based Complement Alternat Med, 2013. **2013**: p. 318781.
8. Molassiotis A, et al., *Complementary and alternative medicine use in breast cancer patients in Europe.* Supportive care in Cancer, 2006. **14**(3): p. 260-267.
9. Verhoef MJ, et al., *Complementary therapies for cancer patients: Assessing information use and needs.* Chronic Disease in Canada, 2009. **29**(2).
10. Jacobson JS, Workman SB, and Kronenberg F, *Research on Complementary/Alternative Medicine for Patients With Breast Cancer: A Review of the Biomedical Literature.* Journal of Clinical Oncology, 2000. **18**(3): p. 668.
11. Han E, et al., *Alternative Therapy Used as Primary Treatment for Breast Cancer Negatively Impacts Outcomes.* Annals of Surgical Oncology, 2011. **18**(4): p. 912-916.
12. Risberg, T., et al., *[Does use of alternative medicine aggravate the survival prognosis in cancer?].* Tidsskr Nor Laegeforen, 2003. **123**(5): p. 628-30.
13. Wiesener S, et al., *Legal status and regulation of CAM in Europe.* Forsch Komplementärmed und Klass Naturheilkd, 2012. **19**(suppl 2): p. 29-36.
14. Salamonsen A, *Doctor-patient communication and cancer patient's choice of alternative therapies as supplement or alternative to conventional care.* Scandinavian Journal of Caring Science, 2013. **27**(1): p. 70-76.
15. Jeannie LH, et al., *Continuity of care: a multidisciplinary review.* BMJ, 2003. **327**(7425): p. 1219-1221.
16. Stub T, Alraek T, and Salamonsen A, *The Red flag! risk assessment among medical homeopaths in Norway: A qualitative study.* BMC Complement. Altern. Med, 2012. **12**(1): p. 150.
17. MacPherson H and Kaptchuk T, *Acupuncture in Practice: Case History Insights from the West*. 1997, Edinburgh: Churchill Livingstone.
18. Singer M and Baer H, *Introducing medical anthropology. A disipline in action*. 2 ed. 2012, Plymouth: AltaMira Press.
19. Maciocia G, *The Practice of Chinese Medicine*. 1994, Edinburgh: Churcill Livingstone.
20. Berger S, Braehler E, and Ernst J, *The health professional–patient-relationship in conventional versus complementary and alternative medicine. A qualitative study comparing the perceived use of medical shared decision-making between two different approaches of medicine.* Patient Education and Counseling, 2012. **88**(1): p. 129-137.
21. Davis EM, *Risky Business: Medical Discourse, Breast Cancer, and Narrative.* Qualitative Health Research, 2008. **18**(1): p. 65-76.
22. Runciman W, et al., *Towards an International Classification for Patient Safety: Key concepts and terms.* Int. Journal for Quality in Health Care, 2009. **21**(1): p. 18-26.
23. Fisher P, Dantas F, and Rampes H, *The safety of homeopathic products* J R Soc Med, 2002. **95**(9): p. 474-476.
24. Ernst E, *Towards a scientific understanding of the placebo effects*, in *Understanding the Placebo Effect in Complementary Medicine*, D. Peters, Editor. 2001, Churchill Livingstone: London. p. 17-29.
25. Stub T, *Safety of Treatment Provided by Homeopaths - Homeopathic Aggravations, Adverse effects and Risk Assessment*, in *Department of Community Medicine.*

NAFKAM - The National Research Center in Complementary and Alternative Medicine. 2013, UiT The Arctic University of Norway, Tromsø NAFKAM skriftserie No.9 Tromsø.

26. Bao P-P, et al., *Ginseng and Ganoderma lucidum Use after Breast Cancer Diagnosis and Quality of Life: A Report from the Shanghai Breast Cancer Survival Study.* PloS ONE, 2012. **7**(6): p. e39343.
27. Ma, H., et al., *Estrogenic botanical supplements, health-related quality of life, fatigue, and hormone-related symptoms in breast cancer survivors: a HEAL study report.* BMC Complementary and Alternative Medicine, 2011. **11**(1): p. 109.
28. Harris, R.M., et al., *Phytoestrogens Are Potent Inhibitors of Estrogen Sulfation: Implications for Breast Cancer Risk and Treatment.* Journal of Clinical Endocrinology & Metabolism, 2004. **89**(4): p. 1779-1787.
29. Wu WH, et al., *Estrogenic Effect of Yam Ingestion in Healthy Postmenopausal Women.* Journal of the American College of Nutrition, 2005. **24**(4): p. 235-243.
30. Wu AH, et al., *A controlled 2-mo dietary fat reduction and soy food supplementation study in postmenopausal women.* The American Journal of Clinical Nutrition, 2005. **81**(5): p. 1133-1141.
31. Wardle JL and Adams J, *Indirect risks of complementary and alternative medicine*, in *Traditional, complementary and integrative medicine*, Adams J, et al., Editors. 2012, Palgrave Macmillian: Hampshire. p. 212-219.
32. Tovey P and Broom A, *Oncologists' and specialists cancer nurses' approaches to complementary and alternative medicine and their impact on patient action.* Social Science & Medicine, 2007. **64**: p. 2550-2564.
33. Lindring i nord, et al., *Håndbok i lindrende behandling (Handbook for palliative care)*. 2012, Universitetssykehuset Nord-Norge (University Hospital of North Norway): Tromsø.
34. Verhoef MJ, Boon HS, and Page SA, *Talking to cancer patients about complementary therapies: Is it the physicians's responsibility?* Current Oncology, 2008. **15**(2): p. 18-23.
35. Deng GE, et al., *Evidence-Based Clinical Practice Guidelines for Integrative Oncology: Complementary Therapies and Botanicals.* Journal of the Society for Integrative Oncology, 2009. **7**: p. 85-120.
36. Navo MA, et al., *An Assessment of the Utilization of Complementary and Alternative Medication in Women With Gynecologic or Breast Malignancies.* Journal of Clinical Oncology, 2004. **22**(4): p. 671-677.
37. Richardson MA, et al., *Complementary/Alternative Medicine Use in a Comprehensive Cancer Center and the Implications for Oncology.* Journal of Clinical Oncology, 2000. **18**(13): p. 2505-2514.
38. Risberg T, et al., *Knowledge of and attitudes toward complementary and alternative therapies: a national multicentre study of oncology professionals in Norway.* European Journal of Cancer, 2004. **40**: p. 529-535.
39. Salamonsen A, *Mind the Gap! Lay and Medical Perceptions of Risks Associated With the Use of Alternative Treatment and Conventional Medicine.* Forsch Komplementmed,, 2015. **1; DOI 10.1159/000376555**.
40. Breisameter C, *Medical decision-making and communication of risks: an ethical perspective.* J Med Ethics, 2010. **36**: p. 349-352.
41. Stub T, Salamonsen A, and Alræk T, *Is it Possible to Distinguish Homeopathic Aggravation from Adverse Effects? A Qualitative Study.* Forsch Komplementärmed und Klass Naturheilkd, 2011. **19**(1): p. 13-19.

42. Gamst, A., et al., *Integrative care and bridge building among health care providers in Norway and Denmark.* J Altern Complement Med, 2006. **12**(2): p. 141-6.
43. Elwyn G, et al., *Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices.* British Journal of General Practice, 2000. **50**(460): p. 892-899.
44. Salamonsen A, Kruse T, and Eriksen SH, *Modes of Embodiment in Breast Cancer Patients Using Complementary and Alternative Medicine.* Qualitative Health Research, 2012. **22**(11): p. 1497-1512.
45. Kvale, S., *Det kvalitative forskningsintervju*. 2001, Oslo: Gyldendal Norsk Forlag AS.
46. Fontana A and Frey JH, *The Interview from Neutral Stance to Political Involvement*, in *Collecting and Interpreting Qualitative Materials*, V. Knigth, Editor. 2008, SAGE Publications: London. p. 115-159.
47. Rosenstein AH and O'Daniel M, *Original Research: Disruptive Behavior and Clinical Outcomes: Perceptions of Nurses and Physicians: Nurses, physicians, and administrators say that clinicians' disruptive behavior has negative effects on clinical outcomes.* AJN The American Journal of Nursing, 2005. **105**(1): p. 54-64.
48. Saha S and Beach MC, *The impact of patient-centered communication on patients' decision making and evaluations of physicians: A randomized study using video vignettes.* Patient Educ Couns, 2011. **84**(3): p. 386-392.
49. Roter DL and Hall JA, *Doctors Talking with Patients, Patients talking with Doctors*. 1992, Westport: Auburn House.
50. Engel, G.L., *The Need for a New Medical Model: A Challenge for Biomedicine.* Science, 1977. **196**(4286): p. 129-136.
51. Peat J, *Health Science Research. A handbook of quantitative methods*. 2002, London: SAGE Publications.
52. Dillman DA, Smuty JD, and Christian LM, *Internet, mail and mixed-mode surveys. The Tailored Design Method.* . 3 ed. 2009, New Jersey: John Wiley & Sons, Inc.
53. Hyland ME, Lewith GT, and Westoby C, *Developing a measure of attitudes: the holistic complementary and alternative medicine questionnaire.* Complementary Therapies in Medicine, 2003. **11**: p. 33-38.
54. Bishop FL, Yardley L, and Lewith G, *Developing a measure ot treatment beliefs: The complementary and alternative medicine beliefs inventory.* Complementary Therapies in Medicine, 2005. **13**: p. 144-149.
55. Harris RA, et al., *Researcg Electronic Data Capture (REDCap) - A meta-driven methodology and workflow process for providing translational research informatics support.* J Biomed Inform, 2009. **42**(2): p. 377-381.
56. Cassileth BR, et al., *Complementary Therapies and Integrative Oncology in Lung Cancer. ACCP Evidence-Based Clinical Practice Guidelines (2nd Edition).* CHEST, 2007. **132**(3): p. 340-354.



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Standards for Reporting Qualitative Research: A Synthesis of Recommendations

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Abstract

Purpose
Standards for reporting exist for many types of quantitative research, but currently none exist for the broad spectrum of qualitative research. The purpose of the present study was to formulate and define standards for reporting qualitative research while preserving the requisite flexibility to accommodate various paradigms, approaches, and methods.

Method
The authors identified guidelines, reporting standards, and critical appraisal criteria for qualitative research by searching PubMed, Web of Science, and Google through July 2013; reviewing the reference lists of retrieved sources; and contacting experts. Specifically, two authors reviewed a sample of sources to generate an initial set of items that were potentially important in reporting qualitative research. Through an iterative process of reviewing sources, modifying the set of items, and coding all sources for items, the authors prepared a near-final list of items and descriptions and sent this list to five external reviewers for feedback. The final items and descriptions included in the reporting standards reflect this feedback.

Results
The Standards for Reporting Qualitative Research (SRQR) consists of 21 items. The authors define and explain key elements of each item and provide examples from recently published articles to illustrate ways in which the standards can be met.

Conclusions
The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research. These standards will assist authors during manuscript preparation, editors and reviewers in evaluating a manuscript for potential publication, and readers when critically appraising, applying, and synthesizing study findings.

Qualitative research contributes to the literature in many disciplines by describing, interpreting, and generating theories about social interactions and individual experiences as they occur in natural, rather than experimental, situations.[1–3] Some recent examples include studies of professional dilemmas,[4] medical students' early experiences of workplace learning,[5] patients' experiences of disease and interventions,[6–8] and patients' perspectives about incident disclosures.[9] The purpose of qualitative research is to understand the perspectives/experiences of individuals or groups and the contexts in which these perspectives or experiences are situated.[1,2,10]

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Qualitative research is increasingly common and valued in the medical and medical education literature.[1,10–13] However, the quality of such research can be difficult to evaluate because of incomplete reporting of key elements.[14,15] *Quality* is multifaceted and includes consideration of the importance of the research question, the rigor of the research methods, the appropriateness and salience of the inferences, and the clarity and completeness of reporting.[16,17] Although there is much debate about standards for methodological rigor in qualitative research,[13,14,18–20] there is widespread agreement about the need for clear and complete reporting.[14,21,22] Optimal reporting would enable editors, reviewers, other researchers, and practitioners to critically appraise qualitative studies and apply and synthesize the results. One important step in improving the quality of reporting is to formulate and define clear reporting standards.

Authors have proposed guidelines for the quality of qualitative research, including those in the fields of medical education,[23–25] clinical and health services research,[26–28] and general education research.[29,30] Yet in nearly all cases, the authors do not describe how the guidelines were created, and often fail to distinguish reporting quality from the other facets of quality (e.g., the research question or methods). Several authors suggest standards for reporting qualitative research,[15,20,29–33] but their articles focus on a subset of qualitative data collection methods (e.g., interviews), fail to explain how the authors developed the reporting criteria, narrowly construe qualitative research (e.g., thematic analysis) in ways that may exclude other approaches, and/or lack specific examples to help others see how the standards might be achieved. Thus, there remains a compelling need for defensible and broadly applicable standards for reporting qualitative research.

We designed and carried out the present study to formulate and define standards for reporting qualitative research through a rigorous synthesis of published articles and expert recommendations.

Method

We formulated standards for reporting qualitative research by using a rigorous and systematic approach in which we reviewed previously proposed

recommendations by experts in qualitative methods. Our research team consisted of two PhD researchers and one physician with formal training and experience in qualitative methods, and two physicians with experience, but no formal training, in qualitative methods.

We first identified previously proposed recommendations by searching PubMed, Web of Science, and Google using combinations of terms such as "qualitative methods," "qualitative research," "qualitative guidelines," "qualitative standards," and "critical appraisal" and by reviewing the reference lists of retrieved sources, reviewing the Equator Network,[22] and contacting experts. We conducted our first search in January 2007 and our last search in July 2013. Most recommendations were published in peer-reviewed journals, but some were available only on the Internet, and one was an interim draft from a national organization. We report the full set of the 40 sources reviewed in Supplemental Digital Appendix 1, found at http://links.lww.com/ACADMED/A218.

Two of us (B.O., I.H.) reviewed an initial sample of sources to generate a comprehensive list of items that were potentially important in reporting qualitative research (Draft A). All of us then worked in pairs to review all sources and code the presence or absence of each item in a given source. From Draft A, we then distilled a shorter list (Draft B) by identifying core concepts and combining related items, taking into account the number of times each item appeared in these sources. We then compared the items in Draft B with material in the original sources to check for missing concepts, modify accordingly, and add explanatory definitions to create a prefinal list of items (Draft C).

We circulated Draft C to five experienced qualitative researchers (see the acknowledgments) for review. We asked them to note any omitted or redundant items and to suggest improvements to the wording to enhance clarity and relevance across a broad spectrum of qualitative inquiry. In response to their reviews, we consolidated some items and made minor revisions to the wording of labels and definitions to create the final set of reporting standards—the Standards for Reporting Qualitative Research (SRQR)—summarized in Table 1.

To explicate how the final set of standards reflect the material in the original sources, two of us (B.O., D.A.C.) selected by consensus the 25 most complete sources of recommendations and identified which standards reflected the concepts found in each original source (see Table 2).

Results

The SRQR is a list of 21 items that we consider essential for complete, transparent reporting of qualitative research (see Table 1). As explained above, we developed these items through a rigorous synthesis of prior recommendations and concepts from published sources (see Table 2; see also Supplemental Digital Appendix 1, found at http://links.lww.com/ACADMED/A218) and expert review. These 21 items provide a framework and recommendations for reporting qualitative studies. Given the wide range of qualitative approaches and methodologies, we attempted to select items with broad relevance.

The SRQR includes the article's title and abstract (items 1 and 2); problem formulation and research question (items 3 and 4); research design and methods of data collection and analysis (items 5 through 15); results, interpretation, discussion, and integration (items 16 through 19); and other information (items 20 and 21). Supplemental Digital Appendix 2, found at http://links.lww.com/ACADMED/A218, contains a detailed explanation of each item, along with examples from recently published qualitative studies. Below, we briefly describe the standards, with a particular focus on those unique to qualitative research.

Titles, abstracts, and introductory material. Reporting standards for titles, abstracts, and introductory material (problem formulation, research question) in qualitative research are very similar to those for quantitative research, except that the results reported in the abstract are narrative rather than numerical, and authors rarely present a specific hypothesis.[29,30]

Research design and methods. Reporting on research design and methods of data collection and analysis highlights several distinctive features of qualitative research. Many of the criteria we reviewed focus not only on identifying and describing all aspects of the methods (e.g., approach, researcher characteristics and role, sampling strategy, context, data collection and analysis) but also on justifying each choice.[13,14] This ensures that authors make their assumptions and decisions transparent to readers. This standard is less commonly expected in quantitative research, perhaps because most quantitative researchers share positivist assumptions and generally agree about standards for rigor of various study designs and sampling techniques.[14] Just as quantitative reporting standards encourage authors to describe how they implemented methods such as randomization and measurement validity, several qualitative reporting criteria recommend that authors describe how they implemented a presumably familiar technique in their study rather than simply mentioning the technique.[10,14,32] For example, authors often state that data collection occurred until saturation, with no mention of how they defined and recognized saturation. Similarly, authors often mention an "iterative process," with minimal description of the nature of the iterations. The SRQR emphasizes the importance of explaining and elaborating on these important processes. Nearly all of the original sources recommended describing the characteristics and role of the researcher (i.e., reflexivity). Members of the research team often form relationships with participants, and analytic processes are highly interpretive in most qualitative research. Therefore, reviewers and readers must understand how these relationships and the researchers' perspectives and assumptions influenced data collection and interpretation.[15,23,26,34]

Results. Reporting of qualitative research results should identify the main analytic findings. Often, these findings involve interpretation and contextualization, which represent a departure from the tradition in quantitative studies of objectively reporting results. The presentation of results often varies with the specific qualitative approach and methodology; thus, rigid rules for reporting qualitative findings are inappropriate. However, authors

Table 1

Standards for Reporting Qualitative Research (SRQR)[a]

No.	Topic	Item
	Title and abstract	
S1	Title	Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended
S2	Abstract	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions
	Introduction	
S3	Problem formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement
S4	Purpose or research question	Purpose of the study and specific objectives or questions
	Methods	
S5	Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale[b]
S6	Researcher characteristics and reflexivity	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability
S7	Context	Setting/site and salient contextual factors; rationale[b]
S8	Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale[b]
S9	Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues
S10	Data collection methods	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale[b]
S11	Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study
S12	Units of study	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)
S13	Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts
S14	Data analysis	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale [b]
S15	Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale[b]
	Results/findings	
S16	Synthesis and interpretation	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory
S17	Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings
	Discussion	
S18	Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/ generalizability; identification of unique contribution(s) to scholarship in a discipline or field
S19	Limitations	Trustworthiness and limitations of findings

(*Table continues*)

Table 1
(Continued)

No.	Topic	Item
	Other	
S20	Conflicts of interest	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed
S21	Funding	Sources of funding and other support; role of funders in data collection, interpretation, and reporting

[a]The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.
[b]The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

should provide evidence (e.g., examples, quotes, or text excerpts) to substantiate the main analytic findings.[20,29]

Discussion. The discussion of qualitative results will generally include connections to existing literature and/or theoretical or conceptual frameworks, the scope and boundaries of the results (transferability), and study limitations.[10–12,28] In some qualitative traditions, the results and discussion may not have distinct boundaries; we recommend that authors include the substance of each item regardless of the section in which it appears.

Discussion

The purpose of the SRQR is to improve the quality of reporting of qualitative research studies. We hope that these 21 recommended reporting standards will assist authors during manuscript preparation, editors and reviewers in evaluating a manuscript for potential publication, and readers when critically appraising, applying, and synthesizing study findings. As with other reporting guidelines,[35–37] we anticipate that the SRQR will evolve as it is applied and evaluated in practice. We welcome suggestions for refinement.

Qualitative studies explore "how?" and "why?" questions related to social or human problems or phenomena.[10,38] Purposes of qualitative studies include understanding meaning from participants' perspectives (How do they interpret or make sense of an event, situation, or action?); understanding the nature and influence of the context surrounding events or actions; generating theories about new or poorly understood events, situations, or actions; and understanding the processes that led to a desired (or undesired) outcome.[38] Many different approaches (e.g., ethnography, phenomenology, discourse analysis, case study, grounded theory) and methodologies (e.g., interviews, focus groups, observation, analysis of documents) may be used in qualitative research, each with its own assumptions and traditions.[1,2] A strength of many qualitative approaches and methodologies is the opportunity for flexibility and adaptability throughout the data collection and analysis process. We endeavored to maintain that flexibility by intentionally defining items to avoid favoring one approach or method over others. As such, we trust that the SRQR will support all approaches and methods of qualitative research by making reports more explicit and transparent, while still allowing investigators the flexibility to use the study design and reporting format most appropriate to their study. It may be helpful, in the future, to develop approach-specific extensions of the SRQR, as has been done for guidelines in quantitative research (e.g., the CONSORT extensions).[37]

Limitations, strengths, and boundaries

We deliberately avoided recommendations that define methodological rigor, and therefore it would be inappropriate to use the SRQR to judge the quality of research methods and findings. Many of the original sources from which we derived the SRQR were intended as criteria for methodological rigor or critical appraisal rather than reporting; for these, we inferred the information that would be needed to evaluate the criterion. Occasionally, we found conflicting recommendations in the literature (e.g., recommending specific techniques such as multiple coders or member checking to demonstrate trustworthiness); we resolved these conflicting recommendations through selection of the most frequent recommendations and by consensus among ourselves.

Some qualitative researchers have described the limitations of checklists as a means to improve methodological rigor.[13] We nonetheless believe that a checklist for reporting standards will help to enhance the transparency of qualitative research studies and thereby advance the field.[29,39]

Strengths of this work include the grounding in previously published criteria, the diversity of experience and perspectives among us, and critical review by experts in three countries.

Implications and application

Similar to other reporting guidelines,[35–37] the SRQR may be viewed as a starting point for defining reporting standards in qualitative research. Although our personal experience lies in health professions education, the SRQR is based on sources originating in diverse health care and non-health-care fields. We intentionally crafted the SRQR to include various paradigms, approaches, and methodologies used in qualitative research. The elaborations offered in

Table 2

Alignment of the 21 Standards for Reporting Qualitative Research (SRQR) With Recommendations From 25 Original Sources[a]

		Reference no.[b]																						
No.	Topic	11,12	15[c]	19	20[c]	23	24,25[d]	26	27	29[c,d]	30[c,d]	31[c]	32[c]	33	34	41	42	43	44[c]	45	46	47	48	49	50
S1	Title						*	*		*														*	
S2	Abstract						*			*	*			*											
S3	Problem formulation				*	*	*	*	*	*	*	*		*	*	*	*	*			*			*	*
S4	Purpose or research question	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		*	*	*	*	*	*
S5	Qualitative approach and research paradigm	*	*	*	*	*	*	*		*	*		*	*		*	*	*			*	*	*	*	*
S6	Researcher characteristics, reflexivity	*	*	*	*	*	*	*	*	*		*	*	*		*	*	*	*	*	*	*	*	*	*
S7	Context		*	*	*	*	*	*	*	*	*	*		*		*	*		*	*	*		*		*
S8	Sampling strategy	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		*	*	
S9	Ethical issues pertaining to human subjects	*			*		*			*	*		*	*		*	*	*		*	*	*			*
S10	Data collection methods	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
S11	Data collection instruments/ technologies	*	*				*			*	*	*	*	*		*		*			*				
S12	Units of study	*	*		*		*	*		*	*	*	*	*		*					*			*	
S13	Data processing	*				*	*	*		*	*	*	*				*				*				*
S14	Data analysis	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
S15	Techniques to enhance trustworthiness	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		*	*	*
S16	Synthesis and interpretation	*	*		*	*	*	*	*	*	*	*	*	*		*	*	*			*	*	*	*	*
S17	Links to empirical data	*	*		*	*	*	*	*	*	*	*	*	*		*	*	*	*			*	*			*
S18	Integration with prior work, implications, transferability, and contribution(s)	*		*	*	*	*	*	*	*	*	*	*	*		*	*	*	*	*	*		*	*	*
S19	Limitations	*			*	*	*	*		*				*		*	*	*			*				*
S20	Conflicts of interest						*			*															
S21	Funding									*						*								*	

[a]The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research. In the table, the asterisks indicate which sources mentioned which topics.
[b]The numbers in column headings are the numbers of the citations in the reference list at the end of this report. Those citations are of original sources describing criteria for reporting and/or critical appraisal of qualitative research, which the authors used in creating the SRQR.
[c]Focuses on reporting standards (all other sources focus on quality standards or guidelines for critical review/evaluation).
[d]Addresses quantitative and qualitative research.

Supplemental Digital Appendix 2 (see http://links.lww.com/ACADMED/A218) should provide sufficient description and examples to enable both novice and experienced researchers to use these standards. Thus, the SRQR should apply broadly across disciplines, methodologies, topics, study participants, and users.

The SRQR items reflect information essential for inclusion in a qualitative research report, but should not be viewed as prescribing a rigid format or standardized content. Individual study needs, author preferences, and journal requirements may necessitate a different sequence or organization than that shown in Table 1. Journal word restrictions may prevent a full exposition of each item, and the relative importance of a given item will vary by study. Thus, although all 21 standards would ideally be reflected in any given report, authors should prioritize attention to those items that are most relevant to the given study, findings, context, and readership.

Application of the SRQR need not be limited to the writing phase of a given study. These standards can assist researchers in planning qualitative studies and in the careful documentation of processes and decisions made throughout the study. By considering these recommendations early on, researchers may be more likely to identify the paradigm and approach most appropriate to their research, consider and use strategies for ensuring trustworthiness, and keep track of procedures and decisions.

Journal editors can facilitate the review process by providing the SRQR to reviewers and applying its standards, thus establishing more explicit expectations for qualitative studies. Although the recommendations do not address or advocate specific approaches, methods, or quality standards, they do help reviewers identify information that is missing from manuscripts.

As authors and editors apply the SRQR, readers will have more complete information about a given study, thus facilitating judgments about the trustworthiness, relevance, and transferability of findings to their own context and/or to related literature. Complete reporting will also facilitate meaningful synthesis of qualitative results across studies.[40] We anticipate that such transparency will, over time, help to identify previously unappreciated gaps in the rigor and relevance of research findings. Investigators, editors, and educators can then work to remedy these deficiencies and, thereby, enhance the overall quality of qualitative research.

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References

1 Lingard L, Kennedy TJ. Qualitative research in medical education. In: Swanwick T, ed. Understanding Medical Education: Evidence, Theory and Practice. Oxford, UK: Wiley-Blackwell; 2010:323–335.
2 Harris IB. Qualitative methods. In: Norman GR, van der Vleuten CPM, Newble DI, eds. International Handbook of Research in Medical Education. Dordrecht, Netherlands: Kluwer Academic Publishers; 2002:45–95.
3 Denzin N, Lincoln Y. Introduction: The discipline and practice of qualitative research. In: The Sage Handbook of Qualitative Research. 3rd ed. Thousand Oaks, Calif: Sage Publications, Inc.; 2005:1–32.
4 Ginsburg S, Bernabeo E, Ross KM, Holmboe ES. "It depends": Results of a qualitative study investigating how practicing internists approach professional dilemmas. Acad Med. 2012;87:1685–1693.
5 Yardley S, Brosnan C, Richardson J, Hays R. Authentic early experience in medical education: A socio-cultural analysis identifying important variables in learning interactions within workplaces. Adv Health Sci Educ Theory Pract. 2013;18:873–891.
6 Embuldeniya G, Veinot P, Bell E, et al. The experience and impact of chronic disease peer support interventions: A qualitative synthesis. Patient Educ Couns. 2013;92:3–12.
7 Pinnock H, Kendall M, Murray SA, et al. Living and dying with severe chronic obstructive pulmonary disease: Multi-perspective longitudinal qualitative study. BMJ. 2011;342:d142.
8 Brady MC, Clark AM, Dickson S, Paton G, Barbour RS. Dysarthria following stroke: The patient's perspective on management and rehabilitation. Clin Rehabil. 2011;25:935–952.
9 Iedema R, Allen S, Britton K, et al. Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: The "100 patient stories" qualitative study. BMJ. 2011;343:d4423.
10 Kuper A, Reeves S, Levinson W. An introduction to reading and appraising qualitative research. BMJ. 2008;337:404–407.
11 Giacomini M, Cook, DJ. Users' guides to the medical literature: XXIII. Qualitative research in health care A. Are the results of the study valid? JAMA. 2000;284:357–362.
12 Giacomini M, Cook, DJ. Users' guides to the medical literature: XXIII. Qualitative research in health care B. What are the results and how do they help me care for my patients? JAMA. 2000;284:478–482.
13 Barbour RS. Checklists for improving rigour in qualitative research: A case of the tail wagging the dog? BMJ. 2001;322:1115–1117.
14 Dunt D, McKenzie R. Improving the quality of qualitative studies: Do reporting guidelines have a place? Fam Pract. 2012;29:367–369.
15 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007;19:349–357.
16 Cook DA, Bowen JL, Gerrity MS, et al. Proposed standards for medical education submissions to the Journal of General Internal Medicine. J Gen Intern Med. 2008;23:908–913.
17 Tracy SJ. Qualitative quality: Eight "big-tent" criteria for excellent qualitative research. Qual Inq. 2010;16:837–851.
18 Lincoln YS. Emerging criteria for quality in qualitative and interpretive research. Qual Inq. 1995;1:275–289.
19 Mays N, Pope C. Qualitative research in health care. Assessing quality in qualitative research. BMJ. 2000;320:50–52.
20 Burns N. Standards for qualitative research. Nurs Sci Q. 1989;2:44–52.
21 Ryan GW. What Are Standards of Rigor for Qualitative Research? 2005. http://www.wjh.harvard.edu/nsfqual/Ryan%20Paper.pdf. Accessed April 20, 2014.
22 The EQUATOR Network: Enhancing the quality and transparency of health research. http://www.equator-network.org. Accessed April 6, 2014.
23 Côté L, Turgeon J. Appraising qualitative research articles in medicine and medical education. Med Teach. 2005;27:71–75.
24 Bordage G, Caelleigh AS. A tool for reviewers: "Review criteria for research manuscripts." Acad Med. 2001;76:904–951.
25 Task Force of Academic Medicine and the GEA-RIME Committee. Appendix 1: Checklist of review criteria. Acad Med. 2001;76:958–959.
26 Malterud K. Qualitative research: Standards, challenges, and guidelines. Lancet. 2001;358:483–488.

27 Inui TS, Frankel RM. Evaluating the quality of qualitative research: A proposal pro tem. J Gen Intern Med. 1991;6:485–486.
28 Devers KJ. How will we know" good" qualitative research when we see it? Beginning the dialogue in health services research. Health Serv Res. 1999;34:1153.
29 Duran RP, Eisenhart MA, Erickson FD, et al. Standards for reporting on empirical social science research in AERA publications. Educ Res. 2006;35:33–40.
30 Newman M, Elbourne D. Improving the usability of educational research: Guidelines for the reporting of primary empirical research studies in education (The REPOSE Guidelines). Eval Res Educ. 2004;18:201–212.
31 Knafl KA, Howard MJ. Interpreting and reporting qualitative research. Res Nurs Health. 1984;7:17–24.
32 Kitto SC, Chesters J, Grbich C. Quality in qualitative research. Med J Aust. 2008;188:243–246.
33 Rowan M, Huston P. Qualitative research articles: Information for authors and peer reviewers. CMAJ. 1997;157:1442–1446.
34 Cohen D, Crabtree B. Guidelines for designing, analyzing, and reporting qualitative research. Qualitative Research Guidelines Project, Robert Wood Johnson Foundation. 2006. http://qualres.org/HomeGuid-3868.html. Accessed April 6, 2014.
35 Elm E von, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. Strengthening the reporting of observational studies in epidemiology (STROBE) statement: Guidelines for reporting observational studies. BMJ. 2007;335:806–808.
36 Davidoff F, Batalden P, Stevens D, Ogrinc G, Mooney S; SQUIRE Development Group. Publication guidelines for quality improvement in health care: Evolution of the SQUIRE project. Qual Saf Health Care. 2008;17(suppl 1):i3–i9.
37 Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c332.
38 Maxwell JA. Designing a qualitative study. In: Bickman L, Bog D, eds. The SAGE Handbook of Applied Social Research Methods. 2nd ed. Sage Publications, Inc.; 2009:214–253.
39 Meyrick J. What is good qualitative research? A first step towards a comprehensive approach to judging rigour/quality. J Health Psychol. 2006;11:799–808.
40 Bearman M, Dawson P. Qualitative synthesis and systematic review in health professions education. Med Educ. 2013;47:252–260.

References Cited Only in Table 2

41 Attree P, Milton B. Critically appraising qualitative research for systematic reviews. Evid Policy. 2006;2:109–126.
42 Blaxter M. Criteria for the evaluation of qualitative research. Med Sociol News. 1996;22:34–37.
43 Critical Appraisal Skills Programme (CASP). Qualitative Research Checklist. 2013. http://www.casp-uk.net/wp-content/uploads/2011/11/casp-qualitative-research-checklist-31.05.13.pdf#!casp-tools-checklists/c18f8. Accessed April 6, 2014.
44 Frambach JM, van der Vleuten CP, Durning SJ. AM last page. Quality criteria in qualitative and quantitative research. Acad Med. 2013;88:552.
45 Kuper A, Lingard L, Levinson W. Critically appraising qualitative research. BMJ. 2008;337:687–689.
46 Law M, Stewart D, Letts L, Pollock N, Bosch J, Westmorland M. Guidelines for the critical review of qualitative studies. McMaster University Occupational Therapy Evidence-Based Practice Research Group. 1998. http://www.usc.edu/hsc/ebnet/res/Guidelines.pdf. Accessed April 20, 2014.
47 Pearson A, Field J, Jordan Z. Appendix 2: Critical appraisal tools. In: Evidence-Based Clinical Practice in Nursing and Health Care: Assimilating Research, Experience and Expertise. Oxford, UK: Blackwell Publishing Ltd.; 2009:177–182. http://onlinelibrary.wiley.com/doi/10.1002/9781444316544.app2/summary. Accessed April 13, 2014.
48 Popay J, Rogers A, Williams G. Rationale and standards for the systematic review of qualitative literature in health services research. Qual Health Res. 1998;8:341–351.
49 Sandelowski M, Barroso J. Writing the proposal for a qualitative research methodology project. Qual Health Res. 2003;13:781–820.
50 Stige B, Malterud K, Midtgarden T. Toward an agenda for evaluation of qualitative research. Qual Health Res. 2009;19:1504–1516.