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STUDIEPROTOKOLI

Patient Safety Culture in Norwegian Home Health Care – a study protocol

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Abstract

The Safety Attitudes Questionnaire (SAQ) is a widely used instrument to measure safety attitudes among health care providers. The overall aim of this project is to provide research that contributes to developing better patient safety cultures in Norwegian home health care. First we will develop a tool for measuring patient safety culture in home health care services, by validating the Norwegian translation of the SAQ in the home health care setting. Second, we will study safety attitudes amongst health care employees in home health care – and whether patterns in attitudes are related to professional background, gender, age and workplace. Third, we will investigate the experienced quality of collaboration and communication between employees in home health care – and other parts of the health care services. Last, we will compare findings related to safety attitudes across services in primary health care (home health care, nursing homes, out-of-hours clinics and general practitioner (GP) practices). As part of the overall Safety Culture in Primary Care (SIP) project, this project will follow the same design as previous completed SIP studies in other services of primary care in Norway.

Keywords

The Safety Attitudes Questionnaire, patient safety culture, home health care

Introduction

The report *To Err is Human* (1999) estimated that more people died from medical errors in hospitals in the US than from car accidents or breast cancer, and contributed to an increased interest in patient safety (Kohn, Corrigan, & Donaldson, 2000). Since then studies have found a connection between burnout among staff and the staff's experience of safety culture (Profit et al., 2014; Garcia et al., 2019); and also between burnout and the occurrence of nosocomial infections like urinary tract infections and infections in surgical wounds (Cimiotti, et al., 2012).

The Norwegian Directorate of Health has defined patient safety as "protection against needless harm following health care services or the lack of them" (Norwegian Directorate of Health, 2017). Until recently, patient safety has mainly been addressed in the hospital care setting (Modak, et al. 2007). Health care services in home care is becoming increasingly important (Genet et al., 2011).

Safety culture and safety climate

The mostly used definition of safety culture was produced by T.R. Lee in 1996:

The safety culture of an organisation is the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of, and organisation's health and safety management (Guldenmund, 2000, p. 228).

The concept is developed within the framework and research of organisational psychology and is regarded as a group phenomenon rather than that of an individual (Guldemund, 2000, p. 15–16). Safety culture is often defined the same as, and used interchangeably with, the concept of safety climate (Halligan, & Zecevic, 2011). Guldenmund (2000, p. 243) concluded in his review that there was no satisfactory model for the two concepts. However, there is an agreement that organisational climate consists of the attitudes of an organisation's members; characteristic of behaviour and expression of feelings, while organisational culture is considered to be the cause of them. To prevent patients from being harmed, it is crucial that an organization develops a robust safety climate in its working units, and establishes a learning system (American College of Healthcare Executives, 2017, p. 3). Dr Lucian Leape, who is considered to be the father of the modern patient safety movement, has stated that "By prioritizing, developing, and sustaining an organizational culture focused on safety, we can drive the future of healthcare to a place where patients and those who care for them are free from harm" (American College of Healthcare Executives, 2017, p. 1).

Using safety climate surveys to measure staff perception of patient safety culture is a relevant approach to addressing patient safety culture in health care. It may help predict cultural obstacles like variability in risk related to tasks, work environment, staff behaviour and patient outcome (Deilkås et al., 2019).

Challenges in home health care

Studies of safety culture in health care had their origin in hospitals (Modak, et al., 2007), but adverse events are also common in the primary care setting that delivers the largest volume of health care. For this reason, studies of safety culture are of increasing interest also in this sector (Deilkås, 2010).

The coordination reform was introduced in Norwegian health care to improve the coordination between different service levels (Ministry of Health and Care Services, 2009, p. 32). This reform resulted in shorter hospital stays for the patients, and nursing homes and home health care services have taken over the responsibility at an earlier stage. This may have prevented adverse events from being revealed and could lead to readmission of conditions that were the result of treatment in the hospital. The patient numbers in nursing homes have decreased (Melby, et al. 2019, p. 32), while the provision of home health care has increased (Ramm, 2013). Medical follow-up and organisational work have become more dominant in the home health care sector, requiring more competence and time (Fjørtoft, et al., 2020). Patients living at home have to relate to several different health care employees. The

contact with them is frequent (Gjevjon, 2013) and may increase the risk of communication failure between services, medical hazards and readmission to hospitals. Safety in patient care depends on close cooperation between employees, patients, representatives for next of kin and leaders (Simmons et al., 2016, p. 473). To understand and improve patient outcomes in both specialist and primary care services, it is necessary to utilise similar methods, to provide comparable patient safety measures between service levels that can be interpreted in relation to each other (Jha, & Pronovost, 2016, p. 1831–1832). The intention is to build a common understanding and flexibility of how to handle common situations where adverse events arise.

The project Safety Culture In Primary Care (SIP) is a cooperation between the Norwegian Research Center (NORCE) and the University of Bergen. This main project includes completed and planned safety culture studies in general practice, out-of-hours clinics, nursing homes, child health clinics and school health services, home health care, mental health services and municipal emergency units (Bondevik, Hofoss, Hansen & Deilkås, 2014; Bondevik et al., 2014; Bondevik et al., 2017). The SIP-project has published and submitted publications about safety culture in Norwegian general practice, out-of-hours clinics and nursing homes. Users of home health care services shall feel secure that there have been established systems and cultures to report, analyse, learn from and prevent adverse events (Ministry of Health and Care Services, 2015, p. 77). As many of the users belong to vulnerable groups, it is important to ensure that the safety attitudes and daily practices among the health care providers are satisfactory. Mostly, the employees work alone with the patients in the home health care setting with large responsibility for follow-up in both medical and practical tasks (Fjørtoft et al., 2020).

The recipients of home health care

It is important to acknowledge the value of feedback from patients and next of kin. They observe whole elapses of the health care system and witness adverse events and lack of overlap between the services. In one Finnish study (Sahlström, Partanen, & Turunen, 2018), patients in both primary- and specialist health care pointed to the lack of information fluency related to administration of medication or other treatments, inadequate treatment procedures, or insufficiencies regarding nutrition. The patients suggested preventable measures like checklists, increased attention to the quality and adequacy of equipment, and health care personnel's knowledge of the illness of the patients to prevent adverse events. They emphasized the need of continuity of skilled personnel, colleges consulting each other, and that health care workers, patients and their next of kin cooperated.

Patients receiving home care and their next of kin may also have a different understanding of patient safety than the home care personnel. While the latter primarily link patient safety to the service offered to the patient and the time spent in their home, the patient and their next of kin will have a wider understanding of the expression since the home to them is always present. They will also use other terms like *challenges*, *worries and risks* to define safety, and these may be connected to physical, spatial and interpersonal relations. Examples may be whether or not they trust the personnel coming to their home, or fear of falling while carrying out household chores (Tong, C. E., Sims-Gould, J., & Martin-Matthews, 2016). One study points to the deficiencies of the physical environment of the home healthcare patient and their caregiver. The caregiver may also have impairments, be overworked and uninformed, which may inflict harm to self and care recipient (Henriksen, K. 2009). Lang, Edwards and Fleiszer (2007) emphasize the isolated working conditions which the caregivers work under, and the lack of supervisory, collegial support and adequate equipment. Surveys

of safety issues have neither been able to properly capture the role of the patient's caregiver, nor the connection between the caregiver and the patient's health and safety (Macdonald et al. 2013).

A study in Mid-Norway using a short form of the Safety Attitudes Questionnaire (SAQ), indicated that a considerable proportion of home health care units may have a high risk of adverse events caused by immature safety- and teamwork climates (Olsen and Bjerkan, 2017, pp. 6–17). The study concluded that there is a need for more research on patient safety culture, and patient safety attitudes amongst health care providers in home health care services. Nevertheless, the SAQ has not been scientifically validated for home health care. We will therefore start this project with a study aiming to both validate the SAQ and investigate the patient safety culture in home health care services.

The Safety Attitudes Questionnaire

The interest in patient safety culture has led to the development of different instruments to measure attitudes of safety culture among health care personnel. The Hospital Survey and Patient Safety Culture (HSOPSC) was originally developed for use in the hospital setting, but has also been adapted for use in nursing homes by the Agency for Health Care Research and Quality (Castle, et al., 2010; Sorra, Franklin, Streagle, 2008). Through the last years this tool has also been adapted to Norwegian nursing homes.

Another internationally recognized tool for measuring safety culture is the Safety Attitudes Questionnaire (SAQ). The SAQ was also originally developed for hospitals and has since been adjusted to different health care services outside the hospital setting. Several studies have shown an association between the results of the SAQ, and patient outcome (Profit, J., et al., 2012; Berry, et al., 2016). The SAQ identifies areas where patient safety is exposed to adverse events and can motivate leaders to implement strategies for quality improvement, so that risk can be reduced (Bondevik, et al., 2019). The questionnaire was developed by researchers at the University of Texas, Center of Excellence for Patient Safety, US, and has proven to be sensitive for mapping health care personnel's individual attitudes to patient safety. The questionnaire includes six major safety culture factors: Teamwork climate, Safety climate, Job satisfaction, Perceptions of management, Working conditions and Stress recognition. It is a generic instrument, which means that it can be adapted to all services in the health care sector (Sexton, et al., 2006).

In 2007, the Safety Attitudes Questionnaire Ambulatory Version (SAQ-AV) was developed to measure patient safety culture in the primary care services. It is a reliable tool for comparing attitudes between different health care professions outside the hospital setting. SAQ gives data that makes it possible to study measures related to patient safety, and changes in attitudes among health care personnel over time (Sexton, et al., 2007). Results from studies show that there is an association between the prevalence of patient harm, and health care personnel's experience of safety culture within their own workplace (Colla et al., 2005, pp. 364–366; Deilkås & Hofoss, 2008). The SAQ can identify possible weaknesses in a clinical setting and motivate interventions for quality improvement at the workplace, and reduce unwanted medical events (Pronovost et al., 2005; Pronovost et al., 2006). By comparison of safety culture at different hospitals, departments and units in particular, the differences appear to be significant (Deilkås & Hofoss, 2010). Therefore, interventions meant to improve patient safety need to include the different levels.

The overall aim of this project is to provide research that contributes to developing better patient safety cultures in Norwegian home health care. First, we will develop a tool for measuring safety culture in home health care, by validating the adapted Norwegian translation of the Safety Attitudes Questionnaire – Ambulatory version. Second, we will study safety attitudes among health care providers in home care and whether patterns in attitudes are related to professional background, gender, age and working place unit. Third, we will investigate the experienced quality of collaboration and communication between employees in home care – and other parts of the health services. Finally, we will compare findings related to safety attitudes across services in primary health care (home care, nursing homes, OOH clinics and GP practices).

Research questions

Based on the aim of the study we intend to answer the following research questions.

- Will the data from this study confirm the proposed six-factor model of the original SAQ?
- Are the individual items of the SAQ highly correlated within its respective factor?
- Does SAQ show good internal consistency?
- Do patterns in safety attitudes amongst health care providers in home health care relate to professional background, gender, age and working place unit?
- Are the items relevant and appropriate in terms of the patient safety climate construct?
- Are the items clear and easy to understand?
- What is the experienced quality of collaboration and communication between employees in home health care and other parts of the health services?
- Which recommendations can employees give for improvement of patient safety culture in the home health care service?
- What are the similarities and differences related to safety attitudes across services in primary health care (home health care, nursing homes, OOH clinics and GP practices)?

Methods and analysis

Study design

This is a cross sectional study. Quantitative and qualitative data will be collected, analysed and compared.

Clarification of concepts

Home Based Care exists of different services offered to people in their homes. The service of interest in this study is received by those whom the law defines as patients; a person who addresses the health care services with the request of health care, or to whom the health care service gives or offers healthcare (The Patient and User Right Act, 1999, § 1-3). This consequently excludes the term *user* from this study.

As the service of interest is organized differently than the prior studied health services, it has been necessary to clarify the term describing the workplace of the employees. In the SAQ for home health care, we have chosen the terms *unit* and *group*, because both terms are used interchangeably amongst the included personnel of this study.

Translation procedures and adaptation of the SAQ

The original SAQ-AV questionnaire has been translated following modified principles adapted from Beaton et al. (2000). Initially, the original English version was translated into Norwegian using a professional translation bureau. Next, an expert committee with clinicians and researchers adapted the initial translated version to the primary care setting. This adapted version of the questionnaire was translated back into English by a second independent

dent translation bureau being blinded to the original version. Based on this back-translated version, the committee made necessary adjustments in order to clarify possible misunderstandings.

Adapting the SAQ to the home healthcare service

Two revisions were completed to adapt the SAQ to the home healthcare service. In the first revision, two employees at the Western Norway University of Applied Science, with experience from home healthcare, gave feedback on the nursing home version of SAQ. With some changes, the questionnaire was then sent by email to a selected number of employees in two of the Departments of Home Healthcare in one of the participating municipalities for feedback. The project group evaluated all the comments, and an electronic version of the questionnaire was made with the online survey platform Qualtrics. Employees in two home healthcare districts tested the technical solutions of the form. Nursing professional consultants have been the liaison between the project group and the service in this pilot.

To not compromise the validity of the questionnaire, we have tried to minimize the changes. It has been necessary to take into consideration the conditions in which the employees work. Professionals who are part of the multidisciplinary team have been replaced or added. Some of those taken out have been cleaning personnel and kitchen personnel, while some of the added are pharmacies and next of kin.

Availability of medical equipment is not the same in home health care as in nursing homes. While nursing homes have their own storage of equipment, it is only the authorized nurses in home healthcare in the municipalities that have access to a small selection of equipment in bags they bring along on their rounds.

Questions 60 and 61 in the nursing home version of the SAQ request grading of whether the medical refill is made often enough and if it is made correctly. In contrary to nursing homes, the home healthcare does not have its own storage of specific inventory, but rather stores the medication of patients who are not able to handle it themselves. They also have the responsibility to make sure the patients at all times get the right kind of medication, which is achieved through contact with the patients' general practitioners.

In the first part of the SAQ –AV, the respondents are asked to indicate the quality of the communication and cooperation with different health services. This is followed by 62 statements which cover the subjects: Teamwork climate, Safety climate, Job satisfaction, Perceptions of management, Working conditions and Stress recognition. In the third part of the questionnaire, the respondents are asked to register sociodemographic characteristics like age, gender, profession, and work experience. At the end of the questionnaire, the respondents can give their own comments in free text. The question asked is: *In your opinion, which three measures are most important for improving patient safety at this unit/group?*

All the participating home healthcare units will get feedback after completion of the survey analysis, to be able to identify patient safety challenges and direct the necessary measures. For reasons of confidentiality, the sociodemographic characteristics will be reported in groups, to ensure that it will not be possible to identify an individual respondent.

Scoring

The SAQ-AV is a 62- item questionnaire where the respondents rate their agreement using a 5-point Likert scale: 1=disagree strongly, 2=disagree slightly, 3=neutral, 4=agree slightly, 5=agree strongly. For all questions, "Not applicable" will be included as a response category and combined with missing values in the data analyses. Scores of negatively worded items will be reversed, so that higher scores in the data set always indicate a more positive evaluation of the safety culture in the home healthcare services.

Upcoming data collection

We have invited employees working in three different municipalities in Norway, with an overall estimated population of near 300 000. The chosen municipalities differ in size to capture possible differences between home healthcare services in urban and rural areas. The approximate amount of man-labour years in the home health care services of the included municipalities is 1 200, and the number of patients receiving home healthcare is around 4 300. In order to explore the psychometric properties of the SAQ, consisting of 30 variables, we need 300 complete responses. The included respondents must be employees working in at least 20% positions. A considerable number of workers in this service have contracts less than 20% but work 20% or more by taking extra shifts. We consider these employees as important contributors to the cultures we intend to study and calculate the actual number of shifts. The degree of consensus amongst staff in home healthcare services is a measure of the organizational climate's strength. In order to describe the degree to which members of the staff share perceptions within the working place, we aim to obtain a response rate of 70% from each participating unit. This also gives us the opportunity to explore the variation in organizational climate measurements across different home health care services.

Distribution of survey

The SAQ will be sent out by e-mail to healthcare providers in the home health care services, and the participants will respond anonymously. We will need a minimum of five respondents in each unit to ensure the anonymity of the respondents. The leaders of participating services will provide lists with e-mail addresses of all employees. Reminders will be sent automatically from Qualtrics after two weeks. The total data collection period will be four weeks. It takes approximately 15 minutes to complete the SAQ-AV.

Data storage

Data will be stored in SAFE (Sikker Adgang til Forskningsdata og E-infrastruktur) at the University of Bergen. SAFE is a system that supports secure uploading, downloading and storage of research files for research projects at the University of Bergen. The data connection to SAFE is encrypted. This validates the identity of the researchers to the SAFE server, and vice versa. Additionally, it ensures that data is being sent confidentially and uncorrupted.

User participation

Patient safety culture presupposes user participation, and it is important to develop user-reported effect targets (Ministry of Health and Care Services, 2012; Ministry of Health and Care Services, 2015). In this project there are two groups of users: (1) the employees in home health care services, and (2) the users of these services. Accordingly, there will be established two reference groups: One group of employees recruited from home health care services in the participating municipalities. This group will include different professions working in these services. The second reference group will be recruited from users (and next of kin) of the home health care services in the largest of the participating municipalities.

These two reference groups will each meet three times together with representatives from the research group. Prior to the data collection period, in the first meeting, the user groups will discuss relevant safety issues and concerns related to these health services. In the second meeting, after the data collection period, preliminary results will be presented in the user groups – and possible explanations of the findings will be discussed. The third meeting will be held towards the end of the project period, and the final results and conclusions will be discussed amongst the users. Both user groups will be asked to give input on possible implications of the findings – to improve the quality of these services.

Analysis

The Qualtrics files with anonymous SAQ-AV data will be converted into SPSS files for analysis. Cronbach's alpha is a measure of factor score consistency and will be estimated to demonstrate to which extent the responses of items within a factor are correlated pairwise. Cronbach's alpha scores above 0.7 are considered adequate. Item-to-own-factor correlations will be checked to see if the items correlated more with the factor they are hypothesised to belong to, than to the other factors.

The original SAQ described six factors: Teamwork climate, Safety climate, Working conditions, Job satisfaction, Perceptions of management and Stress recognition. Confirmatory factor (CFA) analysis will be done by AMOS, and we will test the hypothesized factors from the six-factor model of the SAQ-AV. CFA provides goodness-of-fit indices, which show how the survey responses comply with the pre-hypothesised factor model (Schwendimann et al., 2013).

Descriptive statistics will be provided by mean, standard deviation and percentages. Statistical analyses will include independent samples *t*-tests and multiple linear regression. Organization-level variances in patient safety culture/patient safety culture components (inter-organization variance) will be estimated by mixed effect models. The qualitative data will be analysed by systematic text condensation (Malterud, 2012)

The original SAQ six factors model is presented here: https://link.springer.com/article/10.1186/s12913-019-4244-5/tables/3

Ethics and dissemination

The project will be based on data regarding safety culture among health care employees working in home health care services. The study will be conducted in compliance with the ethical guidelines of the Helsinki Declaration. All participants will receive written information about the purpose of the study, and that the data will be collected anonymously and treated in confidence. The study has been approved by the Norwegian Social Science Data Services – the governmental agency for protecting survey research respondent privacy according to the Norwegian Personal Data Act (NSD Ref. No. 2016/50446). As the study is not affected by the Norwegian Health Research Act, approval from an ethics committee is not needed.

This project is planned as a PhD study. Four articles are planned to be published in scientific peer-reviewed journals. Relevant conferences to present the project, will be the National Care Research Conference 2021, and the Norwegian Patient Safety Conference, Transforming Care Conference: 5th Transforming Care Conference – Venice 2021. In addition, the study results will be presented in local research seminars and in meetings with user groups and health care authorities in the participating municipalities.

Artikkelen er fagfellevurdert. Medforfatter Oddvar Førland er ansvarlig redaktør i Tidsskrift for omsorgsforskning. Derfor har den redaksjonelle behandlingen og beslutningen om publisering av artikkelen blitt håndtert av gjesteredaktørene i samarbeid med redaksjonen. Oddvar Førland har ikke hatt innsikt i vurderingsprosessen.

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