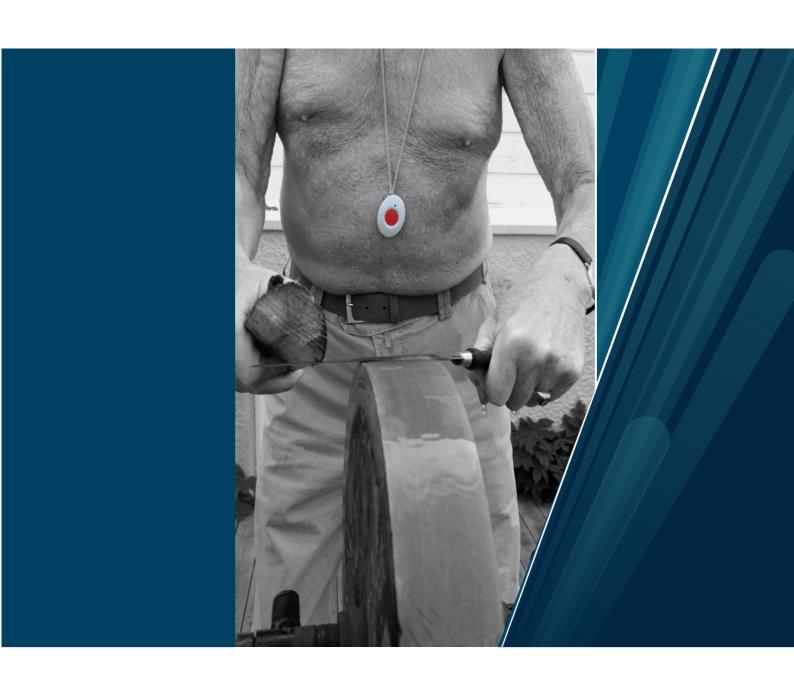
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Exploring patient safety in rural general practice - a mixed-methods approach

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Summary

Unsafe medical practices and incidents where safety hazards cause harm to patients occur daily in general practice. The costs to society, health care personnel and individual patients are substantial and deserve attention. "Hazards" can be regarded as local error-producing factors, latent failures, which create conditions for unsafe medical practice to take place. "Harm" occurs when these conditions breach safety barriers and reach the patients. Individual doctors who make mistakes created by these factors are most likely to continue to make mistakes until the underlying conditions are remedied.

The responsibility for establishing safety barriers in healthcare systems is assigned to health professionals, health organisations and the government. In Norway, there is a general practitioner (GP) scheme involving more than 4700 doctors at present. It includes a patient list system that enables the care of individuals over time, i.e. continuity of care. Continuity varies between municipalities in Norway. In small municipalities, the GP scheme is affected by the frequent use of locums (substitute GPs). Rural GP clinics also face challenges in care provision in terms of vast transportation distances and possible support of secondary care specialists. Little is known about patient safety threats in these clinics, which is the basis for my research for this doctoral dissertation.

In the first study we interviewed rural general practice patients and in the third study GPs and other health care personnel. In these studies we asked about their experiences with hazards, harm, patient safety incidents and low quality of care. The second study was a quantitative analysis of disciplinary actions against doctors in Norway in 2011-2018. The doctoral dissertation is based on a mixed-method approach to analyse these results in combination.

In paper I and III the participants described many different safety hazards and harm. In paper I patients coped with these conditions by accepting, confronting or planful problem-solving. In paper III the rural general practice staff described how vulnerability for patient safety incidents were linked to frequent use of locums, work overload and contextual factors like bad weather and distance to hospitals. The personnel used knowledge of local context and an awareness to risk of error to hinder patient safety incidents. Results from paper II showed that primary care doctors got 8 times more disciplinary actions than hospital doctors. Rural GPs got relatively most disciplinary actions, 1.7 times more compared to urban GPs.

To perform a scientific analysis of qualitative and quantitative results, I have used pragmatism as a theory of science and a mixed-methods design. In brief, this means transforming the quantitative results in Paper II into narrative descriptions. These descriptions are then jointly analysed with the results from Papers I and III. The analysis shows that safety hazards and harm in rural general practice are diverse and seem to occur nation-wide. The causes of harm are both individual and system safety hazards such as frequent use of locum GPs, lack of continuity of care, long distances and high workload. Patients, health care personnel, and the Norwegian Board of Health Supervision (NBHS) are aware of this. Harming patients in rural areas is likely to continue. However, health care workers and patients both help to reduce risks through an awareness of potential safety hazards, the use of local contextual knowledge and confronting errors, especially those made by locum GPs. The method of risk reduction used by the NBHS is system-based by taking disciplinary action against individual doctors based on individual behaviour.

Sammendrag (Summary in Norwegian)

Utrygg medisinsk praksis som skader pasienter, forekommer daglig i allmennpraksis.

Risikofaktorer for slik skade handler om feil på individ-nivå, system-feil eller organisatoriske feil. Feil på individnivå hos legen kan ofte egentlig handle om underliggende feil i helsesystemene. For å hindre gjentakelse er det systemene som må endres eller utbedres.

Ansvaret for å hindre feil hviler på helsepersonellet, legekontorene, helsesystemet og hos myndighetene. I Norge er primærhelsetjenesten organisert i form av en fastlegeordning. Alle innbyggere skal kunne velge sin egen lokale faste lege. Daglig jobber mer enn 4700 fastleger med å diagnostisere, behandle og følge opp pasientene sine. En slik omsorg over tid blir gjerne kalt kontinuitet. Kontinuitet varierer mellom kommunene i Norge. I små kommuner er kontinuiteten blant annet påvirket av hyppig bruk av vikarleger. Helsetjenesten i distrikt er påvirket av store reiseavstander for pasientene til legekontoret, og til spesialisthelsetjenesten på sykehus. Lite er imidlertid kjent om pasientsikkerheten ved slike legekontor i distrikt.

Dette er grunnlaget for min forskning til denne doktorgradsavhandlingen.

I to studier intervjuet vi pasienter, og deretter fastleger og helsepersonell som alle bor og jobber i distrikt. Vi har undersøkt deres erfaringer med uheldige hendelser, utrygg medisinsk praksis, pasientskader og lav kvalitet på helseomsorgen. Vi har også gjort en kvantitativ analyse av administrative reaksjoner gitt norske leger mellom 2011-2018. I denne artikkelen undersøkte vi forekomsten og utbredelsen av administrative reaksjoner. Doktorgraden baserer seg på en mixed-methods tilnærming til disse resultatene.

I artikkel I og III beskrev studiedeltakerne mange forskjellige risikofaktorer og skader. I den første artikkelen beskrev pasientene hvordan de mestret disse forholdene ved å akseptere, konfrontere eller ved planlagt problemløsning. Artikkel III beskrev fastleger og helsepersonell på fastlegekontor i distrikt hvordan sårbarhet for uheldige hendelser var knyttet til hyppig bruk av vikarleger, arbeidsoverbelastning og kontekstuelle faktorer som dårlig vær og lang avstand til sykehus. Helsepersonellet brukte kunnskap om lokal kontekst og en bevisst oppmerksomhet rettet mot risiko for feil for å unngå uheldige hendelser.

Resultatene i artikkel II viste at leger i primærhelsetjenesten fikk 8 ganger flere administrative reaksjoner enn sykehusleger. Fastleger i distrikt fikk relativt sett flest reaksjoner, 1.7 ganger flere enn fastleger i byene.

For å gjøre en samlet analyse av artiklene til avhandlingen har jeg brukt pragmatisme som vitenskapsteori og et «sammenfallende mixed-methods design». For artikkelen om administrative reaksjoner innebar det å transformere tall-resultatene til representative tekstutsagn. Deretter ble resultatene fra alle tre artikkelen analysert på nytt. Uheldige hendelser og utrygg medisinsk praksis ved distriktslegekontor er varierte og forekommer antakelig over hele landet. Individuelle- og system-feil utgjør risikofaktorer som kan skade pasienter. Hyppig bruk av vikarleger, manglende kontinuitet, lang reiseavstand og høy arbeidsbelastning er alle mulige risikofaktorer. Basert på indikasjoner fra trendanalysene, vil skade av pasienter på legekontor i distrikt sannsynligvis fortsette å skje i fremtiden. Helsepersonell og pasienter sørger for risikoreduksjon gjennom en bevisst årvåkenhet om potensielle risikofaktorer, gjennom bruk av lokal kontekstuell kunnskap og gjennom å konfrontere feil, spesielt gjort av vikarleger. Statens Helsetilsyn oppnår risikoreduksjon ved å gi administrative reaksjoner til enkeltleger basert på individuell risikoatferd og feil.

List of papers

Paper I

Harbitz MB, Brandstorp H, Gaski M. Rural general practice patients' coping with hazards and harm: an interview study. *BMJ Open*. 2019;9(10):e031343.

Paper II

Harbitz MB, Stensland PS, Abelsen B. Medical malpractice in Norway: frequency and distribution of disciplinary actions for medical doctors 2011-2018. *BMC Health Serv Res*. 2021;21(1):324.

Paper III

Harbitz MB, Stensland PS, Gaski M. Rural general practice staff experiences of patient safety incidents and low quality of care in Norway: an interview study. Family Practice. 2021; 39(1):130–136.

Abbreviations and definitions

GP General practitioner

CIT Critical incident technique

Context is the interrelated conditions or situation in which something

exists or occurs, and that can help explain it (Cambridge dictionary)

COREQ Consolidated criteria for reporting qualitative research

NBHS The Norwegian Board of Health Supervision

Adverse event An event that results in unintended harm to the patient by an act of

commission or omission rather than by the underlying disease or

condition of the patient¹

Error The failure of a planned action to be completed as intended or the use

of a wrong plan to achieve an aim (commission). This definition also

includes failure of an unplanned action that should have been completed

(omission)1

Hazards Local error-producing factors, latent failures, that create conditions for

adverse events in healthcare systems²

Harm Any physical or psychological injury or damage to the health of a

person, including both temporary and permanent injury¹

Incident A patient safety event that reached the patient, whether or not the

patient was harmed1

Patient safety The prevention and mitigation of harm caused by errors of omission or

commission that are associated with healthcare, and involving the

establishment of operational systems and processes that minimise the

likelihood of errors and maximise the likelihood of intercepting them when they occur¹. Several definitions exist.

Patient safety incident An unintended incident that resulted or could have resulted in hazardous

health care conditions and/or unintended harm to the patient³.

Quality The degree to which health services for individuals and populations

increase the likelihood of desired health outcomes and are consistent with

current professional knowledge1

Risk Possibility of loss or injury¹

1 Introduction

1.1 Structure of this dissertation

In the pre-phase of my PhD project I conducted a systematic literature search on patient perspectives on patient safety in general practice. This process opened my eyes to the great paucity of research on the nature of harm and factors affecting patient safety in general practice ^{4.5}, and especially in rural general practice. We developed a research protocol based on three different perspectives on patient safety and conducted the research accordingly. We believed that we needed to investigate more deeply the challenges patients and health care personnel face in relation to patient safety, and the causes of patient safety incidents. One of the earliest drafts of a research question was "Is it safe to become ill in rural general practice?" We then chose different methods to investigate the content and occurrence of patient safety incidents. For this doctoral dissertation I have performed a new analysis based on results from the three papers. The dissertation will present the three papers I have written and the new, mixed-methods approach to analyse the papers collectively.

1.2 Aim

The aim of this dissertation is to obtain new knowledge of the field of patient safety in rural general practice. Based on a mixed-methods approach to three scientific papers, the dissertation investigates factors that affect patient safety in rural general practice clinics.

1.3 Patient safety

Every day, everywhere, patients are being harmed by the health service designed to help them^{2,6-8}. There is a long tradition of academic literature on harm created by the health care system intended to treat the patients. In 1974, Ivan Illich argued that technological medical processes could be harmful in many ways⁹. In 1991, the Harvard Medical Study published two milestone articles that showed evidence that hundreds of thousands of people were harmed by hospital health care every year^{10,11}. In 1999, the famous book from the Institute of Medicine "To err is human" extrapolated the results from the Harvard Medical Study and estimated that 44 000 to 98 000 Americans die every year due to medical errors in United States hospitals⁷. This ignited a global patient safety initiative, and in 2002 the fifty-fifth World Health Assembly was titled "Quality of care: patient safety" 12, resulting in a call to all member states to recognise "the need to promote patient safety as a fundamental principle of all health systems". In 2004, the World Alliance for Patient Safety launched their forward programme¹³, largely based on hospital research^{6,7,11,14,15}, recognising the potential for patient safety and consumer involvement. The National Quality Forum defined "patient safety" in 2006 as "The prevention and mitigation of harm caused by errors of omission or commission that are associated with healthcare, and involving the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur". The Institute of Medicine defines patient safety as "The prevention of harm to patients"16.

For primary health care the amount of evidence on patient safety has recently begun to increase¹⁷, supported by increasing numbers of qualitative studies¹⁸⁻²¹. A meta-ethnographic synthesis of qualitative patient safety studies in primary care settings considered patient safety to be "a subjective feeling or judgement grounded in moral views and with potentially hidden psychological consequences affecting care processes and relationships"²².

There are debates about whether patient safety is a real 'thing' that can be described and defined, or whether it is a more vage, contested and contextually driven concept²³. It has been stated that "... like Voltaire's God, patient safety is now everywhere and nowhere²³". To illustrate, an adverse event can involve several different patient safety issues.

The first phase of an adverse event can be called the "error phase". In this first phase, exsisting safety hazards reach the sharp end of health care and cause undesired results and substandard medical help for the patient². It is estimated that 2-3 error incidents occur per 100 consultations in primary care and 4 % of these may be associated with severe harm¹⁷. Some of the vast published evidence on this first phase consists of clinical performance or active failures², poor communication skills²⁴, diagnostic errors²⁵, medication errors ²⁶ and prescription erros¹⁷, delayed referrals²⁶, health care infections²⁷, types of incidents¹⁷, patient factors like noncompliance²⁸ and a taxonomy of medical errors²⁹.

The second phase is the impact phase, also called the harm. This phase involves the outcome of the error. Studies have found the rate of harm considered probably avoidable to be 35.6 per 100 000 patient years in primary care²⁶. What consequences could these events have had, or did actually have for the patient? Scientific literature has produced classification systems^{3,30} using categories such as psychological harm, physical harm, non-medical harm (legal, social, economic³¹). Research on this phase focuses on typology, epidemiological studies²⁷ and investigating incident reports^{32,33}.

The third phase investigates what happened, why, and what can be done to avoid future harm. Studies have examined what works safely³⁴, and the epidemiology of of malpractice claims³⁵. Another field of interest has been patient safety culture³⁶ in order to understand the shared

beliefs values and assumptions that underlie how people perceive and act upon safety issues³⁷. There are also patient safety movements³⁸ in this third phase.

For patients the meaning of patient safety seems to refer to high standards of health care delivered in a continuous relationship^{18,19} involving trust^{20,21}. Patients report being proactive in protecting themselves from potential harm^{19,21}, although the effectiveness of this has been questioned³⁹. Patients or relatives who experience unsafe medical practice can file a complaint about the incident. When patients report on the safety of health care, dominating issues are clinical ^{31,35,40,41} (diagnosis of e.g. myocardial infarction, strokes, malignancies, or medication errors), system and organisational factors ^{42,43}, and communication and relational issues^{19-21,44}. If a patient complaint involves serious harm or potentially irresponsible medical care, the complaint is sent to the NBHS. The NBHS assesses whether the involved health care personnel should be disciplined for providing substandard or negligent care⁴⁵. There are five major disciplinary actions; warning, loss of prescription right, license restricted, license revoked and suspension⁴⁵. Figure 1 explains the flow in the Norwegian complaint system, from patient complaint to potential disciplinary action. General practitioner is a common specialty for physicians that receive disciplinary actions^{46,48}.

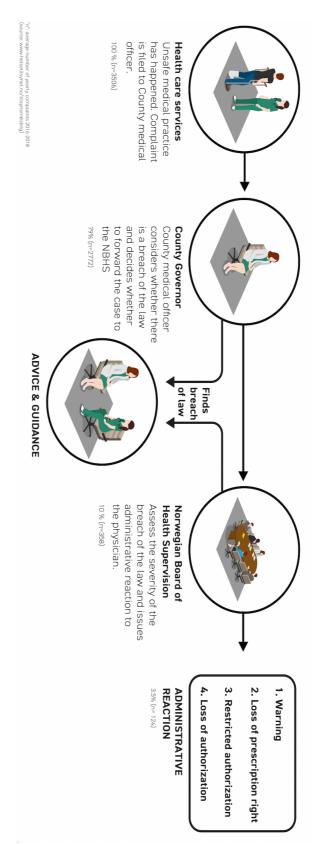


Figure 1: From medical malpractice to disciplinary action

1.3.1 Theories

James Reason's contribution to understanding the causes and prevention of errors cannot be underestimated. In the book Human Error² his original and useful contribution can be found in his differentiation between latent and active failures ², and the "Swiss cheese model" to describe the interplay between failures, safety barriers and patient harm². Latent failures (or latent errors) are incognito factors that exist as defects in the health system and design. These defects make health care personnel more susceptible to make mistakes. Active failures (or errors) are individual unsafe acts that cause an injury ². In his suggested model, "safety hazards" are local error-producing factors and latent failures, and losses are the "harm" that reaches the patients. The layers of cheese represent different types of safety barriers, while the "holes" are metaphors for both active and latent errors.

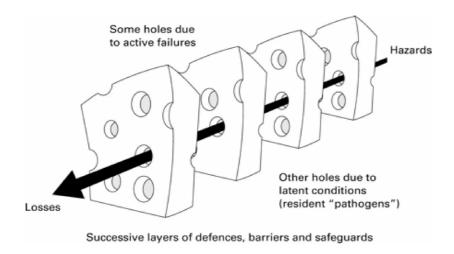


Figure 2: Reason's Swiss cheese model of human error of accident causation in complex systems, here a more labelled version from 2001⁴⁹.

Avedis Donabedian published in 1966 a paper entitled "Evaluating the Quality of Medical Care" 50. In this paper, Donabedian argues for three domains to assess quality: structure, process and outcome. *Structure* includes the physical and organisational resources available

for health care personnel. The social distribution of care, gaining access to care in a community, is influenced by many factors not controlled by the individual health care professional.

Processes are the actions involved in the delivery of health care. This domain is how health care personnel perform their work and how health care system and patient interact. The technical performance of the personnel depends on knowledge and judgement in comparison to best practice, i.e. the procedure which on average produces the greatest improvement in health. If the fraction of what is achievable with best practice is called effectiveness, technical performance is proportionate to effectiveness, and bound by the strengths and weaknesses of clinical science ²⁸. The process also depends on the interpersonal relationship that allows patients to communicate the information necessary for arriving at a diagnosis and the most appropriate methods of care ²⁸. The criteria and standards of the interpersonal process are not well developed, but include the qualities of privacy, confidentiality, informed choice, empathy, honesty, tact and sensitivity – celebrating the uniqueness of each person. Patients and their families are also partly responsible for quality care and must carry some of the responsibility for the success or failure of care.

Outcome is what happens to the health status of patients and populations as the result of the interaction⁵⁰. Improvement in knowledge and salutary changes in behaviour are included in the broader definition of health status²⁸.

The third and final theory I want to address is *noise*, i.e. the chance variability of judgements⁵¹, which in many cases is unwanted. Professionals in many organisations, including doctors, are expected to produce similar or even identical responses in similar cases. But the fact of the matter is that human decisions such as diagnosis, management, treatment and follow-up care can easily be influenced, causing variation in reasoning and decisions^{51,52}.

Evidence of diagnostic variation is increasing, especially among pathologists⁵³ and radiologists⁵⁴. One study showed that GPs' ordering of cancer screening tests significantly decreased as the day progressed⁵⁵ To investigate the differences in practice and performance among doctors, unwanted variability in medical decisions can be a place to start.

1.3.2 Patient safety in rural Norway

In Norway, one of the clinicians to address patient safety was Peter F. Hjort. In 2000 he published a single-case study and introduced a Norwegian terminology for patient safety ⁵⁶. Following that landmark article came recommendations, national public reports ⁵⁷, campaigns ⁵⁸, regulations ⁵⁹ and books ⁶⁰. One obvious feature of these, also seen internationally ⁴, was the lack of emphasis on the primary care setting. There are of course exceptions, one being SKIL, a centre for quality in medical services outside hospitals, which has since 2014 focused strongly on quality and patient safety initiatives in non-hospital health care.

General practice is often a patient's first and only contact with the health care system.

Rural primary care health personnel have a duty to promote patient safety and to ask, encourage, invite and welcome patients to be involved. The European Rural and Isolated Practitioners Association has described rural practices in Europe as "diverse but can be characterised by remoteness from centres of excellence, professional isolation, challenges in accessing education and training and requires a broader range of skills and knowledge" of the EU population live in rural areas 2. The definition of rural varies. In Norway, Statistics Norway has provided a centrality index based on approximately 13 500 basic statistical units and two sub-indexes that describe the amount of workplaces and services that people can reach within 90 minutes of driving 3. There are six levels of centrality where the

second least central and the least central indexes can be considered rural. 13.9% of Norway's inhabitants live in rural areas⁶³, which constitutes 238 out of 422 municipalities.

A classical depiction of rural doctoring is found in the true story book *A Fortunate Man*⁶⁴. The writer John Berger gives a profound description of a country doctor in a solo practice in rural Gloucestershire, England. The reader is introduced to the medical practice of Doctor Sassal, who lives with his family in the same town as he practises⁶⁴. He performs medical practice as a way of life, rewarded with endless experiences of human lives, but at the cost of being under immense pressure. The book shows how good rural general practice is something very different than the technically complex procedures performed in hospitals; it is about knowing the patients well, caring for them in their homes, bearing uncertainty and knowing when to just stand and observe, and when to push for a diagnosis.

Other services of rural practices described in more academic literature are fly in fly out/drive in drive out services or short term locum or agency staff ⁶⁵. A service called "offshore rotation jobs" where doctors work for two weeks and have four weeks leave have been described ⁶⁶. All the different rural services seem to aim to recruit and retain skilled professionals in rural and remote areas. A conceptual definition of what constitutes rural general practice could be "the provision of primary care services at great distance from hospitals and large urban centres, involving a need for special equipment, skills and organisation" ⁶⁷.

The differences in practice between rural and urban clinics were described in detail in a retrospective cohort study⁶⁸ from 1995. American medical postgraduates practising in rural and remote counties were more likely to be in private and solo practice⁶⁸. They spent more time on patient care, on call, and performed a significantly broader range of medical procedures. A greater proportion of rural graduates were taken to court for medical malpractice⁶⁸. The most prominent differences between rural and urban general practice are

access, comprehensiveness and continuity⁶⁹. Rural patients travel greater distances to their GP⁶⁹ or local emergency departments⁷⁰. In a French cross-sectional, multicentre, national study of over 20 000 consultations, the annual number of consultations was higher, and consultations were longer and took place more frequently in patients' homes in rural areas. Urban patients were younger, and the mean number of chronic conditions managed was higher in rural areas than urban areas⁷¹. The study concluded that French rural GPs tend to have a higher workload than urban GPs. A recent German cross-sectional study supports these findings; here, home visits from GPs were more frequent and lasted longer in rural than in urban regions⁷².

In Norwegian GP clinics, GPs and authorised practice staff work side by side. Since 2001, inhabitants of Norway can choose their own regular GP and are then entitled to systematic care over time by the same doctor through a patient list system. Taking personal responsibility to provide care for a list of individuals over time creates continuity. Three dimensions can be used to describe continuity: interpersonal continuity of care (seeing the same people or team), longitudinal continuity (coordination and management of care in an accessible and familiar environment), and informational continuity (continuity of patient medical records and information)⁷³. This can enhance the relationship between the GP and the patient, which can increase trust and improve compliance⁷⁴. However, in municipalities with a small population, continuity as expressed the median length of GPs' work contracts is 2.8 years, while for larger municipalities the figure is 8.75 years⁷⁵. In small municipalities without GPs in charge of the patient list, the care of patients is covered by frequent use of locums (substitute GPs)⁷⁵. In 2014, there were 67 GP lists without a regular GP in Norway ⁷⁶. Of the locums working on these lists, 75% were employed in rural municipalities ⁷⁶. At the end of 2021, the number of GP lists without a GP was 221⁷⁷. This form of "locum relays" on the patient-lists, using fee-

for-service schemes and replacing regular GPs, is likely to be expensive for municipalities and negative for the continuity of patient care ^{74,78}. However, in Scottish general practice, rural and remote patients tended to have the highest satisfaction with their general practice in terms of patient-centred care and continuity of care⁷⁹. That study may, however, suffer from selection bias, since population variables were neither reported nor adjusted for. Do people living in rural areas, who work in the primary sector of the economy, relate differently to health, illness and death? Are rural clinics more home-like than urban ones? It has been shown that a home-like atmosphere can be of value⁸⁰.

Do rural health care personnel enhance their performance because they live in the same community, perhaps know the patients, and realise that one day they might be the patient themselves when they get old? Estimates show that by the year 2040 the amount of people older than 80 years will double in rural districts in Norway⁸¹. Wholey et al. postulated that factors like greater longevity, lack of medical expertise due to low condition-specific volume, and triage-and-transfer decisions could cause a greater proportion of adverse events in a rural than in an urban setting.⁸²

1.3.3 Patient safety summary

I have attempted to show that there are several definitions of patient safety. Patient safety can be regarded as an expanding research field, and a health policy concept to measure, monitor and model the health care services. But it is also a clinical skill that requires awareness of our performance as health care workers and of the systems and context that surround us. It is beyond the scope of this dissertation to provide an extensive and historical outline of patient safety. Others with far more experience have provided this³⁸.

2 Methods

This dissertation includes two qualitative papers, one quantitative paper and a mixed-methods approach to perform a combined analysis of the papers. In this section, I will first give an overall summary of the methods used in the three papers. I will then move on to comment on the theory of science that underpins the mixed-methods approach, and describe the design and methods used for that approach.

2.1 Methods, Papers I-III

Acknowledging the fact that patient safety as a concept is understudied and a term rooted in a theoretical and academic background, we wanted to interview the "stakeholders"; the patients and the health care personnel who might have some useful experiences relevant to patient safety. The population was based on people we thought would have new or unreported experiences. In paper I, Patients who sought above the age of 18, with a somatic or psychiatric symptom as their presenting problem were included. The patient perspective as a resource for knowledge of patient safety has been undervalued and overlooked⁸³. There are increasing calls for the patient perspective in science⁸⁴ and in safety work¹⁴. We believe that this may also apply to other medical staff besides GPs. Rural medical secretaries, nurses and GPs were included in the third study. Locums were excluded. For Papers I and III we developed an interview guide based on open-ended questions about feeling unsafe or experiencing unwanted situations in the GP clinic (see the <u>appendix</u> for the interview guides). We wanted to allow the participants themselves to define hazards, harm and adverse events. In Paper II we explain how disciplinary actions can represent a proxy for medical malpractice. We wanted to study the distribution, frequency and external factors that might influence malpractice. We obtained data on all disciplinary actions against doctors in Norway in 2011-2018. There are five potential actions, where a warning is the least serious and revocation or

suspension of the licence is the strongest form of action. Different types of doctors in Norway are organised differently and perform different kinds of work, spread over the entire country. Acknowledging that we merely examined a selected, albeit serious, part of medical practice, this study could provide nation-wide perspectives. The complete dataset included 13 variables such as type of action, speciality of the doctor, type of doctor, and centrality index of the workplace. For statistical analysis we calculated frequencies, cross tables, rates and linear regression models (Y = a + bX) and for trends in actions over time $(Y_i = actions in year i, X_i = year i, i = 1,...8)$. Rates of disciplinary actions were calculated per 1000 doctors and comparison of rates were done by basic division.

The findings in Papers I and III emerged from our analysis of face-to-face, telephone or Skype interviews. In Paper III we used the critical incident technique⁸⁵ to methodologically gather data on patient safety incidents (see the appendix for the interview guide). This technique enabled us to narrow the interviews down to incidents, and to address tacit knowledge and actual performance⁸⁵. We considered patient safety incidents to be critical incidents and therefore asked participants to prepare to describe a specific event where a patient was, or could have been, harmed. The interviews in Papers I and III were analysed using systematic text condensation⁸⁶, a structured way of collecting knowledge from interviews. Systematic text condensation is an analysis process using cross-case analysis to develop or enrich descriptions and concepts of phenomena based on experience⁸⁶. The analysis process consists of four steps, moving from a preliminary overview and suggestion of themes to new thematic codes and condensates, and then to a final synthesis. During the analysis process in Paper I, we chose to use Lazarus' theory of coping⁸⁷ for a further creative abductive analysis. The concept of abduction, often described as "inference to the best explanation", was coined by Charles Sanders Pierce. He explained how abduction differs

from deduction and induction by being a "process of forming an explanatory hypothesis. It is the only logical operation which introduces any new idea"88. A form of creative abduction is when theories are developed or broadened through systematic observations and repeated processes89. Alvesson and Skölberg describe how a single case is interpreted and understood from an overarching theory. If the findings from the case concur with the theory, it strengthens the theory and can broaden it89.

2.2 Ethical considerations

All the studies were approved by the Regional Committee for Medical and Health Research Ethics (2016/2314 REK Nord), and conducted according to the guidelines of the Norwegian Centre for Research Data (Project Nos. 201373, 52557 and 53124). We were also granted approval for the use and analysis of data from NBHS (internal reference 2017/1033). All the papers have been published open access. The mixed-methods analysis in this dissertation might avoid biased (harmful) conclusions because of the use of multiple perspectives. There is a requirement for two-factor authentication, which has been met for all data stored and managed during the dissertation period.

2.3 Theory of science

Pragmatism can serve as a philosophical position for social research, regardless of the research method used⁹⁰. Essentially, pragmatism aims to understand the philosophical enquiry required to lessen social problems identified via human experiences. The pragmatic maxim, articulated by Charles Sander Pierce, states: "Consider what effects, that might conceivably have practical bearings, we conceive the object of our conception to have. Then, our conception of these effects is the whole of our conception of the object." For Pierce, pragmatism was about the meaning of any concept that has application to the real world⁹¹.

James Dewey continued to develop pragmatism away from abstract concerns towards practical issues and an emphasis on human experience⁹². Experience was concerned with the questions: What is the source of our beliefs? What are the meanings of our actions? Experience must involve a process of interpretation; beliefs must be interpreted to generate actions, and actions must be interpreted to generate beliefs. Many experiences can be termed habits (such as calling one's father on Mondays to ask how things are going). For more problematic, "non-habitual" situations, Dewy describes the situation of *inquiry* occurring within a specific context (such as how to illuminate important and real patient safety issues in rural areas). Dewey treats experiences as historically and culturally located 90. Inquiry is the process of asking and answering questions, where research is a form of inquiry performed more carefully and concisely, see Figure 3. The problem recognised is how to find real-life and valid safety issues in rural general practice. The nature of the problem is connected to the different reasoning logics and epistemological assumptions. For in-depth understanding of a new phenomenon (patient safety), we considered that knowledge and insights could come from patients' and health care workers' lived and articulated experiences ^{93,94}. To explore the frequency and distribution of the phenomenon we gathered data on medical malpractice from the Norwegian Board of Health Supervision.

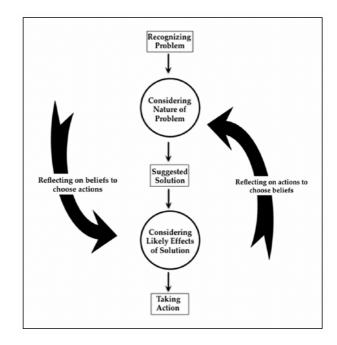


Figure 3. *Dewey's model of inquiry*

Qualitative and quantitative research seek to understand social research in terms of ontology, epistemology and the logics of methodology⁵⁰. Ontology is a branch of philosophy that studies existence and the fundamental nature of reality. The study of epistemology seeks to understand the nature and origin of knowledge. Methodology refers to the values, beliefs, and views that researchers apply to their research. Within the philosophy of science, post-positivists (quantitative research tradition) claim that the world exists apart from our understanding of it and retain the idea of objective truths. Constructivists (qualitative research tradition) insist that the world is created by our conceptions of it and believe that knowledge is subjective. For Dewey these two assertions are equally important claims about different aspects of the same world⁹², and different kinds of experience of the same phenomenon under study⁵⁰. Considering the likely effect of using pragmatism as a way to reach a solution, we must ask "What difference does it make to acquire knowledge one way or another?" and "What works for whom under what conditions?" To use multiple standpoints and research methods to gain knowledge and insight, we have emphasised solutions that are contextualised

in practice and solutions that work in theory. We realise that rural general practice is a complex care system located in a context-dependent state of human experience⁹⁵. We also appreciate a pluralist and multidimensional view of ethics and values, listening for concepts from patients, health care personnel and supervisory officials about patient safety. The effects of these choices may provide a broader, bottom-up type of knowledge, where one method's weakness is compensated for by another method's overlapping strengths^{96,97}.

2.4 Mixed methods

For this dissertation my aim was to conduct an integrated analysis of my published papers. To analyse a mix of quantitative and qualitative data, I chose a mixed-methods approach to the research question of the dissertation. Mixed-methods research is formally defined "as the class of research where the researcher mixes or combines quantitative and qualitative research techniques, methods, approaches, concepts or language into a single study"96. In their book "Educational Research", Johnson and Christensen stress how mixed-methods research can usually provide validation and stronger evidence for a conclusion through triangulation, complementarity, initiation and expansion of findings from different methods that study the same phenomenon97. Mixing data can thus provide a fuller and more meaningful answer to a research question96.

2.4.1 Concurrent design

To be able to perform an analytical dialogue between the different qualitative and quantitative papers I chose a concurrent mixed-methods design⁹⁸ for the analysis. Basic concurrent mixed-methods design is subject to four conditions: a) the qualitative and quantitative data are collected separately but with proximity in time, b) the quantitative and qualitative analysis do not build on each other during the data analysis phase, c) data must be fully collected and

analysed separately in an inference stage, d) a final integration is then drawn which integrates the inferences made from the separate qualitative and quantitative data and findings⁹⁸.

2.4.2 Mixed-methods analysis

The research process for the mixed-methods analysis follows four suggested steps⁹⁶: Step 1 is called *data reduction*. After reduction follows *data transformation*. The three datasets are then ready for *data consolidation*, *comparison and correlation*. The remaining final step is called *data integration*⁹⁷.

Data reduction

Data reductions involved reducing the number of dimensions⁹⁶ from the results section of each of the three research papers. For the paper II it also involved limiting the scope of results to fit the research question of the dissertation. This meant reducing the data on doctors who worked in rural general practice.

Data transformation

The quantitative data in Paper II needed to be transformed into narrative representations to allow for qualitative analysis⁹⁹. This involved transforming the reduced quantitative data to verbal descriptions, or conceptual qualitative representations, a method suggested by Tashakkori and Teddlie⁹⁹. The process of data transformation began by searching scientific literature for frameworks on "data transformation". The few descriptions I could find did not explain how to arrive at a conceptual qualitative representation. Instead they described different profiles⁹⁹, or how to change from numerical values in a questionnaire (4-point Likert-type scale) to qualitative labels such as "disagreement" or "in agreement" depending on the responses on the scale¹⁰⁰.

In order to look for an underlying conceptual qualitative representation between the papers¹⁰⁰, I transformed the types of disciplinary action by giving them new qualitative labels. I also wrote a narrative description of a trend analysis on rural GPs (see the appendix for the calculation). In the method suggested by Tashakkori and Teddlie⁹⁹, five kinds of transformation profiles are described: modal, average, holistic, comparative and normative⁹⁹. The profiles are not mutually exclusive, may overlap, and might be mixed⁹⁹. For my analysis three profiles were selected and mixed: *A modal profile*, based on the most frequently occurring attributes in the group, a *comparative profile*, the result of comparison of units, and a final *holistic profile*, based on the overall impression.

Data consolidation, comparison and correlation

At this step of the analysis, three datasets are ready to be compared to each other to uncover regularities or irregularities, and convergent, divergent or contradictory findings¹⁰⁰. The goal of this step is to report similarities, disagreements and contradictory themes⁹⁷. Examining the relationship between the datasets can result in the creation of new or consolidated codes⁹⁶.

Data integration

This was the final step of the analysis, creating a coherent whole from the data. This represents the final result of the mixed-methods analysis ⁹⁶.

3 Results

The structure of this section resembles that of the previous section. I will present my results from the three papers, and then describe the results from the four-step mixed-methods analysis.

3.1 Paper I - Rural general practice patients' experiences

In the first article we wanted to investigate patient perspectives on hazards and harm. Our objective was to identify and analyse rural general practice patients' experiences of hazards and harm that comprise adverse events, and their strategies for coping with them. Twenty interviews included ten women and ten men with an average age of 53 years. They lived from 126 – 286 km away from hospital. The interviews resulted in 134 pages of patient experiences. Based on their own definitions, the patients described experiences of many different safety hazards and forms of harm. Examples of safety hazards were lack of confidentiality, communication problems, disrupted continuity, long distances and bad weather, and patient-doctor relationship issues. Delayed diagnosis, wrong diagnosis or medication, feeling unsafe and inadequate follow-up were mentioned as harm. The most discussed coping strategies were: (1) to accept the events, (2) to confront them, and (3) to engage in "planful problem solving". We gained insight into the participants' tendency to accept hazards and harm caused by their regular GP, while they were often willing to confront those that a locum GP had created. Participants coped by using planful problem solving with hazardous situations like breaches of confidentiality, not being taken seriously, as well as during potential/actual emergencies.

3.2 Paper II: Disciplinary actions for doctors in Norway

Doctors are subject to disciplinary actions in cases that always involve medical malpractice, often initiated by a complaint from a patient or relative. Figure 1 shows the flowchart from patient complaint to administrative action. Our objective for this study was to investigate the frequency and distribution of disciplinary actions given to doctors by the Norwegian Board of Health Supervision. We were interested in organisational and geographical factors and whether they could influence the disciplinary actions. Based on an analysis of 953 disciplinary actions in the study period, primary care doctors received 70% of all warnings, 79% of all losses of prescription rights and 57% of revocations/restrictions of licence. For hospital doctors, the respective figures were 16%, 9% and 27%. Comparing the rates of actions, primary care doctors received eight times as many as hospital doctors. The rates of disciplinary action for GPs in general practice was 98.7, and for private specialist 91.0. Rural GPs received the most disciplinary actions of all: 1.7 times more than their urban GP colleagues, and 23.3 times more than junior doctors in hospitals. The time trends for hospital doctors and general practitioners were not statistically significant.

3.3 Paper III – Rural general practice staff experiences

Based on the findings from Papers I and II, we were interested in new perspectives to learn more about the situations where patients were or could have been harmed. Our objective in this study was to investigate rural general practice staff experiences of patient safety incidents and low quality of care. Eight GPs, one nurse and seven medical secretaries participated in the study, representing over 200 years of clinical experience in rural GP clinics. The participants described experiencing vulnerability in rural general practice, created by the frequent use of locums, work overload and contextual factors like bad weather and distance to hospitals. The findings also suggest a wide range of patient safety incidents, where the health care personnel

used local contextual knowledge and a greater awareness of risk of error to prevent these incidents.

3.4 Mixed-methods analysis

The following section is a description of the results that emerged from the mixed-methods analysis. The presentation will follow the analytical steps described in the methods section.

3.4.1 Step 1: Data reduction

Paper I: *Patient-defined hazards:* lack of confidentiality, communication problems, disrupted continuity, long distances and bad weather, patient-doctor relationship issues like the GP doesn't believe the patient, or doesn't really look at the patient or listen to what the patient says. GP's clinical skill issues like examining patients with their clothes on.

Patient defined harm: Wrong medication, delayed diagnosis, wrong diagnosis, feelings of being unsafe, experiencing inadequate follow-up care.

Coping strategies: Patients described accepting hazards and harm that involved their regular GP. Participants used a confrontative coping strategy towards locums. In municipalities with a high turnover of locums participants had to take responsibility for their own adherence to treatment guidelines. Patients described coping through planful problem-solving when their concerns were not taken seriously, or when faced with potential emergency situations.

Paper II (based on the data transformation in step 2)

Modal profile: The majority of rural GPs disciplined by the NBHS have provided irresponsible or negligent care that caused harm to patients or a near miss. The real or potential harm was physical, social or psychological. This affected the patient's safety and

could have had a very negative outcome for the patient. The disciplined rural GPs could potentially damage society's faith in health care services.

Comparative profile: In the inter-professional comparison between different types of doctors, GPs had the greatest share of irresponsible or negligent care that caused harm to patients or near misses. The intra-professional comparison between GPs shows that disciplined rural GPs were considered by the NBHS to provide relatively more negligent or irresponsible care than their urban counterparts. They were also considered to cause "serious" and "very serious" harm to patients relatively more frequently than urban GPs.

Holistic profile: Among disciplined doctors who work in Norway, the largest share of doctors, relative to the number of workers, are found in rural municipalities. This group has provided much negligent and irresponsible care that caused harm to patients or near misses, and this is unlikely to change in the future.

Paper III

Frequent use of locums, work overload, bad weather conditions and long distances to hospital are risk factors for patient safety incidents. Examples of irresponsible care, lack of follow-up care, lack of support and lack of trust were found. Medical secretaries and nurses contribute to patient safety through constantly watching out for errors and using local contextual knowledge about people and society.

3.4.2 Step 2: Data transformation

The basis for the data transformation step is to look for underlying conceptual qualitative representations between the papers¹⁰⁰. To grasp what constitutes disciplinary actions I started reading "Introduction to the supervisory authorities"⁴⁵, several supervisory reports, cases (available at www.helsetilsynet.no), legislation and other scientific papers on the subject^{101,102}.

The goal of disciplinary actions is risk reduction: to protect patients by correcting doctors' professional practice and reestablishing trust in the health care service⁴⁵. Figure 1 in Paper II illustrates the workflow for disciplinary actions. Patients, relatives, colleagues or others must have found an incident of medical care by a doctor to be irresponsible, substandard or negligent. These patient safety incidents, containing a deliberate or unintended unsafe medical practice, resulted or could have resulted in patient harm ^{45,103,104}. The complaint is a subjective feeling or experience of concern. It is the sole basis for this type of event-based supervision performed by the NBHS. Patients' complaints generally concern clinical, relational or management problems^{105,107}. Clinical domains often represented in these cases are myocardial infarction, stroke and malignancies¹⁰⁴. The stated aim of the NBHS is that the actions are to improve patient safety and people's trust in health care services in general⁴⁵. A demand for responsible health care is a demand for safety. Each case that results in a disciplinary action involves medical malpractice and represents serious incidents affecting patient safety or public trust in health care.

The legislation regulating disciplinary actions shows an increase in real or potential harm with the increasing seriousness of the reaction. I therefore argue that the disciplinary actions represent 1) degrees of irresponsible or negligent care, 2) degrees of real or potential harm, and 3) a risk reduction initiative by the NBHS. In <u>Table 1</u> these representations are labelled and linked to the different types of disciplinary action.

Table 1: Descriptions of the disciplinary actions and qualitative labels

Type of	Description	Qualitative label
disciplinary action		
Warning	Patients potentially being harmed physically, socially or psychologically. An intentional or careless irresponsible action/lack of action by the doctor affecting the patient's safety and potentially very detrimental to the patient. Warning is also given when doctors behave in a manner that could damage society's trust in the health care service.	Irresponsible or negligent care causing harm or near misses. Risk reduction takes the form of a warning as an incentive to the doctor to improve his/her clinical practice, hopefully improving patient safety for the local population.
Loss of prescription rights	This reaction is also based on incidents where potential or real harm has happened to patients. Many of these cases are based on reports directly from pharmacists to the County Governor. Prescription of addictive drugs has been irresponsible and not in accordance with the doctor's qualifications. Irresponsible prescription to the doctor himself, his family or patients. The removal of these rights will improve patient safety because patients no longer receive the wrong medication.	Irresponsible or negligent care causing harm or near misses. Risk reduction takes the form of a warning as an incentive to the doctor to improve his/her clinical practice, hopefully improving patient safety for the local population.
Licence restricted	This involves a more serious form of potential or real harm. The doctor has not provided a responsible and caring service that could be expected based on the doctor's qualifications. A warning is not an adequate reaction and restriction of the licence is needed in order for the doctor to provide responsible and safe health care. Learning and correction of behaviour is not enough to improve safety and public trust.	Irresponsible or negligent care causing serious harm or serious near misses. Risk of harm reduced by restricting patient contact, loss of right to write medical certificates, or the doctor must work under continuous supervision and guidance.
Licence revoked	This is the most severe reaction and thus involves the most serious harm or near misses. The doctor has through his actions proven himself unfit to provide health care services. The reasons may be serious mental illness, physical weakening, long absence from work, use of alcohol or drugs, gross lack of professional knowledge or irresponsible conduct.	Irresponsible or negligent care causing the most serious harm or serious near misses. Removing the doctor from the health care service is the only measure to improve safety and public trust in health care.

The trend results in Paper II are measurements of the disciplinary actions treated as a time series. I have performed trend measurements of rural GPs (se appendix for calculation). The trend measurements can be used to justify statements about tendencies in the data, by relating the measurements to the times at which they occurred. The reason to use linear regression models is that a time trend captures the trajectory of the variable (disciplinary actions) over time (2011-2018), providing forecasts of a variable. What will the future of disciplinary actions look like? The trend variable can be a proxy for future unsafe medical events, providing an estimate of such events. The trend analysis suggests no future changes in harm or potential harm to patients in rural general practice.

3.4.3 Step 3: Data consolidation, comparison and correlation

Safety awareness and barriers to harm

Patients, GPs and medical secretaries know about some of the hazards in rural GP clinics. They use different techniques to reduce the harm resulting from these hazards. The NBHS confirms that relatively more doctors are disciplined for harming or potentially harming patients in rural than in urban areas. Paper I describes patients' personal understanding of safety and links patient safety awareness to relational, external and latent errors. Paper II links safety awareness in rural areas to active personal errors by GPs. Paper III describes system causes of error and how safety awareness is influenced by relational and contextual factors and the clinical experience of health care personnel.

The safety barriers described are preventative and provided by different partners. The barriers explored are personal in Paper I, system-based (legal) in Paper II, and contextual (such as how clinical procedures are performed in a particular setting) and relational in Paper III.

In the papers harm is described as wrong or delayed diagnosis, wrong medication, inadequate follow-up care, evoking feelings of unsafe, irresponsible care, lack of trust and support.

The effects of continuity of care on patient safety

The combination of studies indicates the use of locum GPs as an important hazard for patient safety incidents. Paper I describes another hazard in connection with patients' expressed need to maintain a relationship with their regular GP. Paper III builds on these findings by describing how system factors like work overload and frequent turnover cause low continuity and possibly impaired patient safety.

Personal error vs. system error

In Paper II the NBHS disciplined doctors based on the harm or potential harm they had caused. The analysis shows how the NBHS focuses on personal active errors. The requirements for specialisation, clinical skills, training and education are the same for rural and urban GPs in Norway. Given that the GPs have the same education and training, the competence level of GPs is thus the same in urban and rural areas. A comparison of disciplined rural and urban GPs might therefore suggest that other factors such as context and external and latent errors affect the occurrence of safety hazards and harm. From Papers I and III, these error-producing factors might be frequent use of locum GPs, work overload and long distances to hospitals. The trends suggest no future changes in harm or potential harm to patients in rural general practice.

3.4.4 Step 4: Data integration

In Norway, diverse safety hazards and harm are occurring in rural general practice. Patients, health care personnel and the NBHS are aware of this. Evidence from the analysis suggests that both individual and system safety hazards cause harm to patients. Safety hazards and harm can be influenced by external and contextual factors. Frequent use of locum GPs, lack

of continuity of care, long distances and high workload are all potential risk factors for real or potential patient harm. Causing harm to patients in rural areas is likely to continue. Health care workers and patients both provide risk reduction activity through awareness of potential safety hazards, the use of local contextual knowledge and confronting errors, especially those made by locum GPs. Through its disciplinary actions, the NBHS performs risk reduction to avoid potential or real harm or near misses for rural patients.

4 Discussion

In this doctoral thesis, results from my three different papers have been used in a mixed-methods approach to gain insight into factors that affect patient safety in rural general practice clinics. The findings reveal a wide variety of safety hazards and harm in rural Norwegian general practice. Patients, health care personnel and the NBHS are aware of this. Based on indications from our trend analysis, harming or potential harming of patients in rural general practice is likely to continue. System and external factors such as frequent use of locum GPs, lack of continuity of care, long distances and high workload are risk factors for real or potential patient harm. The safety barriers explored were elements of continuity of care, personal experience and contextual knowledge. This adds new knowledge to the poorly researched field of rural patient safety

Frequent use of locum GPs, lack of continuity of care, long distances and high workload can represent structural hazards. This is apparent when applying the theoretical approach of James Reason's Swiss cheese model² and Avedis Donabedian's structure-process-outcome model⁵⁰ to the findings. I will elaborate on this in the following section.

4.1 Use of locums

Locum doctors are professionally and legally subject to the same standards as other doctors. However, in Norway, locums employed for one year or less are not required to specialise in family medicine¹⁰⁸. The reasons why locums are used may vary. The GP who owns a patient list may be ill, have paternity / maternity leave, or be absent on a specialisation course. There is also a possibility to use locums as a buffer against burnout and workload issues. The use of locums allows health care organisations to maintain adequate staffing and job flexibility. Locums in a German focus-group study from a hospital setting argued for financial gain and

professional autonomy when they chose to work as locums¹⁰⁹. These examples suggest a health care system will sometimes have a sudden need for temporary staff, which can be met by locums. Probably the most problematic use of locums with regard to patient safety is tied to GP lists without a regular GP. This number of these lists was 67 in 2014 but it has increased 3.3 times to 221 in 2021⁷⁷. Patients on those lists risk meeting one locum the first time, and another the next time. The extent and trends of locum use warrant future investigation. A recent narrative review found limited empirical evidence of the safety and quality of the use of locums¹¹⁰. The limited evidence they found suggested a negative effect on quality and safety of locums who were less familiar with patients and less aware of the local context necessary to deliver safe care¹¹⁰. There were also indications of a lack of support systems around employed locums, like inadequate pre-employment checks, unclear management structures, poor supervision and lack of reporting of performance¹¹⁰. This meant that locums performing substandard work were able to move between organisations without performance issues being addressed.

The underlying causes of locum use are perhaps mostly a question of governmental and municipal planning and management. Municipalities are responsible for hiring qualified locums. In 2014, 39% of the GP locums in Norway were recruited by the municipalities themselves, and 50% of those locums had already worked in the same municipality⁷⁶. This could enhance patient familiarity, context awareness and increased patient safety. Should there be municipal guidelines on training, supervision and evaluation when a new locum is hired? In the one document I could find on the subject, the NBHS only mentions a check of licence and references when a new locum is hired¹¹¹. The Ministry of Health and Care Services is responsible for providing high-quality equitable health care to the population. If we assume that a stable, lasting GP-patient relationship is better for the patient and for the

GP, the Ministry must work to provide stable attractive GP positions and improve the quality and safety for the use of locums.

What the patients and health care personnel in my papers describe, however, are processrelated²⁸ hazards of technical performance and interpersonal relationships. One of the patients in the first study described feeling tired of presenting his medical history to a new locum every time, and one locum who did not speak Norwegian was asked by the patient to go back home. In Paper III, participants described doctors with physical illnesses including age- and disease-related cognitive impairment and substance abuse on arrival at the clinics. In the academic world those doctors have been called "problem doctors" or even "bad apples" 113. My research indicates that these individuals still operate in rural primary care. Although it is important to limit the patient safety risk linked to such doctors, sustainable and widespread patient safety improvement calls for system or structure level solutions to this problem^{110,112,113}. The focus must be on how organisations use locums and how they are allocated and supported. More research is needed to examine the differences in practice and performance between locums and regular GPs. Unwanted variability in medical decisions can be a place to start. To address variability in medical decision-making in primary care, the first step would be to investigate the extent of noise involved. To detect the level of noise in primary care, experiments would be needed in which several doctors made multiple independent judgements of the same cases. A study could investigate the extent of noise between doctors in primary health care. Data could be variability in follow-up tests, medication use, referrals and revisits from the same population of patients. After that, the researchers would have to explore where the noise came from. Are some doctors "noisier" than others? Are there differences between locums and regular GPs? Or between different

types of locums, such as those recruited directly by municipalities and those who come from locum agencies? In many situations, noise is a more important source of error than bias is⁵¹.

4.2 Continuity

In the mixed-methods analysis, patient safety has been linked to the doctor-patient relationship and to local knowledge of people over time. These factors can be regarded as elements of continuity of care¹¹⁴. In fragmented, brief patient-doctor relationships, relational continuity is difficult to accomplish¹¹⁵. An association has been found between continuity of care and decreased mortality, reduced need for emergency primary care and fewer hospital admissions⁷⁸. A substantial amount of avoidable significant harm could be prevented through greater personal and informational continuity of care²⁶. How can continuity affect outcome? Some evidence suggests continuity increases patient trust and improves compliance⁷⁴. Many patients consider their GP or team of health care workers as the "keepers of their story", those who know them and their circumstances. Continuity of care and the sense of personal responsibility for patients can be closely linked. Cumulative knowledge of a patient's private and medical history could help regular GPs to provide better care. Seeing the same patient is not the same as knowing and caring for that patient. In a large and comprehensive Scottish prospective observational study, the researchers found patients' perceptions of the doctor's empathy predicted health outcomes; in fact, GPs' empathic communication ability was the only consultation factor that predicted better outcomes measured in symptoms and wellbeing¹¹⁶.

Diagnostic errors in general practice probably account for most harm to patients²⁶. The small, yet sometimes crucial hints that patients often present are perhaps more readily understood by a GP who knows the patient than by a similarly qualified doctor without such personal knowledge. Could this influence health outcomes? An interesting study would be to examine

how continuity affects fine-tuned clinical skills, such as appreciation of changes in blood values within the normal range, or involvement in complex patient cases. It requires time, at least one year and often five years, to establish an interpersonal relationship with extensive accumulated knowledge about a patient's medical history, personality and social network¹¹⁷. Continuity in primary health care implies a sense of connection, a partnership in health, between patient and practitioner. This partnership has been found to foster improved communication, trust and a "sustained sense of responsibility" 114,118. The notion of using the patient's personal knowledge to improve safety is increasingly being recognised¹¹⁹. A recent review of reviews found promising modes of patient engagement in patient safety such as involvement in medication, self-management of chronic diseases, adverse event reporting and medical record accuracy¹²⁰. Patient safety also depends on effective face-to-face communication between patients and health care staff ²². For doctors it means open communication²² based on patient-centred values¹²¹ and active listening involving established skills, questions and structure^{122,123}. Doctors can seek to understand and address patient priorities by asking, "What matters to you?" 124. Health care leaders and practitioners need to fully engage with patients, families and care partners in ongoing co-design and co-production of their care¹²⁵. Following an incident of harm, there is a potential for improved safety which requires an open and honest dialogue when the standard of care is breached. There must be an apology, the harm must be addressed and appropriate improvements should be discussed¹²⁵. In the light of my findings, could the patient safety risk from fragmented health care services represent elements of poor communication, lack of trust and no sustained sense of responsibility^{114,118}? If this is the case, what are the most effective ways to combat this? Recruiting and retaining qualified GPs seems to be a place to start and should follow established, recommended procedures¹²⁶.

4.3 The rural context

The findings from the mixed-method analysis suggest that patient safety measures should be based in the local context and involve the patients themselves. It is important to know the people, know the society, whom to call in an emergency, knowledge about local emergency facilities, and alternative means of transportation. Distance to hospital and severe weather were also brought up as contextual factors. Are all the above-mentioned factors specific to the rural context? Can they partly explain why rural GPs are disciplined more often than urban doctors?

Aspects of health care shortages in rural areas have been provider shortage, maldistribution, quality deficiencies, access limitations and inefficient utilisation¹²⁷.

In a comparison of rural and urban general practices in 34 countries, rural practices were found to be more often solo practices, they had fewer other primary care workers available, they were better equipped, and their service profiles were broader ¹²⁸. In a cross-sectional study comparing changes in the primary care workforce in rural and urban areas from 1993-2011, the share of female GPs had increased in rural areas but was still lower than in urban areas. In rural areas, GPs worked more and performed more medical procedures ¹²⁹. In a retrospective descriptive study of referrals, primary care visits resulting in referral were significantly less common in rural than in urban areas ¹³⁰. These findings are questioned by findings from a study conducted by the Office of the Auditor General of Norway. The authors report vast variability in referral rates when comparing municipalities and GPs ¹³¹. They write: "Neither the proportion of elderly people, how centrally located the municipality is, the size of the municipality, whether the doctor is a specialist in general medicine, nor whether the doctor is self-employed or not, can fully explain the differences in referral rates". The appreciation of rural context can suffer from "geographical narcissism". In a paper on

"geographical narcissism in psychotherapy" the writer explains how "there is a subtle, often unconscious, devaluation of rural knowledge, conventions, and subjectivity, and a belief that urban reality is definitive... urban norms on power, space, and time may contribute to an ongoing, cumulative microtrauma for people in the rural world". In this context, "urban narcissistic disowning" of the realities of rural vulnerability comes at the expense of nature, distance, weather and social dependence¹³².

External and contextual factors in rural areas influence clinical practice. Other ways to explore the influence of rurality would be to measure noise and external factors such as rurality. The design of the study on GPs' ordering of cancer screening tests and appointment time⁵⁵ could be adopted to measure other clinical decisions and external factors like rurality.

My research supports the idea of rural contextual influence on patient safety. This warrants further study. There is some research on the importance of contextual factors for quality improvement initiatives. In the Michigan Keystone Project (hospital setting), the researchers found six contextual factors that explained why the quality improvement project in fact worked¹³³. If the result of a project is influenced by contextual factors, it must also mean that the intervention needs to adapt to the context in order to succeed consistently. Otherwise, it risks becoming a superficial imitation that achieves the outer appearance but not the mechanisms that produce the outcomes in the first instance ⁹.

Rural GPs often work in isolation, without immediate access to specialist care. Could this isolation affect their workload and thus patient safety in rural general practice? An established stability strategy is to support team cohesion and ensure relevant professional development¹²⁶. In Trondheim, a city in Norway, a new project is examining the effects of virtual meetings between clinical teams of primary and secondary care doctors and the patient. An

anaesthesiologist, a physiotherapist, a psychologist, a GP and the patient will all meet virtually to discuss complex pain issues (personal message, Professor Borchgrevink, NTNU). Could this team solution compensate for some of the isolation that rural GPs face?

There is a need for knowledge and strategies to address workload issues that affect job safety and health such as burnout, moral distress and fatigue¹²⁵. "Happy doctors mean happy patients" was the take-home message from a recent patient safety report by the General Medical Council¹³⁴. General practitioners face personal and professional stress with increased strain on their mental well-being. A recent Cochrane review on mindfulness found that mindfulness interventions appeared to have a small positive effect on stress and burnout¹³⁵.

4.5 Legitimation

In mixed-methods research, legitimation involves assessing the trustworthiness of the different sets of data and the subsequent data integration ⁹⁶. Legitimation is the preferred term for validity in mixed-methods research, and in this dissertation I will address the different types of legitimation suggested by Onwuegbuzie and Johnson ⁹⁸. At the end of this section, eight of the types will be described and I will provide a short table to further describe the particular content for each of the three papers.

In quantitative research the importance of validity has been long accepted. One suggestion for classifying quantitative validity divides it into four major types: statistical conclusion validity, internal validity, construct validity and external validity¹³⁶. Statistical conclusion validity is concerned with the extent to which data in the study can reveal a link (or lack thereof) between the variables in statistical terms. With the null hypothesis H₀ stating that the quantity

to be measured is zero (null), a Type I error is a rejection of a true H₀, (a false positive conclusion). A Type II error is not rejecting a false H₀ (a false negative conclusion). Internal validity seeks to ensure that the study investigates what it is meant to investigate (controlling for extraneous and confounding variables). Construct validity is achieved by using established definitions and measurement procedures for variables. External validity is the extent to which results can be transferred to other contexts, i.e. be generalised.

In Paper II we had all the cases of disciplinary actions from 2011-2018 available, which meant that observed differences were de facto differences in the study period. There was no need for H_0 testing. In the trend analysis however, we used linear regression calculations between two categorical variables; time and number of actions against GPs and hospital doctors. We concluded that there was no significant relationship between the variables because of the calculated p-value > 0.05. This meant that the observed trend occurred randomly > 5% of the time, as seen in the statistical tables. For internal validity we discussed the possibility of selection bias performed by the Chief County Medical Officer. Cases assessed by the NBHS are processed equally and uniformly, which improves internal validity. External validity means transferring the disciplinary actions to a broader context of medical malpractice. We discussed how disciplinary actions cannot be a representative measure of medical malpractice in Norway because of the vast potential for malpractice in the millions of patient contacts during the study period.

For qualitative research where a primary goal is to capture the lived experience of people^{93,94}, "validity" involves other, more applicable criteria for this type of research. One set of criteria¹³⁷ includes credibility (replacing internal validity), transferability (replacing external validity) and dependability (the degree to which research findings are consistent and repeatable). Other sets of criteria exist⁹⁸. In Papers I and III we addressed credibility by

discussing definitions of concepts and words. When patients talked about feeling unsafe and experiencing harm, could this be applied to a definition of patient safety? The transferability of these studies is linked to the context of the studies, being in rural and remote municipalities, and thus not immediately comparable to semi-urban and urban contexts and populations. One way to establish dependability is to let an external researcher conduct an inquiry audit on the data collection, analysis and results. Good dependability would imply that regardless of the researcher, the findings, interpretations and conclusions stem from the data source. This was not done for the papers, but it could have added valuable insight. For Papers I and III, peer reviewers carefully examined the methods, interview guide and our interpretations of the data. All their remarks were published online with the papers. We were also a group of three researchers designing and analysing the studies to improve dependability.

For this dissertation the appropriateness of the mixing of methods has to be determined⁹⁷. The purpose or rationale was to investigate different experiences of harm, near misses and hazards in rural general practice clinics as underlying constructs of patient safety. The perspectives were gathered from patients, GP clinic staff and analysis of disciplinary actions by the NBHS. The rationale for using a mixed-methods analysis was to complement the strengths of one quantitative study with the strengths of two qualitative studies⁹⁶. Mixed methods can bridge the gap between qualitative and quantitative research, and minimise the weaknesses of singlemethod studies⁹⁷. There are different frameworks for assessing the validity of findings in mixed-methods research⁹⁸. I will here address the eight different types of legitimation suggested by Onwuegbuzie and Johnson⁹⁸

Sample integration: The relationship between qualitative and quantitative sampling designs

The combination of samples strengthens generalisability for Norwegian rural general practice.

Inside-outside view: The degree to which the research/researcher uses the insider's view and the outside observer's view. A combination of the insider's and outsider's view was used. The transformation of the data from Paper II was the author's subjective decision (outsider) to enable data integration.

Weakness minimisation: Non-overlapping weaknesses and complementary strengths.

Several topics are related without being asked for or brought up by the researchers. The weakness of the variables in Paper II is to some degree strengthened by the findings from Papers I and III. The results in Papers I and III are not fully supported by Paper II due to the lack of variables. The evidence does not allow for a robust conclusion as to the underlying causes of error. In terms of the objectives of this dissertation, a conclusion would be possible.

Sequential: Are inferences affected by reversing the sequence? The major topics in all articles supported the idea that sequence does not matter.

Conversion: *Transforming the data*. Evidence on how to perform data transformation and integration was very limited. This could have been influenced by the author's background as a practising rural general practitioner and a researcher at the Norwegian Centre for Rural Medicine.

Paradigmatic mixing: The researcher's epistemological, ontological, axiological, methodological and rhetorical beliefs that underlie the quantitative and qualitative approaches are successfully (a) combined or (b) blended into a usable package.

The concurrent mixed design and the mixed-methods approach followed systematic steps to blend into a usable integration of the data. There are different methods in the papers and in the dissertation that underpin my belief in a pragmatic theory of science. What constitutes this belief is documented in the methods section of the dissertation.

Political: Persuading the consumers of mixed-methods research, including stakeholders, to value the approach stemming from both the quantitative and qualitative components.

I have aimed at pluralism of perspectives in the three different research papers. Two of the three articles have been covered by national newspapers^{138,139}. The use of pragmatism and the value of practical theories and presentation of results might naturally be valued by consumers and stakeholders because the results provide answers to important patient safety questions and enhance insight to future safety work and research. The NBHS has suggested amending §56 in the Health Personnel Act from a "warning" to an "order" to receive guidance and competence enhancement (my translation).

Table 2: Type of legitimation and associated content in Papers I, II and III

Legitimation	Paper I	Paper II	Paper III
Sample	10 women, 10 men	All disciplinary actions	11 women, 5 men.
integration	(21-79 years,	(n=953) given to doctors in	Consisting of 7
	average age 53	Norway between 1 January	medical assistants, 1
	years) living in rural	2011 and 31 December	nurse and 8 GPs
	municipalities	2018. For the inference, data	working in rural GP
		on actions given to doctors	clinics.
		in rural areas analysed.	
Inside-	Patients' view	NBHS' views (outsider)	Personnel's view
outside	(insider) analysed	analysed by three researchers	(insider) analysed by
	by three researchers	(MBH, PSS, BA - outside	three researchers
	(MBH, HB, MG -	view) and peer reviewed by	(MBH, PSS, MG –
	outside view) and	two reviewers and one	outside view) and peer
	peer reviewed by	editor.	reviewed by three
	two reviewers and		reviewers and three
	one editor.		editors.
Weakness	S: Acutely ill	S: Whole population	S: The experienced
minimisation	patients, closely	nationwide dataset. Reliable	sample, incident-
	patient-focused	data processing at the	focused data, real
	data, purposive	NBHS ¹⁴⁰ .	everyday safety issues
	sampling, reflexive		revealed. Same
	analysis, established	W: Selection bias. Does not	centrality index as
	theory, shared	represent all occurrences of	Paper I. Increased use
	centrality index with	medical malpractice. Few	of locums and work
	56% of	variables available for	overload are reported
	municipalities in	analysis. Lacks info on	by all GP clinics in
	Norway.	causes of actions and	Norway.
		demographic variables such	
	W: Internal validity	as locum/regular position,	W: Locums excluded.
	of word definitions,	specialisation, sex, years of	Skype interviews
	retrospective	work experience, place of	instead of face-to-
	accounts, context	education.	face. Barriers to
	effect, informants	Inter-professional	reporting on this
	want to please the	comparison might equally be	sensitive topic.
	interviewer?	a measure of difference in	
		organisational protection, or	
		the reaction pattern of the	
		NBHS, rather than actual irresponsible conduct.	
Companion		S: Data transformation of the	
Conversion			
		findings for rural GPs.	

S =strengths, W =weaknesses

Conclusion

Patients are being harmed in Norwegian rural general practice. Frequent use of locum GPs, lack of continuity of care, long distances and high workload are all potential risk factors for real or potential patient harm. Risk reduction is performed by patients themselves, local health care workers, and the health care system itself. Incentives and initiatives from local and national health care leaders to address the safety issues mentioned here and develop safer health care are needed. Greater insight into patient safety in general practice can be revealed through future qualitative, quantitative and mixed-methods studies.

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BMJ Open Rural general practice patients' coping with hazards and harm: an interview study

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ABSTRACT

Objective The aim of this study is to identify and analyse rural general practice patients' experiences of hazards and harm that comprise adverse events, and their strategies for coping with them.

Design Interview study using systematic text condensation and coping strategy theory in an abductive analysis process.

Setting Nine rural general practice clinics in Norway. **Participants** Twenty participants, aged 21–79 years, all presenting with recent onset of somatic and/or psychiatric complaints.

Results Participating rural general practice patients described their experiences of a variety of hazards and harms. Their three most discussed cognitive and behavioural coping strategies were: (1) to accept the events; (2) to confront them and (3) to engage in planful problem-solving. While the participants demonstrated a tendency toward accepting hazards and harm that their regular general practitioner created, they were often willing to confront those that locum (ie, substitute) general practitioners created. Participants used planful problem-solving in situations they deemed hazardous, such as breaches of confidentiality or not being taken seriously, as well as during potential/actual emergencies.

Conclusions Patients at rural general practice clinics actively identify and respond to hazards and harm, applying three coping strategies. Thus, patients themselves may serve as an important safety barrier against hazards and harm; their potential contributions to improving patient safety must be appreciated accordingly and reflected in future research as well as in everyday clinical practice.

INTRODUCTION

A challenging question regarding patient safety in general practice is how to reduce hazards and avoid harm to patients. In his 'Swiss Cheese model', I James Reason suggested that 'hazards' are local error-producing factors, latent failures, that create conditions for adverse events in healthcare systems. 'Harm' occurs when these conditions breach safety barriers and reach the patients. The responsibility for establishing safety barriers in healthcare systems is assigned to health professionals, health organisations and

Strengths and limitations of this study

- Narrow and purposive sampling within an under-researched rural context.
- Patient-defined hazards and harm.
- ► Reflexive analyses supported by established theory.
- Questions may arise regarding internal validity of definitions and of retrospective accounts.
- Probability of a cultural effect and a bias appearing when informants seek to please the interviewer.

governments.^{1 2} The financial and emotional costs of harm are likely to be substantial.^{3 4}

In a Norwegian population study, about 10% of patients had experienced harm from medical care, for which the general practitioner (GP) was often blamed.⁵ All inhabitants of Norway are entitled to choose their own regular GP⁶ and over half of Norway's GP clinics can be classified as rural. In these practices, the GP continuity is often low and frequent use is made of locums (substitute GP).8 Patients in rural areas have a lower life expectancy and poorer health status as compared with those in urban areas. 9 10 Also, rural general practice clinics face such challenges in providing care as: accessibility, limited healthcare services, lack of healthcare providers, and challenges related to distance and transportation. 11 12 Studies of safety in general practice from the patients' perspective have focused on suburban or urban populations that are frequent GP users, have chronic conditions and are elderly, 13-17 while few studies have focused directly on patients in rural clinical settings.¹⁴

The field of medicine tends to undervalue and thus overlook the patient's perspective as a resource for patient safety. Calls are increasing for studies to include patients because patients' experiences, with both perceiving hazards and coping with the aftermath of harm, may provide important insights regarding patient safety. The aim of this study, therefore, is to identify and



analyse patients' experiences of hazards and harm in rural GP clinics as well as their strategies for coping with them.

METHODS Contributors

The research and author group consisted of one current and one former rural GP (now a researcher) and one senior researcher with a PhD in health science. We chose a qualitative approach for our study, based on interviews and fieldnotes. We considered face-to-face interviews to be best suited to gaining insight into participants' lived and articulated experiences. All authors contributed to designing, analysing, interpreting and critically revising the manuscript. MBH performed the interviews in nine different rural GP clinics and kept fieldnotes based on observations and interactions with staff and patients at each GP clinic. The interviews were digitally audiotaped and transcribed verbatim by MBH. We did not seek saturation.

Patient and public involvement

An interview guide was tested on an ad hoc rural patient advisory group. Pilot interviews were performed with these patients using open-ended questions, deliberately encouraging the patients to introduce their own experiences and whatever topics they considered relevant to the study. This resulted in an interview guide (see online supplementary file) in which we allowed the participants themselves to define hazards, harm and adverse events. The patients did not participate in the design of the study.

The study has followed the Consolidated criteria for Reporting Qualitative research checklist.²⁴

We used systematic text condensation inspired by Giorgi's phenomenological thematic cross-case anal-Systematic text condensation is a pragmatic method using cross-case analysis to develop new descriptions and concepts of a phenomenon based on the perspective of how they are experienced.²⁶ Initially, all researchers read through the data material in its entirety, following the stepwise analysis process of systematic text condensation,²⁶ manually coding according to semantic content. One finding was that participants spontaneously emphasised hazardous and harmful events and their own coping. Lazarus theory on coping²⁷ was chosen to support the further abductive process using theory both to help us recognise an overarching pattern²⁸ and as a 'can opener'.²⁹ The first of the two processes identified in Lazarus' theory regarding coping involves a cognitive appraisal: do any of the current stressors carry a potential for harm? The second involves a coping appraisal: what might be done to prevent or overcome harm?²⁷ Through this process, three themes emerged: (1) participants as active healthcare agents; (2) participants' confronting, hiding or accepting hazards and harm events, but without

damaging the participant/GP relationship and (3) participants' acceptance of GP decisions, including the potentially increased travel distance to hospital care.

The next step of our systematic text condensation involved identifying meaning units associated with each theme, and temporarily removing part of the text from its context (decontextualisation). The third and fourth steps (mainly done by MBH) involved dividing the themes into subgroups and then making a condensate of suitable meaning units. The three emerging subgroups were: 'the active healthcare agent', 'keep relationships' and 'acceptance'. For the first subgroup, part of the condensate was formulated as follows:

Taking agency in their own health included a range of attitudes and knowledge about their own health, the GP service and potential emergency situations. Some participants had learned to contact the GP service based only on their own suspicion of illness. Others chose to wait as long as possible to see if the symptoms would pass, thus sparing them a GP consultation.

These condensates were then reconceptualised, becoming diverse descriptions and concepts that the research group continued to discuss and reformulate, until agreement on a common understanding had been reached. Participants' statements were anonymised and assigned a random capital letter. We did not perform participant validation.

Recruitment

Nine of the 12 rural GP clinics that were approached agreed to participate; these ranged from the least to the second-least central municipalities in Norway.⁷ In one municipality, a locum GP refused us access to potential participants. Participants were recruited by healthcare secretaries at the GP clinics' reception counters, as the opportunities presented themselves. Criteria for inclusion were that potential participants be above the age of 18, with a recent onset of a somatic or psychiatric complaint as their presenting problem. Once they agreed to participate, pro bono, participants were given forms to sign confirming that they had received information about the study's focus and their interviewee rights. Since these patients were engaging in a first contact in connection with the recent onset of a clinical issue, they were representatives of a large portion of GP clinic patients and consequently of particular interest. 19 Their perspectives were likely to differ from those of elderly people with chronic conditions.

Sample

One telephone interview and 19 face-to-face interviews were conducted between January and April of 2017, immediately following the patients' medical consultations, with each interview lasting an average of 30 min. The face-to-face interviews took place at the local health facility meeting rooms.



Participant demographics and presenting medical complaints

	19–29 years	30–49 years	50–69 years	>70 years
Female	3	1	5	1
Male	0	4	2	4
Presenting issue				
Respiratory	1	0	3	1
Musculoskeletal	0	1	1	2
Psychiatric	0	1	1	0
Other complaints	2	3	2	2
Mean number of chronic diseases	0.3	8.0	0.6	2.4

RESULTS

Population

Participants included 10 women and 10 men, aged 21–79 years, with 53 being their average age. The participant demographics and their reasons for seeking medical help are detailed in table 1. Municipalities varied in size and in travel distance to a hospital, as detailed in box 1. Approximately one-third of the patients who were approached chose not to participate, with lack of time, being too ill or lack of interest being the main reasons mentioned.

Hazards and harm

Participants identified various hazards they encountered before and during consultations with their regular or locum GP, as well as experiences with harm (see table 2 for an overview). A 53-year-old woman in a rural municipality described the harm she experienced as follows:

I have trouble with gynaecological problems, and so, among other things, I went to see my GP. He took a test, a gynaecological test, that was sent to Tromsø, but it really could have been done and looked at under a microscope right here - that wasn't right. He didn't take any more tests either, so they just figured I had some sort of inflammation and they gave me medicine for that. But it didn't get any better. Then they thought, well, maybe that wasn't such a good idea after all, so I was referred to a gynaecologist in Alta. (L)

Others recounted breaches of medical confidentiality which left them feeling unsafe. For example, one 57-year-old woman was told by her former GP—in public,

Box 1 Distance to the hospital

- ► Finnmark county—three municipalities. By car: 179–286 km to hospital; by boat: 42-65 nautical miles (depending on weather conditions)
- Troms county—three municipalities. By car: 126-165 km to hospital
- Nordland county—three municipalities. By car: 105-199km to hospital

Patient-defined hazards and harm in rural general Table 2 practice

Hazards	Harm			
Lack of confidentiality	Wrong medication			
Communication problems	Delayed diagnosis			
Disrupted continuity	Wrong diagnosis			
Long travel distance and bad weather	Evoking feelings of being unsafe			
Patient-doctor relationship issues	Inadequate follow-up			
GP's clinical skill issues				

at the local post office—that her husband needed to quit smoking or else the GP would refuse to continue treating him.

Participants also spoke about communication challenges connected to having to change GPs frequently. At one GP office where locum GPs often filled in for the regular GP, one 79-year-old man who was experiencing newly onset chest palpitations said this about locums and communication:

It's very tiring to have to keep repeating my medical history to a new GP every time. Because of the high use of locums, I trust the GP service less... and I don't speak English well and he [the locum] didn't speak much English at all, and certainly no Norwegian, so we just couldn't communicate. It wasn't possible. (I)

A 'safe' GP was described as someone who knew the patient, the patient's journal, history and work situation. Friendly GPs who knew their patients well were described as 'especially safe'. Such clinical skills and behaviours as performing thorough examinations, asking colleagues for second opinions and ordering blood tests, were mentioned as contributing to the participants' feeling of safety. A 48-year-old man, with a newly discovered and suspicious-looking mole, said that a GP should be honest and curious when speaking with a patient:

A good GP is someone who sees you, really looks at you, and listens to what you have to say. (D)

Many others considered transparency in clinical work to be important, especially when the doctor tested for some diagnosis the patients had not thought of. One 56-year-old man, experiencing a problem with his knee, said:

The doctor should know what he's doing – and let me know what he's doing. (Q)

An 'unsafe' GP was, for example, one who didn't believe the patient, or who needed many consultation visits to take care of a single medical issue. Participants also reported that some GPs seemed more interested in their computers or ultrasonic monitors than in their patients. A 49-year-old man suffering from shoulder pain described it this way:



I know of GP offices where they don't even take off your coat before they examine you. (N)

Coping strategies

Participants offered a variety of examples of hazards and harm they experienced at rural GP clinics; these were often linked to feeling unsafe. The three most discussed cognitive and behavioural coping strategies were: accepting, confronting and engaging in planful problem-solving. We elaborate on these findings below.

Accept or confront

Participants expressed that their relationship with the GP impacted whether they accepted or confronted hazards and harm at their GP clinic. In situations where bad weather, long travel distances or lack of treatment continuity presented possible hazards, participants commonly coped by accepting them.

Regarding GP relationships

Participants described accepting hazards and harm that involved their regular GP. We did encounter examples of participants using a confrontive coping strategy, but those involved locum GPs. Even when their regular GPs made obvious medical errors or caused actual harm, patients stated that they did not choose to initiate a legal process, or even demand that the doctor be placed under supervision, although they were aware both of their right to do so and of whom to contact. Participants explained that they had not contacted someone like the county governor because human error occurs in all professions and their regular GPs were only human, just like them. As one middle-aged woman expressed it:

I just want to say, I'm sure they did the best they could. Everybody can make mistakes, you make mistakes, everybody can. Right? So, you have to understand that. Nobody is perfect. I don't want to, you know, judge them and just dump them. I don't want to be mean. (L)

Another female participant described her regular GP as a local 'king'. Since everyone was dependent on their GP, it was considered dangerous to risk alienating him or her.

One participant recounted an incident when his wife, who suffered from a serious disease, had had her test results overlooked and her symptoms trivialised by their GP, delaying her receiving a proper diagnosis by a full year. Patients rejected the possibility of registering a formal complaint or of starting a process leading to the GP being put under professional supervision, with one pointing out:

We have to keep on living with the same GP, and that's a relationship we don't want to push over the edge. And it's obvious that once we'd trampled all over them, it wouldn't be easy go back there. (E)

Others, not the majority but still quite a few, described utilising more assertive ways of coping. Some switched

to GPs in a neighbouring municipality, others to distant, private GP clinics. Some had written a short note detailing their complaints and asked some colleague of the locum GP to pass it on. One man in his 70s suffering from heart palpitations recalled tackling his communication difficulties with foreign locum GPs:

...and I hardly understand a word they [the various locum GPs] say. I got to where I just stood up and left and said: "You should just go home! They can use you there. We don't have any use for you here." They can't even communicate! (E)

Impact of continuity, distance and weather

Despite preferring to be examined by their own GP, most participants were frequently examined by a foreign locum GP or a GP intern. This was not often reported as problematic. A woman with chest pain said the following about the medical care she received from a locum GP:

Participant: So, I trust him completely and what he found out. I'm sure that, like he said: "If you just take two paracetamols for the pain, you'll manage to relax."

Interviewer: *But did he know your story* [recurring anxiety and depression]?

Participant: No, I didn't tell him anything. (B)

Travel time to the nearest hospital of up to 2½ hours was considered by many participants as being both short and safe. They argued that many people in Norway had just as long or even longer distances to travel. A middle-aged woman with dyspnoea said this about rural emergency transportation:

Except for the weather, when the Sea King [search and rescue helicopter] can't land and when the roads are blocked and everything like that, then I think maybe it's not that safe. But we would have to move nearer to a hospital and go and live there if we were going to be afraid of that kind of stuff. (M)

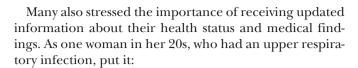
Planful problem-solving

This coping strategy was invoked frequently and emphatically when participants felt their health problems were not being taken seriously, or when they felt they were faced with potential emergency situations.

Caring for one's own health

All participants demanded that the GPs take the patients' concerns seriously. They described how they had arrived with written lists of what they wanted to discuss. One participant in her 40s described how she insisted that the GP contact the local hospital for a second opinion:

If you have been sick a lot like I have, I know I can make certain demands. I can say [to the GP]: Listen. Just go call the local hospital and hear what they think. (T)



I think that you have some responsibility too, if you have the chance to inform yourself about your own illness. I don't mean trying to be your own internet GP. But just find out a little about it; yes, know yourself, and the mechanisms behind your illness. (G)

We also found examples in municipalities with a high turnover of locum GPs where participants had to take responsibility for their own adherence to treatment guidelines. A man with cancer, following several prior myocardial infarcts, said this about the follow-up routines:

I watch out for myself. I have to. I have to make sure I come down here [to the GP's office] because nobody is going to call me in for a check-up. (E)

In emergency situations

At their own initiative, participants from all the municipalities brought up the theme of emergency awareness and preparedness. They were familiar with their local emergency facilities and often with alternate means of transportation as well, such as the large passenger ferry that would be converted into an ambulance boat during periods of extreme weather. A 45-year-old woman described her emergency preparedness in this way:

...and when the Emergency Medical Communication Centre [EMCC] at Hammerfest doesn't answer, who do you call? Well, then you call the EMCC at Bodø. Because, sometimes, that's how it's been for me. (T)

A man who lived on a small island without a local GP said this about emergency awareness:

My father was actually the one who brought a defibrillator to this island. It's hanging on the wall at the local store in case something happens... and when it came, they [the store's employees] got trained how to use it. (N)

DISCUSSION

Our findings highlight rural general practice clinic patients' experiences of hazards and harm that comprise adverse events, and address some of the ways they cope with them. Patients' experiences broadly align with existing empirical literature regarding patients' perspectives on patient safety, highlighting the human elements of safety: a subjective and nuanced construction based on good communication. 4 30 31

We add new evidence documenting how patients use coping strategies in relation to perceived hazards and in the aftermath of harm, and we argue that patients' experiences must be acknowledged and integrated into

medical safety practice as well as into ongoing and future research.

The patients' experiences of hazards and harm, and the ways they cope with them described herein are consistent with the two-step cognitive model for stress management and coping strategies.²⁷ Participants described how they first assessed safety threats (cognitive appraisal) and then chose cognitive or behavioural responses to these threats (coping). Participants seemed to accept hazards and harm experiences that had been caused by their regular GP, arguing both that human errors are understandable and that having a good relationship with their GP is important. In cases of harm or error, participants refrained from initiating legal action or demanding that the GP be placed under professional supervision. Thus, coping was shaped by both personal resources and contextual determinants.³² This could indicate that patients are aware of both the contextual and the interpersonal reasons for not taking legal action. We encountered participants who did not passively accept a hazard or harm created by locum GPs, but rather confronted the experience and the practitioner, directly or indirectly. In Norway, locum GPs are often on short employment contracts (weeks) with decreased centrality and population size correlating to the duration of the contract.8 Perhaps that lack of continuity leaves room for patients to be more critical and less concerned with establishing and maintaining a quality patient-doctor relationship.

According to James Reason's Swiss Cheese metaphor, safety barriers (so called cheese slices) have unintended weaknesses—holes. When such holes align, hazards are able to pass through and cause patients harm. Mapping our findings onto the safety barriers described in Reason's Swiss Cheese model highlights how patients' coping with these hazards may function as safety barriers (see figure 1). Our findings suggest that patients themselves may both function and act as safety barriers against harm; this challenges the standard models, in which safety barriers are perceived as being external factors.¹² Our data also support the idea of including patients in the designing and developing of safety barriers in order to incorporate personal and contextual aspects into improvements to general practice.³³ This complements the contribution which good communication and person-centred healthcare make to helping patients feel and be safe⁴ and opens for potential patient contributions to improving and operationalising safety in general practice. 19 Feedback from various patients indicates that many of them had accepted hazards and harm without their GP's knowledge. Consequently, encouraging GPs to ask their patients for feedback about hazards and harm routinely and systematically-might improve both patients' and GPs' ability to collaborate as well as increase the safety of current and future care. We believe patients' narratives about hazards represent a rich resource for improving GPs' clinical behaviour, increasing their awareness of their own biases³⁴ and how they think intuitively.³⁵ We question whether narratives from unknown patients

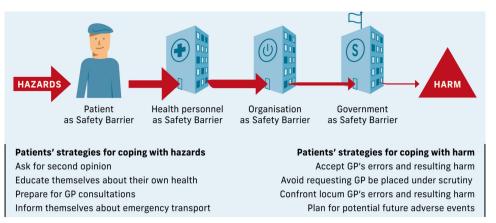


Figure 1 Patients as safety barriers against hazards in general practice.

could offer the same potential³⁶ for learning as do those from one's own patient group. Encouraging the inclusion of patients as safety barriers in healthcare and in the design of future studies, using qualitative and/or quantitative designs, may also deepen insight regarding larger and more representative populations.

The strengths of this study include its close-up, patient-focused data, its narrowly defined and purposive sampling, its clear study aim utilising reflexive analysis and supported by established theory. Excluding patients with chronic disease complaints allowed us to focus on newly ill patients; though they are frequent users of rural GP services and constitute an important population,³⁷ they have been the focus of far fewer studies. Although only the least and second-least central municipalities were chosen for inclusion in the study, these represent a level of centrality shared by over 50% of Norway's municipalities, based on the established index. We did not define hazard, harm, error, patient safety or adverse events for the patients in our study, but rather allowed them to apply their own interpretations of their meaning. Presenting patients with set definitions of concepts and words would have limited the range of potential meanings the patients could discover and present to us. Also, conducting the interviews immediately after GP consultations allowed us to document the patients' spontaneous reactions and reflections; this helped to prevent recollection bias from distorting their reports. It may also have helped to deepen the patients' perspectives by bringing memories of prior GP clinical setting experiences of hazards and harm to their awareness.

It is plausible that questions may arise regarding internal validity of concept and word definitions, as well as of retrospective accounts. The method and sampling might increase the probability of a context effect and a bias²³ arising when informants want to please the doctor. Based on the methods,²² the complexity of general practice³⁸ and the diversity of patients and GP clinics, it is difficult to claim a generalisability for our findings. Another important consideration is the first author's prejudices, and the standard of reflexivity during the interviews

and analysis²³ as he himself is a rural GP, interested in patient-centred communication and in safety.

CONCLUSION

The exploration of patients' experiences and coping strategies reveals that rural GP clinic patients actively identify and respond to hazards and harm. We have identified three coping strategies that patients use. Thus, patients themselves may serve as an important safety barrier, contributing to improving patient safety. Their contribution must be appreciated accordingly and reflected in future research.

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Contributors All authors contributed to the conception of the article and analysis and interpretation of the results. Study design: MBH, HB, MG; data acquisition: MBH and drafting the manuscript: MBH, HB, MG. Reviewing and critically revising the final version of the manuscript: MBH, HB, MG. MBH finalised and submitted the manuscript. MBH, HB and MG replied to reviewers' comments and amended the manuscript accordingly.

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RESEARCH ARTICLE

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Medical malpractice in Norway: frequency and distribution of disciplinary actions for medical doctors 2011–2018



Martin B. Harbitz^{1*}, Per Steinar Stensland² and Birgit Abelsen¹

Abstract

Background: Physicians who perform unsafe practices and harm patients may be disciplined. In Norway, there are five types of disciplinary action, ranging from a warning for the least serious examples of malpractice to loss of licence for the most serious ones. Disciplinary actions always involve medical malpractice. The aims of this study were to investigate the frequency and distribution of disciplinary actions by the Norwegian Board of Health Supervision for doctors in Norway and to uncover nation-wide patient safety issues.

Methods: We retrospectively investigated all 953 disciplinary actions for doctors given by the Board between 2011 and 2018. We categorized these according to type of action, recipient's profession, organizational factors and geographical location of the recipient. Frequencies, cross tables, rates and linear regression were used for statistical analysis.

Results: Rural general practitioners received the most disciplinary actions of all doctors and had their licence revoked or restricted 2.1 times more frequently than urban general practitioners. General practitioners and private specialists received respectively 98.7 and 91.0 disciplinary actions per 1000 doctors. Senior consultants and junior doctors working in hospitals received respectively 17.0 and 6.4 disciplinary actions per 1000 doctors. Eight times more actions were received by primary care doctors than secondary care doctors. Doctors working in primary care were given a warning 10.6 times more often and had their licence revoked or restricted 4.6 times more often than those in secondary care.

Conclusion: The distribution and frequency of disciplinary actions by the Norwegian Board of Health Supervision clearly varied according to type of health care facility. Private specialists and general practitioners, especially those working in rural clinics, received the most disciplinary actions. These results deserve attention from health policy-makers and warrant further studies to determine the factors that influence medical malpractice. Moreover, the supervisory authorities should assess whether their procedures for reacting to malpractice are efficient and adequate for all types of physicians working in Norway.

Keywords: Patient safety, Rural practice, Primary care, Secondary care, Medical litigation system, Disciplinary action, Medical malpractice

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Background

Patients affected by medical malpractice experience increased morbidity and mortality [1-3]. Unsafe medical practices, where patients are harmed by the medical care system designed to help them, are prevalent in both primary and specialized care [3-7] and the associated emotional and financial costs are substantial [1, 2, 8]. Medical litigation systems in different countries that address cases of malpractice by physicians vary in form [9– 11]. However, the medico-legal principles are universal in that patients or their relatives must express a concern or file a complaint about a physician or a health institution. In order to be disciplined, the physician must, through his or her medical conduct, have provided substandard or negligent care that led, or could have led, to patient harm [9, 10, 12]. In Norway, this process is the responsibility of the National Board of Health Supervision (NBHS), which receives the most serious patient complaints and assesses whether a doctor should be disciplined. Unlike the litigation system in the United States, decisions by the NBHS do not award financial compensation to patients, and the NBHS assesses only the legal aspect, i.e. whether the health care provider is responsible according to health care legislation. In a few rare and extraordinary cases, civil courts also impose additional legal penalties.

Most recent studies aiming to determine the causes that led to disciplinary actions analysed types of medical error [9, 13] and characteristics of physicians (sex, age, profession and work experience) in relation to such actions [13, 14]. Based on the perspectives of Reason [15] and Donabedian [16] regarding quality and errors in health care, factors such as system design, organizational culture and lack of management or training can create 'latent' upstream errors that in the end cause 'active' patient harm. The factors involved can be external factors that are not under the control of a medical institution (e.g. geographical, political or cultural issues) organizational factors (structure, organizational culture, working conditions) [17]. To discipline only individual doctors for mistakes created by these factors is not logical because errors are bound to continue until the underlying conditions are remedied. There are some indications that suggest that doctors who work in general practice receive more complaints than those who work in hospitals [18]. A Danish retrospective register study did not establish any relationship between general practitioner (GP) location (urban or rural) and the occurrence of malpractice complaints [19]. An Australian cohort study found a higher risk for complaints in remote areas in Australia than in urban areas [20]. The scarce evidence on the influence of external and organizational factors on medical malpractice warrants greater attention because a thorough evaluation might reveal important implications for improving patient safety. Therefore, the aim of this study was to investigate these factors and descriptive data of all doctors in Norway disciplined between 2011 and 2018.

Methods

In this retrospective descriptive study, we analysed the frequency, trends, total and geographical distribution, rates and organizational factors of all doctors in Norway who were disciplined between 2011 and 2018. The dataset consisted of all disciplinary actions given to doctors in Norway. When dealing with whole population datasets, observed differences are considered de facto differences.

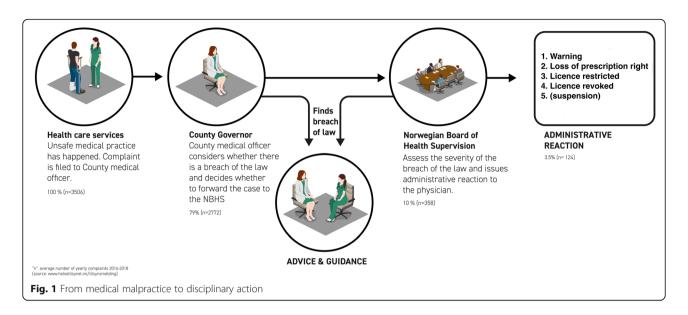
The medical litigation system in Norway

In Norway, several acts regulate how patients, family members, health care personnel and health authorities can or must report medical malpractice to the NBHS. The event must have resulted in death or an unexpected serious outcome. Reported cases are usually first assessed by the local NBHS representative, the chief county medical officer. If the reported violation is serious and potentially irresponsible [12], the case is forwarded to the NBHS [21]. Figure 1 presents a flowchart of the reporting process.

There are five potential disciplinary actions; a warning is the least serious and having one's licence revoked or suspended is the strongest form of action [12], see Fig. 1. The most frequent and serious patterns of violations by physicians include sexual misconduct, failure to meet the required standard of care and unprofessional conduct [9, 12, 13].

The Norwegian health care system

In Norway, all inhabitants can choose their own local regular GP [22]. More than 4700 doctors are currently working as regular GPs [23], and are part of a patient list system which enables an enduring patient-GP relationship [24]. GPs are usually self-employed [25] and often share a local clinic with a few colleagues. Over half of Norway's GP clinics are classified as rural [24]. For many of those living in rural areas, it takes more than 40 min to reach a local emergency primary care clinic [26], and substantially longer to reach a hospital. Physicians working in hospitals are employed by regional health authorities (state enterprises). There are four regional health authorities, which are responsible for 39 hospitals and over 12,900 physicians [27] (2018 figure). Hospitals provide the public with free specialized treatment. There are university hospitals, regional hospitals and smaller local hospitals that serve the inhabitants of a local area. In addition, there are almost 1000 private specialists working in Norway. They work in their own private



facilities and provide specialist outpatient diagnostics that are almost equivalent to hospital diagnostics. The private specialists receive subsidies from the regional health authorities but are self-employed [28].

Sample

The sample consisted of all disciplinary actions given to doctors in Norway between 1 January 2011 and 31 December 2018. After submitting a formal application to the Norwegian Centre for Research Data (project #53124) and a formal request to the NBHS, we were allowed access to a dataset for analysis. Data from the NBHS have been proven to be reliable and predictable [29]. The first author MBH examined each disciplinary action and corresponded with the NBHS if data were missing. MBH anonymized the dataset by replacing names of clinics and hospitals with a centrality index number [24] based on the geographic location. Every municipality in Norway has a centrality index number from 1 (most central) to 6 (least central). In the present study, we merged two consecutive index numbers (see Results) to represent urban areas (centrality index 1–2), semi-urban areas (centrality index 3-4) and rural areas (centrality index 5-6). The complete dataset contained 13 variables including registration date, issue date of the disciplinary action, type of action, speciality of the recipient physician and workplace centrality index number at the time of the medical error. The cause of the disciplinary action was not available due to privacy regulations. There were ten different types of physicians included in the dataset: 1) GPs in general practice, 2) GPs in emergency primary care clinics, 3) nursing home doctors, 4) private specialists, 5) medical interns, 6) junior hospital doctors, 7) senior hospital consultants, 8) company doctors, 9) other doctors and 10) licensed medical students.

Data analysis

Descriptive statistics were used to analyse the dataset. MBH performed frequency counts and cross-tabulation of variables to calculate annual frequency and distribution of disciplinary actions. We specified linear regression models (Y = a + bX) to analyse for significant trends in actions over time $(Y_i = actions in year i, X_i = year i, i =$ 1,...8). Rates of disciplinary actions were calculated per 1000 physicians. Comparative rate analysis was performed by basic division. Statistics Norway, the Norwegian Medical Association and the Norwegian Directorate of Health provided activity data and information on services. Geographical distribution of doctors was only available for GPs. Because of privacy considerations, involving suspension and revocation cases specialization licences (n = 4) were not further analysed. Furthermore, doctors disciplined outside Norway (n =110) were not analysed. We considered GPs in general practice, GPs working in emergency primary care clinics and nursing home doctors as representing primary care doctors, while junior hospital doctors and senior hospital consultants were grouped as secondary care doctors. The data were analysed using IBM SPSS Statistics 26 (IBM Corp. Statistics 26, SPSS Inc. 2019, USA).

Results

The NBHS provided a dataset of 953 disciplinary actions. Three of these (0.4%) lacked geographic location and were thus excluded from the analysis.

Annual frequency

Table 1 shows the annual and total frequencies of disciplinary actions for physicians by the NBHS in the study period. A total of 950 disciplinary actions were

Table 1 Disciplinary actions. Total and by reaction type. 2011–2018. Frequency and percent

	2011 n (%)	2012 n (%)	2013 n (%)	2014 n (%)	2015 n (%)	2016 n (%)	2017 n (%)	2018 n (%)	Total n (%)
Disciplinary action type	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)	(70)
Warning	59 (61)	71 (59)	64 (62)	54 (55)	99 (62)	62 (57)	58 (47)	78 (56)	545 (57)
Licence restricted	6 (6)	7 (6)	7 (7)	6 (6)	14 (9)	10 (9)	12 (10)	10 (7)	72 (8)
Loss of prescription right	7 (7)	12 (10)	7 (7)	6 (6)	8 (5)	7 (6)	7 (6)	7 (5)	61 (6)
Licence revoked	23 (24)	30 (25)	25 (24)	32 (33)	38 (24)	28 (26)	47 (38)	45 (32)	269 (28)
Suspension/loss of specialization approval	2 (2)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	4 (0)
Total	97 (100)	120 (100)	103 (100)	98 (100)	160 (100)	108 (100)	124 (100)	140 (100)	950 (100)

taken, and 57% of these were warnings, while 36% involved the revocation or restriction of a licence.

Trends

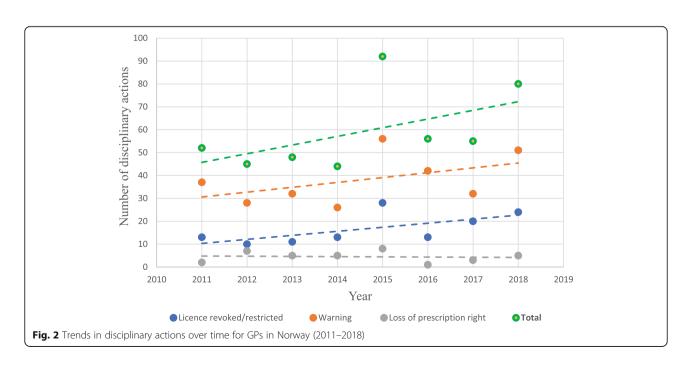
For GPs (Fig. 2) none of the linear regression models showed statistically significant time trends: total number of disciplinary actions (b = 2.58, p = .41), warnings (b = 1.07, p = .58), loss of prescription rights (b = -.18, p = .65), and revocation/restriction of licence (b = 1.7, p = .12). A similar analysis for secondary care doctors (Fig. 3) also revealed no significant time trends; total number of disciplinary actions (b = -0,49, p = .57), warnings (b = -.50, p = .36), loss of prescription rights (b = -.12, p = .68), and revocation/restriction of licence (b = .13, p = .68).

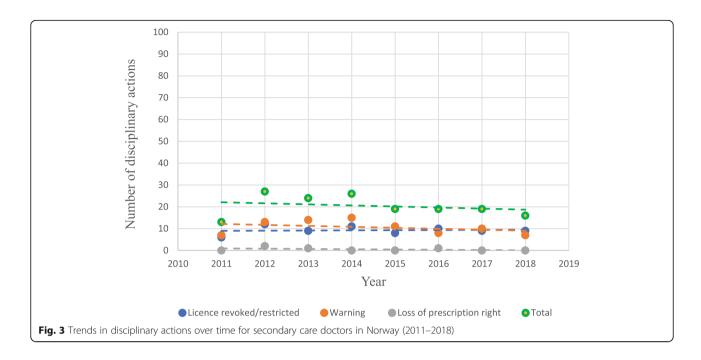
Total and geographical distribution

Table 2 presents the distribution of disciplinary actions given between 2011 and 2018 to different types of

doctors. The presentation only includes disciplinary actions originating from Norway. Primary care physicians were given 70% of all warnings, 79% of all losses of prescription rights and 57% of revocations/restrictions of licences. For secondary care physicians, the respective numbers were 16, 9 and 27%. Other categories of doctors accounted for 14, 11 and 16%, respectively.

Table 3 presents the total number of disciplinary actions by centrality of the GP's workplace municipality. Table 4 shows the rates of actions for the same GPs. Rural GPs received 1.7 times more disciplinary actions than their urban colleagues (148.9/88.4). For the most serious type of action, rural GPs had their licence revoked or restricted 2.1 times more frequently than GPs in urban areas (47.4/22.5). Regarding the type of disciplinary action linked to unprofessional handling of medication, urban GPs had 2.1 times more cases of loss of prescription rights than rural GPs (8.4/4.1).





Rates and organizational factors

Table 5 presents the rates of disciplinary actions per 1000 doctors among different categories of doctors. GPs received the most actions at 98.7 per 1000. A warning was given 2.4 times more frequently than revocation or restriction of the licence. GPs in general practice received 1.6 times more disciplinary actions than GPs

in emergency primary care clinics and 3.7 times more disciplinary actions than nursing home doctors. Private specialists received the second highest proportion of disciplinary actions, and the most actions per consultation. Private specialists were also the group with the highest proportion of doctors with a specialization degree.

Table 2 Disciplinary actions (in Norway) by type of action and doctor, 2011–2018

	Warning n (%)	Loss of prescription rights n (%)	Licence revoked or restricted n (%)	Suspension/revocation of specialization licence n (%)	Total n
Primary care doctors					
GPs in general practice	307 (57)	33 (77)	126 (49)	1 (25)	467
GPs in emergency clinics	58 (11)	0 (0)	16 (6)	0 (0)	74
Nursing home doctors	9 (2)	1 (2)	4 (2)	0 (0)	14
Secondary care doct	ors				
Junior doctors	16 (3)	1 (2)	19 (7)	0 (0)	36
Senior consultants	70 (13)	3 (7)	51 (20)	1 (25)	125
Other types of docto	rs				
Private specialists	59 (11)	4 (9)	26 (10)	0 (0)	89
Medical interns	5 (1)	1 (2)	2 (1)	0 (0)	8
Company doctors	0 (0)	0	0 (0)	1 (25)	1
Other doctors	11 (2)	0	13 (5)	1 (25)	25
Licensed medical students	0 (0)	0 (0)	1 (0)	0 (0)	1
Total n (%)	535 (100)	43 (100)	258 (100)	4 (100)	840 ^a

^a110 disciplinary actions occurred outside Norway

Table 3 Total numbers of disciplinary actions for GPs by type of action and centrality of workplace municipality, 2011–2018

a	Warning	Loss of prescription rights	Licence revoked or restricted	Total
Urban GPs	110	16	43	169
Semi-urban GPs	125	14	48	187
Rural GPs	72	3	35	111
Total	307	33	126	467

^aAverage number of GPs (2016–2018) split by centrality index https://www.ssb.no/statbank/table/12720/tableViewLayout1/

In hospitals, senior consultants received the most disciplinary actions. Per 1000 senior consultants, 17.0 received a disciplinary action. Junior doctors received 6.4 disciplinary actions per 1000 doctors, 2.7 times fewer than senior consultants.

The rate comparisons between primary and secondary care doctors revealed that primary care doctors received 8.0 times more disciplinary actions than secondary care doctors. Further, primary care doctors received a warning 10.6 times more often, had their licence revoked or restricted 4.6 times more often and lost their prescription rights 14.8 times more often than secondary care doctors. Rural GPs, the group with most disciplinary actions per 1000 physicians (148.9), received such actions 8.7 times more frequently than senior consultants and 23.3 times more frequently than junior doctors.

Discussion

In this study, we investigated the distribution and frequency of disciplinary actions given to physicians in Norway between 2011 and 2018. Our findings reveal considerable differences. One of the core findings in this study is that rural GPs had the highest rate of disciplinary actions among all physicians. Furthermore, GPs and private specialists had higher rates than other groups of physicians. Because a disciplinary action is a sign of medical malpractice and a possible indicator of problems related to patient safety, we will discuss our findings in the context of the research aims.

Organizational and systemic factors

According to our findings, physicians who work in small clinics or alone (GPs and private specialists) had

respectively 4.3 and 3.9 times higher rates of disciplinary actions than those working in large organizations (hospital doctors). This difference may partly be explained by the supervisory system of the NBHS. Based on its system-wide perspective of patient safety [6, 15, 16, 30– 32], the NBHS seeks to identify systemic causes as a primary goal when a medical error occurs [33]. The theory is that addressing a single systemic error will be more efficient in benefitting more future patients than reacting to a single medical error, thus enhancing health care services for the future. Many individuals are involved in health care in hospitals, while in general practice and private specialist clinics, much of the organization is de facto the physician. For example, an acutely ill patient arriving at hospital would interact with a large group of health care workers before diagnosis and treatment were initiated. If the same patient came to a GP clinic or a private specialist, he or she would interact with a health care secretary and one GP or one private specialist. Thus, clinical decisions and patient responsibility clearly vary between these two contexts. Despite providing very different types of health care, GPs and private specialists have almost identical frequencies of disciplinary actions. The apparent focus of the NBHS on system causality and the lack of system protection in primary care make GPs and private specialists more vulnerable to disciplinary actions.

More disciplinary actions for rural GPs

Comparing the GPs in our study, we found that rural GPs received 1.7 times more disciplinary actions than their urban counterparts. A Danish study reported no statistically significant association between litigation

Table 4 Rates of disciplinary actions per 1000 GPs by type of action and centrality of the workplace municipality, 2011–2018

a	Warning	Loss of prescription rights	Licence revoked or restricted	Total	No. of consultations per action ^b	Number of municipalities ^c
Urban GPs	57.5	8.4	22.5	88.4	2.9 * 10 ⁵	68
Semi-urban GPs	60.3	6.8	23.2	90.3	$2.6 * 10^5$	190
Rural GPs	97.4	4.1	47.4	148.9	1.2 * 10 ⁵	170

^aAverage number of GPs (2016–2018) split by centrality index https://www.s00sb.no/statbank/table/12720/tableViewLayout1/

^bTotal number of consultations (2011–2018) by GPs in each workplace municipality. Data provided on request by Statistics Norway

^cReport "New Centrality Index for Municipalities", Statistics Norway, 2017, ISBN 978-82-537-9627-7, Oslo

Table 5 Rates of disciplinary actions per 1000 doctors, and actions per 1 million consultations, by type of action and doctor. 2011–2018

	Disciplina	ary actions per 1	1000 doctors		Consultations		Demographics	
	Warning	Loss of prescription rights	Licence revoked or restricted	Total	Consultations per year ^{a-c}	Actions per 1 million consultations	Number of doctors ^{d-i}	Percentage of specialists
Primary care d	octors				15,681,763	4.42		49.1
GPs in general practice	65.0	7.0	26.7	98.7			4724	
GPs in emergency clinics	49.3	0.0	13.6	62.9			1175	
Nursing home doctors	16.9	1.9	7.5	26.3			533	
Secondary care	e doctors				11,026,425	1.82		
Junior doctors	2.8	0.2	3.4	6.4			5601	10.9
Senior consultants	9.6	0.4	7.0	17.0			7312	94.6
Other types of	doctors							
Private specialists	60.3	4.1	26.6	91.0	2,006,196	6.04	978	99.6
Medical interns	6.2	1.2	2.4	9.8			817	

^aAverage number (2016–2018) of consultations by GPs in general practice, GPs in emergency clinics and nursing home doctors (estimated using 4 contacts/bed/year) https://www.ssb.no/helse/statistikker/fastlegetj & https://www.ssb.no/statbank/table/10903/ & https://www.ssb.no/pleie/

figures and rurality [19], although Australian researchers found more patient complaints [20] in this context. Rural GP clinics face challenges in care provision in terms of accessibility, limited health care services, use of locums and issues related to vast distances and transportation [34, 35]. Rural patients have been found to report lower levels of relational continuity [35]. In a recent interview-based study on rural general practice patients, we found that patients were more willing to accept mistakes and errors by their regular GP than by locum GPs [36]. If we assume that continuity of care is an important quality indicator of health care [32], one hypothesis is that the use of locums or GPs on short-term contracts [37] results in more cases of medical malpractice in rural areas. Another possible explanation is that being located far from hospitals may affect rural GPs' clinical decisions [38]. Furthermore, rural GPs see, almost exclusively, all the acutely ill patients, whereas in urban areas, more specialists are available, and these patients can bypass GPs by being taken by ambulance directly to hospital. Many rural GPs work frequent shifts in emergency primary care units, possibly resulting in fatigue, sleep deprivation and cognitive overload, all of which are risk factors for committing errors [39].

Strengths and limitations

Using the NBHS national database for analysis, all disciplinary actions were processed equally and uniformly at a national centre, avoiding different types of selection or affective bias. The datasets from the NBHS and Statistics Norway were complete and trustworthy, providing the opportunity for a nationwide analysis and new knowledge.

^bAverage number (2016–2018) of contacts in somatic and psychiatric hospitals. https://statistikk.helsedirektoratet.no/bi/Dashboard/37f4e0dd-61fd-4846-a7c1-d87553ce2c1a?e=false&vo=viewonly

[&]amp; https://www.helsedirektoratet.no/rapporter/aktivitetsdata-for-psykisk-helsevern-for-voksne-og-tverrfaglig-spesialisert-rusbehandling

^cAverage number (2016–2018) of contacts for private specialists. https://www.helsedirektoratet.no/rapporter/aktivitetsdata-for-avtalespesialister

^dAverage number of GP contacts between 2016 and 2018. Source: https://www.ssb.no/statbank/table/12720/

^eFull-time equivalent GPs in emergency primary care centres. Report from National Register 2018, National Centre for Emergency Primary Health Care, Tone Morken, Norway

Average number of physicians employed in nursing homes and institutions in 2011 and 2013–2017. From the report "Physicians in primary and secondary care", 2018. IS-2789. OSLO: Norwegian Directorate of Health

⁹Average number of licensed specialists between 2011 and 2018. Source: https://www.ssb.no/statbank/table/03750

^hAverage number of working physicians < 70 years, 2011–2018. Source: physician statistics, Norwegian Medical

Association: https://legeforeningen.no/Emner/Andre-emner/Legestatistikk/Yrkesaktive-leger-i-Norge/Stillingsgrupper/

Average number of medical interns employed between 2013 and 2017. From the report "Physicians in primary and secondary care", 2018, IS-2789, OSLO: Norwegian Directorate of Health

The 950 disciplinary actions must, however, be interpreted in the context of approximately 230 million patient contacts that occurred between 2011 and 2018. Our findings do not represent all occurrences of medical malpractice in Norway. There is a possibility of selection bias, as some serious complaints could have been addressed by the local chief county medical officer instead of being forwarded to the NBHS [40]. In the present study, we addressed some external and system factors affecting disciplinary actions, keeping in mind a famous quote of Donabedian: 'Systems...are enabling mechanisms only. It is the ethical dimension of individuals that is essential to a system's success'.

Implications for practice

Our findings demonstrate the potentially vulnerable position of doctors working alone and in small clinics. The organizational and systemic factors designed to support doctors may be weak in some of the small rural clinics where the disciplinary actions were the most frequent. There seems to be an unexploited potential to improve patient safety by offering doctors in these clinics a stronger support system. There was a marked difference between primary and secondary care doctors in the rates of disciplinary actions given, indicating a higher degree of system protection in secondary care facilities.

Future research should analyse other types of data, and include case studies and in-depth qualitative studies to investigate why GPs, especially rural GPs, are more frequently disciplined.

Conclusions

There are clear differences in the distribution and frequency of disciplinary actions given by the NBHS to physicians working in different health care settings. Private specialists and GPs, especially those working in rural clinics, received the most disciplinary actions. These results warrant the attention of health care leaders responsible for ensuring patient safety. Hopefully they will be inspired to initiate further studies to identify the main factors influencing medical malpractice. The results of this study may also assist supervisory authorities in their quality assessments to determine whether their disciplinary system is efficient and adequate for all the different categories of physicians working in health care in Norway.

Abbreviations

GP: General practitioner; NBHS: The Norwegian Board of Health Supervision

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Authors' contributions

MBH, BA and PSS contributed to the conception of the article and the analysis and interpretation of the results. MBH, BA and PSS reviewed and critically revised the final version of the manuscript before MBH finalized and submitted the manuscript. The author(s) read and approved the final manuscript.

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Availability of data and materials

A de-identified dataset might be made available upon reasonable request of the authors. This will need approval by the NBHS and NSD to ensure anonymity and data protection.

Declarations

Ethics approval and consent to participate

The study was approved by and conducted according to the guidelines of the Norwegian Centre for Research Data (NSD), (project # 53124, approved 23.05.17), thus ensuring anonymity and data protection. The NBHS approved the use and analysis of the data (internal reference 2017/1033, approved 20.02.2017).

Consent for publication

Not applicable.

Competing interests

None declared.

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Qualitative Research

Rural general practice staff experiences of patient safety incidents and low quality of care in Norway: an interview study

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Abstract

Background and objectives: General practitioners (GPs), nurses and medical secretaries (practice staff) are responsible for the continuous provision of safe care in rural general practice. Little is known about their role in situations where patients were or could have been harmed in a rural setting. Therefore, we sought to investigate rural general practice staff experiences of patient safety incidents and low quality of care.

Methods: Descriptive qualitative interviews using the critical incident technique. Systematic text condensation analysis involving GPs and practice staff in eight rural municipalities in Norway.

Results: Sixteen participants (eight GPs, one nurse and seven medical secretaries) with mean work experience of 11.8 years were interviewed for a total of 11.5 hours. We identified three main factors that make rural GP clinics vulnerable to patient safety incidents and low quality of care: use of locums, work overload and rough weather and distance to hospital. There was a wide range of patient safety incidents. The healthcare personnel explained how they used local knowledge about people and context and greater awareness of risk of error in order to prevent these incidents from happening.

Conclusion: Rural GP clinics that suffer from frequent use of GP locums and work overload are vulnerable to patient safety incidents. Practice staff use various forms of continuity of care to prevent safety incidents from happening; this highlights the strengths but also some major safety concerns in these GP clinics. Staff at these clinics proved to be a resource for patient safety research. Podcast: An accompanying podcast on patient safety is available as Supplementary Data, in which

Martin Bruusgaardf Harbitz and Per Stensland provide insights into the context of this study.

Lay summary

When we go to see the doctor, we all want our diagnosis and treatment to be safe and free from mistakes. Unfortunately, patient harm and low quality of care happen every day in medical practice. This article looks at staff experiences of these mistakes; the staff were general practitioners, nurses and medical secretaries. We show how the use of locum doctors, work overload and long distance to hospital are linked to examples of patient harm. Our findings also show how nurses and medical secretaries may help to prevent harm to patients.

Key words: General practitioners, interview, medical secretaries, patient safety, primary health care, rural health

Key Messages

- Patient safety in rural general practice needs attention.
- · Qualitative interviews reveal troublesome issues.
- Frequent use of locums can impair patient safety in rural general practice.
- Irresponsible practice, lack of follow-up, low trust and low support were found.
- Nurses and secretaries can play an important role in promoting patient safety.

Background

Medical secretaries and nurses (practice staff) are often the first healthcare personnel that people meet when seeking medical help at a primary care facility. Up to 90% of all healthcare contacts in Western societies take place in general practice (1) where it is estimated that 2–3% of the consultations include an unintended incident that resulted or could have resulted in patient harm—a patient safety incident (2,3). The associated emotional and financial costs are substantial (4–6). In a Norwegian population study, patients blamed the general practitioner (GP) after having experienced a patient safety incident (7). However, the literature reveals little research on the role and experience of GPs and other staff in this area.

All registered inhabitants of Norway are entitled to be on a GP's list. Most of the treatment costs are covered by the state. In Norwegian GP clinics, authorized practice staff work together with the GPs. They support the GPs in clinical procedures and tests. The GPs are responsible for all the patients on their patient list; this is a systematic way of providing continuity of care, defined as the care of individuals over time. Continuity enhances GP knowledge about patients, which can increase patient trust and improve compliance (8). However, continuity varies across Norway. GPs' median length of work experience is 2.8 years in municipalities with a small population, while the figure increases threefold for municipalities with a large population (9). In small municipalities, GP continuity is affected by frequent use of locums [substitute GPs] (9). In 2014, there were 67 GP lists without a regular GP. Over 52% of the locums working on these lists were recruited by agencies and did not have a permanent address in Norway, and 75% of the locums worked in rural municipalities (10). Today the number of GP lists without a regular GP is 182 (11), which gives rise to more and more 'relays of locums' profiting from fee-for-service schemes and replacing the stable regular GPs (12). The municipalities are responsible for hiring qualified locums and the government requires GPs to specialize in family medicine in order to practice; this is, however, not a requirement for locum GPs (13). Rural GPs receive 69% more disciplinary actions than urban GPs (14). Little is known about patient safety threats in these clinics, which calls for research in the area (8,15,16). The purpose of this article is to investigate rural general practice staff experiences of patient safety incidents and low quality of care, using critical incident technique (CIT) interviews.

Methods

Contributors

We chose a descriptive qualitative approach for our study, based on interviews and notes (17). To enhance validity and relevance (18), we interviewed GPs and practice staff working in rural GP clinics. Due to the ongoing COVID-19 pandemic, we had to redesign our study from meetings in person to Skype interviews. In cases of communication breakdown on Skype, we continued interviewing over

the phone. M.B.H. and M.G. conducted the interviews and kept notes based on observations and reflections during interviews. All authors contributed to designing the study, analysing the material, interpreting and critically revising the manuscript. The interviews were digitally audiotaped and transcribed verbatim.

Recruitment and participants

To capture the most prominent and typical safety issues in rural municipalities with challenging distance to hospital, we performed purposive sampling of experienced rural primary healthcare workers. Eight district medical officers in Northern Norway were contacted in March 2020 about the study and they all confirmed participation. The district medical officers recruited local GPs and practice staff with permanent positions and considerable work experience, locums were excluded. Sixteen participants agreed to participate, one declined because he was not currently doing clinical work. All of the GP clinics were located in rural municipalities, according to Statistics Norway. The interviewees signed a document on study aims and rights.

Interview design and procedure

We chose to investigate clinicians' behaviour and experiences with patient safety incidents through the 'Critical Incident Technique' (CIT) (19). Since its original development (20), CIT has proven useful in addressing tacit knowledge and actual performance in incidents occurring in hospitals (21) and general practice (15). We judged patient safety incidents to be critical incidents. We asked participants to prepare to describe a specific event where a patient was, or could have been, harmed. See Table 1 for interview questions. We did not seek saturation, although after 16 interviews we concluded that the dataset was consistent with the study aim.

Data analysis

Systematic text condensation is a pragmatic method (22) using cross-case analysis to develop new descriptions and concepts of phenomena based on perspectives on how they are experienced (23). See Table 2 for the analytic process. Participants' statements were anonymized and assigned a random letter. We did not perform participant validation. The study followed the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist (24).

Results

Participants

Table 3 presents descriptive data about the interviews, the participants and the context.

Themes

The main themes and subthemes that constitute our findings are presented in Table 4. Table 5 presents quotations illustrative of the subthemes.

Table 1. Interview questions used in the critical incident technique, March 2020

Interview guide	Follow-up questions
'Can you tell me about the unsafe event	'How did the patient react? What were the
when you were unable to prevent harm	consequences?'
to the patient?'	'What was your emotional response?'
	'Were there any circumstances that may have made this event happen?'
'What were the professional and	'Have you had colleagues that you thought
personal characteristics of the doctor or	posed a risk to the patients' safety?'
other healthcare personnel in this event?'	'Can you describe what this risk consisted of?'
'What did the doctor or healthcare personnel do in this event?'	'Is this something you repeatedly practice?'
Did you do anything to prevent the	'What did you learn from the experience?
incident?'	'How did you talk about this event with your colleagues?'
'Are there any other typical situations	What patient safety responsibility do local
you find risky for patient safety?'	decision makers and administrative staff have?'

Table 2. The stepwise process of systematic text condensation

Steps in systematic text condensation (23)	Codes and themes
Step 1: Initially, all researchers read through all transcribed interviews and field notes, following the stepwise analysis process of systematic text condensation, starting with identifying preliminary themes.	1) risk characteristics, 2) medical errors, 3) actions to avoid harm, 4) coping with risk.
Step 2: Manually coding the interviews according to semantic content. This involved identifying meaning units associated with each theme, and temporarily removing parts of the text from their context (decontextualization) and sorting them into code groups.	
Step 3: By expressing the content of the meaning units across all participants under each code group we realized that our initial names of themes did not suitably cover our new code groups.	Tural vulnerability, Allible rural practice, Neeping rural practice safe.
Step 4: The fourth and final step involved reconceptualization of the data to make a synthesis of the condensates.	 vulnerability in rural practice, a wide range of patient safety incidents keeping the clinic safe.

Theme 1: vulnerability in rural general practice

Use of locums. All clinics mentioned the use of locums and frequent turnover of GPs as risk factors for errors and irresponsible practice. The participants described how locums appeared to feel less responsible for following up previous assessments and test results. Locums also lacked local knowledge and participants experienced language barriers.

GPs and practice staff found that patients had difficulty in understanding locums from other parts of Norway or from abroad. Participants described how many locums focused on short-termism and financial gain by seeing as many patients as possible. The use of locums and short-term GPs seemed to affect not only patient treatment but also the local healthcare system as a whole. Interviewees said clearly that the lack of stable personnel reduced healthcare quality by hindering the establishment of routines and making it difficult to correct errors that had occurred.

Work overload. The health workers, especially the GPs, found that a major challenge was the frequent shifts at emergency care units, resulting in fatigue, sleep deprivation and cognitive overload.

All participants agreed that this overload was due to staff shortages, and the lack of routines and a buffer in the system. The overload was often amplified when colleagues became ill or merely went on holiday. One GP even remembered being called back several times because the municipality unexpectedly had no doctor.

Practice staff explained how being alone at work led to challenges in priorities, such as leaving the phone ringing while treating a patient. However, the GPs spoke most about being alone and vulnerable when several patients arrived simultaneously.

Weather and distance to hospital. During the interviews we heard stories about roads to hospitals being closed due to avalanche risk and dangerous driving conditions. The local health service needed to provide pragmatic care in acute situations when neither aeroplanes nor rescue helicopters could land.

Theme 2: a wide range of patient safety incidents

The interviewees linked most of the wrong and harmful medical practice to the underlying conditions described in the section above. Participants from clinics with lower turnover and a tolerable workload reported fewer incidents. Examples of drug/alcohol abuse and psychiatric problems were reported in the material. For reasons of anonymity, we cannot describe the most extreme examples of malpractice.

Irresponsible care. Some clinics had used locum GPs for many years. Here, we heard stories about unprofessionally high prescription rates of opioids, anxiolytics and excessive sick notes. Several practice staff recalled locums or short-term GPs not taking patients' problems seriously. One example was a young GP intern who refused to take advice from his supervisor by not admitting a patient to hospital and asked other patients just to google if they had any medical

Table 3. Descriptive data of 16 rural GP staff who participated in the study, April 2020

	General practitioners	Nurses	Medical secretaries*	Total
Average clinical work experience	12.1 years		11.5 years	201 years
Number of participants	4 women	1 man	7 women	11 women
	4 men			5 men
Type of interview	Skype: 3	Skype: 1	Skype: 3	Skype: 7
	Phone: 5		Phone: 4	Phone: 9
Average interview duration	45.1 minutes	53 minutes	39.4 minutes	690 minutes
Average distance to hospital	By car on average 184 km	(98–272 km)		
	By boat: 42-65 nautical mi	les (depending on weat	her conditions)	
Average population size in 2020	2081 inhabitants			
Average GP clinic staff descriptions	Clinics: 1–6 GPs, 2–10 pracat the clinics.	ctice staff. There were n	o additional authorized health ca	are staff working

^{*} Norway averages 0.8 medical secretaries per GP. Data on nurses in general practice clinics not available.

Table 4. Themes and subthemes

Themes	Subthemes
Theme 1: Vulnerability in rural general	Use of locums
practice	Work overload
	Weather and distance to
	hospital
Theme 2: A wide range of patient	Irresponsible practice
safety incidents	Lack of follow-up
	Lack of trust and support
Theme 3: Keeping the clinic safe	Local knowledge
	Constantly watching out for
	errors

questions or problems. There were also stories about patients not being examined before receiving a diagnosis, or receiving incorrect medication, i.e. not according to Norwegian treatment guidelines, despite having a correct diagnosis.

Lack of follow-up, trust and support. Reading and handling medical lab results were situations frequently described as irresponsible. Practice staff could see if the doctor had read and taken action on lab results indicating illness. They told us of some locum GPs who deliberately seemed to choose not to deal with test results or refer patients to specialist care. The GP clinic staff mentioned colleagues and locums they felt they could not trust. They were by no means the majority but were linked to the clinics with greatest turnover. The study participants described how they felt a knot in their stomach in response to such situations.

Theme 3: keeping the clinic safe

While we heard many examples of malpractice, there were also many cases of practice staff trying to prevent such incidents. Using local knowledge and constantly watching out for errors were the two most prominent ways of trying to keep the clinics safe.

Local knowledge. There were stories of patients bypassing appointments with the locum GP just because the medical secretary thought another doctor was better able to treat their condition. Practice staff were crucial in this role since they had usually lived locally for many years. They were vividly portrayed as those with the best knowledge of the local community and skilled in treating common ailments according to Norwegian guidelines.

Constantly watching out for errors. The attitude of looking out for errors was mostly described by experienced practice staff usually

at clinics with frequent use of locums. We heard several stories about practice staff who had become accustomed to teaching the doctors what to do. Doctors who were judged unsafe or inexperienced needed supervision and sometimes correction to avoid patient safety incidents. The practice staff described how they watched and checked if procedures were followed correctly, if tests were ordered properly, and if the doctor read and acted upon test results. If not, they would not hesitate to intervene, like one medical secretary who stopped an inexperienced short-term GP from giving a patient a potentially lethal dose of insulin.

There were also some non-clinical situations worth noticing. One medical secretary called a locum's references to check his previous job performances, although the agency vouched for him. When she discovered that he had been repeatedly reported for making serious mistakes, she called the locum doctor agency and told them that this locum was unsatisfactory. He was referred back to the agency.

Discussion

Summary of findings

This study generated novel insight into patient safety incidents in rural GP clinics by combining experiences from different types of rural healthcare workers. The findings suggest that system factors like use of locums and work overload are risk factors for irresponsible care and medical errors.

A fragmented healthcare system

Our findings support the limited evidence that use of locums affects quality and safety of healthcare (25). Most locums in our material were described as good clinicians placed in healthcare organizations with low ability to combine locum work with systematic quality of care. Repeated use of locums creates a disintegrated service where doctors operate for a short time span. This leads to fragmented patient-doctor relationships where traditional relational continuity is difficult to accomplish, aligning with other recent findings in today's general practice (26). In rural areas with many seniors with complex and chronic conditions, this lack of continuity of care raises particular concern, being likely to increase the risk of patient safety incidents (27), decrease patient satisfaction (28) and even affect mortality (8).

Excessive workload as described here can cause fatigue and impaired psychomotor performance (29). Emotional exhaustion and sleep deprivation have also been demonstrated (30,31). Studies show how these factors predispose clinicians to poor cognitive performance

Table 5. Illustrative quotations

Theme and subtheme

Illustrative quotations

Theme 1 Use of locums Work overload

Weather and distance to hospital

'[The locums have] mainly been rushing through as many patients as possible to earn maximum money in minimum time, and then they leave. So chronic patients... have been very much left to themselves'. (G) 'So we discovered, I guess it was in 2016 or 2017, that several thousand patient notes (and test results) were incomplete and unsigned in our database' (X)

".. in comes a locum GP, who doesn't know the population, doesn't know the system, doesn't know the distance to the hospital, they don't know how things work. And when they treat the locals for a time, there are bound to be medical errors. They don't master the language if they're foreign doctors'. (G)

'One locum after another is damaging and expensive. But I don't mean that a locum GP is an inferior doctor; I reckon he or she may be a terrific doctor. But short-term workers make it difficult to establish a quality healthcare system built on routines and equal treatment for everyone. So not because of the locum GP personally, but because you can't create the environment necessary to combat adverse events and provide continuity and flow'. (L)

For my part, I've experienced being so tired at work after way too many consecutive shifts that... I don't think any adverse events happened, but I thought afterwards: hell, I was really exhausted then. But we're only two GPs so we work long periods of shifts split into two'. (B)

"...and the last of the three patients presented with sepsis, well then I'd simply had enough. Then the [blood-stained, but less] injured patient took too

much of my attention compared to the one with sepsis.

So they should have been sent to hospital in a different order'. (C)

'During the holiday I was called back, and then the municipality had had no doctor for two days. Ambulance staff had handled the

acute patients... then I had to work for many consecutive days as the only GP here.

You limit how many patients you see during the day so you can sleep because of sleepless nights. No one else could take the day shift because I was alone'. (B)

'We're always being told that distance to hospital shouldn't be part of our assessment. And in theory, that's all well and good. But distance as a factor in the medical assessment, does sadly play a bigger role than we'd like to acknowledge'. (N)

Theme 2 Irresponsible practice Lack of follow-up Lack of trust and support

'A patient with diabetes came to the clinic. And the short-term GP... was going to administer insulin to the patient. And if the patient had been given that dose,

I don't think he would have survived. The GP said he

didn't know how to give insulin'. (X)

'... (one foreign doctor) was supposed to be a gynaecologist, but when one of our colleagues here asked him... no he couldn't do gynaecological examinations. I felt very uneasy about him seeing how little knowledge and language skills he had'. (J)

'(the patient was supposed to be) referred to the hospital for an x-ray diagnosis, but in fact (the doctor) didn't do it. But the patient didn't know this, so she was waiting around at home for an appointment she never got...this created extra work for the other doctors'. (X)

'First of all, he (medical intern) wanted to give me the important advice never to trust anybody, especially not the colleagues that you think you can trust here. So that's a problem'. (K)

Theme 3
Constantly watching out for errors
Local knowledge

'I guess I learned what I've always said all these years, that you have to constantly watch them... Pay attention so that they (the doctors) do things right, and do what they're supposed to do'. (X) 'A man was calling, and X answered the phone. She'd

worked at the clinic for about 17–18 years... and the caller was around 50 and asked for a doctor's appointment, saying there was no rush. But X noticed he wasn't talking as he usually did and there was something strange about that. So she booked him

an appointment at the emergency clinic straightaway... and actually he'd had a stroke and was sent straight to hospital'. (F)

and bias behaviour (32). Work-related problems may thus lead to doctor turnover and discontinuity (33). Discontinuity or 'gaps in care' related to failures in communication and care coordination can cause distress and dysfunctional use of healthcare (16). In primary care, discontinuity limits quality initiatives (34) and may have organizational effects on patient safety. When key practitioners leave, they may take with them institutional memory and visions of quality development (34). From a theoretical perspective, the organization suffers by losing stored 'human capital', generating human resource costs (35). Depleting social capital by losing staff affects relations and shared trust within the organization (35). The workload challenges call for staff who are present over time, skilled leadership and

organization-directed interventions to systematically enable clinical improvements (4).

Safety support staff

In this study practice staff improved patient safety by providing contextual and experience-based knowledge to locums and GPs. This can be understood as supplying elements of continuity of care (36). Our findings show that by passing on patient information from one locum to the next, ensuring follow-up and providing information on patients' medical history, family and context, practice staff contribute to patient safety through organizational and informational continuity (36). However, we also presume that important parts of

professional and medical information about patients is inaccessible to practice staff.

A minority of the locums described in this study provided irresponsible and unsafe healthcare, and the practice staff acted here more as supervisors. Our study revealed examples of locums with a record of poor work in rural settings. Information on the quality of their previous performance had been readily available to the agencies. Attention should be paid to the information the municipalities receive from locum doctor agencies. To our knowledge, the Norwegian Board of Health Supervision has conducted no inspections of the activity of these agencies. We also question the profitability of the locum doctor markets, which affect the national regular GP scheme, patient-doctor relationships, continuity of quality care and patient safety.

Strengths and limitations

The strength of this study is primarily the sampling of GPs and practice staff. We included healthcare workers with over 200 years of combined working experience. Combined with incident-focused data, the material gave access to novel and real everyday safety concerns in rural GP clinics. We believe that the field of general practice tends to undervalue and overlook practice staff as a resource for patient safety work and for research. The interviews were conducted in the practice location where the patient safety incident had occurred. The exclusion of locums in our study may have precluded a maximum variation sample. We considered that the experiences of regular workers would highlight the most prominent and typical safety issues in rural general practice, which was the primary interest of the study. The use of locums as an important patient safety issue had, to our knowledge, not previously been highlighted in European patient safety research (37). We share our reflective analysis acknowledging that attention must be paid to the first author's preunderstanding in interviews and analysis (18), as he is a rural GP. We consider that his background and knowledge of the field were assets in communicating with the participants and for the scope of the study.

Using Skype could perhaps limit interview richness. However, the CIT approach elicits stories rooted in real incidents, and we heard personal and sensitive stories. Interviews were conducted at the local workplace, in small rural communities where 'everybody knows everybody'. The sensitive topics could make participants experience barriers in reporting some incidents (38). Therefore, participants might have found it easier to discuss safety concerns regarding temporary staff rather than themselves or their co-workers. Nevertheless, five of the 16 interviewees did actually disclose their own personal error incidents.

The data were gathered from rural municipalities. In Norway, however, more than 50% of municipalities are equally rural. Findings from a retrospective study in 2016 showed that 29% of GPs equally distributed in Norway used a locum GP in their practices (10). This number has probably increased. We believe this indicates rural generalizability of our findings and warrants national attention to the patient safety issues presented here.

Implications for practice

We are worried about patient safety in rural GP clinics with frequent use of locums and work overload. There is an unexploited potential to improve patient safety by offering these clinics a stronger support system and creating new organizational structures that deliver safer care (26,39) The need to recruit and retain skilled healthcare staff is evident (40). Follow-up studies of locums and patient safety seem necessary and important.

Conclusion

GPs and practice staff experienced patient safety incidents at rural GP clinics. The incidents revealed in this study were diverse. Frequent use of locum GPs and work overload were risk factors for patient safety incidents. Practice staff used various forms of continuity of care to provide patient safety, highlighting strengths but also some major safety concerns in these clinics. Attention is required from local and national healthcare leaders to address patient safety in general practice, especially the consequences of poor continuity and locum profitability. There is a call for further research to understand patient safety challenges in this setting.

Supplementary material

Supplementary material is available at Family Practice online.

Declaration

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Ethical approval: The study was approved by the Regional Committee for Medical and Health Research Ethics (2016/2314 REK Nord) and conducted according to the guidelines of the Norwegian Centre for Research Data (project #201373), assuring anonymity and data protection.

Competing interests: The authors declare no competing interests.

Patient consent for publication: Not required.

Data availability: Data are available upon reasonable request.

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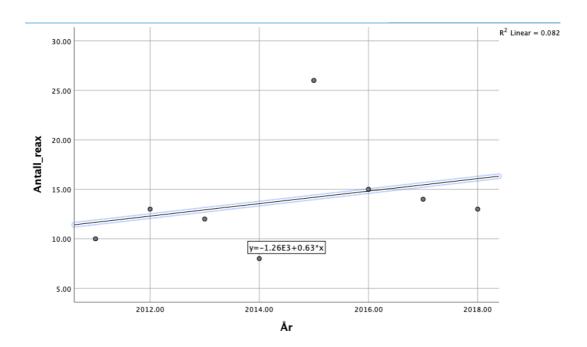
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Appendix

Trend analysis for Paper II

The linear regression model for rural GPs (centrality index 5-6) showed no statistically significant time trends: total number of disciplinary actions b=0.63, p=0.49. Warning b=0.26, p=0.59. Loss of prescription right b=-0.08, p=0.33. License revoked or restricted b=0.45, p=0.37.



Coefficientsa Standardized 95.0% Confidence Interval for Coefficients **Unstandardized Coefficients** В Std. Error Beta Sig. Lower Bound **Upper Bound** Model (Constant) -1257.179 1731.428 -.726 .495 -5493.829 2979.472 .859 .734 År .631 .287 .491 -1.472 2.734

a. Dependent Variable: Antall_reax

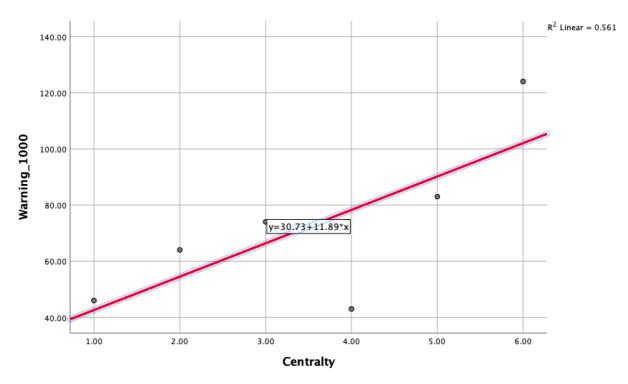
The p-value >0.05 means that the relationship between time and number of actions in statistical terms could well be coincidental. $Y = -1.26 * 10^3 x \ 0.63 X$. Time being the X, the explanatory factor of Y (number of actions). X cannot significantly predict Y; therefore we

must assume that the future development of disciplinary actions for rural GPs will be status quo.

Linear regression models of centrality and reactions per 1000 GPs.

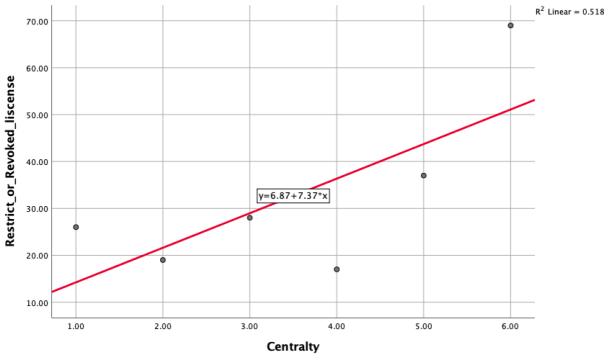
These trend lines show no statistically significant correlation. However, the correlations are strong: R = 0.72 - 0.75, and the p-value is low for warnings and restricted/revoked licence. Measurements over a longer period could give significant results.

Warnings per 1000 GPs by centrality

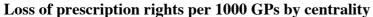


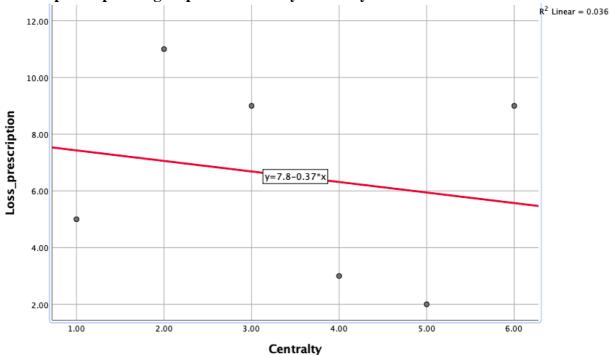
$$B = 11.9, R = 0.75, R2 = 0.56, p = 0.09$$

Restricted or revoked licence per 1000 GPs by centrality



B = 7.4, R = 0.72, R2 = 0.52, p = 0.10





 $B = -0.4,\, R = 0.19,\, R2 = 0.04,\, p = 0.72$

When actions per 1000 rural GPs by centrality were examined, no statistical linear correlation was found. For the actions "warning" and restricted/revoked licence, there seems to be an association between disciplinary actions and rurality (R>0.7 and p \leq 0.10 for both actions).

Lack of significance in the statistical analysis can probably be explained by the low number of actions in the dataset (n=111). This leads to the question of why there is an association between rurality and some disciplinary actions. What is it about rural GP clinics, the system, the staff, or the patients that influences this potential relationship?

Interview guide Paper I

Interview guide used for all 20 interviews held in three counties in northern Norway, January-April 2017:

- Tell me what it's like to be a patient in this municipality?
- Tell me, in as much detail as you wish, about your local GP service.
- What expectations do you have of your GP?
- What aspect of health care is most important to you?
- Tell me about your encounters with medical secretaries.
- When you become ill, do you receive health care that makes you feel safe? Please explain.
- Have you experienced adverse treatment in primary health care? If so, how does that affect you today?
- What does the term "patient safety" mean to you?
- Who are the "safe" care personnel, in your opinion? Who are the ones who are "unsafe"?
- Is there anything in particular that you're truly satisfied with regarding the local health care service?

Questions regarding context:

- What do people say about this GP clinic?
- Is this a safe community?
- Have you seen any stories about this GP service in the local media or in the press?
- If you were in charge of the local health care service, with all the money you would need, what would you do to increase the safety of patient treatment here?

 Supplementary material BMJ Open

Harbitz MB, et al. BMJ Open 2019; 9:e031343. doi: 10.1136/bmjopen-2019-031343

Interview guide, Paper III	Follow-up questions
'Can you tell me about the unsafe event when you were unable to prevent harm to the patient?'	'How did the patient react? What were the consequences?' 'What was your emotional reaction?' 'Were there any circumstances that may have made this event happen?'
'What were the professional and personal characteristics of the doctor or other healthcare personnel in this event?'	'Have you had colleagues that you thought posed a risk to patients' safety?' 'Can you describe what this risk consisted of?'
'What did the doctor or healthcare personnel do in this event?'	'Is this something you repeatedly practice?'
'Did you do anything to prevent the incident?'	'What did you learn from the experience? 'How did you talk about this event with your colleagues?'
'Are there any other typical situations you find risky for patient safety?'	'What responsibility for patient safety do local decision makers and administrative staff have?'



Region: REK nord Sakshehandler:

Telefon:

Vår dato: 23.01.2017

Vår referanse: 2016/2314/REK nord Deres referanse:

Deres dato: 06.12.2016

Vår referanse må oppgis ved alle henvendelser

Martin Harbitz Institutt for samfunnsmedisin

2016/2314 Er det trygt å bli syk i Distrikts-Norge?

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK nord) i møtet 05.01.2017. Vurderingener gjort med hjemmel i helseforskningsloven § 10, jf. forskningsetikkloven § 4.

Forskningsansvarlig: UiT - Norges arktiske universitet

Prosjektleder: Martin Harbitz

Prosjektomtale (original):

Forskningen vil bidra med ny og økt forståelse av pasientsikkerhet i primærhelsetjenesten. Primærhelsetjenesten, da særlig i Distrikts-Norge er en lite prioritert forskningsarene, med dertil økt behov for kunnskap. Dette studiet inngår i et doktorgradsprosjekt hvor formålet med forskningen er å undersøke og kategorisere pasientsikkerhet i Distrikts-Norge ved å kombinere ulike perspektiver. Vi planlegger å brukesekvensiell utforskende mixed-method design, med ett litteraturstudie, to intervju-studier og ett forklarende studie på data fra Helsetilsynet.

Vurdering framleggingsplikt

De prosjektene som skal framlegges for REK er prosjekt som dreier seg om "medisinsk og helsefaglig forskning på mennesker, humant biologisk materiale eller helseopplysninger", jf. helseforskningsloven (h) §

2. "Medisinsk og helsefaglig forskning" er i h § 4 a) definert som "virksomhet som utføres med vitenskapelig metodikk for å skaffe til veie ny kunnskap om helse og sykdom". Det er altså formålet medstudien som avgjør om et prosjekt skal anses som

framleggelsespliktig for REK eller ikke.

Selv om dette er en helsefaglig studie og funnene i studien indirekte vil kunne gi en helsemessig gevinst faller ikke prosjektet inn under definisjonen av de prosjekt som skal vurderes etter helseforskningsloven. Iht.informasjonen som framkommer i søknaden vurderes studien til å være rettet mot selve helsetjenesten, heravpasientsikkerheten i primærhelsetjenesten som tilbys til befolkningen i distrikts-Norge.

Godkjenning fra andre instanser

Det påhviler prosjektleder å undersøke hvilke eventuelle godkjenninger som er nødvendige fra eksempelvispersonvernombudet ved den aktuelle institusjon eller Norsk senter for forskningsdata (NSD).

Vedtak

Etter søknaden fremstår prosjektet ikke som et medisinsk og helsefaglig forskningsprosjekt som fallerinnenfor helseforskningsloven. Prosjektet er ikke framleggingspliktig, jf. hfl § 2.

Besøksadresse: MH-bygget UiT Norges arktiske universitet 9037 Tromsø Telefon: 77646140 E-post: rek-nord@asp.uit.no Web: http://helseforskning.etikkom.no/

Klageadgang

Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK nord. Klagefristener tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK nord, sendes klagen videre tilDen nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

May Britt Rossvoll Sekretariatsleder

Kopi til:martin.b.harbitz@uit.no



Martin Harbitz

Institutt for samfunnsmedisin UiT Norges arktiske universitet

9037 TROMSØ

Vår dato: 21.03.2017 Vår ref: 52557 / 3 / HIT Deres dato: Deres ref:

TILBAKEMELDING PÅ MELDING OM BEHANDLING AV PERSONOPPLYSNINGER (artikkel 1)

Vi viser til melding om behandling av personopplysninger, mottatt 27.01.2017. All nødvendig informasjon om prosjektet forelå i sin helhet 20.03.2017. Meldingen gjelder prosjektet:

52557 Er det trygt å bli syk i Distrikts-Norge? UiT Norges arktiske universitet, ved *Behandlingsansvarlig* institusjonens øverste lederDaglig ansvarlig Martin Harbitz

Personvernombudet har vurdert prosjektet, og finner at behandlingen av personopplysninger vil væreregulert av § 7-27 i personopplysningsforskriften. Personvernombudet tilrår at prosjektet gjennomføres.

Personvernombudets tilråding forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, ombudets kommentarer samt personopplysningsloven og helseregisterloven med forskrifter. Behandlingen av personopplysningerkan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via eteget skjema, http://www.nsd.uib.no/personvern/meldeplikt/skjema.html. Det skal også gis meldingetter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, http://pvo.nsd.no/prosjekt.

Personvernombudet vil ved prosjektets avslutning, 07.01.2020, rette en henvendelse angåendestatus for behandlingen av personopplysninger.

Vennlig hilsen

Kjersti Haugstvedt

Hildur Thorarensen

Kontaktperson: Hildur Thorarensen tlf: 55 58 26 54Vedlegg: Prosjektvurdering

Dokumentet er elektronisk produsert og godkjent ved NSDs rutiner for elektronisk godkjenning.

NSD – Norsk senter for forskningsdata AS

Harald Hårfagres gate 29 NSD – Norwegian Centre for Research Data NO-5007 Bergen, NORWAY Faks: +47-55 58 96 50

Tel: +47-55 58 21 17

nsd@nsd.no www.nsd.no Org.nr. 985 321 884

Formålet er å undersøke og kategorisere pasientsikkerhet i Distrikts-Norge ved å kombinere ulike

perspektiver.Utvalget vil bli rekruttert via sekretær på legekontor, jf. epost fra prosjektleder 20.3.17.

Utvalget informeres skriftlig og muntlig om prosjektet og samtykker til deltakelse. Informasjonsskrivet er godtutformet, såfremt endringer diskutert på epost 20.3.2017 utføres.

Det behandles sensitive personopplysninger om helseforhold.

Personvernombudet legger til grunn at forsker etterfølger UiT Norges arktiske universitet sine interne rutiner fordatasikkerhet.

Forventet prosjektslutt er 07.01.2020. Ifølge prosjektmeldingen skal innsamlede opplysninger da anonymiseres. Anonymisering innebærer å bearbeide datamaterialet slik at ingen enkeltpersoner kan gjenkjennes. Det gjøres ved å:

- slette direkte personopplysninger (som navn/koblingsnøkkel)
- slette/omskrive indirekte personopplysninger (identifiserende sammenstilling av bakgrunnsopplysninger somf.eks. bosted/arbeidssted, alder og kjønn)



Martin Harbitz
Institutt for samfunnsmedisin UiT Norges arktiske universitet

9037 TROMSØ

 Vår dato: 23.05.2017
 Vår ref: 53124 / 3 / AGH
 Deres dato:
 Deres ref:

TILBAKEMELDING PÅ MELDING OM BEHANDLING AV PERSONOPPLYSNINGER (artikkel 2)

Vi viser til melding om behandling av personopplysninger, mottatt 20.02.2017. Meldingen gjelderprosjektet:

53124 Administrative reaksjoner mot leger i perioden 2011-2015 Behandlingsansvarlig UiT Norges arktiske universitet, ved institusjonens øverste lederDaglig ansvarlig Martin Harbitz

Personvernombudet har vurdert prosjektet, og finner at behandlingen av personopplysninger vil væreregulert av § 7-27 i personopplysningsforskriften. Personvernombudet tilrår at prosjektet gjennomføres.

Personvernombudets tilråding forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, ombudets kommentarer samt personopplysningsloven og helseregisterloven med forskrifter. Behandlingen av personopplysningerkan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via et eget skjema, http://www.nsd.uib.no/personvernombud/meld_prosjekt/meld_endringer.html. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database,http://pvo.nsd.no/prosjekt.

Personvernombudet vil ved prosjektets avslutning, 01.02.2018, rette en henvendelse angåendestatus for behandlingen av personopplysninger.

Vennlig hilsen

Kontaktperson: Agnete Hessevik

1 FORMÅL

Prosjektet er en deskriptiv retrospektiv studie som skal beskrive populasjonen administrative reaksjoner gitt fraHelsetilsynet til leger i Norge over en 5 års periode. Prosjektet ønsker å beskrive variasjon i reaksjonstype fra Helsetilsynet, variasjon i legetype (fastlege/sykehuslege) og variasjon i geografisk utbredelse.

2 UTVALG

Utvalget er leger i Norge som har mottatt administrativ reaksjon fra Helsetilsynet grunnet pliktbrudd.

3 DATAMATERIALETS INNHOLD

Datasettet består av 579 administrative reaksjoner gitt til leger i årene 2011-2015. Opplysningene utleveres fraHelsetilsynet, som har godkjent utlevering av opplysningene til forskningsprosjektet.

Ifølge variabellisten mottatt 22.04.2017 vil datamaterialet inneholde følgende opplysninger:

- type reaksjon (advarsel, tilbakekall av autorisasjon/lisens, begrenset autorisasjon/lisens, tap av rekvireringsretthelt eller delvis, tilbakekall av spesialistgodkjenning, suspensjon på ubestemt tid)
- årstall for vedtak
- type lege (allmennpraksis, sykehus, privat praksis, legevakt)
- kommunens sentralitet (etter SSB sin sentralitetsindeks, grad 0-3)

Helsetilsynet har oppgitt at de ikke har anledning til å tilpasse datasettet. Helsetilsynet vil derfor utlevere navnpå virksomheten for legene som har mottatt reaksjon. Forsker vil så gjøre om denne variabelen til kommunenssentralitet etter SSB sin sentralitetsindeks.

Personvernombudet vurderer at datamaterialet slik det utleveres vil være indirekte identifiserbart. Etter at navn på virksomhet er erstattet med kommunens sentralitet, må forsker gjøre en vurdering av om datamaterialet da eranonymt, eller om det er indirekte identifiserbart basert på variablene.

Personvernombudet forutsetter at opplysningene som utleveres ikke er taushetsbelagte.

Personvernombudet tar høyde for at opplysningene kan anses for å være sensitive personopplysninger etterpersonopplysningsloven § 2 nr. 8 b).

4 PERSONVERNOMBUDETS VURDERING

Personvernombudet finner at opplysningene kan behandles med hjemmel i personopplysningsloven §§ 8 d) og 9h). Vi finner også at forsker kan fritas fra sin informasjonsplikt med hjemmel i personopplysningsloven § 20 b). Personvernombudet har gjort en vurdering av om samfunnsnytten klart overstiger personvernulempen for de

registrerte i dette prosjektet. Samfunnsnytten ved å skaffe kunnskap om tilsynssakers distribusjon i landet anses som høyere enn ulempen det medfører for utvalget. Forsker vil kun få utlevert navn på virksomhet, og man kan ikke ut fra disse opplysningene i seg selv kunne si hvilken lege i den aktuelle virksomheten som reaksjonen gjelder. Forsker får ikke tilgang til direkte identifiserende opplysninger, slik at å gi individuell informasjon anses som umulig eller uforholdsmessig vanskelig. Videre skal det kun behandles identifiserende opplysninger ien kort periode, og ingen enkeltpersoner skal kunne gjenkjennes i publikasjoner.

5 PROSJEKTSLUTT

Forventet prosjektslutt er 01.02.2018. Ifølge prosjektmeldingen skal innsamlede opplysninger da anonymiseres. Anonymisering innebærer å bearbeide datamaterialet slik at ingen enkeltpersoner kan gjenkjennes. Det gjøres ved å slette/grovkategorisere indirekte identifiserende opplysninger/variable



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9037 TROMSØ

Vår dato: 28.04.20 Vår ref: 201373

VURDERING (artikkel 3)

Prosjekttittel

Pasientsikkerhet på legekontor i distriktskommuner

Behandlingsansvarlig institusjon

UiT Norges Arktiske Universitet / Det helsevitenskapelige fakultet / Institutt for samfunnsmedisin

Prosjektansvarlig (vitenskapelig ansatt/veileder eller stipendiat)

Martin Bruusgaard Harbitz, martin.b.harbitz@uit.no, tlf: 95152496

Type prosjekt

Forskerprosjekt

Prosjektperiode

20.03.2020 - 31.12.2020

28.04.2020 - Vurdert

Det er vår vurdering at behandlingen av personopplysninger i prosjektet vil være i samsvar med personvernlovgivningen så fremt den gjennomføres i tråd med det som er dokumentert i meldeskjemaet den 28.04.2020 med vedlegg, samt i meldingsdialogen mellom innmelder og NSD. Behandlingen kan starte. MELD

VESENTLIGE ENDRINGER Dersom det skjer vesentlige endringer i behandlingen av personopplysninger, kan det være nødvendig å melde dette til NSD ved å oppdatere meldeskjemaet. Før du melder inn en endring, oppfordrer vi deg til å lese om hvilke type endringer det er nødvendig å melde:

https://nsd.no/personvernombud/meld_prosjekt/meld_endringer.html Du må vente på svar fra NSD før endringen gjennomføres.

TYPE OPPLYSNINGER OG VARIGHET Prosjektet vil behandle alminnelige kategorier av personopplysninger frem til 31.12.2020.

LOVLIG GRUNNLAG Prosjektet vil innhente samtykke fra de registrerte til behandlingen av personopplysninger. Vår vurdering er at prosjektet legger opp til et samtykke i samsvar med kravene i art. 4 og 7, ved at det er en frivillig, spesifikk, informert og utvetydig bekreftelse som kan dokumenteres, og som den registrerte kan trekke tilbake. Lovlig grunnlag for behandlingen vil dermed være den registrertes samtykke, jf. personvernforordningen art. 6 nr. 1 bokstav a.

TAUSHETPLIKT Vi minner om at informantene har taushetsplikt, og at de ikke kan gi opplysninger som kan identifisere en enkeltpasient direkte eller indirekte, med mindre det blir innhentet samtykke fra den enkelte til dette. Det er svært viktig at intervjuene gjennomføres på en slik måte at taushetsplikten overholdes. Intervjuer og informanter har sammen ansvar for dette, og bør innledningsvis i intervjuene drøfte hvordan dette skal håndteres.

PERSONVERNPRINSIPPER NSD vurderer at den planlagte behandlingen av personopplysninger vil følge prinsippene i personvernforordningen om: - lovlighet, rettferdighet og åpenhet (art. 5.1 a), ved at de registrerte får tilfredsstillende informasjon om og samtykker til behandlingen - formålsbegrensning (art. 5.1 b), ved at personopplysninger samles inn for spesifikke, uttrykkelig angitte og berettigede formål, og ikke viderebehandles til nye uforenlige formål - dataminimering (art. 5.1 c), ved at det kun behandles opplysninger som er adekvate, relevante og nødvendige for formålet med prosjektet - lagringsbegrensning (art. 5.1 e), ved at personopplysningene ikke lagres lengre enn nødvendig for å oppfylle formålet DE

REGISTRERTES RETTIGHETER Så lenge de registrerte kan identifiseres i datamaterialet vil de ha følgende rettigheter: åpenhet (art. 12), informasjon (art. 13), innsyn (art. 15), retting (art. 16), sletting (art. 17), begrensning (art. 18), underretning (art. 19), dataportabilitet (art. 20). NSD vurderer at informasjonen som de registrerte vil motta oppfyller lovens krav til form og innhold, jf. art. 12.1 og art. 13. Vi minner om at hvis en registrert tar kontakt om sine rettigheter, har behandlingsansvarlig institusjon plikt til å svare innen en måned. FØLG DIN INSTITUSJONS RETNINGSLINJER NSD legger til grunn at behandlingen oppfyller kravene i personvernforordningen om riktighet (art. 5.1 d), integritet og konfidensialitet (art. 5.1. f) og sikkerhet (art. 32). UiT har databehandleravtale med Office og Skype som vil benyttes som databehandlere i prosjektet. For å forsikre dere om at kravene oppfylles, må dere følge interne retningslinjer og eventuelt rådføre dere med behandlingsansvarlig institusjon.

OPPFØLGING AV PROSJEKTET NSD vil følge opp ved planlagt avslutning for å avklare om behandlingen av personopplysningene er avsluttet. Lykke til med prosjektet! Kontaktperson hos NSD: Eva J. B. Payne Tlf. Personverntjenester: 55 58 21 17.

