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Utfordringer ved bruk av kliniske retningslinjer i allmennpraksis

En kvantitativ studie av en retningslinje for oppfølging etter innsetting av ventilasjonsrør i trommehinnen, og en kvalitativ studie av allmennlegers erfaringer med kliniske retningslinjer

Kliniske retningslinjer har en sentral plass i medisinen. 'God praksis' i dag baserer seg i økende grad på forskning og Evidence-Based Medicine (EBM), og utvikling av anbefalinger basert på EBM prioriteres i mange land. Likevel er det velkjent at mange retningslinjer brukes i liten grad i allmennpraksis, og årsakene til dette virker sammensatte.

Innsetting av ventilasjonsrør i trommehinnen er en av de vanligste operasjonene utført på barn i Norge, og utføres hovedsakelig på grunn av langvarig væske i mellomøret. Oppfølgingen etter operasjon har tidligere stort sett vært utført av øre-nese-hals leger. St Olavs Hospital endret sin retningslinje for oppfølging for noen år siden, noe som innebar at kontrollene av de friskeste barna skulle utføres av fastlegen. Dette var kontroversiell da det ble innført. Denne retningslinjen, og mange andre, er tilgjengelige i allmennpraksis. Lite forskning har fokusert på utfordringer ved anvendelse av den totale mengden med retningslinjer som forventes brukt i allmennpraksis.

Denne doktoravhandlingen består av to studier med til sammen fire artikler som belyser bruken av retningslinjer i allmennpraksis fra ulike perspektiver. I den første studien belyses implementeringen av én retningslinje, mens i den andre belyses allmennlegers erfaringer med bruk av retningslinjer generelt.

Studie 1 var en kvantitativ, retrospektiv studie av barn under 18 år som hadde fått innsatt dren i trommehinnen. To år etter operasjon ble hørselstester utført og et spørreskjema utfylt. I artikkel I studerte vi *prosessen* rundt implementeringen av den nye retningslinjen på sykehuset og i allmennpraksis. I artikkel II studerte vi om retningslinjen førte til endret *utkomme* for barna, det vil si om det var noe endring i hørsel eller andre audiologiske variabler. Vi fant at sykehuset fulgte retningslinjen de selv hadde utviklet i cirka to tredeler av tilfellene. Mange av barna ble derimot ikke fulgt opp på det stedet de var tiltenkt. Implementeringsstrategien overfor allmennlegene virket utilstrekkelig da den ikke ble

gjentatt. Likevel oppsøkte alle barna unntatt én fastlegen for kontroll selv om barna ikke ble innkalt. Vi fant ingen forskjell i hørsel eller andre audiologiske variabler blant barna som ble fulgt opp av fastlege sammenlignet med barna som ble fulgt opp av øre-nese-hals lege.

Studie 2 var en kvalitativ, fokusgruppestudie med et utvalg på 25 allmennleger i Midt-Norge. Både erfarne og mindre erfarne leger deltok. I artikkel III utforsket vi legenes erfaringer med og refleksjoner omkring *bruk* av kliniske retningslinjer i sin daglige praksis. Artikkel IV utforsket hvilke *konsekvenser* kliniske retningslinjer generelt har for allmennpraksis, både for pasientene og for legene. Vi fant at allmennlegene mente retningslinjene var nødvendige. Likevel hadde de vanskelig for å bruke dem fordi retningslinjene var for mange, for omfattende og for lite tilgjengelige, dessuten mente de at retningslinjene passet dårlig til deres pasienter. Mens fokuset i retningslinjene ofte er på behandling og oppfølging av enkeltsykdommer, sa allmennlegene at de fokuserte mer på hele pasienten. Dette ble spesielt problematisk i møte med multisyke pasienter, som potensielt ville kreve anvendelse av en rekke retningslinjer samtidig på samme pasient. Presset til å følge mange retningslinjer gav flere negative konsekvenser for allmennlegene, deriblant usikkerhet på egen praksis, og tendens til defensiv medisin. Allmennlegene angav også negative konsekvenser for deres pasienter i form av økt risiko for overbehandling og polyfarmasi, samt av og til reduksjon i livskvalitet.

Samlet sett viser studiene flere utfordringer med anvendelse av kliniske retningslinjer i allmennpraksis. Selv den helt enkle retningslinjen etter innsettelse av ventilasjonsrør viste seg kompleks å implementere. Studien var for liten til å kunne gi et sikkert svar på hvilket nivå i helsetjenesten som bør ta oppfølgingskontrollene etter operasjon med ventilasjonsrør i trommehinnen. Allmennlegene gav gode grunner for å ikke følge retningslinjene selv om de opplevde dem nødvendige. Det at de ikke passet til pasientene og kunne gi negative konsekvenser for mange av pasientene, særlig multisyke, ser ut til å være de viktigste grunnene. Disse funnene utfordrer ideen om at 'god praksis' i allmennpraksis hovedsakelig er synonymt med å følge retningslinjer for enkelt-sykdommer.

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Abstract

Background

Clinical guidelines are important in medicine. Quality of care is increasingly based on research and EBM, and developing recommendations based on EBM is prioritized in many countries. Still, it is well known that adherence to guidelines in general practice is low, and, apparently, the reasons for this are complex.

Insertion of ventilation tubes (VTs) in the tympanic membrane is one of the most common ambulatory surgeries performed on children in Norway. It is most often performed because of otitis media with effusion. Previously, all children had their follow-ups performed by otolaryngologists. The University Hospital in Mid-Norway modified their guideline for follow-ups after surgery so that the controls of the healthiest children were to be conducted by general practitioners (GPs). The guideline was controversial when it was introduced.

This guideline is one of many that GPs are expected to apply. While the term 'guideline' has long referred to recommendations that are not necessarily based on a systematic appraisal of the evidence, the term 'Clinical Practice Guidelines' (CPGs) is now to be used only when such systematic appraisals are included (see 1.2.1). However, a very limited amount of research has been done regarding the challenges presented by the total number of guidelines and CPGs that are to be adhered to in general practice.

Aims

The aim of this project was to study the challenges associated with implementation and adherence to clinical guidelines in general practice. More specifically:

- To evaluate the process (Paper I) and patient outcome (Paper II) after implementation of a new guideline concerning follow-ups after inserting VTs in the tympanic membranes of children.
- To explore GPs' experiences with and reflections upon the use of multiple guidelines and CPGs in their daily work (Paper III), and the consequences that applying them may have for general practice (Paper IV).

Material and methods

Study 1 was a retrospective, quantitative, observational study performed at Trondheim University Hospital and in my general practice, both of which are in Mid-Norway. Children under the age of 18 who had undergone an insertion of a VT between Nov. 1, 2007, and Dec. 31, 2008, (n = 136) were included. Two years after surgery, audiological tests were performed and a self-report questionnaire was assessed.

Study 2 was a qualitative, focus group study carried out in Mid-Norway. The study involved 25 Norwegian GPs from four pre-existing groups. The GPs' work histories varied from being recent graduates to having up to 35 years of experience. Interviews were audio-recorded, transcribed and analyzed using systematic text condensation, i.e. applying a phenomenological approach.

Results

In Study 1, we found that, despite multifaceted methods to implement the VT-guideline at the hospital, there was a discrepancy between the guideline and the otolaryngologists' decisions regarding scheduling of follow-up examinations. There was a greater discrepancy between the planned location for the follow-ups and where the patients' checkups were actually performed. The implementation process was apparently inadequate for the GPs as the information was not repeated. Nevertheless, the guideline seemed to secure that post-operative controls would be conducted within general practice. Implementation of the new VT-guideline, in which GPs had responsibility for the follow-up controls of a group of the children, did not negatively affect either the audiological outcomes or the number of subjective hearing complaints two years after surgery.

In Study 2 we found that GPs considered CPGs necessary. Nonetheless, they had difficulties adhering to them because, for example, the CPGs were too many, and they were inaccessible, that is, too long and too comprehensive to navigate through easily. Moreover, the GPs reported a mismatch between the CPGs and their patients. Whereas CPGs are often focused on treatment for single diseases, the GPs reported that their own focus was more on their patients as whole persons. The obligation to apply multiple CPGs designed for single diseases created various complications for the GPs, such as insecurity about their own practice and a tendency to practice medicine defensively. The complications for their patients included an increased risk of polypharmacy, of excessive non-pharmacological

recommendations, of an increased tendency toward medicalization, and of a potentially reduced quality of life.

Conclusion

Overall, the studies documented several challenges regarding adherence to CPGs. Even the simple VT-guideline was complex to implement in an actual clinical setting. In part, this guideline's lack of quality may explain the lack of adherence. Further studies are needed to consider the implications for follow-up after VT surgery. The GPs provided compelling reasons for their low adherence to CPGs in general. The main reasons seemed to involve a mismatch between the CPGs and the patients, and that applying multiple CPGs for single diseases resulted in complications for general practice, especially for multimorbid patients. These findings challenge the idea that 'quality of care' is largely synonymous with adherence to CPGs designed specifically for single diseases in general practice. In this thesis, these findings are discussed in light of what may be called a 'fundamental inadequacy' in determining what is to be considered as valid medical knowledge. These issues may also help explain why CPGs are difficult to adhere to in general practice.

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Writing this thesis has been a challenging and exciting journey. Initially, it was not planned as a PhD, but through supervision and influence from the research environment, the possibility of and plan for a PhD emerged. The work presented in this dissertation was done in Trondheim, Norway. The scientific environment was the General Practice Research Unit, Department of Public Health and General Practice, Norwegian University of Science and Technology.

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List of publications

1. Austad B, Hetlevik I, Bugten V, Wennberg S, Olsen AH, Helvik AS: "Implementing guidelines for follow-up after surgery with ventilation tube in the tympanic membrane in Norway: a retrospective study". *BMC Ear Nose Throat Disord* 2013, 13:2.

2. Austad B, Hetlevik I, Bugten V, Wennberg S, Olsen AH, Helvik AS: "Can general practitioners do the follow-ups after surgery with ventilation tubes in the tympanic membrane? Two years audiological data". *BMC Ear Nose Throat Disord* 2014, 14(1):2.

3. Austad B, Hetlevik I, Mjølstad BP, Helvik AS: "General practitioners' experiences with multiple clinical guidelines: A qualitative study from Norway". *Qual Prim Care* 2015, 23(2):70-77.

4. Austad B, Hetlevik I, Mjølstad BP, Helvik AS: "Applying clinical guidelines in general practice: a qualitative study of potential complications". *BMC family practice*. 2016;17:92.

Abbreviations

AFE	Allmennmedisinsk Forskningsenhet [General Practice Research Unit]
AGREE	Appraisal of Guidelines for Research & Evaluation
AOM	Acute Otitis Media
CME	Continued Medical Education
COREQ	Consolidated criteria for reporting qualitative studies
CPG	Clinical Practice Guideline
dB	Decibel
DECIDE	Development and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence
EBM	Evidence-Based Medicine
ENT	Ear, Nose and Throat
EQUATOR	Enhancing the QUAlity, and Transparency Of health Research
G-I-N	Guidelines International Network
GLIA	GuideLine Implementability Appraisal
GP	General Practitioner
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HUNT	Helseundersøkelsen in Nord-Trøndelag [The Nord-Trøndelag Health Study]
JAMA	Journal of the American Medical Association
kHz	Kilo Hertz
KOPF	Kontinuerlig, Omfattende, Personlig, Forpliktende [Continuous, Comprehensive, Personalized, Binding]
LEON	Laveste Effektive Omsorgs Nivå [Lowest Effective Level of Care]
MeSH	Medical Subject Heading
MTH	Mean Threshold

NAFALM	Nasjonal forskerskole i allmennmedisin [Norwegian Research School in General Practice]
NEL	Norsk Elektronisk Legehåndbok [Norwegian Electronic Medical Guidebook]
NICE	National Institute for Health and Care Excellence
NTNU	Norwegian University of Science and Technology
OME	Otitis Media with Effusion
RCT	Randomized Controlled Trial
RGP	Regular General Practitioner
STC	Systematic Text Condensation
VT	Ventilation tube
WHO	World Health Organization
WONCA	World Organization of Family Doctors

Prologue: The development of this thesis – from ventilation tubes to multiple clinical practice guidelines

The beginning

In 2007, I attended a meeting for GPs in the municipality. The head of the Ear, Nose and Throat (ENT) Department at Trondheim University Hospital asked the GPs if they were willing to take over responsibility for the follow-up controls of the healthiest children after insertion of VTs in the tympanic membrane. The otolaryngologists would still follow up the children with medical syndromes or with severe hearing loss. The GPs agreed, under the condition that they would not be responsible for calling the children in to the controls, but that the children and parents would make the appointments themselves. After that meeting, a written guideline for how and when to perform controls of the children was sent to the GPs by mail.

Quality assurance study

From 2008 to 2009, I worked at the ENT Department to fulfill my one-year hospital practice requirement to become a specialist in general practice (see 1.5.2). By then, the new guideline for follow-ups after VTs had been available for nearly a year, and the hospital wanted to investigate whether or not it had led to any increase in risk for the children. It was controversial among otolaryngologists for follow-ups to be delegated to GPs. As a GP in a hospital setting, I saw these patients from the perspective of both primary and secondary care. Eventually, I became responsible for the project. The fact that it had started out as a retrospective quality assurance study explains why the patients were not randomized.

From VTs to collaboration

At the ENT Department, the topic of follow-ups after VT-surgery was much debated. The only information the GPs received was what had been discussed at the meeting mentioned above plus the written guideline that was mailed to them afterwards. This information was never repeated. Even so, the ENT Department expected the guideline to be implemented in

general practice. This increased my curiosity as to how collaboration between hospitals and GPs really works, and the term ‘collaboration’ was added to the title of the study in early protocols.

From collaboration to implementation of a guideline

The guideline was less than one page in length and relatively simple. It included information about which patients were eligible for follow-ups by the GP, and how the GPs should handle some common complications (see Appendix 2). I found, however, that the guideline was only partially implemented at the hospital, despite it having been announced there and despite the fact that the otolaryngologists themselves had developed it. This aroused my curiosity about the implementation of other and more complex guidelines, such as those for diabetes, depression, cardiovascular disease, etc. When I searched for information about this topic, I found that, though the issue of lack of implementation was well known, the reasons for it were far from fully understood. At this time, I chose to focus on the implementation aspects of the material, both the implementation process (Paper I) and whether the development of a new guideline had led to a change in clinical outcome (Paper II).

From single to multiple clinical guidelines

At the same time, I was overwhelmed by the number of new clinical guidelines I received in my clinical practice, coming from health authorities and hospitals, among others, and I had trouble finding time to read them. The guideline concerning follow-ups after insertion of VTs was just one of many; I was, of course, already familiar with that content. In addition, I experienced colleagues in general practice who apparently took little notice of new guidelines, with the obvious result that the guidelines were not implemented.

I was curious how GPs actually related to and adhered to clinical guidelines, not just specific guidelines but guidelines in general. I found few answers in the literature. Throughout the planning of a new study, I decided to also investigate how GPs adhered to guidelines in a clinical reality generally, and where several guidelines might be applicable simultaneously to the same patient. This was the background for the qualitative study, in which I explored GPs experiences with and reflections on utilization of clinical guidelines in general (Paper III).

During the study’s first focus group interview, the GPs described some situations in which adhering to guidelines did not seem to benefit the patients. They experienced clinical

guidelines as having consequences for general practice, both for the GPs themselves and their patients. These consequences were explored and described in Paper IV.

Summary

Both the focus of this thesis and the research questions have matured throughout the PhD period. For example, only later in the process did I learn of the recently specified research evidence component required by many for the term ‘CPG’ to be applied. The history above explains why I began by studying the VT-guideline and not one of the more commonly known CPGs, such as those for diabetes, hypertension, or others. Furthermore, this thesis addresses various aspects of challenges connected with adherence to clinical guidelines in general practice, with a particular focus on a single guideline and on multiple CPGs.

1. Background

1.1 Overview of the thesis

Clinical practice guidelines are ubiquitous in medical practice. The implementation and use of them, however, seem to be difficult and complex. Grimshaw et al. state that: *"One of the most consistent findings from clinical and health services research is the failure to translate research into practice and policy"* (1).

This thesis includes two studies with a total of four papers that will approach this problem from various perspectives. Study 1 (Paper I and II) concerns the implementation of a single guideline for follow-ups after insertion of VTs in the tympanic membrane of children. Study 2 (Paper III and IV) explores the complexity of the phenomenon of adhering to CPGs as they appear in general practice, and emphasizes reasons for low adherence.

In the background section here, I will introduce central themes for this thesis, such as 'clinical practice guidelines', 'implementation', 'general practice' and 'ventilation tubes'. In addition, since CPGs are mostly based on EBM, I have included a section related to EBM. In the background section, I have primarily included references that were published before our papers were written. This is in accordance with one recommended outline for medical theses (2).

In chapter 2, I will present the theoretical framework for this thesis, including a brief description of natural science and phenomenology.

Chapter 3 describes the present study as it regards objectives, methods and material, in addition to a summary of results. The methods and material are presented separately for the two studies due to their differing designs. Following the result summary, Chapter 4 will discuss important methodological aspects and weaknesses of the studies, including reflections on how my own role as a researcher may have influenced the qualitative study. In addition, some ethical considerations are discussed.

In the discussion of results, newer literature has been added (2) and is discussed in comparison to findings in the present study. I have found it relevant to discuss more profoundly the challenges of implementing the VT-guideline and of adhering to CPGs in

general, as well as such central aspects of contemporary research and health services as multimorbidity, overtreatment, and the dilemmas that arise because CPGs focus on a disease while the GPs focus on the whole person. I have also included a section exploring what I consider to might be a 'fundamental inadequacy' related to what is considered as valid medical knowledge, which may help explain why CPGs are difficult to adhere to in general practice. Finally, I reflect over implications and perspectives for CPGs in general practice in the future.

1.2 Clinical practice guidelines

1.2.1 Definitions of CPGs

According to The Random House Dictionary of the English Language, the American origin of the word 'guideline' is from the late 18th century, presumably in its literal usage as a: *"Rope or cord that serves to guide one's steps especially over rocky terrain, through underground passages etc."* (3, 4). The metaphorical use of the word guideline as *"Any guide or indication of a future course of action"*, is a recent addition (4).

In medicine, we use the terms 'CPG's, 'clinical guidelines', 'medical guidelines', 'practice guidelines', or simply 'guidelines'. These are defined in various though quite similar ways. A broad definition of CPGs is that they aim to guide decisions and criteria regarding diagnosis, management, and treatment in specific areas of health care (5, 6). 'Practice Guideline' is a Medical Subject Heading (MeSH) term (CPG is an Entry Term) and the definition used there is close to the broad definition of CPGs (7). In a narrower and more recent definition, a systematic review and appraisal of research is required in order for it to qualify as a 'CPG'. The Guidelines International Network (see 1.2.2) defines CPGs as: *"Statements that include recommendations intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options"* (8). This is the same definition as the United States' Institute of Medicine has used since 2011 (9).

The daily work of GPs involves a heterogeneous group of recommendations, varying from simple guides or procedures to comprehensive CPGs including systematic appraisals of

evidence. In my papers, the term ‘clinical guidelines’ was used for all types of guidelines and CPGs. However, in this dissertation, I have decided to clarify the term to bring it in line with recent literature. Consequently, I will use the narrower definition, the one including systematic appraisal of evidence, when I refer to a ‘CPG’. When I refer either to guidelines without systematic appraisal of evidence, such as the VT-guideline or a combination of guideline types, I will use the term ‘guideline’ or ‘clinical guideline’.

1.2.2 History of guidelines: from guides to CPGs

Documents providing advice for how to give the highest quality of care have probably been in use throughout the history of medicine. The Hippocratic Oath includes statements about quality of treatment, such as dietary advice to help those who are sick (10). Both during the Roman Empire and the Middle Ages, recommendations and guides were well known (11).

In modern times, guidelines have gradually increased in number and complexity. During the 20th century, the number of protocols, consensus reports and guidelines increased rapidly, especially during the last decades. By 1998, the quantity of guidelines for general practice had become so large that it was compared to the ‘Tower of Babel’ (12); in 2006, the U.S. Agency for Health Care Research and Quality had a list of more than 2000 CPGs for all medical specialties (13). In Norway, when this study started, there were about 60 official, national CPGs amounting to more than 1000 recommendations and filling a total of about 5000 pages (14). Available in addition were more than 100 national guides (not considered as normative as the national CPGs), each up to 100 pages in length, plus numerous local guidelines (see 1.2.3) (14).

Previously, guidelines were often based on tradition, the opinions of authorities or on medical consensus, but with the emergence of EBM (see 1.4) these were no longer considered adequate. Also, as the number of CPGs increased so did their variety in form, content, and the appraisals of research. As this began to seem problematic, attempts were made to improve the quality and validity of the CPGs (9, 15). Over the last years, several different ‘guidelines for guidelines’ have been made, for instance by the World Health Organization (WHO) (16) and the Norwegian Directorate of Health (17). In what follows, I

will briefly present some of the central actors engaged in the process of improving the quality of CPGs.

Naturally, there is a variety of 'quality of the research' and 'evidence' forming the basis of different recommendations and CPGs. In the year 2000, a group of people interested in raising the quality of grading systems in health care established an informal, collaborative working group, The Grading of Recommendations Assessment, Development and Evaluation (GRADE) (18). They grade the evidence behind recommendations into: A (high quality of evidence), B (moderate), C (low) and D (very low), and divide the recommendations into categories of strong or weak. The GRADE system has become the one to be used most frequently for grading recommendations, used in Cochrane systematic reviews and by the WHO, among others (16, 19). They have also designed a guideline development tool called GRADEpro which is described as an: *"All-in-one web solution for summarizing and presenting information for health care decision-making"* (18). In 2011, a 5-year project was started under the name DECIDE (Development and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence) (20). The aim of the project was to improve the dissemination of evidence-based recommendations, building on the work of the GRADE Working Group (20).

In 2003, the Appraisal of Guidelines for Research and Evaluation (AGREE) was founded (21). They designed an instrument to raise the quality of CPGs. It was further developed in 2009 as AGREE II, a tool designed as a: *"Guide to direct high-quality guideline development"* (21). It consists of a 23-item list divided into the following six domains: Scope and purpose (Items 1-3), stakeholder involvement (Items 4-6), rigor of development (Items 7-14), clarity of presentation (Items 15-17), applicability (Items 18-21), and editorial independence (Items 22-23).

Guidelines International Network (G-I-N), which was established in 2002, is an international scientific association of organizations and individuals who are interested and involved in the development of CPGs (22). Their aim is to help their *"members create high quality CPGs that foster safe and effective patient care"* (22). They have created a library of CPGs, systematic reviews, implementation tools, etc., gathered from various countries, and they arrange G-I-N conferences annually. In 2008, the EQUATOR Network (Enhancing the QUAlity, and Transparency Of health Research) was officially launched (23). The Network

had an impact on the promotion, adoption, and development of reporting guidelines (24, 25). These new standards, however, have made the work to create CPGs even more comprehensive; some guideline developers do not adhere to them (26).

The reasons for the increased focus on the development and dissemination of CPGs have been discussed. Some have claimed that CPGs are shaped by politicians and administrators as a response to rising health costs (27); others have claimed that physicians use CPGs in an attempt to protect their professional autonomy from administrative pressures (28). In "The Emergence of Clinical Practice Guidelines", Weisz et al. suggest that CPGs have evolved as *"a change in the method of regulating the quality of medical practice"* (13). The authors claim that the pressure to create CPGs arises from the medical domain's rapidly expanding base of knowledge and research, the increasing role of governments in health care, the recognition of unwanted variations, and the need for protocols for complex therapeutic technologies (13).

1.2.3 Development of CPGs

CPGs are organized and developed differently in different countries. The WHO has listed how 29 European countries organize and develop their CPGs for chronic conditions (29). In the United States, guidelines are prepared by a variety of organizations, primarily in the private sector, rather than having a single version prepared by the Federal Government. These are then submitted to the National Guideline Clearinghouse and made publically searchable through a database (6, 30). Other countries have placed guideline production under the auspices of national agencies, for instance the National Institute for Clinical Excellence (NICE) in England and the Scottish Intercollegiate Guidelines Network in Scotland (31, 32).

In Norway, the Norwegian College of General Practice made their own guidelines for hypertension, diabetes, asthma, and rheumatology. The first guideline, made in 1986 for hypertension, is regarded as a milestone in Norwegian general practice. The hypertension guideline was reviewed in 1993 (33) after a very difficult process due primarily to discussions about the thresholds for intervention – described as 'the blood pressure battle' (34). There was debate as to who should have the authority to develop CPGs for general

practice. Gradually, the Directorate of Health, which is a subordinate agency of the Norwegian Ministry of Health and Care Services, took over the responsibility for developing CPGs. The Directorate is now the only executive agency for providing *national* CPGs (35). The national CPGs have five aims: 1) help provide good quality care; 2) help health professionals prioritize correctly; 3) avoid unwarranted variation; 4) solve challenges of collaboration among different health care providers; and, 5) offer good patient-centered care pathways (36). Recommendations are based on a systematic appraisal of evidence and are most often categorized according to the GRADE system (18).

The Directorate of Health claim to base their recommendations on 'knowledge-based practice', which they define as a combination of research-based knowledge, experience-based knowledge, and patients' own knowledge and involvement (in Norwegian: forskningsbasert kunnskap, erfaringsbasert kunnskap, brukerkunnskap og brukermedvirkning) (17). Still, the practical utility of their CPGs has been criticized for placing too much focus on research and not enough on the doctors' clinical experience and the patients' preferences and values (37). To develop new CPGs, the Directorate creates interdisciplinary working groups consisting of medical professionals, representatives from patient organizations, etc. When they have recommendations completed, they send them out to consultative bodies such as governmental agencies, unions, relevant organizations, and educational institutions. After the consultative comments are processed, the Directorate determines the final recommendations. These then become the national standards for examining, treating and following up the specific disease (17).

Local clinical guidelines are often made by departments at a hospital and are valid for a region of the country. Also, the Norwegian Medical Association has written several professional guides and guide books covering different areas of medicine (38). While the guidelines are not considered normative in the same way as national CPGs, it is presumed that they will be applied to their specific area of application. These guidelines are most often much shorter than the national CPGs, more like procedures, are often consensus-based, and seldom based on a systematic review of evidence. Some examples from Mid-Norway include guidelines for follow-ups after VT surgery (see Appendix 2), handling of relapses in patients with chronic rheumatic disorders (39), and interdisciplinary cooperation for treating children with complex disorders (40).

1.2.4 Critique of CPGs

Though CPGs are seen to provide many benefits, they have also been criticized (41). Here, I will briefly present some of the areas facing criticism.

CPGs have been criticized for not meeting standards for quality. In 1998, only five percent of the 431 CPGs examined met the following three main criteria: describe the type of stakeholder, include searches for published studies, and explicitly grade the strength of the recommendations (42). Another study found that CPGs met less than half of the established methodological standards (43).

Often, high quality evidence is not available to support recommendations (6). In a review of guidelines, only 14 percent of the 4000 recommendations were supported by the highest level of evidence (44). A study of American cardiovascular guidelines up to 2008 found that nearly half of the recommendations were based on the lowest level of evidence (45). An article concluded that even well-designed, randomized control trials (RCTs) may not be applicable to the populations, interventions, or outcomes specified in a CPG recommendation and therefore should not automatically be assumed to serve as high quality evidence for therapy recommendations (46).

It is challenging to keep the CPGs updated as the base of evidence used to create guidelines develops rapidly. An article in the Journal of the American Medical Association (JAMA) reported that about half of the CPGs were outdated after approximately six years, and most guideline developers lacked formal procedures for updating their guidelines (47).

Some claim it to be problematic that there are so many CPGs, even many on the same topic. There are, for instance, ten different guidelines for pharyngitis (48). Sometimes, the recommendations conflict with one another. For example, two major guidelines for colorectal cancer screening published within several months of each other include different sets of screening test options and preferences (49, 50). However, according to UpToDate, discrepancies among recommendations is not necessarily a sign of poor quality (6). A weak evidence base may lead to varying conclusions. On the other hand, CPGs might differ because political and stakeholder interests may influence the recommendations (51). Therefore transparency regarding the stakeholders' involvement and interests is considered important for the quality of guidelines (21).

Despite the fact that multimorbidity (see 1.5.3) is quite common, CPGs are most often made for single diseases. It has been documented that CPGs for single diseases are of little help when treating multimorbid patients (52).

During the last two decades, the scientific environment I have worked in at the General Practice Research Unit at NTNU has identified grounds for criticism of CPGs and their implications. For example, in her thesis, Irene Hetlevik reported that even quite extensive and active implementation of CPGs for cardiovascular disease prevention and diabetes in general practice did not succeed (53). Some years later, Linn Getz et al. performed a modelling study of the 2003 European guidelines on prevention of cardiovascular disease using participants in the second Nord-Trøndelag Health Study (HUNT 2) (54). If the CPG were to be implemented, most adult Norwegians would be classified as being at high risk for fatal cardiovascular disease (54). Halfdan Petursson found that the potential workload involved in implementing the 2007 European hypertension guidelines would require 99 GPs per 100,000 adults to work on this task alone (55). As a comparison, at that time, the total number of GPs in the study area was 87 per 100,000. In other words, adherence to this CPG could destabilize Norway's health care system (55). As a consequence, he questioned the role of EBM in his thesis (56).

1.3 Implementation

1.3.1 Process and outcome

It may be claimed that a guideline is no better than its implementation. To implement a CPG in clinical practice, however, has proven to be difficult (1). In their paper, "Knowledge Translation of Research Findings", Grimshaw et al. claim that the lack of implementation of updated research and CPGs results in patients being at risk of harm (1). According to the European Science Foundation, the process is working rather well from the initial idea, through research, meta-analysis, and Cochrane review. The problem arises, however, because: *"The process from meta-analysis through guidelines to clinical practice is a source of considerable variation throughout Europe and therefore suffers from intransparency and fragmentation"* (57).

Guideline implementation has been studied thoroughly and there are international medical journals whose aim is to publish implementation research (58). Evaluation of improvements may focus on such aspects as structure, effort, process, or outcome (59, 60). Change in 'process' may be related to knowledge, attitude, or behavior, such as if an intervention to implement a new CPG results in a change in the number of doctors adhering to its recommendations (59). The change of 'outcome' relates to the clinical result for the patients, such as if implementation of a new hypertension guideline resulted in improvements of patients' blood pressure levels (61).

1.3.2 Barriers, facilitators and implementation strategies

Several barriers to implementation of CPGs have been identified (62, 63). In a qualitative study of GPs, it was found that some of these were: lack of agreement with the recommendations, environmental factors such as organizational constraints, lack of knowledge regarding the guideline recommendations, and guideline factors such as unclear or ambiguous recommendations (64). Organizational readiness for change is seen as important for implementation (65), although a meta-synthesis of qualitative studies concluded that the purpose of the CPGs may influence adherence just as much as professional attitudes and organizational barriers (66).

Several facilitators for implementation have been demonstrated (67). The likelihood that recommendations would be followed was found to increase when they were supported by clear evidence, were compatible with existing norms and values, did not require new skills or changes in practice routines, were less controversial, and were stated in specific, actionable terms (68, 69).

To implement new research or CPGs, a strategy for implementation is recommended. Previously, the implementation strategy for new CPGs was simply to distribute printed material. A study concluded that printed educational materials might have some beneficial effect on the implementation process, but not on patient outcomes (70). To enhance implementation of CPGs and to help guideline developing groups with their implementation strategy, some implementation tools have been created, such as the 'GLIA Tool' (GuideLine Implementability Appraisal) (71). When presenting new CPGs, the United States' Institute

of Medicine suggest that they be structured in format, vocabulary, and content so that computer-aided decision-making tools may can be used (9).

1.3.3 A more complicated problem?

Despite strategies to overcome barriers, adherence to CPGs seems both difficult and complex (72, 73). Low adherence is most often regarded as a problem that needs to be addressed by altering implementation strategies (74). However, the above-mentioned modelling studies from the Norwegian HUNT material (see 1.2.4) also challenge the *content* of the guidelines for cardiovascular disease and hypertension because of the extent of their implications for the population and the health care system (54, 55).

In addition, some studies question whether it is best for a patient's overall health to adhere to CPGs that are specific for single diseases (75). Parekh et al. introduced the term 'silo-medicine' in 2010, meaning that each part of medicine was encountered as a single disease or risk-factor, instead of meeting patients as whole persons (76). Consequently, CPGs are made for single diseases, or silos, and there could be several CPGs applicable to the same patient (see Figure 1). Little research has been done to explore the extent to which such 'silo-medicine' might point to a deeper problem, one which the existing implementation strategies do not seem to solve (77). One may even question if the theoretical basis for CPGs is appropriate for the treatment of human beings (78, 79). Thus, there is little valid knowledge about how to improve the implementation of CPGs in general practice.

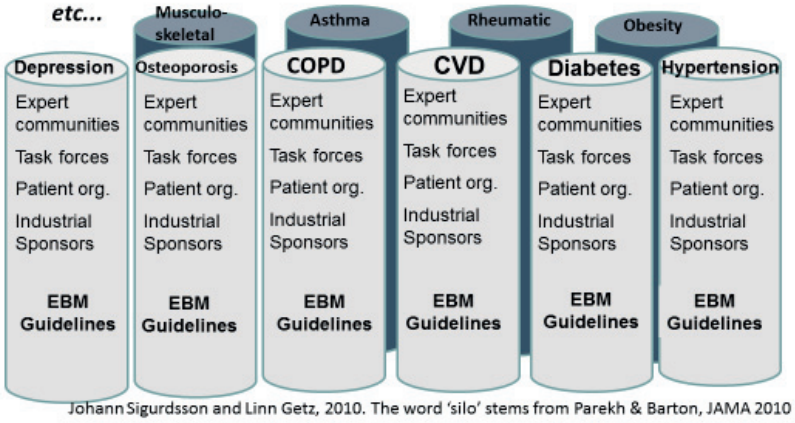

Figure 1: Illustration on 'Silo-Medicine'. *Reproduced with permission from Linn Getz and Johann Sigurdsson.*

1.4 Evidence-Based Medicine

1.4.1 EBM: origin and history

Many CPGs today are based on a systematic appraisal of available research in order to formulate recommendations, i.e. on EBM. It is therefore important to understand what EBM is and its influence on CPGs. EBM originated at McMaster University in Canada (80). The founders were aware of unwanted variations among clinicians and wanted to find a more objective way to seek updated knowledge and better ensure the quality of care for patients. Previously, clinical decisions were only based on, *"intuition, unsystematic clinical experience, and pathophysiological rationale"*, but with EBM, the evidence from clinical research became crucial (81). McMaster University taught their medical students and physicians to search into clinical research for evidence in order to make better clinical decisions.

EBM highlighted critical appraisal of the existing medical evidence and created hierarchies of evidence according to how strong or weak various recommendations might be. For instance, systematic reviews would give the strongest evidence, then RCTs, case-controls studies, etc. The hierarchies are primarily open, and differ somewhat depending on the kinds of questions that are asked (80). The term 'EBM' was first used in 1990 by Gordon Guyatt, one of the central actors in the EBM movement (82). In 1992, the term EBM was introduced as a new paradigm for medical practice (81). An EBM Working Group evolved, with researchers mostly from Canada and United States, and they created a series of articles called 'The Users' Guide to the Medical Literature', published in JAMA during the 1990's (80).

According to the 3rd edition of the Users' Guide to the Medical Literature, EBM involves three fundamental principles: 1) awareness of the best available evidence, which ideally will come from systematic summaries of that evidence; 2) guidance to decide whether evidence is more or less trustworthy; and, 3) that evidence alone never suffices when making a clinical decision (80). The third principle includes taking clinical expertise and the patient's values and preferences into consideration. When these three elements are put together, they are referred to as 'Evidence-Based Practice' (80). In 1996, one of the pioneers of EBM, David Sackett, defined EBM in an article called: "Evidence-Based Medicine. What it is and what it isn't". He wrote:

> *Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannised by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients* (83).

Over the last decades, EBM has grown rapidly as a method and movement and has had enormous influence on today's medicine and thereby on today's CPGs. A Norwegian example of this is that the Norwegian Knowledge Center for Health Services has made the McMaster Plus hierarchal research search strategy (called '6S Pyramid') available to Norwegian physicians (84).

1.4.2 EBM critique

The concept of EBM has been intensely discussed; both too much and too little adherence to the concept have been criticized (56, 85). EBM has been widely criticized for focusing too much on evidence and too little on clinical expertise, despite its own explicitly stated intentions (86). In addition, critique has focused on how seldom, in practice, patients' values and preferences are emphasized when using EBM (87, 88). The ideal that every narrow clinical question, hundreds of thousands of which may exist, could be addressed adequately using EBM has been criticized as being not only unrealistic but also impractical given the cost of research. The RCTs are particularly expensive, and the prioritizing of research topics is inevitably influenced by the sponsors' interests (89). Assigning RCTs to a high rung in EBMs hierarchy of evidence has also been discussed because RCTs may not be relevant to all treatment situations (90). Historically, certain population segments have been under-researched, an example being multimorbid patients; this restricts the degree to which RCTs may be generalized (91).

The theoretical foundations of EBM and the epistemological limitations of the scientific paradigm have also been debated (92). For instance it has been claimed that knowledge gained from clinical research, which is a general priority in EBM, is not directly applicable to the care of individual patients (87). Cohen et al. have summarized and categorized various critiques of EBM into five recurring themes (93), further elaborated in the doctoral thesis by Linn Getz (94). The five themes are:

1. EBM is a poor philosophical basis for medicine.
2. The EBM definition of evidence is narrow and excludes important information.
3. EBM is not evidence-based.
4. The usefulness of applying EBM to individual patients is limited.
5. EBM reduces the autonomy of the doctor/patient relationship.

1.5 General practice

1.5.1 Definitions and characteristics of general practice

General practice plays a key role in the health care systems of many countries (95). Despite variations in organization and tasks among the countries, they do have some things in common. In this section, I have explored some definitions and core values of general practice, and included 'Family Medicine' in the definitions.

In 1978, 'Primary Health Care' was defined in what is known as 'The Declaration of Alma-Ata' (96). General practice, which is a part of Primary Health Care, has several definitions, for instance Leeuwenhorst's from 1974, and Olesen's from 2000 (97). According to WHO, the work in general practice: *"Operates at the nine levels of care: prevention, pre-symptomatic detection of disease, early diagnosis, diagnosis of established disease, management of disease, management of disease complications, rehabilitation, palliative care and counselling"* (98).

The European section of the World Organization of Family Doctors (Wonca Europe) has a comprehensive definition of general practice which includes 12 characteristics and six core competencies of the discipline (99). They have used the image of a tree, known as the 'Wonca Tree', to illustrate a summary of the various aspects of general practice (see Figure 2).

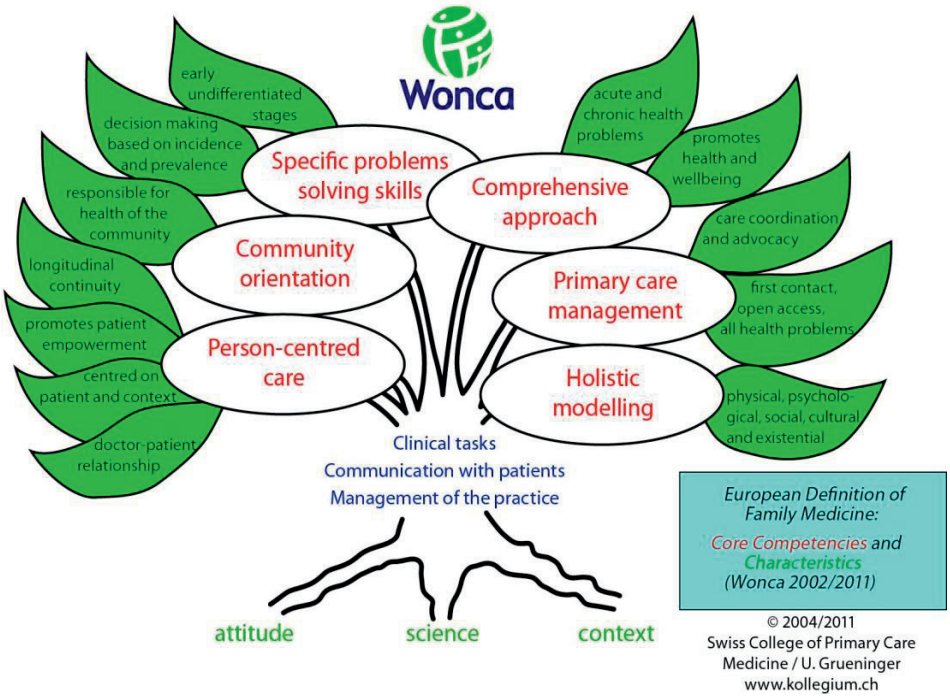

Figure 2. 'The Wonca Tree', as produced by the Swiss College of primary care (2011). *Reproduced with permission from the Swiss College of primary care*

General practice differs from the specialist health care system in several ways, including accessibility and being the first point of contact. Iona Heath, a British GP and former president of the Royal College of GPs, described the difference between general practice and the specialist health care in the following way: *"In hospitals, the diseases stay and the people come and go; in general practice, the people stay and the diseases come and go"* (100). Ian E. McWhinney, an English/Canadian physician and academic, is known as one of the founders of modern family medicine/general practice (101). In the late 1980s, he developed and defined the concept of family medicine as being both a distinct field of practice as well as an academic discipline. His "Textbook of Family Medicine" (published in 1989, 4th edition 2016) is widely used and describes the field of family medicine/general practice (102).

The bio-psycho-social disease model has had great influence on general practice, and practitioners often aim to apply a patient-centered approach, as opposed to one that is doctor-centered (103, 104). The model was introduced in 1977 by George L. Engel (105). In this patient-centered model, the patient's story, and the social and psychological context of the presented problem are explored further than in a strictly applied biomedical model. More emphasis is placed on the patient's presenting problem, and less on single diseases.

In general practice, the doctor-patient relationship often lasts over time. This too leads to an increased focus on the patient rather than simply the disease. Barbara Starfield described the following four main features of primary health care: *"Contact access for each need; long-term person- (not disease-) focused care; comprehensive care for most health needs; and coordinated care when it must be sought elsewhere"* (106). They are known as the 'Four C's' and have been widely quoted, including in WHO and Wonca Europe's definitions of general practice (99).

1.5.2 General practice in Norway

I include here an overview of some of the milestones in Norwegian general practice in order to provide a deeper understanding of the situation for general practice in the studies.

In 1977, two Norwegian general practice associations put into words a vision for general practice as it moved toward the year 2000 (107, 108). Their acronym, KOPF (in Norwegian: Kontinuerlig, Omfattende, Personlig, Forpliktende), stood for the ideal that primary care and general practice should be: *"Continuous, Comprehensive, Personalized, Binding"* (107). The Norwegian College of General Practice has worked for the professional development of general practice in Norway since its establishment in 1983 (107, 108). In 2003, they formulated "Seven Principles for General Practice", describing core values and qualities for assuring good standards of professional general practice. Four of these principles were: to honor the doctor-patient relationship, to do what is most important, to give most to those whose need is greatest, and to use words that are health-promoting (109).

In 1985, a specialty in general practice was introduced. To become a specialist requires five years of training; one of these must be at a hospital and the other four in general practice

(110). In addition, it is mandatory to participate in a supervision group (called 'junior groups' in paper III and IV) for two years. Every five years, the GP has to be re-certified in order to maintain the status of specialist. One of the compulsory tasks is participation in small groups (called 'senior groups' in paper III and IV). The Norwegian Continuing Medical Education (CME) program organizes these groups and the Ministry of Health is formally responsible for CME (111). Being a specialist increases the GP's salary. Most Norwegian Regular GPs (RGPs) are, or are on their way to becoming, specialists.

In 2001, the RGP Scheme ('Fastlegeordningen') was introduced after eight years of pilot projects in a limited number of municipalities. A patient list system was then extended to include the entire population so that each could have access to one RGP. Although it is voluntary, nearly the entire population has an RGP. About 4600 RGPs work in Norway and each one has an average list of approximately 1100 patients (112). The main objectives of the reform were to improve access to GPs' services, facilitate more stable patient-GP relationships, and to ensure equity in the use of health care services for the entire population. A study found that about 80 % of adults over 30 years of age consulted their RGP annually (113).

During the last decades, general practice has developed from being included in the medical curricula only marginally to becoming one of three major disciplines at the four Norwegian medical faculties, with internal medicine and surgery being the other two. In the 1980s and '90s, the Departments of Public Health and General Practice were established, and in 2006, General Practice Research Units were established at all four of the medical faculties. In 2007, the Norwegian Research Fund for General Practice was established in order to promote research in general practice by providing grants to GPs aiming for a PhD (114).

One of the roles of RGPs is to serve as gatekeepers to assure that only those who cannot be treated in primary care adequately are referred to secondary health care. With few exceptions, the population cannot access public secondary care without such a referral. In 2012, a Coordination Reform ('Samhandlingsreformen') between primary and secondary health care was put into practice (115). The goal of the reform was to improve public health in a sustainable way. One of the consequences was that obligations and responsibility where transferred from secondary to primary health care. The aim was to treat patients at the 'lowest effective level of care', known by the Norwegian acronym as the LEON-principle

(Norwegian acronym for Laveste Effektive Omsorgs Nivå). This has been a principle in Norwegian health care for many years, since even before the Coordination Reform formalized it (116).

The regulation regarding the RGP scheme ('Fastlegeforskriften') was introduced in 2013, after being heavily debated (117). As a clarification of a law, the regulation aims to assure that general practice provides everyone necessary medical care, of good quality and at the right time. According to §16, the RGPs are obligated to apply updated knowledge and national CPGs. In the 'Remarks' section, it does open for each GP to use clinical judgment when meeting patients, but it also underlines that the GP must be familiar with the national CPGs (117).

1.5.3 Multimorbidity, overdiagnosis and overtreatment

Multimorbidity, overdiagnosis and overtreatment are important issues in this thesis. In this section, I briefly present these terms.

Multimorbidity

Definitionally, the term 'multimorbidity' is applied when a single patient manifests two or more chronic conditions simultaneously, a situation frequently encountered in general practice (118). A Scottish study found the prevalence of multimorbidity for all ages to be 22%, with the prevalence increasing with age (119). Multimorbidity is referred to as 'The New Normal' (120).

The reasons for multimorbidity seem multifaceted. Some of what contributes to an increase in the number of diagnoses per person might include improved diagnostic capabilities, the ageing of the population, and an increase in individual prevention efforts in terms of 'risk tracking' (76, 121). Another factor is the extending of disease definitions, for instance the lowering of the HbA1c threshold in the definition of diabetes mellitus type 2, which increases the number of people involved (122). Multimorbidity may result in polypharmacy. Boyd et al. detailed the potential treatment schedule that would result if all the recommendations in all the relevant guidelines were followed by a hypothetical 79-year-old

patient with hypertension, diabetes mellitus, osteoporosis, osteoarthritis and chronic obstructive pulmonary disease. The patient would have to take 12 different medications every day and would be advised to engage in 14 non-pharmacological activities (123).

Overdiagnosis and overtreatment

Unnecessary health care has been shown to be a problem, both for multimorbid patients and for patients with single, long-standing conditions or risk factors (55, 124). There is no internationally recognized definition of overdiagnosis and overtreatment, however, and there is controversy regarding the extent of the problem (125). In recent years, the international focus on this theme has increased. In 2002, the BMJ had a theme issue covering 'Too Much Medicine?' which included articles on the medicalization of birth, sex, and death, among other aspects of ordinary life (126). A decade later, they initiated a campaign with the same name (127). JAMA started a similar collection, called 'Less is More' (128). The first international scientific conference in 'Preventing Overdiagnosis' was held in 2013. The now annual conference covers a variety of aspects of overdiagnosis within different specialties, including general practice. The following statement was made during the first conference: *"Overdiagnosis harms people worldwide and exacerbates undertreatment by wasting much needed resources"* (129).

1.6 Ventilation tubes

1.6.1 Ventilation tube surgery

Otitis media with effusion (OME), also called serous otitis media, is defined as middle-ear effusion without acute signs of infection (130). OME often occurs after acute otitis media (AOM), but it may also occur with eustachian tube dysfunction in the absence of AOM (131). Before school age, 90 % of children have had at least one episode of OME (132), and OME is the major cause of acquired hearing problems in children (130). Recurrent AOM is usually defined as ≥ 3 distinct and well-documented episodes of AOM within six months or ≥ 4 episodes within 12 months (133).

Only a fraction of the children with OME or recurrent AOM are in need of surgery to have VTs placed in the tympanic membrane, also known as tympanostomy tubes or grommets (see Figure 3). Still, this is the most common ambulatory surgery performed on children in the United States (134). In Norway, the estimated lifetime prevalence for the surgery is about 12% (135), and according to registered data, 6700 Norwegian children 0-16 years undergo surgery annually (136). The surgery is performed to reduce ear complaints and to improve hearing and speech development (137). Re-surgery is quite common and some children need several operations (138).

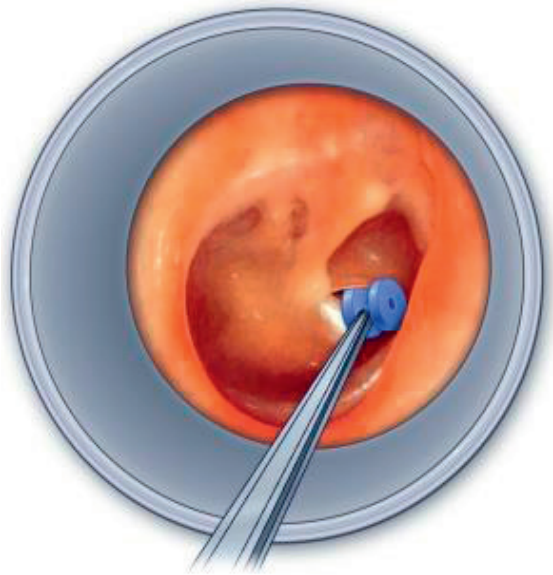

Figure 3. Illustration of a ventilation tube in the tympanic membrane. *Reproduced with permission from Dr. Timothy Hain, Chicago Dizziness and Hearing*

The long-term results of VTs are uncertain and are being debated (139, 140). A Cochrane report concluded that they had a small effect on the hearing threshold for children with OME, but that this effect diminishes after six to nine months (130). For recurrent AOM, a systematic review found VTs to reduce AOMs by only one attack during the first six months after surgery (141). The efficacy of VT for speech development is also uncertain (130).

1.6.2 Follow-ups after surgery – different guidelines

Once surgery has been performed, follow-up care is desirable to assure that the tubes are functional, that hearing loss has been corrected, and that potential complications are properly diagnosed and managed (138). Examples of complications are otorrhea, occlusion of tubes, premature extrusion, persistent perforation, tympanosclerosis, retraction pocket, cholesteatoma, and focal atrophy of the tympanic membrane. However, a meta-analysis concluded that sequelae after VTs are common but generally transient (otorrhea) or cosmetic (tympanosclerosis, focal atrophy) (142).

Guidelines regarding follow-up care give different advice concerning when, how and by whom the control examinations should be performed (143, 144). The American Academy of Otolaryngology - Head and Neck Surgery recommends that the initial follow-up control take place within one month after tube placement, and then at least once every six months until the tubes extrude (145). There are no official Norwegian national guidelines, but the Norwegian Society of Otorhinolaryngology and Head and Neck Surgery recommend that the first control be done one month after surgery, and then once every four months until the results are as good as possible, which may take years (146). A study from Scotland, however, documented that the majority of the outpatient clinic controls resulted in no clinical interventions, and they therefore questioned the need for regular follow-ups. They suggested performing one control after three months, and then further controls only for children with impaired hearing or complications (147). The Swedish Council on Health Technology Assessment completed a systematic literature review focusing on the documentation of VT treatment. They did not reach a conclusion as to the optimal way to follow up children with inserted VTs (148).

Follow-ups are mostly done by otolaryngologists, and, to some extent, by pediatricians, i.e. on a more expensive health care level than general practice (143). In some places, GPs do some of the follow-ups (144). When we performed Study 1, the idea that GPs carry out some of the follow-ups controls was controversial among Norwegian otolaryngologists. Reasons for their skepticism were that the GPs lacked medical equipment, such as an otomicroscope, and lacked knowledge and experience regarding potential post-surgical complications. Another reason for skepticism was their concern that patients might drop out of follow-ups

since they would not be called in to the GPs' controls but would have to book appointment themselves.

1.6.3 The history behind the change of the VT-guideline

The ENT Department at Trondheim University Hospital had experienced that a number of VT-controls had not led to any clinical intervention. They were also confronting increasingly long general ENT-patient waiting lists and felt the need to prioritize those who were most sick, which most often were patients with other diagnoses. These arguments challenged the cost-benefit balance associated with otolaryngologists performing all the post-VT-surgery controls, and raised the question as to whether this group of children was being 'over-controlled'. Some of the children in need of VTs had medical syndromes or other severe co-morbidities. As it was important for the hospital to prioritize these because of their increased risk of complications, they were not considered for GP follow-ups.

Consequently, the ENT Department decided in 2007 to modify their guidelines for follow-up care after insertions of VTs, in agreement with the GPs in the municipality (see Prologue). After the guideline modification, the otherwise healthiest children, i.e. with either normal hearing or only minor hearing loss, were to receive their follow-ups in general practice, the first six months after surgery and then at 18 months. Children with medical syndromes – hearing loss above 30 decibel (dB) in at least one frequency, 0.5-1-2-4 kilohertz (kHz) in the worst ear, or unresolved hearing (not audiological tested, but with suspected severe hearing loss) – were advised to continue receiving their follow-ups at the outpatient clinic. The time frame for controls at the outpatient clinic could vary depending on the severity of the disease.

The GPs received a simple guideline for how to handle complications related to VT treatment, such as treating a plugged tube with eardrops for two weeks followed by another control by the GP, and to refer the patient back if a VT had not been spontaneously rejected within 18 months (see Appendix 2). After insertion of the VT, the parents were informed about the new procedure verbally and in writing and instructed to make follow-up appointments with their GP themselves (see Appendix 3).

2. Theoretical framework

2.1 Natural science and phenomenology

Many scholars have attempted to characterize the basis for knowledge in general practice because the clinical discipline demands such complex competence and skills (149). When GPs encounter patients' problems, which might be complex, traditional biomedical knowledge is only one component of the applicable knowledge base. General practice as a discipline traditionally uses both the humanities and the natural sciences as points of reference (108, 150).

In this thesis, I have used different methodological approaches to seek valid knowledge for different aspects of general practice. The quantitative study in this thesis relies on 'natural science'. Natural science may be concerned with the description, prediction, or understanding of natural phenomena, based on observational and empirical evidence (151). The qualitative study, however, is rooted in a different theoretical framework: phenomenology.

2.2 Phenomenology as philosophy, methodology and method

Phenomenology was first conceptualized by Edmund Husserl (1859-1938). His point of departure was a reaction to how natural science perceived itself, that it considered its theories of reality to be independent of subjectivity, interpretation, assumptions and historical tradition (152, 153). Natural science searches for objective knowledge about the world through what can be measured and counted. Husserl claimed, however, that for even objective matters to be perceived by us, our consciousness must be involved. In other words, the world as it appears will always be recognized through a person (154). Husserl did not deny the validity of natural science but was concerned about its success which, in his view, had resulted in a profound thoughtlessness as fundamental problems and essential connections in our lives had been pushed into the background. Consequently, he wanted to

establish a basic philosophical science that considered the first-person perspective when trying to fully understand the world (152, 153).

Phenomenology may be understood as a philosophy as mentioned above, but also as a methodology and a method. By ‘methodology’ I mean the theoretical analysis of, and principles associated with, obtaining knowledge (epistemology) (155). Phenomenology as a methodology has been introduced into medical research as a means to gain insight into and describe how human beings experience their ‘lifeworld’ (or ‘Lebenswelt’ as Husserl originally named it) (108, 155). It relies on first-person accounts as a source of knowledge, not only on what can be measured and counted (156). What is of interest to phenomenologists is not to know whether a thing is real or not, but rather how a person or groups of persons are experiencing it in their own lifeworld. Subjective experiences are seen as a valid source of knowledge also in relation to medicine.

Phenomenology as a ‘method’ refers to the techniques and procedures for gathering, structuring, and analyzing the data engendered by the research question (see 3.2.2) (108, 155). As a method, a phenomenological approach helps us to explore lived experiences in a more systematic way in order to understand the meaning and significance that these hold for the individual persons – in this thesis, for the GPs (108).

3. The present study

3.1 Objectives / aims of the study

The main objective of this thesis has been to develop knowledge about challenges of adhering to clinical guidelines in general practice. More specifically:

- To evaluate the process and patient-outcome after implementation of a new guideline concerning follow-ups after insertion of VTs in the tympanic membrane.
- To explore GPs' experiences with and reflections on the use of multiple guidelines and CPGs in their daily work and the consequences that applying them have for general practice.

To meet these objectives, four papers have been written.

Paper I

The aim was to evaluate the implementation process of a new clinical guideline delegating to GPs the follow-up controls of the healthiest children after insertion of VTs. We focused on: 1) the extent to which the otolaryngologists planned the follow-ups in accordance with the guideline; and, 2) the degree to which the patients consulted their GPs for follow-up care in accordance with the guideline.

Paper II

The aim was to evaluate the VT-guideline by exploring the audiological outcome of the patients two years after surgery. We focused on whether the implementation of the guideline, having GPs perform the VT controls of one group of children, had negatively affected hearing thresholds, the degree of speech recognition, middle-ear function, subjective hearing complaints, or rates of re-surgery.

Paper III

The aim was to gather in-depth information to explore GPs' experiences with and reflections on the use of multiple clinical guidelines in their daily work. We focused on challenges related to adherence.

Paper IV

The aim was to explore GPs' experiences with and reflections on the consequences for general practice of applying multiple clinical guidelines. We focused on the consequences for themselves as GPs and the consequences for their patients.

3.2 Methods and material

We applied quantitative methods in Study 1 (Papers I and II), and qualitative methods in Study 2 (Papers III and IV). These methods are presented separately.

3.2.1 Study 1: Retrospective, observational study

Design

Our study was initiated two years after the VT-guideline was modified. The study was initiated as quality assurance, to explore whether the children were being safeguarded despite receiving follow-ups at a lower level of health care. Consequently, we did a retrospective observational study and the location of follow-ups was not randomized.

Study sample and setting

We included all patients under the age of 18 who had VTs inserted in at least one ear, at Trondheim University Hospital in Mid-Norway (St Olavs Hospital), within the first 14 months after the VT guideline was modified; i.e. between Nov. 1, 2007 and Dec. 31, 2008. During this period, 137 children underwent surgery. As one child was excluded from the study because of a severe, co-existing disease, 136 were eligible for the study.

The children who completed the audiological consultation became the study sample in Paper I (see Figure 4). In order to make the groups recommended for follow-ups by GPs and those by otolaryngologists more comparable, we excluded from the Paper II study sample those participants from Paper I who had medical syndromes (see Figure 4).

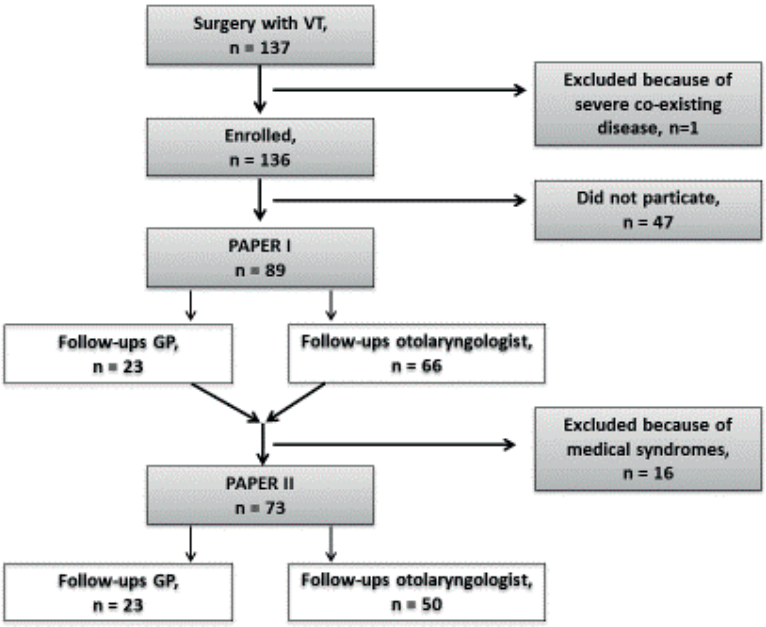

Figure 4. Participants in Study 1, paper I and II

Procedure

The guideline concerning follow-ups after surgical insertion of VTs in the tympanic membrane was put into practice in November, 2007. The implementation strategy, both at the University Hospital and in general practice, was carried out beginning in 2007. The otolaryngologist at the hospital who had inserted the VTs decided which post-surgical follow-ups to delegate.

Approximately two years after surgery (24 ± 3 months), all included children and their parents/guardians were invited by mail to participate in this study regardless of where they had their follow-ups. The invitation included a questionnaire and an appointment for an audiological consultation (See Appendices 1 and 4). Parents and children completed the questionnaire at the time of consultation at the latest, which took place between Nov., 2009 and Dec., 2010.

Data collection

Audiological testing before and 24 ± 3 months after surgery

Information about the audiological tests prior to surgery was obtained from the participants' medical records. If a pre-operative audiological test was lacking, the patient record was examined carefully in an effort to identify cases of suspected hearing loss or unresolved hearing.

The post-surgical tests were carried out at the hospital by two experienced audiologists in a soundproof room (see Appendix 5). Cerumen was removed prior to the examinations. The audiological measures consisted of a pure tone audiogram, speech recognition tests and tympanometry. For those children who, due to age or other reasons, could not cooperate in the examinations, play audiometry or informal hearing tests were used. Results from at least three of the pure tone thresholds in dB at 0.5–1–2–4 kHz had to be present to be analyzed as mean threshold (MTH) (157).

The speech recognition tests were measured with a phonetically balanced monosyllabic Norwegian word list made especially for children, and with three-word expressions (numeral + adjective + noun) (158). The acoustical equipment was calibrated according to International Organization for Standardization (159, 160) and recommended procedures were followed (161, 162). Tympanometry (GSI Tympstar–Middle-Ear Analyzer, Grason-StadlerInc) was used to assess the status of middle-ear functioning (163). The results were categorized as either type A, B or C according to standard rules (see Appendix 5) (164).

Self-report questionnaire

The questionnaire included 16 questions, among them questions about subjective hearing and ear complaints, the number of VT surgeries they had gone through, the date of their most recent surgery, location and frequency of post-surgical follow-ups, and any referrals back to an otolaryngologist (see Appendix 4). The socio-demographic information included parental education and occupation. Before being used in the study, the questions were pilot-tested among employees at the ENT Department.

Statistical analysis

We chose to analyze the groups of follow-ups according to where the participants, at the time of surgery, had been *recommended* to go to have their follow-ups. This means that the analysis was done according to where they had been told to go, not according to where they *actually* went (Paper II, figure 1). Children scheduled for follow-ups at the hospital and by private otolaryngologists were analyzed as one group, the 'otolaryngologist group' (called 'the specialist health service group' in Paper I). Children recommended to have follow-ups performed by their GPs were analyzed as the 'GP-group'.

Data was read optically, quality assured, and then analyzed with IBM SPSS Software (previously called SPSS) (165) and Stata (166). Categorical data were assessed with chi-square tests and Stata Proportion tests, while normally distributed continuous data were assessed with *t*-tests. Hearing thresholds were not normally distributed and were therefore analyzed with non-parametric tests (Mann–Whitney and Hodges-Lehman tests). In addition, the results were re-tested with *t*-tests using the assumption of a normally distributed MTH. The results did not differ depending on the method, and we presented the results from the *t*-tests in Paper II; 95% confidential intervals were calculated from the difference of mean MTH between the groups (see Tables 1 and 2 in Paper II).

When we analyzed the difference between the MTH before and two years after surgery, we analyzed each ear separately (called 'single ears' in Paper II) because the ear with the worst hearing before surgery was not necessarily the worst after two years. In the analysis, we included only results regarding ears that had been hearing tested both before and two years after VT insertion. We performed a linear regression analysis of differences in hearing improvement by type of follow-up, and adjusted for age, re-surgery and shared care. This was done in a separate analysis. A power analysis was performed after the data was collected. With a significance level of 0.05, power of 80%, and a desire to show a 9 dB difference in MTH between the groups, 23 patients were needed in each group. As a result, the study included enough patients to observe group differences in a mean threshold of 9 dB or more.

Ethics

The participants were included only once they had given informed written consent. According to Norwegian regulations, parents/guardians had to consent on their own behalf and on behalf of children under the age of 16, but the children themselves had the right to refuse to participate. Adolescents 16 years and older consented on their own behalf. The Regional Committee for Medical and Health Research Ethics in Central Norway (2009/155-2) and the Norwegian Social Science Data Service (Project number 22169) approved the study. Based on the recorded findings, children requiring prompt attention were offered a medical examination with an otolaryngologist within a few days.

3.2.2 Study 2: Qualitative, focus group study

Design

We wanted to explore GPs' experiences with and reflections on the use of multiple CPGs in their daily work, and the consequences that applying multiple CPGs has for general practice. We chose a qualitative design to explore such knowledge from the GPs' perspective as this is regarded as the best way to arrive at rich descriptions of a complex phenomenon (167, 168). The theoretical framework we used is phenomenology (see Chapter 2). We chose focus group interviews instead of individual interviews both because focus groups are deemed a fast and convenient way to gather data from a number of people and because we thought group discussions would enrich our material (169).

Study sample and setting

We searched for pre-existing groups of GPs because we thought that the participants' familiarity with each other might allow them to reflect more openly (170). The CME system (see 1.5.2) afforded us an overview of the existing local groups that could be approached (111).

For reasons of convenience, we invited only groups from Mid-Norway to participate because this is the region of the country where the researchers live. To ensure a strategic, purposeful sample of GPs within these limitations, we searched for a spread of age and work

experience. We asked two junior groups and two senior groups (see 1.5.2) and planned to include more groups if the material were not adequately saturated. Since the number of GPs in Mid-Norway is limited, I was acquainted with some of the participants in advance of the interviews, though far from all. I used this knowledge to select from groups that included GPs whom I thought would have varying opinions about the research topic; I wanted the material to be as wide-ranging as possible. I contacted the supervisor of the junior groups, sending written information about the project by e-mail (see Appendix 7). The supervisor was not asked to take part in the focus group as I considered that the presence of a supervisor might lead to important, honest nuances being withheld. I contacted the group secretaries of the senior groups by e-mail. All four groups agreed to participate though not all participants of each group attended.

Table 1. Characteristics of the study participants in Paper 3 and 4

	Group 1 (n = 7)	**Group 2 (n = 8)**	**Group 3 (n = 3)**	**Group 4 (n = 7)**	**Total (n = 25)**
Female (n)	3	2	0	5	10
Age in years min – max (mean)	31 – 39 (34.3)	45 – 62 (55.9)	40 – 47 (44.3)	31 – 45 (37.0)	31 – 62 (43.4)
Years as GP[1] min – max (mean)	1 – 4 (2.9)[1]	8 – 35 (22.6)	12 – 13 (12.3)	0 – 4 (2.4)[1]	0 – 35 (9.6)
Specialist in general practice (n)	0	8	3	0	11
Specialist in another medical discipline (n)	1	1	0	1	3

[1]Years of experience in open, unselected general practice. Two of the participants with the least experience as GPs had 5-6 years of experience on an Emergency Ward.

Procedure and interview guide

In 2013, each group was interviewed once at the location where they usually met. Three groups met at medical centers. One group met at a café with a 'silent' section. No one other than the researchers and participants was present. The interviews lasted 60-90 minutes. There were two researchers present at all the interviews, one as a moderator and the other as an assistant. I was the moderator in all the interviews and my role was to ensure full participation in the discussion and to facilitate their elaborating on their varying opinions and views. The assistant was responsible for the audio recordings and the notation of the order of speech, as well posing some questions. Hege Therese Bell, a pharmacist and researcher, was the assistant in the first two interviews, and Bente Prytz Mjølstad, one of the co-authors, was the assistant in the last two interviews.

The interviews started with the moderator reading from a Norwegian chronicle that problematized applying disease-specific CPGs in the treatment of multimorbid and elderly patients in general practice (171). The chronicle, based on a paper by Boyd et al., cited an example of treatment recommended for a hypothetical, multimorbid 79-year-old patient (123). The groups were asked what they thought about the article and to what degree it was recognizable from their clinical practices. An interview guide was used, and it included the following main themes (still using the 'old' definition of the term 'clinical guidelines'):

1) Use of national clinical guidelines in their daily practice.

2) Use of local clinical guidelines in their daily practice – including the VT-guideline.

3) Use of clinical guidelines with multimorbid patients.

4) Clinical guidelines as a method for quality assurance in clinical practice.

5) Characteristics of clinical guidelines that might facilitate or hinder GPs' adherence.

The questions were open-ended and the order flexible. Related topics raised spontaneously during the interviews were followed up. Topics concerning the consequences for general practice of applying multiple CPGs were raised spontaneously by the participants during each of the interviews and were thus further explored. The cover pages of some Norwegian national CPGs and local guidelines were briefly presented. The group interviews were audio recorded and videotaped. The videotapes were only used as a supplement when the audio recordings were insufficient to identify which participant had spoken. The interviews were

transcribed verbatim. Overlapping speech was written as sequential voices. Field notes were made immediately after each interview.

Analysis and interpretation

To analyze the data, 'Systematic text condensation' (STC) was used. STC has been developed by Kirsti Malterud, and is a thematic cross-case analysis based on Giorgi's phenomenological analysis (172, 173). It consists of four steps of analysis:

1) Total impression – from chaos to themes

First, all the authors read all the transcripts. I then listened to each of the interviews several times more in order to form an overall impression and to identify some preliminary themes. At this stage, I sought to become aware of my own preconceptions so I could set them aside.

2) Identifying and sorting 'meaning units' – from themes to codes

The data was then organized and 'meaning units' were identified. These are units of text providing knowledge of the phenomenon being studied. These were then sorted and coded. Coding implies decontextualization, temporarily removing parts of the text from their original context for cross-case synthesis in order to analyze topics. The content of the different codes and coding groups changed several times during the analysis. For example, an early stage in the analyses for Paper IV included a coded group called 'implications for the society'. Later in the analysis process, some of its meaning units were re-sorted into the code group 'implications for the patients', and more specifically into the code 'medicalization'.

3) 'Condensation' – from code to meaning

The meaning units were then abstracted and condensed within each of the coded groups. The code groups were then sorted into some subgroups. Every meaning unit within each subgroup was reviewed by all the authors after which the content was reduced into a condensate. A 'condensate' is an invented quotation that maintains, as far as possible, the original terminology utilized by the participants. When a condensate was agreed upon, an

authentic, illustrative quotation was identified. During this process, the titles and boundaries of the codes and code groups were again adjusted, in line with our evolving understanding.

4) 'Synthesizing' – from condensates to descriptions and concepts

At the final stage of the analysis, the data were reconceptualized. The contents of the condensates were 'synthesized' and the descriptions and concepts were presented as major topics and sub-topics that represented the phenomena studied in Paper III and Paper IV. The results were checked as to whether or not they still reflected the validity and wholeness of the original context, and searched systematically for data from the full transcript that might challenge the conclusions.

All four authors of Papers III and IV participated in the analysis and interpretation of the data. We met several times and reached consensus as to the different topics. All the authors have clinical experience either as GPs (Bjarne Austad, Bente Prytz Mjølstad, and Irene Hetlevik) or as a nurse (Anne-Sofie Helvik), and all four are University researchers and educators. MindJet MindManager (174) and NVivo (175) were used as systematization tools in the analysis process for Paper III but not for Paper IV. That systematization was performed both manually, on paper, and in a WORD document.

Ethics

All participants gave written consent to participate in the study (see Appendix 7). They were anonymized. Because there is a limited number of GPs in Mid-Norway, there was a risk that the GPs who were specialists in another medical discipline in addition to general practice might be recognizable. Therefore, their specific medical discipline was not reported in the papers. The research protocol was submitted to the Regional Committee of Medical Research Ethics in Norway. They answered that formal approval was not required since only health personnel were interviewed (2012/2336).

3.3 Summary of results

3.3.1 Synopsis of Papers I-IV

Paper I

Implementing guidelines for follow-up after surgery with ventilation tube in the tympanic membrane in Norway: a retrospective study

Austad B, Hetlevik I, Bugten V, Wennberg S, Olsen AH, Helvik AS: *BMC Ear Nose Throat Disord* 2013, 13:2.

This paper evaluated the implementation *process* of a new guideline delegating the follow-ups after insertion of VTs in the healthiest children to the GPs. We focused on whether the hospital discharged the patients they were supposed to in accordance with the guideline, and to what degree the children consulted a GP for follow-up care. We performed a retrospective observational study. Two years after surgery, all children who had undergone surgery during the first 14 months after the guideline was changed (Nov. 1, 2007- Dec. 31, 2008), and their parents, were invited to participate in the study (n=136).

Results

A total of 89 children (65.4 %) completed the audiological consultation. The hospital adhered to the guidelines with 68.5 % of the children, delegating more to general practice than recommended in the guidelines (25.8 % vs. 12.4 %), but adhered to the guideline with 100% of the children with medical syndromes (n=16). Despite the fact that parents had to make their children's GP follow-up appointments themselves after six and 18 months, only one (4.3 %) did not meet the GP for follow-up controls. In comparison, five children (7.6 %) did not meet the otolaryngologist for controls. However, sharing of care between the GP and otolaryngologist was common. Nearly 30 % of the patients who were intended to have otolaryngologist follow-ups received additional controls by a GP. In total, 60 % were referred back to an otolaryngologist.

Conclusion

Lack of guideline adherence at the hospital may be explained in part by a lack in the quality of the guideline. The implementation was successful as regards patients consulting their GP for controls.

Paper II

Can general practitioners do the follow-ups after surgery with ventilation tubes in the tympanic membrane? Two years audiological data

Austad B, Hetlevik I, Bugten V, Wennberg S, Olsen AH, Helvik AS: *BMC Ear Nose Throat Disord* 2014, 14(1):2.

This paper evaluates the same VT-guideline as described in Paper I, this time by exploring audiological *outcome* and subjective hearing complaints two years after surgery. Since this was a retrospective, observational study, the material was not randomized. The material is the same as for Paper I, except for the exclusion of 16 children with medical syndromes (n=73).

Results

Despite the material not having been randomized, there were no pre-operative differences in audiological measures (audiometry and tympanometry) or socio-demographic data between the children recommended to have their follow-ups by GPs (n = 23) versus by otolaryngologists (n = 50). Two years after surgery, we found no differences between the children in terms of audiological measures such as audiometry, speech recognition tests, tympanometry nor any differences in parental reports of child hearing or ear complaints. Both groups of children had improved hearing and a lower prevalence of middle-ears with effusion. There were no differences in improvement between the children in the GP and otolaryngologist groups of MTH (12.8 vs. 12.6 dB, p = 0.9) or reduction in the number of middle-ears with effusion (78.0 vs. 75.0 %, p= 0.9).

Conclusion

Implementation of a new clinical guideline for follow-ups after insertion of VTs, in which GPs performed follow-up controls of the VTs for one group of children did not negatively affect audiological outcomes two years after surgery. The study was too small to draw firm conclusions about follow-ups after insertion of VTs.

Paper III

General practitioners' experiences with multiple clinical guidelines: A qualitative study from Norway.

Austad B, Hetlevik I, Mjølstad BP, Helvik AS: *Qual Prim Care* 2015, 23(2):70-77.

This paper reports in-depth information acquired by exploring GPs' experiences with and reflections on the use of multiple clinical guidelines in their daily work. We performed a qualitative, focus group study based on a purposeful sample of 25 Norwegian GPs from within four preexisting groups. We analyzed the interviews with STC, which is a method based on phenomenology.

Results

Several GPs regarded clinical guidelines as providing the foundation for quality in their practices. However, they had difficulties adhering to them, and offered compelling reasons for this. Firstly, colliding recommendations and 'guideline overload' made it difficult to maintain an overview and led to frustration. Secondly, clinical guidelines were often experienced as inaccessible, that is, too long and too comprehensive to navigate through easily. However, these difficulties were compensated for in part by an electronic medical guidebook, which provided easy access to recommendations when needed during a consultation. Finally, a mismatch between clinical guidelines and the patients' needs hindered adherence. The GPs were 'patient-centered' in their approach, thus the guidelines were often incompatible with perceived clinical reality.

The discrepancy between considering the guidelines to be necessary while having difficulties adhering to them caused several dilemmas for the GPs. They handled these by applying their clinical judgment and by focusing on the patients' preferences and quality of life more than on adherence to guidelines.

Conclusion

The GPs provided compelling reasons for low adherence to clinical guidelines despite considering them to be necessary. The results challenge the idea that quality of care in general practice is largely synonymous with adherence to guidelines for single diseases.

Paper IV

Applying clinical guidelines in general practice: a qualitative study of potential complications

Austad B, Hetlevik I, Mjølstad BP, Helvik AS: *BMC family practice* 2016, **17**:92.

While Paper III focused on GPs experiences with the *use* of multiple clinical guidelines, this paper provides in-depth information about GPs' experiences and reflections on the *consequences* of multiple clinical guidelines for general practice. We used the same method and material as in Paper III.

Results

While our aim initially was to explore the *consequences* of applying multiple clinical guidelines, the GPs' responses to our open-ended questions clustered spontaneously around *complications*.

Multiple guidelines resulted in a highly problematic situation for the GPs as they often felt obliged to implement clinical guidelines that seemed not to be suitable for their patients; the map and the terrain simply did not match. The GPs also experienced insecurity as to whether or not their own practice was in accordance with the guidelines, were worried about potential supervision cases were guidelines not adhered to, and admitted to sometimes practicing defensive medicine as a result of this.

The complications for their patients which the GPs experienced when applying multiple clinical guidelines included increased risk of polypharmacy and excessive non-pharmacological recommendations, an increased tendency toward medicalization, and, for some, even reduced quality of life.

Conclusion:

The GPs' experienced various negative consequences for general practice when adhering to multiple clinical guidelines each designed to treat single diseases, including their acting as a driver for polypharmacy and overtreatment.

3.3.2 Key findings

Study 1

Despite applying multifaceted methods to implement the VT-guideline at the hospital, there remained a discordance between the guideline and the actual decisions otolaryngologists' made regarding planned follow-up controls. In addition, there was a greater discrepancy between the planned location for the follow-ups and where the patients' checkups were actually performed. The implementation process seemed insufficient for GPs, as the information was not repeated. Nevertheless, the guideline seemed to secure that post-operative controls would be conducted within general practice. When assessed two years after surgery, implementation of the new VT-guideline in which GPs performed follow-up controls for a group of the healthier children had not negatively affected the audiological outcomes or subjective hearing complaints.

Study 2

We found that GPs considered clinical guidelines and CPGs as necessary. Nonetheless, they had difficulties adhering to them. The GPs reported a mismatch between guidelines, which often are designed for single diseases, and their patients as whole persons. This issue seems to have been the most important reason for low adherence according to the GPs. The obligation to apply multiple guidelines each designed for single diseases created various complications, such as an insecurity about their own practice and the tendency to practice defensive medicine. The complications for their patients included an increased risk of polypharmacy, of excessive non-pharmacological recommendations, an increased tendency toward medicalization, and a potentially reduced quality of life.

4. Discussion

4.1 Discussion of methods

This thesis links two studies that apply two different methods – one quantitative and the other qualitative. Reflections on and critiques of these methods are described individually.

4.1.1 Study 1

Reflections on design and study sample

The best research method to elicit valid information when comparing groups is a randomized controlled design. Since our study was retrospective, a randomized controlled design could not be applied (see 3.2.1). This was clearly a weakness, and has as a consequence that it is difficult to draw firm conclusions out of the audiological comparison between the two groups.

However, after the 16 children with medical syndromes were excluded, the two groups studied in our material did not differ as to audiological evaluation or other pre-surgical variables. That was surprising since the intention had been for the otolaryngologists to follow up those with the worst hearing. There is a possibility that the sample was too small for differences to be detected. Other explanations might be a lack of adherence to the VT-guideline amongst otolaryngologists, or that the guideline itself was not precise enough regarding the allocation of follow-ups.

When we compared the two groups of follow-ups two years after surgery, the relatively low number of participants would seem to imply that the material lacked power to detect important clinical differences; i.e. type 2 errors. We calculated that the study included enough patients to observe a group difference in MTH of 9 dB or higher. The commonly held view is that 5 dB constitutes a clinically significant difference. Still, the difference we observed between the mean MTH of the groups (0.2 dB) is so small that, were it to represent the true value, the difference would not be clinically significant. If I were to conduct this study again, I would do the power-analysis *before* the study started, not after the material had been collected, and include enough participants to be able to identify clinically

significant differences between the groups. However, the aim of Paper II was not to assess the 'best follow-up', but to evaluate whether the implementation of a new guideline, in which the GPs performed the VT controls of one group of the children, would negatively affect the audiological variables.

When looking back at the study design, the size of the sample and the comparing of unequal groups prevented arriving at valid results as to the audiological outcome. We therefore concluded in Paper II that further research is needed to consider the implications for follow-ups after VT surgery. Thus, a prospective study with a randomized, controlled design should be chosen. Nevertheless, the study design was consistent with how things actually take place in clinical practice and in the collaboration between the different levels in the health care system.

Reflections on data collection

A strength of this study is in the quality of the audiological tests, which were carried out by two experienced audiologists and conducted in a soundproof room (see Appendix 5). A weakness was that nearly 40% of the patients lacked any record of pre-surgical hearing tests, due primarily to their young age or their lack of cooperativeness during the tests that were attempted.

The questionnaire did not address specific questions to the parents as to how they experienced the follow-ups, though they were invited to provide supplementary information about the follow-up care. Few respondents utilized this opportunity (see Paper 2). Specific questions about patient satisfaction and safety could also have enriched our material.

Reflections on statistical analysis

One of the statistical challenges was that the pre-operative and post-operative MTH diverged somewhat from a normal distribution (see 3.2.1). We published only the results from the *t*-tests, not from the non-parametric tests. In retrospect, I see that the *argument* we offer in Paper II for having presented only the *t*-tests, i.e. that the results of the tests were the same, is not methodologically adequate. If the mean MTH and median MTH values had been close to equal, then the argument in favor of using the *t*-test would have been more correct. In

additional tests, I found some differences between the mean and median MTH (see Appendix 6). Especially in the worst ear two years after surgery, the median values overall were lower. This is probably due to some outliers with impaired hearing, which thereby increased the mean MTH. In additional non-parametric tests, the results were still the same as the published results (see Appendix 6).

The *improvement* in MTH from before surgery to two years after surgery was, however, closer to being normally distributed. It was not ideal to perform the linear regression analysis of the improvement in separate analyses of age, re-surgery and shared care; that was done, however, due to low statistical power. If I were to carry out this study again, I would consider using a linear mixed model for longitudinal data (176).

4.1.2 Study 2

There are numerous criteria for systematic assessment of qualitative methods, but there is no consensus among researchers as to which criteria to apply or what exact terms to use to describe this (177-179). In this section, I will reflect on the strengths and weaknesses of the study to assist the reader in assessing whether to establish confidence in the findings.

Reflections on design and study sample

Choosing a qualitative design provided us with rich descriptions of the phenomena we explored (167, 168). My experience was that the interactions and discussions in the focus groups encouraged the GPs to explore and clarify their views in ways that might be harder to achieve in individual interviews. I think the choice to involve pre-existing groups whose participants were familiar with each other worked well, adding variety and enriching the complexity of our material. It might have proved problematic, however, had the groups not been well-functioning (169).

While opinions vary as to the ideal number of focus group participants, five to eight is generally regarded as appropriate (169). Shortly before one of the interviews, I learned that only three of the participants could attend. I considered choosing another group, but decided to go through with the interview. Despite the low number of participants, the co-authors and

I found that the discussions had been so rich that we decided to include that group in our material. The number of focus groups needed for a saturated material depends on the purpose and complexity of the research question, but between two and eight groups are suggested as an optimal number (170). I approached four groups initially. The fourth interview did not introduce any substantially new themes. After conducting four focus groups, all the authors read the transcripts critically and found the material to be sufficiently saturated.

Diversity is considered a strength in qualitative studies (180). Our sample of 25 GPs was diverse as regards work experience as well as demographic variables such as age and gender. All participants worked in Mid-Norway. Except for that, the participants were not distinctly different from Norwegian GPs as a group (112).

Reflections on analysis

I wanted to use a method for thematic, cross-case analysis to analyze the phenomena. I chose STC (172) which is a further development of Giorgi's psychological phenomenological analysis (173). The method which is commonly applied in Norway, is thoroughly described in relation to the stepwise analysis, and similarities to and differences from other frequently used qualitative methods are identified and transparent (172).

When I look back, I see that the choice of STC was a pragmatic and, for me, a safe choice because I had been introduced to the method when I was a medical student, in connection with a qualitative study. If I had chosen a different method to analyze the material, it might have highlighted different nuances of the results. Nonetheless, I think STC enabled me to analyze the material thoroughly and properly.

Reflections on reflexivity and the researcher's role

'Reflexivity' is defined as an attitude and a strategy whereby the researcher critically assesses his or her own preconceptions and how these may have affected every step of the research process (177). It is not a question of *if* the researcher has influenced the research process, but *how*. Since the researcher's perspective is limited, perspective and position will

influence on what the researcher sees (181). Consequently, it is necessary to account for the researcher's role in order judge the findings (177).

Before I started my PhD, I had been working as a GP for approximately six years and at an ENT-department for one year. In addition, I had been teaching communications skills to medical students at the University. During the period of preparing my PhD, I have worked half-time as a GP. I experienced a disparity between my own limited use of CPGs in practice and the health authorities' expectations that CPGs should be used. I saw that same disparity in my colleagues' work. My PhD research was done in a scientific environment in which aspects of EBM and CPGs have been openly discussed, and also openly criticized.

In the beginning of my PhD period, I was skeptical of several aspects of CPGs (see Prologue). As a result, I chose as my starting point for the interviews an article that problematized CPGs, especially for multimorbid and elderly patients (171). My skepticism towards CPGs at that time may have influenced the results, at least in the beginning of the interviews. However, since I was conscious of this problem in advance, I was careful to ask open-ended questions and tried to be aware of my own preconceptions (see 3.2.2). In addition, we succeeded, in my opinion, at creating a good atmosphere during the interviews; the groups seemed safe, and all of the participants spoke. The participants disagreed with each other about a variety of topics, which both challenged and expanded my preconceptions. For instance, many of the GPs focused on positive aspects of CPGs, such as the security which they found CPGs provided.

I was the moderator and I shared the same profession as the participants. Advantages and disadvantages of this are discussed in the papers. My being a GP seemed to enable them to speak more freely. Most likely, a moderator from a different profession would have influenced the material differently. In addition, I think my experience as a GP and as a teacher of communication skills were advantageous for me as a researcher. By now, such crucial aspects of interviewing, such as listening, asking open-ended questions, and paraphrasing answers, have become my natural way of communicating in my clinical work. A pharmacist and GP assisted during the interviews. Though their role and influence were less prominent, they too had an impact on the interview material.

Reflections on validity, trustworthiness, and transparency

Some qualitative researchers use the terms 'validity' and 'reliability' when discussing the soundness of a qualitative study (182). 'Validity' is seen to be related to the 'appropriateness' of the tools, processes, and data in the study (182). According to Kvale: *"Validity means whether one has in fact investigated what one wished to investigate"(156)*. Others researchers claim that the terms 'validity' and 'reliability' are not applicable to qualitative research because 'validity' presupposes that there is a reality external to our perception of it; 'reliability' is not applicable because it is difficult, if not impossible, to reproduce qualitative study results (108). Instead, they would replace those terms with 'credibility' and 'dependability', respectively (183). Others prefer to replace both terms with 'trustworthiness' (184, 185). There seems to be agreement, however, that despite differences in the terminology used to evaluate qualitative studies, 'reflexivity' (see section above) and 'transparency' are emphasized as important factors for establishing confidence in the findings (186).

I have aimed for transparency at all stages of the research process. For example, this dissertation includes how the study has been conducted, and by whom: two researchers attended the focus groups; four researchers have read the transcripts and discussed the findings. In addition, field notes have been written during the entire research process. I have sought to make my role and my preconceptions transparent. I have described the theoretical framework and also used the well-known method for analysis, STC, to increase the transparency of the analysis. "Consolidated Criteria For Reporting Qualitative Studies" (COREQ) is a tool for reporting important aspects of qualitative studies. It is comprised of a 32-item checklist to help researchers identify and record essential features of the research team, study methods, analysis, etc. (187). The checklist is somewhat controversial (188). Though it is not discussed in the papers, almost all of the 32 items are covered, explicitly or implicitly, here in this dissertation.

Reflections on transferability

The general aim of research is to produce knowledge of interest to a wider circle than just the participants. However, since qualitative research focuses primarily on a specific issue or phenomenon in a specific context, the research findings are not usually expected to be

transferable. Nonetheless, with a rising trend toward knowledge synthesis of evidence derived from qualitative research, evaluation of its transferability becomes relevant (182). Transferability, also described as 'external validity' or 'generalizability' (182, 183), and is, according to Malterud: *The range and limitations for application of the study findings, beyond the context in which the study was done"* (177).

Our study was conducted in Norway, where the health authorities mandate national CPGs and the hospitals develop local guidelines. In addition, adherence to CPGs is regulated through legislation (117). This may limit the transferability of our findings to countries whose approach to the development and implementation of clinical guidelines differs. For instance, our finding regarding the potential for CPG-adherence to create an 'unmanageable situation' for the GPs might not be transferrable to settings where the pressure on GPs to adhere to CPGs is lower. In addition, since the study's subjects were GPs, the results may not be readily transferable to other specialists. The degree to which our findings may be generalized more widely is open to debate. However, I consider our findings concerning a mismatch between disease-specific CPGs and person-centered care could well be transferable, both to general practice outside Norway and to other sectors of primary care where continuity of care and person-centered care are central.

4.2 Discussion of ethics

One of the ethical considerations when the VT-guideline was changed, was the possibility that the quality of the controls children received when having their follow-ups performed by GPs might be sub-optimal. At the same time, this very possibility of harm was one of the reasons for performing the study: it began as a quality assurance study. In addition, to secure the safety of the participants, after the results of their audiological examinations were known, all those who were in need of additional follow-ups were offered an appointment with an otolaryngologist within days.

In the process of publishing Paper IV, I was asked by the journal editors to publish the raw data because of new rules concerning transparency in research. Even though the participants had been anonymized in the transcript, I could not exclude the possibility that a reader with

local knowledge of GPs in Mid-Norway might be able to identify some of them. Anonymity had been a precondition when the participants gave their written consent to participate in the study. I therefore chose not to publish the raw material, and the journal accepted this.

4.3 Discussion of results

4.3.1 Challenges associated with implementing the VT- guideline

Many benefits are seen to be associated with CPGs (189, 190). In this thesis, which focuses on the challenges of adhering to CPGs, more emphasis has been placed on the difficulties that may result from following CPGs than on the benefits.

In Study 1, we examined a simple guideline, or procedure, that offered only two possible choices: follow-ups by GPs or follow-ups by otolaryngologists. The VT-guideline was adhered to in two thirds of the cases. While more patients were directed to receive follow-ups in general practice than the guideline suggested, fully eight of the 11 children who, in accordance with the guideline, were eligible for GP follow-ups were in fact sent to otolaryngologists to have their controls carried out (see Paper II, Figure 1). Numerous reasons for low adherence has been reported previously, such as bad attitudes, lack of knowledge, lack of organizational readiness, and disagreement with CPGs (64, 191). In our study, the reasons for otolaryngologists' lack of compliance were not explored. However, in my opinion, given the multifaceted efforts to implement the guideline at the ENT unit, the causes for low adherence are probably not to be found in the above-mentioned barriers (192). The otolaryngologists had ownership of the guideline as they had developed it themselves, it was frequently repeated, and it was accessible in the internal quality system (see 1.3.2).

Much implementation research focuses on how physicians could alter their clinical practice in order to adapt to new CPGs or research findings (62). For example, one American study found that primary care providers were hardly aware of the new CPG for OME made by the American Academy of Otolaryngology-Head and Neck Surgery (193, 194). Though the authors concluded that primary care practitioners could benefit from additional training, including workshops taught by otolaryngologists, they did not question the quality, relevance

or sustainability of the CPG in the context of primary care (193). When there is a gap between recommendations and clinical practice, it is important to investigate not only the clinicians but also the validity of the CPG (55, 77). Two documented potential limitations for guideline validity are: if they are not made 'well enough' and if the evidence is not 'good enough' (56).

In our study, it is possible that, after a clinical assessment, the otolaryngologists decided as they did because they considered the VT-guideline's instructions regarding the allocation of some of the follow-ups to be inadequate. There might have been a higher rate of adherence if the guideline had been more accurate and specific, defining in writing a hearing level threshold for follow-ups. It may also have helped if more children had been hearing tested in advance of surgery, making it easier to categorize them into follow-up groups. Nonetheless, we found that where the children had actually had their controls performed was often not in accordance with where they had been recommended to have their controls, and shared care was common (see Paper II, Figure 1).

We did not examine the degree to which the GPs adhered to the VT-guideline when doing the controls, or the quality of their controls. We know, however, that the information about the changed guideline was sent out only once (see Prologue), and that the turn-over of GPs was continual. In Study 2, we found that the distributed paper versions of local guidelines were often difficult for the GPs to remember as the years passed. We collected the Study 1 data two to three years after the VT-guideline had been changed. It was likely that, by then, some GPs performed the follow-up controls without remembering this specific guideline.

The implementation of the new VT-guideline did not seem to result in differences in audiological outcome or re-surgery rates, regardless of the type of follow-up. Methodological weaknesses of the study and lack of power to detect minor differences might be masking real differences between the groups (Type 2 error). However, it is possible that, despite uncertain adherence to the guideline, the controls in general practice were acceptable. The most important aspect of the follow-up controls is said to be the ability to tackle complications and to identify those in need of re-surgery (138). General practice is known for providing coordinated care and serving as the first point of contact for most health care needs (99). If a child develops complications after VT surgery, they are likely to experience symptoms such as otorhea, reduced hearing, or pain, which, in turn, might result in their

contacting a GP (138, 142). If the GP were to feel uncomfortable or incapable of handling the situation, or if there were a recurrence of the disease, he or she could confer with or refer to a specialist.

We found a clear improvement in hearing thresholds in both groups of follow-ups two years after surgery. This finding would seem to be in contrast to research documenting a time-limited hearing threshold effect of VT-surgery (130, 195). However, the first hearing test was performed while the children were ill and in need of surgery. Two years later, when the other hearing test was conducted, many of the children were assumed to have recovered from their OME or residual AOM. Some of the children, however, underwent re-insertions of VTs during the follow-up period, which was closer in time to the collected data. A systematic review documented that, with watchful waiting, the average resolution rate of OME (by ear) at 16 to 24 months was 97 % (195). In another systematic review, where the natural cause of otitis media was studied, the authors claim: *"No intervention can be deemed effective simply because it works; to do so may rob nature alone of the credit for resolution or symptomatic relief"* (196). We have not explored 'watchful waiting', and consequently cannot conclude that the VTs were responsible for improved hearing two years later.

These findings indicate how complex it can be to implement even a simple guideline into clinical practice. This experience is at the core of what links our quantitative and qualitative studies. If it is this complex to implement a single guideline, adhering to multiple guidelines simultaneously can be even more complex.

4.3.2 Challenges of adhering to CPGs in general

In Study 2, the GPs reported encountering several challenges when adhering to CPGs, despite considering them necessary for clinical practice. Examples of the barriers we identified including the guidelines being too many, too long, and too comprehensive to navigate through easily. It was perceived as nearly impossible to maintain an overview over all the recommendations and stay updated. The exceedingly high number of CPGs seems to be a result of the single disease approach, which Parekh referred to as 'silo-medicine', wherein every disease or risk factor is to have its own CPG (see 1.3.3) (76). Silo-medicine has been criticized for not being adequate to tackle the complexity of general practice (197).

This fits well with our finding that GPs experienced negative consequences when having to relate to multiple CPGs.

Most implementation research focuses on adherence to single CPGs. The challenges of relating to multiple CPGs simultaneously is seldom a research topic. We are not the first, however, to point out that too many CPGs can create barriers to adherence (198). In particular, the number of 'low-quality' recommendations has been criticized (199); as a result, important work has been conducted to raise the quality of CPGs. GRADE, AGREE and G-I-N have become central tools in this process (200-202). As another example, a simplification of recommendations was developed for primary care practitioners in England; 18 'high impact', evidence-based quality indicators were identified from among 2365 clinical guideline recommendations (203).

The tendency for CPGs to become overly comprehensive may arise from the desire to include every intervention that could possibly be appropriate for a patient with that single disease. In CPGs that had undergone at least one revision, the number of recommendations has been shown to increase 48% from the first to the most recent version (45). The number of recommendations in the Norwegian CPG for diabetes, on the other hand was reduced from 108 to 65 in the 2016 update (204, 205). The GPs reported that, as a prerequisite for adherence, recommendations needed to be so short and accessible that they could be reached during the consultation, i.e. at point-of-care. CPGs in the form of booklets were thus considered unsuited to this purpose. Several studies have documented the limited effect booklets had on adherence to CPGs (206). Since our interviews were conducted, The Norwegian Directorate of Health has stopped sending booklets to GPs. Instead, they use electronic platforms in order to make new CPGs accessible; their focus on implementation strategy has increased (36, 207). A 2016 Cochrane report examining the adapting of CPGs when using implementation tools concluded that certain tools probably did lead to minor improvements in adherence (208).

Several suggestions for how to improve CPG adherence in general practice exist, but there is no agreement among researchers as to which criteria should be applied (1, 67). A list made by Pronvost included five strategies (209). Two of these are: 1) to identify barriers to adoption and then devise supports to address them; and, 2) to identify systems and technological solutions to promote adherence (209). These two strategies fit well with our

finding that an electronic medical guidebook helped GPs gain access to CPGs at point-of-care. This electronic medical guidebook, 'Norsk Elektronisk Legehåndbok' (210), helped them overcome some of the barriers to CPG accessibility, and is frequently used by Norwegian GPs (211). However, a review concluded that even the newest generation of computerized clinical decision support systems, which is evidence-based and fully integrated with electronic health records, only moderately improved morbidity outcomes, but did not affect mortality (212). The Norwegian Institute of Public Health has an ongoing project seeking to tailor implementation strategies for EBM recommendations using computerized clinical decision support systems (213).

Nevertheless, not all obstacles to adherence can be overcome by using electronic medical guidebooks or computerized clinical decision support systems. Barriers related to the CPGs' quality, relevance to general practice, and sustainability still exist (201, 214). For instance, modelling studies have challenged the sustainability of implementing certain CPGs into general practice (54, 55). A literature review of NICE guidelines relating to primary care documented that nearly two-thirds of the publications cited were of uncertain relevance to patients in primary care (215). Older patients are hardly mentioned in CPGs despite their representing a growing proportion of the population (216). In addition, there is a tendency for appraisals of qualitative studies to be excluded from research reports and CPGs, despite the significance that knowledge based on qualitative studies has for GPs (see Chapter 2) (217-219). These factors may influence the validity of the CPGs, and thus further augment the challenges of adhering to CPGs in general practice.

4.3.3 Patient-centered care

GPs encounter patients with their diseases, worries and preferences all present at the same time. CPG recommendations, however, relate to single diseases. CPGs are described as having a 'one-size-fits-all mentality' and without their recommendations taking values, flexibility or contextualization into consideration (220). They rarely include patients' preferences or their quality of life (221). The GPs in our study experienced this as a mismatch between the patients' needs and the CPGs disease focus and found the pressure to adhere to multiple CPGs to be highly problematic.

This finding seems to be rooted in central, historical aspects of general practice (see 1.5.1). The GP often aims to have a patient-centered approach, more in line with Engel's bio-psycho-social disease model (104, 105). This patient-centered model supports GPs in being more committed to the patients' overall health and quality of life than to following the recommendations for each of various single diseases, as our findings show. Our findings challenges, however, the strict disease-focus in the biomedical model and in CPGs (222). Focusing on the whole patient rather than on single diseases is a well-known characteristic of general practice. In their definition of general practice, Wonca Europe states that patient-centered care is a key feature (see Figure 2) (99). One of Barbara Starfield's four main features of primary care was "person- (not disease) focused care" (106). Patient-centered care is considered to be an important aspect of high-quality care (223, 224), and its significance has been illustrated in the "Ten Commandments for patient-centered treatment" (225). The First Commandment is: *"Thou shalt have no aim except to help patients, according to the goals they wish to achieve"* (225).

4.3.4 Multimorbidity and polypharmacy

We found that CPGs for single diseases provided little help to GPs when treating multimorbid patients. This accords well with an increasing amount of research (52, 226). Multimorbidity is found very frequently, especially among elderly patients (118, 120); those are the patients whom most of the GPs in our study encountered daily. Diseases tend to cluster in diseased individuals – a cardiovascular/metabolic cluster, for instance, and an anxiety/depression/somatoform/pain cluster (227). In one paper, the clusters were explored by analyzing multimorbidity patterns in the Norwegian HUNT 3 material (228). The authors found disease clusters that challenged biomedicine's traditional demarcations between mental and somatic diseases as well as between diagnostic categories within each of these domains (228). It has been documented that multimorbidity is more prevalent in deprived areas (229), and is often associated with self-reported difficulties during childhood (230).

Treating patients with multimorbidity involves a variety of challenges (231-233). As we documented, one of these is that CPGs have traditionally been developed to address one disease or risk factor at the time (76, 234). Even though studies have documented successful adherence to single CPGs (235), our findings indicate that it is difficult to use the combined

total of single-disease CPGs that might apply to a multimorbid patient. The GPs reported that the electronic medical guidebook (see 4.3.2) was of little help in the treatment of multimorbid patients. Two qualitative studies found shortcomings when single-disease CPGs were applied to patients with multimorbidity, although they reached different conclusions (236, 237). One of the studies concluded that GPs make *compromises* between patient-centered care and evidence-based care (236) while the other concluded that *integration* of clinical experience and best evidence is required to practice EBM (237). The role of clinical expertise and patient values in evidence-based practice is being debated. Proponents of EBM have argued that EBM include these aspects of clinical practice (80). Opponents, however, claim that these aspects are not given equal weight (238), and describe EBM as 'a movement in crisis' because of just such negative, unintended consequences (see 1.4.2) (239).

Although CPGs have played an important role in improving the health care provided to many people with long-term conditions, they can accumulate so they drive polypharmacy in people with multimorbidity (240). This was also shown by Boyd et al. (123), and in the article with which we began our interviews (171). The article did not seem to arouse controversy; most of the GPs recognized the patient narrative from their own practices. The GPs' considered polypharmacy to be a major problem for many of their patients, and that the pressure to adhere to multiple CPGs for single diseases was seen as one of the drivers for polypharmacy. A study documenting the increase in the amount of drugs taken between 1995 and 2010 attests to how widespread the problem has become (241). A systematic examination of recommendations in 12 NICE guidelines found that applying multiple CPGs simultaneously could potentially result in serious drug-drug interactions between medications recommended for different conditions (242). A major report from the King's Fund concluded that it is necessary to confront the issue of polypharmacy immediately (243).

The issue of polypharmacy is, however, complicated by the fact that some multimorbid patients need to be taking several medications (244), leading some to refer to polypharmacy as 'a necessary evil' (245). It is essential for general practice to have documentation of the effectiveness of the medications prescribed. These are usually studied one at a time, however. As there is very limited empirical evidence available regarding drug interactions, problems arise when several treatments are applied simultaneously to the same patient (246).

4.3.5 CPGs as drivers for medical overuse

The GPs in our study reported being under pressure to adhere to multiple CPGs, and that this sometimes led them to provide more treatment than they actually deemed necessary. Since I began work on my PhD, the focus on overdiagnosis, overtreatment and medical overuse has increased (128). A systematic review in JAMA found that the number of articles on medical overuse nearly doubled from 2014 to 2015 (247). Medical overuse is being recognized as severe problems in many countries (248-250). In July 2016, the BMJ 'Too Much Medicine' initiative joined forces with the overdiagnosis group of the UK's Royal College of GPs to initiate the campaign, 'Better Medicine: Shared Decisions, Best Evidence' (251). They aim to assist health professionals worldwide to make better informed choices about the care they offer, and to engage in critical debate about low-value interventions (251). An article from this group calls for a 'grassroots revolution' among generalists to tackle overdiagnosis and overtreatment (252).

There is a need for professionals to communicate about the issue of medical overuse and to inform the public about it, both carefully and effectively (253). However, there remains some controversy as to how to define it (254, 255). One frequently quoted definition of overdiagnosis is: *"The diagnosis of conditions that will never cause symptoms or harm during a patient's lifetime"* (125, 256). A definition of overtreatment is: *"Treatment that according to sound science and the patient's own preferences cannot possibly help"* (256). Medical overuse, also referred to as 'too much medicine', includes both overdiagnosis and overtreatment (256). In 2016, 'Medical Overuse' became a MeSH –term (both 'Overdiagnosis' and 'Overtreatment' are among their 'Entry Terms'), where it is defined as: *"Excessive or unnecessary utilization of health services by patients or physicians"* (257).

The controversies in today's debate do not focus on *if* medical overuse is a problem, but rather on which areas of medicine it affects, and how to tackle it (258-260). For example, some claim that the amount of cholesterol-lowering drugs being prescribed constitutes overtreatment (261); others claim that it represents an undertreatment (262), and that such undertreatment has resulted in people being harmed (263). Such controversies also exist regarding the treatment of type 2 diabetes (264, 265), and insertions of VTs (266). The emerging concept of systems medicine, also known as 'P4-medicine' ('Predictive, Preventive, Personalized and Participatory') is also being debated (267, 268). While medical

overuse is a major topic of discussion currently, it is not a new problem. Medical overuse may harm patients and the commitment to 'do no harm' has roots stemming from ancient times (251). In 1964, a modernized version of the Hippocratic Oath was written: *"I will apply, for the benefit of the sick, all measures [that] are required, avoiding those twin traps of overtreatment and therapeutic nihilism"* (269).

Apparently, the reasons for medical overuse are multifactorial and complex and several drivers have been identified (270-272). One that we identified was the pressure to adhere to multiple CPGs each designed to treat single diseases. In an essay, Iona Heath describes the role fear plays as a driver for medical overuse, and how it diverts resources from the sick to the well (273). She writes: *"Overdiagnosis of the well and undertreatment of the sick are the conjoined twins of modern medicine"* (273). Other drivers for overtreatment have been found to be an intolerance of error, a culture of blame (274), and the fear physicians may experience when they consider not intervening (275).

The intent behind CPGs is not to provoke overtreatment but rather to assist practitioners in offering their patients the best treatment possible. Some CPGs do include recommendations for when to refrain from offering treatment (276); others state explicitly that CPGs are to be considered as supplementary to clinical judgment (6). Nevertheless, GPs in our study said that they would sometimes prescribe a medication in order to 'cover their back', rather than because they deemed it medically necessary. This gives an indication of how difficult it can be to manage the pressure to adhere to CPGs in actual practice. This finding is supported by an article that questions whether we have given CPGs too much power (277).

It may seem paradoxical that developing and implementing CPGs for single diseases, with the intention of facilitating the best quality of care, may result in medical overuse and thus potentially do harm (278). The 'Choosing Wisely' campaign is one of several initiatives to counteract medical overuse; it lists specific steps physicians can take to promote the most effective use of health care resources (279, 280). The campaign has, however, suffered setbacks, such as an analysis showing that doctors hadn't altered how they practiced following the launch of the campaign (281). Based on our findings, I believe patient-centered care and GPs daring to non-comply to CPGs when necessary can be countermeasures that help prevent some of the overtreatment in general practice.

4.3.6 CPGs for multimorbidity

In 2012, Guthrie et al. suggested three strategies for adapting CPGs that take multimorbidity into account (282) given that CPGs for single diseases were seen to offer GPs little help in the treating their multimorbid patients. These were: 1) cross reference guidelines using electronic delivery; 2) provide guidance as to which treatments were most likely to benefit patients and least likely to harm them; and 3) make better use of existing evidence, e.g. by modelling the effects comorbidities may have on the benefits and harms of treatments (282). These adaptations have been described as necessary but not sufficient (283). For example, cross-referenced CPGs in cases with more than one comorbidity would be nearly unmanageable (283).

Over the last years, researchers have called for the development of a CPG for multimorbidity (221, 283, 284). In September of 2016, a comprehensive CPG for multimorbidity was published by NICE (285) and may prove to be a milestone. Besides including general principles regarding multimorbidity, it has sections focusing on identifying those most likely to benefit from a 'multimorbid approach', on assessing frailty, and on how to deliver a type of patient care that takes multimorbidity into account. The 'multimorbidity approach' to care differs from the single-condition-focused approach to care and focuses on:

1. How the person's health conditions and their treatments interact and how this affects quality of life.
2. The person's individual needs, preferences for treatments, health priorities, lifestyle and goals.
3. The benefits and risks of following recommendations from guidance on single health conditions.
4. Improving quality of life by reducing treatment burden, adverse events, and unplanned care.
5. Improving coordination of care across services (285).

A summary of this recent CPG for multimorbidity is published in the BMJ (286). The 'multimorbidity approach' seems to put the patients at the center, rather than the disease. This is more in line with the preferences the GPs in our study reported for how to meet their multimorbid patients. It is likely that this multimorbidity approach will be a topic of debate

in the years to come (287), and it remains to be seen what impact this and other CPGs for multimorbidity will have in the future.

Yet, another problem remains. How can one be sure that *"the person's individual needs, preferences for treatments, health priorities, lifestyle and goals"* are actually their own rather than having been 'shaped' by the health care system? In Norway, shared decision-making between doctor and patient is required by law (288), and informed choice is increasingly considered to be the best way to determine appropriate care (289). However, some consider preventive medicine and expanding disease definitions to have changed the ethical premises for informed choice, with the result being medical overuse (290).

4.3.7 A 'fundamental inadequacy' of valid medical knowledge

The challenges of adhering to CPGs seem inherently more complicated than merely a question of quality or implementation strategies (219). Currently, a debate is going on about the theoretical and philosophical foundations of EBM and the role of 'natural science' in general practice (197, 291, 292). Proponents point to the various remarkable advances in medical technology and pharmacology to which EBM has contributed (80). While opponents of EBM do not deny these gains, they focus on the reductionism and fragmentation that result when basing their work solely on 'natural science' (293, 294). According to Kirkengen et al., EBM may function in cases that involve very well-defined problems. However, understanding multimorbidity, complex sickness and medically unexplained syndromes, all of which are quite common in general practice, requires the application of a far more sophisticated framework, one which includes phenomenology (293). Others argue for a complementary approach to science. The authors of the paper, "Why several truths can be true", emphasize that neither natural science nor phenomenology can provide an exhaustive explanation of medical phenomena; both are needed. They recommend that those holding diverging perspectives on medical science and practice actively participate in respectful dialogues (295).

In our qualitative study, we used phenomenology to try to grasp the complex phenomena involved in the challenges of adhering to CPGs. We found that the GPs experienced a mismatch between CPGs and their patients, which was probably the main reason for low

adherence. This mismatch is supported by Kirkengen et al. in their critique of EBM (293). They state that, despite EBM's explicit intention to include clinical expertise and patient values, it in fact builds on a philosophy that reduces the concept of the human body to a sort of advanced, biological clock-works. It seems to me as if today's theoretical view is that the human body can be 'fixed' by 'fixing' each of its fragments. Indeed, Western medicine has ended up producing evidence for parts or fragments of the human body, in part as a consequence of Enlightenment philosophy and the resulting dichotomizing of mind/body and subjective/objective (77, 293). Important aspects of human life, however, such as relationships, the subjective experience of health, life experience, values and quality of life, are all absent from this view of human nature (78, 293). This lack may be called a 'fundamental inadequacy' in the basis for determining what is to be deemed as valid medical knowledge (293). Thus, CPGs will have a reductionist 'built-in-error' as long as they rely solely on EBM and natural science.

I think it is essential to recognize and confront this 'fundamental inadequacy' if we are to understand some of the challenges GPs face when attempting to adhere to disease-specific CPGs. Though some CPGs for certain single conditions may seem to work, problems arise when all parts or fragments are to be put together, such as when GPs strive to encounter their patients as whole persons (100, 108).

5. Conclusion

This thesis has explored challenges of adhering to CPGs in general practice. I began by studying the implementation of a new, single guideline for follow-ups after surgical insertions of VTs in the tympanic membranes of children. The study was too small to draw any firm conclusions about follow-ups. Though the VT insertions did not lead to any differences in patients' audiological outcomes, I did find a partial lack of adherence. This indicates that the process of implementing even a simple guideline in an actual clinical setting can be complex.

Studying the challenges of adhering to multiple CPGs, I found that the GPs have compelling reasons for low adherence, despite considering them necessary. The CPGs were too many and inaccessible, that is, too long and too comprehensive to navigate through easily. These barriers could be overcome to some degree by having access to an electronic medical guidebook. However, the main reason for low adherence to CPGs seemed to lie in the mismatch between CPGs made for single diseases and the GPs' patient-centered approach. This became particularly problematic with multimorbid patients. The various negative consequences GPs' experienced when applying multiple CPGs, each of which had been designed to treat single diseases, included their acting as a driver for polypharmacy and overtreatment.

This thesis has contributed to a critique of the paradigm in which 'best practice' is based on CPGs and biomedical research for single diseases or fragments. Today's biomedical research produces evidence pertaining to parts or fragments of the human body, which is seen as providing the basis for determining diseases, for EBM and for CPGs. GPs, however, encounter their patients as whole persons, with all their diseases, worries, values, and preferences presented simultaneously. The map and the terrain simply do not seem to match. Usually, I had presumed that identifying barriers would open opportunities for finding solutions. However, this 'fundamental inadequacy' of the basis for determining what is valid medical knowledge presents a barrier to adhering to CPGs, one which seems difficult to overcome without the biomedical paradigm being revised. As long as most of the health care system remains deeply rooted in this paradigm, designing an 'alternative' approach will remain a difficult task, one that clearly exceeds the scope of this thesis.

6. Implications and future perspectives

CPGs are here to stay, and their influence seems to increase in general practice as well other parts of medicine. Here, I will briefly describe some considerations and practical implications of this thesis for politics and for GPs, and offer some suggestions for future research.

Health care authorities and developers of CPGs need to be aware of the potential negative consequences of implementing single-disease CPGs in general practice, where multimorbidity is highly prevalent. I recommend those future CPGs that are to be mandated in general practice be designed specifically for general practice; the types and prevalence of diseases GPs encounter are quite different from those met in specialist health care. Since modelling studies have challenged the sustainability of several of the recommendations for general practice, this should be taken into consideration before the guidelines are finally determined. I also recommend that future CPGs include information about what is likely to happen if no treatment is given, in order to improve the likelihood of shared decision-making. In addition, making a Norwegian CPG for the management of multimorbidity in general practice should be considered.

This thesis has challenged the presumption that 'best practice' in general practice is always based on adherence to CPGs for single diseases. Therefore, if the pressure towards adherence were to increase, for instance through economic incentives, more regulations, or a higher frequency of supervision cases, the result will probably be that GPs find themselves in more 'unmanageable situations', and might in turn increase the risk of patients being harmed. Finally, I hope for a change in rhetoric so that CPGs are spoken of less as authoritative rules and more as welcome supplements to clinical judgment. This would be more in line with the original American definition, albeit metaphorical: *"Rope or cord that serves to guide one's steps especially over rocky terrain, through underground passages etc."*.

Most important for GPs, I believe, is to maintain their focus on the whole patient, not just the disease. In this thesis, I have described theoretical limitations of CPGs for single diseases, and documented that they often do not fit into general practice. In a clinical context, CPGs might be seen as treatment recommendations based on research, but not

necessarily as the best treatment for the individual patient. I therefore encourage GPs to use their clinical judgment, and to dare to non-comply when necessary, despite pressures from health authorities or others. Doing so might serve as a countermeasure, preventing some unnecessary medical treatment and contributing to better quality of care.

Based on our findings, I recommend research into the following areas:

I recommend exploring follow-ups after surgery with VTs using an adequately large, RCT in order to draw firm conclusions. I would also recommend that the rates of complication be tracked and that the patients' own experience of safety and satisfaction be explored.

Study 2 was conducted from the GPs' perspective. I recommend that similar research be carried out from the patients' perspective to learn how multiple CPGs for single diseases affect their perception of quality of care, and how to ensure actual shared decision-making. I also recommend research be conducted into the consequences of the new 'multimorbidity approach' to care.

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8. Papers I-IV

Paper I

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RESEARCH ARTICLE Open Access

Implementing guidelines for follow-up after surgery with ventilation tube in the tympanic membrane in Norway: a retrospective study

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Abstract

Background: When clinical guidelines are being changed a strategy is required for implementation. St. Olavs University Hospital in Norway modified their guidelines for the follow-up care of children after insertion of ventilation tubes (VT) in the tympanic membrane, transferring the controls of the healthiest children to General Practitioners (GPs). This study evaluates the implementation process in the hospital and in general practice by exploring two issues: 1) Whether the hospital discharged the patients they were supposed to and 2) whether the children consulted a GP for follow-up care.

Methods: A retrospective observational study was performed at St. Olavs University Hospital, Norway and general practice in Mid-Norway. Children under the age of 18 who underwent insertion of VT between Nov 1st 2007 and Dec 31st 2008 (n = 136) were included. Degree of guideline adherence at the hospital and in general practice was measured.

Results: The hospital adhered to the guidelines in two-thirds (68.5%) of the patients, planning more patients for follow-up by their GP than recommended in the guidelines (25.8% vs. 12.4%). All except one contacted their GP for control. In total 60% were referred back to specialist health services within two years.

Conclusions: The methods for guideline implementation were successful in securing consultations for follow-up care in general practice. Lack of guideline adherence in the hospital can partly be explained by the lack of quality of the guideline. Further studies are needed to evaluate the quality of controls done by the GPs in order to consider implications for follow-up after VT surgery.

Keywords: Implementation, Coordination, Clinical guidelines, Primary care, General practice, Ventilation tube, Otitis media

Background

General practitioners (GPs) receive numerous clinical guidelines from hospitals and others, developed with good intentions for quality improvement. Some guidelines will not be implemented and will therefore not have the desired effect [1-3]. In Norway GPs have the role as gate-keepers, expected to refer to secondary care only what cannot be handled in primary care. A Coordination Reform between the hospitals and primary care was set into practice in 2012 [4]. One of the aims has been to transfer obligations and responsibility from secondary to primary care. Development and implementation of clinical guidelines are regarded to be among the major strategies for knowledge transfer [5]. This makes it utterly important to understand how the implementation process works and identify barriers against implementation [6-9].

Children with otitis media with effusion or recurrent otitis media are frequently treated with a ventilation tube (VT) placed in the tympanic membrane [10-12]. Little research has been done on the follow-up care after this kind of surgery. In 2008 the Swedish Council on Health Technology Assessment (SBU) completed a systematic literature review focusing on the documentation of VT treatment. They could not conclude how and when

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children with inserted VTs best should be followed up [13]. In Norway follow-ups of VTs are mostly done by Ear-Nose-Throat (ENT) specialists [14], i.e. on a more expensive health care level than general practice.

St. Olavs University Hospital in Mid-Norway has modified their guidelines for follow-up after VT surgery recommending that children with normal or minor hearing loss should get follow-ups from their GP, first at six months and again at 18 months after surgery. The GP's received a simple guideline on how to handle complications, such as a plugged tube with ear drops for two weeks followed by another control by the GP, and also to refer back to a specialist if the VT was not rejected within 18 months. Children with medical syndromes, hearing loss above 30 dB in at least one frequency (0.5-1-2-4 kHz) in the worst ear, or unresolved hearing (not audiological tested, but with suspected hearing loss), were still recommended to have their follow-ups at the outpatient clinic [15]. Point of time for control at the outpatient clinic could vary depending on the severity of the disease. Arguments for revision of guidelines were cost-effectiveness and to save outpatient clinic resources. However, one worried that children discharged from the hospital might forget controls due to lack of summoning in general practice.

Lack of adherence to guidelines is well known, both in relation to process [2,16] and outcome [17]. Efforts have been made to explore the phenomenon without conclusion [3,5,18,19]. Implementation research has revealed that multifaceted methods for guideline implementation are more successful than use of single methods [20,21]. As a consequence, multifaceted strategies were used for implementation in this study, both at the hospital and in general practice.

To implement the guidelines at the hospital they were: (1) developed by physicians at the ENT department in order to establish ownership, (2) made accessible in the hospital's internal quality system, and (3) repeated several times during daily work at the Department. To implement the guidelines in primary care: (1) the Head of the ENT Department verbally informed the GPs in a mandatory medical meeting for GPs. After discussing the guidelines the GPs agreed to do the follow-ups as recommended in the guidelines; (2) the GPs received written procedures on how the controls should be performed and how to handle complications [15]; and (3) parents were informed verbally and in writing about the new procedure and instructed to make the appointments with their GP themselves [22].

This study explores the process of implementation of the clinical guideline for follow-up after VT surgery. We focus on whether the hospital discharged the patients they were supposed to according to the guidelines and whether the children consulted their GP for follow-up. Audiological outcome or complications are not focused and, thus, have not been assessed.

Methods

Inclusion criteria were insertion of a VT in the tympanic membrane in minimum one ear in patients under the age of 18 at St. Olavs University Hospital the first 14 months after the change of guidelines; i.e. between Nov 1st 2007 and Dec 31st 2008. A total of 137 children underwent surgery in this period and 136 children were relevant for the study. One was excluded because of a co-existing severe disease.

The implementation strategy both in the hospital and in general practice took place in 2007. The parents received the verbal and written information at time of surgery. Nearly two years after surgery (24 ± 3 months) all 136 children with parents/guardians were invited by letter to participate in this evaluation study exploring adherence to clinical guidelines. The invitation included a self-report questionnaire and an appointment for an audiological consultation. The parents and children completed the self-report questionnaire latest at the time of consultation.

The participants were included after informed written consent. Due to Norwegian regulations parents/guardians had to give consent on their own behalf and on behalf of children under the age of 16. Children and adolescents 16 years and older consented on behalf of themselves. The study was approved by the Regional Ethics Committee in Sør-Trøndelag (2009/155-2) and the Norwegian Social Science Data Service (NSD).

Information about the audiological test prior to surgery was obtained from the medical record when the patients were included in the study. The pure tone thresholds at 0.5-1-2-4 kHz form the mean threshold [23]. To be included in the analysis of the mean threshold at least three of these frequencies had to be present. If a preoperative audiological test was lacking, the patient record was read carefully with the purpose of identifying suspected hearing loss or unresolved hearing.

The questionnaire used in the study included 16 questions, among them the number of VT surgeries they had gone through, the date of their most recent surgery, location and frequency of follow-ups after surgery and potential referral back to the hospital. Furthermore, they were asked to provide socio-demographic data, including parental education and occupation. The questions had been pilot tested among employees at the ENT department before used in the study.

Statistical methods

Data was read optically, quality assured and then analyzed with SPSS 19. Categorical data were assessed with chi-square test, while normally distributed continuous data

were assessed with *t*-test and ANOVA. The groups of children scheduled for follow-up by the outpatient clinic (n = 60) and by private ENT clinics (n = 6) were analyzed as one group, the specialist health service group. Most of the children with medical syndromes also had hearing loss or unresolved hearing; they have been categorized only into a medical syndromes subgroup.

Results

A total of 89 children (65.4%) completed the audiological consultation. Two did not deliver the questionnaire. Data characteristics are listed in Table 1. There were no statistical significant differences between gender and age of the participants, mean threshold in the worst ear prior to surgery or parents' education in the GP group compared to the specialist health service group.

Table 2 gives information about the discrepancy between where follow-ups should have taken place according to the clinical guidelines and where follow-ups were planned to take place when the children left the hospital. The hospital adhered to the guideline in 61 (68.5%) of the children. Despite the new guidelines, eight participants were scheduled for follow-ups with the specialist health services instead of the GPs. Of those eight, four had been referred by local hospitals or private ENT clinics, and returned to those hospitals and clinics for their follow-up appointments, one had VT surgery more than four times and the last three had minor or no extra complications.

Table 1 Participants sex, age, time after surgery, audiological status, and parents' level of education

Female (%)	41.6%
Male (%)	58.4%
Age at examination Mean (min-max)	6.1 years (3.0 – 16.4)
Time after surgery Mean (min-max)	2.1 years (1.8 – 3.1)
Ventilation tube surgery more than once n (%)	50 (56.2%)
Audiological tests before surgery n (%)	
Pure tone, speech or play audiometry	45 (50.6%)
Informal hearing tests	6 (6.7%)
Not hearing tested	38 (42.7%)
Age hearing tested Mean (min-max)	4.9 years (1.6 – 12.7)
Age not hearing tested	2.8 years (0.8 – 14.4)
Mean threshold (0.5-2 kHz) before surgery worst ear Mean (min-max)	31.8 dBHL (10 – 83.8)
Education above high-school level mother n (%)	65 (73%)
Education above high-school level father n (%)	55 (61.8%)

dBHL, decibel hearing level; kHz, kiloHertz.

Table 2 Hospital plan versus guideline recommendation for follow-up of patients after surgery

		Hospital plan for follow-up	
		General practitioner (n = 23)	**Specialist health service (n = 66)**
Hospital guidelines for follow-up	**General practitioner** (n = 11)	3	8
	Specialist health service (n = 78)	20	58

Table 3 explores the hospital's plan for follow-up of the 78 children recommended for specialist health service follow-up in the guidelines. In these cases, the hospital did not adhere to the guidelines for 20 (25.6%) children.

Table 4 reports where the patients according to the questionnaire actually went for follow-up. A total of 41 (10 + 31) (47.7%) consulted their GP for VT control, and of those 25 (61.0%) were referred back to the specialist health service. Among the 20 (7 + 13) children scheduled for follow-ups with and actually had the VT controlled by a GP, 12 (60%) were referred back to the specialist health service. Data concerning reasons for being seen by a specialist, even when assigned to the GP for follow-up, could not be obtained.

Six children did not obtain control of the VT at all, one (4.3%) in the GP group and five (7.6%) in the specialist health service group. The one not controlled in the GP group was explained by lack of information about control being necessary; none answered that they forgot to contact the GP for control themselves. In the specialist health service group reasons for not controlling the VT were: lack of information (one), felt no need for control (one) and other reasons (three). Other reasons were specified as: patient ill (one), doctor ill (one) and not summoned (one).

Discussion

The hospital adhered to the guidelines for two-thirds of the children, but to all children who had medical syndromes. According to the guidelines only 11 of 89 children were eligible for follow-ups by the GP, but the hospital planned 23 for GP follow-ups. Of these, all except one consulted their GP after VT surgery.

Strength in this study is the inclusion of all children who underwent VT-surgery, not only those planned to get follow-up care from their GP. However, the response rate to this study - 65.4% - was somewhat low, and many of the children did not have an audiological evaluation before surgery. The best method for research on guideline implementation is a randomized controlled design with the purpose of giving valid information about the

Table 3 Hospital plan for follow-up of the subgroups of patients that according to the guidelines should be followed-up by specialist health service (n = 78)

		Hospital plan for follow-up	
		General Practitioner	Specialist health service
Subgroups of patients which in accordance to the guidelines should be followed by the specialist health service	**Medical Syndrome** n (% of group)	0 (0%)	16 (100%)
	Hearing loss ≥ 30 dB n (% of group)	11 (32.4%)	23 (67.6%)
	Unresolved or suspected hearing loss n (% of group)	9 (32.1%)	19 (67.9%)

chosen method's efficacy. The evaluation done in this study is however more compatible with how things actually take place in clinical practice and in the collaboration between the different levels in the health care system; i.e. the study contributes with information about effectiveness related to guideline implementation.

A broad variety of guideline implementation strategies have been described [6,8,24-26]. However, as "none of the approaches is superior for all changes in all situations; we probably need them all" according to Grol and Grimshaw [9]. Multifaceted methods, motivation of physicians, repetition of recommendations and guideline availability at consultation are demonstrated to be effective [1,5,20,27,28]. In our study, facilitators for implementation in the hospital were the physicians' ownership to the guidelines and repetition of the recommendations. The guidelines were partly initiated because of increasing waiting lists at the outpatient clinic. Other studies have shown that administrative motivated guidelines can be difficult to implement into practice [9].

Implementation at the hospital

The results may give the impression that guideline implementation at the hospital did not succeed. However, all children with medical syndromes did get follow-ups according to the guidelines, so the divergence concerns those with impaired or unresolved hearing. Many of the children were so young at time of surgery that audiological evaluation was not possible; thereby leaving a large amount with unresolved hearing. Hearing loss > 30 dB in at least one frequency appears quite frequently amongst those in need of VT surgery [29,30]. Therefore, it is possible that after a clinical assessment the surgeon regarded the guidelines as partly being inadequate for allocating follow-ups. For instance the guideline does not mention how to define "unresolved hearing" and how to handle children who have been referred from local hospitals or private ENT clinics, leaving these patients to the surgeons' judgment.

The main point in the new guidelines was to delegate controls to the GPs. This was clearly implemented as the surgeons did not end too few as feared in advance, but too many according to the guidelines. Of the eight children that despite the guideline recommendations were planned for follow-up by the specialist health service, it looks as if the surgeons had valid reasons for this decision in most cases. Therefore, two-thirds concordance may be as successful as could be expected with guidelines not being sufficiently detailed to guide practice in all cases.

Implementation in general practice

The fear that parents should forget to take their children to consult the GP for VT control seems groundless in our material. In Norway, a list-based system in primary care was established in 2001 so the participants knew which GP to consult. This fact, in combination with leaving the responsibility to parents for making the appointments themselves may be reasons for the successful implementation of this routine. Other reasons may be that

Table 4 The accomplished follow-up of the patient after surgery compared to hospital plan for follow-up

		Hospital plan for follow-up		
		General Practitioner	Specialist health service	Total
		(n = 23)	(n = 63)[1]	(n = 86)
The accomplished follow-up	No follow-up	1	5	6
	Only General Practitioner	7	3	10
	Only specialist health service	2	37	39
	Both General Practitioner and specialist health service	13	18	31

[1]Missing information from 3 respondents, all in the specialist health service group.

complications, ear-infections and questions concerning the VT work as "reminders" to control the VT [31].

Even if data concerning reasons for referral back to the specialist health service could not be obtained, it is reasonable to expect that persisting tubes, recurrence of the disease, or complications could be among the major explanations. However, some GPs might have experienced uncertainty in controls of the VT, and this could have influenced the high referral rate back to the specialist health service. The implementation strategy included one meeting, and the written procedure on how to control the VT was sent only once to the GPs. Lack of repetition may represent a barrier towards implementation [5] and contribute to the referral rate back to the hospital; after all most GPs do not control many children with VT. One suggestion could be to include the guideline in the discharge report from the hospital in order to make the GP feel more secure in relation to the procedures.

Shared care

One-third of the children planned for specialist health service follow-up also went to their GP to control the VT. We do not know the reasons, but some possibilities may be ear infections, late summoning from the specialist health service or questions after surgery in combination with easier availability at the GP than at the hospital. In addition, it might be that one control took place at the hospital as planned and the patient thereafter was recommended to have follow-ups by GPs. This finding may also indicate that construction of strictly separate recommendations for follow- ups may not be realistic, some degree of shared care will occur, and may also be wanted for different reasons.

Our material is from a university hospital where the sickest children in need of VT in the region are treated. If the study was committed on a local hospital or a private ENT clinic, the percentage of patients who could be controlled by the GP would presumably be higher.

Conclusion

We have examined the process of implementation of new guidelines for follow-up after surgery with VT in the tympanic membrane. Audiological outcome or complications have not been assessed. The hospital adhered to the guidelines in two-thirds of the patients. Lack of guideline adherence can partly be explained by the lack of quality of the guideline. The main point of the guideline was to have more controls in primary care. This was implemented as the hospital discharged more patients than the guidelines suggested.

The implementation was also successful when it comes to patients consulting their GP for controls. Further research is needed to assess the quality of GPs controls.

Competing interest

The authors declare that they have no competing interests.

Authors' contributions

BA participated in design of the study, analysis and interpretation of the data and drafted the manuscript. IH, VB and ASH participated in design of the study, supervising and editing the manuscript. AHO and SW contributed in data collection. All authors read and approved the final manuscript.

Authors' information

BA is a general practitioner and research fellow. IH is professor in general practice and former general practitioner. VB is an Ear-Nose-Throat surgeon and associate professor. AHO and SW are audiologists. ASH is RN, Dr. Philos and researcher.

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Paper II

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RESEARCH ARTICLE Open Access

Can general practitioners do the follow-ups after surgery with ventilation tubes in the tympanic membrane? Two years audiological data

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Abstract

Background: A university hospital in Mid-Norway has modified their guidelines for follow-up after insertion of ventilation tubes (VTs) in the tympanic membrane, transferring the controls of the healthiest children to general practitioners (GPs). The aim of this study was to evaluate the implementation of these guidelines by exploring audiological outcome and subjective hearing complaints two years after surgery, assessing if follow-ups in general practice resulted in poorer outcome.

Methods: A retrospective observational study was performed at the university hospital and in general practice in Mid-Norway. Children below 18 years who underwent surgery with VTs between Nov 1st 2007 and Dec 31st 2008 (n = 136) were invited to participate. Pure tone audiometry, speech audiometry and tympanometry were measured. A self-report questionnaire assessed subjective hearing, ear complaints and the location of follow-ups. This study includes enough patients to observe group differences in mean threshold (0.5–1–2–4 kHz) of 9 dB or more.

Results: There were no preoperative differences in audiometry or tympanometry between the children scheduled for follow-ups by GPs (n = 23) or otolaryngologists (n = 50). Two years after surgery there were no differences between the GP and otolaryngologist groups in improvement of mean hearing thresholds (12.8 vs 12.6 dB, p = 0.9) or reduction of middle ears with effusion (78.0 vs 75.0%, p = 0.9). We found no differences between the groups in terms of parental reports of child hearing or ear complaints.

Conclusions: Implementation of new clinical guidelines for follow-ups after insertion of VTs did not negatively affect audiological outcomes or subjective hearing complaints two years after surgery.

Keywords: Otitis media, Tympanostomy tubes, Follow-up care, General practice, Implementation, Clinical guidelines, Hearing, Children

Background

A large number of children with otitis media with effusion or recurrent otitis media undergo surgery with ventilation tubes (VTs) placed in the tympanic membrane, also known as tympanostomy tubes or grommets. This is done to improve hearing and speech development and to reduce ear complaints [1]. It is described as the most common ambulatory surgery performed on children in the United States [2]. In a cross-sectional questionnaire study of 40,000 Norwegians, the estimated life-time prevalence of surgery was about 12% [3].

The long-term results of VTs are discussed in the literature [4,5]. A Cochrane report from 2010 concluded that they had a small effect on the hearing threshold for children with otitis media with effusion, but this effect diminishes after six to nine months [6]. For recurrent acute otitis media a systematic review found VTs to reduce only one attack of acute otitis media the first six months after surgery [7]. Still, once surgery has been performed, "follow-up care is required to assure that the tubes are functional, hearing loss has been corrected, and potential complications are properly diagnosed and managed" [8]. Examples of complications are otorhea,

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occlusion of tubes, premature extrusion, persistent perforation, tympanosclerosis, focal atrophy of the tympanic membrane, retraction pocket and cholesteatoma [9].

Clinical guidelines

Guidelines regarding follow-up care give different advices concerning when, how and by whom the controls should be made [10-12]. The American Academy of Otolaryngology - Head and Neck Surgery recommend the initial control within one month after tube placement, then at least once every six months until the tubes extrude [13]. The Norwegian national guidelines are similar with the first control one month after surgery, but then once every four months until the results are as good as possible [14]. A study from Scotland documented however that the majority of the outpatient clinic controls resulted in no clinical interventions, and therefore questioned the need for regular follow-ups. They suggested one control at three months, and then only further controls for children with impaired hearing or complications [15]. The Swedish Council on Health Technology Assessment completed a systematic literature review focusing on the documentation of VT treatment. They could not conclude how and when children with inserted VTs best ought to be followed up [16]. Follow-ups of VTs are mostly done by otolaryngologists, and partly by pediatricians, i.e. on a more expensive health care level than general practice [10,17]. Because of the great number of children with VTs, this may be a burden for the specialist health care service and also imply reduced cost-effectiveness for the overall healthcare system.

Change of guideline

In 2007 a university hospital in Mid-Norway modified their guidelines for follow-up care after VT surgery in agreement with the general practitioners (GPs) in the municipality. Previously, all children had follow-ups at the outpatient clinic. After the guideline modification children with normal hearing or minor hearing loss should have follow-ups in general practice; first at six months and again at 18 months after surgery. Children with medical syndromes, hearing loss above 30 dB in at least one frequency (0.5–1–2–4 kHz) in the worst ear or unresolved hearing (not audiological tested, but with suspected hearing loss), were recommended to continue their follow-ups at the outpatient clinic. Point of time for control at the outpatient clinic could vary depending on the severity of the disease. The GPs received a simple guideline on how to handle complications in relation to VT treatment, such as to treat a plugged tube with ear drops for two weeks followed by another control by the GP and also to refer back if a VT was not rejected within 18 months [18]. The parents were informed verbally and in writing about the new procedure and instructed to make the appointments with their GP themselves [19].

Implementation

Development and implementation of clinical guidelines are regarded to be among the major strategies for knowledge transfer [20]. Therefore it is important to understand how the implementation process works, identify barriers against implementation [21-23] and to analyze the outcome after the guideline has been changed [24]. Lack of adherence to guidelines is well known, both in relation to process [25,26] and outcome [27] and will necessarily have the consequence that desired effects fail to appear [28-30]. Implementation research has revealed that multifaceted methods for guideline implementation are more successful than use of single methods [31,32]. As a consequence, multifaceted strategies were used for implementation in this study, both at the hospital and in general practice. We have in another paper described the process of implementation [33]. The hospital adhered to the guidelines in two-thirds of the patients; delegating more patients to primary care than the guidelines recommended. The implementation was successful when it came to patients consulting their GP for controls; all but one (95.7%) went to control the VTs.

This paper examined the outcome, i.e. the audiological outcome and subjective hearing complaints two years after insertion of VTs. We focused on whether the implementation of new clinical guidelines, allowing GPs to control the VTs in one group of children, negatively affected hearing thresholds, degree of speech recognition, or middle ear function for the children.

Methods

Inclusion criteria were insertion of a VT in at least one ear in patients below 18 years at a university hospital in Mid-Norway within the first 14 months after the guidelines were modified; i.e. between Nov 1st 2007 and Dec 31st 2008. During this period 137 children underwent surgery. One child was excluded because of a co-existing severe disease, so 136 were eligible for the study.

Close to two years after surgery (24 ± 3 months) all 136 children with parents/guardians were invited by letter to participate in this study. The invitation included an appointment for an audiological consultation and a questionnaire. The parents and children completed the questionnaire latest at the time of consultation. After completing the audiological examination, participants with severe medical syndromes were excluded from the analysis in this paper to make the groups followed up by GPs and otolaryngologists easier to compare. The allocation of follow-ups after surgery was not randomized, but was made by the otolaryngologist at the hospital who inserted the VTs. The decision was based on the

guidelines and clinical judgment. The scheduled follow-ups were not always in concordance with the guideline recommendations or where the children actually had their controls for different reasons [33]. Figure 1 contains a flowchart of localization of follow-ups.

The participants were included after informed written consent. Due to Norwegian regulations parents/guardians had to give consent on their own behalf and on behalf of children under the age of 16. Adolescents 16 years and older consented on behalf of themselves. The study was approved by the Regional Ethics Committee in Sør-Trøndelag (2009/155-2) and the Norwegian Social Science Data Service (NSD).

Audiological testing before and 24 ± 3 months after surgery

Information about the audiological tests prior to surgery was obtained from the medical record of the participants. The testing after surgery was committed at the hospital by two experienced audiologists in a soundproof room. Cerumen was removed prior to examination. Based on the recorded findings, the children with need were offered a medical examination with an otolaryngologist within a few days.

The audiological measures consisted of a pure tone audiogram, speech recognition tests and tympanometry. In cases where the child due to age or other reasons could not cooperate in these investigations, play audiometry or informal hearing tests were used. Results from at least three of the pure tone thresholds in decibel (dB) at 0.5–1–2–4 kHz had to be present to be analyzed as mean threshold [34]. The speech recognition tests were measured with a phonetically balanced (1) monosyllabic Norwegian word list specially made for children and with (2) three-word expressions (numeral + adjective + noun) [35]. The acoustical equipment was calibrated according to International Organization for Standardization [36,37] and followed recommended procedures [38,39]. Tympanometry (GSI Tympstar–Middle Ear Analyzer, Grason-Stadler Inc) was used to assess the status of middle ear functioning [40]. The results were categorized as either type A, B or C according to standard rules [41].

Self-report questionnaire

The questionnaire included 16 questions, among them questions about subjective hearing and ear complaints, number of VT surgeries they had gone through, date of their most recent surgery, location and frequency of follow-ups after surgery, and eventual referral back to an otolaryngologist. Socio-demographic information included parental education and occupation. The questions had been pilot tested among employees at the Ear-Nose-Throat department before used in the study.

Statistical methods

The groups were analyzed according to where the participants were scheduled to have follow-ups at time of surgery, not according to the guideline recommendations. Children scheduled for follow-ups by the outpatient clinic (n = 45) and by private otolaryngologists (n = 5) were analyzed as one group, the otolaryngologist group.

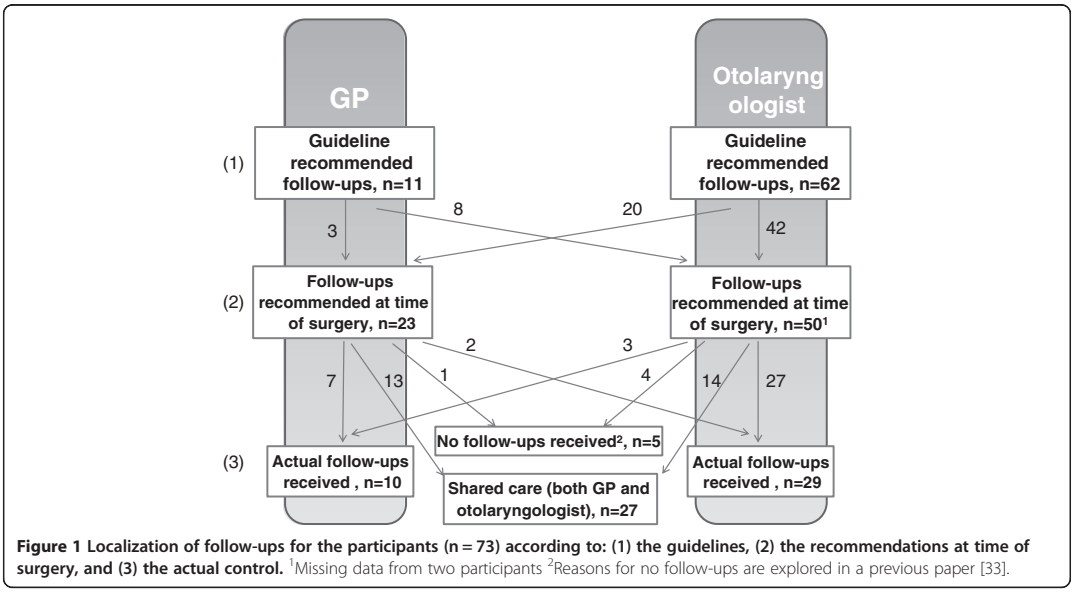

Figure 1 Localization of follow-ups for the participants (n = 73) according to: (1) the guidelines, (2) the recommendations at time of surgery, and (3) the actual control. [1]Missing data from two participants [2]Reasons for no follow-ups are explored in a previous paper [33].

Data was read optically, quality assured and then analyzed with SPSS 21 and Stata 12. Categorical data were assessed with chi-square test and Stata Proportion test. Hearing thresholds and speech audiometry were not normally distributed, and therefore analyzed with non-parametric tests (Mann–Whitney and Hodges-Lehman tests). In addition, the results were retested with *t*-tests (using the assumption of a normally distributed mean) finding the same results as using the non-parametric tests. We present results from the *t*-tests; 95% CI was calculated from the difference of means between the groups. The differences in mean threshold and tympanometry during the follow-up period were analyzed for single ears that underwent VT surgery (excluding myringotomy only) and tested at both time points. Linear regression analysis of differences in hearing by type of follow up was performed adjusting for (1) age, (2) re-surgery and (3) shared care. This was done in separate analysis due to low statistical power. A sample size analysis showed that with a significance level of 0.05, power of 80% and a desire to show a 9 dB difference in mean threshold between the groups, 23 patients were needed in each group. As a result the present study includes enough patients to observe group differences in mean threshold of 9 dB or more.

Results

A total of 89 children completed the audiological examination and 16 of these had severe medical syndromes. Of the 73 participants analyzed in this paper, 23 (31.5%) were scheduled for follow-ups by GPs and 50 (68.5%) by otolaryngologists. Two did not deliver the questionnaire. Not all participants had audiological tests before surgery (see Table 1), but no group differences were found. Those not hearing-tested were younger than those tested (2.5 vs 4.5 years, $p < 0.01$). There were no significant differences between the groups followed-up by GPs or otolaryngologists regarding socio-economic (age, gender, parental education) or audiological variables prior to surgery.

The results from the audiological data and the parental reports of child hearing and ear complaints two years after surgery are listed in Table 2. Some children underwent VT surgery again before the audiological examination in our study (see Table 2). The mean time since last surgery was thereby reduced, and was respectively 22 and 21 months.

The mean threshold for single ears ($n_{GP} = 20$ and $n_{otol} = 39$ ears) improved in both groups (both p values < 0.01) during the follow-up period. There were no significant differences in the mean hearing improvement between the GP and otolaryngologist groups (12.8 vs 12.6 dB, $p = 0.9$). The hearing improvement was still unaffected by scheduled groups of follow-up after adjusting for cofactors in separate analysis as age ($p = 0.9$), re-surgery ($p = 0.9$) and shared care ($p = 0.7$). The proportion of single middle-ears with effusion ($n_{GP} = 20$ and $n_{otol} = 50$ ears) was reduced in both groups after surgery ($p < 0.01$ in both groups). The GP group had a reduction from 90% (18/20) to 25% (5/20) giving a relative reduction of 78%, and the otolaryngologist group from 80% (40/50) to 20% (10/50), a relative reduction of 75%. There were no significant differences between the groups ($p = 0.9$).

In the questionnaire supplementary information about the follow-up care could be provided. Two participants feared lack of competence and equipment at the GP's office; one was not satisfied with the otolaryngologist follow-ups and one commented lack of summoning by the otolaryngologist. Further data of user satisfaction was not conducted. This study has not assessed other

Table 1 Baseline characteristics of socio-demographic data and audiological measures by type of follow-up

	Completed (n)		Type of follow-up:		Δ (95% CI)
	GP	Otolaryngologist	GP	Otolaryngologist	
Socio-Demographic data:					
Gender. Female, n (%)	23	50	10 (43.5)	19 (38.0)	5.5% (-18.9, 29.8)
Male, n (%)			13 (56.5)	31 (62.0)	- 5.5% (-29.8, 18.9)
Age at surgery. Mean (min-max) years	23	50	3.4 (0.9-6.1)	3.9 (1.2-11.8)	- 0.5 yrs (-1.5, 0.6)
Education. One parent or more with higher education[1], n (%)	23	47	20 (87.0)	36 (76.6)	10.4% (-8.0, 28.7)
Audiological measures:					
Audiometry[2]					
Mean threshold[3] best ear, mean (SD) dB[4]	13	27	22.1 (10.0)	22.6 (13.7)	-0.5 dB (-9.2, 8.2)
Mean threshold worst ear, mean (SD) dB	12	27	32.8 (9.2)	33.1 (15.3)	-0.3 dB (-10.0, 9.4)
Tympanometry					
Effusion in one or both middle ears[5], n (%)	12	30	11 (91.7)	26 (86.7)	5.0% (-14.8, 24.8)

[1]Higher education = education after completed high school [2]Pure tone audiometry, play audiometry or informal hearing [3]Mean Threshold (0.5–1–2–4 kHz)
[4]dB = decibel [5]Tympanometry type B, not enlarged ear canal volume.

Table 2 Audiological measures and parental report by type of follow-up 24 ± 3 months after surgery

	Completed (n)		Type of follow-up		Δ (95% CI)
	GP	Otolaryngologist	GP	Otolaryngologist	
Audiometry[1]					
Mean threshold[2] best ear, mean (SD) dB[3]	22	50	11.7 (6.6)	16.2 (11.7)	-4.5 dB (-9.9, 0.8)
Mean threshold worst ear, mean (SD) dB	22	48	19.0 (11.2)	20.8 (14.0)	-1.9 dB (-8.6, 4.9)
Speech recognition tests					
1. Three-words expression[4]					
Best ear 50% perception, mean (SD) dB	16	33	17.0 (6.8)	20.7 (6.8)	-3.7 dB (-7.9, 0.5)
Worst ear 50% perception, mean (SD) dB	15	32	25.9 (13.3)	26.8 (12.8)	-0,9 dB (-9.0, 7.2)
2 Monosyllabic words					
Best ear max perception, mean (SD) dB	22	41	30.2 (7.5)	31.5 (6.1)	-1.2 dB (-4.7, 2.3)
Worst ear max perception, mean (SD) dB	22	40	37.7 (11.4)	37.4 (7.9)	0.5 dB (-4.6, 5.3)
Tympanometry					
Effusion in one or both middle ears[5], n (%)	23	49	6 (26.1)	12 (24.5)	1.6% (-20.0, 23.2)
Parental report of child hearing[6], n (%)					
Better	23	47	20 (87)	39 (83)	4.0% (-13.5, 21.4)
Unchanged			3 (13)	8 (17)	-4.0% (-21.4, 13.5)
Worse			0	0	0%
Parental report of child's ear complaints[6], n (%)					
Better	22	47	16 (72.7)	37 (78.7)	-6.0% (-28.0, 16.0)
Unchanged			5 (22.3)	9 (19.1)	3.2% (-17.2, 24.4)
Worse			1 (4.5)	1 (2.1)	2.4% (-7.2, 12.1)
Re-surgery. One or more surgery during the follow-up period, n (%)	23	50	6 (26.1)	13 (26.0)	0.1% (-21.6, 21.7)

[1]Pure tone audiometry, play audiometry or informal hearing tests [2]Mean Threshold (0.5–1–2–4 kHz) [3]dB = decibel [4]Numeral + adjective + noun (see Methods)
[5]Tympanometry type B and not enlarged ear canal volume [6]In comparison with before VT surgery.

complications than reduced hearing and middle ear function.

Discussion

Implementation of new clinical guidelines for follow-ups after insertion of VTs did not negatively affect audiological outcomes or subjective hearing complaints two years after surgery. Regardless of whether the follow-ups were done by GPs or by otolaryngologists, we found improved mean hearing thresholds (12.8 dB vs 12.6 dB) and a reduced percentage of middle ears with effusion (78% vs 75%).

The strength of this study was that the participants were tested with pure tone audiometry, speech audiometry and tympanometry which give a better overall view of the audiological status than just pure tone audiometry. However, nearly 40% of the children did not have a formal audiological evaluation before surgery because of their low age and difficulties in getting them to cooperate in the tests. The low number of participants implies a possibility that the material lacks power to detect important clinical differences; i.e. type 2 errors. Still, the differences we observed between the groups in mean threshold (0.2 dB) and tympanometry (3%) were so small that if they represent the true values, the differences between the groups are not clinically relevant.

The best method for research on comparing groups is a randomized controlled design with the purpose of giving valid information about the chosen method's efficacy. This was not done in our study. However, the two study groups in our material did not differ by age, sex, parental education or audiological evaluation prior to surgery, even though the otolaryngologists were meant to follow up those with the worst hearing. This was surprising. An explanation could be that the otolaryngologist after a clinical examination considered the location of follow-ups differently than the guidelines, but it is also possible that the guidelines were not precise enough to allocate follow-ups. Again, there is a possibility of type 2 errors. There was a difference though in number of participants in the groups (23 in the GP group vs 50 in the otolaryngologist group). Nevertheless, the aim of this study has not been to measure the "best follow-up", but to examine if follow-up care by the GP can be done without increasing the risk of harm.

Audiological outcome

An increasing number of studies, including the previous mentioned Cochrane report [6], have concluded that there is little or no long-term hearing effect of VT surgery [42,43]. This challenges the need for all children to be controlled by an otolaryngologist, i.e. at a more expensive healthcare level than primary care. In contrast to the Cochrane report, our study demonstrated improved hearing and better middle ear function two years after surgery. Our material was small, and one-fourth of the patients had undergone another surgery in the follow-up period. Also, the interpretation of effusion in the middle ear is difficult because of the possibility of intercurrent disease giving effusion for a short period. This implicates that the results should be interpreted carefully. However, despite adjustment for re-surgery, age and shared care, the improvement of the hearing thresholds and middle ear function were not affected by the group of physicians doing the follow-ups. As far as we know, very few studies have investigated differences in audiological outcome by the follow-up strategy.

Handling complications

Controls after VT surgery are practiced differently internationally, and as the Swedish SBU concluded there is no evidence that one way is superior to another [16]. Thus, once surgery has been performed, it is important to control for complications and to follow up the disease that led to surgery [8]. Some claim that delegating controls to the GPs may lead to increased complications or risk of overlooking a sensorineural hearing loss because they lack experience and good enough equipment to control the children; for instance do very few have otomicroscopy or audiometry [13]. This concern was also mentioned by two of the participants. Severe complications are however rare [44]. According to a meta-analysis "sequelae of tympanostomy tubes are common but are generally transient (otorhea) or cosmetic (tympanosclerosis, focal atrophy)" [9]. The GPs were given a guideline that included advise about how to handle some complications [18]. But still it is possible that these, and other complications, may not be handled according to best practice. However, the GPs can refer back if he or she is uncertain about how to handle complications. In our material 60% were referred back [33]. Reasons for referral back were not assessed, but we discovered that about one-fourth had new ventilation tubes in the follow-up period, so recurrent disease seems to be one reason.

Accessibility

In Norway, the population needs referral from a GP to get access to the public specialist health care system. A list-based system in primary care was established in 2001. As a result, nearly the entire population has one specific GP to consult. This makes it easier to get a consultation with a GP than an otolaryngologist. The accessibility in general practice is also better if the child needs help at another point of time than the specified controls six and 18 months after surgery; for instance because of suspected complications, reduced hearing or questions after surgery. We have earlier documented that one-third of the children went to the GP to control the VTs even though they were scheduled for follow-ups only at the outpatient clinic [33]. This indicates that some degree of shared care will occur. When it comes to diseases like otitis media with effusion or recurrent otitis media with various complaints and need for treatment, the flexibility of follow-ups and shared care may be regarded as an advantage for the patients and their parents.

Future research

Further studies are needed before implications for follow-ups after VT surgery are taken into consideration. A power estimated randomized controlled trial is recommended in order to explore differences in change of hearing thresholds, middle ear function, subjective complaints and complications by type of follow-ups. Future studies should also consider including user satisfaction and other aspects related to the quality of control.

Conclusion

Implementation of new clinical guidelines for follow-ups after insertion of VTs, allowing GPs to control the VTs in one group of children, did not negatively affect audiological outcomes two years after surgery. Regardless of whether the follow-ups were done by GPs or otolaryngologists we found improved hearing thresholds and reduced amount of middle ears with effusion. No differences were found in the parental report of the child's subjective hearing or ear complaints. Because of the limited size of the material we cannot exclude the possibility of overseeing small differences among the two groups. Complications and user satisfaction have not been assessed. Further research is needed to consider the implications for follow-ups after VT surgery.

Abbreviations

VT: Ventilation tube; GP: General practitioner; dB: Decibel.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

BA participated in design of the study, analysis and interpretation of the data and drafted the manuscript. VB and ASH participated in the design of the study, supervising and editing the manuscript; IH participated in supervising and editing the manuscript. AHO and SW contributed in data collection. All authors read and approved the final manuscript.

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Paper III

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Research Article

General practitioners' experiences with multiple clinical guidelines: A qualitative study from Norway

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ABSTRACT

Background: It is well known that general practitioners (GPs) often do not adhere to clinical guidelines, but reasons for this seem complex and difficult to understand. Limited research focuses on the total amount of clinical guidelines as they appear in general practice. The aim of this study was to get in-depth information by exploring Norwegian GPs' experiences and reflections on the use of multiple clinical guidelines in their daily work.

Methods: A qualitative focus group study based on a purposeful sample of 25 Norwegian GPs within four pre-existing groups. The GPs' work experience varied from recent graduates up to 35 (mean 9.6) years. The interviews were analysed with systematic text condensation which is a phenomenological approach.

Results: 1) The GPs considered clinical guidelines to be necessary and to provide quality and safety in their clinical practice. 2) However, they found it difficult to adhere to them due to guideline overload, guidelines that were inaccessible and overly large, and because of a mismatch between guidelines and patients' needs. Adherence was especially difficult in multimorbid patients where several guidelines were expected to be applied at the same time. 3) The discrepancy between judging guidelines as necessary but difficult to adhere to, created dilemmas for the practitioners. The GPs handled these by using their clinical judgement and by putting a greater focus on the patients' complaints and quality of life than on adhering to guidelines.

Conclusions: The GPs provided compelling reasons for low adherence to clinical guidelines despite considering them to be necessary. This challenge the idea that quality of care in general practice is largely synonymous with adherence to guidelines for single diseases.

Keywords: Clinical practice guideline, guideline adherence, general practitioners, patient-centred care, multimorbidity, qualitative research, focus groups.

Abbreviations: GP: General Practitioner; NEL: Norsk Elektronisk Legehandbok (Norwegian Electronic Medical Guidebook); GRADE: The Grading of Recommendations, Development and Evaluation.

How this fits in with quality in primary care

What do we know? Clinical guidelines are developed to improve quality of care, but adherence to guidelines amongst GPs and other clinicians is often low. Several barriers against adherence are identified, but despite strategies to overcome them, guideline adherence seems both difficult and complex. General practice is a broad discipline, and guidelines for several different diseases are available simultaneously. Still, most research focus on adherence to single guidelines.

What does this paper add? This paper provides in-depth information from the GPs' perspective on the use of multiple clinical guidelines in their daily work, and contributes to a deeper understanding of guideline adherence. The GPs in our study provided compelling reasons for low adherence to guidelines despite considering them to be necessary. They experienced a mismatch between guidelines and the patients' needs and quality of life, and seemed more committed to the patients than adhering to the guidelines. The results challenge the idea that quality of care in general practice is largely synonymous with adherence to guidelines for single diseases.

Introduction

Clinical guidelines are developed to improve quality and reduce undesired variations in health care, and also to help health professionals set appropriate priorities.[1] The National Institute for Health and Care Excellence (NICE) in England and the Scottish Intercollegiate Guidelines Network are examples of providers of national clinical guidelines. In Norway the Directorate of Health is the executive agency for providing the country's national clinical guidelines with recommendations mostly categorized according to the GRADE system. [2,3] Local clinical guidelines may vary between different counties, are often developed by hospitals and are consensus based. [4] The expectation is that the guidelines will result in best clinical practice, and adherence to national clinical guidelines is required by Norwegian regulations. [5]

Even though a great deal of effort is put into the development of clinical guidelines, it is well known that GPs often do not adhere to them. [6] When GPs do not follow guidelines as intended, research findings that have been proven effective do not benefit the population at large, posing a challenge both to society and health authorities. A number of studies have identified varying attitudes towards guidelines and different barriers to adherence. [7,8] Organizational readiness for change is seen as important in the implementation process, although a meta-synthesis of qualitative studies concluded that the purpose of the guidelines may influence adherence just as much as professional attitudes and organizational barriers. [9,10] Despite strategies to overcome barriers, guideline adherence seems both difficult and complex. [11,12]

Although low adherence is mostly regarded as a problem that needs to be solved by altering implementation strategies, some studies question whether it is best for the patient's health that a GP adhere to guidelines that are specific for single diseases.[13-15] In multimorbid patients several guidelines for single diseases could be applied simultaneously, and this is described as problematic.[16,17] Boyd et al generated a possible treatment schedule that would result if all the recommendations in the guidelines were followed on a hypothetical 79-year-old patient with hypertension, diabetes mellitus, osteoporosis, osteoarthritis and chronic obstructive pulmonary disease. The patient would have to take 12 separate medications and be recommended for 14 nonpharmacological activities. [18] The prevalence of multimorbidity is as high as 42 % according to a Norwegian study and 23 % according to a Scottish study and patients with multimorbidity is therefore frequently encountered by GPs. [19-21]

General practice is a broad discipline, and guidelines for several different diseases are available. While implementation of different single guidelines is well documented little research have examined aspects related to adherence to multiple guidelines from the GPs' perspective. In this study we have explored Norwegian GPs' experiences and reflections on the use of multiple clinical guidelines in their daily work. [11,22]

Materials and methods

Research design, recruitment and sampling

We chose to have a qualitative design as this is regarded to be the best way to provide rich descriptions of complex phenomenon. [23] The phenomenon of interest in this study was the GPs' *experiences* with multiple clinical guidelines. [24] The theoretical framework we used is phenomenology, a philosophy and methodology that relies on first-person accounts as a source of knowledge. [25,26] Focus group interviews with pre-existing groups were chosen under the assumption that familiarity with each other would allow participants to reflect more openly. [27] The Norwegian Continued Medical Education program for GPs made it possible to get overview over existing local groups and approach them. For convenient reasons we invited groups only from one region of the country, Mid-Norway, to participate. To ensure a purposeful sample of GPs with a spread of age and work experience two of the groups were junior GPs working towards fulfilling mandatory requirements for specialist training in general practice, which as a part of it required two years of group participation. The two other groups were self-directed under the formal Continued Medical Education frame and were all specialists in general practice (referred to as senior GPs). We planned to include more groups if these four groups did not encompassed sufficient variety in gender and experience. All the authors have clinical experiences as either GPs (BA, BPM, and IH) or as a nurse (ASH) and all four are also university researchers and educators.

Interview settings

Each group was interviewed once in 2013 where the groups usually met. Three groups met at medical centres while one met at a silent café and each interview lasted 60-90 minutes. Two researchers participated as a moderator (BA) and an assistant (BPM in two interviews, HTB in the latter, see acknowledgements). The moderator ensured that all participants joined the discussion, and facilitated elaboration of different opinions and views. The assistant was responsible for the audio tapes, noted the order of speech and also posed some questions.

The interviews started by reading from a Norwegian chronicle that problematized disease-specific clinical guidelines for multimorbid and elderly patients in general practice.[28] The chronicle was based on the previously mentioned example of a multimorbid 79-year-old patient. [29] Then the groups were asked what they thought about the chronicle and whether it was recognizable from their clinical practices. During the discussions we used an interview guide to ensure that we covered the GPs' experiences and reflections on the following main themes: 1) Use of national clinical guidelines in their daily practice, 2) use of local clinical guidelines, 3) use of clinical guidelines in multimorbid patients, 4) guideline characteristics that might facilitate or hinder adherence, and 5) quality assurance in clinical practice. The questions were open ended and the order flexible. Related topics raised spontaneously during the interviews were followed up. The front pages of some Norwegian national and local guidelines were briefly presented. The group interviews were audio taped and transcribed verbatim. Overlapping speech was written as sequential voices.

Analysis and interpretation

We used systematic text condensation which is a modified phenomenological approach. [29,30] It consists of the following steps: 1) Obtaining a total impression and bracketing previous preconceptions, 2) identifying and sorting meaning units

that represented different aspects of the GPs' experiences with guidelines and then coding them, 3) condensing and summarizing the coded groups, and 4) synthesizing descriptions and concepts that reflected how GPs relate to clinical guidelines. MindJet MindManager and NVivo were used in this process. All authors participated in the analysis and interpretation of the data. [31,32]

Ethical approval

All participants gave written consent to participate in the study. They were anonymized. The research protocol was submitted to the Regional Committee of Medical Research Ethics in Norway, but formal approval was not required since health personal only were interviewed (2012/2336).

Results:

Participant characteristics are listed in Table 1. We categorized the results into the following major topics: 1) Guidelines as necessary for clinical practice, 2) reasons for low adherence, and 3) handling guideline dilemmas. These findings are further explored below.

1.Guidelines as necessary for clinical practice

Several participants said they regarded clinical guidelines as the foundation for quality in their practice because guidelines rely on evidence-based medicine. One described them as the 'backbone' in his treatment. However, the exclusion of multimorbid patients in studies that guidelines are based on was seen as problematic because it reduced the transferability of guidelines to general practice. One said that guidelines helped in ending problematic discussions with patients. Some of the junior GPs said that guidelines contributed to safety for the GP in the treatment of patients.

"But they also offer me safety and security in my practice. The guidelines mean someone has probably checked the treatment and done the necessary research."(Group 1, M4)

Some senior GPs were not that concerned with safety. Instead they focused on guidelines as an opportunity to provide similar or equivalent health care despite differences in geography, finances etc.

"I think the guidelines contribute to equality... I'm dedicated in my practice to giving the same treatment to the medical professor as to someone who is less well off." (Group 3, M11)

2.Reasons for low adherence to clinical guidelines

We categorized the reasons for low adherence into three sub-topics: 1) guideline overload, 2) inaccessible and overly large guidelines, and 3) mismatch between guidelines and patients' needs.

Guideline overload

Many national guidelines shown to the GPs were unknown to them, but some were familiar. All participants expressed frustration over the large number of these clinical guidelines, although one junior GP wanted more local guidelines. Participants described the large number of available guidelines as a 'jungle' and said it was impossible to keep up with them all.

"It is not possible for a human being to first take the time to learn them, and then remember them. So, you don't do it. It is very difficult to develop a routine for specific diseases that you don't see regularly."(Group 1, M1)

The overwhelming number of guidelines and lack of time in clinical practice were described as some of the reasons that guidelines remained unread. One senior doctor described what he did when he received new guidelines:

"I put these booklets (with guidelines) aside. And I plan to read them when I get the time, but I don't. My motivation is rather low, and I become less and less guilty about not reading them until they finally end up on the shelf, where there are quite a few unread guidelines."(Group 2, M5)

Inaccessible and overly large guidelines

Interviewees in all groups expressed frustration concerning the length and accessibility of the guidelines, and not all GPs knew where to find national guidelines. A 150-page national guideline, or even a shortened, 20-page version was seldom used because of the length. Local guidelines were shorter and sometimes simply procedures, which made them easier to use. However, local guidelines were often sent to GPs only as paper versions and were seldom re-sent. The GPs said it was difficult to remember and find these guidelines as the years passed. If the GPs were going to use guidelines they would have to be so short and easily accessible that they could be located and read during a patient consultation.

"You should have time to read it while the patient is out and has a blood test." (Group 4, M13)

Table 1: Characteristics of the study participants.

	Group 1 (n = 7)	Group 2 (n = 8)	Group 3 (n = 3)	Group 4 (n = 7)	Total (n = 25)
Female (n)	3	2	0	5	10
Age in years min – max (mean)	31 – 39 (34.3)	45 – 62 (55.9)	40 – 47 (44.3)	31 – 45 (37.0)	31 – 62 (43.4)
Years as GP[1] min – max (mean)	1 – 4 (2.9)[1]	8 – 35 (22.6)	12 – 13 (12.3)	0 – 4 (2.4)[1]	0 – 35 (9.6)
Specialist in general practice (n)	0	8	3	0	11
Specialist in another medical discipline (n)	1	1	0	1	3

[1]Years of experience in open, unselected general practice. Two of the participants with the least experience as GPs had 5-6 years of experience in an Emergency Ward.

Several GPs used an updated, Norwegian web-based medical decision support tool called "Norsk Elektronisk Legehandbok" (NEL) when they needed guidance. [33] This tool integrates national guidelines into more general medical information on different topics and makes it possible to get answers related to specific details relatively quickly and at point-of-care.

"NEL can help us sort out the information so it takes us five seconds to get the information that the guidelines address instead of having to read through a thick booklet." (Group 1, W1)

This point-of-care tool led to increased awareness of guidelines and was much praised, but some participants were concerned about the increasing amount of information per topic. That also led to reduced use.

"The shoulder guidelines used to be one page in NEL, and now they are ten pages... So the guidelines should not be too long, the advice should be short and simple, and available online."(Group 1, M4)

The GPs expressed varying opinions about electronic reminders in the patient journal as a way to remember and adhere to guidelines. One said it was brilliant and helped doctors remember different aspects of diabetes control, for example, but this was seen as problematic by others if the same patient had to have several different reminders.

"So basically I think it is okay that there are pop-ups on the screen... you get them instantly and you can skim through them. But if it is overwhelming, like a primeval forest of guidelines, then, 'Help, delete button!'"(Group 3, M12)

Mismatch between guidelines and patients' needs

While guidelines focus on single diseases and how to prevent or treat them in an ideal way, the GPs were 'patient centred' in their approach - focusing on the patients' symptoms and quality of life. That meant that guidelines were often not compatible with clinical reality.

"It is quite artificial because that's not how it is in everyday life. She has all the diseases in everyday life as well, but she doesn't say: 'I have these 5-6 diseases, what will you do about them?' She comes with a symptom: I'm more breathless now than I was last week." (Group 4, W8)

Many of the GPs said that the guidelines would not fit their individual patient, even for what could be seen as a 'simple' medical situation.

"Even in patients where only <u>one</u> guideline is applicable or with <u>one</u> disorder we still only follow the guidelines to a certain extent. And that is probably because it is unrealistic; it does not fit with the reality of what we see in general practice. ... They were created with the best intentions, but they do not fit." (Group 2, M5)

The difference between guidelines and clinical practice was extremely problematic in the treatment of multimorbid patients and those with complex medical stories. The GPs reported frequently encountering multimorbid patients; the senior GPs on daily basis but less often for some of the junior doctors. Applying several clinical guidelines simultaneously to the same patient was described as neither desirable nor feasible. This was described as a major reason for low adherence.

"If a pregnant woman also has hypertension, diabetes, and is overweight, there will be many conflicting guidelines. And the general problem for us is that they conflict, because it reduces the quality of life for the patients if we follow one guideline after another." (Group 2, M6)

3.Handling guideline dilemmas

The discrepancy between seeing the guidelines as necessary and having difficulties adhering to them caused several dilemmas for the GPs. They presented numerous examples of guidelines that conflicted with the patients' own preferences and quality of life. When several guidelines were applicable simultaneously or when recommendations conflicted, the GPs prioritized amongst them and used their clinical judgement to handle the situation.

"If the patient has colon cancer it's not <u>that</u> important that their HbA1c is 7, right?" (Group 3, M11)

The GPs seemed to be more committed to patients' complaints and quality of life than in following recommendations from different guidelines. Although this commitment to patients was problematized and nuanced for some guidelines such as follow-ups after breast cancer, nobody disagreed that the main focus was on the patient and not the guidelines.

"It is important that there are guidelines. But then we have to try to translate them into what the patients want. Some will say that going to the doctor every two weeks is positive, they feel secure, want follow-ups from all the specialists, and will take all the medicines... But there are others who don't want that. We have to sort out what is most important for the patient." (Group 4, W7)

The GPs mainly saw the guidelines as advice that could be considered for specific clinical situations, not as 'laws' they were obliged to follow. However, some felt pressured to adhere to guidelines by regulation, supervisory authorities or the specialist health service, and found this problematic.

"Clinical judgement has become vulnerable, because if you make mistakes, it might be reported, and the people who evaluate our actions are lawyers. And their way of thinking is only based on existing guidelines, and the degree to which it has been documented in writing that we followed the guidelines." (Group 2, M7)

Discussion

Summary of main findings

The GPs considered clinical guidelines to be necessary, but they had difficulties adhering to them because of guideline overload, guidelines that were inaccessible and overly large, and a mismatch between guidelines and patients' needs. They handled these dilemmas by using their clinical judgement and by focusing on the patients' complaints and quality of life rather than on guideline adherence.

Strengths and limitations of the study

Our study was conducted in Norway, where national

clinical guidelines are provided by the health authorities and local guidelines are developed by hospitals. This may limit the transferability of our findings to countries that have a different approach in the development and implementation of clinical guidelines. Diversity is considered a strength in qualitative studies. [34] Our sample of 25 GPs was diverse for demographic variables such as age, gender and work experience but all worked in Mid-Norway. Apart from that, participants did not differ systematically from Norwegian GPs as a group. [35] Shortly before the interview we became aware that only three participants could attend one of the focus groups. We considered choosing another group, but decided to go through with the interview. We found the discussion in this group to be rich despite few participants and included therefore the group in our material. After conducting four focus groups, we critically read the transcripts and found the material sufficiently saturated.

The fact that the moderator was a GP can be seen as both an advantage and a challenge. Talking to one of their own profession, with a presumed common understanding of clinical work, could make the participants speak more openly. A challenge could be that the participants wanted to 'comfort' the moderator, thus leading to important contradicting or nuanced views being overlooked. We therefore tried to bracket our preconceptions by asking open questions, and encouraged participants to provide contradicting views. All authors also critically evaluated the interview guide and the results. Our experience was that the moderator being a GP facilitated disclosure of arguments among the participants.

The interviews started with use of a chronicle.[28] This was done because we wanted to explore their experiences with guidelines in their daily clinical work, which includes treatment of multimorbid and elderly patients. Most of the GPs recognized the patient story in the chronicle from their own practice, and the chronicle did not seem controversial to them. On the other hand, this entrance to the focus group interviews could potentially influence the participants to respond more critically on their use of guidelines, than they actually were. However, we think the participants familiarity with each other contributed to make them feel safe in a way that allowed them to disagree with the chronicle and each other. This enhanced the complexity and variety in our material.

Barriers against adherence: attitudes, overly large guidelines and accessibility

The literature describes a number of barriers to the use of clinical guidelines, including poor attitudes towards them. [7] Participants clearly expressed positive attitudes in our study, and considered guidelines necessary. Low adherence despite positive attitudes may seem contradictory, but others studies support this finding. [37] A French study based on 1759 GPs documented that differing attitudes towards guidelines influenced awareness of them, but did not necessarily affect the use of them. [37]

Making guidelines accessible and in a format that is easy to use are known strategies for adherence.[6] In our study the length of the guideline booklets and the total amount of clinical guidelines seemed to work as barriers against adherence. The number of guidelines was compared with the Tower of Babel already in 1998, and since then many new guidelines have been developed.[38] Guideline overload results from a single-disease-approach, sometimes referred to as 'silos', where each single disease or risk factors have their own guideline. [39] However, the use of a point-of-care tool helped the GPs overcome these barriers and access guidelines. The reasons they gave for using the tool summarizes what they need for access: something that is so easily available that it can be located and used during the consultation; i.e. when in need of guidance. The specific point-of-care tool the participants mentioned is frequently used by Norwegian GPs. According to the company producing it 95 % of Norwegian GPs are customers, and it is used daily by more than 60 % .[40]

Nevertheless, the GPs in our study reported compelling reasons for low adherence despite the possibility of accessible and short guidelines. This suggests that reasons for low adherence go deeper than just being a question of altering implementation strategies or overcoming barriers.

Gap between research and clinical practice

It is well known that there is a gap between research findings and clinical practice.[6] To reduce this gap different strategies for implementation and also clinical guidelines are developed. [41,42] Adherence is important to health care authorities and others in order to provide better quality of care. However, a literature review of NICE recommendations for primary care documented that nearly two-third of the publications cited were of uncertain relevance to patients in primary care.[43] Also, when national clinical guidelines are developed in Norway, the number of participating GPs is often low. This complicates the validity of some recommendations for general practice.

Mismatch between guidelines and patients' needs

Levenstein et al described the physicians' twofold task as: "to understand the patient and to understand the disease".[44] The GPs in our study experienced a mismatch between guidelines and patients' needs which created dilemmas for them. On one side they wanted to follow guidelines and also felt pressured to do so, but on the other side they were committed to the patients' needs and quality of life. We believe understanding this tension is important in order to interpret their experiences with guidelines.

There has been an increasing focus in recent years on how multimorbidity challenges the established treatment and guidelines for single diseases. [45,46] Some studies also question whether the theoretical basis and contemporary guidelines for single diseases give the best quality of care. [14,47,48] GPs encounter patients with all their diseases, worries and preferences simultaneously. [49] Clinical guidelines however, focus on single diseases or fragments of medicine, they are based on research on the same topics, and they rarely include patients' preferences, quality of life or the aspect of multimorbidity.[50,51]

In general practice the consultation often aim to have a patient-centred approach - as opposed to being doctor-centred. [52, 53] In this patient-centred model, the patient's story, and the social and psychological context of the presented problem is explored further than in a strict biomedical model, more in line with Engel's bio-psycho-social disease model. [54] More value is given to the presented problem of the patient, and less

to single diseases. Our findings of GPs being more committed to the patients' needs and quality of life than following recommendations for different single diseases is supported by the patient-centred model, but challenges the evidence-based medicine that guidelines for single diseases often are based on.

Even though studies have documented successful adherence to single guidelines our findings indicate that it is difficult to use the combined total of guidelines for single diseases that might apply to individuals, especially in handling multimorbid patients. [22] The mismatch between guidelines and patients' needs seem to be one of the main reasons for low adherence.

Conclusions

The GPs provided compelling reasons for low adherence to guidelines despite considering them to be necessary. Guideline overload and guidelines that were inaccessible and overly large were barriers against adherence, but possible to overcome. Still, the mismatch between guidelines and patients' needs seems to be the main reason for low adherence because the GPs appeared to be more committed to the patients' complaints and quality of life than to following guidelines. Our results provide information for politicians and health care authorities in the development of guidelines for general practice. The results challenge the idea that quality of care is largely synonymous with adherence to guidelines for single diseases. We recommend more research on the role of clinical guidelines for multimorbid patients, and also on the potential for unwanted consequences of guidelines, such as overtreatment and polypharmacy.

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AUTHORS' CONTRIBUTION

BA participated in design of the study, data collection, the analysis and drafted the manuscript. BPM participated in design of the study, data collection, the analysis, and editing the manuscript. IH and ASH participated in design of the study, the analysis, supervising and editing the manuscript. All authors read and approved the final manuscript.

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Applying clinical guidelines in general practice: a qualitative study of potential complications

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Abstract

Background: Clinical guidelines for single diseases often pose problems in general practice work with multimorbid patients. However, little research focuses on *how* general practice is affected by the demand to follow multiple guidelines. This study explored Norwegian general practitioners' (GPs') experiences with and reflections upon the consequences for general practice of applying multiple guidelines.

Methods: Qualitative focus group study carried out in Mid-Norway. The study involved a purposeful sample of 25 Norwegian GPs from four pre-existing groups. Interviews were audio-recorded, transcribed and analyzed using systematic text condensation, i.e. applying a phenomenological approach.

Results: The GPs' responses clustered around two major topics: 1) Complications for the GPs of applying multiple guidelines; and, 2) Complications for their patients when GPs apply multiple guidelines. For the GPs, applying multiple guidelines created a highly problematic situation as they felt obliged to implement guidelines that were not suited to their patients: too often, the map and the terrain did not match. They also experienced greater insecurity regarding their own practice which, they admitted, resulted in an increased tendency to practice 'defensive medicine'. For their patients, the GPs experienced that applying multiple guidelines increased the risk of polypharmacy, excessive non-pharmacological recommendations, a tendency toward medicalization and, for some, a reduction in quality of life.

Conclusions: The GPs experienced negative consequences when obliged to apply a variety of single disease guidelines to multimorbid patients, including increased risk of polypharmacy and overtreatment. We believe patient-centered care and the GPs' courage to non-comply when necessary may aid in reducing these risks. Health care authorities and guideline developers need to be aware of the potential negative effects of applying a single disease focus in general practice, where multimorbidity is highly prevalent.

Keywords: General practitioners, Clinical practice guidelines, Guideline adherence, Multimorbidity, Overtreatment, Patient-centered care, Polypharmacy, Qualitative research, Focus groups

Background

General practitioners (GPs) provide care for any health problems patients might have and general practice is regarded as a cornerstone of the health care systems of many countries. Clinical guidelines build on Evidence-Based Medicine (EBM) and are designed to improve the quality of health care and reduce unwanted variations [1]. If GPs do not follow guidelines as delineated, treatments proven by research to be effective will not benefit the population at large, thus posing a challenge both to society and health authorities. The Directorate of Health, the executive agency in Norway tasked with formulating national clinical guidelines, categorizes their recommendations primarily according to the GRADE system [2].

It is well known that adherence to clinical guidelines in general practice is low [3]; most clinical guidelines are designed for the treatment of single diseases while an increasing amount of research has documented that guidelines for single diseases are of little use in the treatment

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of patients with multimorbidity [4, 5]. Multimorbidity is frequently encountered in general practice, affecting as many as 23 % of the Scottish [6] and 42 % of the adult Norwegian populations [7]. Treating multimorbid patients involves meeting a variety of challenges, only one of which is that guidelines have been created for the treatment of single diseases [8, 9].

Overtreatment is defined as unnecessary health care and has been shown to be highly problematic, both for multimorbid patients and for patients with single, long-standing conditions or risk factors [10, 11]. The reasons for overtreatment seem multifactorial and complex. Questions arise as to the extent to which multiple guidelines are drivers of overtreatment [12]. Boyd et al. documented that adherence to all guidelines simultaneously for a hypothetical multimorbid 79-year-old woman with five different chronic conditions would result in the prescribing of 12 different medications as well as the recommending of a complex, non-pharmacological regimen [13].

In a previous paper, we documented that GPs offered compelling reasons for low adherence to clinical guidelines, despite considering them necessary [14]. One of the main explanations was the mismatch they experienced when caring for the whole patient while using guidelines focused on single diseases [14]. Caring for the whole person rather than just the single disease is a well-known characteristic of general practice [15]. Nonetheless, GPs are expected to implement a variety of clinical guidelines simultaneously, each of which was designed for the treatment of a single disease. Adherence to guidelines is mandated by medical regulations in Norway [16]. The failure to follow guidelines for each single disease has sometimes resulted in practitioners' work being subjected to professional review.

Despite the gap between clinical practice and guidelines being well known, little research focuses on *how* general practice is affected by the demand to follow multiple guidelines [17]. The aim of this study was to explore Norwegian GPs' experiences with and reflections upon the consequences of guidelines for themselves and their patients, particularly multiple guidelines each designed for the treatment of a single disease.

Methods

Research design, recruitment and sampling

We chose a qualitative design as this is regarded as the best way to explore and provide rich descriptions of a complex phenomenon [18, 19]. The theoretical framework we used is phenomenology, a philosophy and methodology that relies on first-person accounts as a source of knowledge [20, 21]. We chose to hold focus group interviews with pre-existing GP groups under the assumption that their familiarity with each other would allow the participants to reflect more openly [22]. The Norwegian Continuing Medical Education (CME) organizes groups of GPs who are working towards fulfilling the mandatory requirements of specialist training in general practice (junior groups) and registers self-selected groups whose members have already completed their specialization (senior groups) [23]. In Norway, participation in a senior group is a requirement for maintaining one's status as specialist. Utilizing the CME system allowed us to have an overview of the existing local groups that we could approach. For reasons of convenience, we invited groups from only one region of the country, Mid-Norway, to participate. To ensure a strategic, purposeful sample of GPs with a spread of age and work experience, we approached two junior groups and two senior groups and planned to include more groups if the material was not saturated. All four groups agreed to participate.

Interview settings

In 2013, each group was interviewed once at the location where they usually met. Three groups met at medical centers while one met at another meeting room. The interviews lasted 60–90 min. Two researchers participated in all the interviews, one as a moderator and the other as an assistant. The moderator (BA) ensured that all participants participated in the discussion and also facilitated the elaboration of their varying opinions and views. As well as posing some questions, the assistant (BPM or HTB – see Acknowledgments) was responsible for the audio-recordings and the notation of the order of speech.

The interviews started with the moderator reading from a Norwegian article that problematized applying disease-specific clinical guidelines in the treatment of multimorbid and elderly patients in general practice [24]. The groups were asked what they thought about the article and whether it was recognizable from their clinical practices. The interview guide included the following main themes: 1) use of clinical guidelines in their daily practice; 2) use of clinical guidelines with multimorbid patients; 3) guideline characteristics that might facilitate or hinder GPs' adherence; and, 4) guidelines as quality assurance in clinical practice. The questions were open-ended and the order flexible. Topics concerning the complications created for general practice by applying multiple clinical guidelines arose spontaneously during all the interviews and were then further explored. The group interviews were audio-recorded and transcribed verbatim.

Analysis and interpretation

To analyze the data, we used 'systematic text condensation', a thematic cross-case analysis based on Giorgi's phenomenological analysis [25, 26]. It consisted of the

following steps: 1) reading and listening to all the material and obtaining an overall impression; 2) identifying 'meaning units', units of text providing knowledge of the phenomenon being studied, and then sorting and coding them; 3) condensing and abstracting the meaning within each of the coded groups; and, 4) synthesizing the condensations into major topics and sub-topics that reflected the GPs' experiences of how following multiple clinical guidelines affected general practice. All the authors participated in the analysis and interpretation of the data. All the authors have clinical experience as either GPs (BA, BPM, and IH) or as a nurse (ASH), and all four are also university researchers and educators.

Results

Participant characteristics are listed in Table 1. While our aim was to explore the *consequences* of applying multiple guidelines, the GPs' interview responses to our open-ended questions clustered spontaneously around *complications.* We categorized the results into: 1) Complications for the GPs of applying multiple guidelines; and, 2) Complications for their patients when GPs apply multiple guidelines. We sub-divided those two topics into the sub-topics elaborated below.

Complications for the GPs of applying multiple guidelines

A highly problematic situation

Some guidelines were experienced as contributing to safety and aiding the GPs in choosing treatments. Nonetheless, attempts to adhere to the combined total of all applicable clinical guidelines resulted in the GPs feeling they lost the overview over the relevant recommendations, which in turn increased their frustration and a tendency to give up on guidelines altogether. The GPs experienced the situation to be highly problematic. As one GP said:

> *When you have so many chronic diseases and are expected to follow all the guidelines – the result is chaos. (Group 1, M4)*

They asserted that, despite clinical guidelines designed for the treatment of single diseases being of little value when treating multimorbid patients, the GPs still felt themselves to be under pressure to attempt to adhere to all of them – even when, as they put it, the map and the terrain simply did not match. In the following quote, one GP reflects over the shortcomings of clinical guidelines in relation to complex medical histories.

> *There are no guidelines yet which can encompass 'complexity-based medicine'. To grasp how to work with the complexity we confront as GPs requires a massive, theoretical quantum leap. Perhaps in 10–15 years we will realize that all of today's reductionist guidelines within the natural sciences were wrong and had led us astray. (Group 2, M7)*

Increased insecurity

Some GPs experienced a growing insecurity as to whether or not their own clinical practice was in accordance with the guidelines. One claimed that if someone were to look systematically at perhaps 100 patient records from each of the GPs in the focus group, mistakes would probably be found in all of them. The total number of demands in the guidelines was simply impossible to meet. This created insecurity.

> *The insecurity that a 'guideline hell' brings is negative, but that is not talked about very often. (Group 2, M7)*

Some of the senior GPs did not feel less secure. One, who was close to retirement age, said that he did not worry anymore about any professional review procedures. However, regardless of how long they had been in practice, most of the GPs hoped to avoid being subjected to licensing review. They feared that the monitoring authorities would evaluate their work based solely on what they should have done according to existing guidelines, without taking their clinical judgement into consideration.

More 'defensive medicine'

The fear of criticism or of being subjected to professional review for failing to adhere to guidelines seems to have led to GPs practicing more 'defensive medicine', such as increasing their prescribing of drugs and making

Table 1 Characteristics of the study participants

	Group 1 ($n = 7$)	Group 2 ($n = 8$)	Group 3 ($n = 3$)	Group 4 ($n = 7$)	Total ($n = 25$)
Female (*n*)	3	2	0	5	10
Age in years min – max (mean)	31 – 39 (34.3)	45 – 62 (55.9)	40 – 47 (44.3)	31 – 45 (37.0)	31 – 62 (43.4)
Years as GP[a] min – max (mean)	1 – 4 (2.9)[a]	8 – 35 (22.6)	12 – 13 (12.3)	0 – 4 (2.4)[a]	0 – 35 (9.6)
Specialist in general practice (*n*)	0	8	3	0	11
Specialist in another medical discipline (*n*)	1	1	0	1	3

[a]Years of experience in open, unselected general practice. Two of the participants with the least experience as GPs had 5–6 years of experience in an Emergency Ward

more referrals to specialists than they actually thought were necessary. As one GP put it:

> *I often chose to 'protect my back' by doing too much, by following up too thoroughly, for instance, ordering additional x-rays or other extra examinations. (Group 4, K10)*

Another participant pointed out that GPs are rarely if ever subjected to professional review for overtreatment.

> *We never get criticized for doing too much. You don't get in trouble for having initiated unnecessary examinations even if they lead to complications. But you can be sure you'll get in trouble if you haven't done enough! We're much more vulnerable to the entire health care system's expectation that things must be done. There's an intense 'action imperative' to do more. (Group 2, M7)*

Keeping thorough patient records seems to be another way the GPs guarded themselves, especially when they knew they had deviated from the guidelines.

> *When I deviate from the guidelines, I am careful to write my reasons down in the patient record. For instance, if I take a patient off acetylic acid because he developed a stomach ulcer, I write that I am aware of the increased risk of a blood clot. Good record-keeping helps protect me. (Group 3, M11)*

Complications for their patients when GPs apply multiple guidelines

Excessive pharmacological and non-pharmacological treatment

Most guidelines include recommendations for medical treatments for diseases and risk factors. The GPs claimed polypharmacy to be a widespread problem for many of their patients, especially the elderly and multimorbid, and they worried that adhering to multiple guidelines might exacerbate that tendency.

> *It's great that there are guidelines, and I try to follow them. But when the patients have several diseases, there are too many guideline recommendations. Especially when patients are getting older, how much medicine should you give them? (Group 3, M12)*

Polypharmacy was considered problematic as it could result in side effects and/or drug interactions while the actual benefit to the individual patient might remain questionable. One participant stated that GPs have a responsibility to counteract polypharmacy. However, several reported difficulty discontinuing medications, especially if a specialist had initiated the treatment.

> *I see how patients go into the hospital and have new medications added because the hospital has followed the guidelines. We often have to take responsibility later for having the patients discontinue some meds and we thereby 'break the rules'. That's no easy job! But we have to try to see the whole patient. (Group 4, K9)*

Some guidelines include non-pharmacological recommendations. The GPs experienced that some of these proved too time-consuming to follow up on for many of the patients – in some cases, even completely unrealistic. As a result, the GPs tried to individualize the recommendations, to tailor them to the patients' needs rather than adhere to them exactly as stated.

> *The treatment must be planned, individually, based on the patient's functional ability, interests, what he actually manages to follow up on in everyday life, how many activities he can tolerate during a week. The non-pharmacological regimen should not place an additional burden on people already struggling with chronic diseases. (Group 4, K6)*

Increased medicalization

The existing guidelines refer to criteria for disease definition, some of which have changed over time. The GPs had experienced treating several patients diagnosed with diabetes and hypertension after such changes of definitions were made. They also described a growing trend wherein complaints previously considered to be common ailments might now be regarded as diseases that physicians were obligated to treat. They were concerned that an increased tendency toward medicalization might result from increasing the percentage of the population that multiple guidelines now defined as being at risk.

> *It seems to me as if some of the guidelines' recommendations are implying: Everybody needs treatment, but so many people just don't know it yet. We GPs have to counteract this and let our patients know that we don't think they'll live any longer or have a better life if we just put them on one additional drug. (Group 2, M6)*

Reduced quality of life

The GPs shared stories about overly-extensive pharmacological and/or non-pharmacological treatments having contributed to a reduction in quality of life for some of their multimorbid patients. Even though longstanding chronic diseases were considered important to treat and

follow up, dilemmas arose when guidelines recommended treatments that the GPs meant did not benefit the patients' overall situation or quality of life.

> *A patient of mine with atrial fibrillation, COPD and heart failure is often hospitalized because of dizziness. The cardiologists treat him every time with a beta blocker, in accordance with the guidelines, but he gets bradycard, so I deprescribe it after every hospital stay. Seen in isolation, he could conceivably benefit from being on that medication, but he does not tolerate it. I regulate treatment according to the patient's symptoms and overall situation. (Group 4, M14)*

In addition, the GPs experienced that the guidelines did not take into account their patients' varying attitudes towards treatment and taking medications.

> *What matters most is the patients' quality of life. We as GPs have to listen to what the patients say, and do the best we can to relieve their suffering. (Group 3, M13)*

Discussion

Summary of the main findings

For the GPs, the obligation to apply multiple guidelines each of which was designed to treat single diseases created various complications. They found it highly problematic to be required to implement guidelines that did not fit their patients, when the map and the terrain simply did not match. They also experienced greater insecurity about their own practice which, they admitted, increased the tendency to practice 'defensive medicine'. The complications for their patients which the GPs experienced when applying multiple guidelines included an increased risk of polypharmacy, of excessive non-pharmacological recommendations, an increased tendency toward medicalization and a potentially reduced quality of life.

Strengths and limitations of the study

Diversity is considered a strength in qualitative studies [27]. Although all participants worked in Mid-Norway (Table 1), our sample of 25 GPs was diverse as regards work experience as well as demographic variables such as age and gender. Otherwise, the participants did not differ systematically from Norwegian GPs as a group [28]. When we realized shortly before one of the focus group sessions that only three participants would be available to attend, we considered choosing a different group. We decided not to cancel the interview and, despite the small number of participants, the discussion that ensued proved to be so rich that we included the data in our material. After conducting four focus groups, we carried out critical readings of the transcripts and determined that the material was sufficiently saturated. As we only interviewed the GPs, all the descriptions of the complications for their patients of following multiple guidelines were from the GPs' point of view, not that of the patients themselves. Nevertheless, we consider the GPs' perceptions to be reliable since they work closely with their patients and are trained to observe how their patients react to medical advice and treatment.

The study was conducted in Norway where national clinical guidelines are provided by the health authorities and adherence is regulated. This may limit how transferable some of our findings might be to countries following different approaches to the development, implementation and regulation of clinical guidelines.

The fact that the moderator was a GP can be considered both as a strength and a limitation. Talking to a member of their own profession and presuming a common understanding of clinical work may have helped the participants speak more openly. On the other hand, the participants might have wanted to 'comfort' the moderator, and consequently downplayed important contradictory views or nuances. To address this potential limitation, we attempted to make our preconceptions overt, to ask open-ended questions and encourage contradicting views. All authors also evaluated the interview guide and the results critically. Our experience was that the moderator being a GP facilitated the disclosure of whatever disagreements existed among the participants.

We began each of the interviews by reading from an article that we presumed would awaken the GPs' awareness of their experiences with adhering to multiple guidelines and stimulate them to reflect on the consequences [24]. The article did not seem to arouse controversy; most of the GPs recognized the patient story in it from their own practice. Conceivably, this way of opening the focus group interviews may have influenced the participants to respond more critically to the consequences of multiple guidelines than they actually were. However, we think the participants' familiarity with each other helped them to feel safe enough to disagree, both with the article and with each other. This added variety and enriched the complexity of our material.

Implications of the findings in context of existing research

Guidelines as drivers of overtreatment

In recent years, the international focus on overtreatment and overdiagnosis has increased, especially concerning multimorbid and elderly patients [29, 30]. The British Medical Journal's series entitled, "Too Much Medicine", and The Journal of the American Medical

Association's, "Less is More", are examples of this increased focus [31, 32]. The following statement was made at the 2013 international scientific conference, 'Preventing Overdiagnosis': "Overdiagnosis harms people worldwide and exacerbates undertreatment by wasting much needed resources" [33]. Still, the definition of overdiagnosis is not clear and the controversy regarding the extent of the problem continues [34]. The GPs in the present study expressed that, despite their intent to avoid overtreatment, polypharmacy and the recommendation of more treatment than they actually deemed necessary, these tendencies represented a widespread problem for their patients. This would indicate that overtreatment is a challenge for Norwegian general practice.

Overtreatment seems to be multifactorial and complex, and several drivers have been identified [35, 36]. One of the drivers which we identified in our interviews with the GPs was the obligation to implement multiple guidelines each designed to treat single diseases when treating multimorbid patients and patients with a variety of risk factors. This finding is supported in other studies criticizing clinical guidelines for extending disease definitions and thus introducing treatment to a larger segment of the population [37, 38].

At the same time, the expressed intention of clinical guidelines is not to provoke overtreatment but to help in offering patients the best treatment possible. Some guidelines include recommendations for when to refrain from offering treatment; others state specifically that guidelines are only to be considered supplementary to clinical judgement [39, 40]. Also, some multimorbid patients need several medications [41]. However, in our findings, GPs' expressed concern about the need to safeguard themselves legally, prescribing medication in order to 'cover their back' rather than because they considered it medically necessary for the patient. This indicates how difficult the pressure to adhere to guidelines can be to manage in actual practice. This finding is supported by an article in the BMJ that questions whether we have given guidelines too much power [42]. Also, the fact that the Norwegian health authorities expect GPs to follow national guidelines might increase the pressure to adhere to multiple guidelines simultaneously, and thereby contribute to overtreatment [16].

Evidence-based medicine in general practice

Clinical guidelines build on EBM and are most often designed to treat single diseases or risk factors [43]. Documentation of the effectiveness of prescribed medication is essential also within general practice. Problems arise, however, and the complexity increases for both the GP and the patient, when several treatments are applied to the same person [44]. There is very limited empirical evidence regarding the effects of mixing medications since they are usually studied one at a time. It is well known that a single disease focus does not seem to function as intended in primary care [45, 46]. The reasons for this have been highly debated with both too much and too little application of EBM being criticized [47]. A literature review of NICE guidelines relating to primary care documented that nearly two-thirds of the publications cited were of uncertain relevance to patients in primary care, and some have claimed EBM to be a movement in crisis [48, 49]. Questions have also been raised as to whether the lacking success of guidelines is implicit within the traditional, biomedical model in which people are treated as if they were advanced, biological clock-works [50, 51].

One Irish study documented that GPs make compromises between patient-centered care and care based on EBM in the management of multimorbid patients [52]. In our study, the GPs expressed that the obligation to implement multiple guidelines designed for treating single diseases that did not benefit the patients' overall health or quality of life left them in a highly problematic and chaotic situation. Focus on the whole patient rather than single diseases is a well-known characteristic of general practice. In their definition of general practice, the European section of the World Organization of Family Doctors (Wonca Europe) states that patient-centered care is a key feature [53]. One of Barbara Starfield's four main features of primary care was: "long-term person- (not disease) focused care" [54]. The patient-centered model, as opposed to the doctor-centered model, ascribes more value to the presented problem of the patient and less to single diseases [17]. This model challenges the disease focus found in clinical guidelines, and thereby also the biomedical research on which the guidelines are based. Working in a patient-centered way in general practice, we believe, can contribute to counteracting some of the tendency toward overtreatment.

Conclusions

The GPs' experienced various negative consequences when adhering to multiple guidelines designed to treat single diseases, including their acting as a driver for polypharmacy and overtreatment. Adherence to clinical guidelines for treating single diseases was experienced as incompatible with a patient-centered approach to the treatment of patients with multimorbidity; the map and the terrain did not match.

This study contributes to a critique of the paradigm in which 'best practice' is based on clinical guidelines and biomedical research for single diseases or fragments. As long as most of the health care system remains deeply rooted in this paradigm, designing an

'alternative' approach will remain a difficult task, one that clearly exceeds the scope of this study. Still, we believe patient-centered care and the GPs' courage to non-comply when necessary can serve as countermeasures to prevent overtreatment. Health care authorities and guideline developers need to be aware of the potential negative effects of single disease focus in general practice, where multimorbidity is highly prevalent.

Abbreviations
EBM, evidence-based medicine; GP, general practitioner; GRADE, the grading of recommendations assessment, development and evaluation; NICE, the national institute for health and care excellence.

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Availability of data and materials
The data supporting the conclusions of this article can be found at the Department of Public Health and General Practice, NTNU, Norwegian University of Science and Technology, Trondheim, Norway. Due to Norwegian regulations and lack of consent from the participants we cannot share the original audio files openly, because it would be possible to identify the participants.

Authors' contributions
BA participated in design of the study, data collection and analysis, and drafted the manuscript. BPM participated in the design of the study, data collection and analysis, and the editing of the manuscript. IH and ASH participated in design of the study, the analysis, and supervising and editing the manuscript. All authors read and approved the final manuscript.

Competing interests
The authors declare that they have no competing interests.

Consent for publication
All participants gave written consent for publication under the precondition that the material was anonymized.

Ethics approval and consent to participate
All participants gave written consent to participate in the study. They were anonymized. The research protocol was submitted to the Regional Committee for Medical and Health Research Ethics in Central Norway, although formal approval was not required since only health personal were interviewed (2012/2336).

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Appendix 1

Invitation and consent to participate in Study 1

ST. OLAVS HOSPITAL
UNIVERSITETSSYKEHUSET I TRONDHEIM
Klinikk for øre-nese-hals, kjeve og øyesykdommer

NTNU, Faculty of Medicine
Department of Public Health and General Practice

Forespørsel om deltakelse i forskningsprosjektet:

"Oppfølging av barn med ventilasjonsrør i trommehinnen"

Bakgrunn

De vanligste årsakene til at det blir operert inn ventilasjonsrør (dren) i trommehinnen er langvarig væske i mellomøret som reduserer hørselen eller tilbakevendende akutte mellomørebetennelser. Drenene faller som oftest ut av seg selv, men ikke alltid, og da bør de fjernes i narkose. Noen barn trenger også å få operert inn dren pånytt.

St Olavs Hospital innførte endrede retningslinjer for *oppfølging* av barn som har fått operert inn dren i ørene 01.11.07. Endringen innebar at en del av barna skulle følges opp av fastlegen istedenfor på sykehuset som det ble gjort tidligere. Kun barn med spesielle grunner ble prioritert for videre oppfølging ved St Olav.

Det pågår nå et forskningsprosjekt for å finne ut:
1. Hvor god oppfølgingen har vært fra fastlegen og fra sykehuset
2. Hvor godt barna hører og hvilken grad av øreplager de har nær 2 år etter operasjonen
3. Om sykehusets hørselstester for barn kan forbedres

Dere som foresatte til barnet og barnet selv inviteres med dette til å delta i forskningsprosjektet. Dere er utvalgt fordi barnet fikk operert inn dren ved St Olavs Hospital etter at retningslinjene våre ble endret. Før dere bestemmer dere, er det viktig at dere forstår hvorfor forskningen blir utført og hva det innebærer for deg og ditt barn. Ta dere god tid til å lese informasjonen som følger. Spør oss om noe er uklart eller dere vil vite mer.

Hva er hensikten med studien?

Hensikten med undersøkelsen er først og fremst å øke vår kunnskap om hva som er god oppfølging av barn etter å ha fått operert inn dren, og hvordan det går med hørselen til barna.
Dernest ønsker vi å kvalitetssikre de undersøkelsesmetodene vi bruker på barna.

Hvem kan delta?

Alle barn som har fått operert inn dren på St Olav etter at retningslinjene ble endret høsten 2007 med foresatte.

Frivillig deltakelse

Det er frivillig å delta i studien. Dere kan når som helst og uten å oppgi noen grunn trekke deres samtykke til å delta i studien. Dette vil ikke få konsekvenser for barnets videre behandling ved St Olavs Hospital eller fra fastlegen. Dersom dere ønsker å delta, undertegner dere

samtykkeerklæringen på siste side. Om dere nå sier ja til å delta, kan dere senere når som helst trekke tilbake deres samtykke uten at det påvirker barnets øvrige behandling.
Om dere ikke ønsker å delta i studien, er vi takknemlige for om dere ringer telefonnummeret under og *avbestiller* den vedlagte timen.

Hva vil skje hvis dere deltar?

Alle som deltar i prosjektet får en grundig sjekk av hørsel, drenet og øreplager. Dere vil bli innkalt til Høresentralen på St Olav. Der vil det bli tatt en hørselstest, tympanometri (trykkmåling i mellomøret) og bilde av trommehinnene ved hjelp av et spesialkamera. Med bildet kan vi se om drenet sitter på plass og om det er væske i mellomøret. I tillegg vil foresatte bli bedt om å fylle ut to spørreskjemaer med bl.a. spørsmål om hvordan oppfølgingen har vært og om barnet har hatt noen plager fra ørene. Det vil bli innhentet opplysninger fra legejournalen om hørsel før operasjon (der dette er målt) og om når drenet er operert inn.

Der det ut fra undersøkelsene viser seg at barnet trenger videre oppfølging som for eksempel at dren bør fjernes eller legges inn pånytt, vil det bli gitt snarlig legetime uten at trengs noen henvisning fra fastlege!

Ta med samtykkeerklæring og møt på angitte tidspunkt som er vedlagt brevet. Dere trenger ikke å varsle at dere kommer, bare hvis dere ikke kommer.

Samtykke

Samtykkeerklæringen må signeres av foreldre og de av barna som er over 16 år. For barn under 16 år holder det at foreldre samtykker på vegne av seg selv og barnet. Barn også under 16 år har lov til å reservere seg fra å delta. Vi ber derfor om at foreldre er behjelpelige med å informere barnet om hvorfor det skal undersøkes.

Hva hvis jeg ønsker å delta, men ikke kan møte på det angitte tidspunktet?

Med brevet følger det en time til Høresentralen. Dersom timen ikke passer, så ring oss på telefonnummeret under, så ordner vi et annet tidspunkt.

Kostnader:

Konsultasjonen og undersøkelsene er gratis.

Hvilket ubehag kan oppstå i forbindelse med undersøkelsen?

Ingen av undersøkelsene som blir utført i forbindelse med prosjektet er smertefulle for barnet. Dersom det er ørevoks som hindrer innsyn til trommehinnen ønsker vi å fjerne dette. Normalt sett er heller ikke dette smertefullt.

Hva skjer med informasjonen om deg?

Medisinsk informasjon fra konsultasjonen ved Høresentralen (høreprøven, trykkmålingen og bildet av trommehinnen) vedlegges barnets journal, men ikke svarene på spørreskjemaene.

Alle opplysninger som blir samlet inn blir dataregistrert. Alle pasienter får tilgang på informasjon om resultatene av prosjektet. Resultatene vil bli presentert i et skriftlig arbeid. All informasjon vil imidlertid bli anonymisert slik at det ikke vil være mulig å kjenne igjen den enkelte pasient. Prosjektmedarbeiderne har taushetsplikt i henhold til Forvaltningslovens § 13 og Helsepersonellovens § 21. Alle persondata behandles konfidensielt og lagres i en database slik at pasientene kun er registrert med et løpenummer.

Av kontrollhensyn blir grunnlagsdata oppbevart forsvarlig nedlåst fram til 5 år etter prosjektslutt, dvs til senest 31.12.2023. Deretter vil data bli slettet. Det er prosjektleder Bjarne Austad som er ansvarlig for datamaterialet i denne perioden.

Som prosjektdeltakere kan dere kreve at opplysninger som er innhentet blir slettet. Dette gjelder ikke dersom opplysningene allerede er brukt i vitenskaplige arbeider.

Spørreskjemaer:

Sammen med dette brevet følger det to spørreskjemaer. Fyll ut disse og ta dem med på timen til Høresentralen. Om dere ikke får fylt ut spørreskjemaene eller glemmer dem, så kom på timen likevel! Dere vil da få et nytt eksemplar av spørreskjemaene når dere kommer til Høresentralen.

Andre opplysninger:

Studien er tilrådd av Regional komité for medisinsk og helsefaglig forskningsetikk, Midt Norge og Personvernombudet for forskning ved Norsk samfunnsvitenskaplig datatjeneste i Bergen. Alle pasienter er forsikret gjennom Norsk pasientskadeerstatning.

Ansvarlig institusjon er NTNU ved Institutt for samfunnsmedisin (ISM) ved det medisinske fakultet, og er i samarbeid med Øre-Nese-Hals avdelingen ved St Olavs Hospital.

Prosjektleder:
Bjarne Austad, fastlege Sjøsiden Legesenter i Trondheim og universitetslektor ved ISM, NTNU.

Prosjektmedarbeidere:
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Vegard Bugten, PhD. Overlege ved Øre-Nese-Hals, St Olavs Hospital.
Siri Wennberg, seksjonsleder på Høresentralen, St Olavs Hospital
Irene Hetlevik, prof dr med, spesialist i allmenmedisin og leder Allmennmedisinsk forskningsenhet

Telefon henvendelser: 72576057

Med vennlig hilsen

Bjarne Austad
Prosjektleder

Mette Bratt
Avdelingssjef ØNH

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien
"Oppfølging av barn med ventilasjonsrør i trommehinnen"

1. <u>Foreldre/ foresatte på egne vegne</u>

(signatur, dato, telefonnummer)

2. <u>Foreldre/ foresatte på vegne av barn < 16 år</u>

(signatur, dato)

3. <u>Barn/ungdom > 16 år</u>

(signatur, dato, telefonnummer)

(Navn i BLOKKBOKSTAVER på barnet som har operert inn dren)

<u>Jeg bekrefter å ha gitt informasjon om studien</u>

(Signert, rolle i studien, dato)

Appendix 2

Guideline for follow-ups after VTs

Ører - Kontroll av barn med ventilasjonsrør i trommehinnen (v. 1.0)
Utarbeidet ved: St. Olavs Hospital /Kl. ØNH/Kjeve/Øye/ØNH avd./Høresentral

Godkjent av: Bratt, Mette (Klinikksjef)
Dokumentet angår: Helsesekretær, Lege, Sykepleier

Hensikt

Retningslinjen skal sikre god flyt mellom sykehus og primærhelsetjeneste hva gjelder pasienter som har fått innoperert ventilasjonsrør i trommehinnen ved Øre-nese-halsavdelingen St.Olavs Hospital.

Omfang

Gjelder leger, sykepleiere, sekretærer som håndterer pasienten eller pasientinformasjon på St.Olav, og fastlegen som eventuelt kontrollerer pasienten utenfor sykehus.

Grunnlagsinformasjon

Flere diagnoser kan gi trykkendring og eventuelt væske i mellomøret. Uavhengig av operasjonsindikasjon gjelder følgende retningslinje om kontrollopplegg etter kirurgi: Leon-prinsippet, lavest effektive omsorgsnivå til beste for pasienten, ivaretas gjennom denne retningslinjen.

Arbeidsbeskrivelse

1 Etter førstegangs innleggelse av ventilasjonsrør

1.1 Ved avklart/normal hørsel: Kontroll hos fastlege inkludert otoskopi 6 og 18 mndr postoperativt.

→ tett rør → øredråper i 2 uker → kontroll hos fastlegen

→ Ikke avstøtt rør etter 18 mndr.→ henvisning til ØNH

1.2 Ved uavklart hørsel: Kontroll med audiogram på Høresentralen 2 mndr postoperativt.

2 Etter andregangs innleggelse av ventilasjonsrør

Kontroll hos fastlege inkludert otoskopi 6 og 18 mndr postoperativt

3 Barn med syndrom

Kontroll hos lege på Høresentralen/ØNH poliklinikk

Appendix 3

Information to parents after insertion of VTs

ST. OLAVS HOSPITAL
UNIVERSITETSSYKEHUSET I TRONDHEIM

Tannteam/kjevekirugie
Olav Kyrres gate 17
7006 Trondheim

Telefon: 72 57 53 96
Telefaks: 72 57 57 66
www.stolav.no

SUYO/guno 240107
I.grupper/Inntakskontoret/Pasientinformasjon/Til fore…..
(revidert 101007 mbratt, rev 2.9.08 mb)

Vår referanse SUYO/guno Deres referanse Dato

TIL FORELDRE MED BARN MED VENTILASJONSRØR I TROMMEHINNEN

Anbefaling for oppfølging av barn med ventilasjonsrør i trommehinnen:

- **Fastlege vil kontrollere deres barn ca. 6 måneder, og deretter 18 måneder etter operasjonen.**
- **Kontakt fastlegen 5 måneder etter operasjonen slik at tidspunkt for kontroll kan avtales. Fastlegen kaller ikke automatisk inn til kontroll, men er orientert om at operasjonen er utført i et skriv tilsendt fra sykehuset.**
- **I tilfelle det har vært usikkerhet vedrørende hørselsfunn før operasjonen, testes hørselen på Høresentralen 2 måneder etter operasjonen. Dette avtales i så fall med dere før operasjonen.**
- **Det anbefales å fjerne rørene i narkose hvis de ikke har falt ut av trommehinnen innen to år.**

Ved ytterligere spørsmål, vennligst kontakt barnets fastlege i første omgang.

Vennlig hilsen ØNH-avdelingen

HELSE MIDT-NORGE St. Olavs Hospital HF

Olav Kyrres gate 17
7006 Trondheim
Org.nr: 883 974 832

Bankgiro: 8601.05.10270
Telefon: 73 86 80 00
Telefaks: 73 86 72 27

Appendix 4

Questionnaire parents

D	D	M	M	Å	Å

Dato

ID-Nummer i studien | | | | | |

SPØRRESKJEMA

til studien:

”Oppfølging av barn med ventilasjonsrør i trommehinnen”

Avsnitt A: Operasjon

1. Har barnet fått operert inn ventilasjonsrør (dren) mer enn én gang?	
NEI, kun operert 1 gang	☐
JA, operert 2 ganger	☐
JA, operert 3 ganger	☐
JA, operert 4 ganger eller mer	☐
2. Hvis JA, når ble barnet operert sist gang? (svar år og måned så langt du husker dette)	
År/måned 20___/____	

Avsnitt B: Kontroll av barnet etter operasjonen

(sett kryss på det svaralternativet som passer)

3. Har barnet vært til kontroll hos fastlegen for å kontrollere drenet?	
NEI	☐
JA, 1 gang	☐
JA, 2 ganger	☐
JA, 3 ganger eller mer	☐
4. Hvis JA, har fastlegen henvist barnet tilbake til Øre-Nese-Hals lege? *(Hvis du svarte NEI på spørsmål 3 hopper du over dette spørsmålet)*	
NEI	☐
JA, Øre-Nese-Hals lege på St Olav	☐
JA, annen Øre-Nese-Hals lege	☐

5. Har barnet vært til kontroll hos Øre-Nese-Hals lege på ST OLAVS HOSPITAL for å kontrollere drenet?	
NEI	☐
JA, 1 gang	☐
JA, 2 ganger	☐
JA, 3 ganger eller mer	☐
6. Har barnet vært til kontroll hos Øre-Nese-Hals lege UTENOM St Olavs Hospital *(dvs private avtalespesialister, Aleris eller andre sykehus)* ***for å kontrollere drenet?***	
NEI	☐
JA, 1 gang	☐
JA, 2 ganger	☐
JA, 3 ganger eller mer	☐
7. Hvis JA, har Øre-Nese-Hals legen henvist barnet tilbake til Øre-Nese-Hals på St Olavs Hospital? *(Hvis du svarte NEI på spørsmål 6 hopper du over dette spørsmålet)*	
NEI	☐
JA	☐
8. Har barnet vært til kontroll hos andre leger *(eks barnelege)* ***for å kontrollere drenet?***	
NEI	☐
JA, 1 gang	☐
JA, 2 ganger	☐
JA 3 ganger eller mer	☐
9. Hvis JA, har legen henvist barnet videre til Øre-Nese-Hals lege? *(Hvis du svarte NEI på spørsmål 8 hopper du over dette spørsmålet)*	
NEI	☐
JA, Øre-Nese-Hals på St Olav	☐
JA, annen Øre-Nese-Hals lege	☐
10. Hvis barnet IKKE har vært på kontroll hos lege etter drensinnsettelsen *(dvs det er svart NEI på spørsmål 3,5,6,8),* ***hva mener du er årsaken til dette?*** *(Kan sette flere kryss)*	
Ikke fått informasjon om at barnet skal kontrolleres	☐
Ikke følt behovet for at barnet skal kontrolleres	☐
Glemt å ta kontakt med fastlegen selv	☐
Annet. Spesifiser (skriv på neste side eller på baksiden av arket)	☐

Avsnitt C: Hvordan det har gått med barnet ETTER at det fikk dren

11. Etter din oppfatning, hvordan har barnets hørsel blitt etter at det fikk satt inn dren?	
Bedre	☐
Uendret	☐
Dårligere	☐
12. Etter din oppfatning, hvordan har barnets øreplager utviklet seg etter at det fikk satt inn dren?	
Mindre øreplager	☐
Uendret	☐
Mer øreplager	☐

Avsnitt D: Omsorgssituasjonen for barnet og foresattes utdanning og yrke med mer

***13.* Røykes det i hjemmet der barnet bor?**	
NEI aldri	☐
Sjelden	☐
En gang i uka	☐
Oftere enn en gang i uka	☐
14. Hvem har hatt omsorgen for barnet etter at drenet ble operert inn?	
Mor og far har omsorgen sammen	☐
Delt omsorg mellom mor og far	☐
Bare mor	☐
Bare far	☐
Andre. Spesifiser (skriv under eller på baksiden av arket)	☐

15. Hvilken utdanning har mor og far?

(Sett bokstav fra alternativene under foran mor og far.
Eksempel:
Hvis utdanning F stemmer best overens med mors utdanning, settes bokstaven F i ruten bak Mor.
Hvis utdanning E stemmer best overens med fars utdanning, settes bokstaven E i ruten bak Far)

Mor	☐
Far	☐

A. Under 9 årig grunnskole
B. 9-årig grunnskole eller tilsvarende
C. 9 år + 1 eller 2-årig videregående/yrkesskole
D. 9 år + artium/3-årig videregående
E. Videregående + min 1 år eller spesialisert trening
F. Høyskole/universitet <4 år
G. Høyskole/universitet >4 år
H. Doktorgrad/PhD
I. Ukjent

16. Hvilket yrke har mor og far?

(sett bokstav fra alternativene under foran mor og far.
Eksempel:
Hvis yrke F stemmer best overens med mors yrke, settes bokstaven F i ruten bak Mor.
Hvis yrke E stemmer best overens med fars yrke, settes bokstaven E i ruten bak Far

Mor	☐
Far	☐

A. Administrasjon. Ledere og politikere
B. Akademiske yrker
C. Yrker med kortere universitets- og høyskoleutdanning og teknikere
D. Kontor – og kundeserviceyrker
E. Salgs, service- og omsorgsyrker
F. Yrker innen jordbruk, skogbruk og fiske
G. Håndverkere og lignende
H. Prosess/maskinoperatør, transportarbeider mv
I. Yrker uten krav til utdanning.
J. Student
K. Hjemmeværende
L. Arbeidsledig eller trygdet

17. Hvilken alder har foreldre nå?

(Skriv alder i ruten bak Mor og Far)

Mor	☐
Far	☐

Dersom du vil komme med supplerende opplysninger, skriv her:

(Bruk gjerne baksiden om det ble liten plass)

Mange takk for hjelpen!

Appendix 5

Audiological tests

Testresultat og vurderinger

Prosjektløpenr: ☐☐☐☐

Tidspunkt for dren ☐☐, ☐☐, ☐☐ (dag, måned, år)

Hvilket øre opr. m/dren
- ☐ Høyre
- ☐ Venstre
- ☐ Begge

Bare paracentese
- ☐ Høyre
- ☐ Venstre

Hørselsprøve FØR operasjon

- ☐ Rentoneaudiometri
- ☐ Lekeaudiometri
- ☐ Uformell testing - PA5
- ☐ Ikke mulig å teste pga manglende samarbeid
- ☐ Ikke testet

Høyre side

0,25	0,5	1,0	2,0	4,0	
☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	kHz
					dB

Venstre side

0,25	0,5	1,0	2,0	4,0	
☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	kHz
					dB

Hørselsprøve ETTER operasjon

- ☐ Rentoneaudiometri
- ☐ Lekeaudiometri
- ☐ Uformell testing - PA5
- ☐ Ikke mulig å teste pga manglende samarbeid
- ☐ Ikke testet

Høyre side

0,25	0,5	1,0	2,0	4,0	
☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	kHz
					dB

Venstre side

0,25	0,5	1,0	2,0	4,0	
☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	kHz
					dB

Taleaudiometri med BARNELISTER

Høyre side Maks % ved ☐☐☐ dBHL
50% ved ☐☐☐ dBHL

Venstre side Maks % ved ☐☐☐ dBHL
50% ved ☐☐☐ dBHL

Samarbeider ved taleaudiometri?

- ☐ Ja
- ☐ Nei
- ☐ Samarbeider, men opplever resultatet usikkert

Taleaudiometri med HURTIGTEST TREORDS YTRINGER

Høyre side 50% ved ☐☐☐ dBHL

Venstre side 50% ved ☐☐☐ dBHL

Samarbeider ved taleaudiometri

- ☐ Ja
- ☐ Nei
- ☐ Samarbeider, men opplever resultatet usikkert

Samarbeider ved taleaudiometri

- ☐ Ja
- ☐ Nei
- ☐ Samarbeider, men opplever resultatet usikkert

Tympanometri FØR operasjon

	Høyre side	Venstre side
Type A (normal kurve)	☐	☐
Type B (flat)	☐	☐
Type C (undertrykk, toppunkt < -200daPa)	☐	☐
Ikke tatt	☐	☐

Hvis type B, også stort volum (=åpent dren, perforasjon)?

Ja	☐	☐
Nei	☐	☐

Tympanometri ETTER operasjon

	Høyre side	Venstre side
Type A (normal kurve)	☐	☐
Type B (flat)	☐	☐
Type C (undertrykk, toppunkt < -200daPa)	☐	☐
Ikke tatt	☐	☐

Hvis type B, også stort volum (=åpent dren, perforasjon)?

Ja	☐	☐
Nei	☐	☐

Audiografens vurdering av bildet av trommehinnen

Høyre øre

- □ Dren på plass i trommehinnen
- □ Dren i øregangen
- □ Dren borte
- □ Ikke mulig å vurdere om drenet er tilstede

Trommehinneperforasjon ut fra bildet?

- □ Nei
- □ Ja

Væske i mellomøret vurdert ut fra bildet?

- □ JA □ Matt trommehinne/karinnvekst
  □ Tyntflytende væske m/væskespeil
- □ NEI, ikke væske i mellomøret
- □ Ikke mulig å vurdere ut fra bildet

Venstre øre

- □ Dren på plass i trommehinnen
- □ Dren i øregangen
- □ Dren borte
- □ Ikke mulig å vurdere om drenet er tilstede

Trommehinneperforasjon ut fra bildet?

- □ Nei
- □ Ja

Væske i mellomøret vurdert ut fra bildet?

- □ JA □ Matt trommehinne/karinnvekst
  □ Tyntflytende væske m/væskespeil
- □ NEI, ikke væske i mellomøret
- □ Ikke mulig å vurdere ut fra bildet

Ut fra audiografens vurdering, trenger barnet oppfølging med legetime?

- □ Nei
- □ Ja

Appendix 6

Additional statistical tests, Paper II

MEAN VS MEDIAN MTH, PAPER II

Follow-ups by GPs

	Before surgery MTH best ear	**Before surgery** MTH worst ear	**24±3 months after surgery** MTH best ear	**24±3 months after surgery** MTH worst ear
n	13	12	22	22
Mean	22.1	32.8	11.7	19.0
Median	21.3	33.8	10.0	13.1

Follow-ups by otolaryngologists

	Before surgery MTH best ear	**Before surgery** MTH worst ear	**24±3 months after surgery** MTH best ear	**24±3 months after surgery** MTH worst ear
n	27	27	50	48
Mean	22.6	33.1	16.2	20.8
Median	20.0	30.0	12.5	16.3

MTH= Mean Threshold

NON-PARAMETRIC TEST, PAPER II

```
*Nonparametric Tests: Independent Samples.
NPTESTS
  /INDEPENDENT TEST (FØR_best_al FØR_darli_al ETTER_best_al ETTER_darli_al)
GROUP (Oppfølging2) MEDIAN(TESTVALUE=SAMPLE COMPARE=PAIRWISE) HODGES_LEHMAN
  /MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE
  /CRITERIA ALPHA=0.05  CILEVEL=95.
```

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The medians of FØR_best_al are the same across categories of Oppfølging ved utskrivelse.	Independent-Samples Median Test	,506	Retain the null hypothesis.
2	The medians of FØR_darli_al are the same across categories of Oppfølging ved utskrivelse.	Independent-Samples Median Test	,810	Retain the null hypothesis.
3	The medians of ETTER_best_al are the same across categories of Oppfølging ved utskrivelse.	Independent-Samples Median Test	,066	Retain the null hypothesis.
4	The medians of ETTER_darli_al are the same across categories of Oppfølging ved utskrivelse.	Independent-Samples Median Test	,840	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is ,05.

FØR_best_al = Before surgery, best ear (median MTH)

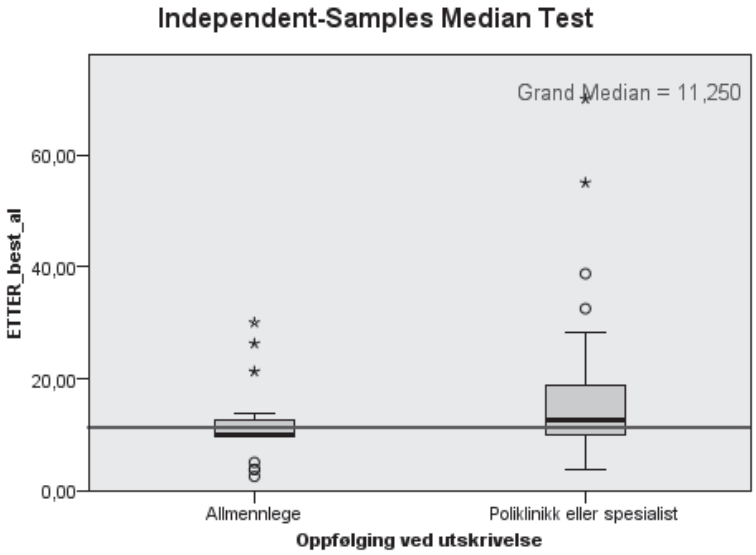
FØR_darlig_al = Before surgery, worst ear (median MTH)

ETTER_best_al = 24±3 months after surgery, best ear (median MTH)

ETTER_darlig_al = 24±3 months after surgery, worst ear (median MTH)

Oppfølging ved utskrivelse = Follow-ups after surgery

DETAILS FROM NONPARAMETRIC TEST NO. 3 (24±3 months after surgery, best ear), PAPER II



Total N		72
Median		11,250
Test Statistic		4,396
Degrees of Freedom		1
Asymptotic Sig. (2-sided test)		,036
Yates's Continuity Correction	**Chi-Square**	3,385
	Degrees of Freedom	1
	Asymptotic Sig. (2-sided test)	,066

1. Multiple comparisons are not performed because the overall test does not show significant differences across samples.

Allmennlege = GP

Poliklinikk eller spesialist = Otolaryngologist

ETTER_best_al = 24±3 months after surgery, best ear (median MTH)

Appendix 7

Invitation and consent to participate in Study 2

NTNU
Det medisinske fakultet
Institutt for samfunnsmedisin

Vår dato 12.01.2013 | Vår referanse
Deres dato | Deres referanse

Kjære kollega

Kliniske retningslinjer i allmennpraksis - invitasjon til fokusgruppeintervju -

Allmennleger mottar en rekke kliniske retningslinjer fra myndigheter, sykehus og andre som er laget med gode intensjoner for å gi bedre pasientbehandling og kvalitet i helsetjenesten. Fra 2013 har Fastlegeforskriften trådt i kraft. Der står det at "Fastlegen skal drive sin virksomhet i tråd med oppdatert kunnskap og nasjonale faglige retningslinjer".

Imidlertid viser studier at mange allmennleger ikke følger retningslinjene. Dersom retningslinjer ikke implementeres i praksis oppnås heller ikke tilsiktet effekt.

Allmennleger kan ha gode grunner for ikke å implementere en del av retningslinjene i sin praksis. Noen retningslinjer er ikke tilpasset den kliniske hverdagen i allmennpraksis, og noen lages uten å involvere allmennleger i selve prosessen. Retningslinjene er også stort sett laget for oppfølging av enkeltsykdommer, mens i allmennpraksis har en stor del av pasientene flere sykdommer. Dette vil i så fall medføre at mange retningslinjer skal anvendes samtidig og anbefalingene kan være sprikende. I tillegg krever enkelte retningslinjer omfattende arbeid både for legen og for pasienten og summen av alle anbefalingene som skal gjennomføres kan medføre større tidsbruk enn det legene har til rådighet.

Postadresse
Medisinsk teknisk forskningssenter
7489 Trondheim

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dmf-post@medisin.ntnu.no
http://www.ntnu.no/ism

Besøksadresse
Håkon Jarls gt. 11

Telefon
+ 47 73 59 88 39
Telefaks
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Stipendiat
Bjarne Austad

Vi ønsker derfor å utforske hvilke tanker og erfaringer fastleger i Trondheim har med bruk av retningslinjer i sin praksis. Videre ønsker vi å få økt kunnskap om hvilke faktorer som kan fremme og hindre anvendelse av retningslinjer.

Rent praktisk ønsker vi å gjennomføre ett fokusgruppeintervju med deres smågruppe / veiledningsgruppe. Det innebærer at ansvarlig for gjennomføringen av prosjektet, Bjarne Austad, vil be om å få delta på et av møtene deres. Intervjuet vil ta om lag 90 minutter og det hele vil bli tatt opp på lydbånd og/eller video slik at det senere kan skrives ned. Det vil bli lagt opp til en mest mulig åpen diskusjon rundt temaet, gjerne med utgangspunkt i pasienthistorier.

Den som ikke ønsker å delta i gruppeintervjuet kan selvfølgelig reservere seg.

Med vennlig hilsen

Bjarne Austad
Spesialist i allmennmedisin
Sjøsiden Legesenter DA
Ph.d.-stipendiat

Anne-Sofie Helvik
Førsteamanuensis
Dr Philos

Irene Hetlevik
Spesialist i allmennmedisin
Professor, dr.med, leder AFE

Allmennmedisinsk Forskningsenhet (AFE)
Institutt for samfunnsmedisin, NTNU.

NTNU
Det medisinske fakultet
Institutt for samfunnsmedisin

Vår dato 12.01.2013 | Vår referanse
Deres dato | Deres referanse

Kliniske retningslinjer i allmennpraksis
- samtykkeerklæring-

Jeg samtykker til å være deltaker i forskingsprosjektet "Kliniske retningslinjer i allmennpraksis" utgående fra Institutt for Samfunnsmedisin, NTNU. Det vil bli tatt lydopptak og videoopptak av intervjuet. Dette materialet vil senere bli omgjort til tekst der alle navn på deltakerne vil bli anonymisert. Det planlegges publisering i et vitenskapelig tidsskrift.

Dato:

Navn deltaker:

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