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The complexity of managing COPD exacerbations: a grounded theory study of European general practice

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ABSTRACT

Objectives: To understand the concerns and challenges faced by general practitioners (GPs) and respiratory physicians about primary care management of acute exacerbations in patients with COPD.

Design: 21 focus group discussions (FGD) were performed in seven countries with a Grounded Theory approach. Each country performed 3 rounds of FGDs.

Setting: Primary and secondary care in Norway, Germany, Wales, Poland, Russia, The Netherlands, China (Hong Kong)

Participants: 142 general practitioners and respiratory physicians chosen to include both urban and rural GPs as well as both hospital-based and out-clinic respiratory physicians.

Results: Management of acute COPD exacerbations is dealt with within a scope of concerns. These concerns range from 'dealing with comorbidity' to 'having difficult patients' to 'confronting a hopeless disease'. The first concern displays medical uncertainty regarding diagnosis, medication and hospitalisation. These clinical processes become blurred both by comorbidity and the social context of the patient. The second concern shows how patients receive the label 'difficult' exactly because they need complex attention, but even more because they are time-consuming, do not take responsibility and are non-compliant. The third concern relates to the emotional reactions by the physicians when confronted with 'a hopeless disease' due to the fact that most patients do not improve and treatment slows down the process at best. GPs and pulmonologists balance these concerns with medical knowledge and practical situational knowledge, trying to encompass the complexity of a medical condition.

Conclusion: Knowing the patient is essential when dealing with comorbidities as well as with difficult relations in the consultation. This study suggests that it is crucial to improve collaboration between primary and secondary care, in terms of, for example, shared consultations and defined work tasks, which may enhance shared knowledge of patients, medical decision-making and improve management planning.

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Article summary

Article focus:

- What are the main problems when managing COPD exacerbations in general practice?
- What do GPs and respiratory physicians suggest as solutions to the main problems?
- Is there a shared body of management problems across European countries?

Key messages:

- Management rests on a balance between medical knowledge and practical, situational knowledge.
- Three main concerns make up the pivotal management aspects: dealing with comorbidity, having difficult patients and confronting a hopeless disease.
- Improved collaboration may support medical decisions, shared patient knowledge and management planning

Strengths and limitations of this study:

This study intends to bring forward shared concerns of managing COPD exacerbations at a cross-cultural level. Several local experiences exist but there is a lack of a general body of knowledge on challenges and solutions. Doing a cross-cultural study however also exhibits methodological limitations, e.g. how to take into account differing health system contexts. Also FGDs do not tell us much about consultations as they are practiced but much about how they are thought to be practiced

INTRODUCTION

It has been shown that many COPD patients are diagnosed too late.[1] Many patients who present to the emergency room with exacerbations have never been diagnosed with COPD.[2] In addition, COPD is often misdiagnosed as asthma, leading to inappropriate treatment.[3;4] As regards management of COPD, much attention has been paid to the importance and difficulties of preventing and treating exacerbations.[5] According to GOLD 2013 the management of COPD exacerbations was included as a specific section on the combined management of COPD.[6] Exacerbations lead to emergency and hospital care[7] and each exacerbation leaves a permanent decrement of lung function.[8] More patients need expensive secondary care and long term health status is hampered if management of exacerbations in primary care is suboptimal.[9]

To find novel solutions for improving COPD care, we need more research on experiences, practice and management approaches of the persons primarily involved in everyday care of COPD, the health care professionals and patients. A considerable amount of qualitative research on the needs and views of COPD patients already exists. It has been shown for example that the uncertainty regarding the differentiation between asthma and COPD also has an impact on COPD patients. In the early stages of COPD, patients do not recognize their symptoms, such as coughing, as the first stages of a severe disease. Consequently, they do not find their symptoms severe enough to warrant a physician's visit.[10] COPD patients also often feel ashamed about their medical condition. They feel it is self-inflicted (caused by smoking) and the resulting shame is undoubtedly an obstacle to seeking medical advice, especially when they continue smoking.[1;10;11] Previous research has shown that breathlessness is one of the most problematic symptoms of COPD.[12] Good self-management with medication is very important for them to regain control of their breathlessness and lives [11;12], however exercise programs are approached with caution because of the breathlessness.[12] Although patients report feeling confident about self-management of their medication, they are not confident about their actions in an emergency situation.[11]

Qualitative studies on health care professionals and their experiences of COPD treatment or care concentrated mainly on stop smoking management.[13-16] We have not found qualitative studies that investigated the views of health care professionals on regular COPD care, although a few studies focus on perceptions of end-of-life care, specific use of spirometry and under-diagnosis of COPD.[17-19]

There are large differences between countries in the way primary care of COPD-patients is organised, and therefore local studies may have limited generalisability. We wanted to know which experiences and challenges were shared by clinicians who care for COPD patients. Therefore, we set out to investigate the experiences and opinions of primary and secondary care physicians regarding COPD care in seven different countries (Norway, Russia, Germany, The Netherlands, Poland, Wales and Hong Kong). This analysis should lead to a clear understanding of the main concerns in COPD care. To be able to investigate this in enough detail we focused on the assessment and management of acute exacerbations. Our aim was to explore how GPs and respiratory physicians reason when managing patients with COPD exacerbations in clinical encounters.

METHOD

Design

The overall aim calls for a qualitative approach that encompasses a basic understanding of human interaction and social processes, e.g. Grounded Theory (GT).[20] Grounded Theory is furthermore, in its sampling and analytic approach, theory driven and strives for theory development of emerging categories.[21] We employed a GT approach which is mainly based on Charmaz's constructionist version but we are also inspired by Corbin & Strauss' paradigmatic model of actions and interactions to help us develop an axis of the analysis.[22;23]

We chose focus groups discussions (FGD) as our data sampling method and designed a study of 3x7 FGDs. [24;25] The study countries were from the start selected due to earlier research collaboration on respiratory diseases in networks (GRIN and GRACE): Wales, The Netherlands, Poland, Russia, Germany and Norway. The study originally was thought to be only European, but early in the process we got the opportunity to include Hong Kong. Hong Kong was in the analysis primarily used for comparative purposes, and worked as a sort of validation of the European findings. Each country performed 3 FGDs with new participants each time: FGD 1 with only general practitioners, FGD 2 with only respiratory physicians, and FGD 3 with a mix of general practitioners and respiratory physicians. The first FGDs were undertaken in March 2011 followed by FGDs 2 in September/October 2011 and FGDs 3 in February/March 2012. All researchers from each country who were responsible for conducting the FGDs participated in a 3 day workshop where they were taught the methodology of GT and focus group discussion methods, both theoretically and with practical exercises. This was done in order to streamline the methods across countries and try to secure a shared knowledge and practice of the methodology, basic to making a cross-country analysis.

All countries used the same topic guide each time with a selection of already formulated prompts. Before conducting FGDs 1 the first topic guide was developed by the main author with input from collaborating countries. A pilot interview was conducted in Tromsø in order to adjust for formulations, phrases and questions. Between FGD 1 and 2 the topic guide was discussed and revised among the same authors but also with input from research leaders from the other countries – all met for a one-day workshop to discuss the categories identified in a preliminary analysis of FGD 1 and to decide on how to sample data according to this, i.e. who to include in FGD 2 and what to ask. Between FGD 2 and FGD 3 a major revision of the topic guide was made, also after a preliminary analysis and development of categories and concepts, but this time input was made by e-mail from most countries apart from the researchers in Norway and The Netherlands who met to discuss the revision. This last topic guide focused especially on providing knowledge on topics that were still unclear but also on solutions to identified challenges and difficulties as well as on collaboration. The two first topic guides included 3 patient stories (see supplementary files) to prompt the discussion on the first 3 topics. These were not part of FGD 3 but instead the topics and the results from FGD 1 and 2 were elaborated into new questions.

The interview guides contained the following topics, based on known issues of concern to GPs:

FGD 1: assessment and medication/hospitalization/self-treatment/use of guidelines/challenging or difficult situations/most important problem/improvement of clinical practice.

FGD 2: assessment and medication/hospitalization/self-treatment/use of guidelines/challenging or difficult situations/most important problem/improvement of clinical practice/collaboration with GPs (the topics in FGD2 were supplemented with more specific sub questions than in FGD 1).

FGD 3: diagnosis of exacerbation/hospitalization of borderline cases/criteria for self-treatment/collaboration between primary and secondary sector/who are the difficult patients (the topics of FGD 3 were supplemented with sub questions aiming at describing bottlenecks and future solutions for each topic).

Sampling and material

All 21 FGDs were performed with both a moderator and an assistant moderator, except for a few where only a moderator was present. The moderator in most cases was the head researcher (authors of this paper) from each country (a professor or doctor in family medicine) and in one case a PhD student who were all closely supervised. The aim was to include 6-8 participants for each FGD.

Participants for FGD 1 were GPs and were sampled purposefully to cover both rural and urban practices. They were invited via an information letter. Several information channels were used in some countries, making contacts via meetings, health boards, email, telephone, mail or personal contact. By the end we had between 6 and 10 participants in each FGD and these lasted between 1 and 2 hours. Several GPs did not wish to participate due to limitation in time and interest.

Participants for FGD 2 were sampled among hospital-based respiratory physicians and private or out-patient respiratory physicians, depending on the specific health system in each country. The number of participants varied between 4 and 7 and the FGD lasted around an hour and a half. The participants were found via email invitations, personal contacts, or at hospital wards (e.g. having a pulmonologist ask colleagues) and sampling was faster and easier than in FGD 1 but also resulted in fewer participants.

Participants for FGD 3 were sampled among both GPs and respiratory physicians to enhance a discussion on the emerging analytic categories in the data. FGD 3 had between 6 and 9 participants and lasted from 1.5 to 2 hours. The sampling took place via email invitations, through personal contact or inviting a key person to ask colleagues. The composition of the FGDs had a balanced number of GPs and respiratory physicians. In some cases the GPs came from the same practice and knew each other. Also respiratory physicians were acquainted with each other, working at the same hospital or out-patient clinic.

All FGDs were performed within university premises and they were transcribed verbatim from audio recording by the local researchers and translated into English by a skilled translator.

Analysis

The analysis took place according to GT methodology from the first round of FGDs, using Nvivo 9. First and third author did the main coding, that is, line-by-line coding in the beginning but we also coded by event, constantly looking for meaningful categories and concepts in the data and making comparisons across all FGDs. The first-round analysis of FGD 1 was performed by the Tromsø team mainly and its purpose was to guide us and decide which categories and concepts should be elaborated or perhaps de-emphasized in the following FGD. The same process took place between FGD 2 and 3. This whole approach aimed for a process of theoretical sampling. Further, the analysis also contained attempts to do focused coding[23] in order to find the most significant categories, concepts and actions of the material, and this was again extended with a preliminary axial coding trying to structure a relation between categories and subcategories.[22] The axial coding was elaborated further in the final analysis, and this was supplemented with a paradigmatic matrix that organizes data into conditions/actions and interactions/consequences and helps develop categories and find relations between them [22]. This paradigm also highlights the actions and interactions of actors involved and helps define the core categories of actions/social processes with their related dimensions which finally are developed into a grounded theory. A special emphasis is put here on intentions and goals of the actors in the process. Memos were written especially in the last phase of the analysis, giving a solid basis to start comprehending the main concerns for the health professionals concerning COPD exacerbations and how they handled them. The analysis made by the Tromsø team was supplemented and discussed with input from the study countries' teams. This created collaboration in terms of the analysis and strengthened validity of the findings.

RESULTS

Balancing management within a scope of concerns

Overall, data displayed several distinct discussions on how to manage COPD exacerbations. Some FGDs were very focused on problematic issues from the beginning, others seemed more straightforward and practical, not paying much attention to any difficulties, while others again from the beginning tuned in on uncertainty concerning medical practice and knowledge, prone to discuss uncertainties and doubts. Some, after prompting by a patient story, were dominated by a demonstration of medical knowledge at the start. However, all FGDs combined their medical concerns and discussions with attempts to describe and understand the patient's social circumstances, as well as to take into account the particular health system and its resources as determining factors in management of exacerbations. When it came to discussions on main challenges, clinical practice and collaboration, several societal problems and political dimensions of health work were addressed, e.g. with a tendency to shift the level of attention from biomedicine to health promotion, health services topics and general health population issues.

The analysis of all FGDs made it evident that the management of COPD, especially of exacerbations, is experienced as trying to balance between medical knowledge and practical, situational knowledge. Balancing management *per se* is the main concern for both GPs and respiratory physicians, resolved mainly by strategies of *knowing* patients, their social resources and health contexts. However, this concern only makes sense when subcategories of concerns are explained and analysed one by one, showing the mechanisms of an interconnected process, i.e. a scope of concerns.

Dealing with comorbidity

‘Dealing with comorbidity’ is a concern which is significant for three different dimensions of clinical management of exacerbations: how to be sure it is an exacerbation, when to prescribe antibiotics or steroids, and when or who to hospitalise. Comorbidity refers here to the existence of disease conditions other than COPD, such as asthma, cardiovascular disease, skeletal muscle dysfunction, metabolic syndrome, osteoporosis, depression, and lung cancer.

Crucial to a diagnosis of exacerbation, we found in the FGDs that the physicians all wished to see the patient when he/she calls the GP and asks for antibiotics because of a worsened condition. To merely give advice or to prescribe over the phone was for some suitable only if you knew the patient well. As such, making a diagnosis of COPD exacerbations was closely connected to seeing, knowing and examining a patient. However, just as important, symptoms like breathlessness and anxiety were understood to be caused by multiple possible diagnoses, that is, the questions of comorbidity blurred the picture. Not everything resembling an exacerbation is one:

> It is difficult, for example, to diagnose COPD in an 80-year old patient. I had such a patient. The doctor [GP] diagnosed her with asthma. This is a non-smoking patient. Her FEV1 is 27%. I have a question: what is it? Is it COPD or asthma? The test with bronchodilator was positive. Such mixed cases are difficult. Although today we treat such cases in the same way, with combined medicines. In general, we have a lot of difficulties in diagnosing the severe patients. (Russia FGD 2)

In terms of theoretical medical knowledge, making a diagnosis could be presented by the physicians as straight forward, but the clinical picture of comorbidity confused the process:

> Yes, but still, it [making a diagnosis] is not difficult at all. It’s the matter of, it’s the many comorbidities among them, everyone at risk for COPD is rather at risk of, well, cancer and cardiac diseases are quite common among COPD patients. (Norway FGD 3)

Diagnosing was perceived overall to be a clinical process made over time, using in particular the patient’s story and experiences to estimate an exacerbation, trying to judge if the patient does have an exacerbation or not.

Comorbidity was also described as a crucial factor when deciding whether or not to prescribe antibiotics and steroids, and this made prescribing decisions difficult:

> …. these patients have often got a load of other things wrong with them, they are high risk individuals, they have been smoking for many years and I think the main worry is about, is the things that we talked about, is multiple pathologies, multiple drugs. (Wales FGD 1)

Concerning steroids, the respiratory physicians in FGD 2 seemed to be overall in favor of prescribing steroids for an exacerbation for a limited time period and discussed more intensely whether to give antibiotics and on what basis, due to resistance considerations. Conversely, for the GPs it was ‘easier’ to prescribe antibiotics, but giving both drugs at the same time was not their first option, especially when considering comorbidity. The side effects of long term use of steroids and the risk of inducing pneumonia were decisive issues for the GPs:

> Usually, we should be concerned whether there is an infective component when we prescribe steroids. Usually chronic COPD patients are weak and if we prescribe steroid for them, it will be easy for them to get infection and often I will prescribe antibiotics as daily practice (Hong Kong FGD 1)

> The comorbidity is high and I reckon that every COPD patient has some form of presence of one or more disorders in addition to a primary disease or disorder…[…]… When visiting the practice I will often put them on a scale. They need

> to be weighed anyway for COPD. So if they have gained 4 kg I am not sure to send them home with a dosage of prednisone and say they'll be fine. (The Netherlands FGD 1)

When considering whether or not to hospitalise, this was illustrated in long debates on pros and cons. The possibility of comorbidities such as heart failure, diabetes, pneumonia, anxiety or psychosomatic disorder were important considerations for the physicians. A suspicion that a patient had an undiagnosed comorbidity might be reason enough to admit a patient.

> E: I think it also depends on the severity of the disease before the exacerbation, that is, how much strength the patient has got left. If he is unstable anyway, even if he isn't exacerbated, then that's a reason to hospitalize him of course. The other possibility would of course be, that you have been treating him with different therapies and you say, I don't see any significant changes, and this has to be analysed in more detail.
> G: And it also depends on the comorbidities, what other diseases he has. (Germany FGD 3)

For COPD exacerbations in general objective assessments, such as low oxygen saturation and rapid respiratory rate, were the most obvious criteria for hospitalization:

> I think there are two important things with this case, firstly how well the GP knows the patient so he can compare them to their baseline and secondly an objective assessment, oxygen saturations, respiratory rate, heart rate, all these sort of things, a clinical consultation, I think. (Wales FGD 2)

On the other hand, after taking into account the patient's basic medical status, how well the patient is known and his general condition, decisions about hospitalisation came down to whether one would risk letting the patient stay at home despite comorbidities or social situation, or wishes:

> [I will assess]…age, comorbidity, the increase of respiratory failure, whether a patient can sleep or he's sitting all night in this position, orthopnea as he can ... what kind of work around the house, he can perform. Can he dress himself, can he move around the apartment, or does it gives him a hard ... can I manage treatment ... And if relatives can help in treating him at home ... (Russia FGD 1)

> On the other hand you also have to see, how multimorbid the patients are. Cardiac decompensation, exacerbated COPD, back and forth again and again, sure it's difficult, but you have to ask yourself "how far can I treat this locally? What can I achieve?" So that we have, right, we all also are in the ambulatory area, we also have our limits. And if we have such complicated cases, where there is something wrong again and again, and we have to ask us diagnostically "What is the real problem?", there I sometimes believe, that some patients, also if they are tired of it, would be better off at a hospital (Germany FGD 3).

> Yes, and so social factors also play a role, if she lives alone and doesn't have any security network at home you can, at any rate, be more unsafe when deciding to send her home, and I assume that one would tell her, in case you don't admit her… you would have a lower threshold to do so if she gets worse. (Norway FGD 2)

The elements of medical decision-making, that is assessment, tests, diagnosis, medication, hospitalisation and overall management, were on one hand discussed within the framework of highly complex medical matters, weighing biomedical, pharmaceutical and technological knowledge against each other, and on the other hand taking into account knowledge of the social context of the patient. Indeed, the patient's social condition, background, resources and personal profile were highly important for all concerns of 'dealing with comorbidity' and clinical decision-making in order to balance medical knowledge:

> There are so many things that you have got to take into account like social circumstances, does he have someone in the house to keep an eye on him, do they have a whole load of other co-existing illnesses, um you know it's very difficult to pick on one thing, it's you trying to make a decision on a number of factors (Wales FGD 1)

Participants' thoughts about use of medication indicated a specific concern for the patient and a wish to know more to support a medical decision. These thoughts were both medically informed and patient-centered, e.g. how high doses were acceptable and for how long time, when was it rational to prescribe antibiotics or steroids according to clinical findings and history, how would the patient accept medication, would he be compliant (both concerning up-take and purchase of medicine), and would he be able to have a dialogue on effects and use with his physician:

> Now we talk a lot, but if you know him, then you know whether he already had something like this in the past. Do you have the case history, does he have compliance? Does he take his medication? Or not? Or is he someone who comes along, I don't know, and maybe had an infection as a trigger, he still smokes heavily and now found his spray and has been using it for 2 days and it doesn't help yet (Germany FGD 1).

Thus knowing the patient in several ways and at several levels was a common approach, and this situational knowledge was used for gaining a complementary understanding of how to treat the patient and determine the necessary medical steps to take.

Having difficult patients

The second concern emerging from the FGDs is 'having difficult patients'. This concern contains a shift in perspective moving from seeing 'comorbidity' as a problem to seeing the patient and individual person as a problem. In this move, personality, situation and context of the patient is in the foreground.

A common dimension of 'the difficult patient' is presented in some of the first reactions from the GPs and respiratory physicians when they start talking about COPD patients. On one hand, it is a relief that the management and treatment of these patients in general has become easier and more successful due to new drugs (although treatment may still be complicated because of complex conditions), but on the other hand some physicians feel annoyance when they perceive that patients have unrealistic expectations:

> In general, these patients are more difficult; the patients, who have a lot of expectations, and believe that all of their 'affairs' will be resolved for them (by someone else). I don't particularly like those patients; they are difficult to cooperate with, perhaps, just because of their belief that everything should be done for them (Poland FGD 1)

More often though, having patients with COPD exacerbations generates concern for the patient, mixed with feelings of being challenged professionally and being unable to give them the best treatment. The patients are difficult exactly because they are seriously ill and suffer and need complex attention, while at same time they are difficult because they are time-consuming, frequent attenders, non-compliant and often do not give the physician the satisfaction of being helpful:

> As for me COPD patients are men with long smoking experience, they are often poor, of low social status, alcohol dependent, they usually don't follow the prescribed treatment. They simply don't have enough money for treatment. I examine them and usually refer to the hospital or to the expert bureau. Generally it is a very sad story, usually leading to disability. There are very few effectively treated patients. (Russia FGD 3)

Especially when discussing self-treatment the patient and his/her social profile turns up as a problem – probably because here the patient is delegated an active role, and behavior and context becomes even more decisive for a decision to prescribe self-medication. Being a 'difficult patient' is further dependent upon a spectrum of difficulties pertaining to the patient himself, such as poor illness perception and understanding (resulting in under- or overtreatment), smoking habits/lifestyle/behaviour, poor intelligence, poor compliance, old age, and bad quality of life/poor economy. But the label of being difficult also results from unsuccessful/lack of interaction and communication with the health professionals to improve one's situation together.

> There are a couple of things we encounter such as most patients are 'dead horses'. This does not sound respectful but there are a lot of patients who want to be left alone. We cannot make them understand what we expect from them. Be active, quit smoking, more exercise, loyal to therapy, take their own initiatives (The Netherlands FGD 2).

> We refer them to this school while they are on a sick leave. We try to convince them of something, especially of the necessity to refuse smoking. It seems that they agree, nod, everything is understood, but they don't come to the second or third meeting. We don't see the light in their eyes; we don't see their initiatives, their participations, any support for their care. Therefore, we have refused to conduct school for COPD patients as we don't see the interest from the patients. (Russia FGD 2)

In other words, a patient was seen as 'difficult' as a result of an interaction, or 'difficult' was an already made characteristic clinging to certain disease profiles, either due to earlier experience with a patient or due to generalised knowledge of COPD patients. Moreover, the difficult patient is a typology referring to the continuum of concerns and not all patients are labeled as such. Some indeed are mainly difficult because they have difficult illness conditions. But still, the physicians' perceptions of having 'difficult' patients' in terms of social and personality related difficulties govern several interactions. The physicians try out several practical solutions to this and one important overall action suggested is to get better at motivating patients. Motivation is the key to several aspects of the difficulties they meet in patients. A repeated advice here is to teach, instruct and inform patients – about the disease, about medicine and especially about the right self-treatment. To teach and motivate is the main action pertaining to 'the difficult patient' – but it builds on the necessity to know and involve the patient in a relationship in order to address him/her properly:

> I think that is what GP's are supposed to do. I think that most GP's, especially the younger ones, think highly of communication. It matches well. It is difficult and the relationship between yourself and the patient is very important. Getting people to quit smoking. The times that you succeed are very rewarding. People are genuinely happier/healthier when they have quit smoking. And the whole story of empowerment as they call it, that you trust the patient to be able to handle his/her own problems. I think that patients are rather dependent (The Netherlands FGD 1)

Confronting a hopeless disease

The third concern in the scope of management deals with how to balance one's approach to a disease that confronts the physician with both his medical professional limits, i.e. the limits for curing and saving lives, and with the patient's existential deterioration at all stages - suffering in general and at end-of-life stages. In this approach the interaction with the patient became characterized by shifting feelings of empathy, hopelessness or frustration, notably related to COPD in general more than to only exacerbations. The severity and poor prognosis of the disease for example *per se* gave either an atmosphere of frustration or simply created a pragmatic attitude:

> They are the most severe patients among the patients with broncho-pulmonary pathology. This is the category of severe patients, which you don't know how to help, in spite of all the standards what exist today. Dyspnea will come anyway. Neither oxygen, nor steroid therapy, neither bronchodilators, nor courses of antibiotics – sometimes nothing for these patients can be done if a patient has severe COPD (Russia FGD 2).

> Another difficult matter is that they don't get better at all…[…]… it's like you prescribe one drug after the other but their conditions worsens gradually and they suffer from difficulties in breathing and in the end we have nothing left to help them with (Norway FGD 1).

Other reactions seen were expressions of sympathy and feeling sorry for the patient in the light of a quickly deteriorating chronic disease:

> And you also have these fatal developments, we know that about COPD, you can use the maximum therapy and the patients do as they are told, but still it gets worse bit by bit. And that's especially dire. That's where you really pity them, because you are so powerless. That's how it is then. (Germany FGD 3)

Another often mentioned dimension of this concern dealt with smoking. Smoking habits and the failure of smoking cessation was considered a main obstacle for the prevention of exacerbations and the discussions on this topic were often marked by hopelessness concerning the patient's capabilities of cessation.

> We give patients with mild or moderate stages of COPD anticholinergics, explain them why they need such treatment. And they do not give up smoking. Sometimes I have the opportunity for a whole hour to talk with the patient. [We] spend a lot of energy and the energy without any feedback. Dim eyes. [They] like smoking, and continue smoking, although they agreed to stop. But he doesn't do anything (Russia FGD 2)

Continuous smoking habits became unintelligible to the physician and his attempts to ease symptoms and relieve a condition, especially when a patient experienced acute exacerbation. Patient's smoking habits in general were an especially dominant concern for the physicians, not merely as a simple life style issue. They invoked strong emotional reactions among the physicians when faced with suffering, deterioration and death due to smoking. In the light of this, the many discussions on smoking cessation may be seen as attempts to strategically manage both a critical disease and an experience of being professionally helpless and emotionally touched. Also non-compliance of medication was a source of discontent and puzzlement amongst the physicians. Such experiences often created an air of hopelessness and helplessness.

The same hopelessness was experienced in relation to systemic factors. For example, if oxygen was not available or hospital care was inadequate. Despite all these negative experiences, an overall preoccupation with the patient was always present, resulting in actions of care even for the patient with 'the hopeless disease'. For those who might still increase their quality of life, discussions on the value of rehabilitation and especially physical exercise came up as an answer and as possible strategies to prevent deterioration into stage III or IV COPD. Rehabilitation was especially brought up as an overall concern for the patients' social life, involving several suggestions of practical advice and how to teach patients and their families, e.g. basic disease management, physical exercise and smoking cessation, organized in COPD schools. However, rehabilitation attempts were hampered by a lack of programs, access, financial priority and collaboration, especially in Russia and Poland.

> It is not being founded. Anyway, there is no tradition of rehabilitation in diseases of the respiratory tract in Poland (Poland FGD 2)

> ... no one said anything about the rehabilitation of patients ... here it is, I think quite an important point ... and, by and large, we do not know how to perform [rehabilitation] (Russia FGD 1)

> … the evidence is very clear, that a rehabilitation program on COPD-exacerbation is something extremely good. The evidence is OVERWHELMING and the health insurance companies nearly NEVER cover the costs for it. And that's something that can drive you mad. That the evidence is crystal clear, but the attitude of the insurance is

> also crystal clear: We won't finance rehabilitation programs. And that is a daily conflict that we have to fight (Germany FGD 2)

> But, but that's the solution, the solution is not to send patients to an extremely expensive rehab center, the solution is gathering people, making people aware, and I 'm convinced if you buy a set of Nordic walking equipment and you find two buddies to walk with, you have both the element of resocialising and a healthy exercise combined, people are given perspectives again, for 30 euros you can set up an exercise program. Thirty euros for Nordic walking equipment, when buying at Aldi it is even cheaper. But what you need is to make the patients aware of it, and when they do not concretize and you will treat them with drugs it will be ineffective. The challenge and art is to motivate the patient, and subsequently imbed Nordic walking equipment. (Netherland FGD 2)

Palliation for COPD patients came up as a topic of discussion in many FGDs. This was phrased as a worry that the patients would not receive the optimal palliative attention, for example compared to cancer patients, or that the physicians did not attend enough to provide palliative care:

> …[…]…not going to make them better, so a lot of them will just slowly progress and they'll get worse and worse and worse and then eventually what we should be doing is referring a lot of them to [palliative care], they shouldn't be down the chest side of things and so, palliative care deals with cancer that's fine, you know, but they don't deal with conditions that aren't cancer, no, no they do, they do but what I'm saying is that now we should be using that a lot more (Wales FGD 2).

[Insert figure 1 here]

DISCUSSION

The management of acute COPD exacerbations was dealt with within a scope of concerns. These concerns ranged from 'dealing with comorbidity' to 'having difficult patients' to 'confronting a hopeless disease'. The first concern relates to medical uncertainty regarding diagnosis, medication and hospitalisation. Here, the clinical process was often presented as straight forward in terms of theoretical medical knowledge, but became blurred by issues of comorbidity and social context. The second concern is when 'difficult' becomes an attribute of a patient. Patients were difficult exactly because they needed complex attention, but even more because personality aspects triggered annoyance, they presented poor illness understanding, and were time-consuming, did not take responsibility and were non-compliant. The third concern relates to the emotional reactions by the physicians when confronted with 'a hopeless disease' due to the fact the disease is chronic and progressive and treatment options slow down the process at best. Physicians both met their own limitations and reacted to end-of-life stages of COPD and patient's poor quality of life. GPs and respiratory physicians balance the concerns of 'dealing with comorbidity', having difficult patients' and 'confronting a hopeless disease' with medical knowledge and practical situational knowledge, trying to encompass the complexity of a medical condition. They engage vividly in suggestions to improve future consultations and patient lives, making an effort to create effective medical routines.

Co-morbidity and the social context of the patient complicated management. In everyday practice the complicated rather than the straight-forward patient profile is probably most common, considering the high prevalence of co-morbidity in this patient group.[26] This also illustrates that physicians feel the lack of good guidelines incorporating co-morbidity issues clearly.[27] Therefore, an important aim for future COPD-guidelines would be to describe management options within the context of the most prevalent co-morbidities in COPD. In addition, there is a need for more pragmatic trials in patients with COPD that do not exclude elderly patients or patients with co-morbidity. Increased collaboration between general practice and hospitals was also suggested as an approach to dealing with uncertainties around comorbidities. Collaboration could lead to standardisation of assessment, establishment of joint consultations in order to make pulmonology services more available to GPs, definition of work tasks specific for each specialty, and more involvement of GPs in hospitalisation decisions and discharge.

COPD patients that experience exacerbations are commonly viewed as difficult patients, with some physicians even saying that they don’t particularly like these patients. Little is known about this emotion among physicians, but this finding is in agreement with qualitative studies among COPD patients where they express the feeling that they are blamed for their self-inflicted disease, not only by their own social environment, but also by healthcare workers.[28-30] The management of COPD exacerbations and stopping smoking require an active role of the patient, so it is understandable that healthcare professionals may feel frustration if their advice is not followed. On the other hand, the resulting emotional impact of blaming patients is likely to have a negative effect on the patient’s mood, which will further hamper the relationship and the clinical process.[30] The ´difficult´ patient is well-known from studies on other kinds of patients and is commonly attributed by physicians to mental disorders, personality traits or morally flawed behavior.[31] Fiester however argues, that the label ´difficult´ is best explained by problematic interactions or reactions to the delivery of care, and he also notes, like we found, that a physician may label a patient ´difficult ´or ´hopeless´ because of her or his own inability to effectively diagnose or treat the problem, or because of a patient’s reaction to this failure. He points to the problem as an ethical one requiring an ethical consultation service. In our study, to overcome ´difficult´, the physicians focus on improving instructions to patients and to target the instructions according to their capacities – that is, mainly an approach to optimise knowledge. The GPs may need supportive actions for this from the health system and society. Concerning self-treatment, concrete future steps were identified in the data such as using management plans including ‘rescue packs’, having a nurse take specific care of self-treatment, and arranging teaching sessions involving the patient’s spouse and family. However, as suggested by Abbot, the most fruitful approach might be to deal with ´the difficult interaction´ rather than targeting either the patient or the physician. [32] Therefore, programs that specifically focus on improving the physician-patient relationship might be worth investigating.

Our finding that physicians feel powerless and frustrated because they have nothing really to offer the patient has been reported in other qualitative studies,[33] but detailed literature on this subject is very limited. Physicians feel that they do their best, approach the patient with care, and try to work according to the guidelines, but that there is little progress, only deterioration in the condition of the patient. Practical future steps include prioritising pulmonary rehabilitation, including adequate resourcing and ensuring that it is accessible for those in need, as well as a specific focus on physical exercise and physiotherapy. Also a more concurrent focus on palliative needs and care and the ability to refer these patients to palliative teams was warranted. Pinnock et al suggest that an assessment should take place related to hospital admission for exacerbations.[34] A patient study determining palliative needs found considerable needs in relation to breathlessness but fewer in the end-of-life stage.[35] This is elaborated in Habraken et al who point to the silence of COPD patients about end-stage needs because they do not realize there are possibilities to improve their condition.[36] This, together with our study of the physicians, suggests potentials for improvement of palliative care.

Overall, the physicians in this study refer in many different ways to the significance of *knowing* the patient - and different dimensions of knowing him/her. We find that *knowing* concerns the disease and comorbidity and it addresses several practical issues of treatment: e.g. a patient's difficulties using an inhaler, the support available from family and relatives, a patient's capacity to learn about colour codes for medicine or his ability access to a rehabilitation center. In other words, knowing the patient also means that a GP does not or cannot always rest on clear evidence-based medicine, but that he together with the patient may deal with changing and context-dependent patient needs. We see this *knowing* in our data, where it shows that patient and physician together try to adapt to the best treatment and take into account situational contexts and practical and social circumstances. This approach is related to a concept promoted by Mol, 'the logic of care', which embraces both the patient and the doctor as active parts who together create adequate treatment.[37] *Knowing* also is an approach that is central to the suggested collaborations between health professionals/health sectors and which is sought to be enhanced through collaboration.

The overall strength of this study is to be found in the design. It was designed as a cross-country study in order to attempt to find common crucial concerns within COPD exacerbation management in different health settings. There is a general lack of such comparative studies and our findings are grounded effectively in the whole empirical material. On the other hand the focus on common issues may overshadow local contexts and local details on management. Also, there is always a danger that a comparative aim looks more for commonalities and convergences than for divergences. However, during the analysis we made an effort to scrutinize any major deviances to determine whether they had significance for the development of new analytical concepts or whether they were dimensions or properties to already found categories. Other variations are part of the detailed examples of the illustrated concerns. Hong Kong was chosen to compare European management to a supposedly different kind of management, but the data from Hong Kong turned out to support and comply with the analysis of the other countries. A weakness in the study and this analysis is that we were not able to specify exactly what role the different health contexts played for the construction of the concerns. That is, we were aware that discussions in the FGDs were embedded in local health systems. They played a part in how physicians talked about their own medical practice, how their practices were framed economically and how working conditions were experienced and practically operationalised. Future analyses will draw in the role of health systems. Methodologically, the fact that the FGDs were performed by different moderators did result in variations of moderation style and subsequent heterogeneity in FGDs. All were trained to perform alike with the same questioning route to follow but focus groups develop independently, often as a result of the participants. However, all major topics were discussed in all FGDs and the differences did not in our view jeopardize the present analysis. Concerning translation there is always a risk that phrases and concepts have lost their significance during translation – certain translations were however discussed with the responsible researcher when the first author became in doubt about its content. Another limitation is that the interviews and the study overall were intended to focus on exacerbations, and while the patient stories and the medical discussions did so, it proved inevitable for the physicians to leave out thoughts and reflections on COPD patients and the COPD disease in general in many other aspects of the interviews. This is especially reflected in thoughts related to the third concern. We were aware of this during analysis and decided not to try splitting the results artificially into what dealt with exacerbations and what did not. Lastly, sampling of the participants was intended to be strategic but turned out to be more pragmatic due to recruitment difficulties and due to differences in health systems.

Unanswered questions and future research derived from our study point to the need for more observational studies on how management in real life takes place. Studies addressing the benefits of management plans and understanding the low status of COPD patients amongst GPs would also be of benefit.

CONCLUSION

Knowing the patient is essential in dealing with comorbidities as well as with difficult relations in the consultation. This study suggests that it is crucial to improve collaboration between primary and secondary care, in terms of for example shared consultations and defined work tasks, which may enhance shared knowledge of patients, medical decision-making and improve management planning. It also suggests that the GPs need supportive actions from the health care system and the society to target difficult consultations. Further studies are needed on barriers in the doctor-patient collaboration and how to reduce the GPs frustration with COPD patients, in order to promote an optimistic and fruitful attitude to this group of patients.

Competing interest statement

All authors have signed the ICMJE conflicts of interest form: None declared.

Contributor statement

All authors participated in the design of the study, revised the article critically for important intellectual content and gave final approval of the version to be published. Further, Risør is the guarantor of the paper and she did the main analysis and interpretation of the data and drafted the article until final version; Iversen, Spigt, Godycki-Cwirko and Francis performed FGDs and contributed to analysis and interpretation of the data; Altiner, Andreeva and Kung performed FGDs; and Melbye contributed with overall conception of the study.

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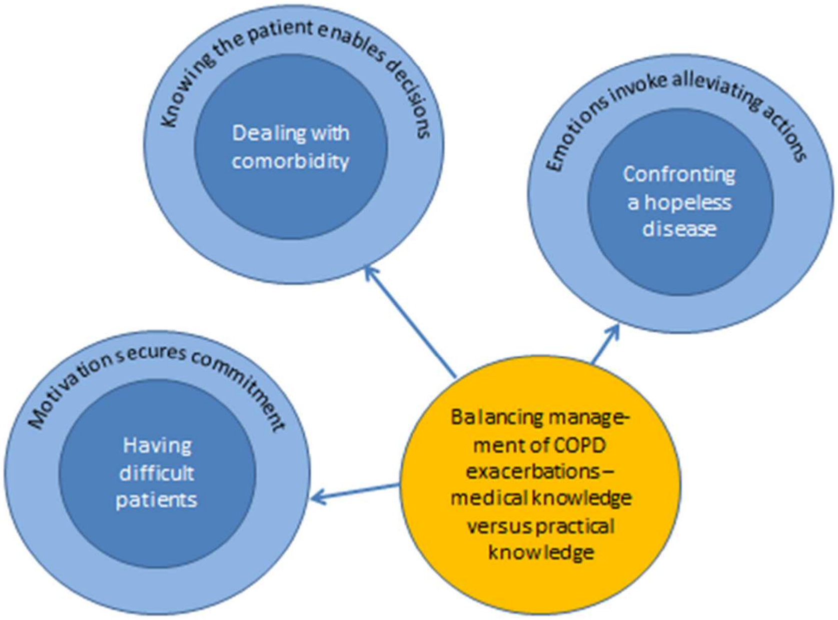

Figure 1: A grounded theory of COPD exacerbation management

Patient stories

1) A 60 year old male patient with moderate COPD has called your practice and asked for medicine, due to increased coughing and shortness of breath the last week. He quit smoking a year ago. You have prescribed anticholinergics for inhalation as maintenance medication. Now he thinks a course of antibiotics might be helpful. He was treated with amoxicillin and prednisolone last winter 9 months ago, and recovered after a few weeks.

2) A 70 year old female patient, still smoking, visits your practice. She was hospitalized due to her COPD one year ago. She uses a combination of inhaled corticosteroids and long acting beta2-agonists, and short acting beta2 agonists on demand. She had a common cold a week ago. Now she has no fever, but breathes heavily and rather fast. She had to sit in her bed last night, and she feels somewhat exhausted. Although you hear wheezes all over her chest, you do not think the obstruction is very severe. You believe her illness is worsened by her anxiety, but consider admitting her to hospital.

3) A 72 year old woman visits you for a follow-up examination. She had a COPD exacerbation three weeks ago, for the second time this winter. She is now in her normal shape. FEV1/FVC ratio is 0.55 and her FEV1 % predicted is 45%. She has reduced her smoking considerably, and smokes only 5 cigarettes a day. She will continue the regular use of a long acting anticholinergic, and is encouraged to use a short-acting beta2 agonist on demand. You consider giving her inhaled corticosteroid in addition. You also consider prescribing courses of oral corticosteroids and antibiotics which she could administer herself if she develops a new exacerbation.

Caring for adult patients with acute exacerbations of asthma or COPD in general practice

Exploration of current practice and options for improved assessment and care

Relevance

Exacerbation of asthma and COPD causes great suffering, premature deaths and considerable health care expenditures in our society. Such exacerbations are treated in hospitals as well as in primary care. However, according to national strategy (Najonal strategi for KOLS-området 2006-2011), general practitioners (GPs) will have an increasingly important role in the care of COPD patients. The project encompasses clinical research in primary care settings, questionnaires among hospitalized patients, and qualitative interviews with patients and doctors. The General Practice Research Unit in Tromsø (AFE Tromsø) will through the project cooperate with GPs from seven Norwegian GP offices, the General Practice Research Unit in Oslo, pulmonologists at the University hospital of North Norway and three district hospitals (Helgelandssykehusene), as well as GP researchers from 5 other European countries. Young GP researchers will be recruited to the project, which will give material for at least two ph.d. theses in the field of general practice.

Aspects relating to the research project

Background and status of knowledge

The prevalence of chronic obstructive pulmonary disease (COPD) among those aged 40 years or older can be estimated to be 5-10 %[1]. Smoking is the main cause of the disease. The prevalence of self reported current asthma was 4.5 %, in a population based survey in USA[2]. Asthma may develop into COPD[3], and COPD patients may exhibit bronchial hyperresponsiveness like in asthma[4]. Accordingly, in many adults it is difficult to distinguish between these diagnoses[5]. Some patients are treated with anti-asthma drugs without fulfilling established criteria for any of the obstructive pulmonary diseases, just by being at risk of getting COPD[6].

Exacerbations of COPD are defined as “an event in the natural course of the disease characterized by a change in the patient’s baseline dyspnoea, cough, and/or sputum that is beyond normal day-to-day variations, is acute in onset, and may warrant a change in regular medication”[7]. COPD exacerbations are caused by a respiratory infection (viral, bacterial or combined) in approximately 80% of cases[8], and viral infections are also common causes in exacerbations of asthma[9].

Exacerbations of asthma and COPD can present with all degrees of severity, from prolonged cough after an airway infection (RTI) to life- threatening respiratory distress. Exacerbations are associated with reduced quality if life[10], premature deaths[1], and great health care costs[11]. Treatment with antibiotics may be crucial in severe cases, and there is evidence that early treatment may be beneficial in bacterial COPD exacerbations, reducing the admission rate to secondary care[12]. There is also a documented effect of treating exacerbations of asthma and COPD with a course of oral corticosteroids[13]. Such treatment is recommended in current guidelines[7;14]. The average exacerbation rate in COPD patients is probably 2-3 per year[11].

Assessment

The 2007 GOLD guideline recommends pulse oximetry and chest radiography when assessing COPD exacerbations, while routine use of spirometry is not recommended[7]. The assessment of COPD exacerbations are, however, still mainly symptom based, and laboratory results and radiographic findings are not included among indications for hospital assessment in GOLD guidelines[7]. Anthonisen set up three criteria for classifying COPD excerbations in his landmark clinical trial published in 1987: Increased dyspnoea, increased amount of sputum , and increased purulence of sputum[15]. If only one of these symptoms was present, antibiotics could not be recommended. Recommendations on antibiotic treatment for COPD excerbations are still based on the presence of these symptoms[7;16].

When Anthonisen's criteria were formulated, there was less awareness about bacterial resistance. Somewhat stricter criteria have been recommended by European guidelines from 2005, reserving antibiotics to COPD exacerbation fulfilling all three of Anthonisen's criteria[17]. Dutch guidelines recommend reserving antibiotics to patients with very poor lung function or other risk factors of severe disease course[14]. We do not know to which degree the guidelines are followed in primary care. In the Netherlands, where antibiotics are less frequently prescribed than in other European countries[18], co-morbidity has been found to be taken into account when antibiotics are prescribed for COPD exacerbations[19].

Self- management

To secure early treatment of exacerbations, many GPs provide their asthma and COPD patient with prescriptions of antibiotics and oral corticosteroids to use during forthcoming exacerbations[11;20]. The patients may thus treat themselves without consulting a GP when their disease worsens. In a Norwegian project[21], asthma and COPD patients were educated on self-care, including better inhaler technique and regulation of medication by symptoms. The regulation included taking oral prednisolone during exacerbations in patients using inhaled corticosteroids, whereas self-treatment with antibiotics was not incorporated. Patients in the intervention group had significantly less GP visit the following year and better health-related quality of life compared to controls. In a Canadian study, supply of both prednisolone and antibiotics were included in the self-management plan. Increased use of both kinds of medicine was observed, but no change in unplanned medical visits[20]. This indicates that supplying patients with antibiotics may lead to over use. Such self-treatment is not recommended in the GOLD guidelines, neither in those developed by International Primary Care Respiratory Group (IPCRG)[22]. Giving patients the responsibility for diagnosis and treatment of exacerbations may delay help-seeking. Some patients want to avoid bothering their doctor[23], and with the medication at hand they may feel even more reluctant to "disturb" their GP.

Gaps of knowledge

Epidemiology and use of health care

Exacerbations of asthma and COPD have mainly been described, as they present in secondary care. More than 50% of those consulting an emergency department in USA are admitted to hospital[24]. Other factors than the severity of the exacerbation influence the consultation rate with GPs in UK as well as at emergency rooms in the U.S[23;25], such as a missing or poor relationship with a GP. In a Dutch and a Swedish study from primary care 53% and 80% of patients with asthma and COPD exacerbation, respectively, were treated with antibiotics[19;26]. Otherwise, evidence drom primary care is sparse.

Assessment of asthma and COPD exacerbations

Supplying patients with prednisolone and antibiotics may reflect an attitude among GPs that examining the patient during exacerbations is often useless, since the condition usually allows a standard treatment. The relevance of differentiating the treatment on the basis of clinical findings and test results needs to be clarified. The European guidelines for lower respiratory tract infection express a worry about the validity of the Anthonisens criteria: " It should be noted that these criteria are subjective and based on only one study. More research in this field is needed"[17].

The CRP test

Markers of systemic inflammation, like C-reactive protein (CRP), are often elevated in COPD exacerbations, especially when a bacterial infection is present[27-29] A CRP value above 50 mg/L in hospitalized patients has been found to be associated with poor outcome[30]. A low CRP value may support a decision not to prescribe antibiotics[28]. It has been suggested to add such a marker to the Anthonisen based diagnostic criteria[31;32] . The CRP test is widely implemented as a near patient test in general practice in Scandinavia, and is already applied in assessing COPD exacerbations[26]. More knowledge is needed about the role of the CRP test in the decision whether or not to treat with antibiotics.

Pulse oximetry

Availability of pulse oximetry is increasing in primary care[33]. Values ≤92% are associated with severe exacerbations[33], and a routine use of the test in COPD exacerbations has been recommended[34]. More knowledge about the predictive value of pulse oximetry in asthma and COPD exacerbations is needed.

Spirometry

Spirometry is now a common examination in Norwegian primary care[35]. Spirometry is not recommended as a routine test in COPD exacerbations in the GOLD guidelines. Sick patients often have difficulties in performing properly[7], and the predictive value of spirometry in these situations seems to be limited[36]. This recommendation is, however, based on data from emergency departments. The picture may be different in primary care, were patients often are less severely ill. For instance, when considering oral corticosteroids, comparison of current and previous spirometries may prove useful.

Self-treatment and health-seeking behaviour

Supplying COPD patients with prednisolone and antibiotics may ensure prompt treatment of exacerbations. Self-assessment may also lead to over treatment and delayed doctor visits. We do not know how self-management is applied today. An impression that assessment by a doctor is unnecessary may signal a low status of their disease in the society. Expecting patients to treat themselves may thus foster feelings of shame for having a self-inflicted disease[37], and more knowledge from the patients point of view could be useful.

Approaches, hypotheses and choice of methods

The four components of the project

Study 1: A clinical study of asthma and COPD exacerbations in primary care, following patients aged 40 years or more with asthma or COPD during their exacerbations.

Study 2: In-depth interviews with patients having moderate or severe COPD, about how they experience access to health care, self-treatment, and emotional barriers in their help-seeking.

Study 3: Focus group discussions with GPs and pulmonologists from 6 European countries on their views about assessment and medical treatment of patients with asthma- and COPD exacerbations, including self-treatment.

Study 4: A survey among patients hospitalized due to asthma or COPD exacerbations about delay, self-treatment and contact with primary care prior to admittance.

Aim of the project

The aim of the project is to gather new knowledge that can contribute substantially to improved guidelines for assessing and treating patients with asthma- and COPD exacerbations in primary care.

Main research questions

- What is the yearly incidence of asthma and COPD excerbations leading to doctor visits or self-care with oral corticosteroids or antibiotics among adults 40 years or more diagnosed with asthma or COPD? (Study 1)
- How do adult patients with asthma and COPD present, when visiting a GP during acute exacerbation, in terms of symptoms, clinical findings and test results? (Study 1)
- How do symptoms, chest findings and test results change in asthma and COPD exacerbation during the 3 weeks after the first consultation with a GP. (Study 1)
- Which symptoms, clinical findings, and test result are emphasized by GPs when deciding whether or not to treat with antibiotics, oral prednisolone and hospital referral? (Study 1)
- Which factors predict a favourable or poor outcome of asthma and COPD exacerbations presented in primary care? (Study 1)
- How do COPD patients experience access to health care during exacerbations of their disease, and what do they think about self-treatment? (Study 2)
- Which role do feelings like shame and reflections on social identity play in COPD patients help-seeking behaviour, and how can health care be organized to optimize access to medical help? (Study 2)
- How do European GPs and pulmonologists think exacerbations of asthma and COPD in adults should be assessed and treated, and in particular what role do the Anthonisen's criteria play in the decision on antibiotic treatment? (Study 3)
- What do European GPs and pulmonologists think about self-treatment with antibiotics and oral corticosteroids in exacerbations of asthma and COPD? (Study 3)
- Are there differences in the views of GPs and pulmonologists regarding assessment and treatment of exacerbations of asthma and COPD , and between the doctors of the different European countries, and how are such differences reflected in national guidelines? (Study 3)
- How is the health behaviour in patients with asthma and COPD exacerbations prior to acute admittance to hospital? (Study 4)

Material and methods

Study 1

380 patients 40 years or older diagnosed with asthma or COPD (or both) have been recruited from 7 GP offices between May 2009 and January 2010. They all have taken part in a baseline examination including registration of recent symptoms (CCQ, a validated questionnaire), chest findings, spirometry with reversibility testing, pulse oximetry, and CRP test. The same kind of spirometers (Spirare II) and oximeters (Onyx II) were used, and the

CRP methodology was quality assured at the 7 offices. The year after baseline the participants are asked to visit their GP during exacerbations, within a few days after the onset of symptoms. Like at baseline, symptoms, chest findings, spirometry, pulse oximetry, and CRP value are recorded, as well as the duration of the actual exacerbation and the treatment given. New appointments with their GP are made after one week and three weeks, and the same examinations will the be carried out. Predictive factors for prescribing antibiotics and prednisolone will be evaluated by univariate and multivariate methods (logistic regression) and the predictive value of Anthonisen's criteria will be compared with models including baseline chest findings, spirometry, and laboratory tests by Receiver Operating Characteristic (ROC) curve analyses. Given an average prescripton rate of antibiotics of 60%, a 20% difference in prescription rate associated with the presence or absence of a predictor, for instance between a prescription rate of 70% and 50%, respectively, can be detected with 90% probability (β=0.9) and with less than 5% risk of false positive result (α=0.05) when 120 exacerbations are included[38]. A material of 150 exacerbations is thus regarded as sufficient. Approximately half of this number has been included so far. Possible predictors of a poor outcome, such as PO2 ≤ 92%, CRP > 50 mg/L, and severe COPD found by spirometry at baseline, will also be evaluated by univariate and multivariate methods. Measures of poor outcome are unplanned re-consultation, lack of recovery after 3 weeks, and hospitalisation.

All data will be recorded on separate forms marked with the case number, not including name or date of birth, and will be stored in a quality assured computerized storing system (EUTRO) at the University of Tromsø. The study has been approved by the Regional committee for health research ethics.

Study 2

Patients with moderate or severe COPD who have experienced at least one exacerbation last year, will be invited to take part, for instance participants in Study 1 or patients at a local rehabilitation unit. The interviews will be based on the methods described by S Kvale[39]. Grounded theory will be used as the basic methodology and the analytic strategy will follow GT's approach to theoretical sampling, coding and constant comparisons[40]. In the final analysis Nvivo 8 will be used as software tool.

We aim at interviewing 20 patients with exacerbations of COPD, and following the GT approach sampling will be made to obtain theoretical saturation of data.

The interviews will be recorded on MP3 recorders and transcribed before analysis. The transcribed version will be marked with case numbers and stored in an unidentifiable form. The interviews will be carried out after the study has been approved by the Regional committee for health research ethics.

Study 3

GPs and pulmonologists from 6 European countries (Wales, The Netherlands, Germany, Poland, Russia (Arkhangelsk region), Sweden and Norway) will be sampled based on a purposeful and stratified approach[41]. In all countries GPs from both urban and rural practices and pulmonologists from both university hospitals (where possible) and regional hospitals will be invited to participate in a FGD (focus group discussion). One FGD with GPs, one with pulmonologists and one with a mix of the two specialties (a total of 3 FGDS for each country) will be conducted, aiming at 5-8 doctors in each group. The FGDs will follow a prepared interviewguide[42], the same for all three interviews. The guide will be developed on a common basis to be used in all countries though admitting exceptional variations if there is a need to discuss country/culture specific items.

All FGDs will be recorded on MP3 recorders and transcribed verbatim. The transcribed version will be marked with case numbers and stored in an unidentifiable form. In the final analysis Nvivo 8 will be used as software tool. Grounded theory will be used as the basic methodology and the analytic strategy will follow GT's approach to theoretical sampling, coding and constant comparisons as in study 2[40].

Analysis will be based on translated transcripts (to English) and take into account differences in terminology and both social and cultural context of each country when developing final theories from the data. Analytic comparisons will be made within each country's data and also across countries. This requires internal agreement on aims and methods, e.g. equivalent methods in all countries and frequent meetings (Skype or live) among researchers in all phases of the project. The project's organisational structure will be developed to support this.

The study needs approval from the ombudsman for personal security in Norway and corresponding bodies in the cooperating countries.

The effort to involve 6 countries in this study is made to provide knowledge on different attitudes and practices among health professionals towards treatment of COPD and to assess their ideas as possible input to improved guidelines for clinical practice. Drawing on more than one country the study will demonstrate possible professional and contextual variations. This may prove fruitful for instructions, teaching and implementation of future guidelines and inspiration for organisation of treatment. Moreover, the approach will create or strengthen networks across professions and countries.

Study 4

A questionnaire is distributed to patients hospitalized with asthma or COPD exacerbation. Questions are asked about what happened between onset of symptoms and admittance to hospital.. Contacts with health care and self-treatment will be described and whether or not GPs are involved before hospitalization. The GPs actions in terms of treatment and referral will add to the data collected in Study 1. The collection of data will be coordinated by two hospital doctors. The study started 1. January 2010, and during one year it will be possible to include 100 patients from the University hospital and 100 patients from three district hospitals

The methodologies in all four studies represent altogether an interdisciplinary approach to the overall aim of the project. This approach is connected closely to the variation in research questions and hence represents the methodological implication of these. Basically the aim and problems concerning COPD exacerbations call for investigations of different kinds and each methodological approach will be carried out on its own disciplinary premises. It is also the ambition to carry out joint analyses across the four studies in order to let the chosen studies inform each other and obtain rich and robust knowledge on the overall project aim.

The project plan, project management, organisation and cooperation

The project period will start September 1. 2010, and last for three years (see the time schedule in the application scheme). The project period may be extended if the ph.d students work part time general practice in periods. Hasse Melbye, head of AFE Tromsø, will be project leader and involved in all four studies. The project team of Study 1 will also consist of Professor Jørund Straand, head of AFE Oslo, Mette B Risør will be included in the research team of Study 2, whereas Mark Spigt and Mette B. Risør will both be involved in Study 3. In addition to the ph.d. students in the project, ph,d, student at AFE Oslo will take part in preparation of the Study 1 manuscripts, and the two hospital doctors coordinating Study 4 will be involved writing manuscripts as well. The cooperation between the European researchers in Study 3, builds on networking since 1998 through the annual meetings of General Practice Respiratory infection (GRIN) network and through GRACE, a network of excellence study in EU 6th framework on lower respiratory tract infections.

Relevant resources at the applicant institution

The project leader has more than 20 years experience in research on respiratoy illness in primary care, and Mette Bech Risør is an experienced researcher in the field of health anthropology. Department of Community Medicine, University of Tromsø, hosting AFE Tromsø, has a good reputation in epidemiological research. AFE Trosmsø has since 2006 been engaged in GRACE (see over) , The research unit has been responsible for respiratory topics, including spirometry, in the Tromsø Study, a population based health survey.

Budget

Shown in the application scheme

Perspectives and compliance with strategic documents

Compliance with strategic documents and relevance to society

The study may prepare for better cooperation between primary and secondary care regarding patients with COPD, which has been called for in several documents from health authorities the last years. See the introductory comments on relevance.

Environmental perspectives

The results of the project may contribute to a decrease in unnecessary use of antibiotics. Over use of antibiotics brings about bacterial resistance, which is a threat for our future health. Better care in rural GP practices may reduce patient travels to hospital.

Ethical aspects

The participant in Study one will undergo more examinations than usual care, but not examinations considered to be associated with increased health risk. All study participants give written consents, and it will be impossible to recognize any of them when the data are analysed and stored.

Gender equality and gender perspectives

Both genders will be well represented among study participants and among the researchers.

Communication with users and utilisation of results

Communication with users

Results will be communicated to GPs and pulmonologist through courses and conferences. The National advisory for COPD, at the National Directory of Health, will also be informed.

Dissemination plan

Scientific papers addressing the research questions above will be published in international peer-reviewed journals. National coordinators of Study 3 can publish results from a national point of view as soon as the common papers are accepted for publication.

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Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups

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Abstract

Background. Qualitative research explores complex phenomena encountered by clinicians, health care providers, policy makers and consumers. Although partial checklists are available, no consolidated reporting framework exists for any type of qualitative design.

Objective. To develop a checklist for explicit and comprehensive reporting of qualitative studies (indepth interviews and focus groups).

Methods. We performed a comprehensive search in Cochrane and Campbell Protocols, Medline, CINAHL, systematic reviews of qualitative studies, author or reviewer guidelines of major medical journals and reference lists of relevant publications for existing checklists used to assess qualitative studies. Seventy-six items from 22 checklists were compiled into a comprehensive list. All items were grouped into three domains: (i) research team and reflexivity, (ii) study design and (iii) data analysis and reporting. Duplicate items and those that were ambiguous, too broadly defined and impractical to assess were removed.

Results. Items most frequently included in the checklists related to sampling method, setting for data collection, method of data collection, respondent validation of findings, method of recording data, description of the derivation of themes and inclusion of supporting quotations. We grouped all items into three domains: (i) research team and reflexivity, (ii) study design and (iii) data analysis and reporting.

Conclusions. The criteria included in COREQ, a 32-item checklist, can help researchers to report important aspects of the research team, study methods, context of the study, findings, analysis and interpretations.

Keywords: focus groups, interviews, qualitative research, research design

Qualitative research explores complex phenomena encountered by clinicians, health care providers, policy makers and consumers in health care. Poorly designed studies and inadequate reporting can lead to inappropriate application of qualitative research in decision-making, health care, health policy and future research.

Formal reporting guidelines have been developed for randomized controlled trials (CONSORT) [1], diagnostic test studies (STARD), meta-analysis of RCTs (QUOROM) [2], observational studies (STROBE) [3] and meta-analyses of observational studies (MOOSE) [4]. These aim to improve the quality of reporting these study types and allow readers to better understand the design, conduct, analysis and findings of published studies. This process allows users of published research to be more fuller informed when they critically appraise studies relevant to each checklist and decide upon applicability of research findings to their local settings. Empiric studies have shown that the use of the CONSORT statement is associated with improvements in the quality of reports of randomized controlled trials [5]. Systematic reviews of qualitative research almost always show that key aspects of study design are not reported, and so there is a clear need for a CONSORT-equivalent for qualitative research [6].

The Uniform Requirements for Manuscripts Submitted to Biomedical Journals published by the International Committee of Medical Journal Editors (ICMJE) do not provide reporting guidelines for qualitative studies. Of all the mainstream biomedical journals (Fig. 1), only the British Medical Journal (BMJ) has criteria for reviewing qualitative research. However, the guidelines for authors specifically record that the checklist is not routinely used. In addition, the checklist is not comprehensive and does not provide specific guidance to assess some of the criteria. Although checklists for critical appraisal are available for qualitative research, there is no widely endorsed reporting framework for any type of qualitative research [7].

We have developed a formal reporting checklist for in-depth interviews and focus groups, the most common methods for data collection in qualitative health research.

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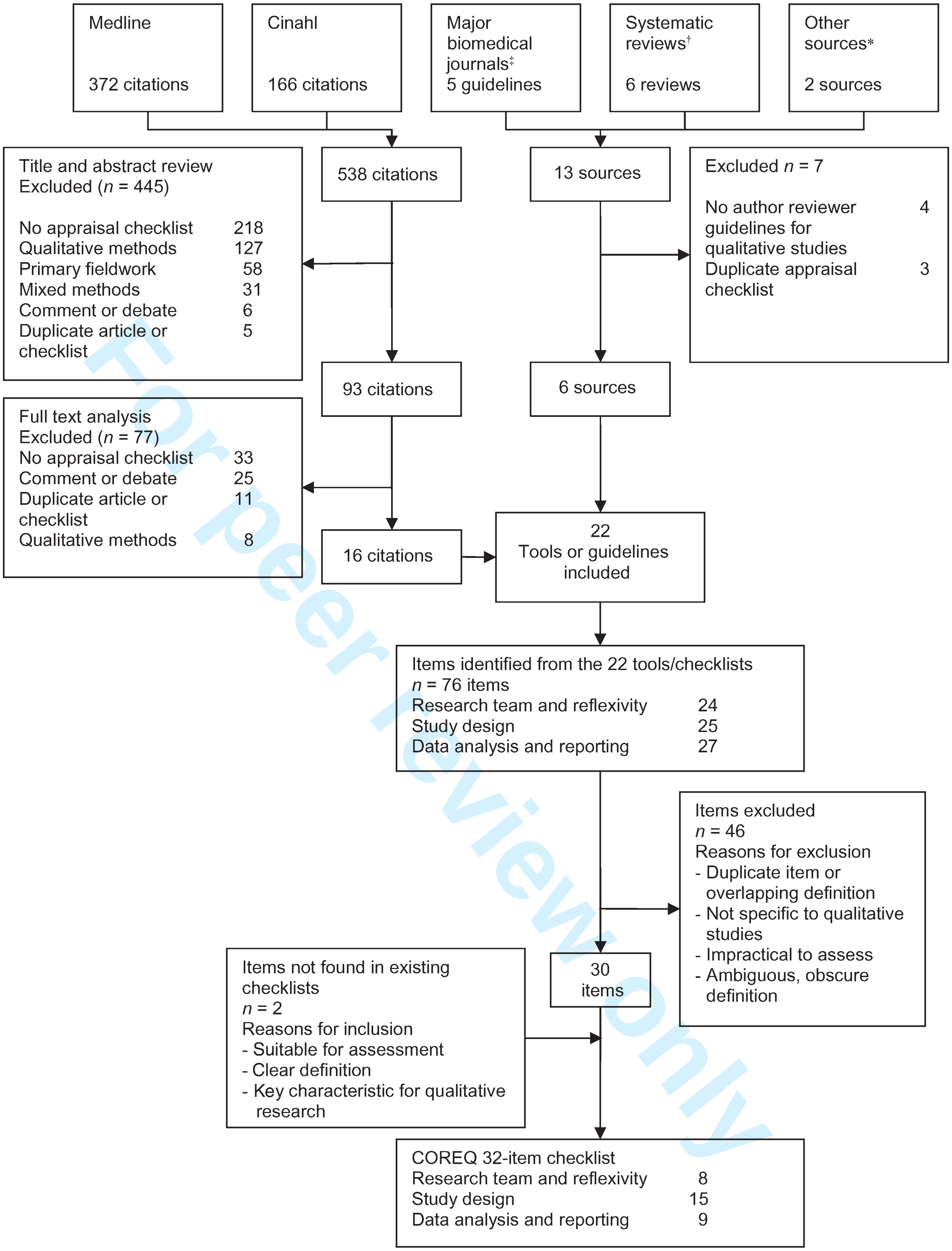

Figure 1 Development of the COREQ Checklist. *References [26, 27], †References [6, 28–32], ‡Author and reviewer guidelines provided by BMJ, JAMA, Lancet, Annals of Internal Medicine, NEJM.

These two methods are particularly useful for eliciting patient and consumer priorities and needs to improve the quality of health care [8]. The checklist aims to promote complete and transparent reporting among researchers and indirectly improve the rigor, comprehensiveness and credibility of interview and focus-group studies.

Basic definitions

Qualitative studies use non-quantitative methods to contribute new knowledge and to provide new perspectives in health care. Although qualitative research encompasses a broad range of study methods, most qualitative research publications in health care describe the use of interviews and focus groups [8].

Interviews

In-depth and semi-structured interviews explore the experiences of participants and the meanings they attribute to them. Researchers encourage participants to talk about issues pertinent to the research question by asking open-ended questions, usually in one-to-one interviews. The interviewer might re-word, re-order or clarify the questions to further investigate topics introduced by the respondent. In qualitative health research, in-depth interviews are often used to study the experiences and meanings of disease, and to explore personal and sensitive themes. They can also help to identify potentially modifiable factors for improving health care [9].

Focus groups

Focus groups are semi-structured discussions with groups of 4–12 people that aim to explore a specific set of issues [10]. Moderators often commence the focus group by asking broad questions about the topic of interest, before asking the focal questions. Although participants individually answer the facilitator's questions, they are encouraged to talk and interact with each other [11]. This technique is built on the notion that the group interaction encourages respondents to explore and clarify individual and shared perspectives [12]. Focus groups are used to explore views on health issues, programs, interventions and research.

Methods

Development of a checklist

Search strategy. We performed a comprehensive search for published checklists used to assess or review qualitative studies, and guidelines for reporting qualitative studies in: Medline (1966—Week 1 April 2006), CINAHL (1982—Week 3 April 2006), Cochrane and Campbell protocols, systematic reviews of qualitative studies, author or reviewer guidelines of major medical journals and reference lists of relevant publications. We identified the terms used to index the relevant articles already in our possession and performed a broad search using those search terms. The electronic databases were searched using terms and text words for research (standards), health services research (standards) and qualitative studies (evaluation). Duplicate checklists and detailed instructions for conducting and analysing qualitative studies were excluded.

Data extraction. From each of the included publications, we extracted all criteria for assessing or reporting qualitative studies. Seventy-six items from 22 checklists were compiled into a comprehensive list. We recorded the frequency of each item across all the publications. Items most frequently included in the checklists related to sampling method, setting for data collection, method of data collection, respondent validation of findings, method of recording data, description of the derivation of themes and inclusion of supporting quotations. We grouped all items into three domains: (i) research team and reflexivity, (ii) study design and (iii) data analysis and reporting. (see Tables 2–4)

Within each domain we simplified all relevant items by removing duplicates and those that were ambiguous, too broadly defined, not specific to qualitative research, or impractical to assess. Where necessary, the remaining items were rephrased for clarity. Based upon consensus among the authors, two new items that were considered relevant for reporting qualitative research were added. The two new items were identifying the authors who conducted the interview or focus group and reporting the presence of non-participants during the interview or focus group. The COREQ checklist for explicit and comprehensive reporting of qualitative studies consists of 32 criteria, with a descriptor to supplement each item (Table 1).

COREQ: content and rationale (see Tables 1)

Domain 1: research team and reflexivity

(i) Personal characteristics: Qualitative researchers closely engage with the research process and participants and are therefore unable to completely avoid personal bias. Instead researchers should recognize and clarify for readers their identity, credentials, occupation, gender, experience and training. Subsequently this improves the credibility of the findings by giving readers the ability to assess how these factors might have influenced the researchers' observations and interpretations [13–15].

(ii) Relationship with participants: The relationship and extent of interaction between the researcher and their participants should be described as it can have an effect on the participants' responses and also on the researchers' understanding of the phenomena [16]. For example, a clinician–researcher may have a deep understanding of patients' issues but their involvement in patient care may inhibit frank discussion with patient–participants when patients believe that their responses will affect their treatment. For transparency, the investigator should identify and state their assumptions and personal interests in the research topic.

Domain 2: study design

(i) Theoretical framework: Researchers should clarify the theoretical frameworks underpinning their study so readers can understand how the researchers explored their research questions and aims. Theoretical frameworks in qualitative research include: grounded theory, to build theories from the data; ethnography, to understand the culture of groups with shared characteristics; phenomenology, to describe the meaning and significance of experiences; discourse analysis, to analyse linguistic expression; and content analysis, to systematically organize data into a structured format [10].

Table 1 Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No Item	Guide questions/description
Domain 1: Research team and reflexivity	
Personal Characteristics	
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?
2. Credentials	What were the researcher's credentials? *E.g. PhD, MD*
3. Occupation	What was their occupation at the time of the study?
4. Gender	Was the researcher male or female?
5. Experience and training	What experience or training did the researcher have?
Relationship with participants	
6. Relationship established	Was a relationship established prior to study commencement?
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. *personal goals, reasons for doing the research*
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic*
Domain 2: study design	
Theoretical framework	
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*
Participant selection	
10. Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball*
11. Method of approach	How were participants approached? e.*g. face-to-face, telephone, mail, email*
12. Sample size	How many participants were in the study?
13. Non-participation	How many people refused to participate or dropped out? Reasons?
Setting	
14. Setting of data collection	Where was the data collected? e.*g. home, clinic, workplace*
15. Presence of non-participants	Was anyone else present besides the participants and researchers?
16. Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date*
Data collection	
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?
20. Field notes	Were field notes made during and/or after the interview or focus group?
21. Duration	What was the duration of the interviews or focus group?
22. Data saturation	Was data saturation discussed?
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?
Domain 3: analysis and findingsz	
Data analysis	
24. Number of data coders	How many data coders coded the data?
25. Description of the coding tree	Did authors provide a description of the coding tree?
26. Derivation of themes	Were themes identified in advance or derived from the data?
27. Software	What software, if applicable, was used to manage the data?
28. Participant checking	Did participants provide feedback on the findings?
Reporting	
29. Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.*g. participant number*
30. Data and findings consistent	Was there consistency between the data presented and the findings?
31. Clarity of major themes	Were major themes clearly presented in the findings?
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?

(ii) Participant selection: Researchers should report how participants were selected. Usually purposive sampling is used which involves selecting participants who share particular characteristics and have the potential to provide rich, relevant and diverse data pertinent to the research question [13, 17]. Convenience sampling is less optimal because it may fail to capture important perspectives from difficult-to-reach people [16]. Rigorous attempts to recruit participants and reasons for non-participation should be stated to reduce the likelihood of making unsupported statements [18].

Table 2 Items included in 22 published checklists: Research team and reflexivity domain

Item	References																					
	[26][a]	[27][a]	[6][b]	[28][b]	[32][b]	[13]	[15]	[14]	[17]	[33]	[34]	[35]	[16]	[19]	[36]	[7]	[37]	[23]	[38]	[39]	[22]	BMJ
Research team and reflexivity																						
Nature of relationship between the researcher and participants		●		●	●		●		●						●				●			
Examination of role, bias, influence	●	●			●	●	●	●							●						●	
Description of role		●		●					●	●				●	●					●	●	
Identity of the interviewer		●		●		●					●		●		●							
Continued and prolonged engagement		●				●							●	●					●	●		
Response to events	●	●				●	●	●														
Prior assumptions and experience		●						●									●			●		
Professional status		●					●								●							
Journal, record of personal experience		●								●				●								
Effects of research on researcher		●				●	●															
Qualifications		●													●							
Training of the interviewer/facilitator			●		●																	
Expertise demonstrated		●																	●			
Perception of research at inception								●						●								
Age							●															
Gender							●															
Social class							●															
Reasons for conducting study		●																				
Sufficient contact													●									
Too close to participants													●									
Empathy																	●					
Distance between researcher and participants							●															
Background								●														
Familiarity with setting																					●	

[a]Other publications, [b]Systematic review of qualitative studies; BMJ, British Medical Journal—editor's checklist for appraising qualitative research); ●, item included in the checklist.

Table 3 Items included in 22 published checklists: Study design

Item	References																					
	[26][a]	[27][a]	[6][b]	[28][b]	[32][b]	[13]	[15]	[14]	[17]	[33]	[34]	[35]	[16]	[19]	[36]	[7]	[37]	[23]	[38]	[39]	[22]	BMJ
Study design																						
Methodological orientation, ontological or epistemological basis		●		●				●	●					●					●	●	●	●
Sampling—convenience, purposive	●	●			●	●	●	●	●	●	●	●	●	●		●		●	●	●	●	●
Setting		●		●	●			●			●				●					●		
Characteristics and description of sample		●			●			●			●		●	●								
Reasons for participant selection	●	●				●		●			●											
Non-participation	●	●		●	●																	
Inclusion and exclusion, criteria		●			●	●													●			
Identity of the person responsible for recruitment				●	●						●				●							
Sample size		●		●	●						●										●	
Method of approach		●									●					●						
Description of explanation of research to participants	●				●										●							
Level and type of participation														●								
Method of data collection, e.g. focus group, in-depth interview	●	●	●	●	●	●		●	●		●	●	●	●		●				●	●	
Audio and visual recording	●	●	●	●	●	●				●	●		●						●		●	●
Transcripts			●	●	●	●			●		●		●						●			●
Setting and location	●	●		●	●		●		●		●				●						●	●
Saturation of data	●	●	●			●			●				●	●							●	
Use of a topic guide, tools, questions	●	●	●								●					●			●	●		
Field notes			●	●	●	●													●			●
Changes and modifications	●	●		●	●														●		●	
Duration of interview, focus group		●				●					●									●		
Sensitive to participant language and views		●										●		●								
Number of interviews, focus groups		●				●																
Time span																					●	
Time and resources available to the study		●																				

[a]Other publications, [b]Systematic review of qualitative studies; BMJ, British Medical Journal—editor's checklist for appraising qualitative research; ●, item included in the checklist.

Table 4 Items included in 22 published checklists: Analysis and reporting

Item	[26][a]	[27][a]	[6][b]	[28][b]	[32][b]	[13]	[15]	[14]	[17]	[33]	[34]	[35]	[16]	[19]	[36]	[7]	[37]	[23]	[38]	[39]	[22]	BMJ
Respondent validation	●	●	●		●		●		●	●			●	●			●	●	●	●		
Limitations and generalizability	●	●		●	●		●		●		●		●	●				●	●			
Triangulation	●	●		●	●	●	●	●	●					●			●		●			
Original data, quotation		●	●	●	●			●	●		●			●		●				●	●	●
Derivation of themes explicit	●	●	●	●	●		●	●			●								●			●
Contradictory, diverse, negative cases	●	●		●	●		●			●				●					●			●
Number of data analysts	●	●	●			●			●			●	●						●			●
In-depth description of analysis	●			●	●			●			●			●							●	●
Sufficient supporting data presented	●	●		●	●		●				●					●						
Data, interpretation and conclusions linked and integrated		●		●	●							●		●						●		
Retain context of data		●					●	●						●					●			
Explicit findings, presented clearly	●	●		●					●	●												
Outside checks													●	●				●	●			
Software used		●				●													●			●
Discussion both for and against the researchers' arguments	●	●		●	●																	
Development of theories, explanations		●					●			●		●										
Numerical data		●									●							●				●
Coding tree or coding system		●					●												●		●	
Inter-observer reliability		●									●										●	
Sufficient insight into meaning/perceptions of participants		●								●												
Reasons for selection of data to support findings		●			●																	
New insight		●						●														
Results interpreted in credible, innovative way									●													
Eliminate other theories													●									
Range of views														●								
Distinguish between researcher and participant voices								●														
Proportion of data taken into account														●								

[a]Other publications, [b]Systematic review of qualitative studies; BMJ, British Medical Journal—editor's checklist for appraising qualitative research, ●, item included in the checklist.

Researchers should report the sample size of their study to enable readers to assess the diversity of perspectives included.

(iii) Setting: Researchers should describe the context in which the data were collected because it illuminates why participants responded in a particular way. For instance, participants might be more reserved and feel disempowered talking in a hospital setting. The presence of non-participants during interviews or focus groups should be reported as this can also affect the opinions expressed by participants. For example, parent interviewees might be reluctant to talk on sensitive topics if their children are present. Participant characteristics, such as basic demographic data, should be reported so readers can consider the relevance of the findings and interpretations to their own situation. This also allows readers to assess whether perspectives from different groups were explored and compared, such as patients and health care providers [13, 19].

(iv) Data collection: The questions and prompts used in data collection should be provided to enhance the readers' understanding of the researcher's focus and to give readers the ability to assess whether participants were encouraged to openly convey their viewpoints. Researchers should also report whether repeat interviews were conducted as this can influence the rapport developed between the researcher and participants and affect the richness of data obtained. The method of recording the participants' words should be reported. Generally, audio recording and transcription more accurately reflect the participants' views than contemporaneous researcher notes, more so if participants checked their own transcript for accuracy [19–21]. Reasons for not audio recording should be provided. In addition, field notes maintain contextual details and non-verbal expressions for data analysis and interpretation [19, 22]. Duration of the interview or focus group should be reported as this affects the amount of data obtained. Researchers should also clarify whether participants were recruited until no new relevant knowledge was being obtained from new participants (data saturation) [23, 24].

Domain 3: analysis and findings

(i) Data analysis: Specifying the use of multiple coders or other methods of researcher triangulation can indicate a broader and more complex understanding of the phenomenon. The credibility of the findings can be assessed if the process of coding (selecting significant sections from participant statements), and the derivation and identification of themes are made explicit. Descriptions of coding and memoing demonstrate how the researchers perceived, examined and developed their understanding of the data [17, 19]. Researchers sometimes use software packages to assist with storage, searching and coding of qualitative data. In addition, obtaining feedback from participants on the research findings adds validity to the researcher's interpretations by ensuring that the participants' own meanings and perspectives are represented and not curtailed by the researchers' own agenda and knowledge [23].

(ii) Reporting: If supporting quotations are provided, researchers should include quotations from different participants to add transparency and trustworthiness to their findings and interpretations of the data [17]. Readers should be able to assess the consistency between the data presented and the study findings, including the both major and minor themes. Summary findings, interpretations and theories generated should be clearly presented in qualitative research publications.

Discussion

The COREQ checklist was developed to promote explicit and comprehensive reporting of qualitative studies (interviews and focus groups). The checklist consists of items specific to reporting qualitative studies and precludes generic criteria that are applicable to all types of research reports. COREQ is a comprehensive checklist that covers necessary components of study design, which should be reported. The criteria included in the checklist can help researchers to report important aspects of the research team, study methods, context of the study, findings, analysis and interpretations.

At present, we acknowledge there is no empiric basis that shows that the introduction of COREQ will improve the quality of reporting of qualitative research. However this is no different than when CONSORT, QUOROM and other reporting checklists were introduced. Subsequent research has shown that these checklists have improved the quality of reporting of study types relevant to each checklist [5, 25], and we believe that the effect of COREQ is likely to be similar. Despite differences in the objectives and methods of quantitative and qualitative methods, the underlying aim of transparency in research methods and, at the least, the theoretical possibility of the reader being able to duplicate the study methods should be the aims of both methodological approaches. There is a perception among research funding agencies, clinicians and policy makers, that qualitative research is 'second class' research. Initiatives like COREQ are designed to encourage improvement in the quality of reporting of qualitative studies, which will indirectly lead to improved conduct, and greater recognition of qualitative research as inherently equal scientific endeavor compared with quantitative research that is used to assess the quality and safety of health care. We invite readers to comment on COREQ to improve the checklist.

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The complexity of managing COPD exacerbations: a grounded theory study of European general practice

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ABSTRACT

Objectives: To understand the concerns and challenges faced by general practitioners (GPs) and respiratory physicians about primary care management of acute exacerbations in patients with COPD.

Design: 21 focus group discussions (FGD) were performed in seven countries with a Grounded Theory approach. Each country performed 3 rounds of FGDs.

Setting: Primary and secondary care in Norway, Germany, Wales, Poland, Russia, The Netherlands, China (Hong Kong)

Participants: 142 general practitioners and respiratory physicians chosen to include both urban and rural GPs as well as both hospital-based and out patient-clinic respiratory physicians.

Results: Management of acute COPD exacerbations is dealt with within a scope of concerns. These concerns range from ‘dealing with comorbidity’ through ‘having difficult patients’ to ‘confronting a hopeless disease’. The first concern displays medical uncertainty regarding diagnosis, medication and hospitalisation. These clinical processes become blurred both by comorbidity and the social context of the patient. The second concern shows how patients receive the label ‘difficult' exactly because they need complex attention, but even more because they are time-consuming, do not take responsibility and are non-compliant. The third concern relates to the emotional reactions by the physicians when confronted with ‘a hopeless disease’ due to the fact that most patients do not improve and treatment slows down the process at best. GPs and respiratory physicians balance these concerns with medical knowledge and practical situational knowledge, trying to encompass the complexity of a medical condition.

Conclusion: Knowing the patient is essential when dealing with comorbidities as well as with difficult relations in the consultations on exacerbations. This study suggests that it is crucial to improve collaboration between primary and secondary care, in terms of, for example, shared consultations and defined work tasks, which may enhance shared knowledge of patients, medical decision-making and improve management planning.

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Summary

Focus:

- What are the main problems when managing COPD exacerbations in general practice?
- What do GPs and respiratory physicians suggest as solutions to the main problems?
- Is there a shared body of management problems across European countries?

Key messages:

- Management rests on a balance between medical knowledge and practical, situational knowledge.
- Three main concerns make up the pivotal management aspects: dealing with comorbidity, having difficult patients and confronting a hopeless disease.
- Improved collaboration may support medical decisions, shared patient knowledge and management planning

Strengths and limitations of this study:

This study intends to bring forward shared concerns of managing COPD exacerbations at a cross-cultural level. Several local experiences exist but there is a lack of a general body of knowledge on challenges and solutions. Doing a cross-cultural study however also exhibits methodological limitations, e.g. how to take into account differing health system contexts. Also FGDs do not tell us much about consultations as they are practiced but much about how they are thought to be practiced

INTRODUCTION

It has been shown that many COPD patients are diagnosed too late.[1] Many patients who present to the emergency room with exacerbations have never been diagnosed with COPD.[2] In addition, COPD is often misdiagnosed as asthma, leading to inappropriate treatment.[3;4] As regards management of COPD, much attention has been paid to the importance and difficulties of preventing and treating exacerbations.[5] According to GOLD 2013 the management of COPD exacerbations was included as a specific section on the combined management of COPD.[6] Exacerbations lead to emergency and hospital care[7] and each exacerbation leaves a permanent decrement of lung function.[8] More patients need expensive secondary care and long term health status is hampered if management of exacerbations in primary care is suboptimal.[9]

To find novel solutions for improving COPD care, we need more research on experiences, practice and management approaches of the persons primarily involved in everyday care of COPD, the health care professionals and patients. A considerable amount of qualitative research on the needs and views of COPD patients already exists. It has been shown for example that the uncertainty regarding the differentiation between asthma and COPD also has an impact on COPD patients. In the early stages of COPD, patients do not recognize their symptoms, such as coughing, as the first stages of a severe disease. Consequently, they do not find their symptoms severe enough to warrant a physician's visit.[10] COPD patients also often feel ashamed about their medical condition. They feel it is self-inflicted (caused by smoking) and the resulting shame is undoubtedly an obstacle to seeking medical advice, especially when they continue smoking.[1;10;11] Previous research has shown that breathlessness is one of the most problematic symptoms of COPD.[12] Good self-management with medication is very important for them to regain control of their breathlessness and lives [11;12], however exercise programs are approached with caution because of the breathlessness.[12] Although patients report feeling confident about self-management of their medication, they are not confident about their actions in an emergency situation.[11]

Qualitative studies on health care professionals and their experiences of COPD treatment or care concentrated mainly on stop smoking management.[13-16] We have not found qualitative studies that investigated the views of health care professionals on regular COPD care, although a few studies focus on perceptions of end-of-life care, specific use of spirometry and under-diagnosis of COPD.[17-19]

There are large differences between countries in the way primary care of COPD-patients is organised, and therefore local studies may have limited generalisability. We wanted to know which experiences and challenges were shared by clinicians who care for COPD patients. Therefore, we set out to investigate the experiences and opinions of GPs and respiratory physicians regarding COPD care in seven different countries (Norway, Russia, Germany, The Netherlands, Poland, Wales and Hong Kong). This analysis should lead to a clear understanding of the main concerns in COPD care. To be able to investigate this in enough detail we focused on the assessment and management of acute exacerbations. Our aim was to explore how GPs and respiratory physicians reason when managing patients with COPD exacerbations in clinical encounters.

METHOD

Design

The overall aim calls for a qualitative approach that encompasses a basic understanding of human interaction and social processes, e.g. Grounded Theory (GT).[20] Grounded Theory is furthermore, in its sampling and analytic approach, theory driven and strives for theory development of emerging categories.[21] We employed a GT approach which is mainly based on Charmaz's constructionist version but we are also inspired by Corbin & Strauss' paradigmatic model of actions and interactions to help us develop an axis of the analysis.[22;23]

We chose focus groups discussions (FGD) as our data sampling method and designed a study of 3x7 FGDs. [24;25] The study countries were from the start selected due to earlier research collaboration on respiratory diseases in networks (GRIN and GRACE): Wales, The Netherlands, Poland, Russia, Germany and Norway. The study originally was thought to be only European, but early in the process we got the opportunity to include Hong Kong. Hong Kong was in the analysis primarily used for comparative purposes adding an extra dimension to the analysis of the European countries. Each country performed 3 FGDs with new participants each time: FGD 1 with only general practitioners, FGD 2 with only respiratory physicians, and FGD 3 with a mix of general practitioners and respiratory physicians. The first FGDs were undertaken in March 2011 followed by FGDs 2 in September/October 2011 and FGDs 3 in February/March 2012. All researchers from each country who were responsible for conducting the FGDs participated in a 3 day workshop where they were taught the methodology of GT and focus group discussion methods, both theoretically and with practical exercises. This was done in order to streamline the methods across countries and try to secure a shared knowledge and practice of the methodology, basic to making a cross-country analysis.

All countries used the same topic guide each time with a selection of already formulated prompts. Before conducting FGDs 1 the first topic guide was developed by the main author with input from collaborating countries. A pilot interview was conducted in Tromsø in order to adjust for formulations, phrases and questions. Between FGD 1 and 2 the topic guide was discussed and revised among the same authors but also with input from research leaders from the other countries – all met for a one-day workshop to discuss the categories identified in a preliminary analysis of FGD 1 and to decide on how to sample data according to this, i.e. who to include in FGD 2 and what to ask. Between FGD 2 and FGD 3 a major revision of the topic guide was made, also after a preliminary analysis and development of categories and concepts, but this time input was made by e-mail from most countries apart from the researchers in Norway and The Netherlands who met to discuss the revision. This last topic guide focused especially on providing knowledge on topics that were still unclear but also on solutions to identified challenges and difficulties as well as on collaboration. The two first topic guides included 3 patient stories (see supplementary files) to prompt the discussion on the first 3 topics. These were not part of FGD 3 but instead the topics and the results from FGD 1 and 2 were elaborated into new questions.

The interview guides contained the listed topics, based on known issues of concern to GPs. The respiratory physicians were asked to discuss the routines in general practice as it was known to them, but inviting them to be open about their own views and concerns. The topic of collaboration was mainly brought into FGD 2 to try to meet a mutual concern and the discussion resulted in change of the third FGD's interview guide:

FGD 1: assessment and medication/hospitalization/self-treatment/use of guidelines/challenging or difficult situations/most important problem/improvement of clinical practice.

FGD 2: assessment and medication/hospitalization/self-treatment/use of guidelines/challenging or difficult situations/most important problem/improvement of clinical practice/collaboration with GPs (the topics in FGD2 were supplemented with more specific sub questions than in FGD 1).

FGD 3: diagnosis of exacerbation/hospitalization of borderline cases/criteria for self-treatment/collaboration between primary and secondary sector/who are the difficult patients (the topics of FGD 3 were supplemented with sub questions aiming at describing bottlenecks and future solutions for each topic).

Sampling and material

All 21 FGDs were performed with both a moderator and an assistant moderator, except for a few where only a moderator was present. The moderators were the head researchers from each country network (a professor or doctor in family medicine), and in one case a PhD student and an epidemiologist. They were all closely supervised. The head researchers all had their main research field in respiratory diseases in general practice and the epidemiologist had a long experience with intervention research in general practice while the PhD student was new to the research field. Co-moderators were either skilled qualitative researchers or GPs with research experience. The aim was to include 6-8 participants for each FGD.

Participants for FGD 1 were GPs and were sampled purposefully to cover both rural and urban practices. They were invited via an information letter. Several information channels were used in some countries, making contacts via meetings, health boards, email, telephone, mail or personal contact. By the end we had between 6 and 10 participants in each FGD and these lasted between 1 and 2 hours. Several GPs did not wish to participate due to limitation in time and interest.

Participants for FGD 2 were sampled among hospital-based respiratory physicians and private or out-patient respiratory physicians, depending on the specific health system in each country. The number of participants varied between 4 and 7 and the FGD lasted around an hour and a half. The participants were found via email invitations, personal contacts, or at hospital wards (e.g. having a respiratory physician ask colleagues) and sampling was faster and easier than in FGD 1 but also resulted in fewer participants.

Participants for FGD 3 were sampled among both GPs and respiratory physicians to enhance a discussion on the emerging analytic categories in the data. FGD 3 had between 6 and 9 participants and lasted from 1.5 to 2 hours. The sampling took place via email invitations, through personal contact or inviting a key person to ask colleagues. The composition of the FGDs had a balanced number of GPs and respiratory physicians.

In some cases the GPs came from the same practice and knew each other. Also respiratory physicians were acquainted with each other, working at the same hospital or out-patient clinic. In some FGDs the moderators knew a few of the participants but this was not a dominant tendency. The participants were not sampled according to gender or seniority but we intended to include physicians working in both rural and urban settings as well as at different types of health workplaces, mainly regarding the respiratory physicians as mentioned above. The ones who were included and informed us about their practice time, about half of the participants, showed long average seniority (approximately 14 years) with the respiratory physicians having the most seniority. GPs practiced in single clinics, shared clinics and group practices as well as in health centers, and respiratory physicians practiced at hospitals (regional as well as university hospitals), outpatient clinics and in several cases at both places.

All FGDs were performed within university premises and they were transcribed verbatim from audio recording by the local researchers and translated into English by a skilled translator.

Analysis

The analysis took place according to GT methodology from the first round of FGDs, using Nvivo 9. First and third author did the main coding, that is, line-by-line coding in the beginning but we also coded by event, constantly looking for meaningful categories and concepts in the data and making comparisons across all FGDs. The first-round analysis of FGD 1 was performed by the Tromsø team mainly and its purpose was to guide us and decide which categories and concepts should be elaborated or perhaps de-emphasized in the following FGD. The same process took place between FGD 2 and 3. This whole approach aimed for a process of theoretical sampling. Further, the analysis also contained attempts to do focused coding[23] in order to find the most significant categories, concepts and actions of the material, and this was again extended with a preliminary axial coding trying to structure a relation between categories and subcategories.[22] The axial coding was elaborated further in the final analysis, and this was supplemented with a paradigmatic matrix that organizes data into conditions/actions and interactions/consequences and helps develop categories and find relations between them [22]. This paradigm also highlights the actions and interactions of actors involved and helps define the core categories of actions/social processes with their related dimensions which finally are developed into a grounded theory. A special emphasis is put here on intentions and goals of the actors in the process. Memos were written especially in the last phase of the analysis, giving a solid basis to start comprehending the main concerns for the health professionals concerning COPD exacerbations and how they handled them. The analysis made by the Tromsø team was supplemented and discussed with input from the study countries' teams. This created collaboration in terms of the analysis and strengthened validity of the findings. The analytic findings are presented below in a structure which firstly delivers the interpretation of findings and sub-findings, secondly illustrates these with quotations and thirdly, in some cases, elaborates or summarizes the interpretation based on inferences from the quotations and on the overall analytic perspective.

RESULTS

Balancing management within a scope of concerns

Overall, data displayed several distinct discussions on how to manage COPD exacerbations. Some FGDs were very focused on problematic issues from the beginning, others seemed more straightforward and practical, not paying much attention to any difficulties, while others again from the beginning tuned in on uncertainty concerning medical practice and knowledge, prone to discuss uncertainties and doubts. Some, after prompting by a patient story, were dominated by a demonstration of medical knowledge at the start. However, all FGDs combined their medical concerns and discussions with attempts to describe and understand the patient's social circumstances, as well as to take into account the particular health system and its resources as determining factors in management of exacerbations. When it came to discussions on main challenges, clinical practice and collaboration, several societal problems and political dimensions of health work were addressed, e.g. with a tendency to shift the level of attention from biomedicine to health promotion, health services topics and general health population issues.

The analysis of all FGDs made it evident that the management of COPD, especially of exacerbations, is experienced as trying to balance between medical knowledge and practical, situational knowledge. Balancing management *per se* is the main concern for both GPs and respiratory physicians, resolved mainly by strategies of *knowing* patients, their social resources and health contexts. However, this concern only makes sense when subcategories of concerns are explained and analysed one by one, showing the mechanisms of an interconnected process, i.e. a scope of concerns.

Dealing with comorbidity

'Dealing with comorbidity' is a concern which is significant for three different dimensions of clinical management of exacerbations: how to be sure it is an exacerbation, when to prescribe antibiotics or steroids, and when or who to hospitalise. Comorbidity refers here to the existence of disease conditions other than COPD, such as asthma, cardiovascular disease, skeletal muscle dysfunction, metabolic syndrome, osteoporosis, depression, and lung cancer.

Crucial to a diagnosis of exacerbation, we found in the FGDs that the physicians all wished to see the patient when he/she calls the GP and asks for antibiotics because of a worsened condition. To merely give advice or to prescribe over the phone was for some suitable only if you knew the patient well. As such, making a diagnosis of COPD exacerbations was closely connected to seeing, knowing and examining a patient. However, just as important, symptoms like breathlessness and anxiety were understood to be caused by multiple possible diagnoses, that is, the questions of comorbidity blurred the picture. Not everything resembling an exacerbation is one:

> It is difficult, for example, to diagnose COPD in an 80-year old patient. I had such a patient. The doctor [GP] diagnosed her with asthma. This is a non-smoking patient. Her FEV1 is 27%. I have a question: what is it? Is it COPD or asthma? The test with bronchodilator was positive. Such mixed cases are difficult. Although today we treat such cases in the same way, with combined medicines. In general, we have a lot of difficulties in diagnosing the severe patients. (Russia FGD 2)

In terms of theoretical medical knowledge, making a diagnosis could be presented by the physicians as straight forward, but the clinical picture of comorbidity confused the process:

> Yes, but still, it [making a diagnosis] is not difficult at all. It's the matter of, it's the many comorbidities among them, everyone at risk for COPD is rather at risk of, well, cancer and cardiac diseases are quite common among COPD patients. (Norway FGD 3)

Diagnosing was perceived overall to be a clinical process made over time, using in particular the patient's story and experiences to estimate an exacerbation, trying to judge if the patient does have an exacerbation or not.

Comorbidity was also described as a crucial factor when deciding whether or not to prescribe antibiotics and steroids, and this made prescribing decisions difficult:

> …. these patients have often got a load of other things wrong with them, they are high risk individuals, they have been smoking for many years and I think the main worry is about, is the things that we talked about, is multiple pathologies, multiple drugs. (Wales FGD 1)

Concerning steroids, the respiratory physicians in FGD 2 seemed to be overall in favor of prescribing steroids for an exacerbation for a limited time period and discussed more intensely whether to give antibiotics and on what basis, due to resistance considerations. Conversely, for the GPs it was 'easier' to prescribe antibiotics, but giving both drugs at the same time was not their first option, especially when considering comorbidity. The side effects of long term use of steroids and the risk of inducing pneumonia were decisive issues for the GPs:

> Usually, we should be concerned whether there is an infective component when we prescribe steroids. Usually chronic COPD patients are weak and if we prescribe steroid for them, it will be easy for them to get infection and often I will prescribe antibiotics as daily practice (Hong Kong FGD 1)

> The comorbidity is high and I reckon that every COPD patient has some form of presence of one or more disorders in addition to a primary disease or disorder…[…]… When visiting the practice I will often put them on a scale. They need to be weighed anyway for COPD. So if they have gained 4 kg I am not sure to send them home with a dosage of prednisone and say they'll be fine. (The Netherlands FGD 1)

When considering whether or not to hospitalise, this was illustrated in long debates on pros and cons. The possibility of comorbidities such as heart failure, diabetes, pneumonia, anxiety or psychosomatic disorder were important considerations for the physicians. A suspicion that a patient had an undiagnosed comorbidity might be reason enough to admit a patient.

> E: I think it also depends on the severity of the disease before the exacerbation, that is, how much strength the patient has got left. If he is unstable anyway, even if he isn't exacerbated, then that's a reason to hospitalize him of course. The other possibility would of course be, that you have been treating him with different therapies and you say, I don't see any significant changes, and this has to be analysed in more detail.
> G: And it also depends on the comorbidities, what other diseases he has. (Germany FGD 3)

For COPD exacerbations in general objective assessments, such as low oxygen saturation and rapid respiratory rate, were the most obvious criteria for hospitalization:

> I think there are two important things with this case, firstly how well the GP knows the patient so he can compare them to their baseline and secondly an objective assessment, oxygen saturations, respiratory rate, heart rate, all these sort of things, a clinical consultation, I think. (Wales FGD 2)

On the other hand, after taking into account the patient's basic medical status, how well the patient is known and his general condition, decisions about hospitalisation came down to whether one would risk letting the patient stay at home despite comorbidities or social situation, or wishes:

> [I will assess]…age, comorbidity, the increase of respiratory failure, whether a patient can sleep or he's sitting all night in this position, orthopnea as he can ... what kind of work around the house, he can perform. Can he dress himself, can he move around the apartment, or does it gives him a hard ... can I manage treatment ... And if relatives can help in treating him at home ... (Russia FGD 1)

> On the other hand you also have to see, how multimorbid the patients are. Cardiac decompensation, exacerbated COPD, back and forth again and again, sure it's difficult, but you have to ask yourself "how far can I treat this locally? What can I achieve?" So that we have, right, we all also are in the ambulatory area, we also have our limits. And if we have such complicated cases, where there is something wrong again and again, and we have to ask us diagnostically "What is the real problem?", there I sometimes believe, that some patients, also if they are tired of it, would be better off at a hospital (Germany FGD 3).

> Yes, and so social factors also play a role, if she lives alone and doesn't have any security network at home you can, at any rate, be more unsafe when deciding to send her home, and I assume that one would tell her, in case you don't admit her… you would have a lower threshold to do so if she gets worse. (Norway FGD 2)

The elements of medical decision-making, that is assessment, tests, diagnosis, medication, hospitalisation and overall management, were on one hand discussed within the framework of highly complex medical matters, weighing biomedical, pharmaceutical and technological knowledge against each other, and on the other hand taking into account knowledge of the social context of the patient. Indeed, the patient's social condition, background, resources and personal profile were highly important for all concerns of 'dealing with comorbidity' and clinical decision-making in order to balance medical knowledge:

> There are so many things that you have got to take into account like social circumstances, does he have someone in the house to keep an eye on him, do they have a whole load of other co-existing illnesses, um you know it's very difficult to pick on one thing, it's you trying to make a decision on a number of factors (Wales FGD 1)

Participants' thoughts about use of medication indicated a specific concern for the patient and a wish to know more to support a medical decision. These thoughts were both medically informed and patient-centered, e.g. how high doses were acceptable and for how long time, when was it rational to prescribe antibiotics or steroids according to clinical findings and history, how would the patient accept medication, would he be compliant (both concerning up-take and purchase of medicine), and would he be able to have a dialogue on effects and use with his physician:

> Now we talk a lot, but if you know him, then you know whether he already had something like this in the past. Do you have the case history, does he have compliance? Does he take his medication? Or not? Or is he someone who comes along, I don't know, and maybe had an infection as a trigger, he still smokes heavily and now found his spray and has been using it for 2 days and it doesn't help yet (Germany FGD 1).

Thus knowing the patient in several ways and at several levels was a common approach, and this situational knowledge was used for gaining a complementary understanding of how to treat the patient and determine the necessary medical steps to take.

Having difficult patients

The second concern emerging from the FGDs is 'having difficult patients'. This concern contains a shift in perspective moving from seeing 'comorbidity' as a problem to how the GPs and respiratory physicians may see the patient and the relationship with the patient as a problem. In this move, the patient as a person and his/her personality, situation and context is in the foreground, not the medical condition per se.

A common dimension of 'the difficult patient' is presented in some of the first reactions from the GPs and respiratory physicians when they start talking about COPD patients. On one hand, it is a relief that the management and treatment of these patients in general has become easier and more successful due to new drugs (although treatment may still be complicated because of complex conditions), but on the other hand some physicians feel annoyance when they perceive that patients have unrealistic expectations:

> In general, these patients are more difficult; the patients, who have a lot of expectations, and believe that all of their 'affairs' will be resolved for them (by someone else). I don't particularly like those patients; they are difficult to cooperate with, perhaps, just because of their belief that everything should be done for them (Poland FGD 1)

More often though, having patients with COPD exacerbations generates mixed feelings of concern for the patient. The patients are difficult exactly because they are seriously ill and suffer and need complex attention, while at same time they are difficult because they are time-consuming, frequent attenders, non-compliant and often do not give the physician the satisfaction of being helpful:

> As for me COPD patients are men with long smoking experience, they are often poor, of low social status, alcohol dependent, they usually don't follow the prescribed treatment. They simply don't have enough money for treatment. I examine them and usually refer to the hospital or to the expert bureau. Generally it is a very sad story, usually leading to disability. There are very few effectively treated patients. (Russia FGD 3)

Especially when discussing self-treatment the patient and his/her social profile turns up as a problem – probably because here the patient is delegated an active role, and behavior and context becomes even more decisive for a decision to prescribe self-medication. Being a 'difficult patient' is further dependent upon a spectrum of difficulties pertaining to the patient himself, such as poor illness perception and understanding (resulting in under- or overtreatment), smoking habits/lifestyle/behaviour, poor intelligence, poor compliance, old age, and bad quality of life/poor economy. But the label of being difficult also results from unsuccessful/lack of interaction and communication with the health professionals to improve one's situation together.

> There are a couple of things we encounter such as most patients are 'dead horses'. This does not sound respectful but there are a lot of patients who want to be left alone. We cannot make them understand what we expect from them. Be active, quit smoking, more exercise, loyal to therapy, take their own initiatives (The Netherlands FGD 2).
>
> We refer them to this school while they are on a sick leave. We try to convince them of something, especially of the necessity to refuse smoking. It seems that they agree, nod, everything is understood, but they don't come to the second or third meeting. We don't see the light in their eyes; we don't see their initiatives, their participations, any support for their care. Therefore, we have refused to conduct school for COPD patients as we don't see the interest from the patients. (Russia FGD 2)

In other words, a patient was seen as 'difficult' as a result of an interaction, or 'difficult' was an already made characteristic clinging to certain disease profiles, either due to earlier experience with a patient or due to generalised knowledge of COPD patients. Moreover, the difficult patient is a typology referring to the continuum of concerns and not all patients are labeled as such. Some indeed are mainly difficult because they have difficult illness conditions. But still, the physicians' perceptions of having 'difficult' patients' in terms of social and personality related difficulties, not explicitly related to the medical condition, govern several interactions. The physicians try out several practical solutions to this and one important overall action suggested is to get better at motivating patients. Motivation is the key to several aspects of the difficulties they meet in patients. A repeated advice here is to teach, instruct and inform patients – about the disease, about medicine and especially about the right self-treatment. To teach and motivate is the main action pertaining to 'the difficult patient' – but it builds on the necessity to know and involve the patient in a relationship in order to address him/her properly:

> I think that is what GP's are supposed to do. I think that most GP's, especially the younger ones, think highly of communication. It matches well. It is difficult and the relationship between yourself and the patient is very important. Getting people to quit smoking. The times that you succeed are very rewarding. People are genuinely happier/healthier when they have quit smoking. And the whole story of empowerment as they call it, that you trust the patient to be able to handle his/her own problems. I think that patients are rather dependent (The Netherlands FGD 1)

Confronting a hopeless disease

The third concern in the scope of management deals with how to balance one's approach to a disease that confronts the physician with both his medical professional limits, i.e. the limits for curing and saving lives, and with the patient's existential deterioration at all stages - suffering in general and at end-of-life stages. In this approach it is primarily the disease in itself which the physicians react emotionally upon. It is the disease that makes the encounter with the patient become characterized by shifting feelings of empathy, hopelessness or frustration, notably related to COPD in general more than to only exacerbations. The severity and poor prognosis of the disease *per se* gave for example either an atmosphere of frustration or simply created a pragmatic attitude:

> They are the most severe patients among the patients with broncho-pulmonary pathology. This is the category of severe patients, which you don't know how to help, in spite of all the standards what exist today. Dyspnea will come anyway. Neither oxygen, nor steroid therapy, neither bronchodilators, nor courses of antibiotics – sometimes nothing for these patients can be done if a patient has severe COPD (Russia FGD 2).
>
> Another difficult matter is that they don't get better at all….[…]… it's like you prescribe one drug after the other but their conditions worsens gradually and they suffer from difficulties in breathing and in the end we have nothing left to help them with (Norway FGD 1).

Other reactions seen were expressions of sympathy and feeling sorry for the patient in the light of a quickly deteriorating chronic disease:

> And you also have these fatal developments, we know that about COPD, you can use the maximum therapy and the patients do as they are told, but still it gets worse bit by bit. And that's especially dire. That's where you really pity them, because you are so powerless. That's how it is then. (Germany FGD 3)

Another often mentioned dimension of this concern dealt with smoking. Smoking habits and the failure of smoking cessation was considered a main obstacle for the prevention of exacerbations and the discussions on this topic were often marked by hopelessness concerning the patient's capabilities of cessation.

> We give patients with mild or moderate stages of COPD anticholinergics, explain them why they need such treatment. And they do not give up smoking. Sometimes I have the opportunity for a whole hour to talk with the patient. [We] spend a lot of energy and the energy without any feedback. Dim eyes. [They] like smoking, and continue smoking, although they agreed to stop. But he doesn't do anything (Russia FGD 2)

Continuous smoking habits became unintelligible to the physician and his attempts to ease symptoms and relieve a condition, especially when a patient experienced acute exacerbation. Patient's smoking habits in general were an especially dominant concern for the physicians, not merely as a simple life style issue. They invoked strong emotional reactions among the physicians when faced with suffering, deterioration and death due to smoking. In the light of this, the many discussions on smoking cessation may be seen as attempts to strategically manage both a critical disease and an experience of being professionally helpless and emotionally touched. Also non-compliance of medication was a source of discontent and puzzlement amongst the physicians. Such experiences often created an air of hopelessness and helplessness which were related to the concern of 'having difficult patients'. But here we wish to emphasize that the feelings of the physicians were triggered by the disease more than by the interaction with the patient.

The feeling of hopelessness was experienced also in relation to systemic factors. For example, if oxygen was not available or hospital care was inadequate. Despite all these negative experiences, an overall preoccupation with the patient was always present, resulting in actions of care even for the patient with 'the hopeless disease'. For those who might still increase their quality of life, discussions on the value of rehabilitation and especially physical exercise came up as an answer and as possible strategies to prevent deterioration into stage III or IV COPD. Rehabilitation was especially brought up as an overall concern for the patients' social life, involving several suggestions of practical advice and how to teach patients and their families, e.g. basic disease management, physical exercise and smoking cessation, organized in COPD schools. However, rehabilitation attempts were hampered by a lack of programs, access, financial priority and collaboration, especially in Russia and Poland.

> It is not being founded. Anyway, there is no tradition of rehabilitation in diseases of the respiratory tract in Poland (Poland FGD 2)

> ... no one said anything about the rehabilitation of patients ... here it is, I think quite an important point ... and, by and large, we do not know how to perform [rehabilitation] (Russia FGD 1)

> … the evidence is very clear, that a rehabilitation program on COPD-exacerbation is something extremely good. The evidence is OVERWHELMING and the health insurance companies nearly NEVER cover the costs for it. And that's something that can drive you mad. That the evidence is crystal clear, but the attitude of the insurance is also crystal clear: We won't finance rehabilitation programs. And that is a daily conflict that we have to fight (Germany FGD 2)

> But, but that's the solution, the solution is not to send patients to an extremely expensive rehab center, the solution is gathering people, making people aware, and I 'm convinced if you buy a set of Nordic walking equipment and you find two buddies to walk with, you have both the element of resocialising and a healthy exercise combined, people are given perspectives again, for 30 euros you can set up an exercise program. Thirty euros for Nordic walking equipment, when buying at Aldi it is even cheaper. But what you need is to make the patients aware of it, and when they do not concretize and you will treat them with drugs it will be ineffective. The challenge and art is to motivate the patient, and subsequently imbed Nordic walking equipment. (Netherland FGD 2)

Palliation for COPD patients came up as a topic of discussion in many FGDs. This was phrased as a worry that the patients would not receive the optimal palliative attention, for example compared to cancer patients, or that the physicians did not attend enough to provide palliative care:

> …[…]…not going to make them better, so a lot of them will just slowly progress and they'll get worse and worse and worse and then eventually what we should be doing is referring a lot of them to [palliative care], they shouldn't be down the chest side of things and so, palliative care deals with cancer that's fine, you know, but they don't deal with conditions that aren't cancer, no, no they do, they do but what I'm saying is that now we should be using that a lot more (Wales FGD 2).

[Insert figure 1 here]

DISCUSSION

The management of acute COPD exacerbations was dealt with within a scope of concerns. These concerns ranged from ‘dealing with comorbidity’ to ‘having difficult patients’ to ‘confronting a hopeless disease’. The first concern relates to medical uncertainty regarding diagnosis, medication and hospitalisation. Here, the clinical process was often presented as straight forward in terms of theoretical medical knowledge, but became blurred by issues of comorbidity and social context. The second concern is when ‘difficult’ becomes an attribute of a patient. Patients were difficult exactly because they needed complex attention, but even more because personality aspects triggered annoyance, they presented poor illness understanding, and were time-consuming, did not take responsibility and were non-compliant. The third concern relates to the emotional reactions by the physicians when confronted with ‘a hopeless disease’ due to the fact the disease is chronic and progressive and treatment options slow down the process at best. Physicians both met their own limitations and reacted to end-of-life stages of COPD and patient’s poor quality of life. GPs and respiratory physicians balance the concerns of ‘dealing with comorbidity’, having difficult patients’ and ‘confronting a hopeless disease’ with medical knowledge and practical situational knowledge, trying to encompass the complexity of a medical condition. They engage vividly in suggestions to improve future consultations and patient lives, making an effort to create effective medical routines.

Co-morbidity and the social context of the patient complicated management. In everyday practice the complicated rather than the straight-forward patient profile is probably most common, considering the high prevalence of co-morbidity in this patient group.[26] This also illustrates that physicians feel the lack of good guidelines incorporating co-morbidity issues clearly.[27] Therefore, an important aim for future COPD-guidelines would be to describe management options within the context of the most prevalent co-morbidities in COPD. In addition, there is a need for more pragmatic trials in patients with COPD that do not exclude elderly patients or patients with co-morbidity. Increased collaboration between general practice and hospitals was also suggested as an approach to dealing with uncertainties around comorbidities. Collaboration could lead to standardisation of assessment, establishment of joint consultations in order to make pulmonology services more available to GPs, definition of work tasks specific for each specialty, and more involvement of GPs in hospitalisation decisions and discharge.

COPD patients that experience exacerbations are commonly viewed as difficult patients, with some physicians even saying that they don’t particularly like these patients. Little is known about this emotion among physicians, but this finding is in agreement with qualitative studies among COPD patients where they express the feeling that they are blamed for their self-inflicted disease, not only by their own social environment, but also by healthcare workers.[28-30] The management of COPD exacerbations and stopping smoking require an active role of the patient, so it is understandable that healthcare professionals may feel frustration if their advice is not followed. On the other hand, the resulting emotional impact of blaming patients is likely to have a negative effect on the patient's mood, which will further hamper the relationship and the clinical process.[30] The ´difficult´ patient is well-known from studies on other kinds of patients and is commonly attributed by physicians to mental disorders, personality traits or morally flawed behavior.[31] Fiester however argues, that the label ´difficult´ is best explained by problematic interactions or reactions to the delivery of care, and he also notes, like we found, that a physician may label a patient ´difficult ´or ´hopeless´ because of her or his own inability to effectively diagnose or treat the problem, or because of a patient's reaction to this failure. He points to the problem as an ethical one requiring an ethical consultation service. In our study, to overcome ´difficult´, the physicians focus on improving instructions to patients and to target the instructions according to their capacities – that is, mainly an approach to optimise knowledge. The GPs may need supportive actions for this from the health system and society. Concerning self-treatment, concrete future steps were identified in the data such as using management plans including 'rescue packs', having a nurse to take specific care of self-treatment, and arranging teaching sessions involving the patient's spouse and family, as has shown to be effective in e.g. Bourbeau et al.[32] . However, as suggested by Abbot, the most fruitful approach might be to deal with ´the difficult interaction´ rather than targeting either the patient or the physician. [33] Therefore, programs that specifically focus on improving the physician-patient relationship might be worth investigating.

Our finding that physicians feel powerless and frustrated because they have nothing really to offer the patient has been reported in other qualitative studies,[34] but detailed literature on this subject is very limited. Physicians feel that they do their best, approach the patient with care, and try to work according to the guidelines, but that there is little progress, only deterioration in the condition of the patient. Practical future steps include prioritising pulmonary rehabilitation, including adequate resourcing and ensuring that it is accessible for those in need, as well as a specific focus on physical exercise and physiotherapy. Also a more concurrent focus on palliative needs and care and the ability to refer these patients to palliative teams was warranted. Pinnock et al suggest that an assessment should take place related to hospital admission for exacerbations.[35] A patient study determining palliative needs found considerable needs in relation to breathlessness but fewer in the end-of-life stage.[36] This is elaborated in Habraken et al who point to the silence of COPD patients about end-stage needs because they do not realize there are possibilities to improve their condition.[37] This, together with our study of the physicians, suggests potentials for improvement of palliative care.

Overall, the physicians in this study refer in many different ways to the significance of *knowing* the patient - and different dimensions of knowing him/her. We find that *knowing* concerns the disease and comorbidity and it addresses several practical issues of treatment: e.g. a patient's difficulties using an inhaler, the support available from family and relatives, a patient's capacity to learn about colour codes for medicine or his ability access to a rehabilitation center. In other words, knowing the patient also means that a GP does not or cannot always rest on clear evidence-based medicine, but that he together with the patient may deal with changing and context-dependent patient needs. We see this *knowing* in our data, where it shows that patient and physician together try to adapt to the best treatment and take into account situational contexts and practical and social circumstances. This approach is related to a concept promoted by Mol, 'the logic of care', which embraces both the patient and the doctor as active parts who together create adequate treatment.[38] *Knowing* also is an approach that is central to the suggested collaborations between health professionals/health sectors and which is sought to be enhanced through collaboration.

The overall strength of this study is to be found in the design. It was designed as a cross-country study in order to attempt to find common crucial concerns within COPD exacerbation management in different health settings. There is a general lack of such comparative studies and our findings are grounded effectively in the whole empirical material. On the other hand the focus on common issues may overshadow local contexts and local details on management. Also, there is always a danger that a comparative aim looks more for commonalities and convergences than for divergences. However, during the analysis we made an effort to scrutinize any major deviances to determine whether they had significance for the development of new analytical concepts or whether they were dimensions or properties to already found categories. Other variations are part of the detailed examples of the illustrated concerns. Hong Kong was chosen to compare European management to a supposedly different kind of management, but the data from Hong Kong turned out to support and comply with the analysis of the other countries. A weakness in the study and this analysis is that we were not able to specify exactly what role the different health contexts played for the construction of the concerns. That is, we were aware that discussions in the FGDs were embedded in local health systems. They played a part in how physicians talked about their own medical practice, how their practices were framed economically and how working conditions were experienced and practically operationalised. Further, GPs and respiratory physicians might not necessarily share the same medical knowledge background. However, a large part of the participants had changed career from e.g. GP to internal medicine, or working in hospital service for several years before becoming a GP. Also many worked in outpatient-policlinics (both GPs and respiratory physicians) or outpatient-clinics combined with either hospital wards or health centers (GPs). This, we believe lumps the two specialties together rather than splitting them concerning medical experience. Hence, regarding the concerns we found in the analysis, it still seems justified to talk about shared concerns. But certainly, we fully acknowledge that there are differences *within* the concerns that are both culture-specific, health system specific and determined by different social and medical practices. We argue that the concerns are alike, but how to administer them in detail, how the specific perception was of patients, how collaboration could be improved etc., varied from country to country. Future analyses of the dataset will draw in more focus on e.g. differences among the countries in self-treatment and the role of health systems. Methodologically, the fact that the FGDs were performed by different moderators did result in variations of moderation style and subsequent heterogeneity in FGDs. All were trained to perform alike with the same questioning route to follow but focus groups develop independently, often as a result of the participants. That the participants sometimes knew each other may have created a barrier for critical discussions, especially if seniors and juniors were together. It did however also in some cases give a more safe setting for in-depth discussions. The moderators' background in general practice and interest in respiratory diseases may on one hand have been an advantage because the topics of the FGDs were well known. But on the other hand it might have created a blind eye towards specific areas. We saw that the PhD student and the epidemiologist more than others asked into themes just to understand what was meant. Also their background in different nationalities and medical discourses may have coloured the interviews, but this counts for the participants as well. Most importantly, all major topics were discussed in all FGDs and the methodological conditions above did not in our view jeopardize the present analysis. Concerning translation there is always a risk that phrases and concepts have lost their significance during translation – certain translations were however discussed with the responsible researcher when the first author became in doubt about its content. Another limitation is that the interviews and the study overall were intended to focus on exacerbations, and while the patient stories and the medical discussions did so, it proved inevitable for the physicians to leave out thoughts and reflections on COPD patients and the COPD disease in general in many other aspects of the interviews. This is especially reflected in thoughts related to the third concern. We were aware of this during analysis and decided not to try splitting the results artificially into what dealt with exacerbations and what did not. Lastly, sampling of the participants was intended to be strategic but turned out to be more pragmatic due to recruitment difficulties and due to differences in health systems.

Unanswered questions and future research derived from our study point to the need for more observational studies on how management in real life takes place. Studies addressing the benefits of management plans and understanding the low status of COPD patients amongst GPs would also be of benefit.

CONCLUSION

Knowing the patient is essential in dealing with comorbidities as well as with difficult relations in the consultations on exacerbations. This study suggests that it is crucial to improve collaboration between primary and secondary care, in terms of for example shared consultations and defined work tasks, which may enhance shared knowledge of patients, medical decision-making and improve management planning. It also suggests that the GPs need supportive actions from the health care system and the society to target difficult consultations. Further studies are needed on barriers in the doctor-patient collaboration and how to reduce the GPs frustration with COPD patients, in order to promote an optimistic and fruitful attitude to this group of patients.

Competing interest statement

All authors have signed the ICMJE conflicts of interest form: None declared.

Contributor statement

All authors participated in the design of the study, revised the article critically for important intellectual content and gave final approval of the version to be published. Further, Risør is the guarantor of the paper and she did the main analysis and interpretation of the data and drafted the article until final version; Iversen, Spigt, Godycki-Cwirko and Francis performed FGDs and contributed to analysis and interpretation of the data; Altiner, Andreeva and Kung performed FGDs; and Melbye contributed with overall conception of the study.

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The complexity of managing COPD exacerbations: a grounded theory study of European general practice

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ABSTRACT

Objectives: To understand the concerns and challenges faced by general practitioners (GPs) and respiratory physicians about primary care management of acute exacerbations in patients with COPD.

Design: 21 focus group discussions (FGD) were performed in seven countries with a Grounded Theory approach. Each country performed 3 rounds of FGDs.

Setting: Primary and secondary care in Norway, Germany, Wales, Poland, Russia, The Netherlands, China (Hong Kong)

Participants: 142 general practitioners and respiratory physicians chosen to include both urban and rural GPs as well as both hospital-based and out patient-clinic respiratory physicians.

Results: Management of acute COPD exacerbations is dealt with within a scope of concerns. These concerns range from 'dealing with comorbidity' through 'having difficult patients' to 'confronting a hopeless disease'. The first concern displays medical uncertainty regarding diagnosis, medication and hospitalisation. These clinical processes become blurred both by comorbidity and the social context of the patient. The second concern shows how patients receive the label 'difficult' exactly because they need complex attention, but even more because they are time-consuming, do not take responsibility and are non-compliant. The third concern relates to the emotional reactions by the physicians when confronted with 'a hopeless disease' due to the fact that most patients do not improve and treatment slows down the process at best. GPs and respiratory physicians balance these concerns with medical knowledge and practical situational knowledge, trying to encompass the complexity of a medical condition.

Conclusion: Knowing the patient is essential when dealing with comorbidities as well as with difficult relations in the consultations on exacerbations. This study suggests that it is crucial to improve collaboration between primary and secondary care, in terms of, for example, shared consultations and defined work tasks, which may enhance shared knowledge of patients, medical decision-making and improve management planning.

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Summary

Focus:

- What are the main problems when managing COPD exacerbations in general practice?
- What do GPs and respiratory physicians suggest as solutions to the main problems?
- Is there a shared body of management problems across European countries?

Key messages:

- Management rests on a balance between medical knowledge and practical, situational knowledge.
- Three main concerns make up the pivotal management aspects: dealing with comorbidity, having difficult patients and confronting a hopeless disease.
- Improved collaboration may support medical decisions, shared patient knowledge and management planning

Strengths and limitations of this study:

This study intends to bring forward shared concerns of managing COPD exacerbations at a cross-cultural level. Several local experiences exist but there is a lack of a general body of knowledge on challenges and solutions. Doing a cross-cultural study however also exhibits methodological limitations, e.g. how to take into account differing health system contexts. Also FGDs do not tell us much about consultations as they are practiced but much about how they are thought to be practiced

INTRODUCTION

It has been shown that many COPD patients are diagnosed too late.[1] Many patients who present to the emergency room with exacerbations have never been diagnosed with COPD.[2] In addition, COPD is often misdiagnosed as asthma, leading to inappropriate treatment.[3;4] As regards management of COPD, much attention has been paid to the importance and difficulties of preventing and treating exacerbations.[5] According to GOLD 2013 the management of COPD exacerbations was included as a specific section on the combined management of COPD.[6] Exacerbations lead to emergency and hospital care[7] and each exacerbation leaves a permanent decrement of lung function.[8] More patients need expensive secondary care and long term health status is hampered if management of exacerbations in primary care is suboptimal.[9]

To find novel solutions for improving COPD care, we need more research on experiences, practice and management approaches of the persons primarily involved in everyday care of COPD, the health care professionals and patients. A considerable amount of qualitative research on the needs and views of COPD patients already exists. It has been shown for example that the uncertainty regarding the differentiation between asthma and COPD also has an impact on COPD patients. In the early stages of COPD, patients do not recognize their symptoms, such as coughing, as the first stages of a severe disease. Consequently, they do not find their symptoms severe enough to warrant a physician's visit.[10] COPD patients also often feel ashamed about their medical condition. They feel it is self-inflicted (caused by smoking) and the resulting shame is undoubtedly an obstacle to seeking medical advice, especially when they continue smoking.[1;10;11] Previous research has shown that breathlessness is one of the most problematic symptoms of COPD.[12] Good self-management with medication is very important for them to regain control of their breathlessness and lives [11;12], however exercise programs are approached with caution because of the breathlessness.[12] Although patients report feeling confident about self-management of their medication, they are not confident about their actions in an emergency situation.[11]

Qualitative studies on health care professionals and their experiences of COPD treatment or care concentrated mainly on stop smoking management.[13-16] We have not found qualitative studies that investigated the views of health care professionals on regular COPD care, although a few studies focus on perceptions of end-of-life care, specific use of spirometry and under-diagnosis of COPD.[17-19]

There are large differences between countries in the way primary care of COPD-patients is organised, and therefore local studies may have limited generalisability. We wanted to know which experiences and challenges were shared by clinicians who care for COPD patients. Therefore, we set out to investigate the experiences and opinions of GPs and respiratory physicians regarding COPD care in seven different countries (Norway, Russia, Germany, The Netherlands, Poland, Wales and Hong Kong). This analysis should lead to a clear understanding of the main concerns in COPD care. To be able to investigate this in enough detail we focused on the assessment and management of acute exacerbations. Our aim was to explore how GPs and respiratory physicians reason when managing patients with COPD exacerbations in clinical encounters.

METHOD

Design

The overall aim calls for a qualitative approach that encompasses a basic understanding of human interaction and social processes, e.g. Grounded Theory (GT).[20] Grounded Theory is furthermore, in its sampling and analytic approach, theory driven and strives for theory development of emerging categories.[21] We employed a GT approach which is mainly based on Charmaz's constructionist version but we are also inspired by Corbin & Strauss' paradigmatic model of actions and interactions to help us develop an axis of the analysis.[22;23]

We chose focus groups discussions (FGD) as our data sampling method and designed a study of 3x7 FGDs. [24;25] The study countries were from the start selected due to earlier research collaboration on respiratory diseases in networks (GRIN and GRACE): Wales, The Netherlands, Poland, Russia, Germany and Norway. The study originally was thought to be only European, but early in the process we got the opportunity to include Hong Kong. Hong Kong was in the analysis primarily used for comparative purposes adding an extra dimension to the analysis of the European countries~~, and worked as a sort of validation of the European findings.~~. Each country performed 3 FGDs with new participants each time: FGD 1 with only general practitioners, FGD 2 with only respiratory physicians, and FGD 3 with a mix of general practitioners and respiratory physicians. The first FGDs were undertaken in March 2011 followed by FGDs 2 in September/October 2011 and FGDs 3 in February/March 2012. All researchers from each country who were responsible for conducting the FGDs participated in a 3 day workshop where they were taught the methodology of GT and focus group discussion methods, both theoretically and with practical exercises. This was done in order to streamline the methods across countries and try to secure a shared knowledge and practice of the methodology, basic to making a cross-country analysis.

All countries used the same topic guide each time with a selection of already formulated prompts. Before conducting FGDs 1 the first topic guide was developed by the main author with input from collaborating countries. A pilot interview was conducted in Tromsø in order to adjust for formulations, phrases and questions. Between FGD 1 and 2 the topic guide was discussed and revised among the same authors but also with input from research leaders from the other countries – all met for a one-day workshop to discuss the categories identified in a preliminary analysis of FGD 1 and to decide on how to sample data according to this, i.e. who to include in FGD 2 and what to ask. Between FGD 2 and FGD 3 a major revision of the topic guide was made, also after a preliminary analysis and development of categories and concepts, but this time input was made by e-mail from most countries apart from the researchers in Norway and The Netherlands who met to discuss the revision. This last topic guide focused especially on providing knowledge on topics that were still unclear but also on solutions to identified challenges and difficulties as well as on collaboration. The two first topic guides included 3 patient stories (see supplementary files) to prompt the discussion on the first 3 topics. These were not part of FGD 3 but instead the topics and the results from FGD 1 and 2 were elaborated into new questions.

The interview guides contained the listed topics, based on known issues of concern to GPs. The respiratory physicians were asked to discuss the routines in general practice as it was known to them, but inviting them to be open about their own views and concerns. The topic of collaboration was mainly brought into FGD 2 to try to meet a mutual concern and the discussion resulted in change of the third FGD's interview guide:

FGD 1: assessment and medication/hospitalization/self-treatment/use of guidelines/challenging or difficult situations/most important problem/improvement of clinical practice.

FGD 2: assessment and medication/hospitalization/self-treatment/use of guidelines/challenging or difficult situations/most important problem/improvement of clinical practice/collaboration with GPs (the topics in FGD2 were supplemented with more specific sub questions than in FGD 1).

FGD 3: diagnosis of exacerbation/hospitalization of borderline cases/criteria for self-treatment/collaboration between primary and secondary sector/who are the difficult patients (the topics of FGD 3 were supplemented with sub questions aiming at describing bottlenecks and future solutions for each topic).

Sampling and material

All 21 FGDs were performed with both a moderator and an assistant moderator, except for a few where only a moderator was present. The moderators were the head researchers from each country network (a professor or doctor in family medicine), and in one case a PhD student and an epidemiologist. They were all closely supervised. The head researchers all had their main research field in respiratory diseases in general practice and the epidemiologist had a long experience with intervention research in general practice while the PhD student was new to the research field. Co-moderators were either skilled qualitative researchers or GPs with research experience. The aim was to include 6-8 participants for each FGD.

Participants for FGD 1 were GPs and were sampled purposefully to cover both rural and urban practices. They were invited via an information letter. Several information channels were used in some countries, making contacts via meetings, health boards, email, telephone, mail or personal contact. By the end we had between 6 and 10 participants in each FGD and these lasted between 1 and 2 hours. Several GPs did not wish to participate due to limitation in time and interest.

Participants for FGD 2 were sampled among hospital-based respiratory physicians and private or out-patient respiratory physicians, depending on the specific health system in each country. The number of participants varied between 4 and 7 and the FGD lasted around an hour and a half. The participants were found via email invitations, personal contacts, or at hospital wards (e.g. having a respiratory physician ask colleagues) and sampling was faster and easier than in FGD 1 but also resulted in fewer participants.

Participants for FGD 3 were sampled among both GPs and respiratory physicians to enhance a discussion on the emerging analytic categories in the data. FGD 3 had between 6 and 9 participants and lasted from 1.5 to 2 hours. The sampling took place via email invitations, through personal contact or inviting a key person to ask colleagues. The composition of the FGDs had a balanced number of GPs and respiratory physicians.

In some cases the GPs came from the same practice and knew each other. Also respiratory physicians were acquainted with each other, working at the same hospital or out-patient clinic. In some FGDs the moderators knew a few of the participants but this was not a dominant tendency. The participants were not sampled according to gender or seniority but we intended to include physicians working in both rural and urban settings as well as at different types of health workplaces, mainly regarding the respiratory physicians as mentioned above. The ones who were included and informed us about their practice time, about half of the participants, showed long average seniority (approximately 14 years) with the respiratory physicians having the most seniority. GPs practiced in single clinics, shared clinics and group practices as well as in health centers, and respiratory physicians practiced at hospitals (regional as well as university hospitals), outpatient clinics and in several cases at both places.

All FGDs were performed within university premises and they were transcribed verbatim from audio recording by the local researchers and translated into English by a skilled translator.

Analysis

The analysis took place according to GT methodology from the first round of FGDs, using Nvivo 9. First and third author did the main coding, that is, line-by-line coding in the beginning but we also coded by event, constantly looking for meaningful categories and concepts in the data and making comparisons across all FGDs. The first-round analysis of FGD 1 was performed by the Tromsø team mainly and its purpose was to guide us and decide which categories and concepts should be elaborated or perhaps de-emphasized in the following FGD. The same process took place between FGD 2 and 3. This whole approach aimed for a process of theoretical sampling. Further, the analysis also contained attempts to do focused coding[23] in order to find the most significant categories, concepts and actions of the material, and this was again extended with a preliminary axial coding trying to structure a relation between categories and subcategories.[22] The axial coding was elaborated further in the final analysis, and this was supplemented with a paradigmatic matrix that organizes data into conditions/actions and interactions/consequences and helps develop categories and find relations between them [22]. This paradigm also highlights the actions and interactions of actors involved and helps define the core categories of actions/social processes with their related dimensions which finally are developed into a grounded theory. A special emphasis is put here on intentions and goals of the actors in the process. Memos were written especially in the last phase of the analysis, giving a solid basis to start comprehending the main concerns for the health professionals concerning COPD exacerbations and how they handled them. The analysis made by the Tromsø team was supplemented and discussed with input from the study countries' teams. This created collaboration in terms of the analysis and strengthened validity of the findings. The analytic findings are presented below in a structure which firstly delivers the interpretation of findings and sub-findings, secondly illustrates these with quotations and thirdly, in some cases, elaborates or summarizes the interpretation based on inferences from the quotations and on the overall analytic perspective.

RESULTS

Balancing management within a scope of concerns

Overall, data displayed several distinct discussions on how to manage COPD exacerbations. Some FGDs were very focused on problematic issues from the beginning, others seemed more straightforward and practical, not paying much attention to any difficulties, while others again from the beginning tuned in on uncertainty concerning medical practice and knowledge, prone to discuss uncertainties and doubts. Some, after prompting by a patient story, were dominated by a demonstration of medical knowledge at the start. However, all FGDs combined their medical concerns and discussions with attempts to describe and understand the patient's social circumstances, as well as to take into account the particular health system and its resources as determining factors in management of exacerbations. When it came to discussions on main challenges, clinical practice and collaboration, several societal problems and political dimensions of health work were addressed, e.g. with a tendency to shift the level of attention from biomedicine to health promotion, health services topics and general health population issues.

The analysis of all FGDs made it evident that the management of COPD, especially of exacerbations, is experienced as trying to balance between medical knowledge and practical, situational knowledge. Balancing management *per se* is the main concern for both GPs and respiratory physicians, resolved mainly by strategies of *knowing* patients, their social resources and health contexts. However, this concern only makes sense when subcategories of concerns are explained and analysed one by one, showing the mechanisms of an interconnected process, i.e. a scope of concerns.

Dealing with comorbidity

'Dealing with comorbidity' is a concern which is significant for three different dimensions of clinical management of exacerbations: how to be sure it is an exacerbation, when to prescribe antibiotics or steroids, and when or who to hospitalise. Comorbidity refers here to the existence of disease conditions other than COPD, such as asthma, cardiovascular disease, skeletal muscle dysfunction, metabolic syndrome, osteoporosis, depression, and lung cancer.

Crucial to a diagnosis of exacerbation, we found in the FGDs that the physicians all wished to see the patient when he/she calls the GP and asks for antibiotics because of a worsened condition. To merely give advice or to prescribe over the phone was for some suitable only if you knew the patient well. As such, making a diagnosis of COPD exacerbations was closely connected to seeing, knowing and examining a patient. However, just as important, symptoms like breathlessness and anxiety were understood to be caused by multiple possible diagnoses, that is, the questions of comorbidity blurred the picture. Not everything resembling an exacerbation is one:

> It is difficult, for example, to diagnose COPD in an 80-year old patient. I had such a patient. The doctor [GP] diagnosed her with asthma. This is a non-smoking patient. Her FEV1 is 27%. I have a question: what is it? Is it COPD or asthma? The test with bronchodilator was positive. Such mixed cases are difficult. Although today we treat such cases in the same way, with combined medicines. In general, we have a lot of difficulties in diagnosing the severe patients. (Russia FGD 2)

In terms of theoretical medical knowledge, making a diagnosis could be presented by the physicians as straight forward, but the clinical picture of comorbidity confused the process:

> Yes, but still, it [making a diagnosis] is not difficult at all. It's the matter of, it's the many comorbidities among them, everyone at risk for COPD is rather at risk of, well, cancer and cardiac diseases are quite common among COPD patients. (Norway FGD 3)

Diagnosing was perceived overall to be a clinical process made over time, using in particular the patient's story and experiences to estimate an exacerbation, trying to judge if the patient does have an exacerbation or not.

Comorbidity was also described as a crucial factor when deciding whether or not to prescribe antibiotics and steroids, and this made prescribing decisions difficult:

> …. these patients have often got a load of other things wrong with them, they are high risk individuals, they have been smoking for many years and I think the main worry is about, is the things that we talked about, is multiple pathologies, multiple drugs. (Wales FGD 1)

Concerning steroids, the respiratory physicians in FGD 2 seemed to be overall in favor of prescribing steroids for an exacerbation for a limited time period and discussed more intensely whether to give antibiotics and on what basis, due to resistance considerations. Conversely, for the GPs it was 'easier' to prescribe antibiotics, but giving both drugs at the same time was not their first option, especially when considering comorbidity. The side effects of long term use of steroids and the risk of inducing pneumonia were decisive issues for the GPs:

> Usually, we should be concerned whether there is an infective component when we prescribe steroids. Usually chronic COPD patients are weak and if we prescribe steroid for them, it will be easy for them to get infection and often I will prescribe antibiotics as daily practice (Hong Kong FGD 1)

> The comorbidity is high and I reckon that every COPD patient has some form of presence of one or more disorders in addition to a primary disease or disorder…[…]… When visiting the practice I will often put them on a scale. They need to be weighed anyway for COPD. So if they have gained 4 kg I am not sure to send them home with a dosage of prednisone and say they'll be fine. (The Netherlands FGD 1)

When considering whether or not to hospitalise, this was illustrated in long debates on pros and cons. The possibility of comorbidities such as heart failure, diabetes, pneumonia, anxiety or psychosomatic disorder were important considerations for the physicians. A suspicion that a patient had an undiagnosed comorbidity might be reason enough to admit a patient.

> E: I think it also depends on the severity of the disease before the exacerbation, that is, how much strength the patient has got left. If he is unstable anyway, even if he isn't exacerbated, then that's a reason to hospitalize him of course. The other possibility would of course be, that you have been treating him with different therapies and you say, I don't see any significant changes, and this has to be analysed in more detail.
> G: And it also depends on the comorbidities, what other diseases he has. (Germany FGD 3)

For COPD exacerbations in general objective assessments, such as low oxygen saturation and rapid respiratory rate, were the most obvious criteria for hospitalization:

> I think there are two important things with this case, firstly how well the GP knows the patient so he can compare them to their baseline and secondly an objective assessment, oxygen saturations, respiratory rate, heart rate, all these sort of things, a clinical consultation, I think. (Wales FGD 2)

On the other hand, after taking into account the patient's basic medical status, how well the patient is known and his general condition, decisions about hospitalisation came down to whether one would risk letting the patient stay at home despite comorbidities or social situation, or wishes:

> [I will assess]…age, comorbidity, the increase of respiratory failure, whether a patient can sleep or he's sitting all night in this position, orthopnea as he can ... what kind of work around the house, he can perform. Can he dress himself, can he move around the apartment, or does it gives him a hard ... can I manage treatment ... And if relatives can help in treating him at home ... (Russia FGD 1)

> On the other hand you also have to see, how multimorbid the patients are. Cardiac decompensation, exacerbated COPD, back and forth again and again, sure it's difficult, but you have to ask yourself "how far can I treat this locally? What can I achieve?" So that we have, right, we all also are in the ambulatory area, we also have our limits. And if we have such complicated cases, where there is something wrong again and again, and we have to ask us diagnostically "What is the real problem?", there I sometimes believe, that some patients, also if they are tired of it, would be better off at a hospital (Germany FGD 3).

> Yes, and so social factors also play a role, if she lives alone and doesn't have any security network at home you can, at any rate, be more unsafe when deciding to send her home, and I assume that one would tell her, in case you don't admit her… you would have a lower threshold to do so if she gets worse. (Norway FGD 2)

The elements of medical decision-making, that is assessment, tests, diagnosis, medication, hospitalisation and overall management, were on one hand discussed within the framework of highly complex medical matters, weighing biomedical, pharmaceutical and technological knowledge against each other, and on the other hand taking into account knowledge of the social context of the patient. Indeed, the patient's social condition, background, resources and personal profile were highly important for all concerns of 'dealing with comorbidity' and clinical decision-making in order to balance medical knowledge:

> There are so many things that you have got to take into account like social circumstances, does he have someone in the house to keep an eye on him, do they have a whole load of other co-existing illnesses, um you know it's very difficult to pick on one thing, it's you trying to make a decision on a number of factors (Wales FGD 1)

Participants' thoughts about use of medication indicated a specific concern for the patient and a wish to know more to support a medical decision. These thoughts were both medically informed and patient-centered, e.g. how high doses were acceptable and for how long time, when was it rational to prescribe antibiotics or steroids according to clinical findings and history, how would the patient accept medication, would he be compliant (both concerning up-take and purchase of medicine), and would he be able to have a dialogue on effects and use with his physician:

> Now we talk a lot, but if you know him, then you know whether he already had something like this in the past. Do you have the case history, does he have compliance? Does he take his medication? Or not? Or is he someone who comes along, I don't know, and maybe had an infection as a trigger, he still smokes heavily and now found his spray and has been using it for 2 days and it doesn't help yet (Germany FGD 1).

Thus knowing the patient in several ways and at several levels was a common approach, and this situational knowledge was used for gaining a complementary understanding of how to treat the patient and determine the necessary medical steps to take.

Having difficult patients

The second concern emerging from the FGDs is 'having difficult patients'. This concern contains a shift in perspective moving from seeing 'comorbidity' as a problem to how the GPs and respiratory physicians may see the patient and the relationship with the patient ~~and individual person~~ as a problem. In this move, the patient as a person and his/her personality, situation and context is in the foreground, not the medical condition per se.

A common dimension of 'the difficult patient' is presented in some of the first reactions from the GPs and respiratory physicians when they start talking about COPD patients. On one hand, it is a relief that the management and treatment of these patients in general has become easier and more successful due to new drugs (although treatment may still be complicated because of complex conditions), but on the other hand some physicians feel annoyance when they perceive that patients have unrealistic expectations:

> In general, these patients are more difficult; the patients, who have a lot of expectations, and believe that all of their 'affairs' will be resolved for them (by someone else). I don't particularly like those patients; they are difficult to cooperate with, perhaps, just because of their belief that everything should be done for them (Poland FGD 1)

More often though, having patients with COPD exacerbations generates mixed feelings of concern for the patient.~~, mixed with feelings of being challenged professionally and being unable to give them the best treatment.~~ The patients are difficult exactly because they are seriously ill and suffer and need complex attention, while at same time they are difficult because they are time-consuming, frequent attenders, non-compliant and often do not give the physician the satisfaction of being helpful:

> As for me COPD patients are men with long smoking experience, they are often poor, of low social status, alcohol dependent, they usually don't follow the prescribed treatment. They simply don't have enough money for treatment. I examine them and usually refer to the hospital or to the expert bureau. Generally it is a very sad story, usually leading to disability. There are very few effectively treated patients. (Russia FGD 3)

Especially when discussing self-treatment the patient and his/her social profile turns up as a problem – probably because here the patient is delegated an active role, and behavior and context becomes even more decisive for a decision to prescribe self-medication. Being a 'difficult patient' is further dependent upon a spectrum of difficulties pertaining to the patient himself, such as poor illness perception and understanding (resulting in under- or overtreatment), smoking habits/lifestyle/behaviour, poor intelligence, poor compliance, old age, and bad quality of life/poor economy. But the label of being difficult also results from unsuccessful/lack of interaction and communication with the health professionals to improve one's situation together.

> There are a couple of things we encounter such as most patients are 'dead horses'. This does not sound respectful but there are a lot of patients who want to be left alone. We cannot make them understand what we expect from them. Be active, quit smoking, more exercise, loyal to therapy, take their own initiatives (The Netherlands FGD 2).
>
> We refer them to this school while they are on a sick leave. We try to convince them of something, especially of the necessity to refuse smoking. It seems that they agree, nod, everything is understood, but they don't come to the second or third meeting. We don't see the light in their eyes; we don't see their initiatives, their participations, any support for their care. Therefore, we have refused to conduct school for COPD patients as we don't see the interest from the patients. (Russia FGD 2)

In other words, a patient was seen as 'difficult' as a result of an interaction, or 'difficult' was an already made characteristic clinging to certain disease profiles, either due to earlier experience with a patient or due to generalised knowledge of COPD patients. Moreover, the difficult patient is a typology referring to the continuum of concerns and not all patients are labeled as such. Some indeed are mainly difficult because they have difficult illness conditions. But still, the physicians' perceptions of having 'difficult' patients' in terms of social and personality related difficulties, not explicitly related to the medical condition, govern several interactions. The physicians try out several practical solutions to this and one important overall action suggested is to get better at motivating patients. Motivation is the key to several aspects of the difficulties they meet in patients. A repeated advice here is to teach, instruct and inform patients – about the disease, about medicine and especially about the right self-treatment. To teach and motivate is the main action pertaining to 'the difficult patient' – but it builds on the necessity to know and involve the patient in a relationship in order to address him/her properly:

> I think that is what GP's are supposed to do. I think that most GP's, especially the younger ones, think highly of communication. It matches well. It is difficult and the relationship between yourself and the patient is very important. Getting people to quit smoking. The times that you succeed are very rewarding. People are genuinely happier/healthier when they have quit smoking. And the whole story of empowerment as they call it, that you trust the patient to be able to handle his/her own problems. I think that patients are rather dependent (The Netherlands FGD 1)

Confronting a hopeless disease

The third concern in the scope of management deals with how to balance one's approach to a disease that confronts the physician with both his medical professional limits, i.e. the limits for curing and saving lives, and with the patient's existential deterioration at all stages - suffering in general and at end-of-life stages. In this approach it is primarily the disease in itself which the physicians react emotionally upon. It is the disease that makes the encounter with the patient become characterized by shifting feelings of empathy, hopelessness or frustration, notably related to COPD in general more than to only exacerbations. The severity and poor prognosis of the disease *per se* gave for example either an atmosphere of frustration or simply created a pragmatic attitude:

> They are the most severe patients among the patients with broncho-pulmonary pathology. This is the category of severe patients, which you don't know how to help, in spite of all the standards what exist today. Dyspnea will come anyway. Neither oxygen, nor steroid therapy, neither bronchodilators, nor courses of antibiotics – sometimes nothing for these patients can be done if a patient has severe COPD (Russia FGD 2).
>
> Another difficult matter is that they don't get better at all…[…]… it's like you prescribe one drug after the other but their conditions worsens gradually and they suffer from difficulties in breathing and in the end we have nothing left to help them with (Norway FGD 1).

Other reactions seen were expressions of sympathy and feeling sorry for the patient in the light of a quickly deteriorating chronic disease:

> And you also have these fatal developments, we know that about COPD, you can use the maximum therapy and the patients do as they are told, but still it gets worse bit by bit. And that's especially dire. That's where you really pity them, because you are so powerless. That's how it is then. (Germany FGD 3)

Another often mentioned dimension of this concern dealt with smoking. Smoking habits and the failure of smoking cessation was considered a main obstacle for the prevention of exacerbations and the discussions on this topic were often marked by hopelessness concerning the patient's capabilities of cessation.

> We give patients with mild or moderate stages of COPD anticholinergics, explain them why they need such treatment. And they do not give up smoking. Sometimes I have the opportunity for a whole hour to talk with the patient. [We] spend a lot of energy and the energy without any feedback. Dim eyes. [They] like smoking, and continue smoking, although they agreed to stop. But he doesn't do anything (Russia FGD 2)

Continuous smoking habits became unintelligible to the physician and his attempts to ease symptoms and relieve a condition, especially when a patient experienced acute exacerbation.

Patient’s smoking habits in general were an especially dominant concern for the physicians, not merely as a simple life style issue. They invoked strong emotional reactions among the physicians when faced with suffering, deterioration and death due to smoking. In the light of this, the many discussions on smoking cessation may be seen as attempts to strategically manage both a critical disease and an experience of being professionally helpless and emotionally touched. Also non-compliance of medication was a source of discontent and puzzlement amongst the physicians. Such experiences often created an air of hopelessness and helplessness which were related to the concern of ‘having difficult patients’. But here we wish to emphasize that the feelings of the physicians were triggered by the disease more than by the interaction with the patient.

The feeling of~~same~~ hopelessness was experienced also in relation to systemic factors. For example, if oxygen was not available or hospital care was inadequate. Despite all these negative experiences, an overall preoccupation with the patient was always present, resulting in actions of care even for the patient with ‘the hopeless disease’. For those who might still increase their quality of life, discussions on the value of rehabilitation and especially physical exercise came up as an answer and as possible strategies to prevent deterioration into stage III or IV COPD. Rehabilitation was especially brought up as an overall concern for the patients’ social life, involving several suggestions of practical advice and how to teach patients and their families, e.g. basic disease management, physical exercise and smoking cessation, organized in COPD schools. However, rehabilitation attempts were hampered by a lack of programs, access, financial priority and collaboration, especially in Russia and Poland.

> It is not being founded. Anyway, there is no tradition of rehabilitation in diseases of the respiratory tract in Poland (Poland FGD 2)

> ... no one said anything about the rehabilitation of patients ... here it is, I think quite an important point ... and, by and large, we do not know how to perform [rehabilitation] (Russia FGD 1)

> … the evidence is very clear, that a rehabilitation program on COPD-exacerbation is something extremely good. The evidence is OVERWHELMING and the health insurance companies nearly NEVER cover the costs for it. And that’s something that can drive you mad. That the evidence is crystal clear, but the attitude of the insurance is also crystal clear: We won’t finance rehabilitation programs. And that is a daily conflict that we have to fight (Germany FGD 2)

> But, but that’s the solution, the solution is not to send patients to an extremely expensive rehab center, the solution is gathering people, making people aware, and I ‘m convinced if you buy a set of Nordic walking equipment and you find two buddies to walk with, you have both the element of resocialising and a healthy exercise combined, people are given perspectives again, for 30 euros you can set up an exercise program. Thirty euros for Nordic walking equipment, when buying at Aldi it is even cheaper. But what you need is to make the patients aware of it, and when they do not concretize and you will treat them with drugs it will be ineffective. The challenge and art is to motivate the patient, and subsequently imbed Nordic walking equipment. (Netherland FGD 2)

Palliation for COPD patients came up as a topic of discussion in many FGDs. This was phrased as a worry that the patients would not receive the optimal palliative attention, for example compared to cancer patients, or that the physicians did not attend enough to provide palliative care:

> …[…]…not going to make them better, so a lot of them will just slowly progress and they’ll get worse and worse and worse and then eventually what we should be doing is referring a lot of them to [palliative care], they shouldn’t be down the chest side of things and so, palliative care deals with cancer that’s fine, you know, but they don’t deal with conditions that aren’t cancer, no, no they do, they do but what I'm saying is that now we should be using that a lot more (Wales FGD 2).

[Insert figure 1 here]

DISCUSSION

The management of acute COPD exacerbations was dealt with within a scope of concerns. These concerns ranged from 'dealing with comorbidity' to 'having difficult patients' to 'confronting a hopeless disease'. The first concern relates to medical uncertainty regarding diagnosis, medication and hospitalisation. Here, the clinical process was often presented as straight forward in terms of theoretical medical knowledge, but became blurred by issues of comorbidity and social context. The second concern is when 'difficult' becomes an attribute of a patient. Patients were difficult exactly because they needed complex attention, but even more because personality aspects triggered annoyance, they presented poor illness understanding, and were time-consuming, did not take responsibility and were non-compliant. The third concern relates to the emotional reactions by the physicians when confronted with 'a hopeless disease' due to the fact the disease is chronic and progressive and treatment options slow down the process at best. Physicians both met their own limitations and reacted to end-of-life stages of COPD and patient's poor quality of life. GPs and respiratory physicians balance the concerns of 'dealing with comorbidity', having difficult patients' and 'confronting a hopeless disease' with medical knowledge and practical situational knowledge, trying to encompass the complexity of a medical condition. They engage vividly in suggestions to improve future consultations and patient lives, making an effort to create effective medical routines.

Co-morbidity and the social context of the patient complicated management. In everyday practice the complicated rather than the straight-forward patient profile is probably most common, considering the high prevalence of co-morbidity in this patient group.[26] This also illustrates that physicians feel the lack of good guidelines incorporating co-morbidity issues clearly.[27] Therefore, an important aim for future COPD-guidelines would be to describe management options within the context of the most prevalent co-morbidities in COPD. In addition, there is a need for more pragmatic trials in patients with COPD that do not exclude elderly patients or patients with co-morbidity. Increased collaboration between general practice and hospitals was also suggested as an approach to dealing with uncertainties around comorbidities. Collaboration could lead to standardisation of assessment, establishment of joint consultations in order to make pulmonology services more available to GPs, definition of work tasks specific for each specialty, and more involvement of GPs in hospitalisation decisions and discharge.

COPD patients that experience exacerbations are commonly viewed as difficult patients, with some physicians even saying that they don't particularly like these patients. Little is known about this emotion among physicians, but this finding is in agreement with qualitative studies among COPD patients where they express the feeling that they are blamed for their self-inflicted disease, not only by their own social environment, but also by healthcare workers.[28-30] The management of COPD exacerbations and stopping smoking require an active role of the patient, so it is understandable that healthcare professionals may feel frustration if their advice is not followed. On the other hand, the resulting emotional impact of blaming patients is likely to have a negative effect on the patient's mood, which will further hamper the relationship and the clinical process.[30] The ´difficult´ patient is well-known from studies on other kinds of patients and is commonly attributed by physicians to mental disorders, personality traits or morally flawed behavior.[31] Fiester however argues, that the label ´difficult´ is best explained by problematic interactions or reactions to the delivery of care, and he also notes, like we found, that a physician may label a patient ´difficult ´or ´hopeless´ because of her or his own inability to effectively diagnose or treat the problem, or because of a patient's reaction to this failure. He points to the problem as an ethical one requiring an ethical consultation service. In our study, to overcome ´difficult´, the physicians focus on improving instructions to patients and to target the instructions according to their capacities – that is, mainly an approach to optimise knowledge. The GPs may need supportive actions for this from the health system and society. Concerning self-treatment, concrete future steps were identified in the data such as using management plans including 'rescue packs', having a nurse to take specific care of self-treatment, and arranging teaching sessions involving the patient's spouse and family, as has shown to be effective in e.g. Bourbeau et al.[32] . However, as suggested by Abbot, the most fruitful approach might be to deal with ´the difficult interaction´ rather than targeting either the patient or the physician. [33] Therefore, programs that specifically focus on improving the physician-patient relationship might be worth investigating.

Our finding that physicians feel powerless and frustrated because they have nothing really to offer the patient has been reported in other qualitative studies,[34] but detailed literature on this subject is very limited. Physicians feel that they do their best, approach the patient with care, and try to work according to the guidelines, but that there is little progress, only deterioration in the condition of the patient. Practical future steps include prioritising pulmonary rehabilitation, including adequate resourcing and ensuring that it is accessible for those in need, as well as a specific focus on physical exercise and physiotherapy. Also a more concurrent focus on palliative needs and care and the ability to refer these patients to palliative teams was warranted. Pinnock et al suggest that an assessment should take place related to hospital admission for exacerbations.[35] A patient study determining palliative needs found considerable needs in relation to breathlessness but fewer in the end-of-life stage.[36] This is elaborated in Habraken et al who point to the silence of COPD patients about end-stage needs because they do not realize there are possibilities to improve their condition.[37] This, together with our study of the physicians, suggests potentials for improvement of palliative care.

Overall, the physicians in this study refer in many different ways to the significance of *knowing* the patient - and different dimensions of knowing him/her. We find that *knowing* concerns the disease and comorbidity and it addresses several practical issues of treatment: e.g. a patient's difficulties using an inhaler, the support available from family and relatives, a patient's capacity to learn about colour codes for medicine or his ability access to a rehabilitation center. In other words, knowing the patient also means that a GP does not or cannot always rest on clear evidence-based medicine, but that he together with the patient may deal with changing and context-dependent patient needs. We see this *knowing* in our data, where it shows that patient and physician together try to adapt to the best treatment and take into account situational contexts and practical and social circumstances. This approach is related to a concept promoted by Mol, 'the logic of care', which embraces both the patient and the doctor as active parts who together create adequate treatment.[38] *Knowing* also is an approach that is central to the suggested collaborations between health professionals/health sectors and which is sought to be enhanced through collaboration.

The overall strength of this study is to be found in the design. It was designed as a cross-country study in order to attempt to find common crucial concerns within COPD exacerbation management in different health settings. There is a general lack of such comparative studies and our findings are grounded effectively in the whole empirical material. On the other hand the focus on common issues may overshadow local contexts and local details on management. Also, there is always a danger that a comparative aim looks more for commonalities and convergences than for divergences. However, during the analysis we made an effort to scrutinize any major deviances to determine whether they had significance for the development of new analytical concepts or whether they were dimensions or properties to already found categories. Other variations are part of the detailed examples of the illustrated concerns. Hong Kong was chosen to compare European management to a supposedly different kind of management, but the data from Hong Kong turned out to support and comply with the analysis of the other countries. A weakness in the study and this analysis is that we were not able to specify exactly what role the different health contexts played for the construction of the concerns. That is, we were aware that discussions in the FGDs were embedded in local health systems. They played a part in how physicians talked about their own medical practice, how their practices were framed economically and how working conditions were experienced and practically operationalised. Further, GPs and respiratory physicians might not necessarily share the same medical knowledge background. However, a large part of the participants had changed career from e.g. GP to internal medicine, or working in hospital service for several years before becoming a GP. Also many worked in outpatient-policlinics (both GPs and respiratory physicians) or outpatient-clinics combined with either hospital wards or health centers (GPs). This, we believe lumps the two specialties together rather than splitting them concerning medical experience. Hence, regarding the concerns we found in the analysis, it still seems justified to talk about shared concerns. But certainly, we fully acknowledge that there are differences *within* the concerns that are both culture-specific, health system specific and determined by different social and medical practices. We argue that the concerns are alike, but how to administer them in detail, how the specific perception was of patients, how collaboration could be improved etc., varied from country to country. Future analyses of the dataset will draw in more focus on e.g. differences among the countries in self-treatment and the role of health systems. Methodologically, the fact that the FGDs were performed by different moderators did result in variations of moderation style and subsequent heterogeneity in FGDs. All were trained to perform alike with the same questioning route to follow but focus groups develop independently, often as a result of the participants. That the participants sometimes knew each other may have created a barrier for critical discussions, especially if seniors and juniors were together. It did however also in some cases give a more safe setting for in-depth discussions. The moderators' background in general practice and interest in respiratory diseases may on one hand have been an advantage because the topics of the FGDs were well known. But on the other hand it might have created a blind eye towards specific areas. We saw that the PhD student and the epidemiologist more than others asked into themes just to understand what was meant. Also their background in different nationalities and medical discourses may have coloured the interviews, but this counts for the participants as well. Most importantly, all major topics were discussed in all FGDs and the methodological conditions above did not in our view jeopardize the present analysis. Concerning translation there is always a risk that phrases and concepts have lost their significance during translation – certain translations were however discussed with the responsible researcher when the first author became in doubt about its content. Another limitation is that the interviews and the study overall were intended to focus on exacerbations, and while the patient stories and the medical discussions did so, it proved inevitable for the physicians to leave out thoughts and reflections on COPD patients and the COPD disease in general in many other aspects of the interviews. This is especially reflected in thoughts related to the third concern. We were aware of this during analysis and decided not to try splitting the results artificially into what dealt with exacerbations and what did not. Lastly, sampling of the participants was intended to be strategic but turned out to be more pragmatic due to recruitment difficulties and due to differences in health systems.

Unanswered questions and future research derived from our study point to the need for more observational studies on how management in real life takes place. Studies addressing the benefits of management plans and understanding the low status of COPD patients amongst GPs would also be of benefit.

CONCLUSION

Knowing the patient is essential in dealing with comorbidities as well as with difficult relations in the consultations on exacerbations. This study suggests that it is crucial to improve collaboration between primary and secondary care, in terms of for example shared consultations and defined work tasks, which may enhance shared knowledge of patients, medical decision-making and improve management planning. It also suggests that the GPs need supportive actions from the health care system and the society to target difficult consultations. Further studies are needed on barriers in the doctor-patient collaboration and how to reduce the GPs frustration with COPD patients, in order to promote an optimistic and fruitful attitude to this group of patients.

Competing interest statement

All authors have signed the ICMJE conflicts of interest form: None declared.

Contributor statement

All authors participated in the design of the study, revised the article critically for important intellectual content and gave final approval of the version to be published. Further, Risør is the guarantor of the paper and she did the main analysis and interpretation of the data and drafted the article until final version; Iversen, Spigt, Godycki-Cwirko and Francis performed FGDs and contributed to analysis and interpretation of the data; Altiner, Andreeva and Kung performed FGDs; and Melbye contributed with overall conception of the study.

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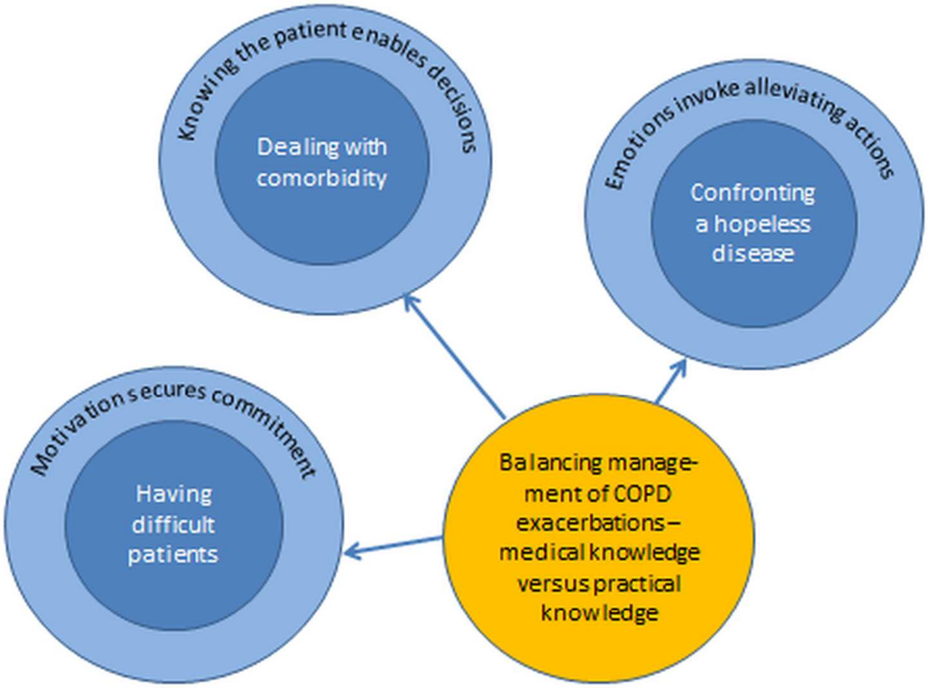

A grounded theory of COPD exacerbation management

Patient stories

1) A 60 year old male patient with moderate COPD has called your practice and asked for medicine, due to increased coughing and shortness of breath the last week. He quit smoking a year ago. You have prescribed anticholinergics for inhalation as maintenance medication. Now he thinks a course of antibiotics might be helpful. He was treated with amoxicillin and prednisolone last winter 9 months ago, and recovered after a few weeks.

2) A 70 year old female patient, still smoking, visits your practice. She was hospitalized due to her COPD one year ago. She uses a combination of inhaled corticosteroids and long acting beta2-agonists, and short acting beta2 agonists on demand. She had a common cold a week ago. Now she has no fever, but breathes heavily and rather fast. She had to sit in her bed last night, and she feels somewhat exhausted. Although you hear wheezes all over her chest, you do not think the obstruction is very severe. You believe her illness is worsened by her anxiety, but consider admitting her to hospital.

3) A 72 year old woman visits you for a follow-up examination. She had a COPD exacerbation three weeks ago, for the second time this winter. She is now in her normal shape. FEV1/FVC ratio is 0.55 and her FEV1 % predicted is 45%. She has reduced her smoking considerably, and smokes only 5 cigarettes a day. She will continue the regular use of a long acting anticholinergic, and is encouraged to use a short-acting beta2 agonist on demand. You consider giving her inhaled corticosteroid in addition. You also consider prescribing courses of oral corticosteroids and antibiotics which she could administer herself if she develops a new exacerbation.

Caring for adult patients with acute exacerbations of asthma or COPD in general practice

Exploration of current practice and options for improved assessment and care

Relevance

Exacerbation of asthma and COPD causes great suffering, premature deaths and considerable health care expenditures in our society. Such exacerbations are treated in hospitals as well as in primary care. However, according to national strategy (Najonal strategi for KOLS-området 2006-2011), general practitioners (GPs) will have an increasingly important role in the care of COPD patients. The project encompasses clinical research in primary care settings, questionnaires among hospitalized patients, and qualitative interviews with patients and doctors. The General Practice Research Unit in Tromsø (AFE Tromsø) will through the project cooperate with GPs from seven Norwegian GP offices, the General Practice Research Unit in Oslo, pulmonologists at the University hospital of North Norway and three district hospitals (Helgelandssykehusene), as well as GP researchers from 5 other European countries. Young GP researchers will be recruited to the project, which will give material for at least two ph.d. theses in the field of general practice.

Aspects relating to the research project

Background and status of knowledge

The prevalence of chronic obstructive pulmonary disease (COPD) among those aged 40 years or older can be estimated to be 5-10 %[1]. Smoking is the main cause of the disease. The prevalence of self reported current asthma was 4.5 %, in a population based survey in USA[2]. Asthma may develop into COPD[3], and COPD patients may exhibit bronchial hyperresponsiveness like in asthma[4]. Accordingly, in many adults it is difficult to distinguish between these diagnoses[5]. Some patients are treated with anti-asthma drugs without fulfilling established criteria for any of the obstructive pulmonary diseases, just by being at risk of getting COPD[6].

Exacerbations of COPD are defined as “an event in the natural course of the disease characterized by a change in the patient’s baseline dyspnoea, cough, and/or sputum that is beyond normal day-to-day variations, is acute in onset, and may warrant a change in regular medication”[7]. COPD exacerbations are caused by a respiratory infection (viral, bacterial or combined) in approximately 80% of cases[8], and viral infections are also common causes in exacerbations of asthma[9].

Exacerbations of asthma and COPD can present with all degrees of severity, from prolonged cough after an airway infection (RTI) to life- threatening respiratory distress. Exacerbations are associated with reduced quality if life[10], premature deaths[1], and great health care costs[11]. Treatment with antibiotics may be crucial in severe cases, and there is evidence that early treatment may be beneficial in bacterial COPD exacerbations, reducing the admission rate to secondary care[12]. There is also a documented effect of treating exacerbations of asthma and COPD with a course of oral corticosteroids[13]. Such treatment is recommended in current guidelines[7;14]. The average exacerbation rate in COPD patients is probably 2-3 per year[11].

Assessment

The 2007 GOLD guideline recommends pulse oximetry and chest radiography when assessing COPD exacerbations, while routine use of spirometry is not recommended[7]. The assessment of COPD exacerbations are, however, still mainly symptom based, and laboratory results and radiographic findings are not included among indications for hospital assessment in GOLD guidelines[7]. Anthonisen set up three criteria for classifying COPD excerbations in his landmark clinical trial published in 1987: Increased dyspnoea, increased amount of sputum , and increased purulence of sputum[15]. If only one of these symptoms was present, antibiotics could not be recommended. Recommendations on antibiotic treatment for COPD excerbations are still based on the presence of these symptoms[7;16].

When Anthonisen's criteria were formulated, there was less awareness about bacterial resistance. Somewhat stricter criteria have been recommended by European guidelines from 2005, reserving antibiotics to COPD exacerbation fulfilling all three of Anthonisen's criteria[17]. Dutch guidelines recommend reserving antibiotics to patients with very poor lung function or other risk factors of severe disease course[14]. We do not know to which degree the guidelines are followed in primary care. In the Netherlands, where antibiotics are less frequently prescribed than in other European countries[18], co-morbidity has been found to be taken into account when antibiotics are prescribed for COPD exacerbations[19].

Self- management

To secure early treatment of exacerbations, many GPs provide their asthma and COPD patient with prescriptions of antibiotics and oral corticosteroids to use during forthcoming exacerbations[11;20]. The patients may thus treat themselves without consulting a GP when their disease worsens. In a Norwegian project[21], asthma and COPD patients were educated on self-care, including better inhaler technique and regulation of medication by symptoms. The regulation included taking oral prednisolone during exacerbations in patients using inhaled corticosteroids, whereas self-treatment with antibiotics was not incorporated. Patients in the intervention group had significantly less GP visit the following year and better health-related quality of life compared to controls. In a Canadian study, supply of both prednisolone and antibiotics were included in the self-management plan. Increased use of both kinds of medicine was observed, but no change in unplanned medical visits[20]. This indicates that supplying patients with antibiotics may lead to over use. Such self-treatment is not recommended in the GOLD guidelines, neither in those developed by International Primary Care Respiratory Group (IPCRG)[22]. Giving patients the responsibility for diagnosis and treatment of exacerbations may delay help-seeking. Some patients want to avoid bothering their doctor[23], and with the medication at hand they may feel even more reluctant to "disturb" their GP.

Gaps of knowledge

Epidemiology and use of health care

Exacerbations of asthma and COPD have mainly been described, as they present in secondary care. More than 50% of those consulting an emergency department in USA are admitted to hospital[24]. Other factors than the severity of the exacerbation influence the consultation rate with GPs in UK as well as at emergency rooms in the U.S[23;25], such as a missing or poor relationship with a GP. In a Dutch and a Swedish study from primary care 53% and 80% of patients with asthma and COPD exacerbation, respectively, were treated with antibiotics[19;26]. Otherwise, evidence drom primary care is sparse.

Assessment of asthma and COPD exacerbations

Supplying patients with prednisolone and antibiotics may reflect an attitude among GPs that examining the patient during exacerbations is often useless, since the condition usually allows a standard treatment. The relevance of differentiating the treatment on the basis of clinical findings and test results needs to be clarified. The European guidelines for lower respiratory tract infection express a worry about the validity of the Anthonisens criteria: " It should be noted that these criteria are subjective and based on only one study. More research in this field is needed"[17].

The CRP test

Markers of systemic inflammation, like C-reactive protein (CRP), are often elevated in COPD exacerbations, especially when a bacterial infection is present[27-29] A CRP value above 50 mg/L in hospitalized patients has been found to be associated with poor outcome[30]. A low CRP value may support a decision not to prescribe antibiotics[28]. It has been suggested to add such a marker to the Anthonisen based diagnostic criteria[31;32] . The CRP test is widely implemented as a near patient test in general practice in Scandinavia, and is already applied in assessing COPD exacerbations[26]. More knowledge is needed about the role of the CRP test in the decision whether or not to treat with antibiotics.

Pulse oximetry

Availability of pulse oximetry is increasing in primary care[33]. Values ≤92% are associated with severe exacerbations[33], and a routine use of the test in COPD exacerbations has been recommended[34]. More knowledge about the predictive value of pulse oximetry in asthma and COPD exacerbations is needed.

Spirometry

Spirometry is now a common examination in Norwegian primary care[35]. Spirometry is not recommended as a routine test in COPD exacerbations in the GOLD guidelines. Sick patients often have difficulties in performing properly[7], and the predictive value of spirometry in these situations seems to be limited[36]. This recommendation is, however, based on data from emergency departments. The picture may be different in primary care, were patients often are less severely ill. For instance, when considering oral corticosteroids, comparison of current and previous spirometries may prove useful.

Self-treatment and health-seeking behaviour

Supplying COPD patients with prednisolone and antibiotics may ensure prompt treatment of exacerbations. Self-assessment may also lead to over treatment and delayed doctor visits. We do not know how self-management is applied today. An impression that assessment by a doctor is unnecessary may signal a low status of their disease in the society. Expecting patients to treat themselves may thus foster feelings of shame for having a self-inflicted disesase[37], and more knowledge from the patients point of view could be useful.

Approaches, hypotheses and choice of methods

The four components of the project

Study 1: A clinical study of asthma and COPD exacerbations in primary care, following patients aged 40 years or more with asthma or COPD during their exacerbations.

Study 2: In-depth interviews with patients having moderate or severe COPD, about how they experience access to health care, self-treatment, and emotional barriers in their help-seeking.

Study 3: Focus group discussions with GPs and pulmonologists from 6 European countries on their views about assessment and medical treatment of patients with asthma- and COPD exacerbations, including self-treatment.
Study 4: A survey among patients hospitalized due to asthma or COPD exacerbations about delay, self-treatment and contact with primary care prior to admittance.

Aim of the project

The aim of the project is to gather new knowledge that can contribute substantially to improved guidelines for assessing and treating patients with asthma- and COPD exacerbations in primary care.

Main research questions

- What is the yearly incidence of asthma and COPD excerbations leading to doctor visits or self-care with oral corticosteroids or antibiotics among adults 40 years or more diagnosed with asthma or COPD? (Study 1)
- How do adult patients with asthma and COPD present, when visiting a GP during acute exacerbation, in terms of symptoms, clinical findings and test results? (Study 1)
- How do symptoms, chest findings and test results change in asthma and COPD exacerbation during the 3 weeks after the first consultation with a GP. (Study 1)
- Which symptoms, clinical findings, and test result are emphasized by GPs when deciding whether or not to treat with antibiotics, oral prednisolone and hospital referral? (Study 1)
- Which factors predict a favourable or poor outcome of asthma and COPD exacerbations presented in primary care? (Study 1)
- How do COPD patients experience access to health care during exacerbations of their disease, and what do they think about self-treatment? (Study 2)
- Which role do feelings like shame and reflections on social identity play in COPD patients help-seeking behaviour, and how can health care be organized to optimize access to medical help? (Study 2)
- How do European GPs and pulmonologists think exacerbations of asthma and COPD in adults should be assessed and treated, and in particular what role do the Anthonisen's criteria play in the decision on antibiotic treatment? (Study 3)
- What do European GPs and pulmonologists think about self-treatment with antibiotics and oral corticosteroids in exacerbations of asthma and COPD? (Study 3)
- Are there differences in the views of GPs and pulmonologists regarding assessment and treatment of exacerbations of asthma and COPD , and between the doctors of the different European countries, and how are such differences reflected in national guidelines? (Study 3)
- How is the health behaviour in patients with asthma and COPD exacerbations prior to acute admittance to hospital? (Study 4)

Material and methods

Study 1

380 patients 40 years or older diagnosed with asthma or COPD (or both) have been recruited from 7 GP offices between May 2009 and January 2010. They all have taken part in a baseline examination including registration of recent symptoms (CCQ, a validated questionnaire), chest findings, spirometry with reversibility testing, pulse oximetry, and CRP test. The same kind of spirometers (Spirare II) and oximeters (Onyx II) were used, and the

CRP methodology was quality assured at the 7 offices. The year after baseline the participants are asked to visit their GP during exacerbations, within a few days after the onset of symptoms. Like at baseline, symptoms, chest findings, spirometry, pulse oximetry, and CRP value are recorded, as well as the duration of the actual exacerbation and the treatment given. New appointments with their GP are made after one week and three weeks, and the same examinations will the be carried out. Predictive factors for prescribing antibiotics and prednisolone will be evaluated by univariate and multivariate methods (logistic regression) and the predictive value of Anthonisen's criteria will be compared with models including baseline chest findings, spirometry, and laboratory tests by Receiver Operating Characteristic (ROC) curve analyses. Given an average prescripton rate of antibiotics of 60%, a 20% difference in prescription rate associated with the presence or absence of a predictor, for instance between a prescription rate of 70% and 50%, respectively, can be detected with 90% probability (β=0.9) and with less than 5% risk of false positive result (α=0.05) when 120 exacerbations are included[38]. A material of 150 exacerbations is thus regarded as sufficient. Approximately half of this number has been included so far. Possible predictors of a poor outcome, such as PO2 $\leq$ 92%, CRP > 50 mg/L, and severe COPD found by spirometry at baseline, will also be evaluated by univariate and multivariate methods. Measures of poor outcome are unplanned re-consultation, lack of recovery after 3 weeks, and hospitalisation.

All data will be recorded on separate forms marked with the case number, not including name or date of birth, and will be stored in a quality assured computerized storing system (EUTRO) at the University of Tromsø. The study has been approved by the Regional committee for health research ethics.

Study 2

Patients with moderate or severe COPD who have experienced at least one exacerbation last year, will be invited to take part, for instance participants in Study 1 or patients at a local rehabilitation unit. The interviews will be based on the methods described by S Kvale[39]. Grounded theory will be used as the basic methodology and the analytic strategy will follow GT's approach to theoretical sampling, coding and constant comparisons[40]. In the final analysis Nvivo 8 will be used as software tool.

We aim at interviewing 20 patients with exacerbations of COPD, and following the GT approach sampling will be made to obtain theoretical saturation of data.

The interviews will be recorded on MP3 recorders and transcribed before analysis. The transcribed version will be marked with case numbers and stored in an unidentifiable form. The interviews will be carried out after the study has been approved by the Regional committee for health research ethics.

Study 3

GPs and pulmonologists from 6 European countries (Wales, The Netherlands, Germany, Poland, Russia (Arkhangelsk region), Sweden and Norway) will be sampled based on a purposeful and stratified approach[41]. In all countries GPs from both urban and rural practices and pulmonologists from both university hospitals (where possible) and regional hospitals will be invited to participate in a FGD (focus group discussion). One FGD with GPs, one with pulmonologists and one with a mix of the two specialties (a total of 3 FGDS for each country) will be conducted, aiming at 5-8 doctors in each group. The FGDs will follow a prepared interviewguide[42], the same for all three interviews. The guide will be developed on a common basis to be used in all countries though admitting exceptional variations if there is a need to discuss country/culture specific items.

All FGDs will be recorded on MP3 recorders and transcribed verbatim. The transcribed version will be marked with case numbers and stored in an unidentifiable form. In the final analysis Nvivo 8 will be used as software tool. Grounded theory will be used as the basic methodology and the analytic strategy will follow GT's approach to theoretical sampling, coding and constant comparisons as in study 2[40].

Analysis will be based on translated transcripts (to English) and take into account differences in terminology and both social and cultural context of each country when developing final theories from the data. Analytic comparisons will be made within each country's data and also across countries. This requires internal agreement on aims and methods, e.g. equivalent methods in all countries and frequent meetings (Skype or live) among researchers in all phases of the project. The project's organisational structure will be developed to support this. The study needs approval from the ombudsman for personal security in Norway and corresponding bodies in the cooperating countries.

The effort to involve 6 countries in this study is made to provide knowledge on different attitudes and practices among health professionals towards treatment of COPD and to assess their ideas as possible input to improved guidelines for clinical practice. Drawing on more than one country the study will demonstrate possible professional and contextual variations. This may prove fruitful for instructions, teaching and implementation of future guidelines and inspiration for organisation of treatment. Moreover, the approach will create or strengthen networks across professions and countries.

Study 4

A questionnaire is distributed to patients hospitalized with asthma or COPD exacerbation. Questions are asked about what happened between onset of symptoms and admittance to hospital.. Contacts with health care and self-treatment will be described and whether or not GPs are involved before hospitalization. The GPs actions in terms of treatment and referral will add to the data collected in Study 1. The collection of data will be coordinated by two hospital doctors. The study started 1. January 2010, and during one year it will be possible to include 100 patients from the University hospital and 100 patients from three district hospitals

The methodologies in all four studies represent altogether an interdisciplinary approach to the overall aim of the project. This approach is connected closely to the variation in research questions and hence represents the methodological implication of these. Basically the aim and problems concerning COPD exacerbations call for investigations of different kinds and each methodological approach will be carried out on its own disciplinary premises. It is also the ambition to carry out joint analyses across the four studies in order to let the chosen studies inform each other and obtain rich and robust knowledge on the overall project aim.

The project plan, project management, organisation and cooperation

The project period will start September 1. 2010, and last for three years (see the time schedule in the application scheme). The project period may be extended if the ph.d students work part time general practice in periods. Hasse Melbye, head of AFE Tromsø, will be project leader and involved in all four studies. The project team of Study 1 will also consist of Professor Jørund Straand, head of AFE Oslo, Mette B Risør will be included in the research team of Study 2, whereas Mark Spigt and Mette B. Risør will both be involved in Study 3. In addition to the ph.d. students in the project, ph,d, student at AFE Oslo will take part in preparation of the Study 1 manuscripts, and the two hospital doctors coordinating Study 4 will be involved writing manuscripts as well. The cooperation between the European researchers in Study 3, builds on networking since 1998 through the annual meetings of General Practice Respiratory infection (GRIN) network and through GRACE, a network of excellence study in EU 6th framework on lower respiratory tract infections.

Relevant resources at the applicant institution

The project leader has more than 20 years experience in research on respiratoy illness in primary care, and Mette Bech Risør is an experienced researcher in the field of health anthropology. Department of Community Medicine, University of Tromsø, hosting AFE Tromsø, has a good reputation in epidemiological research. AFE Trosmsø has since 2006 been engaged in GRACE (see over) , The research unit has been responsible for respiratory topics, including spirometry, in the Tromsø Study, a population based health survey.

Budget

Shown in the application scheme

Perspectives and compliance with strategic documents

Compliance with strategic documents and relevance to society

The study may prepare for better cooperation between primary and secondary care regarding patients with COPD, which has been called for in several documents from health authorities the last years. See the introductory comments on relevance.

Environmental perspectives

The results of the project may contribute to a decrease in unnecessary use of antibiotics. Over use of antibiotics brings about bacterial resistance, which is a threat for our future health. Better care in rural GP practices may reduce patient travels to hospital.

Ethical aspects

The participant in Study one will undergo more examinations than usual care, but not examinations considered to be associated with increased health risk. All study participants give written consents, and it will be impossible to recognize any of them when the data are analysed and stored.

Gender equality and gender perspectives

Both genders will be well represented among study participants and among the researchers.

Communication with users and utilisation of results

Communication with users

Results will be communicated to GPs and pulmonologist through courses and conferences. The National advisory for COPD, at the National Directory of Health, will also be informed.

Dissemination plan

Scientific papers addressing the research questions above will be published in international peer-reviewed journals. National coordinators of Study 3 can publish results from a national point of view as soon as the common papers are accepted for publication.

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Consolidated criteria for reporting qualitative research (COREQ): a 32- item checklist for interviews and focus groups

Allison Tong, Peter Sainsbury and Jonathan Craig. International Journal for Quality in Health Care, 2007. 19(6) 349-357

No Item	Guide questions/description
Domain 1: Research team and reflexivity Personal Characteristics	
1. Interviewer/facilitator	Which author/s conducted the interview or focus group Robert Iversen, Mark Spigt, Nick Francis, Elena Andreeva, Attila Altiner, Kenny Kung Mette Bech Risør acted as assistant moderator in three FGDs
2. Credentials	What were the researcher's credentials? *E.g. PhD, MD* Mette Bech Risør, PhD Mark Spigt, PhD Robert Iversen, Phd student Nick Francis, PhD, MD Elena Andreeva, PhD, MD Maciek Godycki-Zwirko, PhD, MD Attila Altiner, Professor Kenny Kung, PhD, MD Hasse Melbye, Professor
3. Occupation	What was their occupation at the time of the study? Mette Bech Risør, senior researcher Mark Spigt, associate professor Robert Iversen, Phd student Nick Francis, senior clinical research fellow Elena Andreeva, associate professor Maciek Godycki-Zwirko, head of department Attila Altiner, head of department Kenny Kung, clinical assistant professor Hasse Melbye, head of research unit

4. Gender	Was the researcher male or female? Mette Bech Risør, female Mark Spigt, male Robert Iversen, male Nick Francis, male Elena Andreeva, female Maciek Godycki-Zwirko, male Attila Altiner, male Kenny Kung, male Hasse Melbye, male
5. Experience and training	What experience or training did the researcher have? All researchers except Robert Iversen (PhD student) were skilled researchers within family medicine/community medicine. Mette Bech Risør has extensive research experience in qualitative research. All researchers received training in qualitative methodology and analysis before this research project
Relationship with participants	
6. Relationship established	Was a relationship established prior to study commencement? No
7. Participant knowledge of the interviewer	What did the participants know about the researcher? *e.g. personal goals, reasons for doing the research*

	Participants were informed about researcher's professional background, occupation and research field. Also a description of the purpose of the research was given.
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? *e.g. Bias, assumptions, reasons and interests in the research topic* As described on page 6-7
Domain 2: study design Theoretical framework	
9. Methodological orientation and theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis* Grounded Theory
Participant selection	
10. Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball* Purposive
11. Method of approach	How were participants approached? *e.g. face-to-face, telephone, mail, email* They were invited via an information letter. Several information channels were used, making contacts via meetings, health boards, email, telephone, mail or personal contact. Also inviting a key person to ask colleagues. Page 6-7
12. Sample size	How many participants were in the study? There were 142
13. Non-participation	How many people refused to participate or dropped out? Reasons? Refusal was not registered systematically, but several declined due to time limits. Only 11 cancelled after having agreed to participate
Setting	
14. Setting of data collection	Where was the data collected? *e.g. home, clinic, workplace* Participants were interviewed on university premises

15. Presence of non-participants	Was anyone else present besides the participants and researchers? Assistant moderators

16. Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date* The interviewees were either GPs or respiratory physicians. They were chosen to cover both rural and urban practices, university hospitals and minor regional hospitals, outpatient-clinics and private clinics. They had overall long seniority working as medical doctors, see page 7
Data collection	
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested? A topic guide was used to direct the FGDs, including two patient stories/vignettes. The guide was pilot-tested before using it in all countries.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many? No, not with the same informants but we did three FGDs in each country
19. Audio/visual recording	Did the research use audio or visual recording to collect the data? Interviews were taped and transcribed and translated into English.
20. Field notes	Were field notes made during and/or after the interview or focus group? Field notes were made during the FGDs and were used to help analyzers understand the context of the content.
21. Duration	What was the duration of the interviews or focus group? Interviews lasted between 60-120 minutes
22. Data saturation	Was data saturation discussed? Data saturation was part of the theoretical sampling strategy in Grounded Theory.

23. Transcripts returned	Were transcripts returned to participants for comment and/or correction? Transcripts were not returned to the participants.
Domain 3: analysis and findings Data analysis	
24. Number of data coders	How many data coders coded the data? Two main coders (Mette Bech Risør and Robert Iversen) did most of the coding, but codes and themes were discussed with Mark Spigt, Nick Francis and Maciek Godycki-Zwirko until we agreed on the main categories. And the rest of the authors discussed main categories as part of their review of the manuscript
25. Description of the coding tree	Did authors provide a description of the coding tree? No.
26. Derivation of themes	Were themes identified in advance or derived from the data? Themes were identified from the data.
27. Software	What software, if applicable, was used to manage the data? NVivo 9 qualitative data analysis software.
28. Participant checking	Did participants provide feedback on the findings? No
Reporting	
29. Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? *e.g. participant number* Yes. Each quotation was identified with FGD number only
30. Data and findings consistent	Was there consistency between the data presented and the findings? We believe there is consistency between the presented data and the findings.
31. Clarity of major themes	Were major themes clearly presented in the findings? Yes, three major concerns

32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes? Within the main concerns we also discussed diverse cases or minor themes.