

## **Protocol: (InvolvMe) Children and young people with mental illness: theory and practice in development of Norwegian national guidelines**

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### **1. Introduction**

Children and young people with mental illness is a particularly vulnerable group. According to the Norwegian Patient Registry, 55 000 children and adolescents were treated for mental health problems in specialist care (1). The Escalation plan for mental health in Norway emphasizes early intervention (2). Untreated mental illness may result in chronic conditions and serious somatic illness later in life (3). As such, mental illness is a burden to the patients themselves and their next-of-kin, but also in terms of the societal costs associated (3)

Children and adolescents should receive the treatment that is most likely to help them and with the least side effects (4). Treatment options available to the individual child should be made transparent and children and young people should have equal access to the best possible care (although of course dependent on the resources available in each given context) (2). International and national law- and planning documents also emphasize the right of children and young people to participate in decisions that affect themselves, both at the system level in service development and in relation to their own course of treatment (5-7).

#### *Good quality care begins with evidence-based guidelines*

Mental health workers are required to base their practice on national evidence-based guidelines supplemented by other sources of summarized research of good quality (8). In Norway, national guidelines within this area is developed by the Norwegian Directorate of Health (9). Advice and recommendations provided in these guidelines is intended to help health personnel and patients to make good decisions, help reduce unwanted variation and promote good quality in health and care services (4).

Guidelines of good quality are important for patient safety (10). Many different actors produce guidelines, ranging from local hospitals, professional organizations and national authorities. Research has shown that guidelines intended to cover the same patients and treatments may vary in their recommendations (11). In acknowledgement of this, international quality criteria for guidelines have been developed (AGREE) (12). In Norway, the Norwegian Directorate of Health has also published their own manual for guideline development based on these international standards to ensure a systematic, transparent, and robust development process (4). According to these standards an evidence-based guideline should include findings from systematic reviews of research evidence of good quality (4, 13). Furthermore, recommendations coming out of the guideline should take into account the views of clinical experts and patients (12).

#### *Involvement of children and young people in guideline development*

Patient involvement has through the years achieved broad support in society, primarily argued as a democratic right but also under the assumption that patient involvement may improve the quality of

health care services (14, 15). However, patient involvement on both individual and system level face many challenges (16, 17). In regard to guideline development, one such challenge is that effective participation requires health literacy-skills, and in particular, the ability to assess research evidence (16, 17). Because most patients do not necessarily have training in research, this means that their prerequisites for influence are not equal compared to other panel participants (18). Furthermore, there is often a general imbalance of power in relation to status, but also often in sheer number (19). Involvement of children and young people also come with specific ethical considerations (20, 21).

Studies have found that guideline developers may find it difficult to reconcile patients' and professionals' sometimes conflicting wishes (16). Patient involvement and participation in guideline development is also reported to be challenging and confusing when there is no standardized procedure for effective and meaningful involvement (20, 22). In practice, this means that it is up to the individual bureaucrat or health institution to prepare their own methods and models for participation. This may lead to great variation but also uncertainty and little predictability for both professionals and patients. Studies report that roles are often poorly defined, resulting in confusion about responsibility and how the patients' voice will have an impact on the final recommendations for practice (16, 19).

### *1.1 Objectives*

The objective of this project is to explore the "state-of- the art" of national guidelines for treatment of mental illness in children and young people in Norway, and to identify barriers and facilitators to developing evidence-based guidelines.

### *1.2 Research questions and hypotheses, theoretical approach and methodology*

We propose two research questions:

1. What is the quality of Norwegian national guidelines for treating mental illness in children and young people in regard to international standards for evidence-based guidelines? To allow for comparison with national guidelines of other similar health systems, we will appraise the national guidelines published in Denmark and Sweden.
2. What are the barriers and facilitators to producing evidence-based guidelines for treatment mental illness in children and youth?

This project is positioned within the theoretical frameworks of evidence-based practice and shared decision-making (17, 23, 24). Furthermore, this project is developed in the context of current political agenda and legal rules guiding decision making in mental health care (4, 7, 8).

## **2. Methods**

These research questions will be addressed in two phases using first document analysis followed by interviews with guideline developers and patient representatives. These phases are described in more detail below.

### *2.1 Phase 1. Document analysis: critical analysis of the quality of Norwegian national guidelines for treating mental illness in children and young people*

We will critically appraise national guidelines for treating mental illness in children and young people. In Norway, five national guidelines include treatment of those under 18 addressing the following diagnosis: ADHD, bipolar disorder, psychosis, self-harm and eating disorders. To allow for comparison

with national guidelines of other similar health systems, we will appraise the national guidelines published in Denmark and Sweden.

Following standard review methods, two researchers will independently critically appraise the guidelines according to a checklist including international standards for evidence-based guidelines (13, 25). The findings will be summarised descriptively and according to the logic of the checklist (25).

In addition to assessing quality criteria associated with evidence-base underlying the guideline and the transparency of this process, we will also explore how patients were included in the development process by determining the level of decision-making using the categories suggested by Nilsen and colleagues (26). Each guideline will be scored for level of involvement according the following categories (26).

1. No involvement
2. Consultation
3. Collaboration

We will also extract any information describing when and how patients contributed to the guideline.

Since we are including only national guidelines, we will not conduct systematic searches in the scientific literature or other databases. Instead, we will review the Danish and Swedish national health authorities' websites respectively (where national guidelines are published) and retrieve any guidelines available for the five patient groups encompassed by national guidelines in Norway.

As this phase does not require input from respondents, ethical approval is not needed.

## *2.2 Phase 2. Qualitative interviews: exploring barriers and facilitators to producing guidelines in Norway*

To understand and explore the process leading up to the published treatment recommendations, we will interview the directorate representatives leading each of the guideline development processes respectively.

We will also interview the patient representatives that took part in each of these processes. These patients are elected for this position in the guideline panel by the patient organisation they are representing on invitation from the directorate.

The interviews will be conducted using a structured interview guide (27). The interview guide will be designed to include items relevant to how the three types of knowledges (research evidence, professional expertise and patient experience, value and preferences) were managed.

We will use framework analysis as a research design (18, 28). The Framework method is both descriptive and explanatory, focusing on relationships between themes and categories. The method usually includes seven stages: (1) transcription, (2) familiarization with the data, (3) coding, (4) developing a working analytical framework, (5) applying the analytical framework, (6) charting the data into a framework matrix, and (7) interpretation of the data (18). It is important to note that this is an iterative process and that these stages may not take place in this order. The method results in an "analytical framework," which refers to a set of codes and categories developed as part of the analysis to manage and organize the data (28).

As this second phase includes input from those involved in guideline development, ethical approval from the Norwegian regional ethics committee for health research is needed.

All participants will be recruited directly from the committee-list published on the website for the Directorate of Health's website provided as a supplement of the guideline. All participants will be

given oral and written information about the purpose of the study, how the information coming out of the interviews will be managed and used and will be asked to sign a written consent form should they choose to participate.

All interviews will be audio-recorded and transcribed. The audio-recordings will be deleted immediately after transcription. We will not store or link information which may lead to the identification of individual patient representatives being interviewed.

### *2.3 Considerations of risk and ethical issues*

This research field draws on competency in evidence-based practice, political science, ethics, research methodology and clinical expertise. This requires a project group representing different disciplines as well as fields of expertise. We believe our previous research and diverse educational background reflects this.

There are always ethical issues to consider. However, we believe there are few undesirable effects of this project, and that the benefits that may come out of our endeavours greatly surpasses any harms. One such ethical issue is that our project may identify areas of quality improvement in the development of national guidelines. If these findings are communicated without consideration of context, this can result in public mistrust in national guidelines. However, identifying these areas of improvement is also a necessity for good quality health care and patient safety. Furthermore, an explicit positioning of this project, based on the best available evidence referenced above, is that it constitutes “good practice” to support the use of national evidence-based guidelines. Consequently, it is our intention to be mindful of how our results are communicated, taking a constructive approach in supporting the national guideline developers with information that will improve future guideline development work. The results of this study will therefore be reported in the light of this positioning, and with the patients’ interest at heart. The findings of this project will also be particularly useful for the national health administration in preparing targeted interventions improving implementation of national treatment recommendations.

The patient representatives and guideline developers we plan to interview have all had an official mandate in a guideline development process. Consequently, their names and roles are published as a supplement to the guidelines on the directorate’s website. This means that the identity of the participants providing information in our study is not confidential.

However, the objective of our study is to explore barriers and facilitators experienced on a group level with the aim of improving future guideline development. Consequently, we will not report findings so that it can be identified to the individual representative.

The project will follow the directions set by the regional ethics committee and this protocol will be published on an open-access platform to ensure transparency.

## **3. Impact**

Our ambition is to improve evidence-based practice in treatment of children and young people with mental illness by supporting the development and use of national evidence-based guidelines in Norway. To our knowledge, little or no research has explored the quality of national treatment guidelines in Norway, and little is known about the strategies employed in terms of patient involvement of children and young people in guideline development. Consequently, the findings coming out of this project will generate important knowledge that may improve the development and implementation of national guidelines. Furthermore, this project will contribute with practical and usable information about the key building blocks of effective user-involvement interventions in policy decisions.



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