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Self-management of INR – a focus group study

ORIGINAL ARTICLE

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Background

Warfarin is a medication used in conditions with an increased risk of blood clots. Due to the potential for serious side effects, treatment must be closely monitored by measuring the International Normalised Ratio (INR). In some health trusts, Noklus (Norwegian Organization for Quality Improvement of Laboratory Examinations) offers training for patients in self-management of INR. The aim of this study was to explore Norwegian patients' experiences with self-management of INR and their motivations.

Material and method

In 2022, three focus group interviews were conducted at Nordland Hospital in Bodø, with a total of 16 individuals who performed self-management of INR. The interviews were audio-recorded, transcribed and analysed using systematic text condensation.

Results

Participants reported improved self-esteem and a sense of freedom after starting self-management of INR. Some expressed initial concerns about the increased responsibility for their own health, but they gradually developed a more relaxed attitude towards self-management. They also experienced reduced stress levels and gained increased knowledge about their own bodies. The training course enhanced participants' knowledge and confidence.

Interpretation

The study indicates that self-management of INR simplifies the daily life of patients and can have a positive impact on their quality of life.

Main findings

Most participants in this focus group study reported that self-management of INR reduced stress and gave them a greater sense of freedom.

Nearly all participants felt that self-management of INR increased their confidence, knowledge and sense of mastery.

Self-management of INR required participants to take more responsibility for their health, which was initially challenging for some.

Some participants did not perform the required control measurement of the instrument as they were supposed to during self-management of INR.

In Norway, conventional anticoagulant therapy with warfarin (a vitamin K antagonist (VKA)) is checked by the patient's general practitioner (GP) approximately once a month using International Normalised Ratio (INR) testing. The blood test indicates the effect of warfarin by measuring how long the blood takes to clot compared to normal clotting time (1). The treatment must be carefully monitored due to the narrow therapeutic window, and various factors such as food and infections can impact its effect. If the INR value is too high, there is a risk of severe bleeding. Conversely, a low INR value may lead to blood clots (2). Indications for warfarin include deep vein thrombosis, pulmonary embolism, mechanical heart valves and prophylaxis after myocardial infarction (2, Box 1). Alternatives to conventional monitoring of anticoagulant therapy include self-management or self-monitoring of INR. With *self-management* of INR, patients on long-term warfarin therapy can monitor their INR by taking a capillary blood sample, which is analysed using an instrument designed for use by patients (self-tester), interpret the result and, if the INR value exceeds the therapeutic range, adjust the warfarin dose themselves. With *self-monitoring*, the patient measures the INR and the doctor adjusts the warfarin dose. It is crucial that patients receive thorough training before starting self-management or self-monitoring of INR (3).

Box 1 Indications for self-management of INR (2).

In the first phase, the following patient groups < 70 (75) years are relevant:

1. Mechanical aortic or mitral valve
2. Valvular atrial fibrillation
    a. Mitral valve repair
    b. Biological mitral valve
    c. Mitral stenosis/prolapse
3. Thrombophilia with recurrent deep vein thrombosis/pulmonary embolism or embolism in the systemic circulation/embolic stroke
    a. Activated protein C (APC) resistance (Factor V Leiden mutation)
    b. Protein C/S deficiency
    c. Prothrombin mutation

d. Antiphospholipid syndrome (lupus anticoagulant, anticardiolipin antibodies)

e. Antithrombin III deficiency

4. Anticoagulation for an indefinite period or for more than three years, regardless of the indication, where

a. switching to direct oral anticoagulants (DOACs) is not medically justifiable due to lack of clinical evidence, or there is a strong clinical suspicion of thrombophilia in patients < 50 years with a negative thrombophilia test

b. the patient does not wish to switch from warfarin to a DOAC, and the time in the therapeutic range (TTR), as measured by their GP, is > 70 %

The use of warfarin in Norway has decreased over the last ten years, from approximately 100,000 users in 2012 to 22,500 in 2022 (4), and now accounts for about 15 % of the total consumption of anticoagulant medications (5). This reduction is mainly due to the large number of patients being switched to direct oral anticoagulants (DOACs), which are different types of blood-thinning medications that do not require monitoring (6). Because such medications are contraindicated for patients with mechanical heart valves, severe renal impairment or antiphospholipid syndrome, as well as children, pregnant women and nursing mothers (7–9), it is reasonable to assume that warfarin will be used for many years to come. Estimates show that self-management of INR will be an option for 10–80 % of patients on warfarin (10, 11), depending on the eligibility criteria and indications (12). This means there are still between 2250 and 18,000 patients in Norway who could benefit from this.

Meta-analyses from randomised clinical trials show that self-management of INR reduces the risk of complications and death compared to conventional follow-up (11, 13–15). Compared to self-management, training in self-monitoring requires fewer resources. Both international and Norwegian guidelines recommend self-management for users who demonstrate satisfactory motivation and competence (16). Since 2008, the Norwegian Organization for Quality Improvement of Laboratory Examinations (Noklus) has trained over 2000 people in Norway in self-management of INR. Studies involving some of these participants have shown that self-management leads to the same or more time spent within the therapeutic range compared to conventional follow-up (17–19).

The Noklus training programme in INR self-management is described in Appendix 1. GPs are responsible for determining whether a patient is suitable for self-management. This means the patient must be able to follow the training programme, demonstrate satisfactory cognitive function, have a good understanding of Norwegian and be less than 70 years of age. Patients with alcohol/substance problems will be excluded. The responsibility for treatment is transferred back to the GP after the training. Noklus recommends that patients report their INR values to their GP every 12 weeks and attend regular consultations to perform control measurements of the instrument and in the

event of major deviations from the therapeutic range. As of 2024, the training programme is available in ten Norwegian health trusts. It is offered at cost price and is tailored to the needs of each health trust.

A qualitative literature study from 2021 showed that self-monitoring of INR can be both liberating and constraining, as it entails a greater sense of freedom and independence but also more responsibility and challenges (20). Meta-analyses and literature reviews using various questionnaires have generally shown better patient satisfaction and/or quality of life with self-monitoring compared to conventional follow-up (11, 21–23), but some studies indicate that this depends on the type of questionnaire used (24). A quality-of-life questionnaire developed for patients on anticoagulant therapy (25) revealed that patients who undertook self-monitoring or self-management of INR experienced a greater sense of mastery, higher levels of satisfaction and fewer day-to-day challenges compared to patients receiving conventional follow-up (24, 26). Similar findings were also reported in a Norwegian study (18). A recent survey from Italy also found that self-monitoring of INR improved quality of life for 87 % of the participants (27).

Self-monitoring and self-management of INR represent a form of health care in which patients are more actively involved in their own health. From this perspective, we found it meaningful to draw parallels to the concept of empowerment. The concept is based on a positive view of humans in which the individual is an active and acting subject (28). Empowerment processes have shifted away from a paternalistic healthcare model to one that places more emphasis on patients' rights. In health policy, empowerment and user involvement are highlighted as necessary strategies for strengthening disease prevention and health promotion efforts (29). According to Starrin and Askheim, the concept of empowerment has three dimensions (28): a counter-power approach to existing power structures, a market-liberal approach, and a 'therapeutic' approach. The latter is particularly relevant in our study. In this context, empowerment represents a process of personal growth and awareness, where the goal is to develop personal strategies to take control of one's own life.

Very few studies have explored the experiences and perspectives of individuals who self-monitor INR, and none have been conducted in Norway. Differences in culture, healthcare systems, conventional follow-up, training programmes and funding arrangements can limit the transferability of studies from other countries to a Norwegian context. We also found no qualitative studies addressing self-management of INR. This was the background for our wish to explore Norwegian patients' experiences and motivations for self-managing INR through a focus group study.

Material and methods

In August 2022, we held three focus group interviews at the Learning and Mastery Centre at Nordland Hospital in Bodø with patients who self-manage their INR. The training (described in Appendix 1) is funded by Northern Norway Regional Health Authority and administered by Noklus, which uses the

Learning and Mastery Centre's premises. Doctors from the Medical Department at Nordland Hospital in Bodø have clinical responsibility for the course participants and are compensated by Noklus for their work.

Focus group interviews stimulate social interaction and are well suited to exploring participants' experiences, viewpoints, attitudes and thoughts on a common topic (30).

Participants were recruited by the head of the INR self-management section at Noklus, who sent out letters with information about the study and a request for participation to 98 people in the Bodø area. Invitations to participate in a voluntary refresher course that Noklus was holding in autumn 2022 were sent out at the same time. The inclusion criteria were that patients had completed the self-management training programme, were 18 years or older, understood and spoke Norwegian, and were still self-managing their INR. Before the interviews, participants signed an informed consent form and completed a questionnaire with relevant background information.

Three of the article's authors were present during the interviews. ÅL acted as moderator and ADA was the assistant moderator. UØS functioned as an observer but answered a few medical-related questions that were asked during the sessions. The interviews were based on an interview guide developed in collaboration with a user representative who self-manages their INR. The guide included topics such as the participants' background and motivation for self-management, their positive and negative experiences with this, and their access to information and follow-up from Noklus among others.

Each interview lasted approximately 90 minutes. The format was a lightly moderated discussion, with most of the dialogue occurring directly between the participants (31). The moderator's role was to pose relevant follow-up questions and steer the conversation if it strayed too far from the topic. Audio recordings were made and uploaded to SAFE (Secure Access to Research Data and E-infrastructure) at the University of Bergen. Only the authors of the article had access to the recordings. Once transferred to SAFE, the audio recordings were deleted from the recording devices. The recordings were transcribed by ADA, and participants were given random pseudonyms.

The analytical approach was inspired by Malterud's method of systematic text condensation (32). Three of the authors were involved in the analysis. In the first step, ÅL, ADA and UØS each read through the transcripts independently, noting relevant themes in light of the study's research question. The study followed an inductive approach with a relatively open research question and no explicit theoretical framework as an analytical tool. Consequently, the early phase of the analysis was empirically grounded and descriptive.

The identified themes were discussed collectively, and after an internal discussion, we agreed to focus on three main themes. Meaning units were subsequently identified and coded. ADA then wrote condensates for each subgroup based on the meaning units, and each condensate was illustrated with a 'golden quote'. The condensates were then transformed into an analytical text through interpretive work, drawing on other relevant research and the empowerment concept. We applied this concept because, during the analysis, we saw that it could help provide valuable insight and deepen our

understanding of the study's findings. To ensure that no important points were overlooked, themes and condensates were discussed collectively multiple times during the analysis process. We used the personal pronoun 'they' in the results section to ensure anonymity.

The project was approved by the Regional Committee for Medical and Health Research Ethics (REK West, approval date: 1 February 2022, ID 359916).

Results

The three focus groups consisted of 16 participants in total (Table 1).

Based on the analysis, the patients' experiences with self-management of INR were categorised in three main themes:

– A life with self-management reduces stress, gives a greater sense of freedom and requires greater responsibility for own health

– Self-management increases confidence, knowledge and the sense of mastery

– Low threshold for accessing information and help from the health service

A life with self-management reduces stress, gives a greater sense of freedom and requires greater responsibility for own health

This theme relates to experiences that show how self-management has had a tangible impact on the participants' lives. The theme was divided into three subthemes.

A calmer body. Many of the participants experienced stress and inconvenience due to frequent doctor consultations for INR testing. They emphasised that self-management made daily life easier, calmer and less stressful. They found that the doctor consultations often led to logistical challenges related to work, caregiving responsibilities or leisure activities. One of the participants explained it as follows:

'I feel that with self-management, I avoid the stress and save a huge amount of time. And my body is actually calmer when I can just stay home. And I do think that those highs and lows [the INR levels], that's also about stress, you know. You have to get yourself ready, and the time I'm supposed to take it… Yeah.' (Participant 6)

Greater sense of freedom and the opportunity to travel. Most participants agreed that self-management made everyday life easier in relation to holidays and travel, and they felt a greater sense of freedom after they started self-management. Previously, several participants had to visit a doctor during holidays to have their INR measured. One participant, for example, had to have their INR tested at the hospital on 27 December and was very grateful that they had started self-management before the summer holidays. Another described how self-management improved their quality of life:

'Yes, that means I went 13, 14, 15 years with (...) regular testing before I got it [self-management]. And you can probably understand that when I switched to that [self-management], it was revolutionary for my freedom and how I was able to live my life.' (Participant 2)

Greater responsibility for own health. Several participants highlighted the importance of having control over their own health. Some no longer wanted their GP to manage INR testing and warfarin dosing, as they felt they had better control themselves. Meanwhile, some found the increased responsibility for their health to be challenging but said it had become easier over time. A couple of participants admitted to not following the recommendation for performing control measurements of the instrument. Before the self-management training, participants saw themselves as more passive but found that they were now more involved in managing their illness and medication. One participant described it as follows:

'Yes, you do have to take responsibility for your own health. In a more direct way. You kind of become passive, just turning up. Now you actually see what you're doing to your body, in a way. In a really good way.' (Participant 12)

Self-management increases confidence, knowledge and the sense of mastery

This theme relates to experiences of how training in and execution of self-management have helped participants gain a sense of mastery over their lives. The theme was divided into three subthemes.

Getting to know their body better. Many participants said that self-management helped them understand their bodies better. Several observed and experienced a connection between their INR levels and more factors than their GP had informed them about. This included, for example, diet and activities that impacted INR levels. When it came to dietary awareness, some participants had noticed that broccoli lowered their INR values. Some also shared experiences of how trips to southern Europe and alcohol could lead to changes in their INR levels. A couple of others, however, felt it was difficult to know what affected the INR value. One participant, who felt they had established good control over their health, explained it as follows:

'*... And the other thing, which I think has been great, is that I've learned to understand my body. I don't have any dramatic stories..., but sometimes it [the INR level] has been sky high and sometimes it's been really low. But I've learned how to fine tune it...'* (Participant 8)

Gained a solid knowledge platform. The participants felt that the self-management training provided them with a solid knowledge platform. Several mentioned that they had received good support throughout the training period and that the course had improved their confidence. They used the course material and the internet to find relevant information when needed. One participant said the following:

'I practically have my GP in my suitcase, so I don't need to consult other healthcare personnel, quite convenient.' (Participant 14)

Become skilled at self-management. Most participants felt greater confidence with self-management, particularly because they could take additional measurements if they were uncertain. One participant kept a record of their INR values and warfarin dose adjustments in order to learn from past experiences. Another participant found that self-management provided reassurance for their family; during one incident when they felt unwell, the family took an extra measurement to assess the risk of bleeding. After gaining extensive experience with self-management, participants felt they had developed a routine. One of them described it as follows:

'When we've been using it for a while, I think we become so used to it that it becomes very easy. It's not a problem. You sort of know everything. But you can't take too much [warfarin], or things can go wrong.' (Participant 7)

Low threshold for accessing information and help from the health service

This theme relates to participants' experiences and views related to the health service's support during self-management. Since information and follow-up from Noklus was an explicit topic in the focus group interviews, particular attention has been given to findings that shed light on this.

Most participants felt confident with self-management after completing the training programme. However, a few participants mentioned that they would have liked information about the long-term side effects of warfarin, as most of them would need to remain on the medication for the rest of their lives. One participant described the training as follows:

'... the training needs to be thorough to enable you to manage as well as possible. Because people have different needs and face different uncertainties.' (Participant 1)

All participants in the study found that the threshold for asking for help was low. They could call the course hotline if they had questions, and most experienced this as a good source of support. However, several never had contact with Noklus after completing the course. One participant who needed help had been referred to the emergency clinic, where they experienced a lack of competence regarding self-management because the doctors responsible for the training were on holiday. Overall, though, the main impression was that good access to advice and support provided the necessary reassurance:

'It also felt reassuring, because there was this half-hour window from around 2.30 pm to 3 pm when you could call the doctor at the hospital if you were unsure or something wasn't right. Just knowing that was a comfort.' (Participant 3)

Discussion

The aim of our study was to explore Norwegian patients' experiences and motivation regarding self-management of INR. Self-management made participants' everyday lives easier and reduced stress caused by frequent trips

to the doctor. Participants experienced an increase in quality of life and a sense of freedom. Some participants did not always follow the recommendation to perform control measurements of the instrument and were concerned about their ability to carry out self-management. However, for most participants, self-management increased their confidence and sense of mastery by helping them better understand their bodies and become more actively involved in their own treatment. While the access to information and support through the course was valued, participants expressed a need for more information about the long-term side effects of warfarin.

Being able to self-manage their INR values and adjust their medication doses gave participants better insight into their own bodies and health situation. In relation to the concept of empowerment (28, 33), it can be said that self-management contributed to health promotion and improved quality of life for several participants. Completing the training programme was a key factor in these positive experiences. Participants were taught theoretical knowledge about how lifestyle and warfarin affect INR (medical knowledge) and applied this in practice to their own bodies (experimentation) over an extended period, while being well supported by healthcare personnel. This gave them confidence and enabled them to develop personal resources to carry out self-management over time (28). The findings indicate that participants felt they had sufficient knowledge and control over the factors necessary for self-management. Interacting with others in the training programme allowed the participants to reflect on their own experiences and perspectives. User contacts have extensive experience with self-management and can discuss and share their experiences with other patients. Several studies show that patient education programmes can enhance the sense of mastery, reduce the need for treatment, alleviate symptoms and give meaning to everyday life through the sharing of experiences with others (34).

Previous studies have shown that self-monitoring of INR saved time, increased independence and made it easier for patients to travel wherever they wanted without having to attend hospital or GP appointments (20, 22). This concurs with the findings in our study of self-management. Our participants reported that greater knowledge and understanding of their own bodies led to more stable INR values, indicating that they developed a sense of mastery. Other studies also show that being actively involved in and able to influence one's own health and treatment is seen as positive – and therefore important for patients (20). Findings from a qualitative study of people with diabetes have shown that self-management increases self-esteem and the sense of control over one's own life (35).

Some participants in our study reported that taking greater responsibility for their own health was challenging at times. In other studies, participants were concerned that self-monitoring reduced contact with healthcare personnel and could lead to less personalised care (20). Our study further revealed that several participants did not follow the recommendation to perform control measurements of the instrument This is supported by a Norwegian survey in which more than half of the participants failed to perform a control measurement of the instrument at the right time (36). This is concerning as it may result in the patient measuring INR values that are too low or too high

over time, increasing the risk of bleeding or blood clots. Such findings may indicate the need to place greater emphasis on the importance of control measurements of instruments in the training programme and to remind patients of this in a refresher course. None of the participants in our study reported complications related to high or low INR values after starting self-management. To our knowledge, there are no studies from other countries that have examined the use of instrument control measurements in the context of self-management. However, some patients have been found to report incorrect values when measurements exceeded the acceptable range, due to concerns about no longer being allowed to self-monitor (20). This may increase the likelihood of incorrect medication being administered.

Changes in quality of life due to self-monitoring or self-management of INR have not been reported in previous qualitative studies. However, similar to our findings, several surveys show that patients who perform self-monitoring or self-management experience an improved quality of life compared to those receiving conventional follow-up (11, 21–23). It is, however, important to understand the challenges associated with the increased responsibility and to recognise that self-management may not be the right choice for *everyone* on warfarin.

Strengths and limitations of the study

One weakness of the study is that the participants in the focus groups were self-selected and came from a limited geographic region. Additionally, those who perform self-management already belong to a select group. Selection bias is therefore likely due to the overrepresentation of individuals who are particularly interested in and motivated to carry out self-management. After completing the self-management training programme, the patient's GP resumes medical responsibility for warfarin therapy, and there are no data on how many discontinue self-management. Another weakness of the study is that it only included individuals whose first language was Norwegian, as understanding and speaking Norwegian was a prerequisite for participation in the training programme. A few participants in the training course in Bodø were not native Norwegian speakers, but they did not participate in the focus group interviews. Consequently, the study may not capture important variations in experiences related to self-management of INR.

One potential drawback of focus group interviews is that certain participants might dominate the conversation, thereby influencing what other group members say and how the group engages. As a result, social dynamics within the group could impede the openness required for effective discussion, preventing some participants from sharing their experiences and reflections. We did not consider this to be a significant issue, and we noted that several participants expressed disagreement with the majority's experiences.

Two of the authors have a professional association with Noklus, and a possible criticism of the study's validity is that the selection of findings and interpretations might highlight positive elements of Noklus' self-management training programme while 'ignoring' any negative experiences and aspects. This issue was considered throughout the research process, with ongoing discussions about the authors' roles and the potential for biased

interpretations. To reduce potential bias, a conscious decision was made for the two authors without any association with Noklus (ÅL and ADA) to serve as the moderator and assistant moderator during the interviews. ÅL has extensive experience with qualitative research and conducting focus group interviews. Initially, she had no knowledge of anticoagulant therapy with warfarin or the training programme. At the time of the interviews, ADA had completed the 6th semester of medical school. We considered ÅL to be best qualified to lead the interviews, ensuring they were as insightful as possible by asking relevant follow-up questions and guiding participants to keep them on topic. However, as a non-clinician, there was a risk that she might overlook some relevant aspects of INR self-management. UØS had been involved in developing the self-management training programme and therefore served solely as an observer during the interviews.

Despite the attention given to negative experiences with the training programme and self-management in all three interviews, there were few findings related to this aspect. Although we felt there was room for disagreement in the discussions in all the focus groups, it is conceivable that individual interviews, where there is less social influence, might have uncovered negative experiences and objections.

The generalisability of the study's findings is limited, but there is reason to believe they may be transferable to other groups performing self-management after training by Noklus in other regions of Norway. The presence of similar results in studies from other countries strengthens the transferability, despite cultural differences and variations in healthcare systems.

Conclusion

The participants who self-managed their INR and took part in the focus group interviews at Nordland Hospital in 2022 experienced improved quality of life, less stress and a greater sense of freedom after initiating INR self-management. They said that the self-management training had enhanced their understanding of their body and strengthened their sense of mastery. However, they also felt that self-management was a major responsibility. Following the recommendation for performing control measurements of the instrument can also be a challenge in INR self-management.

The article has been peer-reviewed.

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