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Developing a medication-safety self-assessment tool for rural primary care units - a case from Finnish Lapland

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Abstract

Background In rural areas, primary care faces several challenges, and medication therapy is one of the most complex processes in primary care. With a specific, proactive, medication-safety self-assessment tool designed for rural primary care units, healthcare professionals could identify development needs in their medication processes.

Methods The Delphi consensus method with two Delphi rounds was used to create a medication-safety self-assessment tool for rural primary care units in Finnish Lapland. A preliminary tool was designed based on three national and international risk management tools. Statements of the preliminary tool were evaluated with a two-round Delphi panel by 12 experts in primary care and patient safety. Evaluated aspects were suitability for primary care settings, medication safety relevance, and the necessity of the statements to be included in the developed rural, primary care, medication-safety self-assessment tool.

Results In the first Delphi round, a consensus of ≥ 85% on being "sufficiently important and essential" was reached on 39% of the statements ($n = 118/304$), of which 86% ($n = 101/118$) were included, and 14% ($n = 17/118$) were excluded from the final primary care medication- safety self-assessment tool. In the second round, 84% of the statements ($n = 141/167$) reached a consensus, of which 70% ($n = 98/141$) were excluded and 30% ($n = 43/141$) included in the final tool. The included 144 statements were divided into 12 thematic sub-groups: (1) Patient information, (2) Drug information, (3) Communication of drug orders and other drug information; (4) Drug labeling, packaging and nomenclature; (5) Drug storage and distribution, (6) Medication device acquisition and use, (7) Environmental factors, workflow and staffing patterns; (8) Staff competency and education, (9) Patient education, (10) Preventive risk management, 11. Learning from medication safety incidents, and 12. Electronic health record.

Conclusions The developed medication-safety self-assessment tool is targeted for proactive medication risk management in rural primary care settings. While experts reached a consensus for the Primary care Medication Safety Self Assessment tool contents, adopting the tool to suit the rural primary care environments in different countries should be further investigated.

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Keywords Medication safety, Medication process, Risk management, Primary care, Risk assessment, Rural, Self-assessment

Background

Medication errors, described as any preventable event that may cause or lead to inappropriate medication use or patient harm [1, 2], are among the most commonly reported adverse incidents in European healthcare [2–4].

While several studies have aimed to promote systems-based medication safety in hospitals, less emphasis has been placed on proactive medication risk management in primary care settings, especially in rural area hospitals [5]. In rural areas, the population is often older and tends to suffer more from chronic diseases than residents of non-rural regions [6–10]. Consequently, rural primary care has unique challenges, often involving complex medical cases and limited resources [6, 11–17]. To tackle these problems, previous studies have suggested various approaches, such as strengthening multi-professional collaboration [18–23], establishing remote pharmacy services [18, 19], and developing public health programs aiming at medication process evaluation and enhanced safety of care providers [24, 25]. To systematically control the risks associated with the medication process, rural primary care units could benefit from introducing proactive approaches, such as medication safety self-assessment (MSSA), to uncover the central risk points of care [16].

MSSA tools have been adopted for medication risk management in healthcare systems of different countries [26–29]. They use a systematic, collaborative process to evaluate the unit's medication safety guidelines and practices under investigation. However, current MSSA tools focus mainly on the issues of large hospitals and complex tertiary care [6, 26, 30–32], while MSSA tools with targeted primary care criteria have not yet been developed. Due to varying risk profiles in different care environments [4], current MSSA tools may not provide an optimal risk assessment strategy for small rural hospitals with limited resources. In rural areas, such as Finnish Lapland, a key deficiency is often the experienced lack of pharmacy professionals in local primary care settings. Therefore, identifying medication safety risks may need to rely more on the contribution of other available local healthcare professionals, with remote pharmacy services being supportive.

An MSSA tool targeted for medication risk management of rural primary care units would need to encompass the before-mentioned special features of the respective environment. However, to our knowledge, no such adopted MSSA tools currently exist. Using Finnish Lapland as a case example, this study aimed to develop a comprehensive yet practical MSSA tool for rural primary care settings (PMSSA) with limited resources to ensure safe local medication processes.

Methods

Study context

In 2023, Finland established a nationwide public healthcare reform [33, 34], creating 21 wellbeing services counties as service organizers and providers. A central goal of the reform was to ensure equal services and to reduce regional health and well-being inequalities among Finnish citizens. By law, the well-being service counties are responsible for self-monitoring produced services. Therefore, the counties must prepare an electronic self-monitoring plan concerning quality control, risk management, and patient safety [35].

The present study was conducted in the rural Lapland area of Finland. The Lapland Wellbeing Services County is responsible for offering health and social services to its inhabitants. Lapland is Finland's largest and northernmost area (Fig. 1). The area of the Lapland region is 100,367 km^2 with a population density of 1.9 people/km^2, and 25% of the population is over 65 years old and has a high rate of chronic diseases [36, 37]. There are two special care hospitals in Lapland Wellbeing Services County, whereas primary care services are produced in 21 units within the area, with 630 inpatient beds [38]. Altogether, six hospital pharmacies support the healthcare units (Fig. 1), but most primary care units in Lapland lack comprehensive hospital pharmacy services due to long distances.

Consequently, pharmacy services provided for the primary care units are mainly remote services far from the primary care unit (Fig. 1). Typical remote services include overnight delivery of medicines and clinical pharmacy services offered by phone, such as information on intravenous medication administration incompatibles and instructions for using new medicines. Pharmacy services related to long-term medication risk management, medicine handling, and appropriateness of medication-related facilities are inadequate. Improving medication safety through self-monitoring in rural Lapland would require new techniques, such as PMSSA, independent of local hospital pharmacy services.

Delphi consensus method

This study used the Delphi method to develop a PMSSA tool for rural Lapland. The method was chosen as it represents a multistage process for deriving consensus among separate experts [39–42], and it has been previously used successfully in developing MSSA tools for

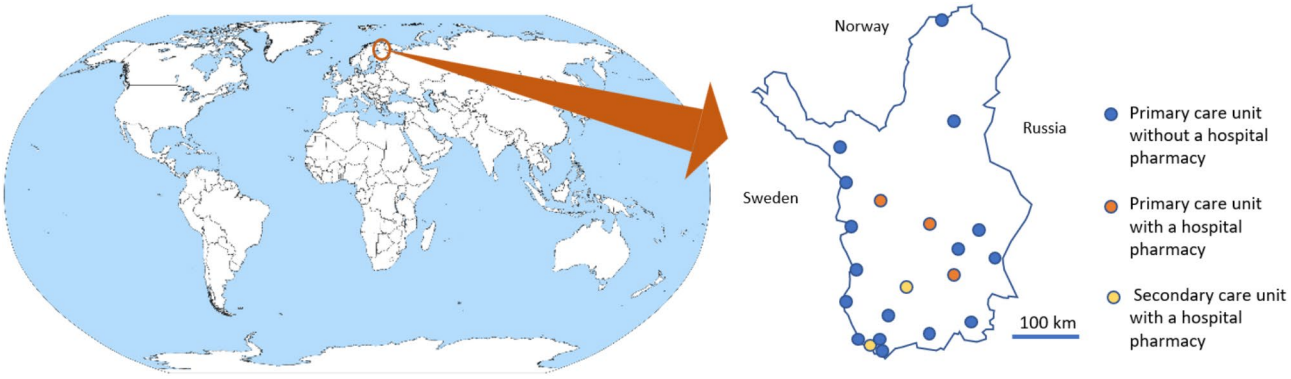

Fig. 1 Healthcare units with and without a local hospital pharmacy in Finnish Lapland

various healthcare settings [26, 43, 44]. The method effectively allows a group of individuals to deal with complex problems based on principles of anonymity, iteration, and feedback [42, 45]. The anonymity of the answers will enable individuals to freely express their thoughts and ideas without fearing judgment. The present study used the eDelphi software, allowing the researchers to observe whether the individual panelists had entered the questionnaire platform. This enabled the monitoring of participation activity and kept all panelists involved until the end of the study.

The present study comprised three phases, including two Delphi rounds with six questionnaires (Q1-6); Delphi round one had four questionnaires (Q1-4), whereas Delphi round two had two (Q5-6). The Delphi questionnaires with instructions were emailed to the panelists between December 2021 and April 2022. After two weeks, the link for each questionnaire was resent, and panelists who had not yet answered were personally reminded. Each questionnaire was kept open until all panelists delivered their responses, and the following questionnaire was released. A descriptive quantitative analysis with numbers and percentages was conducted using MS Excel by the main researcher (PS).

Delphi panelists

A convenience sample of individuals ($n = 12$) identified as primary care and patient safety experts in the Lapland area were contacted by phone and asked to participate in the study in November 2021. After the contacts, the study's introductory written material was emailed to the experts to confirm their participation. In total, 10 panelists agreed to participate. The group was further strengthened with two additional experts from the Finnish Center for Client and Patient Safety to provide a national perspective for developing a specific region-based risk management tool. The final Delphi panel ($n = 12$ experts) consisted of four nurses, five pharmacists, and three physicians.

Phase I: Developing the Delphi instrument

Three existing proactive risk management tools were identified to develop the Delphi instrument (Fig. 2). The first tool was a recently updated MSSA tool targeted at Finnish hospitals [43]. The tool originates from the Institute for Safe Medication Practices (ISMP) MSSA tool [27], which was adapted to the Finnish healthcare environment in 2016 [26, 43].

The second source was the National Guideline for Safe Medication Management and Use in Finland [46]. The guideline recommends that Finnish care units (e.g., hospital wards and nursing homes) develop internal protocols for safe medication practices. The third tool was the Hospital Survey on Patient Safety Culture by the Agency for Healthcare Research and Quality [47]; patient safety culture assessment tools are recommended to be used as part of the regular safety assessment in hospitals [48]. The original survey was independently translated into Finnish by two pharmacists at the Central Hospital of Lapland. The translations were then compared, and the wording that best matched the original query was chosen through a consensus discussion.

To develop the Delphi instrument, the contents of the three selected risk management tools were combined to form statements. The statements ($n = 436$) were further formatted by the study group members (PS, EC, SS, A-RH), who had clinical and academic expertise in proactive medication risk management. As a part of the process, the statements were formatted into the same configuration, favoring a positive approach, e.g., the statement: *"In this unit, there is a lack of support for staff involved in patient safety errors"* was formatted to *"There is enough support for staff involved in patient safety errors".* Additionally, statements concerning specialized health care were irrelevant to rural primary care in Lapland and removed (e.g., central anaesthesia). Statements from different sources with similar meanings were integrated to form one statement. E.g., the following individual statements were integrated into one statement: *"An employee's competence in pharmacotherapy is verified in*

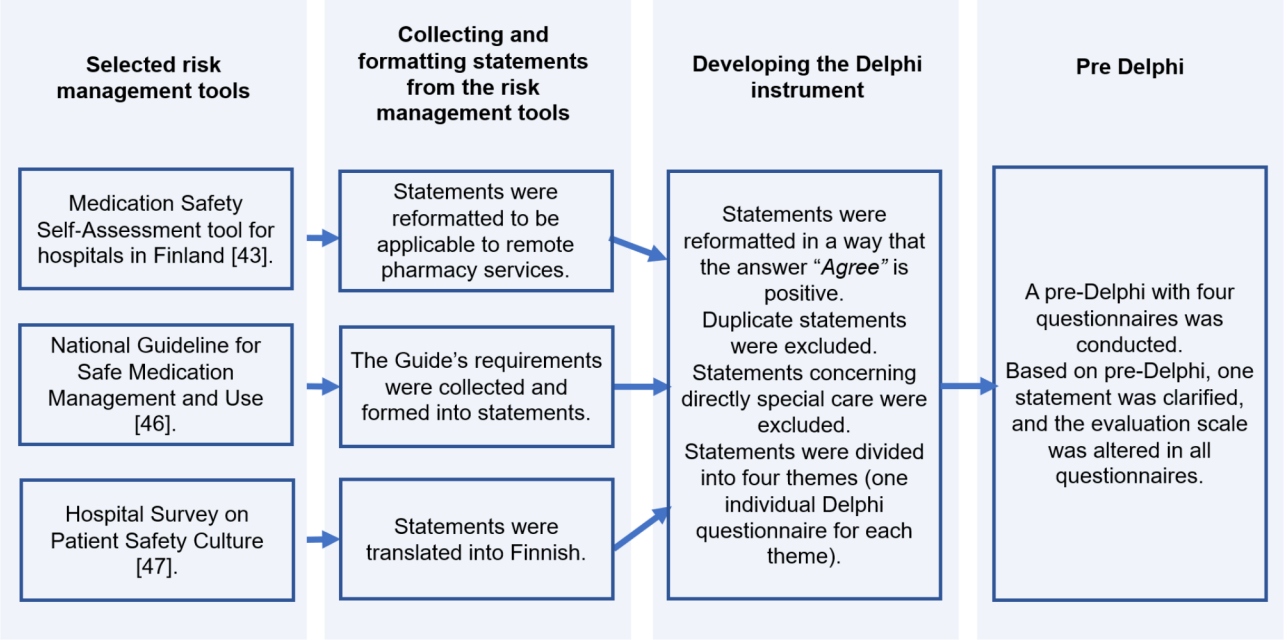

Fig. 2 Phase I of the study: developing the Delphi instrument

the manner defined in the unit's safe medication management and use protocol before the employee can start implementing pharmacotherapy independently for the patients" and "*All new employees and substitutes involved in the medication process are assessed for competency before they begin independent work. The authorization to work independently is given in writing. It is part of the orientation documentation of the employee*". The new single statement was: "*The qualifications of all new employees and substitutes (including doctors and nurses) participating in pharmacotherapy are assessed in the manner defined in the unit-based safe medication management and use protocol before they start working independently. The authorization to work independently is given in writing and is part of the orientation documentation*".

After formatting, the study group identified the following main themes among the statements: (1) Leadership, (2) Personnel and actions in hazard incidents, (3) Environment, equipment and software, and (4) Medication process (Fig. 2). A separate questionnaire was formed for each theme, and four patient safety and primary care experts were invited to validate the questionnaires as pre-Delphi. Statements were evaluated on pre-Delphi with a six level likert scale (---, --, - +, ++ and +++) modified from the study by Dimitrow et al.2014 [49]. Based on the pre-Delphi, one statement was clarified, and a six-step evaluation scale of the statements was altered into a four-step scale (Fig. 2).

Phase II: Delphi round 1

In the first Delphi round, the PMSSA tool's suitability for primary care settings and medication safety relevance were secured with four questionnaires (Q1-4), each representing one of the four themes (Appendix 1). In these questionnaires, panelists evaluated each statement based on its importance to medication safety and the relevance for the primary care environment by using a four-step scale (- / + / ++ / +++), in which "-" represented "not important at all" and "+++" represented "highly important". The practicality of the PMSSA tool to be developed was emphasized to the panelists, meaning the tool should be comprehensive but concise enough to be used in small primary care units. The final tool should also exclude self-evident or otherwise unnecessary statements inappropriate to primary care settings. Consequently, the panelists were asked to be critical in their evaluation of the statements. The panelists were also invited to suggest alterations or new statements and provide relevant comments. All comments by the panelists were anonymous but visible, and the panelists could comment on each other's notions during the Delphi round.

During the analysis, answers - and + were combined into one category of "not sufficiently important or essential" to achieve a concise PMSSA tool concentrating on the most pertinent prioritized statements. Correspondingly, answers + + and +++ were categorized as "sufficiently important and essential". On the first Delphi round, if ≥ 50% of the panelists had indicated an individual statement as "not sufficiently important or essential", the statement was excluded from the PMSSA tool.

The statements with a consensus of ≥ 85% on being "sufficiently important and essential" were included directly in the PMSSA tool. The representative consensus limits were chosen to identify the most critical issues to be evaluated in the PMSSA tool without becoming too broad for practice. Statements which did not reach consensus during the first Delphi round were re-evaluated in the second Delphi round.

Phase II: Delphi round 2

Before administering the second Delphi, the statements which did not reach consensus on the first round were altered based on panelists' comments. To facilitate ease of answering in the second Delphi, the remaining statements of four themes were combined into the following two questionnaires: Leadership, personnel and actions in hazard incidents (Q5), and Environment, equipment, software and medication process (Q6) (Fig. 3). The panelists were also provided access to statements already included in the PMSSA tool, comments made in the first round, and the original statement if the statement was reformatted. In the second round, the panelists were asked to evaluate the necessity of the statement to be included in the PMSSA tool on a scale of yes/no. Similarly, as in the first round, the Delphi panel could suggest alterations or new statements or provide other comments; all comments were anonymous but visible to all panelists during the questionnaire. The statements with a consensus of > 50% were included or excluded from the PMSSA tool. The study group evaluated statements with a precisely 50% level of agreement to decide whether to include or exclude them; the decision was based on the panelists' comments, previously included statements, and study group evaluation.

Phase III: Developing the PMSSA tool

The study group developed the final PMSSA tool based on the statements included in the Delphi process (Fig. 3). The PMSSA tool was developed by re-grouping the included statements into smaller sub-groups based on the previously developed Finnish MSSA tool for secondary care settings [43] and adding a scale of evaluation for each statement. Also, user instructions were provided in the final tool.

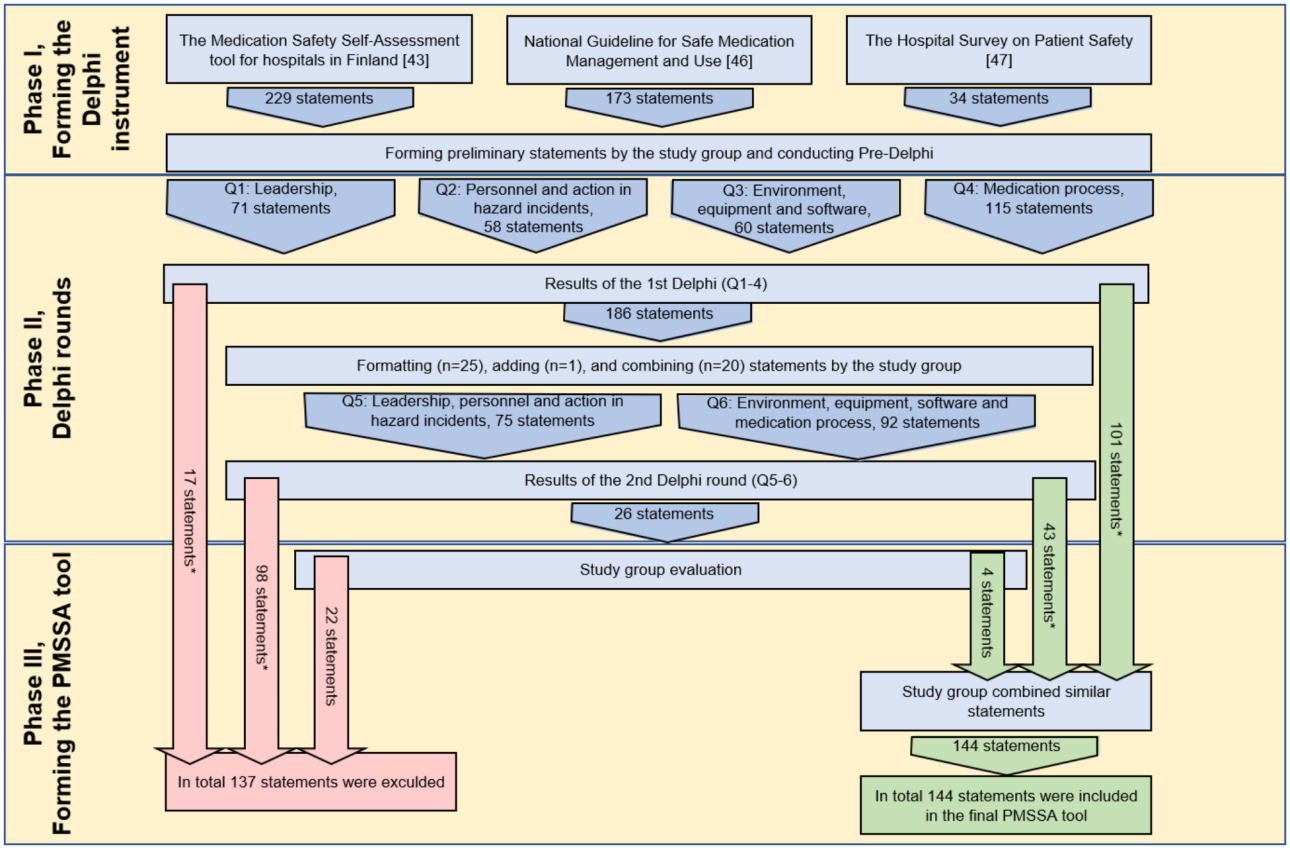

Fig. 3 Research procedure to develop a PMSSA tool for the rural Lapland of Finland. In Phase I, three medication safety tools were used to create the statements for Delphi questionnaires (Q1-6) administered in Phase II. The excluded statements are presented in red, and the included ones in green. * The statements for which a panel consensus (either statement exclusion or inclusion) was reached

Results

All agreed panelists (100%, $n = 12$) participated in all Delphi questionnaires (Q1-6) during the two Delphi rounds. The average response rate to the statements ($n = 471$) of the questionnaires was 93%. The lowest response rate to single statements was 75%, concerning nine out of 471 statements. The results of the present study comprise the consensus reached in the two Delphi rounds, the description of the panelists' comments during the rounds, and the final PMSSA tool developed based on the included statements.

The reached consensus, and the panelists' comments

In the first Delphi round (Q1-4), a consensus was reached on 118 out of 304 statements (39%), of which 86% were included, and 14% were excluded from the final PMSSA tool. During the first Delphi round, the panelists ($n = 12$) provided 198 comments to the statements ($n = 304$) of the administered questionnaires (Q1-4) (Table 1). Based on the comments, 25 statements were altered, one statement was added, and 20 were combined with another statement due to similarities. In the second round (Q5-6), 141 out of 167 statements (84%) reached a consensus, of which 70% were excluded and 30% included in the final PMSSA tool. The consensus percentages varied between 32 and 46% for the first round of Delphi questionnaires (Q1-4), while consensus percentages of 77% and 90% were achieved for the questionnaires (Q5-6) in the second round (Table 2).

During the second Delphi round, the panelists provided 15 comments to the statements ($n = 167$) in both administered questionnaires (Q5-6) (Table 1), with the majority ($n = 9$) concerning supporting opinions for the exclusion of statements. There were no suggestions for new statements. Consequently, the statements for which the consensus was reached (Fig. 3; Table 2) were included or excluded from the final PMSSA tool without any changes.

The final PMSSA tool

In total, 148 statements were included after Delphi rounds. However, when forming the final PMSSA tool (Appendix 2), the study group combined four statements which were considered similar. The included statements were further classified based on the ISMP MSSA tool for hospitals [27] with some alterations. "Quality, processes and risk management" was divided into two sections: "Proactive risk management" and "Learning from medication safety incidents" to increase practicality. In addition, a section for "Risk management supporting features of electronic medication record software" was added. Thus, in the final PMMS tool (Appendix 2), the approved statements ($n = 144$, Fig. 3) were divided into the following twelve thematic sub-groups (n of statements per sub-group provided in brackets): (1) Patient information ($n = 9$), (2) Drug information ($n = 10$), (3) Communication ($n = 19$), (4) Drug labeling, packaging and nomenclature ($n = 6$), (5) Drug storage and distribution ($n = 11$), (6) Medication device acquisition and use ($n = 7$), (7) Environmental factors, workflow and staffing patterns ($n = 13$), (8) Staff competency and education ($n = 15$), (9) Patient education ($n = 10$), (10) Quality control and risk

Table 1 The number and types of comments provided for each questionnaire (Q1-6) by the panelists ($n = 12$) during the Delphi rounds

	Suggestions for new statements ($n = 1$)	Suggestions for content alterations ($n = 31$)	Supporting opinions for inclusion ($n = 34$)	Supporting opinions for exclusion ($n = 65$)	Other comments ($n = 82$)*	In total ($n = 213$)
Round 1						
Q1: Leadership	0	8	8	31	22	69
Q2: Personnel and action in hazard incidents	0	9	12	5	32	58
Q3: Environment, Equipment and Software	0	4	6	3	9	22
Q4: Medication process	1	8	7	17	16	49
Total/round 1	1	29	33	56	79	198
Round 2						
Q5: Leadership, personnel and action in hazard incidents	0	1	1	5	1	8
Q6: Environment, Equipment, Software and Medication process	0	1	0	4	2	7
Total/round 2	0	2	1	9	3	15

*Non-relevant content for formatting, adding, including or excluding the statements

Table 2 The number of included and excluded statements, the level of the achieved consensus for each Delphi questionnaire (Q1-6), and the results of study group evaluation between the Delphi rounds

	Q1: Leadership (*n* = 71)	**Q2: Personnel and action in hazard incidents (*n* = 58)**	**Q3: Environment, equipment, and software (*n* = 60)**	**Q4: Medication process (*n* = 115)**
Delphi round I*				
Included	26	21	12	42
Excluded	7	2	7	1
Level of achieved consensus	26%	40%	32%	37%
Formatting, adding, and combining statements by the study group				
Formatted	6	8	4	7
Added	1	0	0	0
Combined	3	9	4	4
	Q5: Leadership, personnel, and action in hazard incidents (*n* = 75)		Q6: **Environment, equipment, software, and Medication process (*n* = 92)**	
Delphi round II**				
Included	18		25	
Excluded	40		58	
Level of achieved consensus	77%		90%	

*The required consensus rate was ≥ 50% for excluding and ≥ 85% for including a statement on the first Delphi round; **the required consensus rate was > 50% for including and excluding a statement on the second Delphi round

Table 3 The measuring scales of the statements (i.e., procedures to enhance medication safety) in the final PMSSA tool (appendix 2).*

Scale for availability of instructions on procedures		**Scale for implementation of procedures**	
Scale	Description	Scale	Description
Comprehensively instructed.	The procedure described in the statement has been fully guided, and all the staff have become familiar with the instructions and internalized their content. Orientation is documented for the whole staff (e.g., with reading receipts).	Used comprehensively	The procedure described in the statement is followed in every situation in the unit, and the entire staff follows it.
Partially instructed.	The procedure described in the statement is outlined in the unit. However, the instructions are insufficient to allow staff to follow the procedure described. The entire staff is not familiar with the instructions. The orientation documentation has been partially completed.	Partially used	The procedure described in the statement is followed occasionally in certain situations, and/or some of the staff follow the procedure.
Not instructed.	The procedure described in the statement has not been instructed at all in the unit, although it should be.	Not in use	The procedure described in the statement is not in use at all in the unit, although it should be.
N/A	The procedure described in the statement does not apply to the unit's operation.	N/A	The procedure described in the statement does not apply to the unit's operation.

* Adopted from the Medication Safety Self-Assessment Tool for Hospitals in Finland [43] and modified by the study group

management (*n* = 18), 11. Learning from medication safety incidents (*n* = 18), and 12. Risk management supporting features of electronic medication record software (*n* = 8). An evaluation scale was adopted for the PMSSA tool from the Medication Safety Self-Assessment Tool for Hospitals in Finland [43]. In the final PMSSA tool, each statement is evaluated on a four-level scale for the existing part of the instructions and the level of implementation (Table 3).

Discussion

A committed inter-professional panel of medication and patient safety experts contributed to this Delphi study, enabling the development of a self-assessment tool for evaluating medication safety in rural primary care settings in Lapland. To our knowledge, this is the first study to introduce a medication risk management tool focusing on the specific needs of a particular setting of a demographically demanding area.

Several other MSSA tools concerning medication safety in different environments have been developed internationally and in Finland over the past years [26–28, 32, 43, 44]. The present tool represents a continuation of the previous MSSA tools for hospitals [26, 43], which have been well received and adopted as a part of national medication safety guidelines in Finland [46]. In this PMSSA tool, similar thematic sub-groups were formed as in the previous Finnish MSSA tool for hospitals, but in the new primary care-focused tool, the priorities and contents differed from the previous secondary care-focused tools.

The final PMSSA tool consists of 144 statements, less than in many other national and international MSSA tools [27, 43, 50]. Compared to the previous secondary care-focused Finnish MSSA tool [43], the number

of statements remained almost the same in the 'Patient Information and Communication' sub-groups. This indicates that establishing procedures for safe handling of patient information and effective means of communication are equally important in both secondary and primary care. The number of statements in sub-groups "The medication device acquisition and use" and "Drug storage and distribution" was significantly less than in the previous Finnish MSSA tool. This may result from having fewer medication treatment-related devices, complex medication treatments, or high-risk administration routes in primary care, reducing their potential for confusion. No sub-group of PMSSA tool received more statements than the previous MSSA tool.

Based on the expert evaluation during the first Delphi round of the study, the highest degree of consensus was reached on the leadership-related statements. Indeed, leadership is one of the most critical factors affecting organizations' ability to adopt medication safety practices across types of healthcare organizations [51, 52]. In contrast, the smallest consensus during the first Delpihi round was reached on the theme of "Environment, equipment, and software". This could reflect that the health units' seek independence in choosing their working tools and software, potentially representing a reason why the experts' assessments of their importance to patient safety varied.

While there are indications that the quality of healthcare in rural areas of Finland may lag behind the development of the rest of the country [7], understanding patient safety concepts and building a patient safety culture in rural Lapland remains a central target for public health development, to which the present tool aims to contribute. Similarly to in other rural areas, the healthcare system in Lapland uses many remote connections, which should be considered when developing functioning procedures for medication safety [6, 23, 53]. The present PMSSA tool can be used to provide the primary care units with the possibility to independently identify their most critical areas for improvement without the demand for a direct onsite contribution from pharmacy professionals. However, in the case of Lapland, we recommend that the pharmacies still coordinate the self-assessment in healthcare units, which could be completed by the units at least before their annual remote audition. Consequently, pharmacy professionals can focus on supporting the units in managing the most critical and complex medication safety risks during the audits.

Limitations and recommendations

Delphi is a subjective evaluation method; its reliability is affected by the choice of experts, i.e., the number and quality of panelists [39, 40, 42]. While panels of 10–23 experts are generally considered sufficient [42], it was considered essential to keep all the panelists ($n = 12$) involved in all questionnaires (Q = 1–6). To ensure the participation of all panelists, statements with consensus on the first Delphi round did not go through the second round iteration. Therefore, to control the bias, the first-round consensus rate was set high. Additionally, the researcher's influence was minimized by setting the consensus limit of the second round so that only statements with which exactly half of the panelists disagreed remained for the researchers to evaluate [39, 45].

The PMSSA is recommended to be adopted as a part of regular organization-level self-monitoring of care quality and a means for information-based management of health services. In the future, the PMSSA tool should be evaluated as to whether it is compact but comprehensive enough to fulfil its purpose. Also, the PMSSA tool has a potential to be transferable to sparsely populated, technically developed regions of primary care services in other countries. However, the tool should be validated to suit the local regulations, policies, and cultural dimensions that affect risk management practices [54].

Conclusions

The present study introduces a PMSSA tool developed for rural primary care units to support their proactive medication risk management. A consensus (**≥ 85%**) of a committed expert group was achieved on the contents of the PMSSA tool. While remote pharmacy services, distinct to rural areas, emphasizes the importance of self-assessment by units, pharmacy support is still recommended to manage the assessment and related risk management development activities of the units. In the future, the adoption of the tool should be validated to suit risk management practices in different rural primary care environments in different countries.

Abbreviations

PMSSA	Primary Care Medication Safety Self-Assessment
MSSA	Medication Safety Self-Assessment
ISMP	Institute for Safe Medication Practices

Supplementary Information

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Supplementary Material 1: **Appendix 1**. Questionnaires Q1-Q4.

Supplementary Material 2: **Appendix 2**. PMSSA-tool.

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Author contributions

Each manuscript author (PS, EC, SS and AH), has contributed to the study's planning, conducting and re-porting.

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Data availability
Materials described in the manuscript, including all relevant raw data, are available from the corresponding author PS to any scientist wishing to use them for non-commercial purposes.

Declarations

Ethics approval and consent to participate
A study approval was obtained from the Lapland Central Hospital. The study was carried out in accordance with the National Research Ethics Guidelines and Regulations by Finnish Advisory Board on Research Integrity responsible conduct in research and procedures for handling allegations of misconduct in Finland [55]. According to their instructions, a separate ethics committee approval was not sought as the study contained no patients or patient information. Written informed consent was obtained from all participants.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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