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PHARMACOEPIDEMIOLOGY AND PRESCRIPTION

Content validation of a tool for assessing risks for drug-related problems to be used by practical nurses caring for home-dwelling clients aged ≥65 years: a Delphi survey

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Abstract
Purpose Home care services are becoming a critically important part of health care delivery as populations are aging. Those using home care services are increasingly older, more frail than previously, and use multiple medications, making them vulnerable to drug-related problems (DRPs). Practical nurses (PN) visit home-dwelling aged clients frequently and, thus, are ideally situated to identify potential DRPs and, if needed, to communicate them to physicians for resolution. This study developed and validated the content of a tool to be used by PNs for assessing DRP risks for their home-dwelling clients aged ≥65 years.
Methods The first draft of the tool was based on two systematic literature reviews and clinical experience of our research group. Content validity of the tool was determined by a three-round Delphi survey with a panel of 18 experts in geriatric care and pharmacotherapy. An agreement by ≥80 % of the panel on an item was required.
Results The final tool consists of 18 items that assess risks for DRPs in home-dwelling aged clients. It is divided into four sections: (1) Basic Client Data, (2) Potential Risks for DRPs in Medication Use, (3) Characteristics of the Client's Care and Adherence, and (4) Recommendations for Actions to Resolve DRPs.
Conclusions The Delphi process resulted in a structured DRP Risk Assessment Tool that is focused on the highest priority DRPs that should be identified and resolved. The tool also assists the PNs to identify solutions to these problems, which is a unique feature compared to similarly purposed prior tools.

Keywords Geriatric pharmacotherapy · Adverse drug reactions · Drug-related problems · Risk management · Patient safety · Primary care

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Introduction

A drug-related problem (DRP) is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes [1]. Age-related anatomical and physiological alterations combined with the presence of comorbidity and polypharmacy make pharmacotherapy of the aged both challenging and vulnerable to DRPs [2, 3]. These risks can be related to the pharmacological characteristics of medicines or to medicine use processes of individual patients [4, 5].

Long-term home care services for the aged are becoming a critically important part of public health care delivery in Finland as it is in many Western countries [6, 7]. An increasing proportion of older people, cost increases, and consumer preferences are among the major influences on this shift. Aged people in home care are increasingly older and more frail than previously and use multiple medications [8, 9]. They see physicians infrequently but may have more regular, even daily, encounters with home care practical nurses (PNs) [10]. Thus, PNs are in a key position for identifying clients at risk for adverse drug reactions (ADRs) and other DRPs. However, PNs need tools that are feasible for use in routine practice and that focus on identifying the most critical pharmacotherapy risks of the aged.

Even though numerous explicit and implicit criteria for potentially inappropriate medications for the aged have been established [11, 12], there is a lack of validated tools designed to be used by PNs in home care that would screen aged clients at high risk for DRPs and communicate the results to the entire care team. The existing tools [13–21] are meant to be completed by pharmacists [13], by other health and social care workers [15], or by the patients themselves during clinic visits [14, 17, 19, 21]. Moreover, some of the tools are nonspecific for age or geriatric application [13, 17, 18, 21]. We are aware of two nurse-administered risk assessment tools designed for the aged [16, 20]. They primarily focus on nonadherence [16] or nonadherence and the complexity of the patient's medication regimen [20] but ignore geriatric-specific ADRs or medicines that pose greater risks for the aged. In addition, these tools were not designed to be used by PNs, who have a 3-year vocational qualification with modest training in pharmacotherapy but who are the ones who most commonly make home visits and work most closely with the home-dwelling aged clients [22].

The present study developed and content validated a DRP Risk Assessment Tool for use by PNs taking care of home-dwelling clients ≥65 years. The tool is designed (1) to identify those aged ≥65 years at high risk for adverse drug reactions or other DRPs and (2) to assist in recommending the potential risk clients intervening actions for optimizing their pharmacotherapy. The tool is intended to be used by PNs in the context of their routine home visits and to pose minimal administrative and time burdens for learning its routine use.

Methods

The DRP Risk Assessment Tool was developed in two major phases, namely by (1) developing a draft tool on the basis of two systematic literature reviews [11, the other one is unpublished (in preparation)] and the clinical expertise of the research group and (2) determining the content validity of the tool by a three-round Delphi survey [23] involving a panel of 18 experts in geriatric care and pharmacotherapy (Fig. 1).

Systematic literature reviews

The literature on existing criteria for assessing inappropriate prescribing in patients aged ≥65 years was systematically reviewed according to the PRISMA statement criteria [11, 24]. In addition to the abovementioned systematic literature review on potentially inappropriate medications for the aged, we also systematically searched existing tools designed to screen aged patients at risk for DRPs. The following search terms were used: (*elderly or aged or ageing*), (*medication-related problem or drug-related problem or drug-therapy problem*), (*risk*), and (*screening tool or tool or form*). English language articles published during 1985–2010 were searched in the following databases: Evidence-Based Medicine database, Web of Knowledge, Scopus, and CINAHL.

Development of the draft DRP Risk Assessment Tool

According to the findings of the systematic review [11], we identified (1) medicines (e.g., theophylline, amiodarone, digoxin, fluoxetine) and medicine classes (e.g., anticholinergics, sedatives, neuroleptics, nonsteroidal anti-inflammatory drugs, diuretics, hypoglycemics) recognized to pose higher risks for the elderly and (2) potential geriatric-specific ADRs caused by these medicines. Second, according to the findings of the unpublished systematic review that focused on existing age-specific (≥65 years) screening tools (n=5) [14–16, 19, 20], we listed the most commonly mentioned prognostic indicators for DRPs. The review also revealed some other factors to be considered, particularly the structure of the tool and focusing the screening on potentially harmful ADRs instead of producing a long list of problematic medicines [19]. Both of these systematic literature reviews' findings were integrated into the draft tool. Our research group's clinical experience was used in this phase, as well as that of an experienced geriatrician who was not a member of the research group.

As PNs' training concentrates mainly on supportive and technical aspects of nursing rather than on pharmacotherapy

The draft DRP Risk Assessment Tool	• Based on o Two Systematic Literature Reviews [11, unpublished one] o Expertise of the Research Group o Consultation of a geriatrician not involved in the Research Group
Expert Panel Selection for the Pilot Delphi Round and for the Actual Delphi Rounds	• The Pilot Delphi Round (6 experts) o a physician, 6 pharmacists accredited for comprehensive medication review[27] and a graduating pharmacy student (n=8) were invited to participate in the study (a convenience sample of healthcare professionals having expertise in geriatric pharmacotherapy) o 75 % (6/8) enrolled in the study (6 pharmacists accredited for comprehensive medication review) • Actual Delphi Rounds (18 experts) o 22 physicians, 4 pharmacists and 7 nurses who were known to be experts in geriatric care, particularly in geriatric pharmacotherapy were invited to participate in the study (n=33) (strategic sampling) o 55% (18/33) enrolled in the study (11 physicians, 4 nurses and 3 pharmacists)
The Pilot Delphi Round within 1-week period in May 2010	• Aimed to assess o clarity of the instructions for rating the risks for DRPs o face validity of the presented DRP risk assessment items • Recommendations for improvements of the draft DRP Risk Assessment Tool • Response rate 100% (6/6)

Fig. 1 Outline of the development of the Drug-Related Problem (DRP) Risk Assessment Tool and validation of its content by Delphi method. [a] each component of multi-component items are counted as single items. ADR = Adverse-Drug Reaction, DRP = Drug-Related Problem [1]

The First Delphi Round within 2-week period in September, 2010	• Aimed to assess suitability of the presented items in assessing risks for DRPs in the aged ≥65 years (i.e., whether the item 1) indicated a typical ADR caused by a medicine or medicine class that is potentially harmful for the aged, or whether 2) the item was a suitable prognostic indicator for a DRP that requires active management). • response rate 78% (14/18), one panelist dropped out from the next rounds because of being too busy to participate • consensus reached for 36% (33/91) of the items • 11 new items suggested by the panelist, 1 item withdrawn, 1 item divided in to two
The Second Delphi Round within 2-week period in October, 2010	• Aimed to assess suitability (see the definition above) of the presented items in assessing risks for DRPs in the aged ≥65 years • response rate 76% (13/17) • consensus reached for 22% (15/69) of the items
The Third Delphi Round within 2-week period during November-December, 2010	• Aimed to assess importance of the items of the final DRP Risk Assessement Tool (i.e., the significance of each item as an indicator for predicting DRPs in the aged ≥65 years) • response rate 94% (16/17) • final scores 4±1.12 to 4.94±0.24 within range 5(important)–1(unimportant)
The DRP Risk Assessment Tool	• 59 items[a] o 48/102 (47%) items that reached consensus during the Delphi Rounds o 11 items included by the decision of the Research Group

Fig. 1 (continued)

[22], lay language terms were used throughout the draft tool to make it easy to use for them. For example, instead of asking directly whether the client uses statins, the following wording was used: "Does the client use medicines that are intended to lower the cholesterol level (statins)?" For the sake of clarity, International Nonproprietary Names (INNs) of medicines

were avoided whenever possible. Instead, we asked if the client suffered from symptoms that would typically suggest ADRs related to medicines and medicine classes that are problematic for the aged.

The Delphi method

The Delphi method is a systematic technique for formulating a group judgment concerning subject matter for which the information is incomplete or lacking entirely [23, 25]. Its validity relies on a panel of experts having been carefully selected, that their individual judgments be provided independently and anonymously via questionnaires in two or more rounds, and that there be aggregated feedback between rounds. In this study, three Delphi rounds were performed online via the software called eDelfoi [26].

The process for identifying and selecting the expert panel (Fig. 1) resulted in a final panel comprising 11 physicians, 4 nurses, and 3 pharmacists. The primary criterion for selecting each panelist was that they have extensive clinical experience in geriatric care, including pharmacotherapy. The physicians' (n=11) expertise spanned clinical pharmacology, general practice, geriatrics, internal medicine, and nephrology. Five of them had higher academic degrees (PhDs), and two were specializing in neurology and general practice. One of the nurses and two of the pharmacists had a PhD degree.

The Delphi rounds for content validation of the DRP Risk Assessment Tool

We pilot tested the draft tool by conducting a pilot Delphi round before the actual rounds (Fig. 1). A few minor modifications were then made according to the panelists' proposals.

Two authors independently analyzed each Delphi round's responses (including the pilot round), and their results were compared. The few emergent disagreements were resolved between the rounds by discussing them in the research group meetings, with the final form of the next round's tool being decided in those meetings.

Before each Delphi round, it was stressed to the panelists that the final Tool was meant to be administered by PNs and that the panelists should consider a typical PN's ability to answer the items. The panelists' guidance also emphasized the goal of developing a tool which (1) focuses on the most important predictors for DRPs in the aged, (2) is easy to use in the time constraints of routine practice, and (3) requires only modest training for PNs.

During the first and second Delphi rounds, the panelists were asked to rate the suitability of every item in the evolving versions of the draft tool (including each individual component of multicomponent items) in assessing DRP risks for clients ≥65 years. Depending on the item, they were asked to rate whether the item (1) indicated a typical ADR caused by a medicine or medicine class that is potentially harmful for the aged or whether (2) the item was a suitable prognostic indicator for a DRP that requires active management. Round one also included a final open-ended question: *If you think that the draft risk assessment tool ignores some essential aspects of medication risks in routine community clinical practice, please identify each of them*.

The second round survey included items for which consensus had not yet been reached; they were then modified according to the panelists' recommendations. New items suggested by the panelists were added. The panelists also received a list of items on which consensus had been reached in the first round. After the second round the research group decided to add 11 items for which consensus had not been reached during the two first rounds (Table 1). The expert panelists were informed of this decision at the beginning of the third round and invited to the items individually.

During the third final round, panelists rated the importance of each of the final DRP Risk Assessment Tool items (i.e., the significance of each item as an indicator for predicting DRPs). Multicomponent items were rated as one item (Table 1, main items 5, 6, 8, and 14), with importance being rated with the alternatives "important," "moderately important," "cannot say," "moderately unimportant," or "unimportant". In addition to rating the importance of individual items, panelists were asked to identify symptoms listed in the final tool that would be suggestive of ADRs requiring immediate actions (i.e., contacting the physician) (Table 1, item 8).

Data analysis

Items that ≥80 % of the panelists rated as suitable were included in the final DRP Risk Assessment Tool. A similar consensus criterion was applied to the panelists' ratings of the symptoms requiring immediate action. The importance of each main item in the final tool was scored from 5 to 1 (5= important, 1=unimportant). The mean ratings and standard deviations (SD) are reported.

Results

Panelists achieved consensus on 48 of 102 items (47 %) (each main item and each individual item of the final tool's multicomponent items are discussed here as items; see Table 1). In addition to these 48 consensus items, 11 items were retained according to the research group's judgment (Fig. 1), resulting in the 59-item final DRP Risk Assessment Tool. This final version of the tool consists of four main sections: (1) Basic Client Data, (2) Potential Risks for DRPs in Medication Use, (3) Characteristics of the Client's Care and Adherence, and (4) Recommendations for Actions to Resolve DRPs (Table 1).

Table 1 The Drug-Related Problem (DRP) Risk Assessment Tool

Basic Client Data

Name			
Identity number			
Age	Years		
Gender			
Male	□		
Female	□		
Does the client live alone?		Yes	No
		□	□
Does the client have an up-to-date medication card/list?		Yes	No
		□	□
Who administers the client's medicines?			

Potential Risks for DRPs in Medication Use

1. Does the client have seven[a] or more prescription medicines in current regular use? (excluding basic creams)	Yes □	No □
2. Does the client take 12 or more medicine doses regularly each day (excluding basic creams)?	Yes □	No □
Example of counting the doses: Drug 1: 1 tablet 3 times a day=3 doses, Drug 2: 1 dose 2 times a day=2 doses, i.e., in total 5 doses a day		
3. Is the client currently taking medicines for three or more diseases or symptoms? (including acute diseases)	Yes □	No □
4. Has the client started a new medicine in the last 4 weeks? (excluding different brands of the same active ingredient)	Yes □	No □
5. Does the client use medicines that…	Yes	No
a. relieve pain by reducing inflammation (does not apply to paracetamol)?	□	□
b. elevate the rate of urination (diuretics)?[a]	□	□
c. are intended to lower the cholesterol level (statins)?[a]	□	□
d. the physician does not know about?	□	□

6. Does the client use any of the following medicines (please check the ones used)? (the list contains medicines with a narrow therapeutic index, medicines for which regular monitoring would be necessary and medicines that otherwise are problematic for the aged)

Amiodarone[a]	□	Lithium[a]	□
Carbamazepine	□	Methotrexate[a]	□
Digoxin	□	Theophylline[a]	□
Fluoxetine	□	Warfarin	□

7. Has the client used over-the-counter (OTC) medicines or vitamin, mineral or herbal products in the past 2 weeks? State which ones.	Yes □	No □

8. Has the client had any of the following symptoms in the last 4 weeks? (Please tick below "yes" if it has been ongoing and add another tick in the right column, if the symptom is a new one=a symptom that had first occurred within the last 4 weeks)

symptom	yes	new	symptom	yes	new	symptom	yes	new
drowsiness			nausea			memory problems		
fatigue			diarrhea			confusion		
skin rash or itch			constipation			visual problems		
dizziness			dizziness when getting up			stiffness		
urination problems			recurrent falls			troubles in walking		
muscle pains			swellings			low blood pressure, systolic under 110 mmHg[a]		

9. Has the client had more than one fall in the past 12 months?	Yes □	No □

Table 1 (continued)

10. Has the client/relative/visitor noticed any changes in client's condition that could indicate adverse drug reactions related to changes in medicines regimen?	Yes □	No □
Characteristics of the Client's Care and Adherence		
a) Health, health care setting and care taking physician		
11. Does the client have three or more chronic diseases?	Yes □	No □
12. Has the client been in short term care (e.g., interval care) in hospital, nursing home, sheltered housing, health centre ward or some other institution in the past 4 weeks?	Yes □	No □
13. Does the client have more than one physician involved in his/her care? (e.g., general practitioners, specialists, private practitioners)	Yes □	No □
b) Adherence		
14. Has the client had troubles in	Yes □	No □
a. remembering to take the medicines?	□	□
b. following the medicines regimen?	□	□
c. knowing what his or her medicines are used for?	□	□
d. affording the medicines (i.e., economic problems)?	□	□
e. opening the drug bottles or packages or managing with medicines related therapeutic devices?	□	□
15. Does the client consciously sometimes take medicines differently than prescribed?	Yes □	No □
16. Is the client (or his/her caregiver) aware of the client's diseases and their treatments?	Yes □	No □
17. Is the client (or his/her caregiver administering the medication) aware of the medicines that the client uses?	Yes □	No □
18. Have the client's relatives/proxies expressed their concern about the client's medicine use?	Yes □	No □
Recommendations for Actions to Resolve DRPs (*several items can be selected if necessary*):		
	Yes	No
a) Comprehensive Medication Review	□	□
b) Using dose dispensing device	□	□
c) Automated dose dispensing[a]	□	□
d) Visiting the personal physician	□	□
e) Visiting a diabetes or asthma nurse in the health centre or the diabetes or asthma pharmacist in the pharmacy[a]	□	□
f) Weekly control visits by a home care nurse	□	□
g) Follow-up of the client's condition (repeating the risk test)[a]	□	□
Client's permission for possible intervening actions?	□	□

[a] Retained in the DRP Risk Assessment Tool by judgment of the research group

The contents of these four sections are described more in detail in the following paragraphs.

Section 1: Basic Client Data

The first section of the DRP Risk Assessment Tool focuses on basic client demographic data, such as age and gender (Table 1). The Delphi survey rounds yielded the following two additions to the basic client information: (1) an indicator of whether the client has an up-to-date medication card/list and (2) who administers the client's medications. These items are relevant for identifying whether the client's medication management process is fragmented, thus posing a risk for unrecognized and unsolved DRPs.

Section 2: Potential Risks for DRPs in Medication Use

Section 2 consists of ten main items, of which three are multicomponents, representing 38 single items in total. This section of the tool focuses on symptoms potentially suggestive of ADRs (3 main items with 21 single items) or medicines potentially harmful or problematic for clients aged ≥65 years (2 main items with 12 single items, Table 1). The list contains medicines having a narrow therapeutic index, medicines for which regular monitoring would be necessary, or medicines that are otherwise problematic for the aged. The section also includes items indicating risks posed by polypharmacy (three items), initiation of a new medication (one item), and concomitant use of nonprescription medicines or vitamins with prescription medicines (one item).

Section 2's items are mostly binary, with "yes" or "no" options for indicating the client's condition. Of the 18 potential ADRs listed in item 8 (Table 1), three were rated by the expert panel as symptoms requiring immediate actions (fatigue, recurrent falls, and confusion). However, we decided not to emphasize these three symptoms in the final DRP Risk Assessment Tool because that could lead to underestimating the potential significance of other symptoms. Instead, we included an additional rating option for whether the symptom is new (see Table 1, item 8). This addition was suggested by the panelists in the first Delphi round. The research group qualified it as meaning a symptom that had first occurred within the last 4 weeks. In the second Delphi round, the panelists reached consensus for this addition to rating the symptoms.

Section 3: Characteristics of the Client's Care and Adherence

Section 3 consists of eight main items with one multicomponent item, representing 12 single items in total. It includes information about the client's health, adherence to their therapeutic regimen and involvement in one's care, the health care setting, health care units recently visited by the client, and the number of care-taking physicians (Table 1). All of the section's items have a "yes" or "no" rating option.

Section 4: Recommendations for Actions to Resolve DRPs

This section encompasses seven interventions that PNs can recommend for resolving potential DRPs for those at risk (Table 1). The recommendations that PNs make need to be based on a risk assessment resulting from the information gathered by using the DRP Risk Assessment Tool.

Ranking the importance of items included in the final DRP Risk Assessment Tool

Table 2 contains the rating results of the Delphi panel's third round of the importance of the items included in the final Drug-Related Problem (DRP) Risk Assessment Tool (Online Resource 1).

The panelists ranked two items as the most important for predicting DRP risks in the aged ≥65 years: (1) the item indicating whether the client has an up-to-date medication list and (2) the item assessing the client's adherence to his/her medication.

All of the items in the final tool were rated either as important or moderately important in predicting DRP risks for those ≥65 years. Mean scores varied from 4.94±0.24 to 4±1.12, within the range of 5 (important)–1 (unimportant). More dispersion was observed in items with the lowest mean scores. The items with the highest mean scores also had the smallest standard deviations, indicating high concordance between the panelists.

Discussion

DRP Risk Assessment Tool for PNs

Developing the DRP Risk Assessment Tool followed a rigorously selective process to produce an instrument that could be used by PNs supporting medication management for home-dwelling clients ≥65 years but who have only modest formal training in pharmacotherapy. A three-round Delphi process yielded consensus (≥80 % agreement on an item) on 48 DRP risk assessment items and a final agreement on the resulting 59-item tool.

In addition to indicating potential risks from the pharmacological effects of the medications, particularly ADRs, the DRP Risk Assessment Tool includes measures on risks related to poor adherence and to poor medication management, such as not involving clients and/or their caregivers in care, infrequent follow-ups, and poor coordination of care among the client's health care providers. The importance of adherence and medication management for minimizing DRP risks was confirmed by the Delphi panel experts who gave their final highest importance ratings to items indicating whether the client has a timely medication card/list and whether the client adheres to his/her medication. These indicators, either one or both, are missing or have had a minor role in previous tools that assess DRP risks in the aged [14–16, 19, 20] or criteria for inappropriate prescribing for the aged [11, 12].

Another feature of the final DRP Risk Assessment Tool is that, in addition to assisting PNs in identifying home-dwelling aged clients who have or who are at risk for DRPs that require actions, the tool actually guides the selection of such actions. Most of them are related to consulting a physician, another health care provider, or a specially trained pharmacist to review the client's medications and condition [4, 27]. Some clients may also benefit from automated dose dispensing for their medications (i.e., medicines are packed in unit-dose bags according to administration times), a service available to primary care patients throughout Finland [5, 28]. The tool also increases awareness among PNs and the aged of options to improve medication safety (e.g., comprehensive medication reviews, dose dispensing, and consulting an accredited pharmacist).

One third of the individual items in the DRP Risk Assessment Tool are indicators of potentially harmful ADRs. The number of these is high, even though over half of the initially nominated ADRs (28/46, 61 %) and most of the initially suggested problematic medicines (14/18, 78 %) were excluded during the successive Delphi rounds. This indicates the importance of taking ADRs into account as an integral part of medication use and of identifying ways to identify them early and manage them. The DRP Risk Assessment Tool explicitly guides PNs in the detection of

Table 2 Rating results of Delphi panel's third round: the importance of the items included in the final drug-related problem (DRP) Risk Assessment Tool[a] (i.e., the significance of each item as an indicator for predicting DRPs in the aged ≥65 years)

Items of the DRP Risk Assessment Tool in order of the mean scores	Number of panelists who rated the importance of the items as					Mean score±SD
	Important (5)[b]	Mod (4)[b]	Cannot say (3)[b]	Mod (2)[b]	Unimportant (1)[b]	
1. Does the client have an up-to-date medication card/list?	15	1				4.94±0.24
2. Has the client had troubles in a. Remembering to take the medicines? b. Following the medicines regimen? c. Knowing what his or her medicines are used for? d. Affording the medicines (i.e., economic problems)? e. Opening the drug bottles or packages or managing with medicines related therapeutic devices?	14	2				4.88±0.33
3. Who administers the client's medicines?	13	3				4.81±0.39
4. Is the client (or his/her caregiver administering the medication) aware of the medicines that the client uses?	13	3				4.81±0.39
5. Has the client had any of the following symptoms in the last 4 weeks? (Please tick below "yes" if it has been ongoing and add another tick in the right column, if the symptom is a new one=a symptom that had first occurred within last 4 weeks): drowsiness, fatique, skin rash or itch, dizziness, urination problems, muscle pains, nausea, diarrhea, constipation, dizziness when getting up, recurrent falls, swellings, memory problems, confusion, visual problems, stiffness, troubles in walking, low blood pressure, systolic under 110 mmHg	12	4				4.75±0.43
6. Does the client have more than one physician involved in his/her care? (e.g., general practitioners, specialists, private practitioners)	12	4				4.75±0.43
7. Does the client have seven or more prescription medicines in current regular use? (excluding basic creams)	11	5				4.69±0.46
8. Is the client (or his/her caregiver) aware of the client's diseases and their treatments?	13	2		1		4.69±0.77
9. Has the client started a new medicine in the last 4 weeks? (excluding different brands of the same active ingredient)[c]	10	5				4.67±0.47
10. Have the client's relatives/proxies expressed their concern about the client's medicine use?	10	6				4.63±0.48
11. Has the client/relative/visitor noticed any changes in client's condition that could indicate adverse drug reactions related to changes in medicines regimen?	11	4	1			4.63±0.60
12. Does the client consciously sometimes take medicines differently than prescribed?	10	5	1			4.56±0.61
13. Has the client had more than one fall in the past 12 months? [c]	10	4		1		4.53±0.81
14. Does the client use any of the following medicines (please check the ones used)? (the list contains medicines with a narrow therapeutic index, medicines for which regular monitoring would be necessary and medicines that otherwise are problematic for the aged): amiodarone, carbamazepine, digoxin, fluoxetine, lithium, methotrexate, theophylline, warfarin	13			3		4.44±1.17
15. Is the client currently taking medicines for three or more diseases or symptoms? (including acute diseases)	9	6			1	4.38±0.99
16. Does the client use medicines that a. Relieve pain by reducing inflammation (does not apply to paracetamol)? b. Elevate the rate of urination (diuretics)? c. Are intended to lower the cholesterol level (statins)? d. The physician does not know about?	9	5		2		4.31±0.98
17. Has the client been in short term care (e.g., interval care) in hospital, nursing home, sheltered housing, health centre ward or some other institution in the past four weeks?	6	9		1		4.25±0.75
18. Has the client used over-the-counter (OTC) medicines or vitamin, mineral or herbal products in the past 2 weeks? State which ones.	6	8		2		4.13±0.93
19. Does the client have three or more chronic diseases?	9	4		2	1	4.13±1.27
20. Does the client take 12 or more medicine doses regularly each day (excluding basic creams)? Example of counting the doses: Drug 1: 1 tablet 3 times a day=3 doses, Drug 2: 1 dose 2 times a day=2 doses, i.e., in total 5 doses a day	7	5	1	3		4±1.12

[a] The respondents were not asked to rate the importance of the item "The Recommendations for Actions to Resolve DRPs"

[b] Scoring, "important"=5, "moderately important"=4, "cannot say"=3, "moderately unimportant"=2, "unimportant"=1

[c] 15 of 16 panelists rated of the importance of items 9 and 13

specific symptoms associated with potential ADRs requiring attention. Otherwise, ADRs tend to be underreported among the aged as they may consider the symptoms to be a part of normal aging [29].

Expert panelists reached consensus on 48 of 102 initial items (47 %), which is less than the harvest in several other conceptually similar Delphi surveys reported in the health services' research literature [30–32]. The criterion for consensus (80 %) to determine attainment of this goal was high: Consequently, achievement of consensus was low. Therefore, we believe that only the most important items for identifying DRP risks in home-dwelling clients ≥65 years were retained in the final DRP Risk Assessment Tool. Furthermore, our Delphi panel comprised physicians, pharmacists, and nurses who are leading experts in geriatric care and pharmacotherapy in Finland. Thus, they should have had the most comprehensive knowledge of typical potentially harmful ADRs and other risks for DRPs which require active management. In order to keep the panelists focused on the DRP Risk Assessment Tool's intended use, it was stressed to them before each Delphi round that the tool was meant to be administered by PNs and they have to consider a PN's ability to evaluate DRP risks for their individual home-dwelling aged clients.

One of the Delphi technique's limitations is that important items may be excluded if the panelists cannot reach consensus [33]. To avoid such omissions, we retained 11 items (Table 1) in the final DRP Risk Assessment Tool despite their lacking consensus. Based on scientific evidence and our research group's clinical expertise, those items were considered too important for the intended purpose to be excluded. Also, the Delphi panelists rated these retained items as important or moderately important during the third round survey, indicating their endorsement for including these additional 11 items in the final DRP Risk Assessment Tool.

The list of problematic medicines in the final DRP Risk Assessment Tool does not include hypoglycemics, which in several other reported criteria are identified as problematic for the aged [12, 34, 35]. Hypoglycemics are well documented in the literature as a leading cause of emergency department visits and hospitalizations in the aged [36]. The rationales for their omission are the following: (1) the most problematic oral hypoglycemics (chlorpropamide and glyburide) are no longer available in Finland and (2) the DRP Risk Assessment Tool includes items that would identify the symptoms of potential hypoglycemia.

Potential implications for practice

The DRP Risk Assessment Tool developed in this study is designed for direct use in clinical practice, and it has multiple potential applications for timely interventions that would improve the quality and safety of medicine use in home-dwelling clients ≥65 years. As the PNs who visit home-dwelling aged clients would make a more accurate and standardized DRP risk assessment when guided by the tool, sharing their documented information with the client's physician and other health care providers involved in client's care can be readily integrated into routine practice. This may support physicians in making timely clinical interventions to manage a client's potential or manifest DRPs, e.g., harmful ADRs. The tool provides additional information for pharmacists who conduct comprehensive medication reviews [27]. Alternatively, the tool can assist in identifying clients in need of such reviews.

The DRP Risk Assessment Tool has educational implications. The routine use of the tool educates PNs and other health care providers involved in geriatric patients' care teams about geriatric pharmacotherapy and its role in clinical practice in home care. The tool also supports training on how to manage DRPs and to perform quality assurance in the medication use process, e.g., updating and harmonizing medication cards/lists.

Achieving optimal results from the DRP Risk Assessment Tool requires user education, periodic updates, and widespread adoption. If used consistently throughout a nation, the structured DRP Risk Assessment Tool will provide more timely and standardized information, harmonizing the way the health care personnel assess and communicate with each other to prevent, detect, and resolve DRPs of the clients aged ≥65 years.

Strengths and weaknesses of the study

The Delphi technique is an accepted and commonly used method in health services research [11, 23], providing information in a valid and accessible manner. A Delphi survey's success, however, depends on the selection criteria, process, and quality of the expert panel [25, 37]. To ensure a broad representation of skills and competence in geriatric care and pharmacotherapy, we invited panelists from three relevant but different expert professional groups: physicians, nurses, and pharmacists. Conducting the survey online facilitated broad geographic representation of that expertise. As the panelists were carefully selected among the best experts in geriatric care and pharmacotherapy in Finland, we believe they had a comprehensive understanding for validating the content of the DRP Risk Assessment Tool.

A multiprofessional 13–16-member expert panel responded in the three Delphi rounds (Fig. 1). This is consistent with or slightly greater than the panel size in several other Delphi surveys [11, 33, 34, 38, 39]. Thus, we believe that the number of participants is high enough to provide confidence in the stability of the results. Response rates in the Delphi rounds in the current study varied from 76 to 94 %, indicating

the panelists' involvement and commitment to the development of the DRP Risk Assessment Tool.

Even though it was initially based on two systematic literature reviews [11, the unpublished one], the draft DRP Risk Assessment Tool may have missed some relevant aspects of patient care. That is why the expert panelists were asked to suggest additional items based on their clinical expertise. We also drew on the research group's special expertise in geriatric pharmacotherapy and geriatrics to complement the evidence-based origins for items in the final DRP Risk Assessment Tool. Thus, we believe that the development and validation processes have been rigorous enough to overcome potential deficiencies with the methodology.

It may be considered a limitation that our systematic literature review of potentially inappropriate medicines for the aged includes published papers until July 2010 [11]. However, we updated the literature review in 2012, including published papers until June 2012 [40]. Thus, our literature covers the main problematic medicines and medicine classes and is still up-to-date, including, e.g., the most recent update of the Beers Criteria in 2012 [12].

The DRP Risk Assessment Tool's content was validated in this study. The next step is to validate it in the field. We have already conducted a feasibility study among PNs in home care to test their ability to answer the items in the tool reliably and to assess the time spent completing the tool. Preliminary study results indicate that the tool is appropriate to a PN's skill level. The results of these analyses will be reported in detail in subsequent publications.

Conclusion

We have developed and content validated a DRP Risk Assessment Tool intended to be used by PNs in home care for home-dwelling clients ≥65 years. The tool is designed for unintrusive, direct application in clinical practice. The Delphi process used to construct the tool resulted in a structured DRP Risk Assessment Tool that focuses on the identification and resolution of the highest priority DRP risks. In addition to identifying pharmacotherapeutic risks, the tool assists in finding solutions to these problems—a unique feature when the tool is compared to previous risk assessment tools.

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