

Practical Problems with Medication Use that Older People Experience: A Qualitative Study

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OBJECTIVES: To identify the practical problems that older people experience with the daily use of their medicines and their management strategies to address these problems and to determine the potential clinical relevance thereof.

DESIGN: Qualitative study with semistructured face-to-face interviews.

SETTING: A community pharmacy and a geriatric outpatient ward.

PARTICIPANTS: Community-dwelling people aged 70 and older (N = 59).

MEASUREMENTS: Participants were interviewed at home. Two researchers coded the reported problems and management strategies independently according to a coding scheme. An expert panel classified the potential clinical relevance of every identified practical problem and associated management strategy using a 3-point scale.

RESULTS: Two hundred eleven practical problems and 184 management strategies were identified. Ninety-five percent of the participants experienced one or more practical problems with the use of their medicines: problems reading and understanding the instructions for use, handling the outer packaging, handling the immediate packaging, completing preparation before use, and taking the medicine. For 10 participants, at least one of their problems, in combination with the applied management strategy, had potential clinical consequences and 11 cases (5%

of the problems) had the potential to cause moderate or severe clinical deterioration.

CONCLUSION: Older people experience a number of practical problems using their medicines, and their strategies to manage these problems are sometimes suboptimal. These problems can lead to incorrect medication use with clinically relevant consequences. The findings pose a challenge for healthcare professionals, drug developers, and regulators to diminish these problems. *J Am Geriatr Soc* 62:2339–2344, 2014.

Key words: medicines; older people; adherence; medication use; qualitative research

The correct and timely use of medication determines its therapeutic effect, yet a number of steps are involved in taking medicines as recommended, such as reading and understanding the user information, opening and removing the medicine from the outer and inner packaging, any preparation before use, and taking the medicine. Physical constraints such as impaired vision, poor handgrip strength, loss of fine motor skills, and dysphagia can hamper these activities,^{1–5} and these constraints increase as people age.^{1–9} Strategies to manage these practical problems, or a lack thereof, could negatively affect the correct and timely use of medicines (e.g., when doses are omitted because assistance is needed to open a container).^{1,10}

Knowledge of the practical problems that older people experience with the use of their medicines and of strategies for addressing these problems is limited. Studies have investigated one or several specific problems with the use of medicines,^{3,4,6,11–14} but to the knowledge of the authors of the current study, no study has investigated the problems that could occur during the complete sequence of steps that individuals must undertake with the use of their own medicines. Furthermore, only a few studies have addressed the potential clinical consequences of practical problems using applied management strategies.^{1,15,16}

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This study aimed to identify the practical problems that older people experience with the daily use of their medicines and their management strategies to address these problems and to determine the potential clinical relevance thereof.

METHODS

Study Design and Setting

This was a qualitative study using semistructured interviews with older people. Participants were recruited from a community pharmacy and the geriatric outpatient ward of the University Medical Center Utrecht (UMCU), both in the Netherlands. Participants were eligible if they were community dwelling, aged 70 and older, and using at least three different oral prescription medicines daily. Individuals were excluded if a professional or family caregiver managed their medication entirely, or if the medication was delivered in multidose dispensing systems. Recruitment of participants continued until data saturation was achieved. Saturation was defined as the absence of new practical problems and management strategies in five consecutive interviews.

This study was not subject to the Medical Research Involving Human Subjects Act. The UPPER institutional review board reviewed the study, which was conducted in compliance with its requirements (<http://www.uu.nl/vkc/upper>).

Data Collection

Practical problems with medication use were defined as problems related to the presentation and formulation of a medicine and included labeling, information leaflet, material and type of outer and inner packaging, administration device, color, shape, size, taste, surface texture, and any break mark on a medicine.

Participants were interviewed at home. Before the start of the interview, participants were asked to collect all medicines, which were verified with the dispensing record that their community pharmacy provided with their consent. Field notes that the researchers made during the interview were verified with the participants at the end of the interview.

Data Management and Analysis

All interviews were recorded and transcribed verbatim. The transcripts were imported in ATLAS.ti (version 7.0; Scientific Software Development GmbH, Berlin, Germany). The combination of voice recording and field notes ensured the reliability and validity of the transcribed data. Two authors (KN, EB) coded independently. Disagreements in coding were discussed until consensus was reached. Another researcher (MLB, ACGE, or PAFJ) was consulted if consensus was not reached.

An expert panel (MLB, ACGE, PAFJ) independently classified the potential clinical relevance of every identified practical problem and associated management strategy on a 3-point scale.¹⁷ Class 1 relevance was defined as unlikely to cause discomfort or clinical deterioration, Class 2 as having the potential to cause moderate discomfort or clinical deterioration, and Class 3 as having the potential to

result in severe discomfort or clinical deterioration. Disagreements in classification were discussed within the expert panel until consensus was reached.

RESULTS

Fifty-nine people (mean age 78.4, range 70–92) participated in this study; 38 (64.4%) were women, and 30 (50.8%) were living alone. On average, participants used 6.9 prescribed oral medicines (range 3–12). Two hundred eleven problems were reported, ranging from no problems in three participants to 14 problems in one participant, and 184 management strategies were reported for these problems. Although 94.8% of the problems were unlikely to result in discomfort or clinical deterioration (Class 1), 5.2% (11 problems) were considered to have the potential to cause discomfort or clinical deterioration (Class 2 or 3). Table 1 shows the reported problems and management strategies. A taxonomy of the identified practical problems is presented in Figure 1.

Reading and Understanding Instructions for Use

Thirty-seven participants reported problems with reading and understanding the instructions for use. Twenty-two participants were worried about adverse events reported in the information leaflet; as a result, three reduced the dose or did not take the medicine at all. For one participant who regularly omitted doses of pantoprazole, this was considered to have the potential to cause discomfort or clinical deterioration because of the risk of gastric bleeding (Table 2).

I decided to restrict myself to one every 2 days. This is because I consider it harmful rubbish. You can expect all kinds of problems, and the side effects are gigantic. Maybe you think I shouldn't get upset about this, but I wish I hadn't read the instruction leaflet. (Male, 80 years, pantoprazole 20 mg)

Handling Outer Packaging

Nine of the problems with handling the outer packaging concerned opening. The use of scissors or a knife was reported to overcome this problem in five cases.

At a certain moment, the box became more difficult to open. Both ends were stuck down. This wasn't previously the case, so why are they stuck down now? Is this to make life more difficult? You just have to scratch it open with your fingernails. This is actually quite difficult. (Male, 71 years, atorvastatin 20 mg)

Difficulties with the identification of medicines were reported ($n = 3$). Two participants wrote the therapeutic indication on the carton to avoid confusing boxes that looked alike. Problems with the handling of the outer packaging were considered not to have clinical consequences.

Handling Immediate Packaging

Forty-three of the problems with the handling of the immediate packaging concerned the removal of medicines,

Table 1. Practical Problems and Related Management Strategies as Reported by 59 Participants

Practical Problem (n)	Management Strategy
Reading and understanding instructions for use (53 total reported by 37 participants)	
Text too small (12)	No solution or do not read package insert (regularly) (6), use magnifying glass (5), use extra light (1)
Information too difficult (5)	No solution or do not read package insert (regularly) (4), read information on packaging (1)
Information too extensive (12)	No solution or do not read package insert (regularly) (12)
Information on adverse events distressing (24)	Do not read package insert (regularly) (19), no solution (3), use no or lower dose (3)
Handling of outer packaging (19 total reported by 17 participants)	
Identification of product (3)	Write on packaging (2), no solution (1)
Opening packaging	
Box (6)	Other way of opening (3), use sharp equipment (3)
Wrapper around blister (3)	Use sharp equipment (2), no solution (1)
Removing blister from carton box (7)	Remove package insert (7)
Handling of immediate packaging (73 total reported by 38 participants)	
Separating individual units (sachets, vials, blister cups) (9)	Use sharp equipment (5), no solution (2), use nails (1)
Opening packaging	
For the first time (13)	Assistance (6), use sharp equipment (3), use auxiliary aid (2), no solution (2)
Every time (7)	Not closing properly (4), use other packaging (2), assistance (1), use sharp equipment (1), no solution (1), push or twist with palm of hand (1)
Removing medicine from	
Bottle (1)	Use other packaging (1)
Blister (42)	Use sharp equipment (8), no solution (6), use nails (1), change packaging (1)
Medicine dents, opens, breaks, or crumbles (15)	Take pieces (9), take another dose (2), use nails (2), no solution (1)
Tearline tears instead of blister opening (4)	No solution (4)
Pockets too small to push (7)	Use nails (to push on pocket or open lidding foil) (6), remove two tablets at once (1)
Pockets too large to localize product (1)	Using nails (1)
Closing packaging (1)	
Preparation before use (38 total reported by 23 participants)	
Identification of medicine (11)	Store separately from look-a-like medicine (5), writing on packaging (2), read embossment (1), no solution (1)
Holding medicine (12)	No solution (12)
Adjusting dose	
Tablet breaking (9)	
Difficult or painful (5)	No solution (3), assistance (1), using tablet splitter (1)
No equal halves or crumbles (4)	Take another (2), administration of pieces (1), use tablet splitter (1)
Measuring correct volume (1)	No solution (1)
Dissolution or disintegration of medicine (6)	No solution (6)
Drug taking (28 total reported by 17 participants)	
Medicine sticks in throat or mouth (17)	Take additional water or food (12), break tablet (2), no solution (2), take before other products (1)
Locating product in mouth (1)	No solution (1)
Unpleasant taste (10)	Take with food or additional water (5), take before other products (2), no solution (2), swallow tablet whole instead of chewing (1)

14 of which were related to tablets breaking or crumbling when removing them from a blister pack. Nine participants administered the resulting fractions. In three cases, the unintended breaking of a tablet was considered to have the potential to cause discomfort or clinical deterioration (Table 2). For example, one participant who used glyburide risked fluctuations in blood glucose by taking tablet parts instead of a whole tablet.

It often breaks when I'm pressing it out. I always have to look to see where the other half of the tablet is. I often find it lying somewhere else. I try to be careful when I am doing it so that it doesn't break in half, and sometimes it works, and sometimes it doesn't. I consume the tablet

parts as a whole, so to say. (Male, 71 years, glyburide 5 mg)

Other problems with the handling of the immediate packaging concerned difficulty with first-time opening of containers (n = 13) and with repeatedly opening the containers (n = 7). Reported ways to overcome these problems were to ask help of a partner or caregiver (n = 7) and to use a jar opener (n = 2) or a knife (n = 4).

Preparation Before Use

Thirty-eight participants reported problems when preparing their medicine. Eleven participants reported difficulties identifying medicines after removal of their packaging.

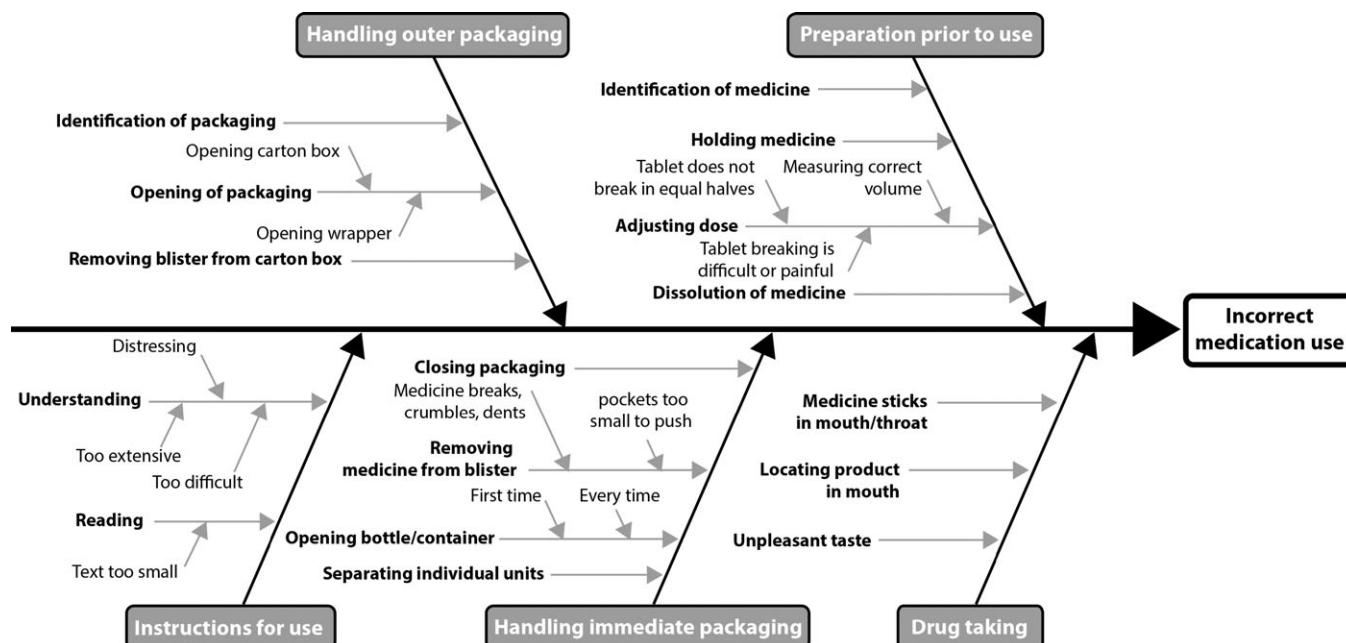


Figure 1. Ishikawa diagram outlining practical causes of incorrect medication use according to sequential step of the medication use process.

Table 2. Details of Cases with Class 2 or 3 Relevance

Practical Problem	Management Strategy	Case	Clinical Relevance ^a
Reading and understanding instructions for use			
Worried by side effects listed on the package insert (n = 1)	Took tablets every other day instead of once every day as prescribed	Pantoprazole 20 mg	Class 3
Handling immediate packaging			
Tablet breaks or crumbles when removed from blister (n = 3)	Took resulting pieces and crumbles	Enalapril 20 mg, furosemide 40 mg, glyburide 5 mg	Class 2
Preparation before use			
Difficulty with identification of medicine (n = 1)	No strategy reported	Pantoprazole 20 mg	Class 2
Difficulty filling measurement cup with correct volume (n = 1)	No strategy reported	Promethazine 1 mg/mL	Class 2
Difficulty with identification of different strengths (n = 1)	Wrote indication on packaging	Levodopa and benserazide: 200/50 and 100/25 mg	Class 3
Tablet does not break into equal halves or crumbles (n = 2)	Took unequal halves	Phenprocoumon 3 mg	Class 3
Drug taking			
Lodging of tablet in mouth or throat when swallowing (n = 1)	Swallowed tablet with additional water	Alendronic acid 70 mg	Class 2
Tablet has an unpleasant flavor (n = 1)	Swallowed with yogurt	Ferrous fumarate 200 mg	Class 3

^aPotential clinical relevance: Class 2: potential to result in moderate discomfort or clinical deterioration; Class 3: potential to result in severe discomfort or clinical deterioration.

One participant experienced difficulty distinguishing two different strengths of levodopa/benserazide tablets because of similarity in appearance. This was considered to have the potential to cause discomfort or clinical deterioration because accurate intake is important to control Parkinson's disease (Table 2).

So, if I have this [participant holds up the bottle of levodopa/benserazide], but then it is bigger than this I believe. I find it difficult to tell. When you put them next to each other, it's easier to see. I should have

been told this when I was given the instructions. So, at first I was taking them randomly because I couldn't see what I was doing. (Male, 74 years, levodopa/benserazide 100/25 mg and 200/50 mg)

Furthermore, breaking of tablets was reported as difficult or painful (n = 5) or as resulting in unequal parts or crumbles (n = 4). This was considered to have the potential to cause discomfort or clinical deterioration in one participant who was taking phenprocoumon because of the narrow therapeutic index (Table 2).

I have to take half a tablet. There is a nice groove. I have good fingernails that fit nicely into the groove. Nine times out of ten I break the tablet in two, and one-half is so big and the other half so big. So, not the same amount every day. (Male, 73 years, phenprocoumon 3 mg)

Drug Taking

Twenty-eight problems related to the taking of medicines were reported. One of these problems concerned lodging of the medicine in the mouth or throat ($n = 17$). For one participant, who used alendronic acid, this was considered to have the potential to cause discomfort or clinical deterioration due to the possible development of esophageal ulceration (Table 2).

It's just that I think the tablet is too big to swallow. I drink a lot of warm water. Then it doesn't get stuck. And you are not allowed to break the tablet, so I take it with a lot of water, warm or hot water. (Female, 83 years, alendronic acid 70 mg)

Problems with the flavor of medicines were reported ($n = 10$). One participant reported swallowing medicines with yogurt to mask the taste. One of these medicines was ferrous fumarate. This was considered to have the potential to cause discomfort or clinical deterioration by decreasing absorption of iron (Table 2):

I start in the morning with seven, and that is an awful lot. Because sometimes you really hate to chew on them. I say chew because they are quite difficult to consume properly. Nowadays I take those that don't go down so well with a little yogurt. I do this with the large one, but also with the small ones, because one of them is bitter. And this is usually quite unpleasant. (Female, 83 years, ferrous fumarate 200 mg)

DISCUSSION

Ninety-five percent of participants experienced one or more practical problems with using their oral prescription medicines. Most participants developed strategies to resolve the practical problems they experienced. Although several participants experienced the same problems, the potential clinical implications varied for each individual participant because they used different medicines and different strategies to resolve the problem. For 10 participants (17%), at least one of their problems was considered to have the potential to cause clinical deterioration, adding up to a total of 11 potentially clinically relevant situations. Ninety-five percent of the problems were considered not to be clinically meaningful, but even so they caused inconvenience and should be resolved. Moreover, if a person experiences problems with multiple medicines, the likelihood increases that these problems will adversely affect health.¹⁸ This is especially likely in frail, more physically restricted individuals with complex medication regimens. Furthermore, the problems found in this study were related to oral medication. People may also have problems administering nonoral dosage forms,

such as eye drops,^{19,20} sublingual sprays,¹³ and inhalers.¹⁰

STRENGTHS AND LIMITATIONS

This study evaluated the complete sequence of handling activities after dispensing. Through this approach, previously unreported practical problems were identified, such as difficulties opening the box; separating linked sachets, vials, or blister cups; holding medicines; and dissolving powders. The strategies participants used to manage these problems and the potential clinical consequences of these strategies were systematically investigated. Previous studies did not investigate participants' management strategies or focused on medication adherence without discussing clinical consequences.^{1,16,21}

There is the risk of reporting bias and recall bias. Also, rare practical problems might have been missed, but because participants were recruited from two settings, and the level of saturation was strict, the study gives a good overview of commonly experienced problems.

IMPLICATIONS FOR DRUG DEVELOPERS AND PRACTICE

To enhance the safety and efficacy of medicines for use in older people, the practical problems that older people may encounter with taking medicines should be taken into consideration during the development, evaluation, prescription, and dispensing of medicines. This is especially relevant for unforgiving medicines (medicines for which a dose other than the prescribed dose can have direct safety implications).²² The pharmaceutical industry can address the needs and concerns of older people during the development of medicines. Currently, information leaflets appear to miss their main aim—at least for older adults—of providing relevant information on the use of the medicine by containing too much, too difficult, and too distressing information. The design of medicine packaging needs to take into consideration the decreased handgrip strength and manual dexterity of older people. Developing tamper-evident and child-resistant closures that remain accessible for older people is a challenge. The usability of pill bottles and containers and of blister packs could be improved. Furthermore, the visual identification of medicines should be addressed during pharmaceutical development to decrease the possibility of people confusing medicines or different strengths. Preferably, medicines should be available in appropriate dosages so that the need for splitting pills is kept to a minimum. When splitting pills is unavoidable, it should be ensured that this results in equal parts in a sufficiently easy way. The ease of holding and swallowing the medicine should also be taken into account during development, because older people have poorer fine motor skills and experience swallowing difficulties more often than younger adults.²³

Thought should be given to addressing the suitability of medicines for use by older people during the evaluation of medicines by regulatory agencies. In addition to the industry and regulators, healthcare providers can address potential practical problems with medication use when prescribing and dispensing medicines to older people.

Because people rarely report practical problems spontaneously to physicians or pharmacists, pharmacists should proactively inquire about practical problems.²⁴ They can select a medicine with the most-appropriate presentation and formulation for the individual, such as a dosage that does not need to be divided, a form that causes fewer swallowing difficulties, or use of more user-friendly packaging.

CONCLUSIONS

Older people experience a broad range of practical problems with the use of their medicines. Incorrect medication use caused by these problems may have clinical consequences. All stakeholders concerned with the development, evaluation, prescription, and dispensing of medicines can and should help diminish the practical problems that older people experience.

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Author Contributions: All authors: study design, interpretation, critical revision, final approval. KN, EB: study conduct. KN, EB, CB, HL, MV: interviews. KN, EB: reading of transcripts, development of analytical framework, data analysis. MLB, ACGE, PAFJ: coding, determining clinical relevance of management strategies. KN, EB: writing manuscript. All authors are guarantors.

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REFERENCES

1. Kairuz T, Bye L, Birdsall R et al. Identifying compliance issues with prescription medicines among older people: A pilot study. *Drugs Aging* 2008;25:153–162.
2. Kelly J, D'Cruz G, Wright D. Patients with dysphagia: Experiences of taking medication. *J Adv Nurs* 2010;66:82–91.
3. Ruscini JM, Semla TP. Assessment of medication management skills in older outpatients. *Ann Pharmacother* 1996;30:1083–1088.
4. Nikolaus T, Kruse W, Bach M et al. Elderly patients' problems with medication. An in-hospital and follow-up study. *Eur J Clin Pharmacol* 1996;49:255–259.
5. Stegemann S, Ecker F, Maio M et al. Geriatric drug therapy: Neglecting the inevitable majority. *Ageing Res Rev* 2010;9:384–398.
6. Atkin PA, Finnegan TP, Ogle SJ et al. Functional ability of patients to manage medication packaging: A survey of geriatric inpatients. *Age Ageing* 1994;23:113–116.
7. Isaac LM, Tamblyn RM. Compliance and cognitive function: A methodological approach to measuring unintentional errors in medication compliance in the elderly. McGill-Calgary Drug Research Team. *Gerontologist* 1993;33:772–781.
8. Ostrom JR, Hammarlund ER, Christensen DB et al. Medication usage in an elderly population. *Med Care* 1985;23:157–164.
9. Tordoff JM, Bagge ML, Gray AR et al. Medicine-taking practices in community-dwelling people aged > or =75 years in New Zealand. *Age Ageing* 2010;39:574–580.
10. Thwaites JH. Practical aspects of drug treatment in elderly patients with mobility problems. *Drugs Aging* 1999;14:105–114.
11. Philbert D, Notenboom K, Bouvy ML et al. Problems experienced by older people when opening medicine packaging. *Int J Pharm Pract* 2014;22:200–204.
12. Barends DM, Groot DW, van der Steen JC et al. Results of a market surveillance study in the Netherlands on break-mark tablets. *Pharmeur Sci Notes* 2006;2006:1–7.
13. Tordoff J, Simonsen K, Thomson WM et al. "It's just routine". A qualitative study of medicine-taking amongst older people in New Zealand. *Pharm World Sci* 2010;32:154–161.
14. van Geffen EC, Meuwese E, Philbert D et al. Problems with medicine packages: Experiences reported to a Dutch medicine reporting system. *Ann Pharmacother* 2010;44:1104–1109.
15. Denneboom W, Dautzenberg MG, Grol R et al. User-related pharmaceutical care problems and factors affecting them: The importance of clinical relevance. *J Clin Pharm Ther* 2005;30:215–223.
16. Schiele JT, Quinzler R, Klimm HD et al. Difficulties swallowing solid oral dosage forms in a general practice population: Prevalence, causes, and relationship to dosage forms. *Eur J Clin Pharmacol* 2013;93:937–948.
17. Cornish PL, Knowles SR, Marchesano R et al. Unintended medication discrepancies at the time of hospital admission. *Arch Intern Med* 2005;165:424–429.
18. Evans DC, Cook CH, Christy JM et al. Comorbidity-polypharmacy scoring facilitates outcome prediction in older trauma patients. *J Am Geriatr Soc* 2012;60:1465–1470.
19. Blenkiron P. The elderly and their medication: Understanding and compliance in a family practice. *Postgrad Med J* 1996;72:671–676.
20. Dietlein TS, Jordan JF, Luke C et al. Self-application of single-use eyedrop containers in an elderly population: Comparisons with standard eyedrop bottle and with younger patients. *Acta Ophthalmol* 2008;86:856–859.
21. Orwig D, Brandt N, Gruber-Baldini AL. Medication management assessment for older adults in the community. *Gerontologist* 2006;46:661–668.
22. Urquhart J. Patient non-compliance with drug regimens: Measurement, clinical correlates, economic impact. *Eur Heart J* 1996;17(Suppl A):8–15.
23. Stegemann S. Challenges and opportunities in the design of age-appropriate drug products. *Z Gerontol Geriatr* 2012;45:479–484.
24. Philbert D, Notenboom K, Koster ES et al. Pharmacy technicians' attention to problems with opening medicine packaging. *J Pharm Technol* 2014;30:3–7.