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Learning from patients: Identifying design features of medicines that cause medication use problems

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ABSTRACT

Usability is a key factor in ensuring safe and efficacious use of medicines. However, several studies showed that people experience a variety of problems using their medicines. The purpose of this study was to identify design features of oral medicines that cause use problems among older patients in daily practice. A qualitative study with semi-structured interviews on the experiences of older people with the use of their medicines was performed (n = 59). Information on practical problems, strategies to overcome these problems and the medicines' design features that caused these problems were collected. The practical problems and management strategies were categorised into 'use difficulties' and 'use errors'. A total of 158 use problems were identified, of which 45 were categorized as use difficulties and 113 as use error. Design features that contributed the most to the occurrence of use difficulties were the dimensions and surface texture of the dosage form (29.6% and 18.5%, respectively). Design features that contributed the most to the occurrence of use errors were the push-through force of blisters (22.1%) and tamper evident packaging (12.1%). These findings will help developers of medicinal products to proactively address potential usability issues with their medicines.

1. Introduction

Medicinal products should be reliable and practicable to use by patients, regardless of age and physical ability. However, several studies showed that patients experience problems with the use of medicines, such as difficulties in opening packaging and accessing the contents, difficulties with the identification of medicines, difficulties breaking tablets for dosing purposes and difficulties swallowing medicines (Atkin et al., 1994; Beckman et al., 2005; Kelly et al., 2010; Marquis et al., 2013; Notenboom et al., 2014; Philbert et al., 2014; Schiele et al., 2013; Sormunen et al., 2014; Thwaites, 1999; Liu et al., 2016). The proportion of patients that experience problems using their medicines increases with advanced age due to decreased mental, sensory and physical abilities. A previous study showed that older people experience a broad range of practical problems with the use of their medicines and that incorrect medication use caused by these problems may have clinical consequences (Notenboom et al., 2014). The problems experienced by especially older users indicate that usability is insufficiently taken into consideration during the development of medicinal products. However, usability is a key factor in ensuring safe and efficacious use by patients.

Contrary to the situation for medicinal products, the evaluation of usability plays a crucial role in the development and design of medical devices. Errors caused by inadequate medical device usability and design shortcomings are a recognized cause for concern and have to be reduced as far as possible. This is usually covered as part of the risk management process that is applied during the entire life cycle of a medical device. During the design and manufacture of medical devices it is mandatory to reduce the risk of use error due to ergonomic features of the device, while considering the knowledge, experience, and training and where applicable the medical and physical conditions of intended users (European Commission, 2007). Processes like Human Factors Engineering (HFE) and risk management techniques such as Failure Mode and Effect Analysis (FMEA) are commonly employed to identify potential use errors, which can then be eliminated or

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reduced as far as possible by a policy of inherently safe design (European Committee for Electrotechnical Standardization, 2015; CEN/CENELEC, 2012). HFE examines how users interact with the device in order to improve human performance by designing devices that take account of the cognitive and physical capabilities and limitations of users. FMEA evaluates the risk of use errors and their potential effects. The results of the risk analysis highlight the shortcomings in the design. A detailed task-analysis of everything a user can do when interacting with a device can be helpful in these processes.

Similar approaches can be adopted during the development and design of medicinal products. Identification and awareness of the specific elements in medicinal product design that potentially hinder the proper use of medicines may contribute to reduce such problems. Experiences from daily practice with comparable products will help medicine developers to anticipate on potential usability issues during the development process of new products. The aim of the present qualitative study was to identify design features of medicinal products that cause use problems among older patients in daily practice.

2. Material and Methods

2.1. Study Design and Recruitment

A qualitative study with semi-structured interviews on practical problems that elderly people experience with the use of their medicines was performed (Notenboom et al., 2014). The participants were recruited from a community pharmacy belonging to the Utrecht Pharmacy Practice Network for Education and Research (Koster et al., 2014) as well as from 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 years or older and used at least three different oral prescription medicines daily. Individuals were excluded if their medication was entirely managed by professional help or by the participant's carer, or if the medication was delivered in multi-compartment pill boxes or in other multi-dose dispensing systems. Eligible people were approached by their community pharmacist or geriatrician. Recruitment of participants continued until data saturation was achieved. This was achieved when no new problems and solutions emerged in five consecutive interviews.

This study was not subject to the Medical Research Involving Human Subjects Act (WMO). The study was conducted in compliance with the requirements of the UPPER institutional review board (http://www.uu.nl/vkc/upper). For this type of study, informed consent is not required in the Netherlands.

2.2. Data Collection

The experiences of older patients with the use of their oral medicines were collected through semi-structured face-to-face interviews. The interviews were guided by a flexible topic list based on problems with medication use reported in the literature. This included any practical problems with the use of their medicines and their strategies to overcome these problems (Notenboom et al., 2014). The topic list ensured that all key aspects of the medication use process were covered. Posing open, direct questions allowed to elicit detailed narratives and stories of the participants' experiences with the use of their medicines.

Before the start of the interview, participants were asked to collect all their medicines; these were verified with the dispensing record provided by their community pharmacy. During the interview, the marketing authorisation number and specific design features of the medicines that were related to the use problems were collected. This comprised the design features of the dosage form, the packaging and any dosing device, e.g. the type of dosage form, the colour, shape, size, palatability, presence of coating and break mark on a medicine, type and characteristics of the outer and immediate packaging, and, if applicable, the type of dosing device and its characteristics.

2.3. Data Processing and Analysis

The audio recordings of the interviews were transcribed verbatim and anonymised. The transcripts were imported in ATLAS.ti software for coding and analysis (version 7.0, Scientific Software Development GmbH, Berlin, Germany). Reliability and validity of the transcribed data were ensured by the combination of voicerecording, field notes and photographs. The transcripts were used to explore the problems with the use of medicines. The practical problems, coping strategies and design features of the medicines were coded in the transcripts (Notenboom et al., 2014).

Next, the practical problems and their coping strategies were categorised into 'use difficulties' and 'use errors' by two researchers independently (KN and MB):

- A 'use difficulty' includes the situation were a participant experiences difficulty performing a task but is able to complete the task without help or coping strategy. An example of a use difficulty is a patient having difficulty removing a cap from a container but after some time of trying, he or she finally succeeds.
- A 'use error' includes the situation were a participant is unable to perform a task as intended and either needs help or applies a strategy to complete the task. Examples of use errors are a patient who is not able to remove a cap from a medicine container by his- or herself and therefore asks another individual to remove the cap, or a patient who needs to use a knife to open the tamper evident feature on the cap of the container.

This approach was derived from international standards for medical devices (European Committee for Electrotechnical Standardization, 2015; CEN/CENELEC, 2012).

The two researchers discussed any disagreements until consensus was reached. The consistent categorisation into use difficulties and use errors was achieved by 'constant comparison'.

To prioritize the few most important design features with the greatest cumulative contribution to the occurrence of medication use problems, the design features related to the use difficulties and use errors were plotted in decreasing order of relative frequency.

3. Results

Fifty-nine people participated in this study. Their median age was 78.0 years (SD 6.2; range 70–92), and 38 were women (64.4%). On average, participants used 6.9 oral prescription medicines daily (SD 2.2; range 3–12) at the time of the interview. Six of the 59 patients (10.2%) experienced no problems with the use of their medicines. A total of 158 use problems were identified, of which 45 were categorized as use difficulties and 113 as use errors. The identified use difficulties and use errors along with the related design shortcomings for the tasks and subtasks of the medication use process are listed in Table 1. Most use difficulties concerned swallowing of medicines (37.8%), followed by the removal of medicines from a blister (13.3%). Most use errors concerned the removal of medicines from a blister (31.9%), followed by the opening of containers (15.9%).

Table 1
Use difficulties (UD) and use errors (UE), and related design shortcomings of the packaging (A) and dosage form (B).

A. Design shortcomings of packaging	UD (n)	UE (n)	Problems experienced with packaging
• **Appearance of packaging**			
The appearance of the outer pack is insufficiently distinct from other products		3	The patient mixed-up look-a-like packaging
• **Tamper evident closures**			
Perforated opening of tamper evident closure on the carton is poorly visible		3	The patient used sharp kitchenware to open the glued flaps
		3	The patient damaged the carton to open the glued flaps
The tamper evident closure of the container is too difficult to open	2		The patient has difficulty opening the tamper-evident closure but succeeds
		6	The patient cannot open the tamper-evident closure
		5	The patient used (sharp) kitchenware to open the tamper-evident closure
• **Child-resistant closures**			
The child resistant closure of the container is too difficult to open	2		The patient has difficulty with the opening of the child resistant closure but succeeds
		1	The patient cannot open the child resistant closure
		2	The patient has difficulty with the opening of the child resistant closure (with desiccant inside) and therefore leaves cap not properly closed
		3	The patient has difficulty with the opening of the child resistant closure (with desiccant inside) and therefore transfers the contents to another container
• **Regular closure system**			
The closure system is too difficult to open		1	The patient used sharp kitchenware to open the container and then leaves cap not properly closed
The cap of the container breaks tablets when fully packed.		1	The patient removes the harmonica plug on the inside of the cap because it crushes/breaks the tablets
• **Container**			
The opening of the container is too small		1	The patient has difficulty removing tablets from the container and transferred them to another container
• **Tearlines**			
The tear line of wrapper is too difficult to use	1		The patient has difficulty opening the wrapper but succeeds
		2	The patient used sharp kitchenware to open wrapper
Tearline on blister is too difficult to use		2	Patient uses sharp kitchenware to separate units because the tearline cannot be teared
No tearline on blister		1	Patient uses sharp kitchenware to separate units because there is no tearline
A label is placed on the tearline between sachets		1	Sachet opens following separation
Tearline between sachets is too difficult to use	2		The patient has difficulty separating sachets but succeeds
		2	The patient uses sharp kitchenware to separate sachets to avoid leaking
Tearline between plastic ampoules too difficult to use		1	More than one ampoule opens
• **Push-through force of blister**			
The push-through force of the blister is too high	4		The patient has difficulty pushing the tablet out but succeeds
		3	The capsule opens/dents while pushing it out.
		4	The patient has difficulty pushing the tablet out but succeeds although also the tearline tears
		6	The patient has difficulty pushing the tablet out but succeeds by using sharp kitchenware to pierce the lidding foil
		5	The patient has difficulty pushing the tablet out but succeeds by using his nails to pierce the lidding foil. Nails regularly get chopped of by doing this.
		1	The patient has difficulty pushing the tablet out and therefore transfers all tablets to a container
• **Push-through force of blister & tablet hardness**			
The push-through force of the blister is too high and/or tablet hardness is insufficient		2	The unscored tablet breaks/crumbles while pushing it out, the patients administers the resulting pieces
		1	The dispersible tablet breaks/crumbles while pushing it out
• **Push-through force of blister & tablet hardness & presence of score line**			
The push-through force of the blister is too high, presence of break mark and/or tablet hardness is insufficient		9	The scored tablet breaks/crumbles while pushing it out, the patients administers the resulting pieces or takes another dosage
• **Size of blister pockets**			
Size of the blister pockets is too small and/or distance between pockets is too small		2	The patient has difficulty placing his finger on one pocket but succeeds by pushing it with two nails. Nails regularly get chopped of by doing this.
		1	The patient has difficulty placing his finger on one pocket and removes two tablets at once
		1	The patient uses sharp kitchenware to separate pockets
Size ratio between blister pocket and tablet is too large	1		The patient experiences difficulty locating the tablet in the pockets but succeeds
	1		The pocket collapses when it is pushed but tablet comes out.
		1	The pocket collapses when it is pushed but no tablet comes out. Patient uses sharp kitchenware to cut the lidding foil
• **Pack volume**			
	7		The patient discarded the package insert

Table 1 (*Continued*)

B. Design shortcomings of the dosage form	UD (n)	UE (n)	Problems experienced with the dosage form
• **Appearance of the dosage form**			
The appearance of the dosage form is insufficiently distinct from other products		7	The patient has difficulty differentiating tablets
	1		The patient has difficulty differentiating tablets but succeeds by differences in embossment
	2		The patient has difficulty differentiating tablets but succeeds by keeping them in the blister and placing marks on the blister.
Dose marking is insufficiently visible	1		The patient has difficulty reading the dose marking on the measuring cup but succeeds
• **Dimensions of the dosage form**			
The dimensions of the dosage form are too small	4		The patient has difficulty holding the tablet but succeeds.
		7	The patient has difficulty holding the tablet. They often drop on the floor. The patient picks it up and takes it or takes another one.
	1		The patient has difficulty holding the tablet but succeeds by wetting a finger and attach tablet to it.
	1		The patient has difficulty locating the product in mouth which makes swallowing difficult but succeeds
• **Dimensions & surface characteristics of the dosage form**			
The dimensions of the dosage form are too large and/or the surface of the dosage form is inconvenient	10		The patient has difficulty swallowing because the medicine becomes stuck in the mouth/throat but succeeds; without solution, by taking this medicine before others or by taking additional water
		6	The patient has difficulty swallowing because the medicine becomes stuck in the mouth/throat but succeeds by taking it with semi-solid food
• **Tablet hardness & push-through force of blister**			
The push-through force of the blister is too high and/or tablet hardness is insufficient		2	The unscored tablet breaks/crumbles while pushing it out, the patients administers the resulting pieces
		1	The dispersible tablet breaks/crumbles while pushing it out
• **Tablet hardness & presence of score line & & push-through force of blister**			
The push-through force of the blister is too high, presence of break mark and/or tablet hardness is insufficient		9	The scored tablet breaks/crumbles while pushing it out, the patients administers the resulting pieces or takes another dosage
• **Break marks**			
Break mark does not function well	1		The patient has difficulty breaking scored tablets for ease of swallowing but succeeds
	2		The patient has difficulty breaking scored tablets for dosing purposes but succeeds
		1	The patient is not able to break the tablet for dosing purposes but succeeds by using tablet splitter
		2	The tablet does not break in equal halves or crumbles when breaking for dosing purposes. Patient takes another tablet
		1	The tablet does not break in equal halves when breaking for dosing purposes. Patient takes unequal parts anyway
		1	The tablet does not break in equal halves when breaking for dosing purposes. Patient uses tablet splitter
• **Taste of the dosage form**			
The dosage form has an unpleasant taste	6		The patient has difficulty swallowing because the medicine has an unpleasant flavor but succeeds; without solution, by taking this medicine before others or by taking additional water
		3	The patient has difficulty swallowing because the medicine has an unpleasant flavor but succeeds by taking it with semi-solid food
		1	The patient has difficulty taking the suspended dispersible tablet because it has an unpleasant flavor. The tablet is swallowed whole.
• **Complexity of the dosage form**			
User does not understand how to use the pharmaceutical form		1	The patients swallows the dispersible tablet as a whole because it does not dissolve completely
	3		The dispersible tablet does not dissolve completely. The patient either leaves the residue or adds extra water to administer residue
		1	The patient uses a spoon to crush particles because dispersible tablet does not dissolve completely
		1	The patient uses boiled water to dissolve dispersible tablets because otherwise it does not dissolve completely

The design features that attributed to the use problems were plotted as presented in Fig. 1(a) and (b) for use difficulties and use errors, respectively. The charts illustrate that the design features that contributed the most to the occurrence of use difficulties were the dimensions of the dosage form (29.6%) and the surface texture of the dosage form (18.5%). With regard to the occurrence of use errors, the design features that contributed the most were the push-through force of blisters (22.1%) and tamper evident features (12.1%). The use problems are described in more detail below, along with representative interview quotes. As the interviews were conducted in Dutch, the quotes are translated from Dutch to English.

3.1. Use problems related to the push-through force of blisters

There were 35 reports of problems with the extraction of medicines from blister packaging caused by a too high push-through force:

"Then, on the back, I move the potato knife along one side. And when I press a little, I can get it out." (Woman, 83 years, example of a use error)

"This costs a little bit of effort though. There are three that I find a little bit difficult. To me. Have a look. I can still do it. Don't give up. And when it doesn't work out with this one, I try another one and

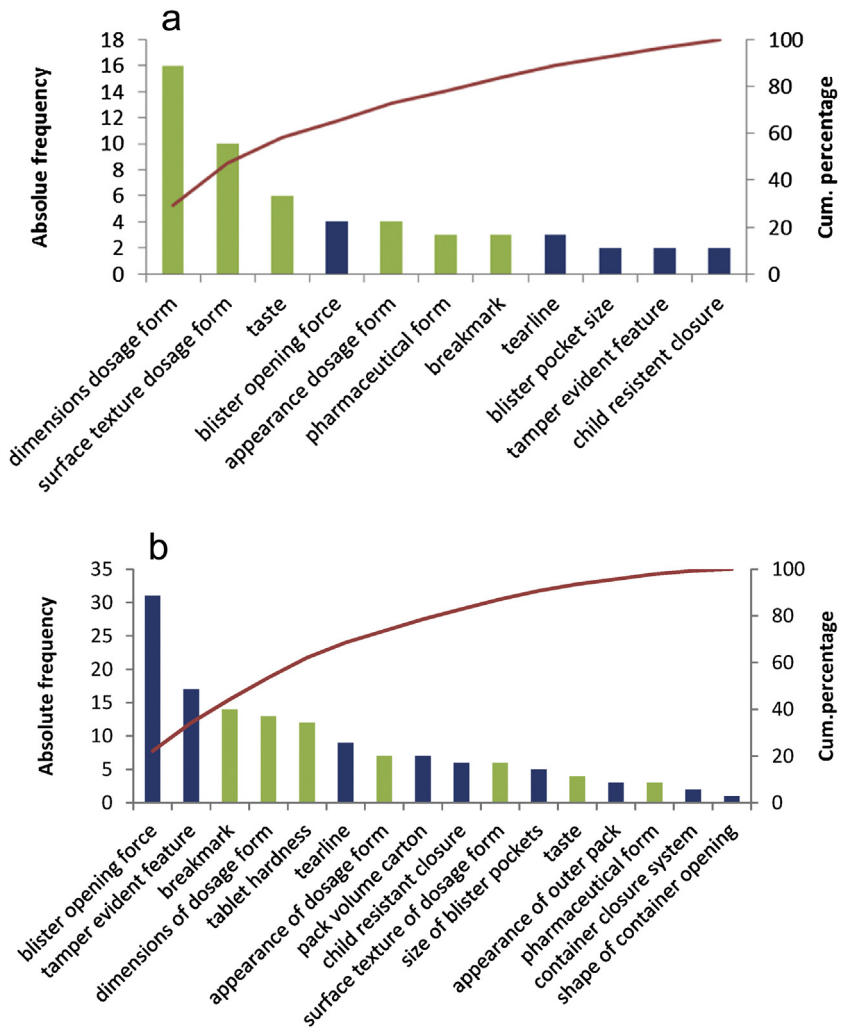

Fig. 1. Pareto charts representing the design features that attributed to use difficulties (a) and use errors (b). The green bars represent design features that are related to the dosage form, the blue bars represent design features related to packaging. (a) Design features that attributed to use difficulties in decreasing order of relative frequency. (b) Design features that attributed to use errors in decreasing order of relative frequency.(For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

get back to this one thereafter."(Woman, 86 years, example of a use difficulty)

In 15 cases the extraction resulted in damage to the dosage form, i.e. breaking or crumbling of tablets (n = 12) and denting or opening of capsules (n = 3). Nine of these twelve tablets concerned a tablet with a score line:

"This one often breaks. When I push it out. Look, because it has a line. A score line. And that one snaps almost every time. I always have to look, to see where the other halve went. That is unwieldy. Very often it lies somewhere else." (Man, 71 years, example of a use error)

3.2. Use problems related to tamper evident closures

Tamper evident closures caused problems with the opening of containers (n = 13) and cartons (n = 6). The containers were equipped with plastic, so-called breakable or tear-away closures that have a portion that breaks on opening:

"Look, it has a band. And you have to pull it open, which costs a huge effort. I also have to turn this and I am not able to do this. So, my cleaning lady comes every Wednesday, and then I ask her in case a bottle needs to be opened. I think these are worthless bottles." (Woman, 86 years, example of a use error)

The cartons were closed with glue. Perforations were applied to facilitate opening, however, these openings were not visible to the participants:

"I use a scissor, there is no other way to open it (interviewer points out the perforation line on the carton). *I can't see that. I can barely see it while I wear my glasses! It is a good thing I know now." (Woman, 83 years, example of a use error)*

Use difficulties and errors associated with break marks on tablets were associated with difficulty of breaking, breaking into unequal portions or crumbles, and with unintended breaking when the tablet is extracted from the blister.

3.3. Use problems related to the dimensions of a dosage form

Use difficulties and errors associated with the dimensions of a dosage form included problems holding a medicine and problems swallowing in which the medicine became stuck in the throat. Use difficulties and errors associated with the surface texture of a dosage form concerned problems swallowing in which the

medicine became stuck in the throat. Participants explained the lodging of the dosage forms by a large size and quick disintegration of the product:

"These are large. I have difficulties with it. It is a problem. I am afraid, just before I take it, that I can't swallow it. It is a little bit of fear too, I guess. I just give it a try. I gargle a little and so, awful. Suddenly, I swallow. It is something of which I always think: yech, I have to. The other ones go down easily, but this one not." (Woman, 72 years, example of a use difficulty)

"Look, these, I always take them with water, but sometimes they get stuck, you know. They are a little brittle and get stuck half way. Then I have to take a large sip of water again. Thus, I can't swallow it easily. I have no difficulties with the other ones, but these things appear to be less solid, they quickly start melting, you know, and it gets stuck and I need to drink a good amount of water otherwise it remains stuck. Then, it goes well." (Man, 72 years, example of a use difficulty),

Further analysis of these design features showed that most of the problems in which the medicine became stuck in the mouth or throat (n = 16) occurred with uncoated tablets (n = 11), of which nine tablets had a diameter ranging between 0.5–1.0 cm. The same problem concerned three coated tablets, of which two tablets had a diameter of more than 1.5 cm and one tablet a diameter between 0.5–1.0 cm. The problem was also reported for two capsules, both with a size larger than 1.5 cm.

4. Discussion

This study identified the specific design features of medicinal products that are associated with medication use problems among older people. Physical constraints, such as impaired vision, reduced manual dexterity or strength, and loss of touch and sensitivity in the hands can interfere with the user's ability to interact with the product and cause use problems. The design features that contributed the most to the occurrence of use errors were the push-through force of blisters and the opening of tamper evident closures. The results provide evidence that optimizing the design of medicinal products will mitigate the risk of medication use problems.

4.1. Strengths and Limitations

Although previous studies reported many problems with the use of medicines, an investigation of the design features of medicines that contribute to the occurrence of use problems had yet to be made. The collection of information reported by participants introduced the risk of reporting bias and recall bias. Therefore, all medicines used by the participants were present during the interview. This helped the participants to bring up any problems as well as to demonstrate the experienced problems. In addition, it allowed the interviewer to notice any unreported problems, e.g. torn cartons or the presence of a potato knife among the medicines. This direct way of observation has high validity in unraveling what really happens during the daily use of the medicines.

Only problems with the use of oral medicines were investigated. Other administration routes, e.g. by inhalation or injection, are often more complex and introduce more opportunities for patients to encounter use problems. Furthermore, patients are not the only users of medicines. Several products are administered to patients by health care providers, such as parenteral injections or infusions.

4.2. Implications for Practice

The occurrence of medication use problems has not gone unnoticed. Regulators recently stressed the impact of product design on medication use. Both the European Medicines Agency's (EMA) and the Food and Drug Administration (FDA) published guidance documents on minimizing the risk of medication errors related to product design. These guidances advocate that medicine developers proactively consider all aspects of the design of the product, and conduct a suitable analysis to identify and assess potential for medication errors (CHMP, 2015; CDER, 2016). Medication errors are commensurable to use errors with medical devices. Like use errors with medical devices, medication errors can be attributable to product design. For both medical devices and medicinal products, use errors can cause a hazardous situation, however, they do not always cause a hazardous situation or lead to harm. A use error may cause harm in one situation but not in another, e.g. a tablet that breaks in pieces following extraction from the blister will not cause a problem when it concerns an antacid, while the same issue with tablet breaking will cause a problem when it concerns a product with a small therapeutic window. Use difficulties, i.e. the situation where a patient is able to perform a task but only with difficulty, are quite often overlooked. However, convenience issues are critical for therapeutic outcomes if it causes non-adherence. Moreover, use difficulties can turn into use errors at a certain moment. Many of the use errors identified in the current study concerned use difficulties for which the participants applied a strategy to overcome the difficulty. These strategies may result in a hazardous situation or cause harm to the patient because the product is not used as intended. Hazardous situations do not always have to be related to the use of the medicinal product itself. The use of sharp kitchenware such as knives can also cause harm to the patient.

The FDA and EMA guidance provide examples of medication errors and of design features which may reduce the risk of medication errors. Little attention is given to the usability of packaging though. This study shows that blister lidding foils and tamper verification features on packaging largely contribute to the occurrence of use errors among older people. The errors associated with tamper evident packaging, such as folding boxes closed with glue and containers equipped with plastic tear-away closures, are particularly challenging. With publishing of the Commission Delegated Regulation (EU) 2016/161, that supplements Directive 2001/83/EC, with detailed rules for the safety features appearing on the packaging of medicinal products for human use, pharmaceutical companies are required to fulfil the requirements of the Falsified Medicines Directive by 9 February 2019 (European Commission, 2015). This implies that by then all pharmaceutical packaging available in Europe needs to be equipped with an anti-tampering device, i.e. a device that reveals irreversibly whether the container has been opened (European Commission, 2015; European Commission, 2011). Consequently, the prevalence of problems with the accessibility of pharmaceutical packaging will increase. In the current study, participants reported they could not see the perforation line to facilitate the opening of the cartons closed with glue or they were not able to break the plastic tear-away closure. Making perforation lines more clearly visible and tear-away closures easier to break will improve the usability of tamper-proof packaging among those suffering from impaired visual acuity or reduced manual strength.

Problems with pushing medicines out through the blister lidding foil could be overcome by peel-off blisters, however usability problems have been reported for these foils too (Philbert et al., 2014; Muhlfeld et al., 2012). Problems with the opening of blister packages were not only caused by a high push-through force, but also with a small size of the pockets or small distance between the pockets and with too much movability of the medicine in the pocket. A recent study confirmed the relevance of a good fit of the dosage form in the blister pocket, i.e. allowing palpability and limited movability of the dosage form

(Braun-Munker and Ecker, 2016). The use errors identified in the current study that were associated with child resistant closures indicate that the use of child resistant closures with integrated desiccant needs to be reconsidered, especially when used among an older population. A difficult-to-open-cap that at the same time has the critical function to protect the medicines inside the container from degradation by moisture appears to be an inappropriate design choice. Patients may not close the container or transfer the contents to other packaging.

5. Conclusion

Use difficulties and errors encountered by people with the daily use of their medicines result from the interaction between the user and the medicinal product. Medicinal products should be designed to meet the needs, capabilities, and limitations of the patients for who they are intended, taking into account for example age and physical ability. Patient-centred design of medicinal products will enable patients to use their medicines safely and easily. As for medical devices, areas for design improvement can be identified through human factor and/or usability engineering. This study identified design features of oral medicinal products that contribute to the occurrence of use problems among an older population. These findings will help developers of medicinal products to proactively address potential usability issues with their medicines.

Disclaimer

The views expressed in this article are the personal views of the authors and may not be understood or quoted as being made on behalf of or reflecting the position of the Medicines Evaluation Board.

Contributors

All authors contributed in the design of this study. KN and MB categorized that data. KN wrote the manuscript. All authors contributed to the interpretation of the analysis, critically revised the manuscript and approved the final manuscript.

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