International Journal of Pharmaceutics 517 (2017) 128–134

Contents lists available at ScienceDirect

International Journal of Pharmaceutics

journal homepage: www.elsevier.com/locate/ijpharm

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

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ARTICLE INFO

Article history:
Received 8 September 2016
Received in revised form 1 December 2016
Accepted 2 December 2016
Available online 5 December 2016

Keywords:
Medication use
Usability
Use errors
Medicinal product design
Packaging
Older patients

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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http://dx.doi.org/10.1016/j.ijpharm.2016.12.004

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%).