How Do Patient Information Leaflets Aid Medicine Usage? A Proposal for Assessing Usability of Medicine Inserts

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Abstract. This Patient information leaflet – PIL provides support to medicine usage. However, there is a lack of empirical evidence on the usability of PILs since most research has focused on their readability and legibility, and legal regulations worldwide have neglected their usability aspects. Considering the importance of this matter, a proposal for assessing PILs' usability is presented here, consisting of three phases: (1) task analysis diagram flow, (2) interaction test, and (3) follow-up interview, and the outputs are analyzed in a qualitative manner. To validate the usability assessment proposed, a study was conducted in Brazil with 60 participants on using medicines differing in their pharmaceutical presentation, based upon the instructions in their PILs. The results showed a direct relation between task complexity-errors; and the decision points-actions/steps. The usability assessment aids in identifying drawbacks in the PILs design and information flow, thus, providing support to improvements towards their effectiveness in medicine usage.

Keywords: patient information leaflets, usability, assessment.

1 Introduction

Several studies have been conducted on patient information leaflets – PILs. Most of them looked at text related aspects, such as readability, legibility and typographic structure [1], [2], [3], [4], [5] and some also investigated pictorial aspects of PILs, as for instance the graphic presentation of visual instructions [6]. Despite their contributions to the communication success of PILs, the majority of these studies has not provided empirical evidence of their effectiveness on medicines usage, that is, how graphic and typographic aspects of PILs may affect the task of using/taking a medicine by a person. In this regard, research with person-centered approach might provide methods and tools to measure usability of PILs.

The concern on effectiveness communication of PILs has been driven regulations in the European Union – EU since 2005, when readability tests of PILs have been required from pharmaceutical companies to have their medicines approved. However, the EU readability tests for PILs may present limitations in assessing their communicational

A. Marcus (Ed.): DUXU 2014, Part III, LNCS 8519, pp. 115–124, 2014.

effectiveness from information design viewpoint. The tests restrict the scope of medicine usage to text comprehension, overlooking task performance and context of medicine use (from prescription to usage). Thus, regardless the contribution of readability tests to message communication, they do not actually prove PILs' efficiency in medicine usage, but how information is understood, and searched/found by medicine users [7] [8]. In this respect, it is interesting to mention a study conducted by Raynor, Knapp, Moody and Young [9] in the same year EU approved their regulation for testing PILs. The authors investigated PILs and the impact of European regulations on the use of medicine, and found that PILs were not read or noticed y several patients, and did not meet their information needs. This ratifies the importance of having PILs tested in their usability to minimally ensure their effectiveness, or at least that they would meet patients' expectations to be noticed by them. In this sense, Waarde and Spinillo [10] when discussing the development of visual information about medicines, claim that the production of PILs should follow a 'writing-designing-testing-process' and embrace all stakeholders. Moreover, they assert that legislation and guidance to develop PILs should be performance based, that is, should be based upon PILs' usability to medicine usage.

However, testing PILs is not a worldwide concern, even when limited to their readability. Countries in Latin America, Africa, Asia and still some in Europe do not require PILs testing in their regulations. Thus, the pharmaceutical companies have been marketing their medicines in those countries with no evidence on their PILs' effectiveness. The effects of lack of comprehension of information on medicine use have been observed in data on hospitalization and even death of patients reported by the press and health authorities worldwide. Taking the wrong dosage or an overdose of a medicine, adverse reactions, and taking medicines that are not suitable for use due to inappropriate storage are examples of problems that can be caused by information draw-backs in PILs. In USA, for instance, a report showed an increase of 65% in the number of hospitalizations from 1999 to 2006 as a result of medication overdose regarding pain-relief medicines, tranquilizers and sedatives [11]. As some of them are over-the-counter medicines, i.e., can be purchased without medical prescription, their PILs are the main source of information on the medicine usage. Similarly, a study conducted in Brazil by Aquino [12] reported that one third of hospitalizations were caused by misuse of medication. The impact of medication misuse on the population health safety has pushed governments to take preventive, educational and legal measures. However, medicine regulations still neglect the relevance of verifying to what extent PILs support medicine usage, as previously mentioned.

2 A Proposal for Assessing Usability of PILs

According to Rubin and Chisnell [13] usability regards how usable a product or a service is. In addition, they claim that to be so, a product or service should be useful, efficient, effective, satisfying, learnable and accessible to its users. Thus, usability regards actual interaction between an artifact and a person, and involves tasks to be performed. In general, the concept of usability is applied to product ergonomics and digital systems, within the scope of HCI – Human-Computer-Interaction. In this re-

spect, several techniques and methods have been used by researchers and developers of products and digital systems to assess usability. Since the nineties publications have been issued on this matter, as for instance Nielsen's paper [14] presenting a list of techniques to verify usability of interfaces, followed by Dumas and Redish' book [15] presenting a guide for usability testing. However, there seems to be a lack in the literature on usability for printed artifacts. Despite the relevance of this topic, most research looks at legibility and comprehension aspects, thus, ignoring how usable printed artifacts actually are for their users. This is particularly pertinent when regards health related printed artifacts, such as PILs.

From a usability perspective, PIL is not only a pharmaceutical source for health treatment, but also an instructional document that provides patients with information on how to interact with a product (medicine). Accordingly, medicine insert is an information design artifact that mediates patient/user + medicine interaction during task performance. Thus, it empowers patients in the decision making process on health treatment. In this sense, identifying the tasks/aspects involved in a medicine usage is of prime importance to verify usability of PILs. Considering this, together with patient/user information needs to support task performance, a proposal for assessing usability of PILs is presented next, consisting of three main consecutive phases: (1) task analysis flow diagram, (2) interaction test, and (3) follow-up interview. The PIL tested can be either an existing one or a mockup of a PIL to be produced. The former is found inserted in actual medicine packages and its usability assessment would serve to produce data for academic/professional/governmental reports. This allows guidance for future improvements on the design of existing PILs, whether for the latter, the usability assessment is conducted within the PIL design process, therefore leading to improvements prior its production.

2.1 Phase 1: Task Analysis Diagram

Initially, a decision/action flow diagram is drawn to identify the actions to be taken by patients/users during task performance, decision points and conditional situations to take/use a medicine according to the information provided in the PIL. The diagram will aid researchers to be aware of possible difficulties in task performance (e.g., measuring dosage) and/or to decide on the questions to be made in the interview (e.g. how to measure dosage). This diagram is based upon Moraes and Mont'Alvão's [16], however adapted to include conditional situations that may be necessary to take/use medicines.

2.2 Phase 2: User + PIL + Medicine Interaction Test

Based upon the task analysis diagram, an interaction test is then conducted in a simulated manner to avoid risks to participants (e.g. using a syringe in a sponge). The number of participants and their characteristics are defined according to the medicine users' profile. The material for testing consists of: an actual PIL or a PIL mockup, the medicine and other material that may be necessary (e.g., sponge for simulated use of syringe). The interaction test is conducted with each participant individually and

isolation. The PIL (existing or mockup) is presented to the participant, who is asked to follow the instructions provided in the PIL to use/take the medicine and to verbalize his/her actions. Participants are informed that they may consult the PIL during task performance whenever they find necessary. The data is recorded through video and audio, but written notes on task observation may be used in case participants feel comfortable with the presence of the researcher in the testing room, or if special glass room is available for this purposed. Time restriction is not posed to participants as it may be a variable to be measured. The interaction test will be over when participants consider that they finished the task, or decide to give the task up. Then, participants will be asked to engage in an interview about the task.

2.3 Phase 3: Follow-up Interview

After the interaction test, a semi-structure interview is conducted with each participant to get their reactions to the task performed, to the PIL tested, their satisfaction with User + PIL + medicine interaction, and their suggestions to improvements. A protocol with questions on these aspects is produced to guide the interviewer and to allow written notes, if necessary. The data recorded in video from the PIL's interaction testing can be used to aid in the interviewing process regarding questions on task performance (e.g., elucidate doubts, identify errors). Video and/or audio recording can be used to register participants' responses. The following table summarizes the proposed sequence of phases to assess usability of PILs. The columns present the phases and their aims; and the material employed.

Table 1. Summary of proposed sequence of phases to assess usability of PILs

Phase	Aims	Material
1. Task analysis diagram	Identify medicine usage according to PIL's information. Foreseen possible difficulties and errors in task performance.	Printed or digital support for drawing the diagram
2. User + PIL + medicine interaction test	Identify difficulties, drawbacks and errors in task performance. Identify possible weaknesses and/or omission of information in PILs when supporting task performance.	PIL Medicine (and related material)
3. Follow-up interview	Identify participants' views on/reactions to their task performance. Gather participants' suggestions to improve PILs.	Protocol with questions Video images from the interaction test

2.4 Analyzing the Data

To a proper understanding of the outcomes from the PIL usability assessment, it is necessary to discuss data in a deeper manner. Thus, qualitative analysis seems to be appropriate. In this sense, for the PIL interaction test, a human error classification for the participants' performance is proposed, considering: (1) information processing errors, (2) action errors, and (3) verification errors (regards particularities of the tasks such as dosage mistake). This classification is based on Barber and Stanton [17]; and Rasmussen [18] taxonomies for human errors, which was adapted for medicine usage mediated by PILs (Table 2).

Table 2. Classification for human errors proposed

1 – Information processing errors
Internal (individual repertoire)
Pi 1| Wrong/Mistaken assumption
External (insert/package/product)
Pi 2| Information was not read/searched
Pi 3| Information was incompletely read/searched
Pi 4| Wrong information searched
Pi 5| Information was searched but not found
Pi 6| Information was searched and founded but not understood
2 – Action errors
A 1|Task/action was not performed
A 2| Task/action was incompletely performed
A 3| Task/action was performed in wrong/inappropriate moment
A 4| Very long or very short Task/action
A 5| Task/action performed in a very little or very large amount/quantity
A 6| Task/action in wrong direction
A 7| Wrong alignment
A 8| Right task/action in wrong/mistaken object
A 9| Right task/action but in a wrong part/component of a right object
A 10| Wrong task/action in a right object
A 11| Wrong task/action in a wrong object
A 12| Selection not done
A 13| Wrong selection done
3 – Verification errors
V 1| Verification not done
V 2| Verification incompletely done
V 3| Verification in a wrong moment
V 4| Right verification in a wrong object
V 5| Wrong verification in right object
V 6| Wrong verification in wrong object
V 7| Verification in a very little or large amount/quantity

Afterwards, the results of task performance are compared across participants to find what errors are common among them, as well as the success or failure of the task executed. This indicates how effective the tested PIL is in using/taking a medicine.

Likewise, for the follow-up interview, responses to each question are compared across participants to identify similarities and differences in their views on the tasks performed when using/taking the medicine mediates by the PIL.

Next, a general data analysis is made by comparing the outcomes of phase 1 and 2, that is, the results of the interviews to those of the interaction test. This allows identifying trends/commonalities among the phases' results, and relations between participants' task performances and their views on the task/PIL. Then, the main drawbacks of these phases are pinpointed and placed within the task analysis diagram, taking into account their effect on the decision/action flow. This not only permits a visualization of the aspects/elements involved in the procedure of taking/using a medicine, but also make valid requirements to improve the design of a PIL possible. Finally, based on the design requirements, adjustments are made in the PIL to meet patients/users' information needs for using/taking a medicine.

Ideally, after making the adjustments in the PIL, the phases 2 and 3 should be conducted again to verify the effectiveness of the redesigned PIL to the medicine usage. Thus, interaction tests and interviews are carried out and adjustments are made so as to reach a satisfactory version for the PIL (Fig 1).

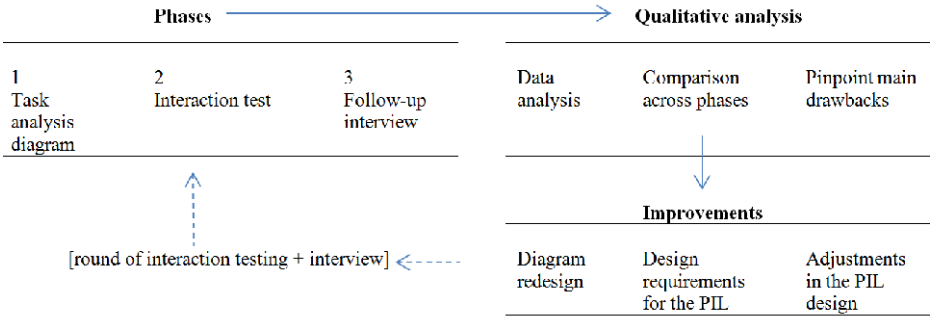
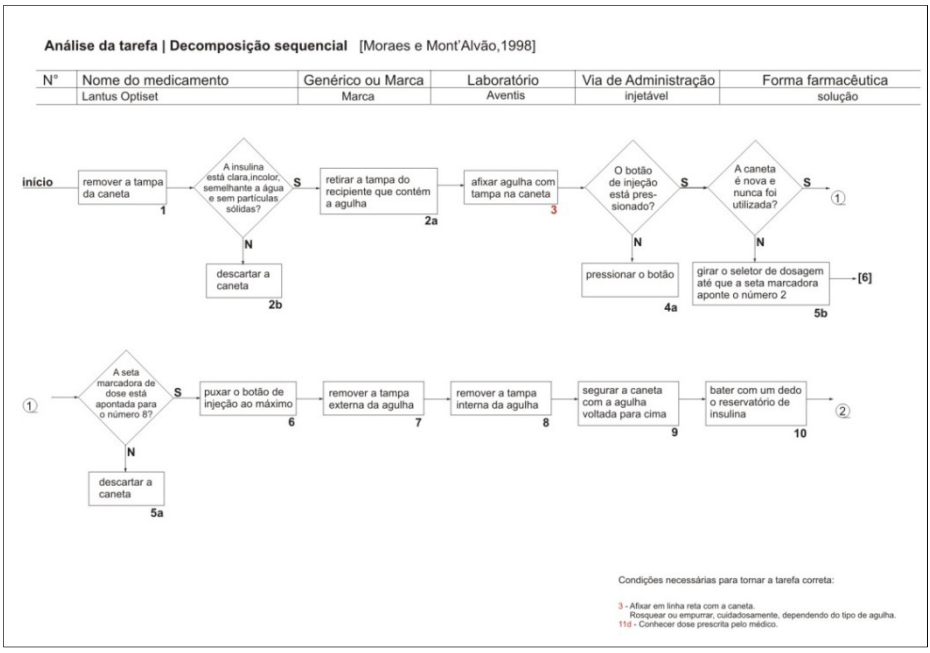


Fig. 1. Sequence of actions involved in the proposed usability assessment for PILs

3 Validating the Proposal for Assessing Usability of PILs

To validate the proposed usability assessment for PILs, a study was conducted in Brazil with 60 participants to use medicines differing in their pharmaceutical presentation: oral suspension, vaginal cream, inhaler, nasal spray and injection pen. They were equally divided into five groups according to the medicine presentation (12 participants per medicine). A task analysis diagram was drawn to each medicine according to their PILs, and decision points, steps and conditional situations were, then, identified in the medicines' procedural tasks. With this information in hand, protocols were designed considering the inputs from the diagrams to the interactions tests and follow-up interviews, which were carried out following the procedures abovementioned.



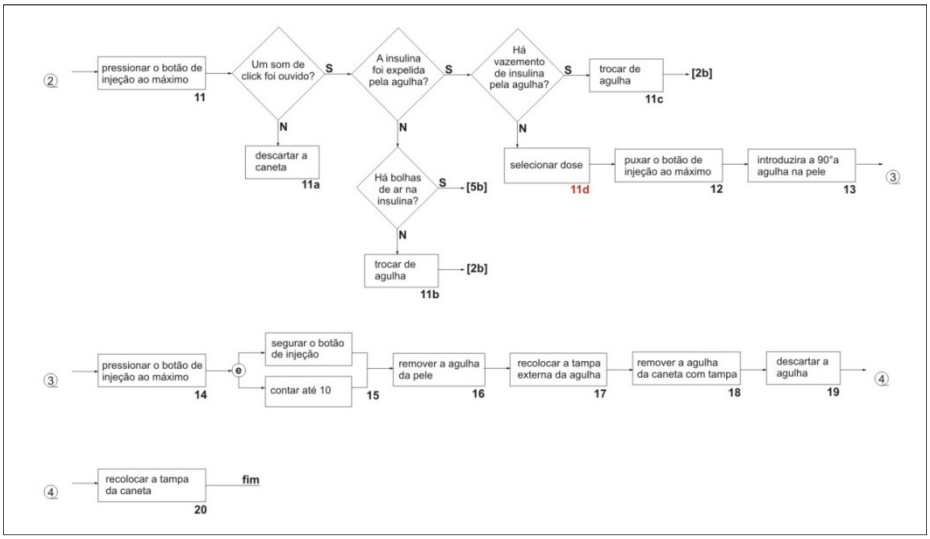


Fig. 2. Task analysis diagram for the injection pen

The results on task analysis diagrams showed that complexity of the tasks was directly proportional to the amount of decision points and actions/steps involved in the medicines' usage. Fig. 2 shows the diagram of the injection pen for taking insulin. The numbers in red (3 and 11d) refer to the conditional situations presented in the PIL on how to use the pen.

In addition, table 3 shows a comparison across the five medicines based upon the information from the diagrams produced. The columns present the number of steps/ actions, the decision points and the conditions to use/take each medicine. According to their PILS, the injection pen and inhaler presented the highest number of actions (N = 20 and N = 19 respectively), whereas the vaginal cream had the lowest (N = 09). The number of decision points and conditional situations were also high for the injection pen comparing to the others. On the other hand, there was no decision point for the vaginal cream according to its PIL.

Table 3. Comparison across the five medicines

Medicine	Actions	Decision points	Conditions
(1) Inhaler	20	3	0
(2) Vaginal cream	09	0	4
(3) Injection pen	19	9	5
(4) Oral suspension	17	1	6
(5) Nasal spray	12	3	3
Total	77	16	18

Regarding the PIL + medicine interaction test, the results indicated that the more complex the task of using a medicine, the greater the number of errors made by the participants (Table 4). Information and action errors were found in all five medicine use tasks. A total of 352 were made by participants in their task performances, particularly regarding action/steps (N = 179). The injection pen showed the highest numbers in all errors categories (total of N = 162 errors), followed by the oral suspension medicine with high figures in information processing (N = 32) and action (N = 39) errors.

Table 4. Errors regarding task performances by participants

Medicine	Information Processing	Action	Verification	Total
(1) Inhaler	20	30	2	52
(2) Vaginal cream	7	13	0	20
(3) Injection pen	60	68	34	162
(4) Oral suspension	32	39	4	75
(5) Nasal spray	2	29	12	43
Total	121	179	52	352

According to these results, the PILs tested failed to support task performance since all participants did not succeed in using the medicines guided by their leaflets. This was ratified by the interview responses, in which participants attributed their difficulties in understanding information and performing the tasks to the poor quality of PILs. The outcomes of the interviews also elucidated important issues regarding the personal opinion of participants on the presentation of user instructions and on the medicines' packaging/container. For instance, difficulties in understanding and carrying out the task of using the insulin were associated to the poor design of the injection pen. Likewise, the inhaler container was criticized for not being easy to handle. Moreover, participants (N = 26) considered that use of visual instructions in the PILs tested facilitated understanding of the medicine procedures of use.

Taking into account the outcomes of the interaction testing and interviews, adjustments were made in the task analysis diagrams so as to acknowledge participants' information needs to undertake the tasks mediated by PILs. Thus, critical aspects related to the steps and decision points were marked in the medicines' task flow to support requirements for the redesign of the PILs tested, allowing improvements.

4 Final Considerations

Based upon the validation outcomes, the usability assessment proposed seems to aid in verifying effectiveness of PILs in supporting medicine usage, and may provide guidance to improve the tested PILs. However, due to its research design complexity, the PIL usability assessment should be conducted by experienced researchers who will be able to convey collected data into design requirements for PILs.

Finally, it is hoped that the PIL usability assessment phases as well as the methods and techniques proposed may serve as a starting point to the discussion on measuring effectiveness of PILs from a person-centered approach. And perhaps, such discussion may lead governmental authorities to raise awareness about the need to require PIL's usability testing from the pharmaceutical companies in the medicine regulations.

Acknowledgements. Thanks are due to Dr Stephania Padovani for her valuable contributions in the InfoBula research project of which this study is part, and to CNPq- National Council for Research and Technology, Brazil for supporting this study.

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