

Readability Testing Patient Information Leaflets



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Legal background

- Patient Information Leaflet (PIL) with specified information, and in local language, legally required since 1992 (within the EU)
- Since 2005 PIL has to be ‘legible, clear and easy to use’ (EU Directive 2004/27/EC)
- Readability test report is big issue: required to get ‘marketing authorization’
(No test -> No registration -> No sales!)



What do we (providers) need

- Expertise regarding text and design of patient information leaflets
- In-depth know-how of the legal requirements
- Qualified interviewers
- Large pool of testers
- Office space, recording equipment
- Coffee, cookies, gift certificates



Readability Test

Preparation:

- Heavily edit the text of existing PIL
- Also adapt the text to:
 - the current EMeA QRD template
 - the EC Readability Guideline (update expected in 2007)
 - other official *guidance* documents
 - country-specific requirements
- At this point at least half of the revisions have been made



Readability Test (cont'd)

Getting started:

- Define most important safety and usage aspects
- Formulate 15 to 20 test questions
- Define testers' profile and recruit/invite them

Readability Test (cont'd)

- Do small-scale pilot test (5 testers)
 - Diagnostic purpose: to identify problems
- Do test round 1 (10 testers)
 - Diagnostic purpose: to identify any remaining problems
- Do test round 2 (10 testers)
 - Check if the revisions result in a better score
- After each round: define problems, propose revisions, update PIL, test again

Profile of testers

For general purpose products (pain killers, statins, flu vaccines):

- Testers recruited from general population (in balanced mix of men/women, young/old, unskilled/bright)

For disease-specific medicines:

- For “the pill” or other hormone therapy: women
- For erectile dysfunction (ED) medicines: men
- For dementia medicines: elderly
- Always also a few non-patients (carers)

Test questions

- The test questions must cover
 - main safety issues
 - side effects
 - instructions for use

Sample questions

If you already take so-called MAO inhibitors, which are specific medicines against depression, and your doctor now also prescribes you this medicine, what do you need to do?

What should you do if you get a headache after you have taken these tablets?

If you have a cardiovascular disease (problems with your heart and blood vessels) can you still use this medicine?

Test criteria

- 90% of the testers in each panel must be able to find the requested information in the leaflet, and 90% of those must understand the information (this is between 81% and 90% !)
- Some countries: ‘16 out of 20 testers answer all questions right’ (which is 80%).
- BTW: A leaflet that scores 80% to 90% is a rather poor leaflet: it is possible to reach 95%+



Scoring

- All answers from all testers are meticulously scored
 - Do they find the requested information?
 - How fast do they find it?
 - Do they understand the found information?
 - Will they take the appropriate action?
- All tester remarks, body language signs of confusion, and ‘behavior’ are also noted



Sample from report

Following bullet item is not suitable for patients:

[Do not use this medicine:]

‘if you have cardiac impairment (NYHA degree of III and IV)’

We recommend to change this phrase into:

‘if the pump function of your heart is insufficient (a condition called ‘heart failure’), and you have discomfort when performing light to moderate exercise or while resting’



Sample from report

The heading ‘Taking this medicine with food and drink’ is confusing. It suggests that under this heading the user can find how to take this medicine (with water, before a meal, swallow whole, et cetera), while the regulations state that this section is about possible interactions with non-medicinal products, in this case alcohol.

We recommend to change the heading into ‘Taking Sumatriptan with alcohol’.

Readability test report

- Report (20-35 pages) describing all 3 test rounds, feedback, and recommended modifications
 - Profile and recruitment of testers
 - Score per tester, per question, per test round
 - Description of identified problems
 - Recommended changes, and whether they have been accepted, and if not, why not
- Appendices (60-80 pages)
 - Beginning, all intermediate, and final versions of PIL
 - Questionnaire and instructions for testers/interviewers

Testers so far...

- SEX: Men 40% / women 60%
- AGE: under 25 years 20%, over 65 years 20%, rest 60%
- EDUCATION: secondary 45%, tertiary 55%
- No difference in score between men and women
- Younger testers (<25 years) scored 19% better (= more correct answers) than elderly testers (>65 years)
- Younger testers also considerably faster (are more used to recognizing structure of information in general, which makes it easier to find requested information in a PIL)
- Testers know we do not test them, but that they test the leaflet. However, men often act as if THEY are tested!

Revisions so far...

Average no. of textual changes per test round:

- During edit and pilot test: 57 changes (67%)
- During test round 1: 18 changes (21%)
- During test round 2: 11 changes (12%)

- With first 5 testers, we identify 67% of all problems
- With first 15 testers, we identify 88% of all problems
- The last 10 testers (=40%), add 12%, while at this point readability is already far above criteria

Revisions

- Many revisions not necessary to reach minimum score & to pass readability test
- Leaflet writers use test results for learning curve

Test in one language only

- Good news for registration holders
 - No need to spend 21 times the testing cost
 - Possibility to do test in a country with an adequate test infrastructure and sufficient professional capacity, to reduce cost and time (and escape long wait lines in UK)
- Bad news
 - Most readability problems are caused by shortcomings in the wording. The readability of a positively tested leaflet can easily be destroyed during the translation phase. (Localization World attendees know this, but many regulatory affairs officials don't...)

Take-away #1

- Companies experienced in medical translation and medical writing might consider to ‘go into’ readability testing
 - Currently it is mostly regulatory affairs consultants offering these services (and what can they possibly know about language...)
 - **Warning:** It is not easy and it requires a lot of attention for minute details and a lot of know-how of the regulations, as well as mushrooming number of files per test (1 original leaflet -> 51 files)

Take-away #2

- Non-medicine sectors can use this methodology. This is certainly valid for medical devices and diagnostics products, but also for finance, software, manufacturing...
 - Ask relevant questions, observe if, how, and how fast testers find the requested information, and if they do, is the information understood and will they act appropriately?

Take-away #3

- Medicine sector
 - Poor patient information results in low compliance rates. 1 in 9 patients don't use medicine because leaflet scares them off. Economic damage: 11% of billions. Public health/human damage: no treatment.
- Same is valid for other sectors
 - Improved instructions reduce number of user errors (less demand on help desk) and increase over-all quality of product (and image of producer)

Questions?



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