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Meeting Abstract

Package inserts and their influence on drug safety and therapy success

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Text

Context: In addition to providing information, package inserts are primarily supposed to increase drug safety and therapy success. However, they are consistently criticized as being difficult to understand and too extensive. Reports of non-compliance after reading contents are even known.

Aim of the study: The PAINT survey (package insert test) examined the comprehensibility of information and possible therapy success influences, from five various drug package inserts and five replicas which were developed for this test.

Material and method: Prior to the written package insert test, a questionnaire was developed with 15 questions relating to content and 17 questions relating to package insert test participant opinions. In cross over testing everyone received an original and a replica, over a 4 week period from September 2002 to April 2003.

Results: 1,105 people answered the questionnaire in the first round and 1,051 in the second (age: 10 to 92 years). In all 15 questions participants gave significantly more correct answers to replicas (92.6 to 94.4 %) in comparison to the originals (74.7 to 85.8 %). Dosage instructions were significantly more frequently misunderstood and the relevance of possible side effects overrated. The combination of condensed information and an improved replica package insert design, motivated participants significantly more to read these versions. In comparison to the originals, when participants read the replicas they needed up to 35% less time to locate the content requested and also displayed significantly more confidence to use the medicine if necessary.

Conclusion: From a drug safety perspective, comprehensibility can and must improve imperatively. Instead of stating the active substance in milligrams, dosage instructions should be specified either in number of tablets or in amount of the ready to use drug. Non-quantifiable statements used in the dosage instructions (e.g. take 1-3 times 2-4 tablets) and in the frequency of side effects (e.g. rare) should be avoided. In the interest of patient comfort, text extent must be more intensely condensed in the package insert and the layout more optimized.