CORRESPONDENCE

Comprehension of the Description of Side Effects in Drug Information Leaflets: A Survey of Doctors, Pharmacists and Lawyers

by Prof. Dr. rer. nat. habil. Andreas Ziegler, Dr. med. Anka Hadlak, Dr. med. Steffi Mehlbeer, Prof. Dr. hum. biol. habil. Inke R. König in volume 40/2013

Not too Much to Ask

After conducting a postal survey among doctors, pharmacists, and lawyers, the authors concluded that definitions of the frequency of side effects that Germany's Federal Institute for Drugs and Medical Devices (BfArM) adopted in consensus with the standardized set of terms established by the European Commission (EC) Pharmaceutical Committee do not, in general, correspond to how the respective terms are defined in ordinary language.

The authors therefore suggest redefining the terms ("very common >10% … very rare <0.01%) and adapting these to ordinary everyday language. One could obviously do so and thereby completely descend into chaos.

The BfArM terms have for years been common parlance in all product information for users (package inserts), technical information for doctors and pharmacists, and patient information for participants in clinical trials.

Rather than redefining them, should it not become a requirement that pharmacists and doctors, who are tasked with advising and informing their patients and/or study participants, familiarize themselves with the national (and international) terminology? As there are only five stages of probability, this is surely not asking too much. Otherwise someone might come up with the idea that regional differences should be considered, because something that is "very common" in Bavaria may well be "uncommon" in Mecklenburg-West Pomerania, or vice versa.

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Prof. Dr. med. Frank P. Meyer
Wanzleben-Börde
U_F_Meyer@gmx.de

Difficult to Reconcile

Ziegler et al. (2013) take from their survey the result that the frequencies of side effects reported in package inserts—which are reported as very common, common, and rare—are not always consistent with the interpretations of probabilities among pharmacists, doctors, and lawyers, and they conclude that that definitions of probabilities of side effects given in the package inserts probably do not correspond to the use of the terms in ordinary language. This raises the question of how—in view of the fact that the information on the package inserts and its interpretation by experts threw up substantial differences—these results would have looked if patients had also be included in the survey.

The subsequent discussion will have to be around whether—since the side effects and their frequencies as mentioned on package inserts are difficult to understand—such package inserts in general are too difficult for patients to understand. This applies for formal criteria as well as criteria relating to the actual content, although we need to remind readers that the obligation to provide comprehensible information to patients is still the responsibility of doctors. Supplementing this with written information on the package insert makes sense only if this information has been worked up in such a way that patients can understand it.

In this context I wish to point out an article by Beate Beime and Klaus Menges (2012), which focuses on the legibility and comprehensibility of package inserts in general and which, in particular, analyses package inserts on the basis of formal criteria, such as font size etc.

They draw the conclusion that it is very difficult to reconcile the legal regulations on providing information with comprehensibility, and they make concrete suggestions as to how at the very least their formal legibility and comprehensibility might be improved.

Finally, the article concludes that package inserts often do not only not make it easier for doctors to provide pertinent information to their patients, but actually make it more difficult. This is the case for the aspect of form as well as for the content. It should be made a requirement for intensive efforts to finally reconcile the demand for precision and for comprehensibility.

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Dipl.-Psych. Dr. phil. Dr. med. Helmut Niederhofer
Klinik für Kinder- und Jugendpsychiatrie, Psychotherapie und Psychosomatik
Sächsisches Krankenhaus für Psychiatrie und Neurologie, Rodewisch
helmut.niederhofer@skhro.sms.sachsen.de

In Reply:

A number of different factors will affect how patients assess any risk associated with a possible treatment. This risk is being discussed with the doctor first of all. As Dr Meyer observes, communication with the patient can be expedient only if the treating physician himself/herself is able to assess the risk correctly. Risk communication should be the subject of intensive training as early as during undergraduate medical training. The crucial element is the time available for the discussion between doctor and patient, since risk communication is a difficult subject and is also time consuming.

In addition to this, a fundamental problem presents itself when using ordinary language to describe probability terms, in that such terms are used differently in different contexts. The description that deaths from a disease are "rare" is interpreted differently when used in ordinary language than the product information, that headache as a side effect is "rare" in the context of the administration of a medical drug. This contextual dependency is very difficult to circumvent.

For the purposes of our article, we intentionally restricted ourselves to investigating whether persons with regularly responsibility for risk communication assign the correct probabilities to the terms used on package inserts. In this context, Dr Niederhofer comments that "This raises the question of how—in view of the fact that the information on the package inserts and its interpretation by experts threw up substantial differences—these results would have looked if patients had also be included in the survey." This aspect has been the subject of comprehensive study in the literature. Several studies showed that the verbal descriptions were not assessed correctly. Furthermore, the risk of persons in the general population is being overestimated; in addition to the list of references that accompanies our article (1) (references 11–17) we wish to draw attention in particular to the publication by Fischer and Jungermann (2), which explicitly refers to German persons in the general population.

In our article we dealt exclusively with the problem of risk estimates in a simple medical context. Of course there is a whole series of legal and other requirements for package inserts. And it is obviously almost impossible to present package inserts neatly and make them short, and comprehensible while also including every single characteristic of the medication (3).

We wholeheartedly support Dr Niederhofer in that intensive efforts are required to ensure that package inserts for patients are conceived in a precise way but are still comprehensible and clearly presented. If the use of new media were to be permitted to support package inserts, then this might become possible.

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Prof. Dr. rer. nat. habil. Andreas Ziegler
Prof. Dr. hum.-biol. habil. Inke R. König
Institut für Medizinische Biometrie und Statistik, Universität zu Lübeck, Universitätsklinikum Schleswig-Holstein, Campus Lübeck
ziegler@imbs.uni-luebeck.de

Conflict of interest statement
The authors of all contributions declare that no conflict of interest exists.