

## ORIGINAL ARTICLE

# Comprehension of the Description of Side Effects in Drug Information Leaflets

A Survey of Doctors, Pharmacists and Lawyers

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## SUMMARY

**Background:** The German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) states that it uses standardized terms to describe the probabilities of side effects in drug information leaflets. It is unclear, however, whether these terms are actually understood correctly by doctors, pharmacists, and lawyers.

**Methods:** A total of 1000 doctors, pharmacists, and lawyers were questioned by mail, and 60.4% of the questionnaires were filled out and returned. In the absence of any particular, potentially suggestive context, the respondents were asked to give a numerical interpretation of each of 20 verbal expressions of probability. Side effects were the subject of a hypothetical physician-patient case scenario. The respondents were also asked to give percentages that they felt corresponded to the terms “common,” “uncommon,” and “rare.” The values obtained were compared with the intended values of the BfArM.

**Results:** The results obtained from the three professional groups resembled each other but stood in marked contrast to the BfArM definitions. With respect to side effects, the pharmacists matched the BfArM definitions most closely (5.8% “common,” 1.9% “uncommon” and “rare”), followed by the physicians (3.5%, 0.3%, 0.9%) and the lawyers (0.7%, 0%, 0.7%). When the context of the side effects was not mentioned, the degree of agreement was much lower.

**Conclusion:** Statements about the frequency of side effects are found in all drug information leaflets. Only a small minority of the respondents correctly stated the meaning of terms that are used to describe the frequency of occurrence of side effects, even though they routinely have to convey probabilities of side effects in the course of their professional duties. It can be concluded that the BfArM definitions of these terms do not, in general, correspond to their meanings in ordinary language.

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Conveying probabilities of medical events is an important part of doctors’ daily communication. Patients must be informed, for instance, of their probability of cure or of specific side effects. Specialists in related disciplines are also required to perform these tasks; explaining potential risks and side effects of treatments and drugs is therefore part of pharmacists’ and doctors’ day-to-day professional lives. Courts, meanwhile, deal with the probability of treatment errors or occupational health risks and the illnesses or payments associated with them.

However, it remains unclear how the probabilities of particular events can be discussed in a comprehensible way. There are essentially three possible methods of representing probabilities. Visschers et al. provide an up-to-date oversight (1).

- Firstly, probabilities can be represented graphically, at least as an addition to other methods. This option will not be discussed here, however.
- Secondly, probabilities can be stated numerically, usually as percentages or odds ratios. Although some would welcome this (2), there arises the essential question of whether these figures are stated and understood correctly.
- Thirdly, probabilities can be expressed verbally.

This option is also preferred by some patients (3). Studies have shown, however, that terms used to denote probabilities are interpreted differently by different individuals. The range of probabilities associated with such terms is therefore very broad (4–6), sometimes more than 80%. In addition, linguistic interpretation also depends distinctly on the characteristics of the person asked (e.g. age, severity of disease) and the context in which a term is used (7).

Comprehension and misunderstanding come into play directly, in particular, when probabilities of side effects are conveyed orally. If the risk is subjectively assessed as high, this has a negative effect on treatment adherence (8). Because of this, and because of the difficulties described above, there have long been calls for a single set of terms to be developed, allocating probability figures unambiguously to the verbal terms used (4). In 1997, this led to the standardized set of probability terms established by the European Commission (EC) Pharmaceutical Committee, adopted in 1999 in the

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**BOX 1**

**Allocation of percentage frequencies with no context**

You have been given a list of typical colloquial terms (in German). After each one please write, spontaneously, the percentage (“X%”) you would have in mind if you yourself used the term in conversation with colleagues. There are no right or wrong answers to these questions, just the spread or match of the probability values stated in particular situations.

Please answer spontaneously!

selten	_____%	häufig	_____%
niemals	_____%	unklar	_____%
sicher	_____%	normalerweise	_____%
unsicher	_____%	fraglos	_____%
oft	_____%	stets	_____%
möglicherweise	_____%	nie	_____%
gelegentlich	_____%	wahrscheinlich	_____%
überwiegend	_____%	immer	_____%
meist	_____%	fraglich	_____%
denkbar	_____%	typischerweise	_____%

Summary of Product Characteristics (SPC) (9). Germany’s Federal Institute for Drugs and Medical Devices (BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte) has adopted this system. For example, its *Package Insert Recommendations* (Empfehlungen zur Gestaltung von Packungsbeilagen) unambiguously allocate probability figures and proportions to the five terms “very common,” “common,” “uncommon,” “rare,” and “very rare” in the context of side effects (10).

Multiple studies have already shown that verbal expressions are not interpreted correctly, leading the general population to overestimate the risk of side effects (11–16). This is also true when proportions are provided in addition to verbal expressions of probability (17). In English-speaking countries, these effects have been described in both patients and doctors (17). In contrast, in German-speaking countries comprehension by specialists working in medicine-related fields has not yet been sufficiently researched.

This study therefore aimed to ascertain doctors’, pharmacists’, and lawyers’ interpretation of terms used

**BOX 2**

**Allocation of percentage frequencies in the context of side effects**

If we want to express a probability, we do so using either words or figures. How we describe probabilities can depend on context. For example, does the word “common” mean the same thing to you in every situation? Please imagine the following situations.

Please answer spontaneously!

Monday, 7:30 a.m., a doctor’s practice somewhere in Schleswig-Holstein...

You are the family doctor of Mr. Meier, a 58-year-old math teacher. During a routine annual examination you discover high blood pressure that requires therapy. The most recent edition of *Deutsches Ärzteblatt* recommended a new drug, Lowerfix. As your patient wishes to know about all the side effects of this drug, you call Theo, a sailing buddy and pharmacist, about it:

*“Lowerfix? Yeah, go ahead. Dizziness is uncommon, diarrhea’s rare. Hey, how old’s the patient? 58? Uh, erectile dysfunction’s common.”*

When you then talk with your patient, he wants you to tell him about side effects using figures—he says he’s not very good with words.

What percentage do you associate with:

- Common \_\_\_\_\_%
- Uncommon \_\_\_\_\_%
- Rare \_\_\_\_\_%

to describe probability and their knowledge of the system established by the BfArM.

**Methods**

**The surveys**

The study participants were doctors, pharmacists, and lawyers. They were interviewed using surveys. Only doctors specializing in anesthesia or internal medicine were included, as these are fields in which pharmaceuticals are used very frequently. Sociodemographic information gathered included sex and age. The questionnaire (in German) is available as supplementary material (*eQuestionnaire*).

Two of the survey questions (*Boxes 1 and 2*) are examined in more detail below:

- In the first question participants were given a list of 20 expressions denoting probability, taken from Suß's work (6). Participants were asked to interpret these terms numerically. As no further information was given, the interpretations recorded here are context-free.
- The second contained a case study in the form of a doctor–patient discussion on side effects. In this context, the probability terms “common,” “uncommon,” and “rare,” for which there are definitions in the context of side effects, had to be assigned free percentages.

The researchers had access to address databases covering the medical associations of the German federal states of Schleswig-Holstein and Bavaria, the pharmacists' and bar associations of Schleswig-Holstein, and the Lawyers' Handbook. A total of 600 doctors, 200 pharmacists, and 200 lawyers were selected from these at random, and surveys were sent to them at two points during 2004 (18, 19).

**Statistical methods**

Age and sex are described for each professional group. The median and quartiles of the percentages with and without context are presented for each group. Finally, the number of survey respondents who had given percentages that were in line with the system established by the BfArM was recorded.

**Results**

1000 surveys were sent out. The response rates were as follows (20):

- 53.5% (pharmacists)
- 71.9% (lawyers)
- 58.9% (doctors).

This gives an overall response rate of around 60%, and for each group the response rate is markedly higher than in Suß's work (which records an overall response rate of less than 15%) (6). The participants were divided among all age groups. The majority of respondents were male, and the proportion of women was

**TABLE 1**

**Description of study participants**

n	Profession	Median age, years (min.; max.)	% women
350	Doctor	52 (33; 86)	14.7
107	Pharmacist	48 (27; 74)	37.1
141	Lawyer	46 (30; 73)	25.4

n: number per group; min.: minimum; max.: maximum

higher among pharmacists and lawyers than among doctors (Table 1). The age of those who did not take part was unknown, but the proportion of female participants was comparable to the overall proportion of women among those who had been contacted.

The proportion of women among contacted pharmacists was 31.5%; among lawyers, it was 26.0%. Among doctors sex could only be reported among those from Schleswig-Holstein, where the proportion of women was 20.3% overall and 18.7% among participants. Thus there was no visible difference between the sex distribution of participants and nonparticipants.

**Numerical interpretation of terms denoting probability**

Table 2 compares the numerical probabilities associated with the terms “common,” “uncommon,” and “rare” according to the BfArM and the figures stated in this study.

Although there is very little difference between the interpretations of the various professional groups, there are substantial differences between the figures reported in answer to the question involving context and the BfArM definitions. Specifically, doctors' interpretations rarely match the BfArM's definitions (3.5% of interpretations of “common,” 0.3% of those of “uncommon,” and 0.9% of those of “rare” matched). Pharmacists' and lawyers' results were similar (matches: 5.8%

**TABLE 2**

**Numerical interpretation of terms used to denote probability with no context and in the context of a doctor–patient discussion on the probability of side effects**

Group %	No context			In context		
	“Common”	“Uncommon”	“Rare”	“Common”	“Uncommon”	“Rare”
Definition*	1 – <10	0.1 – <1	0.01 – <0.1	1 – <10	0.1 – <1	0.01 – <0.1
Doctors	75	15	5	60	10	5
(Q1; Q3)	(60; 80)	(10; 20)	(3; 10)	(30; 70)	(5; 20)	(1; 5)
Pharmacists	75	20	5	50	10	3
(Q1; Q3)	(60; 80)	(10; 28)	(1; 10)	(20; 75)	(5; 24)	(1; 5)
Lawyers	75	20	10	70	20	5
(Q1; Q3)	(61; 80)	(20; 30)	(5; 10)	(50; 80)	(15; 30)	(5; 10)

\* Definition of terms established by the German Federal Institute for Drugs and Medical Devices, BfArM (10); Q1: first quartile; Q3: third quartile

and 0.7% respectively for “common,” 1.9% and 0% respectively for “uncommon,” 1.9% and 0.7% respectively for “rare”). Pharmacists achieved the most matches.

Deviations were greater without the context of side effects: Lower, and therefore more nearly accurate, values were stated in context.

### Discussion

Standardization of terms used to denote probability has been recommended in many studies, and some proposals have been developed as a result (4, 21). The BfArM has published an official guideline for use of the terms “very common,” “common,” “uncommon,” “rare,” and “very rare” in relation to side effects (10). This defines these terms clearly. The guideline has become an integral part of every drug information leaflet.

However, this study has shown that these expressions are not understood correctly even by those who work in medicine-related fields. Few of those surveyed allocated correct percentages to the terms “common,” “uncommon,” or “rare” in the context of side effects. For example, the term “common” is defined as a range of 1% to 10%, but the average frequency stated by doctors was 60%. This demonstrates that they did not know the correct numerical interpretations. This was true for all the groups researched: Doctors, pharmacists, and lawyers all allocated incorrect figures to the expressions of frequency in drug information leaflets. In other words, the results of studies in the general population (16) and those in English-speaking countries (17) can be extrapolated to specialists in medicine-related fields in German-speaking countries.

#### KEY MESSAGES

- Representing probabilities such as the risks of side effects is an important part of providing information to patients, but it is unclear how probabilities should be presented in order for estimates of risk to be understood correctly.
- In order to introduce standardization, Germany's Federal Institute for Drugs and Medical Devices (BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte) developed a set of terms that allocates risks to verbal expressions unambiguously in the context of side effects. This is an integral part of every drug information leaflet.
- Risks expressed using these terms are overestimated by patients. This has a negative impact on treatment adherence.
- According to this study, these risks are also distinctly overestimated by doctors, pharmacists, and lawyers.
- The terms used in drug information leaflets ought to be revised so that the verbal expressions correspond more closely to the general understanding of probabilities.

Overestimating the risks of side effects has already been shown to make patients more likely not to take a drug (8). It can be deduced from the results presented here that the problem may be even more far-reaching, because the probabilities of side effects are overestimated even by those whose job it is to inform others of them. We therefore conclude that the term definitions established by the BfArM do not correspond to everyday use.

#### Conflict of interest statement

The authors declare that no conflict of interest exists.

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eQuestionnaire:  
[www.aerzteblatt-international.de/13m0669](http://www.aerzteblatt-international.de/13m0669)

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# **Ergänzendes Material zu „Verständnis von Nebenwirkungsrisiken im Beipackzettel“ von Ziegler, Hadlak, Mehlbeer, König**

## **Anschreiben**

Sehr geehrte Damen und Herren,

Hiermit bitte ich Sie, an einer Befragung im Rahmen meiner Doktorarbeit teilzunehmen, in der ich klären möchte, ob „nie“ auch immer „nie“ bedeutet.

So könnte Ihr Arzt z.B. sagen: „Einen Hirntumor haben Sie wahrscheinlich nicht.“ oder Ihr Apotheker: „Bei diesem Medikament bekommen Sie häufig Juckreiz.“ oder Ihr Anwalt sagt Ihnen: „Selten habe ich so einen Fall verloren.“ Doch was bedeutet „selten“ hier konkret? Ich möchte herausfinden, wie Ärzte, Apotheker und Juristen Wahrscheinlichkeitsbegriffe definieren und gebrauchen. Gibt es Gemeinsamkeiten und Unterschiede? Reden wir alle aneinander vorbei?

Ich studiere Medizin an der Universität zu Lübeck und führe diese Studie im Rahmen meiner Doktorarbeit durch. Die Leitung unterliegt Prof. Dr. rer. nat. Andreas Ziegler, Direktor am Institut für Medizinische Biometrie u. Statistik an der Universität zu Lübeck. Unterstützt wird die Studie u.a. von den Ärztekammern der Länder Schleswig-Holstein, Mecklenburg-Vorpommern und Bayern sowie den Apothekerverbänden dieser Länder. Insgesamt befrage ich ca. 2000 Ärzte, 1000 Apotheker und 1000 Juristen. Ziel ist es, die Ergebnisse in wissenschaftlichen Zeitschriften zu publizieren.

Ich bitte Sie, mich bei dieser Studie zu unterstützen, denn jede Rückantwort bessert die Aussagekraft meiner Befragung und bringt mich ein Stück weiter in Richtung Dissertation. Für die Beantwortung des Fragebogens benötigen Sie nur ca. 5 Minuten. Benutzen Sie bitte für die Rücksendung den beiliegenden Umschlag. Ihre Daten werden anonym ausgewertet und unterliegen selbstverständlich den gängigen Datenschutzregelungen. Im Übrigen verwende ich zur besseren Übersichtlichkeit ausschließlich die männliche Berufsbezeichnung.

Wenn Sie Interesse oder Fragen jeglicher Art haben, melden Sie sich bitte bei mir unter: [konrad@imbs.uni-luebeck.de](mailto:konrad@imbs.uni-luebeck.de); Tel.: 0451-5002781

Ich danke Ihnen sehr im Voraus für Ihre Teilnahme!

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## Erinnerungsschreiben

Sehr geehrte Damen und Herren,

Vor einer Woche haben Sie von mir einen Fragebogen zugesandt bekommen. Thema war der Gebrauch von Wahrscheinlichkeitsbegriffen unter Ärzten, Apothekern und Rechtsanwälten.

Sollten Sie den Fragebogen bereits ausgefüllt und an mich zurückgeschickt haben, bedanke ich mich sehr für Ihre Teilnahme.

Falls nicht, möchte ich Sie hiermit nochmals daran erinnern. Nehmen Sie sich bitte diese Zeit – es dauert nur ca. 5 Minuten! Bedenken Sie, dass jede Rückantwort die Aussagekraft meiner Befragung bessert, und mich ein Stück weiter in Richtung Dissertation bringt.

Wenn Sie Interesse oder Fragen jeglicher Art haben, melden Sie sich einfach bei mir unter: [konrad@imbs.uni-luebeck.de](mailto:konrad@imbs.uni-luebeck.de); Tel.: 0451-5002781

Ich danke Ihnen nochmals sehr für Ihre Teilnahme!

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# Fragebogen

## Fragebogen

Wahrscheinlichkeiten, Prozentwerte, Abschätzungen - im Beruf wie auch im Privatleben gehen wir ganz selbstverständlich mit Ausdrücken um, die eine Wahrscheinlichkeit ausdrücken sollen. Wer gebraucht nicht Wörter wie „selten“, „häufig“, „gelegentlich“, „immer“. Doch was genau bedeutet denn nun „gelegentlich“? Viele Menschen benutzen Zahlen, um ihre Aussagen zu präzisieren, und gehen so möglichen Missverständnissen aus dem Weg. Wenn ein Arzt uns sagt, dass das Risiko, an einer Erkrankung zu leiden, bei 95% liegt, dann meint jeder, sich etwas darunter vorstellen zu können.

Sie bekommen jetzt eine Liste mit typischen umgangssprachlichen Begriffen. Ergänzen Sie bitte spontan denjenigen Prozentwert („x%“) hinter den Ausdrücken, den Sie im Sinn hätten, wenn Sie selbst im Gespräch mit Kollegen den betreffenden Begriff verwenden würden. Bei der Beantwortung des Fragebogens geht es nicht um „richtige“ oder „falsche“ Antworten, sondern um die Streuung bzw. Übereinstimmung der gegebenen Wahrscheinlichkeitswerte in bestimmten Situationen.

Antworten Sie spontan!

selten	_____ %	häufig	_____ %
niemals	_____ %	unklar	_____ %
sicher	_____ %	normalerweise	_____ %
unsicher	_____ %	fraglos	_____ %
oft	_____ %	stets	_____ %
möglicherweise	_____ %	nie	_____ %
gelegentlich	_____ %	wahrscheinlich	_____ %
überwiegend	_____ %	immer	_____ %
meist	_____ %	fraglich	_____ %
denkbar	_____ %	typischerweise	_____ %



Wollen wir einen umgangssprachlichen Begriff ausdrücken, so verwenden wir dafür entweder Worte oder Zahlen. Wie wir Wahrscheinlichkeitsbegriffe beschreiben, hängt möglicherweise von der Situation ab. Bedeutet z.B. „häufig“ in jeder Situation dasselbe für Sie? Versetzen Sie sich nun bitte in folgende Situationen. Geben Sie Ihre Antworten spontan!

Montagsmorgen, 7.30 Uhr, eine Arztpraxis irgendwo in Schleswig-Holstein...

Sie sind der Hausarzt von Herrn Meier, 58 Jahre, von Beruf Mathematiklehrer. Bei der jährlichen Routineuntersuchung stellen Sie einen behandlungsbedürftigen Bluthochdruck fest. Im letzten Ärzteblatt wurde das neue Medikament „Senkefix“ vorgestellt. Da Ihr Patient sämtliche Nebenwirkungen zu diesem Medikament wissen möchte, rufen Sie Theo, einen Segelfreund und Apotheker, zu diesem Thema an:

„Senkefix“? Ja, gib ihm das Medikament ruhig. Gelegentlich tritt Schwindel auf, selten Durchfall. Sag mal - wie alt war der Patient? 58 Jahre? Naja, häufig treten Potenzstörungen auf!“

Im folgenden Gespräch mit Ihrem Patienten möchte dieser die Nebenwirkungen als Zahlenangaben von Ihnen, da er mit Worten wenig anfangen könne.

Welche Prozentangaben machen Sie zu

häufig	_____	%
gelegentlich	_____	%
selten	_____	%

Ein Jahr später, ein Krankenhaus irgendwo in Bayern...

Sie sind Anästhesist und klären Frau Müller, die einen Unfall beim Bergsteigen erlitten hat, über die morgen anstehende OP auf. Das Medikament „Senkefix“ macht Sie hellhörig. Im letzten Ärzteblatt haben Sie etwas über OP-Komplikationen im Zusammenhang mit diesem Medikament gelesen.

Sie fragen sich, ob und wie Sie den Patienten über Risiken aufklären, die in folgenden Größenordnungen auftreten. Welche Wahrscheinlichkeitsbegriffe, also Worte, würden Sie hierfür verwenden?

1 : 1000	_____
1 : 100	_____
1 : 10	_____
1 : 5	_____
1 : 2	_____

Mittwochnachmittag, 16.00 Uhr, eine Anwaltskanzlei irgendwo in Deutschland...

Sie sind der Rechtsanwalt von Prof. Dr. Schmidt, dem ein Behandlungsfehler vorgeworfen wird. Nach genauer Prüfung der Sachlage teilen Sie ihm mit, dass der Fall möglicherweise nicht vor Gericht verhandelt werden muss. Diese Art von Rechtsstreit haben Sie schon oft im gegenseitigen Ein-vernehmen regeln können. Sie beruhigen Ihren Mandanten und sagen ihm, dass das Ganze wahrscheinlich in einem Monat vergessen sein wird.

Um Ihnen glauben zu können, will er diese Wahrscheinlichkeitsangaben von Ihnen in Prozentwerten hören:

möglicherweise	_____	%
oft	_____	%
wahrscheinlich	_____	%

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Bitte geben Sie abschließend noch einige Eckdaten zu Ihrer Person an!

Geschlecht: männlich  
weiblich

Alter: \_\_\_\_\_ Jahre

Fachrichtung: Innere Medizin  
Anästhesie  
Apotheker  
Rechtsanwalt  
Richter

Einrichtung: Praxis  
Klinik  
Apotheke  
Kanzlei  
Gericht  
sonstiges \_\_\_\_\_

In welchem Bundesland sind Sie aufgewachsen?

\_\_\_\_\_

In welchem Bundesland haben Sie überwiegend studiert?

\_\_\_\_\_

In welchem Bundesland haben Sie Ihren Abschluss gemacht?

\_\_\_\_\_

In welchem Bundesland arbeiten Sie zur Zeit?

\_\_\_\_\_

Nochmals vielen Dank für Ihre Teilnahme!