

Ambivalent Dosage Instructions for Children

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Abstract

Clear and comprehensible dosage instructions are essential to ensure that patients get the best treatment results from their medicines, as well as to avoid possible side effects. However, many usability problems are known to exist in the dosage instructions of package inserts. In particular, the comprehensibility of the recommended dosage instructions for children was investigated, which simultaneously contain the doses based on age and the corresponding body weight. The aim of the study was to determine which dosage base people follow when presented with both categories.

205 people, aged between 19 and 83 years, participated in the study. 62.0 % determined the dose of an antibiotic for an 8-year-old child weighing 40 kg according to the body weight, while 17.8 % chose the lower dose according to the age. 9.3 % tried to calculate a compromise between both the doses by age and body weight, and a further 9.8 % were unable to assess the correct dose themselves and referred to the doctor or pharmacist.

The results clearly illustrate that to avoid comprehensibility problems the dosage instructions for children in package inserts should be provided by one system only – age or body weight.

Zusammenfassung

Übersichtliche und verständliche Dosierungsanleitungen sind unerlässlich, damit die Patienten den bestmöglichen Therapieerfolg erreichen, aber auch um möglichen Nebenwirkungen vorzubeugen. Jedoch sind viele Anwenderprobleme mit Dosierungsanleitungen von Packungsbeilagen bekannt. Deshalb wurde die Verständlichkeit der empfohlenen gleichzeitigen Dosisangabe pro Alter und Körpergewicht für Kinderdosierungen untersucht, mit dem Ziel die von den Patienten bevorzugte Version zu ermitteln.

205 Personen im Alter von 19 bis 83 Jahre nahmen an der Befragung teil. 62,0 % gaben die erfragte Dosierung für ein 8 Jahre altes, 40 kg schweres Kind auf Basis des Körpergewichtes und 17,8 % die niedrigere Dosis auf Basis des Alters an. Weitere 9,3 % der Teilnehmer versuchten anhand der Dosierungsangaben pro Alter und Körpergewicht einen Kompromiss zu errechnen und immerhin 9,8 % waren unfähig die korrekte Dosis selbst zu bestimmen und verwiesen auf den Arzt oder Apotheker.

Anhand der gefundenen Verständlichkeitsprobleme sollten die Dosierungsangaben für Kinder in Packungsbeilagen nur auf Basis einer Bezugsgröße – das Alter oder das Körpergewicht – angegeben werden.

Introduction

Dosage instructions are the most important pieces of information about medicines for patients, as well as medical and pharmaceutical experts, provided in package inserts [1–3].

Clear dosage instructions are vital to achieve the best results of medical treatments and to avoid medication errors and side effects. Different surveys have found that many avoidable side effects have occurred that were based on improper doses [4–6].

Schnurrer and Frölich stated that, in particular, the chief causes of overdoses are: missing dosage adjustments in patients with kidney insufficiency, non-consideration of patient's body weight, and calculation errors [6]. While some patients fol-

low the dosage instructions of their doctors, Verheyen found that 32% of the people vary the doses themselves [7]. Furthermore, many patients do not know the correct dosages of their medicines [8, 9].

In addition, dosage instructions are often difficult to understand [10, 11]. For example, the PAINT1 study showed the following main problems of dosage information in package inserts:

- doses that are not provided in the number of tablets or the volume of the ready-made medicine
- unclear information presentation
- too much information
- dosage instructions in ranges, such as 1–3 times 2–4 tablets, without explanation in which case patients should take 2, 3 or 4 tablets
- use of difficult words [11]

Further indications of comprehensibility difficulties in dosage instructions were found in the PAINT1 study when doses were provided by the child's age as well as by body weight. Particularly, this aspect required further investigation as many German package inserts have this kind of dosage presentation [12].

Methods

Participants were asked to participate in the following study from

March to May 2006, carried out in Jena and Zwickau (Germany), in two pharmacies, one doctor's surgery and different institutes of the Friedrich Schiller University Jena. They were asked to answer the following question using the dosage instructions provided in Table 1: "How many millilitres of an antibiotic should be given to an 8-year-old child weighing 40 kg as a single dose according to the following dosage instructions?"

The provided dosage instructions in Table 1 were taken from a package insert of a medicine available on the German market.

All collected data were coded and inserted into a table using the SPSS 14.0 statistical program via double data input checking. Afterwards, frequencies of the provided answers were calculated. Significant influences caused by demographic data were also checked by using first the median test as a global test and in a second step, the Kolmogorov-Smirnov test combined with "Holm-a-Adjustment" after Shaffer.

Results

In total, 205 people participated in this study (average age: 47 years; minimum age: 19 years; maximum age: 83 years; 71.7% female). The composition of highest education

levels was: 8th class n = 34 (16.6%), 10th class n = 68 (33.2%), A-level n = 33 (16.1%), technical college n = 20 (9.8%) and university n = 50 (24.4%). At the time of the study, participants used the following number of medicines per day: no medicine n = 75 (36.6%), 1 medicine n = 64 (31.2%), 2 medicines n = 23 (11.2%), 3 to 4 medicines n = 21 (10.2%), 5 to 7 medicines n = 15 (7.3%), 8 to 10 medicines n = 4 (2.0%) and more than 10 medicines n = 3 (1.5%).

Fig. 1 shows that more than half of the participants would give an 8-year-old child weighing 40 kg the dose based on the child's body weight, while less than 20% would determine the dose according to the child's age.

Almost 10% tried to calculate an average using both of the dosage instructions for age and body weight. The answers given were: 12.0 ml (n = 7), 12.5 ml (n = 9) and 13.0 ml (n = 3).

Furthermore, almost 10% of the participants were unable to assess the correct dose themselves and preferred to consult their doctor or pharmacist.

In this context, elderly people in particular determine dosages more carefully than younger adults, and both groups are often unsure about the correct doses. People aged 60 years and older were significantly more incapable than younger people to effectively use the provided dosage instruction, or they preferred to administer a lower dose (Table 2). Significant differences were found between the oldest participants (60 years and older) and the group aged 19 to 39 years ($p = 0.004$), as well as between the elderly group and the group aged 40 to 59 years ($p = 0.025$).

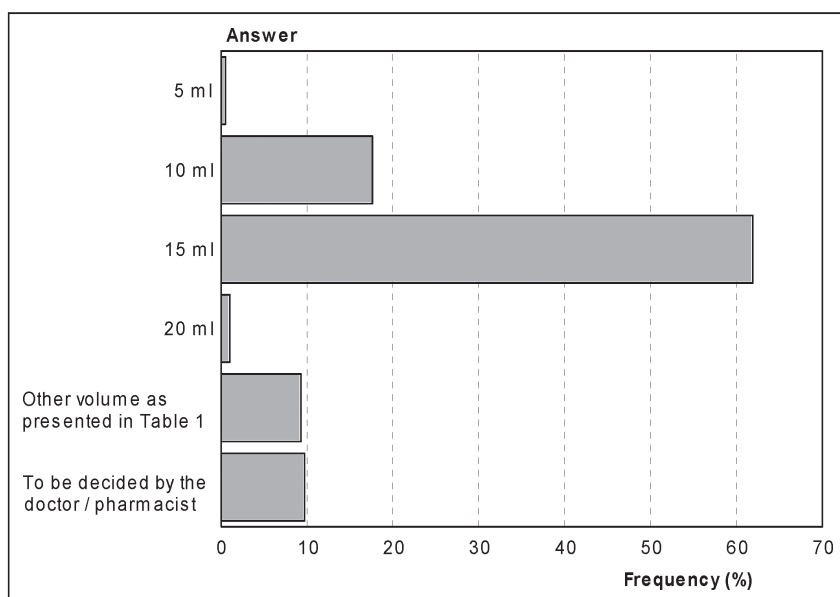
Significant influences were not found based on gender, education level and the number of medicines used daily.

■ Table 1

Dosage instruction table – presented to participants to answer the following question: "How many millilitres of an antibiotic should be given to an 8 year old child weighing 40 kg as a single dose according to the following dosage instructions?"

Age	Adequate body weight	Amount per single dose	Maximum dose per day
6 months to 2 years	5 to 12 kg	2.5 ml If the effect is to low: 5 ml	15 ml
3 to 5 years	13 to 19 kg	5 ml	20 ml
6 to 9 years	20 to 29 kg	10 ml	30 ml
10 to 12 years	30 to 43 kg	15 ml	45 ml
Older than 12 years and adults	more than 43 kg	15 ml If the effect is to low: 20 ml	60 ml

■ **Figure 1**



Answer frequencies concerning the single dose for an 8 year old child weighing 40 kg, using the dosage instructions provided in Table 1 (n = 205 participants).

■ **Table 2**

Answer frequencies concerning the single dose for an 8 year old child weighing 40 kg, itemized by participant age groups.

Participants' answers	Answers' frequencies per age group [%]			
	19 to 39 years (n = 83)	40 to 59 years (n = 62)	60 years plus (n = 60)	Total (n = 205)
5 ml	1.2	0	0	0.5
10 ml	10.8	19.4	25.0	17.6
15 ml	72.3	69.4	40.0	62.0
20 ml	1.2	0	1.7	1.0
Other volume as presented in Table 1	14.5	8.1	3.3	9.3
To be decided by the doctor/pharmacist	0	3.2	30.0	9.8

Discussion

The results of this study clearly illustrate that providing dosage instructions simultaneously by age and body weight is difficult for patients to understand. Apart from reducing the comprehensibility, this format increases the volume of text while decreasing the clarity and locatability of information [13, 14]. Using these dosage instructions in package inserts is not in compliance with

the medicine laws and guidelines which demand that package inserts be easy to read and comprehend [15–17].

Furthermore, the found comprehensibility problems can result in overdosage or underdosage, depending on the child's condition and the medicine's therapeutic index. This is an important point because many children are overweight or underweight [18–21]. Kurth and Schaffrath-Rosario found, from results of

the German health interview and examination survey for children and adolescents (KiGGS; May 2003 – May 2006), that these weight discrepancies applied to more than every fifth child. 8.7 % of German children aged 3 to 17 years are overweight and a further 6.3 % are classified as obese. In addition, 5.1 % are underweight, and a further 1.9 % are considered as extremely underweight [21].

However, simultaneous dosage instructions by age and body weight are common in German package inserts of medicines used for children because the national package insert template [12] and the text templates for different active substances [22] recommend providing both forms in a package insert.

To avoid the found comprehensibility problems, dosage instructions for children should be given by only one source: the age or the body weight, or another appropriate form. Certainly, the age of the child is the quickest available allocation for parents and child caregivers; however, the appropriate basis for dosage instructions must be decided for each active substance/pharmaco-therapeutic group, depending on their characteristics, therapeutic index and performed clinical studies.

Further investigation into the summary of product characteristics (SmPC) is required, because it can not be excluded that medical and pharmaceutical experts would not have similar difficulties in deciding the appropriate dose when more than one allocation base is used. However, experts can use their experience and interdisciplinary skills to determine an adequate dose, in contrast to laymen who do not have this extra skill set to draw from.

Conclusion

It is essential that package inserts for medicines used by children provide the dosage instructions by only one allocation: the age or body weight, or another appropriate version.

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