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Patient Knowledge Regarding Paracetamol at An Internal Medicine Outpatient Clinic in Switzerland: A Cross-Sectional Study

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Abstract

Objectives: To investigate patient knowledge regarding the use and risks of paracetamol.

Methods: Over one month in 2023, patients attending an outpatient internal medicine clinic were invited to an anonymous survey. The survey consisted of a 15-item questionnaire including five knowledge questions about paracetamol and a list of ten medicines to test the patients' ability to identify paracetamol containing products. A knowledge score was calculated and characterized as "good", "satisfactory", or "inadequate".

Results: Among the 250 participants (54% older than 45 years, 45% women), 169 answered all questions and were included in the score evaluation. The median score was 4, with 88% scoring inadequately. Most respondents identified correctly paracetamol's indications (pain and fever, 90% and 52%, respectively), while 37% chose the correct maximum daily dose (4g). Higher scores were reached by younger participants ($p=0.02$, $r=0.18$), women ($p=0.002$, $r=0.24$), and participants who were informed about paracetamol ($p=0.001$, $r=0.25$), had paracetamol at home ($p<0.001$, $r=0.34$) or had used it before ($p=0.002$, $r=0.24$), compared to those who did not. Two preparations were correctly identified by the majority as containing paracetamol or not.

Conclusions: The survey revealed gaps in patients' knowledge regarding paracetamol, in particular regarding the identification of products containing paracetamol. By identifying these gaps, strategies such as better labeling, boxed warnings, or package size restrictions could be implemented to improve patient awareness with the aim to reduce the risk of accidental paracetamol overdose.

Keywords: Paracetamol, Acetaminophen, Over-the-counter, Patient medication knowledge, Survey, Hepatotoxicity, Pain medication, Analgesics, antipyretics

Introduction

Paracetamol (acetaminophen) is a centrally acting analgesic and antipyretic with minimal anti-inflammatory properties [1]. It is typically used for mild to moderate pain (number needed to treat (NNT) in various doses 3 or above, compared to close to 2 for e.g. the nonsteroidal anti-inflammatory (NSAID) ibuprofen) [2] with a maximum recommended dose of 4g per day. Paracetamol can be used as an alternative in patients with contraindications to e.g. NSAID, and it is considered safe during pregnancy and breastfeeding [3, 4]. However, paracetamol can cause hepatotoxicity in supratherapeutic doses

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or in the presence of risk factors such as chronic malnutrition, or induction of the hepatic cytochrome P450, e.g. with CYP2E1 inducers in the co-medication or alcoholism [5, 6]. Furthermore, liver enzyme elevations have been shown in a clinical study in healthy individuals even within the recommended dose range [7].

In Switzerland, paracetamol in a 500mg dose per pill (600mg as rectal suppository) can be purchased as an over-the-counter (OTC) drug, while larger doses (1g dose per pill) are available on prescription or after a documented consultation with a pharmacist. In a previous retrospective study at Inselspital, University Hospital Bern, unintentional paracetamol overdoses (median dose of 8g/day), although less common than intentional cases, had worse outcomes than the latter, including higher rates of acute liver failure and longer hospitalizations [8]. Accidental intoxications tended to present later than intentional cases, potentially leading to worse outcomes [8]. Although not investigated in this study, insufficient patient knowledge about the maximum daily paracetamol dose, risks of supratherapeutic intake, and use of combination drugs (e.g. paracetamol with codeine or caffeine) are additional potential contributing factors to unintentional intoxications. Raising awareness of paracetamol toxicity in the general population might thus represent an important preventive measure to decrease the risk of paracetamol overdose and dose-related adverse effects [8].

Surveys from other countries have revealed difficulties among patients to correctly identify the recommended maximum paracetamol daily dose and medicines containing paracetamol [9, 10], while data from Switzerland are not available. This project aimed thus to investigate patient knowledge and awareness of the correct use and risks of paracetamol in Swiss medical outpatients.

Materials and Methods

We conducted the survey in the outpatient clinic of the internal medicine department at Inselspital, University Hospital Bern, a major Swiss tertiary care provider, during the opening hours of the outpatient clinic (weekdays from 8 am to noon, and from 1 pm to 5 pm) over one month (from February 9 to March 10, 2023). The study was exempted from approval by the local ethics committee of the canton of Bern (Req-2022-00596). Patients aged 18 years or older visiting the outpatient clinic during this period were invited to voluntarily and anonymously participate. We excluded patients who were unwilling or unable to participate (e.g. due to language difficulties, cognitive impairment or having a medical emergency), and those who had filled out the questionnaire during a previous visit.

The survey consisted of a 15-item self-administered questionnaire. The demographic and general questions included sex (self-report), age group, highest completed level of education, previous paracetamol use, whether they had paracetamol at home and whether they had previously received information regarding paracetamol's adverse effects and precautions. The knowledge questions were based among others on previous publications [9-21] and included the recommended maximum daily dose, adverse effects, risk factors for intoxication, potency and indications of paracetamol. Additionally, a list of ten paracetamol- and non-paracetamol-containing products were presented to the participants to identify the ones containing paracetamol (shown by product name and picture to facilitate recognition but with the active substance covered), as done previously by others [16]. From the ten included products, Acetalgin® and Panadol® are paracetamol mono-preparations, Fluimucil Grippe Day & Night®, NeoCitran®, Pretuval® and Vicks MediNait® paracetamol combination drugs, while Algifor®, Aspirin®, Novalgin® and Voltaren® do not contain paracetamol. All products are OTC, except for Novalgin®. Participants were additionally asked whether they had ever taken any of these products.

Before distribution, the questionnaire was pilot-tested by ten laypersons regarding its clarity. The final questionnaire was administered by a pharmacy student, who informed potential participants regarding the nature and the aim of the survey but did not provide any help during the completion. Participants had a choice of language between either German or French. The questionnaires and a translated English version are provided as supplementary material.

The primary outcome was the knowledge score, calculated based on the number of correct answers to the 15 questions (maximum possible score: 15 points). For questions with one correct answer, 1 point was assigned if answered correctly and 0 points for an incorrect or missing answer. For questions with two correct answers, 1 point was assigned if both correct answers were selected, 0.5 points if only one correct answer was selected and 0 points if no correct answers or one correct and one or more incorrect answers were selected. In an additional analysis, a less strict scoring system was applied, where for questions with two correct answers 0.5 points were given for every correct answer, irrespective of other options selected. Based on the score, the level of knowledge was characterized as "good" (score ≥ 12), "satisfactory" (score ≥ 9 – <12), or "inadequate" (score < 9), similar to previous reports in which these three categories were considered for scores ≥ 80%, 60-79% and <60%, respectively [22-24].

Non-normally distributed data are presented as median and range and categorical data as number of cases and percentages. Differences between two or more groups were explored using the Mann-Whitney U and the Kruskal-Wallis test, respectively, using Bonferroni correction for multiple

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comparisons. The effect size was computed by the Wilcoxon effect size (r). Potential predictive factors for the knowledge score were investigated using multiple linear and ordinal regression with sex, age group, education level, use of paracetamol, availability of paracetamol at participant's home and previously received information about paracetamol as covariates. In the survey, the participants could specify their education level based on the options provided in parentheses in Table 1; for comparisons, the simplified categories aligned with the Swiss education system (shown as main categories in Table 1) were used [25]. For binary encoding, we assigned the missing data and/or the minority responses to the most popular answer. For demographics, where participants could select "I do not know", we combined this response and any missing data with the "No" category. Analyses were conducted using the GNU R statistical software (version 4.3.1). Data visualization was performed with Microsoft Office Excel 2016 and GNU R. No power analysis was performed for this descriptive, cross-sectional study; the final number of included patients was determined by the return rate of questionnaires.

Results

A total of 250 out of 492 (51%) patients who visited the outpatient clinic during this period participated in the survey and answered at least part of the questions, while 169 patients (68% of the 250 participants) completed the full questionnaire. Participant characteristics are shown in Table 1. Figures 1 and 2 show the results of the five knowledge questions and the ten products used to test the patients' ability to identify paracetamol containing products, respectively.

Table 1: Participant characteristics (N=250)

	n (%)
Language of the questionnaire	
German	229 (92)
French	21 (8)
Age group (years)	
18-30	45 (18)
31-45	69 (28)
46-65	96 (38)
≥66	39 (16)
Not specified	1 (<1)
Sex	
Female	113 (45)
Male	124 (50)
Other	3 (1)
Not specified	10 (4)
Highest education level	
Compulsory school (primary and secondary school)	30 (12)
Upper secondary level (vocational education and training (VET) certificate, VET baccalaureate, general baccalaureate)	116 (46)
Tertiary level (higher vocational education, universities)	100 (40)
Not specified	4 (2)
Previous paracetamol intake	
Yes	214 (86)
No	19 (8)
I do not know	11 (4)
Not specified	6 (2)
Availability of paracetamol at participant's home	
Yes	185 (74)
No	51 (20)
I do not know	10 (4)
Not specified	4 (2)
Information received about paracetamol from any of these groups	
Physician	83 (33)
Pharmacist	76 (30)
Druggist*	11 (4)
Nurse	9 (4)
Magazine/journal articles	18 (7)
Other**	19 (8)
No information received	87 (35)
Not specified	10 (4)

*In Switzerland, there is a distinction between those working in a pharmacy ("Apotheke") and a drugstore ("Drogerie"). Pharmacists are authorized to dispense prescription medications, while druggists can dispense OTC drugs, alternative remedies, beauty products, and cleaning supplies.

**package leaflet (n=5), internet (n=2), participants nurses or doctors themselves (n=2), personal contacts (n=1), hospital (n=1), source not specified (n=8)

For the total score evaluation, only fully completed questionnaires (n=169) were considered. The median score was 4 points (range 0-15 points) and the score distribution is shown in Figure 3. In total, 149 (88%) participants had an "inadequate" knowledge level, 11 (7%) achieved a "satisfactory" level and 9 (5%) reached a "good" knowledge level. When using the less strict scoring system, the median score was 4.5 points (range 0-15 points) and only for one participant there was a change in the knowledge level category (moved from "inadequate" to "satisfactory").

Women had higher scores than men (median 4.5 vs. 3.5, p=0.002, r=0.24) and older participants (>45 years) scored lower than younger groups (median 3.5 vs. 4.5, p=0.02, r=0.18). Participants who had received information about paracetamol reached higher scores than uninformed ones

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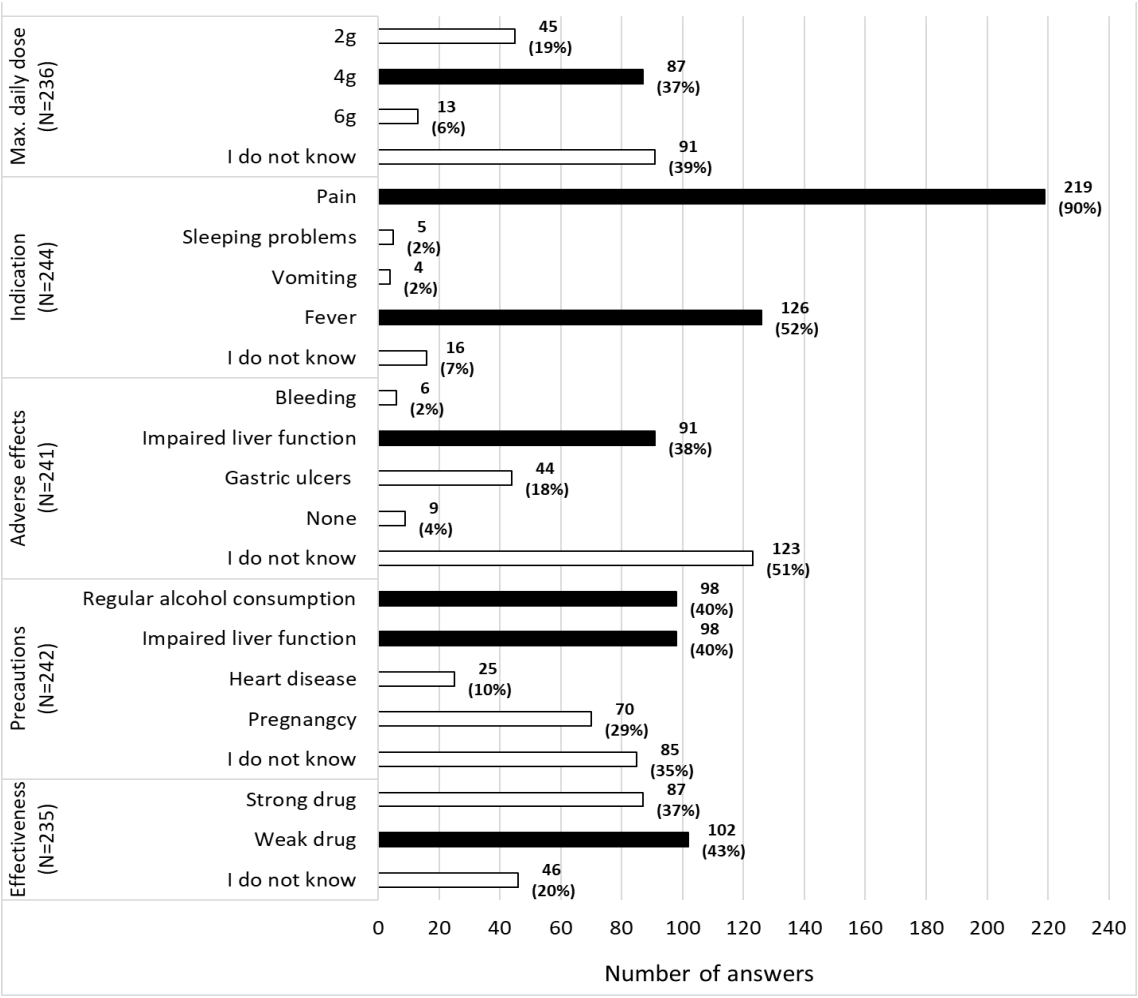

Figure 1: Participants' answers to the specific paracetamol knowledge questions (the total number of available answers for each question is indicated on the left next to each question, correct answers shown in black)

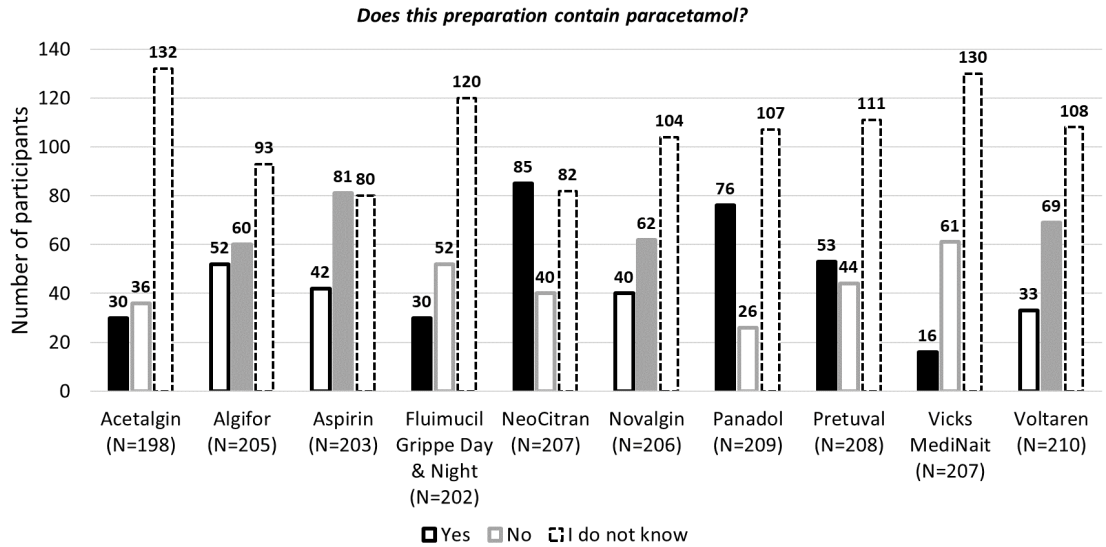

Figure 2: Participants' answers regarding identification of paracetamol as an ingredient in various products (correct answers are filled with the respective colour, "yes" in black and "no" in grey, while incorrect answers have only borders)

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(median 4.5 vs. 3.0, respectively, p=0.001, r=0.25), and less points were achieved by participants who had never taken paracetamol compared to those who had previously taken paracetamol (median 2.0 vs. 4.5, p=0.002, r=0.24). Participants who had paracetamol at home achieved higher scores than those who did not (median 4.8 vs. 2.0, p<0.001, r=0.34). No differences were found regarding the education level. The associations of these comparisons remained unchanged also when binary categories were used (e.g. tertiary level vs. other levels of education, instead of comparison of the various education levels among each other) and when the less strict scoring system was used. The linear regression model revealed a modest association between the score and the included covariates (R-squared= 0.236, p<0.001). Among the covariates, availability of paracetamol at participant's home (which correlated with previous intake), previously received information about paracetamol and female sex were found to be predictors for higher scores (Table 2). The ordinal regression had higher sensitivity for the "inadequate" knowledge level, but failed to predict instances for the "satisfactory" and "good" knowledge levels resulting in a balanced accuracy of 46.8%. In general, the regression models had limited predictivity, underscoring the complexity of the relationships within the dataset.

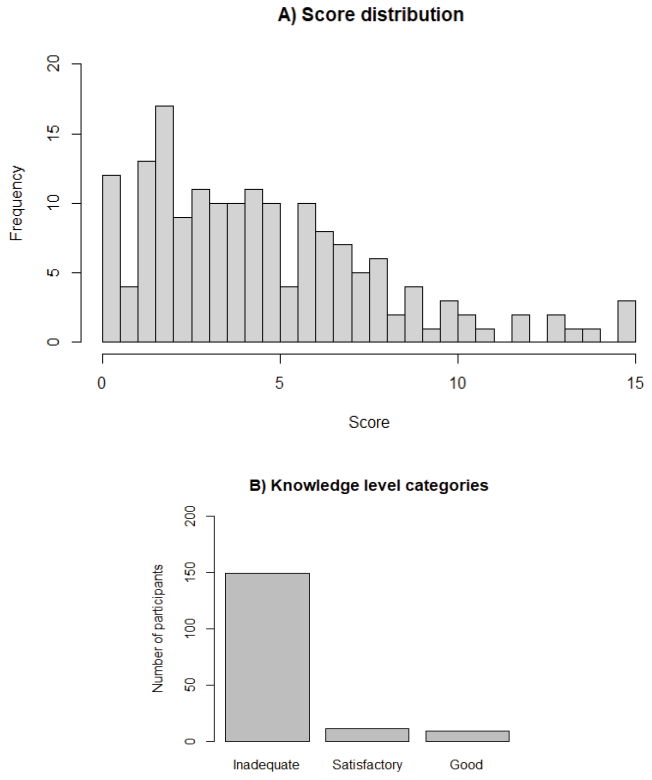

Figure 3: Distribution of A) scores based on the number of correct answers of fully completed questionnaires, B) participants across knowledge level categories (n=169)

Table 2 : Linear regression model results obtained via stepwise selection; the intercept of the model was 0.868, the Rsqr 0.236 and the p-value <0.001.

Parameter	Definition	Estimates	p-value
APAP_home.Yes	Participants who had available at home paracetamol	0.462	<0.001
Informed.Yes	Participants who were informed about paracetamol	0.305	0.001
Sex.female	Female participants	0.197	0.024
Age.young	Participants < 45 years old	0.142	0.101
Intercept		0.868	<0.001

Discussion

In this anonymous survey among patients at the outpatient clinic of an internal medicine department, the majority of the participants were found to have a low level of knowledge regarding paracetamol and only a minority was able to correctly identify paracetamol- prescription and OTC products. Although most participants correctly answered questions regarding indications, precautions and effectiveness, most lacked knowledge about the maximum daily dose and adverse effects and only two of the ten products were correctly classified by the majority of the patients as either containing or not containing paracetamol.

Most patients knew paracetamol's indications (pain and fever). Among participants answering incorrectly about the maximum daily dose (correct answer 4g, selected by 37%), 2g was chosen more often than 6g (19% vs 6%, respectively). Possible reasons for this rather unexpected finding might be that physicians tend to prescribe lower doses than the maximum allowed daily intake e.g. as precaution for older patients or those with liver impairment. Although no recommendation regarding a dose reduction for older patients is provided in the official Swiss product information [26], previous studies have shown that older patients had a greater drug exposure than younger patients following administration of 1g paracetamol intravenously [27], while age and frailty were associated with lower clearance [28]. At the same time, based on the flat dose-response curve, only limited benefit is expected by increasing the dose up to the maximum of 4g daily [29], while liver enzyme elevations can be seen at the maximum dose even in healthy individuals [7]. Therefore, it can be assumed that the current tendency among physicians is not to prescribe the maximum daily dose in most patients, which may also lead to misperceptions among patients regarding this question. Nevertheless, with this approach, it is to assume that patients would use paracetamol within a safe dose range, despite lacking precise knowledge of the maximum daily dose. Compared to previous studies from other countries, fewer participants correctly identified the

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maximum daily dose of paracetamol in France (30% in 2013, 28% in 2017), the USA (23%), Cyprus (12%) and Greece (7%) [11, 14, 18, 30, 31] than in our Swiss study (37%), while in a British survey approximately half of the participants (54%) selected the correct answer [10]. According to older surveys conducted prior to 2008 in the USA, less than 7% of the participants acknowledged the correct maximum daily dose [9, 20]. Although the population might be better informed about paracetamol nowadays than in the early 2000s, the majority still seems to have an insufficient knowledge level.

Questions regarding identification of paracetamol as ingredient among ten products were answered worse than the five knowledge questions. For most products, "I do not know" was chosen by the majority, while only for Aspirin® (non-paracetamol product) and the OTC combination drug NeoCitran® most participants selected the correct answer. However, even for these products, only 40% of the participants indicated the correct answer for Aspirin® and 41% for NeoCitran®. The difficulty of identifying products containing paracetamol was also observed in previous studies, with e.g. a mean±SD score of 6.5±2.5 out of a maximum of 15 regarding identification of medication containing paracetamol in the British survey [10, 14, 18, 30, 31]. Although patients who do not know the active ingredients might check the package information before taking this medication, the inability to identify paracetamol in different prescription and OTC products is concerning, as it could lead to unintentional overdose if multiple products are used concurrently. Preventive measures could include a clearer ingredient labeling on the packaging and specifically asking patients about the use of OTC and combination products before prescribing or distributing paracetamol. Targeted public information could also raise awareness of potential adverse effects and interactions with other prescription or OTC medications.

Younger participants had higher knowledge scores than older groups. Possible explanations include younger generations being better informed and having easier access to information e.g. on the internet, while older participants may have cognitive or vision impairments making it harder to read the package leaflet. Female participants also had higher scores compared to the male group. Possible reasons for this might be that women might be more often affected by painful conditions than men (e.g. menstrual related pain) [32]. Also in previous surveys from other countries, women were better informed than men [10, 11, 18, 31] and the older population scored lower than the younger participants [13, 18]. Participants with prior paracetamol intake or paracetamol available at home reached higher scores than those without; however, the scores reached also among the former were low (median 4.5-4.8). Participants informed about paracetamol by healthcare professionals or other sources scored higher, while about one-third reported receiving no information. This is alarming considering the fact that in Switzerland paracetamol is available only in pharmacies and drug dispensaries and not in e.g. grocery stores like in other countries. Strategies are needed to increase awareness of every customer regarding the use and risks of paracetamol and to promote the safe use of paracetamol containing OTC preparations in the future.

To our knowledge, this is the first study investigating the knowledge level of paracetamol in the Swiss population. Further strengths of the study include the balanced number of male and female participants and the adequate number of returned questionnaires to investigate differences between subgroups. The anonymous self-assessment and the inclusion of "I do not know" as an option could have allowed more honest responses, unlike in-person interviews which may cause stress and embarrassment for participants unsure of the correct answer. Limitations of the study include the cross-sectional design not allowing for causality statements. Although instructed otherwise, it cannot be excluded that some participants might have looked up some of the answers online. Participation was voluntary and based on self-assessment, thus leading to potential sample and recall bias, while the inclusion of only patients of a specific hospital and department does not allow a direct extrapolation to other populations and settings. Approximately one-third of the participants could not fully complete the survey because they were called for their appointment. Although based on similar prior projects and pilot-tested, the questionnaire was developed specifically for this study, is not validated and covers only some aspects of paracetamol use and risks. Products for identification were selected based on local experiences; different products might be more relevant in other regions or based on national sales figures.

Conclusion

In conclusion, the survey identified knowledge gaps regarding the use and risks of paracetamol among a group of Swiss patients. Especially the identification of products containing paracetamol was difficult with only two of the ten presented products correctly classified by most participants as either containing or not containing paracetamol. The findings can provide a basis for the development of specific strategies such as better labeling, use of warning boxes or package size restrictions to correct misperceptions regarding paracetamol and its potential adverse effects in the general population, thus contributing to its safer use in the future.

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The authors report no conflicts of interest in relation to this work.

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