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# **A survey in France about caregiver administered paracetamol to children under 12**

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## **Declarations**

Author contribution: ML and MV prepared the study and all necessary material. ML collected all the data. ML and MA performed the analysis, with the assistance of MF. MA took the lead in writing the manuscript. All authors provided critical feedback and helped shape the research, analysis and manuscript

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**Key words:** Primary Care, Parental Notification, Health Education, Drug Misuse, Acetaminophen.

## **Abstract**

**Background:** In France, acetaminophen (Paracetamol) is the drug most commonly administered by caregivers for children. Paracetamol overdosing is also one of the leading causes of acute liver failure in France.

**Objectives:** The purpose of this survey was to conduct an assessment of parents' knowledge regarding the administration of paracetamol to children under the age of 12 years. The secondary objective was to evaluate the risk of misuse of paracetamol administration.

**Method:** A sampling survey was conducted from June 2018 to October 2018 in the Somme province, France. Self-reported questionnaires were handed out to parents of children under 12 years old who walked into participating pharmacies or medical offices. Collected data were analyzed using Microsoft Excel® and Rstudio® Version 1.1.463 software.

**Results:** 351 questionnaires were collected and analysed. Overall, the survey shows that one-third of parents were not able to correctly identify which medicines contained paracetamol, when they were listed in trade names. Moreover, 55% of parents had made a mistake of paracetamol indication or dosage: 1 in 7 parents would give paracetamol for an incorrect indication, 1 in 8 would expose their children to a risk of overdose, and more than 1 in 3 would use it inefficiently because of underdosing.

**Conclusion:** Half of the children under 12 years old in this survey were in a situation of paracetamol misuse. There is a need to increase the knowledge of parents so as to ensure the safety of their children's. National health authorities, pharmacists and most of all doctors should play a key role in conducting information and health education activities.

### **Key points:**

- Paracetamol is the drug most commonly administered by caregivers for children but caregivers have inadequate knowledge of paracetamol use.

- In our survey, 42% of participants were unaware of paracetamol side effects and half of the participants had made at least one mistake in administering paracetamol to their children.
- Health education is needed to increase knowledge of paracetamol use and awareness of paracetamol toxicity in caregivers.

## **Introduction**

Patients use self-medication for themselves as much as they do for their children [1], and begin to administer drugs to their children on their own very early on, commonly starting between the ages of six months and two years, most often for mild illnesses [1,2]. In 2019/20, about 5,200 new-born to 14 year-olds in England were admitted to hospitals with actual or suspected poisoning by non-opioid analgesics, of which 20% were under the age of five [3]. Paracetamol is one of the most commonly used analgesic-antipyretic in the world and the most frequently prescribed active substance in France, both in private practice and in hospitals [4]. Its consumption has increased by 53% in the last ten years [5], and self-medication was and is still common [6].

Paracetamol exposes the patient to a dose-dependent hepatotoxic risk in two different situations: overdose and paracetamol “mishap” (toxicity observed when paracetamol is taken at a therapeutic dose for several consecutive days with excessive alcohol consumption or with fasting) [7]. The usually accepted threshold of toxicity is 10 g for an adult and 150 mg/kg for a child [8]. In the United States and Europe, paracetamol overdose is the most frequent single cause of acute liver failure compared to viral causes and other iatrogenic causes [9-11].

Acute liver failure produces a systemic inflammatory response syndrome and multi-organ failures. Accidental paracetamol overdosing/poisoning due to a lack of knowledge leads to more cases of acute liver failures and higher mortality rates than cases with suicidal intent

[12], because of a slower and more gradual onset of hepatotoxicity and of a delayed care management by the healthcare system [13]. International studies looking at paracetamol also highlight common errors of dosage (60 to 76%) [14-16], ignorance about side effects (46 to 92%) [1,8,17], and even confusion between paracetamol and ibuprofen, a non-steroidal anti-inflammatory drug (NSAID) [18,19]. This lack of knowledge ultimately led to a risk of under-treatment for fear of a potential unwanted side effects [20].

The objective of this research was to assess the extent of knowledge in a sample of parents concerning use of paracetamol in children aged under 12 years. Such a survey might elicit whether there was signal of a safety concern such as misuse of paracetamol in this age group.

### **Materials and Methods**

A sampling survey was conducted from June 2018 to October 2018 in the Somme province in northern France. It involved a sampling of 30 pharmacies and medical offices drawn at random from the directory, and recruited by telephone. A self-reported questionnaire was handed out to all parents of children under the age of 12 years, whatever the reason for the visit, and whether they had been administering paracetamol or not. The questionnaire was to be completed on site; the questionnaire was excluded from the analysis if it was less than 50% completed. This survey received the approval of the Personal Protection Committee, registered under the number IdRCB 2019-A00590-57.

The self-reported questionnaire intended for parents was developed on the basis of questionnaires used in various thesis works on paracetamol usage by adults [11,23,24]. It covered parental personal background and status (number of children, education), their knowledge about paracetamol (own perception of knowledge level, indications, dosage, side effects) and their knowledge about its use (self-medication, pharmaceutical forms, package leaflet).

The descriptive statistics and univariate analyses were carried out with the software Rstudio® Version 1.1.463. The quantitative variables were compared with the Welch t test. The qualitative variables were compared using the  $\chi^2$  test or Fischer's exact test. For each variable, cases with missing data (md) were omitted and the statistics were conducted with the remaining data.

## **Results**

Among the 700 handed out questionnaires, 368 (52%) were completed (239 in pharmacies and 129 in medical offices), 17 were excluded as they were incomplete. The characteristics of the participants are presented in Table 1.

The children were under the care of a general practitioner ( $n = 291$ ; 83%), a pediatrician ( $n = 50$ ; 14%), or the child protective services ( $n = 8$ ; 2%); two children did not have any medical follow-up. The weight of the child was known for 255 (73%) of the respondents.

When a list of common drugs were presented in trade names, 120 respondents were unable to identify paracetamol-containing drugs (35%; 95% CI 29.8–39.8). Trade names that were wrongly identified as containing paracetamol included Advil® (ibuprofen), Aspegic® (acetylsalicylic acid) and Amoxicillin (Figure 1).

### **Data about paracetamol administered by parents on their children.**

Most respondents ( $n = 292$ ; 83%) had administered paracetamol to their children before. The respondent's children were from 2 months to 12 years old (average  $5.9 \pm 3.1$  years old).

The oral solution (syrup) was the most common pharmaceutical form used by parents when administering paracetamol ( $n = 207$ ; 70%), followed up by the powder sachet ( $n = 76$ ; 26%), suppository ( $n = 56$ ; 19%), and tablet ( $n = 37$ ; 13%) forms ( $md = 56$ ).

Out of 280 responses, 40 parents (14%; 95% CI 9.9–18.1) would not administer the recommended dose indicated by the child's weight, 2 of which had administered too high a

dose. The minimum 4-hour interval between two doses was followed by 96% of participants, but 9 (2.6%) participants believed that a 3-hour interval was sufficient, and 6 (1.7%) were uncertain of the proper time interval between doses ( $md = 0$ ). The maximum authorized number of doses per day was followed by 306 (88%) respondents, however this was sometimes underestimated ( $n = 104$ ; 30%). Some respondents thought they could give up to six doses a day or that there was no recommended maximum dose ( $n = 38$ ; 11%).

### **Misuse of paracetamol administration**

Fever in a child was reported as the main indication for administering paracetamol, followed by the indication of pain ;unauthorized indications were mainly coughing, nausea, and difficulty sleeping (Figure 2).

All in all, out of the 268 questionnaires without missing data for these variables, 32 (12%) presented a risk of overdose for their children, and 104 (39%; 95% CI 33.2-44.8) showed an underdosage. Half of the respondents ( $n = 146$ ; 54%; 95% CI 48-60) made at least one mistake while administering paracetamol to their children: an indication or dosage error (dosage, number of doses every 24 hours, or interval between two doses).

### **Risks in the use of Paracetamol**

The side effects of paracetamol were not known to 148 (43%) respondents. The main side effects reported by the respondents were allergic reactions, gastrointestinal signs and symptoms, drowsiness, addiction and dizziness, 28 respondents believing that paracetamol had no side effects (Figure 3).

When asked about paracetamol overdose, 148 respondents (47%; 95% CI 41.5-52.2) knew the hepatic risk associated with paracetamol overdose but few ( $n = 34$ ; 10%) believed that there was no risk of paracetamol overdose. . Only 51 (15%; 95% CI 11.3-18.8) mentioned death as a risk.



### **Information about paracetamol**

Most participants ( $n = 321$ ; 93%) have used paracetamol from a previous medical prescription. Others had been advised by a pharmacist ( $n = 86$ ; 25%), or friends and family ( $n = 33$ ; 9.5%,  $md = 5$ ). Almost two thirds ( $n = 225$ ; 64%;  $md = 1$ ) of the participants reported they had read the package leaflet for paracetamol. Among the 125 respondents who reported they had not read it, 96 (77%) said it was because they trusted their doctor, 44 (35%) because they trusted their pharmacist, and 20 (16%) said it was too long to read ( $md = 5$ ). Over two-thirds of the participants ( $n = 250$ ; 72%;  $md = 2$ ) said they were well-informed to administer paracetamol to their children without medical advice.

### **Univariate analyses**

Characteristics of caregivers including female gender, aged > 30 years, and a level of education above a high school degree administered paracetamol to their children at a higher rate than caregivers who are male, aged < 30 years and those who have a level of education below a high school degree (Table 2).

According to the univariate analyses, women believed that they had a good level of knowledge of paracetamol administration ( $n = 258$ ; 74%;  $p < 0.05$ ;  $md = 2$ ), and read the leaflet more often than men ( $n = 235$ ; 67%;  $p < 0.01$ ;  $md = 1$ ). In addition, parents of at least two children often defined themselves as being sufficiently well-informed about paracetamol ( $n = 265$ ; 76%;  $p < 0.05$ ;  $md = 2$ ) and had a better knowledge of the risk of hepatotoxicity in case of overdose ( $n = 160$ ; 51%;  $p < 0.05$ ;  $md = 37$ ). Furthermore, parents aged > 30 years were more likely to read the package leaflet ( $n = 235$ ; 67%;  $p < 0.05$ ;  $md = 1$ ).

Higher education is a factor encouraging the practice of caregiver administered medication ( $n = 312$ ; 89%;  $p < 0.01$ ;  $md = 0$ ) and the declared knowledge of the risk of hepatotoxicity in the event of overdose ( $n = 170$ ; 54%;  $p < 0.01$ ;  $md = 37$ ), but not a factor for knowing the best management of dosages or indications.

Parents who administer drugs to their children on their own initiative made fewer errors when asked about drugs containing paracetamol ( $n = 121$ ; 35%;  $p < 0.05$ ;  $md = 6$ ), and had a better knowledge of hepatotoxicity in the event of an overdose ( $n = 160$ ; 51%;  $p < 0.05$ ;  $md = 37$ ).

Own-perception of having sufficient knowledge was the strongest predictor of making no dosage or indication errors (131 versus 84, 48% versus 31%;  $p < 0.05$ ;  $md = 79$ ).

## **Discussion**

Paracetamol is one of over-the-counter medicines available for use in children. However, the over-the-counter and unregulated sale of paracetamol is often unwise and it is critical to provide parents with accurate and adequate information on paracetamol dosing, formulation and potential side effects. [25]

This survey results are generally consistent with those of other study techniques in the literature [1, 2, 12, 14, 17, 19, 21, 24, 26]. For instance, the administration rate and the reported rate of incorrect dosage, particularly by under dosage are similar (21% to 46%) [1,2,12,14,19], while a confusion between paracetamol and ibuprofen varied between 11% and 33% [12,19,24] and few mentioned death as a risk (17% in Hurwitz et al) [26].

The awareness of the risk of hepatic toxicity in the event of paracetamol overdose was higher than those reported in other studies, which ranged from 8% to 35% [17,19,21,26]. The increased awareness of the risk of hepatic toxicity in the event of overdosage can be explained by the fact that the risk is now explicitly stated in the package leaflet, it did not use to be so a few years ago. Paracetamol overdose should also be prevented by discouraging the combination of preparations containing paracetamol.

A high rate of fear of unwanted side effects was reported in another study in children who was under-medicated for post-operative pain, which was explained by a fear of dependence on analgesics in half of the parents [20]. This could be explained by a confusion between opioid and non-opioid analgesics. Providing better information would help prevent under-

dosing paracetamol, therefore helping to reduce the child's fever and leading to a consequent reduction in emergency room visits by parents worried about a persistent fever [27].

Parents were more aware of paracetamol's antipyretic functions (95%) than shown by previous studies focusing on adults (23% to 51%) [12,19]. In this survey, one in seven parents used paracetamol off-label, mainly for nausea, crying and coughing, showing the importance of educating parents the indications for paracetamol usage so they would know how to use it efficiently.

Almost three-quarters of patients practicing self-medication to their children expected advice, information, and education from their doctor [28]. Therefore, getting advice from health care providers plays an essential role, each paracetamol prescription should be accompanied by an oral information on its use [24,28].

Almost two-thirds of the parents had read the package leaflet and yet had made several mistakes. Another study highlighted that one-third of its participants had misunderstood at least one instruction regarding the dosage or the required time interval between two doses, and that two-thirds had misunderstood the side effects [29]. Thus it is legitimate to ask for clearer patient leaflet so as to consider and promote health literacy.

A study carried out in France in 2016 concluded that patients who used paracetamol following some advice from a pharmacist or because of a medical prescription had no better knowledge than patients using it only on self-medication [21]. The current level of information provided by doctors while prescribing paracetamol seemed limited [30]. This limited parent knowledge can be improved by providing written information including the trade name of the paracetamol being prescribed, its dosage specifying the time interval between doses, the general instructions for use, and the quantity or duration of treatment. In addition, routine consultations with parents and their infants may further help to educate parents about paracetamol use and its intended indications [31].

Several actions have been taken to increase the knowledge and awareness of paracetamol use in France. For example, although advice on over-the-counter medicine is still hardly ever evaluated, in 2013, the French National Order of Pharmacists issued recommendations on the "Pharmaceutical Reception of Patients without a Prescription". This document reiterates that the pharmacist must carry out a pharmaceutical interview with the patient, even when the request seems harmless (for example taking paracetamol for a sore throat). More studies on the feasibility and impact of these pharmaceutical talks are needed. [32] Furthermore, the French National Agency for the Safety of Medicines and Health Products (ANSM) has already made it mandatory to mention: "This medicine contains paracetamol. Beware of risks to the liver in the event of an overdose." in any kind of audio advertisement. In July 2019, the ANSM made necessary the posting of the message "overdose = danger" on boxes of paracetamol [33]. The impact of this new measure will have to be assessed, but it should help improve patient knowledge.

In this survey, parents had a better knowledge score than participants without children of another study [19]. However, parents also had a lower score for use, probably due to a more complex implementation of this knowledge for their child. The univariate analysis allowed for identification of the parents at risk who should particularly benefit from medical attention and information supported by services: fathers, young parents, and single child parents.

There are several limitations of our survey. Because the survey was conducted on a voluntary basis, the population could not be extrapolated to the general population: most respondents had a level of education equal to or higher than a general high school degree (baccalaureate) (73% vs 46% of French people) [23]. Despite the instructions given to complete the questionnaire on the spot, some questionnaires may have benefited from human or technical assistance (outside instruction, internet). Hence the knowledge of the participants is undoubtedly overstated, and the patients can be considered to have even less comprehension of the principles surrounding paracetamol. In addition, with the data of this survey is being >3

years old, they may not be relevant to present day. However, we believe that parents' knowledge about paracetamol use in children would have not changed much. With new pharmaceutical forms of paracetamol for children (e.g. DolipraneLiquiz®, an oral solution-containing sachets that does not require dilution and Paralyoc®, an orodispersible tablet) being introduced in the market, further studies evaluating the information received by parents in consultations concerning the paracetamol prescribed for their children as well as their expectations would be of interest to optimise discussion between healthcare professionals and parents, and improve education on proper care.

### **Conclusion**

This survey has highlighted a significant proportion of children exposed to a potential situation of paracetamol misuse. Even if the hepatic risk is better known than in previous studies, the risk of death is still unknown to the parents. The prevention of paracetamol overdoses through informing parents of the dosages to be respected, of the hepatic risks, and of death in the event of involuntary intoxication still needs to be improved and is a current concern for physicians in charge of health education. Moreover, educating parents appropriately about potential side effects associated with paracetamol may prevent paracetamol underdosing in children. The results of our survey suggest a signal worthy of further formal epidemiological evaluation to validate our findings. However, given the widespread use of paracetamol it may be more cost-effective to embark on an education campaign concerning self-medication with analgesics.

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## Annexes

**Figure 1.** Identifying paracetamol-containing drugs among 345 parents presenting at a pharmacy or a medical office in 2018. Percentage (n). Correct answers in black.

**Figure 2.** Paracetamol indications according to 343 parents presenting at a pharmacy or a medical office in 2018. Percentage (n)

**Figure 3.** Side effects of paracetamol according to 347 parents presenting at a pharmacy or a medical office in 2018. Percentage (n).