Appropriateness of Acetaminophen Dosing by Caregivers of Pediatric Patients Presenting to the Emergency Department at the University Pediatric Hospital in Puerto Rico

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Objective: Evaluate the appropriateness of acetaminophen dosing by caregivers seeking care for their children/wards at the emergency department of a pediatric hospital.

Methods: Design: Cross-sectional descriptive study. Setting: The emergency department of the University Pediatric Hospital in San Juan, Puerto Rico. Participants: Eighty-eight caregivers who had, in the past 24 hours, administered a known quantity of acetaminophen to a pediatric patient under their care and were visiting the emergency room with that patient. Intervention: The caregivers were interviewed by the investigators, using a standardized questionnaire. Main outcome measures: The appropriateness of the acetaminophen doses administered by caregivers. The product's dosage form and strength, measurement device used (if any), and demographic data (of the caregiver and child) were also collected. Doses of 10 to 15 mg/kg of acetaminophen were considered appropriate.

Results: Overall, 45% of the caregivers had administered an inappropriate dose. Of these, 70% were subtherapeutic and 30% were supratherapeutic. Although 74% of the caregivers knew their child's/ward's weight, only 50% had used it to determine the dose. Caregivers with previous experience (as caregivers) were most likely to have administered an inappropriate dose ($P = 0.03$). Physicians were the source most consulted (40%) by caregivers, followed by the product's label (35%). Only 9% of the caregivers consulted a pharmacist for dosing recommendations.

Conclusion: Nearly half of all the caregivers administered an incorrect acetaminophen dose, suggesting that there is a need for better caregiver education. Due to their accessibility at the point of sale of OTC medications and pharmacotherapy knowledge, pharmacists could have an active role in promoting the safe and effective use of acetaminophen. [*P R Health Sci J 2021;40:19-25*]

Key words: Pediatric dosing, Acetaminophen, Medication safety, Over the counter, Self-care

Acetaminophen is one of the most commonly used over-the-counter (OTC) medications in pediatric patients. Appropriate dosing is important to ensure its efficacy and safety. Despite the efforts of the healthcare community to promote its correct use, acetaminophen is sometimes administered incorrectly by caregivers. Factors such as child age, caregiver education level, and source(s) of information have been shown to influence whether or not caregivers will administer the proper dose of acetaminophen to their child or ward. The Drug Facts label contains information for dosing that is based both on the child's weight and on his or her age. The differences in doses, along with the fact that many caregivers do not know their children's/wards' weights, can increase confusion and predispose caregivers to administering inappropriate doses of acetaminophen. To complicate matters, Drug Facts labels are written in English, making them harder to understand for caregivers with limited English proficiency, as is the case with a great proportion of caregivers in Puerto Rico.

Studies assessing the patterns of administration of OTC medications to pediatric patients in Puerto Rico are limited.

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The authors have no conflict of interest to disclose.

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Specifically, there are no published data to date that describe acetaminophen use in pediatric patients in Puerto Rico.

Some pediatric patients receive inappropriate doses of acetaminophen from their caregivers. Our study identified several factors that may influence the safe use of this medication. Although a convenience sampling method was used, we believe that this initial study identifies the need for future research in this area and for improved caregiver education regarding pediatric acetaminophen dosing.

Fever remains the most common concern for which parents bring their child to the emergency department (ED) and accounts for approximately one third of pediatric ED visits (1). The highest percentage of pediatric ED visits for fever by ethnicity is for Hispanic patients (2). Acetaminophen, a common OTC medication used in children less than 12 years old, is best known for its antipyretic properties (3). It is an accessible medication with a well-documented safety profile (when used within the recommended doses).

Appropriate acetaminophen dosing is vital to ensure efficacy in fever and pain reduction in children and to avoid safety concerns, such as hepatotoxicity (4). According to the Morbidity and Mortality Report of the Centers for Disease Control and Prevention, from 2001 to 2003, approximately 50,000 children younger than 4 years of age visited an ED because of a medication overdose, of which 26.9% were caused by central nervous system agents, including acetaminophen (5). Underdosing can also influence these statistics and becomes a significant problem, as many pediatric visits to the ED are due to persistent fever that may be associated with subtherapeutic doses of acetaminophen (6). In patients younger than 12 years old, acetaminophen doses should be determined according to the child's weight. The recommended dose of acetaminophen for pediatric patients is 10 to 15 mg/kg/dose every 4 to 6 hours, as needed. Pediatric patients should not exceed 5 doses in 24 hours, and the maximum daily dose is 75 mg/kg/day, not to exceed 4,000 mg/day (4). As an alternative method for determining dosage, the Drug Facts label for acetaminophen includes an age-based dosing chart. However, some children may not receive the appropriate dose if their body mass index is disproportionate to their age (7). In patients over 12 years of age, the standard dose ranges from 325 to 650 mg every 4 to 6 hours, as needed, or 1,000 mg every 6 hours, as needed. The maximum recommended dose for adults is 4,000 mg/day (4). The differences in dosing methods and the fact that many caregivers do not know their children's/wards' weights can increase confusion and predispose caregivers to administer inappropriate doses of acetaminophen (8). The significance of this problem has led to the creation of the Know Your Dose campaign, developed by the Acetaminophen Awareness Coalition, which is intended to educate patients and consumers about the safe and effective use of acetaminophen (9).

The selection of an appropriate dose can be complicated for caregivers because of the different dosage forms and strengths available on the market. The calculation of a specific dose with the liquid formulation may be more complicated than it is with solid formulations (the latter are available at fixed doses). Regardless of the dosage form, caregivers need to fully understand the package's Drug Facts label to determine the appropriate dose (7, 10). In the United States, Drug Facts labels are written in English. However, the Commonwealth of Puerto Rico is a United States territory composed primarily of Spanish-speaking individuals. Therefore, language may be a significant barrier for Spanish-speaking caregivers needing to make informed decisions based on an OTC package's information. It has been demonstrated that both low literacy in English and low health literacy contribute to the poor understanding of medication instructions (7, 8, 11, 12). Other factors that influence acetaminophen dosing's appropriateness, such as the age and weight of the child, frequency of acetaminophen administration, and source(s) of information consulted by the caregiver, have been identified (1, 6, 7, 11, 13).

Previously, another potential complication was the availability of various concentrations of pediatric acetaminophen in suspension form. In 2011, to minimize the potential for medication errors due to confusion between different concentrations of infants' and children's acetaminophen products, manufacturers in the United States voluntarily agreed to produce the same single concentration (160 mg/5mL) for all single-ingredient OTC pediatric liquid acetaminophen products. However, some caregivers may have older formulations of different concentrations in their homes. Although pediatric acetaminophen dosing by caregivers has been studied extensively in the United States, to our knowledge, there are no published data on this deriving from the patient population in Puerto Rico.

The objective of this study was to evaluate the appropriateness of acetaminophen dosing by caregivers seeking care for their children/wards at the University Pediatric Hospital ED. The findings of this study were—and are—intended to provide insight into how acetaminophen is dosed in pediatric patients in Puerto Rico and determine whether more- and more effective- educational campaigns are needed to promote this medication's effective and safe use. Our aim was to describe the demographic and social characteristics of children and their caregivers and determine whether and how those characteristics are associated with inappropriate acetaminophen dosing.

Methods

Study design

This was a cross-sectional descriptive study of acetaminophen dosing using a convenience sample of the caregivers of children presenting at the ED of the University Pediatric Hospital in Puerto Rico from August 2014 through November 2014. This hospital is 1 of 3 pediatric hospitals in the San Juan metropolitan area and has 161 patient beds. A standardized questionnaire

was created by the investigators to explore 4 areas of interest: 1) child demographic data, 2) dosage form and strength, 3) measurement device used (if any), and 4) caregiver demographic data. After acquiring the consent of a given potential participant (i.e., a caregiver with a child/ward currently in the ED), a study investigator first interviewed this individual face to face and then verbally administered the questionnaire.

The study was approved by the institutional review board of the University of Puerto Rico, Medical Sciences Campus (protocol no. B0410114).

Participants

Eligible participants had brought a child of 12 years or younger to the ED and knew the quantity of acetaminophen that that child had consumed in the 24 hours prior to the ED visit. Participants who met the inclusion criteria were identified and referred to the investigators by the triage nurse responsible for recording all the medications administered by the caregiver before arrival at the ED. Because the purpose of the study was to evaluate the appropriateness of acetaminophen dosing by caregivers, caregivers were excluded from the study if the child had received an unintended dose and/or if the administered acetaminophen was part of a multi-ingredient product. An individual who had cared for a child prior to the one being taken to the ED was categorized as "experienced caregiver".

Dosing appropriateness

Appropriate doses were defined as being 10 to 15 mg/kg for the oral formulations (liquid and tablets) and 10 to 20 mg/kg for the suppository formulation of acetaminophen, with the relevant amount of each formulation being determined by weight (4). Doses were recorded in milliliters for the liquid formulations and in units for the solid formulations. Commercially available OTC liquid products designed for children are formulated as a 160 mg/5 mL concentration. In the cases in which caregivers did not remember the concentration of the liquid formulation of acetaminophen administered, the concentration was assumed by the investigators to be 160 mg/5 mL. Appropriate doses were calculated using the child's weight (as reported by the caregiver). In those cases in which the caregiver did not know the child's weight, a nurse determined said weight during the initial ED evaluation.

Objectives

Our study's primary endpoint was the representative assessment of the appropriateness of acetaminophen dosing by the caregivers of pediatric patients. The secondary endpoint was an accurate comparison of the relationship, if any, of the appropriateness of acetaminophen dosing to 1) the criteria for dosing, 2) the dosage form and strength, 3) the measuring device used (if any), 4) the relationship of the caregiver to the child, 5) caregiver experience, 6) caregiver education and, 7) the information source consulted (Table 2).

Data analysis

Data were collected in a Microsoft Office® Excel spreadsheet. Frequencies, percentages, means, standard deviations, and confidence intervals were used for descriptive statistical analysis. Statistical analysis was done with the SPSS 8.0 for Windows program. The chi-square (χ^2) test was used to analyze all the categorical variables, and Student's t-test, to compare continuous variables. A P value of less than 0.05 was considered statistically significant.

Results

Sample handling

A total of 97 caregivers were interviewed; none of them refused to participate in the study. Nine interviews were excluded from the analysis due to incomplete data regarding the administered acetaminophen dose. The remaining 88 (91%) interviews, all of which interviewees met the inclusion criteria, were used to analyze the primary and secondary endpoints.

Demographic data

Demographic data are summarized in Table 1. The mean age of the 88 caregivers who were interviewed was 31 years old, and 82% were the mothers of the children being seen in the ED. The participants were more likely than not to have had no previous experience as a caregiver (52%) and to have a college education (72%). The mean age of the pediatric patients who had been brought to the ED by their study-participating caregivers was 4 years old; their mean weight was 43 kg, and the majority (53%) were male.

Table 1. Demographic data (n = 88)

Variable	Frequency (%)	Mean ± SD	Range
Caregiver			
Age (years)		31 ± 10	17 – 62
Respondent			
Mother	72 (82)		
Father	10 (11)		
Other	6 (7)		
Caregiver experience			
Yes	46 (48)		
No	42 (52)		
Caregiver education			
High school	25 (28)		
College	58 (66)		
Post-graduate	5 (6)		
Child			
Age (years)		4 ± 3	1 month – 11 years
Weight (kg)		43 ± 29	8 – 130
Gender			
Female	41 (47)		
Male	47 (53)		

Abbreviations: SD, standard deviation; kg, kilograms

Although 74% (65/88) of the caregivers had known their child's/ward's weight at the moment of administering the medication, only 50% (44/88) had used it to determine the dose. About 27% (24/88) of the caregivers followed age-based criteria for dosing, while 22% (20/88) did not use weight or age criteria.

The oral liquid formulation was the one that was most commonly administered by caregivers (76% [67/88]). Of the 67 caregivers who reported using a liquid formulation, 70% (47/67) reported using the 160 mg/5 mL concentration, and 30% (20/67) reported that they did not know the concentration of the administered medication. Suppositories and tablet formulations were administered by 6% (5/88) and 18% (16/88) of the caregivers, respectively. Of the caregivers who gave the liquid formulation, 63% (42/67) used a measuring syringe, 31% (21/67) used the measuring cup of the product being administered, 3% (2/67) used a spoon, and 3% (2/67) used a dropper.

In deciding the quantity of acetaminophen to administer, 40% (35/88) of the caregivers used a recommendation provided by the child's physician, 35% (31/88) followed the recommendations of the product package insert, 10% (9/88) consulted a pharmacist, 7% (6/88) followed the advice of a relative, and 8% (7/88) guessed the dose. More than half of the caregivers reported that the child was not the first child to have been under his/her care. For the caregivers who administered liquid formulations, more than half 63% (42/67) had the acetaminophen product that was administered to the child available to be reviewed by the investigators at the time of the survey [data not shown]. None of the caregivers who gave their children/wards tablets or suppositories had the product available at the time of the survey.

Primary Endpoint

Table 2 summarizes the results regarding the appropriateness of the caregiver's acetaminophen dosing and includes stratification by the secondary endpoints. Overall, 45% (40/88) of the caregivers who reported the dose of acetaminophen given to their child/ward had administered an inappropriate dose. Of these, 70% (28/40) were subtherapeutic and 30% (12/40) were supratherapeutic.

Secondary Endpoint

As shown in Table 2, the relationships between the appropriateness of acetaminophen dosing and various selection criteria were evaluated. In selecting the criteria for dosing, only 50% (44/88) of the caregivers had used the weight of the child, 27% (24/88) had used the child's age, and 23% (20/88) had not used either the age or the weight of the child. The only significant association between appropriate acetaminophen dose and the secondary endpoints that were evaluated was caregiver experience ($P = 0.03$). There was also a not statistically significant relationship between the information source consulted and inappropriate dosing ($P = 0.09$).

Discussion

In this study, nearly half of all the participating caregivers had administered an incorrect dose of acetaminophen. Previous studies have reported similar numbers, with some identifying a prevalence of incorrect dosing as high as 57% (1). Although the weight of the child is the best criterion to use for determining the appropriate pediatric dose of acetaminophen, only half of the interviewed caregivers used it when deciding on the optimum dose for their children/wards. This may be related to the fact that some of these caregivers did not know their child's/ward's weight at the time of dosing. However, in this study, the caregivers who had used weight-based dosing had the highest likelihood of administering an appropriate dose.

Table 2. Appropriateness of Acetaminophen dosing (n = 88)

Variable	Total	Appropriate	Inappropriate	SBT	SPRT	P-value
Primary Endpoint						
Acetaminophen dosing	88	48 (55%)	40 (45%)	28 (70%)	12 (30%)	
Secondary Endpoint						
Criteria for dosing						0.3005
Weight	44	27 (61%)	17 (39%)			
Age	24	10 (42%)	14 (58%)			
Neither	20	11 (55%)	9 (45%)			
Dosage form						0.9533
Suspension	67	36 (54%)	31 (46%)			
Tablet	16	9 (56%)	7 (44%)			
Suppository	5	3 (60%)	2 (40%)			
Measuring device						0.4037
Cup	21	14 (67%)	7 (33%)			
Syringe	42	20 (48%)	22 (52%)			
Spoon	2	1 (50%)	1 (50%)			
Dropper	2	1 (50%)	1 (50%)			
Relationship to child						
ED patient						0.3406
Mother	72	40 (56%)	32 (44%)			
Father	10	6 (60%)	4 (40%)			
Other	6	2 (33%)	4 (77%)			
Caregiver experience						0.0300
First child	42	28 (67%)	14 (33%)			
Not first child	46	20 (43%)	26 (57%)			
Education						0.2292
High school	25	10 (40%)	15 (60%)			
College	58	35 (60%)	23 (40%)			
Post-graduate	5	3 (60%)	2 (40%)			
Information source						0.0854
Physician	35	24 (69%)	11 (31%)			
Product label	31	14 (45%)	17 (55%)			
Pharmacist	9	6 (67%)	3 (33%)			
Relative	6	1 (17%)	5 (83%)			
None	7	3 (43%)	4 (57%)			

Abbreviations used: SBT, subtherapeutic; SPRT, supratherapeutic

As Anderson and colleagues have previously described, many children's weights fall outside of the recommended weight-based dosing guidelines outlined on a given acetaminophen package's Drug Facts label (7). Therefore, to ensure that a child receives a safe and effective dose, it is essential to provide additional guidance to caregivers to improve their ability to administer such a dose. As they are commonly positioned at or near the point of sale of pediatric OTC products such as acetaminophen, community pharmacists are in a unique position to provide this guidance.

In a previous study, Goldman et al. (2004) reported that approximately 41% of the caregivers visiting the emergency room had administered a lower-than-recommended dose to the child under their care, which underdosing was associated with an increase in ED visits that could have been prevented (14). Interestingly, in this study, the caregivers who under-administered acetaminophen were dispensing the liquid formulation. To the contrary, caregivers who used tablet formulations were more likely to administer an excessive dose. However, in our study, we did not observe an overall relationship between appropriate dose administration and the formulation used. Most of the caregivers we interviewed had used a cup or a syringe as a measuring device for the liquid formulation. This is an improvement from previous studies that found that caregivers commonly used non-standardized liquid dosing tools to administer medication (15). In this study, only 3% of the participating caregivers used a household device to administer the dose. Although excluded from the final analysis of this study, the following information should be noted: Approximately 10% of the caregivers who were initially interviewed could not tell the study investigators the dose that they administered, either because they did not remember or because they had guessed at the best the dose, in the first place. This is consistent with previous data (6).

Mothers were the caregivers who most frequently dosed their children with acetaminophen. However, no difference was observed between the appropriateness of dosing and the relationship of the caregiver to the child. The majority of the interviewed participants were experienced caregivers, a label given to those participating individuals who had cared for at least 1 other child in addition to the one being attended to in the ED at the time of the interview. Surprisingly, there was a positive association ($P<0.05$) between being an experienced caregiver and inappropriate dosing, suggesting that such caregivers may have a false sense of confidence when dosing a child with acetaminophen.

In addition to caregiver experience, there was a trend towards a relationship between the information source consulted and the appropriateness of dosing; however, the association was not statistically significant ($P = 0.085$). To our surprise, even though acetaminophen products for children can be obtained OTC in community pharmacies, only 9% of the caregivers had consulted a pharmacist to determine the appropriate dose. In terms of the caregivers who had consulted the Drug Fact label, more than half had, nevertheless, given an inappropriate dose. These results suggest the need for caregiver education on how to read and follow instructions on OTC labels.

As previously noted, we did not observe a relationship between the other secondary endpoints evaluated in this study (criteria for dosing, dosage form, strength, measuring device used, caregiver education, and source of consulted information) and appropriateness of acetaminophen dosing.

Limitations

The results of this study provide preliminary data on how caregivers in Puerto Rico dose acetaminophen for their children/wards. Because we performed a descriptive cross-sectional survey with a convenience sample, the results do not necessarily represent the general pediatric acetaminophen dosing practices of caregivers in Puerto Rico. However, we believe that the problems observed in caregiver dosing practices highlight the need for further research and caregiver education. Additionally, responses to a questionnaire may be limited by recall bias due to a given caregiver's limited ability to remember the specific dose that was administered.

Conclusion

Nearly half of the caregivers in this study administered an inappropriate dose of acetaminophen to their children/wards. Pharmacists and other healthcare professionals should actively participate in direct caregiver education to promote the safe and effective use of acetaminophen and other pediatric OTC products. Further study is warranted to identify and better understand the factors contributing to the inappropriate dosing of acetaminophen in pediatric patients in Puerto Rico.

Resumen

Objetivo: Evaluar si la dosis de acetaminofén administrada por los cuidadores de niños que se presentan a la sala de emergencias de un hospital pediátrico es adecuada. Métodos: Diseño: Estudio descriptivo transversal. Escenario: Sala de emergencias de un hospital pediátrico universitario en San Juan, Puerto Rico. Participantes: Ochenta y ocho cuidadores que visitaron la sala de emergencia pediátrica y que administraron una dosis conocida de acetaminofén a pacientes pediátricos bajo su cuidado durante las pasadas 24 horas. Intervención: Los cuidadores fueron entrevistados por los investigadores utilizando un cuestionario estandarizado. Resultado primario: Cuán adecuadas eran las dosis de acetaminofén administradas por los cuidadores. También se recopiló información sobre la forma de dosificación, potencia, utensilio de medición utilizado e información demográfica del cuidador. Se consideró adecuada una dosis de acetaminofén entre 10 a15 mg/kg de peso del menor. Resultados: En general, 45% de los cuidadores administraron una dosis inadecuada de acetaminofén. De estos, 70% administró una dosis sub-terapéutica y 30% una dosis

supra-terapéutica. A pesar de que el 74% de los cuidadores reportaron conocer el peso de los niños, sólo 50% lo utilizó para calcular la dosis. Administración de una dosis inadecuada fue más común en cuidadores que ya habían cuidado de otros niños (P=0.03). La mayoría de los cuidadores consultaron a un médico (40%), seguido por la etiqueta del medicamento (35%) para información sobre acetaminofén. Sólo 9% de los cuidadores reportaron consultar la dosis de acetaminofén con un farmacéutico. Conclusión: Aproximadamente la mitad de los cuidadores administraron una dosis inadecuada de acetaminofén, lo que sugiere la necesidad de una mayor educación. Debido a su accesibilidad en el punto de venta de medicamentos de venta libre y su conocimiento en farmacoterapia, los farmacéuticos pueden tener un rol activo en promover un uso seguro y efectivo de acetaminofén.

Acknowledgements

The authors would like to thank Dr. Rafael Garcia-Berdecia for his contribution to the initial study concept and Dr. Kyle Melin for his help in developing the first draft of the manuscript. This work is original and has not been published elsewhere, nor is it currently under consideration for publication elsewhere. No funding support was received from any source. The authors listed in the manuscript meet the authorship criteria established by the International Committee of Medical Journal Editors (ICMJE). All the authors have approved the manuscript for this submission.

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Appendix 1. Questionnaire used for the Data collection.

Universidad de Puerto Rico
Recinto de Ciencias Médicas
Escuela de Farmacia
Programa Doctoral

Fecha: _____ de _____ de _____

Instrucciones: Utilice las siguientes preguntas para recopilar información de cómo el cuidador dosifica acetaminofén al niño o niña.

Información del niño o de la niña						
Edad (años)	**Peso (lb)**	**Género**		**Característica utilizada para determinar dosis**		
		a. Femenino	**b**. Masculino	**a**. Edad	**b**. Peso	**c**. No sabe

Dosificación de acetaminofén

1. ¿Qué formulación de acetaminofén utilizó?
Marque todas las que aplique
_____ Suspensión oral _____ Supositorio rectal
_____ Tableta oral _____ Otra, especifique: _____

2. ¿Trae el producto de acetaminofén que utilizó?
a. Si **b**. No

	Suspensión Oral	Tableta Oral	Supositorio Rectal
Concentración o Dosis	**a**. 160mg/5mL **b**. 500mg/5mL **c**. 80mg/0.8mL **d**. No recuerdo ***e***. Otro, especifique: _____ _____	**a**. 325mg **b**. 500mg **c**. No recuerda **d**. Otro, especifique: _____ _____	**a**. 80mg **b**. 120 mg **c**. 325 mg **d**. 650mg **e**. No recuerda **f**. Otro, especifique: _____ _____
Cantidad	(mL): _____ No recuerda: ___ No se puede determinar: ___ Comentarios: _____ _____	(#): _____ No recuerda: ___ No se puede determinar: ___ Comentarios: _____ _____	(#): _____ No recuerda: ___ No se puede determinar: ___ Comentarios: _____ _____
Instrumento utilizado en suspensión	Instrumento utilizado para administrar la suspensión: **a**. Vaso que provee el empaque **b**. Jeringuilla **c**. Cuchara casera (5mL) **d**. Cuchara casera (15mL) **e**. Gotero **f**. Otro, especifique: _____		

Información del cuidador

1. Relación con el niño o niña (quien brinda la información)
a. Madre **c**. Encargado
b. Padre **d**. Otro (especifique): _____

2. ¿Quién determinó la cantidad de acetaminofén?
a. Igual a la pregunta 1 **b**. Otro (especifique): _____

Conteste las siguientes preguntas en relación a la persona que determinó la cantidad de acetaminofén.

3. Edad de la persona: _____

4. ¿Es el primer niño o niña que cuida?
a. Si **b**. No

5. Al momento de dosificar, ¿conocía el peso del niño o la niña?
a. Si **b**. No

6. Nivel de educación alcanzado:
a. No fue a la escuela
b. Grado elemental (hasta sexto grado)
c. Grado intermedio (de séptimo a noveno)
d. Grado secundario (hasta cuarto año)
e. Grado asociado/ bachillerato
f. Maestría/Doctorado

7. Fuente de información utilizada para determinar dosis
a. Etiqueta del producto
b. Orientación del médico
c. Orientación del farmacéutico
d. Información brindada por familiar o conocido
e. Adivinando