

SJP

Sarawak Journal of
Pharmacy

Journal Homepage: <http://jknsarawak.moh.gov.my/spj/>



Nurses' Knowledge on Paracetamol Dose Administration in Paediatrics: Scale Development and Validation

Sze Min LEE¹, Shirly HENG¹, Giselle Mei Peng CHAN¹, Roselind DENG², Shirly CHAI^{1,3}

¹ Pharmacy Department, Miri Hospital, Sarawak

² Paediatrics Department, Miri Hospital, Sarawak

³ Clinical Research Centre Miri, Sarawak

Corresponding author name and email: Shirly Chai (shirly_chai@yahoo.com)

ABSTRACT

Introduction: Paracetamol is widely prescribed to treat fever and pain in children. However, paracetamol poisoning can increase the risk of temporary liver dysfunction, irreversible liver failure, and even death from multiorgan failure. Acute hepatotoxicity can be induced by unintentional or intentional paracetamol overdose in paediatrics. Our study aimed to develop a tool to assess the nurses' knowledge on paracetamol dose administration in paediatrics.

Methods: We designed a questionnaire based on published literature. We performed two rounds of content validation and one round of face validation as a minor revision was required for one of the items (item 1). The content validation involved an expert panel of six senior nurses whereas the face validation involved ten raters. The content validity index (CVI) and face validity index (FVI) reflected the content validity and response process validity respectively.

Results: The item-level content validity index (I-CVI) for item 1 improved from 0.67 to 1.00 after the first round of content validation. After modification, the scale-level content validity index, based on the average (S-CVI/Ave) and universal agreement method (S-CVI/UA) indicated good content validity. All face validity indices showed good response process validity.

Conclusion: This questionnaire is shown to be valid to measure nurses' knowledge on paracetamol dose administration in paediatrics.

Keywords: Paracetamol, paediatric, nurse, validation, questionnaire

INTRODUCTION

Paracetamol was discovered over 100 years ago and has been widely used in medical practice for more than half century (1). It is an over-the-counter medication that is most widely prescribed to treat fever and pain in children. In a prospective cohort study, 95.0% of 6476 children have been exposed to paracetamol by the age of 9 months after birth (1).

McNeil Laboratories introduced paracetamol into the pharmacological market in 1955 to use as a prescribed analgesic and antipyretic drug, under the trade name of Tylenol Children's Elixir for children (2). In Great Britain, paracetamol tablets in the strength of 500mg were available over the counter after one year under the trade name of Panadol, produced by Sterling Drug Inc. (2). In Poland, paracetamol became available in 1961 and since then, it became one of the most frequently sold analgesia (2). There are about 100 preparations in the trade offer, which contain paracetamol alone or in combination with other active ingredients (2).

Paracetamol possesses analgesic and antipyretic properties as well as suppression of prostaglandin production which is similar to nonsteroidal anti-inflammatory drugs (NSAIDs). However, the exact mechanism of action of paracetamol is not completely understood. It is believed that the main mechanism of paracetamol is the inhibition of cyclooxygenase (COX) by selectively blocking a variant of COX enzyme that is different from COX-1 and COX-2. According to the Ministry of Health (MOH) Clinical Practice Guideline - Pain is the 5th Vital Sign, paracetamol or non-steroidal anti-inflammatory drugs are used for mild-moderate pain in the analgesic ladder (3).

Paracetamol is mainly metabolized by the liver to form non-toxic metabolites, which are readily eliminated in the urine. In supratherapeutic ingestion, the enzyme saturation causes an increase in the production of a toxic metabolite, N-acetyl-p-benzoquinone imine (NAPQI), which is the reactive component responsible for hepatotoxicity. In normal concentration, it is detoxified by conjugation with endogenous glutathione. However, paracetamol overdose leads to the depletion of glutathione supply, subsequently the occurrence of hepatotoxicity (4,5).

Nevertheless, paracetamol remains one of the most commonly used analgesics and antipyretics due to its excellent safety profile when administered in the recommended therapeutic dose and frequency, by not exceeding the maximum daily dose of 4g/day for adults and 60mg/kg/day for children (3). It is the first line of analgesic and antipyretic, which does not increase the risk of gastrointestinal and cardiovascular adverse effects; hence it might be suitable when NSAIDs are contraindicated.

However, according to the United States Food and Drug Administration (FDA), paracetamol was the major cause of acute liver failure in the United State from 1998 to 2003, and nearly half of hepatic failure cases during this period were due to accidental paracetamol overdose (6). The toxic dose of paracetamol for children aged between one to six years ranges between 150mg/kg and 200mg/kg, determined by the occurrence of paracetamol-induced hepatotoxicity (6). Paracetamol poisoning can cause temporary liver dysfunction, irreversible liver failure, and even death from multiorgan failure. Acute hepatotoxicity can be induced by unintentional or intentional overdose in paediatrics (7). Common reasons for unintentional overdose include accidental ingestion, suprathreshold dosing, more frequent administration than prescribed at recommended therapeutic dose, and co-administration of multiple paracetamol-containing products. Therefore, nurses' knowledge needs to be assessed to reduce the risk of a medication error, such as serving suprathreshold dosing that is due to administration of more than the maximum dose and frequency of paracetamol. Intentional paracetamol ingestions are more prevalent among older children and adolescents who potentially have suicidal intentions (8). However, hepatotoxicity induced by paracetamol are rarely reported with the dosage within the recommended therapeutic dosage (9).

Furthermore, paracetamol toxicity in paediatrics is most likely to occur with a single ingestion of paracetamol >150mg/kg or if the maximum daily dose of >75mg/kg/day is exceeded (maximum of 5 doses per day) up to 4000 mg/day from all paracetamol containing products (10, 11). Most paediatrics who overdose on paracetamol are asymptomatic initially. Hence, to determine the patients who are at risk of hepatotoxicity, the clinician should identify the time of ingestion, dosage, frequency, and formulation of paracetamol being administered. The common signs and symptoms of paracetamol toxicity include jaundice, nausea, vomiting, fatigue, confusion, marked increase of

alanine aminotransferase, and aspartate aminotransferase enzymes within 24-72 hours after ingestion (10).

A study reported that the medication error rates per 1000 patient-days were higher in paediatric units (14.8) than in adult units (5.7) (12). The rate of injury for adult patients is 1–3% while it is 3 times higher for paediatric patients, and significantly higher error rates have been reported during prescribing and administration in comparison to dispensing and monitoring (13-16). Medication prescribing and administration error rates have been reported in various studies ranging from 3.0 to 37.0% and 72.0–78.0% respectively (17-18). Therefore, the aim of our study is to develop a tool to assess nurses' knowledge on paracetamol dose administration in paediatrics, to reduce the risk of unwanted events.

METHODS

We designed a questionnaire to assess nurses' knowledge on paracetamol dose administration in paediatrics. The development and judgement phases were elaborated in the following subsections.

Development Phase

The tool development involved item generation for the knowledge domain related to the paracetamol dose administration in paediatrics. We derived the potential items for assessing the knowledge after reviewing various standard references, published literature in the field of paracetamol toxicity, and discussions with a paediatric pharmacist (4,10, 19-22). The questionnaire contained eight items related to paracetamol dose administration in paediatrics. The tested items were in Malay language and test the knowledge on dosage, frequency, and toxic effects of paracetamol overdose. Each item was provided with multiple-choice options, except for item 6, which required the calculation of the dosage of paracetamol.

Judgement Phase

Each item underwent two stages of the validation process, which included content validation and response process validation.

(a) Content Validation

The Content Validity Index (CVI) assessed the relevance of each item to the knowledge domain by a panel of experts to estimate the content validity (23). All items were given a relevance rating scale to the measured domain to determine the content validity of the items. In this study, we invited six senior nurses from paediatric wards, at Miri Hospital, to judge the degree of relevance of each item independently based on the four-rating Likert scale. The rating scale of relevance included 1 (the item is not relevant to the measured domain), 2 (the item is somewhat relevant to the measured domain), 3 (the item is quite relevant to the measured domain), and 4 (the item is very relevant to the measured domain). We conducted the validation by distributing the form to the panel experts (24). The column for inserting comments or suggestions from the panel was also provided.

We refined the items based on the panel recommendation. Ultimately, all raw ratings were gathered and entered into Microsoft Excel for data analysis. Polit et al. recommended defining each item rated 3 or 4 as valid and coding them as '1', whereas the items rated 1 or 2 as nonvalid and coded as '0' (25). We estimated various content validity indices, i.e. the item-level content validity index (I-CVI); scale-level content validity index (S-CVI); scale-level content validity index, universal agreement calculation method (S-CVI/UA); and scale-level content validity index, averaging calculation method (S-CVI/Ave). An I-CVI value of at least 0.83 determined that the items were relevant and to be retained in the questionnaire (24, 26).

The I-CVI was based on the average scoring for each item that was rated by the experts. The two calculation methods for the S-CVI included the average of the I-CVI scores for all items on the scale, S-CVI/Ave, and the proportion of items on the scale that obtain a relevance rating of 3 or 4 by all experts, S-CVI/UA. S-CVI/UA was calculated by getting the number of items that had 100.0% agreement, and divided by the total number of items in the knowledge domain. The universal agreement would facilitate the assessment of inter-rater reliability. A new tool should achieve at least 80.0% or higher agreement to be considered acceptable content validity (27). Individual item assessment and the average of each item will be taken into consideration during the data presentation.

S-CVI/Ave and S-CVI/UA were calculated by using the formulas as follows (17):

$$\begin{aligned} \text{I-CVI} &= (\text{agreed item}) / (\text{number of rater}) \\ \text{S-CVI/Ave} &= (\text{summation all I-CVI}) / (\text{number of item}) \\ \text{S-CVI/UA} &= (\text{sum of universal agreement scores}) / (\text{number of item}) \end{aligned}$$

(b) Response Process Validation

Face Validity Index (FVI) assessed the clarity of each item by raters, and estimated the response process validity (28). We invited ten nurses from the paediatric wards at Miri Hospital to provide the clarity rating for all tested items on a Likert scale ranging from 1 to 4 (from the least clarity to the easiest clarity, respectively). The scores were entered in Microsoft Excel to estimate the item-level face validity index (I-FVI); scale-level face validity index (S-FVI); scale-level face validity index, universal agreement calculation method (S-FVI/UA); and scale-level face validity index, averaging calculation method (S-FVI/Ave).

Yusoff recommended converting all items rated as 3 or 4 to '1' and items rated as 1 or 2 to '0' (28). He also suggested that the acceptable FVI cut-off score is at least 0.83 if there were 10 raters (28). The I-FVI reflected the average scoring for each item that was rated by the raters. There were two methods of S-FVI computation, i.e. the average of the I-FVI scores for all tested items on the scale (S-FVI/Ave) and the proportion of items on the scale that obtain a relevance rating of 3 or 4 by all raters (S-FVI/UA). Individual item assessment and an average of each tested item will be taken into consideration during the data presentation. The additional universal agreement facilitated the assessment of inter-rater reliability.

The S-FVI/Ave and S-FVI/UA calculation are as follows (28):

$$\begin{aligned} \text{I-FVI} &= (\text{agreed item}) / (\text{number of rater}) \\ \text{S-FVI/Ave} &= (\text{summation all I-FVI}) / (\text{number of item}) \\ \text{S-FVI/UA} &= (\text{sum of universal agreement scores}) / (\text{number of item}) \end{aligned}$$

Ethical Consideration

This study was registered in the National Medical Research Registry (NMRR ID- 22-00042-I9F(IIR)) and approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

RESULTS*Content Validity*

Table 1 shows the ratings in the initial version evaluated by a panel of six experts and Table 2 summarises the ratings for the modified version. We calculated the I-CVI for the 8 items. However, in the initial version, the acceptable universal agreement was not achieved (SCVI/UA = 0.75). In the modified version, most of the items received a relevance rating of 3 or 4 and it achieved acceptable universal agreement between the experts (S-CVI/UA =1).

In addition, the I-CVI ranged between 0.67 and 1.00 in the initial version of the content validity analysis. The I-CVI score for item 1 was 0.67, which is below the minimum acceptable cut-off of 0.83 (24). Two experts commented that the statement required modification as there were two potentially correct answer options for the question being assessed, hence it could be confusing. Therefore, we revised item 1 and the answer options to make the item clearer and more relevant. We invited the panel of experts to re-evaluate all items. The I-CVI for item 1 increased to 1.00. Both S-CVI/Ave and S-CVI/UA values for the 8 items after amendment were 1.00. Therefore, all 8 items were retained as appropriate changes have been made.

Table 1: Ratings on the Initial Version by Six Experts

	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6		Experts In agreement	I-CVI	UA
Item										
Q1	0	0	1	1	1	1		4	0.67	0
Q2	1	1	1	1	1	1		6	1	1
Q3	1	1	1	1	1	1		6	1	1
Q4	1	1	1	1	1	1		6	1	1
Q5	1	1	1	1	1	1		6	1	1
Q6	1	1	1	1	1	1		6	1	1
Q7	1	1	1	1	1	1		6	1	1
Q8	1	0	1	1	1	1		5	0.83	0
								S-CVI/ Ave	0.94	
Proportion relevance	0.88	0.75	1	1	1	1		S-CVI/ UA		0.75
Average proportion of items judged as relevance across the six experts							0.94			

Table 2: Ratings on Modified Version by Six Experts

	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6		Experts In agreement	I-CVI	UA
Item										
Q1	1	1	1	1	1	1		6	1	1
Q2	1	1	1	1	1	1		6	1	1
Q3	1	1	1	1	1	1		6	1	1
Q4	1	1	1	1	1	1		6	1	1
Q5	1	1	1	1	1	1		6	1	1
Q6	1	1	1	1	1	1		6	1	1
Q7	1	1	1	1	1	1		6	1	1
Q8	1	1	1	1	1	1		6	1	1
								S-CVI/ Ave	1	
Proportion clarity	1	1	1	1	1	1		S-CVI/ UA		1
Average proportion of items judged relevance across the six experts							1			

Response Process Validity

Ten raters took part in the response process validation and they were asked to rate the items of questionnaires in the modified version. We calculated the FVI values and summarises them in Table 3. The calculated I-FVI was 1.00 for all items, which indicated an acceptable I-FVI level. Therefore, no further modification is required (28).

Table 3: Ratings on Modified Items by Ten Raters

	Rater 1	Rater 2	Rater 3	Rater 4	Rater 5	Rater 6	Rater 7	Rater 8	Rater 9	Rater 10		Raters In agreement	I-FVI	UA
Item														
Q1	1	1	1	1	1	1	1	1	1	1		10	1	1
Q2	1	1	1	1	1	1	1	1	1	1		10	1	1
Q3	1	1	1	1	1	1	1	1	1	1		10	1	1
Q4	1	1	1	1	1	1	1	1	1	1		10	1	1
Q5	1	1	1	1	1	1	1	1	1	1		10	1	1
Q6	1	1	1	1	1	1	1	1	1	1		10	1	1
Q7	1	1	1	1	1	1	1	1	1	1		10	1	1
Q8	1	1	1	1	1	1	1	1	1	1		10	1	1
												S-FVI/ Ave	1	
Proportion clarity	1	1	1	1	1	1	1	1	1	1		S-FVI/ UA		1
Average proportion of items judged clarity across the ten raters											1			

DISCUSSION

Paracetamol is a common drug prescribed to children for fever or to reduce pain. Therefore, it is essential to ensure that healthcare personnel understand and are well equipped with the fundamental knowledge on the drug to deliver safe health care services to the patients. This is crucial to reduce the risk of unintended administration errors and paracetamol toxicity among the paediatrics. In this tool, we included the items assessing the knowledge on paracetamol dosage,

frequency, and toxic effects of paracetamol overdose. The purpose of the study is to develop a tool to assess nurses' knowledge on paracetamol dose administration in paediatrics.

We developed the tool in the Malay language as the language is more frequently used locally. The item development was based on the standard references, published literature in the field of paracetamol toxicity, and discussions with a paediatric pharmacist (4,10, 19-22). Throughout the judgement phase, a tested item in the questionnaire is modified by changing the options of the answer. We aimed to ensure the context of the items is relevant and clear to the measured domain. Besides, we would like our respondents to have acceptable clarity about all the items under the measured domain. Based on the rating by the panel of experts, the questionnaire demonstrated acceptable content validity after the modification.

The content validity process is essential in developing a new tool as this step is a prerequisite step for any other forms of validation (29,30). Content validation was conducted twice in our study due to the need to improve clarity and relevance for item 1. The modification of the questionnaire was made in item 1 (refer to Appendix A & B). In the first round of content validity, item 1 consisted of two correct answer options, i.e. age and body weight. This might confuse future respondents. Therefore, we modified the answer options. It was also noted that the I-CVI of item 8 in the initial round was 0.83 as 1 expert rated 0 for this item. However, no remarks or comments were given in the feedback column. As the I-CVI for item 8 was above the acceptable cut-off of 0.83, indicating excellent relevance (31). In the modified version, our study demonstrated S-CVI/Ave and S-CVI/UA of 1.00, indicating that the tested items were relevant to the knowledge on paracetamol dose administration. Hence, no further modification was required.

In the response process validation, the result suggested that the raters were satisfied with the tested item by using the modified questionnaire as evidenced by an S-FVI/UA of 1.00. The calculated I-FVI is 1.00 for all items, which indicated an excellent I-FVI level (28). The results demonstrated that all items in the modified version are clear and understandable. Therefore, no modification was made.

The study has several strengths and limitations. Firstly, the developed tool is practical in identifying the gap in knowledge, and subsequently, formulate solution, such as organising continuous medical education to improve the knowledge among the nurses, if necessary. Secondly, the tool could be potentially extended to other populations, such as other healthcare professionals and the general public. In addition, the study provided evidence that the questionnaire was valid in assessing nurses' knowledge on paracetamol dose administration in paediatrics. However, it provided evidence of the content and response process validity of the questionnaires. Hence, a subsequent pilot study involving the targeted respondents should be carried out in the future. Besides, this questionnaire was only useful for the person who can read and understand the Malay language. Therefore, future works may also focus on the translation of the questionnaires into other languages, to increase the scale usability internationally.

CONCLUSION

This study has shown the eight-item questionnaire for the paracetamol dose administration is a valid tool for assessing nurses' knowledge on paracetamol dose administration in paediatrics. Therefore, with further reliability tests, the tool could potentially be used to assess the nurses' knowledge on paracetamol dosing and subsequently, assist in formulating an intervention if required, to reduce the risk of unintentional paracetamol overdose or toxicity among the paediatrics.

ACKNOWLEDGMENTS

We thank the Director-General of Health Malaysia for his permission to publish this article. We would also like to express our gratitude to Ms. Amanda Koay Su Ling for providing useful insight on the item development of the tool to assess nurses' knowledge on paracetamol dose administration and all nurses who have participated in the validation.

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Appendix A: Initial items for Paracetamol Dosing Administration by Six Experts in the First Round of Content Validity.

Tested items
<p>Soalan 1: Dos Paracetamol haruslah sentiasa dikira berdasarkan ____ .</p> <p>A. Umur B. Suhu badan C. Berat Badan D. Tinggi badan</p>
<p>Soalan 2: Berapakah dos maksimum Sy. Paracetamol untuk kanak-kanak berumur kurang daripada 12 tahun?</p> <p>A. 10ml/kg QID B. 15ml/kg QID C. 10mg/kg QID D: 15mg/kg QID</p>
<p>Soalan 3: Berapakah jurang masa minimum Sy. Paracetamol boleh diberi kepada pesakit?</p> <p>A. 4 jam B. 6 jam C. 8 jam D. 12 jam</p>
<p>Soalan 4: Berapakah kekerapan maksimum Sy. Paracetamol boleh diberi kepada pesakit?</p> <p>A. 3 kali sehari B. 4 kali sehari C. 6 kali sehari D. 8 kali sehari</p>

Soalan 5:

Berapakah dos harian maksimum Sy. Paracetamol?

- A. 30 mg/kg
- B. 45mg/kg
- C. 60 mg/kg
- D. 90 mg/kg

Soalan 6:

Berapakah dos yang akan anda berikan, jika doktor preskrib Sy. Paracetamol 120mg/5ml untuk pesakit berikut:

Butiran pesakit	Dos (ml)
(a) Amir, umur 4 tahun, berat badan 16kg, Sy. Paracetamol 240 mg	
(b) Wendy, umur 11 tahun, berat badan 23kg, Sy. Paracetamol 345 mg	
(c) Ali, umur 6 tahun, berat badan 31kg, Sy. Paracetamol 465 mg	
(d) Kristy, umur 2 tahun, berat badan 15kg, Sy. Paracetamol 225 mg	

Formula pengiraan berat badan ideal:

Umur < 9 tahun: berat (kg) = (2 x umur) + 9

Umur > 9 tahun: berat (kg) = umur x 3

Soalan 7:

Berapakah dos harian maksimum Paracetamol jika Sy. Paracetamol dan Supp. Paracetamol dipreskrib bersama?

- A.30 mg/kg
- B.60 mg/kg
- C.90 mg/kg
- D.120 mg/kg

Soalan 8:

Apakah kesan toksisiti jika Paracetamol diberi secara berlebihan?

- I. Peningkatan paras ALT
 - II. Penurunan paras bilirubin
 - III. Kegagalan buah pinggang
 - IV. Hypoglysemia
 - V. Kematian
- A. I, II, III dan V
 - B. I, II, IV dan V
 - C. II, III, IV dan V
 - D. I, III, IV dan V

Appendix B: Modified Items for Paracetamol Dosing Administration by Six Experts in the Second Round of Content Validity.

Tested items
<p>Soalan 1: Dos Paracetamol haruslah sentiasa dikira berdasarkan ____ .</p> <p>A. <i>Body surface area</i> B. Suhu badan C. Berat Badan D. Tinggi badan</p>
<p>Soalan 2: Berapakah dos maksimum Sy. Paracetamol untuk kanak-kanak berumur kurang daripada 12 tahun?</p> <p>A. 10ml/kg QID B. 15ml/kg QID C. 10mg/kg QID D: 15mg/kg QID</p>
<p>Soalan 3: Berapakah jurang masa minimum Sy. Paracetamol boleh diberi kepada pesakit?</p> <p>A. 4 jam B. 6 jam C. 8 jam D. 12 jam</p>
<p>Soalan 4: Berapakah kekerapan maksimum Sy. Paracetamol boleh diberi kepada pesakit?</p> <p>A. 3 kali sehari B. 4 kali sehari C. 6 kali sehari D. 8 kali sehari</p>

Soalan 5:

Berapakah dos harian maksimum Sy. Paracetamol?

- A. 30 mg/kg
- B. 45mg/kg
- C. 60 mg/kg
- D. 90 mg/kg

Soalan 6:

Berapakah dos yang akan anda berikan, jika doktor preskrib Sy. Paracetamol 120mg/5ml untuk pesakit berikut:

Butiran pesakit	Dos (ml)
(a) Amir, umur 4 tahun, berat badan 16kg, Sy. Paracetamol 240 mg	
(b) Wendy, umur 11 tahun, berat badan 23kg, Sy. Paracetamol 345 mg	
(c) Ali, umur 6 tahun, berat badan 31kg, Sy. Paracetamol 465 mg	
(d) Kristy, umur 2 tahun, berat badan 15kg, Sy. Paracetamol 225 mg	

Formula pengiraan berat badan ideal:

Umur < 9 tahun: berat (kg) = (2 x umur) + 9

Umur > 9 tahun: berat (kg) = umur x 3

Soalan 7:

Berapakah dos harian maksimum Paracetamol jika Sy. Paracetamol dan Supp. Paracetamol dipreskrib bersama?

- A.30 mg/kg
- B.60 mg/kg
- C.90 mg/kg
- D.120 mg/kg

Soalan 8:

Apakah kesan toksisiti jika Paracetamol diberi secara berlebihan?

- I. Peningkatan paras ALT
 - II. Penurunan paras bilirubin
 - III. Kegagalan buah pinggang
 - IV. Hypoglycemia
 - V. Kematian
- A. I, II, III dan V
 - B. I, II, IV dan V
 - C. II, III, IV dan V
 - D. I, III, IV dan V