

## Indonesian pediatricians' knowledge of Rome IV criteria and their therapeutic approach to infantile colic

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### Abstract

**Background** Infantile colic is a functional gastrointestinal disorder (FGID) that occurs in approximately 20% of infants under 6 months. Even though this condition is self-limiting, inappropriate therapy affects the baby's future quality of life. Therefore, it is essential for physicians, especially pediatricians, to employ a correct diagnosis based on the currently accepted Rome IV criteria and an appropriate therapeutic approach.

**Objective** To assess the gaps in Indonesian pediatricians' understanding of infantile colic according to Rome IV criteria, their therapeutic approach in managing the condition, and associated factors.

**Methods** We randomly selected 131 pediatricians from the Jakarta Chapter of the *Indonesian Pediatric Society* to complete a questionnaire aimed at assessing their knowledge on the diagnosis of and therapeutic approach to infantile colic. The questionnaire was scored on a scale of 0 to 20. We evaluated the association between questionnaire scores and their association with several variables, including years of clinical experience, accreditation of pediatric residency institution, type of hospital, and guidelines used.

**Results** Out of the 131 pediatricians selected, 75 (57.3%) had used the Rome IV criteria. The mean knowledge score of those participants was 14.24 (SD 3.32) out of 20. Mean therapeutic approach score of all participants was 11.50 (SD 2.80) out of 16 points. There was no significant association between either knowledge or therapeutic approach score with length of clinical experience, accreditation of pediatric residency institution, hospital type, or guidelines used.

**Conclusions** Most surveyed pediatricians who have used the Rome IV criteria have fairly good knowledge of infantile colic. Overall, pediatricians also have a fairly sound therapeutic approach to infantile colic. However, with mean scores of approximately 70% of the maximum score, education is needed to improve on these areas. Knowledge of and therapeutic approach to infantile colic are not associated with length of clinical experience, accreditation of pediatric residency institution, hospital type, or guidelines used. [Paediatr Indones. 2022;62:156-65 DOI: 10.14238/pi62.3.2022.156-65 ].

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Infantile colic is one of a variety of functional gastrointestinal disorders (FGIDs) in which infants aged one to five months have long periods of inconsolable crying.<sup>1</sup> Functional gastrointestinal disorders cannot not be explained by organic, structural, or biochemical abnormalities.<sup>2</sup> Hence, the crying in infantile colic appears to have no apparent cause, making it distressing and worrisome for parents.<sup>1</sup> Without detectable abnormalities to explain the symptoms, detection of FGID is done using a guideline based on symptoms, the Rome criteria.<sup>3</sup> The Rome IV criteria were updated and revised in 2016 to assist pediatricians in diagnosing FGIDs, including infantile colic.

A recent systematic review reported that the prevalence of infantile colic was approximately 20%.<sup>4</sup> Although infantile colic itself is self-limiting in nature and rarely fatal, it does affect quality of life. Failure of well-intended physicians to address this problem correctly may create unnecessary and costly

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solutions.<sup>8,9</sup> Failed diagnosis and treatment may even exacerbate the family's emotional stress.<sup>3</sup> Inconsolable and excessive crying may frustrate the caregiver to the point of triggering 'shaken baby syndrome', a form of child abuse.<sup>10,11</sup> Around 5.6% of parents have engaged in this dangerous behavior at least once by the age of 6 months to stop their infants from crying.<sup>12</sup> The most important things to prevent such a dreadful outcome are for physicians to identify infant colic effectively and to provide treatment goals for infant colic to support and counsel the caregivers on how to best respond to their infant's crying.<sup>13,14</sup>

To our knowledge, Indonesian pediatricians' usage and understanding of Rome IV criteria with regards to infantile colic has never been reported. Therefore, this study was conducted to evaluate Indonesian pediatricians' understanding of infantile colic, with the hope that our results can serve as a basis to reduce the complexity of handling infantile colic and complement educational materials for students, specialist physician trainees, and pediatricians.

## Methods

This cross-sectional study included practicing Indonesian pediatricians in the Greater Jakarta area. Electronic questionnaires were e-mailed to subjects in June-July 2020. We included pediatricians who had been actively practicing within the last 15 years and were willing to participate; we excluded pediatric gastroenterohepatology subspecialists. The study protocol was approved by the Medical Research Ethics Committee of Universitas Indonesia Medical School.

Subjects were selected by random sampling from a list of 441 members of the *Indonesian Pediatric Society* (IPS), Jakarta Capital Region Chapter, who had completed pediatric residency from 2005 to 2019. Selected pediatricians were contacted to request their participation. After they agreed to participate, they were sent a Google link which contained both the informed consent form and the questionnaire.

The questionnaire was constructed by the team of investigators who agreed, at face value, that the instrument was a valid measure to seek the outcome of interest. For instrument reliability testing, 30 sets of results were coded in *SPSS version 20.0* software (IBM, Armonk, New York). Cronbach's alpha values

for the knowledge and therapeutic approach sections were 0.626 ( $\geq 0.6$ ) and 0.643 ( $\geq 0.6$ ), respectively, indicating that the instrument was reliable. Although not all items had a corrected item-total correlation value of more than 0.3, those items were kept because it was essential to assess the knowledge of the definition and alarm symptoms of infantile colic, as well as appropriateness of the pediatricians' management of their patients.

Questionnaire distribution was done in two phases: (1) 30 randomly-sampled participants for instrument reliability testing and (2) 140 randomly-sampled participants. After instrument validity and reliability testing was completed, we distributed the questionnaire to the 140 second-phase participants. We grouped participants by years of clinical experience (<5 vs. 5-15 years), accreditation status of the institution where they completed their pediatric specialist training program (A vs. B), hospital type (teaching vs. non-teaching hospital), and guidelines followed (Rome IV vs. non-Rome IV). Data were analyzed using *SPSS 20.0*. Since the data were not normally distributed, we used the non-parametric Mann-Whitney test to compare median questionnaire scores between groups. Descriptive statistics are expressed as medians with minimum and maximum values. A P value of <0.05 was considered as statistically significant.

## Results

Out of 140 second-phase participants, 101 returned the completed questionnaire. Combining data from the two phases of the study yielded a total of 131 participants, comprising 92 women and 39 men. The median duration of clinical experience was 7 (range 1-14) years; 30.5% of participants had less than 5 years of clinical experience. The participants were predominantly alumni of A-accredited institutions (79.6%). Most participants (80.2%) worked in non-teaching hospitals. More than half (57.3%) claimed to use Rome IV criteria to diagnose infantile colic in their daily practice, and 74% of pediatricians obtained training on infantile colic from continuing medical education (CME) (Table 1).

Out of the 131 pediatricians selected, 75 (57.3%) claimed to have used the Rome IV criteria. The mean knowledge score of those participants was 14.24 (SD 3.32) out of 20. Of all participants in the study, overall

mean therapeutic approach score was 11.50 (SD 2.80) out of 16 points.

The questionnaire items on knowledge of infantile colic, as well as the number of participants who answered each item correctly, can be seen in **Table 2**. More than 80% of the participants correctly answered 50% or more of the questions to assess knowledge on infantile colic. Item B4 was answered correctly by 97.8% of the participants. However, item B5 was answered correctly by only 14.5%. The alarm symptom most frequently identified was failure to grow (item B6), which was correctly chosen by 88.5%.

Four out of seven questions to assess the appropriateness of therapeutic approach were answered correctly by more than 80% of pediatricians; questions regarding the administration of medication and continuing to breastfeed were answered correctly by more than 90% of pediatricians. However, questions assessing the proper use of probiotic administration and changing formula milk as possible approaches were answered correctly by 39.7% and 64.9% of pediatricians, respectively (**Table 3**).

Supplementation with probiotics in infantile colic is not currently a general recommendation, although certain probiotics have been reported to have efficacy. Of 79 pediatricians who decided to give probiotics, most (82.3%) understood that not all probiotics have beneficial effects in infant colic cases. Questions on understanding the duration of probiotic supplementation and the fact that it can be given only to exclusively breastfed infants were correctly answered by 36.7% and 43% of participants, respectively (**Table 4**).

Ninety-one pediatricians considered switching formula milk for their patients with infantile colic, of whom 93.4% reasoned that they suspected a cow's milk protein allergy (**Table 5**). In addition, of the 85 pediatricians suspecting the presence of cow's milk protein allergy, only 76.5% suggested switching to extensively hydrolyzed formula (**Table 6**).

Participants' knowledge of infantile colic did not differ significantly between any of the groups. However, mean knowledge score was slightly higher in those with 5-15 years of experience compared to those with <5 years experience [14.48 (SD 3.28) vs. 14.15 (SD 2.91), respectively (P=0.388)]. Although

**Table 1.** Characteristics of study participants

Variables	(N=131)
Years of clinical experience	
<5 years	40 (30.5)
5-15 years	91 (69.5)
Accreditation status of pediatric specialist training institution (n=93)*	
A	74 (79.6)
B	19 (20.4)
Type of hospital	
Teaching hospital	26 (19.8)
Non-teaching hospital	105 (80.2)
Guideline used to diagnose infantile colic	
Rome IV	75 (57.3)
Non-Rome IV	56 (42.7)
Source of information on therapeutic approach to infantile colic	
CME	97 (74.0)
Non-CME	34 (26.0)

\*Accreditation data before the year 2011 was not accessible

**Table 2.** Participants' knowledge of infantile colic

Question items in knowledge questionnaire	Correct answers, n(%)
B1 Infant cries and fusses without obvious cause*	123 (93.9)
B2 Infant is <5 months of age when symptoms start and stop*	85 (64.9)
B3 Accompanied by mild gastrointestinal symptoms such as regurgitation or fecal incontinence+	118 (90.1)
B4 Infant is difficult to soothe, causing parents to worry*	115 (97.8)
B5 Infant cries for > 3 hours/day, for 3 days/week, within the last 1 week+**	19 (14.5)
B6 Growth is not appropriate for age	116 (88.5)
B7 Vomiting	78 (59.5)
B8 Infant is not exclusively breastfed+	121 (92.4)
B9 Distended abdomen, bloating	79 (60.3)
B10 Infant cries all night long until the next morning+	88 (67.2)

\*Items derived from Rome IV; \*\*Items derived from older criteria (Rome III); +Delusory items (false statement; answer is correct if the item was not chosen); B1 through B5 are questions on infantile colic criteria; B6 through B10 are questions on alarm symptoms

**Table 3.** Therapeutic approach to infant with infantile colic

	Question items in therapeutic approach questionnaire	Correct answers, n(%)
C1	Recommend caregivers to hold and rock the baby	105 (80.2)
C2	Massage the baby's belly in a clockwise motion	95 (72.5)
C3	Administer probiotics	52 (39.7)
C4	Administer medication to reduce the colic	125 (95.4)
C5	Administer ranitidine/omeprazole	119 (90.8)
C6	Continue to breastfeed	130 (99.0)
C7	Change the formula	65 (49.6)

**Table 4.** Consideration of probiotic supplementation for infantile colic (n=79)

	Consideration of probiotic supplementation	Correct answers, n(%)
Appropriate*	Exclusively breastfed infants	34 (43.0)
	Supplement for 3 weeks and stop although colic persists	29 (36.7)
Delusory item**	Supplement until 5 months of age, although colic has resolved	63 (79.7)
	All probiotics can be given for infantile colic	65 (82.3)

\* Answer is correct if the item was chosen

\*\* Delusory items are false statements aimed to outwit participants; answer is correct if the item was not chosen.

**Table 5.** Reason for switching formula (n=91)

Reason for switching formula	Correct answers, n(%)
Suspicion of allergy, poor response to standard treatment, history of allergy	85 (93.4)
Frequent vomiting	25 (27.5)
Failure to thrive	36 (39.6)
Bloating	44 (48.4)

\* Answer is correct if the item was chosen

\*\* Delusory items are false statements aimed to outwit participants; answer is correct if the item was not chosen.

**Table 6.** Types of formula used in infantile colic with suspected cow's milk protein allergy type of formula (n=85)

Reason for switching formula	Correct answers, n(%)
Formula with extensively hydrolyzed protein*	65 (76.5)
Formula with partially hydrolyzed protein**	34 (40.0)
Formula containing amino acids**	29 (34.1)
Formula with soy content**	10 (11.8)
Formula with low lactose content**	21 (24.7)

\*Answer is correct if the item was chosen

\*\*Delusory items are false statement aimed to outwit the participants; answer is correct if the item was not chosen

the number of pediatricians who used the Rome IV criteria as their guideline to manage infantile colic was higher than those who used other guidelines, their level of knowledge of Rome IV was slightly lower [14.24 (SD 3.32) vs. 14.57 (SD 2.97), respectively (P=0.677)] (Table 7). The other guidelines referred to included the ESPGHAN and NASPHGAN guidelines,

information from web searches, CME, or pediatric residency training.

There was no significant difference in therapeutic approach between pediatricians with <5 years and 5-15 years of clinical experience, although those with <5 years of clinical experience had a slightly higher knowledge score [12.10 (SD 2.93) vs. 11.23 (SD 2.71),

respectively (P=0.085)] (Table 8). Likewise, there was no significant difference in therapeutic scores between those who received colic information from non-CME sources vs. CME sources, although median score was higher in the former [12 (range 6-16) vs. 10 (range 6-16), respectively (P=0.252)].

## Discussion

To our knowledge, no previous studies in Indonesia have assessed the prevalence of pediatricians' use of the Rome IV diagnostic criteria for infant colic. We found that, four years after the Rome IV criteria were published, 75/131 (57.3%) pediatricians claimed to use it in daily practice. However, our sample size was

small and limited to the Jakarta chapter of the IPS; the prevalence rate may differ from that in other regions of the country. The mean knowledge score of the 75 pediatricians claiming to use Rome IV was 14.24 (SD 3.32) out of a total score of 20 (Table 7), indicating that although more than half of subjects were familiar with the diagnostic tool, there is still much room for improvement.

In a study on medical doctors' knowledge of basic epidemiological and research methods, Novack et al. showed that newer graduates had higher scores.<sup>50</sup> However, in the present study there was no significant association between knowledge of pediatricians and whether they completed their residency before or after the Rome IV criteria were published. In fact, as shown in Table 8, pediatricians with 5-15 years of experience had

**Table 7.** Association between knowledge of infantile colic and participants' characteristics

Variables	Knowledge score		P value
	Median (range)	Mean (SD)	
Years of clinical experience			0.388*
<5	n=40	14 (4-20)	14.15 (2.91)
5-15	n=91	14 (4-20)	14.48 (3.28)
Accreditation of pediatric training institution (N=93)			0.571*
A	n=74	14 (4-20)	14.68 (2.93)
B	n=19	14(4-18)	14.11 (3.43)
Hospital type			0.911*
Teaching hospital	n=26	14 (4-20)	14.38 (3.30)
Non-teaching institution	n=105	14 (4-20)	14.38 (3.15)
Source of information			0.677*
Rome IV	n=75	14 (4-10)	14.24 (3.32)
Non-Rome IV	n=56	14 (6-20)	14.57 (2.97)

\*Mann-Whitney test

**Table 8.** Association between subjects' characteristics and therapeutic approach score

Variables	Therapeutic approach score		P value
	Median (range)	Mean (SD)	
Years of clinical experience			0.085*
<5	n=40	12 (6-16)	12.10 (2.93)
5-15	n=91	12 (6-16)	11.23 (2.71)
Accreditation of pediatric training institution (N=93)			0.209*
A	n=74	12 (6-16)	11.62 (2.84)
B	n=19	10 (6-16)	10.74 (2.60)
Place of practice			0.809*
Teaching hospital	n=26	11 (6-16)	11.62 (3.05)
Non-teaching institution	n=105	12 (6-16)	11.47 (2.75)
Source of information			0.252*
CME	n=97	10 (6-16)	11.34 (2.85)
Non-CME	n=34	12 (6-16)	11.94 (2.63)

\*Mann-Whitney test

a slightly higher mean therapeutic score of 14.48 (SD 3.28) compared to 14.15 (SD 2.91) in the group with <5 years of experience. As information technology becomes increasingly accessible, CME, journals, and social media allow exchange of information that narrows the differences in pediatricians' knowledge. So, even though Rome IV had been published after they had completed their residency, the older group was able to keep up with the updates by reading books and journals as well as attending CME.

Beasley *et al.*<sup>51</sup> reported that the numerous standards in institution accreditation may not translate to implementing such standards into appropriate clinical practice outcome. Accreditation standards are always changing in order to improve educational quality.<sup>52</sup> Such disparities in standards may explain why no significant association was found between pediatric specialty training institution accreditation level (A vs. B) and the knowledge of pediatricians. Our findings suggest that information on infantile colic received during pediatric residency training were of good quality and similar in both A and B accredited institutions, as both groups had similar scores.

In China, Bai *et al.*<sup>46</sup> found that doctors in tertiary hospitals had better knowledge about the use of antibiotics, while those working in primary healthcare facilities had the lowest scores. They attributed this to the fact that in tertiary hospitals, doctors may have a greater opportunity to participate in research and attend conferences. In contrast, in our study, knowledge was not associated with the type of hospital where participants practiced. Although most of the pediatricians in our study worked in non-teaching institutions, they engaged in CME, particularly with regards to infantile colic.

As shown in **Table 7**, there was no significant difference between the pediatricians' knowledge and the guidelines on infantile colic followed (Rome IV vs. non-Rome IV). Most pediatricians in our study often failed to distinguish the difference between Rome III and Rome IV criteria, as shown in **Table 3**. Item B5 pertains to Wessel's criteria, an item in Rome III, which is no longer included in Rome IV. We purposely added this delusory item to the questionnaire. In a worldwide survey and expert consensus, 'colicky infants' were of a greater prevalence than those who met the more formal criteria such as that of Wessel.<sup>4,5</sup>

Infants who were several dozen minutes short of fulfilling the formal criteria may have been mistakenly diagnosed with something else, creating a false, lower prevalence of infantile colic.<sup>6</sup> This error was one of the justifications for omitting Wessel's criteria in the newer Rome IV criteria.<sup>3</sup> Since the Rome IV criteria for infantile colic is a 'must include all'-criteria, pediatricians who thought that the Wessel's specific 'rule of three' was still in use may have been unable to properly detect infantile colic cases. As such, infantile colic cases may have been underreported by pediatricians in Jakarta. Hence, pediatricians must be aware of the changes in Rome IV, in order to more accurately diagnose infantile colic. Moreover, the insertion of delusory items are critical to questionnaire development to detect more objective results.

One of the most important aspects of infantile colic management is parental reassurance and education. As long as no organic disease is suspected, no medication is needed. Inability to acknowledge this makes infants with colic susceptible to irrational drug use.<sup>22,45</sup> Physicians with more years of experience usually have a greater exposure to different medications and outcomes, resulting in an informal-personal medicine list that may conflict with new guidelines.<sup>49</sup> Despite this claim, a systematic review reported an inconclusive association between clinical years and performance outcomes, but they concluded that doctors who had been practicing longer usually had a lower risk of providing poorer quality of care.<sup>53</sup>

We found no significant association between subjects' therapeutic approach and length of clinical experience, however, the mean score of the group with 5-15 years of experience was slightly higher compared to that of the group with <5 years of experience (**Table 8**). This result may indicate that pediatricians are currently exposed to myriad of information sources to improve their skills, not only from the institution where they trained, but also from periodic CME meetings, as well as journals and other electronic media. Our subjects who graduated 5 to 15 years ago still updated their knowledge of infantile colic, which was reflected in the similar therapeutic approach scores between the two groups. However, neither result was optimal.

Although past studies have concluded that pediatric residency training institution accreditation may have different standard measures according to

year, linking accreditation standards with performance outcomes remains a challenge.<sup>51,52</sup> Despite the absence of significant differences in therapeutic scores between subjects trained in A- and B-accredited institutions, neither had optimal scores, with median scores of 10 and 12, respectively, out of a total of 16 points. In Indonesia, professional organizations are responsible for increasing post-graduate practice quality.

We found no significant difference in therapeutic approach scores between pediatricians who worked in a teaching hospital, where there is expected to be greater opportunity to update knowledge and practice skills with patients, compared to those working in a non-teaching hospital, clinic, or private practice.<sup>46</sup> Type of healthcare facility did not hinder subjects' therapeutic approach skills, since scientific information and guidelines regarding therapeutic approaches can be obtained from various reliable sources, such as CME, medical journals, and from various media, including electronic media. Ideally, pediatricians who understand the diagnostic criteria of a disease should also know how to appropriately manage the condition. More correct answers regarding treatments were obtained from doctors who knew the diagnostic criteria. The Rome IV criteria published guidelines only on diagnosing functional gastrointestinal disorders, including infantile colic, not therapeutic approaches. Interactive and well-designed CME is one key to effective experience sharing and was even associated with more appropriate treatment intervention.<sup>54,55</sup> Nevertheless, we noted no significant differences in therapeutic scores between pediatricians who used CME or non-CME sources ( $P=0.252$ ; **Table 8**). Information on therapeutic approaches to infantile colic can currently be obtained from a myriad of resources, such as either offline or online CME, other guidelines (*NAPSGHAN*, *ESPGHAN*), medical journals, or even scientific information circulating electronic media.

Regarding the pediatricians' approach, a large percentage understood that medications are not necessary to manage infant colic, as shown by items C4 and C5 in **Table 3**. The use of probiotics has gathered some interest. Probiotic supplementation has been reviewed in a number of meta-analyses and was shown to be effective in exclusively breastfed colicky infants. However, probiotic supplementation has not formally been made a recommendation, including

by the IPS.<sup>37,56,57</sup> Moreover, if a pediatrician decided to give probiotic treatments, not all probiotics are appropriate. The regimen is very specific in type and administration, is only effective when administered to exclusively breastfed infants, and must be stopped after 3 weeks if there is no notable response.<sup>56-58</sup> Most of these requirements were misunderstood by pediatricians who used probiotic treatments (Item C3, **Table 3**). Of the 79 subjects who prescribed probiotic treatments, most lacked knowledge about the appropriate requirements. There were also a number of pediatricians who decided to change type of formula for inappropriate reasons (**Table 5**). A formula change should be considered if the baby does not respond to standard treatment and clinical findings support signs of allergy. As such, the first choice and most appropriate formula type would be extensively hydrolyzed formula.<sup>59</sup> **Table 6** shows that there were still misunderstandings in this regard, which may have resulted in ineffective treatment and wasted resources.<sup>3,45</sup>

In conclusion, there is still room for improvement of pediatricians' knowledge regarding infantile colic according to Rome IV criteria and therapeutic approach. Since the Rome IV criteria do not discuss therapeutic approaches in detail, the ability to diagnose infant colic according to Rome IV does not always guarantee that the pediatrician can provide an appropriate therapeutic approach.

## Conflict of interest

None declared.

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