

Current management of children with acute otitis media: a feasibility survey for a pragmatic study

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Abstract

Background Acute otitis media (AOM) is a common self-limiting infection where antibiotics confer limited benefit. Other treatments, such as anti-inflammatory agents have been proposed as an alternative to antibiotics, but no high-quality clinical trials have tested this.

Objective To identify current AOM management practices among Indonesian clinicians. We also required this information for our proposed corticosteroids clinical trial for AOM.

Methods This cross-sectional study surveyed a convenience sample of general practitioners (GPs), pediatricians, and Ear-Nose-Throat (ENT) specialists in Jakarta, Depok, and Bekasi. We addressed their current AOM management practices and willingness to participate in a future trial on corticosteroids.

Results We distributed 2,694 questionnaires through conferences, primary care/hospital visits, and by mail-list group. Of 492 questionnaires received (response rate 18%), 352 were from eligible clinicians. Most clinicians diagnosed AOM by using an otoscope (64-91%). Tympanometry was used by a quarter of ENT specialists. Amoxicillin-clavulanate was the most common antibiotic for AOM, prescribed by pediatricians and ENT specialists, whilst most GPs prescribed amoxicillin. Clinical scenarios indicated most ENT specialists (88%) would prescribe antibiotics and most pediatricians (54%) would choose expectant observation by withholding antibiotics for mild AOM. Almost half of clinicians would consider using corticosteroids in a trial.

Conclusion Most clinicians would prescribe antibiotics for mild AOM. However, slightly over half of pediatricians would solely choose expectant observation. Adequate numbers of potential participating clinicians, who would consider using corticosteroids, make our proposed corticosteroids trial for AOM feasible. We found gaps between clinical practice and evidence requiring further investigation to improve AOM management in Indonesia. [Paediatr Indones. 2019;59:303-17; doi: <http://dx.doi.org/10.14238/pi59.6.2019.303-17>].

Keywords: *otitis media; acute disease; anti-bacterial agents; health services; survey and questionnaires*

Antibiotics are commonly used for treating infectious diseases, including acute otitis media (AOM) in children.^{1,2} International guidelines recommend expectant observation for mild AOM, with antibiotics only given for severe cases.^{3,4} Although antibiotics are effective for AOM, their effects in improving pain and middle ear effusion are weak, they have potentially harmful side effects, and may lead to antibiotic resistance.^{5,6} Currently, there are two conflicting Indonesian guidelines for AOM. One recommends antibiotics for both mild and severe AOM, while the other recommends antibiotics only for severe cases (although 'severe' is not clearly defined).^{7,8} This potentially contributes to high use of antibiotics in the management of AOM in Indonesia, thereby

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increasing the risk of antibiotic resistance and other side effects.^{5,9,10} Finding alternative treatment options could be one way to mitigate the risk of antibiotic resistance. Theoretical considerations suggest that the anti-inflammatory effect of corticosteroids might reduce symptoms.¹ Conflicting evidence on the potential benefits requires a large randomized placebo-controlled trial (RCT) to test efficacy.^{12,13} We plan to undertake a large RCT in Indonesia to further investigate this issue.

To date, there is no available data on the current AOM management for children in Indonesia. However, there have been several studies surveying the management of AOM in other countries.¹⁴⁻¹⁶ A survey study in Turkey showed pediatricians were likely to prescribe antibiotics (60%) and analgesics (e.g., acetaminophen, ibuprofen) for children with AOM.¹⁴ Surveys in India and Israel showed most ENT specialists prescribed antibiotics for AOM (62-98%). Analgesics and decongestants and/or antihistamines were also commonly prescribed. Most ENT specialists in India used an otoscope as a diagnostic tool for AOM, whilst a microscope was more preferable in Israel.^{15,16}

We identified the current management, particularly with regards to prescribing antibiotics for AOM in three cities in Indonesia. This survey study was done to help us identify existing gaps between clinical practice and evidence in the management of AOM in Indonesia. Our survey was also designed to gauge clinicians' willingness to use corticosteroids in a future, randomized trial.

Methods

This study primarily aimed to identify the current management of AOM among clinicians. It also identified the feasibility of a proposed clinical trial to test corticosteroids for AOM in children. We conducted a cross-sectional study for our survey (April - August 2016). Our eligibility criteria were clinicians from three specialties (general practitioners, pediatricians, and ENT specialists) working in primary/secondary or tertiary healthcare facilities in Jakarta, Depok, and Bekasi, Indonesia. We established clinicians' specialties and email addresses from the national professional organizations of general

practitioners (*Indonesian Medical Association*), pediatricians (*Indonesian Pediatric Society*), and ENT specialists (*Indonesian Otorhinolaryngology Head and Neck Surgery Society*). We then distributed paper-based questionnaires through workshops, conferences, primary healthcare and hospital visits. We also distributed electronic-based questionnaires through mailing lists of primary care clinician graduates from two medical schools in Jakarta (*Universitas Indonesia* and *Universitas Pembangunan Nasional Veteran*), identified by alumni and colleagues.

We invited participation in a 10-minute presentation at the following workshops and conferences: (i) The Indonesian National Committee for the Prevention and Management of Hearing Impairment and Deafness Meeting (20 May 2016), (ii) The Continuing Professional Development Program: The Comprehensive Management of Vestibulocochlear Disorders (20-21 May 2016), (iii) The Third Neurotology Update Management: Hearing and Vestibular Disorders in Children (21 May 2016), (iv) The Annual Scientific Meeting of the Indonesian Medical Association (27-29 May 2016), and (vi) The Second Jakarta Pediatric Respiratory Forum (29-30 May 2016). We distributed the questionnaires at the registration table on the first day of the workshops or conferences and collected the questionnaires at the end of the events.

We identified several primary healthcare clinics and hospitals located in Jakarta, Depok, and Bekasi that were conveniently accessible. We contacted the heads or directors of the appointed healthcare facilities and distributed the questionnaires to the emergency, pediatric, and otorhinolaryngology departments. We collected the questionnaires at most 4 weeks after their distribution, unless completed earlier.

Consenting clinicians typically completed the questionnaires in 10-20 minutes (**Appendix 1**). It had 3 sections: 1) current management of AOM in children, including diagnostic treatment items; 2) 3 clinical scenarios [(a.) a child aged < 2 years with mild AOM; (b.) a child aged ≥ 2 years with mild AOM; and (c.) an older child with recurrent and bilateral AOM] in which respondents were invited to describe their management (**Table 1**); and 3) a feasibility survey to identify the number of pediatric AOM patients and clinicians who might be willing to participate in our clinical trial on corticosteroids as an alternative treatment for AOM.

We did not formally determine a sample size estimate. We used convenience sampling based on ease of accessibility to the healthcare facilities and clinicians who attended workshops and conferences specifically for general practitioners, pediatricians, and ENT specialists. The results of this study are reported as the percentage of clinicians in each category of responses. We used Chi-square test to identify the differences between specialty groups using *IBM SPSS Statistics 23* software. All proportions are expressed from respondents who answered that question in the questionnaires.

This study protocol was reviewed and approved by the Ethics Committee of the Universitas Indonesia Medi-

cal School and Bond University Human Research Ethics Committee. We provided a paper- and electronic-based information sheet and consent form to all respondents. Consent was received in written form and the consent process was free of coercion. All information obtained from the respondents was treated as confidential.

Results

Of 2,694 questionnaires distributed, 492 were returned (response rate 18%). Of these, 445 (90%) participated in the survey, **Figure 1**. There were 352

Table 1. Clinical scenarios and their interpretation

Clinical scenarios	Interpretation/diagnosis	Treatment recommendation ³
Clinical scenario 1: “A one-year old boy, accompanied by his mother, came to your practice with a complaint of pain in his left ear for one day. The pain was not severe. He has had a cold for the last two days with a mild fever. At the physical examination, he looked well and alert with temperature 37.8°C. At his ear, nose, and throat examination, there was mucous discharge on the nasal cavities, and his throat looked normal. An otoscopic examination showed redness and bulging tympanic membrane of the left ear.”	A young child (aged < 2 years) with mild AOM	Expectant observation (begin antibiotics if child worsens or fails to improve within 48 to 72 hours of AOM onset) OR antibiotic therapy if close observation and follow-up cannot be ensured.
Clinical scenario 2: “A four-year old girl, accompanied by her parents, came to your practice with a complaint of pain in her right ear for one day. She has had a cold for the last four days. She had no fever. At the physical examination, the patient looked well and alert. At her ear, nose, and throat examination, there was serous secretion in the nasal cavities and her throat looked normal. An otoscopic examination showed redness and bulging tympanic membrane of the right ear.”	An older child (aged ≥ 2 years) with mild AOM	Expectant observation (begin antibiotics if child worsens or fails to improve within 48 to 72 hours of AOM onset) OR antibiotic therapy if close observation and follow-up cannot be ensured.
Clinical scenario 3: “A five-year old girl, accompanied by her parents, came to your practice with a complaint of pain in her right ear for one day, followed by left ear this morning and she had a mild fever. She had experienced acute otitis media in her right ear one month ago. At the physical examination, the patient looked well and alert with temperature 36.8°C. At her ear, nose, and throat examination, there was minimal serous discharge in her nasal cavities and her throat looked normal. An otoscopic examination showed redness and bulging on both tympanic membranes.”	An older child with recurrent bilateral AOM	Expectant observation (begin antibiotics if child worsens or fails to improve within 48 to 72 hours of AOM onset) OR antibiotic therapy if close observation and follow-up cannot be ensured. However, this guideline does not specify the need of antibiotics for recurrent AOM.

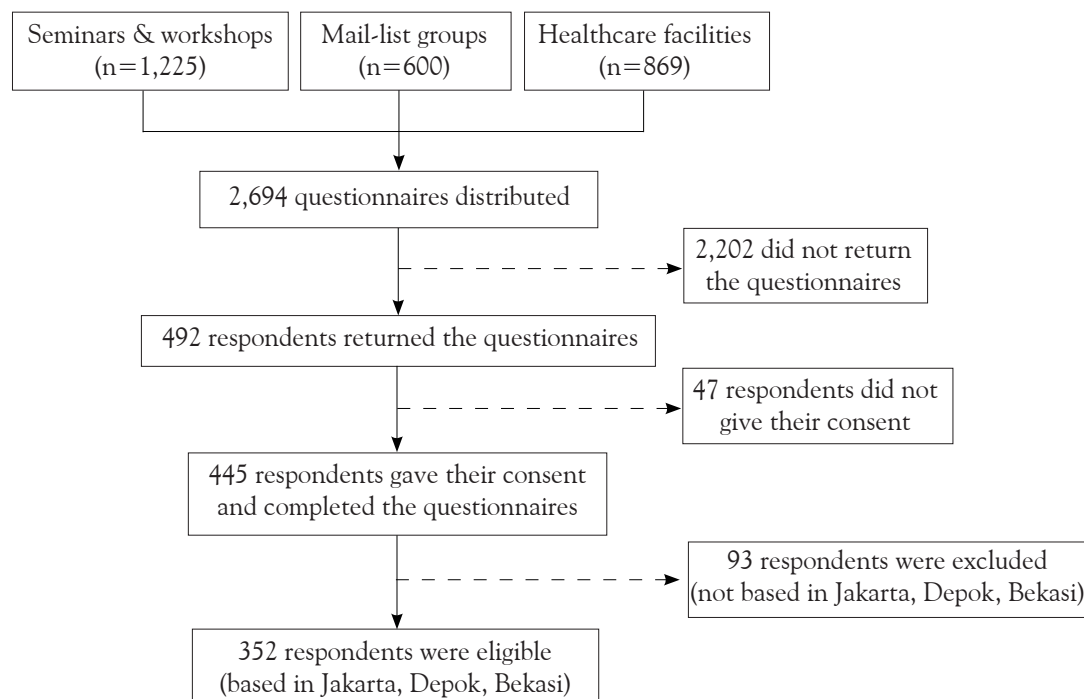


Figure 1. A flow diagram of study recruitment

clinicians who responded (general practitioners 81%, pediatricians 10%, and ENT specialists 9%) and they were based at primary/secondary (44%) and tertiary healthcare (54%) facilities (no response 2%) in Jakarta (82%), Depok (10%), and Bekasi (8%), our target regions. Most were young, <31 years (44%), and female (67%).

A total of 705 children with AOM visited 352 clinicians over a period of seven days prior to answering the questionnaire. Most clinicians had less than three AOM cases during this period (75%), and most of these children were between two and five years of age. ENT specialists had more AOM cases (three to five cases) per week compared to general practitioners and pediatricians.

Most clinicians diagnosed AOM by using an otoscope (64-91%) (Table 2). Three quarters of ENT specialists and 9% of general practitioners used an endoscope. Pediatricians did not use an endoscope. A quarter of ENT specialists, but very few pediatricians (3%) or general practitioners (1%), used tympanometry to identify middle ear effusion. Few clinicians (0-6%) used a pneumatic otoscope, audiometry (0-9%), or tympanocentesis (0-3%) to diagnose AOM.

Amoxicillin-clavulanate was the most common antibiotic prescribed by ENT specialists (58%), pediatricians (46%), and general practitioners (16%) (Table 2). Amoxicillin was the second most common antibiotic prescribed by general practitioners (43%) and pediatricians (37%), whilst ENT specialists prescribed cefixime as the second common antibiotics for AOM (23%). Azithromycin (0-13%), cefadroxil (0-9%), erythromycin (3%), ampicillin (0-3%), and cotrimoxazole (0-3%) were the least common antibiotics prescribed for AOM. General practitioners (66%) mostly prescribed amoxicillin for three to five days, whilst ENT specialists (56%) and pediatricians (54%) prescribed amoxicillin-clavulanate for more than five days.

The clinicians' treatment choices for the three clinical scenarios are shown in Table 3. In the first scenario, 88% of ENT specialists would prescribe antibiotics for AOM, followed by general practitioners (71%) and pediatricians (57%). More ENT specialists (44%) would prescribe corticosteroids when compared to other specialties (general practitioners 30%; pediatricians 23%). In the second scenario, 66% of ENT specialists would prescribe antibiotics, followed by general practitioners (52%) and pediatricians

Table 2. The common diagnostic tools and type of antibiotic prescribed among clinical specialties

Management	General practitioners* (Total=284), n(%)	ENT specialists (Total=32), n (%)	Pediatricians (Total=35), n(%)
Diagnostic examination			
Otoscope	183 (64)	29 (91)	24 (69)
Penlight/headlamp	159 (56)	9 (28)	20 (57)
Endoscope	25 (9)	24 (75)	0 (0)
Tympanometry	2 (1)	8 (25)	1 (3)
Tuning fork	10 (4)	4 (13)	0 (0)
Pneumatic otoscope	8 (3)	0 (0)	2 (6)
Tympanocentesis	1 (1)	3 (9)	0 (0)
Audiometry	4 (1)	1 (3)	0 (0)
Type of antibiotics**			
Amoxicillin-clavulanate	46 (16)	18 (58)	16 (46)
Amoxicillin	122 (43)	0 (0)	13 (37)
Cefixime	34 (12)	7 (23)	2 (6)
Azithromycin	4 (1)	4 (13)	0 (0)
Cefadroxil	26 (9)	0 (0)	0 (0)
Erythromycin	9 (3)	1 (3)	1 (3)
Ampicillin	4 (1)	0 (0)	1 (3)
Cotrimoxazole	8 (3)	0 (0)	0 (0)
Others	6 (2)	0 (0)	0 (0)
More than one	22 (8) [†]	1 (3) [‡]	2 (6) [§]

*One missing data in general practitioner group

**Total 281 general practitioners and 31 ENT specialists provided their options of antibiotic types for AOM

[†]General practitioners chose amoxicillin (77%, 17/22), followed by cefixime (32%, 6/22) and cefadroxil (32%, 6/22) in the multiple antibiotic prescription group.

[‡]ENT specialist did not mention any antibiotic by name but only reported 'depends on the condition'.

[§]Pediatricians chose cefixime (100%, 2/2), followed by amoxicillin (50%, 1/2) and amoxicillin-clavulanate (50%, 1/2) in the multiple antibiotic prescription group.

Table 3. Treatment options for three clinical scenarios among all specialties

Treatment options	Scenario 1 A young child (aged < 2 years) with mild AOM, n(%)				Scenario 2 An older child (aged ≥ 2 years) with mild AOM, n(%)				Scenario 3 An older child with recurrent bilateral AOM, n(%)			
	GP (n=283)	ENT (n=32)	PED (n=35)	Overall (n=350)	GP (n=280)	ENT (n=32)	PED (n=35)	Overall (n=347)	GP (n=279)	ENT (n=32)	PED (n=35)	Overall (n=346)
	Expectant observation	140 (49)	8 (25)	20 (57)	168 (48)	136 (49)	9 (28)	17 (49)	162 (47)	132 (47)	8 (25)	16 (46)
Antibiotics	200 (71)	28 (88)	20 (57)	248 (71)	147 (52)	21 (66)	16 (46)	184 (53)	170 (61)	27 (84)	20 (57)	217 (63)
Corticosteroids	85 (30)	14 (44)	8 (23)	107 (31)	73 (26)	12 (37)	7 (20)	92 (27)	95 (34)	14 (44)	11 (31)	120 (35)
Acetaminophen	217 (77)	19 (59)	31 (89)	267 (76)	151 (54)	12 (37)	22 (63)	185 (53)	128 (46)	13 (41)	18 (51)	159 (46)
Ibuprofen	49 (17)	9 (28)	8 (23)	66 (19)	74 (26)	11 (34)	9 (26)	94 (27)	78 (28)	9 (28)	13 (37)	100 (29)
Decongestant/ antihistamine	201 (71)	29 (91)	24 (69)	254 (73)	222 (79)	30 (94)	29 (83)	281 (81)	145 (52)	29 (91)	21 (60)	195 (56)
Topical antibiotics	71 (25)	2 (6)	7 (20)	80 (23)	69 (25)	2 (6)	6 (17)	77 (22)	73 (26)	2 (6)	11 (31)	86 (25)
Topical analgesics	32 (11)	0 (0)	4 (11)	36 (10)	33 (12)	1 (3)	3 (9)	37 (11)	41 (15)	1 (3)	5 (14)	47 (14)
Physiotherapy	18 (6)	2 (6)	2 (6)	22 (6)	19 (7)	1 (3)	4 (11)	24 (7)	17 (6)	1 (3)	1 (3)	19 (6)

*Clinicians may choose more than one treatment option

(46%). Thirty-seven per cent of ENT specialists and only up to quarter of general practitioners (26%) and pediatricians (20%) would choose corticosteroids. In the third scenario, 84% of ENT specialists would prescribe antibiotics for AOM, followed by general practitioners (61%) and pediatricians (57%).

Corticosteroids were more likely to be prescribed by ENT specialists (44%) compared to other specialties (general practitioners 34%, pediatricians 31%).

Clinicians would mostly prescribe acetaminophen (59-89%), decongestant/antihistamine (69-91%), and antibiotics (57-88%) for a young child with

mild AOM (Scenario 1) compared with other treatment (e.g., ibuprofen, corticosteroids, topical antibiotics, or topical analgesics). From all clinical scenarios, ENT specialists were more likely to prescribe corticosteroids (37-44%) and were less likely to choose expectant observation (25-28%), whereas pediatricians (46-57%) followed by general practitioners (47-49%) were more likely to choose expectant observation compared to ENT specialists. However, as clinicians may choose more than one treatment for the clinical scenario section, there were respondents who chose both expectant observation and antibiotics, which by definition should be mutually exclusive. By identifying those who solely chose expectant observation by withholding antibiotic treatment, pediatricians (43-54%) were still more likely to choose expectant observation compared to other specialties in all three scenarios. The rate of corticosteroid prescribed by pediatricians and general practitioners ranged from 20% to 34% across the three scenarios. A significant difference between specialty groups was identified in the first scenario, where pediatricians were significantly less likely to prescribe antibiotics ($P=0.024$) compared to general practitioners and ENT specialists, and in the third scenario where ENT specialists were more likely to prescribe antibiotics ($P=0.026$) compared to other specialties. With regards to prescribing antibiotics in each scenario among these specialties, ENT specialists were more likely to prescribe antibiotics compared to other specialties, particularly in the first and third scenarios.

As shown in **Figure 1**, of the 352 clinicians from Jakarta, Depok, and Bekasi, 171 respondents (49%) indicated their willingness to participate in our proposed clinical trial testing corticosteroids as an alternative treatment for AOM in children. Their characteristics were similar to the whole survey sample. They managed 443 children with AOM in a week. Most clinicians had less than three cases of AOM during this period (75%), with most of these children aged older than five years. ENT specialists had more AOM cases (three to five cases) per week compared to other specialties. These clinicians had a similar practice in the management of AOM and responses to clinical scenarios to the whole sample. Up to 44% of clinicians, mostly ENT specialists, would consider using corticosteroids in a trial.

Discussion

Our sample of clinicians who worked in Jakarta, Depok, and Bekasi, reported that they mostly diagnosed AOM by using an otoscope. Most general practitioners would prescribe amoxicillin for a short duration (3-5 days), whilst ENT specialists and pediatricians were more likely to prescribe amoxicillin-clavulanate for a longer duration. Clinical scenario results showed there was a high rate of antibiotics prescribed for mild AOM. Up to 44% of clinicians would have prescribed corticosteroids for children with AOM. Both corticosteroids and antibiotics were mostly prescribed by ENT specialists in the scenarios. There is no clear justification for a high rate of antibiotic prescribing by ENT specialists. As ENT specialists saw more patients with AOM in the sampled week compared to other specialties, their contribution to antibiotic prescribing would be higher and, therefore, the risks correlated with antibiotic use, such as adverse events and antibiotic resistance would be increased.^{5,9,10} Another reason for this high use was due to potential complications following AOM, such as spontaneous perforation of the tympanic membrane (15%) and persistent middle ear effusion (25%).^{17,18} High rates of antibiotic prescribing by general practitioners might be influenced by the Indonesian practice guideline recommending antibiotics for both mild and severe AOM.⁷ Interestingly, we found pediatricians were less likely to prescribe antibiotics for all scenarios in the study. One potential justification for this was that international pediatrics practice guidelines do not recommend antibiotics for common colds and only recommend antibiotics for AOM with high risks (e.g., children with severe signs and symptoms, children < 2 years with bilateral AOM, or tympanic membrane perforation).^{3,4,19} Corticosteroids and antibiotics were more likely to be prescribed for AOM in younger children and recurrent bilateral AOM. These are not entirely in accordance with the guidelines, as corticosteroids have not been recommended by any guidelines. The guidelines only recommend the use of antibiotics for children under two years of age with bilateral AOM, whilst our scenario was a case of unilateral AOM.³

Unfortunately, few clinicians (<7%, and none of the ENT specialists) used pneumatic otoscopy, which enables the assessment of tympanic membrane

mobility.^{3,20} A systematic review showed that a pneumatic otoscope performed by a skilled clinician can accurately diagnose AOM with high predictive values. It can replace tympanometry as one diagnostic tool for AOM, as the pneumatic otoscope is a more affordable.²¹ Our clinical scenarios demonstrated that most clinicians would prescribe antibiotics over expectant observation for mild AOM. Evidence recommends expectant observation with sufficient pain management for mild AOM.^{3-5,9} Only 30% of AOM cases are severe and require antibiotic treatment.^{5,9} However, antibiotic prescribing rates for AOM in developed and developing countries are still relatively high. In terms of data from general practices in Australia over five years, 89% of new AOM cases were managed with antibiotics.²² Meanwhile, data from the *National Ambulatory Medical Care Survey* (NAMCS) demonstrated 83.1% of children with isolated AOM were managed with antibiotics.²³ Our study demonstrated that up to 88% of clinicians would prescribe antibiotics for a mild case of AOM. *The Indonesian Practice Guideline* recommends antibiotics for both mild and severe AOM, which may influence the high rate of antibiotic prescribing for AOM in Indonesia.⁷ A red and bulging tympanic membrane could be the other reason for antibiotic treatment in all scenarios. However, the sign of red tympanic membrane is not sensitive (18%), with a low likelihood ratio for a positive result of 1.1, regardless of its high specificity (84%). Although a bulging tympanic membrane will help make the diagnosis, it requires the combination of cloudiness and the impaired mobility of the tympanic membrane to robustly diagnose AOM.²⁰

Recurrent AOM was the second most common reason for antibiotic prescribing in this study. This is defined as “the occurrence of 3 or more episodes of AOM in a 6-month period or the occurrence of 4 or more episodes of AOM in a 12-month period that includes at least 1 episode in the preceding 6 months”.³ *The American Academy of Pediatrics Clinical Practice Guideline* does not recommend the use of prophylactic antibiotics for reducing the number of episodes of AOM in recurrent AOM cases, and yet tympanostomy tubes should be offered.³ Systematic reviews showed that recurrent AOM is not included as one indicator for antibiotic treatment in the management of AOM.^{5,9} However, *The 2014 New South Wales Guideline* includes recurrent AOM into

the high-risk middle ear infection category, which requires immediate antibiotic treatment.²⁴

The high rate of antibiotic prescribing in AOM indicates the need for alternative non-antibiotic treatment for AOM. We propose to test corticosteroids for AOM. Inflammation has been indicated as an important mechanism in AOM, despite the complexity of the pathophysiology of AOM. This involves both cellular and chemical mediators (e.g., cytokines, chemokines, mast cells, and leukotrienes). Corticosteroids could act as an anti-inflammatory agent, particularly in the middle ear,¹² and therefore reduce pain. Insufficient evidence of the effects of corticosteroids for AOM requires a large, high-quality, clinical trial to evaluate corticosteroid efficacy to improve the resolution of AOM, as a monotherapy in mild cases or as an addition to antibiotic therapy in severe cases.¹²

Our feasibility survey demonstrated that there were 171 clinicians who were willing to participate in our clinical trial and who saw 443 children with AOM in a week. They also had similar practices in the management of AOM and responses to clinical scenarios to the whole sample. This study also demonstrated that a sufficient number of clinicians would consider using corticosteroids for AOM. This finding was surprising; however, this high rate could be primed by clinicians' knowledge of the nature of the upcoming clinical trial, which had been provided in the consent form and at the conference presentations prior to the completion of the questionnaires. As nearly half of the clinicians were interested in participating in our trial, it is feasible to conduct a clinical trial on corticosteroids for AOM in children in Indonesia, according to the pre-specified timeline (12 months, including a three-month follow-up).

We believe this the first survey of current practices of clinicians in the management of pediatric AOM in Indonesia, which was the strength of this study. We identified clinicians' preferred treatment options, particularly in choosing corticosteroids, expectant observation, and antibiotics. However, this study also had several limitations, including the low response rate, unclear definition of ‘observation for 48 to 72 hours’ as one answer option in the clinical scenario, and a narrow study-site coverage. We tried several recruitment strategies to increase the response rate, however, as participation was voluntary, it was

the respondents' decision to consent and participate in this survey study. There is no gold standard for an acceptable minimum survey response rate, however, a response rate of at least 70% is desirable.²⁵ Nonetheless, surveys involving voluntary clinicians mostly have low response rates (< 30%).²⁵ There are several factors that influence the willingness of clinicians to participate in a survey study, such as concerns about disruption of their practice, time, and relevance of the survey topic.²⁶ A review assessing survey response rates of general practitioners from published primary care journals demonstrated that the mean response rate was 61% (95% confidence interval 59% to 63%).²⁷ A cross-sectional study comparing the response rates between postal and online survey of general practitioners across Australia showed low response rates for both (12.4% and < 0.1%, respectively), which were similar to our study.²⁸ Several contributing factors were workload of the general practitioners, increasing number of other similar surveys, and no incentives for participating general practitioners. A systematic review identifying strategies to improve response rates on postal and electronic questionnaires demonstrated that the responses were likely almost doubled when there were monetary/non-monetary incentives, recorded delivery, shorter questionnaires, and interesting survey topics.²⁹ We did not have any funding to provide incentives. Other weakness of the study was We did not clearly define the answer option of 'observation for 48 to 72 hours' in the clinical scenarios. The option for observation for 48 to 72 hours was meant for clinicians who would choose to closely observe the AOM patients without antibiotics treatment for 48 to 72 hours. Without a clear definition, clinicians who would prescribe antibiotics, may also choose observation to see the effect of antibiotics. This would limit us to precisely identify the proportion of clinicians who would solely choose observation by withholding antibiotic treatment. As the last study weakness, this study only covered three adjacent cities in two provinces (Jakarta and a small part of West Java), which certainly does not represent the current management practice of AOM in Indonesia in general (total provinces in Indonesia is 34). To generalize these findings to the rest of Indonesia requires a national scale study that includes multiple cities (rural and urban) representing each province in Indonesia, supported by the *Ministry*

of Health, Republic of Indonesia. Given that the self-reported nature of our study is a further limitation, a national study should collect objective data on the actual number of AOM cases (including diagnosis and treatment) from primary care or hospital patient databases. However, our purpose was to survey likely practice and participation in a proposed trial.

There is still a high rate of antibiotic prescribing among Indonesian clinicians for children with AOM. Although it has not been recommended in the guidelines, clinicians would consider using corticosteroids for AOM. Given nearly half of clinicians were interested in participating in a future trial on corticosteroids, our proposed trial is feasible. This survey demonstrated existing gaps in the management of AOM between clinical practice and evidence. It is crucial to translate scientific evidence to clinical practice to improve the quality of the AOM management in children, particularly in Indonesia, by promoting an accurate and affordable diagnostic tool for AOM, such as a pneumatic otoscope, as well as by prescribing antibiotics only for severe AOM, and offering an observation under adequate pain management for mild cases. Therefore, further investigation is required to identify other contributing factors to be able to tackle this problem comprehensively.

Conflicts of Interest

Dr. Ranakusuma (RR) reports grants from The Australian Commonwealth Government, during the conduction of the study.

Dr. McCullough (AMC) reports grants from Advance Queensland Women's Academic Fund - Maternity, an Early Career Researcher award from Bond University, and was named the BUPA Health Foundation Emerging Researcher 2017 during the conduction of the study. She runs two businesses that undertake work outside the submitted work: Not Just Mum and Amanda McCullough Consulting.

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Dr. Pitoyo (YP), Dr Safitri (EDS), Widyaningsih (WW) have nothing to disclose.

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Availability of data and material

The datasets generated and/or analyzed during the current study are available in the Bond University Research repository, [<https://research.bond.edu.au/en/publications/current-management-of-children-with-acute-otitis-media-by-indones>].

References

1. Pettigrew MM, Gent JF, Pyles RB, Miller AL, Nokso-Koivisto J, Chonmaitree T. Viral-bacterial interactions and risk of acute otitis media complicating upper respiratory tract infection. *J Clin Microbiol.* 2011;49:3750-5.
2. Chonmaitree T, Revai K, Grady JJ, Clos A, Patel JA, Nair S, *et al.* Viral upper respiratory tract infection and otitis media complication in young children. *Clin Infect Dis.* 2008;46:815-23.
3. Lieberthal AS, Carroll AE, Chonmaitree T, Ganiats TG, Hoberman A, Jackson MA, *et al.* The diagnosis and management of acute otitis media. *Pediatrics.* 2013;131: e964-99.
4. South Australian Child Health Clinical Network. South Australian Paediatric Practice Guidelines: acute otitis media in children. South Australia: SA Health; 2014. ISBN No.: 978-1-74243-551-0. p.1-10.
5. Venekamp RP, Sanders SL, Glasziou PP, Del Mar CB, Rovers MM. Antibiotics for acute otitis media in children. *Cochrane Database Syst Rev.* 2015;8:CD000219.
6. Bakhit M, Hoffman T, Scott AM, Beller E, Rathbone J, Del Mar C. Resistance decay in individuals after antibiotic exposure in primary care: a systematic review and meta-analysis. *BMC Med.* 2018;16:126.
7. Kementrian Kesehatan Republik Indonesia. Panduan praktik klinis bagi dokter di fasilitas pelayanan kesehatan primer. Jakarta: Menteri Kesehatan Republik Indonesia; 2014. Peraturan Menteri Kesehatan Republik Nomor 5 Tahun 2014. p.176-80.

8. Kelompok Studi Otologi Perhimpunan Dokter Spesialis THT-KL Indonesia (PERHATI-KL). Guideline penyakit THT-KL di Indonesia. Jakarta: Perhimpunan Dokter Spesialis THT-KL Indonesia; 2007. p.55.
9. Rovers MM, Glasziou P, Appelman CL, Burke P, McCormick DP, Damoiseaux RA, et al. Antibiotics for acute otitis media: a meta-analysis with individual patient data. *Lancet*. 2006;368:1429-35.
10. Gillies M, Ranakusuma A, Hoffmann T, Thorning S, McGuire T, Glasziou P, et al. Common harms from amoxicillin: a systematic review and meta-analysis of randomized placebo-controlled trials for any indication. *CMAJ*. 2015;187:E21-31.
11. Juhn SK, Jung MK, Hoffman MD, Drew BR, Preciado DA, Sausen NJ, et al. The role of inflammatory mediators in the pathogenesis of otitis media and sequelae. *Clin Exp Otorhinolaryngol*. 2008;1:117-38.
12. Ranakusuma RW, Pitoyo Y, Safitri ED, Thorning S, Beller EM, Sastroasmoro S, et al. Systemic corticosteroids for acute otitis media in children. *Cochrane Database Syst Rev*. 2018;3:CD012289.
13. Ruohola A, Heikkinen T, Jero J, Puhakka T, Juvén T, Närkiö-Mäkelä M, et al. Oral prednisolone is an effective adjuvant therapy for acute otitis media with discharge through tympanostomy tubes. *J Pediatr*. 1999;134:459-63.
14. Büyükcam Y, Kara A, Bedir T, Gülhan B, Özdemir H, Sütçü M, et al. Pediatricians' attitudes in management of acute otitis media and ear pain in Turkey. *Int J Pediatr Otorhinolaryngol*. 2018;107:14-20.
15. D'silva L, Parikh R, Nanivadekar A, Joglekar S. A questionnaire-based survey of Indian ENT surgeons to estimate clinic prevalence of acute otitis media, diagnostic practices, and management strategies. *Indian J Otolaryngol Head Neck Surg*. 2013;65(Suppl 3):S575-81.
16. Marom T, Bobrow M, Eviatar E, Oron Y, Ovnat Tamir S. Adherence to acute otitis media diagnosis and treatment guidelines among Israeli otolaryngologists. *Int J Pediatr Otorhinolaryngol*. 2017;95:63-8.
17. Neumark T, Ekblom M, Brudin L, Groth A, Eliasson I, Molstad S, et al. Spontaneously draining acute otitis media in children: an observational study of clinical findings, microbiology and clinical course. *Scand J Infect Dis*. 2011;43:891-8.
18. Gribben B, Salkeld LJ, Hoare S, Jones HF. The incidence of acute otitis media in New Zealand children under five years of age in the primary care setting. *J Prim Health Care*. 2012;4:205-12.
19. Hersh AL, Jackson MA, Hicks LA, Committee on Infectious Diseases. Principal of judicious antibiotic prescribing for upper respiratory tract infections in pediatrics. *Pediatrics*. 2013;132:1146-54.
20. Pirozzo S, Del Mar C. Chapter 27. Otitis media. In: Moyer VA, editor. Evidence based paediatrics and child health. London: BMJ Books; 2000. p. 238-47.
21. Blomgren K, Pitkäranta A. Current challenges in diagnosis of acute otitis media. *Int J Pediatr Otorhinolaryngol*. 2005;69:295-9.
22. McCullough AR, Pollack AJ, Plejdrup Hansen M, Glasziou P, Looke DF, et al. Antibiotics for acute respiratory infections in general practice: comparison of prescribing rates with guideline recommendations. *Med J Aust*. 2017;207:65-9.
23. Sidell D, Shapiro NL, Bhattacharyya N. Demographic influences on antibiotic prescribing for pediatric acute otitis media. *Otolaryngol Head Neck Surg*. 2012;146:653-8.
24. New South Wales Ministry of Health. Infants and children, otitis media: Acute management of sore ear. Clinical Practice Guidelines. Sydney: NSW Ministry of Health; 2014. Document number GL2014_023. p.1-17. [cited 2019 June 27]. Available from: https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2014_023.pdf.
25. Bonevski B, Magin P, Horton G, Foster M, Girgis A. Response rates in GP surveys - trialling two recruitment strategies. *Aust Fam Physician*. 2011;40:427-30.
26. Pit SW, Vo T, Pyakurel S. The effectiveness of recruitment strategies on general practitioner's survey response rates - a systematic review. *BMC Med Res Methodol*. 2014;14:76.
27. Creavin ST, Creavin AL, Mallen CD. Do GPs respond to postal questionnaire surveys? A comprehensive review of primary care literature. *Fam Pract*. 2011;28:461-7.
28. Crouch S, Robinson P, Pitts M. A comparison of general practitioner response rates to electronic and postal surveys in the setting of the National STI Prevention Program. *Aust N Z J Public Health*. 2011;35:187-9.
29. Edwards PJ, Roberts I, Clarke MJ, DiGiuseppi C, Wentz R, Kwan I, et al. Methods to increase response to postal and electronic questionnaires. *Cochrane Database Syst Rev*. 2009;3:MR000008.

Appendix 1. Questionnaires of the study

QUESTIONNAIRE: THE MANAGEMENT OF ACUTE OTITIS MEDIA IN CHILDREN IN DKI JAKARTA, DEPOK, AND BEKASI	
<div style="border: 1px solid black; width: 450px; height: 40px; margin: 0 auto;"></div>	
THANK YOU FOR YOUR TIME AND PARTICIPATION IN FILLING THIS QUESTIONNAIRE. PLEASE TICK (V) YOUR ANSWER	
1	INCIDENCE, ATTITUDE, AND BEHAVIOUR
1.1	In your personal practice, how many cases of acute otitis media in children did you see in the past 7 (seven) days? Answer: (.....) cases
1.2	Can you estimate the percentage for each age group of AOM patients who came to your personal practice in the past one month? Answer:% 0 to ≤ 2 year old% 2 to 5 year old% ≥ 5 year old
1.3	The diagnosis of acute otitis media was established using tests mentioned below (you may choose more than one) Answer: <input type="checkbox"/> Clinical history <input type="checkbox"/> Visualization of tympanic membrane using a penlight/ headlight <input type="checkbox"/> Visualization of tympanic membrane using an otoscope <input type="checkbox"/> Visualization of tympanic membrane using a pneumatic otoscope (using Siegel) <input type="checkbox"/> Visualization of tympanic membrane using ear endoscope / microscope <input type="checkbox"/> Tuning fork <input type="checkbox"/> Pure tone audiometry <input type="checkbox"/> Tympanometry / impedance audiometry <input type="checkbox"/> Tympanocentesis <input type="checkbox"/> Others:
1.4	What is the most common antibiotic you give for acute otitis media cases in children (please choose only one of the following): Answer: <input type="checkbox"/> Amoxicillin <input type="checkbox"/> Ampicillin <input type="checkbox"/> Cefixime <input type="checkbox"/> Cefadroxil <input type="checkbox"/> Erythromycin <input type="checkbox"/> Azitromycin <input type="checkbox"/> Amoxicillin-clavulanate <input type="checkbox"/> Cotrimoxazole <input type="checkbox"/> Others:
1.5	What is the most common duration of antibiotics you give for acute otitis media in children Answer: days
2	CASE SCENARIO (there is no 'RIGHT' or 'WRONG' answer)
2.1	CASE-1 A one-year old boy, accompanied by his mother, came to your practice with a complaint of pain in his left ear for one day. The pain was not severe. He has had a cold for the last two days with a mild fever. At the physical examination, he looked well and alert with temperature 37.8°C. At his ear, nose, and throat examination,

	<p>there was mucous discharge on the nasal cavities, and his throat looked normal. An otoscopic examination showed redness and bulging tympanic membrane of the left ear.</p>
Question:	<p>What the best management for the patient above? (you may choose more than one)</p>
Answer:	<p> <input type="checkbox"/> Observation for 48 – 72 hours <input type="checkbox"/> Decongestant and/or anti-histamine <input type="checkbox"/> Antibiotics <input type="checkbox"/> Paracetamol <input type="checkbox"/> Ibuprofen OR other anti-inflammatory drugs (NSAID) <input type="checkbox"/> Corticosteroids <input type="checkbox"/> Antibiotic ear drop <input type="checkbox"/> Analgesics ear drop <input type="checkbox"/> Physical therapy with (you may have more than one answer) <input type="checkbox"/> Nebulizer <input type="checkbox"/> Diathermy <input type="checkbox"/> Laser <input type="checkbox"/> Others </p>
2.2	<p>CASE-2 A four-year old girl, accompanied by her parents, came to your practice with a complaint of pain in her right ear for one day. She has had a cold for the last four days. She had no fever. At the physical examination, the patient looked well and alert. At her ear, nose, and throat examination, there was serous secretion in the nasal cavities and her throat looked normal. An otoscopic examination showed redness and bulging tympanic membrane of the right ear.</p>
Question:	<p>What the best management for the patient above? (you may choose more than one)</p>
Answer:	<p> <input type="checkbox"/> Observation for 48 – 72 hours <input type="checkbox"/> Decongestant and/or anti-histamine <input type="checkbox"/> Antibiotics <input type="checkbox"/> Paracetamol <input type="checkbox"/> Ibuprofen OR other anti-inflammatory drugs (NSAID) <input type="checkbox"/> Corticosteroids <input type="checkbox"/> Antibiotic ear drop <input type="checkbox"/> Analgesics ear drop <input type="checkbox"/> Physical therapy with (you may have more than one answer) <input type="checkbox"/> Nebulizer <input type="checkbox"/> Diathermy <input type="checkbox"/> Laser <input type="checkbox"/> Others </p>
2.3	<p>CASE-3 A five-year old girl, accompanied by her parents, came to your practice with a complaint of pain in her right ear for one day, followed by left ear this morning and she had a mild fever. She had experienced acute otitis media in her right ear one month ago. At the physical examination, the patient looked well and alert with temperature 36.8°C. At her ear, nose, and throat examination, there was minimal serous discharge in her nasal cavities and her throat looked normal. An otoscopic examination showed redness and bulging on both tympanic membranes.</p>
Question:	<p>What the best management for the patient above? (you may choose more than one)</p>

	<p>Answer:</p> <ul style="list-style-type: none"> <input type="radio"/> Observation for 48 – 72 hours <input type="radio"/> Decongestant and/or anti-histamine <input type="radio"/> Antibiotics <input type="radio"/> Paracetamol <input type="radio"/> Ibuprofen OR other anti-inflammatory drugs (NSAID) <input type="radio"/> Corticosteroids <input type="radio"/> Antibiotic ear drop <input type="radio"/> Analgesics ear drop <input type="radio"/> Physical therapy with <i>(you may have more than one answer)</i> <ul style="list-style-type: none"> <input type="radio"/> Nebulizer <input type="radio"/> Diathermy <input type="radio"/> Laser <input type="radio"/> Others
3	BIODATA
3.1	<p>Doctor specialty</p> <p>Answer:</p> <ul style="list-style-type: none"> <input type="radio"/> General practitioner <input type="radio"/> Paediatrician <input type="radio"/> Otorhinolaryngologist
3.2	<p>Type of practice</p> <p>Answer:</p> <ul style="list-style-type: none"> <input type="radio"/> Primary healthcare <input type="radio"/> Private or multi doctor clinic <input type="radio"/> Public hospital <input type="radio"/> Private hospital
3.3	<p>City of practice</p> <p>Answer:</p> <ul style="list-style-type: none"> <input type="radio"/> DKI Jakarta <input type="radio"/> Depok <input type="radio"/> Bekasi <input type="radio"/> Others:
3.4	<p>Age</p> <p>Answer:</p> <ul style="list-style-type: none"> <input type="radio"/> ≤ 30 years old <input type="radio"/> 31 – 40 years old <input type="radio"/> 41 – 50 years old <input type="radio"/> 51 – 60 years old <input type="radio"/> 61 – 70 years old <input type="radio"/> > 70 years old
3.5	<p>Gender</p> <p>Answer:</p> <ul style="list-style-type: none"> <input type="radio"/> Male <input type="radio"/> Female
4	<p>PARTICIPATION ON THE FUTURE CLINICAL RESEARCH ON THE MANAGEMENT OF ACUTE OTITIS MEDIA IN CHILDREN</p> <p style="text-align: center;"><u>Research summary</u></p> <p>Antibiotic resistance has been emerging as a global public health problem. Antibiotics have been prescribed for almost 50% cases of acute respiratory infections (ARIs) in primary healthcare centres. As those cases are mostly self-limited diseases and caused by viruses, antibiotics have little or no clinical benefits. As part of a common complication of viral ARIs, acute otitis media (AOM) is mostly found in children and is a key reason for antibiotic prescription.</p>

	<p>Other strategy than antimicrobial treatment is needed due to the progression into recurrent and persistent AOM. Corticosteroids have an important role as an anti-inflammatory agent. A recent study has shown the use of oral corticosteroid as an additional treatment with antibiotics in cases of AOM with discharge through tympanostomy tubes shortened the duration of otorrhea. There are few small trials on the use of corticosteroids also as an additional treatment of antibiotics in AOM in children and the results of its benefits were varied. Therefore, we plan to conduct a large, well-conducted clinical trial in order to assess the effectiveness of corticosteroid for the treatment of AOM in children</p> <p>After reading this summary of the future research of "Corticosteroid as an alternative treatment for acute otitis media in children" that will be held on February 2017 to February 2018, I would be interested to be involved in this future research</p> <p>Answer: <input type="radio"/> NO, I am not interested to be involved <input type="radio"/> YES, I am interested to be involved. Please complete the following questionnaire below.</p>	
<p>Thank you for your time in completing the survey</p> <p><i>For those who are interested in participating in our future clinical research of "Corticosteroid as an alternative treatment for acute otitis media in children", please complete your contact details and other information below.</i></p>		
5	BIODATA	
5.1	Name and title
5.2	Home address
5.3	Email address
5.4	Telephone no.
	Mobile no.
5.5	Contact preference	<input type="radio"/> Telephone <input type="radio"/> SMS / Whatsapp <input type="radio"/> Email
5.6	Name/type of practice
5.7	Working since (month) / (year)
5.8	Practice address
5.9	Practice phone no.
	Fax no.
5.10	Is there an otoscope in your practice? Answer: <input type="radio"/> Yes <input type="radio"/> No	
5.11	Is there a pneumatic otoscope (with Siegel) in your practice? Answer: <input type="radio"/> Yes <input type="radio"/> No	
5.12	Is there a Tympanometer in your practice? Answer: <input type="radio"/> Yes <input type="radio"/> No	
5.13	Is there a Pharmacy in your practice? Answer: <input type="radio"/> Yes	

		O No. Where can your patient can get their medication?
6	CURRENT EMPLOYMENT	
	Do you work in other practice or institution/organization?	
	Answer:	O No O Yes. Please answer the following questions below
6.1	Name of other practice (primary health centre/clinic/ hospital)
6.1.1	Working since (month) / (year)
6.1.2	Practice address
6.1.3	Practice telephone no. Fax no.
6.2	Name of other employment (lecturer/researcher/scientific writer)
6.2.1	Working since (month) / (year)
6.2.2	Address
6.2.3	Practice telephone no. Fax no.
7	EDUCATION	
7.1	Bachelor	Faculty of Medicine University of City Completion year
7.2	Specialist	Faculty of Medicine University of City Completion year
7.3	Others (PhD, Masters)	Faculty of University of City Completion year
7.4	Internship (PTT)	O No O Yes. Please answer the following questions below: Completion year Duration year
*** Thank you for your interest. We will contact you for further information ***		

Please return this questionnaire to:
 Prof. Dr. dr. SS / dr. RWR
 Address: *****
 or contact us at +62*****