

Validation and Development of a Clinical Prediction Rule in Clinically Suspected Community-Acquired Pneumonia

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Objectives: To develop a mathematical model to predict the probability of having community-acquired pneumonia and to evaluate an already developed prediction rule that has not been validated in a clinical scenario.

Methods: Children who presented with fever and had presumptive clinical diagnosis of pneumonia were evaluated in 4 institutions of different complexity during 1 year. The variables assessed were sex, age, respiratory rate, days with fever, maximum body temperature, presence of tachypnea, cough, chest pain, intercostal retraction, nasal flaring, abdominal pain, vomiting, grunting, rales, decreased breath sounds, wheezing, fatigue, loss of appetite, loss of sleep, and season of the year. The chest radiographs were photographed and then interpreted by 2 pediatric radiologists.

Results: A total of 257 children were evaluated: 179 (69%) had clinical and radiological diagnosis of community-acquired pneumonia, and 78 (30%) had no radiological confirmation. A total of 96 photographs were recorded, and in 64 of the cases, there was agreement in the diagnosis between the evaluating pediatrician and the radiologists (κ index = 0.68).

With the calculated probabilities, it was possible to build a receiving operating characteristic curve and, based on the estimated coefficients we calculated, a value associated to the probability of having pneumonia.

Conclusions: We developed a model including 5 variables of high level of sensitivity for the diagnosis of pneumonia. To use it, it would be useful to apply the appropriate software. In addition, we validated a clinical prediction rule of 4 variables that proved to have 93.8% sensitivity to diagnose pneumonia in children with a fever and localized rales, or decreased breath sounds, or tachypnea, or any combination of these 4 variables.

Key Words: pneumonia, chest radiographs, predictive factors

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Community-acquired pneumonia (CAP) is one of the most prevalent and serious infectious pathological findings involving the pulmonary parenchyma that occurs outside the hospital setting. It primarily affects children and elderly people. Community-acquired pneumonia has a higher incidence in de-

veloping countries than in Europe or in the United States; it is also more severe and is associated to higher mortality.¹

In adults, algorithms of CAP management in the emergency department have been developed. They have been validated in thousands of patients, with the aim of stratifying management according to severity and reducing hospitalization.^{2,3}

In children, CAP is one of the most common pathological findings in the emergency unit.⁴ The clinical suspicion of CAP in the emergency ward searches to real challenge, because it is the starting point to order complementary tests and confirm diagnosis. Leukocytosis has been used as sign to suspect invasive bacterial infection and pneumonia⁵ or like a part of a clinical, radiological, and hematologic score with the purpose of differentiating viral or bacterial CAP.⁶ Although other biological markers such as procalcitonin⁷ or C-reactive protein⁸ have been analyzed, these confirmatory studies support previous clinical-radiological diagnosis of pneumonia.

The clinical suspicion in itself, as the World Health Organization (WHO) has proposed for developing countries,^{9,10} and radiological confirmation of alveolar infiltrates, together with different parameters of the history of the disease and physical examination, leads to the diagnosis of CAP in the emergency department.^{11–26}

The accurate knowledge of clinical aspects of CAP in the emergency department aids the physician to avoid misdiagnosis and administration of inappropriate therapies²⁷ and to optimize the request for chest radiographs, which, in our experience, was the most requested complementary test, accounting for 40.1%.⁴ Because of this expense, we would wonder on necessity to carry out chest radiographs to all the children with a suspected clinical pneumonia. So it is indispensable to have clinical diagnostic guidelines of high predictability.

Diagnostic guidelines have been developed to predict CAP in pediatric emergency units: the WHO guidelines include tachypnea and intercostal retraction for developing countries and have been validated in Gambia and the Philippines⁹; the guideline, developed by Rothrock et al,²¹ proved to have low sensitivity and specificity, and Lynch et al²⁵ developed a prediction rule in a pediatric hospital based on the presence of fever plus 1 or several of the following parameters: decreased breath sounds, crackles, and tachypnea. This rule presented excellent sensitivity (>93%) yet poor specificity (<20%).

OBJECTIVE

The aims of the present study were to develop a mathematical model to predict the probability of having CAP and use it to derive a decision rule that will enable the physician to make an accurate diagnosis of CAP in children based on the clinical symptoms and to prospectively assess a prediction rule described by Lynch et al²⁵ yet not validated in a clinical scenario.

METHODS

During 1 year, from June 2006 to May 2007, we evaluated pediatric patients of 1 to 16 years of age who presented with

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a fever and had clinically suspected pneumonia at the emergency department in the following hospitals: Centro Hospitalario "Pereira Rossell," (Montevideo, Uruguay), Hospital de Agudos "Enrique Tornú" (Buenos Aires, Argentina), Hospital de Agudos "Diego Paroissien," (La Matanza, Buenos Aires, Argentina), and Policlínico del Docente (Buenos Aires, Argentina). Pereira Rossell is a public pediatric hospital of high complexity; Tornú and Paroissien are public general hospitals with pediatric units of low and intermediate complexity, respectively; and Policlínico del Docente is a sanatorium that belongs to a Health Insurance Company and has a pediatric department of intermediate complexity.

The exclusion criteria for enrolment in the present study were as follows: patients younger than 1 year (diagnosis interference of bronchiolitis with CAP) or older than 16 years (clinical features compatible with CAP in adults); patients without a fever during the last 48 hours; and patients with chronic respiratory disease (such as cystic fibrosis, bronchopulmonary dysplasia), congenital cardiopathy, esophagogastric reflux, tumoral disease, cerebral palsy, congenital immunodeficiency, asthmatic crisis requiring corticoid therapy or more than 1 bronchodilator treatment in the emergency unit, history of pneumonia in the last 2 months, or use of antibiotics during the last 15 days. Patients who had a chest radiograph already taken and interpreted by the evaluating physician were excluded from the protocol, because perception of symptoms could change after seeing the radiograph.

The assessment of clinical signs and symptoms was performed by completing a standardized clinical chart including the following information in relation to the episode for which the patient had been admitted in the emergency unit: sex (0 = male, 1 = female); age in months; respiratory rate (units); days with fever since the initial episode; maximum body temperature; presence of tachypnea, cough, chest pain, intercostal retraction, nasal flaring, abdominal pain, vomiting, grunting, crackles, decreased breath sounds, wheezing, fatigue, loss of appetite, or loss of sleep; and season of the year. For all dichotomous variables, 0 corresponds to the absence of sign/symptom and 1 corresponds to the presence of it.

For the variable temperature, the maximum body temperature reported by the mother was considered: the value of reference was 39°C, and levels lower or higher than 39°C were recorded (0 was $\leq 39^\circ\text{C}$ and 1 was $>39^\circ\text{C}$). The variable season was recorded in months, grouping them as summer-autumn and winter-spring (0 was for November, December, January, February, March, April, or May, and 1, otherwise).

After completing the clinical charts, the chest radiographs were taken, and those interpreted as having pneumonia (pulmonary consolidation or asymmetric infiltrate) were considered positive cases.

The chest radiographs were photographed and then interpreted by 2 pediatric radiologists who had not seen the clinical charts of the patients. Their diagnoses were then correlated (presence or absence of consolidation or asymmetric infiltrate) with the previous diagnosis of the evaluating pediatricians.

A verbal informed consent from parents was obtained before completing the clinical charts. We obtained the approval of the research and teaching committees from Tornú and Paroissien hospitals and the research committee from the School of Medicine of Universidad de la República del Uruguay to carry out this protocol. Centro Hospitalario Pereira Rossell and Policlínico del Docente do not have research committees of their own.

Statistical Analysis

1. A univariate analysis was carried out to identify differences between the group of children with CAP and the group of children without pneumonia. The *t* test was used for continuous variables, and the χ^2 test or Fisher exact test was used for categorical data, when appropriate.
2. To derive the decision rule, the following steps were taken. First, a model was developed to be able to predict probability of CAP for a child admitted in the emergency department. On the basis of the estimated probability, a decision rule was defined. If the probability was high, the child was considered to have pneumonia. The limitations of the model lie in
 - selecting the best model to predict the probability of having pneumonia.
 - defining the cutoff point (decision rule), that is, the value on the basis of which the child will be classified as having a positive diagnosis.
 - (a) *Definition of the model.* Using a stepwise approach, the group of variables that maximized the area under the receiver operating characteristic (ROC) curve was selected. With the purpose of improving the explanatory capacity of the model, double interactions were incorporated. They were obtained by means of a stepwise procedure among all possible combinations of the selected variables in the previous step.
 - (b) *Definition of the optimal cutoff point.* Once the model that produced the greater area under the ROC curve was selected, the cutoff point was defined as the probability value (or probability logit) for which the sensitivity of the test based on the model was greater than 0.90, with the highest specificity possible.
3. Finally, with the purpose of evaluating and validation the prediction rule described by Lynch et al,²⁵ we obtained different models that involved only a small number of variables and were therefore simpler to interpret.

TABLE 1.

Variable	Condition	n	Mean (SD)	Difference (95% Confidence Interval)	P (t Test)
Age, y	Diagnosis Yes	179	4.38 (2.92)	-1.00 to 0.64	0.662
	Pneumonia No	78	4.20 (2.64)		
Days of fever	Diagnosis Yes	177	3.12 (1.57)	-0.83 to 0.036	0.072
	Pneumonia No	77	2.72 (1.71)		
Respiratory rate, breaths/min	Diagnosis Yes	177	41.13 (11.45)	-7.05 to -0.92	0.011
	Pneumonia No	76	37.13 (11.13)		
Maximum body temperature, °C	Diagnosis Yes	178	39.27 (0.68)	-0.34 to 0.02	0.076
	Pneumonia No	73	39.11 (0.67)		

RESULTS

A total of 257 children were included in the present study (there were missing data for some of the explanatory variables in the case of some subjects). After completing the clinical charts, the chest radiographs were taken, and those interpreted as having pneumonia (pulmonary consolidation or asymmetric infiltrate) were considered positive cases. Of them, 179 (69%) had a clinical diagnosis of CAP with radiological confirmation (confirmed or positive cases), and 78 (30%) had presumptive clinical diagnosis of CAP without radiological confirmation (nonconfirmed or negative cases).

A total of 96 digital photographs of chest radiographs were recorded and interpreted by 2 pediatric radiologists together who had not seen the 96 clinical charts of those patients. Twelve photographs could not be evaluated because of their poor technical quality. For the other 84 radiographs, there was diagnostic agreement between the evaluating pediatrician and the radiologists in 64 cases (76.19%) (the κ index for interobserver agreement was 0.68).

Univariate Comparisons Between Children With and Without Diagnosis of Pneumonia

Tables 1 and 2 show a summary of the characteristics of the children assessed in the present study and the signs and symptoms informed by the mother and/or the child or recorded by the pediatrician.

From the data in Table 1, we conclude that there were no significant differences between children with and without pneumonia in the average age, average days of fever, and maximum body temperature reported by the mother ($P = 0.662$, $P = 0.072$, $P = 0.076$, respectively). The respiratory rate was significantly higher in the patients who had pneumonia ($P = 0.011$).

Taking into account the data in Table 2, we can conclude that the proportion of patients with pneumonia was higher in the case of children who had grunt ($P = 0.007$), intercostal retraction ($P = 0.004$), nasal flaring ($P = 0.045$), chest pain ($P = 0.007$), cough ($P < 0.0001$), abdominal pain ($P = 0.009$), vomiting ($P = 0.002$), tachypnea ($P = 0.003$), and decreased breath sounds ($P < 0.001$). Furthermore, the proportion of children with pneumonia was significantly higher in winter-spring than in summer-autumn ($P = 0.02$).

Development of a Decision Rule

Definition of the Model

The best model with double-order interactions selected by means of the method, described in Statistical Analysis in the Materials and Methods section of the present study, is shown in Table 3.

The probabilities calculated using this model to predict the probability of pneumonia together with the information on whether the child had indeed pneumonia led to the construction of the ROC curve, which is shown in Figure 1. The following data shows the area under the ROC curve: Area, 0.7769; SD, 0.0297; CI, 0.7188–0.8351.

Based on the estimated coefficients for this model, it was possible to calculate a value for each child who had been admitted in the emergency ward; this value was then associated to the probability of pneumonia for each child. This value, which is called logit, was calculated using the estimated coefficients (Table 3) and the data obtained for each child.

The logit is calculated in the following way: first, the data from each child are multiplied by the estimated coefficients; then, the results are added to the estimated coefficient that corresponds

TABLE 2.

Variable	Condition	Diagnosis: Pneumonia	P (χ^2 Test)
Sex	Male	94/141 (66.7%)	0.227
	Female	85/116 (73.3%)	
Maximum body temperature $\geq 39^\circ\text{C}$	Yes	95/141 (67.3%)	0.584
	No	78/110 (70.9%)	
Fatigue	Yes	143/202 (70.79%)	0.508
	No	36/55 (65.45%)	
Loss of appetite	Yes	143/196 (72.96%)	0.055
	No	36/61 (59.02%)	
Loss of sleep	Yes	64/85 (75.29%)	0.195
	No	115/172 (66.86%)	
Grunting	Yes	45/53 (84.91%)	0.007
	No	134/204 (65.69%)	
Intercostal retraction	Yes	68/83 (81.93%)	0.004
	No	111/174 (63.79%)	
Nasal flaring	Yes	15/16 (93.75%)	0.045
	No	164/241 (68.05%)	
Wheezing	Yes	29/44 (65.91%)	0.589
	No	150/212 (70.75%)	
Chest pain	Yes	25/27 (92.59%)	0.007
	No	154/230 (66.96%)	
Cough	Yes	156/206 (75.73%)	<0.001
	No	23/51 (45.1%)	
Abdominal pain	Yes	56/68 (82.35%)	0.009
	No	123/189 (65.08%)	
Vomiting	Yes	88/110 (80%)	0.002
	No	91/147 (61.9%)	
Tachypnea	Yes	128/168 (76.19%)	0.003
	No	51/89 (57.3%)	
Rales	Yes	110/149 (73.83%)	0.099
	No	69/108 (63.89%)	
Decreased breath sounds	Yes	95/116 (81.9%)	<0.001
	No	84/141 (59.57%)	
Season	Summer-Autumn	53/88 (60.23%)	0.022
	Spring-Winter	126/169 (74.56%)	

to the intercept. The logit value for each child may be easily calculated using an Excel table, entering only each of the 5 variables that are included in the model (see Table, Supplemental Digital Content 1, for the Excel software clinical variables, <http://links.lww.com/PEC/A1>).

Definition of the Optimal Cutoff Point

The last step in the development of the decision rule was to calculate the logit value (ie, the estimated probability of pneumonia) to define the cutoff point to classify a child as having the disease. A possible criterion could be to define as a cutoff point a logit value with at least 90% sensitivity associated to the test and the maximum possible specificity.

Each possible cutoff point yielded different sensitivity and specificity values, which are shown in the ROC curve. Table 4 shows a group of probability values (and logit) calculated using the present model and the sensitivity, specificity, false positives, and false negatives associated with each value.

If we choose as the cutoff point the value 0.52658 (logit = 0.10644), the diagnostic test derived from this prediction model has 93% sensitivity and 33% specificity. The criterion to define the cutoff point is basically biomedical and depends

TABLE 3.

	Estimated Coefficient	SD	P
Grunting	0.919	0.4813	0.0562
Cough	1.5017	0.3771	<0.0001
Rales	0.727	0.3187	0.0225
Decreased breath sound	0.5044	0.3913	0.1974
Vomiting	0.053	0.3835	0.89
Decreased breath sound and vomiting*	2.6113	0.8883	0.0033

*An observation is that when considering interaction between vomits and decreased breath sounds, this interaction is very significant.

on the cost of the error associated with misclassification of subjects; that is to say, it depends on which of the 2 errors is worse: to mistake a child with pneumonia as healthy or to misclassify a child as having pneumonia.

If instead we choose as cutoff point the logit = 0.11, then the decision rule based on this value is as follows:

- If the child has a logit value of 0.11 or greater, then he/she is classified as having pneumonia.
- Otherwise, he/she is classified as healthy.

Simpler Prediction Model

Lastly, Table 5 shows an analysis of 3 frequent clinical signs in children with CAP and fever (decreased breath sounds, rales, and/or tachypnea) and their sensitivity and specificity in isolation and in different combinations.

The decision rule derived in each case consists of classifying a child with fever as having pneumonia if they present:

1. decreased breath sounds;
2. rales;
3. tachypnea;
4. decreased breath sounds or rales;
5. diminished breath sounds or tachypnea;
6. rales or tachypnea;
- 7a. decreased breath sounds, or rales, or any of the 3 variables taken in pairs or the 3 of them, simultaneously;
- 7b. decreased breath sounds, or rales, or tachypnea, or any combination of the 3 variables.

	Sensitivity	Specificity	Positives	Negatives	False Positives	False Negatives
1	0.53073	0.73077	95	57	21	84
2	0.61453	0.5	110	39	39	69
3	0.71508	0.48718	128	38	40	51
4	0.87151	0.32051	156	25	53	23
5	0.81564	0.38462	146	30	48	33
6	0.90503	0.28205	162	22	56	17
7a	0.87151	0.32051	156	25	53	23
7b	0.93855	0.19231	168	15	63	11

The decision rule 7b presents higher sensitivity (93.8%); however, its specificity is very poor. To improve specificity, it is necessary to include more variables in the model. For such a purpose, we previously searched for the model that best provides a greater area under the ROC curve, and although it uses more

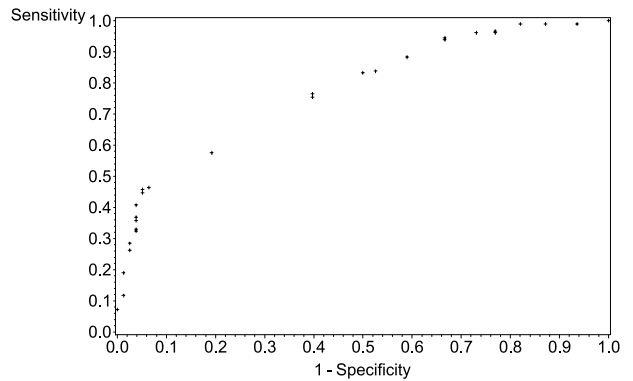


FIGURE 1.

predictor variables, it allows physicians to obtain greater specificity without losing sensitivity.

DISCUSSION

There are difficulties inherent in the diagnosis of CAP, as was demonstrated by Hazir et al.²⁸ They analyzed 1932 children with a diagnosis of mild CAP by only considering the presence of tachypnea following the rule of WHO, and only 263 cases (14%) had radiographically proven pneumonia.

Furthermore, several authors have tried with various results to find clinical combinations of high predictive value for CAP; Mahabee-Gittens et al²² studied 510 patients aged 2 to 59 months with clinically suspected CAP and combined age older than 12 months, respiratory rate of 50 breaths per minute or greater, 96% or less oxygen saturation, and nasal flaring in breast-fed babies. The results of CAP confirmed by radiology showed low sensitivity, according to the presence of different combinations, ranging between 18% and 63% and high specificity between 71% and 98%.

Buñuel Álvarez et al²⁹ retrospectively analyzed the diagnostic usefulness of 3 clinical signs: fever, cough, and crackling rales, found in 350 clinical records of children with clinically suspected CAP. The different combinations of the 3 signs proved to have a poor diagnostic value, because the positive predictive value ranged between 1 and 1.66, and the negative predictive value, between 0.79 and 1.

Rothrock et al²¹ prospectively evaluated an evidence-based guideline, and they concluded that pneumonia could be ruled out in the absence of the 4 signs: respiratory distress (intercostal retraction), tachypnea, rales, and decreased breath sounds.¹⁸ For the 329 children younger than 5 years assessed, that guideline presented only 45% sensitivity and 66% specificity.

Lynch et al²⁵ developed a prediction rule based on the presence of fever plus 1 or several of the following parameters: decreased breath sounds, crackles, and tachypnea; it proved to have excellent sensitivity (>93%), but poor specificity (<20%).

Faced with these discouraging data and urged by the need to improve the diagnosis of CAP in developing countries,^{30,31} we studied children presenting with clinical signs compatible with CAP in 4 institutions of different levels of complexity. For such a purpose, we evaluated 20 epidemiological and clinical variables, and we compared them in the positive cases (radiological confirmation of pneumonia) as well as the negative ones (Tables 1 and 2).

The radiological diagnoses made by the pediatricians had a good correlation (κ index = 0.68) when compared with the ones made by the pediatric radiologists. This correlation depends

TABLE 4.

Probability	Logit	Positive	Negative	False Positive	False Negative	Sensitivity	Specificity
0.82198	1.52983	73	75	3	106	0.40782	0.96154
0.79214	1.33787	80	74	4	99	0.44693	0.94872
0.7462	1.07846	82	74	4	97	0.4581	0.94872
0.73603	1.02544	83	73	5	96	0.46369	0.9359
0.70817	0.8865	103	63	15	76	0.57542	0.80769
0.69709	0.83348	135	47	31	44	0.75419	0.60256
0.68031	0.75519	137	47	31	42	0.76536	0.60256
0.64813	0.61083	149	39	39	30	0.8324	0.5
0.56237	0.2508	150	37	41	29	0.83799	0.47436
0.53978	0.15946	158	32	46	21	0.88268	0.41026
0.52658	0.10644	168	26	52	11	0.93855	0.33333
0.50704	0.02815	169	26	52	10	0.94413	0.33333
0.45914	-0.16381	172	21	57	7	0.96089	0.26923
0.38314	-0.47624	172	18	60	7	0.96089	0.23077
0.35088	-0.61518	173	18	60	6	0.96648	0.23077

on medical training in the radiological diagnosis of pneumonia and can be improved with the appropriate training of the attending physician.³²

Pereira et al,³³ in a sample population of 153 children with presumptive diagnosis of pneumonia, applied and compared 2 statistical models in the same sample: a stochastic and a fuzzy set theory method. Although the predictive value did not improve, the model enabled the evaluators to visualize other relationships between the 7 signs assessed.

In our study, 20 variables were analyzed for each patient in a univariate way, and with the aim of explaining the probability of having CAP, we adjusted different multivariate logistic regression models in which the variables with higher predictive value were selected. The model that best maximized the area under the ROC curve involved 5 variables with double interactions, and it could predict the presence of pneumonia with 93% sensitivity and only 33% specificity. The variables included the following symptoms/signs: grunting, decreased breath sounds, localized rales, cough, and vomiting. Each of the values for these variables in isolation or in double combinations multiplied by certain estimated coefficients was added to a correlation factor, and then a logit value was obtained; if the logit is greater than or equal to 0.11, it indicates high probability of pneumonia (Table 3).

Although this model is more complex in comparison with other models in the literature involving fewer prediction variables, it enables physicians to predict the radiographic presence

of pneumonia with greater reliability, and with present-day advances in medical computer technology and the use of the appropriate software to include the 5 variables, physicians will be able to achieve better diagnostic accuracy.

The limitations of our predictive model reside in the need to select 5 clinical variables for our patients, one of them, vomit with unspecific characteristics in connection with the pneumonia, and it would also be necessary to count on to computer to work with the Excel table (see Table, Supplemental Digital Content 1, for the Excel software clinical variables, <http://links.lww.com/PEC/A1>). This may not be easy to obtain in the emergency departments of developing countries.

When extrapolating the results of this study to other clinical settings, it is important to keep in mind that predictive accuracies are dependent on the prevalence of the confirmed condition. In this study, the prevalence of pneumonia was very high.

Because this study was conducted in an emergency room in developing countries where the percentage of sick patients is likely higher than in developed countries or a private pediatric office, the prevalence of pneumonia also may be higher. A lower prevalence of pneumonia would decrease the reported positive predictive accuracies and the false-negative rates.

Finally, we compared the same 4 variables used by Lynch et al²⁵: fever in all cases, decreased breath sounds, localized rales, and tachypnea and their presence in isolation or in combination, and we obtained a sensitivity level between 53% and 93.8% and specificity between 19% and 73% (Table 4). It is worth noticing that Lynch et al²⁵ obtained a higher sensitivity value for all the variables, between 93% and 98.3%, but a lower specificity than in the case of our sample: 5.7% to 19.4%. In the study of Lynch et al,²⁵ the cutoff point and the decision rule used were not specified.

In conclusion, we have developed a predictive model of 5 variables of high sensitivity for the diagnosis of pneumonia. To use it in practice, it will be useful to apply the appropriate software (see Table, Supplemental Digital Content 1, for the Excel software clinical variables, <http://links.lww.com/PEC/A1>).

In addition, we validated a clinical prediction guideline of 4 variables in a multicenter sample population in the pediatric emergency unit of 4 institutions of different complexity belonging to 2 developing countries. This prediction rule proved to have 93.8% sensitivity to diagnose pneumonia in the case of any child

TABLE 5.

	Decreased Breath Sounds	Rales	Tachypnea	AUC	95% Confidence Interval for AUC
1	X			0.6307	0.5691–0.6924
2		X		0.5573	0.491–0.6236
3			X	0.6011	0.5362–0.6661
4	X	X		0.672	0.6046–0.7394
5	X		X	0.6673	0.5997–0.7349
6		X	X	0.6216	0.5468–0.6964
7	X	X	X	0.7016	0.6336–0.7696

AUC indicates area under the ROC curve.

presenting with a fever and localized rales, or decreased breath sounds, or tachypnea, or any combination of these 4 variables in an emergency unit.

This model developed by Lynch et al²⁵ is simple to use, it has a high sensitivity for diagnosing clinical CAP, it can save unnecessary order of chest radiographs in the emergency room, and it has shown similar statistical values in developed countries than in developing ones.

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