

# The Validity of the Mclsaac Clinical Decision Rule in the Detection of Group A Beta Hemolytic Streptococcus Pharyngitis Using Throat Culture as the Reference Standard\*

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**Background:** During a monthly morbidity and mortality report in family medicine it was noted that one of the most frequent illnesses encountered was sore throat or acute pharyngitis. It accounted among the top five most common comorbidities in out-patient consults and emergency room admissions in 2015-2016.

**Objective:** This study was conducted in Chong Hua Hospital to evaluate if a sore throat scoring system such as the Mclsaac Decision Rule was valid in detecting group A beta hemolytic streptococcus pharyngitis and was reliable as a clinical approach in managing sore throat.

**Design:** A prospective, descriptive survey was done among patients who consulted and eventually admitted at the emergency room and OPD under the family medicine department at Chong Hua Hospital Cebu City.

**Methodology:** A total of 23 participants; children and adults who presented with sore throat were assessed. A data extraction form utilizing criteria from the Mclsaac clinical rule known as "Sore Throat Encounter Form" was used for each patient encounter. The following criteria were accounted; fever  $>38^{\circ}\text{C}$ , swollen, tender anterior cervical lymph nodes, tonsillar exudate and absence of cough. A corresponding point was assigned based on the patient's age. Points are summed up and used as basis of management; patients presenting with a score of -1 and 0 could be managed without antibiotic treatment and no throat culture is required. For scores of 1-3 throat culture is indicated and positive results should be treated. For 4-5 scores an empiric antibiotic treatment should be initiated without the need of throat culture. A throat swab for culture was obtained as a reference standard. In addition, physicians' prescribing practices and their recommendations for obtaining throat swabs were compared with score-based recommendations.

**Results:** Categorical data were expressed in frequency and percentages. Mclsaac clinical decision rule assessment results and findings of gold standards were tested for association using 2x2 Fisher's exact test wherein the p-value lesser than 0.05 alpha was considered significant. Accuracy of Mclsaac clinical decision rule assessment was computed using sensitivity, specificity, likelihood ratio positive, negative, and positive predictive values.

**Conclusion:** The Mclsaac Clinical Decision Rule has demonstrated clinically acceptable diagnostic accuracy in predicting streptococcus pharyngitis. Thus, it can be a reliable and valid risk assessment tool to predict and rule out Group A Beta Hemolytic Streptococcus Pharyngitis.

**Key words:** Group A beta hemolytic streptococcus pharyngitis, throat culture

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## INTRODUCTION

Sore throat (acute pharyngitis) is one of the most frequent illnesses seen at primary care level caused by many etiologies such as bacterial and viral pathogens. Although the group A streptococcus is the most common bacterial cause of acute pharyngitis (Table 8) only a small percentage of patients with this condition usually are positive on throat swab culture, the gold standard for the confirmation of acute streptococcal pharyngitis, the majority are viral in nature. Accurate clinical diagnosis is often difficult to establish, as the clinical manifestations for viral and bacterial infection often overlap, it is a frequent indication for antibiotic prescription in the community resulting in significant healthcare cost and a widespread injudicious antimicrobial therapy contributing to an increasing antimicrobial resistance and untoward side effects.

In Chong Hua Hospital, ATP or acute pharyngitis accounts for top five most common comorbidities found in Family Medicine admissions both adult and pediatric. Most hospital staff at the OPD setting, also presents with complaints of sore throat or odynophagia causing them to take leave of absence from work. These patients usually self-medicate with a variety of antibiotics prior to seeking medical attention.

A number of clinical decision rules have been developed and validated to help physicians more accurately estimate the probability of GABHS pharyngitis. Some have been tested only in adults, some only in children, some only in primary care settings, and some only in emergency departments or health centers. The best clinical decision rule was created by McIsaac and colleagues. It has been found to be clinically accurate in a group of more than 600 adults and children who presented to family physicians with sore throat.<sup>4</sup>

In 2012, the Infectious Diseases Society of America (IDSA) updated the Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis. They noted that these clinical scoring systems are helpful in identifying patients who are at such low risk

of streptococcal infection that performance of a throat culture or a rapid antigen detection test (RADT) is usually unnecessary.<sup>5</sup>

The aim of this study was to evaluate the McIsaac clinical decision rule in predicting whether or not the pharyngitis is attributable to group A beta hemolytic streptococcus. Based on this decision, an evidence based management of sore throat will then be initiated which could substantially lead to reduction of costly diagnostics, unnecessary antibiotic prescriptions and thereby decrease the risks of antibiotic misuse and overuse.

The objective of the study was to demonstrate the validity of the McIsaac Clinical Scoring System as a risk assessment tool used in the decision to treat presumed group A beta-hemolytic streptococcal (GABHS) pharyngitis.

## MATERIALS AND METHODS

### Study Design

A prospective, descriptive survey was done among patients admitted at the emergency room or OPD under the Department of Family Medicine at Chong Hua Hospital.

### Study Setting

Emergency room or OPD under the Family Medicine Department at Chong Hua hospital Cebu City.

### Study Population

This study involved patients who presented with sore throat at the emergency room, ward, floors or OPD under the Family Medicine Department at Chong Hua Hospital Cebu City.

## **Inclusion Criteria**

Male and female patients 5 to 50 years of age who consulted or admitted due to sore throat under the Family Medicine Department at Chong Hua Hospital Cebu City.

## **Exclusion Criteria**

Patients with underlying chronic respiratory, cardiac, hematological or immunological diseases, and patients who already have received antibiotic treatment 2 months prior to present consult were excluded.

## **Data Collection**

Ethical approval for this study was obtained from the Institutional Review Board of Chong Hua Hospital. The department chairman and consultants agreed to include their patients with complaint of sore throat admitted or consulted in Chong Hua Hospital and who were willing to participate in the survey. The physicians were also informed that their management such as use of antibiotics, symptomatic measures with gargle or pain medications and diagnostics such as throat culture results would be taken into account. A data extraction form utilizing criteria from the Mclsaac clinical rule known as "Sore Throat Encounter Form" was utilized for each patient encounter. The following criteria: fever  $>38^{\circ}\text{C}$ , swollen, tender anterior cervical lymph nodes, tonsillar exudate and absence of cough were taken into account and a corresponding point was assigned based on the patient's age. Points were summed up and based on these points; patients presenting with a score of -1 and 0 were recommended to be managed without antibiotic treatment and no throat culture. For scores of 1-3 throat culture was indicated and positive results should be treated. For 4-5 scores an empiric antibiotic treatment should be initiated without the need of throat culture. A throat swab for culture was obtained as a reference standard. In addition, physicians' prescribing practices and their recommendations for obtaining throat swabs were compared with score-based recommendations.

For the present study, the main outcomes were the sensitivity and specificity of the score approach in hospital-based populations. Sensitivity was determined from the number of patients for whom the score recommendation was to prescribe an antibiotic or take a throat swab for culture (those who "tested positive") and the number who had a group A streptococcal infection as indicated by a positive culture result ("true positives"). Specificity was determined from the number of patients for whom the score did not indicate antibiotics or a throat swab (those who "tested negative") and the number in whom culture results were negative ("true negatives").

All patients with a score of 4 or more were considered to have received an antibiotic prescription and not to have undergone a throat swab.

## **Data Analysis**

Categorical data were expressed in frequency and percentages. Moreover, Mclsaac clinical decision rule assessment results and findings of gold standards were tested for association using 2x2 Fisher Exact test wherein the p-value lesser than 0.05alpha was considered significant. The accuracy of Mclsaac clinical decision rule assessment was computed using sensitivity, specificity, likelihood ratio positive, negative, and positive predictive value. IBMSPSS ver 21 was used as statistical software.

## **Ethical Statements**

The study was conducted after approval from the Family Medicine Department and ethics committee of Chong Hua Hospital. All participants were informed of their rights. They were given information about the purpose of the study and details of the research procedures before the study were initiated. Informed consent and assent were obtained from the participants before interview was started. All patient consents were documented by the interviewer. All data were kept confidential.

## RESULTS

**Table 1.** Parameters of Mclsaac Clinical Decision Rule.

Sore Throat Scoring Parameters	Frequency	Percentage
<b>Symptoms</b>		
History of fever	23	100.0
Tonsillar swelling or exudates	22	95.7
Absence of cough	15	65.2
Tender anterior cervical nodes	9	39.1
<b>Patient's Age</b>		
< 15 years	4	17.4
15-45 years	17	73.9
≥46 years	2	8.7

Among the 23 participants, upon their medical examination, 100% of them had history of fever, 95.7% had tonsillar swelling, 65.2% had no cough, and 39.1% had tender anterior cervical nodes. On the other hand, 73.9% of patients were 15-45 years of age, 17.4% were <15 years of age, and only 8.7% were >45 years of age.

As revealed in Table 2, among the 23 cases, 39.1% had strep throat ruled out, 39.1% had been recommended for throat swab culture and sensitivity, and then be treated accordingly, and 21.7% were to be diagnosed of probable strep throat, thus, be considered for empiric antibiotic therapy.

**Table 2.** Patients' level of risk of strep throat by Mclsaac Clinical Decision Rule.

Level of Risk - Strep Throat	Frequency	Percent
0-1 point : strep throat ruled out	9	39.1
1-3 points: order throat swab or culture sensitivity; treat accordingly	9	39.1
4-5 points: diagnose probable strep throat; consider empiric therapy	5	21.7
Total	23	100

**Table 3.** Test of association between the Mclsaac Clinical Decision Rule assessment and the throat swab culture findings.

Risk Score	Throat Swab Culture		Total
	Negative	Positive	
0 to-1 point	9	0	9
1-3 points	9	0	9
4-5 points	3	2	5
Total	21	2	23

$\chi^2= 7.89$ , DF =2,  $p=0.019$

Table 3 shows that there was a significant association between 4-5 risk scores and positive results in the Throat Swab culture wherein of the 5 cases with score of 4-5 points, 2/5 had been positive for Throat Swab culture ( $p=0.019$ ).

The accuracy values of Mclsaac Clinical Decision Rule in the detection of Group A beta hemolytic streptococcus pharyngitis using throat culture as the reference standard were as follows, sensitivity of 100% of positively predicting streptococcus pharyngitis, 85.7% of ruling out negative for streptococcus pharyngitis, with positive likelihood ratio of 7.00 indicating that those with 4-5 points in the risk score had 7 times higher to have streptococcus pharyngitis than those who were not within the risk score range, and the scoring system cut off yielded positive predictive value of 40% and negative predictive value of 100%. (Table 4)

**Table 4.** Accuracy of Mclsaac Clinical Decision Rule in the detection of group A beta hemolytic streptococcus pharyngitis using throat culture as the reference standard.

Accuracy Indices	Proportion Estimate	Confidence Lower	Interval Upper
Sensitivity	100.0%	100.0%	100.0%
Specificity	85.7%	70.7%	100.7%
Likelihood Ratio +	7.000	2.455	19.957
Predictive value positive	40%	0%	83%
Predictive value negative	100%	100%	100%
Overall accuracy**	87%	73%	101%

**Table 5.** Pattern of antibiotic treatment per Mclsaac Clinical Decision Rule categories.

Level of Risk - Strep Throat	Frequency	Percent	Recommended Antibiotics Treatment
0-1 point : strep throat ruled out	9	39.1	9 cases / 9 total
1-3 points: order throat swab; treat accordingly	9	39.1	9 cases / 9 total
4-5 points: diagnose probable strep throat; consider empiric therapy	5	21.7	5 cases / 5 total
Total	23	100	23/23 cases

As noted in Table 5, among the 23 cases that had medical examination with presenting symptoms, 100% of them were recommended for antibiotic treatment. However, when Mclsaac Clinical Decision Rule assessment, only 5/23 cases qualified for consideration of empiric therapy after the throat swab culture test. Thus, 18 cases / 23 (78.3%) should have not been subjected to antibiotic treatment.

### DISCUSSION

After the application of Mclsaac Scoring System patients were classified into low, moderate and high risk group according to their summed up scores, such as -1 to 0 as strep throat ruled out group; 1-3 as order throat culture group; and 4-5 as consider antibiotic therapy group.

Further review of the results found that among the 23 participants, all of them had history of fever, 22 of them had tonsillar swelling or exudates, and nine of them had tender anterior cervical nodes. These criteria were noted to increase the likelihood of GABHS pharyngitis according to the Mclsaac clinical scoring system. Only four participants who were less than 15 years old had 1 point added on their scores due to increase likelihood of children developing GABHS compared to adult. Moreover, participants within the age of 15-45 received zero point and those more than 45 years of age received -1 point. Participants without cough also received an additional point because presence of it is more commonly associated with viral pharyngitis as pointed by MH Ebell.

Table 4 shows the accuracy values of Mclsaac Clinical Decision Rule in detecting Group A beta hemolytic streptococcus pharyngitis with a sensitivity of 100.0% and specificity 85.7%; a positive likelihood ratio of 7.00 which indicated that those with 4-5 points in the risk score had 7 times higher to have streptococcus pharyngitis than those who were not within the risk score range, and the scoring system cut off yielded positive predictive value of 40% and negative predictive value of 100%.

All 23 cases with presenting symptoms, were recommended for antibiotic treatment. However, when Mclsaac Clinical Decision Rule assessment was applied, only 5/23 cases qualified for consideration of empiric therapy after the throat swab culture test. Thus, 18/23 (78.3%) should have not been subjected to antibiotic treatment. Final analysis of these results showed that unnecessary throat swab cultures were taken by 5 patients who scored 4-5; redundant antibiotic prescriptions to 9 patients who scored 0-1; and an overall use of antibiotics was given to 9 patients who scored 1-3 regardless of throat culture results. These results implied that the current practices of family physician of recommending the patients for antibiotic therapy were not consistent with the Mclsaac Clinical Decision Rule recommendation.

### CONCLUSION

The Mclsaac Clinical Decision Rule has demonstrated clinically acceptable diagnostic accuracy in predicting

streptococcus pharyngitis. It can be a practical assessment tool that can be utilized as clinical pathway which can guide physicians on their therapeutic decisions in treating children and adults presenting with sore throat. Moreover, use of the sore throat score system would retain the selective approach of management preferred by physicians while minimizing the need for additional tests. This approach is valid and reliable and could help to reduce unnecessary diagnostics and antibiotic use in family practice.

#### RECOMMENDATION

The Mclsaac Clinical Decision Rule should be considered as one of the clinical pathways utilized in the family medicine department. This simple score approach system can be routinely used at the ER or OPD prior to recommending throat swab culture or use of empiric therapy. Further study is recommended in a larger population to verify the higher accuracy demonstrated by Mclsaac Clinical Decision Rule.

#### REFERENCES

1. Ebell MH, Smith MA, Barry HC, Ives K, Carey A. A collection of point-of-care guides <http://www.aafp.org/afp/poc>.
2. Hing E, Cherry DK, Woodwell DA. National ambulatory medical care survey: 2003 Summary. *Adv Data* 2005; 365: 1–48.
3. Mclsaac WJ, Goel V, To T, Low DE. The validity of a sore throat score in family practice *CMAJ* 2000; 163: 811–5.
4. Ebell MH, Smith MA, Barry HC, Ives K, Carey M. The rational clinical examination. Does this patient have strep throat? *JAMA* 2000; 284: 2912–8.
5. Bisno AL, Gerber MA, Gwaltney JM Jr, Kaplan EL, Schwartz RH, for the Infectious Diseases Society of America. Practice guidelines for the diagnosis and management of group A streptococcal pharyngitis. *Clin Infect Dis* 2002; 35:(2): 113–25.
6. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/9581337/A> clinical score to reduce unnecessary antibiotic usage.
7. Little P, Williamson I. Sore throat management in general practice. *Family Practice* 1996 ;13: 317-2.