Introduction

Pharyngitis or 'sore throat' is a common ailment the world over, and is especially common in children. In the United States, it is estimated that every child has at least one episode of pharyngitis annually. There are a number of different agents, both viral and bacterial that can cause pharyngitis. About 10.0 – 30.0% of acute pharyngitis in children is caused by GABHS; viral infection accounts for the majority of the others. Pharyngitis due to group A beta hemolytic streptococcus (GABHS) assumes a special significance because of the risk of subsequent rheumatic fever (RF) and chronic rheumatic heart disease (RHD) in the infected child. About 0.3 – 3.0% of patients of untreated GABHS pharyngitis go on to develop RF. Carditis occurs in about 70.0% of children with RF and about a fourth of these go on to develop chronic RHD.

In wealthy countries, RF and RHD have been largely controlled since the 1950’s. In contrast to high-income countries the incidence of RF in low and middle-income countries is approximately 5 per 100,000 per year. The prevalence of RHD ranges from 1.0 to 10 per 1000 and the incidence from 10 to 100 per 100,000 per year. The estimated excess mortality rate due to RHD in these countries is 1.0 to 2.0 % per year. Thus about 12 million people are affected by RHD/RF, resulting in about 40,000 deaths annually.

The signs and symptoms of GABHS pharyngitis and non-GABHS pharyngitis overlap broadly. For example, pharyngeal exudate may be present in more than one third of patients with non-group A streptococcal pharyngitis. Therefore, under ideal conditions, unless the physician is able to confidently exclude the diagnosis of streptococcal pharyngitis on epidemiological and clinical grounds, a laboratory test should be performed to determine whether group A streptococci are present in the throat.

In low and middle income countries, because bacteriological culture facilities are not readily available and cost can be prohibitive to patients, physicians often make a clinical diagnosis and offer presumptive treatment. In these settings, clinical prediction instruments that allow physicians to make rationale decisions on diagnosis and treatment course would be very useful.
Individual signs and symptoms have not been found to be accurate enough to make a diagnosis alone, therefore, clinical prediction rules have been developed that use several key elements of patient history and physical examination to predict the probability of GABHS pharyngitis. Using a clinical prediction rule provides the clinician with a rational basis for assigning a patient to a low risk category, which requires neither testing nor treatment; a high risk category in which empiric treatment may be indicated; or in some cases, a moderate risk category which may require further diagnostic testing, if available.

While there are numerous studies on GABHS pharyngitis diagnosis in the literature, there are only a few that describe clinical prediction rules for GABHS pharyngitis in children, who are at highest risk for its sequelae, and very few studies outside of North America (Table 1).

The World Health Organization Acute Respiratory Infections (ARI) treatment program suggests that, in the absence of laboratory diagnosis for children under five years of age, acute streptococcal pharyngitis should be suspected and presumptively treated when pharyngeal exudate plus enlarged and tender cervical lymph nodes are found.

When Steinhoff et al. evaluated these recommendations in a prospective study; the guidelines were shown to be highly specific, but with low sensitivity. Steinhoff et al. studied 451 children 2-13 years of age complaining of sore throat and pharyngeal erythema in an urban pediatric clinic in Egypt. The prevalence rate of GABHS pharyngitis by culture was 24.0%, and serology was not reported. The clinical features most highly associated with positive throat culture were pharyngeal exudate and enlarged anterior cervical lymph nodes. Presence of one or both of these signs had a high sensitivity of 0.84 but a low specificity of 0.40.

Since it is not desirable to treat all pharyngitis cases with antibiotics and laboratory facilities for culture and serology are not generally available in low and middle income country settings, it would be useful to have guidelines that are created specifically for clinical identification of GABHS pharyngitis in these regions. Thus, there is a need for careful validation in children of existing clinical decision rules, and for development of improved rules. These new rules should be developed and evaluated in a variety of environments, to determine their local utility in situations of varying clinical presentation.

We therefore undertook this study to formulate a new clinical prediction rule that would have improved sensitivity yet retain adequate specificity and applicability in multiple country settings.
Methods

Study Population

From August 2001 until April 2003, 1638 children were enrolled at the outpatient clinic of Cairo University Pediatric Hospital in Egypt. The study protocols were approved by both local (site specific) and national (government) level institutional review boards at each of the clinical sites, at the World Health Organization in Geneva, and by the Committee on Human Research at the Johns Hopkins Bloomberg School of Public Health. Written consent was obtained from the parent or guardian accompanying the child to the clinic and child assent was obtained from all participating children age 5 and old.

Patients presenting to the outpatient clinics with respiratory symptoms of cough, cold, or sore or red throat were enrolled unless they met the exclusion criteria: oral antibiotic use within the 3 days prior or intramuscularly administered antibiotics within the 28 days prior to the clinic visit, history of previous rheumatic fever or rheumatic heart disease, or presence of another illness requiring hospitalization. After enrollment, demographic information was recorded and a physical examination was performed. Data was collected on specific signs and symptoms associated with pharyngitis using standard definitions. The forms used for data collection are enclosed. We used a simple to use commercial rapid antigen test for diagnosis of GABHS pharyngitis (Strep Max OIA Test; Biostar, Denver CO). The rapid antigen test was performed by the physician conducting the physical examination for each child and results were recorded in a standard format.

Statistical Methods

Children participating in the study were categorized as having acute GAHBS pharyngitis or nonspecific pharyngitis based on rapid antigen test results. The sensitivity, specificity and positive predictive value of each sign and symptom in predicting a diagnosis of GAHBS pharyngitis were calculated. In addition, a $\chi^2$ statistic was calculated to assess whether or not signs and symptoms were significantly associated with GABHS pharyngitis. Variables that were statistically significantly associated with GABHS pharyngitis were
chosen for the next stage of analysis. Logistic regression was used to model the probability of GAHBS pharyngitis in terms of these variables.

Each selected sign or symptom was defined in such a way that it was a positive predictor of GAHBS pharyngitis (i.e. absence of cough instead of cough) and therefore had a positive coefficient in the regression model. Next, backwards and forward stepwise regression techniques were used to create a subset of signs and symptoms that were independent predictors of GABHS pharyngitis ($P < 0.05$). A score for GAHBS pharyngitis was then calculated from this subset using a simple count of signs and symptoms present for each child.
TREATMENT OF PHARYNGITIS STUDY (TOPS)
A randomized equivalence trial of intramuscular vs, oral antibiotics in the treatment of streptococcal pharyngitis in children in developing countries summary

Background / Rationale:
Group A beta-hemolytic streptococcal pharyngitis (GABHS pharyngitis) is the precipitating cause of rheumatic heart disease (RHD). GABHS pharyngitis is a common illness, which if not treated with antibiotics, can cause disease of the cardiac valves known as rheumatic fever. Primary prevention of acute rheumatic fever is accomplished through accurate identification and antibiotic treatment of GABHS pharyngitis to eradicate the organism from the pharynx. Improved treatment for GABHS pharyngitis in children less developed countries will reduce the large burden of preventable cardiac disease in these regions.

In developing countries, intramuscularly administered benzathine penicillin G (BPG) is the current treatment, recommended by the World Health Organization, however, there are disadvantages to this treatment regimen. Intramuscularly administered BPG is associated with pain and tenderness at injection site and risk of allergic reaction to penicillin. Also safe injection practices are required to administer the shot and proper cold chain must be maintained for the drug to be effective both of which continues to be a problem in developing countries. Additionally intramuscularly administered BPG remains active in the blood stream for up 28 days, which may increase potential for development of antimicrobial resistance.

In recent years 2 studies have shown that amoxicillin, a synthetic form of penicillin taken once a day may be an effective choice for treatment of streptococcal pharyngitis. The reported rates of treatment failure for oral amoxicillin once day are extremely low and may in fact be lower than intramuscularly administered BPG. Additionally with once a day amoxicillin, the duration of antibiotic exposure is limited to 10 days, which is likely to limited the amount of antimicrobial resistance created during treatment with this drug.

Description/Design:
There are two primary objectives of this study:
1) To compare microbiological effectiveness of a single shot of intramuscular penicillin G (600,000-1,200,000 IU) versus, a once daily dose of oral amoxicillin (750 mg/qd x 10 days) in the treatment of strepococcal pharyngitis, assessed by throat culture taken at the time of diagnosis and 3 weeks later to determine if the organism has been eradicated from the pharynx.
2) To assess the effect of intramuscular penicillin versus, the effect of oral amoxicillin on nasopharyngeal colonization rate of penicillin resistant S pneumoniae, assessed by nasopharyngeal swabs taken at the time of diagnosis and 3 weeks later to determine if the rates have increased.

The secondary goals are to assess adverse events associated with each treatment regimen: to assess the role of compliance in the effectiveness of amoxicillin treatment in eradicating GABGS from the pharynx and to assess the cost of intramuscular versus, oral antibiotics in the treatment of streptococcal pharyngitis.
Using standard calculations, a sample size of 144 participants per treatment group will be required to assess whether or not the two treatments are equivalent. Treatment regimens will be considered equivalent if there is less than a 5% absolute difference between treatment failure rates. This means that if the treatment failure rate for BPG is 12% and the treatment failure rate for amoxicillin falls somewhere between 12% and 17% the two treatments should be considered equivalent.

TOPS is a prospective, randomized, active control equivalence trial conducted in parallel with the ongoing Group A Streptococcal Pharyngitis (GRASP) diagnostic study. The purpose of the GRASP study is to define new clinical guidelines for the diagnosis of streptococcal pharyngitis in children in developing countries.

Children who are enrolled in the GRASP diagnostic study will be eligible for enrollment in TOPS. A rapid antigen test will be performed upon enrollment into the GRAPS study to determine if the child is antigen positive for GABHS pharyngitis and eligible for TOPS. If the child is eligible for the study he/she will be invited to participate in TOPS. Parental permission/consent and child assent will be obtained. In addition to the GRASP study procedures, a nasopharyngeal swab will be obtained at baseline and follow up, the child will be randomized to receive oral or intramuscular antibiotics, a urine test will be performed during antimicrobial therapy and the child and parent will be asked questions about the treatment received a follow up. Data forms for the study are enclosed.

**Importance of Research:**
If both BPG and amoxicillin are found to be comparable, WHO and local policies may be changes to recommend the use of oral amoxicillin as a treatment for streptococcal pharyngitis.
Patient Data Forms For GRASP And TOPS

WHO / USAID / JHSPH GRASP/TOPS STUDY

Date: ---- / --- -- / ---- GRASP Patient ID#:

TOPS Patient ID#:

PATIENT SCREENING FORM (VISIT 1)

Complete this form for children age more than 24 months and less than 12 completed years with cough or cold or sore throat, or pharyngeal erythema.

Identification

1. Child's Name:
2. Parent or Guardian's Name
3. Telephone Number
4. Address:
5. Distance of residence from clinic: (kilometers)
5a. Time it takes to get to clinic Hours Minutes

6. Date of Birth:

6a. Age __
6b. If less than one year of age, use months:
7. Sex: (Please circle one)

1. Male
2. Female

Study Eligibility

8. Children are eligible for the study if they meet the following criteria:

Age: More than 24 completed months and less than 12 completed years

0. No
1. Yes

and

Physician observes or parent/child reports one or more of the following symptoms:

Cough 0. No 1. Yes
Cold 0. No 1. Yes
Sore Throat 0. No 1. Yes
Pharyngeal erythema 0. No 1. Yes

Exclusion Criteria Children are NOT eligible for the study if they meet any of the following criteria:

(Please circle yes or no for each criteria)
Documented antibiotic use in the last 3 days 0. No 1. Yes
Documented intramuscular penicillin G in the last 28 days 0. No 1. Yes
Presence of ear discharge or impetigo at the time of examination 0. No 1. Yes
History of previous rheumatic fever or rheumatic heart disease 0. No 1. Yes

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**WHO / USAID / JHSPH GRASP/TOPS STUDY**

Date: --/--/----

GRASP Patient ID#: ------------

TOPS Patient ID#: ------------

<table>
<thead>
<tr>
<th>History of allergy to amoxicillin or penicillin</th>
<th>0. No</th>
<th>1. Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any other infection requiring antibiotics</td>
<td>0. No</td>
<td>1. Yes</td>
</tr>
<tr>
<td>Presence of other severe illness or major system disease that requires hospitalization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EXCEPT. Malnutrition or Tuberculosis</td>
<td>0. No</td>
<td>1. Yes</td>
</tr>
<tr>
<td>Previous enrollment in the study</td>
<td>0. No</td>
<td>1. Yes</td>
</tr>
<tr>
<td>Physician diagnosis of wheezing, bronchitis, or pneumonia</td>
<td>0. No</td>
<td>1. Yes</td>
</tr>
<tr>
<td>Patient unable to return for follow up visit</td>
<td>0. No</td>
<td>1. Yes</td>
</tr>
<tr>
<td>Parent or guardian not available to give informed consent</td>
<td>0. No</td>
<td>1. Yes</td>
</tr>
</tbody>
</table>

EPI INFO FILE: GRSPSCR.REC

Revised, 09.12.01
**PATIENT PHYSICAL EXAM FORM (VISIT 1)**

**HISTORY OF SYMPTOMS PRESENT WITHIN THE LAST 5 DAYS**

Parent/guardian and child should be asked if child has exhibited any of the following symptoms in the past five days:

<table>
<thead>
<tr>
<th>SYMPTOM</th>
<th>PRESENT</th>
<th>ABSENT</th>
<th>DURATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever (Report by parent/guardian of fever or Temperature above 38.1 °C Rectal or 38.5 °C Oral)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chills (Sensation of cold)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Runny Nose (History of nasal discharge)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nasal Congestion (increased difficulty breathing)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sore Throat (Throat pain)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difficulty or Pain Swallowing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Earache (Ear pain)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Activity Level Below Normal (Change in activity compared to normal)</td>
<td></td>
<td></td>
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<tr>
<td>Disturbed Sleep (Change in sleep patterns from normal)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hoarseness (Presence of harsh quality of voice that is different from normal)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Remarks (Please list)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**History**

- Does this child have a history of streptococcal infection (confirmed by a health professional) in the last year?
- Has another person in the family had a sore throat in the past 5 days?

**VITAL SIGNS**

- Heart Rate: - - - beats per minute
- Temperature: - °C (Please fill in temperature and circle method)
  1. Axillary
  2. Oral
  3. Ear
- Height: - - - centimeters (Height in nearest centimeter of standing child)
- Weight: --.- kilograms (Weight of child to the nearest 0.1 kg)
WHO / USAID / JHSPH GRASP/TOPS STUDY

Date: ---- / ---- / -----   GRASP Patient [D#: DD/MM/ YY
TOPS Patient ID#:

SIGNS PRESENT
Please examine child and indicate if sign is absent or present

<table>
<thead>
<tr>
<th>SIGNS</th>
<th>PRESENT</th>
<th>ABSENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cough (Observation of coughing during consultation)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hoarseness (Presence of harsh quality of voice that is different from normal)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharyngeal Erythema (Redness of the pharynx that is greater than that of the buccal mucosa, excluding tonsils)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tonsillar Erythema (Redness of the tonsils)</td>
<td></td>
<td></td>
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<tr>
<td>Erythema Posterior (Redness of the posterior wall of throat)</td>
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<td></td>
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<tr>
<td>Fauoral Erythema (Redness of the passage from mouth to pharynx)</td>
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<tr>
<td>11+ Tonsillar Enlargement Degree to which tonsils extend into the midline. Defined as &lt; 25% of distance of midline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2+ Tonsillar Enlargement Degree to which tonsils extend into the midline. Defined as tonsils are &gt;25% and &lt; 50% of distance of midline.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3+ Tonsillar Enlargement Degree to which tonsils extend into the midline. Defined as tonsils &gt;50% and &lt;75% of distance of midline.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4+ Tonsillar Enlargement Degree to which tonsils extend into the midline. Defined as tonsils are touching</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tonsillar Exudate (White or yellow matter on tonsils)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cervical Lymph Node Tenderness (Tenderness of node on gentle palpation, confirmed by statement or facial expression)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nares Excoriations (Scratches or lesions around nostrils)</td>
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</tbody>
</table>

**Pharyngeal Exudate**
(White or yellow matter on the pharynx)
Palatal Petechiae
(Presence of lesions on the palate)
Strawberry Tongue
(Tongue with papillar swelling)

Diameter of largest Cervical Lymph Node (any diameter >11): (centimeters)
OTHER CONDITIONS PRESENT

Please examine child and indicate if conditions are present

<table>
<thead>
<tr>
<th>Condition</th>
<th>Present</th>
<th>Absent</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Malnutrition</td>
<td></td>
<td></td>
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<tr>
<td>(Marasmus, Kwashiorkor,</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Protein Energy Malnutrition)</td>
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<td></td>
<td></td>
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<tr>
<td>Vitamin A Deficiency</td>
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<td></td>
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</tr>
<tr>
<td>(physician observation of Bitot's</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>spots or report of night</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>blindness)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Diarrhea</td>
<td></td>
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<tr>
<td>(More than 3 abnormal stools in</td>
<td></td>
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<tr>
<td>the past 24 hours)</td>
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<tr>
<td>Tuberculosis</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>(diagnosis by health care</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>professional)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Other (Please list)</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

TREATMENT GIVEN

(Please check appropriate box and indicate dosage)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Daily Dosage (mg)</th>
<th>Duration (# Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Penicillin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intramuscular Penicillin (Benzethine G)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral Ampicillin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral Erythromycin</td>
<td></td>
<td></td>
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<tr>
<td>Oral Azithromycin</td>
<td></td>
<td></td>
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<tr>
<td>Oral Amoxicillin</td>
<td></td>
<td></td>
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<tr>
<td>Other (Please list)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

REMINDER:

1. PLEASE TAKE THROAT CULTURE AND BLOOD SPECIMEN
2. PLEASE ASK PARENT/GUARDIAN TO MAKE APPOINTMENT AND BRING CHILD BACK IN 21-32 DAYS.

IF PARTICIPATING IN TOPS THERAPEUTIC TRIAL:

1. TAKE NASOPHARYNGEAL CULTURE
2. GIVE PARENT/GUARDIAN FILTER STRIP FOR URINE TEST
3. RANDOMIZE PATIENT TO TREATMENT REGIMEN
DATE:     --- / ---- / ---- GRASP Patient 1D#:  
DD/MM/ YY  TOPS Patient 1D#:  
TOPS ENROLLMENT/ TREATMENT ALLOCATION  
(Visit 1)  

1 Rapid Test Results: (Please circle one)  
0. Negative  
1. Positive  
2. Indeterminate  

2. Is this patient enrolled in TOPS?  
0. No  
1. Yes  

2. Assigned Treatment Regimen: (Please circle one)  
1- Treatment A - Benzathine Penicillin G  
2- Treatment B - Amoxicillin  

3. If child was given Treatment A, Benzathine Penicillin G, then what is the lot number of the medication (PENLOT)  

4. If child was given Treatment B, Amoxicillin, did child:  
1. Swallow full dose  
2. Swallow partial dose  
3. Spit out medicine or did not swallow or take dose at all  

5. Name of person who performed rapid test: --------------------------------------
NASOPHARYNGEAL CULTURE SPECIMEN COLLECTION

1. Patient Name:

2. Time specimen collected: hours (24 Hour Time, for example 3pm = 15:00 hours)

3. Time received by laboratory: hours (24 hour time)

LABORATORY NP SPECIMEN RESULTS

1. Colony Count (Please circle one):
   - 0 < 25 colonies on 1st quadrant/ specimen area
   - 1+ > 25 colonies in specimen area, < 25 colonies in 2nd quadrant
   - 2+ > 25 colonies in 2nd quadrant, < 25 colonies in 3rd quadrant
   - 3+ > 25 colonies in 3rd quadrant, < 25 in 4th quadrant
   - 4+ > 25 colonies in 4th quadrant (growth in 1st quadrant should be confluent)

2. Optochin solubility test:
   Zone of inhibition size: mm

3. Bile solubility test:
   Zone of inhibition size: mm

4. Oxacillin disc test:
   Zone of inhibition size: mm

5. Name of Laboratory Technician:

6. Date: / / 

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URINE SPECIMEN COLLECTION

1. Patient Name:

2. Date specimen should be collected:  
   DD/ MM/ YY

3. Time specimen collected: AM / PM (Please circle one)

Instructions For Parents for Urine Collection
To be collected in 7 days

1) Collect urine midstream in a clean cup or container. a) Tell your child urinate a small amount in the toilet and then stop. b) Instruct the child to then urinate a small amount in the cup. c) Remove the cup and allow the child to finish urinating in the toilet. 2) Place glassine envelop on a flat surface. 3) Hold paper strip with fingers on one end of the strip. 4) Dip end of strip into urine. 5) Place paper strip on glassine envelop to dry. 6) When paper strip is dry place inside glassine envelope 7) Place glassine envelope in mailing envelope. 8) Bring envelope back to clinic at the follow up visit and give it to your doctor.
TOPS STUDY PARENT FOLLOW UP FORM
VISIT 2

1. Rate the degree of pain/discomfort your child was in prior to his/her visit
   0. None 1. Some 2. Excessive

2. Rate the degree of pain/discomfort your child is in now
   0. None 1. Some 2. Excessive

3. Did the treatment your child received decrease your child's pain?
   0. None 1. Some 2. Excessive

4. Were you satisfied with the amount of time that the doctor spent with you and your child?
   0. No 1. Somewhat 2. Completely

5. Were you satisfied with the information your doctor provided you about the health of your child?
   0. No 1. Somewhat 2. Completely

6. Were you satisfied with the way the doctor interacted with your child?
   0. No 1. Somewhat 2. Completely

7. What was the average amount of time you waited at the clinic to receive health care for your child during the study period?
   0. <20 min 1. 20-60 min 2. >60 min

8. How do you rate your overall satisfaction with the health care your child has received?
   0. Not satisfied 1. Satisfied 2. Completely Satisfied

If your child was given an oral treatment please answer the following:

9. Did your child have trouble swallowing the tablet?
   0. No 1. Yes

10. Did your child have any other side effects?
    0. No 1. Yes

If your child was treated with an injection please answer the following:

11. Did your child experience soreness at the site of injection?
    0. No 1. Yes

12. Did your child experience any other side effects?
    0. No 1. Yes

13. If yes, please list them: