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Providers' Use Of Standards Of Care For Methicillin Resistant Staphlyococcus Aureus Abcesses

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Providers' Use of Standards of Care for Methicillin Resistant Staphylococcus Aureus

Abscesses

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Mississippi University for Women

Advanced Nursing Research and Evidence-Based Practice Strategies

Fall 2007

Providers' Use of Standards of Care for Methicillin Resistant Staphylococcus Aureus

Abscesses

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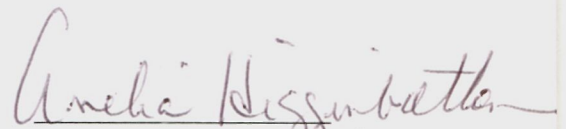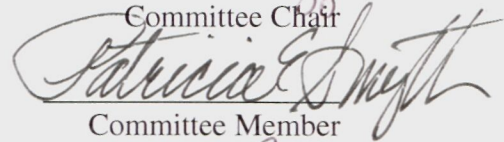
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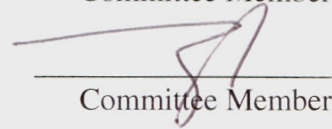Providers' Use of Standards of Care for Methicillin Resistant Staphylococcus Aureus
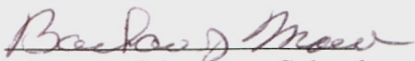
Abscesses

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DEDICATION

Jeff Moffett-
I would like to dedicate this research project to my wife Jennifer and my children Jacob, Joshua, and Jessica who have supported me in every way during this academic effort. I would also like to dedicate this to my co-researchers who have worked diligently to bring this project to a successful completion. Thank you all.

Lisa Gatwood-
I dedicate this research project to my three beautiful children and family that has supported me through this educational experience.

Suzanne Cox-
I would like to dedicate this project to my husband who has been perfect through this entire ordeal. You've helped me achieve all my dreams. That means more to me than you'll ever know.

Victoria Ashley Ford-
I would like to dedicate this project to my family, most importantly my extremely supportive husband for all the moments of undivided attention, love and encouragement.

ACKNOWLEDGEMENTS

ABSTRACT

Methicillin Resistant Staphylococcus Aureus (MRSA) skin and soft tissue infections are increasing in prevalence throughout the United States. The purpose of this study was to evaluate the treatments provided to patients with abscesses and assess the effectiveness of the treatment provided based on rate of return visits. Sister Callista Roy's Adaptation Model was used as the theoretical framework to guide this study. A thorough review of recent research regarding the incidence of MRSA abscesses, causative isotypes, and treatment provided was conducted. The study consisted of a nonexperimental, quality assurance project using a retrospective chart review design in a rural emergency department in South Mississippi. The population consisted of all races, genders, and ages of patients who had a discharge diagnosis of abscess. The sample included 200 medical records of patients that were treated for an abscess and positively cultured for MRSA. Data was systematically collected using a data collection tool designed by the researchers. Data collected included the patients' age, race, gender, number of visits for abscess within the past year, type of provider seen, treatment provided including education given, follow-up within 48 hours, and number of return visits within 90 days. Data was analyzed by a statistician with the use of descriptive statistics including fit tests, percentiles, and frequencies using the Statistical Package for the Social Sciences (SPSS) software program. The researchers used the data collected to determine the actual implementation of the Centers for Disease Control and Prevention recommendations and the effectiveness of this treatment based on the rate of return visits. The goal of this study was to increase the mounting support for the establishment of a standard of care for the treatment of abscesses. The results of the data were inconclusive with over 28 variations in treatment provided. Bactrim was identified as the most prescribed antibiotic and demonstrated the highest number of return visits. This data cannot be generalized due to the inconsistence with follow up in an acute care setting and the broad spectrum of treatments provided. Several variables including use of intravenous antibiotics, intramuscular antibiotics, topical antibiotic therapies, and educational materials may have affected the rate of return visits. The researchers were unable to identify a standard of care due to the inconsistent treatment and rate of return. This further supports the researchers' position that further research is needed to identify a standard of care in the treatment of MRSA abscesses.

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CHAPTER III: DESIGN AND METHODOLOGY

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CHAPTER V: SUMMARY & CONCLUSIONS

CHAPTER ONE

Dimensions of the Problem

Introduction

Methicillin resistant staphylococcus aureus (MRSA) skin and soft tissue infections are becoming increasing prevalent throughout healthcare settings. The treatment provided varies widely between providers and practices due to the lack of a clear consensus on treatment (Monroe, 2007). The spectrum ranges from no treatment to intravenous antibiotics, incision and drainage, and multiple prescriptions for oral antibiotics. MRSA is not a reportable disease in most states and the exact incidence is unknown. Recent studies by the Centers for Disease Control and Prevention (CDC) have examined isolates from skin and soft tissue infections and identified a new strain of MRSA associated with community acquired infections. This strain, community acquired methicillin resistant staphylococcus aureus (CA-MRSA), is emerging in groups without recent hospitalizations or invasive procedures. These isolates have an increasing resistance to antimicrobial agents, and treatment failure data is inadequate (Gorwitz et all, 2006). Based on the limited research available the CDC released recommendations for the treatment of MRSA in skin and soft tissue infections. These recommendations included the following: consideration of staphylococcus aureus in patients complaining of "spider bites," specimens should be collected for culture and susceptibility testing, incision and drainage should be performed routinely, empiric antimicrobial therapy should be administered to patients with purulent lesions, antimicrobial therapy should be guided by local susceptibility data with a beta-lactam agent as a first-line therapy, intravenous antimicrobial agents should be considered for patients with severe

staphylococcal infections, patient education on methods to prevent spread of infection, decolonization agents should be used only when patients have multiple recurrences of MRSA infections or if there is an ongoing transmission of MRSA within a closely-associated group, standard precautions should be implemented in both the inpatient and outpatient setting, and patient's treated for skin and soft tissue infections should be scheduled for a return visit within 48 hours for evaluation of response to therapy (Gorwitz et all, 2006).

Problem Statement

The incidence of CA-MRSA has continually increased within the past five years. The actual incidence is unknown but healthcare providers are reporting "virtually epidemic proportions" of MRSA skin and soft tissue infections (Hedden, 2007). The number of providers using CDC recommendations for the treatment of staphylococcus aureus abscesses is not known. Research regarding the effectiveness of these recommendations is limited. The effectiveness of the CDC recommendations has not been appropriately evaluated. There are multiple treatment regimens being prescribed without research to support these therapies. Ineffective treatment will lead to an increase in antimicrobial resistance and mounting spread of MRSA within the community. Support for the effectiveness of the CDC recommendations is needed for the implementation of a standard of care among providers. There is a lack of research available regarding the implementation of these recommendations.

Statement of Purpose

The purpose of this project is to review the treatment prescribed by providers and evaluate the return rate for each treatment. The effectiveness of treatment provided can be assessed by the number of return visits within a 90 day period. The review of treatments provided will determine whether the recommendations should be implemented as a standard of care for this increasingly prevalent disease.

Significance of the Study

In some parts of the United States, 60% to 75% of all community-acquired isolates of *S. aureus* are now methicillin-resistant (Moerelling, 2006). The most basic recommendation is to include MRSA in the differential diagnosis of skin and soft-tissue infections; it is the most common presentation (Sherman, 2007). Efficacy data are lacking for decolonization with agents like nasal mupirocin and antiseptic body washes. It may be appropriate in cases in which standard prevention measures have proven inadequate for patients with multiple recurrences of MRSA infection and or members of a household or other well-defined group in which transmission is ongoing (Sherman, 2007).

This study is significant to healthcare providers for all age groups. The incidence of community acquired MRSA skin and soft tissue infections continue to rise, There is need for education to the public. Practitioners need to ensure that proper treatment is given to reduce the recurrence rate and decrease the spread of this infectious disease. This study will provide support for the needed implementation of a standard of care for the treatment of abscesses.

Theoretical Foundation

In the proposed study, researchers will use Roy's Adaptation Model to review provider's treatment of staphylococcus aureus abscesses, rate of return visits, and assess the need for a standard of care. Roy theorized that ineffective responses lead to illness and that healthcare providers treat illness by helping the patient to manage stimuli (Perrett, 2007). Stimuli are categorized based on their effects on the human system. Focal stimuli directly affect the system, contextual stimuli are all of the factors that contribute to the effect of the focal stimuli, and the residual stimuli are those that have an unclear effect on the system. Roy theorized that a person consists of six interrelated subsystems: the regulator, cognator, physiological-physical mode, self-concept-group identity mode, role function mode, and interdependence mode. According to Roy, the regulator is the automatic response to stimuli through the neural, chemical, and endocrine processes, and the cognator is the response through one of the four adaptive modes. The physiological-physical mode consists of the physical and chemical processes that aid adaptation in meeting the five basic needs of oxygenation, nutrition, elimination, activity and rest, and protection. The self-concept-group mode consists of psychological and spiritual beliefs a person holds about oneself to meet the basic need of identity integrity. The role-function mode exists to meet the need for social integrity through identifying the primary, secondary, and tertiary roles one occupies. Finally, the interdependence mode centers on the need for relational integrity that consists of the person's receptive and contributive behaviors to relationships (Patton, 2004).

In this study, the ineffective management of stimuli can be illustrated by the formation of the abscess in response to infection by staphylococcus aureus. The

conceptual stimuli will be the staphylococcus aureus infection and the focal stimuli will be the patient's demographic data. The regulator coping mechanisms will be the body's physical, neural, chemical and endocrine response to the infection, and the cognator coping mechanisms will be the patient's emotional response to the infection and the provider will assist the patient with these mechanisms. The physiological-physical mode of adaptation will be represented by the physical manifestations of the infection such as the abscess itself and the success of the providers treatment will monitored through this mode. The self-concept mode can be evaluated by the patient's perception of their body image related to the abscess. The practitioner will assess how the abscess affects the role function mode by identifying the degree of limitation in daily activities or work missed due to the abscess, and the interdependence mode can be determined by the support system available and impact of the infection on personal relationships. The treatment provided including procedures and medication prescribed will be the practitioner's management of the stimuli, and any education given regarding ways to decrease risk of infection contribute to the patient's acquired coping mechanisms. The researcher's review of the rate of return visits for the same infection will represent Roy's final step of the nursing process, which evaluates if adaptive goals have been met. The resolution of these abscesses after appropriate treatment that addresses all levels of adaptation, represented by a standard of care, supports Roy's theory that all modes of adaptation are interrelated. This research will contribute to the increasing evidence that the Roy adaptation model can be used to guide current and future nursing practice.

Definition of Terms

Standard of Care

Theoretical- Medical actions other health professionals would conduct under similar circumstances that are used for the cure of a disease.

Operational- Treatment for abscesses as recommended by professional organizations such as Centers for Disease Control or World Health Organization as identified on the data tool (Appendix B, page 39). Procedures performed, medications given or prescribed and education and instruction given by providers of a South MS emergency department as measured by data collection tool numbers 5,6, 9, 12, 13, and 14.

Abscess

Theoretical- An enclosed collection of infective material somewhere in the body. It is the result of the body's defensive reaction to foreign material.

Operational- An inflamed and erythematous cutaneous collection of infective material positively cultured for MRSA as documented by the data collection tool # 11.

Providers

Theoretical- Professionally trained healthcare staff.

Operational- Physicians, nurse practitioners, and physician's assistants in a South Mississippi emergency department as measured by question eight on the data collection tool.

Research Question

The goal of this study is to review the treatment provided to patients with abscesses and determine whether the CDC recommendations were followed. The rate of return visits will be used to evaluate the effectiveness of the treatment provided. The

research questions address the wide spectrum of treatments provided and the effectiveness of these treatments based on rate of return visits.

1. What are the current practices for treatment of abscesses presenting to the emergency room?

2. What is the rate of return visits within a 90-day period for each treatment provided?

Assumptions

The author assumes that the charts reviewed in the study have accurate documentation of the diagnoses of abscess. It is also assumed that the investigator does not misinterpret the documentation of the provider.

Limitations

The sample was not limited to age, race, or gender. The population was limited to those who seek care in single emergency room in south Mississippi. One limitation was the charts were reviewed from an emergency department instead of a primary care clinic; therefore rate of return visits and previous visits may not be accurate. Education and treatment provided may not be appropriately charted, and because information will be gathered from archived charts all information may not be available.

Summary

The purpose of this study was to assess the current practices for treatment of abscesses and evaluate the effectiveness of these treatments as evidenced by the rate of return visits. The CDC recommendations are the most recent guidelines regarding the treatment of MRSA skin and soft tissue infections but the actual implementation and effectiveness of these guidelines has not been studied. Recent research has proven the

incidence of this infectious disease is continually rising; yet evidence supporting specific

treatments has not been collected. The goal of this study is to support the need for an

established standard of care for the treatment of abscesses in the outpatient setting.

CHAPTER TWO

Review of Literature

Introduction

An extensive search of peer reviewed journal articles was conducted to determine the current practices for the treatment of abscesses nationwide. This review revealed an abundance of research regarding the increasing incidence of community associated Methicillin-Resistant Staphylococcus Aureus (MRSA). Previous research focused on the causative isolates and incidence of these infections within specific populations. The purpose of the proposed research is to review the actual treatment provided and assess the effectiveness of actual practice.

Review of Literature

In a recent article in *Emerging Infectious Diseases,* researchers were consulted by emergency room physicians who noticed an increase in the number of visits for skin and soft tissue infections caused by MRSA in a Baltimore, Virginia medical center. The researchers in this article decided to review the actual incidence of MRSA in the emergency room, describe the isolates causing the skin and soft tissue infections (SSTIs), and review the rate of SSTIs within the emergency room and outpatient clinics. The data for this quantitative multi-site, retrospective study was gathered from October 1, 2000 through September 30, 2005. More than 45,000 visits were reviewed for incidence of SSTIs and molecular typing was performed on 296 MRSA isolates from cultures previously obtained. Patient demographic information and risk factors were obtained from computerized medical records. Patients were grouped based on site of infection and community-associated or healthcare-associated if the patient had been hospitalized, lived

in a long term care center, had surgery, or dialysis within the previous year. Statistical analysis was performed using proportions and SPSS version 12.5. Variables were compared using x^2 or Fisher exact tests and Student t tests. The results of this study were statistically significant with $p \leq 0.001$. Identification of isolates had a sensitivity of 84%, specificity of 100%, and positive predicted values of 100% and negative predicted values of 80%. No theoretical framework was identified (Johnson et al, 2007).

The author's results of this research demonstrated both an increase in the number of visits for SSTIs and the incidence of MRSA. Molecular typing indicated the predominant isolate to be the USA300 clone. The researchers felt that their study helped provide support to other recent studies illustrating an increase in the number of community-associated MRSA infections and an increase in the incidence of USA300 clone as the causative isotype. The strengths of this study were the large number of visits reviewed, the availability of complete medical records using the computerized medical record system, and the consistency of findings with recent research. The limitations were that the study was retrospective; therefore, many of the cultures were not available for molecular typing, the population consisted of mostly male veterans of low socioeconomic status and could not be generalized to the population as a whole, and there was no data on treatment collected. This study will provide support for this researcher's planned study on the need for establishing a standard of care due to the increasing numbers of MRSA infected SSTIs. It also provides support for the recommendation of culturing all SSTIs to appropriately treat the causative isotype (Johnson et al, 2007). The following article reviews the susceptibility of MRSA isolates to different treatments.

Another group of researchers studied the prevalence of MRSA in SSTIs at eleven university-affiliated emergency rooms around the United States. In this multi-site, quantitative, prospective prevalence study, researchers identified 422 patients over age 18 with an SSTI, of less than one week's duration, in the month of August of 2004. Emergency room physicians collected the patient's demographic data, risk factors for MRSA, and treatment provided on a standardized form. Cultures were obtained from the largest site of infection and processed according to standard techniques at each hospital's laboratory. Patients were contacted by telephone two to three weeks after their visit for follow-up data collection. Descriptive statistics were used to review patient's demographic attributes and incidence of MRSA. Bivariate analysis and multivariate logistic regression was used to review factors associated with MRSA infection. No theoretical framework was identified (Moran et al, 2006).

The results of this study were consistent with the previously reviewed study. In this study the USA300 clone was present in 97% of the MRSA isolates, and 99% of the MRSA isolates had characteristics of community-acquired MRSA. The most pertinent statistic to the current research was that the MRSA isolate was resistant to the antibiotic treatment prescribed in 57% of the patients, and 100% were susceptible to rifampin. The researchers recommended the use of contact precautions for treatment of all patients with known MRSA infections and the need to provide antibiotic treatment based on results of cultures. They also recommended further research to review trends in antibiotic resistance and to identify the most favorable treatment. The strengths of this study were the large sample size, diversity of participants, large range of risk factors reviewed, and a $p \leq$ 0.001. The weaknesses were that only 59% were contacted for follow up, only 42% of

those eligible to participate were enrolled in the study, patients with non-purulent abscesses were not eligible, and two of the researchers received funding for consulting and lectures from Pfizer and Aventis. The current research will support the recommendations for identification of an optimal treatment plan for this increasingly prevalent infection. The following article provides further support for the identification of the USA300 clone as the leading cause of community acquired MRSA (Moran et al, 2006).

Buckingham, et al. (2004) discovered that an outbreak of Methicillin-resistant Staphylococcus aureus in a Memphis, Tennessee children's hospital was related to a bacterial strain associated with community exposure. The authors used a quantitative study of 289 children who were selected based on presentation during the study period from January 2000 to June 2002. Data were collected from medical record reviews with the Institutional Review Boards permission. The requirement for informed consent was waived. Categorical data were analyzed using the Fisher's exact test and compared (Buckingham, et al. 2004).

The study revealed that 52% of the isolates were community associated and 48% of the isolates were health care associated (2004). The researchers recommended accurate identification and treatment of methicillin resistant staphylococcus aureus along with susceptibility testing for the most effective antibiotics. Strengths of this study include a time frame that allowed a trend to be established. This revealed an increase in community acquired cases as the study went on while the number of health care associated cases was stable. Weaknesses include a limited geographical area. The researches do point out that specific areas need to monitor for regional effectiveness in treatment. This study

contributes useful information to the current research project by emphasizing the prevalence of MRSA infections as well as provides data for consideration regarding treatment. While this study is about noninvasive MRSA it is important to recognize the increasing seriousness associated with invasive MRSA and the prevalence of increasing cases in the community.

Klevens et. al. (2007) discovered that among the 8987 cases observed, most invasive MRSA cases were health care related, however the prevalence of community acquired cases was increasing. The researchers used a standardized form in the emergency department of 9 separate sites to acquire data from personnel in the emergency department. The study was conducted using emergency department physicians and personnel to identify, treat, and submit data on the patients (Klevens, et al. 2007). These data were then analyzed and the patients' records and laboratory records were reviewed. Descriptive statistics were used and these were analyzed using SAS version 9.1.3. The researchers discovered 58.4% of cases met the criteria defining health care associated infections (2007). Therapy was also reviewed and the data revealed that concordant antibiotic therapy was used 82.4% of the time. The recommendations include appropriated therapy for the infection and proper identification of the infection at presentation (2007). Limitations include varied personnel collecting data and the risk of misclassification of infection etiology. Strengths include a broad geographical sample as well as a high population. The study serves the current project by establishing that the MRSA infection is not stagnant but rather is worsening and is more likely to increase in seriousness. Therapies used need to be appropriate.

Furuya, Cook, Lee, Miller, Larson, Hyman, Della-Latta, Mendonca, and Lowy (2007) conducted a methodological comparison of prevalence of Community Associated Methicillin Resistant Staphylococcus Aureus (CA-MRSA). This quantitative study includes N=3022 staphylococcus aureus isolates obtained from a clinical laboratory retrospectively within a six month period. Of these 1087 were determined to be methicillin resistant. These specimens were wound, blood, or nasal cultures. The researchers used the data to determine the prevalence across Manhattan and New York City using three different methods (Furuya, et al., 2007).

The researchers performed a retrospective review of clinical and surveillance cultures in a health care setting. The data were then separated into Methicillin Susceptible Staphylococcus Aureus (MSSA) and MRSA by their susceptibility to oxacillin. The researchers defined a possibility of CA-MRSA if the culture was susceptible to Clindamycin. A prospective review of cultures was performed in an emergency department. The screening of nares for MRSA colonization was performed on adult patients that presented seeking treatment. In this review, the patients had to be over eighteen years of age and consent to participate in the study. If the culture obtained identified isolates of staphylococcus aureus growth, the Kirby-Bauer disk diffusion was used to determine antibiotic susceptibility. The third method was performed using a cross sectional survey of subjects in the community of northern Manhattan. The subjects were contacted by phone from a random list and visited in the home if they consented to participate in the survey. A culture of the participants' nares was obtained. The difference in antibiotic resistance among the three prevalence estimates was compared by chi-square analysis (Furuya, et al., 2007).

The researchers discovered in method one that 36% of the isolates were MRSA and that 8.9% supported the prevalence of possible CA-MRSA. However, the researchers identified that defining susceptibility to antibiotics lead to an underestimation of CA-MRSA. The difference among all three methods was not statistically significant (P=0.47). Although, the prevalence rates grossly varied from 5.5% in method one and 50% in method three (P=0.001) (Furuya, et al., 2007).

Limitations to this study were recognized by the difficulty to define CA-MRSA across the methods included in this study. The researchers revealed in the literature that their data did not support identifying the increasing prevalence of CA-MRSA. However, the researchers identified antibiotic selection susceptibility to be significant in MSSA and MRSA (P<0.0001) (Furuya, et al., 2007). Identifying prevalence factors of CA-MRSA was difficult in research. The common value found in most research studies' pertaining to CA-MRSA was that there is a high resistance to antibiotics.

Schneider-Linder, Delaney, Dial, Dascal, and Suissa (2007) performed a quantitative retrospective case control study using the General Practice Research Database (GPRD) in the United Kingdom. Using the primary care database, the researchers were able to obtain a substantial sample to perform their research on the receipt of antimicrobial agents and diagnosis of community acquired methicillin resistant staphylococcus aureus (CA-MRSA). The sample eligibility consisted of the following: no previous diagnosis of MRSA, no hospitalization in the past 2 years, and greater than 2 years follow-up recorded in the database (Schneider-Lindner, Delaney, Dial, Dascal, & Suissa, 2007).

"The researchers used conditional logistic regression to approximate the odds ratio (OR) of the affiliation between prescribed antimicrobial drugs and subsequent diagnosis of MRSA. Researchers then performed a separate statistical model that contained variables for all antimicrobial drug categories. The data revealed evidence of association between previous antimicrobial drug prescriptions and the diagnosis of CA-MRSA. The OR and the 95% confidence intervals support that the risk for CA-MRSA increased with the number of antimicrobial prescriptions" (Schneider-Lindner, Delaney, Dial, Dascal, & Suissa, 2007).

The researchers compared the incidence of CA-MRSA in the United Kingdom to the prevalence in the United States surveillance study and found them to be highly consistent. Use of the GRPD enabled the researchers to increase their sample size to provide a more valid study. Limitations to this study are identified as lack of information in multiple areas (i.e. severity of wound infection, patient lifestyle characteristics, and actual MRSA strain) (Schneider-Lindner, Delaney, Dial, Dascal, & Suissa, 2007). This review of literature supports the need for the United States to make CA-MRSA a reportable infection. Further, this study supports the need to further research to find the appropriate use of antimicrobial drugs to limit the prevalence of CA-MRSA.

In one particular quantitative study, conducted through a microbiology laboratory that services five hospitals and several pediatric offices in northern New England, the dependent variable was whether a strain of *Staphylococcus Aureus* was healthcare associated methicillin-resistant S*taphylococcus aureus* (HCA-MRSA) or Community-Acquired methicillin-resistant S*taphylococcus aureus* (CA-MRSA). The independent variable was the culture acquired from the patient. The study design was a multi-site

retrospective chart review of children 0 to 18 years old with MRSA isolated by the

microbiology lab between 1997 and 2001 (Dietrich & Mermel, 2004).

The researchers accessed 1,036 records identified by lab reports as children 0 to

18 years with MRSA. Theses reports were then identified as either health care associated

MRSA (HCA-MRSA) or community acquired MRSA (CA-MRSA) using specific

criteria. The source of data was a review of the patient's chart. A 2-sided Fischer's exact

test or Pearson's x 2 was used to calculate the results of the study. The increase in

proportion each year of MRSA was tested with at least squares linear regression (2004).

The results of the study showed that 40% of the pediatric patients studied had

community acquired MRSA. CA-MRSA cases were usually superficial and deep soft

tissue infections, and many of the isolates were susceptible to multiple classes of

antibiotics. The total number of *S. aureus* infections remained relatively constant over the

study period however, the proportion of the *S. aureus* cases attributed to MRSA steadily

increased over the five years. The researchers suggested that hospital or clinic personnel

ask family members questions targeted at identifying risk factors for MRSA acquisition

to help guide initial choice of therapy. They recommended screening cultures should be

obtained from any open wound. The efficacy and safety of the newer quinolones for

treatment of CA-MRSA in children should be investigated. The researchers indicated a

need for quick collection of specimens for culture and susceptibilities and a need for

rapid tests, which will reveal the presence or absence of virulent factors. This study was

significant to these researchers in that it indicated an increase in infections over time and

also an increase in virulence. The study indicated increasing incidence of community

acquired *S. aureus* (2004).

Because MRSA is not a reportable infection in all states makes it difficult to determine actual prevalence in the United States. Although, the literatures supports the need for aggressive treatment therapy and proper antibiotic selection in order to decrease the spread of this infectious organism. By understanding the susceptible antibiotic regimens to CA-MRSA, healthcare providers will be able to treat patients efficiently and decrease the incidence of CA-MRSA. In summary the research indicates a need to identify appropriate treatment measures for cutaneous abscesses. With staphylococcal infections on the rise further research is needed in a variety of aspects related to the infectious process to help providers give appropriate care.

MRSA Nasal Colonization

The next review of literature determined that MRSA colonization varies with demographic and organism characteristics. Information was obtained regarding the colonization of staphylococcus aureus in participants greater than one year of age and samples collected by nasal swabs were screened for oxacillin resistance. Researchers used the National Health and Nutrition Examination Survey (NHANES) to weight the prevalence across the United States population (Kuehnert, et al., 2006).

There were 9929 participants examined for this quantitative study. Statistical data revealed that colonization of staphylococcus aureus prevalence was 32.4% in these participants. Participants shown to have the highest risk for colonization were in the six to eleven age group (P<0.001). Using multivariate analyses, the researchers determined that the prevalence of staphylococcus aureus was affected by age, sex, and race/ethnicity. The researchers recognized that the differences were greater among non-Hispanic white males and Mexican Americans. In using a second multivariate model the prevalence of

MRSA colonization was increased in non-Hispanic black participants greater than sixty years of age. This model did not incorporate the survey weights (Kuehnert, et al., 2006).

The researchers went further to determine antibiotic resistance in the staphylococcus aureus and MRSA subgroup. There were 297 Methicillin Susceptible Staphylococcal Aureus (MSSA) and 75 MRSA isolates for this study. The data revealed that 77.1% were susceptible to all non-B-lactam agents tested, yet only 12.5% were susceptible to penicillin (Kuehnert, et al., 2006).

Limitations of this study were with the measurement of prevalence in a cross-sectional design and participants were not serially cultured. Second, a cohort effect was possible among age groups in different demographic regions. Third, previous antimicrobial exposure, occupation, or other underlying conditions were not analyzed to determine the multiple effects on colonization. Fourth, the data obtained were collected in 2001-2002; therefore, colonization rates may have changed. Finally, using small sample sizes, all MRSA isolates may have not been detected. (Kuehnert, et al., 2006) There are however strengths to this study. Researchers did determine that there were antibiotic resistances in MRSA and that rapid identification of MRSA could lead to more aggressive treatment and decolonization and spread of this infectious organism (Kuehnert, et al., 2006). With increasing incidence of skin and soft tissue infections presenting to emergency departments and other outpatient settings, the treatment provided for these patients is not consistent. This study is relevant to support continuing research on the spread and aggressive treatment therapy for patients.

Theoretical Framework

The following study by Tsai (2005) used the Roy Adaptation Model as a theoretic framework, as will be done in this researcher's study. This was a quantitative study that used information gathered throughout the continental USA. The independent variable was the theory of chronic pain and the dependent variable was financial hardship.

The design type was a secondary data analysis strategy with study variables developed from the original data sets of a previous study and based on a theory of chronic pain derived from the Roy Adaptation Model. The sample size was 235. Probability sampling was used, with over sampling. People in the group were selected if they were aged 65 and older. Only the 1998 data were used for this study and only people who had arthritis and were 65 years or older (Tsai, 2005).

Data were obtained from the study of Ageing, Status, and Sense of Control carried out in 1998 in the United States of America. Variables were constructed from the original questionnaires of this study. The theory was tested with 235 elders with arthritis using a secondary data analysis strategy. Researchers took the original data and identified scores on financial hardship and used these to attempt to identify if financial hardship affected pain and distress (2005).

This sample was tested with univariate analysis. Chi-square and goodness-of-fit indices were calculated. The researchers found that elders who experienced pain more often were more likely to be disabled and experienced more financial difficulties, though financial problems only affected distress to a small degree. Social support, financial hardship and age most often caused distress that led to depression. Tsai (2005) found this study significant in helping identify use of a theory in research.

Tsai (2005) felt the need for further study to better understand the relationship between chronic pain, distress and depression. The researcher of this study identified the need to narrow the study to persons with only one type of arthritis or possibly broaden the study to look at pain, distress and depression people without arthritis, since many arthritis sufferers have difficult financial situations.

A strength of the study was that the researchers were able to use a broad sample. One limitation was that this was a secondary data analysis and only variables in the original study were available, which limited the possibility of looking at other issues that might have been of interest to these researchers.

Summary

Researchers have identified MRSA SSTIs as an increasingly prominent problem throughout the United States. The review of literature reveals a focus on the causative isotypes rather than the treatment provided. The researchers did discuss the results of the antimicrobial sensitivity of the SSTIs cultured but did not review the actual treatment provided for these abscesses. The authors of several articles had treatment recommendations consistent with the recommendations of the CDC. Further research regarding the effectiveness of treatment provided and the increase in antimicrobial resistance was recommended by the authors of all literature reviewed. Examination of the recent research reveals a lack of evidence supporting any specific treatment plan or recommendations for decreasing the incidence of MRSA in the community.

CHAPTER THREE

Design and Methodology

Introduction

This study consists of a nonexperimental, quality assurance project using a retrospective chart review to examine the treatment provided for patients' with abscesses in the outpatient setting. Data will be obtained from archived charts at a Southern Mississippi emergency department. This facility provides urgent care to both an urban city and the surrounding rural areas. The population consists of middle and lower socioeconomic groups of all races.

Population and Sample

The proposed population encompasses patients of all genders, races, and ages, who present to a Southern Mississippi emergency department with a diagnosis of abscess. The sample includes selected medical records of all patients seen in the emergency department between the months of January 2007 and March 2007 with a discharge diagnosis of abscess.

Protection of Human Subjects

Prior to collection of data, approval from the Human Subjects Institutional Review Board (IRB) at Mississippi University for Women and the medical facility where data collection will occur will be obtained. After approval from the IRB, a written letter of consent will be obtained from the administration of the South Mississippi medical center. The data collection tool will not contain any identifying information such as name, birth date, medical record number, or social security number. The collected data will be kept in a locked file accessible only to the researchers.

Procedure for Data Collection

Data will be collected from the first 200 archived charts dated between January 2007 and March 2007 with a discharge diagnosis of abscess and a culture positive for Methicillin Resistant Staph Aureus (MRSA). By using the Emergency Department's E-point system a query for diagnosis of cutaneous abscess will be obtained. The E-point system is a charging system which requires diagnosis entry. A log of patient's medical record numbers will be kept to avoid repetitive data collection on the same patient and to allow researchers to access information on return visits. In addition, culture and sensitivity reports will be obtained to analyze organism of infection and susceptibility to prescribed antibiotic therapy. The facility AS400 system will be used to obtain return visits within 90 days of initial visit. The AS400 system contains all patient encounters at this facility.

The data collection tool (appendix B) will be used to systematically collect information without the use of identifying factors other than the medical record number. The data collection tool includes demographic data and treatment provided. Data will be collected over the period of one month by all researchers.

Instrumentation

A chart review tool was designed by the researcher to assess the actual treatment provided to patient's presenting to the emergency room with an abscess (Appendix B). The demographic data of age, gender, and race of each client was included on the tool. The type of provider who prescribed or administered the treatment is also included on the chart review tool. Lastly, the incidence of return visits within 90 days after treatment and

return for wound recheck within 48 hours was also included. The data collection tool has face validity as evaluated by the research committee.

Treatment of Data

The Statistical Package for the Social Sciences (SPSS) software program will be used to analyze the data. Analysis of the data will include descriptive statistics and percentages. A T - test between providers was completed. An ANOVA between treatment regimens was done. The names of patients and the emergency room where data will be collected will not be published. All data collected will be stored in a locked, fire proof safe and kept for five years after completion of the study, then shredded.

Summary

This study will consist of a retrospective chart review to assess the treatment provided for abscesses in the outpatient setting. A chart review tool created by the researcher will be used to collect the data without identifying information being collected. Statistical analysis of the data will be performed using SPSS software.

Chapter Four

Data Analysis

Introduction

The purpose of this project was to review the treatment prescribed by providers for cutaneous staphylococcal infections and evaluate the return rate for each treatment. In this chapter the results of the data collected will be discussed.

Profile of Study Participants

Participants in this study were visitors to the emergency department of a south Mississippi hospital. Patients were of various ages, races, and socio economic groups. The age range of patients seen with cutaneous lesions was birth to age 70 with the greatest number of patients seen being in the 21 to 30 age group.

Age of Patients

Category
0 - 10
11 - 20
21 - 30
31 - 40
41 - 50
51 - 60
61 - 70

5.0%
4.0%
6.0%
16.0%
14.0%
20.5%
34.5%
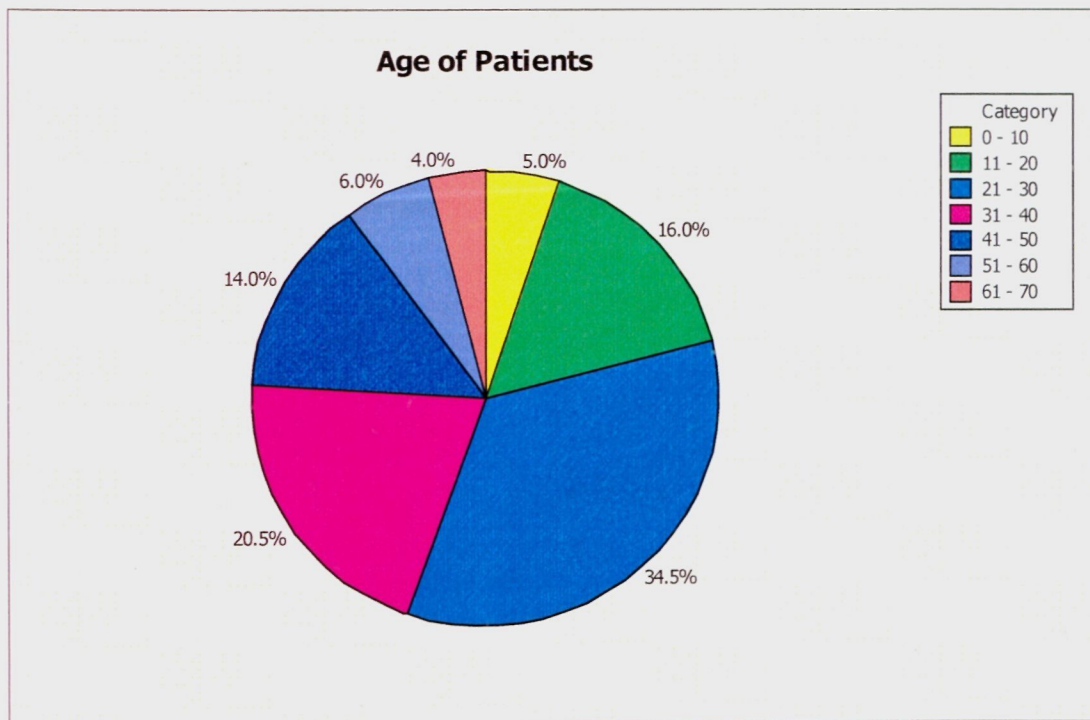
Patient's race was dispersed among three categories with the largest group

consisting of Caucasians with 56.5%, African Americans 39.0%, and Hispanics 4.5%.

Racial Make-up of Patients

Category
African American
Caucasian
Hispanic

4.5%

39.0%

56.5%
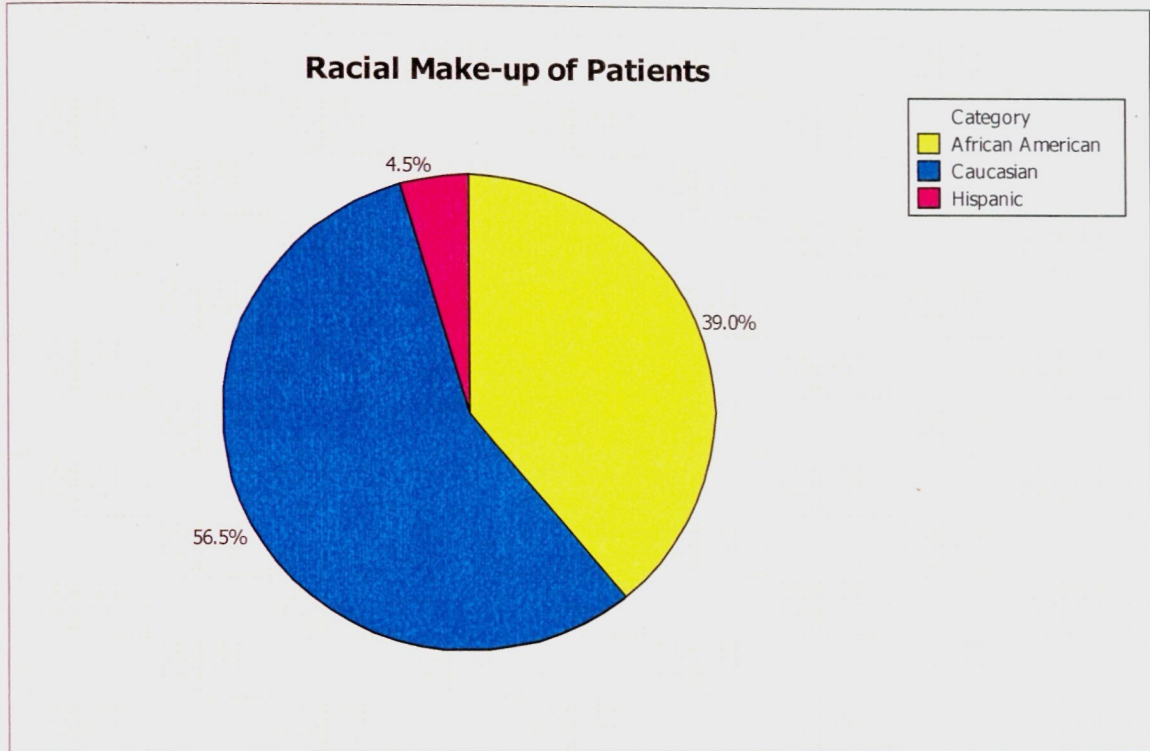
The distribution of gender of patients was uneven with a significantly larger group

of females than males.

Gender of Patients
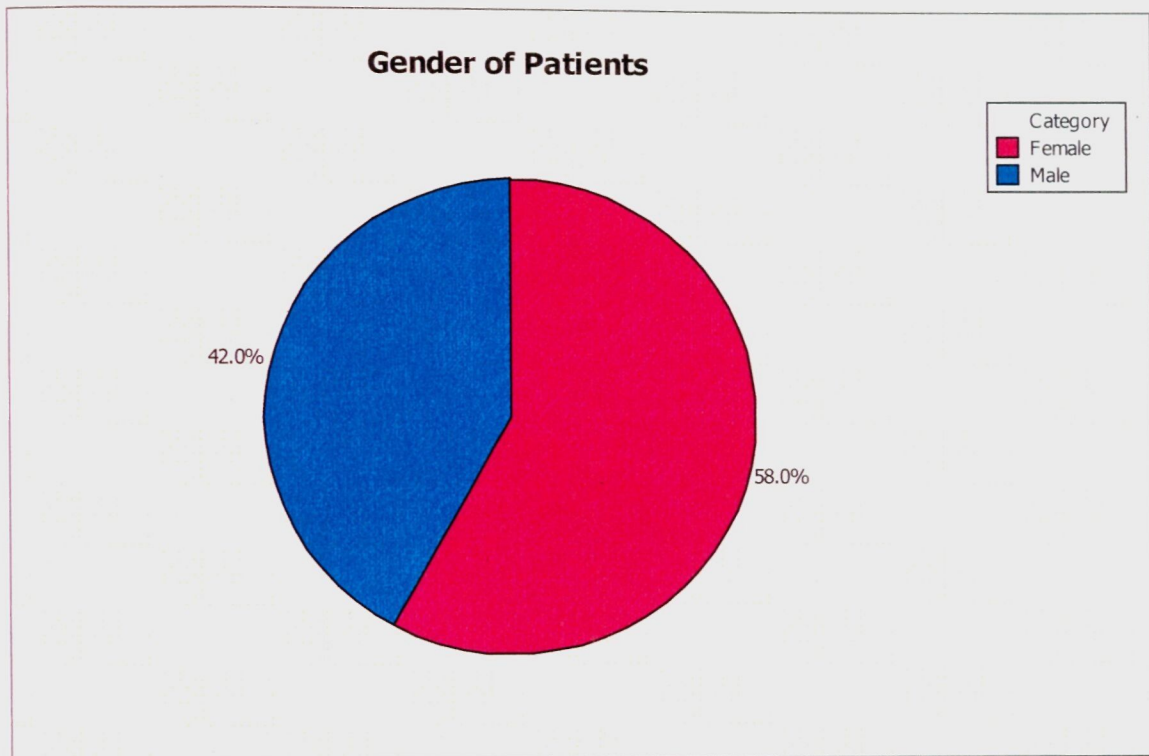
Statistical Results

First the researchers reviewed the current practices for treating abscesses

presenting to the emergency department. The following table shows the frequency and

percent of each type of oral antibiotic prescribed.

Frequency and Percentage of Antibiotics Prescribed

Oral Antibiotic	Frequency	Percent
Bactrim	118	59%
Bactrim and Clindamycin	31	15.5%
Bactrim and Doxycyline	2	1%
Bactrim and Rifampin	20	10%
Bactrim and Other	1	0.5%
Clindamycin	16	8%
Clindamycin and Doxycyline	1	0.5%
Clindamycin and Other	2	1%
Doxycyline	2	1%
No Antibiotics	2	1%
Other Antibiotics	5	2.5%

Oral Antibiotic Prescribed

Category
- Bactrim
- Bactrim, Clindamycin
- Bactrim, Doxycyline
- Bactrim, Other
- Bactrim, Rifampin
- Clindamycin
- Clindamycin, Doxycyline
- Clindamycin, Other
- Doxycyline
- Nothing
- other
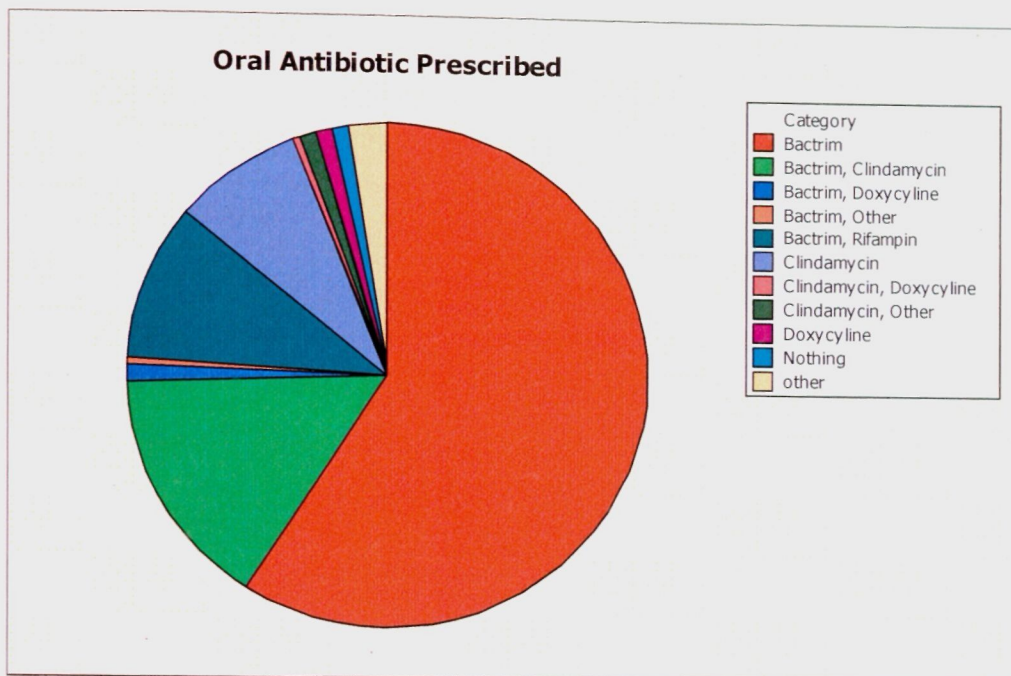
Using a chi-square goodness of fit test at the 1% significance level the data do provide sufficient evidence to conclude that there is a difference in the distribution of combination oral antibiotic prescriptions. The evidence against there being no difference is very strong with a p-value of less than 0.0001.

Ninety-nine and one half percent of the patients had an incision and drainage and 100% of the patients had a culture and sensitivity test performed. Fifty one and one half percent of the patients did not receive educational materials at their discharge while 48.50% of the patients did receive them.

The second question reviewed the rate of return visits for each treatment provided. At the 1% significance level the data do provide sufficient evidence to conclude that there is a difference in the distribution of the number of return visits within 90 days. The evidence against the number of return visits being evenly distributed was highly significant with a p-value of 0.0001.

Number of Return Visits within 90 days
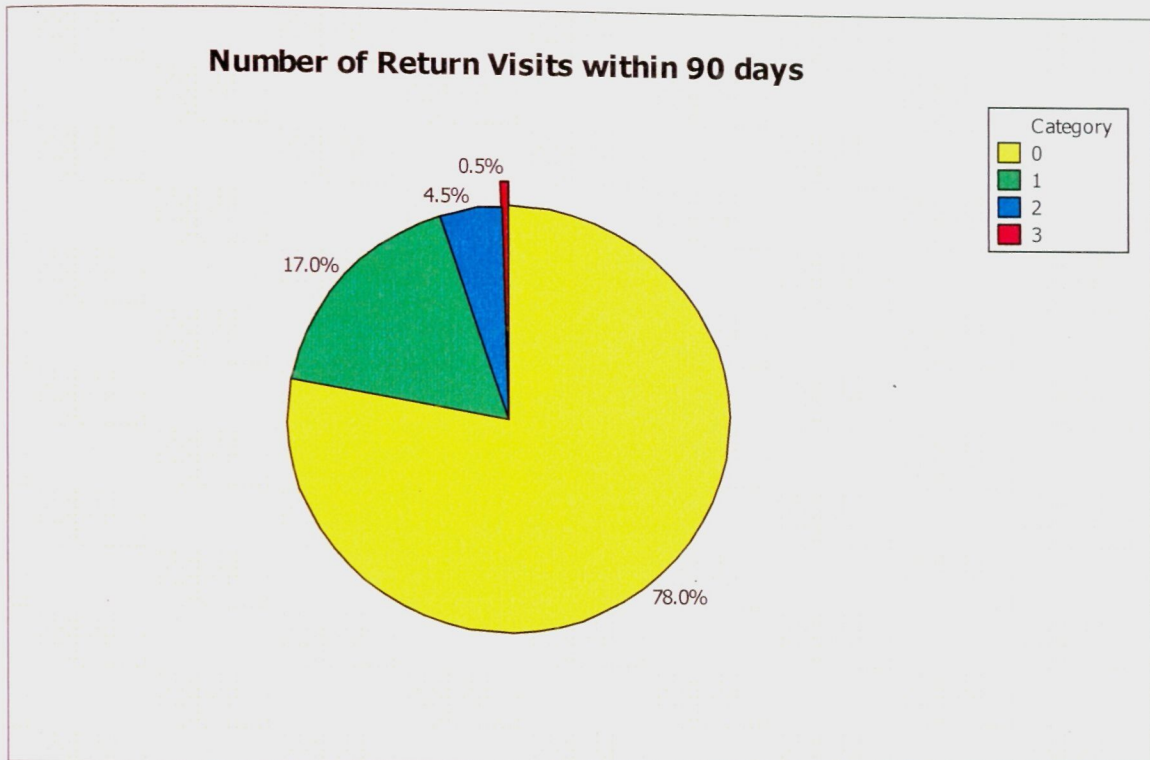
One hundred percent of those who were seen in the emergency department and received no treatment did not have a return visit. Of the patients who were prescribed Doxycyline 100% never returned to the emergency room. Of those patients prescribed Bactrim, approximately 79% did not return to the emergency room and of those given Clindamycin 68% also, never returned. Sixty percent of those that were given an alternate type of oral antibiotic did not return.
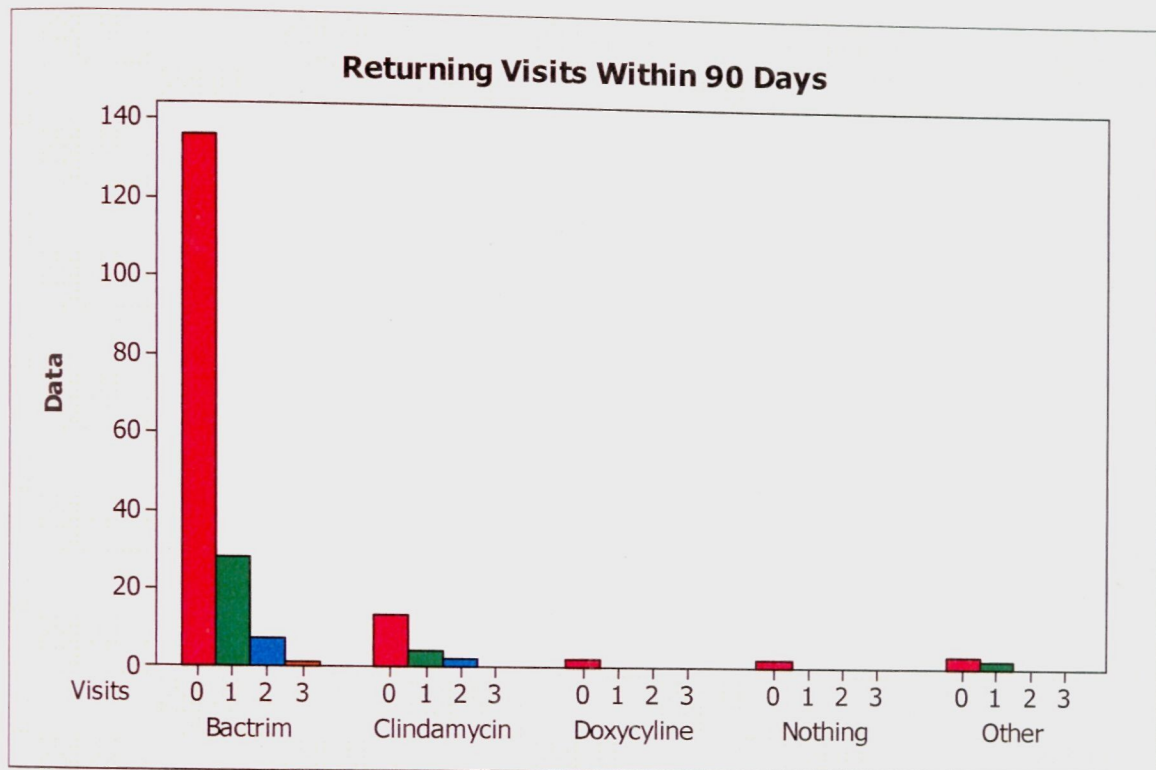
Returning Visits Within 90 Days

Data (y-axis): 0, 20, 40, 60, 80, 100, 120, 140

Visits: 0 1 2 3 (Bactrim) | 0 1 2 3 (Clindamycin) | 0 1 2 3 (Doxycyline) | 0 1 2 3 (Nothing) | 0 1 2 3 (Other)

At the 1% significance level the data do provide sufficient evidence to conclude that there is a difference in the distribution of number of days returning based on what type of oral antibiotic is prescribed. The evidence against the number of days returning is evenly distributed and is highly significant with a p-value of < 0.0001.

The following table shows the frequency and percent of those that are given an intramuscular antibiotic and the number of returning visits within 90 days. Sixty-one and one half percent of those that received Clindamycin as an intramuscular antibiotic had zero returning visits within 90 days. 100% of patients that received another type of intramuscular antibiotic did not return.

Rate of Return for Patients Receiving Intramuscular Clindamycin

Clindamycin	Frequency	Percent
0 Visits	8	61.54%
1 Visit	4	30.77%
2 Visits	1	7.69%

The following table shows the frequency and percent of the patients that were given an intravenous antibiotic and the number of returning visits within 90 days. 100% of those given Clindamycin intravenously did not return within 90 days. Of the patients that were not given any intravenous antibiotics 77.72% did not return within 90 days.

Rate of Return for Patients Receiving Intravenous Antibiotics

Clindamycin	Frequency	Percent
0 Visits	2	100%
Other Intravenous Antibiotics	**Frequency**	**Percent**
0 Visits	4	80%
1 Visit	1	20%
No Intravenous Antibiotics	**Frequency**	**Percent**
0 Visits	150	77.72%
1 Visit	33	17.10%
2 Visits	9	4.66%
3 Visits	1	0.52%

The distribution of return visits based on intravenous antibiotic prescribed is unequal. One can conclude that at the 1% significance level the data do provide sufficient evidence to conclude that the distribution of return visits were different among patients that received intravenous antibiotics.

Chapter Five

Summary and Conclusions

The Outcomes

The purpose of this project was to review the treatment prescribed by providers for cutaneous staphylococcal infections and evaluate the return rate for each antibiotic treatment. The conceptual framework was Roy's Adaptation Theory. The guiding research questions for this study were:

(1) What are the current practices for treatment of abscesses presenting to the emergency room? (2) What is the rate of return visits within a 90-day period for each treatment provided?

The sample consisted of 200 randomly selected medical records from the emergency department of a south Mississippi hospital. Data were collected using a data collection tool developed by the researchers. Data were analyzed using percentages and chi square goodness of fit tests.

Limitations

This study was limited because some participants may have followed up with a private physician or in the emergency department of another hospital if their infection persisted or returned. The study was also limited by whether the treatment regimen was accurately recorded by the provider and or staff. Additionally, the study was limited by the inability to assess the severity of the patients' infection using the researcher developed tool. Thus researchers could not identify treatment based on level of severity.

Discussion and Conclusions

The data indicated that Bactrim was the most prescribed medication, either alone or in combination, for lesions that were identified as Methcillin Resistant Staphylococcus Aureus. There were more return rates for Bactrim than for other antibiotics; however, Bactrim was prescribed in a much higher proportion allowing for increased possibility of return visits. The Center for Disease Control has established that Bactrim is the preferred antibiotic as part of a standard of care for treatment of MRSA. (Gorwitz R., Jernigan D., Powers J., Jernigan J. et.al., 2006).   Clindamyacin was also used alone and in combination with Bactrim with low return rates in 90 days. This would indicate the use of Clindamyacin as a possible element in a standard of care for MRSA. In this sample it was used less than Bactrim and thus data is inconclusive and would require further study.

In a study conducted by Moran, et. al. 2006, the researchers recommended the use of contact precautions for treatment of all patients with known MRSA infections and the need to provide antibiotic treatment based on results of cultures. They also recommended further research to review trends in antibiotic resistance and to identify the most favorable treatment.

The researchers in this study identified that there were approximately 28 different treatments or combinations of treatments used by providers on the 200 patients in this study. While oral antibiotics were reviewed in this paper, intravenous antibiotics were also used, as well as various combinations of oral and intravenous treatments. Combinations of oral medications with topical treatments were provided in some cases. There did not seem to be a set standard of care followed by providers in this study as can

be seen by inconsistent treatment of lesions. This lack of a consistent approach supports the researchers' position that a standard of care should be instituted for treatment of MRSA.

Implications for Nursing

Controlling the spread of MRSA requires providers to prescribe a standard of care for patients with MRSA. Equally important is the need to educate the patient about how MRSA is spread, how to decrease the spread in the home through proper hand washing, wound care and cleaning (Sherman, 2007). Nurses must provide the patient with information and education on prevention and treatment duration which will depend on severity of illness and clinical response. Also important for the nurse practitioner is to recognize treatments which are most effective and use these to help guide patient care (Hedden, 2007). According to Roy's adaptation theory the physiological-physical mode consists of the physical and chemical processes that aid adaptation in meeting the five basic needs of oxygenation, nutrition, elimination, activity and rest, and protection. This is the mode that the practitioner will be able to address with effective treatments (Patton, 2004).

Nursing staff as well as providers must remember frequent hand washing. They must also be sure to sanitize equipment such as blood pressure cuffs, tables and other items that may come in contact with the infected patient so that the infection will not be spread to the client who next enters the exam area (Buckingham, et al. 2004).

Future Research

More research is needed to identify more specific treatment plans and the recurrence of MRSA among family members and or community members. The

researchers recommend further research in the clinic setting in multiple clinics where follow up visits can be more accurately assessed. Using this study as a pilot study, a larger sample covering a greater geographical region could reveal more significant data. A research study using a specific treatment regimen, such as use of Bactrim, Bactroban or Altabax and Hibiclens along with patient education could be compared to other treatment regimens. This would help identify if a full treatment regimen decreased recurrence of MRSA and thus help develop a definitive standard of care for treatment of MRSA.

Conclusion

This research supported practitioners' knowledge that use of Bactrim when treating MRSA is appropriate. The study also indicated that studying results of MRSA treatment in the emergency department did not reveal enough data related to return visits possibly due to the limitations of the study. If repeating this study the researchers would use multiple clinic settings to collect data. The tool would also be reformatted to allow for identifying the severity of the wound which would help increase understanding of treatment choices by the provider.

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Appendix A

IRB Approval

FORM A
MISSISSIPPI UNIVERSITY FOR WOMEN
INSTITUTIONAL REVIEW BOARD
IDENTIFICATION OF INVESTIGATORS AND BRIEF DESCRIPTION OF
INVESTIGATORS AND BRIEF DESCRIPTION OF
PROPOSED RESEARCH REVIEW
TITLE OF STUDY:

Providers Use of Standards of Care for Methicillin Resistant Staphylococcus Aureus

PRINCIPAL
INVESTIGATOR: Victoria Ashley Ford, Suzanne Cox, Lisa Gatwood, Jeff Moffett

_____
(Signature)
DEPARTMENT School of Graduate Nursing   Date) April 14,2008
RESEARCH ADVISOR: Mrs. Amelia Higginbottom, RN, MSN, CFNP

_____
(Signature)

Instructions: In the space below (use additional sheets where necessary):
1. Briefly describe the purpose and nature of the present research proposal. State what, if any, benefit is to be gained by the subject(s) or what information is to be added to the general body of knowledge as a result of this research.
2. List all procedures to be used on human subjects with a description of those you consider beyond already established and accepted techniques.
3. Describe the necessary safeguards to be applied to protect the subject.
4. State whether or not you consider the subject to be "at risk." If you consider the subject to be "at risk", in what respect do the potential benefits to the subject or contributions to the general body of knowledge outweigh the risks?
5. If you consider the subject to be "at risk," state exactly what you tell him in lay language to obtain informed consent relative to each procedure wherein he is "at risk. " This must be a form that is given or read to the subject particularly for this purpose. If subjects are children what will be told to parent or legal guardian?
6. State from whom documentation of informed consent will be obtained.
7. Attach copies of all questionnaires to be used.

1.) The purpose of this project is to review the treatment prescribed by providers and evaluate the return rate for each treatment. The number of return visits can assess the effectiveness of treatment provided within a ninety-day period. The review of treatments provided will determine whether the recommendations should be implemented as a standard of care for this increasingly prevalent disease.

2.) This research will consist of a retrospective chart review and no procedures will be used on human subjects.

3.) After approval from the IRB, a written letter of consent will be obtained from the administration of the South Mississippi medical center. The data collection tool will not contain any identifying information such as name, birth date, medical record number, or social security number. The collected data will be kept in a locked file accessible only to the researchers.

4.) The subject will not be "at risk" because only a retrospective chart review will be performed and all data will be protected.

5.) The subject is not considered "at risk".

6.) Informed consent will be obtained from the administration of a South Mississippi medical center.

7.) No questionnaires will be used in this research.

FORM B
EVALUATION FORM FOR
INSTITUTIONAL REVIEW BOARD

Date Submitted to Committee: April 8,2008

Title of Investigation: Providers' Use of Standards of Care for Methicillin Resistant
Staphylococcus Aureus

Principal Investigator: Victoria Ashley Ford, Suzanne Cox, Lisa Gatwood, Jeff Moffett

Funding Agency: No additional funding will be obtained.
Funding Agency Grant Number: (NIH, BEH, when applicable): Not applicable.

Anticipated number of human subjects to be studied (when applicable): 200

Projected duration of Investigation: Approximately one month to collect data.

Age range of human subjects: All ages will be included in chart review data collection.

Any mental or physical impairment present in the subjects:
Subject's mental or physical impairments will not be known to investigators reviewing
charts.

Criteria for subject selection:
Any patient who was seen in a South Mississippi Emergency Department with a
discharge diagnosis of abscess.

Potential for beneficial effect to human subject arising from investigation: This study will
provide support for the needed implementation of a standard of care for the treatment of
abscesses.

Potential adverse effects (psychological, behavioral and physiological) arising from
investigation: No potential for adverse effects due to use of retrospective chart review.

Potential or established side effects of drugs used in investigation:
No drugs will be used in the investigation.

Brief justification of research where immediate benefit to specific human subject is
absent or unknown:
No research will be performed that will effect the human subject.

For On-Going Investigations Only. Number of subjects studied:
Not applicable.

Documented adverse psychological, behavioral, physiological and pharmacological

effects of study:

_____

Precautions used to detect, prevent, minimize or reverse adverse side effects:

_____

Change in methods or procedures (when applicable):

_____

Change in intent, direction or scope of research (when applicable):

_____

FORM C
SAMPLE OF INFORMED CONSENT
INSTITUTIONAL REVIEW BOARD :

Dear XXXXXXXXXX,

    We are graduate students in the nurse practitioner program at Mississippi University for Women. We are conducting a research study regarding the treatment of methicillin resistant staphylococcus aureus cutaneous abscesses and their return visits. The results of this study will contribute to the recognition of a need for a standard of care in this increasingly prominent diagnosis. This study has been approved by the Mississippi University for Women's Committee on use of Human Subjects in Experimentation.

    Your facility's participation would involve allowing us to review medical records of patient's that present to your emergency department with a diagnosis of abscess. All information obtained will be kept confidential and used only for the purpose of this study. Neither names, nor any identifying data will be used, and the name of your facility will not be published.

    Your participation in this study is strictly voluntary, and your facility may withdraw at any time prior to data analysis. Information will be obtained in the form of a retrospective chart review. After the research study is complete, we will provide you with results of the data collected.

    If you have any questions concerning this study please contact Ashley Ford at (601) 264-6286, 19 Hunters Way, Purvis, MS 39475; Suzanne Cox (601) 736-0168, 1030 Prospres Ridge Road, Columbia, MS 39429; Lisa Gatwood (601) 270-2611, 20 Jubilee Point, Hattiesburg, MS 39402; Jeff Moffett (601) 580-4657, 34 Kinderley Drive, Laurel, MS 39440, or the chair of our research, Mrs. Amelia Higginbottom, RN, MSN, CFNP, at (662) 329-7321. Thank you for willingness to consider this request.

Sincerely,

Ashley Ford
Suzanne Cox
Lisa Gatwood
Jeff Moffett

****

I have read this letter of consent and have been given the opportunity to ask questions. I give my consent to participate in the above study. In addition, the researchers will assure that confidentiality is maintained and HIPPA regulations are followed.

_____   _____   _____

Name (please print)   Signature   Date

FORM D
GUIDELINES FOR THE PROTECTION OF HUMAN RIGHTS
INSTITUTIONAL REVIEW BOARD
Review Form D
If "no" checked, please explain in writing and attach.

1. Right to Privacy　　　　　　　　　　　　　　　　　YES / NO
1.1 Obtained free and informed voluntary written consent. YES _____
1.2 Provide for anonymity　　　　　　　　　　　YES _____
1.3 Information obtained held in confidence　　　YES _____
1.4 When a reasonable possibility exists that others may obtain access to information, plans for protecting the confidentiality are explained to the subject. YES _____

2. Right to Self-determination
2.1 Voluntary consent obtained without overt or covert coercion. YES ----_____
2.2 Deception of subject or concealment of purpose avoided YES _____
2.3 When concealment is necessary, it is communicated to the subject and a contract is made to inform the subject as the design permits.　　　N/A _____
2.4 Explanations are not ambiguous and the terminology used is appropriate to the subjects level of understanding.　　　　　　YES _____
2.5 Subject free to withdraw consent at any point and informed of such. YES _____
2.6 Obtained third party written consent if necessary.　　　YES ____

3. Rights of Minors and Legally Incompetent Person
3.1 If a minor, informed written consent from parents required and obtained. N/A ____
3.2 If legally incompetent, informed written consent from legal guardian required and obtained.　　　　　　　　　　　　N/A _____
3.3 Supplemental written consent obtained from minor when minor has capacity to comprehend implications of study.　　　N/A _____

4. Right of Conservation of Personal Resources
4.1 Time, freedom from constraint, and personal resources are not abused. YES _____
4.2 Subject is informed about the nature, extent, and possible consequences of study. YES

5. Right to Freedom from Arbitrary Hurt
5.1 Subject protected from arbitrary mental and/or physical suffering as a result of study.　　　　　　　　　　　　　　　　　YES ____

6. Right to Freedom from Intrinsic Risk of Injury
6.1 Subject has full information about proposed investigation if there is a risk of emotional and/or physical injury.　　　　　YES ____

7. Additional Safeguards
7.1 Deviation from any of the above principles.　　_____ NO
7.2 Evidence demonstrated that appropriate expert advice has been received that it is acceptable to deviate.　　　　　　　N/A _____
7.3 The researcher has demonstrated that research assistants have been, or will be trained in the ethics involved in carrying out the research design.　　YES _____

_____　　_____
Vice President for Academic Affairs Date
REFERENCE: ANA Ethical Guidelines APA Ethical Principles University of Michigan, Guidelines for the Protection of Human Rights University of Indiana, Guidelines for the Protection of Human Rights

Wesley Medical Center
Institutional Review Board Submission Form

Date: <u>April 2008</u>

Title of project: <u>Providers' Use of Standard of Care for Staphylococcus Aureus Abscesses</u>

Principal Investigator: <u>Victoria Ashley Ford, Suzanne Cox, Lisa Gatwood, Jeff Moffett</u>
Phone: <u>601-264-6286</u>

Name of contact person: <u>Lisa Gatwood</u>   Phone: <u>601-270-2611</u>

E-mail: <u>LANDMGAT@aol.com</u>
Sponsor: <u>Amelia Higginbottom MSN, APRN, BC, ANP/PNP</u>

The PI must submit material for consideration by the IRB at least two (2) weeks prior to a scheduled IRB meeting in order to process the material for the individual members of the IRB Committee.

The PI must submit the following:

A. The full protocol addressing the following, if applicable to the study:
  - The title of the study
  - The purpose of the study
  - The sponsor of the study
  - The results of the previously related research
  - The subject selection criteria
  - The subject exclusion criteria
  - The justification for use of any special/vulnerable subject populations
  - The study design
  - The description of the procedures to be performed
  - The provisions for managing adverse reactions
  - The circumstances surrounding the consent procedure
  - The procedure for documentation of informed consent
  - The compensation to subjects for their participation
  - The compensation for injured research subjects, if any
  - The provisions for protection of the subject's privacy
  - The extra costs to subjects for their participation in the study
  - The extra costs to third party payers because of the subjects participation

B. The informed consent form specific to Wesley Medical Center and the PI.

C. The HIPAA authorization form specific to Wesley Medical Center.
D. All questionnaires that will be used with participants.
E. All recruitment materials and a description of recruitment processes.
F. The Investigator's Brochure (if available).
G. Grant applications if applicable.
H. HHS-approved sample informed consent document and protocol for HHS-supported multi-center trials.
I. Any other relevant materials, including all advertisements, including public service announcements for their ethical propriety.
J. PIs may submit protocols to the IRB only after the PI has received approval in writing from any hospital departments that will participate in the study, such as nursing, pathology, pharmacy, laboratory, or infection control.
K. Send 18 copies of the above information to the IRB Coordinator listed below.

L. Te protocol, after IRB approval, will be placed in the Wesley Medical Center IRB website.

Submit information with this form to:
Roger Flowers, IRB Coordinator
Pastoral Services
Box 16509
Hattiesburg, MS 39404

601-459-1388
roger.flowers@wesley.com

Appendix B

Research Tool

Subject # _____

Data Collection Tool

1. Age:
- ❑ 0-10 years old (1)
- ❑ 11-20 years old (2)
- ❑ 21-30 years old (3)
- ❑ 31-40 years old (4)
- ❑ 41-50 years old (5)
- ❑ 51- 60 years old (6)
- ❑ 61-70 years old (7)

2. Race:
- ❑ Caucasian
- ❑ African- American
- ❑ Hispanic
- ❑ Other

3. Gender:
- ❑ Male (1)
- ❑ Female (2)

4. Type of Provider:
- ❑ MD (1)
- ❑ NP (2)
- ❑ PA (3)

5. Number of visits within previous year for abscess:
- ❑ 0
- ❑ 1
- ❑ 2
- ❑ 3

6. Number of return visits within 90 days:
- ❑ 0
- ❑ 1
- ❑ 2
- ❑ 3

7. Incision and Drainage performed:
- ❑ Yes (1)
- ❑ No (2)

8. Culture and sensitivity performed:
- ❑ Yes (1)
- ❑ No (2)

9. Oral antibiotic prescribed:
- ❑ None (1)
- ❑ Bactrim (2)
- ❑ Clindamycin (3)
- ❑ Rifampin (4)
- ❑ Doxycyline (5)
- ❑ Other (6)

10. Parenteral antibiotic given: IM IV
- ❑ Clindamycin (1) ☐ ☐
- ❑ Gentamycin (2) ☐ ☐
- ❑ Other (3) ☐ ☐

11. Bactroban prescribed:
- ❑ Yes (1)
- ❑ No (2)

12. Hibiclens prescribed:
- ❑ Yes (1)
- ❑ No (2)

13. Education materials given at time of discharge:
- ❑ Yes (1)
- ❑ No (2)

14. Did patient return for recheck within 48 hours:
- ❑ Yes (1)
- ❑ No (2)

Subject #_____

Data Collection Tool

1. Age:
- ❑ 0-10 years old (1)
- ❑ 11-20 years old (2)
- ❑ 21-30 years old (3)
- ❑ 31-40 years old (4)
- ❑ 41-50 years old (5)
- ❑ 51- 60 years old (6)
- ❑ 61-70 years old (7)

2. Race:
- ❑ Caucasian
- ❑ African- American
- ❑ Hispanic
- ❑ Other

3. Gender:
- ❑ Male (1)
- ❑ Female (2)

4. Type of Provider:
- ❑ MD (1)
- ❑ NP   (2)
- ❑ PA   (3)

5. Number of visits within previous year for abscess:
- ❑ 0
- ❑ 1
- ❑ 2
- ❑ 3

. Number of return visits within 90 days:
- ❑ 0
- ❑ 1
- ❑ 2
- ❑ 3

. Incision and Drainage performed:
- ❑ Yes (1)
- ❑ No (2)

Culture and sensitivity performed:
- ❑ Yes (1)
- ❑ No (2)

9. Oral antibiotic prescribed:
- ❑ None (1)
- ❑ Bactrim (2)
- ❑ Clindamycin (3)
- ❑ Rifampin (4)
- ❑ Doxycyline (5)
- ❑ Other (6)

10. Parenteral antibiotic given: IM   IV
- ❑ Clindamycin (1)   ▢ ▢
- ❑ Gentamycin (2)   ▢ ▢
- ❑ Other (3)   ▢ ▢

11. Bactroban prescribed:
- ❑ Yes (1)
- ❑ No (2)

12. Hibiclens prescribed:
- ❑ Yes (1)
- ❑ No (2)

13. Education materials given at time of discharge:
- ❑ Yes (1)
- ❑ No (2)

14. Did patient return for recheck within 48 hours:
- ❑ Yes (1)
- ❑ No (2)

Appendix C

Letter of Consent

Dear _____,

     We are graduate students in the nurse practitioner program at Mississippi University for Women. We are conducting a research study regarding the treatment of methicillin resistant staphylococcus aureus cutaneous abscesses and their return visits. The results of this study will contribute to the recognition of a need for a standard of care in this increasingly prominent diagnosis. This study has been approved by the Mississippi University for Women's Committee on use of Human Subjects in Experimentation.

     Your facility's participation would involve allowing us to review medical records of patient's that present to your emergency department with a diagnosis of abscess. All information obtained will be kept confidential and used only for the purpose of this study. Neither names, nor any identifying data will be used, and the name of your facility will not be published.

     Your participation in this study is strictly voluntary, and your facility may withdraw at any time prior to data analysis. Information will be obtained in the form of a retrospective chart review. After the research study is complete, we will provide you with results of the data collected.

     If you have any questions concerning this study please contact Ashley Ford at (601) 264-6286, 19 Hunters Way, Purvis, MS 39475; Suzanne Cox (601) 736-0168, 1030 Prospres Ridge Road, Columbia, MS 39429; Lisa Gatwood (601) 270-2611, 20 Jubilee Point, Hattiesburg, MS 39402; Jeff Moffett (601) 580-4657, 34 Kinderley Drive, Laurel, MS 39440, or the chair of our research, Mrs. Amelia Higginbottom, RN, MSN, CFNP, at (662) 329-7321. Thank you for willingness to consider this request.

Sincerely,

Ashley Ford
Suzanne Cox
Lisa Gatwood
Jeff Moffett

****

I have read this letter of consent and have been given the opportunity to ask questions. I give my consent to participate in the above study. In addition, the researchers will assure that confidentiality is maintained and HIPPA regulations are followed.

_____   _____   _____

Name (please print)   Signature   Date