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PARENTAL VIEWS OF OTITIS MEDIA

AND ANTIBIOTIC TREATMENT

by

Courtney Leigh Ross, B.A.

A Dissertation Presented in Partial Fulfillment of the Requirements for the Degree Doctor of Audiology

COLLEGE OF LIBERAL ARTS LOUISIANA TECH UNIVERSITY

May 2007

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ABSTRACT

Antibiotic resistance is a rapidly growing problem throughout the world. Antibiotic resistance can be due to a number of factors, including unnecessary antibiotic prescriptions, antibiotic misuse, and transmission of resistant bacteria.

Otitis media is the most often diagnosed childhood illness and accounts for the majority of the United States' annual antibiotic prescriptions. Both parents and physicians can contribute to unnecessary antibiotic treatment for otitis media. Understanding parental views of otitis media and antibiotic treatment may help reduce unnecessary antibiotic prescriptions and lead to the subsequent reduction in antibiotic resistance.

The purpose of this capstone project is to develop a questionnaire that effectively gathers information about parent/guardian views toward otitis media and antibiotic treatment. The population of interest for this pilot study is parents/guardians of children 2 to 5 years of age. Individuals of all ages, races, and backgrounds will be encouraged to participate.

The questionnaire was developed using a variety of items and response styles. The questionnaire items are broken into different categories/sections, including knowledge-based, opinion-based, behavior-based, and demographic. The respondents are provided with instructions for each section. The questionnaires will be placed at South Arkansas Otolaryngology Associates, where parents/guardians will have the opportunity to complete them while waiting to see the physician. There will be a drop-box in the otolaryngology clinic for the participants to return the questionnaires.

The primary investigator will collect the completed questionnaires for analysis. The questionnaire data will be entered into a spreadsheet and analyzed using measures of central tendency. The results of the questionnaire can be used to determine the effectiveness of the study and can also be used to assist with future research.

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Author <u>Cluffley R. Mm</u> Date <u>5/107</u>

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CHAPTER 1

INTRODUCTION, REVIEW OF LITERATURE, AND STATEMENT OF THE PROBLEM

Introduction

Antibiotic resistance is one of the world's most serious public health problems, and the overuse and misuse of antibiotics are the leading causes of the resistance. Otitis media (infection of the middle ear) is the most frequently diagnosed childhood disease. Otitis media accounts for approximately 10 million of the United States' annual antibiotic prescriptions. At least 8.5 million of these prescriptions are not necessary for resolving the disease.

Parental misconceptions regarding otitis media and antibiotic treatment, as well as parents' antibiotic administration practices, may contribute to the abundant spread of antibiotic resistance. Although physicians are responsible for providing patients with antibiotic prescriptions, parental pressure can influence physician decisions.

In order to reduce the spread of resistance, prescription and administration practices must change. As always, education is the key for success. However, before education can begin, healthcare professionals need more evidence of parent's views about current antibiotic treatment.

1

There is a need to learn what facts parents have about otitis media and antibiotics, what antibiotic administration practices they use, their opinions concerning antibiotic treatment, and their physicians' prescribing practices. Survey research can be a valuable means of collecting such information. A questionnaire may be useful, but in order to develop an effective instrument, researchers need to have a foundation of information about otitis media and antibiotics. They also should take a close look at the research of others.

The purpose of this capstone project is to develop a questionnaire that will gather information about parent/guardian views of otitis media and antibiotic treatment.

Review of Literature

Viruses Versus Bacteria

In order to understand otitis media and antibiotics resistance, one must be knowledgeable about bacteria and viruses. It is also useful to understand the differences between bacteria and viruses and the roles each plays in infections and resistance.

<u>Viruses</u>. Viruses are microorganisms that are smaller than bacteria. They are microscopic cell parasites that cannot live independently. Viruses carry conventional genetic information in their deoxyribonucleic acid (DNA) or ribonucleic acid (RNA); however, viruses lack the synthetic machinery for this information to be processed into new virus material (Mims et al., 1998). In other words, viruses are unable to replicate without assistance. In order to reproduce and contaminate other cells, viruses must penetrate host cells and use the cells' chemical machinery (<u>www.medterms.com</u>, n.d.).

This machinery, such as the mitochondria and ribosomes, enables the viruses to replicate and transport DNA or RNA to other host cells.

The RNA or DNA carried by a virus particle is contained within a capsule that is made up of many individual protein molecules (Mims, Playfair, Roitt, Wakelin, and Williams, 1998). The unit created by the nucleic acid and the capsule is known as the nucleocapsid. In many cases, virus particles consist only of the nucleocapsid, while in others, the virus is surrounded by an outer envelope or membrane. This outer envelope is generally a lipid bilayer of host cell origin into which virus proteins and glycosides are inserted. The make-up of a virus determines to which family of viruses it is assigned.

Viruses are grouped into several major families based on shape, behavior, and other characteristics. Deoxyribonucleic acid viruses, RNA viruses, and rhinoviruses are three of the major families. Examples of DNA virus families are herpes viruses, adenoviruses, and poxviruses. Ribonucleic acid viruses consist of picornaviruses (rhinoviruses), retroviruses, and calciviruses. Rhinoviruses are the typical cause of the common cold (Mims et al., 1998).

Treatment of viruses can be a challenge as mutations may occur during reproduction. This ability to mutate is responsible for the capability of some viruses to change slightly in each infected individual, which makes treatment more difficult. The human immune system has the ability to destroy, or at least limit the production of, certain viruses. For example, the human immune system is able to destroy a cold virus and limit the production of the herpes virus. Other viruses, such as acquired immune deficiency syndrome (AIDS), escape the body's attention due to their small size. There are anti-viral medications that can inhibit the replication of some viruses; however, vaccines, when available, offer the best protection.

Vaccines are preventative measures taken to stop an infection before it begins. The vaccination process involves implanting a weakened form of a bacteria or virus into the human body in order to stimulate antibody production.

Antibiotics do not work against viral infections because viruses live within cells and are so small the drugs are ineffective. Viruses live inside host cells, which act as a disguise. Antibiotics do not identify the cells as infected. Also, antibiotics are specialized to attack specific forms of bacteria. So, even if they did recognize the viruses they would not be able to eliminate them.

<u>Bacteria</u>. Bacteria are single-celled microorganisms known as prokaryotes, opposed to eucaryotes, which are the cells from which humans are derived. Bacterial cells are often composed of thick capsules and contain numerous internal structures. The internal structures are responsible for the metabolic functions that are essential for the survival of the bacterium. Bacteria are composed of DNA, ribosomes, inclusion granules, and cytoplasm. Bacteria possess all the genetic material necessary to live independently, eat, and reproduce. However, bacteria do not grow larger, but rather increase in number by dividing. Although bacteria are able to live independently, some prefer to live off other organisms. Bacterial cells contain structures within their cells walls called receptors that enable them to attach to the surface of host cells, often human hosts. Bacteria do not, however, enter the host cells after attachment.

Bacteria come in various shapes and sizes. Some are round (cocci) and some are rod-shaped. A few groups of bacteria are staphylococci, streptococci, pneumococci, and

neisseriae. Among the most common infection-causing bacteria, are *Streptococcus pneumonaie* and *Haemophilus influenzae*. Infections caused by such bacteria often require antibiotic therapy for resolution. Antibiotics, when used appropriately, can kill bacteria or prevent reproduction, allowing the body to fight against the infection.

The most crucial difference between bacteria and viruses is that bacteria can survive outside of a host, while viruses cannot. Bacterial infections can be treated using antibiotic therapy, while viral infections are not affected by antibiotic treatment. These characteristics alone determine how infections develop and spread and how they are treated.

Otitis Media

As defined in *Merriam-Webster's Medical Dictionary* (1995), otitis media is "inflammation of the middle ear marked by pain, fever, dizziness and abnormalities of hearing" (p. 486). The middle ear space is made up of the tympanic membrane, or eardrum; the three middle ear bones, and the eustachian tube. The eustachian tube connects the middle ear with the nasal passage and equalizes pressure within the middle ear space with that in the ear canal. If the eustachian tube is not functioning properly, pressure may build up behind the tympanic membrane and fluid may also be pulled from the nasal passages into the middle ear space.

Otitis media is the most commonly treated childhood illness in the United States. According to Cook (2005), an estimated 50% of children will have an episode before their first birthday and 80% will have an episode by their third birthday. Over 30 million visits are made to a physician each year for otitis media, and in excess of three million dollars are spent every year on care for otitis media patients (Edmiston, n.d.). There are many risk factors associated with susceptibility to otitis media. For example, attending a daycare can lead to increased incidence of upper respiratory infections (URI), which often precede otitis media (Cook, 2005). Children can easily transmit infections to each other when sharing toys and playing together.

Compared to breastfeeding, bottle-feeding also increases the chances of infants and toddlers developing an infection of the middle ear. Breast milk contains maternal antibodies that may offer some passive protection to children during their first year of life. Also, the physical positioning associated with breastfeeding may help clear the eustachian tube of obstruction or blockage, allowing the middle ear to drain.

Another factor that increases the risk of otitis media is the presence of secondhand smoke. Cook (2005) suggested that incidents of all forms of respiratory problems during childhood are increased when smoking occurs in the household. Finally, as Cook suggested, family history of middle ear disease creates a risk of otitis media. Although limited genetic information is available, there is reason to believe that susceptibility to otitis media can be hereditary.

There are different types of otitis media, each of which can contribute to antibiotic resistance. In order to treat otitis media appropriately, physicians must be able to differentiate between the types and know the underlying causative micro-organism.

<u>Otitis Media with Effusion</u>. Otitis media with effusion, also known as serous otitis media, is defined as fluid in the middle ear without the signs or symptoms of infection. Otitis media with effusion is very common and often occurs preceding or following an acute infection or when the eustachian tube is not functioning properly, causing a build-up of serous fluid in the middle ear cavity. The eustachian tubes of

infants and small children are horizontal and more open. The nasal passage and middle ear space are almost level with each other, and the eustachian tube connects the two spaces. This may allow fluid to easily reach the middle ear space. Infants and small children also do not have the advantage of gravity. Therefore, fluid can reach the middle ear easily because the eustachian tube runs directly from the nasal cavity to the middle ear space.

Diagnosing otitis media with effusion may present a challenge because individuals experiencing otitis media with effusion are usually asymptomatic. If otitis media with effusion is diagnosed at all, it may be because a child is visiting the physician for another reason. In order to identify otitis media with effusion, the otoscopic examination would need to reveal a fluid line or bubble behind the tympanic membrane. Also, tympanometry, a test of middle ear functioning, would show decreased mobility of the tympanic membrane. And, individuals may show signs of decreased hearing acuity.

When audiometric testing is performed, audiologists may find that a child with otitis media with effusion has a mild conductive hearing loss in the low frequencies (250 Hz and 500 Hz) of the affected ear. However, most commonly, children with otitis media with effusion have normal hearing acuity.

Treatment for otitis media with effusion is usually unnecessary because 80% to 90% of cases spontaneously resolve on their own. The precise role bacteria play in otitis media with effusion is unknown; therefore, antibiotic treatment is not necessary in most cases. Treatment is usually necessary; however, if fluid does not resolve after a couple of days or if the child is experiencing pain. <u>Acute Otitis Media</u>. Another type of ear infection is acute otitis media and is the type of ear infection most commonly diagnosed. Acute otitis media often arises as a complication of a preceding upper respiratory infection (Cook, 2005). According to Cook, occlusion of the eustachian tube may occur because of the inflammation and secretions, causing negative pressure in the middle ear cavity, which will result in serous effusion in the middle ear. The effusion provides a fertile media for microbial growth, along with the introduction of upper airway viruses and/or bacteria into the middle ear.

Typical symptoms associated with acute otitis media are ear pain and fever. Other symptoms can include nausea, vomiting and loss of appetite. Otoscopic exmination may reveal an inflamed tympanic membrane, possibly bulging, and fluid which appears clear or suppurative, often described as having a pus-like appearance (Mims et al., 1998). Tympanometry can be used to verify the presence of fluid and to measure mobility of the tympanic membrane, and it often reveals Type B tympanograms suggesting no mobility of the tympanic membrane. Also, audiometry may reveal a mild to moderate conductive hearing loss. Unfortunately, tympanometry and audiometry cannot help a physician distinguish between infected and non-infected fluid. While audiometric testing procedures can suggest the presence of middle ear fluid they cannot determine the type of fluid, which requires an analysis of a sample of the fluid.

A number of bacteria and/or viruses could be responsible for the development of acute otitis media; however, acute otitis media is most often a bacterial infection. The three most common bacteria associated with acute otitis media are *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis*. Figure 1.1 represents the incidence of microbial pathogens responsible for acute otitis media.

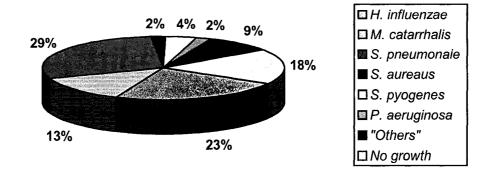


Figure 1.1: Microbial Pathogens Responsible for AOM.

Without a sample of the middle ear fluid, physicians cannot be sure which pathogen is present. The only way to retrieve a sample of middle ear fluid is to extract it from the middle ear cavity; a process called tympanocentesis. This process can be very painful and will create a perforation in the tympanic membrane; therefore, it is rarely performed as a way to diagnose otitis media. However, the knowledge of what pathogens are present in middle ear fluid can help determine if antibiotics are necessary for treatment and which is the most appropriate to prescribe. For instance, Woo (2005) suggested that infections caused by *Haemophilus influenzae* and *Moraxell catarrhalis* are more likely to spontaneously resolve than infections caused by *Streptococcus pneumoniae*. Physicians would also be more likely to prescribe appropriate antibiotics if the type of bacteria is known.

Like otitis media with effusion, acute otitis media often resolves without the use of antibiotic therapy. In fact, research consistently shows that at least 80% of all acute otitis media cases clear up on their own (Centers for Disease Control and Prevention, 2000). On the other hand, some may require antibiotic treatment, especially if the condition persists and the child is under 2 years of age. If the condition is not treated, or treated inappropriately, the tympanic membrane may rupture to provide release from pressure of the fluid. This occurrence can cause long-term complications such as chronic infection and hearing loss.

<u>Chronic Otitis Media</u>. Chronic otitis media can be described as a long-standing infection of the middle ear and can arise from a more virulent pathogen than those that cause acute otitis media. These harmful pathogens can be very destructive to the middle ear structures and can result in a perforation of the tympanic membrane.

Chronic otitis media may also arise from a permanent perforation in the tympanic membrane. The perforation is often the result of a previous infection in the middle ear, such as acute otitis media. Such perforations occur when fluid in the middle ear causes an excessive build up of pressure against the tympanic membrane. Chronic otitis media can take one of three forms: non-infected chronic otitis media, suppurative chronic otitis media, or chronic otitis media with cholesteatoma.

Non-infected chronic otitis media can be identified when there is a perforation in the tympanic membrane and inflammation, but no infection or fluid is present. This condition could last indefinitely, and, as long as the ear stays dry, the middle ear can remain stable for many years. Repairing the tympanic membrane is only necessary for improving hearing or to prevent infection.

Suppurative chronic otitis media can be identified when there is a perforation in the tympanic membrane and infection in the middle ear cavity. Cloudy and sometimes foul-smelling fluid drains from the open cavity. Antibiotic treatment usually helps to eliminate the infection. The final form is chronic otitis media with cholesteatoma. A perforation that does not heal may lead to a cholesteatoma, a growth in the middle ear composed of skin cells and debris. Cholesteatomas can cause hearing loss and are prone to infection that results in drainage. Cholesteatomas can be very dangerous and, if not treated aggressively, can grow large enough to erode the structures of the middle ear and the mastoid bone as well as intracranial structures. Antibiotics for the infection and surgical removal of the growth are necessary.

The last two types of chronic otitis media can be coupled and called chronic suppurative otitis media with cholesteatoma. The symptoms are a combination of the pus-like, foul-smelling drainage and the cholesteatoma. The bacteria associated with chronic otitis media are more virulent, or dangerous than those related to acute otitis media. These harmful organisms include *Staphyloccocus aureus*, *Pseudomonas aeruginosa*, and other gram-negative bacteria. These bacteria produce numerous toxins and enzymes that have the ability to destroy extensive areas of tissue and bone. Figure 1.2 displays the incidence of these bacteria in chronic otitis media.

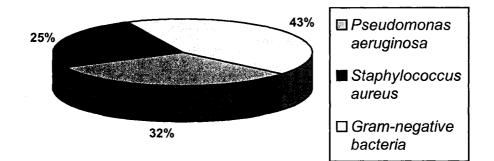


Figure 1.2: Incidence of *Staphyloccocus aureus*, *Pseudomonas aeruginosa*, and other gram-negative bacteria in COM.

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Although the use of antibiotics in treating otitis media is controversial, it is evident that such treatment is necessary for dangerous conditions like chronic otitis media.

Antibiotics

Mims, Playfair, Roitt, Wakelin, and Williams (1998) defined antibiotics as "metabolic products of fungi, actinomycetes and bacteria that kill or inhibit the growth of microorganisms" (p. 411). As suggested by Mims et al., some agents are completely synthetic (i.e., produced artificially) but most are chemically modified in order to improve their antibacterial or pharmacologic properties.

<u>History</u>. A common misconception is that penicillin was the first antibiotic to be used commercially to fight bacterial infections. According to Edmiston (n.d.), the first antibacterial agents developed commercially were the sulphonamides, or sulfa drugs in the 1930s. This class of drugs is completely synthetic (Mims et al., 1998). The sulfa drugs were effective at combating a variety of pathogens, including those associated with pneumonia and scarlet fever; however, the pathogens quickly developed a resistance, or ability to withstand the harmful effects of these agents (Edmiston, n.d.).

In 1928, research scientist Alexander Fleming first acknowledged penicillin's anti-infective activity. However, penicillin did not enter into commercial production until 1940. With the threat of war in Europe looming, the Department of Defense made the development of penicillin a major priority. Penicillin had the potential to fight against a broad spectrum of bacteria, and it was seen as a "wonder drug" for treating life-threatening infections. World War II became the staging area for this antibacterial agent. Regrettably, after its release to the general public, resistance to penicillin developed rapidly, just as it had with the sulfa drugs.

Over the next few decades, antibiotic development increased rapidly. It was during this period that aminoglycosides, macrolidees, semisynthetic penicillins and cephalosporins were developed. New drugs are continuously being developed and old drugs are being modified to fight against resistance. The chemical compounds of antibiotics, such as penicillin, may be altered to combat the resistant bacteria.

Currently, new antibiotics are being produced. For example, in October 2005, United Press International announced the discovery of a new class of antibiotics. The antibiotic plectasin, proved to be active against many species of bacteria, including some pneumonia-causing strains of Streptococcus pneumoniae (United Press International, 2005, para 2).

Because antibiotics are developed to fight different types of bacteria, they require distinct chemical make-ups. The ways antibiotics fight bacteria also differ, depending on the type of bacteria and the type of antibiotic agent being used.

Antibiotic Function. Antibiotics are purely adjunctive in the fight against infection because the human body possesses the ability to "cure" itself. The purpose of any antibiotic is to inhibit bacterial growth or kill bacteria for a period of time so the body's natural defenses can eliminate the infection. All antibiotics do not function the same way. Antibacterial agents are identified as either bactericidal or bacteriostatic. Bactericidal agents kill bacteria by interrupting growth and reproduction. Bacteriostatic agents slow down the growth of bacteria or inhibit bacteria from multiplying until an individual's immune system can eliminate the invader (Mims et al., 1998). Therefore, one could argue that bacteriostatic agents are just as effective as bactericidal agents because, in the end, the result is the same. Aside from being bactericidal or bacteriostatic, antibiotics may also be classified according to the site of action. There are four main target sites for antibiotics: cell wall, cell membrane, protein synthesis, and nucleic acid (DNA or RNA) synthesis. The concept of selective toxicity is the basis for antibiotic activity and is associated with the site of action. As described by Mims et al., selective toxicity is achieved by utilizing the variations in the structure and metabolism of bacteria and host cells. Ideally, the antibiotic should attack a target site present on the infecting bacteria but absent from the host cells. In other words, antibiotics should inhibit bacteria without affecting human cells.

Depending on the site of action, certain classes of antibacterial agents are used. Each class of antibiotics targets a different site. For example, penicillins target the cell wall and aminoglycosides target protein synthesis (Edmiston, n.d.). The chemical makeup of an antibiotic will determine how to best attack a bacterial cell. Some antibiotics, like penicillins, will fight bacteria from the outside. Others, such aminoglycosides, will be absorbed by the bacterial cells and alter the function of the internal components.

Site of action can partially explain why antibiotics are ineffective in the treatment of viruses. Antibiotics often attack the infection without entering a cell host. Other antibiotic agents will make their way into a cell and kill it by disturbing the metabolic processes that are necessary for growth and reproduction. Viruses invade their host cells; therefore, an agent would always have to enter the host cell in order to reach the virus. Inappropriately treating a viral infection with antibiotics is not only ineffective, but may also contribute to the growing problem of resistance by spreading antibiotic resistant organisms. Damoiseaux, Balen, Hoes, Verheij, and Melker (2000) sought to determine the effect of antibiotic treatment for acute otitis media in children between the ages of six months and two years. This study was a further attempt to gather beneficial information to help with the worldwide fight against antibiotic resistance.

Subjects were chosen based on their diagnosis of acute otitis media were between the ages of 6 and 24 months. Exclusion criteria were the use of antibiotics four weeks prior to the study, Amoxicillin allergy, compromised immunity, craniofacial abnormalities, Down's syndrome, or being entered into the study before. Fifty-three general practitioners diagnosed and dispensed medication.

Two hundred-forty children were enrolled in the study and data for 232 were reported. The subjects were randomly assigned to a placebo group or an antibiotic group. Neither the physicians nor the subjects knew which medication was received. Because it is routine in the Netherlands to use decongestant nose drops when diagnosed with acute otitis media, each subject in both groups received a prescription. The subjects were also allowed to use acetaminophen as needed; however, the amounts were to be recorded in the 10-day diary they were asked to keep.

During the initial visit with their patients, the physicians obtained a case history and otoscopic results. The parents of the subjects were asked to record aural and gastrointestinal symptoms and administration of all medications. Follow-up appointments with the physicians were scheduled on days four and 11 of the study. The physicians visited the subjects in their homes after six weeks to gather information about present and past symptoms and medication consumption. At day four, persistent symptoms were evident in 59% of the Amoxicillin group and 72% of the placebo group. On the eleventh day, 64% of the Amoxicillin group and 70% of the placebo group experienced treatment failure. Fever, pain, and crying occurred one day longer for the placebo group than the Amoxicillin group. Because no significant differences in recovery were revealed, the investigators concluded that waiting to prescribe an antibiotic would be justified for patients with uncomplicated acute otitis media.

In southwest England, Little, Gould, Williamson, Moore, Warner, and Dunleavey (2001) investigated ways of fighting antibiotic resistance by finding an alternative treatment method for acute otitis media. The objective was to compare the effects of immediate antibiotic prescriptions and delayed antibiotic prescriptions for children diagnosed with acute otitis media.

Forty-two physicians recruited patients for this study. The physicians were told what characteristics to look for when diagnosing their patients, and the children had to be between the ages of six months and 10 years. Exclusion criteria were those that suggested infections too severe for the subjects to participate. Three hundred-fifteen children were enrolled and placed into two groups. Little and his colleagues suggested that there was no subject selection bias because there was not a significant difference in group size.

The physicians were given sealed envelopes with advice for one of two treatment plans. One plan involved prescribing immediate antibiotic treatment while the other plan offered an antibiotic prescription, but the parents were instructed to wait 72 hours to observe whether the infection resolved on its own. As parents gave permission for their children to participate, the doctors randomly opened one of the envelopes. The physicians had no knowledge of which plan their patients would receive prior to the visit. The advice sheets explained what the physician was to discuss with the parents and, although they did not have to repeat the explanation verbatim, the sheet provided wording to use as a guide.

The subjects receiving immediate antibiotics were prescribed Amoxicillin. If the subjects were allergic to penicillin, Erythromycin was prescribed. The delayed group was prescribed similar antibiotics but instructed to wait 72 hours before retrieving the antibiotics from the nurse. The subjects in both groups were encouraged to use acetaminophen for fever and pain reduction. The parents were asked to keep a diary and record information about the conditions of their children. The diary entries were to include comments about symptoms, severity of pain, episodes of distress, and doses of acetaminophen. Three days after the visit to the physician, the parents were contacted by a research assistant to resolve any problems with keeping the diary.

Little and his associates found that the symptoms of the immediate antibiotic group lasted one day longer than the delayed group. However, the group that received immediate antibiotics experienced more diarrhea. There was no significant reduction in pain between the two treatment groups.

Little et al. stated that the parents of the children using antibiotics immediately believed that antibiotics were the appropriate treatment for acute otitis media. According to Little et al., this suggested that parents may push for antibiotic prescriptions in the future, thus contributing to antibiotic resistance. The delayed antibiotic group parents seemed to be very satisfied with the "wait and see" method for treating the infection. Research results such as these may help convince physicians and parents to forgo immediate antibiotic treatment for otitis media. Decreasing the use of unnecessary antibiotic prescriptions may drastically reduce the development of antibiotic resistance.

Antibiotic Resistance

As mentioned earlier, the problem with antibiotic resistance began with the distribution of the first antibacterial agents in the 1930s. With each new agent, resistance developed and spread. History suggests that bacteria may never run out of ways to develop resistance, but society may run out of ways to develop antibacterial agents. It is crucial to understand the various types of antibiotic resistance and how each withstands the effects of harmful agents.

<u>Types of Resistance</u>. Antibiotic resistance occurs when antibiotics taken to terminate an infection do not kill the responsible bacteria, allowing them to survive and continue to multiply (Schumann and Nollette, 2000). Some bacteria are inately resistant to certain antibacterial agents, and others acquire it over time.

Schumann and Nollette described two types of antimicrobial resistance: intrinsic resistance and acquired resistance. Intrinsic or relative resistance was defined as "the gradual increase in the minimal inhibitory concentration that occurs in susceptible organisms over time" (p. 286). According to Schumann and Nollette this occurs when a particular species of bacteria lacks the drug-susceptible target or it possesses natural barriers that prevent the agent from reaching the intended target.

An example of intrinsic antibiotic resistance occurs with *Streptococcus pneumoniae*, one of the primary causes of acute otitis media. Schumann and Nollette reported that the original dosage of the antibiotic amoxicillin was 40 to 45/mg/kg/day, but

has increased to 80 to 90 mg/kg/day in order to achieve effective middle ear fluid concentrations to treat *Streptococcus pneumoniae*. Fitzgerald (1998) stated that the mechanism in antimicrobial resistance in *Streptococcus pneumoniae* is an altering of protein binding sites within the bacterial cells. This alteration results in resistance to lower doses of amoxicillin.

The second type of antibiotic resistance, as described by Schumann and Nollette (2000), is acquired or absolute resistance. This occurs when an organism that was once sensitive to an antibiotic suddenly is no longer sensitive to it, independent of dosage. This type of resistance occurs when a bacterium changes its genetic composition or the organism becomes tolerant to an agent. In other words, the agent no longer affects the organism.

An example of this resistance can be seen when the antibiotic amoxicillin is used to fight the bacteria *Haemophilus influenzae*, which also causes acute otitis media. Amoxicillin is not effective for treating this infection. According to Fitzgerald (1998), the mechanism of antimicrobial resistance in *Haemophilus influenzae* is the production of a beta-lactamase enzyme, which renders amoxicillin ineffective by deactivating it. In order to fight the infection, antibiotics, such as amoxicillin with clavulanate, are necessary. These drugs contain beta-lactamase inhibitors, which slow down the production of the enzyme (Schumann and Nollette, 2000). A bacterial cells' production of enzymes to stop the effects of amoxicillin is one of many mechanisms of antibiotic resistance.

<u>Mechanisms of Resistance</u>. Mims et al. (1998) and Schumann and Nollette (2000) discussed three primary mechanisms by which resistance occurs. The most common mechanism of resistance is drug inactivation, which occurs when bacterial cells produce enzymes that inactivate the antibiotic, changing its ability to attach to the penicillin-binding proteins. Penicillin-binding proteins are receptors on the inner membrane of bacterial cells that are used by antibiotics. This mechanism of resistance is expressed in gram-negative bacteria such as *Haemophilus influenzae* and *Moraxella catarrhalis*, which are commonly associated with otitis media. Shoemaker (2005) provided the diagram shown as Figure 1.3 as a visual explanation of drug inactivation.

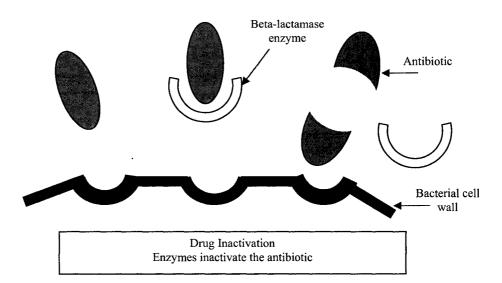


Figure 1.3: Drug Inactivation. From The mutation factor: How bacteria become resistant. By S. Shoemaker, 2005. Louisiana Speech-Language-Hearing Association Convention. New Orleans, LA. Reprinted with permission of the author.

A second mechanism of resistance is decreased permeability, which is a bacteria's ability to prevent an antibiotics entry into the cell, keeping it from its target. This mechanism involves structures called porins. Porins are small channels that are present in the outer membrane of bacterial cells, and they allow nutrients and other molecules, including antibiotics, to enter the cell. Structural alterations may occur in the porins, and certain antibiotics may not be able to pass into the bacterial cell. Figures 1.4 and 1.5 (Shoemaker, 2005) represent decreased permeability:

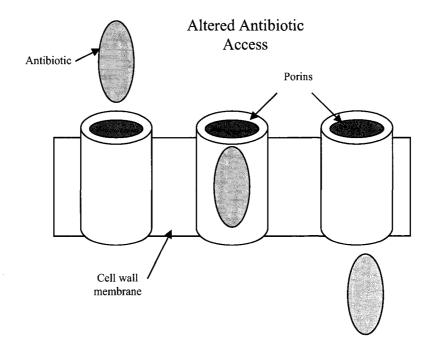


Figure 1.4: Unaltered Porins. From The mutation factor: How bacteria become resistant. By S. Shoemaker, 2005. Louisiana Speech-Language-Hearing Association Convention. New Orleans, LA. Reprinted with permission of the author.

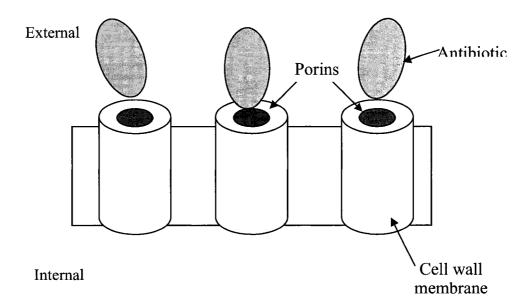


Figure 1.5: Altered Porins. From The mutation factor: How bacteria become resistant. By S. Shoemaker, 2005. Louisiana Speech-Language-Hearing Association Convention. New Orleans, LA. Reprinted with permission of the author.

A third resistance mechanism involves an alteration of the target site or the enzymes produced by the bacteria so that the antibiotic will no longer interfere with it (Schumann and Nollette, 2000). As described by Schumann and Nollette, alterations may consist of a single mutation in the primary target, incorporation of foreign DNA, modification of penicillin-binding proteins, etc. Penicillin-binding proteins control the formation of the bacterial cell wall, and when a penicillin or cephalosporin, such as a beta lactam antibiotic, binds to one of these proteins, it disrupts the formation. As a result, the bacterial cell cannot divide, so it dies. If the structure of the PBPs is altered, antibiotics will no longer be able to attach to the cell wall and disrupt its formation. This mechanism is expressed in penicillin-resistant *Streptococcus pneumoniae*, as seen in acute otitis media (Mims et al., 1998). Shoemaker's (2005) illustrations (Figures 1.6 and 1.7) provide a good example of alteration of target sites.

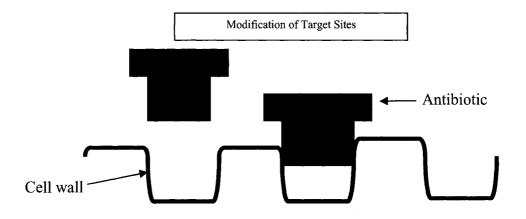


Figure 1.6: Effects of Antibiotics on Normal Bacteria Target Sites. From The mutation factor: How bacteria become resistant. By S. Shoemaker, 2005. Louisiana Speech-Language-Hearing Association Convention. New Orleans, LA. Reprinted with permission of the author.

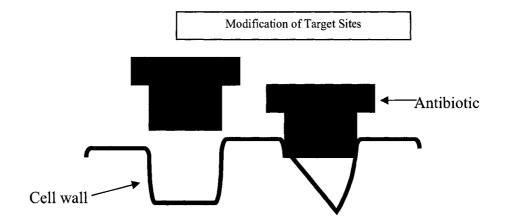


Figure 1.7: Effects of Antibiotics on Modified Bacteria Target Sites. From The mutation factor: How bacteria become resistant. By S. Shoemaker, 2005. Louisiana Speech-Language-Hearing Association Convention. New Orleans, LA. Reprinted with permission of the author.

Schumann and Nollette (2000) described three additional mechanisms of antibiotic resistance. Drug efflux occurs when a bacterial cell allows an antibiotic to enter, but pumps it out again. The elimination of the target by creating new metabolic pathways is another mechanism. Genes that are resistant can be transferred from their original hosts into new organisms, causing the organisms to become resistant to additional agents. Finally, the geographic spread of resistant clones is another possible mechanism of antibiotic resistance. This occurs when modified bacteria reproduce and spread from one carrier to another.

The spread of resistant bacteria among human hosts is of great concern, especially to healthcare professionals. Several contributors to the development of antibiotic resistance have been identified.

Factors Contributing to Antibiotic Resistance. Many factors contribute to the emergence of antibiotic resistance. The excessive and/or inappropriate use of

antibiotics is probably the most important factor leading to increased antibiotic resistance, especially when associated with otitis media. According to the Centers for Disease Control and Prevention (1999), 50 million courses of antibiotics are prescribed unnecessarily each year. One must wonder why so many unneeded prescriptions are dispensed. As with resistance, there are many reasons for the abundance of antibiotic prescriptions. Both physicians and parents contribute to this problem.

Schumann and Nollette (2000) noted that physicians' prescription practices are among the largest contributors to antibiotic resistance. Although physicians are aware of increasing resistance, they continue to prescribe antibiotics to children who will be unlikely to benefit from them. Some unneeded prescriptions may be due to misdiagnosis of acute otitis media; however, this is not the leading contributor.

Sorum et al. (2002) suggested several reasons for physicians' prescription practices. First, physicians may practice defensive medicine, in that the prescription is given with prevention in mind. Second, some physicians think it requires less time and effort to write a prescription than to explain to parents why antibiotics are not needed. Third, Sorum et al. suggested that physicians are being sensitive to socioeconomic pressures with which parents must contend, such as work schedules, daycare policies, and cost of return visits. Finally, physicians' perceptions of the wants and needs of the parents may lead to an unnecessary prescription.

Palmer and Bauchner (1997) investigated whether parents' desire for antibiotic prescriptions influenced physicians' decision to use antibiotic treatment for infections such as otitis media. Therefore, the primary objective of Palmer and Bauchner's study was to describe parents' opinions and concerns as compared to those of physicians.

The subjects were assigned to either a parent group and a physician group. The parent group was a convenience sample of 400 subjects from three medical practices in the Boston, Massachusetts area. Two of the participating sites were private practices in suburban locations. One practice had two physicians and accounted for 87 participants (P1); the other site was a larger practice with seven physicians and accounted for 226 participants (P2). The third site was an inner-city community health center that provided 100 subjects (CHC). The division of physicians included 100 pediatricians across Massachusetts whose names were chosen from the Fellowship Directory of the American Academy of Pediatrics.

Palmer and Bauchner used two survey methodologies. Parents were interviewed by research assistants in the waiting room prior to being seen by the pediatrician. Information was obtained about socioeconomic status, education level, and experiences with antibiotics. The subjects/parents were asked about their knowledge of possible side effects of antibiotics and which illnesses they believed required antibiotics. The interviewer used open-ended and closed-ended questions. These data were analyzed using chi-square.

The physicians were mailed a two-page questionnaire and asked to return it in the stamped envelope provided. A second copy of the questionnaire was sent, and a follow-up phone call was made to each physician to help ensure returns. Palmer and Bauchner mirrored the questions on the parents' survey to examine how much knowledge the physicians had about parental concern and antibiotic prescriptions. Chi-square analysis was also used for the data generated from this questionnaire.

Palmer and Bauchner found that when asked if their children were receiving too many antibiotics, 29% of the parents said yes; 85% of the parents stated that receiving too many antibiotics could cause problems. The majority (93%) of the participants reported that antibiotics were almost always necessary for treating ear infections. Analysis of physicians' responses revealed that 71% had received requests for an antibiotic from at least four parents over a one month period. Thirty-five percent agreed to the prescription even though, in their opinion, it was not necessary.

Palmer and Bauchner's findings suggested that with more education about antibiotics and their proper use, parents may be able to make better decisions about treatment of infections. The authors also suggested that with better communication between parents and physicians, over-prescription of antibiotics would decrease. The investigators cautioned that the results from their study may not be generalized to other populations because a variety of participants was not used, it was hard for participants to recall exact events, and subject responses may not have been accurate. Only 61 physicians returned the survey; therefore, the data given may not have been representative of the population of interest. Palmer and Bauchner suggested additional research to gather information about antibiotic prescribing tendencies.

Because it has been suggested that physicians are motivated to prescribe antibiotics based on the belief that parents want their children to have them, Mangione-Smith, McGlynn, Elliott, Krogstad and Brook (1999) investigated these behaviors. The researchers had two objectives: (1) to determine what parents' pre-visit expectations are and whether physicians' perceptions of those expectations result in the prescription of unnecessary antibiotics; and (2) to examine the relationship between expectation fulfillment and parental visit-specific satisfaction.

Ten physicians from two private practices and 306 parents attending sick visits during a five-month period participated in this study. The inclusion criterion was that the parents be able to speak and write English. Also, the children had to be between 2 and 10 years of age, had complaints of earaches and sore throat, and had received no antibiotic treatment for two weeks prior to the study.

In order to avoid the Hawthorne effect as a potential threat to validity, the physicians were not informed that one of the primary purposes of the investigation was to explore the relationship between parental expectations and antibiotic prescriptions. After each visit, the physicians were asked to complete a questionnaire to provide information about diagnosis, treatment, and perceived parental expectations for antibiotics. The parents completed a pre-visit questionnaire designed to obtain demographic data and information about attitudes toward and expectations for antibiotics. Parents also completed a post-visit questionnaire to reflect whether their expectations were fulfilled and their overall satisfaction with the visit. To gather case history information, medical records were randomly obtained for a portion of the subjects.

Mangione-Smith and her associates found that parental expectations were significantly connected to the prescription of antibiotics. When the physicians thought the parents wanted antibiotics, prescriptions were provided 62% of the time. In contrast, if the physicians did not perceive that the parents wanted the prescription, they did so only 7% of the time. Some physicians admitted to prescribing an unnecessary antibiotic so time would not have to be spent giving an explanation as to why a prescription was not

needed. However, when parents did not receive an antibiotic, there was no reported decrease in satisfaction.

The physicians' perceived expectations were not in agreement with those of the parents. Lack of communication was the only parameter for which the parents reported dissatisfaction with the visit to the physician. The investigators stated that if communication between physicians and parents was more open, inappropriate antibiotics would not be prescribed as often. Most physicians have been educated about the risks of building antibiotic resistance, but they continue to prescribe antibiotics when it is the parents' wish. Magione-Smith, et al. suggested that parents should also be educated about the disadvantages of antibiotic treatment. When parents are well-informed and physicians take time to explain the lack of benefits of antibiotic use, fewer unnecessary prescriptions will be given.

Baucher, Pelton, and Klein (1999) reported that physicians admitted to responding to parents' request for antibiotic prescriptions. Physicians noted that parental pressure was the reason for inappropriate antibiotic use 54% of the time. A similar study by Mangione-Smith (2001) revealed that physicians prescribed antibiotics for presumed viral infections 62% of the time. The physicians did so because they thought the parents wanted an antibiotic. When physicians did not think parents wanted an antibiotic, they only prescribed them 7% of the time.

Mangione-Smith suggested that what happens during the doctor-parent interaction is a key determinant of the over-prescription of antibiotics. Baucher et al. (1999) found that 78% of the physicians thought educating parents was essential for decreasing antibiotic use. However, these physicians also admitted that there was "not enough time" for education; therefore physicians just complied with parents' requests for antibiotic prescriptions.

<u>Concerns About Otitis Media and Antibiotic Resistance</u>. Otitis media is the most frequently diagnosed childhood illness for which antibiotics are prescribed. In many cases, these prescriptions may not be necessary. In order to reduce the number of unnecessary antibiotic prescriptions and the spread of antibiotic resistance, physicians, parents, and other health care professionals should be educated about otitis media and the risks associated with overuse of antibiotics.

Education

Education is a key component to reducing antibiotic resistance. Awareness among the medical community and the general public is crucial. Both physicians and parents need to be made aware of increasing antibiotic resistance and the factors contributing to its spread.

<u>Physicians</u>. Physicians should be well aware of the risks involved with prescribing antibiotics for treatment of otitis media. Guidelines have been established by the Centers for Disease Control and Prevention (2000) and the American Academy of Pediatrics (2004) to help physicians prescribe antibiotics judiciously for the treatment of acute otitis media.

In 2004, the American Academy of Pediatrics released a practice guideline for the treatment of acute otitis media. The guideline stressed the importance of careful diagnosis, use of narrow-spectrum antibiotics, and allows, as an acceptable option, the initial observation of non-severe cases of acute otitis media (i.e., watching during the first few days of an infection to observe whether there is resolution without treatment). The

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observation method should only be practiced with children age 2 years of age and older with mild pain, absence of high fever, and for children who are likely to return for follow-up visits if symptoms persist or worsen.

After reading reviews about the growing concern with the overuse of antibiotics in treating acute otitis media, Cates (1999) decided he and his colleagues should change their policy for routine antibiotic prescription and measure the outcome over the following year. The purpose of his study was to identify an effective way to reduce the use of antibiotics for treating acute otitis media.

Cates used the patients in his practice as the experimental group and patients from a local practice as a control. The two practices maintained approximately the same number of patients throughout the length of the study. However, no specifics about the subjects were given.

The subjects treated by Cates and his partners received a handout that explained the limited benefit of antibiotics for treating acute otitis media. The parents were given an antibiotic prescription that was to be filled after a couple of days only if there was no improvement. Parents were asked to give their children pain-relievers and/or feverreducers when needed. The control group was given a prescription for Amoxicillin and did not receive a handout with explanations of antibiotic treatment.

Cates found that after changing the prescription policy, the number of antibiotic prescriptions was reduced by 19% from the preceding year. Cates reported finding other sources that revealed that the national number of prescriptions was reduced by 3% that same year. Cates found in his study that most of the parents were satisfied to receive the handout and deferred the prescription, which often was not filled.

Because the information given about this study is so vague, it is difficult to assess the validity of the results. Without subject characteristics, generalizability cannot be determined. Cates suggested that investigations into antibiotic reduction continue in order to add to the knowledge base.

There is research to support withholding antibiotics when treating acute otitis media. For instance, in the early 1980's, Buchem, Peeters, and Van 'T Hof (1985) had already recognized the growing problem of unnecessary antibiotic treatment for acute otitis media. Buchem et al. investigated whether treating acute otitis media with decongestant nose drops and pain relievers would be a satisfactory treatment method.

From March 1, 1981 to August 1, 1982, 60 physicians in the Netherlands participated in Buchem et al's study. The patients for whom data were collected had to be two years of age or older and could not be diagnosed with any other infections that required antibiotics at the time of the study. The physicians treated all patients exhibiting acute otitis media symptoms with decongestant nose drops and pain relievers. The practitioners recorded the success of the treatment over the 17-month period, and 45 also recorded the incidence of acute otitis media diagnoses between February and April 1982.

If the condition of the patients worsened, a referral was made to an ear, nose, and throat specialist; the patients were then entered in another study. This alternate study focused on treatment with antibiotics, myringotomy, or both and the effectiveness in children ages 2 to 12 years.

During the study, 4860 children were treated and approximately 490 turned into severe cases. Of the severe cases, 126 were directed into the other treatment study.

Approximately 90% of the children treated with nose drops and pain relievers, recovered a few days after seeing the physician.

Following the study by Buchem et al., the Netherlands became the first to adopt this analgesics-only method of treatment. Antibiotic resistance in the Netherlands has decreased drastically since implementing this treatment strategy.

Noting an increase in antibiotic consumption, Siegel et al. (2003) investigated whether a method used in England to treat acute otitis media with a safety-net antibiotic prescription would be accepted by parents in the United States. Siegel and his colleagues noted that antibiotics do not have a great effect on children with otitis media and they were interested in an alternative for treating the infection in order to prevent antibiotic resistance to some extent.

Therefore, Siegel et al. provided parents with an antibiotic prescription for their children's acute otitis media, but were asked only to fill it if the condition worsened or did not improve after 48 hours. The parents were contacted by a nurse within 10 days of enrollment and asked a series of questions about the treatment plan. The questions included if, when, and why they filled the prescriptions.

After all follow-up interviews were completed, Siegel and his colleagues found that parents of 120 of the 175 subjects did not get the antibiotic prescription filled. Those who did use the antibiotic did so for a variety of reasons; however, the majority did so because of their child's pain. Only three of the 120 subjects who did not fill the prescription reported that they would be unwilling to repeat the treatment plan in the future; 117 reported that they would not use an antibiotic if their children had another episode of acute otitis media. Siegel et al. concluded that the safety-net antibiotic prescription treatment plan may have been beneficial in fighting antibiotic resistance because unnecessary antibiotic treatment was avoided. These findings supported the "wait and see" method and were a precursor to other studies yielding similar results, like those later established by Finkelstein, Stille, Rifas-Shiman, and Goldmann (2005).

Being aware of this research may help physicians confidently withhold antibiotics from their patients. Physicians can also provide a rationale to concerned parents who are skeptical of this new strategy. It is crucial that physicians take time to explain diagnoses and treatment choices to parents. Parents. The more information parents have about their children's condition and the treatment options, the more likely they are to forgo antibiotic prescriptions. Pechere (2001) offered some suggestions as to what should be involved in patients'/parents' antibiotic education. First, parents need to know what diseases actually require antibiotic treatment, understand the differences between bacterial and viral infections, and know why antibiotics are not always the appropriate treatment. Next, parents should have a solid grasp on the importance of taking antibiotics in the prescribed dosages and for the prescribed duration. Pechere suggested that parents be educated about the "absence of significant alterations of immunity associated with antibiotic treatment. Parents should also be helped to understand the danger of keeping part of an antibiotic prescription for future use and the importance of obtaining a new prescription for antibiotics.

Parental understanding that medication does not always equal a cure is vital to reducing antibiotic resistance. Brallier (1993) reported that biologist Hans Kreb once said "you and your family must clearly understand that the great ultimate healer is always nature itself and that the drug, the physician, and the patient can do no more than assist nature, by providing the very best conditions for your body to defend and heal itself" (p. 63).

Physicians should be the primary educator for parents and should explain the rationale for prescribing or not prescribing antibiotics in a way that parents will understand. When unsure about writing a prescription for antibiotics, physicians should

also offer treatment options. Parents tend to trust their physicians; so, physicians seem to be the logical choice to teach parents about the risks of antibiotic resistance.

Physicians, however, should not have sole responsibility for increasing awareness about antibiotic resistance. Other healthcare professionals should do their part. For example, nurses and pharmacists have as much, if not more, contact with parents. Therefore, these professionals should encourage parents to learn more and provide the necessary resources for parental education.

Audiologists have a responsibility to their patients, as well. Parents are often more comfortable asking an audiologist questions than they are a physician. Therefore, audiologists should be prepared to provide as much information as possible.

The Alliance Working for Antibiotic Resistance Education (AWARE) is an example of an organization that shares information to educate parents. The *Salt Lake Tribune* (2004) described this group as a coalition of health plans, pharmaceutical companies, and healthcare professionals dedicated to spreading the word about the overprescribing of antibiotics. Information is readily available to those interested in expanding their knowledge of common illnesses and antibiotic resistance.

There is a need for parents to be educated about the risks involved with the inappropriate prescription of antibiotics. Trepka, Belongia, Chyou, Davis, and Swartz (2001) measured the changes in parental knowledge and awareness of antibiotic use, as well as resistance after interventions throughout the community.

The study was conducted in northern Wisconsin and the subject population chosen was from a region whose residents receive healthcare from a regional medical network. There were two groups in the region. The Central group served as the control and the North group served as the intervention group. Each group included approximately 215 households with children under four years of age.

All parents were contacted by a member of the research team and given a questionnaire that explored their knowledge and beliefs about and their practices with antibiotics, and their awareness of antibiotic resistance. Throughout the intervention region, activities were provided to educate parents about antibiotics and the advantages and disadvantages of using antibiotics. Along with written materials, parents were given opportunities to attend presentations provided by two nurse educators. The newspaper in the intervention area also published an article discussing antibiotic resistance. Physician-oriented presentations were given by a member of the research team. The control group received a minimal amount of information about antibiotics. Approximately eight months after intervention had ceased, parents were contacted for a post-intervention survey which was identical to the pre-intervention survey.

Trepka, et al reported that of the 430 pre-intervention participants, 365 completed the post-intervention survey. However, there was no significant difference in the final number of the control and intervention groups. The number of parents who thought antibiotics were not necessary for most infections increased substantially in the intervention group. The number of parents who thought antibiotics were not necessary for most infections also increased in the control group but not as significantly as for the intervention group. The percentage of parents expecting antibiotics decreased by about 5% in the intervention group, while the control groups expectations increased by about 3%. Trepka and her colleagues stated that theirs was the first published study on the education of parents about antibiotic resistance. The researchers interpreted the results to suggest that intervention was successful in increasing parental awareness about the risks and proper use of antibiotics.

The conclusions drawn by Trepka and her colleagues are encouraging. The data suggest that when educated about treatment options for infections, parents may be more willing to try alternative methods.

Statement of Problem

Antibiotic resistance is a growing problem throughout the world. There are many contributing factors that increase the spread of resistance. A major concern is that parents may not have the knowledge base needed to make the best decisions about antibiotic treatment for infections, especially otitis media.

In order to properly educate parents, healthcare professionals need evidence of what parents know about antibiotics, resistance, and infections. An instrument, such as a survey, should be developed to collect information concerning parental knowledge, behaviors, and opinions associated with antibiotic treatment for otitis media and other infections. Therefore the specific purpose of this capstone project is to develop a questionnaire to gather information about parent/guardian views about otitis media and antibiotic treatment.

CHAPTER 2

SURVEY RESEARCH METHODOLOGY, QUESTIONNAIRE DEVELOPMENT, AND PILOT STUDIES

The primary purpose of this capstone project is to develop an instrument to measure parental knowledge, behaviors, and opinions associated with antiobiotic treatment for otitis media. As the interest is in gathering relatively restricted information from parents in a given environment, survey research methodology will be used. A secondary purpose is to plan a pilot study to use the instrument with parents of young children who have experience with the use of antiobiotics to treat otitis media. The main justification for conducting a pilot study is to help the researcher refine the methods and materials such as identifying and removing ambiguities in the questionnaire items.

Survey Research Methodology

Survey research methodology is the most commonly used method of measurement in the field of applied social sciences (Trochim, 2006). Survey research, according to Trochim, is a broad umbrella which covers any measurement procedures that involves asking questions. Interviews and questionnaires are the principal instruments used in survey research.

Interviews

Interviews are the most personal form of survey research in that they allow probing to obtain more or different data and allow the interviewer to assess the communicative interaction with the respondent to determine how the data-collection process may be affected. Interviews may be completed face-to-face in person or by telephone. Each type of interviewing techniques offers unique advantages and disadvantages.

One advantage of personal face-to-face interviews is that they allow the interviewer to ask follow-up or clarifying questions because they are face-to-face with the respondents. Personal interviews are also generally easier for respondents, especially when the goal is to gather impressions or opinions. In addition, if the respondent indicates that he or she does not understand a question, the interviewer can clarify matters leading to more relevant responses. On the other hand, Trochim suggested that personal interviews are costly and time-consuming, interviewers need to be trained, and the interaction between the interviewer and respondent can have a strong influence on the data collected.

Telephone interviews are advantageous because information can be gathered rather quickly because all respondents are asked the same questions which are usually short-answer or multiple-choice. The interviewer also has an opportunity to ask follow-up questions for clarification or expansion of responses as necessary. Trochim identified some disadvantages to telephone interviews. First, people often do not appreciate the intrusion of calls to their homes and the interviewer may spend a great deal of time calling individuals who ultimately will not participate. Second, many people have

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replaced their land-line phones with cells or their telephone numbers are unlisted. This may lead to inaccessibility to a representative sample, Third, telephone interviews need to be relatively short; otherwise, participants may perceive further imposition on their time and privacy. There are literature reports of the use of interviews to investigate parental involvement with antibiotics for treatment of childhood illnesses.

Jonsson and Haraldsson (2002), both physicians, gathered information about parents' perspectives on otitis media and antibiotics. Their research was conducted in Reykjavik, Iceland with the participation of six general practitioners and 21 parents of preschool children with newly diagnosed acute otitis media.

The general practitioners assisted in the sampling by asking parents of their patients to participate in the study. The parents were purposefully sampled in order to assure diversity in the population of interest. Jonsson and Haraldsson interviewed approximately half the sample.

The researchers scheduled in-home interviews with the parents and allowed the participants to choose the most convenient time. Jonsson and Haraldsoon used a semistructured interview with their self-generated topic list. The topic list contained approximately 35 points of interest to be discussed with the parents. The interview, instead of being a question-answer format, was more of a guided discussion between the interviewer and the respondent.

The interviews were recorded, transcribed, coded, and indexed according to the subjects. The data were analyzed to identify the concepts and categories of interest.

Jonsson and Haraldsoon stated that they chose semi-structured interviews because this allowed them to open a kind of inquiry that had previously been relatively unexplored. Using this method of survey research, the researchers obtained information about how parents perceived otitis media and the use of antibiotics for treatment. The subjects were not limited to responding only to close-ended questions. They were able to speak openly about their opinions and perceptions. Based on the data collected, Jonsson and Haraldsoon viewed this research methodology as successful for the purposes of their investigation.

Braun and Fowles (2000) also used an interview format to gather information about individuals who wanted antibiotic prescriptions. The researchers chose their sample from three primary care clinics in Minnesota. The subjects were selected on the basis of symptoms, age, and desire for antibiotic prescriptions. Five hundred five subjects participated; 249 parents of symptomatic children and 256 symptomatic adults. The participants were evenly distributed among the three primary care clinics.

Braun and Fowles used telephone interviews for data collection. A trained interviewer conducted the telephone interviews with a script developed by the researchers. Verbal consent was obtained from the participants prior to initiation of the interview. The final participation rate was over 90 %.

The survey contained demographic questions and a series of specific questions about the symptoms and whether the subjects wanted antibiotic prescriptions. Item responses were dichotomous, either *Yes/No* or *Agree/Disagree*. The data were analyzed by computing frequency distributions.

By using a telephone interview, the Braun and Fowles were able to survey a large number of individuals and obtain a high response rate. Although the researchers learned that there were some problems with the script and questionnaire instrument, they viewed their method of data collection as successful.

The investigations of Jonsoon and Haraldsson (2002) and Baun and Fowles (2000) illustrate the use of telephone research methodology with the population of interest in this capstone project. The studies also provided examples of ways to address the disadvantages inherent to this type of investigation.

Questionnaires

Questionnaires are the second most commonly used method of survey research. Questionnaires may come in different forms but are most often thought of as paper-andpencil instruments that respondents complete (Trochim, 2006). Questionnaires can be administered by mail, in groups, by drop-off, or via the internet. Each method of administration has advantages and disadvantages.

According to Trochim, mailed surveys are advantageous because researchers are able to send the same instrument to a large number of individuals while controlling the costs of administration. This survey method also allows respondents to complete the questionnaires at their own convenience. A primary disadvantage is the potential for a low return rate as the investigator has relatively little control over the number of individuals who complete and return the survey. Thus the mortality threat to internal validity is a common problem in survey research that uses mailed questionnaires as the instrument of data collection.

Trochim suggested that group-administered questionnaires allow researchers to achieve a high response rate by using their survey with individuals in pre-existing group settings, e.g., offices and classrooms. Respondents also had opportunities to request clarification if unclear about the instructions or the meaning of a question. This method is also budget-friendly because it does not require postage or additional supplies, such as envelopes. A major disadvantage to group-administered questionnaires, as Trochim suggested, is that the diversity of the sample population is limited. For example, individuals working in the same office or students in a university setting may share similar educational backgrounds as well as other demographic characteristics.

Group-administered questionnaires often have high response rates. The questionnaires are given to a group of respondents to be filled out immediately. After completing the questionnaires, the respondents return them to the administrator.

Internet questionnaires are a new trend for survey research methodology. Use of internet capabilities allows researchers to sample a wider range of individuals across the country and around the world with little or no cost. On-line questionnaires eliminate the need for paper, pens, and postage because they can be returned with the touch of a button. And, convenience, as a major concern to individuals who consider completing a survey, is addressed. Although internet questionnaires simplify the survey process, there are some disadvantages. First, researchers must develop a way to direct the attention of the population of interest to the internet site where the questionnaire is located. The researcher may need to send mass electronic mail (e-mail) messages with a link to the questionnaire. This however, would require e-mail addresses for individuals in the population of interest. Another disadvantage is that many people may not have internet access and/or they may be novice internet users.

In spite of some disadvantages, researchers have used questionnaires in their quest to learn more about parents' views on otitis media and antibiotic use. For example,

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Finkelstein, Stille, Rifas-Shiman, and Goldmann (2005) used a questionnaire to investigate whether parents and physicians were receptive to watchful-waiting or withholding of antibiotics to allow the inflammation of acute otitis media to resolve without medication. The sample population, parents and physicians, was chosen based on the diversity of the communities in which they lived. The state Medicaid program and large commercial health plans were used as sources for addresses of parents of children under the age of six years. Pediatricians and family physicians were selected based on the location of their medical practices in the sample communities.

Finkelstein, et al chose to mail questionnaires to the subjects. Parents received the initial mailing and two follow-up mailings; the physicians were sent only one follow-up mailing.

The parental questionnaire included questions meant to gather demographic information. The questionnaire also contained general knowledge questions concerning otitis media and antibiotics, as well as statements about parental satisfaction of treatment. Response possibilities were multiple-choice and a five-point satisfaction scale.

The physicians' questionnaire used opinion-based and behavioral questions concerning otitis media and antibiotic treatment. Response scales were based on level of concern for current issues with antibiotic use and frequency of certain behaviors.

Finkelstein et al. had a final response rate of 40% for parents, with 2054 of the 5129 questionnaires returned. Of the physicians surveyed, 160 of the 292 returned their questionnaire for a response rate of 58%. These response rates are acceptable as Babbie (2000) pointed out that a response rate of at least 50% can be considered adequate for analysis and reporting purposes.

The study of Finkelstein and his colleagues (2005) is an example of the potential for a disappointing response to mailed questionnaires. The researchers mailed thousands of questionnaires in order to achieve a 40% response from the parents. However, the study does illustrate ways to control for the problem of subject mortality by including plans for follow-ups to the initial mailing.

Yen, Walsh-Kelly, and Hennes (2001) used a self-administered questionnaire to investigate physicians' views of the management of acute otitis media. Using a single mailing, Yen et al surveyed 450 staff physicians at a large urban children's hospital. The questionnaire, developed by the researchers, had eight multiple-choice questions and one rank-ordered question. Demographic questions were also included.

Two hundred thirty-six of 450 questionnaires were completed and returned for a response rate of 52%. Yen and his colleagues discussed the limitations of their study and response rate was one of their concerns. Yen et al also noted an inadvertent bias in the questionnaire format, i.e., responses were limited due the multiple-choice response format. These observations will be useful considerations in the design of similar studies.

The investigations reported by Finkelstein et al (2005) and Yen, et al (2001) emphasized the importance of careful planning for questionnaire development. Special consideration must be taken when deciding which method of administration will be the most efficient and when choosing the questionnaire format and content. These decisions will have an impact on the success of a study using survey research methodology.

Questionnaire Development

Suskie (1992) reminded us that the process of developing a questionnaire can be a major project and involves considerable time and resources. To achieve valid and reliable responses and to contribute to the success and credibility of the survey research efforts, planning is essential.

Planning

Planning a survey research study involves much more than choosing questions and response formats. There are many steps to be taken prior to writing the first question. The first step is to establish the goals or objectives of the study. Suskie advised researcher to "refine the problem." That is, the more specific the objectives, the easier to choose and frame questions.

The researcher should determine how the results of the questionnaire responses will be used. According to Suskie, surveys are "tools that are used to help make decisions" (p. 3). If the questionnaire is not being developed to contribute to making a specific decision, the researcher needs to determine why there is a need for the information. For example, the researcher may question whether the information will be used to aid in future studies. The research may also consider whether the data obtained from the questionnaire responses will determine the need for education or intervention. The appropriate questions cannot be asked without consideration of why the answers are important.

After establishing the goals for a survey and identifying the need for the information, the researcher should specify the critical questions of the survey will be used to answer. The inclusion of unnecessary questions will only lengthen and complicate the

survey. Bradburn, Sudman, and Wansink (2004) encouraged researchers to consider whether a question is asked because it would be interesting to have a response or whether a question is essential to achieving the goals of the study. If responses to a particular question are not going to be used for a specific purpose, that question probably should be omitted from the questionnaire (2004). Bradburn et al emphasized that each question in the survey should be closely examined to verify its contribution to the objectives of the study.

The researcher must also determine what information is needed to answer the research questions and how each piece of information will contribute to the objectives of the investigation. Suskie (1992) suggested that the author of a questionnaire should be particularly critical of the demographic information section. Bradburn et al (2004) concurred that asking too many personal questions may seem intrusive to the respondents and discourage their participation. Using the fewest questions possible to gather the desired information may be an appropriate guide for the developer of a questionnaire instrument.

The next step in planning is to consider what others have done on the topic being investigated (Suskie, 1992). Suskie asked, "Why reinvent the wheel when you can take advantage of what others have done before you?" (p. 4). Within ethical constraints, researchers developing questionnaires may make use of previously asked questions. At the least, reviews of related questionnaires used in similar research can be helpful when choosing which questions to ask and how to ask them.

According to Suskie, another step in planning a survey is to decide how the results will be analyzed and reported, i.e., what will the researcher do with the

information after it has been collected. Suskie recommended that the best way to make this decision is to ask whether the purpose of the study is to describe or explain some phenomenon. If the purpose is to describe various groups of people, the information can be summarized and reported as totals and percentages. However, if the purpose is to explain, predict or explore, the researcher will need to use more complicated statistical analyses, such as factor analysis, regression analysis, or analysis of variance.

The researcher should also identify who will be surveyed because, according to Suskie, the characteristics of the target population will affect the kind of information being sought. The educational level and age are among the characteristics of the respondents that must be considered when developing appropriate questions. For example, the terminology used in the questions may need to be simplified for some groups (e.g., if they are young or only have grade-school reading levels).

Next, the number of individuals to be surveyed should be determined. The researcher makes the decision as to how many respondents are adequate to meet the goals of the study. According to Suskie, the number of people surveyed depends on the amount of sampling error a researcher is willing to accept. Sampling error describes the possible difference between the findings and the true results if the researcher were able to obtain valid responses from "everyone". The smaller the sample size, the greater the sampling error. Suskie stated that a random sample of 196 people will yield a sampling error of 7% while a sample of 9604 will yield a 1% sampling error.

Response rate, or mortality as a potential threat to internal validity, is a significant variable to consider when planning a survey study. The response rate can be affected by a number of factors which, according to Suskie, include the topic to be investigated, the characteristics of the accessible population, the potential level of response from the population of interest, and the length and appearance of the questionnaire.

And so, the researcher must consider how many completed surveys he or she would like to receive for reporting and data analysis and project the expected response rate. Overall response rate is one guide to the representatives of the sample respondents. Babbie (2000) provided some rules of thumb about return rates and maintained that a return rate of 50% is adequate for analysis and reporting, a response of 60% is good, and a response rate of 70% is very good. To obtain the desired number of usable questionnaires, the researcher may wish to distribute twice that number, initially. For example if the researcher would like to have 100 usable questionnaires and projects a 50% response rate, at least 200 surveys should be sent.

After determining the desired number of completed questionnaires, the researcher should choose the subject selection procedures. For the survey results to be meaningful, the sample must be representative of the group from which the sample was taken, i.e., the population of interest. Random selection is an ideal sampling procedure in that every person in the population of interest has an equal chance of being chosen to participate in the study.

There are several random sampling procedures all of which assume that the researcher has a complete and accurate list of all the individuals from whom he or she wishes to select the sample. Because this is rarely the case, the researcher has the option of using non-random sampling procedures. Suskie (1992) presented judgment and convenient sampling as two basic, non-random procedures for subject selection.

Judgment sampling, as described by Suskie, allows the researcher to carefully choose the sample so that in the researcher's best judgment, the sample is representative of the population of interest. This method requires that the researcher knows the potential subjects well enough to make an accurate judgment about their characteristics if interest.

Convenience sampling, as a second non-random method for subject selection, allows the researcher to choose subjects from individuals who meet eligibility criteria for participation in the study and who are easily accessible for purposes of the study. Suskie suggested convenience sampling for small-scale research investigations such as pilot studies.

Pilot Studies

Teijlingen and Hundley (2001) defined a pilot study as a small-scale version of a major study. Pilot studies are described as trial runs, pre-testing, or a "trying-out" of an instrument.

Advantages of pilot studies were discussed by Teijlingen and Hundley. For example, pilot studies may allow researchers to identify possible factors that will contribute to a less than successful main research project as well as the inappropriateness of the proposed instrumentation. Pilot studies may also help convince funding agencies that the research proposal merits funding.

As suggested by Teijlingen and Hundley, questionnaires can be piloted in order to test wording, question order, or the range of multiple-choice categories. Respondents to the pilot instrument can provide valuable information by not only answering the questions but by offering feedback about what does and does not work in the survey. The process for delivery and return can also be evaluated in a pilot study. Although pilot studies can be very beneficial in survey research, there are limitations to their usefulness. Pilot studies are typically used with a small number of people and the sample may not be representative of the population of interest (Elmes, Kantowitz, & Roediger, 2003). Another limitation is that there is no way of knowing if the pilot data are a "fluke". Therefore, the researcher would have to scrutinize the pilot data for validity and reliability before proceeding to the major study.

Suskie (1992) recommended that pilot testing as the most important step in survey research and pointed out that it is the step most often omitted by inexperienced researchers. Pilot testing may be the difference between a successful study and a failure.

After the researcher has developed a plan for the survey, the job of creating the instrument or data collection (the questionnaire) can begin. The process of creating the questionnaire is a tedious and time-consuming task that involves, at a minimum, choosing the questions and response styles, formatting, and a plan for pre-coding.

Developing the Capstone Questionnaire

In the planning stages for the development of this capstone project, the first step was to establish the goals or objectives for the study. The goal of this project conceptualized as the development of a questionnaire to effectively gather information about parental/guardian views toward otitis media and antibiotic treatment. It was also determined that this would be a pilot study.

The second stage in the development of the questionnaire was to determine how the results would be used. The results from the questionnaire study will first be used to evaluate the effectiveness of the use of survey methodology. The long-range goal is that the information gathered may also be used as a foundation for future research on this same topic.

The third step in the development of this questionnaire was to develop the critical questions to be asked. It was recognized that in order to learn more about parents'/guardians' views toward otitis media and antibiotic treatment, a variety of questions should be framed to investigate parent/guardian knowledge about otitis media and antibiotics, the behaviors of these same individuals as associated with antibiotic treatment, and their opinions toward the practice of their children's physicians with regard to the prescription of antibiotics for otitis media. In addition, questions would need to be developed to gather background and demographic information about the parents/guardians that could be used to determine the relationship, or lack of, among variables such as gender, race, educational levels, etc.

As these are rather broad areas, there was a need to examine each in detail. Numerous questions were generated and evaluated as to how each related to this study. Questions were eliminated that, while interesting, did not directly relate to the relevance of this study.

After the research questions were chosen, the methods for asking the questions were examined. How questions are asked can bias or influence the way an individual responds. Suskie (1992) emphasized the importance of writing questions that can be clearly understood and provided suggestions for doing so. Suskie's suggestions for writing clear questions included (a) keep it short; (b) keep it readable; (c) be sure it asks only one question; (d) keep it interesting; (e) write all definitions, assumptions, and qualifiers so as to be clearly understood; (f) make the questions as specific as possible; (g) consider using behavioral questions; (h) avoid loaded, leading, or sensitive questions;(i) avoid biased questions; (j) make the items easy and fast to answer; and (k) design the item to yield data that are meaningful and easily interpreted.

Suskie's suggestions were used in developing each question for this survey instrument. Also, a great deal of time was devoted to examining the terminology used. The questions could not be too technical or complex and had to be appropriate for individuals from different educational, cultural, and ethnic backgrounds.

The comfort level of the respondents while answering the questions was considered. It is important for respondents to be as comfortable as possible when completing the questionnaire so that honest responses will be forthcoming. Therefore the questions were worded so as to avoid negative and biased items and terms. In addition to the close attention to the wording of questions, response styles were considered.

Because the purpose of this study was to develop an effective questionnaire, the methods to elicit responses were investigated. Since this questionnaire was developed to be used in a pilot study, several response styles were chosen. Data analysis should provide some insight into the effectiveness of the response styles.

Four response styles were chosen: Likert rating scales, dichotomous (Yes/No), multiple choice, and free-response. Each style has its own advantages and disadvantages and may affect responses in a different way.

The best-known rating scale, according to Suskie, is the Likert scaling. Questionnaire items contain response categories such as "strongly agree," "agree," "disagree," and "strongly disagree" are commonly referred to as a Likert scale. The particular value of this format is the unambiguous ordinality of response categories which allows the research to judge the relative strength of agreement intended by the respondents. These rating scales can be used when asking knowledge-based and behavior-based questions.

Suskie also stated that the main advantage to Likert rating scales is that most people are familiar with them and will find them easy to complete. These scales also enable a researcher to gather a great deal of information quickly and compactly. A disadvantage is that it can be difficult to write specific items for Likert scales.

The Likert rating scale was chosen for the knowledge-based and behavior-based questions for this instrument. Because these questions can be intimidating, the goal in using this familiar response style would be to ease any fears the respondents may have about answering "incorrectly."

For the first section of the questionnaire (See Figure 2.1), the knowledge-based questions, the Likert rating scale was used. The use of the "Not Sure" choice can be optional, depending on whether the author wants to force a choice. If respondents fear answering "incorrectly," they may tend to go with the safe response of "Not Sure." For this reason alone, the "Not Sure" option was not used for this questionnaire.

A frequency Likert rating scale was used for the behavior-based questions in Section 2 of the questionnaire (See Figure 2.2). Instead of asking whether a parent/guardian practices certain behaviors, they were asked how often they practice it. Again, the attempt was to reduce the respondents' uneasiness toward choosing what they may judge to be an unpopular answer.

Section 1

For each statement below, please check ($\sqrt{}$) the box that most accurately reflects your (parent/guardian) level of agreement or disagreement.

		Strongly Disagree	Disagree	Agree	Strongly Agree
1.	Ear infections can cause hearing loss.				
2.	Any type of antibiotic would be appropriate for treating an ear infection.				
3.	Ear infections should always be treated with an antibiotic.				
4.	Some ear infections can resolve without antibiotic treatment.				
5.	No long-term physical effects result from overuse of antibiotics.				
6.	Only certain types of antibiotics work for treating ear infections.				
7.	Over time, the human body may begin to resist antibiotics.				

Figure 2.1: Parent/Guardian Questionnaire, Section 1.

Section 2

For each statement below, please check ($\sqrt{}$) the box that most accurately describes your (parent/guardian) actions.

		Never	Rarely	Sometimes	Always
1.	I stay on schedule for antibiotic dosage prescribed for my child.				
2.	I use one antibiotic to treat all my children.				
3.	I give my child the full prescription of antibiotics.				
4.	When my child misses a dose of antibiotics, I give him/her two doses at the next scheduled time.				
5.	I save leftover antibiotics for future use.				
6.	I stop giving my child the antibiotic prescription when he/she feels better.				
7.	I request an antibiotic prescription for my child when one is not offered by the doctor.				
8.	My child's doctor prescribes antibiotics over the phone, without an examination.				

Figure 2.2: Parent/Guardian Questionnaire, Section 2.

The second response style chosen was dichotomous, offering two response choices. There are many variations of the dichotomous response, but the Yes/No response pattern was chosen. An advantage of the Yes/No response style is that it can be used for the simplest or the most complex data analysis. These data can be easily summarized and reported by percentages, as well.

Suskie reported that a major disadvantage to Yes/No responses is that very few questions are purely Yes or No as most questions have a gray area. Another disadvantage is that Yes/No responses can be boring and respondents can easily lose interest.

The Yes/No response style for the opinion-based questions is used in Sections 3 and 5 of this questionnaire (Figures 2.3 and 2.5).

Section 3

For each item below, please check ($\sqrt{}$) beside the response that most accurately describes your reaction to the statement.

- Has your child been diagnosed with an ear infection for which he/she has received an antibiotic prescription? Yes
 - _____No
- 2. My child has received the same antibiotic more than once.
 - ___Yes No
- 3. I am satisfied when the doctor does not provide an antibiotic prescription.
 - ____Yes
 - ____No
- The doctor's explanation of his/her diagnosis is helpful for understanding my child's ear infection.
 Yes
 No
- 5. The doctor should provide an antibiotic prescription for my child on each visit. Yes

No

The doctor should provide more information about his/her diagnosis.
 Yes
 No

Figure 2.3: Parent/Guardian Questionnaire, Section 3.

Even though Suskie had a legitimate point about the gray areas of most questions, the researcher designed this section to require the respondents to choose one answer. For purposes of this study, it is important to identify the true opinions of the respondents.

The next response style chosen was multiple-choice which, according to Suskie, allows respondents to answer questions quickly and easily. Also, these responses can be easily tallied leading to compactness in reporting.

The major disadvantage to multiple-choice questions, as Suskie suggested, is that the author must include all of the possible answers. As another consideration, if the instructions are not clear, the respondents may choose more than one response. This will make data analysis more difficult and may even result in data that are not usable.

The multiple-choice response style was chosen for the demographic/background questions in the fourth section of the questionnaire (Figure 2.4) for its usefulness in collecting factual information. For the first three items in Section 4, a fill-in-the blank method for marking answers was chosen. Each answer option has a blank line to the left of it. The respondents will be instructed to place a check mark beside the responses that are most suitable for them. This is one of the simplest response formats used in questionnaires (Trochim, 2006).

Section 4

For the following questions, place a check ($\sqrt{}$) beside the responses that accurately describe you (parent/guardian), and provide specification when requested.

What is your (parent/guardian) gender?
 Male
 Female

2. What is your (parent/guardian) current age? (please specify)

Figure 2.4: Parent/Guardian Questionnaire, Section 4.

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3. How many children between 2 and 5 years of age are currently under your (parent/guardian) care?

(please specify)_

- 4. What is your (parent/guardian) relationship to the children for whom you are providing care?
 - ____Father
 - ____Mother
 - ____Grandfather
 - ____Grandmother Brother
 - ____Biother
 - Uncle
 - ____Onen
 - Foster Parent
 - Other (please specify)
- 5. What is your (parent/guardian) marital status?
 - ____Now married
 - _____Widowed
 - ____Divorced
 - ____Separated
 - ____Never married
- 6. What is the highest level of education you (parent/guardian) completed?
 - Elementary school
 - ____Junior high/middle school
 - ____High school
 - ____GED
 - ____Associate degree
 - ___Bachelor's degree
 - ____Master's Degree
 - Professional Degree (MD, DDS, DVM, LLB, JD, DD)
 - ____Doctoral degree (Ph.D, Ed.D, Au.D., SLP.D)
- 7. What is your (parent/guardian) occupation? (please specify)
- 8. What is your (parent/guardian) race/ethnicity? (optional)
 - _____White, Caucasian
 - ___Black, African American
 - Spanish, Hispanic, Latino
 - ____American Indian, Alaska Native
 - ____Asian
 - ____Other (please specify) _____
- 9. I primarily get my information about antibiotics from

 Doctors	
DI	

- ____Pharmacists
- ____Magazines Internet
- Television
- Other parents
- Other sources (*please specify*)

Figure 2.4 : Continued.

The fourth and fifth sections of the questionnaire (See Figures 2.4 and 2.5) offer open-ended, or free-response options, which allow the respondents to compose their own responses. The items in these sections are not time-consuming and do not require extensive responses.

Section 5

For each item below, please check ($\sqrt{}$) beside the response that most accurately describes your reaction to the statement.

1. Were the instructions for completing this questionnaire easy to follow?

____Yes

____ No

2. Were the questions on this questionnaire clear?

Yes

___ No

3. Do you think this questionnaire was too time-consuming?

___ Yes

____ No

4. Did you feel uncomfortable answering any of the questions included in this questionnaire? If yes, which please list them in the space provided.

____Yes

___ No

5. Would you be willing to complete future questionnaires?

____Yes

____ No

In the space below, please provide any comments or suggestions you may have about this questionnaire.

Figure 2.5: Parent/Guardian Questionnaire, Section 5.

Suskie 1992) suggested that open-ended questions are advantageous when many

answers are possible or when a multiple-choice question may overlook some important

responses. The free-response style is useful for pilot studies because the researcher will have a pool of responses to consider when revising the questionnaire for the larger study.

However, according to Suskie, open-ended questions are not popular with respondents because they require additional effort and take more time to complete. Often with free-response, respondents will leave the questions unanswered; thus defeating the purpose of the questionnaire.

This style was chosen for only three questions. There are two questions in Section 4 (# 2 and #3) of the questionnaire (See Figure 2.4) that require specific numerical answers. An open-ended question was also used at the end of the questionnaire, in Section 5 (See Figure 2.5). This question asks that the respondents provide comments or suggestions for the questionnaire, as well as identify their likes and dislikes about the questions and the format. The responses to this section will assist with making changes to the questionnaire to enhance its efficiency.

The next step in the development of the questionnaire was to create sufficient instructions for the completion of the questionnaire. Suskie suggested that the instructions (See Figure 2.6) be phrased in clear and simple terms so that the respondents will provide appropriate but honest responses. In addition, the instructions should indicate whether the respondents are to place a check mark or an X beside the appropriate answer or write their answer. Short instructions also help the respondents make sense of the questionnaire, make the questionnaire seem less chaotic, and help put the respondent in the proper frame of mind for answering the questions.

Along with the questions and instructions, the questionnaire should include additional components. Suskie and Bradburn et al. (2004) recommended including a title, identifying a sponsor, and providing a closing, and thank you on all surveys.

Section 1

For each statement below, please check ($\sqrt{}$) the box that most accurately reflects your (parent/guardian) level of agreement or disagreement.

Section 2

For each statement below, please check ($\sqrt{}$) the box that most accurately describes your (parent/guardian) actions.

Section 3

For each item below, please check ($\sqrt{}$) beside the response that most accurately describes your reaction to the statement.

Section 4

For the following questions, place a check ($\sqrt{}$) beside the responses that accurately describe you (parent/guardian), and provide specification when requested.

Section 5

For each item below, please check ($\sqrt{}$) beside the response that most accurately describes your reaction to the statement.

In the space below, please provide any comments or suggestions you may have about this questionnaire. For example, is the questionnaire too long? Is the wording of the instructions and items clear?

Figure 2.6: Parent/Guardian Questionnaire, Instructions for Sections 1-5.

Suskie (1992) reported that including the title and sponsor of the study on the questionnaire will help convince the respondents of the professionalism of the study and increase response rate. She also stated that the title informs the respondents of what is to come and can motivate them to complete the questionnaire. The title of the survey should be made as intriguing as possible to pique the respondents' interests without creating bias.

Suskie recommended identifying the sponsor of the study in order to give it credence and legitimacy. When the title and sponsor appear on the questionnaire, the respondents may be more likely to take it seriously.

This questionnaire has a header on the first page that lists the title of the questionnaire and the researcher's name and academically affiliated institution. The general title, *Parent/Guardian Questionnaire*, was chosen. Although this title may not immediately pique the interest of the respondents, prevention of research bias was more important. If the important terms, *ear infections, antibiotics,* or *parental views* had been used, there may have been some negative effect on the responses provided. These terms may even intimidate the respondents leading to a decision not to complete the questionnaire.

A self-administered survey also needs closing which, according to Suskie, will contain a repeat of the instructions for returning the questionnaire. The closing should also contain a *Thank You* message to the respondents. Bradburn et al. (2004) stressed that researchers are fortunate to find individuals who are willing to donate their time and energy to completing surveys and as such deserve a sincere *Thank You* at the end of the questionnaire.

On the final page of the questionnaire developed for this study, the instructions for returning the forms are repeated. A line thanking the respondents for their participation was also included.

Formatting the questionnaire was the next step in development. The format of a questionnaire determines how easy it is for respondents to read and understand the

questions and the kinds of answers required. Also, the format contributes to how easily the data can be organized, analyzed, and reported by the researcher.

Question placement, or order, should be taken in to consideration when formatting a questionnaire. Inappropriate placement of the questions could discourage respondents from completing the questionnaire. Bradburn et al. (2004) stated that questions should be ordered in a way that motivates the respondents to complete the questionnaire. They also suggested that the questions be ordered in such a way that holds the respondents' interests, and there should be some variety in the items used.

Bradburn and his colleagues offered much advice for the ordering of questions. They noted that people generally look at the first few questions before deciding whether to complete a questionnaire. If the first questions appear too threatening or "boring," the chances of respondents completing the survey will greatly decrease.

Bradburn et al. recommended leading with fact-based questions and then moving on to opinion-based questions. Bradburn and his colleagues suggested beginning with interesting and non-threatening questions that are easy to answer. Another recommendation from Bradburn et al was that the most important questions be placed at the beginning in case respondents do not complete the entire questionnaire. This will help ensure that the information most needed will be gathered even if the other questions go unanswered. However, in the event that some questions are not answered, the researcher would then have to determine how he or she will approach data analysis and whether incomplete questionnaire responses will be used for data analysis.

Suskie (1992) suggested that the first questions in a survey should be intriguing, impersonal, and relatively easy to answer and that demographic questions should not

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appear as the first questions. Suskie's suggestions mirrored those of Bradburn and his colleagues (2004). The remaining questions should then flow naturally and logically and questions about similar topics should be grouped as a way to keep the respondents focused on primary ideas (Suskie, 1992).

Suskie was of the opinion that the final questions on the instrument should be the ones the respondents may be the less enthusiastic about answering. Suskie provided the following suggestions for the kinds of questions that should be placed at the end of a questionnaire: delicate, intimate, or sensitive questions; complex questions that may take a long time to read or a lot of thought to answer; open-ended questions; and boring questions, including demographic items. The researcher would hope that by the time the respondents reached these kinds of questions, they would be engaged to the point that they would complete the questionnaire.

The beginning of this questionnaire (See Appendix A) began with knowledgebased questions which are followed by behavior-based questions. The opinion-based questions were placed in the middle of the questionnaire and the demographic items and open-ended question were used at the end of the instrument.

The numbering of the questions was another part of the questionnaire development. Bradburn et al. (2004) recommended numbering the questions on paper questionnaires and noted some advantages to doing so. First, numbering may alert respondents that a question has been skipped. Second, a small number of questions may suggest that the task will be simple and not require too much time. Finally, respondents can recognize that they are making progress and are close to being finished. An added

advantage is that having the questions numbered will help the researcher with data organization and analysis.

In the questionnaire designed for this study, each section received separate numbers as opposed to numbering the questions from start to finish. However, the openended questioning for Section 5 was not numbered. A number could suggest that this item is a "question" with the implication that there is a "right" or "wrong" answer. That is not the case and feedback about this questionnaire will be extremely beneficial for future research.

The appearance and layout of the questionnaire were examined during development, as well. As suggested by Bradburn and his colleagues (2004), the appearance of a questionnaire can have a great impact on the participation of the respondents. The questionnaire should look as simple as possible to the respondents. A less cluttered questionnaire with substantial white space appears easier to complete, and may result in fewer errors made by the respondent and the researcher.

It is also helpful to make the questionnaire appear as short as possible. Using as few pages as possible may contribute to the return rate. If a questionnaire is more than a couple of pages in length, respondents may be less likely to complete it. There are different views on whether to use the front and back of a page. Suskie (1992) suggested using both sides of a page to make the questionnaire look shorter. Bradburn et al. (2004), on the other hand, advised against using both sides because the respondent may easily overlook the back of a page.

This questionnaire uses only the front of each page and is four pages in length. Four pages was determined to be the minimal length in order to obtain information pertinent to the purpose of the study (See Appendix A).

Another suggestion offered by Bradburn et al., was that questions should not be placed in two columns in order to save space. This may be confusing to the respondents and can make data processing more difficult.

Some survey researchers may choose to place the response categories in a horizontal line in order to save space. However, Bradburn and his colleagues suggested that this may also confuse respondents and complicate data processing. Instead, they recommended placing the response categories vertically, leaving plenty of space between. This format will give the questionnaire a more open look with the appearance of an easier completion.

Bradburn and his colleagues also noted that single questions and their response categories should never be split between pages. If a question and its categories do not fit comfortably on a page, they should be moved to the next page. The space between the previous questions could then be increased.

The typeface can also have an impact on questionnaire readability and completion. Bradburn et al suggested that the type should be large enough and clear enough to eliminate strain in rapid reading for all respondents. Size 12-point type is typically recommended but 10-point type is also readable in most fonts.

Bradburn and his colleagues mentioned that the use of different print effects for different portions of the questionnaire may also be useful. In the questionnaire used for this study, bold face or italics were used for the instructions with the questions left in normal font. Hopefully, this will help the respondents more easily distinguish between directions and questions.

The use of good formatting techniques should provide an uncluttered appearance to the questionnaire. Also, the questionnaire will have a professional appearance lending to the credibility of the study which in turn will influence the seriousness with which respondents approach completion of the instrument. All of these suggestions were used in the development of this questionnaire (See Appendix A).

As a reminder for the importance of having a questionnaire that is neat and looks professional, Suskie (1992) suggested additional considerations for proofreading, duplication, and packaging of the instrument.

Before reproducing the questionnaire for distribution, the author must proofread. This very important step will identify spelling, typographical, and grammatical errors as well as formatting problems. Such mistakes, if not found, will detract from the neatness of the instrument, may create confusion for the respondents in their attempts to complete the questionnaire, and most certainly will not enhance the credibility of the study or the researcher.

When duplicating the questionnaire for distribution, the creator should choose quality materials and printing techniques. Professionally acceptable quality paper along with professional printing should be used.

Packaging is another important consideration for the researcher. A cover letter, informed consent forms, and a self-addressed return envelope should accompany the questionnaire. All these materials should be placed in one package or envelope for delivery and should be packaged in the order in which the respondent is to use the items.

The cover letter speaks in the absence of the researcher. Suskie emphasized that the cover letter says all the things the researcher would say in person to establish rapport with the respondents and to convince them to participate in the study. Suskie suggested that a cover letter should be developed so as to (a) highlight the importance of the study, (b) appeal to the respondents' self-interests, (c) communicate the professional nature of the study, (d) address the issues of confidentiality, and (e) be as personal as possible.

A cover letter to the respondents for this study is included in the questionnaire packet (See Appendix B), which introduces the researcher and briefly explains the study. It is stressed that the respondents' choice to participate will not affect their relationships with their physicians or the university, and their responses will remain confidential. Finally, instructions for completing and returning the questionnaire are provided. The cover letter also includes a telephone number in the event that a respondent wishes to contact the researcher directly.

Also, informed consent forms (see Appendix C) are included with this questionnaire packet. The forms briefly explain this study, emphasize confidentiality, and offer contact information. One form will be returned with the questionnaire and the other should be retained by the respondent.

After the questionnaire and accompanying forms are ready for reproduction and packaging, the survey will be initiated as a pilot study. Chapter 3 provides a discussion of the methods and procedures and data analysis to be used in the pilot study.

CHAPTER 3

METHODS, PROCEDURES,

AND DATA ANALYSIS

Antibiotic resistance has been called one of the world's most pressing public health problems, and nearly all significant bacterial infections are becoming resistant to the most commonly prescribed antibiotic treatments. Treatment of otitis media requires approximately 10 million antibiotic prescriptions each year, 85 to 95% of which are not necessary (Woo, 2005). Woo maintained that the repeated or improper use of antibiotics is the primary cause of increased antibiotic resistance.

Although physicians provide antibiotic prescriptions, parents may also contribute to the growing problem of antibiotic resistance. Parental pressure on physicians for antibiotics, as well as parental actions after receiving the prescription, can increase the likelihood of resistance. Parental understanding of infections, e.g., otitis media, and antibiotic resistance is a key factor in resolving this growing problem.

Before healthcare professionals can develop educational programs to increase understanding, efforts must be made to determine what parents know about ear infections and antibiotic resistance and what, if any, misconceptions they may have. The purpose of

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this capstone project is to gather information about parents' level of knowledge of antibiotic use and its association with otitis media. The instrument of data collection will be a questionnaire specifically designed for purposes of this study.

The development of the questionnaire to be used was described in Chapter 2 of this dissertation. Chapter 3 is a conceptualization of the use of this questionnaire in a pilot study with parents/guardians of young children to investigate their knowledge and opinions of the use of antibiotics for the treatment of Otitis media.

Chapter 3 will identify the research design, describe the subjects and the nature of their participation, and the use of the instrumentation and procedures for data collection. The plan for data analysis data will also be addressed.

Research Design

This study is a form of descriptive research whose purpose is to describe the characteristics of a particular population in some chosen area. Survey research methodology is one of the best methods for gathering original data about a large population. Survey research methodology can use questionnaires, interviews, or a combined questionnaire-interview. For this study, a questionnaire will be developed and dispersed to collect the desired information from a sample of the population of interest.

This research project is meant to be a pilot study and along with collecting data about the sample population, it will examine the effectiveness of the questionnaire used for data collection. The information can be used at a later time for collecting data from a larger population and/or developing educational programs for parents concerning antibiotic treatment and resistance.

Study Participants

Primary Investigator

The primary investigator for this study is a fourth-year audiology doctoral student at Louisiana Tech University, in Ruston, Louisiana. The primary investigator has completed all the academic coursework for the clinical doctoral program in audiology, including Introduction to Research, Hearing Disorders, Anatomy and Physiology of the Hearing Mechanism, Auditory Processing Disorders, Pediatric Audiology, Differential Audiology, Physiological Tests of Auditory Function, Amplification, Vestibular System Disorders, and Rehabilitative Audiology.

Fourteen quarters of supervised clinical practicum have been completed. Four quarters of supervised clinical practicum took place at the Louisiana Tech Speech and Hearing Center, and 11 quarters were in external facilities. Lynne Raney Audiology, a private practice in El Dorado, Arkansas served as an external facility for two quarters. Facilities/Agencies in Louisiana were Overton Brooks VA Medical Center, Louisiana State University Health Sciences Center, Green Clinic, and The Ear, Nose, and Throat Center. A fourth year clinical residency was completed at the Arkansas Otolaryngology Center in Little Rock, Arkansas.

The external facilities provided a population of patients who ranged in age from birth to geriatric. The practicum sites offered a variety of experiences in diagnostic and rehabilitative audiology as well as hearing instruments. The student was required to perform diagnostic tests including pure tone audiometry, speech audiometry, behavioral observation audiometry (BOA), visual-reinforcement audiometry (VRA), play audiometry, impedance testing, acoustic reflex decay, otoacoustic emissions (OAEs), auditory brainstem response (ABR) testing, auditory processing tests, posturography, and electronystagmography (ENG).

The student provided aural rehabilitation for children with auditory processing disorders and adults with cochlear implants. Hearing aid evaluation and counseling practicum was also required along with hearing aid modifications and repairs.

Subjects

The subjects for this study will be chosen based on one inclusion criterion. The subjects must be parents or guardians of children two to five years of age. There are no exclusion criteria for participation in this study other than the age of the children. Because this is a pilot study and there is no requirement for sample size, the subjects will be selected using nonrandom, convenience sampling. For this type of sampling, subjects are chosen nonrandomly on the basis of availability. Participation in this study is voluntary.

A sample size of at least 200 subjects, or a response rate of at least 60% of the sample population, is a common suggestion for survey research (Elmes, Kantowitz, & Roediger, 2003). However, this is a pilot study, and a smaller sample size will be sufficient. The investigator's goal for this study is to obtain as many completed questionnaires as possible over a two-month time period.

The sample population will include parents and guardians of children two to five years of age who visit the South Arkansas Otolaryngology medical practice located in El Dorado, Arkansas. There is one doctor of otolaryngology and one doctor of audiology who serve the patients at the facility neither of whom will participate in the study. The physician who owns the clinic will be asked, via letter, for permission to use the facility for data collection (Appendix D). He will be asked to sign the letter if he agrees to allow data collection in his practice.

South Arkansas Otolaryngology is the primary ear, nose, and throat center in southern Arkansas. Therefore the population being served is as diverse as southern Arkansas itself. Patients who visit the clinic come from all areas of southern Arkansas and north central Louisiana. Approximately 20 patients visit the clinic each day, and they range in age from infancy to geriatric.

A sign (Appendix E) will be posted for all patients to see when entering the clinic. Both first-time patients and established patients will be free to participate. The potential subjects (i.e., those who are parents/guardians of children ages 2 to 5 years) will determine whether or not they would like to participate in this study. After determining whether they meet the inclusion criterion, parents may choose to participate in the study by completing the questionnaire that has been developed. Questionnaire packets will be readily available to eligible parents/guardians.

The packets will contain a cover letter (Appendix B) explaining the study and the instructions, two informed consent forms (Appendix C), and a questionnaire (Appendix A), and a sharpened pencil. The packet will be given to the subjects in a letter-sized manila envelope.

Informed consent must be obtained before the information on the questionnaire can be used for the study. The subjects will be asked to complete one informed consent form and along with the questionnaire and place the manila envelope in a secured box before leaving the facility. The subjects will be instructed to keep the other informed consent form.

Instrumentation

The instrumentation for this pilot study will be a questionnaire (Appendix A) developed by the primary investigator. The goal of this questionnaire will be twofold. The first goal is to gather information about parental knowledge of ear infections and antibiotic treatment. The second goal is to evaluate the effectiveness of the questionnaire as the instrument of data collection for the study. The steps taken to develop the questionnaire were discussed in Chapter 2 of this dissertation document.

The questionnaire has five sections. Each section will elicit a different type of information and will provide a different response mode. Because this is a pilot study, varying response modes may be useful in revealing inconsistencies across the population being surveyed. This information can be used to develop a more effective questionnaire at a later time. Subjects will also have the opportunity to provide feedback as to which response modes they prefer.

Section 1 has seven knowledge-measuring statements designed to gather information about the subjects' knowledge of ear infections and antibiotics. A Likert rating scale will be used for responses in this section. Subjects are instructed to place a check ($\sqrt{}$) in the box that most accurately reflects their agreement with each statement. The 4-point scale will offer the options "Strongly Disagree," "Disagree," "Agree," and "Strongly Agree." Section 2 pertains to the subjects' practices in response to the use of antibiotics. There are eight statements that measure frequency of behaviors during the time at which the child is being treated with antibiotics in this section. As in Section 1, a 4-point Likert scale will be used for responses. The subjects are instructed to place a check ($\sqrt{}$) in the box that most accurately describes the frequency with which they exhibit each behavior. The rating options are "Never," "Rarely," "Sometimes," and "Always."

Section 3 elicits opinion-based responses and has six items. The statements are meant to obtain the subjects' opinions regarding certain physician behaviors. These statements use a Yes/No response format. The subjects are asked to place a check ($\sqrt{}$) on the line beside the response that most accurately describes their reactions to each statement.

Section 4 gathers demographic information about the subjects. There are 10 items in this section. The information targeted includes subject characteristics such as gender, age, and educational level. Two response modes are used in Section 4. Questions 1, 4, 5, 6, 8, and 9 require that the subjects place a check ($\sqrt{}$) beside the response that accurately describes them. Questions 2, 3, and 7 ask that the subjects write their responses in the space provided. The question regarding race/ethnicity is optional because it may cause discomfort and subjects may choose not to respond.

The fifth and final section asks the subjects to provide feedback about the questionnaire instrument. There are five *Yes/No* questions about the questionnaire, as well as an open-ended question that asks the respondents to comment or give suggestions. The subjects are encouraged to note what they like and dislike about the format of the questionnaire.

The first two sections of the questionnaire will be formatted as tables. The first two columns identify the number of the statement and provide the statements, respectively; the final four columns contain the response choices. The table in Section 1 has of six rows and Section 2 has nine rows. The rationale for using tables is to give the questionnaire a shorter appearance and to facilitate ease in responding.

Sections 3, 4 and 5 are formatted so there is only question per line and the response choices are listed vertically. This design will reduce confusion for the subjects responding to the questionnaire items and the investigator analyzing it. In addition, the format reduces the risk of the respondent overlooking questions and response choices. A vertical format also gives the questionnaire a more open look with more blank space; thus, it appears easier to complete (Bradburn et al., 2004). Finally, the fifth section of the questionnaire has a short-answer format, for which approximately six inches of blank space is provided for responses.

The survey will have a header as a title for the questionnaire, primary investigator's name, and the university name. The final draft of the pilot questionnaire will be four pages in length and will be printed on high-quality, $8 \frac{1}{2} \times 11$ -inch white paper. The pages will be printed on one side only to reduce the risk of overlooked pages; the pages will be stapled in the top left corner before being placed in a letter-sized manila envelope.

The questionnaire has been pre-coded (Appendix F) to assist with data analysis. Each response option has an assigned number. For example, the response "Strongly Disagree" has been assigned the number 1, and "Strongly Agree" has been assigned the number 4. The lowest number represents the least amount of agreement, and the highest number represents the greatest amount of agreement. These numbers will be used for data entry prior to analysis. The short answer, or hand-written, responses will be manually entered into the analysis program by the primary investigator.

Procedures

South Arkansas Otolaryngology will have to grant permission to use its facility and patients for the study. A physician consent letter (Appendix D) will be presented to the owner of the clinic. He will be asked to sign the letter if he wishes to allow his facility be used for data collection. After receiving approval from all of the required individuals, the primary investigator will begin the process of data collection.

The first task to be completed is to prepare and assemble the questionnaire packets that will be distributed to the accessible population. The informed consent forms and questionnaires will be printed on high-quality, $8 \frac{1}{2} \times 11$ -inch white paper, and all five pages will be stapled in the top left corner. Each set will be assigned a number that will be used for data analysis. The number will be hand-written in the upper left-hand corner of back of each page of the packet, and will allow for better organization of the data for analysis. The number will serve as verification that informed consent was granted and will become the subject identification number after the forms are separated. The separation of the forms is necessary to ensure confidentiality. After combining the forms and assigning each set a number, the forms will be placed in a letter-sized manila envelope, along with a sharpened pencil. The envelope will also receive the same number as its contents.

Each assembled packet will have two informed consent forms, one questionnaire, and one sharpened pencil. Initially, a total of 50 questionnaire packets will be assembled

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ready for immediate distribution. Additional packets will be compiled as needed. The packets will be placed in a basket in the waiting area, along with the posted sign, at South Arkansas Otolaryngology.

Parents and guardians of children between the ages of two and five years will be invited to participate in the study by a sign (Appendix E) posted in a highly visible location the waiting area of the clinic. The sign (Appendix E) will offer instructions for completion as will as express appreciation for parent/guardian participation. If the parents/guardians would like to participate, they can pick up one of the pre-assembled questionnaire packets, complete each page, and replace the forms in the manila envelope.

The subjects will be instructed to complete and return the questionnaire packet to the secured box located beside the pick-up basket before leaving the clinic. The subjects should follow the instructions provided for completing the informed consent and the fourpage questionnaire. Before beginning the questionnaire, the subjects will be instructed to read and sign the first informed consent form and keep the second for their records. The questionnaire contains instructions for completing each of the five sections.

The first three sections ask that the subjects place check marks ($\sqrt{}$) beside the most appropriate response, and the fourth section asks them to check ($\sqrt{}$) their responses when necessary and/or write in their responses in the spaces provided. The fifth and final section asks that the subjects write their answers in the space provided. Subjects should have enough time to complete the questionnaire packet during their waiting periods at the clinic.

The subjects will be asked to return the completed forms to the manila envelope, seal it, and return the packet to the designated secured box. After the packets have been

returned, they will be placed in a secure file box in the investigators' office so that the information provided by the subjects will remain confidential. Once the packets have been placed in the secure file box, only the primary investigator will have access to them.

The completed questionnaire packets will be transported in the secure file box from South Arkansas Otolaryngology to Louisiana Tech University, where they will be stored in the office of the dissertation director. The secured packets will be unsealed and the data analyzed by the primary investigator.

Before data analysis of a questionnaire can occur, the primary investigator must verify that the subject completed the attached informed consent form. The assigned numbers located on the back upper left-hand corner of each page will be used for recording the receipt of informed consent and the data from the survey. This information will be logged into a pre-formatted Microsoft Excel spreadsheet. The informed consent forms will then be placed into a second secured file box that will remain in the dissertation director's office at the university. The completed forms will remain at the university for no less than three years after which time they will be destroyed by shredding.

After verifying that informed consent has been obtained, the data from the questionnaire can be coded and entered into the spreadsheet. The questionnaire will be pre-coded by the primary investigator prior to being dispensed. Each response option was assigned a number to make data analysis less complicated. The number corresponding to each response will be entered into the appropriate cell on the spreadsheet, and all hand-written responses will be manually entered, as well. The data-

logging process will be repeated for each completed questionnaire packet. When all of the data have been collected, coded and recorded, analysis can begin.

<u>Data Analysis</u>

The data analysis for this study will be completed with Microsoft Excel, which is a spreadsheet-based program capable of performing basic statistical calculations. A spreadsheet will be set-up for entering data obtained from the questionnaires. The first column of the spreadsheet will contain the subjects' identification numbers, which will be written on the questionnaire packets prior to dispensing. The second column will be use to note that informed consent was obtained. The rest of the remaining columns will be used to log the subjects' responses to the questionnaire items. These columns will be named based on the section and question number. For example, the column for the first question in Section 1 will be named "1Quest1." Question 2 in Section 1 will be named "1Quest2," and so on. The pre-coding numbers assigned to the response options will be used for data entry.

This study uses a descriptive research design and descriptive statistical analysis will be used. After all of the data have been recorded in Microsoft Excel, the responses will be analyzed. Measures of central tendency (mean, median, and mode) will be calculated along with frequency distributions. The data will be analyzed for the respondents as a group and the responses will also be compared based on the demographics of subjects. For instance, the measures of central tendency can be used to compare how male subjects responded compared to female subjects. The same can be done to compare different age groups, educational levels, etc.

Conclusions

After the data have been analyzed, conclusions can be drawn from the results. The primary investigator can examine the data to determine if the goals of the study were achieved. Three specific questions may be answered: Is the instrument an effective tool for collecting the desired information? Does the information provided by the respondents give healthcare professionals insight about parents' knowledge, behaviors, and opinions associated with antibiotic treatment? The investigator can also determine how the information collected from this study may be used for future research. APPENDICES

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APPENDIX A

PARENT/GUARDIAN QUESTIONNAIRE

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Parent/Guardian Questionnaire Courtney L. Ross, Primary Investigator Louisiana Tech University

Time Started:	
Date:	

Section 1

For each statement below, please check ($\sqrt{}$) the box that most accurately reflects your (parent/guardian) level of agreement or disagreement.

		Strongly Disagree	Disagree	Agree	Strongly Agree
1.	Ear infections can cause hearing loss.				
2.	Any type of antibiotic would be appropriate for treating an ear infection.				
3.	Ear infections should always be treated with an antibiotic.				
4.	Some ear infections can resolve without antibiotic treatment.				
5.	No long-term physical effects result from overuse of antibiotics.				
6.	Only certain types of antibiotics work for treating ear infections.				
7.	Over time the human body may begin to resist antibiotics.				

Section 2

For each statement below, please check ($\sqrt{}$) the box that most accurately describes your (parent/guardian) actions.

		Never	Rarely	Sometimes	Always
1.	I stay on schedule for antibiotic dosage prescribed for my child.				
2.	I use one antibiotic to treat all of my children.				
3.	I give my child the full prescription of antibiotics.				
4.	When my child misses a dose of antibiotics, I give him/her two doses at the next scheduled time.				
5.	I save leftover antibiotics for future use.				
6.	I stop giving my child the antibiotic prescription when he/she feels better.				
7.	I request an antibiotic prescription for my child when one is not offered by the doctor.				
8.	My child's doctor prescribes antibiotics over the phone, without an examination.				

Section 3

For each item below, please check ($\sqrt{}$) beside the response that most accurately describes your reaction to the statement.

1. Has your child been diagnosed with an ear infection for which he/she has received an antibiotic prescription?

____Yes ____No

2. My child has received the same antibiotic more than once.

____Yes ____No

3. I am satisfied when the doctor does not provide an antibiotic prescription.

4. The doctor's explanation of his/her diagnosis is helpful for understanding my child's ear infection.



5. The doctor should provide an antibiotic prescription for my child on each visit.

____Yes ____No

6. The doctor should provide more information about his/her diagnosis.

Section 4

For the following questions, place a check ($\sqrt{}$) beside the responses that accurately describe you (parent/guardian), and provide specification when requested.

1. What is your (parent/guardian) gender?

___Male ___Female

- 2. What is your (parent/guardian) current age? (please specify)
- 3. How many children between 2 and 5 years of age are currently under your (parent/guardian) care?

(please specify)_____

4. What is your (parent/guardian) relationship to the children for whom you are providing care?

Father	
Mother	
Grandfather	
Grandmother	
Brother	
Sister	
Uncle	
Aunt	
Foster Parent	

- Other (please specify) _____
- 5. What is your (parent/guardian) marital status?
 - Now married
 - _____Widowed
 - ____Divorced
 - ____Separated
 - ____Never married
- 6. What is the highest level of education you (parent/guardian) completed?
 - Elementary school Junior high/middle school High school GED Associate degree Bachelor's degree Master's Degree Professional Degree (MD, DDS, DVM, LLB, JD, DD) Doctoral degree (Ph.D, Ed.D, Au.D., SLP.D)
- 7. What is your (parent/guardian) occupation? (please specify)
- 8. What is your (parent/guardian) race/ethnicity? (optional)
 - ___White, Caucasian
 - ____Black, African American
 - _____Spanish, Hispanic, Latino
 - ____American Indian, Alaska Native
 - ____Asian
 - ____Other (please specify) _____
- 9. I primarily get my information about antibiotics from
 - ____Doctors
 - ____Pharmacists
 - ____Magazines
 - ____Internet
 - _____Television
 - ____Other parents
 - Other sources (please specify)

Section 5

For each item below, please check ($\sqrt{}$) beside the response that most accurately describes your reaction to the statement.

1. Were the instructions for completing this questionnaire easy to follow?

____Yes

____ No

2. Were the questions on this questionnaire clear?

____Yes

____No

3. Do you think this questionnaire was too time-consuming?

____Yes

____No

4. Did you feel uncomfortable answering any of the questions included in this questionnaire? If yes, which please list them in the space provided.

____Yes

____ No

5. Would you be willing to complete future questionnaires?

____Yes

____ No

In the space below, please provide any comments or suggestions you may have about this questionnaire. For example, is the questionnaire too long? Is the wording of the instructions and items clear?

Time Completed: ______ Date: _____

> Before returning the completed forms, please place them in the envelope provided and seal it. Thank you for your participation.

APPENDIX B

QUESTIONNAIRE COVER LETTER

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Courtney L. Ross, B.A. Louisiana Tech University Department of Speech (318) 257-4764

March 31, 2006

Dear Parent or Guardian,

My name is Courtney Ross, and I am a 3^{rd} Year Doctor of Audiology student at Louisiana Tech University. As a part of my requirement for graduation, I am required to complete a dissertation. In order to fulfill my doctoral degree requirements, I am conducting a research study centered around children 2 to 5 years of age. I have developed a questionnaire to be completed by parents/guardians of children in this age range.

Please understand that your participation will in no way affect your relationship with your physician or Louisiana Tech University. If you choose not to participate, you will not be penalized in any way. Your physician will not have access to your questionnaire, and your information will remain confidential.

Please complete the informed consent located on the first page of the packet, and keep the marked page for your records. Please answer each question and return the completed packet in the envelope provided before seeing the physician. Thank you for your time and cooperation.

Sincerely,

Courtney L. Ross, B.A. Audiology Doctoral Student Louisiana Tech University

APPENDIX C

INFORMED CONSENT FORMS

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HUMAN SUBJECTS CONSENT FORM

The following is a brief summary of the project in which you are asked to participate. Please read this information before signing the statement below.

TITLE OF PROJECT: Parental Understanding of Antibiotic Resistance in Relation to Otitis Media

PURPOSE OF STUDY/PROJECT: To gather information about parents'/guardians' level of knowledge regarding antibiotic use and its association with otitis media.

PROCEDURE: Parents/guardians will complete a questionnaire, on a voluntary basis, that will be dispersed at South Arkansas Otolaryngology Center. Completed questionnaires will be placed in an envelope, be sealed, and returned to the receptionist or the primary investigator to be stored in a secured file box.

INSTRUMENTS: This study will use a questionnaire developed by the primary investigator to gather relevant data.

RISKS/ALTERNATIVE TREATMENTS: There are no risks involved in the study.

BENEFITS/COMPENSATION: No compensation is given to the participants for completing the questionnaire.

I, ______, attest with my signature that I have <u>read and understood the following</u> <u>description of the study</u>, "Parental Views of Otitis Media and Antibiotic Treatment", and its purposes and methods. I understand that my participation in this research is strictly voluntary and <u>my participation or refusal to participate in this study will not affect my relationship with</u> <u>Louisiana Tech University</u>. Further, I understand that I may withdraw at any time or refuse to answer any questions without penalty. Upon completion of the study, I understand that the results will be freely available to me upon request. I understand that the results of my survey will be <u>confidential</u>, accessible only to the principal investigators, myself, or a legally appointed representative. I have not been requested to waive nor do I waive any of my rights related to participating in this study.

Signature of Participant or Guardian

Date

CONTACT INFORMATION: The principal experimenter listed below may be reached to answer questions about the research, subjects' rights, or related matters.

Courtney L. Ross, B.A. (318) 257-4764

Members of the Human Use Committee of Louisiana Tech University may also be contacted if a problem cannot be discussed with the experimenter:

Dr. Les Guice (318) 257-3056 Dr. Mary M. Livingston (318) 257-2292

(Please return this form to the envelope provided.)

HUMAN SUBJECTS CONSENT FORM

The following is a brief summary of the project in which you are asked to participate. Please read this information before signing the statement below.

TITLE OF PROJECT: Parental Understanding of Antibiotic Resistance in Relation to Otitis Media

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PROCEDURE: Parents/guardians will complete a questionnaire, on a voluntary basis, that will be dispensed at South Arkansas Otolaryngology Center. Completed questionnaires will be placed in an envelope, be sealed, and returned to primary investigator to be stored in a secured file box.

INSTRUMENTS: This study will use a questionnaire developed by the primary investigator to gather relevant data.

RISKS/ALTERNATIVE TREATMENTS: There are no risks involved in the study.

BENEFITS/COMPENSATION: No compensation is given to the participants for completing the questionnaire.

I, ______, attest with my signature that I have <u>read and understood the following</u> <u>description of the study</u>, "<u>Parental Views of Otitis Media and Antibiotic Treatment</u>", and its purposes and methods. I understand that my participation in this research is strictly voluntary and <u>my participation or refusal to participate in this study will not affect my relationship with</u> <u>Louisiana Tech University</u>. Further, I understand that I may withdraw at any time or refuse to answer any questions without penalty. Upon completion of the study, I understand that the results will be freely available to me upon request. I understand that the results of my survey will be <u>confidential</u>, accessible only to the principal investigators, myself, or a legally appointed representative. I have not been requested to waive nor do I waive any of my rights related to participating in this study.

Signature of Participant or Guardian

Date

CONTACT INFORMATION: The principal experimenter listed below may be reached to answer questions about the research, subjects' rights, or related matters.

Courtney L. Ross, B.A. (318) 257-4764

Members of the Human Use Committee of Louisiana Tech University may also be contacted if a problem cannot be discussed with the experimenter:

Dr. Les Guice (318) 257-3056 Dr. Mary M. Livingston (318) 257-2292

(Please keep this copy for your records.)

APPENDIX D

PHYSICIAN CONSENT LETTER

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Courtney L. Ross, B.A. Louisiana Tech University Department of Speech (318) 257-4764

March 31, 2006

South Arkansas Otolaryngology Center 613 Thompson Street El Dorado, AR 71730

Dear South Arkansas Otolaryngology Center,

As a part of my requirement for graduation, I am required to complete a dissertation. In order to fulfill my doctoral degree requirements, I am conducting a research study centered around children 2 to 5 years of age. I have developed a questionnaire to be completed by parents/guardians of children in this age range. The questionnaire is related to antibiotic use, antibiotic resistance, and otitis media.

I am requesting permission to administer my questionnaire to parents/guardians who visit your office. With your permission, the questionnaire packets will be placed at the checkin area, along with a sign asking the parents/guardians to participate in my study. The participants will be asked to complete the questionnaire packets and return them to the designated drop-box, which will remain secure in order to protect the participants' personal information. The personal information collected using the questionnaire will be used for the purpose of my study, and will only be available to my dissertation director, Sheryl Shoemaker, Au.D., and myself.

Your decision to grant permission for the use of your facility will in no way affect your relationship with Louisiana Tech University. Please feel free to contact my dissertation director or me with any questions or concerns you may have regarding this study. I appreciate your time and consideration.

Sincerely,

Courtney L. Ross, B.A. Audiology Doctoral Student Louisiana Tech University

APPENDIX E

PARTICIPATION SIGN

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ATTENTION

PARENTS AND GUARDIANS OF CHILDREN 2 TO 5 YEARS OF AGE

Please take and complete a questionnaire packet.

Please return the packet to the drop-box when you are finished.

The information you provide will be used as part of my doctoral dissertation and will not be shared.

Thank you for your time and cooperation!

Courtney L. Ross, B.A. Audiology Doctoral Student

Louisiana Tech University 318-257-4764

APPENDIX F

PRECODED QUESTIONNAIRE

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Parent/Guardian Questionnaire

PRECODING

Time Started:	
Date:	

Section 1

For each statement below, please check ($\sqrt{}$) the box that most accurately reflects your (parent/guardian) level of agreement or disagreement.

		Strongly Disagree	Disagree	Agree	Strongly Agree
1.	Ear infections can cause hearing loss.	1	2	3	4
2.	Any type of antibiotic would be appropriate for treating an ear infection.	1	2	3	4
3.	Ear infections should always be treated with an antibiotic.	1	2	3	4
4.	Some ear infections can resolve without antibiotic treatment.	1	2	3	4
5.	No long-term physical effects result from overuse of antibiotics.	1	2	3	4
6.	Only certain types of antibiotics work for treating ear infections.	1	2	3	4
7.	Over time the human body may begin to resist antibiotics.	1	2	3	4

Section 2

For each statement below, please check ($\sqrt{}$) the box that most accurately describes your (parent/guardian) actions.

		Never	Rarely	Sometimes	Always
1.	I stay on schedule for antibiotic dosage prescribed for my child.	1	2	3	4
2.	I use one antibiotic to treat all of my children.	1	2	3	4
3.	I give my child the full prescription of antibiotics.	1	2	3	4
4.	When my child misses a dose of antibiotics, I give him/her two doses at the next scheduled time.	1	2	3	4
5.	I save leftover antibiotics for future use.	1	2	3	4
6.	I stop giving my child the antibiotic prescription when he/she feels better.	1	2	3	4
7.	I request an antibiotic prescription for my child when one is not offered by the doctor.	1	2	3	4
8.	My child's doctor prescribes antibiotics over the phone, without an examination.	1	2	3	4

Section 3

For each item below, please check ($\sqrt{}$) beside the response that most accurately describes your reaction to the statement.

- 1. Has your child been diagnosed with an ear infection for which he/she has received an antibiotic prescription?
 - <u>1</u>Yes <u>2</u>No
- 2. My child has received the same antibiotic more than once.

3. I am satisfied when the doctor does not provide an antibiotic prescription.

 $\underline{1}$ Yes $\underline{2}$ No

- The doctor's explanation of his/her diagnosis is helpful for understanding my child's ear infection.
 <u>1</u> Yes
 <u>2</u> No
- 5. The doctor should provide an antibiotic prescription for my child on each visit.
 - <u> 1 Yes</u> <u> 2 </u>No
 - 6. The doctor should provide more information about his/her diagnosis.

<u>1</u>Yes <u>2</u>No

Section 4

For the following questions, place a check ($\sqrt{}$) beside the responses that accurately describe you (parent/guardian), and provide specification when requested.

1. What is your (parent/guardian) gender?

```
\underline{1} Male
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- <u>2</u>Female
- 2. What is your (parent/guardian) current age? (please specify) <u>Manually enter data</u>
- 3. How many children between 2 and 5 years of age are currently under your (parent/guardian) care?

(please specify) <u>Manually enter data</u>

- 4. What is your (parent/guardian) relationship to the children for which you are providing care? <u>1</u> Father/Mother
 - 2 Grandfather/Grandmother
 - 3 Brother/Sister
 - <u>4</u> Uncle/Aunt
 - <u>5</u> Foster Parent
 - 6 Other (please specify) Manually enter data

- 5. What is your (parent/guardian) marital status?
 - _1_Now married
 - <u>2</u>Widowed
 - <u>3</u>Divorced
 - <u>4</u>Separated
 - _5_Never married
- 6. What is the highest level of education you (parent/guardian) have completed?
 - _1_Elementary school
 - 2 Junior high/middle school
 - <u>3</u>High school/GED
 - <u>4</u>Associate degree
 - <u>5</u>Bachelor's degree
 - 6_Master's Degree
 - ___7_Professional Degree (MD, DDS, DVM, LLB, JD, DD)
 - 8_Doctorate degree (Ph.D, Ed.D, Au.D., SLP.D)
- 8. What is your (parent/guardian) occupation? (please specify) Manually enter data
- 9. What is your (parent/guardian) race/ethnicity? (optional)
 - _1_White, Caucasian
 - 2 Black, African American
 - <u>3</u> Spanish, Hispanic, Latino
 - 4 American Indian, Alaska Native
 - ____5_Asian
 - 6 Other (please specify) Manually enter data
- 10. I get my information about antibiotics from:
 - __1_Doctors
 - _2_Pharmacists
 - <u>3</u> Magazines
 - _4_Television
 - <u>5</u>Other parents
 - __6_Other sources (please specify) Manually enter data

Section 5

For each item below, please check ($\sqrt{}$) beside the response that most accurately describes your reaction to the statement.

1. Were the instructions for completing this questionnaire easy to follow?

- <u>2</u>No
- 2. Were the questions on this questionnaire clear?
- <u>1</u>Yes <u>2</u>No

3. Do you think this questionnaire was too time-consuming?

<u>1</u>Yes

<u>___</u>_No

4. Did you feel uncomfortable answering any of the questions included in this questionnaire? If yes, which please list them in the space provided. <u>1</u> Yes

<u>2</u> No

5. Would you be willing to complete future questionnaires?

- <u>1</u>Yes
- <u>___</u>No

In the space below, please provide any comments or suggestions you may have about this questionnaire. For example, is the questionnaire too long? Is the wording of the instructions and items clear?

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