CRITICAL PATHWAY FOR ACUTE OTITIS MEDIA IN INFANTS AND CHILDREN (AGES 6-36 MONTHS)

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ABSTRACT

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Otitis media is one of the most common pediatric diseases. Approximately 7 out of 10 children are afflicted and this includes children from all races, ages and social groups (Bonadio, 1994). Acute otitis media (AOM) is the most common specific diagnosis made by clinicians treating youngsters in primary care family practices and pediatric settings. The highest incidence of disease occurs between the ages of 6 to 36 months (Bonadio, 1994). Complications of acute otitis media and its sequelae often affect the child years beyond the original infection in the form of learning and speech disabilities and hearing deficits.

There is a need for consistent, holistic, low cost and effective treatment of acute otitis media in the primary care setting to treat the initial disease, establish continuity with follow up and decrease the incidence of morbidity related to chronic otitis media. The purpose of this project is to develop a logical, research-based pathway for practitioners working in primary care for infant and toddler-aged patients presenting with uncomplicated episodes of acute otitis media.

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INTRODUCTION

Acute otitis media is of great importance to the primary care provider because of the huge numbers of children the disease affects and complications from the disease itself. Acute otitis media (AOM) is one of the most common diseases of early childhood. According to Brook (1994), two thirds of children in the United States experience at least one episode of AOM by their second birthday, and one in seven have recurrent infection with more than six episodes by that age. Newton (1995), presented data from a United States research study which showed that acute otitis media was responsible for one-third of the total urgent pediatric visits to primary care centers. More than 50% of children will have experienced an episode of AOM before they reach their first birthday. In 1990, there were a reported 24.5 million visits to physicians and practitioners for the treatment of AOM (Klein, 1994).

Health care costs related to the treatment of acute otitis media range anywhere from 1-3 billion health care dollars annually (Bonadio, 1993; Facione, 1990). Approximately one-fourth of all medications prescribed are for the treatment of acute otitis media in children. The most common surgical procedure in children requiring the use of general anesthesia in the United States today is myringotomy with insertion of tympanotomy tubes. Based on

1990 statistics, there were approximately 1 million children undergoing this procedure which is equivalent to one is seven children. This procedure is performed most often for frequent AOM and chronic middle ear effusion and it ventilates the middle ear and allows for drainage (Facione, 1990; Klein, 1994).

Otitis media, left uncontrolled without consistent clinical management, can significantly decrease the quality of life for the children it affects. The disease in its acute phase is most often painful affecting sleep patterns and appetite (Facione, 1990). Long-term complications include significant hearing loss, impaired cognitive development and learning disabilities. Specific complications will be discussed later in this discussion.

Definitions

Acute Otitis Media: Acute otitis media is an inflammation with purulent infection of the middle ear cleft: characteristically lasts up to three weeks but usually only a few days. The tympanic membrane is reddened, bulges and usually has prominent myringial vessels. An effusion forms in the middle ear and the drum will become more opaque. There will also be poor mobility of drum when examined by pneumatic otoscopy. Symptoms include: Pain (otalgia), fever (pyrexia) and drainage (otorrhea).

Myringotomy with tympanotomy tubes: Myringotomy is the surgical puncture of the tympanic membrane for removal of

fluid from the middle ear with the insertion of tympanotomy tubes for long-term drainage of the middle ear.

Pneumatic Otoscopy: Pneumatic otoscopy is an otoscope with a bulb attached to illicit a puff of air to assess tympanic membrane mobility.

Tympanometry: Tympanometry is a procedure that assesses the condition of the middle ear. It measures how well the tympanic membrane functions.

Project Objectives

The purpose of this project is to develop a critical pathway for the nurse practitioner in a primary care setting utilizing the background, demographics, pathophysiology and microbiology of acute otitis media. Statistics have shown that the nurse practitioner or Advanced Practice Nurse (APN) will see and treat many cases of acute otitis media in small children especially between the ages of 6 to 36 months (Bonadio, 1994; Facione, 1990; Hathaway, Katz, Dershwitz, & Marx, 1994). The prevalence of acute otitis media and its morbidity, sequelae and its possible long-term complications compounds the importance of a proper and consistent treatment protocol for the primary care provider. Following a treatment protocol should result in improved outcomes and resolution of the chronicity of otitis media.

The specific goal of this project is to develop a critical pathway for the primary care advanced practice nurse to follow when treating uncomplicated episodes of acute otitis media in infants and toddlers, age 6 to 36

months. The pathway will include critical assessment information, history and physical, treatment guidelines, educational components, evaluation, expected outcomes and follow up for the next visit. The pathway will be focused and precise and will be able to be followed within a 15-minute visit. The pathway will also include attention to referral to physicians and/or specialists.

The pathway will be based on an extensive literature search, where common components will be isolated and substantiated by research. This information will then be condensed into a logical pathway for the nurse practitioner in primary care.

The pathway will be based on the theoretical framework of the Scope of Practice of the Advance Practice Nurse. The dimensions of the scope of practice for the APN will be operationalized as actions within the critical pathway.

Conceptual Framework

The framework from which the primary care APN works within is based upon the American Nurses Association Scope of Practice (1985), as well as the American Academy of Nurse Practitioners Scope of Practice (1992). The American Nurses Association (1985), describes the framework for the Nurse Practitioner's practice of nursing as the health continuum. Nursing actions across the health continuum include health promotion, specific protection against disease, early diagnosis and treatment to prevent or limit disability, and rehabilitation (ANA, 1985). The Nurse Practitioner provides

primary health care based upon their experience, competence and in accordance with their knowledge base. The APN is responsible for all aspects of management of health problems encountered by the client and the APN is also accountable for the client's outcomes, including both wellness and cost outcomes (ANA, 1985). The APN provides nursing and health care services to patients and their families accentuating health promotion and disease prevention while focusing on education and advocacy of the patient, family and community (American Academy of Nurse Practitioners, 1992).

The ANA describes two areas of patient care as delivered by the Advanced Practice Nurse. These dimensions are the direct nursing care role and the indirect nursing care role. The direct nursing care role elaborates and expands upon the actions of the traditional nursing process. The indirect nursing care roles influence the type, quality and delivery of direct care. These roles are also essential to enhance the overall delivery of direct care (ANA, 1985). The dimensions of the direct nursing care roles are described in Table 1.

These direct nursing care dimensions apply to all primary care illnesses and presentations including acute otitis media. Indirect nursing care roles compliment and enhance the elements of direct care. Examples of indirect nursing roles are as follows in Table 2.

Utilizing indirect and direct nursing care roles in the primary care setting allows for planning and implementing

Table 1.

The APN's Direct Nursing Care Role (ANA, 1985)

Action	Description
Assess	Health status, illness conditions, response to illness, health risks of individuals, families and groups. Assessment through history taking, physical examinations and laboratory test data. Strengths and weaknesses, coping skills, behaviors. Environmental assessment.
Diagnose	Actual or potential health problems and/or needs based upon the assessment of the data collected.
Plan	Therapeutic interventions mutually with individuals and family. Enhancement of or initiation of self-care and problem-solving skills.
Intervene	Treatment of illness in its earliest stage, manage chronic illness, limit disability by providing prompt treatment. Coordination of care with other health care professionals or resources. Provide continuity and assist the client to deal with the health care system effectively.
Evaluate	Mutually with the client/family regarding effectiveness of interventions, comprehensiveness and continuity of the care and therapeutic interventions that were initiated. APN to participate in on-going self-evaluation. Involvement in the peer review process and institutional quality assurance programs.

holistic care and appropriate interventions for the client of all ages and their families.

The theoretical framework for APNs working in advanced practice allows for organized, client-focused care with the emphasis on wellness and outcomes. This process has become the standard of care for Advanced Practice Nurses and these standards of nursing provide specifications for acceptable

Table 2.

Indirect Nursing Roles of the APN (American Academy of Nurse Practitioners, 1993)

Roles	Actions
Advocate	Participates in community programs and effects change in legislation related to the needs of patients and families.
Change Agent	Initiating change in the patient and family with increased knowledge base. Implementing change within the primary care setting by using the pathway.
Collaborator	Collaborates with other specialties and disciplines for ongoing continuity and coordination of care.
Consultant	Consults with other disciplines and specialties and refers to other providers according to the standards of practice.
Educator	Provides educational opportunities for the patients and their families.
Researcher	Actively participates in research related to the clinical area and setting. Maintains knowledge of current trends. Supports research by defining clinical research questions. Conducts research in primary care and incorporates research findings into practice.

levels of care and a basis for the determination of excellence (ANA, 1985).

Literature Review

The purpose of the literature review is to examine current research on acute otitis media including the microbiology and pathophysiology of the disease. The objective is to establish research-based criterion for the physical assessment and diagnosis of acute otitis media. The review of literature will also survey the course of treatments most widely recommended, the duration of

treatment, treatment alternatives and standard patterns of referral.

Demographics and Risk Factors

The peak incidence of this disease occurs between the ages of 6 to 36 months, with peak frequency between the ages of 6 to 12 months (Bonadio, 1993; Facione, 1990; Newton, 1995 & Klein, 1994). According to Bonadio (1993), 25% of acute otitis media occurred during the first year of life, 22% during the second year of life, 15% during the third year, and less than 10% after the age of seven years. If the child has not had an episode of AOM prior to age three, the chances of developing middle ear infection are significantly decreased (Klein, 1994). The term "early and often" refers to the child who develops acute otitis media in the first months of life and has frequent recurrent episodes thereafter. Age of the first episode is significantly associated with the number of recurrent episodes and more-prolonged middle ear effusion after the acute episode. Forty-four percent of infants whose first episode of acute otitis media occurred before six weeks of age experienced six or more recurrent infections before their first birthday (Bonadio, 1993).

Acute otitis media is seen more often in males (60 to 70 percent of AOM), although the reason is not known (Facione, 1990). These numbers were based on measurements of single and recurrent episodes, number of office visits and the number of surgical procedures (Klein, 1994).

Race has been shown to be a factor in the incidence of AOM. Specific racial groups such as: the Native Americans and Alaskans and Canadian Eskimos have an increased incidence of acute otitis media (Klein, 1994; Facione, 1990). It has also been shown that African-American children have fewer cases of otitis media than those of the Caucasian race. Data is insufficient for determining the reason for this occurrence (Klein, 1994; Casselbrant, 1995).

Otitis media has been shown to occur throughout the entire year, however, most cases do occur throughout the fall and winter months with a decline of acute cases during the spring and summer. This reflects a seasonal pattern of upper respiratory infections as well (Klein, 1994).

Other factors have been identified that place children into categories of greater risk and potential for the development of acute otitis media. Familial and genetic heredity has been suggested as one of these factors. Having a sibling or parent with chronic otitis media makes the child twice as likely to develop AOM (Teele, 1980). Children with single and recurrent episodes of otitis media were more likely to have siblings and parents with histories of significant middle ear infections as compared to those children who did not develop episodes of AOM (Klein, 1994).

Other predisposing factors include anatomical and congenital abnormalities such as cleft lip and palate and those children who have neuromuscular diseases such as muscular dystrophy or generalized hypotonia. The increased

incidence of acute otitis media is related to the anatomical differences and neuromuscular function in these children (Klein, 1994; Facione, 1990).

Social factors that contribute to the increased incidence of AOM are lower socioeconomic status, possibly likely related to the availability of affordable healthcare and the family's perceptions of the disease and education levels (Facione, 1990). There may also be a relationship between illness and cleaning practices. The lack of an automatic dishwasher may result in inadequate cleaning of bottles and cups. There are no specific data available for exact reasons for this trend. Households with cigarette smokers present and the prevalence of passive smoking leaves the child at three times more at risk for developing AOM (Facione, 1990).

Feeding practices also play a role in the development of acute and recurrent otitis media. The reclined position of the child during feeding combined with the immature position of the eustachian tube increases the incidence of AOM (Bonadio, 1994; Brook, 1994; Facione, 1990; Klein, 1994; Agency for Health Care Policy and Research (AHCPR, 1994). The benefits of increased mother to baby immunities as the result of breast-feeding has been shown to be an important factor in the prevention of respiratory infections, including otitis media, in infancy. As a result, those infants who are bottle-fed from birth may experience increased incidence of AOM (AHCPR, 1994). The child's

attendance in a large day-care setting has been shown to increase the incidence of otitis media, respiratory and gastrointestinal infections (Klein, 1994; Facione, 1990; AHCPR, 1994).

Physiologic Description

Acute otitis media is an inflammatory process of the middle ear canal and its contiguous structures. It most commonly occurs in conjunction with eustachian-tube dysfunction, obstruction and impaired middle ear canal ventilation. The most widely held theory regarding pathogenesis of AOM is that the eustachian tube is sufficiently obstructed to cause impaired middle ear canal ventilation and result in the absorption of air, atelectasis and development of persistent high negative pressure in the middle ear canal. Transudation of plasma into the tympanum and the middle ear canal is cased by the atelectasis. The negative pressure gradient toward the middle ear canal predisposes to reflux, aspiration and the insufflation of nasal passage secretions into the middle ear canal. Bacteria is then trapped and proliferates, resulting in infection (Bonadio, 1994). Klein (1994), adds that the acute episode of otitis media occurs from a sequence of events. He explains that the patient has an antecedent condition such as a viral or allergic reaction. This condition results in the congestion of the mucosa of the upper respiratory tract and in the eustachian tube that results in obstruction of the tube. The secretions of the

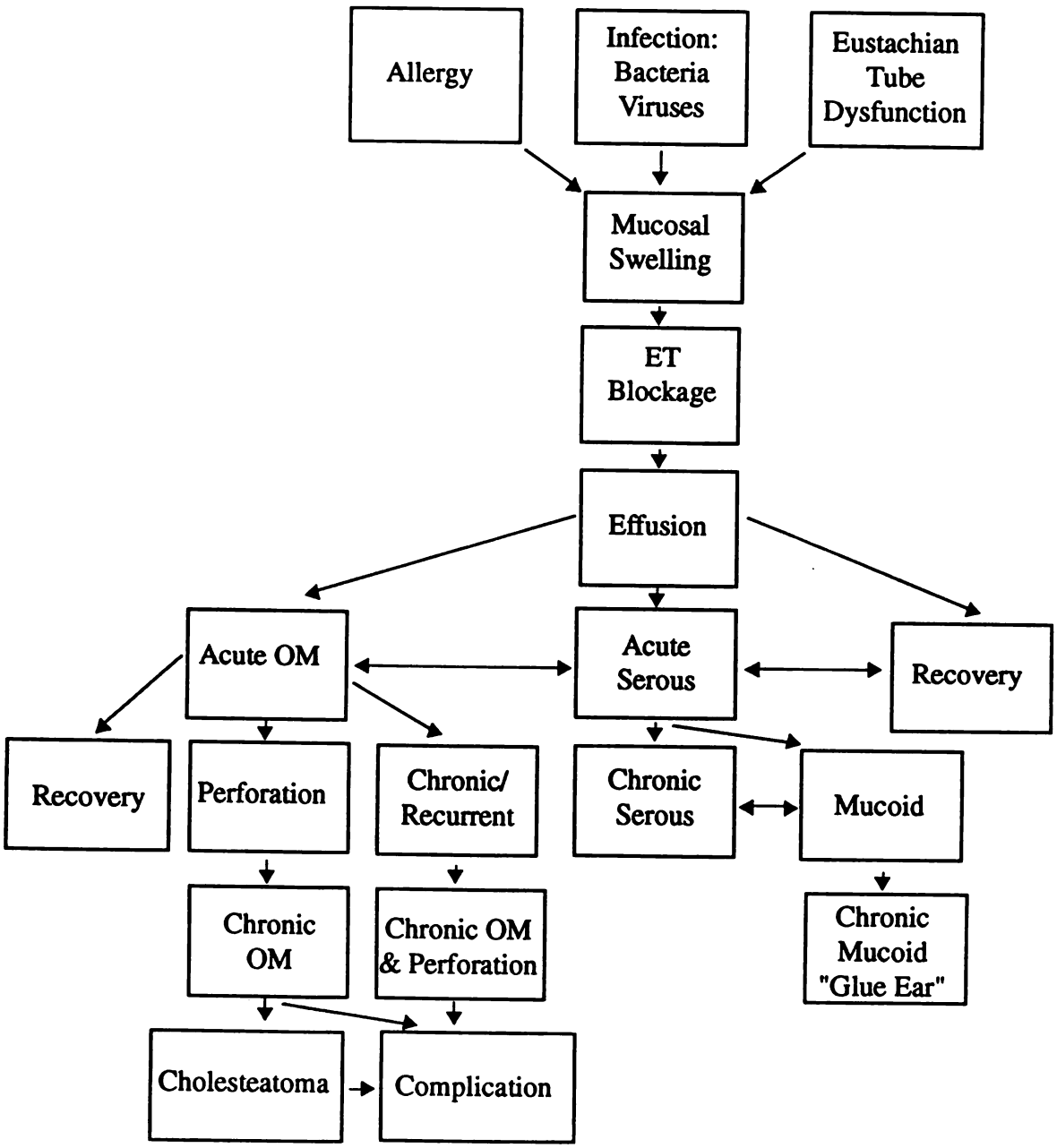
middle ear have no avenue for escape. The secretions accumulate, colonize and a resulting suppurative infection occurs. Figure 1 is a depiction of this process.

Microbiology

It is important to understand the microbiology of acute otitis media so that appropriate treatments can be carried out. Knowledge of the pathogens responsible for otitis media enable the most appropriate treatment regimen to be selected and will minimize further complications (Brook & Van De Heyning, 1994). The rationale for using antibiotics is based on the presence of virulent bacteria in acute otitis media.

Epidemiological and virological data show a powerful association between the incidence of AOM and upper respiratory infections (Bonadio, 1994). Upper respiratory infections can impair the function of the eustachian tube thus helping to create negative pressure in the middle ear, and a suitable environment for the development of acute otitis media (Brook & Van De Heyning, 1995). Viruses have also been implicated as the infectious cause of acute otitis media. According to Bonadio (1994), a viral isolate in the middle ear effusion occurs in 10% to 25% of cases of AOM. The most common viral etiological agents isolated in the middle ear effusion of children with AOM are those that cause upper respiratory epidemics, including the enterovirus (Bonadio, 1994). Other viruses associated with AOM are

Figure 1. Pathophysiology of Otitis Media (Brook, 1994).



respiratory syncytial virus, influenza A and influenza B, rhinovirus, and adenovirus (Brook, 1994). The high rate of unresponsiveness of AOM to antimicrobial therapy may be due to the infection caused by virus rather than bacteria and probably contributes to the chronicity, relapse and frequency of the disease (Brook, 1994).

A bacterial pathogen is isolated from the middle ear fluids of approximately two-thirds of children with acute otitis media (Brook & Van De Heyning, 1994; Bonadio, 1994; Newton, 1995; Klein, 1994; Brook, 1994). Studies differ slightly in percentages, but three organisms are found most often in the middle ear fluids. Streptococcus pneumoniae, Haemophilus influenzae, and Moraxella catarrhalis are the principle pathogens in acute otitis media (AHCPR, 1994; Brook, 1994; Brook & Van De Heyning, 1994; Newton, 1995; Mandel, Casselbrant, Rockette, Bluestone, Kurs-Lasky, 1995; Paradise, 1995; Diven, Evans, Alper, Burckart, Jaffe, Doyle, 1995; Facione, 1990; Bonadio, 1994; Klein, 1994). The general distribution of pathogens causing AOM according to literature is represented in Table 3.

Symptoms and Physical Findings

There is a range of common symptoms with which infants and children suffering from AOM present. Based on Pearse and Bridges-Webb (1993), infants commonly present with non-specific symptoms such as fever, crying, and vomiting. According to Pichichero (1994), it is extremely uncommon for

Table 3.

Distribution of Pathogens

Pathogen	Distribution in %	Resistant Bacteria
S. Pneumonia	30 to 35%	N/A
H. Influenzae	20 to 22%	15-30% ampicillin resistant
M. Catarrhalis	10 to 15%	75% are **beta-lactamase
S. Pyogenes S. Aureus	5%	N/A
Other Bacteria	20 to 30%	

**Beta-lactamase producing pathogens are of a particular concern to the practitioner because its numbers are increasing and it is resistant to most common antibiotic treatment (Bonadio, 1994).

a child less than two and a half years of age to have the ability to clearly express verbally that an ear ache is present. Instead, parents often note other common indicators of otalgia such as ear tugging, restlessness during sleep, diminished appetite, irritability or fussiness, runny nose and fever (Bonadio, 1994; Facione, 1990).

Based on Klein's work (1994), signs and symptoms of acute otitis media include otalgia, otorrhea, hearing loss, fever, irritability, headache, lethargy, anorexia or vomiting. Klein (1994) adds that uncommon signs of ear infection are tinnitus, vertigo and nystagmus. Facione (1990) suggests that the prominent signs and symptoms of acute otitis media are ear ache (otalgia), with worsening ear pain at night. This is caused by increased vascular

pressure in the reclined position causing the drum to bulge painfully. Other manifestations include otorrhea, presenting as a purulent and often foul-smelling discharge, hearing loss, tinnitus, periauricular swelling and mild balance disturbances (Facione, 1990).

Physical Exam Findings

The acutely painful ear (or, in infants, the apparently painful ear) is commonly assumed to be due to acute otitis media but a precise diagnosis should be based upon the physical exam. The most critical aspect of the physical exam for exact diagnosis of acute otitis media is the internal ear exam, or the otoscopic examination. According to the AHCPR (1994) guidelines, pneumatic otoscopy must be used for the diagnostic evaluation of otitis media. Bonadio (1994) adds that it takes skill and practice to perform a reliable otoscopic exam. The performance of the pneumatic otoscopic exam may also be accompanied by technical difficulties, such as inadequate patient compliance with the procedure, an obstructed visual field or lack of uniform pressure applied to the middle ear system. Pearse and Bridges-Webb (1993) conclude that redness of the ear drum without other symptoms is not conclusive for a diagnosis of acute otitis media. Redness may be caused by other factors such as prolonged crying or nasal congestion.

Klein (1994), suggests that four characteristics of the tympanic membrane should be evaluated when pneumatic otoscopy is performed. These are position, color, degree of

translucency, and mobility. The normal tympanic membrane is in a neutral position (neither retracted nor bulging), pearly gray, translucent and responds quickly to positive and negative pressure, indicating an air-filled space (Klein, 1994).

Bonadio (1994), elaborates on the otoscopic abnormalities that accompany acute otitis media. Bonadio (1994) states:

> "By examining the tympanic membrane and visible contents of the middle ear canal, an inference is made regarding middle ear canal status. Any pressure differential existing across the tympanic membrane results in stress applied to the tympanic membrane. Although translucent, the tympanic membrane can reflect inflammatory and barometric changes in the middle ear canal" (p. 197).

Abnormal findings of the tympanic membrane as observed by otoscopic examination and their related causes are summarized in Table 4. The findings described in Table 4 are common tympanic membrane changes found through otoscopic examination. Tympanometry has been used to assist in the diagnosis of an air or fluid-filled middle ear space (Bonadio, 1994; Klein, 1994). Tympanometry allow the assessment of the compliance of the tympanic membrane and provides an estimate of middle ear pressure. Tympanometry uses an air pump to vary ear canal air pressure, thus altering the stiffness of the tympanic membrane. A signal

Table 4.

Tympanic Membrane Findings (Bonadio, 1994)

Tympanic Membrane	Abnormal Findings	Causes
Color	Pearly grey to red or yellow/dark grey	TM inflammation or hemorrhage, middle ear canal purulent secretions, tympanic membrane edema
Clarity	Opaque	Tympanic membrane edema, middle ear canal purulent effusion ro landmark obscurity
Contour	Retraction distention	Barometric changes in the middle ear canal increased hydrostatic pressure
Mobility	Pressure changes	Middle ear effusion or atelectasis

The findings described in Table 4 are common tympanic membrane changes found through otoscopic examination.

is then transmitted into and through the tympanic membrane and middle ear, reflected back in to the ear canal, and received by a microphone. The tympanogram records air pressure in millimeters of water and it also records TM compliance (Bonadio, 1994; Klein, 1994).

Bonadio (1994) recommends the use of tympanometry to objectively measure compliance of the middle ear system. Bonadio (1994) notes that tympanometry can be reliably performed in children as young as six months of age and it is quite accurate in assessing middle ear effusion with a 82% to 90% accuracy rate.

The Agency for Health Care Policy and Research (AHCPR, 1994), published guidelines based on the largest literature search and meta-analysis ever undertaken on otitis media. The AHCPR (1994) guidelines are for the treatment of chronic

otitis media or otitis media with effusion and not for acute otitis media, but some of the treatment and diagnostic recommendations can be appropriately applied. AHCPR (1994) does not recommend the use of tympanometry for routine diagnosis of otitis media. AHCPR (1994) states the tympanometry may be used as a confirmatory test as an option.

Treatment of Acute Otitis Media

Treatment recommendations for acute otitis media vary from country to country and have changed over time. Treatments are currently changing again because of the emergence of beta-lactamase-producing bacteria in otitis media. Thus, traditional choices in antibiotic therapy are also beginning to give way to new options in antibiotic therapy.

In the pre-antibiotic era, acute otitis media was feared for its high incidence of serious morbidity and mortality. There are several serious systemic complications that can arise such as mastoiditis, labyrinthitis, brain abscess, meningitis and bacteremia (Brook & Van De Heyning, 1994). In 1916, 85% of brain abscesses were due to complications of otitis media as compared to 2.6% in 1990 (Facione, 1990). Acute otitis media was responsible for mortality rates as high as 4% prior to the 1960's (Facione, 1990). Infectious complications like mastoiditis, central nervous system abscess, and bacterial meningitis occurred in as many as 20% of acute otitis media cases during the pre-

antibiotic era, but presently complicate less than 1% of cases (Bonadio, 1994). The American Academy of Pediatrics concur with this position and point to the severe complications of otitis media seen prior to the advent of antibiotics as a justification of an aggressive-treatment policy (Facione, 1990).

In other countries such as the Netherlands, Scandinavia and the United Kingdom acute otitis media is not treated routinely with antibiotic medications (Facione, 1990; Pichichero, 1994; VanBuchem, Knottnerus, & Peters, 1995). The trend in these countries is to rely on the spontaneous cure rate of acute otitis media that is as high as 14% to 88% without treatment (Pichichero, 1994; Newton, 1995). When relying on a spontaneous cure, clinicians in these areas consider symptomatic therapy such as pain medication, as satisfactory and appropriate management of patients with AOM (Facione, 1990; Newton, 1995; Pichichero, 1994). For purposes of this project, information will be based upon the treatment practices in the United States.

According to Bonadio (1994), "antibiotic therapy is beneficial in treating acute otitis media by promoting the eradication of bacteria, shortening the duration of symptoms and period of morbidity, and preventing intracranial and infratemporal suppurative complications" (p. 199). As suggested by Pearse and Bridges-Webb (1993) the intent of acute otitis media treatment should be to alleviate the symptoms, eliminate the infecting agent, promote restoration

of normal hearing, and prevent recurrence, chronicity or complications. Pharmacologic management of AOM should be guided by considerations such as components including medication cost, rate of adverse reaction, geographic susceptibility patterns of organisms that cause acute otitis media, and patient age and medical history (Bonadio, 1994; Paradise, 1995). Based on Klein's (1994) research, management of acute otitis media should include the elements of comfort, microbiology, side effects, availability, convenient dosing schedule, palatability and reasonable cost. The antimicrobial agent should have a spectrum of activity that includes S. Pneumoniae and H. Influenzae and documented clinical and microbiological efficacy (AHCPR, 1994; Bonadio, 1994; Brook, 1994; Canafax & Giebink, 1994; Facione, 1990; Klein, 1994; Pichichero, 1994; Paradise, 1995). Clinical efficacy should be measurable based on substantial resolution of signs and symptoms within 48 to 72 hours and prevention of relapse, recurrence, and suppurative sequelae (Klein, 1994).

Klein (1994) recommends that the oral drug should be palatable in terms of smell, texture, taste, and after taste. In the 6 to 36 month age group, this is especially relevant. Dosage scheduling should be appropriate and convenient for the family. A once or twice-a-day dosing is preferable and increases compliance with the prescribed regimen by both the child and the parents. Toxicity has been found to be rare with the current approved roster of

drugs indicated for AOM, but any side effects should be limited in incidence. Cost is also an important factor when prescribing the appropriate drug. A high population living in the United States do not have prescription insurance coverage and are forced to pay out-of-pocket for their medicines which can be very costly (Klein, 1994).

The 11 currently antimicrobial agents with their costs, palatability, dosages and trade names are listed in Table 5. The cost information was obtained from a Meijers pharmacy that has stores state wide throughout Michigan. The costs that are quoted are accurate as of December, 1996. Based on the information provided in Table 5, it is apparent that there are many choices of antimicrobial therapy for treatment of acute otitis media. If cost is an issue with the client's family, there are several low cost choices that may be suitable for treatment.

Current Recommendations

Based on current research, the most common pathogens implicated in acute otitis media are S. Pneumoniae, H. Influenzae and M. Catarrhalis and most patients with these bacterium isolated from middle ear effusion do respond favorable to amoxicillin (AHCPR, 1994; Brook & Van De Heyning, 1994). From a study published in 1991, there were fewer treatment failures among patients receiving amoxicillin ($p=0.009$) than in those given placebo (Kaleida, Casselbrant, Rockette, Paradise, Bluestone, Blatter, Reisenger, Wald & Supance, 1991).

Table 5.

Antimicrobial Agents for Therapy of Acute Otitis Media (Bonadio, 1994; Klein, 1994)

Generic Name	Trade Name	Dosage	Cost (for 10 days)	Palatability Ranking
Amoxicillin	Amoxl trimox	40mg/kg TID	$8.99	5th
Amoxicillin/ clavulanate	Augmentin	20mg/kg TID	$68.20	3rd
Cefaclor	Ceclor	20mg/kg BID	$38.15	2nd
Cefixime	Suprax	8mg/kg QD	$67.45	1st
Cefpodoxime proxetil	Vantin	10mg/kg BID	$23.08	no info
Cefprozil	Cefzil	30mg/kg BID	$70.59	no info
Clarithromycin	Biaxin	7.5mg/kg BID	$65.72	no info
Erythromycin sulfamethoxazole	Bactrim	30-60mg/kg BID	$6.68	6th
Loracarbef	Lorabid	30mg/kg BID	$73.95	no info
Erthromycin-sulfisoxazole	Pedizole	40mg/kg TID	$5.05	4th

Increasing numbers of beta-lactamase resistant bacteria has been found in H. Influenzae and M. Catarrhalis. This has effected the efficacy of amoxicillin. Despite this development, based on the review of literature, amoxicillin remains the drug of choice for the treatment of acute otitis media because of its 20-year record of clinical success. Amoxicillin is palatable, has limited side effects and relatively low in cost (Physicians Desk Reference, 1996; Bonadio, 1994; Klein, 1994). Amoxicillin also has a low expected clinical treatment-failure rate in children (Klein,

1994). As a result of these factors, amoxicillin is the most commonly prescribed "first-line" antibiotic for uncomplicated acute otitis media and multiple studies have continued to document positive clinical outcomes in those patients receiving amoxicillin (AHCPR, 1994; Bonadio, 1994; Brook, 1994; Canafax & Giebink, 1994; Pichichero, 1994; Paradise, 1995).

Duration of Treatment

The duration of antimicrobial therapy for treatment of acute otitis media is based on traditions and is being questioned by many clinicians and researchers. According to Mandel et al. (1995), the optimal length of antimicrobial administration for treatment of AOM is not know. Standard textbooks recommend a 10-day course of treatment (Emergency Diagnosis and Treatment, 1992; Diseases, 1997). Studies that have been done to test shorter and longer durations of treatment yield more questions than definitive answers.

Traditionally, the recommended duration of antibiotic therapy for AOM is 10 days. This was established as necessary for optimal bacteriologic eradication for Group A beta-hemolytic streptococcal in tonsillopharyngitis and then became the empirical standard for virtually all outpatient antimicrobial regimens in the United States (Pichichero, 1994). In an American study that compared 5 versus 10 days of antibiotic treatment, patients without otorrhea had similar response to both regimens. However, patients with otorrhea had significantly higher treatment failure rate

with the shorter regimen (Pichichero, 1994). Three studies have demonstrated that bacteriological cure of AOM occurs after three to six days in 85% to 95% of those treated with amoxicillin (Sato, Quartey, Liebeler, & Giebink, 1995). Hendrickse and Kusmiesz (1988) showed equivalent acute otitis media clinical cure rates in those receiving 5 rather than 10 days of oral antibiotics for uncomplicated acute otitis media. Another study showed similar rates of symptomatic improvement, signs of hearing loss and rates of recurrence of AOM in those patients receiving a 3-day course of treatment rather than the traditional 10-day course of amoxicillin therapy (Caput, Levine & Savage, 1992). Most researchers and clinicians agree that 10 days is a longer period than necessary for many children but it may be shorter than necessary for others. Paradise (1995) supports an individualized treatment duration based on each patients severity of infection, the child's previous history of otitis media and their response to current therapy. Mandel et al. (1995) performed a trial to see whether treating for 20 days instead of the traditional 10-day treatment period would improve the results of treatment. The study was performed over a three year period and was based on 267 children with uncomplicated otitis media. The authors concluded that they do not recommend the routine use of an additional 10-day course of antimicrobial treatment if a child is symptom-free after the initial 10 days of treatment for AOM (Mandel et al., 1995).

The duration of antimicrobial treatment continues to be debated (Brook & Van De Heyning, 1994). The current recommendations are for a 10 day duration of antimicrobial therapy until further studies are available that may yield more definitive options based on clear and statistically powerful data.

Treatment Alternatives

Based on factors of side effects, palatability, dosage schedule, convenience, cost, compliance and availability, the clinician can prescribe any of the 11 approved drugs for AOM. Less frequent dosing schedules have been shown to improve compliance (Paradise, 1995). Side effects of medications have also been known to decrease patients compliance to medications. Amoxicillin has been documented to have the least amount of side effects from the field of approved antimicrobials (Bonadio, 1994). Cefaclor has been shown to have a propensity to produce a serum sickness-like reaction and the latest trials have shown that the efficacy of cefaclor is lower than other antimicrobials (Pichichero, 1994). Amoxicillin-clavulanate and erythromycin have both been shown to produce diarrhea as a side effect, but this can be reduced by taking the medication with meals (Pichichero, 1994).

Some of the newer cephalosporins, such as suprax, vantin and lorabid, have more convenient dosing schedules and have superior palatability, but as seen in Table 5, these drugs also tend to be more expensive. Cefixime, for

example, has a once-a-day dosing schedule which would tend to increase patient and caregiver compliance to the treatment regimen, but the cost of cefixime is significantly higher than amoxicillin (Meijers Pharmacy, 1996).

The most important reason to choose an alternative antimicrobial agent is the bacteria's resistance to the first-line antibiotic. According to Paradise (1995), choosing a beta-lactamase resistant drug alternative should be based on the heightened risk of a beta-lactamase producing pathogen or if the clinician feels that the patient is in urgent need of prompt relief. Also, if there has been a community-wide trend towards a beta-lactamase-producing pathogen, an alternative such as augmentin should be chosen (Paradise, 1995). Other circumstances for choosing a stronger medication include symptoms that persist for more than 48-72 hours after using amoxicillin and an episode within the last two months that failed to respond to amoxicillin. One might choose to treat with a beta-lactamase resistant drug from the outset if the patient is immunocompromised in any way or if symptoms are exceedingly severe (Paradise, 1995).

Other treatments such as decongestants, antihistamines and oral steroids have been used in the treatment of AOM. Bonadio (1994) states:

> "..in patients with either symptomatic or asymptomatic acute otitis media with middle ear effusion, the administration of decongestant/

antihistamine medication has not been shown to hasten symptomatic improvement, middle effusion resolution, or prevent acute otitis media when initiated at the onset of upper respiratory symptoms" (p. 202).

According to the AHCPR (1994) guidelines, the panel of experts concluded that steroids, decongestants and antihistamines did not effect the resolution of acute otitis media. Paradise (1995), also agrees that a combination of antihistamines and decongestants have been discredited and are ineffective in the treatment of AOM and evidence that mucolytic agents are effective is not convincing. The literature abounds with conflicting studies, but most studies seem to question the value of these medications rather than support their use.

The efficacy of steroids, either systematically or intranasally, for acute otitis medial also remains uncertain (AHCPR, 1994; Paradise, 1995). It is noted that in cases when a child has not had a varicella, the use of steroids carries life-threatening risks of varicella should develop (Paradise, 1995). According to Klein (1994), there is little evidence suggesting that a course of systematic corticosteroid therapy combined with an antimicrobial agent is of value. Conversely, Rosenfeld (1995), states that combining an antibiotic with an oral steroid when treating AOM with effusion appears "promising", but at this time,

cannot be recommended secondary to sparse and inconsistent evidence which lack statistical significance.

Topical anesthetic drops are frequently used for children with painful acute otitis media. It is noted that these preparations should never be used for AOM with tympanic membrane perforation because the medication may enter the middle ear canal (Bonadio, 1994).

Otalgia is a common symptom of acute otitis media and current literature supports pain control in the form of acetaminophen with codeine for severe pain and plain tylenol or ibuprofen for mild to moderate pain and fever (Bonadio, 1994).

Referral Criterion

Follow up recommendation vary relative to the appropriate time for the follow up visit. Hathaway, Katz, Deshewitz, and Marx (1994), cite a recent survey of pediatricians and nurse practitioners with the standard range for follow up being 10 days to 6 weeks. Follow up is essential in order to detect persistent pathology or hearing loss. According to Paradise (1995), follow-up for the non-complicated case of acute otitis media to be one month. At that visit, Paradise recommends an exam with a tympanogram to indicate whether the otitis has resolved completely.

Those patients with persistent effusion after four months need a referral to an ear, nose and throat specialist for consideration of myringotomy, tympanostomy tubes or adenoidectomy (Pearse & Bridges-Webb, 1993). Other referral

criterion: a) infants and children who have more than three episodes of acute otitis media within six months should be referred to the otolaryngologist; b) five or six episodes of otitis media in one year's time; c) the persistence of supportive infection despite antibiotic therapy; d) an effusion that persists for several months and becomes mucoid in nature (Brook, 1994; Facione, 1990). The AHCPR (1994), recommend a referral if an effusion has lasted a total of three months. The 1992 Clinical Indicators Compendium prepared and published by the American Academy of Otolaryngology, suggests a three-month waiting period for a child with persistent middle ear effusion prior to a referral from the primary care clinician to the otolaryngologist. Referrals are made because of prolonged periods of middle ear effusion and frequent episodes of acute otitis media can result in degraded language input and conductive hearing loss (AHCPR, 1994). Research has shown that there is an association between recurrent AOM in the preschool years with subsequent linguistic, cognitive and academic impairment. These complications are especially prevalent in those children with the onset of middle ear effusion during the first 12 months of life (Bonadio, 1994).

Prevention

Some general principles can be applied in the prevention of AOM and these principles should be the basis of patient education. Breastfeeding has been found to provide some degree of protection, although this is not

absolute (AHCPR, 1994; Paradise, 1995). Educating the caregiver on bottle feeding position may also assist in decreasing the chance of AOM. Correct bottle feeding position is at an incline or sitting position; therefore decreasing fluid going into the middle ear. Other suggestions include enrolling children in small, rather than large, group day care centers, maintenance of good general hygiene and avoiding exposure to infectious disease (AHCPR, 1994; Klein, 1994; Paradise, 1995). Data concerning the role of tobacco smoke exposure playing a possible role in the pathogenesis of acute otitis media is not yet firm, but avoidance is most certainly worthwhile in the light of its role in the causation of upper respiratory diseases (AHCPR, 1994; Paradise, 1995).

Clinicians should also advise parents of the seasonal incidence of acute otitis media and the expectation that the child's condition may improve in the late spring and summer months. Aggressive treatment and management may be postponed until the course of disease has been determined in the following respiratory season (Klein, 1994).

Chemoprophylaxis has also been shown to be successful in reducing the number of new episodes of acute otitis media in children who have a history of recurrent infections. There has been a 40% to 88% success rate in the reduction of recurrent episodes if the child was treated with prophylactic antimicrobial therapy (AHCPR, 1994; Klein, 1994).

Summary

Otitis media is the most common respiratory tract infection of infants and early childhood. A bacterial pathogen can be isolated from approximately 65% of children with AOM. The three most common pathogens are S. Pneumoniae, H. Influenzae, and M. Catarrhalis.

A pneumatic otoscopic exam should be used to diagnose acute otitis media and tympanometry is a helpful adjunct tool to confirm the diagnosis. Common symptoms are fever, irritability, crying, loss of appetite, pulling at ear, otorrhea, otalgia, nausea and vomiting. Common physical findings are tympanic membrane redness, bulging, retraction, dullness opaqueness, perofrmation, purulent drainage and indicative tympanometry readings.

The treatment most often recommended in the United States is a 10-day course of antimicrobial therapy with amoxicillin. If a beta-lactamase-resistant pathogen is suspected or if symptoms and presentation are severe, amoxicillin-clavulanate is recommended with a 10-day course of treatment. Factors to be aware of when prescribing alternative antimicrobial therapy are cost, compliance, palatability, efficacy, dosage schedule and side effects.

Referrals are based on persistent middle ear effusion and frequent recurrent episodes of acute otitis media. Prevention is based on environmental and social issues and the use of chemoprophylaxis has been effective in reducing recurrent episodes of acute otitis media.

The literature has presented much uncertainty in the duration of antimicrobial therapy in the treatment of AOM. Studies have suggested further investigation in regard to the use of decongestants, antihistamines and steroid therapy. There are also discrepancies in the ideal time to follow up and referral to otolaryngologists and ear, nose and throat specialists.

Critical Pathway

Based upon the literature review and the scope of practice from which the Nurse Practitioner functions, a critical pathway for infants and toddlers, ages 6 to 36 months is suggested for an APN working in the primary care setting. The review of literature has revealed the most commonly accepted practices when treating acute otitis media in this age group. This practice will be condensed and applied to the non-complicated patient ages 6 to 36 months presenting to the primary care setting with the complaint of acute otitis media. The therapeutic interventions and treatment plan are based on the literature review. Interaction with the client and family, along with care provided, will be given in an organized and logical sequence based on the APN dimensions of practice from the American Nurses Association nurse practitioner scope of practice (ANA, 1985).

The critical pathway (Table 6) will be presented in the form of what content that must be accomplished within a 15 minute visit to the primary care setting. Follow up and

Table 6.

First Visit to the APN

Assessment	**Thorough focused patient and family medical history** current medications; developmental milestones; allergies and reactions; immunizations; past illnesses; familial history. **History of present illness** -onset, duration, symptoms, what alleviates symptoms, what worsens symptoms, sequelae. **Social history/Feeding history** -breast or bottle fed **Environmental history** -home environment; -other children ill in the home or day care; -day care (size of day care) **Strengths of patient and family/Coping skills/Physical examination** -vital signs with temperature, thorough pneumatic otoscopic exam. Thorough head and neck examination, throat exam, cervical node exam. Full respiratory exam along with auscultation of heart and lung sounds.
Diagnosis	**Impression** based on history -irritability, fever, pulling at ears, sleeplessness **Diagnosis** based on history and exam -pneumatic otoscopy: Dull, retracted, bulging, non-mobile tympanic membrane, erythema. -tympanometry may also be helpful when diagnosing middle ear effusion and can be used as an adjunct to pneumatic otoscopy.
Plan	**Treatment:** -Tylenol or children's ibuprofen per weight for pain control Amoxicillin suspension 40mg/kg/day in divided doses for 10 days. -If symptoms are severe: Start with Amoxicillin-clavunate 40mg/kg in divided doses for 10 days. -If allergic to penicillin: Give appropriate alternative antibiotic from the list of 11 approved antimicrobials. -Follow up in office in 48-72 hours if no improvement. -Follow up in 10 day in the office for recheck of symptoms **Education:** -correct medication administration and dosage of tylenol and ibuprofen. -therapeutic feeding methods for bottle feeding. -signs of improving and worsening symptoms -discussion of smoking habits or day care if applicable **Expected outcomes:** -meds taken in compliance to plan -total resolution of symptoms

evaluation of interventions will be the second 15 minute visit. Table 7 shows the critical pathway for the possible return visit in 48 to 72 hours. Table 8 is the critical pathway for the 10 day return visit.

Critical Pathway Evaluation

The evaluation of the critical pathway is performed by evaluating the outcomes of the interaction and the interventions that were carried out. Another aspect of evaluation is the APN's satisfaction with organization of the pathway and whether it meets the needs of the target population and the goals set forth by the APN. The pathways' focus was to provide a logical and sequential set of actions based on what is currently known about acute otitis media and its treatment. The purpose of an evaluation is to assess the outcomes of treatments and interventions.

Initial evaluation of the critical pathway takes place during and after the first visit with the client and their family. The APN should mentally note if he/she felt the interaction was positive and that the parental caregiver comprehended the instructions. The APN should note if there was a satisfactory amount of time for questions and answers and a good rapport was initiated with both the parental caregiver and the child.

Ongoing evaluation continues at the 48 to 72 hour period when the patient was to return if symptoms had not improved. If the patient does return, this outcome is

Table 7.

Recheck Visit at 48 to 72 Hours

Assess	Thorough physical exam and history of continued illness. Assess appropriateness of original plan.
Plan	If symptoms have persisted without improvement and there are no new symptoms or source of infection: **Treatment:** -Change Amoxicillin to Augmentin 40mg/kg/day in divided doses for a duration of 10 days. -May consider using other approved antibiotics that are known to have a strong efficacy against beta-lactamase resistant bacteria (Example: vantin, cefzil, lorabid, biaxin). -Advise parent to have child recheck if no improvement of symptoms within 48 hours. -Return in 10 days for recheck to evaluate for full resolution of symptoms. **Education:** -reinforce previous teaching.

Table 8.

Follow-up Visit at 10 Days

Evaluate	-Perform complete pneumatic otoscopy evaluate for full resolution of symptoms. -If symptoms have not resolved, consult physician. **Consider OME:** -If symptoms of OME do not resolve within one month. -Treat OME per AHCPR guidelines

positive in terms of compliance and the recognition on the part of the parental caregiver that symptoms were still present. At this visit, it is important to assess whether the parental caregiver gave the medication correctly and timely.

Final evaluation of the pathway takes place at the 10-day return visit. The patient is assessed by pneumatic

otoscopy. The tympanic membrane should be without signs of effusion or continued infection. The patient should be without any signs of sequelae.

The parental caregiver should report that the medication was given as prescribed at the previous visit. Other expected outcomes such as bottle-feeding technique should also be evaluated for further teaching or parents verbalization of complete understanding. Any other teaching or issues that were addressed at the initial visit should be evaluated and discussed based on the expected outcomes that were established for each issue.

Finally, the APN should critique the critical pathway in terms of logic, organization and appropriateness to the targeted population. The APN should also evaluate whether the pathway provided for continuity and comprehensiveness. These aspects of evaluation would be on-going as the APN sees patients for the chief complaint of acute otitis media. With each case, the APN should not whether or not the pathway was appropriate and met its goals and any aspects that should be modified.

Further evaluation of the pathway can be accomplished through a chart audit. Information from the chart audit can evaluate if the pathway was used and the outcome of illness. The chart audit can indicate if the patients' symptoms resolved and how many patient's follow up. Another important evaluation is to find out how many children

developed chronic otitis media after treatment with the use of the critical pathway.

Implications for the APN

Acute otitis media is the most common outpatient complaint that children present to the primary care setting. The APN will most assuredly come into contact with and treat many children with this complaint. Based on this premise, it may be helpful to the APN to have a logical, formatted critical pathway to work form based on the latest in acute otitis media research and practice guidelines.

From the standpoint of advanced practice and primary care, the pathway will uphold the goals of primary care which include continuity and comprehensiveness (Starfield, 1992). The pathway provides continuity by allowing an uninterrupted succession of events. Continuity is achieved through the progression of the pathway and the documentation of expected outcomes and the evaluation of these goals. Comprehensiveness is achieved through the actions of the direct advanced practice nursing care roles or dimensions (ANA, 1985). The critical pathway is comprehensive in its holistic structure and evaluation components. Finally, the pathway is comprehensive because of the referral component. This provides a full range of services available to the client if necessary (Starfield, 1992).

The critical pathway may also prove to be cost effective in terms of efficiency. The pathway for the visit it organized and sequential. There is a logical progression

of events within the patient's visit. This maintains the course of the visit in goal-directed pattern of events and maintains focus throughout the interaction, resulting in a time efficient visit. Time lost in clinic settings means increased costs and lost revenue. The critical pathway allows for a timely and holistic treatment process while still focusing on all aspects of the client's needs.

Other implications include the APN's involvement in the process and on-going development of the critical pathway. The APN is in the position to critique and modify the pathway to best suit the needs of the population he/she serves. The APN also plays an integral part in the evaluation process.

Implications of the pathway may include education for other APN's as well as APN students. The pathway is easy to follow and may assist APN students in their grasp of the subject. The pathway can also be discussed at an APN peer review session, this may prompt even further exploration of implications and use of the pathway.

Other clinic setting implications could be the incorporation of the medication chart for clinical application. The chart would have to be routinely updated in regards to the medications and latest costs. The medications used in the pathway may also be used as a standing order agreement in the collaborative agreement between the physicians and the APN.

Finally, the APN should be motivated to be involved in the latest trends related to the pathway and keep abreast of current research. The APN may also be involved in the research based on the possible outcomes of implementing a critical pathway. Success of the acute otitis media pathway may prompt the APN to be a researcher and create other pathways for frequently seen common complaints in the primary care setting.

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CRITICAL PATHWAY FOR ACUTE OTITIS MEDIA IN INFANTS AND CHILDREN (AGES 6-36 MONTHS)

By

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ABSTRACT

CRITICAL PATHWAY FOR ACUTE OTITIS MEDIA IN INFANTS AND CHILDREN (AGES 6-36 MONTHS)

By

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Otitis media is one of the most common pediatric diseases. Approximately 7 out of 10 children are afflicted and this includes children from all races, ages and social groups (Bonadio, 1994). Acute otitis media (AOM) is the most common specific diagnosis made by clinicians treating youngsters in primary care family practices and pediatric settings. The highest incidence of disease occurs between the ages of 6 to 36 months (Bonadio, 1994). Complications of acute otitis media and its sequelae often affect the child years beyond the original infection in the form of learning and speech disabilities and hearing deficits.

There is a need for consistent, holistic, low cost and effective treatment of acute otitis media in the primary care setting to treat the initial disease, establish continuity with follow up and decrease the incidence of morbidity related to chronic otitis media. The purpose of this project is to develop a logical, research-based pathway for practitioners working in primary care for infant and toddler-aged patients presenting with uncomplicated episodes of acute otitis media.