INFLUENCES OF ANTIBIOTIC MEDICATION COMPLIANCE FOR 
THE TREATMENT OF ACUTE OTITIS MEDIA IN CHILDREN

By

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A clinical research project submitted in partial
fulfillment of the requirements for the degree of

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To the faculty of Washington State University:

The members of the Committee appointed to examine the clinical research project of WENDY ANNE HUGHES find it satisfactory and recommend that it be accepted.

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FOR THE TREATMENT OF ACUTE OTITIS MEDIA IN CHILDREN

Abstract

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CHAIR: Gail Synoground

OBJECTIVE: To determine the relationship of antibiotic medication compliance and factors affecting parental rationale for medication compliance. To describe and compare the relationships: a) between antibiotic compliance and perceived benefit, relationship with clinician, family belief in medication, perception of illness, financial obstacles, and adverse reactions; b) between medication compliance for groups receiving written instructions and verbal instructions for the home treatment of acute otitis media; and between self-reported compliance and medication measurement after completion of antibiotic therapy.

DESIGN: Exploratory descriptive with a structured interview.

SETTING: Spokane Regional Health District Pediatric Clinics in Spokane, Washington, October through December of 1996.

PARTICIPANTS: Parents of 10 children (9 males and 1 female) between the ages of birth and 12 years of age, diagnosed and treated with antibiotic therapy for acute otitis media. Parents were alternately assigned to a group receiving written and verbal education, or only verbal education.
MAIN OUTCOME MEASURES: All parents received verbal information regarding the diagnosis and treatment of acute otitis media and demonstration of a calibrated medicine spoon to be used for medication administration. In addition, one part of the group (n=4) received written educational materials to reinforce verbal education. Medication compliance was measured by parental report on the medication administration record and measurement of remaining antibiotic suspension. Parents were then interviewed at the 10-14 day follow-up appointment using the structured interview format of a Modified Ratings of Medication Influences Scale.

RESULTS: Although this study attempted to show a relationship between parental rationale for medication compliance behaviors and written educational materials, the results did not support a significant difference between the group receiving only verbal education and the group which received verbal and written education. Parental report of perception of the child’s illness as a strong factor affecting compliance was present in 90% of the parental report in the semi-structured portion of the Modified Ratings of Medication Influences interview. Pearson's product moment correlation coefficient of 0.9141 (p=0.000) indicates significant relationship between parental report of medication compliance and practitioner measurement of residual antibiotic solution.

CONCLUSIONS: A larger sample is required to determine relationship between medication compliance and influences of individual behavioral factors in the Modified Ratings of Medication Influences Scale. In this pilot study, parental report of medication compliance was not statistically different than residual measurement for the assessment of the degree of medication compliance, indicating similar accuracy for the
assessment of medication compliance.
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Otitis media in children is a common health problem with multiple etiologies. Otitis media occurs three or more times in almost every child by seven years of age (Giebink & Canafax, 1988) and results in greater than $3.5 billion a year in pediatric medical costs (Williams, Chalmers, Stange, Chalmers, & Bowlin, 1993). Current primary treatment modalities include antibiotic therapy in combination with symptomatic oral analgesic and antipyretic agents (The Otitis Media Guideline Panel, 1994). The therapeutic regimens for acute otitis media are dependent upon care givers for administration of medications and compliance with the selected treatment plan.

Purpose

The problem examined in this study was the extent of antibiotic medication compliance for the treatment of acute otitis media for two groups of parents, one receiving only verbal instructions and the other group receiving verbal as well as additional written instructions for the home treatment of acute otitis media. The purpose of this study was to determine the relationship of antibiotic medication compliance and to determine factors affecting parental rationale for medication compliance. Selected factors identified as relevant to medication compliance include: perceived benefit, relationship with clinician, family belief in medication, perception of illness, financial obstacles, and adverse reactions (Weiden, et al., 1994). Factors contributing to therapeutic regimen compliance and non-compliance were assessed through structured interview in this study.
Background and Significance

Otitis media in infants and preschool children interferes with family life, speech and language development, and can predispose a child to more serious infections such as mastoiditis or meningitis. Ample research exists regarding appropriate medical and nursing interventions for otitis media (The Otitis Media Guideline Panel, 1994; Hardy & Fowler, 1993; Strauss, 1993; Williams, et al., 1993; Macknin, 1992; Bernstein, 1995), though little has been addressed regarding pediatric medication compliance, specifically medication compliance with antibiotic treatment of acute otitis media (Mattar, Markelio, & Yaffe, 1975; Finney, Friman, Rapoff, & Christophersen, 1985; Williams, Maiman, & Broadbent, 1986).

Review of Literature

Introduction

Otitis media in children is a common health problem causing care givers to seek medical attention for affected children. For effective care of the family in a primary care setting, it is useful for the practitioner to have knowledge regarding current diagnosis, treatment, risk factors, and possible situations which may influence care giver willingness or ability to comply with a prescribed therapeutic regimen for the treatment of acute otitis media.

Otitis Media Pathophysiology

Acute otitis media is inflammation and fluid accumulation in the middle ear that leads to an acute infection. The most common symptoms of acute otitis media in
children include irritability, lethargy, night awakening, difficulty feeding, rhinorrhea, nasal stuffiness, cough, and pulling on ears. Clinical signs identified by the Otitis Media Guideline Panel (1994) are (a) fluid in the middle ear, (b) elevated temperature, (c) decreased tympanic membrane mobility, and (d) erythematous or perforated tympanic membrane. Essentials of diagnosis identified by Berman and Schmitt (1995) include recent onset, red or yellow immobile tympanic membrane, ear discharge, and earache.

Anatomically, children are predisposed to developing otitis media. The eustachian tube which drains the middle ear space to the posterior pharynx is shorter, more compliant, and more horizontally placed than the adult eustachian tube. The result is an accumulation of middle ear secretions and the creation of a negative pressure environment with a potential for aspiration of contaminated nasopharyngeal secretions to the middle ear space. Maturational changes of skull enlargement and elongation produce a more vertical and functional eustachian tube in most adults (Berman & Schmitt, 1995).

Acute otitis media causes physiologic changes in the middle ear and the eustachian tubes that may predispose 10% to 35% of children to recurrent acute otitis media or otitis media with effusion (Daly, 1994). Acute otitis media begins with the exposure to bacteria, viruses, or antigens which initiate the inflammatory process in the nasal mucosa. Increased vascular permeability and blood flow, as well as epithelial changes result in eustachian tube obstruction by venous engorgement of tissue and mucous plugs. When the middle ear space is isolated over a prolonged period of time, the result is chronic otitis media with effusion (Bernstein, 1995).
Risk Factors

Otitis media and respiratory tract infections in children are multifactorial, and can be examined related to modifiable and non-modifiable risk factors. Children with positive family history of recurrent otitis media, males, children less than 3 years of age, and infants having more than two older siblings are at increased risk for otitis media; these risk factors are not modifiable (Alho, Koivu, Sorri, et al., 1990). Modifiable risk factors for otitis media and respiratory infection include day care attendance, short duration of breast feeding, allergen exposure in allergic children, and parental smoking (Alho, Koivu, Hartikainen-Sorri, et al., 1990). Addressing these modifiable risk factors is the basis for preventative education.

Alho, Koivu, Hartikainen-Sorri, et al. (1990) examined antenatal and perinatal factors related to acute otitis media and respiratory infection in a random sample of 2512 children who were followed from fetal stage to two years of age. Low birth weight, neonatal ventilation therapy, and prematurity had no influence on incidence of acute otitis media. A correlation was noted between male gender and increase in all acute otitis media and respiratory infections. In a separate study, the presence of two or more older siblings in the family was closely correlated with all infections. The previous correlation was attributed to postnatal effects of sibling illness exposure (Alho, Koivu, Sorri, & et al., 1990).

Early cessation or absence of breast feeding was also associated with increased incidence of otitis media and viral respiratory infection. An infant acquires passive immunity through breast milk, however, the passive immunity ceases soon after
Acute otitis media


Environmental Effects

Multiple research studies have associated passive smoking with increased incidence of otitis media and respiratory infections (Porro, Calamita, Rana, Montini, & Criscione, 1992; Charlton, 1994; Entzel, Pattishall, Haley, Fletcher, & Henderson, 1992; Maw, Parker, Lance, & Dilkes, 1992). Air pollution in the form of cigarette smoke, sulfur dioxide, ozone, nitrogen dioxide, formaldehyde, and wood stove particulates is known to cause changes in the lower respiratory tract and irritation of nasal mucous membranes, though further research is needed to determine if the irritation leads to significant increase in pediatric ear, nose, and throat illnesses (Koltai, 1994).

Passive smoking has been highly correlated with respiratory illness (Porro, et al., 1992). Approximately 33% of the cases of otitis media with effusion occurred in children with parental smoking (Charleton, 1994). Entzel et al. (1992) obtained serum cotinine concentrations of children and determined children with elevated serum cotinine concentrations had longer duration of middle ear effusion than children with absent or decreased cotinine concentrations. This conclusion was also demonstrated by Maw, et al. (1992) where resolution of otitis media effusion was less frequent if mother or both parents smoked, and directly related to the number of cigarettes smoked.
Ponka, Nurmi, Saminen, and Nykyri (1991) found "the effects of passive smoking, number of siblings, number of household members, and incomes of families were not statistically significant (p. 230)," in relation to incidence of all childhood illness. The findings focused on the significance of child care arrangements and increased incidence of illness. This study was not specific for otitis media and respiratory illness. Diarrhea, eye infections, acute tonsillitis, and bronchitis were found to be increased in group child care settings (Ponka, et al., 1991).

Child care arrangement has been indicated as a contributing factor to increased rates of otitis media, respiratory illness, and enteric illness. Children in day care settings are at 50% greater risk for ear infections than children not in a day care, though risks decrease in home care settings with less than seven children (Hardy & Fowler, 1993). Rasmussen (1993) placed the risk for protracted secretory otitis media at 2.6 times normal for children in day-care for 12 or more months during the first four years of life. The conclusion was drawn that the larger the size of the child care group, the greater the exposure to respiratory pathogens which may cause otitis media (Hardy & Fowler, 1993).

Family Impact

Acute otitis media has a serious impact on family life and coping ability, especially if chronic recurrence or otitis media with effusion are present. A qualitative study by Wuest and Stern (1990) examined the influence of otitis media with effusion on family life and coping in a sample of 30 children from 12 families in New Brunswick, Canada. Families move through a process of learning to manage a child's illness
based on the effect of otitis media on the child, disruption of family life, and the family relationship within the health care system. Coping moves along the continuum of passive to active sequential management of otitis media within the family. The steps to family management are (a) acquiescing, (b) helpless floundering, (c) becoming an expert, and (d) managing effectively (Wuest & Stern, 1990).

The degree of impact that otitis media has on a family depends on the duration of illness. Comparison has been made between otitis media and chronic illness; however, most cases of otitis media with effusion or recurrent otitis media are time limited because of maturational changes in physiology and immune status (Wuest & Stern, 1990).

Data analysis of the 1988 National Health Interview Survey of 17,110 subjects (Newacheck & Taylor, 1992) included frequent or repeated ear infections in the reporting of childhood chronic illness prevalence, severity, and impact. Findings of this study placed respiratory allergies and repeated ear infections as highly prevalent chronic illnesses with respective prevalence rates of 9.7 per 100 and 8.3 per 100. Of these children, 66% had little or no activity limitation, 29% experienced some limitation of activity, and 5% had severe conditions causing "frequent bother and limitation of activity" (Newacheck & Taylor, 1992, p. 364).

**Common Treatments and Effectiveness**

Broad spectrum antibiotics remain the standard of care in the United states for most cases of acute otitis media, although the etiology may be bacterial, viral, or allergic in origin (Bernstein, 1995). When otitis media becomes recurrent or develops
Acute otitis media effusion, treatment becomes much more controversial and often involves tympanotomy tubes, adenoidectomy, antibiotic prophylaxis, or multiple combinations of antihistamines, decongestants, and steroids (Williams et al., 1993; Giebink, 1994).

**Prevention in Primary Care**

Giebink (1994) acknowledges current secondary prevention is expensive and antimicrobial prophylaxis reduces frequency of acute otitis media, but does not reduce the duration of otitis media with effusion. Primary interventions of breast feeding, smoking cessation, cleft palate identification, and vaccine administration are advocated as alternative interventions for otitis media prevention.

Otitis media and respiratory illness are interrelated, and provide another field for active primary prevention. Narce-Valente & Kligman (1992) and Kligman & Narce-Valente (1990) identify a child's visit to a physician for illness as a "teachable moment" when parents are open to screening and counsel related to passive smoking. When illness is seen as an opportunity, patient education and risk factor modification are possible with the goal of decreasing repeated episodes of illness.

Primary prevention for otitis media is not limited to smoking cessation, but can be expanded into the realm of all modifiable risk factors. Race, gender, and family history are not modifiable, but ample education may be provided in the primary care setting related to breast feeding, bottle propping, allergen exposure, day care exposure, and respiratory illness (Daly, 1994; Giebink, 1994).

Primary care practitioners recognize the significant benefits of primary prevention and health promotion, as well as traditional secondary and tertiary intervention. Primary
prevention in the form of patient education assembles the knowledge of contributing factors and aims at the elimination of factors to prevent the development of illness. Secondary and tertiary interventions respectively aim to resolve the illness and minimize the impact resulting from the disease (Leavell & Clark, 1965).

Bond and Hussar (1991) describe methods and strategies for improving medication compliance, beginning with the assessment of known risk factors for non-compliance. Risk factor identification is followed by development of an individualized treatment plan which includes patient participation and education related to illness, treatment, medications, home monitoring, and the incorporation of various compliance aids such as schedules, packaging, and follow-up evaluation and modification of the therapeutic regimen as necessary to achieve maximum compliance.

Improving medication compliance is the focus of the National Council on Patient Information and Education. Established guidelines for improving childhood medication compliance outlined in Table 1 have been developed, and are easily incorporated into the primary care setting (The National Council on Patient Information and Education, 1989).
Table 1.

<table>
<thead>
<tr>
<th>Goal</th>
<th>Practice</th>
</tr>
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</table>
| 1. Develop and practice good communication skills. | A. Elicit information about parental concerns  
B. Be friendly  
C. Avoid complex medical terminology  
D. Make instructions simple and specific (Repeat) |
| 2. Encourage children to be active participants in treatment. | A. Be aware of developmental theory  
B. Talk to the child  
C. Encourage and praise appropriate participation |
| 3. Motivate compliance by specifying benefits of treatment. | A. Explain monetary, temporal, situational, and physical benefits of compliance  
B. Encourage questions and provide answers |
| 4. Concrete steps to promote compliance. | A. Determine behavioral goals  
B. Explain diagnosis, treatment, and follow-up  
C. Involve parents in problem solving of barriers  
D. Simplify and tailor regimen to lifestyle  
E. Provide checklists, medication records, and written instructions.  
F. Model and rehearse treatment (measure spoon)  
G. Use positive feedback for parent and child  
H. Increase provider availability through telephone and office visits. |


Medication Compliance

Medication compliance is affected by several factors. Bond and Hussar (1991) identify disease, therapeutic regimen, and interaction between the health care professional and the patient as the major factors influencing medication compliance.

The previous factors assume patients want to have control over illness and treatment with the assistance of a supportive primary care provider. The primary care provider must consider patients' perceived threat from disease as well as individual hinderences
to adherence to prescribed treatment such as complexity, duration, safety, cost, and adverse effects (Bond & Hussar, 1991).

Medication compliance is more specifically related to prescribed daily dose frequency. Eisen, Miller, Woodward, Spitznagel, and Przybeck (1990) monitored the medication compliance of 105 patients receiving antihypertensive medications in electronic medication monitoring devices which recorded the date and time of medication removal. Results indicated medication compliance is improved from 59% on a three-time daily dosed medication to 74.9% on a two-time daily medication, and further increased to 83.6% compliance on a once-daily dosing regimen.

Pediatric medication compliance is dependent upon parental intervention. Parents must acquire developmentally appropriate medication administration strategies, as well as knowledge and sufficient motivation to comply with therapy. Additional factors contributing to pediatric therapeutic regimen compliance were discussed by Rapoff and Barnard (1991). These include age and gender of child, social class, inability of child to self-regulate, dysfunctional family situations, and adverse effects of medication.

Rapoff and Barnard (1991) reviewed existing literature regarding pediatric medication compliance, including three studies of antibiotic medication compliance for children diagnosed with otitis media. Trends identified in the review of literature indicate that medication compliance decreases over time of treatment and ranges between 5% compliance in low income public population samples to 63% in private practice middle-class population samples. The authors indicate medication compliance
measurement for all populations may be skewed by method of data collection.

**Medication Non-Compliance**

Medication non-compliance is the degree of non-adherence to a prescribed treatment regimen and is the result of multiple factors, including environmental, psychosocial, and financial variables. Morris and Schulz (1993) examined compliance from the patient's perspective and characterized taking medication as being a "psychological, interpersonal, and social process (p. 594)."

In the review, aspects of non-compliance were discussed with common examples, such as:

1) Negative physical experiences (side effects)
2) Outcomes desired by patient differed from physician
3) Self regulation for control of symptoms
4) Interference with daily life (e.g. diuresis, decreased quality of life perceived.)
5) Financial problems
6) Gambling and testing (e.g. quit anti-epileptic medication to see if still have seizures.)
7) Fear of medication
8) Poor patient-physician relationship
9) External sources of health information (e.g. family, friends, media, and advertising) (Morris & Schulz, 1993).

**Compliance Assessment**

Compliance is "defined as the degree of adherence to a prescribed drug regimen..."
"Accurate assessment of medication compliance requires a combination of subjective and objective measures. Indirect measures are more subjective and include self-report, interview, therapeutic outcome, pill count, and computerized monitors. Direct measures have higher sensitivity and specificity and include biological markers, pharmacological indicators, and assay of body fluids (Bond & Hussar, 1991; Pullar, Kumar, Tindall, & Feely, 1989; Rudd et al, 1989; Eisen et. al, 1990).

Pill counts are most commonly used to assess medication compliance by comparison of number of pills missing to number of pills and doses prescribed for a set period of time. The greatest limitation of this form of assessment is potential for manipulation by the patient in the form of dumping, loss, or combining daily doses (Rudd et al., 1989).

Pullar et al. (1989) conducted a study to assess medication compliance using both pharmacological indicator and return tablet count. Low-dose phenobarbital was used as a trace marker compounded with therapeutic oral hypoglycemics. The use of phenobarbital allowed for measurement of phenobarbital level-to-dose ratios compared to compliance by return pill count. Results indicated less than 50% of the patients whose pill count compliance was between 90% and 109% (e.g. excessive dosing or pill dumping may cause compliance greater than 100%) had phenobarbital level-to-dose ratios less than 90% of the lowest threshold control (Pullar et al., 1989).

Bandura's Social Learning Theory

Social learning theory describes the psychosocial aspects of health behavior as
well as methods to promote behavior change. Behavior can be associated with medication compliance research through the theory that behavior is dependent upon individual self-efficacy, self-confidence, and outcome expectations. The patient or caregiver may change behavior because of perceived threat of disease, benefit of medication, and belief in self-ability to carry out a behavior such as medication administration as ordered (De Geest, Abraham, Gemoets, & Evers, 1994).

De Geest et al. (1994) performed a qualitative study to assess long-term medication behavior self-efficacy with the development of an open-ended questionnaire. Based on Bandura's Social Cognitive Theory, personal attributes, behavior, and environmental factors were interrelated and provided the conceptual framework for measuring the self-efficacy of medication behavior in long-term therapies. The result was a reliable and valid instrument for the assessment of self-efficacy related to compliance behaviors.

**Ratings of Medication Influences Scale**

Weiden, et al. (1994) identified non-compliance with therapeutic neuroleptic regimens as a barrier to effective treatment of schizophrenia. To assist assessment of attitudes and behaviors which influence medication compliance, a longitudinal study of 115 schizophrenic out-patients was conducted using the Rating of Medication Influences Scale (ROMI). Part I assesses the patient's self perceived reasons for compliance (Table 2.), Part II assesses the patient's self perceived reasons for noncompliance (Table 2.), and Part III documents the rater's impressions of motivation for noncompliance and compliance with therapeutic regimens. Patient report
subscales provided information about compliance and non-compliance related items (Table 2.) Individual items were then statistically analyzed to determine reliability and validity.

Table 2.

<table>
<thead>
<tr>
<th>ROMI Compliance Items</th>
<th>ROMI Non-Compliance Items</th>
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<tbody>
<tr>
<td>Perceived benefit</td>
<td>No perceived benefit</td>
</tr>
<tr>
<td>Positive relationship with clinician</td>
<td>Negative relation with clinician</td>
</tr>
<tr>
<td>Positive relationship with therapist</td>
<td>Negative relation with therapist</td>
</tr>
<tr>
<td>Positive family belief</td>
<td>Practitioner opposed to medication</td>
</tr>
<tr>
<td>Relapse prevention</td>
<td>Access to treatment</td>
</tr>
<tr>
<td>Pressure/force</td>
<td>Financial obstacles</td>
</tr>
<tr>
<td>Fear of rehospitalization</td>
<td>Denial of illness</td>
</tr>
<tr>
<td></td>
<td>Medication is unnecessary</td>
</tr>
<tr>
<td></td>
<td>Desires rehospitalization</td>
</tr>
<tr>
<td></td>
<td>Distressed by side effects</td>
</tr>
<tr>
<td></td>
<td>Embarrassment or stigma</td>
</tr>
<tr>
<td></td>
<td>Substance abuse</td>
</tr>
<tr>
<td></td>
<td>Family opposed to medication</td>
</tr>
<tr>
<td></td>
<td>Lack of family support</td>
</tr>
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</table>

Interrater reliability for the ROMI was determined in a sample of 5 paired raters and 25 subjects (Weiden, et. al, 1994). Interrater reliability for the self-report compliance and noncompliance related items was adequate as indicated by Kappa coefficient >0.60 for all individual items except family support. All rater judgement items in Part III had unacceptable or marginal interrater reliability scores and were removed from use in the ROMI.

Validity of the ROMI was determined by analysis of internal consistency, principal components analysis, and correlation with other subjective measures of compliance and noncompliance. Cronbach’s alpha indicated moderate interitem
homogeneity. The Pearson correlation between the ROMI and the Drug Attitude Inventory at one month post-discharge was 0.56 (p<0.001) for compliance items, and 0.57 (p<0.001) for noncompliance items. In summary, the ROMI has been determined to be a reliable and valid instrument for the assessment of attitudes toward medications and factors related to medication compliance and noncompliance (Weiden, et. al, 1994).

Research Questions

This study was designed to answer the following research questions:

1. To what extent is there a relationship between antibiotic compliance as measured by residual medication measurement and self-report of selected factors affecting compliance (i.e. perceived benefit, relationship with clinician, family belief in medication, perception of illness, financial obstacles, and adverse reactions)?

2. To what extent is there a relationship between self-reported compliance and medication measurement after completion of antibiotic therapy?

3. To what extent is there a difference between parental rationale for medication compliance for groups receiving verbal instructions only versus written and verbal instructions for the home treatment of acute otitis media?

Definition of Terms

Acute otitis media: inflammation and infection of the middle ear, as well as acute symptoms of ear pain, fever, and/or nasal congestion diagnosed by pneumatic otoscopic examination by the primary care provider.

Compliance: a positive behavior in which the care giver incorporates knowledge
about acute otitis media with perceived benefit of prescribed antibiotic treatment for resolution of acute otitis media (Bond & Hussar, 1991). Compliance is "defined as the degree of adherence to a prescribed drug regimen. Full compliance means following the instructions of the prescriber (Cramer, 1995, p. S27)." Calculated as (Number of doses taken/Number of doses prescribed) x 100 (Eisen et al., 1990).

**Health promotion:** verbal and written education focused on assessed needs and knowledge deficit related to treatment of acute otitis media to assist the child to reach his/her optimum level of functioning with resolution of acute infection.

**Non-compliance:** the degree of non-adherence to a prescribed treatment.

**Outcome expectation:** the patient and provider's anticipated result for the physical and psychological condition following completion of a therapeutic regimen.

**Risk factor:** any environmental or demographic characteristic which has been indicated in research as associated with increased incidence of acute otitis media or respiratory infection. Examples include parental smoking, child age less than three years, day care attendance, and gender.

**Self-efficacy:** "the perception that one can master a certain task or perform adequately in a given situation (De Geest, et. al, 1994, p. 234)."
Chapter II

Method of Study

The problem examined in this study was the extent of compliance with antibiotic medication for the treatment of acute otitis media. Specifically, the relationship of factors contributing to medication compliance and noncompliance behavior were assessed with the potential outcome of determining the effectiveness of additional written educational materials to increase medication compliance in the treatment of acute otitis media.

Methodology

A descriptive study survey was conducted with a convenience sample of parents of children attending Spokane County Health District Pediatric Clinic between October and December 1996. The children of parents were selected upon diagnosis of acute otitis media by the primary care practitioner. Criteria for participation included: (a) child less than 12 years of age; (b) voluntary consent for participation; (c) primary diagnosis of current acute otitis media; and (d) child free from otitis media and/or effusion for a time span of 4 weeks or more. All children with a history of tympanotomy tube placement were eliminated from study on the basis of advanced treatment provided by an ear, nose, and throat specialist. The study had one parent withdraw after the initial visit and four declined participation. Ten parents completed all requirements of the study. Children were alternately divided at the time of consent into two groups, the first receiving verbal instructions (Group 1, n=6), and the second receiving written and
verbal instructions (Group 2, n=4) for the home care of a child with acute otitis media.

Primary physical examination, diagnosis of acute otitis media, and medical
treatment per protocol of broad spectrum oral antibiotic suspension was provided.
Informed consent was obtained by the researcher and nurse practitioner and recorded
on the signed Consent Form (Appendix B). Demographic data, as well as parental
report of lifetime otitis media history were obtained during the initial visit and recorded
on the Data Collection Guide (Appendix C).

All parents received verbal education regarding basic physiology, antibiotic
treatment, risk factors and options for modification to be shared with other family
members, and Group 2 received additional identical information in printed format
(Appendix D). On Day 2 of treatment, parents received a telephone call from the
researcher to answer any questions regarding the study or medication administration
record. On Day 11-14, compliance was assessed at a clinic visit with parental report on
a medication administration record (Appendix C). The researcher measured the
amount of remaining antibiotic suspension, and administered the Modified Ratings of
Medication Influences Scale (Appendix C) using a structured interview format at the
follow-up appointment between Day 11-14. Teaching regarding otitis media
pathophysiology and treatment as outlined in the written format was reinforced at
completion of the study and results made available to families upon request.

Setting

The study was conducted at three community based pediatric clinics in Spokane,
Washington. The population served by the clinics included families of low to medium
socio-economic status receiving primary Nurse Practitioner care through Spokane County Health District Pediatric Clinics. The clinics were conducted at several established sites to accommodate families with limitation in health care availability as well as transportation concerns.

Sample

A convenience sample of 10 parents of children less than 12 years of age who visited the clinics from October to December 1996 were invited to participate in the study. All children (male=9, female=1) were selected after the primary diagnosis of acute otitis media.

Instrumentation

The Ratings of Medication Influences Scale Parts I and II were used to assess parental perceptions of factors which influence individual medication compliance and non-compliance behaviors. Because of the similarities between medical and psychological treatment compliance behavior, the ROMI Rater Training Guide Supplement lists "common situations that commonly occur among 'medical' patients side-to-side with the specific ROMI items that ask for analogous issues among 'psychiatric' patients (Weiden, 1994, p. 1)". Based on this information, the ROMI Parts I and II were modified to assess factors related to medication compliance and noncompliance in the treatment of acute otitis media. The modified ROMI may be found in Appendix C. The researcher for this study obtained written consent to modify and reproduce the Ratings of Medication Influences Scale (Appendix E).
Human Subjects

Protection of human subjects included signed, informed consent and approval of the study obtained through the researcher's clinical research project committee at the Intercollegiate Center for Nursing Education and Washington State University Institutional Review Board prior to beginning the data collection. Permission to conduct the study was also obtained through Spokane County Health District (Appendix F). The Institutional Review Board Form was filed at Washington State University (Appendix A).

Parents of the children were informed by the researcher of the nature of the study as outlined on the consent form. Benefits of education and acute otitis media resolution were presented, as well as the risks of the study. Antibiotic therapy was explained, including possible adverse effects specific for the antibiotic of choice. Parents agreeing to participate in the study had the opportunity to ask questions of the researcher and received a copy of the signed consent form (Appendix B).

Ethical considerations included confidentiality and the right to decline compliance with prescribed antibiotic treatment. The researcher obtained written informed consent from parents to participate in the study. Confidentiality was maintained through locked filing of the data. Identifying data was collected using a combination of chart review, parental interview, and researcher assessment. Subjects were allowed to withdraw from the study at any time or decline compliance with prescribed medication with no prejudice or decrease in quality of care.
Chapter III

Findings

Statistical analysis was done using SPSS (1993), a computerized statistical program. Descriptive statistics were performed to determine the mean, median, mode, and standard deviation of demographic data. Pearson's product moment correlation was used to determine the degree of relationship between medication compliance as reported and measured, as well as between compliance and ROMI subscales and individual items (Burns & Grove, 1993).

Data from 10 parents of children (male=9, and female=1) with acute otitis media met criteria for inclusion in the study. Four children (40%) were given only verbal instructions about home treatment and six children (60%) were given both verbal and written instructions. The children ranged in age from 9 months to 4 years 10 months of age (mean 2.53 years). Sixty percent of the children had experienced prior ear infections, though medical documentation varied due to use of multiple care providers. Of the children who experienced prior episodes of otitis media, 50% (3 children) had a positive family history of recurrent otitis media.

Research Question 1

To what extent is there a relationship between antibiotic compliance as measured by residual medication measurement and self-report of selected factors affecting compliance (i.e. perceived benefit, relationship with clinician, family belief in medication, perception of illness, financial obstacles, and adverse reactions)?
Statistical analysis with Pearson's product moment correlation indicates no significant correlation between parental antibiotic compliance and total ROMI compliance scales (p = .367, coefficient 0.3204). Correlation coefficient for parental antibiotic compliance and total ROMI noncompliance scales was -0.2690 with p = .452. Individual ROMI compliance and noncompliance factors show no significant correlation to antibiotic medication compliance with all p > .05. See Appendix G.

Parental perception of the child's illness proved to be a strong motivation for medication compliance or noncompliance as reported in the semi-structured part of the modified ROMI (See Table 2). One parent did not fill the prescription because she felt the child was "doing better", though she did acknowledge the confirmed diagnosis of acute otitis media. Another parent completed the medication administration record with 100% reported and measured compliance with variation of less than 1.5 hours from scheduled dosing regimen. The mother reported the reason for exact compliance was that the family was living with friends after recent immigration to this country, and the ill child was fussy and disturbing to the crowded household (2 families with a total of 5 people in a 2 bedroom apartment).

Parental responses to the semi-structured questions in Part I and Part II of the Modified ROMI gave insight to the strong relationship of perception of illness to motivation for compliance (Table 3.). Responses to the non-compliance question were more varied and individual to family situation and the child's tolerance of the medication.
<table>
<thead>
<tr>
<th>Interview</th>
<th>“What is the main reason you are willing to give the medication?”</th>
<th>“What is the main reason you felt reluctant or wished you didn’t have to give medication during this illness?”</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>He needed it to get well.</td>
<td>None.</td>
</tr>
<tr>
<td>2</td>
<td>I would have given it if he had been sick or hurting, but he wasn’t.</td>
<td>He seemed better and has been fine without any medicine.</td>
</tr>
<tr>
<td>3</td>
<td>To make him feel better...it always helps.</td>
<td>None with this illness...if he had been allergic.</td>
</tr>
<tr>
<td>4</td>
<td>To make her better...only if the medicine is absolutely necessary.</td>
<td>Depends on the medication because allergies run in the family.</td>
</tr>
<tr>
<td>5</td>
<td>Baby needs to get well as soon as possible.</td>
<td>No reluctance, though he did have diarrhea which was inconvenient.</td>
</tr>
<tr>
<td>6</td>
<td>So he can get better.</td>
<td>No reason not to give, but it is hard to keep track with sitter and other parent.</td>
</tr>
<tr>
<td>7</td>
<td>To help with the pain and make the ears better.</td>
<td>Kids are hard to give medicine to... especially the more times a day it must be given.</td>
</tr>
<tr>
<td>8</td>
<td>To help him get better.</td>
<td>If he had been allergic or had a reaction.</td>
</tr>
<tr>
<td>9</td>
<td>So he would feel better. Ear infections hurt.</td>
<td>Not enough food in his stomach would make his tummy upset.</td>
</tr>
<tr>
<td>10</td>
<td>To help him get better.</td>
<td>No reluctance.</td>
</tr>
</tbody>
</table>

**Research Question 2**

To what extent is there a difference between self-reported compliance and medication measurement after completion of antibiotic therapy?
Pearson's product moment correlation of compliance report and compliance measurement values was 0.9141, p=.000. A significance value of <0.05 indicates near equivalence of measured and reported medication compliance.

Research Question 3

To what extent is there a difference between parental rationale for medication compliance for groups receiving verbal instructions only versus written and verbal instructions for the home treatment of acute otitis media?

Independent sample t-test shows no significant statistical difference (t=0.16, df=8, p=0.879) in compliance for the verbal and written educational group (Group 2), and the verbal education group (Group 1). Parental rationale, expressed as total modified ROMI Compliance items and Non-compliance items, shows no significant difference between Group 1 and Group 2. (See t-test values in Appendix F.)
Chapter IV
Discussion

The sample population demonstrated behaviors of varied compliance (0-100%) by report and residual medication measurement. Previous studies have indicated both indirect methods of medication compliance assessment are often subject to manipulation by the patients for the purpose of appearing more compliant than actual observation or other direct measures would validate (Bond & Hussar, 1991; Pullar et al., 1989; Rudd et al, 1989; Eisen et. al, 1990).

Though the results of statistical analysis showed no significant correlation between compliance and individual modified ROMI items, the subjective responses to the semi-structured interview questions (Table 2) reveal perception of illness to be a major influence for medication compliance with the goal of alleviating illness and pain expressed by all parents, to include the one who did not even fill the current prescription. Reasons for non-compliance were more varied with 50% (5) stating there were no reasons for not giving the medication this time, though 50% (5) also stated adverse reactions as concerns even if none were experienced during this episode of otitis media. One mother stated that medication was difficult to give to her child and that she has been less compliant in the past with multiple dose antibiotic regimens than with this antibiotic which was give once daily.

Findings of interest included canceled appointments (50%, n=5) due to reports of chaotic home environment (2), inclement weather (2), and no desire for a follow-up
exam (1). Two ROMI surveys were done over the phone because of inability of the parent to get to the clinic for a follow-up visit at the completion of antibiotic therapy, and 40% (4) required one to three rescheduled appointments because of "work", "forgotten appointment", and transportation difficulties. Telephone contact was difficult and required an average 3.6 calls to locate the parent for the 2 day telephone follow-up, with one parent receiving messages through a message phone because she is unable to afford her own phone. Five out of ten medication bottles were disposed of prior to the recheck at 11-14 days because "the medication was gone", and one medication administration record was "lost". These difficulties were not adequately expressed on the modified ROMI scale items, but were noted by the researcher as subjective comments which may have impact on future studies of compliance behaviors with a public health clinic population.

Antibiotic treatment included amoxicillin (7), trimethoprim-sulfisoxazole (1), cefixime (1), and amoxicillin clavulanate (1) liquid suspensions. Resolution of AOM was demonstrated in 80% (8) of the children, though unresolved infection persisted in two children. Of the unresolved AOM, both were treated with amoxicillin with calculated compliance ranging between 94.7% and 100% for the ten day treatment with amoxicillin.

Limitations

The results of this study are limited by the sample size, as well as the obvious gender bias. Gender bias was expected due to the non-modifiable risk factor of male gender increasing likelihood of recurrent acute otitis media. The use of parents who
are willing to consent to follow-up contact may result in self-selection of a more compliant population willing to report about behaviors and perceptions related to medication administration.

Presentation of the verbal instruction was a potentially confounding variable because rapport with established clients and differences in wording between the two care providers may change the effectiveness of the verbal education. Also, the study was conducted using only one episode of acute otitis media per child, therefore possibly missing trends in medication compliance behavior evident over repeated measures or prescription regimens.

Since the sample was selected from Spokane area parents of children attending county funded pediatric clinics, the results may not be generalizable to populations with greater cultural diversity or socioeconomic status. However, results may provide valuable information about compliance behaviors and parental perceptions in low to middle income families if the study is replicated with sufficient sample size.

Implications for Practice

Medication compliance requires assessment and intervention in the primary care clinical setting. Assessments including parental perception of illness and patient educational intervention regarding treatment were potentially applicable to the clinical setting.

The practitioner may apply social learning theory to improve self-efficacy and the empowerment of the patient. Improvement of the parent-provider relationship as well as rehearsal of steps to tailored home treatment provide the basis for increased
compliance. Elimination of barriers to treatment is more likely to occur when the parent fully participates in the planning and implementation to alleviate a child's discomfort related to acute otitis media.

The efficacy of written materials in addition to verbal instruction was not supported in this study, nor by Schwartz-Lookinland, McKeever, and Saputo (1989). Schwartz-Lookinland et al. emphasized the importance of the client-provider relationship and provision of information during clinical contact to increase client satisfaction and compliance in their study of Hispanic mothers with children diagnosed with AOM. Emotional arousal served as the initial event to motivate action to alleviate the child's discomfort. Recommendations included interventions to increase self-esteem and client satisfaction through skill acquisition (i.e. how to use a medication syringe) and verbal education with longer client provider contact for positive reinforcement. The use of written educational materials and medication calendars when available should not be abandoned because of theoretical, as well as actual increase in compliance in previous studies (Zenk & Ma, 1989).

Recommendations to increase compliance with follow-up appointments includes telephone contact (Jones, Jones, & Katz, 1989) and selective elimination of the ear re-check at day 11-21 of treatment (Hathaway, Katz, Dershewitz, & Marx, 1994). Hathaway et al. found that in children >15 months of age with no symptoms of illness after antimicrobial treatment for AOM, the parental assessment of ear infection resolution was accurate in 97.6% of the children, therefore making the frequently missed follow-up appointment unnecessary for many children. Selective posttreatment
follow-up is recommended for children at risk for persistent or recurrent otitis media, symptomatic children, and children less than 15 months of age.

Assessment of medication compliance may easily be done with medication administration records to assist the parents with scheduling, as well as provide documentation for discussion of difficulties with medication administration should initial treatment fail. The subjects in this study did not appear to have manipulated the subjective medication administration records as shown by the near equality of reported and measured compliance.

Clinically, the antimicrobial failures were similar to previous studies (Barnett & Klein, 1995). Expected resolution is 62% when treated with the inappropriate antimicrobial drug, 93% with appropriate antibiotic selection, and 80% when non-bacterial AOM is present. Streptococcus pneumoniae types 19, 23, 6, 14, 3, and 18 are most commonly isolated in 30-40% of AOM cases with penicillin resistance varied per geographic area, haemophilus influenzae in 21% of cases, and moraxella catarrhalis in 12%.

The 20% antimicrobial failure rate of this study may be related to penicillin resistance caused by beta-lactamase producing bacteria, though amoxicillin remains a first line antimicrobial for the treatment of acute otitis media. If treatment fails, treatment with a beta-lactamase stable agent such as an oral cephalosporin, TMP-SMX, or erythromycin-sulfisoxazole is suggested (Barnett & Klein, 1995; Otitis Media Guideline Panel, 1994). Barnett and Klein (1995) also encouraged naso-pharyngeal swabbing and cultures for acutely ill appearing children with resistant AOM.
Conclusions

Parental rationale for antibiotic medication compliance for the treatment of acute otitis media is dependent upon perception of illness. Many other factors have been suggested in previous studies, though further study is needed to confirm the relationship of any individual items discussed from the Modified Ratings of Medication Influences Scale. Continued emphasis on patient and parental education and empowerment should be considered valuable intervention for the nurse practitioner to increase compliance with therapeutic regimens.
References


Appendix A

Washington State University Human Subject Review

Summary Form
Principal Investigator: Wendy A. Hughes, R.N. Academic Title: Graduate Student
Department/Division: Intercollegiate Center for Nursing Education/FNP Program
Zip Code: 99204-5296 Telephone: (509) 324-7334
Project Title: Influences of Antibiotic Medication Compliance for the Treatment of Acute Otitis Media in Children
Anticipated Starting Date: September 1996
Anticipated Termination Date: November 1996
Is the project seeking funds? Yes ___ No XXX
Granting Agency: 

TYPE OF PROJECT: Check the review procedure required (attach Human Subject Review Worksheet).

___ Exempt

XXX Expedited

___ Full Board Review

ABSTRACT: Briefly describe the purpose, procedures and research design (be sure to include what the subjects will do)

The problem to be examined in this exploratory descriptive study is the description of parental rationale for compliance with antibiotic medication for the treatment of acute otitis media for groups receiving verbal instructions and written instructions for the home treatment of acute otitis media. The purpose of this study is to assess factors which contribute to antibiotic medication compliance and to determine parental rationale for medication compliance. Factors identified as relevant to medication compliance include: perceived benefit, relationship with clinician, family belief in medication, perception of illness, financial obstacles, and adverse reactions (Weiden, Rapkin, Mott, Zygment, Goldman, Horvitz-Lennon & Frances, 1994). Factors contributing to therapeutic regimen compliance and non-compliance will be identified in this study.

This study is designed to answer the following research questions:
1. To what extent is there a relationship between antibiotic compliance and perceived benefit, relationship with clinician, family belief in medication, perception of illness, financial obstacles, and adverse reactions?
2. To what extent is there a relationship between self-reported compliance and medication measurement after completion of antibiotic therapy?
3. To what extent is there a relationship between medication compliance for the group receiving written instructions and the group receiving verbal instructions for the home treatment of acute otitis media?

A convenience sample of the parents of 30 children attending Spokane County Health District Pediatric Clinic will be obtained upon screening for the diagnosis of acute otitis media by the primary care practitioner. Criteria for participation include: (a) child less than 7 years of age; (b) voluntary consent for participation; (c) primary diagnosis of current acute otitis media; and (d) child free from otitis media and/or effusion for a time span of 4 weeks or more. All children with a history of tympanotomy tube placement will be eliminated from study on the basis of advanced treatment provided by an ear, nose, and throat specialist.

Primary physical examination, diagnosis of acute otitis media, and medical treatment per protocol of broad spectrum oral antibiotic suspension will be provided. Informed consent will be obtained, as well as parental report of lifetime otitis media history. Demographic data will be obtained during the initial visit.

The parents will receive verbal education regarding basic physiology, antibiotic treatment, risk factors and options for modification to be shared with other family members, and the experimental group will receive identical information in printed standard format. On the Day 2 of treatment, parents will receive a telephone call from the researcher to answer any questions regarding the study or medication administration record. On Day 11-14, compliance will be further assessed at a clinic visit by parental report on a medication administration record and by researcher measurement of remaining antibiotic suspension, as well as administration of the Modified Ratings of Medication Influences Scale in a structured interview format. Teaching regarding otitis media pathophysiology and treatment as outlined in the written guide will be reinforced at completion of the study and results will be made available to families upon request.

Principal Investigator: The information provided in this form is accurate and the project will be conducted in accordance with applicable Federal, State and University regulations.

Signature __________________________ Date ______________

Faculty Sponsor (If principal investigator is a student.): The research is in accordance with applicable Federal, State and University regulations.

Signature __________________________ Date ______________

Chair, Dean or Director: The research is in accordance with applicable Federal, State and University regulations.

Signature __________________________ Date ______________

Institutional Review Board: This project has been properly filed as required by Federal, State and University regulations.

Signature __________________________ Date ______________

WSU IRB APPROVED

DATE 10-14-96
INITIALS MVM
WSU HUMAN SUBJECTS REVIEW: REVIEWER’S COMMENTS

P.I.: Wendy Hughes, Nursing, WSU-ICNE (5291)
Title: Influences of Antibiotic Medication Compliance for the Treatment of Acute Otitis Media in Children
Review Category: Expedited
Review Type: Modification
Date Sent To Reviewer(s): 10/31/96
Reviewer Name(s): Michael Renee Dennis Warner

Coordinator’s Comments
Wants to Include older children
Originally Approved: 10/10/96

Reviewer’s Comments & Questions (attach additional sheets as necessary)

1. Data Confidentiality:
   OK

2. Informed Consent Procedures:
   OK

3. Risk/Benefit Ratio:
   Favorable

4. Subject Recruitment/Exclusions:
   OK

5. Scientific Validity:
   Good

6. Additional Comments:
   Increased number of children from 7 to 12.
   Adequate justification provided.

WSU IRB APPROVED
DATE 11-4-96
INITIALS M.D.

REVIEWER: Please indicate your recommendation below and return this form to OGRD, campus zip 3140.
Reviewer’s Recommendation: APPROVE DEFER DENY UPGRADE REVIEW CATEGORY
Reviewer’s Signature: Dennis Renee Warner Date: 1 Nov. 96
Date Received From Reviewer(s): 11-4-96
Appendix B

Subject Consent Form
Appendix B

Otitis Media Medication Consent Form

I am Wendy Hughes, a student in the Graduate Program at Washington State University, Intercollegiate Center for Nursing Education. I am conducting a research study to evaluate the factors which contribute to medication compliance and noncompliance for antibiotic treatment of children for acute otitis media (ear infection). The College of Nursing and the Washington State University Institutional Review Board have approved this research project.

You have been chosen because you are the care giver of a child 7 years of age or less being screened for acute otitis media. It is important for you to understand that participation is voluntary and that you may withdraw at any time without prejudice.

If you agree to participate, your participation in the study will include the following:
* An interview during this office visit about your child's name, age, and frequency of ear infections (Ten minutes in duration.).
* A physical examination to confirm diagnosis of a middle ear infection (Ten minutes)
* A prescription for antibiotic treatment of the ear infection
* A demonstration of the correct way to administer the medication using a standard medication measurement device (Five minutes).
* You will have the opportunity to discuss the diagnosis and treatment of ear infections. Some care givers will also receive a written pamphlet about ear infections.
* You will receive a medication schedule to keep track of dates and times the medication is given (Ten minutes daily for ten days).
* On Day 2 of antibiotic treatment, you will receive a telephone call to discuss use of the medication schedule (Five minutes).
* A re-check will be scheduled to assess for resolving otitis media on Day 11-14 of treatment.
* At the final office visit, any remaining medication or container will be collected and a three page survey of medication beliefs will be done by the researcher during the interview for completion of the research study (15 to 30 minutes).

Benefits of participation include learning about children's ear infections. Your child will receive routine screening and care for the diagnosis and treatment of acute otitis media (ear infection) regardless of participation in this study. Potential risks include disruption of daily routine to complete the medication administration record and disclosure of personal beliefs regarding things that make it easy or difficult to give the antibiotic to your child.
All of the data gathered in this study will be kept confidential. The identity of the child or parents will not be revealed when the study is reported or published.

If you have any questions, please ask the primary practitioner or call Wendy Hughes, RN (324-1686). You will be offered a copy of this form to keep.

*************************************************************************************************

I have read the Otitis Media Medication Form and have had the opportunity to have the nature, demands, risks, and benefits explained to me, and have decided to participate. I also understand that this consent form will be filed in a locked, secure area with access restricted to the principal investigator or authorized representatives of the particular department. I will receive a copy of this document, and may withdraw from participation in this study at any time after signing this document.

______________________________  __________________________
Signature of or Legal Guardian   Date

______________________________  __________________________
Signature of Witness or Investigator   Date

Wendy Hughes, RN
Intercollegiate Center for Nursing Education
Appendix C

Data Collection Guide
Appendix C

Data Collection Guide
Questions for Parents

Date

1. Age ____ months/years
2. Gender: Male/Female

History
3. History of otitis media:
   a. Episodes reported ____
   b. Medical documentation ____
4. Family history of recurrent otitis media: Y/N, if Yes, then who?

5. Name of child

6. Names of parents

7. Address

8. Phone Number

9. Clinic Care Provider

10. Date of telephone contact

11. Date of exit interview

12. Assessment of otitis media

13. Percent compliance report (see chart)

14. Amount of medication remaining (in milliliters)

15. Amount of medication dispensed (in milliliters)

16. Amount required for prescribed dosing (in milliliters)

17. Percent compliance by medication measurement
Medication Administration Record

Antibiotic: ________________________________ ________________________________

Give _____ milliliters by mouth ______ times daily for 10 days.

<table>
<thead>
<tr>
<th>Day</th>
<th>Time - Dose 1</th>
<th>Time - Dose 2</th>
<th>Time - Dose 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>
Rating of Medication Influences
Alteration of ROMI by Dr. Peter Weiden

Parent's name: _______________________________________________________

Date _______________________

Rater's name: _______________________________________________________

BEGINNING THE INTERVIEW:

A) SEMI-STRUCTURED INTERVIEW
   For interviewing patients with whom you are not well acquainted, it is helpful to
   begin the interview with a few background questions. Reviewing the overall
   situation and setting will help you obtain more accurate information regarding
   factors which directly affect compliance.

   Suggested prompt:
   "I'm trying to learn about people's attitudes toward giving antibiotic medications
to children. I'd like to understand what makes people willing to give medications
and what makes them reluctant to give medication. But, before I ask you about
your opinions, I need to ask you a little background information."

   You should ask about the following general areas which may impact on
compliance. The topics include:
(1) Living situation (e.g. family members, others in residence).

   ________________________________________________________________
   ________________________________________________________________
   ________________________________________________________________

(2) Treatment setting.

   ________________________________________________________________

(3) Prescribed medication regimen (specific antibiotic, dose, frequency, and
duration of treatment, include other current medications).

   ________________________________________________________________
   ________________________________________________________________

(4) Parent's overall attitude toward treatment and medication (positive vs.
   negative).

(5) The family's and care giver's overall attitude toward treatment and
   medication.
B) STRUCTURED INTERVIEW

"Now I'd like to ask you some questions about why you give the medication to your child. There are no right or wrong answers, it's just what you think. I'm only interested in your opinion, not what your doctor or family may think."

Begin the interview with an open ended question, such as, "What is the main reason you are willing to give medication?"

"Now I am going to read you some reasons other people are willing to give medication to children. Please tell me if any of these reasons have influenced your willingness to give your child medication during this illness."

PART I: REASONS FOR COMPLIANCE

"ARE YOU WILLING TO GIVE YOUR CHILD MEDICATION BECAUSE":

1. PERCEIVED DAILY BENEFIT NA 1 2 3 9
   You believe the medication makes your child feel better?
   None Mild Strong

2. POSITIVE RELATION WITH PRESCRIBING CLINICIAN 1 2 3 9
   Your relationship with your child's primary care provider influences you?

3. POSITIVE RELATION WITH THERAPIST **Not applicable to pediatric population*** 1 2 3 9
   Your relationship with your therapist influences you?

4. POSITIVE FAMILY BELIEF 1 2 3 9
   Someone in your family or a friend believes that your child should take the medicine?

5. RELAPSE PREVENTION 1 2 3 9
   You believe giving medication prevents your child's illness or symptoms from returning?
<table>
<thead>
<tr>
<th></th>
<th>PART II: REASONS FOR NONCOMPLIANCE</th>
</tr>
</thead>
</table>
| 6. | PRESSURE/FORCE  
You are pressured or forced to give the medication? |
| 7. | FEAR OF HOSPITALIZATION  
You are afraid your child may worsen and require hospitalization or surgical treatment for ear infections (tube placement)? |

**PART II: REASONS FOR NONCOMPLIANCE**

"Even if you always give your child's medication, there may be times when you are reluctant to give it, or wish you didn't have to. What is the main reason you felt reluctant or wished you didn't have to give the medication during this illness?"

- [ ] [ ] [ ] [ ]
- [ ] [ ] [ ] [ ]
- [ ] [ ] [ ] [ ]
- [ ] [ ] [ ] [ ]

"Now I am going to tell you some reasons other parents are reluctant to give their child's medication. Please tell me if any of these reasons apply to you."

"ARE YOU RELUCTANT TO GIVE YOUR CHILD'S MEDICATION BECAUSE":

<p>| | | | | |</p>
<table>
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</thead>
</table>
| 8. | NO PERCEIVED DAILY BENEFIT  
You believe the medication does not help your child feel better? |
| 9. | NEGATIVE RELATION WITH CLINICIAN  
Your bad relationship with your child's prescribing primary care provider influences you? |
| 10. | NEGATIVE RELATION WITH THERAPIST **Not applicable to proposed population** |
| 11. | PRACTITIONER OPPOSED TO MEDICATIONS  
One of your practitioners does not believe your child need to take the medication? |
| 12. | FAMILY/FRIEND OPPOSED TO MEDICATION  
Someone whose opinion is important to you is against your child taking the medication? |
13. ACCESS TO TREATMENT PROBLEMS
You have difficulty getting to your appointments, and/or getting the medication?

14. EMBARRASSMENT OR STIGMA OVER MEDICATION/ILLNESS
You have inconvenience related to day care medication administration or refusal to admit an ill child?

15. FINANCIAL OBSTACLES
You don't have enough money to pay for treatment or medication?

16. ALTERNATIVE TREATMENT
You would rather give over-the-counter medications, home remedies, or cultural healing to treat your child's infection?

17. DENIAL OF ILLNESS
You don't believe your child has an ear infection?

18. DISTRESSED BY SIDE EFFECTS
The side effects of the medicine are too upsetting to you or your child?

19. DESIRES ADVANCED TREATMENT
You would feel more comfortable if your child received surgical treatment for ear infections?


Part B
1. Adverse effects of antibiotic (Please check all that apply.).
   ___ Vomiting
   ___ Diarrhea
   ___ Rashes
   ___ Anaphylaxis (Serious reaction requiring emergency treatment for respiratory and systemic allergic reaction).
   ___ Other--Please list.
Appendix D

Otitis Media Educational Pamphlet
Otitis Media

a guide to ear infections

A - The middle ear

B - Eustachian tube
OTITIS MEDIA

Otitis media is caused by bacterial or viral infection of the middle ear (A). This often occurs with "cold" or "allergy" symptoms, such as runny nose and cough. Ear infections are common in children less than three years of age, because the horizontal direction of the eustacian tube (B) is not as effective for draining fluid from the middle ear as the adult eustacian tube.

SIGNS OF ILLNESS

* fever
* pulling at ears
* drainage from ear
* irritability and pain when lying down
* vomiting
* runny nose
* cough
* difficulty hearing
* fatigue
* loss of appetite

TREATMENT

The goal of treatment is to kill the bacteria and relieve discomfort.

Your child's antibiotic is _______________.
Give ___ ml/tsp by mouth ___ times daily for ____ days.

Remember...
* Try not to miss doses.
* Give the antibiotic as directed.
* Do not save leftover antibiotic because it loses its strength after 14 days.

Ear infections hurt worse at bedtime, and may cause a fever greater than 102 degrees F until the antibiotic begins to work. For these reasons, you may give acetaminophen or ibuprofen as directed.

FOLLOW-UP

The practitioner will re-check your child's ears in 2 to 3 weeks for resolving infection.

Your appointment is:
Date ____________
Time ______________

SEEK MEDICAL ATTENTION IF...

* Fever and pain persist after 48 hours of antibiotic treatment.
* Your child develops a stiff neck or severe headache.
* Your child seems to be getting worse.
* Your child vomits the antibiotic.
Appendix E

Letter of Permission
Appendix E

July 23, 1996

Wendy A. Hughes
1722 W. Shannon
Spokane, WA 99205

Dear Wendy,

Thank you for your letter and your interest in the ROMI. It is very exciting for us to hear that the ROMI has potential for application in diverse settings and populations. In fact, although we designed the ROMI with a schizophrenic population in mind, we hoped that it could ultimately make a valuable contribution to investigations on compliance in general.

You have my permission to modify the ROMI in any way that is meaningful to your project. I am enclosing a copy of the training guide and the article which appeared in Schizophrenia Bulletin describing the development and psychometric properties of the ROMI. I would be quite interested in learning about the results of your study and the manner in which the ROMI was utilized. Please stay in touch and keep me abreast of your work.

Sincerely,

Peter Weiden, M.D.
Schizophrenia Program
St. Luke's/Roosevelt Hospital
Dept. of Psychiatry
411 West 114th Street
Suite JB
New York, N.Y. 10025
October 23, 1996

Wendy Hughes, RN, BSN
1722 W. Shannon
Spokane, Washington 99205

Dear Wendy,

We have reviewed your request to work with our Nurse Practitioner, Brad Hametiaux as you conduct your clinical research project looking at medication compliance behaviors of adult caregivers of children with acute otitis media. Brad is very willing to work with you and the project is clearly outlined. As the Director of Community and Family Services, I am willing to have you work with Brad at our facility to conduct your research study.

I would be interested in having you share your results with our staff when the project is completed.

Sincerely,

Barbara Feyh, RN, MS
Director,
Community and Family Services
Spokane County Health District
Appendix F

Pearson's Correlation Coefficients
### Pearson's Correlation Coefficients

<table>
<thead>
<tr>
<th>Modified ROMI Scale Items</th>
<th>Compliance Measured</th>
<th>Compliance Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item 1 - Perceived benefit</td>
<td>$r = . , p = . $</td>
<td>$r = . , p = . $</td>
</tr>
<tr>
<td>Item 2 - Positive relationship</td>
<td>$r = .1733 , p = .632 $</td>
<td>$r = .0970 , p = .790 $</td>
</tr>
<tr>
<td>Item 4 - Positive family belief</td>
<td>$r = .4408 , p = .202 $</td>
<td>$r = .3215 , p = .365 $</td>
</tr>
<tr>
<td>Item 5 - Relapse prevention</td>
<td>$r = -.2117 , p = .557 $</td>
<td>$r = -.2625 , p = .464 $</td>
</tr>
<tr>
<td>Item 6 - Pressure/force</td>
<td>$r = .1501 , p = .679 $</td>
<td>$r = .2828 , p = .428 $</td>
</tr>
<tr>
<td>Item 7 - Fear of hospitalization</td>
<td>$r = .2949 , p = .408 $</td>
<td>$r = .4143 , p = .234 $</td>
</tr>
<tr>
<td>Total Compliance Subscale</td>
<td>$r = .3481 , p = .324 $</td>
<td>$r = .3204 , p = .367 $</td>
</tr>
<tr>
<td>Item 8 - No perceived benefit</td>
<td>$r = . , p = . $</td>
<td>$r = . , p = . $</td>
</tr>
<tr>
<td>Item 9 - Negative relationship</td>
<td>$r = .1501 , p = .679 $</td>
<td>$r = .2239 , p = .534 $</td>
</tr>
<tr>
<td>Item 11 - Practitioner opposed</td>
<td>$r = -.2432 , p = .498 $</td>
<td>$r = -.1897 , p = .600 $</td>
</tr>
<tr>
<td>Item 12 - Family opposed</td>
<td>$r = -.9881 , p = .000 $</td>
<td>$r = -.8956 , p = .000 $</td>
</tr>
<tr>
<td>Item 13 - Access to treatment</td>
<td>$r = . , p = . $</td>
<td>$r = . , p = . $</td>
</tr>
<tr>
<td>Item 14 - Stigma of illness</td>
<td>$r = . , p = . $</td>
<td>$r = . , p = . $</td>
</tr>
<tr>
<td>Item 15 - Financial obstacles</td>
<td>$r = -.2273 , p = .528 $</td>
<td>$r = .0353 , p = .923 $</td>
</tr>
<tr>
<td>Item 16 - Alternative treatment</td>
<td>$r = -.2468 , p = .492 $</td>
<td>$r = -.2319 , p = .519 $</td>
</tr>
<tr>
<td>Item 17 - Denial of illness</td>
<td>$r = . , p = . $</td>
<td>$r = . , p = . $</td>
</tr>
<tr>
<td>Item 18 - Side effects</td>
<td>$r = .1800 , p = .619 $</td>
<td>$r = .3800 , p = .279 $</td>
</tr>
<tr>
<td>Item 19 - Desires advanced tx</td>
<td>$r = .0363 , p = .921 $</td>
<td>$r = -.1885 , p = .602 $</td>
</tr>
<tr>
<td>Total Noncompliance Subscale</td>
<td>$r = -.4097 , p = .240 $</td>
<td>$r = -.2690 , p = .452 $</td>
</tr>
</tbody>
</table>

Note: Items represented as $r = $ correlation coefficient and $p$ is the level of significance.

Statistically significant items are present if $p < 0.05$. Items represented as $(r = . , p = . )$ indicate that a correlation coefficient could not be calculated.
Independent t-Test Values
Comparison of Groups Receiving Verbal and Written Education

<table>
<thead>
<tr>
<th>Category</th>
<th>t-value</th>
<th>Degrees of Freedom</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication Compliance</td>
<td>t=.18</td>
<td>7.68</td>
<td>p=.862</td>
</tr>
<tr>
<td>Compliance Subscale</td>
<td>t=1.67</td>
<td>7.92</td>
<td>p=.135</td>
</tr>
<tr>
<td>Noncompliance Subscale</td>
<td>t=-.69</td>
<td>6.39</td>
<td>p=.514</td>
</tr>
</tbody>
</table>