Phase I – Planning Grants for
Collaborative and Multidisciplinary Pilot Research (CaMPR)
Irving Institute for Clinical and Translational Research of Columbia University

TITLE: Improving Appropriate Use of Antibiotics for URI in Children of Recently Immigrated Latinos

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Improving Appropriate Use of Antibiotics for URI in Children of Recently Immigrated Latinos

Research Aim

Antimicrobial resistance is one of the most pressing public health issues facing the world today, and there is consistent evidence for a link between antibiotic use and increasing antimicrobial resistance in the community. Nevertheless, inappropriate use of antimicrobials, particularly for viral upper respiratory infections (URI), continues to be a global problem. Reasons for this include public expectations and demand for medication, lack of understanding about the ineffectiveness of antibiotics against viral illness, and the ease of access to antibiotics without prescription in many parts of the world. In addition, improper use of prescribed antibiotics compounds this problem. Antibiotic misuse and resistance are more common in countries in which antibiotics are available over the counter and in which cultural patterns regarding medication use and beliefs about medication effectiveness differ. Latinos represent the fastest growing 'minority' population in the U.S. and have generally immigrated from countries in which antibiotics are available without prescription. Antibiotics are readily available without prescription in local bodegas (small independent grocery stores), botanical stores, and small independent pharmacies in New York City, as is the case in other urban areas with large immigrant populations from countries in which antibiotics are readily obtained over-the-counter, including South and Central America, Africa, and most of Asia. Although this problem has been recognized for years by enforcement agencies, the magnitude of the problem (there are >7,000 bodegas in Manhattan alone) and the cultural norms of many recent immigrants have been stumbling blocks to effective intervention. Furthermore, even when antibiotics are properly prescribed, families may not take them correctly due to problems with health literacy. There is an especially high risk of problems with health literacy leading to medication errors in non-English speaking, immigrant populations.

Children have an extraordinary number of URIs yearly. Parents commonly seek antibiotics for their child’s URI since many do not know that a virus is the usual cause of the common cold; many also believe that antibiotics kill viruses. They seek antibiotics not only from their child’s health care provider, but also from local bodegas. Therefore, parents of young children are prime targets for interventions to decrease antimicrobial resistance.

The long term goal of this project is to develop and test an intervention to decrease inappropriate antibiotic use for URI in children among recently immigrated Latino community members, based on the CDC action plan to combat antimicrobial resistance. The specific aim of this planning grant is to bring together a new collaborative team to develop a tailored, culturally appropriate intervention using the Precede-Proceed Health Education Model, to address predisposing, enabling, and reinforcing factors which result in judicious and appropriate antibiotic use among families of recently immigrated Latinos. The tools developed with this planning grant will then be incorporated into a protocol for a future large randomized clinical trial.

Public Health Significance

Antimicrobial resistance is one of the most pressing public health issues facing the world today, threatening to overturn the great strides that we have made over the last century in reducing the threat of infectious diseases. The consequences are grave. An increase in antimicrobial resistance can result in prolonged illness, longer periods of infectivity, and a greater risk of death. It also results in the need for higher cost drugs. Two main causes of antimicrobial resistance are the misuse of antibiotics when unnecessary, especially for viral illness like upper respiratory infections, and the incorrect use of prescribed antibiotics. Children aged 6 months to 3 years have on average 3 to 5 episodes of URI per year, most occurring during the winter months. Children in daycare or other group activities are at higher risk, and it has been specifically shown that respiratory infections are common among children in NYC Head Start Programs. Upper respiratory infections can be associated with symptoms such as fever, poor eating and sleeping, symptoms which can trigger parents to seek antibiotics. Indeed, 56% of Latino homemakers and bodega employees surveyed in NYC reported that antibiotics helped cure a cold and 72% reported that antibiotics would help prevent an ear infection. In a recent survey in northern
Manhattan, 39% of 631 Latino households (n=2,840 individuals) reported that one or more persons had taken antibiotics in the previous 30 days, a rate even higher than that reported in a prevalence survey over a decade ago in Mexico.\(^7,\,16\) Antibiotic use in the community has been directly linked to resistance, not only among persons taking antibiotics, but antibiotic use by one person in close living quarters (child care centers, military) leads to the transmission and colonization of resistant organisms to others.

Parents in our community who seek antibiotics for a child’s URI obtain them in three main ways, through provider prescription, through purchase in a foreign country and through purchase at a local bodega. Inappropriate prescribing of an antibiotic for viral URI has been associated with certain patient characteristics including lower patient income,\(^14\) a perception by the physician that the patient expects an antibiotic,\(^15\) and being a pre-school and low-income child. Almost 20% of 217 Latinos living in South Carolina admitted acquiring antibiotics outside the U.S. and 16.4% reported transporting these into the country.\(^3\) This is likely to represent under-reporting, since most community members know that these practices are illegal. Antimicrobial agents are sold over-the-counter in bodegas and other independent stores in U.S. neighborhoods, particularly those which have a high prevalence of recent immigrants from countries in which selling antibiotics without prescription is legal. Community members and bodega employees report that selling antibiotics without prescription is perceived as performing a public service and meeting an unmet demand.\(^3\) In fact, in many other countries traditional and unlicensed providers commonly provide care, advice and treatment for illness.

Even when antibiotics are properly prescribed, families may not take them correctly. Approximately 25% of the adult population in the U.S. cannot understand written materials that require basic reading proficiency.\(^17\) Although miscommunication is prevalent among all patient subgroups, parents at greatest risk of failing to understand medication instructions are those residing in low-income or inner-city communities. The Institute of Medicine found that 40 million people have trouble linking information from that found on a dosage table to instructions provided by their physician.\(^18\) In a study of patients at two public hospitals, investigators found that 24.3%-58.2% of patients did not understand directions to take medication on an empty stomach.\(^19\) Therefore, if a parent is unable to read or fully understand prescription labels and medication instruction, incorrect drug usage is likely. In an informal survey of 48 adult in- and out-patients at NewYork-Presbyterian Hospital, 60% of had inadequate functional health literacy, with Spanish speakers at greatest risk; 85% of the Spanish-speaking participants as compared with 38% of the English-speaking patients had inadequate literacy.

In 2001, a multiagency federal task force led by CDC issued a blueprint for public action to combat antimicrobial resistance (http://www.cdc.gov/drugresistance/actionplan/). Among the top action items were public health education campaigns to promote the appropriate use of antibiotics. They recommend culturally appropriate educational and behavioral interventions to (1) educate people about antimicrobial resistance, in particular the non-necessity of antibiotics for viral illnesses, and (2) improve patient adherence to appropriate therapies. They specifically target community-based programs that serve selected populations and communities such as daycare centers and schools. For example, several studies have confirmed that persons with more knowledge about antibiotics were less likely to request them for URI.\(^26-28\) As part of the CDC’s “Campaign for Appropriate Use of Antibiotics in the Community”, educational materials have been prepared and distributed, and a clinical trial was conducted to assess the effectiveness of these materials among a predominately white population in northern Wisconsin.\(^20\)

While community-based interventions have demonstrated some improvements in antibiotic prescribing and use,\(^21-24\) it is likely that interventions seeking to impact antibiotic use in a recently immigrated Latino families need to be targeted specifically to their needs.\(^29\) A large proportion of the recently immigrated population obtains antibiotics by other means, and use of these drugs remains unaccounted for among this group. The cultural beliefs and practices among the Latino population are sustained within the community when persons immigrate to the U.S. A program with a long-term impact on the use of antibiotics without prescription will require community-based partnerships and participatory interventions, and there is evidence that such a specifically targeted approach could be successful.\(^30\) This proposed planning grant will test a framework and develop an intervention that
could be applied to other ethnic groups to develop culturally relevant, sustainable interventions to impact the judicious and appropriate antibiotic use among families of recently immigrated Latinos.

Phase I Multidisciplinary Approach

Research team. The research team members bring interdisciplinary expertise from the College of Physicians and Surgeons, Mailman School of Public Health and School of Nursing, Table 1. This is a newly developed team that has come together specifically for this planning grant and has not worked together before. This planning grant will afford us the opportunity to forge new collaborations between several schools and departments, and the team has great promise for addressing important clinical and public health issues by combining the unique approaches that stem from our different fields of training and expertise.

Dr. Larson, School of Nursing, focuses her research on antimicrobial resistance and patterns of antibiotic use. Dr. Stockwell, Department of Pediatrics, has expertise in designing effective strategies to meet the primary care needs of underserved populations. Dr. Catallozzi, Department of Pediatrics, is an expert in qualitative research and health literacy. Dr. Rodriguez, Department of Population and Family Health, is the Director of the Columbia University Head Start and Early Head Start programs. Dr. Landers, Department of Population and Family Health, focuses on the design of materials and strategies to support parents and families in their role as primary caregivers, including family literacy programs at Head Start. Dr Meyers, Department of Pediatrics, is an expert in cultural competency and health literacy. Ms. Barnett will serve as the research assistant to assist in conducting training sessions and family interviews, administer pre- and post-tests, and manage the weekly phone calls. She is a fluently bilingual Latina and experienced in conducting such community-based trials.

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<thead>
<tr>
<th>Expertise</th>
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Conceptual underpinnings. Health-related behaviors such as use of antibiotics are complex and reflect social, cultural and ethnic beliefs which vary within subpopulations. While the ultimate goal of this planning grant is to develop an intervention to reduce the use of non-prescription antibiotics in the Latino community living in the U.S., we could not develop a successful intervention program without first understanding the knowledge, attitudes and antibiotic use practices in that population. Therefore, we have completed several preliminary studies. First, we surveyed several New York City neighborhoods and confirmed that antibiotics were available for sale over the counter without prescription in all surveyed bodegas in Washington Heights.8 We conducted a systematic review of the literature31 to examine knowledge, attitudes and practices about antimicrobials among Latinos but found no studies describing their cultural beliefs regarding the use of antibiotics. Hence we conducted a series of eight focus groups among Latino community members, bodega employees, and health care professionals providing services in this community to identify factors which influence Latino community members to self-prescribe antibiotics.32

This assessment was guided by the educational and environmental approach to health promotion planning espoused by Green and Kreuter, in which factors which predispose, reinforce or enable healthy behaviors must be identified and activated (Figure 1). Predisposing factors include
knowledge, beliefs and opinions. Enabling factors include having the necessary skills, equipment and resources. Reinforcing factors relate to peer support, feedback, and systems in which people function.

Figure 1. Components of the Precede-Proceed model used as conceptual underpinnings for this study

We were able again to confirm that members of this community have significant knowledge deficits about appropriate use of antibiotics and frequently buy, use and sell antibiotics over the counter. Finally, we have been working collaboratively with the Get Smart Program, CDC (http://www.cdc.gov/getsmart/), to obtain consultation from their 28 funded state projects to reduce antimicrobial resistance in the community. We have obtained Spanish-language educational materials from several of these states, which we are using in a current CDC-funded RCT (1 U01 CI000442-01, “Stopping URIs and Flu in the Family: The Stuffy Trial”, PI: Larson).

Setting and sample. Changing the behavior of parents of young children can be difficult; interventions which are focused in clinics or which involve only provider-based initiatives miss large segments of the population which are outside the ‘mainstream’ of health care. Further, if the education takes place in the medical office, it is one short moment in time and may not be reinforced at other times and places for that family. Therefore, the CDC antibiotic resistance action plan specifically recommends interventions be implemented through community-based programs. Early Head Start (EHS) is a community-based, federally funded program for low-income families with infants and toddlers and pregnant women. Early Head Start is an off-shoot of the Head Start program, created in 1965. These programs provide comprehensive education, health, nutrition, and parent involvement services. Two of the cornerstones of the EHS program are child and family development which include parent health education; concern for child and family health are integral parts of the EHS philosophy. Integrating our intervention into the existing EHS structure will build upon the foundation of trust that exists between the participating families and the EHS staff hopefully leading to better acceptance and internalization of the proposed message. In addition, since educational modules successfully developed at one Head Start site can be disseminated locally and nationally to other EHS sites, this intervention could have a national impact.

The Columbia EHS program has 194 infants and toddlers in 25 parent/child groups; the program has two sites, in Washington Heights and Hamilton Heights. Dr. Rodriguez is the Director of this program. The majority of Columbia EHS parents are foreign born, with Mexican (50%), Dominican (28%) and Ecuadorian (21%) families comprising the largest groups. The majority of families have Medicaid or SCHIP. From November 2007-February 2008, there were 200 episodes of class absences for reasons of illness including fever and URI. These did not include the times that a child
had a URI mild enough to participate in the EHS classes. In EHS, approximately 15% of mothers lack basic literacy, even in their native language.

EHS families receive biweekly home visits by bilingual educators/family workers, who also monitor the children’s health services. Center-based services consist of weekly parent/child groups aimed at strengthening family bonds and stimulating child development. Teachers use routines, music and home culture and language in the curriculum, and parenting, health and safety, nutrition and child development themes are woven into the sessions. Our intervention would be integrated into these workshops. For this pilot study, we will focus on families with at least one child aged 0 to 36 months old, who are part of the Columbia EHS program. We will randomly select two of the 25 groups, which have on average of 8 families each and all parents in these groups will take part in piloting the interventional materials.

**Intervention**

The proposed intervention to be designed during this planning grant will seek to decrease the population risk of antibiotic resistance by testing two interventions recommended by the CDC antibiotic resistance action plan designed to increase (1) parental self-efficacy in providing supportive care to their child during a URI, and (2) proper use of antibiotics when prescribed. These outcomes together should over time lead to decreased risk of antibiotic resistance. The CDC specifically recommends that educational and behavioral interventions for antimicrobial resistance be implemented through culturally competent, community-based programs; this planning grant will assess the feasibility of integrating such an intervention into Early Head Start (EHS) programs.

The first activity of this planning grant will be to design and refine three participatory learning modules that will be tested during the standard EHS parent workshops. The first will focus on how to manage URI and the risks associated with overuse of antibiotics based on CDC’s “Get Smart” Campaign materials. The session will include case scenarios of what to do when a child has a URI. Parents will also be informed about the dangers over the counter remedies. During this session parents will be provided with a cold care kit. We will test naming this kit a “botiquín para la gripe”, which connotes a medicine chest or first aid kit. This “botiquín” will include nasal saline drops and recipe in Spanish on how to make more saline drops from household items, a bulb syringe for nasal congestion, facial tissues, alcohol hand sanitizer, disposable thermometers, reminders on proper administration of anti-pyretics, and Spanish-language informational brochures about prudent antibiotic use and antibiotic resistance. It will also include a wheel with which parents can match symptoms with suggested home-based interventions and information regarding when to call a health care provider. Such kits have been used in several states by the CDC, but there has been little evaluation of the outcomes of the program.\(^2^9\) We will review and distribute the “botiquín” with participating EHS parents to pilot their use and report their experiences which will be used in planning the use of these kits on a large scale basis.

The last two EHS sessions will be based on the Health Education and Adult Literacy (HEAL) curriculum which has been designed by Drs. Meyer, Catallozzi, and HEAL coordinator Emelin Martinez. The curriculum was developed after conducting focus groups with parents in the Washington Heights community to determine what information they wanted from health care providers regarding their child’s care and medications. The curriculum includes information on reading over the counter and prescription medication labels, reviewing instructions for taking medications, understanding how to measure medication, and understanding the importance of completing courses of medication. There is also a portion devoted to reviewing home remedies, their safety, and communication about home remedies to health care providers. Table 2 summarizes the planning of interventions based on our theoretical model.

Table 2. Intervention strategies addressing components of the Precede-Proceed model

| Predisposing factors | Increase knowledge and change beliefs and opinions regarding self-prescribing of antibiotics through participatory learning sessions focusing on prudent antibiotic use and health literacy. |
Enabling factors

1) During the cold and flu season, distribute “botiquín” (cold care kits) which will include nasal saline drops and recipe, bulb syringe, facial tissues, alcohol hand sanitizer, disposable paper thermometers, anti-pyretic instructions, informational tools to provide supportive care at home and informational brochures about prudent antibiotic use and antibiotic resistance.

2) Distribute brochures being developed by Columbia’s Center for the Health of Urban Minorities that include sources of free or low cost health care for uninsured residents in Northern Manhattan, including sources of walk in health care and those which routinely have appointments available within a week.

Reinforcing factors

1) Discussion groups within intervention participants within their EHS groups to reinforce education provided.

2) Home visits

Home visits will be made monthly during the 3-month trial period as part of the standard EHS visits, as well as when a parent reports URI symptoms, as follows. Parents will be asked to call twice/week to report whether or not their child had URI symptoms. A phone call with a reported URI will trigger a follow-up home visit to verify symptoms and information reported regarding remedies used. The use of the telephone messages and the home visits will allow us to assess for the future planned clinical trial the reliability of telephone reporting. We have used this system in previous studies in which we found a correlation of .93-.97 between telephone reporting and information provided during a home visit. Parents will receive a monthly stipend of $25 as long as they call in 75% of the time (i.e. 6 calls/month) to report presence or absence of a URI. We will make reminder follow-up calls to parents who have missed the weekly call.

Phase I Planning Activities and Timeline

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Evaluation:

Two types of evaluation will be conducted to ascertain which activities in this planning grant would be most effective in a future pilot intervention: an assessment of the feasibility and quality of the intervention, and its effects on knowledge, attitudes, and practices (KAP). The first will employ the Snyder Model (http://www.uqconnect.net/action_research/arp/snyder.html), an action research approach that allows for short cycle evaluation (feedback on the workshops) as well as long cycle evaluation. With regard to the short cycle evaluation, individual in-depth interviews of parents directly after workshops will allow for feedback and the capacity to adjust the workshops or information given to parents in the future. Specific performance indicators will be used (e.g. effectiveness of educational modules, how they were taught about the cold care kit, etc). With regard to the long cycle
evaluation, we will conduct individual interviews at months 2, 3 and 4 to gain insight into the function of the program in the lives of the families and the feasibility of the use of the cold care kits. For example, parents will be asked about how the information and cold care kits they have received have impacted their decision-making regarding illnesses in the family and their interactions with health care providers. We will conduct interviews with three families per group or six families total. Each family will be interviewed a total of four times over the four month period to follow changes through the curriculum and their use of the cold care kits, for a total of 24 interviews. This qualitative information will help us to assess the feasibility of the use of the cold care kits in the EHS population and the acceptability and preferences for these educational modules.

Prior to the workshops, those families participating in the evaluation will take a pre-test to identify their knowledge, attitudes and behaviors regarding URI in their children, use of antibiotics and general health literacy. Potential effects on knowledge and attitudes will be assessed by pre- and post-test surveys adapted from questionnaires previously developed for several NIH-funded clinical trials (see Appendix). Impact on behaviors will be assessed by the pre- and post-tests, individual interviews, phone calls, and home visits. During the home visit, families will describe all interventions they used for their child’s last URI. They will also be asked specifically to show the research assistant all remedies used. The research assistant will note what remedies are used, where they were obtained, and how they are being used. The feasibility and utility of the use of these surveys and home visits will be assessed during this planning grant in order to ascertain whether they should be used in a future intervention.

Long-term Aims, include plans for future funding

The goal of this planning grant is to design a clinical intervention that could be used in Early Head Start Programs and through the CTSA Community Engagement Core resources in Northern Manhattan. If the pilot intervention is successful, we will use the results for a larger grant submission to apply the intervention in Early Head Start programs in several cities nationally, which have large Latino populations, linking with the Community Engagements cores of other CTSA sites (e.g. University of Texas sites) with the coordination of Dr. Boden-Albala. If the intervention is successful it is also likely that a similar intervention would be effective in other populations, which have recently immigrated from countries in which antibiotics are available without prescription over the counter or other marginalized populations. For application and adoption of the program with African-American populations, for example, we currently have a collaborative project planned with Morehouse School of Medicine, which is one unit of the Atlanta CTSA consortium. We would work with them to adapt and modify materials for this population as well.

References


