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Strategies for Uncomplicated Upper Respiratory Infections and Patient Satisfaction

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Strategies for Uncomplicated Upper Respiratory Infections and Patient Satisfaction.

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Executive Summary

Strategies for Uncomplicated Upper Respiratory Infections and Patient Satisfaction.

Problem

Overuse or inappropriate use of antibiotics is a major contributing factor to reduced drug efficacy, and increased prevalence of resistant pathogens. The two delayed prescription strategies combined with the patient education showed a promising reduction in inappropriate antibiotics use. However, it is not yet clear which delay prescription strategy is the most effective between these two strategies.

Purpose

The purpose of this QI project was to investigate if an educational program increased patients' knowledge of proper antibiotic use, perceptions of severity of symptoms, their belief in symptomatic treatment for viral illnesses, their satisfaction in their treatment plan and the differences in number of antibiotic prescriptions filled for two different delayed antibiotics strategies designed to reduce inappropriate use of antibiotics for adult patients with uncomplicated URIs patients' at an urgent care clinic in Charles County, Maryland

Mission

Promote appropriate antibiotic use in the adult patients with uncomplicated URIs through a coordinated program of education and delayed prescription strategies in an urgent care setting.

Vision

Encourage antibiotic stewardship through a coordinated program that promotes the appropriate use of antibiotic, improve patient outcomes, reduces microbial resistance and decrease the spread of infections caused by multidrug-resistant organisms.

Goals

The goals of the study were to measure the impact of an educational program on the variables above and compare the two different delayed prescribing strategies.

Plan

Self-report instruments were used to investigating the effectiveness in an education program to improve patients' knowledge of appropriate antibiotics use and compare two different delayed prescribing strategies in reducing antibiotic prescriptions filled.

Outcomes and Results

The patient led delayed prescription strategy, in addition to the patient education, resulted in a statistically significant decreased of antibiotic prescriptions filled by subjects diagnosed with an uncomplicated URIs. The patients' antibiotic use was strongly related to the severity of symptoms on day three. More than 50% of the patients stating that symptomatic treatment helped. The perceived helpfulness of symptomatic treatment is strongly associated with decreased antibiotics use in this study. The educational program did not make any statistically significance in decreasing the use of antibiotics, but it did help to increase the patient's satisfaction.

Acknowledgements

I dedicate this work to my supportive family. Thank you for your constant support, understanding, encouragement and love. I am very grateful for my husband and children's patience and sacrifice over the last three years. You have allowed me to pursue my doctoral degree and reach this pinnacle of academic achievement.

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Problem Recognition and Definition

Problem

Overuse or inappropriate use of antibiotics, particularly broad-spectrum antibiotics, in primary care is a major contributing factor to reduced drug efficacy, increase prevalence of resistant pathogens in the community, and escalate the appearance of new co-infections (Arroll, Goodyear-Smith, Thomas and Kerse, 2013; Dekker, Verheij, Van and Velden, 2015). The factors contributing to inappropriate antibiotics use include patient demand, lack of education on proper antibiotics use, perceived duration of illness, lack of diagnostic that lead to diagnostic uncertainty; attempting to provide something to mitigate symptoms making the person miserable, trying to decrease the length of time for office visit and increasing patients' satisfaction (Arroll, et al., 2013; Avent, et al., 2016; De la Poza et al., 2016; Hoffmann & Del Mar, 2015; Saleem, et al., 2016). In fact, patient demand is a driving force.

About 53% of all patients' seeking urgent care for the evaluation of viral symptoms requesting or expecting to receive antibiotics prescriptions for their symptoms. This too often results in the primary care clinicians prescribing antibiotics despite strong evidence that antibiotics typically provide no benefits at all for viral pathology (Vervloet, et al., 2016) and without consideration of antibiotics resistance developing. This has become a global public health crisis (World Health Organization, 2013) with the slow development of new antibiotics (Al-Tawfiq & Alawami, 2017) to replace those that are no longer effective. Al-Tawfiq & Alawami (2017) reported in Saudi Arabia, a 13.2% resistance to ampicillin for *Haemophilus influenzae* and 59% resistance to penicillin for *Streptococcus pneumonia*. To make matters worse, according to the Center of Disease Control (CDC, 2014) a growing number pathology of

healthcare-associated infections are caused by bacteria that are resistant to multiple antibiotics. These include: MRSA, vancomycin-resistant *Enterococcus*, extended-spectrum cephalosporin-resistant *K. pneumonia* (and *K. oxytoca*), *E. coli* and *Enterobacter* spp., carbapenem-resistant *P. aeruginosa*, carbapenem-resistant *K. pneumonia* (and *K. oxytoca*), *E. coli*, and *Enterobacter* spp. In order to decrease the development of antimicrobial resistance, patients, healthcare providers, healthcare facility administrators, and the policy makers must work together to employ effective strategies to prevent inappropriate use of antibiotics.

Durante, McBride, Miklo, Killeen, & Creech (2017) studied different methodologies used to limit the use of antibiotics in adults with uncomplicated upper respiratory infections (URIs), including delayed antibiotics prescribing, providing education to clinicians, and the use of laboratory tests to justify efficacy of antibiotics intervention. They found delayed prescription writing alone could result in a 52% reduction in inappropriate antibiotics use, and when education on symptoms was added, a further reduction (64%) was noted. Several studies (Arroll, et al., 2013; De la Poza et al., 2016; Høye, Gjelstad, & Lindbæk, 2013; Coxeter, Del Mar, McGregor, Beller, & Hoffmann, 2015; Vervloet, et al., 2016) also suggested that delayed antibiotics prescriptions help to reduce antibiotics use without damaging effects when used with reasonable symptom control. The delayed prescription strategies also showed high potential for decreasing inappropriate use of antibiotics without decreased clinical benefit in several European and Asian countries, as well as the United States (Arroll, et al., 2013; De la Poza et al., 2016; Høye, Gjelstad, & Lindbæk, 2013; Coxeter et al., 2015; Vervloet, et al., 2016).

Delayed prescription strategies consist of prescribing an antibiotics but directing the clients to only fill the prescription if the symptoms worsen after they started to get better or if there is no improvement in symptoms in seven to ten days. However, it is not yet clear which

delay prescription strategy is the most effective between these two strategies (Arroll, et al., 2013; De la Poza et al., 2016; Høye, Gjelstad, & Lindbæk, 2013; Vervloet, et al., 2016). De la Poza et al., (2016), concluded that the efficacy between the two delayed prescription strategies should be evaluated in different settings and populations.

Project Purposes

The purpose of this QI project was to investigate the efficacy of an educational program in improving patients' knowledge of proper antibiotic use, their belief in symptomatic treatment for viral illnesses, the patient's perception on the severity of symptoms, the effectiveness between the two delayed antibiotics strategies designed to reduce inappropriate use of antibiotics for adult patients with uncomplicated URIs (cold symptoms, influenza, sore throat, bronchitis, cough and nasal congestion) and the patients' satisfaction in their treatment plan at an urgent care clinic in Charles County, Maryland.

Project Question

The project question was: Would there be a difference for inappropriate antibiotic use in adults who presented with URI symptoms when an education program that included proper antibiotic use and symptomatic treatment was offered in addition to one of the two delayed prescription strategies while maintaining patient satisfaction?

PICO Statements

Population. Adult patients (18-65) with URIs symptoms seeking care at the urgent care clinic.

Interventions. Patient led delayed prescription strategy. Collection delayed prescription strategy and an education program

Comparison. Difference in number of antibiotic prescriptions filled between the patient

led delayed prescription strategy and the collection delayed prescription strategy. Comparison of knowledge of symptomatic treatment, severity of symptoms, need for antibiotic use before and after education, and patient satisfaction differences between the patient led delayed prescription strategy and the collection delayed prescription strategy.

Outcome. Difference in number of antibiotic prescriptions filled between the patient led delayed prescription strategy and the collection delayed prescription strategy. Differences in knowledge of symptomatic treatment, severity of symptoms, need for antibiotic use before and after the education intervention. Patient satisfaction differences between the patient led delayed prescription strategy and the collection delayed prescription strategy

Population

Adult between the ages of 18-65 who presented with URI symptoms to an urgent care clinic for treatment.

Intervention One. The patient led delayed prescription strategy. Patients seeking care for an uncomplicated URI, assigned to this intervention, were given a prescription for an antibiotic appropriate for a possible bacterial infection based on URI history, and physical examination findings and the provider's preference. Patients in this arm or the study were told they could fill the antibiotics prescriptions at any time but were encouraged to fill their prescriptions only if their symptoms were not improved or worsened in ten days after the initial symptoms.

Intervention Two. The collection delayed prescription strategy. Adults seeking care for an uncomplicated URI received the same anticipatory and educational material as those participating in intervention one; however, these patients were told they had to return to the clinic for their antibiotic prescriptions if their symptoms were not improved or had worsened ten days from the onset of their symptoms.

Project Significance, Scope and Rationale

The rapidly increasing rate of antimicrobial resistance to superbugs threatened patients who were suffering from multiple antimicrobial resistant bacterial infections. The annual mortality from drug-resistant bacteria may exceed 10 million by 2050 (Spinks et al., 2013). The Centers for Disease Control and Prevention (CDC) reported 266.1 million antibiotics prescriptions were filled by the local pharmacies in the U.S. and the most common conditions for which antibiotics were prescribed in ambulatory care settings were for acute URIs (Ahovuo-Saloranta et al., 2014; Spinks et al., 2013), despite clear evidence, these conditions were mostly viral in origin, and antibiotics did not help, but their inappropriate use not only increased resistance to these drugs but also strained resources, placed patients at risk of adverse effects, and increased the number of future consultations for similar episodes (De La Poza et al., 2016; Drekonja et al., 2015). This led to the White House (2015) releasing a national action plan for reducing inappropriate outpatient antibiotics by 50 percent. The national action plan provided a roadmap that outlines federal activities over the next five years. This plan was designed to enhance domestic and international capacity to prevent and contain outbreaks of antibiotics-resistant infections; maintain the efficacy of current and new antibiotics; and develop and deploy next-generation diagnostics, antibiotics, vaccines, and other therapeutics. This issue was so critical, the President's 2016 budget included more than $1.2 billion dollars, nearly double from last year to combat and prevent antibiotics resistance. We must find effective interventions to reduce inappropriate antibiotics use, such as delayed prescribing strategies, that can be used in ambulatory care settings to decrease inappropriate antibiotics use (Coxeter et al., 2015; Drekonja et al., 2015). Delayed antibiotics prescription helps to reduce antibiotics use in the uncomplicated URIs patients. De La Poza Abad et al. (2016) suggested that while there were

different strategies of delayed prescription, it was not clear which one was most effective. The objective of this project was to investigate the efficacy of two delayed prescription strategies in patients with uncomplicated URIs and measure the effectiveness of an educational program in improving patients' knowledge of proper antibiotic use, their satisfaction in their treatment plan, and their belief in symptomatic treatment for viral illnesses. This project was a quality improvement initiative project based on evidence based practice. Developing new knowledge or for the findings to be generalized outside of the urgent care study population were not the intention of this project.

Theoretical Frameworks

Pender's Health Promotion Model (HPM). The Health Promotion Model (HPM) of Nola Pender (2011) stated that an action or decision made by an individual was affected by their personal characteristics, knowledge and experiences. Health promoting behaviors that improved health, functional ability and quality of life at all stages of development were the desired behavioral outcome of the HPM. The major assumption of the theory was that an individual was constantly and actively interacting with the environment (Pender). He stated that individuals were willing to adopt new behaviors, modify physical environment and thought process to take actions leading to perceived rewarding or desired health outcomes. Applying Pender's HPM concepts to this study suggested that the patients would be receptive to the symptomatic management of a viral illness and reduce demand for inappropriate antibiotic use if they understand that antibiotics are not only ineffective for uncomplicated URIs but the misuse of antibiotics led to the development of antibiotics-resistant bacteria.

Bandura's Self-Efficacy Theory (1997). Bandura described and explained the relationship between one's beliefs and one's ability to implement situation specific behaviors to attain

established goals, expectations, or designated types of outcomes. Perceived self-efficacy beliefs were considered to be central and persuasive factors in determining the course of action selected the degree of effort exerted, and the perseverance to continue in the face of difficulties and setbacks. Based on Bandura's research, for this study, patients who strongly believed that the antibiotics were not the answer to their illness, the longer they were willing to try symptomatic management of a viral illness instead of filling the antibiotics prescriptions as soon as they could. For this reason, all patients received education on why viral illness should not be treated with an antibiotic and how they could treat the symptoms of a viral illness without antibiotics prescription (see Appendix B).

Prochaska's Transtheoretical Model of Behavior Change. Prochaska (Prochaska et al., 2002) suggested that the health behavior change involved progression through six stages of change: precontemplation, contemplation, preparation, action, maintenance, and termination. Individuals often change behavior for a variety of reasons however, after a period of time, they revert to their old ways unless motivators and values become firmly rooted and norms that support lasting change are established within populations (Prochaska, Prochaska & Levesque, 2001). The Transtheoretical Model illustrates that human behavior change rarely progresses in a straightforward fashion and then easily locks into place (Prochaska et al.). In order to achieve sustainability of the antibiotics stewardship program, almost all previous antibiotics initiatives had been grounded in a traditional, information-intensive health education approach that relied heavily on knowledge leading to attitude change that in turn led to lasting behavioral transformation. The goal of all programs was sustainability (Prochaska et al.). Prochaska's Transtheoretical Model of Behavior Change provided the framework for driving the change for inappropriate antibiotic use.

Literature Review

A literature search was conducted using the electronic databases of Academic Search Premier, Cumulative Index to Nursing and Allied Health Literature Complete (CINAHL), MEDLINE, and PsycINFO through the Regis University, Google Scholar, PubMed, and Cochrane Library. Search teams included antibiotics treatment, antibiotics resistance, delayed antibiotics strategies, ambulatory care, family practice, urgent care, emergency department, primary care, respiratory tract infections. This search yielded 313,399 results from Academic Search Premier, CINAHL, psynINFO and MEDLINE. To narrow down the search, exclusions included duplicate articles, non-English articles and publication dated between the years of 2013-2017. This resulted in 97,105 articles. Using the same limits and keywords with exclusion to adult patients, full text, scholarly (peer reviewed) journals, academic journals, randomized controlled trials (RCT); adding additional limits including randomized controlled trials (RCT), meta-analysis and reviews, the results yielded 168 results. According to the National Health and Medical Research Council (NHMRC) Evidence Hierarchy (2013), RCT, meta-analysis and reviews were at the top of the pyramid and ranks as the highest level I evidence where the best evidence is located. To further narrow down the search, key words were limited to delayed prescription strategy and uncomplicated upper respiratory. This yielded 41 articles again using the search engines Academic Search Premier, CINAHL, PsynINFO and MEDLINE. Further limiting the keywords to delayed prescription strategy and patient satisfaction decreased article to 12. Changing the limit to delayed prescription strategy and efficacy yielded an additional four articles; using delayed prescription strategy and antibiotics use yielded 17 articles. Limiting the search to delayed prescription strategy and patient education yielded another four articles, and fusing delayed prescription strategy and follow up yielded

another four articles. Three systematic reviews and meta-Analysis on antibiotics use and URIs from the Cochrane Database System Review were reviewed. Together a total of 27 articles were reviewed and applied to develop this project**.**

The emerging themes from reviewing the 27 applicable articles were: 1) delayed prescriptions strategies helped to decrease antibiotics use in the patients with uncomplicated URIs. 2) Provider's explanation and education reinforced to efficacy of the strategies to decrease inappropriate antibiotics use 3) patients' satisfaction was not related to antibiotics prescriptions but to their understanding of the disease process and perception of the providers spending time with them. There was a gap in the literature as to the efficacy between the two delayed prescription strategies and population of patients presenting at urgent care outpatient clinics.

For the past twenty years, many interventions showed driving forces to decrease inappropriate antibiotics use included targeting physicians and patients. Successful strategies included education, physician audit and feedback, delayed prescribing strategies, financial incentives to providers and patients, and health information technologies (Butler et al., 2013; De la Poza et al., 2016; Glasziou, 2016; Little et al., 2014; Ryan et al., 2014; Sargent 2016; Shaughnessy, 2016). Restraining forces included expressed patient pressure for antibiotics and concern over patient satisfaction scores when antibiotics were not prescribed. (Ahovuo-Saloranta et al., 2014; Coxeter et al., 2015; De la Poza et al., 2016; Harris, Hicks, & Qaseem, 2016; Lindbæk, 2014; Little et al., 2014; Ryan et al., 2014; Yang, Liu, Wang, Yin, & Zhang, 2014). However, further studies emphasized patient satisfaction depends more on the patient-centered quality of the encounter, such as the provider spending enough time with the patient to explain the patient's illness, than on the receipt of an antibiotics prescription (Agnew, Taaffe, Darker, O'Shea, & Clarke, 2013; De la Poza et al., 2016; Glasziou, 2016; Ryan et al., 2014). To

capitalized on this driving force, i.e. to increase patient satisfaction and decrease antibiotics prescriptions for uncomplicated URIs, research suggested providers can promote appropriate antibiotics use by labeling acute bronchitis as a "chest cold" or "viral upper respiratory infection" to emphasize viral origin of pathology and then providing patient information sheets about alternatives to antibiotics for managing symptoms of viral infection (Coxeter et al., 2015; De la Poza et al., 2016; Shaughnessy, 2016, Yang et al., 2014;).

According to Butler, Rollnick, Pill, Maggs-Rapport & Stott (2013), patients who expected antibiotics and when the providers perceived that patients expect antibiotics they were10 times more likely to be prescribed. General practitioners describe this as the most uncomfortable decision about prescribing that they make. Antibiotics prescribing was rising in primary care, especially for respiratory tract conditions (Barlam et al., 2015). There were growing concerns about cost, increasing workload for these usually self-limiting conditions and the rising prevalence of antibiotics resistant bacteria (Arroll, et al., 2013; Avent, et al., 2016; Barlam et al., 2015; Butler et al., 2013; and De la Poza et al., 2016). This health concern could be targeted not only at providers, but also at the patients' level. Collaboration between patient and provider required that each individual brought their expertise and expectation to the forefront and work together for a common positive outcome (Zaccagnini & White, 2014).

Multiple studies (Coxeter et al., 2015; De la Poza et al., 2016; Lecky, Hawking, Quigley, & Butler, 2015; McNulty et al., 2015; Ryan et al., 2014; Shaughnessy, 2016) disclosed a decrease in antibiotics prescribing for uncomplicated URIs and increased satisfaction ratings when providers gave advice on symptomatic therapy and explained why antibiotics were not needed for uncomplicated URIs. Providing a symptomatic prescription pad used to provide recommendations for management of symptoms without antibiotics, allowed patients to walk

away with a plan of action that did not include inappropriate antibiotics (De la Poza et al., 2016; Little et al., 2014; Sargent, McCullough, Del Mar, & Lowe, 2016).

Another strategy according to the *Antibiotics: the Spanish strategy* (2016), when it was unclear whether an antibiotics was needed, was to delay or postdate antibiotics prescriptions with watchful waiting or the wait-and-see approach and offer the possibility of future antibiotics treatment if the condition did not improve or worsen. This delayed antibiotics prescriptions strategy was also shown to increase patient satisfaction and decrease antibiotics use (Butler et al., 2013; De la Poza et al., 2016; Glasziou, 2016; Little et al., 2014; Ryan et al., 2014; Sargent 2016; Shaughnessy, 2016) and did not result in poor symptom control or clinically significant complications of respiratory infections (Arroll, et al., 2013; Coxeter et al., 2015; De la Poza et al., 2016; Del Mar, Dooley, and Foxlee, 2013; Lecky et al., 2015; Little et al., 2014; McNulty et al., 2015; Ryan et al., 2014; Shaughnessy, 2016).

Two methods to delay antibiotics use studied differed slightly. One method was to allow patients to collect the prescription from the clinic when symptoms were not self-limiting within seven to ten days (collection), and another method was patient led strategy. The provider was to give prescriptions to patients during the initial visit but asking them to wait to fill the prescription in seven to ten days if the symptoms did not resolve and/or if the symptoms worsened (Agnew et al., 2013; Barlam, Morgan, Wetzler, Christiansen & Drainoni, 2015; Little et al., 2014; McNulty et al., 2015).

A few studies on acute sore throat and URIs have suggested that an immediate prescription or delayed antibiotics prescription could reduce return office visits compared with a no prescription strategy but the trials were underpowered to compare efficacy between strategies and to be generalized for the larger population (Arroll, et al., 2013; De la Poza et al., 2016;

Drekonja et al., 2015; Little et al., 2014; Spurling et al., 2013). No articles comparing between the two different delayed prescription strategies to delay patients from filling the antibiotics prescription were found.

However, studies revealed that the severity of symptoms and the duration of symptoms were the same for patients who received immediate antibiotics compared to those who were not started on antibiotics immediately. Satisfaction was similar across groups (Arroll, et al., 2013; Coxeter et al., 2015; Lecky et al., 2015; Little et al., 2014; McNulty et al., 2015; Shaughnessy, 2016; Spurling, Del Mar, Dooley, and Foxlee, 2013; Ryan et al., 2014).

Studies did show that the perceptions that antibiotics had no effect or were not very effective was higher for patients in the two delayed antibiotics strategies and the no antibiotics strategy compared to the immediate prescription strategy (Spurling et al., 2013; McNulty et al., 2015; Lecky et al., 2015; Shaughnessy, 2016; Ryan et al., 2014) and the delayed prescription strategies reduced antibiotics use when compared with an immediate strategy (Agnew et al., 2013; Barlam, Morgan, Wetzler, Christiansen & Drainoni, 2015; De la Poza et al., 2016; Little et al., 2014; McNulty et al., 2015). No differences were observed for complications, adverse effects, or the need for unscheduled care among the strategy groups, and no differences were observed in the perception of general health status (Arroll, et al., 2013; De la Poza et al., 2016; Drekonja et al., 2015; Little et al., 2014; Spurling et al., 2013).

Several studies (Agnew et al., 2013; De la Poza et al., 2016; Durante et al., 2017; Little et al., 2014) suggested that the combination effect of delayed antibiotics prescription and education compared to delayed antibiotics prescription alone were more effective to decrease inappropriate use of antibiotics. In fact, a study by Agnew et al (2013) suggested that the patient education material such as an education leaflets in addition to delayed prescription decreased the rate of

inappropriate antibiotics use from 72% to 43%; however several studies concluded that more studies are necessary to demonstrate the efficacy between the two delayed prescription strategies in different settings and patient populations (Agnew et al., 2013; De la Poza et al., 2016; Little et al., 2014).

While delayed prescribing was not a perfect solution, it did compromise between an immediate prescription and a no prescription strategy. As such, even though some patients would still receive unnecessary antibiotics using a delayed prescription strategy, the evidence suggested these strategies did significantly reduce antibiotics overuse and therefore should be embraced. The challenge remained for researchers to define exactly what was involved in delayed prescribing, and how clinicians could use it in different practice contexts (Little et al., 2014; De la Poza et al., 2016).

Market and Risk Analysis

Strengths, Weakness, Opportunities and Threats

A SWOT analysis was completed so that the strength and opportunities of this project could be uncovered and exploited. The identified weakness and threats to this project were eliminated when possible and minimized when it was not possible to eliminate them entirely.

Strength. One of the strength of this project was the support from the urgent care clinic where the project will take place. The urgent care clinic is new with state of the art medical equipment. It was certified by The Joint Commission since September 2015. The medical director and manager of the urgent clinic were supportive and provided the target population for the project. The staff members (providers and medical assistants) were participated in the project at no additional cost. The office manager offered flex clinic times to free up clinical staff to help with the project. Seventy-seven percent of the study participants rated the experience as satisfied

to very satisfied. In addition to that this project established an environment of support, trust and co-operative learning between providers, medical assistants and managers. It makes the mundane clinic challenging, interesting, motivating, engaging, and fun. It has been a great team building experience.

Weakness. The disruptions in the continuity of care, as the staff members were distracted from their involvement in the project. Longer office visit for the project participants compared to the regular patient visits. Since the longer office visit was explained in the consent forms, all the study participants understood of the longer than usual visit. The role confusion of the staff members was addressed by regular meetings and discussions. Insufficient training on data collection and other research related processes were addressed with timely training sessions.

Opportunities. Opportunities are defined as the external factors that are likely to have a positive effect on achieving or exceeding the clinic's objectives, or goals not previously considered (Zaccagnini & White, 2014). This project has reduced the use of antibiotics in the patients with uncomplicated URIs by 25% and directly decrease cost to the health insurance companies. All 67 study participants expressed favorable views of the delayed antibiotic strategies.

Threats. Losing patients to another clinic was one of the threats of this project. However, 53 of the 67 participants (79%) did not seek help at another clinic. Only seven patients went to at another clinic for evaluation. The concern of potential revenue loss of the hospital pharmacy was not founded since the sample size for the study was only 67 patients.

Driving, Restraining and Sustaining Forces

Driving forces. One of the most significant driving forces for this project was the overwhelming evidence from numerous clinical trials suggested the ineffectiveness of antibiotics

for uncomplicated URIs but the risk of antibiotics resistant bacteria when antibiotics were used inappropriately (Ahovuo-Saloranta et al., 2014; CDC 2014; Spinks et al., 2013). The risk of emerging antibiotics resistance bacteria included not only greater costs to the health care system but increased mortality and morbidity (Coxeter et al., 2015; Drekonja et al., 2015). Another driving force was the gap in the literature as to what methods are most efficient and effective in reducing inappropriate use of antibiotics. Numerous studies concluded education and delayed prescriptions were helpful but that additional study was essential (Agnew et al., 2013; De la Poza et al., 2016; Little et al., 2014). Another driving force was the approval and support from the quality improvement team of the urgent care clinic that agreed to support the project and the care providers recognizing the benefits from the study and willingly participating in the study.

Restraining forces. Restraining forces for this project included the limited time to conduct the project, the lack of monetary incentive for participants, the time commitment to already burdened staff, fear of liability and cultural and institutional inertia. One of the providers from another clinic mentioned that if a patient expressed the desire for an antibiotic, it was best to give out the antibiotics prescription "without arguing with the patient." The belief was that this would decrease patient complaints, return visits and loss of patients to another urgent care clinic.

Key Stakeholders

The stakeholders of this project were patients, potential patients who may benefit from a decrease in bacterial resistant antibiotics, insurance company that may appreciate a decrease in cost of care with decrease in unnecessary antibiotics use, the urgent care clinic staff including two physicians, one nurse practitioners (NP), four medical assistants (MAs), and the quality assurance team of the urgent care clinic. Although this QI project could not be generalized, the findings might lead to additional studies that could benefit future patients and other stakeholders

mentioned above. The project team, also key stakeholders, included the lead researcher, the two physicians, four MAs the project mentor (NP), the project advisor and the pharmacists at the hospital pharmacy.

Cost-Benefit Analysis

Cost for this project was minimal because of the donation of the clinic and staff for the place, equipment, and time; however, should this project be duplicated or continued, staff resources would cost approximately $29,830. The need and the resources to conduct the project include the involvement of three providers (two physicians and one nurse practitioner), four medical assistants, exam rooms, equipment to obtain vital signs. The CDC's (2016) "Get Smart about Antibiotics" program was designed to educating the patients in danger of inappropriate use of antibiotics. It was free of charge and included posters, brochures, and a viral medical (Rx) prescriptions. The use of the telephone, CDC handouts, exam room and equipment to obtain patients' vital signs did not add any additional cost to the clinic but if duplicated would cost $45-$50. The estimate for the cost of paper and printing (data collecting sheets, inform consents, duplications handouts from the CDCs and etc.) for this project was $50. The urgent care clinic saw about 30-40 patients daily. About half of the visits were for evaluation of URI symptoms and three to five people per day fit all the inclusion criteria. The time to recruit and enroll a patient into the study was 30 minutes. A complementary 30 minutes follow up visit was offered to all the participants. Fifty-seven of the 67 patients returned for the complementary visit making the total time per participant one hour. Sixty seven participants x 0.5 hour (screening) and 57 patients returned for the complementary visit x 0.5 hours. The total additional time the providers spent with the study participants was 63.5 hours. The additional hours divided among the three providers calculated to 21.16 hours per provider. The MAs that sent reminder emails and texts to

patients on day three and day seven, scheduled complementary follow up appointment, notify the providers that study participants desired antibiotics prescriptions, and put antibiotic prescriptions to front desk for the patients to pick up were calculated to be 50 hours. The principal investigator spent approximately 200 hours on planning, meetings; preparing documents and write-up of the project making the cost of duplicating this study $28,846 (see Table 1).

Table 1

Market and Risk Analysis

Item	Cost
Physicians	$120/hour x 21.1 hours x 2 physicians $5064
Nurse Practitioners	$88/hour x 21.1 hours $1856
Medical Assistant	$14/hour x 50 hours $700
Principal Investigator	$88 x 200 $17,600
Printing, paper	$50
Complementary office visit	$80 (rate for follow up visit) x 57 participants $4560
Total	$29,830

One cost that was not well documented was the economic burden of caring for clients that were infected with antibiotics resistant bacteria (Kesselheim, Avorn & Sarpatwari, 2016). This makes it very difficult to judge the cost benefit of decreasing inappropriate use of antibiotics. Research showned that drug resistance bacteria increase mortality (Bjerrum, 2014; Kesselheim et al., 2016; Lindbæk, 2014) and premature deaths caused by antibiotics resistant bacteria reduced the size of the working age population (Llor & Bjerrum, 2014; Kesselheim et al., 2016; Lindbæk, 2014). Drug resistant bacteria also increase morbidity by causing prolonged disability from illness and again, a reduction in the size of workforce and productivity. In

addition, increased morbidity of the dependents may require the productive members of the family to act as care givers who would otherwise be economically productive. There was no cost estimate of decrease quality of life for the disabled or for care provider fatigue.

Lindbæk, (2014) added that if resistance rates increase substantially, it could result in further indirect costs such as people choosing not to undergo certain medical procedures because of the heightened risks involved or refraining from undertaking certain activities, such as travel and trade. Lindbæk also suggested some people might experience general negative psychological effects or even panic further adding to the cost of health care and decrease in quality of life.

Michaelidis et al (2016) used published data to develop point and range estimates for the hidden societal cost of antibiotics resistance (SCAR) attributable to each ambulatory antibiotics prescription in the United States. The published data on the antibiotics-resistance associated costs of hospitalization, second-line inpatient antibiotics use, second-line outpatient antibiotics use, and antibiotics stewardship were explored. The total SCAR attributable to each ambulatory antibiotics prescription was estimated to be $13.09 or almost 70% of the total SCAR was the cost of hospitalization (Michaelidis et al., 2016). The second-line outpatient antibiotics use was 15 % of the total SCAR at $2. The costs of second-line inpatient antibiotics use were $1 or 8 % of the total SCAR, and antibiotics stewardship was the same as the inpatient antibiotics at $1 or 8%. If an average antibiotics cost was $30, the total SCAR attributable to each ambulatory antibiotic prescription would increase antibiotics costs by 65 % to $49.50 if incorporated into antibiotics costs paid by patients or payers (Michaelidis et al., 2016).

Project Objectives

Mission

Promote appropriate antibiotic use in the adult patients with uncomplicated URIs through a coordinated program of education and delayed prescription strategies in an urgent care setting.

Vision

Encourage antibiotic stewardship through a coordinated program that promotes the appropriate use of antibiotics, improve patient outcomes, reduces microbial resistance and decrease the spread of infections caused by multidrug-resistant organisms.

Project Goals

The goals of this project were to analyze difference in number of antibiotic prescriptions filled between the patient led delayed prescription strategy and the collection delayed prescription strategy. Comparison of knowledge of symptomatic treatment, severity of symptoms, need for antibiotic use for viral illness before and after the education intervention and patient satisfaction differences between the patient led delayed prescription strategy and the collection delayed prescription strategy.

This project was a quality improvement initiative project and was not designed to develop new knowledge or for findings to generalize outside of the urgent care study population.

Outcome Objectives

The objectives of this project were to measure: 1) the differences in number of antibiotics used for subjects assigned to intervention one and those assigned to intervention two; 2) the knowledge of symptomatic treatment, severity of symptoms, need for antibiotic use for viral illness before and after the education intervention; 3) patient Satisfaction differences between the two delayed prescription strategies (see Appendix I).

Evaluation Plan

Participants

Clinical staff. Two board certified emergency medicine physicians, one nurse practitioner, and four medical assistants at an urgent care clinic located in Charles County Maryland participated in collecting data for this project.

Subjects. Adult patients, ages 18-65 presenting to the urgent care clinic with the final diagnosis of uncomplicated URIs, were in general good health with no significant comorbidities such as uncontrolled diabetes, blood pressure, active cancer, poorly controlled psychiatric disorders and that require specialists' management or referral were be invited to participate in this project; unless, for any reasons, a care provider felt delaying antibiotics would not be in the patient's best interest. In that case, the patient not invited to participate in the project. Other inclusions criteria included subject's fluent in speaking and reading English with no history of significant comorbidities defined below. In addition to that, the subject had no documented allergy to acetaminophen or ibuprofen, was immunosuppressed, or was breast feedings. A written consent form was obtained from all participants.

The project lead investigator (PI) and the faculty mentor completed CITI training (see Appendix E). This project was approved by the clinical director of the urgent care clinic (see Appendix I) and approved by the Regis University Institutional Review Board (see Appendix L).

Definition of Variables

Uncomplicated upper respiratory infections. The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) coding system was used to classify diagnoses and symptoms. For inclusion in the project, patients had to be coded for acute pharyngitis, rhinosinusitis, acute bronchitis, cold, influenza, or viral syndrome without

complications.

Significant comorbidities. Uncontrolled diabetes or hypertension, cancer, poorly controlled psychiatric disorders, require specialists' management or referral, history of asthma, an active gastric ulcer disease, require hospital admission for meningitis, pneumonia, epiglottitis or Kawasaki disease, were febrile, unable to tolerate oral fluid, have respiratory rate of greater than 20, an oxygen saturation level of < 92% on room air and signs of using accessory muscles for breathing.

Vulnerable population. Fetuses, pregnant women, children, prisoners, and institutionalized individuals will be included in this project.

Methodology and Measurement

Procedures. All adult patients that documented, on a clinic form, their reason for seeking care as any one or combination of URI symptoms (e.g., cough, earache, nasal congestion, sinus problems, sore throat) currently were asked to complete a simple quiz (see Appendix K) to assess their knowledge of when antibiotics could be effective and when they would be inappropriate to use. The patients returned the completed quiz to their provider during the office visit, and the provider kept it with the patients' records. The provider completed and documented the patient's history, results of the physical examination, diagnosis, plan of care and coded the diagnoses and symptoms using the ICD-10-CM coding system. If a patient's other diagnosis was coded as acute pharyngitis, rhinosinusitis, acute bronchitis, cold, influenza, or viral syndrome without complications, the provider reviewed the completed quiz with the patient and gave the patient the educational brochure *What Everyone Should Know and Facts about Antibiotics* (CDC, 2017) [see Appendix A]. Then discussed with the patient the answers on the quiz and key points of the brochure.

Next, the provider explained the differences between a viral and a bacterial infection, symptomatic treatment for a viral illness and how inappropriate antibiotics use could lead to antibiotics resistance and the development of super infections that no longer respond to antibiotics. Finally, the provider shared the usual course of a viral illness emphasizing it was normal to feel worse rather than better over the first one or two days after the onset of the URI symptoms. A *Symptomatic Prescription* developed by the CDC (2016), for use by the care provider was given to the patient (see Appendix B). This *Symptomatic Prescription* suggested various over-the-counter medications and treatments for symptom relief such as dextromethorphan, a cough suppressant; guaifenesin, a mucus-thinning expectorant; saline nasal spray and humidification and Tylenol and/or Motrin for pain and fever relief. The provider clarified best options for the client knowing the patient's history and symptoms and reassured that at this time antibiotics were not needed immediately and if taken now could cause harm without decreasing the symptoms or course of the illness.

All the URI patients received the similar anticipatory guidance as described above since the literature was clear that education was essential to help decrease inappropriate use of antibiotics. No antibiotics were prescribed to treat an uncomplicated URI; however, patients were advised to schedule a follow-up visit if new symptoms presented that were not expected from a viral illness or if symptoms worsened, after the patient started to feel better. At this time, the patient retook the CDC's (2016) *Get Smart with Antibiotics Quiz* to assess the patient's understanding of appropriate antibiotics use after the teaching session. A 75% (six out of eight questions answered correctly) on the post-quiz *Get Smart About Antibiotics Quiz* suggested the patient understood appropriate antibiotic use. If patients failed to achieve the six out of eight correct answers, education needs in necessary areas were addressed and clarified with the

patients. The scores of the quiz were not used for analysis purpose but to serve as identifying the patients' education needs and to open dialogue on antibiotics use and URIs between the patients and the providers.

Then, if the patient met the inclusion criteria for the study, the provider discussed the project with the patient and asked if the patient was willing to participate. If the patient was interested in participating in the study, an informed written consent form (see Appendix F) was reviewed with the person and all questions about the study were answered. If the individual agreed to participate in the study, he/she was asked to sign the form. The signature was witnessed by the provider. One copy of the signed consent form was given to the participant and one was kept by the provider. The provider assigned a code to the subject on the consent form and documented only the code on an enrollment sheet (see Appendix G) and on the Follow Up Response Form (see Appendix H). All documents that identified a subject by name or if a name was linked to the code assigned, including the signed consent forms and assigned participant numbers were kept in a locked cabinet at the provider's charting station during the study and only the principal investigators and the providers had access to any document that identified the participant by name or identification number. Following the completion of the study, all these documents were placed in a locked cabinet in the PI's office. Only the PI had access to this cabinet. The records will be kept for three years then shredded.

Next, provider initiated the "Follow Up Response Form" for the subject and recorded the subjects answer to the quiz question, "Do you believe you need antibiotics?" Next, the patients' understanding of the education material presented and the participants' assigned interventions were documented. The first patient enrolled in the study was assigned to Intervention One. The next participant was assigned to Intervention Two and so on. **Intervention One.** The patients

who were assigned to Intervention One, or the delayed patient-led prescription strategy, in addition to receiving the educational brochure from the CDC *What Everyone Should Know and Facts about Antibiotics* (see Appendix A) and a *Symptomatic Prescription* (CDC, 2016) [see Appendix B], were given the brochure *What is Delayed Prescribing?* (CDC, 2016) [see Appendix C] and a prescription for an antibiotics chosen by the provider based on the subject's history, examination and standard of care for most likely bacterial infection. The prescription included instruction to the pharmacy to not fill this prescription 11 days post written date to prevent participants filling the antibiotics prescriptions after the study was completed. While the subjects were told they could fill their prescriptions at any time, they were encouraged to wait ten days post URI symptoms onset and then only if they were still not feeling better or if the symptoms had worsened again after they had been feeling better. **Intervention Two.** Subjects assigned to Intervention Two, or the delayed prescription collection strategy, received the *same handouts and treatment guidance as the participants in the Intervention One except instead of the brochure What is Delayed Prescribing?(CDC, 2016),* they received the brochure *What is Watchful Waiting?* (CDC, 2016) [see Appendix D]. Like those in Intervention One, they might elect to start antibiotics at any time and were also cautioned to wait ten days post URI symptoms onset and then only if they were still not feeling better or if the symptoms worsened again after they had been feeling better; but instead of immediately receiving the prescriptions, the participants were told to pick up their prescriptions at any time by sending an email, a text or calling the medical assistant at the clinic and identifying themselves by their assigned participant number. When a patient asked for the antibiotics prescription, the medical assistant informed the provider of the request and the provider wrote the antibiotics prescription for the patient to pick up at the urgent care clinic front desk and to fill the prescription at the hospital pharmacy.

All study participants were directed to fill the antibiotics prescriptions at the hospital pharmacy which was usually the least expensive option and because urgent care clinic shares the same EHR. This was important because the urgent care providers had direct access to the hospital pharmacy records and they could generate a list of patients to monitor if and when they filled their prescriptions.

The number of antibiotics prescriptions filled by the study participants was verified from the patients' pharmacy records which was part of the EHR. The principal investigator assessed the study participants' pharmacy records of the EHR daily to record the filling of antibiotic prescriptions. If a participant filled the antibiotics prescription, the number of days between receiving the prescription and filling the prescription was documented on the Follow Up Response Form (Appendix H) by the provider.

The MA scheduled a follow-up visit ten days from the day the patient consented to participate in the study, free of charge to the participant. Participants were told they could cancel or reschedule this visit if not needed or desired. Since this is a walk-in urgent care clinic, cancellation or reschedule follow-up appointments of the study participants did not have significant impact to the clinic's productivity.

Instruments. The CDC's *Get Smart Antibiotics* Quiz (CDC, 2016) (Appendix K) assessed the knowledge of appropriate antibiotics use and is available from the CDC website at https://www.cdc.gov/getsmart/community/about/quiz.html. Although the CDC did not provide any statistics for quiz validity, this quiz had been used by the clinic participating in the study for the past year. To validate patient perceptions of the quiz, a sample of 20 patients with uncomplicated URIs were invited to complete the quiz and a follow-up questionnaire both before and after an education session with their provider. The questionnaire asked what the patient

thought was the purpose of the quiz and whether or not he/she felt the quiz accurately measured his/her knowledge about inappropriate use of antibiotics. Nineteen of the twenty participants reported that their score on the quiz were reflective of their knowledge. Efficacy of the education program measured patients' understanding on proper antibiotics use as documented by a) the patients' belief in the need for antibiotics, b) the patients' perception on education affect their decisions to fill the prescriptions for antibiotics. A Chi-Square Test of Association was used to assess the association.

The Wisconsin Upper Respiratory Symptom Survey 21(WURSS-21) (Appendix L) is a self-administered questionnaire developed in the United States to evaluate the severity of the common cold. Composite reliability coefficients ranged from 0.87 to 0.97, and Cronbach's alpha ranged from 0.76 to 0.96 (Barrett et al., 2009). Illness-specific health-related quality-of-life (WURSS) correlates closely with physical health. Both versions of WURSS-44 and 21 yielding Pearson correlation coefficients of 0.920, 0.925, and 0.937 on Days 2, 3 and 4, respectively. These findings are evidence of convergent validity of the WURSS-21 (Barrett et al., 2009). Duration and severity of symptoms as documented by WURSS 21 scores.

The Follow Up Response Form (Appendix H) measured the patient's understanding of appropriate antibiotics use, and symptomatic treatment for uncomplicated URIs. Face validity was established by one FNP and two physicians. Effectiveness between intervention one and two in decreasing antibiotics use as documented on the follow-up respond form as a) if patients filled the antibiotics prescriptions and b) days (post screening) the patients filled the antibiotics prescriptions. Belief in the symptomatic treatment as documented on the follow-up respond form as yes or no. Patient satisfaction as documented on the Follow-Up Response Form using a zero to five points Likert scales ranging from "not at all satisfied" to "very satisfied."

Both physicians and FNP served on the committee of the quality improvement (QI) teams of the hospital affiliated with the clinic where the study will take place. The QI team included a diverse group of individuals who had different roles and perspectives on the patient care and the hospital was currently conducting research on inappropriate antibiotics use supported by The Agency for Healthcare Research and Quality (AHRQ). The QI committee members participating in this project are subject matter experts on the research on the research of inappropriate antibiotics use. The primary investigator (PI) for the project and the faculty directing the project completed CITI training (see Appendix E and Appendix F) and approval was obtained for the study from the urgent care clinic's medical director. IRB approval was attained from the Regis University prior to beginning the project. UMCC hospital IRB was not required since the study was a QI project and was not being conducted in the premise of the hospital.

Risk Evaluation

Potential risks for the participants included fear of not receiving standard of care if they do not participate in the project, fear of not answering the quiz currently or having their scores influence the level of care, and possible fear of delayed healing from not starting immediate antibiotics therapy. Although all the HIPAA guidelines were meticulously followed, there was fear of breeches of privacy, or fear of care providers becoming disappointed in them for starting the antibiotics and no longer being willing to treat them in the future. There was a risk for physical and emotional distress from waiting to start antibiotics, and possible delay treatment; however, all the participants were informed that the participation in the project was voluntarily and they could revoke consent to participate at any time. All the documentation related to the project including subject identification was stored in a locked and secured cabinet of the urgent

care clinic and will be shredded and destroyed in three years. Only the PI, office manager and care providers had access to this documentation. HIPAA is strictly mandated in the urgent care clinic.

All participants were provided contact information for the PI, project mentor, faculty and IRB representatives and told how to contact the urgent care clinic during business hours with questions and support. All participants were instructed to schedule follow-up visit if they did not feel well or noted new symptoms.

The participants were given verbal and written instructions (see Appendix C and D) that they could fill and start antibiotics any time after the office visit, regardless of continued participation in the project or not. They were also reminded they could drop out of the project at any time but did not need to drop out of study if they elected to start the antibiotics immediately. No compensations were offered for participation in the study other than the free follow-up appointment.

The collaborating urgent care providers and supporting staff agreed to participate and provide the clinic space and equipment for the project without financial compensation from the project. The benefits to the participants were the free project related office follow-up visit, the additional education on inappropriate antibiotics use and possibly a decrease in adverse effects associated from antibiotics from decrease use.

Project Findings and Results

Sample Description

From October 11, 2017 to Oct 21, 2017, a total of 108 subjects met the inclusion criteria and were invited to participate in the study. Sixty-seven subjects agreed to participate. Fifty of the participants provided complete data sets with no missing values. Overall 33 participants (49.3%) were male and 34 (50.7%) were female. Fifty-nine (92.2%) of the subjects reported some college education (Table 2). Of the 59 participants, an additional 17 (26.6%) stated having an advanced degree beyond bachelor's degree as well. The most common diagnosis was viral pharyngitis (n=13; 19.4%), followed by sinusitis (n=12; 17.9%) and URI (n=11, 16.4%).

Table 2.

Baseline Patient Characteristics

Characteristics	Intervention One Patient Led (n=33)	Intervention Two Collection (n=34)	Total (n=67)
Gender			
Male	19 (28.4%)	14 (20.9%)	33 (49.3%)
Female	15 (22.4%)	19 (28.4%)	34 (50.7)
Age			
18-30	14 (20.9%)	10 (14.9%)	24 (35.8%)
31-40	5 (7.5%)	11 (16.4%)	16 (23.9%)
41-50	6 (9%)	6 (9%)	12 (17.9%)
51-60	6 (9%)	2 (3%)	8 (11.9)
61-65	3 (4.5%)	4 (6%)	7 (10.4%)
Types of URIs			
Bronchitis	5 (7.5)	3 (4.5)	8 (11.9)
Pharyngitis	7 (10.4)	6 (9)	13 (19.4)
Sinusitis	5 (7.5)	7 (10.4)	12 (17.9)
Cold	5 (7.5)	5 (7.5)	10 (14.9)
Viral syndrome	2 (3)	3 (4.5)	5 (7.5)
URI	6 (9)	5 (7.5)	11 (16.4)
Otalgia	4 (6.0)	4 (6.0)	8 (11.9)
Educational level			
High School	2 (3.1%)	3 (4.7%)	5 (7.8%)
Some College	22 (34.4)	20 (31.3)	42 (65.6)
Advanced Degree	9 (14.1)	8 (12.5)	17 (26.6)
Not Answered	0	3 (4.7%)	3 (4.7%)
Severity of symptoms			

Not sick/very mild	0	0	0
Mild	4 (6%)	1 (1.5%)	5 (7.5)
Moderate	17 (25.4)	16 (23.9)	33 (49.3)
Severe	13 (19.4)	16 (23.9)	29 (43.3)
Need for antibiotics			
Yes	26 (38.8%)	25 (37.3)	51 (76.1%)
No	0	3 (4.5%)	3 (4.5%)
Not sure	8 (11.9%)	5 (7.5%)	13 (19.4%)

Comparison Between Intervention One and Intervention Two

Overall 34 (50.7%) of the subjects ended up filling the antibiotics prescriptions and 33 (49.3%) did not fill their antibiotics prescriptions (see Table 3). For subjects who ended up filling their prescriptions, 20 (20.9%) of the subjects filled their prescriptions in 1-3 days post screening (day zero), and 14 (20.9%) subjects waited till day 4-6 post screening to fill their antibiotics prescriptions (see Table 3).

The Chi-Square Test of Association showed that there was an association between antibiotics used and different intervention groups (X^2=9.344, p<0.05). In Intervention One--the patient led delayed prescription strategy, 23 subjects (34.3%) did not use antibiotics, compared to the ten subjects (14.9%) in Intervention Two- the collection delayed prescriptions strategy did not fill their antibiotics prescriptions (see Table 4).

While the subjects in the patient led delayed prescription strategy use antibiotics less than those in the collection delayed prescription strategy, it is worthwhile to mention that there was an association between the days the subjects filled their prescriptions for antibiotics in different intervention groups. Nine subjects (13.4%) from the collection strategy and five subjects (7.1%) waited four to six days before using antibiotics.

Our study results showed that Intervention One- the patient led delayed prescription strategy decreased the antibiotics use more effectively compared to the Intervention Two- collective delayed prescription strategy. We predicted that the collective strategy would decrease

antibiotics use more than the patient led intervention. The hassle of having to call our clinic for a prescription would serve as a deterrent. The low use of antibiotics observed in the patient led delayed was unexpected. During the follow up visit, several subjects from the patient led strategy reported that having the antibiotics prescriptions on hand served as a "safety net". They were willing to try symptomatic treatment longer because of that.

Table 3

Antibiotic Rx Filled and Patient Satisfaction Between Interventions

Characteristics	Intervention One Patient Led (n=33)	Intervention Two Collection (n=34)	Total
Antibiotic Rx filled			
Yes	11 (16.4%)	23 (34.3%)	34 (50.7%)
No	23 (34.3%)	10 (14.9%)	33 (49.3%)
Days antibiotics filled			
Not filled	23 (34.3%)	10 (14.9%)	33(49.3%)
Day 1-3	6 (9%)	14 (20.9%)	20 (20.9%)
Day 4-6	5 (7.5%)	9 (13.4%)	14 (20.9%)
Day 7-10	0	0	0
Patient satisfaction			
Very unsatisfied-somewhat unsatisfied	0	0	0
Somewhat satisfied	3 (4.5%)	12 (17.9%)	15 (22.4%)
Satisfied	20 (29.9%)	16 (23.9%)	36 (53.7%)
Very Satisfied	11 (16.4%)	5 (7.5%)	16 (23.9%)

Table 4

Filling of Antibiotic Rx Between Interventions

			ABx Rx filled		
			no	yes	Total
Intervention	Intervention A	Count	23	11	34
		% of Total	34.3%	16.4%	50.7%
	Intervention B	Count	10	23	33
		% of Total	14.9%	34.3%	49.3%
Total		Count	33	34	67
		% of Total	49.3%	50.7%	100.0%

Statistics

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	9.344[a]	1	.002		
Continuity Correction[b]	7.909	1	.005		
Likelihood Ratio	9.576	1	.002		
Fisher's Exact Test				.003	.002
Linear-by-Linear Association	9.204	1	.002		
N of Valid Cases	67				

Education Program Outcomes

On day 0 (screening day), prior to receiving the educational program and discussion, 51 (76.1%) subjects stated that antibiotics were needed for their conditions. Thirteen (19.4%) subjects were not sure about the need for antibiotics, and three (4.5%) of the subjects stated that they did not need antibiotics. After reading the CDC *Get Smart About Antibiotics* brochure, completing the post reading quiz and discussion with the providers, 64 (95.5%) subjects reported that antibiotics were not necessary with three (4.5%) subjects stated that they were not sure (see Table 5). All the 67 (100%) subjects verbalized understanding of the educational material. Fifty-eight participants (86.6%) said that the education material affected their decisions on filling the antibiotics prescriptions; while, nine (13.4%) stated the education material they received on screening day did not affect their decisions on filling the antibiotic prescriptions. There was no association between the impact of patient education and antibiotics use (X^2=-3.039, p>0.05 Chi-Square Test) [See Table 6].

Table 5

Perception on Education Program Affecting Decision on Filling Antibiotic Prescriptions

Characteristics	Intervention One Patient Led (n=33)	Intervention Two Collection (n=34)	Total (n=67)
Perceived need for antibiotic before education			
Yes	26 (38.8%)	25 (37.3%)	51 (76.1%)
No	0 (0%)	3 (4.5%)	3 (4.5%)
Not sure	8 (11.9%)	5 (7.5%)	13 (19.4%)
Perceived need for antibiotics after education			
Yes	0 (0%)	0 (0%)	0 (0%)
No	32 (47.8%)	32 (47.8)	64 (95.5%)
Not sure	2 (3%)	1 (1.5%)	3 (4.5%)
Patients' Perception on the education materials affecting decision on filling antibiotic prescriptions			
Yes	30 (44.8%)	28 (41.8%)	58 (86.6%)
No	4 (6%)	5 (7.5%)	9 (13.4%)
Patients filled antibiotics			
Yes	11 (16.4%)	23 (34.3%)	34 (50.7%)
No	23 (34.3%)	10 (14.9%)	33 (49.3%)

Table 6

Rx Filled and Education's Effect on Decision

			Ed Material affect ABx Rx decision		
			yes	No	Total
ABx Rx filled	no	Count	31	2	33
		% of Total	46.3%	3.0%	49.3%
	yes	Count	27	7	34
		% of Total	40.3%	10.4%	50.7%
Total		Count	58	9	67
		% of Total	86.6%	13.4%	100.0%

Statistics

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	3.039[a]	1	.081		
Continuity Correction[b]	1.918	1	.166		
Likelihood Ratio	3.203	1	.073		
Fisher's Exact Test				.150	.082
Linear-by-Linear Association	2.994	1	.084		
N of Valid Cases	67				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 4.43.
b.

Impact of Education on Patient Satisfaction

There was an increase in patient's satisfaction to the treatment they received for those that said the education material affected their decisions on antibiotics use (X^2=12.392, p<0.01) [see Table 7], regardless of the intervention group they were assigned (X^2=0.165, p>0.05); but, the subjects' perceptions on the need for antibiotics before (X^2=2.418, p>0.05) and after (X^2=3.048, p>0.05) the education were not associated with antibiotics use.

Our study indicated that while the subjects reported that the education material influenced their decision to fill the antibiotic prescriptions, the statistical analysis showed a different pattern. The educational material did not make any impact in actual antibiotic used in the subjects with uncomplicated URIs. However, the patient satisfaction revealed that the subjects appreciated additional time spent with the providers and knowledge gained on their conditions. This suggestion could not be verified by the study.

Chi-Square Test of Association (see Table 6) showed that there were no association between the impact of patient education and antibiotics use (X^2=-3.039, p>0.05), however, there was a difference with the patient's satisfaction and those who felt that the education material affects their decisions on antibiotics use (Z=-3.198, p<0.01). In addition to that, there were no

association between the impact of patient education and different intervention groups (X^2=0.165, p>0.05). The Chi-Square Test of Association also illustrated that the subjects' perceptions on the need for antibiotics before (X^2=2.418, p>0.05) and after (X^2=3.048, p>0.05) education were not associated with antibiotics use at the end of study.

A total of 67 participants were recruited for this project. Before education session, 51 of the 67 subjects said that they needed antibiotics for their conditions. At the end of the study, 34 of the subjects ended up using antibiotics. There was a 25% reduction in antibiotics use. The educational program did not make any statistically significant in decreasing the use of antibiotics. All the study participants verbalized understanding of the education material. Most subjects (n=51, 76.1%) who started with stating they wanted antibiotics prior to the education, verbalized that antibiotics might not be necessary after the education. Fifty-eight of the 67 (86.6%) of the participants felt that the education would impact their decision on antibiotics use, but statistical analysis showed that there were no association between the impact of patient education and antibiotics use (X^2=-3.039, p>0.05) [See Table 6].

Table 7

Patient's Satisfaction and Education

Pt Satisfaction * Ed Material affect ABx Rx decision Crosstabulation

			Ed Material effect ABx Rx decision		
			yes	No	Total
Pt Satisfaction	Somewhat Satisfied	Count	9	6	15
		% of Total	13.4%	9.0%	22.4%
	Satisfied	Count	33	3	36
		% of Total	49.3%	4.5%	53.7%
	Very Satisfied	Count	16	0	16
		% of Total	23.9%	0.0%	23.9%
Total		Count	58	9	67
		% of Total	86.6%	13.4%	100.0%

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	12.392[a]	2	.002
Likelihood Ratio	12.025	2	.002
Linear-by-Linear Association	10.288	1	.001
N of Valid Cases	67		

a. 3 cells (50.0%) have expected count less than 5. The minimum expected count is 2.01.

Symptomatic Treatment

In general, 36 (53.7%) subjects felt that symptomatic treatment was helpful, 14 (20.9%) of the subjects did not think it help, and 17 (25.4%) subjects were not sure if symptomatic treatment helped (see Table 8). Twenty-five subjects (37.7%) who perceived symptomatic treatment as helpful ended up not using antibiotics. There is an association between antibiotics used and the patient's perception on the helpfulness of symptomatic treatment (X^2=13.693, $p \leq 0.001$). The subjects who were unsure or felt that symptomatic treatment was not helping 34 subjects (23%) filled their antibiotics prescriptions during the study. Seven (10.4%) of the subjects who believed that symptomatic treatment was helpful waited longer to fill their antibiotic prescriptions compared to those who felt unsure or that the symptomatic treatment was not helpful (see Table 9). There was an association between days subjects waited to fill their antibiotics prescriptions and the patient's perception on the helpfulness of symptomatic treatment (X^2=15.360, $p \leq 0.001$).

More than half of the subjects stating that symptomatic treatment helped, and symptomatic treatment was included in the educational program, the perceived helpfulness of symptomatic treatment was strongly associated with decreased antibiotics use in this study. The perception of helpfulness of the symptomatic treatment seemed to encourage the subjects to try the treatment longer and hold off filling their antibiotic prescriptions.

Table 8

Symptomatic treatment and Filling Antibiotic Rx

			Helpfulness of Sym Tx			
			no	yes	Not Sure	Total
ABx Rx filled	no	Count	5	25	3	33
		% of Total	7.5%	37.3%	4.5%	49.3%
	yes	Count	9	11	14	34
		% of Total	13.4%	16.4%	20.9%	50.7%
Total		Count	14	36	17	67
		% of Total	20.9%	53.7%	25.4%	100.0%

Statistics

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	13.693[a]	2	.001
Likelihood Ratio	14.458	2	.001
Linear-by-Linear Association	1.544	1	.214
N of Valid Cases	67		

Table 9

Perceived Helpfulness of Antibiotics and Day Prescriptions Filled

			Helpfulness of Sym Tx			
			no	yes	Not Sure	Total
Day ABx Rx Filled	Not filled	Count	5	25	3	33
		% of Total	7.5%	37.3%	4.5%	49.3%
	Day 1-3	Count	7	4	9	20
		% of Total	10.4%	6.0%	13.4%	29.9%
	Day 4-6	Count	2	7	5	14
		% of Total	3.0%	10.4%	7.5%	20.9%
Total		Count	14	36	17	67
		% of Total	20.9%	53.7%	25.4%	100.0%

Statistics

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	15.360[a]	2	.000
Likelihood Ratio	16.233	2	.000
Linear-by-Linear Association	1.584	1	.208
N of Valid Cases	67		

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 6.90.

Duration and Severity of Symptoms

The median of severity of symptoms on day zero or day of screening was rated as three or moderate (81-120 on WURSS 21) with zero corresponding to not sick and four as severe (see Table 10). Thirty-three (49.3%) of the subjects complained of moderate severity symptoms upon first visit, and 29 (43.3%) rated their symptoms as severe. The presence of symptoms at the day of screening or first visit was similar among the two intervention groups ($p>0.05$). Overall 62 (92.6%) of the subjects were experiencing moderate to severe symptoms.

On day three (see Table 11), 29 (43.3%) of the patient reported moderate symptoms severity, 26

(38.8%) rated their symptoms as severe. Of all the 26 participants who rated their symptoms as severe, 18 (69.2%) of those were subjects assigned to Intervention B. Twelve (17.9%) subjects rated their symptoms as mild at day three compared to only five (7.5%) reported of mild symptoms on day zero. On day seven (see Table 12), no participants rated their symptoms as severe. Only five (7.5%) participants rated their symptoms as moderate. 46 (68.6%) of the participants rated their symptoms as very mild to mild. thirteen (19.4%) of the subjects reported of not sick. On day ten, (see Table 13) fifty-two (77.6%) of the subjects reported of not sick, seven (10.4%) with very mild symptoms, no participants reported of moderate or worse symptoms and eight subjects did not return their day 10 survey.

Table 10

Severity of Symptoms on Day Zero Between Intervention Groups

			Intervention		
			Intervention A	Intervention B	Total
WURSS 21 D0	Mild (41-80)	Count	4	1	5
		% of Total	6.0%	1.5%	7.5%
	Moderate (81-120)	Count	17	16	33
		% of Total	25.4%	23.9%	49.3%
	Severe (>120)	Count	13	16	29
		% of Total	19.4%	23.9%	43.3%
Total		Count	34	33	67
		% of Total	50.7%	49.3%	100.0%

Table 11

Severity of Symptoms on Day Three Between Intervention Groups

			Intervention		
			Intervention A	Intervention B	Total
WURSS 21 D3	Mild (41-80)	Count	9	3	12
		% of Total	13.4%	4.5%	17.9%
	Moderate (81-120)	Count	17	12	29
		% of Total	25.4%	17.9%	43.3%
	Severe (>120)	Count	8	18	26
		% of Total	11.9%	26.9%	38.8%
Total		Count	34	33	67

	% of Total	50.7%	49.3%	100.0%

Table 12

Severity of Symptoms on Day Seven Between Intervention Groups

			Intervention		
			Intervention A	Intervention B	Total
WURSS 21 D7	Not sick (0)	Count	9	4	13
		% of Total	13.4%	6.0%	19.4%
	Very Mild (1-40)	Count	8	17	25
		% of Total	11.9%	25.4%	37.3%
	Mild (41-80)	Count	15	6	21
		% of Total	22.4%	9.0%	31.3%
	Moderate (81-120)	Count	1	4	5
		% of Total	1.5%	6.0%	7.5%
	not answer	Count	1	2	3
		% of Total	1.5%	3.0%	4.5%
Total		Count	34	33	67
		% of Total	50.7%	49.3%	100.0%

Table 13

Severity of Symptoms on Day Ten Between Intervention Groups

			Intervention		
			Intervention A	Intervention B	Total
WURSS 21 D10	Not Sick (0)	Count	27	25	52
		% of Total	40.3%	37.3%	77.6%
	Very Mild(1-40)	Count	3	4	7
		% of Total	4.5%	6.0%	10.4%
	not answer	Count	4	4	8
		% of Total	6.0%	6.0%	11.9%
Total		Count	34	33	67
		% of Total	50.7%	49.3%	100.0%

Table 14

Difference with Antibiotics Used and The Severity of Symptoms

Ranks

	Intervention	N	Mean Rank	Sum of Ranks
WURSS 21 D0	Intervention A	34	31.62	1075.00
	Intervention B	33	36.45	1203.00
	Total	67		
WURSS 21 D3	Intervention A	34	28.04	953.50
	Intervention B	33	40.14	1324.50
	Total	67		
WURSS 21 D7	Intervention A	34	33.35	1134.00
	Intervention B	33	34.67	1144.00
	Total	67		
WURSS 21 D10	Intervention A	34	33.46	1137.50
	Intervention B	33	34.56	1140.50
	Total	67		
ABx Rx filled	Intervention A	34	27.84	946.50
	Intervention B	33	40.35	1331.50
	Total	67		
Day ABx Rx Filled	Intervention A	34	28.07	954.50
	Intervention B	33	40.11	1323.50
	Total	67		

Statistics

	WURSS 21 D0	WURSS 21 D3	WURSS 21 D7	WURSS 21 D10	ABx Rx filled	Day ABx Rx Filled
Mann-Whitney U	480.000	358.500	539.000	542.500	351.500	359.500
Wilcoxon W	1075.000	953.500	1134.000	1137.500	946.500	954.500
Z	-1.136	-2.747	-.289	-.319	-3.034	-2.749
Asymp. Sig. (2-tailed)	.256	.006	.772	.750	.002	.006

The Mann-Whitney U analysis (see Table 14) indicated that there was a difference with antibiotics used and the severity of symptoms (Z=-3.034, p=0.002). More specifically, there was a difference with antibiotics used and the severity of symptoms on day three (z =-2.747, p =.006) while there were no difference with antibiotics used and the severity of symptoms on day zero (*Z*=--1.136, p>0.05); day seven (*Z*=-0.289, p>0.05) or day ten (*Z*=-0.319, p>0.05). The study

showed that most subjects reported experiencing moderate to severe symptoms when they came to the clinic for evaluation. The severity of symptoms gradually decreased after day three, the majority of the participants were feeling better by day seven and closed to 80% reported no symptoms on day ten. Our study showed that the subjects' antibiotics used was strongly related to the severity of symptoms on day three.

Patient Satisfaction

All 67 (100%) subjects expressed favorable views of the treatment and rated at least 3 or somewhat satisfied on a 0-5 Likert scale. 15 (22.4%) rated somewhat satisfied, 36 (53.7 %) rated 4 or satisfied, 16 (23.9%) subjects rated "very satisfied" (see Table 15).

A Mann-Whitney U test (Table 16) indicated that there was a difference (Z= -2.666, P=0.008) with the patient led delayed prescription strategy ranked higher in the patient satisfaction than the collection delayed prescriptions. Thirty-one subjects (46.3%) of the participants in the patient led delayed prescription were satisfied and very satisfied with the treatment compared to the collection delayed prescriptions, 21 subjects (31.4%) were satisfied and very satisfied with the treatment. Fifty-three (79.1%) of the subjects stated that they did not seek help from another clinics or providers with seven (10%) subjects stated that they did seek help at other places. Seven subjects (10.4%) did not return their survey or return for day 10 complementary office visit. Overall, 67 (100%) of the participants rated their treatment from somewhat satisfactory to very satisfied. There was no rating below somewhat satisfactory. In addition to the high patient satisfaction, the clinic retained 79% of the subjects. 36 (53.7 %) rated 4 or satisfied, 16 (23.9%) subjects rated "very satisfied".

Table 15

Patient Satisfaction Between Interventions

			Pt Satisfaction			
			Somewhat Satisfied	Satisfied	Very Satisfied	Total
Intervention	Intervention A	Count	3	20	11	34
		% of Total	4.5%	29.9%	16.4%	50.7%
	Intervention B	Count	12	16	5	33
		% of Total	17.9%	23.9%	7.5%	49.3%
Total		Count	15	36	16	67
		% of Total	22.4%	53.7%	23.9%	100.0%

Table 16

Ranking of Patient Satisfaction Between Interventions

Ranks

	Intervention	N	Mean Rank	Sum of Ranks
Pt Satisfaction	Intervention A	34	39.66	1348.50
	Intervention B	33	28.17	929.50
	Total	67		

Statistics

	Pt Satisfaction
Mann-Whitney U	368.500
Wilcoxon W	929.500
Z	-2.666
Asymp. Sig. (2-tailed)	.008

a. Grouping Variable: Intervention

Limitation, Recommendations, Implications for Practice

Limitations

One limitation to the study was how broadly URIs were defined so that the patient groups were comprised of subjects with a wide range of respiratory infections. This resulted in a heterogeneous sample which increased variance, making type II error more likely. The subjects were not randomized between the two delayed prescription strategies; although the two groups were well balanced for the patient characteristics, diagnoses, and severity of symptoms. While the study investigated and encouraged symptomatic treatment, complications associated with delayed prescription strategies or treatment failures were not assessed.

Recommendations

More research needs to be done to identify if educational programs and patient support in combination with the delayed prescription strategies would further reduce the inappropriate use of antibiotics. Although there is compelling evidence regarding the benefits of the delayed prescription strategies and patient education, additional investigation needs to be conducted on possible increased complications associated with delayed prescription strategies. Finally, continued study with a larger sample size, more homogenous groups and that includes a no prescription group with subjects from different ethnic groups is also recommended.

Implications for Practice

The results of the study suggested encouraging patients with a URI the subjects to try symptomatic treatment for at least three days prior to filling the antibiotics prescriptions could be a successful strategy for decreasing inappropriate antibiotic use. The results of this project illustrated that the delayed prescription strategy was associated with a high level of patient satisfaction along with decrease inappropriate antibiotics use.

Summary

At the beginning of the study, prior to the education session with the providers, fifty-one (76.1%) of the sixty-seven subjects felt that antibiotics were necessary for their condition. At the conclusion of the study, thirty-four (50.7%) of the sixty-seven subjects ended up using antibiotics (see Table 4). Assuming all fifty-one of the subjects planned to use antibiotics if the prescriptions were given to them, the delay prescription strategies had decreased the utilization of antibiotic by 25.4% while maintaining good patient satisfaction. This finding is consistent with the systemic reviews that delayed antibiotic prescriptions are associated with decreased antibiotic use in uncomplicated URIs (Agnew et al., 2013; De la Poza et al., 2016; Little et al., 2014). While the education program seemed like a success to educate subjects on inappropriate antibiotics use and the subjects even felt that the education program influenced their decision on antibiotic use, the results showed differently. The severity of the symptom on day three post office visit seemed to be the major determinant of antibiotic use in subjects. The education program failed to show any statistically significant direct impact on decreasing antibiotic use. However, the symptomatic treatment, which was part of the educational program, was strongly associated with decreased filling of antibiotic prescriptions. Also, the educational program contributed to patient satisfaction. The collection group reported a 17.9% higher rate of filling antibiotic prescriptions than the patient led group. This was a surprised finding since most studies (De la Poza et al., 2016; Little et al., 2014; Sargent, McCullough, Del Mar, & Lowe, 2016) suggested that subjects assigned to the collection strategies had lower use of antibiotics than the patient led strategy presumably due to the hurdle of having to return to the clinic for the prescription. Our study showed that subjects seemed to be willing to wait and try the symptomatic treatment longer when they have the antibiotic prescriptions on hand.

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Appendix A

What Everyone Should Know and Facts about Antibiotics

Antibiotics resistance is a growing problem, both in the United States and across the world. The main driving factors behind antibiotics resistance are the overuse and misuse of antibiotics. Learn more below about when antibiotics are and are not needed for common infections, and the potential harms of using antibiotics.

If You Have a Cold or Flu, Antibiotics Won't Work for You

Are you aware that colds, flu, most sore throats, bronchitis, and many sinus and ear infections are caused by viruses? Did you know that antibiotics do not help fight viruses? It's true. For the overwhelming majority of common respiratory infections, antibiotics are not helpful.

Get Smart…Read the Chart! To know which common illnesses are usually viral or bacterial and when antibiotics are necessary.

Common Condition: What's got you sick?	Common Cause			Are antibiotics needed?
	Bacteria	Bacteria or Virus	Virus	
Strep throat	✓			Yes
Whooping cough	✓			Yes
Urinary tract infection	✓			Yes
Sinus infection		✓		Maybe
Middle ear infection		✓		Maybe
Bronchitis/chest cold (in otherwise healthy children and adults)*		✓		No
Common cold/runny nose			✓	No
Sore throat (except strep)			✓	No
Flu			✓	No

* In some cases, acute bronchitis is caused by bacteria, but even in these cases antibiotics still do not help.

What Everyone Should Know and Facts about Antibiotics

Antibiotics cure bacterial infections, not viral infections such as: Colds or flu, most coughs and bronchitis, most sore throats, runny noses

Taking antibiotics for viral infections will not: Cure the infection, keep other individuals from catching the illness, and help you feel better

Antibiotics Can Cause More Harm than Good

Taking antibiotics when you have a virus may do more harm than good:

- Taking antibiotics increases your risk of getting an antibiotics-resistant infection later.
- Antibiotics kill the healthy bacteria in the gut, allowing more harmful bacteria, such as *C. difficile*, to grow in its place.
    - Although this infection is more commonly found in hospitals, it also occurs in clinics outside of the hospital.
- Antibiotics cause 1 out of 5 emergency department visits for adverse drug events.
    - Antibiotics are the most common cause of emergency department visits for adverse drug events in children under 18 years of age.

It's important to only take antibiotics for bacterial infections since they can put you or your child at risk for harmful side effects and antibiotics-resistant infections.

What Everyone Should Know and Facts about Antibiotics

Facts about Antibiotics Resistance

- Antibiotics resistance is one of the world's most pressing public health problems.
- Every time a person takes antibiotics, sensitive bacteria are killed, but resistant ones may be left to grow and multiply.

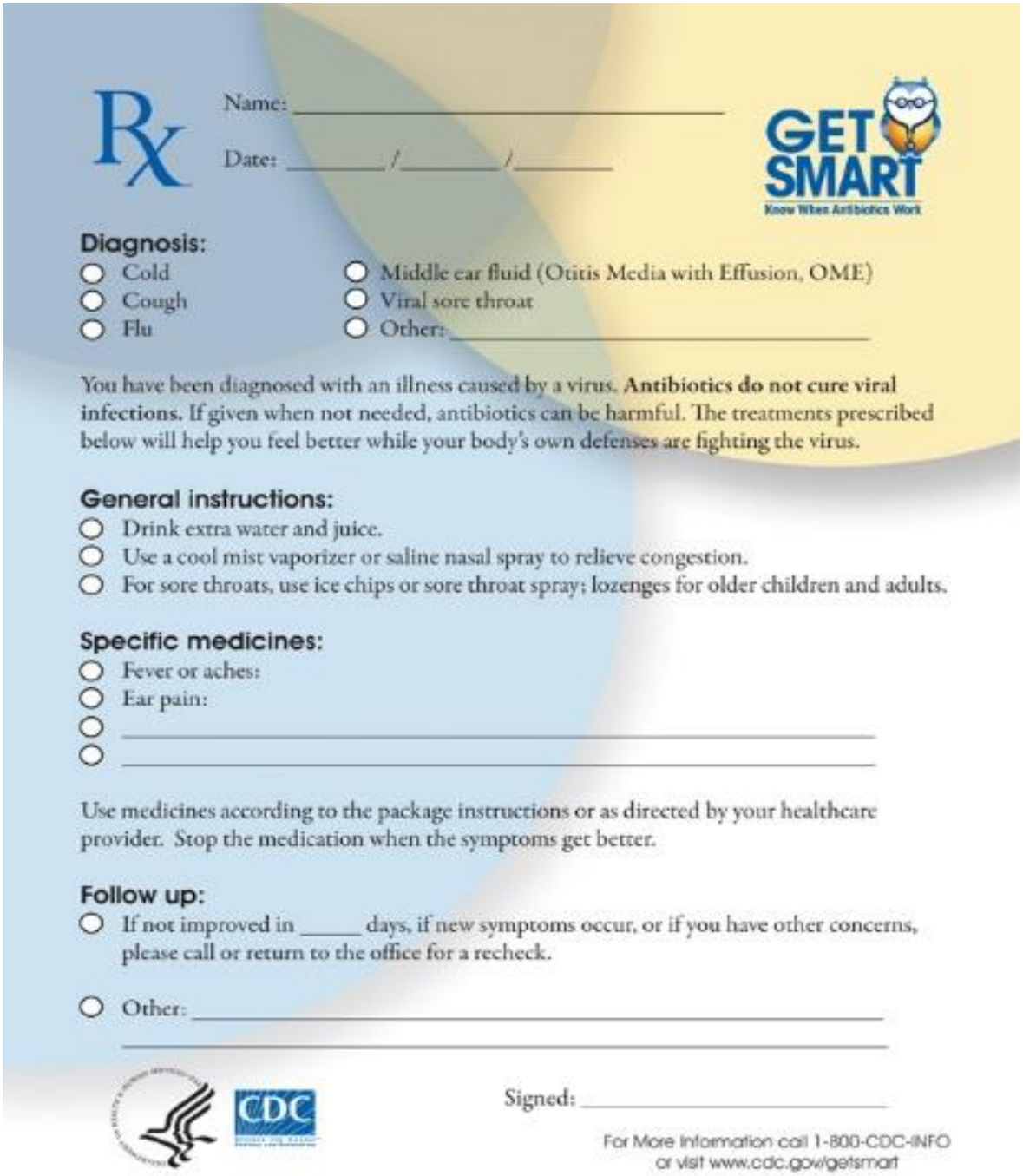
- Overuse of antibiotics is a major modifiable cause of increases in drug-resistant bacteria.
- Overuse and misuse of antibiotics threatens the usefulness of these important drugs. Decreasing inappropriate antibiotics use is a key strategy to control antibiotics resistance.
- Antibiotics resistance in children and older adults are of particular concern because these age groups have the highest rates of antibiotics use.
- Antibiotics resistance can cause significant suffering for people who have common infections that once were easily treatable with antibiotics.
- When antibiotics do not work, infections often last longer, cause more severe illness, require more doctor visits or longer hospital stays, and involve more expensive and toxic medications. Some resistant infections can even cause death.

Antibiotics Prescribing: Attitudes, Behaviors, Trends and Cost

- At least 30% of antibiotics courses prescribed in the outpatient setting are unnecessary, meaning that no antibiotics is needed at all. Most of this unnecessary use is for acute respiratory conditions, such as colds, bronchitis, sore throats caused by viruses, and even some sinus and ear infections
- Total inappropriate antibiotics use (which includes unnecessary antibiotics use plus inappropriate antibiotics selection, dosing, and duration) may approach 50% of all outpatient antibiotics use
- The number of antibiotics prescriptions written for children has decreased in recent years
    - Antibiotics cause 1 out of 5 emergency department visits for adverse drug events (ADEs). Antibiotics are the most frequent cause of ADEs leading to emergency department visits in children, and 7 of the top 10 drugs involved in ADEs leading to emergency room visits are antibiotics

Appendix B

Symptomatic Prescription Rx



Rx

Name: _____

Date: _____ /_____ /_____

GET SMART
Know When Antibiotics Work

Diagnosis:

- ○ Cold
- ○ Cough
- ○ Flu
- ○ Middle ear fluid (Otitis Media with Effusion, OME)
- ○ Viral sore throat
- ○ Other: _____

You have been diagnosed with an illness caused by a virus. **Antibiotics do not cure viral infections.** If given when not needed, antibiotics can be harmful. The treatments prescribed below will help you feel better while your body's own defenses are fighting the virus.

General instructions:

- ○ Drink extra water and juice.
- ○ Use a cool mist vaporizer or saline nasal spray to relieve congestion.
- ○ For sore throats, use ice chips or sore throat spray; lozenges for older children and adults.

Specific medicines:

- ○ Fever or aches:
- ○ Ear pain:
- ○ _____
- ○ _____

Use medicines according to the package instructions or as directed by your healthcare provider. Stop the medication when the symptoms get better.

Follow up:

- ○ If not improved in _____ days, if new symptoms occur, or if you have other concerns, please call or return to the office for a recheck.
- ○ Other: _____
  _____

CDC

Signed: _____

For More Information call 1-800-CDC-INFO
or visit www.cdc.gov/getsmart

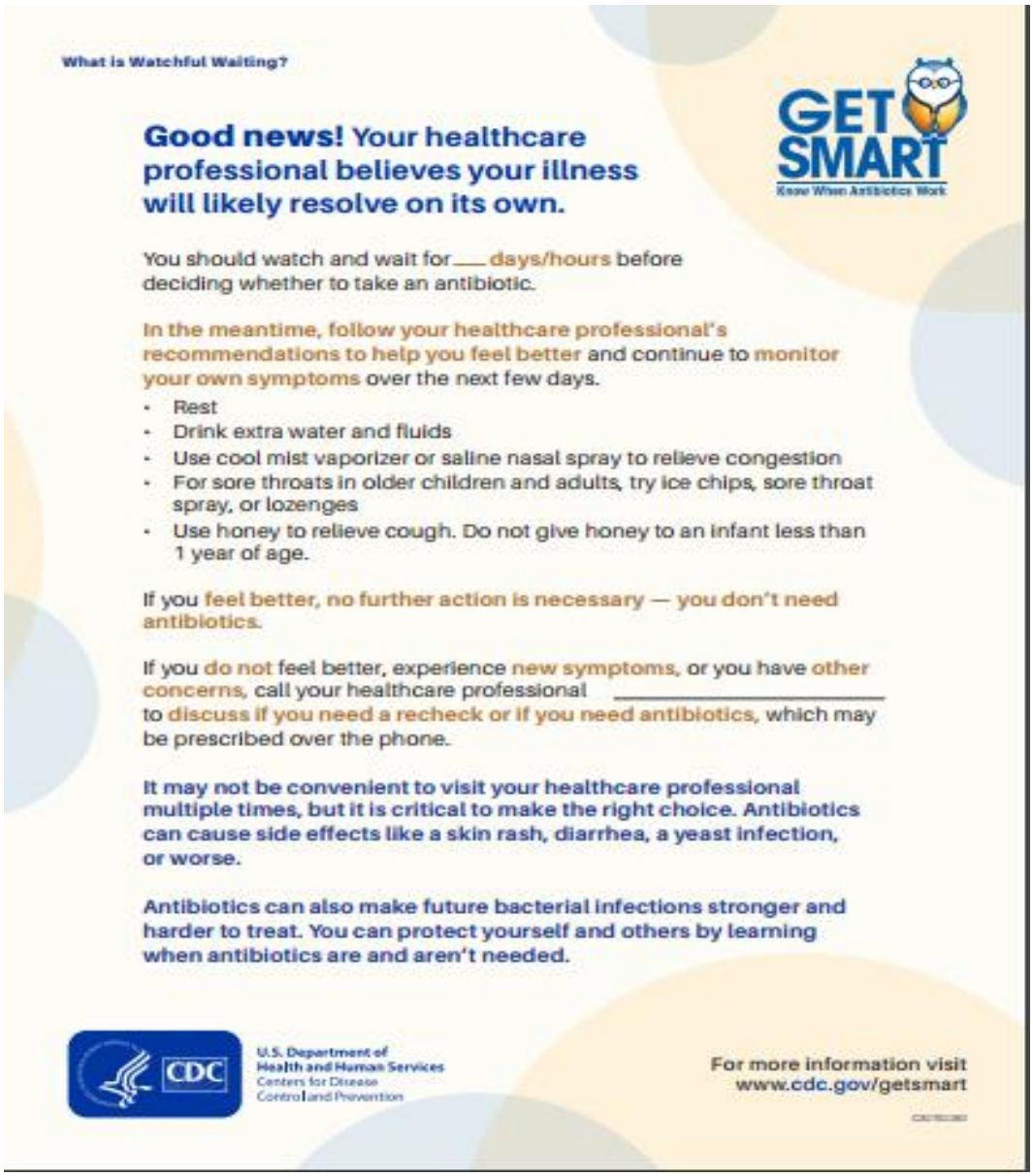
Appendix C

Delay Antibiotics Prescription

You may fill the antibiotic prescription that you received on screening day at **ANYTIME in the next 10 days at the UMCC hospital pharmacy**

Appendix D

Patient Collection Strategy



What is Watchful Waiting?

GET SMART
Know When Antibiotics Work

Good news! Your healthcare professional believes your illness will likely resolve on its own.

You should watch and wait for ___ days/hours before deciding whether to take an antibiotic.

In the meantime, follow your healthcare professional's recommendations to help you feel better and continue to monitor your own symptoms over the next few days.

- Rest
- Drink extra water and fluids
- Use cool mist vaporizer or saline nasal spray to relieve congestion
- For sore throats in older children and adults, try ice chips, sore throat spray, or lozenges
- Use honey to relieve cough. Do not give honey to an infant less than 1 year of age.

If you feel better, no further action is necessary — you don't need antibiotics.

If you do not feel better, experience new symptoms, or you have other concerns, call your healthcare professional _____ to discuss if you need a recheck or if you need antibiotics, which may be prescribed over the phone.

It may not be convenient to visit your healthcare professional multiple times, but it is critical to make the right choice. Antibiotics can cause side effects like a skin rash, diarrhea, a yeast infection, or worse.

Antibiotics can also make future bacterial infections stronger and harder to treat. You can protect yourself and others by learning when antibiotics are and aren't needed.

CDC
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

For more information visit
www.cdc.gov/getsmart

** Please call our medical assistant Takeem or Tabitha at 301-609-4699 **<u>ANYTIME</u>** in the next ten days should you decide on collecting your antibiotic prescription at the urgent care clinic and fill your antibiotic prescription at the UMCC hospital pharmacy**

Appendix E
CITI Training Certificate

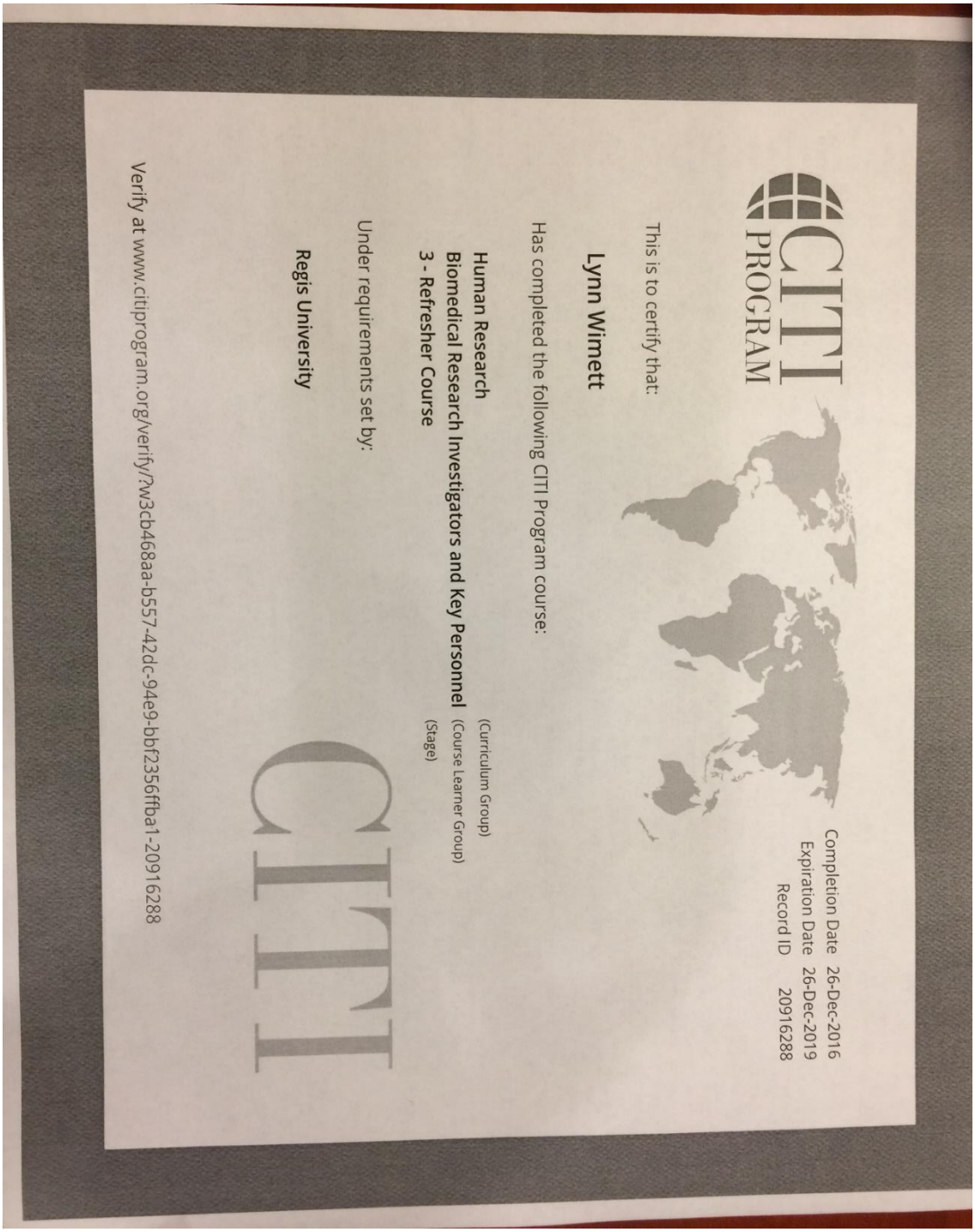
COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details.
See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- Name: Foong-Chee Cheah (ID: 5384142)
- Email: fcheah@regis.edu
- Institution Affiliation: Regis University (ID: 745)
- Institution Unit: Nursing
- Curriculum Group: Human Research
- Course Learner Group: Social Behavioral Research Investigators and Key Personnel
- Stage: Stage 1 - Basic Course
- Report ID: 18667089
- Completion Date: 02/09/2016
- Expiration Date: 02/08/2019
- Minimum Passing: 80
- Reported Score*: 93

REQUIRED AND ELECTIVE MODULES ONLY DATE COMPLETED
Belmont Report and CITI Course Introduction (ID: 1127) 02/09/16
History and Ethical Principles - SBE (ID: 490) 02/09/16
The Federal Regulations - SBE (ID: 502) 02/09/16
Assessing Risk - SBE (ID: 503) 02/09/16
Informed ENROLLMENT - SBE (ID: 504) 02/09/16
Privacy and Confidentiality - SBE (ID: 505) 02/09/16
Regis University (ID: 1164) 02/09/16
For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution
identified above or have been a paid Independent Learner.
CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

CITI Training Certificate



Appendix F

Informed Consent

Title of Study: The Difference in Antibiotics Prescriptions Filled between Patients Receiving the Delayed Patient-led Prescription Strategy and Those Receiving Delayed Prescription Collection Strategy for Uncomplicated Upper Respiratory Infections

Principal Investigator:
Name : Foong-Chee Joann Cheah FNP-BC
Department : UMCC Urgent care clinic
Address : 500 Charles St., La Plata MD 20646
Phone : 301-609-4699
E-mail : fcheah@regis.edu

Background:
You are being invited to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully. Please ask the researcher or anyone listed below under contact information any questions you have about the study or if you would like to know more about the study.

The purpose of this research is to compare and study two different delayed antibiotics strategies and patient satisfaction with a treatment plan designed to appropriately care for adult subjects with an uncomplicated upper respiratory infection such as colds, influenza, sore throat, bronchitis, cough or nasal congestion at the University of Maryland Charles Regional Medical Center (UMCC) Urgent Care Clinic in Charles County, Maryland.

Your expected time commitment for this study is approximately 45-75 minutes over the next ten days.

- 10-15 minutes today to learn about the study and consider participation,
- 10-15 minutes to reply to an email and complete a 21 question survey three days from today
- 10-15 minutes to reply to an email and complete a 21 question survey again seven days from today
- 15-30 minutes follow-up visit ten days from will be scheduled for you. There will not be any charges to you for the follow-up visit.

Study Procedure:
We are inviting all adult subjects who come to this urgent care clinic for treatment of symptoms of cough, earache, nasal congestion, sinus problems, or sore throat to participate in this study. Whether you decide to participate in our study or not, you will receive the exact same evaluation and treatment plan with two exceptions. The first is how you receive a prescription for an antibiotics if it is determined that you do not need the antibiotics at this time. The second difference is if you participate you will be offered a free follow-up appointment ten days from now to discuss your experience of being part of the study and in part to assure you have recovered from your illness. You may elect to cancel the follow-up visit or to stop participation in the study at any time even if you signed the consent form previously.

If you decide to participate in this study, you will be assigned to one of the two possible ways for you to receive antibiotics if they are needed. Both plans give you access to antibiotics immediately if you need them but each in a slightly different way. The researcher will compare the two methods to see which method is more satisfying for the subjects and which method is better at encouraging using antibiotics appropriately. Both strategies include a prescription for antibiotics, and regardless of which strategy is assigned to you, you are encouraged to only fill the prescription for the antibiotics if you are not feeling better after ten days of feeling sick or if you feel worse after starting to feel better in three or more days from now.

If you participate, I ask that you fill out a 21 question questionnaire about your symptoms today, again in three days and one last time in seven days (a total of three questionnaires). These questionnaires take about 10-15 minutes each to answer. The first one you will complete now and return to me. You can return the day three and day seven questionnaires to me in any of following ways, whichever one is easiest for you.

By email: If you provide me with the email address you would like me to use, I will send you a link for the online version of the survey with a reminder to please fill it out on day three and again a reminder to fill it out on day seven.

By hand: If you prefer to fill the questionnaires out by hand, two copies of questionnaires will be given to you today with the date on top to fill of when to complete it (one three days from now and another one seven days from now). You may return both questionnaires to the provider in person during your free office visit or mail them to me if you elect not to return for your follow-up visit. Please ask me for the return postage paid envelopes if this is the method you prefer for returning the questionnaires.

You will receive an email from the clinic in three days and again in seven days to check on how you are doing, answer questions that you may have and to remind you to complete the survey again.

Risks for Participation in the Study:
The risks to you of participating in the study are minimal. There is the additional time commitment on your part to complete the surveys but you will have the same access to antibiotics if you participate or elect not to participate in the study. The only difference is the

way you would get your antibiotics prescription. If this causes you any stress, you may choose to withdraw from the study. You may withdraw from the study at any time for any reason and whether you choose to participate or not to participate, it will not reflect on you in anyway. Your provider will continue to support you in meeting your health care needs and offer you, as always, the highest quality standard of care.

To help ensure your privacy of participation or not, your care providers will not have access to any data that they would not have access to if you were not in the study. The researcher will only report data as group information with no names attached to report. To help assure no one will know anything about your participation, survey answers or day and time you personally filled the prescription your name and clinic identification number will not be associated with any paperwork for the study. No one will have access to your data except the researcher unless they would have access to that information regardless of if you were in the study or not and need the information to provide you quality care in the future. All the documentation related to the project including anything that links your name or other identifying information to any documents will be stored in a locked and secured cabinet at the urgent care clinic for three years and then be shredded.

Benefits for Participation in the Study:
There is no financial incentive for you to participate in the study. However, as a thank you, the clinic will offer you a free of charge ten day follow-up visit if desired and you will be contributing to our clinic's data base as to what interventions are most effective in satisfying for you and future subjects that present with an upper respiratory infection. We thank you for your time and consideration.

Alternative Procedures:
Regardless of your participation or not in the study, your provider will address your health care goals and, with you, design a plan of care consistent with current evidence (standard of care) and your preferences today and in the future.

Confidentiality if You Elect to Participate:
Just a reminder, please do NOT write any identifying information on your questionnaire. Today, I will collect the first completed questionnaire from you then code it to identify you only to the researcher and provide you with code to use for any other documents you complete for the study. Every effort will be made to preserve your confidentiality including the following:

- Assigning code names/numbers for participants that will be used on all researcher notes and documents. No other identification of participants such as name or clinic identification numbers will be on any documents.
- Any documents with any identifying participant information will be kept in a locked file cabinet in the personal possession of the researcher. When no longer necessary for research, all materials will be destroyed.
- The researcher and the members of the researcher's committee will review the researcher's collected data. Information from this research will be used solely for the purpose of this study and any publications that may result from this study. All participants involved in this study will not be identified and their anonymity will be maintained.

- Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents. These incidents include, but may not be limited to, incidents of abuse and suicide risk.

Person to Contact:
Should you have any questions about the research or any related matters, please contact the researcher at
Name : Joann Cheah
Phone : 301-609-4699
E-mail : fcheah@regis.edu

OR

Dr. Lynn Wimett, a nurse practitioner and faculty member overseeing this research project:
Phone : 303-458-4063 (W)
: 720-203-1366 (C)
Email : lwimett@regis.edu

This study was approved by the Regis University Institutional Review Board

If you have questions regarding your rights as a research subject, or if problems arise which you do not feel you can discuss with the Investigator, or faculty member, please contact the clinical director, Erin Kim CRNP. Phone: 321-868-8313, email: erin.kim@health-first.org.

Regis Institutional Review Board Chair:
Dr. Margaret Oot-Hayes, PhD, RN
781-768-7163
margaret.oot-hayes@regiscollege.edu

Consent

Title of Study: The Difference in Antibiotics Prescriptions Filled between subjects Receiving the Delayed Patient-led Prescription Strategy and Those Receiving Delayed Prescription Collection Strategy for Uncomplicated Upper Respiratory Infections

Voluntary Participation:
Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study. If you do decide to take part in this study, you will be asked to sign this consent form. If you decide to take part in this study, you are still free to withdraw at any time and without giving a reason. You are free to not answer any question or questions if you choose. This will not affect the relationship you have with the providers/researcher.

Unforeseeable Risks:
There may be risks that are not anticipated. However every effort will be made to minimize any risks.

Costs To Subject:
There are no costs to you for your participation in this study. A complementary (free) 10 day follow-up appointment is offered to participants if they desire.

Compensation:
There is no monetary compensation to you for your participation in this study.

Consent:
By signing this consent form, I confirm that I have read and understood the information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Signature:_____

Print Name:

Date:

Witness Signature:_____

Print Name:

Date:

Appendix G

Enrollment Sheet

Number	Intervention 1	Intervention 2
1	Patient ID label	
2		
3		
4		
5		
6		
7		

Patient ID label will be placed in the space

-- Odd number subjects will be assigned to Intervention One

The first patient enrolled will be 1001, third patient will be 1002

-- Even number subjects will be assigned to Intervention Two

The second patient enrolled will be 2001, fourth patient will be 2002

--This enrollment sheet contains subjects' ID and the study participant numbers assigned to the subjects. Like all the documentation related to the project, it will be stored in a locked and secured cabinet of the urgent care clinic for three years. Only the PI, office manager and care providers have access to this documentation. HIPAA is strictly mandated in the urgent care clinic.

Appendix H

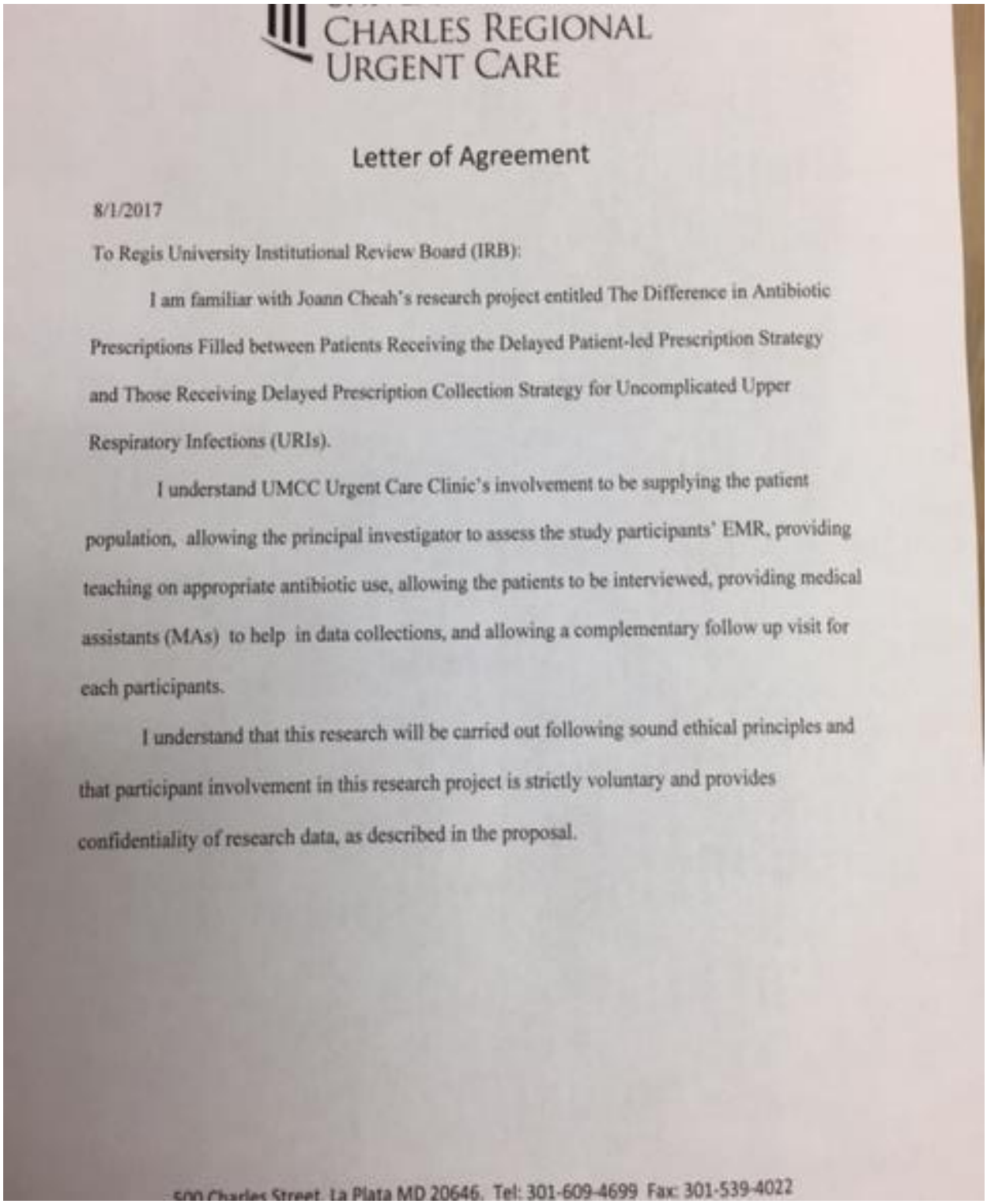
Follow Up Response Form

Patient ID: Intervention Arm: One or Two Final diagnosis ICD-10:

	Day 0—at office visit	Day 3	Day 7	Day 10 post office visit
Do you believe you need antibiotics? (before education) Same question after education	Y/N Y/N			
Does the education material helps with - 1.Understanding of your illness and progression? 2. influence your decision of filling the antibiotics Rx	Y/N Y/N			
Do you believe symptomatic treatment helps				Y/N
Did pt fill the antibiotics Rx? If yes, how long did pt wait after D0 to fill the Rx? How badly do you feel?Today? Day three? Day seven? Day ten? (WURSS 21 Score)	Baseline WURSS score Today_____	1. No 2. Day 1-3 3. Day 4-6 4. Day 7-9 5. Day 10+ Day three_____	1. No 2. Day 1-3 3. Day 4-6 4. Day 7-9 5. Day 10+ Day seven_____	1. No 2. Day 1-3 3. Day 4-6 4. Day 7-9 5. Day 10+ Day ten_____
Are you satisfied with the treatment?				0,1,2,3,4,5 (1-not at all, 5-very satisfied)
Did you seek help at another clinic due to dissatisfied treatment plan?				Y/N

Appendix I

Letter of Agreement from Urgent Care Clinic



CHARLES REGIONAL URGENT CARE

Letter of Agreement

8/1/2017

To Regis University Institutional Review Board (IRB):

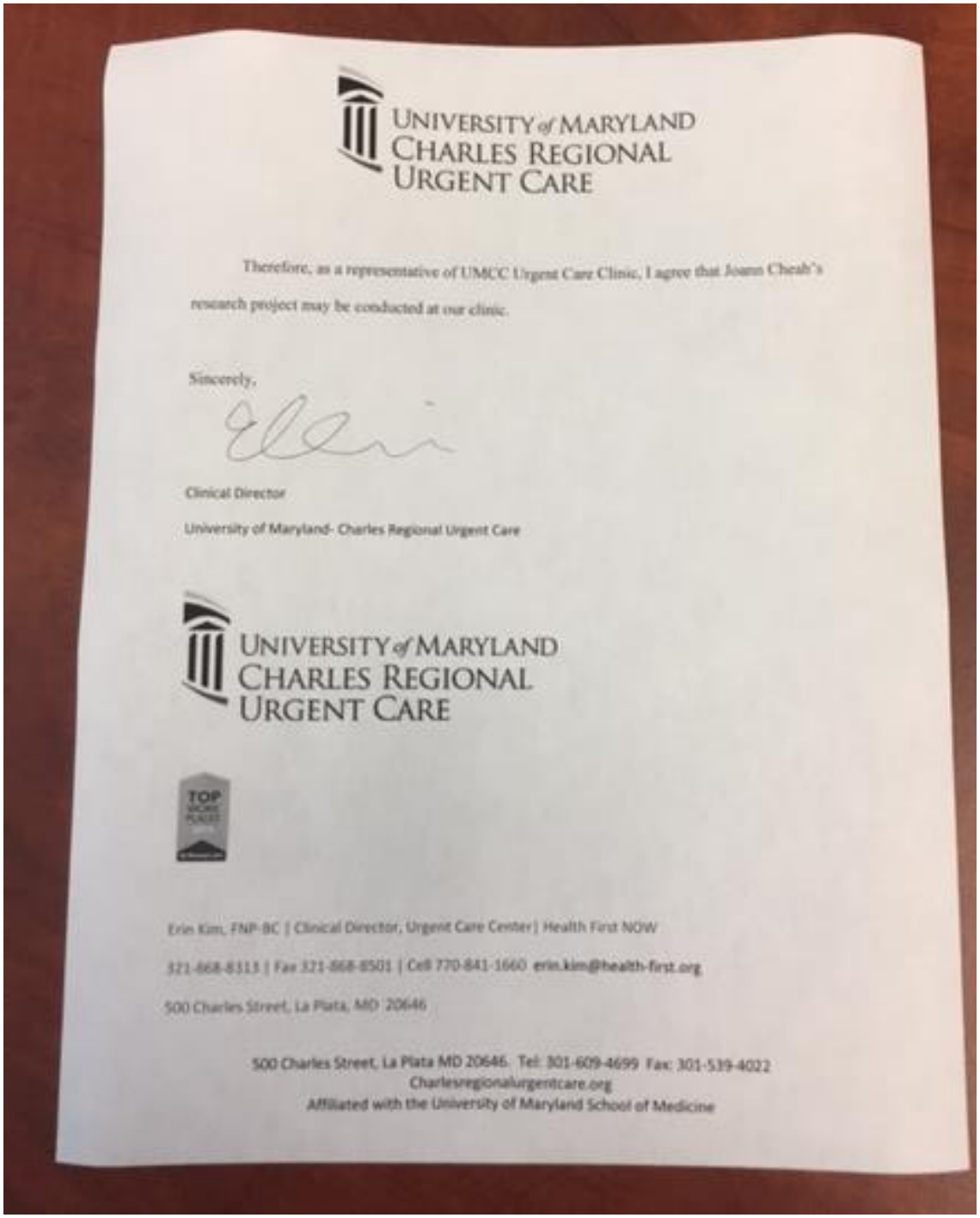
I am familiar with Joann Cheah's research project entitled The Difference in Antibiotic Prescriptions Filled between Patients Receiving the Delayed Patient-led Prescription Strategy and Those Receiving Delayed Prescription Collection Strategy for Uncomplicated Upper Respiratory Infections (URIs).

I understand UMCC Urgent Care Clinic's involvement to be supplying the patient population, allowing the principal investigator to assess the study participants' EMR, providing teaching on appropriate antibiotic use, allowing the patients to be interviewed, providing medical assistants (MAs) to help in data collections, and allowing a complementary follow up visit for each participants.

I understand that this research will be carried out following sound ethical principles and that participant involvement in this research project is strictly voluntary and provides confidentiality of research data, as described in the proposal.

500 Charles Street, La Plata MD 20646. Tel: 301-609-4699 Fax: 301-539-4022

Letter of Agreement from Urgent Care Clinic



UNIVERSITY of MARYLAND
CHARLES REGIONAL
URGENT CARE

Therefore, as a representative of UMCC Urgent Care Clinic, I agree that Joann Cheah's research project may be conducted at our clinic.

Sincerely,

Clinical Director

University of Maryland- Charles Regional Urgent Care

UNIVERSITY of MARYLAND
CHARLES REGIONAL
URGENT CARE

TOP

Erin Kim, FNP-BC | Clinical Director, Urgent Care Center| Health First NOW

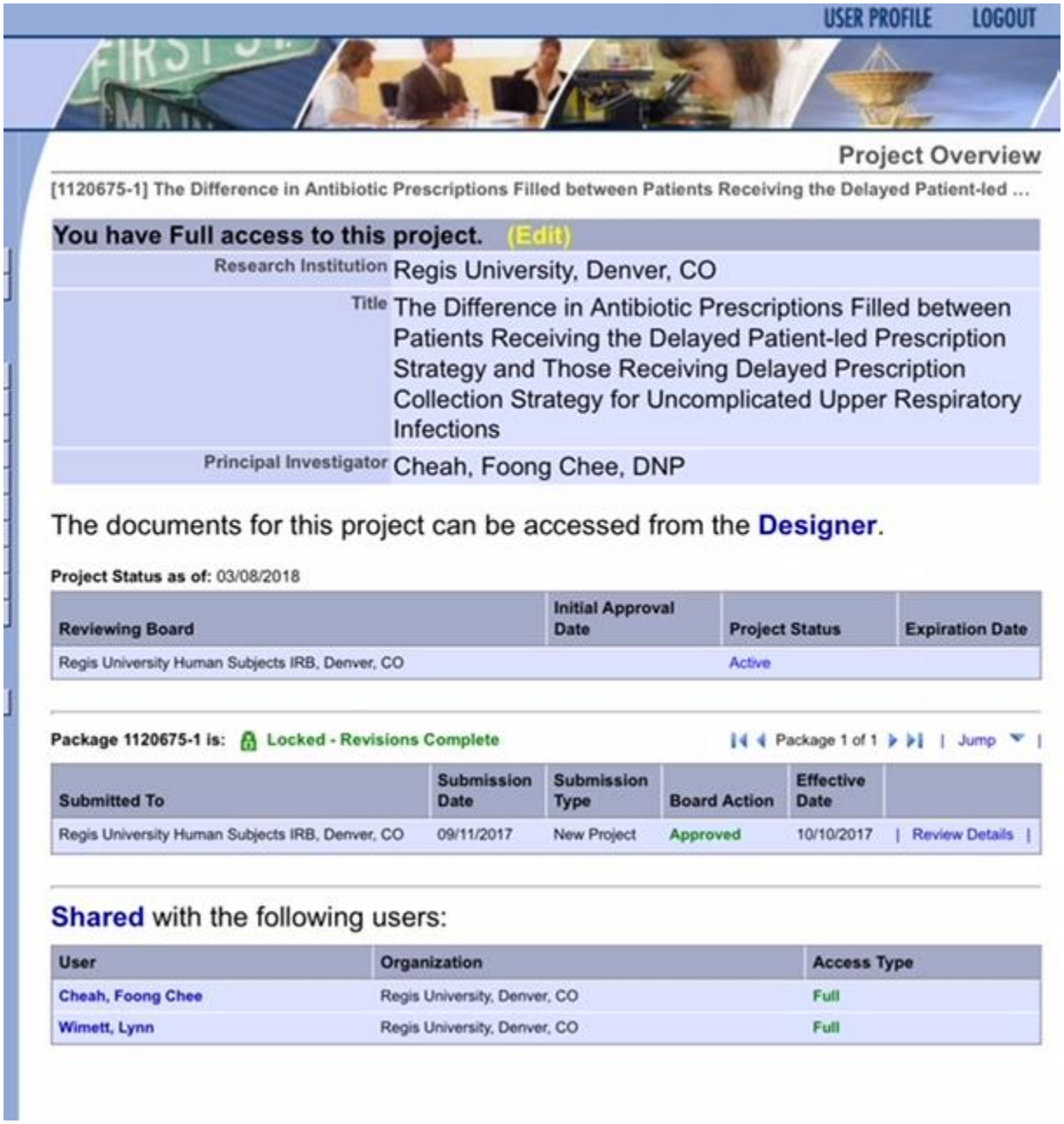
321-868-8313 | Fax 321-868-8501 | Cell 770-841-1660 erin.kim@health-first.org

500 Charles Street, La Plata, MD 20646

500 Charles Street, La Plata MD 20646. Tel: 301-609-4699 Fax: 301-539-4022
Charlesregionalurgentcare.org
Affiliated with the University of Maryland School of Medicine

Appendix J

Regis University IRB Approval



USER PROFILE LOGOUT

Project Overview

[1120675-1] The Difference in Antibiotic Prescriptions Filled between Patients Receiving the Delayed Patient-led ...

You have Full access to this project. (Edit)

Research Institution	Regis University, Denver, CO
Title	The Difference in Antibiotic Prescriptions Filled between Patients Receiving the Delayed Patient-led Prescription Strategy and Those Receiving Delayed Prescription Collection Strategy for Uncomplicated Upper Respiratory Infections
Principal Investigator	Cheah, Foong Chee, DNP

The documents for this project can be accessed from the **Designer**.

Project Status as of: 03/08/2018

Reviewing Board	Initial Approval Date	Project Status	Expiration Date
Regis University Human Subjects IRB, Denver, CO		Active	

Package 1120675-1 is: Locked - Revisions Complete Package 1 of 1 | Jump |

Submitted To	Submission Date	Submission Type	Board Action	Effective Date	
Regis University Human Subjects IRB, Denver, CO	09/11/2017	New Project	Approved	10/10/2017	| Review Details |

Shared with the following users:

User	Organization	Access Type
Cheah, Foong Chee	Regis University, Denver, CO	Full
Wimett, Lynn	Regis University, Denver, CO	Full

Appendix K

Get Smart Antibiotic Quiz

****Do you believe you need antibiotics for your symptoms today? ****

Yes

No

get-smart-antibiotics-quiz : Get Smart Antibiotics Quiz

Question 1

Antibiotics fight infections caused by

Antibiotics

Bacteria

Viruses and Bacteria

Question 2

Bacteria are germs that cause colds and flu.

True

False

Question 3

Which of these illnesses should be treated with antibiotics?

Runny Nose

The Flu

Cold

Strep Throat

Question 4

Bacteria that cause infections can become resistant to antibiotics.

True

False

Question 5

I can prevent antibiotics-resistant infections when I: *(hint: More than one may apply)*

don't take an antibiotics for a viral infection

don't save an antibiotics for the next time I am sick

don't take an antibiotics prescribed for someone else

take my antibiotics exactly as my healthcare provider tells me

Question 6

What can happen if I get an antibiotics-resistant infection? (hint: More than one may apply)

I may have a longer-lasting illness

I may have to visit my doctor more

I may require hospitalization

I may need more costly medicine that may cause side effects

Question 7

Alexander Fleming discovered the first antibiotics in 1928. What was the antibiotics named?

Mold

Penicillin

Vancomycin

Doxycycline

Question 8

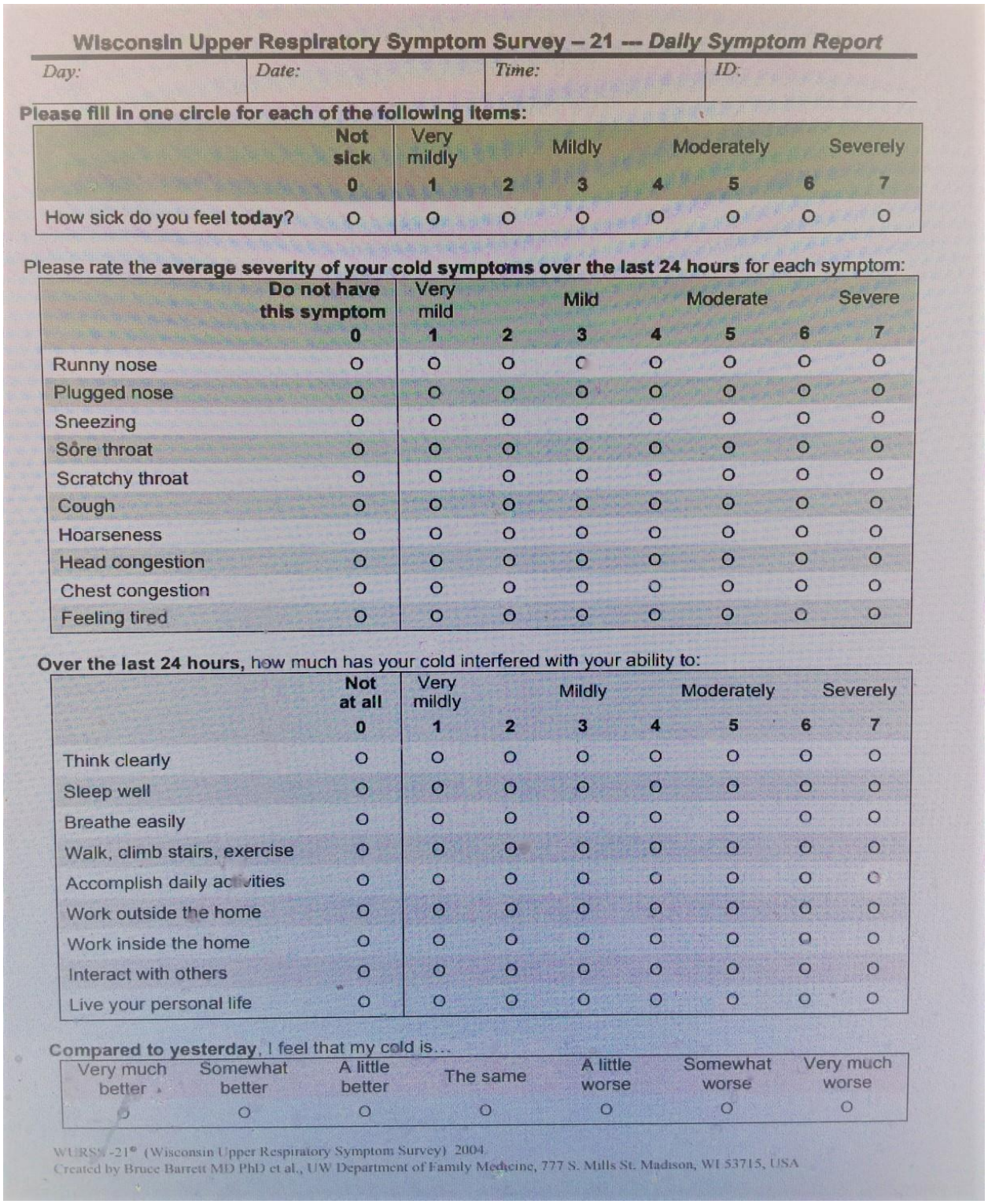
Antibiotics resistance has been called one of the world's most pressing public health problems.

True

False

Appendix L

WURSS-21



Wisconsin Upper Respiratory Symptom Survey – 21 — *Daily Symptom Report*

Day:	*Date:*	*Time:*	*ID:*

Please fill in one circle for each of the following items:

	Not sick	Very mildly		Mildly		Moderately		Severely
	0	1	2	3	4	5	6	7
How sick do you feel **today**?	O	O	O	O	O	O	O	O

Please rate the **average severity of your cold symptoms over the last 24 hours** for each symptom:

	Do not have this symptom	Very mild		Mild		Moderate		Severe
	0	1	2	3	4	5	6	7
Runny nose	O	O	O	O	O	O	O	O
Plugged nose	O	O	O	O	O	O	O	O
Sneezing	O	O	O	O	O	O	O	O
Sore throat	O	O	O	O	O	O	O	O
Scratchy throat	O	O	O	O	O	O	O	O
Cough	O	O	O	O	O	O	O	O
Hoarseness	O	O	O	O	O	O	O	O
Head congestion	O	O	O	O	O	O	O	O
Chest congestion	O	O	O	O	O	O	O	O
Feeling tired	O	O	O	O	O	O	O	O

Over the last 24 hours, how much has your cold interfered with your ability to:

	Not at all	Very mildly		Mildly		Moderately		Severely
	0	1	2	3	4	5	6	7
Think clearly	O	O	O	O	O	O	O	O
Sleep well	O	O	O	O	O	O	O	O
Breathe easily	O	O	O	O	O	O	O	O
Walk, climb stairs, exercise	O	O	O	O	O	O	O	O
Accomplish daily activities	O	O	O	O	O	O	O	O
Work outside the home	O	O	O	O	O	O	O	O
Work inside the home	O	O	O	O	O	O	O	O
Interact with others	O	O	O	O	O	O	O	O
Live your personal life	O	O	O	O	O	O	O	O

Compared to yesterday, I feel that my cold is…

Very much better	Somewhat better	A little better	The same	A little worse	Somewhat worse	Very much worse
O	O	O	O	O	O	O

WURSS-21® (Wisconsin Upper Respiratory Symptom Survey) 2004
Created by Bruce Barrett MD PhD et al., UW Department of Family Medicine, 777 S. Mills St. Madison, WI 53715, USA

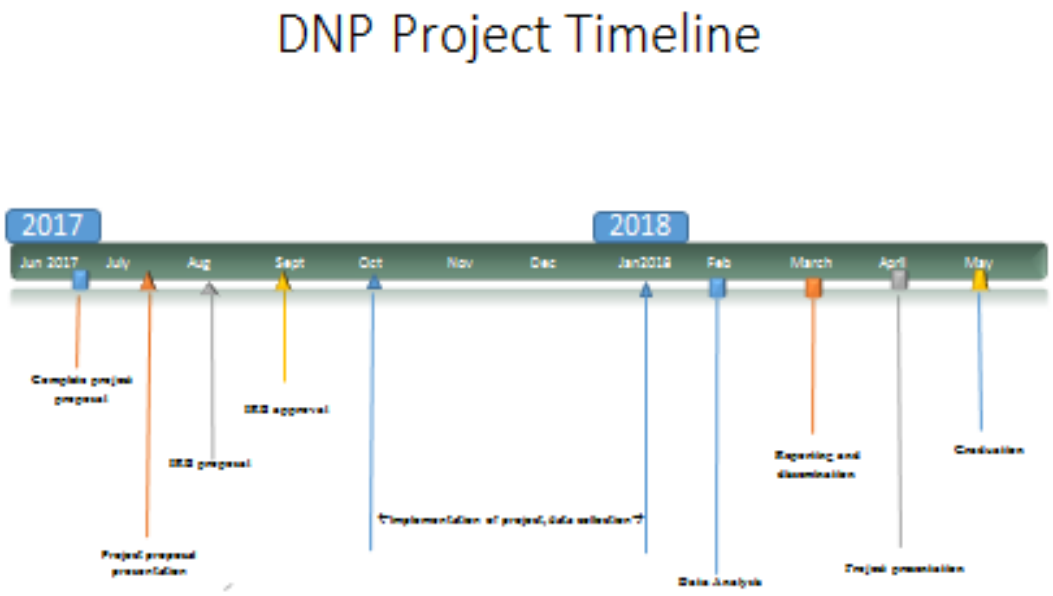
Appendix M

Project

The Difference in Antibiotics Prescriptions Filled between Patients Receiving the Delayed Patient-led Prescription Strategy and Those Receiving Delayed Prescription Collection Strategy

RESOURCES	ACTIVITIES	OUTPUTS	SHORT & LONG-TERM OUTCOMES	IMPACT
Participation of adult patients with URIs who visit the urgent care center Participation of providers, admin and support staffs of the urgent care clinic Access to the urgent care clinic's office place, EMR records, equipment, and miscellaneous office supplies. Education resources from CDC Telephone access to study participants Assistance of IT specialist for selection and utilization of statistical analysis and interpretation	**Approach and recruit** 1. adult patients who are diagnosis with uncomplicated URIs and no immediate antibiotic use is necessary (collection) 2. adult patients who are diagnosed with uncomplicated URIs and received Rx for antibiotic during visit (patient led) 3. Adult patients with URI diagnosis whom received immediate antibiotics (immediate antibiotic) **Follow up phone calls** to participants 3 days and one week post office visit. Document 1.Antibiotic use and # of days between Rx fill from office visit 2.Pt's satisfaction with strategies 3.Patients' belief in the effectiveness of antibiotics Choosing appropriate **methods for data analysis**	Recruitment of sufficient amount of study subjects Collect relevant and complete data and responds from the participants Potentially decreased # of antibiotic prescriptions filled, good patient satisfaction and decrease believe in the effectiveness of antibiotics use in URIs Meaningful and logical interpretation of data.	**Short Term Outcomes** Decrease antibiotic prescriptions fill by the patients with uncomplicated URIs **Long Term Outcomes** Continue using delayed prescription strategies and maintain good patients' satisfaction in uncomplicated URIs patients Change the patients' belief in the need for antibiotic therapy for uncomplicated URIs	**Future Impact on Health Care** Decrease inappropriate antibiotic use, and patients understand the only treatment for uncomplicated URIs is symptomatic treatment.

Appendix N


DNP Project Timeline
2017
2018
Jun 2017
July
Aug
Sept
Oct
Nov
Dec
Jan2018
Feb
March
April
May
Complete project proposal
Project proposal presentation
IRB proposal
IRB approval
Implementation of project, data collection
Data Analysis
Reporting and dissemination
Project presentation
Graduation