Implementing Antimicrobial Stewardship in an Ambulatory Urgent Care Clinical Setting: A Quality Improvement Project

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Abstract

Antibiotic prescriptions for the treatment of common viral infections such as acute uncomplicated bronchitis are discouraged because they contribute to both avoidable adverse events and the development of bacterial resistance. A quality improvement project consisting of a Plan-Do-Study-Act cycle that evaluated and reported the antibiotic prescription rate for the treatment of acute uncomplicated bronchitis was implemented in an ambulatory, urgent care setting. Appropriate antibiotic stewardship was validated by having an antibiotic prescription rate that closely follows a nationally recognized expert consensus recommended level of 10% or less for an otherwise healthy population of adults 18-64 years of age. Antibiotic prescribing rates was based on a comparison of retrospective and prospective data collected from chart audits. Prescribing rates were compared to nationally accepted standards and were measured through descriptive statistics, paired sample *t*-test, Wilcoxon Signed Rank, Kruskal-Wallis, and Friedman Test analysis.

Keywords: antibiotic stewardship, quality improvement, acute bronchitis treatment

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Introduction

Nature of the Problem

A significant portion of all ambulatory care visits are for viral etiology complaints (Shapiro, Hicks, Pavia, & Hersh, 2014; Spinks, Glasziou, & Del Mar, 2013). There are well-established guidelines for prescribing antibiotics in certain clinical scenarios that indicate viral etiologies, such as acute bronchitis (Table 1; Figure 1). Evidence suggests that healthcare providers do not follow guidelines for viral illnesses due to a purported variety of factors, including patient demand, a lack of accountability for prescribing antibiotics, concerns over time and money, misconceptions regarding the diagnoses, uncertainty over the diagnosis and concerns over patient expectation dissatisfaction with subsequent inappropriate prescribing practice (Ackerman, Gonzales, Stahl, & Metlay, 2013; Dempsey, Businger, Whaley, Gagne, & Linder, 2014; Vinnard et al., 2013).

The White House Forum on Antibiotic Stewardship reported that 23,000 people die from antibiotic-resistance germs and an estimated 30-50% of all antibiotics are inappropriately prescribed (President's Council of Advisors on Science and Technology, 2014). This report concluded that the annual economic impact of antibiotic-resistant infections on the US economy is estimated to be $55 to $70 billion per year and that antibiotic-resistant infections resulted in eight million additional hospital days. Furthermore, a 30% reduction in antibiotic-resistant infections could reduce the domestic impact by about $20 billion per year, including Medicare expenditures (President's Council of Advisors on Science and Technology, 2014). The National Committee on Quality Assurance ([NCQA], n.d.) included "avoidance of antibiotic treatment in adults with acute bronchitis" as a quality measure in the Healthcare Effectiveness Data and

Information Set (HEDIS®) beginning in 2014 for providers billing commercial and Medicaid insurance plans.

The NCQA is an independent organization that works to improve health care quality through evidenced-based standards and measures (NCQA, n.d.). NCQA accreditation demonstrates provider and organization commitment to quality that many employers, regulators, insurance organizations, and consumers use to make informed decisions. NCQA, Centers for Medicare & Medicaid Services (CMS) and commercial insurance payer programs, such as Blue Cross Blue Shield, report quality measures, which quantifies of the value of the care that is given to patients. Quality measures convert medical information from patient records into a rate or time that allows a performance assessment (CMS, 2015). These measures promote quality of care and efficiency, or an "absence of waste," and better health care at lower costs (CMS, 2015). Quality measures, such as antibiotic prescribing rates, are part of the data transparency health plan tools used by these payer organizations for benchmarking healthcare institutions.

HEDIS® is a widely used tool developed and maintained by NCQA to measure performance on care and service on a broad range of health issues (NCQA, n.d.). These performance measures consists of 81 measures across 5 domains of care that allows an "apples-to-apples" comparison to other healthcare organizations or to regional or national benchmarks (NCQA, n.d.). HEDIS® is one component of the NCQA's accreditation process. It is not a static tool so measures can be added, deleted, or revised on an annual basis. The HEDIS® 2016 Measures include a performance measure of "Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis" which applies to patients with both commercial and Medicaid insurance and states that the antibiotic prescribing rate should be zero (NCQA, n.d).

The Physician Quality Reporting System (PQRS), formerly known as the Physician Quality Reporting Initiative (PQRI), is a CMS pay-for-reporting program that provides payment adjustments for quality reporting. Starting in 2016, there will be a 2% financial penalty for covered professional services if providers do not participate in this program or meet meaningful use (CMS, 2015). CMS has established an option to submit CQM information using clinical data registries, including HEDIS®, for the purpose of meeting meaningful use. CMS also reports on a website the names of providers and practices who satisfactorily report under PQRS.

A convenience sample of urgent care clinics (n=3) in a large metropolitan area in the southeast United States was audited for a fourteen day period of time (one provider schedule cycle) in December 2015 before initiating the quality improvement program to determine the rate of antibiotics that were currently being written for the selected, mostly viral, diagnoses of acute bronchitis. During this time, providers listed an acute bronchitis diagnosis 87 times on patients' charts and wrote an antibiotic prescription 80 times for these same patients, for a combined antibiotic prescribing rate of 92 percent. Individual provider prescribing rates varied from 57-100 percent, which is far above the nationally recommended benchmark levels of antibiotic prescribing rates of 10% or less for these diagnoses (discussed further in the Literature Review section) and indicates a need for significant improvement.

Pathophysiology

Acute bronchitis is one of the lower respiratory tract infections (LRTI) and is sometimes referred to as a "chest cold" to indicate to laypersons its viral etiology (Albert, 2010). It is an inflammation of the large and medium sized airways (or bronchi) of the lungs and different from chronic bronchitis (Albert, 2010). Symptoms may include either a productive or nonproductive cough, dyspnea, wheezing and chest discomfort or tightness. The infection may last up to two

weeks, but the associated cough may last up to 8 weeks (Smith, Fahey, Smucny, & Becker, 2014). Diagnosis is based upon signs and symptoms; however the color of the sputum is not a sensitive or specific indicator of differentiating between viral and bacterial infections (Albert, 2010). A majority of the cases (90% or more) are caused by viral infections and treatment commonly involves rest, antipyretics and anti-inflammatory medicines (Albert, 2010). Unfortunately, antibiotics are routinely prescribed between 60% and 80% of the time in the United States for adults with acute bronchitis (Steinman, Gonzales, Linder, & Landefeld, 2003). The majority of adults with acute bronchitis should not be treated with antibiotics that are designed to treat bacterial infections. Therefore, the antibiotic prescribing rate for acute bronchitis should be 10% or less (Braman, 2006). The Centers for Disease Control and Prevention (CDC) and the American Academy of Family Physicians (AAFP) have published recommendations and initiated campaign efforts to curb the antibiotic prevalence rate for treating bronchitis (CDC, 2015a; Wong, Blumberg, & Lowe, 2006).

Purpose of the Project

The purpose of this project was to initiate a quality improvement (QI) program for the treatment of acute uncomplicated bronchitis in adult patients seen in an ambulatory, urgent care setting. According to Marino (2007), “the first rule of antibiotics is try not to use them, and the second rule is try not to use too many of them” (p.817). Adherence to a nationally recognized expert consensus recommendation on antibiotic prescribing rates for acute bronchitis in an otherwise healthy adult population was measured and reported based upon data collected from pre-chart reviews with educational presentation and discussion, followed by post-education chart reviews. The goal of this QI program is to provide evidenced-based, cost-effective care while also supporting appropriate antibiotic stewardship. An established acute bronchitis clinical

practice guideline algorithm will be followed (Figure 1). This algorithm allows for antibiotics to be written in certain specific circumstances for patients diagnosed with acute bronchitis, such as those who may also be having an acute exacerbation of chronic obstructive pulmonary disease (COPD) or early-onset of community acquired pneumonia (CAP; Jenkins, et al., 2013). Prospective studies have found that the likelihood of accurately diagnosing pneumonia increases in patients who are ill-appearing, have a high fever (over 38^{o}C), tachypnea (more than 24 breathes/minute), or tachycardia (greater than 100 beats/minute), have lung consolidation, egophony, or fremitus on physical examination, have an elevated white blood cell (WBC) count, or have a chest x-ray that is diagnostic of pneumonia or consolidation (Braman, 2006).

Project Aim Statement

The urgent care provider antibiotic prescribing rate for acute bronchitis in an otherwise healthy adult population will be reduced to 10% or less within three months. An antibiotic prescription absolute rate reduction of more than 20% will be considered an improvement and a reason to continue or expand the current Plan-Do-Study-Act cycle (Ackerman et al., 2013). The operational definition for an otherwise healthy adult population are adults 18-64 years of age who have acute uncomplicated bronchitis and have no comorbid conditions, such as COPD or congestive heart failure (CHF), or immunocompromised conditions, such as human immunodeficiency virus/acquired immunodeficiency disease (HIV/AIDS) or are currently receiving chemotherapy (Braman, 2006). The operational definition for the antibiotic prescribing rate is the number of times an antibiotic is written for an otherwise healthy adult person with an initial diagnosis of acute uncomplicated bronchitis divided by the number of times an initial diagnosis of acute uncomplicated bronchitis is given to that otherwise healthy adult individual. This objective will be measured by performance benchmarking the antibiotic

prescribing rates of the providers against a nationally recognized expert consensus rate. Each provider will receive a monthly scatter diagram (Figure 2) that compares the provider's prescribing rate with the recommended rate. An antibiotic prescription rate of 10% or less for an initial diagnosis of acute uncomplicated bronchitis in an otherwise healthy adult population will be the ultimate goal.

Problem Statement

The problem to be addressed is the historical high rate of antibiotic prescriptions currently being written for acute uncomplicated bronchitis, which is usually a viral infection, in the urgent care setting. The goal is to lower the antibiotic prescription rate currently being written for a diagnosis of acute uncomplicated bronchitis to a nationally recognized expert consensus recommended level of 10% or less. The target group to be impacted is the providers who routinely staff the conveniently selected urgent care clinic. This group of providers will be influenced by having their antibiotic prescription rates compared on a monthly basis against their counterpart providers and the nationally recognized expert consensus recommended level (Figure 2).

Background and Significance of the Problem

The cost of healthcare in the United States consumes an increasing portion of the gross domestic product (GDP) while the quality of healthcare continues to lag behind other countries (Rouse, 2009). Unnecessary drug expenditures contribute to the direct cost of medical care, treatment of adverse drug reactions, and the emergence and associated cost of treating infections associated with antimicrobial drug resistance. One must also account for the indirect cost associated with the education necessary to reinforce patient behavior in seeking medical treatment, a reduction in requests for future antibiotic prescriptions for common viral illnesses

and a reduction in unnecessary provider visits which decrease the access to healthcare for patients who are in need of healthcare that is medically necessary and indicated.

Antibiotic overuse is a main factor contributing to antibiotic resistance in formerly easily treated bacterial pathogens (Michaelidis, Kern & Smith, 2015). The degree of antibiotic resistance has resulted in "super bugs," or organisms resistant to readily available or all antibiotics (CDC, 2015a). Carbapenem-resistant *Enterobacteriaceae* (CRE), *Clostridium difficile*-associated diarrhea, extensively drug-resistant tuberculosis caused by *Mycobacterium tuberculosis* (XDR-TB), *Neisseria gonorrhea* resistant to third-generation cephalosporins and fluoroquinolone-resistant *Escherichia coli* (E. coli) urinary tract infections (UTIs) among other current antibiotic-resistant threats pose a substantial risk to public safety (Abbo, Smith, Pereyra, Wycoff & Hooten, 2012; President's Council of Advisors on Science and Technology, 2014).

No published evidence categorically supports the clinical benefit of antimicrobial treatment for patients who are otherwise healthy with a diagnosis of acute bronchitis (Albert, 2010; Braman, 2006; Hart, 2014). Antibiotics can have serious side effects even when taken properly, including nausea, diarrhea, vaginal yeast infections, tendon damage and Stevens-Johnson syndrome (Vinnard et al., 2013). According to Mossad (2013) antibiotics account for 20% of all drug-related emergency department visits in the United States.

Evans, Rogers, Weaver and Burns (2011) conducted an anonymous internet-based cross-sectional survey and found that healthcare providers (physicians, nurse practitioners, and physician assistants) were aware that antibiotic resistance was a major health problem in their practice and stated that there was a need to improve their own and their colleagues' knowledge of appropriate antibiotic prescribing. The clinicians in this survey endorsed interventions that focused on delivering provider education regarding appropriate antibiotic prescribing.

Interestingly, a majority of the respondents felt like their colleagues, but not themselves, were the ones over-prescribing antibiotics. Dempsey, Businger, Whaley, Gagne, and Linder (2014) uncovered a similar finding that clinicians felt that other providers, but not themselves, were responsible for over-prescribing antibiotics. Participants felt that there was no accountability, oversight, or feedback for prescribing antibiotics other than their own conscious and that quality and feedback reports and reviews that did not ostracize anyone would be helpful and would encourage providers to lower their antibiotic prescribing rates (Dempsey et al., 2014). This study also found strategic methods to decrease inappropriate antibiotic prescribing included providing patient handouts or other educational materials, quality reports, and prompts from a clinical decision support.

The Centers for Medicare & Medicaid Services (CMS) has released rules for payment incentives for "meaningful use" of electronic health records (EHRs) that follow a three-staged approach. Stage 3, starting in 2016, focuses on improved outcomes for patients. Part of these meaningful use objectives are reporting on quality initiatives, which is usually done by conveying clinical quality measure (CQM) results and submitting this data from certified EHR technology (CMS, 2015). CQMs help measure and track the quality of health care services provided to patients.

Clinical Question

How can the antibiotic prescription rate for patients with the diagnosis of acute uncomplicated bronchitis match the nationally recognized expert consensus rate of 10% or less, thereby reducing the variance in provider practice patterns?

Definition of Terms

Antibiotic Stewardship

Antibiotic stewardship is a system wide effort to improve the use of antibiotics “in order to maximize their benefits to patients, while minimizing both the rise of antibiotic resistance as well as adverse effects to patients from unnecessary antibiotic therapy” (President’s Council of Advisors on Science and Technology, 2014, p. 42). Antibiotic stewardship goals include the reduction of the occurrence of antibiotic-resistance organisms, improving patient outcomes by accurately treating the diagnosis, decreasing patient harmfulness from antibiotic use and reducing antibiotic-related pharmacy costs (President’s Council of Advisors on Science and Technology, 2014).

Barriers to Antibiotic Use

Barriers to antibiotic stewardship include “higher priority clinical initiatives, staffing constraints and insufficient funding” (President’s Council of Advisors on Science and Technology, 2014, p. 43). Focusing on the demand for and inappropriate prescribing of antibiotics along with both provider and patient education can lead to improved antibiotic stewardship.

Antibiotic Resistance

Antibiotic resistance occurs when bacteria or microbes become resistant to one or more antimicrobial agents (CDC, 2015a). This resistance can be either innate or acquired. Innate resistance implies that the organism has always been resistant to the antimicrobial agent whereas acquired resistance occurs when the organism either develops a mutation or transfers genes which causes the resistance (CDC, 2015a). Acquired resistance is the most common current use of the term and specifically refers to bacteria resistance to an antimicrobial drug that was once able to treat an infection caused by that microorganism. Bacterial resistance is usually the result of antibiotic overuse, both in human and veterinary medicine, which increases the bacterial

population that can survive in the antibiotic environment while causing any susceptible bacteria to die off (CDC, 2015a). It should be noted that bacterial resistance is a microbial trait and not an individual characteristic as commonly believed by many lay persons.

Quality Improvement

Quality improvement (QI) is a component of quality management, but is a different concept than quality assurance (QA). QI is a purposeful change in a process in order to improve the reliability of achieving an outcome, whereas QA is focused on preventing mistakes and avoiding problems in order to satisfy a given requirement. QI can be thought of as being proactive or prospective, where QA is reactive or retrospective. Quality improvement is related and complementary to providing evidenced-based practice (EBP) care, but has a wider scope than EBP and can even be used to measure the success and impact of providing EBP. The goals of a QI program is to improve the performance of a delivery system and the operational activities by "making care patient centered, safe, timely, efficient, and accessible" (Brown, 2014, p. 355). QI programs monitor safety and quality on an on-going basis, but also collect special-purpose data to identify problems and are a precursor to taking corrective action. QI programs can be easily done on a microsystem level such as at the unit or service line ranking. One of the most widely used methods in quality management is the Plan-Do-Study-Act (PDSA) model.

Conceptual Model

The Model for Improvement will serve as the conceptual model for this scholarly project. The Model for Improvement contains three questions and a cycle element for testing innovation (Langley, Nolan & Nolan, 1992). The three questions are: 1) what are we trying to accomplish? 2) how will I know if a change is an improvement? and 3) what changes would we make that will result in an improvement? After these questions are answered, a test of change, through a

plan-do-study-act (PDSA) cycle, can be implemented to learn what does and does not work. The aim, or definition what we are trying to accomplish, should be as specific as possible and should include numerical goals that help clarify the expectations. When performance data is analyzed, the difference between personal results and result goals may be an embarrassment, but can also become an improvement target (Berwick, 2003). Improvement cannot be determined without measurement. Measurement should not be done for judgment, but rather for knowing which changes help and which do not (Berwick, 1996). Data should be measured over time to observe trends and can be collected with a simple collection form. A small series of changes can be investigated and usually include enough information to see if these changes will contribute to the desired goals. Promising changes that appear to contribute to an improvement can be further investigated, while useless ones can be discarded (Berwick, 1996).

The PDSA model is the second component of the model of improvement (Langley et al., 1992). PDSA is a four-step method and may also be known as the Deming wheel, since it was popularized by Dr. W. Edwards Deming, an early proponent of modern quality assurance and improvement. It is based on the concept of the scientific method of hypothesize, experiment and evaluate and is a continuous process "focused on assessing, planning, acting, monitoring and evaluating, reassessing, and acting again" (Anderson, 2015, p. 363). The PDSA model provides cyclical feedback to improve knowledge, to sequentially refine and reduce variation in a specific process until the goal is achieved. PDSA cycles are where inductive learning adjustments are made in order to grow the knowledge regarding making modifications and then actively reflecting on the consequences of these alterations (Berwick, 1996). Each adjustment requires another test through its own PDSA cycle. Small and frequent PDSA tests are better than big and slow ones and "failed" tests are just as important as successful ones (Berwick, 2003). When a

successful transformation is found, the scalability of the modification can be assessed in a "1:3:5:all" approach, where the PDSA is tried on 1 unit of measurement, then 3 units, and, if it continues to hold true, then 5 units followed by a system wide implementation (Bartley & Jacobs, 2013).

The four stages of a PDSA are similar to the scientific method and consists of: 1) the plan stage, where a change aimed at improvement is identified, 2) the do stage, where the change is tested or tried, 3) the study stage, where the results are observed, the change is analyzed and the results are interpreted, and 4) the act stage, where adaptations are identified and implemented (Taylor et al., 2014). The act stage involves either adopting or abandoning the proposed change or redoing the cycle under different conditions (Esain, Williams, Gakhal, Caley & Cook, 2012). It is vital that the organizational climate is open and supportive to using this model and that an evaluation is developed at the initial planning stage before the cycle is begun (Moule, Evans & Pollard, 2013). This evaluation helps to determine *a priori* the measure of whether the PDSA achieved what was intended and is similar to setting the alpha level on an experiment. A good healthcare PDSA cycle should look at an improvement that satisfies a patient demand, a clinical need, or a patient or healthcare provider want and answer three primary questions: 1) what is the change intending to achieve? 2) how can the change be measured? and 3) what changes are required to achieve the identified outcome (Esain et al., 2012)?

The plan stage of this project is as follows:

Purpose of the cycle. Decrease the antibiotic prescribing rate for acute uncomplicated bronchitis in the otherwise healthy adult population in an urgent care (UC) setting per HEDIS® 2016 nationally recognized guidelines.

What questions will be answered? 1. Will tracking and discussing UC provider antibiotic prescribing rates for otherwise healthy adult patients with acute uncomplicated bronchitis lead to lower prescribing rates? 2. Will giving providers access to clinical practice guidelines and patient education material help lower the antibiotic prescribing rates for otherwise healthy adult patients with acute uncomplicated bronchitis?

Predicted answers. 1. Informing UC providers of their antibiotic prescribing rate for otherwise healthy adult patients with acute uncomplicated bronchitis will lead to a decreased in the providers' prescribing rates. 2. Providing UC providers with clinical practice guidelines and patient education material will help the providers discuss the current recommended treatment of acute uncomplicated bronchitis to otherwise healthy adult patients and their family members and will help lower the antibiotic prescribing rates for patients with acute uncomplicated bronchitis.

What change is being tested? What will lead UC providers to decrease their antibiotic prescribing rate for acute uncomplicated bronchitis in otherwise healthy adult patients to a more recommended level?

What data will need to be collected? The number of acute uncomplicated bronchitis diagnoses and the number of antibiotic prescriptions written for this diagnosis.

How will this data be collected/When will this data be collected? Electronic chart audits from a selected UC clinic over a three month period.

The Do stage occurs when the plan is carried out. The collected data, any observations, and any problems encountered will be recorded during this stage.

The Study stage is where the data will be analyzed and the results will be summarized. A determination will be made during this stage if the results agree with the predictions made during the Plan stage.

The Act stage will have four options depending on the result of the PDSA cycle: 1) adopt the change "as is," 2) adapt the change and test again, 3) expand the change and test again, or 4) abandon the change. Since this project is the start of a larger PDSA cycle and only involves one unit of the "1:3:5:all" approach, the "adopt the change as is" option should not be considered as a final choice for this endeavor.

Summary

Antibiotics have a successful history of treating and preventing serious infections that have historically caused both morbidity and mortality in humans. However, prescribing antibiotics for viral infections that cause acute respiratory tract infections is defined as inappropriate (Colgan & Powers, 2001). Antibiotic overuse, especially for symptoms that will resolve without treatment or for non-bacterial illnesses, and a failure to complete the prescribed antibiotic course have been associated for quite some time with an escalating antibiotic resistance and an increase in bacterial organisms that no longer respond to common antibiotics. Antibiotic resistance is outpacing the development of new antibiotics (President's Council of Advisors on Science and Technology, 2014). Developing a new antibiotic by the pharmaceutical industry is estimated to take 11 years and cost $1.2 billion. Antibiotic resistance was previously manageable because the resistance growth was gradual and new antibiotics were continued to be developed. Only eight new antibacterial agents were approved by the Food and Drug Administration (FDA) from 2003-2015 however, whereas 30 new antibiotics were confirmed from 1983-1992 and 17 from 1993-2002 (President's Council of Advisors on Science and Technology, 2014). One of the ways to bring the antibiotic crisis under control is through increasing the longevity of current antibiotics by improving the appropriate use of existing

antimicrobials. The judicious use of currently available antibiotics is also one way to compensate for the dearth of new antimicrobials being discovered and marketed.

Literature Review

This section provides an overview of the literature pertinent to the area of interest and a review of the terms being discussed. A systematic review of the subject matter, the concepts of antibiotic resistance and acute bronchitis and a relevant clinical practice guideline will be presented.

PRISMA Search Strategy

A comprehensive and rigorous search strategy was completed based off of a modified Cochrane strategy which had just been completed for a systematic review of the topic and published in March 2014 (Smith et al., 2014). The search was therefore restricted to 2014 and 2015 and was done in both PubMed and CINAHL databases (Figures 3 and 4). A total of 801 articles were found in PubMed and 196 articles found in CINAHL (Figure 5). Articles were excluded if the main focus was on upper respiratory tract infections or other conditions such as pneumonia, cystic fibrosis or acute exacerbation of chronic obstructive pulmonary disease, antibiotic adherence or the use of delayed antibiotic prescriptions, hospitalization treatment, not an adult population, opinion articles, or an interpretation or restatement of a previously cited study. Duplicate articles were also excluded. Seventy-three full text articles were then screened for eligibility and evaluated for outpatient treatment of acute bronchitis in the healthy adult population. This resulted in thirty-eight articles that were included in the final qualitative analysis.

Background Search Strategy

A background search strategy was also completed in addition to the PRISMA search strategy in order to get a richer understanding of the historical perspective of antibiotic resistance and the treatment for acute bronchitis. Therefore, a PubMed online search of articles written and

available in full text in the English language within the last five years was originally conducted during May 2015 and updated during the months of June and July 2015 (please see Figure 6 for a list of MeSH terms used). The publication date demarcation was removed if the originally referenced articles found within the search articles were required to be accessed for clarification. The searches included various combinations of the terms “anti-bacterial agents,” “antibiotic,” “antibiotic resistance” and “uri,” “ambulatory care,” “urgent care,” and “bronchitis” (Figure 6). Another search was done of “pdsa” and “quality improvement.” Searches were also done that included “clinical practice guideline” and “bronchitis” along with “Cochrane review” and “bronchitis.” A PRISMA checklist was completed for the Cochrane systematic review of bronchitis (Figure 7).

PRISMA Results

Antibiotic prescribing rates remain abnormally high (54% - 85%) in acute bronchitis (Barlam, Morgan, Wetzler, Christiansen, & Drainoni, 2015; Barnett & Linder, 2014; Dallas et al., 2015; Jones et al., 2015). This is consistent with previous findings from the last forty years that have found that antibiotics are routinely prescribed between 60% and 80% of the time in the United States for adults with acute bronchitis (Steinman et al., 2003). The effects of using antibiotics in the treatment of acute bronchitis has been mixed. Systematic reviews have shown that antibiotics may be modestly beneficial with moderate-quality evidence, but these studies have also included smokers (Smith et al., 2014; Wark, 2015). However, studies ranging from very low-quality to moderate-quality evidence has looked at benefits from specific antibiotics and have not shown any improvement for the most part (Llor, et al., 2013; Wark, 2015). Although antibiotics in acute bronchitis may be modestly beneficial in frail, elderly, and comorbid patients and can result in short-term improvement and a very minimal reduction in

symptoms, where patients may feel better one-half day sooner on average and may report feeling subjectively better faster, in other patients, there has been no significant difference noted in patient improvement or limitations at the usual follow up time of about one week (Moore et al., 2014; Smith et al., 2014, Yamamoto et al., 2014). Overall, antibiotic prescription rates continue to increase for bronchitis along with the amount of broad-spectrum antibiotics, which is concerning given the slowing development of new antibiotics and the rise in antibiotic resistance (Andreeva & Melbye, 2014; Donnelly, Baddley, & Wang, 2014; Lee et al., 2014; McCullough, Zimmerman, & Rodriguez, 2014; Smith et al., 2014; White, 2014) Although Jones et al. (2015) found no correlation of antibiotics to patient characteristics, others found antibiotic prescribing to be higher in certain circumstances such as when the patient requests them, if fever is present, if symptoms have continued for more than one week, if an abnormal lung exam is noted, in smokers or older patients, in both privately-insured or high socio-economic patients and indigenous patients and, interestingly enough, the longer a provider has been in a clinic session, which may indicate that provider-fatigue is a possible cause (Barlam, et al., 2015; Dallas, et al., 2015; Kroening-Roche, Soroudi, Castillo & Vilke, 2012; Llor, et al., 2014; McNulty, Nichols, French, Joshi, & Butler, 2013; White, 2014). Curiously, although patients may request antibiotics when they are not needed, 25% did not end up finishing the medicine once it was given (McNulty et al., 2013).

A great amount of provider variation was noted, with a small number of providers writing the greatest amount of antibiotics (Barlam et al., 2015; Jones et al., 2015). This indicates a potential for a Pareto principle prioritization, where focusing on a small group of providers may result in a large shift in prescribing practices, instead of randomly addressing provider education. Provider support for limiting antibiotic use has focused on diagnostic uncertainty. Biomarker

point-of-care testing, including C-reactive protein and procalcitonin, has helped reduce a provider's diagnostic uncertainty as to whether antibiotics should be written or not and to reassure patients, but no one test has been shown to be superior to others (Aabenhus, Jensen, Jorgensen, Hrobjartsson & Bjerrum, 2014; Anthierens et al., 2015; Llor et al., 2014; Michaelidis, Zimmerman, Nowalk, Fine, & Smith, 2014). Clinical decision support has been shown to help lessen the total costs of care and can result in both a lower overall likelihood of prescribing antibiotics and a lower amount of broad-spectrum antibiotics written (Litvin, Ornstein, Wessell, Nemeth & Nietert, 2013; Mainous, Lambourne, & Nietert, 2013; Michaelidis et al., 2015; McCullough et al., 2014; Rattinger et al., 2012). Communication training and skills may help establish buy-in from patients regarding the clinical decision not to prescribe antibiotics and include trying to determine the patient expectations while obtaining a history and using a "running commentary" while performing the physical examination (Anthierens et al., 2015; Mustafa, Wood, Butler & Elwyn, 2014). Patients have been shown to request antibiotics in certain circumstances, such as when their symptoms continued over a particular length of time or if the symptoms included pain or interfered with their activities of daily living or sleep (McNulty et al., 2013). Providers can offer an alternative to antibiotics if they can provide an alternative to help alleviate the patient's underlying cause for concern.

Background Information

Antibiotic Resistance

The first commercially available antibiotic, a sulfonamide, was developed in 1932 followed by the first penicillin in 1942 (Bosch & Rosich, 2008; Van Epps, 2006). The function of an antibiotic (or antimicrobial agent) is to either kill or inhibit the growth of bacteria and is not effective against viruses. Antibiotic resistance was described as early as 1943 (Pearson, 2007).

Antibiotic resistance is growing and is a threat not only in the United States, but worldwide and is now considered to be a major public health threat (WHO, 2014). According to the CDC (2015a), at least 2 million people in the United States have an antibiotic-resistant infection each year, causing at least 23,000 deaths yearly from these infections. Antibiotics are the second most commonly prescribed medication class in the United States and without better antibiotic stewardship, resistance will become even more of a significant problem (Hopkins, McCroskey, Reeves, & Tanabe, 2014).

The National Ambulatory and National Hospital Ambulatory Medical Care Surveys are nationally represented surveys of ambulatory patient visits in the United States, including visits to medical offices, hospital outpatient departments and emergency departments. According to the surveys that were conducted in 2007-2008, antibiotics were written during 10% of all ambulatory visits, or about 101 million visits (Shapiro et al., 2014). Most of these antibiotics were written for respiratory problems (41% of all antibiotics written).

Acute Bronchitis Presentation and Treatment

Acute bronchitis is a clinical diagnosis without any definitive, objective test (Wong et al., 2006). It is often a self-limited illness, more common in the fall and winter months, whose hallmark symptoms is a cough and which is sometimes indistinguishable from other illnesses, such as an upper respiratory infection, allergic rhinitis, postnasal drip, sinusitis, reflux or asthma (Albert, 2010; Bush 2013). The cough that is associated with bronchitis results from bronchial edema and mucus formation, which may produce either clear or purulent sputum and may last up to three weeks in 50% of patients and up to eight weeks in a few patients (Hueston & Mainous, 1998). Therefore, colored (i.e., green) sputum does not differentiate between bacterial and viral infections. Viral infections are the cause for 90-95% of acute bronchitis infections (Albert,

2010). Although the current HEDIS® measurement states that theoretically no antibiotics should be written for patients with acute bronchitis, the above statistic implies that antibiotics could be realistically be written for 5-10% of these patients (NCQA, n.d.).

The physical examination on a patient presenting with acute bronchitis is often normal, but may include a low-grade fever (under 100.4°F) along with wheezing or rhonchi (Hart, 2014). Sputum cultures are one way to differentiate between the more common viral causes and the less than 10% of the bacterial cases of acute bronchitis, but are challenging in obtaining and often unreliable in guiding treatment strategies (Bush, 2013). Other diagnostic testing, such as chest x-rays or laboratory data, has limited evaluation assistance and is usually not recommended, unless it is to rule out other ailments. Acute bronchitis is therefore largely a diagnosis of exclusion, with the only diagnostic tool being tincture of time to see if another disease discloses itself.

Cough control is the main treatment focus for acute bronchitis, but there is no “best” treatment strategy to achieve this goal (Hart, 2014). Various trials have demonstrated for the last forty years that antibiotics are not useful for acute bronchitis (Smith et al., 2014). Healthcare providers may know that antibiotics are usually not effective in treating acute bronchitis, but may prescribe them anyway, especially in response to patient expectations (Albert, 2010; Hueston & Mainous, 1998). In fact, the antibiotic prescribing rate for acute bronchitis has continually increased between 1980 and 2010 (Barnett & Linder, 2014; Steinman et al., 2003). A Cochrane meta-analysis has concluded that antibiotic participants were less likely to have a cough, less likely to have a night cough, and have decreased sputum production by one-half day, but this review also included both older patients and smokers (Chandran, 2001; Smith et al., 2014). The review concluded that in spite of this small benefit, there was still no compelling reason to prescribe antibiotics when the disadvantages of antibiotic treatment were considered.

Unfortunately, the antibiotic prescribing rate for acute bronchitis in the United States is reported as being between 60-80% (Barnett & Linder, 2014).

Clinical Practice Guidelines

Clinical practice guidelines (CPGs) are an evaluation of the current scientific knowledge of a specific diagnosis or treatment problem and should be described as the best practice for the typical patient (Long, 2015). CPGs consolidate research findings and are tools that can be used to help direct clinical practice, but may be problematic when generalizations are blindly applied to unique patient circumstances. A systematic review of clinical practice guideline (CPG) databases (n = 19) was conducted during September 2015 to ensure that the most up-to-date and accurate acute bronchitis guideline would be followed for this project. Although six guidelines were found, they were all versions of the same guideline, which is the "management of uncomplicated acute bronchitis in adults" guideline summary NGC-009444 that can be found at the National Guideline Clearinghouse of the Agency for Healthcare Research and Quality (AHRQ) and was used for this project (Figure 1).

One method of evaluating CPGs for bias is through the Appraisal of Guidelines Research and Evaluation (AGREE II) instrument (Brouwers et al., 2010). An AGREE II Instrument was completed for the "Management of Uncomplicated Acute Bronchitis in Adults" clinical practice guideline (Figure 8). The domains of "Scope and Purpose" and "Clarity of Presentation" were rated high, while "Stakeholder Involvement" was rated low. The other domains were rated in-between high and low scores. The overall subjective rating for this guideline was 5 on a 7-point scale with a recommendation that the guideline should be used, but that the next update should have more input and feedback from the stakeholders and intended users. The strength and limitations of the recommendations were rated low (2/7) and are of particular concern. This

CPG's treatment recommendations include that antibiotics should be avoided (level of evidence A: randomized controlled trials) and that only symptomatic treatment be provided, including beta2-agonist bronchodilators for patients who are wheezing and antitussive agents for short-term cough relief (both level of evidence C: observational studies).

Conclusion

Acute bronchitis is a mostly viral, self-limiting illness that has a main symptom of either a productive or nonproductive cough. Therefore, the main treatment goal of acute bronchitis management is cough control. Unfortunately, the current therapy regimen within the United States is often antibiotic usage, even though the existing recommendations state that this action is not beneficial. This reality is concerning given the dearth of new antibiotics being developed, the escalation in antibiotic resistance and the extent of adverse drug events or allergic reactions documented as being caused by antibiotic usage. More information is needed on how to affect provider clinical decision making and prescribing behaviors in order to address this public health threat.

Methodology

Population and Setting

The Urgent Care Division at a healthcare organization in a large metropolitan area in the southeastern United States was comprised of 26 Urgent Care Clinics, including 3 dedicated to only children and one 24-hour clinic. These clinics were staffed with providers that include physicians (both Medical Doctors [MDs] and Doctors of Osteopathy [DOs]) and advanced practice clinicians (physician assistants [PAs] and nurse practitioners [NPs]). The clinics were staffed with single full-time equivalent (FTE) providers, 1.5 FTE providers, usually a single provider augmented with a secondary provider during times of historical increased census such as weekends, or double providers (2 FTEs). A "float pool" of providers were utilized for clinic coverage when the normally assigned provider were off. Clinics were open for 12 hours, with the exception of the one 24-hour clinic, 363 days of the year; clinics were usually closed only on Thanksgiving and Christmas.

For this quality improvement project, a group of providers (n = 4, representing 3.5 Full-Time Equivalents [FTEs]) was conveniently chosen who regularly staffed one of the urgent care clinics (n = 1; the children's-only clinics and float providers were automatically excluded from consideration). All of the providers at this clinic were advanced practice clinicians; two providers were PAs and two were NPs. Three providers were female and one provider was male. By starting with one clinic, this plan followed the "1:3:5:all" approach mentioned earlier of transforming a successful PDSA throughout an organization.

Instruments

A simple data tool that consisted of recording the frequency of the diagnosis of acute bronchitis in an otherwise healthy adult population and the number of times an antibiotic was

written for that individual during that visit was done based upon chart review (Figures 9 and 10). An otherwise healthy adult person was operationally defined as an adult 18-64 years of age who had no comorbid conditions such as COPD or CHF, or immunocompromised conditions, such as human immunodeficiency virus/acquired immunodeficiency disease (HIV/AIDS) or currently receiving chemotherapy treatment. The frequencies noted on this tool were then used to calculate an antibiotic prescribing rate, which was operationally defined as the number of times an antibiotic was written for an otherwise healthy adult person with an initial diagnosis of acute bronchitis divided by the number of times an initial diagnosis of acute bronchitis was given to that otherwise healthy adult individual.

Approvals for the Project

The quality improvement project was approved by the East Carolina University Doctor of Nursing Practice faculty and program director, the Vice President and the Medical Director for the Urgent Care Division at Carolinas HealthCare System and the Nursing Science Advisory Council of Carolinas HealthCare System (Figures 10 and 11). Waivers for the project were granted by the Institutional Review Boards of Carolinas HealthCare System and East Carolina University (Figures 12 and 13).

Procedure

The author met with the four urgent care providers and clinic staff to discuss the project at the selected urgent care clinic during their regularly scheduled monthly provider and staff meeting on February 10, 2016. The approval of the project from both the Vice President and the Medical Director of the Urgent Care Division was shared along with the Division's plan to implement the HEDIS® 2016 performance measure of "Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis." The current recommendations for the diagnosis and treatment of

acute uncomplicated bronchitis in the healthy adult patient was reviewed and the nationally recommended antibiotic prescribing rate for this diagnosis was discussed. Providers were given printed copies of a clinical practice guideline "Acute Bronchitis in Children, Adolescents, and Adults" for their personal use (Figure 1). This CPG can help guide providers if antibiotics are warranted for an individual with acute uncomplicated bronchitis. This review hopefully helped furnish providers with the education regarding appropriate antibiotic prescribing that was identified as being needed by participants in other previously identified studies. Staff were instructed on "managing up" the treatment for viral illnesses and "talking points" for providers to discuss acute bronchitis in the healthy adult patient population were reviewed during this meeting. Providers' concerns, such as misdiagnosing a bacterial infection, in evaluating and treating healthy adult patients with bronchitis were addressed.

Laminated patient education material that consists of "Virus or Bacteria: What's Got You Sick?" and "6 Smart Facts about Antibiotic Use" which were obtained from the CDC "Get Smart: Know When Antibiotics Work" (2015b) campaign program were placed in conspicuous areas of the patient examination rooms (Figures 15 & 16). These materials can serve as some of the strategic methods, the educational materials and clinical decision support, which were requested by providers in a prior study by Dempsey et al. (2014).

The clinic providers were informed that their antibiotic prescribing rate would be monitored and reported on a monthly basis for a total of three months (Figure 2). These actions were meant to "unfreeze" the current UC providers' perceptions of acute bronchitis and the patient expectations regarding the treatment of acute bronchitis. This tracking provided the accountability and feedback that was requested by providers in a previous study (Dempsey et al., 2014).

Electronic medical record (EMR) charts were audited on a monthly basis using a set review flow process (Figure 17), looking for the diagnosis of acute bronchitis (ICD-9-CM code 466.0 or 490, ICD-10-CM codes J20.x, J21.x, J22, J40, J47.x, or J98.8) within the appropriate patient age range and inclusion criteria. The chart was reviewed to ensure that the patient did not have an underlying comorbid medical condition that would affect treatment, such as chronic obstructive pulmonary disease (COPD) or HIV/AIDS, and to ensure that the visit was not a recheck or follow up of a previously diagnosed acute bronchitis. If no significant underlying medical condition existed and the patient met the various inclusion criteria, the chart was reviewed to see if an antibiotic was written. The antibiotic prescribing rate, which was operationally defined as the number of times an antibiotic is written for an otherwise healthy adult person with an initial diagnosis of acute bronchitis divided by the number of times an initial diagnosis of acute bronchitis was given to that otherwise healthy adult individual, was recorded and measured against a nationally recommended level of 10 percent. Each provider, along with selected members of the Urgent Care Division leadership team, received a monthly scatter diagram (Figure 2) that compared the provider's prescribing rate with the recommended rate. Monthly feedback from the providers on what helped and what problems they experienced in trying to achieve the recommended antibiotic prescribing rate were discussed. This part of the PDSA consist of "moving" the provider's behaviors to writing less antibiotics for acute bronchitis in the otherwise healthy adult patient population.

After three months, a meeting with the urgent care clinic providers occurred to discuss the treatment and management strategies in their evaluation and treatment of acute bronchitis in the healthy adult patient population. Based upon the Model for Improvement, the PDSA,

including the provider's recommendations for any changes, was proposed to be scaled up to include other urgent care clinics, but was not part of this project.

Ethical Considerations

Privacy is not sought within a PDSA because a Hawthorne effect is intended to change a specific action. A quality improvement project takes a directive approach at attempting to influence a provider's actions. The directive approach followed the recommendations of an earlier reported study that found that participants felt that there was no accountability or feedback for prescribing antibiotics and that feedback reports would be helpful and encourage providers to lower their antibiotic prescribing rates (Dempsey et al., 2014). Provider performance data was not confidential and the urgent care division had other quality improvement projects in progress at the time of this project that had a similar data collection and reporting feedback mechanisms so the providers were accustomed to getting these types of reports on their individual practice performances.

Results

The main goal of analysis was to determine if the antibiotic prescribing rate for acute bronchitis in an otherwise healthy adult population could be reduce to 10% or less within three months by the providers at a specific urgent care clinic and to reduce the amount of variance within provider practice patterns. This variance may lead to patient dissatisfaction and confusion when one provider gives a certain treatment (an antibiotic) for a certain illness, but another one will not. This goal was measured by performance benchmarking the antibiotic prescribing rates of the providers against a nationally recognized expert consensus rate of 10% or less. The two more experienced providers (Providers A and B) diagnosed acute bronchitis more often (n = 97) than the less experienced providers (Providers C and D; n = 50), but the antibiotic prescribing rate was not associated with the provider's years of experience (Table 2). Individual providers started out with an antibiotic prescribing rate ranging from 57% to 100%, indicating a certain amount of clinical variation in treatment practice which was not statistically significant according to a Kruskal-Wallis Test (X^2 (3, n = 4) = 3.00, p = .392), but all ended with an antibiotic prescribing rate of zero percent (Figures 18-21). Thus, the goal of reducing the amount of antibiotics that were being written for acute bronchitis in an otherwise healthy adult population was reduced to a nationally recognized expert consensus rate and the amount of treatment variation was also clinically reduced.

Data Analysis

Major Exclusions

The exclusion criteria for this PDSA were that the adult patient had no co-morbid conditions, no abnormal vital signs such as fever, tachycardia or tachypnea, and that the patient was not a recheck. Although a few of the patients were excluded due to having elevated vital

signs or co-morbid conditions such as diabetes mellitus or being on immunosuppressants, the vast majority were excluded for rechecks. Interestingly, the patients who were rechecks normally received an antibiotic prescription prior to the initiation of the PDSA, but did not receive an antibiotic prescription afterwards.

Statistical analysis

Data analysis calculations were obtained from International Business Machines Corporation Statistical Package for the Social Sciences version 20 (IBM SPSS Statistics 20). Data was directly entered by hand into SPSS by the author. The significance level was set at an alpha level equal to 0.05 prior to the start of data collection. A paired-samples t-test was conducted to evaluate the difference between the number of antibiotic prescriptions written for acute uncomplicated bronchitis and the expected number of antibiotic prescriptions that theoretically should have been written. Paired sample (or repeated measures) t-tests are used to evaluate changes in measurement for the same participants determined after some intervention. Assumptions in a t-test are that there is one categorical independent variable (pre- and post-intervention assessments) and one continuous dependent variable (the antibiotic prescription rate). The sample mean and the population mean may be considered identical when the n is above 30. The sample mean assumption was not felt to be critical since this project involved the first cycle of a PDSA. The theoretical number of antibiotics was determined by using both a 10% and 0% value of the number of acute uncomplicated bronchitis diagnoses. There was a statistically significant decrease in the number of antibiotics written in January ($n = 43$; $M = 9.25$, $SD = 8.14$) to March and April ($n = 0$; $M = 0.00$, $SD = 0.00$), $t(3) = -5.20$, $p = .014$ (two-tailed). There was a statistically significant decrease in the antibiotic prescribing rate in January (86%; $M = 74.75$, $SD = 10.70$) to April (0%; $M = 0.00$, $SD = 0.00$), $t(3) = 6.99$, $p = .006$ (two-

tailed). The mean decrease in the antibiotic prescribing rate was 74.75 with a 95% confidence interval ranging from 40.71 to 108.79. The eta squared statistic (.94) indicated a large effect size. The Wilcoxon Signed Rank Test is a nonparametric alternative to the repeated measures t-test which also confirmed a statistically significant reduction in antibiotic prescribing rates from January to April 2016, z = -2.023, p = .043, with the median antibiotic prescribing rate decreasing from pre-intervention (Md = 85) to post-intervention (Md = 0).

The Friedman Test is a non-parametric test that is used when the same sample of participants (the involved providers) are measured at three or more points in time (January, February, March and April). The results of the Friedman Test indicated that there was a statistically significant difference in the antibiotic prescribing rates across the months of January to April X^2 (3, n = 4) = 12.00, p = .007. Inspection of the median values showed a decrease in the antibiotic prescribing rates from pre-intervention (January; Md = 71) to post-intervention (April; Md = 0). A Friedman Test was also done in order to determine if the providers were lowering their antibiotic prescribing rates by simply not using the diagnosis of acute uncomplicated bronchitis. This test indicated that there was no statistically significant difference in the amount of acute uncomplicated bronchitis being diagnosed between January and April 2016 X^2 (1, n = 4) = .000, p = 1.000.

A comparison was made using the two providers (Provider A and Provider B) who were at the urgent care clinic during March 2015 and March 2016 to ensure that a seasonal or yearly variation was not the cause for the decreased antibiotic prescribing rate. Provider A wrote 21 antibiotics for 21 acute bronchitis diagnoses in adult patients aged 18 to 64 years (100%) and Provider B wrote 15 antibiotics written for 15 acute bronchitis diagnoses (100%) during March 2015. While a Wilcoxon Signed Rank Test did not reveal a statistically significant change in the

number of acute bronchitis diagnoses between March 2015 and March 2016, $z = -.45$, $p = .655$, Provider A wrote zero antibiotics for 16 acute bronchitis diagnoses adult patients aged 18 to 64 years (0% prescribing rate) and Provider B wrote zero antibiotics written for 20 acute bronchitis diagnoses (0% prescribing rate) during March 2016. Furthermore, a Wilcoxon Signed Rank Test did not result in a statistically significant difference in the number of acute uncomplicated bronchitis that were diagnosed between January and April 2016, $z = -1.22$, $p = .223$.

Discussion

The problem that was addressed in this project was the historical high rate of antibiotic prescriptions being written for acute uncomplicated bronchitis in the urgent care setting. Historically, the antibiotic prescribing rate for acute bronchitis is between 60% and 80% in the United States (Barnett & Linder, 2014; Fleming-Dutra et al., 2016). The pre-intervention antibiotic prescribing rate for the providers involved in this project was similar and ranged from 57% to 100% (Figures 18-21). A quality improvement program was initiated to reduce this prescribing rate to 10% or less within three months by performance benchmarking the prescribing rates of the providers against a nationally recognized expert consensus rate. The post-intervention antibiotic prescribing rates for all of the involved providers were 0% within two months of initiating the intervention to providers, which included a clinical practice guideline for an acute bronchitis algorithm and patient examination room education materials (Figures 1 & Figures 15-16).

The purpose of PDSA cycles are to perform small frequent tests of change to determine what works, what does not work and then build on the lessons learned (Berwick, 2003). Based on the results obtained from this project, the specific implementations that were discussed in the methodology section should be kept and instituted with more providers in more clinics to determine if the prescribing changes will hold on a larger scale.

Implications of Study

Economic Data

Unnecessary drug expenditures in the form of unnecessary antibiotic prescriptions written for viral illnesses contribute to the direct cost of medical care. The average wholesale price (AWP) of antibiotics used to routinely treat acute uncomplicated bronchitis in an otherwise

healthy adult person ranges from $13.14 to $1373.20 (Table 3). This translates into a direct healthcare savings $1,235.16 to $129,080.80 in just a three month period of time at a single urgent care clinic. This does not include any potential treatment of adverse drug reactions or the associated cost of treating antimicrobial drug resistance infections. The indirect cost associated with the education has been found to be negligible and does not necessarily increase either the amount of return visits or illness duration, decrease patient satisfaction, or prolong the patient visit time (Gonzales & Sande, 2000; Hare, Gaur, Somes, Arnold, & Shorr, 2006).

Adverse Drug Effects

Adverse side effects occur in 5% to 25% of the patients who take antibiotics and serious adverse effects such a *C. difficile* occurs in 0.1% of patients (Vega, 2016). This translates into 5 to 24 patients theoretically spared from having side effects from taking antibiotics in just a three month period of time during this PDSA cycle at a single urgent care clinic.

Limitations

There were several limitations to this quality assurance project. First, the endeavor consisted of a small convenience population over a constricted time period that limits the generalizability to other geographical or practice areas. The small sample size was appropriate in beginning the PDSA cycle's continuous and cyclical process until the goal of reducing the antibiotic prescribing rate for acute bronchitis in the otherwise healthy adult population is decreased to 10% or less and provider practice variation is lowered across the entire Urgent Care Division. As previously stated, acute bronchitis is more common in the fall and winter months (Albert, 2010). The seasonality of this undertaking was done between January and April 2016, which can be considered winter and spring months, and may have impacted the resultant number of acute bronchitis diagnoses, which should be expected to be higher during the fall and winter

than during the summer months, but should not have affected the antibiotic prescribing rate, which depends strictly on the number of times an antibiotic was written for that diagnosis. The post-intervention number of acute bronchitis diagnoses within this PDSA cycle were observed to be similar from the pre-intervention time period and from a similar time period during the preceding year.

Second, the use of ICD-10-CM codes were used as an inclusion criteria in the methodology design. This assignment did not measure inter-rater reliability in making a diagnosis of acute bronchitis, but required providers to make the diagnosis without an agreed upon definition. Acute bronchitis is a clinical diagnosis of exclusion, sometimes indistinguishable from other respiratory illnesses, and without confirmatory tests. Therefore, a patient with acute bronchitis may also be categorized as having an upper respiratory infection, allergic rhinitis, postnasal drip, sinusitis, reflux or asthma (Albert, 2010; Bush 2013). Many patients in this PDSA cycle were noted to have similar clinical findings, but had a final diagnosis of URI or other ICD code and were therefore excluded from analysis. Provider education on inter-rater reliability for diagnosing acute bronchitis should be addressed before another PDSA cycle is instituted.

Third, this project was subject to the Hawthorne effect. Hawthorne effect was intended to be created and an integral part of the PDSA cycle because the providers were well aware that their antibiotic prescribing rates were being tracked. The whole goal of tracking specific data is to encourage better compliance or adherence to an identified objective. Tracking antibiotic prescribing rates should continue since sustaining improvements without continuing interventions and tracking will be difficult to maintain.

Finally, this study did not track the patients who were diagnosed with acute bronchitis to determine if they were seen later outside of the urgent care clinic for worsening symptoms or if they received an antibiotic at a later date. In fact, if the patient returned at a later date to the urgent care, they were specifically excluded from this survey which formed a large number of exclusions. Patients may return for a variety of reasons, including a continued cough or sputum that becomes purulent, neither of which necessarily indicates a bacterial infection (Hueston & Mainous, 1998). The clinical practice guideline and patient examination room education materials that were utilized for this PDSA should also be used for patients who return for rechecks. This inquiry also did not examine patient satisfaction with the visit and if there was a difference in satisfaction scores that were correlated with getting an antibiotic. As mentioned previously however, patient satisfaction has not been found to be associated with whether an antibiotic prescription was received (Gonzales & Sande, 2000; Wong et al., 2006).

Diffusion of Innovation Application

Diffusion of innovation is a theory developed by Rogers which refers to the consistent and predictable pattern of adoption of new ideas over time by a population of social system participants (Rogers, 1995). The theoretical concepts include innovation, communication channels, time and social system. Innovation can be thought of as both a process and an outcome and is considered new if it is concerned with the application of some sort of discontinuous change (Greenhalgh et al., 2005). It is not the same as invention or incremental or expansionary development. Communication channels allow the transfer of information among people or organizations. Time is necessary for any innovation to be adopted. Social system is the internal and external influences on a potential adopter. There are five stages to adoption

process which are identified as knowledge, persuasion, decision, implementation and confirmation.

Innovation awareness and persuasion is influenced by both the structure and quality of the social network (Greenhalgh et al., 2005). Since the diffusion process is a social act, it is important to get buy-in from certain key individuals, called opinion leaders or champions, who can exert influence in spreading information about the innovation and influence the motivation of adopting the change by either positively or negatively swaying others through their authority or status. Other key factors include capacity, reinforcement and support (Greenhalgh et al., 2005). Capacity are the resources for the implementation process that are available, such as monetary and technical assistance. Reinforcement and support from leadership, in terms of both people and processes, are affiliated with capacity and can sustain innovation.

Certain barriers should be avoided to foster a culture that is receptive to a diffusion of innovation. Motivation for change will be stifled if the transformation is considered to create extra work without any direct benefit, does not fit, or worse directly conflicts, with the existing infrastructure or culture of the organization, or incurs a cost to the group implementing the modifications. Risks can be a barrier to innovation diffusion and can be the result of such things as does the usage pose any sort of a threat, will implementing it cause a social embarrassment, and is it worth the cost or time of effecting the change. Innovations that are relatively less complex and disruptive, less time consuming, and less costly or financially risky are easier to adopt.

The theory of innovation diffusion was employed to optimize implementing the antibiotic stewardship program. The first item that was accomplished was to identify a “champion” who had a position of authority or expertise within the organization and who backed the innovation

(the author). This champion was a peer of the other individuals within the Urgent Care Division, with the same educational and role's background as the respective clinic's providers, so that geographical proximity and homophily could be attained. Neither factor could be accomplished if a provider who had a purely administrative role or was from another department came to discuss starting the antibiotic stewardship program. Using a healthcare provider who practiced in a similar setting to give a breakfast or lunch detailing the program could also be effective. This type of implementation would be similar to pharmaceutical representatives doing a drug detailing lunch, which is a previously accepted concept. Organizational reinforcement and support was provided by tying the program into the electronic health record (EHR) and by providing room posters supporting antibiotic stewardship. Future reinforcement may be provided by tying bonuses to meeting antibiotic prescribing rate benchmarks for certain diagnoses, such as acute bronchitis.

Triple Aim Goals

The triple aim of improving the healthcare system within the United States is geared toward improving the patient care experience, improving population health and reducing the per capita costs of health care for populations (Berwick, Nolan & Whittington, 2008). Implementing the antibiotic stewardship program within the urgent care setting met two of these aims: improving the health of the population by decreasing the amount of antibiotic overuse and antibiotic resistance and reducing the healthcare per capita costs by lessening the expenditure for unnecessary medicines, drug-related emergency department visits, and preventable additional hospital days associated with treating infections associated with antimicrobial drug resistance. An initiative to reduce waste in the form of valueless service may be employed in an attempt to reduce and control the per capita cost (Berwick, Nolan & Whittington, 2008). As mentioned in

the previous section, future initiatives may include tying provider financial incentive programs to performance measures such as meeting benchmark recommendations on antibiotic prescribing rates for certain diagnoses, such as acute bronchitis.

Recommendations

Behavioral

Incorporating evidence-based practice into healthcare settings often require certain behavioral modifications to take place. Healthcare providers perceive their jobs as being difficult, demanding and with strong individual accountability and have been resistant to control and work standardization strategies (Berwick, 2015). These approaches have often been interpreted as policing and interfering and are usually ineffective because the policies result in feelings of alienation (Storey & Buchanan, 2008). Improvement aims should be clearly and publicly communicated by leadership individuals with objective performance goals. Education material and work shortcuts should be created and championed by respected staff members. Material such as the “CDC Get Smart: Know When Antibiotics Work” program and the “CDC OTC Prescription Pad” focuses on promoting appropriate outpatient antibiotic use and are designed to be easily implemented in clinical settings. Staff can also contribute to managing patients’ expectations by providing “pre-visit” education to patients, such as informing the patient that sputum color does not correlated with disease etiology. Variations to expert guidelines should be allowed, but only with explanations. Standardized performance appraisals should include how well these metrics are met.

Providers should also be educated on certain behavioral responses that may be encountered during the work day and how to prepare for them. For example, an antibiotic is more likely to be written, whether it is appropriate or not, the more times a patient sees a

provider, such as patient rechecks (Fleming-Dutra et al., 2016). Providers should be prepared to examine a patient more closely, including ordering more diagnostic testing if needed, if the patient returns with the same medical compliant, but also be prepared not to write an antibiotic prescription "just in case" if it is still not warranted. Antibiotic prescriptions have been demonstrated to increase the longer a provider is in clinic due to "provider fatigue" (Linder et al., 2014). Providers and administrative staff should therefore incorporate short breaks within clinic schedules to help guard against this fatigue.

Pareto principle

The Act stage has four options depending on the result of the PDSA cycle: 1) adopt the change "as is," 2) adapt the change and test again, 3) expand the change and test again, or 4) abandon the change. The recommendation from this PDSA cycle is to expand the change to more clinics and test again. The Pareto Principle can be applied to quality improvement projects by focusing on correcting a few key culprits (the 20%) to affect a great majority of the concerns (the 80%), thereby ensuring a greater probability of success. A large source of provider practice pattern variance is the individual provider preference that influences the decision whether to write an antibiotic or not. This has been confirmed in a recent study that found 10% of the involved providers prescribed antibiotics during at least 95% of patient visits to them for acute respiratory infections (Jones et al., 2015). When expanding the PDSA to more providers and clinics, a focus should be on the roughly 20% of the providers who are responsible for about 80% of the antibiotic prescriptions for acute uncomplicated bronchitis in the otherwise healthy adult patient population. Utilizing Diffusion of Innovation strategies, these providers can be detailed on the clinical guidelines and feedback reports by respected peers (Gjelstad et al., 2013; Vinnard et al., 2013).

Incentives

Incentives can be an effective way to promote change within healthcare and can have either a positive or negative influence on following recommendations. Recent systematic reviews found that there are modest positive effects from offering financial incentives in return for providing quality of care (Flodgren, et al., 2011; Scott, et al., 2011). Incentives can be used as an extrinsic motivational source to increase evidenced-based treatment and to alter preventive, diagnostic and treatment decisions. It is important to carefully and thoughtfully design the criteria that triggers the incentive before implementing the program, however, to avoid encouraging undesirable outcomes. Quality measures are already being measured and benchmarked for both providers and healthcare organizations with non-participation currently involving payment penalties.

Perceived patient demand, especially in the form of patient satisfaction surveys, time pressures and provider discontentment in failing to meet patient expectations have all been identified as barriers to guideline adherence barriers (Dempsey et al., 2014). Patient satisfaction has not been associated with receiving an antibiotic prescription, but rather if the patient understood their illness and if the patient felt like their provider spent adequate time with them (Wong et al., 2006). Having educational material, such as educational posters, readily available are an efficient means of informing patients. Patients have further stated that they do not necessarily want an antibiotic, but rather an effective treatment plan (Colgan & Powers, 2001; Rowbotham et al., 2012).

Conclusions

Providing provider accountability in the form of oversight and constructive feedback, such quality dashboards, along with peer comparisons are some of behavioral interventions to

lower inappropriate prescribing rates (Meeker et al., 2016). Peer comparisons should be different from traditional auditing and include positive reinforcement. If possible, feedback should include a safety analysis where providers are informed when patients have return visits or harms that are caused by their antibiotics, such as antibiotic-associated diarrhea. Providers can use tools such as a "running commentary" to reassure, share information, educate patients and set realistic expectations with patients (Dempsey et al., 2014). Rephrasing the communication and using point of care testing can help alter patient beliefs.

Although not addressed in this study, electronic medical record alterations, such as clinical decision support systems or having to explicitly input a free-text accountable prescribing justification, may also help reduce the amount of antibiotics written and alter prescribing practices without disrupting the workflow, such as traditional alerts and reminders which can be disruptive and ignored (Mainous et al., 2013; McCullough et al., 2014; Meeker et al., 2016; Rattinger et al., 2012). These are especially helpful when suggestive alternatives are given. EMRs can be pre-programmed with order sets that contain recommended tests and treatments based on specific diagnoses (Ackerman et al., 2013; Rattinger et al., 2012).

Finally, this project does not claim that there is no role for antibiotics in treating acute uncomplicated bronchitis within an otherwise healthy adult patient population. The antibiotic prescribing rate is much greater than the nationally recognized expert consensus of what it should be and there is a large opportunity for improvement. There is no question that antibiotics have saved countless lives. Antibiotic resistance, however, "threatens patient care, economic growth, public health, agriculture, economic security, and national security" (President's Council of Advisors on Science and Technology, 2014, p. 1). Antibiotic stewardship will help improve population health by reducing the of the occurrence of antibiotic resistance and decreasing

patient harm from antibiotic use, reduce the per capita costs of health care for populations by decreasing antibiotic-related pharmacy costs, and improve the overall patient care experience.

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Table 1

Acute Respiratory Infection Diagnostic and Treatment Criteria

Condition	Diagnostic Criteria	Antibiotic Treatment Criteria
Acute Bronchitis	1. Acute cough (productive or not) 2. Cough duration < 21 days	Antibiotics **NOT** warranted

Reference: Rattinger et al. (2012).

Table 2

Antibiotic Prescribing Data

		January	February	March	April
Provider A	Number of Bronchitis Diagnosis	20	12	16	9
	Number of Antibiotics Written	20	7	0	0
	Antibiotic Prescribing Rate (%)	100	58	0	0
Provider B	Number of Bronchitis Diagnosis	7	5	20	8
	Number of Antibiotics Written	4	1	0	0
	Antibiotic Prescribing Rate (%)	57	20	0	0
Provider C	Number of Bronchitis Diagnosis	3	8	10	7
	Number of Antibiotics Written	2	1	0	0
	Antibiotic Prescribing Rate (%)	67	13	0	0
Provider D	Number of Bronchitis Diagnosis	13	2	5	2
	Number of Antibiotics Written	11	1	0	0
	Antibiotic Prescribing Rate (%)	85	50	0	0

Table 3

Common Acute Bronchitis Antibiotic Prices

Medicine	Price/unit (USD)	Total price of prescription (USD)
Amoxillin 500 mg	0.65	19.50
Amoxillin 875 mg	0.75	15.00
Amoxillin-clavulanate 500 mg-125 mg	51.50	1030.00
Amoxillin-clavulanate 875 mg-125 mg	68.66	1373.20
Azithromycin 250 mg	2.19	13.14
Cefdinir 300 mg	1.94	38.80
Clarithromycin 250 mg	5.08	101.60
Clarithromycin 500 mg	3.60	72.00
Ciprofloxacin 250 mg	5.26	105.20
Ciprofloxacin 500 mg	6.15	123.00
Doxycycline hyclate 100mg	0.67	13.40
Levofloxacin 250 mg	19.67	196.70
Levofloxacin 500 mg	21.74	217.40
Levofloxacin 750 mg	50.61	506.10
Trimethoprim/Sulfamethoxazole	1.58	31.60

Reference: Prices obtained from drugs.com price guide on 4/14/16.
Note: USD = United States dollars.

Figures

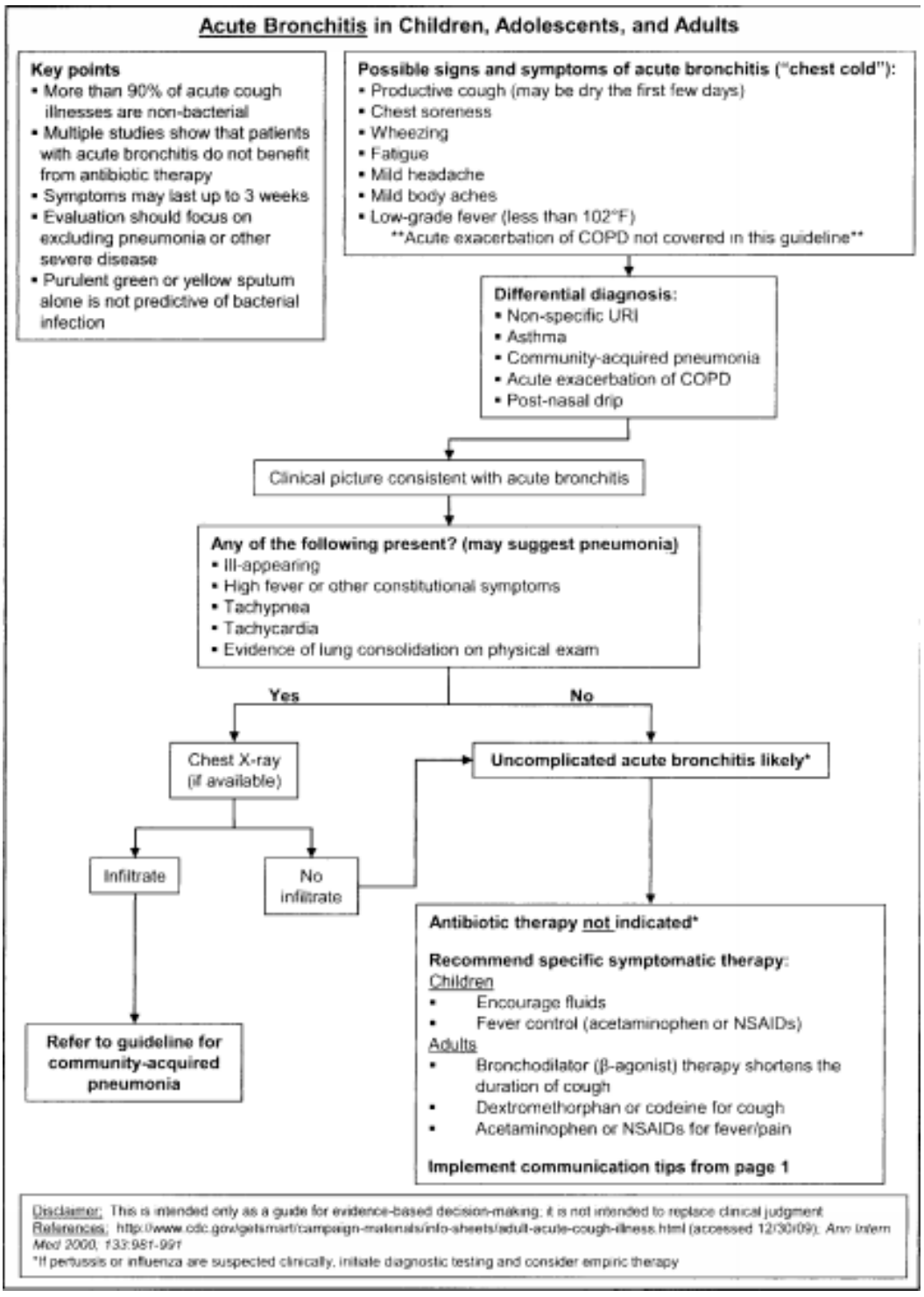

Figure 1. Acute bronchitis algorithm.
Reference: Gonzales & Sande (2000); Jenkins et al. (2013).

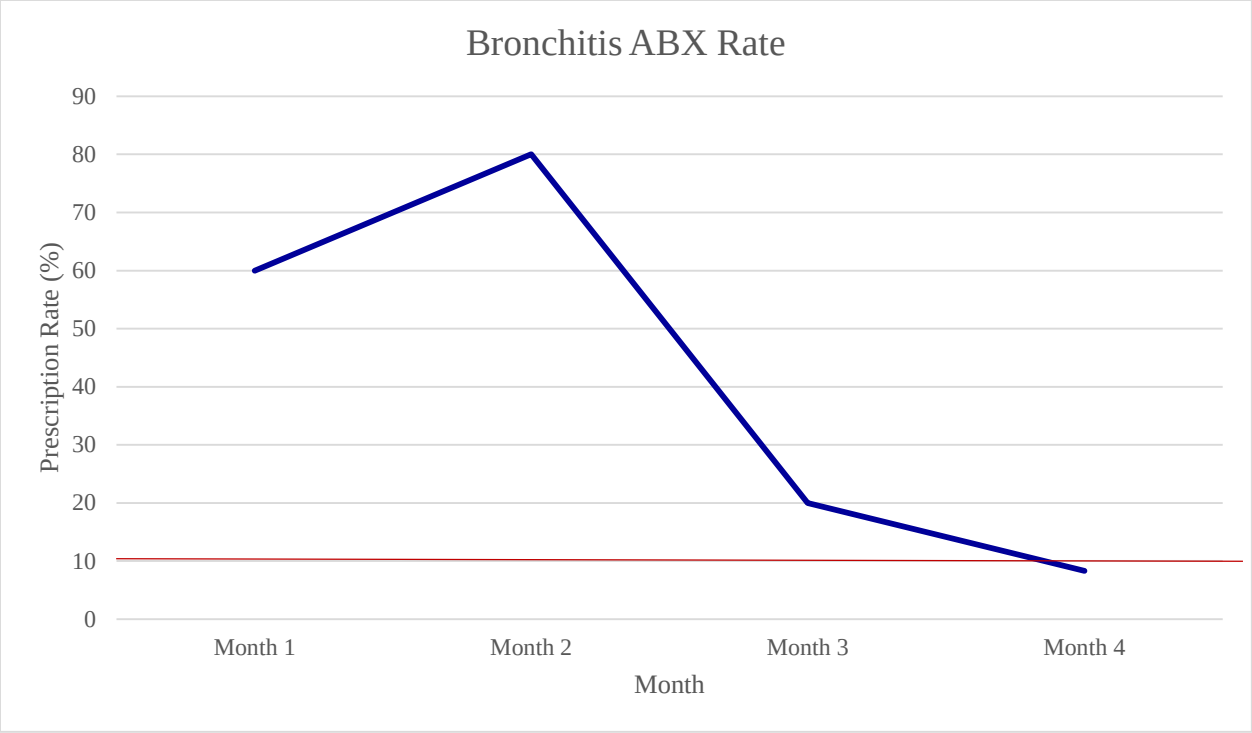

Figure 2. Example of a “Move Your Dot” measurement. ABX = antibiotic. Flat red line is recommended or target rate and blue line is prescriber actual prescription rate.

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((((((((("Anti-bacterial agents"[mh]) OR Lactams[mh]) OR tetracyclines[mh]) OR aminoglycosides[mh]) OR glycopeptides[mh]) OR macrolides[mh]) OR antibiotic*[tw]) OR (((alamethicin[Text Word] OR amdinocillin*[Text Word] OR amikacin[Text Word] OR amoxicillin*[Text Word] OR ampicillin[Text Word] OR aurodox[Text Word] OR azithromycin[Text Word] OR azlocillin[Text Word] OR aztreonam[Text Word] OR bacitracin[Text Word] OR bacteriocin*[Text Word] OR brefeldin*[Text Word] OR butirosin*[Text Word] OR candicidin[Text Word] OR carbenicillin[Text Word] OR carfecillin[Text Word] OR cefaclor[Text Word] OR cefadroxil[Text Word] OR cefamandole[Text Word] OR cefazolin[Text Word] OR cefixime[Text Word] OR cefmenoxime[Text Word] OR cefmetazole[Text Word] OR cefonicid[Text Word] OR cefoperazone[Text Word] OR cefotaxime[Text Word] OR cefotetan[Text Word] OR cefotiam[Text Word] OR cefoxitin[Text Word] OR cefsulodin[Text Word] OR ceftazidime[Text Word] OR ceftizoxime[Text Word] OR ceftriaxone[Text Word] OR cefuroxime[Text Word] OR cephacetrile[Text Word] OR cephalexin[Text Word] OR cephaloglycin[Text Word] OR cephaloridine[Text Word] OR cephalosporin*[Text Word] OR cephalothin[Text Word] OR cephapirin[Text Word] OR cephradine[Text Word] OR chloramphenicol[Text Word] OR chlortetracycline[Text Word] OR citrinin[Text Word] OR clarithromycin[Text Word] OR clavulanic acid*[Text Word] OR clindamycin[Text Word] OR cloxacillin[Text Word] OR colistin[Text Word] OR cyclacillin[Text Word] OR dactinomycin[Text Word] OR daptomycin[Text Word] OR demeclocycline[Text Word] OR dibekacin[Text Word] OR dicloxacillin[Text Word] OR dihydrostreptomycin*[Text Word] OR distamycin*[Text Word] OR doxycycline[Text Word] OR echinomycin[Text Word] OR edeine[Text Word] OR erythromycin*[Text Word] OR floxacillin[Text Word] OR framycetin[Text Word] OR fusidic acid[Text Word] OR gentamicin*[Text Word] OR gramicidin[Text Word] OR imipenem[Text Word] OR lactam*[Text Word] OR lasalocid[Text Word] OR leucomycins[Text Word] OR lymecycline[Text Word] OR mepartricin[Text Word] OR methacycline[Text Word] OR methicillin[Text Word] OR mezlocillin[Text Word] OR mikamycin[Text Word] OR minocycline[Text Word] OR miocamycin[Text Word] OR moxalactam[Text Word] OR mupirocin[Text Word] OR mycobacillin[Text Word] OR

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or oxacillin or oxytetracycline or penicillanic acid or penicillic acid or penicillin* or piperacillin or pivampicillin or polymyxin* or pristinamycin* or prodigiosin or rifabutin or ristocetin or rolitetracycline or roxarsone or rutamycin or sirolimus or sisomicin or spectinomycin or streptogramin* or streptovaricin or sulbactam or sulbenicillin or talampicillin or teicoplanin or tetracycline or thiamphenicol or thiostrepton or ticarcillin or tobramycin or troleandomycin or tylosin or tyrocidine or tyrothricin or valinomycin or vancomycin or vernamycin* or viomycin* or virginiamycin* or beta-lactam*[MeSH Terms]))))) AND ((((Bronchitis[mh]) OR bronchit*[tw]) OR ((bronchial[tw]) AND infect*[tw])) OR "Respiratory tract infections"[mh])) AND ((((((((("randomized controlled trial"[pt]) OR "controlled clinical trial"[pt]) OR randomized[tiab]) OR placebo[tiab]) OR "drug therapy"[tiab]) OR randomly[tiab]) OR trial[tiab]) OR groups[tiab])) NOT ((animals[mh] NOT humans[mh]))) AND (("2014/01/01"[PDat] : "2016/12/31"[PDat]))

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#24	Search (#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23)	839857
#23	Search ((alamethicin[Text Word] OR amdinocillin*[Text Word] OR amikacin[Text Word] OR amoxicillin*[Text Word] OR ampicillin[Text Word] OR aurodox[Text Word] OR azithromycin[Text Word] OR azlocillin[Text Word] OR aztreonam[Text Word] OR bacitracin[Text Word] OR bacteriocin*[Text Word] OR brefeldin*[Text Word] OR butirosin*[Text Word] OR candicidin[Text Word] OR carbenicillin[Text Word] OR carfecillin[Text Word] OR cefaclor[Text Word] OR cefadroxil[Text Word] OR cefamandole[Text Word] OR cefazolin[Text Word] OR cefixime[Text Word] OR cefmenoxime[Text Word] OR cefmetazole[Text Word] OR cefonicid[Text Word] OR cefoperazone[Text Word] OR cefotaxime[Text Word] OR cefotetan[Text Word] OR cefotiam[Text Word] OR cefoxitin[Text Word] OR cefsulodin[Text Word] OR ceftazidime[Text Word] OR ceftizoxime[Text Word] OR ceftriaxone[Text Word] OR cefuroxime[Text Word] OR	414973

	cephacetrile[Text Word] OR cephalexin[Text Word] OR cephaloglycin[Text Word] OR cephaloridine[Text Word] OR cephalosporin*[Text Word] OR cephalothin[Text Word] OR cephapirin[Text Word] OR cephradine[Text Word] OR chloramphenicol[Text Word] OR chlortetracycline[Text Word] OR citrinin[Text Word] OR clarithromycin[Text Word] OR clavulanic acid*[Text Word] OR clindamycin[Text Word] OR cloxacillin[Text Word] OR colistin[Text Word] OR cyclacillin[Text Word] OR dactinomycin[Text Word] OR daptomycin[Text Word] OR demeclocycline[Text Word] OR dibekacin[Text Word] OR dicloxacillin[Text Word] OR dihydrostreptomycin*[Text Word] OR distamycin*[Text Word] OR doxycycline[Text Word] OR echinomycin[Text Word] OR edeine[Text Word] OR erythromycin*[Text Word] OR floxacillin[Text Word] OR framycetin[Text Word] OR fusidic acid[Text Word] OR gentamicin*[Text Word] OR gramicidin[Text Word] OR imipenem[Text Word] OR lactam*[Text Word] OR lasalocid[Text Word] OR leucomycins[Text Word] OR lymecycline[Text Word] OR mepartricin[Text Word] OR methacycline[Text Word] OR methicillin[Text Word] OR mezlocillin[Text Word] OR mikamycin[Text Word] OR minocycline[Text Word] OR miocamycin[Text Word] OR moxalactam[Text Word] OR mupirocin[Text Word] OR mycobacillin[Text Word] OR nafcillin[Text Word] OR nebramycin[Text Word] OR enigericin[Text Word] OR nisin[Text Word] OR novobiocin[Text Word] OR nystatin[Text Word] OR ofloxacin[Text Word] OR oligomycins[Text Word] OR oxacillin[Text Word] OR oxytetracycline[Text Word] OR penicillanic acid[Text Word] OR penicillic acid[Text Word] OR penicillin*[Text Word] OR piperacillin[Text Word] OR pivampicillin[Text Word] OR polymyxin*[Text Word] OR	

	pristinamycin*[Text Word] OR prodigiosin[Text Word] OR rifabutin[Text Word] OR ristocetin[Text Word] OR rolitetracycline[Text Word] OR roxarsone[Text Word] OR rutamycin[Text Word] OR sirolimus[Text Word] OR sisomicin[Text Word] OR spectinomycin[Text Word] OR streptogramin*[Text Word] OR streptovaricin[Text Word] OR sulbactam[Text Word] OR sulbenicillin[Text Word] OR talampicillin[Text Word] OR teicoplanin[Text Word] OR tetracycline[Text Word] OR thiamphenicol[Text Word] OR thiostrepton[Text Word] OR ticarcillin[Text Word] OR tobramycin[Text Word] OR troleandomycin[Text Word] OR tylosin[Text Word] OR tyrocidine[Text Word] OR tyrothricin[Text Word] OR valinomycin[Text Word] OR vancomycin[Text Word] OR vernamycin*[Text Word] OR viomycin*[Text Word] OR virginiamycin*[Text Word] OR beta-lactam*[Text Word])) OR (alamethicin or amdinocillin* or amikacin or amoxicillin* or ampicillin or aurodox or azithromycin or azlocillin or aztreonam or bacitracin or bacteriocin* or brefeldin* or butirosin* or candicidin or carbenicillin or carfecillin or cefaclor or cefadroxil or cefamandole or cefazolin or cefixime or cefmenoxime or cefmetazole or cefonicid or cefoperazone or cefotaxime or cefotetan or cefotiam or cefoxitin or cefsulodin or ceftazidime or ceftizoxime or ceftriaxone or cefuroxime or cephacetrile or cephalexin or cephaloglycin or cephaloridine or cephalosporin* or cephalothin or cephapirin or cephradine or chloramphenicol or chlortetracycline or citrinin or clarithromycin or clavulanic acid* or clindamycin or cloxacillin or colistin or cyclacillin or dactinomycin or daptomycin or demeclocycline or dibekacin or dicloxacillin or dihydrostreptomycin* or distamycin* or doxycycline or echinomycin or edeine or erythromycin* or floxacillin or framycetin or	

	fusidic acid or gentamicin* or gramicidin or imipenem or lactam* or lasalocid or leucomycins or lymecycline or mepartricin or methacycline or methicillin or mezlocillin or mikamycin or minocycline or miocamycin or moxalactam or mupirocin or mycobacillin or nafcillin or nebramycin or enigericin or nisin or novobiocin or nystatin or ofloxacin or oligomycins or oxacillin or oxytetracycline or penicillanic acid or penicillic acid or penicillin* or piperacillin or pivampicillin or polymyxin* or pristinamycin* or prodigiosin or rifabutin or ristocetin or rolitetracycline or roxarsone or rutamycin or sirolimus or sisomicin or spectinomycin or streptogramin* or streptovaricin or sulbactam or sulbenicillin or talampicillin or teicoplanin or tetracycline or thiamphenicol or thiostrepton or ticarcillin or tobramycin or troleandomycin or tylosin or tyrocidine or tyrothricin or valinomycin or vancomycin or vernamycin* or viomycin* or virginiamycin* or beta-lactam*[MeSH Terms])	
#22	Search antibiotic*[tw]	286838
#21	Search macrolides[mh]	90508
#20	Search glycopeptides[mh]	50294
#19	Search aminoglycosides[mh]	132359
#18	Search tetracyclines[mh]	41454
#17	Search Lactams[mh]	117070
#16	Search "Anti-bacterial agents"[mh]	284106
#15	Search (#11 OR #12 OR #13 OR #14)	316490
#14	Search "Respiratory tract infections"[mh]	300985
#13	Search (bronchial[tw]) AND infect*[tw]	8817
#12	Search bronchit*[tw]	29882
#11	Search Bronchitis[mh]	27026

Figure 3. PubMed search strategy.

Search ID#	Search Terms	Search Options	Last Run Via	Results
S19	S9 AND S10 AND S18	Limiters - Published Date: 20140101-20161231 Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	196
S18	S14 NOT S17	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	458,234
S17	S15 NOT S16	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	55,526
S16	(MH "Human")	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	1,396,118

S15	(MH "Animals")	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	61,815
S14	S11 OR S12 OR S13	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	462,992
S13	AB(randomized OR placebo OR "drug therapy" OR randomly OR trial OR groups)	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	399,388
S12	TI(randomized OR placebo OR "drug therapy" OR randomly OR trial OR groups)	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	83,802
S11	(MH "Randomized Controlled Trials") OR (MH "SingleBlind Studies") OR (MH	Expanders - Apply related words; Also search within the full text of the articles	Interface - EBSCOhost Research Databases	44,812

	"DoubleBlind Studies") OR (MH "Intervention Trials") OR (MH "Therapeutic Trials") OR (MH "TripleBlind Studies") OR (MH "Preventive Trials")	Search modes - Find all my search terms	Search Screen - Advanced Search Database - CINAHL Plus with Full Text	
S10	S5 OR S6 OR S7 OR S8	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	60,496
S9	S1 OR S2 OR S3 OR S4	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	110,299
S8	(MH "Bronchitis+")	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	2,620
S7	TX(bronchit*)	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced	6,502

			Search Database - CINAHL Plus with Full Text	
S6	TX(bronchial) AND TX(infect*)	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	3,200
S5	(MH "Respiratory Tract Infections+")	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	53,594
S4	(MH "Antibiotics+")	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	48,269
S3	(MH "Antibiotics, Lactam") OR (MH "Tetracyclines") OR (MH "Antibiotics, Macrolide") OR (MH "Antibiotics, Peptide") OR (MH "Aminoglycosides")	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	3,596

S2	TX(antibiotic*)	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	78,241
S1	TX(alamethicin OR amdinocillin* OR amikacin OR amoxicillin* OR ampicillin OR aurodox OR azithromycin OR azlocillin OR aztreonam OR bacitracin OR bacteriocin* OR brefeldin* OR butirosin* OR candicidin OR carbenicillin OR carfecillin OR cefaclOR OR cefadroxil OR cefamandole OR cefazolin OR cefixime OR cefmenoxime OR cefmetazole OR cefonicid OR cefoperazone OR cefotaxime OR cefotetan OR cefotiam OR cefoxitin OR cefsulodin OR ceftazidime OR ceftizoxime OR ceftriaxone OR cefuroxime OR cephacetrile OR cephalexin OR cephaloglycin OR	Expanders - Apply related words; Also search within the full text of the articles Search modes - Find all my search terms	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text	50,042

	cephalORidine OR cephalospORin* OR cephalothin OR cephapirin OR cephradine OR chlORamphenicol OR chlORtetracycline OR citrinin OR clarithromycin OR clavulanic acid* OR clindamycin OR cloxacillin OR colistin OR cyclacillin OR dactinomycin OR daptomycin OR demeclocycline OR dibekacin OR dicloxacillin OR dihydrostreptomycin* OR distamycin* OR doxycycline OR echinomycin OR edeine OR erythromycin* OR floxacillin OR framycetin OR fusidic acid OR gentamicin* OR gramicidin OR imipenem OR lactam* OR lasalocid OR leucomycins OR lymecycline OR mepartricin OR methacycline OR methicillin OR mezlocillin OR mikamycin OR minocycline OR miocamycin OR moxalactam OR mupirocin OR mycobacillin OR nafcillin OR nebramycin OR enigericin OR nisin OR novobiocin OR			

	nystatin OR ofloxacin OR oligomycins OR oxacillin OR oxytetracycline OR penicillanic acid OR penicillic acid OR penicillin* OR piperacillin OR pivampicillin OR polymyxin* OR pristinamycin* OR prodigiosin OR rifabutin OR ristocetin OR rolitetracycline OR roxarsone OR rutamycin OR sirolimus OR sisomicin OR spectinomycin OR streptogramin* OR streptovaricin OR sulbactam OR sulbenicillin OR talampicillin OR teicoplanin OR tetracycline OR thiamphenicol OR thiostrepton OR ticarcillin OR tobramycin OR troleandomycin OR tylosin OR tyrocidine OR tyrothricin OR valinomycin OR vancomycin OR vernamycin* OR viomycin* OR virginiamycin* OR betalactam*)			

Figure 4. CINAHL search strategy.

(("anti-bacterial agents"[Pharmacological Action] OR "anti-bacterial agents"[MeSH Terms] OR ("anti-bacterial"[All Fields] AND "agents"[All Fields]) OR "anti-bacterial agents"[All Fields] OR "antibiotic"[All Fields]) AND uri[All Fields]) AND ("2010/05/27"[PDat] : "2015/05/25"[PDat])

(("anti-bacterial agents"[Pharmacological Action] OR "anti-bacterial agents"[MeSH Terms] OR ("anti-bacterial"[All Fields] AND "agents"[All Fields]) OR "anti-bacterial agents"[All Fields] OR "antibiotic"[All Fields]) AND ("ambulatory care"[MeSH Terms] OR ("ambulatory"[All Fields] AND "care"[All Fields]) OR "ambulatory care"[All Fields] OR ("urgent"[All Fields] AND "care"[All Fields]) OR "urgent care"[All Fields])) AND ("2010/05/27"[PDat] : "2015/05/25"[PDat])

(("anti-bacterial agents"[Pharmacological Action] OR "anti-bacterial agents"[MeSH Terms] OR ("anti-bacterial"[All Fields] AND "agents"[All Fields]) OR "anti-bacterial agents"[All Fields] OR "antibiotic"[All Fields]) AND ("bronchitis"[MeSH Terms] OR "bronchitis"[All Fields])) AND ("2010/05/27"[PDat] : "2015/05/25"[PDat])

(("anti-bacterial agents"[Pharmacological Action] OR "anti-bacterial agents"[MeSH Terms] OR ("anti-bacterial"[All Fields] AND "agents"[All Fields]) OR "anti-bacterial agents"[All Fields] OR "antibiotic"[All Fields]) AND ("sinusitis"[MeSH Terms] OR "sinusitis"[All Fields])) AND ("2010/05/27"[PDat] : "2015/05/25"[PDat])

(pdsa[All Fields] AND ("quality improvement"[MeSH Terms] OR ("quality"[All Fields] AND "improvement"[All Fields]) OR "quality improvement"[All Fields])) AND ("2010/05/27"[PDat] : "2015/05/25"[PDat])

("practice guideline"[Publication Type] OR "practice guidelines as topic"[MeSH Terms] OR "clinical practice guideline"[All Fields]) AND ("bronchitis"[MeSH Terms] OR "bronchitis"[All Fields])

("Cochrane Database Syst Rev"[Journal] OR ("cochrane"[All Fields] AND "review"[All Fields]) OR "cochrane review"[All Fields]) AND ("bronchitis"[MeSH Terms] OR "bronchitis"[All Fields])

Figure 5. PubMed search with terms.

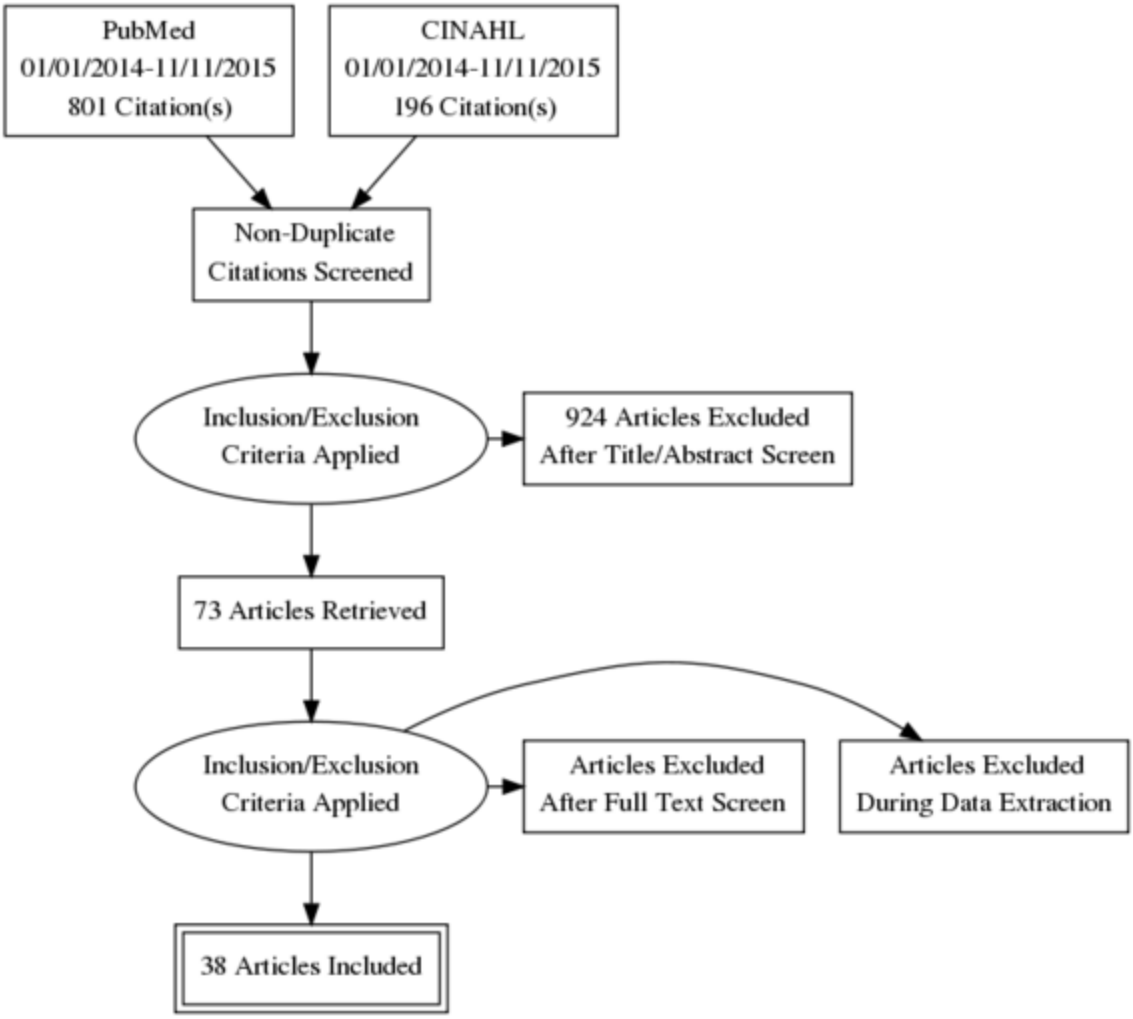


Figure 6. PRISMA flow diagram.

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both	N
ABSTRACT			
Structure summary	2	Provide a structured summary, as applicable; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number	Y, p.1-2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known	Y, p.3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS)	Y, p.3
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists, if and where it can be accessed, and, if available, provide registration number including registration number	Partial; Has review protocol, no access/registration #
Eligibility requirement	6	Specify study characteristics (e.g., PICOS, length of follow up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale	Y, p.3-4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage) in the search and date last searched	Y, p.4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated	Y, p. 51-54 (appendix 1-4)
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in the systematic review)	Y, p.3
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for	Y, p.4

		obtaining and confirming data from investigators	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made	Y, p.4
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data analysis	Y, p.4
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means)	Y, p.5
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency for each meta-analysis	Y, p.5
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies)	Y, p.6-9
Additional analysis	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified	Y, p.10-12
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram	Y, p.5-6, no flow diagram
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations	Y, p. 20-35
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12)	Y, p.8-9
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot	Y, p.10-13

Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency	Y, p.10-13
Risk of bias across studies	22	Present results of any assessment of risk bias across studies (see item 15)	Y, p.6-9
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see item 16])	Y, addressed on p.13 (states none was done)
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers)	Y, p.13
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias)	Y, p.14
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research	Y, p.14-15
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review	Y, p. 58

Figure 7. PRISMA 2009 Checklist for “Antibiotics for acute bronchitis.”

References: Moher, Liberati, Tetzlaff, & Altman (2009); Smith, Fahey, Smucny, & Becker (2014).

	Rating	Comments
Domain 1. Scope and Purpose		
1. The overall objective(s) of the guideline is (are specifically described.	7	Focuses on uncomplicated acute bronchitis in adults
2. The health question(s) covered by the guideline is (are) specifically described.	6	
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	7	Adults; excludes patients with underlying comorbid conditions
Domain 2. Stakeholder Involvement		
4. The guideline development group includes individuals from all relevant professional groups.	4	Physician representatives only, but from a variety of organizations
5. The views and preferences of the target population (patients, public, etc.) have been sought.	4	Internal and external peer (physician) review and feedback, but intended users are listed as “advanced practice nurses, health plans, physician assistants, physicians”
6. The target users of the guideline are clearly identified.	7	Intended users are listed as “advanced practice nurses, health plans, physician assistants, physicians”
Domain 3. Rigour of Development		
7. Systematic methods were used to search for evidence.	7	MEDLINE keyword searches, studies back to 1966 including bibliographies form articles and textbook studies

8. The criteria for selecting the evidence are clearly described.	6	
9. The strengths and limitations of the body of evidence are clearly described.	7	Level of evidence grades (A-D) are provided
10. The methods for formulating the recommendations are clearly described.	6	Treatment trials are discussed
11. The health benefits, side effects, and risks have been considered in formulating recommendations.	5	Treatment benefits and side-effects are discussed
12. There is an explicit link between recommendations and the supporting evidence.	7	Rates and CI levels are given, levels of evidence are provided
13. The guideline has been externally reviewed by experts prior to its publication.	2	Literature review done during another sponsored guideline development, but not reviewed nor endorsed by the sponsoring organization (CDC)
14. A procedure for updating the guideline is provided.	2	Directed to contact guideline developer, but no scheduled update is listed (this update was done in 2012 and last update was 2008)
Domain 4. Clarity of Presentation		
15. The recommendations are specific and unambiguous.	7	
16. The different options for management of the condition or health issue are clearly presented.	6	
17. Key recommendations are easily identifiable.	6	Each recommendation is discussed in a different section

Domain 5. Applicability		
18. The guideline describes facilitators and barriers to its application.	3	Some discussion is done, but barriers are not specifically mentioned
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	5	Proposed algorithm figure is given
20. The potential resource implications of applying the recommendations have been considered.	2	Some brief discussion is mentioned
21. The guideline presents monitoring and/or auditing criteria.	1	
Domain 6. Editorial Independence		
22. The views of the funding body have not been influenced the context of the guideline.	7	
23. Competing interests of guideline development group members have been recorded and addressed.	1	Not mentioned
Overall Guideline Assessment		
Rate the overall quality of this guideline.	5	
I would recommend this guideline for use:		
Yes		
Yes, with modifications	X	

		Should have update and more input/feedback from various stakeholders/intended users
No		

Figure 8. Agree II Instrument for “Uncomplicated Acute Bronchitis” guideline. Ratings on questions 1-23 are based on a 7-point Likert scale of 1=Strongly Disagree to 7=Strongly Agree. Rating on overall quality of guideline is based on a 7-point Likert scale of 1=Lowest possible quality to 7=Highest possible quality.

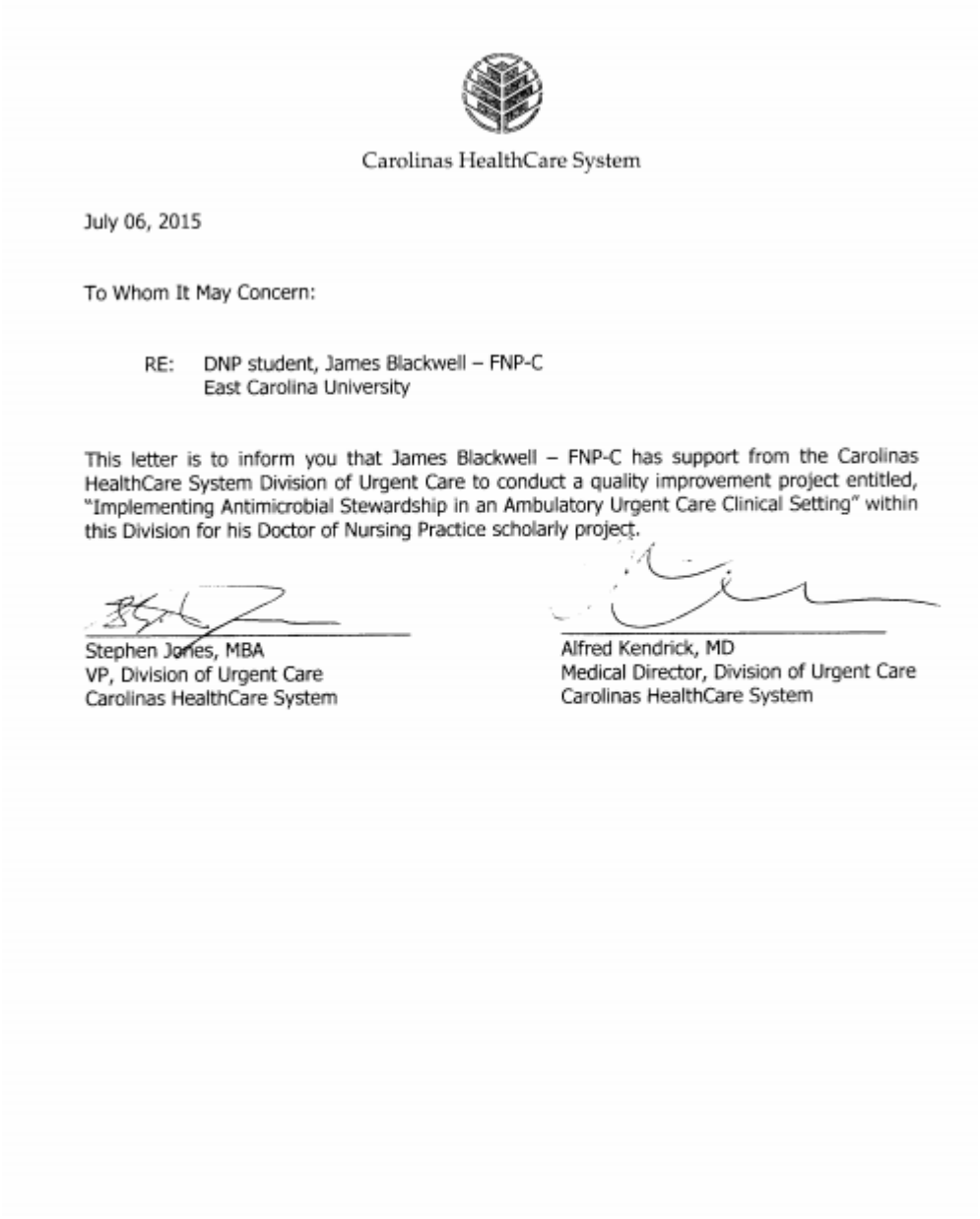
References: Brouwers et al. (2010); Gonzales & Sande (2000); Jenkins et al. (2013).

Provider:					
Date	Patient #	ICD Code	Antibiotic Written (Yes/No)	Appropriate (Yes/No)	Notes

Figure 9. Data Collection Tool 1. Used to track individual provider data. ICD = International Statistical Classification of Diseases and Related Health Problems, a medical classification list by the World Health Organization that contains codes for diseases, signs and symptoms, abnormal findings, and causes of injury or diseases.

	Acute Uncomplicated Bronchitis Diagnosis	ABX Written	ABX Prescribing Rate (%)
Provider A			
Provider B			
Provider C			
Provider D			

Figure 10. Data Collection Tool 2. Used to collect aggregate provider data. ABX = antibiotic. Used to count the number of times a diagnosis of acute uncomplicated bronchitis was recorded and an antibiotic was written for that diagnosis by a specific provider on a patient's chart within the last month.



Carolinas HealthCare System

July 06, 2015

To Whom It May Concern:

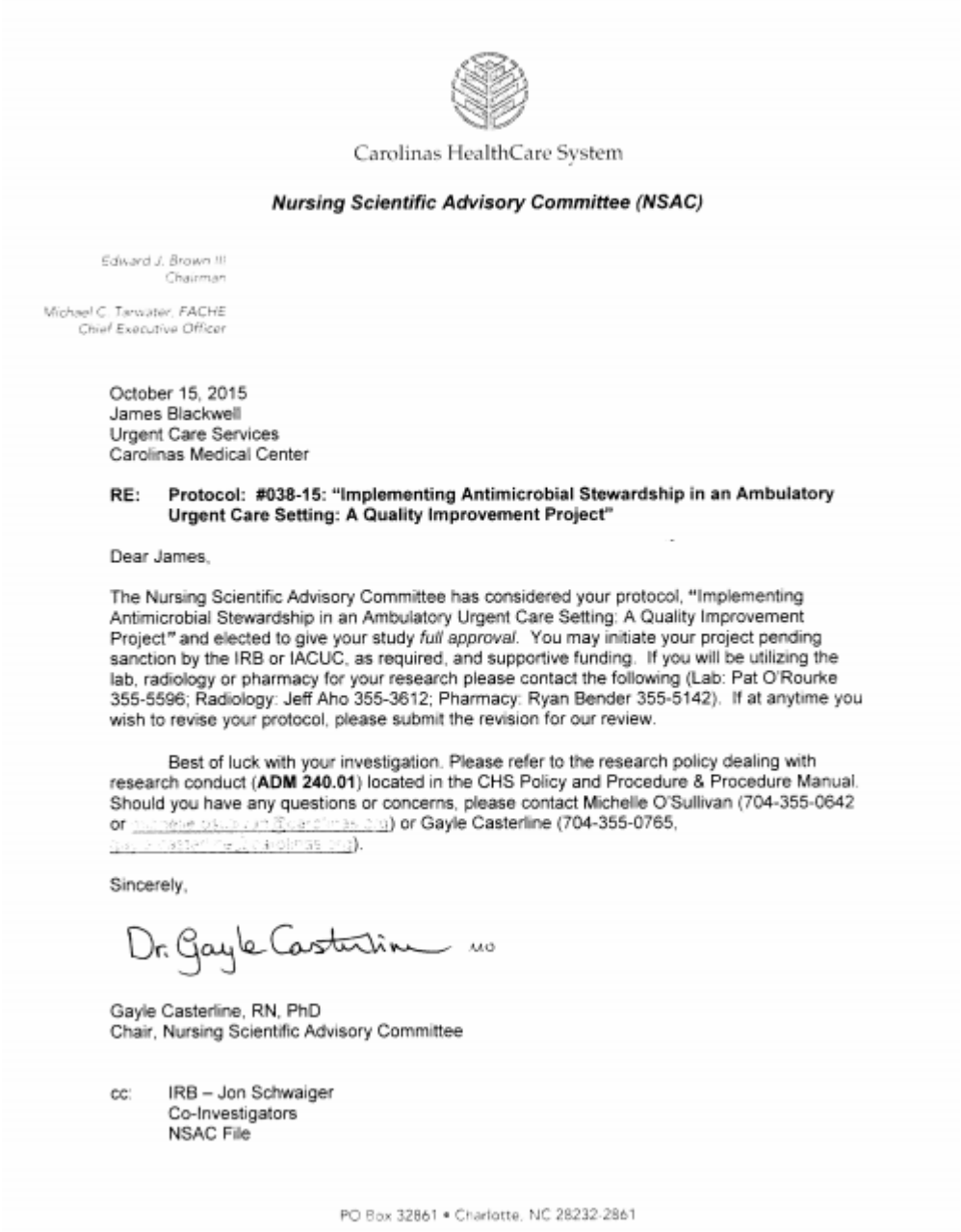
RE: DNP student, James Blackwell – FNP-C
East Carolina University

This letter is to inform you that James Blackwell – FNP-C has support from the Carolinas HealthCare System Division of Urgent Care to conduct a quality improvement project entitled, "Implementing Antimicrobial Stewardship in an Ambulatory Urgent Care Clinical Setting" within this Division for his Doctor of Nursing Practice scholarly project.

Stephen Jones, MBA
VP, Division of Urgent Care
Carolinas HealthCare System

Alfred Kendrick, MD
Medical Director, Division of Urgent Care
Carolinas HealthCare System

Figure 11. Vice President and Medical Director of Carolinas HealthCare System Urgent Care Division Approval



Carolinas HealthCare System

Nursing Scientific Advisory Committee (NSAC)

Edward J. Brown III
Chairman

Michael C. Tarwater, FACHE
Chief Executive Officer

October 15, 2015
James Blackwell
Urgent Care Services
Carolinas Medical Center

RE: Protocol: #038-15: "Implementing Antimicrobial Stewardship in an Ambulatory Urgent Care Setting: A Quality Improvement Project"

Dear James,

The Nursing Scientific Advisory Committee has considered your protocol, "Implementing Antimicrobial Stewardship in an Ambulatory Urgent Care Setting: A Quality Improvement Project" and elected to give your study *full approval*. You may initiate your project pending sanction by the IRB or IACUC, as required, and supportive funding. If you will be utilizing the lab, radiology or pharmacy for your research please contact the following (Lab: Pat O'Rourke 355-5596; Radiology: Jeff Aho 355-3612; Pharmacy: Ryan Bender 355-5142). If at anytime you wish to revise your protocol, please submit the revision for our review.

Best of luck with your investigation. Please refer to the research policy dealing with research conduct (**ADM 240.01**) located in the CHS Policy and Procedure & Procedure Manual. Should you have any questions or concerns, please contact Michelle O'Sullivan (704-355-0642 or [redacted]) or Gayle Casterline (704-355-0765, [redacted]).

Sincerely,

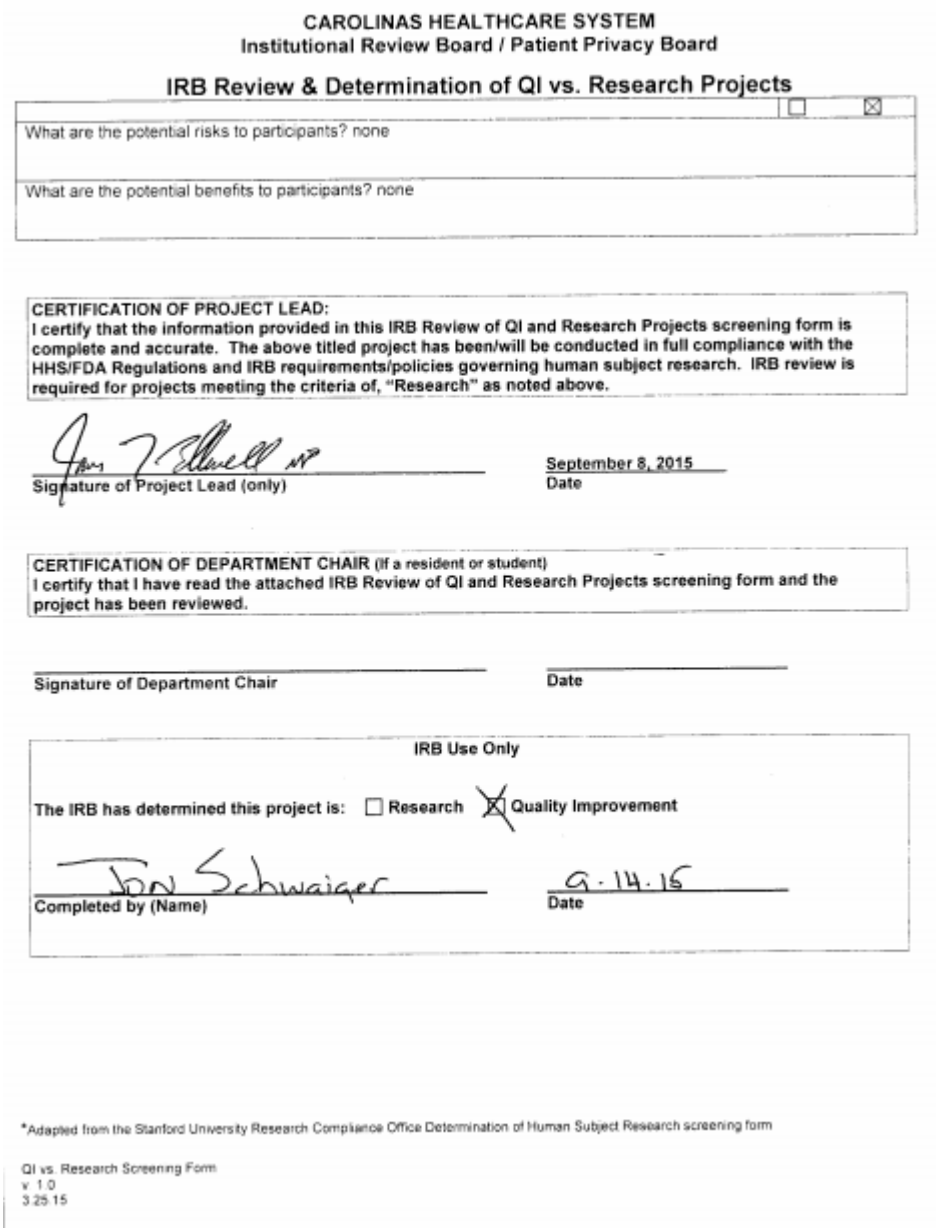
Dr. Gayle Casterline MD

Gayle Casterline, RN, PhD
Chair, Nursing Scientific Advisory Committee

cc: IRB – Jon Schwaiger
Co-Investigators
NSAC File

PO Box 32861 • Charlotte, NC 28232-2861

Figure 12. Carolinas HealthCare System Nursing Scientific Advisory Committee Approval



CAROLINAS HEALTHCARE SYSTEM
Institutional Review Board / Patient Privacy Board

IRB Review & Determination of QI vs. Research Projects

☐ ☒

What are the potential risks to participants? none

What are the potential benefits to participants? none

CERTIFICATION OF PROJECT LEAD:
I certify that the information provided in this IRB Review of QI and Research Projects screening form is complete and accurate. The above titled project has been/will be conducted in full compliance with the HHS/FDA Regulations and IRB requirements/policies governing human subject research. IRB review is required for projects meeting the criteria of, "Research" as noted above.

Signature of Project Lead (only)

September 8, 2015
Date

CERTIFICATION OF DEPARTMENT CHAIR (If a resident or student)
I certify that I have read the attached IRB Review of QI and Research Projects screening form and the project has been reviewed.

Signature of Department Chair

Date

IRB Use Only

The IRB has determined this project is: ☐ Research ☒ Quality Improvement

Jon Schwaiger

9.14.15

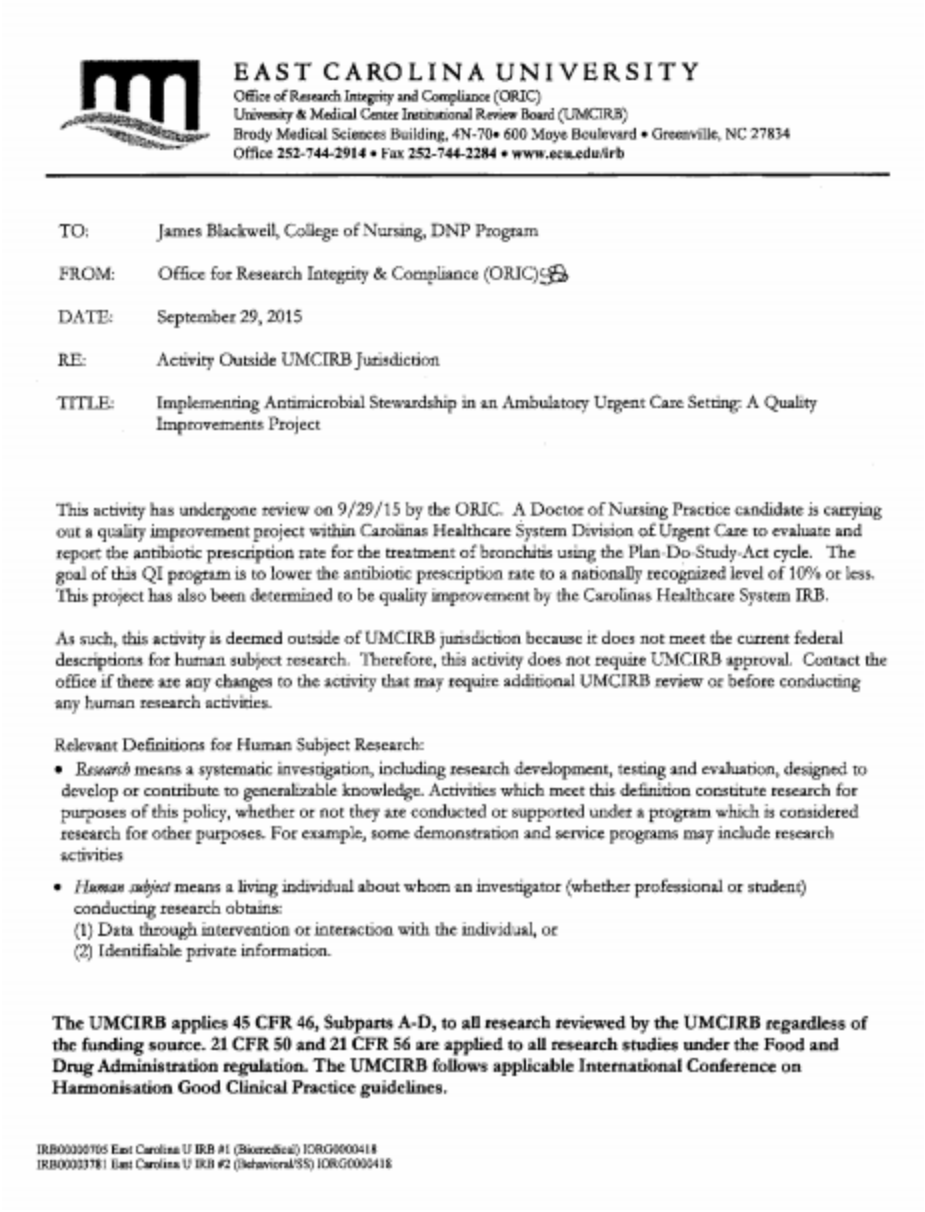
Completed by (Name)

Date

*Adapted from the Stanford University Research Compliance Office Determination of Human Subject Research screening form

QI vs. Research Screening Form
v. 1.0
3.25.15

Figure 13. Carolinas HealthCare System Institutional Review Board Waiver



EAST CAROLINA UNIVERSITY
Office of Research Integrity and Compliance (ORIC)
University & Medical Center Institutional Review Board (UMCIRB)
Brody Medical Sciences Building, 4N-70• 600 Moye Boulevard • Greenville, NC 27834
Office 252-744-2914 • Fax 252-744-2284 • www.ecu.edu/irb

TO: James Blackwell, College of Nursing, DNP Program

FROM: Office for Research Integrity & Compliance (ORIC)

DATE: September 29, 2015

RE: Activity Outside UMCIRB Jurisdiction

TITLE: Implementing Antimicrobial Stewardship in an Ambulatory Urgent Care Setting: A Quality Improvements Project

This activity has undergone review on 9/29/15 by the ORIC. A Doctor of Nursing Practice candidate is carrying out a quality improvement project within Carolinas Healthcare System Division of Urgent Care to evaluate and report the antibiotic prescription rate for the treatment of bronchitis using the Plan-Do-Study-Act cycle. The goal of this QI program is to lower the antibiotic prescription rate to a nationally recognized level of 10% or less. This project has also been determined to be quality improvement by the Carolinas Healthcare System IRB.

As such, this activity is deemed outside of UMCIRB jurisdiction because it does not meet the current federal descriptions for human subject research. Therefore, this activity does not require UMCIRB approval. Contact the office if there are any changes to the activity that may require additional UMCIRB review or before conducting any human research activities.

Relevant Definitions for Human Subject Research:

- *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities
- *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains:
  (1) Data through intervention or interaction with the individual, or
  (2) Identifiable private information.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

IRB00000705 East Carolina U IRB #1 (Biomedical) IORG0000418
IRB00003781 East Carolina U IRB #2 (Behavioral/SS) IORG0000418

Figure 14. East Carolina University Institutional Review Board Waiver

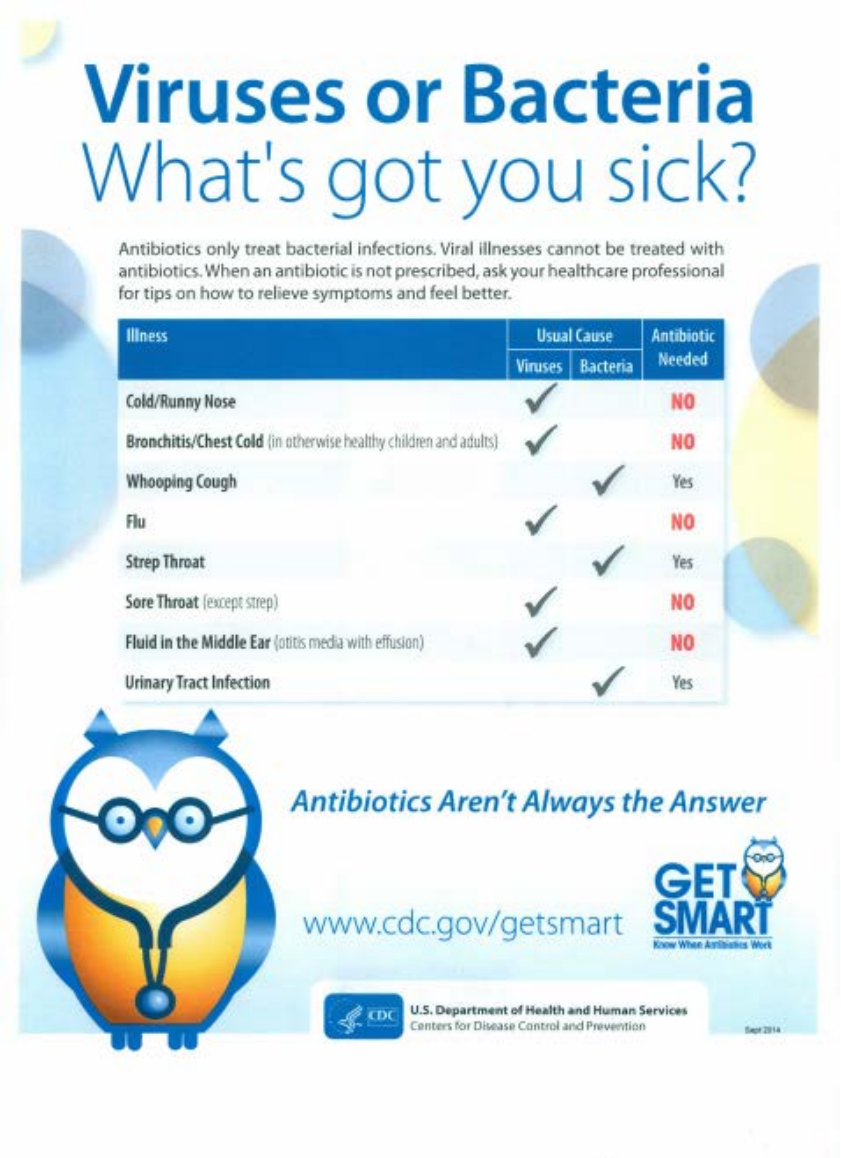


Figure 15. Viruses or bacteria: what's got you sick?
Reference: CDC (2015b).

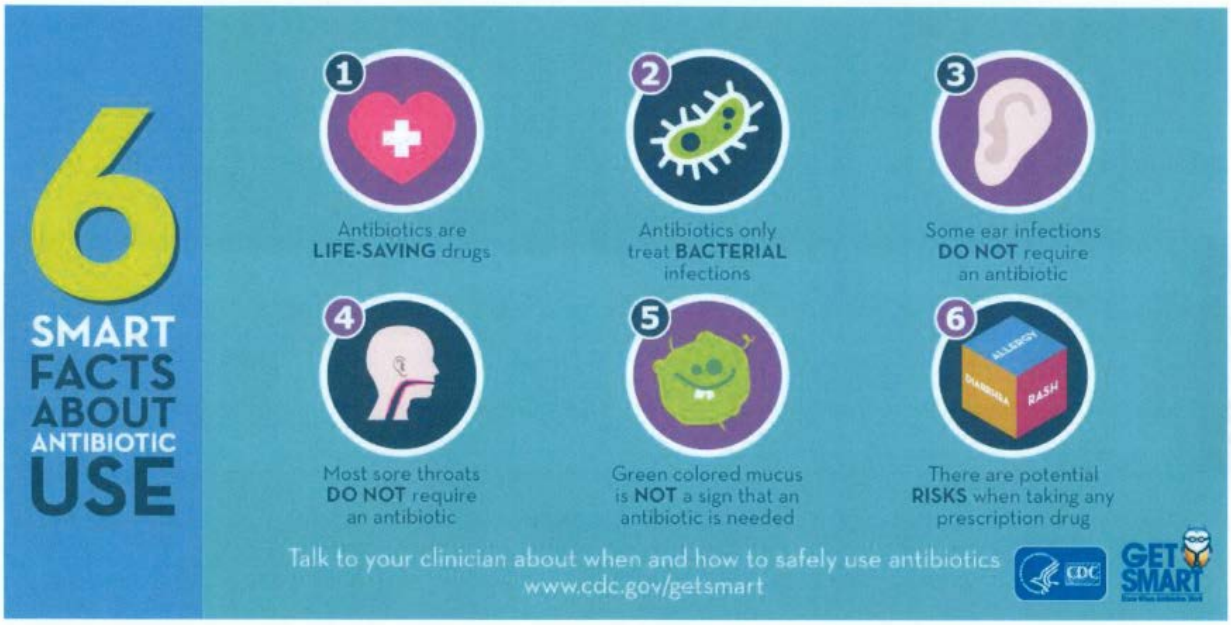


Figure 16. 6 Smart facts about antibiotic use.
Reference: CDC (2015b).

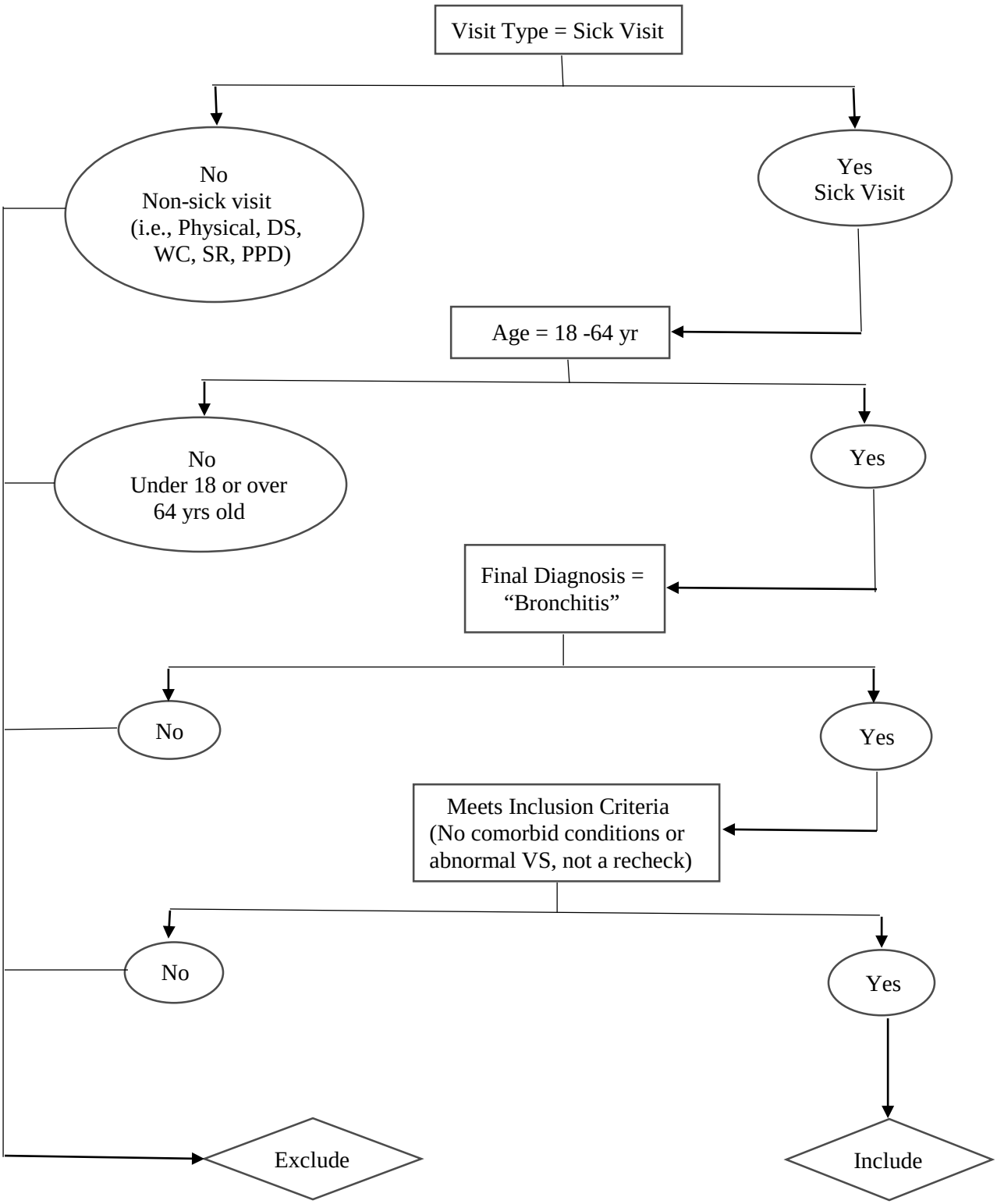


Figure 17. Electronic Medical Record Review Flow Process. DS = drug screen, WC = worker’s compensation, SR = suture removal, PPD = purified protein derivative skin test, yr = year, VS = vital signs.

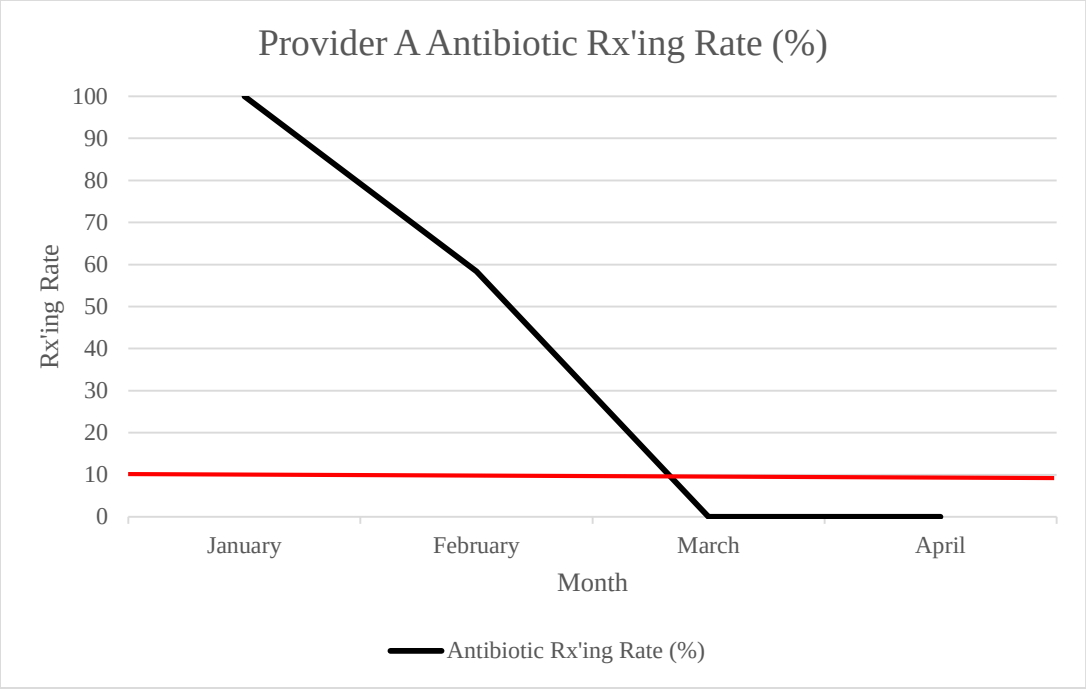


Figure 18. Provider A antibiotic prescribing rate monthly measurement. Rx'ing = prescribing. Flat red line is recommended or target rate and black line is prescriber actual prescription rate.

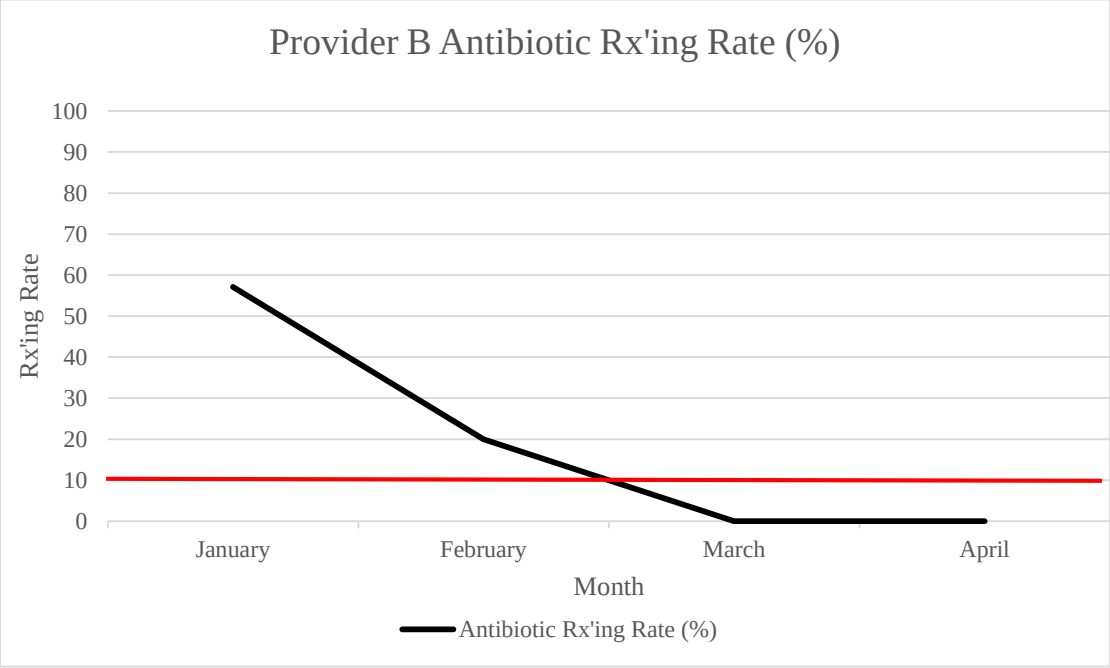


Figure 19. Provider B antibiotic prescribing rate monthly measurement. Rx'ing = prescribing. Flat red line is recommended or target rate and black line is prescriber actual prescription rate.

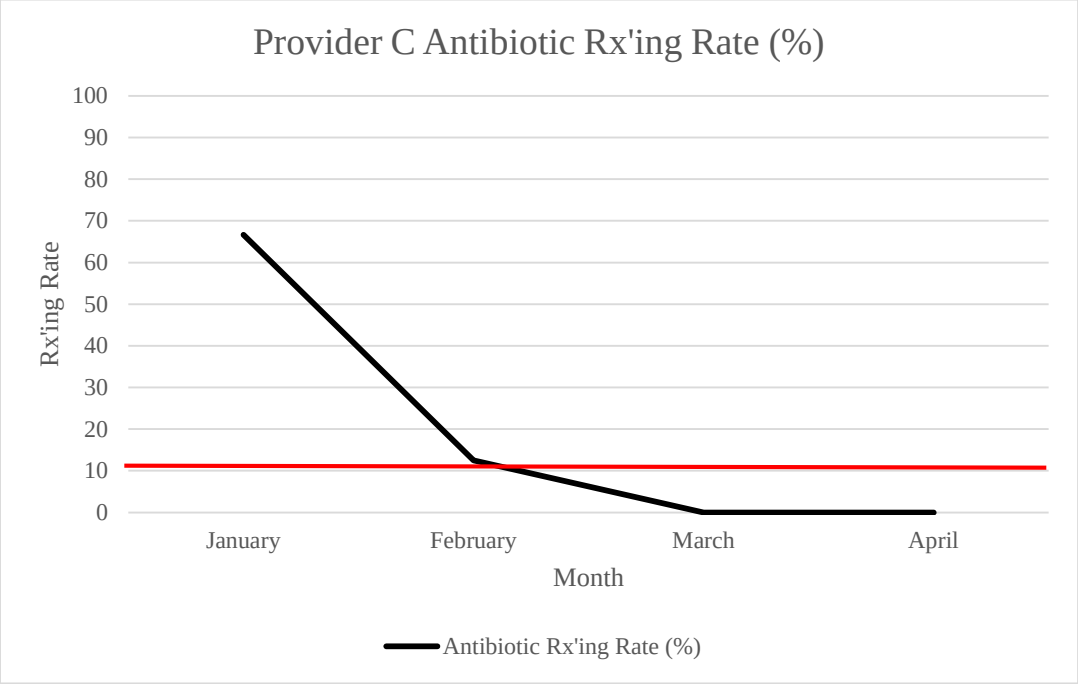


Figure 20. Provider C antibiotic prescribing rate monthly measurement. Rx'ing = prescribing. Flat red line is recommended or target rate and black line is prescriber actual prescription rate.

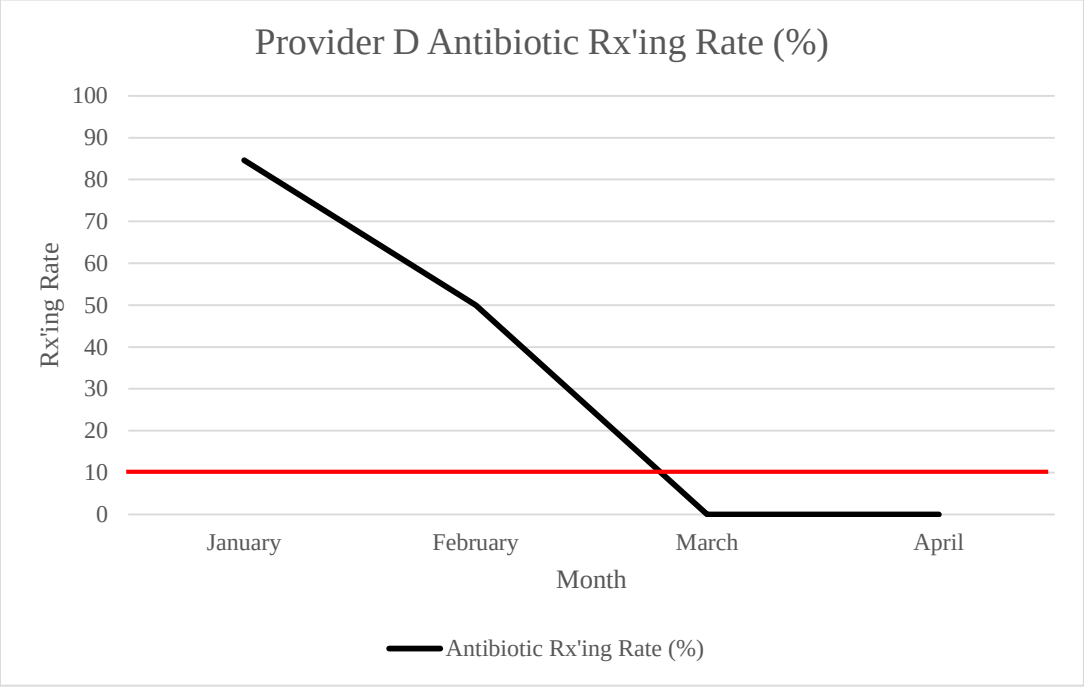


Figure 21. Provider D antibiotic prescribing rate monthly measurement. Rx'ing = prescribing. Flat red line is recommended or target rate and black line is prescriber actual prescription rate.

Activity	Time
Approvals for study (CHS UC Division & ECU)	May – June 2015
Project Committee/Abstract Approval	June 2015
IRB Submission/Waiver	CHS – September 2015 ECU – October 2015
PDSA Implementation	January – April 2016 (Preliminary data collection – December 2015)
Data Analysis	May 2016
Project Presentation	July 2016
Scholarly Paper	June 2015 – July 2016

Figure 22. DNP Scholarly Project Timeline. CHS = Carolinas HealthCare System, UC = Urgent Care, ECU = East Carolina University, IRB = Institutional Review Board, PDSA = Plan-Do-Study-Act cycle.