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The document mentioned above has been reviewed and accepted by the student's advisor, on behalf of the advisory committee, and by the Assistant Dean for MSN and DNP Studies, on behalf of the program; we verify that this is the final, approved version of the student's DNP Project including all changes required by the advisory committee. The undersigned agree to abide by the statements above.

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Dr. Elizabeth Tovar, Advisor

Final DNP Project Report

Adult Acute Sinusitis Antimicrobial Stewardship Program in a Primary Care Setting

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University of Kentucky

August 2017

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Abstract

BACKGROUND: Inappropriate antibiotic prescribing is a well-documented global health crisis (Centers for Disease Control, CDC, 2013). Antimicrobial stewardship (AS) is the purposeful selection of the correct drug, dose, route and duration of antimicrobial treatment to decrease microbial resistance, adverse drug effects and cost while improving patient outcomes (Dellit et al., 2007; CDC, 2016). Antimicrobial Stewardship Programs (ASP) are multidisciplinary programs designed to improve AS.

PURPOSE: To describe baseline prescribing patterns and evaluate the effect of an antimicrobial stewardship program (ASP) for adult acute sinusitis on provider knowledge and antibiotic prescribing practice. among primary care providers in an internal medicine clinic in an academic medical center in Kentucky

METHODS: In this pre/post-test quasi-experimental design study a baseline chart audit was conducted to determine baseline prescribing practices. An evidence based ASP was developed and implemented to assess pre/post provider knowledge as determined by changes survey scores after the education based ASP. Following the ASP, a focus group structured on the Health Belief Model was conducted to elicit perceived barriers to deliver guideline recommended care.

RESULTS: The sample contained 22 patient charts for the baseline chart audit. The chart audits revealed that care was concordant the majority (59.1%) of the time, the lowest scoring component of the chart audit was timing (50%) and was significantly different between concordant and unconcordant care. Eleven providers completed the pretest and participated in the ASP and focus group 9 of the 11 providers completed the post-test 1 week after the ASP. Overall knowledge increased from after the ASP

(M = 52.27, SD =26.11) vs. (M = 55.56, SD = 24.3). Concordant care was delivered in 59.1% of cases. Providers reported a desire for support in appropriate prescribing and in educating patients on appropriate antibiotic use.

CONCLUSION: Care was concordant the majority (59.1%) of the time, and correct antibiotic selection occurred 100%. Key areas for improvement include waiting for long enough symptom duration ... correct symptom duration. The ASP was feasible to implement and was well received by attendees. Future ASP sessions should include a multidisciplinary team, multiple sessions which include active participation, and communication skills. Future studies should identify specific provider, clinical and patient components that influence the effectiveness of outpatient stewardship programs.

Keywords: Antimicrobial Stewardship Program, Sinusitis, Adult, Antibiotics

Adult Acute Sinusitis Antimicrobial Stewardship Program in a Primary Care Setting

Inappropriate antibiotic prescribing is a well-documented global health crisis (Centers for Disease Control, CDC, 2013). The National Action Plan for Combating Antibiotic-Resistant Bacteria calls for reducing inappropriate outpatient antibiotics by 50% by the year 2020 (The White House, 2015). As many as 50% of outpatient antibiotics prescribed are unnecessary and/or inappropriate (CDC, 2016) and acute respiratory conditions result in the most frequent inappropriate antibiotic prescribing (Fleming et al, 2016). Thirty million adults report being diagnosed with a sinus infection annually and although 84% of sinusitis cases are viral, 82.7% of visits resulted in an antibiotic prescription (Blackwell, Lucas & Clarke, 2014; Sharp, Deman, Puumala, Leopold, 2007). Due to gross misuse of antimicrobial agents, the Infectious Disease Society of America (IDSA) along with the CDC advocate for the creation and implementation of antimicrobial stewardship programs (ASPs) to promote prescription of the right drug, dose and duration of antibiotics (CDC, 2013; Dellit et al., 2007; IDSA, 2011). The purpose of this study is to improve antibiotic prescribing and stewardship related to adults with acute sinusitis in the outpatient setting

Background

Antibiotic Use

An estimated 262.5 million antibiotics are prescribed each year (CDC, 2015). Nationwide, five prescriptions are written for every six people (CDC, 2015). Kentucky has the highest antibiotic prescribing rate in the country, with 1281 antibiotics prescribed per 1000 people (Hicks, 2014). Up to 50% of antibiotics prescribed are inappropriate, 33% are unnecessary, and 64% of all antibiotics prescribed are written in the outpatient setting (Fleming et al, 2016; Hicks, 2014). Respiratory tract infections receive the highest number of antibiotics

in the outpatient setting (CDC, 2016). Inappropriate antibiotics are those which are an incorrect drug, dose, route or indication. Unnecessary antibiotics are those prescribed without an indication, such as too early in the natural course of a disease.

Resistance and Stewardship

Inappropriate antimicrobial use is described as prescription of non-optimal antibiotic regimen, dose, duration and route (IDSA, 2011); it can cause iatrogenic harm such as clostridium difficile (Dantes et al, 2015). Inappropriate antimicrobial use also contributes to the evolution of bacterial resistance (Goossens, Ferech, Vander Stichele, & Elseviers, 2005). Antibiotic resistant infections account for 20 billion dollars in health care costs and a loss of 35 billion dollars in productivity each year (CDC, 2013). Superbug infections occur at a crude rate of 2 million people infected annually in the United States, with 23,000 deaths directly due to resistant infections (CDC, 2013). Due to these sequelae, the IDSA and the CDC advocate for the creation and implementation of antimicrobial stewardship programs (ASPs) to promote prescription of the right drug, dose, duration and route of antibiotics (CDC, 2013; Dellit et al., 2007; IDSA, 2011). ASPs are also aligned with The National Action Plan for Combating Antibiotic-Resistant Bacteria, which has the goal for reducing unnecessary antibiotic use by 50% by the year 2020 (The White House, 2015).

Though ASP success within the inpatient setting has been validated by many studies, fewer studies have been conducted in the outpatient and primary care settings (Arnold & Straus, 2005; Ranji, Steinman, Shojania & Gonzales, 2008; Song 2014). Research on inpatient stewardship has taken precedence due to the 2013 CDC Antibiotic/Antimicrobial Resistance Threat Report, which ranks Clostridium Difficile as an urgent resistance threat. Stewardship in the outpatient setting is a currently evolving area of practice.

To support outpatient stewardship, The CDC's Get Smart: Know When Antibiotics Work campaign (2016) identified four core elements of outpatient antimicrobial stewardship program development: (a) *Commitment* to stewardship on a multidisciplinary level; (b) *Action* for policy and practice to support stewardship; (c) *Tracking and reporting* of antibiotic use and drug resistance; (d) *education and expertise* on current guidelines, practice behavior, and drug resistance. These core elements are consistent with previous guideline and Cochrane Review recommendations. The Core elements simplify the 2007 IDSA recommendations for ASP creation and implementation and the 2005 Cochrane review of interventions for ambulatory stewardship through organizing intervention by category, or element. The Get Smart campaign also contains information for patients, providers, measurements, partnerships and references; meaningful uses of this information ranges from vague to explicit (CDC, 2015).

Acute Sinusitis Antimicrobial Stewardship. Acute respiratory tract infections account for the majority of inappropriate antibiotic prescriptions in the outpatient setting (Fleming et al, 2016; Blackwell, Lucas & Clarke, 2014). One in eight adults (30 million or 11.8% of adults) report being diagnosed with a sinus infection every year (Blackwell, Lucas & Clark, 2014). Consistent with other URIs, 84% of sinusitis cases are viral (Autio et al., 2015; Gwaltney, Wiesinger, & Patrie, 2004), however 82.75% of outpatient sinusitis visits resulted in an antibiotic prescription (Fairlie, Shapiro, Hersh & Hicks, 2012; Sharp, Deman, Puumala & Leopold, 2007). Inappropriate antibiotic use for URI treatment, including sinusitis, is linked to antibiotic resistance (Costelloe, Metcalfe, Lovering, Mandt, & Hay, 2010; Goossens, Ferech, Vander Stichele, & Elseviers, 2005). Practicing stewardship for acute sinusitis is an important primary care stewardship focus, since acute sinusitis accounts for the majority of outpatient antibiotic prescriptions (15-21% of adult outpatient antibiotics) (Fairlie, Shapiro, Hersh & Hicks, 2012).

The American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) published a 2015 clinical practice guideline update to improve appropriate antibiotic use for acute sinusitis (Rosenfeld et al., 2015). The guideline update expanded the recommendation from treating acute sinusitis with Amoxicillin to Amoxicillin with or without Clavulanate or watchful waiting. Treatment should be initiated after 10 days of symptoms or the presence of double sickening. Diagnostic symptoms of acute sinusitis are: purulent nasal drainage, with or without nasal obstruction/congestion, and/or facial pain and pressure. The practice change supports provider autonomy and accounts for regional resistance rates. Regional resistance rates to Amoxicillin range to 35% for strep pneumonia, haemophilus influenza, and moraxella catarrhalis, with susceptibility to Amoxicillin-Clavulanate of over 99% (IDSA, 2012). The CDC endorses the Rosenfeld et al.'s 2015 AAO-HNS Clinical Practice Guideline Update as recommended treatment for acute sinusitis (CDC, 2016).

In addition to finding 82.75% of acute sinusitis cases received an antibiotic, Fairlie et al. (2012) analyzed population based surveys, National Ambulatory Medical Care Survey (NAMCS) and National Hospital Ambulatory Medical Care Survey (NHAMCS) data, and reported the nationwide proportion of antibiotics prescribed for adult acute sinusitis as follows: amoxicillin with or without clavulanate (33%; 17% and 16% respectively), macrolide (29%), quinolone (19%) and cephalosporin/other (19%). During the time period of Fairlie et al., 2012 study, the guideline recommended therapy was amoxicillin only, leading researchers to separate amoxicillin (17%) from amoxicillin with clavulanate (16%) and state the most common antibiotics prescribed for adult acute sinusitis were macrolides (29%) (Fairlie et al, 2012; Chow et al, 2012). Combining amoxicillin with or without clavulanate to meet current guidelines (Rosenfeld et al, 2015) indicates the most common antibiotics prescribed for adult acute sinusitis

were amoxicillin with or without clavulanate (33%). For this project, amoxicillin with or without clavulanate were combined to represent 33% of antibiotics prescribed for adult acute sinusitis.

In addition to clinical practice guidelines, there are also quality measures through the Centers for Medicare and Medicaid to provide financial incentive for guideline-adherent care. The 2016 Physicians Quality Reporting System (PQRS, 2016) measure #331 recommends treatment of adults with acute sinusitis with Amoxicillin with or without Clavulanate or watchful waiting. PQRS #332 recommends ideal antibiotic treatment should occur after ten days and before four weeks of symptoms or with the presence of double sickening (worsening of symptoms after initial improvement). PQRS is a merit-based incentive payment system through the Centers for Medicare and Medicaid (CMS) (CMS, 2015). Treatment information for measures #331 and #332 is based on Rosenfeld et al.'s (2015) AAO-HNS evidence 2015 Clinical Practice Update: Adult Sinusitis. Because of the potential influence on reimbursement and recommendations consistent with the CDC's practice guidelines, the PQRS measures #331 and #332 served as the quality measures to help develop the education based ASP and evaluate whether practice was consistent with guideline recommended care.

Purpose

The purpose of this study was to describe baseline prescribing patterns and evaluate the effect of an antimicrobial stewardship program (ASP) for adult acute sinusitis on provider knowledge and perceived practice. The objective was to evaluate the effect of the education based ASP by comparing pre/post provider knowledge and practice. This purpose is consistent with The National Action Plan for Combating Antibiotic-Resistant Bacteria (The White House, 2015), the IDSA (2011), and the CDC (2017).

Specific aims:

- Assess baseline antibiotic prescribing patterns for acute sinusitis in adult patients.
- Develop and implement an evidence based ASP based on PQRS measures #331 and #332 for primary care providers
- Evaluate effects of ASP implementation on provider knowledge related to antibiotic prescribing standards for acute sinusitis in adults.

Methods

Design

This study was a pre-test/posttest quasi-experimental design with a descriptive retrospective chart audit and focus group. The study contained three phases:

1. Phase 1: Baseline Assessment
 - Provider Knowledge: Survey on PQRS measures #331 and #332
 - Prescribing Patterns: Retrospective chart audit on diagnosis and treatment of sinusitis per PQRS measures #331 and #332
2. Phase 2: Educational Intervention
 - ASP: created by the PI, based on the CDC recommendations and PQRS measures #331 and #332
 - Focus group following ASP
3. Phase 3: Post Assessment
 - Provider Knowledge: Survey
 - Prescribing Patterns: Chart Audit

All aspects of this study were approved by the Institutional Review Board (IRB), Nursing Research Council & Internal Medicine Research Council prior to implementation. This ASP was

evidence based, but only able to use two of the CDC's four elements to outpatient antimicrobial stewardship: tracking and reporting, and education and expertise (CDC, 2016).

Setting and Sample

This was a single center study, conducted at an internal medicine clinic in an academic medical center in Kentucky. Two sample groups consisted of 1) providers and 2) patients (indirectly through their medical records).

Providers. The provider population included voluntary non-resident primary care providers (physicians, advance practice registered nurses, and physician's assistants) at the internal medicine clinic. Provider demographics were not collected to maintain anonymity with a small sample size. Providers who participated in the focus group completed informed consent forms. Those providers who completed the knowledge surveys were given survey cover letters with a waiver of informed consent (Appendices A, B, C and D). All consent forms contained the following information: purpose, risks, benefits, procedures, voluntary participation, anonymity, counseling, and PI contact information.

Patients. Assessment of the patient population included a retrospective chart audit of 22 randomly sampled adult patients (>18 years) with ICD 9 or 10 codes (Table 3) for acute sinusitis who were treated between March 15-June 15, 2016 at the internal medicine clinic. A random selection of charts was performed by the UK Center for Clinical and Translational Science (CCTS) Enterprise Data Trust (EDT). CCTS is a recognized as a third party honest broker and data proprietor. Demographic information included: gender, age, race, and insurance type. A waiver of informed consent was submitted for the retrospective chart audit since information used was previously collected for non-research purposes.

CCTS provided a list of 499 encounters with medical record numbers mined using a query with the inclusion criteria of: adult patients (>18 years) treated between March 15-June 15, 2016 at the internal medicine clinic with ICD 10 codes for sinusitis (J01.00, J01.10, J01.20, J01.30, J01.40, J01.80, J01.90). The majority of patient encounters were excluded for the following reasons: (a) pediatric patient; (b) other outpatient clinic within the academic medical center's healthcare system; (c) duplicated medical record number; and (d) no diagnosis of acute sinusitis.

Procedures

Phase 1.

Baseline retrospective chart audit. The baseline assessment chart audit was conducted on a sample of 22 randomly selected adult (≥ 18 years) patients seeking treatment at the internal medicine clinic with acceptable acute sinusitis ICD codes (J01.00, J01.10, J01.20, J01.30, J01.40, J01.80, J01.90) between March 15-June 15, 2016. Power analysis determined a necessary sample size of 103 randomly selected adult patients to achieve a power of 80% with an alpha of .05; however, data received from CCTS had insufficient patient numbers meeting the inclusion criteria and only a total of 22 patients were eligible for review.

Patient variables assessed included: patient age, gender, race, and insurance type. Clinical variables assessed were pertinent to the diagnosis and treatment of adult acute sinusitis, and included: diagnosis of sinusitis, allergies, *symptoms* (including presence of double sickening), *timing* of diagnosis, and *treatment* (including antibiotic prescription, indications for an alternative to first-line antibiotic treatment, and dose of antibiotic). Key measures on the chart audit tool examined if care was concordant or unconcordant to PQRS measures #331 and #332, Concordant care was defined as correct documentation of: *symptoms* (purulent nasal drainage

with or without facial pain and nasal obstruction), for the correct duration of *time* (10 days to 4 weeks OR double sickening) and *treatment* (selection of amoxicillin with or without clavulanate, watchful waiting, or alternative treatment if indicated, and dose of antibiotic). Unconcordant care was defined as antibiotic prescription without documentation of concordant symptoms, timing, indication for alternative antibiotic to first-line treatment, or duration of dose.

Information was collected on a chart audit tool (Appendix E) and transcribed into excel and SPSS. Information collected on the chart audit tool also included data related to PQRS quality measures: PQRS #331 (when to prescribe an antibiotic for acute sinusitis) and #332 (what antibiotic to select). The baseline chart audit represents the tracking and reporting element of stewardship.

Pre-test provider knowledge survey. The pre-test provider knowledge survey (Appendix F) occurred during the first five minutes of the ASP and focus group session. Prior to the education session, participants were asked to complete the pre-test survey. All surveys were voluntary, de-identified, and provided to non-resident primary care providers. The pre-and post-provider knowledge surveys (Appendix F, G) were created by the PI and based on the quality measures PQRS #331 and #332. The survey consisted of 6 items and contained a combination of multiple choice and free text. Questions one and two asked if providers had prior awareness of PQRS measures #331 and #332 respectively; questions three through six were pertinent to the PQRS measure content for symptoms and treatment. Each of the four pertinent PQRS questions was weighted to account for 25% of the score, with a total of 100%. Pre-and post-provider knowledge surveys were identical. A total sample of 11 providers completed the pre-test and were present for the ASP. The anonymous surveys were completed by hand and collected in

person. No identifying information or demographics were collected on providers. Survey responses were transcribed into excel and SPSS.

Phase 2.

Antimicrobial stewardship program and focus group. A total sample of 11 providers participated in the ASP and focus group. The education based ASP was an evidence based power point presentation developed by the PI using evidence review, including CDC fact sheet and reviewed by her clinical mentor. Presented by the PI, the ASP covered: purpose, aims, and background of antibiotic stewardship, along with the PQRS sinusitis measure group. The focus group was structured on the Health Belief Model and facilitated discussion on perceived susceptibility, severity, benefits and barriers to guideline recommended management of adult acute sinusitis. The ASP with focus group lasted 30 minutes. The ASP represents the education element of stewardship.

Phase 3.

Post-test provider knowledge surveys. Post-test provider knowledge surveys were delivered one week after delivery of the ASP. Surveys were distributed to all non-resident providers electronically via e-mail from the clinic manager. The e-mail contained links to the REDCap survey with survey cover letter informing participants consent was indicated by voluntary completion of the surveys. All surveys were voluntary, de-identified and provided to non-resident primary care providers. Data was organized in excel spread sheets.

Post-test chart audit. The post-test chart audit was not feasible to complete due to time restrictions. The goal for the post-test chart audit was a time-matched sample with the sample patient inclusion criteria, to be performed after the ASP. The same chart audit tool and variables were to be collected.

Data analysis

Descriptive statistics, including frequency distributions, means (M), and standard deviation (SD) were used to describe patients' demographic characteristics. Continuous variables were compared using the Independent Sample t -tests. For categorical variables, the chi-squared test for independent samples was used, or Fishers exact test if values were less than 5 in any cell. All analyses were conducted using SPSS version 22; an [α] level of .05 was used for statistical significance throughout.

Results

Participants

Providers. Clinic demographics include: 21 physicians, 6 advanced practice registered nurses, and 1 physician's assistant. Resident providers were not included to maximize homogeneity over time. A convenience sample of 11 eligible providers were present and consented to participation in the ASP. An additional 17 providers did not attend the luncheon and could not be included. A total of 11 providers completed the pre-survey and 9 of these 11 completed the post-survey. No demographics were measured in order to protect anonymity in this small sample. All of respondents of the post-test survey reported they completed the pre-test and ASP, as indicated by a yes/no question and the of the post-test survey.

Patients. The total sample size of the group of patients identified for the chart audit consisted of 22 patients. Patient demographics are displayed in Table 1. The sample included: 4 males and 18 females, ages ranging from 19 to 74 ($M = 49.14$, $SD = 15.72$); 18 white, 4 non-white, and 14 participants had private insurance, 2 had Medicare, and 6 had Medicaid. There were no significant differences in gender, age, race or insurance and the delivery of guideline concordant care or unconcordant care defined as documentation of: correct symptoms (purulent

nasal drainage with or without facial pain and nasal obstruction), for the correct duration of time (10 days to 4 weeks OR double sickening) and antibiotic selection (amoxicillin with or without clavulanate, watchful waiting, or alternative treatment if indicated).

Phase 1

Baseline assessment. Medical records from the sample of 22 patients at the internal medicine clinic with acute sinusitis ICD codes (J01.00, J01.10, J01.20, J01.30, J01.40, J01.80, J01.90) were analyzed based on demographics, symptoms, duration of symptoms, antibiotic selection, and dose (described in Figure 1). Evaluation of group differences in demographic variables between patients receiving concord and unconcordant care was conducted and no significant differences were found (Table 1).

Care Components. Care components assessed in the chart audits included documentation of: *Symptoms*, *timing*, and *treatment* (antibiotic and dose). Concordant treatment consists of appropriate symptoms, timing, antibiotic selection and dose duration. See figure 1.

Care concordant with the PQRS measures was delivered 59.09% of the time ($n=13$). This includes 8 patients who received concordant antibiotics, and 5 who appropriately did not receive antibiotics. Concordant symptoms were documented in 72.7% ($n=16$) of patients; concordant timing of symptoms was documented in 50% ($n=11$) of patients, and concordant antibiotic prescription was documented in 47.1% ($n=8$) of cases. Figure 1 shows the distribution of patients among care components.

Table 2 further presents distribution of adherence to individual care components between concordant and unconcordant care. Timing significantly differed between concordant and unconcordant care (90.1% vs. 9.1%, $P=.009^*$).

Antibiotic use. Antibiotics were prescribed in 77.3% of cases ($n=17$), of those 17 cases, 41% ($n=8$) were Amoxicillin with or without clavulanate, 29.4% ($n=5$) were macrolides, 17.6% ($n=3$) were levofloxacin, and 11.8% ($n=2$) were doxycycline. Antibiotics were prescribed concordantly with PQRS measures 47.1% ($n=8$) of the time, 52.9% ($n=9$) were not. Of the non-concordant antibiotics prescribed, 88.9% ($n=8$) were unnecessary, and 11.1% ($n=1$) were for a dose longer than recommended.

Frequency of antibiotic selection was similar between concordant and unconcordant care (Table 2). There were no significant differences between groups receiving concordant vs. unconcordant care across the following variables: receiving an antibiotic prescription (23.1% vs. 22.2%, $P=.855$), receiving Amoxicillin with or without clavulanate (38.5% vs. 22.2%, $P=.735$), receiving a macrolide (15.4% vs. 33.3%, $P=.683$), receiving levofloxacin (15.4% vs. 11.1%, $P>.999$), and receiving doxycycline (7.7% vs. 11.1%, $P>.999$). Though not statistically significant, it is important to note amoxicillin with or without clavulanate was prescribed at a higher rate in the concordant group (38.5% vs. 22.2%, $P=.735$), while macrolides were prescribed at a higher rate in the unconcordant group (15.4% vs. 33.3%, $P=.683$).

First line antibiotics (amoxicillin with or without clavulanate) were prescribed 41% ($n=8$) of the time, though only 71.4% ($n=5$) of these were included in concordant care. The remaining 28.6% ($n=3$) were prescribed to patients who did not have concordant symptoms documented for the recommended duration; and thus were deemed unnecessary based on PQRS criteria? . Of all non-first line recommended antibiotics, 100% ($n=12$) had a documented indication for an alternative antibiotic treatment. The PQRS measures do not provide a recommended second line treatment, but require documentation of an indication for an alternative. Given the parameter of

first line treatment or documentation of an indication for an alternative with no second-line treatment suggestions, 100% (n=17) of the antibiotics were selected appropriately.

Pre-test provider knowledge survey. A total of 11 providers participated in the pre-test provider knowledge survey. The overall mean score for the provider knowledge survey was 52.27% ($SD = 26.11$) out of 100%. A score of roughly 50% indicates that on average providers correctly answered two out of four questions on the survey. Within the pre-test provider knowledge survey, 27.3% (n=3) providers were aware of PQRS measures #331 and #332. The frequency of identification of correct answers is as follows: diagnostic symptoms, 63.6% (n=7); duration of symptoms, 45.5% (n=5); first line antibiotic, 27.3% (n=3), and indication for alternative antibiotic, 72.7% (n=8) (see Table 3).

Phase 2

Phase two consisted of the educational ASP and focus group. A total of 11 providers participated in the ASP and focus group. The ASP was a power point presentation which covered: purpose, aims, background antibiotic stewardship, and PQRS sinusitis measure group. Following the ASP, the focus group was structured on the Health Belief Model and designed to allow for discussion on perceived susceptibility, severity, benefits and barriers to guideline recommended management of adult acute sinusitis. The ASP with focus group lasted 30 minutes.

During the focus group, providers reported barriers to practice included: lack of time, pressure from patients, and lack of understanding from patients. Providers also reported that support in appropriate antibiotic timing, and support in educating patients on symptom management would help overcome the barriers to appropriate prescribing. Providers also gave

positive feedback about the program as evidenced by parting statements of appreciation and stating they were glad this specific need had been recognized.

Phase 3

Post-Test Provider knowledge surveys. A total of nine providers completed the post-test provider knowledge survey. All post-test responders indicated they completed the pre-test, per a yes/no question at the end of survey. The overall mean score for the post-test was 55.56% ($SD = 24.30$). An overall score of 55.56% still indicates roughly answering two out of four questions correctly. Within the post-test provider knowledge survey, 66.7% ($n=6$) providers were aware of PQRS measures #331 and #332. The frequency of identification of correct answers is as follows: diagnostic symptoms, 33.3% ($n=3$); first line antibiotic, 33.3% ($n=3$), duration of symptoms, 55.5% ($n=5$); and indication for alternative, 100% ($n=9$). An independent-sample t-test was conducted to compare the overall provider survey score for pre-and post-tests. The post-test mean is higher than the pre-test, indicating gained knowledge from the ASP. However, there was no significant difference in scores between the pre-test ($M = 52.27, SD = 26.11$) and post-test ($M = 55.56, SD = 24.30; t(18) = -.288, p = .776$, two-tailed). There were no significant differences between frequency of correct answers on individual questions between pre-and post-surveys. Scores increased for all questions except the question on sinusitis symptoms (63.6% vs. 33.3%) (Table 4).

Practice vs. knowledge.

Frequencies of concordant care found in the chart audit and corresponding survey questions were compared to examine provider practice alongside provider knowledge. No statistical comparison could be made between documentation practices (as determined by the chart audit) and knowledge (as determined by provider surveys) because the surveys were

anonymous and no tracking occurred (Table 5). Per the chart audit, providers performed better on symptom documentation than on the pre-and post-provider knowledge survey (77.3% vs. 63.6% vs. 33.3%) and alternative indication documentation (100% vs. 72.7% vs. 100%). Concordant documentation and correct answers on timing and first line antibiotic selection as similar between all three measures.

Post-Test chart audit. No data for the post-test chart audit and comparison was collected due to time restriction. Data to be collected was identical to the baseline chart audit. Collecting the same data would have allowed for comparison of prescribing behavior before and after ASP to assess for changes.

Discussion

Findings from this descriptive study indicate that the majority of sinusitis cases treated by providers in this internal medicine clinic were consistent per PQRS measures #331 and #332 [59.1% ($n=13$)]. However, among patients who received antibiotics, 47.1% of all antibiotics prescribed were unnecessary and for 52.9% of the patients who received an antibiotic, the choice of antibiotic prescribed was inappropriate. Among these inappropriate choices, 88.9% of were deemed unnecessary because of an inadequate duration of symptoms at the time of prescription. Secondly, the ASP was well received and in general mean knowledge scores increased from pre- to post-test. The major findings of this study are consistent with previous research that identified timing as key component related to inappropriate antimicrobial prescribing (Pynnonen et al, 2015) and similar rates and frequencies compared to national averages for adult acute sinusitis (Fairlie et al, 2012), and that communication and education support are important provider perceived barriers than need to be addressed perceived provider barriers (Dempsey et al., 2014). Further discussion of findings are presented in the following sections.

Antibiotic Timing

In this study prescribing an antibiotic too early was the most likely reason for antibiotic prescriptions to be unconcordant. Antibiotic timing was statistically significantly different between concordant and unconcordant care (90.9% vs. 9.1%, $P = .009$). This is also consistent with Pynnonen who found antibiotics were frequently prescribed too early in the disease course (Pynnonen et al., 2015). Antibiotics prescribed outside of the time frame are considered unnecessary because the patient does not meet the diagnostic criteria for acute sinusitis; these findings are consistent with national trends of over prescribing antibiotics for acute sinusitis because they are unnecessary (Fairlie et al, 2012; Rosenfeld et al., 2015).

Patients seeking an antibiotic too early is also consistent with barriers to guideline recommended care as reported by providers in this study. This study and other qualitative studies (Dempsey, 2014) report patient expectations for receiving an antibiotic prescription and lack of knowledge related to when antibiotics should be prescribed as barriers to delivering guideline recommended care. Educating patients on the importance of correct timing for treatment is a clear education opportunity for primary care providers and healthcare workers. Successful education would help empower patients to manage symptoms, make environmental modifications, decrease health care visits, and decrease unnecessary antibiotics.

Antibiotic Selection

In addition to timing, class of antibiotics prescribed was assessed. Antibiotic prescribing trends are presented in figure 2 and are compared to national practice rates. No statistical comparison could be made between the National Trend and internal medicine clinic because sample sizes were not provided by researchers Fairlie et al., 2012 in their analysis of the NAMCS and NHAMCS data between 2000 and 2009. Overall, in this small sample the internal

medicine clinic appears to have lower rates of overall antibiotic prescribing (77.3% vs. 83%), indicating less unnecessary antibiotics; and higher rates of selecting the first line antibiotic Amoxicillin with or without Clavulanate (41% vs. 33%). The trend of less unnecessary antibiotics and more appropriate first line antibiotics could be due to provider preference, inclusion of resident providers within the chart audit, cost, and time. A recent study on sinusitis prescribing patterns found resident and student providers have better antibiotic prescribing rates than experienced providers (Pynnonen et al., 2015), it is possible that integration of resident with attending providers in this clinic lead to fewer unnecessary and more appropriate antibiotics than the national trend, which may be unique characteristics with academic medical centers.

As previously described in the results, antibiotics were prescribed concordantly with PQRS measures 47.1% ($n=8$) of the time. Of the 52.9% ($n=9$) of antibiotics not prescribed concordantly with the PQRS measures, 88.9% ($n=8$) were prescribed before 10 days of symptoms without the presence of double sickening, indicating they were unnecessary. The remaining 11.1% ($n=1$) of inappropriate antibiotic prescriptions was prescribed for 21 days, greater than the recommended 5-10 days. First line antibiotics were selected 41% ($n=7$) of the time. All cases with a non-first line treatment, including macrolides, had a documented indication for an alternative treatment. This indicates 100% ($n=17$) of antibiotics were selected appropriately per the PQRS quality measures.

Although the PQRS measures #331 and #332 do not provide a recommendation for second line treatment (PQRS, 2016), the CDC recommends second line treatment as Doxycycline or Levaquin, and to avoid macrolides (CDC, 2016). In this sample, macrolides were prescribed in 29.4% ($n = 5$) of cases. If the PQRS adapts the CDC's recommendation to avoid macrolides, then the rate of inappropriate antibiotics would increase from 11.1% ($n=1$) to

35.3% ($n=6$). Of the inappropriate antibiotics, 83.3% ($n=5$) would be due to the selection of a macrolide as second-line treatment. Understanding discrepancies between guideline recommended care and quality measure care will be helpful in anticipating future changes to quality measures, as well as provide a deeper understanding of prescribing patterns. This reflects an evolution of science and the translation of knowledge into practice since the PQRS measure were published prior to the CDC recommendations. The CDC's recommendations represent the latest evidence. Though understanding current quality measures used by institutions is important for standard practice, providers should also be aware of current evidence based practice to ensure best practice

Lack of clear national benchmarks for antibiotic prescribing may be a factor in prescribing practices because it makes progress difficult to measure. The White House National Action Plan (2015) reported a goal of decreasing unnecessary antibiotics by 50% by the year 2020. The CDC reports over 30% of antibiotics are unnecessary (CDC,2016). While decreasing unnecessary antibiotics by 50% by the year 2020 appears clear, to accurately measure a decrease in unnecessary antibiotics, specific information on rates of unnecessary antibiotics are needed. Understanding unnecessary antibiotic use requires more detailed reporting of antibiotic use and clinical variables related to drug use.

In this study, macrolides were prescribed at similar rates between this sample size and the national trend (Fairlie et al, 2012). In addition to being costly (Cramer et al, 2016) macrolides have a lower efficacy rates for treating sinusitis (Anon et al., 2004) and higher rates of resistance (IDSA, 2012). However, providers may be more likely to choose azithromycin because of a shorter dose duration (5 vs 10 days), dosing (daily vs BID) and less frequent gastrointestinal side

effects compared to Augmentin (RxList, n.d.). Education to providers and patients should include emphasis on the cost, lack of efficacy, and resistance related to macrolide use.

ASP and focus group.

The ASP was created based on PQRS measures #331 and #332 and CDC's (2016) recommendations for diagnosis and treatment of acute sinusitis and presents the education element of the CDC's core elements of outpatient stewardship (CDC, 2016). A total of 11 providers participated in the ASP and focus group and it was well received. Though the sample was too small to definitively assess a statistical difference between the pre-and post-surveys, the increase in mean scores suggests the ASP was effective in increasing knowledge

During the focus group, providers reported lack of time, pressure from patients, and lack of understanding from patients as barriers to prescribing antibiotics per the PQRS recommendations. Providers also reported interest in support for appropriate antibiotic timing and patient education. Barriers expressed by providers in this study are similar to barriers found in a recent qualitative survey of primary care providers by Dempsey and colleagues (2014) who identified the following perceived barriers to appropriate antibiotic prescribing as: (a) patient demand; (b) lack of accountability; (c) time and money saving; (d) treatment misconceptions; (e) diagnostic uncertainty; and (f) fear of patient dissatisfaction.

Future education based ASPs could benefit from multidisciplinary collaboration (Arnold et al, 2004), serial sessions, and inclusion of web-based modules or other active education techniques (Ranji Steinman, Shjojanian & Gonzales, 2008), communication training (Drekonja, Filice, Greer & Olson 2015; van der Velden et al, 2012) and electronic clinical decision support (McDonagh et al, 2016). These techniques are all endorsed by the CDC's Get Smart, Know When Antibiotic's Work Campaign (CDC, 2016). In this focus group providers agreed that their

biggest barrier was communication with patients regarding when antibiotics are appropriate. An effective strategy to address this would be communication training, which involves patient education on appropriate antibiotic use. This strategy would address reported perceived barriers to guideline recommended care, and has been shown to decrease overall antibiotic prescribing rates (Drekonja et al., 2015).

Though the key systematic reviews cited by the CDC have mixed conclusions on the effect of various stewardship program components and approaches, each review which examined communication skills training for patient interactions found significant reduction in overall number of antibiotics prescribed (CDC, 2017) Further research on identifying influential provider and patient factors is needed. Possible provider factors include years of experience, area of specialty, and location of practice. Patient factors may be level of education, access to follow up care, age, and possible comorbidities. Influential factors and specific ways to combat these factors are needed to effectively overcome barriers to providing guideline recommended care This need has been identified by similar studies (Pynnonen et al., 2015) and was confirmed by the focus group in this study.

The focus group was held immediately after the ASP which was held during a scheduled lunch hour. The scheduled time may have limited participation and attention of providers due to the session occurring during a lunch period in the middle of a clinic day. Providers could have been distracted by clinical issues and eating in a timely fashion. Separating the focus group and ASP may have allowed for increased participation by allowing time to process ASP content without usurping a lunch hour.

Pre-test/posttest.

A total of 11 providers participated in the pre-test survey; and nine in the post-test survey. All nine of the respondents from the post-test completed the pre-test. Overall trend of mean provider scores improved from pre-test ($M = 52.27, SD = 26.11$) to post test ($M = 55.56, SD = 24.30; t(18) = -.288, p = .776$, two-tailed), though not significantly. This is consistent with a Cochrane review conducted by Arnold et al (2004) which reported only minor and observational changes occurred after a single intervention; at this point in the ASP, providers had only received the education component of the ASP, and no baseline chart audit with feedback had been conducted. Scores increased for all questions pre-test to post-test except the question asking about key symptoms (Table 5). Providers were able to identify fewer symptoms on the post-test. Possible explanations include: the ASP and or question were not clear or valid measures of knowledge, provider apathy, lack of clinical content for the survey question, and continued influence effect from prior knowledge. Further inquiry via focus group is warranted to further explore possible explanations.

Practice vs. knowledge.

Provider practice in general appeared to be similar or better than perceived provider knowledge (Table 5). There are several possible reasons for this, though understanding them definitively is not within the scope of this project. The clinical context of practice may act as a cue to action for providers, allowing them to recognize clusters of symptoms more effectively than to generate a list of symptoms on demand. The chart audit contained a random selection of all providers, which could have captured a more accurate representation of the provider knowledge base. Documentation is a representation of knowledge, and so may be a more valid form of understanding provider knowledge than a survey.

Limitations

A key limitation to this study was the small sample size for the baseline chart audit and the provider knowledge surveys. The samples were too small to determine meaningful statistical significance. The goal sample size was 120, however because of the sampling issues previously discussed, the total sample for this study was only 22. It is possible the data was difficult to mine with the given inclusion criteria, creating what appeared to be a large sample size. Including all ICD-10 codes may have been too broad. Future studies should work with CCTS to better define criteria for an improved sample. Narrowing down to the most frequently used codes for acute sinusitis may have ensured patients selected would have the appropriate diagnosis. Because many patients excluded were pediatric and ineligible, raising the age for inclusion to 19 would ensure patients were 18 through the entire year of sampling, decreasing possible pediatric patients.

Timing of the ASP and chart audit are an additional limitation. Initially, the ASP and baseline chart audit were designed to occur during the late fall. Due to external circumstances, the time frame was adjusted to the late spring with the hopes of completing a time-matched post-ASP chart audit. The post-ASP was not able to be completed, which unfortunately resulted in a short time period for the baseline chart audit. In future studies, a broader period will be requested in IRB applications to cover both fall and spring for inclusion of the influenza season and to have a large pool of sinusitis cases from which to randomly select.

Research on outpatient stewardship has been ongoing during the development of this project. Key resources published by the CDC's Get Smart Campaign (CDC, 2016) were not all available at the time of the project development, and should be included in future ASPs. Continued research to standardize and validate education based ASPs and provider knowledge

surveys is needed, along with more detailed tool kits to develop and implement stewardship programs. Standard and validated ASPs and provider knowledge surveys would allow for larger scale tracking of clinical, provider and population based data when combined with NAMCS and NHAMCS

Practice Improvement Recommendations

General recommendations for outpatient stewardship improvement are for all outpatient clinics to embrace the CDC's four elements of outpatient stewardship of commitment, action, tracking and reporting, and education and expertise (CDC, 2017). Providers and practices should:

- *Commit* to improving antimicrobial stewardship to decrease antimicrobial resistance, adverse drug effects, and to improve patient outcomes.
- *Act* to support antimicrobial stewardship practice policies on administrative, research, and practice levels.
- *Track and report* antibiotic use and resistance rates to understand personal, clinic, and health care system prescribing and resistance patterns.
- *Educate* and seek expertise on current practice guidelines, policy, and stewardship practices.

Specific recommendations for improving antibiotic stewardship for sinusitis in the internal medicine clinic evaluated in this project are for providers to *commit* to PQRS measure #331 and #332 along with the CDC's second line treatment recommendations for the diagnosis and treatment of acute sinusitis as a standard of practice (PQRS, 2016; CDC, 2017).

Commitment should occur through engaged partnership through the CDC's Get Smart Campaign (CDC, 2016) active audits of provider prescribing, use of posters, and public health

lectures for patients on acute sinusitis. Audits should be published to all providers in the clinic to increase peer accountability (Meeker et al, 2016). Providers should *act* by clearly documenting indications for selecting second line antimicrobial therapy. Administration should endorse a no-macrolide policy for the treatment of acute sinusitis unless all alternative treatments are contraindicated (CDC, 2016). The clinic should *track and report* antibiotic frequencies and allow for peer to peer comparison of rates (CDC, 2017). Finally, the clinic should collaborate with pharmacy and infectious disease to develop multidisciplinary active *education* for providers and patients on treatment guidelines and symptom management. Patient education should include posters and printed material. Provider education should be free of charge and web based to be taken at provider's convenience (CDC, 2017)

Further Investigation

Project continuation. Further work should begin with establishing a more representative baseline chart audit, and modifying the ASP to address limitation as previously discussed. Creating a new baseline chart audit should obtain the desired sample of 103 randomly selected patients in this clinic. The chart audit should occur over the course of an entire calendar year. A time-matched post ASP chart audit should be performed to assess for any impact of the ASP as evidenced by changes in provider prescribing behavior. Once the ASP is deemed effective in this site, it should be expanded to all primary care clinics in this healthcare system.

The ASP should be developed with a multidisciplinary team and include the CDC's Get Smart About Antibiotic's printed materials. Partnership with the CDC provides clinics and clinicians with additional resources for stewardship. Education should be provided to patients and providers. Provider education should be multiple sessions, active, and should remain free of

charge. Emphasis on the provider education should be on ways to communicate with patients who expect an antibiotic, the importance of appropriate diagnostic criteria, first and second-line treatment, and timing for treatment. Collaboration with administration and information technology to investigate the possibility of an electronic medical record decision support tools such as hard stop for non-first line antibiotic selection justification should be discussed. Patient education should be provided during acute sinusitis visits and should be documented in the plan.

Outpatient stewardship. Future studies on outpatient stewardship should continue examine the effectiveness of different techniques to modify provider prescribing behavior. Education, peer accountability, electronic decision support tools and accountable justification techniques have all been shown to decrease overall and unnecessary antibiotic prescribing, though to varying degrees (CDC, 2016). Increased understanding of the effectiveness of different interventions would help to improve stewardship (CDC, 2017). Knowledge on intervention effectiveness should be included in a more specific outpatient stewardship tool kit, which clinics and providers could implement for multiple disease processes. Additional research is needed on identifying the most meaningful data to track for prescribing behavior and resistance. Finally, research is needed on effective ways to modify patient expectations for treatment (CDC, 2017; Dellit et al, 2007). Providers identified patient expectations and pressure for antibiotics as a key barrier to the delivery of guideline recommended care. Furthermore, research has shown that patient education sessions are also effective techniques at reducing overall antibiotic prescribing rates (McDonagh, et al, 2016). An effective patient education arm to the ASP would be helpful for this clinic.

Conclusion

Antimicrobial stewardship is a multidisciplinary practice to improve antimicrobial prescribing to improve patient outcomes, decrease adverse drug effects, and decrease costs through adherence to clinical practice guidelines to promote appropriate treatment while decreasing microbial resistance (CDC, 2016; Dellit et al, 2007). *Antimicrobial stewardship programs* are multi-disciplinary programs designed to improve judicious use of antibiotics This study was an education based antimicrobial stewardship program designed to assess current provider prescribing behavior and knowledge and provide education on PQRS measures #331 and #332 to promote guideline adherent care. While the sample sizes were too small to definitively state any meaningful statistical significance, the chart audit suggests the majority of sinusitis cases are treated per PQRS guidelines [59.1% ($n=13$)]. However, the majority of antibiotics were not prescribed concordantly [52.9% ($n=9$)]. The lowest scoring components of treatment include timing and antibiotic selection [50% ($n=11$)]. When care was non-adherent, the most likely factor was time, $p=.009^*$

The provider knowledge survey results suggest knowledge increased after the ASP; pre ($M = 52.27$, $SD = 26.11$); post ($M = 55.56$, $SD = 24.30$; $t(18) = -.288$, $p = .776$, two-tailed). The decrease score on the symptom questions suggests the ASP needs clarity on symptomology. Finally, when comparing the provider knowledge surveys to the chart audit, it appears that provider knowledge and practices are overall similar.

Further investigation is needed on the most effective strategies to improve outpatient stewardship practices for providers and patients. Evidence based strategies for further investigation have been provided in the discussion. Increased knowledge on effective outpatient stewardship may help improve results of similarly designed studies, and overall improve patient

outcomes through increased antibiotic stewardship for acute sinusitis and additional outpatient diagnoses.

References

- Autio, T.J., Tapiaine, T., Koskenkorva, T., Narkio, M., Lappalainen, M., Nikkari, S., Hemmila, H., Koskela, K.A., Koivenun, Pl., Alho, O.P. (2015). The role of microbes in the pathogenesis of acute rhinosinusitis in young adults. *The Laryngoscope* 125(1). doi: 10.1002/lary.24862.
- Blackwell, D.L., Lucas, J.W., Clarke, T.C. (2014). *Summary health statistics for U.S. adults: National health interview survey, 2012*. Retrieved from http://www.cdc.gov/nchs/data/series/sr_10/sr10_260.pdf
- Centers for Disease Dynamics, Economics & Policy (2010). Outpatient Antibiotic Use. Retrieved from http://www.cddep.org/projects/resistance_map/outpatient_antibiotic_use
- Centers for Disease Control and Prevention (n.d). *Antibiotics aren't always the answer*. Retrieved from <http://www.cdc.gov/getsmart/community/materials-references/print-materials/adults/b-general-color.pdf>
- Centers for Disease Control and Prevention (2013). *Antibiotic/Antimicrobial Resistance Threat Report 2013*. Retrieved from <http://www.cdc.gov/drugresistance/threat-report-2013/>
- Centers for Disease Control and Prevention (2016). *CDC News Room, CDC: 1:3 Antibiotic Prescriptions Unnecessary*. Retrieved from <http://www.cdc.gov/media/releases/2016/p0503-unnecessary-prescriptions.html>
- Centers for Disease Control and Prevention (2017). *Get Smart for Healthcare in Hospitals and Long-Term Care: Core Elements of Hospital Antibiotic Stewardship Program*. Retrieved from <https://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html>
- Centers for Disease Control and Prevention (2015). *Get Smart: Know When Antibiotics Work*.

Retrieved from <http://www.cdc.gov/getsmart/community/programs-measurement/measuring-antibiotic-prescribing.html>

Centers for Disease Control and Prevention (2015). *Get Smart: Know When Antibiotics Work in Doctor's Offices, For Patients*. Retrieved from <https://www.cdc.gov/getsmart/community/for-patients/common-illnesses/sinus-infection.html>

Centers for Disease Control and Prevention (2016). *Get Smart: Know when Antibiotics Work in Doctor's Offices*. Retrieved from <https://www.cdc.gov/getsmart/community/for-hcp/outpatient-hcp/adult-treatment-rec.html>

Centers for Disease Control and Prevention (2016). *Get Smart: Know when Antibiotics Work in Doctor's Offices*. Retrieved from <https://www.cdc.gov/getsmart/community/improving-prescribing/outpatient-stewardship.html>

Centers for Disease Control and Prevention (2017). *Get Smart: Know when Antibiotics Work in Doctor's Offices: Improving Prescribing: Systematic Reviews*. Retrieved from <https://www.cdc.gov/getsmart/community/improving-prescribing/evidence/systematic-reviews.html>

Centers for Disease Control and Prevention (2015). *Healthy adult poster: Warning! Antibiotics don't work for viruses like colds and the flu*. Retrieved from <http://www.cdc.gov/getsmart/community/materials-references/print-materials/adults/p-healthy-adult.html>

Centers for Disease Control and Prevention (2015). *Prescription pads*. Retrieved from <http://www.cdc.gov/getsmart/community/materials-references/print-materials/hcp/viral-rx-pad.html>

- Centers for Disease Control and Prevention (2016). *The Core Elements of Outpatient Antibiotic Stewardship*. Retrieved from https://www.cdc.gov/getsmart/community/pdfs/16_268900-coreelementsoutpatient_508.pdf
- Centers for Disease Control and Prevention (2015). *Viruses of bacteria – what’s got you sick*. Retrieved from <http://www.cdc.gov/getsmart/community/materials-references/print-materials/everyone/virus-bacteria-chart.html>
- Chow et al, (2012). IDSA Clinical Practice Guidelines for Acute Bacterial Rhinosinusitis for Adults and Children. *Clinical Infectious Disease*, 54(8). doi: 10.1093/cid/cis370
- Costelloe, C., Metcalfe, C., Lovering, A., Mant, D., Hay, A.D. (2010). Effect of antibiotic prescribing in primary care on antimicrobial resistance in individual patients: Systematic review and meta-analysis. *BioMedical Journal*, 18. doi: 10.1136/bmj.c2096.
- Cramer, J.D., Kern, R.C., Tan, B.K., Peters, A.T., Evans, C.T., Smith, S.S. (2016). Potential national savings from prescribing guideline-recommended antibiotics for acute rhinosinusitis. *Laryngoscope*, 126(3). doi: 10.1002/lary.25719.
- Dellit, T.H., Owens, R.C., McGowan, J.E., Gerding, D.N., Weinstein, R.A., Burke, J.P., Huskins, W.C., Paterson, D.L., Fishman, N.O., Carpenter, C.F., Brennan, P.J., Hooton, T.M. (2007). Infectious Disease Society of America and the Society for Healthcare Epidemiology of America guidelines for developing an institutional program to enhance antimicrobial stewardship. *Clinical Infectious Disease*, 44 (2). doi: 10.1086/510393
- Dantes, et al. (2015). Association between outpatient antibiotic prescribing practices and community-acquired clostridium difficile infection. *Open Forum Infectious Disease*, 2(3). doi: 10.1093/ofid/ofv113

- Dempsey, P.P., Businger, A.C., Whaley, L.E., Gagne, J.J., Linder, J.A. (2014). Primary care clinicians' perceptions about antibiotic prescribing for acute bronchitis: a qualitative study. *BioMed Central Family Practice* 14(194). DOI: 10.1186/s12875-014-0194-5
- Drekonja, D.M., Filice, G.A., Greer, N., Olson, A. (2015). Antimicrobial stewardship in outpatient settings: A systematic review. *Infection Control & Hospital Epidemiology*, 36(2) DOI: <https://doi.org/10.1017/ice.2014.41>
- Fairlie, T., Shapiro, D.J., Hersh, A.L., Hicks, L.A. (2012). National trends in visit rates and antibiotic prescribing for adults with acute sinusitis. *Archives of Internal Medicine*, 172(19). doi: 10.1001/archinternmed.2012.4089
- Flemming et al, (2016). Prevalence of inappropriate antibiotic prescriptions among US ambulatory care visits, 2010-2011. *Journal of American Medical Association*, 315(7). doi:10.1001/jama.2016.4151
- Gill, J.M., Fleischut, P., Haas, S., Pellini, B., Crawford, A., Nash, D.B. (2006). Use of antibiotics for adult upper respiratory infections in outpatient setting: a national ambulatory network study. *Family Medicine*, 38(5).
- Goosens, H., Ferench, M., Vander Stichele, R., Elseviers, M., ESAC Project Group (2005). Outpatient antibiotic use in Europe and association with resistance: A cross-national database study. *The Lancet*, 375 (9459). doi:10.1016/S0140-6736(05)17907-0
- Gwaltney, J.M., Wiesinger, B.A., Patrie, J.T. (2004) Acute community-acquired bacterial sinusitis: the value of antimicrobial treatment and natural history. *Clinical Infectious Disease*, 38(2)
- Heikkinen, T., Jarvinen, A. (2003). The common cold. *The Lancet* 361 (9351). DOI: 10.1016/S0140-6736(03)12162-9

- Hicks, L.A., Bartoce, M.G., Roberts, R.M., Suda, K.J., Hunkler, R.J., Taylor, T.H., Schrag, S.J. (2015). US outpatient antibiotic prescribing variation according to geography, patient population, and provider specialty in 2011. *Clinical Infectious Disease*, doi: 10.1093/cid/civ076
- Infectious Disease Society of America (2011). Promoting antimicrobial stewardship in human medicine. Retrieved from http://www.idsociety.org/Stewardship_Policy/#
- MacDougal, C., & Polk, E.R. (2005). Antimicrobial Stewardship Programs in Health Care Systems. *Clinical Microbiology*, doi:10.1128/CMR.18.4.638–656.2005
- McDonagh, M., Peterson, K., Winthrop, K., Cantor, A., Holzhammer, B., & Buckley, D.L (2016). Improving antibiotic prescribing for uncomplicated acute respiratory tract infections. *Comparative Effectiveness Reviews*, 163 Report No.: 15(16)-EHC033-EF
- Meeker, D., Knight, T.K., Fridberg, M.W., Linder, J.A., Goldstein, N.J., Fox, C.R., Rothfield, A., Diaz, G., & Doctor, J.N. (2014). Nudging guideline-concordant antibiotic prescribing: a randomized clinical trial. *Journal of American Medical Association: Internal Medicine*, 174(3) doi: 10.1001/jamainternmed.2013.14191.
- Meeker, D., Linder, J.A., Fox, C.R., Friedberg, W., Persell, S.D., Goldstein, N.J., Knight, K., Hay, J.W., Doctor, J.N. (2016). Effect of behavioral interventions on inappropriate antibiotic prescribing among primary care practices: A randomized clinical trial. *Journal of American Medical Association*, 315(6), doi:10.1001/jama.2016.0275
- Physicians Quality Reporting System (2016). 2016 PRQS measure #331: Adult sinusitis: Antibiotic prescribed for acute sinusitis (appropriate use). Retrieved from https://www.pqrspro.com/cmsmeasures/2016/adult_sinusitis_antibiotic_prescribed_for_a_cute_sinusitis_appropriate_use/

- Physicians Quality Reporting System (2016). *2016 PQRS measure #332: Adult sinusitis: Appropriate choice of antibiotic*. Retrieved from https://www.pqrspro.com/cmsmeasures/2016/adult_sinusitis_appropriate_choice_of_antibiotic_pqrs-2016/
- Pynnonen, M., Lynn, S., Kern, H.E., Novis, S.J., Akkina, S.R., Keshavarzi, N.R., Davis, M.M. (2015). Diagnosis and treatment of acute sinusitis in the primary care setting: a retrospective cohort. *The Laryngoscope*, 125(10). doi: 10.1002/lary.25363
- Ranji, S.R., Steinman, M.A., Shojania, K.G., Gonzales, R. (2008). Interventions to reduce unnecessary antibiotic prescribing: a systematic analysis. *Medical Care*, 46(8). doi: 10.1097/MLR.0b013e318178eabd.
- RxList.com (n.d). *Augmentin*. Retrieved from http://www.rxlist.com/augmentin-drug.htm#side_effects_interactions
- RxList.com (n.d.) *Zithromax*. Retrieved from <http://www.rxlist.com/zithromax-side-effects-drug-center.htm>
- Rosenfeld, R.M. et al (2015). Clinical practice guideline (update): Adult sinusitis. American Academy of Otolaryngology - Head and Neck Surgery 152 (2) doi: 10.1177/0194599815572097
- Sharp, H.J, Denman, D., Puumala, S., Leopold, D.A. (2007) Treatment of acute and chronic rhinosinusitis in the United States, 1999-2002. *Archives of Otolaryngology, head & neck surgery* 133(3).
- Shapiro, D.J., Hicks, L.A., Pavia, A.T., Hersh, A.L. (2014). Antibiotic prescribing for adults in ambulatory care in the USA, 2007-09. *Journal of Antimicrobial Chemotherapy*, 69(1). doi: 10.1093/jac/dkt301

The Centers for Medicare & Medicaid Services, (2015). Physicians Quality Reporting System:

Measure Codes. Retrieved from

[https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html)

[Instruments/PQRS/MeasuresCodes.html](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html)

The White House (2015). *National action plan for combating antibiotic-resistant bacteria.*

Retrieved from

https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating

[_antibiotic-resistant_bacteria.pdf](https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf)

Table 1 <i>Demographics between concordant and unconcordant care.</i>				
Variable	Total	Concordant	Unconcordant	Significance
Age (m, sd)	49.1 (15.7)	54.9 (8.9)	45.2 (18.4)	<i>P</i> =.16
Gender % (<i>n</i>)				<i>P</i> >.999
Male	18.2 (4)	50 (2)	50 (2)	
Female	81.8 (18)	61.1 (11)	38.9 (7)	
Race (%)				<i>P</i> >.999
White	81.8 (18)	61.1 (11)	38.9 (7)	
Non-White	18.2 (4)	50 (2)	50 (2)	
Insurance (%)				<i>P</i> =.367
Private	63.6 (14)	50 (7)	50 (7)	
Medicare	9.1 (2)	100 (2)	0 (0)	
Medicaid	27.3 (6)	66.7 (4)	33.3 (2)	
Table 1				

Table 2

Distribution of adherence to individual components of PQRs guidelines; Concordant Care vs. Unconcordant Care %, (n)

	Total N=22	Concordant n=13	Unconcordant n=9	Significance P=
Symptoms	72.3 (16)	56.3 (9)	43.8 (7)	>.999
Timing	50 (11)	90.9 (10)	9.1 (1)	.009*
Double Sickening	4.6 (1)	100 (1)	0 (0)	>.999
Antibiotic	77.3 (17)	58.8 (10)	41.2 (7)	>.999
First Antibiotic	31.8 (7)	71.4 (5)	25.6 (2)	.735
Alternative	50 (11)	54.6 (6)	45.5 (5)	>.999
Dose	59.1 (15)	60 (9)	40 (6)	>.999

Table 2

Table 3

Antibiotic use between concordant and unconcordant care.

	Concordant <i>n</i> =13	Unconcordant <i>n</i> =9	Significance <i>P</i> =
No antibiotic	23.1 (3)	22.2 (2)	.855
Amoxicillin with or without Clavulanate	38.5 (5)	22.2 (2)	.735
Z-pack	15.4 (2)	33.3 (3)	.683
Levofloxacin	15.4 (2)	11.1 (1)	>.999
Doxycycline	7.7 (1)	11.1(1)	>.999

Table 4

Provider Knowledge Survey Scores; Frequency of correct scoring on individual components between pre-and post-test

% (n)	Pre	Post	Trend	Significance
	N=11	N=9		P=
Total	52.27	55.56	↑	.776
Are you aware of PQRS measure #331?	27.3 (3)	66.7 (6)	↑	.190
Are you aware of PQRS measure #332?	27.3 (3)	66.7 (6)	↑	.190
What are the symptoms of acute sinusitis?	63.6 (7)	33.3 (3)	↓	.369
How many days after sinusitis symptom onset are antibiotics appropriate?	45.5 (5)	55.5 (5)	↑	>.99
What is the first line antibiotic(s) of choice?	27.3 (3)	33.3 (3)	↑	>.99
What are at least three indications to not use the first line antibiotic of choice?	72.7 (8)	100 (9)	↑	.285

Table 4

Table 5

Frequencies of concordant care per Chart Audit vs. Correct answers on pre-and post-test surveys

	Chart Audit % (n) N=22	Survey, Pre % (n) N=11	Survey, Post % (n) N=9
Symptoms	77.27 (16)	63.6 (7)	33.3 (3)
Timing	54.6 (12)	45.4 (5)	55.5 (5)
First-Line Antibiotics	31.8 (7)	27.3 (3)	33.3 (3)
Alternative Indication	40.91 (9)	72.7 (8)	100 (9)
Dose	68.2 (15)	n/a	n/a

Table 5

Figure 1. Distribution of care components

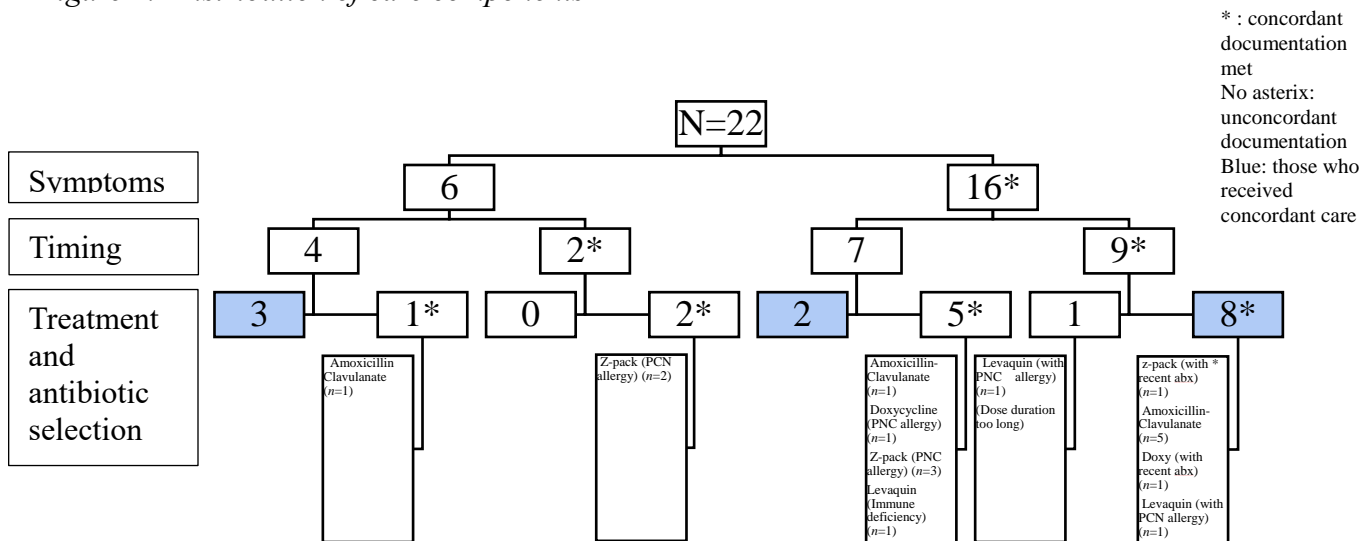
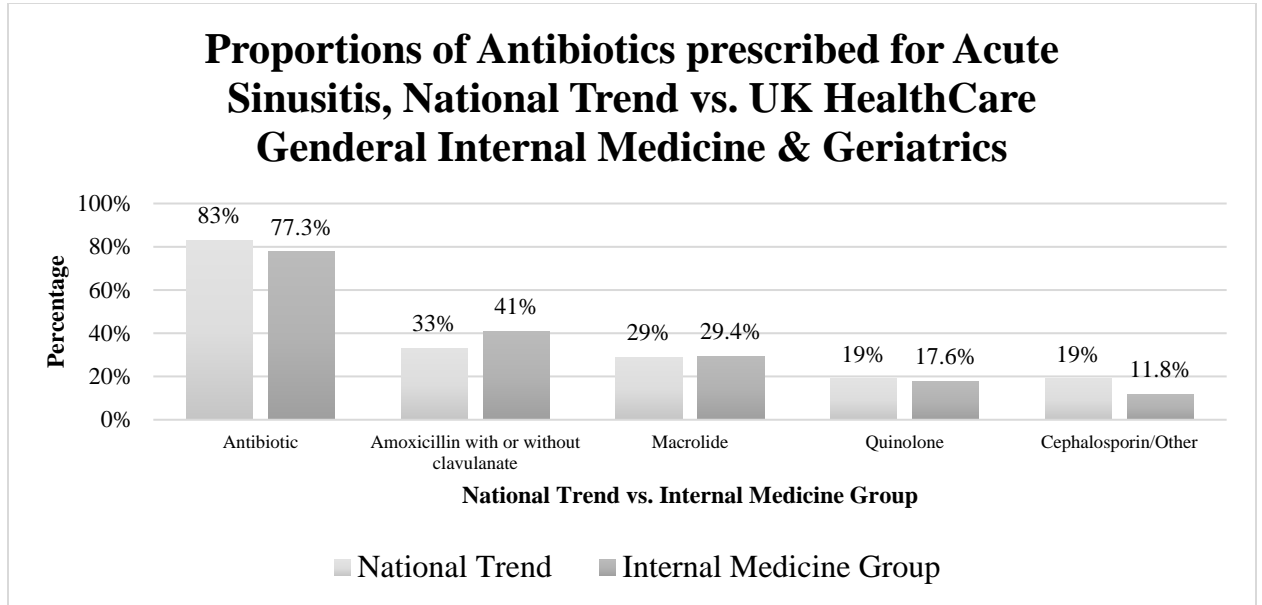


Figure 2. Proportions of antibiotics prescribed for acute sinusitis, National trends vs. UK HealthCare General Internal Medicine & Geriatrics



(Fairlie, Shapiro, Hersh & Hicks, 2012)

Appendix A

Form F Educational Intervention Cover Letter

To : UK *General* Internal Medicine and Geriatrics Providers:

The purpose of the study is to align antibiotic prescribing for adults with acute sinusitis with PQRS measures #331 and #332 through: a) Assess current antibiotic prescribing patterns and provider knowledge for acute sinusitis in adult patients, b), develop and implement an education and evidence based ASP based on PQRS measures #331 and #332, and c) Evaluate provider knowledge and practices before after ASP implementation to assess effect of ASP as evidenced by changes in antibiotic prescribing and provider knowledge.

Although you will not get personal benefit from taking part in this research study, your participation in the education session may offer meaningful insight to PQRS measurement standards for the treatment of acute sinusitis. Minimal risks and discomforts are expected to be associated with participation in this study. Benefits to participation include contributing to knowledge of antibiotic prescribing patterns for adults with acute sinusitis and increased knowledge of PQRS measurement standards associated with CMS reimbursement.

There are no known risks to participating in this study.

IF ANONYMOUS: Your participation in this study is anonymous which means no names will appear or be used on research documents, or be used in presentations or publications. The research team will not know that any information you provided came from you, nor even whether you participated in the study.

Please be aware, while we make every effort to safeguard your data once received on our servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still en route to us.

If you have questions about the study, please feel free to ask; my contact information is given below. If you have complaints, suggestions, or questions about your rights as a research volunteer, contact the staff in the University of Kentucky Office of Research Integrity at 859-257-9428 or toll-free at 1-866-400-9428.

Thank you in advance for your assistance with this important project.
Sincerely,

Katelyn Hellman
College of Nursing, University of Kentucky
PHONE: 616-881-9974
E-MAIL: kmde222@uky.edu

Appendix B

Consent to Participate in a Research Study

Adult Acute Sinusitis Antimicrobial Stewardship Program in a Primary Care Setting WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about antibiotic prescribing for adults with acute sinusitis. You are being invited to take part in this research study primary care providers are likely to treat patients for acute sinusitis, which is the most common acute respiratory tract infection seen in the primary care setting. If you volunteer to take part in this study, you will be one of about 30 people to do so.

WHO IS DOING THE STUDY?

The person in charge of this study is Katelyn Hellman, RN, BSN, DNP(c) of University of Kentucky, Department of College of Nursing. Ms. Hellman is a doctoral student and is being advised by Dr. Elizabeth Tovar. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to align antibiotic prescribing for adults with acute sinusitis with PQRS measures #331 and #332 through: a) Assessment of current antibiotic prescribing patterns and provider knowledge for acute sinusitis in adult patients, b) Develop and implement an education and evidence based ASP based on PQRS measures #331 and #332, and c) Evaluate provider knowledge and practices before after ASP implementation to assess effect of ASP as evidenced by changes in antibiotic prescribing and provider knowledge.

By doing this study, we hope to learn current antibiotic prescribing patterns for adults with acute sinusitis, provider knowledge of PQRS measures #331 and #332, and the impact of a brief educational intervention.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

There are no known reasons why you should not participate in the educational intervention. Participation in one aspect of this study does not mandate or preclude participation in the other aspects of this study. Resident physicians will not be invited to participate in the follow-up survey to help ensure a consistent sample of providers.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at UK General Internal Medicine and Geriatrics. You will need to come to the staff meeting ON ESTABLISHED DATE/TIME/LOCATION one time during the study. The visit will take about 30 minutes. The total amount of time you will be asked to volunteer for this study is 40 minutes over the next year for the remainder of the education session and a follow up survey.

WHAT WILL YOU BE ASKED TO DO?

As a participant, you will be asked to be present for an educational intervention on PQRS measures #331 and #332. The PI will be collecting data on antibiotic prescribing behavior before and after the intervention. No consequences will occur for choosing to not participate, to withdrawal, or to use individual clinical judgement in treatment of adults with acute sinusitis.

Time-line:

1. October- November 2015: provider knowledge survey followed by education intervention
2. October or November and consecutive four months thereafter: retrospective chart audit for antibiotic prescribing behavior from first business day after the education intervention and consecutive four months, backdated 1 year.
3. April -May 2017: post-assessment chart audit for antibiotic prescribing behavior from first business day after provider education intervention to four months thereafter; post-assessment provider knowledge survey to be distributed the first Monday after completion of the four-month chart audit time period.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Potential risks and discomforts include: violating confidentiality for patient and provider participants, embarrassment, frustration and negative evaluation. The PI has attempted to minimize risk

by providing for patient and provider confidentiality and maintaining provider clinical decision making autonomy. Education is supported by CMS through PQRS measures #331 and #332; provider autonomy in clinical decision making remains unchanged. Participants may choose to withdraw from the study at any time. No punitive or incentivized action will be taken against providers for sinusitis treatments. If participants experience emotional distress from study participation, they can contact the PI for information regarding free psychological services offered to employees of the University of Kentucky.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. You may have increased understanding of PQRS measures #331 and #332 after the educational intervention. Your willingness to take part may (a) help the University of Kentucky better understand antibiotic use rates for acute sinusitis; and (b) help researchers understand effectiveness of educational antimicrobial stewardship interventions.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

Costs for participating in this study include:

- 10 minutes for pre-intervention survey completion
- 30 minutes for education session
- 10 minutes for post-intervention survey completion.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

Data collected will be stored electronically on a secure server through the college of nursing. Access to the database will be password protected. The database can be accessed on the PI's password protected encrypted laptop with VPN access. Informed consent will be stored in Dr. Tovar's locked office in a locked file cabinet.

The education portion of this study is de-identified. We will make every effort to keep confidential all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is.

For the survey, "Please be aware, while we make every effort to safeguard your data once received on our servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still en route to us."

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Tovar at (409) 599-5984 immediately.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

The medical costs related to your care and treatment because of research related harm or frustration and embarrassment will be your responsibility.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Katelyn Hellman at (616) 881-9974. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity between the business hours of 8am and 5pm EST, Mon-Fri at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

POTENTIAL FUTURE USE

Contacting Research Subjects for Future Studies

Do you give your permission to be contacted in the future by Katelyn Hellman or Dr. Tovar (regarding your willingness to participate in future research studies about how to prevent, detect, or treat acute sinusitis and the benefits of the education session?

Yes **No** _____ **Initials**

WHAT ELSE DO YOU NEED TO KNOW?

There is a possibility that the data/tissue/specimens/blood collected from you may be shared with other investigators in the future. If that is the case the data/tissue/specimen/blood will not contain information that can identify you unless you give your consent/authorization or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued.

Signature of person agreeing to take part in the study

Date

Printed name of person agreeing to take part in the study

Name of [authorized] person obtaining informed consent

Date

Signature of Principal Investigator or Sub/Co-Investigator

Appendix C

Form F

Survey Cover Letter

To : UK General Internal Medicine and Geriatrics Providers:

The purpose of the study is to align antibiotic prescribing for adults with acute sinusitis with PQRS measures #331 and #332 through: a) Assess current antibiotic prescribing patterns and provider knowledge for acute sinusitis in adult patients, b), develop and implement an education and evidence based ASP based on PQRS measures #331 and #332, and c) Evaluate provider knowledge and practices before after ASP implementation to assess effect of ASP as evidenced by changes in antibiotic prescribing and provider knowledge.

Although you will not get personal benefit from taking part in this research study, your responses may help us understand more about current antibiotic prescribing patterns for adults treated for acute sinusitis. Minimal risks and discomforts are expected to be associated with participation in this study.

We hope to receive completed questionnaires from about 30 people, so your answers are important to us. Of course, you have a choice about whether or not to complete the survey/questionnaire, but if you do participate, you are free to skip any questions or discontinue at any time.

The survey/questionnaire will take about 5-10 minutes to complete.

There are no known risks to participating in this study.

Your response to the survey is anonymous which means no names will appear or be used on research documents, or be used in presentations or publications. The research team will not know that any information you provided came from you, nor even whether you participated in the study.

Please be aware, while we make every effort to safeguard your data once received on our servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still en route to us.

If you have questions about the study, please feel free to ask; my contact information is given below. If you have complaints, suggestions, or questions about your rights as a research volunteer, contact the staff in the University of Kentucky Office of Research Integrity at 859-257-9428 or toll-free at 1-866-400-9428.

Thank you in advance for your assistance with this important project. This survey will be open between February 6th – February 10th.

Sincerely,

Katelyn Hellman
College of Nursing, University of Kentucky
PHONE: 616-881-9974
E-MAIL: kmde222@uky.edu

Appendix D

Form E
Include in IRB Application to
Waive Requirement for Informed Consent

If you are requesting IRB approval for waiver of the requirement for the informed consent process, or alteration of some or all of the elements of informed consent (i.e. medical record review, deception research, or collection of biological specimens), complete Section 1 and Section 2 of this form and include it with your IRB application submission.

Note: The IRB does not approve waiver or alteration of the consent process for research that is subject to FDA regulations, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1

Check the appropriate item:

1) I am requesting waiver of the requirement for the informed consent process.
2) I am requesting alteration of the informed consent process. <i>If you checked the box for this item, describe which elements of consent will be altered, and/or omitted, and justify the alteration.</i>

SECTION 2

The IRB may consider your request provided that **all** of the following conditions apply to your research and are appropriately justified. Explain in the space provided for each condition how it applies to your research.

) The research involves no more than minimal risk to the subject. The baseline chart review will be retrospective collect information on patients which has already occurred. The post-assessment chart review will collect data after a voluntary education intervention which is not intended to replace clinical judgement. The data will be collected retrospectively.
) The rights and welfare of subjects will not be adversely affected. No identifying patient information will be maintained. Clinical judgement of providers will not be compromised.
) The research could not practicably be carried out with out the waiver or alteration.

Data collected will be retrospective on 206 patients, informed consent cannot be obtained from individual patients without breaching confidentiality of treatment.

) Whenever possible, the subject will be provided with additional pertinent information after they have participated in the study.

Results of the study will be provided to UK General Internal Medicine and Geriatrics.

Appendix E
**Assessing Antibiotic Prescribing Behavior for Adults with Acute Sinusitis
 Chart Audit Tool**

Study number: _____
Gender: _____
Age: _____
Race: _____
Insurance: _____

At adult acute bacterial sinusitis visits ICD9: 461.0, 461.1, 461.2, 461.3, 461.8, 461.9;
 ICD10: J01.00, J01.10, J01.20, J01.30, J01.40, J01.80, J01.90, patient encounter codes
 acceptable are: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99281, 99282,
 99283, 99284, 99285, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99324, 99325, 99326,
 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348,
 99349, 99350

PQRS Measures			
Information	Yes	No	Comments
Was the patient symptomatic for greater than 10 days, less than 4 weeks			
Was the patient exhibiting signs and symptoms worsening within 10 days after initial improvement, “double sickening”			
Were the symptoms: purulent nasal drainage, nasal obstruction, facial pain-pressure-fullness or both			
Was the patient prescribed an antibiotic?			
Was the first-line antibiotic amoxicillin with or without clavulanate?			
Was an allergy to penicillin documented?			
Was an indication to use alternative first line treatment documented?			
Was the dose of antibiotic 5-10 days?			

Confidential

M1

Pre-Assessment Provider Knowledge Survey

Please complete the survey below.

- 1) Are you aware of PQRS measure #331?
 Yes
 No
- 2) Are you aware of PQRS measure #332?
 Yes
 No
- 3) How many days after sinusitis symptom onset are antibiotics appropriate
 3 days of diagnosis or 5 days of symptom onset
 7 days of diagnosis or 10 days of symptom onset
 7-10 days
 3-5 days
- 4) What is the first line antibiotics of choice?
 Amoxicillin only
 Amoxicillin-Clavulanate only
 Macrolide
 Amoxicillin with or without Clavulanate
- 5) What are at least three indications to not use the first line antibiotic of choice?
- 6) What are key symptoms of acute sinusitis?

Confidential

M2

Post-Assessment Provider Knowledge Survey

Please complete the survey below.

- 1) Are you aware of PQRS measure #331?
 Yes
 No
- 2) Are you aware of PQRS measure #332?
 Yes
 No
- 3) How many days after sinusitis symptom onset are antibiotics appropriate
 3 days of diagnosis or 5 days of symptom onset
 7 days of diagnosis or 10 days of symptom onset
 7-10 days
 3-5 days
- 4) What is the first line antibiotics of choice?
 Amoxicillin only
 Amoxicillin-Clavulanate only
 Macrolide
 Amoxicillin with or without Clavulanate
- 5) What are at least three indications to not use the first line antibiotic of choice?
- 6) What are key symptoms of acute sinusitis?
- 7) Did you complete the baseline provider knowledge survey?
 yes
 no