INNOVATIONS in pharmacy

Volume 7 | Number 1 Article 2

2-9-2016

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Recommended Citation

Klepser ME, Altom A, MacCallum C, Nordquist E, Klepser DG. Description of the methods for describing and assessing the appropriateness of antibiotic prescribing and adherence to published treatment guidelines in an academic medical clinic. *Inov Pharm.* 2016;7(1): Article 2. http://pubs.lib.umn.edu/innovations/vol7/iss1/2

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Description of the methods for describing and assessing the appropriateness of antibiotic prescribing and adherence to published treatment guidelines in an academic medical clinic.

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Key words: Antimicrobial utilization, Ambulatory clinic, Antimicrobial stewardship, Antimicrobial use metrics, Outpatient setting, benchmarking

Abstract

Overuse and inappropriate use of antibiotics have been associated with increased rates of antimicrobial resistance and increased healthcare expenditures. Tracking inpatient antimicrobial use has helped quantify the value of stewardship programs aimed at improving the rational use of antibiotics among hospitalized patients. Unfortunately, similar methods for tracking and assessing antibiotic use in the outpatient setting have not been well described. We developed a novel method to capture trends and assess appropriateness of antibiotic usage. This strategy is based on identification of antimicrobial prescriptions in an electronic medical record system, linking prescribing to patient data, and capturing information regarding dosing and indications for use. Using information on dose, frequency, and duration of the antibiotic prescribed, a parameter to quantify antibiotic exposure (Prescribed Therapeutic Regimen, PTR) is calculated. This parameter is compared to a database of information on agents recommended in published guidelines (Recommended Therapeutic Regimen, RTR). By linking an ICD-9 code and the prescribed antibiotic we determine the appropriateness of the PTR by comparing it to the RTR for a given indication. Data are used to establish a baseline pattern of antibiotic use in the clinic to gauge the impact of future stewardship activities. Additionally, individual clinics and prescribers are given a snapshot of their antibiotic use compared to other clinics and prescribers. This is a novel means of describing antibiotic use in the outpatient setting that could serve as a standardized model for various adult and pediatric outpatient practices.

Introduction

Outpatient antibiotic use has been correlated with the emergence of resistance among microbes and community acquisition of infections secondary to resistant bacteria such as *Streptococcus pneumoniae*, *Staphylococcus aureus*, and *Escherichia coli*.[1-3] Importantly, infections caused by resistant pathogens have been associated with increased treatment costs, poorer outcomes, and increased rates of hospital admission and readmission.[2] Unfortunately, population data continue to suggest that antimicrobial prescribing patterns for the management of various community-acquired conditions such as upper respiratory tract infections (e.g., pharyngitis and sinusitis), urinary tract infections, pneumonia, and cellulitis continue to be excessive or inappropriate.[3-12]

Antibiotics are over-prescribed for conditions that have a low probability of being caused by bacterial pathogens, and the choice of agent and duration of therapy often are not congruent with published guidelines.[4-7, 9] Numerous studies suggest that overuse of antibiotics in the outpatient setting is a significant problem.[3-12] Respiratory tract infections represent a constellation of diagnoses for which outpatient antibiotic use has been identified as particularly concerning.[3-9] Furthermore, inappropriate use of antibiotics for urinary tract infections and skin and skin structure infections has led to the emergence of increasingly resistant pathogens being identified as the source of these infections. A report from the Center for Healthcare Research & Transformation at the University of Michigan summarized antibiotic prescribing trends in Michigan from 2007-2009.[1] Among adult patients, it was noted that approximately 50% of antibiotic prescriptions in a third party payer system received antibiotics considered to be "antibiotics of concern" (i.e., broad spectrum antibiotics) by the National Committee for Quality Assurance (NCQA). In response to data such as these, The National Action Plan for Combating Antibiotic-Resistant Bacteria was developed by the Task Force for Combating Antibiotic-Resistant Bacteria in response to Executive Order 13676.[13, 14]

Among the outcomes stated by the Task Force, was to reduce inappropriate antibiotic use by 50% in the outpatient setting by the year 2020.[15]

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Although antimicrobial stewardship programs have been developed to facilitate the appropriate use of antibiotics within hospitals, few similar programs exist to assist with the management of antibiotic usage in outpatient settings. One complicating factor has been lack of a standardized means to assess and benchmark antibiotic utilization in the ambulatory setting. Inpatient antimicrobial stewardship programs use parameters such as the Defined Daily Dose (DDD) or Days of Therapy (DOT) to measure antibiotic use. DDD is defined as the assumed average maintenance dose per day for a drug used for its main indication.[16] Although widely used, it has been recognized that the value of DDD is limited because this parameter does not take into account dosing variability for different infections or individual characteristics such as age, weight, or renal/hepatic function. As a result, the utility of DDD in a diverse population over a range of infectious processes is questionable.

Unlike the hospital setting where purchasing data and dispensing records are readily available and for evaluation of antimicrobial usage patterns, analogous data may be difficult to obtain in clinic setting. The primary challenge in the outpatient setting is that antimicrobials are prescribed in one setting and the prescription is often filled in another. Additionally, patients from one clinic go to a myriad of different pharmacies. These factors have made it difficult to link prescribing to dispensing in the outpatient setting. As a result, most of the data reported regarding antibiotic use in the ambulatory care setting have come from wholesalers or insurance claims. Although these data may provide a global idea of antibiotic use, they can be cumbersome, time consuming, and costly to collect. This degree of information is virtually useless with respect tracking the impact of stewardship interventions at the clinic or prescriber level. These data provide limited information regarding the appropriateness of the antibiotic, dose, or duration for a given indication and patient and can be difficult for individual clinics to obtain. Additionally, these data are not provided in a timely fashion, thus further limiting its clinical utility. For these reasons, it impractical to attempt to build and assess an outpatient antimicrobial stewardship program using these data sources.

Recognizing the limitations associated with existing strategies for gathering outpatient antimicrobial usage data at a clinic level, the World Health Organization (WHO) piloted the use of prescription records as a means to assess antibiotic use.[17] Although the concept of using prescription records for tracking outpatient antibiotic use was insightful, it was still recommended to compare regimens to DDD. Unfortunately, comparison of individual antimicrobial regimens with DDD is associated with the same one-size fits all limitation noted earlier.

Recognizing the need for an improved means with which to track and assess the appropriateness of antimicrobial use the outpatient setting, we developed a novel strategy to accomplish this task. The primary purpose of this manuscript is to describe a novel, robust method to track and assess the appropriateness of antimicrobial prescribing in an academic medical clinic among various patient populations and for numerous indications. Antimicrobial utilization data generated by these methods are intended to allow for internal and external benchmarking globally, by indication, by specialty clinic, and by prescriber and provide a platform upon which to gauge the impact of stewardship initiatives in an outpatient setting.

Description of Methods

Methods were developed for use at the Western Michigan University Homer Stryker M. D. School of Medicine Clinics (WMed) in Kalamazoo, Michigan. There are 10 individual clinics (Family Medicine, Infectious Diseases, Internal Medicine, Internal Medicine Subspecialties, Medicine-Pediatrics, Orthopedics, Pediatrics, Pediatric-Subspecialties, Psychiatry, and Surgery) located within the WMed Clinics. There are approximately 30,000 active patients seen by the various clinics.

Data Collection Procedures

Data are retrieved from the WMed electronic medical record (EMR) (eClinicalWorks version 10) for all patients seen in clinic for a given time period. Demographic data (medical record number, age, sex, ethnicity) are collected at the patient level, while information regarding antibiotic allergies, diagnosis code(s), provider, provider description (e.g. resident, faculty, physician assistant, etc.), and a full medication list are collected at the patient visit level (Table 1).

Episodes of antimicrobial prescribing are identified by assigning a dichotomous variable to the medications prescribed at each visit according to an antibiotic or non-antibiotic scheme. Additionally, antibiotic count variables are created to indicate the number of antibiotics prescribed at each visit, and the number of antibiotics prescribed for each patient during the targeted timeframe. Antibiotic count variables can then be used to estimate a per-patient antibiotic prescription rate. For each antibiotic prescribed, the indication for use is identified by examining the posted International Statistical Classification of Diseases and Related Health Problems (ICD-9) Codes for the clinic visit at which the agent was prescribed (Table 2).[18] By cross-referencing antibiotic prescriptions with ICD-9 codes, the antibiotic usage

rate for specific diagnoses can be assessed. Additionally, patient data that may influence selection of an antibiotic or dose such as allergic reaction, body mass index, and renal function, are collected from encounters as close to the antibiotic prescription date as possible. Antibiotics prescribed for the selected indications are compared to the agents recommended for use in published treatment guidelines.[19-24] If the prescribed antibiotic is not listed as a recommended agent within the guidelines, its use is deemed inappropriate. A prescription for an antibiotic will be deemed unnecessary if an ICD-9 code for an infectious disease is not associated with the patient encounter.

For each antibiotic prescription identified, a Prescribed Therapeutic Regimen (PTR) is calculated by determining a total amount of antibiotic prescribed for each patient episode: PTR = Antibiotic Dose (mg or units) x Frequency (times a day) x Duration (days). For the indications of interest, a Recommended Therapeutic Regimen (RTR) is calculated to determine the appropriateness of the antimicrobial regimen: RTR = Antibiotic Dose (mg or units) x Frequency (times a day) x Duration (days). Data used in RTR calculations were derived from published guidelines for the selected indications (Table 3).[18-24] Data regarding the recommended dose adjustment for renal function were gathered for each antibiotic (Lexicomp version 2.3.2) and RTR ranges calculated for each level of renal function as appropriate. For each antimicrobial recommended by a treatment guideline, a maximum (RTR_{max}) and minimum (RTR_{min}) RTR are calculated for each level of renal function by multiplying the upper end of the recommended dose by the longest recommended duration and the lower end of the dosing recommendation by the shortest recommended duration, respectively (Table 3). Exceptions to this rule are made for agents that have specific durations associated with explicit doses (e.g., for community-acquired pneumonia, levofloxacin can be dosed as either 750 mg once daily for 5 days or 500 mg once daily for 7-14 days). RTR data were compiled in a Microsoft Excel spreadsheet.

The appropriateness of a given course of antimicrobial therapy is gauged according to a two-step process. First, the prescribed agent is compared to the RTR database for the given indication to determine if the agent is listed as a recommended by published guidelines. Second, if the use of the agent prescribed is recommended for an indication within the guidelines, the appropriateness of the prescribed dosing regimen is assessed by determining if the PTR falls within the age and renal function adjusted RTR_{min}-RTR_{max} range.

Summary reports for antibiotic prescription rates and appropriateness are generated for the entire clinic, individual clinics, individual prescribers, and by indication. These reports are used to identify opportunities for education/intervention and to assess the impact of these actions.

Significance

It has been documented that antibiotics are frequently prescribed for non-bacterial infections, in suboptimal regimens and without regard to spectrum of activity.[3-12] These patterns of excessive or inappropriate use of antibiotics have been linked to the emergence of resistance.[1-3] To help preserve the utility of the antibiotics currently available, strategies for tracking antimicrobial use with subsequent application of antimicrobial stewardship principles have advocated.[25] For almost 20 years now, antimicrobial stewardship programs have been used within institutions to successfully improve antibiotic usage patterns. Although analogous programs in the outpatient setting have been lacking, publication of Executive Order 13676 has stimulated interest in this area. Before programs can be developed to improve antibiotic usage patterns, there is a need to develop a standardized and accepted way to quantify and assess the appropriateness of antibiotic use in the outpatient setting.

Use of prescription records to track outpatient use appears to be a good strategy for studying antibiotic usage patterns in the outpatient setting. This approach allows us to assess prescriber behavior and based on their intent. The WHO has previously explored the use of prescription data for this purpose; however, the methods proposed for assessment of the appropriateness utilized comparisons to DDDs. As mentioned, the use of DDD has considerable limitations and does not account for disease or patient specific dose adjustments. The method we have developed had the advantage in that appropriateness of use and dosing takes published treatment guidelines and patient factors such as age, weight, and renal/hepatic function into consideration. For example if a patient is allergic to a preferred regimen and the provider prescribes an alternate agent, the choice of agent may be justified. For age and weight these parameters can be important when assessing regimens for pediatric or morbidly obese patients. This approach provides much more useful information to the clinician as it provides feedback based upon evidence-based recommendations. We believe that the method we propose not only overcomes some of the limitations of DDD, but also combines quality indicators of both antibiotic utilization and a process measure (e.g. appropriate therapy).

Since most of the prescriptions are transmitted electronically to pharmacies, a variety of options were available to us to gather prescription data. Requesting transaction requests from an e-prescription network such as Surescripts may have allowed us to gather the antibiotic usage data we desired;

however, timeliness, cost, and adequacy of the data were concerns. Additionally, upon discussing our plan with our information technology department, it was believed that use of data contained with our EMR would provide us the most efficient means by which to collect prescription data and link it to patient specific information.

This approach has not been without limitations and potential drawbacks. For example, it was noted that depending on the EMR used, doses may not be entered as a numeric field rather a product strength was entered. This translates into data being captured as a text field as opposed to a numeric field and thus requires conversion. Also, if an antibiotic dose or duration were to be changed following consultation with the dispensing pharmacy and not recorded in the EMR the actual PTR would not be reflected. Lastly, it may be somewhat time consuming for IT to determine how data can be extracted for specific systems. However, once appropriate data fields have been identified, it will likely become much easier to generate results.

The approach we have described is an efficient means to track and assess antimicrobial use by outpatient providers. We believe that this strategy could become a standardized model for tracking and assessing outpatient antibiotic use.

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Table 1: Examples of data fields extracted from the EMR

Data Field	Purpose of Evaluation
Allergies	Determine if use of a recommended agent was contraindicated based on history of allergic reaction.
Allergy Reaction	Determine if use of a recommended agent was contraindicated based on history of allergic reaction.
Appointment Provider	Determine which clinician prescribed the antimicrobial.
Demographic data (i.e, age and weight)	Determine appropriateness of the agent and dose selected.
Encounter Date	Identify when the antimicrobial use episode occurred in order to link laboratory data and additional encounters.
ICD-9/Assessment Code	Identify infectious condition for which the antimicrobial was prescribed.
Medical Record Number	Group data for an individual patient together.
Medication Name	Identify antimicrobial use episode.
Medication Signetur	Allow for calculation of PTR.
Medication Status	Identify active and discontinued medications.
Next Patient Appointment	Identify follow-up visits for the same condition.
Provider Role	Identify primary physician, resident, or physician's assistant.
Serum creatinine and glomerular filtration rate	Determine if the agent was dose appropriately for renal function.

Table 2: Diagnosis codes for selected infections:[18]

Diagnosis	ICD-9 Code
Urinary Tract infection	599.0, 595.0, 595.9
Unspecified local infection of skin and subcutaneous tissue	680.x-682.x
Pneumonia, organism not specified	486
Acute bronchitis	466.x
Streptococcal sore throat	034.0
Pneumococcal pneumonia	481
Acute sinusitis	461.x
Chronic sinusitis	473.9
Otitis	381.x - 382.9

Table 3: Calculated antimicrobial RTR_{min}-RTR_{max} ranges for adults treated as outpatients with selected indications.[19-24]

Indication	Antimicrobial	CrCl (mL/min)	Recommended Daily Dose Range	Duration Range (days)	RTR_{min}	RTR_{max}
Rhinosinusitis	Amoxicillin/ Clavulanate	≥30 10-29 <10	1,500 mg-4,000 mg* 500 mg-1,000 mg* 250 mg-500 mg*	5-7 5-7 5-7	7,500 mg* 2,500 mg* 1,250 mg*	28,000 mg* 7,000 mg* 3,500 mg*
	Doxycycline	No Adjustment	200 mg	5-7	1,000 mg	1,400 mg
	Levofloxacin	≥50 ≥20-49 10-19	500 mg 250 mg 125 mg	5-7 5-7 5-7	2,500 mg 1,250 mg 625 mg	3,500 mg 1,750 mg 875 mg
	Moxifloxacin	No Adjustment	400 mg	5-7	2,000 mg	2,800 mg
Streptococcal Pharyngitis	Amoxicillin	≥30 ≥10-29 <10	1,000 mg 500 mg-1,000 mg 250 mg-500 mg	10 10 10	10,000 mg 5,000 mg 2,500 mg	10,000 mg 10,000 mg 5,000 mg
	Penicillin VK	No Adjustment	1,000 mg	10	10,000 mg	10,000 mg
	Benzathine Penicillin	No Adjustment	1.2 MU	1	1.2 MU	1.2 MU
	Cephalexin	≥10 <10	1,000 mg 250 mg-1,000 mg	10 10	10,000 mg 2,500 mg	10,000 mg 10,000 mg
	Cefadroxil	≥10 <10	1,000 mg 667 mg	10 10	10,000 mg 6,670 mg	10,000 mg 6,670 mg
	Clindamycin	No Adjustment	900 mg	10	9,000 mg	9,000 mg
	Azithromycin	No Adjustment	500 mg on day 1 250 mg on days 2-5	5	1,500 mg	1,500 mg
	Clarithromycin	≥30 <30	500 mg 250 mg	10 10	5,000 mg 2,500 mg	5,000 mg 2,500 mg
Community-Acquired Pneumonia	Azithromycin	No Adjustment	500 mg on day 1 250 mg on days 2-5	5	1,500 mg	1,500 mg
	Clarithromycin	≥30 <30	500 mg-1,000 mg 250 mg-500 mg	7-14 7-14	3,500 mg 1,750 mg	7,000 mg 3,500 mg
	Doxycycline	No Adjustment	200 mg	5-10	1,000 mg	2,000 mg
	Levofloxacin	≥50 20-49 ≥10-19	500 mg-750 mg 250 mg-375 mg 125 mg-250 mg	5-14 5-14 5-14	3, 500 mg 1,750 mg 875 mg	7,000 mg 3,500 mg 1,750 mg
	Gemifloxacin	>40 ≤40	320 mg 160 mg	5-7 5-7	1,600 mg 800 mg	2,240 mg 1,120 mg
	Moxifloxacin	No Adjustment	400 mg	5-14	2,000 mg	5,600 mg
Uncomplicated Cystitis	TMP/SMX***	≥30 15-29	320 mg** 160 mg**	3 3	960 mg** 480 mg**	960 mg** 480 mg**
	Nitrofurantoin	≥60	200 mg	5	1,000 mg	1,000 mg
	Fosfomycin	No Adjustment	3,000 mg	1	3,000 mg	3,000 mg
	Ciprofloxacin	≥5	500 mg	3	1,500 mg	1,500 mg
	Levofloxacin	≥10	250 mg	3	750 mg	750 mg

Pyleonephritis	Ciprofloxacin	≥5	1,000 mg	7	7,000 mg	7,000 mg
	Levofloxacin	≥50 20-49 10-19	750 mg 375 mg 125 mg	5 5 5	3,750 mg 1,875 mg 625 mg	3,750 mg 1,875 mg 625 mg
	TMP/SMX	≥30 15-29	320 mg** 160 mg**	14 14	4,480 mg** 2,240 mg**	4,480 mg** 2,240 mg**
Cellulitis	Clindamycin	No Adjustment	1,200 mg-1,800 mg	5	6,000 mg	9,000 mg
	Dicloxacillin	No Adjustment	2,000 mg	5	10,000 mg	10,000 mg
	Cephalexin	≥50 ≥10-49 <10	2,000 mg 1,000mg-1,500 mg 250 mg-1,000 mg	5 5 5	10,000 mg 5,000 mg 1,250 mg	10,000 mg 7,500 mg 5,000 mg
	Doxycycline	No Adjustment	200 mg	5	1,000 mg	1,000 mg
	Minocycline	No Adjustment	200 mg	5	1,000 mg	1,000 mg
	TMP/SMX	≥30 15-29	320 mg-640 mg** 160 mg-320 mg**	5 5	1,600 mg** 800 mg**	3,200 mg** 1,600 mg**
	Penicillin VK	No Adjustment	1,000 mg-2,000 mg	5	5,000 mg	10,000 mg
	Linezolid	No Adjustment	1,200 mg	5	6,000 mg	9,000 mg
Impetigo	Dicloxacillin	No Adjustment	1,000 mg	7	7,000 mg	7,000 mg
	Cephalexin	≥10 <10	1,000 mg 250 mg-1,000 mg	7 7	7,000 mg 1,750 mg	7,000 mg 7,000 mg
	Erythromycin	No Adjustment	1,000 mg	7	7,000 mg	7,000 mg
	Clindamycin	No Adjustment	1,200 mg-1,600 mg	7	8,400 mg	11,200 mg
	Amoxicillin/ Clavulanate	≥30 10-29 <10	1,750 mg* 500 mg-1,000 mg* 250 mg-500 mg	7 7 7	12,250 mg* 3,500 mg* 1,750 mg*	12,250 mg* 7,000 mg* 3,500 mg*

***Dose based on amoxicillin component**
****Dose based on TMP component**
*****TMP/SMX = Trimethoprim/sulfamethoxazole**