Use of an Innovative Pharmaceutical Class Scoring Tool for Prioritized Annual Formulary Review

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Abstract

Background: *Though The Joint Commission requires health systems perform annual formulary review, guidance for how to perform this review is lacking. Published methods include comprehensive review of all pharmaceutical classes; however, this approach may not be the most efficient or effective option for a health system with a large formulary.*

Objective: *To create a prioritization system for annual formulary review through development of a pharmaceutical class scoring tool.*

Methods: *Drug information pharmacists developed the scoring tool, which used external and internal data to score pharmaceutical classes in 4 categories: safety, efficacy, cost, and utilization. The primary outcome, number of formulary changes resulting from pharmaceutical class review, was compared between the highest-scoring and lowest-scoring class to assess the tool's ability to prioritize high-yield class reviews.*

Results: *The tool calculated scores for 91 pharmaceutical classes, altogether containing 962 medications. After review of the highest-scoring class, corticosteroids, 2 formulary changes were made: one dosage form was removed from formulary, and one medication was restricted to outpatient use only. Zero formulary changes resulted from review of the lowest-scoring class, pharmaceutical adjuvants.*

Conclusions: *The tool described in this study prioritized annual formulary review efforts by identifying a pharmaceutical class with meaningful formulary optimization opportunities as the highest-scoring class, while correctly identifying a class with no optimization opportunities as the lowest-scoring class.*

Keywords: Hospital formulary; formulary committee; drug information services; drug class review

Introduction

Review of a health system's formulary is vital to ensure the safest, most effective, and most fiscally responsible medications are available for use.[1,2] The Joint Commission (TJC) requires health systems perform annual review of their formulary for efficacy and safety; however, guidance for how to perform this review is lacking.[3,4] Most strategies involve an iteration of a pharmaceutical class review, which entails evaluation of medication entities within each pharmaceutical class for new efficacy, safety, and cost data.[3]

Published strategies from 1984 onward involve grouping medications into pharmaceutical classes according to the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification System, mechanism of action, or indication for use and assigning a specific number of class reviews per month.[5,6] Persson et al described a hybrid approach of scheduled class reviews along with continuous safety reviews.[6] This approach led to 23 formulary modifications: 3 additions, 15 removals, and 5 therapeutic interchanges. However, it took a full year to review all 17 pharmaceutical classes on formulary.

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In 2018, Froedtert & the Medical College of Wisconsin (MCW) Center for Medication Utilization (CMU) surveyed health systems across the United States about annual formulary review strategies. Of the 33 respondents, 19 performed a comprehensive review each year. Others used methods similar to those described by Persson et al by performing scheduled class reviews, as well as ad hoc reviews prompted by internal or external safety, usage, and cost triggers.

While comprehensive, a detailed annual review of all pharmaceutical classes may not be the most efficient or effective option for a health system with a large formulary. In addition, pharmaceutical classes range in complexity when considering the number of medications included, efficacy data, and safety concerns. Thus, a one-size-fits-all approach may lead to unnecessary time spent on uncomplicated class reviews and missed opportunities for formulary optimization in more complicated classes.

Use of a formulary review strategy that accounts for this variance in drug class complexity has been effective for other health systems. Abu Esba described a focused method for annual formulary review.[7] Detailed reviews of medications and classes were chosen based on concerns related to safety, efficacy, and usage. In-depth reviews were then performed for 8 therapeutic classes along with all low-use medications. Though the entire formulary was not reviewed, this prioritized review resulted in 81 formulary modifications.

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Use of external and internal triggers has been described by Abu Esba, but it remains unclear how to best apply these triggers when determining which classes to review. Much of the data used to determine if a medication or class should be reviewed is expressed in a qualitative format. Use of a quantitative tool could clarify which medications to prioritize for review. This study seeks to create a system to prioritize annual formulary review efforts through use of a pharmaceutical class scoring tool.

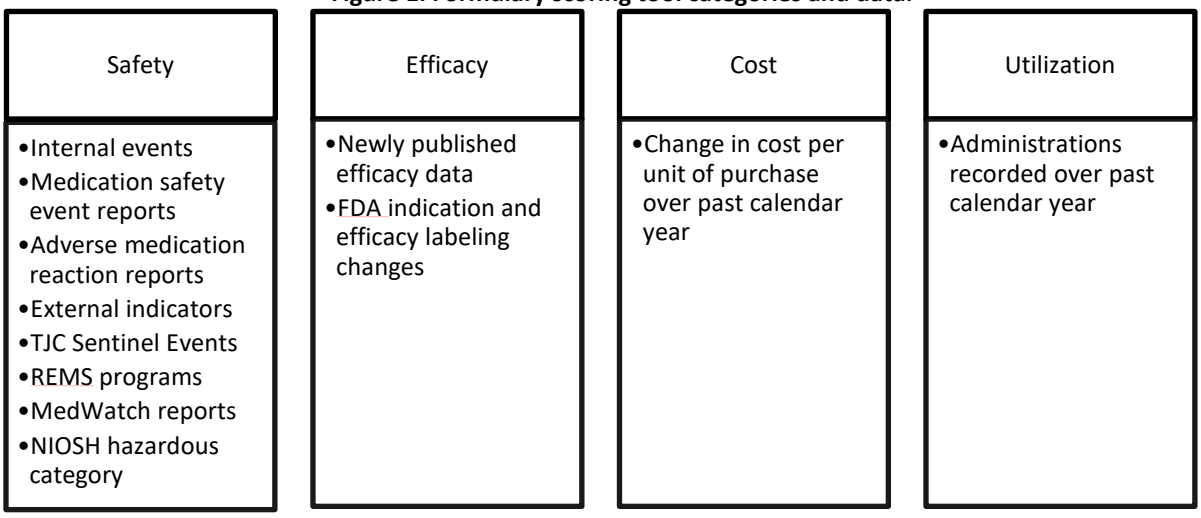
Methods

This study was conducted at Froedtert & MCW, which is comprised of multiple hospitals and clinics across Wisconsin. Three hospitals within the system share one formulary: Froedtert Hospital, Froedtert Menomonee Falls Hospital, and Froedtert West Bend Hospital. Medication entities, defined as their generic name irrespective of formulation or route of administration, in this formulary were included in the study. Medications that were restricted to outpatient use, investigational use, or supplied by patients were excluded.

Drug information pharmacists, a medication safety pharmacist, and a pharmacy manager collaborated to design the tool and choose the factors that would be scored. Four major categories were chosen to capture important factors for making formulary decisions: safety, efficacy, cost, and utilization (Figure 1).Each category was weighted equally using a scale of 0 to 5. Since each category had different data inputs (different number of sources and range used), they were normalized to a 5-point scale. This was accomplished by taking the points earned by the pharmaceutical class divided by the total possible points to get the proportion of points earned. Then, this number was multiplied by 5 to convert to the 5-point scale (Figure 2). For example, the safety category had 20 total possible points. If a pharmaceutical class earned 12 out of 20 points, that class earned 60% of the total possible points (12/20 = 0.6). Converting to a 5-point scale, this would equate to a safety score of 3.

All data reports were exported or converted to Microsoft Excel spreadsheets for ease of use; Excel VLOOKUP functionality was used to populate data from various reports into the tool. Internal safety events, including medication errors and adverse reactions for the past calendar year, were quantified using reports from a voluntary error reporting system. External safety indicators included data from TJC and United States Food and Drug Administration (FDA), and were not subject to a timeframe restriction. Of note, existence of a Risk Evaluation and Mitigation Strategies (REMS) program was scored nominally (ie, 1 for yes and 0 for no) and National Institute for Occupational Safety and Health (NIOSH) categories were scored in a reciprocal fashion (ie, NIOSH category 1 scored 3 points, NIOSH category 2 scored 2 points, and NIOSH category 3 scored 1 point). Newly published efficacy data were quantified using a PubMed keyword search of the generic medication name with filters for past calendar year (January through December 2020) and English language. A single database was chosen for consistency and sustainability purposes; searching every medication name in the health system formulary is a time-intensive process, and likely the additional benefit gained from searching multiple databases would not outweigh the time and resource limitations for a sustainable process. U.S. FDA labeling changes were extracted from the Drugs@FDA website, which provides this data in a monthly fashion. Once exported, the report was filtered to the submission category “Efficacy” to remove label changes unrelated to efficacy from data collection. Group Purchasing Organization (GPO) cost change data was provided by the institution’s wholesaler. Number of administrations over the past calendar year were collected using electronic health record reporting software. Figure 2 shows the scales used for each metric along with calculations for each category score.

Figure 1. Formulary scoring tool categories and data.



Abbreviations: *FDA, U.S. Food & Drug Administration; NIOSH, National Institute for Occupational Safety and Health; REMS, Risk Evaluation and Mitigation Strategies; TJC, The Joint Commission.*

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Medications were divided into pharmaceutical classes as defined by the electronic health record. A safety, efficacy, cost, and utilization score was calculated for each formulary medication entity and then added to generate a total medication entity score. The total scores of individual medication entities within each pharmaceutical class were averaged for the pharmaceutical class score. Use of an average score prevented classes with the highest number of medication entities from achieving the highest scores by default.

After all scores were calculated, the highest-scoring and lowest-scoring pharmaceutical classes underwent review using a standardized template created by the project team. The review template was modeled after the institutional monograph template and past class reviews. The review template included the same sections as the scoring tool with required (eg, data and summary of each category) and optional fields (eg, if notable differences between medications within the same class such as route of administration, pharmacokinetics, or storage requirements) to grant flexibility to focus on the unique considerations of each pharmaceutical class. The highest-scoring class underwent written review as the results were later presented to the health-system Pharmacy and Therapeutics committee; the lowest-scoring class review was discussed verbally with the drug information pharmacy team and documented in meeting minutes.

Figure 2. Scoring tool components and calculations.

Safety Score

Medication Errors		ADRs		FDA MedWatch Safety Alerts		NIOSH Category		TJC Sentinel Events		REMS Program	
Events	Score	Events	Score	Alerts	Score	Category	Score	Yes/No	Score	Yes/No	Score
0	0	0	0	0	0	None	0	Yes	1	Yes	1
1	1	1	1	1	1	1	3	No	0	No	0
2 - 4	2	2	2	2	2	2	2				
5 - 9	3	3	3	3	3	3	1				
10 - 50	4	4	4	4	4	$Medication\ Entity\ Safety\ Score = \frac{points\ earned}{total\ possible\ points} \times 5$					
> 50	5	> 4	5	> 4	5						

Efficacy Score

Newly Published Data		FDA Efficacy Labeling Changes		
Articles	Score	Changes	Score	
0 - 5	0	0	0	$Medication\ Entity\ Efficacy\ Score = \frac{points\ earned}{total\ possible\ points} \times 5$
6 - 20	1	1	1	
21 - 100	2	2	2	
101 - 1000	3	3	3	
1,001 - 10,000	4	4	4	
> 10,000	5	> 4	5	

Cost Score

Change in Cost		
Percent Change	Score	
0	0	$Medication\ Entity\ Cost\ Score = \frac{points\ earned}{total\ possible\ points} \times 5$
< 0 (negative)	1	
+1 - 5%	2	
+6 - 10%	3	
+11 - 25%	4	
> +25%	5	

Utilization Score

Administrations in EHR		
Administrations	Score	
0	0	$Medication\ Entity\ Utilization\ Score = \frac{points\ earned}{total\ possible\ points} \times 5$
1 - 10	1	
11 - 100	2	
101 - 1,000	3	
1,001 - 10,000	4	
> 10,000	5	

Abbreviations: *ADR, Adverse Drug Reaction; FDA, U.S. Food & Drug Administration; NIOSH, National Institute for Occupational Safety and Health; TJC, The Joint Commission; REMS, Risk Evaluation and Mitigation Strategies; EHR, Electronic Health Record.*

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The primary outcome was the number of formulary modifications for the highest-scoring and lowest-scoring pharmaceutical classes. A formulary modification includes the addition or removal of a medication entity or preparation, as well as a change in restrictions for use. If the tool functioned correctly, the highest-scoring pharmaceutical class would have more opportunities for formulary modifications compared with the lowest-scoring pharmaceutical class. Secondary outcomes, which assessed the accuracy of the scored categories, included median score and highest-scoring pharmaceutical classes for each category. If the tool performed as intended, median scores should be similar across categories, and there should be clear rationale for why the top-scoring pharmaceutical classes earned such high scores.

Results

At the time of this study, the formulary included 1066 medication entities within 91 pharmaceutical classes. Application of exclusion criteria removed 104 medications due to outpatient-only restriction; 962 medication entities were evaluated in the scoring tool.

The highest-scoring pharmaceutical class was corticosteroids with an overall score of 6.82. Fourteen out of 91 pharmaceutical classes (15%) had a score of 6 or more, and the second-highest scoring class was pressors at 6.69. Corticosteroids on formulary included betamethasone, budesonide, cortisone, dexamethasone, fludrocortisone, hydrocortisone, methylprednisolone, prednisolone, prednisone, and triamcinolone. Of note, cortisone was removed from formulary between the time of data collection and summation of scores due to low utilization and inability to obtain the product from manufacturers. Pharmaceutical adjuvants scored the lowest. This class included lanolin, simple syrup, white petrolatum, and prescription compounding vehicles. As seen in Table 1, corticosteroids consistently scored higher than the median in each category whereas pharmaceutical adjuvants consistently scored lower. Table 2 shows the highest-scoring pharmaceutical classes for each category of the scoring tool.

Table 1. Highest-scoring and lowest-scoring pharmaceutical classes.

Subscore	Median	Corticosteroids	Pharmaceutical Adjuvants
Safety	0.14	0.32	0
Efficacy	1.20	1.70	0.75
Cost	0.52	0.90	0.25
Utilization	2.83	3.90	0.50
Total	5.05	6.82	1.50

A written class review was performed on the highest-scoring class: corticosteroids. As a result, 3 formulary modification suggestions were initially made, and 2 changes were implemented. The 2 changes that were implemented included removal of a particular medication entity formulation due to disproportionately high cost without a benefit for safety or efficacy, along with restriction of a medication entity formulation to outpatient use based on its indications and high cost. No formulary modifications were made for the pharmaceutical adjuvants class. All 4 of the medications were low in cost, did not have data to support new indications for use, and did not have safety concerns.

Table 2. Top 5 Highest-scoring classes within each scoring tool category (descending order within each category).

Safety		Efficacy		Cost		Utilization	
Pharmaceutical Class	Score	Pharmaceutical Class	Score	Pharmaceutical Class	Score	Pharmaceutical Class	Score
Antineoplastics	0.58	Nutrients	1.93	Antiseptics & disinfectants	1.25	Beta blockers	4.22
Analgesics-narcotic	0.50	Chemicals	1.79	Stimulants	1.17	Skeletal muscle relaxants	4.17
Progestins	0.46	Macrolide antibiotics	1.75	Miscellaneous Psychotherapeutic*	1.13	Antihyperlipidemic	4.13
Anticoagulants	0.43	Corticosteroids	1.70	Antidiarrheals	1.00	Antimyasthenic agents	4.00
Estrogens	0.42	Antimalarial	1.67	Migraine products	1.00	Pressors	4.00

*Eg, acamprosate, donepezil, memantine, varenicline

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Discussion

This study was the first to describe a numeric scoring tool to prioritize pharmaceutical class reviews. The primary outcome supported the ability of the tool to discern high-impact and low-impact pharmaceutical class reviews. The tool allowed for a review of safety, efficacy, cost, and utilization for each pharmaceutical class and formulary medication entity to both meet TJC requirements and enable formulary optimization.

There were strengths and limitations within each scoring category. In the safety category, the tool identified high-risk medications appropriately. Medications with the highest safety scores have historically high rates of serious adverse events; 3 out of the 5 medications are considered high-alert medications by Institute for Safe Medication Practices (ISMP)[8], even though the high-alert medication list was not a component of the scoring tool. Though accurate, the safety scores were unexpectedly low, which led to inadvertent lower weighting of safety compared with the other categories. This lower weighting is likely due to the large number of safety indicators included, which diluted the impact of each individual indicator, along with the inherent limitations of using Excel VLOOKUP to extract data. Thus, additional normalization of safety scores by use of a multiplier may be necessary.

Antimalarials and corticosteroids were rightfully among the top 5 highest-scoring classes within the subscore for efficacy due to the extensive evaluation of medications in these classes for use in coronavirus disease (COVID-19). However, other high-scoring classes did not appear to be identified correctly. The top-scoring class according to efficacy subscore, nutrients, is comprised of macronutrients for total parenteral nutrition: lipids, dextrose, and amino acids. These medications are unlikely to have groundbreaking new efficacy data; however, the tool identified them as such due to error introduced by the newly published data scores. A keyword search of “amino acids,” will result in a high number of articles that mention amino acids or each word separately within the abstract; however, most of these articles are unlikely to evaluate the efficacy of amino acids for therapeutic purposes. The same is true for the chemicals pharmaceutical class, which includes common substances for nonpharmaceutical uses, including ethyl and isopropyl alcohol, acetic acid, and acetone.

Though accurate, the results for cost were also surprising. It was expected for most medication costs to increase over 12 months; however, this was not the case in this study due to changes in organizational contracting opportunities during the study period. Thus, the results for this section were correct, even though they did not contribute to the pharmaceutical class scores in the manner that was expected. This section may be more useful in future years when contracts do not undergo such great changes.

The utilization category contained the highest scores, which led to a higher weight being inadvertently assigned to this section. These higher subscores were likely due to the administration report being specifically designed for this project. Therefore, the utilization data were more easily transferred to the tool without some of the limitations seen with other categories.

Overall, there are notable strengths to using this scoring tool method for performing annual formulary review to prioritize a selection of pharmaceutical classes for in-depth review versus reviewing every formulary medication. The strengths of the scoring tool are attributable to the methodology of tool development; drug information pharmacists were key contributors to help ensure that the most pertinent data related to safety, efficacy, cost, and utilization were included. The scoring tool facilitated initial review of all medication entities; so, the drug information pharmacists could then focus their efforts on the highest-scoring pharmaceutical classes. This approach improves efficiency and practicality of annual formulary review for health systems with large formularies that may not have the resources to perform an in-depth review of each medication entity. Additionally, data collection for the tool is easily protocolized to allow for use of pharmacist extenders to complete the initial scoring.

Like any new process, this system for performing annual formulary review did have some limitations and opportunities for improvement. One limitation is generalizability to other health systems; this tool would need adjustments for health systems that do not use the same electronic health record for portions of the tool using reports derived from the electronic health record (ie, cost, utilization). Another limitation was the format of certain reports used to collect data for each medication entity. As mentioned in the discussion of efficacy results, some data did not transfer as easily or completely as other data. There were also certain scored elements that could only be collected manually, which decreased efficiency of the tool. Other elements of the scoring system were not able to be fully assessed due to the volume of results, such as ensuring that all articles included in the efficacy score truly demonstrated new efficacy of the medication entity. In addition, some categories were inadvertently weighted higher than others; a normalization of scores may be necessary in future iterations. Lastly, the COVID-19 pandemic in 2020 skewed the results for efficacy and utilization, as many publications were focused on COVID-19 treatments, and a large number of patients received medications aimed to treat the virus.

Conclusion

Use of a scoring tool to prioritize pharmaceutical class reviews allows for health systems with large formularies to systematically review all medication entities, while focusing the majority of their efforts on high-impact class reviews. The tool described in this study identified a pharmaceutical class with meaningful formulary modification opportunities as the top-scoring class, while also correctly identifying a class with no

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formulary modification opportunities as the lowest-scoring class.

This tool will be further optimized to improve its accuracy and efficiency. A time study may help determine rate-limiting steps and measure the impact of the tool in terms of reducing the number of working hours required to complete annual formulary review. Reports designed to increase data capture by the tool and minimize manual data entry will be added. Safety scores will be further normalized to combat their inadvertent lower weight among the scoring tool categories. The medication cost data may be reassessed to score cost decreases equally as highly as cost increases to identify opportunities for cost savings. Lastly, medications restricted to outpatient use will be added to allow for review of the entire formulary. The annual formulary review process will continue to be optimized as the scoring tool evolves to allow for efficient, effective review of the health system formulary.

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