Leveraging and Improving Refill Protocols at Your Health System

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Abstract

Objectives Medication refill processing is a repetitive and predictable time-intensive task for ambulatory primary and specialty care. Refill protocols are a clinical decision support (CDS) tool that allows clinicians to quickly and safely determine appropriateness of a refill request. Our health system opted to improve the quality and breadth of electronic health record vendor-supplied protocols to consistently leverage best practices and emerging evidence and to create novel protocols that further support clinicians.

Methods We established a refill protocol governance group to guide new protocol build and to review existing protocols regularly to keep current with emerging guidelines. Data-driven prioritization was used to create new protocols for the most frequently refilled medications, as well as for less-prescribed but higher risk medications. Ad-hoc specialist inclusion as subject-matter experts provided greater detail, accuracy, and broader consensus in protocol criteria.

Results Approximately 11 million refills are processed each year by our health system’s providers. The proportion of refill requests supported by a protocol increased over a 2-year period from 49 to 82%, representing a net increase of 3.63 million refills in the second measurement year as compared to the start of the first measurement year. All published refill protocols were reviewed by the governance group over the measurement years for compliance with clinical guidelines. In addition to the structure of the refill protocols’ CDS, the process was supported by filters that enable practices to quickly approve refills that pass protocol, providing more time for clinicians to review refills that fail a protocol or for which no protocol exists.

Conclusion A refill protocol is a valuable CDS tool that can improve efficiency, effectiveness, and user satisfaction when processing refill requests. A refill protocol governance structure is an effective way to review, edit, and build refill protocols within a health system.

Keywords
► primary care
► prescription
► electronic health record
► protocols
► clinical decision support

Background and Significance

The management of medication refill requests is a common task performed by most ambulatory medical practices. Primary care practices and specialty practices alike process refill requests in the absence of a patient visit. These requests may come directly from patients or through a pharmacy, and may be received via telephone call or via electronic communication.1 On average, primary care physicians receive between 10 and 25 refill requests per day, with an average time...
of 30 minutes per day spent assessing and responding to refill requests. Our system processes approximately 11 million medication refills per year. Prior to 2018, providers were given no information about the appropriateness of a refill for a patient. This required that a clinician spend time reviewing the patient’s chart prescription after prescription, patient after patient, and clinician after clinician, on a daily basis. The required review is a predictable checklist that is best done from a quality, safety, and efficiency standpoint, in the context of a protocol. Without a thoughtful, team-based structure and a data-driven approach that is responsive to user feedback, clinicians continue to act in isolation, responding to each refill request as if it is a surprise, applying refill criteria sporadically rather than uniformly, and becoming frustrated by the inefficiencies of the software in use and the system of care.

Providers frequently manage medication refill requests by either consciously or subconsciously applying certain rules to the circumstances surrounding the request, in an effort to ascertain appropriateness of the request. These rules form the basis of a refill protocol and serve to answer questions regarding the patient’s status to determine whether a medication can be safely and responsibly refilled. The rules can roughly be divided into two main subgroups: temporal (time-related) rules, and metric (measurement-related) rules. Temporal rules include assessing whether a patient had a recent visit or has a future visit scheduled as well as the timeliness of recommended laboratory testing. Metric rules are applied to determine if recent laboratory testing values fall within acceptable ranges to safely permit medication refill, and to ensure that vital signs are adequately controlled and/or not adversely affected by the medication. In a refill protocol, all rules must be true for a protocol to pass; a single rule that is false causes the entire protocol to fail.

There are several challenges that providers face in consistently applying medication rules when faced with a refill request. Both temporal and metric rules result in informational needs, whereby a provider must be presented with data and then must compare those data to a standard to determine whether the rule passes or fails. Unique considerations among medication classes result in the need for many different and distinct metric rules. For example, beta-blockers and angiotensin-converting enzyme (ACE) inhibitors are both antihypertensive medications. Beta-blockers can cause bradycardia but not hyperkalemia, but the reverse is true for ACE inhibitors. On occasion, different considerations can apply to two distinct medications within the same medication class. For instance, paroxetine and sertraline are each serotonin reuptake inhibitors, but paroxetine carries a higher risk during pregnancy. This uniqueness, when multiplied by thousands of medications, makes it very challenging for each of us to manually apply all of the needed checks consistently and uniformly to all medication refill requests. Adding the time pressures of a busy clinician’s day and the need to keep up to date with most recent prescribing guidelines makes unsupported appropriate refill management nearly impossible.

The electronic health record (EHR) is used by the majority of ambulatory practices in the United States. A number of EHRs have the capability to collate specific rules into a refill protocol. Such refill protocols can display both temporal and metric rules at the point of care, limiting or eliminating the need for clinicians to manually collate their data with each refill. Distinct refill protocols can be created for each medication class, or when there are significant monitoring differences among members of that class, for individual medications. EHR-driven refill protocols are a form of clinical decision support (CDS) that are highly scalable and sustainable for maintaining safe and responsible prescribing behaviors in both primary and specialty ambulatory practices.

**Objectives**

The goals of this initiative were to create a governance structure to build, edit, and review refill protocols, to prioritize refill protocol construction, to develop a way to allow practices to process refill requests efficiently, and to expand the quality and extent of CDS alerts for providers.

**Methods**

**Discovery**

Penn Medicine is a large, academic medical center with 6 hospitals and 10 large multispecialty clinic sites. The health system employs 8,923 physicians and conducts over 5.6 million ambulatory visits per year in urban, suburban, and rural outpatient offices. We are fortunate to have a robust informatics support structure with resources available to take on this work. Penn Medicine utilizes Epic EHR across the enterprise.

Our health system evaluated external solutions for delivering refill protocols to clinicians, including vendor-released protocols and refill protocols maintained by third-party companies. We began by recreating six vendor-released refill protocols in our EHR and having a handful of dual-role family physician/clinical informaticists test those protocols in their practices. After this trial period, we determined that we needed evidence-based protocols that we could build, prioritize, and update in a timely manner based on our network’s needs and that this was not available through third-party companies at the time.

This discovery period led to a decision to create a governance committee whose role is to review all EHR vendor-supplied refill protocols on a line-by-line basis for evidence or best practice recommendations, to create new refill protocols based on service line or health system needs, and to review our health system’s existing refill protocols to ensure that they continue to comply with the latest guidelines or recommendations. In our approach to refill protocols, we opted not to address medication interactions, often referred to as drug–drug interactions, as these are addressed in another layer of CDS within our EHR.

**Governance Structure, Hierarchy, and Duties**

The governance group consists of three dual-role family physician/clinical informaticists, one family physician with
obstetrics and gynecology privileges, one family nurse practitioner, one clinical pharmacist, one business process consultant, and multiple ad-hoc specialist consultants. The specialist consultants serve as subject-matter experts and bring peer-reviewed protocol criteria from their own specialty EHR governance groups. Proposed new refill protocols or changes to existing protocols are brought to the group through crowdsourcing of practicing providers, through individual subspecialty EHR governance groups, through literature review, and through important updates in medication guidelines. The governance group reports to the Ambulatory Clinical Decision Support Committee and to the Associate Chief Medical Information Officer (–Fig. 1). Another role of the refill protocol governance group is to assess and rank health system needs and to appropriately prioritize resources for new refill protocol creation.

The processes of refill protocol creation, editing, and review are all very similar, and occur in a line-by-line fashion. A refill protocol consists of inclusion criteria (i.e., what are the circumstances and conditions for which we want the protocol to display), and protocol criteria (which “yes/no” statements must all be true for the protocol to pass). Protocol criteria must all be true for the protocol to pass; a single failed condition will cause the protocol to fail. Conditions and protocols that pass are listed in green, and conditions and protocols that fail are listed in red, and clinicians are able to view these statements when they consider whether to refill a medication or not (–Fig. 2).

The refill protocol governance charter specifies that there must be consensus on each inclusion criterion and each protocol criterion for use in the protocol. Failure to achieve consensus results in remanding the criterion to further literature research, subspecialty advisement, or discussion.

There have been cases where two distinct specialties that prescribe the same medication for different indications regularly have different recommendations based on best practice for their specialty. For example, when prescribing carbamazepine, neurologists typically do not check carbamazepine levels when prescribing this medication for seizure disorder, but psychiatrists do check levels to ensure compliance when prescribing for bipolar disorder. This impasse was bridged by adding a conditional criterion that is excluded or included based on the specialty department.

We anticipate that there may be a circumstance in the future where we cannot achieve consensus between two specialties for a medication with two different indications and/or monitoring requirements. For example, rheumatologists may request that the patient had a visit in the past 3 months when prescribing azathioprine for rheumatoid arthritis, but gastroenterologists may be comfortable with a visit in the past 6 months when prescribing azathioprine for ulcerative colitis. While this has not yet occurred, if it does during future protocol creation, we would have the ability to display specialty-specific criteria through use of a department filter rule where the refill was requested. If the refill is requested in a rheumatology practice, the 3-month visit rule will apply, but if the refill is requested in a gastroenterology practice, the 6-month visit rule will apply.

**Refill Protocol Prioritization**

With hundreds of distinct medications being refilled in our health system each day, it became clear that we needed to develop an approach to prioritize routine refill protocol creation. Our EHR vendor estimates that it takes 10 hours to build and test each refill protocol, and while we had found much of that time to be front-loaded, there was still a limit to resources available for this work. While our health system was able to support refill protocol creation and editing, other health systems that are significantly limited in these resources could consider contracting their EHR vendor to determine options to obtain additional support, or could consider contracting with a third-party vendor that provides solutions to support refill protocols. Rather than creating protocols at will, we opted to use data to guide our new refill protocol build efforts, and focused on creating protocols for the most commonly refilled medications in the health system.

We used a Structured Query Language (SQL) query to find each refill processed throughout the health system, counted them by medicine, sorted the query from highest to lowest number of refills for each distinct medication-dose combination, and extracted the data to an Excel pivot table for further data management. Medications or medication classes that were the most infrequently prescribed or that had existing refill protocols were eliminated, and the top 30 medications without a refill protocol were sent to the

![Fig. 1](Refill protocol governance structure.)
governance group to prioritize build. Medications that were used heavily in certain specialties were flagged, and outreach to representatives from specialty groups was conducted to assist with protocol creation.

**Improving Refill Efficiency**

Once multiple refill protocols were created, we looked to implement refill protocols across our health system, and to leverage protocols and filters to allow practices to reduce the time they needed to spend processing refills. A key component of this process was utilizing ancillary practice staff (nurses and medical assistants) to perform some of the refill duties that otherwise fell onto providers. By allowing nurses to quickly approve refill requests that passed protocols, and by having medical assistants schedule patients or pend laboratory orders for patients with failed criteria, we hoped that we could allow our teammates to work to their highest level leveraging the decision support and limit the percentage of overall refills that required direct intervention by a provider.

**Results**

**Impact of Governance Structure**

Through utilization of the refill protocol governance structure, we were able to increase the number of refill protocols in our production EHR environment from 6 to 83 over a 5-year period (Fig. 3). We used some of the vendor-supplied refill protocols, but elected not to recreate all of these in our EHR, as some were less commonly prescribed in our health system, and thus did not match up with our strategy of building protocols for the most frequently prescribed medications to achieve the greatest impact. Approximately 89% of our vendor-supplied refill protocols were amended at least in part to incorporate evidence-based guidelines, best practices, or health system or service line initiatives. Notable examples of the latter include reducing high-risk medication prescribing for the elderly and controlled medication prescribing stewardship. Among refill protocols currently being used, 100% were reviewed on an annual, rolling basis.

Engagement with specialists and their colleagues allowed the refill protocol group to build 11 refill protocols (12% of the total protocols currently being used) which the group felt they were not comfortable creating on their own, i.e., without specialist consultation.

**Impact on Clinical Decision Support**

Our data query revealed that approximately 11 million refills were processed each year in our health system. Among these 11 million refills, there were approximately 25,000 discrete medication–dose combinations. Of those medication–dose combinations, the top 4,000 medication–dose combinations represented 99% of all refills processed in the health system.

By focusing our refill protocol build on the top 30 most-prescribed medications or medication classes in our health system, the percentage of medication refill requests that were supported by a protocol increased from 49 to 82% over a 3-year period (Fig. 4). This resulted in an increase in CDS from 5.39 million events per year in year 1, to over 9 million events per year in year 3.
Impact on Practice Refill Efficiency

Through native EHR reporting tools and SQL queries, we determined that a health system level that for all medications that are supported by a refill protocol, 72% of those requests pass (i.e., all rules are met to safely authorize refills), although there is some variability in this number from practice to practice. When looking at all medication refill requests, 58% are supported by a refill protocol and pass, 24% are supported by a refill protocol and fail, and 18% are not supported by a refill protocol (Fig. 5).

Because over half of all refill requests were previously vetted by a refill protocol for appropriateness and met all conditions required, provider verification is complete, and a nurse may approve the refill request with cosignature in the EHR from a provider. Selecting only refill requests with passed refill protocols is easily achieved in the EHR by applying a filter.

For the 24% of refill requests that fail a protocol due to a temporal rule (an overdue lab test or visit), a nurse or medical assistant may pend appropriate orders for the patient and/or schedule patients for a visit or lab test as appropriate prior to forwarding to a provider for cosignature. If a refill fails due to a metric rule (an abnormal lab value or vital sign), the refill request is forwarded directly to a provider, who makes a decision about refills and further workup. The remaining 18% of refills without a refill protocol are forwarded to the provider for management.

Discussion

Using the above refill protocol governance structure, we successfully increased the number of distinct medications or medication classes for which CDS was available, and increased the number of CDS events generated. We developed a method to build and review refill protocols, a schema for prioritizing new protocol creation in our health system, and tools and workflow for providers and staff to consider at a practice level.

We reviewed our approach for building and enhancing refill protocol CDS within our health system. This began with collating a like-minded group of clinicians who are passionate about this work to form a governance structure. While there is no optimal size or composition of this group, we found several important features that make the group successful: (1) members are adept at accessing information needs, (2) the group shares a goal of balancing safety with usability, (3) the size of the group is large enough to share different viewpoints, but small enough to reach consensus, (4) specialists join as ad-hoc members, as adding a permanent specialist member from each specialty would be unwieldy, (5) at least one member of the committee is familiar with EHR architecture to advise whether the committee’s recommendations can or cannot be achieved, and (6) the addition of a clinical pharmacist broadens the evaluation and the discussion. We have future plans to create refill protocols for use within treatment protocols, such as oral chemotherapy, but have opted not to build these for use in clinical research protocols.

In our approach to building refill protocols, we identified a need for flexibility, to accommodate variances in medication dosing or monitoring. While refill protocols were frequently constructed for an entire medication class, there were times when we needed to “carve out” a new protocol for an individual medication within the class. One example was sodium-glucose-cotransporter-2 (SGLT-2) inhibitors, which at the time of writing had different renal dosing guidelines across each medication. When there was specialty disagreement about medication monitoring guidelines, the committee served as arbiters to guide these subject-matter experts to a solution that was acceptable for all. We found ancillary benefits of using a single, standardized refill protocol per medication (or medication class) across the health system as described by Nelson et al. These benefits included ease of editing, modular format of medications and criteria, scaling of protocol scope to the full enterprise, and integration with native tools and workflows within our vendor EHR.

A key success to this project was leveraging data to guide our refill protocol build focus. The need for data to drive refill
protocol focus became evident after we attained a critical mass of refill protocols, which numbered around 35 in our health system. Our goal was to focus our build on refill protocols that reach the greatest number of clinicians. One challenge that we have identified is how to prioritize refill protocol creation for medications that are inherently higher risk (due to monitoring needs, potential for abnormal vital signs, or potential for adverse events) but are prescribed less frequently. A second challenge that we have identified is in assessing patient-level impact of refill protocol CDS. A deeper analysis may be helpful to determine to what extent refill protocols change behavior revolving around prescribing, and whether any such change in behavior results in improved patient outcomes or in reduction of harms. There is also future opportunity to assess how providers are personally affected by refill protocols. This could be measured objectively, by determining the time spent processing refill authorizations, and subjectively, by surveying providers about their level of satisfaction with refill protocols and obtaining their opinions about how concordant the protocols are with their practice of medicine.

At a practice level, refill protocols have the potential to allow all members of the health care team to be involved in the refill process. In our health system, refill protocols can permit nurses in ambulatory settings to approve all passed refills, removing roughly half of all refill requisitions from the provider’s inbasket. Medical assistants can pend orders in certain circumstances for signature by a provider, thus increasing their breadth and depth of their work and reducing provider burden. This approach to refill management utilizes a wider swath of the ambulatory health care team, and allows team members to work at the top of their license. Assuming that a full-time primary care provider receives an average of 10 to 25 refills per day, this workflow modification has the potential to remove up to 60 refills from a provider’s inbasket per week, with a daily time savings of up to 15 to 30 minutes per day. This workflow can be scaled across multiple ambulatory practices and specialties. One potential roadblock to implementation of this workflow may be the scope of practice of nurses, which varies by state law. While it is likely that patient refill requests will be processed faster by using this team-based approach, further study would be helpful to determine if that is actually the case.

Medication refill management may be accomplished at a practice level, as described above, or at an entity or system level. In the latter approach, refill requests are routed to a centralized refill team, which may be composed of nurses who approve refills with passed protocols, and medical assistants who pend orders and schedule appointments for multiple ambulatory practices. We have not moved our medication refill management to this centralized model, but have taken preliminary steps toward piloting such a workflow.

Conclusion
A refill protocol is an effective CDS tool for practice. Refill protocols have potential to improve medication refill safety and efficiency. Formulating a robust governance structure to systematically review new and established protocols can be helpful to keep protocols current. Analyzing prescribing trends within the health system helps to provide a focus on which protocols to build. Refill protocols can allow other members of the health care team to assist with the refill process.

Clinical Relevance Statement
Refill protocols are effective CDS tools for evaluating refill appropriateness, which can be further enhanced and nuanced by committee review and analysis of health system needs.

Multiple Choice Questions
1. Which of the following refill protocol criteria are time-related (temporal)?
   a. Last glomerular filtration rate (GFR) value
   b. Last systolic blood pressure measurement
   c. Last human immuno-deficiency virus (HIV) viral load
   d. Last appointment in office

Correct Answer: The correct answer is option d. Refill protocol criteria may include time-related (temporal) criteria and measurement-related (metric) criteria. The patient’s last appointment is a time-related measurement. The other three options above are measurement-related (metric) criteria.

2. Which of the following is a desirable feature when considering a governance structure for reviewing refill protocols?
   a. Committee members who hold steadfastly to their opinions
   b. Members are adept at assessing informational needs
   c. Large, multispecialty group to incorporate all possible medication viewpoints
   d. Exclusion of clinical informaticists, who may be influenced by their EHR vendor

Correct Answer: The best answer is option b. The ideal governance structure for refill protocols incorporates committee members who strive for consensus, are skilled at finding necessary information, and ideally include one clinical informaticist who understands what can or cannot be accomplished within the EHR framework. The committee welcomes ad-hoc (rather than full-time) specialist consultant members as subject-matter experts when necessary.

Protection of Human and Animal Subjects
No human subjects were involved in this project.

Conflict of Interest
None declared.
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