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Editorial

"Medication utilization. . .the great multiplier!"

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"Medication Utilization", or alternatively "Drug Utilization" is a term that is widely used in health care. While cost concerns for medications are usually the central focus, utilization should be equally targeted. The problem is that prescription medications are usually warranted and the tools for managing utilization are frequently ineffective in the long-term and is not always substantiated by rigorous research. Utilization accounts for an additional prescription to a patient's regimen. The problem is magnified further when the cost of medications equals or exceeds acute care charges as with Specialty Medications, i.e., medications usually injectables self or physician/nurse administered, require special handling, have high cost per dose, and may require special approvals prior to dispensing. These medications are still too costly for patients and require insurers to charge premiums that increase the costs of health care, even with 50% cost discounts. Thus, if utilization multiplies cost, what are we to do?

Definitions

First, what is "Medication Utilization"? Medication Utilization can be defined as the number of prescriptions taken by a patient measured by the number of Rx-per-utilizer, or number of Rx-per-utilizer-per month. But utilization is more than a count of medications.

Patient Utilization was defined in the Omnibus Budget Reconciliation Act of 1990, Section 4401, known as Obra 90.[1]This federal law placed expectations on the pharmacist to interact with the patient. Included in this law was the requirement for prospective drug utilization review that included:

- Therapeutic Duplication
- Drug-Disease Contraindications
- Drug-Drug Interactions
- Incorrect Drug Dosage
- Incorrect Duration of Treatment
- Drug-Allergy Interactions
- Clinical Abuse/Misuse of Medication

Obra 90 defines those areas of a patient's medication which the patient and pharmacist should review and thus, begin to provide a scope for utilization.[1] Other definitions of drug utilisations expand upon individual patient usage and focus on applications of drug utilisation such as:

- **Research:** "Drug Utilization Research" which was defined by the WHO in 1977 as "the marketing, distribution, prescription, and use of drugs in a society with special emphasis on the resulting medical, social and economic consequences".[2]
- **Oversight:** "Drug Utilization Review" (DUR) defined by multiple sources including the Academy of Managed Care Pharmacy as "an authorized, structured, ongoing review of prescribing, dispensing and use of medication".[3]
- **Quality Improvement:** "Medication-Use Evaluation" (MUE) which is defined by the American Society of Health System Pharmacists (ASHP) as "a performance improvement method that focuses on evaluating and improving medication-use processes with the goal of optimal patient outcomes".[4]

Regardless of the specific definition, Medication Utilization covers a broad spectrum of appropriate usage to the outcomes of therapy. This breadth of definition leads to a number of methods available for managing utilization as a process.

Appropriateness

If usage is the primary focus of drug utilisation, then how do we judge appropriateness and provide oversight for the medications prescribed and taken by patients? Traditionally, "pre-certification", also referred to as "prior authorization", is the primary tool for evaluating appropriate usage. Prior Authorization is the procedure for pre-approval of a medication based on its labeled approved usages. However, the volume of prescriptions is so great that every prescription or claim cannot reasonably be pre-reviewed. As a result, prior authorization is reserved for the most expensive, high risk, and frequently abused medications. FDA product labeling provides the approved uses for medications targeted for prior authorization. Medica-

tions prescribed for "off label" or non-approved uses lead to concerns for effectiveness and risk of adverse effects that have not been adequately studied. However, as medical practice is sometimes ahead of official oversight, prior authorization also allows for research justification, e.g., the provision of at least three double-blinded, placebo-controlled trials of the subject medication used in the same patient population as the patient. Consideration is also given to "common practice in the community" when sufficient literature is available to judge effectiveness and risk.

A by product of the "appropriateness concern" is the application of tiered formularies. These formularies attempt to control usage by selection of cost-effective options to treat diseases and conditions common in the affected populations. Generic substitution and therapeutic interchange, i.e., the switch of one product to another of generally equal effectiveness and risk profile, do not decrease utilization. Rather they tend to move product selections to less expensive options or to medications more tolerable to patients.

The use and abuse of antimicrobials has also lead to antibiotic stewardship programs, most commonly employed in acute and long-term care settings, that aim to combat antibiotic resistance by requiring compliance with therapeutic guidelines, sensitivity testing, and therapeutic interchange. Utilization in this context is controlled under mandatory usage and oversight criteria.

Appropriateness is not a 'one trick pony". Definitions of utilization whether focused on individual patients or on a population have led to more comprehensive evaluative tools. Drug utilization review (DUR)[3], medication therapy management (MTM)[5], and comprehensive therapy management (CMR)[6] provide an approach to the overall analysis of a patient's medication profile. These approaches review appropriateness, therapeutic selection, the risk profile as judged by hundreds of clinical flags and edits, drug-induced problems, and cost-effectiveness. While not specifically intended to reduce utilization, specific categories of medications like controlled substances including opiates, as well as potential age-related misuse, come under the umbrella of recommendations arising from these approaches.

However, appropriateness is not the only measure of utilization and is not the only tool used to manage utilization.

Utilization Management Tools

Once appropriateness has been established, there are well established tools for use in both acute care and ambulatory care to manage utilization. The motivation for these tools and methods is frequently cost control, but the rationale can usually be anchored to a need for risk management. Common tools employed are:

- Maximum Number of Medications Allowed
- Prior Authorization based on usage criteria
- Step Therapy (ST)
- Quantity Limits (QL)
- Medication Refill Limits
- Max Dollar Limits

Of these tools, maximum number of medications, dollar limits, and refill limits are arguably intended to reduce utilization. For example, some State Medicaid programs use a maximum number of prescriptions to limit their exposure to drug spend. Unfortunately, there is little evidence of whether these limitations are sustainable, or whether patients tend to utilize alternative locations of service, e.g., Emergency Departments, to get the needed medications. Further, some programs tend to ring fence certain therapies like hypertension, diabetes type II, antibiotics, hypothyroidism, etc., to ensure that diseases and conditions that will lead to more severe problems are covered regardless of limits.

Other common tools include Quantity Limits, Medication Refill Limits and Maximum Dollar Limits that may actually decrease the size or number of prescriptions. These limits may still be overridden by prior authorization so there are no guarantees. Step Therapy directs utilization to first-line therapies that are usually less expensive, but may also be required to treat common diseases with regimens that have well documented effectiveness and risk.

The fundamental problem with utilization management tools is that while they may achieve their short-term objectives at point-of care, there is little evidence that the results are sustainable, or even that these measures improve utilization or lower cost in the long-term. There is evidence that utilization management tools shift use to preferred medications, a one-off cost reduction technique. But are the number of medications reduced, or is the patient's condition improved?

The Academy of Managed Care Pharmacy (AMCP) commissioned a study to determine the value of common utilization management tools in managed care. With the caveat that there is literature beyond managed care, the tools identified above were included in this analysis. Their findings indicated that evidence is mixed and that more research is necessary. Their conclusions:

> "There is strong evidence for the effectiveness of several managed care pharmacy tools for achieving intended outcomes such as increased utilization of preferred drugs, formulary compliance, and decreased prescription drug spending. Although these tools achieve reductions in utilization and expenditures, it is unclear whether patients are impacted positively or negatively. While some stud-

ies examine the effect of managed care pharmacy tools on medical utilization and costs, the results are mixed. Unlike other interventions, MTM interventions demonstrate improvements on several clinical measures, although the evidence needs to be expanded, especially with regard to Medicare Part D MTM programs. While there is a breadth of literature on some managed care pharmacy interventions, there are several interventions that require additional research, especially with regard to clinical and humanistic outcomes, in order to provide decision makers with a more comprehensive understanding of the value of managed care pharmacy tools."[7]

Research Opportunities

Utilization and utilization management is an approach to patient/population care improvement. Yet, the market place has generally emphasized those tools that provide some cost reduction and support benefits, i.e., formularies. Even with that emphasis there is mixed evidence that cost reductions, net of the cost of intervention, are realised. The broad employment of utilization management tools demands that they should be supported and well researched. Yet, is the emphasis on cost reduction the appropriate primary goal of utilization?

The emphasis of utilization management is different than cost reduction, if utilization is defined by appropriateness of care, the use of only those therapies with proven benefit, reduction in the use of inappropriate therapies, and risk reduction of drug-induced disease and adverse effects. New tools need to be developed and supported by evidence of their effectiveness. For example, safety and risk metrics need to be devised for population risk pools. Disease incidence may be risk adjusted by the probability of disease by age and gender banding. Further, appropriateness and selection of medications needs to be focused on those populations with a significant chance of benefit and acceptable risk. This focus requires research into current and new benefit designs as well as research into the pharmacodynamics of medications in each risk band.

Utilization is the multiplier of therapy and consequently cost. As the cost of medications rise there needs to be a recognition that alternative approaches to overall management of therapy requires new tools, refinement of current tools, and strong evidence that patient outcomes are improved in the long-term. This mandates that research must be undertaken to demonstrate approaches that achieve improvements in overall care with costa eduction being only one of the goals. Oversight of patient care must manage effectiveness, risk and cost simultaneously. More importantly, effectiveness must be maximized simultaneously with minimizing risk. This is arguably the purview of utilization. Therefore, the research possibilities are endless.

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