Editor's Note

The year 2020 marks the 25th anniversary of the *Journal of Managed Care and Specialty Pharmacy*. To commemorate this milestone, we will be publishing a series of articles that document the changes to the journal and profession over the past 2 and a half decades. Each month we will reprint an original article from a previous year, dating back to 1995.

The reprinted articles will feature topics of significance in our industry. Each reprinted article will be accompanied by a contemporary reflection that will consider the historical significance of the topic, as well as the current and future state.

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Editor-in-Chief

VINTAGE RERUN

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PRACTITIONER UPDATE

Disease State Management

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OBJECTIVE:

To explore how healthcare management has evolved from managing separate components to disease management.

DATA SOURCES:

Recent published articles and the authors' experiences.

STUDY SELECTION:

Not applicable.

DATA EXTRACTION:

Not applicable.

DATA SYNTHESIS:

Disease state management integrates services from all areas of healthcare. To evaluate whether a disease is being treated effectively, clinical, physical, and quality of life, indicators need to be measured. Protocols and intervention strategies need to be developed at minimal cost without compromising patient care. Patient and physician satisfaction need to be evaluated to measure the success of the disease management process.

CONCLUSION:

The old paradigm of component management of medical care is losing ground and being replaced by systems focused on patient outcomes as the best way to deal with the issues of access, quality, and cost.

KEY WORDS:

Disease state management, Outcomes, Costs.

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During the 1980s, the effort to control costs and maintain quality medical care depended in large part on component management—the separate management of specific healthcare components such as drug costs through formularies and price caps, and hospital costs through rate setting. None of these mechanisms has been wholly successful. It is clear that cost-effective optimal care must take into account the interdependence of components. It is very important to implement a strategic overview of cost linkages between pharmaceutical care, hospitalization, DUR/DUE, formulary management, and patient education.

Recently, practice guidelines have been suggested as an alternative that could reduce inappropriate care and maintain stable prices.^{1,2} Although still in the developmental stages, this new paradigm of managing all components of a disease simultaneously may have a significant impact on how U.S. medical care is delivered and monitored. This article will explore how practice guidelines have led to disease management strategies that may be used in the future. We

will also examine the impact of these new ideas about comprehensive medical care management on those most involved in the prescribing, distribution, and use of pharmaceuticals.

All parties involved in providing healthcare want to improve its quality. But since medical care is not free, improvement often involves increased cost. Different measures can be used to determine the benefit of the care provided. Those who advocate disease management practice guidelines suggest that improved patient care is achieved by following certain strategic steps. Practice guidelines, disease management protocols, or disease maps are of clinical benefit if they³:

improve knowledge, making clinicians aware of the recommendations; attitudes, getting clinicians to agree with and accept the recommendations as a new “standard of care”; behavior, getting clinicians to change practice patterns to conform with the guidelines; and outcomes, improving patient health, controlling costs, etc.

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Conceptually, this seems like the perfect solution to the healthcare management dilemma. On the practical side, strategies that work effectively at the micro level may be fraught with difficulty when implemented on a broad scale. This may be true of disease state management; however, as data management, monitoring, and feedback mechanisms in evolving health systems improve, this new paradigm will be a major force affecting the delivery of medical services.

COMPONENT MANAGEMENT

Component management, the prevalent approach to managing healthcare during the 1980s, focused on controlling costs within each segment of the healthcare system with little regard for the other segments. Hospitals, physicians, laboratories, and pharmaceuticals were treated as distinct entities with unique cost centers.^{4,5}

Customized management techniques were established for each component or institution to squeeze out waste and inefficiency. Each was analyzed separately, and statistical norms for each cost component were established. Rewards and penalties were used to influence providers to adhere to the norms. These mechanisms were derived strictly from economic logic, widely ignoring clinical practice. Providers were rewarded for maintaining low use of services and low costs and penalized for high use and high costs. Users of the system were motivated to worry more about costs than about patients. Clinical logic was typically circumvented, and the patient–physician relationship was minimized, diminishing the physician's effective moral authority. The introduction of management into the healthcare system began with the largest component, the hospital, and proceeded downward into the others.^{4,6,7}

The government has used component management techniques to contain hospital costs by implementing the diagnosis-related group (DRG) system, and the resource-based relative value scale (RBRVS) to control physician reimbursement. The DRG system sets flat fees for procedures.⁴ The RBRVS bases the worth of a procedure on the resources that go toward preparing the physician to be able to perform the procedure and provide the service. These resources include the physician's work, overhead, and liability, each modified by regional variances.⁸ All of these measures focus on cost, consequently ignoring the clinical benefits of particular procedures or processes and the negative consequences of the restrictions. Hospital stays may be shorter as a result of DRGs, but the effects on patients remain to be determined. Reduced Medicare fees and capitation have lowered costs, but physicians seem to be discontent.⁴

Component management techniques, reasonable first attempts to manage healthcare costs, unfortunately have not resulted in large or long-lasting savings. There are three main reasons for this lack of success in managing drug budgets and other aspects of the healthcare delivery system:^{4,5}

1. The close interrelationships among costs across components are not recognized.
2. The service component of treatment, not the disease, is

regarded as the central unit of cost.

3. Physicians are alienated from the healthcare managers.

There is still inadequate recognition of the reality that components in healthcare are interrelated and do not operate in a vacuum, so that a small change in one component may inadvertently cause a large and unexpected change in another. The rewards and penalties applied to providers or patients can actually deter coordination of care, because pressures to reduce the cost of one component (i.e., hospital days), generally results in an increase in the cost of another (i.e., physician visits). Limitations on one component may lead to increased patient morbidity and mortality, with an increase in total healthcare costs.^{4,5} The application of component management to pharmaceuticals is especially likely to be counterproductive. Medications, often the primary therapy, affect many other aspects of treatment, including hospitalization.⁵

Each disease is unique and must be analyzed differently. Diseases vary in cost structure, economic behavior, and clinical practice requirements. Each involves a variety of costs, including physician visits, hospitalization, testing requirements, drug therapies, and surgery. These are often accompanied by a loss of wages and productivity for the patient. An effective way to control costs in one disease may be very costly with another disease. Component management has traditionally been applied to all diseases without sensitivity to these unique differences. The component technique is not able to detect interactions among different cost components or manage the costs resulting from these interactions.^{4,5}

An important element in patient care is the relationship between practitioner and patient. Because physician use is often controlled in managed care, component management has been criticized for according little respect to this relationship. Managers control line items in budgets often without detailed knowledge of the medical dynamics involved in treating a patient. Thus, behavior patterns not consistent with good clinical practice are often imposed on the physician. The result may be a lack of provider confidence in management and diminished inclination to support its efforts. Physicians continue to resist any intervention in the physician–patient relationship essential to high-quality care. It is impossible to establish an effective management system that does not enlist the support of the professional healthcare community.^{4,5}

The failure of component management to reduce overall healthcare costs is illustrated by the New Hampshire Medicaid Program. A three-prescription-per-month payment limit was established to reduce drug costs an estimated \$300,000 to \$400,000 per year. The result was a 35% decrease in the use of medications, including essential medicines such as insulin, thiazides, and diuretics. These savings were offset by an increase in hospitalizations and a 50% increase in nursing home administrations.^{4,5,9}

DISEASE STATE MANAGEMENT

...A comprehensive, integrated approach to care and reimbursement based on the natural course of a disease, with treatment designed to address an illness with maximum effectiveness and efficiency.¹⁰

Component management has not been very successful in controlling the cost and quality of healthcare. Disease state management (DSM) offers a new approach that integrates services from all aspects of healthcare to improve patient outcomes and reduce the cost of treating a disease. Disease management focuses on each disease as a separate entity with distinct cost patterns that vary during its course. Each disease has a unique set of available therapies and interventions. Cost management techniques are customized for each disease and patient, not each cost component or institution. The rewards and incentives for managing costs by disease use both the clinical and economic logic. Physicians are willing to adopt disease state management protocols because they are team-driven, are built around the physician-patient relationship, and thus possess moral authority.^{4,6}

Disease Selection Asthma, diabetes, depression, and ulcers are a few of the diseases that meet the requirements for disease state management. In the selection of a disease category for management, the following criteria are important:

- ▼ The total cost of the disease.
- ▼ The prevalence of the disease in the population.
- ▼ Whether the disease can be defined by specific criteria that do not overlap into other areas.
- ▼ Whether the disease has a low incidence, with high-cost acute conditions and significant practice variations.
- ▼ Whether the disease is a chronic condition with high-cost complications and patient compliance issues.
- ▼ Whether the treatment method is known and whether it is possible to intervene.
- ▼ Whether there are opportunities to improve management of the disease, given recent clinical findings.

Diseases having been chosen on this basis, prevalence and impact per case, should ensure that their management will have the highest value.

Clinical Practice Guidelines Clinical practice guidelines (also known as protocols, algorithms, critical pathways, and care maps) need to be defined for each disease selected. Guidelines are an attempt to reduce wide practice variations and ensure quality care. The Agency for Healthcare Policy and Research (AHCPR) has issued 11 guidelines since 1989. AHCPR guidelines include consumer, non-physician and physician input, while others (e.g., American College of Physicians) include only physician providers. The common objective among guideline developers, however, is to improve healthcare provider decision-making in specific clinical circumstances.¹²

Practice guidelines help the provider understand the clinical treatment and disease process of a given disease. Uncer-

tainty and inappropriate variations are reduced; yet some variation is still allowed, depending upon a specific patient's outcome. Providers meet regularly to review guidelines and measure outcomes to ensure that the quality and cost of care are continually monitored.⁴

Patient Identification A disease state having been chosen for management, the next important step is to identify the patients who will benefit most. This can be done by analysis of patient data in large managed care databases, reviewing incidence, severity, medications, and noncompliance. Patients can also be identified through prescription claims, medical claims, or patient charts in physicians' offices or community pharmacies. Patient targeting relies on applying the practice guidelines to these databases. The clinical logic in the databases must have a strong foundation in continuous output from respected practitioners and must also be consistent with clinical outcome studies.¹³ Managed care organizations (MCOs), PBMs, and claim processors are most able to target patients because of their vast amount of medical and prescription claims information. As technology links physicians' offices, laboratories, and pharmacies into the network of information, this ability will expand tremendously.

Intervention Protocols For disease management to be successful, patients, physicians, pharmacists, and other healthcare workers need to be empowered and educated about a disease process, its treatment, and their role. Prevention, treatment, and compliance become components of the management program. Once a patient, his or her physician, and other caregivers are "enrolled" in the program, each has a responsibility for varying types of interventions. Interventions include¹³:

- ▼ Disease and severity of the illness
- ▼ Number of patients targeted
- ▼ Demographics of the patient population
- ▼ Type of managed care organization
- ▼ Data lead and lag time
- ▼ Behavioral changes desired

Types of interventions include telephone calls, letters, videotape/CD-ROM, seminars, and electronic messages. Overall, patients are expected to take more responsibility for their own disease management. The interventions are all aimed to better inform the patient and provider as they deal with the specific disease state. The challenge is to design and implement effective intervention programs at minimal cost.⁴

Outcomes Management In the context of disease management, outcomes research evaluates the effect of an intervention, whether by a product, procedure, or technology, on both health and cost outcomes. The only way to find out if a given treatment is having a desired effect is by evaluating the outcome, whether clinical (i.e., a test result), physical function (i.e., a patient can walk), or quality of life (i.e., the patient has an improved perception of well-being).¹³

Outcomes research shifts the focus from the cost containment, which attempts to minimize the money spent on one component of care, to cost-effectiveness, which ensures

throughout the healthcare system the best use of resources to achieve desired therapeutic outcomes.⁴ Superior outcomes will depend on the continuous advancement of the disease selection process, patient identification methods, updating of the clinical practice guidelines, and improvement of intervention strategies.¹³

IMPACT ON HEALTHCARE RECIPIENTS AND PROVIDERS

The movement away from component management of pharmaceutical use and toward disease management will affect to some degree all players in the healthcare market. It is instructive to consider the reaction to this revolutionary view by key healthcare participants: payers, pharmaceutical firms, physicians, pharmacists, and patients.

Payers In one sense, the introduction of disease state management strategies will be a victory for many payers. Self-insured employers, in particular, have tired of component management and have called for an outcomes approach to the healthcare provided their employees. Business coalitions, perhaps 125 in the U.S. today, representing millions of lives covered by managed care plans, have taken up the call. They are expecting accountability from the health plans they support with their medical benefit dollars.

Payers have listened to their employees' concerns about access and the quality of care. It is also clear that a healthy employee is a productive employee. Employers are beginning to consider the long-term investment aspects of healthcare and healthcare expenditures. As fringe benefits rose in the early 1980s, the component management of pharmaceuticals was compelling. Generic substitution, formulary management, and rebates promised reduction in outlays, and therefore, were strategies much used by PBMs and MCOs in controlling pharmaceutical costs for employer groups.

The concepts of management direction espoused by the total quality management (TQM) and continuous quality improvement (CQI) philosophy have fostered much discussion of the quality of medical care provided by employer-financed healthcare. Medical care report cards, clinical guidelines, and outcomes management are all part of the initial effort by payers to assess the outcomes and quality of care provided by the system. One can expect that, before the year 2000, disease management strategies mandated by payers and implemented by MCOs and PBMs will be used to control pharmaceutical expenditures and monitor outcomes.

Pharmaceutical Firms The major pharmaceutical manufacturers confronted the managed care marketplace early on by ignoring this small market segment. More recently, these firms have relied on promotion and marketing strategies used in retail and hospital environments to respond to volume purchasers and those who command market share. These strategies worked when the managed care market was small; now it is the predominant medical care delivery system, and product-focused marketing must be reexamined. Disease state management provides an opportunity for pharmaceutical manufac-

turers to reconsider how they will choose to present and market their products.

With disease state management, the pharmaceutical industry is, in fact, redefining its business. The old approach of selling products (drugs) is giving way to selling results (outcomes). In the component-based approach, the pharmaceutical manufacturer was often forced into a single option: that of competing in a price/rebate war with other products in a therapeutic category. In an industry accustomed to high product margins, this strategy is successful in the short term, but not in the long term, especially when the remaining high-margin segment is getting smaller. Incorporating the pharmaceutical product into a disease management protocol provides an opportunity for positioning the firm quite differently; newer marketing programs incorporate risk sharing, direct-to-patient marketing and sales, educational marketing to caregivers, and other innovations. Managers focus on cost-effectiveness of a product in disease state management programs.

Physicians Practicing physicians often view the ongoing expansion of practice guidelines with cynicism and mistrust. All too often, the "guidelines" are little more than thinly veiled cost-minimization strategies,¹⁴ encouraging generic/therapeutic substitution or, in the situation of the hospitalized patient, early discharge. Over the past several years, AHCPR has devoted substantial resources to the development of prescribing/treatment guidelines. Even so, many practice guidelines are viewed as "cookbook" medicine, downplaying the role of clinical judgment in the care of the patient.³ Further guidelines development will probably be carried out in each managed care institution by a committee reflecting local practice parameters. Such a committee may also be expected to exercise an ongoing management function, overseeing providers' implementation of the program.

Disease management will continue at the "theory stage" as long as attempts at managing disease are weak and unenforceable and do not include measurable and clinically relevant outcomes. Of critical importance in the movement toward an outcomes-based approach to disease state management will be the availability of reliable outcomes data from studies done at the local level. Without this, the physician will continue to view many practice guidelines as irrelevant and not grounded in practice.

One cannot therefore assume that disease state management/practice guidelines are unacceptable to the physician and destined for failure. As medical decision-making becomes increasingly complex, as new technologies emerge, and as health resources are restricted, the physician will come to expect, and at times demand, assistance in making clinical and therapeutic decisions. The question is not when disease management will be integrated into practice, but who will develop these models and whether they will be accepted and embraced by medical care providers. Absolute "musts" in the adoption of these strategies are (1) the evolution of disease management protocols, based on patient outcomes, that are not solely cost or product driven, and (2) the reporting of information back

to the provider.

Pharmacists In this era of managed care, it is challenging to consider the future of the traditional model of pharmacy practice (i.e., a community-based retail practice dependent on the providing of a product). Traditionally, management decisions in the pharmacy have followed a retailing model of inventory control and gross margin maintenance. In recent years, as pharmaceutical prices have increased and third-party fees have declined or at best, remained constant, the challenges facing the pharmacy manager have been substantial. Many independent community pharmacies have been forced to recognize that they are no longer in a margin business, but in a volume business where product turnover and customer service reign supreme. Some have been forced to close their doors.

The role and function of the traditional pharmacist in the disease state management paradigm is certainly not clear. It is evident that pharmacists in the managed care setting will play an important role in measuring and evaluating the outcomes of pharmaceutical interventions. These pharmacists contribute in no small way to the development of disease state management protocols and prescribing guidelines. And again, as data regarding the outcomes of care become readily available with increased reliability, these protocols and guidelines will be increasingly relevant to practice. The community pharmacist will need to team with the managed care pharmacist in this effort.

It is generally recognized that an informed patient is central to the success of disease management protocols. The patient's recognition of possible serious adverse effects and his or her understanding of and compliance with the medication regimen will often determine the success of a disease management strategy. The potential contribution of community-based pharmacists in this matter is not to be underestimated. Some PBMs have initially chosen to incorporate the community pharmacist in helping achieve positive outcomes. Others have chosen to bring the patient education and monitoring functions "inside," using mail and telephone strategies to educate and inform the patient, leaving little more than a distribution role for the community-based pharmacist.¹⁵ The eventual role of such pharmacists could be great if they take responsibility for patients' drug therapy.

Patients Patients become concerned when care seems fragmented. Today's patient desires care that is, or at least appears to be, coordinated. Except in some special circumstances, patients are unwilling to accept what appears to be "trial and error" medicine. From the perspective of the patient, disease management is promising only if it is not perceived as experimental or contributing to fragmentation of care. To the degree

that the opposite can be demonstrated, (i.e., programs based on sound data and clinical reasoning that foster coordinated care) the patient can be enlisted as an advocate in the development of treatment guidelines.

Under disease management protocols, patients will be expected to act responsibly with regard to their medical condition. Responsibilities may include compliance with medication and other treatment regimens, self-monitoring of disease conditions, and routine follow-up. If it is determined that they are not acting responsibly, they may be expected to assume a larger share of costs or to accept the reduction or elimination of certain benefits. Whatever the mechanism, the informed/educated patient will be expected to be responsible and share some risk in his or her care.

CONCLUSION

In the future, payers for medical care will expect development, monitoring of, and adherence to a formulized standard of practice, whether that be called disease management, practice guidelines, outcomes management, disease maps, or prescribing guidelines. In 1995, disease state management is in its infancy; from a data-integrity and integration standpoint, much is still needed before it can be fully implemented.¹⁴

To be a part of this outcomes-centered paradigm, the pharmaceutical industry must move from product-driven marketing to a marketing view based on outcomes. Firms that are successful in this effort will have the opportunity to be proactive rather than reactive.¹⁶ When disease management strategies are based on sound clinical judgment and reliable data, physicians accustomed to the managed care environment will come to value them, since they will improve patient outcomes and deliver useful feedback to the provider.

The community-based pharmacist faces a challenge under the disease management paradigm as serious as those confronting the research-based pharmaceutical manufacturers. Pharmacists will have the opportunity to change the orientation of their practices. For those who do, the future is bright.

Finally, patients under this new view of medical care, may be expected for the first time to assume some responsibility for their health outcomes. This will be viewed favorably by those who want to be proactive in their own care. Others may question treatment guidelines that include the expectation that they participate actively.

The old paradigm of component management of medical care is losing ground and being replaced by systems focused on patient outcomes as the best way to deal with the issue of access, quality, and cost. While this may be a revolutionary change in management of medical care, it promises to offer Americans maximum value for their healthcare dollars. ▲

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CONTEMPORARY REFLECTION

The Evolution of Disease State Management: Historical Milestones and Future Directions

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SUMMARY

Twenty-five years ago, the *Journal of Managed Care Pharmacy* introduced its readers to disease state management, which attempted to break the siloed culture of the U.S. health care system. Disease state management has been transformed, in part, to population health management. This shift was marked by 3 main inflection points: the rise of the web-enabled smartphone, the Patient Protection and Affordable Care Act (ACA), and the adoption of artificial intelligence (AI). The introduction of smartphones filled the communication gap through improved patient engagement and accessible mobile applications, giving patients access to their clinical data. In addition, through the ACA, bundled payment models moved away from a volume-based to a value-based payment approach and attempted to incorporate population health concerns, such as the social determinants of health. The advancement of AI will allow the health care system to collect comprehensive health data and to predict the population at higher risk. Despite these advancements, some challenges from 25 years ago remain, yet rapid technology advancements may expedite the next wave of change.

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Twenty-five years ago, disease state management sought to improve patient outcomes by maximizing the interrelationship between physicians, payers, pharmaceutical companies,

pharmacists, and patients to manage chronic conditions. On the 25th anniversary of the *Journal of Managed Care & Specialty Pharmacy*, in which Hadsall and Sargent (1995) first introduced the concept of disease state management to readers,¹ we reflect on the evolution of disease state management. We also address 3 key inflection points—the rise of the web-enabled smartphone, the Patient Protection and Affordable Care Act (ACA), and artificial intelligence (AI)—that have collectively transitioned disease state management to population health management.