

# Primer on Disease Management

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**PLEASE NOTE:** The content of the article was current at the time it was written. The exam for this article is not valid for CE credit after 09/24/2003.

## **Learning Objectives**

Upon completion of this CE program, the reader should be able to:

1. Describe the components and steps of Disease Management (DM);
2. Compare and contrast DM and traditional health care delivery;
3. Explain why employers think DM is valuable;
4. Describe the essential elements of a DM program evaluation; and
5. Discuss some barriers that must be overcome in order for DM to be successful.

**Abstract:** Since its introduction in the mid-1990s, disease management (DM) has often been a misused and much abused phrase. Nonetheless, DM can best be described as an evaluative approach to health care delivery that attempts to improve outcomes for patients with a specific disease while optimizing the overall use of health care resources. DM differs from traditional health care delivery in many ways, but, most noticeably, DM offers a broader perspective of the health care provided. Numerous organizations, including pharmacy benefit management companies, managed care organizations, pharmaceutical manufacturers, employers, and others, can have roles to play in DM programs, but a direct patient-provider relationship is a prerequisite for DM to be successful. Key components of DM programs include the following: a continuum of care perspective, focus on patient health-related outcomes, optimization of economic outcomes, use of clinical practice guidelines, focus on chronic diseases, implementation of continuous quality improvement, integrated health databases, feedback to health care providers, and an expanded role of pharmacists in drug therapy monitoring. The 8 primary steps to implementing a DM program are explained as well as the primary aspects of DM program evaluation. While DM has captured the attention of most health care organizations, the lack of rigorous evaluations of DM programs and the continued use of component management have prevented DM from being universally implemented with success.



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## **Introduction**

Disease management (DM) is an evaluative approach to health care delivery that attempts to improve outcomes for patients with a specific disease while optimizing the overall use of health care resources. DM has been widely implemented by many health care organizations since its introduction in the mid-1990s. This article describes the essential components of a DM program, the steps of DM, and how to conduct a DM program evaluation. Some of the controversies of DM will also be discussed, such as which organizations have a role to play in disease DM and barriers to implementing a successful program.

## **Primer on Disease Management**

“The direct-patient contact historically enjoyed by pharmacists places them in a unique position with regard to disease management today, enabling them to intervene with physicians to ensure proper prescribing and with patients to ensure adherence and positive outcomes.”

—Monroe and Dalmady-Israel<sup>1</sup>

Since the mid-1990s, the phrase “disease management” (DM) has been included in many conversations among physicians, pharmacists, and other health care professionals. These conversations have occurred in numerous organizations, including managed care organizations (MCOs), pharmacy benefit management companies (PBMs), pharmaceutical manufacturers, employers, pharmacies, and even health insurance companies. But what exactly is the current status of DM? Why are so many individuals and organizations claiming to be doing DM, yet, there are few rigorous evaluations of DM programs found in the pharmacy and medical literature, and traditional component management continues to be the norm for most health care organizations? This article will address these questions and will attempt to provide the reader with an overview of DM, tests of a DM program, an explanation of who is participating in DM, and a discussion of how DM differs from traditional health care delivery. The steps of DM will be described as will techniques for DM program evaluation, and, finally, some thoughts will be offered on the future of DM.

## **Disease Management: A Misused and Much Abused Phrase**

While it may seem that almost everyone is claiming to be doing DM, few people agree on what exactly is DM. In fact, the phrase “disease management” has been called among the most abused words in existence today,<sup>2</sup> and others have argued that DM is just a popular buzzword and often means what the speaker/author wants it to mean.<sup>3</sup> Complicating the situation further, other

frequently used words are often meant to be synonyms of DM: disease state management, outcomes management, health management, and patient health management.

Some state that many pharmaceutical manufacturers view DM programs as glorified compliance programs (e.g., mailing out pamphlets on compliance or on drug information) and a method to increase sales of pharmaceuticals (through increased compliance).<sup>4</sup> DM is perceived by some PBMs and MCOs to be a variation of drug utilization review and it is used as a method to control costs. Employers seem to be equally confused about what exactly is DM. A survey of 375 employers revealed that they believed mailing of educational brochures is the most common intervention in their DM programs, and few of their DM programs actually involved individual patient/case management.<sup>5</sup> One could argue whether these employers are really participating in DM at all. These are all incomplete perceptions of DM and dangerously distort people's opinions of real DM programs. These types of approaches are shortsighted and could cause DM to be just a new tool for product marketing.<sup>6</sup> The old saying "buyer beware" holds true for DM, as each program must closely undergo a content analysis to determine its real value.

### **What Really is Disease Management (DM)?**

DM can best be described as an evaluative approach to health care delivery that attempts to improve outcomes for patients with a specific disease while optimizing the overall use of health care resources.<sup>7</sup> The two essential elements of DM are contained in this definition: (1) improving patient outcomes and (2) optimizing resource utilization. The first element prevents DM from simply becoming a cost-cutting technique. In DM, patient outcomes are measured and managed. Epstein describes the relationship between outcomes management and DM:

No clear distinction can be made between outcomes management and disease management. The only distinction may be technical; DM does not necessarily require outcomes assessment but outcomes management requires outcomes assessment before implementation.<sup>8</sup>

The second element, optimizing resource utilization, may lead to decreased health care costs. This is the big promise of DM. Traditional fee-for-service structures lead to overutilization, while capitation structures can lead to underutilization and decreased access to health care services.<sup>4</sup> Currently, the financial structure in our health care system seems to be oriented toward acute medical events rather than an entire disease process. For example, financial incentives for a physician to screen for cardiovascular disease (e.g., cholesterol testing) are few, compared with the financial incentives to treat the acute medical event (e.g., cardiac bypass surgery). DM tries to correct this by looking at the big picture of a disease: medication usage, laboratory test results, emergency department/urgent care visits, hospitalizations, radiologic procedures, outpatient clinic visits, and preventive medicine. It manages health care through a system-wide approach and manages the disease rather than the health care system.<sup>4</sup>

Using this system-wide perspective, DM allows one to determine which interventions result in the greatest health care value, using the following equation:

$$\text{Value} = \text{outcome/cost}$$

The greatest value will be obtained as patient outcomes are improved and costs are minimized. Thus, when the 2 essential elements of DM are followed, in theory, the quality of health care will be substantially improved.

### **How Does Disease Management Differ From The Traditional Health Care System?**

The American health care system is primarily based on component management (e.g., separate entities often managed by different methods/players). Attempts to lower hospital costs have included reductions in length-of-stay limits for patients. Drug formularies have been created to manage drug usage and control drug expenditures. Administrators often focus on controlling costs within each individual segment of the health care system, thereby ignoring the other segments. Gonzalez and Crane argue that component management has 3 major shortcomings: (1) the close interrelationships across components are forgotten, (2) the service component of treatment, rather than the disease, becomes the focus when determining basic unit costs, and (3) the patient-focused clinicians are aligned against budget-minded administrators.<sup>9</sup>

Component-based management of health care treats pharmacy as a separate cost category, ignoring the great effects the use of pharmaceuticals can have on other aspects of health care costs. For example, vancomycin may be a responsibility of the pharmacy drug budget in hospitals, but often its relationship to the high expense of lab tests for vancomycin blood levels is often forgotten. Further, focusing solely on drugs while disregarding other related components will not work to control health care costs for long.<sup>10</sup> This argument was evidenced in the 1980s when the state of New Hampshire limited the number of prescriptions for elderly Medicaid recipients to 3 per month per person. This policy resulted in a 50% increase in the number of nursing home admissions and a 20% increase in the rate of hospital admissions, thereby increasing the entire health care expenditures, even though the pharmacy expenditures were 35% lower.<sup>11</sup> While component-based management such as this may have seemed prudent, it has not resulted in health care savings; often such methods are counterproductive because of interactions among different components.<sup>12</sup> Component-based management of the health care system causes it to become fragmented, and treatment is emphasized over prevention. If DM approaches are ignored, we can expect to see additional strategies aimed at reducing the use of pharmaceuticals as drug costs continue to rise at an alarming rate. Prescription drugs now account for up to 15% of a health plan's total budget, and they continue to increase 12% to 18% each year.<sup>13</sup>

In contrast, a DM approach looks at the big picture of health care and focuses on a whole defined population of patients that have a specific disease.<sup>14</sup> Incentives are provided for prevention and wellness, and the acute exacerbations of a disease are not the sole consideration as the whole continuum of care is considered. DM takes into account the various phases in the continuum of care of diseases, as seen in Table I.<sup>15</sup> These 9 phases do not necessarily occur in a linear order for all diseases. For example, the use of medication, including compliance issues, is important at all 9 phases. An in-depth knowledge and understanding of the continuum of care are required before DM interventions can be realized.<sup>8</sup> These interventions will differ according to diseases; therefore, the unique differences between diseases must be considered to effectively control costs.<sup>12</sup> Regardless of the disease, however, patient outcomes must be considered in all phases.

## **Who is Participating in Disease Management?**

DM program participants today are numerous and represent a wide variety of health care organizations and professionals. MCOs, including health maintenance organizations (HMOs), have been among the pioneers in DM who often have the integrated data bases needed for DM programs and who provide the direct patient-provider contact needed for DM. A 1998 survey of 79 MCO medical directors revealed that 61% of the MCOs surveyed had implemented DM programs, with 71% supporting programs for asthma.<sup>16</sup>

Many organizations either partner with MCOs or have stand-alone DM programs. Forty-eight percent of MCOs who had DM programs were partnering with one or more outside sources, including PBMs, pharmaceutical companies and others.<sup>16</sup> The majority of PBMs and pharmaceutical manufacturers have become active in DM, although both types of organizations have struggled to find their place in DM programs, as most lack the completely integrated medical data bases to implement pure DM programs.<sup>10</sup> In the mid-1990s, many of the largest PBMs were purchased by pharmaceutical manufacturers, only to be sold again within a few years. Some pharmaceutical manufacturers have formed DM divisions or have incorporated DM subsidiaries.

In the past, pharmaceutical manufacturers have claimed their drug products reduce health care costs by preventing high-cost medical care. Therefore, DM finally gives these companies the opportunity to substantiate these claims.<sup>17</sup> DM also stresses the importance of medication compliance (adherence) and thus offers an opportunity to increase product sales, where appropriate. MCOs do not appear to be hesitant to partner with pharmaceutical companies financially, as 66% of MCO medical directors agreed or strongly agreed that they would accept grants or funds from pharmaceutical companies for independent DM programs.<sup>16</sup>

Other organizations that are developing DM programs, often in a partnership with a PBM or a pharmaceutical manufacturer, include insurance companies, academic health centers, and employers. In DM, partnerships involving multiple pharmaceutical manufacturers are common, as the therapeutic treatment options in most diseases are provided by more than one pharmaceutical company, so it is difficult for one company to guarantee a high return for its partners.<sup>9</sup> The Health Plan of Upper Ohio Valley, for example, which has more than 100,000 members, is developing DM programs in conjunction with West Virginia University.<sup>18</sup> Information technology (IT) companies often provide clinical decision support software, provider profiling software, or even medical artificial intelligence applications to assist with medical decision making in DM programs.

There is a role for most health professionals in DM programs. Pharmacists have become especially involved in DM, although there does seem to be considerable confusion about the distinctions between a disease-based pharmaceutical care approach to care and DM. Over 23% of community pharmacists claim to offer at least one DM program to their patients,<sup>19</sup> and over 700 pharmacists in 27 states have passed one or more of the disease state management examinations offered by the National Institute for Standards in Pharmacist Credentialing (NISPC)/National Association of Boards of Pharmacy (NABP).<sup>20</sup> It will be interesting to see how DM progresses over the next few years, as there remains considerable debate whether DM

should be driven by providers of care (such as pharmacists, physicians, and MCOs) or IT companies and pharmaceutical manufacturers.<sup>21</sup>

### **Why do Employers Think Disease Management is Valuable?**

Two primary goals of most DM programs are to decrease inpatient costs, which comprises the largest percentage of health care expenditures, and to improve the quality of life of patients, thus allowing patients to continue with their usual daily activities, including going to work. Employers benefit greatly from these 2 goals, and are now realizing benefits of DM programs. In one national survey of 375 employers, 43% had implemented DM programs in 1998, compared with 31% in 1996.<sup>5</sup> This increase in DM programs may be owing, in part, to their belief that DM can help stem rising health costs. In 1999, the costs of employer-sponsored health plans jumped 7.3%, compared with just 0.2% as recently as 1997.<sup>22</sup>

DM also holds promise in its potential to improve overall health and, therefore, productivity, of employees. The cost of lost worker productivity is staggering. Burton and colleagues (1999) developed a measure of the productivity of employees called the Worker Productivity Index (WPI).<sup>23</sup> The WPI accounts for productivity while employees are on the job plus absenteeism and disability. Applying the WPI to 564 customer-service workers, these researchers calculated the impact of specific diseases and health risk factors and determined that the employees studied lost an average of 4.43 hours per week, most of it attributed to lost productivity, or “presenteeism.”<sup>23</sup> Those with digestive diseases lost an average of 15.96 hours per week, making it the most debilitating disease of those studied, according to the WPI.<sup>23</sup> The study concluded that while it is important for employee health programs to target the sickest patients and the ones with high costs, it is equally as important to intervene with the patients who are well and at low risk to keep them that way. Companies such as Motorola are taking these numbers to heart, as they have developed their own in-house DM programs for such conditions as diabetes, high cholesterol, high blood pressure, depression, asthma, and gastrointestinal (GI) disorders.<sup>13</sup>

### **Tests of a Disease Management Program**

To distinguish the “charlatan” DM programs from pure ones, it is necessary to closely examine the DM program in question to determine if it meets the standards of a DM program. A pure DM program should contain all of the following mandatory components and may contain several other components, described here as optional components. The components are listed and described below.

#### ***Mandatory Component: Continuum of Care Perspective***

As previously discussed, the main foundation of any DM program is that it will have a continuum of care perspective and not strictly focus on acute medical events. In reality, this philosophy can be difficult to be put into actual practice, as each component in health care is managed by different people who have different motivations and goals.<sup>4</sup> It is also important that the DM program not single out pharmaceuticals as the only intervention, but should consider nonpharmaceutical approaches to wellness and health. While there may be a great temptation to decrease drug expenditures, Halpern argues that if this is the primary intent of the program, then DM will not meet its principles (of improving patient outcomes and optimizing resource use).<sup>24</sup>

***Mandatory Component: Focus on Patient Health-related Outcomes***

A DM program must include measures of patient health-related outcomes and methods to improve these outcomes. Epstein discusses 3 types of outcome measures that may be included in DM programs:

- Clinical (clinical events, physiologic, and metabolic measures);
- Economic (direct and indirect medical); and
- Humanistic (functional status, patient satisfaction, quality of life, and control of symptoms).<sup>8</sup>

DM programs are perfectly positioned to investigate how any aspect of health care delivery may be related to patient outcomes. For example, how does medication noncompliance affect functional status? Can a screening program decrease medical costs? Does a patient education program result in fewer adverse clinical events?

***Mandatory Component: Optimization of Economic Outcomes***

Improved economic outcomes including direct, indirect, nonmedical, and intangible costs are a major incentive for organizations to become involved in DM. Harris maintains that health care costs will be decreased if the health care needs of a population are known, as is the case with DM programs.<sup>3</sup> Marwick further argues that DM is based on the principle that the actions of physicians and the resulting outcomes dictate health care costs,<sup>4</sup> and DM certainly attempts to influence those actions and outcomes.

***Mandatory Component: Use of Clinical Practice Guidelines***

DM programs should identify the factors that influence key health care costs and choices. Clinical practice guidelines are one method to influence these choices. They have been advocated to do the following:

- Reduce measurable variability in clinical practice, with the goal of improving patient outcomes or decreasing resource use;
- Create standards of care;
- Provide educational tools to demonstrate the modeling of best clinical practices;
- Provide data to clinicians on the variability of practice; and
- Enable benchmarking studies.<sup>25</sup>

Simply stated, guidelines can serve as a kind of road map upon which health care decisions are based. The guidelines should be flexible enough to allow for exceptions in treatment approaches because of patient differences.<sup>25</sup> The use of clinical practice guidelines has dramatically increased among HMOs recently, as only 33.6% of HMOs used them in 1996, compared with 76.4% in 1998.<sup>26</sup>

***Mandatory Component: Focus on Chronic Diseases***

DM programs primarily focus on costly, chronic diseases. These are diseases for which patients are easily identified and for which health care professional interventions have the potential to greatly impact health outcomes. A recent survey of pharmacists involved in DM revealed that diabetes and asthma are the two most common diseases for which DM programs are offered, as

seen in Table II.<sup>19</sup> Because chronic diseases mean lifelong costs and health care provider encounters, proper management today can mean potential cost savings in the future. The focus of DM is, most often, one of the most costly diseases, similar to the way that pharmacy and therapeutics committees concentrate on expensive drugs as a criteria to evaluate.<sup>9</sup> Some also view DM as an opportunity to view diseases as patients see them, with more emphasis on care beyond the inpatient setting.<sup>27</sup>

***Mandatory Component: Implementation of Continuous Quality Improvement***

Another important aspect of DM programs is the complete permeation of a continuous quality improvement (CQI) philosophy. There must be ongoing reengineering, reassessment, measurement, and data feedback.<sup>28</sup> DM affords a system to help measure quality and to do things right the first time. The CQI philosophy is based on the principle that it is far more efficient and cost effective to treat patients right the first time, rather than retreat, retreat, retreat. All DM participants should be trained to use CQI tools and techniques to improve the quality of care provided. To date, one of the weaknesses of those participating in DM programs has been ignoring the CQI principles of reassessment and continual evaluation.

***Mandatory Component: Integration of Health Care Databases***

In its purest form, DM necessitates the complete integration of health care data and an infrastructure to enable the study of population-based outcomes.<sup>8</sup> Without integrated health information systems, DM becomes impractical, if not impossible, and important data will be missing. For example, if the medical and pharmacy data systems are not integrated, often one will not know why a medication was dispensed. Gunter argues that DM is a data-driven activity, and any organization that is truly interested in establishing DM programs must be fully committed to integrate, at a minimum, billing, clinical, laboratory, and pharmacy systems.<sup>28</sup> This change will require a significant financial investment for many organizations but will have a payoff in the long term. There are many software products offered by outcomes vendors available to assist with data collection and analysis for DM.<sup>29</sup>

***Mandatory Component: Feedback to Health Care Providers***

Closely related to two of the previously discussed mandatory components, clinical practice guidelines and integrated healthcare databases, is the use of feedback to health care providers. The performance of physicians and other health care professionals should be compared with the clinical practice guidelines and they should receive feedback of their variance with the guidelines. By exposing physicians to the outcomes of their decisions, medical decision making and patient care should improve.<sup>3</sup> The timeliness of data is a crucial factor, as physicians will be far more impressed by data with comparisons to his/her peers from the last month than from the last year. The act of providing feedback to physicians and other health care providers has been called the most difficult component of DM programs.<sup>30</sup>

***Mandatory Component: Expanded Role of Pharmacist in Drug Therapy Monitoring***

DM programs promote an expanded role for pharmacists by targeting medication compliance and preventive care. Halpern echoes this sentiment, stating “Pharmacists must be included as integral factors in DM. DM hinges on accessibility to information in health care systems, and pharmacists are often the most accessible providers.”<sup>24</sup> More colleges of pharmacy are now promoting this expanded role of the pharmacist in their curricula.<sup>31</sup> The expanded role of

pharmacists in DM programs has some very exciting possibilities, and, currently, many colleges of pharmacy, health care consultants, and professional pharmacy organizations are training pharmacists to become active participants in these programs. These programs may be completely independent of other health care organizations, but, regardless, documentation of the pharmacists' interventions is crucial, and the more integrated these programs are with a complete health information system, the better. It is believed by many that DM could be the vehicle through which pharmacists can prove they both decrease overall health care expenditures and improve the health-related outcomes of their patients.

***Optional Component: Capitation or Risk-sharing Agreements***

Often, DM programs include capitation or risk-sharing agreements. These agreements can take numerous forms, but usually involve a single therapeutic class or disease, setting cost targets, and sharing the savings among the partners if cost targets are met. Armstrong and Langley discuss these agreements in-depth and advise that one of the most important aspects of such agreements is the clear delineation of agreed-upon targets.<sup>32</sup>

***Optional Component: Pharmacy Computer Systems that can Send/Receive Clinical and Intervention Data***

An increasingly important component of DM programs is the ability for inpatient, ambulatory, and community pharmacies to have access to clinical data and to document their interventions. Manual systems to document DM interventions and to bill for cognitive services are both inefficient and ineffective.

***Optional Component: Benchmarking with other DM Programs***

As more organizations participate in DM programs, benchmarking will become a useful tool to compare the effectiveness of various programs and to determine the best practice(s). There will certainly be competition issues that may limit benchmarking to a certain degree, although DM companies and PBMs who work with several clients will be able to apply successful techniques from one DM program to another. New opportunities for benchmarking are being made available through the Internet and new software, such as [www.trubenchmarks.com](http://www.trubenchmarks.com), [www.pharmetrics.com](http://www.pharmetrics.com), and [www.medai.com](http://www.medai.com).

***Optional Component: Joint Marketing Agreements***

Many DM programs currently include joint marketing agreements involving pharmaceutical manufacturers, often in conjunction with a risk-sharing agreement. As previously mentioned, providing feedback to physicians about their adherence to the guidelines and clinical and economic outcomes of their patients is usually a difficult step. This is a natural role for pharmaceutical manufacturers, as they already have sales forces in place that are experienced in presenting technical information to physicians and in changing their behaviors.<sup>30</sup> There are joint marketing agreements in existence today where pharmaceutical representatives inform physicians about an insurance company's clinical practice guidelines and how that physician's prescribing patterns relate to that of his/her peers. In some cases, this may occur for disease states in which the representative's company does not have any pharmaceuticals on the market.

## **How Do I Initiate A Disease Management Program?**

While there is no established methodology for DM, several authors have proposed how it should be performed, and these proposals share essentially the same steps.<sup>9,12,15,28</sup> These steps are outlined below. Pharmacists usually are not solely responsible for the development and implementation of DM programs; however, as DM programs are initiated by PBMs, MCOs, and other entities, it is critical that pharmacists become familiar with these steps of the DM development process.

### ***Presteps: Preparation for the DM Program***

In order to successfully implement a DM program, several presteps should be undertaken to ensure the program will be built upon a solid foundation. These presteps include the following:

1. A DM-friendly Organizational Culture – Administration and management support is essential, as is a “big picture” perspective;
2. Formation of a DM Team – This will be different for each disease state, but should include general practice and specialty physicians who support DM, quality improvement personnel, pharmacists, nurses, and other relevant health care professionals, health information system specialists, statisticians, and management;
3. Partner Identification – Determine if partners will be needed and select innovative partners who have a track record of previous DM program success; and
4. Identification of Health Information System needs.

### ***Step 1: Selection of Disease State***

Pre-established criteria should be in place for the selection of the disease state for the DM program. As an example, for a disease to be chosen for Lovelace’s Episodes of Care™ Program, a disease must meet at least 2 out of 5 criteria: high patient volume, high overall cost, high variation in care delivery, high risk to patients, and projected ability to make significant improvements.<sup>28</sup> Ultimately, the final decision comes down to the question, “Is this disease a problem in our patient population?”

### ***Step 2: Collection of Baseline Cost and Utilization Data***

The purpose of this step is to obtain an answer to the question, “How well are we managing this disease?” Ideally, at least 12 months of data should be evaluated for assessment of practice patterns and to identify key patient demographics and physicians who provide the care for this patient group. Opportunities for improvement should be identified and patients who will benefit the most from interventions. Sufficient data should be analyzed to identify organizational and seasonal trends. For example, if only 6 months of data were collected from January through June, an organization might improperly conclude their asthmatics were improperly managed because of an increase in the use of services, although this may be just because of the exacerbation of asthma by spring pollens.

### ***Step 3: Development of Protocols***

These protocols include clinical practice guidelines, wellness and screening programs, and administrative protocols. These guidelines are best developed at the local level with active health care provider participation, and should not be so rigid as not to allow for the variability seen among individual patients.<sup>24</sup> Clinical guidelines can be created for physicians, pharmacists, or other health care professionals.

### ***Step 4: Health Professional Education of Guidelines***

The best guidelines in the world will be useless if they are not implemented into actual daily practice. Health professionals should be educated in the use of the guidelines and should be held accountable for their adherence to the guidelines. This is, perhaps, the most crucial step, as the success of a DM program rests on the use of the guidelines by the health care professionals for whom it was created.<sup>32</sup> Education should be tailored to fit the organization, and may be accomplished through various mediums: newsletters, lectures, and personal visits from the DM team leaders. One effective way to disseminate the guidelines within an organization is to put them on-line within the computer system, so practitioners can see and use them when assessing patients, rather than having a binder of clinical practice guidelines collect dust on a shelf. Hadsall maintains that “for DM to be successful, patients, physicians, pharmacists, and other health care workers need to be empowered and educated about a disease process, its treatment, and their role.”<sup>12</sup>

### ***Step 5: Data Collection and Management***

Once health care professionals are educated in the use of the clinical practice guidelines, data should be collected to measure patient outcomes and use of health care services. Sources of data include medical claims, prescription claims, patient charts, quality of life surveys, and patient satisfaction surveys.

### ***Step 6: Interventions to High Variance Patients and Health Professionals***

In population-based medicine, intervention opportunities are sometimes best detected from the health information system, not in the physician’s office,<sup>8</sup> and DM is a prime example of this. The DM program’s health information system will allow the team to identify those patients and physicians who significantly deviate from the clinical practice guidelines. The DM team must avoid quickly punishing physicians for such practice, but should allow for patient variability and exception. The interventions to change physician practice patterns can take many forms: letters and visits to physicians, additional education through the use of audiotapes and videotapes, and financial incentives, such as making a percentage of the physician’s salary based on compliance to the approved guidelines.

Patient education is also important to alter lifestyle risk factors and to emphasize wellness and medication compliance. While targeting high-risk patients is important, it is important not to forget healthy patients as well. Because of a statistical phenomenon known as regression to the mean, patients consuming high resources will likely consume less in the future, regardless if an intervention is done or not, and low resource-consuming patients now will likely consume higher amounts in the future. A study by Rhône-Poulenc Rorer and Scott & White, a 163,000-member HMO in Texas, demonstrated this effect as the mean cost for their high resource-consuming asthmatics fell from \$1,581 per patient in 1995 to \$710 in 1996 and then to \$607 in 1997 without

an intervention. Thus, the highest cost-consuming patients should not be the only ones targeted in DM programs, although extra effort can be directed toward those patients.<sup>33</sup>

### ***Step 7: Education of Health Professionals on Benchmarking with Peers***

Whether they deviate from the clinical practice guidelines or not, all health care professionals should be given continuous feedback on how their practice patterns and outcomes of their patients compare with their peers. Health professionals who exceed benchmarks should receive positive reinforcement. The success of this step will depend, in part, on the information system used and the availability of “real-time” data.

### ***Step 8: Reassessment of DM Program***

This involves updating the protocols as needed (e.g., new drugs or procedures) and asking whether major changes are needed in the system.

## **How Do I Evaluate My Disease Management Program?**

As previously discussed, DM programs have been implemented by a plethora of organizations since the mid-1990s, and, yet, there are few rigorous evaluations of DM programs to be found in the peer-reviewed literature. There are many anecdotal reports of DM programs that have reduced overall costs and improved patient outcomes as well as many brief published reports on DM programs that have “promising results soon to be published,” but still the lack of published studies remain. Whether a DM program is being evaluated as part of a formalized research project or simply for internal CQI efforts, there is a need for a comprehensive program evaluation.

One proposed model for DM program evaluation contains 7 steps:<sup>34</sup>

1. Adopt a systems perspective.
2. Establish a framework for evaluation.
3. Identify key structures, processes, and outcomes of the DM program.
4. Develop specific performance measures for the program’s structure and processes plus its clinical, economic, and humanistic outcomes.
5. Collect, process, model, and analyze performance measurement data.
6. Compare data/results with internal and external criteria, standards, and goals.
7. Conduct a formal evaluation of how well the program met its objectives.

Additionally, there are some specific questions that can help guide the evaluation of a DM program:<sup>34</sup>

- What are the specific short-term, intermediate and long-term goals for the DM program?
- Who will be responsible for the collecting, processing, modeling, and analyzing of the data for the project, and how will it performed?
- What criteria (national standards, plan’s own data, and regional performance data) will be used to evaluate the program?

- Who will be in the study, and what inclusion/exclusion criteria will be used? How will these patients be identified and addressed?
- Identify the key factors relating to superior patient outcomes and/or optimal costs?
- Which costs will be included in the program evaluation, who will measure these costs, and how can the total cost of the disease be determined?
- What treatment practice guidelines will be used and who will be responsible for implementing them?
- What is the expected length of the program, and when will it be assessed? If the program fails to meet its goals, what specific actions will be done?

From a practical perspective, it seems inconceivable that an organization would place so many resources into the development and implementation of a DM program without placing resources into its evaluation. DM will likely remain an interesting idea and not a standard of practice if program evaluation is not readily incorporated into DM planning.

### **The Future of Disease Management**

The concept of DM has many theoretical advantages to improve health care and decrease overall costs and, as a result, it has been widely discussed in the health care community. Yet, there are some critical barriers that have prevented DM from being universally implemented and accepted. Holdford has outlined 4 of these barriers to the implementation of DM programs:<sup>35</sup>

1. **Structure of the Health Care System:** Results in part because of the short-term orientation of providers and payers. For example, an organization may claim to be interested in DM, but if it evaluates the performance of its director of pharmacy operations according to the attainment of drug budget goals, rather than overall health care costs, DM will likely not thrive in that environment.
2. **Information Needs:** Information needed to adequately evaluate DM programs is often neither available nor accessible, may be in a form that is not useful, or may be in a fragmented form. Even if the medical information system is totally integrated, there are still inherent limitations with using claims databases for population-based medicine. For example, it may be difficult to adequately assess the use of metered-dose inhalers by asthmatics because of vacation supplies, samples given out in physician offices, and patients storing inhalers in multiple locations.
3. **Problems in DM Alliances:** These problems can include risks (economic, competitive, and legal) of entering into an alliance, disputes over control of the program and the data, lack of trust between the partners, and incompatible goals. Even if the DM program is not conducted by an alliance, economic risks may develop if the program is too successful. As Harris argues, “an example of a DM program that confers an actuarial disadvantage on an organization would be a well-advertised program for AIDS, cancer, diabetes, asthma, or another serious chronic disease. Although such a program might help an organization better manage the risks of these diseases, it might also serve as magnets for persons who have them.”<sup>3</sup>

4. Limitations of Contractual Agreements: Contracts for DM programs are invaluable, but problems might still arise – organizational cultures of the partners may be different, and the MCO might not trust a DM program run by a pharmaceutical manufacturer. If a DM program is sponsored by a pharmaceutical manufacturer, but that company’s drug product is not included in the DM clinical practice guideline, then there may be difficulty completing the DM program.

Additionally, there appear to be some other hurdles that DM needs to overcome. Health professionals, including pharmacists, are still not widely reimbursed for their cognitive services provided as part of DM programs. Restrictive cost-component management strategies prevail in many circles where “the pharmacy services department of a plan typically is charged with reducing overall drug spending without explicitly accounting for the impact drugs have in reducing costs elsewhere in the plan.”<sup>13</sup> And, as discussed, there are still few rigorous evaluations of DM programs in the literature that have demonstrated that it both improves patient outcomes and reduces overall health care costs.

Despite these barriers and hurdles, there are signs that DM has, and continues to make, an impact on the delivery of health care. The percentage of health care organizations participating in DM programs continues to increase steadily. Several large evaluations are currently underway, including the Improving Cardiovascular Outcomes for Nova Scotians (ICONS) DM project in Canada.<sup>36</sup> Perhaps, most importantly, both practitioners and patients continue to be convinced that DM adds value to our health care system.

**Table I** <sup>15</sup>  
***The Phases in the Continuum of Care:  
How Diseases are Viewed by Disease Management***

<u>Phase</u>	<u>Description</u>
Disease Prevention	Includes immunizations, exercise, modification of risk factors, such as smoking and alcohol consumption
Initial Disease Awareness and Symptom Recognition	Patient seeks medical help after experiencing symptoms
Diagnosis	Diagnosis made by a health care professional.
Initial Treatment	Medical interventions to control acute symptoms
Stabilization	Acute symptoms managed; prevention begins to minimize further exacerbations
Resolution	Resolution of symptoms and maintenance therapy becomes focus; patient education emphasized
Discharge	Patient's condition and education deemed sufficient to leave acute care setting
Reintegration	Transition made to life with the disease state; support groups, home care, hospice, and rehabilitation
Maintenance Interventions	Maintenance treatment, medication compliance (adherence), patient understanding of disease state, and quality of life emphasized

**Table II** <sup>19</sup>  
*Types of DM Programs that are Offered by Pharmacists  
(of those Pharmacists who Offer at least one DM Program)*

Diabetes	63.5%
Asthma	44.2%
Hypertension	34.3%
High Cholesterol	26.5%
Vitamins/Herbal Therapies	24.3%
Osteoporosis	13.3%
Congestive Heart Failure	10.5%
HIV/AIDS	3.0%
Immunizations	3.0%

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