Case Study of American Healthways' Diabetes Disease Management Program

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Disease management has been defined as a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant (Disease Management Association of America, 2005). The purpose of this article is to provide an overview of the diabetes disease management program offered by American Healthways (AMHC) and highlight recently reported results of this program (Villagra, 2004a; Espinet et al., 2005).

INTRODUCTION

For many years there has been escalating concern over the substantial difference between how health care should be delivered to achieve the best possible outcomes and how it is actually delivered. The magnitude of this variance in care has become increasingly apparent as the body of empirical evidence documenting the problem continues to grow (Schuster, 1998; Institute of Medicine, 2001; Fisher and Wennberg, 2003; McGlynn et al., 2003). These gaps in care are so large that a panel of experts convened by the Institute of Medicine (2001) called it a quality chasm. There is also recognition that resolving this problem will require changes at multiple levels in the health care delivery system. One response to this problem has been to develop disease management programs to assist individuals with chronic conditions.

Since the inception of these programs, there has been an evolving understanding of the challenges to evaluating the effectiveness of the programs, which has driven a corresponding evolution in the methodology used for program assessment. Practical methods of evaluation have relative strengths and weaknesses. Potential threats to validity in reporting results have been reviewed with the types of bias for which to be cognizant and the method of evidence for which to evaluate (Linden, Adams, and Roberts, 2004).

AMHC

For more than 20 years, AMHC has been working with hospitals, physicians, health plans, and patients to improve health, enhance the fundamental care experience, and reduce the cost of care.

The focus of AMHC's disease management programs is to promote recognized standards of care through member and physician care-support interventions, and to assure program effectiveness in delivering health status improvement and cost reduction outcomes (Table 1). AMHC has demonstrated clinical health status outcomes and cost savings in several studies for patients with heart disease, heart failure, and diabetes (Villagra, 2004a; Espinet et al., 2005; Villagra, 2004b; Rubin, Dietrich, and Hawke, 1998; Clarke, Crawford, and Nash, 2002; Gold and Kongstvedt, 2003; Ahmed, 2004).

These programs, which predominantly target people with chronic diseases, currently reach more than 1.5 million individuals in

Table 1

American Healthways' (AMHC's) Disease Management Programs Summary Information

Target Population
- People with one or more of the following conditions: diabetes mellitus, heart failure, coronary artery disease, chronic obstructive lung disease, asthma, atrial fibrillation, chronic kidney failure, end stage renal disease, and other conditions that respond to care management support and have been shown to have significant variations in care.

Eligibility Requirements
- Patients that have one or more of the previously mentioned conditions or diseases.
- Members of a private health insurance plan that has contracted for our services.

Size of the Program and Persons Served
- 53 health plan customers including local, regional, and national carriers.
- Disease management programs provided to more than 1.5 million patients.

Length of Operation
- AMHC was incorporated in 1981 and began operation of hospital-based Diabetes Treatments Centers of America in 1983. These units focused on evidence-based care, patient education and patient self-care skills.
- AMHC developed its first disease management program for non-hospitalized diabetes patients in 1993.

Services Included Within the Program
The program services are designed to educate and support patients through structured, repeated interactions with highly trained nurses, including:
- Patient care telephone calls by nurses using computer-assisted clinical decision-support tools.
- Web-based patient education and physician information services.
- Remote patient physiological monitoring.
- Ongoing patient education including newsletters and reminder cards.
- Care coordination across specialists and with other organizations.

Payment Structure
- Charges are typically on a per disease participant per month fee that is paid based on participants identified with a specific disease.
- Diseases are in a hierarchical order where individuals are included only once for billing and reporting purposes. This approach is used to avoid "double counting" the substantial number of individuals who have comorbid conditions under management.
- In certain situations, a portion of the fee may be at risk, but this increases the base price as the at-risk portion must be covered with reserves or a reinsurance premium.

General Structure of the Program and Care Management Responsibilities, etc.
- Corporate offices responsible for development of disease management program and nurse training in disease management programs.
- Eight regional call centers staffed with respect to the targeted population's cultural and ethnic demographic.
- Identified patients are contacted by trained registered nurses who make scheduled outbound care calls to, and accept inbound calls from, eligible participants.
- The frequency and content of outbound calls is based on physician request, predictive model prioritization, patient health risk assessments, and nurse clinical judgment.
- Field-based registered nurses who interact with physicians to review cases.

Program Goals
To improve clinical outcomes, lower accumulative health-care costs and improve satisfaction of the patient and physician by:
- Reinforcing evidence-based medical care aligned with the physician's treatment plan for the patient.
- Educating patients to enable them to become more effective self-managers of their diseases.
- Supporting patients and physicians in creating and sustaining behavior changes that result in better health.

SOURCE: American Healthways, 2005.

all 50 States, Puerto Rico, Guam, and the District of Columbia with a highly personalized, patient-centric approach. Programs are designed to closely monitor patients' conditions, educate them to become more effective self-managers, and support them in effecting healthful behavior changes. Program implementation and execution include significant effort to attain local market cultural competency through careful attention to factors such as prevalent language, local diet considerations, community values, and other cultural and social norms. While providing services to all individuals in the program, those with the greatest risk for future medical complications are identified

with a predictive modeling tool and targeted to receive additional interventions designed to reduce the risk of avoidable costly events in the future (Baker, 2002; Ash et al., 2001).

AMHC's programs achieve savings not by restricting access to care, but rather lower costs by bridging gaps in care and helping participants better adhere to their physician's plan of care and evidence-based standards of care pertinent to their disease(s). This approach leads to improved health and delayed onset of complications and comorbidities, resulting in less demand on the system and lower cost. Improved beneficiary health status is achieved by assisting beneficiaries to better self-manage their chronic conditions, through continuous education and support, setting of attainable goals, telephone and remote monitoring and, when warranted, by intensive coordination of services.

PROGRAM ORIENTATION

Initially AMHC, like other early disease management organizations, focused on a single disease. As various disease management programs began to mature, it was recognized that many patients with the index condition had important comorbidities (Villagra, 2004b). Critics of these early programs raised concerns about neglect of comorbidities and fragmentation of care, especially when different disease management programs were offered by separate entities (Anderson, 2002). Over the subsequent years, AMHC has added other targeted diseases and transitioned from a disease-centric to a patient-centric approach. As such, common comorbidities are addressed even when AMHC is contracted to provide only a single targeted disease program.

These programs are designed to promote patients' understanding of their diseases, educate them to become more effec-

tive self-managers, and to support them in creating and sustaining the behavior changes that result in better health. Education and coaching are accomplished by nurses through telephone outreach that includes a focus on positive lifestyle changes, goal setting for behavior change, and development of patient self-care skills that promote greater patient control and graduated autonomy. While the patient recognizes this as a trusted and accessible source of education and support, the relationship is designed to avoid the creation of a new dependency on the health care system. Eighty-eight percent of randomly surveyed members reported being very satisfied with "…how well the program helps you be in control of your health care…" and 86 percent reported being very satisfied with "…how well the information supplied by the program helps you to manage your condition…" (American Healthways, 2004).

AMHC's programs are also designed to help the patient assist in, and coordinate, their medical care in a highly fragmented health care system. Patients are encouraged to maintain personal health and medication/allergy summaries that improve the efficiency and effectiveness of information flow between physicians in the absence of a common medical record. The informed patient is more likely to ask the right questions of their physicians, demonstrate improved adherence to care plans and make changes in behaviors that impede the course of their chronic disease (Maljanian et al., 2005).

Outcomes are only partially driven by the clinical or medical issues that a patient faces. Psychosocial and other life issues are important drivers of inappropriate utilization of medical services (ten Brinke et al., 2001; Simpson, Carlson, and Trew, 2001; Keenan, Marshall, and Eve, 2002). Our nurses are trained to listen carefully to

what a patient says about his life circumstances and recognize how these issues might affect a patient's health. In addition, our nurses are trained to help recognize depression in patients, allowing for earlier detection and treatment in a disease management population (Badamgarav et al., 2003).

The tool by AMHC that makes nurse interaction efficient, consistent, and scalable is a proprietary Microsoft® Windows®-based client-server clinical information application called Population Works℠ (PopWorks). PopWorks incorporates clinical logic to guide the nurse's interaction with the patient. The logic incorporated into this system is based on the concepts of the practice of evidence-based medicine. The practice of evidence-based medicine means "…integrating individual clinical expertise with the best available external clinical evidence from systematic research…" (Sackett, 1996). Clinical expertise includes "…thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care…" (Sackett, 1996). Part of the distinction is that purely creating logic built around standards of care for single diseases can create recommendations or interventions that are contraindicated in the presence of another disease or are unlikely to be followed considering social or cultural factors.

As the nurse is speaking with a patient, data are entered into PopWorks. A unique set of interventions consisting of scripted talking points and possible goals to be considered are dynamically created and prioritized for that individual in real time. These interventions can be tailored to a specific cultural and/or social environment.
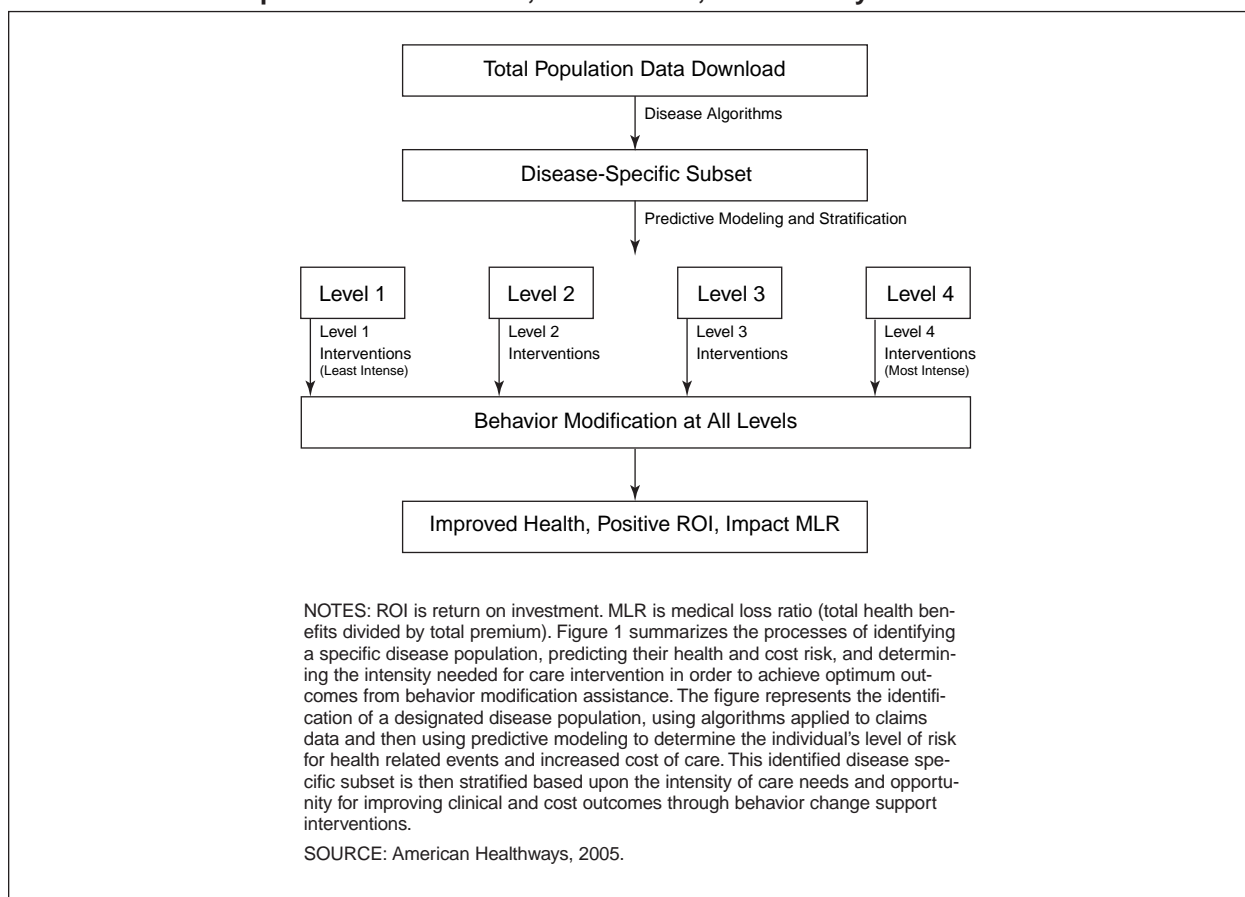
Patient Identification and Segmentation

Patients eligible for disease management programs have one or more of the defined conditions or diseases and have health service benefits provided by either a government-sponsored or private health insurance plan that has contracted for AMHC services. Specific individuals are identified using disease-specific algorithms which employ ICD-9-CM (Centers for Disease Control and Prevention, 2005) coding, *Current Procedural Terminology* (CPT®) (American Medical Association, 2005) coding, and when available, pharmacy data. These algorithms are set to minimize false positives and maximize sensitivity.

Analytical techniques with predictive modeling are then used to help further segment the population and identify those individuals at increased risk of medical complications (Figure 1). This enables the provision of targeted preventive interactions with the goal of greatly reducing, or altogether avoiding, costly health-care episodes. Technically, predictive modeling identifies individuals at risk of adverse health events and outcomes by applying analytical techniques such as linear or logistic regression analyses, classification/decision trees, or neural networks (Lacson and Ohno-Machado, 2000; Snow et al., 2001). AMHC uses neural network techniques, which are derived from theories of human cognition and employ non-statistical algorithms to explain or predict variations in data. This technique provides high predictive power based on the capacity for incorporating complex categorical data and non-linear continuous data (Crawford et al., 2005).

The key to creating significant beneficial population outcomes is to engage a large enough number of individuals with the

Figure 1
Population Identification, Stratification, and Pathway to Outcomes

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NOTES: ROI is return on investment. MLR is medical loss ratio (total health benefits divided by total premium). Figure 1 summarizes the processes of identifying a specific disease population, predicting their health and cost risk, and determining the intensity needed for care intervention in order to achieve optimum outcomes from behavior modification assistance. The figure represents the identification of a designated disease population, using algorithms applied to claims data and then using predictive modeling to determine the individual's level of risk for health related events and increased cost of care. This identified disease specific subset is then stratified based upon the intensity of care needs and opportunity for improving clinical and cost outcomes through behavior change support interventions.

SOURCE: American Healthways, 2005.

targeted disease(s) irrespective of their personal motivation to engage in self-care. In our experience, this goal is achieved through an engagement process, in which every identified patient is automatically included in the program. We contact all patients. They can opt-out of the program or limit the type of contact to mail or telephone calls only. Typically, only 4 to 7 percent opt-out or limit the type of program interactions, and patients are not excluded from the program, regardless of severity of disease or number of comorbidities The patient is engaged by leveraging effective behavioral health approaches to behavior change such as Prochaska et al. (1992) trans-theoretical model. By undergoing comprehensive training on Prochaska's stages of change, AMHC's clinicians are prepared to appropriately classify how amenable a person is to making a positive lifestyle change at a particular point in time. As a result, interventions are more specifically tailored to a person's personal preferences, thus increasing the likelihood that an individual will be successful in enacting behavior changes.

Integrated Medical Management

The program is designed to be integrated into the customer health plan's medical management program. The flexibility and scalability of the program allows for integration with a wide variety of management options such as case management, utilization management, and/or precertification functions to provide a comprehensive and

fully integrated medical management program for the population. In addition to integrating with existing internal programs, relationships with outside vendors such as pharmacy and behavioral health companies are also established.

Disease Management as a Total Population Management Tool

AMHC's program is a management tool as opposed to an extra benefit. A benefit approach often equates to a voluntary or enrollment model for participation. Reliance on an enrollment model imposes the burden on the patient, resulting in very low participation and leaving the non-enrolled without the benefit of disease management support. Paradoxically, those with the greatest need are most likely to be those who are least likely to enroll in care management services or seek disease related information specific to personal conditions (Elliott, 1995; Garay-Sevilla et al., 1999).

An engagement approach is a total population approach that captures the diagnosed-but-currently-healthy patients in addition to the very ill patients. Utilizing a total population approach improves member health status in the short term and delays or prevents the onset of complications in the medium and long term.

Prevention Among the Chronically Ill

All forms of prevention are incorporated into the program—primary, secondary and tertiary. Age- and sex-appropriate primary prevention is taught and encouraged through an online risk assessment tool available to the diseased population as well as a payer's total population. Risk factor modifications for the index disease, as well as common comorbidities of that disease are also addressed. Appropriate treatment to limit event recurrence and disease progression, such as use of lipid-lowering agents, are encouraged by educating the patient regarding benefits of treatment while alerting the physician when such gaps in care are suspected.

PHYSICIAN PARTICIPATION

Prior to engaging patients in the disease management program, we establish a local or regional Physician Advisory Council made up of local physician-opinion leaders. After Physician Advisory Council members are introduced to the disease management program, they continue to meet quarterly to review local activities and outcomes, and provide suggestions and feedback to improve the program.

On commencement of the program, physicians are notified which of their patients will participate. They also are provided sample patient materials so they will be aware of the information their patients receive. Historically, these materials are well accepted by physicians as they conform to widely published and accepted clinical guidelines. Based on a randomly administered satisfaction survey to participating physician providers, 75 percent stated they were very satisfied with "…the program's impact on your patient's knowledge about the disease…" (American Healthways, 2004).

In addition, we foster physician participation by providing nurses within the community to visit physicians to explain how the program may help address or support a specific patient's needs. These nurses also are trained to provide academic detailing regarding evidence-based medical care. The absence of an ulterior motive of selling products, such as pharmaceuticals, allows for the development of a trusting relationship with the physician.

AMHC provides tools and information to physicians in a non-intrusive manner, respecting their individual desire to participate at

whatever level they choose. Once informed about the programs, our goal is for physicians to view our services as a resource, and not as additional work. We feel we are achieving this goal, as 74 percent of physicians surveyed marked very satisfied with "…the overall benefit of this program to your patients…" (American Healthways, 2004) on the randomly administered satisfaction survey for providers. Interactions with physicians include mailings (introductory letters, quarterly newsletters, standards of care flow sheets and patient reports) and telephone conferences regarding patient-specific issues. These issues may include a significant change in symptoms, possible medication errors or urgent/emergent conditions. AMHC Web-based tool (e-Resident) also is used to give physicians secure access to information about individual patients. This is presented in a format that was designed by practicing physicians.

Physician's Payment

AMHC's programs do not provide direct financial compensation for physicians. Any change in the physician payment methodology or fee schedule is handled by the health plan.

It is recognized that there are important physician activities surrounding coordination of care that would further amplify the effectiveness of disease management programs. A criticism of disease management is that there may not be appropriate compensation for the doctor's participation in disease management activities. Some payers are experimenting with physician incentives to achieve better alignment with goals of the disease management programs. For example, physician incentives can be linked to greater participation with our program and to achieving specific clinical performance targets.

PROGRAM RESULTS

The current disease management literature has defined standard parameters for designing a disease management product and for measuring the outcomes from these products. (Linden et al., 2004; Disease Management Association of America, 2005). AMHC references these standards as their products are enhanced, deployed, and outcome results measured. Linden et al. (2004) provides an excellent roadmap for disease management organizations in providing the tools to accurately assess effectiveness and to minimize threats to validity of program outcomes. Potential threats to validity in reporting results are listed with the types of bias for which to be cognizant and the method of evidence for which to evaluate. AMHC uses these methods and those proposed by the DMAA 2004 Consensus Guidelines on Measurement to accurately report outcomes. AMHC will use a prospective random controlled trial (RCT) design as defined by Medicare to evaluate outcomes with the 2005 Medicare pilot project. The CMS chronic care improvement projects will be the first truly random controlled studies of the outcomes for disease management programs, assuring validity and generalization of the results. AMHC will participate in two of the chronic care improvement project pilots starting in August and September 2005. These Medicare RCT pilots will contribute to the disease management community's body of knowledge regarding the advancement and dissemination of disease management best practice for a Medicare fee-for-service (FFS) population.

Several different measurement methodologies have been used to assess the effectiveness of disease management programs. Three primary metrics are:
- *Quality of Care*—How many patients are receiving exams and tests as outlined in

the standards of care for their diseases/conditions? Does disease management have an impact on patient compliance?

- *Proxies for Health Outcomes*—A report on hospital and emergency room utilization rates as proxies for unwanted health outcomes (i.e. decreased bed days, emergency room visits, length of stay, lab values).
- *Cost Measures*—Have the programs lowered the total health-care costs of the population?

AMHC uses a total population approach that includes all patients in a population with the targeted diseases or conditions into the denominator when calculating cost and quality measurements. Such a measurement methodology focuses on the total health and cost of the population while reducing bias that can be introduced by measuring subgroups of a population. Reported outcomes consist of clinical metrics reflecting adherence to evidence-based standards of care, financial improvement, and program satisfaction from the perspective of the patient and the physician.

In addition, financial officers in payer organizations commonly review AMHC's program outcomes. For that reason we have submitted our results for independent third-parties audits by firms such as Ernst & Young (Hoffman, 2001).

MEASURING OUTCOMES

In the absence of a RCT, the preferred method by which to measure and report the impacts of a disease management program remains controversial. Common methods involve a pre-post or parallel group methodology.

The pre-post design compares populations of individuals with a specific disease at different points in time. With this approach, it is necessary to correct for inflation in medical cost and utilization over time. This can, however, introduce biases. Additionally, bias is introduced by the natural tendency for high-cost patients in the base period to have lower cost in the followup period, and vice versa. This phenomenon has been previously described as regression to the mean (Welch, 1985). While the study of parallel groups can address both of these problems, it must be corrected for variances in demographics and comorbid disease frequency in different populations. Despite the existence of the regression to the mean phenomenon in disease management research, studies that have compensated for this continue to find a decrease in health care costs in chronic disease management (Tinkleman, 2004).

Of particular interest is the article by Villagra and Ahmed (2004), where these two different methods for calculating disease management program effectiveness were compared across 10 urban centers engaged in AMHC programs. A staggered implementation of disease management over a 3-year period created natural experiments that allowed a comparison of disease management versus no-disease management site pairs, matched by regional proximity and dates. Standard statistical correction for case mix, shifts in demographics, and comorbidities were made before analysis.

In the pre-post comparison, the average cost of the 10 sites during the intervention period was 8.1 percent less than in the baseline period (p<0.01). Results from all five-site pairs of the parallel groups were aggregated into intervention and control groups. Overall cost per diabetic patient of the intervention group was $417 compared to $554 in control sites (24.7 percent lower, p<0.0001). Pharmacy cost behaved paradoxically showing an increase in the pre-

post comparison and a decrease in the parallel group analysis. Further study is planned to understand this observation.

Quality outcome indicators showed higher scores in the intervention group compared to control sites and baseline period. Differences reached statistical significance for dilated retinal exam, microalbumin testing, lipid screening, and tobacco use. A positive trend was observed in HbA1c testing and prescriptions for angiotensin converting enzyme inhibitors or angiotensin receptor blockers.

In summary, analysis of both the pre-post and the parallel group designs demonstrated positive clinical and financial results of the AMHC disease management program.

In the retrospective study conducted by Espinet et al. (2005), the impact of disease management programs on diabetes-related Health Plan Employer Data and Information Set (HEDIS®) quality indicators from 20 health plans was examined. (In this multistate study, AMHC disease management programs were purchased for only a segment of the population (the health plan's fully insured members and those self-insured employers electing the disease management program). These health plans, seeking National Committee for Quality Assurance (2001) (NCQA) accreditation, collected, and subsequently reported HEDIS® 2002 results using standard NCQA methodology. The six diabetes-related HEDIS® measures analyzed were: (1) HbA1c Testing Rate, (2) HbA1c Control Rate, (3) LDL-C Screening Rate, (4) LDL-C Level Rate, (5) Eye Exams Rate, and (6) Nephropathy Monitoring Rate. Patient records were selected randomly for detailed review without regard to participation in the disease management program. Of the 7,993 members reviewed, 61.8 percent were full participants in the disease management program, 28.5 percent were non-participants,

and the remaining 9.7 percent were classified as partial participants. Full participants were defined as participating in the disease management program for more than 6 months, while partial participants were engaged 6 months or less.

HEDIS® metrics were then examined with respect to each patient's participation in the disease management program. The overall national compliance rate across all six HEDIS® quality measures for diabetes was statistically higher among full participants than non-participants ($p<0.001$). Although results from partial participants fell between the rate of full participants and non-participants, they did not exhibit a statistically significant difference from the non-participant with the exception of dilated retinal exams ($p<0.001$) (Espinet et al., 2005).

In summary, this analysis demonstrates that AMHC disease management programs are associated with significantly better HEDIS® quality metrics as assessed by a random sample of members. It also demonstrates that involvement in the program for longer than the initial 6 months is associated with incremental improvements in these quality indicators.

CONTINUED EVOLUTION OF DISEASE MANAGEMENT PROGRAMS

Although the two reports discussed here demonstrated innovative ways in which to validate the effectiveness of a disease management program, these approaches are not practical methods by which purchasers of disease management can assess their individual experiences. Traditional methods in use are widely recognized to be susceptible to biases such as asymmetric cost distributions and regression to, and progression from, the mean phenomenon. Determination of medical-cost trend also remains controversial. To address these issues, researchers at Johns

Hopkins University are working on an updated methodology that will extend the Hopkins Standard Outcomes Metrics and Evaluation Methodology published in 2003 (American Healthways, 2003).

In addition, AMHC will be participating in a prospective RCT study as design by CMS to evaluate outcomes with the 2005 Medicare Health Support program. The results of these studies will contribute to the disease management community's body of knowledge regarding the advancement and dissemination of best practice for a Medicare FFS population.

Further evolution in the delivery of disease management services is likely in the foreseeable future. Research examining the impact of a patient's receptivity to disease management health care messaging is underway. This analysis will likely provide greater insight into which components of a disease management program are most effective at creating positive behavior change in various types of individuals. Future disease management programs may tailor the interventions for each patient based on that individual's health care messaging archetype.

Finally, other changes will target enhancing the physician practice-disease management information exchange and care plan integration. Pilot projects are underway examining novel ways in which disease management programs can have more impact at the point of care. Involvement by the disease management program at this point in the care delivery system affords the greatest opportunity to transfer information in a timely and effective manner while assuring that the program is fully aware of how it can best support and amplify components of the physician's care plan.

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