DISEASE MANAGEMENT: A CASE FOR COST EFFECTIVENESS AND QUALITY CARE

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Summary

- The increasing prevalence of chronic diseases in India
- Overview of Disease Management
- Evolution and current state of Disease Management globally
- Value Proposition and actuarial issues in estimating ROI from Disease Management programs
- Overview of Disease Management in India
- The outlook for Disease Management in India

In the first section the paper will provide an overview of the concept of Disease Management and detail the evolution of Disease Management Programs internationally.

The second section details mechanisms for measuring the financial impact of Disease Management programs and the final section will discuss current programs in India and the possible road ahead.

India's Chronic Disease Burden

The significant economic growth in India over the last decade has left the healthcare system struggling to keep up with the demands of an increasingly sophisticated and empowered population. Over this period changing lifestyles, high stress levels and a sedentary work culture has shifted the disease burden from infectious to lifestyle diseases such as diabetes, cardiovascular diseases and chronic respiratory diseases. This chronic disease burden is significant and rapidly growing:

- India has over 35 million people with diabetes
  - a number that is predicted to increase to around 80 million by 2030
  - diabetic nephropathy[1] is expected to develop in 6.6 million of the 35 million patients suffering from diabetes.
- According to WHO reports the number of people with cardiac ailments in India is growing alarmingly
  - if unchecked, 50% of the world's cardiac cases will be from India by the year 2012.
- The number of people in India with hypertension is expected to see a quantum leap from an estimated 118.2 million in 2000 to 213.5 million in 2025.
- The projected foregone national income for India due to heart disease, stroke and diabetes during the period 2005 - 2015 is estimated to be more than $200 billion.

The healthcare delivery system with its focus on the treatment of acute conditions rather than preventive care is poorly equipped to deal with the treatment for these chronic conditions. A reimbursement system that favors expensive treatments in high-cost institutional settings over less expensive treatments in lower-cost community settings has developed and without incentives to treat all aspects of chronic conditions, health care is uncoordinated, wasteful and lacks continuity.

There is very poor patient-compliance in India with effective treatment regimes. In spite of the fact that individual households bear 70–75% of healthcare costs there is demonstrated poor patient compliance to therapy adherence. In a study conducted by The Tribune – NCR Edition on therapy compliance, it was estimated that:

- only 1/3rd comply fully,
- the other 1/3rd comply only partially, and
- 1/3rd did not comply at all.

World Health Organization (WHO) publications support these findings as they predict that more than 50% of the medicines prescribed are not taken at all. In large scale studies of diabetes, hypertension and hyperlipidemia, it was evident that in spite of a higher incidence of these conditions and their associated complications at a younger age in India, only 4% patients followed dietary advice and 55% had uncontrolled clinical outcomes. Monitoring follow-up is also difficult in the Indian healthcare system.

Well designed Disease Management (DM) programs would provide a major step forward in addressing the challenges India faces in meeting its growing chronic disease burden.

If experience in the rest of the world is a guide we believe that India is at the early stages of the development of a significant DM industry. As in other countries, actuaries will likely be called on by stakeholders in this emerging industry to assess the effectiveness of these programs.

[1] Diabetic nephropathy is damage to kidneys caused by diabetes.

In this paper we will provide an overview of DM programs, discuss the industry in other countries, particularly the United States of America (USA), which has led the world in developing stand-alone programs focused on the treatment of chronic conditions. It also describes some of the analytical challenges faced by actuaries in assessing the effectiveness of DM programs. We believe this will provide valuable lessons for Indian stakeholders as the local DM industry develops. A brief overview of the DM industry currently in India is explained thereafter

Overview of Disease Management (DM)

DM is a process of reducing healthcare costs and/or improving quality of life for individuals by preventing/minimizing the effects of a disease, usually a chronic condition, through integrative care.

DM identifies those suffering from (or at risk for) a chronic condition and encourages their compliance with evidence based protocols through a variety of out-reach activities (typically the use of nurse call centers, websites and mailings). DM programs may incorporate all parts of the health care system, including hospitals, physicians, nurses, laboratories, and pharmacies. Most commonly selected chronic illnesses for disease management programs have included asthma, diabetes, congestive heart failure, and coronary artery disease. They have also included other respiratory diseases, arthritis, depression, HIV/AIDS, and hypertension. For example, in diabetes management the program would be designed to manage the disease itself, as well as the complications, such as cardiovascular illness, renal disease, eye disease, and others. It would include patient education and interventions to ensure compliance with self-care, such as diet and medication, as well as compliance with routine medical care, such as blood sugar, eye and foot exams.

The objective of a DM program is to keep the disease progression in check and reduce the likelihood of preventable exacerbations such as acute hospital based interventions which can be far more expensive than the DM services. It offers the enticing value proposition that the quality of health care will increase as patients improve compliance with evidence based guidelines, and that costs will decrease by eliminating unnecessary treatments and avoiding costly acute events.

The benefits to the various stakeholders include:

- Individuals
    - Improved quality of life
    - Greater convenience e.g. services at home
    - Reduced costs e.g. from unwarranted use of acute services
- Government
    - A healthier more productive population
    - Reduced spending on healthcare
- Health plans and other payers
    - Reduced costs
    - A competitive differentiator
- Healthcare providers
    - Improved compliance with best practices
- Pharmaceutical Companies (Pharma)
    - Increased sales
    - Improved public relations

Global Evolution of Disease Management

We discuss the evolution of DM as we believe it provides a number of lessons for stakeholders as the industry develops in India.

History

DM began in the USA in the early 1980s with the development of programs and infrastructure that enhance patients' ability to appropriately manage their conditions (diabetes in particular). A number of staff/ group model HMOs[2] with multi-specialty physicians using common guidelines and protocols (e.g. Harvard Community Health Plan and Kaiser) embraced the concept. Pharmaceutical companies quickly identified it as a way to promote and sell drugs. Pharma invested heavily in the development of programs but payers came to view them as self-serving promotion of brand drugs. Several entrepreneurs stepped in during the mid-1990s to develop independent Disease Management Organizations (DMOs) that have since grown into a $2 billion a year industry.

The early DMOs typically focused on a single disease and sold services based on extremely optimistic projections of cost savings from their program. Surviving DMOs have since evolved to provide programs that span numerous diseases and comorbidities and most recently wellness programs to reach the healthy and those at risk of developing chronic conditions because of family history and life-style issues.

While DMOs have been increasingly plagued by the lack of unequivocal evidence supporting cost savings from their programs, the management and prevention of chronic conditions is still widely accepted as being the single largest opportunity to improve health care quality and reduce costs in the USA.

In the last decade, DM programs have become an established and growing part of the health care landscape in the USA with the advent of Federal and State DM mandates, widespread employer and benefit consultant acceptance, a growing number of pay for performance (quality) initiatives and the development of national standards for DM services; still millions of patients and many diseases remain untouched by DM. Purchasers of health care benefits have established DM/Wellness services as a competitive necessity and are considering how to expand DM and wellness programs and integrate their delivery with other medical management initiatives.

Many countries have been closely following developments in DM and wellness in the USA and have imported many of the tools and approaches developed. In addition many of the USA DMOs have established partnerships and operations in other markets.

[2] A corporation that is financed by insurance premiums and has member physicians and professional staff who provide curative and preventive medicine within certain financial, geographic, and professional limits to enrolled volunteer members and their families typically on a capitated basis.

DM and Key Healthcare Issues – Cost and Quality

We focus attention on developments in the USA because it has the most advance market for most DM and wellness services and it has often served as a leading indicator of global trends in DM. However, the issues we discuss are relevant to most other markets.

Over the past ten years, DM has established itself in the USA as a medical management service that can potentially reduce medical cost trend and improve health outcomes. Two seminal reports from the Institute of Medicine, *To Err is Human (1999)* and *Crossing the Quality Chasm (2001)*, brought the poor quality of healthcare into the forefront in the USA. More recent studies cite the magnitude of healthcare quality issues including a study published in Health Affairs (Schoen, 2006) reporting numerous statistics of poor quality. These include:

- Only 49% of adults received recommended screening and preventive care
- Only 58% of adults with chronic conditions were given a self management plan
- Only 66% of adults have accessible primary care physicians
- 26% of adults went to the ER for conditions that could have been treated by an outpatient physician

Significant unnecessary variation in health care practices continue to be highlighted in the latest Dartmouth Atlas report, indicating a lack of evidence based medical practice by many medical practitioners (The Dartmouth Atlas of Health Care, 2006).

In addition, the health status of Americans is reported to be declining, fueled by the obesity epidemic (rise from 19.4% of the adult USA population in 1997 to 26.4% in 2006) and the associated and alarming increase in diabetes (5.1% in 1997 to 7.8% in 2006) (CDC 2006 National Health Interview Survey). A National Business Group on Health report indicates 60% of healthcare costs can be attributed to preventable healthcare problems that are caused by lifestyle related issues. Poor control of chronic diseases is also worrying, with reports based on the National Health and Nutrition Examination Survey (NHANES) indicating that 67% of those with high blood pressure do not have their blood pressure controlled (BP < 140/90) and 48% of diabetics do not achieve blood sugar control (Hb A1C < 7%) (2007 Milliman analysis of NHANES 2003-2004).

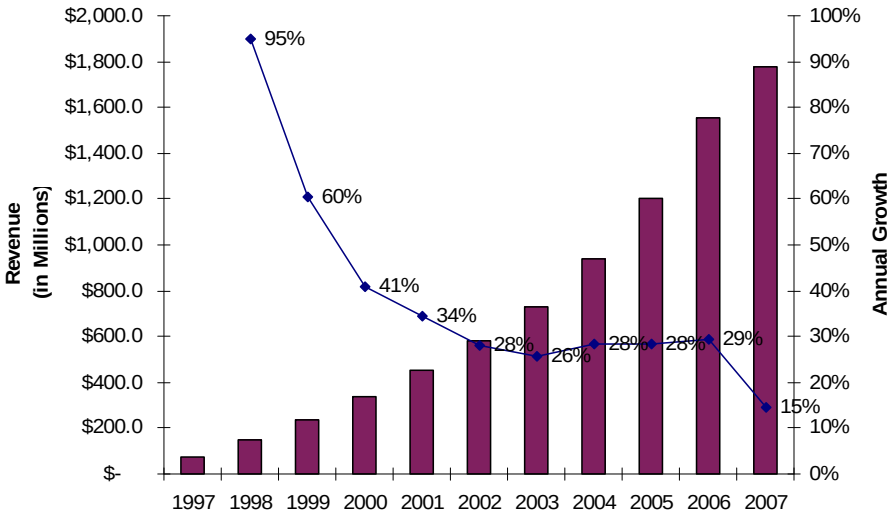
In response to these cost and quality concerns, the paradigm for healthcare delivery is shifting from a reactive, acute care disease state delivery model to a proactive care enhancement, preventive health care delivery model. The core competencies of DM and wellness initiatives fit well with this proactive, preventive model and position the DM industry well as a provider of services that can effectively respond to these cost and quality issues.

Similar declines in health status and an increased focus on the poor quality of healthcare has occurred across the globe.

The Market for DM

In the USA stand alone DMO industry revenue has grown from $78 million in 1997 to nearly $1.2 billion in 2005 with projected growth to $1.8 billion by 2008 according to the Disease Management Purchasing Consortium (DMPC). Since 2002, annual growth in DMO revenue has leveled off at approximately 25%. The current market for DM in the USA is considered by many to be markedly under-penetrated.

Estimated Annual Disease Management Revenues (Estimates for 2007)



Source: Disease Management Purchasing Consortium

In other markets the provision of DM services is not as widespread and the cost of providing DM services is typically not reported separately.

Key Healthcare Trends Driving the Continued demand for DM/Wellness like Services

In most countries, the issues of rising medical costs, poor healthcare quality and the declining health status of citizens increasingly dominates the political and social agenda and we believe that a number of key healthcare trends will result in continued growth in the demand for DM and wellness like services. Again, although most markets are experiencing similar trends we focus on the USA because it has the most mature market for DM services.

Consumerism

Increases in healthcare costs have driven a move towards empowering consumers to be more involved in their healthcare. Consumerism is driving the need for tools to assist consumers in making decisions on how to spend their healthcare resources efficiently and fits well with DM services.

In the USA the emergence of Health Savings Accounts (HSAs[3]) and Health Retirement Accounts (HRAs) has further shifted the financial impact of healthcare decisions onto consumers under the (*still unproven*) premise that empowered, informed consumers will make more cost effective health care decisions. HSAs in conjunction with high deductible health plans grew 43% in 2007 to total 4.5 million insured lives. The discussion on consumerism has filtered over into the broader commercial and Government markets (Medicare[4] and Medicaid[5]). For example, the launch of a Medicare website in September 2006 "My Health My Medicare" that in addition to its primary focus of Part D assistance, allows seniors to create personal health profiles.

Preventive Care/Wellness

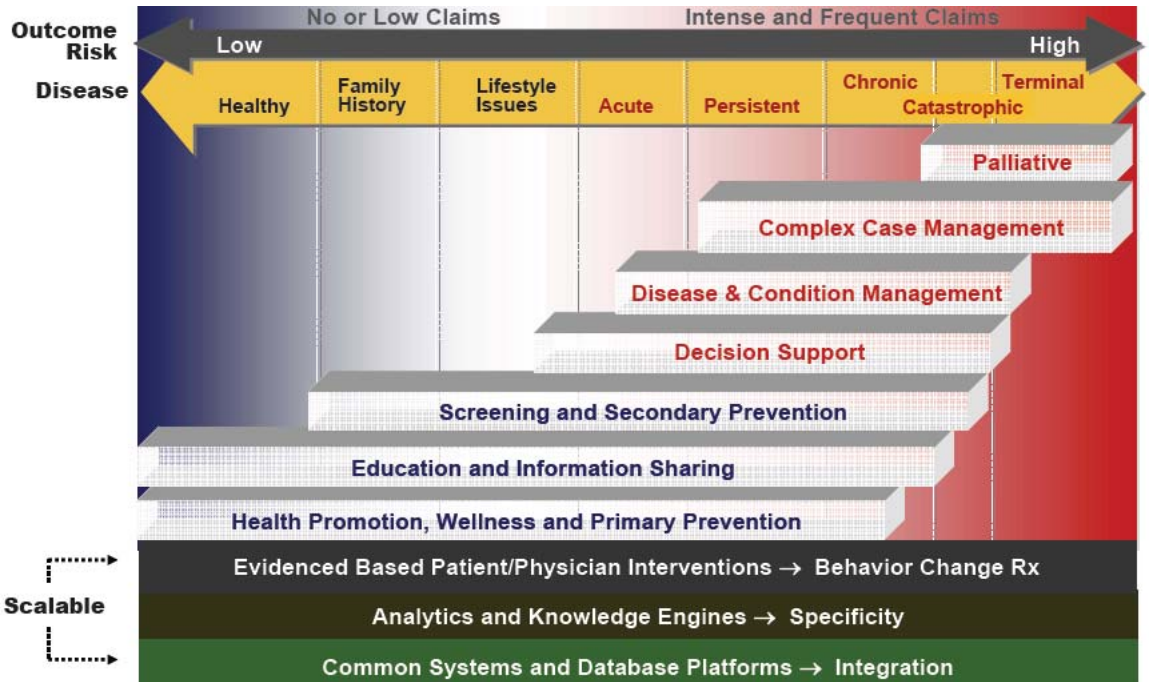
In many countries across the globe, the national discussion is focused increasingly on the alarming rise in the numbers of citizens suffering from costly lifestyle dependent chronic conditions (particularly diet and obesity) and the important role of prevention and wellness in helping to solve the country's healthcare problems.

In the USA, the current discussion is still limited to "better health reduces costs" without addressing the more difficult question of preventive care often increasing costs unless it replaces existing and unnecessary care (e.g. induced labor, lumbar surgery and stent procedures). Cost savings for those who don't get sick may be overwhelmed by the costs of providing comprehensive preventive treatment to everyone else. The health care industry has responded to the increased demand for preventive care and wellness services by developing the concept of "Whole Person Health" and DMOs have evolved from providing services for single disease states into providing services for a wide-range of conditions and wellness and preventive care.

The diagram below illustrates how the leading DMOs in the USA have positioned themselves to provide health enhancement services that respond to "Whole Person Health".

[3] Health Saving Account: An account that allows individuals to pay for current health expenses and save for future qualified medical and retiree health expenses on a tax free basis.
[4] The United States government's health insurance program for: "senior citizens" -- people 65 years of age or older, certain younger people with specific disabilities, and people with end-stage renal disease (ESRD) -- permanent kidney failure requiring dialysis or a transplant.
[5] State programs of public assistance to persons regardless of age whose income and resources are insufficient to pay for health care. The United States Federal Government provides matching funds to the State Medicaid programs.

Distribution of Health Care Services along the Healthcare Continuum



Source: Adapted from Healthways Investor report.

Improved Medical Information Technology

Many countries have invested heavily in information technology in healthcare and this will likely improve efficiencies in patient identification and real time response to health needs. To the extent that they give physicians the capability of providing wellness and DM like services more efficiently and effectively than is currently possible, this could undermine standalone DMOs.

In the USA, while there is widespread national support for increased investment in information technology in health care (in 2004 President Bush mandated that Electronic Health Records (EHR) must be available for most Americans within ten years to collect all of their healthcare information), individual physicians have not yet made the necessary investments in IT capabilities to respond to this trend. DMOs and others have been filling the void but relationships with physicians will need to be developed by DMOs to ensure a future role in the healthcare system.

Quality Initiatives to Promote Evidence Based Medical Practice

Most countries are increasingly developing initiatives to improve quality of care delivery through promotion of evidence based medical practice.

Some of the recent steps undertaken in the USA include:

- White House executive order to promote quality and transparency in cost (2006)
- In 2005, the Center for Medicare and Medicaid Services (CMS) increased the prospective payment rates for hospital inpatient operating costs by 3.3% for hospitals that submit performance data on 10 designated quality measures. A reduction in payment of 0.4 percentage points is applied to hospitals that fail to submit data relating to the quality of inpatient care furnished by the hospital.
- Scoring well on Health Plan Employer Data and Information Set (HEDIS) metrics developed by the National Committee on Quality Assurance (NCQA) is considered a competitive advantage for health plans and some plans have initiated pay for performance (P4P) programs to incentivize physicians to improve scores: Five California health plans, Aetna, Blue Cross/Blue Shield of California, CIGNA CA, Health Net and PacifiCare pay physicians for documented performance. The Association pays up to $150 million per year to medical groups based on adhering to standards of care and performance.
- Bridges to Excellence, a non-profit coalition comprised of large employers, health plans, the National Committee for Quality Assurance (NCQA), MedStat and WebMD pay physicians annual bonuses if they adhere to established quality care standards. Payments have been up to $100 million in annual bonuses for physicians who improve quality for diabetes, heart disease treatment, and medical office modernization by using information system technology.
- The Leap Frog Group represents many of the nation's largest corporations and public agencies that buy health benefits on behalf of their employees, dependants, and retirees. They have implemented initiatives to reward physicians and hospitals for improving the quality, safety and affordability of health care.

DM services complement this trend, as their ultimate mission is to improve health outcomes through the promotion of evidence based medical practices.

Major Threats to DMOs

Although DM and wellness services have become mainstream in many markets, there are key challenges facing the independent DMO model of delivery, particularly in the USA where they are most prevalent.

Value proposition under threat leading to price pressure and commoditization

The ability of DM and wellness services to reduce costs is conceptually logical but has very little empirical support and is a major threat to establishing the value of DM. Most of the studies to evaluate DM have taken place in the USA because as already stated the market is more mature than in other markets. As other markets gain experience similar studies will likely emerge.

The recent report evaluating the first two years of the Medicare Coordinated Care Demonstration (MCCD) project in the USA published by Mathematica (March 2007), reports no reduction in expenditures for Medicare Part A and B services for any of the 15 operating programs. In addition, the interim evaluation of the Medicare Health Support (MHS) pilot programs by RTI International (June 2007) indicates that "fees paid to date far exceed any savings produced." These much anticipated outcomes reports could undermine the market potential in the Medicare market segment and have repercussions for the commercial market.

Outcomes reports for commercial DM programs in the USA have been disappointing as well. Ron Goetzel MD highlights the inconsistency in DM programs delivering Return On Investment (ROI) in his seminal report *Return on Investment in Disease Management*. His paper summarizes the results of 44 studies covering five clinical areas (asthma, congestive heart failure (CHF), diabetes, depression and multiple condition categories) with a very mixed set of results.

There are numerous methodological flaws in most public studies that have been used by the DM industry to "prove" cost savings in the USA. In December of 2006, the Disease Management Association of America (DMAA) published its *Outcomes Guidelines Report* to develop industry consensus on the much debated, often controversial methods used in measuring DM outcomes.

While it is likely that the DM industry can survive and grow without verifiable cost savings, this lack of proven medical cost reduction will likely lead to a slow down in growth and reduction in fees which could shrink profit margins for DMOs.

Health Plan in-sourcing may significantly reduce the size of the industry

In-sourcing DM services by health plans is a recent trend in the USA with several of the large health plans purchasing DMOs including United (Optum), WellPoint (HMC) and Aetna (Active Health Management). This poses a major threat to the DMO industry. For health plans that are facing declining membership and increased price competition, this provides a potentially attractive source of revenue and greater efficacy from care management programs that integrate DM with other programs. Health plans can argue that they are better positioned to deliver DM as they have the most comprehensive access to claims data, more capitol resources, established relationships with providers and employer sponsors, and administrative synergies. It can also be argued that care management is a core competency of health plans and this raises the question of how prudent it is to outsource a core competence. DM is not capital intensive and a health plan can replicate an external DM program within two to three years, although it may not be as effective. The current market trend towards comprehensive DM programs that include a wider range of diseases and preventive care could make it more difficult for health plans to develop in house capabilities cost-effectively.

Penetration by stand alone DMOs in markets outside the USA is limited so it is difficult to predict how this trend will slow growth in other markets.

Alternative Providers of DM/Wellness like Services

Although DM/Wellness type service offerings are now accepted as a cost of doing business in the USA and other markets, the questions surrounding the cost savings from DM may drive pressure for DMOs to reduce fees and/or influence purchasers to look for alternative, cheaper DM delivery mechanisms so they can "check the box". Competitors for portions of DM/Wellness services currently exist in the direct to consumer market although they are unlikely to be head-to-head competitors in the near future because services are typically only provided to those consumers who actively seek them and are engaged in changing behavior. Those who are reluctant to change health risk behaviors will likely not seek out these services, while these individuals are a target population for DMO services.

The online competitors in the USA include:

- Revolution Health (www.revolutionhealth.com): Launched April 2007, provides free healthcare content and offers a membership (fee paying) that gives access to healthcare advisers and a health insurance marketplace. Steve Case (AOL founder) is a major investor.
- WebMD (www.webmd.com): Leader in on line health information traffic.
- Microsoft: MSN health website currently ranks third in on line health visitors and is focused on electronic health records
- Google

A more significant alternative provider of DM/Wellness services is physicians who have the potential to displace DMOs. Provider care delivery has historically been a disease exacerbation treatment model and not a preventive/wellness model. In addition, physician compensation has forced many physicians who may have been of the preventive care delivery mindset to relinquish these services. In the USA, there is a movement to financially incentivize physicians to provide DM/Wellness like services through what is being phrased "patient centered (or centric) medical home model." The belief is that physicians are best positioned to deliver DM/Wellness like services as they are a known and influential partner with their patients. In May of 2007, the Patient Centered Primary Care Collaborative (www.patientcenteredprimarycare.org) was formed between employers and physicians to "advance a model of care, called the patient-centered medical home model, that would transform how primary care is organized and financed to provide better outcomes to patients, more appropriate payment to physicians, and better value, accountability and transparency to purchasers and consumers." The medical home physician is expected to provide DM/Wellness like services and be compensated for such.

Value Proposition

A major criterion for DM programs is that they have the potential to save money. If the savings from decreased use of medical care are greater than the fees that are paid to a DM vendor (or the internal costs to develop and run a DM program internally), the program has generated a positive return on investment (ROI[6]). However, spending money on DM seldom leads to immediate savings. It is often an investment in reducing future healthcare costs.

Aside from the pure cost savings aspect, there have been other measures of success. One of these favored by academics is "Quality-Adjusted Life Year" (QALY). The theory behind QALYs is that there will be an improvement in the quality of life of a patient who is successful in a DM program and that this can be measured. QALY places a weight on time in different health states: a year in perfect health is worth one, a year of less than perfect health or life expectancy is worth less than one. Using QALYs, the quality and quantity of life following healthcare interventions is estimated and compared to the costs of a DM program. QALY considers the long-term societal impact of investment in DM but because of the potential extra costs on already overextended healthcare budgets there is often a reluctance to use QALY to justify investment in a DM program.

In the USA, DM programs have typically used three methods for calculating cost savings:

1. Comparison of requested services to approved services.
   - During the course of managing a member's disease, programs often approve or deny payment for services based upon protocols for managing a disease. Savings are calculated by comparing requested services with approved services.
2. Comparison of medical expenses for a control group to an intervention group for a like period.
   - The medical expenses of enrollees in a DM program are compared with the medical expenses of a group of people who have not enrolled in the program but have the same chronic disease as enrollees.
3. Comparison of pre-enrollment medical expenses (baseline year) to post-enrollment expenses (intervention year).
   - Total healthcare costs for all enrollees for the year prior to enrollment in a DM program are compared with the same enrollees' healthcare costs during subsequent periods after enrollment.

The first method is typically used in limited utilization management programs, and may overstate savings because the maximum number of services is typically requested even if not required. The second method is theoretically desirable but hard to achieve in practice. The pre- and post-comparison or the "actuarial method" is most often used.

Issues in Estimating ROI

There are always issues associated with actuarial analyses, ranging from choice of appropriate methods and assumptions to dealing with less-than-perfect data. There are several that are at the core of analysis of DM results. The issues listed are by no means exhaustive but are examples that can confound a "true" estimate of the ROI of a DM program. Our discussion is based on the experience of practitioners in other countries, particularly the USA[7], but we expect that practitioners in India will be faced with similar issues as they are asked to assess the financial impact of DM programs that are emerging.

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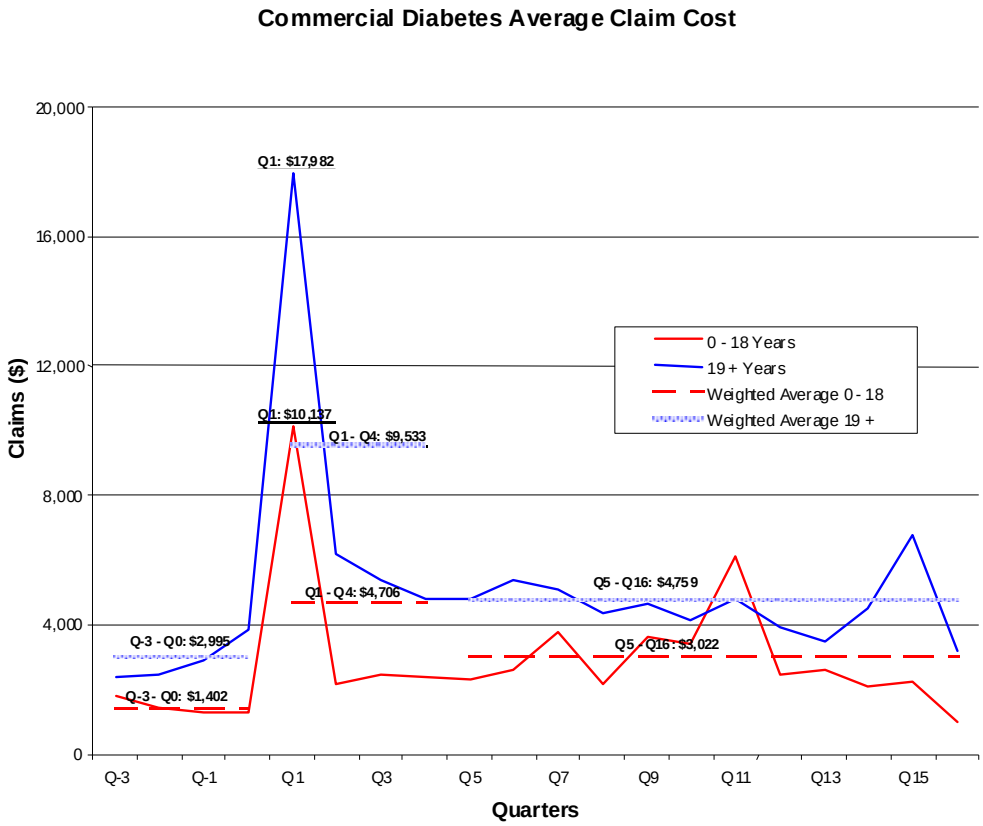
[6] ROI is the ratio of money saved to money consumed expressed as a percentage (benefits – costs) / costs [x 100%]

[7] "Is there an actuary in the house" by Cathy Murphy-Barron, Rob Parke and Marcia Sander. Contingencies July/August 2004

Regression to the Mean

Members recruited in a DM program during a high point of individual medical utilization and cost (e.g., post-hospitalization) typically return to lower levels of utilization and cost due to the natural course of the underlying disease process. This trend occurs with or without active intervention by a DM program. Below we illustrate the impact of regression to the mean for a diabetes population under age 65 in the USA. At the time of a significant event related to the disease (i.e., hospitalization or emergency room visit) the mean cost is substantially higher than prior to the event. While the post-event mean cost is higher than the pre-event mean, it is markedly less than the mean at the time of that significant event. Results are similar for other typical DM illnesses such as coronary artery disease (CAD) and congestive heart failure (CHF).



Source: *Insight into Two Analytical Challenges for Disease Management*, Milliman Research Report

Selection Bias

There can be significant differences in utilization and costs of services by members who agree to participate in a DM program and those not participating. This is referred to as "selection bias." Selection bias may be caused by such things as:

- Population-based factors such as geographic, economic and cultural differences that may affect the prevalence of a condition as well as the degree of compliance with treatment protocols.
- Personal factors such as age, illness severity and motivation. These may influence a person's willingness to enroll in a DM program.

In addition, selection bias may be introduced by decisions to exclude from the program (or from the outcomes measurement, even though enrolled) those with substantial co-morbidities, the terminally ill, or those undergoing treatment for cancer or transplants.

Data

The quality, completeness and consistency of the underlying data can also have a big impact on the evaluation of a DM program. For example, for a health plan with an outside DM vendor, there may be inconsistencies between the health plan's data and the DM vendor's data. This could result in a situation where a member has disenrolled from the health plan but is still identified as a member of the DM program by the vendor. More subtle, but no less an issue is one of incomplete coding of claims. At times, the coding may not contain information as to diagnosis or other items pertinent to the ongoing analysis.

Statistical Credibility

DM populations are a small percentage of the total population. They are also a high-cost, high-variance population. As described under "*Selection Bias,*" certain members of a group with a particular disease may be excluded from the DM program or from the evaluation of the program, thus making the group even smaller and results less credible. Similarly, attempting to adjust for population differences by stratifying the populations (e.g., by age) can result in group sizes that limit the credibility of the results. Ignoring statistical credibility can lead to misleading conclusions.

Severity

Not all people with the same condition will incur the same amount of healthcare costs. The variation is pronounced in populations targeted for DM programs. For example, a DM population with static or declining growth may experience increased severity due to the progressive nature of the disease over time and the increased healthcare costs associated with additional severity. As a result, comparing the DM group to a control group without adjusting for the severity change may result in misleading conclusions.

Other Issues

These issues discussed above are most closely associated with DM analysis. However, there are other issues familiar to actuaries that must also be considered in this context. Healthcare costs will vary between two time periods, independent of the introduction of a DM program. Among the factors that need to be considered in the evaluation of the "true costs" of a DM program are:

- Trend. If pre-enrollment expenses are used as a basis for comparison to post-enrollment expenses, they will have to be trended to the current time period. This trend involves more than just the general increase in prices over time. Many factors impact trend rates: new technology, new information about existing technology, changes in industry practice, changes in medical practice, and changes in underlying benefits, among others. In any particular year, any one of these factors may have a greater impact on the disease in question than on another disease or on overall healthcare costs, particularly because a specific DM population may access different types of care and use different providers than the average population.

- Changes in Health Care Delivery Infrastructure. When comparing the costs of a pre-enrollment population to their costs after intervention, it is difficult to isolate the impact of

the DM program from the impact of changes in healthcare delivery. Physicians and hospitals are continually changing their practice patterns and these can drastically change utilization for people with a chronic illness. The more time there is between the baseline experience and the intervention experience, the greater the impact of changes in the delivery of care. Other changes within the delivery system, such as changes in provider payments and coding practice shifts may also have an impact on the services delivered and their costs.

- Benefit Design. Changes in the services covered under a health plan or DM program always affect future costs. Benefit design changes may impact medical costs for the DM population differently than the population not covered by the program. In addition, where there are options, changes may also alter patient mix by attracting certain types of members to the options that most favor reimbursement and/or treatment for their illness.

- Claims Adjudication. Any change in a health plan or DM program's claims adjudication processes can impact claims estimation. Changes in timeliness of payment, procedure coding (such as the introduction of new codes) or modification of payment rules can produce significant changes in ultimate healthcare costs or the emergence of those costs.

- Incurred or Paid Claims. Some DM programs use paid claims and begin counting post-enrollment claims three months after enrollment to allow for payment for services received before enrollment. Use of incurred claims better reflects changes in adjudication patterns, provider payments, and benefits. However, the agreement to use paid claims may reflect the constraints of availability of data.

Status of DM in India

Like other countries, the Indian healthcare industry is facing the challenges of increasing healthcare demand, rising costs, uneven quality and a shifting disease profile towards chronic lifestyle diseases. The delivery system has not been able to meet these challenges.

Health insurance exists in the various manifestations of Mediclaim (primarily inpatient coverage) with less than 10% of the population currently covered by some form of health insurance, either social or private. Recent trends indicate that coverage is spreading rapidly with the private health insurance sector registering a 35% growth in premium collection in 2005 - 2006 over the previous year. Insurer strategies to cover chronic conditions are yet to fully develop and DM programs are still in the nascent stage.

DM in India is operating at two levels – National programs run by the central government and local or smaller initiatives run by Non Governmental Organizations (NGOs), insurers, Pharma companies and DMOs. While the government programs have been running for over a decade, development of DM in the private sector (providers and users) is recent and in the early stages of development.

DM type services are currently available in some regions all with a different focus and method of delivery. We describe some of these programs and other related developments.

Provider Wellness Initiatives

According to industry analysts, there has been a growth of 25 per cent in the preventive health care market over the past five years. There is a growing awareness among the urban corporate educated employees about health-related issues which has boosted the market for preventive health check-ups in hospitals. Annual health checkups, which were largely the privilege of corporate executives, are now being sought by the middle class and most hospitals routinely cater to walk-in patients with tailor-made packages for all age groups. Most checkups are paid for out of pocket by individuals directly.

National AIDS Control Program (NACP)

In 1987, a NACP was launched to coordinate a national response to AIDS covering surveillance, blood screening and health education. In 1992, the government set up NACO (National AIDS Control Organization), to oversee the formulation of policies, prevention work and control programs related to HIV and AIDS. In 2001, the government adopted the National AIDS Prevention and Control Policy.

The Ministry of Health and Family Welfare Annual Report indicates that in 2005, there were 5.2 Million identified patients and that the Government, in collaboration with local NGOs and international donors, had established 101 ART (Anti-Retroviral Treatment) Centers in 29 states that provide IEC (Integrated Education Campaigns), Counseling, Drug dissemination, follow up and monitoring and that 52,663 patients were receiving free ART.

The Government runs similar programs for mental health, TB, Malaria, leprosy and Diabetes/CVD and Stroke. Although these programs have been in operation for a while, only the number of patients identified and activity descriptions are reported. Outcomes from these programs such as reductions in morbidity and mortality have yet to be reported. In addition, integration of these programs with generic health services within existing healthcare infrastructure is limited, particularly with private healthcare providers.

Pharma sponsored DM

A Pharma sponsored DM program has been running for the last 6 years in 22 cities. This program covers Diabetes, Cancer, Neuropathy pain, Glaucoma, Obesity, Arthritis, Erectile Dysfunction & Renal impairment. The recruitment for the program is largely driven by referrals from physicians and pharmacists. Services include call center help lines, onsite Counselors, Physiotherapists & Phlebotomist. It also includes home delivery of medicines. The cost of the DM program is borne by the pharmaceutical company.

There is some skepticism about the program as it seen as an organized campaign to promote the pharmaceutical companies' own products, some of which may be part of clinical trials. It should also be noted that this program is not true DM as the central focus is on compliance with medication with other services wrapped around the drug usage.

Specialist Diabetes Centers

A specialist diabetic clinic has set up a regional diabetes DM program. The center uses defined guidelines in a multidisciplinary team environment and provides outreach services. It offers pre-defined packages to the enrolled population with premiums based on likely utilization of services. For example, the Annual Diabetes Package (1 year OP treatment) offered at Rs 2,500 ($62), includes 4 HbA1c, 2 Lipid Profile and 2 Renal Profile Blood Sugar tests and monthly consultations or whenever clinically required. The Diabetic Screening and one year outpatient treatment product is available at Rs 4,000 ($87). The program also conducts free camps and has a mobile outreach service using local partners which has helped to generate awareness and recruit chronically ill patients. The program also includes advice and management of co-morbidities.

Although the program is successful and has published results which demonstrate improved clinical outcomes, the replicability of the program is untested.

Insurance Company Diabetes Care

An insurance company has established the first ever critical illness plan for Diabetics which provides financial support to meet the cost of complications. It promotes wellness through partnerships with private health centers and incentivizes compliance through premium reductions of 5% - 30% off the first year's base premium. The premium is reduced following positive results after periodic check-ups which include tests for HbA1c, blood pressure, lipids and weight control.

Although this product has helped establish the company as a leading innovator for such products, its sales have been limited. Sales channels are the same as those used for the generic health insurance product and identifying and accessing the diabetic population has proved difficult. In addition, premiums are high.

Stand alone DMO

A stand alone DMOs was setup in 2000 which provides home-based patient care products. The products are being marketed to both Individuals and Corporations and cover chronic diseases and surgical conditions (Cardiac bypass surgery, Joint replacements) and post hospitalization at patient's home. Each product describes the likely course of treatment including the visits and tests planned for the covered conditions.

Although the post hospitalization program is well established and has support from providers, sales have been disappointing. The poor sales are likely due to a number of factors including high

premiums, an unwillingness of members to invest in health improvement and the program is an add-on to products that cover hospitalizations that the program is attempting to avoid. In addition, although Corporate provision of health care is spreading, very large employers often setup their own health plans rather than use insurance companies limiting sales to these groups.

Guidelines and Treatment Protocols

There is a growing recognition that to be effective India specific standard treatment protocols and guidelines are required which are sensitive to India's different geographies, ethnic groups, climatic conditions, dietary habits, literacy and socio- economic levels. In 2001, the Association of Physicians of India (API), Cardiology Society of India (CSI), the Indian College of Physicians (ICP), and the Hypertension Society of India (HSI) developed guidelines for Hypertension. In addition, the WHO has developed guidelines for chronic obstructive pulmonary disease in 2003 and has also published diabetes definition and diagnosis guidelines.

This is an important step in defining the basis and specifications of DM programs. In addition, an increasing number of recent publications have focused on risk factors, compliance issues and outcome research for chronic conditions in India.

Disease Management Association of India (DMAI)

A group of healthcare professionals has established a new non-profit organization, the Disease Management Association of India (DMAI) to propagate DM concepts and tools in India. The new association, modeled on the Disease Management Association of America (DMAA), was launched in April 2008. Initially, the DMAI will provide a platform for patient groups, Pharma, healthcare and related industries and academia to disseminate information and share best practices and outcomes.

OUTLOOK FOR DM IN INDIA

The need of DM is apparent in India with the huge prevalence and expected rise in chronic conditions. Private health care and health insurance are growing rapidly and Insurers are under pressure to expand insurance products beyond the traditional inpatient cover. They will be forced to look at developing alternative health insurance products covering chronic conditions and outpatient care and this will encourage the growth of DM.

There is much to learn from the global experience, including encouraging collaboration among physicians and other providers, the need for patient education (that may include primary prevention, behavior modification programs, and compliance/surveillance) and the appropriate use of information technology (including use of specialized software, data registries, automated decision support tools, and callback systems).

To improve the quality of care provided to the increasing numbers of Indian's suffering from chronic conditions and manage costs we believe all stakeholders need to take steps to facilitate the development of effective DM in India. These include:

Government

The government has the major role to play. It is not only the policy maker, but also a provider and payer for healthcare and can influence a refocus on preventive care and service delivery.

- Select key clinician champions as leaders and provide adequate resources for pilot DM programs.
  - Provide financial incentives for primary care to focus on managing chronic disease and for organizational improvements that will support better chronic DM.

- Encourage integration of all elements of service delivery, including prevention, the role of patients' in managing their own care and social care.
  - Introduce appropriate clinical outcomes measures in the assessment of public programs.
  - Develop Public Private Partnerships and collaborate with other players.

- Develop disease registries and data collation through centrally-funded procurement of an Integrated Care Record Service (ICRS).
  - This will allow the identification of disease or at risk populations so that services can be better geared to meet their needs and impact analyses undertaken.

Insurers

- Embrace DM as a key tool in managing long term costs and broaden current product offerings.
  - Increase promotion of stand alone products aimed at diseased populations.
  - Include DM programs in generic products that could result in lower premiums with compliance.

- Support pilot programs exploring DM delivery models in collaboration with providers and DMOs to evaluate which work best in India.

Providers and Medical Fraternity

- Collaborate in developing and disseminating chronic DM protocols and advocate for the benefits of DM programs.

DMOs

- Involve physicians and providers as key stakeholders.
  - Develop program that incentivize physician participation to facilitate referrals and follow ups

- Establish strategic networks of providers, pharmaceuticals, diagnostics and informatics.
  - Ensure seamless program delivery and manage costs.

- Develop new delivery strategies
  - The use of mobile devices, the internet and other media is expanding rapidly. No single delivery strategy will be successful for all risk groups.

- Develop a viable value proposition that demonstrates both clinical improvements and financial benefits.
  - Incorporate global learning in using appropriate criteria for disease selection, population selection and ROI calculation

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