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Evidence of a Return on Investment (ROI) from Selected Disease Management Programs: A Review of the Literature

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Running Header: Disease Management Return on Investment

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ABSTRACT

The American health care system is largely focused on managing acute problems or acute exacerbations of chronic illness, with little attention being paid to care coordination and disease management. Recently, interest has been building for introducing disease management programs, especially for seniors covered by Medicare. Although there is growing evidence that these programs improve health outcomes, very little is known about whether they achieve cost savings and a positive return on investment (ROI).

We examined the results of 43 studies that investigated the financial impact of disease management programs directed at the following conditions: asthma, congestive heart failure, diabetes, depression, and multiple illnesses. Studies were classified in terms of their design rigor and results were summarized. We note the small number of studies in this area and the variability in program design and implementation. We conclude that medical cost savings and a positive ROI may be found for programs directed at congestive heart failure and multiple disease conditions. There is also some evidence that diabetes disease management programs may save more than they cost, but additional studies are needed. Results are mixed for asthma management

programs. Depression management programs may cost more than they save, at least in terms of medical expenditures.

Many caveats and limitations are noted in this review. In particular, most disease management programs have been evaluated in environments that rely upon relatively expensive clinical personnel rather than centrally delivered programs using telephone, Internet and mail. Medicare, in particular, should continue to conduct well-designed demonstrations that test the health and economic gains from disease management programs.

KEYWORDS - Disease management, cost-benefit, return on investment, financial impact

INTRODUCTION

Enthusiasm about disease management programs is growing. This is evidenced by the number of Medicare demonstrations underway testing alternative disease management models, by legislative proposals for new disease management programs that include provisions for widespread access to disease management vendors, and by heightened interest by health plans and employers that are implementing these programs as a means of improving patients' health and saving health care dollars.^{1,2,3} Despite high expectations, the value of disease management programs in controlling health care costs is still largely unknown.

In a recent *Health Affairs* article, Sandra Foote put forth a convincing argument that Medicare should strongly consider testing population-based disease management (PDM) programs in fee-for-service (FFS) Medicare.³ Her assertion, supported by a panel of experts assembled by the Health Insurance Reform Project, was that PDM programs hold promise for improving the health of seniors, their quality of life, and their day-to-day functioning, while possibly saving Medicare large sums of money by reducing unnecessary and expensive health care utilization. This line of thinking was also endorsed in testimony before the Senate Special

Committee on Aging in 2002 delivered by Dan Crippen, then director of the Congressional Budget Office (CBO).⁴

As the disease management industry continues to expand, with annual revenues increasing from \$85 million in 1997 to more than \$600 million in 2002,³ it is important to examine the assumptions related to the financial impact of these programs on health care expenditures. As noted by Short et al., "In theory, disease management and intensive case management programs offer health plans and employers opportunities to reduce health care costs and improve quality without resorting to restrictive utilization management or benefit reductions. In practice, disease management programs must demonstrate cost savings if they are to help slow rapidly rising health costs."¹

Evidence supporting the basic elements of disease management has been accumulating for many years^{5,6,7,8} and reports of the actual experience with these programs are emerging in the private sector from employers and health plans. Evidence of significant improvements in quality of care and health outcomes as a result of disease management programs can be found for several disease categories, including diabetes,⁹ heart failure,^{10,26} arthritis,⁴³ and depression.¹¹ A review of literature by the Institute of Medicine (IOM) found substantial evidence that "programs

providing counseling, education, information feedback, and other supports to patients with common chronic conditions are associated with improved outcomes.”¹²

Understandably, most studies have focused on whether these programs encourage application of evidence-based clinical guidelines in the treatment of acute and chronic disease, and whether adherence to guidelines improves patient health and functioning. However, a small subset of studies have also considered financial savings from disease management programs and, in particular, whether such programs can achieve a positive return on investment (ROI).

This paper examines the still very limited but growing research literature on medical cost savings and ROI attributed to disease management programs in five clinical areas: those focused on asthma, congestive heart failure (CHF), diabetes, depression, and multiple risk categories. These diseases were selected because there were several available financial impact studies for each disease category. The disease management programs studied may not be generalizable to other disorders, but these programs (with the exception of depression) are among the most frequently offered by leading disease management vendors, as reported by Health Industries Research Companies.¹³ Mental health problems are addressed by disease management less

often, but depression is a major comorbidity of asthma, diabetes, heart disease, and other disorders, and a highly prevalent disorder in its own right,¹⁴ so we focus on disease management programs for it as well.

Although several financial impact studies are reviewed within each category, there are some notable limitations to this review that should be mentioned even before our analysis is presented. For one, disease management is defined and practiced differently across studies, thus limiting direct "apples to apples" comparisons. Some programs rely upon face-to-face clinician-based interventions, while others employ larger scale health plan- or employer-sponsored programs delivered by mail, Internet and telephone to targeted patient groups. Some programs direct their activities at physicians by providing them with cues, reminders and reports to prompt them to deliver evidence-based medicine programs. Others may bypass the physician and offer self-care interventions directed at the patients themselves. Finally, many ongoing commercial disease management programs have not yet been rigorously evaluated and results of these efforts have not been reported in peer-reviewed journals.

The studies examined cut across different age groups and were conducted in various settings. As such,

information about the value of disease management programs resembling those offered by managed care organizations and employers in the care of elderly Medicare enrollees is limited. In addition, as noted in the Results section, the disease management interventions uncovered in this review varied considerably in terms of their design, comprehensiveness, intensity, duration and cost. Studies examining their effectiveness often used small sample sizes that limited analyses of cost data. Also, many studies employed before and after designs when comparing patient expenditures, thus introducing a common internal validity threat of regression to the mean.

In spite of these important limitations, we believe it would be helpful to policy makers considering the value of disease management, and in particular its value for the Medicare program, to learn from the available evidence on ROI for programs that have been evaluated and reported in the literature. This should help them make better decisions about whether such programs, at face value, hold promise for employers, health plans, and Medicare from a purely financial perspective.

As noted, this analysis of disease management programs is an economic one. We acknowledge that the primary aim of these programs *should be* to improve health and functioning

of patients - rather than to save money. Nonetheless, program funders, including employers and in the case of Medicare, the Congress and the Office of Management and Budget (OMB), require a "business case" argument for all new programs and benefits (i.e., in Medicare, these programs when "scored" are expected to be at least cost-neutral, returning as many dollar benefits as they cost). Thus, when introducing new health management initiatives, it is often necessary to develop a cogent and defensible financial impact analysis, with an associated ROI.

This review is not intended to be a rigorous meta-analysis of disease management studies, since various methods are used in the literature to assess financial impact for a diverse set of programs serving heterogeneous populations. Instead, we provide an overview of several studies, some more rigorous and some less, that exemplify disease management programs in practice, and draw conclusions based upon the overall direction of findings from these studies. We present this analysis as a first impression of the cost-benefit ratio for various programs.

Previous Reviews on Return on Investment

Much of the ROI research has emerged from employer-sponsored health, demand, and disease management programs. Many employers are currently working with their health

plans, or hiring third party vendors, to implement health and disease management programs for their employees and dependents.¹⁵

Goetzel et al.¹⁶ conducted a comprehensive review of the ROI literature. The authors identified 22 studies that met the criteria for inclusion in the review. These studies generally used a rigorous study design, had a minimum sample size, used an adequate observation period, performed analysis of administrative or claims data, and applied appropriate multivariate statistics to controls for confounding variables. The review found that ROI estimates ranged from a low of \$1.40 to a high of \$13 per dollar spent, depending on program type. The review acknowledged that negative results were not likely to be reported in the literature, and that the quality of some of the studies was less than optimal.

More recently, Aldana¹⁷ reviewed the financial impact of health management programs. In his analysis of 32 program evaluations focused on health care cost outcomes, Aldana found only four studies that reported *no effects* on health care costs, but none of these studies used randomized designs. Thirteen of the 32 studies calculated cost/benefit ratios and these averaged \$3.48 for every dollar expended. The one large ROI study employing an experimental design^{18,19}

reported a benefit-to-cost ratio of \$5.90 to \$1.00. As above, several caveats were highlighted in the Aldana review, many of which related to the difficulty of achieving adequate internal validity when conducting "real-life" vs. laboratory research. However, most recent corporate evaluations have used sophisticated econometric methods to evaluate financial impact²⁰ and many analyzed data over several years.²¹

DEFINING DISEASE MANAGEMENT

The Disease Management Association of America (DMAA) defines disease management as a multi-disciplinary, coordinated, continuum-based approach to healthcare delivery and communications for populations with, or at risk for, established medical conditions.²² DMAA notes that effective disease management programs should contain the following elements: 1) an identified population with specific health and disease conditions; 2) the application of evidence-based practice guidelines to treat those patients; 3) a process that encourages collaboration among physicians and support-service providers; 4) risk stratification and matching interventions with need; 5) patient self-management education (that may include primary prevention, behavior modification programs, and compliance/surveillance); 6) process and outcomes measurement, evaluation, and

management; 7) routine reporting and providing feedback loops (that may include communication with the patient, physician, health plan and ancillary providers, and practice profiling); and 8) appropriate use of information technology (including use of specialized software, data registries, automated decision support tools, and callback systems).²²

A recent analysis by Villagra of the frequency with which published disease management programs actually meet DMAA requirements found that all programs examined engaged patients in self-care education; report clinical, cost, utilization or satisfaction outcomes; and all described a population identification method. However, only 59% of programs cited reported specific guidelines, 66% described collaborative relationships with treating physicians, and 41% gave feedback to physicians.²³ These findings further underscore the diversity of programs that fall under the broad heading of disease management.

Disease management can be distinguished from case management, although these two concepts overlap. Disease management programs typically target a population of patients with a specific health condition in order to apply well-established guidelines regarding the care of these patients. In contrast, case management is focused on coordinating care for individual high-risk and potentially

high-cost patients who often have multiple and complex health conditions. These patients may be treated by multiple physicians, have complex drug regimens, and are therefore likely to become very expensive if left unmanaged.¹ Good disease management facilitates good case management, and vice versa.

METHODS

Data Sources

We compiled relevant articles from three primary sources: the National Library of Medicine's MEDLINE and HealthSTAR electronic databases; reference lists from published reviews of high-quality peer-reviewed studies; and unpublished but demonstrably high-quality studies identified by the authors and other content experts.

Studies were classified into four broad research design categories: 1) randomized clinical trials (RCT) employing experimental design; 2) controlled before and after (CBA) studies employing a quasi-experimental design in which data for the intervention group are compared to data from a matched control group, or where appropriate statistical methods are used to control for potential confounding variables when comparing treatment and comparison group subjects; 3) descriptive before and after (pre-post) studies employing pre-experimental designs that lack control subjects; and 4) cross sectional analysis whereby patients

receiving care in compliance with evidence-based guidelines are compared longitudinally to those who do not.

Procedures

The analysis categorized studies into the main research design groups. When reviewing and analyzing results, more weight was given to randomized clinical trials (RCT) and controlled before and after (CBA) designed studies since these, by definition, are most rigorous and subject to fewer internal validity problems. Since the analysis was primarily focused on financial results, particular attention was given to studies where dollar savings were calculated, usually by comparing differences in costs per patient for treatment vs. control subjects.

In the analysis, we distinguished between studies reporting cost savings and those that calculated return on investment. Many studies that report cost savings leave out an accounting of what was spent in running the program which, in turn, achieved those cost savings. This analysis used terminology readily understood by finance experts when deciding upon the relative merit of various program investments, typically reported in terms of Net Present Value (NPV) or the benefit-cost (ROI) ratio.

In the studies examined, cost and benefit information was most often derived from administrative claims data rather than through extrapolation of self-reported or claims-based health care utilization records. We examined the differences in expenditures between intervention and

control subjects at the conclusion of the study, subtracting out baseline cost differences. To calculate cost-benefit ratios, we sought out studies that reported program expenses and savings. In some cases, costs and savings were recalculated from charts and tables found in the published studies. This was done to isolate direct from indirect expenditures or combine data across several patient groups. Thus, in some cases, the calculated costs and benefits reported here may differ somewhat from those reported by the study authors.

To facilitate the analysis, the number of subjects examined in the study, the study duration, cost savings and program expenditures were recorded for each study reviewed, along with non-financial impacts emerging from the intervention. A detailed analysis of studies considered in the review is available from the authors. (*Note to reviewers: This reference table is provided as Appendix A*). We isolated the studies with relevant financial data in tables 1-5 for each of the four disease conditions examined, plus multiple condition studies. To further simplify our results, we summarized our main findings in tables 1A, 2A, 3A, 4A, and 5A.

RESULTS

Asthma Disease Management Programs

Twelve studies were examined in this review of asthma disease management programs: seven RCTs (two of which allowed for a calculation of ROI), two CBA studies, and three pre-post evaluations. (See table 1). Examining findings from the RCTs, we observed that the two RCTs with ROI data conducted by Kelly et al.²⁴ and Greineder et al.²⁵ used relatively small samples in their intervention groups (38 and 29, respectively). Intervention program expenses reported by Kelly et al., and Greineder et al. averaged \$293 per participant (\$395 and \$190 respectively) while savings averaged \$1,068 per participant (\$543 and \$1,592, respectively). It should be noted that Kelly et al.'s program expenses were upwardly adjusted to account for projected drug costs not included in the original analysis. Considering unadjusted values, the ROIs for the two controlled studies were \$1.38 and \$8.37 to \$1.00, respectively. Adding drug costs in Kelly et al.'s analysis would have produced an ROI of less than \$1.00 (i.e., \$0.72).

Insert Table 1 About Here

Reviewing results from the five other randomized trials, per participant costs averaged \$525 for the two studies reporting program expenses. The two studies produced an average loss of \$98, with one study showing

savings of \$48 while another showing a loss of \$245. Three other studies reported their findings in Finnish Marks. Their results showed no significant differences in direct medical costs between intervention and control groups. For the two studies in this grouping reporting costs and benefits, the ROI for one was \$.07 to \$1.00 while the other showed a net loss (\$-0.70 to \$1.00).

The two CBA studies reported a very different net savings (\$23 and \$1,092), whereas the three pre-post studies reported average savings of \$1,391 per participant. ROI values for the two CBA studies with both cost and benefit data were calculated as \$3.74 and \$7.86 to \$1.00.

Table 1A summarizes the results across all 12 studies, regardless of the level of rigor employed in those studies. The table shows that an average of 449 subjects participated in asthma disease management program interventions over a 1.3-year period. Per-participant costs averaged \$269 and savings \$729. An overall ROI of \$2.72 to \$1.00 was calculated for studies providing both cost and benefit data. However, of the seven randomized trial studies examined, four produced savings but only one was definitive in demonstrating a positive ROI.

Insert Table 1A About Here

Congestive Heart Failure (CHF) Disease Management Programs

Twelve studies were examined in our literature review of CHF disease management programs: five randomized trials - four of which used U.S. dollars and a fifth that reported findings in Australian dollars; four CBA studies; and three pre-post evaluations. (See table 2).

Insert Table 2 About Here

The four RCTs conducted by Rich et al.,²⁶ Cline et al.,²⁷ Krumholtz et al.,²⁸ and Kasper et al.²⁹ report intervention program costs ranging from \$208 to \$904. Kasper et al. reported program losses of \$2,474 while the other researchers reported savings ranging from \$460 to \$7,515. Consequently, the ROIs ranged from a loss of \$2.74 to \$1.00 to savings of \$14.18 to \$1.00, with an average ROI of \$3.66 to \$1.00.

A fifth clinical trial conducted by Stewart et al.³⁰ involved a very small sample (49 intervention subjects). The intervention cost was \$190 Australian and consisted of a single home visit. Program savings were calculated as \$5,500 Australian. Thus, the ROI generated from the analysis (\$28.90 to \$1.00) appears unrealistic given the nature of the intervention and the small sample size.

Of the four controlled before and after studies, two (Riegel et al.³¹ and vanVonno et al.³²) reported program expenses (\$330 and \$1,706, respectively). Program savings

reported across all four studies averaged \$1,490. When considering the two studies with cost and benefit data, one reported an ROI of \$0.62 to \$1.00 while the second was barely "break even" at \$1.08 to \$1.00. For the three before and after studies, per-participant costs averaged \$2,715 (driven largely by the very expensive Fonarow et al.³³ study) while savings averaged \$8,462 per participant. The average ROI for these studies was calculated as \$3.12 to \$1.00.

Table 2A summarizes the results across all 12 studies focused on CHF. As shown, an average of 170 subjects participated in CHF disease management program intervention studies during a slightly less than one-year period. Per-participant costs averaged \$1,399 and savings averaged \$3,884. The average ROI across all studies was calculated as \$2.78 to \$1.00. Of the five RCTs examined, all but one produced a positive ROI.

Insert Table 2A About Here

Diabetes Disease Management Programs

Eight studies were examined in our literature review of diabetes disease management programs: four RCT studies; one CBA study; one cross-sectional study; and two pre-post evaluations. (See table 3).

Insert Table 3 About Here

It should be noted that two RCT studies listed in the table, those conducted by Herman et al.³⁴ in 2003 as part of the Diabetes Prevention Program Research Group³⁵, were not technically disease management program evaluations. Rather, these studies tested the health and economic impacts of alternative methods for preventing diabetes exacerbation using lifestyle modification methods and medication when compared to placebo. Since these studies used large sample and excellent experimental design methods, they are shown within the context of other disease management programs directed at patients with existing diabetes disease.

As shown, the two Herman et al. trials were relatively costly, averaging \$2,661 per participant, as compared to the more usual diabetes disease management programs such as the one reported by Laffel et al.³⁶ that averaged \$265 per participant.

Program savings were negative in the Herman et al. prevention trials (averaging a loss of \$2,230). However, positive results were found for the other two clinical trials (averaging a savings of \$204 per participant). Thus, while the ROIs from the Herman et al. prevention trials were negative, averaging -\$0.84, the ROI from the Laffel et al. trial was estimated to be slightly better than break-even (\$1.04 to \$1.00).

The Sidorov et al.³⁷ CBA study reported average program costs as \$580 and savings as \$1,294, thus producing a \$2.23 to \$1.00 ROI. For the three remaining studies, the range of savings was from \$528 to \$818 per participant. However, since no cost data were provided, an ROI could not be calculated.

Table 3A summarizes the results across all diabetes disease management studies reviewed, including the Herman et al. prevention-focused studies. An average of 2,011 subjects participated in these programs over a 2.5-year period. Per-participant costs averaged \$611 while savings were \$434. For all studies reporting costs and benefits, a \$0.70 to \$1.00 ROI was calculated (lower than a break-even). Examining results of the Herman et al. randomized trials, these programs did not produce a positive ROI, at least not in the short run. On balance, these studies point to the possibility that diabetes disease management programs may break even, if treatment costs are well managed. While the single CBA study reported a positive ROI, these results are more suspect since less rigorous methods were used to evaluate the program's financial impact.

Insert Table 3A About Here

Table 3B summarizes results from a literature review performed by Klonoff and Schwartz³⁸ of earlier diabetes

disease management programs. Most of the studies cited were performed in the 1970's and 1980's using non-experimental design methods. Nonetheless, their findings are instructive in that they report average program expenses at \$271 and average savings at \$600, producing an ROI of \$2.21 to \$1.00. However, since most of these studies did not involve randomization into treatment and control groups, these seemingly positive results should be interpreted with caution.

Insert Table 3B About Here

Depression Disease Management Programs

Eight studies were examined in our literature review of depression disease management programs: all were RCTs. Results from these trials, as well as an independent review of depression program savings as compiled by Simon et al.,^{39,}⁴⁰ are reported in tables 4, 4A and 4B.

Examining aggregate results from the eight RCTs reported in table 4, we show an average sample size of 289 intervention subjects, and average study duration of 1.1 years. Per-participant program expenses averaged \$1,479 and ranged from \$51 to \$5,549, signaling much variation in what was termed a disease management program. Intervention program savings were all negative, averaging \$512 in our analysis and \$497 in Simon et al.'s review. The aggregate

ROI for depression disease management programs was therefore negative, averaging -\$0.35 to \$1.00, meaning these programs cost more than they saved, at least in terms of medical expenditures.

Insert Table 4 About Here

Insert Table 4A About Here

Insert Table 4B About Here

Multiple Condition Disease Management Programs

Three multiple condition program evaluations were examined in our literature review: one an RCT (Coleman et al.⁴¹), a second cross-sectional analysis (Munroe et al.⁴²), and a third pre-post study (Lorig et al.⁴³). The Coleman et al. intervention targeted common geriatric medical problems including urinary incontinence, falls, depression, high-risk medication management, and functional impairment in older adults. The Munroe et al. disease management program, run by pharmacists, targeted patients with hypertension, diabetes, asthma, and/or hypercholesterolemia. The Lorig et al. intervention targeted patients with heart disease, lung disease, stroke, or arthritis. The financial details for these studies are shown in table 5.

Insert Table 5 About Here

Combined, these studies ran an average of 1.4 years and had an average of 322 intervention subjects. Intervention

program expenses (from the two studies reporting costs) were \$135 and \$224. Intervention program savings were \$590 and \$3,521 for the two interventions reporting costs and \$581 for the third study reviewed. The two ROIs calculated were \$4.37 and \$10.87 to \$1.00. It should be noted however that the RCT conducted by Coleman et al. did not show statistically significant differences in costs between study and control groups. This may be attributed to any number of factors, including small sample size, lack of power, low penetration rates, and the limited nature of the intervention, which involved half-day seminars for patients every 3 to 4 months.

DISCUSSION

We reviewed the literature reporting financial impact and cost-benefit for four types of disease management programs, and for programs focused on multiple conditions. We attempted to identify studies that were rigorously conducted, over a sufficient time period and with an adequate number of subjects. We uncovered 43 studies that satisfied our inclusion criteria. We were interested in determining whether assumptions about the positive economic impact of disease management programs correspond to actual results from well-designed studies using rigorous methods. We also wanted to inform public policy experts about private

sector innovations in disease management to determine whether they might hold promise for Medicare and Medicaid patients.

We sidestepped the issue of whether disease management programs are effective from a health improvement perspective - we assumed that following evidence-based clinical guidelines would improve the health and functioning of patients, but also acknowledge that all health care interventions may produce unintended consequences. Admittedly, we did not perform thorough clinical reviews of these programs and the methods employed since these have been reviewed elsewhere.¹² Our question was whether disease management held the potential for saving money and producing a positive ROI.

Our findings were mixed at best, and full of caveats. From a purely financial perspective, we found that disease management programs directed at patients suffering from CHF may save more money than they cost. These programs produced a positive ROI, even in the short run, i.e., within a year or two. In addition, programs that target multiple health and disease conditions and that emphasize self-care and informed decision-making also hold promise to be cost beneficial.¹²

We encountered mixed results when considering programs directed at asthma, diabetes, and depression. For example, when evaluating large-scale prevention programs directed at pre-diabetic patients³⁴ (not pure disease management programs), we determined that these programs cost more than they save, at least in the short term. However, diabetes disease management programs directed at patients with active disease may produce savings and a positive ROI. The Herman et al. research offered strong evidence that interventions that combine pharmacotherapy and lifestyle modification (i.e., exercise and nutrition), may be most useful in preventing debilitating and costly disease cost-effectively.

The evidence concerning ROI for asthma programs seems less conclusive. There is some evidence that a positive ROI can be realized from these programs, but findings are not consistently positive, especially when examining rigorous evaluations.

In the case of depression management programs, none of the current studies examined found a medical cost-offset for appropriate treatment of depression patients using pharmacological agents and/or psychotherapy. Quite uniformly across the various studies examined, good treatment of depression costs more money (about \$500 more a year).

The story may be different when considering productivity and functionality outcomes (e.g., absence, disability, on the job productivity and performing activities of daily living)⁴⁴ where treatment in accordance to evidence based medicine may save more than it costs.

Limitations

Several implications follow from this research, but before those are noted it is worth considering the following limitations. First, as mentioned earlier, the disease conditions examined in this review do not span the entire set that may be of interest to doctors, patients, employers, health plans, and Federal policy makers. The intent of this review was to comment on whether certain disease management programs appear to work, not whether all such programs are likely to work. Evidence from programs directed at other diseases, and from programs directed at the same diseases but using more efficient patient and physician education strategies, should be accumulated and analyzed as well.

Second, the number of disease management programs considered for each disease category was small. This precluded the utility of reporting variances for the ROI projections made, and it also suggests that mean values should be interpreted with caution. The small sample sizes probably would not support the notion that ROIs are

significantly different from 1.0 in a statistical sense, and this is one of many reasons why additional tests of different approaches to delivering disease management would be valuable.

Third, many authors have used the terms disease management and population-based disease management programs,²² but most of the programs reviewed are not truly population-based. The term "population" is used quite loosely, often meaning a group of patients who meet certain criteria for inclusion in the study, instead of an all-inclusive group of people with a disease or condition of interest. We know of no disease management program evaluations that are focused on all patients with a certain condition in a health plan although most programs support inclusion of all patients identified with the target disease, albeit with variable intensity. Each program evaluation comes with its own set of inclusion and exclusion criteria, many of which seem valid or justifiable on their face. For example, diabetes programs may exclude those with end-stage renal disease, or depression programs may exclude patients who were recently hospitalized for suicide attempts. Such patients may be atypical among the larger groups of patients with these diseases. The point is that "population-based disease management" does not conform to a

standard definition, and rarely includes all patients with a certain condition. Thus, the programs summarized in this article should probably be viewed as sample-based, not population-based, as should most other disease management programs.

Fourth, the "file drawer" problem may be formidable here. This term is used by meta-analysts to comment on the number of unpublished studies that would show radically different findings (in this case, largely negative ROIs). It is unknown whether such studies exist, and how many there may be, but this review may reflect a selection bias problem in that programs with better results may be more likely to be published. Conversely, it may also be true that positive program results have not yet been published. Some of the largest disease management programs are delivered by freestanding vendors or managed care organizations operating on a platform quite distinct from the traditional delivery system and academic research centers. These organizations are less likely to structure their programs as formal experiments or publish research findings because these are difficult to perform and costly. Consequently, we may not be aware of positive results from large-scale interventions if those results have not been prepared for scientific journals. In short, the reader is cautioned about the

generalizability of findings presented in this review. Again, this points to the need for further testing of disease management programs among various populations, especially seniors.

Fifth, studies that rely upon a pre-post design, commonly employed in these types of evaluations, suffer from a common internal threat to validity, namely regression to the mean. Simply stated, many patients who are identified as very sick and costly will improve over time regardless of how they are managed clinically (i.e., they will regress toward "average" values on many measures). Thus, studies that only examine expenditures at one time and then again at a certain follow-up point will inevitably benefit from a regression to the mean phenomenon, and consequently appear to be performing better than they actually would have if a control or comparison group of similar patients had been followed over the same time period.

Finally, it is worth putting the notion of ROI in perspective. It is probably fair to say that many economists and investment analysts who know little about the health care field would be surprised to hear terms like "the ROI was only 1.08" when describing the financial impact of a disease management program. In today's economy, an 8% annual return on investment is likely to be considered

favorably by most reviewers. Such a return is higher than inflation (so at least part of the return is real, not just nominal) and returns from many stocks and mutual funds have not been that high since the 1990s. We, like others, prefer higher ROIs, but we may be guilty of denigrating good programs with ROIs that seem low. Such a perspective should be used when evaluating the results reported here. Every dollar spent on disease management is a dollar that cannot be spent doing something else, so the issue is not so much the absolute magnitude of the ROI; the more important focus should be on the relative ROI, with comparison to other investments.

Implications

The findings from this study, as well as some of its limitations, suggest that testing disease management programs in Medicare and non-Medicare populations would make sense. There is convincing evidence that such programs improve health outcomes, and that some may also save money and produce an ROI. As shown, most of the relevant research has been conducted in the private sector, where a profit motive has been an important driver in the decision of which programs to implement and at what cost.

In Medicare, program managers are less concerned with profit than with solvency. In the long run, decisions

concerning government financed health care programs must be driven by both health and economic outcomes. These programs should not passively wait for patients to get sick and then to pay for acute care services one at a time, if evidence suggests that population-based, coordinated care and disease management approaches may be beneficial. Employers, health plans and Medicare should test these approaches rigorously, and then decide whether these programs should be the norm rather than the exception.

As shown in this review, there are many variations of disease management, and not all programs may be equally practical and economically viable. In particular, disease management programs that leverage administrative databases and mass communication technologies such as tailored mail, telephone and Internet interventions may be inherently less costly and result in more favorable ROIs than programs operated as direct extensions of outpatient clinics. More research is needed therefore, to test the assumptions surrounding population based disease management programs in order to determine which kinds of programs work best.

Medicare must be modernized so that care is coordinated and population-based. In Dan Crippen's testimony to the Senate, he reported a small minority of Medicare enrollees (5%) consume a very large proportion of total Medicare costs

(47%). This is the group that would benefit most from well-designed and well-implemented disease management programs. In addition, Mr. Crippin noted that half of Medicare enrollees spend only 2% of Medicare's total budget. This is quite remarkable! It means that a significant proportion of enrollees are probably healthy and able to manage their health appropriately, or at least prudently. For these relatively healthy seniors, more resources should be shifted to "health management" programs that aim to keep this group healthy and prevent expensive and debilitating disease from occurring.

This review has touched upon a small but increasing body of literature examining the financial implications of health and disease management programs. As noted, there is a need for more demonstrations that test efforts to keep seniors healthy and to effectively treat them when sick. These demonstrations should consider both the health and cost impacts from such interventions.

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