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EVIDENCE REPORT AND EVIDENCE-BASED RECOMMENDATIONS

Chronic Disease Self Management for Diabetes, Osteoarthritis, Post-Myocardial Infarction Care, and Hypertension



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EXECUTIVE SUMMARY

Introduction

Chronic diseases currently affect well over one hundred million Americans. Though chronic diseases are not immediately life threatening, they pose a significant threat to the health, economic status and quality of life for individuals, families and communities.^{1,2} The greatest burden of chronic disease is concentrated in the 65-year and older age group. In 1995, 79% of noninstitutionalized persons who were 70 years and older reported having at least one of seven of the most common chronic conditions: arthritis, hypertension, heart disease, diabetes, respiratory diseases, stroke, and cancer.¹ Demographic trends portend alarming increases in the next 20 years.

There is a growing enthusiasm for self-management programs, either as stand alone program or as integral components of chronic care models, in controlling and preventing chronic disease complications.³⁻⁷ Despite this enthusiasm, there is no agreed definition of what constitutes a “chronic disease self-management program” nor is there agreement on which elements of self management programs are most responsible for any beneficial effects.

We therefore sought to use empirical data from the literature to address the following research questions posed by the Centers for Medicare and Medicaid Services (CMS).

1. Do these programs work?
2. Are there features that are generalizable across all diseases?
3. Does this intervention belong in the medical care system?
4. Define chronic disease self-management and distinguish between it and disease management.
5. What is the role or potential of technology?

6. What is the impact of chronic disease self-management programs on quality of life, health status, health outcomes, satisfaction, pain, independence, and mental health (e.g., depression, emotional problems)?
7. To what extent does self-management educate a patient on how to care for himself/herself (e.g., take medications appropriately, consult with a physician when necessary, etc.)?
8. What is the patient's retention of self-management skills after the intervention? Is a follow-up intervention needed at some point?
9. How does the approach for self-management differ for people with multiple chronic diseases?
10. Is a generic self-management approach preferable to a disease-by-disease approach?
11. Should this intervention be targeted to a subset of the population or available to everyone?
Are there particular chronic conditions that should be addressed (e.g., diabetes, arthritis, stroke, cancer, Parkinson's, hypertension, dyslipidemia)?
12. What is the role of the physician? Can physicians be used to reinforce learning?
13. Cost effectiveness or cost savings—does the intervention appear to reduce health care costs by reducing disease, physician office visits, hospitalizations, nursing home admissions, etc.?
14. Delivery mechanism: What do we know about whom (which provider type? trained lay person?) should deliver this service? Do we know which care settings have proven effective (e.g., physician's office, senior center, other community or clinical settings)?

To address these questions, we focused on evaluating the effect of self-management programs for the four chronic conditions most commonly studied in controlled trials of older adults: osteoarthritis, diabetes mellitus, hypertension, and post myocardial infarction.

Methods

Conceptual Model

In order to avoid the premature loss of potentially relevant studies, we broadly defined "chronic disease self-management" as a systematic intervention that is targeted towards patients with chronic disease to help them to actively participate in either or both of the following activities: self-monitoring (of symptoms or of physiologic processes) or decision-making (managing the disease or its impact based on self-monitoring). All interventions included in this study attempt to modify patient behavior to reach specific goals of chronic disease self-management.

We attempted to understand the characteristics particular to chronic disease self-management programs that may be most responsible for their effectiveness. Based on the literature and expert opinion, we postulated five hypotheses regarding effectiveness of chronic disease self-management programs:

- 1 Patients who receive interventions tailored to their specific needs and circumstances are likely to derive more benefit than those receiving interventions that are generic. (Tailored)
- 2 Patients are more likely to benefit from interventions received within a group setting that includes others affected by the same condition than they are to benefit from an intervention that was provided by other means. (Group Setting)
- 3 Patients who are engaged in a cycle of intervention followed by some form of individual review with the provider of the intervention are more likely to derive benefit than from interventions where no such review exists. (Feedback)

- 4 Patients who engage in activities using a psychological intervention are more likely to derive benefit than from interventions where there is no psychological emphasis. (Psychological)
- 5 Patients who receive interventions directly from their medical providers are more likely to derive benefit than those who received interventions from non-medical providers. (Medical Care)

Outcome measures

For the diabetes studies we used hemoglobin A1c, fasting blood glucose, and weight as outcomes. For osteoarthritis, we used measures of pain and function. As would be expected, we used systolic and diastolic blood pressure for hypertension. For post MI care, we used return to work and mortality. For all conditions, we also collected intermediate outcomes such as knowledge, feeling of self-efficacy, and health behaviors that are postulated to be related to clinical outcomes. We separately assessed studies reporting costs.

Databases for Literature Search

To identify existing research and potentially relevant evidence for this report we searched a variety of sources including the Cochrane Library (containing both a database of systematic reviews and a controlled-trials register), the *Assessment of Self-Care Manuals* published by the Oregon Health Sciences University (March 2000), and *An Indexed Bibliography on Self-Management for People with Chronic Disease*⁸ published by the Center for Advancement of Health (CAH). In addition Medline, PsycInfo, and Nursing and Allied Health databases were search.

Seventy-three other review articles on disease management were obtained; each review discussed at least one intervention aimed at chronic disease self-management. We retrieved all relevant documents referenced. We also contacted experts in the field and asked for any studies

that were in press or undergoing review. Finally, we exchanged reference lists (but not analyses or results) with a leading east coast university also performing a review of chronic disease self-management programs, but not limited to older adults

Article Selection and Data Abstraction

Article selection, quality assessment, and data abstraction were done in standard fashion by using two trained physician reviewers working independently; disagreements were resolved by consensus or third-party adjudication.

Statistical Analyses

We answered many of the research questions through meta-analysis. We conducted separate meta-analyses for each of the four medical conditions. We included all controlled trials that assessed the effects of an intervention or interventions relative to either a group that received usual care or a control group. The majority of our outcomes were continuous and we extracted data to estimate effect sizes for these outcomes. For each pair of arms, an unbiased estimate⁹ of Hedges' *g* effect size¹⁰ and its standard deviation were calculated. A negative effect size indicates that the intervention is associated with a decrease in the outcome at follow-up as compared with the control or usual care group.

Because follow-up times across studies can lead to clinical heterogeneity, we excluded from analysis any studies whose data were not collected within a specified follow-up interval chosen based on clinical knowledge.

For each condition and outcome, we conducted the same analysis. We first estimated a pooled random effects estimate¹¹ of the treatment effect and a pooled effect size for continuous outcomes across all studies and its associated 95% confidence interval. For each of the original five hypotheses stated above, study arms either met the hypothesis (a “yes”) or did not (a “no”)

and thus, no missing values exist. For each hypothesis, a simple stratified analysis would have produced a pooled estimate of the treatment effect for all the “yes” study arms together, and a pooled estimate for all the “no” study arms together. To facilitate testing the difference between the two pooled estimates, we constructed these estimates using meta-regression in which the only variables in the regression were a constant, and an indicator variable equal to one if the study arm met the hypothesis and zero if the study arm did not. For some outcomes and hypotheses, all study arms were either "yes" or "no." In this case, we could not fit a model.

As an overall test of the hypotheses, we combined the pain outcomes from osteoarthritis studies, hemoglobin A1c outcomes from diabetes studies, and systolic blood pressure outcomes from hypertension into one analysis using effect size and fit the five separate regressions as above. We also fit a sixth regression that had a constant and all five-indicator variables for the separate regressions included.

Sensitivity Analyses

Within each regression, and especially in the combined analysis, our primary analysis ignored the fact that individual studies had multiple intervention arms and thus could contribute more than one treatment effect to the analysis. The correlation between treatment effects within the same study, due to the fact the each intervention arm was compared to the same control or usual care arm, was ignored in this analysis. Our sensitivity analyses consisted of refitting the meta-regression models using a two-level random effects model that contains a random effect at the study level, as well as one at the arm level. This hierarchical approach controls for the correlation within arms in the same study. None of these sensitivity analyses results differed markedly from that of the primary analysis.

Post Hoc Analyses

We presented the results of the above analyses to a group of experts in chronic disease self-management. Based on this presentation, members of this group suggested a series of additional analyses exploring other possible mechanisms for an effect of self-management programs. These included classifying the studies according to categories proposed in the RE-AIM Model,¹² classifying the studies according to potential “essential elements” proposed by this group,¹³ assessing whether the effectiveness of self-management programs varied by severity of illness, and assessing whether interventions more likely to improve the “intermediate variables,” such as knowledge and perception of self-efficacy, were more likely to improve health outcomes

Results

Question 1. Do these programs work?

Question 2. Are there features that are generalizable across all diseases?

Question 6. What is the impact of chronic disease self-management programs on quality of life, health status, health outcomes, satisfaction, pain, independence, mental health (e.g., depression, emotional problems)?

Question 10. Is a generic self-management approach preferable to a disease-by-disease approach?

These questions are all related and were the focus of our meta-analysis. We first present a disease-by-disease assessment of the evidence for efficacy, then our assessment of generalizable or generic elements of a self-management program.

Diabetes

There were 14 comparisons from 12 studies that reported hemoglobin A1c outcomes. In an overall analysis of the effectiveness of chronic disease self-management programs, these studies reported a statistically and clinically significant pooled effect size of -0.45 in favor of the intervention (95% CI: (-0.26, -0.63)). The negative effect size indicates a lower hemoglobin A1c in the treatment group as compared to the usual care or control group. An effect size of -0.45 is equal to a reduction in hemoglobin A1c of about 1.0. For change in weight, there were 10 comparisons from 8 studies. There was no statistically significant difference between change in weight in the intervention and control groups (effect size of -0.05; 95% CI: (-0.12, 0.23)). There were 10 comparisons from 9 studies that reported fasting blood glucose outcomes. The pooled effect size was -0.41 in favor of the intervention (95% CI: (-0.23, -0.60)). This effect size equates to a drop in blood glucose of 1 mmol/l.

Our assessment of publication bias revealed likely publication bias in studies reporting hemoglobin A1c outcomes. Therefore, our results regarding efficacy of chronic disease self-management programs for improving hemoglobin A1c must be interpreted with caution.

Osteoarthritis

For both pain and function outcomes there were 10 comparisons from 7 different studies. The pooled results did not yield any statistically significant differences between intervention and control groups (pooled effect sizes of -0.04 and -0.01 for pain and function respectively). Our assessment of publication bias did not yield any evidence of publication bias.

Hypertension

For hypertension there were 23 comparisons from 14 studies that reported systolic and diastolic blood pressure changes. The overall pooled result of the chronic disease self-

management programs was a statistically and clinically significant reduction in systolic and diastolic blood pressure (effect size for systolic blood pressure -0.32; 95% CI: (-0.50, -0.15); effect size for diastolic blood pressure -0.59; 95% CI: (-0.81, -0.38)). An effect size of 0.32 is equivalent to a change in blood pressure of 3.5 mm of mercury, the corresponding value for an effect size of 0.59 is 6.5 mm of mercury. In our assessment of publication bias, there was evidence of publication bias. Therefore our pooled result favoring chronic disease self-management programs for hypertension must be viewed with caution.

Post Myocardial Infarction Care

There were 9 studies that reported mortality outcomes. There was no effect of chronic disease self management programs on improving mortality (pooled relative risk 1.04; 95% CI: (0.56, 1.95)). For return to work there were 10 comparisons from 8 studies. The pooled relative risk did not show any difference between groups (relative risk 1.02; 95% CI: (0.97, 1.08)). Our assessment of publication bias showed evidence of publication bias for the mortality outcome but not the return to work outcome.

Tests of hypothesis of elements essential to chronic disease self-management efficacy

Other than an increased effectiveness seen in hypertension studies reporting systolic blood pressure outcomes that used tailored interventions, there were no statistically significant differences between interventions with or without the 5 features hypothesized to be related to effectiveness (tailoring, use of group setting, feedback, psychological component, and medical care). Indeed, many of the effects seen were inconsistent across outcomes within the same condition. For example, in hypertension studies, for the hypothesis “use of a group setting,” there was a greater than 50% increase in the effect size for improvement in systolic blood

pressure, but only a 5% increase in the effect size for improvement in diastolic blood pressure (with neither result reaching statistical significance).

Our "across condition" analysis shows effect sizes that, in general, go in the direction of supporting increased effectiveness associated with the use of these intervention features, however none of the differences are statistically significant.

Post Hoc Analyses

Our "post hoc" tests of possible "essential elements" of chronic disease self-management programs was unrevealing. The RE-AIM theory¹² suggests that the following components: one-on-one counseling interventions (individual), group sessions (group), telephone calls (telephone), interactive computer-mediated interventions (computer), mail interventions (mail) and health system policies (policy 1 and policy 2) led to positive outcomes. With few exceptions, there were no results that were statistically significant. An exception is the result for the use of one-on-one counseling sessions, which did show a statistically significant increased effect size when used.

For the "Essential Elements of Self-management Interventions" evaluation, we did not find as much variation among studies and components as is necessary for optimal power in the analysis. Most of the studies scored positively for "problem identification and solving," and did not score positively for the "ensuring implementation component." Given these data, we did not find evidence to support either any one of these three broad "essential elements" as necessary, nor some threshold (such as two out of three) in terms of efficacy. This was not an optimal test of these hypotheses due to the lack of variation in the data.

Our analysis of the effect of self-management intervention on “intermediate variables” such as knowledge and self-efficacy did not produce consistent results supporting an effect in the expected direction.

Lastly, it was suggested we stratify by baseline patient severity. Only the assessment of hemoglobin A1c demonstrated an increased effect size in patients who had higher (worse) value of hemoglobin A1c at baseline, and this difference did not quite reach statistical significance.

Question 3. Does this intervention belong in the medical care system?

Whether chronic disease self-management belongs in the medical care system or in the community is a decision that needs to be made by policy makers, based on many factors. One of the first hypotheses we tested was whether patients who receive interventions directly from their medical providers are more likely to have better outcomes than those who received interventions from non-medical providers; no effect was found. Of the controlled studies that made it into our meta-analysis, no studies of osteoarthritis or hypertension used medical providers in their self-management interventions. Regarding diabetes, one intervention used medical providers; the results of this intervention were not significantly different than those using lay leaders. One post-myocardial infarction intervention used medical providers; the effects on mortality and return to work were not statistically different from those of the other interventions.

Question 4. Define chronic disease self-management and distinguish between it and disease management.

For purposes of this review, we initially defined chronic disease self-management broadly as a systematic intervention that is targeted towards patients with chronic disease to help them to actively participate in either or both of the following activities: self monitoring (of

symptoms or physiologic processes) or decision-making (managing the disease or its impact based on self-monitoring). Our analytic attempts to “define” chronic disease self-management by identifying the components most responsible for the success of the program were unsuccessful.

The draft evidence report was presented to a group of experts in chronic disease self-management at a meeting convened by the Robert Wood Johnson Foundation on December 14, 2001. The panel’s aim was to focus on interventions offered to patients who need a more intense level and type of self-management support. They agreed that all self-management programs should address the following three areas.

Disease, medication and health management. While patients need medical information about their particular disease (diabetes, arthritis, asthma, etc.), the majority of the content in most successful self-management programs emphasized generic lifestyle issues such as exercise, nutrition, and coping skills. More disease-specific medication-specific information can be useful, but such information rarely constitutes more than 20 percent of the content of programs.

Role management. Patients benefit from programs that help them maintain social support, connection to work and family, and normal functions of daily life.

Emotional management. Programs should encompass managing depression and stress, adaptation to change, and maintaining interpersonal relationships.

A monograph authored by Dr. Jesse Gruman (Center for the Advancement of Health, 2002) summarized the discussions from this meeting. The experts concluded that the essential elements of self-management programs should include the following:

1. Problem-solving training that encourages patients and providers to identify problems, identify barriers and supports, generate solutions, form an individually tailored action plan, monitor and assess progress toward goals, and adjust the action plan as needed.
2. Follow-up to maintain contact and continued problem-solving support, to identify patients who are not doing well and assist them in modifying their plan, and to relate the plan to the patient's social/cultural environment.
3. Tracking and ensuring implementation by linking the program to the patient's regular source of medical care and by monitoring the effects of the program on the patient's health, satisfaction, quality of life, and health system quality measures.

The experts also recommended that any chronic disease self-management program be composed of two tiers to accommodate the wide variety of patients with chronic conditions. The first tier would include a low-intensity intervention designed to reach mass audiences and open to anybody with a particular illness. The second tier would include a high-intensity intervention targeted to people who require one-on-one support and case management. This program could be offered to those who have not successfully managed their condition with the minimal support of tier #1, those who have complicated conditions, and those whose life circumstances or conditions change significantly.

Question 5. What is the role or potential of technology?

The advent of new technologies makes communication between patients, providers, and others more convenient than ever. However, none of the randomized controlled studies on chronic disease self-management for our study conditions in older patients used email or the Internet. Thus, we were not able to quantitatively assess the impact of these technologies. A

recently reported study of back pain in middle aged adults reported modest improvements in outcomes and costs for subjects randomized to a physician-moderated “email discussion group” and educational material compared to a control group that received a magazine subscription. This study suggests that incorporating these technologies into future randomized studies would be a worthwhile endeavor.

Question 7. To what extent does self-management educate a patient on how to care for himself/herself (e.g., take medications appropriately, consult with a physician when necessary, etc.)?

Most CDSM studies that assess knowledge and self-efficacy reported beneficial improvements. Most studies did NOT measure whether medications were taken appropriately or “necessary” physician visits were made. The two studies that did assess compliance were hypertension studies. One had a borderline beneficial overall result; the other reported a significant beneficial result. One study was based on a conceptual model that specifically considered that changing medication-taking behavior was going to be easier than changing diet behavior or other such behaviors. This study did not actually measure compliance, but rather measured “commitment to taking medications” and showed that this differed between intervention and controls and that it was one of only three variables among those tested to be associated with significant changes in blood pressure (the other two were “belief in severity of the disease” and “beliefs in efficacy of therapy”). Many studies assessed utilization, but none assessed whether the utilization was necessary.

Question 8. What is the patient’s retention of self-management skills after the intervention? Is a follow-up intervention needed at some point?

We were unable to find studies that actually included a “follow-up intervention” which incorporated refresher skills on self-management. In light of this, we used a meta-regression model to test whether self-management interventions that provide follow-up support led to better results than those that did not. We classified interventions that maintained contact with the patient through contracts, provider feedback, reminders, peer support, material incentives, or home visits as including “follow-up support.” Of the interventions which could be included in our meta-analyses, 19 had “follow-up support” while 28 did not. Pooled results were not statistically different between the two groups.

Question 9. How does the approach for self-management differ for people with multiple chronic diseases?

We found no evidence on this topic.

Question 11. Should this intervention be targeted to a subset of the population or available to everyone? Are there particular chronic conditions that should be addressed (e.g., diabetes, arthritis, stroke, cancer, Parkinson’s, hypertension, dyslipidemia)?

We were able to quantitatively assess the effects of chronic disease self-management programs on patients with diabetes, osteoarthritis, and hypertension. In addition, we were able to pool results for post myocardial infarction programs. There were insufficient studies on stroke, cancer, Parkinson’s and dyslipidemia to allow pooling.

In an attempt to assess whether chronic disease self-management programs were more effective for more severe patients, we undertook a post-hoc quantitative analysis. Two clinicians independently categorized each diabetes and osteoarthritis program as focusing on either more severe or less severe patients. The clinicians were unable to categorize the hypertension and post- MI programs in such a fashion, due to the lack of heterogeneity of the patients. In the diabetes analysis, there was no statistical difference between the effectiveness of programs targeted to more severe and less severe patients, in terms of change in hemoglobin A1c or weight. For osteoarthritis studies, there was no statistical difference in change in pain or functioning.

Question 12. What is the role of the physician? Can physicians be used to reinforce learning?

Our meta-analysis did not reveal any statistically significant differences supporting the role of physicians at enhancing the efficacy of chronic disease self-management programs.

Question 13. Cost effectiveness or cost savings—does the intervention appear to reduce health care costs by reducing disease, physician office visits, hospitalizations, nursing home admissions, etc.?

A total of 19 clinical trial studies were identified in this review of the economic impact of Chronic Disease Self-Management (CDSM). These include 9 studies on diabetes, 4 studies on osteoarthritis, one study on hypertension, two on post-myocardial infarction, and three non-disease-specific programs for chronically ill patients. They represented only a subset of possible strategies for CDSM. Thus our economic review has limited generalizability beyond the studied interventions.

Costs of the intervention were rarely reported and health care costs as an outcome of the intervention were rarely studied. Changes in health care utilization were seldom reported, and in many cases only studied on a limited scale (not including all types of services). The follow-up period was short, while many outcomes will not be evident for many years (e.g., rigid metabolic control may result in delay or prevention of diabetic complications, but only after several years).

Among the four diseases reviewed, the programs to promote self-management with osteoarthritis patients have the best economic information and most consistently report reductions in health care utilization and costs, even to the point of cost-savings. Such findings are compatible with observational studies.¹⁴⁻¹⁶ Programs for diabetic patients have mixed results, and overall are weaker in the economic information they report. There is only one hypertension program identified that include any economic information, and the information provided does not allow us to adequately judge cost-effectiveness of the program. The two reviewed MI studies both lacked a rigorous collection of economic data, but the limited evidence presented suggests that home-based rehabilitation programs could potentially be a cost-effective alternative to group rehabilitation or standard care. As for the three general, non-disease-specific programs, two RCTs and two observational studies reported that low-cost, community-based CDSM programs may potentially be cost-saving.

Limitations

Despite finding evidence that CDSM programs have a clinically and statistically significant beneficial effect on some outcomes, we were unable to discern which elements of CDSM programs are most associated with success. This may have been because we did not test the right hypotheses regarding CDSM elements, or because key variables describing these components were either not recorded adequately or not recorded at all in the published articles,

or that the individual components themselves each have relatively weak effects. We considered contacting original authors for additional information regarding their interventions, but rejected this due to time and resource constraints. Furthermore, our experience has been that any study published more than a few years ago has a much lower likelihood for getting a favorable response to such a request. In addition, we may have lacked the statistical power, due to the small number of studies available, to discern the reasons for the relatively small amount of heterogeneity in the study results. We note that the preceding challenges are common to all studies of complex, multicomponent interventions, and these challenges did not prevent us from detecting important differences in the effectiveness of interventions for prevention of falls¹⁷ or increasing the use of cancer screening and immunizations.¹⁸

An additional primary limitation of this systematic review, common to all such reviews, is the quantity and quality of the original studies. We made no attempt to give greater importance to some studies based on "quality." The only validated assessment of study quality includes criteria not possible in self-management (double-blinding). As there is a lack of empirical evidence regarding other study characteristics and their relationship to bias, we did not attempt to use other criteria.

As previously discussed, we did find evidence of publication bias in hemoglobin A1c, mortality, and systolic and diastolic blood pressure outcomes in diabetes, post-myocardial infarction care, and hypertension, respectively. Therefore, the beneficial results that we report in our pooled analysis need to be considered in light of the possible existence of unpublished studies reporting no benefit.

Conclusions

1. Chronic disease self-management programs probably have a beneficial effect on some, but not all, physiologic outcomes. In particular, we found evidence of a statistically significant and clinically important benefit on measures of blood glucose control and blood pressure reduction for chronic disease self management programs for patients with diabetes and hypertension, respectively. Our conclusions are tempered by our finding of possible publication bias, favoring beneficial studies, in these two clinical areas. There was no evidence of a beneficial effect on other physiologic outcomes such as pain, function, weight loss, and return to work.
2. There is not enough evidence to support any of the proposed elements as being essential to the efficacy of chronic disease self-management programs. More research is needed to try and establish the optimum design of a chronic disease self-management program, and whether or not this differs substantially depending on the particular chronic disease or characteristics of the patient.
3. While no randomized studies of chronic disease self-management programs for older adults assessed the use of email or the Internet, one recently reported randomized study of email use in the self-management of middle aged adults with back pain was sufficiently promising to warrant testing such interventions for chronic disease self-management in the Medicare population.
4. There is no evidence to conclusively support or refute the role of physician providers in chronic disease self-management programs for older adults.
5. The evidence is inconclusive but suggests that chronic disease self-management programs may reduce health care use.