Incenting Medicare STARS Clinical Health Measures: 
Evaluation of Part C HEDIS Measures

By

Martin S. Kus, MD

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Abstract

Background: Medicare Advantage (MA) health Plans provide health insurance to a large portion of Medicare recipients. Since passage of the Affordable Care Act, MA Plans have received substantial bonus payments based on their STAR rating, a measure of the quality of health care delivered by the Plan. Part C of the Healthcare Effectiveness Data and Information Set (HEDIS) provides the clinical measures used to assign a STAR rating to the clinical performance of a MA health care Plan.

Objective: To evaluate the clinical measures listed in Part C of the HEDIS set to determine which measures would be best incentivized by a MA Plan in physician contracts.

Methods: The measures listed in Part C of the HEDIS data set were assessed to identify those with the potential to change physicians’ practice towards a higher STAR rating. Eight measures were selected: breast cancer screening, colorectal cancer screening, osteoporosis management, diabetic eye exam, diabetic kidney disease monitoring, diabetic glucose control, blood pressure management, and rheumatoid arthritis (RA) management. Individual measures were evaluated from the framework of the relevant stakeholder perspectives involved in performance of the measure: the patient, the insurance provider, the physician, and society. Result tables were used to report each measure’s performance and feasibility for physician-contract incentives by each of the four relevant perspectives. Each clinical measure was assigned a score based on its performance within the four selected perspectives.

Results: Of the eight relevant clinical measures of the Part C HEDIS data set, blood glucose control and RA management offered the greatest benefit to the patient based on the magnitude of improved health and avoidance of disease complications. Diabetic kidney disease management was found to be the most favorable candidate from the insurer’s perspective owing to the low cost of testing and treating, while avoiding expensive complications. The
physicians’ perspective received most benefit from diabetic eye and kidney disease measures due to the absence of significant barriers in completing the measure and the ease of reporting measure completion. Societal benefits were greatest in colorectal cancer screening based on their ability to both reduce a significant societal disease burden and the potential to improve health care disparities.

**Conclusion:** This evaluation of the clinical measures of Part C HEDIS data plan found that diabetic kidney disease monitoring benefitted all stated perspectives and is a good measure to incentivize in physician – MA carrier contracts.
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Evaluation of Effectiveness of Clinical HEDIS Measures for Medicare Advantage

Introduction

Since the 1970s, Medicare beneficiaries have been able to choose to receive their health benefits through private health plans instead of directly, through “Original” Fee-for-Service Medicare. This program was named Medicare Choice by the Balanced Budget Act of 1997 and is currently known as Medicare Advantage (MA) since the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Enrollment in these plans has steadily increased, tripling since 2004 from 5.3 million enrollees to 17.6 million today. Currently, 31% of all Medicare beneficiaries obtain their health care benefits through Medicare Advantage Plans.1

The Centers for Medicare and Medicaid Services (CMS) hold that private health organizations delivering MA health services are accountable for the care they provide their enrollees.2 Thus, in 2007, a STAR ratings system was established for MA Plans as a consumer tool intended to help enrollees choose from competing health Plans that offer MA. CMS asserted that research supported the use of symbols, such as Stars, as a valuable tool for consumers in determining the relative value of summary quality measures in their selection of Plans and providers.3 Since then, a STAR rating classification system has been used to grade the health services provided by to Medicare beneficiaries by MA plans.

In 2012, under provisions of the Affordable Care Act (ACA), the STAR ratings began to be used to adjust payments to MA health plans. Thus, the stated purpose of the STAR ratings system has been adjusted. Whereas initially it was intended to help consumers choose the best MA plan for them, today it both provides quality information to consumers and determines MA quality bonus payments.3,4 The payment structure has also changed. Initially bonus payments were awarded to MA Plans who receive four or more STARS based on threshold performance
measures. Today, bonuses are based on a MA organization’s measures as they deviate from the mean, regardless of actual performance data or improvement. Plans that outperform their competitors receive higher star ratings and, thus, more bonus payments; plans that perform poorly forfeit bonus payments as a result of low star ratings.⁴,⁵

In an effort to improve their overall STAR rating, some MA plans have opted to financially incent participating physicians towards a clinical practice model which helps improve performance on HEDIS measures.⁶,⁷ As it is not financially feasible to incentivize physicians towards all HEDIS measures, care must be taken in choosing which measures to pursue. A brief overview of the makeup of STARS measures is provided to describe its structure.

Medicare STAR ratings are based on performance measure data collected from five sources which provide information about the general health status of beneficiaries, patients’ experience of care, complaints and disenrollment, pharmacy use, and quality of care. The source responsible for quality of care information is the Healthcare Effectiveness Data and Information Set (HEDIS). This set is a list of performance measures that assess an MAO’s clinical effectiveness, accessibility to members, and resource utilization.³

Medicare HEDIS measures are developed and managed by the National Committee for Quality Assurance (NCQA). They are selected and shaped to be used for "comparison among health care systems, not measures for quality improvement."⁸ The attributes used in selection are relevance (meaningful, clinically important, cost-effective), scientific soundness (evidence based, valid, accurate), and feasibility (measurable).⁸

The STARS HEDIS measures are divided into two domains: Part C and Part D. Part D measures evaluate pharmacy benefits; those of Part C evaluate the clinical realm. There are 32 Part C HEDIS measures that assess clinical performance. They are divided into 5 domains: staying healthy, managing chronic diseases, member experience, complaints and changes in
health care performance, and health plan customer service. These are presented in Figure 1. Of these, eight are chosen for evaluation based on their potential for a clinical health benefit related to an outpatient office visit (Table 1).

The purpose of this paper is to evaluate the HEDIS Part C clinical measures in order to help determine which would be best incentivized in a physician contract. Whereas cost-effectiveness factors in measure selection, other factors can be considered. First, the degree of health benefit to a patient which results from achieving a HEDIS measure is important. All things being equal, incentivizing a measure which greatly improves health is preferable to one that is less beneficial. Further, considering the barriers encountered by the physician in pursuit of a HEDIS measure differentiates which would be more or less likely to succeed. Lastly, the degree to which a HEDIS measure improves societal health or decreases socioeconomic (SES) disparities is a significant factor to consider. These various perspectives will be used as an evaluation tool in helping determine which HEDIS Part C clinical measure should be incented.

Methods

No validated evaluation system or tool exists for this type of analysis. The Part-C HEDIS measures identified previously as “clinical” will be individually evaluated. These include: breast cancer screening; colorectal cancer screening; osteoporosis management; diabetic retinopathy care; testing for diabetic nephropathy; diabetic glycemic control; hypertension control; and treatment for rheumatoid arthritis. This appraisal will include the perspective of the various stakeholders involved in the performance of each individual HEDIS measure. The relevant perspectives include that of the patient, the MA insurance provider (“Plan”), the physician, and society.
After describing the specific guidelines and metrics involved in achieving the HEDIS measure, it will be assessed from the perspective of the patient. A literature review will examine the scientific basis of the NCQA’s decision to choose the HEDIS measure and, if appropriate, the recommendations of the U.S. Preventive Services Task Force (USPSTF). The measure will be examined for magnitude of disease burden involved, evidence of health benefit purported to result from compliance with the guideline, and the magnitude of that benefit. Lastly, the measure will be examined for any harms that may result from its implementation.

The MA insurance plan’s perspective will begin with an assessment of the financial burden that the Plan will be responsible for. An evaluation of available cost-benefit data for the measure will follow. As the cost of health maintenance is seldom singular, the required frequency of the costs will be taken into account. Long-term benefits will also be considered to examine the potential of decreasing future healthcare expenditures and, equally important, the risk of increased future expenditures should the measure not be pursued.

The physician’s perspective in terms of the HEDIS measure will focus on the barriers and concerns a physician faces in completing the measure. The ease with which the rate of measure completion can be monitored will also be considered as a factor in deciding which measures can be incentivized.

Finally, the societal perspective of the measure will be examined for its ability to improve public health and lessen the disease burden of the population. The presence or absence of SES and racial disparities in the applicable disease process will be described in order to identify a potential to improve such disparities.

The results of this “perspectives” analysis of each clinical HEDIS measure will be summarized in light of its potential to improve its corresponding health burden for each relevant stakeholder and serve as a viable measure for contract incentives. The individual measures will
also be compared against each other by the degree of benefit for each perspective. A score ranging from 1-5 will be assigned to each measure. 1 signifying a poor choice for contract incentives, 5 signifying strong evidence in favor of physician-contract incentives.

Results

Breast Cancer Screening

_HEDIS Measure C01: Percent of female plan members aged 50-74 who had a mammogram during the past 2 years._

Patient Perspective

Screening for breast cancer remains a controversial topic with several differing guidelines published by professional organizations. The American College of Obstetricians and Gynecologists offers the most conservative screening strategy. It recommends annual mammography for all women, beginning at age 40. The American Cancer Society recommends annual screening for women aged 45-54 transitioning to biannual mammography for women 55 or older. The USPSTF recommendation closely resembles the current HEDIS measure. Despite the various screening recommendations, evidence supports the USPSTF and HEDIS guidelines due to a mortality benefit for screening women aged 50-74 with no corresponding benefit to those younger or older. Similarly, a review of 5 trials showed a 29% breast cancer mortality reduction in women aged 50-69, finding none for women between 40 and 49 years of age.

Significant patient harms identified in breast cancer screening are over-diagnosis and a high false positive rate. Over-diagnosis is the detection of a tumor with a low-probability of being or progressing to clinical symptoms or death over a patient’s lifetime. Both over-diagnosis and false positive findings result in significant psychological stress to patients as well as
unnecessary surgical biopsies and chemotherapy treatments. A recent 25-year review of breast cancer incidence found a 22% rate of overdiagnosis.\textsuperscript{15}

Insurance Provider

Screening for breast cancer is a significant financial burden costing an average of $266 per mammogram.\textsuperscript{16} In the US, 50 million screening mammograms are performed every year totaling more than $7 billion annually.\textsuperscript{17}

Cost-effectiveness analysis supports the current HEDIS guidelines stating that strategies which begin screening at age 40 are very cost-ineffective while screening biannually from ages 50 to 64 reduce mortality at 7.8%, costing $18,999 per additional life year.\textsuperscript{18}

Physician

Physician compliance is a barrier to appropriate screening women for breast cancer. Although compliance rates are increasing, they have historically been as low as 57% due primarily to physicians' inaccurate information about the health benefits of mammography. Poor consensus from the various agencies that publish breast cancer screening recommendations served to further isolate physicians who already had difficulties accepting the evidence for mammography.\textsuperscript{19} Another study confirms these barriers, reporting that 29% of physicians believed annual mammography in women older than 50 is too frequent, 16% believed that screening was unnecessary in asymptomatic women, and 12% believed it less important in women without a family history of breast cancer.\textsuperscript{20}

Identifying compliance with the current guidelines is easily accomplished by the insurance plan through monitoring of submitted insurance claims data, making this guideline easy to measure and incentivize in contracts.
Society

The benefits of breast cancer screening from the perspective of the community and society is complex. The mortality benefit from the appropriate use of mammography is unquestionably a valued societal benefit despite its poor cost-effectiveness. As the incidence of breast cancer is higher among African-American women, this measure has the potential to decrease this disparity in health by targeting the African American community and benefitting this population more, proportionally. These benefits should be in perspective of the financial burden that this measure represents for the entire population.

Colorectal Cancer Screening

HEDIS Measure C02: Percent of plan members aged 50-75 who had appropriate screening for colon cancer.

Patient

This HEDIS measure closely resembles the USPSTF recommendation for colon cancer screening, beginning at age 50. According to the USPSTF, screening can be accomplished with high-sensitivity fecal occult blood testing (FOBT) of 3 consecutive stool samples annually, flexible sigmoidoscopy every 5 years with fecal occult blood testing every 3 years, or colonoscopy every 10 years if results are normal.

FOBT is safe, convenient to patients who can perform the test at home, and effective. A Cochrane review shows that FOBT reduced the relative risk of death from colon cancer by 16%. Flexible sigmoidoscopy reduces the relative risk of mortality by 28%, of the incidence of colon cancer by 18%, and the incidence of left sided colon cancer by 33%. Colonoscopy carries an absolute risk reduction of mortality of 60% and incidence of cancer by 17%. 
Unlike FOBT, flexible sigmoidoscopy and colonoscopy are both invasive procedures which can be barriers for patients. In a mixed-method analysis, the greatest identified barriers were fear of the procedure and the bowel preparation required beforehand.\textsuperscript{26} The barriers identified to be less prevalent are low self-worth, “para-sexual” sensitivities, fatalism, negative past experiences, and skepticism about the financial motivation behind the screening.

Colonoscopy and flexible sigmoidoscopy differ from FOBT in that they bear a risk of harm. A recent USPSTF systematic review reported 2 to 5 bowel perforations per 10,000 colonoscopies and 5-14 major hemorrhagic events per 10,000 colonoscopies.\textsuperscript{27}

\textbf{Insurance Provider}

According to Consumer Reports, the average cost of colonoscopy in the US is $1,100 ranging from $800 - $3160. Flexible sigmoidoscopy costs an average of $740 while FOBT costs only $10.\textsuperscript{28} The outpatient visits for the referral and the review of the results are not included in these figures. These costs carry special significance for MA plans not only because they are substantial and recurring, but also because the ACA requires that the entire cost of screening be covered with without a co-payment.\textsuperscript{29}

Although these costs are substantial relative to many medical tests, cost analyses have concluded that, when compared to no screening, all colon cancer screening strategies are cost-saving.\textsuperscript{30} An incremental cost-effectiveness analysis of the three screening modalities yields no single optimal screening strategy. While FOBT testing is fairly inexpensive compared to colonoscopy, factors such as the frequency of testing for FOBT and its inferior sensitivity for colon cancer serves to make them equal in a cost-benefit analysis. There is consensus, however, that stool DNA testing, computed tomographic colonography, and capsule endoscopy are not yet cost-effective compared to the screening tests currently recommended.\textsuperscript{31}

\textbf{Physician}
The barriers physicians encounter in successfully completing colon cancer screening include deferment of testing to a later time due to psychosocial issues, impeding or more pressing comorbid medical illness, considering screening a low priority during a short outpatient office visit, and a perception that a patient may lack willingness to seek preventive care. Lack of local or accessible gastroenterologists has also been noted in remote or rural areas.

Identifying compliance with colon cancer screening recommendations is accomplished easily by the insurance plan through monitoring of submitted insurance claims data, making this guideline easy to measure and incentivize in contracts.

Society

In light of the significant mortality benefit conferred by colon cancer screening, the ability to decrease the incidence of cancer, and its cost-effectiveness, colon cancer screening strategies appear to significantly benefit the community and the entire healthcare system. In fact, according to a randomized trial from Nottingham, England conducted between 1981 and 1991, patients with a positive colon cancer screening test lived longer than those with a negative test due to appropriate treatment of the malignancy, incidental identification of comorbid illnesses during the workup, and greater engagement with health services.

Although the rates and mortality of colon cancer has been decreasing over the past 2 decades, the incidence of colon cancer remains significantly elevated in African-American men. An increased focus on colorectal cancer screening in this minority group can serve to decrease racial disparities and promote improved health equality.

Osteoporosis Management in Women who had a Fracture

HEDIS Measure C12: Percent of female MA plan members aged 67-85 who broke a bone and got screening or treatment for osteoporosis within 6 months.
Patient

The USPSTF recommendations screening asymptomatic women for osteoporosis beginning at age 65 with dual-energy x-ray absorptiometry (DEXA). Although this HEDIS measure is not a screening strategy, a comparison to the USPSTF recommendation shows it to be more cost-effective. The age of testing is similar for both the USPSTF recommendation and HEDIS measure. The population tested by the HEDIS measure, however, has a significantly higher pre-test probability of disease (the presence of an existing fracture makes osteoporosis more likely). The rate of positive findings will be higher in the HEDIS population making it cost-effective.

Treating osteoporosis and increasing bone marrow density reduces future fractures. The reduction in fractures is the target benefit of osteoporosis testing and treatment as it can significantly improve a person's quality-of-life and health. A recent meta-analysis demonstrates that bisphosphonate therapy, a common osteoporosis oral treatment, has a strong, dose-dependent, linear relationship to increased spine bone-marrow density compared to placebo. A meta-analysis from China found that intravenous bisphosphonate therapy increases bone density by a factor of 2.98, reducing the fracture rate by 32%. Treatment with a combination of several available osteoporosis treatment medications offers the greatest patient benefit, decreasing the relative risk of vertebral fractures by 40-60% and that of non-vertebral fractures by 60-80%.

These benefits, however, must be weighed against the potential harms of treatment for osteoporosis. Oral bisphosphonate therapy causes gastrointestinal symptoms that cause as many as 20% women to discontinue its use. Intravenous bisphosphonates therapy causes a significant flu-like illness in 30% of subjects and it has the potential to be severely nephrotoxic.
Because testing is infrequent, an average price of $132 for a DEXA scan, with a range from $150 - $250 is a reasonable cost in detecting osteoporosis following a fracture.\textsuperscript{42} Cost-effectiveness analyses support routine screening of women aged 55-80, finding it superior to not screening.\textsuperscript{43} As noted above, the HEDIS measure is very likely more cost effective than a screening strategy.

Treatment, however, is very expensive. Bisphosphonate therapy alone costs $125 - $148 per month for brand name drugs, and $38 - $70 for generics.\textsuperscript{42} Cost-benefit analyses support treating women aged 70 or greater while recommending against treating women under 50 years of age. Whether it is cost-effective to treat women between ages 50 and 69 is unclear.\textsuperscript{44} The total cost of osteoporosis treatment is significant at over $5 billion to treat all eligible women. This strategy would reduce fracture rates by 35\% with an annual cost of a quality year (QALY) gained of $66,722.\textsuperscript{45}

Physician

One of the barriers that physicians face in testing for and treating osteoporosis is the safety concern of the treatment drugs. There is no universal clinical treatment guideline to follow due to the uncertainty of bone experts about the management of osteopenia, frequency and timing for follow up DEXA scans, and the appropriate amount of calcium and Vitamin-D to prescribe. Making treatment decisions in the face of this kind of uncertainty and fear of harms is a difficult undertaking made more difficult when treating patients with significant comorbidities which make harms of treatment more likely to occur.\textsuperscript{46}

Physicians also report that osteoporosis screening and treatment is not always a priority in a short outpatient visit with older women who have many medical problems.\textsuperscript{47}
Tracking progress and compliance with this osteoporosis measure is accomplished easily by the insurance plan through monitoring insurance claims data, making this guideline easy to measure and incentivize in contracts.

Society

A considerable amount of variation in the incidence of testing for osteoporosis following fractures between different races and persons of differing SES background. African-American and Hispanic women are less likely to receive osteoporosis testing both before and following a fracture when compared to white women. The results are similar for women with lower education and income levels when compared to more women from a higher SES background.

The disease burden placed on the population by osteoporosis is significant. The monetary component to fracture care in women with osteoporosis includes medical treatment and rehabilitation which costs $17 - $20 billion annually. The non-monetary burdens include family stress from caring for an aging and injured family member, and the risk of health deterioration that can occur when an elderly person is immobilized following a fracture.

Diabetes Care – Eye Exam

*HEDIS Measure C13: The percent of MA enrollees aged 18 – 75 with diabetes who had a retinal eye examination during the year.*

Patient

Diabetic retinopathy (DR) is the most frequent cause of blindness among adults. During the first 20 years of disease, nearly all type-1 diabetics and 60% of those with type-2 have retinopathy. The severity of DR at baseline is also directly related to the incidence of proliferative retinopathy, the more advanced form of disease which involves of new and fragile blood vessels into the retina and vitreous. The incidence of proliferative retinopathy is 30% in
those diagnosed before age 30, 24% in those requiring insulin who were diagnosed after age 30, and 10% in those not requiring insulin.\textsuperscript{51}

While the incidence of DR among diabetics with severe disease is high, the incidence in those with mild disease is significantly lower. Patients with mild disease exhibit good glycemic control, older age, and no retinopathy on prior examinations. They receive little benefit from annual screening examinations. These patients may benefit from screening every three years in light of the health care costs associated with screening and the frequency of other diabetic outpatient visits, which range from 8 – 12 visits per year. Annual screening in this low-risk group increases 2-3 days of sight at a cost of $540 - $690 per patient.\textsuperscript{52} Despite this data and in the absence of other empirical data, all diabetics are recommended to be screened for DR every year.\textsuperscript{50}

Except for the inconvenience of a screening outpatient appointment, no additional barriers or harms are identified to annual DR screening in diabetics.

Insurance Provider

The national average cost of an eye examination is $114 but can cost as little as $50 at discount clinics and with contracted insurance rates. Although biannual screening may be a more efficient allocation of resources, annual screening of diabetics is cost-effective leading to a small health benefit at a moderately additional cost compared to biannual screening.\textsuperscript{53}

Physician

The barriers identified to annual screening examinations were patients’ financial constraints and the inconvenience of another outpatient medical appointment added to the multiple annual visits expected of every diabetic patient.\textsuperscript{52,54} While some areas of the country reported long wait times for a diabetic eye examination, these were not found to be barriers to care.
Tracking progress and compliance diabetic eye examinations is accomplished easily by the insurance plan through monitoring insurance claims data, making this guideline easy to measure and incentivize in contracts.

Society

An economic review found that annual screening for DR in type-1 diabetics without retinopathy and every 6 months for those with identified disease was calculated to save 70,000 – 80,000 person-years of sight, while saving $70 - $80 million annually in the US. For type-2 diabetics, the savings were greater than 94,000 person-years of sight with a savings of over $250 million annually.

The incidence of DR varies among racial groups. A small study found that after controlling for A1C values, blood pressure, and gender, African-Americans had a significantly increased incidence of diabetic retinopathy compared to white patients (50% versus 19%). A Veterans Affairs study had similar findings. After controlling for confounders, the incidence of DR was 36% in African-Americans, 29% in Hispanics, and 22% in non-Hispanic whites. Conflicting evidence exists, however. A cross-sectional analysis of 778 diabetics aged 45-85 found that, despite the increased rates in African-American patients, race was not an independent predictor of DR. The independent predictors of DR were identified as longer duration of diabetes, higher fasting glucose levels, greater waist-hip ratio, and the use of insulin or other diabetic medications. Regardless of the independent risk factors, a difference in diabetic retinopathy by race exists providing an opportunity to decrease this disparity with incentivized practice parameters.

Diabetic Care – Kidney Disease Monitoring

**HEDIS Measure C14**: The percent of MA enrollees aged 18-75 with diabetes who had a kidney function test during the year.
Patient

Diabetic kidney disease (DKD) is the leading cause of end-stage renal disease (ESRD) accounting for 50% of ESRD in the developed world. Diabetics are at increased risk for ESRD than non-diabetics with an odds ratio of 33.7 for insulin-dependent diabetics and 7.0 for non-insulin dependent patients. The resulting population-attributable risk of renal failure in diabetics is 42%.

Despite the significantly increased risk of ESRD, pharmacologic therapy for diabetics has been shown to be extremely effective in reducing its incidence. Specifically, therapy with angiotensin-converting enzyme (ACE) inhibitors significantly impedes progression to clinical proteinuria and ESRD. The Microalbuminuria Study Group found that 7.2% of patients on ACE inhibitor therapy progressed to proteinuria compared to 21.9% of those without.

The barriers encountered by patients in diabetic kidney screening were late referral to nephrologists, old age, multiple co-morbidities, and lack of education and awareness among ethnic minorities. No harms of screening are identified.

Insurance Provider

The purpose of screening diabetics for DKD is early identification and early treatment to prevent progression to ESRD. The costs of caring for diabetics with ESRD is extraordinarily high. For the Medicare population in 2011, DKD expenditures were nearly $25 billion. The cost of dialysis can be $500 per treatment and the typical regimen includes three treatments per week. This amounts to $60,000 per year not including the cost of medications and vitamins.

To contain these costs, annual screening helps identify early DKD, allowing for early treatment to combat disease progression. Screening and treatment with ACE inhibitors has been shown to be very cost-effective, with a QALY of $7,900 - $16,500. According to a systematic review of the cost-effectiveness of ADA recommendations, screening was found to
be cost-effective but, more importantly, early identification of disease and treatment with ACE inhibitors was cost-saving.\textsuperscript{53}

Physician

Aside from the presence of co-morbidities or acute illnesses which may take precedence over addressing diabetic nephropathy screening in the setting of a short outpatient health visit, no specific barriers to physicians are identified. Tracking and monitoring appropriate screening within a physician’s practice is easily accomplished through claims data.

Society

Over the past two decades, the incidence of ESRD attributable to DKD has stabilized. The rates continue to rise among high-risk groups such as African Americans, Native Americans, and Hispanics.\textsuperscript{60} There is evidence that SES status is a significant factor, if not the primary factor, involved in this disparity.\textsuperscript{67} An evaluation of SES status in relation to diabetic kidney disease also notes that poor SES status is associated with poorer glycemic control and higher rates of complications, such as nephropathy.\textsuperscript{68}

Diabetes Care – Blood Sugar Controlled

\textit{HEDIS Measure C15: The percentage of diabetic MA enrollees aged 18-75 whose most recent HbA1c is greater than 9\% or who were not tested during the measurement year.}

Patient

Euglycemia, a normal blood level of glucose in the blood, is the most important factor in the treatment of diabetes. Intensive glycemic control has been shown to delay the onset of and to slow the progression of diabetic eye, kidney, and nerve complications.\textsuperscript{69} Poor glycemic control results in retinopathy, nephropathy, coronary arterial disease, cerebral arterial disease, and distal neuropathy.\textsuperscript{70} Diabetics with poor glucose control are also at risk for hearing
impairment, sleep apnea, fatty liver disease, dental disease, cognitive impairment, and depression.\textsuperscript{71} Diabetes can also be a heavy psychosocial toll which often results in diminished self-care, poor long-term glycemic control, and ultimately, increased long term complications.

According to the American College of Physicians, the goal of glycemic control should be as low as possible with minimizing risk of adverse events or significant inconvenience to the patient. They recommend a target hemoglobin A1c (HbA1c) level of 7\% for most, but not all, patients.\textsuperscript{72} For patients who exhibit difficulty in maintaining tight glycemic control without complications, such as hypoglycemia, an individualized HbA1c goal is recommended. A recent retrospective study agrees with the personalized HbA1c goals for these patients, reporting that more than 20\% of type 2 diabetics who are treated with intensive therapy nearly doubles the risk of severe hypoglycemia.\textsuperscript{73} In light of this evidence, the HEDIS HbA1C goal of less than 9\% is a safe target to use clinically in glycemic control.

Insurance Provider

Diabetes is a significant contributor to healthcare spending. The US, home of 8\% of the world’s diabetic population, is responsible for 50\% of the world’s diabetes expenditures.\textsuperscript{74} The annual cost of diagnosed diabetes exceeds $245 billion, more than half of which is related to complications such as myocardial infarctions, stroke, ESRD, retinopathy, and foot ulcers.\textsuperscript{75} Individuals with diabetes have medical expenditures 2.3 times higher than those without diabetes, averaging $13,700 per year.\textsuperscript{76}

Intensive glucose control interventions in increase expenditures but has been shown to be very cost-effective due to its ability to halt or slow the development of complication.\textsuperscript{77} A similar analysis of intensive diabetic control reported the incremental cost per QALY to be 6,028 UK pounds, a low figure compared to many other routine interventions.\textsuperscript{78}
There has been concern about possible harms in select patients striving to achieve very conservative HbA1c goals, such as the 7.0% goal recommended by the ADA.\textsuperscript{79} The target HbA1c value identified in the HEDIS measure (9.0) is a safe and conservative goal, unlikely to cause adverse hypoglycemic events in diabetic patients.

Time and resource constraints encountered by a physician in the outpatient setting are a barrier to glycemic control in diabetics. This barrier has been called “clinical inertia” or “benign neglect”, defined as overly cautious prescribing practices due to fear of side effects, underestimation of patient needs, failure to set clear treatment goals, or lack of encouragement to reach goals.\textsuperscript{80} Poorly organized disease planning or the absence of clearly defined treatment goals can also be a physician barrier in achieving glycemic control. Where a proactive approach includes a treatment plan with milestones attached to future visits, an absence of planning threatens to forego education and the patient’s pursuit of health in favor of a patient’s currently symptomatic illnesses or concerns.\textsuperscript{81}

Tracking and monitoring HbA1c levels presents a possible difficulty in using this HEDIS goal as an incentive. Today’s coding systems utilize the 10\textsuperscript{th} Edition of the International Classification of Disease (ICD) codes. The code for diabetes does not allow for a “controlled” or “uncontrolled” classification qualifier. Using claims data received by the insurance provider may present a similar problem. Whereas claims traditionally record only the completion of a test, tracking HbA1c levels would require adding the test results to the claim.

Society

Minorities are disproportionately represented among the 25.8 million people in the US with diabetes.\textsuperscript{82} Native Americans make up 33\% of diabetics, African-Americans represent 12.6\%, and Hispanics 11.8\%. Non-Hispanic whites, Asian-Americans, and Alaska natives represented the lowest proportion of the total, 7.1\%, 8.4\%, and 5.5\% respectively. Although
studies note that psychosocial differences are involved in racial diabetes prevalence. African Americans continue to have poorer glycemic control after controlling for these psychosocial factors.\(^83\)

**Controlling Blood Pressure**

*HEDIS Measure C16: The percentage of MA members aged 18-85 with high blood pressure which was adequately controlled (<140/90 for members aged 18-59 and for those aged 60-85 with a diagnosis of diabetes; <150/90 for members aged 60-85 without a diagnosis of diabetes) during the measurement year.*

**Patient**

Hypertension is a significantly prevalent disease process in the US affecting 29% - 31% of the population.\(^84\) Despite increased awareness, treatment, and improvements in blood pressure control over the past few decades, only 50.1% of people with hypertension are controlled below the 140/90 target level.\(^85\) Poor blood pressure control is responsible for many significant complications such as heart failure, myocardial infarction, sudden death, and stroke.\(^86\) Hypertension is also the most important risk factor for intracerebral hemorrhage and a significant risk factor for kidney disease and ESRD.\(^87,88\)

Treatment for hypertension includes many varied therapeutic options which, when used appropriately to control blood pressure, have been shown to reduce cardiovascular events by 20% - 25%.\(^89\) Similarly, evidence shows that blood pressure control reduces cerebrovascular events by 42%.\(^90\) Despite the significant benefits of adequate blood pressure control, strict blood pressure control can result in adverse effects. A large randomized trial of intensive blood pressure control reported an increase in the incidence of hypotension, syncope, bradycardia, arrhythmias, hyperkalemia, angioedema, and renal failure in patients receiving the intervention compared to standard therapy.\(^91\)
There are many barriers to hypertension treatment for patients. Patients often discount the consequences of elevated blood pressure because they experience no symptoms from the disease process. These beliefs affect patient’s motivation in achieving good control. Daily activities, work, and family concerns are often higher priorities than outpatient visits and healthy lifestyle modifications, such as exercise. Financial constraints can also affect a patient’s ability to purchase medications. Beliefs that taking medications makes someone weaker or less healthy can affect treatment as much as the fear of medication side effects.92

Insurance Provider

As approximately 76.4 million Americans have elevated blood pressure, treatment of hypertension is the most common reason for outpatient office visits and for the use of prescription drugs.94 As the population ages and obesity increases, the incidence and healthcare burden of hypertension is likely to grow, especially in persons older than 65 years of age.93

Stroke, hypertension, heart failure, and other cardiac diseases account for 17% of all medical spending in the US, amounting to $149 billion annually. They account for 30% of all Medicare spending. Of these four disease processes, hypertension is responsible for the greatest share of this spending in prescription expenditures.94

Under the HEDIS program, insurance carriers will likely find that improving the care of those with moderate hypertension is more cost effective than focusing on severe hypertension. Successful treatment of severe hypertension down to the recommended goal is more difficult and expensive than that of moderate hypertension. A relaxed set of goals for persons with severe hypertension may rectify this unintended HEDIS consequence.95

Physician
Physicians face several barriers and difficulties in treating hypertensive patients. One unique to hypertension treatment is relative difficulty in obtaining a diagnosis. Whereas most disease processes can often be diagnosed with one set of test results, the diagnosis of hypertension requires multiple blood pressure measurements on different days, requiring repeat outpatient visits, some of which should occur outside the medical office setting. As hypertension is a mostly an asymptomatic disease process, compliance rates are often difficult to maintain creating another barrier for physicians to achieve their HEDIS goal. In a cohort of nearly 200,000 hypertension elderly patients, nearly a quarter did not refill their hypertension medications.

As mentioned previously, therapeutic inertia is a barrier to physicians in the treatment of hypertension. For hypertension, therapeutic inertia is the failure of a physician to increase therapy for a patient already treated in response to poor blood pressure control. This is becoming a common and recognized barrier to blood pressure control rates.

Tracking and monitoring blood pressure levels may be difficult. The ICD-10 code for hypertension does not allow for a “controlled” or “uncontrolled” classification qualifier. As claims data are not submitted for blood pressure testing, another form of reporting must be established to follow blood pressure data.

Society

Hypertension is a heavy burden on societal health. In 2011, cardiovascular disease, often related to hypertension, accounted for nearly one-third of all deaths within the US. Every day, more than 2,150 Americans die of cardiovascular disease, an average of one death every 40 seconds. A third of these deaths occurred before age 75, younger than the average life expectancy of 78.7 years.
There is a significant difference in these death rates between racial groups. The death rate for white males is 271.9 per 100,000, while that for African-American males is 352.4 per 100,000. The same rate for white women is 188.1 per 100,000, while that for African-American women is 248.6 per 100,000. A longitudinal study of more than 15,000 young adults in the US revealed that higher household income and being married were independently associated with better blood pressure. The factors that were associated with poorer blood pressure were older age, male sex, African-American ethnicity, higher body mass index, greater waist circumference, smoking, and higher alcohol intake.

Rheumatoid Arthritis Management

*HEDIS Measure C17: Percent of MA members with Rheumatoid Arthritis who were dispensed at least one anti-rheumatic drug.*

Patient

Rheumatoid Arthritis (RA) is a chronic, systemic, and inflammatory disorder which leads to destruction of joints and joint deformities. Typically, “classic” RA begins with stiffness, pain, and swelling of the peripheral joints of the hands and feet, moving centrally as the disease progresses. However, patients demonstrate a wide variability in the pattern of joint inflammation, severity of symptoms, and the timing of RA exacerbations. Whereas most of the disease activity (joint inflammation) is treatable and reversible, inflammation can cause joint tissue erosion and other structural damage that may be both cumulative and irreversible.

While the primary focus of the RA disease process is on articular tissue, 40% of patients develop extra-articular manifestations which can affect the skin, eyes, lungs, heart, kidney, blood vessels, salivary glands, central and peripheral nervous systems, and the bone marrow. Of note, RA brings a significant risk of coronary artery disease which may include heart failure and atrial fibrillation.
Disease Modifying Anti-Rheumatic Drugs (DMARDs) have been the mainstay of RA treatment since the 1970s. Although their effectiveness varies among individuals, they have been shown to decrease inflammation in RA patients and halt radiographic progression of articular disease.\textsuperscript{106} Significant toxicities are associated with DMARDs and other medications commonly used to treat RA. They suppress the immune system, increasing the risk of serious infections, and negatively affect the healing process.\textsuperscript{107} Bacterial infections, especially pneumonia and skin infections, increase 2-4 fold with the use of RA medications. Tuberculosis reactivation, systemic fungal infections, and viral infection reactivations have all been observed to occur from treatment of RA.\textsuperscript{108}

The barriers and difficulties commonly encountered by patients with RA patients are difficulty in recognition of disease and medication compliance. Joint pain is only one of the several varied manifestations in which RA can initially present. Also, considering the ubiquitous nature of "joint pain", it is often difficult for someone suffering from new-onset RA to make an appointment with a physician in a timely manner.\textsuperscript{109} Medication adherence is another significant problem among RA patients. Although all treatable disease processes suffer from some level of medication non-compliance, the medication adherence rates for RA have ranged from 30% - 80%.\textsuperscript{110}

Insurance Provider

The aggregate economic burden of RA in the US is $19.3 billion annually. Using this figure, the cost that each patient individually accrues on average is $14,900 annually. The portion of this expense that involves medical visits and prescriptions, the portion insured by the MA plan, is $8.4 billion or 44% of the total.\textsuperscript{111} Medication costs represent a large portion of the RA expense to an insurer. A recent article reported that several RA drugs have steeply increased in price. The price of Enbrel, a medication commonly used in RA treatment, has risen by 80.3% since 2013 and now exceeds $4,000 for a 30-day supply. The price of Humira also
rose by 68.7% to $3,700 for a monthly supply while that of Xeljanz rose by 44.3% to over $3,100 per month.\textsuperscript{112}

An analysis of the cost of RA medications noted that if the definition of cost-effectiveness is set at 35,000 UK pounds per QALY, none of the medications appear to be cost-effective. If the threshold was lifted to 50,000 or 100,000 UK pounds per QALY, some of the medications may be cost effective.\textsuperscript{113} A related editorial claims that the economic consequence of failing to slow RA progression far outweigh the costs of any currently available therapy. The author recommends that not to focus on the cost of the medications but on the degree to which they are successful in halting progression of RA.\textsuperscript{114}

Physician

Like their patients, physicians treating persons with RA also deal with the problem of non-compliance. A review of RA patients reported a compliance rate of 80.3%.\textsuperscript{115} The most common reasons cited for poor adherence to the RA medication regimen were side effects and the fear of side effects. Compliance was worst among younger and more active RA patients with a higher income level. Factors that correlated with better compliance were more frequent rheumatology appointments, satisfaction with health care provider, and sufficient education about the treatment of RA.

Tracking a physician’s compliance with the RA treatment HEDIS measure is easily accomplished through claims data.

Society

As noted previously, the total annual cost of treating RA patients is $19.3 billion, each patient costing $14,900 annually. While the direct medical costs are covered by the MA plan, the indirect costs, which include premature mortality, the deterioration in quality-of-life, and the cost of caregiving, are borne by the society.\textsuperscript{111} All MA plans cover at least one DMARD. The
majority of plans require a co-payment from the insured at an average of 29.5% of the total cost of the medication, rather than a fixed dollar co-payment. This out-of-pocket cost ranged from $2,712 - $2,774 annually before reaching the catastrophic phase of coverage, after which the insured is responsible for 5% of the cost.116

Evaluation of the disparities in RA prevalence revealed no race-related data but showed a SES difference. Persons without a university degree had an increased risk of RA compared to those with a degree (relative risk of 1.4).117 In patients with established RA, those with a low SES status suffer worse disease activity, physical health, mental health, and quality-of-life compared to RA patients with a high SES status. This difference decreases over time.118 These differences are influenced by age, gender, marital status, and work disability. SES status is also associated with physical limitations resulting from RA and are predictive for work-related income reduction, reduced transport mobility, and the development of social dependency.119

Discussion

In evaluating the clinical HEDIS measures for potential physician incentives in contracts with MA plans, each of the measures was examined from the perspective of the relevant stakeholders involved in measure completion. The vantage points considered were that of the patient, the insurance carrier, the physician, and society. The scores applied to each perspective of a HEDIS measure was based on its feasibility to be incented in a physician contract as seen in Table 2 – Table 9. The scores were collected for comparison between measures in Table 10.

From the patient’s perspective, all measures scored well and are possible candidates for use as incentives except one: breast cancer screening. Although the clinical guidelines used in the HEDIS measure resemble other published recommendations, published literature reveals a
significant risk of harms to a large portion of the female population from screening. The harms identified are over-diagnosis and a significant false positive rate, both of which serve to supply a large emotional health burden on women who test positive by mammography. They also significantly burden the healthcare system in unnecessary expenses of subsequent medical evaluation and treatments. The measures that stood out as exceptionally good candidates for contract incentives were diabetic glycemic control and RA management. From the perspective of the patient, achieving better glycemic control benefits a patient's quality of life and health, primarily by avoiding the serious cardiovascular, renal, ocular, and nervous complications of diabetes. Similarly, the early identification and treatment of RA has the potential to greatly decrease RA patient's future disability resulting in decreased economic/occupational losses and improved quality-of-life.

The insurance provider's perspective yielded only one measure that performed well. The HEDIS measure for DKD monitoring revealed that both testing and treatment options were cost-effective. Successful treatment has the potential to greatly reduce future costs to MA plans by avoiding ESRD and the accompanying expenses of dialysis. The HEDIS measure that performed worst from this perspective was the diabetic eye exam. The reasons for the low assessment is the annually recurring expense of eye examinations and the cost of laser treatment, both of which are highly cost-ineffective.

The HEDIS measures that performed best in from the physician's perspective were diabetic eye exam and DKD monitoring. Both of these measures scored well due to their ease of tracking mechanisms for HEDIS measure completion through insurance claims data. They also lacked any significant physician barriers towards successful HEDIS measure achievement. The least advantageous measures to physicians were osteoporosis management and blood pressure control. Both posed significant barriers to a physician's ability to meet treatment goal thresholds due to historically high patient non-compliance rates.
All clinical HEDIS measures showed physician contract potential from the societal perspective. The benefits to the society were either financial, decreasing the vast expenditures of endemic rates of complications, or in the realm of health, decreasing to the total societal burden of disease (prevalence). For most measures, the disease processes in question demonstrated prevalence rates with inequalities in either racial or SES, making them candidates for decreasing health disparities. Colorectal cancer screening performed best from the societal perspective due to the significant mortality benefit and the ability to target for the racial subgroup most affected by colon cancer screening, African-American men.

The clinical HEDIS measure that showed most potential in contract incentives was diabetic DKD monitoring. From every examined perspective, it conferred many benefits and few harms. For patients, it identifies early DKD for which an effective treatment exists that can curtail many life-threatening complications. Both screening and treatment options were cost-effective and successful in reducing the vast expenses of ESRD, which are attractive factors to MA insurers. Physicians encounter few barriers and an easy method for compliance tracking. Lastly, there are substantial financial and disease-burden benefits to society in reduction of ESRD incidence.

This evaluation has several limitations. The first is the absence of a validated evaluation tool for use in analyzing clinical HEDIS measures. The format and tool used here is the product of many meetings and discussions with insurance industry experts who are active in the insurance sector. The second is the absence of an objective scoring system which controls for inter-person variability. Despite the subjective scoring system used here, however, the measures that either outperformed or fell short of the average would likely have settled there even with a validated scoring system. Lastly, this analysis lacked a systematic review system for each subject, relying greatly on a manual search of the PubMed/MEDLINE literature, UpToDate,
published review and editorial articles, and their references. Thus, there exists a possibility that relevant factors have been overlooked and not considered.
References


42. Consumer Reports. Drugs to treat osteoporosis: Comparing effectiveness, safety, and price. consumerreports.org. September 20113.


### Figure 1: Domains of Part C HEDIS Measures

#### Staying Healthy
<table>
<thead>
<tr>
<th>C01</th>
<th>Breast Cancer Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>C02</td>
<td>Colorectal Cancer Screening</td>
</tr>
<tr>
<td>C03</td>
<td>Annual Flu Vaccine</td>
</tr>
<tr>
<td>C04</td>
<td>Improving or Maintaining Physical Health</td>
</tr>
<tr>
<td>C05</td>
<td>Improving or Maintaining Mental Health</td>
</tr>
<tr>
<td>C06</td>
<td>Monitoring Physical Activity</td>
</tr>
<tr>
<td>C07</td>
<td>Adult BMI Assessment</td>
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</table>

#### Managing Chronic Diseases
<table>
<thead>
<tr>
<th>C08</th>
<th>SNP Care Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>C09</td>
<td>Care for Older Adults – Medication Review</td>
</tr>
<tr>
<td>C10</td>
<td>Care for Older Adults – Functional Status</td>
</tr>
<tr>
<td>C11</td>
<td>Care for Older Adults – Pain Screening</td>
</tr>
<tr>
<td>C12</td>
<td>Osteoporosis Management</td>
</tr>
<tr>
<td>C13</td>
<td>Diabetes Care – Eye Exam</td>
</tr>
<tr>
<td>C14</td>
<td>Diabetes Care – Kidney Disease</td>
</tr>
<tr>
<td>C15</td>
<td>Diabetes Care – Sugar Control</td>
</tr>
<tr>
<td>C16</td>
<td>Controlling Blood Pressure</td>
</tr>
<tr>
<td>C17</td>
<td>Rheumatoid Arthritis Management</td>
</tr>
<tr>
<td>C18</td>
<td>Reducing the Risk of Falling</td>
</tr>
<tr>
<td>C19</td>
<td>Plan All-Cause Readmissions</td>
</tr>
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</table>

#### Member Experience
<table>
<thead>
<tr>
<th>C20</th>
<th>Getting Needed Care</th>
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<tbody>
<tr>
<td>C21</td>
<td>Getting Care Quickly</td>
</tr>
<tr>
<td>C22</td>
<td>Customer Service</td>
</tr>
<tr>
<td>C23</td>
<td>Rating of Health Care Quality</td>
</tr>
<tr>
<td>C24</td>
<td>Rating of Health Plan</td>
</tr>
<tr>
<td>C25</td>
<td>Care Coordination</td>
</tr>
</tbody>
</table>

#### Complaints and Changes in Health Care Performance
<table>
<thead>
<tr>
<th>C26</th>
<th>Complaints about the Health Plan</th>
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<tbody>
<tr>
<td>C27</td>
<td>Members Choosing to Leave the Plan</td>
</tr>
<tr>
<td>C28</td>
<td>Beneficiary Access and Performance Problems</td>
</tr>
<tr>
<td>C29</td>
<td>Health Plan Quality Improvement</td>
</tr>
</tbody>
</table>

#### Health Plan Customer Service
<table>
<thead>
<tr>
<th>C30</th>
<th>Plan Makes Timely Decisions about Appeals</th>
</tr>
</thead>
<tbody>
<tr>
<td>C31</td>
<td>Reviewing Appeals Decisions</td>
</tr>
<tr>
<td>C32</td>
<td>Call Center – Foreign Language Interpreter and TTY Availability</td>
</tr>
</tbody>
</table>
Table 1: Part-C Clinical* HEDIS Measures

<table>
<thead>
<tr>
<th>Number</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>C01</td>
<td>Breast Cancer Screening</td>
</tr>
<tr>
<td>C02</td>
<td>Colorectal Cancer Screening</td>
</tr>
<tr>
<td>C12</td>
<td>Osteoporosis Management</td>
</tr>
<tr>
<td>C13</td>
<td>Diabetes Care – Eye Exam</td>
</tr>
<tr>
<td>C14</td>
<td>Diabetes Care – Kidney Disease</td>
</tr>
<tr>
<td>C15</td>
<td>Diabetes Care – Sugar Control</td>
</tr>
<tr>
<td>C16</td>
<td>Controlling Blood Pressure</td>
</tr>
<tr>
<td>C17</td>
<td>Rheumatoid Arthritis Management</td>
</tr>
</tbody>
</table>

* The term “clinical” refers to the measures which both affect a patient’s health and is addressed primarily in a physician outpatient visit.
### Table 2: Summary of C01 – Breast Cancer Screening

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Summary of Findings</th>
<th>Grade*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Measure supported by good clinical evidence. Significant risk of harm from over-diagnosis and high false positive rate leading to unnecessary procedures and treatments.</td>
<td>2</td>
</tr>
<tr>
<td>Insurance Provider</td>
<td>Screening is a significant and recurring financial burden. Moderately cost effective although not cost saving.</td>
<td>2</td>
</tr>
<tr>
<td>Physician</td>
<td>Conflicting screening guidelines confuse clinicians about the benefits of screening and their proper utilization. Measure completion is easily tracked through claims data.</td>
<td>3</td>
</tr>
<tr>
<td>Society</td>
<td>Mortality benefit despite financial cost of screening to society. A racial difference in prevalence of breast cancer exists which may be a target for screening implementation.</td>
<td>4</td>
</tr>
</tbody>
</table>

* Grading system: 1 – Should not be incented; 3 – may be incented; 5 – Should be incented
Table 3: Summary of C02 – Colorectal Cancer Screening

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Summary of Findings</th>
<th>Grade*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Based on good clinical evidence. Significant mortality benefit. FOBT is convenient and non-invasive. Colonoscopy and flexible sigmoidoscopy are invasive and pose a small risk of harm</td>
<td>4</td>
</tr>
<tr>
<td>Insurance Provider</td>
<td>Can be expensive and is a frequently recurring cost. Generally considered cost-effective</td>
<td>3</td>
</tr>
<tr>
<td>Physician</td>
<td>Physicians do not prioritize colon cancer screening highly. HEDIS measure completion is easily monitored by claims data.</td>
<td>3</td>
</tr>
</tbody>
</table>

* Grading system: 1 – Should not be incented; 3 – may be incented; 5 – Should be incented
Table 4: Summary of C12 – Osteoporosis Management

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Summary of Findings</th>
<th>Grade*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient</strong></td>
<td>Based on solid clinical evidence. Similar to the screening recommendations of the USPSTF. Treatment offers strong clinical benefits. Some rare and moderate side effects.</td>
<td>4</td>
</tr>
<tr>
<td><strong>Insurance Provider</strong></td>
<td>Testing is an infrequent expense. Testing is cost-effective. Treatment is very expensive with a QALY of $66,722</td>
<td>3</td>
</tr>
<tr>
<td><strong>Physician</strong></td>
<td>There is a lack of familiarity with osteoporosis drugs and fear of causing patient harm. Osteoporosis experts frequently disagree about guidelines. Screening for osteoporosis can be a lower priority topic in a short outpatient office visit. Tracking progress of measure is easily dose with claims data.</td>
<td>2</td>
</tr>
<tr>
<td><strong>Society</strong></td>
<td>There are both racial and SES differences in testing women for osteoporosis following a fracture. The burden on society is financial (very expensive), emotional (stress to family members and caregivers), and occupational (affects ability to work).</td>
<td>3</td>
</tr>
</tbody>
</table>

* Grading system: 1 – Should not be incented; 3 – may be incented; 5 – Should be incented
QALY – annual cost of a quality year
Table 5: Summary of C13 – Diabetic Eye Exam

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Summary of Findings</th>
<th>Grade*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Clinically significant outcome for diabetics. Cost-benefit data suggests less frequent visits in well controlled diabetics. Other than the inconvenience of an extra outpatient office visit, no harms exist.</td>
<td>4</td>
</tr>
<tr>
<td>Insurance Provider</td>
<td>Large, annually recurring expense. Treatment is expensive.</td>
<td>1</td>
</tr>
<tr>
<td>Physician</td>
<td>No significant barriers to physicians. Certain sections of the US reported long wait times for outpatient eye examinations. Easy to track through claims data.</td>
<td>4</td>
</tr>
<tr>
<td>Society</td>
<td>Avoiding blindness is an important societal benefit. Incidence of DR varies between racial groups which is an opportunity for targeted interventions to reduce this disparity.</td>
<td>3</td>
</tr>
</tbody>
</table>

* Grading system: 1 – Should not be incented; 3 – may be incented; 5 – Should be incented
Table 6: Summary of C14 – Diabetic Kidney Disease Monitoring

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Summary of Findings</th>
<th>Grade*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Significant disease burden with effective treatments. No significant barriers or harms.</td>
<td>4</td>
</tr>
<tr>
<td>Insurance Provider</td>
<td>Screening is cheap and avoids ESRD treatment, which is extremely expensive. Screening is cost effective while treatment of early disease is cost-saving.</td>
<td>5</td>
</tr>
<tr>
<td>Physician</td>
<td>No barriers identified. Tracking is easily accomplished through claims data.</td>
<td>4</td>
</tr>
<tr>
<td>Society</td>
<td>There is a racial difference in incidence which is likely explained by SES.</td>
<td>4</td>
</tr>
</tbody>
</table>

* Grading system: 1 – Should not be incented; 3 – may be incented; 5 – Should be incented
### Table 7: Summary of C15 – Diabetic Glycemic Control

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Summary of Findings</th>
<th>Grade*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Significant disease burden for which there is an effective treatment. Appropriate glycemic control effectively avoids the complications of diabetes. The HEDIS HbA1c goal is a safe target.</td>
<td>5</td>
</tr>
<tr>
<td>Insurance Provider</td>
<td>The expense of treating diabetes and its complications is extremely high. Treating diabetics in the absence of complications is 2.3 times higher than for non-diabetics. Treatment is cost-effective due to its ability to halt or slow complications</td>
<td>2</td>
</tr>
<tr>
<td>Physician</td>
<td>The HEDIS measure sets a reasonable HbA1c goal. Barriers include clinical inertia and reactive disease management. Difficult to track using billing codes and claims data.</td>
<td>3</td>
</tr>
<tr>
<td>Society</td>
<td>Diabetes is a significant societal burden. Minorities represent a disproportionately large portion of the prevalence of diabetes.</td>
<td>4</td>
</tr>
</tbody>
</table>

*Grading system: 1 – Should not be incented; 3 – may be incented; 5 – Should be incented*
Table 8: Summary of C16 – Blood Pressure Control

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Summary of Findings</th>
<th>Grade*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient</strong></td>
<td>Significant disease burden for which there are effective treatments. Treatment carries a small risk of complications. Many barriers resulting from the asymptomatic disease course of hypertension.</td>
<td>4</td>
</tr>
<tr>
<td><strong>Insurance Provider</strong></td>
<td>Hypertension has a high and growing prevalence. Spending accounts for 17% of all US expenditures. Difficulty in controlling blood pressure in those with severe disease carries a risk of foregoing emphasis on their treatment in favor of those more easily treated to target goals.</td>
<td>3</td>
</tr>
<tr>
<td><strong>Physician</strong></td>
<td>Complexity in making a diagnosis is one barrier encountered by physicians. Non-compliance hinders the physician’s achievement of HEDIS goal. Therapeutic inertia is a barrier. Tracking may be difficult using standard ICD 10 codes and claims data.</td>
<td>2</td>
</tr>
<tr>
<td><strong>Society</strong></td>
<td>Significant societal burden. There is a racial disparity in the prevalence of hypertension. The burden that the African-American community bears from hypertension is disproportionately high.</td>
<td>4</td>
</tr>
</tbody>
</table>

* Grading system: 1 – Should not be incented; 3 – may be incented; 5 – Should be incented
### Table 9: Summary of C17 – Rheumatoid Arthritis Management

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Summary of Findings</th>
<th>Grade*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient</strong></td>
<td>Very significant health burden. Causes disability. Numerous extra-articular complications are possible. Although treatments are effective, they have rare but serious side effects. Barriers include difficulty in attributing symptoms to RA, delaying diagnosis. Poor compliance rates in some studies.</td>
<td>5</td>
</tr>
<tr>
<td><strong>Insurance Provider</strong></td>
<td>Treatment is very expensive and the price of medications has recently increased. Not cost-effective.</td>
<td>2</td>
</tr>
<tr>
<td><strong>Physician</strong></td>
<td>Non-compliance is a barrier to a physician achieving the HEDIS goal. There is room to grow in assuring better compliance in the future. Measure is easily tracked through claims data.</td>
<td>3</td>
</tr>
<tr>
<td><strong>Society</strong></td>
<td>Significant societal burden. Potential for steep decline is quality-of-life for immediate family and community. Financially expensive to purchase medications (co-pay). Economic losses due to disability.</td>
<td>4</td>
</tr>
</tbody>
</table>

* Grading system: 1 – Should not be incented; 3 – may be incented; 5 – Should be incented
Table 10: Results of Clinical HEDIS Measures by Perspectives

<table>
<thead>
<tr>
<th>HEDIS Measure</th>
<th>Perspectives</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient</td>
</tr>
<tr>
<td>C01 – Breast Cancer Screening</td>
<td>2</td>
</tr>
<tr>
<td>C02 – Colorectal Cancer Screening</td>
<td>4</td>
</tr>
<tr>
<td>C12 – Osteoporosis Management</td>
<td>4</td>
</tr>
<tr>
<td>C13 – Diabetic Eye Exam</td>
<td>4</td>
</tr>
<tr>
<td>C14 – Diabetic Kidney Disease Monitoring</td>
<td>4</td>
</tr>
<tr>
<td>C15 – Diabetic Glycemic Control</td>
<td>5</td>
</tr>
<tr>
<td>C16 – Blood Pressure Control</td>
<td>4</td>
</tr>
<tr>
<td>C17 – Rheumatoid Arthritis Management</td>
<td>5</td>
</tr>
</tbody>
</table>

* Grading system: 1 – Should not be incented; 3 – may be incented; 5 – Should be incented
Limited Systematic Review of the Literature: Are HEDIS Measures for Diabetes Cost-Effective

Introduction

Higher costs are usually associated with better quality. This underlying belief extends to health care where there is an underlying belief that better medical care results from the greater value provided by higher costs. However, due to increasing financial constraints, the health care climate today attempts to achieve both high quality and low cost by using effective procedures and highly trained medical providers within efficient health plans. Previous cost-effect analyses within the medical literature have yielded mixed results. While some systems have shown that quality and cost can have a positive relationship, some show no effect on quality due to costs, and others a negative or inverse effect.

The challenge of achieving higher quality at a lower cost is especially relevant to care for diabetes. Diabetes is one of the most prevalent chronic diseases within the United States and is associated with some of the most cost-consuming complications. Persons with diabetes comprise a small portion of the US population while accounting for a large portion of health care expenditures. The per-capita costs consumed by diabetics are 2.5 times higher than for those without diabetes. These negative economic trends are well recognized prompting greater emphasis on preventive and maintenance care for those with diabetes. This emphasis has yielded positive trends but even with today’s increased focus on preventive care, less than 75% of diabetics meet their preventive medical goals.

To address these and other chronic disease concerns, the National Committee for Quality Assurance (NCQA) has established the Health Effectiveness Data and Information Set (HEDIS), a measure used to institute standardized protocols by which disease processes are monitored and treated. These measures are used to grade and evaluate the disease management services provided by managed
health care plans. Cost-effectiveness is a key part of the evidence-based rationale of HEDIS measures and the NCQA has selected performance measures that “encourage the use of cost-effective activities and/or discourage the use of activities that have low cost-effectiveness.”\textsuperscript{8,9}

The current HEDIS measures for diabetic care are listed in \textbf{Appendix Table 1}. They include annual monitoring of Hemoglobin A1c (HbA1c), providing adequate blood pressure control, and screening for retinopathy and nephropathy. A managed care plan incurs direct and indirect costs implementing these measures. Direct costs include outpatient office visits, laboratory expenses, and specialist visits for retinopathy screening. Indirect costs include administrative costs to implement and monitor the program, incentives provided to physicians to encourage program use, and outreach costs used to inform their diabetic members of services when they are due. The measured benefits of diabetic HEDIS guidelines are analyzed by the changes in spending on outpatient visits, disease management services, inpatient encounters, surgical procedures, and pharmacy costs.

\textbf{Appendix Table 1: Current HEDIS measures for diabetes}

<table>
<thead>
<tr>
<th>2016 HEDIS measures for diabetes*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hemoglobin A1c (HbA1c) testing annually</td>
</tr>
<tr>
<td>• HbA1c poor control &gt;9</td>
</tr>
<tr>
<td>• HbA1c control &lt;8</td>
</tr>
<tr>
<td>2. BP control, &lt;140/90</td>
</tr>
<tr>
<td>3. Eye exam (retinal) performed</td>
</tr>
<tr>
<td>4. Medical attention for nephropathy</td>
</tr>
</tbody>
</table>

* The percentage of members 18 to 75 years of age with diabetes (either type 1 or type 2) who had each of the following during the measurement year.

In order to evaluate the cost-effectiveness of the HEDIS measures for diabetes, I conducted a systematic review of the literature on managed health plans focused on the relationship between the level of HEDIS measure implementation and the resulting costs of services provided. The costs of services are divided into outpatient, inpatient, surgical/procedure, disease management, and pharmacy.
The goal of this systematic review is to assess whether higher rates of HEDIS compliance result in lower healthcare spending in these areas. Health plan data will be analyzed for expenditures/resource utilization compared to the degree of adherence to HEDIS measures. Study designs include cohort studies, randomized trials, and cross-sectional studies.

Methods

The scope of this systematic review is an assessment of literature to answer the question, “Are HEDIS measures for diabetes cost-effective?” To limit the heterogeneity of the studies found, the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement was used to guide the approach and reporting of results.\textsuperscript{10} No published review protocol exists for this topic.

Data Sources

To identify relevant articles, PubMed and Cochrane database engines were searched with keywords appropriate for categories of “HEDIS measures” and “cost-effectiveness” from 1995 to 2016. The search strategy was initially guided by a health services librarian at the UNC Health Services Library. Keywords and MESH headings were generated to create a comprehensive list of search terms relevant to the interventions and outcome measures of interest. Clinicaltrials.gov was also searched for unpublished studies yielding no new or unpublished results. Appendix Table 2 displays the complete search strategy for both the PubMed and Cochrane databases.
Appendix Table 2: PubMed/MEDLINE and Cochrane Library Search Terms

<table>
<thead>
<tr>
<th>PubMed/MEDLINE Complete Search Strategy, 4/1/2016. Limited to date range 1/1/1995 to 4/1/2016</th>
<th>Items found</th>
</tr>
</thead>
<tbody>
<tr>
<td>Search</td>
<td>Query</td>
</tr>
<tr>
<td>#1</td>
<td>Search (hedis OR &quot;Healthcare Effectiveness Data and Information Set&quot;) Filters: Systematic Reviews</td>
</tr>
<tr>
<td>#2</td>
<td>Search (hedis OR &quot;Healthcare Effectiveness Data and Information Set&quot;)</td>
</tr>
<tr>
<td>#3</td>
<td>Search (hedis OR &quot;Healthcare Effectiveness Data and Information Set&quot;) AND cost effectiveness</td>
</tr>
<tr>
<td>#4</td>
<td>Search (hedis OR &quot;Healthcare Effectiveness Data and Information Set&quot;) AND cost effectiveness AND diabetes mellitus</td>
</tr>
<tr>
<td>#5</td>
<td>Search hedis AND cost effectiveness</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cochrane Library Complete Search Strategy, 4/1/2016. Limited to date range 1/1/1995 to 4/1/2016</th>
<th>Items found</th>
</tr>
</thead>
<tbody>
<tr>
<td>Search</td>
<td>Query</td>
</tr>
<tr>
<td>#1</td>
<td>Search (hedis OR &quot;Healthcare Effectiveness Data and Information Set&quot;)</td>
</tr>
<tr>
<td>#2</td>
<td>Search (hedis OR &quot;Healthcare Effectiveness Data and Information Set&quot;) AND cost effectiveness</td>
</tr>
<tr>
<td>#3</td>
<td>Search (hedis OR &quot;Healthcare Effectiveness Data and Information Set&quot;) AND cost effectiveness AND diabetes mellitus</td>
</tr>
<tr>
<td>#4</td>
<td>Search hedis AND cost effectiveness</td>
</tr>
</tbody>
</table>

Study Eligibility

Selection of included studies was based on the inclusion and exclusion criteria in Appendix

Table 3. Prospective/retrospective cohort, cross-sectional, and randomized trials published in English between January 1, 1995 and April 1, 2016 that analyzed either HEDIS-based diabetic patient care within a managed health plan or the plans themselves, and reported the association of the use of HEDIS measures for diabetes and cost-effectiveness were considered. Diabetic patient care studies that compared costs of HEDIS-based diabetic care against “traditional care”, not led by HEDIS, were accepted. Studies of health care plans that compared the cost burden of diabetic members within health care plans against the degree to which HEDIS measures were accurately followed were accepted. Comparators were either patients whose diabetic care was not led by HEDIS measures at all or other plans with a greater or lesser degree of adherence to HEDIS measures. Outcomes included the per-member-per-month (PMPM) costs to health plans or adjusted resource utilization rates which allow better comparisons among regions with wide variations in health care pricing.
Appendix Table 3: Inclusion/Exclusion Criteria for Studies of HEDIS Cost-Effectiveness

<table>
<thead>
<tr>
<th>Category</th>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
</table>
| **Population** | Commercial and federal health plans within the US that submitted HEDIS reporting data  
Adults aged 18-75 with diabetes participating in managed care plans | Health plans with missing or incomplete HEDIS reporting data |
| **Interventions** | Cost-benefit analysis of diabetes management using HEDIS measures as quality guidelines.  
Resource-use and quality analysis of diabetes management using HEDIS as quality measure  
HEDIS measures used as a guide to diabetic care | Analysis that does not correlate cost or resource utilization against quality measures  
Analysis of disease management interventions other than diabetes  
Analysis of previously published data sets  
Computer-based model analysis based on historical data |
| **Comparators** | Comprehensive diabetes management based on HEDIS guidelines vs traditional diabetes management  
Diabetes management analysis before and after implementation of HEDIS based care model  
Resource utilization/cost and HEDIS quality measures between differing health plans  
Cost-benefit analysis of single plans  
Diabetics receiving traditional care (not guided by HEDIS measures) | Studies analyzing only one or two parts of HEDIS diabetic measures.  
Studies comparing HEDIS measures other than diabetes |
| **Outcomes**   | Cost-benefit analysis of HEDIS measures in dollars per benefit  
Cost-benefit analysis of HEDIS measures in resource use per benefit | Studies reporting quality of life-years outcomes |
| **Timing of outcome measurement** | Studies analyzing data of at least 12 months | Studies of data less than 12 months |
| **Time period** | Studies published from January 1, 1995 to April 1, 2016 | Studies published earlier than 1995 |
| **Settings**   | Health care plans within the US | Plans outside of the US |
| **Language**   | English | All other languages |
| **Admissible evidence** | Eligible study designs include prospective cohort studies, retrospective cohort studies  
Randomized controlled trials  
Cross-sectional studies | Case-controlled studies  
Case series / Case reports  
Systematic reviews  
Editorials and opinion pieces  
Economic modeling studies |
Study Selection

Studies identified by the database searches were compiled and duplicates removed. Titles and abstracts from all sources identified by the search strategy were reviewed for inclusion and exclusion criteria (Appendix Table 3). Reference lists of selected studies were also searched for additional studies not captured by the search strategy. The hand-selected full-text articles were retrieved and assessed for eligibility. Following title and abstract evaluation, remaining studies were assessed for final eligibility.

Data Items and Extraction

The selected studies were analyzed for relevant data which were compiled in an evidence table with the following categories: study participants, statistical methods, comparison groups, timeframe of study, outcome measures, and results. Particular attention was placed on the statistical methods used, outcome variables, and results. Statistical methods and outcome variables were considered key measures as the cost-benefit association found in each study had to be compared to that of the other included studies (i.e. variations from a mean had to be compared to studies reporting raw PMPM cost differences or Pearson correlations of HEDIS/cost.). There is no process in place to confirm or obtain data from investigators.

Risk of Bias

Included studies were evaluated for pre-determined outcomes and synthesized in evidence tables with the following categories: study design, population/groups evaluated, outcome measures, and the duration of observation. The quality of each included study was assessed using a predefined checklist based on STROBE\textsuperscript{11} and CONSORT\textsuperscript{12} reporting recommendations. These recommendations include an assessment for selection bias, measurement bias, confounding, random error, and generalizability. Using the results of the quality assessment recommendations, each study was rated as good, fair, or poor.
Summary Measures

The principle summary measures sought from included studies were cost of care and HEDIS grading. The cost of care included individual and aggregate data of outpatient visits, evaluation and treatment costs, surgical or procedural costs, inpatient costs, and pharmacy services. HEDIS data sought were either the presence/absence of HEDIS utilization within a health plan or the degree to which HEDIS measures for diabetes were adhered to by a health plan. The cost-benefit results sought from included studies were the PMPM costs differences, correlation coefficients of cost and HEDIS adherence level, and the observed vs expected costs of plans by the degree to which HEDIS measures were utilized.

Synthesis of Results

A qualitative synthesis of included trials was performed discussing characteristics of included populations, interventions, and data analysis methods used to determine the relationship of cost to health plans and adherence to HEDIS guidelines. The synthesis was accomplished by comparing each study against the rest for the direction of the cost-benefit analysis, its statistical significance, and corresponding conclusions.

Risk of Bias Across Studies

Included studies were analyzed for individual risk of bias determined previously (STROBE and CONSORT checklists). Risks that were present in multiple studies were identified and analyzed further for corresponding results of the same studies. Identified risks of bias among studies were reported in the results of this systematic review and analyzed in the discussion.

Additional Analyses

No additional analyses were performed.
Results

The search of PubMed and Cochrane databases yielded 62 articles (72 articles with 10 duplicates removed.) Additional studies found by reference hand-search (12) resulted in 74 studies for assessment using title and abstract data. Ten studies were selected for full-text review. Reapplying the eligibility criteria resulted in the exclusion of five studies, two of these were excluded due to analysis of previously collected data sets with incomplete description of methods. Three additional studies were excluded for cost-benefit evaluation of only a portion of the HEDIS measures. Five retrospective cohort studies were ultimately included. The PRISMA flow diagram for this systematic review is shown in Appendix Figure 1.

Study Characteristics

Appendix Table 4 displays the characteristics of included studies in context of study design. Of the five studies included, three were based on the annual HEDIS compliance data submitted to NCQA. One used internal insurance data from the Geisinger Health Plan, and one used data from a volunteer cohort of 24 national health plans. All studies were retrospective cohorts aiming to find a correlation between healthcare expenditures on diabetic care with quality of care, based on adherence with the NCQA published HEDIS guidelines for diabetic treatment. The timeframe of three studies was 12 months. One study reported claims data spanning 84 months while the claims data for another covered 36 months.

The participants in one study were matched cohorts within an insurance plan. The inclusion criteria were members with diabetes who were at least 18 years of age, identified by at least 2 claims for diabetes with the International Classification of Diseases, Ninth Revision codes on different days before 2006. The intervention group (n=1875) was those who received care at a facility participating in the Geisinger diabetes system of care (DSC) bundle, while the control group (n=1875) received care at facilities that delivered standard diabetic care without the DSC bundle. Crossovers, defined as either
members who switched care from a DSC-participating facility to one without DSC or the other way around were excluded. Four hundred fifty-four (454) members not receiving DSC care, who were noted to be younger with fewer comorbid conditions, could not be matched and were excluded.

Of the studies based on data from multiple insurance plans, four excluded plans due to missing data. Two studies excluded plans with less than 400 diabetic members. One also excluded plans with Relative Resource Use (RRU) data that deviated significantly from the mean.

The intervention and outcome variables in the case-matched cohort study were per-member-per-month (PMPM) dollar values calculated from regression model coefficients based on observed versus expected (O/E) cost ratio. The PMPM value was applied to study groups in 4 categories: inpatient, outpatient, professional, and total.

Intervention and outcome variables in the studies evaluating data from multiple insurance plans used RRU values based on O/E ratios. Two studies included correlation coefficients in their analysis. Two others also calculated PMPM expenditure data. In three of the studies, resulting RRU and PMPM values were applied to two study groups: combined medical services (which were further broken into inpatient services, evaluation and management services, and surgery and procedure services) and ambulatory pharmacy services. One study did not report the sub classification of combined medical services reporting using only combined medical and ambulatory pharmacy services. One study further divided its results by plan types (HMO, PPO, POS).

Measures to control for bias included one study using the Simes procedure to minimize random errors and another, which excluded RRU data significantly deviating from the mean.

Risk of Bias
A potential source of bias in the insurance study by Quast\textsuperscript{2} is selection bias. One third of the annual plan data retrieved from NCQA were excluded for incomplete data. The exclusion of such a large portion of available data risks missing significant trends that may altered the results of this study. The Simes procedure was utilized to reduce the chance of random error.

In both of their studies of insurance data submitted to the NCQA, Turbyville et al.\textsuperscript{13,14} reported widely variable results which, although equal and reliable, may not be valid. The exclusion of all plans except HMOs also presents a risk of selection bias towards better organized plans which may be more likely to yield positive results.

There is a significant risk of selection bias in the study by Roski et al.\textsuperscript{16} as all of the 32 insurance plans examined were volunteers. Such a small sample has a relatively high chance of being unreliable. Further, 28 of the 32 plans in their study were subsidiary members of one large insurance plan. The study by Maeng et al.\textsuperscript{15} is also at risk for selection bias as it excluded 454 members that could not be matched from the control group. Those excluded tended to be younger with fewer comorbidities, which likely favors the intervention group in the outcomes. Selected members of the control group also tended to receive care at small rural clinics with less access to care than the intervention group, which received care in an urban setting. Lastly, prescription costs, which are responsible for the majority of diabetic spending, were not included in the analysis.

Results of the Individual Studies

In the study of the Geisinger DSC intervention by Maeng et al,\textsuperscript{15} there were no overall cost differences in the first year of the intervention. Every consecutive year, however showed a PMPM cost savings. In first year, the savings amounted to $42 PMPM, a 7.4\% (p=0.21) decrease compared to the control group. In year three, costs were $73 PMPM less than those of the control group (12.5\% decrease, p<0.05). In year 5, the cost benefit was $124 PMPM less than the control group (18.8\%
decrease, p<0.01). The sixth year yielded a savings of $104 (14.7% decrease, p<0.01). The inpatient care spending showed similar trends with a $143 PMPM savings in year 5 (46.8% decrease, p<0.01) and $131 PMPM savings in year 6 (41.3% decrease, p<0.01). The outpatient spending increased in the first year of the study by $20 PMPM (13%, p<0.05) but subsequently decreased with the greatest savings in year 5 of $12 PMPM (6.5% decrease, p=0.37). Professional services also showed a $15 PMPM increase in the first year (9.7%, p<0.01) followed by years of savings with the greatest benefit at year 5 in which it saved $20 PMPM (11.2% decrease, p<0.05).

In his study of the NCQA health plan data, Quast\textsuperscript{2} found a negative correlation coefficient between quality and total cost of care (-0.053, p=0.21), as well as quality and inpatient care (-0.061, p=0.08). A positive correlation was found between quality and surgical/procedure care (0.044, p=0.21), as well as between quality and pharmacy care (0.069, p=0.05).

In their study of volunteer insurance providers, Roski et al.\textsuperscript{16} created scatterplots of measuring quality of care (HEDIS measures) against the cost of care (RDI or RRU). They found no correlation in total costs, inpatient costs, surgical costs, nor evaluation/management costs. The scatterplot for pharmacy costs however, showed a Pearson’s correlation coefficient of 0.513 (P<0.003). In a similar study of all HMO plans submitting HEDIS related data to NCQA, Turbyville et al.\textsuperscript{14} used scatterplots to report the correlation between quality of diabetic care (HEDIS guidelines) and total medical cost (RRU). No correlation was observed except in the case of pharmacy spending which revealed a Pearson’s coefficient of 0.34 (p<0.05).

In their study of the 2007 NCQA plan data from HMOs, Turbyville et al.\textsuperscript{13} found a negative correlation between quality of care (HEDIS adherence) and total overall spending (-0.201, p<0.0008) which is driven, mainly, by the quality correlation with surgical services (-0.219, p=0.006) as well as with
inpatient services (-0.164, p=0.03). A positive correlation was observed between quality and pharmacy costs (0.162, p=0.03).

Synthesis of Results

Results from included studies are summarized in Appendix Table 5.

The study of the Geisinger plan shows that strict adherence to the DSC (driven by the HEDIS diabetes guidelines) diminished costs.\(^\text{15}\) As expected, the initial year tended to increase costs slightly but the trend in savings in subsequent years were substantial. Pharmacy data were not analyzed.

Both Quast\(^2\) and Turbyville et al\(^\text{13}\) show a negative correlation between quality and total costs driven mostly by the savings in inpatient care costs. Pharmacy costs showed a positive correlation with quality of care in both studies although it was statistically significant in only one of them. The scatterplot analyses of RRU against quality (HEDIS adherence) by Roski et al\(^\text{16}\) and Turbyville et al\(^\text{14}\) revealed no correlation between overall cost of care and quality. In analysis of the subsets of the total, both studies show a positive correlation between quality and pharmacy costs.

Risk of Bias Across Studies

The Geisinger Health Plan study by Maeng et al\(^\text{15}\) showed significant selection bias in excluding healthy controls from matching and in the significantly differing healthcare settings between study groups. Exclusion of pharmacy data also poses a risk to the accuracy of the results as pharmacy expenditures tend to be the largest component of spending in diabetic patients. Although no financial interests are claimed, all authors were noted to be employees of the Geisinger Health System.

The remaining plans all share significant risks of selection bias as two studies used only HMO-submitted data\(^\text{13,14}\), one study included a very small sample of volunteer plans (most of which were part
of a larger, national health plan)\textsuperscript{16}, and the last excluded incomplete plan data which accounted for a third of the total available.\textsuperscript{2}

Except for the Geisinger plan study, all studies also shared the potential of measurement bias. Collecting large amounts of data aggregated into one data point carries the risk of missing variations within the data and compromising internal validity.\textsuperscript{2,13,14,16}

\textit{Additional Analysis}

No additional analyses were performed.

\textbf{Discussion}

\textit{Summary of Evidence}

Of the five studies evaluating diabetic expenditures (RRU) and quality of diabetic care (degree to which plan members met the HEDIS guidelines), three showed a trend towards cost effectiveness which was statistically significant in two.\textsuperscript{13,15} Of those two, one was graded as poor quality\textsuperscript{15} while the other provided good evidence.\textsuperscript{13} The trend towards cost-savings, whether it was significant or not-significant, was driven by savings in inpatient care, outpatient care, and, in one study, surgical/procedural care.

Differences in diabetes spending among examined health plans varied widely with some studies showing little variation\textsuperscript{16} and others, large variations.\textsuperscript{14} Pharmacy costs were noted to correlate positively with quality of care (degree of adherence to HEDIS measures) in all but one study which did not include pharmacy data in its analysis. These findings indicate cost-ineffectiveness. This is the only finding in this systematic literature review that should be considered reliably accurate and reproducible.
The study with the poorest level of evidence due to several large sources of bias was also the study with the most significant cost savings. Significant risk of bias was present in the cohort matching between the study groups and in the characteristics of the base population of the control group. The outcome variables did not include pharmacy costs, a significant part of diabetes expenditures. Nevertheless, the study suggests that a rigorous, physician-led, team approach may produce substantial cost savings. More studies are needed to validate this approach to care.

Limitations

There are several limitations to this systematic review. A majority of included studies show at least some risk of selection bias. One study excluded healthy controls subjects, two considered only HMO claims data, another excluded one third of the available claims data, and the last recruited plan data from volunteers. As is expected, this bias tends away from the mean and toward the hypothesis that stricter adherence to HEDIS guidelines saves money.

This is true also for reporting and publication bias, which may also possible limitations to this analysis. In designing and conducting a study, authors often report outcomes that show the most desired effects minimizing outcomes likely to result in null or neutral effects. Publication bias is an extension of reporting bias resulting in publication of data that support those desired effects.

Another possible limitation in this systematic review is the search strategy. While “cost-effectiveness” is a MESH term that includes “cost-benefit” and other similar iterations, the inclusion of “HEDIS” in the search strategy may serve to limit retrieval of studies relevant studies. Conversely, the metrics used within the diabetic HEDIS measures could have been individually entered. Terms such as “blood pressure control”, “glycemic control”, “diabetic nephropathy screening”, etc. could have been substituted in place of “HEDIS” and may have yielded more studies that met the inclusion criteria.
Conclusion

This systematic review concludes that available evidence does not support the hypothesis that stricter adherence to the NCQA published HEDIS diabetes guidelines will decrease expenditures on diabetics. Results from the studies reviewed are inconsistent. Although some of the studies showed a benefit with statistical significance\textsuperscript{13,15}, others did not. The only reliably constant finding identified is that stricter adherence to the HEDIS data set diabetes guidelines increases pharmacy expenditures.\textsuperscript{2,13,14,16} One study described a rigorous novel approach to standard care of diabetics (Geisinger’s DSC) which showed promise of significant cost savings.\textsuperscript{15} Due to several design flaws, it requires validation, but was found to confer the greatest magnitude of savings.
References


Appendix Figure 1: PRISMA Systematic Review Flow Chart

Define Search Terms
(See Table 1)

PubMed/MEDLINE search
(n= 47)

Cochrane Library search
(n= 25)

Additional Sources
(n= 12)

Records with duplicates removed
(n= 74)

Abstract Review
(n= 74)

Records Excluded
(n= 64)

Full Text Review
(n= 10)

Records Excluded (n= 5)
Analysis of pre-existing data (n=2)
Study outcome includes only 1-2
of the relevant measures (n= 3)

5 studies included for article
abstraction and qualitative synthesis
## Appendix Table 4: Characteristics of Included Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Design</th>
<th>Population/ Groups</th>
<th>Outcome variables</th>
<th>Time</th>
<th>Sources of bias / Weaknesses</th>
<th>Measures to control for bias</th>
<th>Quality Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maeng et al., 2016</td>
<td>Retrospective cohort</td>
<td>Diabetic members &gt;18yr of Geisinger Health Plan (337,305 months from 3,750 members)</td>
<td>Inpatient and outpatient facility costs, professional costs, and total medical costs measured on a per-member-per-month basis (PMPM) Prescription costs were excluded</td>
<td>84 months of claims data</td>
<td>Selection: 454 members in control not matched, they tended to be younger with less comorbidities Crossovers were excluded Selection: control group tended to get care at smaller offices, likely fewer resources which favors the intervention group. Measurement: analysis does not include the cost of implementing DSC and incenting physicians to use it. Prescription costs are also excluded</td>
<td>None described</td>
<td>Poor</td>
</tr>
<tr>
<td>Quast T 2015</td>
<td>Retrospective cohort</td>
<td>407 commercial health plans who submitted annual HEDIS data to NCQA (National Committee for Quality Assurance). (813 over 3 years)</td>
<td>Health plans are analyzed for quality and resource use. Reported as a correlation of RRU to quality of care.</td>
<td>36 months of claims data</td>
<td>Measurement: aggregation of all members in a single data point misses variations within groups. Is a poor performing plan wasteful or serving a population that has a greater need of care? This study demonstrates some correlations but cannot elucidate causal relationship between quality and costs. High exclusion rate</td>
<td>Simes procedure to reduce random errors</td>
<td>Fair</td>
</tr>
<tr>
<td>Study</td>
<td>Study Design</td>
<td>Population/Groups</td>
<td>Outcome variables</td>
<td>Time</td>
<td>Sources of bias / Weaknesses</td>
<td>Measures to control for bias</td>
<td>Quality Rating</td>
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<td>-----------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Turbyville et al, 2011</td>
<td>Retrospective cohort</td>
<td>173 HMO plans that submitted HEDIS data in 2007 met criteria</td>
<td>Variation around the mean is reported for quality of care, medical services, and pharmacy services. Quality of care measures are correlated (Pearson) with RRU (O/E) on scatterplots for inpatient, surgery, E&amp;M, and pharmacy</td>
<td>12 months of claim data</td>
<td>Measurement: although the data are equal and reliable, validity is suspect due to high variation External validity: only HMO plans were evaluated</td>
<td>Exclusion of plans that differed significantly from the mean.</td>
<td>Good</td>
</tr>
<tr>
<td>Turbyville et al, 2011</td>
<td>Retrospective cohort</td>
<td>168 HMO plans that submitted HEDIS data in 2006 were included</td>
<td>Observed to expected utilization ratios and PMPM figures by HMO. Figures adjusted by diabetes categories. Correlation between quality against resource utilization (RRU), and quality against pharmacy use shown in scatterplot</td>
<td>12 months of claim data</td>
<td>External validity: only HMO plans were evaluated</td>
<td>None described</td>
<td>Good</td>
</tr>
<tr>
<td>Roski et al., 2008</td>
<td>Retrospective cohort</td>
<td>Volunteer sample of 24 HMOs and 8 PPOs. (314,742 subjects)</td>
<td>Costs of inpatient care, eval and management, surgery-procedure, and pharmacy. Recorded by RDI (actual/expected costs) PMPM dollar values</td>
<td>12 months of claims data</td>
<td>External validity: small sample of volunteers Selection: All HMO plans were subsidiaries of on large, national HMO Measurement: 40% of members did not have pharmacy benefit</td>
<td>None described</td>
<td>Fair</td>
</tr>
</tbody>
</table>
## Appendix Table 5: Findings from Review of Included Studies of the Cost-Effectiveness of Diabetes HEDIS measures

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants (n)</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Time</th>
<th>Outcome Measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maeng et al., 2016</td>
<td>1,875 members of Geisinger Health Plan vs 1,875 controls recorded as 178,612 months vs 158,693 months for a total of 337,305 member-months</td>
<td>Members using a bundled Diabetic System of Care (DSC) based on HEDIS measures</td>
<td>Diabetic members not using the DSC</td>
<td>84 months of claims data</td>
<td>Inpatient and outpatient facility costs, professional costs, and total medical costs measured on a per-member-per-month basis (PMPM)</td>
<td>6.9% cost-savings in DSC members $630 PMPM $677 PMPM (p&lt;0.05) Values increased with time in program 13% increase in DSC outpatient costs in the first year $175 PMPM $155 PMPM (p&lt;0.05) Value decreased with time in program</td>
</tr>
<tr>
<td>Quast T., 2015</td>
<td>407 commercial health plans who submitted annual HEDIS data to NCQA (National Committee for Quality Assurance). (813 over 3 years)</td>
<td>Level of HEDIS (defined as “quality care”) is measured against relative resource use (RRU) instead of actual costs to control for regional variations in prices</td>
<td>Aggregate data is analyzed for quality of care per resources used. Data is reported by year, plan type (HMO,PPO,POS), region</td>
<td>36 months of claims data</td>
<td>Correlation coefficients are reported between RRU and quality. RRU data is aggregated into 2 categories: 1. Medical services (inpatient facility use, procedures, and surgery) 2. Ambulatory pharmacy services Quality is defined as degree of adherence to HEDIS measures.</td>
<td>There is an overall negative correlation of RRU to quality care for all diabetic care signaling a net benefit of adherence to care -0.053 (p=0.13) Net loss for surgical care: 0.044 (p=0.21) Net benefit for inpatient care: -0.061 (p=0.08) Net loss for ambulatory pharmacy: 0.069 (p=0.05) There is also a slight net-benefit (not statistically significant) for all individual plan types.</td>
</tr>
<tr>
<td>Roski et al., 2008</td>
<td>Volunteer sample of 24 HMOs and 8 PPOs. (314,742 subjects, 18-75y/o with diabetes based on claims)</td>
<td>Correlation was measured between resource use in diabetes (RDI) and comprehensive diabetic care (CDC), based on HEDIS measures</td>
<td>Aggregate data is analyzed for quality of care per resources used. Data is reported for each plan by inpatient care, surgical care, eval and management, and pharmacy</td>
<td>12 months of claims data</td>
<td>Both per-member-per-month (PMPM) and RDI ratio (actual vs expected costs) were reported for each health plan</td>
<td>No statistically significant correlation was found between quality and costs for total costs, inpatient costs, surgical costs, and evaluation/management costs. Pharmacy costs had a positive Pearson correlation of 0.513 (p&lt;0.003) but was driven by a few outliers</td>
</tr>
</tbody>
</table>
### Appendix Table 5 continued: Findings from Review of Included Studies of the Cost-Effectiveness of Diabetes HEDIS measures

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants (n)</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Time</th>
<th>Outcome Measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turbyville et al, 2011</td>
<td>173 HMO plans that submitted HEDIS data in 2007 met criteria</td>
<td>Quality of care (HEDIS measures) and RRU (relative resource utilization) were calculated for plans and outcomes</td>
<td>Correlations between quality of diabetic care and RRU were correlated for medical services and pharmacy use. Values are also distributed around the mean to demonstrate variation.</td>
<td>12 months of claim data</td>
<td>Variation around the mean is reported for quality of care, medical services, and pharmacy services. Quality of care measures are correlated with RRU on scatterplots to determine quality-cost ratio</td>
<td>The correlation of quality to RRU is negative signaling a possible net benefit of HEDIS measure use -0.201 (p&lt;0.008) Pharmacy benefit correlation is positive signaling better care with more utilization 0.162 (p=0.03) Surgical and inpatient services are also negative (diminished with better care) -0.219 (p=0.006) and -0.164 (p=0.03)</td>
</tr>
<tr>
<td>Turbyville et al, 2011</td>
<td>168 HMO plans that submitted HEDIS data in 2006 were included</td>
<td>HEDIS measures were designated as quality measures.</td>
<td>Expected resource use rates (based on mean within an area) are compared to actual use (stratified by diabetes category). Total per-member-per-month data was also recorded (PMPM). Data was stratified by region.</td>
<td>12 months of claim data</td>
<td>Observed to expected utilization ratios and PMPM figures. Figures adjusted by diabetes categories.</td>
<td>Medical care O/E ratio ranged from 0.25 to 2.45 (mean=1) PMPM ranged from $174.20 to $387.85 Pharmacy use O/E ratio ranged from 0.39 to 3.09 (mean=1) PMPM ranged from $186.67 to $291.88 Pharmacy spending correlates with increased quality. Rho=0.34, P&lt;0.5 Medical care shows poor correlation on scatterplot.</td>
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