To: Third Way

From: Avalere Health

Date: December 16, 2014

Re: Estimated Federal Impact of Policy Proposals for Use of Decision Aids

Summary

Third Way asked Avalere Health to examine the potential federal costs or savings of implementing a policy which would advance the use of decision aid (DA) for shared decision-making between doctors and patients in preference-sensitive care. The policy recommends that the use of DA be standard medical practical practice starting in areas where cost-saving potential has been documented and proposes five key strategies:1) create a verification process where health plans report on whether patients were offered DAs in their decision-making process; 2) establish federal standards for DAs; 3) require health professionals with sub-standard use of DAs to seek pre-authorization of payments for services affected by DAs; 4) engage health professionals in the shared decision-making process and use of DAs through CME and medical school curriculum; and 5) reform state informed consent laws to reflect that shared decision-making and the use of DAs is the standard for valid informed consent.

Avalere estimated the impact of DAs for four conditions that are prevalent among the Medicare population: breast cancer, ischemic heart disease, hip and knee osteoarthritis, and lower back pain. We estimate that the proposed policy would reduce federal spending by approximately $9 billion over the 2015-2024 federal budget window. This amount reflects the change in spending resulting from patients' shifts from selective surgical treatment to the alternative procedure.

Estimated in Federal Spending due to DA Policy

$ in millions, by fiscal year

	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	**2015-2024**
Breast cancer	-8	-7	-6	-5	-5	-4	-4	-4	-4	-5	-52
Ischemic Heart Disease	-180	-174	-169	-166	-163	-162	-160	-159	-157	-155	-1,646
Hip & Knee Osteoarthritis	-693	-697	-693	-702	-715	-734	-757	-785	-813	-842	-7,428
Lower Back Pain	-26	-25	-23	-21	-20	-19	-19	-19	-18	-19	-208
Total change in spending	**-908**	**-902**	**-889**	**-892**	**-900**	**-916**	**-936**	**-962**	**-987**	**-1,013**	**-9,305**

Background

Many health problems do not have one obvious course of treatment but, instead there are several options with various possible outcomes. For example, patients facing chronic back pain and screening for early-stage breast or prostate cancer have options ranging from doing nothing to multiple treatments.[1] When the evidence suggests that there is more than one reasonable option, patients often experience confusion about their choices and how to make a decision.[2] Physicians also frequently fail to provide all of the information necessary for patients to make informed decisions regarding their care and, instead, may act paternalistically toward patients.[3]

Several studies documented extreme variation in medical spending across the nation for Medicare patients even after adjusting for differences in illness.[4] Despite differences in treatment options, there appear to be little or no relationship between the level of spending and health outcomes.[5] Fisher and Wennberg et al. found that although average baseline health status of cohort members was similar across regions with differing spending levels, neither quality of care nor access to care was better for Medicare patients in high-spending regions.[6]

A decision aid (DA) can help better inform patients by describing the options and the likely outcomes in a way that patient can understand. DAs are tools that patients can utilize to educate themselves about options for their care and likely outcomes. They can be navigated online, on paper, using a telephone, or watching a DVD presentation. Information from the DAs is used to supplement information given by health care professionals and can give patients the chance to take an active role in preference-sensitive decisions about their care.

DAs are part of larger process called shared decision-making between patients and health professionals. Shared decision-making is a structured way for both to discuss medical decisions based on evidence-based information about potential courses of treatment and outcomes.[7] It was found that shared decision-making reduced the prevalence of invasive procedures,[8] and patients who use DAs were much more likely to report greater satisfaction with their care and their decisions.[9]

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[1] Annette M. O'Connor, Hilary A. Llewellyn-Thomas, and Ann Barry Flood, "Modifying Unwarranted Variations in Health Care: Shared Decision-making Using Patient DAs," available at http://geiselmed.dartmouth.edu/cfm/education/PDF/shared_decision_making.pdf

[2] Glyn Elwyn, Eric Weinberger, "Patient, help heal thyself," The Boston Globe, October 13, 2013. Accessed January 27, 2014. Available at: http://www.bostonglobe.com/magazine/2013/10/12/patient-help-heal-thyself/AdMqTwmx3jNtN7z9KCGNYP/story.html.

[3] Melanie Evans, "Providers help patients address emotion, money, health literacy," Modern Healthcare, December 7, 2013. Accessed February 13, 2014. Available at: http://www.modernhealthcare.com/article/20131207/MAGAZINE/312079983.

[4] Jonathan Skinner, Elliott Fisher, "Regional Disparities in Medicare Expenditures: An Opportunity for Reform", National Tax Journal, Vol. 50 no. 3 (September 1997) pp. 413-425.

[5] Elliott S. Fisher, David E. Wennberg, Thrse A. Stukel, Daniel J. Gottlieb, F. L. Lucas, and Étoile L. Pinder, "The implications of Regional Variations in Medicare Spending. Part 1: The Content, Quality, and Accessibility of Care," Annals of internal medicine, 2003, vol. 138, no 4, pp. 273-287.

[6] Fisher, E.S., et al. "The implications of Regional Variations in Medicare Spending. Part 1: The Content, Quality, and Accessibility of Care," Annals of internal medicine, 2003, vol. 138, no 4, pp. 273-287.

[7] France Legare, Holly O. Witteman, "Shared Decision-making: Examining Key Elements and Barriers to Adoption Into Routine Clinical Practice," Health Affairs, 32, no. 2, (2013), Accessed January 27, 2014. Available at: http://content.healthaffairs.org/content/32/2/276.full.pdf+html?sid=4b54cb3e-d868-4429-a9fb-713b0f08c85e

[8] A.M.O'Connor, et al., "Modifying Unwarranted Variations in Health Care: Shared Decision-making Using Patient DAs," available at http://geiselmed.dartmouth.edu/cfm/education/PDF/shared_decision_making.pdf

[9] "Shared Decision-making for Breast Cancer Patients Leads to High Levels of Patient Satisfaction, and Comfort with Decisions and Treatment Preferences," Agency for Healthcare Research and Quality, US Department of Health and Human Services, Accessed February 4, 2014. Available at: http://www.innovations.ahrq.gov/content.aspx?id=2811.

Data Sources

We used the following data sources to develop our estimate:

- 2014 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds.
- 2014 Medicare Physician Fee Schedules.
- 2012 Medicare Standard Analytic Files (SAFs).
- 2014 Medicare Part D Pricefinder.
- Timothy Whelan, Mark Levine, Andrew Willan, Amiram Gafni, Ken Sanders, Doug Mirsky, Shelley Chambers, Mary Ann O'Brien, Susan Reid, and Sacha Dubois, "Effect of a Decision Aid on Knowledge and Treatment Decision Making for Breast Cancer Surgery: A Randomized Trial". JAMA. 2004;292(4):435-441.
- Anne Kelly, and Christine R. Agius, "Improving Adherence to Endocrine Therapies: The Role of Advanced Practice Nurses". Available at http://www.cancernetwork.com/oncology-nursing/improving-adherence-endocrine-therapies-role-advanced-practice-nurses-0/page/0/1
- Shailesh Agarwal, Lisa Pappas, Leigh Neumayer, Kristine Kokeny, and Jayant Agarwal, "Effect of Breast Conservation Therapy vs Mastectomy on Disease-Specific Survival for Early-Stage Breast Cancer". JAMA, 2014, 149(3): 267-274.
- Matthew W. Morgan, Raisa B. Deber, Hilary A. Liewellyn-Thomas, Peter Gladstone, R.J. Cusimano, Keith O'Rourke, George Tomlinson, and Allan S. Detsky, "Randomized, controlled trial of an interactive videodisc decision aid for patients with ischemic heart disease". Journal of General Internal Medicine. 2000;15(10):685-693.
- Ayse Akincigil, John R. Bowblis, Carrie Levin, Saira Jan,Minalkumar Patel, and Stephen Crystal, "Long-Term Adherence to Evidence Based Secondary Prevention Therapies after Acute Myocardial Infarction". Journal of General Internal Medicine, 2007, 23(2): 115-21.
- Roger S. Blumenthal, Gregory Cohn, and Steven P. Schulman, "Medical Therapy Versus Coronary Angioplasty in Stable Coronary Artery Disease: A Critical Review of the Literature", Journal of the American College of Cardiology, 2000, 36(3): 668-673.
- Arterburn, D., et. al . "Introducing Decision Aids At Group Health Was Linked To Sharply Lower Hip And Knee Surgery Rates And Costs". Health Affairs. 2012;31(9):2094-2104.
- Centers for Disease Control and Prevention. "Osteoarthritis". Available at http://www.cdc.gov/arthritis/basics/osteoarthritis.htm
- Richard a. Deyo, Daniel C. Cherkin, James Weinstein, John Howe, Marcia Ciol, and Albert G. Mulley, "Involving Patients in Clinical Decision: Impact of Interactive video Program on Use of Back Surgery". Medical Care, 2000, 38(9): 959-69.

Assumptions and Methodology

Standard Approach for Measuring the Impact of DA

We conducted this analysis based on published research of randomized controlled trials (RCT) of DAs for individual conditions. In the clinical trials of DAs, the impact of DA was measured by comparing treatment decisions between patients in a treatment and control group. The patients

in the treatment group were provided with decision aid before making the decision, whereas the control group was asked to make the decision based on the traditional information. These studies generally showed that patients tend to choose less invasive alternative procedures, which suggests that the use of DA can lead to reduced utilization of high cost treatments.

For the four conditions selected for this analysis, elective surgery is one of the treatment options and the alternative procedures often include less invasive choices such as drug therapies. Since for each condition there is more than one alternative procedure, we selected the procedure that is commonly used with enough information and data to analyze. We estimated the per procedure costs for both surgery and the alternative procedure using the Medicare data.[10] Subsequently, we estimated the number of cases where the use of DA would shift patients from elective surgery to the alternative. Then we calculated the change in Medicare spending as a result of changes in treatment.

Table 1. Standard Inputs and Assumptions Used in All DA Estimates

Input / Assumption	Description
Total FFS population in a given year	Obtained from the 2014 trustees report
Estimated FFS population that would choose elective surgery without DA	Based on utilization rates observed in 2012 Medicare data
Impact of DA	We discounted any published effects of DAs by 75% to account for complexities associated with Medicare enrollees, DA implementation, and physician preferences
Cost of treatments	
Surgery (inpatient, outpatient, and physician)	Taken from relevant 2014 Medicare fee schedules
Post-acute care	Not included in evaluation
Drugs	Taken from 2014 Medicare Part D Pricefinder
Drug adherence	We assume a patient who chooses the less aggressive therapy will require ongoing drug therapy, and the adherence rate was adjusted based on the published estimates of adherence rates

Estimated Effect of DA in Breast Cancer

Breast cancer is the most common cause of cancer deaths in women over 65 years of age. The treatment approach to this cancer includes prevention, early detection through appropriate screening, treatment of localized tumors and management of advanced disease.[11] The physician may assume a key role in these interventions by providing education and support to patients and their families.

[10] The average costs of surgery and drugs for each condition were estimated based on relevant 2014 Medicare Physician Fee Schedules and 2014 Medicare Part D Pricefinder.
[11] Lodovico Balducci, D. Melissa Phillips, "Breast Cancer in Older Women", 1998 October 1;58(5):1163-1172.

Recent research has shown a significant rise in the rate of bilateral mastectomies over the last several years.[12] However, the results of randomized trials have demonstrated equivalent survival rates for mastectomy and breast-conserving therapy (BCT) for the treatment of early stage breast cancer.[13] Some women with early stage breast cancer who receive full mastectomies due to breast cancer may have equivalent or better outcomes if they instead receive BCT. Consequently, the choice of treatment should be based on a patient's preferences.

We estimate approximately 16 thousand mastectomies were performed on Medicare patients in 2012, which is about 0.04% of the total Medicare FFS population. We assume same proportion of patients with early stage breast cancer will have mastectomies in the following years.

Based on the literature, the use of DA could result in 75 percent reduction in mastectomies.[14] We discounted this effect by 75 percent to account for complexities associated with Medicare FFS patients, physician preferences, and differences in DA implementation settings. Therefore, we estimate that the implementation of DA in clinical settings will shift 19 percent of patients who would otherwise choose mastectomy to BCT. We assume the DA effect will be the same every year.

The most common BCT includes lumpectomy plus five-year adjuvant tamoxifen therapy. To project the total number of patients who will be on BCT each year between 2015 and 2024 as a result of DA, we incorporated both drug adherence rate and mortality rate of breast cancer patients in the calculation. Based on the literature, we estimate that the adherence rate for tamoxifen will decline from 77 percent at first year to about 50 percent at five years,[15] and the annual mortality rate for patients treated by BCT is one percent.[16].

Estimated Effect of DA in Ischemic Heart Disease

Cardiovascular disease is the leading cause of deaths in adults. Standard modes of therapy for ischemic heart disease include coronary bypass surgery, angioplasty, and medical therapy.[17] In cases of severe coronary artery disease, there is strong evidence that coronary artery bypass surgery can result in a definite survival advantage. However, with less severe disease this survival advantage is uncertain.[18]

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[12] Allison W. Kurian, Daphne Y. Lichtensztajn, Theresa H. M. Keegan, David O. Nelson, Christina A. Clarke, and Scarlett L. Gomez, "Use of and Mortality After Bilateral Mastectomy Compared With Other Surgical Treatments for Breast Cancer in California, 1998-2011". JAMA. 2014;312(9):902-914.

[13] Timothy Whelan, Mark Levine, Andrew Willan, Amiram Gafni, Ken Sanders, Doug Mirsky, Shelley Chambers, Mary Ann O'Brien, Susan Reid, and Sacha Dubois, "Effect of a Decision Aid on Know ledge and Treatment Decision Making for Breast Cancer Surgery: A Randomized Trial". JAMA. 2004;292(4):435-441.

[14] Whelan T, et al. "Effect of a Decision Aid on Know ledge and Treatment Decision Making for Breast Cancer Surgery: A Randomized Trial". JAMA. 2004;292(4):435-441.

[15] Anne Kelly, and Christine R. Agius, "Improving Adherence to Endocrine Therapies: The Role of Advanced Practice Nurses". Available at http://www.cancernetwork.com/oncology-nursing/improving-adherence-endocrine-therapies-role-advanced-practice-nurses-0/page/0/1

[16] Shailesh Agarwal, Lisa Pappas, Leigh Neumayer, Kristine Kokeny, and Jayant Agarw al, "Effect of Breast Conservation Therapy vs Mastectomy on Disease-Specific Survival for Early-Stage Breast Cancer". JAMA, 2014, 149(3): 267-274.

[17] Matthew W. Morgan, Raisa B. Deber, Hilary A. Liew ellyn-Thomas, Peter Gladstone, R.J. Cusimano, Keith O'Rourke, George Tomlinson, and Allan S. Detsky, "Randomized, controlled trial of an interactive videodisc decision aid for patients w ith isc hemic heart disease". Journal of General Internal Medicine. 2000;15(10):685-693.

[18] Morgan, M.W., et al. "Randomized, controlled trial of an interactive videodisc decision aid for patients w ith ischemic heart disease". Journal of General Internal Medicine. 2000;15(10):685-693.

Research has suggested that many patients who receive coronary artery bypass graft (CABG) surgery or angioplasty (i.e., stents) for their heart disease may have equivalent outcomes via medical therapy. Some reports have focused on the economic incentives associated with CABG or stent procedures, as well as the cardiovascular surgeon's "desire" to "cure" the patient via a surgical intervention.[19]

We estimate approximately 217 thousand heart surgeries were performed on Medicare patients in 2012 and these patients comprise 0.58 percent of the total Medicare FFS population. We assume in the following years, same proportion of patients will have heart surgeries. We do not include CABG surgeries performed on patients with significant co-morbidities nor patients with multiple stents in a single visit, as we believe these patients are unlikely candidates for the alternative medical treatment.

According to the literature, patients who use DA for heart disease are 21 percent more likely to choose medical therapy rather than surgery.[20] We discounted this effect by 75 percent for the same reason as described in the previous section and estimate that the use of DA would result in 5 percent patients shifting from heart surgery to medical therapy. We assume DA will have the same effect every year.

We assume patients who choose medical therapy over heart surgery will have long-term use of a variety of medication for heart disease, including angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARB), beta blockers, calcium channel blockers, and clopidogrel. To project the total number of patients who will be on these drug therapies each year between 2015 and 2024 as a result of DA, we applied both drug adherence rate and annual mortality rate in the calculation. The literature showed that the drug discontinuation rate is 32 percent in the first year and 50 percent at two years.[21] We assume patients drop out in the first two years due to reasons such as side effects of the drugs and costs of therapies, and patients who remain in the therapy will continue to take drugs for the long term. Therefore, we assume after the first couple of years, the adherence rate will level off and remain at 50 percent.

Estimated Effect of DA in Hip and Knee Osteoarthritis

Osteoarthritis (OA) affects more than 12.4 million adults aged 65 years and older.[22] Total hip and knee replacements are among the most common orthopedic procedures, exceeding 250,000 and 650,000 annual procedures, respectively. [23] However, clinical guidelines suggest that while the complications associated with total knee replacement (TKR) or total hip replacement (THR) have declined over the years, there is no clear level of functional impairment that requires surgery versus other forms of non-surgical therapy.[24] Debates remain about which patients are most likely to benefit from joint replacement surgery.

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[19] O'Connor, A. "Heart Stents Still Overused, Experts Say". New York Times. August 15, 2013.
[20] Morgan, M.W., et al. "Randomized, controlled trial of an interactive videodisc decision aid for patients with ischemic heart disease". Journal of General Internal Medicine. 2000;15(10):685-693.
[21] Ayse Akincigil, John R. Bowblis, Carrie Levin, Saira Jan,Minalkumar Patel, and Stephen Crystal, "Long-Term Adherence to Evidence Based Secondary Prevention Therapies after Acute Myocardial Infarction". Journal of General Internal Medicine, 2007, 23(2): 115-21.
[22] Centers for Disease Control and Prevention. "Osteoarthritis". Available at http://www.cdc.gov/arthritis/basics/osteoarthritis.htm
[23] David Arterburn, Robert Wellman, Emily Westbrook, Carolyn Rutter, Tyler Ross, David McCulloch, Matthew Handley, and Charles Jung. "Introducing Decision Aids At Group Health Was Linked To Sharply Lower Hip And Knee Surgery Rates And Costs". Health Affairs. 2012;31(9):2094-2104.
[24] Katz JN. "Total joint replacement in osteoarthritis." Best Pract Res Clin Rheumatol. 2006;20(1):145–53.

According to the literature, the introduction of DAs in OA is associated with 26 percent fewer THR surgeries and 38 percent fewer TKR surgeries.[25] We discounted this effect by 75 percent and estimate that the use of DA would result in 10 percent and 7 percent reductions in TKR and THR surgeries, respectively. We assume DA effect will be the same every year.

We estimate approximately 452 thousand hip or knee replacements were performed in 2012, and we assume the annual growth rate is the same as it is for the total Medicare FFS population. We do not include patients who received bilateral or multiple joint procedures as we believe these patients require surgical intervention and would not receive a DA. We also exclude patients who received hip or knee revision surgery.

There are effective treatments for hip and knee OA that may help patients avoid the need for a surgery, including physical therapy, walking aids, anti-inflammatory medications, corticosteroid injection, and joint supplements. Due to data limitation, for this analysis, we examined the costs associated with surgery versus cortisone injection.

To project the total number of patients who will need cortisone injections between 2015 and 2024 as a result of DA, we applied both drug adherence rate and annual mortality rate in the calculation. Based on the data,[26] on average, OA patients take injections once a year. Since corticosteroid drug is a potent and effective solution, we assume the adherence rate will decline by 10 percent each year.

Estimated Effect of DA in Lower Back Pain

Back pain affects 8 out of 10 people at some point during their lives and it is more prevalent among people ages between 40 to 80 years old.[27] On average, health care expenditures for individuals with back pain have been estimated to be about 60% higher than those without back pain,[28] and some experts believe surgery for chronic back pain is overused

. One study found that in patients with herniated disks, the primary benefit of surgery (i.e. microdiskectomy) is accelerated relief of sciatic and outcomes after four years are similar with or without surgery.[29] This same study found that the use of DA with lower back surgery patients was associated with a 32 percent reduction in microdiskectomies.

We estimate that approximately 47 thousand microdiskectomies were performed for Medicare patients in 2012, or approximately 1.3 surgeries per 1,000 Medicare FFS enrollees per year. We assume this rate of surgery will continue over the next 10 years absent the DA policy. We do not include patients with spinal stenosis in our analysis as the literature showed higher surgery rates for this group of patients as a result of using DA.

Common non-surgical treatments for lumbar herniated disk include rest, anti-inflammatory medications, physical therapy, and epidural steroid injection (i.e. cortisone injection). Of these therapies, only epidural injections have been proven effective at reducing symptoms.[30]

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[25] Arterburn, D., et. al . "Introducing Decision Aids At Group Health Was Linked To Sharply Lower Hip And Knee Surgery Rates And Costs". Health Affairs. 2012;31(9):2094-2104.
[26] The data is based on 2012 five percent Medicare Standard Analytic Files (SAFs).
[27] Back Pain Fact Sheet. Available at http://www.inthefaceofpain.com/content/uploads/2012/05/factsheet_Back.pdf
[28] Xuemei Luo, Ricardo Pietrobon, Shawn X. Sun, Gordon, G. Liu, Lloyd Hey, "Estimates and patterns of direct health care expenditures among individuals with back pain in the United States." Spine. 2004;29:79-86.
[29] Richard a. Deyo, Daniel C. Cherkin, James Weinstein, John Howe, Marcia Ciol, and Albert G. Mulley, "Involving Patients in Clinical Decision: Impact of Interactive video Program on Use of Back Surgery". Medical Care, 2000, 38(9): 959-69.
[30] Herniated Disk in the Lower Back. Available at http://orthoinfo.aaos.org/topic.cfm?topic=a00534

Therefore, we assumed patients who chose not to receive a microdiskectomy due to the DA would instead receive cortisone injections.

To project the total number of patients who will need cortisone injections between 2015 and 2024 as a result of DA, we applied both drug adherence rate and annual mortality rate for Medicare FFS patients in the calculation. On average, patients take injections once a year. Since corticosteroid drug is a potent and effective solution, we assume the adherence rate will decline by 10 percent each year.