

HEALTH CARE SPENDING GUIDING PRINCIPLES



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TABLE OF CONTENTS

Purpose and Need for Guiding Principles	5
Overview of Guiding Principles Development	6
How to Use This Document	6
1.0 Patient-Centered Guiding Principles for Evaluating Health Care Spending	9
Evaluation of health care spending should:	
1.1 Consider impacts of changes in health spending on patients and society	10
1.2 Incorporate estimates of the actual amounts paid for medical care	12
1.3 Recognize differences in spending across patients and time	14
1.4 Account for changes in disease- or condition-specific epidemiologic measures such as incidence and prevalence	16
1.5 Be adjusted for inflation	18
1.6 Be based on data relevant to the analysis objectives	20
1.7 Be accompanied by sensitivity analyses to elucidate uncertainty that may exist in the evaluation	22
1.8 Place conclusions and policy recommendations in the appropriate context	24
2.0 Patient-Centered Guiding Principles for Reforming Health Care to Address Rising Health Care Spending	28
Policies reforming health care to address rising spending should:	
2.1 Be designed to achieve the intention of the Triple Aim framework of health care improvement	30
2.2 Be rooted in patient-centered value	33
2.3 Recognize the differing needs of a diverse U.S. population	35
2.4 Preserve or improve short- and long-term patient outcomes	38
2.5 Address the burden associated with the financing of health care and the resultant distributional consequences	42
2.6 Target significant sources of inefficient health care spending across health care settings, services provided and differing conditions	44
2.7 Discourage the use of low-value care and encourage the use of high-value care	46
2.8 Address factors driving overall health care demand, including behavioral, cultural and socioeconomic factors	48
2.9 Address misaligned incentives that distort utilization and price	50
2.10 Incentivize innovations in health care delivery systems and treatments	52
References	54



PURPOSE

The purpose of these principles is to guide a rigorous, evidence-based evaluation and discussion of health care spending estimates and policies. These principles seek to improve health care spending efficiency and to maximize patient health, consistent with the goals of patient-centered care as defined by the Institute of Medicine. Readers of this document should use it to (1) guide and evaluate health spending analyses' methodological rigor, limitations and alignment with patient-centered care, and (2) guide and evaluate health spending policy, including identification of tradeoffs (patient's health, spending), risks of unintended consequences and implications for patient-centered care. Users should leverage the results of their analyses to inform policymakers, media and the general public where appropriate.

WHY THE NEED FOR GUIDING PRINCIPLES

The continued rise in health care spending and patient out-of-pocket (OOP) costs in the United States has led to an intense debate among policymakers and other health care stakeholders on managing increasing costs. Numerous factors contribute to increased spending and OOP costs, including an aging population; structural, administrative and process complexity in the health system; innovative methods for disease prevention; improved speed and accuracy of diagnoses; adoption of novel treatments; health care prices and component costs; and benefit design.

Some of these factors also result in improved health outcomes and efficiency of care. However, constrained state and federal health care budgets indicate that the potential consequences of unchecked health care spending are real and significant. Such consequences include greater health disparities, lower budgets for other social services and general infrastructure, and erosion of consumer purchasing power. The relationships between health care spending and health outcomes are myriad and complex. Therefore, efforts to address rising health care spending must be balanced and based on evidence to avoid the unintended reversal of recent gains in health outcomes.

OVERVIEW OF GUIDING PRINCIPLES DEVELOPMENT

The National Pharmaceutical Council (NPC) has established a set of principles to assess health care spending estimates and health care spending policies to ensure alignment with the goals of patient-centered care as defined by the Institute of Medicine. NPC developed these principles in a multiple-step process using established standards (e.g., all principles include citations). In the first step, NPC surveyed the relevant literature to develop a draft set of principles with supporting examples. These draft principles were reviewed in a blind fashion with external key policy opinion leaders, including academics, patient groups, payers (public and private), providers and think tanks. NPC incorporated feedback from these interviews into the final set of principles.

HOW TO USE THIS DOCUMENT

These principles seek to improve health care spending efficiency and maximize patient health. They cover health care spending analyses, overall health care reform approaches and specific health care spending policies. The principles can be applied to federal, state, health plan or employer policies and supporting analyses above the individual service or treatment level. Examples of health care spending policies include, but are not limited to, health care legislative or regulatory changes (e.g., elimination of drug rebates, price capitation for health care services), changes in reimbursement approaches (e.g., alternative payment approaches, greater use of budget caps), benefit design (e.g., greater use of high-deductible health plans, tax deductions for health insurance premiums), and coverage policies (e.g., exclusion of low-value care services, narrow networks of providers).

The 18 guiding principles described in this document are divided into two categories:

Patient-Centered Guiding Principles for Evaluating Health Care Spending. The first step in addressing health care spending is to accurately diagnose the root causes of increased spending. The diagnosis of root causes requires using transparent, evidence-based and consistently applied methods. Professional associations and other authoritative sources advance best practices and guidelines for conducting health economic analyses, including health care spending analyses. A few example organizations that have developed standards and best practices relevant for health care spending analyses are the National Health Expenditure Accounts from the Centers for Medicare and Medicaid Services (CMS, 2017), the Triple Aim (expanded to the Quadruple Aim) from the

National Academy of Medicine and Consolidated Health Economic Evaluation Reporting Standards (CHEER) from ISPOR—The Professional Society for Health Economics and Outcomes Research. These principles have two goals: (1) evaluate the rigor and appropriateness of the methods underlying analyses of health care spending, and (2) ensure the alignment of health care spending analyses with patient-centered care.

Patient-Centered Guiding Principles for Reforming Health Care to Address Rising Health Care Spending. These principles establish evidence-based standards for evaluating whether policy reforms address rising health care spending in a manner that improves patient health and system efficiency. These principles have two goals: (1) establish patient-centered principles to evaluate U.S. health care spending reform approaches, and (2) provide a set of standards to evaluate individual health policies against the goal of patient-centered care.

The purpose of each set of guiding principles and an example application are in Table 1.

Table 1: Health Spending Guiding Principles

	Patient-Centered Guiding Principles for Evaluating Health Care Spending	Patient-Centered Guiding Principles for Reforming Health Care to Address Rising Health Care Spending
Purpose	<ul style="list-style-type: none"> (1) Examine the rigor and appropriateness of the methods used to estimate health care spending over time and across subpopulations. (2) Ensure that health care spending analyses are evaluated in a manner consistent with the goal of patient-centered care. 	<ul style="list-style-type: none"> (1) Establish patient-centered principles to guide and evaluate reforms designed to control rising U.S. health care spending. (2) Evaluate individual health care spending policies for their intended and possible unintended impacts on patients' health.
Example application	<ul style="list-style-type: none"> (1) Review analyses (e.g., publications) to determine study quality and agreement with generally accepted methodological standards for analyzing health care spending. (2) Review analyses to ensure consistency with patient-centered care. 	<ul style="list-style-type: none"> (1) Evaluate legislative, regulatory and/or payer (public or private) health spending reform agendas to determine their alignment with building a patient-centered health care system in the U.S. (2) Review legislative, regulatory and/or payer (public or private) health care spending policies or actions to determine their likely impacts on short-term and long-term patient health.

Each guiding principle includes four components: (1) a definition, (2) supporting detail and citation(s) to provide additional context and clarity, (3) a brief description of how to use the principle and (4) an illustrative example.

These guiding principles intend to assist with rigorous, evidence-based evaluation and discussion of health care spending estimates and policies. However, health care spending analyses and policies vary substantially in objectives and scope, so not all guiding principles may apply to every instance.

1.0 Patient-Centered Guiding Principles for Evaluating Health Care Spending

Evaluation of health care spending should:



1.1 Consider impacts of changes in health spending on patients and society.



1.2 Incorporate estimates of the actual amounts paid for medical care.



1.3 Recognize differences in spending across patients and time.



1.4 Account for changes in disease- or condition-specific epidemiologic measures such as incidence and prevalence.



1.5 Be adjusted for inflation.



1.6 Be based on data relevant to the analysis objectives.



1.7 Be accompanied by sensitivity analyses to elucidate uncertainty that may exist in the evaluation.



1.8 Place conclusions and policy recommendations in the appropriate context.

These principles serve as a checklist to assess whether methods used for estimating health care spending are appropriate, i.e., following recommendations from professional associations and other authoritative sources. Further, these principles can be used to examine whether analyses to evaluate health care spending policies align with the goals of patient-centered care.

For this document, we define “health care spending analyses” as analyses of health care spending above the individual service or treatment level. Examples of health care spending analyses include segment-level (e.g., inpatient, drug, office), condition-specific aggregate spending, population-level, and organization-level (e.g., accountable care organizations, hospitals) analyses.



1.1 Evaluation of health care spending should consider impacts of changes in health spending on patients and society (Institute of Medicine, 2011)

Supporting Detail

Health care spending analyses should be grounded in patient-centered care, which the Institute of Medicine defines as “Providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions” (Institute of Medicine, 2011). As such, policy recommendations should consider the tradeoffs between health care spending changes and their potential impacts on outcomes important to patients and society. Examples of outcomes to consider include patient health and functioning, patient experience, patient financial burden, patient access to care, caregiver burden and productivity.

How to Use This Guiding Principle

When assessing the consistency of a health care spending analysis with patient-centered care, the reviewer should confirm that the analysis accounts for the effects on outcomes important to patients and society. When data on outcomes that are most important to patients and society are not available, the discussion should note this critical limitation and whether deference was given to patients’ needs.

Illustrative Example

In a study of expenditure data from health departments in Florida and Washington, Bekemeier and colleagues examined the potential influence of states’ investment in maternal and child health services on population health outcomes (Bekemeier et al., 2014). They estimated the relationship between the level of investment in various services and critical indicators of family health in the population (i.e., the prevalence of low birth weight and infant mortality). Investments included expenditures for the Women, Infants, and Children Program, family planning, and maternal, infant, child and adolescent health. The authors concluded that there are long-term health benefits from investments in public maternal and infant care services, especially in populations living in poverty.

The following (Assessment 1) summarizes how this study assessed policy performance based on impacts to patients and society.

Assessment 1. Evaluation of the Bekemeier Study (Bekemeier et al., 2014)

#	Criteria	Evaluation
1	Did the analysis account for the impacts of differences in health spending on the population outcomes important to patients and society?	The study assessed the impact of maternal and child health services spending on the prevalence of low birth weight and infant mortality. The authors explained that low birth weight contributes to a significant burden to society, including high direct medical costs, higher childcare expenses and increased caregiving burden.
2	If applicable, did the study acknowledge the limitation and implications of excluding key outcomes? Was deference given to patients' needs?	Not applicable.



1.2 Evaluation of health care spending should incorporate estimates of the actual amounts paid for medical care (White and Whaley, 2019; IQVIA Institute for Human Data Science, 2021)

Supporting Detail

There are significant variations between U.S. list prices/charged amounts and actual/net amounts paid for medical care (White and Whaley, 2019; IQVIA Institute for Human Data Science, 2021). Therefore, health care spending analyses should incorporate estimates of actual/net amounts paid by relevant parties (i.e., the patient, the health care provider and the third-party payer). If actual/net amounts paid are unavailable, sensitivity analysis should examine potential variations between charged amounts/list prices and actual paid amounts.

How to Use This Guiding Principle

The reviewer should confirm that spending estimates use actual/net paid amounts for each relevant stakeholder (i.e., payers, patients, providers). When actual/net paid amounts are not available, the study should incorporate appropriate estimates and provide clear documentation on how the estimates of amounts paid were calculated. In general, the actual/net amounts paid for medical care services and prescription medications vary significantly within stakeholder type. The amount paid is often unavailable to researchers. In this case, the study should document assumptions used to estimate amounts paid and test these assumptions in comprehensive sensitivity analyses.

Illustrative Example

Hernandez and colleagues studied the difference between the list and net prices of branded pharmaceutical products between 2007 and 2018, using a database that included rebate estimates (Hernandez et al., 2020). The study found that list prices increased by almost 160% (9.0% average per year), but net prices increased by only 60% (4.4% average per year) (see Table 2). Due to significant differences in the list and net price, the authors concluded that the use of list prices would overestimate payers' drug costs.

Table 2. Examples of Changes in List Prices and Changes in Actual Amounts Paid for Select Treatments Between 2007 and 2018

	All (n = 602)	M.S. Agents (n = 4)	Insulins (n = 7)	Lipid- Lowering Agents (n = 11)	Noninsulin Antidiabetic Agents (n = 10)	Tumor Necrosis Factor Inhibitors (n = 3)	Anti- neoplastic Agents (n = 44)	Single source (n = 276)	Multisource (n = 287)
List price changes over time (%)									
Change from 2007 to 2018	159%	439%	262%	278%	165%	166%	59%	196%	109%
Net price changes over time (%)									
Change from 2007 to 2018	60%	157%	51%	95%	–1%	73%	35%	63%	59%

M.S. = multiple sclerosis

Notes: Single-source drugs: drugs that had no generic version available between 2007 and 2018. Multisource drugs: products subject to generic competition in the same periods.

Source: Hernandez et al. (2020)

The following (Assessment 2) assesses the use of actual paid amounts in this health care spending analysis.

Assessment 2. Evaluation of the Hernandez Study (Hernandez et al., 2020)

#	Criteria	Evaluation
1	Was the spending calculated using estimates of the actual/net amounts paid by stakeholders relevant to the analysis for the sources of medical care under evaluation?	The study evaluated the U.S. payers' perspective; therefore, it considered drug prices paid by payers by type (i.e., Medicaid vs. non-Medicaid).
2	Did the study document the estimation of actual/net paid amounts for each relevant stakeholder?	The study used estimated net prices. Net price is product unit revenue less manufacturer concessions (rebates, coupon cards, discounts, return provisions and other deductions accounted for in the reporting of sales).
3	If the amount paid was unavailable to the author, did the study document assumptions used to estimate amounts paid and test these assumptions in comprehensive sensitivity analyses?	The study reported multiple limitations. For example, net pricing data is limited to branded products owned by publicly traded companies.



1.3 Evaluation of health care spending should recognize differences in spending across patients and time (Dieleman et al., 2017)

Supporting Detail

Rather than focusing solely on mean or median changes in health care spending for patients with a specific condition, health care spending analyses should consider the distribution of per-patient costs resulting from differences in patients' ages, underlying health conditions, comorbidities, and severity and treatment/utilization patterns resulting from changes in clinical practice or patient access [e.g., coverage policy, benefit design (including out-of-pocket responsibility)]. This distribution should be examined across both patients and time. Doing so can provide a more comprehensive assessment of health care spending and help identify the variance in and root causes of health care spending for specific health conditions (Dieleman et al., 2017). It may not be possible to perform this type of analysis when dealing with small patient populations such as those with a rare disease.

How to Use This Guiding Principle

Health care spending analyses should report results for both the total population and critical subpopulations that may differ from the population average. Further, studies analyzing changes over time should incorporate corresponding changes in the demographics, treatment and utilization patterns (resulting from changes in clinical practice or patient access, including financial burden), and key population health outcomes. Therefore, studies should always report their rationale for selecting specific analyses to account for differences in health care spending across patients and time. Researchers may not always have access to data to conduct rigorous subpopulation analyses or time-series assessments of changes in underlying population health and treatment or utilization patterns. In addition, the patient population may be too small to conduct this type of analysis, especially for rare diseases. In these circumstances, researchers should document the lack of data as a limitation of the study.

Illustrative Example

In a study of patients with heart failure (Yoon et al., 2016), the authors reported the average per-patient cost of heart failure and factors that may contribute to higher costs. The annual cost of heart failure depended on the patient's age, race or ethnicity, history of substance abuse and comorbid conditions.

The following (Assessment 3) summarizes methods that this study used to account for differences in spending across patients and time.

Assessment 3. Evaluation of the Yoon Study (Yoon et al., 2016)

#	Criteria	Evaluation
1	Did the authors report key subpopulations that may have differed from the population average? If not, was the rationale for not including them documented?	The authors reported demographic and clinical risk factors for high spending.
2	If the study analyzed changes over time, did it report changes in the demographics, treatment/ utilization patterns, patient access and key population health outcomes during the studied time frame? If not, was the rationale for not including them documented?	Not applicable because the study did not compare health care spending over time.



1.4 Evaluation of health care spending should account for changes in disease- or condition-specific epidemiologic measures such as incidence and prevalence (Dieleman et al., 2017)

Supporting Detail

Changes in condition-specific epidemiologic measures contribute to health care spending changes (Dieleman et al., 2017). For example, disease-specific spending could increase with time due to prevalence increases while individual treatment costs decline. Focusing solely on disease-specific spending would miss the fact that treatment costs per patient are declining. Therefore, health care spending for diseases and conditions should be estimated in two ways: (1) for all people living with the condition and (2) for an individual living with the condition. This approach eliminates confounding from changes in the number of new cases each year or changes in the number of people living with a chronic condition because of behavioral, environmental, prophylactic therapy, treatment or public health changes.

How to Use This Guiding Principle

Health care spending analyses should report both population-level and patient-level spending. Suppose the study reports overall health care spending only. In that case, authors should document this limitation and state the implications of omitting the estimates adjusted by the disease prevalence.

Illustrative Example

In comparing U.S. and western European countries, Thorpe and colleagues examined how disease prevalence and treatment rates may have affected the per-capita health care spending for the 10 most costly conditions in the U.S. and European countries (Thorpe et al., 2007). Based on an analysis of data from surveys of the noninstitutionalized population aged 50 years and older, this study found the prevalence and rates of medication treatment for almost all of the 10 conditions examined were considerably higher in the U.S. than in European countries. The authors concluded that these findings indicate the importance of health policies aligned with goals to reduce the prevalence of chronic illness.

The following (Assessment 4) summarizes methods that this study used to account for changes in disease- or condition-specific epidemiologic measures.

Assessment 4. Evaluation of the Thorpe Study (Thorpe et al., 2007)

#	Criteria	Evaluation
1	Did the study report health care spending both at the per-person and population levels?	<p>After reporting differences in disease prevalence and treatment rate as potential factors for the higher per-capita health care spending in the U.S. vs. Europe, this study did not report health care spending per person for each condition.</p> <p>The authors reported that estimating the cost per diagnosed case of each condition would have been challenging.</p>



1.5 Evaluation of health care spending should be adjusted for inflation (Dunn et al., 2018)

Supporting Detail

Analyses should incorporate inflation to adjust rising health care spending for base changes in costs of goods and labor (Dunn et al., 2018). Examples of appropriate indexes include the Consumer Price Index for All Urban Consumers and the gross domestic product (GDP) implicit price deflator.

How to Use This Guiding Principle

Health care spending analyses should report the year of the data used to estimate spending and indicate which index was used to adjust for general inflation. The reviewer should evaluate whether the index was appropriate in the context of the analysis. If not adjusted for inflation, the reviewer should (1) confirm whether the study provides a rationale for the approach and (2) evaluate the implication of using unadjusted health care spending.

The analysis context will determine the most appropriate inflation index (Dunn et al., 2018). For example, an analysis from the societal perspective should use the GDP implicit price deflator. In contrast, analysis from the patient perspective should consider the overall Personal Consumption Expenditures (PCE) index to adjust health expenditures in terms of purchasing power. Either the Personal Health Care deflator or the PCE health-by-function index can be used to adjust spending associated with a specific disease. However, the Producer Price Index should be used to adjust inpatient service expenditures.

Illustrative Examples

In a study of changes in spending for 155 health conditions between 1996 and 2013, the authors adjusted all components of health spending estimates into 2015 dollars to account for inflation. In addition, the spending estimates were actual amounts paid (vs. charges) (Dieleman et al., 2017). The authors adjusted costs using the economy-wide consumer price index from the International Monetary Fund.

The following (Assessment 5) summarizes methods this study used to account for inflation.

Assessment 5. Evaluation of the Dieleman Study (Dieleman et al., 2017)

#	Criteria	Evaluation
1	Did the study report the year of the data used to estimate the spending?	The study reported various data sources used to estimate health spending and the years of the data for each source.
2	Did the study adjust spending data for general inflation? <ul style="list-style-type: none">• If so, did the study use the appropriate index?• If not, was a reason provided?	The study adjusted all spending data to be expressed in 2015 dollars and used an appropriate index.



1.6 Evaluation of health care spending should be based on data relevant to the analysis objectives (Smith et al., 2018)

Supporting Detail

It is critical to ensure that data selected are relevant to the specific objectives of the spending analysis, the relevant population and the relevant observational period (Smith et al., 2018). The research should provide precise descriptions of the studied population, analysis metrics and data collection period. Furthermore, the study should discuss the generalizability of its findings. For example, suppose study data underrepresent certain populations (e.g., the uninsured population, the unemployed). In that case, the study should state who is included and excluded from spending estimates and how using such data may impact the interpretation of the study results.

How to Use This Guiding Principle

When evaluating a health care spending analysis, the reviewer should confirm that the analysis is accompanied by clear descriptions of the population studied and the period of analysis. In addition, the study should discuss the generalizability of its outcomes.

Illustrative Example

Cutler and colleagues (2019) examined reasons for the slowdown in per-capita spending for Medicare beneficiaries between 1999 and 2012 based on an analysis of the Medicare Current Beneficiary Survey (MCBS) (Cutler et al., 2019). To address the exclusion of Medicare Advantage enrollees' claims from the study data, the study reweighted data so that the population represented in the data matched the socioeconomic and health statuses of the total Medicare beneficiaries, including Medicare Advantage recipients. The study then validated the weighting method by ensuring that the estimated service-specific spending matched national totals in another database, the National Health Expenditure Accounts.

The following (Assessment 6) summarizes how this study ensured the data used for the analysis were relevant to the analysis objectives.

Assessment 6. Evaluation of the Cutler Study (Cutler et al., 2019)

#	Criteria	Evaluation
1	Did the study provide precise descriptions of its metrics, the population studied and the study period?	To estimate the aggregate spending among Medicare beneficiaries between 1999 and 2012, the authors used a database of Medicare beneficiaries, MCBS (1999-2012).
2	Did the study discuss the generalizability of its findings?	Because MCBS did not include Medicare Advantage enrollee claims, the study implemented a weighting method to correct the potential bias from this limitation. Further, the study concluded that the implications of the future of cost growth are unclear due to various environmental factors that are difficult to predict.



1.7 Evaluation of health care spending should be accompanied by sensitivity analyses to elucidate uncertainty that may exist in the evaluation (Walker and Fox-Rushby, 2001)

Supporting Detail

Health care spending analyses should acknowledge the inherent uncertainty associated with health care spending data (Walker and Fox-Rushby, 2001). Specifically, the study should vary unit cost and utilization pattern assumptions when actual values range or are assumed. Unit cost-related assumptions include reimbursement rates, discounts/rebates, patient cost share and payer mix. Utilization-related variables include patient mix characteristics, coverage, payer mix and treatment patterns. The purpose of varying unit costs and utilization-related variables is to determine whether the study's conclusions are valid across a range of reasonable assumptions.

How to Use This Guiding Principle

Rigorous sensitivity analyses should accompany health care spending analyses. Specifically, the researcher should test the impact of critical assumptions by demonstrating how changing these assumptions affect the overall study results. The study also should address the potential effects of uncertainty by (1) reporting confidence intervals, standard deviations or standard errors around each key analysis input and (2) demonstrating the effects of parameter uncertainty by varying key input values on analysis results.

Illustrative Example

Irwin and colleagues analyzed the impact of a supervised injection facility on opioid-dependent individuals in Baltimore. Specifically, the study reviewed population-level outcomes and reduced health care spending resulting from lower resource use (Irwin et al., 2017). Population-level outcomes reported were the number of human immunodeficiency virus (HIV) and hepatitis C transmissions prevented, skin infections prevented and overdose deaths prevented. For health care resource metrics, the study reported overdose-related medical care and medication-assisted treatments. The researchers conducted sensitivity analyses by varying each of the critical model inputs to estimate the range of net savings after instituting a supervised injection facility.

The following (Assessment 7) summarizes how this study accounted for uncertainty around data used for the analysis.

Assessment 7. Evaluation of the Irwin Study (Irwin et al., 2017)

#	Criteria	Evaluation
1	Did the study examine how changing critical assumptions affected the overall study results?	Key assumptions such as the facility operating cost, syringe-sharing rate, soft-tissue infection rate, overdose rate, overdose death rate and referral rate for medication-assisted treatment were varied by $\pm 50\%$.
2	Did the study report confidence intervals, standard deviations or standard errors around each key analysis input?	The study did not report descriptive statistics around any of the model inputs used to estimate outcomes.
3	If the analysis used an economic model, did the study conduct sensitivity analyses around inputs' parameter uncertainty?	The study did not conduct any sensitivity analysis informed by statistical inference; all sensitivity analyses used arbitrary ranges.



1.8 Evaluation of health care spending should place conclusions and policy recommendations in the appropriate context (Husereau et al., 2013)

Supporting Detail

Findings and conclusions of spending analyses require appropriate context (Husereau et al., 2013). When applicable, study findings and recommendations should incorporate (1) how the findings or policy recommendations may impact all relevant stakeholders (e.g., patients, caregivers and society); (2) the costs, outcomes, and cost relative to the benefits that are important to the relevant stakeholders; (3) how the study's findings are supported by its results; (4) the study's limitations and uncertainty; and (5) the potential tradeoffs between cost savings and the delivery of care, the impact on downstream population health, and other relevant outcomes.

How to Use This Guiding Principle

Conclusions and policy recommendations in the appropriate context will satisfy the following requirements: (1) The study analyzes and clearly states the impact of changes for all relevant stakeholders; (2) the impact analysis includes the costs, outcomes, and cost relative to the benefit measures that are important to the relevant stakeholders; (3) the study's results justify the conclusions and policy recommendations; (4) the conclusions and policy recommendations appropriately consider the study's limitations and uncertainty; and (5) the study clearly states both short- and long-term potential tradeoffs between cost savings and impacts. The study should consider impacts on the delivery of care, downstream population health and other relevant patient outcomes.

Illustrative Example

In a study based on the Medical Expenditure Panel Survey and Global Burden of Disease databases, Wamble and colleagues assessed changes in aggregate annual health care spending across conditions with high mortality and morbidity rates between 1996 and 2015 (Wamble et al., 2019). To better understand the outcomes associated with changes in aggregate health care spending across conditions evaluated, the authors estimated the changes in aggregate annual disability-adjusted life-years (DALYs) lost for each condition and the prevalence of each condition during this period. As presented in Table 3, some of the increase in aggregate spending may be explained by the increased prevalence of the condition, the improved outcomes and inflation between 1996 and 2015. For instance, although the total spending for HIV/AIDS more than tripled between 1996 and 2015 when unadjusted for inflation, per-person annual spending adjusted for inflation using the Consumer Price Index for All Urban Consumers actually decreased, because the number of people living with HIV/AIDS more than doubled. Furthermore, the DALYs lost were reduced by more than sixfold because of the availability of improved treatment regimens that lowered death rates and decreased morbidity.

Table 3. Per-Patient Annual Health Spending Over 20 Years for Select Conditions

Year	Breast Cancer	Lung Cancer	Cerebrovascular Disease	COPD	Diabetes	HIV/AIDS	Ischemic Heart Disease
Total annual aggregate spending (in billions), unadjusted for inflation							
1996	\$1.93	\$5.57	\$9.55	\$7.72	\$10.33	\$2.48	\$20.97
2015	\$12.56	\$6.92	\$21.14	\$20.46	\$66.45	\$7.95	\$52.08
Aggregate annual disability-adjusted life-years lost (in millions)							
1995	1.18	3.30	2.34	2.24	2.60	2.21	8.89
2015	1.30	3.53	2.24	3.03	3.94	0.36	7.79
Number of people living with the condition in each year							
1996	679,522	323,556	2,381,383	15,403,441	9,704,312	227,358	3,626,991
2015	2,680,767	455,305	4,354,596	15,615,194	27,700,589	498,849	13,847,877
Total per-patient annual spending, adjusted for inflation using the CPI-U							
1996	\$4,342	\$26,318	\$6,134	\$767	\$1,629	\$16,716	\$8,845
2015	\$4,744	\$15,379	\$4,916	\$1,327	\$2,429	\$16,129	\$3,809

COPD = chronic obstructive pulmonary disease; CPI-U = Consumer Price Index for All Urban Consumers;

HIV = human immunodeficiency virus

Source: Wamble et al. (2019)

The following (Assessment 8) summarizes whether the above study placed conclusions and policy recommendations in the appropriate context.

Assessment 8. Evaluation of the Wamble Study (Wamble et al., 2019)

#	Criteria	Evaluation
1	Did the study analyze and clearly state the impact of changes for all relevant stakeholders?	The study analyzed the relationship between health care spending increases and improvements in health. Results were for the entire U.S. population (vs. reporting separate estimates of spending for patients, public payers and private payers). The analysis did not include subpopulations.
2	Did the impact analysis include the costs, outcomes, and cost relative to the benefit measures that are important to the relevant stakeholders?	The study considered both costs and benefits. The analysis used annual changes in total costs of care per patient as the cost measure. In parallel, yearly changes in DALYs per patient were the mortality and morbidity measure. The study did not include direct costs (e.g., OOP) to the patient.
3	Did the study's results justify the conclusions and policy recommendations?	The study had three policy implications: First, focusing on cost alone may lead to bad policies. This conclusion is justified, since the data show that increasing costs can be a source of value. Second, the study states that increased costs can be a source of high value in some conditions. The study found that increased costs were a source of high value for several of the diseases analyzed. The third conclusion is that the value of cost increases varies; therefore, policies should protect high-value creation and reduce low-value creation at the disease level. The varying results by disease support the need for this type of approach, but the authors do not consider implementation barriers to this approach.

Assessment 8. Evaluation of the Wamble Study (Wamble et al., 2019), *continued*

#	Criteria	Evaluation
4	Did the conclusions and policy recommendations appropriately consider the study's limitations and uncertainty?	The authors noted that the critical limitation of the study was that the base-case analysis assumed all improvements in population health outcomes were due to medical interventions. The authors recognized that the improved health outcomes could be attributable to public health factors and improved medical treatment. The authors explored the impacts of different allocations of health improvements between public health changes and medical care improvement. The sensitivity analysis did not alter the study conclusions. The authors also discussed several database-specific limitations, which may affect the generalizability of the results.
5	Did the study clearly state both short- and long-term potential tradeoffs between cost savings and impacts? Did the study consider effects on the delivery of care, downstream population health and other relevant patient outcomes?	The policy implications considered the tradeoffs between cost containment and population health. The study did not consider the potential tradeoffs of using cost savings for other high-value investments. Impacts on the delivery of care were not applicable here.

2.0 Patient-Centered Guiding Principles for Reforming Health Care to Address Rising Health Care Spending

Policies reforming health care to address rising spending should:



2.1 Be designed to achieve the intention of the Triple Aim framework of health care improvement.



2.2 Be rooted in patient-centered value.



2.3 Recognize the differing needs of a diverse U.S. population.



2.4 Preserve or improve short- and long-term patient-centered outcomes.



2.5 Address the burden associated with financing care and the resultant distributional consequences.



2.6 Target significant sources of inefficient health care spending across health care settings, services provided and differing conditions.



2.7 Discourage the use of low-value care and encourage the use of high-value care.



2.8 Address factors driving overall health care demand, including behavioral, cultural and socioeconomic factors.



2.9 Address misaligned incentives that distort utilization and price.



2.10 Incentivize innovations that improve patient-centered outcomes in health care delivery systems and treatments.

Health care spending policy is defined, for this document, as health system or health plan policies that attempt to control or redistribute health care spending at a level above the individual service or treatment level. Examples of health care spending policy include, but are not limited to, changes in reimbursement approaches (e.g., alternative payment approaches, greater use of budget caps), benefit design (e.g., greater use of high deductible health plans, tax deductions for health insurance premiums), and coverage policies (e.g., exclusion of low-value care services, narrow networks of providers), as well as structural changes to the health system (e.g., elimination of drug rebates, price capitation). Patient-centered health care spending policy should seek to both improve health care spending efficiency and maximize patient health.

These principles have two goals: (1) Establish patient-centered principles to guide reforms addressing rising health care spending and 2) provide a set of standards to evaluate individual health policies against the goals of patient-centered care. While these principles are intended to evaluate health care policy reforms prospectively, the examples included here are retrospective for illustration.



2.1 Policies reforming health care to address rising spending should be designed to achieve the intention of the Triple Aim framework of health care improvement (Bisognano et al., 2012)

Supporting Detail

As stated in the Triple Aim framework developed by the Institute for Healthcare Improvement (IHI), “in order to optimize the performance of the U.S. health care system, a policy needs to be designed to pursue the following aims simultaneously: (1) improving the patient experience of care (including quality and satisfaction), (2) improving the health of populations and (3) reducing per-capita costs of health care” (Bisognano et al., 2012). Overall reform efforts should focus on all three prongs of the Triple Aim framework, while the goals of individual policies may focus on a subset. However, reduced per-capita costs should not be achieved at the expense of the patient experience or population health. Furthermore, the goal of reducing per-capita costs of health care should not prevent the adoption of high-value care that increases costs.

Furthermore, the IHI stated that “the Triple Aim will not be achieved until it is achieved for all” (Wyatt et al., 2016). Thus, policymakers should design health care spending policies that achieve all three aims for all people. Specifically, these policies should improve quality of care and health outcomes for those groups of individuals historically linked to discrimination or exclusion such as racial and ethnic minorities, religious minorities, populations based on gender and sexual orientation, people with mental and physical disabilities, and the socioeconomically disadvantaged.

How to Use This Guiding Principle

The goal of any policy reform framework and every specific policy to moderate health care spending should be consistent with that of the Triple Aim framework. Reviewers should assess the following three potential policy impacts: (1) patient experience of care, (2) population health and (3) per-capita costs. Policies should not advance cost reductions at the expense of patient experience of care and population health. In addition, per guiding principle 2.7, health spending policies should not prevent the adoption of high-value patient care that increases costs.

Illustrative Example

The Delivery System Reform Incentive Payment (DSRIP) program in Texas is a Medicaid waiver program that began in 2011. Underpinning the DSRIP are the Triple Aim framework goals of improving population health, enhancing the patient care experience and reducing costs within the Medicaid and low-income uninsured (MLIU) population in Texas. Under the first waiver, DSRIP 1.0 (2011-2017),

the participating providers, led by a regional coordinator, carried out a regional health care needs assessment focused on unmet needs within the MLIU population. Based on the review, providers selected from the state menu of infrastructure and service redesign projects that addressed one or more regional needs. Providers were paid to design and implement innovative projects and achieve health outcome improvements in patients served by these projects.

The second waiver, DSRIP 2.0, which began in October 2017, maintained the regional health care partnerships structure. However, it required providers to define their populations at the broader system level (e.g., all patients served by the major components of a provider's health system vs. patients served by specific projects).

Revere and colleagues conducted an evaluation of DSRIP 1.0 and 2.0 by mapping the significant features of the program and the Triple Aim framework objectives.

The Revere study noted that there was a substantial increase, at a general level, in the effectiveness of care and patient-centered care metrics under DSRIP 1.0. Although there were continued increases seen in performance metrics under DSRIP 2.0, the change to a broader system-level focus under DSRIP 2.0 and the resultant expansion of the MLIU study population resulted in a flattening in the trajectory of improvement when compared to the metrics seen in DSRIP 1.0.

Contrarily, some metrics worsened over the one-year DSRIP 2.0 measurement period. For example, the latent tuberculosis infection treatment rate declined by 27%, and controlling for high blood pressure decreased by 7%. Furthermore, when using utilization as a proxy for costs, it was unclear whether DSRIP reduced costs. Between the baseline year and performance year three in DSRIP 1.0, the authors observed a reduction in 30-day hospital re-admissions for most causes and emergency department (ED) visits for behavioral health and substance abuse. However, the other utilization measures, including mental health admissions and re-admissions and ED visits for diabetes, showed increased utilization. In DSRIP 2.0, only two measures (risk-adjusted congestive heart failure 30-day re-admissions and risk-adjusted all-cause re-admissions) showed improved utilization. The remaining utilization metrics (i.e., ED visits for behavioral health and substance abuse, behavioral health and/or substance abuse 30-day re-admissions, mental health admissions, and ED visits for diabetes) showed an increase rather than an expected decrease in utilization (Revere et al., 2020).

The following (Assessment 9) evaluates whether the Texas DSRIP program meets the intention of the Triple Aim framework.

Assessment 9. Evaluation of the Texas DSRIP Program (Revere et al., 2020)

#	Criteria	Evaluation
1	<p>Was the policy designed to achieve the intention of the Triple Aim framework?</p> <p>Evaluate the program's success in:</p> <ol style="list-style-type: none">1. Improvement in patient care experience2. Improvement in population health3. Reduction of costs of health care	<p>This program was designed from the outset to achieve the intention of the Triple Aim. In their evaluation of the Texas Medicaid waiver program from 2011 through 2018, Revere and colleagues (2020) found the program to have shown positive, measurable results across two of three objectives (i.e., improvement in population health and enhancing the patient care experience) for the MLIU population in Texas.</p> <p>When using utilization as a proxy for cost, DSRIP 2.0 increased health care resource utilization.</p>



2.2 Policies reforming health care to address rising spending should be rooted in patient-centered value (Institute of Medicine, 2011)

Supporting Detail

Policymakers should design the health care system to maximize the value per dollar spent on the patient. The Institute of Medicine defines patient-centered care as “providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions” (Institute of Medicine, 2011). Patient-centered care involves all aspects of the health care system, from assessing value and determining coverage policies to care delivery. Health care reform should encourage the adoption of patient-centered care.

How to Use This Guiding Principle

Every policy reform initiative to moderate health care spending should be rooted in patient-centered value. For instance, patient-centered reforms should involve listening to patients and their family members and/or caregivers to define successful outcomes from the perspective of patients. Reviewers should evaluate policies to determine the extent that they move the system closer to or further away from a patient-centered health care system. For example, reviewers should examine the potential effects of implementing the policy on patients’ and caregivers’ health, out-of-pocket medical and nonmedical spending, and the patients’ and caregivers’ abilities to work or study.

Illustrative Example

The American College of Physicians defines Patient-Centered Medical Home (PCMH) as “a care delivery model where treatment is coordinated through their primary care physician to ensure they receive the necessary care when and where they need it, in a manner they can understand” (American College of Physicians, 2021). Centralized coordination that facilitates partnerships among patients, physicians and patients’ families may help with early diagnosis and treatment of comorbidities and potentially reduce the costs of uncoordinated care, such as duplicative procedures.

Crits-Christoph and colleagues (2018) examined how Pennsylvania’s Chronic Care Initiative (CCI), a statewide PCMH initiative implemented from 2008 to 2011, affected health care utilization and costs among HIV-positive Medicaid patients with comorbidities. The study compared health care utilization associated with patients treated in CCI practices and elsewhere using a claims database.

Crits-Cristoph and colleagues found that the CCI group experienced a statistically significant reduction in inpatient services, whereas the non-CCI group had increased inpatient claims. On the other hand, the study found an increase in outpatient care and pharmacy utilization for CCI patients compared with non-CCI patients (increase of 11.7% and 8.0% in the average number of claims per month, respectively).

The following (Assessment 10) evaluates whether the CCI program in Pennsylvania is grounded in patient-centered care.

Assessment 10. Evaluation of the CCI Program in Pennsylvania (Crits-Christoph et al., 2018)

#	Criteria	Evaluation
1	Did the policy positively impact short- and long-term patient health (including caregiver impact)?	The authors found that the CCI program positively impacted short-term patient health. Specifically, patients in the CCI group experienced a significant reduction in inpatient services. They concluded that the CCI intervention appeared to shift inpatient costs and utilization to outpatient care and use of non-HIV medications. The impact on long-term outcomes was not clear.
2	Did the policy enable care that is respectful of and responsive to individual patient preferences, needs and values, including: <ul style="list-style-type: none">• Defining value (including successful outcomes) from the patient perspective?• Ensuring that patient values guide all clinical decisions?	The goal of the PMCH is to ensure patients receive the necessary care when and where they need it in a manner they can understand. The extent that Pennsylvania’s CCI program provided this care in a patient-centered manner is not clear.
3	How did the policy impact patient access to care, including nonmedical spending?	The goal of the PMCH is to ensure that patients receive necessary care where and when they need it. Patient outcomes improved, suggesting positive impacts on access to care.



2.3 Policies reforming health care to address rising spending should recognize the differing needs of a diverse U.S. population (The National Health Council, 2019)

Supporting Detail

The U.S. health care system treats a diverse set of patients, differing in multiple ways – from their underlying biology and associated treatment response (heterogeneity of treatment effect) to their preferences and priorities (The National Health Council, 2019). Heterogeneity of treatment effect (e.g., efficacy and adverse events) can occur in members of the same family and across ethnic or socioeconomic groups. Similarly, differences in preferences and priorities (e.g., for survival or quality of life) may be observed among patients and providers and between provider and patient. Health care reform initiatives should respect and support the disparate needs of a diverse population.

How to Use This Guiding Principle

Reviewers should evaluate each policy to determine how it supports the needs of a diverse U.S. population. Not every individual policy can address the diverse needs of the U.S. population. However, health care spending policy should include targeted approaches to address the unique needs of specific populations. If reform does not support the needs of a particular population, a strategy to mitigate the consequence to this population should be explored. At a minimum, policies should not reduce the capacity to support these varied needs.

Illustrative Example

Note: This example is not a commentary on the expansion of Medicare; instead, it uses the following expansion analysis of Medicare's ability to meet the needs of a diverse population as an example of how to evaluate a policy.

Medicare is the largest purchaser of health care in the United States, serving millions of Americans with disabilities and those over age 65. Landers and colleagues analyzed the role of Medicare in increasing access to care for racial and ethnic minorities and decreasing inequality in health coverage over a period from when the program began in 1966 (Landers et al., 2020).

In this analysis, Landers and colleagues (2020) noted that research has shown disparities in access to quality care for insured minorities within the Medicare program remain today. For instance, among Medicare beneficiaries, Landers found that those older and from racial and ethnic minority backgrounds report worse health indicators and receive a lower quality of care than white Medicare beneficiaries. Within Medicare Advantage plans, a recent study found that racial and ethnic minority beneficiaries' ratings of their experiences with the health care system and health care access were worse than or equal to the ratings reported by white beneficiaries.

Further, Medicare contains noncapped, OOP deductibles and coinsurance, as well as coverage gaps for dental, vision and long-term services and supports. People of color are less likely to have supplemental coverage for these gaps. Given such disparity among the Medicare population, the authors stressed that any novel program should address other causes of health disparities such as housing availability, neighborhood conditions, food insecurity and educational opportunities. In addition, the novel program should consider other measures of inequality such as diversity and inclusion training for health care professionals and investments that could diversify the supply of clinicians (Landers et al., 2020).

The authors noted that the Affordable Care Act contains requirements for collecting health care data for minority populations in federally supported health care programs, which the authors believed was key to reducing disparities.

The following (Assessment 11) evaluates how Medicare program expansion meets the needs of a diverse U.S. population.

Assessment 11. Evaluation of the U.S. Medicare Program and Expansion Proposal (Landers et al., 2020)

#	Criteria	Evaluation
1	Did the policy have a non-uniform impact on health outcomes across the population?	Landers and colleagues found that disparities in access to quality care for insured minorities within the Medicare program remain. For instance, among Medicare beneficiaries, those who are older and are from racial and ethnic minority backgrounds report worse health indicators and receive a lower quality of care than white Medicare beneficiaries.
2	Did the policy enable care that is respectful of and responsive to diverse patient preferences, needs and values?	The study did not evaluate how well the Medicare program meets diverse needs but did suggest potential areas that could, including housing availability, neighborhood conditions, food insecurity and educational opportunities.
3	How did the policy impact patient access to care? Were some patient populations disadvantaged compared to others?	Patient financial burden and access were not uniform across patient populations. Medicare contains noncapped, OOP deductibles and coinsurance, as well as coverage gaps for dental, vision and long-term services and supports. People of color are less likely to have supplemental coverage for these gaps.
4	Did the policy reduce the capacity to support varied patient needs?	Not applicable.



2.4 Policies reforming health care to address rising spending should preserve or improve short- and long-term patient outcomes (National Quality Forum, 2009)

Supporting Detail

Health care reform approaches developed without consideration of their impact on short- and long-term outcomes or benefits for different patients can lead to worse patient outcomes. Understanding potential changes in both short- and long-term patient outcomes requires evaluating how reform might affect care over the natural trajectory of different clinical conditions (National Quality Forum, 2009). Such considerations will better assess a patient's remaining lifetime health status and health care costs. As defined by the National Quality Forum (2009), this natural trajectory runs from prevention in the at-risk population to evaluation, initial management and follow-up care. Health care reform should create cost savings by modifying patient care in a manner that preserves or improves both short- and long-term outcomes.

How to Use This Guiding Principle

Aligned with the goal of the Triple Aim framework discussed in guiding principle 2.1, policy reform should sustain or improve the patient experience and the population outcomes in an extended timeline. At a minimum, no patient-centered health care reform framework or specific health policy should negatively impact outcomes to reduce spending. In 2009, the National Quality Forum presented the patient-centered framework for evaluating the efficiency of the U.S. health care system. This framework provides a helpful construct for assessing the impact of policy on outcomes. Leveraging this framework, reviewers should evaluate policy impact on outcomes throughout the entire life cycle of health care. This evaluation includes: 1) preventing events in the at-risk population; 2) providing evaluation and initial management during the acute phase; 3) providing follow-up care during the recovery and stabilization phase, including the strategy to manage disability; and 4) preventing the next episode. This framework aims to incorporate all care required to restore patients' long-term quality of life and functional status. The framework demonstrates the relationships between preventive care, treatment for the acute event and long-term follow-up care (National Quality Forum, 2009).

Illustrative Example

In 2011, the Centers for Medicare and Medicaid Services (CMS) introduced Bundled Payments for Care Improvement (BPCI) to reduce the total cost of an episode of care while maintaining or improving the quality of care. The BPCI sought to minimize costs by bundling together payments based on historical Medicare billing for hospital and post-hospital care. Participants chose from three payment models, 48 clinical episodes, three episode lengths and three risk tracks.

Bundled payments may lead to unintended consequences, like underutilization for the sickest patients, later exacerbating the condition. So, while a bundled payment model may achieve positive short-term results in terms of cost, it may also produce adverse outcomes in the long term (e.g., increase in re-admissions) (LaPointe, 2020; Hardin et al., 2017).

CMS published the final BPCI evaluation for the entire five-year performance period of the initiative, from October 2013 through September 2018. The assessment includes Medicare claims-based impact estimates for key outcomes for Models 2, 3 and 4 and estimated savings to the Medicare program over the entire five years of the initiative (The Lewin Group, 2021).

“Consistent with previous reports, BPCI participants responded to the initiative’s incentives by reducing Medicare FFS payments. We continue to see this result from general patterns of reduced utilization and intensity of Post-Acute Care (PAC) use, with reductions in institutional care and decreases in the number of Skilled Nursing Facility (SNF) days among patients who receive SNF care. This decline did not translate into overall savings to Medicare after taking into account reconciliation payments made to participants. There are few indications in claims-based results that BPCI affected quality of care. However, three out of the 11 Model 3 SNF clinical episodes analyzed had an increase in readmissions, E.D. use, or mortality, potentially indicating a decrease in quality. However, these three clinical episodes suffer from small sample sizes, both overall and per SNF, making it difficult to ascertain whether these results are a signal or simply noise.

This final report shows differences in findings between surgical and medical clinical episodes. Under Model 2 hospitals, relative declines in total payments and payments for SNF, inpatient rehabilitation facility (IRF), and readmissions were similar for surgical and medical clinical

episodes. Under Model 2 Physician Group Practices (PGP)s, relative declines in total payments, as well as SNF, IRF and HHA payments, were larger for surgical clinical episodes than medical clinical episodes. With respect to the effect of BPCI on quality of care as measured by readmissions, E.D. use, and mortality, there were no changes for Model 2 hospital-initiated episodes, and while there were a few indications of change for Model 2 PGP-initiated episodes, the direction was not consistent.

Results in the Year 5 Evaluation & Monitoring Annual Report also indicated that changes in functional status did not differ between beneficiaries in BPCI episodes and comparison beneficiaries, based on survey results, although fewer BPCI beneficiary respondents reported the highest level of satisfaction with their care. Quality of care was also maintained among vulnerable populations, including populations dually eligible for Medicare and Medicaid, with dementia, or with recent institutional PAC use (The Lewin Group, 2021)."

The following (Assessment 12) evaluates how BPCI impacted short- and long-term patient outcomes.

Assessment 12. Evaluation of the Bundled Payments for Care Improvement (The Lewin Group, 2021)

#	Criteria	Evaluation
1	What impact does the policy have on short-term patient outcomes? Relevant short-term outcomes include prevention, initial evaluation and treatment, and follow-up care.	There are few indications in claims-based results that BPCI affected quality of care. The instances of outcome changes were likely due to the small sample size. In addition, functional status was unchanged when compared to the status group. However, fewer beneficiaries report the highest level of satisfaction with care under the BCPI program.
2	What impact does the policy have on long-term patient outcomes? Long-term outcomes include the ability of care to restore patients' long-term quality of life and functional status.	The study did not report impacts on long-term outcomes.



2.5 Policies reforming health care to address rising spending should address the burden associated with the financing of health care and the resultant distributional consequences (Baicker, 2019)

Supporting Detail

Increasing total health care spending will require additional funding via higher premiums, higher patient out-of-pocket (OOP) costs, increased tax burden, and/or government funding diverted from other public services such as education and infrastructure. In some instances, these spending increases may be justified by the value of the care provided or be offset by increases in other areas of the economy; in other instances, this is not true. When the value of care is not high, and other gains do not offset spending increases, rising premiums and high patient OOP costs (in the form of high-deductible health plans, coinsurance and high max OOP caps) often result in consumers and patients losing insurance or being underinsured. Increasing taxes or shifting funding from other public services has consequences for the broader public and the economy. These effects are often not uniformly experienced within and outside the health system; instead, the consequences of these resultant distributional effects are often disproportionately worse for patients with lower socioeconomic status, thus creating significant disparities (Baicker, 2019).

How to Use This Guiding Principle

Individual policies to improve health outcomes may result in unintended negative consequences, such as increased disparities and reduced public services, due to health care spending changes. Therefore, reviewers should evaluate the distributional impacts, such as disparities and broader economic burden, resulting from proposed health care spending changes. This examination should identify potential sources of increased disparities, including higher premiums, higher patient OOP costs, increased tax burden, or government funding diverted from other public services such as education and infrastructure.

Illustrative Example

California's laws and regulations create an effective budget cap for public expenditures. To assess the consequences of this public expenditure budget cap on individuals relying on public spending, Tran et al. (2017) used 25 years of General Fund expenditure data from California to estimate the effects of rapidly increasing health care spending on nonmedical social spending for tobacco control activities, restoring and expanding the number of high school counselors, and increasing the number of state preschool slots.

The authors found that while health care spending for Medicaid and other medical benefits increased over the 25 years from 14.1% to 21.3% of the General Fund expenditure, spending on public health and social programs fell from 34.8% in fiscal year 1990 to 21.4% in fiscal year 2014. The health care spending increase was associated with a 5.3-year gain in life expectancy between 1985 and 2010 in California, compared with an average improvement in the U.S. of 3.9 years during the same period. However, the authors suggested that reallocating ineffective medical care spending (assumed to be 21% of medical care spending) to cost-effective nonmedical social spending could have either prevented 10,500 premature deaths annually or helped an additional 418,000 high school students to graduate. The authors recognized that reallocation from inefficient care to nonmedical social spending interventions would not be simple to implement. Consequently, any estimates of the benefits from nonmedical social spending were subject to uncertainty.

The following (Assessment 13) evaluates the distributional consequences resulting from the interaction between California's effective budget cap on public spending and increasing health care spending.

Assessment 13. Evaluation of California Budget Cap for Public Expenditures and Rising Health Spending (Tran et al., 2017)

#	Criteria	Evaluation
1	Does the policy create higher premiums, higher patient OOP costs (in the form of high-deductible health plans, coinsurance, high max OOP caps), increased tax burden, or divert government funding from other public services?	Tran et al. (2017) stated that California's laws and regulations create an effective budget cap on public spending, which led to decreased nonmedical social spending because of increased spending on Medicaid and other medical expenditures.
2	Does the proposed policy have positive or negative consequences for the broader public and economy? This evaluation includes the worsening of disparities.	Tran et al. (2017) estimated that 21% of increased health care spending was on ineffective care. The combination of the increased health spending and budget cap prevented this 21% from being spent on other public services. The authors estimate that these funds could have either prevented 10,500 premature deaths annually or helped an additional 418,000 high school students graduate.



2.6 Policies reforming health care to address rising spending should target significant sources of inefficient health care spending across health care settings, services provided and differing conditions (VBID Health, 2017)

Supporting Detail

An efficient health care system can appropriately assess and reduce opportunity costs, which are defined as the loss in patient health outcomes attributable to spending on wasteful, inefficient and low-value care that reduces the funds available for high-value care. Analysis has shown that opportunity costs exist throughout the entire U.S. health care system (VBID Health, 2017). Therefore, improving the value of health care spending requires understanding significant sources of inefficiency across settings of care (outpatient and inpatient), services (procedures, drugs, diagnostics, devices, screenings), and stakeholder types (patients, payers, providers, manufacturers) (Cylus et al., 2016).

How to Use This Guiding Principle

Overall, health care reform approaches should focus on identifying and eliminating significant sources of inefficient care across the entire health system. However, no single policy will target all important sources of inefficient care; instead, individual policies should improve or, at a minimum, maintain the current efficiency level. Therefore, reviewers should evaluate individual policies to determine whether they improve or, at a minimum, maintain the current efficiency level.

Illustrative Example

The Choosing Wisely campaign is a nationwide initiative by the American Board of Internal Medicine Foundation to promote conversations between physicians and patients to make intelligent, effective health care choices that lead to high-quality care. The Washington State Alliance conducted a campaign in support of this initiative in Washington state. The campaign was developed using a Milliman MedInsight Health Waste Calculator™ analysis of the All-Payer Database in Washington state from January 1, 2014, to December 31, 2017. The analysis examined 47 of 48 of the calculator measures of tests, procedures and treatments known to be overused in both the commercially insured and Medicaid populations. On average, 846,973 individuals received services each year that were considered to be low value. The net result was \$703 million spent on low-value care over the four years. Almost all of the wasted expenditure was driven by 11 of 47 low-value care practices identified.

Results of the analysis were made available to key stakeholders throughout the state as part of its Choosing Wisely campaign. In addition, the Washington Health Initiative proposed several actions to reduce this wasteful spending on both the demand side and the supply side of care. For example, officials recommended that clinicians “incorporate the reduction of overuse into local practice culture.” The result was a 10% decrease in low-value care in the commercially insured population and a 24% decrease in the Medicaid population (Washington Health Initiative, 2019).

The following (Assessment 14) summarizes how the study reviewed sources of inefficient health care spending.

Assessment 14. Evaluation of Washington State’s Choosing Wisely Campaign (Washington Health Initiative, 2019)

#	Criteria	Evaluation
1	Does the policy improve or, at a minimum, maintain the current efficiency?	During the Choosing Wisely campaign, Washington state experienced a 10% and 24% decline in the use of low-value care in the commercially insured and Medicaid populations, respectively, over four years of reported data.
2	Is the policy part of a broader reform effort to address significant sources of inefficient care practices across conditions, services and stakeholder types?	The Washington Health Initiative focused on the use of low-value services across 47 care practices and conditions identified in the Choosing Wisely initiative. The focus of this effort spanned tests, procedures and medications. In addition, the effort spanned settings of care from inpatient to important ambulatory settings.



2.7 Policies reforming health care to address rising spending should discourage the use of low-value care and encourage the use of high-value care (VBID Health, 2017)

Supporting Detail

The value delivered by the health care system is not uniform across interventions, diseases or populations. This variation exists for many reasons, such as different outcomes associated with different interventions for different populations; different condition characteristics by population, like disease severity; the level of disease-specific treatment innovation; the level of access to treatments; and other factors. Patient care is considered low value when it is wasteful, inefficient or the benefits don't justify the costs or risks. Conversely, high-value care is when the benefits are high relative to the costs and risks. Health care reforms should recognize this inherent variation and seek to encourage the use of high-value treatments and discourage the use of low-value treatments (VBID Health, 2017).

How to Use This Guiding Principle

The health care system should be designed to spend dollars to maximize value for the patient. Therefore, health care reform initiatives should incorporate incentives, such as coverage policies and patient out-of-pocket costs, that encourage high-value care and discourage low-value care (Institute of Medicine, 2010). Reviewers should evaluate each new policy to determine whether it encourages high-value care or discourages low-value care. At a minimum, new policies should not discourage high-value care or incentivize low-value care.

Illustrative Example

Value-based insurance design (VBID) is a demand-side approach to health policy reform, aiming to increase health care quality and decrease costs by using financial incentives that promote cost-efficient health care services and consumer choices. Richardson and colleagues (2019) examined the VBID-X benefit model in a health care plan designed to bring the VBID model to the consumer insurance and exchange market by reducing or eliminating cost-sharing for a select set of high-value drugs and services, such as low-density lipoprotein testing, and increasing cost-sharing for low-value drugs and services, such as high-cost imaging (Richardson et al., 2017). Reductions in cost-sharing for high-value services varied. The cost-sharing for low-value care services was increased to offset reduced high-value service cost-sharing.

The targeted approach aims to avoid increases in premiums and deductibles while staying cost-neutral; the authors cited a recent survey conducted by the Kaiser Family Foundation reporting that 75% of individuals with chronic conditions and high deductibles skipped or delayed care. The authors concluded that VBID-X designs explicitly recognize the possibility of increasing accessibility to services deemed to improve patient-centered outcomes without increasing total health care costs.

The following (Assessment 15) summarizes how the policy achieved discouraging use of low-value treatments and encouraging use of high-value treatments.

Assessment 15. Evaluation of the VBID-X Benefit Model Design (Richardson et al., 2019)

#	Criteria	Evaluation
1	Did the policy encourage the use of high-value care and discourage the use of low-value care to maximize value? If not, did the policy remain neutral with regard to low- and high-value services?	The VBID-X program was modeled to incentivize patients to shift their use of low-value services to high-value services and medications. The program achieves this goal by reducing copays and cost-sharing for high-value care and vice versa for low-value care. As a result, VBID-X remains cost-neutral while improving patient-centered outcomes.



2.8 Policies reforming health care to address rising spending should address factors driving overall health care demand, including behavioral, cultural and socioeconomic factors (Adler and Prather, 2015; Artiga and Hinton, 2018)

Supporting Detail

Beyond a patient's underlying biology, factors that drive demand for health care services include behavioral (e.g., smoking, diet), cultural (e.g., diet, views toward health system) and social determinants of health (Adler and Prather, 2015; Artiga and Hinton, 2018). Per the Centers for Disease Control and Prevention (CDC), "social determinants of health include aspects of the social environment (e.g., discrimination, income, education level, marital status), the physical environment (e.g., place of residence, crowding conditions, built environment [i.e., buildings, spaces, transportation systems, and products that are created or modified by people]), and health services (e.g., access to and quality of care, insurance status)" (CDC, 2010). These effects are often not uniformly experienced within and outside the health system; instead, the consequences of these resultant distributional effects are often disproportionately worse for patients with lower socioeconomic status, thus creating significant disparities (Baicker, 2019). Therefore, health care reform approaches should address the barriers created by these underlying factors to the extent that it is possible to change them.

How to Use This Guiding Principle

State, federal, and commercial initiatives that address rising health care spending should consider behavioral, cultural and socioeconomic factors contributing to higher health care spending. For example, health care reform approaches should include (1) incentives that encourage healthy behaviors linked to reduced health care spending and (2) initiatives to reduce cultural barriers that may prevent patients from accessing high-value care. Overall reform approaches should directly address these critical drivers of health care demand. In addition, when a policy targets a population with significant behavioral, cultural and socioeconomic factors, those factors must be considered. Otherwise, the policy may be less successful.

Illustrative Example

The Affordable Care Act included a federal mandate requiring restaurant chains with more than 20 locations to report the calories of items on their menus or menu boards. This requirement was designed to change eating behaviors that contribute to the high rate of obesity in the U.S. (35% of the population in 2011-2012). There is evidence that overweight individuals have an increased risk for many health conditions, including type 2 diabetes, heart disease, stroke and some cancers. Overweight individuals also have an estimated 42% higher annual cost of medical care than individuals of average weight.

Before this national mandate to report calorie information was implemented, the requirement was introduced in New York City in 2008. Following the New York City requirement, two studies (surveys of awareness and cash register receipts) attempted to determine whether customers at fast-food restaurants were aware of the calorie information and whether this information influenced the number of calories purchased from the restaurant (Elbel et al., 2009; Cantor et al., 2015).

Both studies showed that consumers were aware of the information and claimed to use the information, although awareness and use declined during the interval between the two studies. However, both studies showed that there were no statistically significant changes in levels of calories or nutrients purchased in restaurants displaying calorie information on their menus. In addition, the second study showed that there was no decrease in the frequency of visits to the fast-food chain restaurants with menu labeling. Thus, the authors of the second study concluded that “Menu labeling at fast-food chain restaurants, which the Affordable Care Act requires to be implemented nationwide in 2016, remains an unproven strategy for improving the nutritional quality of consumer food choices at the population level. Additional policy efforts that go beyond labeling and possibly alter labeling to increase its impact must be considered.”

The following (Assessment 16) summarizes how the study addressed factors driving overall health care demand, including behavioral, cultural and socioeconomic factors.

**Assessment 16. Evaluation of the Federal Mandate for Calorie Reporting on
Fast-Food Chain Restaurant Menus (Elbel et al., 2009; Cantor et al., 2015)**

#	Criteria	Evaluation
1	Does the overall reform approach address behavioral, cultural and socioeconomic factors contributing to rising health care spending?	This policy directly attempted to address the behavioral factors behind the U.S. obesity epidemic by requiring that restaurants with more than 20 sites provide caloric information on the menu. While the policy’s intention aligns with this guiding principle, the above study found that caloric information did not result in measurable changes in visits to or choices at fast-food chain restaurants.
2	When the policy is not explicitly focused on behavioral, cultural and socioeconomic factors contributing to rising health care spending, does the policy target a population with significant cultural and socioeconomic factors? If so, how has the policy addressed those considerations?	Not applicable (this policy focused explicitly on behavioral factors).



2.9 Policies reforming health care to address rising spending should address misaligned incentives that distort utilization and price (Peter G. Peterson Foundation, 2020; American College of Physicians, 2009)

Supporting Detail

Misaligned incentives within the U.S. health care system play a key role in driving health care services' utilization and pricing. This effect can be negative by creating and promoting low-value care. Sources of misaligned incentives can include reimbursement policy, competition, regulation, malpractice laws and tax policy (Peter G. Peterson Foundation, 2020; American College of Physicians, 2009).

Examples of these misaligned incentives impacting price and utilization exist throughout the health care system. For example, patients may not receive high-value health care services due to reimbursement policies that restrict provider or site-of-care options. Another example is the tax incentive for selecting generous employment-based health benefits for highly paid individuals, leading to the overconsumption of low-value medical care. In a third example, when various regulations and tax policies influence consolidations in the health care market, limited competition may lead to higher health care prices. Finally, a fragmented health care system may result in inefficient care coordination due to more administrative complexities. Therefore, the overall health care reform approach needs to identify and address the most critical structural deficiencies.

How to Use This Guiding Principle

State, federal or commercial reform initiatives targeting rising health care spending should address misaligned incentives contributing to wasteful spending and higher prices for health care services. Such policies should include active monitoring strategies to identify unintended consequences as they emerge. Misaligned incentives are not expected to be the focus of every individual policy. However, each new policy should be evaluated to determine whether it creates additional price and/or utilization distortions.

Illustrative Example

The Affordable Care Act included a proposal to levy an excise tax on high-cost health insurance plans (known as the Cadillac tax). The aim was to help fund the extended health care coverage under Medicaid expansion and control rising health care costs. A study by Warshawsky and Leahy (2018), using National Compensation Survey data to analyze who would be impacted by this tax, estimated that between 11% and 12% of workers participating in employer-provided health plans in 2020

would be subject to this tax. The authors further estimated that the percentage of workers would rise to approximately 25% by 2025 (Warshawsky and Leahy, 2018). The percentages of workers subject to this tax would vary by worker characteristics (region, number of employees at the company, unionization, industry and occupation). The authors concluded, “Economic theory would predict that employees and employers will substitute away from high premium plans and toward plans with higher deductibles and lower premiums. In addition, firms’ attempts to reduce their overall tax burden should lead to tighter negotiations with providers and, eventually, to more serious engagement by employers, employees, and insurers in managing health plans and reducing costs.” However, the authors did not cite any studies supporting these assumptions (Warshawsky and Leahy, 2018).

The following (Assessment 17) summarizes how the study addressed structural deficiencies that may distort utilization and price.

Assessment 17. Evaluation of the Excise Tax on High-Cost Health Insurance Plans (Warshawsky and Leahy, 2018)

#	Criteria	Evaluation
1	Does the overall reform approach address misaligned incentives contributing to wasteful spending and higher prices for health care services?	The Cadillac tax was intended to address the structural distortions resulting from the tax subsidization of high-cost employer health plans. Warshawsky and Leahy (2018) estimated that 25% of employees would be impacted by 2025. The authors speculate that the increased tax pressure would drive employers and employees to lower-cost plans with higher deductibles.
2	Does the reform approach include active monitoring of potential impacts?	Not applicable (the policy was repealed and never implemented).
3	When the policy is not targeting misaligned incentives, does the policy introduce new utilization or price distortions?	If implemented, the Cadillac tax may have harmed patients with employer plans by accelerating the market trend of increasing deductibles and out-of-pocket costs (Dorn, 2019).



2.10 Policies reforming health care to address rising spending should incentivize innovations in health care delivery systems and treatments (Institute of Medicine, 2013; McClellan et al., 2017)

Supporting Detail

Continuing innovations in health care delivery systems and treatments are critical to address inefficiencies in the current system and improve patient outcomes in many acute and chronic diseases. Health care spending policies should provide incentives to payers, providers and developers to improve system efficiency or provide high-value care that improves patient health outcomes. Where possible, such policies should avoid creating disincentives (Institute of Medicine, 2013).

How to Use This Guiding Principle

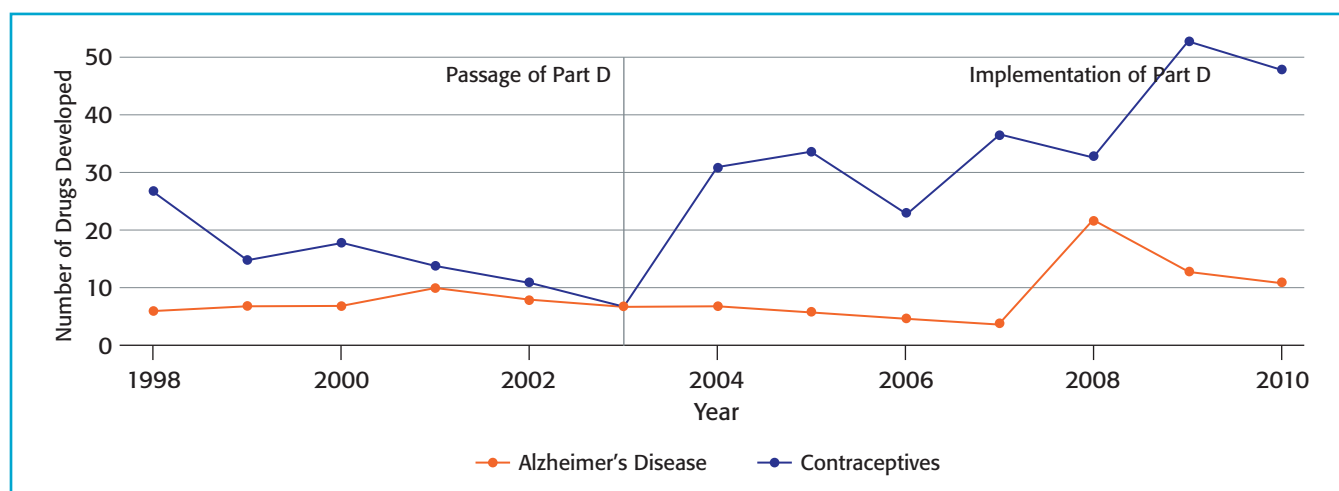
Policy reforms to moderate health care spending should consider the potential consequences of the overall initiative on innovations in health care delivery systems and treatments. As such, reviewers should evaluate policies for impacts on innovation incentives and potential consequences for patients.

Illustrative Example

The medicare prescription drug benefit (Medicare Part D) is an optional federal program covering self-administered prescription drugs among Medicare beneficiaries. The program was implemented in 2006 and was followed by an increase in self-administered prescription drugs among seniors. Blume-Kohout and Sood (2013) assessed the positive impact of Medicare Part D on pharmaceutical research and development by using time-series data on the number of drugs entering preclinical and clinical development, categorized by therapeutic class and phase. The authors found that the passage and implementation of Medicare Part D was associated with significant increases in pharmaceutical research and development activities for therapeutic classes with higher Medicare market shares.

Figure 1 presents a comparison of the research and development activities for drugs developed between 1998 and 2010 for treatments for Alzheimer's disease compared to drugs developed in the same period for hormonal contraception (Blume-Kohout and Sood, 2013).

Figure 1. Numbers of Drugs Developed for Treatment of Alzheimer's Disease Compared to Hormonal Contraceptives Before and After Implementation of Medicare Part D



Source: Blume-Kohout and Sood (2013).

The following (Assessment 18) summarizes how this example addressed the reward for long-term innovation in health care delivery systems and treatments.

Assessment 18. Evaluation of the Impact of Medicare Part D on Long-Term Innovations and Population Health Outcomes (Blume-Kohout and Sood, 2013)

#	Criteria	Evaluation
1	Does the policy affect innovations in health care delivery systems and treatments?	Blume-Kohout and Sood (2013) found that the passage and implementation of Medicare Part D was associated with significant increases in pharmaceutical research and development activities for therapeutic classes with higher Medicare market shares. Specifically, the authors found that the number of drugs entering phase 1 trials after the passage of Part D more than doubled for antipsychotic, antidepressant, and gastrointestinal ulcer treatments, even though the success rate for these drugs before phase 3 trials appears to have been low. While the authors found a correlation between passage of Part D and innovation, they did not establish causality.
2	Do the changes in incentives impact population health outcomes?	Blume-Kohout and Sood (2013) did not estimate the impact of Medicare Part D on population health outcomes.

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