Research Prioritization Topic Briefs

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Improving Health Systems

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Contents

Topic 1: Enrollee Support for Patients in High Deductible Health Plans

What types of enrollee support provided by employers, insurers, or health organizations positively impact access to and utilization of health care services and patients' care experience in insurance arrangements with high deductibles?

Criteria	Brief Description
Introduction	
Overview/ definition of topic	• Increasing numbers of payers and employers are offering a higher proportion of plans with significant cost-sharing, especially high deductible health plans (HDHPs).[1,2] • HDHPs are defined by the Internal Revenue Service (2013) as a health plan with an annual deductible not less than $1,250 for self-only coverage or $2,500 for family coverage and with annual out-of-pocket expenses not exceeding $6,250 for self-coverage or $12,500 for family coverage.[3] • When coupled with a health saving account (HSA), these plans are termed to be Consumer Directed Health Plans (CDHP). • The primary rationale for these plans is to reduce costs for health care payers and purchasers including insurers, patients, and employers. • A substantial body of literature, including the RAND Health Insurance Experiment, supports the premise that increased cost exposure for patients can lead to reductions in health care utilization and costs.[4-7] o A key finding was that patients did not differentiate between cutting back on needed or preventive services and unneeded services. • More recent literature specific to high deductible plans indicates that these plans can positively or negatively impact a number of relevant patient outcomes including:[4,8,9] o Reducing the use of health care services, especially specialty services o Reducing the use of branded drugs in favor of generic versions o Reducing overall health care spending o Reducing preventive or high-value care • This brief will focus on the impact of programs to ameliorate the potentially negative effects of high deductible health plans on access, utilization, and patient-centered outcomes (PCOs). • Enrollee support programs may be offered by employers, insurers, or health organizations and take many forms, but they often include the following broad areas: o Information about benefit design: Covered services and costs incurred that count toward their deductible ▪ This information is especially relevant for understanding coverage of

	preventive services, which are typically not subject to deductibles. o Information about quality: Information about provider, clinic, and hospital quality o Information about price: Information about the cost of health care services o Information about treatment options and decision support: Information about the *risks and benefits* of comparative treatments, and their relative value
Relevance to patient-centered outcomes	• While HDHPs are primarily methods to control costs, they may impact access, utilization of health care services, and patient-centered outcomes, including enrollee satisfaction. o Enrollee support programs for patients with HDHPs can affect enrollee behavior and therefore impact the same outcomes.
Burden on Society	
Recent incidence and prevalence in populations and sub-populations	• 58 percent of covered workers in small firms (<200 workers) and 28 percent of workers in large firms (200+ workers) were enrolled in HDHPs (deductible of at least $1,000 in 2013).[2] • 20 percent of covered workers were enrolled in an HDHP with a savings options (also known as a CDHP).[2] • As of July 2014, the number of people with a CDHP rose to nearly 17.4 million (annual growth rate of approximately 15% since 2011).[1] • The gender distribution of lives covered by a CDHP was evenly split. • 52 percent of CDHP enrollees in the individual market were age 40 or over. • States with the highest levels of HSA/HDHP enrollment were: Illinois (1,054,916), Texas (1,042,642), Ohio (802,511), Pennsylvania (691,750), and Michigan (690,932). • Preferred provider organizations (PPOs) were the most popular CDHP product types, representing more than 75 percent of plans. • The average deductible for CDHP enrollees in 2013 was $2,003 ($2,379 for small firms and $1,802 for large firms).[2] • In a member survey by America's Health Insurance Plans (50% response rate), most responding companies reported offering online access to HSA account information, health education and cost information, physician-specific information, and personal health records as consumer decision support tools.[11] o Access to HSA information (e.g., to track spending and view balances): 84 percent o Health education information: 91 percent o Hospital-specific quality data: 70 percent o Physician-specific quality data: 57 percent o Physician-specific information (e.g., hospital affiliation, education): 88 percent o Provider cost information (e.g. rates for procedures and drugs): 66 percent o Personal health records: 75 percent • Many consumers appear to have only limited knowledge about their health benefits, which may limit the intended effects of the increased cost exposure.[12]
Effects on patients' quality of life, productivity, functional capacity,	QUALITY OF LIFE/FUNCTIONAL CAPACITY/MORTALITY • Use of HDHPs can indirectly impact patient outcomes if the increased cost exposure leads to reductions in utilization or access to health care, especially appropriate and needed care.

mortality, and use of health services	o This may be an increased concern for preventive services and vulnerable populations (e.g., people with low income or those with high-cost chronic conditions).[8] • Early reports indicate decreased satisfaction with HDHPs.[4,13] • Evidence about CDHC's effects on quality remains mixed.[4] USE OF HEALTH SERVICES/PRODUCTIVITY • HDHPs have consistently been shown to reduce health care utilization and costs.[4-6,8] • Total health care expenditures from all payment sources (families, employers, and insurers) for families enrolling in CDHPs for the first time was 14 percent less than for similar families enrolled in conventional plans.[8] • It is estimated that a rise in the use of CDHPs from its current level of 15 percent up to 50 percent would result in societal health care savings of $57 billion annually.[8] • Enrollment in CDHPs was associated with moderate reductions (3-5%) in preventive care, despite the fact that these plans waived the deductible for preventive care.[8] • Reed et al. (2012) surveyed people in California who had a CDHP and found: o Fewer than one in five understood that their plan exempted preventive office visits, medical tests, and screenings from their deductible.[14] o Roughly one in five said that they had delayed or avoided a preventive office visit, test, or screening because of cost.[14] • HDHP enrollees with chronic conditions had a higher probability of delayed or foregone care and fewer outpatient visits.[15,16] • Within HDHPs, utilization patterns did not change among women, but men had fewer emergency department visits in the first year and increased hospitalizations in the second year.[17] • Many studies have examined the effect of HDHPs on prescription drug use. Most of these studies showed HDHPs are linked to reductions in medication use and corresponding decreases in medication adherence for chronic diseases including: o Asthma[18,19] o Heart conditions[18] o High cholesterol[38,39] o Diabetes[19] • Common limitation in these studies related to favorable selection into HDHPs, i.e., healthier and less costly enrollees choose HDHPs.[4]
How strongly does the overall societal burden suggest that CER on alternative approaches to this problem should be	FACTORS IN FAVOR • With passage of the Affordable Care Act, methods of payment for health care are changing and incentivizing the use of HDHPs.[8,20] o A 40 percent excise tax will be assessed, beginning in 2018, on the cost of coverage for health plans that exceed a certain annual limit ($10,200 for individual coverage and $27,500 for self and spouse or family coverage).[20] o Mandatory coverage for certain preventive services, e.g., flu shots, mammogram

given high priority?	screenings, osteoporosis screenings. o Premium subsidies and cost-sharing subsidies for low- and middle-income families purchasing insurance through a qualified health insurance exchange.[8] o Transitional state-based reinsurance program for high-cost beneficiaries in the individual market.[8] • Health cost containment remains a high priority for both patients and payers. FACTORS AGAINST • Obtaining strong scientific evidence might be challenging. o For example, researchers are unlikely to conduct randomized control trials to test outcomes associated with various HDHPs. o Selection bias is a known issue, but it is difficult to account for when comparing HDHP versus traditional health plans.[4]
Options for Addressing the Issue	
Based on recent systematic reviews, what is known about the relative benefits and harms of available management options?	BENEFITS • We did not find systematic reviews on the impact of enrollee support programs for patients using HDHPs. • High availability of support tools, although of uncertain quality and effectiveness, coupled with data on the impact of the underlying premise employed by the support tools, can suggest potential impacts of these tools for enrollees in HDHPs. • Benefit design: o Reed et al. (2012) found associations between knowledge of benefits and induced behavioral change.[12] ▪ Despite limited knowledge about their deductibles, enrollees reported changing care-seeking behavior because of the cost.[12] o Haviland et al. (2012) found challenges with educating enrollees about their plan provisions.[8] • Quality: o A literature survey by Marshall et al. (2000) found that consumers rarely searched for this information, often didn't understand the information, or did not trust the information.[21] o In a recent survey, 35 percent of respondents reported seeing information on their health plan, provider, or hospital quality.[22] ▪ Among these, about half reported using this information to make a decision about their care. • Price: o A few states have taken steps to implement price transparency tools. ▪ New Hampshire's HealthCost price transparency program, started in 2007, helped focus attention on provider price differences and has caused some hospitals to moderate demands for rate increases.[23] ▪ Tu et al. (2009) found that in New Hampshire, HDHPs increased consumer demands for price-shopping tools. However, consumer use of NHHealthCost.org has been modest and the program did not fulfill a

	primary goal of encouraging consumer price-shopping. ▪ Hospitals reported that their volumes for outpatient elective services have declined as a result of reward-based price shopping tools.[24] • Education/decision support: o Haviland et al. (2012) found the data and quality of existing decision support tools to be "generally inadequate."[8] o Provision of decision support remains limited in scope and there is variability in the usability of the information.[22] o There is evidence that the use of decision aids impacts patient-centered outcomes.[22] ▪ Increased patient knowledge about their condition and its treatment ▪ More likely to select non-surgical options ▪ Increased patient compliance with treatment plans ▪ More realistic treatment expectations o Chen et al. (2012) found that plan benefit characteristics such as free preventive coverage, higher deductible, moderate coinsurance rate, family coverage, and enrollment in health savings accounts were positively associated with using Internet-based decision tools.[25] HARMS: • Without sufficient knowledge and/or effective support, poor decisions (e.g., foregoing covered preventive services) could have negative health consequences and result in unnecessary care or higher medical costs later.[12]
What could new research contribute to achieving better patient-centered outcomes?	• New research could randomize enrollees to receive various enrollee support programs and compare across relevant patient-centered outcomes. • Comparative effectiveness of HDHPs with and without support tools (e.g., price transparency, decision support, benefit design) could provide important information about the impact of various support tools on delayed/foregone care (e.g., increases in emergency department visits, hospitalizations, and death), treatment adherence (especially in chronic disease patients), health care resource use, and costs. • Comparative effectiveness and economic analysis studies from the patient perspective could improve and empower patient decision making for treatments below their deductible threshold. • New research could explore how to educate HDHP enrollees about covered preventive care services. • New research about the optimal design features for enrollee decision aids could improve the effectiveness of these tools.
Have recent innovations made research on this topic especially	• Passage of the Affordable Care Act and the resulting State Insurance Exchanges, which have the stated purpose of improving health care quality while reducing costs, makes this topic timely and compelling.[26]

compelling?	
How widely does use of these health insurance approaches now vary?	• Consumer decision-support tools are available to the majority of CDHP enrollees.[1] • The mix and quality of these support tools varies between plans.
What is the pace of other research on this topic as indicated by recent publications and ongoing trials?	• A review of ongoing research yielded very few ongoing studies on enrollee support or deductibles. • **Clinicaltrials.gov** o Search: "high-deductible" ▪ Total ongoing trials: 0 ▪ Total completed trials: 0 o Search: "deductible" ▪ Total ongoing trials: 1 ▪ Total completed trials: 1 ▪ Note: Ongoing study is analyzing a Health Care Price Transparency Tool within the Harvard Pilgrim Health Care system for employees enrolled in deductible and tiered network health plans. Primary outcome: total health care costs. o Search: "price" ▪ Total open studies: 7 ▪ Note: Harvard pilgrim study, Analyzing the Impact of the Now iKnow Health Care Price Transparency Tool (not yet recruiting). • **NIH Reporter** o Search: "high-deductible" ▪ Projects: 2 ▪ Publications: 0
How likely is it that new CER on this topic would provide better information to guide clinical decision making?	• Although it is unclear whether HDHPs are associated with improved patient outcomes, they are becoming increasingly common.[2,10] • Cost exposure can impact health care behaviors.[12] • Decision support tools are intended to improve patient provider communication and improve patient decision making, and they can impact clinical decision making.[22]
Potential for New Information to Improve Care and Patient-Centered Outcomes	
What are the facilitators and barriers that would affect the implementation of new findings in practice?	BARRIERS • Reluctance by hospitals and providers to provide individual level price and quality data. • Reluctance by enrollees to engage with health plans and employers about their health care needs. • Access to support programs may be difficult for some enrollees. FACILITATORS • Data reporting on quality is required for some hospitals through Medicare's Hospital Compare.[27] • Incentives for HDHPs from the Affordable Care Act[26] and CMS.[28] • Increased emphasis on patient-centered health care.

How likely is it that the results of new research on this topic would be implemented right away?	• New research about communicating with enrollees about benefit design will be disseminated fairly quickly. • New research about decision aids may take more time to implement given the time it takes to develop and test decision aids. • New research about the availability of price and quality data may take longer to implement given the potential pushback by providers and hospitals.
Would new information from CER on this topic remain current for several years or would it be rendered obsolete quickly by subsequent studies?	• CER information on this topic will be useful for years and will not likely be readily rendered obsolete. • CER studies will need to take into consideration the rapidly changing insurance and payment landscape and ensure the study designs occur in a variety of settings to maintain current and future value.

CER = Comparative Effectiveness Research; CMS = Centers for Medicare & Medicaid Services; HAS = health savings account; HDHP = High Deductible Health Plan; CDHP = Consumer Directed Health Plan; PCO = patient-centered outcome; PPO = preferred provider organization

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Topic 2: Comparison of ACOs and Traditional Health Systems for Improving Patient-Centered Care

How do Accountable Care Organizations (ACOs) compare to traditional non-ACO health systems in improving patient-centered care, e.g., access to appropriate care, improved care coordination, or improved care experiences?

Criteria	Brief Description
Introduction	
Overview/Definition of topic	OVERVIEW: • Accountable Care Organizations (ACOs) were first conceived in a discussion between Elliott Fisher and Glenn Hackbarth at a Medicare Payment Advisory Commission in 2006.[1] • ACOs were signed into law in 2010 as part of the Patient Protection and Affordable Care Act (PPACA).[2] • The number of ACOs has increased rapidly from 41 in 2010 to over 600 in 2014.[3] • The main purpose of ACOs is to improve care coordination, improve access to care, improve patient experiences, and control costs. • There are various, but similar, definitions of ACOs. The following definition by the Robert Wood Johnson Foundation captures the essential elements: o "A group of health care providers with collective responsibility for patient care that helps providers coordinate services—delivering high-quality care while holding down costs."[4] • A key feature of ACOs is the sharing of financial risks and rewards for providers: o Delbanco, et al. (2011) describes four types of shared-risk models:[5] ▪ Bonus Payment at Risk: Provider is at risk of not receiving a bonus payment based on quality and/or efficiency metrics. ▪ Market Share Risk: Patients are incentivized by lower copays or premiums to select certain providers, so providers are at risk of loss of market share. ▪ Risk of Baseline Revenue Loss: Providers face a financial loss if they fail to meet certain cost or quality thresholds, and/or if actual costs exceed a target cost. ▪ Financial Risk for Patient Population (Whole or Partial): Providers manage patient treatment costs for all or a designated set of services within a predetermined payment stream and are at risk for costs that exceed payments (e.g., partial/full capitation, global budget). o These financial arrangements can be: ▪ <u>One-sided:</u> sharing of savings only (not losses). ▪ <u>Two-sided:</u> sharing of savings and losses. • There are four primary types of ACOs currently in the market:[3, 6] o CMS Pioneer ACOs: CMS Innovation Center initiative designed specifically for organizations with experience offering coordinated, patient-centered care. The 32 original Pioneer ACOs were selected via a competitive process and were designed to test the effectiveness of a particular model of payment.

	▪ First two years are a shared savings payment model, i.e. the ACO captures of portion of any savings ▪ Years 3-5, plans that demonstrate savings in the first 2 years, will be eligible to move to a population-based payment arrangement and full risk arrangements o Medicare Share Savings Program (MSSP) ACOs: CMS Program established to fulfill the statutory obligation set forth by the Affordable Care Act to establish a permanent program that develops a pathway forward for groups of health care providers to become ACOs. o Medicaid ACOs: State-developed ACOs within their Medicaid programs. o Commercial ACOs: More diverse and not held to the same performance metrics as CMS or MSSP ACOs. Members face penalties if they seek care outside the ACO.
Relevance to patient-centered outcomes	• ACOs are intended to improve health care coordination, health care quality, and to decrease costs. If successful, they could impact the patient's experience with health system (care coordination), health outcomes (quality), and efficiency (costs). • However, patient experience may be negatively affected. o Potential harms of ACOs include: less coordination resulting in delays, decreased patient satisfaction, increased costs, lack of physician participation, and restrictions on more expensive specialty care.[7]
Burden on Society	
Recent incidence and prevalence in populations and sub-populations	• As of June 2014, there are 626 ACOs across the United States—however, this number is increasing according to the reporting trend: [3,8] • The first National Survey of Accountable Care Organizations reported that 51 percent of ACOs were physician-lead and 33 percent were jointly led by physicians and hospitals.[9] • ACO growth rates are focused in areas that have high population density, which include Southern California, Texas, and the Northeast. ACO activity is low in the South and Midwest regions. Growth in the following states have occurred due to Medicaid pilot programs: Colorado, Maine, Oregon, Utah and Vermont.[8] • The Medicare Shared Savings Program ACOs are spread across the United States and categorized into 10 regions, each labeled by a representative city. (N corresponds to the number of ACOs in that region):[10] 1. Boston (CT, ME, MA, NH, RI, VT), N=31 2. New York (NJ, NY, PR, VI), N=44 3. Philadelphia (DE, DC, MD, PA, VA, WV), N=43 4. Atlanta (AL, FL, GA, KY, MS, NC, SC, TN), N=91 5. Chicago (IL, IN, MI, MN, OH, WI), N=59 6. Dallas (AR, LA, NM, OK, TX), N=41 7. Kansas City (IA, KS, MO, NE), N=21 8. Denver (CO, MT, ND, SD, UT, WY), N=9 9. San Francisco (AZ, CA, HI, NV), N=43 10. Seattle (AK, ID, OR, WA), N=5 *Some ACOs are in multiple regions. <u>CMS Pioneer ACOs (N=23):</u> • CMS Pioneer Model initially selected 32 organizations to participate.[11] • As of May 2014 the number of Pioneer ACO's has come down to 23.[10]

	o Seven ACOs (22%) transitioned to the MSSP and two ACOs (6%) left the program entirely.[10] Medicare Shared Savings Program (N=338) • Currently there are 338 organizations (with 4.9 million assigned beneficiaries across 47 states and U.S. territories) that have entered into MSSP (May 2014).[10] Medicaid ACOs: • The states participating in Medicaid ACO Learning Collaborative include: Colorado, Maine, Massachusetts, Minnesota, New York, Oregon, Vermont, and Washington.[12] • Other states with Medicaid ACOs include: Iowa[3,13] and Utah.[14] Commercial ACOs (N=287): • Currently, there are 287 ACOs with commercial contracts. • This is a diverse group of ACOs that are spread across the country.
Effects on patients quality of life, productivity, functional capacity, mortality, and use of health services	• ACOs are intended to improve care coordination, quality, and costs. • There are 33 quality metrics that the Pioneer ACO Model and Shared Savings Program measure within 4 domains:[15] o Patient/Caregiver Experience (7 items) o Care Coordination/Patient Safety (6 items) o Preventive Health (8 items) o At Risk Populations ▪ Diabetes (6 items) ▪ Hypertension (1 item) ▪ Ischemic Vascular Disease (2 items) ▪ Heart Failure (1 item) ▪ Coronary Artery Disease (2 items) • Peterson and Muhlestein (2014) reported that for a sample of commercial ACOs, the following domains were used as quality metrics:[3] o Access to Care o Chronic Disease Management o Decreased Utilization o Patient Satisfaction o Preventive Care • Dubois, et al. (2014) evaluated whether a sample of ACOs were prepared to maximize the value of medications for achieving quality benchmarks and cost savings. 46 ACOs responded (26% response rate):[16] o Only 7 percent responded that they were able to quantify the cost offsets in order to demonstrate value. o 9 percent reported having the ability to notify physicians when a prescription has been filled. o 17 percent had protocols in place to prevent medication duplication and polypharmacy. o 22 percent have quality metrics in place for a diversity of conditions.
How strongly does	FACTORS IN FAVOR:

the overall societal burden suggest that CER on alternative approaches to this problem should be given high priority?	• ACOs offer a new risk model to incentivize stakeholders to improve quality and coordination and reduce costs. • ACOs are positioned to evaluate and measure outcomes for comparison and assessment. • Care coordination, quality, and costs remain high priority research topics. • There is a large chronic disease burden and ACOs are in a position to address this rising burden. FACTORS AGAINST: • ACOs are still in the early stages of evaluation; therefore, it is too early to say whether ACOs are likely to be successful.
Options for addressing the issue	
Based on recent systematic reviews, what is known about the relative benefits and harms of available management options?	• We were unable to identify systematic reviews that compared ACOs to traditional models in improving patient-centered care. • Overall, ACOs are a relatively new phenomenon and there is limited data on their overall impact, especially on quality of life. BENEFITS: • Centers for Medicare and Medicaid Services (CMS) Pioneer ACO model has provided preliminary results demonstrating some modest savings.[11] o CMS Pioneer ACO Model has reported small, but non-significant, reductions in total Medicare spending ($20 per beneficiary per month compared with a non-Pioneer ACO comparator). o Eight of the Pioneer ACOs had significantly lower costs in total Medicare spending per beneficiary ($32.58 to $102.21 per month lower compared with a non-Pioneer ACO comparator). o The Pioneer Program generated a total of $147 million in savings with $76 million returning to 12 (38%) out of 32 participating ACOs.[3] o One (3%) out of 32 ACOs shared in losses.[3] • Results for ACOs in the MSSP were available for the first cohort. o Of the 114 ACOs that started in MSSP in 2012, 54 (48%) kept costs below the budget benchmarks.[3] o Two ACOs (2%) spent over the budget benchmark.[3] • A 2014 survey of 46 ACOs (176 contacted, 26% response rate) evaluated the readiness of ACOs in addressing the “triple aims” of improved population health, improved patient experience, and lower per capita cost.[16] The proportion that reported being ready in the following categories was: o Transmitting prescriptions electronically (70%) o Ability to integrate medical and pharmacy data into a single database (54%) o Formulary in place that encourages generic use when appropriate (50%) • In 2011, Oregon developed the Oregon ACO Experiment, which established Coordinated Care Organizations (CCOs).[17] o In 2013, ED visits decreased 17 percent from 2011 and cost in the ED decreased by 19 percent.[18] o In 2013, hospitalizations for CHF decreased by 27 percent, COPD by 32 percent,

	and adult asthma by 18 percent.[18] o In 2013, primary care visits increased by 11 percent and spending for primary care visits increased by 20 percent.[18] o In 2013, enrollment in primary care clinics increased by 52 percent since 2012.[18] • In 2013, the Colorado Department of Health Care Policy and Financing reported the following performance for their Accountable Care Collaborative (ACC):[19] o 15-20 percent reduction for hospital readmissions and 25 percent reduction in high cost imaging services relative to a comparison population prior to program implementation. o 22 percent reduction in hospital admissions among participating beneficiaries with COPD relative to a comparison population. o Lower rates of exacerbating conditions compared to clients not enrolled in the ACC program (e.g., hypertension, 5% lower rate; diabetes, 9% lower rate). o Although emergency room visits increased, beneficiaries in the ACC had a lower rate of increase compared to those not enrolled (1.9% versus 2.8%). o $44 million in gross ($6 million in net) reduction for beneficiaries enrolled in ACC compared to those not enrolled. POTENTIAL HARMS: • If ACO implementation is performed improperly, patient experience may be negatively affected through less coordination resulting in delays, decreased patient satisfaction, increased costs, lack of physician participation, and restrictions on more expensive specialty care.[7] • ACOs may lead to hospital mergers and provider consolidation that result in greater market share, which can give them leverage over insurance companies and potentially drive up health care costs and limit patient choices (e.g., provider collusion).[20,21]
What could new research contribute to achieving better patient-centered outcomes?	• Overall, the convergence of incentives and enthusiasm for ACO implementation and the lack of comparative data suggest the need for substantial additional research. • New research could compare ACOs and traditional non-ACO systems in terms of: o Care coordination (e.g., Client Perceptions of Coordination Questionnaire) o Quality (e.g., Healthcare Effectiveness Data and Information Set [HEDIS] measures) o Resource use (e.g., repeated tests, out-of-pocket costs). o Others: Patient Reported Outcomes, 30-day readmissions, etc. • New research could evaluate patient-centered outcomes that are not captured by the existing quality and cost metrics, e.g. quality of life, mortality, etc. • New research could compare ACOs with different financial programs on quality, cost, and patient-centered outcomes. • New research could compare how various shared risk models perform relative to one another on improving patient-centered outcomes and how effects may differ for select vulnerable populations (e.g. rural, low-income).
Have recent innovations made research on this topic especially compelling?	• Passage of the PPACA with Section 3022 mandating that ACOs be implemented makes this topic timely and vital to health care reform. • The number of ACOs has increased rapidly from 41 in 2010 to over 600 in 2014.[3]

How widely does care now vary?	• Lewis, et al. (2013) performed a cross-sectional study to identify the prevalence of ACOs in the United States in 2012.[22]
	  o The distribution of ACOs is uneven because most were implemented in high-cost areas that were high performers on selected quality measures.
	  o ACOs were less likely to be established in high-poverty and rural areas.
	• According to a report by Peterson, et al (2014), areas of high-population density have faster growth, as well as areas with Medicaid pilot programs.[8]
	• According to a report by Auerbach, et al. (2013), ACO penetration rate (percentage of Fee-For-Service Medicare beneficiaries participating in ACOs) was higher in the Northeast and Midwest (10.8% and 9.0%, respectively) compared to the South (4.3%) and, West (6.9%).[23]
	• Auerbach, et al. (2013) also reported that the following factors were associated with ACO formation:[23]
	  o Greater fraction of hospital risk sharing (capitation)
	  o Larger integrated hospital systems
	  o Primary care physicians practicing in large groups

What is the pace of other research on this topic as indicated by recent publications and ongoing trials?	**ClinicalTrials.gov:**
	• Search strategy: "Accountable Care Organization"
	• 5 studies: 1 recruiting, 3 not yet recruiting, 1 completed.
	  o Notable studies:
	  ▪ Immunization reminder systems in an ACO (Not yet recruiting)
	  ▪ Medication adherence and health care costs after ACO (Not yet recruiting)
	NIH Reporter:
	• Search strategy: "Accountable Care Organization"
	• 9 hits
	CMS Pioneer ACO Model:
	• Data on patient-reported outcomes (PROs) should be available by 2015.
	• Data on overall health care resource utilization will be available by 2015.
	Other ACOs that are tracking their progress:
	• The following states are known to be currently tracking the progress of their ACOs: Oregon,[18] Iowa,[13] Vermont (potential collaboration with Dartmouth-Brookings),[24] and Colorado[19].
	• Blue Shield of California for CalPERS[25]
	Groups that are tracking ACOs and their progress:
	• The National Survey of Accountable Care Organizations is a detailed survey of ACOs that includes questions regarding contract arrangements, organizational structure, and ACO capabilities and activities.[9]
	• Leavitt Partners periodically updates Health Affairs through blogs and reports on the performance and status of ACOs in the United States.[8]

Is it likely that new CER on this topic would provide better information to guide clinical decision making?	• Focus on improved care coordination, quality, and costs coupled with financial incentives for providers is very likely to impact clinical decision making.

Potential for New Information to Improve Care and Patient-Centered Outcomes	
What are the facilitators and barriers that would affect the implementation of new findings in practice?	FACILITATORS: • American Recovery and Reinvestment Act of 2009 reserved $29 billion for CMS to allocate payments to provider-systems that establish health information technology (IT) systems to improve care. • Having a champion or strong leadership (e.g., physicians, other community providers, and politicians).[26-28] • Financial support for health IT development. • Development of ACOs can be done quickly with fewer resources compared to health maintenance organizations or integrated delivery systems.[7] • Brookings-Dartmouth Accountable Care Organization Collaborative identified three factors that facilitated ACO formation at 4 pilot sites:[29] 1. Committed executive leadership and strong governance 2. Strong payer-provider relationship 3. Experience with performance-based payment • They also identified four facilitators of system transformation:[29] 1. Robust health IT infrastructure 2. Strong managed care capabilities 3. Performance measurement and transparency 4. Effective physician engagement BARRIERS: • Variability between health care systems that will become ACOs (e.g., the size and coverage area; variety of group practices) • Initial lack of integration among contracted health systems.[17] • Cost of implementing and integration of health IT infrastructure.[30] • Concerns about ethical issues such as patient autonomy and choice, privacy and confidentiality, and patient engagement.[31] • Compliance with extensive reporting requirements.[7]
How likely is it that the results of new research on this topic would be implemented right away?	• Implementation will move at a moderate pace given infrastructure and coordination needs.
Would new information from CER on this topic remain current for several years or be rendered obsolete quickly by later studies?	• Information regarding establishment of ACOs and payment reform successes (and failures) will help identify best practices in reforms, make clinical improvements sustainable, and will be used by future ACOs.[3] • The ACO market is evolving rapidly and it is unclear if data on ACOs would remain current for several years.

ACO = Accountable Care Organization; CMS = Centers for Medicare and Medicaid Services; IT = information technology; MSSP = Medicaid Shared Savings Program; PPACA = Patient Protection and Affordable Care Act

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Topic 3: Comparison of Care Management Plans with and without Non-medical/Non-pharmaceutical Therapeutic Options for Chronic Pain

How do care management plans that include non-invasive/non-pharmaceutical therapeutic options (e.g., reiki, yoga, acupuncture, exercise, physical therapy) compare with plans that do not in terms of patient-centered outcomes related to chronic pain, especially back pain and cancer pain?

Criteria	Brief Description
Introduction	
Overview/Definition of Topic	• Non-invasive/non-pharmacological (NI/NP) therapies provide additional options to improve outcomes for patients with chronic pain while avoiding the potential harms with more conventional approaches, e.g., surgery or opioids. • NI/NP options overlap with the field of complementary and alternative medicine (CAM) but also include other options like exercise and physical therapy. • NI/NP therapies commonly used to treat back pain and cancer pain include: o Back pain: exercise, physical therapy, behavioral treatment, acupuncture, spinal manipulation (e.g. chiropractic), and massage. [1-3] o Cancer pain: physical activity, physical and occupational therapy, orthotics, assistive devices, breathing exercises, relaxation therapy, imagery, hypnosis, massage, use of heat or cold, acupuncture, and acupressure.[4] • NI/NP therapies including CAM have been gaining acceptance and market share.[5,6] • Integration of NI/NP into health care systems: o Some NI/NP services (i.e. physical therapy and chiropractic) are common benefits in state Medicaid programs, Medicare, and private health insurance plans.[7-9] o However, most CAM therapies are paid for out-of-pocket with the total out-of-pocket cost of CAM in the U.S. estimated at $34 billion per year.[5,10] o All 50 states, Puerto Rico, and the U.S. Virgin Islands now license chiropractors, and about 85% of states license some of the other CAM providers such as naturopathic physicians, acupuncturists, or massage therapists.[11] o 17 states, the District of Columbia, and the United States territories of Puerto Rico and the United States Virgin Islands have licensing or regulation laws for naturopathic doctors.[12] o Health service managers have reported that CAM therapies increase the holistic value of their healthcare services.[13] • There is no literature directly linking care management plans with greater integration of or access to NI/NP and patient outcomes. Therefore, this brief focuses separately on access to NI/NP and the effects of NI/NP in order to inform the indirect link to patient outcomes; i.e. care management plans with greater access to evidence based NI/NP interventions may lead to improved patient outcomes.
Relevance to patient-centered outcomes	• Improved patient access to effective NI/NP therapies may impact quality of life, patient satisfaction, and patient engagement.

	• Patients often do not limit themselves to a single modality of care: o They do not see CAM and conventional medicine as being mutually exclusive.[6] o They may view conventional medicine practitioners as purveyors of drugs, without understanding the cause of their pain.[14] o Physical therapists are often viewed as experts on pain, offering hands-on delivery and explanation of care.[14] o They view exercise as an autonomous practice they can perform without oversight.[14]
Burden on Society	
Recent Incidence and prevalence in populations and subpopulations	<u>NI/NP:</u> • Every year, 3.1% of the U.S. population uses office-based physical therapy services, occupational therapy services, or both at a mean cost of $1,381 per patient.[7] • Fifty-four percent of the physical therapy expenditures for patients less than 65 years of age were funded by private insurance.[7] • Most data available on NI/NP prevalence and incidence relates to CAM. o National surveys demonstrate a substantial and growing number of visits to CAM providers.[15] o 40 percent of Americans use CAM healthcare approaches to treat specific conditions,[16,17] promote overall well-being,[15] and/or practice a philosophy of control over one's own health.[6,18] o CAM use is more prevalent among women, adults aged 30–69, the educated, the affluent, former smokers, and people hospitalized in the last year.[19] o CAM is most often used to treat musculoskeletal problems (e.g. back pain) (17.1%), neck pain (5.9%), joint pain or stiffness (5.2%), arthritis (3.5%), and other conditions (1.8%).[19] o The use of CAM therapies increased from 2002 to 2007, including deep breathing exercises, meditation, yoga, acupuncture, massage therapy, and naturopathy.[19] <u>Back Pain:</u> • NI/NP accounts for 30% of the direct medical costs for chronic lower back pain.[20] o Physical therapy alone accounted for 17% of the expenditures on chronic lower back pain, while the costs for surgery accounted for only 5%. • Incidence: Back pain has an annual incidence of 139 per 100,000 people in the U.S.[21] • Prevalence: 5% to 22% of adults older than 18 years have experienced lower back pain in the previous three months.[20] <u>Cancer Pain:</u> • Most cancer patients (75-90%) experience pain due to the cancer itself (the tumor pressed on bones, nerves, or other organs), the treatment, or diagnostic tests.[22] o 50% to 70% of cancer patients experience uncontrolled/untreated pain at some point during their illness, depending on the stage of the disease.[23] • 40% of cancer patients do not get adequate pain relief despite available options.[23]
Effects on patients' quality of life, productivity, functional capacity, mortality, and use of	<u>NI/NP:</u> • Surgical and pharmacological approaches to treating back and cancer pain can be effective but also entail risks, e.g. surgical complications and the potential for opioid addiction.[24,25] o The overall rate of inpatient surgical complications is substantial with estimates ranging from 3% to 17.4%.[26]

health services	○ U.S. societal costs of opioid abuse are estimated at $53.4 billion which includes $42 billion in lost productivity, $8.2 billion in criminal justice costs, $2.2 billion in inpatient and outpatient medical costs, and $944 million due to medical complications (2%).[27] <u>Back Pain:</u> • Back pain is an important health issue with serious societal and economic implications.[28] • Quality of Life: In the Medical Expenditure Panel Survey, 24.7% of people with back problems reported limitations in their physical functions, work, and daily activity.[29] • Productivity: Workers who report back pain lose an average of 5 hours/week of productive time.[30] • Use of Health Services: Back pain accounts for 2% of all physician office visits and is the fifth most common reason for primary care office visits.[31] <u>Cancer Pain:</u> • Quality of Life: Cancer pain has a significant impact on quality of life by influencing physical, psychological, and spiritual aspects of well-being.[32] • Patients with advanced cancer have more severe pain, and many cancer survivors have pain that continues after cancer treatment ends.[22] • Use of Health Services: Most NI/NP therapies for cancer pain are paid for out of pocket. Low priority is given to cancer pain treatment, thus reimbursement for pain assessment and treatment is inadequate.[33,34]
How strongly does the overall societal burden suggest that CER on alternative approaches to this problem should be given high priority?	• The large societal burden for back pain and cancer pain suggest alternative treatments should be given a high priority.
Options for Addressing the Issue	
Based on recent systematic reviews, what is known about the relative benefits and harms of available management options?	• We did not find systematic reviews or individual studies comparing care management plans that include NI/NP therapeutic options vs. plans that do not in terms of patient-centered outcomes related to back pain or cancer pain. • However, if greater integration and access leads to greater use of evidence based NI/NP therapies, patient centered outcomes are likely to be improved. <u>Integration and access to NI/NP:</u> • Integrating NI/NP approaches with conventional care is said to “fill gaps” in treatment effectiveness for people experiencing complex, chronic conditions.[13] • Individuals with health insurance coverage for CAM are more likely to use CAM therapies than those without it.[15,19] ○ Full and partial insurance coverage for CAM is significantly associated with frequent (>8) visits to a CAM provider.[15] <u>NI/NP therapies for back pain:</u> • Exercise and physical therapies have been shown to significantly reduce pain intensity and disability in short-term follow-up studies.[35] • A 2010 systematic review of published studies on NI/NP treatment for lower back pain

	reported that none of the 83 included studies reported adverse events of treatment.[35] • A systematic review of CAM approaches for low back pain found that: 1) evidence was of poor to moderate grade, 2) the benefit of CAM treatments was mostly evident immediately or shortly after the end of the treatment and then faded with time, 3) very few studies reported long-term outcomes, and 4) the trial results were inconsistent.[3] o Acupuncture:[3] ▪ Associated with significantly lower pain intensity than placebo but only immediately post-treatment. ▪ Not different from placebo in post-treatment disability, pain medication intake, or global improvement in chronic nonspecific low back pain. ▪ Results regarding comparisons with other active treatments (pain medication, mobilization, laser therapy) were less consistent. ▪ Two reviewed studies showed acupuncture was more cost-effective compared to usual care or no treatment for patients with chronic back pain. o Manipulation (e.g. chiropractic):[3] ▪ Significantly better than placebo or no treatment in reducing pain immediately or short-term after the end of treatment. ▪ Better than acupuncture in improving pain and function in chronic nonspecific low back pain. ▪ Results from comparisons with massage, medication, or physiotherapy were inconsistent, either in favor of manipulation or indicating no significant difference between the two treatments. o Mobilization (manual therapy of stagnant tissues and joints):[3] ▪ Superior to no treatment but not different from placebo in reducing low back pain or spinal flexibility after the treatment. ▪ Better than physiotherapy in reducing low back pain and disability (Visual Analog Scale [VAS] score: -0.50, 95 percent Confidence Interval [CI]: -0.70, -0.30). o Massage:[3] ▪ Superior to placebo or no treatment in reducing pain and disability only amongst subjects with acute/sub-acute low back pain. ▪ Significantly better than physical therapy in improving back pain or disability (VAS: -2.11, 95 percent CI: -3.15, -1.07). ▪ Some evidence indicated higher costs for massage use compared to general practitioner care for low back pain. o Harms:[3] ▪ Reporting of harms in RCTs in CAM trials was poor and inconsistent. ▪ In several included studies, some subjects receiving CAM therapies reported soreness or bleeding on the site of application after acupuncture and worsening of pain after manipulation or massage. ▪ Two included case-control studies reported cervical manipulation was shown to be significantly associated with vertebral artery dissection or vertebrobasilar vascular accident. <u>NI/NP therapies for cancer pain:</u> • Purported benefits of NI/NP therapies include patient-driven control of cancer and cancer-related pain, additional "strength" to undergo conventional therapies, symptom

	relief, and increased ability to fight off the disease.[22,36] • Unlike conventional treatment for cancer pain (typically opiate therapy), NI/NP and CAM approaches are relatively toxicity-free.[22] • However, the evidence of benefit is low according to a systematic review,[22] thus NI/NP therapies for cancer pain may provide little actual benefit while adding considerable costs to the patient and/or payer.
What could new research contribute to achieving better patient-centered outcomes?	• New research on the impacts of access to and coverage for NI/NP, and how different organizations compare, will inform policies regarding access to NI/NP. • Research on health management plans offering NI/NP versus those that do not would improve current understanding of the effectiveness and costs of NI/NP as it relates to insurers and by extension the patients who use NI/NP. • Research on patient preferences for access to NI/NP can inform the implementation into management plans. • Future well-powered head to head comparisons of NI/NP treatments and trials comparing NI/NP to widely used conventional treatments that report on all clinically relevant outcomes are needed to draw better conclusions.[3]
Have recent innovations made research on this topic especially compelling?	• No major recent innovations have made research on this topic especially compelling. • However, recent positive studies for some NI/NP approaches—e.g., acupuncture for osteoarthritis pain, tai chi for fibromyalgia pain, and massage/spinal manipulation/yoga for chronic back pain—indicate NI/NP approaches have potential for greater acceptance in the conventional medical community.[37]
How widely does use of NI/NP now vary?	• Insurance coverage of NI/NP including CAM varies greatly depending on state laws, regulations, and differences among specific insurance plans.[38] • The structure of the physical therapy benefit varies by insurer.[7] o Physical therapy is a mandatory benefit in Medicare and is an optional benefit in state Medicaid plans. o Physical therapy is an available benefit in approximately 70% of employer-sponsored insurance plans. • Chiropractic care is included in most health insurance plans, including major medical plans, workers' compensation, Medicare, some Medicaid plans, and Blue Cross Blue Shield plans for federal employees, among others.[39] • Most other CAM approaches are paid for out of pocket.[5,10] o For example, more than 90 percent of massage therapy sessions are paid for out of pocket.[40]
What is the pace of other research on this topic as indicated by recent publications and ongoing trials?	<u>NI/NP and back pain</u> • Search: "non-invasive AND "back pain" o **PubMed**: 140 entries o **Clinicaltrials.gov**: 17 entries, 4 were ongoing, 8 completed o **NIH RePORTER**: 44 entries, 2 clinical trial studies • Search: "physical therapy" AND "back pain" o **PubMed**: 6973 entries o **Clinicaltrials.gov**: 137 entries, 53 were ongoing, 56 completed o **NIH RePORTER**: 138 entries, 4 clinical trial studies <u>NI/NP and cancer pain</u>

	• Search: “non-invasive” AND “cancer pain” o **PubMed**: 65 entries o **Clinicaltrials.gov**: 1 actively recruiting entry o **NIH RePORTER**: 0 entries • Search: “physical therapy” AND “ cancer pain” o **PubMed**: 3007 entries (most are not actually related to cancer pain) o **Clinicaltrials.gov**: 0 entries o **NIH RePORTER**: 0 entries <u>Complementary and alternative medicine</u> • **Clinicaltrials.gov** o Search: (“complementary medicine” OR “alternative medicine”) AND “back pain” ▪ 52 results, 16 were ongoing, 29 completed o Search: (“complementary medicine” OR “alternative medicine”) AND “cancer” ▪ 201 results, 46 were ongoing, 117 completed • **NIH RePORTER** o ("complementary medicine" OR "alternative medicine") AND “back pain” ▪ 373 projects, 26 clinical trial studies o ("complementary medicine" OR "alternative medicine") AND cancer ▪ 4155 projects, 625 clinical trial studies • Of note, the AHRQ Effective Health Care Program has recently funded a systematic review of Noninvasive Treatments of Low Back Pain to be completed in mid-2015.
How likely is it that new CER on this topic would provide better information to guide clinical decision making?	• New CER on the use of NI/NP vs. invasive or pharmacologic treatments or CER comparing different NI/NP approaches (e.g. yoga vs. physical therapy) for back pain and/or cancer pain would be very likely to improve clinical decision making. • If evidence from new CER indicates positive impacts from increased access to NI/NP, the use of NI/NP therapies would likely increase. • Increased licensure and accreditation of NI/NP professionals will likely lead to greater insurance coverage and thus increased use by covered patients.
Potential for New Information to Improve Care and Patient-Centered Outcomes	
What are the facilitators and barriers that would affect the implementation of new findings in practice?	FACILITATORS • NI/NP therapies including CAM are popular among patients in the US,[9,19] and health insurers that have incorporated NI/NP therapies into their policies have stated that their primary motivation is market demand.[41] • Conditions such as back pain and symptoms accompanying cancer treatment do not have widely accepted conventional medicine treatment approaches, thus NI/NP is increasingly recommended by clinicians.[13] BARRIERS • There is conflicting evidence regarding the efficacy and safety of CAM.[42] • Many rigorously conducted studies have shown that some CAM therapies are no better than placebo.[42] • Many conventional medicine practitioners are skeptical of CAM therapies and may be hesitant to recommend it to their patients.[5] • Patients may lack awareness, time, motivation, and financial ability to initiate and/or follow through with physical therapy.[43]

	• Health management plans have varying coverage approaches for NI/NP therapies.
How likely is it that the results of new research on this topic would be implemented right away?	• If evidence from new CER indicates positive impacts from increased access to NI/NP, access to NI/NP would likely increase at a moderate pace.
Would new information from CER on this topic remain current for several years or would it be rendered obsolete quickly by subsequent studies?	• New information would likely remain current for several years given the limited number of available treatments, the risks associated with invasive and pharmacologic approaches, and the popularity for NI/NP.

References for Topic 3: Comparison of Care Management Plans with and without Non-medical/Non-pharmaceutical Therapeutic Options for Chronic Pain

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