Research Prioritization Topic Briefs

PCORI Scientific Program Area:
Improving Healthcare Systems

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Contents

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Topic 1: Health IT and Treatment Adherence in Chronically Ill Patients

Compared to usual care alone, what is the effect of the addition of information technology (e.g., personal health record/patient portals and decision support) on chronically ill patients' adherence to treatment plans?

Criteria	Brief Description
Introduction	
Overview/ definition of topic	• Chronic illnesses, defined as diseases of long duration and generally slow progression,[1] are costly, complicated to manage, and common. • Most prevalent chronic diseases in the United States (percent of U.S. population): o Obesity (36%)[2] o Major Depression (9.1%)[3] o Asthma (8.4%)[4] o Diabetes (8.3%)[5] o Chronic Obstructive Pulmonary Disease (COPD) (6.3%)[6] o Heart disease (6.0%)[7] o Cancer (2.8%)[8] • More than 25 percent of all Americans and 66 percent of Medicare patients (65+) are estimated to have at least two chronic conditions.[9,10] • Many aspects of the U.S. health care system are designed primarily to address acute health problems and are not optimally designed to address chronic diseases.[11,12] • About 50% of patients with chronic illness are adherent to their treatment plans, i.e. they take medications and execute lifestyle changes in accordance with agreed recommendations from their healthcare providers.[13,1415] o Poor adherence to treatment plans has severe effects on quality of life, morbidity, mortality, and health care costs.[15] • This brief will focus on three of the most common types of health information technology (IT). 1. Personal health records (PHRs), defined as secure and confidential electronic applications used by patients to maintain and manage their health information. ▪ PHRs can include:[16] ▫ Dietary plans ▫ Data from home health monitoring systems ▫ Diagnosis lists ▫ Medication lists ▫ Allergies ▫ Immunization history 2. Patient portals, defined as secure online websites that give patients convenient access to their personal health information such as discharge summaries, medications, and lab results and allow them to communicate with their health care providers.[17] 3. Decision support systems (also called clinical decision aids), which provide clinicians, staff, patients, and caregivers with tools that enhance clinical decision-making. ▪ Decision support systems can include:[18] ▫ Computerized alerts and reminders for patients and caregivers

	▫ Clinical guidelines for providers ▫ Condition-specific order sets for providers ▫ Patient data reports for patients, caregivers, and providers ▫ Diagnostic support for providers
Relevance to patient-centered outcomes	• Improved information flow between patients and their provider team through use of information technologies may impact adherence, patient satisfaction, patient engagement, and ultimately, quality of life, mortality, and potentially other important outcomes.
Burden on Society	
Recent incidence and prevalence in populations and subpopulations	PREVALENCE • >130 million Americans (~42%) have a chronic condition.[5] • >77 million Americans (~25%) have at least two chronic conditions.[10] INCIDENCE (percent of U.S. population diagnosed per year) o Obesity (4%)[19] o Depression (6.7%)[20] o Asthma (0.36% for adults; 1.3% for children)[21] o Diabetes (0.62%)[22] o COPD (3.8%)[23] o Heart disease (0.4%)[24] o Cancer (0.53%)[25]
Effects on patients' quality of life, productivity, functional capacity, mortality, and use of health services	• QUALITY OF LIFE/FUNCTIONAL CAPACITY/MORTALITY o 70 percent of deaths in U.S. per year are from chronic diseases.[5] o Non-adherence to treatment plans is estimated to cause ~125,000 deaths/year.[26] o Obesity severely decreases functional status and quality of life independent of the effects of the diseases with which it is associated.[27] o Although treatment of major depression can improve quality of life, depressed patients still have poor quality of life even when depressive symptoms are in remission following treatment.[28] o Asthma,[29,30] diabetes,[31] COPD,[32] heart disease,[33] and cancer[25] are also associated with increased mortality and decreased quality of life and functional capacity compared to patients without these diseases. • USE OF HEALTH SERVICES/PRODUCTIVITY o More than 75 percent of health care costs are attributable to chronic conditions.[34] o About 25 percent of people with chronic diseases report that they have ≥1 daily activity limitations.[5] o Obesity significantly increases health care utilization and direct medical costs as well as indirect costs such as lost productivity (absenteeism and presenteeism), increased disability, and premature mortality.[35] o Non-adherence also leads to billions of dollars in potentially avoidable costs.[36]
How strongly does the overall societal burden suggest that CER on alternative approaches to this problem should be given high priority?	FACTORS IN FAVOR • High potential for positive impact on a huge population with chronic diseases that is currently not managed well. • Many information technologies are already being implemented so research into ways to maximize their positive effects on patients is rational and has the potential to be highly beneficial. FACTORS AGAINST • Unclear whether PHR or patient portals in particular improve adherence and therefore

	patient outcomes, especially in patient populations that are not technologically adept.[37] • Unclear if physicians are willing to incorporate decision support systems into medical practices.[37]
Options for Addressing the Issue	
Based on recent systematic reviews, what is known about the relative benefits and harms of available management options?	• Although most health IT literature indicates positive or mixed outcome results and many reviewed studies included patient centered outcomes, many published studies lack elaboration about key elements and implementation of the technologies, potentially limiting the generalizability of results to other settings.[38] • Studies demonstrating neutral or negative outcomes may not have been published (publication bias), particularly if health IT vendors were involved in funding studies that had negative results.[39] • Reviews described below assigned equal weight to studies, regardless of study quality (e.g., a poorly designed case series was given equal weight as a meticulously performed randomized control trial).[37-39] BENEFITS • Systematic review of health IT in 2014 reported that 56 percent of studies reported uniformly positive results; additional 21 percent reported mixed-positive results.[38] o Over half (57%) of these studies evaluated clinical decision support.[38] ▪ In particular, the reviews found that clinical decision support was often associated with improvements in adherence to asthma treatment protocols.[38,40] o This review did not report results about PHR or patient portals.[38] • AHRQ technology assessment conducted in 2012 found most studies reported a positive effect of IT on outcomes such as coordination of care and use of health resources.[37] o Most studies evaluated clinical decision aids.[37] o Most studies that found favorable impacts of health IT on chronic diseases focused on diabetes, heart disease, and cancer.[37] ▪ Clinical decision support was associated with improved adherence to recommended therapy for heart disease[41] and diabetes.[42] o 12 studies evaluated PHR/patient portals. ▪ Nine studies (75%) had at least one outcome with a statistically significant positive impact on health care process outcomes.[37] ▪ One study showed adherence to recommended treatment increased when patients used PHR and portals.[43] • Review of published literature from 2007-2010 found 92 percent of published studies reached overall positive conclusions.[39] POTENTIAL HARMS • Breaches of privacy and patient confidentiality remain a concern. o A survey conducted in 2009 found about 30% of respondents felt the privacy risks outweighed the potential benefits of health IT.[44]
What could new research contribute to achieving better patient-centered outcomes?	• The following comparative effectiveness research studies could improve various patient-centered outcomes: o Research on the impact of health IT on patient's satisfaction with their treatment plans. o Comparison of adherence to treatment plans, costs, health care utilization of chronic disease patients whose health care includes IT components such as PHR and patient

	portals, compared with chronic disease patients whose care does not include IT components. o Comparative effectiveness on the use of health IT vs. no health IT in under researched populations, e.g. elderly, pediatric, low socioeconomic status, and rural chronic disease patients. o Comparative effectiveness on the use of health IT vs. no health IT in additional disease areas (i.e. outside of diabetes, heart disease, and cancer). o Health IT use in technologically challenged populations. o Patient preferences for health IT features.
Have recent innovations made research on this topic especially compelling?	• Societal trend toward increased use of technology. • In 2013, the Centers for Medicare & Medicaid Services (CMS) began implementing Medicare and Medicaid Electronic Health Records (EHR) Incentives Program to encourage health care professionals and hospitals to demonstrate meaningful use of certified EHR technology.[45]
How widely does use of health IT now vary?	• In general, adoption rates of health IT have been poor. o National survey done in 2010 found that only 10 percent of U.S. adults used PHR.[46] ▪ Patients report that endorsement by their physicians and reassurance about security of confidential health information are vital to adopting PHRs.[47,48] o As of 2011, only about 6 percent of patients used patient portals.[49] ▪ Patients are concerned the portals will depersonalize the quality of relationships with providers.[50] ▪ Patients also find portals difficult to use.[50] o Availability of clinical decision support requires massive up-front investments, as well as existence of and compatibility with information technology such as electronic health records.[51] o Even when available, clinical decision support system alerts are often ignored by physicians.[52]
What is the pace of other research on this topic as indicated by recent publications and ongoing trials?	Clinicaltrials.gov Search: "personal health record" AND chronic disease Total ongoing trials: 320 Total completed trials: 424 Most pertain to diabetes, COPD, and asthma. Search: "patient portal" AND chronic disease Total ongoing trials: 144 Total completed trials: 180 Most pertain to liver diseases. Search: "clinical decision support" AND chronic disease Total ongoing trials: 17 Total completed trials: 16 Many are testing ways to improve evidence-based care for chronic diseases. NIH Reporter Search: "personal health record" AND chronic disease

	Ongoing Projects: 4 Published research studies: 5 Search: “patient portal” AND chronic disease Ongoing Projects: 4 Published research studies: 56 Search: “clinical decision support” AND chronic disease Ongoing Projects: 12 Published research studies: 14
How likely is it that new CER on this topic would provide better information to guide clinical decision making?	• A great deal of evidence suggests that health ITs have the potential to lead to positive outcomes and decrease variation in clinical decision making.[11,37-39] • New CER that compares methods of implementing health IT could improve clinical decision making and adherence to treatment plan for patients with chronic diseases.
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 • Difficulties with creating and implementing user-friendly forms of health IT.[37] • Provider concerns about unreimbursed time to learn and implement technologies and their disruption to workflow.[37] • Potential for breaches of confidential health information.[37] • Patient and provider concerns about the depersonalization of the patient/provider relationship.[37] • Many health IT applications are not standardized and cannot interface with one another which might make them unsustainable or only applicable to small, specialized populations.[37] • High up front implementation costs.[37] • Potential for difficulties using health IT in populations that lack computer literacy or access to technology.[37] FACILITATORS • Incentives from CMS currently encourage health systems to implement health IT.[45] • High rates of satisfaction with health IT applications can encourage patients and providers to implement them.[37] • Competition between health care providers and insurance plans. • Potential long-term cost savings. • General technological advancements throughout society and increasingly widespread use of mobile devices and social media.
How likely is it that the results of new research on this topic would be implemented right	• On one hand, health systems have financial incentives to implement health IT so results of new research might be prioritized for rapid implementation. • Alternatively, large infrastructure changes require long-range planning and timelines which might delay implementation.

away?	
Would new information from CER on this topic remain current for several years or would it be rendered obsolete quickly by subsequent studies?	• CER that evaluated the best ways to implement and improve patient, caregiver, and provider use of health IT would likely remain current for several years, even if the technologies themselves evolved.

CER = Comparative Effectiveness Research; CMS = Centers for Medicare & Medicaid Services; EHR = electronic health record; IT = information technology; PHR = patient health record

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Topic 2: Multicomponent Interventions and Medication Adherence in Chronically Ill Patients

What are the comparative effects of multicomponent interventions on chronically ill patients' adherence to their prescribed medications?

Criteria	Brief Description
Introduction	
Overview/Definition of topic	OVERVIEW • Chronic illnesses, defined as diseases of long duration and generally slow progression,[1] are costly, complicated to manage, and common. • Most common chronic diseases in the United State are (% of Americans affected): o Obesity (36%)[2,3] o Depression (9.1%)[4] o Asthma (8.4%)[5,6] o Diabetes (8.3%)[7] o COPD (6.3%)[8] o Heart disease (6.0%)[9] o Cancer (2.8%)[10] o Hyperlipidemia (33.5%)[11] o HIV (0.4%)[12] • Treatment adherence, i.e. taking medications, following a diet, and/or executing lifestyle changes in accordance with provider recommendations, for chronic illnesses is about 50 percent in developed countries.[11] • Poor adherence to treatment plans and medications has severe effects on quality of life, morbidity, mortality, and health care costs.[13,14] TOPIC DEFINITION: • This brief will focus on the comparative effects of multicomponent interventions on chronically ill patients' adherence to their prescribed medications. • Multicomponent interventions are those that combine multiple components into a single intervention package. • A review of available systematic literature found various types of multicomponent interventions used to improve adherence to medication use that can be grouped into the following categories: o Provision of tools to improve medical adherence (e.g. provision of medication table). o Patient motivation, education, and training interventions (e.g. face-to-face motivational interviews).

	o Treatment and medication adherence-related reminders (e.g. phone or mail contact if refills were missed).
Relevance to patient-centered outcomes	• Multicomponent interventions to improve adherence in chronically ill patients can impact a number of patient-centered outcomes including patient satisfaction, treatment adherence, morbidity, and mortality.[14]
Burden on Society	
Recent incidence and prevalence in populations and sub-populations	PREVALENCE: • >130 million Americans (~42%) have a chronic condition[13] INCIDENCE (% of Americans diagnosed per year): • Obesity (4%)[11] • Depression (6.7%)[19] • Asthma (0.36% for adults; 1.3% for children)[1] • Diabetes (0.62%)[10] • COPD (3.8%)[20] • Heart disease (0.4%)[21] • Cancer (0.53%)[22] NON-ADHERENCE TO MEDICATIONS (%):[23] • Depression (26%) • Diabetes, oral therapies (16-22%) • Hyperlipidemia (21%) • Hypertension (11%) • Adult persistent asthma, ICS (37%) • Coronary artery disease, ACE inhibitor (15%) • Chronic heart failure (19-25%)
Effects on patients quality of life, productivity, functional capacity, mortality, and use of health services	QUALITY OF LIFE/FUNCTIONAL CAPACITY/MORTALITY: • 70 percent of deaths in the United States per year are from chronic diseases.[13] • Non-adherence to treatments plans is estimated to cause ~125,000 deaths/year.[8] • Non-adherence also leads to billions of dollars in potentially avoidable costs.[24] • Obesity severely decreases functional status and quality of life.[25] • Although treatment of major depression can improve quality of life, patients still have poor quality of life even when symptoms are in remission following treatment.[7] • Asthma,[26,27] diabetes,[6] COPD,[28] heart disease,[29] and cancer[22] are also associated with increased mortality and decreased quality of life and functional capacity compared with patients that do not have these diseases. • About 25 percent of Americans have multiple chronic diseases,[30] compounding negative health effects.[31,32]

	USE OF HEALTH SERVICES/PRODUCTIVITY: • More than 75 percent of health care costs are attributable to chronic conditions.[33] • About 25 percent of people with chronic diseases report that they have ≥1 daily activity limitations.[13] • Obesity significantly increases health care utilization and direct medical costs as well as indirect costs such as lost productivity due to absenteeism and working while sick (presenteeism), increased disability, and premature mortality.[34]
How strongly does the overall societal burden suggest that CER on alternative approaches to this problem should be given high priority?	FACTORS IN FAVOR: • High potential for positive impact on a huge disease population. • Improving adherence to medications has the potential to greatly improve morbidity and mortality. • Behavioral modification can result in positive spillover effects for patients with multiple chronic conditions. • Potential for increased productivity if chronic disease(s) are controlled due to improved medication adherence. • Improving adherence to medications can improve patient safety. FACTORS AGAINST: • Interventions may be costly and time consuming. • Lack of sufficient infrastructure to implement multicomponent interventions, such as access to resources involving technology, funds, and trained staff. • Adherence to medications can be difficult to measure.
Options for Addressing the Issue	
Based on recent systematic reviews, what is known about the relative benefits and harms of available management options?	BENEFITS: HIV:[15,16,35] • Saberi, et al found that multicomponent interventions had a positive impact on antiretroviral medication adherence in patients with HIV.[15] o Multi-component Interventions: electronic reminder devices (including alarms, electronic pillboxes, and pagers), mobile telephones, PDAs, computer software, and Internet & mobile applications. • Two systematic reviews reported an improvement in adherence after implementation of multicomponent interventions that included an education program compared with standard care.[16,35] o Nurse delivered multi-component interventions included: home visit; providing a watch with a programmable timer to facilitate pill taking; promoting treatment self-efficacy; and semi-structured phone calls.[16] o Multicomponent intervention: defined as a program with individual education with between 1 and 3 additional interventions (e.g., self-management training, counseling, phone support, home visits, pill-sorting boxes, and med planners).[35] COPD:[36]

	• A majority of the studies (5) reported an improvement in adherence in COPD patients at 6 to 12 months after multicomponent interventions were implemented. o Multi-component intervention included: face-to-face motivational interviews, provision of medication table, education about symptom control, telephone follow-up, integrated self-management and co-ordination of care, visit by nurse/provider weekly phone calls, and follow up. Depression:[17] • Systematic review including 32 studies found improvement in adherence due to multicomponent interventions for depression (adherence improvement OR=2.22; 95% CI: 1.67, 2.96). o Multi-component intervention: Collaborative care model (case managers to link primary care provider with mental health specialists). • Multicomponent interventions were also shown to improve clinical end points (e.g., treatment response, remission, and depression symptoms). Chronic conditions in general:[18] • A majority of studies were performed in the United States and evaluated multiple chronic conditions. • Six out of the eight evaluable studies reported improvements in adherence after implementation of multicomponent interventions. o Multicomponent intervention: Unit-of-use packaging combined with med education, adherence education, packaging education, mailed refill reminders, phone or mail contact if refills were missed, and customized dosing schedules. POTENTIAL HARMS: • Use of inefficacious multicomponent interventions would waste provider time and health care resources. • There was limited evidence of specific harms related to multicomponent interventions in the identified reviews.
What could new research contribute to achieving better patient-centered outcomes?	• Comparative effectiveness research could identify which multicomponent elements are most effective and efficient for improving adherence. • Comparative effectiveness research on patient preferences for specific components of multicomponent interventions could increase patient satisfaction and adherence.
Have recent innovations made research on this topic especially	• Increased availability of smart phones and other telecommunication technologies provides an additional portal for multicomponent interventions. • Electronic monitoring devices offer technologically advanced methods to monitor exposure to each component of a multicomponent intervention to improve patient adherence.[37]

compelling?	
How widely does care now vary?	- We did not find data to assess care variation for the use multicomponent vs. single component interventions to improve adherence but their use likely remains relatively low. - Based on systematic review of the current literature, multicomponent interventions vary in adherence results; however, most have reported a positive association. [15-18,35,36]
What is the pace of other research on this topic as indicated by recent publications and ongoing trials?	ClinicalTrials.gov Search: "adherence" AND "chronic disease" - Completed: 149 studies - Open: 193 studies - Note: Most of the studies focused on: COPD (40); Depression (10); Diabetes and related (33); Hepatitis C (24); HIV (14). Search: "adherence" AND "multicomponent" - Completed: 8 studies - Open: 10 studies - Note: Most of the studies focused on: HIV (3); Diabetes (2); Search: "adherence" AND "multicomponent" AND "chronic disease" - Completed: 1 study - Open: 1 study - Note: Studies were on HIV and peptic ulcer disease. NIH Reporter Search: "adherence" AND "multicomponent" - Projects: 50 - Publications: 282 Search: "adherence" AND "chronic disease" AND "multicomponent" - Projects: 16 - Publications: 26 SUMMARY: - Most studies have focused on HIV. - Chronic disease studies are limited (e.g., COPD, depression).
How likely is it that new CER on this topic would	- CER on the use of multicomponent interventions is somewhat likely to inform clinical decision making, especially in health systems with good care coordination.

provide better information to guide clinical decision making?	• However, randomized studies that can identify the independent effects of each component of a multicomponent intervention are difficult to design and conduct given the need for multiple treatment arms and large sample sizes.
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: • Provider burden and potential for silo mentality. • Patient and health system burden related to increased office visits and investments in infrastructure (e.g., staff training and technology). • Coverage and reimbursement by health care payers. • Multicomponent interventions may be system specific and difficult to transfer to other health systems. FACILITATORS: • Feasibility of designing multicomponent intervention (i.e., multicomponent interventions often involve combining existing interventions into a cohesive package). • Technological advances may facilitate care coordination and the use of multicomponent interventions. • Incentives to use electronic medical records may provide a portal for physician offices and medical centers to utilize technology for innovative practices.
How likely is it that the results of new research on this topic would be implemented right away?	• Moderate—conditional upon the level of evidence supporting the use of multicomponent interventions and stakeholder preferences. • If it is technologically complicated, implementation within a health system could take a long-time. • Lack of empirical evidence and a cohesive definition of multicomponent interventions to improve adherence may limit widespread adoption.
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 be expected to be somewhat durable; however, this will depend heavily on the specific component of the intervention, the disease, and the level to which the interventions are aligned with patient and provider preferences.

COPD = chronic obstructive pulmonary disease

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Topic 3: Communication Technologies and Patients with Chronic Conditions

What are the comparative effects of different communication technologies (e.g., mobile health, telehealth, Skype) used in care management on the outcomes of patients with chronic conditions?

Criteria	Brief Description
Introduction	
Overview/ definition of topic	OVERVIEW: • Chronic illnesses, defined as diseases of long duration and generally slow progression,[1] are costly, complicated to manage, and common. • Most common chronic diseases in the United States are (% of Americans affected): o Obesity (36%)[2] o Depression (9.1%)[3] o Asthma (8.4%)[4] o Diabetes (8.3%)[5] o Chronic obstructive pulmonary disease (COPD) (6.3%)[6] o Heart disease (6.0%)[7] o Cancer (2.8%)[8] • Most care models are designed to address acute health problems and do not adapt well to chronic diseases.[9,10] TOPIC DEFINITION: • The brief focuses on how communication technologies facilitate care management or integrated care (i.e., interactions between providers and their patients) and improve patient outcomes. o Telemedicine is defined as communication technologies that facilitate medicine practiced at a distance.[12] • Communication technologies have primarily been used to: o Provide patient education to improve self-management. o Facilitate information exchange between patient and provider (e.g., telemonitoring and telephone support or follow up).[12-16] • There are two broad classifications of communication strategies: o Synchronous interactions which take place in real time such as videoconferencing and Skype. o Interactions in which information is stored for later response such as email or discussion/bulletin boards. • Examples of interventions: o Routine voice contact with a person such as a case manager, nurse specialist, or pharmacist. o Voice contact with an interactive voice response (IVR) system. o Video contact with a health professional, e.g., videoconferencing. o Messaging with a health professional, e.g., using email, web messaging, or online chat. o Telemonitoring, e.g., automatic transmission of data such as symptoms or vital signs.
Relevance to patient-centered outcomes	• Communication technology to support integrated care or care management can impact patient adherence, patient engagement, satisfaction, quality of life, and, ultimately, morbidity and mortality.

Burden on Society	
Recent incidence and prevalence in populations and sub-populations	PREVALENCE • >130 million Americans (~42%) have a chronic condition[5] INCIDENCE: Most common (% of Americans diagnosed per year) o Obesity (4%)[17] o Depression (6.7%)[18] o Asthma (0.36% for adults; 1.3% for children)[19] o Diabetes (0.62%)[20] o COPD (3.8%)[21] o Heart disease (0.4%)[22] o Cancer (0.53%)[23]
Effects on patients' quality of life, productivity, functional capacity, mortality, and use of health services	• QUALITY OF LIFE/FUNCTIONAL CAPACITY/MORTALITY o 70 percent of deaths in U.S. per year are from chronic diseases.[5] o Non-adherence to treatment plans are estimated to cause ~125,000 deaths/year.[24] o Non-adherence also leads to billions of dollars in potentially avoidable costs to both the health care system and the patient.[25] o Obesity severely decreases functional status and quality of life independent of the effects of the diseases with which it is associated.[26] o Although treatment of major depression can improve quality of life, patients still have poor quality of life even when symptoms are in remission following treatment.[27] o Asthma,[28,29] diabetes,[30] COPD,[31] heart disease,[32] and cancer[23] are also associated with increased mortality and decreased quality of life and functional capacity compared with patients without these diseases. o About 25 percent of Americans have multiple chronic diseases,[33] compounding negative health effects.[34,35] • USE OF HEALTH SERVICES/PRODUCTIVITY o More than 75 percent of health care costs are attributable to chronic conditions.[36] o About 25 percent of people with chronic diseases report that they have ≥1 daily activity limitations.[5] o Obesity significantly increases health care utilization and direct medical costs, as well as indirect costs such as lost productivity due to absenteeism and working while sick (presenteeism), increased disability, and premature mortality.[37]
How strongly does the overall societal burden suggest that CER on alternative approaches to this problem should be given high priority?	FACTORS IN FAVOR • High potential for positive impact on diseases that are hugely burdensome to patients and society and that are currently not well managed. • There are many financial incentives for using communication technologies to improve integrated care/care management for patients with chronic diseases. FACTOR AGAINST • These technologies or interventions will require the active participation of the patient, which may be difficult in the chronically ill.
Options for Addressing the Issue	
Based on recent systematic reviews, what is known about the	• Six reviews were identified covering a broad range of telemedicine interventions and chronic diseases. BENEFITS *Diabetes:*

relative benefits and harms of available management options?	• Asynchronous communication both in addition to usual care and as an alternative to usual care demonstrated a trend toward improved HbA1c, HDL, total cholesterol, weight, and blood pressure, but not consistently across studies.[12,14,15] *Hypertension* • Blood pressure telemonitoring resulted in improved control of blood pressure.[12,13] • Most studies did not find significant impacts on quality of life or health care utilization.[12,13] *Congestive heart failure (CHF)* • Asynchronous communication resulted in improvements in adherence when patients discussed their medical records with their physicians.[14] • Telemonitoring reduced all-cause mortality and CHF-related hospitalizations, improved quality of life, reduced costs, and improved quality of care.[12,16] • Structured telephone support reduced CHF-related hospitalizations and costs and improved quality of life and overall quality of care.[12,16] *Asthma:* • Internet-based support resulted in improved lung function and asthma control and was correlated with the frequency of use of the intervention.[14] • Telemedicine interventions improved quality of life.[12,14], o They were correlated with non-significant decreases in health care utilization (physician visits).[14] *COPD* • Asynchronous communication improved self-management of dyspepsia.[14] • Telehealth care significantly reduced the odds of emergency department visits and hospitalizations but did not improve quality of life or decrease mortality.[16] *Chronic pain, neurological conditions, and unspecified chronic conditions:* • Internet-based self-care resulted in: o Decreased back pain.[14] o Non-significant decreases in health care utilization (physician visits).[14] o Increased self-efficacy in using non-medical techniques to manage pain.[14] o A decrease in fatigue and improvements in self-reported personal wellbeing in multiple sclerosis patients.[14] o Increased knowledge and acceptance of illness, empowerment, and social support among rural women with unspecified chronic illness.[14] o Improvements in functioning and self-care and reductions in health-related distress among patients with chronic back pain.[14] POTENTIAL HARMS • Breaches of privacy and patient confidentiality o A survey conducted in 2009 found about 30% of respondents felt the privacy risks outweighed the potential benefits of health IT.[38] • There are potential risks for people who may not be able to distinguish acute (life-threatening) conditions from more benign conditions, in terms of choosing the most appropriate form of communication to their provider (e.g., asynchronous communication may not be appropriate in an acute life-threatening complications of chronic disease, while there is potential for wastage of resources for benign conditions).[14]
What could new research contribute to	• Comparative effectiveness research on alternative communication strategies, e.g. telephone vs. internet-based communication, could inform which strategies work best. • Comparative effectiveness research on patient and provider preferences for these

achieving better patient-centered outcomes?	technologies could enhance clinician and patient participation, satisfaction, and shared decision-making. • New research on the preferred technologies for the less tech-savvy could increase the coverage of these potentially beneficial technologies. • New research could determine which additional chronic disease areas are amenable to improvement with the use of these technologies, i.e. cancer, obesity, and depression. • New research could identify the outcomes that are most important to patients (and providers) with respect to communication technologies (e.g., psychosocial, behavioral, knowledge, health utilization, costs, and quality-of-life outcomes). • Comparative effectiveness research could determine the long-term outcomes of implementing these communication strategies in chronically ill patients. • New research to estimate the most efficient uses of these technology platforms could guide clinical and resource allocation decisions.
Have recent innovations made research on this topic especially compelling?	• Societal trend toward increased use of technology. • Increased research and clinical emphasis on shared decision-making and patient empowerment.
How widely does care now vary?	• Treatments known to be beneficial for chronic illnesses are actually implemented only about 50 percent of the time.[9] • A wide variety of communication technologies could be used; these vary by provider and health system.
What is the pace of other research on this topic as indicated by recent publications and ongoing trials?	Clinicaltrials.gov Search: ("telemedicine" OR "telehealth") AND chronic disease Total ongoing studies: 47 Total completed trials: 34 *Most related to mental disorders, obesity, inflammatory bowel disease, heart failure, diabetes & other endocrine disorders, COPD and asthma* NIH Reporter Search: (telemedicine OR telehealth OR eHealth) AND "chronic disease" Projects: 16 Publications: 63
How likely is it that new CER on this topic would provide better information to guide clinical decision making?	• The current evidence suggests that telemedicine is a promising tool to improve care management of chronically ill patients. New CER would likely guide both clinical and resource allocation decisions regarding which communication strategies to implement and how to implement them to improve patient outcomes.
Potential for New Information to Improve Care and Patient-Centered Outcomes	
What are the facilitators and barriers that would affect the	BARRIERS • Difficulties with creating and implementing user-friendly forms of health IT.[39] • Provider concerns about unreimbursed time to learn and implement technologies, disruption of workflow, and additional liabilities.[39]

implementation of new findings in practice?	• Potential for breaches of confidential health information.[39] • Patient and provider concerns about the depersonalization of the patient/provider relationship.[39] • Many health information technology (IT) applications are not standardized and cannot interface with one another, or other technology infrastructure (e.g. electronic health records).[39] • High up front implementation costs. • Access to ability to use required technologies. FACILITATORS • High rates of satisfaction with health IT applications can encourage patients and providers to implement them.[39] • Competition between health care providers. • Potential long-term cost savings. • Technological advancement. • High penetration of a wide variety of communication technologies (e.g., email, Skype, mobile phones, Internet discussion boards, and chat rooms). • The marginal cost of using some communication technologies is low (i.e., many people have access to the Internet, telephone service, and smart phones for other purposes).
How likely is it that the results of new research on this topic would be implemented right away?	• While utilization of health IT is currently low, the societal trend is toward more use of technology. • Health systems have financial incentives to implement health IT so results of new research would likely be prioritized. • Large infrastructure changes require long-range planning and timelines.
Would new information from CER on this topic remain current for several years or would it be rendered obsolete quickly by subsequent studies?	• New CER on the impact of communication technologies on patient-reported outcomes will be durable; however, the specific technologies may evolve over time.

CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; IT = information technology; IVR = interactive voice response

References for Topic 3: Communication Technologies and Patients with Chronic Illness

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Topic 4: Patient and Caregiver Engagement in Chronic Mental Illness

Compared to usual care, do treatment strategies that involve both patients and their families/caregivers improve outcomes among patients with chronic mental illness (e.g., bipolar disorder and major depression), including members of historically underserved populations?

Criteria	Brief Description
Introduction	
Overview/ definition of topic	• This brief examines the impact of involving families and/or caregivers in the treatment of patients with serious chronic mental illness, with a focus on bipolar disorder and major depression. • Serious mental illnesses include major depression, schizophrenia, bipolar disorder, obsessive compulsive disorder (OCD), panic disorder, posttraumatic stress disorder (PTSD), and borderline personality disorder.[1] • Treatments for mental illnesses primarily include the use of medications and psychosocial interventions. • Including family members or caregivers in the treatment of mental health conditions can include: [2] o Family/caregiver education and involvement in care planning and self-management activities. o Family/caregiver-assisted treatment, in which family members or caregivers act as surrogate therapists. o General or disorder-specific family/caregiver treatment, in which family/caregiver behaviors theorized to fuel symptoms are directly addressed.
Relevance to patient-centered outcomes	• Involvement of family members and caregivers may impact treatment adherence, social support, treatment satisfaction, quality of life, and mortality of patients with mental illnesses.
Burden on Society	
Recent incidence and prevalence in populations and sub-populations	• Mental illnesses overall are the leading cause of disability in the United States and affect an estimated 26.2 percent of adult Americans in a given year.[3,4] • Nearly 50 percent of U.S. adults will develop at least one mental illness during their lifetime.[5] • **Major depression:** o Affects approximately 14.8 million American adults, or about 6.7 percent of the U.S. population age 18 and older in a given year.[3,6] o Lifetime prevalence of 16.2 percent.[7] o Depression is often not recognized, diagnosed, or treated by primary care providers.[8] • **Bipolar disorder:** o Affects approximately 5.7 million American adults, or about 2.6 percent of the U.S. population age 18 and older in a given year.[3,6] o Lifetime prevalence of nearly 4 percent.[9] • There is limited data on the burden to family members and caregivers of patients with serious mental illness.
Effects on patients'	**QUALITY OF LIFE/FUNCTIONAL CAPACITY/MORTALITY**

quality of life, productivity, functional capacity, mortality, and use of health services	• The effects of mental illnesses include disruptions of daily function; incapacitating personal, social, and occupational impairment; and premature death.[5] • **Major depression:** o Associated with an increased risk of mortality.[10] o Leading cause of disability in the United States for ages 15-44.[4] o Poorer health status[11] and lower scores on physical and emotional function compared to patients with other chronic conditions.[12] o Has long-lasting decrements in psychosocial functioning that are equal to or greater to those of patients with diabetes and osteoarthritis.[13] o Difficulty with intimate relationships and less satisfying social interactions.[14] o Higher levels of household strain, social irritability, financial strain, and limitations in occupational functioning.[15] o Often negatively affects the course of many other chronic diseases, such as stroke, diabetes, cancer, Parkinson's disease, and HIV/AIDS.[16] • **Bipolar disorder:** o Bipolar patients had lower health-related quality of life (HRQOL) compared with other medical conditions including early heart surgery, asthma, obesity, and oxygen dependency.[17] o The majority of patients report a profound effect of bipolar disorder on their ability to have good education, meaningful vocation, financial independence, and healthy social and intimate relationships.[18] o Suicidal rate per year of bipolar disorder patients is estimated to be 0.40% per year, 22 times greater than the general population.[19] USE OF HEALTH SERVICES/PRODUCTIVITY • Mental disorders led the list of the five most costly conditions in 2006.[20] • Treatment of mental disorders is also associated with significant out-of-pocket payments.[20] • Seriously mentally ill older adults had higher rates of emergency care, longer hospitalizations, increased frequency of falls, substance abuse, and alcoholism compared with primary care patients.[21] • **Major depression:** o The cost of mental health care in the United States in 2006 was estimated to be $57.6 billion, equivalent to the cost of cancer care.[22] o Patients with major depression are among the highest users of health care and incurred substantial indirect costs resulting from premature deaths, reduced productivity, and increased disability associated with the disease.[23] o More annual sick days and higher rates of short-term disability than other chronic diseases.[16] o African Americans and Mexican Americans are the least likely to receive depression care, especially guideline-concordant care.[24] o Higher psychotherapy versus pharmacotherapy use, especially among ethnic/racial minorities facing disparities in depression care.[24] • **Bipolar disorder:** o The economic burden of bipolar disorders was approximately $151 billion dollars in the United States in 2009.[25]

	o In a national database of insurance claims: ▪ 40% of all claimants who filed a behavioral health care claim had bipolar disorder.[26] ▪ 3% of all claimants had bipolar disorders, but they accounted for 12% of total expenditures.[26] o The inpatient hospitalization rate of bipolar patients was more than eight times greater than that for all other patients with behavioral health care diagnoses (39.1% vs. 4.5%).[9] o Both annual insurance payments and annual out-of-pocket expenses were greater for persons with bipolar disorder than for those with other behavioral health care diagnoses.[26]
How strongly does the overall societal burden suggest that CER on alternative approaches to this problem should be given high priority?	FACTORS IN FAVOR • Large affected population with high levels of disability and health care utilization. • Family members and caregivers may also benefit from the education about the illness, its effects on functioning, and its treatment.[27] FACTOR AGAINST • Developing and advancing a psychosocial intervention appropriate for testing in an randomized control trial can take a long time given the need to recruit both patients and family members.[28] • It can be difficult to recruit both mental health patients and their families for participation.[28]
Options for Addressing the Issue	
Based on recent systematic reviews, what is known about the relative benefits and harms of available management options?	BENEFITS • Multiple reviews have evaluated the addition of family members or caregivers to therapeutic plans for patients with mental illness.[2,28-31] • The Veterans Affairs Evidence-based Synthesis Program reviewed evidence from the United States from 1995 to 2011 on efficacy and effectiveness of family involved psychosocial treatments, including general family therapy, disorder specific family therapy, marital psycho-educational therapy, family-focused therapy, and family-focused health promoting interventions. o Generally, family-involved treatments were as or more effective than alternative psychotherapies, with two exceptions in PTSD and male opioid users with pregnant female partners.[28] o The strength of evidence was generally low except for substance abuse, which had moderate quality evidence.[28] o Randomized trials of family interventions for mental health conditions were especially sparse for PTSD, anxiety disorders, sexual functioning, depression, eating disorders, and personality disorders.[28] o Patient-centered outcomes, including treatment adherence, social support, treatment satisfaction, couple/family conflict, and couple/family communication were rarely reported.[28] • **Bipolar disorders** o Evidence from other countries failed to demonstrate a significant added effect for family intervention as an adjunctive treatment to pharmacotherapy for bipolar disorders.[31]

	• **Major depression** o The current evidence was too sparse and heterogeneous to draw conclusions on the overall effectiveness of family therapies in the treatment of depression in comparison to other interventions.[28-30] POTENTIAL HARMS • No evidence of significant negative impacts on patient outcomes.[2,28-31] • Families can provide an important source of potential stress that may exacerbate mental health symptoms.[2] • Engagement in the treatment of mental illnesses may also exert a great amount of burden on family members or caregivers.
What could new research contribute to achieving better patient-centered outcomes?	• Well-designed comparative effectiveness studies to replicate preliminary findings in patients experiencing high levels of family distress or more severe symptoms.[28] • Comparative effectiveness studies comparing family/caregiver interventions to interventions directed solely at patients.[28] • Comparative effectiveness studies directly comparing different types of family interventions.[2] • Comparative effectiveness studies focused on resource utilization and relevant patient-centered outcomes including treatment adherence, social support, treatment satisfaction, couple/family conflict, couple/family communication, and intimate partner violence.[28] • Comparative effectiveness studies that include appropriate inclusion of ethnic/racial groups and underrepresented groups to understand disparities in care use, especially guideline-concordant use.[24] • Comparative effectiveness studies to examine the effects of family involved interventions on caregiver outcomes, patient preferences, and methods of engaging patients and their families in family treatment.[28] • Comparative effectiveness research to examine if the effects of family-involved interventions vary between adults and children or for various family structures or sizes.
Have recent innovations made research on this topic especially compelling?	• No major innovations. • There are numerous family-involved interventions that are in various stages of development or are currently being evaluated (e.g., Family Member Provider Outreach Program, Coaching into Care, REACH).[28]
How widely does care now vary?	• The National Comorbidity Study Replication showed that less than half of patients with mental disorders received any treatment in the previous 12 months and only one-third of treatments met minimal standards of adequacy.[32] • Given the paucity of the evidence, it is unlikely that this intervention is widely used.
What is the pace of other research on this topic as indicated by recent publications and	<u>Clinicaltrials.gov</u> Search: “mental illness” AND “family engagement” Total ongoing trials: 1 *study* Total completed trials: 0 *studies* • *Study: Family-centered mental health treatment of children.*

ongoing trials?	Search: “mental illness” AND “engagement” Total ongoing trials: 127 *studies* Total completed trials: 260 *studies* *A minority of these studies are about engaging family members or caregivers in the treatment of mental illnesses.* • *Bipolar disorder: 8 studies* • *Major depressive disorder: 10 studies* • *Depressive disorder: 48 studies* Search: “mental illness” AND “family” Total ongoing trials: 437 *studies* Total completed trials: 1028 *studies* *A minority of these studies are about engaging family members or caregivers in the treatment of mental illnesses.* • *Bipolar disorder: 51 studies* • *Major depressive disorder: 79 studies* • *Depressive disorder: 236 studies* NIH Reporter Search: “mental illness” AND “family engagement” Projects: 1 *(Include engaging family members or caregivers)* Publications: 7 *(3 include engaging family members or caregivers)* Search: “mental illness” AND “engagement” Projects: 80 Publications: 856 • *Very few projects or publications include engaging family members or caregivers.* Search: “mental illness” AND “family” Projects: 638 Publications: 112 • *Very few projects or publications include engaging family members or caregivers.*
How likely is it that new CER on this topic would provide better information to guide clinical decision making?	• New CER that confirms the initial positive efficacy and effectiveness estimates in larger populations is very likely to inform 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?	BARRIERS - Family therapies are not well-defined interventions, which could limit the generalizability of study results. - Use of patient-only psychological interventions for the treatment of depression is standard care with good supporting evidence.[27,30] - There are limited financial incentives for psychosocial treatments.[32] - Need to gain patients' permission to engage their family members or caregivers in the treatment. - Patients and their families may have different preferences regarding which family member to engage and to what extent. - Highly variable process by which psychosocial therapies are validated and coverage determinations are made.[33] - Provider burden given necessary training and supervision. FACILITATORS - The Patient Protection and Affordable Care Act (ACA) could increase access to mental health care by offering new choices for good quality, reliable, low cost private health insurance and by opening Medicaid to more people with mental illness.[34] - Family members are motivated to participate.
How likely is it that the results of new research on this topic would be implemented right away?	- If new research confirms early effectiveness estimates, inclusion of family/caregiver engagement could be readily incorporated into practice, given it did not rely on technology or large organizational changes. - The implementation of therapeutically-related interventions may be somewhat slowed by the lack of evidence-based standards on the appropriate levels of training necessary for family members or caregivers.[33]
Would new information from CER on this topic remain current for several years or would it be rendered obsolete quickly by subsequent studies?	- Comparative effectiveness research to evaluate the effectiveness of engaging family members or caregivers in the treatment of mental illness is likely to remain current for several years. - However, the specific methods through which families and/or caregivers are engaged are likely to vary and evolve.

ACA = Affordable Care Act; PTSD = posttraumatic stress disorder; OCD = obsessive compulsive disorder

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Topic 5: Rural and Frontier Trauma

Compared with direct transportation to a regional trauma center, what is the effect of stabilization at a local hospital (followed by transfer to a regional trauma center) on survival and other patient-centered outcomes?

Criteria	Brief Description
Introduction	
Overview/definition of topic	DESCRIPTION OF CONDITION • Patients with severe trauma in civilian rural and frontier settings. Severity of injury is defined using a scoring system such as the Injury Severity Score (ISS) or New Injury Severity Score (NISS).[1] ISS and NISS scores are anatomical scoring systems that provide overall scores for patients with severe traumatic injuries. Values above 15 indicate severe level of injury in one to six body regions (head, chest, abdomen, extremities). • Patients with severe trauma who require direct transport by either ground or air emergency medical services to a trauma center or a local hospital with follow-on transfer to a trauma center. • Transport destination decision criteria are based on triage protocols, availability of beds, and availability of air-emergency medical services. • Referral bias favors younger patients transported to trauma centers, specialist availability, and triage team readiness.[1]
Relevance to patient-centered outcomes	TRAUMA CHARACTERISTICS[1] • Injury severity • Type of injury • Mechanism of injury OTHER PATIENT CHARACTERISTICS[1] • Medical comorbidities • Age (e.g., pediatric or elderly), sex • Pregnancy PATIENT-CENTERED OUTCOMES[1] • Mortality: prehospital mortality, inpatient mortality, posthospital mortality (within 1 year of discharge) • Morbidity: complications during operations, rate of infections, thromboses/emboli, secondary complications post-discharge • Pain and discomfort • Functional capacity: level of disability following trauma • Psychological disability • Time to return to work • Quality of life • Out-of-pocket costs • Time to hospital discharge
Burden on Society	
Recent prevalence in populations and subpopulations	PREVALENCE • In the United States, injury is the leading cause of death for individuals under age 45.[2] In 2010, injuries accounted for over 181,000 deaths in the United States.[1] In 2008, 30 million injuries required an injured person to visit an emergency department; 5.4 million (18%) of these injuries required EMS transports.[1] • More than 38 million people in the United States do not have access to a certified trauma center within a 1-hour drive from their homes.[3] Rural populations have a two-fold increase in injury severity and mortality rates relative to urban and suburban counterparts.[4] Disparities in access to care are more pronounced in rural areas compared with urban

Criteria	Brief Description
	areas and for certain subgroups, including African American and foreign-born patients, patients of low socioeconomic status, and the elderly.[3] • Injuries represent a heavy economic burden in the United States and are one of the leading contributors to long-term disability and short- and long-term loss of quality of life.[5] Fatality rates are disproportionally higher when injuries occur in rural areas. Rural fatality rates are more than twice as high as urban rates for a variety of injuries including motor vehicle crashes, traumatic occupational injuries, drowning, unintentional firearm injuries, residential fires, and electrocutions.[4] • One of the major factors associated with increased risk in rural populations is access to emergency medical services in the form of availability of professional and paraprofessional service providers.[6]
Effects on patients' quality of life, productivity, functional capacity, mortality, use of health care services	• Health-related quality of life: A significant number of patients experience significant deficits in physical and emotional functioning following a severe traumatic injury.[7] • Productivity: Traumatic injury is the leading factor associated with loss of productivity and capacity to return to work. [7] Between 80,000 to 90,000 individuals with traumatic brain injury (TBI) experiencing long-term or permanent disability each year in the United States.[7,8] • Health care service utilization: Additional health care needs might include home health; physical, occupational, and speech therapy; skilled nursing; and rehabilitation post-hospital discharge in the short and long terms.[7,9]
How strongly does this overall societal burden suggest that CER on alternative approaches to this problem should be given high priority?	• In the United States, injury is the leading cause of death for individuals under the age of 45. Given the almost twice as high fatality rates for rural compared with urban patients, CER on alternative approaches to reduce the inequalities in adverse outcomes seems paramount. Studies, however, also need to take issues of infrastructure of care into consideration. For example, the transfer of less severely injured patients to Level 1 trauma centers can overburden the center and can negatively impact patient outcomes relative to stabilization at a local emergency room and subsequent transfer. Moreover, extant research has primarily used urban and suburban samples with limited data with rural samples. Insufficient research on effective field triage for rural patient populations has been conducted and thus should be given high priority.[1]
Options for Addressing the Issue	
Based on recent systematic reviews, what is known about the relative benefits and harms of the available management options?	• We could not locate any systematic reviews addressing this topic. • We found three cohort studies that assessed differences between direct transports to a trauma center and indirect transports (i.e., transports of injured patients from the scene to a local hospital with subsequent transfer to a trauma center).[9-11] Two studies determined differences in mortality,[10,11] and the third study assessed differences in costs between direct and indirect transport in a Canadian rural setting.[9] In summary, the available studies indicate that direct transport to a trauma center reduces mortality in severely injured patients and is less expensive than initial transport to a regional hospital with subsequent transfer to a trauma center. In the larger study (n=1,112) that assessed mortality, triaging severely injured patients to hospitals that were incapable of providing definitive care was associated with a 3.8 times greater risk of death (odds ratiodds atio [OR] 3.8, 95% confidence interval 1.6–9.0). This finding, however, was not specific to rural areas.[11] The analysis involved secondary data from a multicenter trial with 19 university medical centers but specifically looked at patients who underwent direct triage to a Level 1 trauma center compared with patients first seen a nontrauma center and later transferred to a trauma center.[11] • Likewise, in the second cohort study, indirect transport of patients with TBI resulted in a statistically significantly higher risk for mortality at 2 weeks compared with direct transport (OR 1.48, 95% confidence interval 1.03–2.12).[10] Mode of transport (air vs. ground) and prehospital intubation did not significantly predict mortality at 2 weeks.[10] • In a Canadian rural setting, direct transport was also cheaper than indirect transport, both with ground (Canadian$ 4,987 vs. 3,847 [year 2000]) and helicopter transport (Canadian$ 7,426 vs. 7,680 [year 2000]).[9]
What could new research contribute	• The available evidence suggests greater benefits for patients with TBI who have a direct transport to a trauma center than for those who receive an initial stabilization in a local

Criteria	Brief Description
to achieving better patient-centered outcomes?	hospital. The available evidence, however, has considerable limitations with respect to study design (retrospective cohort studies) and applicability. Both of the two studies assessing mortality were conducted in suburban settings, so they might have limited applicability to rural or frontier settings. Consequently, the strength of the available evidence is low. • New CER would have to investigate a broader population of critically injured patients than the current studies do. In addition, new research needs to focus on subgroups with respect to injury severity, type of injury, and patient characteristics (e.g., age, pregnancy, race/ethnicity) to determine who benefits the most and who benefits the least from direct transport to trauma centers. • To contribute to achieving better care, it is crucial that new CER focus on patient-relevant outcomes other than mortality and for research to examine whether limited access is related to worse patient-centered outcomes beyond mortality.
Have recent innovations made research on this topic especially compelling?	• Trauma care has advanced greatly over the past decades. Hypotensive resuscitation, establishment of trauma systems and in-hospital trauma protocols, minimally invasive trauma surgery, and selective conservatism are among the main recent developments. Rapid access to adequate trauma care can determine patient-centered outcomes of critically injured patients.
How widely does care now vary?	• Rural trauma care varies considerably based on local resources, geographic distance to the closest local hospital for stabilization, availability of air versus ground transport, types of service provider teams and the level of services provided on the transport, availability of beds at the trauma center, and local guidelines for interhospital transfer for rural trauma patients.
What is the pace of other research on this topic (as indicated by recent publications and ongoing trials)?	• Our searches revealed only one ongoing study that is relevant to this topic. We did not find any ongoing or completed and unpublished studies in ClinicalTrials.gov. • One ongoing study identified through NIH reporter is on the impact of pediatric trauma centers on the outcome of injured children in Ohio. Because most injured children are treated in centers that lack trauma center designation and do not consistently, if at all, report trauma-related data, a significant gap in knowledge exists regarding the volume, treatments, and outcomes of injured children. Adding in data from nontrauma centers will allow the investigators to evaluate in-hospital mortality, length of stay, operations, and complications by relevant covariates based on treatment site. Patients transferred from the scene to a nontrauma center will be compared with those transferred directly from the scene to a designated trauma center. Results from this study will provide important information about statewide pediatric injury rates in rural areas. Maps of injury burden, resources, and access will be generated. They will estimate both distance traveled and time elapsed between injury and admission to the final point of care to characterize the relationship between rurality and treatment of pediatric trauma. This study is expected to be completed by July 2015.
How likely is it that new CER on this topic would provide better information to guide clinical decision making?	• New CER could reduce current gaps in the evidence and uncertainties by conducting more methodologically sound prospective research in rural or frontier settings. Although evidence gaps have not been systematically investigated, the most recent the Centers for Disease Control and Prevention (CDC) guidelines state that proximity to trauma centers, use of air medical services, integration of local hospitals for initial stabilization, and secondary triage at nontrauma hospitals are poorly understood.[1] Thus, new CER has the potential to influence current triage models, shape guidelines such as the Guidelines for Prehospital Management of Traumatic Brain Injury and CDC's Prevention's Guidelines for Field Triage of Injured Patients and ultimately lead to better patient-centered outcomes.[1,12]
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	FACILITATORS[13,14] • Administrative support and availability of resources for staff in all facilities involved (e.g., local hospitals, hospital, trauma centers) • Established trauma systems BARRIERS [13,14]

Criteria	Brief Description
practice?	• Complexity of trauma presentations/characteristics will always influence transport destination decision criteria and this may lead to variability in implementation of new findings. • Limited infrastructure and information systems particularly for rural areas. • Staff training availability, resistance, and/or noncompliance.
How likely is it that the results of new research on this topic would be implemented in practice right away?	• Given the paucity of research in this area, it is difficult to predict if results from new research will be implemented right away. If information garnered from CER shows similar outcomes to currently used methods, it is unlikely that results from new research will be implemented right away. Further, implementation depends on availability of resources and technology in specific rural areas. • Resources such as CDC's Guidelines for Field Triage of Injured Patients and Guidelines for Interhospital Transfer of Injured Patients for Rural Communities would need to be updated first with evidence from newer studies to facilitate implementation.[1] However, we found no evidence on the length of time taken to get new evidence into updated guidelines.
Would new information from CER on this topic remain current for several years, or would it be rendered obsolete quickly by subsequent studies?	• Currently few ongoing studies directly relate to this area. For example, studies examining specific characteristics such as injury severity, type of injury, age, and pregnancy status that affect patient-centered outcomes have not been conducted. Information from well - designed studies on this important CER topic would likely remain relevant for several years.

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Topic 6: Medical Homes versus Care Management for Chronic Conditions

Compared with care management supported by insurance companies, what is the effect of care management provided by medical homes (including those with physicians and those with other types of providers e.g., community care, nurse practitioner, physician assistant) on patient-centered outcomes among patients with multiple chronic conditions?

Criteria	Brief Description
Introduction	
Overview/definition of topic	CHRONIC CONDITIONS Although no uniform definition of chronic disease exists, it has been defined through the following recurrent themes: non–self-limited nature; an association with persistent and recurring health problems; and duration measured in months and years, not days and weeks.[1] Both physical and mental health disorders and diseases can be chronic conditions. Children with chronic conditions are often referred to as children with special needs, defined as having chronic physical, developmental, behavioral, or emotional conditions and requiring health and related services of a type or amount beyond that required by children generally.[2] Individuals with chronic conditions, particularly those with multiple chronic conditions, account for a disproportionately large share of health care utilization and costs in the United States.[1] Many have one or more limitations of daily activity or other functional limitations and reductions in quality of life.[3,4] CARE MANAGEMENT FOR INDIVIDUALS WITH CHRONIC CONDITIONS How to optimize care for this patient population at an affordable cost is a major challenge. The concept of chronic care management as a patient-centered and cost-effective approach to managing chronic illness has been evolving for years. The Chronic Care Model (CCM), developed by Wagner (1998), offers a conceptual foundation for improving care.[5] The CCM identifies six elements of a delivery system that lead to improved care for individuals with chronic conditions:[6-8] the community, the health system, self-management support, delivery system design, decision support, and clinical information systems. Currently, two common approaches to care management for people with chronic conditions are the patient-centered medical home (PCMH) and care management programs developed and administered by insurance companies or disease management companies. Both embrace the CCM developed by Wagner to varying degrees. The PCMH embodies the principles established by the American Academy of Family Physicians (2007)[9]and expands on the CCM as a team-based health care delivery model led by a primary care practitioner. Patients in PCMHs are expected to have better access to care and more coordinated care; receive higher quality care; and be more engaged in patient self-management, thereby promoting the “triple aim.”[10] Today’s chronic care management programs evolved from disease management programs

Criteria	Brief Description
	defined by the Disease Management Association of America as having the following attributes: "supports the physician or practitioner/patient relationship and plan of care, emphasizes prevention of exacerbations and complications utilizing evidence-based practice guidelines and patient empowerment strategies, and evaluates clinical, humanistic, and economic outcomes on an ongoing basis with the goal of improving overall health."[11, p. 671] The majority of these programs are external to the primary care office with care managers working remotely with patients. Patients, providers, and payers would benefit from greater evidence concerning the benefits, challenges, and costs related to both of these approaches, both individually and in relation to each other. All payers would benefit from knowing which of these two approaches is more effective and economical.
Relevance to patient-centered outcomes	Care management is expected to influence the following patient-centered outcomes: • Disease-related health outcomes, including functional capacity and mortality • Quality of life • Utilization of services and costs of care, particularly potentially avoidable health care use • Satisfaction with care including knowledge, access, engagement, and improved self-management behaviors
Burden on Society	
Recent prevalence in populations and subpopulations	PREVALENCE In 2005, 133 million Americans—almost 1 out of every 2 adults—had at least one chronic illness.[3] In addition to heart disease, cancer, and stroke, asthma and diabetes are other leading chronic diseases, with diabetes alone affecting 25.8 million Americans in 2010. Diabetes is more prevalent in adults ages 65 or older (26.9%) compared with youth ages 20 or younger (0.25%).[12] One out of four have at least two chronic conditions that require ongoing medical care. The proportion is even higher in the Medicare population, where two-thirds of beneficiaries have two or more chronic conditions and one in seven have six or more chronic conditions.[13] The most prevalent multiple chronic conditions include the following: • One-third of the Medicare population has hypertension and high cholesterol along with diabetes or ischemic heart disease.[13] • Arthritis, which affects 52.5 million adults, is projected to increase to 67 million adults by 2030.[14] Common comorbidities among individuals with arthritis include heart disease (24%), chronic respiratory conditions, and diabetes.[15] • Up to 75% of adults with diabetes also have hypertension, and patients with hypertension also often show insulin resistance.[16] • Many individuals with chronic physical health conditions also suffer from mental health conditions. For example, depression occurs in 27% of diabetes patients and

Criteria	Brief Description
	more than 40% of individuals with cancer.[4] - Multiple chronic conditions have been found to occur in specific combinations. An example of this is metabolic syndrome, which occurs when individuals have at least three of the five following chronic conditions: obesity, hypertriglyceridemia, low-serum high-density lipoprotein, hypertension, and glucose intolerance.[17] According to the National Survey of Children with Special Health Care Needs, 12.8% of children under the age of 18 (9.4 million) are estimated to have special health care needs.
Effects on patients' quality of life, productivity, functional capacity, mortality, use of health care services	MORTALITY Seven out of 10 deaths among Americans each year are from chronic diseases, including heart disease, cancer, and stroke.[3] Among individuals with diabetes, mortality rates increase if individuals also suffer from other chronic conditions. Specifically, among elderly Medicare beneficiaries, mortality rates of 12.8 per 100 are related solely to diabetes, increasing to 24.0 per 100 among those with diabetes and depression and 30.0 per 100 for those with diabetes, depression, and chronic obstructive pulmonary disease (COPD).[18] Similarly, comorbid conditions have been found to be related to increased mortality in elderly cancer patients.[19] QUALITY OF LIFE We found limited data concerning the effect of multiple chronic conditions on quality of life, distinct from having at least one of these conditions. Older cancer patients have a high prevalence of one or more comorbid conditions; the combination has been found to be associated with worse physical and mental health-related quality of life.[20] Among individuals with one or more chronic condition, approximately one-fourth have one or more limitations of daily activity.[3] - Of the 52.5 million adults diagnosed with arthritis, over 42% report attributable activity limitation. In addition, 31% of working-age adults with an arthritis diagnosis report being limited in work because of their condition.[14] - Diabetes increases the risk of progressive neuropathy, retinopathy, and atherosclerotic complications, including heart attack and stroke.[21] Among children with special health care needs, virtually all have one or more functional difficulty (91%), including bodily difficulties (69%), activity and participation difficulties (61%), and other emotional and behavioral-related difficulties (59%).[22] PRODUCTIVITY - Although having one chronic condition can result in reduced productivity, including work impairment, having at least three chronic conditions was found to have a greater effect than the sum of the individual conditions.[23] - Patients suffering from major depression, a common mental health disorder that

Criteria	Brief Description
	often co-occurs with other chronic illnesses, miss an average of 4.8 workdays during a 3-month period. Additionally, patients suffer 11.5 days of reduced productivity, resulting in 200 million lost workdays each year among all depression sufferers. This loss of productivity costs employers $17 to $44 billion each year.[4] HEALTH CARE SERVICE UTILIZATION • Individuals with multiple chronic conditions use a larger array of services and use them more frequently than others. Individuals with only one chronic condition see an average of 4 physicians annually compared with an average of 14 physicians by individuals with multiple chronic conditions. Because of the large number of physicians the patient sees, coordination of care is even more important.[17] • People with chronic diseases account for 81% of hospital admissions, 76% of all physician visits, and 91% of all prescriptions filled.[1] • In 2005, total national health expenditures from all sources, including patient out-of-pocket expenses, equaled $2 trillion; 75% went toward treating chronic diseases. Health care for people with a chronic condition cost $6,032 annually, which is five times higher than for those without these conditions.[1] • The treatment of chronic disease accounts for 99% of Medicare spending and 83% of Medicaid spending.[1] • The Agency for Healthcare Research and Quality found that in 2006 $57.5 billion was spent on mental health care.[4]
How strongly does this overall societal burden suggest that CER on alternative approaches to this problem should be given high priority?	The care for individuals with multiple conditions is very costly.[1] However, higher cost is not necessarily associated with better quality of care, better patient outcomes, or higher levels of patient satisfaction. As the baby boomer population ages, the burden of care for multiple chronic conditions is going to increase, affecting not only the individuals themselves, but also their families and the health care infrastructure overall. To meet this increased burden appropriately, alternative approaches to service delivery and care management are going to be increasingly important. Because chronic conditions are a major component of health care costs in the United States,[1] finding ways to optimize care of individuals with chronic conditions is a high priority.
Options for Addressing the Issue	
Based on recent systematic reviews, what is known about the relative benefits and harms of the available management options?	No systematic reviews were identified that directly compared medical homes with care management programs supported by health insurance companies. We, therefore, focused on the separate bodies of evidence that evaluated the effectiveness of each approach relative to usual care. We also found limited systematic reviews focusing on adults with multiple chronic diseases or children with special health care needs. Therefore, we included reviews of care management of patients with single chronic conditions. Also, we cite, when available, meta-reviews (reviews of systematic reviews) rather than individual systematic reviews.

Criteria	Brief Description
	MEDICAL HOMES Adults: • Although the reviews focused on evaluations of medical homes serving all patients, evidence in several studies suggests that improvements may be more pronounced among sicker patient populations.[24] Many or most of the studies presented do not clearly specify what fraction of patients have multiple conditions or what those conditions are. • The most consistent findings are that medical homes typically show improvements in specific process measures related to quality of care, notably enhanced prevention and chronic disease management, usually defined as reaching process measure outcomes in the treatment of diabetes or hypertension.[25-27] Patient and staff satisfaction are not always, but are typically, improved.[24,25] • One review identified a small but significant reduction in emergency care utilization[28]; based on studies included in three reviews, medical homes typically had no impact on hospital admission rates.[25,27,28] • Only a few studies have evaluated the impact of medical homes on health care costs, and results are mixed. Of the studies included in these systematic reviews, some show slight cost savings, some show greater total costs, but most found no discernable impact.[25-28] • The systematic reviews to date have largely focused on intermediate outcomes, such as preventive care and chronic care management. Data on mortality are limited and so far inconclusive.[24] Children Two systematic reviews focused on children with special health-care needs. Approximately half of children with special health-care needs receive care in a medical home.[26] • For children with special needs, the evidence from a review that included 30 studies supported a positive relationship between being enrolled in a medical home and desired outcomes, such as better health status and timeliness of care.[29] • Patient satisfaction is generally higher with patient-centered medical home programs, although low scores were identified for coordination of referrals, wait times, cultural sensitivity, and connections to outside resources.[26]
	CARE MANAGEMENT PROGRAMS • Among patients with diabetes, one review found limited evidence for improvement in clinical processes of care and A1c levels and insufficient evidence to determine effectiveness on other biomedical and/or physiological health outcomes.[30] • Among patients with COPD, limited evidence, based on a small number of studies, suggests that care management results in improvement in patient satisfaction, self-

Criteria	Brief Description
	management behavior, biomedical and/or physiological health outcomes, quality of life, and mortality.[31] • Limited evidence, based on a small number of studies, suggests a reduction in the total cost of care.[30,31] • Limited evidence, based on a small number of studies, suggests that multiple interventions in asthma or COPD relative to a single intervention or usual care showed improvement in quality of life and rate of hospitalization relative to usual care.[32]
What could new research contribute to achieving better patient-centered outcomes?	Understudied areas include • comparisons of patient-centered outcomes between insurance company-supported care management programs and care coordination received in medical homes; • explicit evaluations of patient-centered outcomes among persons with multiple chronic conditions; generally, individuals included in reviews could have either one or more of these conditions. However, one systematic review was limited to studies of patients with just one chronic condition;[31] and • components of these complex interventions likely to be associated with better patient-centered outcomes.
Have recent innovations made research on this topic especially compelling?	Indicators that measure patient-centered care have been developed and validated, facilitating future research. Ouwens et al. identified a set of 56 metrics that span eight major domains relevant to patient satisfaction: access; follow-up; coordination; involvement; information; communication and respect; and physical, emotional, and psychological support.[33]
How widely does care now vary?	The number and scope of independent care management programs provided by insurance companies currently in operation are not known. Approaches to implementing medical homes are evolving and are likely to continue to do so in the near future, particularly as the Centers for Medicare & Medicaid Services (CMS) provides funding to states in support of their implementation of these models.
What is the pace of other research on this topic (as indicated by recent publications and ongoing trials)?	ClinicalTrials.gov: • Ongoing trials: 5 • Completed trials: 3 NIH reporter: • 15 projects/4 publications CMS has funded several ongoing studies evaluating medical home models: the Multi-payer Advanced Primary Care Demonstration, the Federal Qualified Health Center Advanced Primary Care Demonstration, the Comprehensive Primary Care Initiative, and the Medicaid Health Home Demonstration. All demonstration studies are quasi-experimental designs and vary considerably on design features and requirements of participating practices. These studies focus broadly on transforming medical practices into advanced primary care

Criteria	Brief Description
	practices or medical homes with the aim of improving population health, generally, and care management of patients with chronic conditions, specifically. All comparisons are relative to usual care. In addition, CMS funded the largest randomized trial of disease management programs, Medicare Health Support, relative to usual care.[34,35]
How likely is it that new CER on this topic would provide better information to guide clinical decision making?	The available evidence includes no direct comparisons of care management provided by insurance companies versus by medical homes. The two approaches have been studied separately and in comparison to usual care. Also, earlier systematic reviews of care management programs versus medical homes have not focused on outcomes for the portion of the patient population with chronic diseases. Therefore, we believe a new comprehensive review of these two approaches (care management versus medical homes) relating to interventions and outcomes for individuals with chronic diseases would be valuable, acknowledging that any comparisons would be indirect. Interpreting the results of such a comparison would be complicated because the complexity of the patients studied is so often not described, the study methodology varies widely, and the time horizon of most studies has been too short to evaluate major outcomes of interest such as mortality. A major challenge in any future comprehensive review will be to find a sufficient number of studies and evidence related to outcomes for patient populations with multiple chronic diseases; consideration should be given to including a broader set of studies focused on a single chronic condition because programs for patients with just one chronic condition could offer lessons learned. We believe that a new review should include the grey literature because additional evidence is likely to be available from government reports, particularly CMS program evaluations. States are taking a leadership role in encouraging the health plans and providers in their states to implement innovative models of health care delivery. One important focus in these initiatives is improvements in care management for patients with chronic conditions. New CER could provide important information to states, health plans, and providers on the components of earlier initiatives that were found to be successful and these lessons could be used in shaping new programs.
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 • Practices are highly motivated to improve the quality of care they provide and to improve the process-of-care measures typically used to evaluate quality.[36] • There is a growing recognition that insurance-supported care management programs should involve the implementation and integration of combined interventions (e.g., patient education with professional education or revision of professional roles versus patient education only).[11,32,37,38] • A growing number of providers are receiving financial incentives for meeting quality-

Criteria	Brief Description
	of-care targets that may facilitate adoption of better care management approaches. For example, the Affordable Care Act mandates that in 2015 CMS begins paying more to physicians who provide quality care at lower costs and reduce payment to physicians who have higher costs without better quality of care.[39] BARRIERS • Small practices face significant barriers in terms of time, resources, and information systems to becoming recognized medical homes.[36,40] • The multiplicity of recognition programs and changing standards make it difficult for practices to determine the most critical elements of the medical home to implement.[41] • The lack of integration of insurance-supported care managers into the primary care practice hinders the ability of the care managers to interact directly with primary care providers and facilitate timely changes in care management.[34] • Although primary care practices may be familiar with care management concepts, they may not have the resources needed to provide the additional services and staff training it entails.
How likely is it that the results of new research on this topic would be implemented in practice right away?	• Practices have been evolving into patient-centered medical homes. As of 2013, over 6,000 practices had achieved National Committee for Quality Assurance Medical Home Recognition, representing almost 30,000 providers in 49 states (roughly 15% of all primary care providers).[42,43] • There is considerable interest in developing care management programs in Medicaid programs for quality improvement or cost savings.[44] • Even if independent care management was shown to be superior, primary care practices that oversee care coordination for their patients with complex medical needs may be unwilling to change their practices in the short term. They may be suspicious of such outside involvement and view care management as their responsibility.
Would new information from CER on this topic remain current for several years, or would it be rendered obsolete quickly by subsequent studies?	Determining the best approaches to primary care management for individuals with chronic conditions is receiving much attention, with the heightened focus showing no signs of abating; we believe that this field will remain a very dynamic area for the next many years. The care management programs that would be considered through this review are typically complex interventions with multiple components. It is unknown whether the evidence of the effectiveness of the individual components and/or organization of the multiple components will be useful for several years or if the models will change so dramatically over time that a review would become outdated fairly rapidly.

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Topic 7: Patient Engagement in Quality Improvement Projects

Does the inclusion of patients in health systems' quality improvement projects lead to better patient outcomes than quality improvement projects that do not include patients as part of the quality improvement team?

Criteria	Brief Description
Introduction	
Overview/definition of topic	DESCRIPTION OF ISSUE • The quality of health care delivery in the United States is high and constantly improving, yet it is not ideal and lags behind other countries in both quality and value.[1,2] • Health care organizations, in general, seek to continuously improve the quality and value of services they provide. Performance improvement is a condition of participation by the Centers for Medicare & Medicaid Services.[3] • Traditionally, quality improvement projects have included only employees of the organization.[4,5] • Patients are increasingly interested in participating proactively in their own health care and in monitoring and improving the quality of the health care they receive.[6-9] The American Hospital Association recommends integrating patients comprehensively into all types of hospital operations.[10] • Involving patients in quality improvement projects undertaken by health systems is a novel step in the evolution of the patient engagement movement.[11] • Patients can be involved in quality improvement projects in various ways. In addition to contributing to policy discussions on quality, patients could contribute to projects at the local level by participating in various stages of the Plan-Do-Study-Act cycle that The Joint Commission recommends to evaluate and improve quality.[12] In this approach, a plan is developed to address a specific quality concern (Plan), a new program is implemented (Do), which is then evaluated (Study) for possible further revisions (Act). Similarly, patients could act as quality planners on improvement projects (Plan), as the monitors and reporters of the outcomes of safety improvement projects (Study), or as participants in the projects themselves (Do, Act).
Relevance to patient-centered outcomes	PATIENT-CENTERED OUTCOMES • Patients and providers often assess quality of care from different perspectives with patients focusing on interpersonal issues and providers focusing on clinical issues.[13] Incorporating patients into quality improvement initiatives may help bridge this divide. • One of the major goals of quality improvement initiatives is to improve patient-centered outcomes. These outcomes include health outcomes (e.g., functional status, relief from pain, survival), health care outcomes (e.g., efficiency and safety), and patient satisfaction with care.

Criteria	Brief Description
Burden on Society	
Recent prevalence in populations and subpopulations	PREVALENCE - The quality of health care in the United States is suboptimal, although it appears to be showing signs of improvement: o A report from the Agency for Healthcare Research and Quality (AHRQ) found that Americans did not receive 30% of the care that was required for prevention or treatment of specific medical conditions in 2009.[14] However, this was an improvement from 2005, when Americans failed to receive 34% of health care services they should have received.[14] o A 2003 study involving a random sample of individuals living in 12 metropolitan areas in the United States concluded that Americans receive evidence-based care when needed only 55% of the time.[2] Studies have also reported that adverse patient safety events remain common in both inpatient and ambulatory settings.[1]
Effects on patients' quality of life, productivity, functional capacity, mortality, use of health care services	QUALITY OF LIFE, PRODUCTIVITY AND HEALTH CARE SERVICE UTILIZATION - Quality is the most critical determinant of health care outcomes and value.[2,4] Therefore, quality improvement efforts directly influence health outcomes (including mortality, quality of life, and quality of life) and health care outcomes (including utilization of services and efficiency). - Whether patient engagement in quality improvement is likely to affect patient outcomes is uncertain. Engaging patients in this effort coincides with a growing movement toward patient engagement and activation and offers the potential to accelerate positive change.
How strongly does this overall societal burden suggest that a CER on alternative approaches to this problem should be given high priority?	The continued shortcomings in the quality of health care in the United States and common occurrence of adverse events require health care organizations and providers to actively and constantly engage in performance improvement activities seeking to improve quality. Research is needed to evaluate the feasibility of patient engagement in quality improvement efforts and the impact of their involvement on the process itself and on outcomes.

Criteria	Brief Description
Options for Addressing the Issue	
Based on recent systematic reviews, what is known about the relative benefits and harms of the available management options?	We found no systematic reviews addressing the question as posed. The most relevant publication is a recently published study of 74 randomly selected European hospitals.[11] In this study, very few hospitals involved patients in quality management meaningfully at the hospital level, and even fewer involved patients in quality management at the level of individual clinics or wards. In this specific study, there was no association between the level of patient engagement and the presence of four measures of patient-centered care (a policy on patient rights, surveys of patient satisfaction, fact sheets for post-discharge care, patient educational materials). No other outcomes were assessed. A systematic review of controlled trials of patient engagement in projects to reduce adverse events in acute care settings identified six appropriate studies over the period 2000 to 2012.[15] Although no harms were identified, there was no clear evidence of efficacy in any of the studies, and many patients were uncomfortable directly confronting their health care providers about safety concerns. The study concluded that although patient engagement in safety is an attractive methodology to pursue, there is a substantial lack of evidence in the field.
What could new research contribute to achieving better patient-centered outcomes?	• New research could contribute information relevant to the question posed by this topic brief: Does the inclusion of patients in quality improvement initiatives lead to better outcomes when compared with initiatives that do not include patients? • New research could help clarify which of the many competing approaches to patient involvement are most effective in driving quality improvement and what elements of these different approaches are most important. • New research could explore the experience of the small group of hospitals that have engaged patients on their major quality improvement boards (see below).
Have recent innovations made research on this topic especially compelling?	Formerly, the patient engagement movement focused predominantly on such issues as patient education, health literacy, and patient satisfaction. The movement toward patient-centered care is expanding rapidly and in many different directions.[16-18] In 2013, *Health Affairs* published an entire issue dedicated to patient engagement (February 2013, Volume 32, Number 2). The case for involving patients in quality improvement has been made in several recent publications.[19-21] Some of the new approaches now in use that promote patient engagement in quality improvement work are described below. No evidence is currently available regarding their comparative effectiveness. The urgent need for continuous quality improvement makes comparative effectiveness research on these approaches compelling. Patient participation in research and policy planning: The Patient-Centered Outcomes Research Institute (PCORI) has taken a leadership role in involving patients in setting research priorities and promoting patient-centered research, and similar pleas have emerged from the private sector.[22] Patient participation on advisory councils: Patients can act as advisors to practices and hospitals, providing their perspective on policy and quality issues. As an example, the state

Criteria	Brief Description
	of Maine required the use of a patient advisory council for practices seeking to enroll in the CMS-sponsored Multipayer Advanced Practice Pilot Program, and practices establishing these councils uniformly and enthusiastically valued the input provided.[23] Engaging patients and families to participate on governance boards has been cited as a key element of a comprehensive quality improvement program.[24,25] Patient involvement in helping detect quality problems: Patients are willing, able, and motivated to identify safety and quality breakdowns in their own care, and the concerns they identify have typically escaped detection by the ongoing quality assessment.[26-31] The use of patient-reported outcomes to monitor the quality of the care has been evaluated in clinical trials in England, Sweden, and now in the United States at Partners Healthcare and the Dartmouth Spine Center.[32] Patient participation directly in quality improvement teams and projects: Involving patients in top-level quality improvement committees and patient advisory councils was initiated at institutions such as the Dana Farber Cancer Center and has now spread to other institutions,[33] but the impact of their participation has yet to be formally evaluated. Similarly, there is recent evidence that involving patients in deliberations and planning is beneficial in many other areas within and outside of health care. Examples include the involvement of patients in the AHRQ Community Forum[34] and the universal involvement of patients in PCORI's planning and discussions. Patient participation at the bedside: A recently described model for care collaboration includes patient involvement in their day-to-day care during an inpatient stay. In a demonstration program, the model dramatically improves both patient and staff satisfaction and was associated with a notable reduction in mortality in these post-cardiac surgery patients.[35] The unique aspect of this approach is that it generates quality and safety in real time, obviating the need for quality review or improvement committees.
How widely does care now vary?	The quality of medical care varies enormously across the Unites States and across various socioeconomic groups.[36] The degree of patient engagement across U.S. health care organizations has not been measured to the best of our knowledge, but generally, it appears the vast majority of health care organizations have incorporated many or most of the first-generation patient engagement processes (e.g., satisfaction surveys, health literacy and health education programs, patient rights statements, use of informed consent) but few or no second-generation engagement processes (e.g., involving patients on quality boards, in improvement projects, or as engaged partners in their own care). Studies in Europe have found similar results.[37] Over 500 health care organizations (approximately 1 out of 10 U.S. health care organizations) participate in the patient-centered programs sponsored by the Planetree organization, which espouses and promotes patient-centered care and encourages health care organizations to focus on improving the quality of the patient's health care experience.[38]

Criteria	Brief Description
	An informal survey of U.S. healthcare systems identified fewer than 20 for which patients or family members participate on the major quality improvement board.[33]
What is the pace of other research on this topic (as indicated by recent publications and ongoing trials)?	ClinicalTrials.gov: • Ongoing trials: None found • Completed trials: None found NIH reporter: • None found
How likely is it that a new CER on this topic would provide better information to guide clinical decisionmaking?	A CER could provide important information in clarifying which of the many different ways that patients can contribute to quality improvements has the greatest beneficial impact or potential, but several challenges lie ahead. First, a CER on the question of whether patient engagement in quality improvement projects results in improved patient outcomes requires intermediate links in the chain of evidence to be established before it can meaningfully influence clinical decisionmaking. Specifically, a new CER needs to establish the extent and conditions under which quality improvement projects influence patient outcomes and then consider the additive effect of patient engagement in quality improvement projects. Second, the diversity of ways that patients can be involved in quality improvement work makes isolating key variables challenging. Third, factors that determine patient outcomes are numerous and interrelated (including culture, resources, leadership, staffing, individual personalities, workload, distractors). Finally, most of the programs being implemented are novel; outcome data are not going to be available for several years in many cases.
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: • Implementation of new findings in this area is likely to be facilitated by the expanding literature extolling the benefits of patient engagement.[39] Furthermore, there is an increase in requests from patients and patient advocacy groups for more of a voice (e.g., “Nothing about me without me”[8,38,40]). Health care organizations are looking to position themselves as providing patient-centered care as a selling point and literature is emerging on the business case for patient involvement [9] • Implementation is also likely to be facilitated by increasing federal efforts to engage patients in their own health care, such as the CMS Partnership for Patients Program (http://partnershipforpatients.cms.gov/), efforts by AHRQ,[13] and the Department of Veterans Affairs national-level Office of Patient Centered Care and Cultural Transformation (http://www.va.gov/health/newsfeatures/20120827a.asp). Other advances include the recent action by the Department of Health and Human Services that gives patients direct access to the results of their laboratory tests.[41] • Additional facilitators on the patient side that facilitate patient engagement in hospital settings include self-efficacy, provider support and availability, and access to information.[14] • Additional provider-level facilitators that facilitate patient engagement in hospital settings include motivation of providers, organizational structure, and processes that support these initiatives.[14]

Criteria	Brief Description
	BARRIERS: - Limited published evidence exists that patient engagement in quality improvement groups improves patient-relevant outcomes. - Implementation may be impeded by cultural beliefs in health care organizations that operations should be directed by employees, not customers/patients—remnants of the cultural mindset that divides patients from providers. - Barriers on the patient side to patient engagement in the hospital setting include fear, uncertainty, low levels of health literacy, lack of support from providers engaged in care,[14] illness, and power inequality in relation to health professionals.[42] Barriers on the provider side to patient engagement in the hospital setting include burden and concerns about litigation.[14]
How likely is it that the results of new research on this topic would be implemented in practice right away?	We believe that research results identifying successful programs or program elements would be quickly and widely adopted nationally, given the current emphasis to improve the quality and safety of health care and to engage patients meaningfully. Moreover, quality improvements can save money and improve patient satisfaction; organizations looking for a competitive advantage would be especially interested in programs of this type.
Would new information from a CER on this topic remain current for several years, or would it be rendered obsolete quickly by subsequent studies?	The study of patient engagement is a novel and extremely dynamic area at the moment. New programs and new types of programs are emerging constantly. Moreover, the fact that these programs were all implemented recent necessarily implies that high-quality outcomes data will not be forthcoming immediately.

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Topic 8: Linkages between Providers and Community

Effects of linkages between health care providers and community-based organizations on patients' health-related behaviors, such as weight management, compared with usual care

Criteria	Brief Description
Introduction	
Overview/definition of topic	OVERVIEW Unhealthy behaviors are the leading cause of mortality and contribute significantly to disease prevalence and reduced quality of life.[1,2] However, patients are not receiving appropriate preventive services to address these unhealthy behaviors in the primary care setting because of multiple barriers.[3] An attractive alternative to providing preventive services in the clinical setting is to develop linkages between health care and community organizations, such as local health departments or community-based programs, to facilitate the delivery of services to address unhealthy behaviors. Linking or integrating organizations to deliver preventive services is consistent with the social-ecological perspective that health behaviors are influenced by factors at multiple levels and that interventions coordinated across organizations and across levels are more likely to succeed.[4] A monograph published by the American Medical Association concludes that in a "rational health system," public health and primary care would work together to meet the needs of the community.[5,6] However, currently, these kinds of linkages are uncommon.[5,6] DESCRIPTION OF CONDITION • Linkages between health care providers and community organizations are defined as integration of programs and activities between health care providers and community-based organizations (CBOs) to promote overall efficiency and effectiveness and achieve gains in population health.[7] Linkages present an alternative to providing certain services, such as preventive care, in a clinical environment through referrals to community organizations.[5] These referrals may, for example, be standard phone-based referrals, through automated computer systems linking organizations, or via fax.[4,8,9] • Programs and activities should address one of the following health behaviors for which evidence exists that health care providers can influence through screening and counseling, according to the U.S. Preventive Services Task Force (USPSTF):[10] o Alcohol use o Breastfeeding o Adults with healthy diet who have known risk factors for cardiovascular and diet-related chronic disease o Obesity-related behaviors in adults o Obesity-related behaviors in children o Sexually transmitted infections (STIs) prevention

Criteria	Brief Description
	o Tobacco use in nonpregnant adults o Tobacco use in pregnant women
Relevance to patient-centered outcomes	The types of programs and activities described above are expected to influence the following patient-centered outcomes. • Patient knowledge and attitudes influencing health behaviors • Patient-reported access to care • Patient engagement with care • Patient health-related behaviors , including self-management behaviors • Physiological measures (weight, blood pressure) • Health-related quality of life
Burden on Society	
Recent prevalence in populations and subpopulations	PREVALENCE • Unhealthy behaviors are extremely prevalent in U.S. populations and contribute significantly to chronic disease incidence, quality of life, and mortality.[11] In 2008 to 2010, about 6 in 10 (64.9%) U.S. adults were current drinkers; about one in five adults (20.2%) were current smokers. Of current smokers, less than one-half (45.8%) attempted to quit smoking in the past year. Less than one-half (46.1%) of adults met the federal guidelines for aerobic physical activity, and less than one-quarter (23.0%) of adults met the federal guidelines for muscle-strengthening physical activity. Over 6 in 10 adults (62.1%) were overweight or obese (body mass index [BMI] ≥ 25). In addition, estimates indicate that unhealthy behaviors have significant economic consequences. For example, it is estimated that productivity losses between 2000 and 2004 related to smoking behaviors totaled approximately $97 billion.[12] • Delivery of preventive services, including those screening and counseling services to address unhealthy behaviors, in primary care is low.[3] • Linkages between health care providers and CBOs can enhance the delivery of these preventive services, but the number of such linkages is likely to be extremely low.[13]
Effects on patients' quality of life, productivity, functional capacity, mortality, use of health care services	QUALITY OF LIFE • Dietary risks, tobacco smoking, and high BMI are the top 3 risk-factor contributors to Disability Adjusted Life Years (DALYs) in the United States, ranking above blood pressure, blood glucose, and blood cholesterol. In 2010, each was associated with over 10% of DALYs in the United States. Physical inactivity and alcohol use were ranked sixth and seventh, respectively.[1] MORTALITY • Modifiable behavioral risk factors are the leading causes of mortality in the United States.[2] Smoking, poor diet, and physical inactivity account for a third of all deaths in the United States.

Criteria	Brief Description
How strongly does this overall societal burden suggest that a CER on alternative approaches to this problem should be given high priority?	• Given the extremely high prevalence of unhealthy behaviors and their contributions to disease prevalence, reduced quality of life, and mortality, a high priority for health systems, payers, and funders of health services research should be identifying effective mechanisms to deliver evidence-based preventive services such as screening and counseling. Because of multiple barriers to delivering preventive services to address unhealthy behaviors in primary care, it is appropriate to investigate alternatives such as developing linkages between health care and community organizations, including local health departments, to facilitate the delivery of these services. However, research is needed to understand the effectiveness and efficiency of these linkages.
Options for Addressing the Issue	
Based on recent systematic reviews, what is known about the relative benefits and harms of the available management options?	• A targeted literature review conducted for the Agency for Healthcare Research and Quality (AHRQ) in 2013 of existing evidence related to effectiveness of clinical-community resource relationships for the delivery of select preventive services that are USPSTF A and B recommendations (alcohol, breastfeeding, diet, obesity, STIs, and tobacco use) identified 27 studies. The numbers of studies using common outcomes to allow for assessment or comparisons of effectiveness were insufficient. The investigators concluded that the field is "broadly understudied."[14] • A scoping literature review conducted for AHRQ examined 19 articles focused on 36 linkage interventions and found that evidence on the effectiveness of linkage interventions is limited, and no studies evaluated linkages themselves.[5] • A scoping literature review to the Canadian Health Services Research Foundation also concluded that more rigorous research and evaluation are required to validate the effectiveness of linkages.[15]
What could new research contribute to achieving better patient-centered outcomes?	The following areas of research have the potential to contribute to better patient-centered outcomes: EFFECTIVENESS RESEARCH[5,14,15] • What is the comparative effectiveness of settings or practices with linkages between health care providers and community organizations in improving relevant patient-centered outcomes, such as patient knowledge, attitudes, access to care, engagement in care, and health behaviors, when compared with settings and practices without linkages? o How do the characteristics of health care providers, patients, and community organizations influence the comparative effectiveness of linkages for the delivery of preventive services? (*see Facilitators and Barriers section below*) o How do characteristics of the linkage intervention itself influence the comparative effectiveness of linkages for the delivery of preventive services? (*see Facilitators and Barriers section below*) o How does the external policy and funding context influence the comparative effectiveness of linkages for the delivery of preventive services? o Does the comparative effectiveness of linkages between a health care provider and community organization vary by specific clinical preventive services? • What are appropriate theories, models, or conceptual frameworks to guide research in this

Criteria	Brief Description

	area?
	DISSEMINATION/IMPLEMENTATION RESEARCH[5,6,14,16,17]
	• How do the characteristics of the linkage, health care providers, patients, and community organizations influence the adoption, implementation, and maintenance of linkages for the delivery of preventive services? (*see Facilitators and Barriers section below*)
	  o What factors can motivate health care providers and community organizations to develop linkages for the delivery of preventive services?
	  o What factors can influence sustained engagement of health care providers and community organizations?
	• How does the external policy and funding context influence the adoption, implementation, and maintenance of linkages for the delivery of preventive services?
	  o How important is reimbursement by payers? What is the role of other financial incentives, and how can they be structured?
	• What are key elements in the linkage process (e.g., planning, engaging opinion leaders) that contribute to effective implementation?
	OTHER RECOMMENDATIONS FOR RESEARCH[5,14]
	• Use standard measures ,such as those included in the set of existing and potential measures of clinical-community relationships recently developed by AHRQ to allow for meaningful synthesis of findings.[18,19]
	• Adopt a systems approach to studying linkages
	• Use qualitative as well as quantitative methods

Have recent innovations made research on this topic especially compelling?	• The recent development of a set of existing and potential measures by AHRQ that can be incorporated into future research makes research on this topic more feasible and more likely to yield information that can be synthesized across studies.[18,19] • The Community-based Care Transitions Program (CCTP) tests various models for improving transitions of care among Medicare patients, by involving CBOs or acute care hospitals that have partnered with CBOs in the care transitions process.[20] Evaluations of CCTP initiatives are likely to provide additional evidence and add to the interest in the area of linkages. • Quality Improvement Organizations (QIOs) are private organizations contracted by CMS in U.S. states (as well as the District of Columbia, U.S. Virgin Islands and Puerto Rico) to enhance the effectiveness, efficiency and quality of care provided to Medicare beneficiaries.[21] An evaluation of the effect of QIO activities in New York state for outpatient diabetes care found that participants in the QIO had significant improvements in lipid and A1c monitoring compared to nonparticipants.[22] These findings suggest that QIOs can improve care, and more evaluations in this area are likely to contribute to increasing interest.
How widely does care now vary?	• The number of linkages between health care providers and CBOs to enhance the delivery of preventive services is likely to be low. In one study of 124 primary care practices participating in a research initiative to improve health behaviors of patients, practices, on average, referred patients to community programs for education, counseling or support for tobacco use, alcohol use, diet, or physical activity only "occasionally."[13]

Criteria	Brief Description
What is the pace of other research on this topic (as indicated by recent publications and ongoing trials)?	ClinicalTrials.gov: - Ongoing trials: o Improving Diabetes Care and Outcomes on the South Side of Chicago (start date: March 2010; end date: July 2015). As part of an approach to improve care and outcomes for people with diabetes, this trial incorporates patient advocates and health care centers that will link patients to local resources for care management.[23] - Completed trials: o None found. NIH reporter: - Multilevel Health Promotion in African American Churches (Project start date: January 2013; project end date: December 2015). As part of a multilevel health promotion intervention using principles of community-based participatory research, this project links to care services for African American churchgoers.[24]
How likely is it that a new CER on this topic would provide better information to guide clinical decision making?	A scoping literature review conducted for AHRQ concluded that the integration of clinical and community organizations is an attractive option to increase the delivery of important health services, but that evidence regarding the effectiveness of such linkages is lacking.[5] CERs on clinical-community linkages have the potential to fill this gap in the evidence and influence clinical decisionmaking in the following ways: - Currently, providers are unlikely to refer patients to community resources for preventive services,[13] and where linkages exist, providers may be unaware of the availability of these services. A CER to establish the evidence for linkages and dissemination of findings could provide useful information to clinicians and health care organizations to determine whether pursuing such linkages is an effective way to improve health status for their patients. - For linkages between primary care and public health to guide clinician decisionmaking, there needs to be an understanding of what contributes to the success of these linkages. Numerous factors are likely contributors to the success or failure of linkages[5,15] (*see Facilitators and Barriers, below*). These factors require comprehensive and systematic study.
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[5,7,15,25,26] Characteristics of the linkage intervention - Fit of the linkage intervention with the community's needs and organizations' missions - Well-established accountability and leadership structures, as well as an effective system for data collection Characteristics of the health care providers or community organizations (individuals or organizations) - Leadership support and advocacy; leadership that can effectively engage other organizations and catalyze integration - An understanding of community needs and how to meet those needs

Criteria	Brief Description
	Characteristics of the relationship between health care and community organizations • A history of collaborations and having a shared mission or purpose are described as facilitators to linkages for the delivery of preventive services • Shared vision, mission or purpose • "Spanning infrastructure" (personnel, technologies, resources) that promote communication and enable the linkage • Clearly established roles and responsibilities, trust among collaborators, open and clear lines of communication between entities • Collaborative planning processes Characteristics of the policy or funding context • Grants or program funding from funding organizations (e.g., U.S. or state government, foundations); reimbursement by payers; and influence by purchasers (e.g., employers) for insurance reimbursement for services • Use of existing funding mechanisms, such as those from the Affordable Care Act, to drive linkages between public health and primary care • Government endorsement of the value of linkages between health care and community organizations BARRIERS[6,15,25,26] Characteristics of the linkage intervention • Lack of well-designed integrative information infrastructure such as surveillance tools Characteristics of the health care providers or community organizations (individuals or organizations) • Lack of common agenda and resource limitations at an organizational level • Power and control issues, such as concerns about changes in power structures among collaborating organizations; characteristics of the relationship between health care and community organizations • Relationship issues, attitudes, and beliefs that do not align with collaboration Characteristics of the policy or funding context • Substantial financial resources and policies to support the "spanning infrastructure" as well as training for implementation and maintenance of these new systems • An Institute of Medicine report on the integration between public health and primary care concluded that the current focus of health policy and investment is lacking and cannot support an infrastructure for developing linkages between primary care and public health on a national scale.

Criteria	Brief Description
How likely is it that the results of new research on this topic would be implemented in practice right away?	• Significant barriers to linkage implementation, most notably the funding context, are likely to limit immediate adoption of new research.
Would new information from a CER on this topic remain current for several years, or would it be rendered obsolete quickly by subsequent studies?	• The reviews that have been conducted have noted the limited evidence of effectiveness and the heterogeneity of studies.[5,14] Very few ongoing trials are identified in this review. New research, therefore, is likely to remain current for a number of years.

Updated Topic 8: Linkages between Providers and Community

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Research Prioritization Topic Brief

Topic 9: Multidisciplinary Treatment Approaches to Chronic Pain

Does a multidisciplinary treatment approach (e.g., including nutritionists, psychotherapists, physical therapists, holistic practitioners, and physicians) improve the management of chronic pain compared with treatment from individual providers (usual care)?

Criteria	Brief Description
Introduction	
Overview/definition of topic	DESCRIPTION OF CONDITION • Pain is typically defined as a subjective experience, grounded in an unpleasant sensory and/or emotional perception associated with actual or potential tissue damage.[1] • Chronic pain lasts more than several months (between 3 and 6) and adversely affects the individual's well-being.[2] • Chronic or persistent pain continues in situations in which it would be expected to remit.[2] • The Agency for Healthcare Research and Quality (AHRQ) identified four types of pain: neuropathic, inflammatory, muscle, and mechanical/compressive.[3] • When chronic pain does not respond to initial standard-of-care treatment, numerous guidelines suggest a multidisciplinary program.[4,5]
Relevance to patient-centered outcomes	PATIENT-CENTERED OUTCOMES • Efficacy: speed of response/remission of self-perceived pain, health-related quality of life, functional impairment • Adverse events (safety and tolerability): overall adverse events, withdrawals because of adverse events, serious adverse events, specific adverse events or withdrawals because of specific adverse events (including hyponatremia, seizures, suicidality hepatoxicity, weight gain, gastrointestinal symptoms, sexual side effects) and drug interactions (pharmacologic and alternative treatments)
Burden on Society	
Recent prevalence in populations and subpopulations	PREVALENCE • Estimates of prevalence depend on how chronic pain is defined.[3] • When chronic pain is defined as "severe pain," "moderate pain," "joint pain," "arthritis," or functional limitation that restricts the ability to work, an Institute of Medicine (IOM) report estimates that approximately 100 million Americans experience chronic pain.[2] SUBGROUPS Chronic pain is correlated with other chronic diseases (neuropathy, fibromyalgia), anxiety,

Criteria	Brief Description
	depression, unemployment, English as a second language, race and ethnicity, income (lower) and education (high school education or less), sex (female) and gender, age group (younger ages), geographic location (urban location), military veterans, cognitive impairments, surgical patients, cancer patients, and the end of life.[2,6,7]
Effects on patients' quality of life, productivity, functional capacity, mortality, use of health care services	QUALITY OF LIFE, PRODUCTIVITY, AND HEALTH CARE SERVICE UTILIZATION • Chronic pain is associated with all-cause mortality (hazard rate [HR] 1.49, 99% CI 1.21–1.84) and all circulatory system disease deaths (HR 1.68, 99% CI 1.20–2.35).[8] • Unrelieved chronic pain results in longer hospital stays, rehospitalization, increased outpatient visits, and expenditure on prescription drugs.[9] • Chronic pain impairs overall enjoyment of life, mood, concentration, energy levels, and sleep quality.[9] • Concerns over opioid addiction may have led to undertreatment of chronic pain in the past.[10] Despite the concomitant rise in opioid prescription and opioid abuse, studies have not always distinguished between opioid addiction and opioid tolerance and withdrawal as physical and time-limited side effects of opioid medication use.[10] • Chronic pain costs society between \$560 and \$635 billion annually. These 2010 estimates include the cost of health care due to pain ranging between \$261 and \$300 billion and the cost of lost productivity ranging from \$297 to \$336 billion.[2]
How strongly does this overall societal burden suggest that CER on alternative approaches to this problem should be given high priority?	According to the IOM, the magnitude of suffering caused by pain and the limitations around response to pain constitute a crisis in America:[11] effective pain management is a moral imperative. The IOM notes the value of comprehensive treatment and need for interdisciplinary approaches as potentially transformative approaches. Although systematic reviews of the literature prespecify minimum standards required for multidisciplinary programs, we did not find evidence to support the specific and unique contributions of each proposed component.[3,12] One review proposed a minimum standard of exercise, relaxation training, group therapy led by a clinical psychologist (1.5 hour/week), patient education sessions (1 day/week), physiotherapy treatments (2 days/week) for pacing strategies, medical training therapy, and neurophysiology information provided by trained physicians.[12] This would include testing whether a specific component (e.g., relaxation training with and without adjunct group therapy) shows efficacy as a main effect or in combination with other components.

Criteria	Brief Description
Options for Addressing the Issue	
Based on recent systematic reviews, what is known about the relative benefits and harms of the available management options?	• A recent technical brief noted that benefits from multidisciplinary treatment are expected from simultaneously addressing multiple influences on chronic pain. The technical brief found no indication that combining different treatments would elevate risk from individual treatments but noted that attrition (a potential marker of increased pain or stress that results in patient withdrawal) in multidisciplinary programs could be variable but potentially high, ranging from 0 to 48 percent.[3] • A systematic review of psychological treatment in fibromyalgia noted that 11 of 59 treatments involved a multimodal approach but offered no insights on relative benefits and harms.[13] • A review of multidisciplinary treatment for chronic pain found substantial improvements in varied outcomes for patients with fibromyalgia and low back pain but not for patients with mixed or diverse origins of pain.[12] The same review concluded that strong evidence exists that multidisciplinary care is superior to standard care or no care and moderate evidence that multidisciplinary treatment is superior to nonmultidisciplinary treatments (e.g., relaxation therapy).[12] The review made no mention of harms. • Another review comparing multidisciplinary treatment for chronic low back pain to control treatment found no effect on pain or function.[14]
What could new research contribute to achieving better patient-centered outcomes?	Common themes across systematic reviews suggest that new research should[3,13,15,16] • define the optimal combination of components (i.e., additive and synergistic) to produce treatment success, • identify patient characteristics that predict treatment response, and • address the cost-effectiveness of types of treatment components and intervention characteristics (e.g., frequency, intensity, mode, and agent of delivery).
Have recent innovations made research on this topic especially compelling?	• Provisions of the Affordable Care Act (ACA) (2010) focus attention on pay-for-performance measures.[17] This alignment of financial incentives with quality measures is likely to focus attention on conditions such as poorly managed chronic pain that result in substantial negative effects on individuals, systems of care, and society.
How widely does care now vary?	• Traditional care varies substantially along numerous intervention domains: type of care, mode of delivery, specific components, and dosage. Different treatment goals (such as decreasing pain intensity or increasing physical activity) in the biopsychosocial model can induce variability in treatment under the multidisciplinary model of care.[18] Boon et al. (2004) illustrated seven different models of team-oriented care for chronic pain (parallel, consultative, collaborative, coordinated, multidisciplinary, interdisciplinary, and integrative), which illustrates that there is no single prevailing model of care.[19]

Criteria	Brief Description
What is the pace of other research on this topic (as indicated by recent publications and ongoing trials)?	ClinicalTrials.gov: Ongoing trials: • One trial in Spain on multidisciplinary approaches to chronic low back pain, specifically evaluating the efficacy of two complementary therapies (relaxation techniques and cognitive-behavioral intervention) to standard physical therapy. (anticipated completion date is January 2015).[20] • One trial in the Kaiser Permanente health system in the United States comparing interdisciplinary pain program with usual care (anticipated completion date is June 2014).[21] Completed trials: • A trial conducted in Germany sought to understand the additive value of a specific component of multidisciplinary rehabilitation. The study compared behavioral medical rehabilitation plus behavioral exercise therapy with behavioral medical rehabilitation alone (completed December 2013).[22] • Another trial, set in Canada, compared multidisciplinary chronic pain therapy with a waitlist control (completed in November 2011).[23] • In addition to these two trials, ClinicalTrials.gov also lists a retrospective cohort study, conducted in Germany (completed in January 2011) evaluating the influence of multimodal day-unit pain therapy for patients with mixed chronic pain syndromes.[24] NIH reporter: • None identified
How likely is it that new CER on this topic would provide better information to guide clinical decision making?	Research thus far in the United States, in particular, has been focused on building up the knowledge base about specific components of pain management rather than conducting a CER of multidisciplinary treatment versus usual care. As many systematic reviews note, unresolved questions remain regarding the optimal combination of treatment components and their effect on a range outcomes and measures (e.g., cost-effectiveness, behavioral outcomes like return to function, and psychological outcomes like reduced stress and pain). A substantial new CER will be required to provide better information for clinical decisionmaking.
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 • Increasing evidence shows that chronic pain is best treated under a biopsychosocial model of care.[2] • New advancements in alternative/complementary medicine are building the case for efficacy for components of multidisciplinary treatment.[12] BARRIERS • Payment from insurance companies---it is difficult to document dosage for behavioral interventions so reimbursement policies should be standardized and based on evidence-based treatments[2] • Lack of incentive for disciplines to work together and bridge the multidisciplinary gulf[2] • Lack of provider training[2] • Patient recognition of treatment failure and drop-out[2,3,12-16]

Criteria	Brief Description
How likely is it that the results of new research on this topic would be implemented in practice right away?	The frequent inclusion of multidisciplinary approaches in guidelines for chronic pain management indicate providers are being urged to move toward building collaborative teams to improve care for chronic pain.[4,5,12] With the ACA, it is difficult to predict how quickly multidisciplinary care can be put into practice given the uncertainties in reimbursement across patient levels of care. Institutional barriers, such as HIPAA that protect against disclosure of information, can limit expansion of multidisciplinary treatment models.
Would new information from CER on this topic remain current for several years, or would it be rendered obsolete quickly by subsequent studies?	Considerable uncertainty exists regardless the stability of estimates of effectiveness produced by a new CER. Traditionally, the evidence has been built by identifying the efficacy of a single type of treatment, which is then added in the context of multidisciplinary care. However, the research is in its nascent stages of development, so data on treatment efficacy for individual components are still being generated. As evidence accumulates, the next step in the field of chronic pain is to then assess stability of the estimates and generalizability. Once the components have been scientifically validated, the final steps are to identify how intervention components and characteristics (e.g., frequency, intensity, mode, and agent of delivery) are to be combined in true multidisciplinary care for chronic pain. At this stage, a CER can serve as an effective tool to test and establish the ideal combination of components and intervention characteristics that would comprise evidence-based care for chronic pain, and the degree to which this combination would apply to different chronic pain conditions. Another consideration is the degree to which secular changes in health care organization affect the type of care and its delivery, because funding may determine how medical specialties interact and collaborate as part of patient-centered medical teams.

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Updated Topic: Insurance Approaches and Chronically Ill Patients

What are the comparative effects of recently developed health insurance approaches, specifically high deductible plans, bundled payments, and condition management plans, on chronically ill patients' access to care, use of care, and patient-centered outcomes?

Criteria	Brief Description
Introduction	
Overview/ definition of topic	• Chronic illnesses, defined as diseases of long duration and generally slow progression,[1] are costly, complicated to manage, and common. • Most prevalent chronic diseases in the United States (percent of population affected): o Obesity (36%)[2] o Major Depression (9.1%)[3] o Asthma (8.4%)[4] o Diabetes (8.3%)[5] o COPD (6.3%)[6] o Heart disease (6.0%)[7] o Cancer (2.8%)[8] • Evidence suggests treatments known to be beneficial for chronic disease patients are actually implemented only about 50 percent of the time.[9] • Most care models are designed to address acute health problems and do not adapt well to chronic diseases.[10] • This brief will focus on the effects of the following health insurance approaches on access to care, use of care, and patient-centered outcomes for patients with chronic diseases: o <u>High deductible health plans</u> (HDHPs), defined in 2013 by the Internal Revenue Service (IRS) 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.[11] o <u>Bundled payments</u>, defined in 2013 by the Centers for Medicare & Medicaid Services (CMS) as payments to providers for multiple services received during an episode of care.[12] o <u>Condition management plans</u>, also called disease management plans, are provided by some health insurance plans (usually managed care plans) as comprehensive programs that are designed to help patients manage their conditions, reduce health care service use and associated costs, and improve quality of life.[13]
Relevance to patient-centered outcomes	• Outcomes of morbidity, disease control, and mortality are especially relevant in the chronic disease population. • While HDHPs, bundled payments, and condition management plans are primarily methods to control costs, they sometimes include features that attempt to preserve or improve quality of care. o HDHPs may result in increases in foregone or delayed care, which may reduce costs but negatively impact patient-centered outcomes.

	o Bundled payments and condition management plans may result in more efficient care planning and delivery, thereby improving patient satisfaction. ▪ However, they could decrease use of high cost options and decrease care quality.
Burden on Society	
Recent incidence and prevalence in populations and sub-populations	PREVALENCE AND SUB-POPULATIONS • INCIDENCE (percent of U.S. population diagnosed per year) o Obesity (4%)[14] o Depression (6.7%)[15] o Asthma (0.36% for adults; 1.3% for children)[16] o Diabetes (0.62%)[17] o COPD (3.8%)[18] o Heart disease (0.4%)[19] o Cancer (0.53%)[20] • PREVALENCE o >130 million Americans (~42%) have a chronic condition[5]
Effects on patients' quality of life, productivity, functional capacity, mortality, and use of health services	• QUALITY OF LIFE/FUNCTIONAL CAPACITY/MORTALITY o 70 percent of deaths in United States per year are from chronic diseases.[5] o Obesity severely decreases functional status and quality of life.[21] o Although treatment of major depression can improve quality of life, patients with major depression still have poor quality of life even when symptoms are in remission following treatment.[22] o Asthma,[23,24] diabetes,[25] COPD,[26] heart disease,[27] and cancer[20] are also associated with increased mortality and decreased quality of life and functional capacity compared with patients who do not have these diseases. o About 25 percent of Americans have multiple chronic diseases,[28] compounding negative health effects.[29,30] • USE OF HEALTH SERVICES/PRODUCTIVITY o More than 75 percent of health care costs are attributable to chronic conditions.[31] o About 25 percent of people with chronic diseases report that they have ≥1 daily activity limitations.[5] o Obesity significantly increases health care utilization and direct medical costs, as well as indirect costs such as lost productivity due to absenteeism and attending work while sick (presenteeism), increased disability, and premature mortality.[32]
How strongly does the overall societal burden suggest that CER on alternative approaches to this problem should be given high priority?	FACTORS IN FAVOR • Obtaining cost control for chronic care is a high priority for the United States.[31] • With passage of the Affordable Care Act, methods of payment for health care are changing and incentivizing the use of these insurance features. FACTOR 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 health insurance approaches.

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 on these health insurance approaches and therefore focused on individual studies. o HDHPs ▪ One study found implementation of a HDHP had no effect on overall (total medical plus pharmacy) health care costs compared to a health plan that did not implement a HDHP, likely because patients with the highest healthcare utilizations remained high-utilizers after the introduction of the HDHP.[33] ▪ This study did identify reductions attributable to the HDHP in the number of outpatient visits and had mixed effects on the number of inpatient admissions and emergency room visits.[33] ▪ Another study of patients with chronic conditions found those with HDHPs had a higher probability of delayed or foregone care due to prohibitively high out-of-pocket costs.[34] ▪ Another study analyzed HDHP stratified by gender.[35] ▪ 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, possibly related to delayed or foregone care.[35] ▪ Another study found that patients with chronic conditions had fewer outpatient visits because of their increased exposure to costs.[36] ▪ Many studies have examined the effect of HDHPs on prescription drug use (see Reiss 2011[37] for summary). ▪ Most show HDHPs are linked to reductions in medication use and corresponding decreases in medication adherence for chronic diseases including: ▫ Asthma[38,39] ▫ Heart conditions[38] ▫ High cholesterol[38,39] ▫ Diabetes[39] ▪ Decreases in medication adherence are associated with poor patient outcomes such as increased hospitalization and mortality rates.[37] o Bundled payments ▪ Two studies showed improvements in care (e.g., decrease in use of erythropoiesis-stimulating agents and intravenous vitamin D analogues) to end-stage renal disease patients that might later translate to improvements in health outcomes, but no data are available yet.[40,41] ▪ The bundled payment model PROMETHEUS showed that implementation of bundled payments involved significant operational challenges.[42] ▪ Implementing bundled payments on a national scale would likely take a great deal of time and effort.[42] ▪ A bundled payment program in Minnesota, DIAMOND, involves paying certified practices a monthly flat rate for providing bundled services to patients with depression. [43]

	▪ The program resulted in high rates of depression remission and high levels of provider satisfaction.[43] ▪ The DIAMOND model is currently being implemented in other locations.[43] o Condition management plans ▪ A review of 20 CMS disease management plans found that reducing costs enough to cover the expense of the program was challenging.[44] ▪ Only 3 of 20 programs had evidence of quality improvement at or close to budget neutrality.[44] ▪ One study found lower utilization and costs as well as improvements in recommended testing for a population of diabetes patients.[45] ▪ Another study found lower costs, fewer inpatient stays and emergency department visits, and a trend toward improved lipid control in population of heart disease patients.[46]
What could new research contribute to achieving better patient-centered outcomes?	• While expensive and logistically difficult, patients could be randomized to receive or not receive health plans with these insurance features and compared across relevant patient-centered outcomes. • Comparative effectiveness research is a vital component of chronic disease management.[47] o Before/after natural experiments and quasi-experimental designs are possible and have potential to contribute information on associations between these insurance approaches and patient-centered outcomes. • Comparative effectiveness of HDHPs versus usual health plans could provide important information about impact of HDHPs on delayed/foregone care (e.g., increases in emergency department visits, hospitalizations, and death) and treatment adherence in chronic disease patients. • Comparative effectiveness of bundled versus individual payments for chronic disease patients could provide important information about the impact on health care utilization. • Comparative effectiveness of condition management plans versus usual health plans for chronic disease patients could provide important information about the impact on treatment adherence and health care utilization. • Research on condition management plans could also provide information on the relative impact in different chronic diseases (e.g., are these plans more effective for certain diseases such as diabetes and heart disease compared to others like cancer?)
Have recent innovations made research on this topic especially compelling?	• 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,[48] makes this topic timely and compelling. • In 2011, CMS began transitioning to a bundled payment system to care for patients with end-stage renal disease.[12] • Also in 2011, CMS began the Bundled Payments for Care Improvement initiative that called on organizations to participate in several models of bundled payment plans.[49]
How widely does use of these health	• As of 2012, about 13.5 million people (about 4.3% of the U.S. population) had an HDHP.[50] o Proportion of the population with HDHP is likely to increase with passage of the

insurance approaches now vary?	Affordable Care Act.[51] • CMS Bundled Payments for Care Improvement Initiative is still calling for applications from health care organizations.[12] o Initiative has identified 48 conditions for bundling.[49] o Together these represent 70 percent of spending for episodes of care.[49] • Study in 2005-6 found only 21 percent of patients with at least one chronic disease utilize disease management program.[52] o Patients with diabetes and congestive heart failure had higher adoption rates (both 28%).[52] o Patients with asthma had a lower adoption rate (17%).[52]
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 these health insurance approaches. <u>Clinicaltrials.gov</u> Search: “high-deductible” Total ongoing trials: 0 Total completed trials: 0 Search: “bundled payment” Total ongoing trials: 0 Total completed trials: 0 Search: “condition (or disease) management plan ” Total ongoing trials: 0 Total completed trials: 0 <u>NIH Reporter</u> Search: “high-deductible” Projects: 2 Publications: 0 Search: “bundled payment” Projects: 0 Publications: 0 Search:: “condition (or disease) management plan” Projects: 0 Publications: 0
How likely is it that new CER on this topic would	• CER on this topic is likely to improve clinical decision making, especially for bundled payments and care management plans, which may establish a different set of financial incentives for providers and health systems.

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.[51] • Though bundled payments for end-stage renal disease were only recently implemented, studies show they are associated with improvements in care.[40,41] • Utilization and measures of adherence to treatment plans have been shown to be improved in patients who participate in disease management programs.[45,46]
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 • Although these health plan features were designed to reduce direct costs to patients and health plans, it is possible that high quality health care cannot be maintained while reducing costs. o Bundled payments may incentivize plans to choose cheaper products or procedures and lead to lower quality care.[53] o Bundled payments may incentivize providers to increase volume, with potential reductions in health care quality.[53] • Patients might be disinclined to participate in plans that have these features. o Patients might be reluctant to enroll in HDHPs if deductibles are unaffordable.[54] o Patients might be discouraged from participating in plans that use bundled payments if they provide lower quality care.[53] o Patients with chronic diseases are reluctant to participate in disease management programs.[52] o Providing patients with incentives that encourage them to choose health care providers that utilize bundled payments will be integral to the success of bundled payment programs.[55] FACILITATORS • Incentives for bundled payments, HDHPs, and disease management programs from the Affordable Care Act[48] and CMS.[12] • Growth of Accountable Care Organizations (groups of health care providers to coordinate high quality care for Medicare patients).[56] • Growing interest in Patient Centered Medical Homes.
How likely is it that the results of new research on this topic would be implemented right away?	• If the research speaks to the issues that policy and clinical decision makers and patients are concerned about, the results will be implemented but the pace will likely be gradual since changes to insurance policies take time to implement.
Would new information from CER on this topic remain current for several years	• CER information on this topic will be useful for years and will likely not 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.

or would it be rendered obsolete quickly by subsequent studies?	

CER = Comparative Effectiveness Research; CMS = Centers for Medicare & Medicaid Services; HDHP = high deductible health plan; IRS = Internal Revenue Service

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