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Research Prioritization Topic Briefs

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Improving Health Systems

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Research Prioritization Topic Brief 1: Decision Support for Chronic Disease Care Guidelines

PCORI Scientific Program Area:
Improving Healthcare Systems

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Executive Summary for Topic 1: Decision Support for Chronic Disease Care Guidelines

Comparative Research Question. Compare the effectiveness of alternative redesign strategies – using decision support capabilities, electronic health records, and personal health records – for increasing health professionals' compliance with evidence-based guidelines and patients' adherence to guideline-based regimens for chronic disease care.

Brief overview of the topic. The increasing prevalence of chronic disease in the United States population,[1-4] particularly the costs and complexities of treating the subset of patients with multiple chronic diseases,[5-10] presents a challenge to both patients[11] and providers.[12,13] The move to evidence-based medicine, as well as the widespread incorporation of health information technologies into the daily practice of medicine thus far has failed to produce the anticipated level of improvement in patient outcomes. Clinical decision support tools that translate evidence-based guidelines into sophisticated electronic systems appear to hold great promise for achieving the goal of multiple efforts by public and private entities over the last few decades: delivering patient-centered care.[14-22] However, there are still significant challenges.

Evidence-based guidelines are available for some conditions, but not all, and health professionals are often unaware of or fail to comply with existing guidelines.[14,23,24] Even more challenging is that multiple guidelines may be applicable to patients with multiple chronic conditions, and these often competing and overlapping recommendations are almost impossible to reconcile.[12] Thus, achieving the goal of tailored, patient-centered care that effectively engages the patient in his or her own care remains a difficult endeavor.

Patient-Centeredness: The research review is focused on the clinician-patient dyad, especially their communication at the point of care. Decision support systems assist physicians in adhering to guidelines, communicating evidence to patients, and engaging them in a discussion of treatment options.[15-18,25] For patients, these systems help ensure they receive optimal treatment for optimal outcomes, are informed of their options, and have the opportunity to be co-decision makers in their treatment.[26-29]

Impact on Health and Populations: Non-adherence by health professionals to evidence-based guidelines, and non-compliance with recommended treatments by patients, adds cost to a health care system spending billions of dollars on costly and prevalent chronic diseases.[5] Almost half of the population has one chronic condition and 26% have multiple chronic conditions.[30] For every additional chronic condition, costs increase and outcomes decline.[31] Patients with multiple chronic conditions have higher risk of morbidity, mortality, disability, and lower quality of life. In addition, multiple chronic conditions require complex treatment, multiple medications, and (when possible) robust care coordination. Chronic diseases afflict Americans of all ages, but heavily burden Medicare and Medicaid populations, in part because they are older and often belong to vulnerable populations.

Assessment of Current Options: Studies have demonstrated that the use of decision support systems for clinicians and patients can improve adherence to evidence-based guidelines.[27] Existing research suggests the use of clinical decision support systems also improves processes of care,[32] though there is limited and inconsistent evidence on the effect of decision support systems on patient outcomes.[18,33-

[38] However, several gaps in research currently exist: there are limited studies on the use of decision aids by patients to improve adherence to guideline-related behaviors;[26] limited research on the use of decision support systems by health professionals other than physicians; lack of clinical practice guidelines that specifically address multiple chronic conditions; and few examples of healthcare systems redesign approaches to improve adherence to evidence-based guidelines for patients with chronic conditions.[39-44]

Likelihood of Implementation in Practice: Advances have been made in the adoption and use of decision support systems. Programs have been working to improve the translation of clinical guidelines into clinical decision support systems and develop standards to structure medical knowledge in shareable and executable formats for electronic systems.[45,46] While many more providers have access to electronic health records and other health technology systems,[47,48] greater understanding of implementation considerations and usability testing can help address issues of provider adoption of decision support systems.[49,50] Furthermore, recent health reform efforts have shifted reimbursement systems to paying for quality versus paying for volume of services.[51,52] Finally, more concerted attention is being paid to the inclusion of patients in decision-making about their care, creating tools to help them understand their conditions and available treatment options, and measuring outcomes of care that matter to patients. All these factors influence the likelihood providers will implement new research and evidence on decision support tools into practice.

Durability of Information: Comparative effectiveness research studies in this area will need to take into account the changing and varying landscape of healthcare and health information technology, and consider the use of a multi-site design to assess the effectiveness of different approaches on improving adherence to evidence-based guidelines. Given ongoing evolution in the technology field—specifically related to the development and successful deployment of sophisticated health information technologies within a variety of health systems and practice types to educate both providers and patients about evidence based medicine and joint decision-making—there is a need for comparative effectiveness research data on this topic.[22,53,54]

Topic 1: Decision Support for Chronic Disease Care Guidelines

Criteria	**Brief Description**
Introduction	
Overview/definition of topic	Description of the Health System Problem • Patients are not receiving evidence-based guideline recommended care for their health conditions, including serious chronic conditions that require and benefit from appropriate management, including medication, lifestyle adjustments, and monitoring. Lack of adherence to guideline recommendations results in underuse, overuse and misuse of services, specifically: ○ One study found that only 55% of adults were receiving the recommended care, including appropriate level of care for chronic conditions.[55] • Development and deployment of clinical practice guidelines is the most widespread application of evidence-based medicine. However, despite the existence of 1411 individual summaries of clinical guidelines in the National Guideline Clearinghouse (NGC), providers have consistently demonstrated low levels of conformance with established clinical guidelines.[14] ○ Reasons for lack of provider adoption and uptake of clinical practice guidelines are varied, including:[14,23,24] ▪ Lack of awareness, familiarity with, or agreement with guidelines; ▪ Limited applicability of recommendations for actual management; ▪ Lack of description of the patient population to which the guidelines apply; ▪ Uncertainty of the effects on health outcomes; ▪ Organizational barriers, including need to adapt guidelines to local standards of care and administrative policies; ▪ Ineffective integration into electronic health record (EHR) systems, which often simply provide a link to the guideline that must then be perused under sub-optimal conditions/in real time, or pop-ups that are distracting, etc. • In other cases, there is an absence of sufficient evidence-based guidelines to direct care, especially for multiple chronic conditions and complex chronic conditions.[12] ○ Clinicians have difficulty taking into account multiple chronic conditions, patient preferences, and socio-personal characteristics that influence treatment adherence.[12]

Relevance to patient-centered outcomes	• Providers report greater difficulty treating patients with chronic conditions, due to lack of training to coordinate care, educate patients, and address the psychological and social aspects of chronic conditions.[13] • As a result, physicians believe there are unmet needs and adverse outcomes for patients.[31] ○ For patients: Poor adherence to behaviors recommended by evidence-based guidelines or lack of use of guidelines is associated with higher rates of morbidity and mortality. • The greatest risk factors for preventable death include tobacco use, high BMI, alcohol use, high blood pressure, and high fasting glucose.[31] ○ All of these risk factors are strongly associated with poor lifestyle, and all have associated evidence-based guidelines and a variety of potential lifestyle interventions. However, these guidelines suffer from underuse (by physicians) and/or low adherence (by patients).[11] • Patients with multiple chronic conditions, who also tend to take multiple medications, are especially at risk for poor health outcomes. Polypharmacy, the taking of multiple medications concurrently, increases the risk of non-adherence[1] and complications such as adverse events[6,7] and mortality.[8] ○ Risks related to poor medication adherence include poor health outcomes related to the condition being treated, preventable hospitalizations and emergency department visits, missed days from work, and higher risk of mortality, and increased use of health services in general.[9,10] ○ Conversely, improved medication adherence is associated with positive outcomes such as increased spending on medication and decreased use of hospital and emergency services,[56] positive health outcomes,[57] and decreased mortality.[58] • CSD and patient decision aids are a means of helping people make informed choices about healthcare that take into account their personal values and preferences.[59] ○ Decision aids can take the form of EHR-based tools, patient portals, CDS systems and/or other aids, and changes in physician workflow that facilitate shared decision-making.[60] • CDS has the potential to improve provider adherence to evidence-based guidelines,[14-18] improve care processes,[19,20] and improve patient understanding[21,22,28] ○ There is mixed evidence on that CDS can improve patient outcomes.[18,33-36,61,62] ○ There is potential of CDS to improve symptoms or clinical markers, decrease morbidity, and improve patient satisfaction,[19,37,38] but more research is needed. • Furthermore, the integration of clinical support tools, such as those for clinical prediction, supports national initiatives, such as meaningful use, related to health IT, reductions of unnecessary testing, and building a more patient-centered health system.[63]

Burden on Society	
Extent of the health system problem	• Cost to the system of lack of adherence to evidence-based guidelines is significant. Although chronic conditions affect people of all ages, a disproportionately large number are over age 65, require complex care for their health needs, and are members of vulnerable populations.[64] • Rates for the top five chronic conditions have climbed since 2002, including among adults 25 and older,[1] and could be ameliorated by adherence to clinical guidelines. • Financial burden: ○ Billions of dollars are spent on chronic conditions:[5] ▪ Heart disease and stroke (in 2010, $315.4B); cancer (in 2010, $157B); diagnosed diabetes (in 2012, $245B in direct medical costs and decreased productivity or absence from work); obesity (in 2008, $147B). ○ Medicare populations have higher rates of multiple chronic conditions than the general population[65] ▪ 93% of the $300 million spent on Medicare in 2010, went towards care for people with two or more chronic conditions,[11] and cost increases with every additional chronic condition[31] ○ 60% of Medicaid spending is used to cover 5% of the population, most of whom have multiple chronic conditions and disabilities.[66] • Disease burden: ○ A 2010 survey found that 5% of Medicare beneficiaries have asthma, 12% have COPD, 28% have diabetes, 31% have heart disease and 58% have hypertension, and that these rates increase among dual eligible beneficiaries. It is estimated that more than two-thirds of Medicare beneficiaries have more than two chronic conditions, adding complexity and cost to their care.[67] ○ Another study reported the most common diseases among non-elderly Medicaid beneficiaries were diabetes (9%), cardiovascular disease (28%), and respiratory diseases (23%).[68] ○ All told, the CDC/NHIS estimates that almost half of US adults are afflicted with chronic conditions and an estimated 26% of adults have multiple chronic conditions (rising from 21% in 2001 to 26% in 2010). [30] Multiple chronic conditions rates are highest among older adults, women, and non-Hispanic whites and blacks.[69]

Effects on patients' quality of life, productivity, functional capacity, mortality, use of health care services	• Patients and providers can/would benefit from CDS tools. ○ Patients who are more informed about their treatment options tend to pursue different treatments than those who are less informed.[69] ○ Physicians tend to offer different treatments not based on patient preferences,[70] but instead based on their own sense of what is best or on medical consensus.[71] • Patients want to take part in decision-making. ○ Low health literacy can limit patient understanding of the complex information about treatments and their probable outcomes (e.g., in terms of quality of life). This is a barrier to patient participation in the decision-making process.[72] ○ It is also contributes to patient doubt about whether they are receiving the best care; improving literacy and shared decision-making through discussions with physicians can build confidence in treatment.[73] • Patients' use of decision aids can improve knowledge of options and help patients have more accurate expectations of possible benefits and harms, reach choices that are more consistent with their informed values, and participate more in decision-making without increasing their anxiety.[29] ○ Policy, systems, and environmental (PSE) interventions through media, access, promotion, pricing, and social support can help reach at-risk populations.[74] ○ Clinical decision support tools promoting shared patient-provider decision-making can increase patient knowledge about treatment and screening options and prompt more patient-provider discussions.[75] • Studies show (moderate) positive impacts on cost.[75] ○ A different meta-analysis through 2013 concluded that while a majority (71%) showed cost benefits from CDS, only 13% directly measured financial impact.[76] ▪ CDS seems to have little effect on satisfaction and variable effects on decisions; the effects on outcomes of decisions (persistence with choice, quality of life) remain uncertain.[70] ▪ Tools to support decision-making or patient understanding of treatments and options are often sub-optimally developed.[33]
How strongly does this overall societal burden suggest that CER on alternative approaches to this problem should be given high priority?	• The prevalence of chronic disease and complex medical conditions is expected to continue to increase, having substantial implications on morbidity and mortality as well as use of and cost to the health care system.[2] ○ According to one study, by 2025, chronic diseases will affect an estimated 164 million Americans – nearly half (49%) of the population.[3] Another estimates that between 2010 and 2030, there will be an additional 27 million Americans with hypertension, 8 million with coronary heart disease and 3 million heart failure.[4] ○ Changing demographics and an aging elderly population (by 2050 the US population ages 65 and older is projected to reach 89 million—more than double the 40.5 million elderly people in 2010[4]), who are more likely to have multiple chronic conditions,[69] will place further strain on the health care system. ○ One study projects that the demand for adult primary care services will grow by approximately 14% between 2013 and 2025.[4]

	• Risk factors leading to chronic conditions are strongly associated with poor lifestyle and have associated evidence-based guidelines and a variety of potential lifestyle interventions.[1]
Options for Addressing the Issue	
Based on systematic reviews, what is known about the relative benefits and harms of the available management options? Note if no systematic reviews are available, and summarize results from seminal recent studies on the relative benefits and harms of available management options.	CDS systems for providers: • CDS systems inform care delivered by clinicians. Often, providers use these systems at the point of care with alerts integrated into their EHR to inform choices and knowledge based on patient information and clinical guidelines.[25] • Computerized decision-support systems and EHRs can improve compliance with clinical guidelines for patients with chronic conditions.[14-18] • A systematic review of the role CDS systems in the care of hospitalized patients with diabetes found some evidence CDS has beneficial effects[19] while a pragmatic randomized trial found that a shared electronic decision support system to support primary care of diabetes improved process of care and some clinical markers of the quality of diabetes care.[38] ○ Another systematic review and meta-analysis of randomized controlled trials and observational studies, however, noted insignificant benefit of CDS in the management and control hypertension.[17] • A decision-maker-researcher partnership systematic review found that computerized CDS systems have the potential to improve care processes in chronic disease management, while another systematic review found it could improve provider performance. • However, there is mixed evidence on the effectiveness of CDS in improving patient outcomes, specifically as it relates to chronic conditions.[18,33-38] ○ Some studies have shown modest improvement in some clinical markers of quality,[37] including for diseases like diabetes and coronary artery disease care.[19] Others show limited or no change in patient outcomes with the use of clinical decisions support systems.[34,35,37,62,77,78] • Evidence suggests that necessary components/conditions for effective CDS include: ○ Implementing CDS a) as part of clinical workflow, b) at the time of decision-making, and c) at a time of recommendations, not just assessments;[33] ○ Integrating CDS into computer systems (EHRs) and physician ordering, and offering the six major CDS functions: alerts, interpreting, assisting, critiquing, diagnosing, and managing decision support.[55] CDS for patients: • Health IT and CDS can help increase patient participation decision-making. For example, PATIENT (Promoting Adherence to Improve Effectiveness of Cardiovascular Disease Therapies), a pragmatic trial involving members of a health maintenance organization, evaluated the effectiveness of two EHR-linked, automated reminders compared with usual care and found reminders increased patient adherence rates to cardiovascular medications.[26] • One system, a Dynamic Computer Interactive Decision Application (DCIDA), supports patient decision-making by presenting information and the decision to each person in an individualized way in order to maximize their ability to make choices that reflect their own informed, stable values. Thus, reducing four common patient decision aids design errors: unstable values, order effects, overweighting of rare events, and information overload.

Preliminary results suggested DCIDA has potential to improve quality of patient decision-making.[27]

- The most up to date Cochrane systematic review of patient decision aids found that among 115 studies involving 34,444 participants, patient decision aids increase patient's knowledge about treatment options and reduce their decisional conflict related to feeling uninformed and unclear about their personal values.[28,29]
    - High-quality evidence shows patient decision aids increase patient knowledge and reduce aspects of decisional conflicts, the proportion of patients remaining undecided, and the proportion of patients who play a passive role in the decision-making process.[21,29,79,80]
    - Moderate-quality evidence suggests decision aids compared to usual care stimulate people to take a more active role in decision-making, and improve accurate risk perceptions when probabilities are included. There is low-quality evidence that decision aids improve congruence between the chosen option and the patient's values. There is a variable effect of decision aids on length of consultation and on choices. Patient decision aids reduce the number of people choosing discretionary surgery and have no apparent adverse effects on health outcomes or satisfaction.[29]
- Patient decision aids also have the potential to improve understanding and decision-making for low literacy patients.[81]
    - The "edutainment" decision aid model guides developers through the design process to develop decision aids that take into account design considerations for poor readers and naïve computer users to improve patient understanding.[82,83]
    - Tailored decision support information can be effective in supporting informed choices and greater involvement in decisions among adults with low levels of education.
    - However, more research is needed on the use of patient aids by low-literacy populations.[29]

Shared decision-making:

- CDS tools promoting shared patient-provider decisions can increase knowledge about treatment and screening options and prompt patient-provider discussions;[76]
- It can be incorporated into the EHR to prompt providers to initiate SDM; transmit educational materials to the patient and elicit preferences; decide on treatment together; and perform tailoring necessary to reflect preferences.[84]
- To date, no systematic reviews exist on the effect of shared decision-making on outcomes in patients with chronic conditions.[81]

Health systems redesign to support use of evidence-based guidelines:

- To date, there are no systematic reviews of health systems redesign and the use of evidence-based guidelines. There are some promising case studies identified below:
    - Boot Camp Translation successfully engages community members in a process to translate evidence-based medical care into locally relevant and culturally appropriate language and constructs and may be an appropriate first step in building a local or regional community of solution.[39]

	○ Patient-Centered Medical Home models, which incorporate the Chronic Care Model, can influence delivery of proper care to patients with chronic conditions. ■ Cross-sectional analysis found that certain PCMH practice systems were related to lower diabetes costs, but effects are small compared with total costs.[40] Redesign of primary care according to principles of the chronic care model can shift COPD management from acute rescue to proactive maintenance.[41,42] Evidence has shown that the PCMH model can overcome some of these issues and improve patient outcomes and adherence to therapy.[43] ■ Case studies of 11 leading integrated delivery systems (IDSs) found their advanced IT capabilities have led to improved patient satisfaction due to superior service outcomes and the IDS's ability to access clinical information from any point within its delivery system, reduced prescription errors and adverse drug reactions, enhanced quality-improvement efforts, reduced costs associated with telephone calls and paper processing, and enhanced ability to recruit clinical personnel.[44]
What could new research contribute to achieving better patient-centered outcomes?	There are numerous opportunities for new comparative effectiveness research (CER) on this topic. Important research questions that need to be answered include: • **GAP:** Current studies on the use of CDS systems on patient outcomes are limited or offer mixed evidence on the effect of CDS on patient outcomes. What is the comparative effectiveness of using CDS systems either on their own or combined with other interventions (e.g., educational component, financial incentives, and organizational model) to implement evidence-based guidelines compared to usual care processes, on outcomes for patients with chronic conditions including complex chronic conditions and multiple chronic conditions? Research in this area would include an assessment of whether CDS improves patient's quality of life measures (morbidity, mortality, unnecessary hospitalizations, missing days from work and emergency department visits) and how this varies by patient characteristics or diseases. • **GAP:** To date, there is lack of evidence concerning implementation of evidence-based guidelines in new health system models such as ACOs and PCMH. What is the comparative effectiveness of CDS implementation and adoption in different types of health system models such as ACOs, PCMHs and fee-for-service? What features (e.g., incentive structures) of the models are critical to motivating CDS adoption and use, in such comparisons? • **GAP:** Current studies of CDS use by healthcare professionals other than physicians is limited. Further studies are needed to identify contexts in which CDS systems use by health professionals is most effective. What is the comparative effectiveness of CDS interventions that target other health professionals (e.g., nurses, pharmacists, care coordinators) compared to CDS interventions that target physicians only on care processes and outcomes for patients with chronic conditions?
Have recent innovations made research on this topic especially	• Advances in Guideline Translation into CDS ○ Findings from the AHRQ-funded CDS demonstration projects show it is possible to effectively translate evidence-based knowledge into useful actionable care through

compelling?	CDS; however, not all guidelines provide the needed information in a clear and unambiguous manner.[45]
	- Advances in CDS standards:
	  - ONC's Standards & Interoperability Framework HealtheDecisions initiative seeks to identify, define, and harmonize CDS standards, developing standards to structure medical knowledge in a shareable and executable format for use in CDS and define how a system can interact with and utilize an electronic interface that provides helpful, actionable clinical guidance.[46]
	- The harmonization efforts of CDS standards and clinical quality measures.
	  - The ONC and CMS sponsored Clinical Quality Framework initiative develops CDS and electronic Clinical Quality Measures (eCQM) standards in parallel and utilize different approaches for representing patient information and computable expression logic.[49]
	- Greater understanding of implementation considerations:
	  - Usability testing optimized the CDS systems to better address barriers such as lack of provider education, confusion in dosing calculations and titration schedules, access to relevant patient information, provider discontinuity, documentation, and access to validated assessment tools.[50]
	- Move to provide financial incentives for improving quality of care delivered to patients
	  - Starting in 2014, the EHR Incentive Programs requires eligible professionals to report on clinical quality measures to demonstrate Stage 2 meaningful use in order to continue to receive financial incentives.[51]
	  - The ACA promotes the use of "pay-for-performance" models to encourage experimentation to identify designs and programs that are most effective for improving quality, efficiency, and overall value of health care;[52] these programs link payment and reimbursement to provision of high quality services versus paying for each service a hospital provides.

How widely do management options vary now?	- There is tremendous variability in management options:
	  - Variability in CDS modalities used to implement evidence-based guidelines: i.e., alerts, smart forms, info-buttons;
	  - Variability in CDS implementation across care settings;[53]
	  - The use of patient decision-aids vary across sites and disease conditions;[22]
	  - Health systems are beginning to experiment with use of decision aids as part of routine practice[54]

What other research is ongoing in this area currently?	- There is ongoing research on guideline translation into CDS.[85]
	- New payment and delivery models are just beginning to be tested.
	  - Two provisions under the Affordable Care Act, Sections 4004(i) and 4106, encourage states to expand and promote coverage of evidence-based preventive services for adults and Section 4108 creates the Medicaid Incentives for Prevention of Chronic Diseases Program.[50]
	  - Decision support services for chronic diseases and preference sensitive options are still in the early phases of demonstration projects.[22]

How likely it is that new CER on this topic would provide better information to	The use of CDS systems suggest its potential to improve provider and patient adherence to evidence-based guidelines; more research is needed to assess:

guide health system practice?	• Impact of CDS on healthcare provider performance. Some evidence already exists to suggest the use of CDS systems improve provider adherence to evidence-based guidelines, but further research is needed. • Effect of CDS systems on patient outcomes. Evidence for impact on outcomes is limited or mixed based on a review of current literature;[33,18,34,35] • Assess effectiveness of multifaceted interventions for chronic disease management; • How patient decision aids can be used to improve adherence to evidence based guidelines for chronic conditions. Further research on how to incorporate and increase adoption of user-friendly, patient-centered e-health tools needed;[27] • The potential for other health professionals (nurses, pharmacists, etc.) to use CDS systems to manage chronic conditions; • Optimal CDS systems to use for multiple chronic conditions. Assess impact of CDS systems on healthcare provider performance: • Understanding of CDS systems impacts on specific aspects of the prescribing process remains relatively limited;[72,86] • Mixed/inconclusive evidence of CDS for drug therapy management benefits in improving process of care measures and patient outcomes;[2] • One challenge with the management of chronic diseases is the difficulty synchronizing a patient's therapeutic history with the guideline-based sequence of treatments;[86,87] • Application of a guideline-based therapeutic strategy in the context of chronic diseases requires a clear picture of a patient's therapeutic history.[32] Offer evidence on the effect of CDS on patient outcomes: • The current review of literature offers limited evidence on impact of CDS on outcomes.[18,33-35] ○ Almost half of medication management IT improved processes of care but few measured clinical outcomes; this body of literature not uniformly distributed across settings, people, medication phases, or outcomes.[88] ○ CDS systems have the potential for improving process of care for therapeutic drug monitoring and dosing; but existing studies small and of modest quality, and effects on patient outcomes were uncertain.[89] ○ Proposed computerized guidelines for recommending therapeutic strategies for potential to impact physician decisions to improve compliance recommendations and restore the therapeutic history of a patient.[90-93] Assess effectiveness of multifaceted interventions for chronic disease management: • In 14 studies a CDS systems was combined with another intervention. Two studies were excluded from the analysis because of low quality. Four studies with a CDS systems alone and four studies with a CDS systems and reminders showed improvements of the process of care. CDS systems with feedback on performance with or without reminders improved the process of care (one study) and patient outcome (two studies). CDS systems with case management improved patient outcome (two studies). CDS systems with reminders, feedback on performance, and case management improved both patient outcome and the process of care (two studies).[32]

	• Most effective strategies for diabetes management often involve multiple components; one strategy (reminders only or an educational intervention) often less effective. More studies needed to examine effect of several care management strategies simultaneously (e.g. use of clinical information systems, provider financial incentives, organizational model) on processes of care and outcomes.[87] • Diabetes care improved significantly in response to multifaceted intervention features use of EHR-based registry, including audit and feedback, computerized reminders, and financial incentives.[94] • Patient education, provider feedback, and reminders were associated with significant improvements in provider adherence to guidelines and in patient disease control.[95] • A multidisciplinary group of physicians worked to create a "bundle" of best practice measures for diabetes and deployed as part of a multifaceted intervention to improve physician performance in diabetes care, including audit and feedback, computerized reminders, and financial incentives. Diabetes care improved significantly in response to a multifaceted intervention featuring the use of an EHR-derived registry in an integrated delivery system. More work is needed to demonstrate that such improvements will translate into improved patient health outcomes.[94] Conduct evaluations of use of CDS by other health professionals beyond clinicians: • Positive results of pharmacist-led IT interventions indicate the IT intervention with inter-professional communication appear to be effective; further evaluation needed.[96] • Care management technology complemented by a nurse-directed interactive program (adding member interaction with a nurse to a physician alerting system) increased rate of identification of clinical issues compared to claims alerts alone.[97] • Introduction of CDS systems to nurses may not necessarily lead to a positive outcome, though further studies are needed to identify contexts in which CDS systems use by nurses is most effective.[98] • Some general practitioners suggested that nurses might find the guideline content more clinically useful and might be more prepared to use a computerized decision support system, but lack of feedback from nurses who had experienced the system limited the ability to assess this.[99] The development of clinical practice guidelines for multiple chronic conditions: • There is a lack of a sufficient evidence-based guidelines to guide care for patients and clinicians, especially for multiple and complex chronic conditions.[12] • Clinicians have difficulty taking into account multiple chronic conditions, patient preferences, and socio-personal characteristics that influence treatment adherence.[85]
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?	<u>Facilitators</u> • The level of health IT and EHR adoption is increasing across the country. ○ An increase in the uptake of health IT (due to for e.g. HITECH programs, CMS Incentive Programs, etc.) expands opportunities to leverage technology options to improve care; 78% of physicians practices[47] and 70% of hospitals[48] had adopted an EHR in 2013.

	○ Health IT has the potential to improve quality of medical and health care and compliance with evidence-based guidelines, though limited evidence of benefits to patient outcomes.[100] • Several provisions under Title IV - Prevention of Chronic Disease and Improving Public Health of the Affordable Care Act expand access to health care services that help Medicaid beneficiaries prevent and manage chronic disease.[50] ○ Two provisions, Sections 4004(i) and 4106, encourage states to expand and promote coverage of evidence-based preventive services for adults and Section 4108 creates the Medicaid Incentives for Prevention of Chronic Diseases Program, a nationwide program that will test and evaluate the effectiveness of a program to provide financial and non-financial incentives to Medicaid enrollees of all ages who participate in programs to address at least one prevention goal. ○ Further, Section 3201 discusses how programs eligible for Medicaid Advantage payment must use health IT programs, including CDS, for patient-centered and appropriate care. • National incentives encourage the use of CDS systems and increase patient engagement through the use of personal health records and patient portals. ○ Under Stage 2 meaningful use, eligible hospitals and professionals must use CDS to improve performance on high-priority health conditions[101] and provide patients with the ability to provide patients the ability to view online, download and transmit their health information.[102] Barriers • There are various issues with CDS implementation that must be addressed. ○ Lack of clinician adoption and use of CDS: ▪ There is limited uptake of CDS by providers due to lack of integration of CDS systems into workflow.[103,104] ▪ Three main areas of concern among clinicians include timing of the guideline trigger, ease of use of the system, and helpfulness of the content.[85] ○ Insufficient evidence base on CDS for multiple chronic conditions: current clinical guidelines do not usually address how to treat patients with multiple chronic conditions or comorbidities.[105] ○ Difficulty translating and incorporating guidelines into CDS and into practice: ▪ Written guidelines do not allow for direct translation into computable code; this task requires a high level of clinical and programming knowledge and expertise.[45,104,105] ▪ Adoption of EHR standards, including terminologies and exchange formats, has been slow; mapping to proprietary and local terminologies is difficult.[45,105] ▪ Data quality remains an issue; missing and inaccurate data can make it difficult for the CDS application to generate appropriate and effective interventions and applications.[103,105]
How likely is it that the results of new	• The likelihood of new evidence being adopted right away will depend on health IT maturity of different delivery organizations and care settings.

research on this topic would be implemented in practice right away?	• Current studies suggest customization of CDS is still required on a site-to-site basis suggesting new research will need to factor in site specific factors.[45] • Decision support services for chronic diseases and preference sensitive options are still in the early phases of demonstration projects.[106]
Would new information from CER on this topic remain current for several years, or would it be rendered obsolete quickly by subsequent studies?	• CER studies in this area will need to take into account the changing and varying landscape of healthcare, health IT and consider the use of a multi-site design to assess the effectiveness of different approaches to the use of decision support for adoption and use of evidence-based guidelines. • Given this is a new and evolving field where there is a significant need, there evidence base/CER data on this topic will be useful for years.

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Research Prioritization Topic Brief 2: Pharmacy Services Integration into Patient Care

PCORI Scientific Program Area:
Improving Healthcare Systems

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Executive Summary for Topic 2: Pharmacy Services Integration into Patient Care

Comparative Research Question. Compare the effectiveness of various strategies to better integrate pharmacists or pharmacy services in patient care on patient-centered outcomes (e.g., reduction in inappropriate medication use and polypharmacy, access to preventive vaccines (influenza, pneumonia), reduction in adverse events and hospital re-admissions, improved disease- or condition-specific outcomes).

Brief Overview of the Topic. As more prescription drugs become available, medication use is steadily increasing in the United States. Yet there are many ways that medication use could be improved. Prescribers fail to follow evidence-based guidelines, and patients fail to follow their prescribed regimens – resulting in preventable health problems. In addition, medication errors and mismanaged polypharmacy (taking multiple drugs) too frequently result in patient harm.

As part of a larger movement toward patient-centered care, some pharmacists are becoming more directly involved in patient care. Interventions led by clinical pharmacists include:

- reviewing individual prescriptions as they are written for appropriateness and safety,
- reconciling medications at the time of transition out of the hospital,
- providing a comprehensive review of medications and an action plan for patients (known as medication therapy management),
- monitoring test results and adjusting medication dosages accordingly,
- educating and counseling patients about their medication use, and
- delivering preventive care such as vaccines or screenings.

Clinical pharmacists may be co-located with other health care providers, or may be in a community pharmacy. In some states, advance practice pharmacists have some authority to write prescriptions.

Patient-Centeredness. The evidence does not all point in the same direction, but an increasing number of studies are showing that various pharmacist-led interventions can have a positive effect on clinical outcomes, particularly when their efforts are targeted to disease-specific outcomes such as cholesterol, blood pressure, and blood glucose levels. Separate literature has shown that these clinical outcomes can affect patient-centered outcomes. But with a few exceptions, most studies of pharmacist-led interventions have not been large enough or long enough to detect effects on outcomes such as quality of life, hospitalization, or death.

Impact on Health and Populations. One study estimates that sub-optimal drug use leads to untreated illness and preventable adverse events on such a scale that these problems cause 10 million hospital admissions, 78 billion outpatient visits, and 4 million emergency room visits every year. Clinical pharmacists seek to affect these statistics by avoiding patient harm caused by poor prescribing, improving patient adherence to health-improving drugs, maximizing the benefits of those drugs by optimizing dosages, and preventing illness through immunizations and other preventive care.

There is extensive literature on pharmacist-led interventions to improve patient care:

- Multiple studies have shown pharmacist reviews of prescriptions, both as they are written and at the time of hospital discharge, to identify prescriptions that need to be changed and to prevent adverse events; fewer studies have shown that this reduces hospitalizations.

- Studies of medication therapy management have shown improvements in clinical measures and hospitalizations for diabetes and congestive heart failure patients.
- Programs using pharmacists to monitor test results to optimize dosages of medications for anticoagulation, diabetes, and high blood pressure have found that this improves immediate clinical outcomes; two observational studies found that in the case of anticoagulation therapy, pharmacist management reduced the number of complications that required medical care.
- Pharmacist-led education and counseling can improve clinical outcomes, and one study found that this patient education led to improved quality of life.
- Multi-faceted interventions combine these strategies, often using medication therapy management, patient education, and other services. A review of 27 complex interventions found that 20 had positive outcomes, with 3 improving quality of life, 1 reducing mortality and heart failure events, 12 improving clinical measures, and 4 improving process measures.
- Two studies have shown that pharmacist provision of vaccines can improve vaccination rates.

Assessment of Current Options. In addition to the extensive published literature on the use of clinical pharmacists, we identified 25 ongoing studies. However, this body of research does not answer some key questions about the comparative effectiveness of these interventions:

- What is the comparative effectiveness of the pharmacist-led interventions currently being tried in patient care? Are some interventions more effective for some patient populations?
- Many programs are implementing multi-faceted interventions (e.g., combining MTM, patient education, and monitoring test results together). What is the comparative effectiveness of individual interventions versus multi-faceted interventions?
- For any given intervention, what is the comparative effectiveness of giving pharmacists the authority to write or change prescriptions versus requiring them to work with another health professional to change the medication regimen?
- For any given intervention, what is the effectiveness of co-locating a pharmacist with the care team, compared to using a community pharmacist?
- For any given intervention, what is the effectiveness of using a pharmacist to deliver the intervention, compared to other non-physician providers such as nurse practitioners or physician assistants?

Likelihood of Implementation in Practice. Many health systems and team-based primary care practices have already experimented with including clinical pharmacists in the care team, and pharmacist groups are actively promoting the idea of clinical participation by pharmacists. However, the lack of financing models and the requirement of significant planning around practice redesign may be barriers to implementation.

Durability of Information. Because the use of clinical pharmacists is a general approach to care and not a specific treatment, research on this topic is likely to remain current for many years.

Topic 2: Pharmacy Services Integration into Patient Care

Criteria	Brief Description
Introduction	
Overview/definition of topic	<u>Description of the Health System Problem</u> • The percentage of Americans taking at least one prescription drug increased from 38 percent in the period 1988–1994 to 49 percent in the period 2007–2010, and the percentage of Americans taking three or more prescriptions increased from 11 percent to 22 percent.[1] • The IMS Institute for Healthcare Informatics estimates that $213 billion in costs could be avoided by addressing six problems related to pharmaceutical use: ○ lack of adherence ($105.4 billion); ○ delayed evidence-based treatment ($39.5 billion); ○ antibiotic misuse ($35.1 billion); ○ medication errors ($20.0 billion); ○ suboptimal generic use ($11.9 billion); and ○ mismanaged polypharmacy ($1.3 billion).[2] <u>Description of Interventions</u> • Usual care involves a pharmacist filling prescriptions and checking for possible problems, based on the information available at the pharmacy. • There are many examples of pharmacists taking a more active role in patient care. These interventions include: ○ **Review of prescriptions as they are made.** Pharmacists may be involved in reviewing medication regimens in inpatient, outpatient, or nursing home settings. This most often includes identifying potential errors and resolving issues with polypharmacy. It may also include identifying when additional medications are needed according to evidence-based guidelines. This review is often done without a face-to-face patient encounter. ○ **Reconciliation of medication lists during care transitions.** Because new medication regimens are often tried during a hospital stay, transition-oriented interventions involve a community-based pharmacist and a hospital-based pharmacist communicating about a patient's drug list so that it is clear to the patient and the patient's providers what the drug regimen will be after discharge. ○ **Medication Therapy Management (MTM)**. This generally includes performing a comprehensive medication review, confirming a medication list, formulating a medication treatment plan that may include recommendations for changes to the current medication regimen, and documenting and communicating the plan to the patient and prescribers. ▪ CMS currently requires all Medicare Part D plans to have a MTM program for selected enrollees. ○ **Monitoring test results.** In some programs, pharmacists are responsible for monitoring patients' medication-related lab results (such as the INR for warfarin or HbA1C for diabetes medications) and adjusting, or making recommendations to adjust, dosages accordingly.

Criteria	Brief Description
	○ **Patient education and counseling on adherence.** Some interventions seeking to improve patient adherence involve pharmacist-delivered education about the importance of taking the medication as prescribed, and an opportunity for the patient to ask questions. ○ **Multi-faceted clinical pharmacist interventions.** Many programs have implemented combinations of the above interventions, such as a clinical pharmacist who performs MTM, delivers adherence-oriented counseling, and monitors treatment response. ○ **Delivery of vaccines and other care**. Pharmacists may administer vaccines, screen for certain conditions, or provide other advice about common medical problems. ■ Since 2009, all states have allowed pharmacists to administer vaccines. Some require certification or limit the types of vaccine that pharmacists can administer. Some allow pharmacist administration only for adult vaccines.[3] • Implementation of these interventions can vary significantly: ○ **By setting.** Clinical pharmacists may be co-located with the care team in a hospital, a primary care office, or a nursing home; or they may be located in a community pharmacy. Community pharmacists have varying levels of communication with prescribing physicians, and may or may not have access to a patient's medical record. ○ **By prescribing authority.** In many states pharmacists are allowed to prescribe certain drugs, under collaborative agreements with physicians. This allows them to immediately implement the recommendations they might make rather than giving information to the prescribing physician and waiting for the change to be made. ■ In VA settings, 43 percent of pharmacists have an advanced scope of practice and can prescribe medications.[4]
Relevance to patient-centered outcomes	• Inappropriate pharmaceutical use may lead to problems such as diseases that go untreated, medication errors and polypharmacy, and vaccine-preventable diseases. All of these can lead to poor patient-centered outcomes, including pain, hospitalization, and death. ○ For example, for individuals with diabetes, poor glycemic control (higher HbA1c levels) can cause problems with eyes, nerves, and kidneys that result in disability; good control is associated with better functional status and well-being.[5] ○ Vaccine-preventable diseases kill more individuals every year than breast cancer, HIV/AIDS, or traffic accidents.[3] • Clinical pharmacists provide services that are intended to improve pharmaceutical use (and as a result, patient-centered outcomes): ○ reviewing medication regimens for appropriateness and safety, thus preventing adverse events and improving prescribers' use of evidence-based guidelines to manage disease and improve outcomes; ○ interacting directly with patients to provide education, counseling, and assessment, with the goal of improving patient adherence to recommended drug regimens and thus better management of disease and better outcomes; and ○ directly providing care such as immunizations, leading to prevention of disease.

Criteria	Brief Description
Burden on Society	
Extent of the health system problem	• Of the $213 billion in costs the IMS Institute for Healthcare Informatics estimates could be avoided by improving pharmaceutical use, most is due to unnecessary healthcare utilization such as 10 million hospital admissions ($140 billion), 78 billion outpatient visits ($45 billion), and 4 million emergency room visits ($6 billion) due to a combination of untreated illness and preventable adverse events.[2] *Pharmaceutical underuse* • There are significant gaps in prescribers' use of medications, even when there are clear clinical guidelines. A 2006 review of 2,456 patients found that physicians prescribed medications that were medically indicated for selected conditions only 63 percent of the time.[6] • Once they have a prescription, patients may not fill it, and even fewer continue to take the medication as prescribed over time.[7,8] One meta-analysis found that about a quarter of patients typically do not take their medications as prescribed.[9] Adherence is typically lower in patients with chronic conditions that require long-term therapy, compared to patients with acute conditions.[10] • Nonadherence (not taking a drug at all) and partial adherence (skipping doses or otherwise taking less medicine than prescribed) may be intentional, such as when a patient does not take a drug to avoid troublesome side effects or high costs, or unintentional, such as when a patient forgets to take the medication or does not understand how the medication should be taken. • Nonadherence and partial adherence increase morbidity and mortality because patients are not receiving optimal therapeutic doses of their medications. For example: ○ Patients who are nonadherent to cardiovascular medicines are more likely to have heart attacks and more likely to die.[11] ○ Partial adherence to antipsychotic medication can result in exacerbation of psychotic symptoms, increased use of inpatient and acute outpatient services, increased costs, and psychotic relapse leading to rehospitalization.[12] ○ Partial adherence to osteoporosis medication is associated with a higher risk for fragility fracture and lower quality-adjusted life years gained compared to full adherence.[13] *Medication Errors and Adverse Events* • A 2006 Institute of Medicine report concluded that at least 1.5 million preventable adverse drug events (i.e., adverse events due to medication errors) occur every year in the United States.[14] More recent studies have made estimates of over 7 million preventable adverse drug events per year.[15] These adverse events can result in emergency department visits, hospitalization, and death. ○ In one study of 779 medication errors, 58 percent reached the patient, and 9 percent of those (5 percent of all cases) caused patient harm. Of those, 15 percent resulted in hospitalization, and one error resulted in death.[16]

Criteria	Brief Description
	- The likelihood that a patient will experience an adverse drug event (due to errors or other problems) is related to how many drugs that patient takes: patients who take multiple drugs (known as polypharmacy) are much more likely to experience an adverse event.[17] *Vaccine-preventable diseases* - There were 529,135 cases of vaccine-preventable disease in the United States in 2010.[18] Many of these diseases result in serious patient harm, including lost productivity, hospitalization, and death. - The CDC estimates that each year, an average of 226,000 people in the United States are hospitalized due to influenza and between 3,000 and 49,000 people die of influenza and its complications. Pneumococcal disease resulted in about 3,300 deaths in 2012.[19] - A 2003 study estimated that influenza epidemics annually resulted in $16.3 billion in in lost earning and loss of life.[20] Flu vaccination coverage for the 2013-14 season was 58.9 percent for children age 6 months to 17 years and 42.2 percent for adults over 17, both significantly below HealthyPeople 2020 targets of 80 percent coverage.[21,22] - In 2013, non-flu vaccine coverage rates for children were at or near HealthyPeople 2020 targets, however there is evidence of an increase in vaccine refusal rates and an increased risk for vaccine preventable diseases.[23,24]
Effects on patients' quality of life, productivity, functional capacity, mortality, use of health care services	- Inappropriate medication use is associated with: ○ disease progression, increased comorbid diseases, and death;[25] ○ increased health care utilization, including emergency room visits, hospitalization, and rehospitalization;[24,26-28] and ○ decreased workplace productivity.[28] - Most studies on the effects of pharmacist interventions have focused on short-term clinical effects, not patient-centered outcomes such as quality of life and mortality. Studies that have attempted to measure changes in hospitalizations or mortality usually have not found statistically significant effects, possibly due to small study populations and short time frames. Some exceptions include the following: ○ The Asheville Project long-term community pharmacy diabetes care program, which included long-term pharmacist follow-up consultations, resulted in fewer days of sick time and increased productivity.[29] ○ Optimizing polypharmacy is related to an increase in patient satisfaction.[30,31] Polypharmacy and non-optimized drug regimens can lead to added stress for patients who have to manage the purchase and storage of each of their medications as well as how and when to take each of their medications. ○ One study found a pharmacists-based smoking cessation program incorporating nicotine replacement therapy and behavioral modification found patients had significantly improved health-related quality of life.[32]
How strongly does this overall societal burden suggest that CER on alternative approaches to this problem should be given high priority?	Factors in Favor - Inappropriate medication use is widespread and costly. It results both in poor outcomes for patients and higher overall health system costs. - Medications and preventive vaccines are effective interventions – especially compared to invasive procedures or hospitalizations that may result if a disease is allowed to progress without pharmaceutical treatment.

Criteria	Brief Description
	• Community pharmacists may be more accessible to patients than physicians, because community pharmacies are widely distributed. The Bureau of Labor Statistics reports that in 2013 there were 287,420 pharmacists and 198,160 primary care physicians.[33] • Walk-in retail medical clinics located in pharmacies (such as MinuteClinic) are an increasingly popular point of contact for patients to receive basic care from a mid-level practitioners such as a nurse practitioner or physician's assistant. In this context, patients may be particularly open to clinical pharmacy services. Factors Against • Integrating pharmacists into patient care requires a major health system redesign. While some care redesign models have proved extremely successful, others have struggled to match their results and sustain significantly different models of care. • Pharmacist involvement in patient care will not address many of the diverse socio-economic factors that influence patient adherence, such as demographics, social support structure, mental health status, health literacy, treatment regimen, and doctor patient relationship. These factors may be less important in some of the other causes for inappropriate medication use.[34,35]
Options for Addressing the Issue	
Based on systematic reviews, what is known about the relative benefits and harms of the available management options? Note if no systematic reviews are available, and summarize results from seminal recent studies on the relative benefits and harms of available management options.	Benefits *Studies of pharmacist review of prescriptions as they are made* • Reviews have generally found that pharmacist review of medications in a variety of settings can reduce adverse drug events.[36] • **Hospital setting.** Three reviews found studies that involved pharmacist participation in patient rounds or other medication review in the inpatient hospital setting. o A 2006 review found ten studies; most reported positive changes. Among the statistically significant results were four studies with fewer adverse drug events or medication errors, four that reported shorter lengths of stay, and one that reported improved health and psychiatric status.[37] o A 2013 Cochrane Review of four studies found no effect on mortality or hospital readmissions, but did find a reduction in emergency department contacts.[38] o A 2014 review found 4 RCTs using medication review for older patients in the hospital. Although these studies reported large numbers of changes in prescriptions due to problems caught by the pharmacists, none showed a statistically significant change in readmission rates.[39] • **Nursing homes**. A 2013 Cochrane Review of eight studies in nursing homes found seven with medication review as a component. Although these interventions led to the identification and resolution of medication-related problems, there was no evidence that the interventions reduced adverse drug events, hospital admissions or mortality.[40] • **Outpatient settings.** A 2010 Cochrane review found seven studies meeting their criteria whose main focus was interventions targeted at health professionals, in which pharmacists educated providers about recommended prescriptions. Three studies reported statistically significant changes in process measures such as the number of prescriptions for recommended medications. They generally did not report clinical outcomes related to this improved prescribing.[41]

Criteria	Brief Description
	Studies of pharmacist reconciliation of medication lists during care transitions • A 2006 review found 11 studies that involved a pharmacist in the care transition process at hospital discharge. Among the four that measured readmissions, two found statistically significant improvements. The four studies that measured adherence all reported improvements. The two that measured health status and mortality did not find significant improvements.[37] • A 2014 prospective RCT in a large, tertiary care academic medical center found that involving clinical pharmacists in hospital care, medication reconciliation, and discharge medication plan communication significantly reduced the number of medication discrepancies in the medical record 30 days after hospital discharge.[42] *Studies of pharmacist-led MTM* • A CMS-sponsored evaluation of MTM programs in Medicare Part D found that MTM reduced hospitalizaitons for diabetes and congestive heart failure patients, but not in patients with chronic obstructive pulmonary disease.[43] • In the Iowa Family Medicine RCT, pharmacists collaborated with physicians and provided MTM services. Pharmacists made an average of four recommendations per patient in the intervention group, and significantly more patients in the intervention group (63.9 percent) achieved blood pressure control than in the control group (29.9 percent).[44] • The VA’s Patient Aligned Care Team (PACT) program also reduced HbA1c and LDL in diabetic patients over 6 months of a pilot program to integrate pharmacists into the medical home, where they provided MTM services.[45] *Studies of pharmacists monitoring test results* • Programs using pharmacists to monitor test results generally target the monitoring of therapeutic response to drugs for a specific condition, such as anticoagulants (used for congestive heart failure and atrial fibrillation) and drugs that treat high blood pressure and diabetes. Studies of these pharmacist monitoring programs have shown success in managing the immediate clinical outcomes associated with these therapies, such as INR, blood pressure, and HbA1c levels. They have less frequently reported patient-centered outcomes. • Anticoagulation therapy management: ○ A 2010 review of 24 studies of pharmacist management of anticoagulation therapy found that across all studies, pharmacist care had statistically significant effects on the prevention of total bleeding, but not on other outcome measures such as major bleeding, thromboembolic events, or death.[46] ○ One retrospective, observational cohort study of outpatient anticoagulation therapy found that patients receiving pharmacist care (rather than monitoring by a primary care physician) were 39 percent less likely to experience an anticoagulant-related complication that required medical care. [47] ○ A retrospective study of inpatient coagulation therapy for Medicare beneficiaries found significantly lower death rates, fewer complications, and shorter lengths of stay for patients in a hospital with pharmacist-managed anticoagulation therapy.[48] A prospective, nonrandom study similarly found improved INR control when pharmacists were managing inpatient anticoagulation therapy.[49]

Criteria	Brief Description
	• Blood pressure management: ○ An RCT of 402 patients published in 2009 used pharmacists to monitor blood pressure and make recommendations to the primary care physician about changes in the drug regimen. The intervention led to blood pressure control in significantly more patients.[50] ○ An RCT of 450 adults published in 2013 used home blood pressure monitoring transmitted to a pharmacist, who adjusted blood pressure medications based on the results. Results showed a statistically significant improvement in the intervention group’s blood pressure at 6, 12, and 18 months.[51] • Diabetes management: ○ Two small, non-random studies found that programs in which a pharmacist monitored HbA1c levels and adjusted insulin doses resulted in a reduction in HbA1c levels for these patients that was both statistically and clinically significant.[52,53] *Studies of pharmacist-led patient education and counseling* • A 2010 Cochrane review of outpatient pharmacist interventions found eight studies meeting their criteria whose main focus was patient education by a pharmacist. Five of these studies reported statistically significant changes in clinical patient outcomes (asthma symptoms, distance until breathless, cholesterol levels, or HbA1c levels). One additional study reported a statistically significant improvement in patient quality of life.[41] • A retrospective cohort study published in 2014 found that pharmacist education and motivational interviewing had a statistically significant effect, increasing patients’ adherence to their medications, improving their blood glucose levels and cholesterol levels, and reducing the likelihood of an ER visit by patients with diabetes.[54] *Studies of multi-faceted pharmacist interventions* • A review of RCTs between 1989 and 2009 evaluated the impact of medication therapy management and patient education on patient outcomes. The review found only 2 of 8 studies had statistically significant improvements in clinical outcomes; the most effective programs were working with patients newly diagnosed with a chronic condition or who had not yet achieved their therapeutic goal. The two projects measuring quality of life did not find a significant improvement.[55] • A review of 224 studies through 2009 reported clinical outcomes in programs with clinical pharmacist services. Interventions included patient education, medication therapy management, and including a pharmacist on the care team. This review found that pharmacist intervention was effective in improving quality of life and clinical outcomes such as decreasing hemoglobin A1c values in diabetic patients as well as LDL cholesterol and blood pressure.[56]

Criteria	Brief Description
	• A 2010 Cochrane review found 27 studies meeting their criteria with complex pharmacist-led interventions that typically involved MTM, monitoring disease control, and patient education. Seven did not report statistically significant changes in measured outcomes. The other 20 studies reported significant changes using a wide variety of measures: three studies reported improvements in quality of life; one reported significant changes in mortality and heart failure events; twelve studies reported improvements in clinical measures such as blood pressure (6 studies), hemoglobin A1c (3 studies), peak expiratory flow rate (1 study), cholesterol (1 study), and INR (1 study); and four studies showed improvements in process measures related to prescribing and adherence.[41] • Results from an RCT published in 2014 showed that pharmacist care including MTM, monitoring, and education for adults with hypertension was successful in lowering blood pressure over six months.[57] *Studies of pharmacist provision of vaccines and other preventive care* • Two studies of pharmacist provision of vaccines have shown increases in influenza and tetanus-diphtheria-acellular pertussis vaccinations[58] and pneumococcal vaccinations.[59] • A 2013 review found 50 studies of preventive screenings carried out in pharmacies. Most studies demonstrated that this is a feasible method for screening patients, but did not measure changes in clinical or patient-centered outcomes that resulted from identifying problems via this screening.[60] • An RCT of 101 smokers, published in 2009, tested the effectiveness of a pharmacist-led 3-session face-to-face group smoking-cessation program compared to one 5- to 10-minute standard care session delivered by telephone. Participants in both groups were offered either immediate-release bupropion or nicotine patch at no cost. Biochemically confirmed abstinence rates at the end of 6 months were significantly higher in the face-to-face treatment group.[61] Harms • Most studies do not identify harms due to clinical pharmacist care.[36] A VA study found that pharmacist recommendations resulted in patient harm in less than 1 percent of the cases reviewed.[39]
What could new research contribute to achieving better patient-centered outcomes?	• There is already extensive literature on the use of clinical pharmacists, at least 25 clinical studies are ongoing, and an open NIH solicitation may include further research relevant to this question. However, gaps remain. • Questions that could be addressed by CER that do not appear to have been addressed by existing research include: ○ What is the comparative effectiveness of the many pharmacist-led interventions currently being tried in patient care? Are some interventions more effective for some patient populations? ○ Many programs are implementing multi-faceted interventions (e.g., combining MTM, patient education, and monitoring test results together). What is the comparative effectiveness of individual interventions versus multi-faceted interventions?

Criteria	Brief Description
	○ For any given intervention, what is the comparative effectiveness of giving pharmacists the authority to write or change prescriptions versus requiring them to work with another health professional to change the medication regimen? ○ For any given intervention, what is the effectiveness of co-locating a pharmacist with the care team, compared to using a community pharmacist? ○ For any given intervention, what is the effectiveness of using a pharmacist to deliver the intervention, compared to other non-physician providers such as nurse practitioners or physician assistants?
Have recent innovations made research on this topic especially compelling?	• As more medications become available every year, the potential for overprescribing and harmful interactions increases. • Increased attention on hospital readmissions is leading hospital systems to seek interventions that can help keep patients from returning to the hospital. • Value-based systems (such as Accountable Care Organizations and integrated health delivery systems that receive capitated payments) are seeking ways to reallocate resources to bring down the total cost of care. • Due in part to increased insurance coverage, demand for primary care services is increasing faster than the supply of primary care physicians. At the same time, there has been increased interest in team based primary care. This is leading many organizations to rethink the organization of primary care practices, bringing in non-physicians to take on more tasks. • Electronic health records, computerized physician order entry, and e-prescribing are improving patient safety by eliminating some sources of medication errors and making more information available to the full patient team on a more timely basis. • The subfield of pharmacy informatics is introducing technological innovations that can further improve patient safety and adherence via mobile apps, telemonitoring, and pill-bottle sensors that can detect when a patient has not taken his or her medications.
How widely do management options vary now?	• As described above, there are a wide variety of interventions that are in current use. Within each intervention, there can be important sources of variation: ○ Clinical pharmacists may participate in patient care in both inpatient and outpatient settings. ○ Some interventions may take place via review of the medical record without seeing or talking to patients. In others, pharmacists may have face-to-face appointments with patients. ○ Pharmacists' legal authority to write or change prescriptions, even in a collaborative agreement with a physician, varies by state.
What other research is ongoing in this area currently?	• We found 25 U.S. research projects that appear to be ongoing studies. We searched clinicaltrials.gov, innovation.cms.gov, innovations.ahrq.gov, and projectreporter.nih.gov using the keyword "pharmacist" and identified studies whose primary intervention is participation by a pharmacist in clinical care. The majority of studies (15 of 25) involve a clinical pharmacist working in an outpatient patient care setting. • In addition to these ongoing studies, the NIH Adherence Network currently has an open funding opportunity announcement seeking Research Project Grant (R01) applications that propose interventions to significantly improve medication adherence. The announcement does not direct applicants with regard to the interventions to be tested, but it is possible that some grants will involve services provided by pharmacists.[62]

Criteria	Brief Description
	Studies of pharmacist review of prescriptions as they are made • A prospective cohort study is using pharmacists in inpatient pediatric wards and physician computer order entry to reduce medication errors in a children's hospital.[63] *Studies of pharmacist reconciliation of medication lists during care transitions* • No studies were found that exclusively involved the intervention of reconciliation of medication lists during care transitions. However, one multi-faceted pharmacist intervention study (listed below) is focused on care transitions. *Studies of pharmacist-led MTM* • In one Health Care Innovations Award, community pharmacists provide medication therapy management services and intensively coordinate with the primary care physician, and are seen as an extension of the medical home care manager.[64] • A study that includes a home visit within 7 days of hospital discharge includes an intervention by a care team (pharmacist and a physician or nurse practitioner) that conducts medication therapy management.[65] *Studies of pharmacists monitoring test results* • In one cluster-randomized trial, pharmacists are collaborating with barbershops to collect blood pressure readings. In collaboration with physicians, they will have authority to increase medication dosages to improve blood pressure control.[66] *Studies of pharmacist-led patient education and counseling* • A VA hybrid effectiveness-implementation study is using pharmacist education of patients and information technology to improve medication adherence after stent placement.[67] • One Health Care Innovations Award focuses on the transition from hospital to home, by using hospital pharmacist-to-community-pharmacist collaboration.[68] • One study involves coaching by community pharmacists related to health literacy and medication adherence.[69] • Two studies involve pharmacist interaction outside the health care setting: one by telephone[70] and one with home visits.[71] *Studies using multi-faceted pharmacist interventions* • Most of the studies we identified involve some combination of medication review and education by the pharmacist. ○ Most are targeted to patients with specific conditions, such as Alzheimer's Disease,[72] asthma,[73] cardiovascular conditions,[74-76] kidney disease,[77-79] and diabetes.[78] ○ One is a polypharmacy clinic for patients with ten or more medications.[79] ○ Others studies target multiple conditions[80,81] or do not state their target population.[82,83] • A pilot efficacy study is using patient education, MTM, and medication reconciliation during the transition from hospital to home in a collaboration between hospital and community pharmacists.[84] *Studies using the provision of vaccines and other preventive care*

Criteria	Brief Description
	• One study aims to expand the evidence supporting pharmacy provision of adolescent vaccines, such as the human papillomavirus vaccine.[85] This topic also appears to be of interest internationally. Clinicaltrials.gov lists at least 20 ongoing trials in other countries related to clinical pharmacy services, including five in Canada.
How likely is it that new CER on this topic would provide better information to guide health system practice?	• There is already extensive literature on this topic and a large number of studies ongoing, including an open solicitation for grant applications. • However, CER could contribute by offering targeted examinations of which of the many innovations being experimented with are the most effective. • In addition, many of the existing studies have been small and short term; larger, longer-term studies might provide more robust information.
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 • The delegation of medication management to a clinical pharmacist may be attractive to primary care physicians who often do not have adequate time to focus on the complex medication management needs of chronically ill patients. • Hospitals and health systems are interested in interventions that can lower the total cost of care. • Payers, Accountable Care Organizations, and health systems that receive global capitated payments are playing an increasing role in care coordination. These organizations have an interest in optimizing pharmaceutical use and vaccines to prevent the higher costs of adverse events and hospitalizations. Barriers • Integration of pharmacists into patient care usually requires some degree of practice redesign, which is time-consuming and requires leadership. • Most states allow pharmacists to initiate, modify, or discontinue a prescription if they have a collaborative agreement with a physician. However, this authority may be limited to very specific sets of drugs (e.g. contraceptives), or to certain settings (e.g. teaching hospitals).[86] • In most health plans, pharmacists currently cannot bill for the clinical services they provide. Payment for pharmacists' clinical services to date have often been initiated as grant-funded pilot projects or demonstration programs, which is not a viable option for widespread adoption. • Provider organizations may want very clear information about how using a clinical pharmacist will save or earn money before they will be willing to pay for the position. • The current pharmacist workforce is roughly balanced with demand.[87] If demand for clinical pharmacists increases dramatically, it might be more challenging for provider organizations to fill these positions. • Other barriers identified in a survey of pharmacists and payers included insufficient space for meeting with patients; lack of interest by patients; resistance by physicians or other health care providers; and lack of access to patient information.[88]

Criteria	Brief Description
How likely is it that the results of new research on this topic would be implemented in practice right away?	• Among organizations actively seeking to optimize their patient care teams, research that clearly shows that the use of a clinical pharmacist is effective and could improve health system efficiency would likely be implemented within a few years. A fair amount of planning is needed around roles and financing before the change can be implemented.
Would new information from CER on this topic remain current for several years, or would it be rendered obsolete quickly by subsequent studies?	• Because the use of clinical pharmacists is a general approach and not a specific treatment, CER on this topic would likely remain current for many years.

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Research Prioritization Topic Brief 3: Models of Comprehensive Support Services for Infants and Their Families Following Discharge from Neonatal Intensive Care Unit

PCORI Scientific Program Area:
Improving Healthcare Systems

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Executive Summary for Topic 3: Models of Comprehensive Support Services for Infants and Their Families Following Discharge from Neonatal Intensive Care Unit

Comparative Research Question. Compare the effectiveness of diverse models of comprehensive support services for infants and their families following discharge from neonatal intensive care unit.

Brief Overview of Topic. In the United States, approximately 7% of all infants require admittance to the neonatal intensive care unit (NICU) – a rate that has remained steady in recent years.[1-4] Non-Hispanic black infants and those born to women aged 40 and over are most likely to receive NICU care.[3] The most common reasons for NICU stays include infants who are born prematurely (before 37 weeks gestation) or have a medical condition that requires special care. Prematurity is the leading cause of infant mortality in the United States, and the rate of NICU admissions is disproportionately higher for premature births compared to the overall rate of NICU admissions: 10-15% of these infants require admittance to the NICU.[5] For premature infants who survive and those with complex health needs, there are tremendous health, educational, and social needs across their life course. These needs correspond to high financial costs for families as well as for health, education, and social systems.[6] The medical and health care costs for premature infants alone is $16.9 billion annually.[7]

Patient-Centeredness. Investigating models of care for infants who need NICU care and their families has clear relevance to both patient- and family-centered outcomes. The AAP recommends both parental involvement as members of the multidisciplinary discharge planning team as well as in the ongoing care of their infant, and parents report needing additional information and support.[8] Home visits by a nurse has been reported to be effective at meeting parental information and support needs.[8]

Impact on Health and Populations. After discharge, many parents and caregivers must continue therapies initiated in the hospital, and parents report fear and lack of self-confidence when assuming those new responsibilities.[8] It takes time for the family of a high-risk infant to prepare to care for their infant in a home setting, obtain the necessary support services, and mobilize community resources. The AAP Committee on Fetus and Newborn discharge planning guidelines indicate that the care after discharge must be coordinated carefully to provide multidisciplinary support to the family, should begin early in the infant's hospitalization, and should be focused on the individual needs of the infant and the family.[6] To provide continuity of care and address the needs of the infant, family, and/or caregiver, there are several models of post-NICU support services that are available to families; application of these approaches vary based on the infant's medical status and the needs of the family/caregiver. Approaches include comprehensive clinical care models, which involve specialty clinics that often coordinate with primary care providers and may include home health care for infants with special health care needs. In addition, support services that can address the social, emotional, and economic needs of the family – such as home visiting services and parent education and support – may be provided along with clinical services.

Assessment of Current Options. While comprehensive follow-up care for infants in the NICU, starting with careful planning prior to NICU discharge, may reduce life-threatening illnesses and hospital readmission, there is limited ongoing research that examines the effectiveness of these available options. There are significant gaps in the research that address how these comprehensive models of care – including specialty medical clinics and combined medical and social service wraparound models – compare for improving short- and long-term health, quality of life, and family outcomes for infants and their families who have been discharged from the neonatal intensive care unit.

Likelihood of Implementation in Practice: The AAP, the Association of Maternal and Child Health Programs (AMCHP), and State Title V and Children with Special Health Care Needs programs support early and comprehensive discharge planning, combined with models that support the needs of infants and their families. The support of these three organizations suggest the recommendations from this research would have a high likelihood of implementation and impact.

Durability of Information: Current research has not yet assessed the effectiveness of differences in program focus, content, and administration,[8] or the extent to which individual clinics are implementing AAP guidelines.[9] There is limited ongoing research in this area and no federal initiatives specifically targeting NICU follow-up programs, though there is increasing federal attention to infant and early childhood programs such as home visiting as well as reducing early elective deliveries prior to 39 weeks, which reduces the number of infants at risk for NICU admission. There is also a need for comparative research on the effectiveness of the various models of care, including community-based/home visiting models and innovative approaches for different populations. For example, further research is needed on understanding the best approach for those parents who have public insurance, infants with different types and complexity of conditions, and for families who live in rural areas who may need to travel significant distances to specialty providers.[9] Given these gaps, research in this area has a high likelihood of remaining current.

Topic 3: Models of Comprehensive Support Services for Infants and Their Families Following Discharge from Neonatal Intensive Care Unit

Criteria	Brief Description
Introduction	

Overview/definition of topic	• In the United States, approximately 7% of all infants require admittance to the neonatal intensive care unit (NICU). Infants born to older mothers, aged 40 and over, are most likely to receive NICU care. Differences in NICU admission are also observed by race and Hispanic origin. Non-Hispanic black infants are about 40% more likely than white and approximately 60% more likely than Hispanic infants to be admitted to a NICU.[3] The most common reasons for NICU admittance include infants who are born prematurely (before 37 weeks gestation) or have a medical condition that requires special care and/or dependence on technology. Compared to the overall rate of NICU admission, the rate is disproportionately higher for premature births, the leading cause of infant morbidity and mortality in the United States: 10-15% of these infants require admittance to the NICU.[5] With current advances in medical care and technology, smaller and more premature infants are being saved, and many of these infants require care in the NICU.[10] Despite such advances, admissions to the NICU in the United States have remained steady in recent years.[1-4]
	• Infants born preterm that require NICU care are at higher risk of poor outcomes during the first year of life, including respiratory, cardiovascular, neurologic, gastrointestinal, metabolic, visual and hearing disorders. In particular, infants can experience breathing problems, feeding difficulties, cerebral palsy, developmental delay, and vision and hearing problems. Complications from these health issues can last throughout their lives.[6]
	  ○ Rates of neonatal morbidity from conditions like chronic lung disease, septicemia, periventricular leukomalacia and retinopathy of prematurity (ROP) have remained high.[6,9] For example, ROP – one of the most common causes of blindness in childhood – develops in approximately 16,000 infants born prior to 31 weeks gestation each year.[11]
	  ○ Bronchopulmonary dysplasia, defined as the need for supplemental oxygen for at least 28 days after birth, is the most common chronic lung disease in infancy.[12] It commonly occurs in infants who are born at 30 weeks gestation or less and who have a birth weight of less than 1500g.[12,13] About 1.5% of all newborns in the U.S. are born weighing less than 1500g[14] each year and roughly 20% of those will develop bronchopulmonary dysplasia.[12,15] Treatment requires costly health services and interdisciplinary follow-up is often required.[12,16]
	  ○ In a study comparing infants born at 22-25 weeks gestation to those born at 26-34 weeks gestation, the incidence of six health conditions were significantly greater in the 22-25 weeks gestation group compared to the latter. These health conditions included patent ductus arteriosus (PDA) in prematurity, chronic lung disease (CLD), intraventricular hemorrhage (IVH), retinopathy of prematurity (ROP), necrotizing enterocolitis (NEC) and severe infection.[17]

Criteria	Brief Description
	○ The ability for the infant to tolerate full oral feedings is often a prerequisite for NICU discharge. However, optimizing nutritional support for low birth weight and very low birth weight infants can be difficult due to complicating medical conditions, which can lead to feeding difficulties after discharge.[10] ○ Respiratory illnesses are the leading cause of re-hospitalizations after NICU discharge.[18] Readmission rates have been found to be as high as 27% within one year of discharge.[17] • The medical and health care costs for premature infants alone is $16.9 billion annually.[7] • Currently, the American Academy of Pediatrics (AAP) recommends that the timing of a high-risk infant’s discharge be based on several criteria: when the infant is able to coordinate breathing and oral feedings, ingest adequate volumes for weight gain, maintain normal body temperature, and maintain stable cardiorespiratory function.[6] These recommendations are based on current scientific research and evidence-based outcomes. • In addition, the AAP specifies that an infant needs an active program for parental involvement and preparation for care of the infant at home, and arrangements for health care after discharge by a physician or other health care professional who is experienced in the care of high-risk infants.[6] These guidelines do not currently address other types of caregivers. • Thus, the transition to home after NICU is a critical time for infants, families and caregivers, and discharge planning and comprehensive follow-up care are necessary components of care for high risk infants in the NICU. Furthermore, the components must be tailored to address the specific needs of the infant and the family. • There are multiple models of comprehensive follow-up care for infants and families after discharge from the NICU that show promising evidence of effectiveness. Types of models presented in the literature include [8,19,20]: ○ Clinical: evidence-based standard follow-up care includes outpatient visits to a specialty follow-up clinic. Clinic visits are scheduled more frequently immediately after discharge and decrease with health improvements of the infant. Some follow-up clinic programs include a neonatologist on the health care team. Clinic-only programs have been criticized by families/caregivers who have difficulty traveling to the follow-up appointments on a regular basis. This is especially difficult for individuals living in rural areas and those without appropriate transportation. ▪ Another branch of evidence-based clinical comprehensive care include home visits by nurses who provide clinical services to infants in their homes. Nurses can assist parents with some of the critical medical issues that arise in the transition home, including infant nutritional intake and breastfeeding, as well as medication administration and special treatments for infants who need them, including oxygen supplementation and pulse oximetry. ▪ Clinical care models also include linkages to a primary care physician/pediatrician.

Criteria	Brief Description
	○ Comprehensive Support Services: Comprehensive support services include both clinical follow-up programs and wraparound support services to address family and caregiver needs such as parental support and education on infant stress cues, signals for interaction, and overall child development, as well as fostering parent-child interactions, overall parenting skills, and infant cognitive development. These programs vary in their approach and the settings in which services are provided, and include intervention modalities such as telephone check-ins, videoconferencing, home visiting, parent education, and support groups. Studies that have reported these types of interventions show promising practices[8,20,21] but further research is needed to determine the most effective approach, especially for diverse populations and healthcare settings and circumstances. • State Maternal and Child Health agencies and programs for Children with Special Health Care Needs have also provided key leadership and partnership in developing and supporting NICU follow-up programs. Funded by the Maternal and Child Health Bureau block grants through Title V of the Social Security Act, these agencies are working to facilitate access to a medical home for families; provide follow-up services and home visitation for NICU infants; conduct developmental, physical and environmental assessments; and provide education and guidance.[5] • In the existing literature, study outcomes are most often focused on clinical measures, including hospital readmission within 30 days and number of emergency department visits within the specified study time. Developmental and physiological assessments of the infant are carried out as well, but there is little evidence of long-term follow-up of the children.[19] • A literature review[8] of interventions transitioning premature infants from hospital to the home found three studies that measured parents' perceptions of the discharge process.[22-24] In addition to clinical outcomes, these studies also measured maternal satisfaction and maternal stress, anxiety, and depressive symptoms. • Two comprehensive reviews[25,26] of parent perceptions of NICU discharge found that most parents feel unprepared for discharge and have unanswered questions. One of the reviews[26] reported that parental perceptions are often different from those of the health care team. These results, although not in response to specific models of care, should be taken into consideration when planning and researching models in the future. • Despite the presence of these models, there have been limited studies that assess their effectiveness and there is a lack of current research in this area.[5,7]
Relevance to patient-centered outcomes	Key Patient-Centered Outcomes • The AAP identified parents as key individuals in the multidisciplinary NICU discharge planning team, which should also include the neonatologist, neonatal nurses, social workers, and other professionals as needed for individual families.[6] These guidelines do not specifically address other caregivers in the family; this is an important gap to recognize, as many infants are cared for by individuals other than a parent. • Hospitalization of the infant after birth causes parents to experience high levels of stress. The transition from the hospital to the home can cause fear as the families assume responsibility of their fragile infant and learn to care for their unique medical and developmental needs.[8]

Criteria	Brief Description
	• Family satisfaction with the consistency of providers in the transition from NICU to post-NICU primary care is an important component in the transition process. Patient dissatisfaction can increase fear, stress, and anxiety.[8,25,27] ○ One review of parents' perceptions of NICU discharge teaching found overall that there is a clear lack of information about parents' perceptions of their readiness for discharge.[26] Despite this dearth, some studies reviewed provided important insight. A study[28] from 1983 found that parents often experience less anxiety as a result of knowing they will be included in discharge planning.[26] ○ Results of a Danish program,[23] which included an education program during hospitalization, a visit and orientation by the family's health visitor, a discharge conference, and a publication of relevant booklets, indicated that 90% of families felt secure at the time of discharge after having participated in the intervention.[26] • Programs that provide continuity of care from the hospital to the home are necessary for the family to feel confident and capable in caring for their newborn.[8] • Discharge planning and care practices that incorporate the needs of the family are recognized by the American Academy of Pediatrics as an essential attribute of high-quality neonatal and family care.[6,20,21,29] ○ This approach puts families at the center of the care plan, and effective interventions should focus on the family for implementation.
Burden on Society	
Extent of the health system problem	• With increased survival of very preterm and very ill infants, many infants are discharged with unresolved medical issues that complicate their subsequent care.[6] Thus, follow-up care for these infants is critical. • The AAP reports that infants born preterm with low birth weight who require neonatal intensive care experience a much higher rate of hospital readmissions and death during the first year after birth compared with healthy term infants. Careful preparation for discharge and good follow-up after discharge may reduce these risks. [6] • The cost of a preterm low birth weight birth averages $58,000 compared to $4,300 of an average term birth.[5] The medical and health care costs for premature infants alone is $16.9 billion annually.[7] • Infants born prematurely and/or with complex medical issues often also require additional types of interventions in infancy and across their lifetimes, including early intervention services and special education services. The Institute of Medicine found that early intervention services cost an estimated $611 million ($1,200 per preterm infant), and special education services associated with a higher prevalence of four disabling conditions including cerebral palsy (CP), mental retardation (MR), vision impairment (VI), and hearing loss (HL) among premature infants added $1.1 billion ($2,200 per preterm infant).[27] • A systematic review reported health care costs savings among patients receiving follow-up intervention models of care.[30]
Effects on patients' quality of life, productivity, functional capacity, mortality, use of	• Families ○ Parents and caregivers experience high levels of stress during hospitalization of the infant and fear when bringing the infant home and assuming responsibility of caring for their infant, who may have complex needs. [8]

Criteria	Brief Description
health care services	○ High levels of stress and lack of adequate knowledge among parents of preterm infants can lead to misperceptions of their infants and difficulty interacting with them in a developmentally sensitive manner.[22] ○ More than 20% of parents report problems in transition of care from hospital to home.[19] ○ Comprehensive NICU follow-up care, especially wraparound services, are poorly reimbursed by most insurance companies, including Medicaid. Many families of infants in the NICU experience significant financial burdens due to the cost of caring for a chronically ill child, which results in using Medicaid as their primary insurance.[31] ○ One population-based study[32] performed a retrospective cross-sectional analysis on risk factors that commonly contribute to obstetric-related outcomes and therefore influence neonatal outcomes. A bivariate analysis of risk factors found risk factors that were statistically associated with NICU admission included: identifying as Black, identifying as Hispanic, having eclampsia, and preterm labor including premature rupture of membranes (PTL/PROM) were associated with NICU admission. ● Infants ○ Preterm infants and those requiring NICU care use more health care resources and services both within the NICU and after discharge.[30] Comprehensive support models offer an opportunity to provide more efficient care to patients and their families.[21] ○ Infants born preterm experience more adverse health effects than those born at term.[33] Infants born preterm that require NICU care are at higher risk of poor outcomes during the first year of life, including respiratory, cardiovascular, neurologic, gastrointestinal, metabolic, visual and hearing disorders.[6] ○ Exposure to the NICU environment can have long-lasting negative effects related to the noxious over-stimulating environment.[29] ○ Infants that are admitted to the NICU are more likely to experience complications that are commonly associated with the NICU, such as intubation and increased infant mortality, than infants that are not admitted to the NICU.[32] ○ “Late-preterm” infants, born at 34 $^{0}/_{7}$ through 36 $^{6}/_{7}$ weeks, are at higher risk of morbidity and mortality than term infants, yet due to their size and weight being similar to term infants they may not receive the specialized health care that they need.[33] Engle, et al. propose the use of “late-preterm” instead of “near term” to emphasize the health needs of the infant born in that time frame. Terminology regarding the health of the infant at birth is important for all future health care decisions for the infant and the family. For example, the 34 $^{0}/_{7}$ gestation time is a cutoff for admission to a level 2 or 3 NICU. Ineffectively placing the infant in the proper NICU care could lead to ineffective follow-up care.[33]
How strongly does this overall societal burden suggest that CER on alternative	<u>Factors In Favor</u>

Criteria	Brief Description
approaches to this problem should be given high priority?	• Prematurity is the leading cause of infant mortality in the United States. For premature infants who survive and those with complex health needs, there are tremendous health, educational, and social needs across their life course. These needs correspond to high financial costs for families as well as for health, education, and social systems. • Comprehensive models of NICU follow-up care can result in improved quality of life for the infant and family. In addition to addressing the medical needs of the infant, programs can offer wraparound services to parents/caregivers that assist not only with the unique needs of caring for a high-risk infant but support other family situations, such as economic and mental health needs of the family. • Comparative effectiveness research on the models of comprehensive follow-up NICU care could address the benefits and risks of follow-up care on the health and long term well-being of the infant and family, including physical and mental health costs, lost wages, school performance, and other measures. • Neonatal networks, a "collaboration involving more than one clinical site where a common protocol is used for a randomized trial, observational study, or quality improvement project"[34] are used to identify interventions for improving the health of neonates. Multi-site studies are an essential contributor to neonatal outcomes because neonatal health issues (death or neurodevelopment impairment) have relatively low prevalence.[34] This model could be leveraged in CER studies of comprehensive follow-up care for post-discharge NICU infants and their families. <u>Factors Against</u> • Strong research to create evidence-based approaches to care will require costly monitoring of families who participate in different models of care. Comparison groups will also have to be carefully designed to assure that all families benefit from at least one of the models. • <u>Long follow-up periods:</u> to date there are few long-term follow-up studies about NICU discharge interventions.[19,26] This is likely due to the long follow-up periods that are necessary to measure long-term developmental outcomes of infants admitted to the NICU. Long-term follow-up requires ample funding and coordinating capacity. <u>Large sample size necessary</u>: Data from 2003 approximates that 60,000 infants are born with low birth weight, under 1500 g, per year in the U.S., which is 1.5% of all newborns.[12,14] The coordination necessary between multiple hospitals and health care providers to reach an adequate sample size to evaluate heterogeneity would be costly.
Options for Addressing the Issue	
Based on systematic reviews, what is known about the relative benefits and harms of the available management options? Note if no systematic reviews are	• While there have been limited studies that examine comprehensive follow-up programs for infants discharged from the NICU, three systematic reviews were identified that have demonstrated a comprehensive analysis of discharge planning and follow-up care programs for infants in the NICU and children with special health care needs. • A systematic review on patient discharge interventions to reduce readmission and subsequent ED visits reviewed 5 NICU interventions.[19] Three studies resulted in reduction in ED use following initial hospitalization. Commonalities included early engagement and education with families, various degrees of home visitation, and expanded access to health care providers and resources following discharge.

Criteria	Brief Description
available, and summarize results from seminal recent studies on the relative benefits and harms of available management options.	○ The authors of this review concluded with three hypotheses to guide future work regarding discharge transitional care. They are: 1) appointing a dedicated individual or coordinating hub reduces subsequent utilization of NICU; 2) individualized task learning and feedback from the caregiver(s) enhances effectiveness of discharge planning; and 3) timing of intervention (at admission vs discharge) enhances effectiveness.[19] ○ Persistent literature gaps that the authors identified were: 1) follow-up with primary care provider; 2) importance of condition-specific interventions; 3) studies focusing on children with complex medical conditions; and 4) most appropriate individuals for discharge-focused transitional care interventions.[19] ○ The authors recommend future studies adapting common features of effective interventions that are aligned with professional associations' recommendations and guidelines. • Lopez et al., 2012[8] ○ This review concluded there are five components necessary for successful transition from hospital to home for premature infants. 1. Communication between health care provider and family at home: all three methods studied (telephone, videoconferencing, and pager availability) proved effective in reducing anxiety and improving coping for parents. 2. Home visits- benefits included: success with breastfeeding, fewer visits to the ED, and shorter length of stay if hospitalization was necessary. Benefits were more extensive with the greater number of home visits conducted. 3. Assessment of the infant and home situation: outcomes measured were infant's status, maternal health, parenting skills, and home environment factors. 4. Education and Support groups: positive outcomes included: positive parent-infant interactions, less maternal anxiety and depressive symptoms, support group discussions allowed for exchange of information and avenue for learning, reduced anxiety among parents, and increased confidence in maintaining the health of the infant. 5. Role of Nurse: nurse involvement was an important element in all programs reviewed. ○ The authors concluded with recommendations for evidence-based discharge programs for premature infants. These recommendations included: 1) classes for parents providing both education and support prior to discharge; 2) home visits by a nurse; and 3) maintaining communication with primary nurse between home visits. ○ Recommendations for future research included: 1) effectiveness of program components, including number and length of time of home visits and content and timing of educational classes; and 2) a means of communication between care giver(s) and primary nursing contact. • Parker et al., 2006 [20]

Criteria	Brief Description
	- This review analyzed a broader range of follow-up programs, including both those that were NICU-specific and others that were relevant to other health conditions. Among the programs aimed at very low birth weight babies, three of the four articles were also reviewed in Auger, et al. 2014 (Brooten 1986, Casiro 1993, and Finello 1998). This confirms that there are few recent studies about comprehensive follow-up programs aimed specifically at post-NICU infants. - Noted in the article is that "despite increased provision in many health care systems, evidence about the effectiveness, costs and impact of [pediatric home care] is unclear."[20] - Authors report that further research is needed to determine which support services are needed by the sickest babies and, if provided, what benefits would result and at what cost. The authors call for "an adequately sized RCT, with good-quality health economics and a perspective on family impact."[20] • In an Issue Brief released by the Association of Maternal and Child Health Programs, some State Title V Programs were highlighted as case studies of state models to support NICU follow-up programs .[5] While this is not a systematic review, the information on the programs below highlights some of the most important benefits of various comprehensive models and important next steps in the field. - **Colorado**: Ensuring the Transition to a Medical Home for Premature Infants ▪ The Colorado Department of Public Health and Environment (CDPHE) Health Care Program for Children with Special Needs (HCP) convened a summit in 2012 titled "Key Stakeholder Colorado Premature Infant Summit: Assuring Premature Infant Follow Up through a Medical Home." ▪ As a result of the summit, key action steps were identified. These included increasing parent support efforts and access for parents of premature infants and increasing the availability of and access to education programs for health care professionals. In addition, efforts to increase communication across providers included developing connected data systems to better understand the Colorado population of premature and high-risk infants and their families, and continuing collaboration across agencies and organizations to meet the needs of premature and high-risk infants and their families. ▪ Finally, the summit recognized the need for additional policy attention to this issue and recommended including the needs of premature infants and their families in policy discussions and decisions. - **Iowa**: Child Health Specialty Clinics ▪ Iowa adapted the state program for care for infants and toddlers, Early ACCESS, to serve the needs of infants who were discharged from the NICU. To accomplish this goal, the Heartland Area Education Agency contracted with Title V agencies for an RN to provide care coordination. The RN spent one day per week in each NICU to ensure that babies were being referred to Early ACCESS and to facilitate communication between NICU graduates and providers. - **Utah**: Neonatal Follow-up Program

Criteria	Brief Description
	- The Utah Neonatal Follow-up Program (NFP) uses a multidisciplinary approach in which various medical and developmental specialists gather to monitor and evaluate each qualifying child. - Program components include referring families to appropriate intervention and financial services; sending a summary of each evaluation to the child's medical home and referring NICU; and providing psychosocial support to families, including counseling for mothers at risk for future preterm births. - This program has shown beneficial effects and successes, including receiving a high level of parent satisfaction. In addition, it has demonstrated strong cross-provider communication capabilities, including a robust relational database that is being integrated with electronic health records (EHR), and sharing outcome measures with referring NICUs through EHR; and sharing information with other State of Utah Children's Health Programs through the Child Health Advanced Records Management (CHARM) data integration system.
What could new research contribute to achieving better patient-centered outcomes?	• Currently, there is no nationally representative data on the composition of high-risk infant follow-up care programs in the United States.[21] • There is a gap in literature regarding models of care specifically tailored for children with complex medical conditions.[19] Many of the discharge and follow-up care plans are for specific conditions. More research is necessary to address infants that were discharged from NICU. • Families of infants that were discharged from the NICU are especially susceptible to feelings of fear about the baby's condition and lack of self-confidence in care giving.[8] • Systematic reviews have identified that further research is needed to explore the effectiveness of the number and length of time of home visits; content and timing of educational classes and support groups; and the benefit to the infant and family outcomes.[8] • Additional research could inform models of continuing care from NICU providers to post-NICU primary care providers; this could result in implementing a standardized discharge program that could be modified to meet the specific needs of the family.[27] • More research is needed to examine how the AAP guidelines are being implemented in practice and the extent to which families are active partners in developing plans for post-NICU care. • Further research may also inform the types of measures that could be used to assess patient- and family-centered outcomes of models of care in addition to hospital readmission and emergency department visits [19] • There is a dearth of literature regarding post-NICU models of care that fully address the social determinants of health that are known to put infants at higher risk for adverse health events. Follow-up programs that address environmental conditions of the infant and the family will provide more comprehensive support services and have longer-lasting effects on the health and development of the child.

Criteria	Brief Description
	• Few NICU follow-up programs were identified that focused services on the health of the mother and family.[22,35] For example, to our knowledge only one study[35] reported screening for post-partum depression as one of the assessments conducted during the home visits. Based on the overwhelming circumstances of bringing an infant home from the NICU, greater emphasis needs to be placed on the health and well-being of the mother and the frequent interactions with health care providers provide an opportunity for this. • Overall, new research in this area could address several overarching CER questions: ○ How do comprehensive models of care – including specialty medical clinics and combined medical and social service wraparound models – compare for improving short- and long-term health, quality of life, and family outcomes for infants and their families who have been discharged from the neonatal intensive care unit? ○ How do comprehensive models of care compare for different populations of infants and their families who have been discharged from the neonatal intensive care unit, including those who have public insurance, infants with different types and complexity of conditions, and families who live in rural areas who may need to travel significant distances to specialty providers?
Have recent innovations made research on this topic especially compelling?	• There are multiple recent innovations in this area that makes research compelling. This includes the Affordable Care Act funding of evidence-based maternal, infant, and early childhood home visiting programs. While not NICU-specific models of care, these programs focus on, among other areas, newborn health and healthy child development among at-risk populations .[36] • The Department of Health and Human Services Strong Start Initiative aims to reduce preterm births and improve outcomes for newborns and pregnant women. One of the Strong Start strategies is to reduce the rates of early elective deliveries prior to 39 weeks, which can reduce the number of infants who are at risk for NICU admission.[40] • Interventions that use technology are also promising. For example, a Swedish study used videoconferencing in the home to provide contact with NICU nurses via camera equipment installed in the home on a 24-hour basis. The intervention lasted from the time the infant was on leave from the hospital until complete discharge, ranging from 6 to 22 days.[37] • Use of emerging technologies to provide more continuous care has the potential to improve the caregiving experience for both the family and the health care providers. Health care providers can make more informed decisions by seeing a real-time video image of the infant and caregivers at home.[8] • Efforts to develop and increase the use of shared data systems, electronic medical records, and other methods of communication, as described in the Colorado and Utah case studies above, are compelling. They indicate the need for and move toward enhanced communication among diverse providers who serve infants and their families.
How widely do management options vary now?	• Currently, there are multiple options for post-NICU care that are often tailored to the needs of the individual infant and family, and are offered in a range of clinical and community settings. These options include phone call support after discharge, scheduled follow-up visits in specialty clinics and primary care settings, post-discharge parental education, home visiting by nurses and other professionals, and wrap-around community based supports.[19]

Criteria	Brief Description
	• However, discharge and follow-up programs depend heavily on the capacity and resources of the hospital/clinic or community-based organization and on the ability of the patients and families to access the health care. For example, in rural areas some families live up to 100 miles away from specialty follow-up clinics.[9]
What other research is ongoing in this area currently?	• NICU-specific follow-up care research has not been particularly active in the past 10 years. The systematic reviews indicate that there have been few rigorous studies conducted on this topic since the early 2000s.[8,19] However, there is some related research ongoing in this area currently. • The March of Dimes NICU Family Support® program offers information and comfort to families during hospitalization of the newborn, the transition home, and in the event of newborn death.[38] A quasi-experimental, post-only design study was used to gather information on the eight sites that utilized that program. March of Dimes family-centered approach had a positive impact on stress level, comfort level, and parenting confidence of NICU families. ○ This program continues to be utilized in hospitals around the country and is currently in 120 hospitals.[39] • As described above, there are evidence-based models of maternal, infant, and early childhood home visiting programs that are being systematically evaluated. While these are not focused specifically on this population, the wraparound services provided are highly relevant to the needs of infants and families. • There are new models emerging for home care and care coordination with other patient populations that may be relevant, but more research is needed to systematically examine them.
How likely is it that new CER on this topic would provide better information to guide health system practice?	• As there is currently no nationally representative information on the composition of high-risk infant follow-up programs in the United States, comparative effectiveness research has an extremely strong potential to provide information that would guide health system practice. This guidance would inform patients, families, and providers. • There is limited information on how providers, especially primary care providers, are implementing the AAP guidelines and other models for NICU discharge planning and transition. New comparative effectiveness research, addressing questions such as those presented above, could provide information on provider-reported outcomes related to the delivery of NICU follow-up services. The results of such research could help to assure that the provider community feels adequately trained to implement the guidelines, especially as additional types of providers, such as non-NICU focused home visitors, work with families discharged from the NICU. • Preterm infants and those with complex medical conditions often need various types of care. New research could also help guide health system practice to better coordinate with services outside of the clinical setting. • Results derived from CER could also provide information that would inform improved electronic communication across care providers and interventions.
Potential for New Information to Improve Care and Patient-Centered Outcomes	
What are the facilitators and barriers that would	Facilitators

Criteria	Brief Description

affect the implementation of new findings in practice?	- Information sharing among clinical and other types of providers, such as social workers and home visitors, would facilitate the implementation of patient- and family-centered models of care. Because infants discharged from the NICU may have multiple health conditions and the family may need other types of supports, multiple providers and agencies that have information on each infant and family should be involved. Sharing information among providers would facilitate more effective care for infants and families.
	- Maximizing the use of new payment models including ACOs and health homes would provide additional flexibility in the use of the findings.
	
	Barriers
	- Different reimbursement models, including public and private payers, may cover different types of providers and interventions, causing frustration to providers. This may also cause frustration to patients and their families, as it may limit the choices that parents and families have available to them despite what is recommended as the most appropriate support model for their infant and family.
	- There have been several criticisms in scientific merit of previous effectiveness studies,[40] due to:
	  ○ Differences in definitions of developmental care.
	  ○ Difficulties trying to isolate 1 or more variables that were considered developmental care and linking them to long-term clinical outcomes.
	  ○ Success of implementation depends on individual interpretations of data and guidelines. Due to length of time necessary to monitor overall development of infants over a long period of time, it may take years to reach consensus.

How likely is it that the results of new research on this topic would be implemented in practice right away?	- Results of new research on models of comprehensive care have the potential to be implemented in practice. Many studies are at least 10 years old, there is little recent comparative information between programs, and there is a lack of representative data on the composition of programs. - Hospitals and follow-up clinics want to provide high-quality care for their patients, and the AAP NICU discharge planning guidelines represent a critical component of this care for NICU patients. Evidence from CER that examines the effectiveness of the AAP guidelines and the benefits and risks of different models of NICU follow-up care would inform new evidence-based guidelines and assist hospitals and other providers to provide evidence-based, high-quality care. - Comprehensive programs that follow-up with patients outside of the hospital setting often have the capacity to link patients to additional support services as soon as an issue is identified. Comprehensive support services with a wraparound component place a strong emphasis on early intervention. Evidence from CER that examines the effectiveness of NICU follow-up care on quality of life outcomes could inform evidence-based practices for transitioning children into early intervention services. There may also be opportunities to develop partnerships with other agencies, such as the MCHB, who are doing related work in early childhood health and development.
Would new information from CER on this topic	- As continual advances are made in medical science, life-saving technology is available to more infants who are born very premature or with more complex medical conditions. These infants will continue to require NICU and post-discharge care to address their medical needs and provide clinical wraparound support to their parents and caregivers.

Criteria	Brief Description
remain current for several years, or would it be rendered obsolete quickly by subsequent studies?	• Reaching consensus on evidence-based models will benefit both providers and families, especially as approaches must be targeted to the unique needs of each infant and family. • Overall, given the limited availability and pace of current research, it is very likely that new information from CER on this topic would remain current for several years.

References for Topic 3: Models of Comprehensive Support Services for Infants and Their Families Following Discharge from Neonatal Intensive Care Unit

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Research Prioritization Topic Brief 4: Health System Approaches to Suicide Prevention

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Improving Healthcare Systems

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Executive Summary for Topic 4: Health Systems Approaches to Suicide Prevention

Comparative Research Questions. Compare the effectiveness of evidence based interventions for prevention of suicide in non-VA individuals.

Brief Overview of the Topic. Suicide or "suicidality" refers to a continuum including: (1) completed suicide, (2) suicide attempt, (3) preparatory acts toward imminent suicidal behavior, (4) suicidal ideation, (5) self-injurious behavior without intent to die, (6) non-deliberate self-harm, and (7) self-harm behavior with unknown suicidal intent.[1] While prevention and treatment strategies exist, there has been limited rigorous research to inform an evidence base; those evidence-based strategies that do exist are not necessarily being delivered to the intended populations and/or are poorly integrated consistently across health care systems. Constraints in available data and service protocols limit the options available to patients as well as health systems research focused on sustainable implementation.[2]

Patient-Centeredness. Patients at different stages of suicidality who receive appropriate care (to mitigate mental health suffering and self-inflicted injuries as well as reduced likelihood of successful suicidal actions) will experience an improved quality of life. With suicide risk and management assessment protocols in place, clinicians can be trained to empower patients to contribute to their treatment plan with continuing benefits after the treatment has ended. Providing appropriate treatment along this spectrum will also serve to reduce the burden on caregivers who are otherwise suffering the social, economic, and personal consequences. Suicide-specific preparatory training and continuing education will facilitate clinician preparation and provide clear protocols for screening, treatment, and referral. Policies that afford communication and a team approach to care provide both better care and follow-up for patients as well as professional support for clinicians. Finally, establishing systems to identify those most at risk and to integrate evidence-based services (targeted as needed) will support the sustainability of services and minimize system inefficiencies to the benefit of all stakeholders.

Impact on Health and Populations. There are a handful of suicide prevention strategies that moderate evidence shows to be effective.[3] However, integration of these policies, skills, and systems across all levels of care is not yet standard practice. Without valid screening tools and written protocols for treatment and referral, patient care is limited unnecessarily by the health system. Furthermore, formal protocols imply the need for establishing review of adverse clinical outcomes in healthcare settings.[3]

Assessment of Current Options. There have been few rigorous evaluation studies to assess the effectiveness of standard and new strategies to prevent and treat suicidality.[2] For example, technology-based screening and prevention programs likely represent a growth area, but formal evaluation of innovative platforms is essential to inform patient-centered guidelines and the range of evidence-based treatment referral options available to clinicians and caregivers. Further, research to identify valid and reliable measures of program effects, patient outcomes, and health outcomes that could be applied with consistency across clinical trials would facilitate assessment of best practices (meta-analyses) and inform translational research to take programs into practice. Improved methods are also needed to test programs and protocols for different sociodemographic groups in different cultural and clinical settings.[4]

Likelihood of Implementation in Practice. With Affordable Care Act (ACA) support for depression screening and mental health care coverage as an Essential Health Benefit,[5] clinical expectations of suicide management are changing. Informing written policies and protocols to provide a range of treatment options consistent with individual patient needs and preferences will also serve clinicians' interests. The National Action Alliance for Suicide Prevention (a public-private partnership) is planning imminent release of health systems recommendations.[6]

Durability of Information. Prevention and treatment of suicidality rests on a commitment to eradicating suicide through effective health systems and health care delivery. New suicide prevention interventions mostly utilize the same crisis response models presented through evolving technologies for the interface and delivery of mental health services to suicidal individuals, and many of the recommendations to address suicide focus on health systems, suggesting that new information would likely continue to serve this health goal over the coming years.

Topic 4: Health Systems Approaches to Suicide Prevention

Criteria	Brief Description
Introduction	

Overview/definition of topic	Suicide
	• The term suicide can refer to a continuum of thoughts and behaviors ranging from suicidal ideation or completed suicide. Research now distinguishes seven categories of "suicidality," including: (1) completed suicide, (2) suicide attempt, (3) preparatory acts toward imminent suicidal behavior, (4) suicidal ideation, (5) self-injurious behavior without intent to die, (6) non-deliberate self-harm, and (7) self-harm behavior with unknown suicidal intent.[1]
	• In the first decade of the 21st century, nearly 330,000 Americans lost their lives to suicide. The suicide mortality rate— from 1999-2010, the annual rate of suicide increased nearly 30% steadily among those aged 35 to 64 years[7] —is a critical public health issue that suggests that more coordination and integrated interventions are needed.[8]
	• Non-fatal suicide attempts have serious health implications as well.
	  ○ For every person who dies by suicide, more than 30 others attempt suicide.[9]
	  ○ Survivors of attempted suicide may have serious injuries like broken bones, brain damage, or organ failure and often have depression and other mental health problems.[10]
	• In 2012, The Surgeon General report on the incidence of suicide in the past year suggested that more than 8 million adults (3.7%) reported having serious thoughts of suicide, 2.5 million (1%) reported making a suicide plan, and 1.1 million (0.5%) report a suicide attempt.[9] Suicide rates vary across age, sex, racial and ethnic groups:
	  ○ **Sex**: The suicide rate was consistently higher among males from 1991-2009.[9]
	  ○ **Race/Ethnicity**: Suicide rates (2005–2009) were highest among American Indian/Alaskan Natives (17.48 suicides per 100,000) and Non-Hispanic Whites (15.99 per 100,000).[9]
	  ○ **Age**: Suicide is one of the leading cause of death among adolescents and young adults: ages 15-24 (3rd); ages 25-34 (2nd); ages 35-44 (4th).[7] High school students are particularly at risk.[9] Almost 16% of high school students report having seriously considered suicide, and 7.8% report having attempted suicide at least once in the past year.[9]
	• Suicidality in subpopulations of concern (e.g., LGBTQ[11]) require community-based, targeted interventions.[4]
	• Suicidal ideation, suicide attempts, and suicidal outcomes co-occur with other forms of mental illness. Studies have consistently found that 90% of those who die by suicide had a (often undiagnosed and untreated) mental health disorder at the time of their deaths.[12] Clinical risks identified for suicide include: psychiatric illness (most commonly depression, alcohol abuse, anxiety), being widowed or divorced, living alone, experiencing an adverse event, chronic mental illness, and family history of suicide attempts.[13]
	Suicide Prevention Program Formats[14]

Criteria	Brief Description
	• *Primary* suicide prevention looks to decrease the rate of new cases of suicide in the general population. *Secondary* suicide prevention aims to reduce the likelihood of attempted suicide in high-risk patients. *Tertiary* suicide prevention efforts, in response to completed suicides, aim to diminish contagion (clusters of suicides in a geographical area) and copy-cat suicides.[1] • Acosta[14] lays out nine program formats as follows: ○ **Training on coping skills and self-referral**: Health promotion programs to increase awareness of the signs of suicide and mental health problems; enhance individual protective factors; and reduce known risk factors. ○ **Marketing campaigns**: Fact sheets, testimonials and hotline advertisements to reduce stigma and build public awareness. ○ **Gatekeeper trainings**: Education of friends, family members, clergy, coworkers and schools to identify when someone is in distress and provide referrals for help. ○ **Crisis hotlines**: Immediate support to individuals in distress. ○ **Appropriate response**: Community programs to develop appropriate responses to suicide to prevent "contagion" of suicidal behavior in vulnerable populations. ○ **Screening programs**: Standard instruments used in primary care and non-mental health settings to identify those at risk for suicidal behavior. ○ **Provider trainings**: May focus on: (1) mental health awareness; (2) general suicide risk assessment and management training; (3) evidence-based therapies. ○ **Targeted mental health interventions**: Dialectical behavior therapy (DBT) and cognitive behavioral therapy (CBT) to treat patients at-risk for suicidal behaviors. ○ **Social/policy interventions**: Interventions to restrict physical access (e.g. access to firearms, safeguards on bridges, etc.). • **Multi-component interventions:** Parallel to the enormously effective Screening, Brief Interventions and Referral to Treatment (SBIRT) model[15] for substance use treatment, the Suicide Prevention Resource Center (SPRC) recommends the *Safety Planning Intervention (SPI)* be implemented to present coping strategies and a range of services to those exhibiting suicidal ideation and behavior,[16] inclusive of (1) Recognizing warning signs of an impending suicidal crisis[17]; (2) Employing internal coping strategies[18]; (3) Utilizing social contacts to distract from suicidal thoughts; (4) Contacting mental health professionals or agencies[19]; (5) Reducing potential use of lethal means[20]; and (6) Provider follow-up with client.[3,16,20] <u>Brief History of Suicide Prevention Policy</u> • Following United Nations guidelines, suicide survivors mobilized in the mid-1990s to encourage the establishment of a national strategy to prevent suicide in the U.S., resulting in two Congressional Resolutions. Subsequently, a 1998 national consensus conference (Reno, Nevada) produced a list of 81 recommendations, launching the modern suicide prevention movement.[21] There followed the release of the National Strategy for Suicide Prevention (NSSP) in 2001, the creation of a National Suicide Prevention Lifeline in 2001, and the 2002 development of a Suicide Prevention Resource Center (SPRC) by SAMHSA.[21] • Created in 2004, the Garrett Lee Smith Act has since funded a range of suicide prevention programs in youth, on college campuses and tribal communities in the U.S.[7,22] • The National Action Alliance for Suicide Prevention (established 2010, representing over 200 public and private organizations) is dedicated to suicide prevention in at-risk populations.[8]

Criteria	Brief Description
	○ The Alliance is developing training guidelines to equip the clinical workforce with knowledge and skills to support suicidal individuals. ○ The Alliance is working with Centers for Medicare & Medicaid Services to ensure that suicide prevention services are integrated into healthcare reform. ○ The Alliance works to promote awareness and prevention efforts in the juvenile justice system, in the workplace, and in the military, including veterans and their families.[6] ○ The Alliance created the Research Prioritization Task Force (RPTF; collaboration among 11 organizations) to set forth a national agenda for suicide prevention.[4] (*See p. 11 for recommended CER topics consistent with the RPTF 2014 Prioritized Research Agenda*.) • The Affordable Care Act (ACA) addresses suicide prevention in two ways: ○ First, all new individual and small group insurance plans are required to cover mental health and substance use disorder services as one of 10 Essential Health Benefits.[5] ○ Second, ACA funds a variety of suicide prevention programs, including the National Strategy on Suicide Prevention, Garrett Lee Smith, state/tribal grants, the National Suicide Prevention Lifeline Program, and Suicide Prevention Resource Center.[23] • The Indian Health Service connects Native American communities to suicide prevention programs, many of which are also listed in the National Registry of Evidence-Based Programs and Practices and/or as a best practice by the Suicide Prevention Resource Center. Thus, most of the listed programs are not culturally tailored to local communities, and most tailored programs do not appear to have been subjected to rigorous evaluation.[24]
Relevance to patient-centered outcomes	• Primary, secondary, and tertiary prevention of suicidality directly impacts the social, mental and economic wellbeing of the patient and their caregivers. Patient-centered models, with increased caregiver education and integration of screening and treating common mental health problems, have encouraged behavioral health integration at each level of care.[3] • Prevention efforts are geared towards addressing risk factors (e.g. mental health, targeted population interventions). Treatment for depression, including efforts to monitor and reduce suicidal ideation during treatment, is a key component of patient-centered care. Treatment can also address and mitigate secondary patient injuries following a suicide attempt. • Health systems interventions help to build effective prevention networks of healthcare providers, providing them with the resources to address this critical public health concern.[3] Multicomponent approaches such as the Safety Planning Intervention (SPI) provides individual coping strategies and a range of interpersonal systemic contacts to the benefit of patients.[16] • See "Burden on Society" section below for details on the economic and social impact.
Burden on Society	
Extent of the health system problem	Suicide • There are economic, personal, and social costs associated with attempted suicide, injuries, and deaths, with broad ramifications for family and friends.[25] • Hospitalization and emergency department costs (2003) arising from self-harm reached almost \$6.4 billion.[7] With the burden of suicide falling most heavily on adults of working age, economic costs result almost entirely from lost wages and work productivity.[26] The estimated monetary cost of suicide (32,637 deaths) in 2005 was over \$42.2 billion (2014 dollars) in medical costs and inferred lost work arising (vs. \$25.3 billion associated with 18,124 homicides). Annual suicide rates have risen by nearly 6000 since then.[7]

Criteria	Brief Description
	Suicide Prevention • Systems dynamic models estimate that under optimal conditions over a single year, implementing evidence-based psychotherapeutic interventions in emergency departments could decrease the number of suicide attempts by 18,737; and if offered over 5 years, it could avert 109,306 attempts. Over one year, the model estimated 2,498 fewer deaths from suicide, and over five years, about 13,928 fewer suicide deaths.[27] • The National Institutes of Health spent approximately $37 million on suicide prevention research in fiscal year 2013.[28] Further, despite the success of some interventions in reducing suicide attempts and suicide rates (see "Options for Addressing the Issue" below), there remain systemic and methodological issues to be addressed. • Systemic Challenges ○ Gaps in health system readiness include the absence of written policies and procedures, challenges to coordinated care across providers within and between facilities, and insufficient training.[3] Integrating services into acute care scenarios[29] requires sustainability studies and strategies.[3] There is a need for research to address the feasibility and generalizability of research findings.[2] ○ The Patient Health Questionnaire–9 (PHQ-9) is probably the most widely used measure of depression and suicide risk screening in primary care due to its established psychometrics, brevity, and inclusion of an item that assesses for recent thoughts of death and self-harm.[29-31] There is anecdotal evidence of clinical concerns with the PHQ-9, given a high rate of positive tests and the subsequent clinical burdens to provide expanded prevention and treatment services to patients testing positive. Rarely are patients screened for depression.[3] • Methodological Challenges (many promising suicide prevention intervention trials remain inconclusive due to methodological problems[2]) ○ Compared to many common health conditions, base rates of suicide are low, making it a difficult behavior to study.[2] Thus, studies require prohibitively large sample sizes in order to evaluate whether the rate of suicide has decreased after an intervention has been implemented.[14,17,32,33] Intermediate outcomes (most commonly suicide attempts , either self-reported or recorded in hospital records; provider competency measures), are often used as the primary outcome in prevention research.[14] Qualitative studies are needed to operationalize additional intermediate outcomes (ideation, intent, etc.) as well as risk and protective factors to improve the quality of subsequent evaluations.[2] ○ For ethical human subject protections reasons, many of the studies do not include actively suicidal participants.[2] Further, it is challenging to identify effective control groups, especially for studies using psychological autopsies.[34] Thus, many studies focus on risk factors not unique to suicide, which can be problematic because many of the associated risk factors (e.g., depression, substance use) are widespread.[2]

Criteria	Brief Description
	○ There are many steps that can be taken to improve the quality of the research so that more definitive statements can be made about what does and does not work in the area of suicide prevention/intervention. Suggestions to improve the quality of reviews include describing the demographic characteristics of study participants; describing intervention characteristics (e.g., intervention settings dose/duration of the intervention); and using a common set of risk/protective factors and outcomes to facilitate aggregation of data across studies.[2]
Effects on patients' quality of life, productivity, functional capacity, mortality, use of health care services	Overall, suicide prevention programs have been shown to have a positive impact on patient quality of life, through decreasing suicide attempts and reducing risk factors (such as poor coping skills in response to depression and suicidal ideation). • For example, relevant to health systems usage and teacher referrals as gatekeepers, school-based suicide prevention programs lead to significantly lower rates of suicide attempts and greater student knowledge and more adaptive attitudes about depression and suicide.[35] • Two treatments that focus on mindfulness – Dialectical Behavior Therapy (DBT)[36,37] and Mindfulness-Based Cognitive Therapy (MBCT)[38] – have shown efficacy in relation to suicidal behavior including major depression[39-41] as well as other quality of life improvements (e.g. substance abuse treatment[42-45]). It is not yet known how ACA coverage has affected access. • While there may be important impacts on individual quality of life, we did not find formal evaluations of stigma campaigns, social media sites, or support groups.
How strongly does this overall societal burden suggest that CER on alternative approaches to this problem should be given high priority?	Factors In Favor • A conventional model of managing suicide is activated when the primary care provider (PCP) becomes aware of closely related risk factors, such as depression.[18] This "as indicated" approach is insufficient considering that about half of people who die by suicide have seen their PCP within the 30 days prior to death.[29,46-48] • The movement to patient-centered medical homes and the integration of behavioral mental health care and treatment[17,19] will continue to decrease the overall burden on individuals and society. Yet there is still work to be done to address pervasive stigma that function as barriers to patient help-seeking, with tailored approaches necessary for different cultural contexts. Further study of fundamental biological, psychological, social, and cultural factors that contribute to apparent risk among diverse populations and groups is needed.[7,34] • CER investments to identify alternative approaches to facilitate greater patient involvement in treatment course including access to a range of care options could help ease the overall burden of suicide. • Disparities across different sociodemographic groups and subgroups with correlated health behaviors/problems underscore the opportunity and importance of studying tailored programs to targeted population subgroups. These include geographic disparities.[49] • Education of physicians and restricting access to lethal means are approaches that have been found to prevent suicide. Other methods including public education, screening programs, and media education need more testing. Ascertaining which components of suicide prevention programs – for example, broader evaluation of physician education and depression/mental health identification and treatment – are effective in reducing rates of suicide and suicide attempt is essential in order to optimize use of limited resources.[17] • Evaluation methodologies require attention to facilitate rigorous research designs. Factors Against

Criteria	Brief Description
	• Continued use of inefficient evaluation methodologies would incur further research costs without improved outcomes measurement. (See “Extent of the health system problem” above for methodological recommendations to support rigorous patient-centered CER.)
Options for Addressing the Issue	
Based on systematic reviews, what is known about the relative benefits and harms of the available management options? Note if no systematic reviews are available, and summarize results from seminal recent studies on the relative benefits and harms of available management options.	• Nearly all the suicide prevention efforts put forth since the 2001 NSSP release have been confined to clinical interventions and counseling and education, strategies which essentially depend on changing the behavior of suicidal individuals themselves, family members, and care providers.[7] However, despite a wide variety of potential management approaches (see Acosta’s nine categories of suicide prevention programs above), there has been limited research evaluating the effectiveness of many specific socio-behavioral interventions. The most effective evidence-based interventions tend to fall into three main categories[14]: ○ **Social/policy interventions** ▪ Curriculum-based prevention for teens.[50] ▪ Restricting access to means through installation of physical barriers; encouraging help-seeking by placement of signs and telephones; increasing the likelihood of third party intervention through surveillance and staff training; and guidelines for journalists to encourage responsible reporting.[51] ▪ Limiting access to lethal means[20], including carbon monoxide, paracetamol, securing public places, firearms, and other means.[17] ○ **Increased provision of high-quality mental health care through targeted mental health interventions** ▪ Among patients who recently made a suicide attempt, those receiving cognitive therapy were 50% less likely to reattempt suicide than patients receiving usual care.[19] Likewise, an intensive individual follow-up with a counselor for several weeks after hospitalization for a suicide attempt was shown to help lower the suicide recurrence rate.[20] ▪ Consistent with the self-management and collaborative care focus for psychiatric illnesses widely adopted in primary care[29,52], adopting a chronic disease model for suicide risk (patients receive periodic mental health “checkups” in between acute episodes and/or periods of treatment in order to facilitate long-term management and reduce the likelihood for relapse) can be especially useful for the early detection and management of reemerging suicidal crises among chronically high-risk patients.[27,45] ○ **Effective acute crisis response, such as through provider or physician trainings, postvention programs, or crisis hotlines.** ▪ While brief training may not impact suicide rates, there are models of physician training yields declines in annual suicide rates.[17] ▪ The implementation of emergency call centers had a significantly positive impact on the reduction of suicide rates and suicidal ideation.[20] Other interventions (training of general practitioners, the reorganization of care, programs in schools and information campaigns) show mixed results in preventing suicide but may, under certain conditions, significantly impact intermediate outcomes.[20,53]

Criteria	Brief Description
	• More recently, suicide prevention efforts have been available through internet websites and mobile devices. Online suicide prevention websites, such as IMAlive.com, offer a virtual crisis center where volunteers are available to chat any time. Mobile apps provide another pathway with nearly 20 applications for iOS and Android phones that offer information, easy access to resources, and opportunities to communicate with others. Evaluations of technology-based suicide prevention platforms are limited and these assessments are only gradually beginning to emerge, suggesting an important CER gap (e.g. is virtual care as effective as productive patient/staff interactions?).
What could new research contribute to achieving better patient-centered outcomes?	Currently, most approaches focus on individuals at imminent risk of death from suicide, however there is a need to provide primary prevention services to individuals who are vulnerable but do not present with urgent risk.[7] Intervening earlier in mental health trajectories may not only prevent suicide but also would stem the accrued losses in quality of life (e.g., interventions to address mental health problems and substance abuse may improve patient quality of life before suicidal ideation develops and/or leads to suicide attempts). Further, CER evaluations of the most effective types of interventions are needed (a 2010 review of 1,209 abstracts of suicide prevention studies found that only 12% described intervention studies, in comparison to the 48% that were epidemiological studies of suicide and the additional 12% that describe the biological and genetic factors that may relate to suicide[54]). There are several ways that new research could contribute to achieving better patient-centered outcomes: • *What is the comparative effectiveness of different screening approaches (e.g. depression screening, passive and active ideation) on suicidality and process outcomes (such as which methods increase denial of ideation)?* Several challenges present themselves in screening for suicide prevention including inability to discriminate false-positive cases, false-negative cases escape preventive detection, and inability of clinical services to reach many individuals who have suicidal intent.[7] The Research Prioritization Task Force (RPTF) recommends studies of the relative value of different screening approaches.[4] • *For people who screen positive for suicidality, is the Safety Planning Intervention more effective in reducing suicidal behavior (attempts and death by suicide) in emergency department settings or in primary care settings?* The Research Prioritization Task Force published an agenda for future research recommending the development of a program using the Screening, Brief Intervention and Referral to Treatment (SBIRT) model that has been used successfully in substance abuse detection and treatment.[4] Following that model, the multi-component *Safety Planning Intervention* (currently under study in a single urban emergency department and one national Veterans study[16]) is recommended by the Suicide Prevention Resource Center (SPRC) for emergency department implementation. Yet, as noted, about half of people who die by suicide saw a primary care provider within the prior month.[29,46,47] PCORI research would make a valuable contribution to health system protocols through a four-cell randomized controlled trial of hospital emergency departments and primary care settings vs. treatment as usual protocols in hospital emergency departments and primary care settings.

Criteria	Brief Description
	• *What is the comparative effectiveness of (a) universal prevention curricula, (b) targeting at-risk students, and (c) the combination thereof, compared to (d) no intervention to minimalize suicidality among adolescents?* Universal teen suicide prevention programs (often implemented as primary prevention curricula in high school settings) focus on reducing risk factors or strengthening protective factors for all adolescents. Examples include the Cincinnati Teen Suicide Prevention and Depression Awareness program[55] and the RPTF-recommended Sources of Strength (SOS) suicide prevention program.[35,56] Secondary prevention programs specifically target at-risk teens who have shown suicide risk factors during screening. Some examples include Promoting CARE[57] and the Coping and Support Training Program (CAST).[58] Although both primary and secondary prevention programs present noteworthy benefits and significant risks, neither type of program has been rigorously evaluated for effectiveness in suicide prevention. While two separate studies of adolescents (a targeted CBT intervention[59] and a school-based prevention curriculum)[35] showed similarly significant decreases in suicidal ideation or attempts, the field needs a rigorously designed experiment to assess which will minimize suicidality among adolescents. • *What is the comparative effectiveness of CBT, DBT, and MBCT approaches for at-risk populations (such as emergency care patients treated for self-harm; patients screened at risk for suicidality in primary care settings) on target suicidality outcomes?* At this time, most of the evidence base for these treatment approaches has been derived from studies of adult populations and thus, until further studies among adolescents confirm approaches for minors, CER studies addressing this question are not warranted for children/adolescents.
Have recent innovations made research on this topic especially compelling?	• Recent innovations in the way suicide prevention programs are distributed to the public have made new research on this topic particularly compelling. Suicide prevention websites and mobile apps with virtual crises centers are increasingly becoming available to those populations in need of these services. The online services, such as IMAlive.com, offer volunteers to chat with and easy access to information on suicide resources. This new way of spreading information and reaching out to patients needs to be examined more closely to determine whether this method can effectively prevent suicidality for a wider population. • Adoption of electronic health records and health information exchange has been shown to have a positive impact and lead to communication and care coordination between mental health and medical providers.[49] • There has been limited research on alternative approaches to suicide prevention, such as the effect of spirituality and religion on suicide attempts. While spirituality can be a risk factor for suicide, it has also been shown to be a mediating variable that may provide the social support needed to prevent suicide attempts.[60,61]
How widely do management options vary now?	Currently, there are a wide range of management options for suicide prevention from technical to physical interventions that are implemented in a variety of settings. However, most suicide prevention interventions do not take cultural context into account, despite the fact that studies have shown this plays a role in suicide.
What other research is ongoing in this area currently?	• Ongoing research (multi-component interventions) on suicide prevention specific to military and veteran populations have been shown to help decrease rates of suicide[62] and should be examined for translation to general populations.

Criteria	Brief Description
	• The National Institutes of Health have invested $38 million in suicide research and $21 million in suicide prevention research annually (FY2014-2015).[26] Clinical trials are testing relative effectiveness of different anti-depressants in reducing suicidal ideation and behavior.[63,64] • The National Action Alliance for Suicide Prevention RPTF agenda (2014) indicates suicide research priorities.[4,65] • There is also research on the etiology of suicide (an approach that integrates molecular, clinical, and environmental data with health outcomes) and recommendations that the RPTF continue to work in this field to advance suicide prevention.[4,66]
How likely is it that new CER on this topic would provide better information to guide health system practice?	• There are extensive networks of public and private efforts dedicated to addressing suicidality; this mobilization of commitment and resources — on top of increasing media attention to youth suicidality related to bullying and active duty and veteran suicidality, as well as ACA coverage expanding access — bears strong promise for constructive impact from new CER. • Dynamic health system projection models could aid in suicide prevention policy by helping focus translational research and implementation efforts. Thus, research to assess the impact of suicide prevention interventions (studies with more complex understanding of suicidal behavior, longer time frames, and inclusion of additional outcomes that capture the full benefits and costs of interventions) would be instructive for health system policies.[27]
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?	<u>Facilitators</u> • Prevention research builds on studies of the epidemiology of suicide and potential risk factors (e.g. research on effective screening instruments and practices, actionable risk stratification algorithms and the more general study of risk factors).[32] ○ Actionable risk stratification algorithms inform tools used by primary care physicians to effectively screen for suicide. Screening tools for depression, suicidal ideation or suicidal acts administered to youth have reliably identified at-risk individuals. Further research is need to evaluate whether the same screening tools are effective across different cultures, especially those determined to be at-risk for suicidal behavior.[17] ○ New technology for patient contact available 24 hours a day (apps, internet-based chat services) are available and require rigorous evaluations, but may support broader translation and implementation of preventive services. ○ Though research has documented risk factors for suicidal behaviors, further research is needed to help define boundaries populations for targeted interventions.[67] • The Affordable Care Act addresses access to mental health services. ACA requires that all new individual and small group insurance plans cover mental health and substance use disorder services as one of 10 Essential Health Benefits.[5] Depression screening is considered preventive care which is provided at no cost.[60] ACA expansion of health insurance coverage may directly affect suicide rates. <u>Barriers</u> • Anecdotal evidence of healthcare provider's concerns that rapid reporting of suicide attempts and referral to treatment will intrude on personal privacy.[7] • Health care workers may be reluctant to get involved in research. Universal or community-wide interventions are not always open to evaluation.[32]

Criteria	Brief Description
	• High levels of contact with past-year mental health and primary care services prior to suicide[48] points to lack of access to sufficient care, treatment adherence, clinical follow up, and self-management techniques to help patients stabilize, in the absence of expanding clinician training. • As of 2004, states with higher rates of residents who lack health insurance had higher rates of depression and suicide, although other factors such as isolation and gun ownership are confounders.[49] • Suicidal young adults have been found to differ from non-suicidal youth by having higher measures of depressed mood, negative automatic thoughts, and hopelessness.[61] Feedback from this population will be influenced by their depressed perspective, undermining research regarding patients' perspectives of care quality and treatment needs. • The need for interdisciplinary collaboration among individual practitioners, public health agencies, researchers, government agencies and other organizations of different priorities is a challenge to addressing the multi-dimensional nature of this topic.[7,34]
How likely is it that the results of new research on this topic would be implemented in practice right away?	• Rapid implementation of new research findings in suicide prevention interventions depends on the type of intervention being evaluated. Generalizability and feasibility studies are necessary for healthcare providers to choose cost-effective, evidence-based practices.[2] • Moving evidence-based interventions into practice will require actionable strategies to improve access for different at-risk populations. Technological innovations such as IMAlive.com virtual crisis center and suicide prevention mobile applications are already in use. Evaluations of such interventions would allow for effective investment in evidence-based practices.[10,43]
Would new information from CER on this topic remain current for several years, or would it be rendered obsolete quickly by subsequent studies?	• Interventions currently in place (such as barriers to access of means of suicide and hotlines) have been used for decades. New suicide prevention interventions still utilize the same models presented in a different way with new technology. For example, the IMAlive.com virtual crisis center is essentially the same hotline urgent response model that has been used for years. Additionally, the social climate regarding suicide, particularly the stigmatization of suicide, has remained relatively unchanged over the last decade. The longevity and continued relevancy of existing interventions suggests that any new interventions in the field would remain current for several years. • CER studies that apply improved evaluation methodologies could have a lasting impact on research in the field. ○ Operationalized terms for measurement of suicide-related outcomes (ideation, intent, etc.) and other measures of risk and protective factors would improve the quality of subsequent evaluations.[2] ○ Systems for data banking and data sharing would allow for meta analyses.[67]

References for Topic 4: Health Systems Approaches to Suicide Prevention

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