Research Report

Health Services and Primary Care Research Study

Comprehensive Report

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Preface

In March 2018, Congress directed and authorized the Agency for Healthcare Research and Quality (AHRQ) to contract with an independent entity to assess health services research (HSR) and primary care research (PCR) funded by federal agencies. The goal of this Health Services and Primary Care Research Study was to provide an independent assessment of the current breadth, scope, and impact of HSR and PCR supported by the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Veterans Affairs (VA). The study sought to identify research gaps and propose recommendations for maximizing the outcomes, value, and impact of HSR and PCR investments, including strategies for better coordination and potential realignment of research agendas.

This document provides the final report of the study to the U.S. House and Senate Committees on Appropriations. The document should be of interest to health services and primary care researchers, other stakeholders—including health care delivery leaders, consumers, purchasers, insurers, and improvement organizations—as well as congressional and other policymakers concerned with the role of federally funded research in advancing the fields of HSR and PCR.

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Summary

Background

On March 23, 2018, when H.R. 1625, the Consolidated Appropriations Act 2018, became law, Congress directed and authorized the Agency for Healthcare Research and Quality (AHRQ) to contract with an independent entity for a study on health services research (HSR) and primary care research (PCR) supported by federal agencies. AHRQ contracted with the RAND Corporation to conduct this report, beginning on September 19, 2018.

The goal of the study was to provide an independent assessment of the current breadth, scope, and impact of HSR and PCR supported by the U.S. Department of Health and Human Services' (HHS's) 11 operating divisions and the U.S. Department of Veterans Affairs (VA) since fiscal year 2012. In support of this goal, the study was to identify research gaps and propose recommendations to AHRQ for maximizing the outcomes, value, and impact of HSR and PCR investments during the next five to 20 years and beyond, including strategies for better coordination and potential consolidation of research agendas.

The Need for This Study

The value of HSR has been well documented. Since its emergence as an independent field of study in the 1960s, HSR has helped establish an evidence base to support decisionmaking and improvements in the quality, safety, effectiveness, and efficiency of health care in the United States. HSR findings have been used to improve the design of health care benefits, inform health care policy, and help providers and patients make better decisions about health care.

PCR has also emerged as a distinct field in its own right, addressing a central component of the health care system. The Council of Academic Family Medicine and other organizations have identified key characteristics of primary care, which highlight the importance of PCR, including its ability to touch the lives of all Americans, focus on the whole person, give attention to common conditions often not treated in hospitals or specialty clinics, and provide evidence that is critical for the delivery of high-quality primary care (Wittenberg, undated).

Consistent with this broad acknowledgment of the many meaningful contributions of HSR and PCR to improving health care, there has been growing recognition of the need to better understand the impact of HSR and PCR and to prioritize potential future directions of research among federal agencies and other stakeholders. A 2018 conference on HSR sponsored by the National Academy of Medicine called for "a set of activities required to transform the field," including an expanded vision of HSR, a taxonomy of issues and priorities for action, tools and insights to use in effecting change, the development of data infrastructure, and the creation of a "working network" of stakeholders—including patients—in research (National Academies of

Medicine, 2018). Although there has been less investment in planning for the future of PCR, there is a growing recognition that primary care is "too important to fail" (Meyers and Clancy, 2009), and that planning for research that effectively supports the goals of primary care is critically important.

Research Questions

The current study attempts to build on the work done to date in examining future directions for HSR and PCR. Based on the goal of the study, the RAND team worked with AHRQ to develop a set of five key research questions:

- What is the breadth and focus of federal agency research portfolios in HSR and PCR?
- What is the overlap among federal agency research portfolios and the coordination that occurs between federally funded HSR and PCR?
- What are the impacts of federally funded HSR and PCR and challenges to assessing and achieving impacts?
- What are the gaps in federally funded HSR and PCR and approaches to prioritizing gaps?
- What are options for improving the outcomes, value, and impact of future federally funded HSR and PCR?

To answer these questions, the RAND team formed two technical expert panels (TEPs) constituted of stakeholder leaders in the fields of HSR and PCR, conducted interviews with key informants from five stakeholder groups in HSR and PCR, and performed an environmental scan and portfolio analysis to enumerate and catalog federally funded HSR and PCR projects from October 1, 2011 through September 30, 2018.

Federal Agency Portfolios in HSR and PCR Have Distinct Focus Areas Based on Their Individual Congressional Authorizations, Missions, and Operational Needs

Study participants and federal agency points of contact identified eight agencies in the scope of the study with portfolios of research in HSR and PCR, according to the definitions of the study: the Administration for Community Living (ACL), AHRQ, the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), and the Veterans Health Administration (VHA).

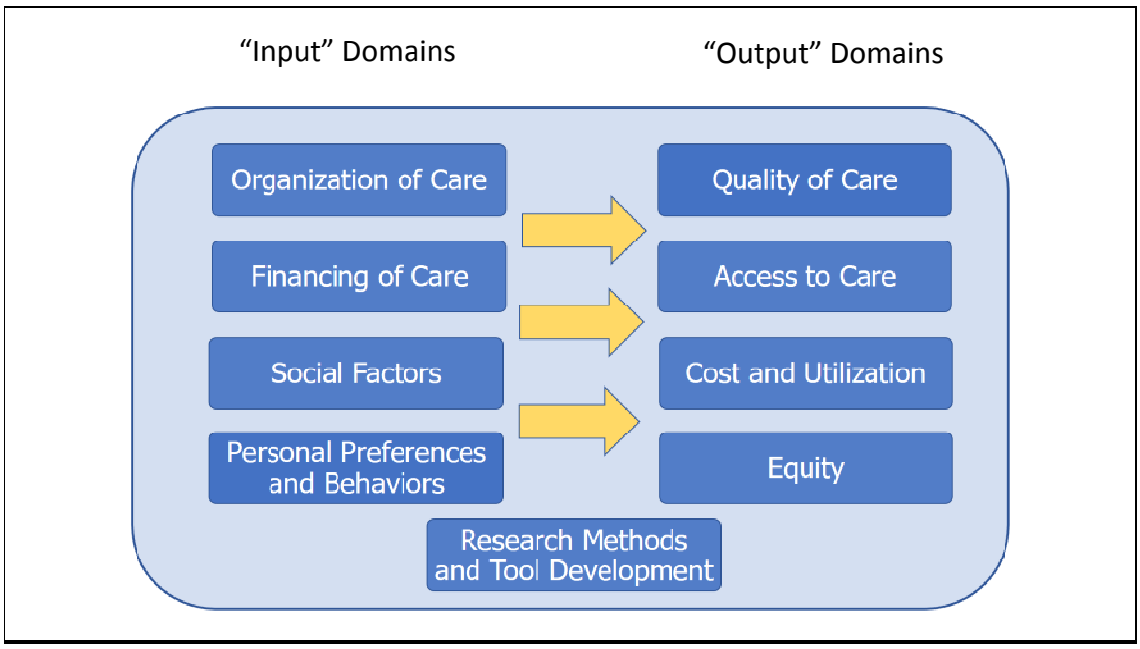
These agencies have developed research portfolios of HSR and PCR around focus areas that address the requirements of their individual congressional authorizations, missions, and operational needs. The agency portfolios differ along three key dimensions—scope of the health care system examined, research objectives, and research audiences—which reflect distinct

agency emphases in HSR and PCR. For example, study participants across the range of stakeholders noted AHRQ as the only federal agency that has statutory authorizations to generate HSR and be the home for federal PCR, and the unique focus of its research portfolio on system-based outcomes (e.g., making health care safer, higher quality, more accessible, equitable, and affordable) and approaches to implementing improvements across U.S. health care settings and populations.

NIH's portfolio of HSR and PCR addresses a similarly broad scope of health care but tends to be organized around specific diseases, body systems, or populations. The CDC's portfolio of HSR and PCR is organized around diseases, conditions, and injuries, but focuses on prevention and health promotion spanning community and health care settings. The portfolios of other agencies tend to focus on specific health care settings or other populations (e.g., CMS on Medicare and Medicaid beneficiaries, VHA on veterans' health care and health, and ACL on community-living elderly and disabled individuals), or research audiences (e.g., ASPE on federal policymakers).

To differentiate the topical areas of focus within agency's HSR and PCR portfolios, the study team worked iteratively with AHRQ and the study's TEPs to develop the research domain framework shown in Figure S.1. The framework includes four domains of health care "outputs" typically of interest to health care policymakers and other stakeholders, four domains of health care "inputs," and a domain of research methods and tool development integral to the advancement of HSR and PCR and implementation of research evidence into practice.

Figure S.1. Research Domain Framework for HSR and PCR



Results of the environmental scan and portfolio analysis's systematic enumeration of HSR and PCR projects confirmed a number of these distinctive focus areas of agency research portfolios, including AHRQ's relative emphasis on Patient Safety, Health Information Technology (HIT) Applications and Tools, and Evidence Review and Synthesis; CMS on Cost and Utilization and on Financing of Care; CDC on Prevention; and ACL on Social Factors. At the same time, the scan results showed other agency portfolios to include projects in these areas, albeit to a lesser extent, as well as strong emphasis across all agencies on the research domains of Quality of Care and Organization of Care. While the qualitative results from TEP and interview participants indicated how agencies would be expected to approach these topics differently, the relatively broad categories of the scan analysis were not able to detect these distinctions. Thus, the study next addressed the question of the degree to which research funded by agencies in similar topic areas is complementary or redundant, and the extent and ways in which federal HSR and PCR funding is coordinated among agencies.

Agency-Funded HSR and PCR on Similar Topics Is Largely Complementary, but Potential Overlap in Portfolios Needs to Be Identified More Proactively

Study participants across various stakeholder groups noted that overlap in research funding—that is, when agencies fund research in the same topic area—is generally complementary and advantageous rather than redundant. Complementary research includes instances when agencies fund projects addressing different facets of a research topic, as well as when agencies devote or combine resources for similar projects on an underfunded topic in an additive fashion.

Several interview participants pointed to coordination of research portfolios as a more problematic issue than redundancy. Participants observed that agencies acted to address redundancy in research portfolios and worked to ensure that funding of the research reflected the distinct roles and added value of each agency after such redundancies were recognized. Participants also observed federal agencies to be adept at utilizing appropriate and effective mechanism for coordination—formal and informal—*once overlaps in portfolios were recognized.* Informal coordination mechanisms include personal staff connections and networks, which were also considered critical facilitators of formal coordination.

However, study participants commented on the lack of systematic processes for proactively identifying potential overlap in HSR and PCR portfolios across agencies. The process of discovering overlaps was said to be "sporadic," "accidental," or "anecdotal" and to occur "by happenstance." Individual study participants also noted research areas they considered to lack sufficient coordination. Challenges to coordination of HSR and PCR portfolios mentioned by study participants included the breadth and volume of research activities across the federal HSR and PCR enterprise, differing time frames of research among agencies, and the lack of targeted funding for a lead agency to coordinate PCR in particular.

Federally Funded HSR and PCR Have Resulted in Wide-Ranging Impacts, Which Are Often Cumulative Across Agency Portfolios

Health services and primary care in the United States are complex, multilevel, and layered systems in which the process of change is not always well understood and effecting positive change often requires leveraging multiple strategies. Understanding how HSR and PCR can and have had impact on these systems is important for assessing the contributions of federally funded research to the fields of HSR and PCR and for informing the prioritization of research gaps.

Based on existing frameworks of research impact as well as discussions with TEP and interview participants, we identified six categories of impact, which we illustrate with examples of federally funded HSR and PCR: (1) scientific impact, (2) professional knowledge and practice impact, (3) health care systems and services impact, (4) policy impact, (5) patient impact, and (6) societal impact. It is unlikely for a single research project to generate impact across all categories, and the impacts of specific projects may not always occur in a linear order. However, the types of impacts identified represent a progression from interim research impacts (i.e., on scientific knowledge, professional practice, health care systems, and policy) to direct outcomes for patients and wider outcomes for society. As such, they represent a general guiding framework for assessing the accumulated impact of portfolios of research within an agency or that span agencies.

In addition to identifying types of impact, study participants noted important challenges to assessing impact, including the difficulty of tracing the accumulation of impacts across specific projects or sets of projects within a portfolio, especially when research is funded by multiple agencies. Impact may take time to accumulate and be realized, which further complicates attribution to specific projects or sources of funding. Moreover, many types of impact are by their nature difficult to systematically measure. Study participants also called attention to challenges in achieving HSR and PCR impact. These barriers included a lack of investment in high-risk studies and various disconnects between research and implementation.

The Variety of Gaps in HSR and PCR Reflect the Challenge of Improving U.S. Health Care, Which Requires New Research Approaches and Strategies for Prioritizing Research Needs

TEP and interview participants identified a wide range of pressing research gaps in HSR and PCR. These gaps are driven by the complexity and rapidly changing landscape of the U.S. health care system. Many of these gaps are related to specific "inputs" and "outputs" of health care services in the study's research domain framework (Figure S.1). However, many of the gaps also reflect the difficulty of understanding the *linkages between health care inputs and outputs* to produce important outcomes, and the limitations of currently used research approaches to generate and disseminate evidence in ways that positively impact real-world health care systems and practice. At the same time, these gaps also represent opportunities to find new ways to use

research to solve problems and improve the health care system, and ultimately the nation's collective health.

Our analysis highlighted *key gaps*, that is, research gaps that were raised by multiple study participants within a perspective or across stakeholder perspectives. Study participants noted that many of these gaps have been the subject of research studies sponsored by federal agencies and other funders, but that further research is needed, or different research approaches are required to make a positive impact on health care delivery and health outcomes.

Table S.1 lists the key cross-cutting gaps in research approaches that impede the impact of HSR and PCR for improving real-world health care systems and practice.

Table S.1. Key Cross-Cutting Gaps in Research Approaches to HSR and PCR Identified by Study Participants

Research Domain	Gaps in HSR and PCR
Cross-Cutting	• Examining health care outcomes for a fuller range of populations and settings • Following change in implementation and outcomes of health care interventions over time • Communicating results that are actionable by health care delivery stakeholders • Producing relevant and timely results for health care delivery improvement • Using theory to connect findings and advance knowledge on health care change • Leveraging digital health and linking various new sources of health care–related data

Table S.2 summarizes the key research domain gaps raised by study participants for HSR.

Table S.2. Key HSR Gaps Identified by Study Participants

Research Domain	Gaps in HSR on . . .
Organization of Care	• Health care workforce needs, composition, and roles in new delivery models[a] • Reducing burdens of health IT on health care providers[a]
Financing of Care	• Effects of evolving models of financing on the range of health care outcomes • Effects of health care payment models on different patient populations
Social Factors	• Role of health care systems in addressing social determinants of health[a] • Effect of social factors on demand for health care services[a]
Personal Preferences and Behaviors	• Integrating patient preferences into care[a] • Addressing health and health care misinformation[a]
Quality of Care	• Developing harmonized measures to meaningfully, accurately, and feasibly assess quality of care[a]
Access to Care	• Identifying both root causes and evidence-based solutions for barriers to access[a]
Cost and Utilization	• Challenge of lowering cost while improving care[a] • Reducing waste in health care[a] • Costs of new care therapies and delivery models[a] • Reducing costs across the health care system
Equity	• Solutions to reduce disparities in health care

[a] Similar gap included in key PCR gaps (Table S.3).

Table S.3 lists key research domain and cross-cutting gaps for PCR. The letter "a" in Tables S.2 and S.3 denotes gaps that were similar for both HSR and for PCR, though often exhibiting distinct aspects.

Table S.3. Key PCR Gaps Identified Study Participants

Research Domain	Gaps in PCR on . . .
Organization of Care	• Health care workforce needs, composition, and roles in new delivery models for primary care[a] • Reducing burdens of health IT on primary care providers[a]
Financing of Care	• Effects of evolving models of financing on primary care delivery and outcomes[a] • Effects of health care payment models on different patient populations[a]
Social Factors	• Role of health care systems in addressing social determinants of health[a] • Effect of social factors on demand for primary care services[a]
Personal Preferences and Behaviors	• Integration of patient preferences in primary care[a] • Addressing health and health care misinformation[a]
Quality of Care	• Developing primary care–specific measures that capture quality in ways meaningful to patients and providers[a]
Access to Care	• Identifying both root causes and evidence-based solutions for barriers to access[a]
Cost and Utilization	• Challenge of lowering cost while improving care[a] • Decreasing underutilization as well as overutilization in primary care[a] • Costs of new delivery models for primary care (e.g., PCMH) [a]
Equity	• Role of primary care in addressing equity
Cross-Cutting PCR Gaps	• The core functions of primary care • Primary care transformation and role in the wider health care system

[a] Similar gap included in key HSR gaps (Table S.2).

Study participants and Federal Advisory Group members emphasized the need to prioritize research gaps to effectively and efficiently allocate limited research funding. Criteria for prioritization mentioned included the potential impact of the research, the potential to address a gap in an underfunded research area, the potential to address foundational areas of research, and the timeliness of the research. Federal Advisory Group members also noted that, within federal agencies, an important criterion for prioritization is the alignment of an issue with the agency's mission, comparative advantage, and expertise in funding research on the topic.

Recommendations

The findings above document the distinct focus areas of federal agency HSR and PCR portfolios, which have been developed based on the agencies' congressional authorizations, missions, and operational needs. They have also examined how agencies coordinate research funding on similar topics in complementary ways according to their distinct focus areas and expertise, and how federally funded HSR and PCR have had a wide range of impacts that are often cumulative across research portfolios. At the same time, the study has identified the need

for federal agencies to more proactively recognize areas of potential overlap in research portfolios, to improve the communication, relevance, and timeliness of research results, and to prioritize the myriad gaps in research in order to keep pace with and guide the complex and rapidly changing U.S. health care system.

We propose three sets of recommendations to improve the impact of federally funded HSR and PCR based on our review of the key study results and suggestions of study participants:

- Cross-cutting recommendations on approaches to research, dissemination, and implementation of federally funded HSR and PCR (Table S.4)
- Recommendations to improve the impact of HSR (Table S.5)
- Recommendations to improve the impact of PCR (Table S.6).

In Chapter 7 we describe in more detail the steps that might be taken to implement the recommendations.

Our first set of recommendations in Table S.4 addresses three key gaps in research approaches for both HSR and PCR identified by study participants: (1) improve *relevance* and *timeliness* of research, (2) increase *innovation* in research, and (3) improve *translation of research* into practice. We suggest specific steps for each recommendation.

Table S.4. Cross-Cutting Recommendations on Approaches to Research, Dissemination, and Implementation

Recommendations	Suggested Action Steps
Improve the relevance and timeliness of HSR and PCR	• Create funding mechanisms that support more rapid, engaged research approaches, such as embedded research and learning health systems models, and dissemination of their results. • Expand funding to refine mixed qualitative and quantitative methods suited to generating evidence on the implementation of change in complex health care systems.
Encourage innovation in HSR and PCR	• Create funding mechanisms that support innovative high-risk, high-reward research.
Improve translation of HSR and PCR into practice	• Train and assist researchers in effectively communicating results in formats actionable for health care delivery stakeholders. • Fund research to identify the most effective channels to communicate research results for different users of HSR and PCR. • Require researchers to consider implementation issues earlier in the study development and proposal process and explicitly apply theories of change to help connect disparate results. • Expand funding for the synthesis of evidence across research studies on topics of interest to health care delivery and other users of HSR and PCR.

Our second set of recommendations in Table S.5 focuses on improving the impact of federally funded HSR and addresses three key themes identified by study participants related to: (1) prioritization of the many ongoing and emergent research gaps in HSR, (2) coordination of federally funded HSR by proactively identifying potential overlap in agency research portfolios, and (3) alignment of federally funded HSR through continued support of AHRQ as an independent agency within HHS to serve as the funded hub of federal HSR.

Table S.5. Recommendations to Improve Impact of HSR

Recommendations	Suggested Action Steps
Identify HSR priorities for agencies to effectively allocate research funding	• Initiate a strategic planning process across federal agencies to prioritize HSR areas for funding investments.
Proactively identify potential overlap in agency HSR portfolios	• Establish a review process and data systems to proactively identify areas of potential HSR overlap across agencies.
Maintain a funded entity to address core HSR needs and coordinate federal HSR efforts	• Maintain AHRQ as an independent agency within HHS to serve as the funded hub of federal HSR.

Our third set of recommendations in Table S.6 focuses on improving the impact of federally funded PCR. These recommendations also address key themes identified by study participants related to prioritization, coordination, and alignment of federal agency research portfolios, but attending to the distinct needs of the PCR field. First, a separate interagency prioritization process for PCR would ensure that core primary care research needs are attended to, incorporate the specific stakeholders needed to inform prioritization, and span clinical research as well as HSR. Second, a process to proactively identify potential overlap in federal agency PCR portfolios would focus on coordination of PCR to maximize the impact of the limited resources available for federally funded PCR and rely on staff from different agencies expert in federal PCR portfolios. Last, with respect to alignment of federal PCR efforts, we recommend providing funding for a hub of federal PCR that includes targeted funding for *both* research on core functions of primary *and* coordination of PCR across federal agency research portfolios.

Table S.6. Recommendations to Improve Impact of PCR

Recommendations	Suggested Action Steps
Identify PCR priorities for agencies to effectively allocate research funding	• Initiate a strategic planning process across federal agencies specifically dedicated to prioritizing PCR areas for funding investments.
Proactively identify potential overlap in agency PCR portfolios	• Establish a review process to proactively identify areas of potential PCR overlap across agencies.
Fund an entity to address core primary care research needs and coordinate federal PCR efforts	• Provide targeted funding for a hub for federal PCR.

Conclusion

This study has identified a number of important gaps in HSR and PCR, many of which are driven by the complexity and rapidly changing landscape of the U.S. health care system. As in the past, there is a great opportunity for federally funded HSR and PCR to have meaningful impact and guide understanding of new models of care delivery and payment, inform health care stakeholders on best practices for implementing specific health care innovations and interventions, and disseminate and promote health system change.

The study also has identified opportunities to improve approaches to research funding and methods to ensure that federally funded HSR and PCR can keep pace with and continue to guide change in health care delivery systems. Additionally, it has offered separate recommendations for HSR and PCR to improve the outcomes and value of federal research investments, including strategies for better prioritizing, coordinating, and aligning agency research portfolios. The results of the study provide a balanced, evidence-based understanding of federally funded HSR and PCR that policymakers can use in shaping the future of the federal HSR and PCR enterprise.

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The members of the HSR TEP included:

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- Pam Dardess, M.P.H. (Institute for Patient- and Family-Centered Care)
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Abbreviations

ACF	Administration for Children and Families
ACL	Administration for Community Living
ACO	Accountable Care Organization
AHRQ	Agency for Healthcare Research and Quality
AIDS	acquired immunodeficiency syndrome
ASPE	Office of the Assistant Secretary for Planning and Evaluation
ATSDR	Agency for Toxic Substances and Disease Registry
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CCSQ	Center for Clinical Standards and Quality
CDC	Centers for Disease Control and Prevention
CMMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare and Medicaid Services
CPC	Comprehensive Primary Care
EHR	electronic health record
FDA	Food and Drug Administration
FQHC	federally qualified health center
FY	fiscal year
GAO	Government Accountability Office
HAI	healthcare–associated infection
HHS	U.S. Department of Health and Human Services
HIT	health information technology
HIV	human immunodeficiency virus
HRSA	Health Resources and Services Administration
HSR	health services research
HSRProj	Health Services Research Projects in Progress
ICs	Institutes and Centers
IHS	Indian Health Service
IOM	Institute of Medicine
MTD	methods and tool development
NCATS	National Center for Advancing Translational Sciences
NCHWA	National Center for Health Workforce Analysis
NCI	National Cancer Institute
NHLBI	National Heart, Lung, and Blood Institute
NHSN	National Healthcare Safety Network
NIA	National Institute on Aging

NIAAA	National Institute on Alcohol Abuse and Alcoholism
NICHD	National Institute on Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIDILRR	National Institute on Disability, Independent Living, and Rehabilitation Research
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NIMHD	National Institute on Minority Health and Health Disparities
NINR	National Institute on Nursing Research
ONC	Office of the National Coordinator for Health Information Technology
PACT	patient-aligned care team
PCMH	patient-centered medical home
PCORI	Patient-Centered Outcomes Research Institute
PCR	primary care research
RCT	randomized controlled trial
RePORTER	Research Portfolio Online Reporting Tools
SAMHSA	Substance Abuse and Mental Health Services Administration
TEP	technical expert panel
VA	U.S. Department of Veterans Affairs
VHA	Veterans Health Administration

1. Introduction

Congressional Mandate

On March 23, 2018, when H.R. 1625, the Consolidated Appropriations Act of 2018, became law (Frelinghuysen, 2018), Congress directed and authorized the Agency for Healthcare Research and Quality (AHRQ) to contract with an independent entity for a study on health services research (HSR) and primary care research (PCR) supported by federal agencies. Per this congressional directive, AHRQ contracted with the RAND Corporation to conduct this assessment, titled the "Health Services and Primary Care Research Study," beginning on September 19, 2018.

Study Goal

The goal of the study was to provide an independent assessment of the breadth, scope, and impact of HSR and PCR supported by the U.S. Department of Health and Human Services' (HHS's) 11 operating divisions and the U.S. Department of Veterans Affairs (VA) since fiscal year (FY) 2012. In support of this goal, the study was to identify research gaps and propose recommendations to AHRQ for maximizing the outcomes, value, and impact of HSR and PCR investments during the next five to 20 years and beyond, including strategies for better coordination and potential consolidation of research agendas. This report presents the final comprehensive results and recommendations of the study.

This study offered an important opportunity to identify the strengths and contributions of the many HHS agencies and the VA to the federal HSR and PCR enterprise, and to gain insights on how to better align these research programs to serve the needs of the evolving U.S. health care system. The results of the project are intended to provide a balanced, evidence-based understanding of federally funded HSR and PCR that policymakers can use in shaping the future of the federal HSR and PCR enterprise.

The Importance of HSR and PCR

Since its emergence as an independent field of study in the 1960s, HSR has helped establish an evidence base to support decisionmaking and improvements in the quality, safety, effectiveness, and efficiency of health care in the United States (National Academies of Medicine, 2018). HSR has provided insights into such topics as health promotion and disease prevention, the effectiveness of new health care technologies and other innovations, the quality of health care services, and outcomes associated with clinical practice—including primary care. HSR findings have been used to improve the design of health care benefits, inform health care policy, and help providers and patients make better decisions about health care.

PCR has also emerged as an important field in its own right, addressing a central component of health care. While research on health services in the context of primary care overlaps PCR and HSR, PCR also more broadly includes clinical research on conditions typically addressed in the primary care setting and exhibits distinct features related to the unique role of primary care in the health care system. The Council of Academic Family Medicine and other organizations have delineated these key characteristics of PCR (Wittenberg, undated; Peek, Cohen, and deGruy, 2014). The results and application of PCR are likely to touch the lives of all Americans, as most people receive the majority of their health care in primary care practices. PCR comprehensively studies the whole person, acknowledging that patients often face multiple diseases and live in the context of their family and community. PCR studies common, important conditions that are often not treated in hospitals or specialty clinics; and provides evidence that is unique to, and critical for, the delivery of primary care**.** As a result, PCR is essential to support efficient and coordinated delivery needed for high-quality primary care.

The Need for an Assessment of HSR and PCR

Consistent with this broad acknowledgment of the many contributions of HSR and PCR to improve health care, there has been growing recognition among federal agencies and other stakeholders of the need to better understand the impact of HSR and PCR and to prioritize potential future directions of research. The ongoing need for HSR and PCR studies is clear: The U.S. health system is complex and faces many challenges—including high costs and disparities in access and quality of care—which require a foundation of evidence-based research to be effectively addressed. Further, advances in technology, new data resources and analytical tools, and new key areas in health research—such as the social determinants of health—have opened many opportunities to enhance the impact of HSR and PCR (NAM, 2018). At the same time, constraints on federal funding, as well as the many competing topics vying for support, mean that investments in research need to be viewed strategically to maximize their value and limit potential duplication among studies. In a recent examination of trends in funding for HSR, Simpson et al. noted that "the future size, scope, and focus of federal support for HSR remain uncertain given recent trends including continued pressures on federal discretionary spending" (2018). They suggested that the HSR community might benefit from stepping back to assess the "changing nature, purpose and impact" of HSR and to revisit existing priorities.

A 2018 conference, sponsored by the National Academy of Medicine, brought HSR leaders and other stakeholders together to explore the evolution and past accomplishments of the HSR field and identify potential directions for future research (NAM, 2018). Conference participants called for "a set of activities required to transform the field" (NAM, pp. 4–5), including an expanded vision of HSR, a taxonomy of issues and priorities for action, tools and insights to use in effecting change, the development of data infrastructure, and the creation of a "working network" of stakeholders—including patients—in research.

While these and other efforts have helped to scope the future of HSR, there has been less investment in planning for the future of PCR, despite the importance of primary care to improve Americans' health (Chien et al., undated). Given that some have called primary care "too important to fail" (Meyers and Clancy, 2009), the development of a research agenda that effectively supports the goals of primary care is of critical importance. The current study attempts to build on efforts to date examining future directions for HSR and PCR.

Study Research Questions and Approach

Based on the goal of the study described above, the RAND team worked with AHRQ to develop a set of five key research questions shown in Box 1.1.

Box 1.1. Study Research Questions

- What is the breadth and focus of federal agency research portfolios in HSR and PCR?
- What is the overlap among federal agency research portfolios and the coordination that occurs between federally funded HSR and PCR?
- What are the impacts of federally funded HSR and PCR and challenges to assessing and achieving impacts?
- What are the gaps in federally funded HSR and PCR and approaches to prioritizing gaps?
- What are options for improving the outcomes, value, and impact of future federally funded HSR and PCR?

To answer these research questions, the RAND team utilized three primary data collection methods, as specified in AHRQ's statement of work for the study:

- **Technical expert panels (TEPs) constituted of leaders in the fields of HSR and PCR:** The purpose of the TEP meetings was to convene individuals with expertise in research, policy, and the use of HSR and PCR to provide group-facilitated expert perspectives on the study's key research questions, as well as feedback on methods and preliminary results from other tasks.
- **Key informant interviews with leaders from multiple stakeholder groups in HSR and PCR:** The interviews provided in-depth input from a wide range of stakeholders to inform assessment topics and results from other study tasks. Interview participants consisted of experts from five stakeholder groups: researchers focusing on HSR and PCR, health care delivery system leaders, other users of HSR and PCR (e.g., consumers, payers/purchasers, insurers), state-level health care policy and decisionmakers, and federal HSR and PCR leaders.

- **Environmental scan and portfolio analysis of federally funded HSR and PCR extramural research projects from October 1, 2011, through September 30, 2018:** The scan provided an overall picture of the breadth of federally funded HSR and PCR during this period, including information regarding the research projects funded by different agencies across research domains and topical subcategories.

The RAND team qualitatively analyzed the TEP and interview transcripts to identify themes discussed by study participants on each of the research questions. Environmental scan data on federally funded research projects were analyzed with manual coding and machine learning methods to provide a quantitative assessment of the breadth and focus of federal agency research portfolios in HSR and PCR. Based on the results of the qualitative and quantitative analyses, and suggestions of the TEP and interview study participants, the RAND team developed strategic recommendations for AHRQ and others to consider in maximizing the outcomes and impact of future investments in federally funded HSR and PCR.

Organization of This Report

The remainder of this report is organized as follows:

- Chapter 2 describes the methods used in this study.
- Chapter 3 examines the breadth and focus areas of federally funded HSR and PCR.
- Chapter 4 centers on overlap and coordination among agencies that funded HSR and PCR.
- Chapter 5 discusses different types of impact, as well as challenges to assessing and achieving the impact of federally funded HSR and PCR.
- Chapter 6 describes key gaps in HSR and PCR and a framework for prioritizing gaps.
- Chapter 7 presents our conclusions and recommendations for improving the outcomes, value, and impact of federally funded HSR and PCR.

The report also contains four appendixes, which provide supplementary results and detailed information on the methods for the environmental scan and portfolio analysis (Appendixes A and B), descriptions of agency research portfolios in HSR and PCR (Appendix C), and additional research gaps identified by study participants (Appendix D).

2. Study Methods

In this chapter, we describe the research methods used in this study. We first present the definitions of HSR and PCR that were used to identify relevant federally supported research projects and to develop a research domain framework to categorize projects according to key health services and primary care topics. We next describe the Federal Advisory Group and technical review process that AHRQ and the RAND team developed to guide the study.

We then review the data collection and analytic methods used to answer the study's research questions. As noted in Chapter 1, these included three primary data collection methods:

- Two TEPs constituted of stakeholder leaders in the fields of HSR and PCR, respectively
- Interviews with key informants from five stakeholder groups in HSR and PCR
- An environmental scan and portfolio analysis of federally funded HSR and PCR extramural projects from October 1, 2011, through September 30, 2018.

After describing the data collection methods, we discuss the qualitative methods used to analyze the themes identified by TEP and interview participants and the quantitative methods used to analyze the data set of federally funded research projects collected through the environmental scan. We conclude the chapter with a discussion of the limitations of the study methods.

Definitions of HSR and PCR

The study team worked iteratively with AHRQ and the study's TEPs to develop and operationalize definitions of HSR and PCR based on concepts in the literature but tailored to the needs of the study.

The *definition of HSR* used in the study is based on Lohr and Steinwachs (2002):

> A multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and ultimately, our health and well-being.

For purposes of the study, the definition of health care broadly encompasses health, mental health, substance abuse, and long-term care services, as well as social and other services as they connect to health care. In addition, the HSR definition above emphasizes *inputs* or antecedents of health care (e.g., social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors) and *how they affect* and produce *outputs* or outcomes of health care (e.g., access to health care, the quality and cost of health care, and ultimately, our health and well-being). Thus, the HSR definition for this study excludes research on the inputs

or outputs of health care that does not also examine their relationship to the provision or delivery of health care—for example, a study that exclusively focuses on the availability of healthy food options in communities, trends in national health care expenditures, or epidemiology of the prevalence of diseases or health status without attention to how these factors affect or are affected by health care services. Lastly, given the above concentration on scientific investigation, the study's HSR definition excludes narrow program monitoring and accountability reporting that is not intended to contribute to broader scientific knowledge and understanding of health services.

The *definition of PCR* used in this study consists of research that addresses primary care as defined by the Institute of Medicine (IOM) (1996):

> The provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.

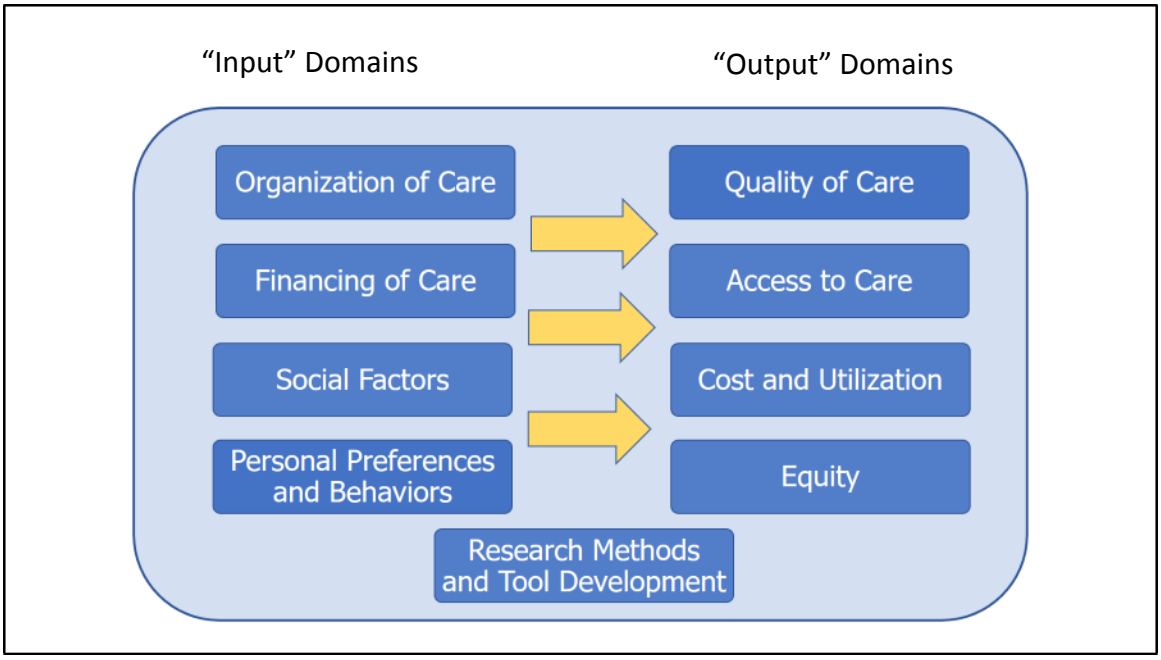
The study's definition also specifically encompasses the research areas defined in the legislation that establishes AHRQ as the statutory home for PCR in HHS. The statute calls for research concerning: (a) the nature and characteristics of primary care practice; (b) the management of commonly occurring clinical problems; (c) the management of undifferentiated clinical problems; and (d) the continuity and coordination of health services (42 U.S.C. 299 et seq). Expanding on the IOM definition of family and community, we additionally include the role of primary care providers and systems in addressing community health needs and social determinants of health (Park et al., 2018; American Academy of Family Physicians, 2019; Artiga and Hinton, 2018; Advisory Committee on Training in Primary Care Medicine and Dentistry, 2016).

We note that, under this definition, PCR includes research on the delivery of primary care that overlaps with HSR, as well as other research related to primary care, such as clinical studies of common conditions in primary care without a health services component (Starfield, 1996).

Research Domain Framework of HSR and PCR

The study team also worked iteratively with AHRQ and the study's TEPs to develop a conceptual framework of HSR and PCR domains in order to differentiate the types of research funded across federal agencies and to support the identification of gaps in research. The framework includes four domains of health care "outputs" typically of interest to health care policymakers and other stakeholders (Quality of Care, Access to Care, Health Care Costs and Utilization, and Equity of Care), four domains of health care "inputs" (Organization of Care, Financing of Care, Social Factors, and Personal Preferences and Behavior), and a domain of research methods and tool development (MTD) integral to the advancement of HSR and PCR and implementation of research evidence into practice (see Figure 2.1). Below we provide short descriptions of each domain.

Figure 2.1. Research Domain Framework for HSR and PCR



The domains for "inputs" of health care include the following:

- **Organization of Care.** Structures and routines of care and the process of how they change or improve, from the composition and functioning of care teams to the composition and dynamics of health care delivery systems and markets, including both social (e.g., workforce, clinician, and staff experience) and material assets (e.g., health technologies, physical facilities).
- **Financing of Care.** Programs and mechanisms for determining how health care organizations and professionals are paid to deliver care.
- **Social Factors.** Social, economic, and community determinants of health.
- **Personal Preferences and Behaviors.** Health-related behaviors (e.g., diet, exercise, and other lifestyle factors, care seeking, adherence to therapy), knowledge of health care and health conditions, and preferences for care and involvement in care decisionmaking.

The domains for "outputs" of health care include the following:

- **Quality of Care.** Assessments of care process as well as intermediate and definitive outcomes of care, including provision of recommended care, clinical control of chronic conditions such as hypertension or asthma, patient safety, patient experience, health-related quality of life and mortality.
- **Access to Care.** Geographic availability of providers, having a usual source of care, ability to receive care in person or remotely in a timely manner, or having adequate health insurance coverage.

- **Cost and Utilization.** Resource use in terms of costs and expenditures, utilization of treatments and services, and value (i.e., relative cost per unit of quality or outcome).
- **Equity.** Differences in quality, access, or cost and utilization of care across populations, and improvement of these outputs particularly for vulnerable or underserved populations.

The domains for MTD include *Health Information Technology (HIT) Applications and Tools* (e.g., design and testing of telehealth, mobile, EHR clinical decision support systems, and other functionality), *Model Development and Validation* (e.g., psychometric instruments, risk prediction models), *Toolkit Development* (i.e., documented strategies and materials to facilitate implementation of health care interventions or best practices), *Evidence Review and Synthesis* (i.e., systematic reviews of health care research findings), and *Simulation Modeling* (i.e., mathematical models incorporating simulated inputs to examine or predict health care processes or outcomes).

Research Subcategories of Interest

In addition to the research domains above that provided a framework for categorizing HSR and PCR projects, the study team, with feedback from AHRQ and the study's TEPs, identified research subcategories of interest that represented important specific health care outcomes or research areas expected to differentiate HSR and PCR supported by different federal agencies. Two categories—*Patient Safety* (e.g., medical errors, harms produced by health care) and *Definitive Health Outcomes* (e.g., mortality, health-related quality of life)—primarily reflected "deeper dive" subcomponents within the Quality of Care research domain, while three others reflected specific cross-cutting categories of research—*Aging*, *Pediatrics*, and *Prevention*.

Details on how these research domains and subcategories were further defined and operationalized for the environmental scan and portfolio analysis are provided below and in Appendix B.

Study Advisory and Technical Review Process

AHRQ and the RAND team developed a Federal Advisory Group and a technical scientific review process specifically to guide this study.

Federal Advisory Group

AHRQ formed a Federal Advisory Group for the study consisting of representatives from seven federal agencies and operating divisions with key interests and funding programs in HSR and PCR. These agencies and operating divisions included six from HHS—AHRQ, Office of the Assistant Secretary for Planning and Evaluation (ASPE), Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), National Institutes of Health (NIH), Office of the National Coordinator for Health Information Technology (ONC)—and one from the VA, the Veterans Health Administration (VHA).

The purpose of this advisory group was to provide feedback on the design and preliminary results of the study, as well as aid in identifying and collecting relevant data on HSR and PCR projects within agencies as discussed later in the methods for the environmental scan and portfolio analysis. The Federal Advisory Group met via teleconference on three occasions to receive updates on study progress and discuss the overall study design and plan for the environmental scan (December 2018), preliminary results of from the TEPs, interviews, and environmental scan and portfolio analysis (April 2019), and prioritization processes for HSR and PCR gaps (June 2019).

Technical Review Process

To ensure the scientific rigor of the study and mitigation of any potential bias in the research, the RAND team instituted an expanded, ongoing technical review process. This process included three technical reviewers, two reviewers from outside RAND with expertise in HSR and PCR, and one RAND reviewer not part of the study team with expertise in health care as well as research similar to this study in education and other fields. The reviewers provided ongoing feedback on study decision points and interim products during the project through group teleconference review sessions to enable rapid and efficient feedback. Teleconference sessions reviewed the overall study design, study participant sampling process, design of the environmental scan, and draft interview guides (November 2018), the proposed list of TEP members and first TEP meeting agenda and discussion guides (January 2019), the second and third TEP meeting agendas and discussion guides (March and April 2019, respectively), and preliminary TEP and interview results (June 2019). The RAND team followed up each session with written responses to reviewer comments and revisions made to protocols and materials.

In addition, the technical reviewers provided written reviews for two study document deliverables, a draft Environmental Scan and Portfolio Analysis Report (January 2019) and a draft of this Comprehensive Report (September 2019). The RAND study team followed up with written responses to reviewer comments and document revisions to all technical reviewers, whose formal approval was required before the documents could be finalized.

Data Collection and Analytic Methods

Study Participant Sampling for the Technical Expert Panels and Interviews

The RAND team compiled a combined sampling pool of potential study participants to use for both the TEPs and stakeholder interviews. Individuals included in this sampling pool were identified through four primary sources: nominations from stakeholder organizations representing different interests in conducting and using HSR and PCR, members of previous TEPs on HSR and PCR conducted by various organizations, members of existing advisory

panels on HSR and PCR, and nominations from select RAND professional staff of individuals from organizations outside RAND with areas of expertise relevant to the research questions.

Potential interview participants were identified from this sampling pool for four of the five interview stakeholder groups: (1) HSR and PCR researchers, (2) health care delivery system leaders, (3) other users of HSR and PCR, and (4) state-level health care policymakers. The study team also conducted additional outreach to associations of state-level stakeholders to augment the pool of potential interview candidates for this stakeholder group. In each of these four groups, our aim was to select individuals representing diverse backgrounds; for example, in the health care delivery system leaders group, we selected individuals from different types of systems of various size, ownership, and geographic location as noted below.

The study team developed a separate sampling procedure for the fifth interview stakeholder group—federal HSR and PCR leaders. Agency representatives in the study's Federal Advisory Group, described above, as well as points of contact at other agencies, were asked to nominate potential interview candidates knowledgeable about the portfolios of HSR and PCR funding within their agencies.

The total sampling frame for the study's TEPs and interviews consisted of 253 individuals. These included nominations from 23 stakeholder organizations. As described below, TEP members were recruited first, then participants for the stakeholder interviews.

Technical Expert Panels

The purpose of the TEP meetings was to convene individuals with expertise in research, policy, and the use of HSR and PCR to provide group-facilitated perspectives on the study's key research questions, as well as feedback on methods and preliminary results from other tasks.

Technical Expert Panel Structure and Selection

The study team identified specific stakeholder roles to include in the TEPs to ensure inclusion of the range of relevant HSR and PCR stakeholder perspectives. In conjunction with AHRQ, the study team refined the three primary roles for the TEPs to include perspectives from (1) researchers, (2) health care delivery system leaders, and (3) other users of research. Within each of these primary roles, the team further specified secondary roles to be represented on each TEP, as shown in Table 2.1.

Individuals on the list of potential TEP members that had been generated using the sampling method described above were then grouped according to the primary and secondary stakeholder perspectives required for each TEP.

Table 2.1. Primary and Secondary Roles for Technical Expert Panel Members

Primary Role	Secondary Roles: HSR TEP	Secondary Roles: PCR TEP
Researchers	HSR expert (clinical background), HSR expert (nonclinical background), disparities, patient safety	Family practice, internal medicine, pediatrics, geriatrics, disparities
Health care delivery system leaders	Large integrated health system, safety net health system, small community-based rural hospital or health system, and/or academic medical center	Community health center organization, large primary care medical group, small or rural primary care practice
Other users of research	Insurer executive, consumer representative	Insurer executive, consumer representative

To further ensure a range of perspectives, the RAND team developed a set of criteria for balancing the overall composition of each TEP and selecting among the potentially large number of candidates for each TEP role. The balance criteria included

- *range of expertise* (specialties within HSR or PCR, medical and allied health professionals, patient safety, disparities, pediatrics, and other areas)
- *breadth of funding* (whether the potential member is solely funded by one agency and/or has a differently funded portfolio)
- *avoidance of potential conflicts of interest* (e.g., current RAND employment, prior key role at AHRQ)
- *geography* (regional areas as well as rural/urban settings)
- *representation of underrepresented groups* (particularly gender and race/ethnicity)
- *newer perspectives* (individuals who might not have participated in similar TEPs/interviews on multiple prior occasions, or who have unique perspectives).

Individuals were selected and invited with the goal of obtaining a diversity of perspectives using these criteria. First-choice candidates who declined were replaced by other candidates to maintain balance across criteria on each TEP. Of the 39 individuals invited to participate in the HSR TEP, 9 (23 percent) accepted. Of the 21 individuals invited to participate in the PCR TEP, 11 (52 percent) accepted. Scheduling conflicts were the most common reason for declining participation, particularly given the short time between the commencement of invitations in mid-December 2018 and the scheduled dates for the first TEP meetings in January 2019.

To increase the breadth of perspectives included in the study overall, participants could be included in either a TEP (HSR or PCR) or an interview, but not both. TEP selection was completed first, and all individuals who declined to participate in a TEP were asked whether they would be willing to be considered for the stakeholder interviews.

Technical Expert Panel Meetings

Each TEP met three times during the study. TEP meetings were facilitated by senior study team members based on a structured discussion guide. In addition to providing feedback on

study methods and preliminary results from other tasks, the TEPs discussed the study's key research questions over the course of the three meetings. The first meeting of each TEP discussed the breadth and focus of federal agency research portfolios in HSR and PCR, overlap and coordination of agency HSR and PCR portfolios, and the impact of federally funded HSR and PCR. The second meeting of each TEP discussed research gaps in HSR and PCR and prioritization of gaps. The third meeting of each TEP continued the topics of research gaps and prioritization, as well as discussed recommendations to improve the federal HSR and PCR enterprise. Copies of the TEP discussion guides are available upon request from the study team.

The first TEP meetings were held in person separately for HSR and PCR, respectively, on January 22 and 23, 2019, each lasting approximately eight hours. The second and third meetings for each TEP were held via teleconference calls lasting two hours on April 1 and 2, 2019, and then May 6 and 7, 2019, respectively. After each set of meetings, the RAND team analyzed summary notes and transcripts to extract key themes that were synthesized as part of forming the initial codebook for the qualitative thematic analysis of TEP and interview data as described below.

Stakeholder Interviews

The purpose of the stakeholder interviews was to provide balanced, in-depth input across a wider range of stakeholder perspectives on the key study questions. These perspectives included the five stakeholder groups specified in the study's statement of work: (1) HSR and PCR researchers, (2) health care delivery system leaders, (3) other users of HSR and PCR (e.g., consumers, purchasers, insurers, and improvement organizations), (4) state-level health care policymakers, and (5) federal HSR and PCR leaders.

Interview Selection and Recruitment

Individuals from the sampling pool described above who did not participate in a TEP were purposefully selected for the interviews. The study team identified a set of eight to ten first-choice candidates and similar alternates for each stakeholder group in order to include a breadth of perspectives within and across the five interview stakeholder groups using similar balance criteria as for the TEPs.

Recruitment for interviews was conducted via email invitation followed up by email and telephone calls. First-choice interview candidates who declined were replaced by one of the alternates for their stakeholder group. Choice of alternates depended on the characteristics of the person being replaced and the range of expertise and backgrounds of interview candidates who had already agreed to participate. Recruitment for each stakeholder group continued until at least eight participants had been recruited within each group.

A total of 50 individuals participated in the interviews. Thirty-three individuals who were invited declined to participate,[1] yielding an overall acceptance rate of 60 percent. Table 2.2 presents the number of interviews conducted in each stakeholder group, with additional detail on stakeholder expertise included within each group. Table 2.3 displays the relative geographic diversity of the interview sample across stakeholder groups.

Table 2.2. Interviews Conducted by Stakeholder Group

Stakeholder Group	Total Interviews	Stakeholder Group Details
Researchers	10	PCR (2), HSR (2), health economics, nursing, geriatrics, patient safety, disparities, behavioral health
State-level policymakers	9	State and local health departments (3), state-level private insurers and purchasers (2), state hospital association, state primary care association, state improvement org, state policy expert
Delivery system leaders	8	Private integrated health systems (3), academic medical system, urban safety net hospital system, physician group association, regional safety net health center system, behavioral health system
Other research users	10	Consumer groups (3), purchasers (2), health services policy experts (3), improvement and accreditation orgs (2)
Federal research leaders	13	AHRQ (2), ASPE, CDC, CMS (2), HRSA, NIH (3), ONC, SAMHSA, VHA
Total	50	

Table 2.3. Interviews Conducted by Geographic Region

Geographic Region	Research	State-Level Policy Makers	Delivery System Leaders	Other Research Users	Federal Research Leaders	Total Interviews
Northeast	4	2	2	2	0	10
Midwest	2	2	2	1	0	7
West	2	4	3	1	0	10
South	2	1	1	6	13	23
Total	10	9	8	10	13	50

[1] Individuals who declined interviews included eight researchers, seven state-level policymakers, nine delivery leaders, seven other research users, and four federal research leaders.

Interview Guide Development and Data Collection

The study team developed three sets of interview guides—one for the HSR and PCR researcher stakeholder group; one for the federal HSR and PCR leaders' stakeholder group; and one applicable to the health care delivery system leaders, state-level health care policymakers, and other users of HSR and PCR stakeholder groups. Each interview guide covered all five key research questions for the study. Question wording and probes were tailored to the context and expertise of the stakeholders included in each guide. Copies of the interview guides are available upon request from the study team.

Study team members met weekly to debrief on stakeholder recruitment and interview data collection. Interviewers reflected on respondent comprehension of interview questions and information being yielded, and the team modified phrasing and items to emphasize in the discussion guides when needed.

Interviews were semistructured and lasted approximately an hour. Each interview was conducted via telephone by a study investigator experienced in qualitative data collection, and all interviews were audio-recorded (with permission) and transcribed for analysis, except one for which detailed manual notes were used in the analysis.

Thematic Analysis of Technical Expert Panel and Interview Data

Four study team members skilled in qualitative analysis developed the thematic coding scheme, coded the TEP and interview transcripts, and summarized the themes. The study team developed an initial codebook based on the main topics in the interview guides corresponding to the study research questions (see Table 1.1), emergent themes identified from team reflections on the initial interviews and interview transcripts from each stakeholder group, and review of themes from the first TEP meeting notes.

The four team members then test-coded for all initial themes in two interview transcripts selected for their extensive responses across interview questions. The team members discussed and resolved discrepancies in coding by consensus, with changes to coding definitions and procedures updated in the codebook. Three team members then coded the remaining TEP and interview transcripts using the Dedoose qualitative analysis software platform (SocioCultural Research Consultants, 2018). The four team members met weekly to review coding questions, refine coding definitions, and explore potential new codes that emerged during analysis.

The summarization of themes was organized around the study research questions, with individual team members assigned as the lead for summarizing the codes for a research question across interviews using a common template. Each lead reviewed the quotations coded for their research question and compiled a bulleted summary of key themes, exemplar quotes for each theme, and the number and types of stakeholders who identified that particular theme. A second team member reviewed the bulleted summary for organization and completeness, followed by other members of the qualitative analysis team, who also reviewed quotes not included in the

initial bulleted summary for potential relevance. The summaries were then used as the basis of the results text for corresponding sections of the report.

In the results text, we report key themes, that is, themes that were raised by multiple study participants within a stakeholder perspective or across stakeholder perspectives (i.e., one of the stakeholder interview groups, the HSR TEP, or PCR TEP). Quotes provided in the text are examples from those participants. On occasion, we report a theme reported by a single participant when relevant, which is indicated in the text.

Environmental Scan and Portfolio Analysis

The purpose of the environmental scan and portfolio analysis (or "scan") was to catalog a data set of federally sponsored HSR and PCR projects, collect and derive indicators needed to differentiate types of HSR and PCR projects, and produce quantitative analyses of the breadth and focus of HSR and PCR portfolios across federal agencies.

Scope of the Scan

The scope of federal HSR and PCR projects covered in the scan was delimited on three parameters: the federal agencies included, the time frame of when federal HSR and PCR projects were funded, and funding mechanisms.

Federal Agencies Included

AHRQ's statement of work for the study specified the agencies in the scan to include the 11 operating divisions within HHS, plus the VA. The operating divisions of HHS are as follows:

- Administration for Community Living (ACL)
- Administration for Children and Families (ACF)
- AHRQ
- Agency for Toxic Substances and Disease Registry (ATSDR)
- CDC
- CMS
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- NIH
- Substance Abuse and Mental Health Services Administration (SAMHSA).

In addition, two specific offices within the Immediate Office of the Secretary were identified for inclusion—ASPE and ONC. Within the VA, the scope covered HSR and PCR funded by the VHA. HSR and PCR projects funded by the Department of Defense or the Patient-Centered Outcomes Research Institute (PCORI, a nongovernment institute established by the 2010 Patient Protection and Affordable Care Act) are not included in the scan.

Time Frame of Funding

AHRQ's statement of work for the study specified that the scan include federally funded HSR and PCR projects with funding start dates between FY 2012 and FY 2018, which correspond to the calendar dates October 1, 2011, through September 30, 2018. Projects with funding start dates prior to October 1, 2011, are not included in the scan, even if their periods of performance continue into the study period.

Funding Mechanisms

The scan included HSR and PCR projects funded through both research grant and contract mechanisms. Grant projects typically allow researchers broad discretion to propose a specific study design to address a general topic, which is then assessed by other researchers in a scientific peer review process. Contract projects typically entail a more specified predefined statement of work, set of deliverables, and monitoring of the research by federal agencies, with agency staff assessing and awarding contract proposals often on shorter timelines than the grant peer review process.

The scan also included only *extramural research*, that is, funding of research conducted by nonfederal institutions, since the structure and data for intramural research conducted by agency staff were determined to be too variable across agencies to feasibly characterize in a systematic manner within the time and resources available for the scan. However, the report characterizes *intramural research* using qualitative data from the study's two other primary data collection tasks—TEPs and stakeholder interviews. The study focused on intramural research that is internally vetted with the intention of being released or published more broadly for external stakeholders and does not include other analyses conducted by agencies solely for use by policy and decisionmakers within the federal government.

Per the study's aims to characterize funding for studies that examine a research question intended to contribute to scientific knowledge on an HSR or PCR topic, the scan did not include extramural funding for research infrastructure related to research education and training (e.g., career awards), conferences and workshops, or research center grants that only included funding for research support but not specific studies. Although such funding is important to supporting the HSR and PCR enterprise, they were not considered research projects *per se* for purposes of this study. However, successful applications for research funding that were supported by these research infrastructure activities would be included in the scan as separately funded projects.

Likewise, per the research definitions presented previously in the chapter, the scan excludes service grants or other projects in which evaluation components focus exclusively on program monitoring or accountability and are not intended to contribute to broader scientific study and understanding of health services or primary care.

Adjudication of Projects for Inclusion in the Scan

In addition to falling within the above scoping criteria, a project had to be adjudicated as addressing HSR, PCR, and/or MTD to be considered as in-scope for the scan.

HSR Adjudication

To ensure that projects included as HSR in the scan focused on the delivery and provision of health care services per the study's definition, the scan required that projects adjudicated as HSR fulfill at least one of two conditions: (a) address at least one of three "output" domains (Quality of Care, Cost and Utilization, or Equity) *and* at least one of the "input" domains, or (b) address the Organization of Care "input" domain. The Access to Care output domain was not included in condition (a) since this domain was developed later than the other domains and implementation of the HSR adjudication criteria, and was generally coded to projects together with at least one other output domain, such as Quality of Care or Equity, that would ensure the projects' inclusion in the scan as HSR.

PCR Adjudication

Projects were identified as meeting the study's definition of PCR through a separate assessment based on whether it addressed primary care professionals, services, or settings, regardless of whether it also met any of the adjudication criteria above for HSR. This process ensured that the scan would include PCR projects that do not overlap with HSR, as well as PCR projects that do.

Methods and Tool Development Adjudication

Similarly, MTD projects were identified through a separate assessment of whether a project met the definitions for at least one of the five MTD categories (i.e., HIT applications and tools, model development and validation, toolkit development, evidence review and synthesis, and simulation modeling). Many projects were adjudicated as MTD were also adjudicated as HSR and/or PCR.

As described above, an individual project could be determined to meet all or none of these three in-scope adjudication classifications and are thus not mutually exclusive. For detailed definitions, coding specifications, and adjudication procedures for research domains and in-scope criteria, see Appendix B.

Data Sources

The environmental scan drew on two primary data sources: publicly available databases of federally funded grant projects, and contract and grant data provided to RAND directly by federal agencies.

Public Databases of Federally Funded Research Projects

The largest source of data for the environmental scan—and the primary source of grant project data—consisted of the publicly available NIH Research Portfolio Online Reporting Tools (RePORTER) database. Although developed and managed by NIH, the RePORTER database includes grant projects funded by agencies across HHS as well as the VA (National Institutes of Health, 2017a).

The study team also reviewed the Health Services Research Projects in Progress (HSRProj) database developed by AcademyHealth and the University of North Carolina at Chapel Hill (AcademyHealth, undated; U.S. National Library of Medicine, 2019a), as well as agency-specific project databases, including the AHRQ Project Research Online Database, the AHRQ HIT portfolio website, and the HRSA grant database (Agency for Healthcare Research and Quality, undated-c; Agency for Healthcare Research and Quality, undated-d; Health Resources and Services Administration, undated-a). These databases were not found to contain any in-scope projects that were not already present in RePORTER, though the AHRQ Project Research Online Database and HSRProj were found to contain supplemental information (notably project abstracts and topic lists) that was merged into the consolidated scan data set. The study team also reviewed other federal grant data sources, including HHS's Tracking Accountability in Government Grants System, Grants.gov, and the Office of Planning, Research and Evaluation Resource Library, though these were not found to provide any additional project-level data for the scan.

Agency-Provided Data on Research Projects

As mentioned previously in the chapter, the study's Federal Advisory Group aided in the identification and collection of relevant data on HSR and PCR projects within agencies. In particular, the representatives from the agencies in the advisory group (AHRQ, ASPE, CDC, CMS, NIH, ONC, and VHA) helped describe and identify relevant HSR and PCR portfolios and data sources for inclusion in the scan, identify other points of contact within their agencies knowledgeable about specific HSR and PCR funding areas, and obtain needed data on relevant HSR and PCR agency projects not available from public sources, especially contract projects. The representatives also provided feedback via "member checking" of preliminary scan results for the HSR and PCR projects in their respective agencies. This feedback was used to refine the scan methods and analysis but did not constitute endorsement of scan results by agency representatives.

AHRQ additionally identified and initiated contact with representatives of other federal agencies within the scope of the scan for similar assistance. Representatives from five of these agencies responded, including ACL, ATSDR, FDA, HRSA, and SAMHSA.

Data Sources by Agency

Data on extramural research grants, including those from NIH, AHRQ, CDC, VHA, ACF, and FDA, were derived from the NIH RePORTER database. Data on extramural research contracts and grants were provided directly by several funding agencies: AHRQ provided data

on its relevant extramural research contracts; CDC on relevant extramural research grants and cooperative agreements; CMS on relevant extramural research contracts from two divisions—the Center for Medicare and Medicaid Innovation (CMMI) and Center for Clinical Standards and Quality (CCSQ); VHA on relevant research grants from its Health Services Research and Development and Quality Enhancement Research Initiative programs; and ACL on relevant research grants from its National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR).

Representatives for ASPE and HRSA provided descriptions of the HSR and PCR funded by their agencies but were not able to provide systematic data on extramural research projects for the scan analysis in time for this study. Representatives for ACF did not respond in time to be included in the study. Representatives for FDA, HRSA, IHS, ONC, SAMHSA, and ASTDR confirmed that these agencies do not regularly fund extramural HSR or PCR projects per the definitions of this study.

Challenges Collecting Federal Contract Project Data

Collecting project-level data on contracted extramural research proved highly challenging, since data systems for federal contracts are neither designed nor suited to identify research projects, let alone HSR- and PCR-related projects. These contract databases also tend to provide less information about the content of research projects needed to distinguish domains and categories of research, compared with the RePORTER and other grants databases that are designed to catalog and describe federally funded grant projects.

This required the study team to rely on agencies to identify and provide contracted projects. However, given the structure of the available federal contract databases, this task proved challenging to agency staff as well, and was one reason some agencies could not provide project-level data for the study's environmental scan and portfolio analysis. Other agencies that were able to provide comprehensive project-level data for contracted research either had developed separate internal research databases for tracking contract projects or expended considerable effort to compile data on HSR and PCR contracts for the study. This process also required frequent iteration between the study team and agency staff to obtain additional details for project descriptions in order to adequately adjudicate research domains and categories.

Scan Data Set Elements

The study team identified a set of core data elements to collect on each research project in the scan in order to characterize the portfolios of HSR and PCR funding, as listed below. Project descriptive information, such as the project title, descriptive narrative or abstract, and any keywords or topical categories, was important to differentiate projects by content area and type of research. This information included the main research domains and specific categories of research described previously, as well as health care or community settings and clinical conditions (if applicable). Other project information needed for the scan database included administrative

information on funding mechanisms, funders, and funded institutions, as well as the period of performance and level of effort.

Project Descriptive Information

- Project reference number (*if applicable*)
- Project title
- Project descriptions, narrative, and/or abstract
- Keywords and/or topical categories (*if available*).

Project Administrative Information

- Funding mechanism (grant or contract type)[2]
- Grant or contract number
- Lead project funder (agency, program, point of contact)
- Other project funders
- Lead and other funded institution.

Project Period of Performance and Level of Effort

- Project start date
- Project end date
- Funding amount.

Scan Analytic Approach

The scan analysis relied on a combination of manual and automated reviews of project descriptions to categorize each project according to the research domain framework presented earlier in this chapter. Manual reviews were conducted on agency-provided projects as well as a sample of the projects from the RePORTER research grants database. These manual reviews were used to train a natural language processing and machine learning algorithm to automate classification of the remaining RePORTER project records that were not manually reviewed. Details of these steps are provided below.

Manual Reviews of Projects

The study team manually reviewed over 3,000 projects to determine whether they met the criteria for the various categories within the research domain framework (i.e., the overall HSR, PCR, and MTD classifications, the eight HSR and PCR domains, the five research MTD categories, and/or the five research subcategories of interest). The team discussed approximately 20 percent of these reviews. These discussions were crucial to iteratively refining the research domains and categories of the framework and ensuring interrater agreement.

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[2] For a list of grant activity codes in the NIH RePORTER database related to research infrastructure that were excluded from the scan, see Appendix B.

Four researchers on the study team participated in the manual reviews. These reviews included all agency-provided project records as well as both targeted and randomly sampled projects from NIH RePORTER. Projects were selected for targeted reviews on the basis of an initial determination that they were likely to be in-scope for our scan according to one or more of the following criteria: (a) being present in the HSRProj database, which is manually curated to include HSR projects; (b) being tagged in the HSRProj database with Medical Subject Heading terms (U.S. National Library of Medicine, undated; U.S. National Library of Medicine, 2019b) related to specific categories in the research domain framework; (c) being tagged with the term "health services" in the RePORTER database's Research, Condition, and Disease Categorization list (National Institutes of Health, 2018); or (d) being identified as likely in-scope in preliminary results from the machine learning algorithm described below. Projects were also randomly sampled from the RePORTER database in order to provide a representative set of out-of-scope projects to include when training the machine learning algorithm.

A subset of these projects was independently reviewed by two team members in order to compare results and identify potential sources of inconsistency in the framework definitions and classification rules or their application. These independent reviews of the same projects were also used to calculate interrater agreement for each of the research categories within the framework. Independent reviewers agreed 93 percent of the time on whether a project was overall within the scope of the scan framework (i.e., meeting the criteria for HSR, PCR, and/or MTD classification), with an interrater reliability kappa of 0.86 (ranging from –1.00, lowest reliability, to 1.00, highest reliability). Reviewers agreed on specific research domains and categories ranged between 79 percent and 100 percent of the time, with kappas from 0.43 to 1.00.[3] In cases in which two reviewers disagreed, a third reviewer was enlisted to provide an additional opinion; this, together with group discussion, was used to produce a final coding determination.

Machine Learning Adjudication of Research Domains and Categories

Automated classification algorithms are frequently used to analyze large amounts of text data that would be infeasible to completely review manually, such as the descriptions of projects in this study's scan data set (Sebastiani, 2002). Previous efforts to analyze federally funded research portfolios have relied on various forms of automated algorithms, including search-term-based logical rulesets, unsupervised clustering, and supervised machine learning (Wilczynski et al., 2004; Freyman, Byrnes, and Alexander, 2016; Villani et al., 2018). Similarly, within the RePORTER database, NIH applies an automated "text-mining" algorithm to project descriptions to determine the Research, Condition, and Disease Categorization for project records.

[3] For details on interrater agreement and reliability of manual reviews, see Appendix A.

As described below, we drew on these and similar efforts to automate our analysis of the roughly 90,000 project descriptions we did not manually review. To do this, we relied on natural language processing to map project descriptions onto indices of relevant words and phrases, and then input those indices into a machine learning model to classify projects according to our research domain framework (Sebastiani, 2002). As in other supervised learning approaches, we treated the manual reviews as "gold-standard" classifications to both train the machine learning model and validate its accuracy (Wilczynski et al., 2004; Villani et al., 2018).

The machine learning algorithm used the narrative text found in the project abstract or description field to generate classification scores for each project and category based on a logistic regression model. We applied a straightforward natural language processing approach to these project descriptions, namely a "bag of words" method, which treats frequently occurring words and two-word phrases as unrelated objects. The algorithm was run five separate times following a stratified K-fold cross-validation approach, with one-fifth of the manually reviewed data reserved each time in order to test algorithm accuracy and identify false positives and false negatives, leaving the algorithm to be trained on the other four-fifths of the manually reviewed data (Kohavi, 1995). While the algorithm is imperfect and thus classifies some projects incorrectly, it was calibrated to produce a similar number of false positives and false negatives in order to maximize the validity of the overall classification results reported in Chapter 3.

The results of our scan are presented in Chapter 3 and Appendix B. Manual classifications, as the "gold standard" upon which the algorithm classifications were based, were given precedence in calculating these results. Manual classifications were tallied first, and then combined with the algorithm classification results for projects that were not manually reviewed. Additional details on the number of reviews we conducted and on the machine learning methods are provided in Appendix A, together with measures of interrater agreement and algorithm accuracy.

The scan results we report in Chapter 3 are based on the number of projects, rather than funding amounts, due to data quality issues. Nearly 4 percent of the projects that were classified as in-scope for the study scan were missing funding information, with substantial variability across agencies and research domains. Federal stakeholders familiar with the funding amount data in the RePORTER database also noted challenges in validly calculating total project funding amounts, given complexities in aggregating across multiple project records of different types per project in the database. Since the purpose of the scan analysis was to examine the breadth of federally funded HSR and PCR and the types of projects funded by agencies across research domains and categories, the number of projects was considered an appropriate and more comprehensive metric.

Limitations of Study Methods

The sample of TEP and interview participants for the study was designed to provide a diverse range and depth of qualitative perspectives within and across stakeholder groups for federally funded HSR and PCR. We selected from five stakeholder groups for the interviews and from three stakeholder groups for the TEPs, while aiming for diversity within those groups as described above. However, it was not possible to guarantee that all possible perspectives were included. The sample of TEP and interview participants was neither designed nor intended to provide a representative distribution of perspectives among these sets of stakeholders.

For the environmental scan and portfolio analysis, we were not able to obtain comprehensive project-level data on extramurally funded research for all agencies in the study scope. This was due to various challenges related to limitations of existing federal data systems for tracking research contracts, and time and resource constraints for collecting project-level data of both agency staff and the study team. However, the study was able to collect comprehensive project-level data for six agencies, including those considered by stakeholders to be key extramural funders of federal HSR and PCR. In addition, the results of the environmental scan and portfolio analysis are sensitive to the definitions and consistency of the manual coding applied, as well as to the machine learning algorithms and specifications used. Consequently, we provide detailed information on the study's machine learning methods, manual interrater reliability, and machine-adjudicated accuracy estimates in Appendix A, and on the study's research domain definitions and specific coding rules in Appendix B.

The mixed methods approach of the study allowed using the strengths of the qualitative and quantitative methods to complement the limitations of the other. For example, the environmental scan and portfolio analysis was well suited to document the breadth and general distribution of HSR and PCR portfolios among agencies, but the qualitative data from the TEPs and interviews were better suited to understand the coordination among agencies and the impact of federally funded research. Both methods were integral in developing and refining the research domain framework.

3. Breadth and Focus Areas of Federal Agency Research Portfolios in HSR and PCR

This chapter addresses the study's first key question: What is the breadth and focus of federally funded HSR and PCR? There are two main components to this chapter. First, we present findings on the HSR and PCR portfolios and focus research areas of the federal agencies in the study's scope, based on expert information from the TEPs and stakeholder interviews, as well as documentary sources. Second, we report results from the environmental scan and portfolio analysis, which enumerates the extramurally funded HSR and PCR projects of agencies by topic according to the study's research domain framework (see Figure 2.1 in the previous chapter).

Agency HSR/PCR Portfolios and Research Focus Areas

The breadth and scope of federally funded HSR and PCR are a function of the types of research sponsored by different federal agencies, which in turn are shaped by the congressional statutory authorizations and mission of each respective agency. Research is part of the core mission of three of the agencies we studied: AHRQ, ASPE, and NIH. Other agencies within the study's scope generate HSR and PCR through research activities in support of their primary mission (e.g., CMS evaluates demonstrations to improve quality and cost of care for Medicare and Medicaid beneficiaries, and the VHA conducts research to improve delivery of care for military veterans). Over time, HHS agencies and the VHA have developed portfolios of HSR and PCR around particular focus areas that address the requirements of their individual missions and operational needs.

Distinct Characteristics of Agency HSR and PCR Portfolios

TEP and interview participants and federal agency points of contact identified eight agencies in the scope of the study with portfolios of research in HSR and PCR according to the definitions provided in Chapter 2: ACL, AHRQ, ASPE, CDC, CMS, HRSA, NIH, and VHA. Table 3.1 summarizes the missions, key characteristics differentiating research portfolios—namely, scope of the health care system examined, research objectives, main research audiences—and particular focus topics in HSR and PCR of each agency.

Table 3.1. Agency Missions, HSR and PCR Portfolio Characteristics, and Research Focus Topics

Agency Mission	Scope of Health Care System Examined	Research Objectives	Main Research Audiences	HSR Focus Topics	PCR Focus Topics
ACL • To fund services and supports provided by networks of community-based organizations • To fund investments in research, education, and innovation	**Services:** Health care and supportive services **Population:** The elderly and disabled individuals	• Improving care to support community-living elderly and disabled individuals	• Policy- and decisionmakers for community supports for elderly and disabled • Community-based organization and service leaders	• Community-based care and support models for individuals disabled by spinal cord, burn, and traumatic brain injuries • Rehabilitation health services and financing • Effects of health policies on community living of elders and disabled	• Coordination of health care and other services for community-living elderly and disabled individuals • Health technology and telehealth for community-living elderly and disabled individuals
AHRQ • To produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable • To work within HHS and with other partners to make sure that the evidence is understood and used	**Services:** All services across the health care system **Population:** All individuals in the U.S. health care system	• Improving health care systems and outcomes • Informing health care policy- and decisionmakers at different levels of the health care system	• Health care delivery leaders • Health care providers and professionals • HSR and PCR researchers	• Quality of care, with emphasis on patient safety • Health care access and disparities • Organization of delivery systems and markets • Health care financing and costs • HIT adoption and effective use • Implementation tools, methods, and evaluation • Evidence synthesis and dissemination • Data resources for the HSR community	• Defining nature and models of primary care • Primary care team-based staffing models and retention • Primary care improvement and transformation • Promoting uptake of evidence in primary care practice • Care of people with multiple chronic conditions • Integration of behavioral health and primary care

Agency Mission	Scope of Health Care System Examined	Research Objectives	Main Research Audiences	HSR Focus Topics	PCR Focus Topics
ASPE • To inform policy development in health, disability, human services, data, and science, and provide advice and analysis on economic policy. • To conduct research and evaluation, policy analyses, and estimates of the cost and benefits of policy alternatives being considered by HHS and Congress	**Services:** Related to specific federal health programs **Population:** Individuals served or affected by specific federal health programs and initiatives	• Informing policy- and decisionmaking on federal health care priorities	• HHS and Congressional leaders • Individual HHS agency leaders	• Access to care • Health insurance coverage • Health care costs and spending, including value-based care programs • Behavioral health care • Health care for special populations served by federal programs	• Access to primary care • Primary care improvement and transformation in the IHS system • Payment policy changes for primary care services in Medicare and Medicaid
CDC • To protect the health of Americans by fighting disease and supporting communities and citizens in health promotion • To conduct critical scientific research and provide health information to understand and address threats to public health	**Services:** Prevention and health promotion, in community and health care settings **Population:** General public, including both ill and healthy individuals	• Protecting health from threats posed by specific diseases, conditions, and injuries	• Public health officials • Public individuals and communities	• Prevention services and access to care as necessary • Population health outcomes measurement, data collection, and analysis • Disparities in prevention services and health outcomes • Cost effectiveness of prevention interventions	• Prevention services in primary care • Primary care linkages to broader public health and community prevention resources

Agency Mission	Scope of Health Care System Examined	Research Objectives	Main Research Audiences	HSR Focus Topics	PCR Focus Topics
CMS • To administer the Medicare program and work in partnership with state governments to administer Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace • To strengthen and modernize the nation's health care system, and to provide access for beneficiaries to high-quality care and improved health at lower costs	**Services:** Health care services paid for by CMS programs **Population:** Beneficiaries covered by Medicare, Medicaid, and other CMS programs	• Improving health care access, quality, cost, and population health for CMS beneficiaries	• Policy- and decisionmakers for CMS programs	• Quality measures development, particularly for hospital and other health care facilities • Evaluating demonstrations of new payment and delivery models	• Primary care transformation and payment models • Primary care role in new payment and delivery models
HRSA • To improve access to health care services for people who are uninsured, isolated, or medically vulnerable	**Services:** Safety net systems **Population:** Individuals who are uninsured, isolated, or medically vulnerable	• Improving services for safety net and other vulnerable populations • Monitoring and development of the U.S. health care workforce	• Policy- and decisionmakers for HRSA programs and health care for underserved populations • Policymakers for health care workforce development	• Maternal and child health care • Rural health care access and quality • HIV/AIDS health care for under- or uninsured • Projections of health care workforce supply and demand • Health care workforce education and training	• Primary care access and quality for underserved populations • Primary care improvement in community health centers • Primary care workforce development and forecasting

Agency Mission	Scope of Health Care System Examined	Research Objectives	Main Research Audiences	HSR Focus Topics	PCR Focus Topics
NIH • To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability	**Services:** Clinical and other health-related services across the health care system **Population:** Individuals having or at risk for illness or disability, including specific populations (children, aged, and minorities)	• Enhancing health related to specific diseases, body systems, and populations	• Researchers • Health care providers	• Implementation of clinical care practices and interventions • Quality, access, and equity of health care and health related to specific diseases, body systems or populations	• Disease-specific clinical screening and treatment in primary care • Integration of behavioral health and primary care
VHA • To provide accessible, high-quality, cost-effective health care for military veterans	**Services:** All health care services in VHA system **Population:** U.S. military veterans	• Improving the VHA health care delivery system • Improving veterans' health, including diseases and conditions affecting the veteran population	• VHA system leaders • VHA health care providers	• Quality measurement • Implementation science • Embedded research	• Access and telehealth in primary care settings • Management of multimorbidities and complex, high-risk patients • Integrated primary and behavioral health care • Primary care transformation across the VHA system

We first provide an overview of the distinct characteristics of the HSR and PCR portfolios of these agencies. Later we describe in more detail the individual research portfolios of each agency and also indicate which agencies have no or negligible HSR or PCR in their research portfolios as defined by the study. Detailed descriptions of agency HSR and PCR portfolios are provided in Appendix C.

The particular focus, strengths, and expertise of federal agency HSR and PCR portfolios tend to be differentiated by three dimensions:

- The scope of the health care system studied (i.e., whether a specific health care setting or population, a broader range of health care settings or populations, or the intersection of health care with public health and community settings)
- The research objectives (i.e., whether focused on system processes and outcomes and/or disease-specific care and outcomes)
- The main audience(s) for the research.

Study participants across the range of federal and non-federal stakeholders noted that AHRQ, as the only agency with congressional authorizations to generate HSR and be the home for federal PCR, has a unique focus within its research portfolio on systems-based outcomes and approaches to implementing improvements across health care settings and populations in the United States. It is also the only agency whose research primarily targets health care delivery leaders, as well as providers and researchers. As the leader of a state-level payer organization commented:

> [T]o my mind, AHRQ is the driving entity looking at do we have the best possible understanding of the major processes, delivery systems, tools to make care meet those IOM six dimensions [safe, timely, effective, efficient, equitable and patient-centered], and are we comparing different tactics and strategies fairly and well? . . . that's right at the center of AHRQ's swim lane.

NIH similarly seeks to enhance the health of persons generally throughout the United States; its portfolio of HSR and PCR plays a fundamental role in funding research on the effectiveness and implementation of care practices and interventions typically focused on specific diseases, body systems, or populations, according to the individual missions of the agency's component Institutes and Centers (ICs). The main audiences for this research tend to be the research community and health care providers.

A health policy interview participant described the important role of the type of HSR and PCR funded by NIH and how that compares to research on broader systems-level outcomes:

> NIH funds health services research that is very specific to body part, disease endpoints and outcomes. . . . And so it's a subset of health services research. . . . It's absolutely important. But it is not the broad sort of system-level performance outcomes . . . in terms of the cost, quality, safety outcomes, endpoints.

A federal interview participant from NIH noted how those broader system outcomes, "because they're not necessarily specific to a given disease or organ or population, have been a really natural place for AHRQ that NIH can't do as much with." A researcher interview participant also emphasized the conceptual contrast of a systems perspective:

> AHRQ is more systems-focused looking at how services are delivered, who delivers it, from the workforce perspective, from the administrative organizational perspective. . . . How can we change health care systems to impact patient outcomes? . . . Of course, patients are at the center of AHRQ's research projects. . . . But the way AHRQ conceptualizes it is different than the way the NIH conceptualize, in terms of looking from the system perspective.

The HSR and PCR portfolios of other agencies differ by scope of the health care system addressed and the main audiences for the research. CDC's research, like that of NIH, is largely organized by diseases and conditions, but its HSR and PCR portfolios focus on broad population health outcomes measurement, surveillance, and analysis; and the linkages between prevention, population health, and the health care system. The main audiences for its research are public health officials and the broader public and communities. A federal interview participant from CDC explained how "our population is quite a bit broader than . . . even that of AHRQ. It's not just those who cross the threshold of the hospital. It's those who are healthy, as well as those who actually have a disease." This interview participant also noted that there is an intersection between the health care and public health systems, which has increased over the past few decades:

> The programs that we [CDC] are trying to influence are those that affect a broader public health audience. Sometimes clearly those audiences overlap with the health care system, because . . . the line between health care and public health or population health and prevention are beginning to blur a bit more, than they were two decades ago.

In contrast, ASPE, CMS, and the VHA are more narrowly focused on specific federal health policies and delivery systems, with their research targeted to informing policy and decisionmakers for these programs. ASPE's HSR and PCR portfolios focus on health care policy priorities of HHS leadership and Congress, as well as requests from HHS operating divisions that have limited research capacity or that require unique research expertise and resources possessed by ASPE. A federal interview participant from ASPE explained that, while HSR and PCR from other agencies may inform policy, ASPE specifically operates at the "nexus" of research that supports policymakers in the time frame needed for decisionmaking:

> [ASPE's] work is really designed to inform policymakers. We work at the nexus of research and policy. AHRQ doesn't work at that same nexus. It doesn't mean their work may not inform policymaking. . . . I'd [also] say a lot of our timetables are often shorter than theirs might be, because we're trying to inform real-time decision-making.

CMS generates HSR and PCR through evaluation to inform efforts to improve care and reduce costs for its beneficiaries, particularly those efforts related to quality measurement and payment and delivery innovations for populations and services covered by Medicare, Medicaid, and other CMS programs. As noted by a state policy interview participant, a major portion of this portfolio consists of the agency's CMMI funding of "program evaluation . . . of their payment [demonstrations], their payment models, and by extension, CMS doing [evaluations of] like a Medicaid waiver, their health homes waiver." The VHA conducts HSR and PCR intended to improve the health care and health of military veterans. A federal interview participant from the VHA explained that "within the field of HSR, we have priorities that are dictated by the particular challenges of veterans or the VA Health System," such as care for pain, opioids, suicide, and aging, and priorities of the VHA system to address access to care and coordination with other delivery systems. Given the size and scope of the health policies and delivery systems for which these agencies are responsible, their research and evaluation activities typically contribute unique results and data applicable more generally to the fields of HSR and PCR.

ACL and HRSA sponsor HSR and PCR as part of their broader missions as funders of services for underserved and special needs populations. ACL's HSR and PCR portfolio focuses on improving care to support community-living elderly and disabled individuals. HRSA sponsors HSR and PCR to improve services for safety net and other vulnerable populations, such as those who receive care at federally qualified health centers (FQHCs) supported by the agency's Health Center program. HRSA also serves as a distinct HSR and PCR resource providing analysis and data on the distribution and development of the U.S. health care workforce.

Across agencies, interview stakeholders observed that the time horizons for the research tended to differ by type of audience—shorter term for policy and decisionmakers, medium term for health care delivery leaders and providers, and longer term for research audiences.

Research Portfolios and Focus Areas by Agency

Next, we describe the individual HSR and PCR portfolios of each agency, including the specific topical focus areas that agencies have developed to address their individual missions and operational needs.[1]

Administration for Community Living

Improving care to support health and wellness of community-living elderly and disabled individuals. As indicated in Table 3.1, ACL serves as the federal agency responsible for increasing access to community supports, while focusing attention and resources on the unique needs of older Americans and people with disabilities across the life span (Administration for Community Living, 2019a). Most of the ACL's extramural funding consists of service grants

[1] Detailed descriptions of agency HSR and PCR portfolios are provided in Appendix C.

that do not include research as defined by this study. However, the agency's NIDILRR institute operates several programs that fund research projects with health care–related components (Administration for Community Living, 2019b). This portfolio includes Model Systems Programs that fund centers of excellence to provide and evaluate comprehensive, evidence-based models of care and support for individuals in communities who have spinal cord, burn, or traumatic brain injuries (Model Systems Knowledge Translation Center, undated). The NIDILRR portfolio also contains extramural funding of research on the implementation and effects of health policies on community living of people with disabilities of all ages, rehabilitation research centers that include studies of health services and financing, and grants on health technology that include research on telehealth to support people with disabilities living in community.

Agency for Healthcare Research and Quality

Improving health care systems and outcomes across health care services and populations in the U.S. health care system. AHRQ is the only federal agency that has a congressional authorization to generate HSR, including research to make health care safer, higher quality, more accessible, equitable, and affordable (42 CFR 67.13). AHRQ also has a statutory charge to serve as the lead federal agency for primary care research (42 U.S.C. 299 et seq). Although AHRQ has not received targeted appropriations for this latter mission, the agency funds and disseminates research on primary care systems and innovations, including the nature of primary care as the usual source for addressing personal health care needs, the management of commonly occurring and undifferentiated clinical problems, and the continuity and coordination of health services. The agency also hosts the National Center of Excellence for Primary Care Research, which provides evidence, practical tools, and other resources to improve primary care (Agency for Healthcare Research and Quality, undated-i).

Interview and TEP participants noted that a hallmark of AHRQ-sponsored research is its focus on systems-based improvement across the spectrum of health care settings and populations in the United States. AHRQ's research is organized around broad health care system inputs and outcomes, including quality of care, with an emphasis on patient safety; access and disparities; organization of delivery systems and markets; financing and costs; and HIT adoption and effective use. Patient safety became a particular emphasis after Congress directed AHRQ in 2001 to invest significant resources in this area (Senate Report 106-293, 2002), which has included research on the causes of and effective strategies to reduce medical errors and harms, such as healthcare-associated infections, adverse drug events, and preventable hospital readmissions (Agency for Healthcare Research and Quality, 2018). Interview and TEP participants further commented on AHRQ's special emphasis on implementation tools, methods, and evaluation—particularly for understanding the implementation and wider scale-up of improvement practices—as well as its unique role in synthesizing, disseminating, and translating scientific evidence from HSR and PCR into practice.

In addition, AHRQ produces and maintains several large databases covering the breadth of the U.S. health care system for use by health services and primary care researchers. These databases include the Healthcare Cost and Utilization Project (Healthcare Cost and Utilization Project, 2019), which contains the largest collection of longitudinal encounter-level hospital care data; and the Medical Expenditure Panel, the most complete source of data on the cost and use of health care and health insurance coverage in the United States (Agency for Healthcare Research and Quality, undated-e).

Office of the Assistant Secretary for Planning and Evaluation

Informing policy and decisionmaking on federal health care priorities. ASPE advises the Secretary of HHS on policy development, coordinates the department's evaluation, research, and demonstration activities, and manages cross-department planning (Assistant Secretary for Planning and Evaluation, undated). ASPE research and evaluation are intended to inform policies related to specific federal programs and initiatives at the department or operating division levels within HHS (U.S. Department of Health and Human Services, 2019). Its HSR and PCR portfolios focus on priorities of HHS leadership and Congress, requests from HHS operating divisions that have limited research capacity or require unique research expertise and resources possessed by ASPE, and self-initiated projects, including both short-turnaround and forward-thinking projects to address anticipated policy needs. Over time, ASPE has developed HSR portfolios on federal programs and policies related to access to care, health insurance coverage, costs and spending (including value-based care), behavioral health, and care for special populations served by federal programs. Its portfolios in PCR have focused on access to primary care, payment policy changes for primary care services in Medicare and Medicaid, and primary care improvement and transformation in the IHS system.

Centers for Disease Control and Prevention

Protecting public health from threats posed by specific diseases, conditions, and injuries. The mission of CDC is to protect the health of Americans by fighting disease and supporting communities and citizens in health promotion. As described above, CDC has a broad public and population health focus that includes all people in communities—healthy as well as sick individuals, and whether or not they are engaged in the health care system. To fight disease and support health promotion, CDC largely organizes its research around disease states and health conditions, including both those that are communicable and noncommunicable.

To accomplish this objective, CDC conducts critical science and provides health information to understand and address threats to public health. Although much of this research falls outside the scope of this study, federal and other stakeholders noted several areas in which the agency's research on population health outcomes measurement, surveillance and analysis, and the evaluation of prevention services intersect with the health care system and HSR and PCR topics.

Its HSR-specific portfolio has concentrations on the use of CDC surveillance systems and health outcomes measurement to assess health care quality. For example, CDC's National Healthcare Safety Network (NHSN) provides data on healthcare–associated infections (HAIs) in hospitals and other health care settings used in research on HAI-related patient safety improvement, as well as for CMS quality reporting programs. The agency's PCR focuses on prevention services in primary care, including immunizations and various screening and health promotion activities, and the linkages between primary care and broader public health and community prevention resources.

Centers for Medicare and Medicaid Services

Improving health care access, quality, cost, and population health for Medicare, Medicaid, and other CMS beneficiaries. CMS generates HSR and PCR through the evaluation work it sponsors in support of its business objectives to improve care and reduce costs for Medicare, Medicaid, and other CMS programs. Thus, its HSR and PCR activities are focused on the populations and services covered by its programs (e.g., medical services for elderly in Medicare, medical, and long-term care services for low-income individuals in Medicaid) and on informing policy- and decisionmaking for the agency. The first portfolio of HSR within CMS focuses on the development of quality measures, particularly for hospital and other health care facilities, and evaluation of the impact of reporting quality measures for CMS programs on health care systems and providers. The agency's second and larger portfolio consists of evaluations of demonstrations funded by CMMI of new payment and delivery models. Within CMMI-sponsored research, PCR-related evaluations have also focused on models promoting primary care transformation (e.g., patient-centered medical homes [PCMHs] in multipayer and safety-net practices), and on the role of primary care in new payment and delivery models (e.g., Accountable Care Organizations [ACOs]).

Health Resources and Services Administration

Improving services for safety net and other vulnerable populations and analyzing the distribution and development of the U.S. health care workforce. HRSA's mission is to improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs (Health Resources and Services Administration, 2019). Study participants noted HRSA for its support of services for safety net and other vulnerable populations, as well as health care workforce development. Most of HRSA's extramural funding provides grants for direct services and service infrastructure that do not include research. However, HRSA has long-established programs of research and evaluation related to its main functional areas, which the agency has more recently expanded in part to inform decisions about costs, interventions, and quality of care for the populations it serves (Dievler and Fisher, 2017).

The agency's Bureau of Primary Health Care collects extensive data on the community health centers it funds nationwide for underserved populations, which it makes available to the wider research community, as well as contracts externally for analyses. Other HRSA research for specific populations and services include the Maternal and Child Health Bureau's intramural research on issues such as health care, preventive and early intervention services for maternal and child populations; the Office of Rural Health's funding of extramural Rural Health Research Centers; and the Ryan White HIV/AIDS Program, which conducts research on health care disparities, services, and innovative models of care for under- and uninsured individuals served by its funded HIV centers. More broadly, the National Center for Health Workforce Analysis (NCHWA) serves as a national resource for projections of health care workforce supply and demand, and analysis of the distribution and education of the nation's health workforce (Health Resources and Services Administration, undated-b). As with other HRSA programs, NCHWA provides extensive data and information for use by the wider research and policy community.

National Institutes of Health

Enhancing health of the nation with a focus on specific diseases, body systems, and populations. NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. Although the vast proportion of NIH's research portfolio is focused on basic, clinical, and translational research, federal and research interview participants and TEP members noted that NIH ICs fund a considerable amount of HSR and PCR. These portfolios of research play a fundamental role in funding HSR and PCR on the effectiveness and implementation of care practices and interventions typically focused on specific diseases, body systems, or populations, according to the individual missions of the agency's component ICs.[2] PCR interview and TEP participants reported that NIH has been a significant source of funding and sponsor of important studies in the PCR field. They commented that ICs organized to address specific diseases or body systems tend to focus on screening, managing, and coordinating care for those diseases or body systems by primary care providers. ICs organized to address particular populations were also noted to sponsor research related to broader influences on population health, such as the effect of insurance payment and coverage of care.

Federal and research interview participants observed that some ICs within NIH have a stronger emphasis on HSR and PCR than others based on their particular congressional mandates and other directives, as well as concerns of their extramural research communities, such as to increase the adoption of evidence-based clinical interventions by practitioners. ICs identified by study participants as sponsoring significant amounts of HSR and PCR include the National

[2] NIH also contains Institutes, Centers, and Offices that focus on professions (NINR), treatment modalities (NCCIH), and research areas (Office of Behavioral and Social Science Research).

Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Cancer Institute (NCI), National Heart, Lung, and Blood Institute (NHLBI), and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Other ICs identified by study participants to fund HSR and/or PCR include the National Institute on Aging (NIA), the National Institute on Child Health and Human Development (NICHD), the National Institute on Minority Health and Health Disparities (NIMHD), the National Institute on Nursing Research (NINR), and the National Center for Advancing Translational Sciences (NCATS).

In addition, federal interview participants noted that certain trans-NIH initiatives funded through the agency's Common Fund have provided opportunities for its research to more broadly engage health care delivery systems. These initiatives include the Common Funds' Health Economics program from 2001 to 2017 and the Health Care System Research Collaboratory begun in 2012, which aims to enhance the capacity to conduct research with health care systems and strengthen the relevance of research results to health practice. ICs now also directly support additional pragmatic clinical trials in the Collaboratory.

Veterans Health Administration

Improving the VHA health care delivery system and veterans' health. The VHA conducts HSR intended to improve the health care and health of veterans, and to advance the field based on the unique capabilities of the VHA system. The VHA's HSR portfolio is focused on the particular health challenges facing veteran populations and the priorities of the VHA system. These include improving the quality and safety of specific services that are significant for veterans, such as pain management, suicide prevention and other types of mental and behavioral health care, trauma and traumatic brain injury, and health care for women—the fastest-growing segment of the veteran population. To address specific challenges in the VHA system, its research portfolio has also focused on broader HSR issues, such as ways to define and improve access to care, expanded use of telehealth, rural health care, and coordination of care with other health delivery systems outside of the VHA. Major topics in the VHA's PCR portfolio, in addition to access and telehealth, have included management of multimorbidities for complex, high-risk patients; integrated primary and behavioral health care; and evaluation of a national rollout of medical home transformation across the VHA system.

Federal and research stakeholders additionally commented on the VHA's strength in certain methods related to its role as the largest nationally integrated health system in the country, including development of systemwide, standardized quality and safety measures, and the application of 25 years of comprehensive, longitudinal electronic health record (EHR) data to perform unique types of HSR analyses, as well as to understand the use of EHR data systems to measure and improve care. Other methods areas for HSR within the VHA include implementation methods and evaluation for translating evidence-based practice into veterans' care, and best practices for embedding researchers with clinical and operational partners in health services.

Agencies Without Reported HSR or PCR Portfolios

We confirmed with representatives of the following agencies that their operating division or office funds no or negligible amounts of HSR or PCR according to the definitions of this study: ATSDR, FDA, ONC, and SAMHSA. Federal stakeholders reported that ONC works closely with AHRQ and other agencies, including the National Library of Medicine in NIH on research related to the implementation and use of HIT. SAMHSA was reported to rely on evidence of effective interventions for mental health and substance abuse from NIH institutes and other agencies, and engage with ASPE for research needs related to SAMHSA's programs.

We were not able to confirm with representatives of ACF or IHS whether their agencies support any research portfolios in HSR or PCR. Other federal stakeholders noted that ACF's extramural grant funding is mostly dedicated to supporting service provision and infrastructure, but as described for ACL and HRSA above, this does not preclude funding of HSR or PCR. Although IHS has a focus on quality improvement for the Indian health care system it supports, the agency was described as having relatively limited capacity to conduct research per se and tending to engage with ASPE for HSR or PCR needs related to Indian health care programs.

Environmental Scan of Federally Funded Extramural HSR and PCR

Next, we present results of our systematic scan of extramurally funded HSR and PCR portfolios from the six agencies for which the study was able to collect comprehensive project-level data and review results with agency contacts. As discussed in Chapter 2, there were two primary sources of these data—the RePORTER database, which includes federal grants for health-related research across HHS and the VHA; and agency-provided data, which include both contract and grant projects. We report the number of projects collected and in-scope between FY 2012 and FY 2018, as well as the percentage of an agency's projects by research classification in order to emphasize focus areas in each agency's portfolio.[3]

Table 3.2 shows the total number of extramurally funded projects collected for each agency (excluding those missing abstracts or coded in RePORTER as related to research infrastructure), and the proportion of projects identified as in-scope according the report's definitions of three classifications: HSR—the scientific investigation of health care services broadly defined—including health, mental health, substance abuse, long-term care, and social and other services, as they connect to health care; PCR—scientific investigation of primary care, which includes projects that are HSR as well as those that are not; and MTD—which includes development of research methods (e.g., psychometric instruments, quality measures, risk adjustment, and stratification models) and other tools (e.g., HIT applications, implementation toolkits) related to the study of health care.

[3] See Appendix B for confidence intervals for the results, and results by year.

Many, though not all, projects with MTD components are also classified as HSR or PCR research (i.e., investigations examining a research question intended to contribute to scientific knowledge on an HSR or PCR topic). Thus, all three in-scope classifications are not mutually exclusive, and the percentages reported in each category do not sum to 100. See Chapter 2 for research domain definitions and Appendix B for detailed category coding specifications.

In Table 3.2, the total number of projects for ACL and CMS consists only of projects that were directly provided by these agencies in response to RAND's request for HSR, PCR, and MTD projects as defined by the study (CMS extramurally funded projects are exclusively contracts, which are not included in the RePORTER database, and ACL relies on a different database to archive its extramural projects). Unsurprisingly, relatively large proportions of the projects collected from these agencies were in-scope to the study—CMS (99 percent) and ACL (85 percent)—which reflect the selective identification of projects by the agencies for the study as well as the nature of the research and evaluation work they fund, especially CMS.

Table 3.2. HSR, PCR, and Methods and Tool Development Projects, by Funding Agency

	ACL	AHRQ	CDC	CMS	NIH	VHA	All Agencies[a]
Total projects in scan data set[b]	68	1,155	1,093	75	86,321	3,013	93,075
Projects classified as HSR	53 (78%)	653 (57%)	267 (24%)	57 (76%)	6,891 (8%)	794 (26%)	8,767 (9%)
Projects classified as PCR	2 (3%)	149 (13%)	28 (3%)	9 (12%)	750 (1%)	150 (5%)	1,090 (1%)
Projects classified as HSR and/or PCR	53 (78%)	668 (58%)	268 (25%)	58 (77%)	6,948 (8%)	797 (26%)	8,845 (9%)
Projects classified as MTD	26 (38%)	432 (37%)	104 (10%)	17 (23%)	3,501 (4%)	310 (10%)	4,416 (5%)
Projects classified in-scope (HSR, PCR, and/or MTD)	58 (85%)	915 (79%)	328 (30%)	74 (99%)	8,707 (10%)	889 (30%)	11,045 (12%)

NOTE: Percentages do not sum to 100, as projects can meet criteria for multiple or no categories. These results are based on a combination of manual reviews and machine learning–based automated classification of projects in the scan data set. For additional details, see Chapter 2 and Appendixes A and B.

[a] The "All Agencies" tallies include projects from the six agencies in the table as well as 46 FDA and ACF projects from the RePORTER database that our machine learning algorithm classified as in-scope to the scan. FDA and ACF projects are not reported separately since we did not perform member-checking of those results with the agencies as required by the scan methodology.

[b] The "Total Projects" numbers are based on the scan data set, which includes data from the RePORTER database and directly from individual agencies, following merging of nonunique project records and the exclusion of projects that met any of the following criteria: (a) projects with pre-FY 2012 start dates; (b) projects with post-FY 2018 start dates; (c) projects missing abstracts; (d) projects with RePORTER activity codes related to research infrastructure and support; and (e) projects conducted intramurally by agency staff. See Chapter 2 for additional details.

The total number of projects for AHRQ, CDC, and VHA consists of both RePORTER and agency-provided projects (with duplicates removed between the two sources).[4] NIH projects are all contained and sourced from the RePORTER database. Of these four agencies, AHRQ has the highest proportion of in-scope projects across all three classifications (79 percent). NIH has the smallest proportion of in-scope projects (10 percent) but contributes the largest number (8,707).

Table 3.3 displays the number and percentage of agency projects by the main research domains of health care outputs and inputs in the framework presented in Chapter 2. The denominator of the percentages is the total number of projects identified as HSR and/or PCR, shown in the top row of the table.[5] A single project often was counted as meeting the classification criteria for multiple

Table 3.3. HSR and/or PCR Projects, by Research Domain and Funding Agency

Research Domain	ACL	AHRQ	CDC	CMS	NIH	VHA	All Agencies[a]
Total HSR and/or PCR projects	53	668	268	58	6,948	797	8,845
Quality of Care	87%	80%	80%	90%	89%	87%	88%
Cost and Utilization	17%	39%	37%	88%	27%	24%	28%
Access to Care	34%	13%	36%	19%	26%	39%	26%
Equity	15%	14%	35%	10%	33%	16%	30%
Organization of Care	85%	90%	87%	74%	86%	93%	87%
Financing of Care	15%	13%	4%	66%	2%	3%	4%
Social Factors	40%	16%	28%	2%	29%	18%	27%
Personal Preferences and Behaviors	62%	26%	56%	14%	76%	60%	69%

NOTE: Percentages do not sum to 100, as projects can meet criteria for multiple or no categories. These results are based on a combination of manual reviews and machine learning–based automated classification of projects in the scan data set. For additional details and definitions of research domains and categories, see Chapter 2 and Appendixes A and B.

[a] The "All Agencies" tallies include projects from the six agencies in the table as well as FDA and ACF projects from the RePORTER database that our machine learning algorithm classified as HSR and/or PCR. FDA and ACF projects are not reported separately since we did not perform member-checking of those results with the agencies as required by the scan methodology.

[4] Further details on the source and extent of data available for each of the funding agencies can be found in Tables A.1 and A.2 in Appendix A.

[5] MTD-only projects were not coded for the research domains.

domains; therefore, the domain percentages do not sum to 100. The first four domains in Table 3.3 are the output domains (Quality of Care, Cost and Utilization, Access to Care, and Equity).

In the first row, the HSR and PCR portfolios of all agencies have a strong emphasis on Quality of Care (from 80 percent to 90 percent). Quality of Care includes studies that measure process of care (e.g., the provision of a treatment as appropriate), as well as both intermediate (e.g., disease control, adverse patient safety events, patient experience) and definitive outcomes of care (e.g., quality of life, mortality), whether assessed at the level of a specific health care intervention, clinical service, or health care systems more broadly. As might be expected, CMS has the strongest emphasis on Cost and Utilization (90 percent), given its primary role as the health care payer for beneficiaries in its Medicare, Medicaid, and other programs. Agencies with the next strongest emphasis on Cost and Utilization are AHRQ (39 percent) and CDC (37 percent). VHA, CDC, and ACL have the strongest relative emphasis on Access to Care of these six agencies (39 percent, 36 percent, and 34 percent, respectively), which accords with the descriptions of their HSR and PCR portfolios. CDC and NIH have the strongest relative emphasis on Equity (35 percent and 33 percent, respectively).

The last four domains in Table 3.3 are the input domains (Organization of Care, Financing of Care, Social Factors, and Personal Preferences and Behaviors). The HSR and PCR portfolios of all agencies have a strong emphasis on Organization of Care. This is particularly the case for AHRQ (90 percent) and VHA (93 percent), but also NIH, ACL, and CDC (ranging from 85 percent to 87 percent). Similar to the Quality of Care domain, Organization of Care includes structures and routines of care spanning organizational levels from provider teams to clinical services and higher levels of health care systems. Based on the portfolio descriptions, it might be expected that some agencies, such as NIH, would emphasize the former, while others, such as AHRQ, would emphasize the latter; however, this is not differentiated in these data.

CMS has the highest proportion of HSR/PCR projects focused on Financing of Care (66 percent), similar to the results for the Cost and Utilization output domain above, followed by ACL (15 percent) and AHRQ (13 percent). Of note, Financing of Care has a much lower emphasis overall compared to the rest of the research domains (only 4 percent of the total HSR/PCR projects across all agencies). ACL has the highest proportion of HSR/PCR projects focused on Social Factors, which includes social, economic, and community determinants of health and health care. NIH (29 percent) and CDC (28 percent) follow on relative emphasis of Social Factors. NIH has the largest percentage of projects addressing Personal Preferences and Behaviors (76 percent), followed by ACL (62 percent), VHA (60 percent), and CDC (56 percent), with lower proportions for AHRQ (26 percent) and CMS (14 percent). The portfolios of these agencies may vary on the degree of emphasis they place on personal preferences (e.g., preference for particular care, shared care decisionmaking) versus personal behaviors (e.g., smoking, exercise, treatment adherence, other health-related behaviors).

Table 3.4 presents more-specific research categories of interest in HSR and PCR. Definitive health outcomes (e.g., mortality and quality of life) and patient safety (i.e., medical errors and

harms produced by health care and their prevention) are subsets included in the Quality of Care domain.[6] CMS, NIH, and VHA have the strongest emphasis on Definitive Health Outcomes (36 percent, 28 percent, and 38 percent, respectively). CDC's HSR and PCR portfolio has a relatively lower emphasis on definitive health outcomes (15 percent). Despite the agency's noted expertise in this area, most of CDC's epidemiological and surveillance research on health outcomes without a link to health care services is out-of-scope for this study. This result also indicates that CDC's health service–related research is less focused on definitive outcomes than on other process and intermediate health outcomes that fall under the Quality of Care domain more generally.

Table 3.4. HSR and/or PCR Projects, by Research Areas of Interest and Funding Agency

Area of Interest	ACL	AHRQ	CDC	CMS	NIH	VA	All Agencies[a]
Total HSR and/or PCR projects	53	668	268	58	6,948	797	8,845
Definitive health outcomes	21%	19%	15%	36%	28%	38%	28%
Aging	21%	22%	15%	76%	18%	18%	19%
Patient safety	6%	40%	29%	7%	12%	19%	16%
Pediatrics	6%	10%	19%	2%	19%	0%	16%
Prevention	9%	37%	82%	17%	71%	38%	65%

NOTE: Percentages do not sum to 100, as projects can meet criteria for multiple or no categories. These results are based on a combination of manual reviews and machine learning–based automated classification of projects in the scan data set. For additional details and definitions of research domains and categories, see Chapter 2 and Appendixes A and B.

[a] The "All Agencies" tallies include projects from the six agencies in the table as well as FDA and ACF projects from the RePORTER database that our machine learning algorithm classified as HSR and/or PCR. FDA and ACF projects are not reported separately since we did not perform member-checking of those results with the agencies as required by the scan methodology.

AHRQ has the strongest relative emphasis on Patient Safety (40 percent) in line with its legislative mandate in this area, followed by CDC (29 percent), particularly given its focus on healthcare-associated infections. CDC and NIH have the strongest emphasis on Pediatrics (19 percent). CMS has a far larger proportion of projects focused on Aging (76 percent) than the other agencies (15 to 22 percent), in line with Medicare and other CMS programs that serve a substantial number of elderly beneficiaries. CDC has the strongest emphasis on Prevention (82 percent), as might be expected by the description of its research portfolio, followed by NIH (71 percent) and AHRQ (37 percent). In the case of AHRQ, it should be noted that many

[6] Except for a small body of studies on the treatment of patient safety–related harms, which are included in the Patient Safety category but not the Quality of Care domain per the study's definitions. See also Appendix B.

patient-safety projects are also considered prevention in terms of avoiding or reducing the incidence of medical error or harms.

Table 3.5 presents results for MTD and methods of interest categories by funding agency.[7] The denominator for these categories includes all in-scope projects, since MTD includes projects that were not coded to the other research domains.

Table 3.5. All In-Scope Projects, by Methods and Tool Development/Methods of Interest Categories and Funding Agency

MTD and Methods of Interest Categories	ACL	AHRQ	CDC	CMS	NIH	VHA	All Agencies[a]
Total projects classified in-scope	58	915	328	74	8,707	889	11,045
HIT applications and tools	17%	26%	6%	7%	13%	9%	14%
Model development and validation	29%	23%	16%	23%	24%	22%	23%
Toolkit development	12%	9%	5%	0%	2%	4%	3%
Evidence review and synthesis	9%	13%	2%	4%	4%	1%	5%
Simulation modeling	0%	2%	3%	0%	4%	2%	4%

NOTE: Percentages do not sum to 100 as projects can meet criteria for multiple or no categories. These results are based on a combination of manual reviews and machine learning–based automated classification of projects in the scan data set. For additional details and definitions of research domains and categories, see Chapter 2 and Appendixes A and B.

[a] The "All Agencies" tallies include projects from the six agencies in the table as well as FDA and ACF projects from the RePORTER database that our machine learning algorithm classified as HSR, PCR, and/or MTD. FDA and ACF projects are not reported separately since we did not perform member-checking of those results with the agencies as required by the scan methodology.

AHRQ has the strongest emphasis on HIT Applications and Tools (26 percent) in accordance with its specific program of research on implementation and use of HIT for health care improvement. Model Development and Validation appears to have similar levels of emphasis (22–24 percent) within the AHRQ, CMS, VHA, and NIH portfolios of in-scope projects, with this MTD category slightly more common in the ACL portfolio (29 percent) and slightly less common in the CDC portfolio (16 percent). ACL has the strongest relative emphasis on Toolkit Development (12 percent), which might be expected given the role of its

[7] Unlike the MTD categories (HIT Applications and Tools, Model Development, and Validation), the Methods of Interest categories (Evidence Review and Synthesis, and Simulation Modeling) were also coded for the other research domains in the framework.

NIDILRR research institute on facilitating the implementation of interventions for the agency's focal populations (i.e., care and support for community-living elders and disabled individuals). AHRQ, CDC, and VHA follow in relative emphasis on Toolkit Development (9 percent, 5 percent, and 4 percent, respectively).

AHRQ shows the highest emphasis on Evidence Review and Synthesis (13 percent), also in accord with the agency's focus on this function to accelerate implementation of evidence into practice. NIH and CDC have the highest relative emphasis on Simulation Modeling (4 percent and 3 percent, respectively), with smaller emphasis on this set of research methods by AHRQ and VHA (2 percent each).

Chapter Summary

HHS agencies and the VHA have developed research portfolios of HSR and PCR around particular focus areas that address the requirements of their individual congressional authorizations, missions and operational needs. These portfolios differ along three key dimensions—scope of the health care system examined, research objectives, and research audiences. For example, AHRQ, as the only agency that has statutory authorizations to generate HSR and be the home for federal PCR, focuses its research portfolio on systems-based outcomes and approaches to implementing improvement across health care settings and populations in the United States. NIH's portfolio of HSR and PCR addresses a similarly broad scope of health care but tends to be organized around specific diseases, body systems, or populations. The CDC's portfolio of HSR and PCR is organized around diseases, conditions, and injuries, but focuses on prevention and health promotion spanning community and health care settings. The portfolios of other agencies tend to focus on specific health care settings or other populations (e.g., ACL on community-living elderly and disabled individuals, CMS on Medicare and Medicaid beneficiaries, and VHA on veterans' health care and health), or research audiences (e.g., ASPE on federal policymakers).

Results of the environmental scan and portfolio analysis's systematic enumeration of HSR and PCR projects confirmed some of these distinct emphases. These included the relative emphasis of AHRQ on Patient Safety, HIT Applications and Tools, and Evidence Review and Synthesis; CMS on Cost and Utilization and on Financing of Care; CDC on Prevention; and ACL on Social Factors.

At the same time, the scan results showed other agency portfolios to include projects in these areas, albeit to a lesser extent, as well as strong emphasis across all agencies in the analysis on the research domains of Quality of Care and Organization of Care. The qualitative results from TEP and interview participants indicated that agencies would be expected to fund different approaches to these topics, such as portfolios within NIH focusing on quality of care for specific diseases, and portfolios within AHRQ focusing on quality outcomes for health care systems more generally. However, the relatively broad research categories of the scan analysis were not able to detect such distinctions.

The next chapter uses the qualitative TEP and interview data to examine the degree to which overlap in research funded by agencies in similar topic areas is complementary or redundant, and the extent and ways in which federal HSR and PCR funding is coordinated among agencies.

4. Overlap and Coordination of Federal Agency Research Portfolios in HSR and PCR

The previous chapter described the breadth, scope, and focus of the HSR and PCR portfolios of different federal agencies. That discussion indicated that agencies have distinct focus areas and also fund research covering similar topics, particularly when looking at broad domains such as Quality of Care and the Organization of Care. To understand the nature of any overlap in portfolios, this chapter examines instances in which federal agencies fund research in similar topical areas to understand the nature of any overlap in portfolios. In particular, we sought to determine whether and in what circumstances that overlap is *complementary* (e.g., covering different aspects of a topic or covering a common topic in regard to a different population) or *redundant* (i.e., essentially duplicating the focus of another agency's study). We also sought to identify mechanisms agencies use to coordinate their research efforts.

In the chapter, we first differentiate various types of overlap in HSR and PCR funded by agencies and describe formal and informal mechanisms of coordination. We then note research areas considered by individual study participants to lack sufficient coordination and discuss challenges to interagency coordination of federally funded HSR and PCR projects.

Types of Overlap

TEP and interview participants across several stakeholder groups noted that overlap in research funding—that is, when different agencies fund research in the same topic area—can be complementary and advantageous, rather than redundant. Complementary research includes instances when agencies fund projects addressing different facets of a research topic, as well as when agencies devote or combine resources for similar projects on an underfunded topic in an additive fashion. At the same time, stakeholders acknowledged that redundancies in research efforts do occur across agencies. When such redundancies are recognized, study participants from within and outside the federal government observed that agencies generally work to avoid duplication and ensure funding of research that reflects the mission and expertise of each agency. Indeed, some examples of complementary agency research were motivated by the identification of redundant overlap by federal leadership, policymakers and stakeholders, or the agencies themselves.

Overlap in Research Portfolios Was Mostly Complementary

Agencies Funding Research on Distinct Aspects of a Topic

While study participants acknowledged overlap in research portfolios that might create duplication, this overlap, if coordinated properly, was observed to be important in allowing agencies to fund the complementary research approaches needed to make headway on particular problems in health care delivery. As described by a leader of a consumer group, these "fuzzy boundaries" can create "sweet spots" for agency research efforts to complement each other:

> Yeah, there's been fuzzy boundaries that might create duplication. But I kind of think of it as like a nice Venn diagram, where there is overlap and it creates that sweet spot, where everybody is doing what they're supposed to be doing, based on their mandate as an agency. When there is a sweet spot, that's where action and change can really take place. I think there should be some overlap, quite frankly.

A researcher in health care disparities similarly described the overlap in research areas between AHRQ and NIH as complementary and generally useful:

> AHRQ . . . covers any disease state. NIH is organized around disease states or populations. So there's going to be overlap, but I think there's a lot of areas where they don't overlap. And I don't think the AHRQ-NIH overlap is problematic—I think it's . . . actually good. . . . [T]here are issues that are not organized around a specific disease, which is the way NIH is organized, and AHRQ is better suited for that.

For example, a federal research leader at CMS described how research evidence generated by other agencies such as AHRQ and NIH informs the types of payment and delivery models that are tested by CMMI.

> Are there areas of overlap? Certainly. But I see the contribution that each of us [agencies] makes as different, but complementary. Like we can't implement a model in CMMI out of thin air, right? It should be based on the evidence that AHRQ produces out of the research that they do about how the systems are currently functioning. And the way that we measure quality, for example, or the kind of expectations we impose upon our model participants should be informed by the work NIH does around what should care around a chronic condition look like clinically, right? So we each play a critical distinct, but complementary role.

The same federal research leader reported work on a diabetes prevention model that involved collaboration with CDC "working hand-in-glove" utilizing not only CDC research expertise in diabetes prevention, but also CDC's prevention certification for providers and data collection. Likewise, a federal research leader from AHRQ recounted how similar overlap on the topic of PCMH reflected collaboration with AHRQ providing foundational evidence on PCMH used to develop the CMMI's Comprehensive Primary Care demonstration model, as well as modeling to inform the design of the evaluation.

> In primary care, when CMS decided, CMMI specifically, to develop new models of payment for primary care, they came and met with AHRQ. And we taught them about the PCMH and what we were seeing in the evidence were important factors. And they developed CPC [Comprehensive Primary Care] partially based on consultations with us. . . . They were going to evaluate that program, and we ran the data and did some modeling and . . . worked with them to develop changes to the program and their evaluation that made it possible that they'd be able to see an effect. And they listened to that. And I think this very large program was much better because of the partnership. It was AHRQ's investments in primary care research methodologies that allowed us to guide them on that.

Overlap with the VHA on the PCMH topic also reflected complementary use of AHRQ evidence on primary care transformation to inform the VHA's implementation and evaluation of its patient-aligned care team (PACT) medical home model. The federal research leader from AHRQ continued:

> Another place we've also had some collaborative successes is with the VA. The VA as a complete system recognized the importance of primary care way before a lot of other folks and really wanted to develop that. We partnered with them on their development of the PACT model, which is their PCMH. And they used some of our work . . . I'd love to continue to see more.

The consumer group leader above provided an example of complementary research overlap that included distinct research roles among agencies, as well as facilitated coordination with other research roles (e.g., CMS payment policy) and private sector stakeholders, such as the Joint Commission.

> [W]e recognized that everybody had a role to play where CMS, you need to make sure that CMS would pay for a universal bilirubin test, that the Joint Commission would issue a sentinel event alert, alerting hospitals to test all babies; that CDC would fund some research on the impact of implementing a universal bilirubin screening in a large health care system and where AHRQ did studies at other hospitals who did that, as well. . . . It was really gratifying to see them all get around what we needed to accomplish, and they all did their piece without competing or doing the same kind of research.

A federal research stakeholder at ASPE described how their office is an active consumer of other agencies' research both to avoid duplication and fulfill its unique role in translating research for the policymaking process.

> We [ASPE] definitely are consumers of AHRQ and NIH research, so in terms of trying not to duplicate, but it is our job to know what's going on at those agencies so that we can take advantage of all that they're doing so that it can feed into policymaking. So that's not directly an AHRQ role, but it's directly, I think, an ASPE role. We don't try to duplicate it, but we have to know and value and compile it, synthesize it, maybe summarize it so that it can be further consumed into the policymaking process.

Agencies Funding Additional Needed Research on a Topic

Other stakeholders noted cases in which agencies sponsor similar projects on important but underfunded topics. This type of additive overlap allows focusing of resources across agencies to address pressing or neglected issues in health care delivery and improvement. One such area commented on by several stakeholders was PCR, such as the case of a PCR researcher who noted "some overlap" between NIH and AHRQ in PCR funding but added that "the funding is inadequate in the first place, so I would hate to see any overlap eliminated." A state-level policymaker agreed:

> My impression is that the funding for primary care research . . . is so small that overlap is not an issue. There's not a lot to go around, so I don't think overlap is what we've got to worry about. Maybe the overall size of the funding and what the priorities should be are relevant conversations, but less so overlap.

A federal research stakeholder from AHRQ similarly described the general lack of direct overlap in PCR projects due to the "dearth of funding." This stakeholder noted that the overlap that does exist in federally funded PCR tends to consist of "the kind of projects you should test more than once before you put all your money down on it; so it's the important checking of projects" for confidence in results.

A delivery system leader pointed to health care workforce research as an area that exhibits both additive and distinct complementary overlap among agencies:

> It's hard to say there's overlap when there's such dramatic underfunding of services transformation. One area that's of particular [note] to me is the different roles that HRSA and AHRQ have in workforce research; that AHRQ seems more interested in teams and in advanced models of workforce planning. HRSA tends to be more focused on the individual disciplines, in my observation, and also in sort of traditional ratio-based planning for workforce, sort of different perspectives. I wouldn't say that I see much in the way of overlap just because it's such an underfunded area.

Overlap Among Research Portfolios Was Viewed as Less Problematic Than Coordination

Difficulty Identifying Current Redundancies

In general, TEP and interview participants had difficulty identifying current problematic examples of redundant overlap. As a state public health leader remarked:

> Nothing that I think would be problematic or notable, you know . . . what comes to mind, for example, is CDC may be supporting a program . . . then GAO [Government Accountability Office] may come along and, at Congress' request, do an evaluation, . . . and the program would have reports . . . intended to impact our work at a state and a county level. So it wouldn't be, you know, duplicative, but certainly [reports] on a similar program or topic. But other than that, nothing really comes to mind as a duplication of sorts.

Like other health system delivery leaders, this one did not see obvious instances of overlap among HSR and PCR funded by federal agencies, partly due to the difficulty of tracing the origins of the many studies they are trying to use. However, given the challenge faced by industry professionals in identifying overlap, the leader encouraged funders to strive for as "integrated and coordinated" a research agenda as possible:

> I think there is some overlap, but I don't come away saying, "Gee, I've already seen this, or didn't I see this in a different—" I mean, because there's so much also private research at quasi-public institutions like the Kaiser Family Foundation or Commonwealth Fund or Peterson Foundation. So, I'm trying to read all of these things and it's blurry. I think from the federally funded standpoint, I think some sort of way to organize and eliminate the overlap where it does occur, so that it was a single research agenda—that may be impossible to accomplish, but I think that would certainly be advantageous for those of us who are in the industry, trying to keep our heads down every day, to keep executing. I think the more that we can be integrated and coordinated on the research agenda, the better. But I don't have a specific area where I would say these two things are overlapping and one of them needs to go away.

Concern About Coordination More Than Redundancy in Research Portfolios

Other stakeholders were explicit in stating that redundancy in overlap among agencies was not as much a concern as the coordination of research funded by agencies. As an insurance industry leader stated, "I don't think overlap is the issue. I think disconnect is the issue." A leader of a state-level payer organization likewise remarked:

> I worry less about redundancy than I do about inconsistency. Is SAMHSA and AHRQ, who are both looking at issues on opioids and its relation to primary care, doing a whole different set of measuring what that means? And [is that] out of sync with what patient-centered medical homes are doing, which are also looking at the engagement of primary care docs in substance abuse issues?

Agencies Were Generally Sensitive to Redundancy in Research Portfolios

This emphasis on coordination more than overlap may be related to observations that federal agencies are generally sensitive to redundancies in research portfolios and inclined to avoid and resolve instances once recognized. A federal research leader from NIH commented that, among other agencies such as AHRQ, CDC, and FDA with which the agency interacts, "everybody sees the merit in facilitating transfer of research from one agency to the other" and "the value of coordinated research."

A federal research leader from CDC noted that challenges with managing the interface among agency research portfolios frequently involve "miscommunication and expectations of the classic lanes for different organizations . . . and when people cross lanes, that causes consternation amongst everybody." Part of the inclination to stay within "lanes" is a desire of agencies to focus on research that produces value-added based on the distinct strengths of an agency's portfolio, as described by a federal research leader from the VHA:

> Obviously, we have a lot of veterans with diabetes, but we're still going to be a drop in the bucket of all the health services research that comes out of NIDDK, or NHLBI. So we are focusing a little more on things that have elements that are more specific to care in the VA, like multi-morbid chronic disease, or patients with co-occurring mental health disorders, or the role of telehealth and things like that. But, you know, just a single kind of vanilla intervention for patients who just have diabetes is not really a great space for us.

There is also general recognition of the consequences from federal leadership and policymakers for appearing to be performing duplicative research or operating outside of their "lanes." A PCR researcher provided an example of AHRQ and PCORI, a nongovernment institute, which both receive funding through the PCOR Trust Fund established by the Affordable Care Act:

> I don't think there's much overlap. I think AHRQ and PCORI is certainly where there was the highest risk of overlap and I think, for the most part, they sorted it out. . . . [T]he primary care discipline, researchers within family medicine and people working on policy, have worked very hard to help them prevent overlap because we know that overlap could politically hurt both.

Examples of Agencies Resolving Redundancy in Research Portfolios

Indeed, stakeholders described examples of complementary agency research that were motivated when leadership, policymakers, and other stakeholders identified and pressed agencies on problematic overlap in research efforts. For example, several federal research stakeholders described active complementary research efforts among several agencies around HAIs. An AHRQ federal stakeholder discussed how the agency is in contact with CDC, NIH, and other agencies through "various committees, the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria—PACCARB, an HHS workgroup, and the National Action Plan to Prevent Healthcare-Associated Infections," with "CDC's focus more from the public health angle, [and] AHRQ looking at the health care delivery system [with] a focus on implementation and spread" of HAI prevention interventions. A CMS federal stakeholder likewise discussed that agency's involvement in the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria and use of CDC's National Health and Safety Network surveillance system for data on HAIs in hospitals and other health care facilities. A leader of a consumer group agreed:

> Yeah [the HAI National Action Plan] was a step forward in collaboration, [even though] the action plan's goals were not met in the first round. . . . [I]n general, agencies work in silos. I've seen in my arena of patient safety a bit more collaboration among agencies than there was in the past, and that's a good thing.

However, the impetus for the HAI National Action Plan was a congressionally requested GAO report and subsequent hearings, which were partially motivated by consumer and other stakeholder agitation for progress on a rising HAI epidemic, and which criticized HHS for redundant research across multiple agencies. Of particular concern were redundant priorities

related to prevention practices and data systems for measuring and reporting HAI trends (Mendel et al., 2014). As recalled by a state-level health care industry leader:

> At one point, especially in the HAI space, it was pretty redundant. But . . . [the chair of Steering Committee for the National Action Plan to Prevent Healthcare-Associated Infections] had, through HHS, tried to bring together the partners, and I participated in some of those calls where they had CDC, they had AHRQ and CMS at the table to try to do some sense making internally. We've gotten better at that. I think at first everybody was just trying to, you know, rush there first.

In other instances, federal stakeholders identify and address emerging overlap in research portfolios on their own, such as with the example provided in Chapter 5 regarding the formation of a federal work group on PCMH research.

A leader of a consumer group offered another example illustrating how, once they are "around a table," federal agencies work to leverage areas of overlap in research portfolios with both other federal and nonfederal stakeholders:

> As a consumer, when I first met CDC, HRSA, the ASPE Office, AHRQ, NQF, we all came together around a table and it was amazing, as a consumer, that they didn't know each other. We thought that they worked together on solving problems, but we basically brought them together and then they identified the overlaps and they really leveraged those overlaps. But there was no real duplication, because everybody was doing it from their own angle.

Mechanisms of Coordination

As mentioned above, study participants often discussed overlap and coordination of research portfolios together. Here we describe formal and informal mechanisms that stakeholders reported using to coordinate federally funded HSR and PCR among agencies, as well as the dynamics of that coordination, areas perceived to have insufficient coordination, and challenges in coordinating HSR and PCR among federal agencies.

Formal Mechanisms of Interagency Coordination in HSR and PCR

TEP and interview participants described several formal mechanisms of coordination of HSR and PCR among agencies:

- Interagency steering committees and task forces
- Agency advisory committees and other processes for regular information sharing among agencies
- Project-specific advisory committees, roles, and coordination
- Federal departmental clearance process.

Interagency Steering Committees and Task Forces

Interagency steering committees or task forces are often the result of high-visibility policy issues of urgent concern. The steering committee for the HAI National Action Plan was spurred by growing concern among consumers, public media, and congressional leaders about the emerging HAI epidemic in the 1990s and early 2000s, as referenced above. A federal stakeholder described the current opioid crisis as spurring similar interagency coordination and research planning:

> So the opioid epidemic is really a major problem. The department identified it as a major priority, one of the Secretary's four priorities. There's been a lot of discussion across the department, across the agencies who is best situated to do study A. There's been research planning, if you will. Then there's communication among the agencies to drive it, develop coordination around the research enterprise, the data enterprise. . . . It's almost the forcing event in a way, in a positive way . . . such that we're coordinating in ways that maybe we would not have done before because we're accountable to the Secretary. . . . So that has helped us stay focused and collaborative.

Another federal stakeholder commented on how a congressional policy priority resulted in an interagency work group on diagnostic safety:

> Congress identified diagnostic safety as a high-priority area. And they essentially told AHRQ, "Please get together an interagency work group, so you all can work together and try to solve this problem, you know, and come back with recommendations."

In other instances, an agency might form such a workgroup after discerning that other agencies were beginning to fund research on an emerging topic, such as PCMHs:

> I think AHRQ has been seen [by] people within the department, we've reached out and they've reached back to us about primary care. So when we were doing PCMH work, we had a federal work group and we had almost every federal agency in that space coming regularly and talking about what they were doing and what their biggest questions were and AHRQ letting them know what we were doing and staying out of lanes and coordinating, aligning. It worked really well.

Agency Advisory Committees and Processes for Regular Information Sharing

Participating in standing advisory committees was another mechanism for staying informed about other agencies' research agendas and coordinating overlap. A federal stakeholder illustrated this mechanism through an example of a teleconference call for AHRQ's Advisory Committee.

> I was just on [AHRQ's] Advisory Committee call, and they're rolling out—identified three priority areas. I was just noticing that two of them are pretty close to things that we're working on, and so we're talking about collaborating. One of them was high cost or high needs patient. [Then] multiple chronic conditions. And then they are interested in improving diagnosis, and that's an area that some of our researchers have been leaders in, so we're thinking about trying to partner with them.

A federal stakeholder from ASPE described a process that the agency has implemented for regular consultation and information sharing with other agencies on mutual research interests and agendas:

> Every year we develop a research plan. We have a formal consultation process where we go out to visit each of our agencies. We talk with them about, "Here are some ideas we have about research projects we think might be of interest to you." They will ask us in turn about projects they would find it of interest to partner on with us, or for us to go do. We develop an annual research plan. It gets approved by our leadership, and then we put it into effect for the year.

Project-Level Coordination

Agencies also engaged in various project-level mechanisms to coordinate research efforts, including sitting on project-specific advisory committees and cofounding projects. A federal interview participant from AHRQ described the formation of federal steering committee for their recent EvidenceNOW project (Agency for Healthcare Research and Quality, 2019b) and its ability to manage and leverage overlap among agencies.

> For EvidenceNOW, we set up a similar kind of federal steering committee, which for the first few years and especially in the development phase was very, very active, you know, allowed us to make sure that our initiative and CMS's new payment models, that we were clear about who could participate and how we would not in any way hurt their evaluation plans. And, in fact, they gave permission and incorporated EvidenceNOW into their evaluation plans in the few places where there could've been overlap and encouraged people to do both their payment and our technical assistance support. NIH, specifically NHLBI, looked at our program very closely and helped us see that there was no overlap. They had one program, . . . but targeting a slightly different aspect of the issue. So really little worry about duplication and a lot of good coordination.

Researchers also cited experiences in which agencies coordinated dual funding of projects. Although members of the study's Federal Advisory Group mentioned the relative rarity and recent restrictions put on these arrangements, a health disparities researcher mentioned utilizing dual applications for funding between AHRQ and NIH, such as a study where "AHRQ had a study section that I thought was better suited to review the proposal, but NHLBI had the bigger budget. So I got dual submission and . . . it worked out perfectly." Another researcher described an experience in which the initial funding agency suggested a dual submission:

> I think they try not to overlap too much, [and] there is some collaboration. I was talking about silos before, but sometimes when I have submitted a grant, they will say, "This should get referred to another agency." And then we talk with the project officer ahead of time. They say, "You might want to have dual review." So if they have overlap, and then if you have a score . . . sometimes they'll scrape money together from both to get it done.

Departmental Clearance Process

As with many federal departments, agencies within HHS are often required to submit policy-relevant agency publications or programs for internal clearance and review by other agencies. As a federal stakeholder explained, although clearance typically happens after a research or evaluation project has been completed, it provides a "communication vehicle" for staying on top of other agencies' research portfolios.

> The [HHS] department clearance process itself is a way of coordinating what's happening. There's an interim communication process where agencies that are doing work send it into the department for possible review. And, oftentimes, we're learning and keeping in touch based on reports that are being released. AHRQ, every year, releases an annual report on disparities and quality [which] they release before to the department. . . . So we're part of that clearance process. That helps us keep up with what the agency is doing. All of our agencies are big. They're busy, and it's . . . impossible to keep on top of everything that they're doing. But that clearance process is a communication vehicle, if you will.

A federal stakeholder from CMS describes using the clearance process and other mechanisms, such as project-level participation in design teams, to coordinate with other agencies on the front end of developing a new CMMI payment model for demonstration.

> As we're thinking about the design of a new model, we start doing our scanning and figuring out, "Well, we need to touch base with this person. We need to touch base with that person." So as we're doing the design, we start reaching out. And often we'll have those partners or sister agencies . . . identify someone to help, sit on our design team. And for every model, we develop an Innovation Center Investment Plan . . . that goes through an official formal clearance throughout the agency and throughout the whole department. Most of the agencies that I've identified are all operating division within the Department of Health and Human Services, and so it gets cleared that way. And our sister agencies—not only are they working with us on the development of the model, they also get the opportunity to officially comment on the model and shape, what it looks like in that comment process.

It should be noted that such clearance processes are generally limited to agencies within a federal department such as HHS, and other mechanisms would have to be utilized to coordinate with agencies in other federal departments.

Informal Mechanisms of Interagency Coordination in HSR and PCR

Personal professional relationships of staff across agencies are often formed through work on formal interagency committees and mechanisms described above, as well as movement of staff among agencies. Federal stakeholders pointed to the importance of such personal staff connections and networks to identifying and coordinating potential areas of overlap in federally funded HSR and PCR.

> Personal relationships are really important. That's why we go out to meet with them, to help build personal relationships. We talk with agency counterparts throughout the year. You know, we have

> lots of opportunities to engage with our agency counterparts, and it's important that we do that and that we know them, and they know us. The first important thing is personal relationships. If it was just a paper process, it wouldn't work.

A different federal stakeholder illustrated how being able to "phone a friend" at another agency can be leveraged to connect to appropriate other contacts at that agency for particular projects or research efforts.

> The reality with any big, complex organization like HHS, having a personal relationship with the other side helps facilitate that relationship. And I know a handful of folks at AHRQ that are sort of my go-to people to call, handful of people at HRSA and the same with SAMHSA and other places that I call when I need to phone a friend. And then they help connect me to the appropriate person, but that happens in a bilateral fashion.

Dynamics of Interagency Coordination in HSR and PCR

The dynamics involved in agency coordination of a research topic are often governed by authorization from departmental leadership or policymakers, and the agency to which funding has been appropriated. As explained by two different federal stakeholders:

> Opioids is a good example where you have a specific act of Congress that authorizes or even authorizes and appropriates particular monies, and then [it's led] depending who it's appropriated to.
>
> The way this happens in the federal government is when there's an interagency committee, one agency takes the lead, but everybody has to report back on their work.

As explained by other federal stakeholders, other agencies become involved depending on the expertise or distinct value-added that particular agencies bring to the research topic.

> It depends on the topic . . . [and] the type of collaboration depends on the expertise of the sister agency. CDC has a pretty broad footprint, I might argue, around specific disease topics and we worked with other operational divisions and staff divisions, accordingly. Same thing with ACF or ACL, with respect to child health, the maternal and child health issues or community-based issues.
>
> Another way we work with [other agencies] . . . is we partner with them on things where we have value add, particularly around evaluations.

A member of the HSR TEP also described different ways agencies can coordinate their research efforts, such as by employing a divide-and-conquer strategy or more interactive collaborative approaches:

> What does "coordinate" mean exactly? I can see two very distinct streams. One is you divide up the territory and "coordinate" means we'll do this, you'll do this, and you'll do that. Or it can be much more truly interactive, like joint study sections, co-funding, getting people around a room like this and saying, "Not only is this the topic, but this is what we think are the right priorities for

> research under this topic, and so we're all going to sort of sing from the same hymn book on that."

Another member of the HSR TEP suggested that information sharing strategies more broadly can provide the foundation to proactively identify commonly worked research topics and eventually lead to various types of coordination.

> I was thinking about the definition of "coordinating" as well, and I think there's sometimes a third definition, it's the sharing of information. I know that CMS, underneath some of its patient safety work, brings together a lot of the different federal agencies, CDC, IHS, AHRQ, for monthly calls in which they share projects that they're working on and share information. I don't know that there's any coordination of the work. There's more information sharing, which is helpful, but I think, you know, a step further beyond that really is what's needed to make an impact. It could lead to coordination, ideally.

In response to these results, members of the study's Federal Advisory Group noted that the appropriate form of coordination in a research area is frequently a balance between formal and informal mechanisms, depending on the complexity and magnitude of the research topic and numbers of agencies involved. Formal coordination mechanisms from large interagency task forces to project-specific advisory committees may be necessary depending on the range of agencies and size of the research efforts being funded. However, the time and resources, as well as unintended risks of overemphasizing agency "turf" versus collaboration, involved with formal mechanisms may not warrant their use for all topics. When not specified by leadership or policy authorization, members of the Federal Advisory Group, like other stakeholders cited above, generally considered agencies adept at developing appropriate mechanisms of coordination—including formal and/or informal—to positively leverage overlap in portfolios for a given research topic or initiative.

Lack of Systematic Processes for Identifying Potential Overlap in Portfolios

Although TEP and interview participants generally agreed that agencies were inclined and able to coordinate research when overlaps in portfolios were recognized, a number of stakeholders commented that identifying overlaps to ensure coordination appeared to be, in the words of a leader of an accreditation organization, "sporadic attempts." Even the leader of the consumer organization who provided examples of effective interagency leveraging of overlaps described those efforts as "kind of accidental coordination" that occurred through instigation of consumer groups. A state-level payer stakeholder and member of the PCR TEP, respectively, offered similar perceptions:

> I think [coordination] is happening by happenstance—having been there—rather than by, "Oh, we'll own this, you own that."

> In my world, I know of many instances of interactions and collaborations. For example, NIA and PCORI co-manage the big initiative on falls and NIA has done a number of planned collaborative conferences with FDA and with CMS, but it's all anecdotal.

As a consequence, a member of the HSR TEP encouraged

> really thinking about, you know, what are the different strengths . . . as we look at that long list of federal agencies, what strengths do they bring to the table, and I don't think we need to be duplicative. I think that we can actually be complementary.

A consumer stakeholder also advocated for a common interagency approach for multiagency, multistakeholder research and improvement efforts to address the "big problems" of "a health care system that's uncoordinated" itself:

> I think as a nation, as we try to solve problems, one of the big problems in my opinion is that we have a health care system that's uncoordinated, a health care system that doesn't always address issues that matter to the patient population and that—my recommendation is that HHS, that they have an interagency approach to solving problems. But it has to be fluid and it has to operate with a sense of urgency. It needs to engage the patient community in that interagency. I think you know, when it's around a certain problem to solve—let's say it's sepsis or let's say it's the opioids or let's say it's newborn safety, I think it needs to be a multiagency, multi-stakeholder approach, where everything is coordinated. And that's just because like I could see it happen with good results. And we need from Congress way more money invested in this kind of research.

Instances of Insufficient Coordination

While TEP and interview participants stated that federal agencies were able to regularly resolve coordination issues on topics with identified overlap, they acknowledged instances in which insufficient coordination appears to have persisted. Several members of the HSR TEP identified the development of quality measures as a domain that, despite numerous past and current interagency and public-private sectors efforts, has remained difficult to coordinate. Other instances were noted only by single participants as areas they felt lacked sufficient coordination, such as broadly across the agencies addressing mental health and research on the specific issue of providers communicating critical test results to patients, although these were not mentioned by other participants.

Challenges to Coordination

Breadth and Volume of Research Activity

Among the many possible challenges to coordination within large organizations, TEP and interview participants highlighted three in relation to federally funded HSR and PCR. The first, as noted by a federal stakeholder, is the breadth and volume of research activity of agencies within HHS, let alone other departments:

> What are the challenges in coordination? One of the obvious one is it's a big department, and so there's lots of activity happening every day. And some things that may be very meaningful on one particular day for an agency may be relevant, you know, three weeks down the road to us. And so there's lots of productivity in the department. And being able to track all that is always a challenge in a big organization.

Differing Time Frames of Research Across Agencies

The second challenge noted by a another federal stakeholder concerns differing time frames of research among agencies, including the time lag between the identification of research needs and the production of results:

> And one of the challenges is more rapid cycle research. The older HSR paradigm of brilliant researchers discover problems, study and learn about it for a year, write a grant application a year and a half later, get money to study it five years later, finish their study, take a year to write it up, and it gets published. That's seven or eight years. That's not what HRSA and SAMHSA and IHS need. We've got to be able to shorten that cycle . . . PBRNs or AHRQ's ACTION Network are great potential examples of how that could be done. But learning systems where we can say here's the problem, find a solution, set a bunch of people on it and a year later being able to say here's some preliminary things that look like they're working, and two years later being able to say now we know this. . . . Two years may be too long still for some policymakers, but it's a heck of a lot better than the eight-year cycle we're in right now.

Lack of Targeted Funding for Coordinating PCR

The third challenge concerns the lack of targeted funding for agency coordination of PCR. For example, a member of the HSR TEP stated that, although AHRQ is the designated lead agency for PCR, it does not receive resources for that mission (see also Chapter 3), which inhibits its ability to coordinate the domain with other agencies that fund PCR:

> NIH doesn't have a primary care center. CDC is interested in primary care to the extent that it's about prevention and public health, but that's not the whole primary care. HRSA has the workforce part of primary care, but that's just the workforce. That's not the services that are delivered. The VA probably comes closest, because it actually is a deliverer of primary care and funds research on effective primary care delivery, but that's just the VA and just veterans. I guess, AHRQ is the lead agency . . . named the lead agency, but there are no resources attached to it to carry out that mission. And I don't think that AHRQ [can] convene all of the other agencies to talk about their primary care interests.

Chapter Summary

Study participants across various stakeholder groups emphasized the value of complementary overlap in research portfolios across agencies, if properly coordinated. Several interview participants pointed to coordination of research portfolios as a more problematic issue than redundancy. Participants observed that agencies acted to address redundancy in research portfolios and worked to ensure that funding of research reflected the distinct roles and value-added of each agency after such redundancies have been recognized. Participants also observed

federal agencies to be adept at utilizing appropriate and effective mechanisms for coordination, including formal and informal mechanisms, once overlaps in portfolios have been recognized. Informal coordination mechanisms include personal staff connections and networks and were considered critical facilitators of formal coordination.

However, study participants commented on the lack of systematic processes for proactively identifying potential overlap in HSR and PCR portfolios across agencies. The process of discovering overlaps was said to be "sporadic," "accidental," or "anecdotal," and to occur "by happenstance." Individual study participants also noted research areas they considered to lack sufficient coordination. Challenges to coordination of HSR and PCR portfolios mentioned by study participants included the breadth and volume of research activity across the federal HSR and PCR enterprise, differing time frames of research among agencies, and the lack of targeted funding for a lead agency to coordinate PCR in particular.

5. Impacts of Federally Funded HSR and PCR

Health services and primary care in the United States are complex, multilevel, and layered systems in which the process of change is not always well understood, and effecting positive change often requires leveraging multiple strategies. Understanding how HSR and PCR can and have had impact on these systems is important for assessing the contributions of federally funded research to the fields of HSR and PCR and for informing the prioritization of research gaps. We asked TEP and interview participants to describe the types of impact that HSR and PCR can have and to discuss challenges in defining and assessing this impact. Through discussions with study participants, we learned of examples of federally funded HSR and PCR studies that had clear impact, as well as the many challenges in measuring and achieving that impact.

This chapter is organized in three sections. First, we describe different *types* of research impact based on both discussions with study participants and existing frameworks of impact. Next, based on feedback from the study participants, we describe challenges to *assessing* research impact; and, finally, we describe challenges to *achieving* impact of HSR and PCR.

The findings presented in this chapter do not represent a complete catalog of the impact of federally funded HSR and PCR, which would have been beyond the scope of this study. However, the examples provided throughout this chapter demonstrate key types and mechanisms of impact, which are useful for understanding and assessing the impact of HSR and PCR portfolios.

Defining Types of Research Impact

Study participants emphasized various kinds of impact generated by HSR and PCR. Many of these correspond to types of research impact that have been specified in existing frameworks for HSR and PCR (Buykx et al., 2012; Kuruvilla et al., 2006; Centers for Disease Control and Prevention, 2017a; Donovan and Hanney, 2011). We synthesized these impact frameworks and themes from the TEP and interview discussions to identify the following six categories of HSR and PCR impact:

1. **Scientific impact.** Knowledge generation, research methods, capacity building, training, and leadership.
2. **Professional knowledge and practice impact.** Education and training curricula, professional certification, and clinical guidelines.
3. **Health care systems and services impact.** Quality of care and service delivery, improved information and health services management, cost containment and effectiveness, resource allocation, and health workforce.
4. **Policy impact.** Information base for political and executive decisionmaking, influence and involvement in decisionmaking processes.

5. **Patient impact.** Patient and family experience of care; health literacy; health knowledge, attitudes, behavior, and outcomes.
6. **Societal impact.** Population health, trust in health care, economic productivity, employment benefits and income.

It is unlikely for individual research projects to generate impact across all the above categories, and, as study participants pointed out, the impacts of specific projects may not always occur in a linear order. For example, a project may have scientific impact and generate new knowledge, which might in turn have an impact on policy, but not on clinical guidelines or health care systems and services. Further, because these impact categories are quite broad, it will likely be necessary to identify subcategories within these categories as well as to identify metrics that can be used to measure impact; thus, we expect that the combination of impacts from any study or line of research could vary in multiple ways.

But, as explained in several of the cited research impact frameworks, the types of impacts identified represent a progression from interim research impacts (i.e., on scientific knowledge, professional practice, health care systems, and policy) to direct outcomes for patients and wider outcomes for society. As such, the categories represent a general guiding framework for assessing the accumulated impact of portfolios of research within an agency or that span agencies.

Below we describe the six categories of impact and illustrative HSR and PCR examples of each. We then provide case illustrations of two research areas—HAIs and PCMH (related to HSR and PCR, respectively) that describe the accumulation of research impacts through various coordinated efforts across agency portfolios over time.

Scientific Impact

Study participants described research impact—as it is traditionally conceived by the research communities—through indicators of knowledge generation. For example, members of the HSR TEP suggested a "Hall of Fame" measure for assessing impact that includes publication in high-impact journals, number of citations, and altmetrics scores (Azer and Azer, 2019), as well as citation in influential reports, such as those produced by the National Academy of Medicine. Others focused on development of a research "method or some way of [conducting] services research that would change the future of HSR."

Scientific impact in the areas of HSR and PCR may include not only knowledge generation, but research methods and capacity training as well. For primary care, scientific impact has often taken the form of foundational knowledge that laid the groundwork for future practice transformation and model creation. Multiple state-level delivery systems leaders, PCR TEP members, and other interview participants identified various research streams with scientific impact, including Bodenheimer's work on the building blocks of effective primary care (Bodenheimer et al., 2014), ecological studies from Starfield on the benefits of primary care being greater than the sum of its parts (Starfield, Shi, and Macinko, 2005b), Milstein's work on aspects of high-performing primary care (Simon et al., 2017), and Stange's research on the direct

observation of primary care that laid the groundwork for understanding its complexity (American Academy of Family Physicians, undated).

Professional Knowledge and Practice Impact

Multiple HSR TEP, research, and other stakeholders emphasized the professional and practical impact of research that is seen when research findings are incorporated into clinical guidelines as a conduit toward change in clinical practice:

> The thing that I think about is impact on guidelines, right? Do professional societies, you know, are they interested and is there uptake of the evidence by professional societies or other decisionmakers or payers?

PCR TEP members and a delivery leader interview participant identified the Systolic Blood Pressure Intervention Trial (NHLBI, undated) and the Action to Control Cardiovascular Risk in Diabetes studies (Action to Control Cardiovascular Risk in Diabetes, 2019) as examples of HSR projects directly leading to changes in guidelines and ultimately clinical practice. The Women's Health Study was highlighted by the same delivery systems leader as having had an impact on the use of estrogen therapy in practice. Researchers also highlighted important use of research in changing guidelines, though more often pointing to a body of work rather than a specific study (e.g., use of research by CDC's Advisory Committee on Immunization Practices; clinical guidance on management of strokes, myocardial infarctions, blood pressure, and cholesterol).

Professional societies were mentioned by several TEP members as an important route for impact, first via clinical guidelines and then ultimately by changes to practice. One HSR TEP member noted the potential impact of research on professional knowledge and practice through the inclusion of research findings in professional education curricula and training: "Something is the gold standard if it's the way that we train medical students, residents, nurse practitioners, nursing students . . . are the findings from an HSR study or an HSR program, to what extent are those embedded in training?" However, this potential is not always realized as, for example, "medical school faculty don't teach it well [or] don't teach it all."

Health Care Systems and Services Impact

A range of stakeholders emphasized changes to health care systems and services as a critical impact of HSR and PCR. These stakeholders included not only health care delivery leaders, but federal, state-level, researcher, and other stakeholders as well. At the most granular level, changes to health care systems and services might mean thinking about the impact of research in terms of practice models. A number of studies or avenues of research were cited as having particular impact in the area of practice models and practice transformation, especially some related to primary care practice. Both an employer/payer and a delivery system leader stakeholder noted the impact of microsimulation modeling studies that helped build the business case for practice transformation. Finally, the continued development and penetration of primary

care medical homes were cited as indicators of high impact by researchers, state-level representatives, and others.

Stakeholders also noted the importance of understanding the level to which health care systems have been informed by research, resulting in changes in systems structures and programs and in approaches used by those directly involved in the delivery of care. In the words of a state hospital association stakeholder:

> [A]s a health services researcher, I want to be able to answer how does this improve access, how does this improve the quality of care, and how does this reduce the cost of care? So when I'm doing this work in that space, those are the three questions that I better be able to answer. And when it's translated down to implementation, that's where you really ultimately see [the impact].

Similarly, a member of the HSR TEP focused on uptake and use of evidence-informed practices as a measure of research impact on health care systems: "Rather than just the effectiveness of an intervention itself, look at the effectiveness of the uptake and the effectiveness to which it's been adopted or actually changed system practices." This could also be described as "the degree to which the finding [becomes] 'hard wired' into practice." This change could occur literally, such as when a clinical pathway is incorporated into an EHR order set that clinicians use, but could also refer to various changes in organizational policies, processes, and norms of care that occur indirectly. Other impacts in this vein, as suggested by a state-level stakeholder, include reduction in provider burden and increase in the efficiency of medical practices.

To achieve the uptake and use of HSR and PCR findings, one federal stakeholder pointed to the need for research evidence to reach "implementers," including but not limited to health systems administrators, quality improvement professionals, and clinicians. At the same time, delivery system leaders highlighted the importance of researchers producing evidence on new practice models and innovations that health care systems are trying to implement or are considering implementing. In the words of one delivery systems leader, both these goals are attainable through close collaboration between researchers and health care system stakeholders:

> You have to work with health service providers and health system people and managers and implementers, . . . they hold some of the impact keys as well as the researcher, right? So the trick is how do you measure your contribution in terms of that meaningful impact? I think you have to do it in terms of does health services research result in beneficial changes done by managers or health system people, right? You actually see changes in decisions that are made as a result of any research findings that you're producing.

A federal research leader described how his agency has changed its approach to study proposals and design to encourage researchers to build in linkages to health service uptake and impact earlier in the development of projects:

> We're refining our applications to spell out more clearly what they see the next steps of their proposal to be. We're replacing what used to be a fairly bland dissemination and implementation section with something more specific about what would really be needed to convince a stakeholder to actually take any action based on the research. So is the study going to be sufficient, or would you have to take a single center study, to study it in a multicenter study and learn more about the implementation? Would you have to do a budget impact analysis? But to force them to think in ways they don't always think about what the obstacles might be for the research making a difference.

A representative of a state-level safety net association further highlighted thinking about impact in terms of building relationships between health care delivery organizations and research collaborators: "It's something that increases knowledge, gives us an opportunity to learn new things, and allows for development of relationships so that then there's a resource later on. So in some of these research things that we've worked on with [the state university], it's built relationships with people that are then resources for us when we need some other information." Likewise, a member of the HSR TEP stressed "partnership with industry or industry uptake" as a type of impact.

Policy Impact

Policy impact—meaning changes to policy with the goal of ultimately improving health care—was identified as an important aspect of impact by both TEP and interview participants. A representative of a state-level improvement organization emphasized the importance of policymaker awareness, with a first step being to "turn up the volume about the need to pay attention." Federal stakeholders and TEP members also highlighted the influence of research on both legislative and regulatory policy. As one federal stakeholder commented, "We're trying to work with our contractors around keeping in mind that the audience is not always the research community. It's the policymaking community, so we need to be able to have multiple ways of communicating."

A member of the HSR TEP encouraged keeping a "broad" view of policy in considering the impact of research, including a "Supreme Court or any court decision," as well as federal program and private policymaking bodies, such as "CMS conditions of participation . . . the Joint Commission, for instance, if they change something based on HSR, or some national patient safety goal." TEP members and federal and other policy stakeholders also pointed to the role of research in developing quality measures that are subsequently incorporated into federal quality reporting and value-based payment programs, such as the Medicare Advantage Star rating system.

Many interview participants and TEP members cited examples of impact at the federal or state level that resulted either directly or indirectly from HSR, such as aspects of the Affordable Care Act that were inspired by work in HSR. The TEP also noted that the funding and development of alternative payment models have embedded a vehicle for change into the health care system.

Two other interview participants noted that continued work in these areas, including evaluation, has had impact as well.

A variety of examples of policy impact were at the state level. TEP participants and interview participants cited projects that influenced state-level initiatives, such as the Alternative Quality Contracts in Massachusetts, which was informed by work on quality measurement, pay for performance, capitation, and global payments. Another state-level representative highlighted research used by policymakers in Maine to expand Medicaid coverage, while yet another identified the use of research on postpartum depression to push state legislatures to implement voluntary home visits for newborns and their mothers in their state.

Patient Impact

TEP and interview participants also focused on HSR's and PCR's impact on patients, as one HSR TEP member commented, "The patient-related impact is separate and should be counted." Several researchers and TEP members described this as impact that was "meaningful" to patients. One researcher specified impact in terms of an increase in patient knowledge, which leads patients to become better consumers of health care. Interview participants from varied backgrounds, including consumer, federal, and research stakeholders, conceptualized impact on patients more broadly, citing improvement in patients' general health, patient-centered outcomes such as quality of life, and patient safety.

In the area of PCR, one researcher interview participant cited recent NIH-funded work by Levine and colleagues that found that patients with any source of primary care reported significantly better health care access and experience (Levine, Landon, and Linder, 2019). In addition, AHRQ's patient safety portfolio (discussed in more detail later in this chapter) was repeatedly noted as having had impact as a body of work that ultimately translates into safer and better care for patients.

Societal Impact

In terms of societal impact, study participants focused mostly on population health. As one health care delivery leader stated, "Ultimately, impact should be measured in improved health." Other health care delivery and state public health and hospital leaders talked about the "Triple" or "Quadruple Aim" in terms of how other health care system impacts result in improved population health:

> We're funding health research. So we actually have to produce health, right? So the impact is about health. It is about the triple aim or the quadruple aim. It's actually how do you produce health in a way that's affordable, in a way that . . . it's a reasonably pleasant experience for people, and that is doable by a workforce.

A member of the HSR TEP also pointed to broad impact of HSR and PCR on "not just [the] patient, but the general public, . . . because there are lot of issues about trust in the health care

system, the people who may or may not even see the doctors, that is needed to influence health in a positive way." One specific example in the area of primary care and societal impact was cited by a researcher interview participant who highlighted NIH-funded work showing that a greater supply of primary care physicians is associated with improved mortality (even as the supply of primary care physicians declined per capita over the same ten-year period).

Case Illustrations of Impact in HSR and PCR

In the next section, we describe two major examples in HSR and PCR that illustrate the accumulation of different types of research impact delineated above, often involving coordinated efforts, across agency portfolios over time. The choice of the two case illustrations—HAIs for HSR, and PCMH for PCR—were informed by themes that emerged consistently from both the TEPs and interviews.

Healthcare–Associated Infections

HAIs, particularly those developed during hospitalization, represent a major patient safety concern with significant effects on health at both the public and personal levels. For years, before HAIs were publicly recognized as a major and ultimately preventable problem in health care, the epidemiological and infection control communities had been working on this issue (Mendel et al., 2011). These communities generated ***scientific impact*** by developing the basic scientific understanding on the microbes and pathology associated with HAIs, assessing the current public health surveillance systems and methodologies for monitoring HAI rates, and creating a host of guidelines and prevention practices, which became the first HAI prevention toolkits to have ***professional knowledge*** and ***practice impact.***

In the early 2000s, two other historic forces drew attention to HAIs: (1) public awareness campaigns spearheaded by consumer groups advocating action to address the growing HAI epidemic and, (2) the patient safety movement to reduce patient harms experienced during receipt of health care. These forces culminated in a 2008 report by the GAO (Government Accountability Office, 2008) and subsequent congressional hearings on the need for federal coordination that catalyzed an interagency HAI Action Plan and set the stage for changes in policy, funding, and stakeholder engagement.

Within the realm of HAIs, central line–associated bloodstream infections (CLABSIs) provide a clear example of how federal agencies and other entities can collaborate to fund research with the potential for impact at all levels of health care. As noted above, there was a solid scientific evidence base indicating that CLABSIs could be prevented, including a landmark study from Pronovost et al. (2006). In addition to its clinical guidelines on CLABSI prevention, CDC developed a measure for CLABSIs that could be collected through the National Healthcare Safety Network (Centers for Disease Control and Prevention, 2017b) (***scientific impact, professional knowledge and practice impact***). Meanwhile, AHRQ—working in collaboration with private

philanthropic entities—funded the Comprehensive Unit-Based Safety Program (CUSP)—a strategic framework for safety improvement that integrates communication, teamwork, and leadership with evidence-based clinical prevention practices—to address CLABSIs, as well as other HAIs. The program was cited as a "measurable national success story in quality improvement" (Pronovost, Marsteller, and Goeschel, 2011). Between 2001 and 2009, CLABSIs dropped by 63 percent (Centers for Disease Control and Prevention, 2011). Empirical research found that more than 1,000 intensive care units across the country reduced CLABSI rates by a total of 41 percent when they used tools based on CUSP to improve patient safety (***health care systems and services impact***) (Health Research & Educational Trust, 2012).

The results from the CUSP program, and other patient safety work funded by AHRQ, would later inform CMS policy around value-based payments for CLABSIs (***policy impact***) (Centers for Medicare and Medicaid Services, 2019b). Currently AHRQ, CMS, and other stakeholders are working together to ensure ***patient*** and ***societal impact*** through the Partnership for Patients to improve the quality, safety, and affordability of health care through the reduction of Hospital-Acquired Conditions (including HAIs) (Centers for Medicare and Medicaid Services, undated-c). In 2019, the National Scorecard on Rates of Hospital-Acquired Conditions estimated that from 2014 to 2017 hospital-acquired conditions fell by 13 percent, saving about 20,500 lives and about $7.7 billion in healthcare costs (Agency for Healthcare Research and Quality, 2019c).

Patient-Centered Medical Home

The PCMH is a model of primary care that attempts to operationalize the core functions and attributes of primary health care (i.e., being comprehensive, patient-centered, coordinated, accessible, and focused on quality and safety) (Agency for Healthcare Research and Quality, undated-a). This model is based on findings from a large body of research in primary care, including prior work defining primary care (World Health Organization, 1978; Institute of Medicine Committee on the Future of Primary Care, 1996; Starfield, Shi, and Macinko, 2005a; Green et al., 2004) and precursor models (Bodenheimer, Wagner, and Grumbach, 2002; Murray, 2005; Ad Hoc Task Force on Definition of the Medical Home, 1992; Grumbach and Bodenheimer, 2004; The Robert Graham Center, 2007). In 2007, four medical professional associations in primary care developed and endorsed the *Joint Principles of the Patient-Centered Medical Home* (American Academy of Family Physicians, 2007).

In 2010, findings from the country's first national demonstration of a PCMH model, consisting of 36 family practices over two years, provided the first national-level evidence documenting the successes and challenges of PCMH implementation (Stange et al., 2010). This privately sponsored study spurred further diffusion of the model (***health care systems and services impact***) and research into PCMH implementation and outcomes (***scientific impact***).

Since then, there have been significant investments of federally funded PCR into PCMH implementation and outcomes. AHRQ has funded a variety of PCMH research, including three major grant initiatives "to understand the challenges faced by primary care practices as they

transform into PCMHs and to help create an infrastructure to assist them with this transformation"—the first on primary care transformation, the second on infrastructure to support transformation, and the third on costs of supporting transformation (Agency for Healthcare Research and Quality, 2015). The agency has also served as a clearinghouse for dissemination of PCMH resources, including definitions of the PCMH model, tools for implementation and practice facilitation, evidence and evaluation findings, guidance on evaluation methods, and a searchable database for additional resources (Agency for Healthcare Research and Quality, undated-h) (***scientific impact, health care systems and services impact***).

AHRQ additionally established a federal interagency workgroup, the Federal PCMH Collaborative, for agencies across the federal government to share lessons and research findings on PCMH implementation as well as coordinate federal research, dissemination, and implementation efforts. The wide range of these efforts conducted by other federal agencies has included the VHA's and DoD's large-scale implementation of the PCMH model in their respective health care delivery systems (U.S. Department of Veterans Affairs, 2019b; U.S. Department of Veterans Affairs, 2011), HRSA's technical assistance and funding programs to support PCMH adoption among FQHCs (Health Resources and Services Administration, 2018), CMS's CPC and other alternative payment models for PCMH-based care (Centers for Medicare and Medicaid Services, 2019a, 2019b), and OMB's integration of the PCMH into employee benefit plans. As an example of federal collaboration on PCMH efforts, a federal interview participant described how the workgroup facilitated AHRQ's engagement with CMS to help inform the development of the CPC payment demonstration and evaluation (***scientific impact, health care systems and policy impact***).

Over the past decade, PCMH-influenced models of care have proliferated in private practices across the country (Jackson et al., 2013; Edwards et al., 2014; Nielsen, 2016). This proliferation has been encouraged by formal PCMH certification programs for primary care practices offered by accreditation organizations (Burton, 2012), as well as the wave of federal, state, and multi-payer payment reform initiatives that often incorporate incentives for PCMH models of care and certification (e.g., Centers for Medicare and Medicaid Services, 2019a; Primary Care Collaborative, 2019b; Primary Care Collaborative, 2019a) (***policy impact, health care systems and services impact***).

Studies documenting PCMH transformation and outcomes—many of which have been federally funded—have likewise multiplied (Agency for Healthcare Research and Quality, undated-g). Findings indicate that transforming primary care is challenging (Martsolf et al., 2015; Crabtree et al., 2010). There is evidence that practices of transformation vary in how they put the concepts of PCMH into practice (Rittenhouse et al., 2013; Solberg, 2011; Tomoaia-Cotisel et al., 2016), and that implementation can improve outcomes such as cost, quality, and patient satisfaction (Friedberg et al., 2014, 2015; Strickland et al., 2011; Rosenthal, 2008; Shi et al., 2017; Farrell et al., 2015) (***health care systems and services impact, patient impact***). Federally funded PCR has also helped to improve and develop

methods for studying PCMHs (Miller et al., 2013; Tomoaia-Cotisel et al., 2013; Devers, 2013) (***scientific impact***).

Beyond primary care service delivery systems, educational institutions have been increasingly focused on strengthening "interprofessional practice and education" (Nester, 2016) (***professional knowledge and practice impact***) in part because of team-based care at the core of the PCMH model. Medical home-type implementation and certification have begun to be adapted into specialty settings as well (National Committee for Quality Assurance, 2017) (***health care systems and services impact, policy impact***).

Challenges in Assessing the Impact of HSR and PCR

In addition to describing types of impact, study participants were asked to discuss challenges in assessing the impact of HSR and PCR. Three themes that emerged from these discussions were the difficulty in attributing impact, the lengthy time delay to observing impact, and the difficulty of measuring some types of impact.

Difficulty in Attributing Impact

Many TEP participants noted that the complexity of health care systems and the complex ways in which research findings are translated and implemented in such applied fields as HSR and PCR make it difficult to attribute impact to any one study. As one PCR TEP participant explained:

> If you think about a lot of health services research, it ends up being a cumulative body of evidence that might influence things, as opposed to saying this one study. . . . [I]n general, in health services research, we end up accumulating evidence that ultimately will have an impact from the design limitation and evolution of programs and policies. But it's hard to attribute something to one particular spot, or one particular study. So that part is incredibly challenging.

Thus, as one state-level insurer representative noted, although it is important for health service organizations, such as health plans, to ground changes in specific research evidence, the best evidence is rarely provided by the findings of a single study but rather by a body of studies.

Patient safety was identified by multiple interviewees (including researchers and federal stakeholders) and the HSR TEP as an important and impactful area of work that could not be tied to any one particular research study or project. Although there were identifiable landmark demonstration projects—such as Pronovost's and colleague's studies on preventing CLABSIs and other HAIs using the CUSP change methodology, as discussed above (Pronovost, Marsteller and Goeschel, 2011)—study participants noted significant strides in patient safety improvement over recent years that were difficult to pinpoint to a specific research project or newly demonstrated practice.

Likewise, although individual studies may have proximal impacts on health care research, policy, and practice, multiple TEP participants and interview participants, including federal and other policy stakeholders, agreed that it is most useful to assess impacts at the level of research portfolios in order to evaluate the results of research investments and needs for further funding. Another federal stakeholder observed the role of evidence review and synthesis in aggregating, assessing, and amplifying research findings across studies; doing so quickly and efficiently, given health care systems' rapidly evolving needs for new evidence is important for shortening the time to impact for HSR and PCR (Guise, Savitz, and Friedman, 2018).

Time Delay to Achieving Impact

HSR TEP participants, as well as multiple interview participants (including state-level stakeholders, delivery systems leaders, and others), noted that impacts of federally funded HSR and PCR are often realized after various time delays, making it challenging to assess the impact of a particular research project. One reason given for how a delay can affect the assessment of impact is that the consequences of the intervention may take longer to manifest than the life of the project. A delivery leader interview participant cited practice transformation evaluations as a specific area where this challenge has manifested:

> They tend to report results of two years of work or three years of work and that's really too short a period of time to document the benefits of transformation. It's really a five- or eight-year project and we don't have the robust federal funding to do rigorous drilldowns into the impact of transformation.

Another interview participant noted that research findings are often implemented slowly and/or gradually, lengthening the time required to observe an impact. The same participant mentioned that the dissemination and impact of more comprehensive primary care practice models have been delayed due to the slow pace of change in payment policy.

Study participants also discussed ways in which the context for implementation sometimes changes before research findings are broadly implemented. For example, a consumer interview participant commented that research findings are occasionally out of date by the time guidelines are released.

Delays can affect all types of impact including: professional and practice impact, policy impact, patient impact, and societal impact. One researcher interview participant mentioned that improvements in social phenomena such as stigma are especially prone to delayed impact and thus challenging to study.

Difficulty in Measuring Impacts

Some types of impact are relatively easy to measure and assess. For example, data on traditional scientific impact measures (e.g., numbers of citations, journal impact scores) are readily available. Similarly, study participants noted the vast amount of publicly available data

on health outcomes collected and provided by CDC for the public at large, as well as by CMS and the VHA on the large populations they serve. However, similar types of standardized sets of measurement and data infrastructure are not available to describe the impacts of scientific knowledge generation on health outcomes, particularly for health systems and services impact. As observed in the HSR TEP, the uptake, adoption, and use in practice of new evidence-based practices are "harder to assess" and, even if measured, the data are typically "proprietary" to specific health care organizations.

Challenges in Achieving Impact of HSR and PCR

In addition to challenges in *assessing* impact, study participants reported challenges and barriers to *achieving* impact of HSR and PCR. Two general challenges raised were the lack of investment in high-risk research and disconnects between research and implementation. Similar issues emerged in the discussion of gaps in research approaches (see Chapter 6).

Lack of Investment in High-Risk Research

Some interview participants mentioned that the lack of investment in high-risk studies can dampen impact; particularly as such studies may be those with potential for the highest impact. Such studies might be similar to those funded by the NIH Pioneer Awards (which, to date, have typically focused on basic science), which are projects at high risk of poor or null results but that also have potential for high reward in terms of the gain in knowledge and practice. One policy expert interview participant noted that

> a lot of the investment is probably not on the highest-risk, highest-potential value, highest-impact studies. They suffer from the same things that folks have leveraged against other NIH funding that you just do safe studies that are very incremental that don't really contribute that much to care improvement, but they add a little bit of added knowledge or some nuance.

Disconnects Between Research and Implementation

Multiple interview participants stated that research impact was limited because it is partially determined by the dissemination and implementation of research results, yet there is a disconnect between research and implementation. This issue was brought up by delivery system leaders, researchers, and state- and federal-level policymakers. One policy expert interviewed stated that lack of investment in infrastructure and practice change means this topic is understudied, which results in difficulty in putting research into practice. A delivery leader on the HSR TEP stated: "Our biggest challenge is how do we get our clinical teams to adopt new practices? . . . [There are] subtleties to the information you present to them."

Sometimes the failure to translate research results into practice was due to a disconnect between *statistical significance* and *clinically meaningful significance*. One delivery leader noted that the size of a statistically significant effect should also be taken into account in considering

whether or not to adopt an intervention, such as this example related to diabetes control: "Patients had statistically significant reduction in A1c over the course of a year, but it was by 0.1 . . . that's not clinically significant."

Multiple interview participants also noted that the incentives are not well aligned between researchers performing research and organizations implementing research, and, as a result, the two groups often do not communicate well with each other. Academic-based research in particular was viewed as frequently being driven by interests different from what may be needed in practice:

> The ecosystem that supports that environment is a very particular ecosystem that requires a very well-defined set of actors and processes. So it requires individuals who are pursuing academic advancement that need federal grant support typically, in order to achieve academic advancement, they need to write papers. They need to get grants funded. And that is a very different environment from the environment around care being actually delivered to real people, real time and how that care can be improved.

At the same time, a state-level interview participant noted that policymakers often are less interested in hearing about research evidence and more about stories of success, which may be at odds with the results produced by the research community. Specifically, policymakers may make decisions based more on the experience of others: "Policymakers want to be aware—they kind of move in packs. So if they've heard that one state has done this, they will try it themselves."

Implementation issues may also relate to the business case for adopting evidence-based interventions among health care stakeholders. Three HSR TEP members noted that challenges arise when benefits and costs accrue to different entities:

> You know, it's easy to show that delivering some service now will prevent money later. . . . But the entity providing it now and incurring the cost is one thing. It may be the same entity down the road, but it's different people. So the savings won't accrue to that entity, or it may be a different entity down the road, and so now you're talking about, you know, why does that initial entity not implement the results of this wonderful study. Well, yeah, they're going to lose their shirts if they do.

In interviews, consumer stakeholders noted that the disconnect between research and practice implementation could to some degree be due to lack of engagement by patients and frontline providers in both HSR and PCR, resulting in research that is less relevant and usable for change:

> I think a lot of the health services research could be more effective and more impactful if the funders were to engage the patient and consumer community as decisionmakers in what gets funded. And that I think more patients and consumers and caregivers need to be engaged as partners in the research that is funded, because I have seen a lot of research that answers research questions that matter to researchers. And I think that it's—it doesn't always serve . . . it doesn't always answer the questions that matter most to patients.

Lastly, TEP and interview participants identified certain limitations on agencies' ability to facilitate the impact of the research they sponsor. One federal agency representative noted that agencies have a very specific "lever" that they can pull, which may limit the potential impact of sponsored research, especially if an agency encounters difficulties coordinating with other agencies on a topic. Researchers from both interviews and the HSR TEP noted that contracted research has the benefit of quicker turnaround but may not necessarily be published and available to the wider field through standard channels. A few HSR TEP members and interview participants (both federal and state-level) noted that agencies are sometimes reluctant to promote findings that are perceived to be politically sensitive. Moreover, as noted by a federal interview participant, political decisionmaking processes beyond the influence of agencies frequently determine whether research findings are translated into policy change and impact. Finally, a HSR policy interview participant as well as several HSR TEP members perceived that agencies, and AHRQ specifically, could improve their efforts to inform policymakers of both the implications as well as the impact of their funded research.

Chapter Summary

Health services and primary care in the United States are complex, multilevel, and layered systems in which the process of change is not always well understood, and effecting positive change often requires leveraging multiple strategies. Understanding how HSR and PCR can and have had impact on these systems is important for assessing the contributions of federally funded research to the fields of HSR and PCR and for informing the prioritization of research gaps.

Based on existing frameworks of research impact as well as discussions with TEP and interview participants, we identified six categories of impact, which we illustrated with examples of federally funded HSR and PCR: (1) scientific impact, (2) professional knowledge and practice impact, (3) health care systems and services impact, (4) policy impact, (5) patient impact, and (6) societal impact. It is unlikely for a single project to generate impact across all categories, and the impacts of specific projects may not always occur in a linear order. However, the types of impacts identified represent a progression from interim research impacts (i.e., on scientific knowledge, professional practice, health care systems, and policy) to direct outcomes for patients and wider outcomes for society. As such, they represent a general guiding framework for assessing the accumulated impact of portfolios of research within an agency or that span agencies.

In addition to identifying types of impact, study participants noted important challenges to assessing impact, including the difficulty of tracing the accumulation of impacts across specific projects or sets of projects within a portfolio, especially when research is funded by multiple

agencies. Impact may take time to accumulate and be realized, which further complicates attribution to specific projects or sources of funding. Moreover, many types of impact are by their nature difficult to systematically measure. Study participants also called attention to challenges in achieving HSR and PCR impact. These barriers included a lack of investment in high-risk studies and various disconnects between research and implementation.

6. Research Gaps and Prioritization of Federally Funded HSR and PCR

One of the study's key research questions focuses on identifying research gaps—understudied or underfunded areas in HSR and PCR that, if addressed, would move the fields forward and enhance the various research impacts as described in the previous chapter. While gaps indicate needs for research that HSR and PCR has yet to fully address, they also represent opportunities to find new ways to use research to solve problems and improve the health care system, and ultimately the nation's collective health. The wide range of research gaps described in this chapter were elicited from both TEP and interview participants.

In this chapter, we first present key gaps in HSR and PCR as defined below, including cross-cutting gaps in research approaches, as well as those specific to HSR and PCR, respectively. A comprehensive ranking of HSR and PCR gaps was beyond the scope of this study, especially given the broad range of gaps identified by participants. At the same time, study participants and Federal Advisory Group members emphasized the need to prioritize research gaps to more effectively and efficiently allocate limited research funding. Toward this end, the last section of the chapter offers potential criteria and mechanisms for prioritizing research gaps.

Overview of Gaps Identified by Technical Expert Panel and Interview Participants

Many gaps are related to specific "inputs" and "outputs" of health care services in the study's research domain framework (Figure 2.1). For example, gaps related to health care inputs include gaps in understanding the Organization of Care, such as the needs to identify barriers to implementing new models of care or to understand the workforce needed for these models. Gaps related to health care outputs include lack of adequate quality-of-care measures for certain services or outcomes.

However, many gaps in HSR and PCR reflect the *complexity* of the health care system and the difficulty of understanding the *linkages between health care inputs and outputs* to produce important outcomes, for example, the need to better understand the effects of new financing and delivery models on costs and quality of care, or of interventions to address the social determinants of health on health outcomes, costs, and equity. Moreover, other critical gaps identified by study participants relate to research approaches and to the ability to generate and disseminate evidence in ways that positively impact real-world health care systems and practice.

Below, we highlight *key gaps* in these areas, that is, research gaps raised by multiple study participants within a stakeholder perspective or across stakeholder perspectives (see Chapter 2). Study participants noted that some of these gaps have been the subject of research studies but

that further research is needed, or different research approaches are needed to make a positive impact on health care delivery and health outcomes. Other gaps mentioned by individual study participants are shown in Appendix D.

Table 6.1 lists the key cross-cutting gaps in research approaches that impede the impact of HSR and PCR for improving real-world health care systems and practice.

Table 6.1. Key Cross-Cutting Gaps in Research Approaches to HSR and PCR Identified by Study Participants

Research Domain	Gaps in HSR and PCR
Cross-Cutting	• Examining health care outcomes for a fuller range of populations and settings • Following change in implementation and outcomes of health care interventions over time • Communicating results that are actionable by health care delivery stakeholders • Producing relevant and timely results for health care delivery improvement • Using theory to connect findings and advance knowledge on health care change • Leveraging digital health and linking various new sources of health care–related data

Table 6.2 summarizes key research domain gaps raised by TEP and interview participants for HSR.

Table 6.2. Key HSR Gaps Identified by Study Participants

Research Domain	Gaps in HSR on . . .
Organization of Care	• Health care workforce needs, composition, and roles in new delivery models[a] • Reducing burdens of health IT on health care providers[a]
Financing of Care	• Effects of evolving models of financing on the range of health care outcomes • Effects of health care payment models on different patient populations
Social Factors	• Role of health care systems in addressing social determinants of health[a] • Effect of social factors on demand for health care services[a]
Personal Preferences and Behaviors	• Integrating patient preferences into care[a] • Addressing health and health care misinformation[a]
Quality of Care	• Developing harmonized measures to meaningfully, accurately, and feasibly assess quality of care[a]
Access to Care	• Identifying both root causes and evidence-based solutions for barriers to access[a]
Cost and Utilization	• Challenge of lowering cost while improving care[a] • Reducing waste in health care[a] • Costs of new care therapies and delivery models[a] • Reducing costs across the health care system
Equity	• Solutions to reduce disparities in health care

[a] Similar gap included in key PCR gaps (Table 6.3).

Table 6.3 lists key research domain and cross-cutting gaps for PCR.

Table 6.3. Key PCR Gaps Identified by Study Participants

Research Domain	Gaps in PCR on . . .
Organization of Care	• Health care workforce needs, composition and roles in new delivery models for primary care[a] • Reducing burdens of HIT on primary care providers[a]
Financing of Care	• Effects of evolving models of financing on primary care delivery and outcomes[a] • Effects of health care payment models on different patient populations[a]
Social Factors	• Role of health care systems in addressing social determinants of health[a] • Effect of social factors on demand for primary care services[a]
Personal Preferences and Behaviors	• Integration of patient preferences in primary care[a] • Addressing health and health care misinformation[a]
Quality of Care	• Developing primary care-specific measures that capture quality in ways meaningful to patients and providers[a]
Access to Care	• Identifying both root causes and evidence-based solutions for barriers to access[a]
Cost and Utilization	• Challenge of lowering cost while improving care[a] • Decreasing underutilization as well as overutilization in primary care[a] • Costs of new delivery models for primary care (e.g., PCMH)[a]
Equity	• Role of primary care in addressing equity
Cross-Cutting PCR Gaps	• The core functions of primary care • Primary care transformation and role in the wider health care system

[a] Similar gap included in key HSR gaps (Table 6.2).

The letter "a" in Tables 6.2 and 6.3 denotes gaps that were similar for both HSR and for PCR, though often exhibiting distinct aspects. These gaps are described together in the sections below. All entries in both tables should be read as areas that need more or better research (e.g., the first entry in table 6.2 refers to *gaps in HSR on* health care workforce needs, composition, and roles in new delivery models).

Cross-Cutting Gaps in Research Approaches to HSR and PCR

TEP and interview participants identified six key cross-cutting gaps in research approaches and dissemination of findings that limit the extent to which HSR and PCR can improve real-world health care systems and practice. The first two relate to the range of health care populations and settings covered by HSR and PCR. These are followed by gaps in the development and communication of results in ways that are actionable, and in the relevance and timeliness of results for improving health care delivery. Another relates to gaps in using theory to connect findings and advance knowledge on health care changes, and the last addresses gaps in leveraging and linking new sources of health care-related data afforded by advances in digital health and other technologies.

Examining Health Care Outcomes for Fuller Range of Populations and Settings

Effects of Health Care Interventions on Fuller Range of Patient Populations

TEP and interview participants noted that many health care interventions are tested on specific populations such as patients without major health conditions other than the one of interest, or elderly beneficiaries in Medicare. For an intervention to be broadly applicable to clinical practice, health care delivery systems and providers need evidence as to whether and how the intervention can be adapted so that it is effective for wider populations of patients. One study participant observed "so much research that's conducted has so many exclusions that it doesn't represent the real world."

Change and Improvement in More Generalizable Health Care Settings

Similarly, multiple study participants commented that much evidence on change and improvement is generated from research in highly integrated health care systems, such as the VHA or Kaiser-Permanente, which are not typical of the settings in which most health care in the United States is delivered. In addition to research on and generalizable to the more fragmented private and commercial health care systems, other health care settings that participants identified as constituting large or important sources of care include safety net providers such as FQHCs and other community health centers, as well as hospitals serving low-income and vulnerable populations, in both rural and urban areas.

One participant called for more reporting of contextual factors irrespective of the setting in which research is being conducted. This participant argued that "most of things we're studying . . . are context-dependent; we actually don't expect them to work the same in one situation [versus] the other."

Following Change in Implementation and Outcomes of Health Care Change over Time

Several study participants commented that HSR and PCR studies are often neither *designed* nor *funded* for long enough periods to examine adaptations, sustainability, or outcomes of health care changes or interventions over time. As one participant noted, "Interventions are adapted and evolve over time as they're implemented," sometimes with the intention to better tailor the new intervention or practice to the local context but other times due to other operational, cultural, or policy pressures typically experienced in health care delivery organizations. Examining the nature of these pressures and natural adaptions that occur is important to understanding variation in fidelity to the initial intervention and its consequences for sustainability and effectiveness of the intervention over time. Another study participant gave the example of a project in which "we have no data about the fidelity of the intervention that the various grantees implemented. . . . So we are hard pressed to try to come up with an explanation for the rather minimal changes that we observed." Other participants emphasized that doing so requires being attentive to the context in which a new health care intervention or practice is implemented. In the words of one study participant, "There is always a very local component to implementation."

Communicating Results to Be Actionable by Diverse Health Care Stakeholders

Actionable results provide understanding of *how to implement* as well as what to implement. As described by a delivery system leader: "We know some [results], but it trickles out. Meanwhile, they keep inventing new stuff rather than helping us sort out the stuff we already have." Delivery system leaders and other study participants expressed the need to articulate key steps in a change process, using terms like "pathway," "playbook," and "construct[ing] the workflow," while "empowering practices to [each] figure out what it needs to do and how to do it better." Research needs to offer actionable answers to hard questions like, as one participant put it, "So what do I do differently tomorrow? . . . I know that that's true [the new intervention works], and now how do you structure it to be easy to do the new thing, or to override what I thought was the right way to go?"

Study participants also called for research studies to communicate findings so that they are *actionable* and can be implemented relatively quickly by *diverse health care stakeholders,* including not only health care delivery leaders and providers, but also payers, patients, and community leaders. Broader systems perspectives on research questions often lead to inclusion of wider sets of stakeholders.

Producing Relevant and Timely Results for Health Care Delivery Improvement

Multiple study participants pointed to gaps in the relevance and timeliness of HSR and PCR findings for improving health care delivery. They specifically called for the use *and* development of methods that better address these needs.

Several participants discussed the use of the randomized controlled trial (RCT), one of the hallmark study designs in health research in which subjects are randomly assigned to one or more intervention conditions and a control condition. The strength of RCT designs is the assurance they provide that differences in outcomes are the result of the interventions and not other causes. However, participants noted that, to maintain control over the study conditions, conventional RCTs are conducted in highly restricted environments compared to typical health care settings and exclude or ignore the complex dynamics of health care delivery. These aspects limit both generalizability to typical health care settings and understanding that stakeholders often need in order to guide implementation. As one researcher and health care delivery leaders described:

> Many agencies are interested in funding randomized clinical trials that are very controlled, and there's really very few that will fund research that's in the midst of a complex, adaptive, health system that is messy. In terms of federal agencies, probably AHRQ has the best track record there, but also some of the private funders . . . because [they] want to see meaningful change. In really controlled settings, they're often so controlled that they never translate into real meaningful change.

Pragmatic clinical trials. Study participants noted that, for these reasons, NIH and other federal agencies have increasingly funded pragmatic clinical trials, which compare health care interventions in more typical health care settings where patients receive their usual care, enroll more representative populations, and are designed to inform decisionmakers on the real-world implications of the intervention (Weinfurt, 2017).

Qualitative and mixed methods. Participants indicated the need for *better integration of methods from both qualitative and quantitative approaches* in order to better link health care context and process with outcomes and produce relevant evidence for stakeholders on effective health care interventions and change. Study participants also pointed to the need to expand *the use of* qualitative methods, such as interviews, focus groups, and observational methods, that more directly examine the context of health care delivery and process of change in health care systems.

Engaged research models. When focusing on the need of HSR and PCR to "actually improve what [patients] get," one interview participant concluded that this "will be done much more quickly [and] with better results with people working very closely in an iterative fashion in the sort of messy, real world of care delivery." Participants discussed three approaches to engaged research. The first two approaches in particular blur the lines between traditional health care quality improvement activities and HSR.

Embedded research models place health services researchers within service units to work collaboratively with health care delivery leaders and staff to develop research projects on issues relevant to the unit (Vindrola-Padros et al., 2017). By coproducing knowledge, researchers enhance the capacity of the health care delivery organization. One health service policy stakeholder noted the VHA as one agency that has invested in this model by "really pulling to get their research centers to partner with implementation . . . [and] working . . . on best practices in embedded research." Outside the VHA, participants provided other examples of this model, such as developing long-standing partnerships between academia and delivery systems or employing academic researchers in delivery systems for short-term fellowships or sabbaticals.

Learning health systems likewise were described by participants as an approach to increasing the relevance and timeliness of research for health care delivery stakeholders. Learning health systems are an emerging set of research models in which health care delivery systems seek to develop improvements in care based on rigorous analysis of their own storehouses of EHR and other service data (McLachlan et al., 2018; Etheredge, 2014; Greene, Reid, and Larson, 2012). Others have noted the importance that research findings from local learning health systems are shared to improve care more broadly (Friedman, Wong and Blumenthal, 2010).

Study participants also mentioned participatory approaches, such as ***community-based participatory research***. Although not necessarily more rapid than conventional research methods, community-based participatory research emphasizes relevance by engaging

broader patient and community stakeholders in the research. As one research interview participant explained:

> I do believe the whole learning health system research approach . . . and practice-based research and participatory models are really anchored in the reality of practice and health care organization operations, so that the research is really growing out of the questions that arise at the actual care delivery side of things and therefore are addressing questions that are going to be relevant and that can be directly applied.

Using Theory to Connect Findings and Advance Knowledge on Health Care Functioning and Change

Several study participants commented on the need to apply, develop, and refine theories of health care functioning and change in HSR and PCR, not for theory's sake, but to help connect disparate findings and advance understanding of how to improve health care delivery. As one researcher and delivery leader summarized:

> We need [to] figure out how to bring theory back so that it results in better questions and I think we might even have more impact because then some of these very diffused findings, they just hang out there because they're not attached to a larger spread of understanding. And if we bring theory in then . . . [they] could [also] potentially bring new methods to us.

While a range of social and behavioral science theories can and have been applied in HSR and PCR, three sets of theories mentioned by study participants were systems science (a general field of related theories on the properties and interactions among components of social and/or technical systems), complexity science (a branch of systems science focused on understanding dynamics and change in complex systems), and implementation science (a field of theories and research developed in HSR and PCR focused on understanding the adoption, use, and spread of practices, interventions, and innovations in health care).

Leveraging Digital Health and Linking of Varied New Sources of Health Care–Related Data

TEP participants discussed an emerging gap in research on leveraging new sources of health care–related data afforded by advances in digital health and other technologies. Digital health includes a range of technologies, including social media, mobile apps, other platforms for patient-generated health information, "big data" analytics (including artificial intelligence, data mining), as well as EHRs maintained by health care providers. Participants noted that procedures for handling patient privacy and consent and infrastructure for linking these various sources of digital health data for analysis have yet to be developed.

Gaps Related to Specific Research Domains

In addition to the cross-cutting gaps in research approaches above, interview and TEP participants identified gaps related to the topical domains in the study's research framework (see

Figure 2.1). Below we describe key gaps related to each of the health care input domains of Organization of Care, Financing of Care, Social Factors, and Personal Preferences and Behaviors; as well as to the health care output domains of Quality of Care, Access to Care, Cost and Utilization, and Equity.

These domains are discussed in the order shown in the framework and presented in Tables 6.2 and 6.3 for HSR and PCR gaps, respectively. Gaps that were similar for HSR and PCR (denoted with the letter "a" in the tables) are discussed under the same respective domain below, with PCR-specific aspects distinguished with italicized text. As mentioned previously, key gaps in each domain are those that were raised by multiple stakeholders within or across stakeholder perspectives. Additional research gaps identified by study participants can be found in Appendix D.

Organization of Care

Health care workforce needs, composition, and roles in new delivery models in primary care and other settings. In both interviews and TEP meetings, the importance of studying workforce-related issues through research was highlighted by participants from diverse perspectives, including delivery system leaders, state-level representatives, researchers, and others. One broad research gap related to workforce was the lack of knowledge around various configurations of the workforce (i.e., team-based structures and processes of care) and the effects such configurations could have on the health care system, including shortages. One state-level representative said: "Workforce is just a constant struggle for us, understanding that the health care system is transforming, and part of that transformation, undoubtedly, leads to the demand for health care providers with different skill sets along the way. And how do we equip those providers to adjust their practices in order to fit the demands of a transforming health care delivery system?" Other gaps related to workforce composition and roles included research to address the lack of specialists in the pediatrics workforce and optimal staffing for emergency mental health care. Particularly in *primary care*, a number of participants noted needed research on the emerging roles of nurse-practitioners, physician assistants, and clinical pharmacists in interprofessional team-based care. In addition, participants discussed a critical need for additional research in primary care to better understand and address provider stress and burnout.

Reducing burdens of HIT on health care providers, especially in primary care. Despite the expectation that HIT, in particular, EHR systems, will increase the efficiency and safety of health care delivery, study participants noted the widespread unintended consequences of these technologies, and the additional reporting tasks that they enable, in substantially increasing administrative and documentation burden on health care providers. One federal stakeholder asked, "How do they think about health IT as a facilitating tool, rather than an end-all and a be-all? In other words, how do they construct the workflow, . . . [which] clinical team member does what component of the work, how do they evaluate that, how does it come together?" Another federal stakeholder asked how HIT could be used in primary care "to improve the effectiveness

and efficiency, quality, safety of primary care and not create more burdens and harm." This participant felt that increasing HIT burden without improving its usability could "sink a ship that is barely staying afloat at the moment."

Financing of Care

Effects of evolving models of financing on the range of health care outcomes, including in primary care. The need to better understand the effects of financing and payment mechanisms was highlighted by study participants for a range of health care outcomes. For example, payment reform came up as a means of supporting health care systems in addressing challenges with social factors and social determinants of health faced by their patients. Financing likewise featured extensively in the discussion of quality measurement and of the relationship between quality and payment to promote value. Participants also highlighted the need for risk adjustment methodologies that are more immune to health care delivery systems and providers "gaming the system," for example, when they focus more on raising the reported risk profile of their patients rather than improving care. A health economics researcher noted that research on these gaps in financing mechanisms could be improved by taking into account the continuous, evolving nature of payment reform as it occurs in much of the health care system: "The question isn't what's going to be the best payment mechanism for all time . . . , but much more opportunity for continuous learning and improvement because let's face it, payment models are impossible to get right the first time."

One gap particular to *PCR* was the need to understand the role of comprehensive primary care within payment models such as ACOs. One interview participant noted that accurately attributing the value of primary care within an ACO is complex and challenging. The importance of this type of work was echoed by another interview participant, who noted that "there's a need to get out of pure fee-for-service for primary care and to really understand the effect of alternative payment models and how those work."

Effects of health care payment models on different patient populations across health care settings. Participants noted that more research is needed concerning the ways in which new payment models affect health care and health outcomes not only for the general population or elderly adults on which most studies have tended to focus, but also on vulnerable and special-needs populations. Examples given included payment reform for specialized care (e.g., end-stage renal disease) and for patients who require additional caregiver support (e.g., children and patients with dementia).

Social Factors

Role of health care systems in addressing social determinants of health in primary care and other settings. Study participants emphasized the importance of social and community factors in affecting the health outcomes especially for high-need and at-risk individuals. However, less clear for participants were the feasible and effective roles that health care delivery

systems could play in addressing social determinants of health. Open questions raised by participants included the appropriate role of health care delivery systems, if any, in directly assisting patients with needs in housing and transportation, and effective models for health care systems to collaborate with other community resources (e.g., social service agencies, community coalitions, school-based health initiatives) to address these needs. One *PCR* interview participant described these issues in the context of specific types of patients requiring these supports (emphasis added):

> [Patients] with the triad of diabetes, hypertension, and respiratory disease . . . [those who] smoke and they drink. These are the people who represent their own special universe of people who have all the chronic illnesses and all of the adverse social habits and an underlying, almost always, depression. *What is the intensive intervention with those people that would make a difference?* Is it financial support? Is it social support? When we look at their med list, they already have 20 medicines on their list. It's not medication. You could call it the high-risk-score people who score high on chronic illness, habits, and social determinants of health. What is the effective response . . . to those people?

Other participants pointed to the potential for collaboration with community partners and other disciplines to address "root causes" of these social determinants, such as the example provided by a state-level hospital association representative of a hospital working with demographers, land-use researchers, and local policymakers to reroute truck traffic and plant trees in neighborhoods with high frequencies of asthma-related ER visits.

Effects of social factors on demand for health care services, especially in primary care. Study participants also pointed to gaps in understanding the effects of social factors on the demand for health care services and, specifically, on *primary care.* This evidence would be useful for *primary care* and other health delivery systems to more clearly understand the impact of social determinants on services, but also how demand for services might change if these social needs were met.

Personal Preferences and Behaviors

Integrating patient preferences into care in primary care and other settings. Participants indicated that more evidence is needed on how best to integrate and engage the patient, their family, and their caregivers' preferences into their care. Methods for engagement included tools, approaches for shared decisionmaking, measurement of care on dimensions important to patients, and incentives for patients. Broadly, participants mentioned the need to better understand what patients value in their health care. This research need was mentioned in relation to various types of patients, including those with chronic conditions and those utilizing genomic test results to inform their care.

Two *PCR* interview participants elaborated further on this gap. One participant indicated that yet-to-be-developed patient-oriented primary care quality measures would facilitate more engaged patient care, for example, in "prioritization of different conditions, [and] deescalating

medications or treatments to meet people's values" (see quality-of-care discussion below). Another PCR participant highlighted the gap from patient engagement to patient action: "How do we effectively engage patients to become more empowered for their own self-care from chronic conditions and multiple chronic conditions."

Addressing health and health care misinformation, especially in primary care. TEP and interview participants highlighted the research gap centering on misinformation, including the need for research to address both the effect of "misinformation" on personal preferences and behaviors related to health care—most prominently the antivaccination movement—and ways to combat misinformation from various stakeholder perspectives.

Quality of Care

Developing harmonized measures to meaningfully, accurately, and feasibly assess quality of care across all health care settings. Overall, participants in interviews and both TEPs called for improvements in quality measurement. Significant inconsistency was noted across the health care system in quality measures and the way they are implemented. Participants called for research around prioritization of measures and greater harmonization of measures to reduce burden. One interview participant emphasized that the knowledge of how to create measures exists but research funding to create measures is lacking: "We currently don't have valid measures of quality that everybody can use. . . . We know how to create good measures. The funding isn't there, the testing isn't there and the measurement infrastructure to develop, test and then promulgate measures isn't there."

Study participants noted that some areas of health care were particularly lacking in meaningful quality measures. As one PCR researcher commented, *better primary care measures* are "desperately" needed as a barometer of the key functions of primary care, while also not interfering with patient care. Another interview participant reported that primary care lacks non-disease- and non-organ-specific measures that adequately capture the quality of primary care in ways meaningful to both providers and patients:

> These specific outcomes, blood pressure control, hemoglobin A1c control, . . . they just pile up in primary care. But they're not what patients and doctors really care about. So how do we evolve to the next series of [measures]: "patients feel heard," "patients feel safe and cared for," "patients are functioning the way they want," "they're able to reach their life goals," whatever those might be? . . . [new measures] make sense and then leads to things like prioritization of different conditions, deescalating medications or treatments to meet people's values, coordination issues, integration with community services.

Ongoing research gaps were also noted in specific subareas, including (1) measures for pediatric populations, which have lagged behind quality measures for adults; (2) patient safety measures that look at all aspects of patient safety, including overuse or misuse of medical care and diagnostic errors; and (3) outcome-based measures—particularly in behavioral health.

Finally, patient-centered measures that capture what the patient is experiencing and cares about were highlighted as an area in need of more research. Further, although patient-reported measures (patient-reported outcome measures and patient-reported experience measures) have been developed, more research is needed on the practicality and feasibility of such measures, and how they can be implemented. One delivery systems leader noted that, while there is general consensus that such measures are valuable, more research is needed to understand how such measures can be implemented without the documentation burden that detracts from provider time delivering patient care. Study participants also stated that, after more patient-reported outcome and experience measures are developed, additional research will be needed on how to use such information to understand the impact of low-quality care and harm on patients.

Access to Care

Identifying both root causes and evidence-based solutions for barriers to access. Delivery leaders, federal agency leaders, researchers and other interview participants, as well as TEP participants, acknowledged the substantial evidence that has been accumulated to date on existing disparities in access. For example, one interview participant commented that "you've got communities in every city that are basically medical deserts." A *PCR* participant indicated that this gap is not solely geographic, pointing to the ways that other factors, such as health insurance, can create barriers to access:

> [For example, insurance product X] . . . the people that are picking this up . . . [they are the] "working poor," people who don't quite qualify for the Medicaid insurance, . . . but can't quite afford the more expensive insurance policies, either. . . . premiums are cheap, but . . . providers are not willing to accept the plans, what you end up with is you end up with decreased access to care, because you have a limited network from which to choose, if you want to try to use this insurance.

Thus, study participants called for more research attention on the root causes of, and strategies for, addressing barriers to access, especially regarding the health care system's potential role in addressing these causes. Despite noting important federally funded projects that have been conducted, such as AHRQ's 2016 evidence review on telehealth, participants highlighted the need for further evidence on effective interventions to address barriers to access, including telehealth and other strategies such as virtual visits and remote monitoring.

Cost and Utilization

Challenge of lowering cost while improving care, including in primary care. In general, the challenges of the rising costs of care and utilization as a driver of costs were repeated research gaps discussed throughout the TEPs and interviews. An important theme was understanding how to improve care *while lowering costs.* One delivery systems leader said: "Thirty percent or more of what we spend money on adds no value, so, in today's world, where increasingly not-for-profit health systems are economically challenged, we need research on

what works and what doesn't, so that we can be putting evidence-based improvements in place." In discussing *PCR* specifically, one interview participant noted that understanding what proportion of the spending "pie" is related to primary care in different settings and geographies is important.

Reducing waste in health care generally and primary care as well. Although the high prevalence of waste in health care is not a new issue, study participants suggested that a research gap still exists in the use of billing and other data to identify where waste can be reduced. Administrative waste was highlighted as an especially important area that needs more examination. Several study participants also suggested that utilization could be improved by closing the gap in understanding the appropriateness of care (what is the right sort of care for different types of patients) and the factors associated with utilization of inappropriate care. In *PCR* this was specifically framed by a TEP member as an issue that crosses all age groups and multiple aspects of health care, in the context of the right care at the right time: "This [. . .] crosses pediatrics, adult, aging, patient safety, whether it's diagnosis, overutilization of treatment, underutilization of treatment, trying to build a better match between appropriate care and timely care, so that you decrease underutilization, you decrease overutilization."

Costs of new care therapies and delivery models, including medical home models such as PCMH. Costs associated with new therapies or novel delivery approaches that could improve care were cited as underresearched. Specific examples included more precise understanding of increases in cost from new drugs, such as new cancer therapies (raised by both researchers and federal stakeholders), as well as the potential for decreases in cost through delivery approaches such as telemedicine. Participants also highlighted the need to better understand how different types of incentives and accountability built into new payment models relate to cost. In the area of *PCR*, evaluations of new models of care—such as the PCMH—often report health care costs, but typically inconsistently, which limit generalized assessments of the cost effects of such models.

Across both HSR and PCR, some study participants believed that better evidence on the effects of payment models on costs would also encourage health systems to engage in additional experimentation and research of their own on payment models. One researcher stated: "I think if we really do get there in terms of payment models that have accountability for better meaningful outcomes and lower costs, or at least close enough to it, I think systems will have incentives to do studies themselves of what is it that we can do that leads to better outcomes and lower costs, both in their own systems and hopefully sharing across others." Researchers also pointed out the importance of understanding who bears the costs versus cost savings in these arrangements (patient, provider, delivery or payment organization, etc.) and how this could potentially perpetuate inequity in the health care system.

One additional research gap noted specifically for *PCR* was in the area of payment and care reform focusing on coordination of specific conditions between primary and specialized care (i.e., medical homes for end-stage renal disease). One interview participant suggested that, rather than using bundled payments for acute admissions and procedures, the focus should shift instead

to prevention. Such models could be extended to other conditions such as degenerative joint disease or heart failure.

Reducing costs across the health care system. Finally, multiple participants stated that it was important to focus on costs across the health care system as an outcome. One participant said, "For me, the studies that stand out are the ones that actually look at total spend, not many of them do. . . . It's just from experience: we know it's way easier to move the quality needle than it is to move the cost needle."

Others echoed the importance of including cost as an outcome in research and noted that it is reported too infrequently. Another participant suggested that research is particularly needed on how to reduce health care costs in non-Medicare populations, given the amount of evaluation that CMMI has conducted on costs for the Medicare population.

In the realm of *PCR*, in contrast, one interview participant noted that the cost of health care was largely driven by specialty and inpatient care, and the cost of primary care was *not* a gap that needed to be studied: The "main issues of high prices in this country are not that we're paying too much for primary care."

Equity

Solutions to reduce disparities in health and health care. Understanding and ultimately decreasing the effect of disparities on health care was also discussed. One delivery systems leader highlighted the need for more and better data: "The data is not even there to provide us with information to do the analysis, to monitor for disparities. So those are huge gaps in my mind." However, other participants noted that the research gap is not simply the need to document disparities, but to design, test, and implement strategies to change how care is delivered so that disparities are reduced. As one interview participant stressed, given the evidence already generated on the existence of health care disparities, the most important question is, "How do we intervene?"

The role of primary care in addressing equity. A number of study participants raised the role particularly of *primary care* in addressing social factors related to health inequities. Similar to addressing social determinants of health generally, an interview participant framed the issue as helping providers identify roles in reducing disparities that are appropriate and feasible for the primary care system:

> [There is] a huge need to understand how, what are the things that really can be done effectively in primary care to address health equity and to make that much more of a priority for the practice improvement work. What is the appropriate role for primary care practices in moving up strengths and addressing underlying fundamental social determinants of health? There is . . . not enough [research] in really understanding are there effective and efficient ways to do this? Or is it really that it's just going to overburden busy primary care clinicians and that [it] really belongs in the public health and civic space of addressing poverty and educational status and structural racism and things like that.

Cross-Cutting Research Gaps Specific to Primary Care

Next we present two research gaps specific to PCR that cut across the topical research domains. The first addresses needs for greater research attention on the core functions of primary care. The second concerns the transformation and role of primary care in the wider health care system.

The Core Functions of Primary Care

Interview and PCR TEP participants discussed the importance of filling the gap in what they called the "basic science" of primary care. Researching the "basic science" of primary care involves, as described below, documenting "what's actually going on in primary care" today and understanding and developing models of the core functions of primary care in addressing the holistic needs of patients for usual care, maintaining health, and coordinating services for other health and health-impacting services.

This "basic science" can then inform how to improve primary care. One interview participant highlighted how such knowledge can inform changes to service delivery, noting that the health system and primary care in particular have changed substantially since the time that the seminal research on these core primary care functions was conducted:

> The number of acute patients we see in primary care offices has dramatically reduced, the complexity and chronicity has dramatically increased. . . . We need to understand that better because that would immediately change how we think about scheduling, how we integrate the use of virtual care and some of the telemedicine, and all of these other modalities.

Reflecting further about primary care patients, another participant called for study into the core functioning of primary care to include gaining a better understanding of the "ecosystem of primary care" from the standpoint of patient decisionmaking and behavior.

> We actually don't know what people do when they feel ill now; who do they see, what do they do, for what and when, where do they go? We've created so many options out there in the ecosystem of primary care that we don't really understand what's going on. And we probably know that that's very variable depending on the nature of the population.

Stronger basic evidence on the current "ecosystem" of primary care would help to develop and refine theories of drivers and models of effective primary care that can be used to stimulate further improvements to primary care service delivery. For example, the same participant above asked whether the "four Cs" of primary care identified by Barbara Starfield and colleagues in the 1980s and 1990s (comprehensiveness, coordination, continuity, and first contact) operate differently in the current context of primary care than initially conceived.

> It may be that primary care does something very different that may have to do more with prioritizing and integrating and personalizing—hmm, where [are those things] going on out

> there? Is primary care doing [those things]? Maybe [those things are] more what really drives the success of primary care and the four Cs simply facilitated them?

Multiple participants attributed the lack of research on the core functions of primary care to the lack of dedicated funding for core research on this central component of the health care system and the fragmentation of much federal PCR funding across agencies focused on other missions. PCR interview and TEP participants described having to "disguise" core research on the functioning and practice of primary care as organ- or disease-specific studies (e.g., screening for a particular disease in primary care) for NIH grant programs, or as patient safety or other health service topics for agencies like AHRQ. While appreciative for the resources afforded by these funding sources, participants noted that the aims of these programs can limit the ability to fully address core issues in primary care. As one researcher explained, agencies are not usually interested in funding research on such broad questions in primary care:

> I think there's been almost no funding for the things that I've brought up. . . . They come out of a deep understanding of what primary care is and needs to address. They're not the questions that NIH institutes are going to ask. They're not the questions the CDC is going to ask. They're not what SAMHSA's going to ask. And PCORI and AHRQ have very limited pieces. They ask some of them, but certainly not enough money to go around and they have to focus on some very specific assignments they were given with those limited resources.

Another interview participant particularly pointed to the lack of a central hub of funding for PCR:

> So [PCR] is funded through a variety of agencies. The big challenge is none of them have a dedicated primary care funding mechanism or a specific component in their agency that's dedicated to funding primary care research. It's therefore harder to get research funded on things that are not disease specific or condition specific or fit a particular niche [but] that are more about the care of whole people and all their multi-morbidity complexity or about practice transformation issues, primary care community health interface, things like that.

Primary Care Transformation and Role in the Wider Health Care System

While research on the effects of new models of the primary care were discussed under the Organization of Care domain, study participants also identified broader research gaps on the development of new models and their role in the wider changing landscape of the health care system. As one participant described:

> [We need] much more rigorous research on how do you actually re-engineer the primary care practice model to meet the needs of 21st century primary care? A lot of that is around team-based models. What are the different roles and tasks and how do you successfully implement team models? . . . How do patients respond to more team-based care models? Are they sustainable?

This same participant added that, to support primary care transformation, research would also be helpful on how the patient and community voices could be better integrated "as partner[s] in practice improvement . . . co-creating the new practice models . . . empower[ing] patients and communities [in] partnering with primary care clinicians and practices [on] how primary care should work and be more patient and community centered."

Other participants highlighted the need for research on primary care as part of larger systems of care; for example, primary care's role in successful ACOs and in the delivery of ever more complex care. On the latter point, a research interview participant provides the example of caring for a cancer survivor in primary care.

> We start rapidly accelerating new innovations in the treatment of diseases . . . and we have more and more rapidly accelerating, highly-specialized knowledges—How are those being translated to the primary care clinicians so that they can then do the integrative work with a patient as a whole when the patients come back to them? [There's] . . . almost no research on that and no active work going on in how to develop that.

Although research on these issues have been conducted, study participants indicated that "there is a lack of good and consistent studies on these topics." For example, studies on the effects of various new models of primary care (e.g., PCMH) and value-based care programs (e.g., CPC+) were considered to report contradictory evidence on health outcomes and cost effects of these models. Participants noted that sorting out this evidence is needed to provide useful guidance on primary care transformation for health care systems.

Gaps Summary

This section first presented key gaps identified by study participants in research approaches and dissemination that impede the impacts of HSR and PCR for improving real-world health care systems and practices. The first two gaps related to the scope of HSR and PCR is the need to broaden in terms of health care populations and settings on a large scale, as well as assessing health care change over time. These were followed by gaps in the communication of results in ways that are actionable by health care delivery stakeholders, as well as the relevance and timeliness of those results for improving health care delivery. Another gap focused on using theory to connect findings and advanced knowledge on health care changes. The last gaps in that section addressed leveraging and linking new sources of health care–related data afforded by advances in digital health and other technologies.

HSR Gaps

The next sections of this chapter presented key gaps related to each of the topical domains in the study's research framework introduced in Chapter 2. These gaps included needed research on specific topics within health care "input" domains (e.g., Organization of Care, Financing of Care, Social Factors, and Personal Preferences and Behaviors) and health care "output" domains (e.g.,

Quality of Care, Cost and Utilization of Health Care, Access to Care, and Equity). For example, gaps in HSR related to health care input domains included the need to identify barriers to implementing new models of care and to understand the workforce needed for these models. Gaps related to health care output domains included lack of adequate quality of care measures for certain services or outcomes.

PCR Gaps

A number of research gaps for PCR were similar to those for HSR (denoted by the letter "a" in Tables 6.2 and 6.3). The descriptions of these gaps highlighted their distinct PCR-specific aspects. For example, PCR participants noted the gap regarding the lack of adequate quality of care measures included the creation of metrics that adequately capture the quality of comprehensive and holistic primary care in ways meaningful to providers and patients. Several research gaps pertained only to PCR, including the role of primary care in addressing equity and two gaps that crossed research domains. The first PCR-specific, cross-cutting gap emphasized the need for research on the core functions of primary care, and the second concerned research on the transformation of primary care practice and its role as part of the wider health care system.

Framework for Prioritizing Gaps

As described to this point in the chapter, study participants identified a wide range and large number of research gaps in HSR and PCR. However there was also consensus among TEP and interview participants that identifying priorities, and the process of prioritization itself, is critically important. This view was echoed in meetings with the Federal Advisory Working Group. Study participants representing both HSR and PCR suggested a similar general approach to the prioritization process.

Prioritization Criteria

Overall, there was agreement among both TEP and interview participants that transparent and explicit criteria are important to the prioritization process. Possible criteria mentioned included the potential impact of the research, the potential to address a gap in a poorly funded research area, the potential to address foundational areas of research, and the timeliness of the research (Box 6.1 on the following page). The interrelation of these criteria was often noted, as described in more detail below.

Potential Research Impact

Many of the interview and TEP participants highlighted the importance of prioritizing research by its potential for impact. Impact in this context was closely linked to the *likelihood of actionable results.* Multiple HSR TEP members agreed that impact could be described as research that might lead to opportunities to change practices or policies. One TEP member also

related impact to timing, in the sense that research has to be done at the right time to inform legislation and must ultimately prove to be *policy-relevant.*

TEP members also conceptualized impact as *having potential for "high gain,"* with the idea that high-risk, high-gain projects should be considered for prioritization. One TEP member mentioned the NIH Pioneer Awards, noting that it is important to have a portfolio that specifically funds projects with higher risk of poor or null results but also greater potential for gain in knowledge and practice. A research interview participant noted that the potential for innovation often depends on a willingness to accept risk and expressed the wish that CMMI would be more "eager to do high-risk, high rewards kinds of projects and not fear failure . . . [which] is in direct competition with true innovation."

In a later discussion, a TEP member suggested that a practical means to identify research of interest for a more high-risk portfolio would be to conceptualize the major changes or shifts that need to occur for the research to influence health outcomes and then to work backward to understand the first steps needed to make these changes.

Finally, in follow-up to one of the meetings, another TEP member described prioritization based on answers to a set of three questions about potential impact:

1. Is the issue being addressed important?
2. Is data needed to answer the question?
3. If we had the data to answer the question, would action follow in a reasonable time frame?

This three-step process is appealing in its simplicity, though we note that defining "important" is in itself quite complex and requires explicit definition, as discussed in Chapter 5.

Box 6.1. Prioritization Criteria Suggested by Study Participants

Participants identified four prioritization criteria for consideration:

- Potential research impact, which could refer to likelihood of producing actionable findings, potential for high gain, and/or research needed to answer a question.
- Potential to address a gap in a poorly funded area, that is, research to address a gap in an area that is not currently receiving adequate attention or funding.
- Potential to address foundational areas of research, that is, research that serves as a building block to solve core health care system issues or to support future work.
- Timeliness of the proposed research, including its potential to align with policy timelines either in the short or long term.

Potential to Address a Gap in an Underfunded Research Area

Several participants suggested prioritizing research areas that *address a knowledge gap that is poorly funded or not receiving adequate attention.* A member of the HSR TEP suggested an exercise to compare research gaps against both research that is proposed and research that is

already funded in order to disentangle whether "people are proposing things in these gap areas that aren't getting funded or are they not proposing them at all."

Potential to Address Foundational Areas of Research

Some interview and TEP participants raised the idea of prioritizing funding for research that is foundational or that serves as a building block to solve core health care system issues and make progress in other research areas. For example, several participants considered research on "new workforce configurations" to be foundational, noting that it can help ensure that primary care remains a sustainable profession in the future since, in the words of one TEP member, "without a workforce, we'd go out of business."

There was also recognition that, within the field of HSR, foundational research that moves the field forward may not always be as well understood as in the natural or physical sciences:

> Now I've always felt in health services research, we don't have that same sense of what is basic or fundamental. Because health services research itself is largely an applied field. It's sort of part of the definition. But if we could look back and say, "Well, what are some of the fundamental building blocks that if we had good research, that would provide answers to questions in those fundamental areas, it may then serve as a springboard to solution across a range of these gap areas."

Timeliness of the Proposed Research

Both interviews and TEP discussions related prioritization to the timing of addressing research gaps, in particular the ability to align with policy timelines whether in the near or longer term. Participants highlighted the difference between short-, medium-, and long-term needs for research, and how these horizons affect prioritization.

Some participants noted the difficulty of prioritizing research gaps that need to be addressed quickly in order to influence policy. A specific example was study of the Affordable Care Act, with relevant research ideally becoming available in 6 to 12 months from implementation of a major policy change. Prioritizing funding—or even obtaining funding—to perform such work was noted to be a major challenge.

Other participants cautioned against deprioritizing gaps simply because the research might take a long time to perform. One interview participant noted that "you can look at that and say, well, that's a longer-term horizon enough you don't have to pay attention to it, but if we don't pay attention to it now, then the horizon gets further away." Conversely, another interview participant explicitly stated that chronic issues should be given lower priority than more pressing needs. Federal Advisory Group members also noted that, within federal agencies, an important criterion for prioritization is the alignment of an issue with the mission of an agency and its comparative advantage and expertise in funding research on the topic.

During the HSR TEP, there was a lengthy discussion of the tension between funding time-sensitive issues versus funding important, but more chronic, problems. One member proposed that funders of HSR may need to sort research funding into separate "buckets" or categories to ensure that research with varying time horizons is funded. One proposed research category was *long-standing, chronic problems* in health care. Another was *emerging problems that need to be solved,* such as the current opioid crisis, or HAIs. A third category focused on *how to solve problems and who can identify the solutions,* which relates to methods, modeling, technology, and other related fields.

Frameworks to Guide the Prioritization Process

During our discussions of prioritization, some participants identified frameworks or processes that could explicitly guide the prioritization process. Below we list some of these for consideration. Regardless of the framework or process chosen, there was general consensus that any such process should be transparent and explicit (Box 6.2).

Box 6.2. Principles for the Prioritization Process Suggested by Study Participants

- Participants agreed that an explicit prioritization framework would be helpful.
- Suggested frameworks included the Triple and Quadruple Aim, the Commonwealth Fund definition of a high-performing health system, and the IOM definition of primary care.
- Participants agreed that, once a framework is established, identifying a transparent prioritization process would be helpful, using established methods such as the Child Health and Nutrition Research Initiative method or the RAND Delphi method.
- Regardless of the framework and process, continually refining the underlying criteria was believed to be critical to ensuring that changes in health care system priorities are incorporated.

In general, TEP participants were in favor of using known frameworks for possible prioritization, as outlined below:

- The most commonly mentioned framework was the *Triple* or *Quadruple Aim.* The Triple Aim was first developed by the Institute for Healthcare Improvement and defined as "applying integrated approaches to simultaneously improve care, improve population health, and reduce costs per capita" (Institute for Healthcare Improvement, undated). Since the development of the Triple Aim, some have suggested expanding the framework to the Quadruple Aim, which adds the goal of improving the work life of health care providers, including clinicians and staff (Bodenheimer and Sinsky, 2014). One advantage of using the Triple or Quadruple Aim, as noted by TEP members, is that it is widely recognized and thus may be easily understood.

- The *IOM definition of quality*—with its six dimensions of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equitability (Institute of Medicine, 2001)—was mentioned by members in both TEPs. These dimensions—as well as others, such as access—have been incorporated into definitions of a high performing health system, such as that described by the Commonwealth Fund, which referred to a system that ". . . achieves better access, improved quality, and greater efficiency, particularly for society's most vulnerable, including low-income people, the uninsured, minority Americans, young children, and elderly adults" (The Commonwealth Fund, 2019). Using these definitions as part of a prioritization framework would mean ascertaining whether a given study contributes to a better understanding of quality of care, affordability, and of the equitable allocation of health care resources and health in the population.
- TEP participants also referenced the *IOM definition of primary care*: "The provision of integrated, accessible health care services by clinicians who are accountable for addressing the large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community" (Institute of Medicine, 1996). Priorities for PCR that could be extracted from this definition would include research on integrated care, access to care, management and coordination of care, and patient- and relationship-centered care.

Prioritization Processes

Two TEP members also suggested examples of existing methods and processes through which prioritization could occur after framework criteria and principles are established:

- In the HSR TEP, one member highlighted the *Child Health and Nutrition Research Initiative*, which is a systematic yet flexible method for setting research priorities for global child health. The method consists of 15 steps, with the goal of informing those who invest in research about the risks associated with their investments, with the target audience being international agencies, large research funding donors, national governments, and policymakers (Rudan et al., 2008).
- Another process mentioned was the *RAND's Delphi method* (RAND Corporation, undated), which is a structured communication method that relies on a panel of experts to assign ratings, discuss ratings, and then reconsider their original ratings and come to a consensus on prioritization.

Regardless of which framework or process is chosen, one PCR TEP member emphasized the importance of reexamining and refining criteria periodically to ensure that changes in health care system priorities are incorporated as needs and the research evolve.

Stakeholder Engagement in Prioritization

Similarly, regardless of the framework or process used, there was consensus among both TEP and interview participants that it is critically important to engage stakeholders throughout the prioritization process (Box 6.3).

Box 6.3. Stakeholder Engagement in the Prioritization of Gaps Suggested by Study Participants

- Stakeholder engagement throughout the process is important.
- Key stakeholders for inclusion in prioritization are researchers, providers, payers, patients and families, state-level representatives, and employers.
- Patients and families are key to the prioritization process and should be included deliberately and thoughtfully.
- Other potential stakeholders who should be considered are industry representatives and elected officials. However, given competing agendas, inclusion should occur in the context of clear disclosure requirements

Relevant Stakeholders

Both interview and TEP participants identified key stakeholders for inclusion in the prioritization process. One TEP member noted that steering and other advisory committees—whose makeup might be similar to that of a prioritization group—tend to include mostly researchers and experts, and that broader representation should be considered.

Important groups included researchers, providers, payers, patients and consumers, state-level representatives, and employers. However, one interview participant noted that representatives from such groups should be chosen to include those who have demonstrated experience thinking through relevant health delivery issues and ways in which they could be improved. Elected officials were mentioned as key stakeholders, although the concern was cited that elected officials may have a separate agenda whose goals may not align with those of other stakeholders.

Another TEP participant suggested that inclusion of other stakeholders such as industry representatives (e.g., pharmaceutical or device manufacturers) may raise conflict-of-interest issues. This suggestion was offered with the caveat that, while such perspectives should be included, it would be important to ensure that they do not "hijack" the prioritization process. Ensuring a balance among perspectives was considered critical, along with strong disclosure requirements and mechanisms to mitigate conflicts-of-interest.

Patients and Families

One group that received particular attention in study participant discussions was patients, families, and other caregivers. Involvement of patients and families was seen as extremely important, as voiced by the patient/consumer representatives as well as other TEP and interview participants, who believed that obtaining such input is important to ensure that research funding fills gaps in a meaningful way for patients. TEP members also considered the manner in which such input is obtained was important. For example, one TEP member noted that panels whose advisory group included only a single patient stakeholder representative were typically ineffective since it can be difficult for patients to speak up when the representation and power differential may influence their comfort level.

Study participants also emphasized that selecting patient representatives for participation in prioritization must be a thoughtful process. Such patient representatives should have some experience and understanding of the health care system and ideally would have served in the role on similar groups. However, little preparation exists to prepare patients, family members, and caregivers for these roles, who often must learn through participation. Developing a pool of patient representatives who can serve in the prioritization process might be accomplished via the use of toolkits (e.g., PCORI's Patient Engagement Toolkit) (Patient-Centered Primary Care Collaborative, 2019) and trainings. Engaging patients and families throughout the process is equally important, as one participant noted:

> What we've seen in health care systems is that you can get farther if you have stakeholders together at the same time in the same group. . . . Patients and families can understand challenges and why things can't be implemented or aren't a good idea and help come up with creative solutions. But without that involvement, they don't hear the pushback and can't be truly part of the process.

Prioritization Summary

While a comprehensive ranking of HSR and PCR gaps was beyond the scope of this study, TEP and interview participants discussed potential criteria and mechanisms for prioritizing research gaps. Study participants emphasized that criteria for prioritization need to be transparent and explicit, and that the range of relevant stakeholders need to be engaged in the prioritization process—including patients and families. Possible criteria for prioritization include the potential impact of the research, the potential to address a gap in an underfunded research area, the potential to address foundational areas of research, and the timeliness of the research. Federal Advisory Group members also noted that, within federal agencies, an important criterion for prioritization is the alignment of an issue with the mission of an agency and its comparative advantage, and expertise in funding research on the topic.

Chapter Summary

TEP and interview participants identified a wide range of pressing research gaps in HSR and PCR. These gaps are driven by the complexity and rapidly changing landscape of the U.S. health care system. Many of these gaps are related to specific "inputs" and "outputs" of health care services in the study's research domain framework. However, many of the gaps also reflect the difficulty of understanding the *linkages between health care inputs and outputs* to produce important outcomes, and the limitations of currently used research approaches to generate and disseminate evidence in ways that positively impact real-world health care systems and practices. At the same time, these gaps also represent opportunities to find new ways to use research to solve problems and improve the health care system, and ultimately the nation's collective health.

In this chapter, we highlighted key gaps, that is, research gaps that were raised by multiple study participants within a stakeholder perspective or across stakeholder perspectives. Study participants noted that many of these gaps have been the subject of research studies sponsored by federal agencies and other funders, but that further research is needed, or different research approaches are required to make a positive impact on health care delivery and health outcomes.

Study participants and Federal Advisory Group members emphasized the need to prioritize research gaps to effectively and efficiently allocate limited research funding. Criteria for prioritization suggested by study participants included the potential impact of the research, the potential to address a gap in an underfunded research area, the potential to address foundational areas of research, and the timeliness of the research. Federal Advisory Group members also noted that, within federal agencies, an important criterion for prioritization is the alignment of an issue with the mission of an agency and its comparative advantage and expertise in funding research on the topic.

7. Conclusions and Recommendations

Since its emergence as an independent field of study in the 1960s, HSR has helped establish an evidence base to support decisionmaking and improvements in the quality, safety, effectiveness, and efficiency of health care in the United States. HSR findings have been used to improve the design of health care benefits, inform health care policy, and help providers and patients make better decisions about health care.

PCR has emerged as a distinct field in its own right, addressing a central component of the health care system. The Council of Academic Family Medicine and other organizations have identified key characteristics of primary care, which highlight the importance of PCR, including its ability to touch the lives of all Americans, focus on the whole person, give attention to common conditions often not treated in hospitals or specialty clinics, and provide evidence that is critical for the delivery of high-quality primary care (Wittenberg, undated).

Consistent with this broad acknowledgment of the many meaningful contributions of HSR and PCR to improve health care, there has been growing recognition of the need to better understand the impact of HSR and PCR and to prioritize potential future directions of research among federal agencies and other stakeholders (National Academies of Medicine, 2018; Simpson et al., 2018; Meyers and Clancy, 2009).

This report has documented the distinct focus areas of federal agency HSR and PCR portfolios, which have developed based on the agencies' congressional authorizations, missions, and operational needs. It also has examined examples of how agencies have coordinated research funding on similar topics in complementary ways according to their distinct focus areas and expertise, as well as how federally funded HSR and PCR have had a wide range of impacts that are often cumulative across research portfolios. At the same time, the study has identified the need for federal agencies to more proactively recognize areas of potential overlap in research portfolios; to improve the communication, relevance, and timeliness of research results; and to prioritize the myriad of gaps in research in order to keep pace with and help guide the complex and rapidly changing U.S. health care system.

In this chapter, we summarize these results and offer recommendations to improve the outcomes and value of federal HSR and PCR investments, including strategies for better coordination and potential realignment of research agendas. Each recommendation addresses a key gap or other important theme from the findings. Action steps included with each recommendation represent suggestions of study participants or the RAND study team based on the analysis, as specified below.

Summary of Key Results

Federal Agency Portfolios in HSR and PCR Have Distinct Focus Areas Based on Their Individual Congressional Authorizations, Missions, and Operational Needs

HHS agencies and the VHA have developed research portfolios of HSR and PCR around focus areas that address the requirements of their individual congressional authorizations, missions, and operational needs. These portfolios differ in terms of scope, research objectives, and main audiences, which reflect agencies' distinct focus areas in HSR and PCR. For example, study participants across the range of stakeholders noted AHRQ as the only agency that has statutory authorizations to generate HSR and be the home for federal PCR, and the unique focus of its research portfolio on systems-based outcomes (e.g., making health care safer, higher-quality, more accessible, equitable, and affordable) and approaches to implementing improvement across health care settings and populations in the United States. NIH's portfolio of HSR and PCR addresses a similarly broad scope of health care but tends to be organized around specific diseases, body systems, or populations. CDC's portfolio of HSR and PCR is organized around diseases, health conditions, and injuries, but focuses on prevention and health promotion spanning community and health care settings. The portfolios of other agencies tend to focus on specific health care settings or other populations (e.g., CMS on Medicare and Medicaid beneficiaries, VHA on veterans' health care and health, and ACL on community-living elderly and disabled individuals), or research audiences (e.g., ASPE on federal policymakers).

Results of the environmental scan and portfolio analysis's systematic enumeration of HSR and PCR projects confirmed a number of these distinct focus areas. At the same time, the scan results showed that other agency portfolios include projects in these areas, albeit to a lesser extent, as well as strong emphasis across agencies on the broad research domains of Quality of Care and Organization of Care. While the qualitative results from TEP and interview participants indicated that agencies would be expected to approach these topics differently, the broader categories of the scan analysis were not able to detect these distinctions. Thus, the study next examined the degree to which research funded by agencies in similar topic areas is complementary or redundant, and the extent and ways in which federal HSR and PCR funding is coordinated among agencies.

Agency-Funded HSR and PCR on Similar Topics Is Largely Complementary, but Potential Overlap in Portfolios Needs to Be Identified More Proactively

Study participants across various stakeholder groups emphasized the value of complementary overlap in agencies' research portfolios, if the studies are sufficiently coordinated. They noted that agencies acted to address redundancy in research portfolios and worked to ensure that funding of research reflected the distinct roles and value-added of each agency once such redundancies have been recognized. Participants also observed federal agencies to be adept at

utilizing appropriate and effective formal and informal mechanisms for coordination. Informal coordination mechanisms included interpersonal staff connections and networks and were considered critical facilitators of formal coordination.

However, study participants commented on the lack of systematic processes for proactively identifying potential overlap in HSR and PCR portfolios across agencies. Individual study participants also suggested research areas they considered to lack sufficient coordination. Specific challenges to coordination of HSR and PCR portfolios noted by study participants included the breadth and volume of research activity across the federal HSR and PCR enterprise, differing time frames of research among agencies, and the lack of targeted funding for a lead agency to coordinate PCR in particular.

Federally Funded HSR and PCR Have Resulted in Wide-Ranging Impacts, Which Are Often Cumulative Across Agency Portfolios

Understanding how HSR and PCR can and have had impact on these systems is important for assessing the contributions of federally funded research and for informing the prioritization of research gaps. Based on existing frameworks of research impact as well as discussions with TEP and interview participants, we identified six categories of impact, which we illustrated with examples of federally funded HSR and PCR: (1) scientific impact, (2) professional knowledge and practice impact, (3) health care systems and services impact, (4) policy impact, (5) patient impact, and (6) societal impact. It is unlikely for single projects to generate impact across all categories, and the impacts of specific projects may not always occur in a linear order. However, the types of impacts identified represent a progression from interim research impacts (i.e., on scientific knowledge, professional practice, health care systems, and policy) to direct outcomes for patients and wider outcomes for society. As such, they represent a general guiding framework for assessing the accumulated impact of portfolios of research within an agency or that span agencies.

In addition to identifying types of impact, study participants noted important challenges to *assessing* impact, including the difficulty of tracing the accumulation of impacts across specific projects or sets of projects within a portfolio, especially when research is funded by multiple agencies. Impact may take time to accumulate and be realized, which further complicates attribution to specific projects or sources of funding. Moreover, many types of impact are by their nature difficult to systematically measure. Study participants also called attention to challenges in *achieving* impact of HSR and PCR, including a lack of investment in high-risk studies and various disconnects between research and implementation.

The Variety of Gaps in HSR and PCR Reflect the Challenge of Improving U.S. Health Care, Which Requires New Research Approaches and Strategies for Prioritizing Research Needs

TEP and interview participants identified a wide range of research gaps in HSR and PCR, reflecting the complexity and rapidly evolving landscape of the U.S. health care system. Many of these gaps are related to specific "inputs" and "outputs" of health care services in the study's research domain framework (Figure 2.1). However, many of the gaps also reflect the difficulty of understanding the *linkages between health care inputs and outputs* to produce important outcomes and the limitations of currently used research approaches to generate and disseminate evidence in ways that have a meaningful impact on real-world health care systems and practice. At the same time, these gaps represent opportunities to find new ways to use research to solve problems and improve the health care system, and ultimately the nation's collective health.

Our analysis highlighted key gaps, that is, research gaps that were raised by multiple study participants within one stakeholder perspective or across stakeholder perspectives. Study participants noted that many of these gaps have been the subject of research studies sponsored by federal agencies and other funders, but that further research is needed, or different research approaches are required to make positive impact on health care delivery and health outcomes.

TEP participants and Federal Advisory Group members also emphasized the need to prioritize research gaps to effectively and efficiently allocate limited research funding. Study participants noted the importance of the prioritization process using transparent and explicit criteria, and engaging the range of relevant stakeholders including consumer groups. Possible criteria for prioritization mentioned include the potential for impact, the potential to address a gap in a poorly funded research area, the potential to address foundational areas of research, and the timeliness of the research. Federal Advisory Group members additionally noted that, within federal agencies, an important criterion for prioritization is the alignment of an issue with the mission of an agency and its comparative advantage and expertise in funding research on the topic.

Recommendations to Maximize the Outcomes and Value of Federally Funded HSR and PCR

Based on our review of the key study results and suggestions of study participants, we propose three sets of recommendations: cross-cutting recommendations on approaches to research, dissemination, and implementation of federally funded HSR and PCR (Table 7.1); recommendations to improve the impact of HSR (Table 7.2); and, recommendations to improve the impact of PCR (Table 7.3). In the discussion of each recommendation, we suggest the types of actions that are needed to implement the recommendation.

Cross-Cutting Recommendations in Approaches to Research, Dissemination, and Implementation

Our first set of recommendations to improve the impact of federally funded HSR and PCR addresses three key gaps in research approaches identified by study participants, specifically, the need to: (1) improve *relevance and timeliness* of research, (2) increase *innovation* in research, and (3) improve *translation of research* into practice. We suggest specific action steps for each recommendation.

Table 7.1. Cross-Cutting Recommendations on Approaches to Research, Dissemination, and Implementation

Recommendations	Suggested Action Steps
Improve the relevance and timeliness of HSR and PCR	• Create funding mechanisms that support more rapid, engaged research approaches, such as embedded research and learning health systems models, and dissemination of their results. • Expand funding to refine mixed qualitative and quantitative methods suited to generating evidence on the implementation of change in complex health care systems.
Encourage innovation in HSR and PCR	• Create funding mechanisms that support innovative high-risk, high-reward research.
Improve translation of HSR and PCR into practice	• Train and assist researchers in effectively communicating results in formats actionable for health care delivery stakeholders. • Fund research to identify the most effective channels to communicate research results for different users of HSR and PCR. • Require researchers to consider implementation issues earlier in the study development and proposal process and explicitly apply theories of change to help connect disparate results. • Expand funding for the synthesis of evidence across research studies on topics of interest to health care delivery and other users of HSR and PCR.

Improve Relevance and Timeliness of HSR and PCR

The study identified the need to improve the relevance and timeliness of HSR and PCR for health care delivery stakeholders. Study participants noted that many federally funded HSR and PCR studies take a relatively long time to be approved and conducted compared to the pace of change in health care delivery systems. In addition, such research often occurs in highly controlled conditions or atypical settings that are difficult to generalize. These studies typically do not use research designs or methods suited to examining the complex dynamics of health delivery in ways to guide improvement. The action steps described below seek to improve both the relevance and timeliness of HSR and PCR.

Create funding mechanisms that support more rapid, engaged research approaches, such as embedded research and learning health systems models, and dissemination of their results. Embedded research models place health service researchers within health care settings to work closely with leaders and staff to develop and conduct research projects. Learning health systems offer another type of research model in which health care delivery systems seek to

develop improvements in care based on rigorous analysis of their own storehouses of EHR and other care service data. Both types of models involve blurring the lines between traditional health care quality improvement activities and HSR in order to improve the relevance and timeliness of research and, ultimately, health care delivery.

However, current federal funding mechanisms are not suited to funding projects that utilize these models, particularly due to the length of time it takes for typical federal extramural HSR and PCR projects to be awarded. A new delivery system intervention in the current rapid pace of health care systems may already be implemented or substantially evolved by the time a federal grant is funded for its study. Federal funding agencies also have an important role in ensuring that results and methods of embedded research and learning health system models are disseminated beyond the specific health delivery systems in which they are generated.

AHRQ has supported studies of learning health systems and funded projects involving embedded research. The VHA has funded an embedded research initiative within the VHA system. Such efforts can provide a foundation for further support and funding of these models by federal agencies.

Expand funding to refine mixed qualitative and quantitative methods suited to generating evidence on the implementation of change in complex health care systems. Study participants pointed to the need to expand the use of qualitative methods, such as interviews, focus groups, and observational methods that more directly examine the context of health care delivery and the process of change in health care systems. In particular, emphasis was placed on the need to further develop and refine mixed designs that use both qualitative and quantitative methods. More regularly and effectively incorporating mixed qualitative and quantitative methods would help to link health care context and process with outcomes and produce richer and more relevant evidence for stakeholders on effective health care interventions and change. Included in these research methods would be hybrid study designs that take a dual focus on evaluating clinical effectiveness and implementation.

Encourage Innovation in Research

The study found that current funding mechanisms reward safe, but incremental research over innovative, but risky research. Study participants reported this bias for peer-reviewed grant mechanisms, which tend to gravitate to a traditional incremental approach to science, as well as CMMI's demonstrations, given the size and investment in the payment and delivery models being tested. To address the need for innovative research with the potential to yield breakthroughs in health care system design and change, we recommend that individual funding agencies consider the following action step.

Create funding mechanisms that support innovative high-risk, high-reward research. One suggestion by study participants was to fund small-scale pilot studies to test innovative approaches, particularly for strategies to reduce health care costs and for new payment and incentive models, which tend to change rapidly in the current health care environment. Given the

noted bias of conventional funding mechanisms, funding these, or other high-risk, high-reward studies, would likely require separate review processes, selection criteria, and funding streams. Study participants also mentioned lessons from past federal efforts, such as the need to not only fund health care innovations but also learn from them. Efforts by private foundation funders of HSR and PCR, who have launched initiatives to support innovative research, may also provide lessons for federal agencies.

Improve Translation of HSR and PCR Findings into Practice

The study identified a need to improve the translation of research into practice, which is hindered when HSR and PCR findings are not communicated in actionable ways to health care stakeholders. In addition, evidence related to topics of interest is often dispersed across studies and sources. To improve the translation of federally funded HSR and PCR into practice, we recommend that individual federal agencies consider the following action steps.

Train and assist researchers in effectively communicating results in formats actionable for health care delivery stakeholders. Health care delivery leaders and participants from other stakeholder groups, who use HSR and PCR results, highlighted the need to know not only *what* system changes or care interventions have been shown to be effective, but also *how* to implement and adapt innovations into service settings. This includes presenting key details that may affect implementation, as well as the key steps or "playbook" needed to implement and adapt the innovation for replication into new settings. In addition to lists of key steps, case studies or stories can be effective at communicating the dynamics of implementation. Such information can be communicated in research publications and packaged into toolkits with materials (e.g., checklists, training guides, and presentations) that facilitate implementation.

Yet, the expertise to do so is not typically in the expected skill set of researchers. Training in such skills and strategies would allow researchers to better translate findings into actionable formats. This training could also be incorporated into current research training and career advancement grant programs. Resource centers operated by staff in federal agencies or other institutions with this expertise could provide training as well as translate or assist researchers in translating HSR and PCR findings into actionable formats.

Researchers also do not typically receive funding to translate findings into actionable formats for implementation and further dissemination of evidence-based interventions. The VHA and AHRQ offer separate funding mechanisms for dissemination, and the VHA offers a mechanism for intervention studies to apply for additional funding to disseminate to other settings in the VHA system. Such funding mechanisms in these, and other agencies, should be expanded.

Fund research to identify effective channels to communicate research results for users of HSR and PCR. Federal agencies should also investigate the communication channels most frequently utilized by the range of stakeholder audiences for their funded HSR and PCR, which may include newer channels such as social media apps, online video platforms, and podcasts, in addition to conventional channels such as journal articles, written clinical guidelines, or research

reports. The channels that are most effective for a chosen audience may also influence the format as well.

Require researchers to consider implementation issues earlier in the study development and proposal process and explicitly apply theories of change to help connect disparate results. Considering implementation issues earlier in the proposal and study design process could accelerate the translation and dissemination of findings into practice and ultimately address barriers to adoption and the use of research. Study participants also noted that applying and building theories, conceptual frameworks, and logic models of change are useful to help connect disparate HSR and PCR findings and advance knowledge on implementation of improvements in health care systems. For example, such change theories, frameworks, and logic models help indicate why certain interventions may be expected to work in certain settings, explain when they work or do not work, and generate implications for generalizing results to other health care settings.

Similar to funders like the VHA, requirements could include guidelines for developing research projects as well as incentives built into scoring assessments for funding research proposals.

Expand funding for synthesis of evidence across research studies on topics of interest to health care delivery and other HSR and PCR stakeholders. Study participants appreciated synthesized research evidence on HSR and PCR topics, such as those generated through AHRQ's evidence-based practice reports and other sources (e.g., online clearinghouses or research resources of various federal agencies).

Recommendations to Improve the Impact of Federally Funded HSR

Our second set of recommendations focus on improving the impact of federally funded HSR in particular, and addresses three key themes identified by study participants: (1) prioritization of the many ongoing and emergent research gaps in HSR, (2) coordination of federally funded HSR by proactively identifying potential overlap in agency research portfolios, and (3) maintaining alignment of federally funded HSR through continued support of AHRQ as an independent agency within HHS to serve as the funded hub of federal HSR.

Table 7.2. Recommendations to Improve Impact of HSR

Recommendations	Suggested Action Steps
Identify HSR priorities for agencies to effectively allocate research funding	• Initiate a strategic planning process across federal agencies to prioritize HSR areas for funding investments.
Proactively identify potential overlap in agency HSR portfolios	• Establish a review process and data systems to proactively identify areas of potential HSR overlap across agencies.
Maintain a funded entity to address core HSR needs and coordinate federal HSR efforts	• Maintain AHRQ as an independent agency within HHS to serve as the funded hub of federal HSR.

Identify HSR Priorities for Agencies to Effectively Allocate Research Funding

The study found that federal agencies engage in internal strategic planning and research prioritization processes, frequently with input from other agencies. However, no overall prioritization of HSR agendas occurs across agencies, except on a limited number of topics. At the same time, health care delivery stakeholders encouraged federal agencies to have a single agenda for HSR to ensure that priority research areas are being addressed across federal research portfolios. We recommend that HHS and VHA departmental leadership authorize the following steps.

Initiate a strategic planning process across federal agencies to prioritize HSR areas for funding investments. A strategic planning process to prioritize HSR areas across federal agencies would facilitate consensus on research needs. It would also indicate how individual agencies' priorities relate to an overall federal HSR agenda, and to priority areas not currently being addressed. Given the breadth of HSR topics and federal funding, separate but linked processes for prioritizing HSR within sub-fields would help to ensure that efforts are manageable and sufficiently fine grained to provide agendas that are useful for guiding research funding decisions. Ideally, this set of processes would also be linked to the individual strategic planning and research priority processes within agencies, as well as to existing prioritization efforts among health care stakeholders to provide opportunities for more fully aligned federal HSR priorities with the research agendas of private funders. AHRQ's role as the federal agency with statutory authority for HSR would make it a natural lead agency for such a process, but as study participants noted, this effort would need authorization from departmental leadership.

Study participants also emphasized that such a cross-agency process should use transparent criteria, and incorporate input and participation of health care stakeholders—including consumers. Focusing research on problems of importance to health care stakeholders—including health care administrators, clinical leaders, policymakers, purchasers and payers, patients, families, and caregivers—was expected by study participants to increase the likelihood and speed with which findings are adopted. TEP participants also suggested that longer-term issues (e.g., health care consolidation, resolution of health care disparities) and research methods (e.g., better integration of qualitative and quantitative methods in mixed study designs) be prioritized within their own areas or "buckets" to ensure that key needs in these areas are not continually overlooked compared to more immediate, high-visibility topics (e.g., the opioid epidemic).

Proactively Identify Potential Overlap in Agency HSR Portfolios

A strategic planning process across federal agencies would facilitate coordination of HSR agendas, but the study also identified the need to proactively identify potential overlap in agency HSR portfolios. Study participants from various stakeholder groups noted that federal agencies act to address redundancies in research portfolios and are generally adept at coordination once redundancies are recognized, but that identification of potential overlaps in portfolios occurs

inconsistently. We recommend that HHS and VHA departmental leadership consider the following action steps.

Establish a review process and data systems to proactively identify areas of potential research overlap across agencies. Proactively identifying areas of potential research overlap would require: (1) systematic data on planned and current HSR projects across agencies to identify areas of general potential overlap, and (2) a process for staff from different agencies, with expert knowledge on federal HSR portfolios, to review the data to determine whether the overlap is complementary or redundant; and whether it affects research agendas of additional agencies.

Systematic data on federally funded HSR grants are available through the NIH RePORTER database, which contains grant projects across HHS agencies and the VHA, as well as other grants databases used by federal agencies. However, based on our experiences cataloging HSR for this study, implementing this recommendation would require the creation of a federal-wide data system for contracted HSR projects. Data systems for federal contracts are neither designed nor well suited for identifying research projects, let alone HSR-related research. These contract databases also tend to provide less information about the content of research projects needed to distinguish domains and categories of research compared to the RePORTER and other grants databases. Without such a data system for contracted projects, HHS lacks ongoing visibility into the breadth and scope of a significant portion of federally funded HSR.

Maintain a Funded Entity to Address Core HSR Needs and Coordinate Federal HSR Efforts

This study documented the breadth and complexity of HSR, highlighting both the need for research in HSR beyond the capacity of any single agency, and different agencies to contribute to the federal HSR enterprise depending on their missions and operational requirements. At the same time, the study emphasized the critical role of a central entity or hub that is responsible for ensuring that core issues of HSR are funded, and that research conducted across agencies is bridged and coordinated.

The study found consensus across all stakeholder groups on the unique and effective role AHRQ serves in HSR as the only agency focused on health care system outcomes and improvement of health services across health care settings and populations in the United States. It plays a key role in bridging disease-, population-, and setting-specific HSR funded by other agencies, as well as translating and promoting implementation of HSR evidence with health care delivery systems and stakeholders to effect change. This is also its current statutory mandate. Thus, we recommend the following step.

Maintain AHRQ as an independent agency within HHS to serve as the funding hub of federal HSR. This recommendation requires no additional action. We also note that some study participants suggested the possibility of relocating AHRQ from an independent agency in HHS to an institute within NIH. Potential advantages discussed by study participants included the possibility of more stable federal funding and increased status within the academic research community. Risks discussed by study participants included potential drift of AHRQ away from

more impactful research for health services and primary care systems (i.e., toward more academic research) and a loss of focus on broader systems of care (i.e., toward more disease- and organ-specific emphases). Other study participants, including those within NIH, noted the difficulties smaller ICs within NIH would face coordinating with larger institutes, which would be a disadvantage compared to external agencies. We judge that the risks associated with moving AHRQ or its role as the funded hub of federal HSR into NIH outweigh the potential advantages. The risks are particularly concerning given they would affect the distinct role and capabilities of AHRQ in the federal HSR and PCR enterprise. We thus do not recommend that AHRQ or its role as the funded hub of federal HSR be located within NIH.

Recommendations to Improve the Impact of Federally Funded PCR

Our third set of recommendations focuses on improving the impact of federally funded PCR. These recommendations also address key themes identified by study participants related to prioritization, coordination, and the alignment of federal agency research portfolios , but attending to the distinct needs of PCR. First, a separate interagency prioritization process for PCR would ensure that core primary care research needs are attended to. It also would incorporate the specific sets of primary care stakeholders needed to inform prioritization, as well as span clinical research and HSR, both of which are part of the PCR field. Second, a process that proactively identifies potential overlap in federal agency PCR portfolios would focus on coordinating research efforts to maximize the limited federal funding available for PCR and rely on the expert staff of different agencies in federal PCR portfolios. Lastly, with respect to the alignment of federal PCR efforts, we recommend providing funding for a hub of federal PCR that includes targeted funding for *both* research on core functions of primary care *and* coordination of PCR across federal agency research portfolios.

Table 7.3. Recommendations to Improve Impact of PCR

Recommendations	Suggested Action Steps
Identify PCR priorities for agencies to effectively allocate research funding	• Initiate a strategic planning process across federal agencies specifically dedicated to prioritizing PCR areas for funding investments.
Proactively identify potential overlap in agency PCR portfolios	• Establish a review process to proactively identify areas of potential PCR overlap across agencies.
Fund an entity to address core primary care research needs and coordinate federal PCR efforts	• Provide targeted funding for a hub for federal PCR.

Identify PCR Priorities for Agencies to Effectively Allocate Research Funding

The study found that research is lacking on key PCR priorities due to the fragmentation of PCR funding across agencies with missions and research focuses that do not include the core functions of primary care. This gap includes research on how effective primary care practices a holistic approach to addressing personal health care needs, and its role in the wider health care system. To ensure that the distinct needs for PCR are attended to, we recommend that HHS and VHA departmental leadership consider authorizing an effort to:

Initiate a strategic planning process across federal agencies specifically dedicated to prioritizing PCR areas for funding investments. A separate prioritization process would also incorporate other distinct features of the PCR field. These distinct features include the specific sets of stakeholders needed to inform prioritization, and the breadth of PCR spanning both clinical research on common health conditions found in primary care and health services research in primary care context. The latter would need to be linked with the federal HSR prioritization process described above. As with the HSR prioritization process, AHRQ's statutory authority as the home for federal PCR and its current role in synthesizing and bridging PCR across agencies would make it a natural lead agency for such an initiative. However, there currently are no dedicated resources nor departmental authorization for such an interagency prioritization process, which study participants noted would be needed.

Proactively Identify Potential Overlap in Agency PCR Portfolios

There is also a need to proactively identify potential overlap in federal agency PCR portfolios. Study participants considered the risk of redundancy in agency PCR portfolios to be less than with HSR, given the relatively smaller amount of federal funding for PCR. However, early coordination of PCR efforts becomes even more important to maximize the impact of limited resources to address primary care research needs. Thus, we recommend that HHS and VHA departmental leadership consider authorizing an effort to:

Establish a review process to proactively identify areas of potential PCR overlap across agencies. The PCR review process could utilize the data systems developed for the HSR process to identify potential overlap but rely on staff from different agencies expert in federal PCR portfolios. The PCR review process for HSR topics in primary care contexts would need to be coordinated with the HSR review process described above. As with the prioritization process, departmental authorization would be needed for such an interagency initiative.

Fund an Entity to Address Core PCR Needs and Coordinate Federal PCR Efforts

The study found that the lack of a funded hub of federal PCR has created a critical research gap on the core functions and role of primary care within the U.S. health care system, and hampered coordination of federal PCR. AHRQ currently has a statutory mandate to serve as the federal home for PCR but does not receive targeted appropriations for this mission. This requires that the agency's funding for PCR comes from, and is often tied to, portfolios of HSR within the

agency (e.g., patient safety or HIT implementation). Likewise, funding for PCR in other agencies tends to become focused on their particular missions and priorities (e.g., managing specific diseases in primary care for certain populations or specialized federal delivery systems). We recommend the following step.

Provide targeted funding to create a hub for federal PCR. Study participants emphasized that the most expeditious way to create a funded hub to support research on core PCR needs and adequately coordinate federal PCR efforts would be to provide targeted funding for this mission to AHRQ, which already has the statutory authorization for this role. Despite not having received targeted funding for this mission, the agency has been able to sponsor key studies on primary care systems and innovation to help fill this gap. In addition, it operates the National Center for Excellence in Primary Care Research that has expertise in disseminating evidence, practical tools, and other resources to improve primary care.

Study participants also discussed potential advantages to creating the funded hub of PCR as an independent agency or office within HHS. These include possibly greater ability to attract funding for PCR and autonomy to focus on a PCR agenda wider than typical HSR domains.

In either case, the hub of federal PCR should include targeted funding for *both* research on core functions of primary care *and* coordination of PCR across federal agency research portfolios. This targeted funding could be supported through federal appropriations or a fee assessed on health care insurers or delivery systems, similar to the mechanism used for the Patient Centered Outcomes Research (PCOR) Trust Fund, with the rationale that PCR improvement likewise benefits patients across the U.S. health care system. Either option for funding a federal PCR hub would require legislative action by Congress.

Some study participants suggested the possibility of creating the funded hub of PCR as an institute within NIH. We judge the risks associated with locating the funded hub of PCR within NIH to outweigh the advantages, for reasons similar to those mentioned above for AHRQ. Study participants also noted an additional risk. Other institutes and centers within NIH may reduce their funding for PCR if a funded hub for this field was established within the agency. We thus do not recommend that the funded hub of federal PCR be located within NIH.

Conclusions

This study has identified a number of important gaps in health services and primary care research, many of which are driven by the complexity and rapidly changing landscape of the U.S. health care system. As in the past, there is great opportunity for federally funded HSR and PCR to have a meaningful impact and guide understanding of new models of care delivery and payment. It can also inform health care stakeholders on best practices for implementing specific health care innovations and interventions and disseminating and promoting health system change.

Study participants across a broad range of stakeholder groups attested to the unique and important role that AHRQ plays in generating HSR, synthesizing evidence, and scaling up

dissemination to drive improvement of health services across the U.S. health care system. Participants also noted AHRQ's central role in PCR promoting systems-based research, evidence and tools to improve primary care.

However, the breadth and complexity of HSR and PCR, and the need for research in these fields, are beyond the capacity of any single agency. Other federal agencies contribute critical equities and functions in funding HSR and PCR depending on their congressional authorizations, missions, and operational needs. NIH plays a fundamental role in the development of biomedical and clinical treatments and in testing the efficacy and effectiveness of care interventions and strategies for specific diseases, body systems, and populations. ASPE plays a critical role in supporting and translating research to inform policy; CDC in research on prevention and the intersection between the health care system and public and community health efforts; CMS in evaluations of quality measurement systems as well as payment and delivery innovations for beneficiaries in Medicare, Medicaid, and other CMS programs; and the VHA in research on veterans' health and the veterans' health system. HRSA provides critical leadership in research on safety net services and the health care workforce, and ACL focuses on research to support community living of elderly and disabled individuals.

The study also has identified opportunities to improve approaches to research funding and methods to ensure that federally funded HSR and PCR can keep pace with, and continue to guide, change in health care delivery systems. It additionally has offered separate recommendations for HSR and PCR to improve the outcomes and value of federal research investments, including strategies for better prioritizing, coordinating, and aligning agency research portfolios.

Overall, the study has distinguished the strengths and contributions of the many HHS agencies and the VHA to the federal HSR and PCR enterprise, as well as offered insights on how to improve these research programs to serve the needs of the evolving U.S. health care system. The results of the study provide a balanced, evidence-based understanding of federally funded HSR and PCR that policymakers can use in shaping the future of the federal HSR and PCR enterprise.

Appendix A. Details on Scan Data Set, Manual Reviews, Algorithm Classification Methods, and Supplemental Scan Results

This appendix provides additional information about the data set, methods, and results used in the environmental scan to supplement the discussion in Chapters 2 and 3. This appendix first describes the composition of the scan data set, followed by details on the number of manual reviews conducted and measures of interrater agreement. The appendix then provides information on machine learning methods and algorithm accuracy and, last, supplemental scan results providing confidence intervals for the tables reported in Chapter 3 and scan results by year.

Composition of the Scan Data Set

As discussed in Chapter 2, the study team drew on two primary data sources: publicly available databases of federally funded grant projects, and contract and grant data provided to RAND directly by federal agencies. Table A.1 on the following page breaks down the projects in the scan data set by source, funder, and type.

Table A.1. Number of Projects in Scan Data Set, by Type, Source, and Funder

Type	Source	ACL	AHRQ	CDC	CMS	NIH	VHA	All Agencies
Grants	RePORTER	0	850	1,092	0	79,677	2,748	85,531
	Agency-provided	68	33	35	0	0	661	797
	Overlap[a]	*0*	*33*	*34*	*0*	*0*	*396*	*463*
	Total grants	68	850	1,093	0	79,677	3,013	85,865
Contracts	RePORTER	0	0	0	0	6,614	0	6,615
	Agency-provided[b]	0	305	0	75	0	0	380
	Total contracts	0	305	0	75	6,614	0	6,995
	Total projects	68	1,155	1,093	75	86,321	3,013	93,075

NOTE: The grant and contracts numbers are based on the scan data set, following merging of nonunique project records and the exclusion of projects that met any of the following criteria: (a) projects with pre-FY 2012 start dates, (b) projects with post-FY 2018 start dates, (c) projects missing abstracts, (d) projects with RePORTER activity codes related to research infrastructure and support, and (e) projects conducted intramurally by agency staff. See Chapter 2 for additional details.

The All Agencies and All Projects Totals include 1 ACF contract, 185 other ACF projects of unknown type, 9 ATSDR grants, 1,155 FDA grants, and 30 NIH projects of unknown type.

[a] Agency-provided grants also in RePORTER. Not included in sum of Total grants.

[b] No overlap with RePORTER.

Table A.2 describes the extent of the grants and contracts included in the scan data set from each funder, focusing in particular on whether the data set appears to include all, some, or no grants or contracts from each funding agencies. For each agency, these determinations were based on whether project data were available in RePORTER and whether there were any indications that these RePORTER data were incomplete.

While projects available in RePORTER potentially represent complete research grant and contract portfolios for a given funding agency, the projects provided directly by the agencies only represented those grants or contracts that were identified by that agency as likely being in-scope as HSR, PCR, and/or MTD. In addition, for both the CDC and the VHA, there were indications that the grants included in the scan data set from RePORTER were not fully representative of those agencies' research portfolios. A large proportion of the CDC research grants listed in RePORTER were missing abstracts and thus could not be included in the scan data set.

Table A.2. Extent of Projects Included in the Scan Data Set, by Type and Funder

Funder	Grants	Contracts
ACL	Data set contains grants selected by agency contacts as likely in-scope for this study, but not the agency's full grant portfolio.	Agency does not award research contracts.
AHRQ	Data set appears to include the full research grant portfolio. Data set includes all AHRQ-funded grants in RePORTER, which includes all grants in the AHRQ's Project Research Online Database as well as all agency-provided grants.	Data set contains contracts selected by agency contacts as likely in-scope for this study, but not the agency's full contract portfolio.
CDC	Data set contains grants selected by agency contacts as likely in-scope for this study, as well as all CDC-funded grants in RePORTER, except for a large proportion that were missing abstracts.	Agency does not award research contracts.
CMS	Agency does not award research grants.	Data set contains contracts selected by agency contacts as likely in-scope for this study, but not the agency's full contract portfolio.
NIH	Data set appears to include the full research grant portfolio. Data set includes all NIH-funded grants in RePORTER.	Data set appears to include the full research contract portfolio. Data set includes all NIH-funded contracts in RePORTER.
VHA	Data set contains grants selected by agency contacts as likely in-scope for this study, as well as all VHA-funded grants in RePORTER. However, a substantial proportion of the grants directly provided by the VHA were not present in RePORTER (matching against grant number, PI, and/or abstract). This suggests that not all VHA grants may be entered into RePORTER, and thus our data set may be missing some VHA research grants.	Agency does not award research contracts.

Data for the VHA were more complicated. The RePORTER database did not include all the grants provided by the agency, and the agency-provided grants did not include all projects from the RePORTER database identified as in-scope by the study. Thus, it is unclear whether the combined data obtained from the VHA and the RePORTER database represent the complete portfolio of VHA projects including all out-of-scope projects.

Excluded National Institutes of Health Activity Codes

Projects that focused on research infrastructure, career development, conferences, and service provision were excluded from the environmental scan data set based on their NIH activity code. The specific NIH activity codes that were excluded in this way are listed below:

- A03, A10, A22
- B04
- C06, C12, C13, C8A, C8B, C8C, C8D
- D04, D06, D09, D11, D18, D19, D33, D34, D43, D57
- F05, F30, F31, F32, F33, F99
- G01, G02, G05
- H1G, H1M, H1U, H1W, H2A, H2Q, H30, H33, H34, H37, H3A, H3D, H3G, H3H, H46, H47, H49, H4A, H4B, H54, H56, H61, H65, H6M, H76, H7M, H80, H84, H87, H98, HS0
- K01, K02, K05, K07, K08, K12, K18, K22, K23, K24, K25, K26, K43, K76, K99
- P20, P2C, P30, P40, P50, P60, PN2
- R13, R15, R25, R35, R36, R37, R3
- T08, T0B, T12, T15, T23, T32, T34, T35, T37, T42, T90, T94, TL1
- U13, UL1
- X02, X08, X09, X10.

Research Portfolios by Type, Funding Agency, and Year

The four tables below show the relative proportion of contracts as compared to grants for each funding agency, by year, for both the entire scan data set (Tables A.3 and A.4) and for only the set of projects that were found to be in-scope for the study (Tables A.5 and A.6).

Table A.3. Project Type, by Funding Agency

	ACL	AHRQ	CDC	CMS	NIH	VHA	All Agencies[a]
Total projects in scan data set[b]	68	1,155	1,093	75	86,321	3,013	93,075
Contracts	0 (0%)	305 (26%)	0 (0%)	75 (100%)	0 (0%)	0 (0%)	6,995 (8%)
Grants	68 (100%)	850 (74%)	1,093 (100%)	0 (0%)	1,155 (100%)	3,013 (100%)	85,865 (92%)

[a] The "All Agencies" contract and grant numbers include projects from the six agencies in the table as well as 1,155 FDA grants, 9 ATSDR grants, and 1 ACF contract. There were also 185 ACF projects that were missing project type information in Reporter; these were counted in the "All Agencies" total project number but not in the contract or grant project numbers. The FDA, ATSDR, and ACF project numbers are not reported separately since we did not perform member-checking of those results with the agencies as required by the scan methodology.

[b] The "Total Projects" numbers are based on the scan data set, which includes data from the RePORTER database and directly from individual agencies, following merging of nonunique project records and the exclusion of projects that met any of the following criteria: (a) projects with pre-FY 2012 start dates; (b) projects with post-FY 2018 start dates; (c) projects missing abstracts; (d) projects with RePORTER activity codes related to research infrastructure and support; and (e) projects conducted intramurally by agency staff. See Chapter 2 for additional details.

Table A.4. Percent of Projects That Are Contracts, by Funding Agency and Year

Year	ACL	AHRQ	CDC	CMS	NIH	VHA	All Agencies[a]
2012	(No projects)	24%	0%	100%	8%	0%	8%
2013	0%	34%	0%	100%	10%	0%	10%
2014	0%	16%	0%	100%	9%	0%	8%
2015	0%	30%	0%	100%	9%	0%	8%
2016	0%	26%	0%	100%	8%	0%	8%
2017	0%	22%	0%	100%	7%	0%	7%
2018	0%	26%	0%	100%	4%	0%	4%
All Years	0%	26%	0%	100%	8%	0%	8%

[a] The "All Agencies" percentages include projects from the six agencies in the table as well as FDA grants, ATSDR grants, and an ACF contract. The latter is not reported separately since we did not perform member-checking of those results with the agencies as required by the scan methodology.

Table A.5. In-Scope Project Type, by Funding Agency

	ACL	AHRQ	CDC	CMS	NIH	VHA	All Agencies[a]
Total in-scope (HSR/PCR/MTD) projects[b]	58	915	328	74	8,707	889	10,989
Contracts	0 (0%)	175 (19%)	0 (0%)	74 (100%)	387 (4%)	0 (0%)	636 (6%)
Grants	58 (100%)	740 (81%)	328 (100%)	0 (0%)	8,320 (96%)	889 (100%)	10,353 (94%)

[a] The "All Agencies" percentages include projects from the six agencies in the table as well as in-scope FDA grants. The latter are not reported separately since we did not perform member-checking of those results with the agency as required by the scan methodology.

[b] The "Total Projects" numbers are based on the scan data set, which includes data from the RePORTER database and directly from individual agencies, following merging of nonunique project records and the exclusion of projects that met any of the following criteria: (a) projects with pre-FY 2012 start dates, (b) projects with post-FY 2018 start dates, (c) projects missing abstracts, (d) projects with RePORTER activity codes related to research infrastructure and support, and (e) projects conducted intramurally by agency staff. See Chapter 2 for additional details.

Table A.6. Percent of In-Scope Projects That Are Contracts, by Funding Agency and Year

Year	ACL	AHRQ	CDC	CMS	NIH	VHA	All Agencies[a]
2012	(No projects)	15%	0%	100%	5%	0%	8%
2013	0%	28%	0%	100%	4%	0%	10%
2014	0%	7%	0%	100%	5%	0%	8%
2015	0%	22%	0%	100%	6%	0%	8%
2016	0%	20%	0%	100%	6%	0%	8%
2017	0%	17%	0%	100%	4%	0%	7%
2018	0%	18%	0%	100%	2%	0%	4%
All Years	0%	19%	0%	100%	4%	0%	8%

[a] The "All Agencies" percentages include projects from the six agencies in the table as well as in-scope FDA grant projects. The latter are not reported separately since we did not perform member-checking of those results with the agency as required by the scan methodology.

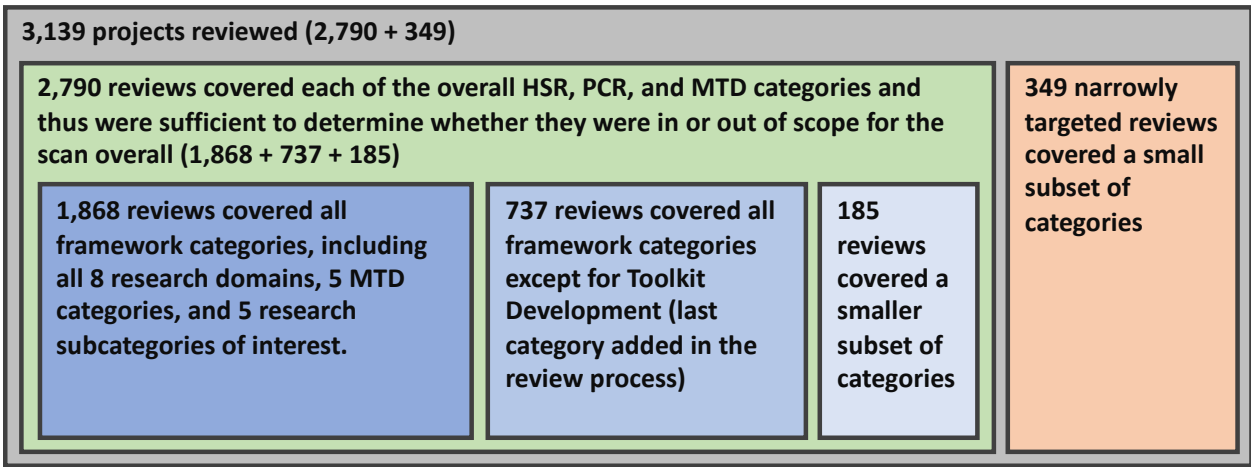
Number of Manual Reviews and Interrater Agreement

The study team conducted manual reviews of 3,139 projects. A total of 2,880 of these reviewed projects were eventually included in the final scan data set of 93,075 project records. The remaining 259 reviewed projects were excluded from the final data set due to their start date falling outside the bounds of the FY 2012 to 2018 study period. While these 259 projects were not counted in the final classification results, they were still used, together with the other manually reviewed projects, to train the machine learning algorithm and test its accuracy.

A total of 2,790 projects (out of the 3,139 total reviewed projects) received reviews that covered each of the overall HSR, PCR, and MTD categories and thus were sufficient to determine whether they were in or out scope for the scan. A total of 1,868 of these 2,790 projects received full reviews that covered all of the classification categories. An additional 737 of these

2,790 projects received reviews of all the classification categories except Toolkit Development, which was added after initial reviews were complete. A further 185 of these 2,790 projects received reviews that did not cover one or more of the other classification categories. And another 349 of the total 3,139 projects received narrowly targeted reviews that covered a smaller subset of individual categories and domains. This information on the varying extents to which these projects were reviewed, including how these groups do and do not overlap, is depicted below in Figure A.1.

Figure A.1. Manually Reviewed Projects Grouped by Extent of Reviews



Some projects were reviewed more than once. A random sample of roughly 200 projects were examined separately by two reviewers in order to measure the degree of interrater agreement on each category, as shown in Table A.7 on the following page. The study team also updated coding guidelines in the middle of the reviewing process for some of the categories after resolving issues that arose in the initial set of reviews. Following this, 711 projects were re-reviewed to ensure their consistency with the updated guidelines.

The study team manually reviewed all 1,176 projects that were directly provided to us by ACL, AHRQ, CDC, CMS, and the VHA and determined whether they were in or out-of-scope for the scan.[1] The final scan data set, which contained 93,075 project records, also included 91,899 projects that were not directly provided by any agency and were instead derived from the RePORTER database. We manually reviewed 1,406 of these projects to determine whether they were in or out-of-scope. The remaining 90,493 projects were classified by the machine learning algorithm.

[1] These 1,176 projects include only those agency-provided projects that fell within the initial bounds of the scan. This number does not include agency-provided projects that were excluded due to missing information or were excluded due to having a start date outside of the FY 2012 to 2018 time period.

Table A.7. Interrater Agreement

Classification Category	Number Reviewed	Number of Double-Coded Projects	Agreed Negative	Disagreed	Agreed Positive	Percent Agreement	Kappa
HSR	394	197	83	18	96	91%	0.82
PCR	394	197	169	15	13	92%	0.59
MTD	386	193	141	16	36	92%	0.76
In-Scope (HSR, PCR, and/or MTD)	386	193	65	13	115	93%	0.86
Quality of Care	390	195	86	40	69	79%	0.59
Cost and Utilization	382	191	137	24	30	87%	0.64
Access to Care	372	186	130	31	25	83%	0.51
Equity	388	194	157	17	20	91%	0.65
Systems of Care	388	194	89	25	80	87%	0.74
Financing of Care	388	194	188	0	6	100%	1.00
Social Factors	380	190	161	19	10	90%	0.46
Personal Preferences and Behaviors	388	194	117	33	44	83%	0.61
Definitive Health Outcomes	362	181	132	31	18	83%	0.43
Aging	362	181	166	7	8	96%	0.68
Multimorbidity[a]	362	181	164	13	4	93%	0.34
Patient Safety	362	181	157	14	10	92%	0.55
Pediatrics	362	181	175	1	5	99%	0.91
Prevention	360	180	125	25	30	86%	0.62
HIT Applications and Tools	386	193	166	13	14	93%	0.65
Model Development and Validation	386	193	156	13	24	93%	0.75
Toolkit Development	330	165	153	3	9	98%	0.85
Evidence Review and Synthesis	386	193	191	0	2	100%	1.00
Simulation Modeling	384	192	187	2	3	99%	0.74

[a] While some projects were classified as multimorbidity studies, this category was not reported in the overall results due to its low kappa measures of interrater agreement (as seen in this table) and machine learning accuracy.

Machine Learning Method Details

The machine learning algorithm relied on a logistic regression model, trained on the manual reviews, to produce classifications for the projects that were not manually reviewed. The algorithm used the narrative text found in the project abstract or description field to generate classification scores for each project and category based on a logistic regression model. A list of 179 less meaningful, commonly used English words (such as "a," "the," "it," "that," "is") were removed from all abstracts before processing (NLTK Corpora, undated).[2]

We employed a straightforward "bag of words" approach to processing text for machine learning analysis. In this approach, the algorithm did not take into account sentence structure or relationships between words, but rather simply checked to see how frequently particular words and phrases are present in an abstract. Only more frequently used words and two-word phrases were selected for inclusion in the model. We set our algorithm to include any words and phrases found in any of three overlapping lists: (1) the 2,000 words and phrases that were most common in all abstracts, (2) the 2,000 words and phrases that were most common in project abstracts manually reviewed as positive for a particular category, and (3) the 2,000 words and phrases that were most common in project abstracts manually reviewed as negative for a particular category. Word frequencies were then weighted and normalized using the commonly used term-frequency inverse document-frequency function. As described by Fabrizio Sebastiani, "This function embodies the intuitions that (i) the more often a term occurs in a document, the more it is representative of its content, and (ii) the more documents a term occurs in, the less discriminating it is" (Sebastiani, 2002).

Within the logistic regression model, the words and two-word phrases that occurred most frequently across all abstracts were assigned coefficients according to their association with positive and negative manual classifications in the training set. Remaining project abstracts were then input into the model, which produced a classification score ranging from 0.0 (not likely to meet category criteria) to 1.0 (highly likely to meet category criteria) for each project. The algorithm was run five separate times following a stratified K-fold cross-validation approach, with one-fifth of the manually reviewed data reserved each time in order to test algorithm accuracy and identify false positives and false negatives, leaving the algorithm to be trained on the other four-fifths of the manually reviewed data (Kohavi, 1995).

While many project classification scores clustered at one end or the other of the 0.0–1.0 range of scores, many other projects received scores more in the middle of the range, indicating a level of algorithmic uncertainty about whether that project should be classified as meeting the criteria for a particular category or not. To generate actual estimates of the number of projects in each category for the scan, however, we had to classify projects as either counted in or out of the

[2] The list of excluded words is from NLTK, "Stopwords Corpus: English," undated.

category. We did this using a numeric decision threshold, with only projects receiving a classification score above that threshold counted as meeting the criteria for that category.

The final estimates of the number of projects in each category are highly sensitive to which decision threshold is chosen to base classifications on. Various strategies can be employed to set classification thresholds, with each appropriate to different purposes. Some of these strategies, such as the naive use of a 0.5 threshold, or selecting the threshold that maximizes the sum of sensitivity and specificity, perform poorly when attempting to accurately estimate the prevalence of a particular subtype in an overall population, especially for subtypes that are uncommon (Freeman and Moisen, 2008). Instead, approaches to threshold setting that attempt to balance the numbers of expected false positive classifications against the number of false negative classifications are more likely to produce an accurate prevalence estimate (Smits, 2010). This "cost-balancing" approach was the one that we used.

To set a threshold in this way, we examined the classification scores produced by the machine learning against the results of the manual reviews, which were stratified into two overall subsets of manually reviewed data:

1. The first subset consisted of all the manual reviews that we conducted on project records that we had initially chosen for review based on their already being identified as likely to be in-scope for our scan. This included reviewed projects that met any one of the following criteria:
    a. The project was listed in HSRProj.
    b. The project was directly provided by funding agencies in response to our data call.
    c. The project was listed in RePORTER as part of the NIH Research, Condition, and Disease Categorization of "Health Services."
    d. The project was selected for manual review based on its being classified as in scope by an earlier version of the machine learning algorithm.
2. The second subset consisted of all the manual reviews that we conducted on a random sample of project records from NIH RePORTER. For these projects, none of the reasons listed above for suspecting that a project might a priori be in-scope applied.

For each of these subsets of manual reviews, we chose a decision threshold that produced an equal number of algorithmically classified false positives and false negatives when compared against the manually reviewed classifications. These two decision thresholds were then applied to the rest of the data set, similarly stratified into the subset of data that was previously identified as potentially in-scope and the subset of data from RePORTER that was not identified as such, to produce classifications for all the projects that had not been manually reviewed.

Algorithm Accuracy

We compared the machine learning algorithm's classifications against the manual classifications for each category. Table A.8 provides various measures of how accurately the machine learning algorithm was able to reproduce the manual classifications for each category.

Table A.8. Machine Learning Algorithm Accuracy

Classification Category	No. Rev. Manually	True Pos.	True Neg.	False Pos.	False Neg.	Percent Agreem't	Sensitivity	Specificity	Kappa
HSR	2,760	1,165	1,394	99	102	93%	92%	93%	0.85
PCR	2,693	161	2,359	86	87	94%	65%	96%	0.62
MTD	2,582	287	2,053	118	124	91%	70%	95%	0.65
In-scope (HSR, PCR, and/or MTD)	2,583	1,184	1,005	194	200	85%	86%	84%	0.69
Quality of Care	2,629	830	1,426	186	187	86%	82%	88%	0.70
Cost and Utilization	2,598	283	2,032	137	146	89%	66%	94%	0.60
Access to Care	2,460	169	1,961	164	166	87%	50%	92%	0.43
Equity	2,632	168	2,220	123	121	91%	58%	95%	0.53
Organization of Care	2,638	880	1,449	151	158	88%	85%	91%	0.75
Financing of Care	2,624	88	2,469	33	34	97%	72%	99%	0.71
Social Factors	2,577	151	2,180	122	124	90%	55%	95%	0.50
Personal Preferences and Behaviors	2,632	409	1,875	173	175	87%	70%	92%	0.62
Definitive Health Outcomes	2,460	174	1,994	148	144	88%	55%	93%	0.48
Aging	2,469	160	2,183	64	62	95%	72%	97%	0.69
Multimorbidity[a]	2,459	36	2,289	67	67	95%	35%	97%	0.32
Patient Safety	2,459	134	2,154	86	85	93%	61%	96%	0.57
Pediatrics	2,459	69	2,348	21	21	98%	77%	99%	0.76
Prevention	2,460	261	1,890	152	157	87%	62%	93%	0.55
HIT Applications and Tools	2,586	100	2,309	89	88	93%	53%	96%	0.49
Model Develop-ment and Validation	2,583	175	2,236	86	86	93%	67%	96%	0.63
Toolkit Development	1,760	20	1,690	25	25	97%	44%	99%	0.43
Simulation Modeling	2,581	9	2,515	29	28	98%	24%	99%	0.23
Evidence Review and Synthesis	2,582	100	2,442	21	19	98%	84%	99%	0.83

[a] While some projects were classified as multimorbidity studies, this category was not reported in the overall results due to its low kappa measures of interrater agreement and machine learning accuracy (as seen in this table).

In this table, the true positive column displays how many projects were classified positive by both the algorithm and the manual reviewer for each domain. Similarly, the true negative column displays how many projects were classified negative by both algorithm and reviewer. The false positive column gives the number of projects that the algorithm classified as positive but were manually reviewed as negative, and the false negative column gives the number of projects that the algorithm classified negative but were manually reviewed as positive. These numbers were then used to calculate the overall accuracy measures of percent agreement, sensitivity, specificity, and kappa.

Despite the existence of misclassifications, if the number of false positives is balanced by an equal number of false negatives (as our algorithm attempts to do), the resulting overall estimate of the number of projects in each classification category will still be valid.

Scan Results by Funding Agency, Including Confidence Intervals

Tables A.9–A.12 are the same as Tables 3.2–3.5 in Chapter 3, with the addition of 95-percent confidence intervals. These confidence intervals are calculated based on the variance observed across multiple machine learning algorithm runs, with each run featuring a different training data set sampled from the full set of manual reviews in the stratified fivefold cross-validation process, as described earlier in Appendix A. These confidence intervals do not take into account any variation in results that might occur during the manual review process; the manual review results are rather treated as fixed.

For most classification categories, the results for ACL and CMS were based entirely on manual reviews, and thus the overall result, the lower confidence interval bound, and the upper confidence interval bound are all identical. AHRQ, CDC, NIH, and VHA results are based on a mix of manual reviews and algorithm results, however, and therefore feature a varying range of confidence intervals. The confidence intervals are wider when any of the following three factors are present: (1) the results include fewer manual classifications and more algorithm classifications; (2) the algorithm is less accurate for a particular category; (3) the results include fewer project abstracts that clearly fall inside or outside a category and more abstracts that appear to fall somewhere in between.

Table A.9. HSR, PCR, and Methods and Tool Development Projects, by Funding Agency, Mean Estimate, and 95-Percent Confidence Interval

	ACL	AHRQ	CDC	CMS	NIH	VHA	All Agencies[a]
Total projects In scan data set[b]	68	1,155	1,093	75	86,321	3,013	93,075
Projects classified as HSR	53 (78%) 53–53	653 (57%) 628–677	267 (24%) 251–282	57 (76%) 57–57	6,891 (8%) 6,745–7,036	794 (26%) 784–803	8,767 (9%) 8,621–8,912
Projects classified as PCR	2 (3%) 2–2	149 (13%) 135–162	28 (3%) 20–35	9 (12%) 9–9	750 (1%) 680–819	150 (5%) 145–154	1,090 (1%) 1,031–1,148
Projects classified as HSR and/or PCR	53 (78%) 53–53	668 (58%) 643–692	268 (25%) 252–283	58 (77%) 58–58	6,948 (8%) 6,803 – 7,092	797 (26%) 787–806	8,845 (9%) 549–834
Projects classified as MTD	26 (38%) 26–26	432 (37%) 403–460	104 (10%) 92–115	17 (23%) 17–17	3,501 (4%) 3,370–3,631	310 (10%) 284–335	4,416 (5%) 4,257–4,574
Projects classified in-scope (HSR, PCR, and/or MTD)	58 (85%) 58–58	915 (79%) 911–918	328 (30%) 262–393	74 (99%) 74–74	8,707 (10%) 8,312–9,101	889 (30%) 870–907	11,045 (12%) 10,640–11,449

NOTE: These results are based on a combination of manual reviews and machine learning–based automated classification of projects in the scan data set. For additional details, please refer to Chapter 2 and Appendix A.

[a] The "All Agencies" tally includes projects from the six agencies listed in the table as well as the FDA, ACF, and ATSDR projects listed in RePORTER, which are not reported separately due to our inability to validate results with these two agencies. Nevertheless, we classified 15 (1 percent) out of 1,155 FDA projects as in-scope and classified 46 (25 percent) out of 186 ACF projects as in-scope. Another nine ATSDR projects were also reviewed; none were classified as in-scope.

[b] The "Total Projects" numbers are based on the consolidated scan data set, which includes data from the RePORTER database and provided by individual agencies, following merging of nonunique project records and the exclusion of projects that met any of the following criteria: (a) projects with pre-FY 2012 start dates, (b) projects with post-FY 2018 start dates, (c) projects missing abstracts, (d) projects with RePORTER activity codes related to research infrastructure and support, (e) projects conducted intramurally by agency staff. See Chapter 2 for additional details on these exclusions. Nonunique project records were identified using core project numbers, with project renewals (type 2), supplements (type 3), and change of grantees (type 7) treated as separate projects and thus excluded from merging.

Table A.10. HSR and/or PCR Projects, by Research Domain and Funding Agency, Mean Estimate, and 95-Percent Confidence Interval

Research Domain	ACL	AHRQ	CDC	CMS	NIH	VHA	All Agencies[a]
Total HSR and/or PCR Projects	53	668	268	58	6,948	797	8,845
Quality of Care	46 (87%) 46–46	535 (80%) 504–565	214 (80%) 190–237	52 (90%) 52–52	6,207 (89%) 5,953–6,460	695 (87%) 677–712	7,795 (88%) 7,525–8,064
Cost and Utilization	9 (17%) 9–9	262 (39%) 243–280	98 (37%) 83–112	51 (88%) 51–51	1,852 (27%) 1,602–2,101	192 (24%) 185–198	2,471 (28%) 2,203–2,738
Access to Care	18 (34%) 18–18	90 (13%) 79–100	97 (36%) 83–110	11 (19%) 11–11	1,803 (26%) 1,670–1,935	312 (39%) 293–330	2,337 (26%) 2,205–2,468
Equity	8 (15%) 8–8	95 (14%) 81–108	93 (35%) 83–102	6 (10%) 6–6	2,319 (33%) 2,173–2,464	125 (16%) 115–134	2,657 (30%) 2,521–2,792
Organization of Care	45 (85%) 45–45	602 (90%) 573–630	233 (87%) 227–238	43 (74%) 43–43	5,985 (86%) 5,801–6,168	745 (93%) 730–759	7,702 (87%) 7,502–7,901
Financing of Care	8 (15%) 8–8	89 (13%) 83–94	11 (4%) 8–13	38 (66%) 38–38	172 (2%) 157–186	20 (3%) 20–20	*339* (4%) 317–360
Social Factors	21 (40%) 21–21	104 (16%) 91–116	74 (28%) 69–78	1 (2%) 1–1	1,987 (29%) 1,874–2,099	146 (18%) 130–161	2,350 (27%) 2,220–2,479
Personal Preferences and Behaviors	33 (62%) 33–33	177 (26%) 161–192	151 (56%) 136–165	8 (14%) 8–8	5,280 (76%) 5,178–5,381	475 (60%) 454–495	6,142 (69%) 6,028–6,255

NOTE: These results are based on a combination of manual reviews and machine learning–based automated classification of projects in the scan data set. For additional details, please refer to Chapter 2 and Appendix A.

[a] The "All Agencies" tally includes projects from the six agencies listed in the table as well as the FDA and ACF projects that are listed in RePORTER and are classified as HSR and/or PCR.

Table A.11. HSR and/or PCR Projects, by Research Areas of Interest and Funding Agency, Mean Estimate, and 95-Percent Confidence Interval

Area of Interest	ACL	AHRQ	CDC	CMS	NIH	VHA	All Agencies
Total HSR and/or PCR Projects	53	668	268	58	6,948	797	8,845
Definitive Health Outcomes	11 (21%) 11–11	124 (19%) 93–154	40 (15%) 28–51	21 (36%) 20–21	1,953 (28%) 1,785–2,120	299 (38%) 281–316	2,455 (28%) 2,279–2,630
Aging	11 (21%) 11–11	149 (22%) 140–157	42 (15%) 31–52	44 (76%) 44–44	1,281 (18%) 1,202–1,359	140 (18%) 135–144	1,681 (19%) 1,591–1,770
Patient Safety	3 (6%) 3–3	270 (40%) 253–286	77 (29%) 71–82	4 (7%) 4–4	855 (12%) 777–932	148 (19%) 142–153	1,377 (16%) 1,299–1,454
Pediatrics	3 (6%) 3–3	67 (10%) 62–71	51 (19%) 48–53	1 (2%) 1–1	1,308 (19%) 1,194–1,421	0 (0%) 0–0	1,457 (16%) 1,335–1,578
Prevention	5 (9%) 5–5	250 (37%) 235–264	221 (82%) 208–233	10 (17%) 10–10	4,918 (71%) 4,618–5,217	303 (38%) 282–323	5,732 (65%) 5,415–6,048

NOTE: These results are based on a combination of manual reviews and machine learning–based automated classification of projects in the scan data set. For additional details, please refer to Chapter 2 and Appendix A.

[a] The "All Agencies" tally includes projects from the six agencies listed in the table as well as the FDA and ACF projects that are listed in RePORTER and are classified as HSR and/or PCR.

Table A.12. All In-Scope Projects, by Methods and Tool Development/Methods of Interest Categories and Funding Agency, Mean Estimate, and 95-Percent Confidence Interval

MTD and Methods of Interest Categories	ACL	AHRQ	CDC	CMS	NIH	VHA	All Agencies[a]
Total projects classified in-scope	58	915	328	74	8,707	889	11,045
HIT applications and tools	10 (17%) 10–10	238 (26%) 224–251	21 (6%) 15–26	5 (7%) 5–5	1,152 (13%) 1,082–1,221	84 (9%) 78–89	1,514 (14%) 1,439–1,588
Model development and validation	17 (29%) 17–17	212 (23%) 192–231	52 (16%) 42–61	17 (23%) 17–17	2,069 (24%) 1,922–2,215	193 (22%) 180–205	2,579 (23%) 2,431–2,726
Toolkit development	7 (12%) 6–7	79 (9%) 65–92	15 (5%) 4–25	0 (0%) 0–0	153 (2%) 98–207	39 (4%) 30–47	294 (3%) 211–376
Evidence review and synthesis	5 (9%) 5–5	120 (13%) 115–124	7 (2%) 2–11	3 (4%) 3–3	352 (4%) 234–469	13 (1%) 10–15	506 (5%) 387–624
Simulation modeling	0 (0%) 0–0	18 (2%) 13–22	9 (3%) 5–12	0 (0%) 0–0	380 (4%) 293–466	15 (2%) 13–16	423 (4%) 329–516

NOTE: These results are based on a combination of manual reviews and machine learning–based automated classification of projects in the scan data set. For additional details, please refer to Chapter 2 and Appendix A.

[a] The “All Agencies” tally includes projects from the six agencies listed in the table as well as the FDA and ACF projects that are listed in RePORTER and are classified as HSR, PCR, and/or MTD.

Scan Results by Year

Finally, Table A.13 provides the scan results by year.

Table A.13. In-Scope Projects, by Overall Category and Year

Category	2012	2013	2014	2015	2016	2017
HSR	1,287	1,273	1,299	1,224	1,323	1,188
PCR	99	144	199	153	189	169
MTD	628	645	582	665	633	585
In-scope (HSR, PCR, and/or MTD)	1,621	1,600	1,592	1,565	1,673	1,481
Quality of Care	1,155	1,086	1,115	1,070	1,202	1,087
Cost and Utilization	370	360	349	318	420	338
Access to Care	331	327	320	335	373	325
Equity	430	375	386	363	436	378
Organization of Care	1,112	1,118	1,140	1,085	1,159	1,027
Financing of Care	39	49	33	59	73	54
Social Factors	349	328	311	313	385	376
Personal Preferences and Behaviors	937	825	871	893	920	819
Definitive Health Outcomes	370	318	349	313	398	338
Aging	198	226	211	199	273	223
Patient Safety	176	177	193	184	204	196
Pediatrics	247	199	210	226	199	208
Prevention	883	755	825	881	833	761
HIT Applications and Tools	244	226	208	249	200	197
Model Development and Validation	351	346	340	401	373	360
Evidence Review and Synthesis	66	72	41	86	72	71
Simulation Modeling	79	80	59	47	62	41

NOTE: These results are based on a combination of manual reviews and machine learning–based automated classification of projects in the scan data set. For additional details, please refer to Chapter 2 and Appendix A.

Appendix B. Detailed Research Domain Framework Definitions and Classification Rules

This appendix provides the following supplementary information on the research domain framework and environmental scan and portfolio analysis results:

- Detailed definitions and classification rules used to operationalize the research domain framework for the scan analysis of federally funded HSR and PCR
- Grant activity codes from the NIH RePORTER database related to research infrastructure that were excluded from the scan
- Scan analysis results by funding agency, including confidence intervals
- Scan analysis results by year.

Detailed Definitions of Research Domains and Categories

Chapter 2 presented the research domain framework that the study developed to identify and differentiate HSR and PCR projects, including brief descriptions of the research domains and categories that comprise the framework. Here we provide detailed definitions of these domains and categories, which include four domains of health care "outputs," four domains of health care "inputs," five categories of HSR and PCR-related MTD, and five HSR and PCR subcategories of interest.

Health Care Output Domains for HSR and PCR

The output domains are as follows:

- **Quality of Care.** This includes studies that assess care process as well as intermediate or definitive outcomes of care. Examples of care process include timely provision of preventive services, accurate diagnosis of health conditions, provision of recommended care, and patient safety-related practices to prevent unsafe procedures and medical errors. Examples of intermediate outcomes include clinical health measures (e.g., adequate control of blood pressure, blood sugar, and asthma symptoms), patient safety related events (e.g., surgical errors, healthcare-associated infections), and patient experience and satisfaction. Examples of definitive outcomes include patient functioning, health-related quality of life, and mortality.
- **Cost and Utilization.** Cost and Utilization research examines health care cost or resource utilization. This includes studies that examine health service use as an intermediate measure in order to better understand some aspect of health service cost or resource utilization.

- **Access to Care.** Access to care research examines barriers and facilitators to patients receiving needed health services. This includes studies measuring availability of care (health facilities, clinicians, medicines, equipment, having access to insurance, being able to make appointments, see a provider in a timely manner, etc.), patient attitudes and behaviors related to accessing care, and the cost of access. It would include evaluations of efforts to improve patient access in additional to observational studies of access.
- **Equity.** Studies that examine whether any health care outputs (e.g., Quality of Care, Cost and Utilization, Access to Care, Personal Preferences and Behaviors [when an output]) differ among subsets of the population as well as studies that are conducted in the context of disparities. Studies whose thrust is to improve the health of an already identified disparity population (such as prisoners) are included, even if comparison is not made to more-advantaged groups (e.g., nonprisoners). Studies examining disparities based on existing health problems are included only if those disparities are exacerbated by social disadvantage and are not directly a result of the health problem itself (e.g., a project that examines quality of care for hypertension among those with mental illness).

Health Care Input Domains for HSR and PCR

The input domains are as follows:

- **Organization of Care.** This includes studies on the structures and routines of care and the process of how they change or improve, from the composition and functioning of care teams to the composition and dynamics of health care delivery systems and markets, including both social (e.g., workforce, clinician, and staff experience) and material assets (e.g., health technologies, physical facilities)
- **Financing of Care.** This includes studies of systems that determine how health care professionals and health care organizations are paid to deliver care.
- **Social Factors.** This includes studies on the social, economic, and community determinants of health and health care.
- **Personal Preferences and Behaviors.** This includes studies of health-related patient behaviors (e.g., adherence to therapy, exercise, or smoking) and patient knowledge, attitudes, and understanding of health and health care.

Research Methods and Tool Development for HSR and PCR

The MTD projects are considered more "developmental" than research focused. Even though these projects may not directly examine either an input or output of health services, they develop methods and tools that are designed to be used as part of HSR and PCR projects or are part of health service delivery (with the exception of out-of-scope projects—see table entry on "Non-HSR/PCR Clinical Trials, Preclinical Research, and Non-HSR/PCR Epidemiology" below). However, some projects can be both HSR and/or PCR as well as MTD, if they have dual aims of both carrying out research as well as developing a particular method or tool for use in future research or health services delivery.

- **HIT Applications and Tools.** Many subcategories exist. Examples include the design and testing of technologies such as telehealth platforms, mobile applications, electronic prescribing, computerized clinical decision support systems, and various EHR functionalities to improve the quality, safety, or efficiency care.
- **Model Development and Validation.** This category includes psychometric instruments such as screening tools and health-related quality of life measures, quality measures, case mix adjustment models, risk-prediction and risk-stratification models, and machine learning and natural-language processing models that relate to health service delivery or primary care. Many research studies involve creating measures, surveys, or models for use in their analysis—these would count as a model development and validation only if they are intended for use beyond the current study, whether in future research and evaluation (e.g., patient safety measures) or incorporation in health service delivery (e.g., a screening tool or a risk-assessment algorithm to inform clinician decisionmaking).
- **Toolkit Development.** Toolkits document interventions or tools and provide strategies to facilitate the uptake and implementation of interventions, initiatives, or best practices. Toolkits contain at least some informational, training, or operational materials useful to health care delivery organizations to incorporate and sustain evidence-based or promising practices into health service delivery (Hempel et al., 2019). Creating, designing, adapting, or updating materials for use in a toolkit will be considered Toolkit Development.
- **Evidence Review and Synthesis.** This category includes systematic reviews and narrative reviews regarding any health services or PCR topic. Some project abstracts mention carrying out an initial literature or evidence review as part of a scoping analysis to inform project research design; these would count as an evidence review and synthesis study only if the evidence review is a primary project output rather than solely being an initial design step in the project. All evidence review and synthesis projects will be counted as research projects.
- **Simulation Modeling.** Studies that use simulation models (i.e., models that use simulated inputs) to examine cost-effectiveness, decisionmaking, and other aspects of health services delivery. This category does not include studies that employ mathematical models that solely use inputs derived from real-world observations, though it does include models that use both simulated and observed input data, such as many agent-based models, Markov Chain models, Monte Carlo models, or other models that use probabilities as inputs.

Research Subcategories of Interest for HSR and PCR

The research subcategories of interest for HSR and PCR are as follows:

- **Aging.** This includes research pertaining to the aging process as it manifests in older people. We do not have a firm age cutoff at which "older people" begins; 65 is often used, 50 is sometimes used, as are other numbers. The aging area of interest includes research about syndromes primarily impacting older persons (often called "geriatric syndromes"), such as urinary incontinence, falls, and sarcopenia, even if the research includes some persons who are not older. The aging area of interest also includes research about the health and health care of older persons as well as research about the practice patterns of geriatricians, or about hospital wards that focus on older patients,

such as geriatric psychiatry wards. We will not include research about conditions that become more common with age—with prominent examples being cardiovascular disease, cancer, and end-of-life care—unless the topic of study is specifically how those conditions are managed in older patients.

- **Definitive Health Outcomes.** This category includes death/mortality, other definitive outcomes, and health-related quality of life and related concepts of self-assessment of health (e.g., self-reported pain level).
  - Definitive outcomes represent permanent or at least long-term harm to the individual and include examples like death, heart attack, amputation, broken bones.
  - The category of health-related quality of life includes concepts such as health-related quality of life, ability to function independently, mobility, and functional status.
  - Intermediate outcomes are *not* included in this concept of "definitive health outcomes." Intermediate outcomes include measures related to the incidence of chronic conditions—such as high blood pressure, diabetes, or presence of cancer—even when these intermediate outcomes are known to be strong risk factors or even direct causes of definitive outcomes such as pain, loss of function, or death.
- **Patient Safety.** This category focuses on research that examines the causes, predictors, and prevalence of accidental or preventable injuries produced by health care as well as research that evaluates interventions meant to reduce harm produced by health care. Important topics include understanding the causes and prevention of medical errors, developing and testing systems to learn from errors and near-errors, and creating a culture that supports these activities (a "safety culture"). An example of a safety culture would occur when a health care professional feels empowered to speak up when he/she notices a risk of harm. This category also includes HSR or PCR that focuses on treatment of injury or disease produced by health care (e.g., studies on how to best treat Methicillin-resistant *Staphylococcus aureus* infection in the intensive care unit).
- **Pediatrics.** This category includes research related to the physical, mental, and social health of children from birth to young adulthood (age 18 or younger for the purposes of this project) and encompassing a broad spectrum of health services ranging from preventive health care to the diagnosis and treatment of acute and chronic diseases. Research about pediatricians, including primary care and specialty pediatrics, as well as children's hospitals, is included. Research on family practice is only included if it pertains to how they manage the care of children. Research on maternal-fetal health is only included if it at least partly focuses on the child's outcomes—not just those of the mother.
- **Prevention.** For our purposes, research on prevention includes evaluation of activities intended to prevent rather than treat disease. This includes cancer screening, management of asymptomatic risk factors including hypertension, diabetes, and hyperlipidemia; and general efforts to promote a healthy lifestyle including adequate sleep, adequate exercise, healthy diet, and refraining from unhealthy substance use. Prevention also includes prevention of injury, such as a health professional providing counseling about seat belt use, gun safety, or sunscreen use. Prevention also includes patient safety studies that examine the factors underlying accidental or preventable injuries or diseases produced by health services (e.g., hospital-acquired infections, diagnostic errors, addiction to drugs prescribed by a health provider).

We also examined one additional HSR and PCR area of interest, multimorbidity, but do not report results for this category due to methodological challenges. The definition we used for this concept was:

- **Multimorbidity.** This category includes research that explicitly addresses how best to care for patients who have more than one chronic medical condition, or describes the care delivered to such patients. This concept is synonymous with "multiple chronic conditions."

We ran into several challenges in categorizing multimorbidity studies, including the difficulty in separating which chronic conditions are distinct from each other as well as the difficulty in distinguishing between studies that actually examined comorbid conditions versus those that accounted for co-occurring conditions solely as a control or confounding variable. As a result, the levels of agreement (kappa) between multiple reviewers, as well as between reviewers and our machine learning algorithm, were consistently poor for this category (see Appendix A).

Additional Classification Rules for Manual Reviews

Coding Logic Workflow

A. Determine if the project is research (i.e., investigates a research question using scientific methods)
   - If it is research
     - go to Step B
   - If it is not research due to being a conference grant, professional development grant, or a center grant without research
     - END REVIEW (leave all other domains blank)
   - If it is not research due to some other reason (e.g., grant for health service provision, or for MTD, without any research component)
     - go to step C only. After step C, end review
B. Determine if the project is clearly in one of the following out-of-scope research categories: non-HSR/PCR clinical trial, preclinical research, and non-HSR/PCR epidemiology (column K)
   - If it is clearly in one of these categories, END REVIEW
C. Determine if the project is in any MTD or methods of interest categories
D. Determine if the project is PCR, covers one or more main research domains, or covers one or more of the other areas of interest
E. Determine if the project is HSR (see below).

Adjudicating HSR

Projects that are determined to be research, but that are not excluded as clearly out-of-scope, are reviewed to see if they meet the criteria for each of the HSR and PCR domains. They are then reviewed to see if they meet the following criteria for HSR overall:

1. Any project that measures Organization of Care
2. Any project that includes one or more HSR domains as a study input and one or more HSR domains as a study output:
    a. The Access to Care output domain is not used to determine whether or not a project is HSR, since this domain was developed later than the other domains and implementation of the HSR adjudication criteria, and was generally coded to projects together with at least one other output domain, such as Quality of Care or Equity, that would ensure the projects' inclusion in the scan as HSR.
    b. While the research domain framework designates four domains as HSR inputs and four domains as HSR outputs, in some studies the following domains may be treated as either inputs, outputs, or both, depending on the study design and analysis.
        i. Quality of Care
        ii. Cost and Utilization
        iii. Organization of Care
        iv. Personal Preferences and Behaviors.

Procedural Rules

Project descriptions do not always provide sufficient information to determine whether a study clearly covers a particular domain or not. In these cases, the reviewer should make reasonable assumptions, based on the information that is provided in the abstract, to determine whether the study probably does or does not cover a particular domain. For example, a study that otherwise does not touch on personal preferences and behavior, and simply mentions measuring "individual-level factors," would not count as a Personal Preferences and Behaviors study. But another study, that simply mentions measuring "individual-level HIV risk factors," would be counted as a Personal Preferences and Behaviors study, since examining HIV risk factors probably includes examining personal behaviors.

Some of our domain definitions make distinctions between studies that examine health service delivery and those that do not. Health service delivery, in our use of the term, is delivery of services primarily intended to improve health or the social factors affecting health by any of a wide range of health providers in a wide range of settings. Some services, when they are primarily focused on health, can count as health services even when delivered in less traditional health settings or by nonprofessional providers. This includes services such as substance abuse counseling delivered by peers in community health settings such as a church, schoolteachers referring students to their school's mental health counselor, or health services delivered by family caregivers at home.

While federal health agencies sometimes fund studies of other activities that affect human health—such as the government imposing a new regulation on car safety, or the opening of a supermarket offering healthy produce, or municipal water quality monitoring—we do not treat these types of activities as health services according to our definition.

Family caregivers are a special case in that they are generally considered as both part of the system of care and as part of the patient-family unit that is targeted by care. So, a study that examines the impact of a health care intervention on caregiver burden, stress, and behaviors would count as both Systems of Care as well as Quality of Care and Personal Preferences and Behaviors.

Some projects include variables for purposes of controlling for effects or matching cases (e.g., patient age and race/ethnicity to statistically control for patient demographics or to derive propensity score matching). Although these variables may be related to concepts in a research domain (e.g., Aging for age, or Equity and Social Factors for race/ethnicity), the report would not be considered to address these research domains unless the report substantively addresses the variables, i.e., examines differences in determinants, effects or outcomes of the variables (e.g., used as independent, dependent, co-variate, or mediating variables).

Regarding Table B.1, the main rules for the HSR domains (the ones we referred to most often) are found above in Section 2. The rules in this table are in addition to those rules, and represent rules for more unusual cases, with a goal of recording the full range of all coding decisions made by the study team for the environmental scan and portfolio analysis.

Table B.1. Additional Rules and Examples for Specific Domains and Categories

Category	Domain	Rules
Research	**N/A**	• Research infrastructure grants, including grants that solely support data set management, research centers, conferences, trainings, and career development, are not considered research. • **Data set management—**Grants that support data collection or management but do not conduct any specific analyses of these data are not considered research, even if the supported data set will be used for future research by others. • **Research centers—**Grants that support research centers are not considered as research, unless the grant description mentions that it will directly support one or more specific research studies. • **Conference, workshop, and training grants** are not considered research, even if they are focused on supporting research dissemination or methods instruction. • **Career development grants,** including dissertation awards, are not considered research. Even though these grants often support research activities, they are primarily intended to fund researcher career development and are not primarily motivated to support the proposed research activities solely for their own sake. • **Research and MTD—**Studies can sometimes be both research and MTD. For example, a study that measures patient satisfaction with a particular telehealth technology and also seeks to improve that technology would count as both a Systems of Care and Personal Preferences and Behavior HSR study as well as a HIT Applications and Tools project under MTD. However, studies that solely focus on one or more MTD categories are not counted as research. • While research studies often focus on a particular health services intervention, they can also be solely observational in nature, such as a project that examines differences in care outcomes for different patient populations, or a project that interviews providers on how they make care decisions. • All evidence review and synthesis projects will be counted as research projects.
Non-HSR/PCR clinical trials, preclinical research, and non-HSR/PCR epidemiology	**N/A**	• The following three categories of health-related research are specifically excluded from our definitions of HSR, PCR, or MTD: non-HSR/PCR clinical trials, preclinical biomedical research, and non-HSR/PCR epidemiology. Just because a research study is not in any of these three categories does not automatically mean that it will be reviewed as in-scope HSR or PCR. These are just three common types of out-of-scope research that we definitely exclude as out-of-scope at the very beginning of our review, with the result being that the study is automatically considered as not focusing on any of the HSR/PCR domains, MTD types, or HSR/PCR methods or areas of Interest. • Non-HSR/PCR clinical trials—While clinical trials that focus on primary care are considered to be PCR, many clinical trials are not. Similarly, while clinical trials can be HSR if they measure aspects of systems of care, personal behavior, cost, or other HSR domains, many clinical trials have no HSR components. These non-HSR/PCR clinical trials are most commonly conducted in a nonprimary care, controlled setting (where the system of care is held constant) and focus on measuring the effectiveness of one particular medical intervention versus another. For such a study to be initially adjudicated as a non-HSR clinical trial and thus out-of-scope research, the intervention studied must not affect any aspect of systems of care (such as who provides care, where care is provided, or how providers communicate with patients) and the study must not examine any other HSR domains, such as processes of care, health care cost and utilization, patient behavior and attitudes toward care, etc. Non-HSR clinical trials that examine patient health outcomes (which would otherwise fall under Quality of Care and sometimes also Personal Preferences and Behavior), but do not examine processes of care or any other HSR domain, will be initially adjudicated as out-of-scope research and will not be adjudicated for the HSR/PCR domains or other areas and methods of interest.

Category	Domain	Rules
		• Preclinical biomedical research studies should be initially adjudicated as out-of-scope research. This category includes research studies that contribute to health service development but do not yet involve delivery of health services to actual patients, or that do not examine how health services are delivered in real-world settings. Preclinical biomedical research includes genetics studies, studies that use mice and other nonhuman test subjects as well as computer simulated biomedical models, and studies that use tissue samples, other biological samples, or medical imagery outside the context of actual service provision. • Non-HSR/PCR epidemiology studies should be initially adjudicated as out-of-scope research. This category includes studies of population health, injury occurrence, and disease progression. For a study to be initially adjudicated as non-HSR/PCR epidemiology and thus out-of-scope research, it must not examine any aspect of health service delivery. Even if a study examines aspects of personal behavior (e.g., a study of how alcohol consumption correlates to heart disease), equity (e.g., a study comparing disparities in disease burden among different racial groups), or social factors (e.g., a study examining health outcomes in food deserts), it will be initially adjudicated as out-of-scope research if it does not examine any aspect of health service delivery. • The development of methods and tools applicable to other kinds of research or to clinical care—such as developing new techniques for microscopy, new imaging techniques, or new laboratory assays—would not qualify as in-scope if they do not affect or are not based on any of the HSR/PCR domains such as Systems of Care, Personal Behavior, Cost and Utilization, etc.
Outputs	**Quality of Care**	• A process of care is a particular action done to a particular patient at a particular time by a health services provider. • Examples of intermediate outcomes of care are blood pressure, asthma, and glycemic control. • A measure of the number of patients enrolled by a provider into health care program would not count as a process measure, but a measure of patient referrals would count. • It does not include measures of patient intent to seek care. • It includes outcomes related to sleep and depression. • It includes measures of drug shortages (which is also an access measure). • It includes measures of insurer coverage decisions. • It includes shared decisionmaking when measured as an outcome of care. • It includes measures of patient experience or satisfaction with a particular health service. • See also Patient Safety and Definitive Health Outcomes (under HSR/PCR Areas of Interest).
	Cost and Utilization	• A cost-effectiveness study that feeds primary or secondary cost data into a cost-effectiveness model falls under Cost and Utilization. • Studies that measure “utilization” and do not provide additional description will be assumed to be concerning resource utilization and therefore Cost and Utilization = 1. However, studies that measure “utilization” but make clear that they do so as part of examining quality of care or access to care will not automatically be adjudicated Cost and Utilization = 1.
	Equity	• Abstracts that mention disparities but whose main or larger thrust is not addressing those disparities are not considered Equity. • We will not automatically count research projects conducted in other countries and measuring or addressing outcomes that are poor/better relative to the United States as being Equity research; however, these can be marked as Equity if they measure and address socially driven disparities within those countries, or address a disparity faced by those countries. • Projects simply focusing on Medicaid data or features of the Medicaid program would not be considered Equity, because (1) Medicaid data is sometimes used because it is more easily available and (2) the standard for receiving Medicaid varies greatly from state to state.

Category	Domain	Rules
		• A project examining the effect of a wraparound service model on clinical, behavioral, and functional outcomes for Child Protective Services–identified children would count as an Equity project because CPS-identified children face socially driven disparities in those areas. • Disabled people are considered as a disparity population if the study intends to address or measure differences in health care outcomes that are not directly related to the disability (e.g., poorer quality of care or stigma experienced by disabled individuals in the health care system would be included under Equity). • A study that measures equity in clinical trial participation would not be considered an Equity study on that basis alone, because clinical trials are more about health research development rather than health service delivery, given that patients may or may not benefit.
Inputs	**Organization of Care**	• Organization of care studies are those that examine one or more of the following aspects of the health care delivery system and how they change or can be improved: health care settings, providers, organizations, and modes of delivery. • **Health care settings—**Organization of care includes studies that examine care delivery in specific types of health care facilities as well as at home or in nontraditional health care delivery settings. • **Health providers—**Organization of care includes studies that examine some aspect of who provides care. These include studies that touch on provider demographics, clinician type (e.g., nurse-practitioner, medical doctor), care coordination, and training. This also includes studies of provider stress, burnout, and other clinician experience issues such as job satisfaction and perceived work-life balance. Studies of provider knowledge, beliefs, and attitudes related to care are also included as systems of care. • **Health organizations—**Organization of care includes studies of organizational-level aspects of care delivery, including organizational business models (e.g., profit/nonprofit, physician-owned, ACOs), size, management practices, staffing levels, and culture. • **Mode of health care delivery—**Organization of care includes studies that examine processes of care or how care is delivered. This includes studies that examine how providers communicate and interact with patients as well as studies that examine the use of practices or technologies that affect patient-provider interactions. • **Just because a study examines a health care intervention in the context of the health care system does not make it an organization of care study.** Organization of care does not include studies of health care interventions that do not touch on any of these aspects of systems of care. An example of a health intervention study that was not organization of care would be a clinical trial that solely examined the effectiveness of one particular drug versus another in a controlled setting. • Many health care interventions do, however, affect some aspect of organization of care and would thus be counted in this category. These include studies of any intervention that affects where care is delivered, who delivers it, and how it is delivered. This includes any intervention that depends on or affects patient-provider interactions, such as use of questionnaires as diagnostic screening tools, provision of counseling or other talk therapy, use of telehealth technology, provision of smartphone-based medication adherence reminders, and so on. Organization of care interventions and studies can vary greatly in size and scope. They can range from large-scale studies of how government regulations on clinician licensing or reporting practices affect health care delivery to small pilot studies on topics such as use of a self-administered home diagnostic test as compared to a laboratory-based diagnostic when screening for a particular disease. • Medical students, nursing students, and other health care provider candidates are not health care providers (e.g., doctors or medical residents), and therefore measures related to them do not fall under organization of care—unless these measures relate to their involvement in a health care setting in which care is being delivered to patients.

Category	Domain	Rules
		• **Implementation process and outcomes** (e.g., adoption of an intervention, perceived acceptability of a new practice, use or fidelity of use of a new practice, dissemination and scale-up to other health care providers and settings) are included under Organization of Care, even if care process or health outcomes are not examined. • Studies that examine processes of care (e.g., Shared Decisionmaking), including qualitative and observational studies, are also counted as organization of care.
	Financing of Care	• Only includes system-level changes and system-level variation in health care financing (e.g., it does not include whether an individual has a particular insurance type) • Includes studies examining state and national level policies that target financing systems (such as the ACA) • Includes studies examining ACOs as the HSR input
	Social Factors	• Includes whether a patient has a particular insurance type. If patient insurance type is presented as a function of patient decisions, then the study would be both Social Factors and Personal Preferences and Behaviors. • Studies that examine patients' social interactions will be considered to be Social Factors as well as Personal Preferences and Behaviors. • Studies that examine how health service delivery or outcomes relate to social factors such as socioeconomic status, ethnicity/race, or gender will be considered both Social Factors and Equity.
	Personal Preferences and Behaviors	• It includes social determinants of health existing solely on the individual and/or family level (not systematically at the community or population level). • It does not include studies of clinician behavior or attitudes, just of patient (and/or patient family) preferences or behaviors. • Patient satisfaction measures are sometimes counted as measures of Personal Preferences, according to the following rules: (a) if the patient satisfaction measure is solely used as a measure of health service quality, then we just treat it as just Quality of Care, but (b) if the patient satisfaction measure is also serving as a measure of general patient attitudes toward a health service, or of patient attitudes that affect care-related behavior (e.g., a study that uses patient satisfaction measures as a way to understand acceptability of a health service for a particular target population), then it would be treated as both Quality of Care and as a Personal Preferences and Behavior study. When this is unclear, we will err on the side of not adjudicating the study as Personal Preferences and Behavior. • Measures of health service utilization, such as the number of emergency department visits or surgeries, would sometimes be Personal Preferences and Behaviors depending on the authors' framing and/or the nature of the services (e.g., knee-replacement surgery is largely voluntary and therefore involves Personal Preferences and Behavior, while appendectomy does not). • Measures of patient actions such as suicide, addiction, and disruptive behavior will be considered Personal Behaviors. These can also be considered measures of care outcomes under Quality of Care, if they are targeted by a particular health service (e.g., a study that measures opioid relapse following methadone treatment would count as both Quality of Care and Personal Behavior).

Category	Domain	Rules
PCR		• Research on services, providers, or settings specifically designated as “primary care” will be considered as PCR. • The terms “family medicine,” “general internal medicine”/“general internist,” “general pediatrics”/“general pediatricians,” “geriatrics”/“geriatricians,” and “generalists” or “nonspecialists” will be generally be considered synonymous with “primary care” for purposes of adjudicating studies as PCR, except when these terms are specifically used to describe clinicians working in nonprimary care settings (e.g., in-patient hospital wards). • Research on services in “ambulatory,” “outpatient,” “physician practice,” or similar settings that often also provide specialty services will not be considered PCR unless the study includes a focus on primary care providers or services as noted above. • Similarly, research on services in settings that often include both primary care and specialty care services, e.g., FQHCs, community health centers, or VA community-based outpatient clinics will not be considered PCR unless the study includes a focus on primary care providers or services as noted above. • Research on care delivery models that are focused on primary care will be considered as PCR even if “primary care” is not specifically mentioned, such as PCMHs, if not qualified by a specialty (e.g., oncology medical home, or behavioral health medical home). • Studies that examine conditions that are often, but not always, treated in primary care (e.g. swimmer’s ear) or examine health services that are often, but not always, delivered in primary care settings (e.g., hypertension screening, diabetes prevention) will not be considered PCR unless the study includes a focus on primary care providers or settings. • Studies that explicitly examine “primary care” services or roles will always be considered as PCR, even when these services are provided in specialty care settings or these roles are performed by specialty clinicians (e.g., when patients rely on their gynecologist, oncologist, cardiologist, or HIV infection disease specialist for their usual/primary care).
MTD	**N/A**	• MTD studies must focus on developing methods or tools related to health service delivery to be included in the scope of our environmental scan. Studies that develop methods or tools to support one of the out-of-scope research topics—non-HSR/PCR clinical trials, preclinical biomedical research, and non-HSR/PCR epidemiology (see definitions above)—will not be included. • Examples of excluded projects would be development of epidemiological surveillance systems, when they are neither intended for use by health providers nor based on data collected by the health care system.
	Model Develop-ment and Validation	• A project advancing evidence review and synthesis methods will be included here in addition to being included in this domain in addition to “Evidence Review and Synthesis.” • It does not include the development of models of clinical care (e.g., patient-centered care, organizational models of care delivery).
	HIT Applications and Tools	• This includes any project that involves the design and testing of information technology used as part of health service delivery, such as telehealth platforms, mobile applications, electronic prescribing, computerized clinical decision support systems, algorithms to assess patient-safety risks, natural language processing algorithms to improve electronic communication between patients and providers, and various EHR functionalities to improve the quality, safety, or efficiency care. • This does not include development of HIT solely for use in conducting research, such as an algorithm that processes data for use in a research model, or a system to administer an online research survey of clinicians. • This only includes projects that design or modify a HIT application or tool in some way. Projects that only examine implementation of HIT (e.g., facilitators and barriers to its use in care settings) would be coded as Organization of Care. Projects that design and test a HIT application or tool as well as examine its implementation would be coded to both categories (HIT Applications and Tools, and Organization of Care).

Category	Domain	Rules
		• Likewise, HIT applications and tools can sometimes involve model development. For example, development of a natural-language processing algorithm to assess patient risk factors within an EHR system would count as both HIT Applications and Tools and as Model Development and Validation.
HSR/PCR Methods of Interest	**Evidence Review and Synthesis**	• A project advancing evidence review and synthesis methods would be included. This was very rare—most studies in this category were straightforward evidence review and synthesis studies rather than projects solely focused on improving evidence review and synthesis methods.
	Toolkit Develop-ment	• Clinical guidelines by themselves are not toolkits. • Projects that develop toolkits solely focused on conducting research (rather than implementing or improving services) would be excluded.
HSR/PCR Areas of Interest	**Aging**	• Projects should be explicitly framed as being about a problem that impacts older people, or differences in the care received (or the ideal way to provide care) between older and younger people. • Examples of geriatric syndromes include urinary incontinence, falls, sarcopenia, dementia, osteoporosis. • Studies that use Medicare data or focus on Medicare patients are assumed to be focused on older people's health and health care and thus are included as Aging, unless they meet one of two conditions: (1) The study explicitly states that they use Medicare data to examine nonaging-related issues (e.g., a study on health care for nonelderly disabled Medicare recipients); or (2) the study examines the Medicare patient population together with the general patient population and does not appear to be either examining health care for the Medicare population specifically or aging-related conditions specifically. • Studies that examine care in nursing homes, community-living centers, or other long-term assisted care facilities are assumed to be focused on older people's health and thus are included as Aging, unless they explicitly state that they are examining care in these settings that is focused on nongeriatric patients or nonaging-related issues.
	Prevention	• Includes studies that examine prevention of injuries or disease, rather than studies that primarily examine how to treat injuries or disease (even if the injury or disease is preventable) • Includes efforts to prevent domestic violence • Includes preventive dentistry (described explicitly or in a more unspecified manner, for example, as unspecified dental care) • Includes studies that examine the factors underlying accidental or preventable injuries or diseases produced by health services (e.g., hospital-acquired infections, diagnostic errors, addiction to drugs prescribed by a health provider)
	Definitive Health Outcomes	• Having/acquiring a disease is not a health outcome in and of itself. • It includes sleep- and depression-related quality-of-life outcomes. • Preterm birth is not a health outcome per se. • Cavities are not health outcomes. • Measures of patient functioning, pain, quality of life, satisfaction with life, and personal well-being are all considered health outcomes. • Measures of patient satisfaction with their health care, health provider, or a particular health service are not considered a health outcome. • Becoming pregnant counts as a definitive health outcome.

Category	Domain	Rules
	Patient Safety	• Studies of opioid-related harm in general are not automatically included as patient safety studies, because they are not necessarily indicative of harm from health care. However, a study focusing on harms resulting from prescribed opioids would be considered a patient safety study. • Patient safety studies are also prevention studies insofar as they examine how to prevent accidental or preventable injuries or diseases produced by health services, or the factors underlying such injuries or diseases.
	Pediatrics	• Studies need not include a majority of pediatric patients (e.g., could study patients between 15 and 39 years of age).

Appendix C. Detailed Descriptions of Agency Research Portfolios

Below we describe in more detail the individual HSR and PCR portfolios of the federal operating divisions in-scope of the study, including both extramural research (i.e., grant and contract awards to nonfederal entities to conduct research) and intramural research (i.e., research conducted primarily by agency staff). Interview and TEP experts commented on the role of intramural research in allowing agencies to address research questions on timely issues, provide scientific design and analytics to support research infrastructure—such as large national data sets—used by the research community to conduct HSR and PCR, and improve the research skills and retention of highly qualified agency staff needed to supervise extramural research funding programs. As noted above, these descriptions are based on expert information from the study's TEPs and stakeholder interviews, as well as documentary sources as indicated.

Administration for Community Living

ACL serves as the federal agency responsible for increasing access to community supports, while focusing attention and resources on the unique needs of older Americans and people with disabilities across the life span (Administration for Community Living, 2019a). Most of the ACL's extramural funding consists of service grants that do not include research as defined by this study. However, the agency's NIDILRR operates several programs that fund research projects with health care-related components (Administration for Community Living, 2019b). This portfolio includes Model Systems Programs that fund centers of excellence to provide and evaluate comprehensive, evidence-based models of care and support for individuals in communities who have spinal cord, burn, or traumatic brain injuries (Model Systems Knowledge Translation Center, undated). The NIDILRR portfolio also contains extramural funding of research on the implementation and effects of health policies on community living of people with disabilities of all ages, rehabilitation research centers that include studies of health services and financing, and grants on health technology that include research on telehealth to support people with disabilities living in community

Agency for Healthcare Research and Quality

AHRQ is the only federal agency that has a congressional authorization to generate HSR, including how to make health care safer, higher quality, more accessible, equitable, and affordable (42 CFR 67.13). AHRQ also has a statutory charge to serve as the lead federal agency for primary care practice research. Although AHRQ has not received targeted appropriations for this latter mission, the agency funds and disseminates research on primary care systems and innovations, including the nature of primary care as the usual source for addressing personal

health care needs, the management of commonly occurring and undifferentiated clinical problems, and the continuity and coordination of health services (42 U.S.C. 299 et seq). The agency also hosts the National Center of Excellence for Primary Care Research, which provides evidence, practical tools, and other resources to improve primary care (Agency for Healthcare Research and Quality, undated-i). A key objective of the agency is not only to generate evidence from HSR and PCR that improves care, but also to ensure the evidence is known and used, particularly by health care delivery systems and providers (Agency for Healthcare Research and Quality, 2019e).

A hallmark of AHRQ-sponsored research noted by stakeholders and TEP experts is its focus on systems-based improvement across the spectrum of care settings and populations in the U.S. health system. AHRQ's research portfolio is not limited by type of disease, condition, patient populations, or payment systems. Even when AHRQ-sponsored research focuses on specific conditions (e.g., HIV/AIDS, diabetes, or other chronic conditions) or vulnerable populations (e.g., low income, minority, elderly, women, and children), it aims to understand both the specific factors affecting how that care is provided in real-world delivery systems and more general evidence on the process of health service improvement.

AHRQ's research portfolios are organized around key health care system inputs and outcomes. One of the largest portfolios has focused on quality of care and patient safety. Patient safety became a particular emphasis after Congress directed AHRQ in 2001 to invest significant resources in this area (Senate Report 106-293, 2002), which has included research on the causes of and effective strategies to reduce medical errors and harms, such as healthcare-associated infections, adverse drug events, and preventable hospital readmissions (Agency for Healthcare Research and Quality, 2018). The agency additionally has focused on access to and disparities in care, such as through its annual National Healthcare Quality and Disparities Report on differences in care by race, ethnicity, income, and other social determinants of health (Agency for Healthcare Research and Quality, 2019f). Other portfolios include research programs on delivery system organization and markets, and on health care financing and costs, although some research stakeholders perceived the latter topics to have declined in relative emphasis by the agency over time. The agency also has maintained a long-standing portfolio of research on HIT implementation to improve care.

On the topic of quality and patient safety, AHRQ has invested particularly in research on measurement to facilitate improvement of health services. This research has included development of specific safety and quality-of-care indicators for organizations and providers to monitor and target improvement efforts, as well as instruments to measure organizational capacity supporting safety and quality improvement, such as the Survey of Patient Safety Culture (SOPS). Over the past two decades, AHRQ also has funded development of the Consumer Assessment of Healthcare Providers and Systems (CAHPS), a series of surveys for patients to rate experiences with hospitals, other providers, and health plans (Agency for Healthcare Research and Quality, 2019a).

Beyond measurement, AHRQ research has a strong emphasis on implementation tools, methods, and evaluation. AHRQ funds a range of toolkits that combine evidence-based care practices with organizational change packages tailored to specific settings, as well as projects to implement and evaluate the dissemination of these tools across health care delivery systems at the local, state, and even national levels. Stakeholders and TEP experts, including researchers, delivery leaders, state policymakers, and other research users, noted the particular focus of this portfolio on understanding implementation and wider scale-up of improvement practices, and developing methods for conducting implementation evaluations.

Stakeholders also commented on AHRQ's unique role in synthesizing and disseminating scientific evidence on HSR and PCR. Most notably, the agency funds evidence-based practice centers (EPCs) that conduct systematic reviews and syntheses of the scientific literature on a wide spectrum of clinical and health services topics (Agency for Healthcare Research and Quality, 2019d). AHRQ and the evidence-based practice centers also support the U.S. Preventive Services Task Force by providing the resources—scientific, administrative, and dissemination—in its mandate under the Affordable Care Act to make independent recommendations about clinical preventive services (U.S. Preventive Services Task Force, 2018).

AHRQ's PCR portfolio has varied across all the main areas described above. Stakeholders and members of both the PCR and HSR TEPs noted the agency's emphasis on studying primary care from a systems perspective to understand its unique nature and functions within the health care system, including managing multiple and often undifferentiated conditions, and its potential to coordinate care with other health and related community services. For example, AHRQ funded some of the earliest studies to define and synthesize evidence on new models of primary care, such as PCMHs. Similarly, it has funded research on roles of different health professionals in team-based models of care, as well as issues of clinician wellness and burnout. Over time, AHRQ's PCR program has evolved from developing capacity for conducting PCR in practice settings and individual studies to improve management of chronic and other common primary care conditions (e.g., the Practice-Based Research Networks) to primary care transformation and mechanisms for moving evidence-based care into practice, such as through the Transforming Primary Care and the current EvidenceNOW initiatives (Agency for Healthcare Research and Quality, 2015; Agency for Healthcare Research and Quality, undated-b).

In terms of AHRQ's intramural research efforts, stakeholders and TEP experts noted the agency's activities in three areas: analyses and reports on key HSR and PCR issues, dissemination activities, and systems for health delivery organizations to share patient safety data. While supported by technical contractors, AHRQ staff lead the development of the National Healthcare Quality and Disparities Report and other analyses, such as the state of primary care in the United States. Agency staff regularly produce conceptual and methods guidance, such as frameworks for defining and conducting PCR, and application of complex adaptive systems theory to health care research. Dissemination activities include the preparation and distribution of implementation toolkits developed by AHRQ-funded research projects, as

well as dissemination of current HSR and PCR evidence such as evidence-based practice center reports and recommendations of the aforementioned U.S. Preventive Services Task Force. The agency also leads the analytic design and support for the Patient Safety Organizations program, which enables health care providers to uniformly report patient safety events and improve efforts to eliminate harm (Agency for Healthcare Research and Quality, undated-f).

In addition, AHRQ produces and maintains several large databases and data repositories available to research and health care delivery stakeholders to facilitate improvement across the breadth of the U.S. health care system. Databases include the Healthcare Cost and Utilization Project (Healthcare Cost and Utilization Project, 2019), which contains the largest collection of longitudinal encounter-level hospital care data, and the Medical Expenditure Panel, the most complete source of data on the cost and use of health care and health insurance coverage in the United States (Agency for Healthcare Research and Quality, undated-e). Data repositories produced and maintained by AHRQ include a reporting and benchmarking database health care organizations can use for the Survey of Patient Safety Culture survey and the system for vendors to administer and report results of CAHPS surveys.

Office of the Assistant Secretary for Planning and Evaluation

ASPE advises the Secretary of HHS on policy development, coordinates the department's evaluation, research, and demonstration activities, and manages cross-department planning. Integral to this role, ASPE conducts research and evaluation, policy analyses, and estimates of the cost and benefits of policy alternatives under consideration by the department or Congress (Assistant Secretary for Planning and Evaluation, undated).

ASPE's research activities involving HSR and PCR are focused on informing policies related to specific federal programs and initiatives either at the department or operating division levels within HHS (U.S. Department of Health and Human Services, 2019). These requirements have drawn upon ASPE's breadth of content matter knowledge and research capacity across the range of programs in HHS operating divisions and its ability to produce research on relatively short timelines to inform real-time policy decisionmaking.

ASPE determines its specific research foci in response to the HHS Secretary's priorities, Congressional mandates, requests from other HHS operating divisions, and self-initiated projects. ASPE typically selects both short-turnaround and forward-thinking projects to build capacity for anticipated needs for which it can uniquely contribute value through expertise or the specific data sources and modeling capabilities it maintains for timely evaluation of health care trends and in response to immediate questions on HHS policy and program decisions. Other criteria for selecting research foci include its objectivity as an independent evaluator for agency-level programs and its availability of research resources relative to other agencies.

Over time, ASPE's health care research portfolios have centered on access to care, health insurance coverage, health care costs and spending, behavioral health innovations, and health

services for special populations, such as American Indians/Alaskan Natives (U.S. Department of Health and Human Services, 2018b). These foci are inclusive of the current Secretary's four priorities—the opioid crisis, health insurance reform, drug pricing, and value-based care (U.S. Department of Health and Human Services, 2018a). ASPE's focus on behavioral health and care for the American Indians/Alaskan Native population largely reflects research support it provides to SAMHSA and IHS, respectively, which possess limited in-house research capacity. ASPE also contributes to research and evaluation of programs in agencies that may have substantial research capacity when it can provide unique expertise and resources, such as projects for CMS that utilized an international drug price database that ASPE had previously acquired, its Transfer Income Model, or its evaluation expertise (U.S. Department of Health and Human Services, 2019).

Within PCR, a key research emphasis for ASPE has been on access to primary care services. Examples include evaluations of the National Health Service Corps to increase the primary care workforce in underserved areas (U.S. Department of Health and Human Services, 2019), of the ECHO telementoring platform to build primary care capacity in underserved areas (U.S. Department of Health and Human Services, 2018b), and of SAMHSA's Primary and Behavioral Health Care Integration Grant Program to integrate primary care services into publicly funded, community-based behavioral health settings (Substance Abuse and Mental Health Services Administration, undated).

Other PCR topics have included primary care transformation (e.g., studying implementation of PCMHs in IHS facilities) (U.S. Department of Health and Human Services, 2018b) and perspectives of Medicaid programs and health centers regarding state telehealth policies (U.S. Department of Health and Human Services, 2019).

Much of ASPE's research is conducted intramurally. Extramural research is funded through contract mechanisms. Decisions to conduct research internally or externally is based on the availability of the Office's resources including staff, data, and contract funding.

Centers for Disease Control and Prevention

The mission of CDC is to protect the health of Americans by fighting disease and supporting communities and citizens in health promotion. To accomplish this objective, CDC conducts critical science and provides health information to understand and address threats to public health (Centers for Disease Control and Prevention, 2019). Interview and TEP participants noted that CDC has a broad public and population health focus that includes all people in communities—healthy as well as sick individuals, and whether or not they are engaged in the health care system. To fight disease and support health promotion, CDC organizes its research around disease states and health conditions, including both those that are communicable and noncommunicable. The agency's research also emphasizes primary prevention (i.e., preventing the onset and reducing the incidence of disease) and secondary prevention (i.e., detecting disease

early and preventing it from becoming worse) more so than tertiary prevention (i.e., managing the symptoms of a disease once it has progressed) which is the traditional focus of health care delivery systems.

As noted by federal and other interview participants, much of CDC's research would not be considered HSR or PCR under the definitions of this study. Most of CDC's extensive population of health and disease surveillance systems collect health outcomes data but generally do not monitor delivery of associated health care services. The CDC also funds many broad public health initiatives and community-based prevention programs that do not involve health care providers or systems. Several state and research interview participants similarly noted that CDC produces evidence-based recommendations and guidelines on prevention practices but typically does not fund research on the implementation of these practices in health care settings. CDC funds many public health and prevention delivery programs through cooperative agreements; however, the evaluations included in these agreements tend to be for program monitoring and accountability that would not be considered HSR or PCR under the definitions of this study.

Yet interview and TEP participants described several areas in which CDC's research on population health outcomes measurement, surveillance and analysis and the evaluation of prevention services intersects with the health care system and HSR and PCR topics. Federal interview participants observed that the line between health care and public health prevention has begun increasingly to blur, particularly since changes in access to health care and the movement toward value-based care. For example, CDC has collaborated with CMS on projects such as the Million Hearts Campaign that incorporates both clinical quality improvement and community approaches to prevention of cardiovascular disease (Million Hearts, undated). Similarly, the CDC's Comprehensive Tobacco Control Program includes the role of health insurance (e.g., coverage of cessation services) and health care providers (e.g., linking of patients to community resources) in the design and evaluation of the program (Centers for Disease Control and Prevention, 2014).

In addition to research on linking of patients within health care systems to public health interventions, CDC has focused on access to health care after an injury or other health incident experienced in a community setting (e.g., after an individual sustains a concussion) or a critical community event (e.g., following a public health emergency).

The intersection between CDC's surveillance of population health outcomes and research on health care delivery has also increased. CDC research has for a while analyzed the extent and content of prevention services delivered, as well as disparities in prevention services and health outcomes. More recently, CDC surveillance systems and health outcomes measures have become progressively incorporated within efforts to measure health care quality. For example, CDC helped derive standardized indicators of HIV viral load that would be meaningful for CDC surveillance as well as CMS quality reporting and HRSA's monitoring of the Ryan-White HIV/AIDS Program. The most notable such example discussed by federal, state, research, and delivery leader interview participants was CDC's NHSN (Centers for Disease Control and

Prevention, 2017b). NHSN collects data on specific HAIs and basic facility-level characteristics from an expanding number of hospitals and other health care settings and has become increasingly used for CMS and other quality reporting as well as for research on HAI-related patient safety improvement.

CDC also has grown its capacity in economic modeling for cost-effective research on the costs and potential savings associated with the adoption of prevention interventions, some of which may accrue to society at large and some specifically to health care systems.

Interview and TEP participants, especially those with PCR expertise, noted that much of CDC's prevention practices are delivered through primary care, including screening and immunizations. Some CDC research on these prevention practices include primary care settings and providers. As described above, CDC projects also have examined primary care linkages to broader public health and community prevention resources.

Most of CDC's health outcomes analysis related to HSR and PCR is conducted intramurally. Research on prevention services that include HSR and PCR components is also funded through extramural grants to individual investigators and university centers.

Centers for Medicare and Medicaid Services

CMS provides health coverage to more than 100 million people through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. CMS seeks to strengthen and modernize the nation's health care system, and to provide access to high-quality care and improved health at lower costs (U.S. Government, undated).

CMS generates HSR and PCR through the evaluation work it sponsors in support of its business objectives. Federal, research, and state interview participants observed that, although CMS evaluation focuses on the populations and services covered by the agency's programs (e.g., elderly for Medicare, low income for Medicaid), the size of these programs and the typical rigor of the evaluation have resulted in a considerable amount of HSR and PCR. It was also noted that since these evaluations have a primarily applied purpose to inform policy and decisionmaking for CMS programs, the research tends to be on a shorter time horizon relative to research programs in research-oriented agencies.

CMS's two main portfolios of HSR and PCR consist of quality measurement in the agency's CCSQ and demonstrations of payment and delivery models in the CMMI.

Research and other policy-related interview participants reported that CMS has become increasingly involved in quality measurement and improvement with changes in policy and agency programs over the past decade that emphasized these tools and functions. In terms of research, CCSQ funds contractor development of certain quality measures, such as for hospital and facility-based services, although most measures used by CMS are developed outside of the agency (e.g., endorsed measures by the National Quality Forum), including those for primary care. CCSQ additionally conducts intramural research supported by contractors to identify trends

or variability in undesirable outcomes on which to focus its improvement and technical assistance programs (e.g., Quality Innovation Network-Quality Improvement Organizations and Hospital Improvement Innovation Networks) or update standards of care for Medicare's conditions of participation. CCSQ also funds independent evaluations of its quality measurement and improvement programs, such as the National Impact Assessment of the CMS Quality Measures Reports required by law (Centers for Medicare and Medicaid Services, 2018). Last, CCSQ staff work with contractors to provide data on Medicare, Medicaid, and other CMS programs to the research community, such as through its Virtual Research Data Center (Research Data Assistance Center, 2019). These data can be used to conduct further independent evaluations of CMS programs, as well as research on more general HSR and PCR topics.

CMMI was established by the ACA in 2010 with the explicit mandate to implement and evaluate demonstrations of models that test new approaches to paying for and delivering health care with the goal of reducing CMS spending and improving quality of care for CMS beneficiaries (Centers for Medicare and Medicaid Services, undated-a; Government Accountability Office, 2018). Federal, state, and other interview participants, as well as TEP members, noted that CMS, particularly since the ACA, does not fund general research on health care payment reforms, systems, or incentives. All CMMI research activity is tied to the design of demonstrations and evaluations of specific models being tested or under consideration for testing for CMS programs. Evidence used for developing models comes from research sponsored by other agencies or funders, or evaluations of previous CMMI model tests (Government Accountability Office, 2018). Models to be tested are selected through a stakeholder consultation process managed by the agency.

By statute, all CMMI model demonstrations must include formal evaluations, which are conducted by independent contractors and constitute the center's largest research-related investment. Models include payment incentives and often technical assistance for facilities or providers to implement a new care delivery approach. The primary purpose of the model evaluations is to inform agency actuarial analysis and leadership decisions on whether a model should be expanded within CMS' payment programs. However, a range of interview participants observed that CMMI evaluations have generated a great deal of evidence on not only whether a model met the agency's criteria for expansion, but also how and why the model worked, and for which types of providers and beneficiaries, thus contributing much understanding about the models and their implementation. At the same time, some state and other interview participants, as well as TEP members, perceived the CMMI evaluations to have contributed more evidence on effects of new payment systems—an important area—than on the technical assistance components and other levers for promoting implementation and scale-up of delivery innovations.

CMMI to date has launched more than 40 model tests (Kaiser Family Foundation, 2018), including various ACO models to incentivize groups of clinicians, hospitals, and other health care providers to coordinate and improve care for Medicare patients; episode-based payment initiatives for procedures such as hip and knee replacement; and initiatives focused on Medicaid

and Children's Health Insurance Program populations (Centers for Medicare and Medicaid Services, undated-b). CMMI models have also included a number of payment and delivery demonstrations specifically focused on primary care transformation, such as Comprehensive Primary Care Plus, the Transforming Clinical Practice Initiative, and Advanced Primary Care Practice demonstrations for PCMHs in multipayer settings and FQHC safety-net providers. ACO demonstrations also typically include a focus on the role of primary care in coordinating services with other providers.

In addition to intramural research required to design new model tests, CMMI staff conduct a modest amount of analysis on targeted questions, typically with existing CMS secondary data, related to the center's mission. The center's dissemination strategy also utilizes multiple communication strategies to inform its main audience, the policy community, of the results of model tests. These include policy companion pieces to the evaluation technical reports that distill key findings, social media postings, as well as publications in the peer-reviewed health policy literature.

Health Resources and Services Administration

HRSA's mission is to improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs (Health Resources and Services Administration, 2019). Study participants noted HRSA for its support of services for safety net and other vulnerable populations, as well as health care workforce development. Most of HRSA's extramural funding provides grants for direct services and service infrastructure that do not include research. However, HRSA also has supported long-established programs of research and evaluation related to its main functional areas, which the agency has more recently expanded in part to inform decisions about costs, interventions, and quality of care for the populations it serves (Dievler and Fisher, 2017).

The agency's Bureau of Primary Health Care not only provides major service funding for community health centers for underserved populations, it collects extensive information on the health centers through its Uniform Data System and patients through a periodic Health Center Patient Survey. The Bureau makes these data available to the wider research community as well as engages an external research contractor to conduct analyses. The agency also established the Community Health Applied Research Network, a nationwide practice-based network of 17 health centers to conduct patient-centered outcomes research among underserved patient populations. Other HRSA research for specific populations and services include the Maternal and Child Health Bureau's long-standing program of intramural research on issues such as the organization and delivery of health care and preventive and early intervention services for maternal and child populations; the Office of Rural Health's funding of extramural Rural Health Research Centers that assess access and disparities of care among rural populations, and the effectiveness of interventions such as telehealth, critical access hospitals, and other service

delivery models for rural residents; and the Ryan White HIV/AIDS program, which conducts research on health care disparities, services, and innovative models of care for under- and uninsured individuals served by its funded HIV centers. More broadly, NCHWA serves as a national resource for projections of health care workforce supply and demand, and analysis of the distribution and education of the nation's health workforce (Health Resources and Services Administration, undated-b). As with other HRSA programs, NCHWA provides extensive data and information for use by the wider research and policy community.

National Institutes of Health

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability (National Institutes of Health, 2017b). Although the vast proportion of NIH's research portfolio is focused on basic, clinical, and translational research, federal and research interview participants and TEP members noted that NIH Institutes and Centers (ICs) fund a considerable amount of HSR and PCR both intramurally and extramurally (in response to special funding opportunities as well as unsolicited, investigator-initiated grants).

NIH's portfolios of research in HSR and PCR also play a fundamental role in funding research on the effectiveness and implementation of care practices and interventions typically focused on specific diseases, body systems, or populations, according to the individual missions of the agency's component ICs.[1] PCR interview and TEP participants reported that NIH has been an important source of funding and sponsor of important studies in the PCR field. They commented that ICs organized to address specific diseases or body systems tend to focus on screening, managing, and coordinating care for those diseases or body systems by primary care providers. ICs organized to address particular populations were noted to also sponsor research related to broader influences on population health, such as the effect of insurance payment and coverage of care.

Federal and research interview participants observed that some ICs within NIH have a stronger emphasis on HSR and PCR than others. They attributed this variability to several reasons, including congressional mandates and other directives, as well as concerns from extramural research communities, such as to increase the adoption of evidence-based clinical interventions by practitioners. For example, when NIMH, NIDA, and NIAAA were relocated back within NIH in the 1990s, Congress had mandated that the agencies commit at least 12 percent of their funding for HSR (Norquist and Magruder, 1998). While there is no longer a mandate, these institutes continue to fund HSR, and NIMH was noted as having an especially strong HSR emphasis, including a program on primary care and mental health. Similarly, the

[1] NIH also contains Institutes, Centers, and Offices that focus on professions (NINR), treatment modalities (NCCIH), and research areas (Office of Behavioral and Social Science Research).

NCI's founding legislation in the 1970s assigned the responsibility for lowering the burden of cancer, which federal interview participants noted to have oriented the institute at an early stage toward research on the systems of care that affect cancer treatment and outcomes in communities. The NHLBI's emphasis on HSR was partially attributed by a federal interview participant to the influential Framingham study, which helped orient the Institute toward broader sets of community risk factors for heart disease. The NIDDK was noted by federal interview participants as focusing on a number of HSR- and PCR-related topics, such as HIT interventions in primary care settings, workforce issues in training of community health workers, health care partnering with community organizations, and even aligning care delivery with reimbursement for intensive behavioral interventions.

Interview participants also observed that Institutes focused on specific populations, including the NIA, NICHD, and NIMHD likewise sponsor research on HSR and PCR questions. Federal and research interview participants noted that NIA and NICHD have both funded research on issues such as coordination of care and the effect of insurance payment and coverage on care, and NIMHD has funded research on disparities in health care utilization and access and the use of nurse practitioners to reduce disparities in care.

TEP and interview participants identified two other ICs that have sponsored HSR and PCR. NINR has supported research on team-based care. NLM has funded projects on data creation, use, and dissemination, as well as health informatics applicable to health services. NCATS funds Clinical and Translational Science Awards to medical institutions across the country. Research interview participants considered much of this work to focus on earlier stages of translation from biomedical science to clinical interventions, although they perceived this to vary as researchers in some Clinical and Translational Science Awards have used the community and patient engagement cores of these centers for later-stage translation of clinical interventions into health care practice.

Last, federal interview participants noted that certain trans-NIH initiatives funded through the agency's Common Fund have provided opportunities for its research to more broadly engage health care delivery systems. The Common Funds' Health Economics program funded research from 2001 to 2017 on the effect of economic factors, such as financial incentives, insurance, and drug pricing, on health care and health (National Institutes of Health, 2017b). NIH issued guidance in 2015 on health economics research funded by the agency, to clarify that research on economic models and methods can be used to support NIH's mission. NIH supports health economics research in which health outcomes and health-related behaviors are the primary focus, and the connection between the subjects of the study and improved understanding of health is clear and explicit, and economic factors should not be used as primary outcomes of NIH-sponsored research. Although the purpose of the notice was to prevent drift in research away from NIH's mission on understanding health-related behavior, utilization, and outcomes (National Institutes of Health, 2017b), some HSR TEP and research interview participants considered the guidance to nonetheless limit opportunities for funding of economic analyses of

health care systems. An initiative funded primarily through the Common Fund since 2012 has been the Health Care System Research Collaboratory, which supports nine large-scale, pragmatic clinical trials that involve partnerships with health care delivery organizations. The program aims to enhance the capacity to conduct research with health care systems and strengthen the relevance of research results to health practice. ICs now also directly support additional pragmatic clinical trials in the Collaboratory (National Institutes of Health, 2017b).

Veterans Health Administration

The mission of the VHA within the VA is to provide accessible, high-quality, cost-effective care for military veterans (U.S. Department of Veterans Affairs, 2016). It operates the country's largest integrated health care system, serving 9 million military veterans through 170 medical centers and more than 1,000 outpatient sites (U.S. Department of Veterans Affairs, 2019b). The objectives of HSR funded by the VHA are to conduct research that will help improve the health care and health of veterans, as well as advance the field of HSR based on the unique capabilities of the VHA system.

The VHA's HSR portfolio is generated through three programs. The VA Health Services Research and Development program awards investigator-initiated grants to researchers within the VHA system to identify and evaluate innovative strategies to improve veterans' care. The Quality Enhancement Research Initiative supports and evaluates the use of quality improvement methods to implement evidence-based practices into routine care for veterans (U.S. Department of Veterans Affairs, 2018b). The VHA's Centers of Innovation embed VHA health services researchers with clinical and operational partners to ensure that research has the greatest possible impact on VHA policies, health care practices, and health outcomes for veterans (U.S. Department of Veterans Affairs, 2018a).

Federal and research stakeholders described the VHA's HSR portfolio as broad and varied and focused on the particular challenges for veterans' health and the priorities of the VHA system. For example, VHA's HSR portfolios address improving the quality and safety of specific services for pain, including opioids and use of complementary and integrative therapies; suicide prevention, co-occurring disorders, and other mental and behavioral health problems; trauma and traumatic brain injury; health care for women, the fastest growing segment of the veteran population; aging, due to the demographics of previous generations of veterans; and management of complex, high-risk patients, based on the greater prevalence of multimorbidity in the veteran population. Given specific challenges of the VHA system, the VHA research portfolio has also focused on broader HSR issues, such as defining and improving access to care, use of telehealth for a range of services, and rural health care, which overlaps with access and telehealth. Coordination of care with other health delivery systems has become a research interest with the recent passage of the Mission Act in 2018 that offers veterans greater options to receive care outside of the VHA (U.S. Department of Veterans Affairs, 2019a).

Primary care is a large component of the VHA system, and PCR likewise comprises a large component of the VHA research portfolio. In addition to access, telehealth, and management of multimorbidities in primary care, other major PCR topics have included integrated primary and behavioral health care, and evaluation of a national rollout of the VHA's medical home model (PACT) across the system.

One research interview participant mentioned that concerns are occasionally raised about the generalizability of some HSR and PCR results from the VHA due to its unique nature as a federally operated, integrated health system. However, other research and delivery leader interview participants reported that many HSR and PCR findings produced by the VHA have been shown to be applicable and useful in other health care settings, for example, use of VHA research on trauma-informed care and telehealth by safety-net community health centers.

Federal and research stakeholders additionally pointed to the VHA's advantages in HSR as the largest and longest-operating nationally integrated health system, including development of system-wide, standardized quality, and safety measures, and application of 25 years of comprehensive, longitudinal EHR data to perform unique types of HSR analyses, as well as to understand the use of EHR data systems to measure and improve care. Other methods areas noted as strengths of the VHA by federal and research interview participants included the Quality Enhancement Research Initiative's emphasis on implementation science and translation of research findings into practice, and the Centers of Innovation emphasis on best practices for embedded research.

Appendix D. List of Other Research Gaps Identified by Study Participants

Primary Research Domain of Gap	Other Related Research Domain(s) of Gap	Specific Gap	Description
Organization of Care	Care Delivery Process	• The impact of the changing health care system on care	• There needs to be a better understanding of how changes to the health care system, including increased consolidation in the health care marketplace and other health reforms, are impacting the care delivered to patients.
Organization of Care	Financing Mechanisms	• The impact of payment policies on outcomes	• There is a lack of understanding of the general effect of current and new payment policies on patient outcomes. As value-based care is becoming a more common policy tool, there needs to be a better understanding of how those policies impact care.
Organization of Care	Quality of Care	• The impact of early interventions in school-based health centers	• Early interventions in school-based health centers have been shown to be effective, but the research on this topic is dated. There needs to be additional research done on this model of care to understand its impacts on health.
Organization of Care	Quality of Care	• The impact of the complexity of the health care system on patient outcome	• The health care system is complex, and new models and reforms are making it increasingly complex. There needs to be more attention paid to how the complexity of the health care system impacts patient care and outcomes.
Care Delivery	Organization of Care	• Care Coordination	• More research is needed on effective strategies for care coordination in the health care system, including within a single practice and between practices.
Care Delivery		• Nonopioid substance use disorder and mental health research	• There needs to be a better understanding of what substance abuse mental health treatments work the best, particularly as it relates to nonopioid substance use, and how to tackle suicides in the primary care system.
Care Delivery		• Specialized care models	• There needs to be more research on models of care for specialty care that are integrated into the larger health care system. One example of this is the treatment of end-stage renal disease.

Primary Research Domain of Gap	Other Related Research Domain(s) of Gap	Specific Gap	Description
Care Delivery		• Private payer models	• There are new models of care being developed for the delivery of health care services. More attention needs to be paid to how these models affect the delivery of health care, especially models being developed by the private sector.
Care Delivery		• Care transitions in peds	• There needs to be more research on the gaps in care from children transitioning from the pediatric to the adult health care system, especially those children with chronic conditions.
Care Delivery		• Multiple comorbidities for elderly	• There needs to be more research on how providers deliver care to older patients with multiple chronic conditions and multiple problems per visit.
Care Delivery		• Opioid addiction treatment in primary care	• There is an understanding that primary care practices are not prescribing medication-assisted therapy. More research and tools are needed to promote prescriptions in primary care practices.
Personal Behaviors and Preferences		• Patient understanding of consent	• There is a lack of research into whether patients actually understand consent forms and what they are consenting to in those forms.
Personal Behaviors and Preferences		• Biometrics on patient engagement	• There is an increased use of biometrics in the health care system (i.e., the use of fingerprints or face scans). There is little research on how patients react to biometrics being used in the health care system.
Organization of Care	Quality of Care	• Coordination between public and private payers	• The federal government and private payers work in tandem to provide health care and health insurance to patients. Little is known about what methods are best to coordinate the efforts of CMS (and other health agencies) and private payers in improving health outcomes.
Health outcomes		• Lack of outcome-based measures	• In general, there are a lot of health outcomes measures, and especially few for behavioral health.
Equity and disparities	Cost and Utilization	• Impact of cost on personal behaviors	• There is little research done on the impact of increased costs through cost sharing and higher insurance premiums on patient behaviors and disparities in outcomes from these increased costs.
Equity and disparities		• Root cause of disparities in utilization	• More research is needed on understanding the root causes of disparities caused by the health care system, including whether provider bias is leading to inequities in treatment.

Primary Research Domain of Gap	Other Related Research Domain(s) of Gap	Specific Gap	Description
Equity and disparities		• Understanding full spectrum of disparities	• More research is needed to better capture the full spectrum of equity and disparities in the health care system. This is more than just looking at the impact of poverty or social disadvantages on health care outcomes.
Policy	Organization of Care	• Unintended consequences	• More research is needed on the unintended consequences of policy changes on the health care system.
Policy	Organization of Care	• Impact of big policy changes	• There is not enough definitive research done on the impacts of big policy changes on the health care system (i.e., the impact of the ACA on primary care, or the potential impact of a single-payer system on health care).
Policy	Research Methods and Tools	• Testing policies before legislation	• There needs to be more research done on policies before they are passed and implemented on the ground.
Research Methods and Tools		• Use of systems thinking in HSR and PCR	• There needs to be more research using a broader lens, for example: ○ One that encompasses the larger end-to-end patient experience (e.g., from one treatment change to how that treatment interacts over time with the other treatments patients are receiving) ○ One that encompasses the larger health care delivery system (e.g., from the care coordination intervention, to how that intervention interacts with other aspects of care coordination already present).
Research Methods and Tools		• Use of system dynamics modeling in HSR and PCR	• There needs to be more research into understanding hypotheses and testing alternative hypotheses for the mechanisms involved (e.g., for linking inputs with outputs).
Research Methods and Tools		• Use of probabilistic methods	• There needs to be more research using probabilistic methods that can communicate more than “Did it work to a statistically significant degree?” Delivery leaders and other stakeholders can then use these results in combination with their own risk tolerance to make choices.

Primary Research Domain of Gap	Other Related Research Domain(s) of Gap	Specific Gap	Description
Research Methods and Tools		• Taking advantage of natural experiments	• Natural experiments are taking place inside health care organizations, but they are not being evaluated, and lessons learned are not being disseminated beyond the organization. Obtaining funding in time to evaluate a natural experiment is especially challenging.
Research Methods and Tools	Care Delivery Process	• Use of RCTs in real-world settings	• There needs to be more RCTs and other causal research in the primary care setting. For example, real-world RCTs need to be done to better understand how to make the correct diagnosis for patient conditions, especially for those with multiple comorbidities.
Research Methods and Tools	Cost and Utilization	• Economic impact analysis as HSR	• There needs to be more research on the economic impacts of various trends in the health care system, including the impact of incentives on patient and provider behavior and the impact of market consolidation on patient care.
Research Methods and Tools		• Issues around data access and privacy	• As more sophisticated research methods are developed and researchers have access to more powerful analytic tools, there is a need for access to data at a more granular level. More research needs to be done to understand the impacts of these new tools and greater access to data on privacy, especially for information on behavioral health and substance abuse, and the role of big data and artificial intelligence in HSR. Particular attention needs to be paid to make sure data for research is not abused.

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