BUILDING A
PATIENT-CENTERED
HEALTH SYSTEM

A patient-centered approach to developing alternative payment models – and the foundation upon which they are built

Partnership to Improve Patient Care
www.PIPCpatients.org
Executive Summary

The U.S. has made significant progress in advancing patient-centeredness in clinical and health systems research over the last several years. At the same time, much work remains to be done. The progress we have made is the fruit of a movement that spans several decades, and the Partnership to Improve Patient Care (PIPC) is proud to have lent its voice to this effort. Advances in policy such as the authorization of the Patient-Centered Outcomes Research Institute (PCORI) in 2010 and patient-centered policies being implemented at the Food and Drug Administration (FDA) highlight the recognition by policymakers that patients should not be in the back seat, but should instead be driving research and are capable of translating patient-centered research into health care decision-making.

Since its founding, PIPC has been at the forefront of patient-centeredness in CER – both its generation at PCORI and translation into patient care. Having driven the concept of patient-centeredness in the conduct of research, PIPC looks forward to bringing the patient voice to the discussion of how to advance patient-centered principles in an evolving health care system.

More recently, work to shift from health care payment based on volume to “value-based” models has taken hold, in part due to broad cost-containment pressure and in part due to the expansion of value-based payment policy via the Affordable Care Act. As these policies seek to define and reward value, apply evidence of comparative clinical and economic value, and reshape physician decision-making, they hold significant implications for the patient-centeredness movement, and the related issues of patient access and the physician-patient relationship. As part of our ongoing commitment to patient-centeredness in health care, PIPC developed this paper to highlight some of the most important opportunities and issues to address in translating principles of patient-centeredness into value-based payment, sometimes called alternative payment models (APM’s).

To provide context for the discussion of the role of patients in APMs, Part One of this white paper identifies what it means to be patient-centered, including how the concept of patient-centeredness informs the role of patient engagement and patient empowerment in the healthcare system. Part Two describes in detail the foundation provided by a patient-centered evidence base that is built on patient-centered research methodologies and standards, as well as a data infrastructure that can collect and report information that is meaningful to patients. Once the evidence base is established, Part Three of the paper discusses how to apply and use the evidence to make a practical difference in the provision of healthcare and on health outcomes. Part Four highlights the concept of value for
the patient. Part Five elaborates on how to build a patient-centered learning healthcare system through a discussion of how to develop measures and align incentives across the healthcare spectrum that provide crucial information on how the system is functioning. With measures and incentives aligned to meet principles of patient-centeredness, we will have the foundation to build patient-centric approaches to value-based payment models and can learn from existing and evolving APMs (e.g., Accountable Care Organizations, bundled payment systems, medical homes) the extent to which they are meeting patient-centeredness criteria, as discussed in Part Six. Finally, Part Seven describes select APMs and their opportunities and challenges for advancing patient-centeredness in care delivery.

PIPC acknowledges that we are designing the house while we are building it, and we view this as a living document that will evolve along with evidence-based medicine and payment policy. We highlight some of the challenges that need to be addressed within those building blocks that lead to patient-centeredness and offer a comprehensive set of recommendations for policymakers and health care decision-makers, including, including those in Congress and at the Center for Medicare and Medicaid Innovation (CMMI). While these recommendations are geared toward influencing improvements in federal policy, they have broader relevance for consideration by policymakers in other federal programs, State health programs, and private payers. Part Eight concludes with the following recommendations:

1. **Policymakers should establish formalized mechanisms that provide a meaningful voice to patients in the creation and testing of APMs.**
   a. Policymakers should create a national advisory panel on patient-centeredness in value-based payment that is comprised of representatives of patients and their caregivers, primary care and specialist physicians and other providers, and other relevant stakeholders.
   b. Implement an open and transparent process for testing and implementing APMs.
   c. Work with stakeholders to identify, and subsequently apply, clear patient-centeredness criteria in its approval and evaluation of APMs.
   d. Support the inclusion of patients and their providers in the development of quality improvement strategies and quality measurement development and adoption.
   e. Center value definitions on value to patients.

2. **Direct CMMI to prioritize policies that promote patient-centeredness within models such as Patient-Centered Medical Homes.**
   a. Test shared decision-making tools within PCMHs.
   b. Better align PCMHs with principles for patient-centeredness, including a recognized role for both primary and specialty care, and patient choice of providers.

3. **CMS, quality organizations, physician and specialty societies should catalyze the expansion of available quality measures and ensure they are appropriately**
Building a Patient Centered Health System

**incentivized in APMs.**

a. Focus on investments in measuring clinical outcomes that are consistent with individual needs, outcomes and preferences, and use that information for quality improvement.
b. Expand support for measure development and endorsement, specifically for patient-reported outcomes measures.
c. Explore clinical data registries as one potential mechanism for enabling robust, comprehensive quality measures in ways that are administratively feasible for providers.

4. **Foster informed choices from the range of clinical care options.**

a. Prioritize APMs that make patient engagement and informed treatment decision-making accessible, through shared decision-making and other tools.
b. Allow physicians participating in APMs to tailor care to an individual patient.
c. Fund research dissemination activities that support the engagement of patients, patient groups, and providers in the development and implementation of dissemination and implementation tools, including shared decision-making tools.

5. **Protect against “one-size-fits-all” cost containment tools under APMs.**

a. Establish safeguards to ensure APMs do not impose blunt access restrictions to tests, treatments or provider options that are best suited to individual patients.
b. Provide oversight and validation of tools to translate evidence into clinical decision-making in APMs.

6. **Support access to innovation.**

a. Ensure patient-centered principles are adopted throughout the health care system, including in the design and implement of new payment models in ways that promote patient-centered care and do not limit access or push “one-size-fits-all” treatment solutions.
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Introduction

The Partnership to Improve Patient Care (PIPC) is pleased that the U.S. has made significant progress in advancing patient-centeredness in clinical and health systems research over the last several years. Recognizing the need to instill patient-centered principles into the foundation of our health care system, we strongly advocated for the authorization of the Patient-Centered Outcomes Research Institute (PCORI) in 2010 to change the culture of research to better respond to patient needs, outcomes, and preferences, an objective that PCORI is embracing as it shifts away from traditional investigator-initiated research topics to targeted and patient-driven research topics. Building on PCORI’s creation and an increased focus on patient-centeredness, Congress specifically allowed the Food and Drug Administration (FDA) to develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions as part of the Food and Drug Administration Safety and Innovation Act in 2012. This was a significant achievement for patient-centeredness in the drug development process. Additionally, the FDA is also increasingly focused on patient-reported outcomes in their policies and quality improvement programs. These developments highlight the recognition by policymakers that patients should not be in the back seat, but should instead be driving research, and are capable of translating patient-centered research into health care decision-making.

Since its founding, PIPC has been at the forefront of patient-centeredness in CER – both its generation at PCORI and translation into patient care. With a focus on the front end of clinical CER, PIPC’s members initially coalesced around the recognition that policymakers will find it difficult to develop a patient-centered payment and healthcare delivery system without an evidence base developed around patient-centered principles. As the concept of patient-centeredness becomes better defined in its application to research, PIPC looks forward to bringing the patient voice to the discussion of how to advance patient-centered principles in a value-based health care system, specifically in the development of new payment and delivery models.

More recently, work to shift from health care payment based on volume to “value-based” models has taken hold, in part due to broad cost-containment pressure and in part due to the expansion of value-based payment policy via the Affordable Care Act. This movement holds significant implications for patients – on the one hand, value-based payment reform can improve care quality, coordination and patient experience. At the same time, many forms of value-based payment put providers at financial risk for spending targets, which will fundamentally change the doctor-patient relationship, and create the risk of stinting on care that is best for the individual patient and, depending on how they are implemented could promote rigid “one-size-fits-all” applications of

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1 Jordan M. VanLare, AB; Jonathan D. Blum, MPP; Patrick H. Conway, MD, MSc Linking Performance with Payment, JAMA. 2012;308(20):2089-2090. doi:10.1001/jama.2012.14834.
comparative effectiveness research. An opinion piece from Wharton School at University of Pennsylvania recognized that research shows that often the more expensive treatment is worth the additional costs, and in “such cases, net value, not cost containment for the sake of cost containment, should be our social goal.”

This broad trend toward value-based or alternative payment models (APMs) underscores the importance of ensuring that value-based tools support patient-centeredness in health care. Failure to advance patient-centeredness in payment reform risks blunting much of the progress that has been made to date in patient-centered research. APMs are increasingly utilizing evidence standards and value-based tools that rely on comparative effectiveness research (CER) and other sources of health care data, presenting both opportunities and challenges as we instill patient-centered principles in a value-based health care system. For example, Congress is beginning to recognize the value of patient-centeredness, referencing shared decision-making as a goal for new accountable care organizations (ACOs) and directing the Centers for Medicare and Medicaid Innovation (CMMI) to embrace concepts such as shared decision-making and evidence-based medicine in its guidance to demonstration project partners. Also, the experience with Patient-Centered Medical Homes (PCMHs) hold great opportunities for engaging patients in informed treatment and health care decision-making, and therefore advancing patient-centeredness.

Health care stakeholders – ranging from patients, providers, and innovators – understand that a value-based health care system that truly supports advancements in personalized medicine must be built on a foundation of patient-centeredness. By incorporating patient-centered principles throughout the building blocks of our health care system, we can provide high-quality care in a manner that is both beneficial to the individual patient and sustainable. Therefore, PIPC developed this paper to highlight some of the most important opportunities and issues to address in translating principles of patient-centeredness to APMs, or value based payment models. We intend for this white paper to better define how principles of patient-centeredness should be considered in the context of developing APMs and a value-based health system.

To provide context for the discussion of the role of patients in APMs, Part One identifies what it means to be patient-centered, including how the concept of patient-centeredness informs the role of patient engagement and patient empowerment in the healthcare system. Part Two describes in detail the foundation provided by a patient-centered evidence base that is built on patient-centered research methodologies and standards, as well as a data infrastructure that can collect and report information that is meaningful to patients. Once the evidence base is established, Part Three discusses how to apply and use the evidence to make a practical difference in the provision of healthcare and on health outcomes. Part Four highlights the concept of value for the patient. Part Five elaborates on how to build a patient-centered learning healthcare system through a discussion of how to develop measures and align incentives across the healthcare spectrum that provide crucial information on how the system is functioning. With measures and incentives aligned to

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meet principles of patient-centeredness, we will have the foundation to build patient-centric approaches to value-based payment models, allowing us to learn from existing and evolving APMs (e.g., Accountable Care Organizations, bundled payment systems, medical homes) the extent to which they are meeting patient-centeredness criteria, as discussed in Part Six. Finally, Part Seven describes select APMs and their opportunities and challenges for advancing patient-centeredness in care delivery.

PIPC acknowledges that we are designing the house while we are building it, and we view this as a living document that will evolve along with evidence-based medicine and payment policy. We highlight some of the challenges that need to be addressed within those building blocks that lead to patient-centeredness and offer a comprehensive set of recommendations for policymakers and health care decision-makers, including those in Congress and at the Center for Medicare and Medicaid Innovation (CMMI). While these recommendations are geared toward influencing improvements in federal policy, they have broader relevance for consideration by policymakers in other federal programs, State health programs, and private payers. Part Eight will conclude with a series of specific recommendations for policymakers seeking to fulfill the promise of patient-centeredness.
Part One

What Does it Mean to be Patient-Centered?

To ensure policymakers develop APMs in a manner that supports patient-centeredness, they first must understand what it means to be patient-centered, including acceptance of specific principles and the role of patient-engagement in the health care decision-making process. This section defines those principles, describes the evolution of the concept of patient-centeredness, and emphasizes the importance of patient-engagement and patient-empowerment.

Principles of Patient-Centeredness: In this section we seek to define the meaning of patient-centeredness.

Our discussion will often reference principles of patient-centeredness. PIPC has translated its original principles of patient-centeredness for CER so that they can be more broadly applied to each building block of an APM or value-based system of care as follows. These principles do not cover all of the components a value-based payment or delivery system may need to work, and instead are focused more narrowly on making value-based payment work for patients. We recognize that value-based payment policy is still evolving, and therefore consider these principles a work in progress that may evolve over time. As described elsewhere in this document, PIPC also proposes a series of policies designed to put these principles into practice. To support patient-centered care, an APM should:

- Start with the goal of improving patient care and clinical outcomes at the individual and population level and incorporate strong incentives for improving care based on measures of clinical outcomes and other outcomes that matter to patients.
- Take a holistic perspective that encompasses all aspects of health care relevant to the patient experience of care and outcomes that matter to patients; Support informed physician and patient shared decision-making from the range of relevant treatment options based on best available evidence, individual patient needs and preferences, and the physician’s expertise and knowledge of the patient.
- Utilize evidence-based decision-support tools that draw on evidence that is technically excellent and appropriate, are developed through transparent processes, guided by clinical experts and patients, remain current with medical progress, and enable physicians to tailor care to the needs of the individual patient consistent with principles of evidence-based medicine.
- Enable patients to conduct personalized assessments of the value of treatments based on information on clinical value and patient health outcomes, and have a voice in how that information is used in their care.
• Account for the diversity, including racial and ethnic diversity, of patient populations, communicating evidence for each option in ways that reflect the differences in individual patient needs.
• Be adopted and implemented through open, transparent processes that give all stakeholders a meaningful voice in APM design and use.
• Support the continued development of and access to medical advances, including personalized medicine and other advances that can help improve patient care and control health care costs.
• Recognize the unique nature and value of targeted therapies that benefit specific groups of patients with rare and orphan diseases.

_The Evolution of Patient-Centeredness Principles_: In this section we provide a historical context for how we define patient-centeredness.

PIPC believes that if innovative payment and delivery models are developed consistent with our principles for patient-centeredness, they will accomplish their goals in a manner that respects patients as unique individuals. Our principles are based on an evolution of defining what it means to be patient-centered. The Institute of Medicine (IOM) defined “patient-centeredness” in 2001 as “[H]ealth care that establishes a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patients’ wants, needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care.”

Much attention was later given to an article written by the former administrator of the Centers for Medicare and Medicaid Services (CMS), Dr. Don Berwick, in which he succinctly described patient-centered care. He defined it as, “The experience (to the extent the informed, individual patient desires it) of transparency, individualization, recognition, respect, dignity, and choice in all matters, without exception, related to one’s person, circumstances, and relationships in health care.” In the context of use of evidence in the practice of medicine, he recognized that “leaving choice ultimately up to the patient and family means that evidence-based medicine may sometimes take a back seat.” He stated, “If, over time, a pattern emerges of scientifically unwise or unsubstantiated choices...then we should seek to improve our messages, instructions, educational processes, and dialogue to understand and seek to remedy the mismatch.” In terms of tactics, he called on the locus of control to remain with patients and families, transparency in all aspects of care, and individualization and customization of care within flexible systems that can adapt to the patient’s circumstances.

Principles of patient-centeredness are further supported by other thought leaders. In cancer care,
the National Cancer Institute embraced the definition published in the Social Science and Medicine journal in 2006, noting that the two attributes considered central to the delivery of patient-centered care are being responsive to patient needs and incorporating the patient’s perspective and experiences in care planning and decision-making. A multi-stakeholder group calling its work “Turning the Tide Against Cancer” proposed value assessment tools that are better aligned with patient-centered care, centered on principles such as patient value as defined by patient needs and preferences. The National Quality Forum’s National Quality Strategy includes “patient-centered experience” as an important measure of the quality of patient care. Even the Triple Aim of improved health outcomes includes better patient care experiences, in addition to improved health outcomes and lower costs.

**The Role of Patient Engagement: Only when patients are meaningfully engaged can we even consider something to be patient-centered.**

Being patient-centered requires engagement of patients, patient groups, providers and caregivers at each stage of building a patient-centered health system. Experts have defined patient and family engagement as “patients, families, their representatives, and health professionals working in active partnership at various levels across the health care system—direct care, organizational design and governance, and policy making—to improve health and health care.” The term patient engagement is generally used to include patients, families, caregivers, and other consumers and citizens. Congress recognized the value of patient engagement in the prioritization and conduct of research when it authorized the creation of PCORI. Congress mandated the inclusion of patient representatives on the PCORI Board of Governors and provided support and resources to ensure the effective participation of patient and consumer representatives on the Board and expert advisory panels. In support of PCORI's patient-centered mandate, PIPC has also developed consensus recommendations on engagement strategies that would capture the preferred outcomes and preferences of patients in the research prioritization process, as well as in the communication of research findings.

PCORI is paving the way for proving the value of patient engagement and providing evidence for best practices that could potentially be translated from patient engagement in research to patient engagement in the implementation of evidence to practice. For example, PCORI has created a

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Patient and Family Engagement Rubric that provides guidance to researchers on how to engage patients in the conduct of research. The rubric identifies the key points of engagement, from planning and conducting the study, to disseminating study results, and calls for engagement in a manner that is consistent with the principles of reciprocal relationships, co-learning, partnership, trust, transparency and honesty.

Patient engagement in research is a strong first step to changing the culture of medicine. There are lessons learned from this work to engage patients that can and should then be embraced by the broader health system. Engagement does not stop at research, a sentiment being recognized more and more by experts and policymakers. In a proposed framework for patient and family engagement, experts identified three stages to focus engagement efforts:

**Direct Care:** At the level of direct care, engagement integrates patients’ values, experiences, and perspectives related to prevention, diagnosis, and treatment, including managing the patient’s health and selecting health care coverage and providers.  

**Organizational Design and Governance:** At the level of organizational design and governance, engagement integrates patients’ values, experiences, and perspectives into the design and governance of health care organizations such as hospitals, accountable care organizations, clinics, and nursing homes.

**Policy-Making:** At the policy-making level, engagement focuses on developing, implementing, and evaluating national, state, and local health care policy and programs. Patients’ engagement in policy, often described as “citizen” or “public” engagement, helps ensure that the health care system writ large is oriented around and responsive to patients’ perspectives.

Policymakers have also made strides in recognizing the value of patient engagement, as evidenced in the regulations for ACOs that require them to have plans for beneficiary engagement. Just as policymakers and patients have called on researchers to get beyond “token” engagement of patients in the conduct of research, the science of engagement must evolve to support measures for effective patient engagement by health systems. So the question is how we make ACOs accountable for patient engagement beyond just having a plan. For example, although regulations call upon ACOs to comply with survey requirements on patient experience of care, few studies measure how many practices actively engage patients to help act on survey data. Engaging patients in quality improvement would make that input actionable, and therefore meaningful.

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10 Id. at 225.
11 Id. at 225.
12 Id. at 226.
In an effort to build the evidence base for effective patient engagement, several specific research questions have been proposed by experts in the field of patient and family engagement such as:

- What factors, or combinations of factors, exert the greatest influence on patient engagement? What are the pathways by which they do this?
- When developing interventions at one level, such as direct care, what supports are needed at the levels of organizational design and governance and of policy making to increase those interventions’ effectiveness?
- How do interventions at the policymaking level affect engagement efforts and outcomes at the other levels?
- Do interventions in which patients share leadership demonstrate better outcomes than those in which patients are only consulted or involved? If so, which interventions are most effective at facilitating engagement at the continuum’s highest end?
- What are the most effective methods for organizations and policy makers to create opportunities for engagement? How can organizations recruit patients to serve on governance committees? How are committee members’ roles and responsibilities defined?
- How can research findings be translated into routine practice? How can we best support implementation and structure interventions that make the most of available resources?\textsuperscript{14}

PIPC would agree with the assertion that health care organizations and policy makers will need to embrace new norms and make substantial changes in their culture, processes, and structure to achieve patient-centeredness.\textsuperscript{15} Doing so requires engaging patients and their families so they understand how their participation ultimately improves their health. Unfortunately, there are some who dismiss engagement as peripheral to the main business of health care, “a fluffy notion that lacks the solid underpinning of scientific rigor on which medical care is supposedly built.”\textsuperscript{16} Others embrace it. A balanced approach argues for both a strong commitment to the idea that patients and the public should be more informed and involved, while also making the case for engagement to be rooted in an understanding of its impact on health care and health status.\textsuperscript{17}

The book by Angela Coulter summarized it well – “Patient engagement is both as a means to an end, and an end in itself. It should be treated as an ethical imperative, but if it also leads to improved quality of care, more appropriate decisions, and better health outcomes, then it is much easier to persuade people that it is definitely worthwhile. To test this, we must look at the evidence and, as will become apparent, there are many theories and studies to be examined.”\textsuperscript{18}

\textbf{Patient Empowerment and Patient Activation: A Meaningful Outcome of Patient Engagement.}

\textsuperscript{14} Carman, \textit{supra} at 227.
\textsuperscript{15} Carman, \textit{supra} at 228.
\textsuperscript{17} Id
\textsuperscript{18} Id. at xiii.
Now that the value of patient engagement is becoming more accepted among health care decision makers, a shift is happening to make that engagement meaningful by both empowering and activating patients. The conversation is viral, becoming even a worldwide discussion. In 2012, more than 250 participants met at the first European Conference on Patient Empowerment, convened by the European Network on Patient Empowerment. One of the organizers stated that “patient empowerment is simply a process to help people gain control, which includes people taking the initiative, solving problems, and making decisions, and can be applied to different settings in health and social care, and self-management.” It was reported that speakers argued that the traditional, paternalistic approach to patient care tends to ignore personal preferences, and creates dependency—there needs to be a shift towards patient-centered care.

In 2010, PIPC Chairman Tony Coelho recognized in Health Affairs that empowerment is the ultimate goal for patient engagement, and thereby a prime component of any truly patient-centered health system. He stated, “More recently, my work for individual empowerment has focused on supporting individual patients in health care and moving toward patient-centered approaches to care.” PIPC's roundtable discussions indicate that the goal line for being patient-centered has moved from simply patient engagement to patient empowerment or patient activation. In essence, the conversation is about how we make patient engagement meaningful so that patients feel empowered, and therefore are more active in their care.

Patient activation emphasizes patients’ willingness and ability to take independent actions to manage their health and healthcare. Intuitively, an active patient would be more likely to take advantage of the shared decision-making tools that are the building block of a patient-centered health system. The evidence linking patient activation with health outcomes, patient experience, and costs has grown substantially over the past decade. Policies and interventions aimed at strengthening patients' role in managing their health care can contribute to improved outcomes and that patient activation can—and should—be measured as an intermediate outcome of care that is linked to improved outcomes. Quality improvement efforts that systematically work to expand the patient’s (and the family’s) ability to participate in care are a pathway toward improving outcomes. For example, a patient activation measure could be an indicator that shared decision-making tools are being effectively implemented in ACOs. A truly patient-centered payment and delivery model should be able to demonstrate that they are making an effort to not just engage patients, but to empower and activate them to participate in their own care.

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Part Two
Developing the Evidence Base

Ensuring that the evidence being generated, the methods in how research is conducted, and the collection of information important to patients is done in a patient-centered manner is critical as policymakers are increasingly incentivizing the use of evidence-based standards in APMs. PIPC has long advocated for the application of patient-centered principles in the development of an evidence base, and we are pleased to see emerging practices to meaningfully apply those principles in research and in the development of data networks. Below, we will highlight some of the emerging work to apply patient-centeredness principles to evidence generation and the development of a patient-centered data infrastructure.

Patient-Centered Outcomes Research: The foundation for patient-centeredness.

Responding to the public call for patient-centeredness, Congress created PCORI to conduct comparative clinical effectiveness research in a manner that is responsive to patient needs, outcomes and preferences, and provides for a patient voice in the research process. While there was some resistance and concern that the existing culture of research was to conduct CER with the goal of promoting "one-size-fits-all" treatments based on averages, there was equal concern among PIPC’s members that a stronger evidence base was needed to support individualized clinical care that focuses on identifying what treatments are most likely to be effective in improving health outcomes for particular patients. This view was reiterated in an article entitled Comparative Effectiveness And Personalized Medicine: Evolving Together Or Apart? in which the authors recognized that although CER and personalized medicine can at first appear to be at odds with each other, “because comparative effectiveness research typically enrolls heterogeneous patient populations, it can uncover subpopulations that might benefit most from particular treatments.” The article concluded that, “comparative effectiveness research can help discern the appropriate role of personalized medicine in improving health care outcomes and rationalizing costs.”

Patient-centered outcomes research is defined by PCORI in a manner consistent with its statutory definition of comparative clinical effectiveness research:

“Patient-Centered Outcomes Research (PCOR) helps people and their caregivers

communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options. This research answers patient-centered questions such as:

- Given my personal characteristics, conditions and preferences, what should I expect will happen to me?
- What are my options and what are the potential benefits and harms of those options?
- What can I do to improve the outcomes that are most important to me?
- How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?

To answer these questions, PCOR:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people;
- Is inclusive of an individual’s preferences, autonomy and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health related quality of life;
- Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and
- Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, availability of services, technology, and personnel, and other stakeholder perspectives.”

To change the research culture to facilitate—and not hinder—a shift to a more patient-centered health system, significant work has been done to identify effective patient engagement strategies, as described above. There is recognition that change is needed in the academic research culture in order to accomplish patient-centered outcomes research. PCORI has captured its legislative mandate in the brand “research done differently” and developed a Patient and Family Engagement Rubric as guidance to researchers on what it means to engage patients meaningfully in the conduct of research. Additionally, the National Health Council has long been at work on the development of usability criteria that can be applied at every step of the research, dissemination and implementation process to ensure that the research question leads to information that is useful to patients and their providers in health care decision-making, a concept that PCORI is also starting to embrace.

Patient-centered outcomes research requires patient-centered methodologies for research that may deviate from traditional practices. Although randomized controlled trials are typically viewed as providing the least biased estimates of comparative effectiveness, the results might not always correspond to what is seen in real-world practice, where physicians apply the treatments to a broader range of patients. Therefore, high-quality, large-scale observational studies are attracting much interest.24

The PCORI Methodology Committee was established by Congress to “develop and improve the science and methods of comparative clinical effectiveness research.” The current PCORI Methodology Standards, including methodologies for observational studies and patient engagement, are a first installment of what will be an ongoing process of both broadening the scope of the standards and revising existing ones.25 Truly changing the culture of research will require that these methodologies be viewed as both rigorous and patient-centered, so that researchers understand the value of patient engagement and real-time observational data for improving patient care. It will also be important for these standards to evolve to reflect scientific advances and to support the incorporation of innovative techniques into patient care. Additionally, these standards should be adaptable to be relevant to studies that engage both large and small patient populations. Upon the acceptance of patient-centered research methodologies, we can expect more attention to the development of a patient-centered data infrastructure that supports patient-centered outcomes research and patient-centered measures of quality.

Expanding and Improving the Data Infrastructure: Supporting a learning healthcare system that improves health outcomes for individual patients.

Patient-centered outcomes research, including but not limited to clinical CER, requires a data infrastructure to support its development and use in practice. Significant work has been done to facilitate the generation of patient-centered outcomes research, from the creation of PCORI to the development of patient registries and data networks. This infrastructure is intended to support better quality measures, performance measures, and patient-reported outcomes measures so that health improvements are measurable.

As delivery system reforms are happening alongside building the infrastructure for measuring health improvement in a patient-centered manner, the challenge is fostering development of a

24 Nancy A. Dreyer, Sean R. Tunis, Marc Berger, Dan Ollendorf, Pattra Mattox and Richard Gliklich Why Observational Studies Should Be Among The Tools Used In Comparative Effectiveness Research Health Affairs, 29, no.10 (2010):1818-1825
patient-centered data infrastructure to support patient-centered payment and delivery reform. This must include protecting vulnerable patients by enabling more active, timely monitoring of quality, patient-experience, outcomes and access in alternative payment models. This will help ensure the health system does not prioritize cost savings over improved health and personalized medicine simply because cost savings are easier to measure and reward. A part of the solution is developing a patient-centered data infrastructure, including the use of patient registries and data networks, which supports patient-centered outcomes research and measures. While not the focus of this paper, key opportunities include advancing patient-centered approaches to clinical data registries and electronic health records.

Provider organizations and physician specialty societies are strongly advocating for patient registries that can provide access to real-time observational data comparing treatments in a manner that can also be stratified by the patient’s unique characteristics as a key component to the expanding data infrastructure. Similarly, efforts to harness the growing data and evidence being generated through electronic medical records (EMRs) in emerging data networks, such as investment in the development of PCORnet: The National Patient-Centered Clinical Research Network, will be key to developing the evidence-base needed to support an evolving value-based health care system.

In addition, ACO’s, such as Medicare Shared Savings Programs, are called upon to develop an infrastructure for reporting on quality and cost metrics, evaluating performance and using results to improve care over time. Because they have regular data feeds from the various sources that make up health care delivery, these ACOs can develop data exchanges that enable both performance improvement and tracking. Yet, obtaining reliable and timely source information is a challenge. An inherent barrier is that electronic health records (EHRs), despite meaningful use requirements, are still limited in availability and completeness. Most small practices have not adopted them consistently, and those that have typically do not have information about the patient beyond their own practice. While we can applaud the ongoing efforts to develop a patient-centered data infrastructure, clearly more work needs to be done. Ultimately, to be patient-centered, APMs will need a data infrastructure that supports both patient-centered outcomes research and the development of outcome measures (as opposed to just process measures of quality) that together support a learning healthcare system.

27 Id. at 92
Part Three

Application and Use of Evidence to Improve Health

The shift to patient-centered outcomes research is important because organizations are already using this research, including CER, to make decisions such as in the development of quality measures and clinical practice guidelines. Additionally, changes in payment paradigms, including the development of APMs, are creating a demand for evidence-based information and incentivizing the use evidence-based standards. Health care stakeholders, including both patients and providers, do not want to see evidence used to limit treatment choices or drive a “one-size-fits-all” model of care. This becomes a risk if evidence is not developed consistent with patient-centered principles that clearly communicate the limitations and applicability of research based on a patient’s unique characteristics. Patient-centered principles are equally important for the dissemination and implementation of patient-centered outcomes research to practice, and this section highlights how policymakers should communicate, incorporate, and use evidence in the development of APMs specifically, and in health care decision-making more broadly.

The dissemination and implementation of evidence resulting in its actual use involves many steps, including the process of traditional research translation, described below. Although not exhaustive, by dividing the traditional research translation process into five steps, researchers at the RAND Corporation sought to better understand the barriers and facilitators of evidence translation. The five steps are:

First is the generation of comparative effectiveness results, which include both the design and the conduct of a study. Second is the interpretation of a study's results, when stakeholders assess the quality and relevance of the evidence and begin to formulate recommended changes to clinical practice. The third step is the formalization of results, at which point clinical experts, health information technology vendors, and other experts convert the recommended changes into clinical practice guidelines, performance measures, and clinical decision support tools. Fourth is dissemination, the process by which the formalized results and related tools are transmitted to local stakeholders. The last step is the implementation of new clinical practices by professionals and patients in local settings.28

By integrating open and transparent processes where all stakeholders have meaningful input into

each step, “traditional” research translation becomes an innovative patient-centered process for using information to improve health. With the development of patient-centered tools for dissemination and implementation, a truly patient-centered health system will adopt these tools and measure their effectiveness in improving health outcomes.

The Science of Implementing Evidence to Practice: Developing patient-centered processes for communicating research.

It is often lamented that there is so much medical research that is not effectively disseminated and used, likely because the processes for dissemination and implementation of evidence does not produce information that is usable for assessing treatment options based on a patient’s unique and diverse characteristics - therefore lacking patient-centeredness. Some find the translation of CER investments into practice, enabling new laboratory discoveries to reach patients’ bedsides, to be frustratingly slow. Yet these same critics advocate harnessing the promise of CER by ensuring the efficient and effective implementation of its findings into practice, which requires substantial investment and planning that will involve health care providers, patients, and other local stakeholders. Therefore, investments in CER must also be accompanied by implementation research so health systems know the techniques to effectively bring research to practice. There remains much to be learned in the domain of implementation of CER.29

How research gets communicated to providers, patients and other decision makers represents an important factor in realizing the opportunity for patient-centered outcomes research to support patient-centered, evidence-based health care. PIPC has long advocated that patient-centered processes for communicating evidence are an essential component of a patient-centered health system, and has developed “best practices” in communication of CER to patients.30 Congress recognized that without improved dissemination strategies, new investments in patient-centered outcomes research - such as the investment in PCORI - would create more evidence, but not necessarily improve patient care.

To foster dissemination, the statute creating PCORI also provided funding to AHRQ from the Patient-Centered Outcomes Research Trust Fund. The statute includes certain requirements for dissemination activities to be consistent with PCORI’s patient-centered mission. For example, it requires AHRQ to create informational tools for physicians, health care providers, patients, payers and policymakers and to develop a publicly-available resource database of both government-funded evidence and research from most other sources. In this work, AHRQ is required to include a description of considerations for specific subpopulations and the limitations of the research, as well

as be transparent about the research methods, how the research was conducted and by whom.\textsuperscript{31} The statute also recognized that PCORI would not immediately have research findings to disseminate, and required AHRQ to not only disseminate PCORI’s research findings but also to disseminate “government-funded research relevant to comparative clinical effectiveness research.”\textsuperscript{32}

PCORI has initiated its own work to develop a “Dissemination and Implementation Action Plan,” which could provide much needed guidance to AHRQ to channel these trust fund resources into effective patient-centered activities. PCORI has recognized that its funding requires attention to practical dissemination, with the goal of speeding the translation of research findings into practice.\textsuperscript{33} Participants in a PCORI-hosted dissemination roundtable stressed the importance of PCORI working with organizations—or groups of organizations—that can bring together disparate parts of the health care system. They noted that collaboration will be as important in creating the action plan as in executing it.\textsuperscript{34} PCORI also has developed an evaluation framework that could also be a resource for evidence of effective implementation strategies as it measures the effectiveness of PCORI-funded research for actually improving health and influencing care decisions.

PIPC has hosted a series of roundtables on dissemination that highlight the importance of engaging and involving both patient and provider stakeholders in the development of tools to disseminate and communicate research findings. PIPC found that patients and providers agreed on the importance of involving clinical experts, practicing physicians, and patient organizations to ensure that CER study results are disseminated in a manner that maximizes the ability of providers and patients to apply the findings of CER to a specific health care decision. Once developed, CER communication tools and materials must be incorporated into the health care delivery system in a manner that enhances the provider and patient interaction and fosters patient-centered care. It will be crucial that these tools provide sufficient context for any such study results to avoid misinterpretations that may actually serve to decrease patient access to the most appropriate care. At the core of PIPC’s recommendations on communicating CER is the fundamental premise that the affected patients and providers must be engaged early and often to both assess the quality of the information and to inform strategies for its use in order for the CER to be trusted and credible and therefore actually used.

\textsuperscript{31} Patient Protection and Affordable Care Act, §9511, “Patient-Centered Outcomes Research Trust Fund,” assigns 20 percent of the Institute’s funding to DHHS. Of this 20 percent, AHRQ receives 80 percent and ASPE 20 percent. While funding was ramped up in fiscal years 2010 and 2011, full funding for AHRQ and ASPE began in fiscal year 2012. Beginning 2012 through 2019 AHRQ receives $24 million each year and ASPE receives $6 million.

\textsuperscript{32} Patient Protection and Affordable Care Act, §937(a)(1)

\textsuperscript{33} Lori Frank, Active Patient Engagement In Research Health Affairs, 32, no.2 (2013):438-439

\textsuperscript{34} Ann Beal, Building Our Blueprint for Dissemination and Implementation, Patient-Centered Outcomes Research Institute. Retrieved at http://www.pcori.org/blog/building-our-blueprint-for-dissemination-and-implementation/
As was seen in the debate over creating PCORI, there was tension between the goal of generating more evidence to inform optimal decision-making, and concern about potential for misuse of CER in “one-size-fits-all” coverage policies or recommendations. As a result, PCORI’s mandate was focused on generating objective scientific research on comparative clinical effectiveness, and not dictating how research results should be applied. In addition, policy-makers took care to incorporate standards for CER communication in the statute itself.\textsuperscript{35}

Shared decision-making is one approach that can be consistent with this goal. It is a strategy used to translate evidence to practice in a manner that better aligns medical care with patients’ preferences and values. It can be implemented with patient decision aids — written materials, videos, or interactive electronic presentations designed to inform patients and their families about care options; each option’s outcomes, including benefits and possible side effects; the health care team’s skills; and costs. And it holds great potential to increase patient knowledge, lower patient anxiety over the care process, improve health outcomes, reduce unwarranted variation in care and costs, and align care with patients’ values.\textsuperscript{36} We must also recognize that culture change is going to be needed to make shared decision-making tools effective, in which there is a robust communication between patients and providers that elicits and honors patient preferences.\textsuperscript{37}

Another challenge for the development of effective shared decision-making tools is the translation of so much evidence that may seem conflicting - studies do not exist in a vacuum. A recent New York Times article highlighted that systematic reviews are increasingly important in day-to-day patient care, especially when there is so much evidence, and it is often inconclusive.\textsuperscript{38} Even the Cochrane Collaborative’s editor-in-chief (which conducts such systematic reviews) recognizes the need to “evaluate aspects of health that are less data-driven, such as patient preference — the age-old question of why a patient does what a patient does.”\textsuperscript{39} This statement underscores the importance of contextualizing evidence so that it is useful to individual patients, as opposed to using evidence to drive “one-size-fits-all” treatment regimens.

In this translation stage, there is concern that, without patient-centered and meaningful shared decision-making, evidence-based medicine can have the unintended consequence of supporting paternalism in medical decision-making. The Affordable Care Act’s framework for shared decision-

\textsuperscript{35} Patient Protection and Affordable Care Act, §937
\textsuperscript{37} Jaime King and Benjamin Moulton. Group Health’s Participation In A Shared Decision-Making Demonstration Yielded Lessons, Such As Role Of Culture Change Health Affairs, 32, no.2 (2013):294-302.
\textsuperscript{39} Id
making, if embraced and promoted by policymakers, could provide a path forward to test shared decision-making tools and ensure that they are used effectively in APMs to promote evidence-based medicine in a manner that is less paternal, more patient-centered. To do so, the existing law notes that the development of shared decision-making tools should involve a broad range of experts and stakeholders, including patients and physicians, and should occur through an open and transparent process. Additionally, recognizing the benefits shared decision-making can have on improving patient-centered care, the law highlighted the need to incorporate patient preferences into the development and use of shared decision-making tools. Because prevalence rates and the most effective interventions for many diseases vary greatly and because no two patients are identical, it is important to recognize variation in individual patients’ needs, circumstances, preferences and responses when developing shared decision-making tools. The law also authorizes CMMI to test shared decision-making models designed to improve patients’ and caregivers’ understanding of medical decisions and assist them in making informed care decisions. Approaches that demonstrate savings or improve quality of care are authorized by law to be implemented throughout Medicare without additional legislation.

Shared decision-making can be an effective tool to elicit and rely on patient values and preferences in clinical decision-making. To achieve this, shared decision-making must provide capacity for providers and patients to consider the range of available treatment or care options, the full body of evidence; discuss care options in the context of the patient’s clinical needs, preferences, and broader life circumstances; and meaningfully weigh these preferences and circumstances in arriving at a treatment choice. If not properly structured, APMs could either fail to capitalize on this opportunity by failing to incentivize patient-centered shared decision-making, or could actively conflict with it by imposing value assessments or care pathways that rely solely on population averages or payer perspectives of comparative value.

Health literacy is also a key component of meaningful shared decision-making. The need to improve health literacy is well-documented, with a national consensus emerging that health literacy represents a systems issue. Advocates for a “Health Care Literate Model” state that it offers the potential for patients to better understand their options; benefit from community services that improve wellness, prevention, and chronic care management; view their relationships with provider teams positively; and make informed decisions.

From a common sense standpoint, it seems clear that communication tools should present results in ways that are useful and

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40 Patient Protection and Affordable Care Act, §3506
42 Howard K. Koh, Cindy Brach, Linda M. Harris and Michael L. Parchman A Proposed 'Health Literate Care Model' Would Constitute A Systems Approach To Improving Patients' Engagement In Care Health Affairs, 32, no.2 (2013):357-367
comprehensible for patients and providers, requiring very different language, and certainly engagement from both stakeholder groups to ensure the communication tools get it right.\textsuperscript{43}

PIPC, in its recommendations for communicating CER findings, emphasizes the importance of patients and providers being engaged in the initial testing of shared decision-making tools, particularly in real-life circumstances.\textsuperscript{44} Others have suggested that more physicians need to be trained in the approach of shared decision-making, and more practices need to be reorganized around the principles of patient engagement.\textsuperscript{45} From the perspective of the bottom line of health systems, effectively educating patients about the benefits of coordinated care and involving them more in medical decision-making could also counter their concerns about network restrictions.\textsuperscript{46} For patients to trust decision-making tools, they must be credible, providing sufficient information on the range of relevant health care or medical options, and relying on data from rigorous study designs so as to not be viewed as justifying network restrictions that are more about cost containment, and less about quality of care.\textsuperscript{47} This challenge for the development of a patient-centered health system can and should be met with an enthusiasm for engaging patients and providers in the development and implementation of shared decision-making tools so that they result in empowered and activated patients.

Ultimately, the success of shared decision-making will depend on the identification of clinical pathways that are uniquely suited to the patient, that are accessible to patients, that clinicians deem to be credible and usable for the patient, and that provide clinicians with the flexibility to treat their patients based on their individual needs. Already, a quick Google search of the term clinical pathways will return multiple articles highlighting the challenges of health information technology in driving clinical care practices; the use of clinical pathways as an alternative to clinical guidelines; and new payment models based on the identification of clinical pathways. The chatter about clinical pathways is most prevalent in the field of oncology, particularly highlighting the opportunity of genetics to influence what clinical pathway is chosen for a given patient. From the perspective of patient-centeredness, development of clinical pathways has great potential as long as these pathways reflect the most appropriate care for individual patients and allow patients and providers the flexibility to tailor individual treatment regimens. Therefore, shared decision-making tools must capture this information in a meaningful way that can be communicated to patients, and convey to patients their options based on both their biology and personal preferences.


\textsuperscript{44} PIPC Best Practices for CER Communication, supra at 4.

\textsuperscript{45} France Légaré and Holly O. Witteeman. Shared Decision Making: Examining Key Elements And Barriers To Adoption Into Routine Clinical Practice Health Affairs, 32, no.2 (2013):276-284

\textsuperscript{46} Robert E. Mechanic, Palmira Santos, Bruce E. Landon and Michael E. Chernew Medical Group Responses To Global Payment: Early Lessons From The ‘Alternative Quality Contract’ In Massachusetts Health Affairs, 30, no.9 (2011):1734-1742

\textsuperscript{47} PIPC Best Practices for CER Communication, supra at 7
Part Four

Improving Value from the Patient’s Perspective

As payment reform seeks to drive greater value in health care – whether through provider pay-for-performance, accountable care organizations, patient-centered medical homes – it remains an open question whether it will drive value that matters to patients. Recent articles have noted some of the ways that the patient’s perspective of value can differ markedly from that of other stakeholders. One of the animating principles guiding PCORI’s creation was capturing value from the patient perspective in comparative clinical research. Carrying that principle through to the delivery of care to patients is essential in order to fulfill the promise of patient-centered health care.

There is a concern among some PIPC members that financial incentives will provide rewards based on isolated quality measures for certain diseases, leaving more complex patients, such as those with disabilities and/or multiple chronic conditions, at a disadvantage. This sentiment is shared by many patient groups that remain concerned that treatment choices under new payment models may be limited because they are based more on cost than on clinical effectiveness for the individual patient. The reason, in part, is that our health system is not yet effectively translating patient-centered outcomes research into practice through clinical guidelines, quality measures, shared decision-making tools, and clinical pathways. PIPC believes that getting a patient to the right care at the right time ultimately is a cost-effective strategy, and improves the patient experience of care that is a foundational element of patient-centeredness. Alignment of financial incentives with patient-centeredness principles will be possible as measures improve, and patients become more actively engaged in their own care. Financial incentives should be used to personalize care, not to limit appropriate care, nor to replace the doctor’s perspective with that of the payment model or insurer.

As noted above, shared decision-making offers one opportunity to support well-informed treatment decision-making that accounts for patient needs and preferences. There are several other key points on the spectrum of value-based payment where this issue will play out. Part Five below describes several primary approaches to alternative payment models, with particular emphasis placed on opportunities and challenges presented by these approaches for advancing patient-centeredness and considering value from the patient’s perspective. In addition, Part Five discusses quality measurement, clinical care pathways and episode-based payment, accountable care organizations, and patient-centered medical homes.

As APMs evolve and proliferate, the ability to appropriately measure, and create incentives for, improvement on health outcomes, patient experience, and other outcomes relevant to patients (e.g., patient-reported outcomes) is essential to supporting patient-centeredness in new payment models. And as with the front-end development of APMs in a value-based health care system, policymakers must consider patient-centered principles in their measurement and evaluation, and ultimately rewarding and incentivizing physicians to provide patient-centered care. This section describes concerns patients have with the current standards of measurement, specifically the lack of measures that capture what is truly meaningful to patients, and highlights the need align incentives to reward physicians to provide care and treatment options important to patients.

**Outcome Measures Versus Process Measures:** What measures are meaningful to patients in their decision-making?

In interviews with PIPC members, several referred to strong concerns with particular quality measures, including those for which development was funded by CMS under its Measure Management System.\(^{49}\) There was a consensus among those interviewed that new payment and delivery systems should measurably improve patient health outcomes, yet they recognized that such measures are not yet broadly, or effectively, available. Although process measures are a first step, a process measure of the quality of care provided during a singular treatment event is different than a measure indicating that a patient’s health was improved over time. In its 2013 report on delivering high quality cancer care, the Institute of Medicine (IOM) developed a conceptual framework for knowledge translation and performance improvement as “part of a cyclical process that measures the outcomes of patient-clinician interactions, implements innovative strategies to improve care, evaluates the impact of those interventions on the quality of care, and generates new hypotheses for investigation.”\(^{50}\) The IOM noted that clinical practice guidelines, quality metrics, and performance improvement initiatives are all tools supportive of that cyclical process.\(^{51}\) The Medicare Payment Advisory Commission Director Mark Miller has

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\(^{51}\) Id.
testified on the topic, stating, "[c]urrent quality measures are overly process oriented and too numerous, they may not track well to health outcomes, and they create a significant burden for providers."52

There is significant support for the triple aim of improving quality, lowering costs and giving patients a better care experience. Yet, stakeholders question whether there are patient-centered tools to support the goals of the triple aim. For example, one PIPC member raised the concern that if quality improvement in an APM is measured only for certain conditions, the unintended consequence could be that vulnerable populations that do not have adequate measures of quality, such as people with disabilities, could suffer. This concern underscores the necessity of patient-centered principles to be applied both in the development and implementation of APMs, and in the tools used to determine whether it is improving quality and the patient experience.

While providers and quality improvement experts face substantial challenges in measure development and use, sound quality measures are nevertheless a key determinant of whether an ACO or other value-based payment model has lived up to its end of the bargain in terms of maintaining quality of care. CMS defines quality measures as follows:

[T]ools that help us measure or quantify health care processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality health care and/or that relate to one or more quality goals for health care. These goals include: effective, safe, efficient, patient-centered, equitable, and timely care.53

As an example, Medicare’s Value Based Purchasing (VBP) payments for 2014 are determined by how hospitals score on three sets of measures. The first are thirteen "measures of timely and effective care" also known as "process" measures. The second set of eight measures is culled from surveys of patients who had recently left the hospital, also known as "patient experience" or "patient satisfaction" measures. The third area was mortality rates among Medicare patients admitted for heart attack, heart failure or pneumonia.54 To improve quality and performance measure development and use, a process that involves multiple stakeholders— including patients—could help prioritize gaps and make recommendations throughout the measure development life cycle: conceptualizing, testing, endorsing, implementing, and evaluating a measure.55

55 Carman, supra at 228.
In addition to quality measures, there is a growing interest in expanding beyond clinical outcomes measures to include measures that capture other patient-relevant dimensions of clinical care, such as patient-reported outcomes measures (PROMs). Organizations such as Avalere Health are beginning to convene interested stakeholders to identify tangible solutions to advancing the appropriate use of PROM’s in existing and future health care system payment and delivery models, as distinguished from traditional quality measures. There are significant issues surrounding the development of PROMs and patient-reported outcomes performance measures (PRO-PMs), as explained by the Brookings Institution in a paper titled *PRO-Based Performance Measures for Healthcare Accountable Entities*. Brookings notes that, given that PROMs represent the patient’s perspective, face validity of PRO-PMs could also be tested with “patient experts” by using qualitative research methods, such as focus groups, semi-structured interviews, and cognitive interviews. Engaging the patients in the process of care, particularly by noting their outcomes, is key to developing better outcomes and therefore improving health. Brookings acknowledges that much more work is needed in this area to develop a robust set of measures that include the patient’s voice in determining whether good outcomes of care have been achieved.

CMS’ Chief Science Officer and Director of CMMI, Dr. Patrick Conway, publicly recognizes the need for collaboration for reliable and meaningful quality measurement that focuses on patient outcomes, including the patient experience. From the perspective of personalized medicine, Dr. Conway has written that there must be exceptions to certain measures based on patient preferences or clinician knowledge not captured in the patient’s record. Along with electronic medical records, he emphasizes the importance of patient registries to capture quality measurement data. Yet Dr. Conway acknowledges that measures can undervalue teamwork and patient outcomes over time, therefore calling for an “explicit investment in measure development as a tool to evaluate application of evidence into practice...” Analogous to efforts to change the culture of CER to rely less on academia and more on patients to set the research agenda, Dr. Conway urges quality improvement collaboratives to “extend beyond the academic center” and “partner with frontline clinicians in the community.”

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57 Anne Deutsch, RN, PhD, CRRN; Laura Smith, PhD, Barbara Gage, PhD, Cynthia Kelleher, MPH, MBA, Danielle Garfinkel, BA, RTI International, Brookings Institution Patient-Reported Outcomes in Performance Measurement Commissioned Paper on PRO-Based Performance Measures for Healthcare Accountable Entities October 22, 2012
Section Six

Value-Based Health Care: Patient-Centeredness in Emerging Payment Models

IPC embarked on this effort to evaluate patient-centeredness beyond federally supported CER because we understand that patient-centered CER is just one of the building blocks for a patient-centered health system. Health care is now evolving in ways that can either extend patient-centered, evidence-based medicine throughout care delivery or can blunt the progress made to date. We recognize that the infrastructure and implementation of patient-centeredness is a work in progress, and that APMs—such as medical homes, accountable care organizations, and clinical pathway- or episode-based payments—which support the evolution toward a value-based health care system are happening parallel to that work. This reality has raised concerns among PIPC members seeking to protect patient-centeredness in our health system, knowing that the foundational elements, though improving and progressing, are in many ways incomplete.

Alternative Payment Models Overview

Many of the concepts that get categorized as “alternative payment models” are not new. According to the American Academy of Family Physicians, the term “medical home” was first introduced in 1967 and gradually evolved to the current “patient-centered medical home” construct. Medicare tested bundled payment for cardiac bypass graft surgery in the mid-1990’s, and the issue of bundling hospital payments around episodes of clinical care was more recently examined by MedPAC in 2008. Clinical care pathways, which have gained prominence more recently, were the subject of an oncology policy summit in 2012 exploring the cancer care pathways, protocols and guidelines, recognizing the growing impact they have on how treatment is delivered and patient outcomes.60

Since 1967, Medicare has had the authority to conduct demonstrations that examine new ways to deliver and pay for health care. Budget neutrality requirements and other limitations of the law incentivized Congress to make innovative payment models within Medicare and Medicaid more attractive. Congress extended that authority in 2010 with the creation of the Center for Medicare and Medicaid Innovation (CMMI).61 As part of health reform, Congress called upon CMMI to test innovative payment and service delivery models to reduce program expenditures while preserving

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or enhancing the quality of care. In that effort, CMMI is already testing several models that aim to be patient-centered, from ACOs, value-based purchasing, bundled payments, primary care transformations (i.e. the Patient-Centered Medical Home), to initiatives focused on Medicaid enrollees, such as programs for beneficiaries dually eligible for Medicare and Medicaid. The Agency states:

The CMS Innovation Center has a growing portfolio testing various payment and service delivery models that aim to achieve better care for patients, better health for our communities, and lower costs through improvement for our health care system.62

As policymakers continue work to build a more efficient health care system, the trend toward a value-based health care system has spurred the development of "alternative payment models." APMs have the goal of transitioning from the traditional fee-for-service model to other ways of reimbursing providers, which holds significant implications for patients. This shift toward value-based payment and alternative payment models holds significant implications for the doctor-patient relationship and patient-centeredness in health care. Referencing the latest Congressional legislation, the Medicare SGR Repeal and Beneficiary Access Improvement Act of 2014, to address provider payments and shift incentives toward participation in APMs, the Brookings Institute stated that, "[t]he most fundamental change in the legislation is to give physicians an option to leave the traditional Medicare fee-for-service system behind."63 By changing the financial incentives, legislative proposals such as the one mentioned will attempt to make APMs more attractive to physicians to participate. Because this shift toward value-based payment is indeed happening, it is important to ensure that patients are engaged at the outset and that patient-centered principles are defined and incorporated in this evolving paradigm.

**Key Issues in APMs: Giving Voice to Patients and Advancing Value for Patients.**

As APMs emerge, many of the key issues identified by PIPC can be organized around three broad themes: giving voice to patients, giving choice to patients, and advancing value for patients. These concepts are closely related and in some regards overlap. We briefly describe some elements of these themes below, before providing a basic description of and specific consideration for different alternative payment models.

**Giving voice to patients:** Achieving this goal centers on process and governance at various levels of APM design and implementation. For example, does the design or implementation of the APM give a meaningful role to patients for their perspectives on the types of APMs selected, how they are designed, and how they are implemented? Is implementation of the APM done in a way that is

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Building a Patient Centered Health System

Does the APM empower the patient by helping them navigate the care system and does it further the goal of eliciting and incorporating patient preferences in clinical decision-making?

When the CMMI was created, there was existing concern that the then-current process for selecting, developing, and implementing Medicare payment initiatives was based on criteria that were not well understood by potential participants, resulting in a call to make the process more transparent.64 CMMI has made strides to remedy this concern in its implementation, but more work remains to be done. The key question in this is: transparency to whom? In terms of patient-centeredness, beneficiaries should be able to understand how decisions are being made in APMs, and have a voice both as advocates for quality improvement and in individual care decisions – which requires transparency on how the APM is making payment decisions that influence beneficiary treatment choices. CMS has issued a request for information seeking input from stakeholders on the possibility of CMMI testing innovative models to increase the engagement of Medicare beneficiaries, Medicaid beneficiaries, Medicare-Medicaid beneficiaries, and/or Children’s Health Insurance Program (CHIP) beneficiaries in their health and health care.65 This is a significant step to determine how APMs can provide added transparency to their beneficiaries.

Giving choice to patients: One of the core concepts behind patient-centered outcomes research is generating evidence that matters to patients and helping them and their caregivers apply it to their unique needs and preferences. This concept must carry through to APMs as well – does the care model help patients tailor optimal care based on the range of available options? In its use of best available evidence, is the APM true to principles of patient-centered outcomes research by incorporating outcomes that matter to patients and enabling the tailoring of evidence to individual needs? Does the patient have a choice of providers that may be best suited to their unique needs?

CMMI is testing a broad range of APMs which could have a wide range of effects on patient choice. As APM demonstrations continue, CMMI should give priority to those that support informed patient choice, and should make this a primary criterion against which APMs are evaluated.

Advancing value for patients: To ensure that, as APMs seek to make providers accountable for value, providers should account for value to the patient. Do the cost and quality incentives established by the APM incorporate or prioritize patient preference or value from the patient perspective, at a population and individual decision-making level? Is the breadth of care covered by the APM consistent with the continuum of care that is relevant to the patient in achieving their treatment and care management goals?

64 Stuart Guterman, Karen Davis, Kristof Stremikis and Heather Drake. Innovation In Medicare And Medicaid Will Be Central To Health Reform’s Success Health Affairs, 29, no.6 (2010):1188-1193
A patient-centered bundled payment system will require a patient-centered concept of value that does not rely solely on cost if we want to ensure patients with more costly needs are not sacrificed to reach savings targets. Yet, value is often discussed as a cost/benefit analysis, and produced without incorporating the perspective of a patient's personal preferences. A patient-centered health system must recognize that value perceptions vary greatly among individual patients, depending on their clinical and life circumstances, preferences, and willingness to make risk/benefit trade-offs. For example, a collaboration of stakeholders published an article in the Clinical Cancer Research journal that reviewed the concept of value for oncology patients, stating, "Workable approaches to a value definition must be responsive to two basic dynamics: the variability of value among individuals and stakeholders, and the variability of value over time." PIPC therefore advocates for a new patient-centered concept of value. As described in our principles, patients should be able to conduct personalized assessments of the value of treatments based on information on clinical value and patient health outcomes. Doing so will require a patient-centered infrastructure that supports patients in making their own assessments of value.

As CMS and other payers work to advance APMs, they should make sure to include incentives for improving care quality and value from the patient perspective. This comprises elements such as the type of clinical quality measures used (e.g., outcomes vs. process), measures of patient preference and patient experience (e.g., PRO PMs), and the way the APM works to apply best available evidence (e.g., from the perspective of value to the payer or the patient).

At the same time, value-based incentives must be defined in ways that are fair and workable from the provider perspective. A recent assessment of value-based payment models identified several problems that "can make all of these methodologies unfair for evaluating providers and potentially problematic for efforts to improve the quality of patient care," such as patients not being assigned to a provider causing their spending to not be appropriately captured, or providers to whom a patient is assigned but has no control over their spending outside their practice, or the age old problems of risk adjustment, among others.

PIPC members agree that the goal is providing patient-centered care. This requires a holistic approach so that APMs are organized around care as it is delivered to and experienced by the patient, supporting the patient’s treatment goals across the continuum of care experience. This

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69 Id.
holistic view should also be applied to the evaluation of quality and cost so that it is considered across the care continuum, not in a single short episode of care. As health care decision-makers increasingly are adopting CER-based evidence and tools, patient-centered care will also necessitate empowering patients so they are informed of and have access to the full range of appropriate treatment options in new payment models. Ultimately, access to the right care at the right time is the goal of patient-centered care, and establishing payment incentives based on definitions of clinical care that do not reflect the shift to personalized medicine or keep pace with medical advances will create significant disincentives for continued innovation and patient access.
Part Seven

Descriptions of Select Alternative Payment Models

There are several existing APMs that merit a detailed description to provide examples of the challenges and opportunities for patient-centeredness. Lessons have been learned already from demonstrations of these APMs in the literature. We will analyze the structure and operation of these APMs, and their capacity for being patient-centered in the future.

**Accountable Care Organizations:** Building in true accountability for patient-centeredness.

Accountable Care Organizations (ACOs) figure prominently in the APM landscape, and are being pursued by Medicare, by States, and in the private sector. As defined by CMMI:

ACOs are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to the Medicare patients they serve. Coordinated care helps ensure that patients, especially the chronically ill, get the right care at the right time, with the goal of avoiding unnecessary duplication of services and preventing medical errors. When an ACO succeeds in both delivering high-quality care and spending health care dollars more wisely, it will share in the savings it achieves for the Medicare program.

The ACO model, if implemented well, can advance the goals of improved quality and patient-centered care. Premier, a national performance improvement alliance of 2,600 U.S. hospitals and 84,000 other health care sites, identified six core structural components that are needed to implement an effective ACO, including: 1) a commitment to providing care that puts people at the center of all clinical decision-making, 2) a health home that provides primary and preventive care, 3) population health and data management capabilities, 4) a provider network that delivers top outcomes at a reduced cost, 5) an established ACO governance structure, and 6) payer partnership arrangements. These core components are consistent with principles of patient-centeredness. Yet, ACOs in their current form must overcome many challenges if they are to include these structural components, and become patient-centered in practice.

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While regulations for ACOs have built in certain provisions for patient-centeredness, there are insufficient measures to determine whether those goals are being met. For example, ACOs seeking to participate in CMMI’s Shared Savings Program must define, establish, implement, and periodically update their processes to promote evidence-based medicine and patient engagement. While achieving quality improvements, ACOs are also called to take into account the circumstances of individual beneficiaries, a policy intended to promote the ideals of personalized medicine. CMMI has not established specific requirements for promoting evidence-based medicine and beneficiary engagement within ACOs, although they do call upon ACOs to specifically define their plans to meet these requirements. Stakeholders remain concerned about an ACO’s accountability for meeting these requirements. Having a plan for promoting evidence-based medicine and engaging beneficiaries does not necessarily mean it is being done effectively. Another potential barrier to increasing patient engagement in ACOs is that patients are administratively assigned to the organizations, rather than choosing their ACO.

Additionally, before an ACO can share in any savings generated, it must demonstrate that it met the quality performance standard for that year. There are also interactions between ACO quality reporting and other CMS initiatives, particularly the Physician Quality Reporting System (PQRS) and meaningful use. The program includes thirty-three quality measures, which span four quality domains: Patient / Caregiver Experience, Care Coordination / Patient Safety, Preventive Health, and At-Risk Population. Seven are related to the patient experience, with the rest being a variety of measures related to admissions or re-admissions, the provision of immunizations and screenings, or a particular measure for an at-risk population. As CMS considers future ACO measures, PIPC hopes for more patient-centered measures to choose from, including those measuring clinical outcomes, patient-related outcomes (PRO PMs, e.g.) and beneficiary engagement (e.g., shared decision-making).

**Episode-Based or Bundled Payment: Protecting patient choice and reflecting patient value.**

Bundled payment policies compensate providers based on a lump sum payment that is intended to account for the range of items and services within a care bundle or episode over a specified period of time. Much of Medicare’s focus to date in this area has been in bundling hospital-based care. The Bundled Payments initiative at CMMI is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. The goals of

72 Social Security Act §1899(b)(2)(G)
73 42 C.F.R. § 425.112
bundling services are to drive cost savings and adherence to certain standards of care; however, the bundled payment model poses significant concerns for patient-centeredness and the impact it can have on patient access to care. Incentives to skimp on care are inherent in any fixed-episode payment system because there is no payment for additional services. It has been suggested that policy makers need to consider the effects of any regulation on patient welfare and cost. For example, a reduction in the number of post-acute providers in a hospital's referral network could adversely affect patients' welfare by limiting access through smaller networks with limited expertise. Monitoring the quality of care provided, and implementing a strong system for outlier patients that may require more costly care, could address these concerns. Thus far, there is little evidence on the ability of bundled payments to improve care or lower costs.

Bundled payment appears to pose particular challenges in advancing the goals of patient-centeredness described above. To date, bundled payment efforts have focused on areas of care where it is thought to be easiest to implement – primarily inpatient episodes with clear, easily defined episodes (e.g., there is a clear event, such as hospital admission, that triggers the episode); well-defined care protocols; and homogenous patient populations. However, even in the hospital setting, bundled payment implementation has faced challenges. Extending bundled payment to other areas of care or more complex patients is likely to pose even greater challenges.

One way to protect against financial incentives that may result in “stinting” on care in bundled payments is to integrate a bundled payment with adequate measures of clinical quality and patient outcomes as a counter-balance to the bundles’ strong and narrowly focused incentives for cost containment. To date, measures linked to bundled payment programs have primarily been process measures. In addition, bundled payment policies typically fail to capture a view of patient care that is more holistic (because they focus only on specific elements of care) and fail to consider longer-term outcomes (because they cover a limited time period, such as care over a 90-day episode). As noted in one recent report, “this may discourage strategies in prevention and wellness, as well as adoption of therapies that demonstrate cost savings beyond the designated time frame.”

**Pathway-Based Payment**

Recent media coverage of adoption of payment models based on clinical pathways underscores a growing interest in care pathways as an element of APMs. The coverage also underscore some of

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76 Neeraj Sood, Peter J. Huckfeldt, José J. Escarce, David C. Grabowski and Joseph P. Newhouse Medicare’s Bundled Payment Pilot For Acute And Postacute Care: Analysis And Recommendations On Where To Begin Health Affairs, 30, no.9 (2011):1708-1717
77 M. Susan Ridgely, David de Vries, Kevin J. Bozic and Peter S. Hussey Bundled Payment Fails To Gain A Foothold In California: The Experience Of The IHA Bundled Payment Demonstration Health Affairs, 33, no.8 (2014):1345-1352
78 Id
the potential concerns with aggressive application of care pathways. According to one article on growth of pathway-based payment for cancer care, “Some oncologists worry that moves to standardize treatment could cause tensions as genetics increasingly guide them toward more individualized approaches.”

The clinical pathways approach has focused on oncology, but recently has expanded to other therapeutic areas such as rheumatoid arthritis. According to an article by the National Comprehensive Cancer Network, clinical pathways “are evidence-based treatment protocols that are used by payors and clinicians” to guide patient care decisions. Pathways may be developed by physician organizations, payers or private vendors. “Pathway restrictions come in a variety of forms,” according to NCCN, and “may impact the care patients receive.” Pathway development is not always transparent, and as a result “patients and other interested groups are left in the dark regarding what constitutes a pathway and the criteria on which it is created.” To ensure clinical pathways do not unintentionally restrict patient access to care, there must be mechanisms in the structure of a clinical pathway to account for rapid updating as technology and evidence changes.

In addition, one report on APMs indicates that providers “felt challenged to appropriately customize care while deviating from pathways only in select instances,” which may encourage a “cookie cutter approach” to medicine. Because they are designed to “push oncologists to adhere to standardized treatment guidelines” and rely on judgments about comparative effectiveness, pathway-based payments represent a key issue at the intersection of APMs and patient-centered care.

As pathway-based payment is considered within APMs, it will be essential to ensure that providers and patients play a central role in pathway development, and protect against inappropriate restrictions on treatment choices based on one-size-fits-all judgments of treatment effectiveness. In addition, greater transparency is needed in the evidence used in developing pathways and in the ability of pathways to keep pace with changes in technology and standards of care.

**Patient-Centered Medical Homes**: Models that are centered around the patient, both in assessing and improving clinical care.

The patient-centered medical home (PCMH) model is being tested by both public and private payers as a means to make clinical care more patient-centered. Evidence suggests that current PCMH models show great promise, and the PCMH model appears particularly well-aligned with PICP’s principles of patient-centeredness. Nonetheless, PCMHs are not without challenges. With a strong focus on primary care, the relationship of a PCMH with primary care physicians and

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82 California Health Institute *supra* at 25.
83 Mathews, *supra*
Building a Patient Centered Health System

specialists is vital. PCMH-based models should ensure patient choice of provider and access to specialists. The empowerment of patients to choose their provider within the PCMH is also considered an essential component of patient-centeredness for PIPC members.

Generally speaking, the PCMH model is based on shifting resources to enhance primary care as an important component of improving the quality and cost-effectiveness of the health care delivery system. Since 2006, twenty-five states have implemented new payment systems or revised existing ones so that primary care providers can function as PCMHs. The goal is for these initiatives to provide a "deep well of experience and innovation that can inform and shape future public and private payment policies." However, challenges remain. For instance, one study found that although all of the surveyed PCMHs sought patient feedback, only 29 percent involved patients and families as advisers and sought feedback through surveys, and only 32 percent involved patients in a continuing role in quality improvement. Another profile of PCMHs found, "[o]ur experience in implementing and evaluating various approaches indicates that medical homes require intensive and targeted patient care coordination supported by committed primary care leadership, as well as new payment structures that include a monthly care coordination fee and outcome-based payments."

In a discussion related to new payment models including patient-centered medical homes, the National Partnership for Women and Families suggested that a truly patient-centered health care system must be designed to incorporate features that matter to patients, which they defined as including “whole person” care, comprehensive communication and coordination, patient support and empowerment, and ready access. The Partnership concluded, "Without these features, and without consumer input into the design, ongoing practice, and evaluation of new models, patients may reject new approaches such as medical homes and accountable care organizations." PIPC would agree with this conclusion, and looks forward to more testing of the PCMH model and an evolution to truly patient-centered medical homes that meet the NCQA standards for incorporating shared decision-making.

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85 Esther Han, Sarah Hudson Scholle, Suzanne Morton, Christine Bechtel and Rodger Kessler. Survey Shows That Fewer Than A Third Of Patient-Centered Medical Home Practices Engage Patients In Quality Improvement *Health Affairs*, 32, no.2 (2013):368-375
Part Eight
Recommendations for Building Patient-Centeredness into APMs

While most health policy experts agree on the notion of developing a “patient-centered health care system,” we do not yet have a delivery system that entirely incorporates or is modeled on delivering patient-centered health care. Therefore, we must promote policies that apply patient-centered principles throughout the health care system – from development of evidence (i.e. PCORI) to the design of new payment and delivery reforms (i.e. APMs). To advance a patient-centered system that meets the principles of patient-centeredness and therefore empowers and activates patients in their own care, PIPC provides the following recommendations:

1. **Provide a meaningful voice to patients.**

   Policymakers should establish formalized mechanisms that provide a meaningful voice to patients in the creation and testing of APMs.

   a. PIPC urges policymakers to create a national advisory panel on patient-centeredness to give patients a voice in emerging alternative payment models and ensure they advance principles of patient-centered care. This panel should include not only patient represents but physician and specialists who play a vital role in supporting patient-centered care. The impact of emerging “value-based” models of provider reimbursement on patient care and the physician-patient relationship will be dramatic. The principles PIPC articulates in this document are ambitious and will require sustained focus, yet mechanisms to ensure the patient voice is heard do not exist.

   b. PIPC urges an open and transparent process for testing and implementing APMs. New payment and delivery systems should have transparent processes for determining coverage and payment decisions, and empower patients to participate in the governance of the system so that decisions affecting access to care are not made behind closed doors. This includes more transparency in the requirements for ACO’s related to the use of evidence-based medicine, evidence-based decision-making, and beneficiary engagement in order to determine whether they are meeting patient-centeredness criteria.

   c. PIPC urges the Centers for Medicare and Medicaid Innovation (CMMI) to work with stakeholders to identify, and subsequently apply, clear patient-centeredness criteria in its approval and evaluation of APMs.

   d. PIPC urges that Congress and CMMI support the inclusion of patients and their
providers in the development of quality improvement strategies and quality measurement development and adoption.

e. PIPC urges that value definitions be centered on value to patients. PIPC recognized that different stakeholders will inevitably bring different perspectives to value, and that policy-level decisions require population-level analysis. At the same time, APMs will have a natural tendency to drive the lowest cost treatments based on what works for averages based on static care episodes or pathways. Policies are needed to support the development and implementation of a patient-centered infrastructure that presents information to patients and their providers in a manner that empowers them to develop an individualized care plan that has value for the patient’s personal needs, preferences and outcomes.

2. **Direct CMMI to prioritize policies that promote patient-centeredness within models such as Patient-Centered Medical Homes.**

Policies will be needed to ensure new payment and delivery models do not define success as simply meeting financial targets that are easier to measure and reward. Of particular concern are bundled payment policies that create strong financial incentives for providers to cut costs based on a narrow, static definition of clinical care. Instead, CMMI should improve upon and promote patient-centered models, such as Patient-Centered Medical Homes.

   a. PIPC urges CMMI to test shared decision-making tools within PCMHs, moving forward to meet the NCQA standards for PCMHs.
   
   b. PIPC urges CMMI to better align PCMHs with principles for patient-centeredness, including a recognized role for both primary and specialty care, and patient choice of providers.

3. **CMS, quality organizations, physician and specialty societies should catalyze the expansion of available quality measures and ensure they are appropriately incentivized in APMs.**

Policymakers should recognize the need to improve the patient-centered infrastructure for measuring and rewarding improved health outcomes. There are significant gaps in quality measurement that will require expanded support for measure development and endorsement.

   a. PIPC urges Congress and CMMI to focus on investments in measuring clinical outcomes that are consistent with individual needs, outcomes and preferences, and use that information for quality improvement, as opposed to payment reforms that reward immediate cost containment over long-term improvements in quality of care and clinical outcomes.

   b. PIPC urges expanded support for measure development and endorsement, specifically for patient-reported outcomes measures.
c. PIPC encourages explorations of clinical data registries as one potential mechanism for enabling development of robust, comprehensive quality measures in ways that are administratively feasible for providers. Clinical registries should meet basic standards for transparency, stakeholder engagement and reliability, but should not impose unnecessary regulatory burdens.

4. **Foster informed choices from the range of clinical care options.**

   a. PIPC urges Congress and CMMI to prioritize APMs that make patient engagement and informed treatment decision-making accessible, through shared decision-making and other tools, so that patients know their treatment options and the rationale for any recommendation of one treatment option over another. This will ensure decisions are not made in a “black box” based primarily on financial incentives.

   b. PIPC urges that physicians participating in APMs maintain flexibility to tailor care to an individual patient to ensure patients receive care that meets their individual needs, circumstances, and preferences.

   c. PIPC urges that existing funds for the dissemination of PCORI-funded and other federally-funded research be used to support the engagement of patients, patient groups, and providers in the development and implementation of dissemination and implementation tools, including shared decision-making tools.

5. **Protect against “one-size-fits-all” cost containment tools under APMs.**

   a. PIPC urges that safeguards are established to ensure APMs do not impose blunt access restrictions to tests, treatments, or provider options that are best suited to individual patients. Medical management tools, including clinical guidelines, clinical pathways, quality measures, and electronic medical records, should be patient-centered and not based on “one-size-fits-all” evidence standards.

   b. PIPC urges effective oversight and validation of tools to translate evidence into clinical decision-making in APMs. To the extent incentives are used to promote a particular clinical guideline or clinical pathway, APMs should be required to demonstrate it was developed and implemented in a manner consistent with patient-centered principles.

6. **Support access to innovation.**

   a. PIPC urges APMs to provide patients with access to innovation. Innovation means many things -- new treatments, improvements to existing treatments, efficiencies in the delivery system, higher quality care and overall a reduction in the economic and health burden of disease.

   PIPC urges policymakers not to lose focus on the building blocks for a patient-centered health care
system by ensuring patient-centered principles are incorporated into the early phases of evidence development, translation and implementation, as well as in the design and implementation of new payment and delivery reform models. In this way, our health care system will be built to improve health outcomes by identifying the treatments that work best for individual patients – not by limiting access or pushing “one-size-fits-all” treatment solutions.

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