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Cite this article as:

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Evaluation Of New Care And Payment Models

Health Affairs, , no. (2013):

doi: 10.1377/hlthaff.2013.0216

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The Center For Medicare And Medicaid Innovation's Blueprint For Rapid-Cycle Evaluation Of New Care And Payment Models

DOI: 10.1377/hlthaff.2013.0216
HEALTH AFFAIRS 32,
NO. 4 (2013): -
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ABSTRACT The Affordable Care Act established the Center for Medicare and Medicaid Innovation to test innovative payment and service delivery models. The goal is to reduce program expenditures while preserving or improving the quality of care provided to beneficiaries of Medicare, Medicaid, and the Children's Health Insurance Program. Central to the success of the Innovation Center is a new, rapid-cycle approach to evaluation. This article describes that approach—setting forth how the Rapid Cycle Evaluation Group aims to deliver frequent feedback to providers in support of continuous quality improvement, while rigorously evaluating the outcomes of each model tested. This article also describes the relationship between the group's work and that of the Office of the Actuary at the Centers for Medicare and Medicaid Services, which plays a central role in the assessment of new models.

In 2010 section 3021 of the Affordable Care Act established the Center for Medicare and Medicaid Innovation to test innovative payment and service delivery models. The goal is to reduce program expenditures in Medicare, Medicaid, and the Children's Health Insurance Program while preserving or improving the quality of care provided. Congress also granted a new, unique authority to the secretary of the Department of Health and Human Services to expand the duration and scope of the testing of such models.

The secretary may expand the scope and duration of testing through rule making, including nationwide testing, if she finds either that a model reduces spending without reducing the quality of care or that it improves the quality of care without increasing spending. To expand a model, the Centers for Medicare and Medicaid Services (CMS) chief actuary must certify that such expansion would reduce, or not result in any increase in, net program spending, and the secretary must determine that the expansion would not deny or limit the coverage or provision

of benefits. The decision to expand the duration and scope of a model being tested will be informed by the evaluations performed by CMS.

The Innovation Center has announced a broad agenda of tests of new payment and service delivery models. These models aim to realign incentives for providers to reward quality and the coordination of care instead of volume of services provided. Central to the success of the center is the ability to assess the effectiveness of models being tested. The center must conduct evaluations with urgency, routinely and rapidly assessing the effectiveness of interventions in the field, to promote continuous improvement of the implementation of those interventions and identify effective policies without delay.

To assess the success of initiatives, the Innovation Center has assembled the Rapid Cycle Evaluation Group, responsible for evaluating the impact of each payment and service delivery model on the cost and quality of care and on health outcomes. As important as it is to have the models assessed rapidly, rigor cannot be sacrificed for speed. The group aims to transform

the evaluation process at CMS in critical ways to meet the standards imposed by the statute. “Rapid cycle” refers both to the approach to assessing the effectiveness of interventions more rapidly and to a philosophy of providing ongoing feedback to participating providers to support continuous quality improvement.

This article presents both the current evaluation philosophy and the specific approaches that the evaluation group will apply to transform the evaluation process at CMS.

New Opportunity For New Ideas

The priority of the CMS Innovation Center is to test models that reduce costs through care improvement, supported by the statute’s call for preference to be given to models that improve the coordination, quality, and efficiency of services. The statute requires an evaluation of each model. The evaluation is to include an analysis of the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria as well as changes in spending.

Since its inception, the center has announced a broad agenda of new models attempting to realign incentives for providers, hospitals, and health systems to promote improved quality, efficiency, and outcomes under the authority of section 3021 of the Affordable Care Act. (A list of models is in Appendix Exhibit 1.)¹

Some examples include testing of the Pioneer and Advance Payment Accountable Care Organization models, which aim to align incentives for health systems to promote higher-quality care for the population served and greater accountability for the total cost of care; the Bundled Payments for Care Improvement initiative, which is a series of models to realign incentives for hospitals and postacute care providers; and the Comprehensive Primary Care initiative, which provides up-front support to transform primary care practice while focusing incentives to reward care coordination, quality, and efficiency. Each model has been developed to create a business case for quality improvement, relying on marketplace innovation to reduce variability and waste while improving patients’ experiences and health outcomes.

Promoting Continuous Quality Improvement

The models that the Innovation Center is testing require structural changes in care delivery. Many of these changes challenge traditional assumptions about the way in which care is provided. Primary care physicians participating in patient-

centered medical homes or accountable care organizations must adapt their practices to deliver on the promise of the new model. It is likely that they will need to invest in new information systems and hire new staff to support more coordinated care. Similarly, hospitals participating in the Bundled Payments for Care Improvement initiative; in accountable care organizations; or in the Partnership for Patients initiative, which aims to save lives by dramatically increasing hospital patient safety and to cut avoidable readmissions, must invest in and redesign their infrastructures to support improved care for their populations and to reduce costs.

Substantial learning and adaptation will be essential for providers or health systems to achieve the greatest efficiencies and improvements. There are no simple “turnkey” solutions.

The CMS Innovation Center does not plan to sit on the sidelines and assess performance at the conclusion of each test. Rather, evaluators will be part of the solution by gathering real-time information and making use of CMS claims data to promote and support continuous quality improvement. For example, in the Pioneer Accountable Care Organization program, the Innovation Center is providing regular raw data feeds to participants, interpretable performance data allowing participants to compare themselves with other Pioneers, and a learning collaborative that enables Pioneers to share their experiences and that encourages the adoption of best practices.

CMS is also encouraging participating providers to collect their own performance data and use that data to better manage outcomes. The agency wants to make sure participating providers have information both about their own performance and about the successes and failures of other model participants so that they can successfully implement the model. The hope is that providing data and rapid-cycle feedback to providers will enhance their ability to improve and test the merits of the model.

At the core of this approach is the recognition that evaluators must not only assess results but must also understand the context of those results. In each of our models, evaluators will collect qualitative information about providers’ practices, their organizations, and the systems in which they practice.

Evaluators must understand how participants implement interventions, their perceptions about the opportunity, and the barriers and enablers to change. Without this thorough understanding of how each participant has acted to improve care, the Innovation Center cannot provide a truly accurate portrait of how favorable outcomes were obtained.

These data will be merged with performance metrics so that CMS can provide actionable feedback to participants about how they can improve. Doing so will allow evaluators to more thoughtfully “connect the dots” and assess what features of interventions are associated with successful outcomes.

Without dissemination of the findings and frequent course corrections, understanding the effectiveness of interventions will not lead to meaningful practice improvement. Evaluators will provide data to a dedicated Learning and Diffusion team at the CMS Innovation Center that will organize learning collaboratives among model participants to spread effective approaches and to disseminate best practices. This close collaboration will help ensure that the best practices are harvested and disseminated rapidly, and it is intended to generate a more collaborative community of providers working together to improve the quality of care. By separating dissemination activities from evaluation activities, CMS preserves the objectivity of this evaluation team.

Evaluating With Speed And Without Sacrificing Rigor

Beyond providing feedback to providers to support their improvement, CMS will strive to assess the overall impact of its models more rapidly than in the past. A key component of this approach is an effort to evaluate each model regularly and frequently after implementation, allowing both the rapid identification of opportunities for course correction and improvement and timely action on that information.

The length of funding for each intervention is assigned to be sure that the program is in the field long enough to have a reasonable chance of success. Yet waiting until the predetermined end date of a program to assess effectiveness is not desirable; better would be to draw conclusions about each model far sooner, if sufficient evidence is available. For example, it may not take five years for savings to be measured in the Comprehensive Primary Care initiative, and measuring key outcomes will begin shortly after implementation. The Rapid Cycle Evaluation Group will seek evidence of meaningful improvement shortly after implementation of each new model.

Again, it is important to note that the rigor of the evaluation cannot be sacrificed for the sake of speed. Failing to characterize accurately the results of innovative models can carry large consequences. The group must be certain that we obtain dependable evidence for the impact of the models on spending and quality of care to

determine which models will achieve the goal of providing higher-quality care at lower costs.

To do so, we must use advanced statistical methods to measure effectiveness. Our methods must provide results that meet a high standard of evidence, even though strict experimental conditions cannot always be met. For example, randomizing the assignment of providers or beneficiaries to payment and service delivery models may often be infeasible because of logistical constraints. As a result, our evaluations will have to account for potential confounding related to providers’ characteristics that might influence outcomes independent of the intervention being studied. We must account for the fact that providers who choose to participate in our models may differ from nonparticipants in important ways, and the populations they serve may differ as well. The group will apply the most advanced methods to carefully adjust for these sources of confounding.

To achieve our goals, appropriate selection of comparison groups will be an essential component of every evaluation. We will be sure to consider environmental and policy characteristics when selecting controls. When appropriate, we will use various methods now common in the social sciences—such as propensity score approaches and instrumental variables—to help control for sources of bias and to clarify specific causal mechanisms. We will make a practice, whenever possible, of identifying multiple comparison groups for each intervention group, to determine the robustness of our findings.

We will increasingly use repeated measures—time-series analyses—which use the same subjects under different conditions over time and allow us to better understand the relationship between implementation of new models and both immediate changes in outcomes and the rate of change of those outcomes. These designs will allow us to better account for trends or patterns of improvement prior to the inception of a model and to isolate the effect of the intervention more precisely on the outcomes we are measuring. These more nuanced statistical methods will be essential to assessing the impact of new models more precisely and rapidly.

Blurring The Lines Between Feedback And Evaluation

The evaluation group is committed to the rapid provision of timely data to providers and interpretation of those data to synthesize both the contextual and operational features of the participating providers and their outcomes. These approaches constitute what is known as forma-

tive evaluation, which generally focuses on the process aspects of an innovation while the innovation is still in its formative stages. Our feedback will allow providers to track their performance compared with their own historical outcomes and the performance of other participating providers and comparison physicians who are not participating in the model being tested.

For example, in the Comprehensive Primary Care initiative, as in all of our initiatives, we will provide at least quarterly feedback on dozens of performance metrics, which include process, outcome, and cost measures. We will also capture contextual information about the organizational structure and specific features of each participant, to identify characteristics associated with superior performance.

We will explore whether practices with certain types of organizational structures, or in which care is delivered not only by physicians but also by nurse practitioners, nurses, allied health professionals, and others, tend to experience improved outcomes. We will feed this information back to model participants in quarterly reporting to help them learn approaches that may hasten improvement and to allow their leaders to manage to specific, measurable outcomes.

Similarly, when we have the necessary data, we plan to conduct regular impact analyses to assess the success of the models overall, beginning shortly after implementation of a new model. In the past, researchers often waited until the end of a demonstration to measure its success, delaying the opportunity to identify meaningful changes. We will now be evaluating critical outcomes quarterly, using rigorous evaluation techniques, to assess the overall impact of the payment model. In this way, we hope to identify, more rapidly than before, successes and areas where improvement is needed.

Impact analyses are considered to be “summative evaluation,” which, in contrast to formative evaluation, is retrospective in nature and requires sufficient rigor to make programmatic decisions. Historically, formative evaluation has used less rigorous methods than summative evaluation. However, with conscientious use of our data, we plan to use methods for performance feedback (formative evaluation) that are similar to our methods of conducting impact (summative) evaluations.

As a result, some of the classic differentiation between the provision of formative feedback and the more rigorous summative evaluation will be blurred. Better collection and use of data will allow us to conduct rigorous, objective, and comprehensive evaluations that will meet our statutory criteria while simultaneously helping pro-

viders improve. When these approaches are applied in a timely manner, we will be able to use the same calculations for both purposes.

Implementing A New Model And Metrics For Success

When a model is considered for testing by the CMS Innovation Center, staff from the Rapid Cycle Evaluation Group, as well as staff from the CMS Office of the Actuary, are immediately assigned to participate in the creation of the model. There is a shared understanding that every model we implement is a test, and we can determine whether a test is successful only if the model can be rigorously assessed. Including the evaluation and actuarial staff in the model design embeds the evaluation concept in the model from the start, laying the groundwork for a model that can be thoroughly evaluated.

From a practical standpoint, evaluation staff are engaged at the outset of every model in determining the generalizability of the intervention to groups other than the targeted population. We also determine the necessary sample size of the intervention group, after considering possible attrition from the model and patient clustering within providers, practices, or health systems. We must also address the availability of necessary data to measure outcomes and the appropriate comparison group or groups for each intervention.

We consider our ability to measure the effectiveness of the model as a whole as well as its effectiveness with subgroups that may differ in important ways. We clarify the challenges of each evaluation in the setting of other policy or practice changes and the varying accessibility of data from different sources. By being engaged at the beginning of the development of each model, we will have the best chance of achieving a robust, statistically sound evaluation.

Establishing effective metrics at the outset of each model is critical to defining success. Innovation Center evaluators have collaborated with the CMS Center for Clinical Standards and Quality to ensure that our metrics are consistent across programs as appropriate, and that we can thoughtfully compare the results of different models. We must be sure to align not only measures of cost and quality but also other important metrics, such as patients' functional status, population health, patient and provider experience, and key social determinants of health.

We plan to identify and promote population health metrics—measures of the functional status, healthy behavior, and health outcomes of a population—so that we may better emphasize the importance of greater disease prevention in-

stead of treating conditions that have already arisen. Our measures of cost will generally focus on the total cost of care of a beneficiary, instead of the cost of care delivered by specific providers, to encourage a more accountable and coordinated health care system that promotes efficiency and comprehensive management of each beneficiary. We will also measure disparities in care in every model, to enable better understanding of which models best address health and health care inequities.

Partnering With The Actuaries

The relationship between the CMS Innovation Center and the Office of the Actuary is a particularly critical one. The Office of the Actuary provides timely, impartial, and authoritative actuarial, economic, and statistical estimates and analysis of health care financing and expenditures.

Similar to the engagement of evaluation staff when new payment and service delivery approaches are conceived, the actuaries are included in model development teams. They provide insight and guidance into the process that will be used to assess the impact of Innovation Center programs on Medicare, Medicaid, and Children's Health Insurance Program spending. The estimate of each model's impact on quality, health outcomes, and costs will need to account for any material differences in model design, provider, marketplace, population, or other factors between the testing phase and the projection period. The Office of the Actuary is in close communication with the model implementation and evaluation teams throughout model development, deployment, and evaluation, to offer consultation at each step of the process.

As described above, after a payment or service delivery model has been tested, the secretary can only expand the duration and scope of the model test through rule making if the model is expected either to reduce spending without reducing the quality of care or to improve the quality of care without increasing spending. In this context, the chief actuary must certify that the expansion would reduce, or not result in any increase in, net program spending. Models also must be modified or terminated after testing has begun unless the secretary determines, and the chief actuary certifies, that the model is expected to improve the quality of care without increasing spending, reduce spending without reducing the quality of care, or improve the quality of care and reduce spending.

To determine the cost impact of the model, the Office of the Actuary will monitor Innovation Center initiatives once testing has begun and will

use data from the evaluation as well as other available sources to certify results.

Developing Methods

The quasi-experimental design of our experiments and the complex and rapidly changing setting of our "laboratory"—the real world—will require the consideration and development of a number of new methods. The simultaneous implementation of numerous models and policy changes presents a key challenge, requiring consideration of when and how to disentangle the effects of multiple co-occurring events.

To address these needs, the Rapid Cycle Evaluation Group is relying on improved data systems that will allow CMS to track the implementation of each model at the beneficiary level. Our evaluations must then consider overlap with Innovation Center and other programs in the selection of similar comparison groups and must account for overlap in the conclusions that can be drawn. We will aim to recruit sufficient samples of patients enrolled in a single model to evaluate the model's effect on outcomes.

However, in addition to disentangling model effects, we aim to study the interactions of different models, to better understand how they may optimally be applied to improve quality and reduce costs. Although we recognize that we may not have sufficient sample size to assess interactions in some subgroups definitively, studying the interactions among interventions will provide rich opportunities to study potential synergies or challenges when different programs interact. Summative evaluations will include numerous sensitivity analyses comparing intervention and comparison groups where single interventions were implemented, as well as subgroups where overlap may exist.

Contributing To The Evidence: Our Path Forward

The key research questions we intend to answer at the CMS Innovation Center are central to delivering on the goal of providing higher-quality care to beneficiaries while reducing costs. We will work with external research contractors on our evaluations of Innovation Center model tests, to provide objectivity in our results.

Effective and proactive intramural research is also under way to support changes to CMS programs and payment policy. Researchers from the evaluation group have organized into affinity groups and are using CMS data to answer critical policy questions that may inform the development of future payment and service delivery models. Our research agenda is developed

collaboratively with CMS leadership to identify research questions whose answers can best support evidence-based policy making. By using our data to better understand variability, waste, and disparities in care, we aim to better inform and generate new policies that will get us closer to our ultimate goal of better care, better health, and lower costs.

Of course, all payers—and all Americans—share the goals of improved care and lower costs. Results from the evaluations of our models will be useful not only to CMS and its beneficiaries but also to commercial and other government payers. As a result, we appreciate the importance of rapid dissemination of our results to other payers, to expand the evidence base for payment reform and to ensure the diffusion of successful interventions through the health care system as a whole. To do so, our goal is both to release our reports rapidly on our website and to publish key results subsequently in the peer-reviewed liter-

ature and disseminate our findings broadly so that taxpayer-funded research is sure to benefit all Americans.

The CMS Innovation Center was born out of the recognition that the health system requires payment and delivery reform. The need to improve the coordination and quality of the care available to the beneficiaries that CMS serves, together with the need to slow spending growth, underscores the urgency of the situation.

A commitment to change must be coupled with an acknowledgment that the solutions that offer promise must be assessed objectively. The members of the evaluation group at the CMS Innovation Center are eager to collaborate with and learn from other federal, state, and commercial partners as we strive to evaluate—rapidly and rigorously—an ambitious agenda to improve the quality of health care received by Medicare, Medicaid, and Children's Health Insurance Program beneficiaries and all other Americans. ■

The author thanks Renee Mentnech, the deputy director of the Rapid Cycle Evaluation Group, for her contribution to the strategies outlined here. He also

thanks John Shatto, the deputy director of the Office of the Actuary, Centers for Medicare and Medicaid Services, for his constructive feedback and careful

comments on this article, and Daniel Farmer for his support. [Published online March 27, 2013.]

NOTE

- 1 To access the Appendix, click on the Appendix link in the box to the right of the article online.

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William Shrank is the director of the Rapid Cycle Evaluation Group at the Center for Medicare and Medicaid Innovation.

In this month's *Health Affairs*, William Shrank, director of the Rapid Cycle Evaluation Group at the Center for Medicare and Medicaid Innovation, Centers for Medicare and Medicaid Services (CMS), describes the approaches his group will take as it evaluates new delivery and payment models launched by the Innovation Center

under the Affordable Care Act. Shrank describes how the Rapid Cycle Evaluation Group will deliver frequent feedback to providers in support of continuous quality improvement, while rigorously evaluating the models' outcomes.

Shrank also describes how his group's work will intersect with that of the CMS Office of the Actuary, which must certify the results of the tested models if the secretary of health and human services is to extend them under the Affordable Care Act.

Before joining CMS, Shrank was an assistant professor of medicine at Harvard Medical School and an associate physician in the Division of Pharmacoepidemiology and

Pharmacoeconomics at Brigham and Women's Hospital in Boston, where he practiced general internal medicine and published more than a hundred articles in the peer-reviewed literature focused on improving the safe, appropriate, and cost-effective use of prescription medications.

Shrank previously served on national advisory committees for the Food and Drug Administration and the Agency for Healthcare Research and Quality, among other government agencies. He earned a medical degree from Cornell University and a master's degree in health services from the University of California, Los Angeles.