Though the development of therapeutics and vaccines remains a critical priority during the Covid-19 pandemic, the rush to innovate has been poorly organized and inefficient, and older adults have been significantly underrepresented in trials to date despite being disproportionately affected by Covid-19. In 2020, the U.S. Centers for Medicare & Medicaid Services (CMS) took the unprecedented step of applying existing payment reforms for care quality through the Merit-based Incentive Payment System (MIPS) to incentivize clinician participation in Covid-19 clinical trials and clinical registries. While CMS has previously attempted to advance biomedical innovation by reforming Medicare’s policies for coverage, coding, and payment, the initiative related to Covid-19 trials and registries represents the agency’s first attempt to incentivize clinical research and investigational product development. The authors describe the opportunities and limitations of the clinical data reporting program for Covid-19, and outline how the policy represents a new opportunity for health care’s value movement.

Accelerating the development of therapeutics and vaccines remains a critical priority during the Covid-19 pandemic. However, the rush to innovate has been poorly organized and inefficient, leading to a proliferation of non-randomized, underpowered studies and insufficient attention to issues such as appropriate demographic representation in study populations. Consequently, an early lesson for policy makers is that investment in research needs a complementary focus on enhancing study rigor and inclusivity. Given that physician referrals are a key determinant of trial enrollment, rethinking the engagement of clinicians in community practice — who have long been disengaged from clinical research — could help to steer patients toward clinically appropriate and well-designed studies.¹
Over the past decade, the U.S. Centers for Medicare & Medicaid Services (CMS) has increasingly used payment reforms to increase clinician accountability for the cost and outcomes of care. In 2020, the agency took the unprecedented step of applying these same, value-based levers to incentivize clinician participation in Covid-19 clinical trials and clinical registries. While CMS has previously attempted to advance biomedical innovation by reforming Medicare’s policies for coverage, coding, and payment, the initiative related to Covid-19 trials and registries represents the agency’s first attempt to incentivize clinical research and investigational product development.

The new clinical trials program also has several implications for health system leaders. First, with regard to care delivery, participation in registries and trials through the policy could play a key role in supporting post-approval monitoring of Covid-19 vaccines. Second, during a time when regulators have temporarily paused many value-based programs, health systems may need to evaluate the new Medicare incentive program as they navigate the financial instability of the pandemic.

In this article, we describe the opportunities and limitations of the clinical data reporting program to incentivize clinician reporting for trials and registries; furthermore, we outline how health systems and commercial payers can leverage this policy to advance a new opportunity for the value movement in health care.

**Medicare’s Incentive for Covid-19 Clinical Trials**

The Merit-based Incentive Payment System (MIPS) is the United States’ largest pay-for-performance program, encompassing >1 million clinicians. CMS evaluates clinician performance across four domains — Quality Measures, Promoting Interoperability, Improvement Activities, and Cost Measures — to calculate a score that determines whether clinicians receive bonus payments or penalties. The MIPS Covid-19 Clinical Trial improvement activity applies to clinicians who either (1) participate in and report data for a Covid-19 clinical trial or (2) report data to a clinical data registry after caring for a Covid-19 patient. Such clinicians earn half of the credit possible for the “Improvement Activities” performance category, which is equivalent to 7.5% of the total MIPS score for the 2020 performance period.2

> Covid-19 has served as a test case for many health policies, including as a case study for how value-based programs can be repurposed to support new initiatives.

This policy offers potential advantages. First, because of the nature of MIPS, clinicians eligible for the CMS incentive by definition have a substantial number of Medicare beneficiaries in their patient panels. Given that elderly people have been disproportionately affected by the virus, incentivizing reporting to clinical data registries can help to inform risk assessments and care planning for older adults, especially those with specific comorbidities (e.g., cancer, kidney disease) that are associated with increased susceptibility to infection and adverse outcomes. For example, 63 health systems and community practices had enrolled in the American Society of
Clinical Oncology (ASCO) Survey on Covid-19 in Oncology Registry through the MIPS incentive as of December 2020.\textsuperscript{3} Second, while >2,000 clinical trials had been initiated for Covid-19 as of December 2020, representation of older adults has been lacking.\textsuperscript{4,5} The MIPS trial incentive could facilitate the enrollment of elderly patients and help to accelerate the completion of these trials. Third, the initial drugs considered for Covid-19 patients included already-available products like hydroxychloroquine, leading some physicians to prescribe them “off-label” for Covid-19 treatment or prevention. But such real-world use will not help to answer the question of whether the product actually works, as observational data may not be available for clinical study for some time and observational data sets are challenging to use in determining product effectiveness. For repurposed drugs, the CMS policy incentivizes clinicians to instead participate in clinical trials (e.g., National Institutes of Health [NIH]-sponsored trials) and report data to verified repositories or registries.

However, the utility of the policy is limited. First, most Covid-19 clinical trials have thus far occurred in inpatient settings because of a focus on hospitalized patients with severe illness. These trials are inaccessible to many MIPS-eligible clinicians, the majority of whom practice in ambulatory care settings and are unaffiliated with health systems or major teaching hospitals.\textsuperscript{6} While outpatient recruitment may be relevant for potential prophylactics and some therapeutics, the site-of-service restrictions on Covid-19 treatments to date may have limited the participation of MIPS-eligible clinicians. Additionally, the CMS policy is flexible about which trial designs are redeemable for MIPS credit, ranging from traditional randomized trials to pragmatic designs. These eligibility criteria may be too broad, leading the Medicare program to reimburse clinicians for participating in insufficiently rigorous studies. Furthermore, clinicians who might most benefit from higher MIPS scores (e.g., independent practices and those caring for underserved patients) may face the highest barriers to participating, given that involvement in clinical trials is a resource-intensive endeavor.\textsuperscript{6,7} Last, while financial incentives for registry participation already exist in MIPS, extending such incentives for clinical trials recruitment and reporting may present ethical concerns, particularly if this financial conflict of interest is not disclosed to patients.

**Adapting Payment Reforms for Covid-19 and Beyond**

The CMS policy represents a novel regulatory strategy for using payment reforms to address major challenges to clinical research in the U.S., but there is room for improvement, particularly given that the program is likely to last through at least 2021.\textsuperscript{2} In the short term, the agency can take several steps to strengthen the application of the policy to Covid-19, while health system leaders can align their clinical protocols and data systems to fully realize the benefits of the incentive program. In the long term, CMS should consider the potential risks and benefits of extending the incentive to non–Covid-19 trials, while commercial payers should follow the agency’s precedent during the pandemic to foster new partnerships with providers to increase patient access to trials.

\textbf{The CMS policy represents a novel regulatory strategy for using payment reforms to address major challenges to clinical research in the U.S., but there is room for improvement.}
For Covid-19, CMS should modify the trials component of the incentive so that participation in randomized, adequately controlled trials is weighted more heavily than participation in less-rigorous study designs. Given that patients of minority racial backgrounds have experienced disproportionate Covid-19 morbidity and mortality, CMS could direct the Quality Payment Program (QPP) service center to provide enhanced support to practices serving underserved communities. In particular, such outreach to clinicians predominantly caring for patients from racial minorities could have improved the representativeness of study populations for Phase-3 trials of Covid-19 vaccines.

With a growing number of Covid-19 therapies and vaccines subject to regulatory approval or authorization, the registry component of the incentive will provide an opportunity to support “real-world” monitoring of product safety and effectiveness in the coming months. Here, operationalizing the incentive also will require leadership from care delivery organizations. Clinical leaders and health care administrators responsible for quality measurement and reporting for their organizations will need to alert the providers in their network about the CMS policy and communicate the process of attestation for the designated QPP reporting period to be eligible for the incentive payment. To achieve the policy’s intended public health goals, health systems also will need to help their clinicians and practices register for the appropriate registry for reporting Covid-19 data (e.g., the jurisdiction-specific immunization registries outlined in states’ draft Covid-19 vaccine playbooks). Furthermore, health systems will need to develop a pathway for extracting the relevant clinical data from their system’s electronic health records and ensure that the necessary data elements (e.g., demographic information) are captured and appropriately structured for submission and use.

After the resolution of the public health emergency, the agency should evaluate the uptake of the incentive by clinician type and region, examine the relative impact on trial enrollment or registry participation, and quantify the improvement activity’s contribution to MIPS-adjusted payments. Health systems could support evaluations by participating in an agency-sponsored QPP user research session, which would offer a forum for clinicians to highlight any challenges associated with working with research partners, reporting data to registries or trials, and performing the attestation process.

These analyses can offer insight about the relative costs and benefits of provider-facing incentives for clinical research. For example, given that clinicians can self-select the improvement activities that they use for attestation, the disproportionate performance benefit accrued from participating in Covid-19 clinical trials may lead to gamesmanship of MIPS scores, undermining the program’s primary focus of fostering quality improvements. With MIPS payment adjustments set to increase from 4% to 9%, policy makers must ensure that incentives are appropriately calibrated to avoid inadvertently undermining the program’s purpose. The trials incentive also may exacerbate the documented disparity in MIPS scores between system-affiliated and independent clinicians as the former are better positioned to participate in trials or clinical registries because of the network effects of health system affiliations for clinical research.
The expanding footprint of hospitals in outpatient health services, the uptake of decentralized clinical trial models during the pandemic, and the creation of provider networks for Covid-19 vaccination programs give health systems the building blocks for advancing clinical research partnerships with public and private payers."

While accounting for these concerns, policy makers also should consider how broadening the incentive beyond Covid-19 could help to advance existing priorities and initiatives, whereas health systems should consider how the partnerships with payers and pharmaceutical companies that have been forged during the pandemic could be expanded for new applications. First, increasing participation in clinical registries aligns with MIPS’ goals to promote interoperability and advance care quality. Likewise, given that MIPS-eligible clinicians generally practice in community-based settings, extending CMS’ pandemic-era clinical trial program may increase the accessibility of clinical research beyond Covid-19. In tandem, the expanding footprint of hospitals in outpatient health services, the uptake of decentralized clinical trial models during the pandemic, and the creation of provider networks for Covid-19 vaccination programs give health systems the building blocks for advancing clinical research partnerships with public and private payers. For example, UnitedHealth Group has partnered with Eli Lilly to study the use of monoclonal antibodies in a Medicare Advantage population during Covid-19, providing an example of how payers and providers can expand access to research and treatment for a specific (and often underrepresented) patient population.9

However, any extension of the trials component of the incentive requires first addressing the ethical tension of provider-facing financial incentives for clinical research. At baseline, CMS should solicit and act on the feedback of clinicians and implement policies for disclosure to patients. The agency could consider limiting payment reforms for clinical trials to select indications for which there is documented underrepresentation of Medicare beneficiaries. For example, heart disease is highly prevalent among Medicare beneficiaries and nearly triples their risk of hospital admissions and doubles the annual cost of care per beneficiary.10 However, older adults remain underrepresented in clinical trials for cardiovascular disease, even after the adoption of the Inclusion Across the Lifespan policy.11 Targeted incentives through MIPS could help to address this disparity in clinical research, especially given that the American College of Cardiology’s Chest Pain – MI and CathPCI registries were both eligible for the Covid-19 improvement activity, fostering awareness among eligible clinicians and hospitals about future opportunities for supporting outcomes measurement and clinical research for this patient population.12

Covid-19 has served as a test case for many health policies, including as a case study for how value-based programs can be repurposed to support new initiatives. Adopting changes in the short term can fine-tune the MIPS incentive for Covid-19, and further research will be needed to evaluate the long-term potential of payment reforms for supporting medical progress.
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