

Value-Based Oncology®

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Avalere Experts Discuss Effects of Inflation Reduction Act, EOM, Health Care Disparities

Julia Bonavitacola

NONSTOP ACTIVITY THIS YEAR in Washington, DC, will keep health care interests and especially pharmaceutical manufacturers busy as they work to understand and implement provisions of the Inflation Reduction Act (IRA), which features provisions to hold down out-of-pocket costs for prescription drugs in Medicare and limit what the government pays as well.

On September 7, Avalere Health convened its experts for an hourlong rapid-fire webinar, "Preparing for Legislative Change and Connecting Equity and Outcomes," which examined what IRA implementation will look up close. The webinar covered other recent actions that affect drug sponsors and health care providers, such as the announcement of the Enhancing Oncology Model (EOM).

IRA Highlights: Changes in Medicare Negotiation, Inflation Rebates, Part D Redesign

The IRA, signed August 16, will be implemented over 14 months.

"The policymaking doesn't stop now that Congress has acted," said Matt Kazan, managing director, "There are a ton of details in this now law that are yet to be decided. And that is in CMS and HHS's court to figure out."

Kazan said CMS and HHS will undertake a program guidance—this process makes things move quickly and is both faster and harder to influence than the normal rulemaking comment process, but it's also harder to track. HHS may hire as many as to hire 100 new employees, he said, which could shape how the policy works.

Ryan Urgo, managing director of Health Policy, said that the IRA was very specific in some areas but ambiguous in others. Urgo said areas that will need clarification include:

- the implementation of the maximum fair price (MFP) associated with the policy for negotiating drug pricing with Medicare;
- what the information exchange will look like between HHS and drug manufacturers in negotiations;
- how zero cost sharing for patients for vaccines and insulin caps will work; and the "smoothing" policy in Part D, which refers to the provision that would allow some beneficiaries to pay cost-sharing in equal amounts over the year instead of higher lump sums.

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Targeted Outreach Efforts Meaningful for Patients With Lung Cancer

Jared Kaltwasser

REGULAR DIGITAL CHECK-INS and patient-reported outcomes (PROs) can improve physician-patient communication and patient care, according to a new report published in *European Journal of Cancer Care*.

The study is based on patients with lung cancer who sought treatment at a Belgian hospital. The hospital used the principles of value-based health care to design a new follow-up protocol and found patients responded favorably.

The study investigators noted that lack of communication can be a significant problem in cancer care. "Both physical and psychosocial problems are often under-recognized by physicians or not expressed by patients," they wrote.

Increasingly, PROs are being seen as a key component of detecting problems and improving patient care. Meanwhile, many health systems around the world have been using value-based care to shift their operations and internal processes toward cost-effective measures that lead to better patient outcomes.

The new study describes an effort to use PROs to increase value and drive better patient outcomes at a hospital in Belgium. The study period ran from January 2018 through September 2020, and 201 patients participated. The effort had 3 components:

- Patients with lung cancer, who were receiving care under 2 hospital physicians, were asked to use a digital platform that enabled the collection of PROs via email and the use of digital care pathways, with telephone follow-up when necessary.
- Next, the investigators identified 30 patients at the start of stage IV treatment to participate in a pilot study in which half of the patients received a weekly questionnaire about their feelings and symptoms, which prompted alerts to health care providers at the hospital; the other 15 patients received the standard care, which did not include weekly questionnaires or automatic alerts to doctors and nurses.
- The final component of the study comprised semistructured interviews with 5 care team members: a physician, nurse, psychologist, palliative care professional, and dietician.

Ninety-two percent of the weekly surveys that were sent received a response, the investigators said. In the pilot study, 90% of participants said the

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surveys were easy to use and all found the questions either relevant or moderately relevant. Most were able to complete the surveys without help, they added.

The authors said the psychologist and palliative care worker found the questionnaires particularly helpful. Seven of the 15 patients in the pilot study's intervention cohort had contact with the psychologist and 4 had multiple conversations with the psychologist. In the standard-care cohort, only 2 patients had contact with the psychologist.

The investigators said the care team members did not track the time it took to administer and monitor the weekly questionnaires, and so it is not possible to know how the program affected the amount of time needed to care for patients. However, they noted that the program did not require an expansion of staff.

The authors concluded that the use of a digital tool to regularly solicit PROs was feasible and had a meaningful impact on patient care.

They noted that their study is limited by its single-center status and the small number of patients and that they did not investigate the clinical implications of questionnaire responses, they said.

Still, their experience shows a digital platform can be user friendly and successfully implemented across a multidisciplinary team.

"As a result, the response rates are high and the weekly follow-up had a positive impact on the patient-provider communication and makes it easier to discuss psychological and palliative care needs," they concluded. ■

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Kazan and Urgo also talked about the negotiation process that is introduced in the IRA, which requires companies to negotiate drug prices with HHS for the first time. Kazan said that negotiations for the first year will start in 13 months. He said all companies that have products that could be selected for negotiations should be thinking about the contracting and rebating strategy with the Part D plans.

"The law says that if you are a selected drug, you must be covered by a Part D plan. But the law is silent on rebate arrangements, utilization, management formulary, etc. So, thinking about how Part D plans are going to react to this policy is just as important as thinking about the negotiation process itself for the manufacturer," said Kazan.

Urgo pointed to the MFP discount, which is excluded from the average manufacturer's price (AMP) calculations but included in Medicaid Best Price, which will lead to changes in Medicaid rebate exposure and the 340B program.

"The legislative text appears to say that the MFP discount will have a recursive and dampening effect on [average sales price] and ASP calculations. That will require a complete rethink in how manufacturers of Part B drugs are thinking about their contracting strategy and their engagement with providers," he said.

Kazan highlighted Congress' late decision to remove commercial volume from what is paid related to inflation rebates, which he said changes the financial obligation that manufacturers will have to pay and also "changes the dynamics in the thinking of a manufacturer about future pricing decisions and weighing commercial versus Medicare volume as part of that calculation."

Urgo pointed out that the inflation adjustment period will start right before the applicable period. "Manufacturers will know what their target price needs to be but they won't

have a lot of time before that applicable period actually begins. So, to the extent that pricing strategy and price increases are typically thought out months in advance, that process is likely going to need to be truncated quite a bit."

Medicare Part D redesign will likely begin in earnest in 2025, but some changes will be brought to the table by 2024, including a 5% cap on beneficiaries and changes to low-income subsidy eligibility.

"There will be a lot of very practical benefits associated with Part D redesign when it comes to that new out-of-pocket cap and the smoothing policy. So, we really can't lose sight of the affordability benefits for patients. But that will come at a cost for manufacturers when it comes to negotiations with plan sponsors," said Urgo.

He said that pricing reimbursement and access teams should work together to start thinking about the real-world evidence that exists for products that could be negotiated and what type of new purchasing agreements could be required to keep providers whole. Kazan said that business units should stay informed on the activities and decisions coming out of CMS and the HHS to keep ahead of the decisions, and public affairs offices should help to translate the negotiation information for stakeholders that could sway the upcoming decisions.

Preparing for EOM to Roll Out

The successor to the Oncology Care Model (OCM), the EOM, will be rolling out on July 1, 2023. According to Blair Burnett, a consultant for Avalere Health, this model will be looking at cancer care more holistically but still within the total cost of care model approach.

One of the big changes in this new model is that there will be a reduction in cancer types that are included, with EOM only covering 7 of the 21 cancer types that OCM did. The covered cancers include breast, lymphoma, small intestine/colorectal, prostate, and chronic leukemia. "Despite the reduction in included cancer types, the 7 implicated in EOM will account for nearly half, about 48%, of episodes in OCM," said Burnett.

The monthly enhanced oncology services (MEOS) payment, which is intended to support larger care transformation activities, has been reduced from \$160 per beneficiary per month under OCM to \$70 per beneficiary per month under EOM. However, practices will receive \$100 per month when they treat patients that are "dually eligible," meaning they receive both Medicare and Medicaid. There are 2 practice redesign risk models, and electronic patient reported outcomes will be mandatory in year 3.

Maddi Davidson, a consultant with Avalere Health, said that it is expected many participants to be incentivized to switch to the EOM because of the methodology changes, ongoing efforts and the overall transition toward value-based care, and the timing of the model. She explained that the EOM payment methodology was overhauled from OCM to make prices more accurate and more attainable because the price will be set using 7 individual cancer regression models compared with only 1 in the OCM. Certain diagnosis-related groups were also excluded from the calculations, which may appeal to hospital-based practices.

Burnett said that Avalere is recommending that all life science companies and manufacturers that will be implicated in these changes "to connect with their priority accounts to understand how these necessary and methodological adjustments that practices are recommending and considering for participation and how that's going to support them or not and how those practices are engaging with external stakeholders."

The new EOM will be addressing equitable cancer care in the roll out by working with the Cancer Moonshot Initiative to close the gaps and address cancer disparities that were exacerbated with the COVID-19 pandemic. Implementation of patient reported outcomes and health resource screening are the 2 ways that EOM is hoping to close health disparity gaps.

Addressing and Reducing Health Care Disparities

Companies are beginning to look toward addressing health care disparities and health equity. But the first step to doing so is often the hardest to begin.

Brigit Kyei-Baffour, associate principal, said that all companies should start with the data. “There are multiple ways in which stakeholders can leverage data to address health equity challenges that are impacting their specific patient communities and use data to develop solutions to drive favorable outcomes,” she said.

Ensuring that algorithms collecting data aren’t biased and tailoring that data to the specific population of interest is just one way that companies can get started with addressing health equity.

Sarah Alwardt, senior vice president of Advisory Services, agreed, saying that real world data should always be where companies begin, and to take within context. She also spoke about how patient perspectives are becoming more valuable in addressing these issues. Patients and caregivers can give their perspective after the data is collected to truly understand the desires of the patients and what outcomes they want from their treatments.

Combining patient perspective with data can help companies understand some actionable next steps and future strategies to close identified through these perspectives. ■

Stakeholders Address Innovative Strategies Driving Cancer Outcomes in New Jersey

Matthew Gavidia

IN RECOGNIZING THE VALUE-BASED aspects that drive patient outcomes within oncology, effective cancer care has been redefined in New Jersey to incorporate cost and health equity at the forefront of innovation. Telehealth, in-home care, and biosimilars have all emerged as potential solutions to reduce rising financial toxicity and access concerns in oncology, but there remains a significant need for collaboration and aligned strategies to optimize population health, noted stakeholders during the 70th Annual Roy A. Bowers Pharmaceutical Conference: Innovation through Crisis—Redefining Health Care Delivery.

At the last panel discussion of the conference, held Monday through the Ernest Mario School of Pharmacy at Rutgers, The State University of New Jersey, Edward Licitra, MD, PhD, chairman and chief executive officer, Astera Cancer Care, opened the conversation by acknowledging the utility of the recently ended Oncology Care Model (OCM) in showing the level of sophistication needed to address common (dehydration, chemotherapy-related toxicity) and complex (reimbursement, social determinants of health [SDOH]) issues for patients through a personalized manner.

“We recognized that we needed to focus more precisely on the cancer conditions themselves, and how we might optimize the care for patients with specific types of cancer conditions because in many population-based, risk-based oncology models, you have to manage populations of patients with breast, lung, or colorectal cancer,” said Licitra.

Astera first collaborated with Horizon to create an episodic care plan for patients with breast cancer, and now, Licitra said, there are 18 different programs that have been launched by his organization in oncology overall. Along with bundled payment models, he said that services typically not reimbursed by fee-for-service Medicare, such as next-generation sequencing, are also being offered to some beneficiaries.

“We think that we can actually roll up at least 50% of cancer under prospective episode-based payment arrangements, which we think then kind of integrate with value-based care programs and population health initiatives that will allow us to provide services to these patients, including home health services, and then ultimately control the cost of care for the provider, patient, and payer,” he said.

Steven K. Libutti, MD, FACS, director, Rutgers Cancer Institute of New Jersey, added that use of bundled payment also has potential in palliative care, or as he described it, “supportive care.”

Episodic plans are typically provided to patients with early-stage disease, in part due to the minimal variance seen for these disease types. But introducing these payment models to patients at more advanced stages of disease can have a significant impact on

quality and cost, Libutti said, as there is often reluctance among care teams to move to supportive care.

He noted that extending the continuum of care to start when a patient first begins treatment to when there are no more viable therapeutic options left to consider can prove especially beneficial for providers, payers, and other care team members, who may have difficulty recognizing when treatment options are exhausted, and that turning to supportive care is ultimately the best option.

“At some point, going to fourth-line therapy may not be in the patient’s best interest and understanding that and making a plan early on with the patient—how far the journey is going to go and what they may need towards the end of the journey if we’re not achieving the goals that we had all hoped for—I would love to see us flesh that out more as a part of these bundles,” said Libutti, who also serves as vice chancellor for cancer programs at Rutgers Biomedical and Health Sciences and senior vice president for oncology services at RWJBarnabas Health.

In oncology care overall, clinical trials are also a cost-effective alternative to provide standard of care at a lower cost than would be typically associated with those therapies. Findings of an analysis by Tennessee Oncology that looked at the price of care for patients across 8 different malignancies who had Medicare as part of the OCM showed that those who were placed into a clinical trial exhibited an 18% reduction in episode costs compared with participants who were given regular standard of care.¹

Payer partnerships, along with the bundled payment models, are also key to covering the costs that would otherwise be placed on the patient, infusion center, and private practice, said Libutti, and increased integration of clinical trials can also reduce the use of third and fourth line “desperation agents” that contribute to waste.

“Not that it’s easy, but it’s one of those things that if you have an organization that can put a relatively high percentage of patients on trial, I think you should be rewarded for that, because I think that there’s benefits that are approved to patients and also payers,” said Licitra.

With the standard of care drug in oncology ranging from \$15,000 to \$20,000 a month, Michael P. Kane, RPh, BCOP, executive director, Oncology Services, Rutgers Cancer Institute of New Jersey, RWJBarnabas Health, noted that improving the eligibility criteria for clinical trials is key as it often excludes the types of patients who typically present at the clinic.

“I would love that population input to say, ‘Hey you have this exclusion criteria for diabetes—why is that when half the patient population have this disease?’” said Kane.

Even in cases where there is agreement on the optimal therapy for a given patient, he stressed that they will still get denials when seeking approval from insurance as the drug may not be part of clinical benchmarks, such as established recommendations by the National Comprehensive Cancer Network.

“So how do we bridge those patients from something that doesn’t have approval compendium, isn’t part of their payer policy yet, but we know it’s best care? What I think would be a better model is if you’re going to receive a drug in that fashion, there has to be a way to capture the data to learn whether it was worthwhile.”

Financial navigators and social workers were other essential resources mentioned by Kane to address the financial toxicity related to care, as well as SDOH issues outside of the clinic, including cost of living, transportation, and food expenses.

“I think the most impactful thing that we can do is to continue to have the modalities for frequent touch points for the patients. That’s everything from telemedicine to remote patient monitoring to apps, because I think all of those things drive better outcomes, control cost, and improve efficiency,” said Licitra.

“One of the biggest concerns I see in my own health system, and this refers to the unwillingness to get rid of old ideas, is the fact that somehow these technologies put a barrier between you and your colleagues or you and your patients. And I don’t think that’s true. I think it’s about implementation,” added Libutti.

“Wouldn’t it be great to have real-time monitoring of some of the things that are going on with your patients so you’re not waiting every week or every month to find out how they’re doing on their agent or how they’re doing in terms of the side effects of toxicity. If I had a blank check, I would invest it in proper implementation of those technologies.”

Announced during the meeting by Libutti and Saira Jan, MS, PharmD, vice president and chief pharmacy officer of Horizon Blue Cross Blue Shield of New Jersey (BCBSNJ), a pilot launched as partnership between Horizon BCBSNJ and Rutgers CINJ/RWJBarnabas aims to move infusion oncology treatments from the clinic to the home setting for eligible RWJBarnabas Health patients.

Along with minimizing patient travel and potential exposure to COVID-19, the Oncology Home Infusion Model seeks to develop innovative benefit design to ensure cost-effective health care delivery for patients while maintaining high quality of care in the home environment. ■

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Experts Discuss Keeping Values in Value-Based Oncology

Julia Bonavitacola

TAKING THE REQUESTS and needs of patients who have cancer into account is vital in ensuring a patient receives quality care that doesn’t put them in financial ruin, according to panelists at the 2022 National Alliance of Healthcare Purchaser Coalitions Leadership Summit.

Areas in which various aspects of health care can improve were talked about by the 3 panelists who emphasized there were cost effective ways to cater to patients of all economic and social classes without decreasing the quality of care received.

Alan Balch, PhD, CEO of the Patient Advocate Foundation, talked about the importance of educating patients on their benefits and making sure patient care is personalized for optimal treatment. “When we ask our patients what’s important and what do they value, it’s not the clinical stuff. They value being respected, listened to, and knowing that their care is personalized,” he said.

Balch said that many of the patients his organization encounters are also just as interested in the financial impact that their medical care will have on them as the clinical outcome itself. The patients in this group are important to engage to make sure they get the care and outcomes they need and are entitled to.

He emphasized providing benefit education to help these populations understand the areas where they can get support, whether through paid time off, sick leave, or disability benefits. He emphasized that patients with cancer in particular need to know these benefits so they don’t fall behind on their care out of the gate.

“You really need to spend a little time and dedicate those resources to helping those patients in particular really understand what benefits you provide, [how] to use them, and where do they go for help when they get in trouble, financially and otherwise,” he said.

Jennifer Griggs, MD, MPH, a professor in the Health Management & Policy and Internal Medicine departments at the University of Michigan-Ann Arbor School of Public Health, said that discrimination in treatment for cancer is also prevalent.

According to her, women who are considered obese, women classified as having a lower socioeconomic status, and Black women are systematically underdosed with chemotherapy in the first cycle. She emphasized the importance of open communication between patients and doctors about questions they each have and that respecting the answers could lead to an improvement in giving accurate medication to patients.

Marianne Gandee, vice president of oncology patient solutions at Pfizer, said that her team has worked on an employer toolkit to provide information on cancer treatment and navigation. She also said her team has put together a clearinghouse for financial literacy that pulled together numerous resources to help patients with a new cancer diagnosis understand their benefits going forward.

“One of the other things we’re trying to do at Pfizer is we’re not trying to solve for communities, we are trying to rely on the leaders in those communities... that have great resources out there already,” she said.

Gandee also said that organizations need to go to patients and advocates first when developing new care tools. Meeting patients and health care providers halfway could provide patients with a better quality of life.

Balch said that appropriate variation in care is needed to treat patients of all social and economic classes effectively, stating that patients feel more prepared and engaged when they have a more individualized approach. It could also help with losing money on patients not being able to come to more generally chosen appointment dates.

Griggs pointed out that many health care workers are currently burned out after the last 2 years, stating that “a depleted clinician is not going to be creative and thinking about how to take their patient from abnormality through to diagnostic completion and then initiation of treatment.” She also said this burnout has affected the way conversations around end-of-life care have gone and could lead to futile treatment.

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Multiple Pegfilgrastim Administration Options Allows for Patient-Centric Model of Care

Laura Joszt

PATIENTS WITH CANCER who require granulocyte colony-stimulating factor (G-CSF) biologics to reduce the incidence of febrile neutropenia have 3 administration options available to minimize hospital or clinic visits. In addition, the use of pegfilgrastim biosimilars can minimize additional financial burdens, according to a review published in *Oncology and Therapy*.

There are 6 pegfilgrastim biosimilars approved by the FDA for the prophylaxis of febrile neutropenia. The first approved in June 2018 was Fulphila from Viatrix/Biocon, which came to market in July 2018. The most recent pegfilgrastim biosimilar approved was Stimufend from Fresenius Kabi, which was approved September 6, 2022, and is expected to launch in early 2023.

Recent guidelines recommend next-day administration of pegfilgrastim after chemotherapy, but a growing body of evidence indicates same-day administration is possible.

“Because of the COVID-19 pandemic, the option of same-day administration is especially pertinent to minimize additional clinic visits and risks of SARS-CoV-2 exposure,” the authors explained. In their review, they discuss administration options for pegfilgrastim and its biosimilars.

Pegfilgrastim also can result in significant savings for patients and the health system. Cost savings of switching from the reference to a biosimilar in a population of 20,000 patients can top \$22 million with 100% conversion, the authors noted. Those savings could provide thousands of additional doses of biosimilar pegfilgrastim or be reallocated to other treatments for cancer.

The authors identified 3 approaches to pegfilgrastim administration that can help minimize clinic visits, especially in the context of COVID-19:

- Same-day administration after chemotherapy
- Use of the FDA-approved on-body injector (OBI) to deliver pegfilgrastim approximately 27 hours after application
- Self-administration by the patient or caregiver more than 24 hours after chemotherapy

According to a decision tree they created, if a patient is comfortable coming back in for a second visit, they should receive pegfilgrastim next day. However, if they do not want to come back in, and they are comfortable with having a device attached to their skin, the OBI administration is the next preferred. If they are not comfortable with a device attached to their skin, they can either give themselves the injection the next day or have a care partner perform the injection. If the patient is not comfortable giving a self-injection and does not have anyone to provide the injection, then they will need to have a same-day administration by a health care provider.

Some of the challenges to consider when choosing the administration route include ensuring proper self-injection techniques for effective self-administration and the lack of an OBI for a pegfilgrastim biosimilar at a lower cost.

While same-day administration may be a preferred option for patients, research found that “patients receiving prophylactic pegfilgrastim on the same

QOL Tool Valuable in Identifying Patients’ Chief Concerns

Julia Bonavitacola

ALTHOUGH A PATIENT REPORTED outcome quality of life tool (PROQOL) did not bring about a QOL difference compared with usual care, it was effective in identifying primary concerns of patients with multiple myeloma (MM), light chain amyloidosis, head and neck cancer, and gynecologic malignancies over time and was a worthwhile tool for clinicians, according to study findings published in *Contemporary Clinical Trials Communications*.

PROs have been pushed for inclusion in clinical research by the FDA, as they can clarify physical or functional impairment and psychological and social effects. Using PRO surveys can help clinicians assess symptoms and give an overall better quality of care. This study aimed to determine whether the PROQOL tool could improve QOL more than usual care at the end of a 12-month follow-up.

The single center nonblinded prospective clinical trial included participants who were 18 years and older; had MM, light chain amyloidosis, head and neck cancer, or gynecologic malignancies; had continued cancer care at Mayo Clinic in Rochester, Minnesota; and were able to use an iPad.

All participants were offered the PROQOL prior to every visit, and the patients would select 1 of 8 categories to focus on: personal relationship, emotional health, physical health, cancer diagnosis and treatment, health behaviors, money, care planning, or something else. Usual care was defined as patients explaining their symptoms or concerns and clinicians addressing those concerns.

There were 233 patients who were enrolled in the hematologic cohort of the study from July 2016 to April 2018, with 60.1% of participants male and a median age of 62 (range, 31-87) years. The solid tumor cohort had 150 patients enrolled between September 2016 and August 2017, where 78.7% were female and the median age was 63 (range, 32-84) years. There were patients in both cohorts who died during the study (11% in the hematologic cohort, 23% in the solid tumor cohort).

The most common overall primary concern was physical health (30.9%), followed by cancer diagnosis and treatment (29.1%). Both selections remained the most popular when patients were allowed to select a second option.

The study found that concerns varied more as patients had more visits. The mean (SD) number of unique concerns increased from 1.9 (0.6) with 1 to 3 visits to 2.7 (0.8) with 4 to 5 visits to 3.9 (1.3) with 6 or more visits.

The most popular sub-concerns that were selected in physical health were fatigue (47.8%), neuropathy (43.4%), and difficulty sleeping (29.9%). The most selected sub-concerns in the cancer diagnosis category were treatment plans (60.5%), prognosis (49.7%), and chemotherapy (28.4%).

Money and physical health were more likely to be selected by the hematologic cohort compared with the solid tumor cohort, at 9.9% vs 5.2% and 45.3% vs 38.0%, respectively. The solid tumor cohort picked health behaviors more often (23.5% vs 13.2%). In addition, women selected healthy behaviors more often (21.3% vs. 12.1%) vs men whereas men were more likely to select physical health (48.0% vs 38.2%).

Patients younger than 65 years demonstrated more concern for money vs older participants (12% vs 5%) whereas care planning was more important in patients 65 years and older (9.1% vs 4.4%).

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Patients younger than 65 years demonstrated more concern for money vs older participants (12% vs 5%) whereas care planning was more important in patients 65 years and older (9.1% vs 4.4%).

The researchers found no significant difference in QOL between patients using the PROQOL and usual care at the end of the 12-month period for either the combined cohort or the individual cohorts. However, 94% of clinicians surveyed were satisfied with the PROQOL and saw an improvement in their patients' well-being.

There were some limitations to this study. The main concerns between clinic visits could not be assessed, and summaries of main concerns and actionable list of resources generated by the PROQOL were not recorded in the electronic health record, which limited integration of PROs in clinical practice.

"The PROQOL tool held considerable value in aiding patients in identifying patients' main concerns over time and was a worthwhile experience for both patients and clinicians," the authors concluded. ■

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"Because of the COVID-19 pandemic, the option of **same-day administration** is especially pertinent to minimize additional clinic visits and risks of SARS-CoV-2 exposure"

day as chemotherapy or 4-5 days after chemotherapy had a significantly higher incidence of febrile neutropenia compared with patients receiving pegfilgrastim on days 1-3 following chemotherapy," the authors wrote.

Other research indicated the efficacy of same-day administration of pegfilgrastim may be dependent on the chemotherapy regimen. Considering health systems may want to minimize outpatient visits for patients with cancer, who are at an increased risk of infection, the benefits of same-day administration of pegfilgrastim outweigh the risks, the authors suggested. This has the added benefit of reducing the workload for health care workers at a time when they are overworked as a result of the pandemic.

Finally, both health systems and patients may benefit financially from increased use of pegfilgrastim biosimilars during the COVID-19 pandemic. Hospitals and health systems have seen their finances significantly impacted during the pandemic, and marginalized and vulnerable populations have also been more likely to be impacted financially during this time, the authors noted.

"Pegfilgrastim biosimilars can play a key role in minimizing the treatment-associated financial burden on patients, payers, and health care systems during the COVID-19 pandemic and beyond," they concluded. ■

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Moonshot 2.0 Looks to Focus on Caregivers, Learn From Patients

Mary Caffrey

THE BIDEN ADMINISTRATION'S reboot of the Cancer Moonshot initiative, also called Moonshot 2.0, has clear goals: to reduce cancer deaths by 50% over 25 years and to "improve the experience of people and their families to living with and surviving cancer."¹

Doing so will require going beyond the traditional measures of success and truly learning from patients and caregivers living with cancer, Danielle Carnival, PhD, the Cancer Moonshot Coordinator in the White House Office of Science and Technology Policy, told those gathered Friday for the National Comprehensive Cancer Network Policy Summit, held in Washington, DC.

Over the past 20 years, Carnival noted, the age-adjusted death rate from cancer has dropped about 25%, aided by groundbreaking advances in treatments, prevention tools such as the human papillomavirus vaccine, improved use of screening that allows lesions to be removed at precancerous stages, and large decreases in long-term cigarette use, "especially in young people."

Carnival, who served on the first Moonshot initiative in 2016, said it created 70 new partnerships and drove passage of the 21st Century Cures Act, invested \$1.8 billion in research, and streamlined the FDA's decision-making timeline for new therapies. "Despite progress of lives extended and lives saved, cancer is still the number 2 cause of death in America," she said. "We lose more than 600,000 Americans a year to cancer, and 1.8 million families each year are devastated by a cancer diagnosis."

But many issues remain. Cancer is often diagnosed late. Too little is done to prevent cancer. "We have stark inequities in access to diagnosis, access to treatments and trials, and inequities in outcomes," Carnival said.

"We know too little about how to target treatments to the right patients," she said and too many cancers lack good strategies for developing treatments, including childhood cancers.

Worst of all, "We leave most patients and caregivers to navigate the disease and its aftermath, including survivorship, on their own and we don't learn from the experiences of most patients."

Those experiences include dealing with treatments that are too toxic and too unaffordable, insurance processes that are impossible to navigate, and survivorship plans that may be incomplete or nonexistent.

Addressing this list—tackling the medical, financial, and emotional burdens of cancer by providing support throughout diagnosis, treatment, and survivorship—represents a "shared agenda" for Moonshot 2.0, Carnival said.

To take on this agenda, the administration has created an interagency "Cancer Cabinet," which includes representatives from HHS, the CDC, the Department of Veterans Affairs, and the Environmental Protection Agency, among other entities. In mid-September, President Joe Biden named former biotech executive Renee Wegrzyn, PhD, to head Advanced Research Projects Agency-Health, or ARPA-H, which will take on the bolder, riskier projects that the National Institutes of Health typically won't pursue.² Alongside these steps, Carnival said, Biden has signed an executive order on biotechnology manufacturing to ensure products are made in the United States.

One such effort includes a large clinical trial, she said, that "if successful, will identify effective blood tests for detection of 1 or more cancers, so that we can

reach more people with early detection and get them into a pipeline to get follow-up and diagnostics.”

Such steps will help close “the screening gap” that results in some populations not receiving their diagnosis with cancer until it reaches later stages.

Broader parts of the Biden administration agenda, such as reducing the out-of-pocket costs for Medicare beneficiaries, “will impact tens of thousands of cancer patients who could see their prescription drug costs go down by thousands annually,” Carnival said. Prevention efforts include new funds to clean Superfund sites and \$200 million in CDC grants for cancer prevention programs that will “reach every state, US territory, and tribal organization.”

Private sector efforts and partnerships are working to improve equity in screening, too. Carnival listed projects across the country that included mobile and home screening projects and development of new tools in concert with pharmaceutical companies and groups that include the American Cancer Society and the National Minority Quality Forum.

In response to a question, Carnival said prior authorization and reimbursement challenges are definitely part of the agenda.

Carnival said the administration wants to hear from those directly affected by cancer and has set up a website, [whitehouse.gov/cancermoonshot](https://www.whitehouse.gov/cancermoonshot), which includes links for patients and families to include written or video testimony.

“The goals and priorities for the Cancer Moonshot must be informed by those with direct experience with cancer. So please share your stories of inspiration and knowledge,” she said. The Moonshot relaunch featured stories from 3 people with direct experience with cancer, “and those 3 individuals happen to be the President, the First Lady, and the Vice President of the United States. This is personal to them.” ■

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Recommendations to Safeguard Quality Shared Decision-Making for Lung Cancer Screening

Allison Inserro

AN INTERNATIONAL GROUP of researchers, practitioners, and stakeholders involved in advocating for high-quality shared decision-making tools used by providers and patients issued 2 recommendations Thursday in response to an updated national coverage determination (NCD) about lung cancer screening released earlier this year by CMS.

In a Viewpoint published in *JAMA Oncology*, the authors wrote that there is concern that the NCD from CMS in February 2022 “may be misinterpreted as lowering the standards for the counseling and shared decision-making visit and potentially lead to poorer quality decisions.”

CMS first released an NCD for lung cancer screening completed via low-dose CT (LDCT) in 2015, allowing Medicare beneficiaries to have the procedure covered beginning at age 55. Under the February revision, CMS dropped the beginning age to 50 years and tobacco smoking history was lowered from at least 30 packs per year to at least 20 packs per year.

In addition, the February NCD simplified requirements for the counseling and shared decision-making visit patients must complete prior to screening. Although the changes were made to reduce the administrative burden on providers, they have also raised concern from the International Patient Decision Aid Standards (IPDAS) Collaboration, which works to improve the quality and effectiveness of patient decision aids with an evidence-based approach. The authors of the Viewpoint are coleaders of IPDAS.

IPDAS was formed to address what the group says is an expansion of patient decision aids (PDAs) with “unknown quality, potential for conflict among developers with an interest in patient choice, and concerns about unintended bias resulting from how evidence is selected and information is presented.”

In the revision to the shared decision-making component, CMS expanded the definition of who can provide patient education to health coaches or health educators. Those individuals should be trained, according to IPDAS, saying that decision coaching is not routinely taught in medical training.

Before the revision, only physicians, physician assistants, nurse practitioners, or clinical nurse specialists could provide such decision coaching.

In the second recommendation, the authors said that PDAs should meet minimal quality standards and cited standards and checklists from IPDAS that set criteria for patient decision-making tools to the minimize risk of bias. In the changes released in February, providers no longer have to document information about the decision-making process in the medical record the way they did before.

“This change should not be interpreted as deemphasizing the importance of providing shared decision-making and using high-quality PDAs,” the authors wrote.

“We are concerned that the new coverage determination will invite the production and use of poor-quality decision aids by clinicians who lack shared decision-making skills,” they said. “Decision aids that meet IPDAS standards address benefits and harms in a balanced manner; use high-quality evidence; clearly specify conflicts of interest for developers; and are written in plain language for increased patient comprehension and inclusion of persons disproportionately impacted by tobacco use.”

The February NCD followed a 2021 update from the United States Preventive Services Task Force, which recommends yearly scans for people aged 50 to 80 years and reduced the pack-years of smoking history from 30 to 20. A pack-year is the equivalent of smoking an average of 1 pack of cigarettes each day for a year.

The screening recommendations seek to improve early detection of non-small cell lung cancer, which accounts for around 85% of all lung cancer cases. ■

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CMS Announces OCM Successor, but Gap Year Remains for Oncology Practices

Mary Caffrey

TODAY, CMS UNVEILED ITS PLAN for a successor to the Oncology Care Model (OCM), its ambitious foray into value-based care delivery that has been credited with changing the landscape for patients with cancer, even if it received mixed reviews on achieving savings in its early years.

However, while the Biden administration addressed complaints that OCM fell short in addressing health disparities—and failed to reward practices that cared for the poorest patients—the new Enhancing Oncology Model (EOM) will not start until July 2023. As of today, the current OCM will expire on Thursday after 6 years.

“There are stark inequities in the ability of people with cancer across race, gender, region, and income to access cancer screening, diagnostics, and treatment,” said CMS Administrator Chiquita Brooks-LaSure. “CMS is working to advance President Biden’s Cancer Moonshot goals by helping Medicare cancer patients better navigate a challenging and often overwhelming journey. The Enhancing Oncology Model will incentivize participating oncology practices—including those in rural and underserved areas—to improve the provision of high quality, coordinated care that addresses patients’ social needs and improves patient and caregiver support.”

Ted Okon, executive director of the Community Oncology Alliance (COA), said the group was “disappointed” that the 1-year gap will occur, despite requests that CMS consider a reprieve for practices that had invested in the OCM and plan to move on to next model. “During this time practices will have to shoulder the extensive investments and operational changes put in place to benefit patients without reimbursement,” he said.

In addition, practices that have used OCM’s reporting system to comply with 2015 Medicare reforms may need to switch to a different framework until the EOM takes effect. The application period for the EOM opens today and continues until September 30, according to a CMS Fact Sheet.

The OCM was proposed by the Center for Medicare and Medicaid Innovation (CMMI) in 2015 and launched in 2016. It accomplished several things:

- It required participating practices to offer several enhanced services, including 24/7 access to the patient’s medical records, use of a certified electronic health record, patient navigation, a documented care plan including survivorship care, and treatment that followed clinical guidelines.
- Practices had incentives to keep patients out of the hospital and the emergency department (ED), and most redesigned their phone trees and practice schedules to accommodate same-day, evening, or weekend appointments. More attention was paid to services such as nutrition that help keep patients out of the ED.
- Practices had to develop systems for tracking and reporting patient quality data, which was needed for reimbursement.

- Practices received both monthly payments based on episodes of care and periodic payments that reflected their ability to deliver quality care and achieve savings.

Leading oncology practices have said the OCM, while far from perfect, propelled them forward to make strides in practice transformation that would have been harder to achieve without Medicare’s leadership. Many commercial payers have developed their own versions of the OCM, and few can envision returning to care without services such as patient navigation or care planning.

CMS’ lack of nimbleness in the model’s early years, as drug development outpaced the OCM’s pricing structures, led to tweaks and add-on payments to the underlying formula. Practices also said they had to get better at working with the model over time. In the later years of the OCM, the more sophisticated users turned the corner and produced significant savings for Medicare.

During a recent webinar, leaders from The US Oncology Network said the OCM had brought \$240 million in savings for Medicare going into 2020, and the network had seen a 24% drop in ED visits and a 37% decrease in hospitalizations.

Physicians have acknowledged that the next incarnation of the model should address health equity, and Kashyap Patel, MD, president of COA, supported this change. The EOM is proposed to run for 5 years through June 2028. It retains some key elements of the OCM; notably, it will be voluntary, not mandatory. It retains the basic structure of the OCM, with 6-month care episodes and requirements for enhanced services, and a 2-part reimbursement structure: monthly payments tied to episodes of care, and backward-looking performance based payments based on quality measures and demonstrated savings.

However, there are some major differences. According to the information from CMS, the model will cover Medicare patients undergoing chemotherapy for major cancer types: breast cancer, chronic leukemia, lung cancer, lymphoma, multiple myeloma, prostate cancer, and small intestine/colorectal cancer. The OCM covered nearly all types of cancer.

Many of the changes are not surprises: the EOM will also add requirements for electronic patient reported outcomes (ePROs). Some will be welcomed by practices that serve budget-conscious patients: no co-payments will be required for enhanced services.

As expected, a major focus of the EOM is addressing health equity: the model will include additional payments to oncology practices for patients who qualify for both Medicare and Medicaid. Practices must report demographic data and outline plans to address health equity. But Okon said COA was surprised that the monthly episode-based payment will drop from \$160 to \$70, cutting revenue for practices when the scope of work will increase.

“Community oncology practices are fully committed to positive, patient-centered improvement of cancer care and look forward to supporting CMMI and practices to make the EOM a success,” Okon said. “The goals of the EOM are ones we wholeheartedly support, especially related to improving cancer health equity, electronic patient reported outcomes, enhanced access to cancer screenings, and more.” ■

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Gandee said that talking about preventive care makes the topic less scary for patients in the long run. “I think the word cancer is still very stigmatized. And it doesn’t need to be scary. And it’s something where I think if we do a better job about talking about the options that are out there, catching things early, that’s where I think we do a better service as a community,” she said.

Balch explained that clinical aspects of care are no longer the only aspects to consider when treating a patient. Social aspects of care need to be a part of treatment plans when taking cost of treatment and transportation into account.

“Housing, food, transportation, all those other things that arise in a patient’s life as they move through it...if they’re not addressed, [they] are going to be a stumbling block to their adherence and their ability to access and afford their care,” he said. ■