

NATIONAL COALITION FOR CANCER SURVIVORSHIP'S

Spring 2019 Cancer Policy Roundtable



**SCOTT
GOTTLIEB, MD**
COMMISSIONER
FOOD AND DRUG
ADMINISTRATION

MORNING KEYNOTE

Dr. Gottlieb, who spoke ten days before departing the Food and Drug Administration (FDA), said that now is the best time to be at the agency. A 12 percent increase in resources permits the agency to address exciting developments related to gene therapy, targeted drugs, nicotine delivery tools, and digital health.

At FDA, Dr. Gottlieb facilitated a policy-making process that relies on professional staff by convening weekly meetings with the center directors. Dr. Gottlieb also recommended that policy changes be made through vehicles that endure, which means making policy change by regulation when possible and by guidance documents when not.

PANEL ONE

WHAT IS THE CANCER EXPERIENCE FOR OLDER ADULTS?

Daisy Diggs | A non-Hodgkin lymphoma survivor treated in a CAR T-cell trial after undergoing years of chemotherapy.

Beverly Canin | A breast cancer survivor who rejected a recommendation of aggressive chemotherapy and Tamoxifen.

Susan Leigh | A survivor diagnosed with Hodgkin lymphoma at age 24 and subsequently diagnosed with breast cancer, bladder cancer, adenocarcinoma of the lung, and cardiac issues.

Lisa Rice | Caregiver to her mother with Alzheimer's disease; navigator of her mother's care after her second breast cancer diagnosis.

Robert Sachs | A non-Hodgkin lymphoma survivor at age 37; a prostate cancer survivor as an older American.

The patient advocates stressed the need for information to manage treatment decision-making. Some of the advocates initially received inaccurate diagnoses, while others received treatment recommendations that they rejected because of side effects and impact on quality of life.

Some advocates recommended that cancer patients always pursue a second opinion and others recommended that patients seek care in a National Cancer Institute-designated cancer center. But the issue of agreement was the need for information, whether obtained from oncologists, through personal research, or from cancer patient organizations or other support networks.

Ms. Leigh described her cancer experience, from 1972 to the present, as a parallel journey to the development of more effective cancer treatments and a greater understanding of the needs of cancer survivors. The profession has matured in critical ways since Ms. Leigh was originally diagnosed and treated for Hodgkin lymphoma and for multiple cancers since. As she embarked on her survivorship journey in 1972, it was difficult for her to obtain information about her health risks going forward. While there is now a greater recognition and understanding of what survivorship is and what cancer survivors need, Ms. Leigh cautioned that much more work remains to be done.

PANELISTS SHARE LESSONS LEARNED AND WAYS TO IMPROVE CANCER CARE SPECIFICALLY FOR OLDER ADULTS.



PANEL TWO

THE COST OF CANCER FOR OLDER ADULTS

K. Robin Yabroff | PhD, MBA, American Cancer Society

Dr. Yabroff presented extensive data on the cost of cancer care and the impact of those costs on individual patient outcomes. Dr. Yabroff presented projections of spending for cancer care, medical financial hardship, and the impact of financial hardship on health outcomes.

Because of the aging and growing population, it is expected that there will be 18 million cancer survivors by 2020. Cancer care spending of \$125.57 billion in 2010 will grow to \$157.8 billion in 2020 (26% increase) solely on the basis of population increase. Increases in costs in the initial phase of treatment and the last year of life could boost spending to \$172.8 billion (with a 2% rate of increase) or \$206.6 billion (with a 5% rate of increase).

Cancer patients, compared to those without cancer, face greater risks for second cancers and chronic conditions, higher health care expenditures, and limitations to their work options and daily activities. Although Medicare provides patients important protections, patients need supplemental insurance for financial protection. For those with both public and private insurance, out-of-pocket spending is increasing. Financial hardship for cancer patients can lead to delays in filling a prescription, taking less medication, and skipping medication doses. There are also psychological and behavioral effects of financial hardship.

States that expanded Medicaid under the terms of the Affordable Care Act reduced disparities in care for those newly insured under Medicaid.

Dr. Yabroff's presentation points to policy recommendations that might help address the burdens patients feel from the cost of cancer care, including:

- Encourage additional states to expand Medicaid and improve cancer care access; and
- Reforming insurance benefit design to more adequately address cancer patients' out-of-pocket costs for their care.

DR. YABROFF SHARED COMPELLING DATA THAT HIGHLIGHTS THE CURRENT AND FUTURE FINANCIAL IMPACT OF CANCER IN OLDER POPULATIONS.



PANEL THREE

TREATMENT DECISION- MAKING FOR OLDER ADULTS

Otis Brawley, MD, MACP, FASCO | Johns Hopkins University

Carolyn B. Hendricks, MD, FASCO | Maryland Oncology Hematology

Stuart M. Lichtman, MD | Memorial Sloan Kettering Cancer Center

The panelists identified obstacles to providing quality care to older Americans, but also opportunities for boosting quality and achieving the delivery of “high-touch care” to older Americans. They described the pressures that they encounter to see 20 to 30 patients per day while adhering to requirements to use electronic health records, which they believe undermine the in-office interaction with patients.

Other obstacles to providing quality care relate to the age and co-morbidities of older Americans. However, all panelists see strategies for determining patient’s functional status. The panelists did not embrace the use of any specific geriatric assessment tool but instead recommended simple strategies to assess patients’ ability to complete activities of daily living.

Although the panelists expressed concerns about the significant use of health care resources at the end of life and whether those resources consistently provide benefits to patients, they also expressed a caution about the under-treatment of older Americans. With appropriate management of toxicities, older Americans can benefit from aggressive treatment and that option should be considered.

The policy actions that resulted from this panel discussion included:

- Enhance reimbursement for patient-centered services (hopefully to address the financial pressure to see such a significant number of patients each day);
- Improve the quality of electronic health records systems and how they are utilized by oncologists;
- Expand the wider availability of educational materials that might be shared with patients.



◀ PANELISTS DREW UPON YEARS OF EXPERIENCE TO OUTLINE WAYS TO IMPROVE TREATMENT-DECISION MAKING, INCLUDING SEVERAL POLICY PROPOSALS.

NATIONAL CANCER INSTITUTE UPDATE



NORMAN E. "NED" SHARPLESS, MD

DIRECTOR
NATIONAL
CANCER
INSTITUTE

LUNCH KEYNOTE

Dr. Sharpless stated that we are living in an extraordinary time in cancer research. There have been recent approvals of groundbreaking cancer therapies, and many other promising drugs are in the pipeline. The National Cancer Institute has had five years in a row of budget increases, including infusions of funds related to the 21st Century Cures Act and Cancer Moonshot, though when this additional funding ends, the NCI will face difficult choices.

The promise from increased funding is tempered by the fact that only about 12% of grants are being funded, a payline that can discourage new research approaches. NCI seeks to address the need for a steady stream of new researchers by creating a special payline for new grants.

NCI is modernizing clinical trials and making them available to more patients by expanding eligibility criteria and developing the National Clinical Trials Network. NCI is also investing significantly in big data efforts, including the genomic research commons, MATCH, and Pediatric MATCH.

A policy action for patient advocates is protecting the NCI budget so that support these new initiatives will continue. The intramural research program also deserves support, for its potential to increase fundamental knowledge of cancer and aging.

PANEL FOUR

ENCOURAGING THE INCLUSION OF OLDER ADULTS IN CLINICAL TRIALS

Clifford A. Hudis, MD, FACP, FASCO | American Society of Clinical Oncology

Meg Mooney, MD, MBA | National Cancer Institute

Harpreet Singh, MD | Food and Drug Administration

Jamie Holloway, PhD | Breast cancer researcher, survivor, advocate

The panelists noted the recent collaborative work in the cancer community to reevaluate clinical trials enrollment criteria and to propose revisions that will hopefully encourage more diversity among clinical trials participants, including enrollment of older Americans.

Dr. Hudis discussed the work of the 113 sites involved in TAPUR – the Targeted Agent and Profiling Utilization Registry Study – to provide access to newly approved drugs and to provide insights about new uses of existing drugs. He also said CancerLinQ will provide data on the action of new drugs in specific populations.

Dr. Mooney noted that the aim should be enrollment of a diverse group of patients so that trial results are generalizable for a broad population, including older Americans. Through the National Clinical Trials Network, there is an effort to broaden eligibility criteria for all trials and to include older Americans.

Dr. Singh noted that the rate of participation in clinical trials is low, which makes it difficult to ensure that trials reflect the diversity of the population. The trend toward smaller and faster trials, part of the effort to get effective drugs to patients faster, serves to exclude people from trials. Despite these trends, she noted that we are closing the enrollment gap in the population from 65 to 74. There is still a lack of data for patients over age 75.

The panelists noted that there are barriers in addition to clinical trials enrollment criteria that must be addressed, including transportation, geography, and availability of community-based trials. There is also a significant need to educate physicians about the enrollment of vulnerable populations in clinical trials.



WITH 60% OF NEW CANCER DIAGNOSES OCCURRING IN THOSE OVER THE AGE OF 65, PANELISTS DISCUSSED WAYS TO IMPROVE RECRUITMENT OF OLDER ADULTS INTO CLINICAL TRIALS.

PANEL FIVE

THE ONCOLOGY CARE MODEL AND OTHER PAYMENT MODELS TO SUPPORT QUALITY CARE

Kerin Adelson, MD | Yale Cancer Center

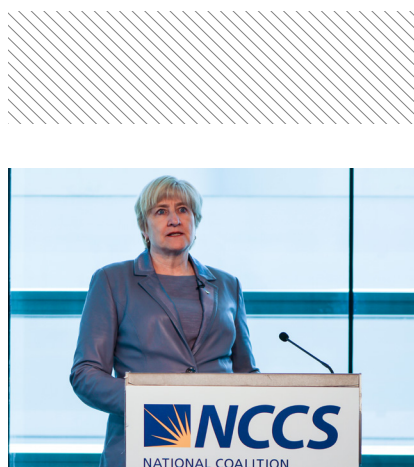
Barbara L. McAneny, MD | New Mexico Cancer Center

Drs. Adelson and McAneny, fully committed to undertaking reform that moves oncology care from volume to value, identified the steep challenges to oncology care system transformation. Dr. Adelson noted that she may have advantages that Dr. McAneny does not, because she is in an academic health center. Dr. McAneny identified special challenges that she faces because she treats low-income patients with limited resources to manage their care.

A serious difficulty for practices participating in the Oncology Care Model (OCM) is relying on the per patient per month episode payments to support practice transformation. Another problem is the availability of technology to support practice transformation. Despite the obstacles to changing practice, both Dr. Adelson and Dr. McAneny have achieved progress on key measures of the OCM, including reductions in emergency department use and hospitalizations and increases in hospice utilization.

A more vexing problem for both is managing the overall cost of care. It is difficult to monitor and control the elements of care that oncologists do not directly manage, and the increases in cost of drugs also complicate the management of overall cost of care.

Both are committed to continuing on the path of practice transformation, with Dr. McAneny pursuing a model called Making Accountable Sustainable Oncology Networks (MASON) through the Center for Medicare & Medicaid Innovation (CMMI) process for alternative payment models.



DRS. ADELSON AND MCANENY SHARED THEIR EXPERIENCES OF EMBRACING VALUE-BASED PAYMENT MODELS IN THEIR PRACTICES, WHILE ENSURING HIGH-QUALITY CANCER CARE.