

2019 ASCO Annual Meeting Highlights for the Advanced Practitioner: Issues in Oncology

Several abstracts presented at the ASCO Annual Meeting reflected the meeting theme of providing high-quality care to every patient. Following coverage by *The ASCO Post*, Editor-in-Chief to *JADPRO*, Pamela Hallquist Viale, RN, MS, CNS, ANP, comments on abstracts revealing disparities afflicting both providers and patients in the cancer care community, as well as initiatives designed to combat them.

Abstracts 10530 and 10503

Discrimination, Gender Bias in Oncology Training and Professional Meetings

By *The ASCO Post*

Visit <https://meetinglibrary.asco.org/record/173416/abstract> and <https://meetinglibrary.asco.org/record/173397/abstract> to read the full abstracts and view disclosures.

Two studies that explored types of discrimination and gender bias in health-care organizations were presented at the 2019 ASCO Annual Meeting.

Discrimination Experienced by Fellows

An abstract that reviewed discrimination and inclusion among hematology and oncology trainees

was presented by Warsame et al (Abstract 10530). The study involved anonymous telephone interviews with 17 hematology and oncology fellows—six Asian, two Black, two multiracial, four white, and three Hispanic/Latino—regarding discrimination, harassment, and inclusion. According to the study, incidents of discrimination toward fellows were common, and they reported experiencing more discriminatory incidents from patients (n = 41) than staff (n = 12).

“Discrimination from patients was most [commonly reported as being] based upon accent and race, but also was reported based on gender, ethnicity, and being perceived as ‘other,’” said first author Rahma Warsame, MD, a hematologist at the Mayo Clinic. Trainees said that having diverse colleagues and supportive programs and being involved in organizational leadership were helpful to promote inclusivity.

Gender Bias in Speaker Introductions

The second study, presented by Duma et al (Abstract 10503), looked at speaker introductions and how professional titles have been used at past ASCO Annual Meetings.

“Gender bias can be reinforced through the use of gender-subordinating language and differences in forms of address,” explained first author Narjust Duma, MD, Chief Hematology/Oncology Fellow at the Mayo Clinic, Rochester.

The study reviewed 781 presentations from the 2017 and 2018 ASCO Annual Meeting video archives, and found that women were less likely

to receive a professional form of address (61% of women vs 81% of men) and more likely to be introduced by first name only (17% of women vs 3% of men). Men who introduced speakers were more likely to introduce women by first name only (24%). Women who introduced speakers were more likely to introduce speakers by their professional title, regardless of gender.

“Our results suggest that unconscious bias may be present and be a driver of gender disparities in medicine,” said Dr. Duma. ●

References

Duma, N., Durani, U., Woods, C. B., Fonkoua, L. A. K., Cook, J., Wee, C.,...Knoll, M. (2019). Evaluating unconscious bias: Speaker introductions at an international oncology conference [Abstract 10503]. *Journal of Clinical Oncology (ASCO Annual Meeting Abstracts)*, 37(15_suppl). https://doi.org/10.1200/JCO.2019.37.15_suppl.10503

Key Points

- Incidents of discrimination toward fellows were common, and they reported experiencing more discriminatory incidents from patients than staff.
- “Discrimination from patients was most [commonly reported as being] based upon accent and race, but also was reported based on gender, ethnicity, and being perceived as ‘other,’” said study authors.
- During the 2017 and 2018 ASCO Annual Meetings, women were less likely to receive a professional form of address and more likely to be introduced by first name only.
- Men who introduced speakers were more likely to introduce women by first name only.

Warsame, R. M., Asiedu, G., Kumbamu, A., Hayes, S., Thompson, C. A., Hobday, T. J.,...Price, K. A. R. (2019). A novel qualitative methodology study to characterize discrimination and inclusion among hematology/oncology trainees [Abstract 10530]. *Journal of Clinical Oncology (ASCO Annual Meeting Abstracts)*, 37(15_suppl). https://doi.org/10.1200/JCO.2019.37.15_suppl.10530

The Advanced Practitioner Perspective Pamela Hallquist Viale, RN, MS, CNS, ANP

As a society, we’ve come a long way in ensuring that everyone is treated with fairness and respect, but there is still progress that can be made. This research validates that gender bias is still evident, even in health care and even during speaker introductions. In addition, discrimination based on accent and race has been reported.

Gender Bias

As a female nurse practitioner, I’ve experienced bias from patients who preferred seeing a physician over a nurse practitioner, and I suppose that is something commonly experienced by many of my peers. I’ve also seen this form of bias start to abate as our patients become more familiar with staff and with their care by new staff. I’ve even had physicians experience the opposite, when a patient I’ve cared for prefers to see the nurse practitioner over the physician.

Gender bias during speaker introductions seems appalling to me in this day and age.

However, there is a simple solution for certain male colleagues who can’t manage to introduce female speakers professionally. The introductions for each speaker should be written out in detail with correct attributions and read in their entirety, modeling how to introduce speakers appropriately.

Discrimination

I’ve had patients who have asked for an English-speaking health-care professional over someone with an accent, and our institution’s policy (although unwritten) was always to explain to the patient that they were getting the best care possible by the individual best suited to give it at that time. I do remember times when we changed practitioners based on a patient’s request, but it was usually because a personality conflict had occurred. To see research presented where patients are unhappy with their caregiver because of accent, race, gender, ethnicity, or “otherness” is extremely sad to me.

Disclosure: Ms. Viale has no conflicts of interest to disclose.

☞ *Continued on the following page*

Abstracts LBA1, LBA5563, and LBA107**ACA Increases Access to Health Care, Early Diagnosis, and Timely Treatment for Patients With Cancer**

By Alice Goodman

Visit <https://meetinglibrary.asco.org/record/178539/abstract>, <https://meetinglibrary.asco.org/record/175434/abstract>, and <https://meetinglibrary.asco.org/record/175047/abstract> to read the full abstracts and view disclosures.

The evidence is in: the Affordable Care Act (ACA) has enabled improved access to earlier diagnosis, earlier care, and reduced racial disparities in access to care for patients with cancer, according to two studies presented at the 2019 ASCO Annual Meeting. In states that adopted Medicaid expansion under the ACA, prior racial disparities in access to timely cancer treatment were no longer observed, according to results of a study presented at the Plenary Session (Adamson et al., 2019).

A separate study found that after implementation of the ACA in 2010, women with ovarian cancer were more likely to be diagnosed at earlier stages and to be treated within 30 days than in previous years (Smith, & Nickels, 2019). And, a third study showed that private insurance, higher income level, better education, and treatment at an academic medical center improved survival for patients with multiple myeloma (Chamoun et al., 2019).

At a press conference where these studies were discussed, ASCO Chief Medical Officer Richard L. Schilsky, MD, FACP, FASCO, FSCT, commented: “The take-home message from these three studies is the importance of access to care and timely care. If you can’t get care, you can’t benefit from care.”

Medicaid Expansion

By January 2019, 33 states implemented Medicaid expansion. An analysis of electronic health records of more than 30,000 patients found that Medicaid expansion greatly improved access to cancer care within 30 days for black people compared with white people.

“Racial disparities in cancer-related care access and outcomes exist across the trajectory of cancer care from prevention to survival. This

disparity is well documented, and there is a lot of interest in developing mechanisms to reduce disparities and improve timely access to cancer care,” said senior study author Amy J. Davidoff, PhD, MS. “One potential mechanism for improved access is insurance coverage under the ACA. Our study provides evidence that Medicaid expansion [under the ACA] can mitigate certain health disparities.” Dr. Davidoff is Senior Research Scientist in Health Policy and Management at the Yale School of Public Health and a member of the Yale Cancer Center, New Haven, Connecticut.

The ACA granted states permission to expand Medicaid coverage for near-poor adults (< 138% of the federal poverty guidelines) and to provide subsidies for people to buy private insurance if they did not qualify for Medicaid. Medicaid is administered by each state and provides full health-care coverage for low-income people. States that expanded Medicaid under ACA have witnessed large increases in enrollment, including newly eligible people and eligible people who had not enrolled previously.

Study Details

The researchers examined de-identified electronic health record-derived data from Flatiron Health of people diagnosed with cancer treated at 280 community-based cancer clinics or academic medical centers, for a total of 800 sites of care. The analysis included 30,386 people between the ages of 18 and 64 diagnosed with advanced or metastatic solid tumors between January 2011 and January 2018. Cancer types included lung, breast, urothelial, gastroesophageal, colorectal, renal cell, prostate, and melanoma.

Patients were assigned to the expanded or nonexpanded category, depending on the state they lived in and whether Medicaid expansion had been implemented at the time of diagnosis. Patients were assigned an expansion status based on linked data from the Kaiser Family Foundation. The primary outcome was start of systemic therapy (chemotherapy, targeted therapy, surgery, immunotherapy, hormone therapy) within 30 days of advanced cancer diagnosis. The experience of patients in states after Medicaid expansion was compared with that before Medicaid expansion or in states that did not have Medicaid expansion by 2018. The experience of black patients was compared with that of white patients.

Regression analysis adjusted for covariates such as patient characteristics, unemployment rate, stage, practice characteristics, state, and calendar quarter. The median patient age was 57 years, nearly half were male, and about three-quarters were white. In the unexpanded cohort, 14.6% were black compared with 8.7% in the expanded cohort.

Overall, for patients in the nonexpanded cohort who received a cancer diagnosis, timely treatment was implemented in 43.5% of black patients vs 48.3% of white patients—a 4.8% difference. However, in the Medicaid expansion cohort, timely treatment was delivered to 50.3% of white patients and 49.5% of black patients—a difference of 0.8%.

“This study extends prior evidence regarding the effect of the ACA and tells us that national health-care coverage policies may reduce disparities. Electronic health records can be a valuable resource for research on treatment patterns, disparities, and interventions,” Dr. Davidoff stated.

Additional Commentary

Commenting on this study at a press conference, ASCO expert William Dale, MD, PhD, Chair of Supportive Care Medicine, City of Hope, Duarte, California, said: “This work is to be commended. This is some of the best evidence we have to date that policies can impact outcome, particularly timely treatment. Everyone benefits and has some level of improvement. People falling behind before had access to care, and disparity disappeared after Medicaid expansion. It is difficult to do a randomized study in social science. The design of this study compared states that accepted expansion with those that did not. It is impressive to see a notable change that was statistically significant. I love when we have evidence like this to inform policy.”

ACA and Ovarian Cancer

A separate study based on data from the National Cancer Database found that implementation of the ACA led to earlier diagnosis and treatment of ovarian cancer among women younger than age 65.

“More than 22,000 women will be diagnosed with ovarian cancer this year, and just half will be

ACA and Health Insurance: Impact on Cancer Care

- The Affordable Care Act (ACA) reduced racial disparities in timely cancer treatment, according to a study assessing Medicaid-expansion-related changes.
- In another study, the ACA enabled diagnosis at an earlier stage and systemic treatment within 30 days of diagnosis for patients with ovarian cancer.
- A third study showed that factors such as private insurance, income and education level, and treatment at an academic center were associated with improved survival in patients with multiple myeloma.

alive in 5 years. We have no screening methods for detection, and by the time patients are symptomatic, the disease is often diagnosed at an advanced stage,” explained Anna J. Smith, MD, a resident in the Department of Gynecology and Obstetrics, Johns Hopkins Baltimore. “We were interested in determining what the impact of the ACA was on an earlier stage at diagnosis and treatment of ovarian cancer, since the ACA has been shown to improve access to care and primary care.” Amanda Nickles Fader, MD, is coauthor of the study.

Data were collected on women diagnosed and treated for ovarian cancer between 2004 and 2009 (pre-ACA; 35,842 patients) and between 2011 and 2014 (post-ACA; 37,145 patients). Stage at diagnosis and time to treatment were assessed for women between the ages of 21 and 64 years and compared with a group of women aged 65 and older (controls, since they had access to Medicare and were more likely to be insured pre- and post-ACA).

Difference-in-differences analysis was performed, using logistical regression to adjust for confounding factors such as race, rural location, income level, education level, Charlson comorbidity score, distance traveled for care, Census region, and care at an academic center. Changes over time were compared between the two groups.

Over time, younger women had a 1.7% gain in early-stage diagnosis (stage I or II) compared with older women. A 1.6% improvement was found for younger women being treated within 30 days of diagnosis compared with women aged 65 and over. Publicly insured women post-ACA had the greatest benefits, with gains of 2.5% in early-stage diagnosis and timely treatment compared with women aged 65 and older.

“The implications of our study are that under the ACA, women with ovarian cancer are more

likely to be diagnosed at an early stage and to receive timely treatment. These gains may have a long-term impact on survival, health, and well-being for women diagnosed with ovarian cancer,” Dr. Smith said.

At a press conference, ASCO expert Merry-Jennifer Markham, MD, Associate Director for Medical Affairs at the University of Florida Health Cancer Center, Gainesville, Florida, weighed in on this study. “Ovarian cancer is a deadly disease. When it is diagnosed at later stages, the prognosis is much worse than in stage I or II. This study shows that access to health insurance can increase earlier diagnosis and treatment, and this should ultimately improve long-term outcomes for women with ovarian cancer.”

Insurance Status and Multiple Myeloma

In a similar vein related to access to care, a third study found that insurance status, higher income level, and treatment at an academic center improved survival for patients with multiple myeloma. In this study, neither race nor gender had a significant impact on survival.

“The outcome of patients with multiple myeloma has dramatically improved due to novel agents and autologous stem cell transplant,” said lead author Kamal Chamoun, MD, a fellow in the Hematologic Malignancies and Stem Cell Transplant Program, University Hospitals, Seidman Cancer Center, Cleveland. “Multiple myeloma is the number one cancer treated with oral medications, and the cost of treatment is high, nearly tripling since 2000. Out-of-pocket costs for patients with myeloma who have Medicare are significantly higher than for patients with other types of insurance, leading to treatment delays, partial treatment, and discontinuation of treatment. We need to take action to limit and reverse the disparity for those who cannot afford private insurance or have lower incomes.”

The study utilized the National Cancer Database to identify 117,926 people living with multiple myeloma between 2005 and 2014. The median age at diagnosis was 67 years. The researchers looked at insurance status at diagnosis, median household income in patients’ zip code area, age, gen-

der, rate, comorbidity score, transplant status, and treatment facility type.

An adjusted analysis found a survival advantage for people older than age 65 who had private insurance: the median overall survival was 41.9 months vs 30.8 months for those with Medicare. This difference was not statistically significant. “A higher proportion of patients with higher income had private insurance, and treatment at an academic center was associated with a survival advantage,” Dr. Chamoun stated.

ASCO Expert Catherine Diefenbach, MD, of NYU Langone Health, New York, commented on this study. “Where you live and what insurance you have should not affect survival for patients with multiple myeloma. Unfortunately, Dr. Chamoun’s study shows that it does. Having private insurance, living in a higher income area, and receiving treatment at an academic center are associated with better and longer survival for patients with multiple myeloma.”

Dr. Chamoun shared a relevant case from his own practice. “I have a patient with myeloma whose out-of-pocket costs were \$20,000 per month, which he was not able to afford. Our institution was able to get this copayment down to \$40 a month, but not all institutions have this infrastructure. These financial challenges are creating real differences in survival. We should all strive to give patients equal access to high-quality care,” she stated. ●

References

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The Advanced Practitioner Perspective Pamela Hallquist Viale, RN, MS, CNS, ANP

The Affordable Care Act (ACA) was not a perfect piece of legislation (and how many of them are?); however, after being confronted with data collected after the ACA, it is difficult to argue that this legislation did not make a significant difference for our patients with cancer. This act translated into earlier diagnosis of cancer and earlier care for patients with cancer, both of which we know translates into improved survival.

Importance of Early Diagnosis

If cancer is diagnosed at later stages, not only are treatments often complicated and costly, but survival frequently negatively affected.

For example, 90% of patients with ovarian cancer who are diagnosed at an early stage survive for at least 5 years compared to 5% of women diagnosed at an advanced stage. However, how many of us have had individuals who came in later because they feared the cost of therapy or didn't have insurance?

The public would benefit from research on the ACA and increased awareness of the benefits of this legislation for patients with cancer. Not only did the ACA improve timely diagnosis of disease, enabling earlier care with potentially curative treatments, but it also reduced racial disparities for patients with cancer.

Caring for a Diverse Population

As advanced practitioners, we are aware that although cancer affects all races, certain groups may suffer a larger burden than others, affecting incidence of cancer, mortality, morbidity, screening rates, stage at diagnosis, and survivorship (Cancer.gov). Although disparities can reflect many factors, including culture and environment, many racial or ethnic groups are likely to be medically underserved. The ACA helped to reduce these racial disparities. This all translates into improved care for our patients with cancer. These outcomes should be shared with every member of the US Congress.

Disclosure: Ms. Viale has no conflicts of interest to disclose.

Press Briefing

Project Facilitate: FDA's Plan to Ease Expanded Access to Novel Therapies

By Caroline Helwick

The U.S. Food and Drug Administration (FDA) plans to provide oncologists with greater help in acquiring expanded access to investigational therapies. Deemed Project Facilitate, the pilot program was announced at a press briefing during the 2019 ASCO Annual Meeting.

Project Facilitate is essentially a call center that will be run by the FDA Oncology Center of Excellence. It's a single point of contact where FDA oncology staff will help oncology providers submit an expanded access request for an individual patient.

"The new Project Facilitate call center aims to help in making these requests for expanded access as streamlined and efficient as possible for physicians who would like to request access to investigational therapies for their patients with cancer," said Richard Pazdur, MD, Director of the Oncology Center of Excellence. From his perspective, it's a

"concierge service" that will operate throughout the expanded access experience, from the initial request for the drug to the completion of treatment.

Project Facilitate is being paired with Expanded Access (EA) Navigator, an "online road map" launched 2 years ago that is operated by the Reagan-Udall Foundation. EA Navigator, which can be used by providers or patients, links to a searchable database of current clinical trials, includes expanded access policy and program details, and is expected to be the initial step in the process.

"EA Navigator delivers transparent, concise, and searchable information provided by companies about their expanded access policies," said Ellen V. Sigal, PhD, Chair of the Reagan-Udall Foundation. "I'm pleased to announce that the EA Navigator now features expanded access opportunities listed in ClinicalTrials.gov for companies in the directory. For the first time, those who need quick access to drug availability and expanded access options will find it in one place without having to visit company websites site by site by site or sift through thousands of studies that don't meet their needs," she added.

“Project Facilitate is not a patient portal, but EA Navigator is both for physicians and patients,” Dr. Pazdur explained. The provider (or patient) may search the EA Navigator for information to guide that choice and then the provider may contact Project Facilitate for help with the request.

Additional Benefits

Furthermore, the program should provide the FDA with much-needed information. “At the current time, the FDA doesn’t know the number of expanded access requests for patients,” Dr. Pazdur said. “And many times, the physician will go to the [drug] sponsor, and the FDA is not aware if the sponsor denies these requests. We also do not know the reasons for drug sponsors’ denying these requests.” The FDA would welcome this information, he added.

Information about patient outcomes will also be gathered during the process, and this may be shared with trial sponsors. “Frequently, we are unaware of patient outcomes such as benefits from the proposed therapy and adverse events associated with that therapy,” explained Dr. Pazdur.

Under the 21st Century Cures Act, companies were required to make information about their expanded access programs public. The Reagan-Udall Foundation component of this expanded access pilot helps, in part, to broadly disseminate that information. According to Dr. Sigal, Project Facilitate and EA Navigator are “necessary tools for patients and physicians.”

Project Facilitate can be reached Monday through Friday, 9:00 AM to 5:00 PM ET, at 240/402-0004 or by e-mail at OncProjectFacilitate@fda.hhs.gov. ●

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As a busy advanced practitioner, your job is to interview, examine, and care for your oncology patients, all in a fairly short period of time. You may struggle with insurance issues and emotional support strategies for your patient, and of course, you always want to be able to present the very best therapy options for your patients.

But do you and your peers always have access to timely and important new strategies for care when you need them? And how difficult is it to access information on investigational or novel therapies during a busy clinic session?

More Support for Providers and Patients

One of the reports out of this year’s ASCO meeting reveals the U.S. Food and Drug Administration’s plan to help oncology professionals acquire expanded access to investigational therapies. As you read above, Project Facilitate is for the oncology professional and not the patient, but you can certainly see how advanced practitioners working with patients who might benefit from timely interventions with a new therapy would like to be able get that information as quickly as possible.

I like the fact that patients can use the Expanded Access Navigator (paired with Project Facilitate) to search current clinical trials as well as expanded access possibilities. Especially helpful to patients is the fact that

one won’t have to go to each individual pharmaceutical company website, although those websites do have useful information for patients as well.

Right to Try Act

Last year, another strategy for helping patients get expanded access to possible therapies (called the Right to Try Act) was passed into law to help patients with access to unapproved therapies. This Act allows eligible patients to have access to eligible investigational drugs if one has:

- Been diagnosed with a life-threatening disease or condition
- Exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug (this must be certified by a physician who is in good standing with their licensing organization or board and who will not be compensated directly by the manufacturer for certifying)
- And provided, or their legally authorized representative has provided, written informed consent regarding the eligible investigational drug to the treating physician

The above programs help to expand treatment possibilities for our patients.

Disclosure: Ms. Viale has no conflicts of interest to disclose.