# Racial Disparities, Advanced Ovarian Cancer, and HER2 Expression: 2023 ASCO Annual Meeting Highlights for the Advanced Practitioner

**Andrew S. Guinigundo, MSN, RN, CNP, ANP-BC,** of Cincinnati Cancer Advisors, discusses the effect of Medicaid expansion on racial disparities in mortality among patients with gastrointestinal malignancies. He also describes the phase III DUO-O trial, which evaluated therapies for patients with advanced ovarian cancer without a *BRCA1/2* mutation. Finally, the first tumor-agnostic global study of fam-trastuzumab deruxtecan-nxki showed encouraging results in patients with different cancers.

## Abstract 6546

### Medicaid Expansion Associated With a Reduction in Mortality for Black Patients With Gastrointestinal Malignancies

*By Jo Cavallo*

Visit https://doi.org/10.1200/JCO.2023.41.16_suppl.6546 to read the full abstract and view author disclosures.

A study investigating the effect of Medicaid expansion on racial disparities in mortality among patients with gastrointestinal malignancies has found that the initiative was associated with a greater reduction in 2-year mortality rates among Black patients living in states with Medicaid expansion compared with those living in states without it. Existing racial disparities in mortality remained the same or worsened for patients living in states without Medicaid expansion but in almost all cases were mitigated for those living in states with it. The study was presented by Naveen Manisundaram, MD, a physician in the Department of Neuroscience at Baylor College of Medicine, Houston, and colleagues during the 2023 ASCO Annual Meeting.

#### Study Methodology

Studies have shown that racial minorities experience disparities in access to cancer treatment and survival. In an effort to improve access to care for disadvantaged populations, the Affordable Care Act provided funding to states to expand Medicaid eligibility criteria and offer coverage to low-income individuals who lacked health insurance.

In this study, the researchers used the National Cancer Database (2009–2019) to conduct a cross-sectional cohort study of patients with pancreatic ductal adenocarcinoma, colorectal

J Adv Pract Oncol 2023;14(6):6-13
https://doi.org/10.6004/jadpro.2023.14.6.9 

cancer, and gastric adenocarcinoma of any stage. Difference-in-difference (DID) analysis was performed to compare adjusted 2-year mortality separately among Black and White patients residing in Medicaid expansion states and nonexpansion states before 2009–2013 and after the 2014–2019 expansion. Differences in receipt of surgery and chemotherapy were also evaluated. A negative DID analysis suggested a greater reduction in mortality for those living in Medicaid expansion states compared with those living in non–Medicaid expansion states.

### Key Results

The researchers included 86,052 patients in their analysis—19,188 patients with pancreatic ductal adenocarcinoma, 60,404 patients with colorectal cancer, and 6,460 patients with gastric adenocarcinoma. They found that the 2-year mortality rate decreased among Black patients with pancreatic ductal adenocarcinoma residing in Medicaid expansion states compared with nonexpansion states following expansion (DID = –9.4%, $P < .001$). Mortality also decreased among Black and White patients with colorectal cancer in Medicaid expansion states compared with nonexpansion states following expansion (DID = –4.2%, $P < .001$ and –2.9%, $P = .047$).

Among patients with gastric adenocarcinoma, Black patients in Medicaid expansion states experienced a marked reduction in mortality compared with those in nonexpansion states (DID = –7.7%, $P = .07$). Both Black and White patients with stage III or IV pancreatic ductal adenocarcinoma had an increase in the receipt of chemotherapy in Medicaid expansion states following expansion (DID = 3.7%, $P = .28$ and DID = 2.7%, $P = .2$). The study also found that the rates of surgery, but not chemotherapy receipt, increased among Black patients with stage IV colorectal cancer in Medicaid expansion states following expansion (DID = 5.7%, $P = .03$ and 1.0%, $P = .66$, respectively). A greater increase in receipt of chemotherapy was observed among Black patients with stage IV gastric adenocarcinoma in Medicaid expansion states than in nonexpansion states (DID = 11%, $P = .06$).

"Medicaid expansion was associated with a greater reduction in 2-year mortality rates for Black patients residing in [Medicaid expansion states] than for those in [nonexpansion states]. Existing racial disparities in mortality remained the same or worsened in [nonexpansion states] but in almost all cases were mitigated in [expansion states] following Medicaid expansion," concluded the study authors.

### Reducing Health Disparities in Cancer Care

At an ASCO press briefing where this study's findings were presented, Dr. Manisundaram commented that the study showed expanding Medicaid could reduce survival disparities between Black and White patients with cancer.

"Expanding Medicaid is one attainable and concrete solution that has been found to be associated with improved survival outcomes," said Dr. Manisundaram. "Additionally, Medicaid expansion can serve as a solution to reduce survival disparities between Black and White patients."

## The Advanced Practitioner Perspective

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Racial minorities experience disparities in the provision of cancer treatment that ultimately affects survival in the United States. One section of the Affordable Care Act of 2010 sought to remedy this through increased federal funds dispersed to participating states to expand the availability of Medicaid, that is, offering the coverage to more individuals by expanding the eligibility criteria. The funding was provided to "participating" states because the expansion was optional.

In today's world, this option of "take the money or not" perhaps has political overtones. However, politics aside, this provided an excellent opportunity for study of policy application in a specific way. Boiling it down, it is simply control group vs. study group; standard vs. intervention applied.

This cross-sectional cohort looked at 86,052 patients with either pancreatic, colorectal, or gastric cancer of any stage utilizing the National Cancer Database. A 10-year period was looked at from 2009 through 2019. Researchers looked at two 5-year intervals: 2009 to 2013 and 2014 to 2019. They were looking for the 2-year mortality rates. For the record, the Affordable Care Act went into effect March 23, 2010. Patients were broken down into several groups. These included White and Black patients, and non-Medicaid expansion states (non-MES) and Medicaid expansion states (MES). They then applied a "difference-in-difference" (DID) calculation to the groups. This type of calculation is used to determine how effective a health policy change was. It looks at the difference between two groups (control vs. intervention) prior to the intervention being applied. It then looks at the difference between the two groups after the intervention is applied to one of the groups. The difference between these two "differences" is the DID calculation. For example, in this study, they looked at the difference in 2-year mortality in White patients with pancreatic cancer in non-MES vs. MES in the first 5-year period, then they looked at the second 5-year period. The difference between those two numbers is the DID.

So, how did these patients do? In every cancer, Black patients fared better once Medicaid was expanded as illustrated by a negative DID number. There was a decrease in 2-year mortality of –9.4%, –2.9%, and –7.7% in pancreatic, colorectal, and gastric cancers, respectively. Interestingly, while DID improved in colorectal cancer for White patients, nonsignificant differences were realized in pancreatic and gastric cancer 2-year mortality among White patients. Additionally, the study looked at the provision of chemotherapy and surgery for these groups. Black patients in the MES group who had pancreatic or gastric cancer had an increased amount of chemotherapy, and Black patients in the MES group who had colorectal cancer had increased surgery rates. White patients had more chemotherapy in the pancreatic group as well, but other categories were similar.

### Implications for the Advanced Practitioner

We as advanced practitioners (APs) work in states that are non-MES and MES. Where we live and work is not something that is easily changed. Nonetheless, when we encounter patients who might benefit from health-care coverage, be it Medicaid or otherwise, we need to help patients obtain coverage, whatever the criteria may be for a given state. I realize this is not every AP's job. When it is not our job, we need to use our resources to their fullest extent, such as connecting patients with nurse navigators, social workers, or other specialized services in your area.

**Disclosure:** Mr. Guinigundo has served as a consultant for Amgen, Jazz Pharmaceuticals, and Pharmacosmos, and on speakers bureaus for Amgen, Astellas, GSK, and Pfizer.

**Abstract LBA5506**

## Addition of Olaparib and Durvalumab to Standard of Care May Prolong Progression-Free Survival in Patients With Advanced Ovarian Cancer

*By The ASCO Post Staff*

Visit https://doi.org/10.1200/JCO.2023.41.17_suppl.LBA5506 to read the full abstract and view author disclosures.

Patients with newly diagnosed advanced ovarian cancer without a *BRCA* mutation who received durvalumab and olaparib in addition to the standard of care had improved progression-free survival compared with those who received the standard of care alone, according to the interim analysis of DUO-O, an international phase III randomized clinical trial. The research was presented by Harter et al at the 2023 ASCO Annual Meeting.

The current standard of care includes chemotherapy (paclitaxel/carboplatin) and bevacizumab, an antiangiogenic agent. Durvalumab is a checkpoint inhibitor and olaparib is a PARP inhibitor. Two recent studies have shown that maintenance olaparib therapy may benefit newly diagnosed patients with a *BRCA* mutation and that bevacizumab therapy may benefit patients with homologous recombination deficiency (HRD)-positive tumors. This led researchers to explore the novel combination of bevacizumab and durvalumab with the addition of olaparib to the maintenance therapy regimen to see whether it would enhance the antitumor effect.

### Key Findings in DUO-O

Patients were randomly assigned to one of three treatment arms. Patients in all arms received the standard of care: upfront paclitaxel/carboplatin chemotherapy plus bevacizumab, followed by maintenance bevacizumab therapy. For patients in arms 2 and 3, durvalumab was added to both the upfront and maintenance regimens. For patients in arm 3, olaparib was also added to the maintenance regimen.

Interim analysis results showed no significant difference in progression-free survival between the standard-of-care arm and the durvalumab arm. Progression-free survival was increased with the durvalumab-plus-olaparib arm compared with the standard-of-care arm. For HRD-positive patients, progression-free survival was 37.3 months vs 23 months for those in the standard-of-care arm. For patients in the intent-to-treat population, progression-free survival was 24.2 months in the olaparib arm vs 19.3 months for those in the standard-of-care arm.

In patients with HRD-positive tumors in the durvalumab-plus-olaparib group, the risk of disease progression was 51% less than for those who received the standard of care. In addition, for patients in the intent-to-treat group who received durvalumab plus olaparib, the risk of disease progression was 37% less than for those who received the standard of care. In the durvalumab-plus-olaparib arm, the risk of disease progression was 32% lower in all subsets of patients—including both HRD-positive and -negative patients—compared with the standard-of-care arm.

About 90% of patients completed the trial regimens. Serious adverse events were reported in 34% of patients in the standard-of-care arm, 43% of patients in the durvalumab arm, and 39% of patients in the olaparib arm.

Researchers will formally assess overall survival and other secondary endpoints in a subsequent analysis.

"While there has been significant progress for patients with advanced ovarian cancer, an unmet need still remains. Our trial results provide encouraging evidence that we can find new treatment approaches for patients with advanced disease," said presenting author Philipp Harter, MD, PhD, Director of the Department of Gynecology and Gynecologic Oncology at the Evangelische Kliniken Essen-Mitte hospital in Essen, Germany.

## The Advanced Practitioner Perspective

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Historically, 85% of patients with advanced ovarian cancer (AOC) have recurrence and progression of their disease despite optimal surgical and initial therapeutic interventions (Lorusso et al., 2012). Hence, there has been an ongoing push to do better for these patients. The idea of maintenance therapy following surgery and initial chemotherapy is an attempt to improve outcomes and has been demonstrated in a variety of settings. For example, olaparib (Lynparza) maintenance has shown improved outcomes for AOC patients with *BRCA* mutation (DiSilvestro et al., 2023). Olaparib with the addition of bevacizumab (Avastin) has likewise shown improved outcomes in the homologous recombination deficiency positive (HRD+) setting (Ray-Coquard et al., 2022). Banerjee and colleagues (2022) found activity with the combination of olaparib, bevacizumab, and the checkpoint inhibitor durvalumab (Imfinzi). However, that study was smaller ($n$ = 63) and was done in a relapsed ovarian cancer setting, and important to note, in non-germline *BRCA* mutated (non-g*BRCA*m) disease. Can the addition of the checkpoint inhibitor enhance antitumor activity?

How do women with AOC without a tumor *BRCA* mutation (non-t*BRCA*m) fare with upfront durvalumab with paclitaxel/carboplatin (PC) and bevacizumab (bev) followed by maintenance durvalumab, bevacizumab, and olaparib? The DUO-O phase III, randomized, placebo-controlled trial sought to answer this question.

The trial enrolled 1,130 patients and randomized them to one of three arms.

- Arm 1 consisted of PC and bev with placebo (instead of durvalumab) followed by maintenance bev, placebo IV (instead of durvalumab), and oral placebo (instead of olaparib).
- Arm 2 was PC, bev, and durvalumab followed by maintenance bev, durvalumab, and oral placebo (instead of olaparib).
- Arm 3 was PC, bev, and durvalumab followed by maintenance bev, durvalumab, and olaparib.

I would describe Arm 1 as "classic" maintenance therapy since bev was the initial US Food and Drug Administration–approved maintenance for AOC. Arm 3 is the experimental arm adding durvalumab and olaparib to the bev. Arm 2 is what I describe as a "truth-verifying" arm. It is making sure that the three-drug combination is truly the best combination. This is important because a three-drug maintenance regimen potentially has more side effects and is surely more financially costly.

The primary endpoint here was progression-free survival (PFS) in Arm 1 to Arm 3 in a non-t*BRCA*m, HRD+ AOC. The study did include patients who were both non-t*BRCA*m and HRD–. This is an important group to include since it comprises about 50% of ovarian cancer patients (Konstantinopoulos et al., 2015).

Indeed, Arm 3 showed a statistically significant difference from Arm 1 with a hazard ratio [HR] of 0.49 with a $p \leq .0001$ in the HRD+ patients in an interim analysis. In the HRD– subgroup, an HR of 0.68 was seen. This is important as the prevailing thought is that this group is less likely to respond to PARP inhibitors, and many early trials excluded HRD– patients. If you are wondering about Arm 2, while there was a numerical improvement in PFS in Arm 2 over Arm 1, it was not statistically significant. Unsurprisingly, Arm 1 had the lowest adverse events reported at 34%, but Arms 2 and 3 were not far off at 43% and 39%, respectively. The three agents together did not produce side effects that were unexpected from the individual agents.

### Implications for the Advanced Practitioner

Advanced practitioners (APs) need to be aware of such findings, especially if their practice includes ovarian cancer patients. Precision oncology continues to expand, and at every conference more data are being presented that further increases the specificity in treating individual biomarkers. The AP's role has not changed. We need to continue to educate patients and even members of the health-care team on the significance of specific biomarkers.

**Disclosure:** Mr. Guinigundo has served as a consultant for Amgen, Jazz Pharmaceuticals, and Pharmacosmos, and speakers bureaus for Amgen, Astellas, GSK, and Pfizer.

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**Abstract LBA3000**

## Study Finds T-DXd Effectively Treats HER2-Expressing Cancers, Regardless of Tumor Location

*By The ASCO Post Staff*

Visit https://doi.org/10.1200/JCO.2023.41.17_suppl.LBA3000 to read the full abstract and view author disclosures.

According to the findings of the international phase II DESTINY-PanTumor02 study presented by Funda Meric-Bernstam, MD, and colleagues at the 2023 ASCO Annual Meeting, fam-trastuzumab deruxtecan-nxki (T-DXd) is an effective treatment option for people with difficult-to-treat, HER2-expressing solid tumors.

Although HER2 is expressed across a variety of tumor types, there are currently no approved HER2-targeted therapies for many types of cancer, especially those that are hard to treat. T-DXd is an antibody-drug conjugate targeting HER2 that is currently approved by the U.S. Food and Drug Administration for HER2-expressing breast cancer, HER2-positive gastric cancer, and lung cancers with HER2 mutations.

### About DESTINY-PanTumor02

DESTINY-PanTumor02 is the first global study of tumor-agnostic applications for T-DXd across a broad range of HER2-expressing solid tumors. Patients with HER2-expressing biliary tract, bladder, cervical, endometrial, ovarian, pancreatic, or other tumors (excluding breast, gastric, colorectal and non–small cell lung cancers) were enrolled in the study.

There were 267 patients enrolled in the trial, including 75 patients with immunohistochemistry (IHC) 3+ expression and 125 with IHC 2+ expression. Patients had locally advanced or metastatic disease that had worsened after at least one systemic treatment or that had no treatment options. They were treated with at least one dose of T-DXd.

### Key Findings

At a median follow-up of 9.7 months, T-DXd resulted in an objective response rate of 37.1%. The median duration of response was 11.8 months. In patients with higher levels of HER2 expression (ie, IHC 3+), T-DXd was even more effective, resulting in an objective response rate of 61.3% and a median duration of response of 22.1 months. Across different disease sites, T-DXd resulted in the following objective response rates:

- Endometrial cancer: 57.5% for all patients (84.6% for IHC 3+ and 47.1% for IHC 2+)
- Cervical cancer: 50% for all patients (75% for IHC 3+ and 40% for IHC 2+)
- Ovarian cancer: 45% for all patients (63.6% for IHC 3+ and 36.8% for IHC 2+)
- Urothelial cancer: 39% for all patients (56.3% for IHC 3+ and 35% for IHC 2+)
- Biliary tract cancer: 22% for all patients (56.3% for IHC 3+ and 0% for IHC 2+)
- Pancreatic cancer: 4% for all patients (0% for IHC 3+ and 5.3% for IHC 2+).

The study participants were mostly able to tolerate treatment with T-DXd; however, 11.6% of participants stopped treatment due to adverse events. The most common treatment-related side effects were nausea, fatigue, and cytopenia.

"HER2 is present in many cancer types, such as breast, gastric, lung, gynecologic, and urothelial cancers, and patients with HER2-expressing, hard-to-treat cancers need new treatment options," said lead study author Dr. Meric-Bernstam, Chair of the Department of Investigational Cancer Therapeutics at the University of The University of Texas MD Anderson Cancer Center. "These results advance our clinical understanding of HER2 expression; reaffirm HER2 as an actionable biomarker across a broad range of tumor types; and show that T-DXd could potentially provide a new treatment option for patients with advanced disease across these tumors, especially in patients with HER2 IHC 3+ or 2+ expression."

**Next Steps**

The researchers are currently collecting additional survival outcomes in the DESTINY-PanTumor02 study.

## The Advanced Practitioner Perspective

**Andrew S. Guinigundo, MSN, RN, CNP, ANP-BC**
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This is the way we have traditionally done cancer research: Step 1: A drug is theorized to be active against a particular tumor type (breast, colon, etc.). Step 2: If that drug shows promise in initial studies, it is tested in said tumor type against the standard of care. Step 3: If that drug proves better than the standard of care, the US Food and Drug Administration (FDA) approves the drug for use in that disease state.

Fast forward to the present. We are at the dawn of the biomarker-driven therapy age. We realize that the same biomarker is sometimes present in multiple tumor types. Some of these biomarkers include, but are not limited to, mismatch repair deficiency (MMRd), microsatellite instability high (MSI-H), *BRAF*, *KRAS*, *BRCA*, PD-L1, tumor mutational burden (TMB), estrogen receptor (ER)/progesterone receptor (PR), *RET*, *NTRK,* and *HER2*. Using the traditional clinical trials model for a particular drug that is associated with a biomarker seen in half a dozen or more cancers is not efficient and very expensive. Tough luck for rare cancers since they might never test the hot new drug using the traditional model.

To begin solving this problem, the tumor agnostic basket study was invented (Moore & Guinigundo, 2023a). It was in 2017 that the FDA granted the first tumor agnostic drug approval in oncology. The drug was pembrolizumab (Keytruda) for tumors that are either MMRd or MSI-H (Tateo et al., 2023). I would love to say that this first approval sparked a deluge of approvals, but it really has been more of a trickle. There has been one approval a year until 2022, when there were two.

Enter trastuzumab deruxtecan (Enhertu; T-DXd). This drug had the breast cancer world all abuzz in 2022 with its data and subsequent approval for use in what is referred to as "HER2-low" breast cancer, that is, HER2 by immunohistochemistry (IHC) +1 or +2 (Modi et al., 2022). Previously, we have thought of only using HER2-associated therapy in HER2 overexpressers, HER2 3+, or fluorescence in situ hybridization (FISH)-positive patients. Those of us in the breast cancer world were suddenly scrambling looking for old pathology reports to check the IHC level. For years, we have documented in progress notes simply "HER2 positive" or "HER2 negative," not predicting that 0, +1, +2 would matter someday. But wait, other tumors also have HER2!

DESTINY-PanTumor02, or DP-02, for short, is seeking to begin to answer that question. DP-02 is an open-label phase II study of T-DXd in patients with HER2-expressing (IHC 3+

or 2+) locally advanced or metastatic disease that progressed after ≥ 1 systemic treatment or that has no treatment options. Breast, gastric, colorectal, and non–small cell lung cancer were excluded from the trial. Biliary tract, bladder, cervical, endometrial, ovarian, and pancreatic cancers were included.

In short, this interim analysis showed promise. In all 267 patients who were included in the analysis, the objective response rate (ORR) was 37.1% and median duration of response (DOR) was 11.8 months. Teasing out 75 HER2 3+ patients, the ORR was 61.3% and median DOR was 22.1 months. Grade 3 and above adverse events were seen in 58.4% of patients, with 11.6% discontinuing because of adverse events in this heavily pretreated group.

**Implications for the Advanced Practitioner**

Advanced practitioners need to keep an eye on this study and this space. This abstract presents interim data. T-DXd is not quite ready for prime time for pan HER2–expressing tumors. We should look to enroll patients on this or similar studies. Such studies can give lots of information about a biomarker across many tumor types as we see here. In summary, "Advanced practitioners should be up to date with advances in cancer biomarker testing and its implications for the use of targeted therapies… to integrate this information into clinical decision-making" (Moore & Guinigundo, 2023b).

**Disclosure:** Mr. Guinigundo has served as a consultant for Amgen, Jazz Pharmaceuticals, and Pharmacosmos, and speakers bureaus for Amgen, Astellas, GSK, and Pfizer.

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