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This clarification comes as a result of a collaborative effort by ASCO, ASH, and NCCN to urge the CDC to clarify their opioid prescribing guideline in order to ensure safe and appropriate access for cancer patients, cancer survivors, and individuals with sickle cell disease.

CDC Issues Key Clarification on Guideline for Prescribing Opioids for Chronic Pain

ASCO, ASH, and NCCN are pleased to acknowledge receipt of a key clarification from the Centers for Disease Control and Prevention (CDC) on prescribing opioids to manage pain from certain conditions. The clarification regarding CDC's Guideline for Prescribing Opioids for Chronic Pain—issued in a letter from the agency to ASCO, ASH, and NCCN—comes as a result of a collaborative effort by these organizations to clarify CDC's opioid prescribing guideline in order to ensure safe and appropriate access for patients with cancer, cancer survivors, and individuals with sickle cell disease.

CDC's clarification letter notes that the agency's guideline was developed to provide recommendations for primary care clinicians who prescribe opioids for patients with chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The letter conveys that CDC's guideline is not intended to deny clinically appropriate opioid therapy to any patients who suffer acute or chronic pain from conditions such as cancer and sickle cell disease, but rather to ensure that physicians and patients consider all safe and effective treatment options for pain management with the goal of reducing inappropriate use.

"This clarification from CDC is critically important because, while the agency's guideline clearly states that it is not intended to apply to patients during active cancer and sickle cell disease treatment, many payers have been inappropriately using it to make opioid coverage determinations for those exact populations," said ASCO Chief Executive Officer Clifford A. Hudis, MD.

CDC's clarification further notes that clinical practice guidelines addressing pain control for survivors of cancer, such as the ASCO Clinical Practice Guideline on Management of Chronic Pain in Survivors of Adult Cancers and NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain, which were published and/or updated more recently than CDC's guideline, provide important guidance on the unique considerations when using opioids to control pain in cancer survivors without worsening the current opioid crisis.

"Pragmatic approaches for pain management exist at the intersection of multiple health concerns," said NCCN Chief Executive Officer Robert W. Carlson, MD. "Our guidelines help clinicians to assess the risk of inappropriate substance use, while still ensuring people with cancer don't suffer unnecessary, severe pain. CDC's acknowledgement that clinical decision-making should be based on the relationship between physicians and their patients is important and in the best interest of people with cancer and sickle cell disease."

In November 2018, ASCO, ASH, CDC, and NCCN representatives met in-person to discuss concordance and variation among current guidelines for chronic pain management and develop a strategy to resolve inconsistencies, as well as improve communication of existing recommendations. External reviews had previously identified perceived inconsistencies among existing guidelines and had noted concern that such inconsistencies may be causing inadvertent confusion in the healthcare community.¹ The organizations also discussed issues related to the CDC guidelines and agreed jointly to seek clarification of the guidelines regarding their applicability to patients with cancer and sickle cell disease. Following the meeting, ASCO, ASH, and NCCN sent a letter to CDC urging the clarification.

"People with sickle cell disease suffer from severe, chronic pain, which is debilitating on its own without the added burden of having to constantly appeal to the insurance companies every time a pain crisis hits and the initial request is

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denied,” said ASH President Roy Silverstein, MD. “We appreciate CDC’s acknowledgement that the challenges of managing severe and chronic pain in conditions such as sickle cell disease require special consideration, and we hope payers will take the CDC’s clarification into account to ensure that patients’ pain management needs are covered.”

Reference

1. Meghani SH, Vapiwala N. Bridging the critical divide in pain management guidelines from the CDC, NCCN, and ASCO for cancer survivors. *JAMA Oncol* 2018;4:1323–1324.

MD Anderson’s Dr. Ronald Walters Named New Board Chair for National Comprehensive Cancer Network

NCCN announced the election of Ronald Walters, MD, to the role of Chair of the Board of Directors, while Ruth O’Regan, MD, was named Vice Chair.

“Defining and advancing high-quality, high-value, patient-centered cancer care globally requires input and oversight from experts across the cancer care continuum. Our board of directors—representing all 28 of the top academic cancer centers that make up our alliance—provides essential leadership and guidance on how NCCN can best help people with cancer to live better lives,” said Robert W. Carlson, MD, Chief Executive Officer, NCCN. “We are incredibly honored to have these 2 internationally respected physicians providing strong leadership and stewardship of our mission and vision going forward.”

Dr. Walters is Associate Head for the Institute for Cancer Care Innovation, and a breast cancer oncologist at The University of Texas MD Anderson Cancer Center, among other roles. He’s been a member of the NCCN Board since 2012, and has served on the NCCN Executive Committee since 2016. He focuses on healthcare reform and system changes to improve quality and address rising costs.

“NCCN’s mission aligns perfectly with my personal efforts to make sure people with cancer everywhere receive high-quality care,” said Dr. Walters. “I’m honored to take on an even larger role in ensuring providers can utilize NCCN Guidelines and best practice standards to elevate care worldwide.”

Dr. O’Regan is the Division Head of Hematology and Oncology and Associate Director for Clinical Research at the University of Wisconsin Carbone Cancer Center. She is an internationally recognized breast cancer physician whose research is focused on identifying new therapies for triple negative breast cancer.

“Working closely with NCCN gives me opportunities to further impact cancer care by helping the organization to share reliable information that keeps clinicians everywhere up-to-date on the latest life-saving research,” said Dr. O’Regan. “The NCCN Guidelines are the most frequently updated medical guidelines in any medical discipline, and they’re all available for free online. I look forward to helping NCCN continue to enhance everything they have to offer the oncology community.”

Drs. Walters and O’Regan succeed Timothy J. Eberlein, MD, from Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine, and Jan C. Buckner, MD, from Mayo Clinic Cancer Center, outgoing Chair and Vice Chair, respectively, both of whose contributions to NCCN have been invaluable and greatly appreciated. Board Treasurer Patrick J. O’Brien, MBA, from

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Our board of directors provides essential leadership and guidance on how NCCN can best help people with cancer to live better lives.

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Always have a ‘plan B.’ In this day and age, plan B might not be chemotherapy, it could be immunotherapy.

Fox Chase Cancer Center, and Secretary Lori C. Pickens, MHA, from Yale Cancer Center/Smilow Cancer Hospital continue as officers of the Board of Directors.

CAR T as Plan B: A Case Study on the Personal and Systemic Difficulties From Immunotherapy and Other Innovative Cancer Treatments

Jeffrey Backer, MD, a cancer survivor and doctor at Emergency Physicians of Central Florida, shared his story with a room full of oncology professionals at the NCCN 2019 Annual Conference. He was joined by nurse coordinator Alix Beaupierre, BSN, RN, OCN, in a conversation that was moderated by Frederick L. Locke, MD, both from Moffitt Cancer Center.

“Being a participant in a clinical trial is scary and daunting, despite my medical training and years of practice,” said Dr. Backer, who was initially treated for aggressive diffuse B-cell lymphoma in 2014. After his second relapse in 2016, he pursued chimeric antigen receptor (CAR) T-cell therapy at Moffitt. Dr. Backer described having to sign a 27-page consent form he barely read before the procedure, plus repeat instances of cytopenia and lingering immune system issues afterwards. Still, he described CAR T-cell therapy as a “miracle treatment” that saved his life, and even allowed him to go back to work in the ER.

He advised fellow patients with aggressive lymphoma to “always have a ‘plan B.’ In this day and age, plan B might not be chemotherapy, it could be immunotherapy.”

Ms. Beaupierre agreed that Moffitt had a difficult start providing appropriate patient and family information to those seeking CAR T-cell therapy, but they learned quickly. Initially, patients had that overwhelming 27-page consent form to review without one-to-one education time with a nurse. Now, patient and family education is provided and reviewed with each patient by a nurse, in the format of easily readable 1- to 2-page handouts, and has further evolved to include a calendar so patients and their caregivers have a visual and tangible tool outlining the timeline of care. They have begun implementing peer-to-peer counseling, connecting new patients to others who’ve been through the process already. The patient and family experience has been improved due to Moffitt’s nursing team’s efforts to provide dedicated education on the common side effects for CAR T-cell therapy, such as high fevers, neurotoxicity, and other potentially life-threatening symptoms that can occur shortly after treatment.

Dr. Locke made a point to say that the side effects are generally manageable.* He also assured community clinicians that they have an important role to play with their patients before and after immunotherapy, but asked that they refer their patients to centers of excellence for CAR T-cell therapy as early as possible—possibly even as soon as the first line of treatment fails to control lymphoma—because the process of planning and then preparing T cells can take a long time.

The coverage and reimbursement process can be another source of delays and difficulties. Immediately following the keynote conversation, NCCN hosted a roundtable discussion focused on how to increase access to innovative therapies and opportunities to break down any unnecessary barriers to care.

The NCCN Roundtable Discussion: Emerging Issues in Oncology—Ensuring Access to, and Delivery of, Innovative Therapies and Patient-Centered Care in Oncology was moderated by Clifford Goodman, PhD, Senior Vice President of The Lewin Group, and included Dr. Locke, along with the following additional panelists:

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- Stefanie Joho, Research/Patient advocate and consultant
- Jennifer Malin, MD, PhD, UnitedHealth Group
- John W. Sweetenham, MD, Huntsman Cancer Institute at the University of Utah
- Lalan S. Wilfong, MD, Texas Oncology

The conversation focused on the impact the high cost of care is having on patients with cancer, from medication costs to hospitalization costs. The issue of adequate reimbursement for CAR T-cell therapy was also discussed, amid concerns about growing disparities for hospitals that can't absorb the financial loss of treating someone on Medicare. Questions about acceptable profit margins along the supply chain and across the care continuum came up.

The panelists also addressed the recently proposed National Coverage Determination (NCD) from CMS. As proposed, the NCD does ensure coverage, but requires the collection of data on how patients respond to treatment. This requirement ensures that immunotherapy will primarily take place at tertiary care facilities with hematopoietic cell transplantation experience, which, panelists noted, already have the infrastructure in place to manage complex cases and collect relevant data.

Dr. Sweetenham stated that he found the NCD to be a reasonable and achievable approach, calling it "short term, a very good decision." He continued, "Patient-reported outcomes (PROs) in general may go well beyond quality-of-life issues. From what we've seen, we can even predict median survival based on PROs, and use them to figure out the best approach for the patient."

Ms. Joho said she agreed on the importance of learning from the people actually being treated, "Until patients are seen as co-investigators, we're limiting the scope of what we can learn from clinical trials."

The NCCN 2019 Annual Conference reflected this growing role for patients and advocates through the Patient Advocacy Pavilion in the main Exhibition Hall. This year marked a new record in patient and advocacy representation, with 18 groups exhibiting at the conference and another 10 providing materials.

There are several forums coming soon where NCCN will continue to amplify these important voices, including the NCCN Patient Advocacy Summit: Delivering Value for Patients Across the Oncology Ecosystem, which will be held at the National Press Club in Washington, DC, on December 11. Visit [NCCN.org](https://www.nccn.org) for a list of all upcoming events.

*For more information on how to treat these side-effects, NCCN worked with the ASCO on the free NCCN Guidelines for Management of Immunotherapy-Related Toxicities (available at [NCCN.org](https://www.nccn.org)) and a related patient-information infographic (https://www.nccn.org/images/pdf/Immunotherapy_Infographic.pdf).

NCCN Recognizes Five Individuals for Outstanding Achievements in Improving Cancer Care

NCCN announced the recipients of a series of awards honoring individuals whose significant contributions fueled progress in improving and facilitating quality, effective, efficient, and accessible cancer care over the past year.

The 2019 awardees were:

- Timothy J. Eberlein, MD, Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine
- Margaret A. Tempero, MD, UCSF Helen Diller Family Comprehensive Cancer Center

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There are two components that make this organization unique: great leadership and a passionate staff.

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“We hope this research will lead to a better understanding of how to improve outcomes for people with colorectal, biliary tract, esophageal, and other cancers.”

- Richard Hoppe, MD, Stanford Cancer Institute
- Michael Kolodziej, MD, ADVI
- Jennifer Burns, NCCN

Outgoing Board of Directors Chair Dr. Eberlein was presented with a Board of Producers Award. He was applauded for his reasonable and fair leadership approaches, his availability for advice, and his emphasis on fostering collaboration throughout the greater cancer care community.

“I think there are 2 components that make this organization unique: great leadership and a passionate staff,” said Dr. Eberlein. “It’s a privilege to be part of the positive impact NCCN has for millions who suffer from cancer all over the world.”

Another Board of Producers Award went to Dr. Tempero in honor of her long history of contributions to NCCN, which include chairing the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) Panel for Pancreatic Cancer, membership on various other panels, serving on 11 committees, involvement with the Policy Advisory Group, and helming *JNCCN—Journal of the National Comprehensive Cancer Network* as Editor-In-Chief since 2014.

“I’m so proud of this organization and feel privileged to have been a part since the very beginning,” said Dr. Tempero, while receiving her award. “I have seen impressive innovation over the years while on this amazing journey with NCCN.”

Dr. Hoppe received the Rodger Winn Award for expert judgment and commitment to excellence in service of the NCCN Guidelines. As the founding Chair of the NCCN Guidelines Panel for Hodgkin Lymphoma and current member of 2 additional panels, Dr. Hoppe has earned a reputation for his collegial and respectful manner, compassion, thoughtfulness, and preparedness. The award is in memory of the first leader of the NCCN Guidelines program.

Dr. Kolodziej was honored as a Partner in Cancer Care in appreciation for his efforts to engage policymakers, employers, payers, and others to improve the accessibility of high-quality cancer care. He described his work with NCCN as “a tremendous responsibility, a tremendous honor, and one of the best parts of my career.”

Jennifer Burns is a Guidelines Coordinator with NCCN’s Clinical Information Operations team. She was named the Pat Daulerio Employee of the Year Award recipient by her peers at NCCN. The award—which honors the memory of a longtime employee in NCCN’s Meetings department—is bestowed on a dedicated staff member who particularly exemplifies the Core Values of NCCN.

“I’m so grateful to be a small part of the mission I believe in so much,” said Ms. Burns.

NCCN Awards Grants to Investigators to Study Trifluridine and Tipiracil in Various Cancers

The NCCN Oncology Research Program (ORP) has funded 3 investigators from NCCN Member Institutions through a collaborative scientific research relationship with Taiho Oncology, Inc. to further evaluate the clinical effectiveness and safety of trifluridine and tipiracil (TAS-102) for treatment of various advanced, solid tumors.

The following studies were awarded funding through NCCN ORP:

- Patrick Boland, MD, Roswell Park Comprehensive Cancer Center, A Phase II Study of TAS-102, Irinotecan and Bevacizumab in Pre-treated Metastatic Colorectal Cancer (TABASCO)

- Amit Mahipal, MBBS, Mayo Clinic Cancer Center, Phase II Trial of trifluridine/tipiracil in Combination with Irinotecan in Biliary Tract Cancers
- Sarbajit Mukherjee, MD, MS, Roswell Park Comprehensive Cancer Center, Use of Trifluridine/tipiracil and Oxaliplatin as Induction Chemotherapy in Resectable Esophageal and Gastroesophageal junction (GEJ) Adenocarcinoma

"NCCN ORP congratulates Drs. Boland, Mahipal, and Mukherjee on their awards," said Wui-Jin Koh, MD, Chief Medical Officer, NCCN. "We look forward to working with them to learn more about how patients with different cancers respond to this treatment, particularly in combination with other agents. We hope this research will lead to a better understanding of how to improve outcomes for people with colorectal, biliary tract, esophageal, and other cancers."

"Taiho Oncology is excited to collaborate with the NCCN ORP to further the investigation of trifluridine/tipiracil in metastatic cancer," said Martin Birkhofer, MD, Senior Vice President and Chief Medical Officer, Taiho Oncology, Inc. "These awards will advance critical clinical research and reflect Taiho's commitment to improving the lives of people with colorectal, gastric, and other advanced cancers."

Submissions were peer reviewed by a Scientific Review Committee, which consisted of medical oncologists from NCCN Member Institutions. The funded concepts were selected based on several criteria, including scientific merit, existing data, feasibility, and the types of studies necessary to further evaluate trifluridine/tipiracil. The studies are expected to start enrolling patients in the next 10 months and be completed within 2 years.

The NCCN ORP draws on the expertise of the investigators at NCCN Member Institutions to facilitate all phases of clinical research in order to advance therapeutic options for people with cancer. To learn more about the NCCN ORP and ongoing clinical trials, visit NCCN.org/ORP.

NCCN Announces Six Quality Improvement Projects in Gastric Cancer Care Approved for Collaboration with Lilly Oncology

The NCCN Oncology Research Program (ORP) and Eli Lilly and Company (NYSE: LLY) today announced 6 projects that aim to improve the delivery of gastric and gastroesophageal junction (GEJ) cancer care in the United States. The quality improvement studies will focus on methods of intervention that can be implemented across a variety of different oncology practice settings. These projects are eligible to receiving funding from Lilly Oncology after completing contract negotiations. Forty-nine letters of intent were submitted in response to the RFP and 19 full proposals were requested for review.

"As part of our mission to facilitate care that helps patients live better lives, we're honored to support research that enhances outcomes and experiences for people with gastric and GEJ cancers," said Wui-Jin Koh, MD, Chief Medical Officer, NCCN. "This project is intended to identify disparities in care between the community and academic setting, and define scalable, shareable solutions that will rapidly improve adherence to guidelines and quality of care."

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“NCCN is honored to support research that enhances outcomes and experiences for people with gastric and gastroesophageal junction cancers.”

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The following studies were selected by the NCCN ORP:

- Dan G. Blazer III, MD; Daniel P. Nussbaum, MD; Linda M. Sutton, MD; Duke University Health System and Duke Cancer Network Affiliates; The DCN Passport: A Novel, Patient-Centered Approach to Improve Care for Gastric/Gastroesophageal Junction Cancer Across an Academic-Community Oncology Network
- Efrat Dotan, MD; Fox Chase Cancer Center; Improving the Approach to and Management of the Older Patient with Metastatic Gastric Cancer
- Jae Kim, MD; City of Hope National Medical Center; Telehealth Intervention for Self-Management of Dietary Quality of Life After Gastric Cancer Surgery
- Veena Shankaran MD, MS; University of Washington/Seattle Cancer Care Alliance/Fred Hutchinson Cancer Research Center; Randomized Pragmatic Trial of a Proactive Financial Navigation Intervention in Patients with Newly Diagnosed Gastric and Gastroesophageal Junction Adenocarcinoma
- Qiuling Shi, PhD; Loretta A. Williams, PhD; The University of Texas MD Anderson Cancer Center; Symptom Management Through an Automated Alert System to Improve Adherence During Systemic Therapy for Patients with Gastric/Gastroesophageal Junction (GEJ) Cancer
- Kuang-Yi Wen, PhD; Sidney Kimmel Cancer Center (SKCC) at Jefferson; mChemoCoping – GC: A Text Messaging System Enabling Real-Time Monitoring and Management of Chemotherapy Side Effects Among Patients with Gastric Cancer (GC)

“NCCN ORP congratulates all of the collaborators, and looks forward to their contributions to the future of gastric and GEJ cancer care,” said Dr. Koh.

“Lilly is proud to work with the NCCN ORP to research better ways for delivering high-quality cancer care to patients with this aggressive disease,” said Maura Dickler, MD, Vice President of Late Phase Development, Lilly Oncology. “By utilizing novel approaches and advancing technology, these studies will help us to address some of the largest disparities in care that exist for patients undergoing treatment for gastric and GEJ cancers.”

The NCCN ORP was responsible for the Request-for-Proposals (RFP) process, application review and evaluation. A committee led by NCCN and including a medical representative from Lilly determined which proposals would be eligible to receive funding. Project funding will be provided directly by Lilly upon mutual agreement of project terms and conditions. The studies will be conducted over a period of 2 years.

The NCCN ORP fosters innovation and knowledge discovery that improves the lives of people with cancer by supporting investigator-initiated trials at NCCN Member Institutions and their affiliates. To date, it has supported more than 140 studies, with numerous publications in peer-reviewed journals.