NCCN Statement on FDA Leadership and Vision for the Future

The FDA plays a critical role in the ability of patients to benefit from medical progress and safe and effective scientific breakthroughs. As such, the FDA requires a leader who will ensure that evidence-based, sound decision-making is preserved so that patients can live better lives.

NCCN, an alliance of 27 leading academic cancer centers in the United States, is dedicated to improving the quality and effectiveness of care provided to patients with cancer. As such, NCCN believes that high-quality cancer care depends on safe and effective products for patients, which are then reflected in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) and compendia, such as the NCCN Drugs & Biologics Compendium (NCCN Compendium), that patients, providers, and commercial and private payers use to make treatment and coverage policy decisions. In turn, NCCN looks forward to working with the future FDA Commissioner to ensure that, as therapies and products are approved, NCCN can continue to promote the importance of continuous quality improvement through updates to the NCCN Guidelines, NCCN Compendium, and other derivative products.

Specifically, NCCN hopes to work with the next commissioner to pursue this goal as the agency implements the 21st Century Cures Act and seeks to reauthorize important programs this year. In addition, NCCN hopes the following will be priorities of the new leadership:

- Emphasize stable, consistent funding to continue to reduce review times and thus improve access for patients: according to researchers at the Tufts Center for the Study of Drug Development, the time required for the FDA approval phase of new drug development (ie, time from submission until approval) has been cut from an average of 2.0 years for the approval phase at the start of PDUFA to an average of 1.1 years more recently.
- Provide important guidance to industry: just as NCCN provides valuable evidence and guidance to patients, clinicians, and payers, the FDA provides a large body of technical guidance to industry that clarifies the drug development pathway for many diseases, and meets with companies during drug development to provide critical advice on specific development programs.
- Promote appropriate care opportunities for patients with cancer, including preventive opportunities (such as strong regulation of tobacco and related products through the Center for Tobacco Products), clinical trial access and availability, and accelerated approval for rare diseases.

Consistent with these goals, Robert W. Carlson, MD, Chief Executive Officer of NCCN, praises the nomination of Scott Gottlieb, MD, to serve as the next FDA Commissioner. “We deeply respect Dr. Gottlieb’s experience in healthcare and particularly his experience with the issues that patients with cancer and providers face, and we look forward to working together to accomplish the goal of high-quality cancer care for all Americans.”

For more information about NCCN’s oncology policy initiatives and to view comment letters and statements sent by NCCN, visit NCCN.org/policy.

NCCN and Pfizer Address Quality Improvement in Breast Cancer Through Clinical Pathways

Evidence- and systems-based standardization of clinical processes, such as the NCCN Guidelines, support decision-making and quality improvement (QI) in the care of patients with cancer. Moreover, clinical pathways have emerged as point-of-care informational tools used by healthcare providers to improve quality of care based on the most current medical evidence and recommendations within the NCCN Guidelines.

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To further encourage and subsequently evaluate such programs, the NCCN Oncology Research Program (ORP) is working with Pfizer Independent Grants for Learning & Change (IGLC) to fund grant proposals for projects utilizing clinical care pathways to address a quality improvement QI initiative along the continuum of care for patients with breast cancer.

The Request for Proposals (RFP) issued by NCCN and Pfizer strongly encourages proposals that address the use of clinical pathways in community centers, low-resource centers, and centers that focus on the treatment of underserved patients with cancer. All US-based organizations, including NCCN Member Institutions, community affiliates of NCCN Member Institutions, other academic medical centers, and community cancer centers are encouraged to submit proposals.

“NCCN recognizes the emerging role of evidence-based clinical care pathways in cancer, and we are pleased to once again align with Pfizer IGLC to improve the quality of care of people with breast cancer, particularly those in underserved communities across the United States,” said Susan Most, RN, MBA, Director, Clinical Operations, NCCN ORP. The RFP seeks proposals in 2 specific areas of interest:

- Clinical Care Pathways Development
 - ▶ Develop and implement programs that improve efficiency and reduce costs to improve the quality of breast cancer patient care, including 1 or more of the following:
 - ◆ May be technology based, but it is not necessary
 - ◆ Support multidisciplinary collaboration
 - ◆ Include partnerships to improve access to multidisciplinary and specialized care
 - ◆ Improve patient adherence to medications and improve patient safety
 - ◆ Address patient emotional needs, psychosocial support, and advocacy issues
 - ◆ May incorporate virtual tumor boards, telemedicine, support services, etc.
 - ◆ May reduce payers’ administrative burden for authorization or providers’ burden for payment of care for patients with breast cancer
- Clinical Care Pathways Implementation or Education
 - ▶ Demonstration of care or process improvement in centers through the utilization of pathway programs
 - ▶ Integration into electronic health records
 - ▶ Implementation throughout healthcare system/affiliates
 - ▶ Strategies for provider training and education

The NCCN ORP, organized to obtain funding to support scientifically meritorious research studies at NCCN Member Institutions and other centers, leads the organization for review and evaluation of applications. A review committee, led by NCCN and including a medical representative from Pfizer, will decide which proposals will receive funding. Grant funding will be provided by Pfizer IGLC.

The RFP deadline is June 26, 2017. For more information about NCCN ORP and to view the RFP, visit NCCN.org/ORP.

NCCN Survey Reveals Oncology’s Concerns About Financial Distress, Patient Access to Care

Oncology community professionals are concerned about the ability of their patients to access cancer screening and treatment under the proposed American Health Care Act (AHCA), according to a survey conducted March 23–24, 2017, at the NCCN 22nd Annual Conference: Improving the Quality, Effectiveness, and Efficiency of Cancer Care at the Rosen Shingle Creek in Orlando, Florida.

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In addition, most of those surveyed believed that anticipated health policy changes would have negative impacts on their practices and on cancer research. More than 70% surveyed noted that patients have voiced concern about the anticipated repeal and replacement of the Patient Protection and Affordable Care Act (ACA), nearly two-thirds of whom have demonstrated increased levels of distress.

The survey was conducted during the period of congressional debate over the AHCA, which was withdrawn the afternoon of March 24 when it became clear there were not enough votes to pass the legislation. Responding to the survey were 76 oncology professionals, including academic and community physicians; nurses; physician assistants; pharmacists; industry professionals; payers; and patient advocates.

“The AHCA is tabled and the ACA remains in place, but concerns about access to cancer screening, care, and research funding remain. Today, patients are in limbo, not knowing what action the federal and state governments will take,” said Robert W. Carlson, MD, Chief Executive Officer of NCCN. “NCCN agrees there are ways to improve the current healthcare system for Americans with cancer, the clinical professionals who care for them, and payers. However, we are concerned for Americans with cancer that affordability, coverage of products and services in cancer treatment, and overall access will be impeded by allowing health insurers to set their own rates, or by providing states the ability to experiment with Medicaid coverage, without appropriate patient protections.”

The NCCN Trends survey found:

- 55% of respondents reported that the anticipated large-scale changes to federal healthcare policy would likely have a negative impact on their practice, research programs, or patient outcomes; 11% anticipated a positive impact; and 34% anticipated a neutral or mixed impact.
- When asked to select from a list of outcomes they anticipated would occur with changes to healthcare policy, those who anticipated a negative impact (55%) indicated:
 - ▶ Fewer patients will have access to health insurance (71%)
 - ▶ High deductibles will limit patient access to care (69%)
 - ▶ Cancer screening rates will decline due to higher copays and deductibles (63%)
 - ▶ Patients' preexisting conditions could be excluded from coverage (57%)
 - ▶ Federal funding for cancer research will decline (56%)
 - ▶ There will be less support for mental health services (50%)
- Those who expected a positive impact (11%) indicated:
 - ▶ With increased competition for insurers operating across state lines, health insurance premiums and copays will decrease for more patients, leading to improved access to care (50%)
 - ▶ Allowing medications to be imported will create more competition and reduced drug prices (50%)
 - ▶ Patient health savings accounts will lead to increased price transparency for medical procedures and medications, causing healthcare costs to decrease (38%)
- When asked, “What kind of impact do you believe changes in federal healthcare policy will have on your patients' ability to afford cancer care?”, 66% of respondents said the impact would be negative; 9% said positive; and 25% said the impact would be neutral.
- And, to the question, “To your knowledge, are your patients affected by health insurance policy and the possible repeal and replacement of the ACA?” respondents answered:
 - ▶ Yes, patients have expressed concern and demonstrated greater levels of distress (50%)
 - ▶ Yes, patients have expressed concern but no evidence of health impact (21%)

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- No, I have not seen any effects (29%)

“President Trump included 3 key elements in his approach to health coverage reform: repairing necessary aspects of the ACA, ensuring greater access, and lowering the total cost of care,” Dr. Carlson said. “We are ready to share our network’s expertise with lawmakers to deliver a value-based health policy to ensure that all Americans with cancer have access to high-quality, effective, and efficient cancer care.”

To view Dr. Carlson’s March 21, 2017, letter to Congress outlining NCCN’s concerns about the health policy proposal and patient access to care, visit https://www.nccn.org/professionals/meetings/oncology_policy_program/pdf/2017_NCCN_AHCA_Letter_Walden_03-22-2017.pdf

For more information about NCCN’s healthcare policy initiatives, visit [NCCN.org/policy](https://www.nccn.org/policy).

Nine New Disease Sites Added to the NCCN Radiation Therapy Compendium

NCCN continues to build its NCCN Radiation Therapy Compendium with the publication of radiation therapy (RT) recommendations from an additional 9 NCCN Guidelines:

- Acute Lymphoblastic Leukemia, Version 2.2016
- Basal Cell Skin Cancer, Version 1.2017
- Dermatofibrosarcoma Protuberans, Version 1.2017
- Gastric Cancer, Version 1.2017
- Hodgkin Lymphoma, Version 1.2017
- Merkel Cell Carcinoma, Version 1.2017
- Ovarian Cancer, Version 1.2017
- Squamous Cell Skin Cancer, Version 1.2017
- Thymomas and Thymic Carcinomas, Version 1.2017

Launched in March 2017, the NCCN RT Compendium now includes recommendations from 33 NCCN Guidelines. Additional cancer types will be published on a rolling basis over the coming months.

The NCCN RT Compendium provides guidance on all RT modalities recommended within the NCCN Guidelines, including intensity-modulated RT, intraoperative RT, stereotactic radiosurgery/stereotactic body RT/stereotactic ablative RT, image-guided RT, low dose-rate brachytherapy/high dose-rate brachytherapy, radioisotope, and particle therapy.

Transparency of NCCN Guidelines and Compendia development is central to the philosophy, policies, and procedures of NCCN. NCCN posts the policies and processes for developing and maintaining the NCCN Guidelines, which are available to the public on the NCCN Web site. Identification of newly published research, NCCN Member Institution review, external stakeholder submissions, and panel review occur on an ongoing basis with at least annual review performed for NCCN Guidelines for each disease.

The NCCN Guidelines are the recognized standard for clinical policy in cancer care and are the most thorough and most frequently updated clinical practice guidelines available in any area of medicine. Other NCCN Guidelines derivative products include:

- NCCN Drugs & Biologics Compendium (NCCN Compendium) contains authoritative, scientifically derived information designed to support decision-making about the appropriate use of drugs and biologics in patients with cancer. The NCCN Compendium is recognized by public and private insurers alike, including CMS and UnitedHealthcare as an authoritative reference for oncology coverage policy.
- NCCN Biomarkers Compendium contains information designed to support

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decision-making around the use of biomarker testing in patients with cancer.

- NCCN Chemotherapy Order Templates (NCCN Templates) include chemotherapy, immunotherapy, supportive care agents, monitoring parameters, and safety instructions based directly on recommendations within the NCCN Guidelines. Special instructions for self-administered chemotherapeutic agents are also provided.
- NCCN Imaging Appropriate Use Criteria (NCCN Imaging AUC) include recommendations pertaining to cancer screening, diagnosis, staging, treatment response assessment, follow-up, and surveillance to support clinical decision-making for patients with cancer. In 2016, NCCN was recognized by CMS as a qualified provider-led entity for creation of imaging AUC.

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For more information and to access the NCCN RT Compendium, visit NCCN.org/RTCompendium.

In Oncology Nursing, One Small Change Can Potentially Prevent Deadly Medical Error in Thousands of Patients

Vinca alkaloids, such as vincristine, are important chemotherapeutic agents that are highly effective at blocking the growth of cancer. Many patients who receive vincristine have a treatment regimen that includes other chemotherapy drugs that are administered intrathecally or injected into the spinal fluid with a syringe. If vincristine is mistakenly administered into the spinal fluid, it is uniformly fatal, causing ascending paralysis, neurologic defects, and eventually death. This mistake, however, is almost completely avoidable with one small administration change—instead of “pushing” intravenous vinca alkaloids via syringe, experts now call for these agents to be diluted into mini-intravenous drip bags.

During the Oncology Nursing Society (ONS) 42nd Annual Congress, MiKaela Olsen, MS, APRN-CNS, AOCNS, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, presented results of a center-wide effort to administer vincristine via mini-intravenous drip bags in a poster titled, “Putting an Old Oncology Nursing Practice to Bed: A Hospital-Wide Initiative Using Evidence-Based Practice to Standardize the Administration of Vinca Alkaloids Using a Minibag, Side-Arm Technique.”

This presentation comes on the heels of the NCCN’s 2016 Just Bag It! Campaign for the safe administration of vincristine.

According to Ms. Olsen and her colleagues, there are a number of barriers to standardizing vincristine administration in mini-intravenous drip bags. For instance, they note that nurses may believe the risk of extravasation to be higher than when pushing the agent. However, when analyzing 12 months of data at Johns Hopkins Hospital, Olsen et al found zero cases of extravasation among >1,300 mini-bag administrations of vincristine after the practice change.

“This was a big change in practice for bedside nurses at Johns Hopkins Hospital who had, to this point, always administered vesicants—other than continuous infusion vesicants—as an intravenous push through the side port of a free-flowing line. Using an evidence-based practice approach to tackle this clinical practice issue was key to our success,” said Ms. Olsen. “Just because it was always done a certain way does not mean it is the safest way.”

According to Ms. Olsen, the program facilitators provided background education to provider, pharmacy, and nursing staff that included a review of cases of patient harm with recommended guidelines for prevention and used the same technique that nurses were used to; however, instead of pushing the medication through a syringe, the nurse holds the mini-bag as it runs through the side port of a free flowing line.

“Nurses performed the procedure in a skills laboratory environment to ensure understanding of proper technique for safe mini-bag administration to prevent extravasation. This approach was key to our success,” said Ms. Olsen.

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Other barriers noted by the researchers include a lack of understanding of the risk of death associated with central nervous system administration of vincristine, as well as a lack of understanding of how to properly administer vinca alkaloids via drip bag.

To thwart these concerns at the time of the administration switch over, a short video was produced for the nursing staff, demonstrating the proper side-arm drip administration of vincristine, and all nursing staff attended a hands-on skill laboratory. Nursing staff are instructed to remain with the patient during the entire 5-minute administration, checking blood returns every 2 minutes and at the completion of the infusion. Additionally, labeling of vincristine must be clear and stated as such: “For intravenous use only—fatal if given other routes.”

“At Johns Hopkins Hospital, our pediatric colleagues made this successful practice change first. After thoughtful design of the step-by-step procedure, policy revisions, and collaboration between nursing and pharmacy, the change was implemented in adult oncology,” said Ms. Olsen. “Our staff feel confident that this new procedure is safe and that it is absolutely the right thing to do to prevent patient harm. Once we made the change, we did not look back. Eliminating the risk of harm was our number one priority.”

“The oncology nursing community plays an imperative role in the day-to-day, hands-on care and protection of patients with cancer. NCCN applauds Johns Hopkins, as well as the staff and faculty of our other member institutions, for their dedication to patient safety,” said Robert W. Carlson, MD, Chief Executive Officer, NCCN. “We are pleased that Ms. Olsen has the opportunity to share her findings with the esteemed ONS audience and hope her work is the impetus for others to change their practices.”

In 2005, Dr. Carlson, a medical oncologist, witnessed sequelae of such a tragedy with a 21-year-old patient with non-Hodgkin’s lymphoma named Christopher Wibeto. Wibeto was transferred to Dr. Carlson’s care after receiving incorrectly administered vincristine at another hospital. Dr. Carlson watched the young man go from having a likely curable condition to deteriorating and dying within 4 days. Motivated by this tragic experience, Dr. Carlson spearheaded a national effort to address this deadly error when he arrived at NCCN, enlisting the help of its Best Practices Committee, which is dedicated to improving cancer treatment protocols.

To ensure that vincristine is always administered properly, NCCN has issued guidelines advising healthcare providers to always dilute and administer vincristine in a mini-intravenous drip bag and never use a syringe to administer the medication. This precaution renders it impossible to accidentally administer the medication into the spinal fluid and greatly decreases the chances of improper dosage.

All 27 NCCN Member Institutions, including The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, have adopted policies in line with these guidelines, which are also recommended by the Institute for Safe Medication Practices, the Joint Commission, the WHO, and ONS.

In March 2017, NCCN issued a challenge to raise the number of reported adopters of these policies to 100 centers or practices. To report adoption of these practices, visit NCCN.org/JustBagIt.

In 2008, the NCCN Best Practices Committee led the charge for NCCN to begin publishing Chemotherapy Order Templates (NCCN Templates), which detail the most common regimens for many cancers and highlight safety parameters. These resources enable practitioners to standardize patient care, reduce medication errors, and anticipate and manage adverse events. There are >1,500 NCCN Templates for 86 cancer types, and they are used by >10,000 subscribers.