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MEDICAL WRITING & RESEARCH
ACCURATE, EVIDENCE-BASED, AND TIMELY MEDICAL CONTENT

Weekly Guideline Update

GUIDELINES THIS WEEK...

National Cancer Comprehensive Network (NCCN)

FDA

ASNC, AATS, ACC, AHA, ASE, EANM, HRS, IDSA, SCCT, SNMMI, and STS joint GL

KDIGO

European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases

NIH (COVID-19 final guidelines)

American Society of Clinical Oncology (ASCO)

Each Wednesday, I bring you news concerning updates to guidelines and recommendations by professional societies. This list is not all-inclusive, of course, but the following recent updates caught my attention.

If there are any guidelines I have missed this week that you would like to see included, please email me at jerm@day-storms.com.

National Cancer Comprehensive Network (NCCN)

The NCCN guidelines can be found at www.nccn.org.

- Bone Cancer Version 2.2024 — The latest update to the NCCN guidelines includes a new footnote regarding the use of denosumab, indicating that an FDA-approved biosimilar is considered an appropriate substitute for the original medication. This change reflects the growing acceptance and integration of biosimilars in clinical practice, offering potentially more cost-effective treatment alternatives without compromising efficacy or safety.

- Histiocytic Neoplasms Version 1.2024 — The NCCN has made many revisions to this set of guidelines since the previous version. A new section on the Characteristic Features of Histiocytic Neoplasms has been added. They now also recommend considering starting targeted agents at lower dose. Under relapsed/refractory, they have now removed the bullet regarding allogeneic hematopoietic cell transplant for highly select patients. Within the algorithm for tissue biopsy analysis of RDD, the NCCN has added a column regarding molecular testing and germline mutations. For suspected pulmonary Langerhans cell histiocytosis, they have strengthened the wording recommending pulmonary function tests (PFTs) AND high-resolution chest CT. Previously, the wording used included "with or without" high-resolution chest CT. A new section regarding the toxicities of other targeted therapies has been added to the Principles of Supportive Care.

- Hodgkin Lymphoma Version 3.2024 — The discussion section has been updated to reflect changes in the algorithm.

- T-Cell Lymphomas Version 2.2024 — In the latest NCCN guidelines update for T-Cell Large Granular Lymphocytic Leukemia (LGLL), ruxolitinib has been added as a category 2A recommendation for patients who do not respond to first-line therapy. It is also listed as a preferred option for second-line therapy following progressive or refractory disease to all first-line treatments, provided it has not been previously used. The guidelines include a new footnote advising that while ruxolitinib is typically dosed at 20 mg twice daily, dose reductions to 10 or 5 mg may be necessary due to the high prevalence of cytopenias in patients with LGLL, alongside recommendations for frequent complete blood count (CBC) monitoring.

- Testicular Cancer Version 1.2024 — Extensive changes have been made since the previous versions. Some of these changes include: (1) CT and MRI contrast recommendations updated throughout the guidelines. (2) The use of the term "salvage" was replaced throughout the guidelines. (3) For stage IIA, a new primary treatment option was added (nerve-sparing RPLND), and recommendations regarding RPLND were included. (4) MSI/MMR or TMB testing were added as possible third-line therapy options.

- Thyroid Carcinoma Version 2.2024 — Regarding denosumab, the NCCN now states that an FDA-approved biosimilar is an appropriate substitute.

FDA

The FDA's revised draft guidance on "Early Alzheimer's Disease: Developing Drugs for Treatment" updates previous guidance from February 2018. It advises on clinical development of drugs for Alzheimer's stages before overt dementia (Stages 1-3), termed "early AD" here, emphasizing biological-based diagnostic criteria and the disease's continuum. Recommendations cover diagnostic criteria, trial enrollment, and outcome measures, including clinical endpoints and time-to-event analysis. The document serves as a platform for dialogue on early AD drug development among various stakeholders. For more details, visit the FDA's guidance documents page.

The FDA's March 2024 paper on "Artificial Intelligence & Medical Products" focuses on ensuring the safe, effective, and ethical use of AI in healthcare, specifically in medical product development and utilization. These guidelines are a collective effort from the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH), and the Office of Combination Products (OCP). The document underlines a patient-centered, risk-based regulatory approach for AI applications throughout the medical product life cycle, from ideation to monitoring and maintenance.

The guidelines highlight four main areas:

- Foster Collaboration to Safeguard Public Health: Engage with developers, patient groups, academia, and international regulators to develop a collaborative regulatory approach focusing on transparency, governance, bias, cybersecurity, and quality assurance in AI medical products.

- Advance Regulatory Approaches Supporting Innovation: Provide regulatory clarity and predictability for AI use, addressing emerging issues, and ensuring robust evaluation and bias mitigation in AI algorithms.

- Promote Development of Standards, Guidelines, and Tools: Encourage safe, responsible AI use by refining evaluation considerations, promoting best practices for safety and performance monitoring, and ensuring data used in AI models are representative and fit for purpose.

- Support Research for AI Performance Evaluation and Monitoring: Support projects that address bias, promote health equity, and ensure continuous monitoring and adherence to standards for AI tools in medical product development.

ASNC, AATS, ACC, AHA, ASE, EANM, HRS, IDSA, SCCT, SNMMI, and STS

The new consensus guidelines from professional societies including ASNC, AATS, ACC, AHA, ASE, EANM, HRS, IDSA, SCCT, SNMMI, and STS focus on the importance of advanced imaging techniques in improving diagnostic accuracy and patient management of cardiovascular infections.

The guidelines advocate for the use of 18F-FDG PET/CT and radiolabeled leukocyte SPECT/CT in cases of suspected prosthetic valve endocarditis (PVE) and cardiovascular implantable electronic device (CIED) infections, especially when traditional echocardiographic findings are inconclusive or when there is a high clinical suspicion despite negative initial imaging. For native valve endocarditis (NVE), advanced imaging is recommended when transesophageal echocardiography (TEE) results are ambiguous, and there is a persistent high clinical suspicion.

These guidelines underscore a multidisciplinary approach, integrating clinical assessments with advanced imaging to enhance diagnostic precision, guide surgical decisions, and tailor treatment strategies, ultimately aiming to improve patient outcomes. They also call for ongoing research to refine the use of these imaging modalities in cardiovascular infection management, highlighting the dynamic nature of guideline development and the need for continuous evaluation of clinical practices.

KDIGO

The KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (CKD) is an update to the 2012 edition, focusing on optimal CKD evaluation, classification, risk assessment, and management of complications, while emphasizing medication management, drug stewardship, and patient-centered care. It introduces updated guidance on measuring estimated glomerular filtration rate (eGFR) and albuminuria, utilizing CKD risk prediction equations, and providing personalized treatment recommendations for kidney and cardiovascular risks. This update reflects recent advancements in diagnostics, treatment, and risk prediction, aiming to enhance CKD prognosis and management. Additionally, it underscores the importance of multidisciplinary teamwork and patient engagement in improving CKD care coordination and outcomes worldwide. The guideline also sets a new research agenda to fill knowledge gaps and advance CKD evidence and care.

European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases

The European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis, and Musculoskeletal Diseases has released evidence-based guidelines for managing osteoporosis in men. Acknowledging the condition's historical underdiagnosis in men, these guidelines emphasize the use of female reference databases for densitometric diagnosis, recommend the FRAX tool for fracture risk assessment, and support age-dependent intervention thresholds. Treatment should be tailored to the individual's fracture risk, with oral bisphosphonates as first-line therapy and denosumab or zoledronate as second-line. For men at very high risk, a sequential approach starting with a bone-forming agent is advised. The guidelines also highlight the importance of ensuring vitamin D and calcium intake, engaging in physical exercise, and maintaining a balanced diet. Patient perspectives have been incorporated, stressing rapid treatment initiation post-diagnosis. The guidelines aim to provide clear, actionable advice to improve the management and outcomes of osteoporosis in men.

NIH

The final update of the NIH COVID-19 Treatment Guidelines reflects recent scientific developments and marks the end of the federal COVID-19 Public Health Emergency. Updated sections focus on viral rebound and symptom recurrence, and therapeutic management for nonhospitalized adults and children with COVID-19, adjusting treatment based on vaccination status and risk factors. This concludes four years of evolving guidance to aid healthcare providers in treating COVID-19 patients. The guidelines will remain online until August 2024.

American Society of Clinical Oncology (ASCO)

The ASCO 2024 guidelines provide crucial recommendations for vaccinating adults with cancer, emphasizing the importance of immunization against infections to avoid treatment disruptions and improve outcomes. Key takeaways include ensuring patients are updated on seasonal and age-specific vaccines before beginning cancer treatment. It highlights the importance of pneumococcal, influenza, RSV, and COVID-19 vaccines for hospitalization prevention due to pneumonia, common in cancer patients. Additionally, the guideline addresses the timing for vaccine administration, advising ideally before cancer treatment starts. Safety concerns regarding live vaccines in cancer patients are discussed, recommending non-live vaccines instead. Furthermore, the guidelines advocate for vaccination of close contacts and caregivers of cancer patients to reduce transmission risks. These guidelines aim to optimize care and safeguard the health of individuals undergoing cancer treatment.