
SITC
2017
November 8-12
NATIONAL HARBOR
MARYLAND
Gaylord National Hotel
& Convention Center
sitc
Society for Immunotherapy of Cancer

November 8-12 • NATIONAL HARBOR, MD

SITC 2017

Variance From Evidence-Based Management of Immune-Related Adverse Events Among Healthcare Providers: Analysis of an Online Management Decision Tool

Krista Marcello, BA; Kevin L. Obholz, PhD; Timothy A. Quill, PhD; Jeffrey S. Weber, MD, PhD

sitc
Society for Immunotherapy of Cancer

#SITC2017

Presenter Disclosure Information

Krista Marcello, BA
Managing Editor, Clinical Care Options, LLC

The following relationships exist related to this presentation:

No relationships to disclose

The development of the resource in this presentation was made possible through unrestricted independent medical education grants supported by Merck & Co., Inc.; Merck KGaA; and Pfizer Inc.

There will not be discussions about the use of products for non-FDA approved indications in this presentation.

Background

- Immune checkpoint inhibitors are being integrated into the care of a rapidly increasing number of patients with many different tumor types
  - Profiles of toxicities, some of which are better tolerated than chemotherapy, are unique and require a specific knowledge base for optimal identification and management
  - Effective immune-related adverse event (irAE) management allows for optimal treatment and mitigates potentially serious treatment-related complications
- Many healthcare providers (HCPs) remain unfamiliar and inexperienced with managing the unique spectrum of irAEs

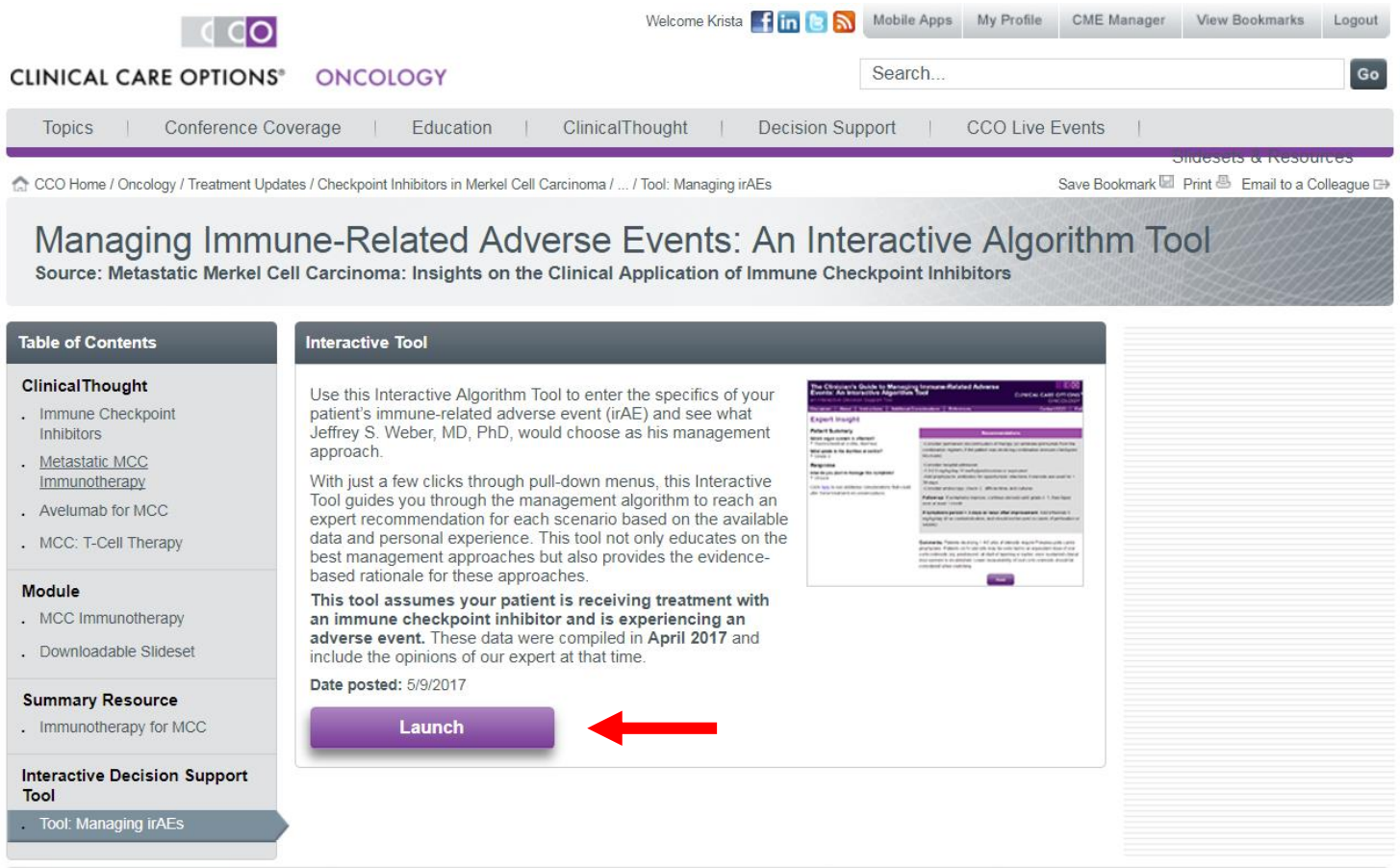
Methods

- CCO developed an online management support tool designed to give clinicians easy access to balanced, evidence-based management recommendations, based on
  - Organ system affected
  - Grade/severity of irAE (CTCAE)
- Recommendations from evidence-based guidance, peer-reviewed published literature, and Dr. Weber's personal clinical experience
- 2 versions of the tool
  - Initial version: data collected from 11/9/2016 through 7/21/2017
  - Updated version: data collected from 5/10/2017 through 9/27/2017
    - Recommendations updated based on available data and guidelines
    - Added categories "rheumatologic" and "other"

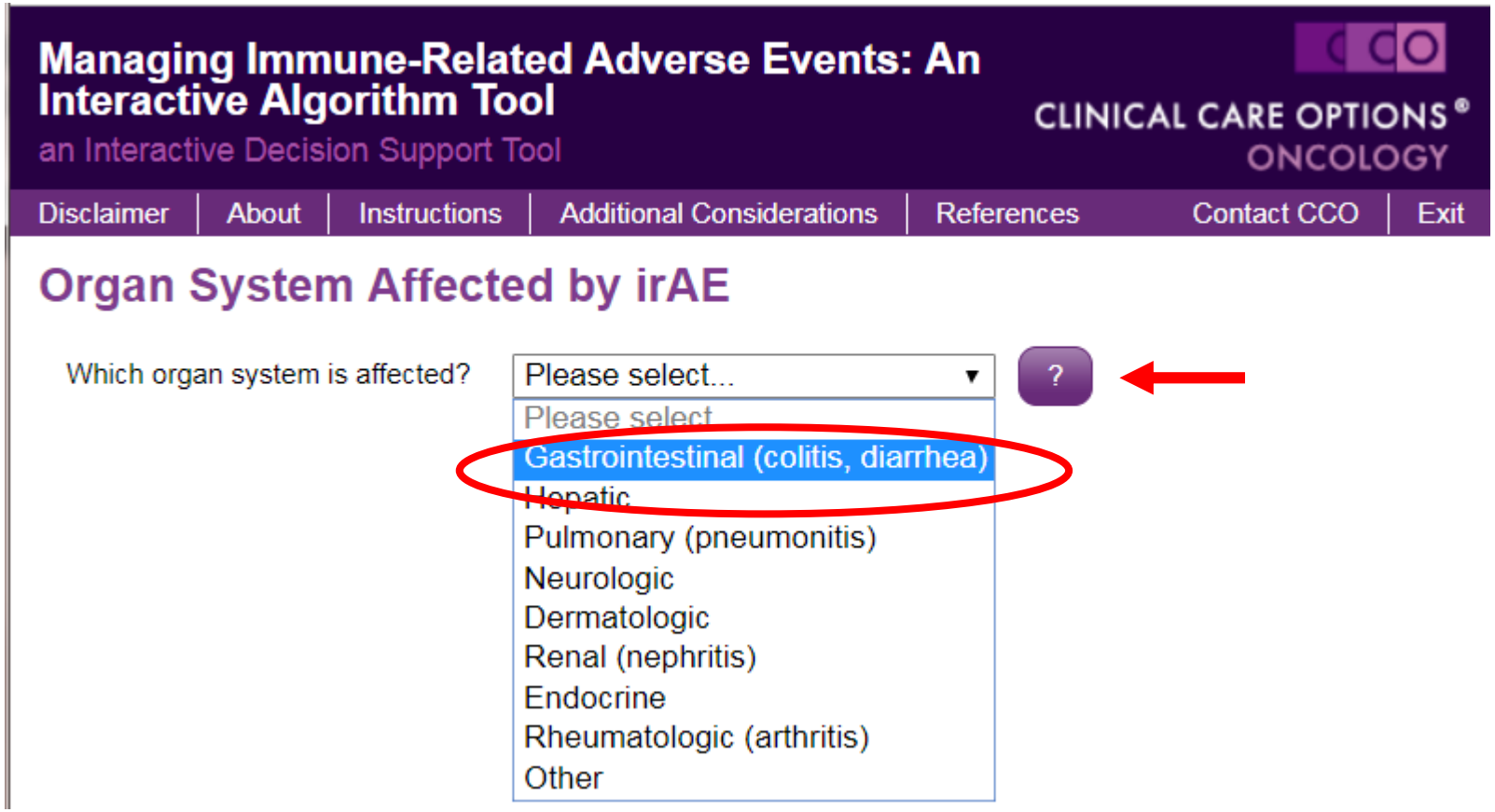
Methods

- Tool users were asked about their intended management plan before evidence-based recommendations were provided
- The current study includes an analysis of cases entered into the tool and comparison of the intended management of HCPs with the evidence-based recommendations in the tool
- Chi-square analysis was performed on the data collected from the tool for statistical significance of the variance of intended management vs evidence-based recommendations

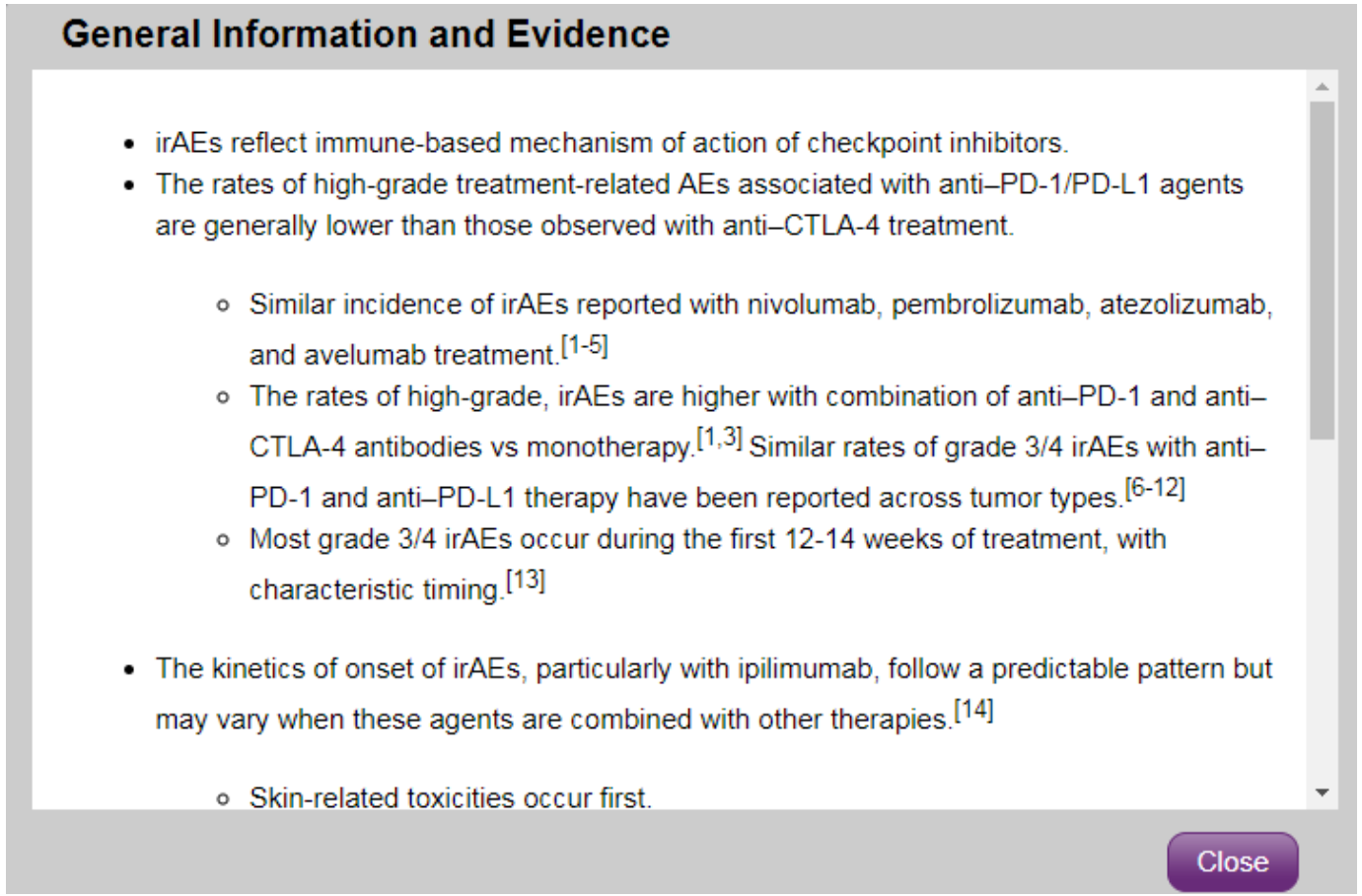
How to Use the Tool: clinicaloptions.com/immuneAEtool



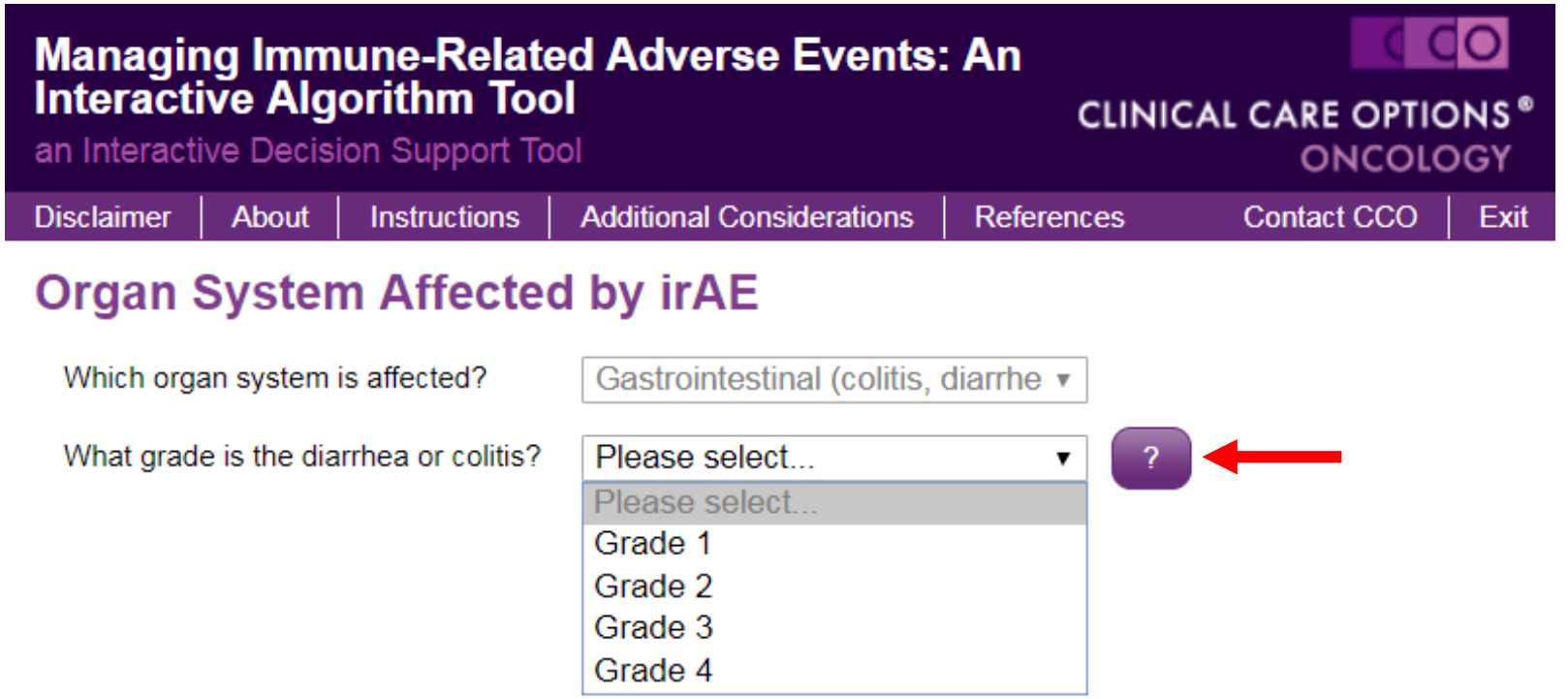
How to Use the Tool: clinicaloptions.com/immuneAEtool



How to Use the Tool: clinicaloptions.com/immuneAEtool



How to Use the Tool: clinicaloptions.com/immuneAEtool



How to Use the Tool: clinicaloptions.com/immuneAEtool

How to Use the Tool: clinicaloptions.com/immuneAEtool

Recommendations

-Consider permanent discontinuation of therapy (or eliminate ipilimumab from the combination regimen, if the patient was receiving combination immune checkpoint blockade)

-Consider hospital admission
-1.0-2.0 mg/kg/day IV methylprednisolone or equivalent
-Add prophylactic antibiotics for opportunistic infections if steroids are used for > 30 days
-Consider endoscopy; check C. difficile titres and cultures

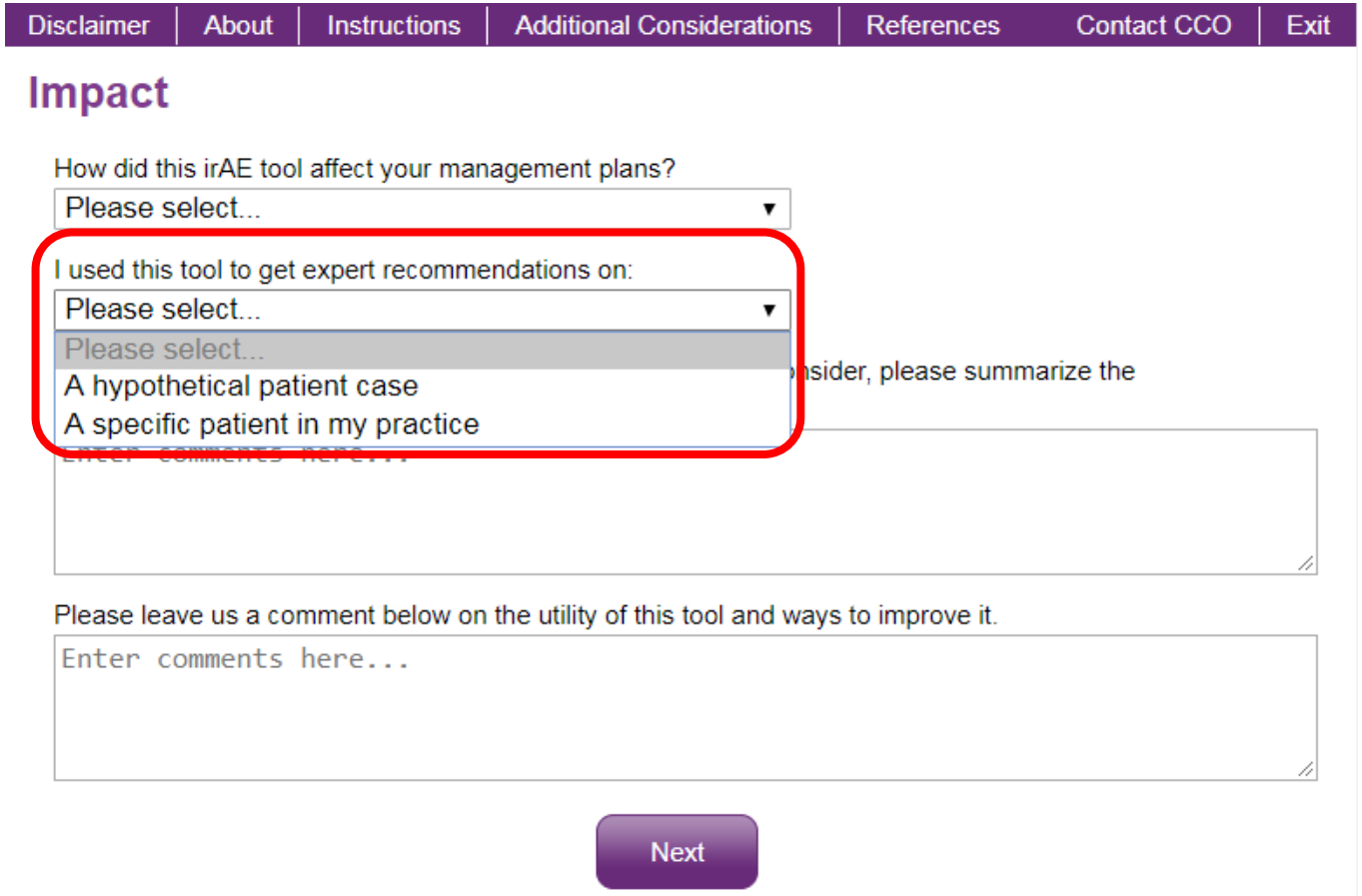
Follow-up: If symptoms improve, continue steroids until grade ≤ 1, then taper over at least 1 month

If symptoms persist > 3 days or recur after improvement: Add infliximab 5 mg/kg/day (if no contraindication, and should not be used in cases of perforation or sepsis)

Comments: Patients receiving > 4-6 wks of steroids require Pneumocystis carinii prophylaxis. Patients on IV steroids may be switched to an equivalent dose of oral corticosteroids (eg, prednisone) at start of tapering or earlier, once sustained clinical improvement is established. Lower bioavailability of oral corticosteroids should be considered when switching.

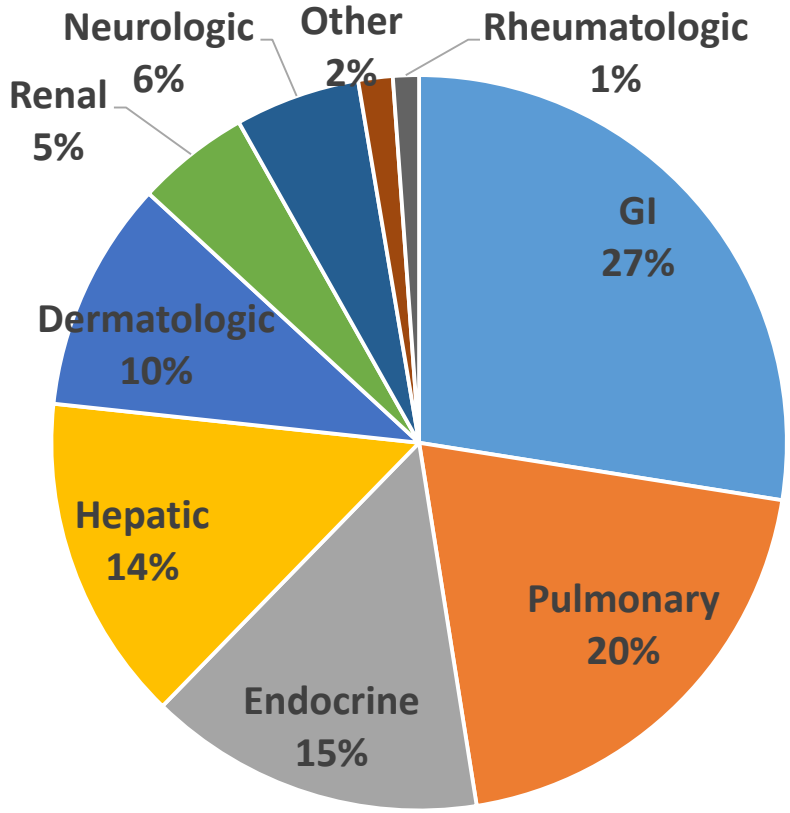
Next

How to Use the Tool: clinicaloptions.com/immuneAEtool

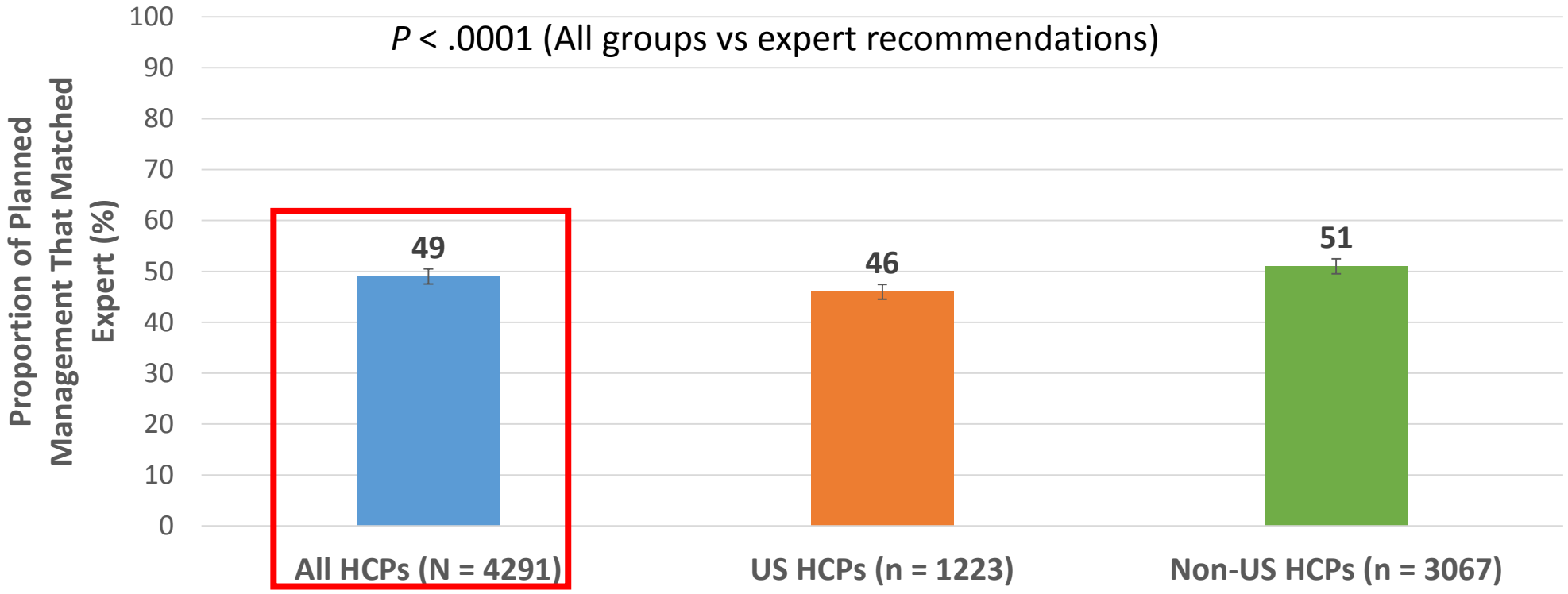


Cases Entered Into Tool by Organ System

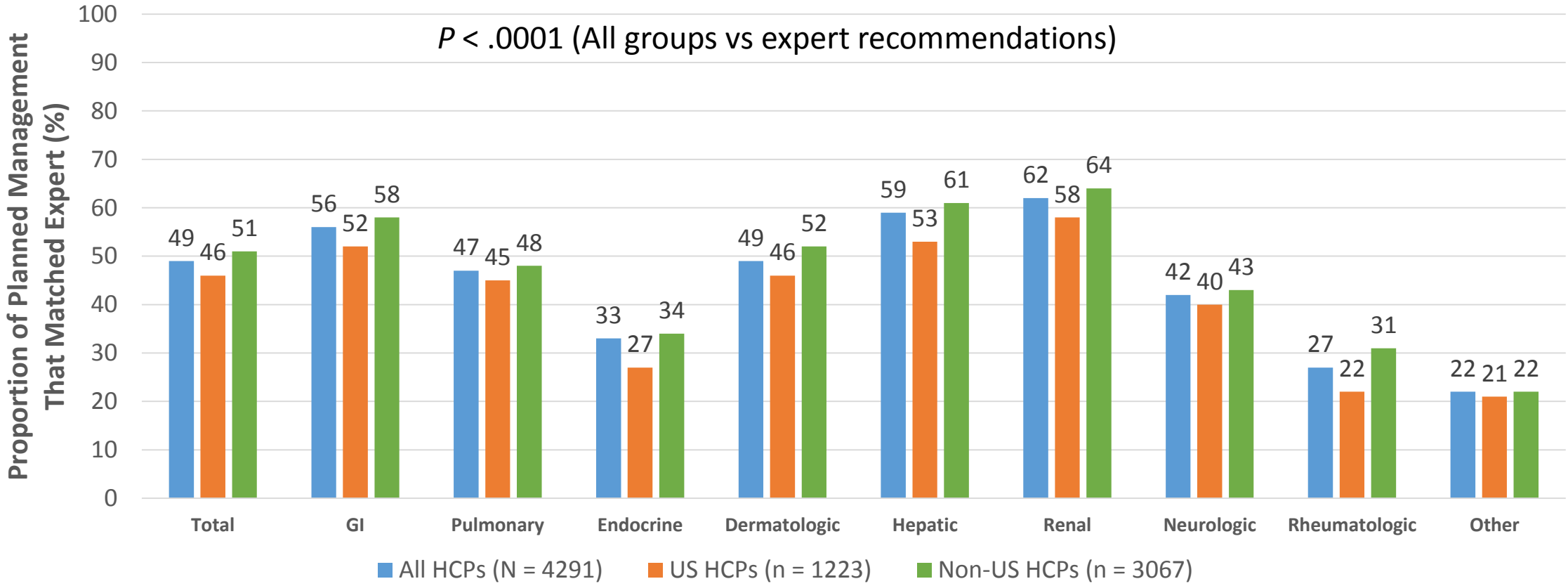
- In total, 4291 cases were entered into the tool by HCPs
- The most frequently entered cases were of GI origin (27%), followed by pulmonary (20%)
- "Rheumatologic" and "other" were added to the most recently updated tool and thus had the fewest cases



Planned Management of HCPs Compared With Evidence-Based Recommendations: Overall Cases Entered (N = 4291)

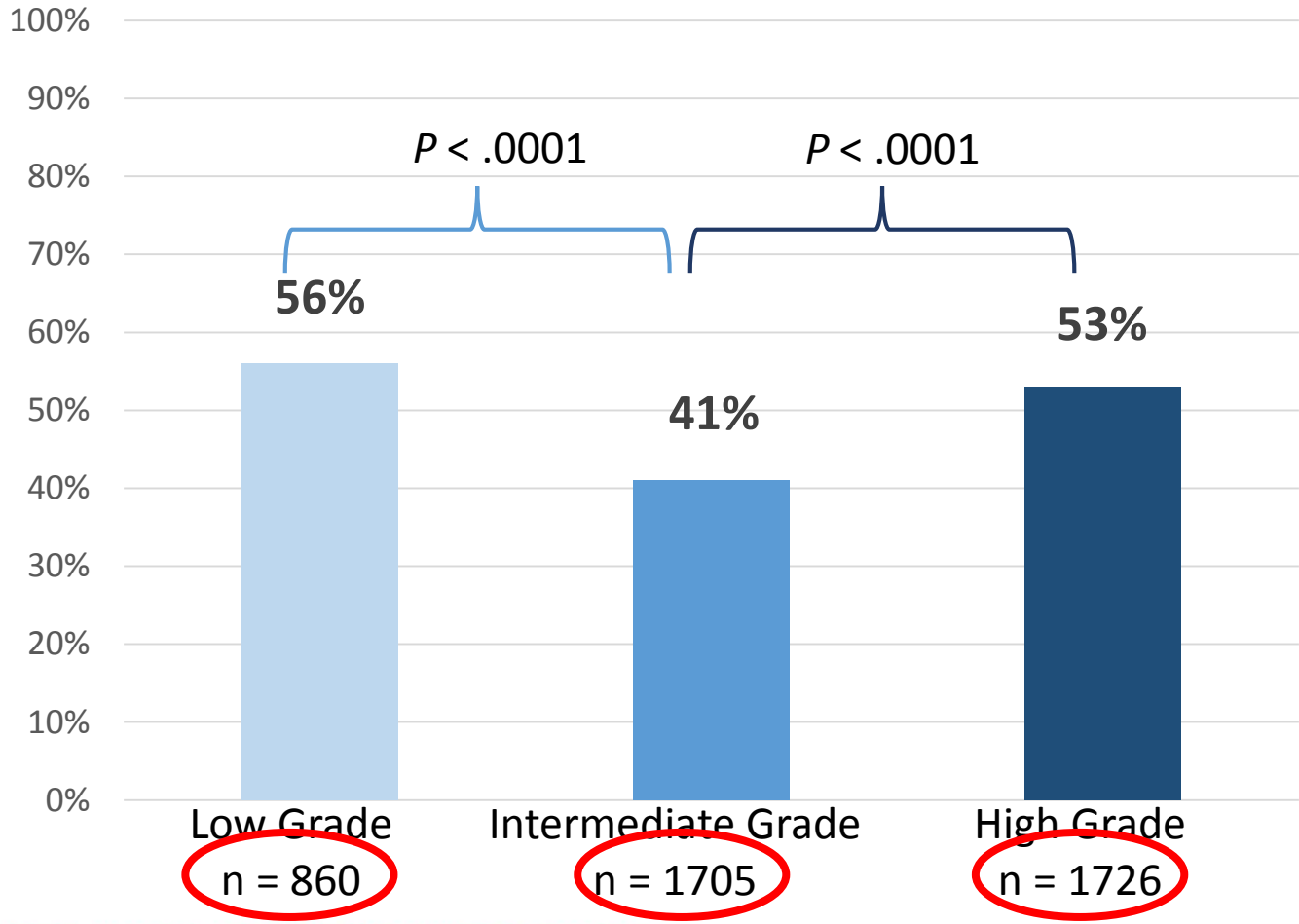


Planned Management of HCPs Compared With Evidence-Based Recommendations: Overall Cases Entered (N = 4291)



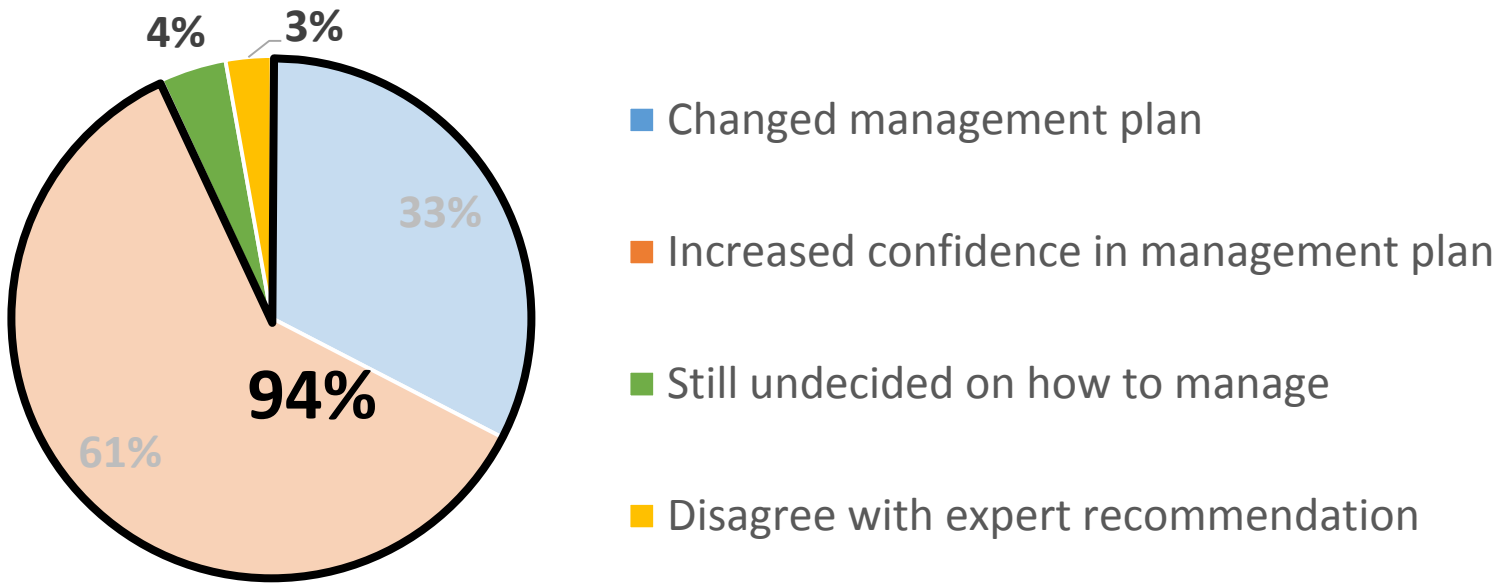
Planned Management of HCPs Compared With Evidence-Based Recommendations by Symptom Grade (N = 4291)

- Greatest variance between initial HCP management plan and evidence-based recommendation occurred with intermediate-grade events
- HCPs used the tool to research management of intermediate- and high-grade events twice as often as low-grade events



Impact of the Tool on Practice

- Of participants who answered the impact survey (n = 957):
  - **94%** indicated that the tool recommendations either confirmed or changed their management plan
  - **30%** were using the tool to manage a specific patient in their clinic



Lessons and Take-home Messages

- Despite available data, product inserts, and guidance on manufacturer Web sites, our analysis suggests many clinicians are not optimally managing irAEs associated with immune checkpoint inhibitor use
  - Overall, 49% of HCPs using the tool selected an initial management plan that matched evidence-based recommendations (46% US HCPs, 51% non-US HCPs; $P < .0001$)
  - Variance between HCP intended management and evidence-based recommendations was significant in each organ system
  - Lower concordance observed with intermediate vs low- or high-grade events
- A fair, balanced, evidence-based online irAE management tool is an important clinical resource that might improve patient care and safety
- The irAE tool will be updated regularly: **clinicaloptions.com/immuneAEtool**

Acknowledgments

- Jeffrey S. Weber, MD, PhD
- Colleagues and coauthors at Clinical Care Options
- Our clinician members
- Merck & Co., Inc.; Merck KGaA; and Pfizer Inc. for their support of our tool development