



Getting Ahead of irAEs: Fostering Change in Structural Systems for Disadvantaged Populations

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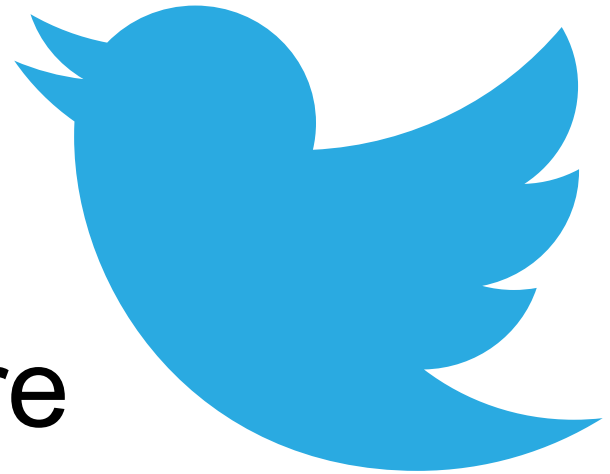
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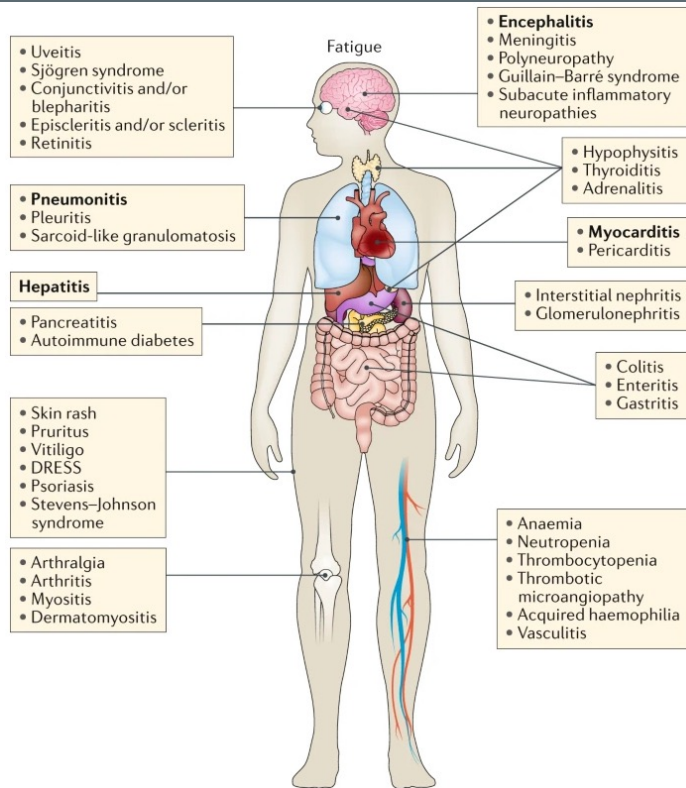
Learning Objective

Recommend improvements to structural systems to better support irAE management in historically disadvantaged patient populations

Immunotherapy is a “Double-edged Sword”

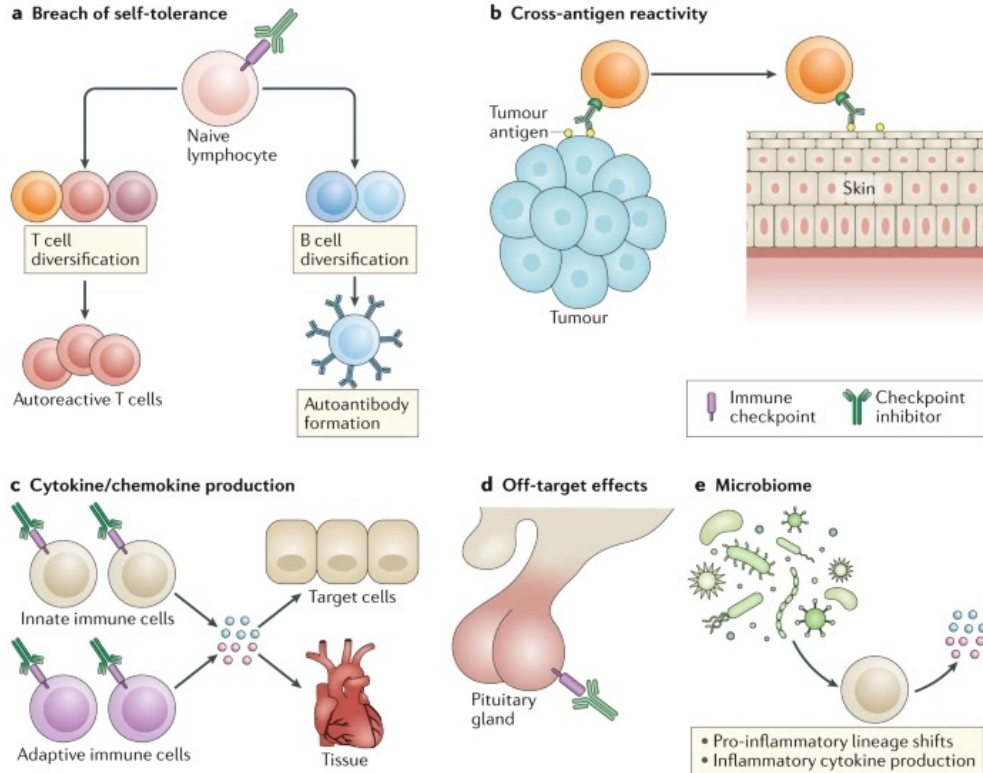


Overview of irAEs



- Disruption of the homeostatic mechanisms induces a unique spectrum of side effects called irAEs
- irAEs reported in 70-88% and ≥ 3 grade in 5-25% of patients
- Most common irAEs: dermatitis, enterocolitis, transaminitis, and endocrinopathies
- Most commonly reported irAEs of any grade: dermatologic toxicities
- Higher incidence of \geq grade 3 irAE: gastrointestinal toxicity
- If untreated, they can rapidly progress to life-threatening conditions and may also be fatal

Possible Mechanisms Underlying irAEs



Polling Question

How confident are you in promoting structural changes that mitigate care disparities for patients receiving immunotherapies?

- A. Not confident at all
- B. Somewhat confident
- C. Confident
- D. Extremely confident

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Results

General ASCO Guidelines

High level of suspicion that new symptoms are treatment-related.

Grade 1:

- ICI therapy should be continued with close monitoring.
- Exception of some neurologic, hematologic, and cardiac toxicities.

Grade 2:

- Hold ICI for most grade 2 toxicities.
- Consider resuming when symptoms and/or laboratory values revert to grade 1 or less.
- Corticosteroids (initial dose of 0.5 to 1 mg/kg/d of prednisone or equivalent) may be administered.

Grade 3:

- Hold ICI.
- Initiate high-dose corticosteroids (prednisone 1 to 2 mg/kg/d or methylprednisolone IV 1 to 2 mg/kg/d). Corticosteroids should be tapered over the course of at least 4 to 6 weeks.
- If symptoms do not improve with 48 to 72 hours of high-dose corticosteroid, infliximab may be offered for some toxicities.
- When symptoms and/or laboratory values revert to grade 1 or less, rechallenging with ICI may be offered; however, caution is advised, especially in those patients with early-onset irAEs.

Grade 4:

- Permanent discontinuation of ICI, with the exception of endocrinopathies that have been controlled by hormone replacement.

Action Items

- Educating patients, care givers, and health care providers
- Refining irAE management guidelines
- Standardizing reporting of irAEs
- Optimizing the choice of immunosuppressive agents
- Pursuing better understanding of irAEs
- Including high-risk patients
- Incorporating diagnostic tools to personalize irAE management
- Utilizing wireless technology and digital health
- Providing a platform to hear the missing patient's voice
- Sharing evolving data

Action Item 1: Educating Patients, Caregivers, and Health Care Providers



Old Model

Discharge instructions:
List of do's and don'ts
Medication reminders
Instructions to see your
doctor in a few weeks
Problem: Does not work.



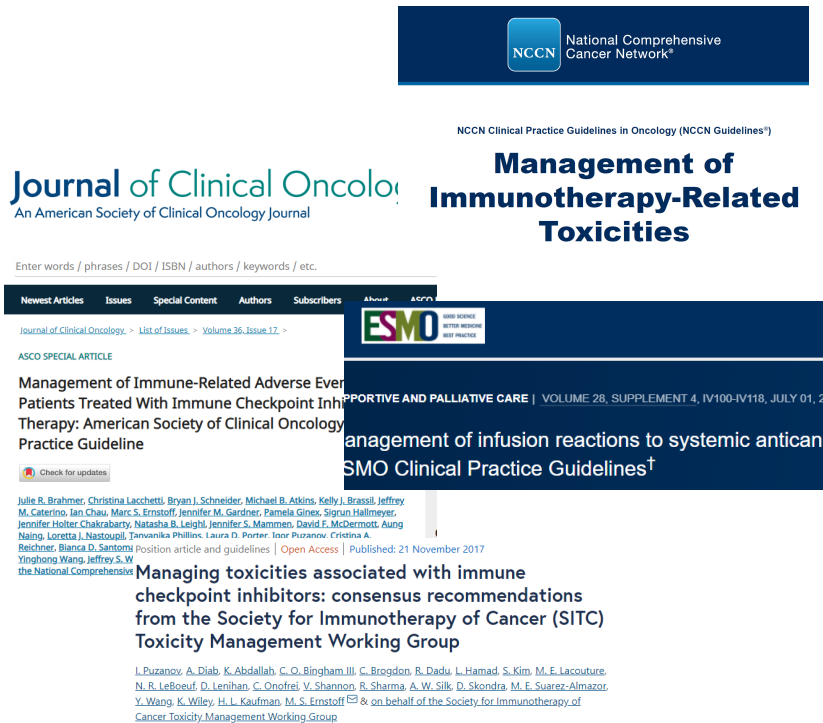
New Model

Patient assessment begins
at admitting.
Assess often to determine
patient's knowledge

- Use of drug-specific wallet cards, educational apps, social network, support group to provide information regarding irAEs and symptom monitoring
- Tailor patient education resources to preference, emotional, literacy and cultural needs of the patient

Action Item 2: Refining irAE Management Guidelines

- Convene irAE Management Summit
- Develop toxicity-specific management committees to create an evidence-based expert consensus guideline
- Publish the outcomes of the activities of the proposed summit
- Make it a regularly planned effort
- Bring in underrepresented groups



The image shows a composite of two web pages. The top page is the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for the Management of Immunotherapy-Related Toxicities. The bottom page is an ASCO Special Article titled "Management of Immune-Related Adverse Events in Patients Treated With Immune Checkpoint Inhibitor Therapy: American Society of Clinical Oncology Practice Guideline".

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)
Management of Immunotherapy-Related Toxicities

Journal of Clinical Oncology
An American Society of Clinical Oncology Journal

Enter words / phrases / DOI / ISBN / authors / keywords / etc.

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Journal of Clinical Oncology > List of Issues > Volume 36, Issue 17 >

ASCO SPECIAL ARTICLE

Management of Immune-Related Adverse Events in Patients Treated With Immune Checkpoint Inhibitor Therapy: American Society of Clinical Oncology Practice Guideline

Check for updates

Julie R. Brahmer, Christina Lacchetti, Bryan I. Schneider, Michael B. Atkins, Kelly J. Braxill, Jeffrey M. Caterino, Ian Chau, Marc S. Ernstoff, Jennifer M. Gardner, Pamela Ginex, Sigurn Hallmeyr, Jennifer Holter, Chakrabarty, Natasha B. Leighi, Jennifer S. Mammen, David E. McDermott, Aung Naling, Loresta J. Nastoupil, Tanwanika Phillips, Laura D. Porter, Igor Puzanov, Cristina A. Reischer, Bianca D. Santoni. Position article and guidelines | Open Access | Published: 21 November 2017
Yinghong Wang, Jeffrey S. W. on behalf of the Society for Immunotherapy of Cancer Toxicity Management Working Group

Supportive and Palliative Care | VOLUME 28, SUPPLEMENT 4, IV100-IV118, JULY 01, 2017

Management of infusion reactions to systemic anticancer drugs: American Society of Clinical Oncology Clinical Practice Guidelines†

Managing toxicities associated with immune checkpoint inhibitors: consensus recommendations from the Society for Immunotherapy of Cancer (SITC) Toxicity Management Working Group

I. Puzanov, A. Diab, K. Abdallah, C.O. Bingham III, C. Brogdon, R. Dadu, L. Hamad, S. Kim, M. E. Lacouture, N. R. LeBoeuf, D. Lenihan, C. Onofrei, V. Shannon, R. Sharma, A.W. Silk, D. Skondra, M. F. Suarez-Almazor, Y. Wang, K. Wiley, H. L. Kaufman, M. S. Ernstoff & on behalf of the Society for Immunotherapy of Cancer Toxicity Management Working Group

Action Item 3: Standardizing Reporting of irAEs

CTCAE does not capture all the irAEs adequately



Need for addition of more terms to the CTCAE for standardized capture of all irAEs.

Incorporate SITC CTCAE Task Force irAE-specific module into future versions of CTCAE.

Action Item 3: Approaches to Improved Screening and Identification of irAEs

- Electronic medical health record alerts
 - Raise awareness of symptoms potentially related to their treatment outside of oncology-specialized centers (such as emergency rooms)
- Immunotherapy wallet cards
 - Wallet cards clearly communicate who the patient is, current medications, and who should be contacted if needed.
 - Patients should be instructed to show the card to all health care providers they see

Contact your oncology provider's office if you experience any of these symptoms:

- Trouble breathing, wheezing, coughing, or chest pain
- Fever (oral temperature $\geq 101.0^{\circ}\text{F}$)
- Decreased urination, blood in urine, or swollen ankles
- Severe and worsening muscle pain or weakness
- Joint stiffness (unable to perform regular daily activities)
- Severe headaches, dizziness, confusion, change in vision, or eye pain
- Any new or worsening symptoms



IMMUNOTHERAPY WALLET ID CARD

PATIENT NAME: _____

EMERGENCY CONTACT NAME: _____

ONCOLOGY TEAM PRIMARY CONTACT: _____

CANCER DIAGNOSIS: _____

ONCOLOGY PROVIDER NAME: _____

PROVIDER HOURS: MON. THRU FRI. _____ AM to _____ PM

TEL. _____ AFTER-HOURS TEL. _____

This patient is receiving IMMUNOTHERAPY for cancer treatment. Side effects may differ from standard chemotherapy but with PROMPT recognition and management, most side effects are treatable. Please contact the oncology provider's office for assistance in managing immune-related adverse events.



IMMUNOTHERAPY WALLET CARD

NAME: _____

CANCER DX: _____

I-O AGENTS RCVD: CHECKPOINT INHIBITOR(S)

CAR-T VACCINES ONCOLYTIC VIRAL THERAPY

MONOCLONAL ANTIBODIES

DRUG NAME(S): _____

IMMUNOTHERAPY TX START DATE: _____

OTHER CANCER MEDICATIONS: _____

NOTE: IMMUNOTHERAPY AGENTS ARE NOT CHEMOTHERAPY AND SIDE EFFECTS MUST BE MANAGED DIFFERENTLY. (SEE BACK)

IMMUNOTHERAPY CARD

IMMUNE-MEDIATED SIDE EFFECTS*, COMMON WITH CHECKPOINT INHIBITORS VARY IN SEVERITY AND MAY REQUIRE REFERRAL AND STEROIDS. PATIENTS HAVE A LIFETIME RISK OF IMMUNE-RELATED SIDE EFFECTS.

*MAY PRESENT AS RASH, DIARRHEA, ABDOMINAL PAIN, COUGH, FATIGUE, HEADACHES, VISION CHANGES, ETC.—CONFERR WITH ONCOLOGY TEAM BEFORE CHANGING I-O REGIMEN OR STARTING SIDE EFFECT TREATMENT.






ONCOLOGY PROVIDER NAME _____

ONCOLOGY PROVIDER NO. _____

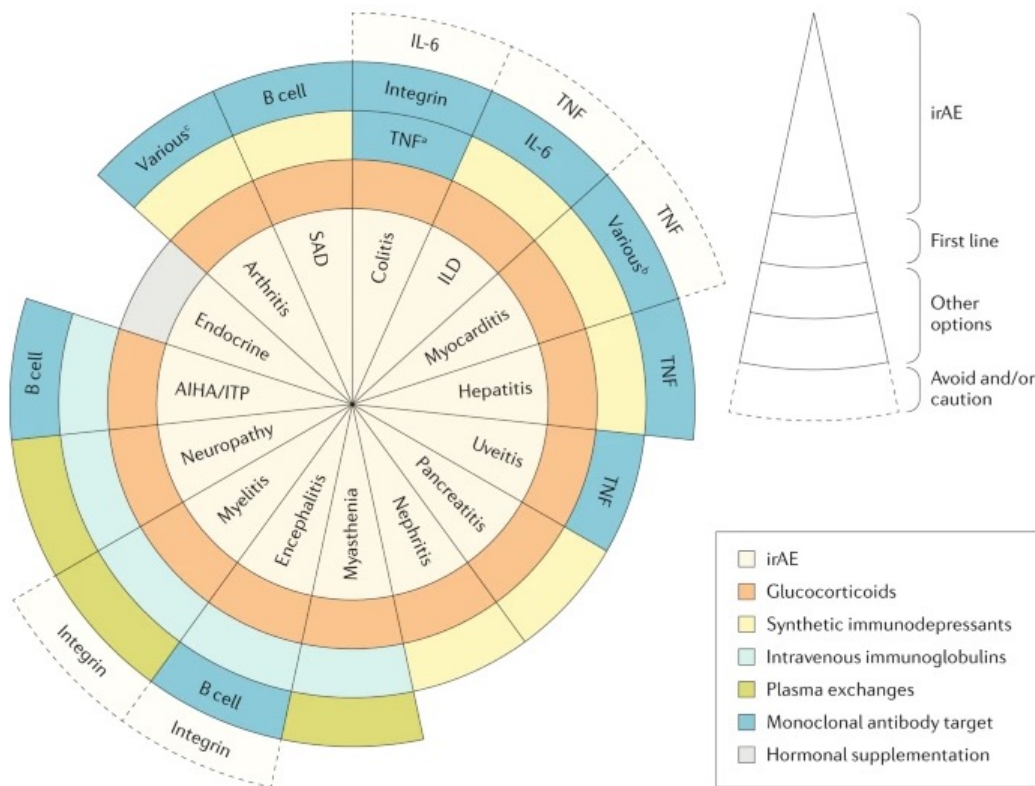
EMERGENCY CONTACT _____

CONTACT PHONE NO. _____

Action Item 3: Standardize Screening for irAEs and Coordination of Care

-  Standardize screening measures within the oncology clinic
-  Standardize nursing assessments
-  Standardize documentation and assessment of adverse events related to immunotherapy
-  Standardize screening timeframes
-  Standardize coordination of care

Action Item 4: Optimizing the Choice of Immunosuppressive Agents



- Data is evolving
- Conduct prospective studies to evaluate
 - Safety and efficacy of immunosuppressant agents in irAE management and their impact on response to immune checkpoint inhibitor therapy
 - Optimize the choice, dosing and duration of use of immunosuppressants in management of irAE

Action Item 5: Pursuing Better Understanding of irAEs

- Knowledge gaps include:
 - After adjustment for factors such as class of the drug, tumor type, age, race, and sex, why do patients have **same irAE but different severity, or different irAEs of the same severity or different irAEs of different severity?**
 - What makes some patients more susceptible to irAEs, and what are **organ-specific/tissue-specific** immune microenvironments that could drive specific irAE?
 - As mechanisms underlying irAEs are thought to be driven by autoimmunity, does **germline** genetic variation affect risk of irAEs?
 - Is it possible that in some cases the toxic effect results from the immune system's attacking what most resembles the tumor due to **shared expression** of antigens between tumor and normal cells (e.g., vitiligo in patients with melanoma)?

Action Item 5: Pursuing Better Understanding of irAEs

- Additional knowledge gaps:
 - Will characterization of immune-effector **pathways driving** irAEs inform the choice of immunomodulatory agents used in management of irAEs?
 - What is the **relationship** between irAEs and response to ICIs?
 - Understand the risk and effectiveness of **vaccination** of patients on immunotherapy-based treatment?
 - What is the role of antiviral, antibacterial, or antifungal prophylaxis as there are several concerns about the risk of **infections**?
 - Will **greater inclusion** of non-White patients change our understanding of irAEs and their management?

Action Item 6: High-risk Patients

Risk factors for irAEs remain unclear

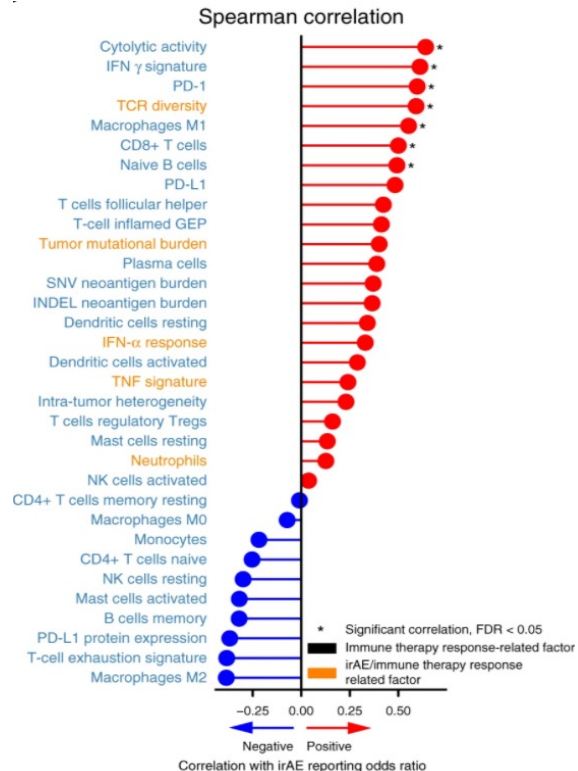
| | |
|-----------------------------------------------------|---------------------------------------------|
| Transplant recipients | Women on CTLA4 and men on PD-1/PD-L1 agents |
| High body mass index | History of HIV, hepB or hepC infection |
| Pre-existing autoimmune diseases | Past history of irAE |
| History of primary or secondary immune deficiencies | Age < 60 yrs |

White patients *may* have higher overall incidences of irAEs, but non-White patients have greater severity

Need to assess patients individually and consider treating with ICI when deemed most appropriate (first-line vs second-line or later)

Action Item 7: Incorporating Diagnostic Tools to Personalize irAE management

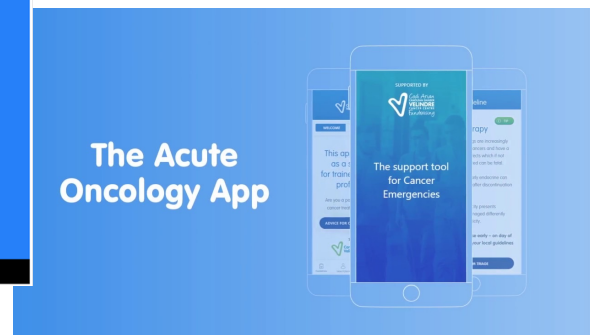
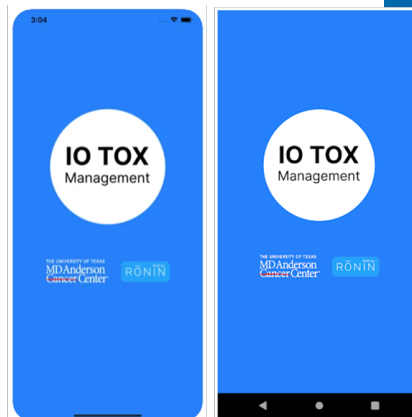
Association between irAE and related factors



| | |
|----------|-------------------------------------------------------------------------------------------------------------------|
| Identify | Identify markers to predict risk for irAE |
| Develop | Develop tools to monitor patients for emergence of irAE |
| Validate | Validate the immune markers and clinical tools in large, prospective studies for reliability and generalizability |

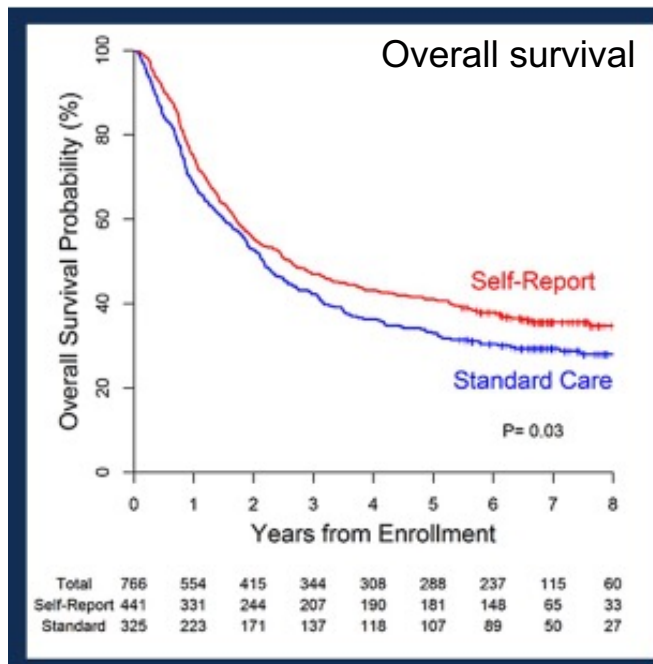
Action Item 8: Utilizing Wireless Technology and Digital Health

- Efficient use of wireless technology and digital resources to equip health care providers
- For use of digital health tools, patient access to technology becomes paramount
 - Socioeconomic status
 - Technology aptitude
 - Device access
 - Internet access



Self-reporting of Symptoms Improved Overall Survival

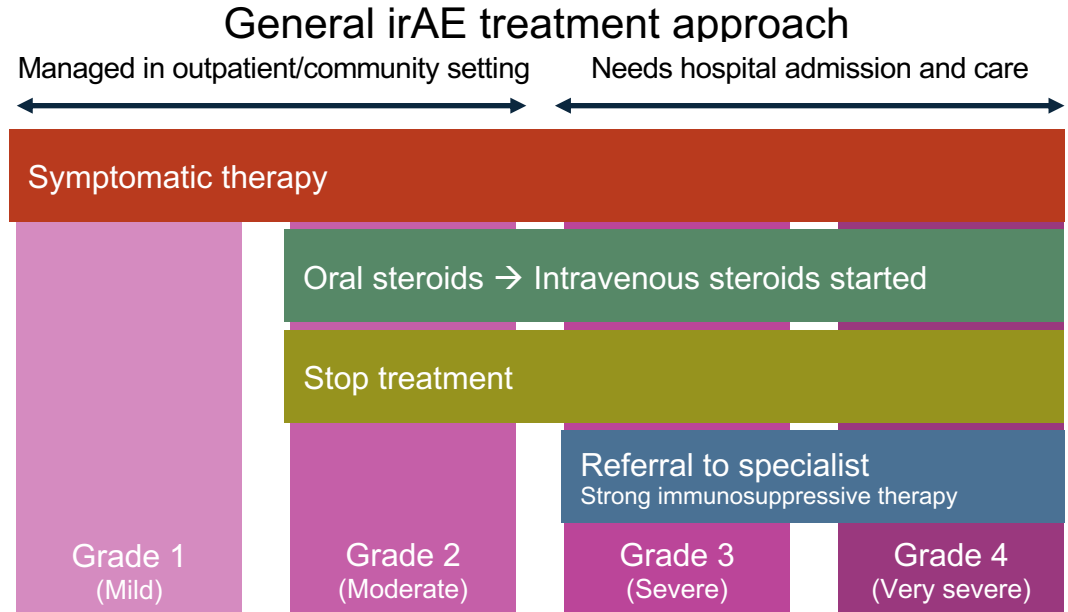
- Patients received routine outpatient chemotherapy for metastatic solid tumors at Memorial Sloan Kettering Cancer Center
- Compared to standard chemotherapy, median survival was 5 months longer among patients in the self-reporting arm (31.2 vs 26.0 months, $P=0.03$)
- Remained significant in multivariable analysis: Adjusted hazard ratio 0.83, 95% CI 0.70 – 1.0



- Proactive monitoring prompts clinician to intervene early, before symptoms worsen and cause serious downstream complication
- Symptoms control enables patients to stay more functional, which is associated with better survival
- Symptom monitoring improves control of toxicities, enabling longer duration of cancer treatment

Patient Education in Identifying irAEs

- irAEs are often treatable with steroids but must be correctly identified
- Patients must know:
 - The potential immune related side effects
 - When to discuss side effects with a medical professional (always and early)



Emphasize to patients that it is extremely important for them to inform their medical care team as soon as possible if they experience any unusual symptoms during or after treatment with cancer immunotherapy

Existing and Possible Patient Education Tools

- Online educational tools that educate patient and caregivers about immune-mediated adverse events
- Print material developed by cancer program or drug company
- Patient education videos
- Patient educational guides
 - ESMO
 - ASCO
 - NCCN

NCCN National Comprehensive Cancer Network®

Understanding Immunotherapy Side Effects

Immune checkpoint inhibitors (a type of immunotherapy) offer a promising new way to treat cancer for some patients. But these medicines can occasionally cause your immune system to attack normal organs and tissues in your body, affecting the way they work. Serious side effects typically occur in less than 5% of patients, but certain mild side effects can occur in up to 30%–50% of patients. Contact your health care professional right away if you think you may be experiencing...

The infographic features a central silhouette of a human body with red dots indicating various side effects. Lines connect these dots to text boxes describing the symptoms and associated conditions.

- Brain inflammation (encephalitis)**
Fever; confusion; changes in mood or behavior; neck stiffness; seizures; extreme sensitivity to light.
- Hormone gland problems (especially the thyroid, pituitary, adrenal glands, pancreas)**
Persistent or unusual headaches; extreme tiredness; weight loss or gain; rapid heartbeat; increased sweating; hair loss; constipation; dizziness or lightheadedness.
- Lung problems (pneumonitis)**
New or worsening cough; shortness of breath.
- Kidney problems**
Decrease in the amount of urine; blood in the urine.
- Skin problems**
Rashes; itching; blistering; painful sores or ulcers.
- Joint or muscle problems**
Severe or persistent muscle or joint pain; severe muscle weakness.
- Eye problems**
Blurry or double vision or other vision problems; eye pain or redness.
- Heart problems (myocarditis, arrhythmias)**
Inflammation of the heart muscle; irregular heartbeat.
- Liver problems (hepatitis)**
Yellowing of the skin or the whites of the eyes; severe nausea or vomiting; pain on the right side of the stomach area; dark urine; bleeding or bruising more easily than normal.
- Intestinal problems (colitis)**
Diarrhea or more bowel movements than usual; stools that have blood or are dark, tarry, or sticky; severe stomach-area pain.
- Nerve problems**
Numbness or tingling in hands or feet; unusual weakness in legs, arms, or face.

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NCCN NCCN GUIDELINES FOR PATIENTS™

2022

Immunotherapy Side Effects

Immune Checkpoint Inhibitors

Presented with support from: **NCCN** **FOUNDATION** **LEUKEMIA & LYMPHOMA SOCIETY**

Available online at [NCCN.org/patients](https://www.nccn.org/patients)

Action Item 9: Providing a Platform to Hear the Missing Patient's Voice

Monitor longitudinal changes in symptoms for early detection of irAEs

Open access

Original research



Evaluating the psychometric properties of the Immunotherapy module of the MD Anderson Symptom Inventory

Tito Mendoza ¹,⁵ Ajay Sheshadri,² Mehmet Altan,³ Kenneth Hess,⁴ Goldy George,¹ Bettzy Stephen,⁵ Lilibeth Castillo,⁵ Enedelia Rodriguez,⁵ Jing Gong,⁵ Christine Peterson,⁴ Jordi Rodon Ahnert,⁵ Siqing Fu,⁵ Sarina A Piha-Paul,⁵ Shubham Pant,⁵ Ecaterina Dumbrava,⁵ Timonthy A Yap,⁵ Filip Janku,⁵ Apostolia M Tsimberidou,⁵ Vivek Subbiah,⁵ Daniel D Karp,⁵ Abdulrazzak Zarifa,⁵ Lacey M McQuinn,⁵ Charles Cleeland,¹ David S Hong,⁵ Aung Naing ⁵

Date: / /
(month) (day) (year)

Participant Initials:

Study Subject #:

TimePoint:

M. D. Anderson Symptom Inventory - Immunotherapy

Part I. How severe are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been *in the last one week*. Please select a number from 0 (symptom has not been present) to 10 (the symptom was as bad as you can imagine it could be) for each item.

| | As Bad As You Can Imagine | | | | | | | | | | |
|------------------------------------------------------------|---------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 1. Your pain at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2. Your fatigue (tiredness) at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3. Your nausea at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 4. Your disturbed sleep at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5. Your feelings of being distressed (upset) at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 6. Your shortness of breath at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7. Your problem with remembering things at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 8. Your problem with lack of appetite at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9. Your feeling drowsy (sleepy) at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 10. Your having a dry mouth at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 11. Your feeling sad at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 12. Your vomiting at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 13. Your numbness or tingling at its WORST? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Action Item 10: Sharing Evolving Data

Disseminate the results of clinical and translational studies to the scientific community in a timely manner



Summary

- Increase irAE awareness through education
- Solidify the irAE management guidelines
- Acquire knowledge by performing preclinical, translational, and clinical studies in diversified populations
- Share the knowledge gained

SMART Goals

Specific, Measurable, Attainable, Relevant, Timely

- Deliver culturally-sensitive patient education, tailored to the needs and capabilities of the patient and caregiver
- Encourage "call early, call often" approach to symptom reporting
- Maintain a low threshold for suspecting irAEs in patients receiving immunotherapies
- Review CTCAE grading of irAEs, in order to personalize management

To Ask a Question

Please click on the *Ask Question* tab and type your question. Please include the faculty member's name if the question is specifically for them.

CME Outfitters

AFTER
THE SHOW

Questions & Answers



To Receive Credit

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Participants will be able to download and print their certificate immediately upon completion.



Oncology Hub

Free resources and education to educate health care providers and patients on oncology <https://www.cmeoutfitters.com/oncology-education-hub/>

Diversity and Inclusion Hub

Free resources and education to educate health care providers and patients on health-related inequities <https://www.cmeoutfitters.com/diversity-and-inclusion-hub/>