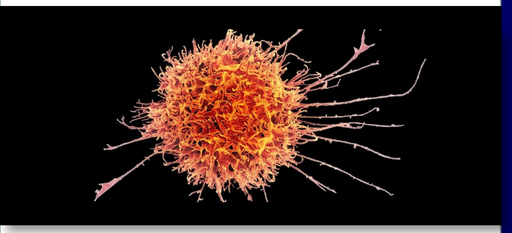
PRESENTER:
Alec Romanowski PharmD
PGY-1 Pharmacy Resident
Guthrie Robert Packer Hospital

INTRO

- An immune-related adverse effects (IrAE) assessment tool may increase confidence in identifying IrAE of patients receiving an Immune Checkpoint Inhibitor (ICI) for the treatment of cancer.



BACKGROUND

- Use of ICIs in cancer therapy has been steadily increasing ever since ipilimumab was FDA approved in 2011.
- Currently there are 7 ICIs approved in the US across 20 cancer types.
- IrAEs are common and may manifest in a wide variety of organ systems and be unpredictable in timing of onset.
- Many health care providers, including oncologists, report that they do not feel very comfortable managing IrAEs.
- Early recognition and treatment is crucial in mitigating IrAE severity.
- There is not a standardized algorithm, guide, or list of symptoms to follow when monitoring patients ICIs.
- The current standard of practice at The Guthrie Clinic is to use a symptom assessment tool that covers the general symptoms that are common with traditional chemotherapy.

Chemotherapy	Immune Checkpoint Inhibitors
Directly attacks cancerous cells	Helps immune system attack cancerous cells
Cytotoxic	Non-cytotoxic
Patient may be immunocompromised	Not immunocompromised
“Traditional” side effects	Immune-related adverse effects
May see benefit earlier	May see benefit later

Immunotherapy and chemotherapy are vastly **different.** **Assessment** for **toxicity** should also **differ.**

Organ System	Clinical Presentation	
	Common IrAE	Rare IrAE
Dermatologic	Pruritis, Rash (maculopapular, lichenoid), vitiligo	Acneiform rash, alopecia, bullous pemphigoid, papulopustular rosacea, psoriasis, Stevens-Johnson syndrome, toxic epidermal necrosis, DRESS
Gastrointestinal	Diarrhea, colitis, lichenoid mucositis	Enteritis, gastritis, pancreatitis
Endocrine	Hypothyroidism, hyperthyroidism, thyroiditis, hypophysitis	Autoimmune Type 1 DM, Primary adrenal insufficiency
Hepatic	Transaminitis, hepatitis	____
Respiratory	Pneumonitis	Pleuritis, sarcoidosis
Rheumatic	Arthralgia, inflammatory arthritis, myalgia	Polymyalgia rheumatica, Giant cell arteritis, vasculitis
Renal	Increase in serum creatinine, nephritis	____
Ophthalmic	____	Uveitis, conjunctivitis, scleritis, episcleritis, blepharitis, retinitis
Neurologic	Neuropathy	Aseptic meningitis, autonomic neuropathy, encephalitis, Gullain-Barre syndrome, myasthenia gravis, posterior reversible leukoencephalopathy, traverse myelitis
Hematologic	____	Aplastic anemia, hemolytic anemia, ITP, lymphopenia, hemophilia
Cardiovascular	____	Cardiomyopathy, myocarditis, pericarditis, impaired ventricular contractions, conduction abnormalities

Title: Comparing identification of adverse effects from immune checkpoint inhibitors between a traditional adverse effect tool and a modified immune-related adverse effect tool

Authors:
Alec Romanowski PharmD
Zane Waite PharmD BCOP

METHODS

- This is a cross-over, pilot study targeting 50 subjects comparing confidence associated with identifying IrAE through the traditional adverse effect (tAE) assessment tool compared to the modified IrAE assessment tool.
- Nursing will physically assess each patient that presents to the outpatient infusion center for an ICI using the tAE tool followed by the IrAE tool.
- Nursing will indicate if they suspect a new IrAE and their level of confidence after assessment with each tool..
- Confidence changes will be assessed through Likert Scale questions.
- A provider will be consulted if an IrAE is suspected to confirm/deny and all patients will be followed by the investigators via EMR review to assess for clinical outcomes.

OUTCOMES

- **Primary outcome:** difference in the confidence that nurses rate their ability to assess for IrAE when using each assessment tool.
- **Secondary outcomes:** accuracy of the new tool for predicting severity of IrAE grading, steroid utilization, incidence of treatment interruptions, incidence of ED visits or hospital admissions for management of IrAE, and satisfaction of the interdisciplinary team.

GUTHRIE