

## Improving the Identification and Management of irAEs (immune-related adverse events)

Problem Statement	Root Causes
<p>There is a need for more proactive symptom identification, assessment, monitoring, and management</p> <ul style="list-style-type: none"> <li>• This is especially true for patients treated with immunotherapy</li> <li>• Patients treated with oral agents are also difficult to monitor for signs of adverse reactions</li> </ul> <p>There is a need for more proactive symptom assessment and monitoring</p>	<ul style="list-style-type: none"> <li>• Immune-mediated adverse reactions often do not appear in a predictable fashion</li> <li>• Patients may not be adequately educated about side effects</li> <li>• Patients may not call the cancer center when they develop symptoms</li> <li>• Nurses may not always reach the patient when they call to assess for symptoms</li> <li>• Certain conditions (eg, pneumonitis) may be difficult to diagnose since patients already have difficulty breathing</li> </ul>

### Immune checkpoint inhibitors FDA-approved for NSCLC: (as of June 2020)

- Ipilimumab (YERVOY)
- Pembrolizumab (KEYTRUDA)
- Nivolumab (OPDIVO)
- Atezolizumab (TECENTRIQ)
- Durvalumab (IMFINZI)

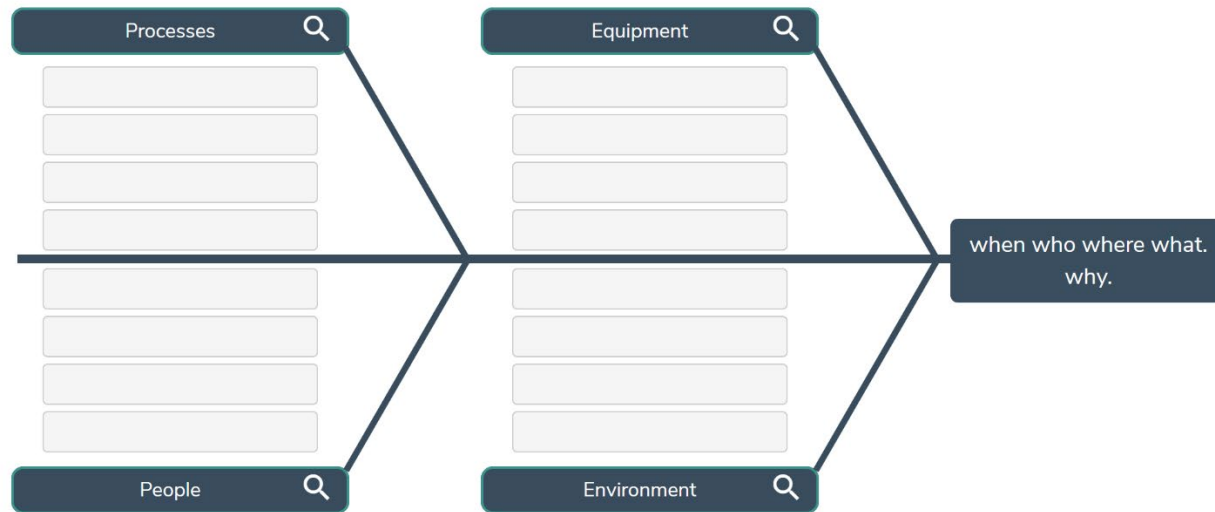
### Begin with the following patient lists:

- Patients with stages III and IV NSCLC from the last 6 months of 2019 (or any defined time period)
- Patients with stages III and IV NSCLC from the last 6 months of 2019 who were treated with a checkpoint inhibitor

### Baseline assessment:

- Proportion of these patients who were treated with a checkpoint inhibitor and who developed a moderate or severe irAE (grades 2, 3 or 4)
  - Denominator: Patients with stages III and IV NSCLC from the last 6 months of 2019 who were treated with a checkpoint inhibitor
  - Numerator: Patients with stages III and IV NSCLC from the last 6 months of 2019 who were treated with a checkpoint inhibitor and developed a moderate or severe irAE (grades 2, 3 or 4)
  - List the types of irAEs and how frequently they occurred
- Proportion of patients who had an emergency room visit for the irAE
  - Denominator: Patients with stages III and IV NSCLC who developed an irAE
  - Numerator: Patients with stages III and IV NSCLC who developed an irAE that resulted in an emergency room visit
- Proportion of patients who were hospitalized for the irAE
  - Denominator: Patients with stages III and IV NSCLC who developed an irAE
  - Numerator: Patients with stages III and IV NSCLC who developed an irAE that results in hospitalization
- Proportion of patients who received guideline-concordant management for the irAE
  - Denominator: Patients with stages III and IV NSCLC who developed an irAE
  - Numerator: Patients with stages III and IV NSCLC who developed an irAE and received management that was concordant with ASCO guidelines
  - ASCO guideline: <https://ascopubs.org/doi/pdf/10.1200/JCO.2017.77.6385>

**Discuss causes and effects:**



**Exploratory questions:**

- How are patients being educated about irAEs? What resources are they receiving? (eg, handout, wallet card, refrigerator magnet, symptom checklist or log, etc.)
- How often are nurses calling patients and asking them about treatment-related symptoms?
  - How often have irAEs been identified and managed using this approach?
- How often are patients calling the cancer center to report irAE symptoms?
  - How often have irAEs been identified and managed using this approach?
- What patient demographic factors may impact the following:
  - How do patients seek care if they develop irAE symptoms? (eg, do they go to the ER, an urgent care, primary care provider, or wait until their next visit?)

**Aim Statement (example):**

- Over the next <xx> months, we will increase guideline-concordant management for patients who develop irAEs by <xx>.

<b>Potential Solutions</b>
<ul style="list-style-type: none"><li>• Incorporate patient-reported outcome (PRO) tools to identify irAE symptoms as early as possible</li><li>• Form an immunotherapy toxicity working group</li><li>• Educate front-line clinicians about irAEs</li><li>• Have nurse navigators actively reach out to patients and assess for irAE symptoms</li><li>• Have patients track and report their symptoms using a symptom tracking tool</li><li>• Provide patient tools that will remind them to call the cancer center as soon as they develop an irAE symptom</li><li>• Develop an electronic clinical alert to remind clinicians about irAEs</li></ul>