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

<table>
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<th>Problem Statement</th>
<th>Root Causes</th>
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| There is a need for more proactive symptom identification, assessment, monitoring, and management  
• This is especially true for patients treated with immunotherapy  
• Patients treated with oral agents are also difficult to monitor for signs of adverse reactions |
| • Immune-mediated adverse reactions often do not appear in a predictable fashion  
• Patients may not be adequately educated about side effects  
• Patients may not call the cancer center when they develop symptoms  
• Nurses may not always reach the patient when they call to assess for symptoms  
• Certain conditions (e.g., pneumonitis) may be difficult to diagnose since patients already have difficulty breathing |
| There is a need for more proactive symptom assessment and monitoring |

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
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>.

**Potential Solutions**

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<td></td>
<td>Incorporate patient-reported outcome (PRO) tools to identify irAE symptoms as early as possible</td>
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<td>Form an immunotherapy toxicity working group</td>
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<td>Educate front-line clinicians about irAEs</td>
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<td>Have nurse navigators actively reach out to patients and assess for irAE symptoms</td>
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<td>Have patients track and report their symptoms using a symptom tracking tool</td>
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<td>Provide patient tools that will remind them to call the cancer center as soon as they develop an irAE symptom</td>
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<td>Develop an electronic clinical alert to remind clinicians about irAEs</td>
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This data collection sheet is a resource from the ACCC educational initiative, Fostering Excellence in Care and Outcomes in Patients with Stage III/IV NSCLC.