Key Session Takeaways

1. The adaptive immune system, and in particular T cells, can be used as a powerful tool to elicit an immune response against tumor cells.

2. Biomarkers for response, response evaluation, and kinetics, as well as side effects of immunotherapy are unique to this group of agents. With regard to immune-related toxicity, points of consideration include (a) always suspect and autoimmune toxicity, (b) rule out competing diagnoses (e.g., infection, disease progression), (c) identify the toxicity (e.g., diarrhea vs. colitis), and (d) grade the toxicity.

3. Converting bench discoveries to clinical advances requires the conduct of a well-designed and efficiently run clinical trial. This requires the coordination of a strong team, including providers, program managers, research nurses, office staff, and data coordinators. Roles and responsibilities overlap, and the quality of the research is affected by all team members.
Immunotherapy for Cancer: From Bench to Bedside

Jarushka Naidoo, MB BCH; Joanne Reimer, BSN RN
Department of Oncology
Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University

Oncology Nursing Society 2017
Plenary Session

Disclosures (JN)
Consulting:
Bristol Myers-Squibb
Astrazeneca/MedImmune

Honoraria:
Bristol Myers-Squibb
Astrazeneca/MedImmune

Research Funding:
Kyowa-Kirin
Merck
Astrazeneca/MedImmune

Disclosures (JR)
Consulting:
Astrazeneca
Merck

Honoraria:
Bristol Myers-Squibb
Astrazeneca/MedImmune
Merck

Immunotherapy: Bench to Bedside
Outline

• Brief Introduction to Cancer Immunotherapy
• Bench Discoveries
• Bedside Applications
• Behind the Scenes of a Clinical Trial
• The Role of the Research Nurse
• A Bench to Bedside Story
• Future Directions
The Human Immune System

The Ultimate Anti-cancer Therapy?

- **Specificity:** virtually infinite antigen recognition
- **Adaptability:** based on tumor genetic & epigenetic changes
- **Memory:** durable responses even after drug discontinuation
- **Universality:** potential anti-tumor effect regardless of tumor type

|----------------------------------------------------------|----------|------------------------------|----------------------|-------------------------|-----------------------|----------------------|------------------|----------------|-------------|------------------|------------------------|

Naidoo et al, Ann Transl Med 2016

---

**Bedside Applications**

Are all PD-L1 tests created equal?

<table>
<thead>
<tr>
<th>Assay</th>
<th>Patient selection</th>
<th>Cut-off’s used in Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nivolumab</td>
<td>28-8</td>
<td>Tumor cells: 1%, 5%, 7%</td>
</tr>
<tr>
<td>Pembrolizumab</td>
<td>22C3</td>
<td>Tumor cells: &gt;50%</td>
</tr>
<tr>
<td>Atezolizumab</td>
<td>SP142</td>
<td>Tumor cells: 1%, 5%, 10%</td>
</tr>
<tr>
<td>Durvalumab</td>
<td>SP263</td>
<td>Tumor cells: &gt;25%</td>
</tr>
<tr>
<td>Avelumab</td>
<td>73-10</td>
<td>Tumor cells: &gt;1%, &gt;5%, &gt;10%</td>
</tr>
</tbody>
</table>

Bedside Applications

Next Steps for PD-L1 Testing

- PD-L1 expression:
  - Core needle biopsy/Excisional biopsy/ Resected tissue
  - FFPE tissue: at least 100 tumor cells
  - PD-L1 IHC 22C3 pharmDx (Dako)
  - Role for PD-L1 testing on cytology samples unknown

ATLAS of PD-L1 testing in NSCLC:

- Blueprint phase 2 project
- Validation of phase 1 in different sample types (resection, biopsy, cytology)
- Inter-observer concordance among 20 pathologists
- Compare needle biopsy vs. resection sample vs. cytology in same patient

**Bedside Applications**

**Unique Response Kinetics with Immune Checkpoint Blockade**

- **Immune-related Response Criteria (irRC)**
  - Characterize atypical responses, seen in 5-10% cases
  - Patients with melanoma treated with ipilimumab (phase II program)
  - irRC (SD + PR) had comparable outcomes to RECIST 1.1 (SD + PR)
  - Suspected radiologic progression reassessed with CT >4 weeks after initial CT

<table>
<thead>
<tr>
<th>Key Difference</th>
<th>RECIST 1.1</th>
<th>irRC</th>
</tr>
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<tbody>
<tr>
<td>Tumor measurement</td>
<td>Unidimensional</td>
<td>Bidimensional</td>
</tr>
<tr>
<td>Target lesions</td>
<td>Maximum diameter</td>
<td>Maximum 15</td>
</tr>
<tr>
<td>New lesions</td>
<td>Progressive disease</td>
<td>Tumor and cutaneous lesions assessed concurrently with axial lesions</td>
</tr>
<tr>
<td>Complete Response</td>
<td>Disappearance of all target and non-target lesions, no new lesions, LD &lt; 10mm short axis</td>
<td></td>
</tr>
<tr>
<td>Partial Response</td>
<td>&gt;30% decrease from baseline</td>
<td>&gt;50% decrease from baseline</td>
</tr>
<tr>
<td>Progressive Disease</td>
<td>&gt;20% increase in tumor burden</td>
<td>&gt;20% increase in tumor burden, new lesions added to calculation</td>
</tr>
<tr>
<td>Stable Disease</td>
<td>Neither progressive disease nor partial response</td>
<td></td>
</tr>
</tbody>
</table>

**Patients with melanoma treated with ipilimumab (phase II program)**

- irRC (SD + PR) had comparable outcomes to RECIST 1.1 (SD + PR)
- Suspected radiologic progression reassessed with CT >4 weeks after initial CT

**Key Difference**

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**Patients with melanoma on KEYNOTE-001 (2 or 10mg/kg pembrolizumab, n=655)**

- Early pseudoprogression: >25% in tumor burden at week 12, no PD at next scan
- Delayed pseudoprogression: >25% in tumor burden post week 12, no PD next scan

**Regimen/Trial**

<table>
<thead>
<tr>
<th>Regimen/Trial</th>
<th>Tumor Type</th>
<th>Patients</th>
<th>ORR</th>
<th>Response Criteria</th>
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<tbody>
<tr>
<td>Nivolumab</td>
<td>Melanoma</td>
<td>135</td>
<td>13%</td>
<td>RECIST 1.0</td>
</tr>
<tr>
<td></td>
<td>Squamous</td>
<td>236</td>
<td>27%</td>
<td>RECIST 1.0</td>
</tr>
<tr>
<td></td>
<td>Renal cell</td>
<td>92</td>
<td>43%</td>
<td>RECIST 1.1</td>
</tr>
<tr>
<td>Pembrolizumab</td>
<td>Melanoma</td>
<td>117</td>
<td>38%</td>
<td>RECIST 1.1</td>
</tr>
<tr>
<td></td>
<td>Renal cell</td>
<td>168</td>
<td>31%</td>
<td>RECIST 1.1</td>
</tr>
<tr>
<td></td>
<td>Melanoma</td>
<td>75</td>
<td>31%</td>
<td>RECIST 1.1</td>
</tr>
<tr>
<td>Atezolizumab</td>
<td>Urothelial</td>
<td>65</td>
<td>28%</td>
<td>RECIST 1.1</td>
</tr>
<tr>
<td></td>
<td>Melanoma</td>
<td>411</td>
<td>40/28%*</td>
<td>RECIST 1.1</td>
</tr>
<tr>
<td></td>
<td>Melanoma</td>
<td>192</td>
<td>26%</td>
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**NRI= not reported, mWHO= modified WHO criteria, squam=squamous, unmet= unmetable, addit= additional, ORR= Objective Response Rate, *Ipilimumab-naïve/pre-treated**

---

**Bedside Applications**

**Pseudoprogression**

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The patient continues therapy with subsequent shrinkage of all tumor lesions. After 3 months of pembrolizumab, he reports a new dry cough and shortness of breath. The chest CT scan is below.

What is the possible causes of this clinical scenario?

A. Lung infection
B. Progressive metastatic disease
C. Pneumonitis
D. All of the above

Bedside Applications
Managing the Side Effects of Immunotherapy

- Inflammatory processes can affect any organ system
- Distinct from chemotherapy side effects
- Evaluation and management are unique
- May be exacerbated by underlying autoimmune conditions/presence of autoantibodies
- Patients with autoimmune conditions not requiring >10mg daily prednisone/equivalent may receive therapy

1. Always suspect an autoimmune toxicity
2. Rule out competing diagnoses (Infection? Progression?)
3. Identify the toxicity (diarrhea vs. colitis)
4. Grade the toxicity

Bedside Applications
Pneumonitis Challenges

How do we diagnose pneumonitis?

Is this: Infection? Progression? Pneumonitis?

How do we manage it?

Grade 1
Close observation

Grade 2
Drug Withholding
Oral Steroid Taper over 4-6 weeks

Grade 3-4
Discontinue Immunotherapy
IV Steroid, Oral Steroid Taper if improves
Other Immunosuppression if worsens, 48hr

What are the outcomes with treatment?
Bedside Applications

Pneumonitis Challenges

<table>
<thead>
<tr>
<th>Condition</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>COP (n=5)</td>
<td></td>
</tr>
<tr>
<td>Ground-Glass Opacities (n=10)</td>
<td></td>
</tr>
<tr>
<td>Hyper-Sensitivity (n=2)</td>
<td></td>
</tr>
<tr>
<td>Interstitial (n=6)</td>
<td></td>
</tr>
<tr>
<td>NOS (n=4)</td>
<td></td>
</tr>
</tbody>
</table>

Associated with: NSCLC histology (p=0.03), Immunosuppressive Therapy (p=0.06)

Naidoo et al, J Clin Oncol 2016

Bedside Applications

Pneumonitis Management Algorithm

<table>
<thead>
<tr>
<th>Grade</th>
<th>Investigations</th>
<th>Management</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Asymptomatic, Radiologic changes only</td>
<td>• Radiologic imaging (High resolution CT chest)</td>
<td>Repeat CT every cycle of treatment, treat at the next step</td>
</tr>
<tr>
<td>2</td>
<td>Mild/moderate new symptoms</td>
<td>• Mortality assessment where necessary</td>
<td>Withhold immunotherapy</td>
</tr>
<tr>
<td>3-4</td>
<td>Severe lung symptoms or worsening symptoms</td>
<td>• Consult Pulmonary/Infectious Diseases Consults and Bronchoscopy</td>
<td>Discontinue immunotherapy</td>
</tr>
</tbody>
</table>

Naidoo et al, Ann Oncol 2015

Behind the Scenes of a Clinical Trial

The Stages of Drug Development

- Bench: pre-clinical phase
  - Clinical phase: sponsor applies to FDA for investigational new drug (IND). The next steps are clinical phases that may take years each
  - Manufacturer applies for new drug application
  - FDA approval: Bedside
## Behind the Scenes of a Clinical Trial
### The Clinical Setting

**Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University**

- Missions of a Comprehensive Cancer Center
  - Research
  - Education
  - Patient Care
- Main campus (Downtown Baltimore):
  - 8 in-patient oncology units/Oncology ICU
  - Outpatient infusion area treats ~200 patients/day
  - Radiation Oncology
  - ~25% of patient population participate in clinical trials
  - Access to specialist care in medical and surgical specialties
- Other Oncology Campuses: JH Bayview, JH Greenspring Station; JHSibley

## Behind the Scenes of a Clinical Trial
### The Clinical Research Team

**Study Site**
- Primary investigator
- Sub-investigators
- Program managers
- Lead Research Nurse
- Research Nurses
- Lead study coordinator
- Office support staff
- Administration Team
  - Infusion nurse
  - Phlebotomist
  - Pharmacist

**Sponsor**
- Pharmaceutical company,
  - Cooperative Group,
  - Government Agency
- Primary Institution
  - Medical Monitor
  - Study Monitors
  - Central Labs
  - Radiology
  - Pathology
  - Data managers
  - Statisticians

## Behind the Scenes of a Clinical Trial
### Oncology Research Teams at JHH

- **By Disease-Specialty**
  - Thoracic Oncology (Lung/Head and Neck)
  - Breast Cancer
  - Gastrointestinal Cancers
  - Genitourinary Cancers
  - Hematologic Malignancies
  - CNS Malignancies

- **By Trial Type**
  - Phase I
  - Tumor Immunology
Role of the Research Nurse
Missions of the Cancer Center

**Research**
- Learn and interpret the study protocol
- Review and prepare key documents (e.g. lab manual)

**Education**
- Educate patient on study schedule/protocol
- Educate administration team on study schedule/protocol
- Consent patient to the study
- Screen patient eligibility for the study

**Patient Care**
- Manage patient while on study: toxicities
- Communicate with patient, study team and sponsor
- Document patient management

---

Role of the Research Nurse
Learning the Protocol

**Purpose of the Study**
- Phase of protocol: Phase I/II/III/IV
- Objectives
- Drugs to be evaluated

**Which Patients are Suitable for the Study**
- Inclusion & Exclusion Criteria

**Study Schedule**
- How often study drug(s) are given
- Samples to be collected
- Tests & Imaging required
- Data to be collected

---

Role of the Research Nurse
Stages of a Clinical Trial

**Start of the Study**
- Patient Recruitment
- Informed Consent
- Screening for Eligibility
- Study Enrollment

**Study Treatment**
- Oversee treatment on schedule

**Follow-up Phase/Completion**
- Follow-up/Surveillance
- Communication
Bench to Bedside Story

Phase I Trial CA209-001:
Open-label multicenter, multi-dose, dose-escalation study BMS-936558/MDX-1106 in Subjects with Selected Advance or Recurrent Malignancies
- Opened in 2008 to 5 disease group and evaluated 5 dose levels
- 2011 Expanded NSCLC in 3 dose levels
- Experience with monotherapy

Bench to Bedside Story
NSCLC Expansion Cohorts

- Enrolled & on study for 2 years
- Enrolled & progressed < 4 months
- Enrolled & progressed > 4 months < 2 yrs
- Died of pneumonitis at 1 month

Bench to Bedside Story
Managing Toxicities

<table>
<thead>
<tr>
<th>New Symptom</th>
<th>Grade 2</th>
<th>O2 sat 80% at rest, 90% with walking</th>
</tr>
</thead>
</table>
### Bench to Bedside Story

**Proceeding to Phase III**

**Phase III Trials: CA209-017 & 057:**

An Open-label Randomized Phase III Trial of BMS-936558 (Nivolumab) versus Docetaxel in Previously Treated Advanced or Metastatic Squamous & Non-squamous Cell Non-small Cell Lung Cancer

- Opened in 2012
- Quickly enrolled
- Opdivo FDA approved for 2nd line NSCLC in 2015

### Bench to Bedside Story

**Toxicities in Phase III Studies**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Agent</th>
<th>Treatment-Related AEs All &amp; Grade 3+4</th>
<th>Most Common Treatment-Related AEs</th>
<th>Pneumonitis Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checkmate 017</td>
<td>Nivolumab</td>
<td>1%</td>
<td>Pneumonitis – 11% Appetite – 10%</td>
<td>Grade 3-4 – 0%</td>
</tr>
<tr>
<td></td>
<td>Docetaxel</td>
<td>60%</td>
<td>Metastasis – 33% Fatigue – 33%</td>
<td>0%</td>
</tr>
<tr>
<td>Checkmate 057</td>
<td>Nivolumab</td>
<td>60%</td>
<td>Fatigue – 10% Nausea – 12% Appetite – 10%</td>
<td>All – 3% Gr 3-4 – 1%</td>
</tr>
<tr>
<td></td>
<td>Docetaxel</td>
<td>60%</td>
<td>Metastasis – 21% Fatigue – 28%</td>
<td>0%</td>
</tr>
<tr>
<td>Keynote 010</td>
<td>Pembrolizumab</td>
<td>63%</td>
<td>Fatigue – 25% Nausea – 11%</td>
<td>All – 3% Gr 3-4 – 2 deaths</td>
</tr>
<tr>
<td></td>
<td>Docetaxel</td>
<td>61%</td>
<td>Fatigue – 25% Nausea – 16%</td>
<td>0%</td>
</tr>
</tbody>
</table>


### Bench to Bedside Story

**Toxicities in combination trials**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Agent</th>
<th>All Treatment-Related AEs</th>
<th>Most Common Grade 1-2 Treatment-Related AEs</th>
<th>Grade 3-4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keynote 021</td>
<td>Chemotherapy</td>
<td>Grade 1: 85% Grade 2: 15%</td>
<td>Fatigue 43% Nausea 40% Anemia 35%</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Pembrolizumab + Chemotherapy</td>
<td>Grade 1: 31% Grade 2: 7%</td>
<td>Fatigue 55% Nausea 50% Anemia 20%</td>
<td>0%</td>
</tr>
<tr>
<td>CheckMate 012</td>
<td>Nivolumab + Ipilimumab</td>
<td>Grade 1: 34-35% Grade 2: 33-37%</td>
<td>Rash 13-24% Diarrhea 18-21% Elevated Anylase 13% Elevated Amylase 3-5% Pneumonitis 3-5%</td>
<td>3-5% 3-5% 3-5% 3-5%</td>
</tr>
<tr>
<td></td>
<td>Nivolumab + Ipilimumab</td>
<td>Grade 1: 45% Grade 2: 24%</td>
<td>Rash 28% Diarrhea 16% Nausea 15%</td>
<td>8%</td>
</tr>
</tbody>
</table>

Future Directions
Translating Research into Experience

- Efficacy of I-O is evidence-based, further trials ongoing
- Managing irAE’s based on experience; further study required

Lessons Learned:
- Pre-screen those not suitable for I-O
- irAE’s (immune related adverse events)
  - Recognizing
  - Grading
- Consider medical specialist consult to evaluate suspected irAE
- Educate patient and caregivers
  - I-O targets the immune system to fight cancer
  - An activated immune system may cause inflammation in any organ
  - Side effects of I-O are different from chemotherapy
  - In emergency, recommend ED physician call oncologist

Future Directions
Educating Providers

A Simplified Guide: Immune Oncology Therapy (I-O)

Future Directions
Educating Patients and Caregivers

At Every Dose

- Side effects:
  - Nausea, diarrhea, rash
  - Fatigue
  - Fever
  - Malaise

- Do not take I-O with:
  - Antibiotics
  - Antidepressants

- Follow up:
  - Bloodwork monthly
  - ASCO guidelines

- Consider referred for:
  - Nutritional support
  - Pain management

- Emergency contact information:
  - Provider phone number
  - Hospital emergency room number

- Support groups:
  - Cancer support groups
  - Local support organizations
Future Directions
Evaluating patients for irAE’s

Before every dose ask: “Do you experience...?”

- Fever, chills, headache, muscle aches or myalgia
- Skin rash, diaphoresis, shortness of breath, chest pain
- Abdominal pain, nausea, vomiting, diarrhea, altered taste or smell
- Cough, sore throat, sinuses, eye or mouth
- Severe musculoskeletal pain

Before every dose check:

- Blood work: CBC, renal function, liver function
- Labs: TSH, calcium, magnesium, creatinine

Appropriate for nurse to report further muscle or joint pain to different irAE role

ONS.org
- Immunotherapy in Cancer Treatment (4 hour online course)
- Immunotherapy community:
  - An opportunity to post questions
  - Share resources
  - Teach others

SITC: Society for Immunotherapy of Cancer
ICLIO: Institute for Clinical Immuno-Oncology

Future Directions
The Cancer Moonshot Initiative

Vice President’s Office
Cancer Moonshot
Federal Task Force
NCI/NIH
National Cancer Advisory Board
“Blue Ribbon Panel”
Working Groups
**Future Directions**

**Blue Ribbon Panel Working Groups**

- **7 Groups (12-15 members: researchers, clinicians, industry, advocates):**
  1. Cancer Immunology
  2. Clinical trials
  3. Implementation Science and Data Sharing
  4. Tumor Evolution
  5. Precision Medicine
  6. Prevention and Early Detection
  7. Pediatric cancer

- Aim: recommend 2-3 major scientific opportunities poised for acceleration
- Working Groups met weekly to discuss and formulate recommendations

**Future Directions**

**Blue Ribbon Panel Recommendations**

1. Directly Engage Patients
2. Create a National Cancer Data Ecosystem
3. Create a Human Tumor Atlas
4. Developing of New Enabling Technologies
5. Create a Cancer Immunotherapy Translational Network
6. Identify Therapeutic Targets to Overcome Drug Resistance
7. Fusion Oncoproteins in Pediatric Cancer
8. Symptom Management Research
9. Precision Prevention and Early Detection
10. Retrospective biospecimen analysis in patients who received standard Tx

**Colleagues and Collaborators**

- **JHH Thoracic Oncology Program**
  - Julie R. Brahmer, MD
  - David E. Ettinger, MD
  - Patrick F. Forde, MD
  - Ronan J. Kelly, MD
  - Josephine Feliciano, MD
  - Georgeanne Jambeter, NP
  - Sarah Sagorsky, PA
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- **JHH Thoracic Oncology Research Program**
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