Recommendations for Cancer Patients and the COVID-19 Vaccine

February 26, 2021
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Introducing Our Moderator

Laurie Kirstein MD, FACS
Introducing Our Speakers

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Deputy Director for Clinical Services
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Abramson Cancer Center
University of Pennsylvania
Pennsylvania, PA

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Pennsylvania, PA
NCCN: Cancer and COVID-19 Vaccination

Lawrence N Shulman, MD

February 26, 2021
The Problem

How to best use a limited vaccine supply to maximally benefit our cancer patients
NCCN and COVID

• NCCN Covid taskforce formed in March 2020

• Met regularly since

• Once COVID vaccine became available for cancer patients, NCCN COVID-19 Vaccination Advisory Committee formed on January 11, 2021

  • Chairs:
    • Steven Pergam, MD, MPH, ID, Fred Hutch Cancer Research Center
    • Lindsey Baden, MD, ID, Dana-Farber/Brigham Cancer Center

  • Broad membership including ethics specialists
“Preliminary” Recommendations
NCCN COVID-19 Vaccination Advisory Committee

• 11 days from start to publication – posted on NCCN website January 22, 2021

• Meant to be a “living document” as new data emerge, and as vaccine supplies vary

• “Due to limitation in prospective data relating to vaccination use in patients with active malignancy, recommendations are based on the expert opinion of the committee”
Patient Factors to Consider

National Academies Framework on Equitable Allocation of Covid Vaccine:

- Risk of infection
- Severe co-morbidity and risk of mortality
- Negative social impact
- Transmission to others

NCCN modifying factors, IN ADDITION to cancer specific factors

- Age
- Comorbidities
- Social and demographic factors that include poverty, limited access to health care, and underrepresented minorities
Ethical Musings......in the face of limited vaccine supply....

• Do you vaccinate highest risk patients even though their chances of good response to vaccine may be less?
  • Hematologic malignancy patients
  • Patients receiving rituximab, etc

• Do you vaccinate patients at highest risk, even if their life-expectancy is short, or do you vaccinate patients at lower risk with higher likelihood of long-term survival?
  • Patient with advanced lung cancer, older, co-morbidities, at high risk to die of COVID
  • Patient with testicular cancer on chemotherapy, young, lower risk to die of COVID but excellent long-term prognosis
NCCN Key Principles (1)

• No vaccine data on cancer pts receiving active therapy at this time – we must generate the data
  • No safety concerns for cancer pts receiving vaccine
  • Efficacy of vaccination in different cancer populations unknown

• Pts with active cancer and on active treatment are at increased risk for complications from COVID and should be prioritized

• Simple and rapid approach to vaccination is important

• Must include racial/ethnic minorities and other high-risk groups

• Caregivers and household contacts should be considered for early vaccination
NCCN Key Principles (2)

• If unlimited supply of vaccine available – everyone should be vaccinated “tomorrow”… but

• Degree of availability of vaccine will affect prioritization specifics
  • “How far down the prioritization list can you go”

• Vaccine should not be wasted – all available vaccine should rapidly make its way into an arm

• The sooner pts are vaccinated, the better

• Appreciation that matrixed cancer centers will need to “Share” priorities with non-cancer patients
  • Solid organ transplant pts, pts with immunologic disorders, etc
## Disease Specific Considerations

<table>
<thead>
<tr>
<th>Cancer/Treatment type</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hematologic Malignancies</strong></td>
<td></td>
</tr>
<tr>
<td>AML induction</td>
<td>Delay until ANC recovery</td>
</tr>
<tr>
<td>Transplant/CAR T</td>
<td>At least 3 mo post Tx</td>
</tr>
<tr>
<td>Marrow failure states (MDS, etc)</td>
<td>When vaccine available</td>
</tr>
<tr>
<td>All others (including rituximab, etc)</td>
<td>When vaccine available</td>
</tr>
<tr>
<td><strong>Solid Tumor Malignances</strong></td>
<td></td>
</tr>
<tr>
<td>Receiving cytotoxic chemotherapy</td>
<td>When vaccine available</td>
</tr>
<tr>
<td>Targeted therapy</td>
<td>When vaccine available</td>
</tr>
<tr>
<td>Checkpoint inhibitors/immunotherapy</td>
<td>When vaccine available</td>
</tr>
<tr>
<td>Radiation</td>
<td>When vaccine available</td>
</tr>
</tbody>
</table>
Other Considerations

For Solid Tumor Patients with active cancer or on treatment:
• Vaccinate regardless of place in chemotherapy cycle – treatment day, nadir, etc OK
• Vaccinate regardless of neutropenia or thrombocytopenia
• If the pt is there, and vaccine available - VACCINATE

For Hematologic Malignancy Patients:
• Rituximab and similar agents not a contraindication, though response to vaccine unknown
• Marrow failure states – vaccinate, though response to vaccine unknown

• Clinical Trials – Unless there is a scientific reason NOT to vaccinate:
  • Pts enrolled on clinical trials should be offered vaccination
  • Vaccination should not be an eligibility disqualifier for enrollment on a trial
So what have we done nationally?..............

- Vaccine supplies have varied greatly by State, County, City
- Rules have varied greatly by State, County, City
- Logistics are complicated and everyone doing their best
- Vaccination rates, and who is getting vaccinated varies
THANK YOU
COVID-19 Vaccination
Special consideration for breast patients

Laurie Kirstein, MD, FACS
Introduction

- Review of lymphadenopathy seen with COVID-19 vaccination
- Recommendations for vaccine injection in breast cancer patients
- Recommendations for screening mammograms in relation to COVID-19 vaccination
Lymphadenopathy (LAD)

- Hyperplastic axillary nodes are known to occur after administration of a vaccine that produces a strong immune response
- LAD is a rare occurrence with routine vaccinations such as influenza, BCG and HPV
- COVID-19 vaccination produces a strong immune response and therefore the rates of LAD are higher
- It is often unilateral but sometimes bilateral

Mehta, Diagnostic Imaging, Feb, 2021
CDC reports of LAD after COVID-19 vaccination - Moderna

- Grade 3 toxicity: Use of pain reliever or prevented daily activity
- Axillary swelling or tenderness was the second most frequently reported reaction
- More common in younger patients

https://www.cdc.gov/vaccines/covid-19/index.html

<table>
<thead>
<tr>
<th></th>
<th>Dose 1</th>
<th>Dose 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vaccine</td>
<td>Placebo</td>
</tr>
<tr>
<td>Axillary swelling/tenderness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-64</td>
<td>Any</td>
<td>11.6</td>
</tr>
<tr>
<td></td>
<td>Grade 3</td>
<td>0.3</td>
</tr>
<tr>
<td>&gt;65</td>
<td>Any</td>
<td>5.1</td>
</tr>
<tr>
<td></td>
<td>Grade 3</td>
<td>0.3</td>
</tr>
</tbody>
</table>
CDC reports of LAD after COVID-19 vaccination - Pfizer

• Only reported as an adverse event
• There were 64 patients reported with LAD in the vaccine group compared to 6 in the placebo group
  • Likely under-represented

https://www.cdc.gov/vaccines/covid-19/index.html
Examples of LAD after COVID-19 Vaccination
Adenopathy after COVID-19 Vaccination
American Cancer Society Recommendations

• “Since the vaccine can cause LAD, it is recommended that the injection occur on the arm contralateral to the breast cancer”
Recommendations for management of unilateral LAD seen on imaging in patients receiving recent COVID-19 vaccination

• Society of breast imaging (SBI):
• Consider obtaining the following information:
  • COVID-19 vaccination status, timing and side (left vs. right arm) of vaccination.
  • To minimize anxiety, consider including this introductory statement:

  • Vaccines of all types can result in temporary swelling of the lymph nodes, which may be a sign that the body is making antibodies in response as intended.
SBI recommendations for unilateral LAD seen on imaging in the setting of COVID-19 vaccination cont’d

• Unilateral LAD on screening exams warrants a BI-RADS 0 assessment
  • allows for further assessment of the ipsilateral breast
  • documentation of medical history, including COVID-19 vaccination.

• After appropriate diagnostic work up, if the unilateral axillary LAD is within 4 weeks of COVID-19 vaccination in the ipsilateral UE:
  • consider a short term follow up exam in 4-12 weeks (BI-RADS category 3) following the second vaccine dose.

• If axillary adenopathy persists after short term follow up:
  • consider lymph node sampling to exclude breast and non-breast malignancy.
SBI considerations: scheduling screening exams

• If possible, and when it does not unduly delay care, consider scheduling screening exams:
  • prior to the first dose of a COVID-19 vaccination
  • OR 4-6 weeks following the second dose of a COVID-19 vaccination.
Summary

• Unilateral LAD is common with Pfizer and Moderna COVID-19 vaccinations, after both the first and second dose
  • More common in younger patients

• It is recommended to give the vaccine in the arm contralateral to the breast cancer, if possible

• Unilateral LAD on imaging after COVID-19 vaccination warrants
  • a medical history from the patient, including vaccination information
  • follow up imaging 4-12 weeks after second dose
  • Nodal sampling if not resolved after short interval follow up imaging
• If not clinically detrimental, screening mammogram should be performed prior to COVID-19 vaccination or 4-6 weeks after the second dose

• THANK YOU!
CD8 T-cells compensate for impaired humoral immunity in COVID-19 patients with hematologic cancer

Erin Bange, MD

February 26, 2021
Multi-institution collaborative effort

COPE
• Multi-site prospective cohort study of patients with cancer hospitalized with COVID-19

MESSI
• Prospective cohort study of patients hospitalized with COVID-19 with blood specimen collection

MSKCC
• Retrospective cohort study of patients with cancer hospitalized with COVID-19 with blood specimen collection
COPE cohort characteristics are generalizable to other US cohorts

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N=100</th>
</tr>
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<tbody>
<tr>
<td>Age, median</td>
<td>68</td>
</tr>
<tr>
<td>Gender, female</td>
<td>48</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>54</td>
</tr>
<tr>
<td>White</td>
<td>33</td>
</tr>
<tr>
<td>Smoking History, Ever</td>
<td>57</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>78</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>41</td>
</tr>
<tr>
<td>Cancer Type</td>
<td></td>
</tr>
<tr>
<td>Solid malignancy</td>
<td>78</td>
</tr>
<tr>
<td>Heme malignancy</td>
<td>22</td>
</tr>
<tr>
<td>Cancer Status, Active</td>
<td>46</td>
</tr>
<tr>
<td>Cancer treatment in last 3 months</td>
<td></td>
</tr>
<tr>
<td>Active surveillance/surgery</td>
<td>53</td>
</tr>
<tr>
<td>Cytotoxic Chemotherapy</td>
<td>24</td>
</tr>
<tr>
<td>Hormone therapy</td>
<td>15</td>
</tr>
</tbody>
</table>
Key clinical determinants of disease severity
Hematologic cancer is an independent risk factor of COVID-19 mortality

Table 3 | COPE: Event rates and point estimates of outcomes by cancer type.

<table>
<thead>
<tr>
<th>Event</th>
<th>Heme</th>
<th>Solid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death within 30 days of discharge</td>
<td>12 (54.6%)</td>
<td>26 (33.3%)</td>
</tr>
<tr>
<td>Unadjusted OR (95% CI)</td>
<td>2.4 (0.82-7.06)</td>
<td>ref</td>
</tr>
<tr>
<td>Adjusted OR (95% CI)*</td>
<td>3.3 (1.01-10.8)</td>
<td>ref</td>
</tr>
<tr>
<td>Adjusted HR (95% CI)*</td>
<td>2.6 (1.19-5.54)</td>
<td>ref</td>
</tr>
</tbody>
</table>

*Logistic regression computed odds ratio (OR) and Cox regression computed hazard ratio (HR), respectively. Adjusted for age, gender, smoking status, active cancer status, and ECOG performance status.
# MESSI Cohort – demographics and clinical characteristics

<table>
<thead>
<tr>
<th></th>
<th>PENN: MESSI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No Cancer</td>
</tr>
<tr>
<td><strong>Number</strong></td>
<td>108</td>
</tr>
<tr>
<td><strong>Age (median)</strong></td>
<td>60.0</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>49 (45.4%)</td>
</tr>
<tr>
<td>Male</td>
<td>59 (54.6%)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>74 (68.5%)</td>
</tr>
<tr>
<td>Caucasian</td>
<td>28 (25.9%)</td>
</tr>
<tr>
<td>Asian</td>
<td>5 (4.6%)</td>
</tr>
<tr>
<td><strong>Mortality (28 days)</strong></td>
<td>12 (11.1%)</td>
</tr>
</tbody>
</table>
Patients with hematologic cancer have an impaired SARS-CoV-2 specific antibody response
Patients with hematologic cancer have diminished levels of CD4 T cells and B cells.
Patients with hematologic cancer have increased levels of activated CD8 T cells
Demographics: MSKCC Cohort

<table>
<thead>
<tr>
<th></th>
<th>Liquid (N=45)</th>
<th>Solid (N=39)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>46.7%</td>
<td>51.3%</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>64</td>
<td>66</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>84.4%</td>
<td>76.9%</td>
</tr>
<tr>
<td>Black</td>
<td>11.1%</td>
<td>10.3%</td>
</tr>
<tr>
<td>Asian</td>
<td>4.4%</td>
<td>7.7%</td>
</tr>
<tr>
<td><strong>Disease Severity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Median)</td>
<td>4.00</td>
<td>3.00</td>
</tr>
<tr>
<td><strong>Mortality</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>44.4%</td>
<td>20.5%</td>
</tr>
</tbody>
</table>

Santosh Vardhana
CD8 T cells associated with survival for all hematologic cancers, including those treated with anti-CD20 therapies
Acknowledgements

COPE

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  • Stella Park
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  • Nick Frazzette
  • Daniel Yoon

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  • Olutwatosin Oniyide
  • Roseline Agykum
  • Thomas Dunn
  • Tiffanie Jones
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  • Adam Widman
  • Susan DeWolf

• Garfall Lab
  • Immune Health Processing Unit
Conclusions

• Patients with hematologic cancer have increased mortality from COVID-19
• Patients with solid tumors have an immune phenotype similar to those without a cancer diagnosis
• Patients with hematologic cancer have impaired B cell and antibody responses to infection
• CD8 T cells may compensate for an impaired humoral immunity and influence survival
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- The Rationale for Radiation Oncology Data Items in STORE 2018
- You Have Questions? We Have Answers!
- New and Improved: Updates to STORE
- AJCC yc Stage Classification—When and How to Use
- Registrar’s Guide to Updating Radiation Data Items
- AJCC Cervix Uteri – Version 9 Cancer Staging System

*Meeting the 2020 Standards for Optimal Cancer Care
- Survivorship Program: Standard 4.8
- Concurrent Abstracting Panel
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