Cancer PROGRAMS

AMERICAN COLLEGE OF SURGEONS

Recommendations for Cancer Patients and the COVID-19 Vaccine

February 26, 2021

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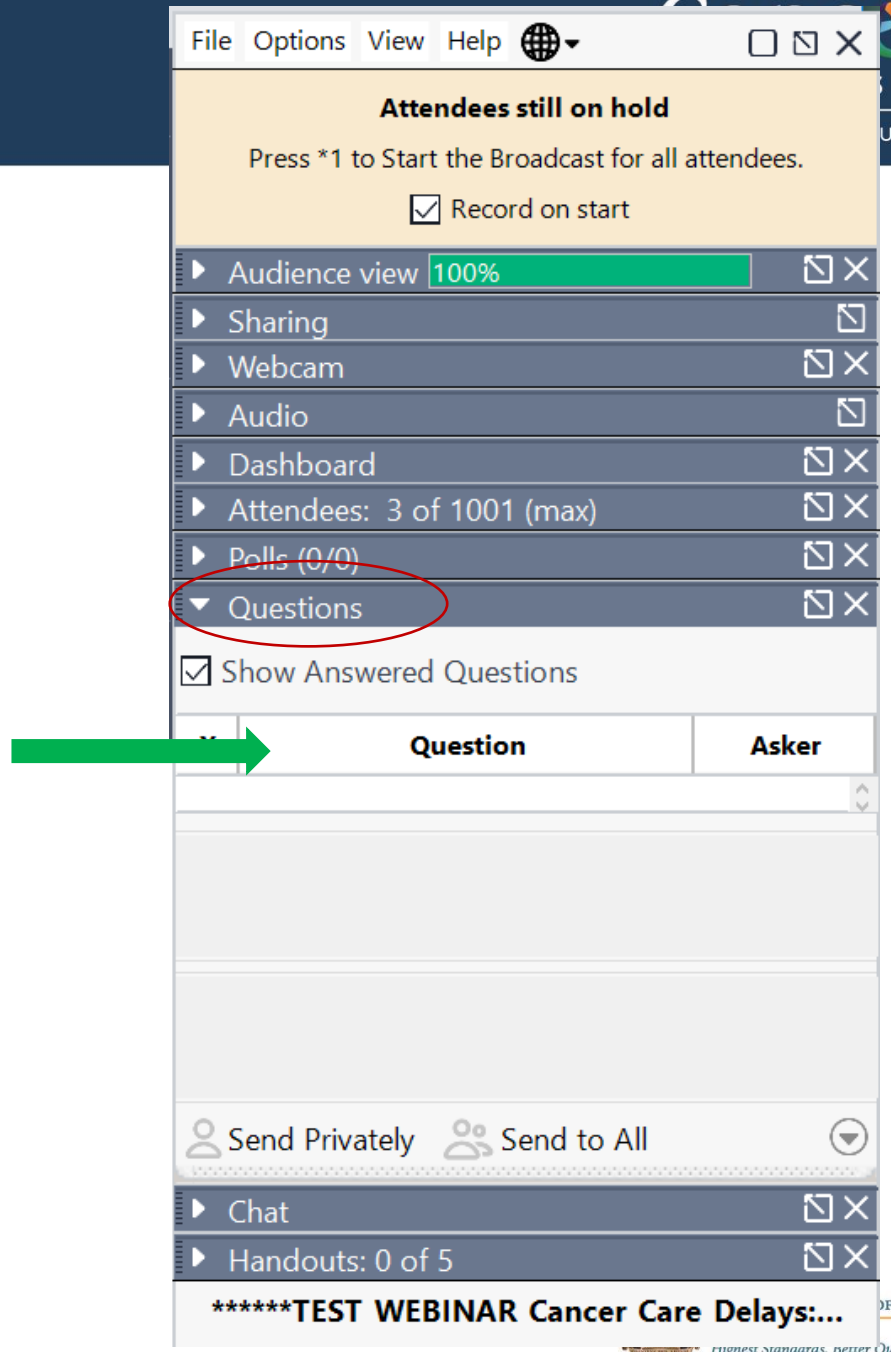

Introducing Our Modertor

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Laurie Kirstein MD, FACS

Introducing Our Speakers

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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

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

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:

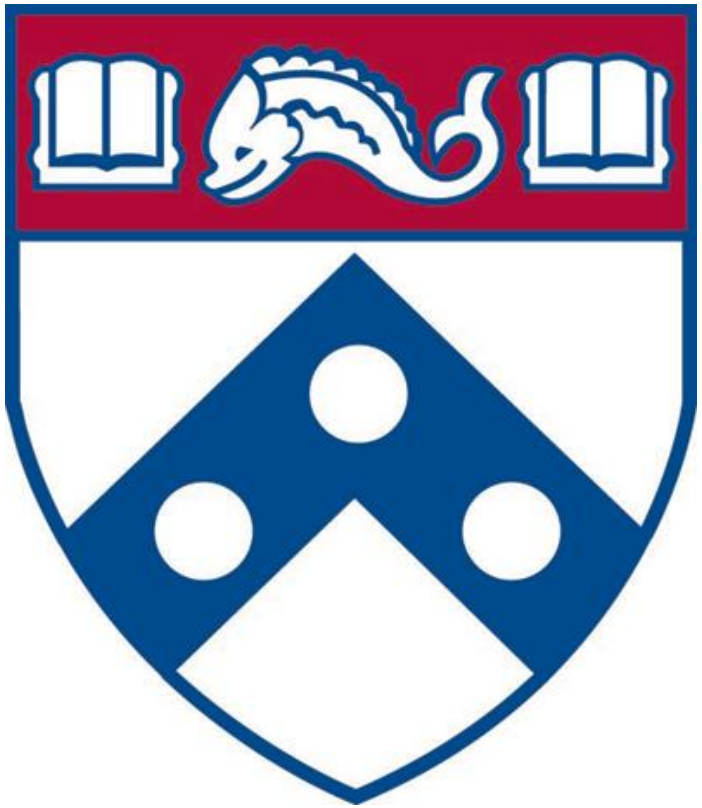
- Rituximab and similar agents not a contraindication, though response to vaccine unknown
- Marrow failure states – vaccinate, though response to vaccine unknown

- ***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 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

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

- 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

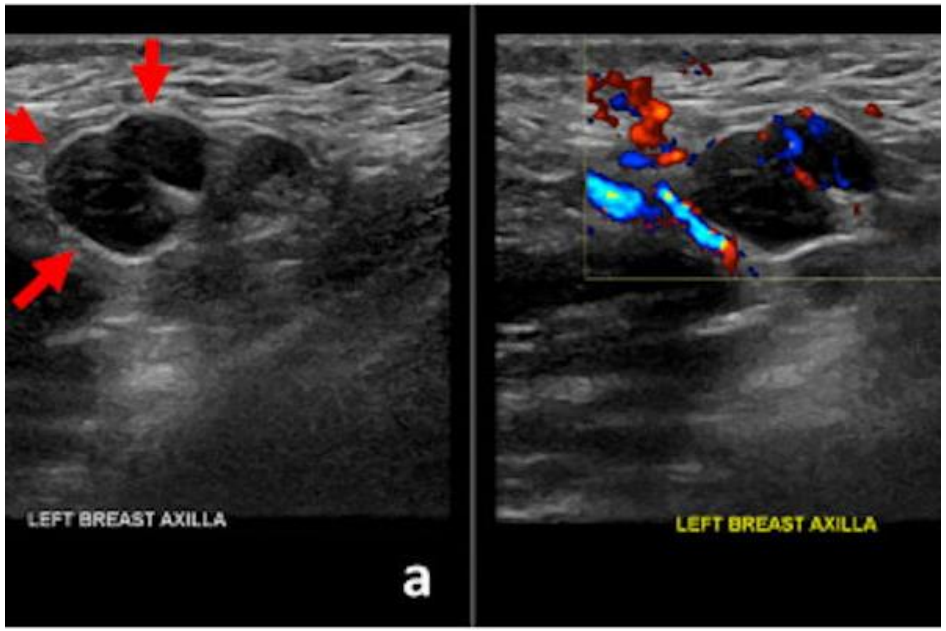
		Dose 1		Dose 2	
		Vaccine	Placebo	Vaccine	Placebo
Age	Axillary swelling/tenderness				
18-64	Any	11.6	5	16	4.3
	Grade 3	0.3	0.1	0.4	<0.1
>65	Any	5.1	4.1	8.4	2.5
	Grade 3	0.3	0.4	0.6	0.2

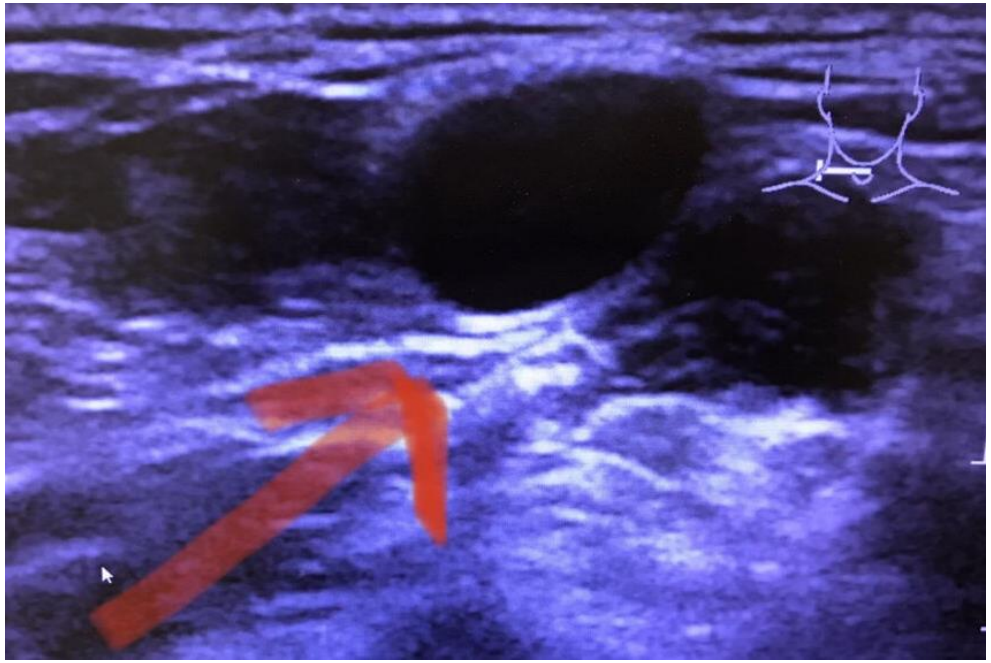
CDC reports of LAD after COVID-19 vaccination - Pfizer

- 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





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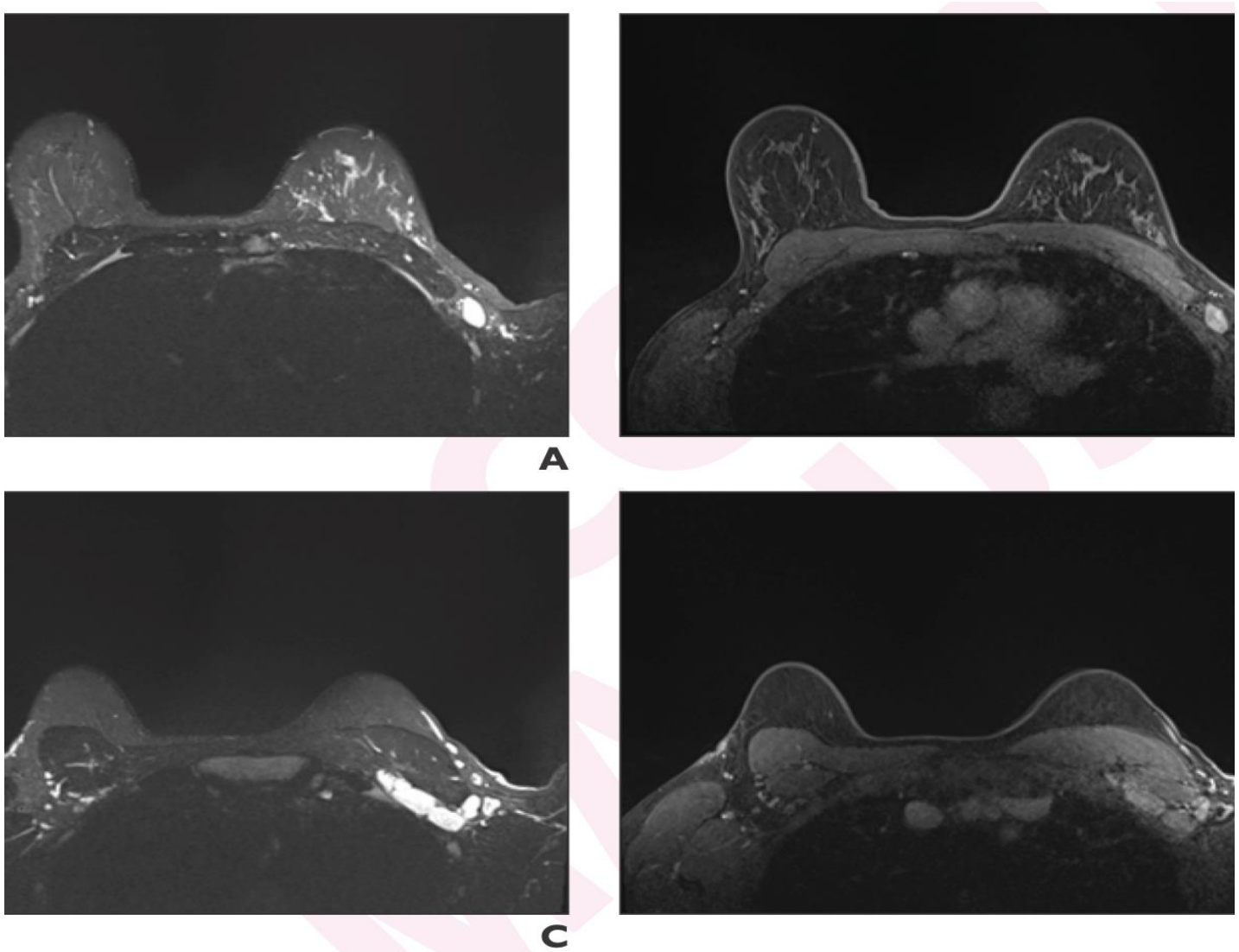
Adenopathy after COVID-19 Vaccination



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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”

Cancer.org

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

Summary Cont’d

- If not clinically detrimental, screening mammogram should be performed prior to COVID-19 vaccination or 4-6 weeks after the second dose

- THANK YOU!

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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

Penn Medicine

Memorial Sloan Kettering Cancer Center

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

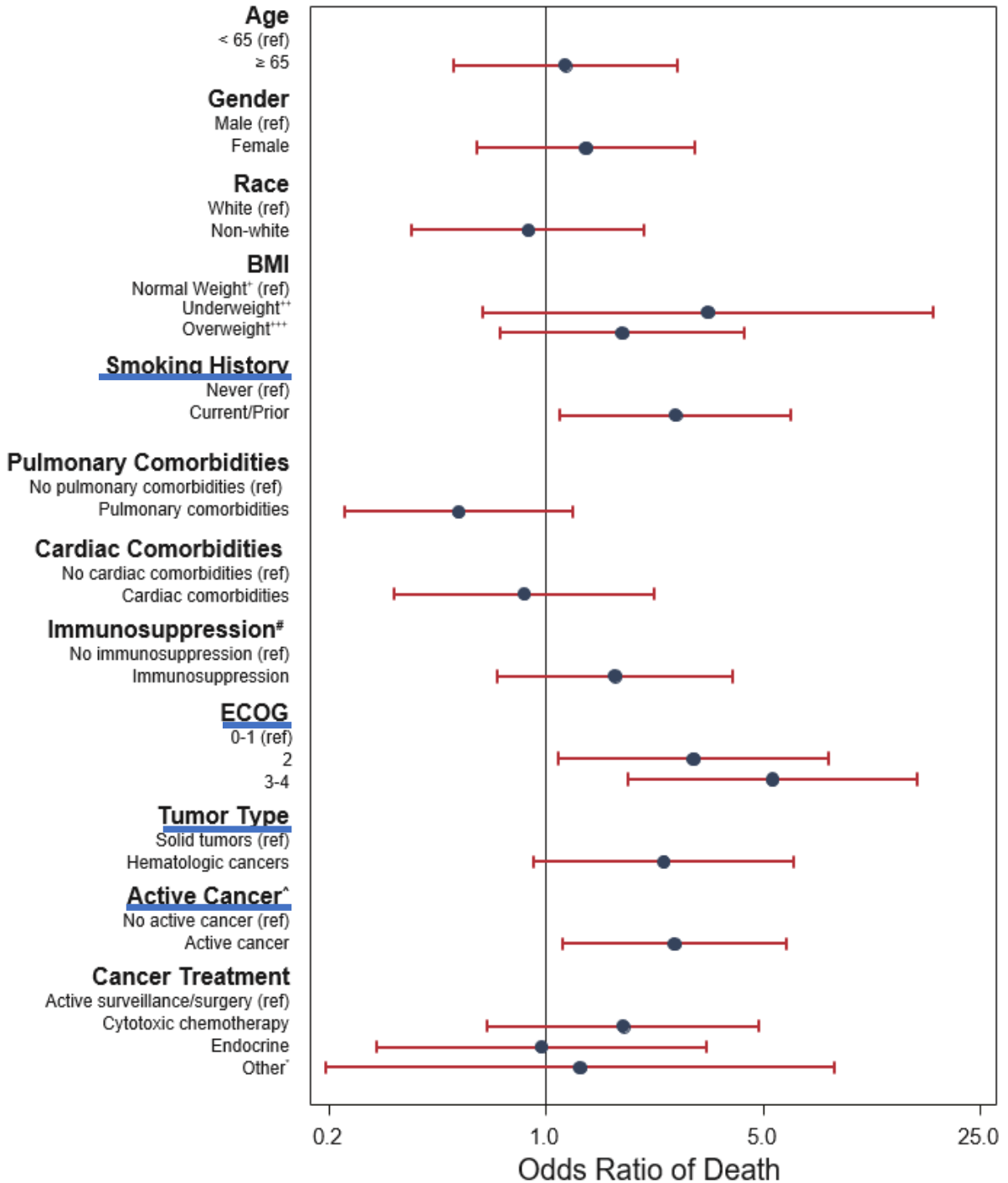
MSKCC

- Retrospective cohort study of patients with cancer hospitalized with COVID-19 with blood specimen collection

COPE cohort characteristics are generalizable to other US cohorts

	N=100
Age, median	68
Gender, female	48
Race	
Black	54
White	33
Smoking History, Ever	57
Comorbidities	
Cardiac	78
Pulmonary	41
Cancer Type	
Solid malignancy	78
Heme malignancy	22
Cancer Status, Active	46
Cancer treatment in last 3 months	
Active surveillance/surgery	53
Cytotoxic Chemotherapy	24
Hormone therapy	15

Key clinical determinants of disease severity



Hematologic cancer is an independent risk factor of COVID-19 mortality

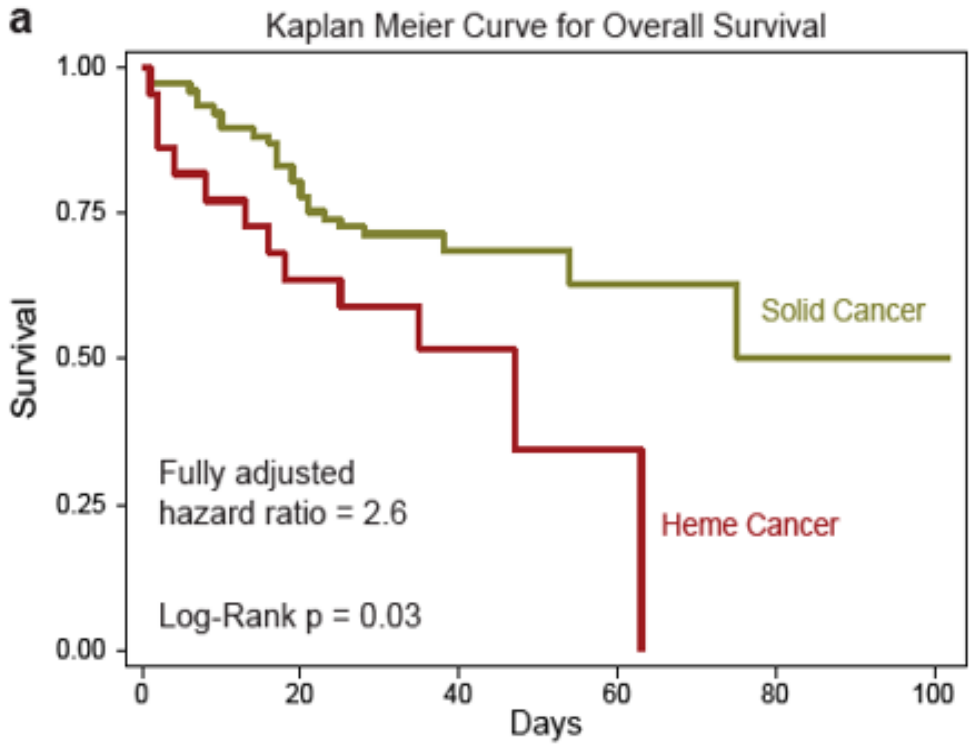


Table 3 | COPE: Event rates and point estimates of outcomes by cancer type.

	Heme	Solid
Death within 30 days of discharge		
Event rate (%)	12 (54.6%)	26 (33.3%)
Unadjusted OR (95% CI)	2.4 (0.82-7.06)	ref
Adjusted OR (95% CI)[+]	3.3 (1.01-10.8)	ref
Adjusted HR (95% CI)[+]	2.6 (1.19-5.54)	ref

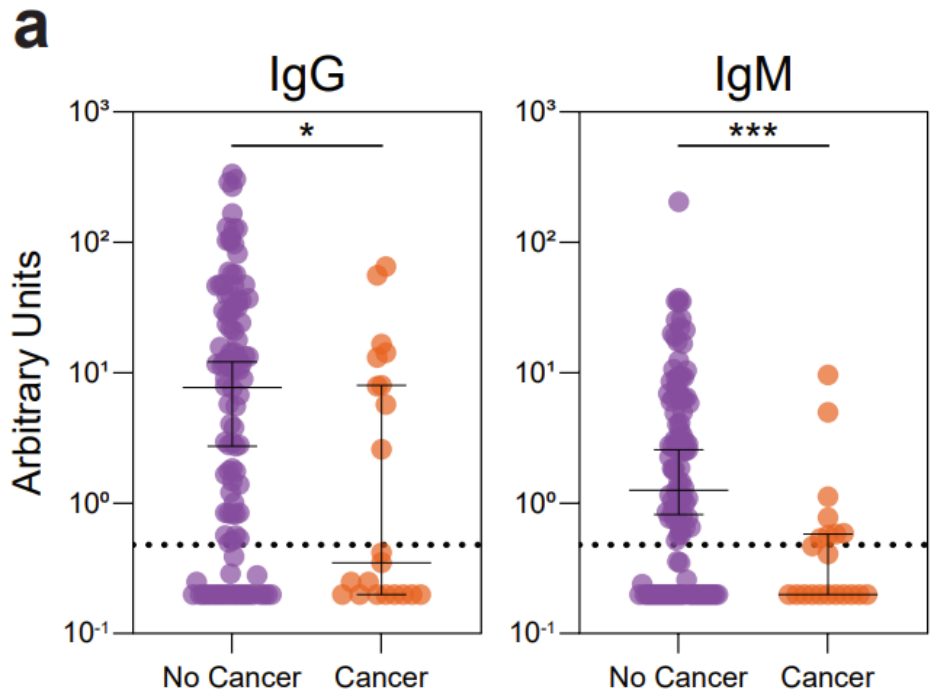
[+]Logistic regression computed odds ratio (OR) and Cox regression computed hazard ratio (HR), respectively. Adjusted for age, gender, smoking status, active cancer status, and ECOG performance status.

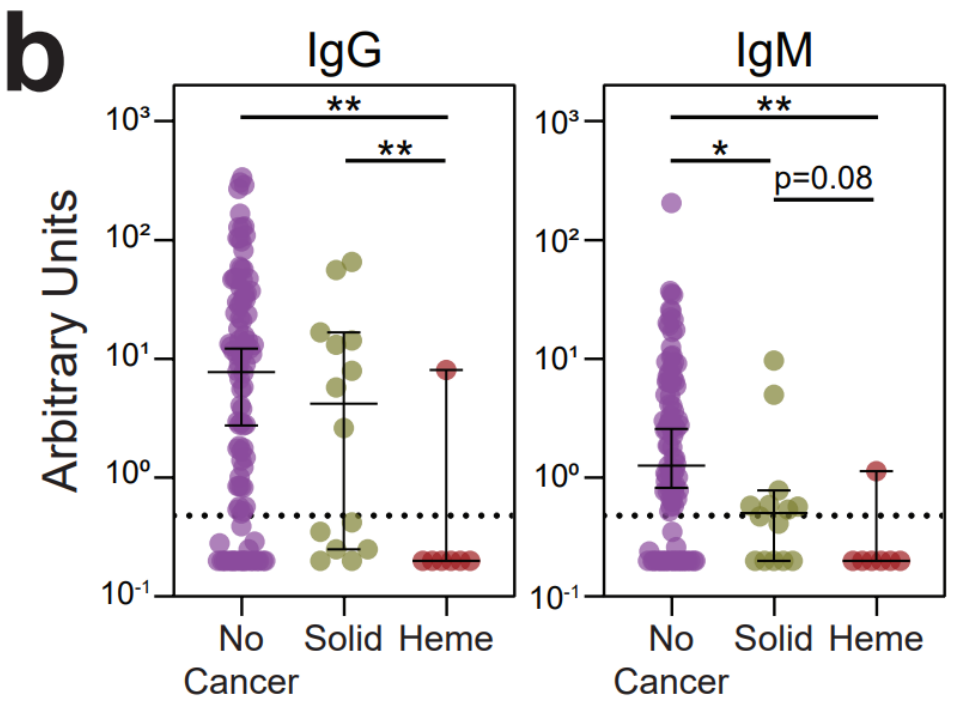
MESSI Cohort – demographics and clinical characteristics

a

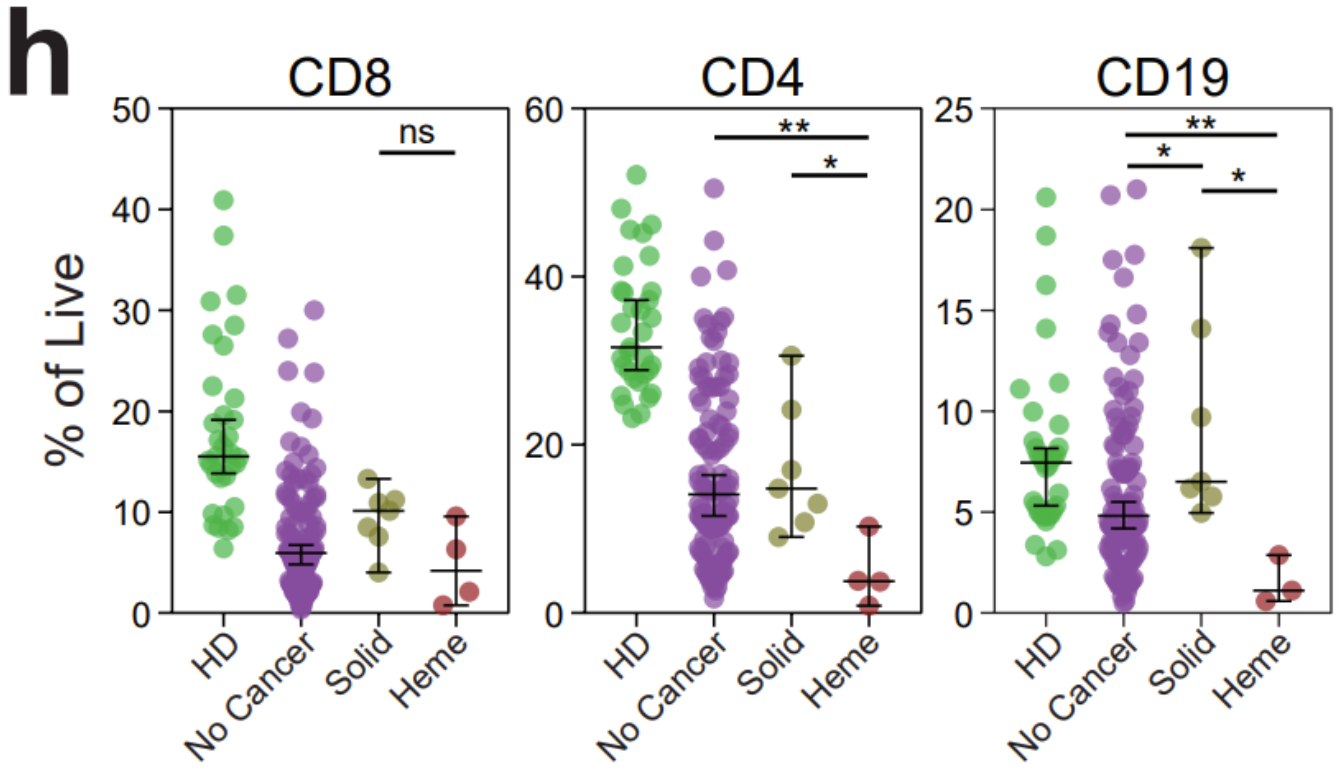
		PENN: MESSI	
		No Cancer	**Active Cancer**
Number		108	22
Age (median)		60.0	66.0
Gender	Female	49 (45.4%)	14 (63.6%)
	Male	59 (54.6%)	8 (36.4%)
Race	Black	74 (68.5%)	16 (72.7%)
	Caucasian	28 (25.9%)	5 (22.7%)
	Asian	5 (4.6%)	1 (4.5%)
Mortality (28 days)		12 (11.1%)	8 (36.4%)

Patients with hematologic cancer have an impaired SARS-CoV-2 specific antibody response

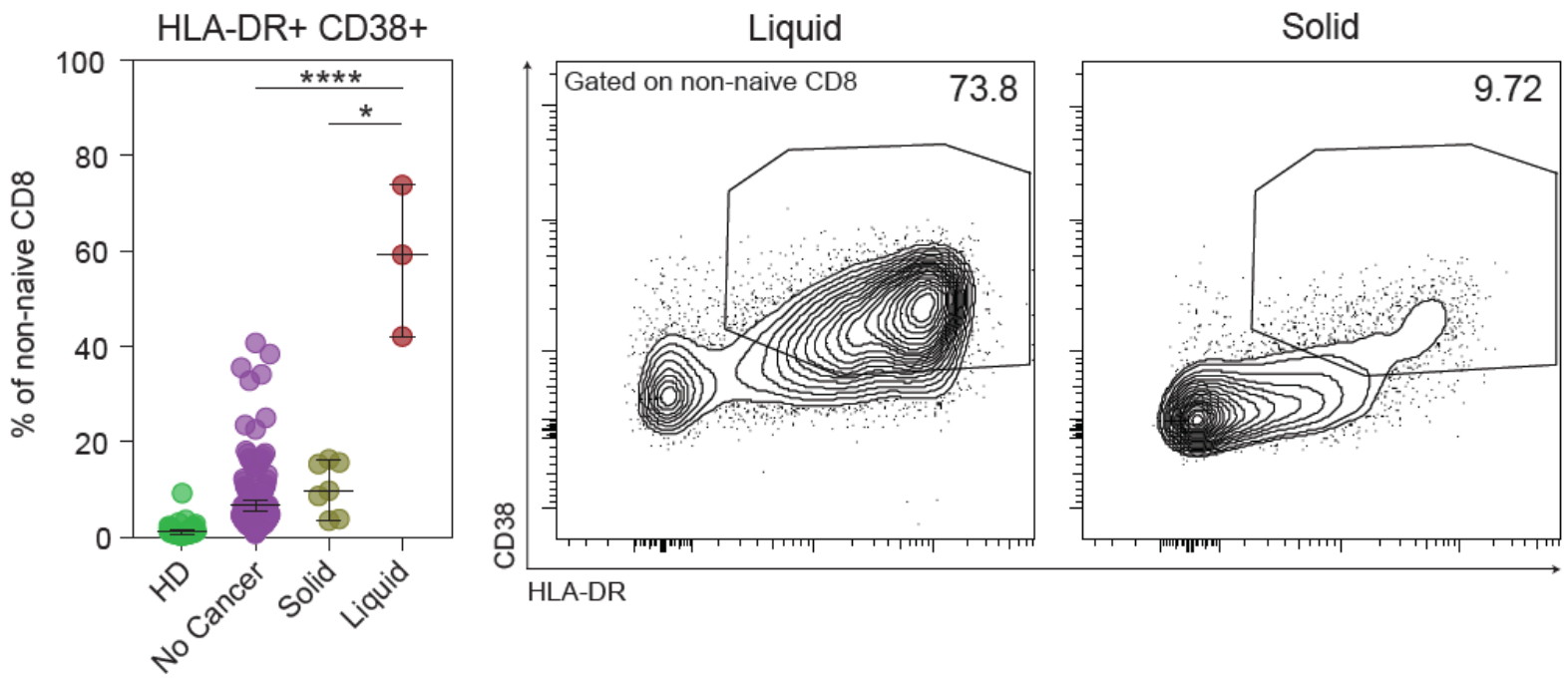




Patients with hematologic cancer have diminished levels of CD4 T cells and B cells



Patients with hematologic cancer have increased levels of activated CD8 T cells

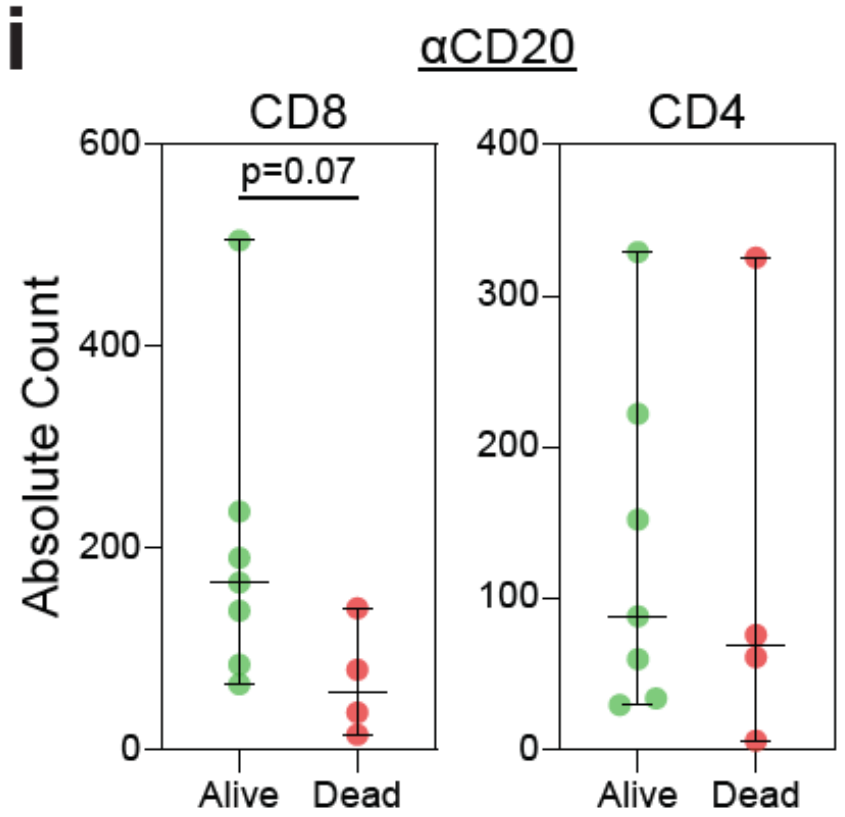


Demographics: MSKCC Cohort

Santosh Vardhana

	Liquid (N=45)	Solid (N=39)
Gender		
Female	46.7%	51.3%
Age		
Median	64	66
Race		
Caucasian	84.4%	76.9%
Black	11.1%	10.3%
Asian	4.4%	7.7%
Disease Severity (Median)	4.00	3.00
Mortality	44.4%	20.5%

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



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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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