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COVID-19 and Oncology Practice

Stephen Kimani, MD, MSc
Clinical Fellow, University of North Carolina
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Disclosures

- **I do not have any financial conflict of interests**
- **I will discuss off-label or investigational use(s) of a product or device**
- **I attest that I am not receiving direct payments from a commercial entity with respect to this activity**

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Disclaimer

- Data about COVID-19 is evolving quickly
- This talk will highlight data supported by peer-reviewed publications
- Any material that is not yet peer reviewed will be flagged as such, if discussed during this talk
- Issues specific to bone marrow transplant or CAR-T population will not be covered

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What are some of the key questions in oncology practice

- Which cancer patients are at greatest risk?
- What are the complications and outcomes?
- What are the best treatment(s) and management situations?
- How do the available COVID-19 vaccines compare?
- Are the available vaccines safe for cancer patients?
- What post-vaccination issues should we watch out for among cancer patients?
- What should we do about patients' anti-cancer treatment(s)?
- How should our oncology practice respond to adopt?

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Objectives

- Describe prevalence, incidence, and outcomes of COVID-19 among select populations of cancer patients in the US
- Compare safety and efficacy of available COVID-19 vaccines
- Discuss the impact of COVID-19 on cancer care delivery with emphasis on unique challenges and opportunities in oncology

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COVID-19 is a rapidly evolving global health issue

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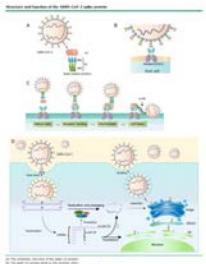
A quick overview of SARS-CoV-2



- Two main processes are thought to drive the pathogenesis of COVID-19(Wiersinga, Rhodes et al. 2020)
  - Viral replication
  - Hyper inflammatory response to the virus leads to tissue damage
- SARS-CoV-2-specific antibodies and cell-mediated responses are induced following infection
  - Duration of protective effects remain unknown
- **Risk of transmission depends on exposure type**
- Notable variants
  - **B.1.1.7 ("UK")**
  - **B.1.351 ("South Africa")**
  - **P.1 ("Brazil")**

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Cancer patients are historically considered at high risk for infections

- **Different mechanisms of immunosuppression**
  - **The cancer itself e.g., bone marrow invasion**
  - **Cancer treatment effects e.g., chemotherapy-induced bone marrow suppression, radiation mucositis**
- **Poor nutrition**
  - **Decreased performance status**
  - **Fragility**
- **High burden of co-morbidities unrelated to cancer**
  - **Advanced age**
  - **Non-communicable diseases**
  - **Frequent exposure to healthcare**(Yu, Ouyang et al. 2020)

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Cancer patients are at higher risk of COVID-19

- Variable incidence but relative higher incidence vs. general population
  - Risk factors: recent cancer diagnosis, older age, comorbidities
- Risk highest for lung cancer and hematologic malignancies
- Incidence rates variable depending on phase of pandemic
  - IR during active treatment ~1-4% (Spring 2020) and ~10 % (Fall 2020)
- Cancer patients have a higher COVID-19 mortality rate
  - Morbidity and mortality in patients with cancer range from 5% to 61% (vs. 2-3% in general population)(Yap, Siu et al. 2021)*

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Cancer is associated with worse clinical outcomes among patients with COVID-19

- **Some COVID-19 clinical studies indicate poorer outcomes for cancer patients, especially those with hematological cancers**(Vijenthira, Gong et al. 2020)(Williamson, Walker et al. 2020)
- **Cancer patients are likely to have more severe illness and death** (Giannakoulis, Papoutsi et al. 2020)
- Factors associated with poor outcomes
  - Cancer disease status (active v. progressive v. stable)
  - Recent anti-cancer therapy
  - Performance status
  - Others: comorbidities, age, socioeconomic status
- Mortality highest for lung cancer (and other thoracic malignancies)

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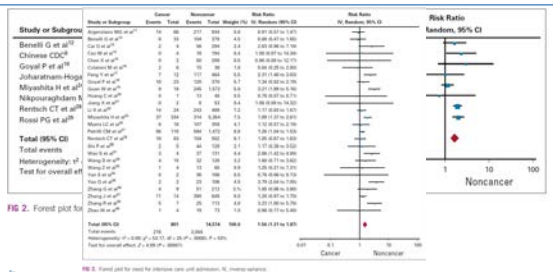
Cancer is associated with increased need for ICU and mortality among patients with COVID-19



(Giannakoulis, Papoutsi et al. 2020)

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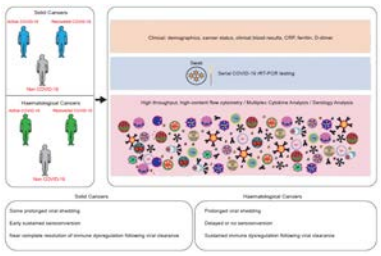
Impact of SARS-CoV-2 on cancer patients' immune status



- (Abdul-Jawad, Baù et al. 2021)

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Duration of cancer history matters

Characteristic	Category	Fully adjusted HR and 95% CI				
		Primary analysis	Early censoring at 6/4/2020	Restricted to those with complete BMI /smoking	Adjusted for ethnicity in those where recorded	Adjusted for ethnicity using multiple imputation
Cancer (non-haematological, vs none)	Diagnosed < 1 year ago	1.72 (1.50-1.96)	1.66 (1.27-2.16)	1.68 (1.46-1.94)	1.67 (1.43-1.96)	1.74 (1.52-1.99)
	Diagnosed 1-4.9 years ago	1.15 (1.05-1.27)	1.34 (1.13-1.60)	1.16 (1.05-1.28)	1.21 (1.09-1.35)	1.17 (1.06-1.28)
	Diagnosed ≥5 years ago	0.96 (0.91-1.03)	0.92 (0.81-1.04)	0.97 (0.91-1.03)	0.98 (0.92-1.06)	0.97 (0.92-1.04)
Haematological malignancy (vs none)	Diagnosed < 1 year ago	2.80 (2.08-3.78)	2.20 (1.14-4.24)	2.86 (2.10-3.88)	2.33 (1.60-3.41)	2.81 (2.08-3.79)
	Diagnosed 1-4.9 years ago	2.46 (2.06-2.95)	3.49 (2.61-4.68)	2.40 (1.99-2.90)	2.53 (2.05-3.11)	2.48 (2.07-2.97)
	Diagnosed ≥5 years ago	1.61 (1.39-1.87)	1.45 (1.06-1.97)	1.61 (1.38-1.89)	1.55 (1.30-1.85)	1.63 (1.40-1.89)

- (Williamson, Walker et al. 2020)

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Are outcomes worse in patients with hematologic malignancies?

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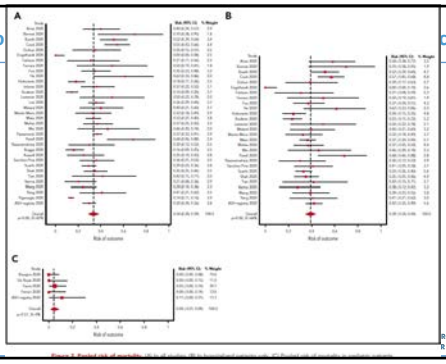
Are outco cies?



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Impact of cancer-directed treatment on COVID-19 outcomes

- Available data linking recent active therapy to poor outcomes are mixed
  - In earlier studies, receipt of cancer therapy was associated with worse outcomes
  - Recent active oncologic therapy does not necessarily increase the risk of mortality from COVID-19
  - (Kuderer, Choueiri et al. 2020)
- The type of cancer treatment may influence the risk, although again, the data are mixed, particularly with regard to recent immunotherapy

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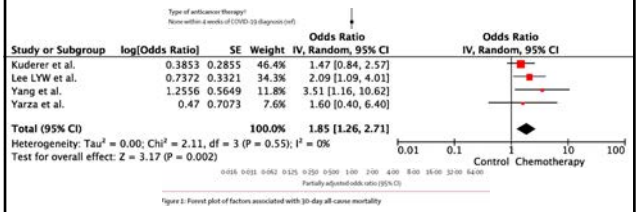
Impact of cancer-directed chemotherapy treatment on risk of death



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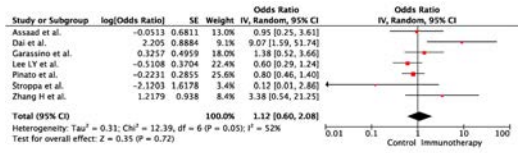
Impact of cancer-directed immunotherapy on risk of death



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A comment on thrombosis and VTE risk

- COVID-19 is associated with an increased risk of both arterial and venous thrombotic events, termed COVID-19-associated hypercoagulable state
- Limited evidence suggests that cancer patients who develop COVID-19 are not necessarily at a higher risk of COVID-19-associated hypercoagulable state(Patell, Bogue et al. 2020)

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COVID-19 treatments and clinical outcomes among patients with cancer

- Baseline COVID-19 severity was strongly associated with receipt of any treatment
  - No statistically significant 30-day all-cause mortality benefit with hydroxychloroquine or high-dose corticosteroids alone or in combination; Remdesivir showed potential benefit.
- Disparities in medication access
  - Black patients were approximately half as likely to receive Remdesivir as white patients.
- No RCT data yet on treatment and outcomes among cancer patients

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Challenges in the care of cancer patients with COVID-19

- Cancer patients with profound immunosuppression may shed viable SARS-CoV-2 for a prolonged period (Aydillo, Gonzalez-Reiche et al. 2020)(Karataş, İnkaya et al. 2020)
  - Post-HSCT or CAR-T, on active therapy (≥2 months)
- Risk of immune-related pneumonitis of immunotherapy (Naidoo, Reuss et al. 2020)

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NIH COVID-19 treatment guidance (updated Feb 11, 2021)

- Off-label use
  - Dexamethasone
- FDA-approved
  - Remdesivir for hospitalized & supplemental oxygen
- FDA EUA for anti-SARS-CoV-2 monoclonal antibodies
  - Outpatient with mild to moderate COVID-19 & at high risk for progressing to severe disease or hospitalization
  - Casirivimab plus Imdevimab
  - Bamlanivimab plus Etesevimab

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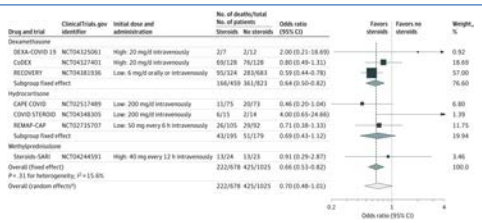
From: **Association Between Administration of Systemic Corticosteroids and Mortality Among Critically Ill Patients With COVID-19: A Meta-analysis**

Sterne, Murthy et al. 2020, JAMA. 2020;324(13):1330-1341. doi:10.1001/jama.2020.17023



*The random-effects analysis estimates both the average and variability of effects across studies. The 95% CI for the average effect (shown here) is wide because there is a small number of studies, some of which have very small sample size. The prespecified primary analysis was the fixed-effect analysis, which should be used to guide clinical interpretation of the results.

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Summary

- **Which cancer patients are at greatest risk?** Lung cancer and hematological malignancies
- **What are the complications and outcomes?** Increased risk of death
- **What are the best treatment(s) and management situations?** Dexamethasone +/- Remdesivir depending on severity. Consider anti-SARS-CoV-2 monoclonal antibodies in select cases

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Objectives

- Describe prevalence, incidence, and outcomes of COVID-19 among select populations of cancer patients in the US
- Compare safety and efficacy of available COVID-19 vaccines
- Discuss the impact of COVID-19 on cancer care delivery with emphasis on unique challenges and opportunities in oncology

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Overview of COVID-19 vaccines (Moderna & Pfizer)

- mRNA-based vaccines
- Double shot
- Approval studies did not include cancer patients
- Infograms courtesy of lapipette.labs
- (Baden, El Sahly et al. 2021) (Polack, Thomas et al. 2020)

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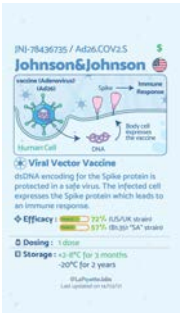
Overview of COVID-19 vaccines (J&J)

- Adenovirus-vector vaccine
- Single shot
- Approval study included some cancer patients
- (Sadoff, Le Gars et al. 2021)



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Summary of vaccines available in the US

	Pfizer/BioNTech	Moderna	Johnson & Johnson
Mechanism	mRNA vaccine	mRNA vaccine	Adenovirus vector vaccine
Schedule	2 doses, 21 days apart	2 doses, 28 days apart	1 dose
Trial participants	43,548 people, ≥16 yo	30,420 people, ≥18 yo	43,783 people, ≥18 yo
Study endpoint	Symptomatic disease	Symptomatic disease	Moderate-to-severe disease
Primary efficacy	95% at least 7 days after dose 2	94.1% at least 14 days after dose 2	72% (≥moderate), 85% severe, at least 28 days after a single dose
Variant efficacy	-	-	57% efficacy in South Africa

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Important considerations on vaccine safety and efficacy in cancer patients

- Vaccine efficacy response cannot be assumed in immunocompromised patients
  - Seroprotection rates following flu vaccination ~30% (vs. immunocompetent) (Landmark Study: Beck, McKenzie et al. 2012)
  - Immunosuppression greater in heme vs. non-heme malignancies
  - Vaccine efficacy likely variable depending on "net immunosuppression"
  - Immunogenicity after anti-B cell antibodies is poor (Landmark Study: Yri, Torfoss et al. 2011)
  - Post-vaccination antibody testing available, but utility unclear
- Eligible individuals with an immunocompromising condition can receive COVID-19 vaccines
- Expert groups recommend holding certain immunosuppressive agents around the time of vaccination or adjusting the timing of vaccination to optimize the vaccine response

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Post-vaccine reactive lymphadenopathy and imaging studies

- Case reports and anecdotes (Lehman, Lamb et al. 2021)
- Affects mammogram, chest CT, FDG-PET
- Moderna:
  - 16% (vs. 4.3% placebo), 2-4 days post-vaccine, median duration 1-2 days
- Pfizer:
  - 64 cases (vs 6 placebo), 2-4 days post-vaccine, mean 10 days
- Not yet reported to date with the Janssen/Johnson & Johnson
- ? Whether a class effect of mRNA vaccines

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How to manage reactive post-vaccine lymphadenopathy

- Limited data, expert guidance
- Management to balance caution and patient safety
- Document vaccination history & site of injection
- Contralateral injection if h/o breast cancer
- Scheduling screening breast imaging 4-6 weeks post-vaccine, when possible

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Summary

- **How do the available COVID-19 vaccines compare?** All three vaccines are quite similar in efficacy for the endpoints we care about (severe illness and hospitalization)
- **Are the available vaccines safe for cancer patients?** There is no evidence to suggest they would not be safe for most cancer patients, although data on safety in patients with cancer is lacking from the published vaccine trials to date
- **What post-vaccination issues should we watch out for among cancer patients?** There are emerging reports of post-vaccine adenopathy that may affect interpretation of cancer imaging studies. Due to lack efficacy data, patients should continue to adhere to public health measures (3 W's)

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Content

- Describe prevalence, incidence, and outcomes of COVID-19 among select populations of cancer patients in the US
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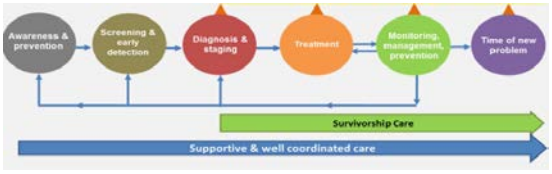
Overview of cancer care delivery continuum



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The impact of COVID-19 pandemic on oncology practice is broad

- Managing infection risk
  - Competing risks of death from cancer versus death or serious complications from infection
- Managing systemic anti-cancer therapy
  - Likely higher lethality of COVID-19 in immunocompromised hosts, including those with cancer
- Care interruptions and disruptions
  - Stay-at-home orders
  - Stretched surge capacities
  - Workforce reassignment (and loss)
- Models of care innovations

(Hui, Yuan et al. 2020); (Kaufman, Chen et al. 2020); (Sharpless 2020)

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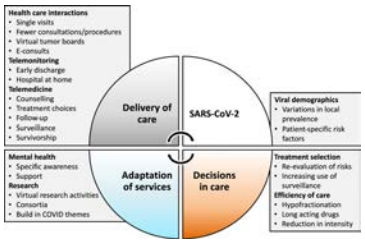
The impact of COVID-19 pandemic on oncology practice is broad



(Wallis, Catto et al. 2020)
European Urology 2020 78731-742DOI: (10.1016/j.eururo.2020.08.030)

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Impact of the COVID-19 Pandemic on Patients with Cancer

- (Moraliyage, De Silva et al. 2021)

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Impact on cancer screening, diagnosis and treatment

- Decrease in rates and timeliness of preventative cancer care
  - Colon cancer (Gupta and Lieberman 2020)(Patel, Issaka et al. 2021)
  - Cervical cancer (Miller, Xu et al. 2021)
  - Breast and lung (Patt, Gordan et al. 2020)(Song, Bergman et al. 2021)
- Delay in staging (Freer 2021)
- Prolonged time to treatment initiation (Cone, Marchese et al. 2020)(Ginsburg, Curtis et al. 2021)(Matsuo, Novatt et al. 2020)
- Reasons for changes are multi-level (Ginsburg, Curtis et al. 2021)(London, Fazio-Eynullayeva et al. 2020)
  - Patient factors
  - Health system
- Survival estimates for treatment delay (Hartman, Sun et al. 2020)

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Management of anti-cancer therapy in cancer patients who test positive for SARS-CoV-2

- September 2020: ASCO Guidance:
  - "Decisions about interrupting anticancer treatment in patients with active COVID-19 should be based on a clinical benefit: risk assessment that considers the *risk of interrupting cancer treatment* vs. the *still poorly defined risk of adverse COVID-19 outcomes* in patients receiving active cancer treatment.
- Key principles
  - For most patients, immunosuppressive cancer therapy should be withheld in those who test positive
  - BTK inhibitors may be continued
  - Oral non-immunosuppressive therapies such as hormonal therapies or molecular targeted agents may be continued

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Impact on clinical trials – Part II: participation

- **Changes in development and funding of cancer trials** (Karzai, Madan et al. 2020)(Zon, Gomes et al. 2020)
- **A major barrier to enrollment and ongoing participation in clinical trials** (Unger, Blanke et al. 2020) (Waterhouse, Harvey et al. 2020)
  - Enrollment in certain cancer-related clinical trials has dropped ≥50% since the start of the pandemic
  - Ceased research-only visits

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Emerging cancer care delivery innovations and modifications

- ASCO survey initial results
  - New use of telemedicine
  - Use of ancillary lab facilities closer to patients' home
  - Staff changes (reduction or reassignments)
- Virtual care and telemedicine are widely adopted (Loree, Dau et al. 2021)(Lou, Teoh et al. 2020)
- Ambulatory oncology to expand home infusions and supportive care (Yackzan and Shah 2021)
- Telephone triage systems (Elkin, Viele et al. 2021)(Osterman, Triglianos et al. 2021)

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Summary

- **What should we do about patients' anti-cancer treatment(s)?** There is no evidence of interaction for targeted therapy and immunotherapy, but mixed results with respect to chemotherapy. Recommend individualized clinical benefit: risk assessment
- **How should our oncology practice respond to adopt?** Embrace new models of care including telemedicine for remote monitoring

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Active registries for cancer patients

- The COVID-19 and Cancer Consortium (https://ccc19.org/)
  - Includes 114 sites (includes comprehensive cancer centers and community sites) collecting data on cancer patients and their outcomes with COVID-19.
- ASH RC COVID-19 Registry for Hematology (https://www.ashresearchcollaborative.org/s/covid-19-registry)
- ASCO COVID-19 Registry Data Dashboard (https://www.asco.org/asco-coronavirus-information/coronavirus-registry/covid-19-registry-data-dashboard)

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UK Recovery trial

RECOVERY
Randomised Evaluation of COVID-19 Therapy

- **World's largest adaptive clinical trial for COVID-19 treatments**
  - Not cancer-specific
  - Regeneron's antibody cocktail
  - Aspirin
  - Baricitinib (an immunomodulatory drug used in rheumatoid arthritis)
  - Dimethyl fumarate (an immunomodulatory drug used in psoriasis and multiple sclerosis)
- **March 11, 2021: 38954 Participants, 180 Active sites**

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Additional Resources

- **ASCO Coronavirus Resources**
  - https://www.asco.org/asco-coronavirus-information
- **NIH Coronavirus Disease 2019 (COVID-19) Treatment Guidelines**
  - https://www.covid19treatmentguidelines.nih.gov/whats-new/
- **NCCN: NCCN COVID-19 Vaccination Advisory Committee guidance**
  - https://www.nccn.org/covid-19/pdf/COVID-19_Vaccination_Guidance_V2.0.pdf (Cancer and COVID-19 Vaccination Version 2.0 03/10/2021)

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