Oncology Pharmacy Practice in the Climate of COVID-19

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KENTUCKY HEMATOLOGY/ONCOLOGY
PHARMACY SYMPOSIUM 2020

Disclosures

- No relevant conflicts to disclose.

Learning Objectives

- Review the impact of COVID-19 on cancer patient treatment and outcomes
- Examine current oncology pharmacy practice changes
- Discuss opportunities for pharmacists to improve cancer patient outcomes

What We Do Know……

1. Cancer WILL NOT hit the PAUSE button due to COVID-19
2. There is NO Pharmacy bubble

Service to Public

Cancer and COVID-19

Location	Design	Population	Notable
China	Multicenter, observational	n=1590 (cancer, n=18)	• Cancer patients at higher risk of severe event 39% vs. 8% (p=0.0003)
Europe	Multicenter, observational	n=890	• Overall 8.6% rate of mortality • Complicated COVID-19 associated with male gender, advanced age, co-morbidities
USA	Multicenter, cohort study	n=928	• Race/ethnicity, obesity, cancer type, type of anticancer therapy, and recent surgery were NOT associated with mortality

Liang W et al. Lancet Oncol. 2020 Mar;21(3):335-337
Pinato DJ et al. Cancer Discov July 31 2020
Kuderer NM et al. Lancet 2020;395:1907-18

CCC19: 30-Day All Cause Mortality

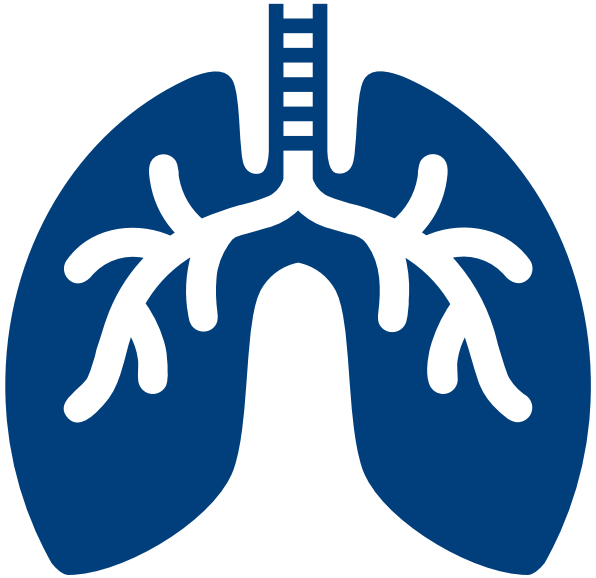
Characteristic	pAOR*	95%CI
Older age, risk per decade	1.84	1.53-2.21
Male gender	1.63	1.07-2.48
Former vs. never smoker	1.60	1.03-2.47
ECOG PS 2 vs. 0/1	3.89	2.11-7.18
Cancer present, stable	1.79	1.09-2.95
Cancer present, progressing	5.20	2.77-9.77
HCQ+Azithromycin vs. neither	2.93	1.79-4.97

* pAOR: partially adjusted odds ratio; adjusted for age, sex, smoking status, and obesity

Kuderer NM et al. Lancet 2020;395:1907-18

TERAVOLT – Thoracic malignancies

- Thoracic Cancers International COVID-19 Collaboration (TERAVOLT) registry – multicenter observational study
- Updated analysis (n=400)
  - Thoracic tumors –> higher risk of death (general population/other cancers)
  - Patients who died – 47% chemo, 22% ICIs, 12% targeted
  - ICU admission lower compared to other tumor types
  - Prior use of steroids or anticoagulants - ↑ mortality
  - Multivariate analysis age >65 years increased risk of COVID-19 mortality (HR= 1.70, 95CI 1.09–2.63; p=0.018)



Garassino MC et al. Lancet Oncol 2020;21:914-22
International Association for the Study of Lung Cancer 2020 Virtual Conference Presidential Symposium – Garassino M. COVID-19 in Thoracic Malignancies

Disease Severity in Cancer Patients

Memorial Sloan Kettering Cancer Center (MSKCC)

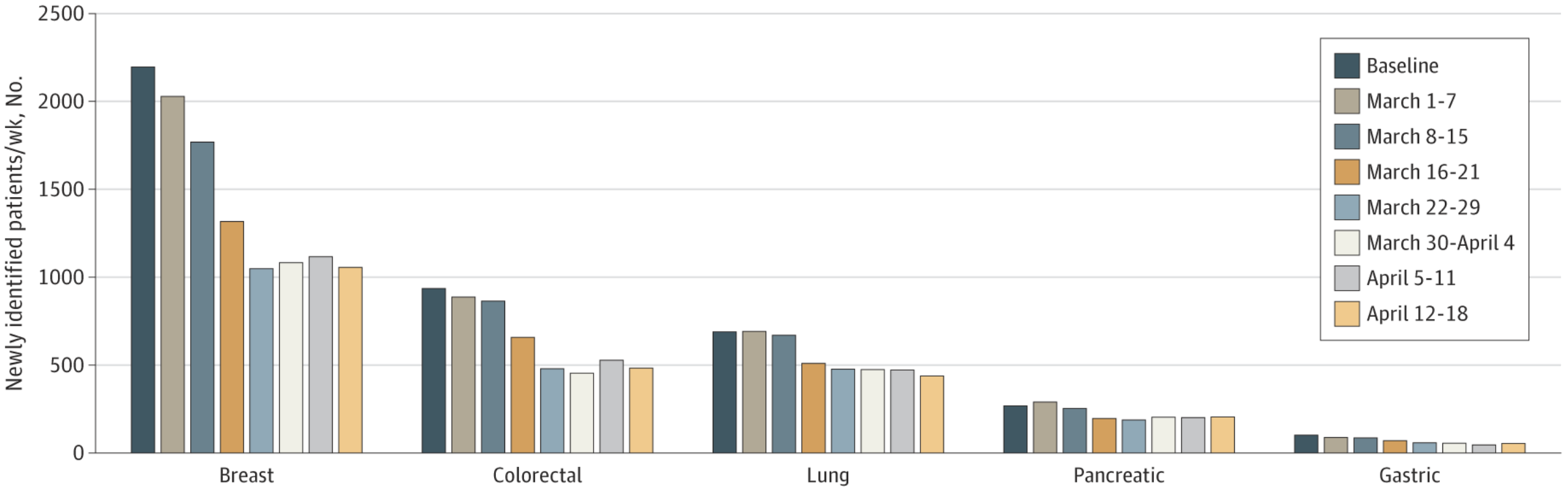
- Retrospective analysis (3/10-4/7/2020)
- N=423 symptomatic COVID (n=2035 tested)
- 40% hospitalized, 20% developed severe respiratory illness, 12% died within 30 days

	Multivariate	
	HR (95%CI)	**P-value**
Age (>65 years)	**1.67 (1.07-2.60)**	**0.024**
Smoking (current/former)	1.39 (0.89-2.17)	0.148
Asthma/COPD	1.24 (0.72-2.13)	0.436
Cancer (non-metastatic)	1.00 (Ref)	--
Cancer (metastatic solid)	0.75 (0.40-1.41)	0.371
Cancer (hematologic)	1.79 (0.97-3.32)	0.063
Cardiac disorder	1.18 (0.73-1.89)	0.505
Lymphopenia or corticosteroids	1.42 (0.86-2.34)	0.165
Immune checkpoint inhibitor	**2.74 (1.37-5.46)**	**0.004**

****Predictors of severe respiratory illness, by COX proportional hazard (n=423)**

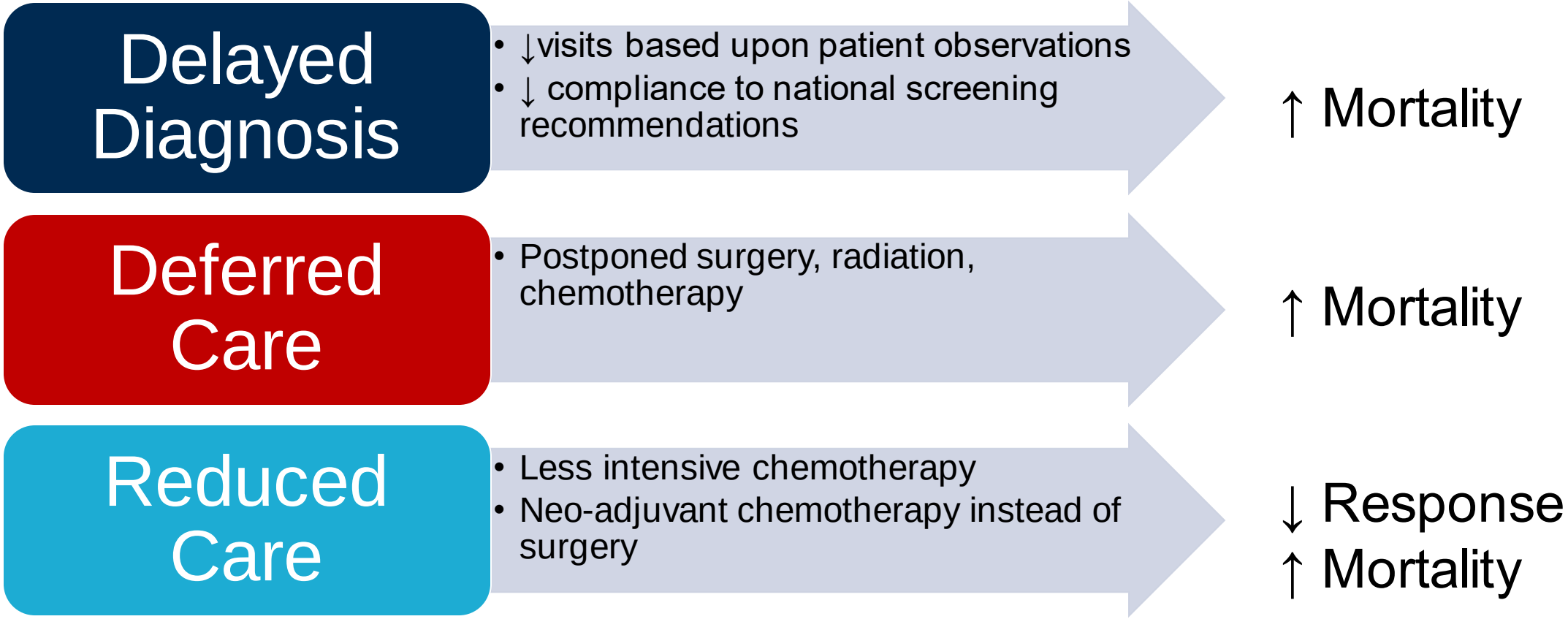
Robilotti EV et al. Nat Med. 2020 Aug;26(8):1218-1223

Another Reason for Concern



Kaufman HW et al. JAMA Netw Open 2020 Aug 3;3(8):e2017267

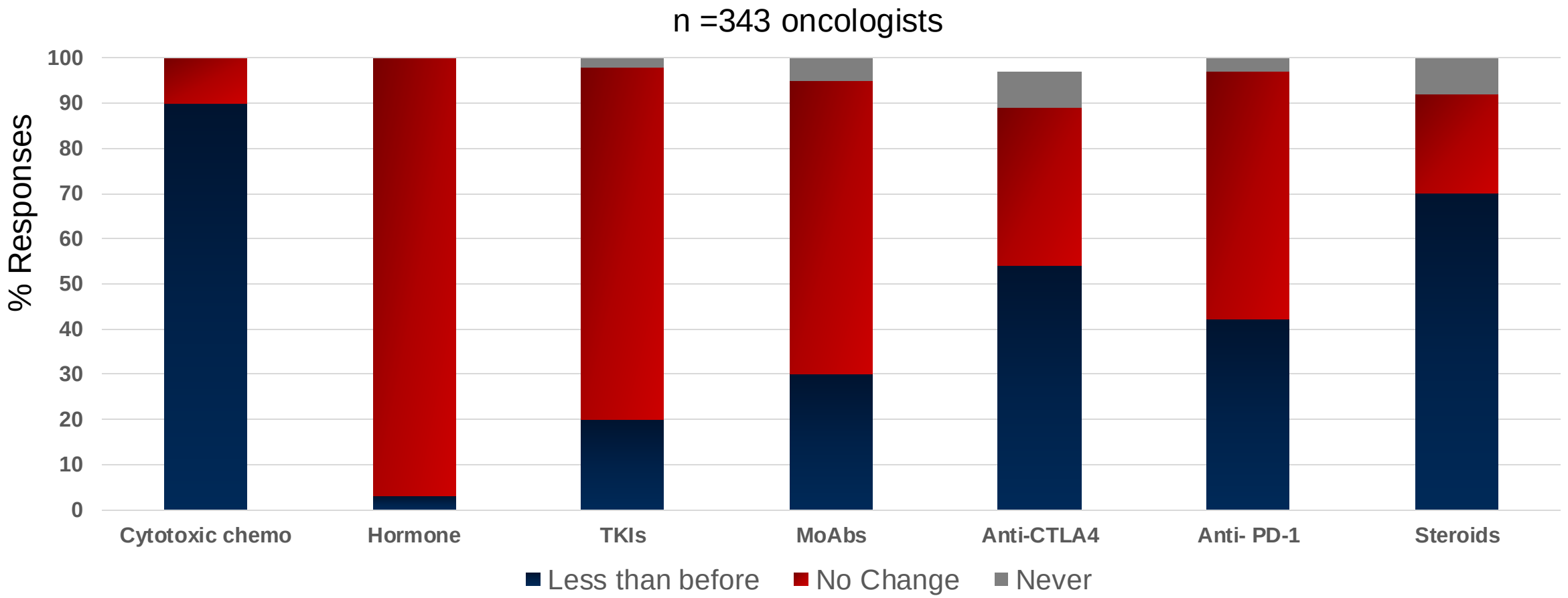
Impact of COVID-19



Bin Han Ong M. Sharpless: COVID expected to increase mortality by at least 10,000 deaths from breast and colorectal cancers over 10 years. The Cancer Letter. 2020 https://cancerletter.com/articles/20200619_1/ Accessed August 15, 2020.

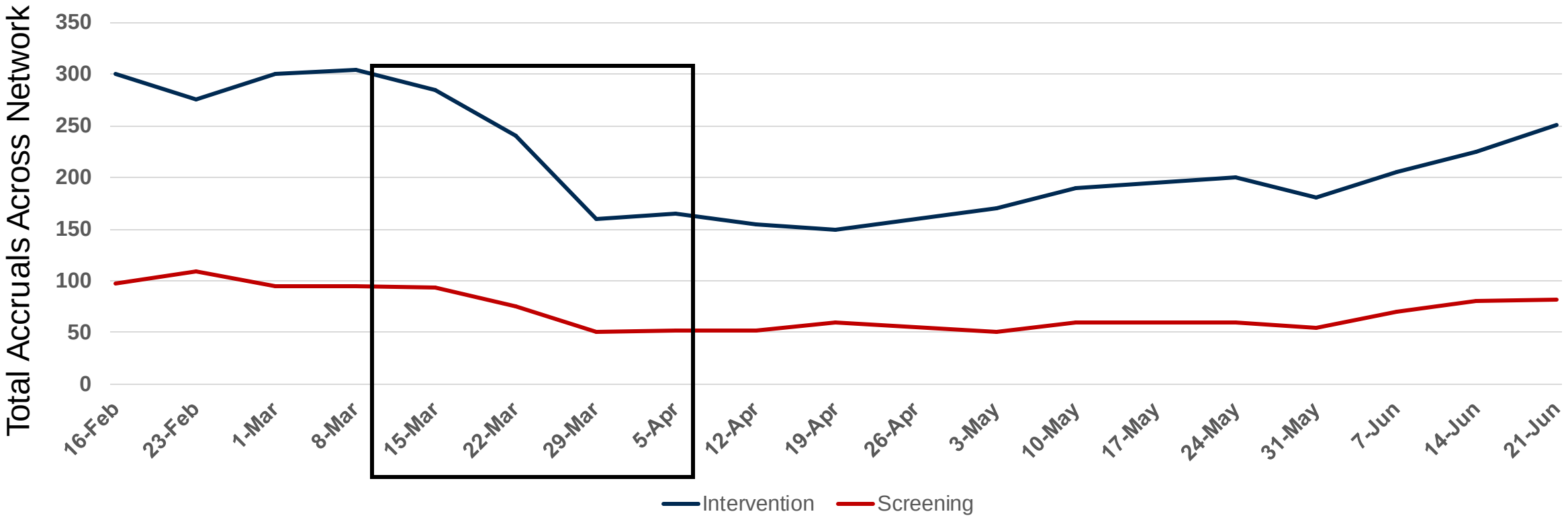
Impact of COVID-19 Decision Making

Question: *Comparing with your previous practice would you recommend the following during the COVID-19 outbreak?*



Uren Y et al. JCO Glob Oncol. 2020 Aug;6:1248-1257

NCI National Clinical Trials Network (NCTN) Trial Activity



[1] www.cancer.gov/research/infrastructure/clinical-trials/nctn/nctn-clinical-trials-network Accessed August 15,2020

Clinical Research/Investigational Drug Services

- Develop COVID-19 SOPs
- Communicate to participants about changes
- E-signatures for IC and other study documents
- Promote telehealth
- Implement patient review of symptoms and AEs
- Remote labs
- Remote study initiation visits and monitoring
- Staff working remotely
- Ship oral agents to home
- Communicate changes to IRBs
- Utilize technology for trial recruitment

Waterhouse DM and Harvey RD JCO Oncol Pract. 2020 Jul;16(7):417-421
Bailey C et al. Cancer Discov. 2020:10:1-4

Ongoing COVID + Cancer Registries

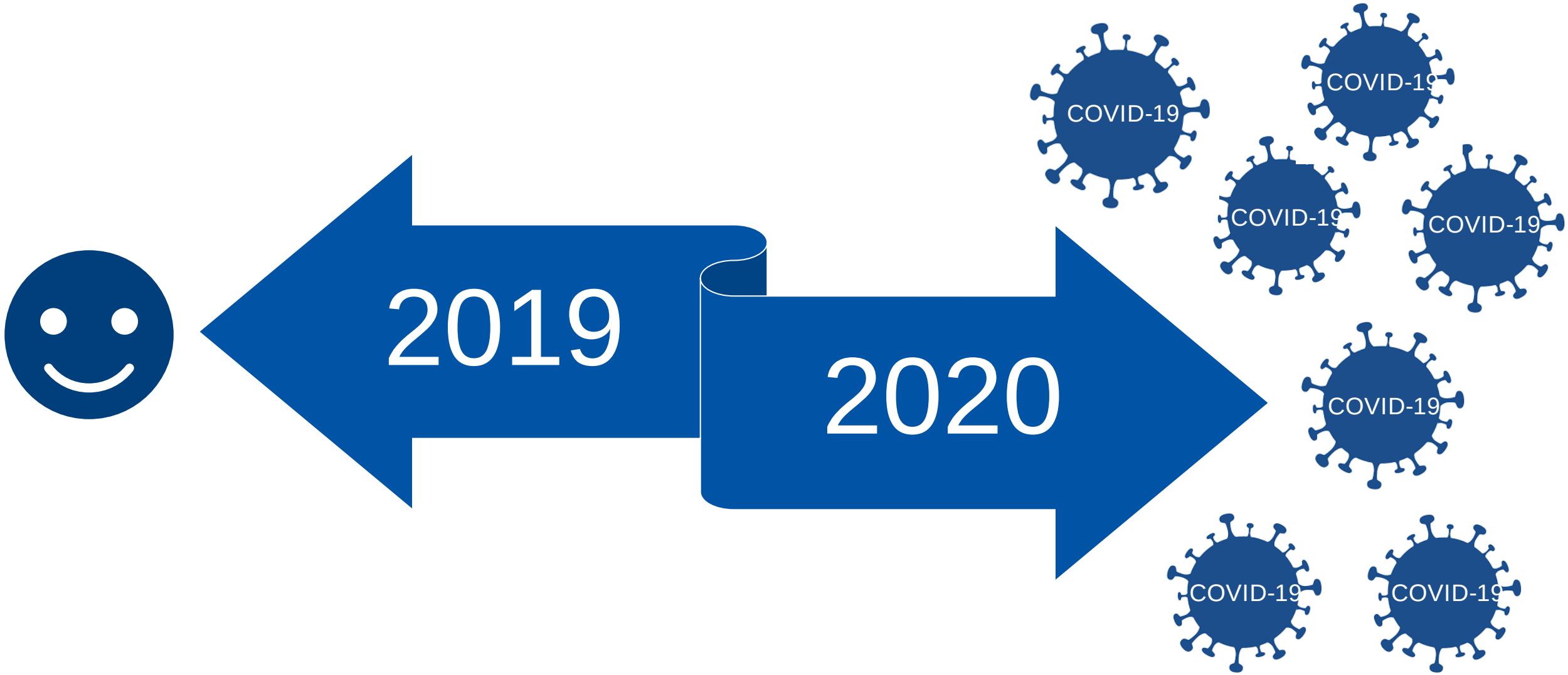
- American College of Surgeons (ACS)
- American Society of Clinical Oncology (ASCO)
- American Society of Hematology (ASH) Research Collaborative
- Center for International Blood and Marrow Transplant Research (CIBMTR)
- COVID-19 & Cancer Consortium (CCC19)
- European Society for Medical Society (ESMO) CoCARE
- NCI COVID-19 in Cancer Patients Study (NCCAPS)
- TERAVOLT

Audience Response Question #1

According to interim data from the COVID-19 Cancer Consortium (CCC19), which of the following is NOT associated with an increased 30-day mortality?

A. ECOG = 2
B. COVID-19 treatment that consisted of azithromycin + hydroxycholoroquine
C. African-American race
D. Progressing cancer

Current State of Affairs



Impact on Profession

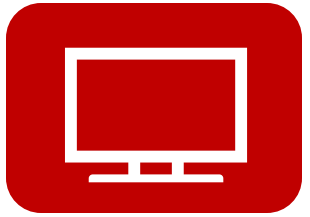
PERSONAL

Communication
- The 4Ps (patients, peers, pharma, parents)

Professional Development
- Trainees
- Meetings
- Interviews

Economic
- Furloughs
- Unemployment

PRACTICE



Virtual care/telemedicine
- Ambulatory outpatient specialists

Treatment changes
- IV -> PO
- De-intensification (protocol ∆s)

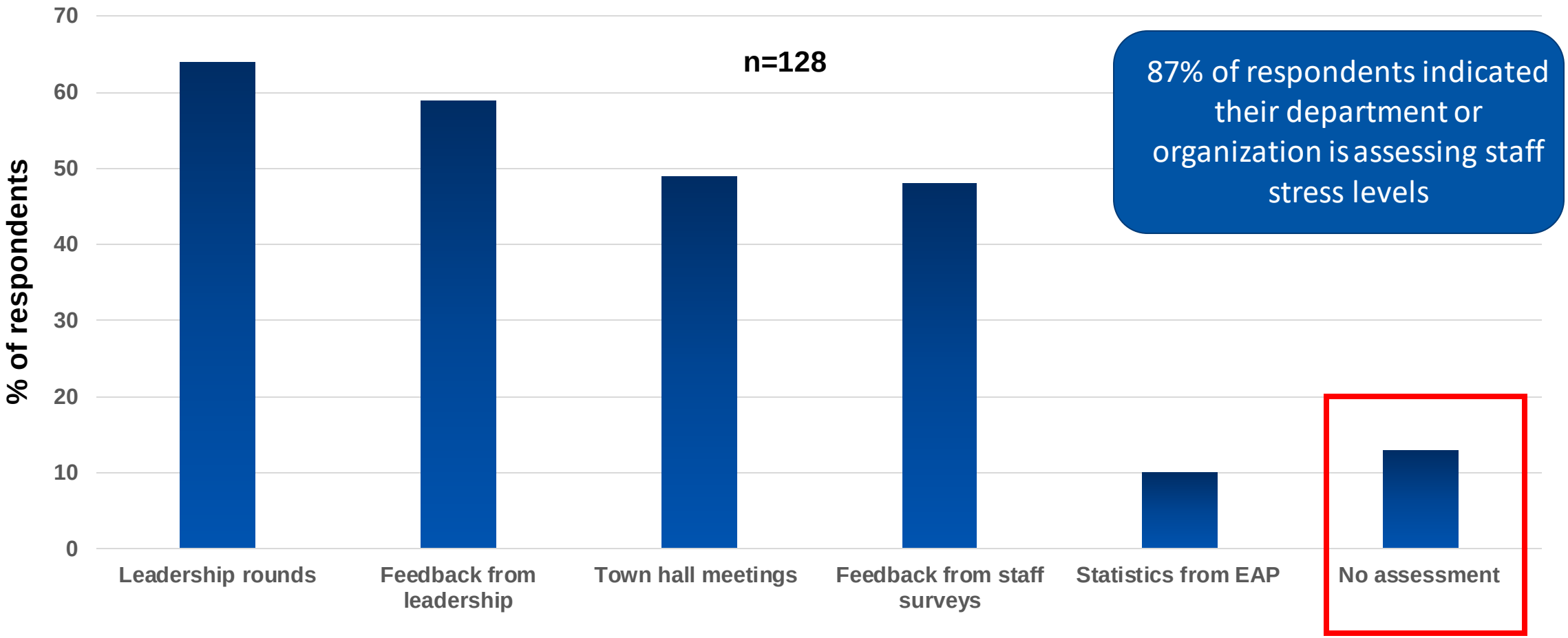
Health care worker safety
- PPE
- Staff shortage to limit exposure

Global Oncology Pharmacy Impact Survey

42 National and Regional Oncology Pharmacy Practice Groups from 28 Countries/Regions

Participate in the Membership Survey!

Stress and Well-Being



https://www.ashp.org/COVID-19/Bi-weekly-PPE-Survey-Results-Covid-19 Accessed August 10

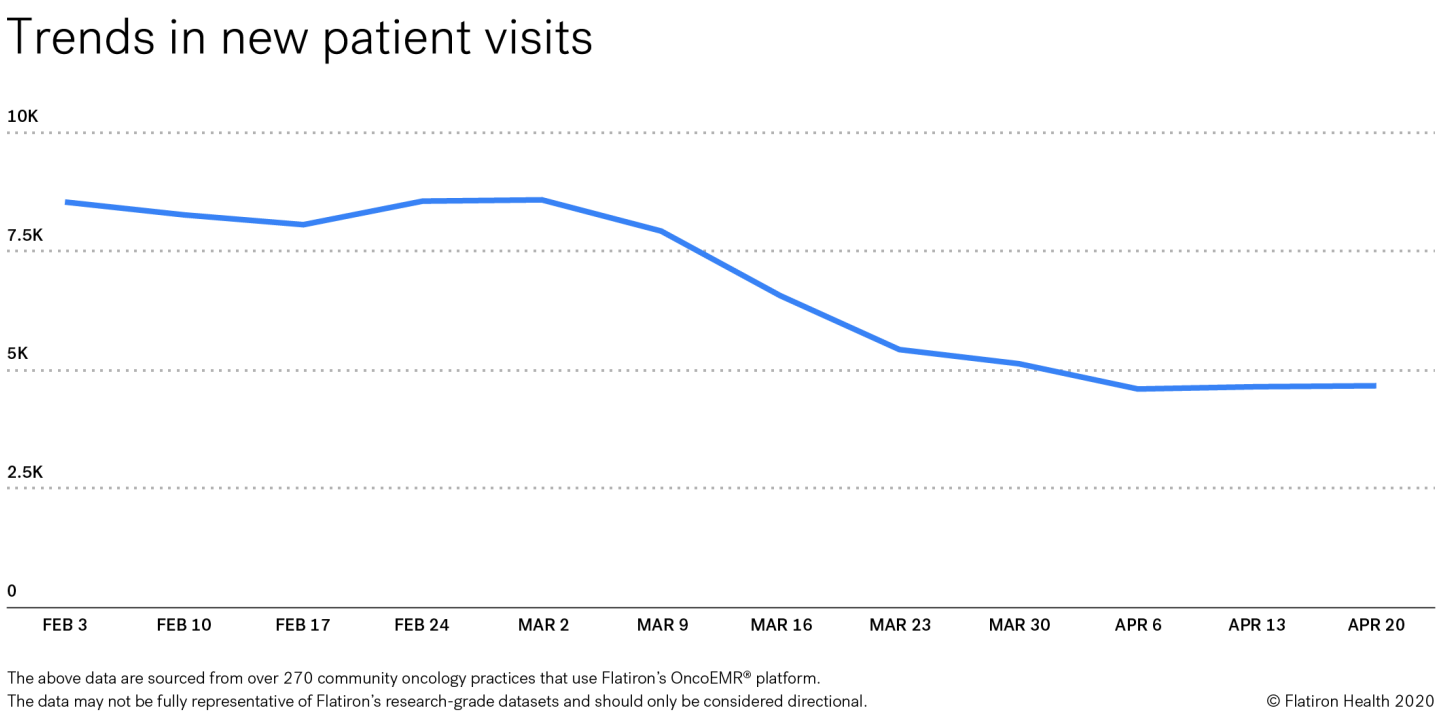
Inpatient and Outpatient Pharmacy Practice

Distribution of Services	
INPATIENT	**OUTPATIENT**
Onsite	**Onsite**
Emergent needs (rapid response)	Emergent needs (rapid response)
Interdisciplinary collaboration	Maintain clinic workflow
Discharge counseling	Interdisciplinary collaboration
Offsite	**Offsite**
Medication education and reconciliation	Medication education and reconciliation
Patient own medication identification	Oral chemotherapy education and follow-up
Therapeutic drug monitoring	Transplant/oncology education
Order verification	Lab follow-ups
Medication adjustments (renal/hepatic)	Therapeutic drug monitoring
Drug-drug interactions	Order verification/chemo order preparation

Mahmoudjafari Z et al. Bio Blood Marrow Transplant. 2020 Jun;26(6):1043-1049

Trends in New Patient Visits

COVID-19 AND U.S. COMMUNITY ONCOLOGY



The above data are sourced from over 270 community oncology practices that use Flatiron's OncoEMR® platform.
The data may not be fully representative of Flatiron's research-grade datasets and should only be considered directional.

Other Notables

- Patient visits involving chemotherapy were reduced by up to 17% in the Northeast
- Non-chemo visits ↓across the country up to 37%
- Cancellations and no-shows doubled, up to 80%

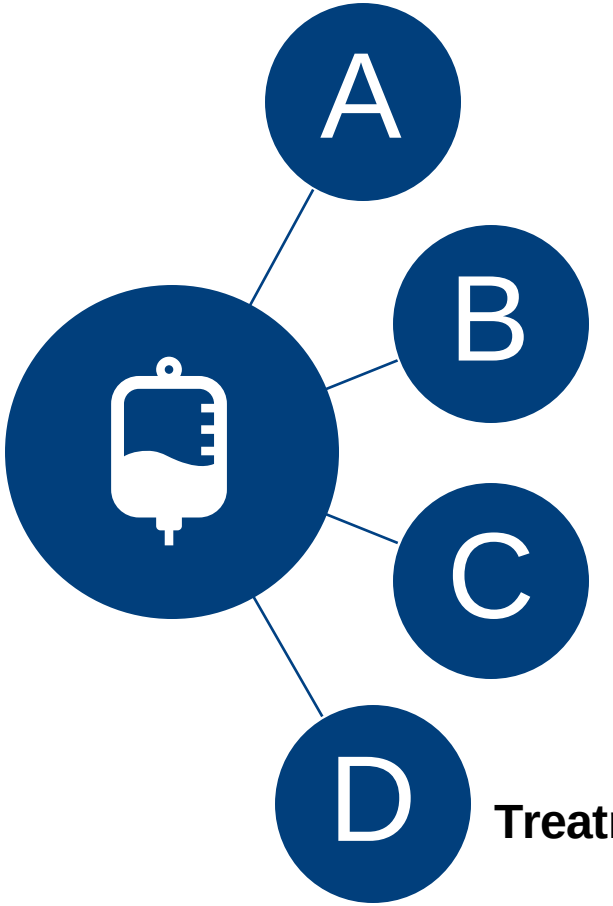
Bin Han Ong M. COVID-19 vs. community oncology:Flatiron's data provides first damage assessment. The Cancer Letter. 2020. https://cancerletter.com/articles/20200501_1/. Accessed June 30, 2020.

Telehealth

- Medicare primary care visits (0.1% Feb 2020 vs. 43.5% April 2020)
- Joint Commission of Pharmacy Practitioners (JCPP) Joint Policy Recommendations to Combat the COVID-19 pandemic
- Oncology pharmacy – oral oncolytic adherence, adverse events management, supportive care, post-transplant medication management
- Billing/reimbursement
- CALL TO PUBLISH – pharmacy telehealth activities!

https://www.hhs.gov/about/news/2020/07/28/hhs-issues-new-report-highlighting-dramatic-trends-in-medicare-beneficiary-telehealth-utilization-amid-covid-19.html Accessed August 15,2020.; COVID-19 Joint Pharmacy Organization Statement on Coronavirus Policy Recommendations Update. Updated April 3, 2020. https://www.aacp.org/sites/default/files/JCPP_COVID19_Joint_Pharmacy_Organization_Statement_on_Coronavirus_Policy_Recommendations_Update.pdf. Accessed August 15, 2020.

Frameworks to Modify Cancer Treatments



A — Treatment that is not time sensitive; can be delivered remotely

B — Treatment omission or delay has marginal effect; cannot be delivered remotely

C — Treatment has moderate clinical influence on QOL

D — Treatment has the potential for cure and cannot be delayed

Schrag D et al. JAMA 2020;323(20):2005-2006

ASCO – Choosing Wisely®

Don't……..

1. Use cancer directed therapies for solid tumor patients with ECOG ≥ 3
2. Perform PET, CT, or bone scans for staging of early prostate cancer
3. Perform PET, CT, or bone scans for staging of early breast cancer
4. Perform surveillance testing (biomarkers) or imaging asymptomatic individuals who have been treated for breast cancer
5. Use G-CSFs for primary prevention of febrile neutropenia with <20% risk (next slide)
6. Undertreat CINV
7. Use combination chemotherapy instead of one-drug when treating metastatic breast cancer unless the patient needs a rapid response
8. Use PET or PET-CT as a part of routine follow-up to monitor for recurrence in asymptomatic patients who have finished initial therapy
9. Perform PSA testing with no symptoms when they are expected to live < 10 years
10. Use a targeted therapy unless a patient's tumor cells have a specific biomarker that predicts an effective response to the targeted therapy

American Society of Clinical Oncology. Ten things physicians should question. Released April 4, 2012. Last reviewed 2019. Accessed August 15, 2020. https://www.choosingwisely.org/societies/american-society-of-clinical-oncology

ASCO Recommendations - Neutropenic Fever

- Prophylaxis – "***may be reasonable***" for patients at risk for NF at a lower expected risk (>10% risk)**
- Acute Care for Potential Neutropenic Fever – Reasonable to evaluate the febrile patient by telemedicine
- Acute Care for Known Neutropenic Fever – follow standard guidelines for NF including isolation, regardless of COVID-19 status

**NCCN short-term recommendations – expand use of G-CSF to intermediate (10-20%) neutropenia risk. Cautionary statement – avoid or discontinue use in confirmed or suspected COVID-19 to avoid ↑ risk of pulmonary inflammatory cytokines

https://www.asco.org/asco-coronavirus-resources/care-individuals-cancer-during-covid-19/cancer-treatment-supportive-care. Accessed August 15, 2020; Taplitz RA et al. J Clin Oncol 2018 36:14, 1443-1453; https://www.nccn.org/covid-19/pdf/HGF_COVID-19.pdf Accessed August 15,2020.

Treatment Adaptations

- Modify regimen to reduce patient visits
  - Examples: **(Colon)**: Adjuvant CAPOX rather than infusional 5-FU, **(Ovarian)**: Q21 day carboplatin/paclitaxel rather than weekly paclitaxel, **(Multiple)**: immune checkpoint inhibitor intervals, **(Prostate)**: leuprolide intervals (Q6 month), **(Breast)**: neo-adjuvant hormonal therapy for ER+/HER2 negative
- Reduce treatment duration
  - Example: **(Breast)**: Short-HER trial – 9 weeks of trastuzumab vs. 12 months (5-year DFS: 85% vs 88%)
- Not initiating therapy
  - Lack of benefit in 2nd or later lines of therapies (advanced cervical, glioblastoma)

Waisberg F et al. JCO Oncol Pract. 2020 Jun 16(6):305-307

Extending-Interval Dosing ICI

- Possible dosing strategies
  - Pembrolizumab 400 mg IV Q6 weeks
  - Nivolumab 480 mg IV Q4 weeks
  - Atezolizumab 1680 IV Q4 weeks
  - Durvalumab 1500 mg IV Q3-4 weeks
- Payers? Every indication?
- Potential pitfalls

Liu SV et al. Front. Oncol. 23 June 2020;10: 1193

The New Infusion Center?

EVIDENCE. CARE. IMPACT.

ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

American Society of Clinical Oncology Position Statement
Home Infusion of Anticancer Therapy

Approved by the ASCO Board of Directors June 23, 2020

"In the context of anticancer therapy, home infusion benefit policies from public and commercial payers should be strictly limited to exceptional circumstances where the benefits of home infusion outweigh the risks.."

https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020_Home-Infusion-Position-Statement.pdf?cid=DM5714&bid=53107298 Accessed August 15, 2020

Cancer Care at Home

- Penn Center for Cancer Care Innovation
  - Cancer Care at Home (CC@H) **launched Feb 2020**
- CC@H provided a foundation for rapid COVID response
- Prior to launch
  - 5-fluoruracil infusions, hydration, supportive care
- Mid-March to mid-June referrals
  - 13 new cancer agents (39 -> 430 patients participating in program)

Select Cancer Treatments

- Bortezomib
- EPOCH (etoposide, vincristine, doxorubicin, cyclophosphamide, prednisone)
- Pembrolizumab maintenance
- Rituximab maintenance
- Leuprolide

Laughlin AI et al. N Engl J Med Catalyst July 7,2020

Professional Development Opportunity

- ASCO – HOPA Quality Training Program (QTP) Workshop
  - Virtual program – December 2020
  - HOPA members; PGY2 residents encouraged to participate
  - **Additional details to come!**

2019 HOPA PMP Meeting – Charlotte, NC

ASCO Quality Training Program

HOPA Hematology/Oncology Pharmacy Association

Audience Response Question 2

A 52-yo Caucasian male from Lewis County just completed cycle 1 (of 12 cycles) of FOLFOX for Stage III colon cancer (KRAS- negative, BRAF- negative, MMR- proficient). What recommendation could you suggest to the oncologist to improve patient management in the setting of COVID-19?

A. Switch to FOLFIRINOX (5-fluorouracil, irinotecan, oxaliplatin)
B. Recommend an immune checkpoint inhibitor (ICI) to provide better tolerability
C. Recommend therapy changed to CAPOX (capecitabine/oxaliplatin) to eliminate 5-FU infusion requirements in the outpatient clinic
D. Switch to oral therapy (regorafenib) to minimize infusion chair time

Strategies for Pharmacists – Take Home Points

- Increase pharmacist involvement in ambulatory patients
- Prepare for staffing shortages and quarantining
- Ensure patient follow-up to prevent readmissions (or additional visits to clinic)
  - Initial comprehensive education
  - Telehealth follow-up
- Confirm pharmacist input into patient triage/treatment
  - Alternative dosing schedules?
  - Appropriate supportive care
  - Informatics/clinical decision support

Kjerengtroen S et al. Am J Health-Syst Pharm. 2020;77:1250-1257

Personal Practice Predictions (Q4 2020)

- Additional oncology drug approvals….they will be expensive
- Teleservices here to stay
- Unemployment rates/uninsured patients ↑ → PA programs
- IVIG drug shortages late 2020
- Site of infusion (academic medical center vs. other) – the debate will continue
- Innovative ambulatory pathways for patient flow/navigation will continue to be evaluated
- Communication to pharma industry will change

Thank You For Your Attention!