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PART 2

Medicolegal Issues During the COVID-19 Pandemic

This three-part series—Part 1 in the June issue covered patient confidentiality—reviews a few topics giving physicians concern during the COVID-19 pandemic.

Maintaining Office Safety

PATIENTS | You retain the right to refuse a patient who will not cooperate with requirements to wear a facemask. If they refuse and can be safely seen later, they should be given an appointment past the expected isolation period. However, you cannot summarily deny care to someone under active treatment without adequate notice to permit them to set up care elsewhere.

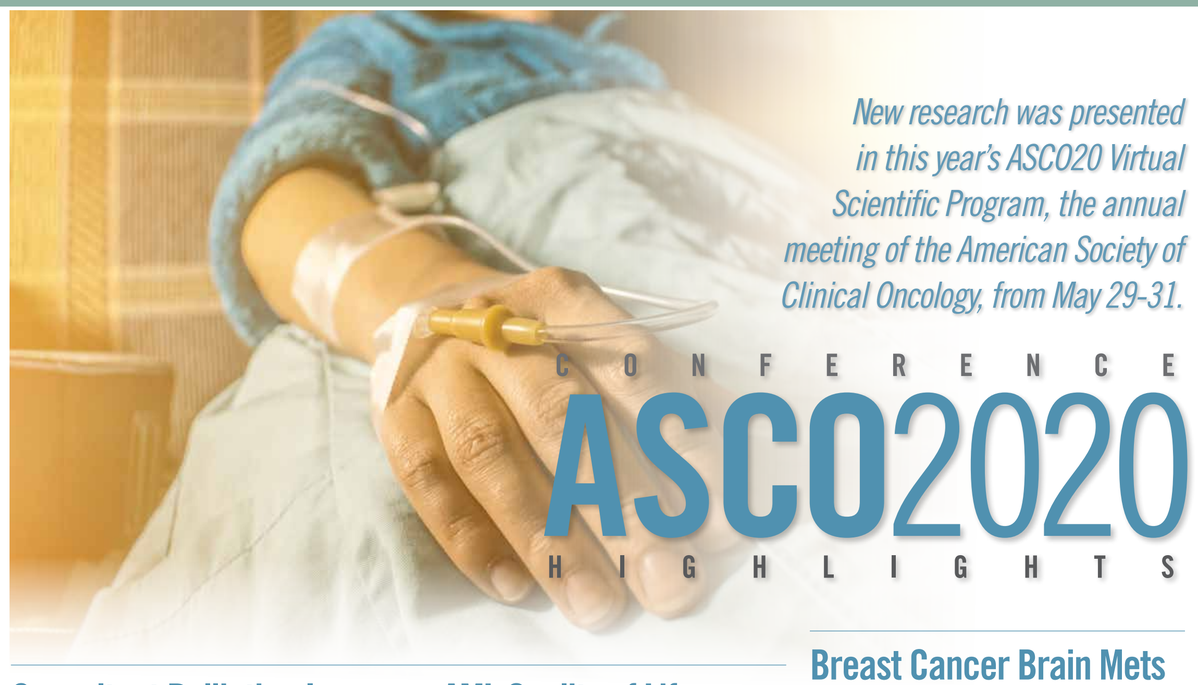
You should also keep the issue of constructive abandonment in mind. Actual termination from your practice because of how a patient conducted themselves is something to deal with when the isolation regimen has ended.

EMPLOYEES | The EEOC has specifically said that nothing in the ADA should be taken to interfere with employers following public health recommendations. As an employer under OSHA obligations to maintain a safe workplace and a physician with a fiduciary duty to safeguard the health of your patients, you may therefore take steps that you would normally be more limited in.

Current employees can be denied access to your premises if they place others at a significant risk. You can require that employees self-report any exposure, answer questions about symptoms, and be tested with sufficient medical basis. You can require temperature checks, should counsel employees to be mindful of how they feel generally and to immediately report any changes, and remind all that hygiene and PPE precautions apply fully. All employees should be required to engage in proper hygienic procedures. If an at-will employee is not cooperating with hygienic conduct, you may fire them immediately.

If an employee was exposed or has tested positive, you will need to inform co-workers, but ask for permission to reveal their identity. If they refuse, tell other employees without naming the source. Since a sudden absence at this time can be revealing, firmly instruct in writing that the employees who remain not discuss a co-worker's PHI. While an employee is on self-isolation, ask only the minimum information necessary to make a work-related determination of their safe return. You can also require that they provide a physician's note saying that they are fit to return.

This article was written by Dr. Medlaw, a physician and medical malpractice attorney.



New research was presented in this year's ASCO20 Virtual Scientific Program, the annual meeting of the American Society of Clinical Oncology, from May 29-31.

CONFERENCE
ASCO2020
HIGHLIGHTS

Consultant Palliation Improves AML Quality of Life

Referring a patient diagnosed with acute myeloid leukemia (AML) to the palliation service at the time grueling therapy begins appears to offer psychological benefits down the road, including improvements in the patients' perceived quality of life, researchers found. For the study, patients with high-risk AML and admitted to receive intensive chemotherapy were randomized to integrated palliative and oncology care or usual care. Those receiving the intervention met with palliative care clinicians at least twice weekly. At 2 weeks—a period recognized as most difficult for patients who are in the midst of long-term hospitalization—the quality of life among patients who received palliation department consultation did not deteriorate, while patients who received standard of care experienced a decline of 8 points in the FACT-Leukemia scale. At 24 weeks, the quality of life improved in both arms of the trial, but by 25 points from baseline in patients who received an intervention, compared with 10 points in the patients receiving standard care.

Larotrectinib Produces Durable Responses

Patients diagnosed with a variety of advanced cancers appear to have durable responses when treated with larotrectinib, an agent that attacks tropomyosin receptor kinase (TRK) fusion pathology, researchers reported. Across three studies, patients were treated with 17 types of cancer, including thyroid (22%), salivary gland (19%), soft tissue sarcoma (16%), lung (12%), colon (7%), melanoma (5%), breast (5%), gastrointestinal stromal tumors (3%), and nine other types (≤ 2% each). About 78% of the patients had received prior systemic therapy and 68% had undergone two or more lines of therapy. More than 70% achieved either a complete (10%) or objective partial response. Overall, about 60% of patients also had an objective response and another 16% experienced disease stabilization with larotrectinib. The median duration of response for all adults in the study was 35.2 months, with some patients having responses that were durable through 51 months of therapy. Median progression-free survival was 25.8 months.

Progression Free Survival Improved with Pembrolizumab for ES-SCLC But Not Overall Survival

Data from the phase III KEYNOTE-604 trial showed that although patients with extensive-stage small cell lung cancer (ES-SCLC) who received pembrolizumab with backbone chemotherapy etoposide/platinum (EP) compared with patients who received EP and placebo did not benefit from improved overall survival (OS), progression-free survival (PFS) rates with the combination did reach the threshold for significance. The KEYNOTE-604 study aimed to improve upon the efficacy of immunotherapy in newly diagnosed ES-SCLC with the combination of pembrolizumab and EP.

The study randomized 453 patients; pembrolizumab 220 mg on day 1 plus EP 100 mg/m² on days 1 and 2 and carboplatin AUC 5 on day 1 or cisplatin 75 mg/m² on day 1 or placebo, matching EP, and carboplatin or cisplatin for up to 31 cycles. The final PFS analysis was significant (4.8 vs 4.3 months; HR: 0.73; 95% CI: 0.60-0.88). The 12-month PFS rate observed with the pembrolizumab combination was 15.9% versus 5.0% with the placebo combination. Even at 18 months, the PFS rate in the pembrolizumab arm was higher than the placebo arm at 10.8% versus 2.1%. In terms of OS, pembrolizumab/EP prolonged OS compared with the control combination (10.8 vs 9.7 months; HR: 0.80), but it did not reach the superiority threshold. The 12-month OS rate was 45.1% in the pembrolizumab arm compared with 39.6% in the placebo arm. At 24 months, the OS rate was 22.5% in the pembrolizumab arm compared with 11.2% in the placebo arm. The safety analysis showed that adverse events (AEs) of any-grade occurred in 100% of patients in the pembrolizumab arm and 99.6% of patients in the placebo arm, in the as-treated population. AEs were grade 3/4 in 76.7% of subjects who received pembrolizumab/EP compared with 74.9% of those who received the placebo combination. Grade 5 AEs/death occurred in 6.3% of patients in the pembrolizumab arm versus 5.4% in the control arm.

Breast Cancer Brain Mets Treated With Tucatinib

The risk of death or progression of brain metastases was reduced in patients with HER2-positive advanced disease who received prior trastuzumab/pertuzumab and T-DM1 when they added tucatinib to a regimen of trastuzumab and capecitabine, study investigators said. Patients who were treated with trastuzumab and capecitabine alone achieved a median overall survival of 12.0 months, but that survival was increased to 18.1 months with tucatinib on board. The median central nervous system progression-free survival was 9.9 months in the tucatinib-treated patients compared with 4.2 months among the patients getting trastuzumab and capecitabine alone. The combined primary endpoint of death or progression of brain metastases was a 68% reduction in favor of tucatinib. Intracranial objective responses were observed in 47.3% of the patients on tucatinib compared with 20.0% on trastuzumab/capecitabine. At 1 year, 70% of patients randomized to tucatinib were alive, compared with 47% randomized to placebo. About 48% of patients had brain metastases at baseline, and among them, 60% had active brain metastases, meaning untreated brain metastases or progressing brain metastases.

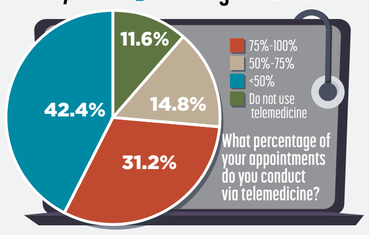
Survival Benefit Emerges in ARAMIS

Men diagnosed with non-metastatic castration-resistant prostate cancer live longer if they are treated with darolutamide than placebo, the final results of the phase III ARAMIS trial revealed, adding to previous reports from the study that it met its primary endpoint of metastasis-free survival and that darolutamide delays radiographic progression, slows time for the need of cytotoxic chemotherapy, and slows progression to pain and skeletal events. For the study, 1,509 men diagnosed with non-metastatic castration-resistant prostate cancer were treated with darolutamide 600 mg twice daily or placebo. All the patients continued androgen-deprivation therapy. About 15.5% of patients who were treated with darolutamide died, compared with 19.1% of those in the placebo group, a 31% relative risk reduction that achieved statistical significance. The drug was well tolerated, with some increases in fatigue reported but no increased risk of cognitive impairment, seizures, falls or fractures, hypertension, or rash.

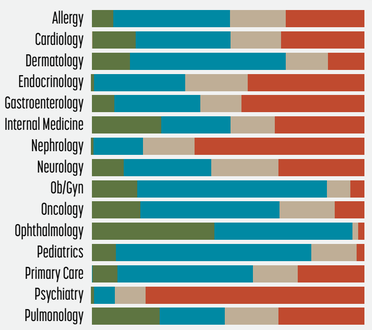
The Impact of COVID-19 on Physician Practices

There's no denying the significant impact the COVID-19 pandemic has made on medicine. "We're practically developing new protocols every day," says PW Editor-in-Chief Linda Girgis, MD. "We now are conducting many visits by telemedicine to limit contact between people and sterilize every surface of the office—for those patients who do come in—like we've never done before." To get a better sense of the impact, we conducted a survey of our physician eNewsletter recipients, during the latter half of 2020. Among the approximately 1,500 recipients representing 15 specialties, we found striking, but understandable, differences by specialty in response to two key questions that reveal and overall trend.

Nearly **90%** of offices are using Telemedicine



[TELEMEDICINE APPOINTMENT PERCENTAGES BY SPECIALTY]



More than **2/3** of physicians are concerned about the future of their practice.

[PERCENTAGES OF CONCERN BY SPECIALTY]

	Yes	No
Allergy	63.0%	37.0%
Cardiology	69.6%	30.4%
Dermatology	84.6%	15.4%
Endocrinology	32.3%	67.7%
Gastroenterology	77.4%	22.6%
Internal Medicine	87.5%	12.5%
Nephrology	52.5%	47.5%
Neurology	54.8%	45.2%
Ob/Gyn	60.5%	39.5%
Oncology	48.4%	51.6%
Ophthalmology	86.4%	13.6%
Pediatrics	77.5%	22.5%
Primary Care	69.6%	30.4%
Psychiatry	45.5%	54.5%
Pulmonology	70.0%	30.0%

Source: 2020 Physicians Weekly COVID-19 Survey

In light of these impacts, Dr. Girgis says "Hang in there, and don't forget to take a pause! We need to speak up and let people know the conditions we are working under and keep pressuring administrators to provide a safe work environment."

Hypofractionated RT for Early Breast Cancer Improves Care

A utilization management policy promoting hypofractionated radiotherapy (RT) appears to be associated with the improvement of evidence-based cancer care for women with early breast cancer, according to a study published in *JAMA Oncology*. The retrospective economic analysis determined a higher uptake of hypofractionated radiotherapy among women who were either directly subject, or indirectly exposed, to the policy. However, Ravi B. Parikh, MD, MPP, Perelman School of Medicine, University of Pennsylvania, and colleagues found that the utilization management policy did not result in measurable cost savings.

According to Dr. Parikh and his colleagues, while utilization management strategies have been associated with cost savings and uptake of evidence-based practice in some clinical settings, there is little evidence of their effectiveness in oncology care. In this study, the authors investigated a utilization management policy developed by a larger commercial payer in 2016 and its association with the uptake of hypofractionated radiotherapy for patients with early-stage breast cancer, as well as its associated costs.

According to the authors, under the utilization management policy, claims for extended-course radiotherapy were not reimbursed for fully insured women who were eligible for hypofractionated radiotherapy. The policy did not apply to women in self-insured or Medicare supplemental insurance plans, which allowed these groups to serve as a comparison group in the study.

The percentage of fully insured patients and self-insured patients who received hypofractionated radiotherapy increased significantly during the study period, from 22.4% in 2012 to 82.3% in 2018, and from 20.3% to 79.8%, respectively. Compared with self-insured patients who were not subject to the policy, there was an increase in hypofractionated radiotherapy among fully insured patients subject to the policy (adjusted percentage point difference-indifference, 4.2%).

And spillover analyses showed a higher uptake of hypofractionated radiotherapy among self-insured patients who were indirectly exposed to the policy (but whose physicians were exposed to the policy) compared with those who were not exposed (adjusted percentage point difference-indifference, 8.5%). This suggests that the use of hypofractionated radiotherapy extended beyond the policy's target audience, the authors wrote.