



[MEDLAW]

PART 1

Medicolegal Issues During the COVID-19 Pandemic

These are extraordinary times with extraordinary challenges, but even within this unique framework, the principles that doctors need to follow remain familiar.

This three-part series will review a few topics giving physicians concern:

Patient Confidentiality

IN THE OFFICE | Re-emphasize to staff, now, that PHI is never to be shared for non-work purposes in writing so you have proof that you did so. The COVID-19 pandemic has caused stress and shock, and there is simply too great a chance for a worried employee to vent that worry in a way that can identify a patient.

REMOTE WORK | HIPAA's rules on patient confidentiality still apply to a covered entity's employees, wherever work is performed. Any devices an employee will use should be strongly password-protected, and all PHI should be encrypted before it is transmitted. The connection must be secure. Talk to your IT person about levels of security that can be set up, such as two-factor authentication or having to login again after a period of absence.

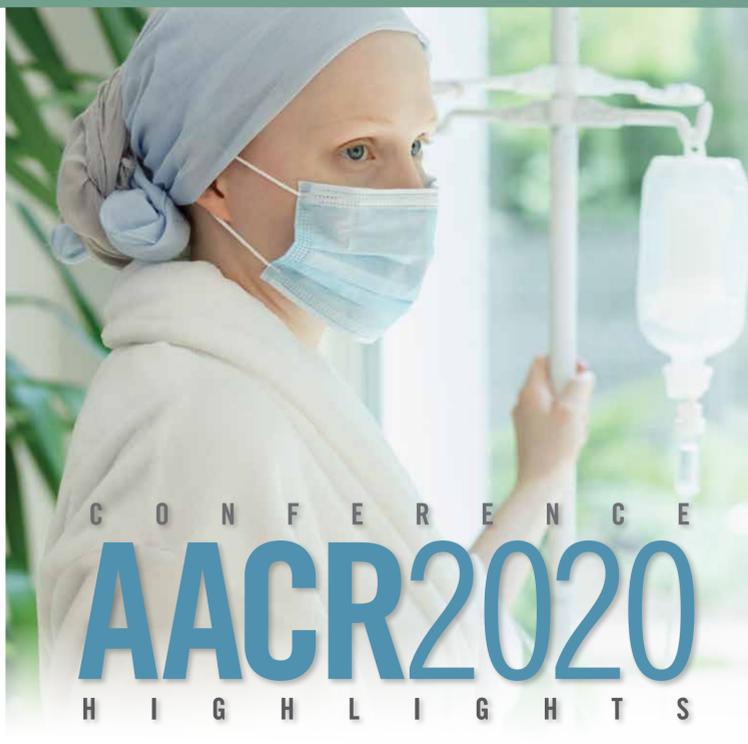
If employees will be using personal computers, specifically deal with that, at least with written instructions and at best with a Bring Your Own Device agreement. It is essential to give any employees being sent home to work a formal written policy on maintaining PHI safely and to require them to sign that they received it. Employees must be cautioned about disposal of paper containing PHI. A cross-cut shredder should be used to destroy what minimal printing is done.

TELEMEDICINE | The Office for Civil Rights (OCR) is temporarily waiving penalties for the use of non-HIPAA compliant communication platforms and/or not having a Business Associates Agreement with the service used during the COVID-19 emergency. The service must not be public facing, but Skype, Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, and Zoom are acceptable.

You should inform the patient that what will be used is potentially not secure and get their express confirmation that they understand and agree. A standardized e-mail to which they reply affirmatively is a good approach for proof.

This is to last during the emergency, a period for which there is no end-date. You will need to stay alert for termination of the current emergency so as to not incur fines that will recommence for what would again then be a HIPAA violation.

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



New research was virtually presented at AACR 2020, the American Association for Cancer Research Annual Meeting, from April 27-28. The features below highlight some of the studies that emerged from the conference.

Treatment Holiday Worsens PFS in BRAF-Mutant Melanoma

Although previous studies suggest objective responses with BRAF and MEK inhibitors in the majority of patients with BRAF-mutant melanoma, data also suggest that acquired resistance limits response durations with these drugs. Preclinical data suggest that intermittent dosing of these agents may delay such resistance. To determine whether intermittent dosing of BRAF/MEK inhibitors improved progression-free survival (PFS) in patients with advance BRAF-mutant melanoma when compared with continuous dosing, researchers randomized patients on 8-weeks of continuous BRAF/MEK inhibitor therapy to either further continuous therapy or intermittent dosing on a 3-week-off, 5-week-on schedule. Median PFS was statistically significantly longer (9 months from randomization) with continuous dosing when compared with intermittent dosing (5.5 months). At a median follow-up of 2 years, median overall survival was 29.2 months in both groups. In the continuous treatment group, 77% of patients discontinued treatment due to disease progression, compared with 84% in the intermittent treatment group. ■

Tumor Immune Biology Differs Between Metastatic & Early TNBC

Although research has linked pre-existing intratumoral immune response—characterized by presence of tumor infiltrating lymphocytes or cytotoxic effector T cells—with improved prognosis in early triple-negative breast cancer (eTNBC) but suggest that immune-rich tumors are not prognostic in metastatic TNBC (mTNBC), whether T-cell immune biology has differential prognosis between eTNBC and mTNBC remains unclear, as different immune biomarkers were used across studies to make these observations. For a study, researchers evaluated the prognostic value of the T effector RNA gene signature (Teff), across two eTNBC and two mTNBC clinical studies using the same biomarker methodology. Although Teff levels were similar within the eTNBC studies and within the mTNBC studies, Teff score was significantly higher in the eTNBC studies. Among baseline prognostic characteristics assessed, lymph node involvement in the eTNBC studies was the only one associated with Teff. Multivariate analysis found elevated Teff to be associated with improved overall survival in two eTNBC studies but to have no prognostic value in two mTNBC trials. Similar results were seen at various Teff cutoffs. ■

Cancer Ups COVID-19 Vulnerability

With prior research indicating that patients with cancer are generally more vulnerable to infections, study investigators felt systematic analysis of diverse cohorts of patients with cancer affected by COVID-19 were needed. The team performed a multi-center study of patients with confirmed COVID-19 infection, 105 of whom had cancer and 536 of whom were age-matched patients without cancer (controls). Patients with cancer had significantly higher risks of mortality (odds ratio [OR], 2.34), ICU admission (OR, 2.84), severe or critical symptoms (OR, 2.79), and

invasive mechanical ventilation (OR, 2.71) when compared with controls. While overall mortality rates were 11.4% for those with cancer and about 5% for those without, patients with hematologic malignancies, lung tumors, and esophageal tumors had mortality rates of 33.3%, 18.1%, and 16.7%, respectively. Patients with early-stage cancers had outcomes similar to those without cancer, but those with metastatic disease had ORs of 5.58 for death, 6.59 for ICU admission, 5.97 for severe symptoms, and 55.42 for invasive ventilation. ■

Pre-existing ESR1 Mutations Predict Endocrine Therapy Failure & Poor Survival

Despite research suggesting that mutation in *ESR1* is an acquired mechanism of resistance to endocrine therapy (ET), the impact of this mutation on therapy response in primary breast cancer remains unclear. To better understand this impact, study investigators analyzed more than 3,200 real-world and population-based early-stage primary breast cancers. Tissues sampled from initial diagnosis, prior to any treatment, were analyzed for the presence of *ESR1* mutations using RNA sequencing. *ESR1* resistance mutations

were identified in 0.9% of cases, of which 1.1% were estrogen receptor-positive. In estrogen receptor-positive disease, presence of *ESR1* mutation was significantly associated with poor relapse-free (RFS) and overall survival (OS), and it predicted poor RFS and OS within the patient group who received ET. "We confirm for the first time that such early mutations predict eventual resistance to standard hormone therapy in the adjuvant setting," write the study authors. ■

The Socioecological Context of Tobacco & Vape Shop Locations

Evidence suggests that, despite increased public health efforts to discourage teens from using hazardous tobacco products, use of electronic nicotine delivery systems (ENDS) remains high, due in part to direct youth targeting by tobacco and vaping companies, with many ENDS containing fruit and candy flavors that are particularly attractive to youth in products with high nicotine levels. For a study, researchers analyzed national/local nicotine product use in youth by gender, age, and racial/ethnic group; explored the socio-ecological context of tobacco/vape shops via geo-spatial mapping; and conducted an environmental scan of social media platforms combined with Google and Yellow Pages searches. Ever use of e-cigarettes was reported by 13.5% of middle schoolers and

37.7% of high schoolers. The location of tobacco and vape shops appeared to correspond with areas with higher percentages of ethnic minorities, regardless of average income. However, lower income cities tended to have more of these shops when compared with very high-income cities. Even after adjusting for store type, tobacco products cost less in neighborhoods with lower median household incomes and in those with a higher proportion of Hispanic residents. The study authors suggest that population-based tobacco (including vaping) prevention and control strategies in coordination with the FDA are critical to reducing use and initiation of these products among all Americans, particularly ethnic minorities and youth. ■

Uninformed & Unresolved: Patient Concerns With New Meds

Results from a survey of 1,000 prescription-receiving Americans found 41% had unanswered questions after being given a prescription, with medication safety (53%), potential side effects (61%) and cost (54%) among the top concerns.

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| 76% | Were not aware of other available treatments |
| 37% | Felt they had little-to-no control over what was provided by their pharmacy |
| 72% | Did their own research about prescriptions provided by their doctor |

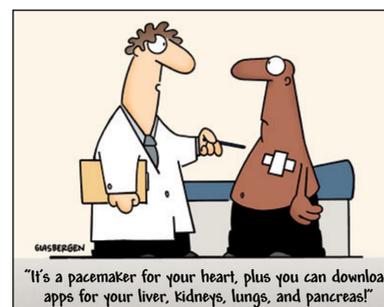
Survey conducted by OnePoll

Most respondents (62%) understood that generics and authorized generics are less expensive versions of brand name medications, but 53% still had questions about the safety or efficacy of a generic versus a name-brand medication. Also, 70% did not know if they would be given a brand name medication, generic, or authorized generic when filling a prescription. Only 37% of respondents were aware that authorized generics and brand name medications have an identical formula, and more than 70% did not know that authorized generics are not the same as generics. Survey results showed that 26% of respondents reported noticing a difference when switching from a name brand medication to a generic.

Research has shown that when patients switch from a branded medicine to a generic, there can be a drop in treatment adherence, often due to the patient's unfamiliarity with the generic drugs' color, shape, and size.

Furthermore, a survey of 500 prescribers revealed strong confidence in authorized generics; 64% said they would be more comfortable taking an authorized generic prescription drug produced by a brand-name company, rather than a copy of the drug produced by another company. Authorized generics offer both patients and doctors familiarity and predictability with the drug and how the patient will respond to it. Because they use identical formulations, authorized generics will have the same effect, with the same benefits and potential side effects as the name-brand drug.

For more information, patients and healthcare professionals can visit authorizedgenerics.com. ■



Comparing Approaches to Oligometastatic NSCLC Management



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While it was previously thought that a subset of patients with limited metastatic disease could potentially achieve long-term survival, established approaches for treating patients with radiation therapy or surgery other than for palliative purposes were lacking prior to single-institutional data emerging over the past 10-15 years that suggest a survival benefit in selected patients when compared with historical controls treated with systemic therapy alone.

To confirm these data in a randomized manner, using progression-free survival as an endpoint, Daniel R. Gomez, MD, and colleagues designed a trial in which patients with oligometastatic lung cancer who did not progress after induction therapy were allocated to one of two treatment regimens in a 1:1 ratio: standard maintenance therapy/observation (MT/O) or aggressive radiation therapy/surgery, which the study team termed local consolidative therapy (LCT). "We tracked toxicity but our primary endpoint was progression free survival (PFS), with relevant secondary endpoints being overall survival and the time to development of new lesions," explains Dr. Gomez, whose study results were published in the *Journal of Clinical Oncology*.

"Our study was closed early by our data safety monitoring board because we found a substantial benefit in PFS with LCT compared with standard care," Dr. Gomez notes. Indeed, with an updated median follow-up of 38.8 months, the PFS benefit was 14.2 months, compared with 4.4 months with MT/O. The LCT group also experienced an overall survival benefit, with a median of 41.2 months, compared with 17.0 months in the MT/O group, as well as longer survival after progression (37.6 months vs 9.4 months). No additional grade 3 or greater toxicities were observed. Among patients in the MT/O group who experienced progression, nearly half received LCT to all lesions following progression and had a median overall survival of 17 months.

"I would view this data as provocative in demonstrating the benefit of LCT for patients with oligometastatic disease," says Dr. Gomez. However, there are limitations that need to be taken into account when interpreting the data, primarily the small size of the trial, the heterogeneous population, and the fact that it was done in the pre-immunotherapy era. Future studies should attempt to expand on the existing data by addressing these constraints." ■

COVID-19 RESOURCE CENTER

physiciansweekly.com/covid19 for the latest updates on the pandemic, including breaking news, expert-written features and editorials, patient education, and more!

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