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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.

Postoperative Infection: A Look at Risks for Long-Term Infection & Mortality

Patients who have an infection within 30 days of surgery appear to be at higher risk of subsequent infections and mortality for up to 1 year, according to a study.

Written by
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Throughout the United States, significant resources are being used to prevent postoperative infections due to their potentially serious consequences. "Much attention has been given to the identification, prevention, and management of postoperative infections, typically within 30 days of surgery or up to 90 days for surgical implants," explains William J. O'Brien, MS. "In the short term, these infections can be devastating for patients in terms of pain, need for reoperation and rehospitalization, and exposure to long-term antibiotics. However, it remains unclear if patients exposed to infection after surgery have higher rates of subsequent infections and mortality within 1 year."

For a study published in *JAMA Surgery*, O'Brien collaborated with with Kalpana Gupta, MD, and Kamal M.F. Itani, MD, to determine if exposure to 30-day postoperative infections was associated with a higher incidence of infection and mortality up to 1 year after surgery. Using data from the Veterans Affairs (VA) national database, the study included more than 650,000 veterans who underwent a broad range of major surgery types during an 8-year period. The exposure group included VA patients who had any 30-day postoperative infection, whereas the control group consisted of VA patients who had no 30-day infection.

Study Highlights

According to the investigators, 3.6% of all participants in the study had a 30-day infection, 6.6% had a long-term infection, and 3.8% died during follow-up. Overall, the incidence of infection during postoperative days 31 to 365 was 6.7%. The most frequent 30-day infections were surgical site infections, urinary tract infections, pneumonia, and bloodstream infections. The most frequent types of infections on postoperative days 31 to 365 were urinary tract infections, skin and soft tissue infections, bloodstream infections, pneumonia, or a combination of two or three types simultaneously (Figure).

"Our key findings were that patients with a 30-day postoperative infection were at nearly twice the risk of mortality and had more than three times the risk of subsequent infection when compared with patients without such an infection," says O'Brien. When compared with patients who had no postoperative infections, those with these infections tended to be older and more frequently had an American Society of Anesthesiologists score greater than 2. The study also found that patients with any postoperative infection were more likely to have undergone emergent surgery and to have undergone surgery with a duration in the highest quartile when compared with patients who had no postoperative infections.

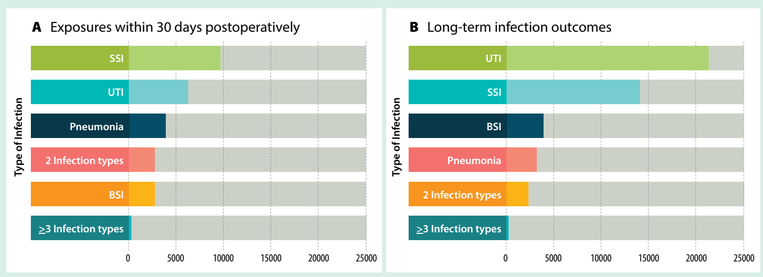
Findings of the study persisted after adjusting for baseline characteristics. Although few published studies have examined rates of long-term infection, results from the current study were comparable to those of previous work that sought to describe mortality risks.

Critical Implications

Efforts to prevent postoperative infections continue to be a high priority in clinical practice and across healthcare settings because of their significant impact on costs, patient outcomes, and resource utilization. The novel contribution of the study by O'Brien and colleagues is that the occurrence of a postoperative infection—regardless of patient characteristics and surgery factors—appears to be associated with a higher likelihood of having a subsequent infection and mortality up to 1 year after the initial surgery.

"Our study demonstrated that postoperative infections in the overall surgical population were relatively uncommon but associated with long-term harm to patients," O'Brien says. "Our study wasn't intended to directly influence surgical practice. Instead, our goal was to better understand the long-term risks of surgical infections. Future work in this area could help us appreciate the extent to which the long-term consequences described in our study are directly related to the postoperative infections." The study team added that the increased harm and cost of long-term infections should be included in cost-benefit calculations of infection prevention initiatives."

Figure Postoperative and Long-Term Infection Types



Abbreviations: BSI, bloodstream infection; SSI, surgical site infection; UTI, urinary tract infection.

Source: Adapted from: O'Brien WJ, et al. *JAMA Surg.* 2020:155(1):61-68.

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.

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

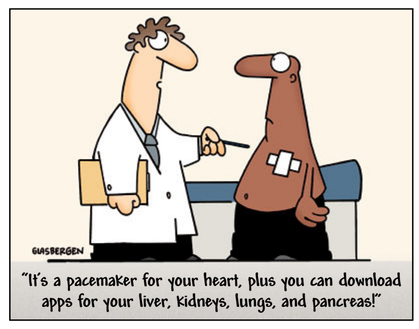
Survey conducted by OnePoll

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.



"It's a pacemaker for your heart, plus you can download apps for your liver, kidneys, lungs, and pancreas!"

COVID-19 RESOURCE CENTER
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Rapid Response & Data Sharing During COVID-19 Pandemic

Contributor
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Physicians and healthcare systems across the world have been and continue to respond quickly as the novel coronavirus disease (COVID-19) pandemic continues to spread. With limited information, they have had to rapidly share what limited information they have with colleagues. "Managing this outbreak is a multidisciplinary effort that requires strategic planning and rapid mobilization of resources," explains J. Jeffery Reeves, MD. "Healthcare in the modern era is inseparably integrated with technology and the electronic health record (EHR). As such, my colleagues and I recognized an opportunity to enhance our EHR system and leverage technology to support the clinical management of the outbreak in our region."

For a study published in the *Journal of the American Medical Informatics Association*, Dr. Reeves and colleagues established the "Incident Command Center" within their institution's EHR system to gather data on prior and current cases of COVID-19, in order to help better prepare regions yet to be heavily affected by the pandemic. The Incident Command Center was developed to provide a direct line of communication between healthcare information teams and physicians, through which the study team was able to identify the need for a rapid screening process, automated testing decision guidance, clinical support tools for testing, reporting and analytical tools, and expansion of their telemedicine platform.

"The EHR can be utilized in times of crisis as a tool to disseminate information, offer guidance on rapidly evolving recommendations, and provide real-time, institution-specific data and analytics that can guide evidence-based decision making," emphasizes Dr. Reeves. "The COVID-19 pandemic highlights the importance of a multidisciplinary team approach to medical care and building cohesive systems capable of sustaining unanticipated trials."

The information-sharing system modeled in this study could help healthcare systems prepare for and manage infectious outbreaks through utilizing technology, establishing multidisciplinary groups, and following ever changing recommendations from federal and global authorities, notes Dr. Reeves. "The EHR and associated technologies are vital and requisite tools in supporting outbreak management that should be leveraged to their full potential," he adds.

Dr. Reeves still sees gaps in the system that, if filled, could create a more united and cohesive approach to addressing infectious outbreaks like COVID-19. "Methods of data gathering and sharing on a larger scale, across healthcare systems within a region, across regions within a state, and across states within a country would be very useful in tracking and managing a pandemic of the current nature," he says. "Identifying a way for health systems to securely share patient data in a meaningful and useful fashion is needed. Additionally, improving the telemedicine system, especially for the elderly population, is important."

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*Except for individuals with HIV RNA >500,000 copies/mL or HBV co-infection, or in whom ART is to be started before the results of HIV genotypic resistance testing for reverse transcriptase or HBV testing are available.

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†Pooled analysis from GEMINI 1 & 2 trials, 2 identically designed, Phase 3, randomized, double-blind (to Week 96, open-label from Week 96 to Week 144), noninferiority trials in treatment-naïve adult patients with HIV-1. At baseline across both treatment arms, 9% were CDC Stage 3 (AIDS), 20% had HIV-1 RNA >100,000 copies/mL, and 8% had CD4+ T-cell count ≤200 cells/mm³. Patients with HBV or major resistance-associated mutations were excluded from the clinical trials. Primary endpoint was the proportion of patients with HIV-1 RNA <50 copies/mL at Week 48 using FDA snapshot analysis with 10% noninferiority margin. The proportion of patients with HIV-1 RNA <50 copies/mL at Week 96 (prespecified secondary endpoint) was 86.0% vs 89.5% for the DTG + 3TC and DTG + TDF/FTC arms, respectively. Treatment difference at Week 96 was –3.4% (95% CI; –6.7%, 0.0%). ADRs (all grades) with ≥2% frequency in patients receiving DTG + 3TC through Week 96 were headache (3%), nausea (2%), diarrhea (2%), insomnia (2%), fatigue (2%), and anxiety (2%).[2-4]

3TC=lamivudine; ABC=abacavir; ADR=adverse drug reaction; ART=antiretroviral therapy; ARV=antiretroviral; CDC=Centers for Disease Control and Prevention; DHHS=Department of Health and Human Services; DTG=dolutegravir; FTC=emtricitabine; HBV=hepatitis B virus; TAF=tenofovir alafenamide fumarate; TDF=tenofovir disoproxil fumarate.

Not an actual patient.

Indication
DOVATO is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults with no antiretroviral treatment history and with no known substitutions associated with resistance to the individual components of DOVATO.

Important Safety Information
BOXED WARNING: PATIENTS CO-INFECTED WITH HEPATITIS B VIRUS (HBV) AND HIV-1: EMERGENCE OF LAMIVUDINE-RESISTANT HBV AND EXACERBATIONS OF HBV
All patients with HIV-1 should be tested for the presence of HBV prior to or when initiating DOVATO. Emergence of lamivudine-resistant HBV variants associated with lamivudine-containing antiretroviral regimens has been reported. If DOVATO is used in patients co-infected with HIV-1 and HBV, additional treatment should be considered for appropriate treatment of chronic HBV; otherwise, consider an alternative regimen.
Severe acute exacerbations of HBV have been reported in patients who are co-infected with HIV-1 and HBV and have discontinued lamivudine, a component of DOVATO. Closely monitor hepatic function in these patients and, if appropriate, initiate anti-HBV treatment.
CONTRAINDICATIONS
• Do not use DOVATO in patients with previous hypersensitivity reaction to dolutegravir or lamivudine
• Do not use DOVATO in patients receiving dofetilide
WARNINGS AND PRECAUTIONS
Hypersensitivity Reactions:
• Hypersensitivity reactions have been reported with dolutegravir and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury
• Discontinue DOVATO immediately if signs or symptoms of severe skin or hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction. Clinical status, including liver aminotransferases, should be monitored and appropriate therapy initiated
Hepatotoxicity:
• Hepatic adverse events have been reported, including cases of hepatic toxicity (elevated serum liver biochemistries, hepatitis, and acute liver failure), in patients receiving a dolutegravir-containing regimen without pre-existing hepatic disease or other identifiable risk factors
• Patients with underlying hepatitis B or C or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations with use of DOVATO. In some cases, the elevations in transaminases were consistent with immune reconstitution syndrome or hepatitis B reactivation, particularly in the setting where anti-hepatitis therapy was withdrawn
• Monitoring for hepatotoxicity is recommended
Embryo Fetal Toxicity:
• Alternative treatments to DOVATO should be considered at the time of conception through the first trimester of pregnancy due to the risk of neural tube defects
• Perform pregnancy testing before use of DOVATO and counsel that consistent use of effective contraception is recommended while using DOVATO in individuals of childbearing potential
WARNINGS AND PRECAUTIONS (cont'd)
Lactic Acidosis and Severe Hepatomegaly With Steatosis:
Fatal cases have been reported with the use of nucleoside analogs, including lamivudine. Discontinue DOVATO if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.
Adverse Reactions or Loss of Virologic Response Due to Drug Interactions with concomitant use of DOVATO and other drugs may occur (see Contraindications and Drug Interactions).
Immune Reconstitution Syndrome, including the occurrence of autoimmune disorders with variable time to onset, has been reported with the use of DOVATO.
ADVERSE REACTIONS
The most common adverse reactions (incidence ≥2%, all grades) with DOVATO were headache (3%), nausea (2%), diarrhea (2%), insomnia (2%), and fatigue (2%).
DRUG INTERACTIONS
• Consult full Prescribing Information for DOVATO for more information on potentially significant drug interactions
• DOVATO is a complete regimen. Coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended
• Drugs that induce or inhibit CYP3A or UGT1A1 may affect the plasma concentrations of dolutegravir
• When coadministering DOVATO with carbamazepine or rifampin, take an additional TIVICAY (dolutegravir) 50-mg tablet, approximately 12 hours from the dose of DOVATO
• Administer DOVATO 2 hours before or 6 hours after taking polyvalent cation-containing antacids or laxatives, sucralfate, oral supplements containing iron or calcium, or buffered medications. Alternatively, DOVATO and supplements containing calcium or iron can be taken with food
USE IN SPECIFIC POPULATIONS
• **Pregnancy:** There are insufficient human data on the use of DOVATO during pregnancy to definitively assess a drug-associated risk for birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established. If planning a pregnancy or if pregnancy is confirmed while taking DOVATO during the first trimester, assess the risks and benefits of continuing DOVATO versus switching to another antiretroviral regimen. For individuals actively trying to become pregnant, initiation of DOVATO is not recommended unless there is no suitable alternative
• **Lactation:** Breastfeeding is not recommended due to the potential for HIV-1 transmission, developing viral resistance in HIV-positive infants, and adverse reactions in a breastfed infant
• **Females and Males of Reproductive Potential:** Perform pregnancy testing before initiation of DOVATO. Advise individuals of childbearing potential to consistently use effective contraception while taking DOVATO
• **Renal Impairment:** DOVATO is not recommended for patients with creatinine clearance <50 mL/min

Please see accompanying full Prescribing Information, including Boxed Warning, for DOVATO in the pocket to the right.

References: 1. DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. US Department of Health and Human Services. https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Updated December 18, 2019. Accessed December 19, 2019. **2.** Cahn P, Madero JS, Arribas JR, et al. Durable efficacy of dolutegravir plus lamivudine in antiretroviral treatment–naive adults with HIV-1 infection: 96 week results from the GEMINI 1 and 2 randomized clinical trials [published online ahead of print December 10, 2019]. *J Acquir Immune Defic Syndr.* doi:10.1097/QAI.0000000000002275. **3.** Data on file. ViiV Healthcare group of companies. Research Triangle Park, NC. **4.** Cahn P, Madero JS, Arribas JR, et al; and GEMINI Study Team. Dolutegravir plus lamivudine versus dolutegravir plus tenofovir disoproxil fumarate and emtricitabine in antiretroviral-naive adults with HIV-1 infection (GEMINI-1 and GEMINI-2): week 48 results from two multicentre, double-blind, randomised, non-inferiority, phase 3 trials. *Lancet.* 2019;393(10167):143-155.

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