



Top 10 Harms Patients Experience In Hospitals – Or Not



Written by
Skeptical Scalpel

The website Health Exec: For Leaders of Provider Institutions recently published the article “Top 10 Harms Patient’s Experience in Hospitals.” It begins with this: “Medical mistakes are one of the leading causes of death in the US.”

The story is based on a white paper, “Top 10 Patient Harms in US Hospitals Based on EHR Data-2019,” from Pascal Metrics, an organization that uses the Global Trigger Tool to analyze data from EHRs in real time. If the Pascal Metrics list was generated from EHR data, its validity should already be suspect. But as you will see, no such data was used to create the list. Because of space considerations, I will only focus on the most egregious falsehoods.

Number 4 on the list is Abnormal Surgical Bleeding. From the article: “Abnormal surgical bleeding is unexpected blood loss that occurs following an invasive procedure. In a study that looked at patients who received a wide variety of specialty surgeries, 29.9% experienced bleeding complications, with associated costs ranging from \$2,805 for patients who experienced said complications from reproductive organ surgeries to \$17,279 for spinal surgeries.”

This study was published in 2011 and was based on 2006-2007 administrative data. It could hardly be relevant to 2019.

The paper involved several hundred thousand inpatients undergoing various types of major surgery. The incidence of bleeding complications was exaggerated in a clever way. Here’s how: for almost 104,000 cardiac operations, 47.4% of patients had some sort of “bleeding-related consequence,” which included blood transfusion. However, only 3.1% patients required reoperation. In other words, the authors considered a blood transfusion alone a significant event.

A 2018 paper in *Annals of Thoracic Surgery* measured pre-and postoperative blood volumes in 54 patients who underwent cardiac surgery and found that the average red blood cells loss was 38%. Therefore, that 40% of cardiac surgery patients might need a blood transfusion is not unexpected.

Number 6 is Organ Injury/Repair/Removal and mentions a Florida surgeon who, during a spine operation, removed a healthy kidney thinking it was a tumor. This case occurred in 2016 and is a series of one patient.

Number 9, Falls with Injury, gives no data about the incidence of falls with injury but rather says “in 2008, one health system had to pay \$2.5 million to a patient who fell in their ER.” How this series of one patient in 2008 relates to the top 10 harms in 2019 is a mystery.

The methodology said to have been used to formulate Pascal Metrics’ top 10 list of patient harms was “adverse event outcomes data generated from its cloud-based multitenant automated patient safety and quality improvement system between June 1, 2018 and May 30, 2019.” Yet, every one of the top 10 patient harms was actually derived from published research papers, records of a lawsuit, or the television program *Inside Edition*.

Health Exec for Leaders reported this garbage without questions. We can only assume that some hospital leaders read and believed it, which is shameful. ■



Food Allergies & Disease Activity in Multiple Sclerosis



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A study has found that patients with multiple sclerosis and have food allergies had more relapses and a higher likelihood of gadolinium-enhancing lesions than those with no known allergy.

While the cause of multiple sclerosis (MS) remains unknown, published studies have shown that both genetic and environmental factors appear to contribute to disease risk and influence the course of MS. Established MS-associated risk factors include female sex, smoking, low vitamin D levels, infection with the Epstein-Barr virus, and obesity during adolescence. Furthermore, clinical research has identified several lifestyle and environmental factors that appear to trigger and exacerbate MS, some of which can affect the immune system.

A Comprehensive Analysis

Several epidemiological studies have investigated the connection between allergy and the risk and disease course of MS, but these investigations have yielded mixed results. For a study published in the *Journal of Neurology, Neurosurgery*

& Psychiatry, Tanuja Chitnis, MD, and colleagues sought to clarify the possible association. They assessed more than 1,300 adults with clinical MS and MRI-confirmed disease activity who had a self-reported history of allergic conditions. Participants were a subset of patients who were enrolled in the Comprehensive Longitudinal Investigation of Multiple Sclerosis at Brigham and Women’s Hospital (CLIMB).

“Patients from the CLIMB study completed a one-time allergy-exposure questionnaire on food and drug allergies,” explains Dr. Chitnis. “We assessed the frequency of allergy, and subtyped patients by allergy type. Patients were categorized as environmental (pollen, grass, etc), allergy, or drug allergy. Those with none of these allergies were classified into the no allergy group. We then assessed the MS relapse rates in the allergy groups and compared them with patients in the no allergy group.”

Clinical and radiological variables and their associations with the different allergy groups were evaluated as part of the analysis. MS disease activity was

assessed by evaluating the cumulative number of attacks over the disease course and by new gadolinium-enhancing lesions that were detected by MRI.

“Overall, we found that patients with MS who had food allergies had a 38% increase in allergies when compared with the no allergy group, even after we controlled for appropriate covariates,” Dr. Chitnis says. Patients with food allergy had a 1.3 times significantly higher rate for cumulative number of attacks when compared with patients with no allergies (Table). This observed effect remained significant even after adjusting for possible confounders like sex, age at symptom onset, and disease category.

In addition, Dr. Chitnis says patients with food allergies demonstrated a 2.5 times higher likelihood of having a gadolinium-enhancing lesion on their brain MRI. In this regard, the environmental allergy and drug allergy groups did not exhibit major differences when compared with the group that had no reported allergies.

Examining the Implications

The effects of allergy on the disease course of MS may have important biological and therapeutic implications. Dr. Chitnis suggests that the association between food allergy and MS disease activity highlights an important role for the gut, which has been shown to impact immunity and inflammation. “Our findings point to a role of food allergy in the causation of new relapse activity in patients with MS,” she says. “Our findings indicate that food allergies may trigger or exacerbate immune mechanisms related to the gut, which in turn increase the risk of MS relapses.”

While the findings currently have limited clinical actionability, there is optimism about the potential translational significance of this research. This research opens a new way of thinking about the immune mechanisms in MS. “We are currently conducting studies to confirm findings from our investigation and to better understand the underlying biological mechanisms of MS by analyzing blood biomarkers of allergy,” says Dr. Chitnis. These insights could lead to new therapeutic and preventative strategies for MS, according to the study. In the meantime, Dr. Chitnis recommends clinicians counsel their patients on preventing or reducing exposures to offending foods in patients with MS who have food allergies. ■

Table Quantifying Attacks by Allergy Type

The table below depicts the association and rate ratio of cumulative number of attacks by allergy type.

Variables	Estimate	Relapse Rate Ratio
Any allergy vs NKA		
Unadjusted	0.1966	1.217
Adjusted*	0.1165	1.124
Environmental allergy vs NKA		
Unadjusted	0.1892	1.208
Adjusted*	0.1211	1.129
Food allergy vs NKA		
Unadjusted	0.3201	1.377
Adjusted*	0.2423	1.274
Drug allergy vs NKA		
Unadjusted	0.1588	1.172
Adjusted*	0.0918	1.096

*The multivariate model adjusted for sex, age at symptom onset, race (non-white vs white), disease category (progressive vs relapsing), and percentage of time on disease-modifying therapy. Disease duration was used as the offset parameter.

Abbreviation: NKA, no known allergy.

Source: Adapted from: Fakhir R, et al. *J Neurol Neurosurg Psychiatry*. 2019;90:629-635.



I have a patient to whom I was prescribing Prozac on a monthly basis. I last saw him 3 months ago, when I gave him a 1-month prescription as usual. After I did so, he became uncooperative and then said that he did not want another appointment, and I have not heard from him since. The pharmacy he listed with my office says that he has not filled a prescription since the last one that I gave him. He has not contacted my office about wanting a prescription. To close matters off, I will be sending him a formal termination letter. Do I have to include a prescription to avoid being charged with abandonment by this difficult patient?

No.

Let’s start with the fact that you are actually not terminating him, which does carry the duty of avoiding abandonment. You will actually be memorializing the fact that he terminated you. In that setting, there is no carryover obligation, because you are not the one ending the care.

However, even if you were the one doing the termination based on his non-compliance, you not only would not be obligated to provide a prescription, you should not do so.

To avoid a claim of abandonment in the termination setting, the doctor is responsible to tide the patient over the transition period to another practice. This includes being available for emergency care during that time and prescribing enough of current medications to cover the interval specified in the termination letter.

However, this patient has already stopped the drug for 2 months. If you prescribe for him now, you would actually be starting a new course of treatment. This would be the opposite of verifying his removal from your practice and could actually be held to vitiate the ending of the physician-patient relationship, because a patient who gets a new prescription could then reasonably conclude that you were now treating them anew.

There is also a professional conduct issue to consider, since you would now be giving a psychoactive medication to someone you have had no clinical contact with for longer than your previous evaluation interval. This is different from a bridging prescription given to a terminated patient leaving active care.

Just send a letter verifying that, as per his statement that he no longer wishes to seek care with your office, that you are closing his file.

This article was written by Dr. Medlaw, a physician and medical malpractice attorney. It originally appeared on SERMO, which retains all rights to it.



Adoptive Cellular Immunotherapy for PML



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In patients with the frequently fatal, rapidly progressive opportunistic brain infection progressive multifocal leukoencephalopathy (PML) for whom reversal of their immunodeficiency—the only treatment for PML—is impossible or would be too slow, there are currently no treatment options. While adoptive cellular immunotherapy is increasingly being used successfully to treat various viral infections in post-transplant patients, whether this strategy offers a potentially powerful means to treat PML remains unclear, explains Erin Beck, MD, PhD.

For a study presented at the American Academy of Neurology’s 2019 annual meeting, Dr. Beck and colleagues sought to determine the safety and feasibility of treatment of PML with adoptive T cell therapy using T cells derived from patients’ first-degree relatives. “Our secondary outcomes were designed to measure efficacy and included survival as well as clinical, radiological, and immunological measures,” says Dr. Beck. “We focused on patients who did not have a readily reversible cause of immunosuppression and who were neurologically worsening at the time of enrollment.” Patients were treated with up to three infusions of polyoma-virus specific T cells (PyVST) each, with at least 28 days between infusions and followed with serial clinical exams, MRIs, and lumbar punctures for at least 1 year following their last infusion.

“We found that treatment with PyVST cells was safe, with no instances of immune reconstitution inflammatory syndrome (IRIS) that required treatment,” explains Dr. Beck. “Our strategy of using related donors was also feasible. Seven out of the 12 patients we treated survived PML, which was encouraging given that they were worsening at enrollment and not expected to do well without treatment.” Lower cerebrospinal fluid JC viral load in patients, JC virus seropositivity in donors, and anti-viral activity in the cell product were associated with survival.

Dr. Beck notes that while the study provides “a great deal about which patients may benefit most from this type of treatment and how to further optimize PyVST cell production and anti-viral activity in order to improve treatment efficacy, the number of patients treated was small and results need to be validated with further studies before being incorporated into general practice.” ■

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