Red Flags That Represent Credible Threats to Patient Safety

Matthew Grissinger, RPh, FASCP

Disruptive behaviors, intimidation in the workplace, and a culture of disrespect among health care professionals have repeatedly surfaced as a significant barrier to patient safety. The hierarchical nature of patient care and the autonomy with which health care professionals have been taught to practice set the stage for a culture that does not respond well to even the slightest queries about possible problems with patient care, particularly from subordinates. It’s clear that such a culture needs to be repaired, and many health care organizations are working to address disrespectful behavior, staff reluctance to speak up about risks and errors, and blatant disregard of expressed concerns. However, there’s a less obvious but no less dangerous risk related to the culture that often goes unnoticed until a serious adverse event happens: Staff members DO speak up about potential concerns, but they are too easily convinced that their concerns are unfounded.

When a person voices a concern, there’s often no disruptive, disrespectful, or obvious intimidating behavior involved per se, but rather an explanation from competent practitioners that dispels the initial concern too quickly, before it has been given sufficient consideration. A pharmacist reassures a technician that the compounding directions are correct when questioned about an unusual volume of ingredients; a pharmacist assures the nurse that the strength of the infusion is correct when questioned about the final volume; a nurse reassures a patient that the medication is correct when questioned about its appearance; a physician convinces a pharmacist that the prescribed dose is correct when questioned because it differs from a protocol—these are all-too-frequent examples that have led to fatal adverse drug events. Those who questioned the patient’s care were easily convinced that others knew more than they did, particularly if the provider who was questioned had an otherwise stellar reputation.

Is this a form of intimidation? Perhaps, but it is more akin to a logical deference to expertise, meaning it is natural and often reasonable for people to defer final judgment to those whom they perceive to be more “qualified.” If the person voicing the concern was reluctant to pursue it, avoided or backed down from the conversation, or felt the provider was not listening, workplace intimidation may play a role. But this is not always the case.

Instead, the issue may be that the person questioning the patient’s care has been easily convinced that his or her concern is unfounded, and the person being questioned has not perceived the voiced concern as a possible, credible patient threat. Neither person possesses a required element to safeguard patients: an appropriately high index of suspicion for errors. A low index of suspicion is particularly problematic in a health care system that already is reluctant to acknowledge human error or value the contributions of every person, regardless of rank, who interacts with the patient.

An index of suspicion is defined as “awareness and concern for potentially serious underlying and unseen injuries or illness.”¹ Suspicion is defined as “the act or an instance of suspecting something wrong without proof or on very slight evidence, or a state of mental uneasiness and uncertainty.”² A high index of suspicion requires consideration of a large differential so that a serious possibility is not accidentally discounted; a potential medical error should always be considered one of the possibilities. An appropriately high index of suspicion should lead a person with a concern to pursue it until it’s proven not to be a credible patient threat, even when met with opposition from experts. It should also prompt the provider to be responsive to voiced concerns and to initiate a suitable investigation to determine whether there is a credible threat to the patient.

The Institute for Safe Medication Practices (ISMP) has previously discussed the need to maintain a high index of suspicion for errors in relation to the topic of mindfulness, a defining characteristic of high-reliability organizations (HROs). Mindfulness refers to the deep and chronic sense of unease and preoccupation with failure that arises from admitting the possibility of error, even with well-designed, stable processes.³ People in HROs worry about system failures and human errors. They ask, “What will happen when an error occurs?” rather than “What will happen if an error occurs?” Like health care, HROs are hierarchical, but position and experience do not necessarily dictate who is an important contributor or decision-maker. They are wary of complacency and naturally suspicious, so they expect people to speak up about any concerns they may have. Their high index of suspicion is a predominant factor in achieving laudable safety records.

To improve patient safety, health care organizations need to raise the index of suspicion for errors, always anticipating and investigating the possibility when any person, regardless of experience or position, voices concern or when patients are not responding to treatment as anticipated. Functional patient-care teams, in which every person’s perspective, skills, knowledge, and observations are considered important and worthy of mention and investigation, must be developed. Staff members need to be mentored on how to resolve potential concerns and to trust in their own experiences to augment the expertise of others. All health care practitioners need to encourage and be receptive to staff members who ask questions, even if staff members just have a sense that “something” is wrong or can’t articulate the concern well.

When concerns are met with quick answers that initially appear to be “evidence” of safety, caution is recommended. Sixteen years ago we published in this column a list of phrases we called

Mr. Grissinger, an editorial board member of P&T, is Director of Error Reporting Programs at the Institute for Safe Medication Practices in Horsham, Pennsylvania (www.ismp.org).
“magic words” that have repeatedly been offered in explanation to voiced concerns and erroneously accepted as “evidence” (Table 1).4 No doubt these still ring true today, along with many others. Such phrases should be viewed as “red flags” that require more reliable answers and actual proof.

ISMP is not discounting the fact that intimidation may play a role in a reluctance to speak up about possible concerns and in a tendency to be easily convinced that a concern is unfounded. We also do not discount the extraordinary courage it may take for many people to step up to these conversations. However, health care practitioners also need to acknowledge that a natural deference to expertise can lead to unintended complacency and tolerance of risk that goes unchallenged. To combat that, all who interact with patients, caregivers) if possible to avoid defensive posturing.

Don’t show frustration or anger; keep emotions in check, even if the initial response is not as expected.

Avoid telling negative stories, making accusations, or using threats.

Diffuse or deflect the person’s anger and emotion by staying calm.

### Table 1 Responses to Voiced Concerns Considered “Red Flags”4

- “The attending told me to order it that way.”
- “The patient says that’s how he takes it at home.”
- “It was published in … (e.g., the Journal of the American Medical Association)” (without providing the reference).
- “This is a special case.”
- “The patient has been titrated up to that dose.”
- “The patient is on a protocol” (without providing the protocol).
- “The dose is the same as listed on the patient’s old chart.”
- “That’s the way the dose is written in the progress notes.”
- “It’s on the list of medications the patient gave me.”
- “We always give it that way.”

### Table 2 Key Skills When Communicating Concerns to Encourage Appropriate Investigation6

- Explain your positive intent—how you want to help the caregiver as well as the patient.
- Use facts and data as much as possible to support your concern.
- Assume the best, but speak up.
- Make an effort to communicate the concern in a safe environment (e.g., away from patients, caregivers) if possible to avoid defensive posturing.
- Don’t show frustration or anger; keep emotions in check, even if the initial response is not as expected.
- Avoid telling negative stories, making accusations, or using threats.
- Diffuse or deflect the person’s anger and emotion by staying calm.

It may take for many people to step up to these conversations. However, health care practitioners also need to acknowledge that a natural deference to expertise can lead to unintended complacency and tolerance of risk that goes unchallenged. To combat that, all who interact with patients must reduce their tolerance of risk and raise their index of suspicion of errors.

A 2010 study conducted by VitalSmarts, the Association of periOperative Registered Nurses (AORN), and the American Association of Critical-Care Nurses (AACN) offers insight into the key skills that can encourage an appropriate response to voiced concerns. These skills are summarized in Table 2. The study concludes that there is cause for optimism—concerns are being voiced nearly three times more often than just five years ago. Health care practitioners need to ensure that these concerns are not only raised but also properly investigated and addressed. You can be sure that those involved in serious errors wish that they had taken the opportunity to do just that.

### REFERENCES


6. Imaging Bulk Package Now Available for Use With Power Injectors

In a recent column in P&T (“Inappropriate Use of Pharmacy Bulk Packages of IV Contrast Media Increases the Risk of Infections,” May 2015), we stated that no Food and Drug Administration (FDA)-approved imaging bulk packages (IBPs) were available. However, it was brought to our attention that the FDA recently approved an Isovue (iopamidol) IBP from Bracco. This is a new dosage-form designation, designed and labeled for multipatient use in the computed tomography (CT) suite in conjunction with an automated contrast injection system or a contrast management system approved or cleared for use with this new presentation. It can also be used with a syringe-based CT injection system and transfer set designed for multipatient use.

Additionally, the Isovue Multipack PBP (pharmacy bulk package) has been renamed Isovue PBP. The PBP product should never be used in radiology for any purpose and should be limited to preparation of syringes in an International Standards Organization Class 5 environment in the pharmacy. The PBP product is not approved for use in automated contrast injection systems. These products are approved for use in angiography, but transferring Isovue from the PBP should be performed in a suitable work area, such as a laminar flow hood, utilizing aseptic technique. The vials are to be penetrated only one time with an appropriate transfer device to fill empty sterile syringes.

The introduction of the IBP product was apparently in response to the sterility issues discussed by the Institute for Safe Medication Practices with using PBPs of contrast for multiple patients in radiology. With the IBP product, the FDA required testing for sterility and chemical compatibility in simulated in-use studies with transfer sets, transfer syringes, and contrast injectors. But keep in mind that sterility is still a concern in radiology if the IBP products are not used exactly as described in the package insert. Other manufacturers besides Bracco may have similar IBP products available in the future.