Healthcare personnel are expected to speak up about patient safety concerns to help intercept errors and avoid adverse patient outcomes. By ‘speaking up,’ we mean raising concerns for the benefit of patient safety and quality of care upon recognizing or becoming aware of a risk or a potential risk. Such risks may include concerns about the safety of an order or treatment modality, a possible missed diagnosis, questionable clinical judgment, rule breaking, dangerous shortcuts, incompetence, and disrespect. Healthcare personnel, especially frontline staff, are well positioned to observe unsafe conditions and bring them to the attention of those who can remediate them.

Speaking up is a behavioral choice under every healthcare worker’s control, but this is quite different than simply voicing a suggestion. A practitioner who bravely expresses a patient safety concern may cause the recipient to become defensive and set themselves up for negative repercussions. In deciding whether to speak up, the practitioner typically engages in a deliberate decision process whereby he or she considers both the positive and negative consequences, as well as the anticipated effectiveness and safety of voicing the concern. It is a balancing act of trying to be proactive and constructive while at the same time considering the possible personal costs of speaking up. As a result, all too often, healthcare personnel will hesitate to voice their concerns, choosing the “safe” response of silence. On the other hand, they may speak up and be ignored or easily convinced that their concerns are unfounded. Silence and dismissed concerns are especially dangerous types of communication breakdowns.

“Safe” Response of Silence

While there are numerous studies and anecdotes that demonstrate the positive relationship between speaking up and patient safety, hesitancy to speak up is an important contributing factor in errors and adverse events. Most practitioners, regardless of their position and specialty, have some experience with hesitating to voice a concern related to patient safety, even when they are aware of the risks and their moral obligation to report their concern. Silence can be caused by a variety of factors, including fear of reprisal, low perceived effectiveness, low motivation, clinical factors, individual factors, social pressures, lack of confidence, fear of...
Table 1. Influencing Factors that Reduce and Enable Speaking Up Behaviors

<table>
<thead>
<tr>
<th>Influencing Factors</th>
<th>Factors that Reduce Speaking Up Behaviors</th>
<th>Factors that Enable Speaking Up Behaviors</th>
</tr>
</thead>
</table>
| Perceived effectiveness of speaking up| ■ Lack of response and impact  
■ Ignoring practitioner concerns  
■ Sweeping concerns under the rug  
■ No improvement in safety  
■ Lack of managerial support  
■ Lack of transparency and follow-up | ■ Readiness and impact  
■ Listening to and valuing concerns  
■ Acting on practitioner concerns  
■ Active managerial/leadership support/approachability  
■ Providing feedback about reported concerns, safety data to units |
| Motivation to speak up               | ■ Low index of suspicion  
■ Low perceived patient harm  
■ Feeling of helplessness, intimidation  
■ Tolerance of risk  
■ No social motivation to speak up  
■ Belief that speaking up is an annoyance | ■ High index of suspicion  
■ High perceived patient harm  
■ Empowered to voice concerns  
■ Fierce intolerance of risk  
■ Coworkers, leaders encourage and model speaking up behavior  
■ Belief that speaking up is a moral obligation |
| Clinical factors                     | ■ Ambiguity of the clinical situation  
■ Uncertainty about patient harm | ■ Clarity of the clinical situation  
■ Perceived risk of patient harm |
| Individual factors                   | ■ Distracted  
■ Prior repercussions  
■ Prior experiences with disrespect  
■ Inadequate coping skills  
■ Unassertive  
■ Diffident cultural background  
■ Insufficient knowledge and skills  
■ Low confidence, prior unfavorable experiences  
■ Fear of damaging collegial relationships  
■ Adaptive conformer (see Table 2) | ■ Keen situational awareness  
■ Joy in work, job satisfaction  
■ Feels responsibility towards patients  
■ Assertive  
■ Knowledge of human factors  
■ Understanding of best practices  
■ Good interpersonal communication skills  
■ High confidence, prior favorable experiences  
■ Trusting collegial relationships  
■ Observer questioner (see Table 2) |
| General contextual factors           | ■ Feeling rushed  
■ Cumbersome reporting process  
■ Lack of teamwork  
■ No input into policy making  
■ No policy to speak up  
■ No established procedure for resolving conflicts about safety | ■ Adequate time to consider potential errors  
■ Streamlined reporting process  
■ Effective teamwork  
■ Interdisciplinary policy making  
■ Organizational edict to speak up  
■ Clear procedure for resolving conflicts about safety not dependent on hierarchical structures  
■ Speaking up included in performance reviews |
| Perceived safety of speaking up      | ■ Psychologically unsafe work environment  
■ Culture of blame, reprisal  
■ Fear of appearing incompetent  
■ Prior negative outcomes  
■ Presence of an audience (e.g., patient)  
■ Lack of manager/coworker coaching before, and support after, speaking up | ■ Psychologically safe work environment  
■ Fair and just culture, culture of safety  
■ Leadership approachable and visible  
■ Certainty about the positive consequences of speaking up  
■ Privacy when speaking up  
■ Managers/coworkers offer coaching and advice before, and support after, speaking up |
| Tools and training                   | ■ No formal training on:  
■ Patient safety theory  
■ Effective communication strategies  
■ Working in teams  
■ No tools provided to help gather and communicate critical concerns | ■ Formal training provided in regular intervals (e.g., patient safety theory, crew resource management, TeamSTEPPS)  
■ Having a speaking up rubric (e.g., SBAR) or structured communication technique (e.g., critical language)  
■ Established opportunities for speaking up (e.g., surgical time outs, SBAR handoffs) |
| Measurement                          | ■ No aggregation or analysis of voiced concerns | ■ Measures the frequency of voiced safety concerns, responses, impact on the messenger and others, and outcomes  
■ Uses these measures for improvement |

*TABLE 2 continued on page 3 — Speaking up >

autoinjector, a carton containing one 70 mg autoinjector, and a carton containing two 70 mg autoinjectors.

The introduction of the new 140 mg/mL autoinjector and the change in packaging have inadvertently contributed to dispensing and patient administration errors. In one example, a pharmacy dispensed two of the 140 mg/mL devices instead of a single 140 mg/mL device for the intended 140 mg dose. In another report, a patient accustomed to injecting two 70 mg/mL devices for the 140 mg dose used two 140 mg/mL devices, resulting in a 2-fold overdose. As these reports suggest, pharmacists and patients may not notice the difference in product strength, which could result in wrong dose errors.

Consider applying auxiliary labels on the cartons to prominently warn against confusion. Staff may also circle product strengths on the cartons using a permanent marker to draw attention to them. Barcode scanning should always be used to ensure the appropriate product is dispensed to patients. As always, patient (or caregiver) education is needed. Pharmacists should verify with the patient the intended dose and review the products being dispensed, along with the carton label and product information. Patients should be encouraged to review the product, label, and accompanying product information prior to every administration and to ask questions if they notice differences in the products dispensed.

**Use methotrexate oral solution only with great caution.** You may not be aware that there is a methotrexate oral solution (XATMEP) that is meant for pediatric use. The drug is indicated for the treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as part of a multi-phase, combination chemotherapy maintenance regimen. It is also approved for use in pediatric patients with polyarticular juvenile idiopathic arthritis who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents. Each mL of the solution contains 2.5 mg of...
Several studies have identified the factors that influence and enable practitioners to voice their patient safety concerns (summarized in Table 1, on page 2). 1-7 For example, many studies emphasized the importance of:

1) The perceived effectiveness of speaking up, such as managerial/leadership support/approachability and feedback
2) Motivation to speak up, such as a high index of suspicion, a high perceived risk, and clarity of the situation
3) Individual factors, such as job satisfaction, situational awareness, confidence, and communication skills
4) Contextual factors, such as effective teamwork and a nonhierarchical process for resolving conflicts
5) Perceived safety of speaking up, such as a psychologically safe work environment and managerial/coworker support
6) Tools and training, including a standardized rubric for speaking up (e.g., SBAR [situation, background, assessment, recommendation])
7) Measurement of the frequency, responses, and outcomes of voiced safety concerns

Table 2. Adaptive Conformer vs. Observant Questioner

<table>
<thead>
<tr>
<th>Worker Faces</th>
<th>Adaptive Conformer (undesired)</th>
<th>Observant Questioner (desired)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstacles</td>
<td>Adjusts, improves without bothering managers or others; fixes it and forgets it</td>
<td>Noisy complainer: Remedies immediate situation but also lets managers and others know when the system has failed</td>
</tr>
<tr>
<td>Others’ risky behaviors (e.g., dangerous shortcuts)</td>
<td>Does not intervene; if it is clear the patient is at risk of serious harm, may report it to a manager</td>
<td>Eager coach: Coaches peers and others to see the risk associated with their behavioral choice, regardless of actual harm, and suggests a safer choice; reports the behavior for learning purposes only</td>
</tr>
<tr>
<td>Own risky behaviors</td>
<td>Rationalizes their behavioral choice to cut corners as required under the circumstances; does not report the behavior</td>
<td>Concerned drifter: Lets manager and others know that they have drifted away from the way processes are designed, and reports the underlying (often system-based) causes so they can be remedied</td>
</tr>
<tr>
<td>Potentially unsafe orders</td>
<td>Defers to experts and gives the prescriber the benefit of the doubt; does not clarify the order unless it is clear that a mistake has been made</td>
<td>Persistent clarifier: Makes no assumptions and clarifies all potentially unsafe orders with the prescriber</td>
</tr>
<tr>
<td>Others’ errors</td>
<td>Seamlessly corrects errors of others, without confronting them</td>
<td>Curious interrupter: Asks what others are doing and lets others know they have made a mistake, for learning purposes only</td>
</tr>
<tr>
<td>Own errors</td>
<td>Creates an impression of never making errors</td>
<td>Self-aware error maker: Lets manager and others know they have made a mistake so everyone can learn; communicates openness to hearing about his or her own errors discovered by others</td>
</tr>
<tr>
<td>Subtle opportunities for improvement</td>
<td>Understands the “way things work around here”</td>
<td>Disruptive questioner: Asks: Why do we do things this way? Is there a better way of providing care?</td>
</tr>
</tbody>
</table>

Adapted from Tucker & Edmondson 8

> Speaking up — continued from page 2

embarrassment if wrong, a disproportionate authority gradient, and many others. In fact, raising patient safety concerns may be perceived as a high-risk, low-benefit proposition for many employees. 1-7

Table 1 — continued on page 4 — Speaking up

> SAFETY briefs cont’d from page 2

methotrexate. Given that parents sometimes measure liquid doses incorrectly, especially when using teaspoons that vary in volume, it is frightening to dispense a 120 mL bottle of methotrexate (2.5 mg/mL) for home use.

All oral liquids should be dispensed with an appropriate dosing device, such as an oral syringe that measures in metric units only, so parents can measure liquid medications accurately. It would be nice if the manufacturer provided an oral syringe to be dispensed with their product. Also, it is critically important to educate parents about dose measurement using the teac-

...
> Speaking up — continued from page 3

Awareness of the factors that influence and enable speaking up behaviors can help leaders create a workforce who can candidly and effectively discuss their patient safety concerns without fear. The goal is to help employees feel comfortable and competent with being an observant questioner who speaks up about patient safety concerns, not an adaptive conformer who quietly remains silent (Table 2, on page 3).8

Dismissed Concerns

When a practitioner voices a concern, there may be 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 a nurse that the strength of a product is correct when questioned about the 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 what he found during investigation. These are real, all-too-frequent examples of backing away from an initial concern that subsequently led to fatal adverse drug events. Those who questioned the patients’ 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 may be more akin to a logical deference to expertise, meaning it is natural and often reasonable for people to defer final judgment to those they perceive to be more “qualified.” The person questioning the patient’s care has been easily convinced that their concern is unfounded, and the person being questioned has not perceived the voiced concern as a possible, credible patient threat. Neither the questioner nor the person being questioned possess a required element to safeguard patients: an appropriately high index of suspicion.

A low index of suspicion is particularly problematic in a healthcare system that is often reluctant to acknowledge human error or value the contributions from 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.”9 Suspicion is defined as “the act or an instance of suspecting something wrong without proof or on slight evidence, or a state of mental uneasiness and uncertainty.”10 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 to not 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 if there is a credible threat to the patient.

Table 3. Examples of “Red Flag” Responses to Voiced Concerns

| That will never happen here |
| That doesn’t apply to me (us) |
| The patient says that’s how he takes it at home |
| It’s just a nuisance alert; it alarms all the time |
| That’s the way we always do it |
| This is how we get the work done here |
| Everyone else is doing the same thing |
| No one ever says anything, so it can’t be too wrong |
| Just do it |
| You must be new here; I’ve been doing this for years |
| It’s not your job to question that |

ISMP has previously discussed the need to maintain a high index of suspicion for errors in our newsletters, including an article continued on page 5 — Speaking up >
about mindfulness, a defining characteristic of organizations with highly reliable outcomes. Mindfulness refers to the deep and chronic sense of unease and preocupation with failure that arises from admitting the possibility of error, even with well-designed, stable processes. People in organizations with highly reliable outcomes worry about system failures and human errors. They ask, “What will happen when an error occurs?” not “What will happen if an error occurs?” 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. Furthermore, position and experience do not necessarily dictate who is an important contributor or decision maker.

To diminish unconvincing threats, healthcare needs 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. Staff need to be trained and mentored to resolve potential concerns and to trust in their own experiences to augment the expertise of others. All healthcare practitioners need to encourage, and be receptive to, those who ask questions, even if they just have a sense that “something” is wrong or can’t articulate the concern well. When concerns are met with quick responses that initially appear to be “evidence” of safety (Table 3, on page 4), caution is recommended. These quick responses should be viewed as “red flags” that require more reliable answers and actual proof.

**Conclusion**

ISMP is not discounting the fact that many complex factors influence whether healthcare personnel speak up about patient safety concerns. We also do not discount the extraordinary courage it may take for many to step up to these conversations. However, tolerance of risk that goes unchallenged is a serious patient safety concern, and to combat that, all who interact with patients must become an observant questioner and raise their index of suspicion of errors. Healthcare leaders and practitioners need to ensure that patient safety concerns are not only raised but also properly investigated and addressed. You can be sure that those involved in serious and fatal errors wish that they had taken the opportunity to do just that.

**References**


One of the most important ways to prevent medication errors is to learn about problems that have occurred in other organizations and to use that information to prevent similar problems at your practice site. To promote such a process, the following selected agenda items have been prepared for you and your staff to stimulate discussion and collaborative action to reduce the risk of medication errors. These agenda topics appeared in the ISMP Medication Safety Alert! Community/Ambulatory Care between September 2019 and December 2019. Each item includes a brief description of the medication safety problem, recommendations to reduce the risk of errors, and the issue to locate additional information. The Action Agenda is also available for download in Excel and Word formats at: www.ismp.org/node/14119.

### Key: ▼ — ISMP high-alert medication

#### Another patient dies after receiving methotrexate instead of metOLazone

<table>
<thead>
<tr>
<th>Issue</th>
<th>Problem</th>
<th>Recommendation</th>
<th>Organization Assessment</th>
<th>Action Required/Assignment</th>
<th>Date Completed</th>
</tr>
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<tbody>
<tr>
<td>11/19</td>
<td>▼ A patient died after receiving daily methotrexate for a month instead of metOLazone. A common cause of drug name mix-ups is searching by just the first few letter characters, which presents multiple look-alike drug names on the screen. In this case, the first three letters are the same (M-E-T), and both are available in 2.5 and 5 mg tablet strengths.</td>
<td>Use at least 5 letters (see ISMP Guidelines for Safe Electronic Communication of Medication Information, <a href="http://www.ismp.org/node/1322">www.ismp.org/node/1322</a>) to reduce the number of different drugs that appear on a screen during a search. Use tall man letters for metOLazone. Employ a hard stop in order entry systems to avoid daily methotrexate orders without an appropriate cancer indication.</td>
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#### Confusion between FIASP and NOVOLOG (both formulations of insulin aspart by Novo Nordisk), which have different onsets of action

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<tr>
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<tr>
<td>09/19</td>
<td>▼ NovoLOG and Fiasp are both formulations of insulin aspart but they are not substitutable. Fiasp contains niacinamide to increase the speed of absorption and is given at the start of a meal or within 20 minutes afterwards. NovoLOG is given 5-10 minutes before a meal. Dispensing errors can occur if the brand name is not on the prescription. In one case, a physician selected Fiasp but the system sent an insulin aspart prescription to the pharmacy; NovoLOG was dispensed.</td>
<td>If Fiasp is intended, prescribers should include the brand name on the prescription. Electronic order systems should communicate the brand name if selected by the prescriber instead of only including the generic name. Practitioners (particularly pharmacists) should confirm the brand name if it isn’t specified on the prescription. Also, patients should be made aware of the intended product and check the drug they receive from the pharmacy.</td>
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#### Match dosing devices to prescribed dose

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<tr>
<th>Issue</th>
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<tr>
<td>09/19</td>
<td>▼ A patient was prescribed haloperidol oral solution concentrate 2 mg per mL at a dose of 0.5 mg (0.25 mL). The patient was provided with a dosing cup that could measure a 25 mL dose. It is unlikely that such a cup would even have markings to measure a 0.25 mL dose. Once home, the patient misinterpreted the directions as 25 mL per dose.</td>
<td>Stock appropriate metric measuring devices that correspond to potential label instructions. Dispense a dosing device that most closely matches the prescribed dose volume and limits the number of instrument fills needed to administer one dose. Confirm dosing directions on the pharmacy label match the dose markings on the provided dosing devices.</td>
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<tr>
<td>09/19</td>
<td>Nearly identical methotrexate and folic acid tablet appearance</td>
<td>Provide clear instructions for weekly dosing of methotrexate, utilizing auxiliary labels to draw attention to the once-weekly frequency. Consider using different manufacturers to differentiate the appearance of methotrexate and folic acid tablets. Only dispense a 4-week supply of methotrexate. During counseling practitioners should provide patients with a copy of ISMP's consumer leaflet on oral methotrexate (<a href="http://www.ismp.org/ext/290">www.ismp.org/ext/290</a>).</td>
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<tr>
<td>11/19</td>
<td>Confusion between doravirine (PIFELTRO) and DOVATO (dolutegravir and lamiVUDine) when using abbreviations (DOR, DOV)</td>
<td>Alert staff to the potential for mix-ups between these two medications. Check your pharmacy and electronic health record systems to ensure these abbreviations are not included in drug name fields. Work with your information technology staff and computer vendor to configure order entry systems to require typing at least 5 letter characters (unless the drug name contains 4 or fewer letters).</td>
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<tr>
<td>10/19</td>
<td>Designing effective warnings</td>
<td>Print visual warnings in big, bold font using mixed case letters, and make sure they are clinically important. Use correct signal words (caution or warning for injuries that might occur; danger for serious hazards that will occur) and color to draw attention to the warnings. Use affirmative wording when possible (e.g., avoid &quot;Not for IV use;&quot; state &quot;For oral use only&quot;); use brief, explicit statements or sentences and embed pictorials. The most effective warning requires the recipient to interact with it to continue.</td>
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<tr>
<td>12/19</td>
<td>Crystvita is contraindicated with oral phosphates and/or active vitamin D analogs (i.e., calcitriol, paricalcitol, doxercalciferol, calcifediol), as it increases phosphate concentrations. Review of 70 reports of concomitant use of Crystvita and a vitamin D product demonstrates a lack of understanding of which vitamin D products are contraindicated—more than half of the reports identified cholecalciferol or ergocalciferol, which are not contraindicated.</td>
<td>Educate practitioners about active vitamin D analogs and their contraindication with Crystvita and build alerts in order entry systems. Prior to prescribing Crystvita, determine if patients take any contraindicated oral phosphates and active vitamin D analogs; if so, ensure patients have discontinued their use for 1 week before starting Crystvita. Also educate patients about the importance of not taking phosphates or active vitamin D analogs while taking Crystvita.</td>
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<tr>
<td>10/19</td>
<td>Mix-ups of various non-therapeutically equivalent NIFEdipine extended-release tablets from Ingenus Pharmaceuticals have been reported. The company distributes generic NIFEdipine extended-release tablets equivalent to PROCARDIA XL and ADALAT CC. These generic formulations, which are not interchangeable, are supplied in bottles that look alike, share similar NDC numbers, and do not specify their brand name equivalent products.</td>
<td>Purchase each medication from a different manufacturer until changes are made to the container labels. If using the products from Ingenus Pharmaceuticals, use auxiliary labels or make a notation on the bottles indicating the equivalent branded product, separate nonequivalent NIFEdipine extended-release products from one another, and use shelf talkers or other signage to help staff identify the correct product.</td>
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<tr>
<td>10/19</td>
<td>A patient who had not been taking his prescribed cloZAPine for several weeks presented to a hospital with agitation and confusion. Upon admission, he was restarted on his home dosage instead of the lower dose recommended by the manufacturer to minimize the risk of hypotension, bradycardia, and syncope. He became unconscious but was successfully resuscitated. The risks associated with rapid re-initiation of cloZAPine after a 2 day or longer interruption in therapy may not be known and the Risk Evaluation and Mitigation Strategy (REMS) program does not address these risks.</td>
<td>Alert prescribers, pharmacists, and nurses to the need to restart cloZAPine treatment at 12.5 mg once or twice daily when there has been a break in therapy for 2 days or longer. Discuss this case internally with fellow healthcare practitioners and health information technology staff. Investigate options to develop computerized decision support to guide practitioners to check the date and time of the patient’s last dose.</td>
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