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ISMP An ECRI Affiliate

Nurse AdviseERR®

Educating the Healthcare Community About Safe Medication Practices

Pump up the volume: Tips for increasing error reporting and decreasing patient harm

Error-reporting systems continue to be an important tool for improving patient safety and represent one of the primary means by which healthcare providers learn about:

- *Potential risks:* hazardous conditions hidden in systems, processes, or equipment
- *Actual errors:* errors and close calls that occur during the delivery of patient care
- *Causes of errors:* underlying weaknesses in systems, processes, or equipment that explain why an error happened
- *Error prevention:* methods to prevent recurring events and, ultimately, patient harm

Error-reporting systems can identify local system hazards, foster a culture of open communication, promote the concept that each staff member is an important contributor to safety, share lessons learned within and across organizations, and provide an initial record of an adverse event.[1] However, error-reporting systems are not utilized to their full potential, largely due to underreporting by frontline healthcare workers and lack of meaningful analysis and change by management in response to error reports. This article addresses the reasons for underreporting as well as tips for increasing the frequency and value of reporting. Later this year, we will publish a follow-up article, in this newsletter, that will address meaningful analysis in response to error reports.

Barriers to Error Reporting

While error reporting (including close calls) is a fundamental component of a safety culture, encouraging healthcare workers to submit reports is no easy task given the potential disincentives to reporting. First, reactions to making errors vary, but candid confessions of mistakes are not particularly comfortable. In fact, people have a natural desire to forget that the incident ever happened. Even if healthcare workers are willing to speak up about errors, they may still believe that the extra work is not worth their time

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Perioperative assessment: Final extension is February 11, 2022!

Because of the ongoing resurgence of the coronavirus disease 2019 (COVID-19) pandemic, we understand that healthcare providers are extremely busy. Thus, we have again extended the deadline for submitting your findings from the ***ISMP Medication Safety Self Assessment® for Perioperative Settings*** to **February 11, 2022**. This is the last data submission extension that we will be able to provide, given the overall timeline for completing the self-assessment project before June 2022. However, we want to give facilities more time to participate in the assessment, particularly since more than 1,100 sites have expressed an interest in participation and have created accounts in the online format. We also have more than 500 facilities that have already submitted their demographic data, but half of these facilities still need to submit their full assessment findings. If you are a US hospital that offers peri-operative services, a freestanding ambulatory surgery center (ASC), or another facility that performs medical and/or surgical procedures under sedation, please take advantage of this opportunity to evaluate your systems, identify challenges, and document regulatory compliance by visiting: www.ismp.org/node/18027.

what's in a Name?

The -terone/-lutamide drug stem names

Medications with the suffixes "-terone" and "-lutamide" belong to a class of drugs known as antiandrogens. Only one antiandrogen in this class has the "-terone" drug stem, abiraterone (**YONSA**, **ZYTIGA**). All other antiandrogens are non-steroidal and use the "-lutamide" stem (**Table 1**). Abiraterone has a similar name and structure as hormonal agents that are "-sterone" drugs (i.e., testosterone) but it is NOT grouped with these drugs. The differing characteristic of abiraterone is how it functions as it inhibits the enzymes that form testosterone precursors. The "-lutamides" generally function by blocking androgen receptors so the body cannot produce testosterone and other androgens.

Table 1. List of antiandrogen medications in the US

Generic	Brand(s)
abiraterone	**YONSA, ZYTIGA**
apalutamide	**ERLEADA**
bicalutamide	**CASODEX**
darolutamide	**NUBEQA**
enzalutamide	**XTANDI**
flutamide	**EULEXIN**
nilutamide	**NILANDRON**

Antiandrogens are primarily used to lower the levels of male hormones in the body and are most commonly used to treat prostate cancer. These medications are administered as primary systemic therapy for regional or advanced disease and as neoadjuvant/concomitant/adjuvant therapy in combination with radiation in localized or locally advanced prostate cancers. There are some off-label uses for antiandrogens such as treating acne,

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if they perceive no benefit will come from reporting, especially if they experience error fatigue due to inevitable and recurring errors that never seem to be addressed. High manager and staff turnover might be a cause of inaction. If management positions change often, there is a greater risk that analysis, learning, and action in response to error reports will not occur.[2] Furthermore, even if analysis and action occur, error reporting will be suppressed if feedback is not provided to the reporters. Additionally, staff may be even less likely to report if the reporting process is time consuming, confusing, or complex.

Second, healthcare workers may not consider reporting to be a priority, especially if the error was captured and corrected before it reached a patient, as with close calls. Close calls may be seen as "unworthy of reporting" since they did not cause patient harm or they may be thought of as a "one-time event" that does not need to be reported.[3] However, the odds of reporting a close call are higher if the error was caught later in the process (closer to the patient), was considered a system *vulnerability* rather than a sign of system *resilience*, and was felt to be an event that "nearly happened" rather than "could have happened."[4,5]Thus, the willingness to report a close call seems to be related to a strong outcome bias and how close the event came to harming the patient.

Finally, nothing can hinder error reporting more than if healthcare workers fear reprisal for reporting or making errors because an organization's culture of safety is not conducive to reporting incidents. The workforce is understandably reluctant to report errors if they are worried that the information will get them or their colleagues in trouble, legally or socially; impact their job or working relationships with others; lead to the perception of being careless or incompetent; or being labeled as an informant. Thus, the likelihood of reporting is highly dependent on the degree of psychological safety felt by healthcare workers. Consider the following example of a nurse who was reluctant to report a dosing error with verapamil to the charge nurse.

A nurse misunderstood an order for a bolus dose of intravenous (IV) verapamil 5 mg followed by a continuous infusion of 5 mg/hour for a step-down unit patient who suddenly developed atrial fibrillation and tachycardia. For the bolus dose, the nurse removed two vials of verapamil from an automated dispensing cabinet that clearly noted the strength on each vial as "5 mg per 2 mL." She confused the "2" in "2 mL" to mean that she should administer "2 vials" to equal the prescribed 5 mg dose. She administered both vials of verapamil (10 mg)—twice the prescribed dose—and immediately recognized her error.

When the patient's physician suddenly appeared on the unit, the nurse was comfortable telling the physician about the error, but she spoke in a hushed tone. The nurse then added that she would have to tell him the rest of the details after the charge nurse moved out of earshot. The verapamil continuous infusion was prepared by the pharmacy and was started 15 minutes later. Luckily, the patient, who was already on telemetry, showed no signs of toxicity over the next several hours.

Despite encouragement from the physician, the error was never reported within the facility. Thus, the opportunity for other clinicians and managers to learn from this mistake was lost because something—perhaps fear of reprisal—prevented this nurse from reporting the error or involving her charge nurse after she made an error.

Tips to Increase Error Reporting

Regardless of the disincentives to report, highly functional internal and external error-reporting systems exist today, including the practitioner-based ***ISMP National Medication Errors Reporting Program (ISMP MERP)*** and the ***ISMP National Vaccine Errors Reporting Program (ISMP VERP)***. From these, best practices that promote active error reporting and opportunities for shared learning can be identified. These best practices fall into the following nine categories that impact the quantity and quality of reports (also see **Table 1** on page 5).

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hair loss, polycystic ovarian syndrome (PCOS), gender dysphoria, or hypersexuality.

All antiandrogens are available as oral formulations (i.e., capsule, tablet). The "-lutamide" drugs are commonly prescribed in combination with a gonadotropin releasing hormone (GRH) analog (e.g., goserelin, leuprolide, histrelin) when treating prostate cancer. However, there is one exception: nilutamide is the only "-lutamide" drug prescribed as monotherapy after surgical castration. In addition, abiraterone is always prescribed with a steroid (e.g., prednisone) when treating prostate cancer.

Antiandrogens are categorized by the National Institute of Occupational Safety & Health (NIOSH) as Group 1 hazardous drugs meaning they may pose a reproductive risk with repeated exposure overtime when handling the medication. Therefore, if these medications need to be crushed, it should only be done in the pharmacy in a biologic safety cabinet. Personal protective equipment (PPE) (e.g., gloves) should be worn when handling these medications.

Antiandrogens are metabolized in the liver so extensive drug-drug-interactions exist and complete medication reconciliation is required prior to initiating these medications with continuous monitoring throughout treatment. A number of reports of various liver complications has been reported with abiraterone. However, flutamide and nilutamide have boxed warnings for hepatic impairment and interstitial pneumonitis, respectively.

Because these medications affect the hormone levels within the body, common side effects include the following: hot flashes, hyperglycemia, decreased libido, headaches, pain, insomnia, and fatigue. Of note, increased seizure risk exists with apalutamide and enzalutamide, and visual disturbances and alcohol intolerance have been reported with nilutamide. Also, apalutamide requires extensive hematological monitoring and testing for anemia and leukopenia.

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Trustworthiness. Those who receive and act on error reports must earn the reporters' trust and prove that the program is sensitive to reporters' concerns, particularly fear of punishment or undue embarrassment for making and reporting errors. Feelings of trust are fostered by leaders who demonstrate an unequivocal passion for safety, acknowledge the high-risk nature of healthcare and human fallibility, and use reports of errors and close calls to assess *system* performance, not *staff* performance.

Open, fair, and learning culture. Leaders who act on error reports must create a just approach to assessing and responding to errors and events, fostering learning, and gaining staff trust and participation in improving patient safety. They must create an environment of internal transparency around risk, promptly identifying system hazards, equipment, and behavioral risks that could cause harm, sharing error reports for learning purposes, and using data (e.g., data from technology, monitoring of triggers), not the number of error reports, to measure risk. Ideally, a Just Culture is needed to encourage the practice of providing essential safety information without the fear of being judged, treated unfairly in the wake of an error, or worried about error rates.[6]

Confidential. Those who receive reports must keep confidential the identity of the reporter, healthcare workers involved in the error, and the location of the event to prevent undue embarrassment or undesirable attention. However, anonymity when reporting is not recommended, as those who receive the report would not be able to talk to the reporter or others involved in an error to learn about the causative factors. Anonymity also signals to reporters that it may not be safe to provide their identity or location, which undermines the idea of trustworthiness. Removing identities after the error has been fully investigated is an option to maintain confidentiality.

Clear. Healthcare workers should be provided with clear definitions and multiple examples of error types, close calls, and hazards, including concerns about their work environment, technology, processes, and patient safety, that should be reported. Be clear about what information and descriptions should be included in the free-text narrative section of the report so a few words, one sentence, or incomplete reports are not the norm.

Easy. Reporting mechanisms should be exceedingly easy, readily accessible, and require minimal training. Those who receive reports must pay attention to the format and length of the required report. If the report is too long, it will stifle reporting. Instead of asking the reporter broad, general questions, the report form should prompt for key identifying information and a free-text description of the event. While a narrative description is often the most useful information in the report, you might also consider asking questions that are specific to the type of event (e.g., for medication errors, the name/dose of the drug[s] involved; for falls, the location of the patient at the time of the fall; for medical devices, the specific make/model of the device) to prompt for the most pertinent information about the event.

When investigating or following up on a close call or error, a reporting tool could help identify missing information about the patient or drug, communication problems, labeling and packaging problems, drug storage problems, environmental problems, and so on (for a sample tool, visit: www.ismp.org/node/541). Probing questions shift a lot of the analytical work away from the reporter and make it easier for the investigator to uncover some of the causative factors that led to the error.

Do not place too much emphasis on frontline workers completing the entire reporting form—key information and a narrative description should be the minimal requirements. A patient/medication safety officer familiar with the reporting system should further investigate events that have merit. Event reporting mechanisms should also be flexible enough to include both formal and informal ways of accepting streamlined information, including oral, written, and electronic submissions.

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PATH to NEW BEGINNINGS
ISMP 24th ANNUAL CHEERS AWARDS

In December 2021, ISMP celebrated its 24th Annual **Cheers Awards**, recognizing individuals, organizations, and groups that have demonstrated an extraordinary commitment to advancing the science and study of patient safety. Join us in congratulating this year's **Cheers Awards** winners, an impressive group of leaders and organizations that have left their footprints on the **Path to New Beginnings**.

- **City of Hope Cancer Center's Protocol Content Administrators Team**, Duarte, California
- **Inova Health System's Intravenous Insulin Team**, Fairfax, Virginia
- **KIDs List Collaborators**, the Pediatric Pharmacy Association, and Rachel S. Meyers, PharmD; Jennifer Thackray, PharmD; Kelly L. Matson, PharmD; Christopher McPherson, PharmD; Lisa Lubsch, PharmD; Robert C. Hellinga, PharmD; and David S. Hoff, PharmD (www.ismp. org/ext/459)
- St. James's Hospital **Medication Safety Minute** (www.ismp.org/ext/820), Dublin, Ireland
- **Raymond J. Muller, RPh, MS, FASHP** (Volunteer Award), New York, New York
- **Tabba Heart Institute**, Karachi, Pakistan

One of the highlights of the evening was the presentation of the 2021 ISMP **LIFETIME ACHIEVEMENT AWARD**. The award honors individuals who have made contributions to patient safety throughout their career. This year's honoree, **Patricia (Patti) Kienle, RPh, MPA, BCSCP, FASHP**, has been an outstanding leader and role model throughout her career, with a longstanding commitment to medication safety.

Thank you to all who attended and supported the **Cheers Awards** event which can be viewed on the ISMP website at: www.ismp.org/node/25784. For ways you can join us on the path to a brighter future for medication safety, visit: www.ismp.org/support.

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Credible and useful. Few things impede reporting more than perceived inaction and failure to use the information contained in a report to improve safety. Unfortunately, most reported problems are not acknowledged or addressed, let alone remediated, and workers often do not perceive error reporting as a good use of their time. Additionally, analyses of reported events are often superficial and do not result in meaningful change.[1]

Leaders must devote resources to not only collect reports, but to analyze reported events and mitigate exposed risks through the effective stewardship of resources. Those who receive reports must provide rapid, useful, and understandable feedback to healthcare workers, across departmental lines, keeping them informed about how their reports are being used to improve systems and processes, even if only to thank the reporter and let them know the event is being investigated. If staff observe changes based upon their reports and feedback, they will be more willing to report hazards and errors.

Rewarding. While not as satisfying as knowing that a report resulted in system-level action, occasional recognition for playing a positive role in patient safety through reporting should be acknowledged by those who receive reports and other organizational leaders.

No severity bias. While a prioritization hierarchy associated with harmful or potentially harmful events may be appropriate for more thorough analysis, those who receive reports and organizational leaders should not allow the severity of the outcome or patient harm drive the response to the report. Not allowing the severity of the outcome to influence decisions helps uphold a commitment to: a) avoid unwarranted punishment of human error or at-risk behavior by overreacting to a singular event, and b) address a potentially fatal system design flaw or reckless conduct, despite the fact the patient was not harmed.

Reinforced imperative. Those who receive reports must establish mechanisms for mentoring new and existing staff about the error-reporting process, stressing the importance of reporting hazards, close calls, and errors by including clear expectations for reporting activities in all job descriptions and during performance evaluations.

Conclusion

By following the tips provided above and in **Table 1** (page 5), organizations can optimize reporting and their capacity for learning about the human, technical, organizational, and environmental factors that determine the safety of the system as a whole. While pumping up the volume of reporting is an admirable goal, do not become too focused on the gathering of error reports. The ultimate measure of success for error-reporting programs is not the number of reports received but rather the learning that occurs, the number and quality of system changes that are made, and the amount of patient harm prevented as a result of system changes prompted by the reports. While it may be difficult to measure risk avoidance and a reduction in patient harm, a reasonable alternative is measuring the number of system changes made as a result of the error-reporting system.[1] Look for a feature article later in 2022 about how to aggregate and prioritize reported events and investigate them thoroughly so meaningful system changes can be implemented and measured.

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Table 1 appears on page 5 — **Pump up the volume** >

Special Announcements

Become an ISMP fellow

ISMP is now accepting applications until **March 13, 2022,** for three **Fellowships** that will begin in the summer of 2022. For details, see **page 6** or visit: www.ismp.org/node/871.

Virtual MSI workshops

Don't miss the opportunity to register for one of our unique 2-day, virtual ***ISMP Medication Safety Intensive (MSI)*** workshops. Our first workshop is scheduled for **January 27-28, 2022**. For details and more dates in 2022, visit: www.ismp.org/node/127.

FREE ISMP webinar

On **January 25, 2022,** ISMP is presenting a **FREE** webinar on the high-alert medications, **heparin, concentrated electrolytes,** and **magnesium**. Faculty will review the safety characteristics of these high-alert medications and identify opportunities for improvement and effective risk-reduction strategies. Continuing education (CE) credit will be provided. For details, visit: www.ismp.org/node/28440.

Obtain 1 hour of CE - FREE!

Read the past six issues (July - December 2021) of **Nurse AdviseERR**, then go to the *Continuing Education (CE) Credit for Nurses* page on our website (www.ismp.org/nursingce) to take a short 10-question test. Once you pass, the CE certificate will be automatically sent to your email.

To subscribe: www.ismp.org/node/138

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Report medication and vaccine errors to ISMP: Please call 1-800-FAIL-SAF(E), or visit www.ismp.org/report-medication-error. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

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Table 1. Best practices that encourage error reporting

Trustworthiness

- Patient safety is clearly reflected in the organization's mission, vision, values, and strategic goals.
- Leaders' decisions demonstrate a visible and unequivocal passion for safety and the prevention of patient harm.
- Leaders acknowledge the high-risk nature of healthcare and human fallibility.
- Leaders are visible in work areas to learn firsthand about the barriers to safe care and to make themselves available for discussions about patient safety.
- Leaders share responsibility for errors when they occur.

Open, fair, and learning culture

- Leaders treat all workers fairly and equitably when responding to an adverse patient safety event.
- Leaders do not discipline individuals who report or commit human errors or at-risk behaviors; disciplinary sanctions are reserved for reckless conduct, knowingly causing unjustifiable harm, and purposely causing harm.
- Leaders utilize errors to assess system performance, not staff performance.
- Leaders openly discuss hazards, close calls, and adverse events, along with the lessons learned and recommended risk-reduction strategies.
- Leaders encourage providers and staff to report hazards and precursors to harm so they can mitigate risks before harm occurs.
- Leaders use reports of errors and hazards outside the organization to make proactive system changes to reduce the risk of similar errors within the organization.

Confidential

- Confidentiality is guaranteed for reporters, individuals involved in errors, location of events, and patient identity.

Clear

- Staff are provided with clear definitions and multiple examples of the types of errors, close calls, and hazards that should be reported.
- The error-reporting process (with examples) is covered during orientation for all providers and staff.

Easy

- Providers and staff have an easy method(s), including informal pathways, for reporting hazards, close calls, and errors.
- The reporting system is so simple that it can be used with minimal training.
- The format used to collect information about events is tested for clarity and ease of use, and edited as needed before or after implementation.

Credible and useful

- Leaders have developed guidelines to identify and prioritize events for which conducting a thorough investigation and/or a root cause analysis (RCA) is appropriate and useful.
- Pathways have been established for sharing the lessons learned from error analysis and RCA (e.g., storyboards, newsletters, staff meetings, educational presentations, daily safety huddles).
- Leaders act upon error and hazard reports by fixing system vulnerabilities, rather than punishing individuals.
- Leaders support system enhancements suggested by staff to reduce the risk of harmful errors.
- Leaders empower staff to correct safety hazards (in conjunction with appropriate communication with leadership).
- Leaders consistently provide feedback to staff regarding the actions planned and taken to prevent errors.
- Pathways have been established for meaningful cross-departmental sharing of memorable error stories and error-reduction strategies.
- Pathways have been established to share meaningful data to demonstrate safety problems and ensure that actions taken have been successful in reducing risk, error, and/or patient harm.
- External reporting is encouraged so that patient safety organizations can disseminate useful information to others and work to address problems at the regulatory, standards, and industry levels.

Rewarding

- Pathways have been established for thanking and rewarding staff who report errors or hazards, and for patient care units for demonstrating measurable improvements in patient safety.
- Demonstrable results and actions taken by the organization based upon the information received in reports are made evident, shared, and celebrated.

No severity bias

- Leaders do not overreact to a singular event with unwarranted disciplinary sanctions even when a patient is harmed.
- The severity of harm from an adverse event does not determine whether leaders address a patient safety event.
- Leaders do not overlook repetitive patient safety problems because patients have not yet been harmed.

Reinforced imperative

- New providers and staff are assigned a mentor to assist with the error-reporting process.
- New providers and staff are required to report at least one safety hazard during their orientation period.
- Participation in error, close call, and hazard reporting is included as core elements in all staff members' job descriptions and performance evaluations.

ISMP Safe Medication Management Fellowships

ISMP is now accepting applications for three unique **Fellowship** programs commencing in **2022**

ISMP Safe Medication Management Fellowship

Location and Term: This Fellowship commences in July 2022. The Fellow will spend 12 months with ISMP, which is located in the suburbs of Philadelphia (Montgomery County), Pennsylvania. Relocation to the Philadelphia area will depend on the state of the COVID-19 pandemic.

Description: Now in its 30th year, this Fellowship offers a **healthcare professional with at least 1 year of postgraduate experience in a healthcare setting** an unparalleled opportunity to work collaboratively with the nation's experts in medication safety to assess and develop interdisciplinary medication error-prevention strategies.

FDA/ISMP Safe Medication Management Fellowship

Location and Term: This Fellowship commences in the summer of 2022. The Fellow will spend 6 months with ISMP, which is located in the suburbs of Philadelphia (Montgomery County), Pennsylvania, and 6 months with the US Food and Drug Administration (FDA), which is located in Silver Spring (near Washington, DC), Maryland. Relocation to these areas will depend on the state of the COVID-19 pandemic.

Description: This Fellowship, open to a **healthcare professional with at least 1 year of postgraduate experience in a healthcare setting**, is a joint effort between ISMP and FDA's Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Divisions of Medication Error Prevention and Analysis I and II. The Fellowship allows the candidate to benefit from ISMP's years of medication safety experience along with FDA's valuable regulatory experience focused on medication error prevention.

ISMP International Medication Safety Management Fellowship

Location and Term: This Fellowship commences in July 2022. The Fellow will spend 12 months with ISMP, which is located in the suburbs of Philadelphia (Montgomery County), Pennsylvania. Relocation to the Philadelphia area will depend on the state of the COVID-19 pandemic.

Description: This Fellowship, open to a **healthcare professional with at least 1 year of postgraduate experience in a healthcare setting**, will help train a medication safety leader interested in seeking a long-term career at an international level. The Fellow will be involved in both US and international medication safety initiatives, helping to address medication safety issues on a national and global level.

Applicants for all three Fellowship programs must be legally eligible to work in the US and have excellent written and verbal communication skills. A competitive stipend is provided with all Fellowship programs.

How to Apply

For a complete description of candidate qualifications and how to apply online, visit: www.ismp.org/profdevelopment/.
For questions regarding the Fellowships or the application process, please contact ISMP at: fellowship@ismp.org or 215-947-7797.

The application deadline for all three Fellowship programs is March 13, 2022.