# PENNSYLVANIA PATIENT SAFETY ADVISORY

Produced by ECRI Institute and ISMP under contract to the Pennsylvania Patient Safety Authority

**Vol. 8, No. 2**

**June 2011**

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## OBJECTIVE

The *Pennsylvania Patient Safety Advisory* provides timely original scientific evidence and reviews of scientific evidence that can be used by healthcare systems and providers to improve healthcare delivery systems and educate providers about safe healthcare practices. The emphasis is on problems reported to the Pennsylvania Patient Safety Authority, especially those associated with a high combination of frequency, severity, and possibility of solution; novel problems and solutions; and those in which urgent communication of information could have a significant impact on patient outcomes.

## PUBLISHING INFORMATION

The *Pennsylvania Patient Safety Advisory* (ISSN 1941-7144) is published quarterly, with periodic supplements, by the Pennsylvania Patient Safety Authority. This publication is produced by ECRI Institute and the Institute for Safe Medication Practices under contract to the Authority.

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The *Pennsylvania Patient Safety Advisory* is indexed in NLM Catalog (http://www.ncbi.nlm.nih.gov/nlmcatalog), a service of the U.S. National Library of Medicine and National Institutes of Health.

The *Advisory* is also indexed in the CINAHL® Plus and CINAHL Plus with Full Text databases.

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# Editorial: The Value of Collaborative Learning for Disseminating Best Healthcare Delivery Practices

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A naïve view of a medical error reporting system, such as the Pennsylvania Patient Safety Reporting System, is that a report will act as a sentinel event for an entire system (e.g., Pennsylvania); it will be disseminated with a solution; all healthcare providers will read about the problem and remember the solution; and it will never happen again. We can only wish that it were so!

Reports of adverse events and near misses associated with medical errors have helped to identify problems in healthcare delivery, the nature of the problems, and possible solutions. They can be used to motivate the implementation of known best healthcare delivery practices. Although facilities in Pennsylvania report making changes based on evidence-based solutions, these have rarely led to sustained improvements in outcomes.[1]

Implementation of optimal treatments for failures in the reliable delivery of healthcare faces the same problems as implementation of evidence-based best practices for the treatment of diseases in patients. Indeed, implementation faces the same problems as diffusion of improved practices in any industry. The study of the diffusion of innovations was pioneered by Everett Rogers.[2] Donald Berwick wrote an excellent summary of the application to the principles to disseminating innovation in healthcare.[3]

The Pennsylvania Patient Safety Authority has confirmed that identifying problems and solutions in *Pennsylvania Patient Safety Advisory* articles is not sufficient to consistently and reliably reduce the number of adverse event reports. There are many reasons that *Advisory* articles would have no different impact than the results of randomized controlled trials published in the *New England Journal of Medicine*. McGlynn has shown that evidence-based best practices are delivered only 55% of the time.[4] Why would optimal ways to reliably deliver that healthcare be any different?

One major failing of education is that it addresses the behavior of providers in the healthcare system, but it does not address the system that is designed to produce the results. The Authority realized the need to change healthcare delivery systems, not just the behavior of providers in the systems. It has realized the importance of effectively disseminating best healthcare delivery practices, as described by Berwick.[3]

The Authority's resulting approach could be called a collaborative learning model, and it has the following five components:

1. The collection and analysis of reports to support generation of evidence-based best healthcare delivery practices
2. Personal communications between the Authority's patient safety liaisons and safety experts within each licensed healthcare facility in Pennsylvania
3. A confidential electronic network—the Patient Safety Knowledge Exchange, or PassKey—to permit confidential communications among patient safety officers
4. Partnering with other institutions on focused patient safety projects
5. Use of the patient safety reporting system to assist in the monitoring of outcomes

The Authority's experience with the collaborative learning model has been encouraging so far. As mentioned in the March 2011 issue of the *Advisory*,[5] the number of wrong-site surgeries is trending downward, perhaps in part as a result of collaboratives with the Health Care Improvement Foundation in the Delaware Valley[6] and with an ongoing collaborative in western Pennsylvania. This issue describes a 37% improvement in the number of blood specimens mislabeled in a consortium of nine hospitals in northeastern Pennsylvania.[7]

Thus encouraged, the Authority has entered collaboratives on falls with the Health Care Improvement Foundation and on surgical site infections with the Pennsylvania


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Consortium of the National Surgical Quality Improvement Program and with the Three Rivers chapter of the Association for Professionals in Infection Control and Epidemiology, among others. So far, 93 licensed Pennsylvania healthcare facilities have participated in at least one collaborative with the Authority.

On inspection, the Authority's collaborative learning model fits Rogers' model of effective dissemination of innovation[2] as described by Berwick.[3] Berwick mentions the importance of the perception of the innovation, the characteristics of the adopters, and the contextual factors of the environment. The suggested healthcare delivery practices in the *Advisory* are evidence based, illustrated by reports from Pennsylvania facilities. By committing to being part of a collaborative, facilities affirm that such evidence-based best practices are compatible with its values, needs, and sense of opportunity. By working with the Authority to reasonably redesign their systems to incorporate the practices associated with the reliable delivery of high-quality healthcare, the facilities adapt the principles to their own environments. The Authority has also found that collaboration results in transfer of information about effectively redesigning systems across facilities by sharing successes and failures, an approach known formally as positive deviance.[8]

The Authority's patient safety liaisons, in personal communications with the facilities' patient safety officers, fill the roles of the innovators, ensuring that best practices are brought to the attention of the workplace. Members of the facilities' collaborative teams—the champions and opinion leaders—function as the early adopters. Their efforts are watched by the early majorities within the facilities, who see and adopt the practices that improve the reliability of their delivery of care. The adoption of the practices by the early majority creates a new level of achievable performance that is then adopted by the later majority on the other side of the bell-shaped curve.

Because of the explicit commitment of the facilities' leaders and the facilities' involvement in the consortium, the collaborations are very visible to others within the organizations and within the consortium. The monitoring of results and dissemination of aggregate results provides evidence of the value of the adopting the practices. They also provide motivation for all facilities within a consortium to continue their efforts to hold their gains.

Both the literature on adoption and dissemination of innovation and the Authority's experience with collaborations support the concept that distribution of evidence-based best practices for the reliable delivery of healthcare is necessary but is insufficient for adoption of those best practices. Adoption of best practices, like politics, is local. Collaborative learning about how to incorporate the best practices into healthcare delivery systems takes advantage of principles for the dissemination of innovation: how the innovation is perceived, who is identified with its adoption, and the synergism of sharing experiences and results. The Authority's efforts to disseminate the adoption of best practices for the reliable delivery of healthcare have been associated with an ongoing reduction in malpractice claims in Pennsylvania.[9] The Authority is optimistic that the five components of its collaborative learning model will help healthcare facilities in Pennsylvania in their objectives to provide safe care to all their patients.

## NOTES


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# Reducing Errors in Blood Specimen Labeling: A Multihospital Initiative


## ABSTRACT

*Patient blood specimen identification is critical for quality patient care. Misidentified specimens can result in delayed diagnosis, additional laboratory testing, treatment of the wrong patient for the wrong disease, and severe transfusion reactions. Specimen identification errors have been reported to occur at rates of 0.1% to 6.5%. From August 2009 through October 2010, the Pennsylvania Patient Safety Authority sponsored a multihospital blood specimen labeling collaborative. The Authority worked with the hospitals to measure blood specimen labeling error rates, document hospital-specific interventions to reduce the labeling error rate, and measure the outcome of the interventions. At the end of the collaborative, there was a 37% aggregate statistically significant decrease in specimen labeling errors. This study discusses the collaborative's objectives, methods, and outcomes. (Pa Patient Saf Advis 2011 Jun;8[2]:47-52.)*


## INTRODUCTION

### Background

Accurate patient identification and correct specimen labeling are critical patient safety issues in healthcare. Inaccurately identified specimens can lead to delayed or wrong diagnoses, missed or incorrect treatments, blood transfusion errors, and additional laboratory testing. The Joint Commission has implemented two hospital National Patient Safety Goals related to patient identification: (1) use at least two patient identifiers when identifying patients, and (2) label containers used for blood in the presence of the patient.[1] The College of American Pathologists includes patient and sample identification as one of its five top patient safety goals.[2] Literature reviews have identified specimen labeling error rates of 0.1% to 6.5%.[3-6]

In 2010, the Centers for Disease Control and Prevention's Laboratory Medicine Best Practices Team published the third phase of an ongoing effort by the Division of Laboratory Science and Standards to develop new systematic evidence review and evaluation methods for identifying pre- and postanalytic laboratory medicine practices that are effective at improving healthcare quality.[7] A key objective of this initiative was to examine the utility and feasibility of including unpublished assessments or studies as part of the systematic evidence reviews of laboratory medicine practices. There was enough evidence from published and unpublished sources to support the following best practices for patient specimen identification: the use of barcoding systems versus no barcoding (eight studies, log odds ratio = 2.45; 95% CI 1.6–3.3) and the use of point-of-care-testing barcoding systems (five studies, odds ratio 6.55; 95% CI 3.1–14.0).

However, solutions to the specimen identification problem are not easily accessible to hospitals. Not all healthcare facilities can afford barcode systems, and even in those facilities that have one, many blood draws and labeling activities are performed in units that do not have access to this technology. For example, in a blood specimen labeling collaborative sponsored by the Pennsylvania Patient Safety Authority, several participating facilities used barcode systems, but staff performing venipunctures in the emergency departments (ED) or neonatal intensive care units did not always have access to the systems. The challenge, then, was to discover if other interventions could improve the specimen labeling error rates within the Authority-sponsored collaborative.

### Blood Specimen Labeling Collaborative Objectives

The goal of the collaborative was a 50% reduction in blood specimen labeling errors over 18 months. The Authority identified the following scope of activities:

— Educate participants (i.e., reliable design, Just Culture™, human factors engineering, event investigations)
— Provide participants with data collection and event investigation tools
— Provide ongoing aggregate data analysis for participants
— Be available for participant mentoring and coaching
— Facilitate interhospital communication and collaboration to reduce blood specimen labeling errors

## MATERIALS AND METHODS

### Participants

Hospital representatives in the northeast region of Pennsylvania were invited to participate in the Authority collaborative. Inclusion criteria were reporting blood specimen


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labeling errors through the Authority's Pennsylvania Patient Safety Reporting System (PA-PSRS), submitting monthly laboratory reports to an Authority analyst, and investigating mislabeling events using a standardized event investigation tool (see the tool at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx). Eight acute care hospitals and one rehabilitation hospital participated in the collaborative. Each hospital assembled a team to participate in the collaborative, and team members included laboratory directors, phlebotomy supervisors, patient safety officers, and risk management, quality and performance improvement, and regulatory compliance personnel. Hospitals selected collaborative participants based on a variety of factors, such as care areas studied, leadership support of the project, and resources available for the time and effort commitment. Because of hospital diversity, the Authority allowed each hospital to select the care areas for study. Hospital collaborative participants decided whether to engage the whole hospital or only certain areas, according to their perception of the greatest problems in blood specimen labeling. Five hospitals engaged the entire facility in the collaborative, and the remaining hospitals chose specific areas: ED, ED and intensive care area, progressive intensive care unit, and medical intensive care unit. Authority representatives included the director of educational programs, the regional patient safety liaison, and a patient safety analyst.

## Data Sources

Authority and collaborative members specified numerator data as the number of blood specimen tubes not accepted for testing because of labeling issues. Collaborative participants entered case data (i.e., events) into PA-PSRS on a continual basis as errors were identified, and the Authority analyst validated the monthly totals for each facility against quality assurance data generated by the hospitals' phlebotomy laboratories. Mislabeled blood specimen samples were defined as those not meeting the same local standards for sample acceptance. Types of mislabeling included wrong, missing, incomplete, or illegible labels. Samples that were properly labeled but not accepted for processing for other reasons (i.e., insufficient blood in tube, presence of hemolysis) were not included. Point-of-care testing was not included. Hospitals could report denominator data as any of three variables, depending on the availability of data at each facility: (1) number of venipunctures, (2) number of accessions, or (3) number of tests. For the statistical analysis, denominator data was combined to represent total number of error opportunities.

Blood specimen labeling error data was collected monthly from August 2009 through October 2010. Baseline error rates were calculated as the number of blood specimen labeling errors per 1,000 opportunities for error after 3 months of data collection. Education was provided from August 2009 through May 2010. Various process improvements were implemented at each facility from April through July 2010. Endpoint error rates were calculated for August through October 2010 and compared to baseline error rates at the facility level and in the aggregate. Exclusionary criteria included failure to implement improvement interventions, failure to report mislabeled specimens through PA-PSRS, and failure to submit laboratory data to the Authority; three facilities were excluded from the data analysis.

## Education

In September and October 2009, the Authority provided educational sessions about reliable design, Just Culture™, and human factors engineering. Subsequently, each hospital team mapped its blood specimen labeling process, assessed the process for compliance through direct observation, and presented an overview of the processes to the rest of the collaborative participants. This was an opportunity for the collaborative participants to identify barriers to labeling compliance that transcended specific care areas and organizations. Common barriers noted by the Authority were those related to technology, communication, education, staffing, workflow, and leadership.

In September 2009, the Authority developed and distributed a standard event investigation tool, which guided collaborative participants through the event investigation process and asked investigators to identify contributing factors for each error. Many collaborative participants were not clinical personnel familiar with

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root-cause analysis; therefore, the Authority held an additional training session regarding event investigation in January 2010. This training session included clinical scenarios and role-playing that allowed collaborative participants to gain familiarity with techniques related to respectful investigation of errors, including gaining trust of staff, allowing for gracious space during an interview, refraining from the use of individual blame, and using active listening skills.

Authority representatives analyzed the data monthly and reconciled any discrepancies found between PA-PSRS reports and laboratory data. Quarterly analysis was provided to each facility. Additionally, the Authority organized biweekly conference calls, tapering to monthly, in which interventions, successes, barriers to success, and mutual support and encouragement were exchanged. Several guest speakers were invited to participate in these calls, including laboratory directors and phlebotomy supervisors with direct experience in specimen labeling projects. Authority representatives were available by means of e-mail and telephone consultation for coaching or mentoring throughout the duration of the collaborative. An additional goal of the collaborative was to develop capable and confident mentors within the participating hospitals who could become resource personnel for other Pennsylvania healthcare facilities that may also want to address blood specimen labeling errors.

## Event Investigation Data

By October 2010, the Authority had collected and analyzed 485 investigations. Facilities reported 520 different contributing factors associated with the mislabeling errors (see Table 1).

The top three contributing factors were (1) procedures not followed ($n$ = 256), (2) distractions and interruptions ($n$ = 70), and (3) unplanned workload increase

*(continued on page 51)*

Table 1. Event Investigations Contributing Factor Data

| DOMAIN | FACTOR | NUMBER |
|---|---|---|
| **Organizational** | Procedures not followed | 256 |
| | No dedicated phlebotomy | 3 |
| | Lack of policies/procedures | 2 |
| | Unclear policies/procedures | 2 |
| | Other | 1 |
| | **Total** | **264** |
| **Work Environment** | Distraction/interruptions | 70 |
| | Equipment malfunction | 7 |
| | Inadequate equipment availability | 6 |
| | Limited access to patient information | 4 |
| | High noise | 3 |
| | Poor lighting | 2 |
| | Other | 9 |
| | **Total** | **101** |
| **Task Factors** | Emergency situation | 22 |
| | Inexperienced staff | 15 |
| | Training issues | 9 |
| | Inadequate resident supervision | 7 |
| | Cardiac/respiratory arrest | 5 |
| | Order entry problem | 4 |
| | Other | 4 |
| | **Total** | **66** |
| **Team Factors** | Unplanned workload increase | 32 |
| | Communication | 15 |
| | Shift change | 3 |
| | Cross-coverage | 2 |
| | Change of service | 1 |
| | Other | 1 |
| | **Total** | **54** |
| **Staff Factors** | Issue related to proficiency | 6 |
| | Agency staff | 5 |
| | Float staff | 5 |
| | Insufficient staff | 5 |
| | Issue related to impairment | 4 |
| | Inadequate system for covering patient care | 3 |
| | Scheduling issues | 1 |
| | **Total** | **29** |
| **Patient Characteristics** | Lack of understanding | 3 |
| | Language barrier | 1 |
| | Lack of family cooperation | 1 |
| | Other | 1 |
| | **Total** | **6** |
| **Grand Total** | | **520** |


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Table 2. Summary of Blood Specimen Labeling Collaborative Barriers and Interventions

| DOMAIN | BARRIERS | INTERVENTIONS |
|---|---|---|
| **Technology** | Technology issues with label printing<br>Lack of strong wireless signal throughout facility<br>Collection technology used only by phlebotomy staff but nursing staff also collect blood specimens in some locations<br>Lack of financial resources for information technology (IT) equipment updates<br>Inability to print blank labels between patient label sets | Changed to new laboratory IT system<br>Installed laboratory printers for labels in care areas<br>Implemented "hold" labels with patient identification versus patient chart labels<br>Investigated label printing option to add blanks between patient label sets<br>Standardized location of all labels<br>Created a bidirectional interface between multiple IT systems |
| **Communication** | Communication issues between nursing and laboratory staff<br>Lack of teamwork and cooperation across service lines | Held monthly meetings with laboratory and nursing staff<br>Addressed staff printing multiple sets of labels at once<br>Shared case studies with staff responsible for laboratory blood specimen draws and labeling<br>Facilitated transferring labels with patients transferred to another department; ensured all labels followed patient to next care setting<br>Implemented a patient-specific binder system for labels |
| **Education** | Lack of knowledge regarding phlebotomy policies/procedures<br>Physicians ordering all labs STAT to get timely results | Implemented mandatory competency testing for specimen labeling process<br>Updated laboratory handbook; provided electronic version to all employees<br>Educated staff regarding proper patient identification procedures<br>Addressed printing of multiple label sets at same time<br>Educated physicians regarding STAT orders |
| **Staffing** | High turnover in laboratory staff<br>Short-staffed; phlebotomists performing 45 to 50 morning draws from a normal high of 25 morning draws<br>Float pool staff not always aware of proper specimen labeling procedures | Leveled work loads<br>Implemented new processes for student phlebotomists<br>Permitted nursing home phlebotomists to work overtime in mornings to assist with blood specimen collection |
| **Workflow** | Lack of care area specific procedures that expedited workflow | Developed mini emergency department (ED) registration to make labels available at time of blood draw in ED<br>Created patient folders to hold labels; patients to give labels to person drawing blood<br>Added third printer to ED to facilitate label printing<br>Began immediate bedside labeling of peripherally inserted central catheter line draws<br>Started hourly batch printing of labels to smooth workflow |
| **Leadership** | Lack of management support<br>Lost momentum for collaborative work; other initiatives with higher priority<br>Loss of clinical leadership; difficult to sustain compliance with improved procedures | Created dashboard/scorecard for collaborative team<br>Used dashboard for laboratory draws to focus staff attention on labeling issues<br>Increased awareness via Pennsylvania Patient Safety Authority-sponsored posters and pins |


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(continued from page 49)

($n$ = 32). This data indicates that the development of strategies to monitor compliance with existing labeling procedures, as well as strategies to maintain compliance in the face of interruptions and distractions, may be a worthwhile endeavor for hospitals.

## Barriers and Interventions

The collaborative participants implemented more than 20 interventions between April and July 2010. They also identified barriers to improvement that they felt affected their hospitals' blood specimen labeling error rates (see Table 2).

There were six major categories of barriers to blood specimen labeling accuracy: (1) technology, (2) communication, (3) education, (4) staffing, (5) workflow, and (6) leadership. The collaborative participants implemented a number of interventions within these domains to improve specimen labeling accuracy.

# RESULTS

## Error Data

Of participating hospitals, six acute care hospitals submitted data about more than 1.3 million opportunities for error (i.e., number of venipunctures, the number of accessions, and the number of tests). Three hospitals were excluded from data analysis because interventions to reduce blood specimen labeling errors were not implemented. Baseline error rates for the hospitals ranged from 0.1 to 4.1 mislabeling errors per 1,000 opportunities for error. Postintervention error rates ranged from 0.0 to 1.3 mislabeling errors per 1,000 opportunities for error. A test of two proportions (z-test) was run to determine the statistical significance of the change in pre- and postintervention blood specimen labeling error rates (see Table 3).

At the facility level, the decrease in blood specimen labeling errors ranged from 57% to 84%. However, one hospital experienced a 67% increase in errors.

From January through March 2010 (see Figure), the aggregate number of error reports peaked. Thereafter, a steady decline in the aggregate number of error reports continued through June 2010, followed by another slight peak in July and August 2010, ending with a mean decrease in error rates of 37%.

Overall, there was a 37% statistically significant decrease in blood specimen labeling errors in the collaborative over the 18-month period (95% CI; $p < 0.04$).

A sensitivity analysis was performed by removing data from each of two facilities with the largest denominator data to test whether the significant decrease observed

Table 3. Reduction in Facility-Specific and Program-Wide Error Rates

| FACILITY | BASELINE ERROR RATES (August through October 2009) | | | POSTINTERVENTION ERROR RATES (August through October 2010) | | | CHANGE | HOSPITAL-SPECIFIC CHARACTERISTICS |
|---|---|---|---|---|---|---|---|---|
| | Rate per 1,000 | LCL | UCL | Rate per 1,000 | LCL | UCL | | |
| **A** | 4.1 | 1.8 | 6.4 | 0.8 | 0.0 | 1.7 | -81%* | One care area of focus; adequate leadership support; targeted interventions |
| **B** | 0.6 | 0.4 | 0.9 | 0.3 | 0.1 | 0.4 | -57% | Multiple care areas of focus; adequate leadership support; targeted interventions |
| **C** | 0.1 | 0.0 | 0.2 | 0.0 | 0.0 | 0.0 | -84%* | Multiple care areas of focus; adequate leadership support; targeted interventions |
| **D** | 2.5 | 1.6 | 3.3 | 0.7 | 0.4 | 1.1 | -71%* | Multiple care areas of focus; adequate leadership support; targeted interventions |
| **E** | 3.2 | 1.5 | 4.9 | 1.3 | 0.2 | 2.4 | -61% | One care area of focus; adequate leadership support; targeted interventions |
| **F** | 0.3 | 0.2 | 0.4 | 0.5 | 0.3 | 0.7 | 67% | One care area of focus; inadequate leadership support; targeted interventions |
| **Pooled Mean** | **0.44** | **0.36** | **0.52** | **0.28** | **0.21** | **0.34** | **-37%*** | |

*$p < 0.05$. Test of two proportions (z-test).


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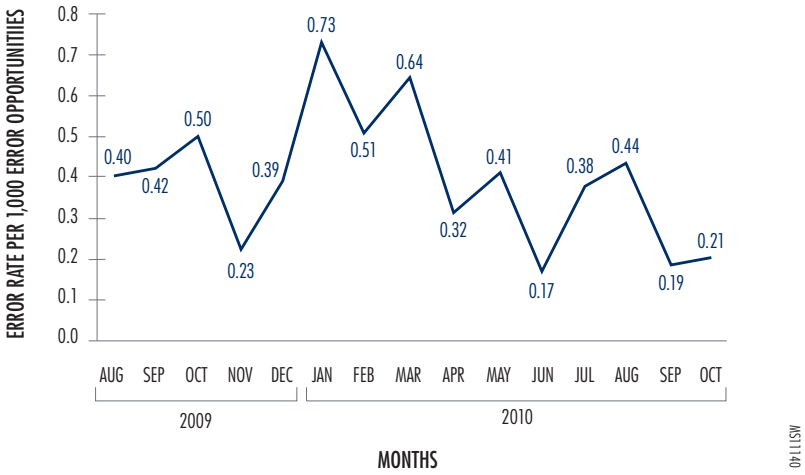
Figure. Collaborative Aggregate Specimen Labeling Error Rate




in the aggregate was overly influenced by the observations at these larger hospitals. The aggregate results remained statistically significant in these two scenarios: 36% decrease in errors (95% CI; $p < 0.01$) and 61% decrease in errors (95% CI; $p < 0.01$).

## DISCUSSION

The peak blood specimen labeling error rates occurred in January 2010 (month 6). This peak likely correlated with increased facilitywide focus and attention to blood specimen labeling issues (shortly after education by the Authority, when surveillance and reporting efforts were likely to be at their highest). If the decrease in error rates was recognized from the peak (January 2010) to the end of the collaborative (October 2010), the decline would be even more significant (i.e., greater than the original goal of a 50% decrease in errors). Additionally, the statistical significance of the collaborative decline (37%) remained even after removing data from the two facilities with the largest denominators, individually, from the aggregate pool.

These positive results apply only to the hospitals that continued to participate in the collaborative and were able to implement some interventions to decrease the blood specimen labeling error rate. Compared to the hospitals included in the study, those hospitals that were excluded experienced a 20% increase in error rates (not statistically significant) (95% CI; $p > 0.05$). Therefore, while the efficacy of sustained attention and implementation of interventions is sound, the effectiveness of this approach cannot be determined through this study.

Lack of standardization of the interventions could be viewed as a limitation of the study. However, the Authority recognized that each of the participating hospitals had unique problems in particular care areas with different patient populations and had varying amounts of resources available for improvement. The hospitals with statistically significant decreases in error rates had in common a sustained focus on the labeling problem and adequate administrative and leadership support. The single hospital that experienced an increase in labeling errors underwent a change in leadership in its care area of focus. According to the hospital leader for the collaborative, this resulted in a lack of follow-through with planned interventions, which may have contributed to the increased error rate.

## CONCLUSION

Specimen identification error analysis combined with interventions to reduce specimen labeling errors can decrease rates of specimen identification error and contribute to improvements in patient safety. Leadership support, sustained attention to the labeling issue, and implementation of interventions to reduce error rates are critical components of a specimen labeling error reduction program.

## NOTES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# Blood Specimen Labeling Collaborative: Path to Results

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**Pennsylvania healthcare facilities that are interested in more information about this collaborative may contact Megan Shetterly through the Pennsylvania Patient Safety Authority at mshetterly@state.pa.us or 717-346-0469.**

## HOW IT ALL BEGAN

During a January 2009 Pennsylvania Patient Safety Authority presentation, a hospital located in the northeast region of Pennsylvania recognized that its patient safety event report data corresponded with year 2007 statewide event data from the Pennsylvania Patient Safety Authority Reporting System (PA-PSRS); specifically, "errors related to procedure/test/treatment" (23%) and "laboratory test problem" (41%) were the predominant event type and subcategory.[1] Anticipating similar experiences at neighboring hospitals, the hospital requested an Authority-sponsored effort to address this issue. The Authority facilitated a blood specimen labeling collaborative among nine hospitals with the goal of decreasing blood specimen mislabeling events by 50%.

Clinical laboratory services play a vital role in the delivery of healthcare. Seventy percent of all information used by clinicians to diagnose conditions and treat patients comes from the laboratory.[2] Adverse events due to mislabeling of blood specimens can result in physical, financial, and emotional costs for patients, their families, and the clinicians who care for them.

## ON THE CUTTING EDGE

A literature search yielded little information related to blood specimen mislabeling. However, the Centers for Disease Control and Prevention previously commissioned a panel of laboratory experts to investigate laboratory medicine best practices. As the Authority's patient safety liaison for the labeling collaborative, I had the opportunity to meet one of the experts and his colleagues during an educational offering in Pennsylvania about process improvement in the laboratory. At this time, I learned more about the national effort, a three-phase project (2006 through 2010). This interaction gave me the opportunity to extract valuable information that I introduced into the collaborative.

## THE JOURNEY

After obtaining senior leadership approval to commit to the time and effort involved with the Authority collaborative (e.g., reporting, conference calls, workshops), each participating hospital assigned a project manager, formed a core team, and selected an applicable care area. With the 50% reduction in mind, the collaborative mantra was, "The right blood specimen is correctly labeled for the right patient every time."

For consistent measurement, the collaborative participants defined mislabeled blood specimen as "the collection of any blood specimen that is not consistent with the policy of each respective hospital," including missing, partial, illegible, or wrong labels and excluding point-of-care testing. Consistent measurement required the participating hospital to decide who was going to collect the data, review the data for accuracy, and ensure timely receipt and timely reporting. Each event was reported through PA-PSRS.

### Challenges

One challenge during the collaborative was an apparent lack of buy-in from staff about reporting near-miss events. In most of these situations, there was a lack of communication between nursing and laboratory personnel. For a project of this magnitude to work, all disciplines have to work together in a culture that promotes effective communication and learning. It should be considered not a "lab project" but rather


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a facilitywide patient safety endeavor. Addressing these issues requires leadership support and a commitment from the project manager to be an agent for change within the organization.

## Learning Experiences

During the collaborative, the participants learned that blood mislabeling was encountered by more than just their respective organizations. They were given an example of a real-life situation in which a mislabeling event resulted in the death of a patient from the transfusion of an incompatible blood type. It was an eye-opening experience for the participants to learn that Serious Events such as these do occur.

Furthermore, the participants did not believe all incidents were being reported through PA-PSRS. They recognized early on that getting their staff to report near-miss events would be critical to the success of this program. How to do this? An eagerness to learn and to use skills would be necessary to achieve the desired results.

Workshops and conference calls were well attended. But the true collaboration developed over time as sharing of experiences among the group helped to forge professional relationships, growth, and learning. Structure and laboratory processes may have varied between each organization, but there were some commonalities. On most teams, either the laboratory supervisor or the director was the project manager. They were well versed in laboratory medicine standards, but some professed little exposure to some of the relevant knowledge and principles involved with mapping of processes: the influence of human factors; the Just Culture™ model; and how to conduct an event investigation.

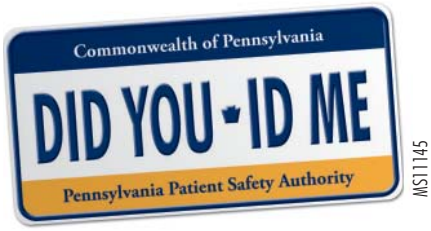
To help meet participants' needs, the Authority provided education and guidance. On-site observations were offered to those who wanted a fresh set of objective eyes to look at their processes. Reviewed items included the categories of standardization, functionality, activity flow, availability of equipment and supplies, communication, distractions, and work assignments. Changes or interventions were instituted according to findings and included decluttering of work spaces and reeducation of staff about identification practices.

Planned redundancy was seen as a key element to integrate into hospital processes. The Authority invited participants to develop a patient identification slogan. One of the project managers came up with a creative idea that was adopted by the collaborative (see Figure). The slogan "Did You ID Me" became useful for identification not only of blood specimens but for other tests and treatments throughout organizations.

## NEXT STEPS

Almost every participant in this collaborative expanded the project to include either other types of specimens (e.g., pathology, urine) or other care areas. Most of the collaborative project managers now serve as consultants for the expanded projects at their hospitals. They have also made their hospitals available as mentor hospitals. (For more information, see the accompanying article in this issue, "Reducing Errors in Blood Specimen Labeling: A Multihospital Initiative.")

Figure. Patient Identification Slogan




## CONCLUSION

One of the most important lessons learned during this collaborative involved culture, which plays a key role and is influenced greatly by leadership. Recently, a nurse manager from a nonparticipating hospital asked, "Can you give me examples of how these collaborative members were able to get staff involved in the process?" He was looking for concrete examples of implementation measures. But the answer that best reflects the participants' work is in their passion for patient safety, the drive to be a change agent, the persistence to see it through, and a "we can" mentality. It was a worthwhile if not easy task. In the end, the group saw a statistically significant 37% decrease in mislabeling of blood specimens and, albeit small, a notable change in the culture at some facilities.

## NOTES

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# Program* Promotes the Establishment of Hospital VTE Prevention Programs

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## ABSTRACT

*The Agency for Healthcare Research and Quality (AHRQ) reports that efforts to reduce the incidence of venous thromboembolism (VTE) can result in substantial reductions in morbidity and mortality in addition to substantial cost savings. VTE is also a focus of the Centers for Medicare and Medicaid Services and the Joint Commission and will be a mandated quality measure in the future. Highmark's QualityBLUE Hospital Pay-for-Performance Program has targeted improvements in averting VTE with 25 hospitals in its service area. Recognizing the scope of the problem is the first step to confronting it. Evidence-based programs are then developed to prevent VTE, and their implementation has substantially reduced the number of VTE events. The successful application of processes that are unique to the individual hospitals and in alignment with best practices has resulted in an 18% decrease in the deep venous thrombosis (DVT) rate and a 21% decrease in the pulmonary embolism (PE) rate in the participating hospitals. The total cost savings of preventing 77 DVT cases and 63 PE cases was projected at nearly $2 million. Lives have been saved, and morbidity has been avoided. This unique program lets hospitals be on the forefront of incorporating activities, well before regulatory agencies mandate such efforts. (Pa Patient Saf Advis 2011 Jun;8[2]:55-62.)*

## INTRODUCTION

In 2008, the Surgeon General's Office acknowledged venous thromboembolism (VTE) as a major public health problem in the United States and requested multiple stakeholders to come together in a coordinated approach to reverse the increasing trend projected for this health issue.[1] VTE—blood clots—is an occlusion of the venous system and includes both deep venous thrombosis (DVT) and pulmonary embolism (PE). DVT occurs when a clot forms in a deep vein, such as in the thigh, calf, or upper extremity. A PE results when a piece of thrombus dislodges from this clot and travels to the lungs. While approximately one-third of patients with symptomatic DVT also develop a PE, only a smaller subset of cases are fatal events because of improved diagnostic testing and effective anticoagulation therapy.[2] VTE is frequently cited in the literature inclusive of the Agency for Healthcare Research and Quality and the National Quality Forum as the most common preventable cause of hospital death.[3-6] Much attention has been focused on the prevention of VTE in surgical patients. In fiscal year (FY) 2010, Highmark Inc., an independent licensee of the BlueCross BlueShield Association, created an indicator for the QualityBLUE Hospital Pay-for-Performance Program focusing on the prevention of blood clots in the high-risk medical population and in intensive care units (ICUs). Unlike the Centers for Medicare and Medicaid Services (CMS) Surgical Care Improvement Project requirements to report timeliness and appropriateness of VTE prophylaxis with select surgical populations, no such current requirements exist for the vulnerable medical population.

## PROBLEM

A review of the literature shows that the incidence of VTE varies widely because the disease can be clinically silent and its diagnosis cannot be consistently confirmed. In an incidence-based model developed by Heit et al., symptomatic VTE is estimated to exceed 600,000 cases annually in the United States, of which approximately two-thirds are healthcare acquired.[7] Two popular cited population VTE studies, one conducted in Worcester, Massachusetts, and the other in Olmsted County, Minnesota, suggest that the annual incidence of VTE is 1 per 1,000 people.[8,9] Another study using the 2003 national inpatient sample from the Healthcare Cost and Utilization Project reported 56% of hospital discharged patients were at moderate to very high risk for developing a VTE.[10] In the Commonwealth of Pennsylvania, the Patient Health Care Cost Containment Council's September 2010 Hospital Performance Report released data showing a 53% increase in PE volumes from 2002 until 2009.[11]

In 2008 the American College of Chest Physicians (ACCP) reported evidence to recommend routine thromboprophylaxis for most hospitalized patient groups, including surgical and medical patients.[12] These evidence-based clinical practice guidelines have been developed to rigorously provide therapeutic interventions to prevent VTE and are specific to patient subsets within the broad category of medical surgical populations such as vascular surgery, orthopedic surgery, neurosurgery, critical care, and oncology. The ACCP guidelines provide a system of graded recommendations to balance risks such as bleeding or death with the benefits of prophylactic therapies specific to patient subsets. This type of reference tool support leads to better clinician compliance with hospital efforts to improve rates of VTE prophylaxis.

* QualityBLUE: A Hospital Pay-for-Performance Program, an initiative of Highmark Inc., an independent licensee of the BlueCross BlueShield Association.


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DVT prevalence varies widely and is reported for patients not receiving thromboprophylaxis for general surgery as 15% to 40%, for medical patients 10% to 20%, and for critical care patients as 10% to 80%.[12] Lack of VTE prophylaxis among medical patients is more prevalent than for surgical patients. The DVT FREE Registry, a trial of 5,451 inpatients and outpatients with an ultrasound-confirmed DVT from 183 geographic sites, found that only 42% of the patients received prophylaxis, and nonsurgical patients were much less likely to have received prophylaxis than were surgical patients.[13]

VTE prophylaxis evidence-based guidelines have been available for hospitals to review and use for nearly 20 years.[14] Yet despite existence of these guidelines, studies have found low rates of compliance with the guidelines. The ENDORSE study (Epidemiologic International Day for Evaluation of Patients at Risk for Venous Thromboembolism in the Acute Hospital Care Setting) assessed the proportion of 68,183 hospitalized at-risk patients who received appropriate prophylaxis in 358 hospitals in 38 countries. Results of the study showed that appropriate prophylaxis was administered to only 59% of the surgical patients and 40% of the medical patients.[15] Appropriate prophylaxis was defined as administration of the correct type of prophylaxis and dose for the correct duration of time specific to a particular patient population as defined by the ACCP guidelines. In another study of 390,024 patients discharged from 500 hospitals in the United States, only 13% of medical discharges and 16% of surgical discharges received appropriate prophylaxis.[16] The studies report that VTE practices in hospitals are suboptimal and it is important for hospitals to improve current practices.

Measures to prevent VTE have been widely studied because of the incidence, associated mortality and morbidity, and annual care costs of more than $1.5 billion.[17] The economic burden of VTE in direct medical costs is large because of not only the index hospitalizations but also the high rate of readmissions and long-term complications resulting from the event. Readmission rates for a VTE (DVT and PE) are 5% for a principal diagnosis and 14% for a secondary diagnosis.[18] The average cost per DVT or PE discharge including 12 months of follow-up was $10,804 and $16,644, respectively.[18] Hospital costs incurred by patients who develop VTE complications are double those for patients who do not develop these complications.[19]

In Highmark's FY 2010 pay-for-performance program population, 25 hospitals reported 2,018 VTE events (across all payers), compared with the 154 Pennsylvania hospitals reporting 14,984 events for federal FY 2009 in the September 2010 Pennsylvania Hospital Performance Report.[11] These volumes of adverse events suggest that much additional hospital focus is needed to create effective prevention programs.

## HOSPITAL PAY-FOR–PERFORMANCE APPROACH

To address this growing healthcare quality of care concern, Highmark Inc. incorporated the VTE prevention and care coordination indicator as part of the QualityBLUE Hospital Pay-for-Performance Program. This indicator allows hospitals to assess and quantify the development of healthcare-acquired VTE and work to prevent these events, as well as to ensure that patients discharged on warfarin therapy have appropriate education to coordinate their care across healthcare settings. The QualityBLUE program is an innovative program designed to "chase zero"—eliminate adverse events that have been identified nationally as areas of opportunity in the health care environment. Highmark's QualityBLUE program began in 2001 with six participating hospitals and has grown to 63 hospitals in Pennsylvania and West Virginia. The program aligns hospital reimbursement dollars with the delivery of high-quality, safe healthcare based on performance. QualityBLUE hospitals are required to implement evidence-based practices designed to deliver high-quality care. Performance is evaluated and scored based on achievement of targeted compliance goals, including the ability to reduce adverse events. Program requirements include defined performance measures, measurement results (process and outcomes), and facility-specific critical analysis.

Twenty-five QualityBLUE hospitals chose to participate in the VTE prevention and care coordination indicator in the FY 2010 program year to improve patient care by reducing occurrences of healthcare-acquired DVT and PE. Patients who developed a DVT or PE during their index hospitalization or 30 days post-discharge were included in the outcome assessment measurement for this indicator. Hospital performance was also scored on process measurements, which included the hospital's compliance for administering VTE prophylaxis on medical patients at high risk for developing a VTE and compliance for providing discharge instructions on anticoagulation therapy for all hospitalized patients discharged on warfarin. To achieve successful reimbursement, hospitals are scored by a standardized method and must demonstrate a decreasing trend of VTE events and 90% or greater compliance for both administering appropriate VTE prophylaxis and providing appropriate discharge instructions to patients on warfarin.

## PROGRAM REQUIREMENTS

### Defined Performance Measures

To participate in the indicator, hospitals were required to measure hospitalwide patients (excluding patients under age 18, those hospitalized for behavioral problems, and obstetrical patients) diagnosed with healthcare-acquired DVT and PE during the index hospitalization or within 30 days following discharge. Patients diagnosed


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with a VTE may or may not have been readmitted to the hospital facility within 30 days. The healthcare-acquired event case-finding methodology included discovery from hospital radiology reports, outpatient encounters, and emergency department visits. This additional case-finding methodology was more difficult for hospitals to pursue if they did not have an electronic medical record system in place.

The hospital was also required to select two units that predominately housed a high-risk medical population for VTE development to measure VTE prophylaxis compliance. Hospitals that selected the VTE indicator for the first time were required to choose an ICU that housed predominately medical patients as one of the two units. Each unit measured the total number of patients that received appropriate VTE prophylaxis or had a documented reason for no VTE prophylaxis being given the day of or day after hospital admission or transfer to the selected unit. The medical population of patients versus surgical population was chosen since the lack of VTE prophylaxis among medical patients is more prevalent.

Lastly, hospitals were required to measure the total number of acute care hospitalized patients discharged to home on warfarin who received comprehensive patient-specific written discharge instructions. This measure was developed to align with the 2010 Joint Commission National Patient Safety Goal 3, "Improving the Safety of Using Medications," and the CMS Venous Thromboembolism National Hospital Inpatient Quality Measures VTE-5, "Venous Thromboembolism Discharge Instructions." The use of warfarin has been related to adverse events that result from complex dosing, insufficient monitoring, and inconsistent patient compliance.[20] The discharge instructions were to include education that addressed the following components: (1) importance of follow-up blood work monitoring, including details of with whom and date; (2) compliance issues related to follow-up appointments and taking medication as instructed; (3) dietary instructions; and (4) the potential for adverse drug reactions or interactions. All four components had to be addressed for the instructions to count as compliant. Sampling was permitted for this measurement for hospitals that discharged more than 25 patients a month on warfarin.

## Critical Analysis: How to Develop a VTE Prevention Program

Each hospital was responsible for writing a critical analysis for the VTE indicator, summarizing key program objectives, implementation strategies, and results. The critical analysis discusses the hospital's improvement strategies, educational efforts, lessons learned, barriers to implementation, and facility-specific return on investment. Common themes and strategies were identified in the hospital's VTE critical analysis, and it provided examples of important steps for creating a VTE prevention program. Hospitals described the initial step as identifying key personnel to form an interdisciplinary VTE team. Examples would be physicians and nurses from surgical and nonsurgical departments, residents, health educators, data abstractors, and personnel from pharmacy, dietary, laboratory, quality services, and information systems departments. A physician champion was identified to lead the team and address any barriers identified by the physician staff. In some hospitals, pharmacists successfully assumed the role of team champion.

Teams were then tasked with reviewing the literature to create evidence-based VTE prevention guidelines (see "Resource List"). Gaps between the current prophylaxis practices and the literature were identified. Guidelines were created to include development of a VTE risk assessment, identification of contraindications to prophylaxis, and the development of VTE prevention physician order sets, including specialty order sets for orthopedics, neurology, and oncology. Depending on the hospital's level of information technology support, the prevention guidelines could be pre-printed documents on the chart or electronic decision support tools such as a mandated risk assessment and standardized computer-generated orders. One of the most challenging steps identified by hospitals was the timely medical executive committee approval process for the guidelines.

A key part of the initiative was education for physicians, hospital staff, and patients. One facility identified education as a "core essential for the success of the program." Examples were VTE grand rounds, mandatory continuing medical education, new physician VTE orientation packets, an interactive storyboard rotated throughout the hospital, participation in March VTE prevention month with posters and newsletters, one-on-one education with physicians, preoperative education materials for patients, community lectures involving the local library and senior residential centers, an annual breakfast program to educate skilled nursing facilities, and screensavers for the computers. More creative strategies were developed to engage physicians to be compliant with the VTE protocols, including the following:

- Provider- and service-specific report cards of VTE events and mortalities were created and reviewed by medical staff.
- Unit-level and physician-level VTE prophylaxis data compliance was displayed on the two study units, including names of noncompliant physicians.
- Compliance letters were sent to physicians with data comparing them to their peers, overall hospital compliance rate, and hospital goals.
- Noncompliant physicians were contacted by nurses regarding completion of prophylaxis orders or appropriate documentation related to contraindications after review of


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## RESOURCE LIST

The following resources were used to develop an evidence-based hospital venous thromboembolism prevention program:

**Academy of Family Physicians and the American College of Physicians**

Current diagnosis of venous thromboembolism in primary care: a clinical practice guideline. Available from Internet: http://www.annals.org/content/146/6/454.full.

**Agency for Healthcare Research and Quality**

Preventing hospital-acquired venous thromboembolism: a guide for effective quality improvement. Available from Internet: http://www.ahrq.gov/qual/vtguide.

**American Academy of Orthopaedic Surgeons**

Clinical guideline on prevention of pulmonary embolism in patients undergoing total hip or knee arthroplasty. Available from Internet: http://www.aaos.org/research/guidelines/pe_guideline.pdf.

**American College of Chest Physicians**

Evidence-based clinical practice guidelines, 8th edition. Available from Internet: http://www.chestnet.org/accp/guidelines/antithrombotic-and-thrombolytic-therapy-8th-edition.

**American College of Obstetricians and Gynecologists (Committee on Practice Bulletins)**

ACOG Practice Bulletin No. 84: Prevention of deep vein thrombosis and pulmonary embolism. Available from Internet: http://www.acog.org.

**Institute for Healthcare Improvement**

IHI improvement map: Venous thromboembolus (VTE) prevention & treatment. Available from Internet: http://www.ihi.org/imap/tool/#Process=5b9bfd5a-1e17-433b-a9d4-602fafef73c8.

**Institute for Clinical Systems Improvement**

Venous thromboembolism diagnosis and treatment [guideline online]. Available from Internet: http://www.icsi.org/guidelines_and_more/gl_os_prot/cardiovascular/venous_thromboembolism/venous_thromboembolism_6.html.

**National Comprehensive Cancer Network**

Clinical practice guidelines in oncology: venous thromboembolic disease. Available from Internet: http://www.nccn.org/professionals/physician_gls/pdf/vte.pdf.

**National Institute for Health and Clinical Excellence**

Venous thromboembolism: reducing the risk. Available from Internet: http://www.nice.org.uk/CG92.

**Society of Hospital Medicine**

Preventing hospital-acquired venous thromboembolism: guide for effective quality improvement. Available from Internet: http://www.hospitalmedicine.org/ResourceRoomRedesign/RR_VTE/html_VTE/00_ImplementationGuide.cfm.

a patient case by pharmacy and the nurse manager.

— An organizational quality dashboard was used to communicate performance outcomes to all staff, including members of the board.

— Electronic decision support tools were used that mandate VTE risk reassessment with change in patient's level of care.

Nursing engagement was viewed as a critical component of success and included surveys to query staff on successes and barriers of the VTE prevention program. The pharmacy manager conducted reviews of patients who were ordered sequential compression devices (SCD) for utilization compliance with immediate educational follow-up for noncompliant staff. Morning huddles were held to discuss a patient's status, including VTE prophylaxis, and decision support software solutions were used that created automatic hard stops to prevent nurses from advancing discharge instructions without addressing the appropriate warfarin patient teaching.

Data collection and analysis is another critical step in the VTE quality improvement program. Monthly tracking of data is required by the QualityBLUE program. Hospital performance on the program, including analysis of the data, is presented two times, during midyear and year-end presentations to the QualityBLUE team. In addition to the required data collection tool measures, the unit prophylaxis compliance, the number of DVT and PE events, and compliance for warfarin discharge education, hospitals evaluated other metrics to drive performance improvement. The hospitals' critical analyses discussed the following:

— Healthcare-acquired VTE trends by service lines and physicians

— VTE prophylaxis ordered on discharge for patients readmitted with a DVT or PE


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— Potentially preventable VTE events, patients with a healthcare-acquired VTE who did not receive appropriate (type, dose, duration, and timely administration) VTE prophylaxis
— Nursing documentation of an SCD being used by a patient, including the time the device was not being used by the patient and secret shopper visual audits to compare nursing documentation with patient experience
— Patient satisfaction survey results related to their experience with SCD (e.g., Did patient understand reason for device? Was the equipment uncomfortable? Did the patient keep device on as ordered?)
— Return trips to the operating room related to bleeding for patients on VTE prophylaxis
— Staff survey results related to the staff's knowledge of the VTE prevention program
— Readmission analysis of VTE patients that includes review of discharge anticoagulation therapy
— Pilot projects that determined that pharmacists might be the best patient educator for warfarin discharge instructions

A hospital's success in decreasing the number of VTE events in their hospital is related to establishing individualized approaches that may be unique to their hospital. However, common themes related to lessons learned in the implementation of the VTE prevention program were noted. (See "Lessons Learned.")

## Measurement Results

For many hospitals, this quality initiative was the first-ever measurement and analysis of facility VTE events, and this analysis prioritized the importance of a VTE prevention program for such hospitals. For the first process measure, hospitals showed a significant increase for VTE prophylaxis compliance in the nine months of the program year. Figure 1 represents combined prophylaxis compliance for the two high-risk units studied for the aggregate of the 25 participating hospitals. A steady improvement from FY 2010 quarter 1 to quarter 3 can be noted. The average first quarter compliance was 76%, which increased to 94%, representing a 24% change from quarter 1 through quarter 3. This is a statistically significant increase ($p$-value < 0.05). Twenty-one hospitals, or 84%, had a 90% or greater VTE prophylaxis compliance for both units in the last quarter of the program year. The range of hospital compliance scores for the final quarter was from 87% to 100%.

The second measurement for the VTE indicator was monitoring compliance for discharge instructions specific to warfarin anticoagulation therapy. The focus of this measure was to ensure that patients or their families received instructions on safely self-administering this drug. Figure 2 shows the steady increase in appropriate warfarin discharge instruction compliance over the nine months of the program year. Aggregate compliance for FY 2010 quarter 1 was 60%, which increased to 92% by quarter 3. This is a statistically significant increase ($p$-value < 0.05).

The 25 QualityBLUE hospitals reported a total of 1,222 DVTs and 859 PEs over a nine-month period. Figure 3 displays the DVT and PE aggregate rate per quarter for all participating hospitals. The aggregate DVT rate is reported at 0.53 per 100 patient admissions for the first quarter of the FY 2010 program year compared with a DVT rate of 0.43 per 100 patient admissions for the third quarter of the year. This decrease in the DVT rate between the quarters represents a percent reduction of 18%, which is statistically significant ($p$-value < 0.05) and translates to a potential 77 averted DVT cases. Potential cost savings of $831,908 is estimated from the 77 DVT averted cases, calculated

### LESSONS LEARNED

— Opportunities did exist for VTE prevention practice changes.
— Real-time, day-to-day monitoring of VTE prophylaxis compliance is needed instead of retrospective data collection.
— Application of standardized processes based on evidence-based guidelines can reduce healthcare-acquired VTE.
— Continuous monitoring of all quality improvement processes and staff feedback is required.
— Input by frontline staff is essential to identify opportunities and barriers.
— Decision support alerts embedded in care processes for the practitioner is the ideal means for sustaining change in practice.
— Clinical pharmacists' roles expanded in the hospital VTE prevention program to include team champion, patient educator for warfarin discharge instructions, and physician educator for ensuring patients receive appropriate prophylaxis (type, dose, duration), including weight adjustment dosing if needed.
— Real-time, face-to-face communication with physicians and nurses regarding best practices and evidence-based medicine proved vital in achieving VTE compliance.
— Repeated educational sessions throughout the year will help to inform physician and nursing staff about the VTE prevention program.
— Engaging nursing staff in fun, creative educational activities, such as hospital safety fairs, can increase awareness and compliance.
— Direct and transparent physician performance feedback is important.


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from the estimated costs of $10,804 to treat one DVT case, including the costs for 12 months of follow-up care.[18] Similarly, Figure 3 shows a reduction that was noted for the PE rate between quarter 1 and quarter 3 of the program year. A rate of 0.38 per 100 patient admissions was reported for the first quarter and a rate of 0.30 for the third quarter. This decrease is a 21% statistically significant change ($p$-value < 0.05) and represents 63 potentially averted PE cases. Cost savings estimated for the 63 averted cases is $1,048,572, based on $16,644 per case and including costs for 12 months of follow-up care.[18]

Figure 1. FY 2010 VTE Prophylaxis Compliance (Units 1 and 2) by Quarter, All QualityBLUE Participating Hospitals—Aggregate

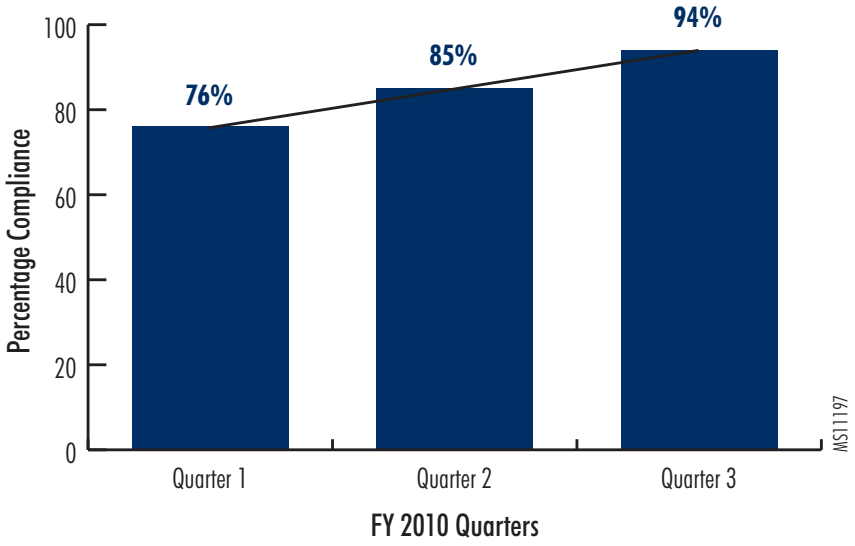
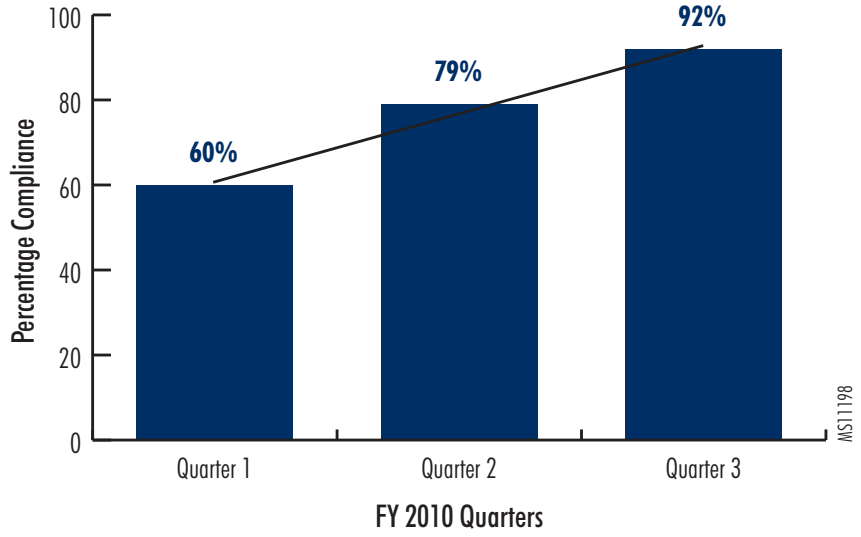



Figure 2. FY 2010 Compliance for Appropriate Warfarin Discharge Instructions by Quarter, All QualityBLUE Participating Hospitals—Aggregate




The aggregate performance of the 25 hospitals participating in the VTE prevention and care coordination indicator showed statistically significant improvements for all indicator performance measurements. These improvements directly relate to better patient outcomes, the ultimate goal for healthcare delivery.

## CONCLUSIONS

The QualityBLUE indicator lets hospitals be on the forefront of incorporating improvements well before they are mandated by regulatory agencies. Currently, CMS and the Joint Commission have voluntary requirements to report the Venous Thromboembolism National Hospital Inpatient Quality Measures. However, starting in 2012, the Medicare and Medicaid Electronic Health Record Incentive Program meaningful use requirements will require participating hospitals to electronically submit these six VTE clinical quality measures.[21]

The QualityBLUE hospital pay-for-performance program could be replicated by health plans nationwide. The program components for operation, data collection tools, and program manual align with national evidence-based practices. Detailed measurement definitions and result expectations are developed annually and keep pace with national healthcare quality agendas and changes in clinical practice. For example, with the development of numerous novel oral anticoagulants such as Pradaxa® (dabigatran etexilate), which has recently been FDA approved to prevent strokes in atrial fibrillation patients, the use of warfarin may be replaced, and monitoring warfarin patient education will be obsolete.[22] Established targets for threshold performance both in compliance


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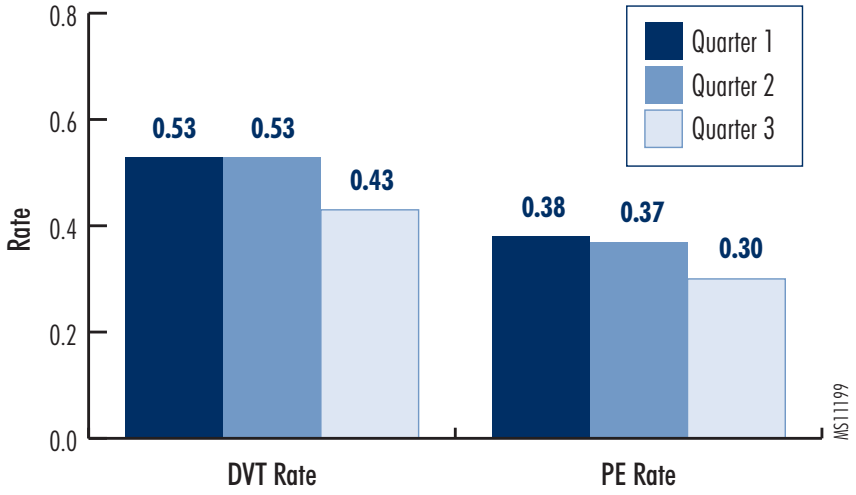
Figure 3. FY 2010 DVT and PE Rates by Quarter, All QualityBLUE Participating Hospitals—Aggregate




**Rate per 100 patient admissions.**

with evidence-based process measures and reducing adverse events are well defined. The expected payoff for widespread adoption of this program would be quantified through significant lives saved by avoiding medical misadventures. In addition to the tremendous toll on human life, the financial burden attributed to these misadventures is staggering. Because this program motivates an entire organization, aligning board, leadership, and frontline workers, improvement occurs and "chasing zero" is no longer simply a concept but a reality for QualityBLUE participating hospitals.

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## Correction

***Controlling the* annual threat *of norovirus gastroenteritis outbreaks. Pa Patient Saf Advis 2010 Dec;7(4):141-8.*** *This article contained statements in error on pages 141 and 142. The statements should read that "reports of non-C.* diff *AGE cases in Pennsylvania nursing homes increased from 633 cases in the third quarter of 2009 to 812 cases in the fourth quarter of 2009 and then surged to 4,040 cases in the first quarter of 2010." These statements have been corrected in the online article. The editors regret the error.*


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# Applying the Universal Protocol to Improve Patient Safety in Radiology Services


## ABSTRACT

*Multiple failed organizational and departmental processes may lead to wrong-patient, wrong-procedure, wrong-side, and wrong-site errors in radiology services. Explanations for such errors are linked to similarities in sites, diagnostic studies, and patient names; breakdowns in communication or teamwork; patient and procedure factors; and failed safety systems. Review of events reported to the Pennsylvania Patient Safety Authority in 2009 identified specific processes that exposed patients to potential harm, including order and scheduling inaccuracies, patient misidentification, and inaccurate procedure verification practices. Implementing and enforcing policies that address patient identification and procedure verification processes to prevent errors, as well as ensuring that staff are continually trained, provides radiology services with opportunities for improvements that not only can be observed by providers but can be expected by patients. (Pa Patient Saf Advis 2011 Jun;8(2):63-9.)*


## INTRODUCTION

Although much of the attention paid to patient and procedure verification has focused on surgery, occurrences of patient misidentification, procedure mistakes, and side or site confusion errors and near misses continue to surface outside the surgical suite. Despite quality improvement efforts, the prevalence of these errors in other disciplines, namely, radiology services, may be more common than generally expected and reported in the literature.[1] In 2009, the Pennsylvania Patient Safety Authority received reports of 652 events specifically related to wrong-procedure or test (50%), wrong-patient (30%), wrong-side (15%), and wrong-site (5%) radiology errors. Predominant testing modalities reported to the Authority included radiography (45%), computed tomography (CT) scan (18%), mammography (15%), magnetic resonance imaging (MRI) (6%), and ultrasound (5%). The Table outlines the number of wrong-patient, wrong-procedure, wrong-side, and wrong-site events associated with each radiologic study.

Ensuring correct patient identification is a recognized healthcare challenge, and the acute care setting poses the greatest challenge because a wide range of interventions are delivered in various locations by numerous staff who work in shifts.[2] The radiology staff—most notably, radiologic technologists—comes in contact with a significant number of patients on a daily basis. Failure to correctly identify patients and correlate their clinical information to an intended radiologic study continues to result in one of four recognized wrong events: wrong patient, wrong procedure, wrong side, or wrong site. Patient misidentification can lead to unnecessary risks, including overexposure to radiation, delay in diagnosis and treatment, and incorrect treatment.

While such errors are preventable, they continue to occur and to contribute to national health and patient safety concerns. Establishing policies and standard practices similar to those developed for surgery and supported by key leadership may help radiology providers in hospitals and outpatient centers reduce variability among individual care providers and teams in preventing unintended procedures and untoward patient outcomes. Prevention of these events requires safety systems that ensure accurate procedure ordering and scheduling, as well as patient identification and verification processes that work to ultimately prevent wrong-patient and wrong-procedure errors. It is essential that the effectiveness of implemented safety systems is continually observed, evaluated, and monitored to prevent future events.

## CAUSES OF THE FOUR WRONG EVENTS

Review of the 652 events identified several failed processes that accounted for the wrong events experienced in radiologic services. These processes were categorized as follows:

- Incorrect order or requisition entry
- Failure to confirm patient identity
- Failure to follow site and procedure verification or procedure qualification processes

### Incorrect Order or Requisition Entry

Patients were erroneously subjected to a radiology study as a result of an inaccurate order entry originating from patient care areas (e.g., floor, emergency department [ED]) or radiology registration or clerical personnel or caused by a technologist who selected the wrong option that generated an inaccurate requisition form. Improper orders included order entries that did not specify whether a procedure was to be done with


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Table. Wrong Events by Radiologic Study Reported to the Pennsylvania Patient Safety Authority, 2009

| RADIOLOGIC STUDY | WRONG EVENT | | | | NUMBER OF WRONG EVENTS | PERCENTAGE OF WRONG EVENTS |
|---|---|---|---|---|---|---|
| | Wrong Patient | Wrong Procedure | Wrong Side | Wrong Site | | |
| Radiography | 93 | 104 | 75 | 24 | 296 | 45.4% |
| Computed tomography | 36 | 69 | 4 | 6 | 115 | 17.6 |
| Mammography | 7 | 87 | 4 | 0 | 98 | 15.0 |
| Magnetic resonance imaging | 7 | 27 | 5 | 0 | 39 | 6.0 |
| Ultrasound | 13 | 13 | 6 | 3 | 35 | 5.4 |
| Nuclear medicine | 4 | 8 | 0 | 1 | 13 | 2.0 |
| Interventional | 3 | 3 | 0 | 0 | 6 | 0.9 |
| Dexa scan | 1 | 1 | 0 | 0 | 2 | 0.3 |
| Positron emission tomography | 1 | 0 | 0 | 0 | 1 | 0.2 |
| Not specified | 31 | 14 | 2 | 0 | 47 | 7.2 |
| **Total Number of Events** | **196** | **326** | **96** | **34** | **652** | |
| **Total Percentage of Events** | **30.1%** | **50.0** | **14.7** | **5.2** | | **100** |

or without contrast and order specifications that were the opposite of what was intended. These types of electronic order entry errors occurred because of the lack of verification between the placed order and the reason for the imaging study and because order entry, for the most part, was not performed by the ordering physician. Such errors contributed to the procedure-type errors that accounted for 50% of the reviewed events (see Table).

The following are some of the reported order entry events:

> *A physician ordered bilateral hands and wrist x-rays. The registrar incorrectly entered orders for bilateral hands and feet. The technician did not verify the physician's order and completed bilateral hands/wrists and feet x-rays.*
>
> *A CT scan of the abdomen and pelvis were ordered with intravenous contrast and no oral contrast. The patient was prepped for oral contrast and the test completed. Requisition did not state, "no oral contrast."*

Event reports submitted to the Authority in 2009 also revealed that physician offices often lacked established protocols for verifying clinical information before scheduling a patient for a radiologic study or procedure. These inadequate protocols led to one of the four wrong events, usually because of one of the following factors:

— The physician did not confirm orders before a staff member scheduled a procedure.

— Two forms of patient identification were not used by the ordering staff member for the receiving radiology staff to verify.

— An incorrect radiologic study or site of study was ordered by the physician and accuracy of the study was not verified, requiring additional scanning of the correct site or performance of the correct study.

Events originating from the physician office include the following:

> *A test order was received for dobutamine nuclear cardiac scan. The scan was started, and when the patient was able to exercise, [staff] called [physician's] office. The physician's office stated that they realized they had ordered the incorrect study.*
>
> *A script was checked for "bone whole body" but the physician's office wanted an ankle brachial index instead. The script was incorrectly marked.*
>
> *A patient arrived for a scheduled MRI of the cervical spine. The physician's order was for the thoracic spine. MRI of thoracic spine was completed. The physician's office notified MRI when they received results of incorrect test. Test was scheduled correctly, but physician's order was incorrect.*


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One of the most common studies inaccurately ordered or scheduled from the physician's office was mammograms. A total of 98 near-miss events (i.e., a medical event that could have harmed a patient, but harm did not occur as a result of chance, prevention, or mitigation) were reported pertaining to the improper order, 59 (60%), or scheduling, 39 (40%), of mammogram services. Physicians ordered a screening rather than a diagnostic mammogram in 43 (73%) events, a diagnostic mammogram was ordered instead of a screening in 10 (17%) events, and in 6 (10%) events, which study had been improperly ordered was not specified.

In other instances, physician orders were accurate, but scheduling errors occurred: 16 (41%) were scheduled as screening mammograms instead of diagnostic, 1 (3%) was scheduled as a diagnostic instead of a screening study, and in 22 (56%) events, the type of study (screening or diagnostic) that was erroneously scheduled was not specified. All the reports indicated that the proper mammogram study was ultimately performed because staff recognized the need to suggest the more appropriate study.

## Failure to Confirm Patient Identity

Patient misidentification accounted for about 30% of the radiology events reported to the Authority in 2009, as noted in the Table. Joint Commission's first National Patient Safety Goal (NPSG), "Improve the accuracy of patient identification," was established to eliminate the errors caused when a procedure or treatment is performed on the wrong patient. NPSG 01.01.01, "Use at least two identifiers when providing care, treatment and services," has been in effect since January 2003 and is applicable to all three Joint Commission accreditation programs (hospital, ambulatory health care, and office-based surgery).[3] The events reported to the Authority consistently noted that technologists failed to use two forms of distinct patient identification (e.g., rather than using a patient's name and date of birth, for example, patients were identified using room numbers, or procedure or radiologic studies). Other identification mistakes resulted when radiology staff selected the wrong patient from a hospital room because the patient misunderstood the name called, patients were not actively engaged in the identification process, or the patient for whom a study was intended had been transferred to another unit, and the new patient occupying the bed was taken for the radiologic study instead. Similarly, orders may not have been canceled for a patient before transfer to another location, and the technologist assumed the new patient occupying the same bed was the former patient. Requiring patients to actively respond to questions (i.e., "What is your name?") rather than passively confirming the patient's information (i.e., "Are you Jane Doe?"), and accepting a "yes" or "no" answer or a head nod, invites opportunities for misidentification errors. As specified by the Joint Commission's NPSG, the patient's room number or physical location should never to be used as an identifier because a patient's location may change during his or her stay.[4] Patient misidentification errors commonly delayed the prescribed procedure for the correct patient or allowed an unnecessary procedure to be conducted on a patient.

Additional factors that contributed to patients receiving inappropriate radiographic studies from failed misidentification processes were transporting the wrong patient to radiology with the right patient chart, performing a radiographic study using the wrong patient name, selecting the wrong patient from the work list, misinterpreting the patient's name or confusing patients having similar-sounding names, placing an order on the wrong patient chart, canceling a request on the wrong patient, and mistaking a family member who had previous studies performed at the same location for the patient. In the events in which a patient had a radiologic study performed under another patient's name and information, radiologists subsequently interpreted studies for the wrong patient. Interception of the error was usually made by the radiologist when comparing the new study to previous films, after reviewing records, or after noting the patient's birthdate. The following events are examples of failed identification processes:

> *Patient came into the hospital to have an ultrasound done. A [radiology] staff member went out to the waiting room to get an outpatient for a chest x-ray and called for "Mary." Mary got up and followed her to the x-ray department where the staff member did a two-view chest x-ray. The staff member did not verify the patient's last name or date of birth. It was the wrong Mary.*

> *Transport called to bring patient A to radiology. Transport brought patient B with patient A's medical record. Technologist verified the name on medical record and asked patient if her name was patient A. Patient responded "yes." The exam was performed. Nurse then called and informed technologist that the wrong patient was transported to the [radiology] department.*

> *Patient was inadvertently scanned in error. Radiology requested this patient in the central transport tracking system not realizing there were two patients with the same name. This patient was brought to the scanner by transport and verified that he was this patient (by name only). The second identifier (date of birth) was not checked. A short time later, it was discovered that the wrong patient had been scanned.*


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### Failure to Follow Site and Procedure Verification or Procedure Qualification Processes

Issues of side or site discrepancy—usually as a result of inadequate verification—made up about 20% of the four wrong radiology events. Performance of radiologic studies were often met with such challenges of laterality, including performing of bilateral studies when only one side was ordered and vice versa, misidentification of the correct body part, and radiographing of additional body parts when not ordered (e.g., cervical and thoracic spine imaged when only cervical ordered). Radiographic errors commonly occurred as a result of misinterpreting the order or prescription (e.g., MRI instead of CT scan), administering contrast when no contrast was ordered or, conversely, not administering contrast when it had been ordered, scanning of a particular body part when another had been ordered, misreading an order or the technologist's failure to verify an order, duplicating procedures because previous test completion was not realized by a technologist, and mislabeling images. Site misidentification instances were noted to occur when (1) technologists were distracted during the procedure, (2) technologists relied on the direction and symptomatology of the patient when an order was not available or when the order or physician's prescription referenced an alternate side or site, and (3) student technologists were indirectly supervised.

> *Staff printed report and noted additional [breast] views needed so the additional [studies] were performed. When staff came out to take the images to the radiologist, [it was] discovered that she had read the wrong report from the printer. This patient needed only to have imaging on the left breast. Staff did two images of the right breast as well as the left. The physician was made aware.*

> *A patient arrived for an upper external arterial ultrasound exam. The technologist identified the patient and began asking the patient about her leg symptoms. The patient described symptoms of the lower extremities, which seemed appropriate for the exam. The technologist was interrupted by phone calls and, distracted, performed a lower extremity exam without first verifying the physician's order. The error was discovered after the end of the exam and the patient was rescheduled.*

> *A patient arrived with physician order for an abdominal x-ray to view the kidneys, ureters, and bladder (KUB) with other modifiers on the form, "left ulcer lower extremity rule out osteomyelitis." When the patient was questioned, he insisted on a history of abdominal pain and the need for KUB. A KUB was done. After the incident, the supervisor was notified. The doctor's office was called to clarify order. Left leg [radiograph] was needed, not a KUB. The patient was called to return for the correct films.*

A review of the event reports found that four (1.2%) of the wrong procedures were performed when an order was misinterpreted because handwritten chart notes, orders, or prescriptions were illegible.

> *A patient registered with a bilateral rib order; [staff] misunderstood the script [because] writing was sloppy. [The technologist] did the x-ray and then realized that the script really said "just right side" after a bilateral study was completed.*

> *A patient came over to the radiology department with an order for a cervical spine x-ray. After completion, the ED called over and said that a lumbar spine was supposed to be done instead. The order was not written clearly and was mistaken for a cervical spine x-ray.*

Patients were also subjected to unnecessary or inappropriate radiology studies as a result of inadequate screening before an imaging study. Failed screening for MRI, pregnancy, and renal function often jeopardized patient safety. Patient recollections of shunts, implants, and other forms of metal (e.g., stents, surgical clips, bullet shards) or current use of a medication that may be contraindicated for the procedure (e.g., metformin) were often inaccurate. In addition, patients were given the wrong type of contrast or contrast was given before laboratory results were checked for renal function. Additional information on failed screenings may be accessed and reviewed in the following *Advisory* issues: MRI (March 2009), pregnancy (March 2008), and renal function (March 2007).

> *A patient was ordered an obstruction series. The patient was taken to the radiology department where she was asked if she was pregnant, and she responded with a "no." Staff person was not aware that a serum pregnancy test had been ordered. X-ray series was completed when the positive pregnancy test results were received.*

> *An elderly patient with right lower quadrant pain [was in radiology] for a CT scan of the abdomen and pelvis. Technologist injected iodine contrast into patient who had a creatinine [level] of 2.4. After the patient [was questioned] for consent for intravenous [access], he stated he was not diabetic and had no history of kidney dysfunction or disease. [Previous] labs were normal. Technologist did not check for current lab results until after the test was done.*

## THE ROLE OF COMMUNICATION IN PREVENTING WRONG EVENTS

In a study that reviewed a prospective database of physician self-reported occurrences, Colorado researchers found that


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wrong-site and wrong-patient surgical and procedure errors continue to occur despite implementation of protocols intended to prevent them (i.e., Joint Commission Universal Protocol) and all wrong-patient cases involved errors in communication.[5] Based on their findings during the January 2002 to June 2008 study period, the authors concluded that "non-surgical disciplines equally contribute to patient injuries related to wrong-site procedures" and suggested that the protocol be expanded to nonsurgical specialties.

Poor communication is responsible for many preventable medical errors.[6] Communication failures that contribute to discontinuity of care stem from a variety of causes, ranging from a lack of interpersonal communication skills to barriers in the work environment to suboptimal use of computer networking tools.[7] The communication errors in the events reported to the Authority resulted from the following types of misinformation: transmission of incomplete or inaccurate information (e.g., the ordering physician requested the wrong procedure, procedures were scheduled without proper patient information), inadequate documentation (e.g., completed studies or canceled orders were not documented), and failure to effectively perform a preprocedure verification or time-out (e.g., proper forms of patient identification were not used and compared to other documents, the ordering or referring physician was not contacted to clarify unclear orders).

In radiology, inadequate communication may result in such patient consequences as anaphylactic shock when allergies to contrast media are overlooked, delay of critical treatments if radiographic studies are not performed at the correct location or the wrong physician is notified of patient results, and unnecessary radiation exposure when the wrong body part is examined or when the wrong patient is selected for a procedure.[8]

> *A patient was admitted complaining of abdominal pain. The physician ordered anterior/posterior CT scan views. Oral contrast was sent to the patient. The patient was preoperative; the surgeon was upset because now surgery is delayed due to contrast. The nurse and [unit] secretary did not inform [radiology] that the CT scan was ordered without contrast.*

Patients were susceptible to unnecessary radiation exposure not only because they or a body part was misidentified, but because failure to communicate changes or other relevant information permitted technologists to perform studies that had already been performed or had been canceled, as in the following event:

> *Order for abdominal ultrasound was in the "to do" box for the ultrasound technologist. The procedure was completed. Afterward, the technologist found a "cancel" order in the system when attempting to complete documentation. The technologist found the "cancel" order in the recycle bin.*

Communication programs can successfully improve the safety culture and performance in radiology. The role of the technologist is not only to gather, document, and transmit patient information; he or she must also verify procedures to be performed or those already completed by communicating with other personnel and the patient to ensure that the correct or intended procedure is received and the correct site is chosen. It may not be enough to simply provide tools (e.g., patient handoff forms), because despite tools designed to assist communication, practices could fail if the proper interactive communication skills are not used in conjunction with them, as in the following event:

> *Patient arrived in the ED and radiology with "hand-off" communication form verified by nurse and transportation for patient. The chart was verified by one technologist and the exam performed by another technologist. The patient was then returned to the floor with chart documentation completed. Radiology received a call indicating that the wrong patient had been transported to the department. Miscommunication between technologists occurred with patient verification.*

## USE OF THE UNIVERSAL PROTOCOL IN RADIOLOGY

The principles of the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ outlined by the Joint Commission[8] can be transferred to disciplines other than surgery to prevent unintended procedures and patient complications.[6] The Universal Protocol was created to ensure that patients were accurately identified and procedures correctly scheduled and performed. All healthcare institutions across all specialties—not just surgical disciplines—have been urged to adhere to the Universal Protocol as a standardized quality assurance tool.[5]

Implementation of consistent processes that promote safe and accurate verification in diagnostic radiology is especially important. Although laterality becomes an issue in a limited number of procedures in interventional radiology,[9] the four wrong events involving an invasive procedure may cause major complications resulting in hospital admission, unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death.[10] In addition to the Universal Protocol, the National Patient Safety Agency, in conjunction with the World Health Organization, implemented a surgical safety checklist especially for interventional radiology, which can be accessed at http://www.nrls.npsa.nhs.uk/resources/?entryid45=73612.[10]

Guidelines for use or adaptation of the Universal Protocol for invasive radiology


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procedures where determination of laterality is required include the following:

— Apply the protocol for proper patient identification.
— Mark the site and side of the proposed procedure.
— Perform a preprocedure time-out to verify the nature of the procedure once the patient is on the procedure or examination table.
— Use the time-out to ensure proper patient identification has been entered into the imaging equipment, to establish proper patient positioning, and to confirm correlation between the guidance system image and the patient's orientation.
— Involve all personnel assigned to the procedure in the time-out process.

## STRATEGIES THAT MITIGATE PREVENTABLE WRONG EVENTS

Mitigation of preventable errors in radiology requires the implementation of system safeguards that improve order and scheduling practices, patient identification, and procedure verification protocols. Consider the following strategies, which are based on a review of events submitted to the Authority and on the literature, when implementing fail-safe, risk reduction systems:

— Appoint strong leadership within the clinical radiology team to advocate the development and implementation of policies and procedures that ensure that the right patient and the right site undergo the right procedure before any intervention begins, and communicate the appointed leader to the radiology staff. Observing and enforcing compliance of procedures and patient identification policies is essential for these practices to be effective. Solicit feedback from those directly affected by the policy to determine if the policy is working as intended and if it provides staff with the necessary information to maintain compliance. (See a sample policy in the toolkit available from the Authority at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx.)
— Verify that both the requisition and the medical record order are consistent in the acute care setting. For outpatients, consider placing the physician's order on top of the requisition form so technologists can review both documents and compare them for consistency before performing any procedure. Review all available documentation, including the patient's history, reason for radiologic study, and previous medical imaging studies. Include a checklist with the radiology requisition to reduce risks of overradiation, delay in diagnosis and treatment, or incorrect treatment. (See the aforementioned Authority toolkit for a sample assessment tool.) Consider software programs that can "red flag" examinations that have been performed on the same patient within a given time frame.
— Empower staff to verify orders that are unclear, illegible, or inconsistent with patient expectations with the ordering physician before performing any study. If issues go unresolved, consult a radiologist to determine whether a patient should undergo a given procedure. Avoid assumptions by implementing verbal "read back" to reconfirm verbal orders and improve the effectiveness of communication when scheduling radiologic studies or procedures as defined by the Joint Commission: "Before taking action on a verbal order or verbal report of a test result, staff uses a record and 'read back' process to verify the information."[11] All members of the radiology team (i.e., radiologists, nursing staff, technologists, clerks, and referring physicians) are accountable for ensuring accuracy of documentation, verification, and transmission of patient and procedural information.
— Ensure that two unique patient identifiers are consistently obtained and verified by two independent technologists to accurately identify patients, as well as conform to the Joint Commission's NPSG 01.01.01. Acceptable identifiers may be the patient's name, birthdate, medical record number, or other patient-specific identifier (e.g., home telephone number).[4] Assess staff competency in sustaining error-free patient identification and compliance with policy.
— Provide technologists with the necessary training to perform radiologic studies correctly. Quality of radiation procedures is directly linked to the skill and competence of those that are entrusted to performing them.[12] The American Registry of Radiologic Technologists (ARRT) recognizes qualified individuals in medical imaging, interventional procedures, and radiation therapy.[13] Verify that technologists have been appropriately credentialed through ARRT and can provide evidence of completing the required continuing education program.
— Advise referring physicians and physician practices to actively acknowledge misidentified patient reports or unordered results received and notify radiologists so that they can accurately report the miscommunicated information to the proper referring physician.[14]
— Develop a campaign to promote patient awareness of identification protocols. The Authority's "Did You ID Me" materials (see aforementioned toolkit), for instance, not only encourages compliance with verification practices but also serves as a fail-safe mechanism for patients to ask staff about proper identification before the radiologic procedure.


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— Survey patients to determine whether staff followed implemented protocols and whether patients felt involved in the process. Questions addressing understanding of the procedure performed, patient identification practices, involvement in procedure verification, and ability to ask questions may serve to monitor communication efforts as well as provide staff with constructive feedback.

— Share adverse events and near misses with staff at departmental meetings to learn from and improve existing risk reduction mechanisms. (See a collection of event examples in the Authority toolkit.) Event examples can be used in staff training sessions to (1) identify potential failures in systems, (2) discuss the successes and barriers of implemented processes, and (3) ensure that the premise of safety is at the forefront for all staff.

## CONCLUSION

Implementation of quality and safety strategies poses a significant challenge for radiology services, yet provides opportunities for improvement. The four wrong events of wrong patient, wrong procedure, wrong side, and wrong site occur more frequently than healthcare providers and patients may realize, and it is unclear whether their consequences, including unnecessary exposure to radiation, delay in treatment, and other possible missed opportunities, affect or may later affect patient well-being.

Although the causes of errors in radiologic services may differ from those errors in surgical settings, they are all rooted in communication inadequacies and lack of effective safety systems. Prevention of radiology-related iatrogenic injuries requires the development of safety strategies and initiatives aimed at improving order or scheduling practices, patient identification, and procedure verification protocols before any radiologic study or invasive procedure. Such initiatives, however, are effective only if they are followed by all who come in contact with patients.

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# Prevent the Occurrence of Bloodborne Disease Transmission Associated with Unsafe Injection Practices


## ABSTRACT

*Lapses in basic safe injection practices and infection control expose patients to needless risk of transmission of bloodborne pathogens. The Centers for Disease Control and Prevention and U.S. public health officials identified 51 reports of outbreaks of hepatitis B virus and hepatitis C virus infection primarily associated with unsafe injection practices in patients in the United States from 1998 through 2009. Of the 75,000 patients who were placed at risk, 620 became infected or died as a result of exposure. Events of unsafe syringe reuse reported to the Pennsylvania Patient Safety Authority from 2004 through 2010 were associated with delivery of injectable medications during surgery, vaccinations, and bedside care. This article describes approaches to integrate safe injection strategies into clinical practice and explains the key components of an infection prevention program, including dispelling the misperceptions associated with unsafe injection practices, increasing the awareness of safe injection practices, and oversight of compliance with safe injection practices. (Pa Patient Saf Advis 2011 Jun;8[2]:70-6.)*


## INTRODUCTION

Outbreaks of hepatitis B virus (HBV) and hepatitis C virus (HCV) infection in patients across the nation have been associated with unsafe injection practices. Lapses in basic infection control expose patients to needless risk of transmission of bloodborne pathogens.[1] The Centers for Disease Control and Prevention (CDC) and U.S. public health officials identified 51 outbreaks of HBV and HCV infection from July 1998 through June 2009. More than 75,000 patients were notified of potential exposure and at least 620 patients became infected or died with HBV or HCV as a result of exposure. The outbreaks were identified in a variety of healthcare settings, including hospitals, long-term care facilities, outpatient clinics and ambulatory surgical facilities, and hemodialysis facilities.[2,3]

These numbers may represent only a fraction of actual cases. Many outbreaks and sporadic transmissions go unrecognized.[4] Identifying epidemiological links to a common healthcare provider or facility is complicated by an incubation period of up to six months, during which a patient may have multiple healthcare encounters,[2] and by the high proportion of patients with new HBV or HCV infections who are asymptomatic or have mild nonspecific symptoms.[4]

Investigations of the healthcare-acquired outbreaks by CDC and state and local health departments have resulted in malpractice suits filed by patients, referral of providers to licensing boards for disciplinary actions, and the revocation of medical and nursing licenses.[4]

Strategies that can be applied to reverse the frequency and magnitude of the transmission of bloodborne pathogens caused by unsafe injection practices include (1) dispelling misperceptions surrounding unsafe injection practices, (2) increasing the awareness of safe injection practices, and (3) oversight of compliance with safe injection practices.[1]

Unsafe injection practices reported to the Pennsylvania Patient Safety Authority include the following:

> *IV propofol was injected into the IV tubing of two patients using the same syringe with the rationale that the probability of communicable disease is extremely low due to the IV port location high away from the IV site. No backflow of fluid was visible and the IV was free flowing.*
>
> *During a procedure, a patient received intravenous propofol from a syringe that had been used on the previous patient. Infectious disease [department] was consulted and recommended this patient and source patient be tested for HIV and hepatitis B and C.*
>
> *A staff person who was administering the vaccine accidentally stuck his own thumb. The patient was then administered the vaccine with the same needle.*
>
> *A patient reported that the nurse used the same syringe from another patient's IV line, drew fluid from his IV bag, and then reused the syringe to flush the other patient's IV.*
>
> *In a patient being intubated, the physician injected more fentanyl into the pulmonary artery catheter using the same syringe that had not been capped and without cleaning the infusion port.*
>
> *During administration of influenza vaccinations, the injection was given and the needle recapped. A second volunteer picked up the same syringe and vaccinated a second person.*


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## DISPELLING THE MISPERCEPTIONS SURROUNDING SAFE INJECTION PRACTICES

Misperceptions surrounding safe injection practices have been associated with a wide variety of procedures, including delivery of intravenous (IV), intramuscular (IM), and intradermal medications, and flushing IV lines or catheters. The delivery of anesthesia was a common factor in approximately half of the identified outbreaks. During outbreak investigation, the following breaches by healthcare personnel were identified in several categories of well-established fundamental principles of infection control:[1,2]

— Unsafe syringe reuse
— Contamination of shared medication by reused syringes
— Contamination of medical equipment, supplies, and the environment

### Unsafe Syringe and Overt Needle Reuse

The dangerous practice of syringe reuse may be related to the misperception that contamination is limited to the needle device when a syringe and needle are reused. Contamination actually extends not just to the needle but also to the syringe when injections are administered by any route.[4] (See Figure.) Prevention of unsafe syringe reuse includes the following rationale:

**Never use the same syringe on more than one patient, even if the needle is changed.** A syringe may become contaminated because the negative pressure generated when the needle is removed may cause aspiration into the syringe of a small amount of blood remaining in the needle, even if blood is not visible.[5] Sterile injection devices, such as syringes, are single-use patient items.[6]

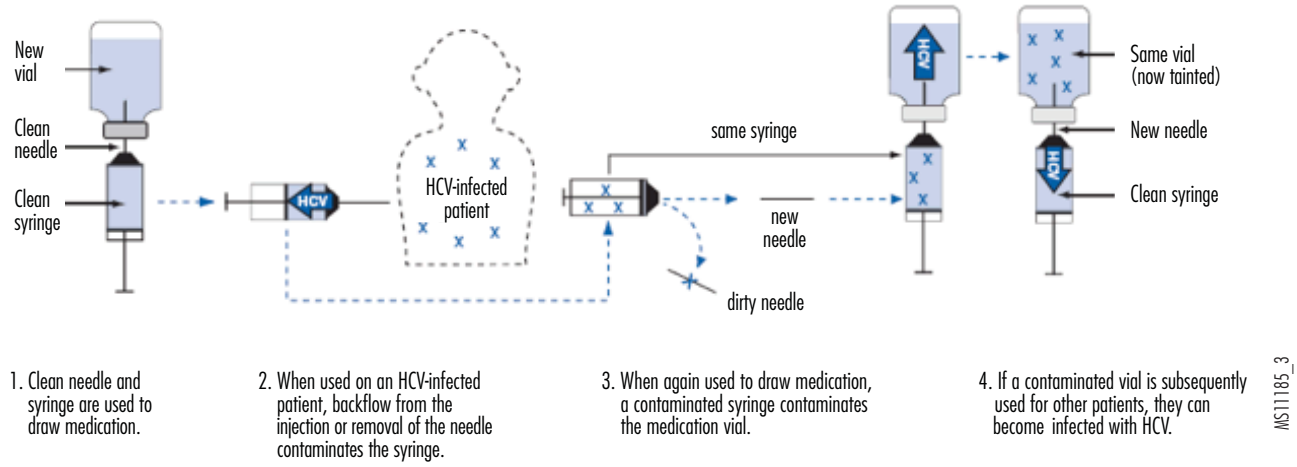
**Never use the same syringe to inject more than one patient, even if the user only pushes the syringe plunger and does not draw back before injecting.** A common misconception is that the syringe does not become contaminated if the plunger is only pushed to inject medications and not pulled to aspirate or withdraw.[1] Even when only positive pressure is applied, a microscopic amount of blood containing viral particles can flow back into the needle and syringe in sufficient quantities to infect subsequent patients, without visible evidence of contamination.[7]

**Never use the same syringe used to draw blood or infuse meds into an IV port, including from the fluid path port that is several feet away from the IV site.** The risk for syringe contamination is not eliminated by the intervening lengths of IV tubing or the presence of heparin locks or check valves.[5,7] Separation from the patient's IV by distance, gravity, or positive infusion pressure does not ensure that small amounts of blood are not present.[7]

The following steps can minimize the risk of reuse of contaminated injection equipment:[8,9]

— Remove packaging immediately before use, and prepare syringes as close to administration time as possible.
— Activate a sharps safety device as soon as a procedure is completed; this isolates the needle so that it never poses a hazard.
— Discard lancets, syringes, and needles into a designated sharps container immediately after use.

Figure. Unsafe Injection Practices and Disease Transmission




**Source:** Centers for Disease Control and Prevention. Acute hepatitis C virus infections attributed to unsafe injection practices at an endoscopy clinic—Nevada 2007. MMWR 2008 May 16 [cited 2011 Feb 28]. Available from Internet: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5719a2.htm.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— Use sharps safety devices whenever possible (e.g., single-use auto disabling lancets, syringes).

## Contamination of Shared Medication by Reused Syringes

Restricting vials to single patient use provides an extra layer of safety to prevent patient-to-patient bloodborne pathogen transmission via contamination of medication vials. Residual content of the vial can be intentionally or unintentionally used on additional patients. The reuse of a needle or syringe to withdraw medication from a vial, IV flush, or medication diluent can transfer contaminants to the vial or fluid and has repeatedly been shown to result in transmission of HBV and HCV[4] (see Figure).

The practice of reusing a syringe for additional doses from a medication vial even for the same patient is considered unsafe as breaches in aseptic technique between doses can result in contamination of the vial. This can occur through unrecognized contact between the syringe and the patient's skin, syringe or needle contact with contaminated IV tubing or heparin lock, or putting the syringe down on a contaminated surface between doses.[1] The rationale for the adoption of practices to prevent contamination of shared medications includes the following precautions:

**Never access a medication vial with a syringe or a needle that has already been used to administer medication to another patient.** Even when the needle is changed and the vial is swabbed with alcohol, reusing a syringe to draw up additional medication can contaminate the vial or bag containing the medication or solution and expose subsequent patients if the bag or vial is reused.[7]

**Never reuse medications packaged as a single dose vial on more than one patient.** Reuse of a vial should be limited to single patients as an extra barrier against unrecognized contaminated syringe reuse or other means of vial contamination. For example, outbreaks linked to multipatient use of single-dose vials of propofol have been reported.[1]

**Never use a common bag of IV solution as a source of a flush or medication diluent for more than one patient.** Accessing an IV bag or medication diluent with a syringe that has already been used to flush a patient's IV or draw blood from a central line increases the number of patients who can be exposed from a single contaminant. Bloodborne pathogens can be present in sufficient quantities to produce infection in the absence of visible blood, without clouding or other visible evidence of contamination.[7]

**Never pool leftover contents from multiple vials to obtain a sufficient dose.** This practice increases the risk of serial contamination of additional vials.[4,6] Many single-dose vials do not have a bacteriostatic or preservative agent; once contaminated, the opportunities for bacterial growth increase relative to elapsed time between uses.[1] Bacteriostatic agents used in multidose vials are not effective against hepatitis and other viruses.

**Never leave a needle, cannula, or spike device inserted into a medication vial rubber stopper (even if the stopper has a one-way valve).** Vial contamination occurs when environmental microorganisms collect on the spiking device or needle. Sterile solutions are then contaminated when poured through or withdrawn from the spout or stopper.[8]

Strategies to reduce the risk of contamination of vials or diluents include the following:[1,8]

— Purchase single-dose medication and flush vials whenever possible. If multidose vials must be used, dedicate them to a single patient using a new, sterile needle and syringe for every access.

— Ensure ports and stoppers are disinfected using friction and a sterile 79% isopropyl alcohol. Alcohol must be allowed to dry before each access to ensure proper contact time.

— Never store or transport syringes or vials in a clinician's pocket.

## Contamination of Medical Equipment, Supplies, and the Environment

Investigations of HBV infection outbreaks resulting in several deaths in long-term care facilities found lack of adherence to standard precautions, such as failure to implement long-standing recommendations against sharing finger stick devices and sub-optimal hand hygiene and glove use.[10] Outbreaks have occurred from contamination of multidose vials and because supplies used to prepare IV medications for multiple patients were stored in a contaminated workspace.[2] Preventing contamination of equipment, supplies, and the environment includes the following strategies:

**Never use equipment designed for single-person use (e.g., reusable finger stick devices, insulin pens, lancets) on more than one patient.** Microscopic amounts of blood in the cartridge may contain infectious viral particles that can inoculate bloodborne pathogens into a patient's finger stickwound.[11] HBV and HBC have been shown to remain infectious in the environment in dried blood for up to a week and 16 hours, respectively; either virus may be present in the absence of visible blood in sufficient quantities to cause infection.[12,13] In 2009, the U.S. Food and Drug Administration issued an alert to remind healthcare providers and patients that insulin pens are designed for single-patient use and should be identified with the name of the patient. Healthcare facilities should review their policies and educate their staff regarding safe use of insulin pens.[14] As with syringes, lancets must never be reused.

Never reuse blood glucose monitors for more than one patient without cleaning and disinfecting the device, washing hands, and changing gloves. There is evidence of risk of patient exposure via indirect transfer of virus from microscopic amounts of blood on a clinician's hands or gloves after contact with a contaminated monitoring device.[11] The practice of using blood sugar measuring devices


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such as glucometers without cleaning and disinfecting between every use creates an immediate jeopardy to patient health by potentially exposing patients and nursing home residents to the spread of blood-borne infections.[15] Clean and disinfect glucose monitoring equipment between uses and routinely between patients. Cleaning must precede disinfection, as some disinfectants are ineffective in the presence of soil.[16] In the absence of manufacturer's recommendations, noncritical medical equipment is disinfected with an Environmental Protection Agency registered hospital solution with specific label claims for HBV and HBC. Follow the recommended solution contact time for maximum effectiveness against blood-borne and other pathogens.[17]

**Never prepare injectable medications in a contaminated workspace (e.g., where needles and syringes are dismantled and discarded).** Any item that could have come in contact with blood or body fluids should not be in the clean medication prep area.[4] Medication preparation should be restricted to a centralized medication area, a clear demarcation of clean and dirty areas in confined workspaces, and never in the patient treatment or procedure area, especially in hemodialysis centers.[2,4]

## INCREASING THE AWARENESS OF SAFE INJECTION PRACTICES

A safe injection is one that does not harm the recipient, does not expose the provider to any avoidable risks, and does not result in waste that is dangerous for the community.[7] Improved education of healthcare professionals in nursing, medical, and vocational schools is urgently needed to ensure appropriate investment in basic infection requirements and to address incorrect beliefs about safe injection practices.[4] Outbreaks identified by CDC and U.S. public health services indicate a lack of awareness and understanding of injection safety and application of basic aseptic techniques.[2] Reinforcement of training includes periodic certification or competency requirements for all clinicians in healthcare facilities.[4] Perz et al. described the following learning objectives to support the development of an injection safety curriculum:[7]

- Recognize the basics of indirect contact transmission of infectious agents.
- Detect and correct unsafe practices.
- Describe safe injection and basic aseptic practices including hand hygiene, glove changing, and avoidance of cross contamination.
- Understand the need for monitoring practices related to injection safety and basic infection control.
- Recognize the potential consequences of syringe reuse and other unsafe practices.
- Identify CDC infection control guidelines and educational materials.

Educational materials, such as the CDC poster "Some Things Should Not Be Reused," can be placed in patient waiting areas and staff lounges to increase awareness of safe injection practices for patients and staff.[18] CDC through its "The One & Only Campaign" website and other organizations provide a variety of resources to assist in education, training, competency evaluations, and monitoring (see "Where Can Providers Go for More Information?").

## OVERSIGHT OF COMPLIANCE WITH SAFE INJECTION PRACTICES

A comprehensive approach to management of unsafe injection practices should be aimed at assessment of the clinician, the team, the workplace, and the institution as a whole to make the process as safe as possible.[19]

Even when new knowledge is discovered and adequate research is available, there are many barriers to implementing research into practice.[1] Gurses et al. published a template that helps healthcare facilities identify barriers to implementation of safe practices, including methods for direct observation, staff interviews, short questionnaires, and practice simulations.[20] A prospective review of an organization's safe injection practices can be assessed with the World Health Organization Guide for Supervising Injections worksheet available at http://infocooperation.org/hss/documents/s15240e/s15240e.pdf. Senior management support for safety programs, frequent safety-related feedback, and removal of workplace barriers to safe work practices have been shown to be significantly related to compliance.[21] Administrative measures to assure compliance with safe injection practices may include the following:[7]

- Develop written infection control policies and measures tailored to the individual practice setting.
- Provide infection control training and at least an annual review of staff practices.
- Clearly designate responsibility for oversight and monitoring; include infection control personnel.
- Establish procedures and responsibilities for reporting and investigating breaches in infection control policy.
- Conduct quality assurance assessments.

Administrators can take the lead by sending a letter to clinicians that supports and describes the facility's safe injection policy and practice expectations[22] and by ensuring establishment of processes to address containing, transporting, and handling patient care equipment that may be contaminated with blood.[6]

Safe injection system design can be achieved by adopting a culture of safety and system reform to provide clinicians with both the reminders and the tools to address human variability factors.[19] This entails creating an environment in which every provider feels empowered to take responsibility to stop any colleague from engaging in unsafe practices.[1] While healthcare workers may witness


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## WHERE CAN PROVIDERS GO FOR MORE INFORMATION?

**ASC Quality Collaboration**
Safe Injection Practices Toolkit
http://www.ascquality.org/SafeInjectionPracticesToolkit.cfm

**American Society of Consultant Pharmacists (ASCP)**
ASCP Summary of New Surveyor Guidance on Infection Control at F-Tag 441
http://www.ascp.com/resources/nhsurvey/upload/FTag%20441%20summary.pdf

ASCP's Summary of Glucometer Cleaning Guidelines
http://www.ascp.com/sites/default/files/GlucometerInfectionControl-rev.pdf

**Association for Professionals in Infection Control and Epidemiology (APIC)**
APIC Position Paper: Safe Injection, Infusion and Medication Vial Practices in Healthcare
http://www.ascquality.org/Library/safeinjectionpracticestoolkit/Safe%20Injection%20Infusion%20and%20Medication%20Vial%20Practices%20in%20Healthcare%20(APIC).pdf

**Centers for Disease Control and Prevention**
2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/isolation2007.pdf

The One & Only Campaign
http://www.cdc.gov/injectionsafety/1anOnly.html

**Georgia Association of Nurse Anesthetists**
Safe Practices for Needle and Syringe Use [discussion of American Association of Nurse Anesthetists' position statement]
http://www.gana.org/documents/1241559948.pdf

**World Health Organization (WHO)**
WHO Best Practices for Injections and Related Procedures Toolkit
http://whqlibdoc.who.int/publications/2010/9789241599252_eng.pdf

unsafe actions, they often are not comfortable speaking up for patient safety. Examples of employee talking points for safe injection practices are described in a CDC video transcript available at http://www.oneandonlycampaign.org/Post/sections/36/Files/SIPC%20-%20FINAL%20VIDEO%20SCRIPT.pdf.

Adopting principles from human factors engineering includes redesigning devices, equipment, and processes to reduce or eliminate the risk of bloodborne pathogen transmission (e.g., using autodestruct syringes that make it easy for staff to comply with using a syringe and needle only once).[1]

## CONCLUSION

CDC and U.S. public health officials have identified 51 outbreaks of HBV and HCV infection in the United States associated with unsafe injection practices, and 620 of 75,000 exposed patients became infected or died with HBV or HCV from 1998 through 2009. Preventing the spread of bloodborne pathogens represents a basic expectation anywhere healthcare is provided. Healthcare providers' awareness, understanding, and implementation of well-established safe injection practices remain suboptimal. The occurrence of outbreaks indicates an urgent need for a multifaceted approach focusing on improved education, surveillance, oversight, enforcement, and safely engineered technologies aimed at ensuring safe injection practices at all levels of healthcare delivery.[1]

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## LEARNING OBJECTIVES

— Distinguish between safe and unsafe injection practices.

— Recognize misperceptions associated with unsafe injection practices.

— Predict consequences of unsafe injection practices.

— Identify appropriate approaches to integrate safe injection strategies into clinical practice.

## SELF-ASSESSMENT QUESTIONS

The following questions about this article may be useful for internal education and assessment. You may use the following examples or develop your own questions.

**Case Scenario**

*While making rounds, the facility patient safety officer notices the following practices. Patient A was administered his daily dose of insulin using a reusable insulin pen. Then, the needle was changed and Patient B was administered his morning dose of insulin. Using a new syringe, intravenous (IV) flush solution was withdrawn from a common bag of IV solution to flush two patients' IV lines and administer IV medication. A second sterile syringe was used to draw a blood specimen on Patient C.*

1. The following list includes infection control actions from the above scenario that are and are not associated with unsafe injection practices. Select the action that is not associated with unsafe injection practices.
   a. Changing the needle on a used syringe or device before injecting medication into more than one person
   b. Accessing a common bag of sterile intravenous solution to flush IV lines of multiple persons


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## SELF-ASSESSMENT QUESTIONS (CONTINUED)

c. Wiping the glucometer with a disinfectant between using it to test blood sugar levels on multiple patients
d. Preparing intravenous medication in the dialysis patient treatment area

2. Which statement *least accurately* describes the misperceptions associated with unsafe injection practices?
   a. The risk for syringe contamination in an IV line is eliminated by distance, gravity, and positive infusion pressure.
   b. Reusing a syringe for additional doses of medication for the same patient is safe.
   c. Secondary use of a syringe is safe because contamination is limited to the needle device.
   d. Preparation of injectable medications is appropriate in a confined workspace with a clear demarcation of clean and dirty areas.

**Continued Scenario**

*In preparation for a surgical intervention on Patient A, the certified registered nurse anesthetist combined the contents of a used bottle of propofol from an earlier case with another partially used vial stored in his lab coat pocket, then administered propofol from that vial using a clean needle attached to the syringe from the previous case. The certified registered nurse anesthetist flushed the IV and used a new syringe and needle to draw a blood specimen. A new syringe and needle were inserted into the vial of propofol, and this was placed on the anesthesia table in preparation for the next case. During an investigation of an outbreak of hepatitis, both patients were subsequently diagnosed with new hepatitis C infections.*

3. The following practices are evident in the above scenario. Select the process that will not contribute to contamination of injection equipment and medication vials.
   a. Administering propofol from the contents of a combined vial stored in a lab coat pocket
   b. Using a second syringe to draw a blood specimen after flushing an IV line
   c. Accessing a vial of medication with a clean needle using a syringe from a previous case
   d. Inserting a fresh needle and syringe into a medication vial and storing this on the anesthesia table for the next case
4. Which of the following system-level interventions would *not* be appropriate to prevent unsafe injection practices?
   a. Develop protocol to change needles on all syringes used for multiple patients.
   b. Unpackage syringes as close to administration time as possible.
   c. Purchase single dose medication and flush vials whenever possible.
   d. Label individual insulin pen devices for each patient using them.
5. Which of the following strategies is the *most appropriate* regarding awareness and oversight of safe injection practices?
   a. Empower patients to speak up about unsafe injection practice for patients.
   b. Write a policy outlining safe injection practice requirements.
   c. Require periodic injection practice education, competence assessment, and monitoring for all clinicians in healthcare facilities.
   d. Present a business plan to the chief executive officer supporting the facility's safe injection policy.


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# Data Snapshot: Errors Involving Methotrexate

## DRUG INFORMATION FOR METHOTREXATE

**Oncology uses:** A variety of leukemias, lymphomas, and other types of cancers.

**Non-oncology uses:** A variety of immune disorders, including psoriasis, severe rheumatoid arthritis, lupus, and multiple sclerosis; Crohn's disease; ectopic pregnancy; inflammatory myositis; myasthenia gravis; Takayasu arteritis; and asthma.

**Elimination half-life:** 3 to 10 hours at low doses; 8 to 15 hours at high doses.

**Absorption, oral:** Dose dependent. The drug is well absorbed at low doses, but after higher doses, absorption is incomplete.

**Distribution:** Occurs slowly. The drug is retained in the liver and kidney at sustained concentrations.

**Toxicity:** Renal failure, hepatotoxicity, immunosuppression, myelosuppression, mucositis.

### Sources

Lexi-Comp Online. Methotrexate [online]. 2010 [cited 2010 Aug 24]. Available from Internet: http://online.lexi.com/crlsql/servlet/crlonline.

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Methotrexate is a folate antimetabolite used in oncology for a variety of leukemias, lymphomas, and other types of cancers.[1,2] Since the drug's introduction, its labeled indications have expanded to include non-oncology uses. It is now used to treat a variety of immune disorders, including psoriasis, severe rheumatoid arthritis, lupus, and multiple sclerosis. Other uses include treatment of Crohn's disease, ectopic pregnancy, inflammatory myositis, myasthenia gravis, Takayasu arteritis, and asthma.

For oncology uses, normal doses of methotrexate are based on body surface area and vary depending on the specific type of cancer being treated.[1,2] The drug is typically given one or two days per chemotherapy cycle (i.e., seven days apart, or days one and eight) every three to four weeks. For non-oncology uses, a low dose is administered once or twice weekly; it is uncommon for a drug to be dosed in this way, and this dosing may lead to confusion, as a once-daily dosing regimen is most familiar to both patients and clinicians. Inadvertently high dosing of methotrexate, such as daily dosing when weekly dosing is intended, can result in toxicity affecting multiple organ systems, which can quickly lead to death. Large cumulative doses and prolonged exposure has been associated with acute and chronic hepatotoxicity as well as myelosuppression. Patients receiving large doses of methotrexate may also present with pulmonary symptoms, mouth sores, stomatitis, or skin lesions.[1,3-5] (For more specifics about methotrexate, see "Drug Information for Methotrexate.")

The literature contains a number of articles that describe errors involving methotrexate.[5-7] For example, Moore et al. analyzed all of the adverse-event reports submitted to the U.S. Food and Drug Administration's Adverse Event Reporting System between November 1997 and December 2001 that indicated potential medication errors involving methotrexate.[6] They identified 106 medication errors associated with methotrexate. Roughly 24% of the errors (25 of 106) resulted in patient death, while another 45% (48 of 106) resulted in serious adverse effects. The authors found that the most common types of errors were confusion about the once-weekly dosing of methotrexate and other dosage errors. The Institute for Safe Medication Practices issued a special alert in 2002 warning practitioners about the risk of inadvertent administration of methotrexate daily rather than weekly.[8] In one case, a 79-year-old patient died after the physician prescribed methotrexate 15 mg daily rather than weekly. The patient received nine doses before the error was discovered. More recently, as reported in the news, an 82-year-old woman suffered bleeding and eventually died after receiving methotrexate 12.5 mg daily instead of weekly.[9] During a hospitalization, the patient's dosing was incorrectly recorded as daily. Tragically, the mistake was not discovered when the patient was discharged to a specialty care facility, and she received a number of daily doses of methotrexate.

Pennsylvania facilities have reported events involving methotrexate to the Pennsylvania Patient Safety Authority. Ongoing individual case review and analysis indicated that dosing errors similar to those cited in the literature[5-8] have been occurring in Pennsylvania. Authority analysts reviewed all methotrexate-related reports submitted to the Authority to identify what is going wrong.

## DATA OVERVIEW

Analysts examined all medication error reports submitted to the Authority from June 2004 through July 2010 that included mention of methotrexate ($n = 253$) in the medication prescribed, medication administered, or event detail data fields. Review of the events found that 204 indicated that some type of error occurred involving methotrexate. (In the remaining 49 event reports, methotrexate was mentioned in the error


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description, but the drug was not used in error.)

Analysis of the events filtered by reported level of harm showed that nearly half the errors involving methotrexate (100 of 204) reached the patient. Roughly 3% of the reports (7 of 204) indicated that some level of patient harm, including death, occurred. Patients required either monitoring to confirm that no harm occurred or intervention to prevent harm in another 15% of the events (31 of 204).

Wrong-dose events were the most common type of events (64 of 204) (see Table 1). Of wrong-dose events, 65.6% (42 of 64) resulted in an overdosage. Of all methotrexate-related events, 20.6% (42 of 204) were wrong-dose/overdosage errors.

Table 1. Top Five Event Types Involving Methotrexate, June 2004 through July 2010 (*N* = 204)

| ERROR TYPE | NUMBER OF EVENTS |
|---|---|
| Wrong dose/overdosage | 42 (20.6%) |
| Wrong dose/underdosage | 22 (10.8%) |
| Wrong time | 21 (10.3%) |
| Dose omission | 21 (10.3%) |
| Wrong drug | 16 (7.8%) |

## MIX-UPS OF DAILY VERSUS WEEKLY DOSING

When looking just at reports of wrong-dose/overdosage events, analysts found that 59.5% (25 of 42) indicated that the patient was to receive methotrexate once or twice a week but was ordered and/or administered the drug daily. This finding prompted a review of all methotrexate-related reports for occurrences of mix-ups between weekly and daily dosing. Analysis of the narratives of all event types uncovered 8 additional reports, for a total of 33 reports that described situations in which an inappropriately high dose was ordered or administered because of a mix-up between daily and weekly dosing schedules. These 33 reports account for 16.2% of all methotrexate-related events. Further analysis of these 33 reports found that 11 patients received at least one erroneous dose before the error was detected, while 20 patients had not received the drug. For the two remaining reports, analysts were unable to verify that the patient received a dose because there was insufficient detail included in the reports' event descriptions. However, based on the harm scores, it appears that the errors reached the patient. The harm scores associated with these 33 reports can be found in Table 2.

Analysts examined these 33 events to determine where in the medication-use process the event originated. Analysis revealed that 84.8% of the problems (28 of 33) began with the prescriber's order. Despite opportunities in the dispensing and administration phases of the medication-use process to intercept these errors, 42.9% of these prescribing errors reached the patient, with five events resulting in patient harm. Order-entry errors accounted for 9.1% of the mix-ups (3 of 33).

Selected events reported to the Authority include the following:

> *Patient has past medical history of rheumatoid arthritis. Patient taking methotrexate 10 mg po once weekly on Mondays and [this prescription was] correctly listed on medication reconciliation form. Physician writes order for methotrexate 5 mg po BID daily. Order transcribed on Kardex and entered by pharmacist as daily versus weekly. One erroneous dose of 5 mg of drug was given. Intercepted by pharmacy staff the next day.*

> *Patient admitted due to severe complications of rheumatoid arthritis. Prior to admission, patient was taking methotrexate 10 mg twice per week. On admission, physician wrote order for methotrexate twice per day and medication was administered for five days. Patient developed neutropenia and was transferred to ICU [intensive care unit]. Patient recovered completely without further sequelae, has no permanent harm, and was discharged to home.*

> *The physician wrote [an order] for methotrexate daily 10 mg. The pharmacist entered the dose and the patient received 5 days of the drug before the error was caught. The records from the facility where the patient came from showed that the patient was taking a total of 10 mg weekly. The patient experienced stomatitis, pancytopenia, and was transferred to the ICU.*

## CONCLUSION

Roughly 20% of reported events involving methotrexate were identified as wrong doses/overdosages. A total of 33 events (16.2% of all methotrexate-related events) were directly related to mix-ups in which the patient was to receive methotrexate once or twice a week but was ordered and/or administered the drug daily. The risk of this type of mix-up is likely higher for methotrexate than for most other drugs, as relatively few other medications are dosed once or twice a week. Nearly 85% of the daily-versus-weekly dosing events (28 of 33) began with the prescriber's order. Just over 15% of these events (5 of 33) resulted in patient harm, with two resulting in patient death.


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Table 2. Harm Scores* of All Events Identified as Involving Inadvertent Daily Dosing of Methotrexate Rather Than Once or Twice Weekly, Reported June 2004 through July 2010

| HARM SCORE | NUMBER OF EVENTS |
|---|---|
| **No Harm (*n* = 28)** | |
| A. Circumstances that could cause adverse events | 1 (3.0%) |
| B1. An event occurred, but it did not reach the individual because of chance alone | 1 (3.0%) |
| B2. An event occurred, but it did not reach the individual because of active recovery efforts by caregivers | 16 (48.5%) |
| C. An event occurred that reached the individual but did not cause harm and did not require increased monitoring | 6 (18.2%) |
| D. An event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm | 4 (12.1%) |
| **Harm (*n* = 5)** | |
| E. An event occurred that contributed to or resulted in temporary harm and required treatment or intervention | 1 (3.0%) |
| F. An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization | 1 (3.0%) |
| G. An event occurred that contributed to or resulted in permanent harm | 0 (0%) |
| H. An event occurred that resulted in a near-death event (e.g., patient required ICU [intensive care unit] care or other intervention necessary to sustain life) | 1 (3.0%) |
| I. An event occurred that contributed to or resulted in death | 2 (6.1%)) |
| **Total** | **33** |

* Adapted from: National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). NCC MERP index for categorizing medication errors [online]. 2001 [cited 2010 Sep 17]. Available from Internet: http://www.nccmerp.org/medErrorCatIndex.html.

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# Time-Out! Wrong-Site Surgery Update

## EVENT EXAMPLES

Edited versions of two recent reports show the importance of a properly conducted time-out:

*A patient was an add-on to the OR schedule for a RIGHT side procedure. The patient was brought to the OR; sign-in procedure was followed; time-out was started and the surgeon left the room. Staff completed the time-out without him, but when he returned to the room, they did a complete time-out all over again. Everyone agreed on the RIGHT side. The patient was not positioned in any manner that emphasized the laterality. The tech and the surgeon were talking but the circulator did not hear the conversation. The surgeon was viewing real-time images with the tech. The procedure was completed without event. The circulating nurse and CRNA [certified registered nurse anesthetist] took the patient to the recovery room. The surgeon was in the recovery room talking to the recovery room nurse about the case. The circulator overheard him say we did the LEFT side. She said you mean RIGHT side and he said no, LEFT. The nurse reminded him that he had signed off on RIGHT. The patient was rolled, confirming LEFT side was done. The nurse said she could not hear the discussion between the surgeon and tech. The tech did admit he knew that RIGHT was agreed upon but he did not alert anyone. … It appears initially that only the tech knew that the doctor was doing the LEFT side instead of the RIGHT. The tech did not make anyone else on the OR team aware of this but clearly documented LEFT side on the documentation form postprocedure.*

*The patient's incorrect leg was prepped and draped for surgery. The error was noticed during time-out, and no incision was made. The patient's leg was not marked in pre-op. The nurse did not check to ensure the leg was marked prior to taking to OR. During time-out, it was noted that incorrect leg was prepped and draped. The drapes were taken down. The patient's correct leg was prepped and draped. A new time-out was completed and all documents were rechecked.*

Wrong-site surgery continues to occur in Pennsylvania (see "Event Examples"). This update focuses on knowledge about doing a time-out effectively. It also addresses a query about the value of reviewing imaging studies in the operating room (OR).

Updated wrong-site surgery reports are shown in the Figure. In the most recent quarter, six (32%) were wrong-site anesthetic blocks. Wrong-site surgery events seem to follow a puzzling multiyear cycle. A yearly cycle could be explained by the seasonal variation in operating volumes or by the learning curve in academic medical centers. For a multiyear cycle, one can only speculate that events increase attention and lack of events diminishes attention—and that the memory of events and the attention to preventing another event lasts at least a year. If a multiyear cycle is real and the speculation proves valid, the implication is that prevention of wrong-site surgery requires continued attention to detail, not just system improvements, and that one must see continuous improvement for a minimum of two years to be sure the improvement is real.

## TIME-OUT

### Evidence-Based Best Practices

The Pennsylvania Patient Safety Authority has established, from prior studies, principles that should be followed during a time-out:[1]

**All noncritical activities should stop during the time-out.** In 31 observations of the time-out processes in 10 facilities that had wrong-site surgery and 4 facilities that had none, noncritical activities stopped in 9% of the cases in facilities that had wrong-site surgery and 75% of the cases in facilities that had none, a statistically significant difference ($p < 0.001$).

**The site mark should be visible and referenced in the prepped and draped field during the time-out.** In a year-long, prospective comparison of 97 near-miss reports, in which the potential error was caught before the skin was punctured, and 44 wrong-site surgeries, using a common event analysis form,[2] the time-out was done after the patient was prepped and draped in 88% of the near-miss events and in 64% of the wrong-site surgery events, a statistically significant difference ($p < 0.01$); the mark was visible in 87% of the near-miss events and in 69% of the wrong-site surgery events, a statistically significant difference ($p < 0.05$). In recent, unpublished comparisons—in a second region of Pennsylvania—of 169 observations of compliance with the Universal Protocol in 12 facilities that had wrong-site surgery and 6 facilities that had none, the time-out was done after the patient was prepped and draped in 85% of the cases in facilities that had wrong-site surgery and in 100% of the cases in facilities that had none, a statistically significant difference ($p < 0.01$).

**Verification of information during the time-out should require an active communication of specific information, rather than a passive agreement, and be verified against the relevant documents.** In 169 observations of compliance with the Universal Protocol in 12 facilities that had wrong-site surgery and 6 facilities that had none, all documents were verified during the time-out in 66% of the cases in facilities that had wrong-site surgery and 86% of the cases in facilities that had none, a statistically significant difference ($p < 0.05$); critical diagnostic test results or imaging studies were verified during the time-out in 73% of the applicable cases in facilities that had wrong-site surgery and 100% of the applicable cases in facilities that had none, a statistically significant difference ($p < 0.01$).

**All members of the operating team should verbally verify that their understanding matches the information in the relevant documents.** In the year-long, prospective comparison of 97 near-miss reports, in which the potential error was caught before the skin


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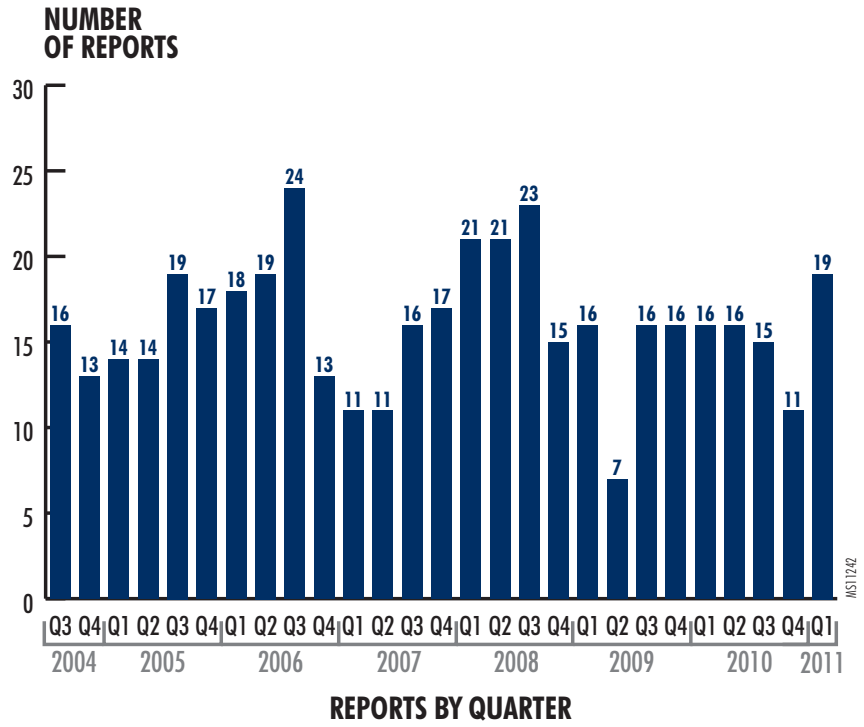
Figure. Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports by Quarter




was punctured, and 44 wrong-site surgeries, using a common event analysis form,[2] the nurse, the surgeon, and the anesthesia provider were all involved in 98% of the near-miss events and in 88% of the wrong-site surgery events, a statistically significant difference ($p < 0.05$).

**The surgeon should specifically encourage operating team members to speak up if concerned during the time-out.** The statewide comparison of policies and procedures in 37 facilities that had wrong-site surgery and 96 facilities that had none[3] showed that including an explicit request by the surgeon for operating team members to speak up if concerned during the time-out was cited in 40% of the facilities that had wrong-site surgery and 76% of the facilities that had none, a statistically significant difference ($p < 0.05$).

Operating team members who have concerns should not agree to the information given in the time-out if their concerns have not been addressed. In the year-long, prospective comparison of 97 near-miss reports, where the potential error was caught before the skin was punctured, and 44 wrong-site surgeries, using a common event analysis form,[2] operating team members raised concerns in 79% of the near-miss events and in 22% of the wrong-site surgery events, a statistically significant difference ($p < 0.001$).

**Any concerns should be resolved by the surgeon, based on primary sources of information, to the satisfaction of all members of the operating team before proceeding.** In the year-long, prospective comparison of 97 near-miss reports, in which the potential error was caught before the skin was punctured, and 44 wrong-site surgeries, using a common event analysis form,[2] the surgeon addressed concerns that were raised in 82% of the near-miss events and in 40% of the wrong-site surgery events, a statistically significant difference ($p < 0.001$).

## Time-Out Survey Results

Hospitals that do surgery and ambulatory surgical facilities (ASFs) in Pennsylvania recently cooperated with the Authority to complete a new survey on the conduct of time-outs. Surveys were forwarded to the OR managers of the 151 acute care, community, and children's hospitals and the 247 ASFs in the commonwealth.

Responses were received from 58 hospitals (38%) and 94 ASFs (also 38%), for a total of 152 responses. Among the hospitals responding, 32 (55%) had reported a wrong-site surgery event. Among the ASFs, 23 (24%) had reported a wrong-site surgery event. The difference between the experience with wrong-site surgery between the responding hospitals and ASFs was significant by Chi-square test ($p = 0.001$). The difference is consistent with the fact that 110 hospitals had reported wrong-site surgery events before the time of the survey (73% of all hospitals doing surgery), whereas only 63 ASFs had reported wrong-site surgery (26% of all ASFs). Responses were received from 32 hospitals that had reported wrong-site surgery (29%) and 23 ASFs that had reported wrong-site surgery (37%). This difference in survey response rates was not statistically significant. Nevertheless, the survey results were analyzed separately for hospitals and ASFs, rather than combined, because of the differences between the two types of facilities.

Because some ASFs specialize in procedures that may be less likely to result in wrong-site surgery (e.g., endoscopies), secondary analyses were done to look for differences between hospitals and ASFs that had reported wrong-site procedures and, therefore, did procedures that were at risk for wrong-site errors.

Most time-outs were led by the circulating nurses. The circulation nurses led the time-outs in 86% of the responding hospitals and 73% of the responding ASFs. Surgeons led the time-outs in 9% of the responding hospitals and 10% of the responding ASFs; anesthesia providers, in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3% and 6%, respectively; and scrub technicians, in 2% and 11%, respectively. The differences between hospitals and ASFs were not statistically significant. These findings were also valid for the subsets that had reported wrong-site procedures.

The site markings were referenced during the time-out in 82% of the responding hospitals and 73% of the responding ASFs; the difference was not statistically significant.

All facilities, without exception, verified the patient's identity during the time-out. Almost all verified the procedure (100% of hospitals and 99% of ASFs). The side or specific location was verified by all hospitals, but only by 84% of ASFs, a statistically significant difference ($p = 0.05$ by Chi-square). However, this difference disappeared for facilities that had reported wrong-site procedures (100% of hospitals and 96% of ASFs), suggesting the difference may be due to the types of procedures done (e.g., endoscopies). Only 55% of hospitals and 20% of ASFs included the patient's position under the drapes (e.g., supine, prone) in the time-out. This difference between hospitals and ASFs was statistically significant ($p = 0.001$) and persisted in the subset of facilities reporting wrong-site procedures.

Information about the patient, procedure, and site was verified a single item at a time according to 22% of hospitals and an almost identical 26% of ASFs, whereas the majority of facilities accepted a single response to verify all the information presented.

Not all facilities required all OR team members to respond. These exemptions were more common in ASFs (see Table 1). The differences persisted for anesthesia providers and scrub technicians in the subset of facilities reporting wrong-site procedures.

Active communication of information, rather than passive agreement, was expected for verification responses by a minority of facilities responding: 43% of the hospitals and 35% of the ASFs. The difference was not statistically significant, although it was significantly lower for the subset of ASFs that had wrong-site surgery than for hospitals that had wrong-site surgery (53% of hospitals, 26% of ASFs, $p = 0.05$).

The documents used for verifying the responses during the time-outs varied (see Table 2). In particular, pathology reports were not likely to be checked in any facilities. Imaging and pathology reports were significantly less likely to be checked during the time-out in ASFs than in hospitals, although the differences held up only for imaging reports in facilities that had reported wrong-site procedures.

There were no consistent significant differences in how time-outs were conducted among hospitals and among ASFs that had and had not reported wrong-site surgery. Therefore, comparisons can be made only against the previously established evidence-based best practices.

A comparison of the results of this survey of current time-out practices with previously established evidence-based best practices shows that improvements in time-out protocols can be made in the following:

— Specifically referencing the site marking during the time-out
— Including the specific location of the procedure and, possibly, the position of the patient under the drapes during the time-out
— Considering active responses to single elements needing verification during the time-out
— Having all members of the OR team engage in responding during the time-out

Diane Rydrych, of the Minnesota Department of Health, and Kathleen Harder, PhD, of the University of Minnesota, have observed time-outs in facilities across Minnesota and made a number of recommendations for Minnesota facilities,[4] including the following:

1. The operating team uses a "time-out towel" or other visual aid to cover the Mayo stand before the procedure.

Table 1. Results of Survey of Time-Out Protocols

| WHO RESPONDS DURING YOUR TIME-OUTS? | HOSPITAL | AMBULATORY SURGICAL FACILITY | P* |
|---|---|---|---|
| Surgeon | 98% | 98% | — |
| Circulating nurse | 93 | 77 | 0.01 |
| Anesthesia provider | 100 | 82 | 0.001 |
| Scrub technician | 90 | 73 | 0.05 |

* Chi-square test

Table 2. Results of Survey of Time-Out Protocols

| WHAT SOURCES ARE USED TO VERIFY VERBAL RESPONSES? | HOSPITAL | AMBULATORY SURGICAL FACILITY | P* |
|---|---|---|---|
| Consent | 100% | 99% | — |
| History and physical | 70 | 63 | — |
| Operating room schedule | 72 | 69 | — |
| Imaging studies | 75 | 24 | 0.001 |
| Pathology report | 24 | 11 | 0.05† |

* Chi-square test

† See text for qualification


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2. The surgeon initiates the time-out immediately before the incision.
3. All team members cease activity except to ventilate the patient.
4. The circulating nurse reads the pertinent information out loud to the team, using source documents.
5. Each member of the team independently provides the pertinent information out loud from the information he or she knows. The anesthesia professional reads the patient's name, medical record number, and procedure from the anesthesia record. The scrub tech states the procedure he or she is set up for, visualizes the site mark, and states where it is located. The surgeon states the patient's name, complete procedure, and site from memory. The surgeon goes last to minimize the confirmation bias that sometimes happens when team members defer to the surgeon and are reluctant to correct misinformation.
6. For multiple procedures, a time-out is done before each procedure.
7. Other information addressed during the time-out is minimal and, if possible, is addressed earlier, during a preoperative briefing.

A structured analysis of interviews of surgeons, OR nurse managers, and OR nurses in a hospital in Australia[5] identified multiple reasons for "ambivalent compliance" with time-outs. Among the important findings are that (1) the surgeons are included in the development of time-out protocols to achieve surgeon ownership and to avoid exclusively nurse-driven protocols, and (2) the surgeons are educated about time-outs.

The UPMC Health System in Pittsburgh recently had surgeons, anesthesiologists, and OR staff develop a uniform time-out for the system that would be consistent with both the Joint Commission's Universal Protocol[6] and with the World Health Organization's Safe Surgery Checklist,[7] which the system wished to introduce into the ORs. One item the providers added to the time-out script was a mention of the patient's position (personal communication). This addition addresses one of the two main causes of wrong-site surgery: disorientation in the operating room when a patient is not in the conventional supine position. (The other main cause is misinformation.)[8]

The Reading Hospital SurgiCenter at Spring Ridge, in Wyomissing, Pennsylvania, produced a video, in response to a near-miss event, that shows how to apply the components of the Universal Protocol, including the time-out. The facility uses the video for staff education and is monitoring compliance with the Universal Protocol monthly. The video is described and available online through the website of *Outpatient Surgery Magazine*[9] and, for

## EVALUATING TIME-OUT PROTOCOLS OR SCRIPTS

The following rubric can be used to evaluate examples available from the Pennsylvania Patient Safety Authority, as well as facility-specific time-out protocols or scripts:

- ☐ The time-out protocol was developed with input from and approval of providers representing all roles in the time-out.
- ☐ A program is available for educating all providers involved in time-outs,
- ☐ The time-out protocol expects that the time-out will be done after the patient is prepped and draped and just before the procedure is begun.
- ☐ The time-out protocol expects all providers to stop noncritical activities to participate in the time-out.
- ☐ The time-out protocol allows for flexibility in posing and responding to the information requested in the time-out protocol, so that the emphasis is on engaging the participants, not on rote memorization.
- ☐ The time-out protocol expects that the information verified will include the patient's identity, the procedure, the site identified by the site marking, and the site identified by any imaging or pathology studies. The protocol may include verification of the patient's position under the drapes.
- ☐ The time-out protocol expects individual responses to individual questions by the leading provider for each role in the operating room (OR) team.
- ☐ The time-out protocol requires that all responses to questions be in the active voice, that is, that they transmit information, not just agreement with information.
- ☐ The time-out protocol requires that any site marking be specifically pointed out by the surgeon during the time-out.
- ☐ The time-out protocol expects that the information communicated in all responses be checked against all documents that could be used to verify that information.
- ☐ The time-out protocol should stipulate that the operating surgeons should explicitly empower other OR team members to speak up if concerned.
- ☐ The time-out protocol permits any OR team member to put a hold on noncritical activities until any concerns have been reconciled.


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Pennsylvania facilities, is available through the Authority's PassKey website.

Other time-out scripts were published in a previous *Pennsylvania Patient Safety Advisory* article.[10] (See "Evaluating Time-Out Protocols or Scripts.")

The Authority would like to receive time-out protocols meeting these qualifications to post on the Authority's Preventing Wrong-Site Surgery web page.

## THE ROLE OF IMAGING STUDIES IN WRONG-SITE SURGERY

A query about the importance of reviewing imaging studies in the OR as a step in preventing wrong-site surgery prompted analysis of the 415 wrong-site surgery reports in the Authority's wrong-site surgery database through 2010.

The analysis did not assume that imaging studies would have been reviewed by anesthesiologists to prevent wrong-site blocks. Unless otherwise stated, colon lesions were assumed to have been localized by colonoscopy. Wrong-site procedures addressing lung lesions and fractures were assumed to have benefited from review of images unless the description of the event indicated otherwise. Wrong-site arthroscopies, ureteroscopies, and spinal procedures were not automatically included. The report had to specifically suggest that a preoperative review of the imaging study might have corrected an information error. Wrong-site emergencies were not included. Reviewing imaging studies might have been helpful in preventing information errors in other reports; some descriptions were too sparse to make any inference.

Reviewing images in the OR might have corrected information errors leading to 42 wrong-site procedures, as follows:

- 14 instances of stenting of the wrong ureter
- 7 wrong-site orthopedic procedures, including one hip replacement, one hip fracture, one sacral fixation, and four fixations of finger injuries
- 6 operations at the wrong spinal site, four at the wrong level, and two on the wrong side
- 5 operations on the wrong lung for localized pathology
- 3 wrong-site breast procedures, including two on the wrong side and one at the wrong site on the correct side
- 2 craniotomies on the wrong side
- 2 wrong-side intraabdominal procedures that might have benefited from localization of the lesions on imaging studies, one involving a computed tomography (CT) scan showing ovarian pathology and one involving an magnetic resonance imaging scan showing renal pathology
- 1 vascular procedure on the wrong leg
- 1 dental surgical procedure
- 1 incorrect localization of a foreign body

Nine reports indicated that erroneous information in available imaging studies led to wrong-site surgery. Four involved incorrect interpretations before spinal surgery. Two involved incorrect interpretations of sinus lesions on CT scans. One was misleading ultrasound documentation of a breast lesion. One was a misleading radiographic interpretation of kidney stones. One resulted from interpreting the wrong patient's films in the OR.

The analysts concluded that there is a net benefit to reviewing imaging studies in the OR before surgery.

## NOTES


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PATIENT SAFETY AUTHORITY

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# PENNSYLVANIA PATIENT SAFETY ADVISORY

## THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS

The Pennsylvania Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error ("Mcare") Act. Consistent with Act 13, ECRI Institute, as contractor for the Authority, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the Pennsylvania Patient Safety Authority, see the Authority's website at http://www.patientsafetyauthority.org.

ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for nearly 40 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. More than 5,000 healthcare organizations worldwide rely on ECRI Institute's expertise in patient safety improvement, risk and quality management, and healthcare processes, devices, procedures and drug technology.

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