Wrong-Side Thoracentesis
Lessons Learned From Root Cause Analysis

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Incorrect operations and invasive procedures continue to occur despite the introduction of the Joint Commission's Universal Protocol and the implementation of time-outs, incorrect surgical procedures are still among the most common types of sentinel events and can have fatal consequences.

**OBJECTIVES** To examine a root cause analysis database for reported wrong-side thoracenteses and to determine the contributing factors associated with their occurrence.

**DESIGN, SETTING, AND PARTICIPANTS** We searched the National Center for Patient Safety database for wrong-side thoracenteses performed in ambulatory clinics and hospital units other than the operating room reported from January 1, 2004, through December 31, 2011.

**MAIN OUTCOMES AND MEASURES** Data extracted included patient factors, clinical features, team structure and function, adherence to bottom-line patient safety measures, complications, and outcomes.

**RESULTS** Fourteen cases of wrong-side thoracenteses are identified. Contributing factors included failure to perform a time-out (n=12), missing indication of laterality on the patient's consent form (n=10), absence of a site mark on the patient's skin within the sterile field (n=12), and absent verification of medical images (n=7). Complications included pneumothoraces (n=4), hemorrhage (n=3), and death directly attributable to the wrong-side thoracentesis (n=2). Teamwork and communication failure, unawareness of existing policy, and a deficit in training and education were the most common root causes of wrong-side thoracentesis.

**CONCLUSIONS AND RELEVANCE** Prevention of wrong-site procedures and accompanying patient harm outside the operating room requires adherence to the Universal Protocol and time-outs, effective teamwork, training and education, mentoring, and patient assessment for early detection of complications. The time-outs provide protected time and place for error detection and recovery.

**IMPORTANCE** Despite the recognized value of the Joint Commission's Universal Protocol and the implementation of time-outs, incorrect surgical procedures are still among the most common types of sentinel events and can have fatal consequences.

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and wrong implant insertions. Although the exact incidence of incorrect operations and invasive procedures is unknown, it has been estimated to occur at a rate of 0.09 to 4.5 per 10 000 cases. Incorrect operations and invasive procedures remain among the sentinel events most frequently reported to the Joint Commission. These adverse events may be associated with patient harm, death, litigation, and loss of patients’ trust in their health care professionals and the health care system.2

Thoracentesis is an important diagnostic procedure in patients with a pleural effusion of unknown origin and as a therapeutic technique to improve the respiratory status of patients with large effusions.6 Approximately 178 000 thoracenteses are performed per year in the United States.7 Significant complications can occur, including pneumothorax, hemorrhage, and death. Systematic implementation of ultrasonography, training, and restriction of thoracentesis to experienced health care professionals has been associated with reductions in the frequency of complications.7 Studies8-10 link improved adherence rates with the Universal Protocol for bedside procedures, including thoracentesis, with quality improvement interventions. When training includes the skill of error detection and opportunities to practice strategies for error recovery, the value of a time-out increases.11 If training of health care professionals progresses from recognition of obvious errors to subtle error detection and from the ability to detect the errors of others to the ability to detect one’s own risk of error, the value of the time-out is likely to approach asymptotical perfection.

The purposes of this study are to examine an RCA database for reported wrong-side thoracenteses and to determine the contributing factors associated with their occurrence as well as to provide further recommendations for the development of resources for the prevention of wrong-side thoracentesis. This study expands the design of patient safety curriculum in error detection and recovery and contributes to the evidence of the value of the Universal Protocol and the practice of time-outs.

Methods

In the VHA, more than 150 health care facilities perform RCAs to guide patient safety improvement.12 The NCPS database currently contains more than 14 500 RCA reports and more than 1 000 000 safety reports. For the purpose of this study, a search of the NCPS database focused on wrong-side thoracentesis in ambulatory clinics and on hospital units other than the operating room reported from January 1, 2004, through December 31, 2011.

The study has an institutional review board exemption through the Ann Arbor Veterans Affairs Healthcare System Research and Development Committee. The search and extraction of data from the database were performed through use of NCPS natural language processing software. These data result from a search for the keyword thoracentesis anywhere in the RCA report. To further focus the results to relevant cases, keyword search parameters were limited to variations of wrong-site, wrong-side, and wrong-lung. In this analysis, 69 candidate cases were reviewed and reduced to 14 relevant cases. Summaries of the 14 cases were reviewed by each of 3 coders (K.E.M., M.M., and D.E.P.).

The primary outcome variable is the occurrence of a wrong-side thoracentesis procedure performed outside the operating room. The primary exposure variables are classified by content and relevance, including patient factors (ie, vital signs), clinical features (ie, diagnostic vs therapeutic), team structure and function (ie, nurse present), adherence to bottom-line patient safety measures (ie, conducting a time-out), complications (ie, pneumothorax), and outcomes (ie, mortality). Medical records were not reviewed as part of this study. As such, particular clinical information may be absent for one or more of the index cases depending on the documentation and the scope of the RCA report.

The research team, including a patient safety physician, a human factors engineer, and a patient safety program analyst, coded the root causes of this study. Root causes are coded according to standard taxonomy and guidelines, including policy and procedures, communication, training, equipment, and fatigue.12,13 Each of the categories is based on characteristics of design from the field of study known as Human Factors Engineering. The contributing factors are designated as such if system design fails to support optimal human performance or directly leads to an error.

Statistical analyses were performed using STATA/IC 11.0 statistical software (Stata Corp). Standard descriptive measures (ie, frequencies, means, medians, and SDs) were computed for variables in the data set. Qualitative data regarding root cause were analyzed by the research team to determine discrepancies and ensure consistency. For interrater reliability, the κ statistic was 0.87,14,15

Results

Analysis from 11 598 RCA reports from January 1, 2004, through December 31, 2011, identified 14 cases of wrong-side thoracenteses occurring outside the operating room. On the basis of information available in the reports, 6 men and 1 woman underwent wrong-side thoracenteses, with 13 patients sitting up during the procedure. Table 1 provides a summary of patient and procedural factors that are extracted from each RCA report when such information is available.

Team structure and function demonstrate that usually a resident performed the procedure (n=10) compared with an attending physician (n=2). Specialties involved included internal medicine (n=9), pulmonary medicine (n=3), and surgery (n=1). The attending physician was present in 6 cases. A nurse was present in 3 cases. Adherence to the Universal Protocol and performance of a time-out are the primary focuses of the study. The results indicate that among cases of incorrect thoracenteses, time-outs are rarely conducted or documented. Laterality was missing from the informed consent form in 10 cases (71.4%), and the site was not marked in 12 cases (85.7%) (Table 2). Most wrong-side procedures occur on the patient’s right side, with the pleural effusion located on the patient’s left side (Figure 1).

The wrong-side errors in this study are detected by less skillful means: clinical deterioration or a dry tap (n=9), patient voicing concern (n=2), chest radiograph (n=1), or post-procedure review (n=1). Complications of the incorrect pro-
procedure occurred among 7 patients and included pneumothorax (n=4) and hemorrhage (n=3). Four patients required additional procedures. Increased length of stay in the hospital was reported for 8 patients (mean of an additional 2.6 days in the hospital and 1.9 days in the intensive care unit). Death during the same admission occurred in 5 patients. Three deaths were primarily related to the patient’s underlying condition (ie, cirrhosis), whereas 2 deaths were directly attributed to the wrong-side thoracentesis. Wrong-side procedures associated with a fatal outcome—a worst-case scenario—are more likely performed by a resident (4 [80.0%] vs 5 [62.5%] for fatal vs nonfatal) and without a nurse present (5 [100%] vs 7 [77.7%] for fatal vs nonfatal).

Thirty root causes have been identified among the 14 incorrect thoracenteses (2.1 root causes per event). The most common contributing factors are poor communication, lack of awareness of policy and procedures, training deficiencies, and equipment unavailability or malfunction (Table 3).

**Discussion**

The root causes of wrong-side thoracenteses are usually multiple and include systems-based latent errors, consistent with James Reason’s Swiss cheese model of adverse events.16 These system failures encompass the lack of adherence to policy and procedures, poor teamwork and communication, absent or misguided supervision, malfunctioning technology, deficiency in education and training, and the need for a pervasive safety culture (Figure 2).

In identifying and categorizing system failures after the fact, the need for patient safety problem-solving work is justified and supported. In an ideal scenario, effective commu-
Wrong-Side Thoracentesis

Figure 1. Influence of Human Factors on Wrong-Side Thoracentesis

Most incorrect procedures were performed on the patient’s right side.

ication enables the team to follow the Universal Protocol that requires a sterile cockpit time-out. Deploying the sterile cockpit rule during time-outs minimizes unnecessary distractions. It is an essential safety barrier that allows error detection and recovery and the opportunity for real-time progress toward a pervasive safety culture. Team members with skills in error detection and recovery perform the time-out in a distraction-free environment. The “sterile cockpit” time-out, even if practiced reluctantly, offers a final opportunity before an invasive procedure for error detection. When teamwork supports the use of the time-out for error detection and planning for unexpected but potential adverse events, the best purpose of the time-out is validated.

Observance of the Universal Protocol and performance of a time-out, as required by the Joint Commission and VHA directive 2010-023 before invasive procedures since 2004, would have prevented the incorrect thoracenteses in this report. The Universal Protocol includes a standardized preprocedure verification process of the correct patient, procedure, and site; marking the site; and conducting a time-out immediately before starting the procedure using a checklist promoting communication among the team members. The VHA directive includes all these elements plus the requirement that 2 team members verify relevant images (i.e., chest radiograph) for correct patient, date, and laterality.

The use of checklists has been associated with improved patient outcomes for invasive procedures. However, policy and procedures alone are unlikely to eliminate wrong-side thoracenteses. The fact that the Universal Protocol and time-outs have been mandated since 2004 and incorrect procedures still occur is evidence of this impasse. Despite evidence of efficacy, the expression “ambivalent compliance” has been used to describe the lack of engagement in bottom-line patient safety behaviors (procedures and evidence-based practices with demonstrated success), such as time-outs. In one study, by self-report, health care professionals described widespread adherence with time-outs before operations; however, observation disclosed significant variation and missing elements in the time-outs. Furthermore, the Universal Protocol and time-outs have not been as rigorously implemented and standardized outside the operating room, perhaps because there is less recognition that what happens in the operating room can also happen with procedures outside the operating room.

Standardization of the time-out process for any invasive procedure performed anywhere in the hospital or clinic is a strong action in the prevention of wrong-side procedures, including thoracentesis. Standardization includes marking of the site in conjunction with active patient, procedure, and site identification and not proceeding with the procedure unless the mark is clearly visible within the sterile field. In the process of marking the site, a recognized human vulnerability is confronted. Humans have difficulty consistently dealing with left and right laterality correctly.

Another method of improving standardization of invasive procedures outside the operating room is the development of procedural teams. Residents rotate on a service in which faculty teach both the clinical and nontechnical skills associated with the performance of invasive procedures. Residents new to the service integrate into existing procedure teams, acquiring a standard set of skills.

Additional solutions include implementation of a no distraction zone or designation of a specific location for procedures. These types of actions would be expected to further formalize the procedure, reduce variability, ensure availability of materials and equipment, and eliminate distractions.

The patient safety practice in the prevention of wrong-side thoracentesis highlighted by this study is recurrent teamwork and communication training. Challenges to effective teamwork include hierarchy, staff shortages, and lack of support for time-outs by physicians. Medical team training, based on crew resource management principles adapted from the aviation industry and focused on nontechnical teamwork and leadership skills to complement professional technical skills, has been associated with better team performance and improved patient outcomes. In this study, breakdown in team structure (eg, nurse and attending physician not present) or function (eg, lack of physician-physician or physician-nurse communication) contributed significantly to wrong-side procedures and to the timely treatment of complications. It is essential to establish a team and roles before the start of the procedure.

The culture of patient safety in a health care facility may be important in the prevention of wrong-side thoracentesis. Organizations that are highly reliable display attributes of a

Table 3. Contributing Factors to Identified Root Causes of Wrong-Side Thoracenteses

<table>
<thead>
<tr>
<th>Contributing Factor</th>
<th>No. (%) of Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>7 (23)</td>
</tr>
<tr>
<td>Training</td>
<td>8 (27)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Equipment</td>
<td>7 (23)</td>
</tr>
<tr>
<td>Policy and procedures</td>
<td>8 (27)</td>
</tr>
</tbody>
</table>

* Among 30 total root causes identified for 14 cases of wrong-side thoracenteses.
Wrong-Side Thoracentesis

A limitation of this study is that RCA reports are voluntarily sent to the NCPS database and therefore may not include all wrong-side thoracenteses. Root cause analysis is not primarily a data collection tool but rather a narrative account of patient safety diagnostics and problem solving. Root cause analysis software does not require the completion of all fields, and the reports are deidentified; therefore, some of the information is not conducive to categorization. However, mining the narrative accounts in RCA reports reveals potential consequences of nonadherence to the Universal Protocol and/or skipping a time-out before invasive procedures. The identified root causes and contributing factors document the need for system improvement.

Conclusions

A number of strategies are available to prevent wrong-side thoracentesis. An initial step involves the formal standardization and implementation of the Universal Protocol and time-outs for invasive procedures. The protocol can be supported and supplemented through the use of tools such as a checklist, site marking, ultrasonography, and the opportunity to practice technical and nontechnical skills in simulation. The implementation of these recommendations will benefit patients, result in potential cost savings, and improve the safety culture.

The VHA continues its efforts to prevent the incidence of incorrect procedures performed outside the operating room with specific initiatives, including online training in correct operations and invasive procedures for residents and staff who perform invasive procedures, several simulation-based curricula, a lessons learned program, and recurrent team training. Similar strategies have reduced the incidence of wrong-site procedures in the operating room.

Current time-out procedures feature error detection strategies and allow for error recovery. Teams that have experience in this process are convinced of its value and are therefore less likely to require a reminder that a policy exists that requires a time-out before performing an invasive procedure. Development of an NCPS patient safety curriculum will continue to focus on teamwork, communication, Human Factors Engineering, and error detection and recovery.

High-fidelity simulation and other interactive educational methods support the development of these nontechnical skills.
Wrong-Side Thoracentesis

Original Investigation Research

JAMA Surgery

Industries

Hum Factors Ergonomics Manufacturing Services

surgical procedures within and outside of the operating room.

Statistical analysis: Mills, Lee, Hemphill.

REFERENCES


