Incorrect Surgical Procedures Within and Outside of the Operating Room

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Objective: To describe incorrect surgical procedures reported from Veterans Health Administration (VHA) Medical Centers from 2001 to mid-2006 and provide proposed solutions for preventing such events.

Design: Descriptive study.

Setting: Veterans Health Administration Medical Centers.

Participants: Veterans of the US Armed Forces.

Interventions: The VHA instituted an initial directive, “Ensuring Correct Surgery and Invasive Procedures,” in January 2003. The directive was updated in 2004 to include non–operating room (OR) invasive procedures and incorporated requirements of The Joint Commission Universal Protocol for preventing wrong-site operations.

Main Outcome Measures: The categories included 5 incorrect event types (wrong patient, side, site, procedure, or implant), major or minor surgical procedures, location in or out of the OR, therapeutic or diagnostic events, adverse event or close call, inpatient or ambulatory events, specialty department, body segment, and severity and probability of harm.

Results: We reviewed 342 reported events (212 adverse events and 130 close calls). Of these, 108 adverse events (50.9%) occurred in an OR, and 104 (49.1%) occurred elsewhere. When examining adverse events only, ophthalmology and invasive radiology were the specialties associated with the most reports (45 [21.2%] each), whereas orthopedics was second to ophthalmology for number of reported adverse events occurring in the OR. Pulmonary medicine cases (such as wrong-side thoracentesis) and wrong-site cases (such as wrong spinal level) were associated with the most harm. The most common root cause of events was communication (21.0%).

Conclusions: Incorrect ophthalmic and orthopedic surgical procedures appear to be overrepresented among adverse events occurring in ORs. Outside the OR, adverse events by invasive radiology were most frequently reported. Incorrect surgical procedures are not only an OR challenge but also a challenge for events occurring outside of the OR. We support earlier communication based on crew resource management to prevent surgical adverse events.

Arch Surg. 2009;144(11):1028-1034

Incorrect surgical procedures can be devastating. Some examples include wrong-site,1 wrong-side, wrong-procedure, or wrong-patient events.2 Based on the database analysis of Seiden and Barach,2 we estimated that 5 to 10 of these events occur daily in the United States. A report from Pennsylvania stated that some aspect of an actual or close-call wrong-site surgical procedure occurs every other day in that state.3 Kwaan et al4 examined a malpractice insurance database for wrong-site surgical procedures and estimated an incidence of 1 in 112,994 nonspine, wrong-site surgical procedures. That study did not include wrong-patient or wrong-procedure events and excluded non–operating room (OR) cases, so it is understandable that this rate appears lower than that reported by Seiden and Barach. The New York Patient Occurrence and Reporting Tracking System database, for which reporting is mandatory, estimated 100 or more wrong-patient, wrong-site, and wrong–invasive procedure events reported per year in that state for 2003–2005.4 Wrong-site surgical procedure was the sentinel event most frequently reported to The Joint Commission.5 The literature indicates that the true incidence of incorrect surgical procedures is not known with confidence. Despite efforts to eliminate incorrect surgical procedures, these events continue to occur.5-7

See Invited Critique at end of article

The Veterans Health Administration (VHA) developed and implemented a pilot program to reduce the risk of incorrect surgical events in April 2002, which resulted in the dissemination of a national directive in January 2003. Subsequently, The Joint Commission issued a Universal Pro-
tocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery, effective July 1, 2004. The VHA issued an updated version of its directive on Ensuring Correct Surgery and Invasive Procedures on June 24, 2004, to be fully consistent with the Universal Protocol and to address implementation questions.

In the VHA for catastrophic events, root cause analysis (RCA) teams examine what happened and why it occurred, and then recommend actions to prevent recurrence. The Joint Commission also requires an RCA for sentinel events. In addition, VHA staff members are required to use RCA for potentially catastrophic close-call events. The VHA staff submits RCAs and incident reports to a central database.

In this study, we analyzed surgical adverse events and close calls from VHA RCAs and incident reports (termed safety reports in the VHA system). The purpose of this analysis is to provide information and proposed solutions regarding incorrect surgical events and to provide a unique perspective by summarizing reports from a large healthcare system over 5 1/2 years.

**METHODS**

**DESIGN**

We analyzed reported surgical adverse events in the VHA and described categories of events. We also describe reporting before and after dissemination of policies to ensure correct surgical procedures. The Research and Development Committee, Veterans Affairs Medical Center, White River Junction, Vermont, approved this project, and the Committee for the Protection of Human Subjects, Dartmouth College, considered this project exempt.

**SETTING AND PARTICIPANTS**

Of 153 major facilities in the VHA, 130 (85.0%) provide surgical services. Operating room reported events could have occurred at any of the 130 VHA facilities providing surgical services, whereas non-OR events could have occurred at any of the 153 VHA facilities.

**DATA SOURCES**

We searched the VHA National Center for Patient Safety database for surgical adverse events occurring between January 1, 2001, and June 30, 2006. Events were not limited to the OR and included incidents in procedure rooms or radiology suites and at the bedside. These data were limited to RCAs and safety reports submitted to the National Center for Patient Safety and were not abstracted from medical records. Results were filtered to include only events pertaining to incorrect surgical procedures or incorrect invasive procedures. An additional search was conducted using a natural language processing search method that uses data and text mining (PolyAnalyst), which produced the final data set for this study.

**CODING PROCESS**

Two independent teams of a surgeon and at least 1 nonclinical researcher coded each report. The teams reconciled differences to arrive at a consensus for a final categorization of each case.

After categorization was completed, two of us (J.N. and P.D.M.) coded the root causes of events into major categories such as education or communication. We coded 10 cases by consensus to develop draft categories of root causes and then independently coded 40 cases in groups of 10 and refined the codebook until we reached an agreement of 80.6% and $k$ of 0.79 for the last 10 cases. We then independently coded remaining cases, reaching consensus when the root causes did not clearly fit into any one category.

**MAIN OUTCOME MEASURES**

**Major and Minor Surgical Procedures**

Major surgical procedures were defined as “procedures performed under general, spinal, and epidural anesthesia, and all carotid endarterectomies and inguinal herniorrhaphies, regardless of anesthesia type.” Minor surgical procedures were defined as any other invasive procedure. All major surgical procedures occur in the OR, but minor surgical procedures may or may not take place in the OR. Major or minor surgical procedures are performed on outpatients or inpatients.

Therapeutic procedures were defined as procedures to treat medical conditions, and diagnostic procedures were defined as procedures to establish a diagnosis. Inpatient procedures were defined as those performed on an inpatient hospitalized for at least 1 night before or after the procedure. Ambulatory procedures were those for which the preoperative plan called for same-day admission and discharge. Cases in which the patient needed admission solely because of the adverse event or close call were counted as ambulatory.

**Event Location, OR vs Non-OR**

An OR was defined as part of a suite in a hospital or in an outpatient ambulatory surgical center with dedicated staff, equipment, and space guidelines consistent with Joint Commission standards. Non-OR environments may be any setting where an invasive procedure is performed, eg, a procedure room in a clinic or emergency department, an interventional procedure room in a radiology department, or at the bedside.

**Adverse Event vs Close Call**

An adverse event was defined as an incident in which the patient had undergone a surgical procedure of any type unnecessarily, such as a procedure performed on the wrong patient or wrong site. This included any incision or puncture to the patient, including injections and administration of regional or general anesthetic not needed for the planned procedure. Topical applications to the skin or via eyedrops were considered close calls.

A close call was defined as an incident in which a recognizable step toward a surgical adverse event occurred without the patient being subjected to a surgical or invasive procedure as previously defined in our definition of adverse event. Some examples included the wrong patient was given a consent form, the wrong procedure was written on the consent form, the wrong surgical site was marked, and the wrong site or wrong patient was prepped. Solely omitting a required step in the VHA directive or Universal Protocol did not constitute a close call. For example, if a step was skipped, such as site marking, but the correct procedure was performed, this was considered a deviation from the directive but not a close call.

**Other Categories**

Service or specialty was coded as the surgical or medical service or specialty department that performed the procedure. Route
sign a category (wrong procedure, and wrong implant. The algorithm used to visit, and leg/foot.

The parts of the body were developed based on this data set:

- Patient safety manager for actual and potential harm using 2 criteria: harm (catastrophic to minor) and probability (frequent to remote). Harm and probability are combined for a score from 1 to 3 called the Safety Assessment Code (SAC), developed by the VHA to help staff prioritize adverse events and close calls.1,14

SAFETY ASSESSMENT CODE

Adverse events reported within the VHA are rated by the patient safety manager for actual and potential harm using 2 criteria: harm (catastrophic to minor) and probability (frequent to remote). Harm and probability are combined for a score from 1 to 3 called the Safety Assessment Code (SAC), developed by the VHA to help staff prioritize adverse events and close calls.1,14

INTERVENTIONS

The VHA required implementation of its initial directive, “Ensuring Correct Surgery and Invasive Procedures,” in January 2003. The VHA held nationwide briefings with Patient Safety and Quality Management staff about the directive and sent educational resources to all VHA medical centers.9 This directive was updated and reissued in mid-2004 to include invasive procedures not conducted in the OR,6 concurrent with the requirement to implement the Joint Commission’s Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery.19

ANALYSIS

We described characteristics of the events and used \( \chi^2 \) analysis to identify relationships between SAC scores, which, for analysis, were categorized as having medium or high harm or not, and other variables, such as specialty and type of adverse events, which were categorized as occurring or not occurring. We used analysis of variance to analyze mean differences in SAC scores over time. The dependent variable was SAC score, and the independent variable was time period. We used 3 time periods for analysis:

1. Before January 2003, or before the VHA directive “Ensuring Correct Surgery” was issued.
2. From January 1, 2003, to June 30, 2004, or when the VHA directive was in effect but there was no Joint Commission requirement and the directive was for OR cases only.
3. From July 1, 2004, to June 30, 2006, or after the VHA directive9 was rewritten to include procedures performed outside the OR and the Joint Commission Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery was effective.19

We calculated a reported adverse event rate for the top 7 categories of OR reported adverse events. We placed the number of reported adverse events over the number of surgical cases for that specialty and multiplied this by 10 000 for a rate of reported adverse events per 10 000 cases. Reported adverse events were for 5 1/2 years (January 1, 2001, to June 30, 2006) and the number of surgical cases was for 6 years (October 1, 2000, to September 30, 2006), so we multiplied the first and last year of fiscal year data on surgical cases by 0.75 to account for this time difference.

RESULTS

We reviewed and analyzed 342 reports of surgical events: 212 actual adverse events (62.0%), 104 close calls (38.0%). One hundred eight reported adverse events (50.9%) occurred in the OR, and 104 reported adverse events (49.1%) occurred elsewhere. Table 1 displays cases by category. Table 2 displays reported adverse events by specialty and event type. For reported adverse events only, ophthalmology and invasive radiology had the most reports, 43 each (21.2%). Figure 2 displays major root cause categories. The analysis of root causes revealed 672 total root causes, 76 (11.3%) of which were not discernible by our coders. Consequently, information is provided for 596
root causes (88.7%). The top root cause was communication problems (21.0%) and included examples such as informed consent issues and problematic communication of critical information between team members, such as handoffs between staff members in which information was missing. Root causes related to time-out problems (17.6%) included issues such as the patient was not properly identified during the time-out.

Ophthalmology had 1.8 reported adverse events for every 10,000 cases, whereas orthopedics had 1.2 reported adverse events per every 10,000 cases. None of the other top 7 specialties of OR adverse events had at least 1 adverse event per 10,000 cases. Data on reported adverse events came from the study database, and events were categorized into specialties by the research team. Data on the percentage of surgical cases were retrieved

Table 1. Reported Surgical Cases by Categorya

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No. of Reported Adverse Events</th>
<th>No. of Reported Close Calls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Surgical Procedure</td>
<td>Minor Surgical Procedure</td>
<td>Subtotal</td>
</tr>
<tr>
<td>Total No. of OR proceduresb</td>
<td>1 119 459</td>
<td>908 774</td>
</tr>
<tr>
<td>Inpatient (n = 614 581)b</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapeutic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outpatient (n = 1 413 653)b</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapeutic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total No. of Reports</td>
<td>48</td>
<td>59</td>
</tr>
<tr>
<td>Non-OR procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapeutic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>48</td>
<td>161</td>
</tr>
</tbody>
</table>

Abbreviation: OR, operating room.

a The date range for reported adverse events and close calls is January 1, 2001, to June 30, 2006. The number of cases in 5 dichotomous categories: reported adverse event vs close call, major vs minor surgery, inpatient vs outpatient, therapeutic vs diagnostic procedure, and OR vs non-OR procedure.
b These data are for procedures that were entered into the surgery package of the Department of Veterans Affairs electronic medical record system (fiscal years 2001-2006: October 1, 2000, to September 30, 2006) and adjusted for 5.5 y by multiplying fiscal year 2001 and fiscal year 2006 data by 0.75. These data are for OR procedures and do not include specialties such as invasive radiology, dentistry (OR oral surgery is included), gastrointestinal tract medicine, dermatology, and internal medicine.
c Data were missing for 28 cases, so the total sample size for this table was 314 rather than 342.

Table 2. Number of Reported Adverse Events by Specialty

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Wrong Patient</th>
<th>Wrong Side</th>
<th>Wrong Site</th>
<th>Wrong Procedure</th>
<th>Wrong Implant</th>
<th>Other</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Ophthalmology</td>
<td>5</td>
<td>16</td>
<td>0</td>
<td>2</td>
<td>22</td>
<td>0</td>
<td>45</td>
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<tr>
<td>Invasive radiology</td>
<td>31</td>
<td>5</td>
<td>1</td>
<td>3</td>
<td>5</td>
<td>0</td>
<td>45</td>
</tr>
<tr>
<td>Orthopedics</td>
<td>1</td>
<td>8</td>
<td>3</td>
<td>2</td>
<td>12</td>
<td>0</td>
<td>26</td>
</tr>
<tr>
<td>Urology</td>
<td>6</td>
<td>12</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>23</td>
</tr>
<tr>
<td>Dentistry</td>
<td>0</td>
<td>2</td>
<td>13</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>16</td>
</tr>
<tr>
<td>General surgery</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>13</td>
</tr>
<tr>
<td>Pulmonary medicine</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>Cardiology</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Vascular surgery</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Cardiothoracic</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Podiatry</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Dermatology</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Gastrointestinal medicine</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Internal medicine</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Plastic surgery</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Otolaryngology</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Obstetrics-gynecology</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>56</td>
<td>65</td>
<td>31</td>
<td>16</td>
<td>41</td>
<td>1</td>
<td>210</td>
</tr>
</tbody>
</table>

Ophthalmology had 1.8 reported adverse events for every 10,000 cases, whereas orthopedics had 1.2 reported adverse events per every 10,000 cases. None of the other top 7 specialties of OR adverse events had at least 1 adverse event per 10,000 cases. Data on reported adverse events came from the study database, and events were categorized into specialties by the research team. Data on the percentage of surgical cases were retrieved...
from the VHA Computerized Patient Record System “surgery package,” and not from the research team. Figure 3 displays reported adverse events by body segment and location. The 2 most commonly reported adverse events were wrong side (66 [31.1%]) and wrong patient (56 [26.4%]). Figure 4 displays the rate of reports per month for adverse events and close calls for the 3 periods by location.

Most events (65%) were actual SAC 1, 23% were SAC 2, and 12% were actual SAC 3. Pulmonary medicine cases (such as wrong-side thoracentesis) ($\chi^2 = 12.45; P < .01$) and wrong-site cases (such as wrong spinal level) ($\chi^2 = 4.81; P = .03$) were associated with the most harm.

Analysis of variance of the mean actual SAC score for reported events across the 3 time points revealed significant change over time ($F, 9.174; P = .01$); mean SAC scores initially decreased then increased again after the updated directive.

**Figure 2.** General categories of root causes of surgical events (N=596). OR indicates operating room.

**Figure 3.** Percentage of reported adverse events by body segment and location (n=208). OR indicates operating room.

**Figure 4.** Percentage of type of reported adverse events by location, ordered according to flowchart (Figure 1) categories (n=212). Each reported adverse event was assigned to only 1 category, so events in categories other than “wrong patient” were performed on the correct patient. This system does not account for events that could have been included in more than 1 category, such as operating on the wrong side of the wrong patient. OR indicates operating room.

**Figure 5.** Rates of reports of actual events and close calls reported per month before any directive, after the Veterans Affairs (VA) directive for events in the operating room (OR), and after the updated directive that included non-OR events and Joint Commission Universal Protocol by location (n=331).

(21.2%). When examining solely OR reported adverse events, ophthalmology exhibited the highest percentage of reports followed by orthopedics, even though these 2 specialties did not have the highest percentage of OR cases. Wrong implant was the category with the most reported adverse events for ophthalmology and orthopedics (48.9% and 46.2%, respectively), but the aspect varied. Ophthalmology events typically included a lens mix-up; for orthopedics, the event was often the unpleasant surprise that the desired-size implant was not available in the OR or elsewhere in the hospital. In a recent study, others found that wrong-lens implants constituted the highest percentage of “surgical confusions” in ophthalmologic cases. Preoperative briefings, including those specifying implant and assuring availability, could help with this problem. Briefings are part of the VHA Medical Team Training program.

We need to work proactively to prevent incorrect surgical procedures; waiting until moments before “take-off” (such as during the final time-out) may, at times, be too late to correct the problem. This is consistent with the findings of Clarke et al. At moments before incision, the team may have already fixed in their mind the surgical procedure to be performed, and other factors (po-
Adverse events and close calls related to surgical procedures continue to occur. In the VHA, reports of adverse events from OR and non-OR settings have been roughly equal. This indicates that events reported in non-OR settings may have been underappreciated in previous studies.

Time-out procedures alone have not been enough to prevent incorrect surgical and invasive procedures.\(^{22}\) We advocate earlier improved communication based on crew resource management principles.\(^{22}\) Through this initial analysis, we examined event types and specialties facing the biggest challenges, based on reported data. Ophthalmology, orthopedics, pulmonary medicine, and invasive radiology cases (with particular attention to issues involving correct implant and patient verification) represent areas of highest utility for corrective actions. It is important to recognize that surgical adverse events were reported for numerous specialties and in non-OR settings. We will continue to promote early and effective communication to prevent surgical and invasive adverse events.

Accepted for Publication: October 15, 2008.

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Author Contributions: Ms Neily and Drs Mills, DePalma, and Bagian had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Neily, Eldridge, Dunn, and Bagian. Acquisition of data: Eldridge, Dunn, Samples, and Turner. Analysis and interpretation of data: Neily, Mills, Eldridge, Dunn, Samples, Turner, Revere, and DePalma. Drafting of the manuscript: Neily, Mills, Revere, and DePalma. Critical revision of the manuscript for important intellectual content: Neily, Eldridge, Dunn, Samples, Turner, DePalma, and Bagian. Statistical analysis: Mills, Eldridge, Dunn, and Turner. Administrative, technical, and material support: Neily, Eldridge, Dunn, Turner, Revere, and DePalma. Study supervision: Neily and Bagian.

Financial Disclosure: None reported.

Funding/Support: This material is the result of work supported with resources and the use of facilities at the Department of Veterans Affairs National Center for Patient Safety at Ann Arbor, Michigan, and the Veterans Affairs Medical Center, White River Junction, Vermont, and the Department of Veterans Affairs Central Office, Washington, DC.

Disclaimer: The views expressed in this article do not necessarily represent the views of the Department of Veterans Affairs or of the US government.

REFERENCES

3. Pennsylvania Patient Safety Authority. Doing the “right” things to correct wrong-
The surgical critical care team is wondering the next morning who transported the intensive care unit patient. As mography may never be reported by the nurse and in-"wrong limb is easily discoverable, the infusion pump's standards. Although there is little doubt that amputating the legal liability, pay for performance, and Internet-driven conclusion.


Patient Safety Systems: A Long Way To Go

he initiatives taken by the VHA Medical Centers toward patient safety are many and laudable. In this study, a distinguished group of authors reports on the adverse events and close calls recorded from 2001 to 2006 in the VHA database. The results uncover the most frequently involved departments (ophthalmology and orthopedics), the most frequently encountered adverse events (wrong eye implant and unavailable orthopedic implant), the most harmful adverse events (wrong-side thoracentesis by pulmonary medicine and wrong-site operations by different specialties), and the most common root cause of the problem (communication). The authors conclude that earlier communication will prevent surgical adverse events, although this is merely a hypothesis and not a data-driven conclusion.

The science of reporting adverse events in the era of legal liability, pay for performance, and Internet-driven public pressure is imperfect. Capturing, recording, and analyzing these complications obeys a few rules and standards. Although there is little doubt that amputating the wrong limb is easily discoverable, the infusion pump’s malfunction during midnight transport for computed tomography may never be reported by the nurse and intern who transported the intensive care unit patient. As the surgical critical care team is wondering the next morn-