PENNSYLVANIA PATIENT SAFETY ADVISORY

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IN THIS ISSUE

Reviews & Analyses

69 **Adverse Drug Events with HYDROmorphone: How Preventable are They?**
Gaps exist in healthcare providers' understanding of the efficacy and potency of HYDROmorphone, as evidenced by medication errors and adverse drug reactions reported in Pennsylvania.

76 **Diagnostic Error in Acute Care**
Misdiagnosis-related harm is preventable. Healthcare facilities have many strategies at their disposal that can help reduce diagnostic error rates.

87 **Hemodialysis Administration: Strategies to Ensure Safe Patient Care**
Without attention to patient safety and error prevention, even a well-established procedure like hemodialysis can result in an adverse event.

97 **Strategies for Avoiding Problems with the Use of Pneumatic Tourniquets**
Failure or misuse of pneumatic tourniquets can lead to muscle ischemia, nerve damage, convulsions, and coma. Addressing cuff availability and educating staff about cuff selection, application, and inflation pressure are fundamental strategies to avoid complications.

Focus on Infection Control

102 Demonstrating Return on Investment for Infection Prevention and Control

Update

108 Quarterly Update on the Preventing Wrong-Site Surgery Project

Other Features

111 Satisfying Educational Needs with the Pennsylvania Patient Safety Authority Web Site

Corrections

112 Beyond the Bundle: Reducing the Risk of Central Line-Associated Bloodstream Infections

112 Medication Errors: Significance of Accurate Patient Weights

About the Pennsylvania Patient Safety Advisory

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.

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Adverse Drug Events with HYDROmorphone: How Preventable are They?

ABSTRACT

Despite the fact that HYDROmorphone (Dilaudid®) is widely used, there appear to be gaps in understanding its efficacy and potency, which can lead to serious medication errors. Analysts reviewed medication errors and adverse drug reactions (ADR) involving HYDROmorphone that were reported to the Pennsylvania Patient Safety Authority. Seventy percent of the wrong drug reports involved mix-ups with morphine. Wrong dose/overdosage medication error reports show that the most common nodes associated with this event type are administering, prescribing, and dispensing. Review of ADR reports shows that the most common reactions reported involved central nervous system reactions and/or respiratory complications. Sixty-five percent of these adverse reactions appear to have been preventable events. Effective risk reduction strategies include establishing standardized protocols for pain management and protocols for reversal agents that can be administered without additional physician orders when warranted, as well as requiring an independent double check before administering intravenous HYDROmorphone doses. (Pa Patient Saf Advis 2010 Sep;7[3]:69-75.)

Introduction

HYDROmorphone (Dilaudid®) is a semisynthetic opioid agonist and a derivative of morphine. It differs pharmacodynamically from its parent drug in potency, onset, duration, and the presence of an active metabolite, but the analgesic effect is the same.[1]

HYDROmorphone is used for moderate to severe pain. Historically, it was only used to treat chronic pain (e.g., cancer pain), but it is now widely used in the management of acute pain, including postoperative pain, acute trauma pain, and other indications.[2,3] HYDROmorphone is usually used as an alternative for morphine in patients who cannot tolerate morphine or cannot achieve adequate analgesia with morphine. Although HYDROmorphone is a potent analgesic, to date, there is no evidence to support its superiority over morphine for the management of moderate to severe pain.[2]

HYDROmorphone can be administered by various routes including intravenous (IV), intramuscular (IM), epidural, and oral routes.[4] The onset of action after an IV dose is 5 minutes and peaks in approximately 20 minutes, which is useful in postoperative patients who require postoperative analgesia.[5] The duration of action ranges from four to five hours.[6]

Despite the fact that HYDROmorphone has been around for decades and is widely used, there appear to be gaps in understanding the efficacy and potency of HYDROmorphone.[2] Clinical studies comparing IV morphine and HYDROmorphone are scarce.[5] However, studies have shown that HYDROmorphone, by any route, is a much more potent mu-opioid receptor agonist than morphine.[5] This difference in potency makes it difficult to compare morphine and IV HYDROmorphone. Most of the doses in equi-analgesic charts are, often times, based on single dose studies, and the exact potency equivalence ratios are uncertain.[4] The estimated relative potency of IV HYDROmorphone compared to IV morphine is 7.5:1; recent reviews of opioid conversions find ratios ranging from around 4:1 to as high as 8:1.[5] For example, an order for an opioid-naïve patient for 2.5 mg to 5 mg of IV morphine would be equivalent to 0.3 mg to 0.67 mg of HYDROmorphone.

The literature has various and inconsistent recommendations about the appropriate starting dose and frequency of administration for HYDROmorphone. For example, HYDROmorphone's product label states that the initial IV dose for opioid-naive patients is 1 mg to 2 mg IV (slowly) every four to six hours as needed.[7] However, there is literature that recommends *against* using 2 mg IV as a starting dose even in nonelderly patients. Chang et al. showed that one-third of adult, nonelderly patients who received 2 mg presented to the emergency department (ED) complaining of acute severe pain and developed oxygen desaturation.[8] In 2002, one drug information reference publisher, Lexi-Comp, revised its HYDROmorphone dosing recommendations based on advice from clinical experts. For opioid-naïve patients, the revised monograph states: "IV: Initial: 0.2-0.6 mg every 2-3 hours as needed; patients with prior opioid exposure may tolerate higher initial doses. Patient controlled analgesia (PCA): Initial: Opioid-naive: Consider lower end of dosing range; after loading: 0.05-0.4 mg/dose; usual lockout range: 5-10 minutes."[9]

The lack of knowledge about HYDROmorphone potency and the difference in potency between morphine and HYDROmorphone has frequently led to serious medication errors, especially when a patient is switched from morphine to HYDROmorphone.[10] In a prospective, randomized, double-blind, clinical trial conducted in an academic medical center of 198 adult patients presenting to the ED with acute severe pain, Chang et al. observed that many of the center's emergency physicians and nurses were hesitant to give 7 mg to 10 mg of morphine as an initial IV dose. In contrast, they observed that these same healthcare providers were not similarly reluctant to administer a roughly equi-analgesic dose of HYDROmorphone (1 mg to 1.5 mg), perhaps because the more potent HYDROmorphone is given in much smaller milligram quantities than morphine, thus providing the illusion that substantially less opioid is

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being administered to the patient.[11] In a prospective interventional cohort study to evaluate the safety and efficacy of 2 mg IV HYDROmorphone administered to nonelderly adult (i.e., 21 to 64 years of age) ED patients in acute severe pain, Chang et al. noted that the lower milligram amount of HYDROmorphone causes less concern among providers and leads, albeit inadvertently, to better analgesia for patients.[8] However, this difference in perception could contribute to harm to patients. In its 2007 Advisory, the Commonwealth of Massachusetts Board of Registration in Medicine reported four patient deaths resulting from the administration of 2 mg to 4 mg of HYDROmorphone as a bolus, with repeat doses of 1 mg to 4 mg.[12]

An adverse drug event (ADE) is defined by the Joint Commission as "any incident in which the use of a medication (drug or biologic) at any dose, a medical device, or a special nutritional product (e.g., dietary supplement, infant formula, medical food) may have resulted in an adverse outcome in a patient."[13] ADEs can be divided into two categories: (1) medication errors, which are considered to be *preventable* ADEs and (2) adverse drug reactions (ADR), which are considered to be *unpreventable* ADEs. Despite this distinct difference in definition, ADR reports may be a source of potentially preventable events, even though the reporter thought the ADE could *not* have been prevented. This article presents an analysis of both medication errors and ADRs involving HYDROmorphone reported to the Pennsylvania Patient Safety Authority and discusses the predominant types of events involving HYDROmorphone.

Medication Errors with HYDROmorphone

Pennsylvania healthcare facilities submitted 1,694 medication error reports to the Authority from January 2008 to October 2009 that described medication errors involving the use of HYDROmorphone. Categorization of the reports by harm score, which is adapted from the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) harm index,[14] shows that 68.2% (n = 1,155) of the events reached the patient (harm index = C to I) and 1.8% (n = 30) of the events resulted in patient harm (harm index = E to I). The care areas most often cited in these reports include medical/surgical units (26.5%, n = 449), pharmacy (15.1%, n = 255), and ED (5.8%, n = 99). The majority of the reports, almost 70% (n = 1,179), involved the adult population between the ages of 17 and 64, while 1.7% (n = 28) involved pediatric patients (ages less than 17 years).

The predominant medication error event types associated with HYDROmorphone (see Table 1) were wrong dose/overdosage (16.9%, n = 287), wrong drug (10.9%, n = 185), and monitoring error/documented allergy (8.1%, n = 137).

Wrong-Drug Errors with HYDROmorphone

In 2007, a review of 8,400 wrong drug medication error reports submitted to the Authority showed that the most commonly involved drug pair was morphine and HYDROmorphone.[15] Present analysis of wrong drug medication errors mentioning HYDROmorphone reveals that 70% involve mix-ups with morphine. (See Table 2.)

Facilities did not enter enough detail into most of the event descriptions to determine all the reasons why these events took place. It was not possible to categorize and determine the most common types (e.g., wrong drug written by prescriber, wrong drug selected during order entry, wrong drug retrieved from stock, drug mislabeled in the pharmacy) of reported wrong-drug errors. Examples of reports with limited information regarding the causes and contributing factors of the events include the following:

Patient was inadvertently given Dilaudid 1 mg by intravenous push (IVP) instead of morphine 2 mg IVP as ordered.

Patient prescribed Dilaudid 1mg IV but was given Demerol® 2.5 mg IV.

Analysts were able to determine the following:

- Of the reports of wrong drug HYDROmorphone errors, 146 (78.9%) specifically mentioned that the breakdown occurred in the administration node.

Table 1. Predominant Medication Error Event Types Associated with the Use of HYDROmorphone (n = 1,135, 67%), January 2008 to October 2009

EVENT TYPE	NUMBER	% OF TOTAL REPORTS (N = 1,694)
Wrong dose/overdosage	287	16.9%
Wrong drug	185	10.9
Monitoring error/ documented allergy	137	8.1
Wrong route	131	7.7
Wrong dose/underdosage	106	6.3
Other (specify)	289	17.1

Table 2. Predominant Medications Associated with Wrong Drug Errors involving HYDROmorphone (n = 146, 78.9%), January 2008 to October 2009

MEDICATION PRESCRIBED	MEDICATION ADMINISTERED	NUMBER	% OF TOTAL REPORTS (N = 185)
HYDROmorphone	morphine	66	35.7%
morphine	HYDROmorphone	63	34.1
HYDROmorphone	lorazepam	6	3.2
HYDROmorphone	meperidine	6	3.2
oxycodone	HYDROmorphone	5	2.7

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A patient was admitted to the ED for chest pain. The ED physician ordered morphine 2 mg, but the patient instead received Dilaudid 2 mg. The morphine and Dilaudid were located next to each other in the narcotic drawer.

- Twenty-seven (14.6%) of the reports involved the dispensing or storage of the wrong medication by the pharmacy.

A nurse went to administer a "prn" dose of Dilaudid to the patient. The nurse found 24 vials of medication in the drawer: 20 were Dilaudid, but 4 were morphine sulfate. The RN [registered nurse] had previously given patient a "prn" dose of Dilaudid but is not sure if the dose was Dilaudid or morphine.

The pharmacist dispensed morphine PCA [patient-controlled analgesia] (as seen on manufacturer's labeling) with a pharmacy label for HYDROmorphone PCA. The patient was to have HYDROmorphone. The nurse receiving the PCA did not catch it, but another nurse, who was about to hang it on the patient, did catch it. The morphine did not reach patient.

- Thirty-five (18.9%) of wrong drug administration errors involved PCA therapy.

At the beginning of night shift, the nurse noticed the patient was very sleepy and found it hard to keep the patient awake. The nurse notified the resident on call and received a verbal order to change the rate of the morphine PCA from a basal rate of 2.8 mg/hr to 1 mg/hr and to continue the "as needed" dose at 1 mg every five minutes. When the nurse and the verifying nurse opened the PCA machine to change the settings, the nurses saw that instead of the syringe being morphine 1 mg/mL, [it] was HYDROmorphone 0.2 mg/mL. The infusion was immediately stopped and vital signs were taken, which were stable.

Wrong Dose/Overdosage Errors

Wrong dose/overdosage medication error reports involving HYDROmorphone show that the most common nodes associated with this event type are administering (67.9%, n = 195), prescribing (18.8%, n = 54), and dispensing (6.6%, n = 19).

Administration. Analysis of the descriptions of events that occurred during the administration node shows that most of the reported cases did not give enough detail to determine specifically what went wrong but simply stated that the patient received a higher dose than what was intended (57.4%, n = 112). However, analysts were able to determine the following for wrong drug/overdosage events occurring in administration node:

Fifty-two (26.7%) reports involved PCA therapy.

A patient had an order for a PCA pump. The pump was programmed for morphine (1 mg/mL) instead of Dilaudid (0.2 mg/mL). Dilaudid was the prescribed medication. We are unsure of how much medication the patient received because all of the settings were not right.

Fifty-seven (29.2%) reports involved programming errors or failure to change the program of an infusion device (both PCA and general infusion pumps).

The patient was on a standard 1 mg/mL of Dilaudid, but an automatic substitution of a 5 mg/mL concentration was sent due to the high dose requirement of patient. The nurse did not reprogram PCA pump, which led [to respiratory distress].

Nineteen (9.7%) reports mentioned problems documenting and/or witnessing "wasting" amounts of HYDROmorphone.

Prescribing. A majority of the HYDROmorphone overdoses that occurred during the prescribing node involved orders for a wrong dose (79.6%, n = 43), followed by an incorrect frequency (18.5%, n = 10). For example, some reports indicated orders were written without designating that HYDROmorphone should be given "as needed," which could have led to the administration of this medication more frequently than was needed.

The prescriber wrote for every five-minute dosing of hydromorphone tablets (2 mg) prn. When contacted, the physician assistant prescriber intended "every 6-hour PRN" dosing. The order was discontinued and rewritten.

An order was written for 1.5 mg/hour of hydromorphone with a 1.5 mg bolus every 10 minutes instead of a bolus of 0.3 mg every 10 minutes. The patient received 16.8 mg over a six-hour period and then was found unresponsive.

An order was written for a postoperative patient to receive 1 mg Dilaudid PCA every 15 minutes with a 16 mg 4-hour dose limit. This was a high dose (usual 0.1 mg to 0.2 mg), which was dispensed; the nurse questioned the order. The original prescriber insisted on the dose, and the nurse then brought the order to the attention of the director of anesthesia, who did not change the order. The patient received the dose as ordered and became difficult to arouse. The PCA order was changed by another prescriber to 0.2 mg every 8 minutes.

It should be noted that 14.8% (n = 8) of the wrong dose prescribing errors involved dangerous dose designations, such as failure to write a dose with a leading zero.

An order was written for "Dilaudid .2 mg IV q 1hr prn pain" without a leading zero, and it was difficult to see if there was a decimal point. The ordering physician was called but was no longer in the hospital. The covering physician returned the call and asked for clarification. That physician asked what is usually given and the nurse replied "2 mg," so the order was clarified as "2 mg." The nurse administered the 2 mg, which led to severe respiratory depression. The covering physician contacted the ordering physician, who intended for the order to be "0.2 mg."

ADR Reports

HYDROmorphone has the typical opioid associated side effects, including light-headedness, dizziness,

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sedation, nausea, vomiting, sweating, flushing, dysphoria, euphoria, dry mouth, and pruritus.[7] HYDROmorphone binds to mu-receptors to produce its analgesic effect. However, it also binds to mu-receptors in the respiratory centers of the medulla, which can lead to clinically significant respiratory depression.[16] Some of the factors that raise patients' risk of harm from opioid-induced respiratory depression include older age (i.e., 65 years of age or older), diseases affecting the respiratory (e.g., asthma, chronic obstructive pulmonary disease) or cardiovascular systems, concomitant use of respiratory-function depressants other than opioids, opioid-naïve patients who are overweight, and patients with sleep disorders (e.g., sleep apnea).[17]

Analysts reviewed ADR reports submitted to the Authority to determine if there were cases that may have been preventable (e.g., errors caused by an excess dose of HYDROmorphone). Analysts searched for "HYDROmorphone" or "Dilaudid" in the suspected medication, other medication, and the event description fields to find ADR reports that may have involved HYDROmorphone alone or in combination with other medications.

There were 937 ADR reports submitted to the Authority between June 2004 and October 2009. Almost 90% (n = 842) of the ADR reports discussed events that were considered to have *not* harmed patients. The three most common broad categories of reactions described in the narratives include allergic reactions, respiratory depression, and central nervous system effects (see Table 3). It was expected that the most common reported type of reactions would have been allergic reactions (38.5%, n=361); for example, patients that experienced itching, rashes, and hives. However, the most common types of reactions reported were events (47.9%, n = 449) in which patients experienced central nervous system reactions (e.g., decreased level of consciousness, oversedation, mental status changes) and/or respiratory complications (e.g., shortness of breath, respiratory depression, respiratory arrest), a known consequence of the drug.

Reports that specifically mentioned a central nervous system and/or respiratory ADR were analyzed to determine if the reaction could have been preventable (e.g., caused by an inappropriate dose ordered, caused by a combination of medications with additive sedative effects with HYDROmorphone). For this analysis, an inappropriate dose was considered to be a dose that was one of the following:

- Greater than a 1 mg dose for the general adult population for an opioid-naïve patient
- 1 mg or greater for an elderly patient who was opioid-naïve
- A frequency of administration that allowed for the administration of HYDROmorphone too frequently for that patient population

Table 3. Predominant Adverse Drug Reaction Categories Associated with the Use of HYDROmorphone, June 2004 to October 2009

EVENT TYPE	NUMBER	% OF TOTAL REPORTS (N = 937)
Central nervous system and/or respiratory depression	449	47.9
Allergic reactions	361	38.5
Nausea/vomiting	39	4.2
Unknown/reaction not specified	34	3.6

Analyses of these events reveal problems with the prescribing of inappropriate doses and multiple medications that have sedative properties. Of the reported central nervous system and respiratory adverse reactions, 292 (65%) appear to have been preventable events, in which patients received a dose in excess of what would be needed to resolve pain symptoms or in which HYDROmorphone was prescribed and administered with other medications that would lead to additive sedative effects.

Overall, 205 (70.2%) of the identified preventable ADR reports that mentioned central nervous system and/or respiratory depressive type reactions to HYDROmorphone were due to inappropriate doses, with 44 (15.1%) of the reports demonstrating problems due to a combination of inappropriate dosing and the prescribing of multiple medications with a sedative side effect profile. (See Table 4.)

Examples of identified "preventable" ADR reports include the following:

> *An elderly patient was admitted with left leg edema ulcerations with significant pain. Within an eight-hour period, the patient received morphine 2 mg IV, Dilaudid 2 mg IV two times, and was started on a Duragesic® (fentanyl) patch. One hour later, the patient was found unresponsive. Narcan® was given, and the patient responded immediately; pulse oximetry was monitored and was 100%. The Dilaudid prn order was discontinued, the Duragesic patch remained on, and the patient had no further episodes of unresponsiveness.*

> *An adult patient was admitted with a right ureter stone. An order was written for Dilaudid 4 mg IV every three hours prn. The patient received a total of three doses within a six-hour time period. Two hours later, the patient was speaking with staff, but within a half hour, the patient was found unresponsive with shallow breathing and a faint heart rate of 40. A code was called, and atropine and Narcan (naloxone) was administered with good response. The patient was transferred to the intensive care unit for further care.*

> *An adult patient was admitted with abdominal pain and received Demerol® (meperidine) 25 mg IV push*

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Table 4. Common "Preventable" Adverse Drug Reaction Categories Associated with the Use of HYDROmorphone (n = 284, 97.3%), June 2004 to October 2009

EVENT TYPE	NUMBER	% OF TOTAL REPORTS (N = 292)
Inappropriate doses	205	70.2%
Inappropriate doses and multiple drugs	44	15.1
Multiple drugs	26	8.9
Inappropriate doses and contraindicated	9	3.1

at noon and 2 p.m., followed by Dilaudid 2 mg IV push at 2 p.m., 3 p.m., 4 p.m., and 6 p.m. At 7 p.m., the patient was found with shallow respirations and difficult to arouse. The patient responded to Narcan, and the orders were changed to Dilaudid 1 mg IV every 2 hours prn.

An elderly postoperative patient received Ativan® 0.5 mg IV at 4:20 p.m. and Dilaudid 2 mg IV at 6 p.m. and 9 p.m. At 11 p.m., the patient experienced decreased level of consciousness and required 2 mg of Narcan IV with immediate response.

An elderly patient in the postanesthesia care unit, following a left laparoscopic colectomy, received fentanyl 125 mcg, Dilaudid 2 mg, and morphine 4 mg within a one-hour time period. Four hours later, on the postoperative surgical unit, the patient required Narcan 1 mg for decreased respirations and oversomnolence.

An elderly patient, admitted with back pain, received morphine 4 mg and a total of 2 mg of Dilaudid within a six-hour period in the ED. When the patient arrived to the nursing unit, the patient's heart rate was 120 and oxygen saturation was 80% on room air. The staff was unable to keep the patient awake. The patient was transferred to a monitored bed for closer monitoring.

Risk Reduction Strategies

Healthcare facilities can strive to identify system-based causes of wrong drug and wrong dose/overdose errors with the use of HYDROmorphone and other opioids and implement effective types of risk reduction strategies to prevent harm to patients. Risk reduction strategies such as constraints and standardization, which focus on system improvement, will be more effective than education alone, which relies on individual performance. Consider the strategies described below, which are based on a review of events submitted to the Authority, observations at the Institute for Safe Medication Practices, and the literature.

Constraints

- Prescribing
  - Consider requiring prescribers to undergo a privileging process to verify proficiency with PCA pain management.[18]
  - Implement standard order sets for PCA therapy, with all sections completed, and limit verbal orders to dose changes.[18]
  - Avoid the use of basal rates with PCA for pain control of an opioid-naïve patient.[19,20]
  - Take into consideration important information about the patient that could affect the prescribing of HYDROmorphone (e.g., patient's current medication profile for drugs with additive central nervous system or respiratory depressant side effects, age, renal function, total current opioid therapy). For a list of HYDROmorphone's contraindications for use and other warnings, see "Prescribing Considerations for HYDROmorphone" available at http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx.
- Storage
  - Reduce stock amounts of HYDROmorphone wherever possible, and eliminate it from floor stock entirely if usage is low.[21]
  - Avoid stocking morphine and HYDROmorphone in the same strength if both drugs are available in patient care units. For example, since both drugs are available in 2 mg and 4 mg prefilled syringes, stock HYDROmorphone 2 mg and morphine 4 mg (but not vice versa, since 4 mg of HYDROmorphone would be an excessive dose for most patients, especially opioid-naïve patients).[21]
  - If the drugs are stored in an automated dispensing cabinet (ADC), consider allowing access to morphine via an override function in emergencies, but require pharmacy order review before removing an initial dose of HYDROmorphone.[21]
  - Store each medication in a separate, individual bin or drawer in the cabinet to help prevent drug selection errors. In the pharmacy, segregate prefilled syringes and vials of these drugs, especially if they contain the same concentration.[21]

Standardization

- Establish protocols for pain management, including a standard pain scale for assessment, guidelines for the use of specific analgesics, standard order forms and screens, guidelines outlining conditions that require a dose reduction, and requirements for monitoring.[21]
- Establish protocols for reversal agents that can be administered without additional physician orders when warranted.[19]
- In standard order forms, guide prescribers to an appropriate dose based on age and opioid tolerance by providing default doses for three types of patients: (1) most patients, (2) patients older than 64 years or with sleep apnea, and (3) opioid-tolerant patients.[20]

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- Consider other medications that the patient has received (e.g., analgesics taken at home, intraoperative medications) or currently has been prescribed (e.g., antihistamines, nighttime sedatives) when determining appropriate doses.[18]

Differentiation

- When able, use tall man lettering to emphasize the "HYDRO" portion of HYDROmorphone on pharmacy labels, auxiliary labels, medication administration records, and drug listings on computer screens or ADCs.[21]
- Consider adding label reminders on HYDROmorphone indicating the brand name equivalent, "DILAUDID," to help prevent confusion with other drugs such as morphine. Some ADCs may also offer the capability of asking "This is DILAUDID. Is that correct?" when nurses retrieve HYDROmorphone.[21]

Redundancies

- Require an independent double check before administering IV HYDROmorphone doses. Since nurses routinely obtain narcotics from floor stock, the typical pharmacist-nurse double check is not in place (as it is with specific patient doses dispensed from the pharmacy). Some ADCs can be programmed to require a witness when selected narcotics are removed or when the override feature is used to access selected narcotics. Reminders can also appear on the screen.[21]

Patient Monitoring

- Establish guidelines for appropriate monitoring of patients who are receiving opioids, including frequent assessment of the quality of respirations (not just a respiratory rate) and specific signs of oversedation. Ensure resources—both personnel and equipment—are available to monitor patients per established guidelines.[19]
- Use standardized formats for documenting pain control and monitoring parameters.[19]
- Ensure that oxygen and naloxone are available where opioids are administered.[19]
- Establish a process to screen patients for obstructive sleep apnea before initiation of PCA therapy, with further assessment by a respiratory therapist if the screening reveals two or more risk factors.[20]

Education and Information

- Require annual competence assessments for all professionals who prescribe, dispense, and administer PCA.[18]
- Create mandatory education programs *for all practitioners* potentially involved with HYDROmorphone use. Include all aspects of safe use; accepted prescribing practices, including those related to the management of the opioid-naïve patient; dosing norms; assessment parameters; and monitoring techniques.
- Provide staff with safety information on the use of potent narcotics via newsletters and in-services. Educate staff about the differences between HYDROmorphone and morphine, as some of the reported mix-ups have been due to the mistaken belief that HYDROmorphone is the generic name for morphine.[21]

Monitoring of ADRs

- As demonstrated by the analysis of ADR reports submitted to the Authority, these reports serve as a potentially rich source of information to identify risk with the use of HYDROmorphone, as well as other opioids in the facility. Consider reviewing ADR reports, as well as the use of "trigger" drugs used to reverse the effects of opioids, like naloxone, to get a broader picture of the harm resulting from the misuse of HYDROmorphone.
- Consider measures other than practitioner reporting of medication errors to evaluate your organization's safe use of HYDROmorphone, including assessing core processes associated with HYDROmorphone use by using process measures.

Visit the Authority's Web site at http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx to view or download a sample tool that can be used to identify and monitor actual or potential problems with the use of HYDROmorphone.

Notes

1. Hill HF, Coda B, Tanaka A, et al. Multiple-dose evaluation of intravenous hydromorphone pharmacokinetics in normal human subjects. *Anesth Analg* 1991 Mar;72(3):330-6.
2. Quigley C. Hydromorphone for acute and chronic pain. *Cochrane Database Syst Rev* 2002;(1):CD003447.
3. Murray A, Hagen N. Hydromorphone. *J Pain Symptom Manage* 2005 May;29 (5 Suppl):S57-66.
4. Sarhill N, Walsh D, Nelson KA. Hydromorphone: pharmacology and clinical applications in cancer patients. *Support Care Cancer* 2001 Mar;9(2):84-96.
5. Hong D, Flood P, Diaz G. The side effects of morphine and hydromorphone patient-controlled analgesia. *Anesth Analg* 2008 Oct;107(4):1384-9.
6. Lexi-Comp Online. Hydromorphone [online]. 2010 [cited 2010 Jul 8]. Available from Internet: http://online.lexi.com/crlsql/servlet/crlonline.
7. Purdue Pharma Pharmaceuticals, Inc. Dilaudid® (hydromorphone) [full prescribing information online]. 2008 Jun [cited 2010 Jul 15]. Available from Internet: http://www.purduepharma.com/pi/prescription/DilaudidHP_Injection_Lyophilized_Powder_PI.pdf.
8. Chang AK, Bijur PE, Napolitano A, et al. Two milligrams i.v. hdyromorphone is efficacious for treating pain but is associated with oxygen desaturation. *J Opioid Manag* 2009 Mar-Apr;5(2):75-80.
9. Institute for Safe Medication Practices (ISMP). Safety brief. *ISMP Med Saf Alert* 2002 Oct 30;7(22):1.
10. Inadvertent mix-up of morphine and hydromorphone: a potent error. PA PSRS Patient Saf Advis [online] 2007

Sep [cited 2010 Jun 17]. Available from Internet: http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2007/sep4(3)/Pages/86.aspx.

11. Chang AK, Bijur PE, Meyer RH, et al. Safety and efficacy of hydromorphone as an analgesic alternative to morphine in acute pain: a randomized clinical trial. *Ann Emerg Med* 2006 Aug;48(2):164-72.
12. Commonwealth of Massachusetts Board of Registration in Medicine. Hydromorphone: Patient safety concerns with hydromorphone versus morphine [online]. Advisory 2007 May [cited 2010 Jul 8]. Available from Internet: http://www.massmedboard.org/pca/pdf/hydromorphone_advisory.pdf.
13. Joint Commission. Sentinel event glossary of terms [online]. Sentinel Event Alert 2006 Jan 26 [cited 2010 Jun 18]. Available from Internet: http://www.jointcommission.org/sentinelevents/se_glossary.htm.
14. National Coordinating Council for Medication Error Reporting and Prevention. NCC MERP index for categorizing medication errors [online]. 2001 [cited 2010 Jun 18]. Available from Internet: http://www.nccmerp.org/medErrorCatIndex.html.
15. Common medication pairs that contribute to wrong drug errors. PA PSRS Patient Saf Advis [online] 2007 Sep [cited 2010 Jun 17]. Available from Internet: http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2007/sep4(3)/Pages/89.aspx.
16. Smith LH. Opioid safety: is your patient at risk for respiratory depression? *Clin J Oncol Nurs* 2007 Apr;11(2):293-6.
17. Pergolizzi J, Boger RH, Budd K, et al. Opioids and the management of chronic severe pain in the elderly: consensus statement of an International Expert Panel with focus on the six clinically most often used World Health Organization Step III opioids (buprenorphine, fentanyl, hydromorphone, methadone, morphine, oxycodone). *Pain Pract* 2008 Jul-Aug;8(4):287-313.
18. Institute for Safe Medication Practices (ISMP). Safety issues with patient-controlled analgesia. Part II—how to prevent errors. *ISMP Med Saf Alert* 2003 Jul 24;8(15):1-2.
19. Institute for Safe Medication Practices (ISMP). High-alert medication feature: reducing patient harm from opioids. *ISMP Med Saf Alert* 2007 Feb 22;12(4):2-3.
20. Institute for Safe Medication Practices (ISMP). Beware of basal opioid infusions with PCA therapy. *ISMP Med Saf Alert* 2009 Mar 12;14(5): 1-2.
21. Institute for Safe Medication Practices (ISMP). Risk of deadly mix-up exists in most hospitals. *ISMP Med Saf Alert* 2004 Jul 1;9(12):1-2.

Self-Assessment Questions

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

A physician wrote an order for a 67-year-old opioid-naïve patient for HYDROmorphone 4 mg intravenous (IV) administration as needed for pain. The patient received one dose and was later found with a low oxygen saturation, low respiratory rate, and decreased responsiveness. The doctor was notified, and naloxone IV was administered to this patient.

1. What is the equianalgesic dose of morphine IV for this patient?
   a. 4 mg
   b. 7 mg
   c. 15 mg
   d. 30 mg
2. HYDROmorphone is to be started at lower doses when administered to all of the following patient populations EXCEPT:
   a. Elderly patients
   b. Patients with respiratory diseases (e.g., chronic obstructive pulmonary disease, obstructive sleep apnea)
   c. Diabetic patients
   d. Opioid-naïve patients
3. The most commonly reported type of medication error involving the prescribing of HYDROmorphone was:
   a. Prescribing HYDROmorphone for patients with a pre-existing documented allergy to an opioid
   b. Prescribing HYDROmorphone when it is contraindicated for that patient
   c. Prescribing a wrong dose of HYDROmorphone
   d. Prescribing HYDROmorphone for the wrong patient
4. The most commonly reported type of adverse drug reaction related to HYDROmorphone was:
   a. Allergic reaction
   b. Central nervous system/respiratory events
   c. Nausea and vomiting
   d. Seizures
5. The following strategies may help to mitigate the risk of harm from HYDROmorphone. Select the *least* effective strategy.
   a. Adding label reminders on HYDROmorphone indicating the brand name equivalent, "DILAUDID," to help prevent confusion with other drugs such as morphine.
   b. Separating the storage of look-alike opioids.
   c. Standardize protocols and concentrations for HYDROmorphone.
   d. Implement redundancies and double checks in the administration process of HYDROmorphone.

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Diagnostic Error in Acute Care

ABSTRACT

Errors related to missed or delayed diagnoses are a frequent cause of patient injury and, as such, are an underlying cause of patient safety related events. Autopsy series spanning several decades reveal error rates of 4.1% to 49.8%. Diagnostic errors are encountered in every specialty and are generally lowest, at less than 5%, for perceptual specialties (e.g., radiology, pathology, dermatology) that rely heavily on visual pattern recognition and interpretation. Error rates in other clinical specialties are higher, ranging from 10% to 15%, which is consistent with the added demands of data gathering and synthesis. Additionally, diagnostic errors are frequently the leading or second leading cause of malpractice claims in the United States, accounting for twice as many alleged and settled claims as medication errors. Studies have shown that cognitive errors and system design flaws—especially communication issues—all contribute to diagnostic error. This article reviews the common causes of diagnostic error, the clinical diagnoses most often affected by diagnostic errors, and risk reduction strategies that facilities, diagnosing physicians, and patients themselves can undertake to decrease diagnostic error and increase patient safety. (Pa Patient Saf Advis 2010 Sep;7[3]:76-86.)

During the last decade, much emphasis has been placed on system solutions to patient safety problems. Hospitals have focused on important issues to mitigate patient harm, including re-engineering systems, improving the culture of safety, reducing communication barriers, and improving patient handoffs. However, diagnostic error, despite being responsible for twice as many adverse events as medication error,[1] has received little attention.

Diagnostic error is a diagnosis that is missed, incorrect, or delayed, as detected by a subsequent definitive test or finding.[2] Not all misdiagnosis results in harm and harm may be due to either disease or intervention. Misdiagnosis-related harm is preventable harm that results from the delay or failure to treat a condition actually present when the working diagnosis was either wrong or unknown or from treatment provided for a condition not actually present. Misdiagnoses represent a substantial unmeasured source of preventable mortality, morbidity, and costs.[3] However, it is not possible to focus on misdiagnosis-related harm without first understanding the broader issue of diagnostic error.

The Pennsylvania Patient Safety Authority's taxonomy does not include a category for diagnostic error, and because only those diagnostic errors associated with a Serious Event (i.e., an event resulting in patient harm) or an Incident (i.e., a near miss or no harm event) are submitted, it is not possible to quantify diagnostic error in Pennsylvania with adverse event reports. Similarly, the Agency for Healthcare Research and Quality (AHRQ) Common Formats—the common definitions and reporting formats that allow healthcare providers to collect and submit standardized information regarding patient safety events—does not include a category specifically for diagnostic error (see http://www.pso.ahrq.gov/formats/commonfmt.htm). Nonetheless, the Authority reviewed exactly 100 events related to diagnostic error reported between June 2004 and November 2009 in an effort to determine if there were system solutions to diagnostic error, or if diagnostic error was so intimately connected to physicians' cognitive processing that system solutions were not tenable. These events were found by searching on terms such as delayed diagnosis, wrong diagnosis, missed diagnosis, misdiagnosed, failure to diagnose, failure to treat, and medical follow-up.

Statistics

Errors related to missed or delayed diagnoses are a frequent cause of patient harm. In 2003, a systematic review of 53 autopsy studies from 1966 to 2002 was undertaken to determine the rate at which autopsies detect important, clinically missed diagnoses. Diagnostic error rates were 4.1% to 49.8% with a median error rate of 23.5%.* Furthermore, approximately 4% of these cases revealed lethal diagnostic errors for which a correct diagnosis coupled with treatment could have averted death.[4] Other autopsy studies have shown similar rates of missed diagnoses; one study reported the rate to be between 10% to 12%[5], while another placed it at 14%.[6] Autopsies are considered the gold standard for definitive evidence of diagnostic error, but they are being performed less frequently and provide only retrospective information.

Diagnostic error is encountered in every specialty. A 2008 review of diagnostic error studies showed a diagnostic error rate of less than 5% in the specialties of pathology, dermatology, and radiology, all of which rely heavily on visual interpretation, and from 10% to 15% in most other fields, where data gathering and synthesis play a much stronger role. The rate of diagnostic error in the emergency department (ED) is reported to be between 0.6% and 12%.[7]

* Of the 11 studies with error rates exceeding 30%, 5 involved special populations (e.g., surgical patients, adult inpatients with AIDS, inpatients older than 85 years of age), and 5 were studies of general adult inpatients with overall autopsy rates lower than 31% (ranging from 12% to 100%), indicating, perhaps, that autopsies were performed primarily on cases with a higher level of suspicion for misdiagnosis to begin with. The remaining study was of medical patients with an autopsy rate of 47% and an error rate of 41%.[4]

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In the Harvard Medical Practice Study, physician errors resulting in adverse events were more likely to be diagnostic (14%) than drug-related (9%), and of these adverse events, misdiagnoses (75%) were more likely to be considered negligent than others (53%).[8] Diagnostic errors are also a leading cause of malpractice litigation, accounting for twice as many claims and settled cases as medication errors. In an analysis of 254 high-severity patient injury cases reported from January 2005 through July 2007, CRICO/RMF found that diagnostic error-related cases accounted for the majority of the top five claims categories: diagnostic error (44%), surgical (17%), medical (15%), obstetrics (11%), and medications (5%). The analysis also found that these cases cost the company more than all other categories combined—$127 million for diagnostic error versus $123 million for all other categories combined.[1]

In 2007, the Agency for Healthcare Research and Quality (AHRQ) identified diagnostic error as an area of special emphasis. AHRQ found that diagnostic error comprised a substantial, costly portion of all medical errors and had resulted in distressing consequences for patients, families, and healthcare professionals. Furthermore, diagnostic error encompassed a broad array of factors including cognitive and systems (e.g., education, training, setting-of-care, disease-specific, domain-specific) issues.[9] Subsequently, AHRQ sponsored research regarding diagnostic error through the Diagnostic Error Evaluation and Research (DEER) project. In 2009, research funded by this grant, in the form of analysis of physician reported errors (n = 583; convenience sample), revealed that 28% of the reported diagnostic errors were rated as major, resulting in patient death, permanent disability, or a near-life-threatening event.[10]

Despite these statistics, diagnostic error remains an underemphasized area of patient safety, being both difficult to detect and to dissect. Detection is difficult for several reasons. First, misdiagnosed patients who have not been harmed may never be known, as there are few, if any, systems designed to detect and uncover benign diagnostic error. Second, even those patients who have been harmed through diagnostic error might simply leave a practice, a physician, or a hospital and seek care elsewhere, hindering the ability to aggregate and study diagnostic error data. Finally, individual physicians may never know the true extent of their own diagnostic error rates; feedback loops regarding misdiagnoses are simply inadequate. It has been argued that the lack of these formal feedback loops contributes to physician overconfidence in their own diagnostic abilities.[7,11,12]

Physician Confidence in Diagnostic Abilities

A prospective, counterbalanced experimental design study found that even experienced physicians were unaware of the correctness of their diagnosis at the time the diagnosis was made. When 72 senior medical students, 72 senior medical residents, and 72 faculty internists were given two- to four-page synopses of 36 diagnostically challenging medical cases, each with a definitive correct diagnosis, students were overconfident in 25% of the cases in which their confidence and correctness were not aligned, residents were overconfident in 41% of the cases, and faculty in 36% of cases. These results show that even experienced physicians may be overconfident about the correctness of their diagnoses at the time that they make them.[11]

Overconfidence is a sign of miscalibration of one's diagnostic ability. Berner and Graber (2008) argue that even though physicians are well aware of the possibility of diagnostic error, few doctors are willing to admit to diagnostic error in their own practice. Graber reported that only 1% of physicians with whom he had personally spoken over a period of several years admitted to having made a diagnostic error in their own practice.[7] Despite a global awareness of the problem of diagnostic error, physicians seldom believe that their own error rates are significant, further compounding the difficulty in analyzing diagnostic error.[12] Given the dearth of feedback loops regarding diagnostic error, this is an understandable phenomenon; most physicians, in the absence of concrete information that diagnoses are wrong, conclude that their diagnoses are correct.

An organization's culture may encourage error collection and embrace error analysis—viewing errors as learning opportunities—or it may ignore or hide them. There are variations of culture along the continuum between these points. Open recognition of diagnostic error is one way to help physicians recalibrate their perception of diagnostic error and reduce overconfidence. Until there are mechanisms in place to collect and openly analyze diagnostic errors, calibration of true individual diagnostic error rates will be difficult for physicians to achieve.

Diagnostic Decision Making

Clinical judgment is an essential component of the diagnostic process in medicine. Cognitive psychology literature has identified a dual-process model of reasoning that has been used to analyze diagnostic reasoning processes that occur in medicine.[13,14] Two systems form the basis of clinical decision making, System 1 (i.e., heuristic, intuitive) and System 2 (i.e., systematic, analytical).[13]

In System 1, the experience of the diagnosing physician determines how well the information (e.g., patient symptoms, history, physical examination findings) is interpreted.[13] Physicians employ heuristics (i.e., cognitive or mental short cuts) to reach decisions, which are correct in the majority of cases. This type of processing has been referred to as pattern-recognition processing.[14] It happens quickly—almost reflexively. Patients presenting with shortness of breath and pain in the jaw and left shoulder, for example, would easily fit into a recognized pattern for "myocardial infarction." Appropriate tests would be ordered, and the physician would analyze test results and diagnose the patient, who would then receive treatment quickly per known medical guidelines.

System 2 typically occurs when the problem is not recognized, or when the physician chooses to review the

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case comprehensively for some reason.[13] It employs hypothesis testing and deductive reasoning, is logically sound, and involves critical thinking. Medical students are taught System 2 decision-making processes early on, creating comprehensive lists of differential diagnoses and analyzing each one for probability and "fit." In the real world, however, there is rarely adequate time to use solely this method. Deliberate consideration and review (i.e., System 2) takes time, and the time pressures that exist in many clinical settings may contribute to errors by causing an abbreviated or shortened clinical assessment.

In reality, physicians use a combination of both models in the practice of medicine. While System 2 is most similar to the scientific approach to medicine, it is rarely used first or alone. Physicians often practice in suboptimal environments. They may be rushed, fatigued, distracted, or faced with severe resource constraints. There may be an emotional reaction to the patient (e.g., positive, negative) or communication issues that may subconsciously influence the cognitive processing of the physician. Therefore, while most physicians undoubtedly would like to practice medicine in an orderly, scientific, well-reasoned fashion similar to System 2's analytical processing, the practice of medicine occurs in situations that have many variables and unknowns. The intuitive model of reasoning used in System 1 is an efficient and effective default method used by all physicians. However, when presented with a challenging case, or one with perplexing characteristics, physicians can make a conscious choice to revert to the analytical approaches of System 2.

Regardless of the system or combination of systems used, diagnosis is a multistep process that requires listening, collecting data regarding symptoms, performing focused examinations, ordering appropriate tests, synthesizing data, and analyzing results, and there are plenty of opportunities for errors among these various steps. Schiff et al.[10,15] developed and used the DEER taxonomy to classify where errors were occurring in the diagnostic processes (see "DEER Taxonomy Chart Audit Tool," one of several associated tools available from the Authority's Web site at http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx). In the 2009 study, 583 errors that physicians self-reported were analyzed. Most of the errors (44%) occurred in the laboratory and radiology testing phase (e.g., failure to order, report, process, and follow up on test results); followed by clinician assessment errors (e.g., hypothesis generation, weighing and prioritizing, recognizing urgencies and complications) (32%); history taking (10%); physical examination (10%); and referral or consultation errors and delays (3%).[10] Clinician assessment errors were most closely linked to cognitive errors.

Graber et al. (2005) analyzed 100 cases of diagnostic error in internal medicine using a taxonomy that included no-fault, system-related, and cognitive factors to clarify the basic etiology of diagnostic errors in internal medicine and to develop a working taxonomy for diagnostic error.[2] Seven of the 100 cases reflected solely no-fault errors, including masked or unusual disease presentation or patient-related factors, such as uncooperative demeanor or deception. Systems-related factors contributed to diagnostic error in 65% of the cases, cognitive factors contributed in 74% of the cases, and in 46% of the cases, both systems-related and cognitive factors contributed to diagnostic error. Overall, 228 system-related factors and 320 cognitive factors were identified, with an average of 5.9 factors per case.[2]

A 2007 analysis of 122 diagnostic errors in the ED involved a random sample of closed malpractice claims from four liability insurers alleging substandard diagnostic care in the ED. Breakdowns were common in the diagnostic steps that required active clinician decision making—specifically, conducting patient medical histories and physical examinations, ordering and interpreting tests, ordering consultations, and creating follow-up plans. Such breakdowns occurred in all but two of the missed diagnoses (97%). Failure to order appropriate tests was the most common breakdown, similar to Schiff's findings.[10] After assimilation of the patient history and physical assessment, physicians must first generate an appropriate diagnostic hypothesis, which then leads to test ordering. An inappropriate or incorrect diagnostic hypothesis will lead to incorrect or absent testing. Cognitive failure occurs when a physician has a correct diagnostic hypothesis but forgets or does not know the correct work-up for that particular diagnosis. In summary, appropriate test ordering, like other steps that involve active decision making, requires these key ingredients: (1) assimilation of physical findings and generation of an appropriate diagnostic hypothesis, (2) the availability of the right information on which to base diagnostic decisions, and (3) correct application of cognitive skills to this information.[16]

Commonly Misdiagnosed Conditions

Commonly misdiagnosed conditions include cancer, infection, fractures, myocardial infarction, embolism, neurological conditions, and aneurysms. Table 1 shows the top five misdiagnosed conditions from several studies, three of which were derived from tort claims, which biases the results toward more serious (and—if missed—more costly) diagnoses.

The top five categories of misdiagnoses from Authority reports from January 2005 through August 2009 were metastatic cancer (12%), fractures (4%), pulmonary embolism (4%), acute coronary syndrome (2%), and appendicitis (2%).

Common Causes of Diagnostic Error

Cognitive Processing Errors

Cognitive processing errors, or errors in thinking, are linked to the heuristics frequently used in System 1 (i.e., intuitive) mental processing. Some of the common heuristics employed during the diagnostic process include the following:[17,18]

- *Representative heuristic* is using "mental matching" to diagnose conditions with characteristic

Table 1. Commonly Misdiagnosed Conditions

STUDY	SETTING	MISDIAGNOSIS	PERCENTAGE (%)
Gandhi TK, Kachalia A, Thomas EJ, et al. Missed and delayed diagnoses in the ambulatory setting: a study of closed malpractice claims. *Ann Intern Med* 2006 Oct 3;145(7):488-96. (n = 181)	Ambulatory	Cancer—all types	59%
		Infections	5
		Fracture	4
		Heart attack	4
		Embolism	3
Schiff GD, Hasan O, Kim S, et al. Diagnostic error in medicine: analysis of 583 physician-reported errors. *Arch Intern Med* 2009 Nov 9;169(20):1881-7. (n = 583)	General internists, medical specialists and emergency physicians at 2 academic medical centers or within 20 smaller teaching or community hospitals	Pulmonary embolism	4.5%
		Drug reaction or overdose	4.5
		Lung cancer	3.9
		Colorectal cancer	3.3
		Acute coronary syndrome	3.1
Kachalia A., Gandhi TK, Puopolo AL, et al. Missed and delayed diagnoses in the emergency department: a study of closed malpractice claims from 4 liability insurers. *Ann Emerg Med* 2007 Feb;49(2):196-205. (n = 79)	Emergency department	Fracture	19%
		Infection	15
		Myocardial infarction	10
		Cancer	9
		Cerebral vascular disease	8
Hanscom R. CRICO/RMF community targets diagnostic error. CRICO/RMF Insight [online] 2007 Sep [cited 2010 Feb 10]. Available from Internet: http://www.rmf.harvard.edu/education-interventions/crico-rmf-insight/archives/092007/art1.htm. (CRICO/RMF diagnosis related claims from 2003 through 2007; n = 314)	80/20 mix of outpatient care and inpatient care	Cancer—all types	38%
		Heart disease	8
		Cerebral vascular disease	5
		Arterial disease	4
		Complications	4

presentations that can predispose diagnosing physicians to a lack of differential diagnoses.

- *Availability heuristic* is the tendency to accept a diagnosis due to ease in recalling a past similar event or case, rather than based upon statistical prevalence or probability.

Biases and limitations related to cognitive processing errors include the following:[17,18]

- *Anchoring* is the tendency to stay with an original diagnosis despite evidence to the contrary.
- *Premature closure* is narrowing the choice of diagnostic possibilities (i.e., hypotheses) too early in the diagnostic process, such that the correct diagnosis is never considered.
- *Satisficing* is the acceptance of less than the ideal or seeking a merely satisfactory solution, which is not necessarily the optimal one.
- *Confirmation bias* is the tendency to seek out data to confirm one's original idea rather than to seek out or validate disconfirming data.
- *Context errors* occur when the diagnosing physician is biased by patient history, previous diagnosis, or other factors and the case is formulated in the wrong context.

Table 2 shows a sampling of Authority reports with corresponding potential cognitive errors.

Cognitive errors may have contributed to the events in Table 2, some of which resulted in significant patient harm, but they are unlikely to be the sole contributing factor in these reports. The 2007 review of closed malpractice claims in the ED[16] found that the mean number of process breakdowns and contributing factors per missed diagnosis was two and three, respectively, clearly illustrating that compounding issues contribute to diagnostic errors. The 2005 review of diagnostic errors in internal medicine identified an average of six contributing factors for each diagnostic error.[2]

Communication Issues

Poor or inadequate communication among clinicians and between clinicians and patients is frequently cited as a contributing factor in diagnostic error.[7,8,10,16] Several facilities identified the contributing factor of "communication problems between providers" in events reported to the Authority. However, the event narratives did not specify the exact communication problem, which prevents more in-depth analysis. For example, the following report was submitted as a failure to diagnose and treat stroke with a contributing factor of "communication problems between providers" with root-cause analysis (RCA) in progress.

> *The patient was admitted via the ED with complaints of lower back pain postfall at home seven days prior. The patient's condition deteriorated with mental status changes, requiring urgent transfer to the intensive care unit. RCA in progress.*

Another report was submitted as a missed diagnosis of acute coronary syndrome with contributing factors of "communication issues between providers" and

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Table 2. Sample Authority Event Reports with Possible Cognitive Errors

EVENT REPORT	POTENTIAL COGNITIVE PROCESSING ERROR[1,2]	POTENTIAL FAILURE(S)
Patient is an infant seen in the ED [emergency department] during high flu season after an episode of vomiting and period of apnea observed by family. Was discharged, but returned later. Family reported that the patient had another episode of apnea. Patient was evaluated and transferred to another facility for clinical impression of apnea and reflux.	**Availability heuristic.** The tendency to accept a diagnosis based upon recent or vividly recalled cases or events rather than on prevalence or probability.	Authority report stated missed diagnosis of apnea and reflux. Physician potentially attributed symptoms to common flu, due to availability. A more thorough physical examination may have led to the discovery of other symptoms indicative of apnea and reflux.
Patient seen in the ED on day one and day two for complaints of shortness of breath and chest pain. Diagnosed with an upper respiratory infection and sent home each time. Subsequently later admitted and died. Coroner preliminary report indicated PE [pulmonary embolus] as cause of death.	**Anchoring heuristic.** The tendency to fixate on first impressions or initial symptoms without considering causes that appear later or those that do not support the initial hypothesis or diagnosis.	Authority report stated missed diagnosis of PE. Physician may have anchored on diagnosis "upper respiratory infection." Once a physician anchors on a diagnosis, it is very difficult to introduce new differential diagnoses. Physician may not have considered alternate diagnoses on subsequent visits.
Patient seen in ED on day one with complaints of abdominal pain. Patient evaluated, treated, and discharged with diagnosis of UTI [urinary tract infection]. The next day, patient presented to another facility and was diagnosed with a ruptured appendix.	**Premature closure.** Acceptance of a diagnosis before it has been fully vetted by considering alternative diagnoses or searching for data that contradict the initial diagnosis.	Authority report stated missed diagnosis of appendicitis. Physician omitted tests that would have led to diagnosis of ruptured appendix. Physician may have failed to consider differential diagnoses during history and physical portion of examination.
Patient presented to the ED on day one with complaints of chest pain. Stress test done, results negative, and patient discharged. The next day, patient returned to the ED with chest pain and tachypnea, and the left leg was blue and mottled. Dopplers of lower extremities confirmed extensive DVT [deep-vein thrombosis].	**Anchoring heuristic.** **Premature closure.** **Representative heuristic.** Mental matching to diagnose conditions with characteristic presentations. Predisposes to lack of a differential diagnosis.	Authority report stated missed diagnosis of DVT. Physician may have anchored on diagnosis "acute coronary syndrome" due to complaints of chest pain. Physician may have latched on to representative symptom of chest pain, failing to perform tests to rule out other potential diagnoses (i.e., differential diagnoses).
A young man came to the ED for fainting and syncope, including the inability to speak for a few seconds with lateralizing symptoms and staring. In the ED, lab work was done but no CT [computed tomography] scan was ordered. Patient was discharged home with diagnosis of syncope and dehydration secondary to stress, with instructions to follow up with primary care physician. Subsequently, the primary care physician admitted the patient directly into the hospital, where a CT scan was performed and a brain lesion diagnosed.	**Premature closure.** **Context errors.** Occur when the diagnosing physician is biased by patient history, previous diagnosis, or other factors and the case is formulated in the wrong context.	Authority report stated missed diagnosis of brain lesion. Physician may have attributed symptoms to "stress" and evaluated patient in this context. Physician may have failed to rule out other less likely but more serious diagnoses. Physician may have formulated diagnosis in the context of a young man with admitted stress and stopped searching for other plausible diagnoses for symptoms.

Notes

1. Scott IA. Errors in clinical reasoning: causes and remedial strategies. *BMJ* 2009 Jun 8;338:b1860.
2. Groopman J. *How doctors think.* New York (NY): Houghton Mifflin Company; 2008.

"lack of information due to dementia." RCA was performed surrounding the physical assessment process.

> *Patient seen in ED; had been sent from SNF [skilled nursing facility] because he was moaning in discomfort. Patient had a history of dementia and was unable to relate what was wrong. Abdomen was distended; enema had been given by SNF earlier in the day. Oxygen saturation level was 86% on room air. [The patient was] noted to have a urinary tract infection, which was treated. He was discharged but returned immediately. Upon return to the ED, he was bradycardic and then proceeded to full arrest. Blood work was run on the specimens that were in the lab from the initial visit and showed that the troponin level was 20 [elevated; indicative of heart muscle damage; possible myocardial infarction].*

Even diagnostic events that do not result in harm can be traumatic for both the patient and the clinician, as the following example illustrates.

> *The physician entered the patient's room and failed to check the identification band. The physician did ask the patient's name and [then] started talking about a brain aneurysm and [relayed that the patient] would be going for surgery. The patient came to hospital with "leg pain." The physician corrected the error later in the day [before the brain surgery occurred].*

In a study involving diagnostic error in ambulatory settings, the diagnostic errors were complex and frequently involved multiple process breakdowns, contributing factors, and clinicians. There was a median of three process breakdowns and three contributing

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factors per error.[19] In a similar study involving diagnostic error in internal medicine, an average of six different root causes were uncovered for each diagnostic error event, two-thirds of which were considered system-related factors.[2]

Other System-Related Factors

The fact that cognitive errors rarely are the sole cause of diagnostic error points toward the possibility of system-level interventions to decrease recurrence of diagnostic errors and to mitigate harm from them when they do occur.[16,20] Common system-related factors that contribute to diagnostic error include those related to specimen identification, test tracking, reporting of abnormal and critical test results, and transitions in care. Diagnostic error reports from the Authority's database illustrate how some of these system-related factors contribute to diagnostic error.

Specimen Labeling

The patient underwent a needle biopsy of the right breast that was diagnosed as ductal carcinoma. Patient then underwent lumpectomy of right breast, and [another] pathologist questioned the results postprocedure after reviewing the tissue. The hospital was notified about the potential wrong diagnosis . . . unable to determine how the specimen was mislabeled.

Communication of Critical Pathology Reports

The patient underwent a transthoracic biopsy of a lung nodule. The pathology result noting cancer was discovered [more than six months later].

Abnormal Test Results

The patient described slipping when coming out of her kitchen; the patient fell on her right side. X-rays were done, and the preliminary report was negative according to the surgeon. The final report revealed a femoral neck fracture, which was available but not seen by the physician [for nearly 15 days].

Poorly Managed Transition in Care

An elderly woman presented to the ED in month one with chest pain and shortness of breath. A chest CT [computed tomography scan] identified multiple emboli and a lung nodule suspicious for carcinoma. The patient underwent a cardiac catheterization and was discharged from the hospital with no documented medical follow-up for the lung nodule. The patient returned to the ED in month six with shoulder pain. A CXR [chest radiograph] was performed, and the patient was discharged with instructions to follow up with her physician for a chest CT in regard to the lung nodule. The patient was admitted to the hospital in month seven and has been diagnosed with carcinoma . . .

Focusing attention on system-related factors underlying issues related to specimen labeling, communication of reports, abnormal test results and transitions in care (e.g., work overload, inadequate staffing, unavailable resources) is one way to identify and reduce diagnostic errors in acute care settings.

Healthcare facilities can help the Authority with analysis of diagnostic error events by using the tools developed in conjunction with this article as a first step in detecting diagnostic error (e.g., the "Deer Taxonomy Chart Audit Tool"), and by submitting event reports with adequate information including the contributing factors and RCA information when performed.

Strategies to Decrease Diagnostic Errors

System-Level Strategies

Changing the perception of diagnostic error from "errors in judgment," "errors in thinking," or "physician mistakes" to errors related to cognitive processing, communication, and system design may be the first step toward recognizing and reducing diagnostic error.[3] Finding and reporting misdiagnosis-related patient harm is the second step, although it may be hard to achieve. When the U.S. Department of Health and Human Services Office of the Inspector General investigated methods for identifying adverse events in hospitals (case study; random sample of 278 Medicare beneficiary hospitalizations), it found that hospitals did not provide, and apparently did not have, event reports for 93% of the events (n = 120).[21] This study analyzed all adverse events, not just those related specifically to diagnostic error (which is more elusive and even more difficult to detect).

Healthcare facilities may consider the following strategies in an effort to increase the detection rate of diagnostic error in their facilities:

- Provide a mechanism to collect diagnostic error reports within the facility (see the "Deer Taxonomy Chart Audit Tool"). Collection and aggregation of diagnostic error data allows for tracking, trending, uncovering patterns, learning across cases, and measuring improvement.[10,15]
- Continuously improve the culture of safety so that identification and analysis of diagnostic error is acceptable and anticipated.[15,20] Include diagnostic error as a key part of the quality assurance plan. Identify any diagnostic-related adverse events and incidents that appear repeatedly as possible "normalization of deviance," and intervene as needed.[20]
- Conduct analysis of events that result in misdiagnosis-related patient harm. Consider a tool similar to the one used in Graber's 2005 analysis of diagnostic error,[2] which helps practitioners not only identify categories of diagnostic error but also provides underlying causes for the failures.

Event analysis in the medical literature shows that most diagnostic-related errors have multiple causes, and even cognitive aspects of diagnostic error can be mitigated by interventions at the system level.[16,20] Healthcare facilities may consider the following system-level strategies to reduce misdiagnosis-related harm:

- Strategies to combat cognitive errors include the following:
  - Provide information about and encourage the general study of clinical and pathological discrepancies to learn about all types of diagnostic error.[15,17] Study and test diagnostic

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accuracy on standardized cases similar to Johns Hopkins University School of Medicine Clinico-Pathological Conferences (http://oac.med.jhmi.edu/CPC/) or AHRQ's Web M&M: Morbidity and Mortality Rounds on the Web (http://www.webmm.ahrq.gov/index.aspx).

— Provide resources for clinical decision support systems that provide accurate estimates of disease probability. DXplain (http://dxplain.org/dxp/dxp.pl) and Isabel (http://www.isabelhealthcare.com/home/default) are two Web-based applications that help physicians make data-driven diagnostic decisions at the point of care. Do not rely solely on physician perception of diagnostic accuracy as a measure of need; research shows that even experienced physicians may be overconfident about the correctness of their diagnoses when they make them.[11] Provide point-of-care access to the Internet, electronic medical references, and journals.[3,7,10,12,16,17,20,22]

— Provide access to computer-assisted feature mapping and/or data visualization tools to enhance the accuracy of diagnostic decision making.[3,12,20]

— Provide resources and encourage the use of clinical guidelines and clinical algorithms. When well-designed, these resources remedy the deficiencies in human judgment by incorporating statistics, epidemiology, and decision theory in a clinically useful format.[16,22]

— Consider diagnostic checklists to prevent reliance on memory for error-prone processes (e.g., soliciting a complete history, performing a targeted physical examination, ordering appropriate tests). These can be organized around high-risk diagnoses (e.g., cancer, infection, fractures, myocardial infarction) or around care settings (e.g., routine wellness visit checklist that reminds about screening protocols, sick visit checklist that lists "don't miss" diagnoses).[3,10,15] A general checklist designed to minimize diagnostic error has been previously published[23] and is available as a pocket card at the Authority's Web site (see "A Checklist for Diagnosis").

— Enhance feedback to clinicians regarding diagnoses and errors to increase calibration and reduce overconfidence regarding their own diagnostic error rate. Improving feedback to clinical practitioners may be the most effective debiasing procedure available. This can be accomplished, in part, by means of postmortem autopsies and/or postmortem magnetic resonance imaging, morbidity and mortality conferences, sentinel event analysis, or retrospective audits of admitting versus discharge diagnoses or of diagnoses of patients who return to the ED within 48 hours of discharge.[7,12,17,20]

- Systems strategies to enhance communication and coordination of care include the following:

  — Migrate toward electronic medical records to ensure that patient information is available to all care providers in real time, in all settings. Develop formal policies regarding the communication of patient information across all care settings.[20] Integrate automatic reminders for reporting test results to patients and scheduling follow-up.[3,7]

  — Ensure an efficient and effective system of communicating abnormal and critical test result procedures directly to the ordering physician and the patient. Monitor the turnaround time of key tests.[10,12,16,20,22]

  — Ensure that specialty expertise is available when needed, at all times and on all days. Monitor consultation timeliness.[7,12,20,22]

  — Consider mandatory second opinions on key error-prone diagnoses and second readings of key diagnostic tests.[12,16,22]

  — Ensure that there is a standardized process for handoff procedures between physicians and across care units.[16]

  — Provide close oversight of trainees' diagnostic evaluations especially in cases of high workload or with complex patients or with patients with atypical presentation. Provide a mechanism for supervisory oversight of diagnostic decision-making strategies.[16]

  — Ensure strong mechanism for follow-up of discharged patients, especially for high-risk diagnoses or symptoms for which a diagnosis has not yet been assigned (e.g., cancer: rule out cancer; myocardial infarction: chest pain and shortness of breath).[15]

- Other system-related factors:

  — Establish pathways for physicians who saw the patient earlier to learn if or when a diagnosis is changed by developing audit protocols to uncover diagnostic error, comparing ED diagnoses to discharge diagnoses, auditing diagnoses of patients who return to the ED within 48 hours after discharge and making note of diagnoses that change from one visit to the next, performing retrospective chart audits to look for changed diagnoses during the course of a hospitalization, comparing consulting/referral diagnoses to referring physician diagnoses by tracking radiology and pathology over-reads and by tracking changes to initial laboratory test results (see the online "Diagnostic Error Measures Worksheet").

  — Develop a mechanism to share the results of these types of audits with all treating physicians in a timely fashion. Soliciting feedback from practitioners regarding diagnostic error

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is a critical step in the learning process.[15,20] In addition to learning when diagnostic error occurs, it is equally important to investigate causes, and this cannot be done without frank conversations with physicians about why these errors occurred.

— Guard against excessive workload and staff fatigue. Minimize disruptions and production pressures so that diagnosing physicians have time to reflect on their diagnostic decisions. Minimize errors related to fatigue by implementing work hour limitations and allowing naps, if needed.[16,20]

Physician Strategies

Physicians themselves play an important role in the detection and prevention of diagnostic error. Individuals may consider the following strategies to reduce diagnostic error in their practice:

- Improve clinical reasoning and metacognition skills by learning about cognitive errors.[17,20]
- Use diagnostic time-outs to actively reflect upon the diagnostic process.[17,20]
- Request second opinions and consultations as needed.[17,20]
- Request diagnostic feedback from healthcare facilities and colleagues to improve calibration regarding diagnostic error.[12,17,20]
- For specialists who modify diagnoses of referral patients, notify the referring physician of the modified or changed diagnosis.[17]
- Disclose the diagnosis to the patient early. Disclose the probability of having the diagnosis, and what to expect if the diagnosis is correct. If there is no clear diagnosis, disclose this, too.[20]
- Maintain long-term continuity of care with individual patients to ensure adequate awareness of past mistakes. Survey past patients, and investigate whether diagnostic error occurred.
- Mentor residents and medical students by openly discussing diagnostic thinking patterns, soliciting their diagnostic reasoning, and providing timely and critical feedback regarding their diagnostic processes.[17,18]

A review of some of the cognitive errors presented earlier shows that even cognitive errors are amenable to both individual and system-level interventions listed above (Table 3).

Using a combination of individual and system-level risk reduction strategies may help decrease both the diagnostic error rate and the rate of misdiagnosis-related patient harm in healthcare facilities.

Patient Education Strategies

Patients can participate in the effort to reduce diagnostic errors. Facilities can endeavor to educate and empower patients to seek timely follow-up care and medical advice and to become active participants in the diagnostic process. For example, educate patients about diagnostic probabilities and uncertainties to minimize disappointments and surprises and to support and enhance patient initiative in questioning the diagnostic process and outcome. (For more information, see the online "Patient Education Regarding Diagnostic Error").

Conclusion

Despite the fact that the diagnostic process has many steps, is frequently shared between multiple providers and sometimes across multiple settings, and occurs over a period of months or even years, healthcare facilities have at their disposal many strategies that could potentially reduce the diagnostic error rate. Implementing interventions that establish strong and reliable feedback loops between and among physicians regarding diagnostic accuracy is a key step in the error-reduction process. Ensuring that all steps in the diagnostic testing phase occur correctly and that all results are communicated back to ordering physicians and patients is critically important, as are methods to enhance the effectiveness of diagnostic decision making.

In addition to system-level interventions, physicians themselves must actively work toward first recognizing, then analyzing, and finally reducing diagnostic error. Acknowledging the lack of feedback mechanisms in healthcare facilities and seeking out ways to give and receive collegial diagnostic feedback is an important first step. Accepting the possibility of diagnostic error is also important; acceptance of a less than perfect diagnostic record may lead to greater metacognition and recognition of diagnostic error when it does occur. Likewise, mentoring residents by actively discussing diagnostic challenges, diagnostic decisions, and even diagnostic failures will help new physicians develop a more accurate perception of their diagnostic abilities and skills. Universities and teaching hospitals also have a role to play: by illuminating the topic of diagnostic error early in each medical student's education, in both didactic and practical learning settings, there is the potential to reduce physician overconfidence and to correct individual calibration of diagnostic error. Allowing medical students and residents to openly question diagnostic decisions, verbalize their own diagnostic reasoning, and receive specific constructive feedback in a timely fashion are important steps toward enhanced diagnostic accuracy.

Involving patients in the diagnostic process may help reduce diagnostic error. By encouraging and empowering patients to give and receive information with their physicians, to question any step in the diagnostic process, and to report changes in their condition or results of second opinions to their physicians, providers can enable patients to become important partners in the diagnostic process.

The Authority encourages each healthcare facility to begin monitoring diagnostic error rates. Once facilities begin collecting data regarding diagnostic error, the Authority invites use of the sample

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Table 3. Sample Authority Event Reports with Associated Individual and System Error Mitigation Strategies

EVENT REPORT	POTENTIAL FAILURE(S)	POTENTIAL COGNITIVE PROCESSING ERROR[1,2]	INDIVIDUAL STRATEGY	SYSTEM STRATEGY
Patient is an infant seen in the ED [emergency department] during high flu season after an episode of vomiting and period of apnea observed by family. Was discharged, but returned later. Family reported that the patient had another episode of apnea. Patient was evaluated and transferred to another facility for clinical impression of apnea and reflux.	Authority report stated missed diagnosis of apnea and reflux. Admitted during high flu season; potentially attributed symptoms to common flu, due to availability. A more thorough physical examination may have led to the discovery of other symptoms indicative of reflux.	**Availability heuristic.** The tendency to accept a diagnosis based upon recent or vividly recalled cases or events rather than on prevalence or probability.	Use checklists for physical examination components. Use decision support resources, if available. Confer with colleagues, and seek out second opinions.	Provide decision support systems to diagnosing physicians. Provide point-of-care clinical resources such as electronic medical records, Internet access, and access to electronic medical journals and prescribing data. Encourage the use of diagnostic checklists to improve systematic examinations and to decrease reliance on memory.
Patient seen in the ED on day one and day two for complaints of shortness of breath and chest pain. Diagnosed with an upper respiratory infection and sent home each time. Subsequently later admitted and died. Coroner preliminary report indicated PE [pulmonary embolus] as cause of death.	Authority report stated missed diagnosis of PE. Anchored on diagnosis "upper respiratory infection." Once a physician anchors on a diagnosis, it is very difficult to introduce new differential diagnoses. May not have considered alternate diagnoses on subsequent visits.	**Anchoring heuristic.** The tendency to fixate on first impressions or initial symptoms without considering causes that appear later or those that do not support the initial hypothesis or diagnosis	Think beyond the most obvious diagnosis. Perform comprehensive and systematic physical examinations. Use a diagnostic time-out and reflective thinking about the patient and symptoms in a calm environment. Consider worst-case scenarios. Ask, "What do I not want to miss?"	Implement a system to automatically screen patients returning to the ED within 48 hours. Provide decision-support information in the form of clinical algorithms based upon evidence-based medicine. Ensure the availability of specialty consultations 7 days per week, 24 hours per day. Encourage physicians to seek out second opinions on high-risk populations (e.g., return to the ED within 48 hours).

Notes

1. Scott IA. Errors in clinical reasoning: causes and remedial strategies. *BMJ* 2009 Jun 8;338:b1860.
2. Groopman J. *How doctors think*. New York (NY): Houghton Mifflin Company; 2008.

"DEER Taxonomy Chart Audit Tool," to trend diagnostic error reports, to identify where in the diagnostic process errors occur, to analyze aggregate results, and to develop and implement both physician- and system-level strategies to reduce diagnostic error occurrence.

Notes

1. Hanscom R. CRICO/RMF community targets diagnostic error. CRICO/RMF Insight [online] 2007 Sep [cited 2010 Feb 10]. Available from Internet: http://www.rmf.harvard.edu/education-interventions/crico-rmf-insight/archives/092007/art1.htm.
2. Graber ML, Franklin N, Gordon R. Diagnostic error in internal medicine. *Arch Intern Med* 2005 Jul 11;165(13):1493-9.
3. Newman-Toker DE, Provonost PJ. Diagnostic errors—the next frontier for patient safety. *JAMA* 2009 Mar 11;301(10):1060-2.
4. Shojania KG, Burton EC, McDonald KM, et al. Changes in rates of autopsy-detected diagnostic errors over time: a systematic review. *JAMA* 2003 Jun 4;289(21):2849-56.
5. Goldman L, Sayson R, Robbins S, et al. The value of autopsy in three medical eras. *N Eng J Med* 1983 Apr 28;308(17):1000-5.
6. Sonderegger-Iseli K, Burger S, Muntwyler J, et al. Diagnostic errors in three medical eras: a necroscopy study. *Lancet* 2000 Jun 10;355(9220):2027-31.
7. Berner ES, Graber ML. Overconfidence as a cause of diagnostic error in medicine. *Am J Med* 2008 May;121(5 Suppl):S2-S23.
8. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard medical practice study II. *N Eng J Med* 1991 Feb 7;324(6):377-84.
9. Agency for Healthcare Research and Quality (AHRQ). Special emphasis notice (SEN): AHRQ announces interest in research on diagnostic errors in ambulatory care settings [notice NOT-HS-08-002 online]. 2007

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Oct 25 [cited 2010 Mar 17]. Available from Internet: http://grants.nih.gov/grants/guide/notice-files/NOT-HS-08-002.html.

10. Schiff GD, Hasan O, Kim S, et al. Diagnostic error in medicine: analysis of 583 physician-reported errors. *Arch Intern Med* 2009 Nov 9;169(20):1881-7.

11. Friedman CP, Gatti GG, Franz TM, et al. Do physicians know when their diagnoses are correct? Implications for decision support and error reduction. *J Gen Intern Med* 2005 Apr;20(4):334-9.

12. Graber M. Diagnostic errors in medicine: a case of neglect. *Jt Comm J Qual Patient Saf* 2005 Feb;31(2):106-13.

13. Croskerry P. A universal model of diagnostic reasoning. *Acad Med* 2009 Aug;84(8):1022-8.

14. Schwartz A, Elstein AS. Clinical reasoning in medicine. In: Higgs J, Jones M, Loftus S, et al, eds. *Clinical reasoning in the health professions*. 3rd ed. Boston (MA): Elsevier; 2008:223-34.

15. Schiff GD, Kim S, Abrams R, et al. Diagnosing diagnostic error: lessons from a multi-institutional collaborative project. In: Henriksen K, Battles JB, Marks ES, et al., eds. *Advances in patient safety: from research to implementation*. Rockville (MD): Agency for Healthcare Research and Quality; AHRQ pub No. 05-0021-2. 2005:255-78.

16. Kachalia A., Gandhi TK, Puopolo AL, et al. Missed and delayed diagnoses in the emergency department: a study of closed malpractice claims from 4 liability insurers. *Ann Emerg Med* 2007 Feb;49(2):196-205.

17. Scott IA. Errors in clinical reasoning: causes and remedial strategies. *BMJ* 2009 Jun 8;338:b1860.

18. Groopman J. *How doctors think*. New York (NY): Houghton Mifflin Company; 2008.

19. Gandhi TK, Kachalia A, Thomas EJ, et al. Missed and delayed diagnoses in the ambulatory setting: a study of closed malpractice claims. *Ann Intern Med* 2006;145:488-96.

20. Graber ML. Taking steps toward a safer future: measures to promote timely and accurate medical diagnosis. *Am J Med* 2008 May;121(5 Suppl):S43-6.

21. U.S. Department of Health and Human Services, Office of the Inspector General. Adverse events in hospitals: methods for identifying events [executive summary online]. 2010 Mar [cited 2010 Mar 8]. Available from Internet: http://oig.hhs.gov/oei/reports/oei-06-08-00221.pdf.

22. Elstein AS. Thinking about diagnostic thinking: a 30-year perspective. *Adv in Health Sci Educ*. 2009;14:7-18.

23. Graber ML. Educational strategies to reduce diagnostic error: can you teach this stuff? *Adv Health Sci Educ* 2009;14:63-9.

Self-Assessment Questions

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

A 35-year-old man with no significant past medical history went to the emergency department (ED) complaining of vomiting and periumbilical abdominal pain for four hours. On physical examination, he was afebrile, with a blood pressure of 114/72 and a heart rate of 85. His abdomen was soft, without rebound or guarding. He was diagnosed with gastroenteritis and discharged with antiemetics and instructions to return to the ED for persistent vomiting, pain, or new fever. The patient presented to his primary care physician's office three days later with complaints of persistent abdominal pain; the vomiting had resolved. The primary physician contacted ED personnel to obtain the report. On examination, the patient was afebrile with normal vital signs. He had a diffusely tender abdomen with some localization to the right of the umbilicus. The patient was sent home, with instructions to take over-the-counter medication for the pain. The next day, the patient returned to the ED with persistent pain. He was seen by the same ED attending physician, who asked a colleague to evaluate the case. The second ED attending physician ordered a computed tomography (CT) scan of the abdomen and pelvis. The CT scan revealed a perforated appendix.*

1. During the first ED visit, which factor *most likely* contributed to the attending physician's incorrect diagnosis of gastroenteritis?
   a. Atypical presentation: lack of classic physical signs of appendicitis.
   b. Lack of awareness: abdominal pain is an uncommon chief complaint in the ED.
   c. Availability heuristic: accepting a diagnosis (gastroenteritis) due to ease in recalling past similar cases.
   d. Premature closure: settling on a diagnosis before ruling out other possibilities.
2. During the visit with the primary care physician three days later, which event *most likely* contributed to the continued diagnostic error?
   a. Lack of communication between the primary care physician and the ED personnel regarding the patient's medical history.
   b. The primary care physician failed to perform a thorough physical assessment of the patient.
   c. Anchoring bias: the primary care physician relied too heavily on the previous medical report when formulating his own medical conclusions and stayed with the original diagnosis despite evidence to the contrary.
   d. The patient was not compliant with the ED discharge instructions, further hindering the diagnosis of appendicitis.

* Adapted from: Agency for Healthcare Research and Quality (AHRQ). Missed appendicitis. AHRQ M&M on the Web 2003 Jun [cited 2010 Jul14]. Available from Internet: http://www.webmm.ahrq.gov/case.aspx?caseID=17&searchStr=appendicitis.

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3. Representative heuristic is the:
   a. tendency to formulate a diagnosis with information obtained from a second party.
   b. tendency to accept a diagnosis based upon the ease of recall of past similar cases rather than based upon statistical prevalence or probability.
   c. use of cognitive shortcuts to formulate a list of diagnostic probabilities representative of the chief complaint.
   d. use of "mental matching" to diagnose conditions with characteristic presentations.
4. The most effective strategy for physicians to evaluate diagnostic decisions and minimize cognitive errors is to:
   a. always get a second opinion on appendectomy cases.
   b. take a diagnostic time-out to think broadly about the case; metacognition.
   c. use diagnostic testing to rule out false-negative presentations.
   d. ask a patient to relay all pertinent information before beginning the physical examination.

   A woman had a pigmented lesion on her leg biopsied by her physician in the hospital and sent to the lab and a pathologist for review. The pathologist correctly determined that the lesion was a melanoma. However, the lab sent the report of another patient (labeled with a different patient name) back to the woman's physician, reporting that the lesion was benign. The physician did not notice the wrong name on the report. The lab realized its mistake eight months later, and notified the physician who told the patient. As a result, the patient's melanoma spread to her groin nodes, and it required more extensive treatment than if the diagnosis been timely.
5. Which system-level intervention could the facility implement to best prevent the type of diagnostic error illustrated above?
   a. Install a diagnostic decision support software system.
   b. Implement a system of authentication of all abnormal test results, verifying critical patient information.
   c. Implement a multisystem electronic medical record so that medical information is available across care settings.
   d. Educate physicians and staff regarding the importance of filing test results in the appropriate medical records.

   A woman presented with multiple breast lumps in her left breast. A biopsy of the dominant lump was diagnosed as Stage I breast cancer. She underwent lumpectomy, which removed all lumps but one. She saw several physicians over the next two years, and although the lump was recorded in her medical chart, no physician ever followed up with her about it. Over this period, the breast cancer developed from a treatable Stage I to Stage III, and it metastasized to her brain.
6. The above case illustrates principles similar to findings in the literature regarding diagnostic error. Which statement below most accurately describes the etiology of many diagnostic errors?
   a. Individual, one-time errors in judgment account for the majority of diagnostic errors.
   b. Patient-related factors account for most instances of diagnostic error-related patient harm.
   c. Diagnostic errors that reach patients appear to result from the alignment of multiple breakdowns, which in turn stem from a confluence of contributing factors.
   d. Diagnostic errors can usually be traced to a single, discrete probable cause, which can be resolved through staff education and training.
7. Which facility-level strategy is most likely to increase detection of diagnostic error?
   a. Ensure a culture of safety exists so that the detection and analysis of diagnostic error is acceptable; provide a mechanism to collect diagnostic error data; and conduct analysis of collected events.
   b. Purchase an error-collection system for frontline reporting; implement mandatory reporting of diagnostic error; and enforce compliance through vigilant auditing of medical records.
   c. Increase autopsy rates within the facility; track misdiagnosis-related patient harm by provider; and create and publicize comparison reports of harm by provider.
   d. Purchase diagnostic decision-support software; implement mandatory reporting of diagnostic error; and train physicians in metacognition.

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Hemodialysis Administration: Strategies to Ensure Safe Patient Care

ABSTRACT

An estimated 367,000 Americans underwent dialysis to treat their renal failure in 2007. The majority of these patients received hemodialysis, typically provided in either freestanding clinics or hospital-based dialysis centers. While the technology for hemodialysis is well established and the treatment is a routine part of healthcare delivery, risks are ever-present, given that hemodialysis patients undergo three treatments each week, take multiple medications, and often have multiple comorbidities. From November 1, 2008, through October 31, 2009, Pennsylvania healthcare facilities submitted 526 event reports involving hemodialysis administration to the Pennsylvania Patient Safety Authority. Medication errors were the most common type event submitted, representing almost 29% (n = 150) of all hemodialysis-related events. Other hemodialysis administration events involved failure to follow policy or protocol such as treatment set-up procedures (12.9%), needle disconnection and needle infiltration (6.1% for each category), and falls (5.9%). Risk mitigation strategies to prevent the likelihood of errors involving hemodialysis administration are provided for medication errors, failure to follow hemodialysis protocol, needle disconnection, needle infiltration, falls, equipment failures, and clotting of the dialysis circuit or blood lines. (Pa Patient Saf Advis 2010 Jun;7[2]:87-96.)

Introduction

An estimated 367,000 Americans underwent dialysis in 2007 to treat renal failure. The most common underlying causes of kidney failure in the United States are diabetes and hypertension.[1] When an individual's kidneys fail, he or she is unable to remove excess fluids, wastes, and minerals from the blood, which causes the buildup of harmful wastes and fluid retention. Dialysis therapy, which is broadly divided into hemodialysis and peritoneal dialysis, removes the harmful wastes and extra fluids and helps to maintain a proper balance of electrolytes like potassium and sodium. During hemodialysis, the patient's blood flows through a tube to a dialyzer, or filter. The dialyzer has two chambers—one for the blood and the other for a cleansing fluid called dialysate—which are separated by a thin, semipermeable membrane. Waste products in the blood (e.g., urea, creatinine, potassium, extra fluid) pass through the membrane and flow into the dialysate and are drained from the patient.

Only about 7.2% of the dialysis population undergoes peritoneal dialysis, a procedure that uses the patient's peritoneum as the semipermeable membrane, allowing the fluid and waste to pass through the lining and flow into the dialysate before it is drained from the patient. Patients can undergo peritoneal dialysis in their homes, whereas patients undergoing hemodialysis, the focus of this article, typically receive the treatment in either freestanding clinics or hospital-based dialysis centers. Hospital-based centers, which treat about 13% of hemodialysis patients, manage both acute and chronic cases, whereas freestanding centers are used almost exclusively for chronic treatment of stable patients with end-stage renal disease (ESRD).[1]

Although the technology for hemodialysis is well established and the treatment is a routine part of healthcare delivery,[2] risks are ever-present, given that chronic hemodialysis patients typically undergo three treatments (each lasting about three to four hours) each week, take multiple medications, and may have multiple comorbidities. During treatment, patients must be monitored for adverse reactions, such as severe hypotension, and other adverse events, such as potentially fatal needle disconnections. Within hospitals, an effective hemodialysis program also requires close coordination with other departments such as the pharmacy, laboratory, and blood bank, which provide services and products necessary during hemodialysis.

Without attention to patient safety and error prevention, even a well-established procedure like hemodialysis can result in an adverse event. To understand the types of errors and patient safety events that can occur during hemodialysis, analysts reviewed event reports submitted to the Pennsylvania Patient Safety Authority involving the administration of hemodialysis and identified important strategies to ensure the safety of patients undergoing hemodialysis.

A Look at the Numbers

In Pennsylvania, there are about 240 chronic dialysis facilities providing 4,275 hemodialysis stations for the state's 14,500 ESRD patients.[3] The 240 facilities include hospital-operated dialysis clinics and units and freestanding dialysis centers. Pennsylvania healthcare facilities submitted 526 event reports involving hemodialysis administration through the Authority's reporting system during a one-year period from November 1, 2008, through October 31, 2009. This analysis excludes reports involving peritoneal dialysis and other similar methods of blood filtration such as plasmapheresis and continuous renal replacement therapy. Additionally, the data is limited to reports from hospital-operated dialysis facilities since freestanding dialysis centers are excluded from the requirements for statewide mandatory event reporting established by Act 13 of the Medical Care Availability and Reduction of Error Act of 2002.[4]

Medication errors top the list of events involving hemodialysis administration, representing 28.5%

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(n = 150) of all hemodialysis-related events reported to the Authority. While medication omissions were the most frequently occurring type of medication error, other medication errors during hemodialysis administration involved heparin infusion mistakes, inadequate handoff of information about patients' medications during transitions between the hemodialysis unit and other care areas, and miscommunication of medication orders.

Other events involved failure to follow policy or protocol (including treatment set-up procedures), laboratory or blood bank errors, procedure complications, needle disconnection, needle infiltration, falls, equipment or facility failures, clotting of the hemodialysis circuit or blood lines, pressure ulcers, skin tears and abrasions, patients leaving against medical advice, and other miscellaneous reports such as a clipboard falling off a hemodialysis machine and hitting a patient's leg during the hemodialysis session. The analysis of the 526 reports also includes 20 posthemodialysis reports involving events related to the hemodialysis procedure. Examples include four reports of patients found soiled with urine and feces upon being returned to their hospital beds following hemodialysis and one report of a patient whose hemodialysis needles were still in place after he was transferred to an emergency department (ED) after losing consciousness in an outpatient dialysis unit. See Table 1 for a breakdown of all events identified in the 526 reports.

There are a few reports that address infection control issues (e.g., failure to use proper infection control techniques for inserting a hemodialysis catheter, failure to disinfect a hemodialysis unit previously used on a patient whose hepatitis B status was unknown); however, the majority of Pennsylvania facility reports involving infection control are submitted separately to the Centers for Disease Control and Prevention's National Healthcare Safety Network.

While medication errors were the most common type of hemodialysis events submitted to the Authority, one of two Serious Events was related to a needle disconnection before the patient's hemodialysis treatment had ended, as described in the following report (for more information on needle disconnections during hemodialysis and prevention strategies, see "Measures to Prevent Needle Disconnections during Hemodialysis"):

> *The patient presented to the facility and was admitted. The patient underwent an operation for bowel obstruction. The patient had a previous medical history of ESRD requiring dialysis and hypotension. The patient was placed on a dialysis machine alert, oriented, and talking with the nurses. When the machine alarmed, staff presented and changed the dialysate. Approximately three minutes later, a nurse entered the room and found the patient with pale color, agonal respirations, positive pulses, and the dialysis line disconnected. The patient was lying in a pool of blood. The rapid response team was called and responded. A code was called.*

The other Serious Event reported to the Authority did not appear to be related to the hemodialysis procedure but was, instead, related to the patient's condition.

Further analysis of the events by harm score—which addresses the extent to which the event reached the patient and the degree of harm to the patient[5]—shows that 87.6% (n = 461) of the events reached the patient (harm index = C to I), and 5.5% (n = 29) of the events were reported by the facility as resulting in harm to the patient (harm index = E to I).

More than half of the reported events involved male patients (56.5%, n = 297), and the majority of patients were age 65 and older (54.6%, n = 287). The care areas most often cited in these reports include the renal unit (22.2%, n = 117), outpatient dialysis clinic (16.9%, n = 89), and medical/surgical unit (11.4%, n = 60).

This article reviews some of the common events that can occur during hemodialysis administration. Risk mitigation strategies are provided for each of these event types: medication errors, needle disconnections, failure to follow hemodialysis protocols, needle infiltration, falls, equipment/facility failures, and clotting. Prevention protocols for other event types identified in the reports—such as errors involving the laboratory and blood bank and the development of pressure ulcers and skin tears—require patient

Table 1. Events Associated with Hemodialysis Administration (N = 526), November 1, 2008, through October 31, 2009

EVENT TYPE	NUMBER	% OF TOTAL EVENTS (N = 526)*
Medication error	150	28.5%
Failure to follow protocol	68	12.9
Laboratory-/blood bank-related	52	9.9
Procedure complication	45	8.6
Needle disconnection	32	6.1
Needle infiltration	32	6.1
Falls	31	5.9
Equipment/facility failure	25	4.8
Clotting of hemodialysis system or lines	23	4.4
Posthemodialysis event (excludes falls)	20	3.8
Pressure ulcer	20	3.8
Skin tear, abrasion	10	1.9
Patient left against medical advice	9	1.7
Other (e.g., lost patient item, patient dissatisfaction, unable to contact dialysis service)	9	1.7

*Percentages do not add up to 100% due to rounding.

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safety interventions that have been reviewed in the general patient safety literature, including past issues of the *Pennsylvania Patient Safety Advisory*. Additional clinical considerations for hemodialysis are outlined in the National Kidney Foundation's guidelines for hemodialysis adequacy and vascular access.[6,7] The guidelines have been developed by the foundation's Kidney Disease Outcomes Quality Initiative.

Medication Errors

Hemodialysis patients typically take between 6 and 10 medications daily.[8] Among the medications routinely administered for hemodialysis patients are intravenous (IV) heparin to prevent blood clotting during treatment, erythropoietic stimulating agents to promote the formation of red blood cells, iron replacement for treatment of anemia, vitamin D preparations, medications to lower parathyroid hormone levels, and phosphate binders. Patients are at risk for medication errors because of the many medications they take, their multiple comorbidities, and the frequent need to change their medications.[9]

Of the 150 hemodialysis events involving medication errors, the greatest percentage involved dose omissions (48%, n = 72). Omissions occurred, for example, when the patient did not receive an intended medication after hemodialysis, did not

Measures to Prevent Needle Disconnections during Hemodialysis

When a hemodialysis blood line disconnects or dislodges from a needle to access the patient's vein or artery, the consequences can range from minimal blood loss to a fatal hemorrhage—particularly with venous needle dislodgements. Unlike an arterial needle dislodgement, which will cause the hemodialysis machine to alarm and shut down, stopping the flow of blood to the dialyzer, venous line dislodgements or disconnections can go undetected because the venous pressure alarm is less reliable in detecting pressure changes in the venous line.[1] During a one-year period, the Pennsylvania Patient Safety Authority received 32 events of line disconnections, representing 6.1% of all the hemodialysis administration events reported during the period (N = 526). In just five to seven minutes, a patient receiving hemodialysis treatment can lose 40% of his or her blood volume from a venous needle dislodgment, resulting in a class IV hemorrhage, the most serious of hemorrhage classifications indicating the need for aggressive treatment to prevent death. In a scientific abstract presented in 2008 at the American Society of Nephrology's annual meeting, a nephrologist and his colleagues at a Pennsylvania hospital estimated there are more than 400 episodes of venous needle dislodgement annually in the U.S. dialysis population and that the mortality rate from these events is 10% to 33%.[1]

In 1998, ECRI Institute reported on two instances of venous line needle dislodgements during hemodialysis that did not trigger a venous pressure alarm.[2] In both cases, the narrow-bore needles used from the treatment created significant flow resistance that produced back pressures that exceeded the patient venous pressure. Even if the needle is fully or partially dislodged, the venous pressure monitor is likely to continue sensing the pressure created by the needle's flow resistance and may miss the smaller drop in pressure associated with the disconnection.

Typically, dialysis staff monitor patients' blood lines to check for problems with the needle connection, but this strategy is an unreliable means to detect needle dislodgements. Other measures to prevent venous line needle dislodgement include the following:[1,3,4]

- Emphasize with dialysis staff that secure needle placement is crucial to preventing dislodgements. Staff must take the time to securely tape the needle to the patient's skin, arm, or access device without taping over the line connector and obscuring potential problems with it.
- Prohibit staff from adjusting alarm limits to minimize nuisance alarms. Typically, the limits are set at ± mm Hg around the existing venous line pressures. Although they may not detect all dislodged needles, continue to use venous pressure monitors because they are useful for detecting obstructions or disconnections that occur elsewhere in the venous line.
- Alert staff to the dangers of solely relying on the venous pressure alarm to detect a venous line needle dislodgement. Require staff to frequently examine the blood lines during patients' hemodialysis treatments if this is not already routine practice.
- Instruct patients to keep all needle and blood line connections from being covered with blankets or other items so that staff can monitor the connections. Educate patients who are capable to watch their blood lines for disconnections and to notify staff immediately—even if the needle is only partially dislodged.

Notes

1. Hurst JA. Venous needle dislodgement (it can happen without warning). Renal Business Today [online] 2009 Sep 9 [cited 2009 Dec 29]. Available from Internet: http://www.renalbusiness.com/articles/venous-needle-dislodgement.html.
2. ECRI Institute. Undetected venous line needle dislodgment during hemodialysis. Medical device safety reports [online]. 1998 Nov [cited 2009 Dec 29]. Available from Internet: http://www.mdsr.ecri.org/summary/detail.aspx?doc_id=8300.
3. ECRI Institute. Hazard report: undetected venous needle dislodgment during hemodialysis can be fatal. *Health Devices* 2003 Aug;32(8):325-6.
4. Zeigler SA. Prevent dangerous hemodialysis catheter disconnections. *Nursing* 2007 Mar;37(3):70.

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receive a medication on the patient care unit before being sent to the dialysis unit for treatment, or missed a scheduled medication on the care unit because the patient was in the dialysis unit. The findings are consistent with a survey of 649 ESRD professionals who reported that the most likely type of medication error in their dialysis centers is omitting one or more medications for a patient.[8]

Although reports of medication omission reported to the Authority do not indicate any harm to the patient, a missed medication can be significant and has the potential to result in harm.[8] Consider the following report submitted to the Authority about a missed dose of an antihypotensive medication:

> *Patient has chronic hypotension. Midodrine ordered 10 mg three times daily on dialysis days and 5 mg three times daily on nondialysis days. Patient had 2 L of fluid removed during dialysis. Dialysis not completed until approximately 6 p.m. Midodrine dose not given at 9 p.m. Patient to be discharged on morning of next day due to late dialysis. On that morning, patient needed a chest x-ray for pain. While the patient was in radiology, the patient became unresponsive, and a code was called. The patient's blood pressure dropped significantly. The patient was given 2 L of IV fluids during the code and transferred to the intensive care unit.*

Heparin was associated with 11.3% (n = 17) of medication events involving hemodialysis. The anticoagulant is listed by the Institute for Safe Medication Practices (ISMP) as a high-alert medication because of its ability to cause significant patient harm when used in error.[10] Examples of heparin errors during hemodialysis administration as reported to the Authority include the following:

> *1,200 units of heparin infused during patient's dialysis treatment. Patient has a documented allergy to heparin.*

> *The patient is to receive 400 units per hour of heparin infusion during dialysis. The patient care technician programs the machine to administer the heparin infusion. The infusion rate is checked by the RN [registered nurse] as she makes rounds in the first hour of a patient's treatment. Upon checking the machine, the RN discovered the infusion rate was set to 5,000 units per hour. The patient was given an extra 4,500 units of heparin in the first hour.*

Other medication events involving hemodialysis administration reported to the Authority suggest ineffective handoff of patient information from one healthcare provider to another when a hospitalized patient is sent from a patient care unit to a renal unit for hemodialysis and miscommunication of drug orders. The following examples from the hemodialysis events reported to the Authority illustrate an ineffective handoff and miscommunication of an order, respectively:

> *The patient receives 20,000 units of Procrit® [a brand name for epoetin alfa] after dialysis. The medication is administered in the dialysis unit. The dialysis RN gave the report to the RN stating that the patient was given Epogen® [another brand name for epoetin alfa]. The RN administered a dose of Procrit at 4:45 p.m., not realizing that Procrit and Epogen were the same medication. The patient received an extra dose.*

> *A vancomycin order for a patient indicated the drug was to be given daily after each dialysis. The order was entered as Q24 hours, give after each dialysis. The nurse read the order as a daily dose with the dose on dialysis days to be given after dialysis.*

Patients with ESRD are also at risk of receiving medications contraindicated for hemodialysis patients—for example, several antithrombotic medications may be contraindicated in hemodialysis patients because of increased bleeding risks[11] and should be used with caution—or of receiving a medication dose that is not recommended for a patient with kidney failure. These types of medication errors are not discussed in this article because it is limited to errors and events occurring during hemodialysis administration.

Failure to Follow Protocol

Sixty-eight events involved failure to follow protocols and procedures during hemodialysis administration. The largest number (n = 14) of these events were related to inadequate communication between healthcare providers about a patient's care or failure to transmit orders about a patient's care to the dialysis setting. (These events exclude inadequate handoff of information about a patient's medications, laboratory tests, or blood needs, which are included in other event categories.) As illustrated in Table 2, the 14 reports represent 20.6% of events involving failure to follow protocol and 2.7% of all 526 events involving hemodialysis administration. Examples reported to the Authority include the following:

> *Physician stated patient was discharged earlier in the day and was not given hemodialysis treatment that the physician wanted the patient to have. No order was written in the patient's chart to have hemodialysis prior to discharge.*

> *The medical service placed a nasogastric tube in a patient while the patient was undergoing dialysis in the dialysis unit. The patient vomited, became unresponsive, and required immediate emergency response. The patient became a full code and was transferred to the critical care unit after receiving advanced cardiac life support. No defibrillation was needed. The purpose of this report is to reiterate that no invasive procedures such as nasogastric tube placement are to be performed on any patients in the dialysis unit unless the procedure is approved by the medical director.*

Table 2 also shows that other events related to failure to follow protocol included incorrect hemodialysis treatment set up, treatment time, or dialyzer; reversed

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hemodialysis lines during treatment; and missing catheter caps, which are important in the prevention of catheter-related infections for patients receiving hemodialysis through a hemodialysis catheter. The following events reported to the Authority describe these scenarios:

> *After treatment, the patient complained of feeling unwell and was hypotensive. The patient was sent to the ED for evaluation. The patient's calcium levels were low, and the patient was admitted for therapy. It was noted later that the mixture in the dialysis machine used to treat the patient was not properly mixed with the amount of calcium indicated in the patient's prescription for dialysis. The patient was discharged the next day without problems.*
>
> *The dialysis clinic had two patients with the same name. Both patients had the same treatment ordered but there was a difference in the treatment time length. Patient #1 was to run for three hours and patient #2 was to run for three and a half hours. When treatment started for patient #1, staff questioned if the treatment was for the correct patient. With proper identification, it was noted that patient #1 was set up for patient #2's treatment. The error was noted early in the treatment so that the patients received the correct lengths of treatment.*
>
> *While checking the patient's vital signs, it was found that the patient's dialysis needles were hooked up backwards. The arterial needle was hooked to the venous dialysis line and the venous needle to the arterial line. Treatment was paused, and the lines were correctly connected arterial-to-arterial and venous-to-venous. The treatment was then continued.*
>
> *The patient arrived in the dialysis unit with no caps on both ports of the new dialysis catheter. Both lines were clamped. The dressing in place was changed the same day the catheter was placed. Vigorous cleansing was done before using the catheter. The physician, special procedures unit, IV team, and floor nurse were notified.*

Similar lapses have been reported in published studies and surveys of hemodialysis. For example, a survey of 649 ESRD professionals found that nearly two-thirds reported that at least one incorrect dialyzing solution was set up for a patient over a three-month period.[8]

A separate survey of clinical directors at four Virginia dialysis centers, each providing more than 500 hemodialysis treatments per month, found that an error in hemodialysis treatment—including a wrong dialyzer, incorrect treatment time, incorrect dialysate flow rate, and reversed lines—occurs once per every 733 treatments.[12]

One of the reports to the Authority regarding incorrect treatment set up involved using an incorrect dialysate solution for two hours during a patient's hemodialysis session. The report is as follows:

> *Hemodialysis machine alarmed that the acid concentrate jug was empty. Upon replenishing the acid concentrate, it was found that the incorrect acid concentrate was hooked up. The order was for 2K/2CA acid concentrate; 3K/2.5CA acid concentrate was found on the machine. The incorrect acid concentrate was on machine from the time the treatment was initiated when the machine alarmed for more acid concentrate. The wrong dialysate acid concentrate was used.*

An error such as this can occur because dialysate solution jugs or containers look alike even though solutions may have different electrolyte combinations to meet the specific needs of each patient. Mix-ups can occur in selecting a patient's dialysate when containers of similar size and with look-alike packaging are stored near each other, despite the differences in electrolyte concentrations. Although the report to the Authority indicated that the patient was unharmed by the event, there are published reports of patient deaths from hemodialysis solution mix-ups.[13] Because of the significant patient harm that can occur from such mix-ups, ISMP lists dialysis solutions as high-alert medications.[10]

Needle Infiltration

There are three ways to achieve vascular access during hemodialysis: (1) using an intravascular catheter; (2) placing a synthetic graft, usually in the patient's arm, to connect an artery to a vein; or (3) creating an arteriovenous fistula by connecting an artery and vein, typically in the patient's arm. With either the graft or the fistula, a needle is used to access the patient's blood for the hemodialysis treatment. Sometimes during the insertion or cannulation of the needle, the needle may

Table 2. Predominant Event Types Associated with Failure to Follow Protocol, November 1, 2008, through October 31, 2009

EVENT TYPE	NUMBER	% OF EVENTS ASSOCIATED WITH FAILURE TO FOLLOW PROTOCOL (n = 68)	% OF TOTAL EVENTS (N = 526)
Inadequate handoff, orders not followed (excludes events involving medications, laboratory, blood bank)	14	20.6%	2.7%
Incorrect treatment set up, treatment time, dialyzer	12	17.6	2.3
Lines reversed	9	13.2	1.7
Catheter cap missing, incompatible	6	8.8	1.1
Tourniquets, clamps, needles left in place; items not removed	5	7.4	1.0

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unintentionally pierce the back wall of the graft or fistula and cause blood to infiltrate into the surrounding tissue. There were 32 reports of needle infiltration, representing 6.1% of all hemodialysis administration events submitted to the Authority during the one-year period. Most of the reports indicate that needle infiltration occurred during the needle insertion. Infiltrations can occur before hemodialysis starts, during hemodialysis, or after hemodialysis with needle removal. Treatment for an infiltration will vary depending on whether heparin, which can promote bleeding, has been administered. In the reports to the Authority, patients typically had already received heparin when the infiltration occurred. Patients were usually treated by removing the needle, applying pressure and ice to the infiltration site, and cannulating with another needle at a spot away from the infiltration site.

One study of needle infiltration of arteriovenous fistulas calculated an annual rate of 5.2% of major fistula infiltrations resulting in the need for additional diagnostic tests and interventions. In some cases, patients had to resort to continuing with an intravascular catheter for hemodialysis treatments, the least preferred method for achieving access, until the fistula could be used again.[14]

Falls

Falls are common among dialysis patients and can occur at any point before, during, or after a patient's dialysis treatment. Dialysis patients are at increased risk of falling for a variety of reasons: being of advanced age, taking multiple medications, having multiple comorbidities, or experiencing weakness, unsteadiness, and dizziness caused by a change in blood pressure after treatment. In reports of hemodialysis events submitted to the Authority, there were 31 reports of falls, representing 5.9% of all hemodialysis administration events over the one-year period. Patients fell before treatment (e.g., when stepping on a scale to be weighed), during treatment (e.g., when interrupting treatment to use a bathroom), and after treatment (e.g., when transferring from the hemodialysis chair). In one report, a patient bumped into the hemodialysis equipment and fell, and in another report, the patient who fell said she slipped on water that had spilled onto the floor, although the report says that "no water was observed on the floor." There were two reports of serious injuries involving lacerations to the head, as in the following report:

> *Patient on rehab, poststroke with hemiparalysis. While on the progressive care unit for dialysis, the dialysis RN walked the patient to the bathroom and instructed him to call for assistance when done. The patient got up on his own and reports that he "got dizzy" and fell. The patient was seen by a physician. A computed tomography scan of the head was negative for injury. The patient was taken to the ED for assessment and received staples for a small, full-thickness laceration to the left posterior scalp. The patient was returned to the rehab unit.*

A study of falls among patients treated at seven hemodialysis units calculated a falls incidence rate of 12.7%, with 10.7% of the falls meeting the researchers' definition of a serious fall—meaning the fall caused a fracture, required hospitalization, or caused death.[15] The study, which included falls occurring outside the hemodialysis units, calculated an average incidence of 1.18 falls/patient-year. A study of falls among hemodialysis patients 65 years of age and older treated at a hemodialysis unit found that 47% of older hemodialysis patients fell over the one-year period and that 19% of the falls resulted in injuries.[16] The falls incidence rate for this group was 1.60 falls/patient-year. This study and others suggest that falls rates among older hemodialysis patients are higher than that of community-dwelling elderly who do not require dialysis.[16,17] In addition, dialysis patients have a higher incidence of hip fractures than the general population and are at greater risk of dying within one year after the fracture compared with the general population.[17]

Equipment/Facility Failure

Hemodialysis equipment and disposables used for treatment can fail, causing treatment interruptions and delays and possible patient harm. In addition, events within the facility (e.g., loss of power) can interfere with a hemodialysis patient's care. Over the one-year period analyzed, 21 reports to the Authority involved equipment failures during hemodialysis administration, representing 4% of all events. One such report is as follows:

> *After two hours of dialysis, the portable reverse osmosis machine shut off. No lights were lit on the machine. The ground fault circuit interrupter was checked and had not been tripped. The patient was taken off of dialysis due to not having a water supply. The doctor, who was in the room at the time, ordered staff to pull the needles. The treatment was done for the day.*

ECRI Institute maintains a database of hazards and recalls for medical equipment. The Institute has found that dialysis equipment ranks high, along with anesthesia equipment, defibrillators, and ventilators, in the number of hazards and recalls issued for these medical devices. While not all hazards and recalls create life-threatening situations, the technology is not immune from device-related hazards and requires an effective technology management program to ensure its safe operation. Such technology management programs include documentation of the most recent version of software installed on dialysis equipment. An analysis of ECRI Institute's database of dialysis-related alerts found that an increasing percentage of problems reported with dialysis equipment were related to software issues or resolved by software revisions.[18]

In addition to equipment failures, other nonmedical emergencies can occur as a result of events such as fire, power failure, water supply interruption, and natural disaster. Four reports to the Authority, or 0.8% of all hemodialysis administration events over

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the one-year period, involved facility failures, including one isolated power failure affecting a hemodialysis patient on a ventilator that required immediate intervention to prevent harm to the patient, as described in the following report:

> *Patient was on dialysis and on a ventilator when the electricity to that unit only went out. The patient was immediately bagged, and the oxygen level was monitored. The patient is now extubated.* [A recommendation accompanying the narrative indicated a faulty electrical outlet for the unit was repaired within 15 minutes.]

Infrastructure failure reports are submitted separately to the Pennsylvania Department of Health;[19] therefore, the limited number of reports of facility failures received by the Authority may not accurately reflect the number of events in this category affecting hemodialysis administration.

Clotting

Reports of hemodialysis administration events submitted to the Authority included 23 instances (4.4% of all events) of clotting in the hemodialysis circuit or lines. Four of the reports indicate that the patient lost blood as a result of clotting, as described in the following:

> *Patient dialysis treatment was initiated. The venous needle had a clot in it. A second venous needle was placed and also resulted in a clot. The third needle was placed by the RN in charge and resulted in a small hematoma. The dialysis line clotted in a very short time, resulting in 200 ml of blood loss. The physician was contacted, and per his request, the patient's fistula is resting today. The patient will have hemodialysis treatment tomorrow with a [red] blood cell count to be drawn to assess the blood loss.*

In addition to blood loss, clotting can lead to a suboptimal treatment from hemodialysis. Unless contraindicated, heparin is used during hemodialysis to prevent clotting of the blood lines and dialysis filter. For patients with allergies to heparin, saline flushes can be used during hemodialysis to reduce clotting.

A study of adverse events and medical errors reported at four Virginia dialysis centers identified clotting of the hemodialysis circuit as the second most commonly reported adverse event behind needle infiltration (medical errors such as medication omissions, reversed lines, and improper treatment set up were analyzed separately). The researchers note that most clotting events occurred when heparin use was contraindicated.[12]

Clotting can also involve the hemodialysis access, although there were no reports of this type among the 526 hemodialysis administration events submitted to the Authority. Fistula First, a federal government initiative that promotes an arteriovenous fistula as the preferred site for removal and return of the blood during hemodialysis, could help to reduce the number of clotted hemodialysis accesses, associated complications, and procedures to remove clots. Unlike the other two alternative access methods—a venous catheter or synthetic graft—fistulas are less prone to clotting.[20] The federal government, which provides coverage for most dialysis treatments through its federal ESRD program, has a goal of 66% of hemodialysis patients using arteriovenous fistulas. As of October 2009, 54.2% of hemodialysis patients were using fistulas, a marked improvement since the Fistula First initiative began in 2003, when only 20% to 30% of patients had fistulas.[21]

Risk Reduction Strategies

Dialysis patients worry that mistakes may occur during their treatment. Of 1,113 dialysis patients surveyed in 2006, almost half indicated that they sometimes, usually, or always worry that a medical mistake will occur during one of their dialysis treatments.[22] Analysis of hemodialysis reports submitted to the Authority confirms patients' fears that mistakes can and do occur. To help prevent future errors involving hemodialysis administration, dialysis facilities can consider the strategies described below.

Medication Errors

- Ensure that pharmacists who participate in rounding on hospital units to review medications prescribed for patients include the medications that patients receive during hemodialysis treatments in their reviews.
- Simplify treatment protocols, including the timing of medication administration during hemodialysis treatment, to reduce the likelihood of medication omissions.[12]
- Perform independent double checks of IV heparin doses and infusions before dispensing.[10]
- Require reconciliation of medications at every transition in the patient's care—including transitions when the patient is sent from a hospital care unit, such as the medical/surgical unit, to the renal unit for hemodialysis and back.
- Ensure clear communication between healthcare providers when a patient is transferred from one level of care to another, specifically emphasizing the use of clear language to provide up-to-date information about the patient's care, treatment and services, medications received, condition, and recent or anticipated changes. The healthcare provider receiving the information should repeat back the information for verification and ask questions to clarify unclear orders or instructions.[23]
- Ask hemodialysis patients to keep a list of all their medications and share it with providers in the dialysis clinic and other care areas where the patient is treated.[24]
- Educate hemodialysis patients about their medications, and ask them to be alert for possible medication errors.[12]

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Failure to Follow Protocol

- Provide dialysis technicians with checklists for appropriate hemodialysis set up. Require double checks of the set up.[8]
- Establish red rules (specific requirements that must be exactly followed) for certain set-up procedures.[8]
- Involve patients in their hemodialysis care so that they speak up if something seems amiss, such as if the label on the dialyzing solution does not match the patient's prescription or the dialyzer is not labeled with the patient's name.[25]
- Enforce measures to prevent hemodialysis treatment mix-ups of patients with similar names. Alert staff to the potential for mix-ups, and use two patient identifiers—for example the patient's name and the patient' date of birth—to verify a patient's identification.
- Trace all lines to their point of origin to verify that correct connections are made.[26] While some arterial and venous lines are colored red and blue, respectively, to help healthcare providers identify the lines, use of the colored lines will not necessarily prevent misconnections. (For more strategies to prevent misconnections, refer to the article "Tubing Misconnections: Making the Connection to Patient Safety" in the June 2010 issue of the *Advisory*.)
- Require aseptic technique for the placement of intravascular and central venous catheters used for hemodialysis.[27]
- Consider the use of bar-coded labels to confirm correct dialyzers, solutions, and other aspects of the patient's hemodialysis treatment.[24]
- When storing or using solutions, separate look-alike dialysis solutions with different electrolyte combinations. When possible, standardize solution purchases to a limited number of vendors to limit product variation.[28]
- Provide regular education for dialysis healthcare providers of the risk of hemodialysis treatment errors and strategies to prevent such errors.

Needle Infiltration

- Ensure that dialysis staff understand the basics of vascular access and are competent in needle cannulation of a fistula and graft.[29]
- Provide training that follows the National Kidney Foundation's clinical practice guidelines for vascular access.[7]
- Evaluate infiltration problems that occur within the dialysis setting to determine whether adjustments to cannulation techniques are necessary to decrease the number of infiltrations.[29]
- Educate staff to respond quickly to needle infiltration events to minimize damage to the access.[7]

Falls

- Provide staff education on fall assessment and prevention, and establish a policy to assess all hemodialysis patients for their risk of falling.
- Instruct staff to ask patients about any falls they may have experienced since the last treatment and to determine whether any adjustments to the hemodialysis treatment or physician notification are necessary.[30]
- Consider adding a physical therapist or exercise physiologist to the hemodialysis unit's multidisciplinary team to work with patients on strength training and balance.[17]
- Evaluate the environment of the dialysis center or unit for hazards that cause falls. Remove any tripping hazards that may obstruct a patient's path.[31]
- Ensure that equipment is readily available to mop up spills.[31]
- Require staff to assess patients' assistive devices such as canes and walkers for stability.[32]
- Weigh patients before and after treatment with shoes to prevent slips and falls.[33]
- Provide a bathroom call bell within easy reach of the patient, and require assistance and attendance in the bathroom for patients who are hemodynamically or physically unstable.[33]
- Instruct staff to assess patients' posthemodialysis blood pressure level, ask whether patients feel steady, and assist patients as they stand up or transfer to a bed or wheelchair after treatment. If patients feel dizzy after treatment, they should be instructed to remain sitting until they meet specific discharge criteria.[8,34]
- Educate patients about their risk of falling and provide falls prevention instruction.
- Evaluate falls that do occur to identify risk factors that may have contributed to the falls and interventions to prevent such falls from happening again.[33]

Equipment/Facility Failure[35]

- Establish a technology management program for regular inspection and preventive maintenance of equipment used in the dialysis unit.
- Maintain an effective recall program to identify and address hazards and alerts involving the dialysis unit's equipment inventory.
- Require staff to remove malfunctioning equipment from service without changing any control settings and to notify appropriate personnel to examine and repair the equipment.
- Develop processes and procedures for managing nonmedical emergencies that threaten the health or safety of patients, staff, and others in the facility.

Clotting

- Ensure that protocols are in place for heparin use during hemodialysis to prevent clotting of the dialysis lines and circuit. Facilities should also ensure

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that hemodialysis staff are provided guidance on implementing the protocols, including identification of patients for whom heparin is contraindicated.

- Provide training that follows the National Kidney Foundation's clinical practice guidelines for vascular access.[7]
- Ensure that hemodialysis staff routinely assess vascular accesses for flow problems that may suggest clot formation, as recommended by the National Kidney Foundation's clinical practice guidelines for vascular access.[7]
- Instruct patients about the importance of fluid and weight management between hemodialysis treatments to help prevent clotting as a result of postdialysis hypotension, which can result in decreased blood flow through the fistula or graft.[36]
- Instruct patients to assess their hemodialysis access for adequate flow between hemodialysis treatments to help identify problems and to immediately notify their doctor or hemodialysis care team of any indications of flow impairment (e.g., absence of or changes to vibrations and sounds in the access).[20] Provide patients with additional tips for maintaining their hemodialysis access (e.g., avoiding tight clothing or jewelry on the access limb to prevent clotting).
- Promote the use of a fistula as the best choice for patients for hemodialysis access.[20]

Notes

1. U.S. Renal Data System (USDRS). Treatment modalities. Volume 2, chapter 4. In: USDRS 2009 annual data report: atlas of chronic kidney disease and end-stage renal disease in the United States [online]. [cited 2009 Dec 29]. Available from Internet: http://www.usrds.org/2009/pdf/V2_04_09.pdf.
2. Ward RA, Ronco C. Improvements in technology: a path to safer and more effective hemodialysis. *Blood Purif* 2009;27(1):6-10.
3. ESRD Network 4, Inc. 2008 annual report [online]. 2008 [cited 2009 Dec 29]. Available from Internet: http://www.esrdnetwork4.org/downloads/nw4ar2008.pdf.
4. Medical Care Availability and Reduction of Error (MCARE) Act. 40 P.S. § 302 (2007).
5. National Coordination Council for Medication Error Reporting and Prevention (NCC MERP). NCC MERP index for categorizing medication errors [online]. 2001 Feb 20 [cited 2009 Dec 29]. Available from Internet: http://www.nccmerp.org/pdf/indexColor2001-06-12.pdf.
6. National Kidney Foundation Kidney Disease Outcomes Quality Initiative. Clinical practice guidelines for hemodialysis adequacy [online]. 2006 [cited 2010 Jan 5]. Available from Internet: http://www.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/index.htm.
7. National Kidney Foundation Kidney Disease Outcomes Quality Initiative. Clinical practice guidelines for vascular access [online]. 2006 [cited 2010 Jan 5]. Available from Internet: http://www.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/index.htm.
8. Renal Physicians Association. Health and safety survey to improve patient safety in end stage renal disease: report of findings from the ESRD professional survey [online]. 2007 Mar [cited 2009 Dec 29]. Available from Internet: http://www.kidneypatientsafety.org/pdf/healthsafetysurveyreports/HSSProfessionalSurveyReport_FNL_3-21-07.pdf.
9. Ledger S, Choma G. Medication reconciliation in hemodialysis patients. *CANNT J* 2008 Oct-Dec;18(4):41-3.
10. Institute for Safe Medication Practices. ISMP's list of high-alert medications [online]. 2008 [cited 2009 Dec 29]. Available from Internet: http://www.ismp.org/Tools/highalertmedications.pdf.
11. Tsai TT, Maddox TM, Roe MT, et al. Contraindicated medication use in dialysis patients undergoing percutaneous coronary intervention. *JAMA* 2009 Dec 9;302(22):2458-64.
12. Holley JL. A descriptive report of errors and adverse events in chronic hemodialysis units. *Nephrol News Issues* 2006 Nov;20(12):57-8,60-1,63-7.
13. Calgary Health Region. External patient safety review [online]. 2004 Jun [cited 2009 Dec 29]. Available from Internet: http://www.calgaryhealthregion.ca/qshi/patientsafety/reports/robson_report.pdf.
14. Lee T, Barker J, Allon M. Needle infiltration of arteriovenous fistulae in hemodialysis: risk factors and consequences. *Am J Kidney Dis* 2006 Jun;47(6):1020-6.
15. Desmet C, Beguin C, Swine C, et al. Falls in hemodialysis patients: prospective study of incidence, risk factors, and complications. *Am J Kidney Dis* 2005 Jan;45(1):148-53.
16. Cook WL, Tomlinson G, Donaldson M, et al. Falls and fall-related injuries in older dialysis patients. *Clin J Am Soc Nephrol* 2006 Nov;1(6):1197-204.
17. Roberts R, Jeffrey C, Carlisle G, et al. Prospective investigation of the incidence of falls, dizziness and syncope in haemodialysis patients. *Int Urol Nephrol* 2007;39(1):275-9.
18. Majchrowski B. Dialysis, hazards, and medical device software: then and now. *Biomed Instrum Technol* 2009 Jan-Feb;43(1):59-62.
19. Medical Care Availability and Reduction of Error (MCARE) Act. 40 P.S. § 313(c) (2007).
20. National Kidney Foundation. What you need to know about your access: getting the most from your treatment [online]. 2006 [cited 2009 Dec 29]. Available from Internet: http://www.kidney.org/atoz/pdf/YourAccess.pdf.
21. Fistula First Coordinating Center. Conversation with: ECRI Institute. 2009 Dec 29.
22. Renal Physicians Association. Health and safety survey to improve patient safety in end stage renal disease: report of findings from the ESRD patient survey [online]. 2007 Mar [cited 2009 Dec 29]. Available

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from Internet: http://www.kidneypatientsafety.org/pdf/healthsafetysurveyreports/HSS%20Patient%20Survey%20Report_FNL_3-21-07.pdf.

23. Joint Commission. National patient safety goals: goal 2 (improve the effectiveness of communication among caregivers) [online]. 2009 [cited 2009 Dec 29]. Available from Internet: http://www.jointcommission.org/NR/rdonlyres/868C9E07-037F-433D-8858-0D5FAA4322F2/0/RevisedChapter_HAP_NPSG_20090924.pdf.
24. Kliger AS. Patient safety in the dialysis facility. *Blood Purif* 2006;24(1):19-21.
25. Renal Physicians Association. Dialysis safety: what patients need to know [online]. [cited 2009 Dec 29]. Available from Internet: http://www.kidneypatientsafety.org/pdf/toolkit/RPA_dialysis_safety.pdf.
26. ECRI Institute. Fixing bad links: preventing misconnections in your hospital [guidance article]. *Health Devices* 2009 Jul;38(7):220-7.
27. Centers for Disease Control and Prevention (CDC). Guidelines for the prevention of intravascular catheter-related infections [online]. 2002 Aug 9 [cited 2009 Dec 29]. Available from Internet: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5110a1.htm.
28. Cohen MR, Smetzer JL, Tuohy MR, et al. High-alert medications: safeguarding against errors. Chapter 14. In: Cohen MR, ed. *Medication errors.* 2nd ed. Washington (DC): American Pharmacists Association; 2007: 332.
29. Brouwer DJ. Cannulation camp: basic needle cannulation training for dialysis staff [online]. 1995 [cited 2009 Dec 29]. Available from Internet: http://www.esrdnet11.org/assets/fistula_first/cannulation_camp.pdf.
30. Renal Physicians Association. Exercise physiologist helps prevent patient falls: West Virginia facility zeros in on contributing factors [online]. [cited 2009 Dec 29]. Available from Internet: http://www.kidneypatientsafety.org/pdf/RPA_spotlight%20article101608.pdf.
31. Heartland Kidney Network. Fact sheet: patient safety in the dialysis facility: a basic and practical approach [online]. 2006 Sep [cited 2009 Dec 29]. Available from Internet: http://www.heartlandkidney.org/quality/downloads/patient_safety_fact_sheet.pdf.
32. Renal Physicians Association. Taking steps to prevent patient falls [online]. [cited 2009 Dec 29]. Available from Internet: http://www.kidneypatientsafety.org/pdf/bestpractices/AltavistaDialysisCenter_Falls.pdf.
33. ESRD Network of New England. Sample policy: fall risk prevention [online]. 2005 Mar [cited 2009 Dec 29]. Available from Internet: http://www.networkofnewengland.org/Patient%20Safety/5%20Diamond%20Program/Slips%20Trips%20and%20Falls/STF-3.pdf.
34. Renal Physicians Association. Understanding and correcting patient fall issues at new facility [online]. [cited 2009 Dec 29]. Available from Internet: http://www.kidneypatientsafety.org/pdf/bestpractices/BP%20Falls%20Fresenius.pdf.
35. ECRI Institute. Dialysis. *Healthc Risk Control* 2009 Sep;4:Special clinical services 5:1-20.
36. American Association of Kidney Patients. What is access clotting? [online]. 2004 Jul [cited 2010 Jan 5]. Available from Internet: http://www.aakp.org/aakp-library/Access-clotting.

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Strategies for Avoiding Problems with the Use of Pneumatic Tourniquets

ABSTRACT

The Pennsylvania Patient Safety Authority has received 140 event reports associated with pneumatic tourniquets (December 2004 through December 2009). Pneumatic tourniquets are used primarily to occlude blood flow and obtain a bloodless field during limb surgery. They also facilitate intravenous regional anesthesia, an alternative to general anesthesia for surgery involving the upper or lower limbs. In this application (also known as a Bier block), the tourniquet prevents infused local anesthetic from flowing out of the limb and also provides a bloodless operating field. This article considers tourniquet problems reported to the Authority and reviews use and maintenance issues that can prevent these types of problems. (Pa Patient Saf Advis 2010 Sep;7[3]:97-101.)

In surgical applications, a pneumatic tourniquet should reliably maintain the minimum pressure necessary to stop blood flow in the limb. This minimum pressure setting is affected by repositioning the limb during the procedure, by changes in systolic pressure, and by cuff width compared to limb circumference. Pneumatic tourniquets typically consist of three basic components: (1) a cuff, (2) a means of inflating the cuff bladder, and (3) a controller (e.g., a pressure indicator, regulator). Most tourniquet controllers also have a timer or an elapsed-time meter for tracking cuff inflation time because there is a limit to tolerable ischemia time.

There are several methods for inflating tourniquet cuffs. Many models operate from compressed-gas sources: air or nitrogen is delivered from a wall outlet or a cylinder with a regulator. Several models use an electric pump to compress ambient (i.e., room) air for cuff inflation; these units are line powered and typically have backup batteries.

Cuff pressure is indicated by liquid crystal display (LCD), light-emitting diode (LED) display, or an aneroid gauge; there may also be indicators for supply pressure and/or low battery. Most of the line-powered and some of the compressed-gas units have alarms for such conditions as excessive cuff pressure, cuff pressure leaks, kinks in tubing, and mechanical failure. A few units incorporate a sensor for determining and tracking limb occlusion pressure (LOP). Tourniquet controllers should have locking connectors that secure cuff tubing to prevent leaks and inadvertent detachment. The connectors must also *be incompatible* with Luer fittings to prevent accidental connection to intravenous (IV) tubing and infusion pump administration sets.

Reusable and single-use tourniquet cuffs are available in a wide variety of lengths and are closed with Velcro™ and ribbon fasteners. Cuff selection should be made according to the patient's limb circumference; cuffs should not overlap beyond the Velcro when applied. Several studies have reported that the use of wide tourniquet cuffs reduces the pressure needed to stop blood flow; as such, it is recommended that a cuff should be wider than half the limb's diameter.[1,2] Contoured cuffs are desirable for limbs that are excessively tapered (i.e., very muscular, obese); conventional cuffs transmit pressure disproportionately to the wider section of the limb rather than uniformly across the cuff width.[3]

Intravenous regional anesthesia (IVRA), more commonly referred to as a Bier block, is performed with a dual-bladder cuff. After the limb is exsanguinated by compressing it with a spirally wrapped (Esmarch) bandage, the bladder farthest from the operating site is inflated, and the anesthetic (e.g., lidocaine) is infused into the limb through an IV cannula. After the anesthetic has been absorbed, typically within 20 minutes, the second bladder is inflated over the anesthetized tissue, and the first is deflated. This procedure requires a tourniquet controller to be interfaced with the dual bladders so that the inflating gas can be channeled to either or both bladders.

Reported Problems

From December 2004 through December 2009, 140 events associated with the use of tourniquets in surgical procedures were reported to the Pennsylvania Patient Safety Authority. The event reports are summarized as follows, accompanied by deidentified examples:

- Events associated with limb redness, bruising, or swelling (41%). Bruising and/or swelling should not occur and suggests excessive pressure.

  Bruising noted along distal section of tourniquet.

  Patient complained of discomfort of her right upper arm. Anterior site is abraded and discolored with abrasion. It appears the tourniquet was too tight.

- Events citing skin tears or blisters (19%), which respectively suggest nonuniformly-applied cuff padding and absorbed prepping solution.

  Removed tourniquet at end of case. Noted bruised area anterior right thigh approximately 5 to 6 inches in length, probably from tourniquet and cast padding.

  18" tourniquet placed on left upper arm for surgery. Upon removal at end of procedure, patient was noted to have a blood blister approximately 8 inches around and 2 inches wide.

  After removal of the underpadding, it was noted that the patient had a 3 cm x 18 cm reddened area that began at the edge of the tourniquet underpadding. The area had Betadine solution present, which was wiped off with a warm, damp towel.

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- Events citing unintended deflation or "tourniquet failure" (14%), suggesting a system leak, an unsecured cuff, a controller malfunction, or a surge in blood pressure.

  Tourniquet was plugged in, and it deflated in the middle of the case. Lost all of the block anesthesia.

  Unexpected amount of bleeding occurred. Pressure increased to 400. Unusual bleeding continued, and Velcro noted to have detached on cuff.

  "BATT FAIL" after working well for 38 minutes. The alarm went off, and the tourniquet released. All the connections were checked and found to be intact. Another tourniquet was obtained and put into service.

  A tourniquet failed after 150 mg lidocaine bolus IV, Bier block was delivered, giving a subsequent risk of seizure and cardiovascular complications.

- Events citing a cuff inflation time for more than two hours (8%); some reports also mentioned limb tingling and/or numbness.

  Patient has had ongoing pain since block wore off, along with a numbness in certain parts of the foot.

  Physician was informed that tourniquet was up for 120 minutes. He asked for 10 more minutes. When 10 minutes were up, he asked for 10 more minutes. When 10 minutes were up [again], he asked for 10 more minutes. Tourniquet was up for a total of 145 minutes.

- Events in which the opposite limb was prepped and, in some cases, the cuff was applied (6%).

  A patient was admitted for right knee arthroscopy. A tourniquet was placed on the left leg and inflated by RN [registered nurse] at the request of the surgeon. The RN began to prep the left leg. The physician did time-out and said "right knee." Tourniquet was deflated and immediately removed.

- Events describing "partial occlusion" (4%), which suggests a system leak, insufficient pressure setting, incorrect cuff size and/or application, or a surge in intravascular pressure within the operative limb from injection of the block.

  A patient experienced bradycardia and decreased responsiveness after administration of lidocaine in the form of a Bier block. The patient was treated with medications (atropine, epinephrine, ephedrine, Narcan®, and Romazicon®), intubated, and transferred to the intensive care unit. [The patient's] mental status is much improved. A question was raised regarding the fit of the tourniquet.

  Doctor asked nurse to check tourniquet on right thigh because he did not have hemostasis intraoperatively. The tourniquet was found to have "unvelcroed." [They] reapplied a tourniquet one size bigger.

- Events citing that the cuff was not removed immediately after deflation (4%).

  [When a] patient returned from the postanesthesia care unit, an operative tourniquet was found on the patient's arm. The patient had complained of numbness and tingling, which was relieved when the tourniquet was removed.

  Patient complained that upper thigh hurt more than the surgery area. [Staff] discovered that the leg tourniquet was intact but deflated.

- Events citing that the opposite limb was injected or incised (4%).

  Patient placed in prone position for left leg popliteal posterior block. Block performed by the anesthesiologist on left posterior popliteal area. Patient was then put in supine position, and approximately a half hour later the anesthesiologist returned to perform the tourniquet block on the front of the leg. The anesthesiologist blocked the right front leg.

  A tourniquet was placed on the incorrect knee. The incision was made on the incorrect knee by the surgeon. Time-out procedures were not followed; site ID was already marked. The surgeon noted the lack of marking and stopped the procedure.

- Event citing use of an Esmarch bandage as a tourniquet for more than two hours, which produced blistering (0.7%).

  Surgeon using 4-inch esmark (sic) as tourniquet was advised of tourniquet time at 60, 90, 105 minutes and repeatedly at 120 minutes [and] did not release esmark until 132 minutes tourniquet time. Surgeon states he is in charge. Circulator advocating for patient.

Why Problems Occur

Extended application time and/or excessive cuff pressure can cause tissue bruising, limb swelling, muscle ischemia, compartment syndrome, and extremity paralysis from peripheral nerve damage. However, swelling and nerve damage may also result from or be exacerbated by other aspects of a procedure. Temporary nerve damage is a frequently reported tourniquet-related adverse event. Although nerve damage can be permanent, it frequently resolves within a year. Compartment syndrome is a relatively rare tourniquet complication; when it occurs, it is likely to require a fasciotomy.

The literature generally indicates that muscle ischemia occurs within one to three hours. Accordingly, there is no rule to determine how long a tourniquet may remain safely inflated; the length of time may vary with the age of the patient and the vascularity of the extremity.[4]

Applying padding under the cuffs of pneumatic tourniquets is a well-established and recommended practice.[2] However, a chemical burn can occur if a skin preparation solution (e.g., Betadine, chlorhexidine) runs beneath the tourniquet and is absorbed by the padding. Padding may also produce uneven pressure distribution if it overlaps or has areas of nonuniformity under the tourniquet cuff. The disadvantage of cast padding, which is commonly used for tourniquet cuff padding, is that its fibers adhere to Velcro and may eventually comprise cuff closure. As an alternative, consider using a stockinette-stitch bandage for cuff padding.

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When cuff pressure is between systolic and diastolic levels, blood can flow into the limb, but constriction of the veins will limit or prevent blood return, which may cause venous congestion and edema. Insufficient LOP and unintended cuff deflation can also result in blood entering the surgical site, subsequently interrupting and lengthening the procedure, and in blood loss. Although less common, nerve damage from hemorrhagic infiltration can also result from inadequate cuff pressure.[4]

Another potential for injury with pneumatic tourniquets occurs when they are used to provide intravenous regional anesthesia. High concentrations of anesthetic can enter the systemic circulation and cause such adverse events as cardiovascular collapse, seizures, cardiac arrest, and coma if either of the following occurs before the injected bolus is absorbed: cardiovascular pressure in the operative limb exceeds cuff pressure (e.g., from the injected bolus), or cuff falls below diastolic pressure. Unintentional pressure loss can result from a damaged tubing connector, deteriorated tubing and cuff bladders, and failed or improperly engaged cuff closures. It can also occur when cuff deflation is inadvertently activated. Although some tourniquet models have an alarm that signals cuff pressure loss, alarm activation is also likely to signal the release of a toxic anesthetic bolus from the limb.

In the past, some manufacturers of pneumatic tourniquets provided fittings that allowed connection of oxygen and nitrous oxide as inflation sources, which is hazardous. Tourniquets inflated with oxygen or nitrous oxide can catch fire and burn violently upon contact with ignition sources present in the OR (e.g., electrosurgical units, surgical lasers, fiberoptic light sources). ECRI Institute has reported an event in which leaked oxygen from a tourniquet connector was trapped under a surgical drape; the drape was ignited by a disconnected fiberoptic cable, and a flash fire severely burned the patient's legs.[5] Tourniquets that can be connected to oxygen or nitrous oxide should be removed from service.[6]

Risk Reduction Strategies for Avoiding Tourniquet Complications

The Association of periOperative Registered Nurses' (AORN) "Recommended Practices for the Use of the Pneumatic Tourniquets" includes 18 categories of detailed recommendations for nurses and physicians who use pneumatic tourniquets.[2] The following risk reduction strategies for tourniquet use are derived from AORN's recommended practices unless otherwise noted. (For additional information, see "Strategies for Pneumatic Tourniquet Use.")

Cuff Selection and Application

A complete selection of reusable or disposable cuffs needs to be available in each location where pneumatic tourniquets are used. Cuff lengths of 8 or 10, 12, 18, 24, and 34 inches are typically stocked. It is desirable to also have contoured cuffs, especially in the larger sizes, for the limbs of very muscular or obese patients.

As the Authority reports illustrate, it is essential to verify the correct surgical site before applying a tourniquet cuff. AORN provides extensive guidance to help ensure proper cuff selection and application. Select a cuff that will overlap between three and six inches when applied.[7] In addition to selecting the correct length cuff, the recommended practices state that the cuff should be wider than half the limb diameter where it is to be applied. If the limb is grossly tapered, a wider, contoured cuff will apply pressure to the limb more uniformly, and limb occlusion can be obtained at a lower inflation pressure. Before the cuff is inflated, the limb should be exsanguinated with an Esmarch bandage.

Inflation Time

AORN recommends that tourniquet inflation time "be kept to a minimum" and notes that "safe inflation time has not been precisely determined" and that "the surgeon should be informed of the duration of tourniquet time at regular, established intervals." Factors such as the patient's age and limb size or the presence of vascular disease may also be relevant when determining safe tourniquet time. For pediatric patients, an inflation time less than 75 minutes for lower extremities has been recommended.[8] It also has been recommended that the final decision of when to deflate a tourniquet be made by the surgeon based on the risks and benefits of delaying deflation until closure is complete.[3]

Limb Occlusion Pressure

Proper cuff inflation pressure is frequently defined as the minimum pressure above systolic that produces a bloodless field. However, rather than simply referencing systolic pressure, it is desirable to base cuff pressure on actual LOP. AORN states that LOP can be determined with a Doppler stethoscope located on an artery distal to the cuff while the cuff bladder is gradually inflated. LOP is equivalent to the cuff pressure at which the pulse stops and remains silent for several beats. AORN also recommends setting cuff inflation pressure for adults at LOP *plus* the following pressures:

- 40 mm Hg *if LOP is less than 130 mm Hg*
- 60 mm Hg *if LOP is between 131 mm Hg and 190 mm Hg*
- 80 mm Hg *if LOP is greater than 190 mg Hg*

For pediatric patients, adding 50 mm Hg to LOP is recommended.[9] The additional pressure allows for any likely increase in blood pressure during the surgical procedure and/or for increased venous pressure from injected anesthetic volume. The anesthetic for a Bier block is injected slowly (e.g., over 90 seconds); both cuffs of a double cuff tourniquet should not be deflated for at least 20 minutes.[10]

Verifying Tourniquet Performance

Prior to each procedure, AORN recommends that users visually inspect cuffs, tubing, connectors,

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Strategies for Pneumatic Tourniquet Use

Before Patient Use

- Maintain an adequate selection of cuffs.
  - Contoured cuffs are desirable for excessively tapered limbs.
  - Do NOT reuse single-use cuffs.
- Ensure electronic controllers are connected to line power and/or have adequate battery capacity; perform self-test.
- Select the proper size cuff, and look for cracked tubing and loose connectors.
- Keep tubing off the floor and routed to avoid accidental contact by personnel.
- Apply a soft padding uniformly to the operative limb cuff site.

After Applying a Tourniquet Cuff

- Do not allow prepping solution to migrate under cuff.
- Determine minimum limb occlusion pressure (LOP).
  - Place a Doppler stethoscope on a distal arterial pulse.
  - Increase cuff pressure until the pulse stops.
- Set cuff inflation pressure for *adult* patients at LOP plus:
  - 40 mm Hg if LOP is less than 130 mm Hg,
  - 60 mm Hg if LOP is between 131 and 190 mm Hg, or
  - 80 mm Hg if LOP is greater than 190 mm Hg.
- Set cuff inflation pressure for *pediatric* patients at LOP plus 50 mm Hg.
- Minimize cuff inflation time.
- Notify the surgical team of elapsed inflation time at regular intervals.
- Monitor cuff pressure during the procedure, especially when repositioning the limb.
- Remove cuff and padding immediately after completing procedure.
- Indicate the following in patient record:
  - Times of inflation and deflation
  - Inflation pressure(s)
  - Site of cuff placement
  - Controller ID number

Include Tourniquet Controllers in the Facility's Technology Management Program

- Inventory tourniquet controllers so that they can be identified and located in the event of hazard and recall notices.
- Schedule units for routine inspection and preventive maintenance.

Source: Association of periOperative Registered Nurses (AORN). Recommended practices for the use of the pneumatic tourniquet. In: *Perioperative standards and recommended practices*. 2007 ed. Denver (CO): AORN Inc; 2009:3753-85.

and the security of the closure mechanism; some clinicians routinely inflate the cuff and check for leaks. Pneumatic tourniquet controllers should be included on a facility's inventory of biomedical equipment. This inventory practice facilitates identification and location of units affected by a recall or other notification requiring user action. It also facilitates scheduling and documentation of routine inspection and preventive maintenance activities that ensure safe and accurate equipment operation. Tubing, cuffs, and batteries are replaced as needed during these activities.[11] Tourniquets with friction fit connectors (e.g., slip-fit Luer connectors, hose barbs) should be removed from service.[12] Units with Luer-lock connectors should also be removed from service to avoid the risk of air embolism from inadvertent connection of tourniquet tubing to an intravenous manifold or infusion pump tubing connectors.[12]

Conclusion

Pneumatic tourniquets are used to produce a bloodless field during limb surgery and frequently also to facilitate intravenous regional anesthesia. However, their failure or misuse can lead to multiple complications including muscle ischemia, nerve damage, convulsions, and coma. As part of a risk reduction strategy to reduce or eliminate adverse events related to their use, consider the following:

- Share this article with all staff responsible for applying, monitoring, removing, and maintaining pneumatic tourniquets.
- Review the procedure for determining LOP with clinicians who set cuff inflation pressure.
- Review the procedure for using a dual-bladder cuff with clinicians who deliver IVRA.
- Ensure that the facility has an adequate selection of tourniquet cuff sizes and that staff know how to properly apply them.
- Develop a policy that addresses monitoring and documenting cuff pressure and inflation time during a procedure.

Notes

1. Moore MR, Garfin SR, Hargens AR. Wide tourniquets eliminate blood flow at low inflation pressures. *J Hand Surg Am* 1987 Nov;12(6):1006-11.

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2. Association of periOperative Registered Nurses (AORN). Recommended practices for the use of the pneumatic tourniquet. In: *Perioperative standards and recommended practices*. 2007 ed. Denver (CO): AORN Inc; 2009:3753-85.
3. Noordin S, McEwen JA, Kragh JF, et al. Surgical tourniquets in orthopaedics. *J Bone Joint Surg Am* 2009 Dec;91(12):2958-67.
4. Canale ST, Beaty JH. *Campbell's operative orthopaedics.* 11th ed. Vol 1. Philadelphia (PA): Mosby Elsevier; 2008.
5. ECRI Institute. OR fires caused by fiberoptic illumination systems [hazard report]. *Health Devices* 1982 Mar;11(5):148-9.
6. ECRI Institute. Inappropriate use of oxygen to inflate or power medical devices [hazard report]. *Health Devices* 1982 Dec;12(2):54-5.
7. U.S. Food and Drug Administration (U.S. FDA). Safe use of pneumatic tourniquet cuffs (April 2007) [online]. 2008 Feb [cited 2010 Jul 15]. Available from the Internet: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=72#2.
8. Lynn AM. Systemic responses to tourniquet release in children. *Anesth Analg* 1986 Aug;65(8):865-72.
9. Tredwell SJ, Wilmink M, Inkpen K, et al. Pediatric tourniquets: analysis of cuff and limb interface, current practice, and guidelines for use. *J Pediatr Orthop* 2001 Sep-Oct;21(5):671-6.
10. Henderson CL, Warriner CB, McEwen JA, et al. A North American survey of intravenous regional anesthesia. *Anesth Analg* 1997 Oct;85(4):858-63.
11. ECRI Institute. Inspection and preventive maintenance procedure for pneumatic tourniquets. *BiomedicalBenchmark*™ 2008 Oct; IPM procedure 443.
12. ECRI Institute. Preventing misconnections of lines and cables [guidance]. *Health Devices* 2006 Mar;35(3):81-95.

Self-Assessment Questions

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

A tourniquet was applied to the left thigh of a hypertensive obese patient for an arthroscopic meniscectomy. 60 cc of 0.5% lidocaine was injected intravenously over approximately one minute. Less than 10 minutes after the injection, the patient's heart rhythm became irregular and she began to seize.

1. These symptoms of lidocaine toxicity are attributable to all of the following reasons EXCEPT:
   a. The cuff was inflated to 50 mm Hg above the patient's systolic pressure.
   b. The cuff was too wide.
   c. A contoured cuff was not used.
   d. The limb was not properly exsanguinated.
   e. The lidocaine bolus was injected too quickly.
2. All of the following problems associated with the use of pneumatic tourniquets have been reported to the Authority EXCEPT:
   a. Skin tears and blisters
   b. Limb tingling and numbness
   c. The wrong limb was prepped or injected
   d. Gangrene
   e. Bradycardia and decreased responsiveness during a Bier block
3. Select the practice that is unlikely to cause an adverse patient event.
   a. Select and apply a cuff that is narrower than half the diameter of the operative limb.
   b. Reuse a single-use cuff.
   c. Apply a cuff over cast padding.
   d. Allow prep solution to migrate under a cuff.
   e. Deflate both cuffs shortly after a injecting a regional block.
4. All of the following statements about selecting and applying tourniquet cuffs are accurate EXCEPT:
   a. Cuff lengths of 8 to 34 inches need to be available to accommodate a typical range of limb sizes.
   b. A cuff should be wider than half the limb diameter at the point of application.
   c. When applied, a cuff should overlap itself by at least 6 inches.
   d. Contoured cuffs are desirable for the limbs of obese patients.
   e. Dual-bladder cuffs are used to perform intravenous regional analgesia.
5. Which of the following statements about limb occlusion is accurate?
   a. It is approximately equal to diastolic pressure plus 80 mm Hg.
   b. It is approximately equal to systolic pressure plus 40 mm Hg.
   c. It is determined in the limb opposite the operative limb.
   d. It is the pressure selected on the tourniquet controller to inflate the cuff.
   e. It is likely to increase during a surgical procedure.

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Demonstrating Return on Investment for Infection Prevention and Control

ABSTRACT

Healthcare-associated infections (HAIs) represent 4.5 infections for every 100 hospital admissions and account for an estimated 99,000 deaths in the United States each year. In 2007, the Pennsylvania Health Care Cost Containment Council reported hospital charges of $35,168 in cases without an HAI to $191,872 in cases with an HAI, with a difference of 15.3 days in the average length of stay. Effective infection prevention and control programs demonstrate a valuable return on investment by releasing hospital resources for alternative uses and beds for new admissions. The Centers for Disease Control and Prevention estimates that the $45 billion annual direct cost of HAIs could be significantly reduced by as much as $31.5 billion with well resourced, quality infection prevention and control programs. Organizations may have inadequate methods to investigate the true cost of HAIs or the cost-effectiveness of infection prevention and control program. This article provides practical methods to engage healthcare executives in evaluating the cost of HAIs in their organization and to dispel common misperceptions about the significance of HAIs, reimbursement, and cost savings associated with effective HAI reduction programs. Using these methods will assist hospital epidemiologists to develop a compelling business case for infection prevention and control programs. (Pa Patient Saf Advis 2010 Sep;7[3]:102-7.)

Introduction

Healthcare-associated infections (HAIs) account for about 1.7 million infections and 99,000 deaths in the United States each year. This number represents 4.5 infections for every 100 hospital admissions.[1] The Centers for Disease Control and Prevention (CDC) March 2009 report on the direct medical costs of HAIs estimates that $35.7 to $45 billion in 2007 dollars is added to the nation's annual healthcare costs to treat these infections. These estimates reinforce the need for a renewed focus on sustainable HAI prevention and surveillance processes.[2] Resources are needed to sustain the momentum of infection prevention. Increasing resources requires establishing a business case for infection prevention and control programs.

An important function of the hospital epidemiologist and the infection preventionist (IP) is to demonstrate the value of infection prevention and control programs to healthcare executives. The most important aspect of a business case for prevention is reduction of harm and loss of life. But from a financial health perspective, boards, executives, and healthcare managers are interested in cutting costs and getting maximum value for expenditures. They may not see the benefit of new infection prevention and control programs if the return on investment is not realized within a certain time frame.[3] An infection control business case analysis of the excess cost of HAIs and of the excessive length of stay can help gain needed resources and physician support.[4] Practical methods are needed to engage healthcare executives in evaluating the true cost of HAIs in their organizations. Hospital leaders' awareness that HAIs impact their patients may not always lead to understanding the extent of the financial burden of HAIs or the cost-effectiveness of infection prevention and control programs. Organizations may have inadequate methods to investigate the true cost of HAI in their institutions. Executives and clinicians in hospitals with HAI rates at or below nationally published rates may become complacent, accepting that a certain degree of patient harm from infections is an unavoidable price of caring for older, sicker patients. Common misconceptions about HAIs need to be dispelled. These misperceptions include (1) the fallacy that the incidence of HAI in most institutions is insignificant; (2) the erroneous belief that additional cost of HAIs is largely offset by reimbursement, making cost savings associated with reduction of HAIs not worth the investment, and (3) the misperception that HAIs are an expected outcome of treating an older, sicker patient population with escalating use of invasive procedures.[5]

Economic Burden of HAI

HAIs consume resources, prolong patients' hospital stays, and are only partially reimbursed at best.

An economic analysis of central line-associated bloodstream infections (CLABSIs) at Allegheny General Hospital in Pennsylvania from 2002 to 2005 examined hospital revenues and expenses in 54 cases of patients with CLABSIs in two intensive care units (ICUs). The average payment for a case complicated by CLABSI was $64,894, and the average expense was $91,733 with a gross margin of minus $26,839 per case and a total operating loss of nearly $1.5 million from the 54 cases.[6]

In addition to revenue loss, there are hidden costs and lost financial opportunities associated with HAIs. For example, when patients are brought back to the operating room (OR) for an incision and drainage of a postsurgical site infection, both the surgical suite and the OR team are tied up, and new cases cannot be scheduled. Primary procedures are often reimbursed at a higher rate than follow-up procedures. [4]

The 2007 Pennsylvania Health Care Cost Containment Council (PHC4) report on HAIs in Pennsylvania hospitals shows that the average charge for care grew from $35,168, with an average length of stay of 4.4 days, for cases without an HAI to $191,872 for

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those cases with an HAI, with an average length of stay of 19.7 days. PHC4 reported that in almost all cases, hospitals do not receive full reimbursement of charges; on average, in 2006 and 2007, hospitals statewide were paid approximately 27% of established charges (see Table).[7]

The misconceptions regarding the financial significance of HAIs are dispelled by the CDC in its 2009 report on the direct medical costs of care related to secondary infection diagnosis, increased length of stay, and expensive HAI outbreaks. The report also describes additional cost components, which reflect the socioeconomic consequences of HAIs such as indirect and intangible costs of HAIs related to diminished quality of life (e.g., permanent disability, lost wages).[2]

CDC reports that the cost of HAIs per patient (based on the 2007 consumer price index) ranges from approximately $20,000 to $25,000.[8] Diagnosis-related group (DRG) based reimbursement is not increased when a patient develops an HAI, as there are no specific DRG codes available for HAIs. Hospitalized patients may be covered by Medicare and Medicaid, which in most cases reimburse fixed amounts based on diagnosis. The hospital then has to absorb the additional costs associated with HAIs, while the HAIs simultaneously prevent the hospital from taking new admissions with reimbursable conditions.[5,9] The Centers for Medicare and Medicaid Services (CMS) regulations, effective in 2008, now refuse reimbursement to hospitals for the excess costs of certain types of infections. (See "The Department of Health and Human Services Action Plan to Prevent Healthcare-Associated Infections.")

The current legal and regulatory landscape has changed in a large part due to the success of hospitals across the country with HAI prevention programs. HAIs that were previously thought of as defensible are now considered to be preventable adverse events. IPs will play a larger role in protecting their hospitals against liability in the future.[10]

Based on recent guidelines from the Society for Healthcare Epidemiology of America (SHEA)[3] and the Association for Professionals in Infection Control and Epidemiology (APIC),[5] a business case exists if the intervention realizes a financial return on investment through hospital profit, loss reduction, or cost avoidance in a reasonable time frame. Comparing the cost of an infection prevention and control program or intervention to the benefits—lowering rates of HAI and preventing harm and death—is the best method for justifying the investment in prevention efforts.

Return on Investment

Possibly the greatest opportunity to demonstrate a positive return on investment in infection prevention and control is by decreasing patients' hospital length of stay and releasing those beds to new patients, consequently increasing volume, revenue, and reimbursement.[11] This opportunity reinforces the evidence that financial investments in infection prevention and control programs offer good value and that resources to implement best practice strategies at the bedside should be made available.[8] In assessing the extent to which HAIs are preventable, CDC estimates that effective infection control programs could prevent up to 70% of infections. This can translate into potential savings nationwide of up to $31.5 billion of the $45 billion expenditures attributed to HAIs.[2]

The components of a high-quality infection prevention and control program include sufficient staff with time to conduct risk-adjusted surveillance; staff education; isolation and outbreak management; report review and development; employee health activities; tasks intended to meet regulatory requirements, including public reporting tasks; clinical implementation of evidence-based best practices; and process improvement activities. Program resource needs include trained IPs, clerical support, at least a part-time epidemiologist, physician champion and clinical nurse liaison hours, supplies, data mining support, and education.[11,12] Successful infection control programs are supported by clinicians, physicians, and executives in an organizationwide culture of safety.

The average cost for staffing that includes two IPs, one member of clerical support staff, and a part-time medical director is estimated at $300,000.[13]

Table. Pennsylvania Healthcare Cost Containment Council Hospital-Acquired Infections, 2007 Report Highlights

2007 CASES	NUMBER OF CASES*	INFECTION RATE PER 1,000 CASES	MORTALITY		AVERAGE LENGTH OF STAY (IN DAYS)		AVERAGE CHARGE	
			Number	Percent	Mean	Median	Mean	Median
Statewide	1,578,600	17.7	35,120	2.2%	4.7	3.0	$37,943	$20,111
Cases *with* a hospital-acquired infection	27,949	N/A	3,416	12.2	19.7	15.0	$191,872	$87,655
Cases *without* a hospital-acquired infection	1,550,651	N/A	31,704	2.0	4.4	3.0	$35,168	$19,748

* The number of cases with infections represents the number of hospitalizations in which the patient contracted a hospital-acquired infection as identified and reported by the hospital.

Source: Pennsylvania Health Care Cost Containment Council (PHC4). Hospital-acquired infections in Pennsylvania in 2007 [online]. 2009 Jan [cited 2010 Apr 21]. Available from Internet: http://www.phc4.org/reports/hai/07/default.htm.

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The Department of Health and Human Services Action Plan to Prevent Healthcare-Associated Infections

The U.S. Department of Health and Human Services (HHS) released an action plan in January 2009, which estimates that 80% of all healthcare-associated infections (HAIs) in hospitals in the United States fall into one of four categories of infections: (1) catheter-associated urinary tract infections (CAUTI), (2) surgical-site infections (SSI), (3) intravascular catheter-related bloodstream infections (CLABSI), or (4) ventilator-associated pneumonia (VAP). The plan further states that hospital length of stay for patients infected with methicillin-resistant *Staphylococcus* aureus (MRSA) has tripled since 2000.[1] HHS has developed targets and metrics in a five-year plan aimed at eliminating infections, including *Clostridium difficile* infections and MRSA.

HHS prioritized recommendations for prevention of these infections based on evidence-based best practices outlined in related Healthcare Infection Control Practices Advisory Committee (HICPAC) recommendations. HAIs will be identified through the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) reporting modules and from administrative and discharge data. As of October 1, 2008, the Centers for Medicare and Medicaid Services no longer provides additional payment for hospital cases with secondary diagnoses of CAUTI, CLABSI, and selected SSI when the condition was not present on admission. These conditions were selected by three criteria: (1) high cost, high volume, or both; (2) assignment to a diagnosis-related group that has a higher payment when present as a secondary diagnosis; and (3) could reasonably have been prevented through the application of evidence-based guidelines.[2]

Notes

1. U.S. Department of Health and Human Services (U.S. HHS). HHS action plan to prevent healthcare-associated infections [online]. [cited 2010 Feb 1]. Available from Internet: http//www.hhs.gov/ophs/initiatives/hai/infection.html.
2. Centers for Medicare and Medicaid Services. Hospital-acquired conditions (HAC) [online]. 2008 Oct [cited 2010 Apr 21]. Available from Internet: http://www.cms.hhs.gov/HospitalAcqCond/.

This cost could be financed by avoiding fewer than nine surgical-site infections (SSI), based on the CDC 2009 direct cost estimates of $34,670 per SSI.[2] Another study of 28 U.S. hospitals estimated that the hospitals' financial loss due to HAIs was 4.3 times greater than the amount the hospitals invested in prevention in 2005.[9]

Examples of cost savings associated with a well-resourced, quality infection control program include the expertise of an IP to eliminate supply waste through the appropriate selection of products and expensive technology, avoidance of regulatory citations[14] and fines for lack of progress in decreasing infection rates,[15] and enhancement of the organization's image by minimizing the threat of outbreaks, resistant pathogens, employee injuries from bloodborne pathogens, HAI disclosures, sentinel events, and malpractice claims.[10,16] Many infection prevention practices can improve quality without much of a financial investment. These include nurse-driven catheter removal protocols, proper equipment disinfection, hand hygiene, process and outcome measurement, and accountability standards for compliance.

Success Models

Hospitals across the country are taking an aggressive stance against HAIs, demonstrating that infections are not an expected outcome of treating older, sicker patients and that hospitals have a significant opportunity to improve their bottom line by eliminating HAIs.[5]

A 2004 Johns Hopkins Hospital study on the effects of a multifaceted infection control intervention program on CLABSI found that implementation of simple, inexpensive interventions prevented 43 CLABSIs and eight deaths and saved nearly $2 million in additional costs to the hospital.[17]

Pennsylvania's public reporting mandate necessitates support for hospitalwide surveillance of HAIs in acute care hospitals. Across the state, HAIs dropped nearly 7.8% from 2006 to 2007. According to PHC4's latest study, 27,949 patients contracted an infection during their hospitalization in 2007—a decrease from 30,237 patients in 2006. This represents a drop in the infection rate of 7.8%, from 19.2 infections per 1,000 cases in 2006 to 17.7 per 1,000 cases in 2007.[7]

St. Christopher's Hospital for Children in Philadelphia implemented a modified neonatal ventilator care bundle, decreasing the ventilator-associated pneumonia (VAP) rate in the neonatal ICU from 3.9 (10 cases) per 1,000 ventilator days in 2006 to 0.3 (1 case) per 1,000 ventilator days in 2008.[18] CDC estimates the cost of one case of VAP to be $28,508.[2]

Making the Business Case for Infection Prevention

An Administrator's Perspective

Administrators see infection prevention and control programs as cost centers because the costs cannot be passed onto anyone else. Infection prevention's value to the organization is based on how well HAIs are prevented and controlled. There are a number of ways in which that value is added; for example, reducing HAI damage to the hospitals' operating budget can also reduce legal liability. The public's demand for accountability for public safety has increased, giving IPs the advantage of more leverage as they represent best practices. The primary cost of HAIs to the hospital is the loss of bed days due to prolonged length of stay. The loss of higher paying, new admissions represents the gross costs of HAIs and the value of

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prevention. For example, an intervention that shortens a patient's stay in intensive care or lessens the need for surgery is a plus because the hospital gets more productivity out of the existing facility. Administrators want to know what comprises an effective infection prevention and control program, the costs and savings to the hospital, how much to invest, and what else could be done with the resources released through HAI prevention. They want the information in a timely fashion for budget consideration—at that time, there will be competition with every other department in the hospital. Administrators can be greatly influenced by a physician champion—physicians control 85% of healthcare spending in the United States, and they control the number of patients coming into the institution.[4]

A January 2010 survey of 203 senior hospital executives across the United States found that, despite current severe financial constraints, hospitals of all sizes are employing sophisticated budget strategies in a commitment to reduce infection rates. Surveyed hospital executives anticipate that focus on patient safety is a key component of an organization's strategy to enhance its reputation in select specialties. Infection prevention and control was identified as one of the top five categories with the highest budget growth potential. However, the report also found that just one-third of respondents are willing to increase spending to reduce errors and infection rates.[19]

From an IP Standpoint

When making the business case for increased infection prevention and control resources, data gathered for the infection prevention and control committee should be shared with people who decide how resources are allocated. Be prepared to discuss which interventions require *minimal* or no financial investment (e.g., standardization of work processes, compliance with checklists, teamwork, communication, collaborative efforts) and which are cost-effective. Any information about the excess number of days and costs attributable to HAIs is likely to be favorably received, as administrators are often receptive to information on the number of beds occupied by patients with HAIs.[4]

In a 2008 survey of IP challenges to maintaining a quality infection prevention and control program, 30% of the 930 respondents suggested that executives and physicians are their most important resources to meet HAI challenges; of those looking for leadership, only half indicated that these executives and physicians are leading the charge against infections in their facilities. Fifty-seven percent cited regular infection prevention and control agenda discussion at board meetings, but only 15% said leadership provided feedback and recommendations. Survey respondents also indicated challenges in the areas of engaging information technology support, measuring compliance, providing adequate staffing, removing indwelling urinary catheters, ensuring appropriate physician medical record documentation, and having sufficient time for surveillance investigation.[20]

Steps to Completing an Infection Control Business Case Analysis

Before asking for more support and presenting infection control programs to management, it is important to accurately and comprehensively identify the key issues in the organization and where best to direct efforts. For example, focus on which types of infections are more prevalent, locations where endemic infection rates are particularly high, or locations where surveillance and prevention efforts have been sporadic or lacking.[4]

Focus the hospital executive team's attention on the number of infections avoided and the dollars saved by infection control interventions that have been successful in the past. Identify a patient group (e.g., intensive care patients), the infection prevented, and all reasonable strategies that might prevent that type of infection.[8] Develop clinical practice priorities based on the Department of Health and Human Services (HHS) action plan, which have the potential to decrease HAIs based on: (1) supporting scientific evidence that the recommended practice is effective, practical, and urgent; (2) recognized gaps in current implementation of the practice (full versus partial implementation); and (3) the "bundling" or implementation of several practices at the same time to ensure the effectiveness of the action plan.[21] Assessment of adequate resources for an infection prevention and control program includes identification of the scope of patient populations being served, the number of trained and certified IPs in the facility, the types of programs in which the IP is involved, and a practice analysis. This analysis describes the frequency and estimated hours required each week for infection prevention and control activities and identifies areas of the program that may be underresourced.[11]

The process of completing a business case can be divided into practical steps to analyze how HAIs are impacting the organization's bottom line, calculate the economic value of reducing HAIs using the facility's internal data, and assist the hospital epidemiologists and IPs in justifying and expanding the infection prevention and control programs.

In an effort to enhance the attention and resources dedicated to the zero-tolerance culture regarding HAIs and to calculate the estimated value (i.e., excess cost) of eliminating HAIs in the organization, APIC and SHEA recommend the following methods:[3,5]

Prepare an executive summary. Start with a statement of purpose. Describe the intervention requested, explain why it should be pursued, and review the financial implications of not pursuing it.

Identify a financial partner. Infection prevention and control specialists need to work with the financial specialists in the organization to identify which services provided were attributable to the infection and the cost of that service.

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Frame the problem. Select an HAI or a population within the last year to be analyzed. Select a number of cases (e.g., 10) of patients who acquired a CLABSI or select a class of HAI for the last year. Develop potential solutions based on these cases.

Meet with key administrators or physician leaders. Before the start of the analysis, obtain agreement that the issue is of institutional concern and has the support of leadership. Administrators can help to identify individuals or departments that may be affected by the proposal and also help identify the critical costs and factors that should be included.

Determine the costs associated with the infection of interest. Emphasize the complications that would not have occurred during a hospital stay without the HAI. With the financial advisor, identify actual or estimated costs and reimbursement, and calculate the difference between profits with and without an HAI. Use available hospital administrative data for the amount of costs that are reimbursed, or use estimates from literature. An alternative method of calculating the attributed cost of an HAI is to multiply the mean increase in length of stay for HAI cases by the mean daily cost for a hospital stay. For example, if the average daily cost for a patient intubated in ICU was $3,000 a day and the average increase in the length of stay was seven days due to a VAP, the increased cost would be $21,000. Estimate additional revenue gained by filling the additional bed days available.

Determine which costs can be avoided through reduced infection rates. Use proposed or actual past reduced infection rates or published data. Calculate the gross margin for the case by subtracting the expenses from the reimbursement. Compare the gross margin for the case to the gross margin of similar cases without an HAI. Analysis of your organization's costs is more credible than general estimates from studies. (An example of this calculation can be found at http://www.premierinc.com/safety/topics/guidelines/downloads/09-hai-whitepaper.pdf.)

Calculate the financial impact. Subtract the upfront and future outlay costs from the estimated cost savings. Determine the annual cost of an infection prevention and control program, as well as the salary and benefits of the IP. When looking at a specific project or intervention, estimate the percent of IP time needed to support the project based on his or her hourly rate. Include the additional reduced costs and benefits expected from impact of the infection control intervention on other processes or other types of preventable infections

Make the business case. Once the analysis of the HAIs in the organization is completed, use this information to target an area that has significant opportunity for improvement and then set the target for elimination of this HAI. Develop an implementation plan, determine current support for the initiative, and answer anticipated questions before presenting the initial findings to critical stakeholders.

Identify process defects and institute changes. Institute necessary systems or practice strategies where indicated.

Measure results. Collecting outcomes, costs, and implementation data allows comparison with units where the intervention has not yet been implemented. Prospectively collecting cost and outcome data once programs are in effect can illustrate stable outcome rates or continued improvement associated with the intervention.

A sample business plan is available at http://www.ihi.org/NR/rdonlyres/EEC35DF1-0324-4C69-A401-05BD178E555E/2735/YumaBusinessPlanTemplate.pdf.

Conclusion

CDC estimates that as much as $31.5 billion of the $45 billion annual direct cost of HAIs could be saved with an effective infection program, which would significantly reduce the economic burden. Reimbursement is currently affected by the determination that some infections can reasonably be prevented through application of evidence-based practices. The evidence is compelling that taking action to invest in an effective infection control program can have a profound positive impact on the organization's bottom line and reputation, prevent the catastrophic effects of HAI, and improve patient safety and satisfaction. Hospital success stories highlight the opportunities for all organizations to make zero HAIs a target, and many protocols can be implemented without much of an investment. Application of practical guidelines to develop an infection prevention and control business case will assist hospital IPs and epidemiologists to justify and expand much-needed programs. The true investment is the organizational commitment from healthcare leaders and clinicians to engage in a fresh approach to providing patient care in a culture of safety and to set the goal number of HAIs at zero. This requires acknowledging the high-risk nature of the organization's activities, as well as investing in infection prevention programs, allocating resources needed for optimal programs, and making infection prevention an institutionwide priority.

Notes

1. Klevens RM, Edwards JR, Richards CL Jr, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. *Public Health Rep* 2007 Mar-Apr; 122(2):160-6.
2. Scott RD. The direct medical costs of healthcare-associated infections in U.S. hospitals and the benefits of prevention [report online]. 2009 Mar [cited 2010 Apr 21]. Available from Internet: http://www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf.
3. Perencevich EN, Stone PW, Wright SB, et al. Raising standards while watching the bottom line: making a business case for infection control. *Infect Control Hosp Epidemiol* 2007 Oct;28(10):1121-30.
4. Stone PW, Hedblom EC, Murphy DM. The economic impact of infection control: making the business case for

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increased infection control measures. *Am J Infect Control* 2005 Nov;33(9):542-7.

5. Murphy DM, Whiting J. Association for Professionals in Infection Control and Epidemiology (APIC). Dispelling the myths: the true cost of healthcare-associated infections. [briefing online]. 2007 Feb 9 [cited 2010 April 21] Available from Internet: http://www.premierinc.com/safety/topics/guidelines/downloads/09-hai-whitepaper.pdf.
6. Shannon RP, Patel B, Cummins D. Economics of central line-associated bloodstream infections. *Am J Med Qual* 2006 Nov-Dec;21(6 Suppl):7S-16S.7
7. Pennsylvania Health Care Cost Containment Council (PHC4). Hospital-acquired infections in Pennsylvania [online]. 2009 Jan [cited 2010 Apr 21]. Available from Internet: http://www.phc4.org/reports/hai/07/default.htm.
8. Graves N. Economics and preventing hospital-acquired infection. *Emerg Infect Dis* 2004 Apr;10(4):561-6.
9. Anderson DJ, Kirkland KB, Kayre KS. Underresourced hospital infection control and prevention programs: penny wise,pound foolish? *Infect Control Hosp Epidemiol* 2007 Jul;28(7):767-73.
10. Hsieh S. Hospitals fight off infections and lawsuits. Mass Med Law Report [online] 2009 Feb [cited 2010 Apr 21]. Available from Internet: http://mamedicallaw.com/blog/2009/02/01/hospitals-fight-off-infections-and-lawsuits/.
11. Association for Professionals in Infection Control and Epidimiology (APIC). IP program evaluation tool [CD-ROM]. .*Prevention Strategist* 2010;3(1).
12. Rutala WA, Weber DJ. Cost and cost benefit of infection control [presentation online]. 2005 Dec [cited 2010 Apr 21]. Available from Internet: http://www.unc.edu/depts/spice/resource.html#Slides.
13. O'Reilly K. Many hospitals cut back on infection control efforts [online]. Am Med News 2009 Jun 22 [cited 2010 Apr 21]. Available from Internet: http://www.ama-assn.org/amednews/2009/06/22/prsa0622.htm.
14. Medical Care Availability and Reduction of Error (MCARE) Act. 40 P.S. § 1303.408 (2007).
15. Health Care Facilities Act. 35 P.S. § 448.817 (1992).
16. Dunagan WC, Murphy DM, Hollenbeak CS, et al. Making the business case for infection control: pitfalls and opportunities. *Am J Infect Control* 2002 Apr;30(2):86-92.
17. Berenholtz SM, Pronovost PJ, Lipsett PA. Eliminating catheter-related bloodstream infections in the intensive care unit. *Crit Care Med* 2004 Oct;32(10):2014-20.
18. Successful reduction of ventilator-associated pneumonia. Pa Patient Saf Advis [online] 2009 Jun [cited 2010 Apr 21]. Available from Internet: http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Jun6(2)/Pages/63.aspx.
19. L.E.K. Consulting. Hospitals apply surgical precision to budgets, brace to support healthcare reform [online]. L.E.K. Consult Exec Insights 2010 Jan [cited 2010 Apr 21]. Available from Internet: http://www.lek.com/UserFiles/File/Executive_Insights/Volume_XII_Issue_4_LEK_Hospital_Purchasing_Survey_Executive_Insights.pdf.
20. Association for Professionals in Infection Control and Epidemiology (APIC). APIC-Premier survey on HAI prevention strategies [online]. 2008 [cited 2010 Feb 1]. Available from Internet: http://www.premierinc.com/about/news/08-sep/SurveySummary_09122008.pdf.
21. U.S. Department of Health and Human Services (U.S. HHS). HHS action plan to prevent healthcare-associated infections [online]. [cited 2010 Feb 1]. Available from Internet: http://www.hhs.gov/ophs/initiatives/hai/infection.html.

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Quarterly Update on the Preventing Wrong-Site Surgery Project

Three years have passed since the first definitive article from the Pennsylvania Patient Safety Authority on wrong-site surgery at the end of June 2007.[1] When compared to the first three years of reporting, the number of events during the more recent three years has doggedly persisted (see Figure). During the first year of focus (2007 to 2008), the number of reported events increased to near a previous high, perhaps because of increased awareness and standardization around the National Quality Forum definitions.[2] After that initial focus on wrong-site surgery, the number of events has decreased each year. However, the Commonwealth of Pennsylvania still averages more than one report per week.*

Numerous studies, available on the Authority's Preventing Wrong-Site Surgery Project Web page,[3] have identified evidence-based best practices for preventing wrong-site surgery. Of the 14 events for this last reported quarter (April 1, 2010, through June 30, 2010), 4 (29%) were repetitions of wrong-site anesthetic blocks. Best practices for preventing wrong-site anesthetic blocks were discussed in the December 2009 and March 2010 issues of the *Pennsylvania Patient Safety Advisory*,[4,5] initiating the recent description of evidence-based best practices for specific procedures.†

> *The patient was to have a block on the right hand. The block was done on left side by the anesthesiologist. . . . The right side was then marked and a second block was completed.*

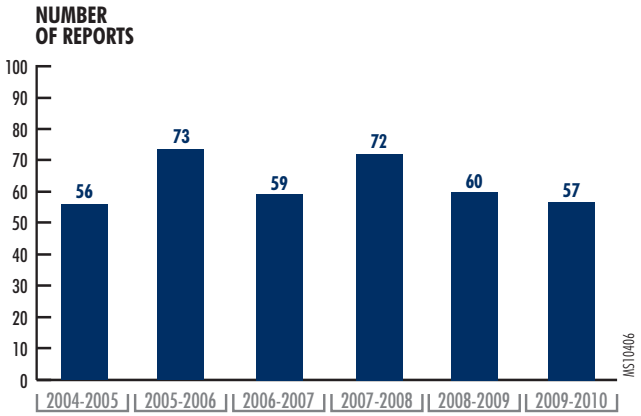
> *The patient was scheduled for right eye surgery. . . . As the nurse was preparing to prep the patient, he noticed the surgeon blocking the left eye. An official time-out had not been done at this time. . . .*

One facility that reported a wrong anesthesia block in the previous quarter submitted additional information to share its recommendations for system improvement:

> *The time-out was performed with two anesthesiologists and another individual. The patient confirmed that the right leg was the operative site, although the patient was to have surgery on the left leg. The anesthesiologist inserted a catheter in the right groin. When the surgeon saw the catheter, she informed the anesthesiologist that the patient was having surgery on the left leg. The anesthesiologist removed the catheter and placed a new catheter on the left side.*

The facility's root-cause analysis indicated that, although a time-out had been done, the anesthesiologist did not mark the site prior to the time-out. The anesthesiologists rely on sites marked by surgeons, but this mark had not yet been made. The facility recommended marking the insertion site, especially since the procedure involved a femoral nerve block completed in the supine position and a sciatic nerve block completed in the prone position.

Figure. Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports by Academic Year, 2004 to 2010



The importance of properly following the Universal Protocol[6] is reinforced by the following reports:

Two patients with the same name were operated on by the same surgeon the same day. The surgeon operated on the first patient, thinking she was the second patient. Fortunately for the patients, both had the same operation, but the Authority considers this event wrong-patient surgery. Two patient identifiers are necessary for proper identification prior to surgery.

The Authority received a report that illustrated reasons for following the Universal Protocol other than preventing wrong-site surgery:

> *[After the anesthetic was injected, but] before the incision was made, the surgeon realized that the consent stated the "index finger." The surgery was cancelled, and rescheduled. The consent was incorrect. The injected anesthetic was on the correct side, correct site (middle finger).*

The surgeon had started the intended procedure when he or she realized that the consent did not cover the correct operation. The incorrect consent would have been identified with proper preoperative verification of the documents, including the documents in the verification of the site marking, and doing a time-out before any localized anesthetic procedure.

Can the "time-out" work? An ambulatory surgical facility reported a save attributed to this last step in the Universal Protocol:

> *The OR [operating room] staff initially draped the wrong leg before knee arthroscopy procedure. The*

* As usual, this update includes any belated additions and corrections from previous quarters.

† All report narratives have been edited to remove identifying information.

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error was caught during the time-out process. The correct leg was draped and the procedure completed by the surgeon.

The recent description in the *Advisory* of evidence-based best practices for specific procedures also included spinal surgery,[4] pain management procedures,[5] ureteral stenting,[5] and hand surgery.[5] Reports in this quarter include problems with two other specific types of procedures: (1) surgery on the wrong scar, skin lesion, or subcutaneous lesion, and (2) procedures involving the wrong device.

Surgery on Scars, Skin Lesions, and Subcutaneous Lesions

Of the 375 total reports of wrong-site surgery, 13 reports (3.5%) involved visible scars, melanomas, moles, or other skin lesions, or palpable subcutaneous lesions. Five involved pediatric patients and their parents.

These events resulted from the presence of multiple visible or palpable candidate sites. In four events, the surgeons referenced the wrong incisional scar in patients with multiple prior procedures. In another five reports, the surgeons excised nearby similar lesions instead of the intended lesions. In three other events, different pigmented lesions were widely excised instead of the intended melanomas. In one, a scar was removed instead of a subcutaneous lesion.

Seven reports cited issues with the information for identifying or marking the sites. The patients or parents were cited six times, including twice when the information was noted to be correct and twice when it was not. Incorrect office notes were also cited once. No other documents were mentioned as a source of information. In fact, two reports indicated that properly collected consents were not part of the verification processes and another two events indicated that information from the patients was not sought.

The site identification and markings were noted to have been done by the surgeons four times (three described as incorrectly), by residents twice, and a nurse once; one anesthesia provider correctly identified a site. When mentioned, most sites were marked by circles. Three reports indicated that the wrong lesions were marked. Another two events were associated with extra circles. Another report suggested that the mark was not close to the lesion.

The following report illustrates multiple high-risk behaviors known to be associated with wrong-site surgery:

Preoperatively, the parent identified the left chest as the site of the lesion to the nursing staff. In the OR, the surgeon was marking a left neck lesion as the site for removal and the nursing staff stated that the site was incorrect site per the parent. The surgeon said that the office notes indicated that the left neck was correct and continued to remove the left neck lesion. When the patient was in the PACU [postanesthesia care unit], the parent said the lesion removed was the incorrect lesion.

The surgeon did not see the patient preoperatively. The site was marked after the patient was in the OR. The site was marked without verifying it with all the documents and the patient or surrogate. The surgeon did not properly respond to concerns raised by OR staff (by reconciling the discrepancies using the information from all the documents and the patient or surrogate).

When operating on skin and subcutaneous lesions that could be present in multiple sites, extra care is needed to ensure that the intended sites are identified, marked, and operated on. The patient may not be a perfect source of information, in part because the lesions may be on a part of the body that is not visible or palpable. Marks should identify the lesions as accurately and unambiguously as possible. In addition to the standard evidence-based practices for preventing wrong-site surgery in general, the following are proposed for skin and subcutaneous lesions:

1. The person doing the surgery should mark the correct lesion as accurately and unambiguously as possible.
2. Precise, detailed, accurate preoperative documents should be maintained to verify the location of the operative site.
3. A mirror and/or a patient advocate should be used, if necessary, to assist the patient in participating in the site verification and marking.

Procedures Involving the Wrong Device

Ten reports of procedures (2.7%) involved a device other than the one intended. (This analysis excludes procedures involving insertion of correct devices with the wrong specifications, such as the wrong-diopter intraocular lens implant, which can be due to different error mechanisms.[7,8]) Seven of the ten reports involved the insertion of a vascular access device other than the one intended. One report involved enteric feeding tubes. One involved tympanoplasty tubes, and one involved a nerve simulator and cardiac pacemaker. Four of the reports specifically noted that the patients had major, long-term medical problems.

Of the seven reports involving the wrong vascular access device, five reports indicated confusion between subcutaneous venous access ports and Hickman or Broviac intravenous catheters (three one way and two the other). One report indicated confusion between a dialysis catheter and an intended port and another confusion between a dialysis catheter and an intended arteriovenous fistula.

Three of the reports identified errors. One incorrect procedure was due to a scheduling error. One report cited a failure to do a time-out. One event involved an incision for a different device, immediately

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corrected, due to a mental error by the surgeon after the time-out.

Insertion of the correct vascular access device from among all the potential options appears to be the most common challenge involving insertion of devices. Vascular access devices are adjuncts to treatment of major, long-term medical problems. The surgeon is usually in a supportive role. The patient may have had many of the different options in the past. To supplement the general evidence-based practices for preventing wrong-site surgery, the following refinements are proposed for procedures involving the insertion of a device, when the device is not part of a controlled specialty inventory:

1. The specific device should be mentioned on the schedule, the consent, and the surgeon's preoperative evaluation of the patient. This information should be checked for its presence and agreement with all the documents in the preoperative verification.
2. The specific device should be mentioned during the time-out.
3. The specific device should be called out when delivered onto the operative field.

Resources, Consultation, and Other Education

The Authority's Preventing Wrong-Site Surgery Web page has been reorganized for easier navigation of its many resources. They include self-assessment tools, sample forms and checklists, educational posters and videos, illustrative figures and tables, patient-education brochures, and online information at other sites.[3]

The Authority has an on-site consultation program for Pennsylvania facilities that wish to analyze their vulnerabilities for wrong-site surgery, particularly following a wrong-site event (or a close call) in a surgical suite. Those interested in taking advantage of this program should contact the Authority office or their regional patient safety liaison (PSL). The Authority's PSLs will assist facilities in assessing their policies and procedures, measuring staff compliance, and doing a thorough analysis of any events using the resources developed by the Authority.[3]

Pennsylvania facilities in need can also request a Webinar to educate OR and surgical staff about evidence-based best practices to prevent wrong-site surgery. Those requests should also be made to the Authority office or the regional PSL.

Notes

1. Doing the "right" things to correct wrong-site surgery. PA PSRS Patient Saf Advis [online] 2007 Jun [cited 2010 Aug 7]. Available from Internet: http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2007/jun4(2)/Pages/29b.aspx.
2. National Quality Forum. Serious reportable events in healthcare—2006 update. Washington DC: National Quality Forum; 2007.
3. Pennsylvania Patient Safety Authority (Authority). Preventing wrong-site surgery [patient safety tool collection online]. [cited 2010 May 3]. Harrisburg (PA): Authority. Available from Internet: http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx.
4. Quarterly update on the preventing wrong-site surgery project: improving, but still room for perfection. Pa Patient Saf Advis [online] 2009 Dec [cited 2010 Aug 7]. Available from Internet: http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/Dec6(4)/Pages/141.aspx.
5. Quarterly update on the preventing wrong-site surgery project: digging deeper. Pa Patient Saf Advis [online] 2010 Mar [cited 2010 Aug 7]. Available from Internet: http:// www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Mar7(1)/Pages/26.aspx.
6. Joint Commission. Revised Universal Protocol; some changes are effective immediately. Joint Commission Online 2009 Sep 9 [cited 2010 Aug 7]. Available from Internet: http://www.jointcommission.org/NR/rdonlyres/25D5EC4D-F17C-4DCB-B0D2-8967EE48D5F1/0/jconlineSept909.pdf.
7. Focusing on eye surgery. PA PSRS Patient Saf Advis [online] 2005 Mar [cited 2010 Aug 7]. Available from Internet: http:// www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2005/Mar2(1)/Pages/12.aspx.
8. Still not seeing clearly—a second look at intraocular lens implant events. Pa Patient Saf Advis [online] 2008 Jun [cited 2010 Aug 7]. Available from Internet: http:// www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Sep5(3)/Pages/106.aspx.

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Satisfying Educational Needs with the Pennsylvania Patient Safety Authority Web Site

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During my initial visits with patient safety officers (PSOs) in the southwest region of the state, the need for patient safety resources and education was a recurring theme. When PSOs, other facility staff, and I have discussed this concern in detail during my visits, we find that this need can be satisfied through the content on the Pennsylvania Patient Safety Authority Web site (http://www.patientsafetyauthority.org).

The redesigned Web site is a repository of information for facility staff. However, facility staff members may be unaware of all the site has to offer. During a 2009 Pennsylvania Patient Safety Reporting System (PA-PSRS) user survey conducted by the Authority, participants, including acute facility PSOs, were asked "How often do you visit the Patient Safety Authority Web site, excluding reporting through PA-PSRS?" Of 568 respondents, 156 (27.6%) stated that they had visited the Web site "less often than monthly," 147 (25.9%) stated that they had visited the Web site "monthly," and 131 (23.1%) stated that they had visited the Web site "2 or 3 times a month."

When I demonstrate the Web site during my facility visits, staff are amazed at the features available to them. Many comment that they were unaware of the number of searchable patient safety research articles (nearly 350); the patient safety toolkits (e.g., checklists, posters, video modules) associated with the articles; or the available Consumer Tips, which engage patients and their families to help prevent medical errors. During a recent visit, a staff member said, "I really haven't been on the Web site for quite a while. In the past, there really wasn't much content available and it was scattered. Now that the *Advisory* articles are searchable and the educational information is grouped in the Patient Safety Tools section, I will definitely use it more often and let my colleagues know about it."

Let's take a closer look at a few of the Web site highlights.

Pennsylvania Patient Safety Advisory Articles

Articles from the Authority's *Pennsylvania Patient Safety Advisory* offer a wealth of data gleaned from actual events received from Pennsylvania facilities through PA-PSRS, the Authority's Web-based event reporting system. So that Authority Web site users are always presented with the most up-to-date information, the home page links to synopses of articles from the most recent *Advisory* issue.

Most know that the Authority Web site houses the *Advisory* in an archive format; however, all *Advisory* articles are also available through the search engine and in an indexed, browsable format. The search engine allows users to search all *Advisory* articles on a subject of the user's choice. The "Browse by Topic" feature—located on the upper, right side of the home page and throughout the site—allows the user to retrieve information on a variety of topics. Users can browse by discipline, audience, care setting, event, or patient safety focus. For example, by selecting "Discipline" (http://www.patientsafetyauthority.org/pages/BBTDiscipline.aspx), users can drill down through a variety of disciplines (e.g., critical care, infectious diseases, pediatrics) to a relevant list of *Advisory* articles, as well as "Patient Safety Tools" and "Consumer Tips."

PSOs can also use the Web site to disseminate select topics. Upon e-mail notification that the Authority has published a new *Advisory* issue, PSOs can review the online *Advisory* table of contents and selectively route specific articles of interest to individuals using the "Email to a Friend" feature located on the right sidebar of any *Advisory* article. While this method works well in the facilities that I visit, the Authority also supports direct readership by all interested staff. PSOs are encouraged to share the "Subscribe to the Advisories" link available throughout the Web site with anyone who is interested in increasing knowledge about patient safety topics.

Patient Safety Tools

Sometimes, while developing an article for the *Advisory,* Authority analysts discover a need to develop a specific tool or collection of tools to address a patient safety concern (e.g., a checklist to assess patient information, medical documentation, and surgical information before a surgical procedure). The resulting tool or toolkits (e.g., self-assessment tools, posters, brochures, links to other resources) enhance the associated *Advisory* article. The toolkits are accessible from anywhere on the Web site through the left-hand navigation bar by scrolling to "Educational Tools" and selecting "Patient Safety Tools." The toolkits are also individually indexed under the "Browse by Topic" feature. For example, the Authority maintains a toolkit, "Preventing Wrong-Site Surgery," that includes all of the Authority's work to date on this topic, such as *Advisory* articles, error analysis forms, a video, data snapshots, and more (http://www.patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Pages/home.aspx). Select

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Continuing Education Associated with the *Pennsylvania Patient Safety Advisory*

Pennsylvania registered nurses and physicians can receive continuing education credits by reading select *Pennsylvania Patient Safety Advisory* articles. The Pennsylvania Patient Safety Authority has teamed up with the Pennsylvania State Nurses Association and the Pennsylvania Medical Society to offer the credits by reading select articles on each entity's Web site. For more information on these continuing education opportunities, visit the respective Web sites at http://www.panurses.org and http://www.pamedsoc.org.

tools can be disseminated to others by the "Email to a Friend" feature, as stated earlier, and could provide valuable information to numerous facility committees.

Consumer Tips

PSOs and facility staff members have also expressed interest in educational materials targeted at patients. The "Patients and Consumers" area of the Web site includes "Consumer Tips" on topics derived directly from data received from Pennsylvania facilities. The "Consumer Tips" are designed to educate patients and their families about a variety of high-focus patient safety topics and actively engage them as advocates in their own healthcare. The "Consumer Tips" are presented in reader-friendly format that can be read online, disseminated by the "Email to a Friend" feature, or printed for distribution. I have seen evidence of Consumer Tip usage during facility visits in patient/family waiting areas, elevators, and inpatient admission and discharge packets.

Scratching the Surface

The Authority Web site is a valuable tool for PSOs, healthcare workers, or anyone interested in patient safety topics. The content examples discussed are just a sample of a vast array of useful information contained in the Web site. The individual usage related to the Authority Web site varies from person to person, but there is a clear need to increase awareness of this established patient safety resource.

Corrections

The following corrections have been made to the respective online articles. The editor regrets the errors.

Beyond the bundle: reducing the risk of central line-associated bloodstream infections. Pa Patient Saf Advis 2010 Mar 18;7(Suppl 1):1-9. This article contained incorrect calculations that need correction about the Pennsylvania hospitals that reported central line-associated bloodstream infections through the National Healthcare Safety Network from July 2008 through March 2009. The calculations should be based on 158 reporting hospitals and corresponding quartile rates.

Medication errors: significance of accurate patient weights. Pa Patient Saf Advis 2009 Mar;6(1):10-5. This article contained incorrect answer choices in question one of the self-assessment questions on page 15. The answer choices should include the following: (a) dobutamine, (b) acetaminophen, (c) heparin, and (d) cefazolin.

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Online Resources Associated with Patient Safety Advisories

Patient Safety Officers have expressed their interest in distributing educational resources within their healthcare facilities. The Pennsylvania Patient Safety Authority provides a growing collection of resources related to *Pennsylvania Patient Safety Advisory* articles to help increase situational awareness and patient safety within healthcare facilities. Examples include sample policies, educational videos and posters, brochures, interactive learning graphics, and reference materials.

This collection of resources is available online at http://www.patientsafetyauthority.org. Topics addressed include the following:

- Preventing wrong-site surgery
- Aspiration screening
- Diagnostic radiation and pregnancy
- ASF patient screening and assessment
- Hospital bed safety
- Airway fires during surgery
- Color-coded wristbands
- Common hazards in the behavioral health patient room

More improvement comes from improving a system than improving the performance of individuals within an existing system.

PATIENT SAFETY AUTHORITY

An Independent Agency of the Commonwealth of Pennsylvania

Whether you would like to learn more about the topics described above, or you need tools to help you meet other challenges, these educational resources can help.

If you would like additional information, please contact us at (866) 316-1070, or e-mail support_papsrs@state.pa.us.

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 Web site 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.

The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP's efforts are built on a nonpunitive approach and systems-based solutions.