

Agenda Item: 5.3.6
Prepared by: Mary Beth Thomas
Meeting Date: January 17,18
2008

Annual Report of the Health Alliance Safety Partnership (HASP)

Summary of Request:

The purpose of this agenda item is to provide an annual report to the Board regarding the activities of the HASP program (Attachment A).

Historical Perspective/Background Information:

The HASP pilot study adapts the airline industry's error reporting program into a health care model. Adopted by the Board in April 2004 and implemented in July 2005, there have been eleven cases of nursing practice errors evaluated by this methodology. In order to increase the number of cases, the Board expanded the number of participating entities in July 2007.

The report outlined in Attachment A provides an overview of the activities of the pilot study since inception. In addition, there is an analysis and synthesis of aggregated data to date. A detailed review of the annual report will presented to the Board by Debora Simmons.

Pros: This reports provides extensive information about the systems contributions to nursing practice errors.

Cons: None noted.

Staff Recommendations:

None. This report is an informational item.

Annual Report

Pilot Review to Date

July 1, 2005 to September 30, 2007

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

TABLE of CONTENTS

Page

INTRODUCTION

Background	3
Overview	4
Tools used in the HASP Process:	7
Eindhoven Classification Scale for Healthcare	8
Eindhoven Algorithm Categorizing Causal Factors	9
Schematic of the Eindhoven Model	10
James Reason's Decision Tree for Culpability	11
David Marx's "Just Culture" Diagram	12

CASE REVIEWS

1 & 2	13
3	13
4	13
5	14
6	14
7	14
8	15
9 & 10	15
Example of a Process Map Developed During Investigation	16

IN DISCOVERY

AGGREGATE PILOT SUMMARY

AGGREGATE PILOT THEMES

CASES MEETING EXCLUSION CRITERIA

PILOT QUALITY ASSURANCE MEASURES

PILOT INITIATION, EXPANSION and EXTENSION

EDUCATION EVENTS

APPENDICES:

- A. Sentinel Event Alert #36: "Tubing Misconnections"
- B. Guenter et al.
- C. World Health Organization "Avoiding Catheter Mis-connections"
- D. Texas Board of Nurse Examiners Bulletin April 2006
- E. Beyea, Simmons, and Hicks
- F. Simmons, et al
- G. Thomas, Simmons, Graves, and Martin

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

INTRODUCTION

BACKGROUND:

Prompted by an understanding of the importance of "Just Cultures" in advancing the patient safety movement, a unique partnership was developed in the state of Texas between The Board of Nursing (BON) for the State of Texas and The Institute for Healthcare Excellence at the University of Texas M. D. Anderson Cancer Center. The group recognized the need to evaluate the relationship between practice environments and regulatory agencies. The pilot developed to address these issues is the Healthcare Alliance Safety Partnership (HASP).

The Healthcare Alliance Safety Partnership (HASP) is a pilot reporting program that adapts the airline industry's highly successful Aviation Safety Action Partnership (ASAP) to healthcare. ASAP is currently used by major airline carriers and consists of the review of error reports by a member of the Federal Aviation Administration (FAA), a member of the pilot union, and a member of an airline carrier, to understand the prevalence of human performance and systems factors that contributed to the errors. The ASAP process has been successful to date because it allows participating organizations to learn about systems factors impacting aviation through reports submitted by pilots. Because ASAP has no jeopardy for the reporting pilot, reports are rich in safety information that may not be learned from traditional aviation reporting systems.

Experts in cognitive psychology, ergonomics and human factors have supported the examination of human error in healthcare. James Reason, the noted Human Factors scientist, discussed the importance of understanding systems factors in healthcare and the need to develop reporting systems that would capture such factors and differentiate them from reckless or negligent behavior. (see graphic on Page 11) However, pragmatic application of safety science within the existing system of regulating healthcare has not been demonstrated. Clearly an alliance of significant stakeholders was needed to explore the efficacy of a non-jeopardy system that meets the obligations of the regulatory duties to the consumer and informs the healthcare system of important

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

safety issues and interventions, thus protecting the public. Consistent with the mission of the Texas Board of Nursing (BON) and the systems focus of recent Institute of Medicine reports (*To Err is Human*, 2000), HASP – created in 2005 – seeks to provide protection to the public while also documenting the role of systems and human performance factors in error occurrence. The HASP program does not replace any existing quality improvement or assurance program at a given institution. It is an added program that falls within the protection of peer review, recognizes the effects of human and systems factors, contributes to the development of just cultures for practitioners and providers and, ultimately, enhances the safety of patients.

The HASP PROGRAM OVERVIEW

There are three phases of a HASP review: The Discovery; the Analysis; and the Resolution. Each step of the HASP process is documented by the HASP team and archived under a unique tracking number. All the evidence and supporting documentations are collected into one “case book” used in the review by the Event Review Committee (ERC).

The Event Review Committee (ERC) consists of six members from participating organizations. The voting members are: a Nursing Officer, who provides an administrative perspective; a member of the Board of Nursing, who represents board and licensure requirements; and, a senior nurse, who is familiar with the peer review process. These three members are responsible for reviewing and analyzing reports submitted, determining whether submitted reports qualify for inclusion in HASP, identifying system and human performance factors, and proposing interventions for the identified causal factors. These three members have voting privileges, which means that after reviewing all available information about an error report, the members are responsible for reaching consensus – or voluntary agreement – about the actions to be taken to increase safety. The additional three members of the ERC, who are nonvoting members include a nurse analyst with system and human factors expertise; a facilitator; and the HASP Secretary.

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

PHASE I: DISCOVERY

1) Voluntary submission of an event report from a registered nurse. The report may be obtained from one of three sources:

- 1) self-report from a nurse,
- 2) referral from the nurse's institutional peer review committee, or
- 3) referral from the Board of Nurse Examiners.

2) The participant files an incident report under their facility's current process in order to meet risk and required reporting. (Texas Department State Health Services, Federal Drug Administration, etc., as appropriate)

3) The report is screened for exclusion criteria. (see Page 20 for Exclusionary criteria)

4) A preliminary notification is made to the BON to:

- a) Verify the nurse's license
- b) Check for past reportable conduct to the BON
- c) Summarize the report in brief
- d) Alert the BON that the report has been filed

5) After screening by HASP nurse analysts, the report is de-identified, receives a unique tracking number, and enters the HASP process.

6) Interviews are conducted with the nurse, following scripted questions.

7) All relevant records, policies and procedures are reviewed by HASP analysts. Interviews with directly- and indirectly-involved parties are conducted in the same structured interview format. Comments are recorded, with identifying information of interviewees and patients removed.

8) Assessments of the environment, workplace and technology issues are performed, as well as observations of clinical practice. Medication data, specifically pharmacy and automated medication delivery service records, is searched, as necessary. Incident and root cause reports generated by the facility are reviewed and added to the evidence.

9) A Cause Map© is created using the de-identified material.

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

10) A preliminary issues list is created and a case book is compiled and sent to members of the Event Review Committee approximately one week prior to the scheduled review meeting.

PHASE II: ANALYSIS

1) HASP nurse analysts identify and cluster causal factors of the event utilizing the cause map and then categorize these causal factors using a modified version of the Eindhoven Classification model (see example on Page 8), which classifies errors based on systems and human performance factors. Consistent with this model, HASP analysts describe systems factors as technical, organizational, patient-related, or human-performance factors.

2) After analysis, the Event Review is conducted and an Action Plan is created that includes prescriptive recommendations for the nurse and the participating institution. Timelines for completion of action items, including any interim reports, are noted as appropriate, and followed up in the Resolution phase.

3) The Chief Nursing Office and the HASP Liaison at the institution where the event occurred, as well as the nurse, receive copies of the action plan.

PHASE III: RESOLUTION

1) The institution and the nurse provide timely responses to the HASP analysts regarding prescriptive recommendations until resolution is complete and approved by the Event Review Committee.

2) HASP presents a final report to the BON in quarterly general meetings as well as an annual review. A representative of the Board is always a member of the ERC to make decisions about the action plans. Congruent with the Board's mandated responsibility to the public, any needed remediation activities for the nurse to promote competency closely monitored.

– Excerpts from Nurse Leader article (see "Practice-Regulation Partnerships, Appendix G)

For more information on the HASP project, see (www.texashasp.org)

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

TOOLS USED in the HASP PROCESS

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

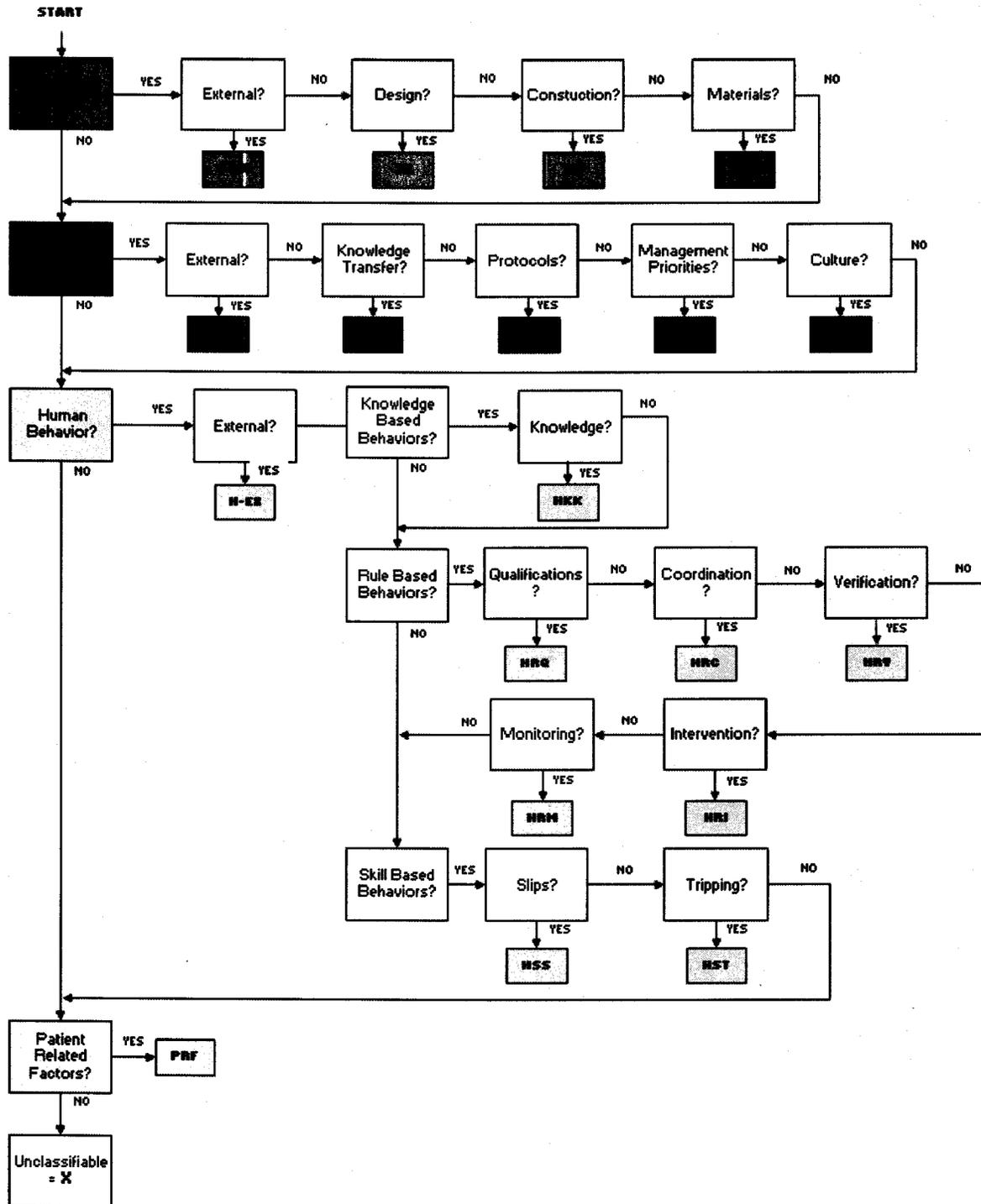
Eindhoven Classification Scale / Modified for Healthcare

Category	Description
Latent Errors	Errors that result from underlying system failures
Human Performance Factors	Human failures originating beyond the control of the individual
	The inability of an individual to apply existing knowledge to a novel situation
	Incorrect fit between an individual's qualifications, training, experience or education and a particular task
	Lack of task coordination within a health care team in an organization
	Failures in the correct and complete assessment of a situation or important factual information including relevant conditions of the patient and materials to be used before starting the intervention
	Failures that result from faulty task planning (selecting the wrong protocol) and/or execution (selecting the right protocol but carrying it out incorrectly)
	Failures during monitoring of process or patient status during or after intervention
	Failures in performance of fine motor skills, sequencing of actions and processing of multiple tasks
	Failures in memory of important facts
Patient-related factor	Failures related to patient characteristics or conditions that influence treatment and are beyond the control of
Unclassifiable	Failures that cannot be classified in other category

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

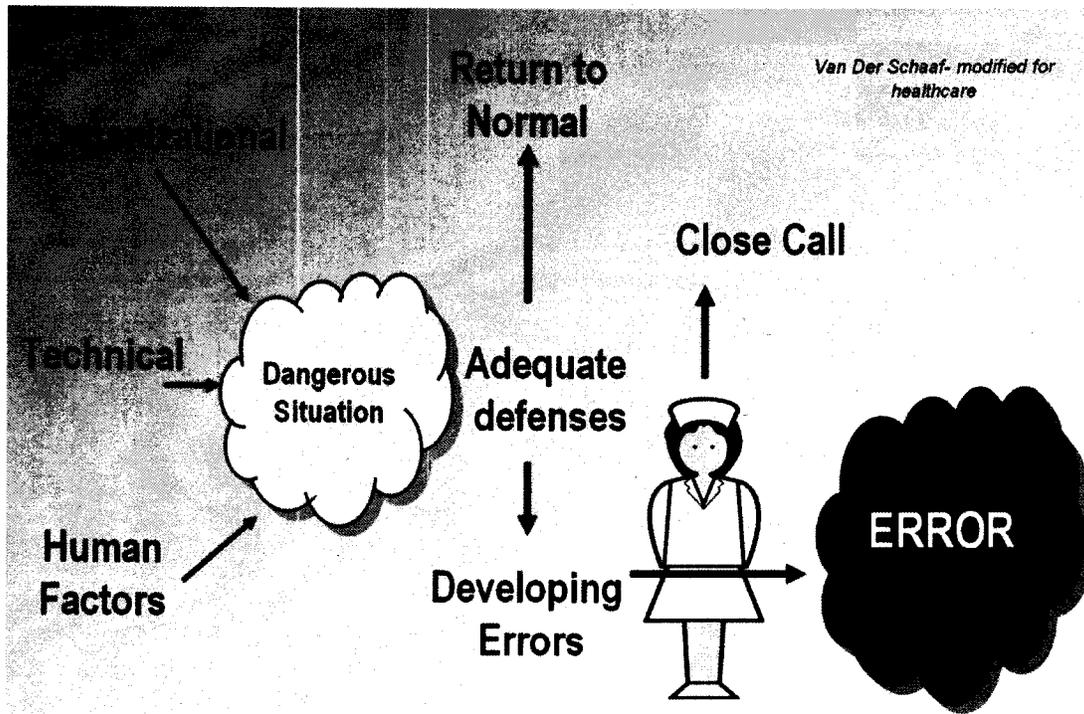
EINDHOVEN ALGORITHM: CATEGORIZING CAUSAL FACTORS



The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

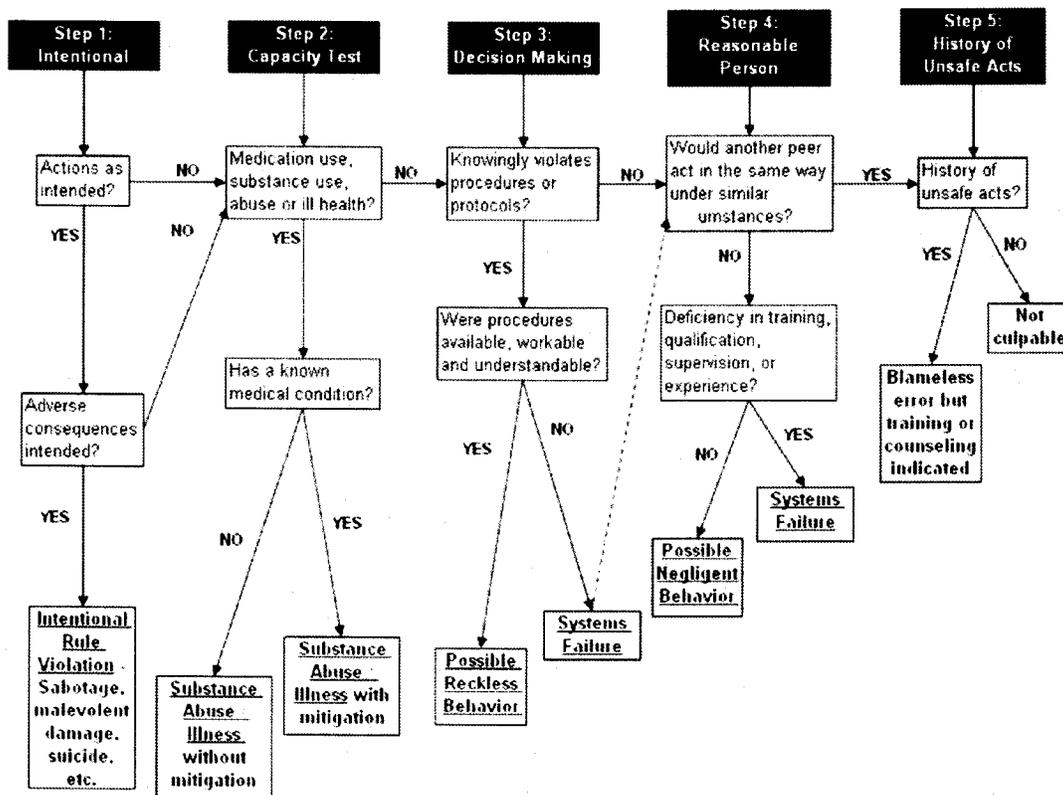
SCHEMATIC of the EINDHOVEN MODEL



The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

JAMES REASON'S DECISION TREE FOR CULPABILITY

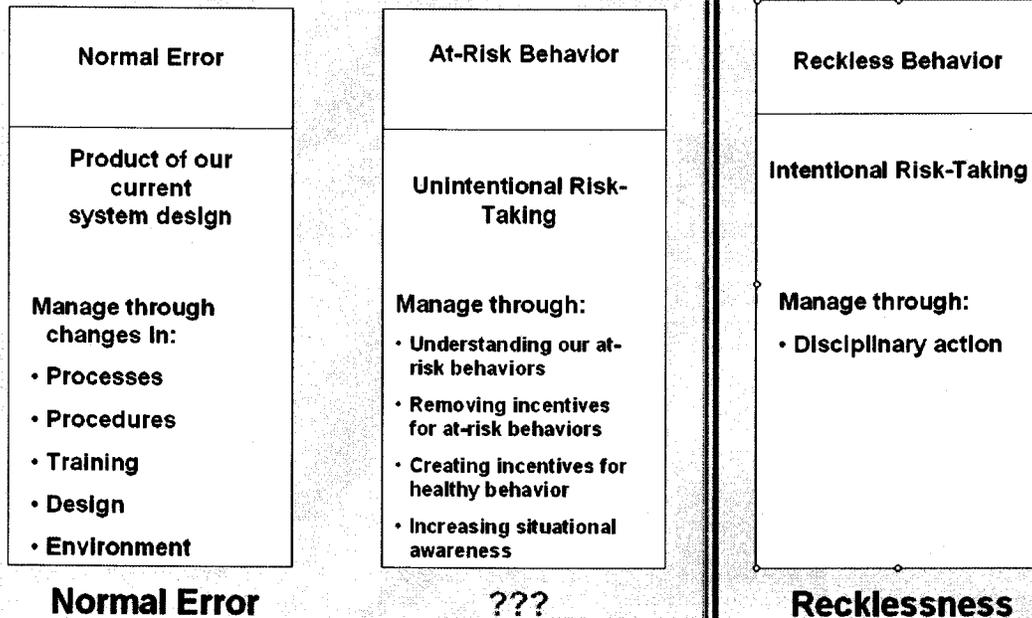


The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

DAVID MARX'S "JUST CULTURE" DIAGRAM

Managing Healthcare Risk – The Three Behaviors



*David Marx – Just Culture

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

CASE REVIEWS

Cases 1 & 2 (two nurses):

TYPE OF EVENT: Medication Monitoring

CONTRIBUTING FACTORS IDENTIFIED:

Technical Factors	2
Organizational Factors	48
Human Factors	14
Patient Factors	11

Case 3:

TYPE OF EVENT: Medication Administration

CONTRIBUTING FACTORS IDENTIFIED:

Technical Factors	8
Organizational Factors	7
Human Factors	12
Patient Factors	1

Case 4:

TYPE OF EVENT: Tubing Misconnection

CONTRIBUTING FACTORS IDENTIFIED:

Technical Factors	5
Organizational Factors	12
Human Factors	7
Patient Factors	6

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

Case 5:

TYPE OF EVENT: Medication Monitoring

CONTRIBUTING FACTORS IDENTIFIED:

Technical Factors	23
Organizational Factors	32
Human Factors	24
Patient Factors	9

Case 6:

TYPE OF EVENT: Blood Administration

CONTRIBUTING FACTORS IDENTIFIED:

Technical Factors	4
Organizational Factors	26
Human Factors	14
Patient Factors	8

Case 7:

TYPE OF EVENT: Multiple events

CONTRIBUTING FACTORS IDENTIFIED:

Technical Factors	6
Organizational Factors	32
Human Factors	22
Patient Factors	3

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

Case 8:

TYPE OF EVENT: Medication Administration

CONTRIBUTING FACTORS IDENTIFIED:

Technical Factors	9
Organizational Factors	18
Human Factors	14
Patient Factors	1

Cases 9 & 10 (two nurses):

TYPE OF EVENT: Blood Administration

CONTRIBUTING FACTORS IDENTIFIED:

Technical Factors	10
Organizational Factors	20
Human Factors	7
Patient Factors	4

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

IN DISCOVERY

Case 11

TYPE OF EVENT: Medication Administration

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

AGGREGATE PILOT SUMMARY

(Through September 30, 2007)

Case Count Summary

Cases Accepted	11
Cases Completed and Closed	8
Cases in Resolution Phase	2
Cases in Discovery Phase	1

Contributing Factor Count Summary*

	1	2	3	4	5	6	7	8	9	10
Technical Factors	2	2	8	5	23	4	9	6	10	10
Organizational Factors	48	48	7	12	32	26	18	32	20	20
Human Factors	14	14	12	7	24	14	14	22	7	7
Patient Factors	11	11	1	6	9	8	1	3	4	4

* For a review of Eindhoven Contributing Factor categorization, see Page 8

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

AGGREGATE PILOT THEMES

TECHNICAL FACTORS

- Issues with computer software have been contributing factors in three cases.
- Labels are not sufficient deterrents to error.

ORGANIZATIONAL FACTORS

- Failure in communication is a contributing factor in most cases.
- Information transfer from one provider to another has been a contributing factor.
- Production pressure or an emphasis on task completion has contributed to a 'sense of hurry and business' consistently throughout most cases.
- Complicated forms and policies & procedures have been contributing factors.
- Poorly displayed information has been a significant contributor in several cases.

HUMAN FACTORS

- High levels of experience and competency have been present in most cases.
- Distractions are present as contributing factor in almost every case.
- A lack of teamwork and availability of assistance have been consistently prevalent.
- Work related emotional stress (nurse) has been present in several cases.
- Lack of knowledge has been present in two cases.

PATIENT FACTORS

- When patient condition appropriate, patients have not been actively involved in their own care.

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

CASES MEETING EXCLUSION CRITERIA*

(Total: 8)

Case Number	Reason
A	Incomplete report; multiple events; no further response from RN
B	Severity
C	Temporary employee
D	RN terminated employment
E	Licensure issues
F	Not a practice issue
G	RN terminated employment
H	RN never responded to request for interview

* Exclusion criteria for the HASP include events that:

1. are intentional
2. involve an intentional disregard for safety
3. involve a knowing violation of safe operating principles,
4. involve criminal activity
5. involve substance abuse including mind-altering substance or physical/medical conditions that impaired or influenced the nurse's actions
6. involves a nurse with any history of substance abuse regardless of whether the Board of Nurse Examiners knows the history and whether rehabilitation has occurred. Nurses with a past history of abuse that have completed the TPAPIN program or an alternative program at the discretion of the Board of Nurse Examiners may petition the Board of Nurse Examiners for a waiver of this exclusion to participate in the HASP
7. involve intentional falsification
8. are reportable under Texas Occupation Code 301.1606 and 22 T.A.C. 226.4(b)(c)

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

PILOT QUALITY ASSURANCE MEASURES

	Median in Days
Event to Report Received (days)	34
Event to ERC (days)	147.5
ERC to Action Plan (days)	17.5
Event to Completion (days)	310
Report to Action Plan	123.5

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

PILOT PROJECT INITIATION, EXPANSION and EXTENSION

INITIAL HASP PROGRAM PARTICIPANTS, July 2005:

The University of Texas M. D. Anderson Cancer Center, Houston

St Luke's Episcopal Hospital, Houston

Texas Children's Hospital, Houston

NOTE: Each participating institution has business agreements with HASP for confidentiality and has passed an IRB review. Each participating institution provides participants for the Event Review Committee, allows full access to the facility and records around an event, and access to any quality or risk management information, such as root cause analysis. Each institution also agrees to provide any necessary remediation support to the nurse involved.

PILOT EXPANSION:

Approval of expansion of the pilot project at meeting with Board of Nurses (BON), October 2006

Seven (7) additional sites launched in July 2007:

SETON HOSPITAL SYSTEM HEALTHCARE ALLIANCE SAFETY PARTNERSHIP

Seton Medical Center

Austin Children's Hospital

Seton Northwest Hospital

COMMUNITY HOSPITALS HEALTHCARE ALLIANCE SAFETY PARTNERSHIP

Palo Pinto General Hospital, Mineral Wells

Sid Peterson Memorial Hospital, Kerrville

Uvalde Memorial Hospital, Uvalde

The Woodlands Community Medical Center – St. Luke's, The Woodlands

PILOT EXTENSION:

Original Texas Medical Center site pilot extended by BON an additional 2 years, July 2007

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

EDUCATION EVENTS

JANUARY 2007:

A two-day training workshop in Human Factors, Causality, Investigation Techniques, and the HASP Process presented in Austin, TX. for 41 attendees.

Attendees were ERC members from HASP expansion facilities and new ERC members from the original 3 facilities. A wide range of participants included CNOs, COOs, VPs, CNEs. Six RN investigators from the Board of Nurse Examiners also attended.

An additional 90 hours in Patient Safety and Human Factors training provided to all pilot organizations: executive leadership, middle managers, and clinical staff.

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

Healthcare Alliance Safety Partnership

APPENDICES

The information provided in this document is part of the Quality Improvement process for the Healthcare Alliance Safety Partnership (HASP) and as such this information is confidential, privileged and protected from discovery.

APPENDIX A



Sentinel Event Alert

Issue 36 - April 3, 2006

Tubing misconnections—a persistent and potentially deadly occurrence

Tubing and catheter misconnection errors are an important and under-reported problem in health care organizations. In addition, these errors are often caught and corrected before any injury to the patient occurs. Given the reality of and potential for life threatening consequences, increased awareness and analysis of these errors—including averted errors—can lead to dramatic improvement in patient safety.

To date, nine cases involving tubing misconnections have been reported to the Joint Commission's Sentinel Event Database. These resulted in eight deaths and one instance of permanent loss of function, and affected seven adults and two infants. Reports in the media and to organizations such as ECRI, the Food and Drug Administration (FDA), the Institute for Safe Medication Practices (ISMP), and United States Pharmacopeia (USP) indicate that misconnection errors occur with significant frequency and, in a number of instances, lead to deadly consequences.

Types of misconnections

The types of tubes and catheters involved in the cases reported to the Joint Commission included central intravenous catheters, peripheral intravenous catheters, nasogastric feeding tubes, percutaneous enteric feeding tubes, peritoneal dialysis catheters, tracheostomy cuff inflation tubes, and automatic blood pressure cuff insufflation tubes. The specific misconnections involved an enteric tube feeding into an intravenous catheter (4 cases); injection of barium sulfate (GI contrast medium) into a central venous catheter (1 case); an enteric tube feeding into a peritoneal dialysis catheter (1 case); a blood pressure insufflator tube connected to an intravenous catheter (2 cases); and injection of intravenous fluid into a tracheostomy cuff inflation tube (1 case).

A review by USP of more than 300 cases reported to its databases found misconnection errors involving the following:

- Intravenous infusions connected to epidural lines, and epidural solutions (intended for epidural administration) connected to peripheral or central IV catheters.
- Bladder irrigation solutions using primary intravenous tubing connected as secondary infusions to peripheral or central IV catheters.
- Infusions intended for IV administration connected to an indwelling bladder (foley) catheter.
- Infusions intended for IV administration connected to nasogastric (NG) tubes.
- Intravenous solutions administered with blood administration sets, and blood products transfused with primary intravenous tubing.
- Primary intravenous solutions administered through various other functionally dissimilar catheters, such as external dialysis catheters, a ventriculostomy drain, an amnio-infusion catheter, and the distal port of a pulmonary artery catheter.

Many of the misconnection cases involved luer connectors—small devices used in the connection of many medical components and accessories. There are two types of luer connectors—slips and locks. A luer slip connector consist of a tapered "male" fitting that slips into a wider "female" fitting to create a secure connection. The luer lock connector has a threaded collar on the "male" fitting and a flange on the "female" fitting that screw together to create a more secure connection. Examples of misconnections involving luer connectors include the following:

- Capnography sampling tube to an intravenous cannula.
- Enteral feeding set to a central venous catheter.
- Enteral feeding set to a hemodialysis line.
- Noninvasive blood pressure (NIBP) insufflation tube to a needleless IV port.
- Oxygen tubing to a needleless IV port.
- Sequential compression device (SCD) hose to needleless "piggy-back" port of an IV administration set.

Root causes identified

The basic lesson from these cases is that if it *can* happen, it *will* happen. Luer connectors are implicated in or contribute to many of these errors because they enable functionally dissimilar tubes or catheters to be connected. Other identified causes include the routine use of tubes or catheters for unintended purposes, such as using IV extension tubing for epidurals, irrigation, drains, and central lines, or to extend enteric feeding tubes; and the positioning of functionally dissimilar tubes used in patient care in close proximity to one another. In the cases reported to the Sentinel Event Database, contributing factors included movement of the patient from one setting or service to another, and staff fatigue associated with working consecutive shifts.

Risk reduction strategies

There are currently no published standards that specifically restrict the use of luer connectors to certain medical devices. Consequently, a broad range of medical devices, which have different functions and access the body through different routes, are often outfitted with luer fittings that can be easily misconnected. Organizations in Europe and the U.S. are now developing standards to restrict the types of devices that use luer fittings in an attempt to mitigate misconnection hazards. According to Jim Keller, vice president, Health Technology Evaluation and Safety for ECRI, and Stephanie Joseph, project engineer for ECRI, the solution to reducing—even eliminating—misconnection errors lies in both engineering controls respecting how products and devices are designed ("incompatibility by design"), and in re-engineering work practices.

"A well-designed device should prevent misconnections and should prompt the user to take the correct action," explains Joseph, author of a guidance article published in the March 2006 issue of ECRI's *Health Devices* journal. As a first step in prevention, Joseph urges hospitals to avoid buying non-intravenous equipment (such as nebulizers, NIBP devices, and enteral feeding sets) that can mate with the luer connectors on patient IV lines. In addition, Joseph emphasizes that the single most important work practice solution for clinicians is to trace all lines back to their origin before connecting or disconnecting any devices or infusions.

Other solutions include specific education and training regarding this problem for all clinicians and having practitioners take simple precautions such as turning on the light in a darkened room before connecting or reconnecting tubes or devices. The risk of waking a sleeping patient is minimal by comparison. Errors have also occurred when patients or family members attempt to disconnect and reconnect equipment themselves. Staff should emphasize to all patients the importance of contacting a clinical staff member for assistance when there is an identified need to disconnect or reconnect devices.

Other approaches to reducing the risk of misconnections that have been identified also have significant potential for unintended consequences. These include:

- Labeling all tubes and catheters—This may not always be practical and may therefore lead to inconsistent implementation. However, the labeling of certain high-risk catheters (epidural, intrathecal, arterial) should always be done.
- Color-coding tubes and catheters—This can lead users to rely on the color coding rather than assuring a clear understanding of which tubes and catheters are connected correctly to which body inlets. In addition, the training and educating of all staff (including temporary agency and travel staff) about the institution's color-coding system requires continuing attention. Finally, color-coding schemes often vary across institutions in the same community, creating increased risk when agency and travel staff are used.

Joint Commission recommendations

The Joint Commission offers the following recommendations and strategies to health care organizations to reduce tubing misconnection errors:

1. Do not purchase non-intravenous equipment that is equipped with connectors that can physically mate with a female luer IV line connector.
2. Conduct acceptance testing (for performance, safety and usability) and, as appropriate, risk assessment (e.g., failure mode and effect analysis) on new tubing and catheter purchases to identify the potential for misconnections and take appropriate preventive measures.
3. Always trace a tube or catheter from the patient to the point of origin before connecting any new device or infusion.
4. Recheck connections and trace all patient tubes and catheters to their sources upon the patient's arrival to a new setting or service as part of the hand-off process. Standardize this "line reconciliation" process.
5. Route tubes and catheters having different purposes in different, standardized directions (e.g., IV

lines routed toward the head; enteric lines toward the feet). This is especially important in the care of neonates.

6. Inform non-clinical staff, patients and their families that they must get help from clinical staff whenever there is a real or perceived need to connect or disconnect devices or infusions.
7. For certain high-risk catheters (e.g., epidural, intrathecal, arterial), label the catheter and do not use catheters that have injection ports.
8. Never use a standard luer syringe for oral medications or enteric feedings.
9. Emphasize the risk of tubing misconnections in orientation and training curricula.
10. Identify and manage conditions and practices that may contribute to health care worker fatigue, and take appropriate action.

In addition, the Joint Commission urges product manufacturers to implement "designed incompatibility," as appropriate, to prevent dangerous misconnections of tubes and catheters.

Resources

ISMP Medication Safety Alert, June 17, 2004, www.ismp.org/MSAarticles/tubingprint.htm

Nursing 2005, 35 (9), September 2005, pg. 73, by Melissa Eakle, R.N., MBA, MSN; Beverly Albrecht Gallauresi, R.N., B.S., MPH; and Audrey Morrison, R.N.

FDA Patient Safety News, Show #31, September 2004; Show #20, October 2003; Show #46, December 2005

"Fatal Air Embolism Caused by the Misconnection of a Medical Device Hoses to Needleless Luer Ports on IV Administration Sets" [hazard report], ECRI, *Health Devices*, June 2004; 33(6):223-5

"Misconnected Flowmeter Leads to Two Deaths" [special report], ECRI, *Health Devices Alerts*, January 25, 2003

"Preventing Misconnections of Lines and Cables," ECRI, *Health Devices*, March 2006; 35(3):81-95

"Safe Systems, Safe Patients: Common Connectors Pose a Threat to Safe Practice." *Texas Board of Nursing Bulletin*, 37(2):6-7, April 2006

Running Head: Enteral Misconnections

Enteral Feeding Misconnections:

A Consortium Position Statement

Peggi Guenter, PhD, RN, CNSN
(American Society for Parenteral and Enteral Nutrition)

Rodney W. Hicks, PhD, MSN, MPA, ARNP
(US Pharmacopeia Center for the Advancement of Patient Safety)

Debora Simmons, MSN, RN, CCRN, CCNS
(USP Safe Medication Use Expert Committee/
University of Texas, MD Anderson Cancer Center)

Jay Crowley
(Food and Drug Administration)

Stephanie Joseph
(ECRI Institute)

Richard Croteau MD
(The Joint Commission)

Cathie Gosnell, MS, MBA, RN
(Safety Institute, Premier, Inc.)

Nancy Pratt, MSN, RN
(Sharp Healthcare)

Tim Vanderveen, PharmD, MS
(Cardinal Healthcare)

Corresponding Author: Peggi Guenter, PhD, RN, CNSN
American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.)
8630 Fenton St. Suite 412
Silver Spring, MD 20910
(610) 649-7994
fax (610) 649-5561
peggi@aspen.nutr.org
Word Count: ###

Financial disclosures: None except* Conflict of Interest: None except*

* Tim Vanderveen, Cardinal Healthcare acquired Viasys, Inc. on June 21, 2007.

Abstract

A consortium of organizations met to address the issue of enteral misconnections, defined as inadvertent connections between enteral feeding systems and non-enteral systems such as intravascular lines, peritoneal dialysis catheters, tracheostomy tube cuffs, medical gas tubing, etc. Sentinel event data and causative factors are presented along with potential solutions to prevent such medical errors. The solutions can be grouped into three areas: 1) education, awareness, and human factors; 2) purchasing strategies, and 3) design changes based on the forces of clinicians, buying groups, manufacturers, regulators, and healthcare accrediting organizations.

Introduction

An invitation from the American Hospital Association (AHA) brought together a number of representatives from various organizations in Washington, D.C., on 11 October 2006 to discuss the current state of practice pertaining to enteral feedings and then focus discussion around patient safety risks associated with medical misconnections involving enteral feeding systems. Discussions included the prevalence of the misconnection problem, the use of Luer fittings in the enteral feeding system and its contribution to the problem, and how best to bring about safer systems in the future. Although the initial focus of the meeting was on Luer fittings, the scope of the discussion was expanded to the entire enteral feeding system to identify areas where misconnections could occur.

Definition of the Problem

The definition of medical misconnections includes seemingly apparent incompatible systems that, when inadvertently connected, can result in life-threatening events in the clinical arena (1). Examples include connections between feeding tubes and intravenous (IV) lines, blood pressure tubing with IV lines, IV lines with tracheostomy cuffs, and so forth. This issue is of such importance that, among the Joint Commission's proposed 2008 National Patient Safety Goals, was a goal that stressed the importance of preventing catheter and tubing misconnections (2).

This discussion focuses on only those misconnections related to enteral nutrition systems, specifically enteral misconnections. Enteral nutrition (EN) is nutrition provided through the gastrointestinal tract via a tube, catheter, or stoma

in order to deliver nutrients distal to the oral cavity (3). An enteral misconnection is an inadvertent connection between an enteral feeding system and a non-enteral system such as an intravascular line, peritoneal dialysis catheter, tracheostomy tube cuff, medical gas tubing, and so forth. In each case, serious patient harm, including death, can occur if fluids, medications, or nutritional formulas intended for administration into the gastrointestinal tract are administered via the wrong route (e.g., into the intravascular system).

The reporting of inadvertent IV administration of breast milk in 1972 is one of the earliest publications of an enteral misconnection (4). One published literature review found more than 60 references to enteral misconnections (5). As with other voluntary adverse event reporting systems, the reporting of enteral misconnections may greatly under represent the number of actual cases. Furthermore, a poor understanding of the causative factors also hinders a true record of incidents involving feeding connectors. Published reports consistently substantiate the severity of this type of error, which, too commonly, results in the death of the patient because of ensuing embolus or sepsis.

Enteral Feeding System

The enteral feeding system for adults and large children is the entire apparatus from the enteral nutrition formula container to the delivery tubing to the enteral tube itself. The system includes all connectors, pumps, or syringes that may come into connection with the system (6). The enteral feeding set is the feeding container or bag attached to the delivery tubing, which ends with a connector. This feeding set may be a one-piece device with the container

connected permanently to the tubing (**Figure 1**). In the case of pre-filled, ready-to-hang formula bags or containers, an enteral administration set must be spiked into the bag, making it a two-piece enteral set (**Figure 2**). The distal end of the enteral set connector attaches to the proximal end of the feeding tube. Some feeding tubes contain only one port, therefore, this single lumen tube does not have a side port for medication administration. Often, clinicians attach adaptive devices, such as Luer-lok stopcocks or extension tubing sets, between the feeding set and the feeding tube. These devices facilitate flushing and medication administration (**Figures 1 and 2**). The general practice is to change the enteral feeding set daily, which results in an interruption of the feedings. There are also a number of other reasons to interrupt or discontinue feedings, including: patient testing, intermittent feedings, patient intolerance, etc., and for flushing and medication administration when the tube does not have side ports and the main port is in use for feeding.

The system used to provide enteral feedings in some pediatric and nearly all neonatal patients differs from the system described above. In infants, low-volume feedings require slower rates. It is common to utilize syringes rather than adult size feeding sets. Some settings use oral syringes for enteral delivery of formula, breast milk, and oral medications (7, 8). The infusion devices (e.g., syringe pumps), however, are only calibrated for use with parenteral syringes. In addition, the design of most infant feeding tubes allows the tubing to accept Luer-slip or Luer-lok connectors for compatibility with parenteral syringes (8, 9). Despite calibration issues with syringe pumps and incompatibility with many

feeding tubes, some facilities have converted to oral syringes for the delivery of low-volume enteral feedings and medications (8). However, use of oral syringes and safety feeding tubes has not been widely adopted, and industry estimates that only a small percentage of patients receive oral liquid medication doses through a feeding tube with an oral syringe.

History of Attempts to Eliminate Misconnections

In 1996, the Association for the Advancement of Medical Instrumentation (AAMI) Infusion Device Committee convened an expert group to address the safety requirements for enteral feeding set connectors and adaptors. This expert group included members from the U.S. Food and Drug Administration (FDA), American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.), various safety organizations such as the Emergency Care Research Institute, now known as ECRI Institute (ECRI), and manufacturers of feeding sets. The resulting voluntary standard, approved in 1996 and reaffirmed in 2005, recommended that adapters and connectors used in the enteral system should be incompatible with female Luer-lok rigid connectors (10). However, no alternative design standards were ever developed or approved based on that document.

A British Standards document does describe the step connector (often referred to as a Christmas tree connector) as being an alternative connector design (11). Some manufacturers developed feeding sets with these step connectors in such a manner that the feeding sets were incompatible with Luer connectors on IV lines. Following release of the AAMI standard, more manufacturers adopted this design. Unfortunately, these standards are voluntary,

lack prescriptive direction, and not universally followed by all device manufacturers, and thus connectors remain a serious hazard to patients.

A number of leading public and private organizations (i.e., USP, ECRI, Institution for Safe Medication Practices [ISMP], FDA) have issued safety warnings that address the potential and actual risk from medical tubing misconnections (See **Figure 3** for a timeline of reported misconnections and alerts). Despite warnings that date back to 1986, the number of case reports continues to accumulate. The Joint Commission issued a Sentinel Event Alert regarding tubing misconnections in April 2006 (1). The alert stated that multiple reports to patient safety organizations including the Joint Commission, ECRI Institute, FDA, the Institute for Safe Medication Practices (ISMP), and the United States Pharmacopeia (USP) indicated these misconnection errors continued to occur with significant frequency and, in a number of instances, resulted in deadly consequences. In the alert, the Joint Commission identified root causes and risk-reduction strategies.

Evidence of Enteral Feeding System Concerns

In March 2007, a review of the USP MEDMARX and the USP-ISMP Medication Errors Reporting (MER) Program, two nationally-recognized voluntary medication error reporting systems, specifically identified cases involving enteral feeding systems. Between January 1, 2000, and December 31, 2006, the reviewers found 24 reported incidents involving an enteral feeding formula, other solutions, or medications intended for the feeding tube but administered via the

wrong route. Of those 24 incidents, 8 (33%) resulted in sentinel events (permanent injury, life-threatening situation, and/or death). Although the absolute number of reported cases is not large, the level of severity associated with the error is critical. Many of the cases resulted from the use of an IV syringe to dispense, prepare, or administer an enteral medication and then inadvertently attaching the syringe to the IV system, resulting in a wrong route error.

These 24 cases represent several factors that can lead to wrong route errors. This categorization of the failure factors illustrates the risks of present enteral nutrition delivery systems (Table 1). The factors include:

- The use of a syringe pump and IV administration tubing
- The use of ready-to-hang spikable enteral bags, bottles, or containers that receive standard IV tubing
- The use of an IV syringe to administer enteral medications, but administered the medications intravenously
- The use of an IV syringe to prepare and administer enteral feedings, but, inadvertently administering the feedings through an intravenous line.
- The absence of the enteral tube that results in medications being administered intravenously

In early 2006, FDA and A.S.P.E.N. developed a survey to help understand the issues associated with enteral connectors and safety. FDA's Center for Devices and Radiological Health sent this survey to hospitals in its MedSun

network, and A.S.P.E.N. sent it to their members. There were 182 clinicians, (including nurses, dietitians, pharmacists, physicians, safety officers, and quality improvement coordinators) that responded to the survey. When asked if their institution had experienced an enteral misconnection incident, 16.1% reported affirmatively, 57.8% reported negatively, and 26.1% reported that they did not know. Because of patient confidentiality issues, this survey did not ask about case details from those who reported in the affirmative. More than 30% of the respondents reported that they used Luer connectors in at least some of their enteral systems, and 20% used additional extension tubing with Luer connectors.

A number of respondents expressed concerns regarding the use of the current enteral connectors. Responses indicated that over the course of time, the enteral connector (e.g., Christmas tree connector) tends to stretch the opening of the feeding tube, and thus the connectors slip out of the tube causing an interruption in the integrity of the system. Feeding pumps create pressure to deliver enteral formulas and that pressure, combined with the small lumen of the feeding tube, caused the connected to disengage. In the pediatric population, the “slip-tip” mechanism of the enteral feeding connector allowed children to pull the system apart, rather easily compared to the twisting mechanism of Luer connectors.

Factors That Contribute to Enteral Misconnections

Human Factors. Errors involving feeding tube misconnections are a result of errors in performance—providers are unaware that the connection is occurring between two wrong tubes. These errors are often made by expert

practitioners who are unaware they are connecting the enteral feeding or medication to the intravenous line but are fully knowledgeable that such a connection poses a danger to the patient. This error in performance is not under the conscious control of the practitioner and so cannot be avoided by increased vigilance. Cognitive psychologist James Reason describes this as "being in automatic mode" or operating at a level of functioning in which the error is not detectable by the participant at the time of the misconnection (12). The human factors literature describes environmental situations that predispose human beings to such errors. Many of these contributors are endemic to the current patient-care environment, including time pressure, rotating shift work, fatigue, attempts to use short-term recall for large amounts of information, inadequate training, and inadequate lighting (e.g., during the night shift in a darkened patient room). In the cases reported to the Sentinel Event Database, contributing factors also included moving patients from one setting or service to another (1).

Physical and Design Factors. Luer connectors are implicated in or contribute to many of these errors because such connectors permit functionally dissimilar tubes or catheters to be connected. The user receives no tactile feedback that he or she has made an error because the connectors fit together easily. Other identified causes include the routine use of tubes or catheters for unintended purposes such as using IV extension tubing to extend enteral feeding tubes (1). Another increased opportunity for misconnection involves the adoption of needle-free connectors as the standard replacement for latex rubber injection ports on IV administration tubing. This change in practice introduces many more

opportunities when a Luer male connector can be attached to a female needle-free connector. Previously the set-up would have required attachment of a needle and was much less likely to be added to an enteral set or syringe. Clearly caregiver safety should be considered along with patient safety, but with the widespread use of these IV set connectors (as many as 3 per IV line), the chances that a female-compatible male Luer connector will be inserted into a needle-free connector is increased by the high number of ports and the complexity of the IV tubing, especially if one is treating acutely ill patients.

Physical characteristics and connections along the enteral nutrition system also contribute to the risk of enteral misconnections. These include connection of the enteral administration set to a pre-filled container (**Figure 2**) in which the two-piece system allows IV tubing to be substituted for an enteral administration set (13, 14). Both types of tubing have a universal spike at the proximal end, but the IV set has a male Luer distal end that can be attached to a female Luer of another system, thus permitting a misconnection. The next point in the system is the use of Luer stopcocks, adapters, or extension sets between the enteral feeding administration set and the feeding tube in order to accommodate medication or flush syringes. These use common small-bore medical connectors that can increase the risk of misconnections. Other factors that may contribute to misconnections are disconnections (either accidental or intentional) at any of the connection points. The more often lines or systems must be disconnected and reconnected, the greater the chance for a misconnection because some

practitioners who reconnect a line may not remember to trace the line to its origin (15).

Solutions

Solutions to prevent misconnections are multi-factorial and must engage a consortium of stakeholders, including healthcare clinicians, patient care institutions, regulating agencies, quality improvement agencies, purchasing groups, and manufacturers. The solutions can be grouped into three broad and not mutually exclusive areas: education, awareness, and human factors; purchasing strategies; and design changes.

Education, Awareness, and Human Factors. Education and alerts by various agencies and clinical educators have been and must continue to be a priority. Educators should emphasize the risk of tubing misconnections in orientation and training. Nurses in healthcare settings where there are multiple common connectors must be continuously aware of the hazards of inadvertently connecting the wrong line (16) and must develop strategies to decrease risks (17). Some strategies include:

- Review currently used systems to assess practices that include the potential for misconnection, including nonstandard, rigged work-arounds (Luer adapters, etc.).
- Train nonclinical staff and visitors not to reconnect lines but to seek clinical assistance instead. Only clinicians or users knowledgeable about the use of the device should make a reconnection (15).

- Do not modify or adapt IV or feeding devices because doing so may compromise the safety features incorporated into their design (15).
- When making a reconnection, practitioners should routinely trace lines back to their origins and then ensure that they are secure (15).
- On arriving at a new setting or as part of a hand-off process, staff should recheck connections and trace all tubes (1).
- Route tubes and catheters that have different purposes in unique and standardized directions (e.g., IV lines should be routed toward the patient's head, and enteric lines should be routed toward the feet) (1).
- Package together all parts needed for enteral feeding, and reduce the availability of additional adapters and connectors—this will minimize the availability of dissimilar tubes or catheters that could be improperly connected.
- Label or color-code feeding tubes and connectors, and educate staff about the labeling or color-coding process in the institution's enteral feeding system (1). The FDA/A.S.P.E.N. survey found that only 37% of respondents reported using a labeling or color-coding system.
- Be sure to identify and confirm the solution's label, because a three-in-one parenteral nutrition solution can appear similar to an enteral nutrition formulation bag. Label the bags with large, bold statements such as "WARNING! For Enteral Use Only—NOT for IV Use" (18).
- Ensure that all connections are made under proper lighting conditions (15).

- Identify and minimize conditions and practices that may contribute to healthcare worker fatigue, and take appropriate risk mitigation action (1).

None of these strategies alone is a solution to the problem, but taken together they will help mitigate risk. A design solution that prevents cross-connections between IV and enteral products would prevent the problem.

Purchasing Strategies. The Joint Commission recommendations to reduce tubing misconnection errors include the recommendation, “do not purchase non-intravenous equipment that is equipped with connectors that can physically mate with a female Luer IV line connector” (1). At present, alternative products that prevent the hazard of enteral misconnections are not always available for purchase (19), perhaps because enteral products that will not accept Luer connectors have yet to be manufactured or they may not be available in the US even though they are freely available in other parts of the world. Although a neonatal product system is available, adult products can still be interchanged and connected to IV equipment. Many health systems are beginning to demand—and are willing to purchase—this specialty IV-incompatible equipment, but the lack of knowledge about marketed products remains an issue.

Group purchasing organizations can work with their contracted suppliers to identify potential industry wide solutions. Healthcare delivery organizations can also support their purchasing committees and departments by recommending

specific brands of safe products until preferred solutions become generally accessible. Specific purchasing strategies to decrease risk of enteral misconnections include:

- Avoid buying enteral equipment that can mate with female Luer connectors (1).
- Purchase adequate numbers of enteral pumps so that IV pumps are not used for enteral delivery for adult patients.
- Ensure that hospital purchasing policies mandate buying only enteral feeding sets that are compliant with American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) standard ID54, which effectively excludes any that could mate with female Luer connectors. These devices must also be clearly labeled (e.g., "Not for IV Use") (10).
- Avoid buying pre-filled enteral feeding containers, except for those with design technology labeled non-IV compatible. This technology, just recently introduced in the U.S., uses a screwtop design that reduces compatibility with IV equipment. The goal is to have this equipment on the market by mid-2008. In all cases, ensure that the enteral administration set is packaged with the enteral feeding bag or container before it is sent to the floor. (The set should be secured to the bag, perhaps with a rubber band, or request that the manufacturer supply preattached sets). In either case the objective is to prevent bags or containers from being spiked with IV administration sets (14).

- Obtain enteral pumps that feature an automatic flush mode so that clinicians will not need to manually flush lines and therefore will be less likely to allow an adapter or Luer device between the enteral administration set and the feeding tube (15, 20).
- Carefully evaluate the need for and reduce the purchases of adapters and connectors that can be used to make enteral feeding sets compatible with female Luer connectors.
- Purchase oral syringes instead of Luer syringes to draw up and deliver medications into the enteral feeding system. Include pharmacy department recommendations to ensure the correct syringe type, along with dispensing and proper labeling protocols.
- Before making a purchasing decision regarding enteral feeding systems, convene a multidisciplinary task force charged with performing a prepurchase evaluation (15).
- Search all manufacturers' products for the safest systems.

Design Changes. The Joint Commission has urged product manufacturers to implement appropriate “designed incompatibility” to prevent dangerous misconnections of tubes and catheters (1). Because vigilance and knowledge are not sufficient barriers to prevent critical and often fatal errors (21), connectors must be redesigned. Without change to a “forcing function” design, errors are not easily avoidable. Forcing function designs have been utilized in medical gases and, most commonly, in the design of cars (e.g., cars cannot be started in drive mode). Forcing function design changes would make incorrect connections

impossible because they would physically prevent the user from taking a harmful action. For the safety of the patient and the efficiency of the provider, the most effective preventive tool requires a physical barrier that is automatically enforced when inappropriate connections are attempted (10,19, 22).

In order to make the environment safe from inadvertent misconnections between intravenous fluids and tube feeding for the gut, the connections must be physically incompatible. The entire line of connections, including the bag or container of feeding, the tubing that connects to the enteral infusion pump, and the final connection to the enteral feeding tube must be unique to prevent mistakes in connection. The enteral nutrition equipment must not fit into IV equipment to prevent work-around solutions or adaptation, as well as inadvertent misconnection. Because of the lethal consequences of infusing enteral feeding into an intravenous line and the documented evidence that this has occurred in numerous hospitals across the country, instituting forcing functions into the design of the equipment is a prudent safety feature.

During the past three decades, a number of manufacturers have attempted to address the issue of wrong-route administration by means of novel adapters, nonstandard connectors, and other unique product designs. Without a dedicated standard for non-Luer and specifically enteral connections, many of these products were not successful in the marketplace—they could be adapted to a Luer connection, forced into a tube that could be connected to a Luer, or were incompatible with other commonly used products. Working in isolation, no individual manufacturer to date has developed a standard that has been as

universally accepted in the marketplace as was the Luer connector decades ago. The current challenge for enteral products is a lack of standards for the desired components. With the exception of the step connector at the distal end of many adult feeding sets, no ideal enteral connector standard is available for manufacturers. Graduated connectors, however, are ipso facto adapters and do not create the forcing function required for a dedicated connection that could accept only an enteral device. Without a defined standard for all of the points of connection for enteral feeding, manufacturers will be severely challenged to create products that interface with parts that they do not manufacture. For example, companies that make feeding tubes are not necessarily the same companies that manufacture enteral formula bags or feeding pump sets.

Another design issue that must be addressed is the need to eliminate the spike-style connector into the pre-filled formula bag. The European standard for enteral feeding bags includes a smaller spike with a threaded collar that screws onto the bag or bottle. Many US companies manufacture this type of bag for their European customers. This threaded collar and screw are not compatible with the currently marketed connector system on IV bags and tubing in the US. This connector will shortly be made available for use in the US, and it should provide a near-term solution while global manufacturers work toward a more permanent solution.

In addition, the connector on the enteral feeding tube universally changes from a small proximal end capable of accepting a male Luer fitting to a fitting for the step connector. In addition, the growing use of oral syringes necessitates the

addition of an oral syringe port on the enteral administration set or the enteral tube. Oral medications typically are administered via the feeding tube in patients receiving enteral feeding. If the volume is sufficiently large, a catheter tip syringe can be used. If the volume is small, the oral syringe is preferable. Both the catheter tip and oral syringe ports must be available. What should *not* be present is a Luer connector, even though these are still found on some enteral feeding tubes.

Dialogue Promoting Change

Engaging manufacturers in equipment redesign is critical. Group purchasing organizations (GPO) have used a variety of opportunities to share their concerns with suppliers and manufacturers of feeding tubes, feeding pumps, and syringe pumps (7, 23–26). Such communications focused on the need to eliminate opportunities for tubing misconnections and other patient safety issues associated with enteral feeding. Discussions addressed system–product redesign and development of a non-Luer standard particularly for pediatric and neonatal products to highlight the need for development of non-Luer standards, changes in pumps, tubing sets (e.g., elimination of the universal spike connection to the formula container), changes in feeding tubes, and modified labeling and containers.

In 2006 a manufacturer (Viasys, Inc., a Cardinal Company Conshohocken, PA) released a line of feeding tubes and enteral feeding administration (extension) sets that accept only oral syringes. The system includes specifically

labeled enteral oral dispensers (syringes), and all three components contain oral/enteral connectors, not Luer connectors, making a wrong connection to the infant's IV impossible (27–29). Calibration of the syringe pump for use with the enteral syringes remains an issue for this product.

Position Statement

Enteral misconnections remain a hazard to patient safety in healthcare settings. Standards that address misconnections of the entire enteral feeding system should be developed to prevent errors. In the interim hospital and healthcare organization patient safety officers should work with their purchasing departments and users to perform a thorough assessment of current products and practices. Following the risk assessment, the organization can implement appropriate steps to reduce risks, including education and training addressing good work practices to reduce harm.

Hospital leaders can work with their respective GPO to continue the dialog with manufacturers, encouraging them to create alternative solutions that are compliant with the AAMI standard. Until resolution of the possibility for enteral misconnections to occur, there remains a risk to patient safety that only astute practitioners can avert through professional actions. For it will only be through the demand for safer standards and devices coming from healthcare institutions and purchasing organizations that the regulatory and manufacturing establishments will make changes which result in eliminating this serious risk.

Acknowledgment

The authors gratefully acknowledge AHA's leadership in convening the 11 October 2006 meeting that led to the development of this article.

REFERENCES

1. The Joint Commission Sentinel Event Alert. *Tubing Misconnections—A Persistent and Potentially Deadly Occurrence*. 2006. Accessed at: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_36.htm 10 June 2007.
2. The Joint Commission. Potential 2008 National Patient Safety Goals. 2007. Accessed at: http://www.jointcommission.org/NR/rdonlyres/470BE327-1F56-4ED1-80EF-D9E8E61C7657/0/08_potential_CAH_NPSG.pdf on March 13. 10 June 2007.
3. American Society for Parenteral and Enteral Nutrition Board of Directors and Standards Committee: Teitelbaum D, Guenter P, Howell WH, Kochevar ME, Roth J, Seidner DL. Definition of terms, style, and conventions used in A.S.P.E.N. guidelines and standards. *Nutr Clin Pract*. 2005;20:281-85.
4. Wallace JR, Payne RW, Mack AJ. Inadvertent intravenous breast milk. *Lancet*. 1972;1(7763):1264-66.
5. Simmons D, Graves K. Small bore medical connectors reference list. 2007. University of Texas MD Anderson Cancer Center. Accessed at www.mdanderson.org/pdf/small_bore_medical_connectors_reference_list.pdf on June 27, 2007.
6. Guenter PA, Silkroski M. *Tube Feeding: Practical Guidelines and Nursing Protocols*. Aspen Publishers, Inc. Gaithersburg, MD; 2001.

7. Huddleston K, Creekmore P, Wood B. Administration of infant formula through the intravenous route: consequences and prevention. *MCN Am J Matern Child Nurs.* 1994;19(1): 40-42.
8. Copelan D, Appel J. Implementation of an enteral nutrition and medication administration system utilizing oral syringes in the NICU. *Neonatal Netw.* 2006;25(1): 21-24.
9. American Society for Parenteral and Enteral Nutrition Board of Directors: Wessel, J., Balent, J., Crill, C., Klotz, K. Standards for specialized nutrition support: hospitalized pediatric patients. *Nutr Clin Pract.* 2005;20:103-16.
10. American National Standards Institute (ANSI)/Association for the advancement of Medical Instrumentation (AAMI). Enteral feeding set adapters and connectors. Arlington, VA: ANSI/AAMI ID54: 1996.
11. British Standard EN 1615. Enteral feeding catheters and enteral giving sets for single use and their connectors—design and testing. London, England: British Standards Institution. BS EN 1615:2000.
12. Reason J. The contribution of latent human failures to the breakdown of complex systems. *Philos Trans R Soc Lond B Biol Sci.* 1990;327(1241): 475-84.
13. Neven A, Wilson R, Kochevar M, McMahon MM. Compatibility of iv administration sets with closed enteral containers. *J Parenter Enteral Nutr.* 2000;24:369.
14. Institute for Safe Medication Practices. ISMP Medication Safety Alert: ISMP Quarterly Action Agenda. IV administration set spiked into enteral nutrition container. 2001. Accessed at

www.ismp.org/Newsletters/acutecare/articles/A2Q01Action.asp?ptr=y 10 June 2007.

15. ECRI. Preventing misconnections of lines and cables. *Health Devices*. March 2006: 81-95.

16. Simmons D. Safe systems, safe patients: common connectors pose a threat to safe practice. *Texas Board of Nursing Bulletin* 2006;37(3):6-7.

17. Eakle M, Gallauresi BA, Morrison A. Luer-lock misconnects can be deadly. *Nursing*. 2005;35(9):73.

18. Institute for Safe Medication Practices. ISMP Medication Safety Alert: ISMP Quarterly Action Agenda. Enteral feeding given iv. 2003. Accessed at www.ismp.org/Newsletters/acutecare/articles/A2Q03Action.asp?ptr=y 10 June 2007.

19. Pratt, N. Tubing misconnections: a perilous design flaw. *Mater Manag Health Care*. 2006;15(11):36-39.

20. Jones SA, Guenter P. Automatic flush feeding pumps: a move forward in enteral nutrition. *Nursing*. 1997;27(2):56-58.

21. Reason J. Beyond the organizational accident: the need for "error wisdom" on the frontline. *Qual Saf Health Care*. 2004;13Suppl 2:ii28-33.

22. US Food and Drug Administration. FDA Patient Safety News. Preventing fatal tubing misconnections. 2004. Accessed at www.accessdata.fda.gov/psn/transcript.cfm?show=31 10 June 2007.

23. Fechner G, Du Chesne A, Ortmann C, Brinkmann B. Death due to intravenous application of enteral feed. *Int J Legal Med*. 2002;116(6):354-56.

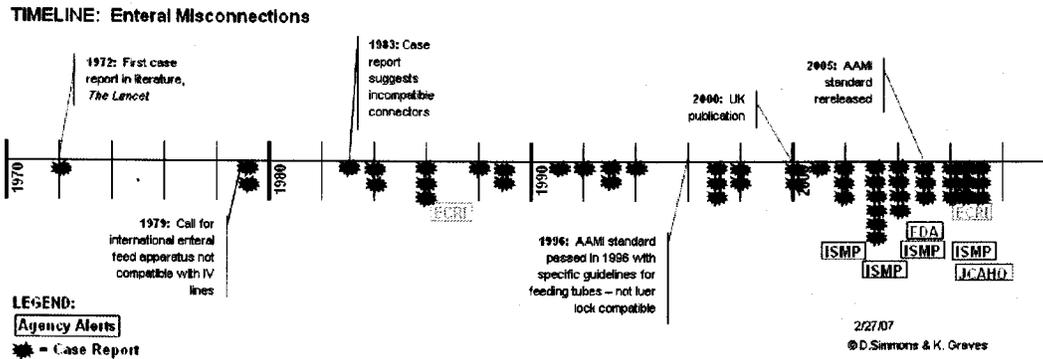
24. Lopez Garcia MJ, Sorribes Monrabal I, Fernandez-Delgado Cerda R. Accidental intravenous administration of semi-elemental formula in an infant. *Clin Pediatr (Phila.)*1992;31(12):757-58.
25. Institute for Safe Medication Practices. ISMP Medication Safety Alert: Problems persist with life-threatening tubing misconnections. 2004 Accessed at <http://www.ismp.org/Newsletters/acutecare/articles/20040617.asp> on June 27, 2007.
26. Kennelly C, Barnes S. Inadvertent iv administration of enteral formula. *Am J Crit Care.* 1998;7(1):80.
27. Page, L. Finding the wrong fit. *Mater Manag Health Care.* 2006; 5(4):24-28.
28. VIASYS Healthcare, Inc. Corflo Anti-IV enteral feeding system. Accessed at www.corfloanti-iv.com 10 June 2007.
29. Baxa, Inc. Oral liquid delivery. Accessed at www.baxa.com on 10 June 2007.

Table 1. Reported Enteral Misconnections and Related Factors (Jan. 2000–Dec. 2006)

Related Factors	Number of Cases	Number of Sentinel Events	Percent of Cases with Sentinel Events (Life-Threatening or Fatal)
Use of Syringe Pump and IV Tubing	1	0	0
Use of Ready-to-Hang Enteral Containers/Bags and IV Tubing	3	2	66%
Enteral Meds Administered IV (Used IV Syringe)	13	3	23%
Other Solution Intended for Enteral Route given IV	4	2	50%
Enteral Tube Not in Place, Med Given IV	3	1	33%
Total	24	8	33%

Data supplied by USP MEDMARX and USP-ISMP Medication Errors Reporting Program.

Figure 3. Timeline Enteral Misconnections and Alerts



**Figure 1. One-Piece Enteral Administration Set in Enteral Feeding System
(Courtesy of Sharp Healthcare)**

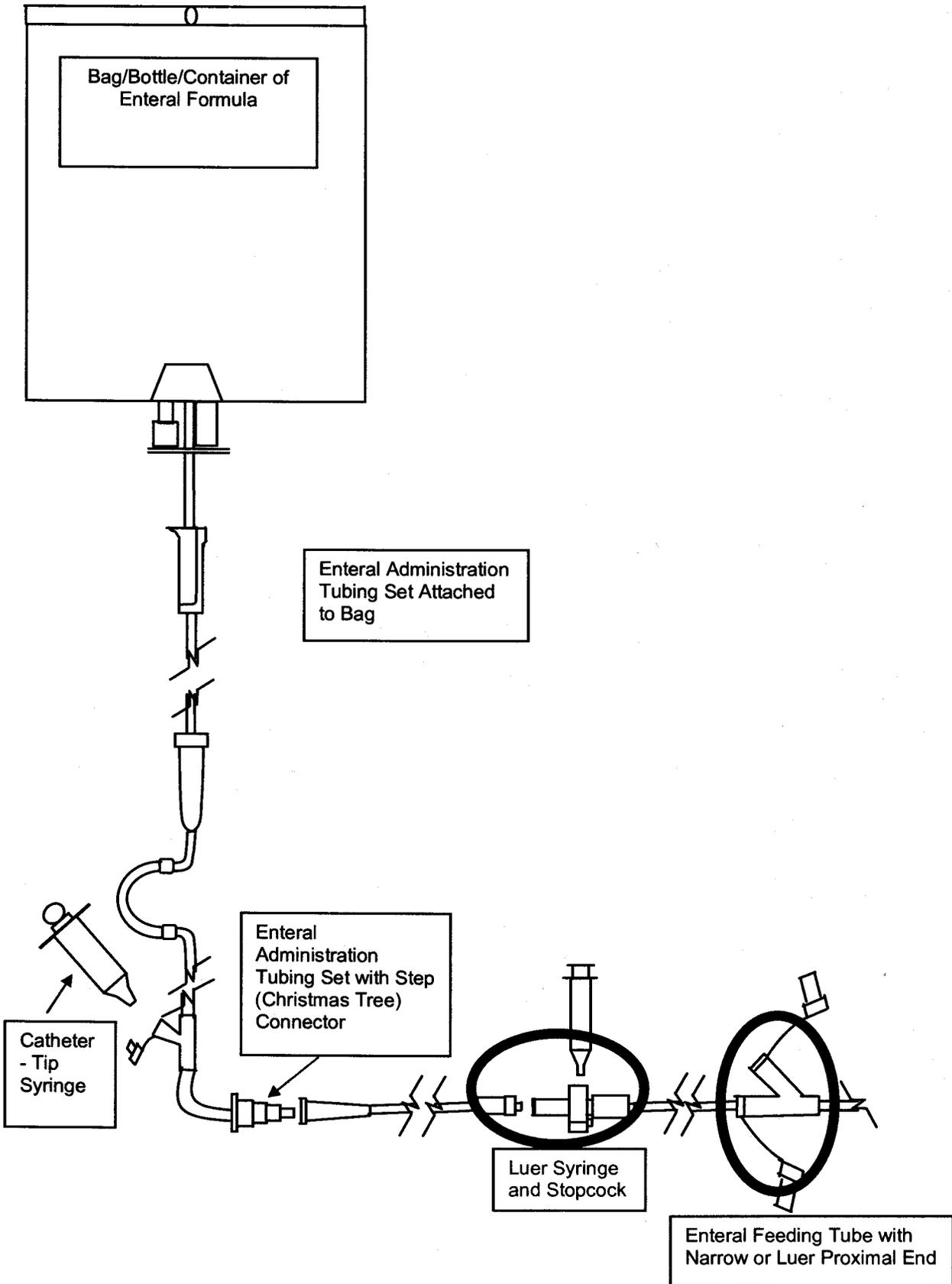
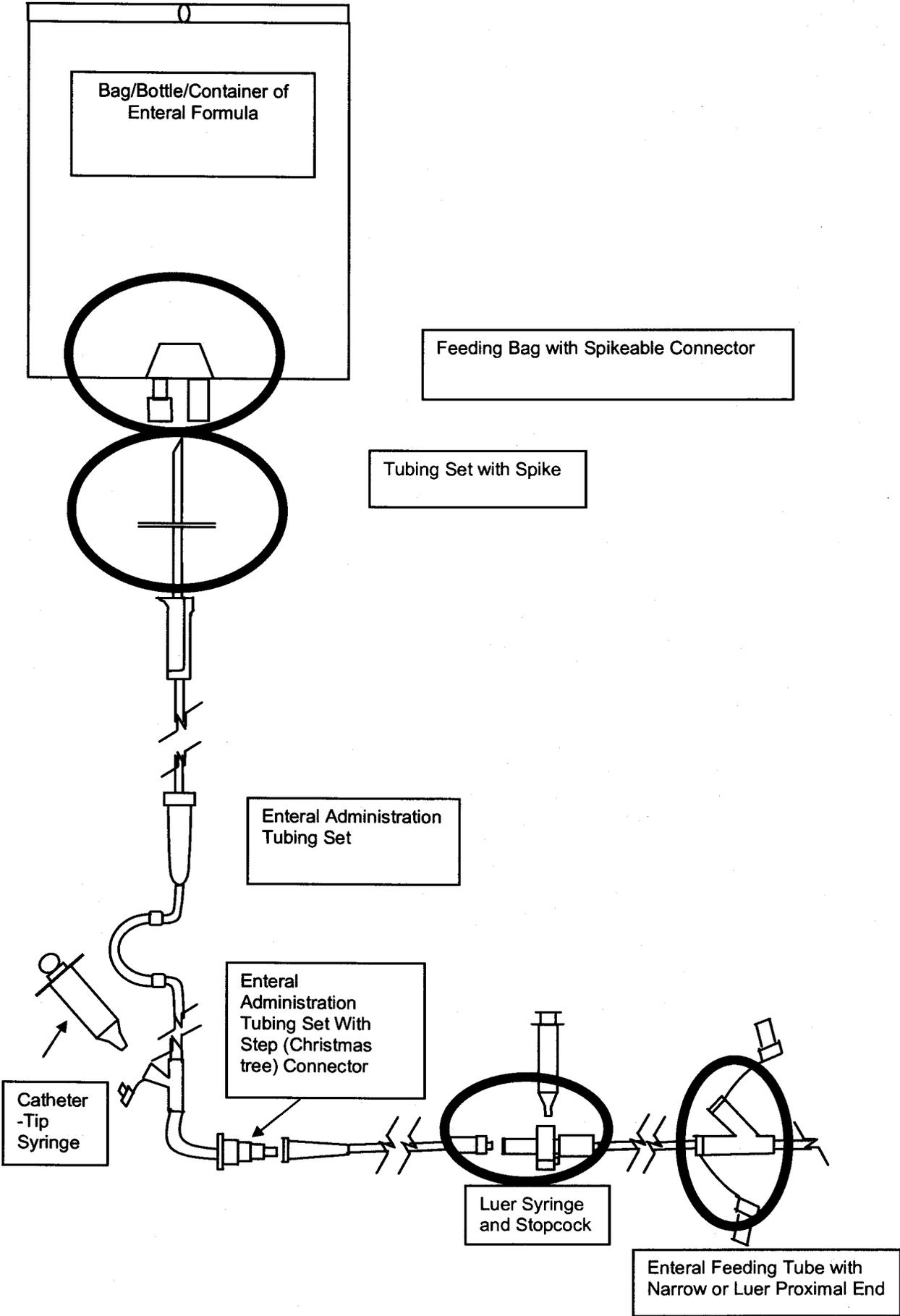


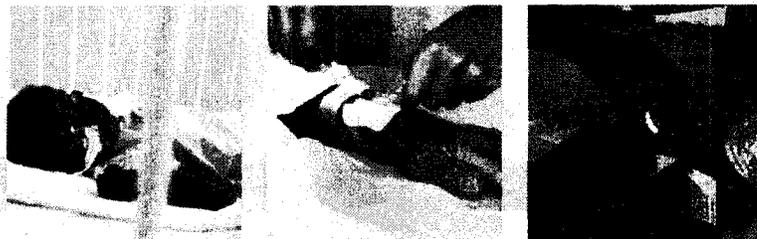
Figure 2. Two-Piece Enteral Administration Set in Enteral Feeding System
(Courtesy of Sharp Healthcare)



Avoiding Catheter and Tubing Mis-Connections

Patient Safety Solutions

| volume 1, solution 7 | May 2007



► STATEMENT OF PROBLEM AND IMPACT:

Tubing, catheters, and syringes are a fundamental aspect of daily health care provision for the delivery of medications and fluids to patients. The design of these devices is such that it is possible to inadvertently connect the wrong syringes and tubing and then deliver medication or fluids through an unintended and therefore wrong route. This is due to the multiple devices used for different routes of administration being able to connect to each other. The best solution lies with introducing design features that prevent misconnections and prompt the user to take the correct action.

Other causes or contributing factors include:

- *Luer connectors. Used almost universally in a variety of medical applications to link medical devices, including fluid delivery (via the enteral, intravascular, spinal, and epidural routes) and insufflation of gas (in balloon catheters, endotracheal cuffs, and automatic blood pressure devices), they have been found to enable functionally dissimilar tubes or catheters to be connected.*
- *Routine use of tubes or catheters for unintended purposes. This includes using intravenous (IV) extension tubing for epidurals, irrigation, drains, and central lines or to extend enteric feeding tubes.*
- *Positioning of functionally dissimilar tubes used in patient care in close proximity to one another. For example, use of an enteral feeding tube near a central intravenous catheter and tubing.*
- *Movement of the patient from one setting or service to another.*
- *Staff fatigue associated with working consecutive shifts.*

Tubing and catheter misconnections can lead to wrong route medication errors and result in serious injury or death to the pa-

tient. Though these errors are highly preventable and can often be easily averted, multiple reports of patient injury and death from such wrong route medication errors indicate that they occur with relative frequency (1-7). This includes erroneous administration routes for aerosols.

In the United States of America (USA), nine cases of tubing misconnections involving seven adults and two infants have been reported to the Joint Commission's Sentinel Event database, resulting in eight deaths and one permanent loss of function (8). Similar incidents have been reported to other agencies, including the ECRI Institute, the United States Food and Drug Administration, the Institute for Safe Medication Practices (ISMP), and the United States Pharmacopeia (USP). Data from these groups reveal that misconnection errors occur with significant frequency and, in a number of instances, lead to deadly consequences (9,10).

The most common types of tubes and catheters involved in the cases reported to the Joint Commission are central venous catheters, peripheral IV catheters, nasogastric feeding tubes, percutaneous enteric feeding tubes, peritoneal dialysis catheters, tracheostomy cuff inflation tubes, and automatic blood pressure cuff insufflator tubes. Examples include specific misconnections involving an enteric tube feeding into an IV catheter (four cases); a blood pressure insufflator tube connected to an IV catheter (two cases); and the injection of intravenous fluid into a tracheostomy cuff inflation tube (one case).

In the United Kingdom, between 2001 and 2004, there were three reports of death, and from 1997 to 2004 there were four reports of harm or near misses following wrong route errors when oral liquid medicines, feeds, and flushes were administered intravenously (11). A review of the National Reporting and Learning System in the United Kingdom identi-

fied 32 reported incidents in which oral liquid medicines were administered by the intravenous route, seven incidents in which epidural medication was administered via the intravenous route, and six incidents in which intravenous medication was administered via the epidural route from 1 January 2005 to 31 May 2006.

► ASSOCIATED ISSUES:

While various approaches to preventing catheter misconnection and wrong route administration have been suggested, meticulous attention to detail when administering medications and feedings (i.e. the right route of administration) and when connecting devices to patients (i.e. using the right connection/tubing) is a basic first step. By implementing preventive measures—many of them simple and inexpensive—wrong route administration errors can be effectively eliminated.

► SUGGESTED ACTIONS:

The following strategies should be considered by WHO Member States.

1. Ensure that health-care organizations have systems and procedures in place which:
 - *Emphasize to non-clinical staff, patients, and families that devices should never be connected or disconnected by them. Help should always be requested from clinical staff.*
 - *Require the labeling of high-risk catheters (e.g. arterial, epidural, intrathecal). Use of catheters with injection ports for these applications is to be avoided.*
 - *Require that caregivers trace all lines from their origin to the connection port to verify attachments before making any connections or reconnections, or administering medications, solutions, or other products.*
 - *Include a standardized line reconciliation process as part of handover communications. This should involve rechecking tubing connections and tracing all patient tubes and catheters to their sources upon the patient's arrival in a new setting or service and at staff shift changes.*
 - *Bar the use of standard Luer-connection syringes to administer oral medications or enteric feedings.*
 - *Provide for acceptance testing and risk assessment (failure mode and effects analysis, etc.) to identify the potential for misconnections when purchasing new catheters and tubing.*

2. Incorporate training on the hazards of misconnecting tubing and devices into the orientation and continuing professional development of practitioners and health-care workers.
3. Promote the purchasing of tubes and catheters that are designed to enhance safety and to prevent misconnections with other devices or tubes.

► LOOKING FORWARD:

1. Physical barriers (e.g. incompatibility by design) should be created to eliminate the possibility of interconnectivity between functionally dissimilar medical tubes and catheters to the extent feasible.
2. Specific labeling of device ports is advocated to avoid connecting intravenous tubing to catheter cuffs or balloons (3).
3. The use of different, dedicated infusion pumps for specific applications such as epidural infusions has also been proposed (12).
4. Using only oral/enteral syringes to administer oral/enteral medications and avoiding the use of adapters and three-way taps are part of several draft proposals from the United Kingdom's National Patient Safety Agency to prevent wrong route errors (13).
5. A combined preventive strategy of performing risk assessments to identify existing misconnection hazards, encouraging manufacturers to design dissimilar catheters and tubes to be physically impossible to connect ("incompatibility by design"), acquisition of equipment whose design makes misconnections unlikely, and policy implementation to minimize misconnection occurrences has been advocated (14,15).
6. The colour-coding of tubing and connections should be standardized. The European standardization body has studied the colour-coding of tubing and connectors in certain applications and has recommended exploring alternatives to Luer connectors in selected applications (16).
7. Industry-based standards and engineering design for medical tubes and catheters that are organ-specific or need-specific and do not interconnect should be established and promoted.

► STRENGTH OF EVIDENCE:

- Expert consensus.

▶ APPLICABILITY:

- ▶ Wherever patients are treated, including hospitals, mental health facilities, community settings, ambulatory clinics, long-term care facilities, clinics, practices, home-care agencies.

▶ OPPORTUNITIES FOR PATIENT AND FAMILY INVOLVEMENT:

- ▶ Encourage patients and families to ask questions about medications given parenterally or via feeding tubes, to assure proper medication delivery.
- ▶ Educate patients, families, and caregivers on the proper use of parenteral sites and feeding tubes in the home care setting and provide instruction on the precautions to take to prevent wrong route errors.

▶ POTENTIAL BARRIERS:

- ▶ Staff acceptance of the concept of wrong route error prevention.
- ▶ Staff acceptance of never modifying incompatible connectors to allow connections.
- ▶ Cost of converting to non-connectable delivery systems.
- ▶ Inability to create an approach or standardization of systems.
- ▶ Difficulties with a consistent or reliable supply chain for some countries.
- ▶ Insufficient generally accepted research, data, and economic rationale regarding cost-benefit analysis or return on investment (ROI) for implementing these recommendations.

▶ RISKS FOR UNINTENDED CONSEQUENCES:

- ▶ Possible treatment delays to obtain compatible equipment if compatible connections are not available.

▶ SELECTED REFERENCES AND RESOURCES:

1. *Tunneled intrathecal catheter mistaken as central venous line access. ISMP Canada Safety Bulletin, 30 October 2005.* <http://www.ismp-canada.org/download/ISMPCSB2005-08Intrathecal.pdf>.
2. *Problems persist with life-threatening tubing misconnections. ISMP Medication Safety Alert, 17 June 2004.* <http://www.ismp.org/newsletters/acutecare/articles/20040617.asp?pr=y>.
3. *Wichman K, Hyland S. Medication safety alerts. Inflation ports: risk for medication errors. Canadian Journal of Hospital Pharmacy, 2004, 57(5):299-301.* <http://www.ismp-canada.org/download/cjhp0411.pdf>.
4. *Ramsay SJ et al. The dangers of trying to make ends meet: accidental intravenous administration of enteral feed. Anaesthesia and Intensive Care, 2003, 31:324-327.*
5. *Pope M. A mix-up of tubes. American Journal of Nursing, 2002; 102(4):23.*
6. *Wrong route errors. Safety First, Massachusetts Coalition for the Prevention of Healthcare Errors, June 1999* (<http://www.macoalition.org/documents/SafetyFirst1.pdf>, accessed 10 June 2006).
7. *Tubing misconnections—a persistent and potentially deadly occurrence. Sentinel Event Alert, April 2006. Joint Commission.* http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_36.htm.
8. *Vecchione A. JCAHO warns of tubing errors. Health-System Edition, 22 May 2006* (<http://mediwire.healingwell.com/main/Default.asp?P=Content&ArticleID=326253>, accessed 10 June 2006).
9. *Cousins DH, Upton DR. Medication errors: oral paracetamol liquid administered intravenously: time for hospitals to issue oral syringes to clinical areas? Pharmacy in Practice, 2001, 7:221.*
10. *Cousins DH, Upton DR. Medication errors: increased funding can cut risks. Pharmacy in Practice, 1997, 7:597-598*
11. *Building a safer NHS for patients: improving medication safety. London, Department of Health, 2004* (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4071443 accessed 10 June 2006).
12. *Koczmar C. Reports of epidural infusion errors. CACCN Dynamics, 2004, 15(4):8.* <http://www.ismp-canada.org/download/CACCN-Winter04.pdf>.
13. *Preventing wrong route errors with oral/enteral medications, feeds and flushes. National Patient Safety Agency Patient Safety Alert, Draft responses to 1st consult, January-March 2006.* <http://www.saferhealthcare.org.uk/NR/rdonlyres/3F9F3FB2-89B6-4633-ACE9-A51EC2023EBC/0/NPSAdraftpatientsafetyalertonoralconnectorsforstakeholderconsultation.pdf>.
14. *Preventing misconnections of lines and cables. Health Devices, 2006, 35(3):81-95.*
15. *Common connectors pose a threat to safe practice, Texas Board of Nursing Bulletin, April 2006.*
16. *Moore R. Making the right connections. Medical Device Technology, 2003, 14(2):26-27.*

© World Health Organization 2007

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; e-mail: permissions@who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

This publication contains the collective views of the WHO Collaborating Centre for Patient Safety Solutions and its International Steering Committee and does not necessarily represent the decisions or the stated policy of the World Health Organization.

APPENDIX D:
Nurses on Guard - Error Prevention and Management

Safe Systems, Safe Patients: Common Connectors Pose a Threat to Safe Practice

by Debora Simmons, MSN, RN, CCRN, CCNS



Debora Simmons, MSN, RN

In 1972 an article in the Lancet described an accidental infusion of a "Milk Drip" meant to be infused intragastrically but was "inadvertently" infused intravenously (Wallace, Payne et al. 1972). The patient had immediate severe consequences of this intravenous infusion of a feeding. Over the following 30 plus years there have been numerous case reports of accidental connections of feeding lines to intravenous lines, intravenous lines and feeding lines to tracheostomy cuffs, blood pressure monitors to intravenous lines and other life threatening connections of compatible tubing to the wrong line (Lanigan 2002; FDA 2003; Eakle, Gallauresi et al. 2005). To date there has been no progress in eradicating this avoidable error.

The common element in each of these tragic errors is the presence of a "luer lock" connector that makes connecting therapeutic products easy but also allows fatal errors when they are mistakenly connected. Blood pressure cuffs to intravenous lines can cause air embolisms, feeding tubes to intravenous lines cause sepsis and fat embolisms and intrathecal infusions of vincristine are fatal. The commonality is that each one of these errors involves a luer lock connector (FDA 2003).

Initial reactions to these case reports may be to question the vigilance of the nurse. How could a careful nurse accidentally connect the wrong lines? The answer is complex and includes many different factors that contribute to making this type of error. First and foremost, nurses are human and humans are not "perfect" at all times despite their intent. One other large problem is that as we become more familiar with a task, we may perform that task incorrectly. This is much like locking your keys in your car accidentally, although you usually perform perfectly, occasionally you do not act perfectly and lock your keys inside the car. This is called "*automaticity*" and is a function of thinking that allows us to perform common tasks without effort but also make mistakes in common tasks without knowing a mistake has been made.

The answer to this dilemma is not far from our reach – changing the design of the connectors will help prevent these errors. In the past, misconnected medical gases caused deaths every year in the operating room when anesthesiologists would inadvertently connect the patient to nitrous oxide and not oxygen. The connections to these two similar gases are now incompatible, which prevents an accidental connection. Redesigning the product so it will not connect is called a *forcing function* because it forces the user to use correct lines and prevents them from connecting incompatible lines. This change is a result of using safe design principles and recognizing the potential, however small, of human error in a critical process (Berwick 2001).

To date, there is no mandated standard in healthcare to change compatibility of these connectors to prevent these errors. Healthcare facilities are encouraged to use connectors that are not universally compatible with other infusion systems and purchase items that are not compatible to all lines – such as blood pressure cuffs without luer lock connectors or feeding tubes that will not connect to intravenous lines (Association of the Advancement of Medical Instrumentation 2001; ISMP 2003; Paparella 2005). Unfortunately nurses and facilities may not be aware of the potential for this error.

Nurses in healthcare settings where there are multiple common connectors must be aware of the possible hazard of inadvertently connecting the wrong line and take steps to protect their patients from this tragic and avoidable error. Changing the design of these connectors so they are not able to be connected is the right solution for this problem – until then here are some suggestions from experts of how to try and avoid this error:

1. All staff should be educated regarding the hazards of these connectors and strategize ways to decrease the risk (Eakle, Gallauresi et al. 2005);
2. It may be helpful to mark all lines with luer connectors at the proximal and distal end or double check lines independently (ISMP 2004);
3. Do not use IV tubing for enteral feedings or IV pumps for Enteral feedings (ISMP 2004);
4. Avoid buying equipment with common luer lock connectors when at all possible – especially for blood pressure cuffs, intrathecal or epidural lines and enteral feedings (Stone 2002; Paparella 2005).

Safe Systems - continued from previous page

Nurses can influence the design and safety of the work environment by being active in decisions about patient products and supporting their institutions in purchasing incompatible connectors. In addition, soliciting professional organizations to support standards that change connectors to be incompatible is also a strategy. Safe design of healthcare products will support the ability of nurses to practice safely and keep patients safe.

Where you can get more information:

Association for the Advancement of Medical Instrumentation, www.AAMI.org

FDA Patient Safety News, www.FDA.gov

Institute for Safe Medication Practice, www.ISMP.org

United States Pharmacopeia, www.USP.org

Joint Commission on Accreditation of Healthcare Organizations, http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_36.htm

References:

Association for the Advancement of Medical Instrumentation (2001). Enteral feeding set adapters and connectors. American National Standard, American National Standards Institute.

Berwick, D. M. (2001). "Not again!" BMJ 322(7281): 247-8.

Eakle, M., B. A. Gallauresi, et al. (2005). "Luer-lock misconnects can be deadly." Nursing 35(9): 73.

FDA (2003). Dangerous Misconnections Between BP Monitors and IV Ports. FDA Patient Safety News. FDA. 2005.

ISMP (2003). Blood pressure monitoring tubing may connect to IV ports. ISMP Medication Safety Alert! ISMP. 2005.

ISMP (2004). "Improvised Drug Delivery: A cause for concern." ISMP Medication Safety Alert(April 22, 2004).

ISMP (2004). Problems persist with life-threatening tubing misconnections. ISMP Medication Safety Alert! ISMP. 2005.

Lanigan, C. J. (2002). "Safer epidural and spinal connectors." Anaesthesia 57(6): 567-71.

Paparella, S. (2005). "Inadvertent attachment of a blood pressure device to a needleless IV "Y-site": surprising, fatal connections." JEmerg Nurs 31(2): 180-2.

Stone, B. A. (2002). "Avoid luer connectors on blood pressure cuffs." Anesthesiology 97(3): 765-6.

Wallace, J., R. Payne, et al. (1972). "Inadvertent intravenous infusion of milk." The Lancet 1972(1): 1264-1266.

Debora Simmons, MSN, RN, CCRN, CCNS is a Clinical Nurse Specialist in critical and acute care with a background in patient safety, technology and complex patient care systems. As Senior Clinical Quality Improvement Analyst for the Institute of Healthcare Excellence at The University of Texas MD Anderson Cancer Center and a member of the technical core for the Center of Excellence for Patient Safety Research and Practice, she contributes to the clinical design and analysis of complex psychosocial and clinical protocols in the UT System and allied institutions relating to patient safety and quality outcomes. She maintains her clinical skills as an instructor of undergraduate nursing. She is a member of the Safe Medications Use Committee for the United States Pharmacopeia and is a member of the board of directors of Consumers Advancing Patient Safety.

In accordance with 301.158, Texas Occupations Code, the Board disseminates information "that is of significant interest to nurses and employers of nurses in Texas." As part of its Strategic Plan for the agency, the Board has identified the need for regular input on nursing practice, licensure, and education. The *Nurses on Guard - Error Prevention and Management* series of articles in the *Bulletin* is one way of meeting that need. Comments regarding this column should be addressed to the Editor at the Board's address. The opinions expressed in the guest column are those of the author and not an opinion or position statement of the Board.

Did you know....

BNE staff frequently receives phone calls and e-mails asking which states are members of the Nurse Licensure Compact (NLC). The best resource for information on states that are members of the Compact (or who are considering joining the Compact) is the web site for the National Council of State Boards of Nursing (NCSBN) (<http://www.ncsbn.org/nlc/index.asp>). Resources on the National Council's web site include: a color map indicating states which have joined the compact or are in the process of implementing the compact and a frequently asked questions handout which explains how the compact works.

Caution: Tubing misconnections can be deadly

In April 2006, The Joint Commission issued a *Sentinel Event Alert* pertaining to the risk of tubing misconnections.¹ This alert describes injury to one patient who suffered permanent loss of function and the deaths of eight patients as the result of tubing misconnections. Every perioperative clinician should be aware of and learn how to avoid this common and potentially deadly error.

A tubing misconnection occurs when a nurse or other clinician unintentionally connects one end of a tube or catheter to the wrong tube or device. For example, one common misconnection occurs when a member of the health care team connects the male end of an enteric feeding tube to an IV catheter or a peritoneal dialysis catheter. It also is possible for a blood pressure insufflator tube to be connected to an IV catheter.¹

Misconnections also can occur when a clinician uses a universal type of connector (eg, a 5-in-1 connector). The use of these connectors facilitates the joining of two types of tubing, even in situations when the tubes never should be joined. Additionally, many misconnections occur because various types of tubing, ports, and other medical devices use the same type and size connection, allowing for easy misconnection.

According to the *Sentinel Event Alert*, the US Pharmacopeia has collected more than 300 incident reports of misconnection problems.¹ These reports identify many misconnection errors such as the connection of IV fluids to

- indwelling urinary catheters,
- epidural catheters,
- nasogastric tubes,
- the distal port of a pulmonary artery catheter, and
- external dialysis catheters.

In one perioperative case, an IV piggyback antibiotic was connected to the ventriculostomy drain of a patient in the postanesthesia care unit.¹

Other published sources reveal tragic events that have occurred as the result of tubing misconnections,² such as reports of nurses who have inadvertently administered breast milk or formula to neonates via the IV route. Other devastating errors include the connection of a sequential compression device to an IV administration set or the fatal error of infusing intrathecal vincristine.²

COMPLEX TUBING REQUIREMENTS

The *Sentinel Event Alert* on tubing misconnections warns that "if it can happen, it will happen."¹ Considering that most clinical situations have complex tubing requirements with various tubing types, it is remarkable that more errors do not occur. It is not unusual for one surgical patient to have a nasogastric tube, a central or peripheral IV line, an indwelling urinary catheter, sequential compression stockings, and tubing for an epidural or patient-controlled analgesia pump. In addition, patients also may have dialysis catheters, blood administration sets, or other drainage systems. As tubing is added, the potential for misconnection increases.

Another factor that can result in confusion or error is when any type of tubing is used for a nontraditional purpose. Consider the practice of using an indwelling urinary catheter

Suzanne C. Beye, RN;
Debra Simmons, RN;
Rodney W. Hicks, ARNP



Tubing misconnections occur when a clinician unintentionally connects one end of a tube or catheter to the wrong tube or device.

**Various
manufacturers use
connectors that are
nearly uniform in
size, which allows
misconnection
errors to occur.**

for wound drainage or for draining an inflamed gall bladder. A nurse might question, "Is it a Foley or a chole-Foley?" This multipurpose use of tubing can easily result in confusion when experienced clinicians are rushed or distracted when providing care.

TUBING CONNECTIONS

Tubes often are connected using a Luer-lock connection system (ie, the connection is made by rotating the connector by a half or three-quarter turn). Most clinicians are familiar with Luer-lock connections, which are used to secure IV tubing to an IV needle. The locking mechanism provides security for the IV connection and helps prevent accidental disconnection. Luer-lock connections also can be found on a wide variety of tubing.

Another common type of tubing connection is the Luer-slip connection (ie, the connection is made by inserting the tapered male end into the female receptor). Although Luer-slip connections are easier to make, they are somewhat less secure. This type of connection often is used between an indwelling urinary catheter and a drainage system. To secure this type of connection, nurses often tape the two ends to prevent the tubing from accidentally disconnecting.

Unfortunately, no published manufacturing standards exist to guide manufacturers in their use of these varied connections. This has resulted in various manufacturers using connectors that

are nearly uniform in size, subsequently allowing misconnection errors to occur. These errors are more likely to happen when a clinician attempts to connect two tubes that should not be connected but for which making a connection is possible. In fact, the misconnection actually may appear to be correct.

PREVENTION STRATEGIES

Suggested strategies to prevent this type of error seem obvious and frequently focus on developing manufacturing standards for the various tubing types so that misconnections simply cannot occur. Despite the Joint Commission's recommendation that hospitals avoid buying non-IV equipment that is capable of connecting with patient IV equipment, these products continue to be used, and errors continue to occur.

Tubing identification methods. Strategies to help identify tubing and appropriate connections include labeling all tubes and catheters or using a color-coding system to help health care providers discern which tubes should be connected. These strategies, however, are unlikely to prevent all misconnection errors. Health care workers might

come to rely on a system that is not necessarily practical in all situations. As an example, if facilities vary in their use of color coding, someone could misinterpret the use of a specific color. Color coding also could create problems for someone who is color blind. In these situations, relying on color coding could result in increased misconnection errors.

Recommendations of the Joint Commission. The *Sentinel Event Alert* sets forth a number of recommendations to help reduce tubing misconnection errors. These include

- avoiding the purchase of non-IV equipment that can connect with IV line connectors;
- testing new tubing and catheter purchases for performance, safety, and usability;
- tracing tubes and catheters to the point of origin before connecting a new device or infusion;
- conducting a line reconciliation process at the time of hand offs;
- using standardized directions for tubes and catheters that have different purposes;
- informing nonclinical staff members, patients, and family members to get help when disconnecting or reconnecting tubes;
- labeling high-risk catheters and not using catheters with injection ports;
- not using standard Luer-syringes for oral medications or enteric tubes;
- emphasizing the risk of

tubing misconnections during orientation and competency assessments; and

- avoiding clinician fatigue.¹

Nursing strategies. Until standards for tubing connectors are developed, published, and fully implemented, it is crucial for all clinicians to take exacting care when managing a patient's tubing connections. First and foremost, clinicians should always trace lines back to their origin before connecting or disconnecting any device or infusion.¹ Clinicians also must ask the following questions before treating each patient.

- What tubing is in place?
- What is the purpose of the tubing?
- To what is each tube connected?
- Is the tubing intended for administration, irrigation, or drainage?

Another important safeguard for health care providers is to handle tubing and connections only when lighting is adequate. Clinicians often work in less-than-optimal lighting conditions, and this alone can result in errors if the clinician is unable to fully visualize the connections or the origin of the tubing.

In some instances, patients or family members may disconnect or reconnect tubes in an effort to "help the nurse." Cautioning the patient and his or her family members to always call for assistance can help ensure

that only correct connections are made.

PATIENT SAFETY PRACTICES

Perioperative clinicians need to be aware of the possibility of misconnections that can and will occur in perioperative settings. Given the fast-paced nature of perioperative settings and the number of patient hand offs that occur across the continuum of care, connection errors are likely to occur. By being attentive when new devices are used in the OR and sharing that information with other clinicians, nurses can help prevent potential errors. Misconnection errors are more likely to occur when an unfamiliar drainage system or a new catheter is being used.

By working together on this challenging issue, members of the health care team can help prevent unintended errors. Tubing misconnections can harm or kill patients, and nurses must exercise great caution while handling and connecting patient tubing and devices. ❖

SUZANNE C. BEYEA

PHD, RN, FAAN

DIRECTOR OF NURSING RESEARCH
DARTMOUTH-HITCHCOCK MEDICAL CENTER
LEBANON, NH

DEBORA SIMMONS

RN, MSN, CCRN, CCNS

ASSOCIATE DIRECTOR
INSTITUTE FOR HEALTHCARE EXCELLENCE
THE UNIVERSITY OF TEXAS,
M. D. ANDERSON CANCER CENTER
HOUSTON, TEX

RODNEY W. HICKS

PHD, ARNP

MANAGER OF PATIENT SAFETY RESEARCH
US PHARMACOPEIA,
DEPARTMENT OF PATIENT SAFETY
ROCKVILLE, MD

Partially funded by an Agency for Healthcare Research and Quality grant, #1P01HS1154401, The University of Texas Center of Excellence for Patient Safety Research and Practice.

REFERENCES

1. The Joint Commission on Accreditation of Healthcare Organizations. *Sentinel Event Alert*. April 3, 2006;36. Available at: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_36.htm. Accessed January 11, 2007.
2. Simmons D. Safe systems, safe patients: common connectors pose a threat to safe practice. *Texas Board of Nursing Bulletin*. April 2006;37(2):6-7. Available at: http://www.mdanderson.org/pdf/simmons_2006.pdf. Accessed January 11, 2007.

RESOURCES

Eakle M, Gallaresi BA, Morrison A. Luer-lock misconnections can be deadly. *Nursing*. 2005;35:73.

ECRI. Fatal air embolism caused by the misconnection of medical device hoses to needleless Luer ports on IV administration sets [Hazard Report]. *Health Devices*. 2003;33:223-225.

ECRI. Preventing misconnections of lines and cables. *Health Devices*. 2006;35:81-95.

Institute for Safe Medication Practices. Problems persist with life-threatening tubing misconnections. *ISMP Medication Safety Alert!* June 17, 2004. Available at: <http://www.ismp.org/newsletters/acutecare/articles/20040617.asp>. Accessed January 11, 2007.

**Error-Avoidance Recommendations for Tubing Misconnections
When Using Small Bore Connectors: A Statement by the
USP Safe Medication Use Expert Committee**

**Debora Simmons, R.N., M.S.N., CCRN, CCNS; Marjorie Phillips, M.S.,
R.Ph., FASHP; Matthew Grissinger, RPh, FISMP, FASCP; and Shawn C.
Becker, M.S., R.N.**

**United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, Maryland 20852
Telephone: 301-816-8216**

FAX: 301-816-8532

June 18, 2007

Abstract:

Members of the United States Pharmacopeia's Safe Medication Use Expert Committee (SMU EC)^a are concerned about the safety of patients because of ongoing mishaps with tubing that uses small bore connectors (commonly called luer locks). In this article, the USP SMU EC provides recommendations to assist healthcare professionals, manufacturers, and consumers in the appropriate handling of tubing with these connectors.

Providers play a significant role in improving patient safety by sharing their experiences with tubing misconnections and suggesting ways to avoid these types of errors in the future.

Introduction:

The United States Pharmacopeia (USP) is a volunteer-based, not-for-profit organization whose mission is to promote the public health by establishing and disseminating officially recognized standards of quality and authoritative information for the use of medicines and related articles for professionals, patients, and consumers.

a. Members of the SMU EC are: Michael Murray, Pharm.D, Chair; Marjorie Phillips, M.S., R.Ph., FASHP, Vice Chair; Suzanne C. Beyea, Ph.D., R.N., FAAN; Maureen Cahill, M.S.N.; William Elliott, M.D., FACP; Elizabeth Flynn, Ph.D., R.Ph.; Howard Greenberg, M.D., M.S., M.B.A.; Matthew Grissinger, R.Ph., FASCP; Mark Horn, M.D.; William Kelly, Pharm.D.; Gerald McEvoy, B.S.; CDR. Ronald Nosek, R.Ph., M.S.; Joanne Schwartzberg, M.D.; Debora Simmons, R.N., M.S.N., CCRN, CCNS; Carl Sirio, M.D.; John Straumanis, M.D.; Mark Sullivan, Pharm.D.; Kathleen Uhl, M.D.; Carol Holquist, R.Ph. Other contributor: Rodney Hicks, Ph.D., R.N.

The recommendations for avoiding medication errors resulting from tubing misconnections as presented in this article are based on reports received

through USP's MEDMARX and USP-ISMP Medication Errors Reporting Programs, reports submitted to The Healthcare Safety Alliance Partnership (HASP), FDA Alerts, and standards set by the AAMI (Association of the Advancement of Medical Instrumentation) and ECRI Institute (formerly the Emergency Care Research Institute). Additionally, research and retrospective analysis was performed by The Institute for Healthcare Excellence at the University of Texas M.D. Anderson Cancer Center. These recommendations may be applied and adopted in various health care settings.

Background

Since 1972, there have been reports of failures to connect the correct tubing to intravenous, epidural, intracranial, intrathecal, and other high risk systems (Wallace, Payne et al. 1972; Berwick 2001; Reason 2004). In one literature review there were more than 80 separate references to errors of this type found in the published literature (Simmons 2006). It is recognized that voluntary reporting may greatly underestimate the number of cases that actually occur. Numerous adverse events have been reviewed and the tubing industry alerted of these events by the Food and Drug Administration, USP, The Joint Commission, and the Institute for Safe Medication Practices.

Errors with tubing misconnections are often the result of cognitive "slips" in performance where the provider is not aware that they are connecting the wrong tubing. Cognitive psychologist, James Reason,

describes this state as being in automatic mode, the level of functioning where the error is not detectable by the participant at the time the event occurs (Reason 1990). Tubing misconnections occur at the subconscious level and as a result are not under the conscious control of the healthcare provider. Therefore, these are not errors that are readily avoidable without a "constraint" design change that puts a physical barrier in place when the misconnections are attempted (Association of the Advancement of Medical Instrumentation 1996; FDA 2003). Constraints are designs that prevent an error from occurring and constraint design would make misconnections physically impossible.

The use of universal connectors, such as luer tip or small bore connectors (see Figure 1) in healthcare is a fundamental failure to design safe systems. In simple terms, any system that carries a high risk of injury if connected unintentionally to another system should have design features that prevent the possibility of inadvertent connection. Unfortunately, in many cases, the only available tubing manufactured and available in the United States for critical monitoring and drug or solution delivery functions has a universally-fitting small bore connector (Paparella 2005; JCAHO 2006). This problem is not limited to the United States and is being addressed by the National Patient Safety Agency (NPSA) in the United Kingdom. The NPSA

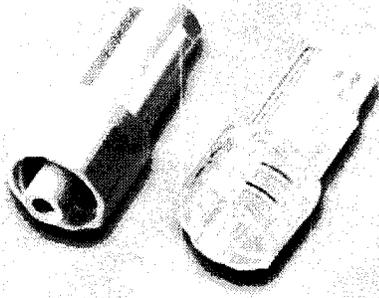


Figure 1. Luer lock connector.

has set deadlines for National Health Service entities in England and Wales to adopt enteral feeding catheters that are not compatible with parenteral syringes (i.e., adopting enteral catheters that do not contain female luer ports). There is no equivalent organization in the U.S., although the Joint Commission has served a similar role as an accreditation organization. The Joint Commission has issued a Sentinel Event Alert (#36 April, 2006) acknowledging the severity of tubing misconnections. Preventing tubing misconnections are a part of the World Health Organization's "Nine Solutions" for patient safety; however, a potential Joint Commission 2006 National Patient Safety Goal on tubing misconnections was not approved after field review.

Public Policy Recommendations

It is also recognized in the literature and in reported cases that tubing misconnection errors carry the most serious consequences including sepsis, embolus and death. Since the redesign of these systems will require extensive resources and time to implement, and until safe designs are

available, the following recommendations are proposed to prevent the present risk of misconnection errors:

1. Recommendations for Regulators and Standard Setters:

- A. The Food and Drug Administration and other standards setting organizations are requested to quickly adopt a standard that encourages rapid conversion of small bore universal catheters to sets that are physically incompatible with intravenous and other medical/circuit systems that are not intended to connect.
- B. The Joint Commission is requested to reconsider tubing misconnections in the next set of National Patient Safety goals.
- C. State Health departments, hospital associations and health professionals' organizations are requested to immediately offer alerts regarding the hazards of universal connectors to members.

2. Recommendations for Manufacturers and Purchasers of Common Small Bore Connectors:

- A. Immediately begin to redesign and develop feeding tubes, feeding sets and adaptors, and connectors for non intravenous equipment such as nebulizers, non invasive blood pressure devices, compression devices, intracranial monitoring and other monitoring tubing, bladder irrigation sets and epidural sets that cannot physically connect with intravenous tubing and any other connectors or with any other medical circuit/system to which it

is not intended to connect (Sheppard, Davis et al. 2004; JCAHO 2006).

- B. Do not depend on the use of color-coding of tubing and labels since this is not an adequate defense against misconnection errors.
- C. Conduct usability tests and risk analysis on all new products that have the possibility of connecting to other tubing, especially if such an inadvertent connection might be fatal or lead to serious patient injury.
- D. Assist healthcare organizations and group purchasing organizations in selecting safer tubing options. Use purchasing power to encourage manufacturers to speed changes in the design process and introduce safer tubing connectors.

3. Recommendations for Healthcare Organizations and Healthcare Practitioners:

- A. Purchase and use for non intravenous functions only, small bore connectors that are incompatible with intravenous tubing whenever possible (Cohen 1993; Association of the Advancement of Medical Instrumentation 1996; Singh 2004; Drake 2005; Eakle, Gallauresi et al. 2005; Paparella 2005; ECRI 2006; Hellwig 2006; Hicks 2006; JCAHO 2006; National Center

for Patient Safety VA 2006; Page 2006; Ryan, Mohammad et al. 2006; Safety 2006; Simmons 2006).

- B. Never use syringes with luer tips (intended for intravenous use) for administering oral medications by the enteral route. Oral (or catheter tip) syringes should be used for administering oral medications and should be available in each patient care area where NG/enteral tube administration may occur. Bedside providers should be trained on a preparation and administration technique that does not involve injection syringes. (ISMP, 2004)

- C. Conduct failure mode and effects analysis (FMEAs) on existing tubing, identify potential risks, educate staff regarding the hazards, and take steps to eliminate the possibility of misconnections. (Reason 2004; Rivera, Velez et al. 2004; Kunac and Reith 2005; JCAHO 2006).

- D. Report all incidents of adverse events regarding misconnections, to the FDA through the MEDWATCH or MEDSUN programs may be required by law).

<http://www.fda.gov/cdrh/yr2000/cdrh/folder/y2kmedwatch.htm>

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/printer.cfm?id=404>

<https://www.medsun.net/about.html>

- E. Report all errors with misconnections to the USP-ISMP Medication Errors Reporting Program, a nationally recognized voluntary medication error reporting program that provides alerts, reviews, web news items, etc. to practitioners, consumers, industry, and the government to help avoid future errors from occurring.

<http://www.usp.org/hqi//patientSafety/mer/>

4. **Special Instructions to Patients, Parents, and Caregivers:**

In all health care and homecare settings, patients, parents, and caregivers should be provided verbal and written information about the incompatibility of tubing, which may be in use.

When in the healthcare setting, patients, parents, and caregivers should also be advised that, should a tubing disconnection occur, NEVER reconnect or insert the tubing into what you think is the appropriate connection. Call the clinical staff immediately to reconnect the lines (Eakle, Gallauresi et al. 2005).

5. **Interim Safety Actions:**

Until the manufacturers develop and supply appropriately designed tubing, healthcare providers, patients, parents, and caregivers are

advised, that while labeling and color coding are not an adequate solution against tubing misconnection errors, the following interventions may be helpful:

- A. Oral syringes should be clearly labeled for the oral route ONLY (Paparella 2004; US Pharmacopeia 2004).
- B. ALL tubing and catheters should be tagged clearly at the proximal and distal ends as well as at each possible connection point (ISMP 2004; Sheppard, Davis et al. 2004).
- C. All policies and procedures should include the function of tracing lines from the proximal to distal ends whenever any connection or reconnection is made. Independent verifications with another licensed healthcare provider are recommended, especially with each tubing reconnection for patients with multiple tubes.

References

Association of the Advancement of Medical Instrumentation (1996). Enteral feeding set adapters and connectors. American National Standard, American National Standards Institute.

Berwick, D. M. (2001). "Not again!" BMJ 322(7281): 247-8.

Cohen, M. R. (1993). "IV administration mix-ups." Hosp Pharm 28(4): 363-4, 367.

Drake, J., Crawford, MW (2005). "Near-miss Injection of an Anesthetic Agent into a Cerebrospinal Fluid External Ventricular Drain: Special Report." Neurosurgery Online 56(5).

Eakle, M., B. A. Gallaresi, et al. (2005). "Luer-lock misconnects can be deadly." Nursing 35(9): 73.

ECRI (2006). Preventing Misconnections of Lines and Cables. Health Devices. 35: 81-95.

FDA (2003). Dangerous Misconnections Between BP Monitors and IV Ports. FDA Patient Safety News. FDA. 2005.

Hellwig, J. P. (2006). "Warning on dangerous tubing misconnections."

AWHONN Lifelines 10(3): 196-202.

Hicks, R., Becker, S (2006). "An Overview of Medication Administration Errors as Reported to MEDMARX, a National Medication Error-reporting Program." Journal of Infusion Nursing 29(1): 20-27.

ISMP (2004). Problems persist with life-threatening tubing misconnections. ISMP Medication Safety Alert! ISMP. 2005.

JCAHO (2006). Tubing misconnections--a persistent and potentially deadly occurrence. Sentinel Event Alert: 1-3.

Kunac, D. L. and D. M. Reith (2005). "Identification of priorities for medication safety in neonatal intensive care." Drug Saf 28(3): 251-61.

National Center for Patient Safety VA (2006). Mix-up (wrong route of administration) of bladder irrigation with intravenous (IV) infusions. Patient Safety Alert. Washington, D. C., VA Central Office. AL06-012: 1-6.

Page, L. (2006). "Finding the Wrong Fit." Materials Management in Healthcare.

- Paparella, S. (2004). "Death by Syringe." Journal of Emergency Nursing 30(6): 552-555.
- Paparella, S. (2005). "Inadvertent attachment of a blood pressure device to a needleless IV "Y-site": surprising, fatal connections." J Emerg Nurs 31(2): 180-2.
- Reason, J. (1990). Human Error. Cambridge, Cambridge University Press.
- Reason, J. (2004). "Beyond the organisational accident: the need for "error wisdom" on the frontline." Qual Saf Health Care 13 Suppl 2: ii28-33.
- Rivera, W., L. I. Velez, et al. (2004). "Unintentional intravenous infusion of Golytely in a 4-year-old girl." Ann Pharmacother 38(7-8): 1183-5.
- Ryan, C. A., I. Mohammad, et al. (2006). "Normal neurologic and developmental outcome after an accidental intravenous infusion of expressed breast milk in a neonate." Pediatrics 117(1): 236-8.
- Sheppard, I., J. Davis, et al. (2004). "Improving patient safety by design - a new spinal/intrathecal injection safety system." Can J Anaesth 53(1): 108-9.

Simmons, D. (2006). Safe Systems, Safe Patients: Common Connectors Pose a Threat to Safe Practice. Texas Board of Nursing Bulletin. 37: 6-7.

Simmons, D., Graves, K (2006). Literature Review -Common Connectors. D. Simmons. Houston, Texas.

Singh, S., Loeb, R.G. (2004). "Fatal Connection: Death Caused by Direct Connection of Oxygen Tubing into a Tracheal Tube Connector." Anesthesia and Analgesia 99(4): 1164-1165.

US Pharmacopeia (2004). "Errors in Obstetrics." USP Patient Safety CAPSLink.

VA National Center for Patient Safety. (2006). Mix-up (wrong route of administration) of bladder irrigation with intravenous (IV) infusions. *Patient Safety Alert, AL06-012*.

Wallace, J., R. Payne, et al. (1972). "Inadvertent intravenous infusion of milk." The Lancet 1972(1): 1264-1266.

Practice/Regulation Partnerships:

The Pathway to Increased Safety in Nursing Practice, Health Care Systems, and Patient Care

In its quest to create and sustain cultures of safety, the Institute of Medicine (IOM) called on the National Council of State Boards of Nursing to develop and design standardized processes to better distinguish human error from willful negligence and intentional misconduct.¹ Though this charge is worthy and is being implemented, boards of nursing also are benefiting from the evidence that is coming forth about human errors and Just Culture.²⁻⁴ Just Culture is a method to promote cultures of safety by regulators, employers, and employees working together to create an open environment where health care risks can be openly discussed. Just Culture seeks to evaluate normal error, at-risk behavior, and reckless behavior to provide appropriate resolution of adverse events.

Mary Beth Thomas, RN, PhD(c),
Debora Simmons, RN, MSN, CCRN, CCNS,
Krisanne Graves, RN, BSN, CPHQ, and
Sharon K. Martin, MED, MT (ASCP), SC

This approach requires new leadership and collaborative initiatives that call on safety science, regulatory authority, and workplace redesign to create new models of patient safety and adequately address the issues surrounding the promotion of patient safety initiatives and the implementation of comprehensive methods for error resolution.

Recent research⁵⁻⁷ and the highly publicized IOM reports have greatly changed the landscape of health care. Predominant themes and findings in these reports indicated a need to examine the causal effects of associated systems factors that contribute to medical errors. The reports suggest that focusing on both human performance and systems factors allow for a better understanding of why errors occur and contribute to the development of more robust interventions, thus increasing safety for both patient and practitioner.^{1,8,9}

Prompted by an understanding of the importance of Just Culture³ in advancing the patient safety movement, a unique partnership was developed in the state of Texas between leaders of the Board of Nurse Examiners (BNE) for the State of Texas and the Institute for Healthcare Excellence at the University of Texas M.D. Anderson Cancer Center to evaluate needed changes in the relationship between practice environments and regulatory agencies to promote a comprehensive approach to error analysis and resolution. This partnership, called the Healthcare Alliance Safety Partnership (HASP), is a BNE pilot program that allows for some exceptions to the mandatory reporting requirements for purposes of research in patient safety (see www.texasbasp.org).^{10,11}

HASP PROGRAM OVERVIEW

HASP is a pilot nonpunitive reporting program that adapts the airline industry's highly successful Aviation Safety Action Partnership (ASAP) to health care. Currently used by major airline carriers, ASAP consists of the review of error reports from a member of the Federal Aviation Administration, a member of the pilot union, and a member

of an airline to understand the prevalence of human performance and systems factors that contributed to the error.¹² The ASAP process has been successful to date because it allows participating organizations to learn about systems factors impacting aviation through reports submitted by pilots. Because ASAP has no jeopardy for the reporting pilot, reports are rich in safety information that might not be learned from traditional aviation reporting systems.

The IOM report *To Err is Human*⁹ recommended using as many innovative safety techniques that are applicable to health care and suggested that a nonpunitive approach to error reporting would increase the understanding of unsafe conditions. Imperatives to study patient safety have escalated since the IOM reports and increased emphasis on safety from accrediting agencies.^{1,8,9} Experts in cognitive psychology, ergonomics, and human factors have supported the examination of human error in health care. James Reason, the noted human factors scientist, discussed the importance of understanding systems factors in health care and the need to develop reporting systems that would capture such factors.⁶ However, pragmatic application of safety science within the existing system of regulating health care has not been demonstrated.

Clearly an alliance of significant stakeholders has been needed to explore the efficacy of a nonpunitive system that meets the obligations of the regulatory duties to the consumer and informs the health care system of important safety issues and interventions, thus protecting the public. Consistent with the BNE mission¹³ and the systems focus of recent IOM reports, HASP seeks to provide protection to the public while also documenting the role of systems and human performance factors in error occurrence.¹¹ The HASP program does not replace any existing quality improvement or assurance program at a given institution; it is an added program that falls within the protection of peer review, recognizes the effects of human and systems factors, contributes to the development of just cultures for practitioners and providers, and, ultimately, enhances the safety of patients.

Three hospitals participated in the initial HASP program: University of Texas M.D. Anderson Cancer Center, St Luke's Episcopal Hospital, and Texas Children's Hospital. Each participating institution has business agreements with HASP for confidentiality and has passed an IRB review. Each participating institution provides participants for the event review committee, allows full access to the fa-

cility and records around an event, and access to any quality or risk management information, such as root cause analysis. Each institution also agrees to provide any necessary remediation support to the nurse involved.

BNE BACKGROUND

The BNE is the state agency that regulates the licensure, education, and practice of over 278,000 professional and vocational nurses in Texas. The focus on the individual nurse's accountability in patient safety has long been the purview of regulatory boards such as the Texas BNE. However, with emerging evidence from patient safety research that multiple factors may contribute to errors in health care, the leaders at the Texas BNE began exploring a new methodology to more thoroughly evaluate reported nursing practice errors. Research studies were providing evidence that system factors, as well as the health care team, the patient, and individual nursing competency factors contributed to errors in health care.^{1,6,7,14-16} These studies suggested that an in-depth review of all of these factors is required to thoroughly evaluate errors in health care.

Because the BNE, as a nursing regulatory agency, did not have access to detailed information about system issues within health care organizations, new models were needed to facilitate partnerships between the BNE, safety experts, and health care organizations to review systems issues that impacted nursing practice. For the BNE to explore new models of nursing regulation, the Texas Legislature needed to amend the Nursing Practice Act. Consequently, during the 78th Texas Legislature in 2003, Senate Bill 718 was

introduced and passed. It allowed the BNE to conduct pilot studies that promoted research and review of innovative methodologies in the regulation of nurses. The pilot programs allowed models that promoted practice environments where fear associated with making a health care error was decreased.¹⁷ By implementing "just cultures" that did not blame or shame those who make errors, it was hypothesized that practitioners participating in reporting systems would increase, thereby promoting a better analysis and resolution of error events. The pilot programs facilitated the BNE's ability to grant some exceptions to the mandatory reporting requirements for nursing practice errors, provided the pilot study ensured an equivalent method for assuring patient safety.¹¹

In December 2003, the BNE released a request for proposals to health care organizations that met the criteria

Clearly an alliance of significant stakeholders has been needed to explore the efficacy of a nonpunitive system that meets the obligations of the regulatory duties to the consumer and informs the health care system of important safety issues and interventions, thus protecting the public.

outlined in the board's rules.¹⁸ In April 2004, University of Texas M.D. Anderson Cancer Center proposed a pilot that was reviewed by an expert panel and ultimately received approval to implement the HASP.

THE HASP PROGRAM

The HASP program evaluation method consists of proven techniques derived from high-risk industries. There are three phases of a HASP review: the discovery, the analysis, and the resolution. Each step is documented by the HASP team and archived under a unique tracking number. All the evidence and supporting documentation are collected into one casebook used in the review by the ERC.

Phase 1: Discovery

The first stage of the HASP process includes the voluntary submission of an event report from a registered nurse. The report may be obtained from one of three sources:

- Self-report from a nurse
- Referral from the nurse's institutional peer review committee
- Referral from the BNE

Each report requires the participant to file an incident report under his facility's current process to meet risk and required reporting (Texas Department State Health Services, Federal Drug Administration, etc, as appropriate). If an incident report is not submitted simultaneously with a self-report to HASP, the self-report is excluded from the program. Since the HASP process does not take the place of internal quality processes, it is mandatory that an incident report is filed to initiate the internal quality and risk processes of the institution or delay appropriate safety measures by the institution.

On receiving a report—and during the discovery phase—the report will be screened for exclusion criteria. Exclusion criteria for the HASP includes events that:

- Contributed to a patient death or serious injury
- Are intentional
- Involve an intentional disregard for safety
- Involve a knowing violation of safe operating principles
- Involve criminal activity
- Involve substance abuse including mind-altering substance or physical/medical conditions that impaired or influenced the nurse's actions
- Involve a nurse with any history of substance abuse regardless of whether the BNE knows the history and whether rehabilitation has occurred. Nurses with a past history of abuse that have completed the TPAPIN program or an alternative program at the discretion of

Since the HASP process does not take the place of internal quality processes, it is mandatory that an incident report is filed to initiate the internal quality and risk processes of the institution or delay appropriate safety measures by the institution.

the BNE may petition the BNE for a waiver of this exclusion to participate in the HASP

- Involve intentional falsification
- Are reportable under Texas occupation code 301.1606 and 22 T.A.C. 226.4(b)(c)

In addition, immediately after receipt of a report, a preliminary notification is made to the BNE to verify the nurse's license, check for past reportable conduct to the BNE, summarize the report in brief, and to alert the BNE that the report has been filed. After screening by HASP nurse analysts, the report is de-identified, receives a unique tracking number, and enters the HASP process.

After the nurse files an initial report of the event, he is interviewed with scripted questions. The resulting information guides the members of the HASP staff who review all relevant records, policies, and procedures. Interviews with directly and indirectly involved parties are conducted in the same structured interview format. Comments are recorded, with identifying information of interviewees and patients removed.

Assessments of the environment, workplace, and technology issues are performed, as well as observations of clinical practice. Medication data, specifically pharmacy and automated medication delivery service records, are searched, as necessary. Incident and root cause reports generated by the facility are reviewed and added to the evidence. The resulting information, along with other gathered evidence, is de-identified and incorporated into the ongoing creation of a Cause Map.¹⁹ A preliminary issues list is begun and a case book is compiled and sent to members of the ERC approximately 1 week prior to the scheduled review meeting.

Phase 2: The Analysis Phase

HASP nurse analysts identify and cluster causal factors of the event using the cause map and then categorize these causal factors using a modified version of the Eindhoven Classification model,⁵ which classifies errors based on systems and human performance factors. Consistent with this model, HASP analysts describe systems factors as technical, organizational, or patient-related, and human performance factors are classified as knowledge-based, rule-based, and skill-based behaviors.

Once an analysis is implemented, a call is made to the ERC, which consists of six people who are members of the other participating organizations. The voting members are a nursing officer, who provides an administrative perspective; a BNE member, who represents board and licensure requirements; and a chair of a peer review committee who

is familiar with the peer review process. These members are responsible for reviewing and analyzing reports submitted, determining whether submitted reports qualify for inclusion in HASP, identifying system and human performance factors, and proposing interventions for the identified factors. These three members have voting privileges, which means that after reviewing all available information about a nurse's error, the members are responsible for reaching consensus or voluntary agreement about the actions taken to protect the public. The additional three members of the ERC, who are nonvoting members, provide technical support and include a nurse analyst with system and human factors expertise, a facilitator, and an administrative assistant.

All materials are presented as anonymously as possible and confidentially at the event review committee (ERC) meeting. During the meeting, an action plan is created that includes prescriptive recommendations for the nurse and the participating institution. Timelines for completion of action items, including any interim reports, are noted as appropriate and followed up in the Resolution phase. The Just Culture algorithm² and James Reason's systems analysis tools¹⁶ are applied to consider individual versus systems responsibility.

True to the theory of systems accountability, each individual and component involved in an event are considered to be accountable and part of the resolution. Therefore, each action plan addresses multiple layers of the event and offers interventions on organizational, individual, and technical factors.

Phase 3: The Resolution

The institution and the nurse provide timely responses to the HASP analysts regarding prescriptive recommendations until resolution is complete and approved by the ERC. HASP then presents a final report to the BNE in quarterly general meetings and an annual review. A board representative is always a member of the ERC to make decisions about the action plans. Congruent with the board's mandated responsibility to the public, any needed remediation activities for the nurse to promote competency are outlined and closely monitored.

An exciting component of the pilot is that by having a partnership with the nurse's employer, new methods for promoting competency are being developed. For instance, one employer assigned a clinical nurse specialist to develop and oversee the completion of a detailed competency-based educational plan for a nurse. The specificity of the plan and the concurrent oversight and evaluation by an expert nurse in the nurse's work setting lends itself to the identification and resolution of individual competency requirements not currently available to the board.

CONCLUSION

The HASP model offers a level of transparency that allows for a natural partnership to explore and improve the practice environment from multiple viewpoints. Significant lessons have been learned by regulators, nurse

leaders, and caregivers that are resulting in a safer environment in which to practice nursing. As a demonstration project, the process has shown considerable results. The HASP process is thorough, uses advanced investigation techniques and theories, and surpasses the usual root cause analysis. The process requires significant time, expertise, and methods to implement effectively.

The current HASP model also highlights a more urgent level of issues within nursing practice: how do we address advanced knowledge in safety, systems analysis, and human factors within a responsible professional model of nursing practice? Currently barriers exist between the practice environment and the ability of the BNE to gain systems information regarding the error event, thereby limiting an analysis of the influence of the system on the nurse's practice. Traditional concerns regarding legal and regulatory compliance, attribution of events solely to the individual, and tension between industry and regulation have prevented full discovery of these issues.

The need for a program that documents adverse medical errors and addresses human performance *and* systems factors is critical, especially in an industry that acknowledges 98,000 deaths per year. Unfortunately, although human factors science has been cited in all of the IOM reports as essential to creating a safer health care system, current working knowledge of human factors in the industry is limited. Since workplace redesign is essential to creating a safer practice environment and depends on an in-depth analysis of the systems influencing nursing practice, pilot programs that incorporate such knowledge are essential to moving safety forward. The current program, HASP, has been developed to answer this critical call.

References

1. Page A, Institute of Medicine, ed. Keeping patients safe: transforming the work environment of nurses. Washington DC: The National Academies Press; 2004.
2. Outcome Engineering. The Just Culture community. Available: <http://www.justculture.org/>. Accessed February 19, 2007.
3. Marx D. Patient safety and the "just culture": a primer for health care executives. New York: Columbia University; 2001.
4. The Just Culture Community. In recognition of a growing community. Available: <http://www.justculture.org>. Accessed April 3, 2007.
5. van der Schaaf TW. Developing and using cognitive task typologies. *Ergonomics*. 1993;36(11):1439-44.
6. Reason J. Human Error. Cambridge, MA: Cambridge University Press; 1990.
7. Helmreich RL. On error management: lessons from aviation. *Br Med J*. 2000;320(7237):781-85.
8. Kohn LT, Corrigan J, Donaldson MS, Institute of Medicine, ed. Crossing the quality chasm: a new health system for the 21st century. Washington DC: The National Academies Press; 2001.
9. Corrigan J, Cohen LT, Davidson MS, Institute of Medicine, eds. To err is human: building a safer health system. 1st ed. Washington DC: The National Academies Press; 2000.
10. The Healthcare Alliance Safety Partnership. Available: www.TexasHASP.org. Accessed February 19, 2007.
11. Texas Board of Nurse Examiners. Board adopts new 22 TAC § 226 concerning Patient Safety Pilot Programs on Nurse Reporting Systems and develops application for proposal of Patient Safety Pilot Program. Available: <http://www.bne.state.tx.us/about/news123103.html>. Accessed February 19, 2007.

12. U.S. Department of Transportation, Federal Aviation Administration. Aviation safety action program. Available: http://www.faa.gov/safety/programs_initiatives/aircraft_aviation/asap/. Accessed February 20, 2007.
13. Texas Board of Nurse Examiners. Compact with Texans. 2007. Available: <http://www.bne.state.tx.us/compact.html>. Accessed February 20, 2007.
14. Benner P, Sheets V, Uris P, Malloch K, Schwed K, Jamison D. Individual, practice, and system causes of errors in nursing: a taxonomy. *J Nurs Admin*. 2002;32(10):509-23.
15. Green A, Wieck KL, Willmann J, Fowler C, Douglas W, Jordan C. Addressing the Texas nursing shortage: A legislative approach to bolstering the nursing education pipeline. *Policy Politics Nursing Practice*. 2004;5(1):41-8.
16. Reason JT. *Managing the risks of organizational accidents*. Burlington, VT: Ashgate Publishing Company; 1997.
17. Senate Research Center. Highlights of the 78th Texas legislature regular session: A summary of the most significant legislation. July 2003. Available: <http://www.senate.state.tx.us/src/pdf/78thHighlights.pdf>. Accessed February 20, 2007.
18. Texas Board of Nurse Examiners. Request for proposal for board of nurse examiner's patient safety pilot program. Accessed February 20, 2007.
19. ThinkReliability. The cause mapping process. Available: <http://www.thinkreliability.com/causemapping.htm>. Accessed February 19, 2007.

Mary Beth Thomas, RN, PhD(c), is the director of nursing practice and education for the Board of Nurse Examiners for the State of Texas. She can be reached at marybeth.thomas@bne.state.tx.us. Debora Simmons, RN, MSN, CCRN, CCNS, is the associate director of the Institute for Healthcare Excellence at The University of Texas M.D. Anderson Cancer Center, where Krisanne Graves, RN, BSN, CPHQ, is a clinical quality improvement analyst. Sharon K. Martin, MED, MT (ASCP) SC, is the vice president of quality management at The University of Texas M.D. Anderson Cancer Center.

Acknowledgments

HASP (www.texashasp.org) is a quality improvement/program evaluation project funded by the Institute for Healthcare Excellence at the University of Texas M.D. Anderson Cancer Center and the University of Texas Center of Excellence for Patient Safety Research and Practice funded by the Agency for Healthcare Research and Quality (1PO1HS1154401).

The authors wish to thank the following contributors for their dedication and support to this project: the Texas Hospital Association, the Texas Nurses Association, the Institute for Safety Medication Practices, Consumers Advancing Patient Safety, Captain Bruce Tesmer, Mark Galley, David Marx, and the Agency for Healthcare Research and Quality. The authors would like to specifically acknowledge the contributions of Susie Distefano, Texas Children's Hospital; Rosemary Luquire, Baylor Health Care System; and Barbara Summers, M.D., University of Texas Anderson Cancer Center.

1541-4612/2007/ \$ See front matter
Copyright 2007 by Mosby Inc. All rights reserved.
doi:10.1016/j.mnl.2007.03.011

The White Paper

Continued from page 29

units to the board of directors. The unit white paper offers a realistic and comprehensive overview of the unit, the team, and the outcomes and the support provided to improve areas of concern. This brief, content-rich document also is a reminder to current staff of their accomplishments and quality health care services.

CONCLUSION

Most individuals want to paint a rosy picture of their facility, unit, or team. The challenge is to create an accurate picture that is neither overly positive nor unnecessarily negative. The goal is to recognize both accomplishments and opportunities for improvement and the strategies to improve outcomes. An excellent white paper can be researched and written in around 6-8 hours, but the time frame depends on the availability of the key information, the skill level of the writer, and the complexity of the unit. Some information will be static—the number of beds a hospital is licensed for or the square footage of a patient room, for instance. Some information will be dynamic, such as vacancy rates and employee turnover. The more changes that have occurred over the past year, the longer the white paper update will take. Unless there have been a lot of changes on your unit during the past year, updating can be done in about 1 hour.

Reference

1. Porter-O'Grady T, Malloch K. *Managing for success in health-care*. St. Louis: Elsevier; 2007.

Sherrie Gish, RN, BSN, CCRN, is a nursing coordinator with the Information Systems Department, Trover Health System, Madisonville, Kentucky. Stacey Beaven, RN, is the vice president of patient care services at Regional Medical Center in Madisonville, Kentucky. Kathy Malloch, PhD, MBA, RN, FAAN, is a health care consultant in Glendale, Arizona. She can be reached at km@kathymalloch.com.

1541-4612/2007/ \$ See front matter
Copyright 2007 by Mosby Inc. All rights reserved.
doi:10.1016/j.mnl.2007.03.005