MEDICATION SAFETY BOOTCAMP

Midwest Medication Safety Symposium

102: Applying Basics

Heather Dossett, PharmD, MHA, BCPS, CPHQ
Medication Safety and
Pharmacy Education Pharmacist
Ascension – St. Vincent's Indianapolis
Heather.dossett@ascension.org

Jessalynn Henney, PharmD
Network Medication
Safety Director
Community Health Network
jkhenney@ecommunity.com

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Phase	Focus	Response to Error/Activities	People Viewed
Pathological	Cheaper and faster targets	Blame/denial that adverse outcome errors exist	As a problem and causes of accidents/losses
Reactive	Prevent adverse publicity and ranking	React to adverse outcomes by looking for solution to only problems identified in adverse outcome errors	As a problem and causes of accidents/losses
Calculative	Systems to manage hazards as a result of regulatory pressures	Based on current regulations/accreditation agencies	As a factor to control
Proactive	Systems to manage hazards; Staff and management begin to believe there is value to safety systems outside of regulatory pressures	Attempt to identify and eliminate latent failures prior to events; Incorporate frontline workers in evaluations	As an integral part of the system
Generative	Safety behavior fully integrated into ALL organization activities; Value systems associated with safety	Strives for resilience – recognizing systems will never be error free; Focus in on capture and mitigation of errors	As solutions and agents of successful recovery

Phase	Daily Activities
Pathological	Blame the person involved with event; Focused on being “caught”; No transparency; Frontline workers reluctant to share information about true practice patterns (making evaluation of true process impossible); Safety is seen as a waste of time and money; Lack of accountability; Breaches/Shortcuts are the norm; Mentality of “Who cares, as long as we’re not caught”, “We have accidents – it’s a dangerous business” or “Fire the idiot who had the accident”
Reactive	Safety recognized as important; Incorporated every time an accident occurs; Focus seen once the event has occurred; Managing events in order to keep our licenses to operate; All actions after event are driven by fear of headlines and bad publicity; Safety improvements are the result of adverse outcome within the organization and those occurring from outside are viewed as “never happened here – if it aint broke/don’t fix it”; No ability to priorities safety actions; Quality/Risk team become “fire fighter” and operational activities do not see safety as a priority
Calculative	Believe systems are in place to manage all hazards; Managed on the basis of procedures and documentation; Uses trail indicators; Q/R team focused on regulations and standards only; Error evaluation still hindered by trust/input form those working the system; Chasing statistics; Lots and lots of audits; Safety is verbally a priority but often takes a step back or not prioritized
Proactive	Anticipating and preventing problems before they occur; People feel comfort speaking up; Managed with workforce involvement and lead indicators; Q/R team about to evaluate errors and systems more readily, with input from frontline workers who speak freely regarding procedures; Q/R team able to receive support from management to implement safety systems even if they are not required by regulation or standard; Q/R team provides support for management in the understanding of human error theory/promote Just Culture; Lessons are learned, new ideas are welcomed; Procedures are “owned” by the workforce and feedback from frontline workers seen as welcoming and encouraging
Generative	Constantly vigilant and transparent demonstrating a preoccupation to failure; Safety is how business is ALWAYS completed; Everyone is involved in making this a safe place; No compromise on safety; Feedback/Input from frontline is expected and seen as essential; Potential for errors brought to Q/R team from the front lines, which has developed an awareness and level of trust; Q/R team involved in process design to anticipate, capture and, mitigation potential errors; Processes are evaluated for error risks prior to implementation; Q/R team provides support for management in the understanding of human error theory/promote Just Culture

Determining Culpability[13]

Reason's Culpability Decision Tree: Objective method for determining culpability

- If multiple unsafe acts contributed to the event, the algorithm should be applied to each one separately

Deliberate Harm	Identifies rare cases where harm was intended
Incapacity	Identifies contribution of ill health or substance abuse
Foresight	Identifies compliance with safe working practices
Substitution	Identifies peers from the same domain/experience may act in same scenario
Repetitive Errors	Identifies previous committed unsafe actions; Does not presume culpability, but recognizes additional training/counseling required

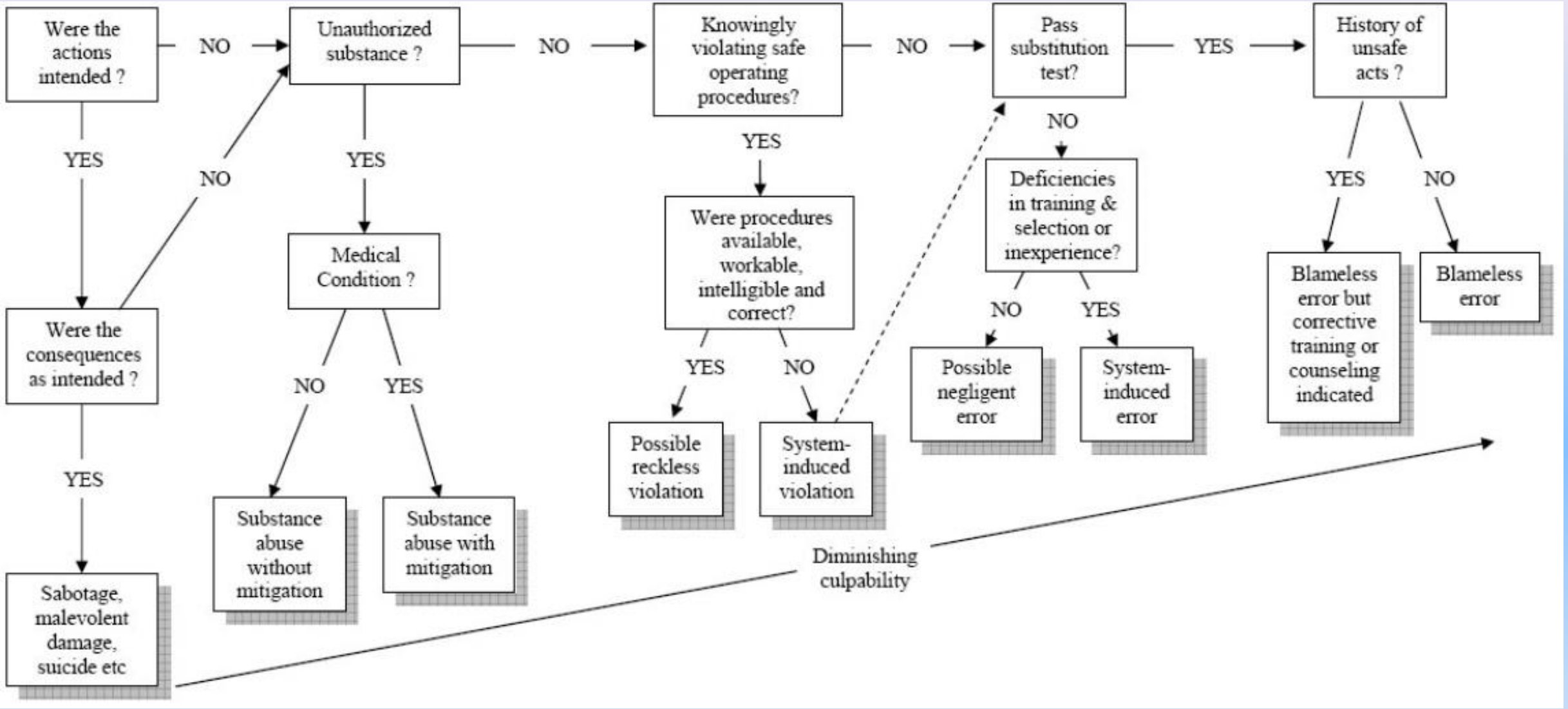
Determining Culpability[13]

Foresight Test: Identifies compliance with safe working practices

- Did the individual knowingly engage in behavior that an average operator would recognize as being likely to increase the probability of making a safety-critical error?
- Did the system promote the violation or discourage the violation; Had the behavior become automatic or part of the 'local working practices?

Substitution Test: Identifies how a peer from the same activity domain/level of experience might behave in same scenario; Provides further clarity to foresight test

- Could a different person (well motivated, equally competent, and comparably qualified) have made the same error under similar circumstances (determined by their peers)?
- Were there system-induced reasons (such as insufficient training, selection, experience)?


Were the actions intended ?
NO
Unauthorized substance ?
NO
Knowingly violating safe operating procedures?
NO
Pass substitution test?
YES
History of unsafe acts ?
YES
NO
YES
NO
YES
NO
YES
Were the consequences as intended ?
Medical Condition ?
Were procedures available, workable, intelligible and correct?
Deficiencies in training & selection or inexperience?
YES
NO
YES
NO
YES
NO
YES
NO
Sabotage, malevolent damage, suicide etc
Substance abuse without mitigation
Substance abuse with mitigation
Possible reckless violation
System-induced violation
Possible negligent error
System-induced error
Blameless error but corrective training or counseling indicated
Blameless error
Diminishing culpability

Frequency Asked Questions

Handling repetitive errors

Two different sources for repetitive errors:

1) **Process**: Task performed is very prone to error
   - Inform process designer/owner of the error rate
2) **Person**: Recent traumatic events or significant distractions in life can cause people to lose focus on the details of their work
   - After education completed, it may be an appropriate to remove individual from current task or supplement the task to aid in controlling the error rate

Lack of qualifications

May reveal person was not fully trained and qualified in the job; Demonstrates system failure by not ensuring appropriate qualifications were obtained

Detecting Medication Incidents[13,17,18]

	ADE Trigger Tool	Chart Review	Direct Observation
Definition	Use of "triggers", or clues, to identify possible adverse events in the medical record	Collect information through various patient cases to retrieve particular data for discovery	Any intervention that a caregiver has initiated with a patient that has improved the quality of treatment/ patient care
Pros	Allows detection of an actual ME; Automatic detection	Retroactive, data available, commonly used standardized criteria; Captures more than incident reporting	Accurate; Capture active errors
Cons	Limited detection to other ME; Only identifies events associated with trigger used (Important note: If a trigger is identified in a record, the “positive trigger” indicates only the presence of a trigger, not necessarily an AE; Requires reviewer to investigate chart to ensure event actually occurred)	Difficult, time-consuming; Labor intensive requiring time for planning criteria and gathering information	Time-consuming; Training difficult
Feasibility	Computerized documentation system needed; Detection bias depending on triggers used (only certain ADEs are detected)	Quality of information gather is dependent on reviewer training and appropriate chart documentation	Good quality data about administration errors; Training
Example	IHI trigger tool (Naloxone, Benadryl, Protamine, Vitamin K, INR value, blood glucose or dextrose for hypoglycemia)	Medication Utilization Evaluations	Process shadowing, IV pump programming

Detecting Medication Incidents[13,17,18]

	Claims and Litigation	Intervention Reporting	Incident Reporting
Definition	Disputes that arise between the organization and third parities (e.g., patients, insurance companies, family, other facilities)	Any intervention that a caregiver has initiated with a patient that has improved the quality of treatment/ patient care	Any intervention that a caregiver has initiated with a patient that has improved the quality of treatment/ patient care
Pros	Local data; Captures latent failures	Detects actual and potential MEs; Pharmacy interventions provide focus to improving prescribing	Variety of sources/personnel; Structured/simple form; Captures active and latent failures; Promotes COS
Cons	Litigation based; Legal implications	Not all interventions are usually recorded, time consuming; Caregiver may not always have access to patients or clinical notes	Not all interventions are usually recorded, time consuming; Caregiver may not always have access to patients or clinical notes
Feasibility	Adverse events detected; Training and time	Time needed to create documentation record	Time needed to create documentation record
Example	Top medications affiliated with patient complaints	Clarifying unclear instructions from the prescriber; Intervening on potentially fatal drug interactions; Responding to clinical decision support alerts	Clarifying unclear instructions from the prescriber; Intervening on potentially fatal drug interactions; Responding to clinical decision support alerts

Table 1

Detection methods used to investigate medication errors and adverse events

Method	Advantages	Limitations	Efficacy	Costs
Chart review	Retroactive; disposable data; commonly used; standardized criteria; poor at capturing latent failures	Difficult; time-consuming; labour intensive; planning criteria/indicators necessary	Gold standard to detect adverse events; less medication errors detected; reviews, papers	Reviewers' training and time (nurses, pharmacists, students, physicians)
Claims data	Local data; captures latent failures	Litigation based; legal implications	Adverse events detected	Reviewers' training and time
Incident reporting (sentinel events)	High-quality data; root cause analysis due; captures active and latent failures	Only detects severe, unexplained events/deaths; underestimated rates (blame and fear of punishment)	Reports and alerts; detects adverse events; less medication errors detected	Root cause analysis
Voluntary reporting	Variety of sources; structured simple form; Captures active and latent failures; promotes a culture of safety	Variable quality; underreporting; blame culture; problem of data integration	Reports and alerts; feedback and corrective actions; medication errors detected	Time for feedback and analysis
Administrative data examination	Disposable and retroactive data; easy; standardized	Absence of clinical data	Statistical	Routine evaluation
Computer monitoring	Multidata source integration; real time; adverse events prevention	Inserted errors; poor software; poor triggers; undetermined future risks	Prescribing faults, prescription errors, and dispensing errors (CPOE)	High costs for software and implementation
Direct care observation	Accurate; captures active errors	Time-consuming; training difficult;	Good quality data about administration errors	Nurse training
Patient monitoring	Data from outpatients; wide impact	Not standardized tools (interviews, questionnaires, focus groups, etc)	Future development	Nurse training

Medication Triggers[19]

Clostridium difficile Positive Stool

A positive *C. difficile* assay is an adverse event if a history of antibiotic use is present.

M1

Partial Thromboplastin Time (PTT) Greater than 100 Seconds

Look for evidence of bleeding to determine if an adverse event has occurred. Elevated PTT in itself is not an adverse event—there must be manifestation such as bleeding, drop in Hg or Hct, or bruising.

M2

International Normalized Ratio (INR) Greater than 6

Look for evidence of bleeding to determine if an adverse event has occurred. An elevated INR in itself is not an AE.

M3

Glucose Less than 50 mg/dL

Review for symptoms such as lethargy and shakiness documented in nursing notes, and the administration of glucose, orange juice, or other intervention. If symptoms are present, look for associated use of insulin or oral hypoglycemics.

M4

Rising BUN or Serum Creatinine Two Times (2x) over Baseline

Review laboratory records for rising levels of either BUN or serum creatinine. If a change of 2X greater than baseline levels is found, review medication administration records for medications known to cause renal toxicity.

M5

Vitamin K Administration

If Vitamin K was used as a response to a prolonged INR, review the record for evidence of bleeding (such as GI bleed or hemorrhagic stroke), excessive bruising, or large hematomas.

M6

Diphenhydramine (Benadryl®) Administration

Diphenhydramine is frequently used for allergic reactions to drugs but can also be ordered as a sleep aid, a pre-op/pre-procedure medication, or for seasonal allergies. If the drug has been administered, review the record to determine if it was ordered for symptoms of an allergic reaction to a drug or blood transfusion.

M7

Romazicon (Flumazenil®) Administration

Romazicon reverses the effect of benzodiazepine drugs. Determine why the drug was used. Examples of adverse events are severe hypotension or marked, prolonged sedation.

M8

Naloxone (Narcan®) Administration

Naloxone is a powerful narcotic antagonist. Usage likely represents an AE except in cases of drug abuse or self-inflicted overdose.

M9

Anti-Emetic Administration

Nausea and vomiting (N/V) commonly result from other drugs in surgical and non-surgical settings, which are treated with anti-emetics. N/V interfering with feeding, post-operative recovery, or delayed discharge suggests an AE. Anti-emetics used successfully for 1 or 2 episodes suggest no AE. Reviewer judgment is needed to determine whether harm occurred.

M10

Over-Sedation/Hypotension

Review the physician progress, nursing, or multidisciplinary notes for evidence of over-sedation and lethargy. Review vital signs records or graphics for episodes of hypotension related to the administration of a sedative, analgesic, or muscle relaxant. Intentional overdose is not considered an AE.

M11

Abrupt Medication Stop

Although the discontinuation of medications is a common finding in the record, abruptly stopping medications is a trigger requiring further investigation for cause. A sudden change in patient condition requiring adjustment of medications is often related to an AE.

M12

Non-Medication Triggers[19]

Cares (n = 14)						
C1	**C2**	**C3**	**C4**	**C5**	**C6**	**C7**
Transfusion of Blood or Use of Blood Products	Code, Cardiac or Pulmonary Arrest, or Rapid Response Team Activation	Acute Dialysis	Positive Blood Culture	X-Ray or Doppler Studies for Emboli or Deep Vein Thrombosis	Decrease in Hemoglobin or Hematocrit of 25% or Greater	Patient Fall
C8	**C9**	**C10**	**C11**	**C12**	**C13**	**C14**
Pressure Ulcers	Readmission within 30 Days	Restraint Use	Healthcare-Associated Infections	In-Hospital Stroke	Transfer to Higher Level of Care	Any Procedure Complication

Surgical (n = 11)		Intensive Care (n = 4)		Perinatal (n = 8)		Emergency Department (n = 2)	
S8	Intra-Operative Administration of Epinephrine, Norepinephrine, Naloxone, or Romazicon	**I1**	Pneumonia Onset	**P3**	Platelet Count Less than 50,000	**E1**	Readmission to the ED within 48 Hours
S9	Post-Operative Increase in Troponin Levels Greater than 1.5 Nanogram/mL	**I4**	Intubation/Reintubation	**P6**	Administration of Oxytocic Agents (such as oxytocin, methylergonovine, and 15-methyl-prostaglandin in the post-partum period)	**E2**	Time in ED Greater than 6 Hours

HYPOGLYCEMIC EVENT ANALYSIS TOOL *(HEAT)*

Not Part of Medical Record

Event Date and Time_____ BG Level_____ Investigating RN_____

Calorie Intake at Time of Event: ☐ NPO ☐ PO ☐ Tube Feeding ☐ IV ☐ TPN with Insulin

- ☐ Patient's dietary status changed within 24 hours of event
- ☐ Status change was discussed with the provider
- ☐ Patient ate since last meal

Amount of meal, prior to event, that was consumed ____% ☐ Unknown

Comments for Reviewer:

Drug Administration

- ☐ Insulin order changed within 24 hours of event

Time between insulin administration and the meal nearest to event:

_____ minutes before meal or _____ minutes after meal

Place Patient Label Here

Name
DOB
ID#
Room #

RECOMMENDATION for an intervention to prevent a similar future event:

Prescriber Notification (Complete Shaded Section at Time of Event)

- ☐ Documentation of prescriber notification of glucose trend before event (severe hypoglycemia)
- ☐ Documentation of prescriber notification of severe hypoglycemia (blood glucose < 40) at time of event

Causative Factors - choose a maximum of 3 of the most important factors (definitions on back)

Prescribing Related (Dosing not in alignment with patient's medical condition prior to event)

- ☐ Home regimen continued as inpatient
- ☐ Event while treating elevated potassium
- ☐ Basal heavy regimen
- ☐ High dose sliding scale insulin
- ☐ Sulfonylurea-related hypoglycemia
- ☐ Inpatient regimen not adjusted due to:
  - ☐ Glucose trend not recognized
  - ☐ Significant reduction in steroid dose
  - ☐ Decreased nutritional intake
- ☐ Event related to outpatient or emergency department drug administration

Process Related

- ☐ Insulin administration and food intake not synchronized
- ☐ POC glucose reading not linked to insulin administration
- ☐ POC glucose reading not synchronized with food intake

Administration Related

- ☐ Wrong drug, dose, route, patient, or time
- ☐ Insulin stacking

Monitoring Related

- ☐ Insufficient glucose monitoring

Invalid Alert

- ☐ Erroneous lab value

Contributing and Other Factors

- ☐ Diabetic agents received prior to admission

Diabetes Type:

- ☐ Type I
- ☐ Type II
- ☐ Gestational

Home Diabetic Regimen

- ☐ Insulin
- ☐ Oral agent

Was the MD notified of the findings?

- ☐ Yes
- ☐ Not available for discussion

Was the RN notified of the findings?

- ☐ Yes
- ☐ Not available for discussion

Definition for Causative Factors:

1. **Basal Heavy Regimen** – Greater than 0.5 Units/KG of basal insulin without any or minimal mealtime insulin OR > 0.3 Units/Kg basal insulin without any or minimal mealtime insulin in patients with renal impairment (CrCl<30 mL/min).
2. **High Dose SSI** –Event due to "high" dose SSI being ordered.
3. **Insulin Stacking** – Rapid acting insulin administered and repeated within 3 hours (or less) OR Regular insulin administered and repeated within 4 hours (or less) resulting in hypoglycemia.
4. **Sulfonylurea-related hypoglycemia** – Sulfonylurea primary cause of or contributed to the event. *Mark especially if sulfonylurea alert fired.*
5. **Event Related to Outpatient or Emergency Department drug administration**- Medication given in ED or prior to admission and is the proximate cause of inpatient hypoglycemia.
6. **Insufficient glucose monitoring**- Improper time gap of ordering or drawing of glucose levels.
7. **Glucose Trend not recognized**- BG level <90 and/or significant change in BG levels where current insulin regimen poses a patient safety risk.
8. **Significant change reduction in steroid dose**- Steroid tapered or discontinued without change in insulin requirements.
9. **Decreased nutritional intake**- Event secondary to lack of insulin adjustment in patient with poor food intake, other enteral nutrition, or NPO.

TIMELINE: Start with event and complete for up to 24 hrs. prior to event

Date/time	POC /Venous	Scheduled Time	Admin Time	Agent	Dose ordered	Dose Admin	Correctional?	Notes
	(Event)						Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	

Optional Narrative:

BJC HealthCare 2014
St. Louis, Missouri