Example of a Health Care Failure Mode and Effects Analysis for IV Patient Controlled Analgesia (PCA)

Processes & Subprocesses	Failure Modes (what might happen)	Causes (why it happens)	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
Prescribing							
Assess patient	Inaccurate pain assessment	Cultural influences; patient unable to articulate	Poor pain control	2	4	8	Standard scale to help assess pain; training on cultural influences
Choose analgesic/mode of delivery	Wrong analgesic selected	Clinical situation not considered (age, renal function, allergies, etc.); tolerance to opiates not considered; standard PCA protocols not followed (or not available); concomitant use of other analgesics not considered; drug shortage; knowledge deficit; improper selection of patients appropriate for PCA	Improper dosing; improper drug; allergic response; improper use of substitute drug	4	3	12	CPOE with decision support, clinical pharmacy program; standard PCA protocol with education on use; point-of-use access to drug information; feedback mechanism on drug shortages with information on substitute drugs available; selection criteria for PCA patients
Prescribe analgesic	Wrong dose (loading, PCA, constant, lock-out), route, frequency	Knowledge deficit; mental slip; wrong selection from list; information about drug not available	Overdose; under-dose; ADR	4	3	12	CPOE with decision support; clinical pharmacy program; standard PCA protocols
	Proper patient monitoring not ordered	Knowledge deficit; mental slip	Failure to detect problems early to prevent harm	4	3	12	Standard PCA order sets with monitoring guidelines
	Prescribed on wrong patient	Similar patient names; patient identifier not clear; name does not appear on screen when ordering medications	Wrong patient receives inappropriate drug and dose; ADR; allergic response	3	3	9	Match therapy to patient condition; alerts for look-alike patient names; visible demographic information on order form or screen
	No order received	Unable to reach covering physician	Poor pain control	2	2	4	Proper physician coverage and communication channels

Processes & Subprocesses	Failure Modes	Causes	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
Dispensing							
Send order to pharmacy	Order not received/processed in pharmacy	Unaware of order on unit; medication used from floor stock, so order not sent; order entered onto wrong form or screen; verbal orders not documented	Drug therapy omitted; Overdose; under-dose; ADR; allergic response if wrong drug used	3	3	9	Flagging system for new orders; policy to send all orders to pharmacy; physician review of new orders with unit staff; shift chart checks; standard verbal order receipt/ documentation process
	Delay in receiving/processing order	Order not flagged; inefficient process for sending orders to pharmacy; order not seen/misplaced after reaching pharmacy	Delay in dispensing drug; use of floor stock before pharmacy order screening; delay of drug therapy	3	4	12	As above; standard, efficient process for pharmacy order receipt; timely review and triaging of orders received in pharmacy
Enter order into computer	Order misunderstood	Illegible order; use of abbreviations, trailing zeroes, naked decimal doses; verbal orders; look-alike drug names; order copy unclear	Overdose, under-dose; allergic response; ADR; delay in therapy; poor pain control	3	4	12	CPOE; preprinted orders; pro-hibit dangerous abbreviations, dose expressions, non-urgent verbal orders; fax original order to pharmacy; seek clarification directly with prescriber
	Order entered incorrectly	Design of software; computer mnemonics; look-alike drugs; failure/absence of double check	Same as above	3	3	9	User-friendly order entry process; look-alike drug alerts; double check process for order entry
	Order entered into wrong patient profile/wrong encounter	Poor presentation of patient demographics (fax interference, light imprint, order copy unclear); look-alike names	Same as above	3	3	9	CPOE; vivid demographics on order forms/screens; high quality fax machines, routine maintenance; *view only* access to prior patient encounters; alerts for look-alike names
	Standard directions (concentration, mixing instructions) in computer wrong	Use of substitute drug due to shortage; overlook default directions in computer when changing processes	Overdose, under-dose; poor pain control	3	2	6	Checklist/testing to ensure revisions in electronic/print when changing processes/ drugs; quick access to information on substitute drugs

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Processes & Subprocesses	Failure Modes	Causes	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
Dispensing (cont'd)							
Produce label	Label inaccurate	Inaccurate order entry	Overdose, under-dose; wrong route; ADR	3	3	9	As above under "order entered into computer" section
	Label unclear	Ambiguous information; poor quality of printer	Same as above; delay in therapy; poor pain control	3	3	9	High quality laser printer; improve presentation of label information with nursing input
	Label not printed	Equipment malfunction; improper interface with pharmacy computer	Missed therapy; delay in therapy; poor pain control	2	1	2	Routine equipment maintenance and performance testing
	Label lost	Inefficient process for printing/retrieving labels; remote location of printer	Same as above	2	2	4	Reorganize workflow and placement of printers to improve efficiency
Prepare medication	Wrong drug	Look-alike products stored near each other; drug shortage; knowledge deficit	ADR; overdose; under-dose; allergic reaction; poor pain control	4	3	12	Separate look-alike products; PCA protocols; feedback mechanism on drug shortages with information on substitute drugs available; readily available mixing protocols; compounding log of ingredients with lot numbers; independent double check
	Wrong diluent	Same as above	ADR; toxicity from diluent	3	3	9	Same as above
	Wrong dilution/ concentration	Knowledge deficit; calculation error	Overdose; under-dose; poor pain control	4	3	12	PCA protocols; independent double check for all calculations
Check medication before distribution	Check not completed	Inadequate staffing patterns	Potential error not detected	3	3	9	Adequate staffing patterns
	Check inadequate	Same as above; environmental factors (distractions, space, lighting, noise); inefficient workflow; human factors	Same as above	3	3	9	As above; environmental and workflow improvements; mental warm-ups before checking to increase task focus; use of verbal checks

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Processes & Subprocesses	Failure Modes	Causes	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
Dispensing (cont'd)							
Deliver medication to patient care unit	Delay in distribution	Inadequate staffing patterns/equipment used for delivery of drugs; inefficient drug delivery system; delivery equipment mechanical failure; shared delivery system	Delay in drug therapy; use of floor stock before pharmacy order screening	3	4	12	Establish dedicated delivery system under direct control of pharmacy; use dedicated staff/equipment for medication delivery; routine maintenance and update of equipment
	Delivered to wrong unit	Inadequate, untimely interface with admission/transfer information	Same as above; omitted doses; unneeded doses on wrong unit (possible administration to wrong patient)	3	3	9	Timely and seamless communication of admissions/transfers to pharmacy
Administration							
Receive order/transcribe onto MAR	Order/MAR misunderstood	Illegible order; use of abbreviations, trailing zeroes, naked decimal doses; verbal orders; look-alike drug names; knowledge deficit	Overdose, under-dose; allergic response; ADR; delay in therapy; poor pain control	3	4	12	CPOE; preprinted orders; prohibit dangerous abbreviations dose expressions, non-urgent verbal orders; seek clarification directly from prescriber/chart; staff training for typical drugs used for PCA
	Order transcribed onto MAR incorrectly	Same as above; too many sections/pages of MAR; lack of support staff training; distractions; failure/absence of double check; knowledge deficit	Same as above	3	3	9	Same as above; pharmacy computer-generated MAR; staff training; environment free of distractions; user-friendly MAR; consistent double check process
	Order transcribed onto wrong MAR	Look-alike patient names; poor presentation of patient demographics on MAR; order transcribed before patient identifier added	Same as above	2	3	6	Look-alike name alerts; vivid demographics on MAR forms; high quality imprint machines

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Processes & Subprocesses	Failure Modes	Causes	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
Administration (cont'd)							
Obtain PCA infusion pump	No pump available	Inadequate supply; hoarding; bottlenecks with cleaning process	Delay in therapy; poor pain control; use of improper pump/no pump; overdose, under-dose	3	3	9	Purchase adequate supply of pumps; central distribution center; efficient cleaning process
	Wrong pump selected	As above; knowledge deficit	Delay in therapy; poor pain control	2	2	4	As above; staff training
Obtain PCA medication	Cannot find dispensed medication	Pharmacy delivery problem; no communication to nurse that medication delivered	Delay in therapy; poor pain control	2	2	4	Efficient pharmacy delivery process and communication
	Wrong drug	Look-alike products stored near each other (automated dispensing cabinets, floor stock, refrigerator); drug shortage; knowledge deficit	ADR; overdose; under-dose; allergic reaction; poor pain control	4	3	12	Separate look-alike products; PCA protocols; feedback mechanism on drug shortages with information on substitute drugs available; independent double check
	Wrong concentration	Same as above; unnecessary multiple concentrations available; knowledge deficit; calculation error	Overdose; under-dose; poor pain control	4	3	12	Same as above; use one standard concentration (use auxiliary warning labels if using different concentration and have pharmacy dispense the drug); PCA protocols; independent double check
	Error during compounding (wrong drug, wrong diluent, wrong concentration)	Unfamiliarity with IV admixture; no pharmacy service at night; failure of double check	ADR; overdose; under-dose; allergic reaction; poor pain control	4	4	16	Full pharmacy IV admixture service; purchase prefilled syringes/cassettes from manufacturer

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Processes & Subprocesses	Failure Modes	Causes	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
Administration (cont'd)							
Program pump	Pump mis-programmed (flow rate, concentration, lock out, loading dose)	Design flaw in pump (e.g., Abbott LifeCare PCA pump) which makes programming error-prone; lack of standard concentrations; failure to limit variety of products used; knowledge deficit; confusion between units of measure (mg vs. mcg); mechanical failure	Overdose; under-dose; poor pain control	4	3	12	Purchase pumps that are easy to program: use FMEA process to determine potential failure modes of pumps to guide purchasing decisions; limit variety of pumps; train staff on use of new pumps; minimize variety of products used for PCA; standardize concentrations used; PCA protocols; independent double check at bedside
Check medication/ pump settings before administration	Check not completed	Inadequate staffing patterns; lack of making the check a priority; previous successful violations; check process not integrated into the way care is delivered	Potential error not detected and likely to reach the patient	4	3	12	Adequate staffing patterns; engaging staff in culture of safety; understand causes for prior successful violations and take action to eliminate barriers to consistent checks; build check processes into the care delivery model in use
	Check inadequate	Same as above; environmental factors (distractions, space, lighting, noise); inefficient workflow; human factors; check not completed at bedside (to ensure check of pump settings, patient, line attachments)	Same as above	4	3	12	As above; environmental and workflow improvements; mental warm-ups before checking to increase task focus; use of verbal checks; check performed at bedside
Administer PCA	Wrong patient	Failure of double check at bedside; failure to check/absent name bracelet; ordered on wrong patient; /transcribed on wrong MAR	Overdose, under-dose; allergic response; ADR; delay in therapy; poor pain control	3	3	9	As above under "medication/pump settings checked" section; match patient therapy with condition; patient education

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Processes & Subprocesses	Failure Modes	Causes	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
Administration (cont'd)							
Administer PCA (cont'd)	Wrong route	Catheter attachment confusion; failure of double check at bedside	ADR; poor pain control	4	2	8	As above under "medication/pump settings checked" section; label proximal ends of lines near insertion ports
	Wrong dose	Failure of double check; family/nurse activation instead of patient activation; Inadequate patient/family education before use; improper use on patients who cannot activate their own PCA; patient/staff/family tampering (drug diversion, criminal intent); patient misuse (accidental activation due to confusion with call-bell, etc.)	Overdose; under-dose; ADR; poor pain control	4	3	12	As above under "medication/pump settings checked" section; patient selection criteria for appropriate use of PCA; staff education; patient education before use (surgical preadmission processes, etc.); inaccessible medication in locked pump with electronic recording of transitions; clear differentiation between call bell and activation button
	Wrong flow rate	Failure of double check; pump not protected from free flow; mechanical failure; insufficient preventive maintenance of pump; inaccurate pump calibration; insufficient power source for pump	Same as above	4	3	12	As above under "medication/pump settings checked" section; proper selection and maintenance of pumps; use of pumps protected from free flow; back-up power source for pump
Document PCA	Drug administration not documented	Human factors; environmental distractions; workload; inefficient process; multiple MAR pages/screens	Inability to properly evaluate pain management; duplicate therapy	3	2	6	Establish user-friendly MAR; review documentation before end of each shift to ensure complete; use flow sheets at bedside to document PCA (and patient monitoring parameters)

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Processes & Subprocesses	Failure Modes	Causes	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
Monitoring							
Monitor effects of medication	Insufficient monitoring of effects of PCA	Workload; knowledge deficit; monitoring parameters not ordered; ineffective communication between caregivers; cultural influences	Failure to recognize the consequences of an error before patient harm occurs; inability to evaluate pain management; poor pain control	3	3	9	Standard order sets with monitoring guidelines; standard scale to help assess pain; training on cultural influences; proper staffing patterns and safe workload; use flow sheet at bedside to document PCA and patient monitoring parameters

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*Scoring Guidelines**

Key for Severity Rating:

Severity Score	Description
1	*Minor* patient outcome: No injury, nor increased length of stray, nor increased level of care
2	*Moderate* patient outcome: Increased length of stay or increased level of care for 1 to 2 patients
3	*Major* patient outcome: Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increase level of care for 3 or more patients
4	*Catastrophic* patient outcome: death or major permanent loss of function (sensory, motor, physiologic, intellectual), suicide, rape, hemolytic transfusion reaction, surgery/procedure on the wrong patient or wrong part of body, infant abduction or discharge to wrong family

Key for Probability Rating:

Probability Score	Description
1	*Remote*: Unlikely to occur (may happen sometime in 5 to 30 years)
2	*Uncommon*: Possible to occur (may happen sometime in 2 to 5 years)
3	*Occasional*: Probably will occur (may happen several times in 1 to 2 years)
4	*Frequent*: Likely to occur immediately or within a short period (may happen several times in one year)

Key for Hazard Score:

Hazard score = Severity Score x Probability Score

Hazard Scoring Matrix:

Failure modes with scores that fall in the gray area (8 and greater) should be given highest priority

Probability	Severity of Effect			
	Catastrophic	*Major*	*Moderate*	*Minor*
Frequent	16	12	8	4
Occasional	12	9	6	3
Uncommon	8	6	4	2
Remote	4	3	2	1

*Scoring method adapted from: VA National Center for Patient Safety, Healthcare Failure Mode and Effect Analysis (HFMEA™)

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