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Effective Corrective and Preventative Action Plans

Thursday, February 19th, 2022

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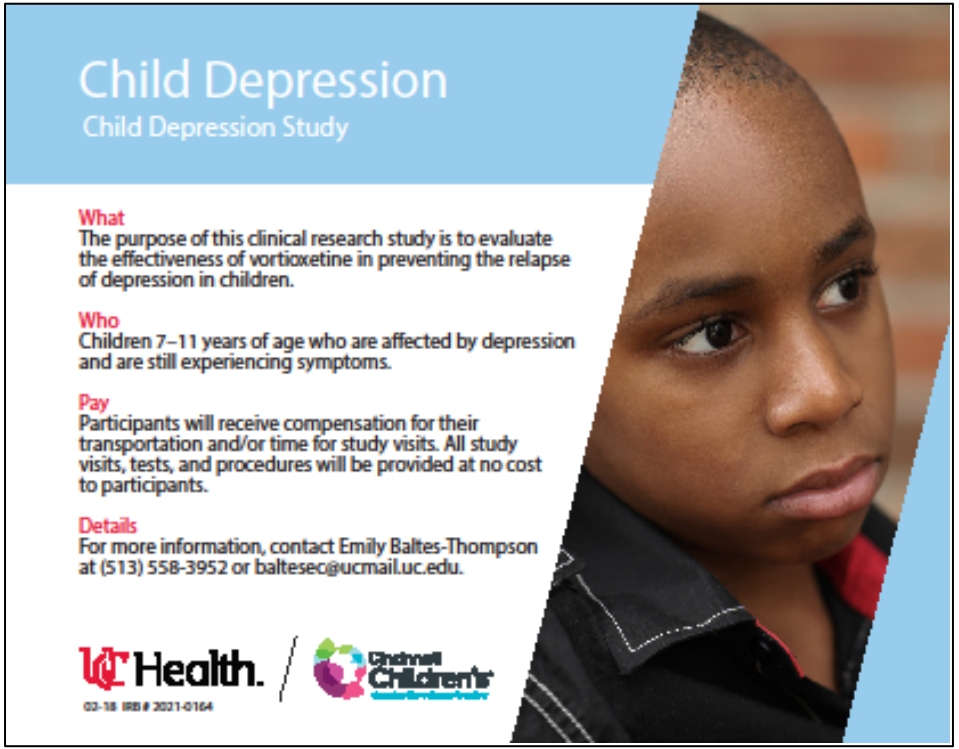
February 2022 Study of the Month #1



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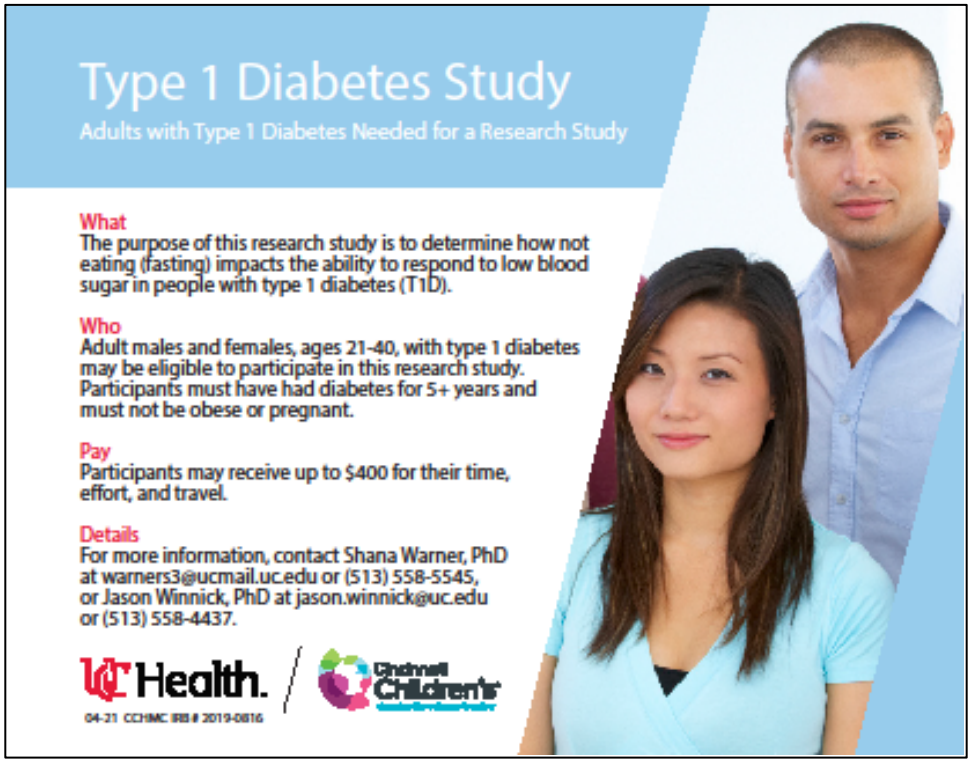
February 2022 Study of the Month #2



Friday, March 4th, 2022

Gender Diversity and Inclusion:

Addressing Microaggressions in the workplace.

Jamilah Hackworth, EdD

Cincinnati Children's Hospital Medical Center

University of Cincinnati

UC Health Clinical Research Orientation and Training (CRO&T)

Thursday, March 10th, 2022

9:00 am - 2:30 pm

Virtual presentation

The last day of registration is EOB Friday, March 4th, 2022

Please reach out to Nate Harris, nate.harris@uchealth.com for any questions

UCGNI/NRC Neuroscience Research Day 2022 April 12, 2022

Virtual PowerPoint presentations and a Guest Speaker 8:30am to 11:30am from undergraduates, medical students, graduate students, medical residents, post-doc fellows, clinical fellows & junior faculty

Abstract Deadline: 5pm March 15, 2022
Upload of accepted presentation PowerPoints due: 5pm April 5, 2022

Abstracts should be no more than 2000 characters. Please subtract 250 characters for each table or figure. Character counts will be for the title and the body of the abstract (author information not counted).

Abstracts should be submitted by clicking HERE for the Forms submission portal.

For more information, please contact Dr. Brandon Foreman at foremabo@ucmail.uc.edu

Don’t forget to visit The UC Office of Clinical Research site on Bearcats Landing!
Visit Bearcats Landing by entering [my.uc.edu](my.uc.edu) into your web browser
(UC login required).

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Today's Presentation:

Effective Corrective and Preventative Action Plans

A presentation discussing the importance of root-cause analysis, process development, and error-proofing in creating effective corrective and preventative action plans. Participants are invited to come with examples of errors in the research process to facilitate discussion of the presentation's key concepts.

Amy Diane Short, MHSA
Assistant Professor
Acting Program Director Master of Health Administration
College of Allied Health Sciences
University of Cincinnati

Effective Corrective and Preventative Action Plans in Response to Promptly Reportable Events

Amy Diane Short, MHSA, CSSBB
UC MHA Acting Program Director
02/17/22

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Agenda

- Why have corrective and preventative action plans (CAPA)?
- CAPA definitions
- CAPA definitions example
- Root cause
- Processes not (just) Training
- Error proofing
- CAPA considerations

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Why CAPA?

To protect the safety, rights, and welfare of research participants and others

Humans make mistakes - a strong process makes mistakes less likely

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CAPA Definitions

- Preventive Action:
  - Stop a potential problem from happening
- Corrective Action:
  - Stop a known problem from happening AGAIN
- Correction:
  - Remediate the problem after it has happened

ISO 9000:2005 Sec. 3.6

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CAPA Definitions Examples

Example: Research participation without a consent

- Preventive Action:
  - Have research associates use a checklist for research activities; use visual management for key process steps
- Corrective Action:
  - Find out why the checklist was not used
  - Correct workflow so that the checklist is the first document in research packets
  - Implement Kanban board
- Correction:
  - Obtain consent from participant retroactively

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ROOT CAUSE

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Root Cause (1)

"The root cause is the initiating, most basic cause of a problem that may or may not lead to a chain of causes or other problems. Eliminating the root cause should prevent recurrence of the problem."

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Root Cause (2)

1. Identify the problem
2. Interview those impacted by the problem
3. Interview those people responsible for the problem, if applicable
4. Questions to identify root causes
5. What happened? What is the problem?
6. Why and how did the problem occur? What were the steps?
7. Who was affected by the problem? Was it one subject or all subjects in the study?
8. What is the magnitude of the problem? Is it in one study or does the problem exist in all studies under this PI or even in an entire clinical department?
9. Keep asking "why" and "how" until you reach the root cause

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Root Cause Tools

- Fishbone Diagram
- Pareto Chart
- Five Whys
- FMEA Analysis
- Process Maps

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PROCESSES NOT (JUST) TRAINING

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Why Is "Human Error" Not an Acceptable Root Cause?

While it may be true that a human error was involved in an adverse event, the very occurrence of a human error implies that it can happen again. Human error is inevitable. If one well-intentioned, well-trained provider working in his or her typical environment makes an error, there are system factors that facilitated the error. It is critical that we gain an understanding of those system factors so that we can find ways to remove them or mitigate their effects.

Our goal is to increase safety in the long term and not allow a similar event to occur. When the involved provider is disciplined, counseled, or re-trained, we may reduce the likelihood that the event will recur with that provider, but we don't address the probability that the event will occur with other providers in similar circumstances. Wider training is also not an effective solution; there is always turnover, and a high-profile event today may be forgotten in the future. This is reflected in Figure 3, the Action Hierarchy, which is based upon safety engineering principles used for over 50 years in safety-critical industries. Solutions that address human error directly (such as remediation, training, and implementation of policies) are all weaker solutions. Solutions that address the system (such as physical plant or device changes and process changes) are much stronger. This is why it's so important to understand the system factors facilitating human error and to develop system solutions.

Review teams should not censor themselves when it comes to identifying corrective actions. This is important because the team's job is to identify and recommend the most effective actions they can think of, and it is leadership's responsibility to decide if the benefit likely to be realized is worth the investment, in light of the opportunity cost and its impact on the system in general. Only the top leadership of an organization can accept risk for the organization, and this is a responsibility that should not be delegated to others. ◆

- National Patient Safety Foundation (2015). *RCA²: Improving Root Cause Analyses and Actions to Prevent Harm.* National Patient Safety Foundation.

- [RCA2: Improving Root Cause Analyses and Actions to Prevent Harm | IHI - Institute for Healthcare Improvement]

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	Action Category	Example	Action
Stronger Actions (these tasks require less reliance on humans to remember to perform the task correctly)	Architectural/physical plant changes	Replace revolving doors at the main patient entrance into the building with powered sliding or swinging doors to reduce patient falls.	
	New devices with usability testing	Perform heuristic tests of outpatient blood glucose meters and test strips and select the most appropriate for the patient population being served.	
	Engineering control (forcing function)	Eliminate the use of universal adaptors and peripheral devices for medical equipment and use tubing/fittings that can only be connected the correct way (e.g., IV tubing and connectors that cannot physically be connected to sequential compression devices or SCDs).	
	Simplify process	Remove unnecessary steps in a process.	
	Standardize on equipment or process	Standardize on the make and model of medication pumps used throughout the institution. Use bar coding for medication administration.	
	Tangible involvement by leadership	Participate in unit patient safety evaluations and interact with staff; support the RCA[2] process; purchase needed equipment; ensure staffing and workload are balanced.	
Intermediate Actions	Redundancy	Use two RNs to independently calculate high-risk medication dosages.	
	Increase in staffing/ decrease in workload	Make float staff available to assist when workloads peak during the day.	
	Software enhancements, modifications	Use computer alerts for drug-drug interactions.	
	Eliminate/reduce distractions	Provide quiet rooms for programming PCA pumps; remove distractions for nurses when programming medication pumps.	
	Education using simulation-based training, with periodic refresher sessions and observations	Conduct patient handoffs in a simulation lab/environment, with after action critiques and debriefing.	SafetyToolkit_ActionHierarchy (2).pdf
	Checklist/cognitive aids	Use pre-induction and pre-incision checklists in operating rooms. Use a checklist when reprocessing flexible fiber optic endoscopes.	
	Eliminate look- and sound-alikes	Do not store look-alikes next to one another in the unit medication room.	
	Standardized communication tools	Use read-back for all critical lab values. Use read-back or repeat-back for all verbal medication orders. Use a standardized patient handoff format.	
	Enhanced documentation, communication	Highlight medication name and dose on IV bags.	
Weaker Actions (these tasks require more reliance on humans to remember to perform the task correctly)	Double checks	One person calculates dosage, another person reviews their calculation.	
	Warnings	Add audible alarms or caution labels.	
	New procedure/ memorandum/policy	Remember to check IV sites every 2 hours.	
	Training	Demonstrate correct usage of hard-to-use medical equipment.	

Action Hierarchy levels and categories are based on *Root Cause Analysis Tools*, VA National Center for Patient Safety, http://www.patientsafety.va.gov/docs/joe/rca_tools_2_15.pdf. Examples are provided here.

ERROR PROOFING

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Six Principles of Mistake Proofing

- Elimination
- Prevention
- Replacement
- Facilitation
- Detection
- Mitigation

A Lean Journey: Six Principles of Mistake Proofing

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Elimination

- Remove process steps that lead to error
- Examples:
  - Medications come in predetermined doses versus individual preparations
  - Motion based light sensors versus flipping switch
  - EHR data flows automatically into appropriate data bases versus double charting

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Prevention

- Process designed to make mistakes impossible
- Examples:
  - EHR hard gates
  - Information sheet at the beginning of online survey
  - Car doors wont lock if keys are inside car
  - Washing machine runs only when door is latched
  - Overflow outlets in sinks

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Replacement

- Building of more reliable processes
- Examples:
  - Zebra labels for specimen samples vs hand-writing
  - Wristband barcode scanning vs verbal checks to reduce patient misidentification
  - Patient registries for chronic illness management

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Facilitation (1)

- Processes designed to be less error prone
  - Includes:
    - Checklists
    - Visual management
    - Asymmetry

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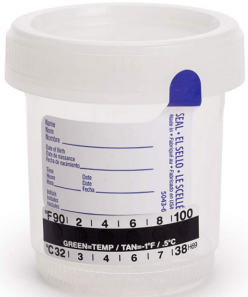
Facilitation (2)

- Visual Management
  - Make process status visible
  - Manage the situation with this information



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Detection

- Flagging the error and stopping the process
- Examples:
  - Truck weigh station
  - Excel restricted data entry field
  - Inspection for errors

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Mitigation

- Minimize the impact of the mistake
- Examples:
  - Fuses in electric breaker box
  - Smoke alarm
  - Surgical time outs

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CAPA CONSIDERATIONS

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SMART CAPA

There are five factors to create a S.M.A.R.T corrective action plan.

S

SPECIFIC

Compliant, addresses the full observation or root cause, accountable to named individual or role

M

MEASURABLE

Action can be measured to demonstrate whether it's adequate to address root cause

A

ACHIEVABLE

Addresses all implicated processes and levels

R

REALISTIC

Plan can be carried out with given resources and knowledge

T

TIME BOUND

Assigned to someone who can accomplish action in a given time period

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CAPA Management

- Implementation
- Measurement
- Tracking
- Accountability
- Evolution

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