

# Root Cause Analysis

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MEDICINE *of*  
THE HIGHEST ORDER

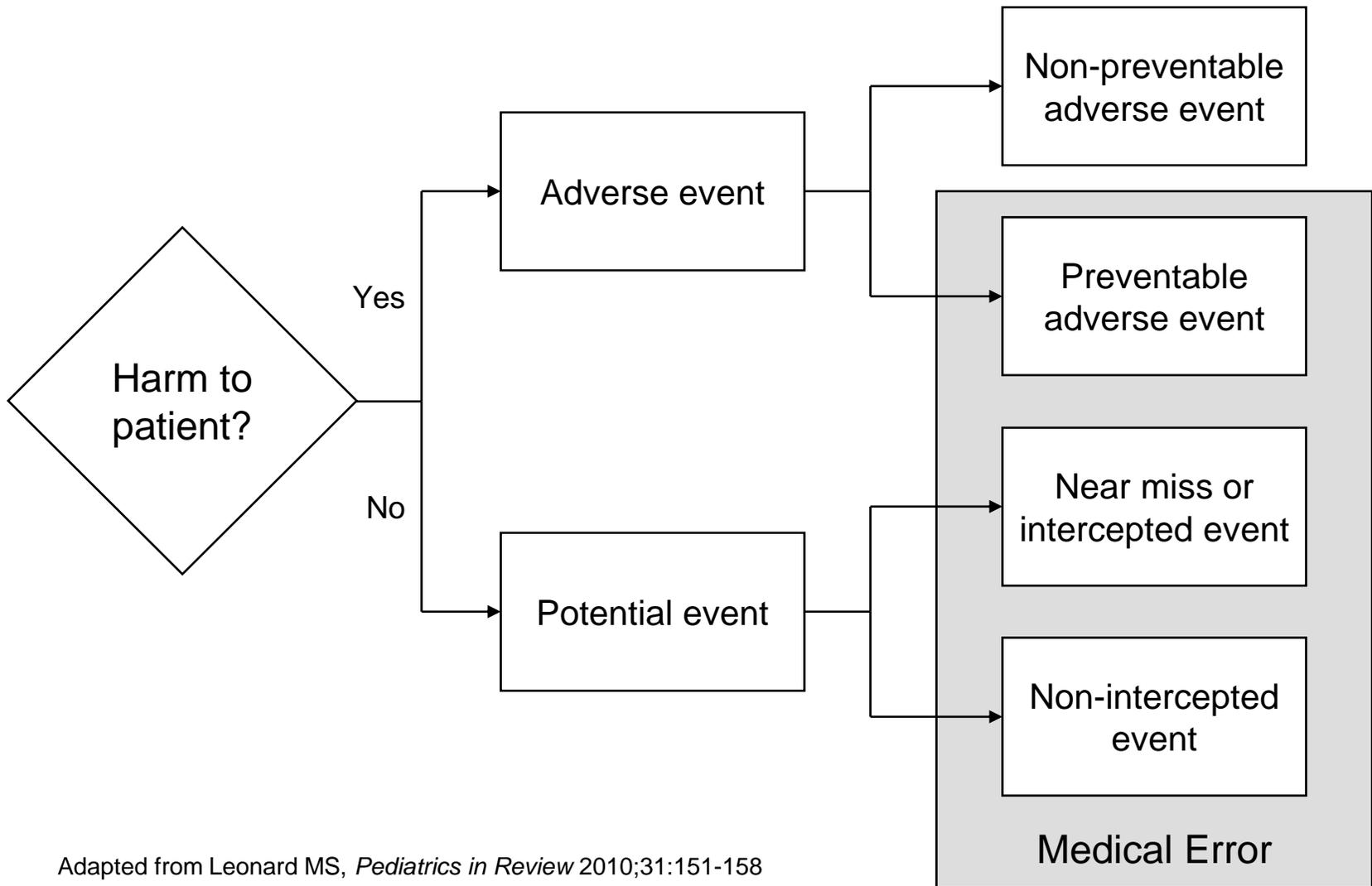


# Root Cause Analysis

- ☆ Detects system design failures
- ☆ Avoids individual blame
- ☆ Identifies opportunities to improve processes and prevent recurrences
- ☆ Used in high-risk industries e.g. aviation

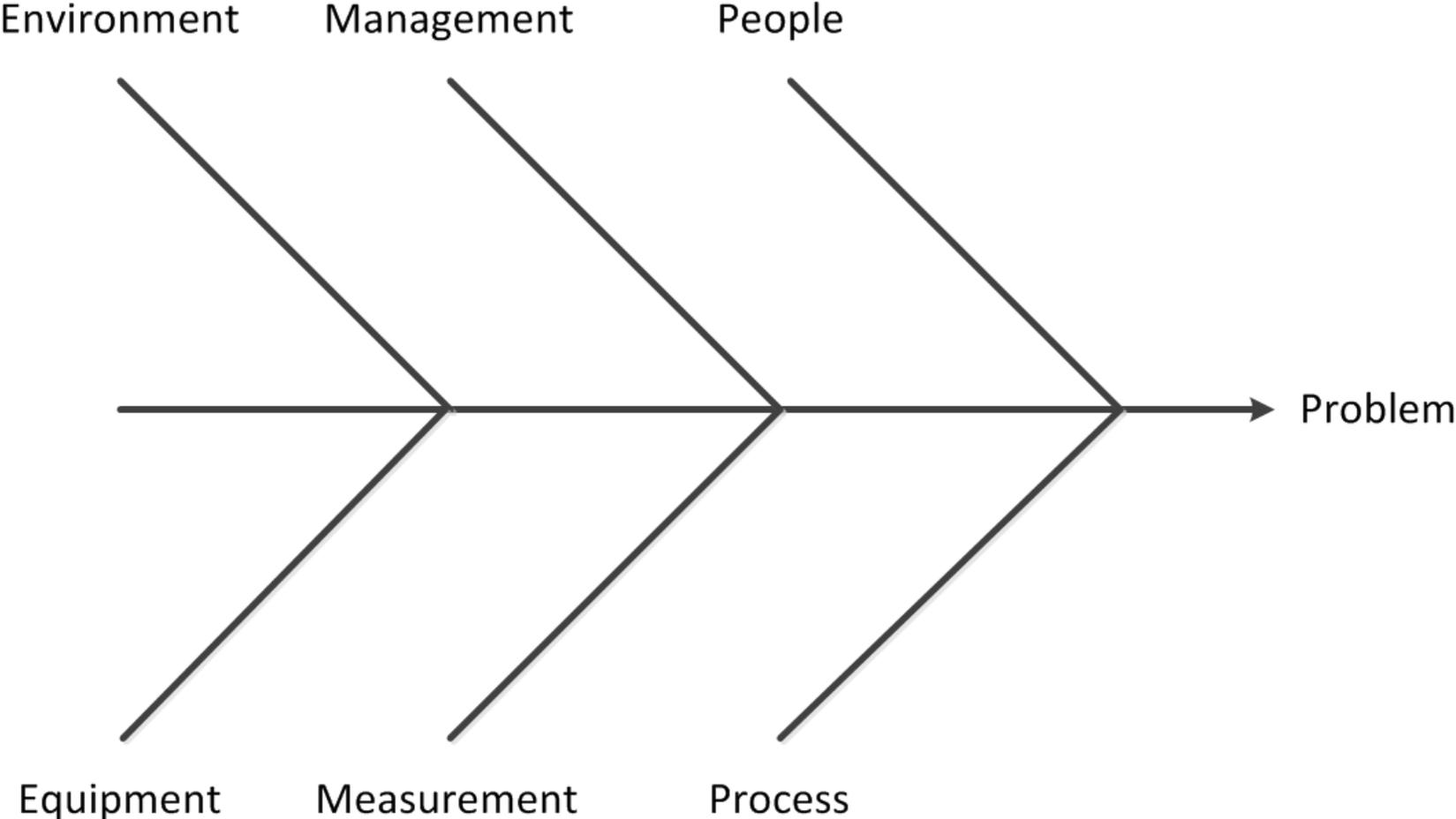
# Root Cause Analysis

- ☆ Gather facts via interviews, chart reviews, etc.
- ☆ Establish a timeline
- ☆ Convene an interprofessional meeting
- ☆ Review relevant findings and contributing factors
- ☆ Determine root cause(s) of the event
- ☆ Develop and implement risk reduction strategies
- ☆ Monitor adherence to improvement plans



Adapted from Leonard MS, *Pediatrics in Review* 2010;31:151-158

# Cause and Effect Diagram



# Study Title

Safety and Efficacy of Study Drug “Q” for Adolescents

# Protocol Summary

- The effects of an anti-depressive medication taken twice daily for ages 13 to 17 years.
- Primary outcome is decreased episodes of depressive behavior.
- Medication compliance and safety reporting is collected daily.
- Subjects are scheduled for weekly visits.

# Protocol Summary

- Case Report Forms are completed online by coordinator at time of visit.
- The sponsor of this study is the PI.
- Study team consists of: PI and two part-time research coordinators.

# Major Risk Factor

Suicidal ideation related to study drug “Q”

# Web Safety Check-in

Three online forms completed daily:

- Medication Compliance
- Subject's Mood Rating
- "Patient Health Severity Measure for Depression" questionnaire

# Timeline

- Day 1      Visit 1: informed consent obtained, subject enrolled.
- Day 8      Visit 2: all online daily forms completed, no issues reported.
- Day 15     Visit 3: all online daily forms completed, no issues reported.

# Timeline

Day 18      Online Medication Compliance form:  
No entry from subject.

Online Questionnaire: incomplete.  
*Alert* email issued for both triggers.  
PI left phone message for family.

# Timeline

Day 19      Online Medication Compliance form:  
No entry from subject.

Online Questionnaire: Incomplete.

Subject's Mood Rating: No entry from  
subject.

# Timeline

Day 19      The mother spoke to PI in the morning and told him that she was unable to complete the web safety checks due to internet failure at her home.

Mother reported no issues with her child and stated she saw her daughter take the medication yesterday. PI stated study staff will follow-up with her the next day.

# Timeline

Day 20      In the morning, the mother found the daughter (Subject) at home lethargic with slurred speech.

Subject was taken by ambulance to hospital, treated in the ED, and subsequently admitted overnight.

Diagnoses: depression, accidental medication overdose.

# Timeline

Day 20      Event has been reported to the IRB.  
Sponsor (PI) has initiated an RCA.