

# *Clinical Chemistry*

Trainee Council

## PEARLS OF LABORATORY MEDICINE

QC design:  
Things you need to know series

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# Introduction

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## ➤ **Quality Control Design**

- In clinical diagnostics settings,
  - the process of identifying the quality required for each test offered and
  - the statistical process controls needed to alert the user if the quality goal is not being met.

# Why do we need quality control?

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- This question sometimes comes up when laboratory expenses are being scrutinized.
- Setting aside regulatory requirements for quality control, aren't clinical diagnostic systems reliably engineered?
- Why do we have to continually check the quality of clinical diagnostic processes?
  - Because all clinical diagnostic processes will experience failure.
  - It is the laboratories' responsibility to ensure the reliability of patient results.

# Failure modes

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## ➤ Pre-Analytical

- Ordering – Incorrect order, mislabeled..
- Sample – Specimen collection, processing, transportation..

## ➤ Analytical

- Operators
- Reagent – Reagent degradation..
- Measuring System – Calibration stability, hardware failure..
- Lab Environment – Power failures, temperature..

## ➤ Post-Analytical

- Archiving

# Analytical failure mode categories

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- Failure modes can be grouped into 2 categories:
  - “Full Stop” malfunctions occur when the testing system does not work (a state that is easy to identify – no specimens are being tested and no results are produced).
  - “Silent” malfunctions/out-of-control conditions occur when the testing system continues to process specimens and produce results, but the results are not suitable for their intended purpose.
- “Silent” malfunctions are the target of quality control.

# Characterizing “silent” malfunctions

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- “Silent” malfunctions in clinical diagnostic processes can be grouped into intermittent or persistent out-of-control conditions:
  - Intermittent out-of-control condition
    - malfunctions do not last long.
    - compromises the testing system for a short period of time.
    - may only affect a single patient sample.
    - E.g. bubble in a reagent line
  - Persistent out-of-control condition
    - malfunctions persist until they are corrected
    - affects multiple patient specimens.
    - E.g. calibration drift is an example.
- Persistent out-of-control conditions have the most potential impact on patient results and are usually the focus of statistical quality control.

# The “quality” of a patient result

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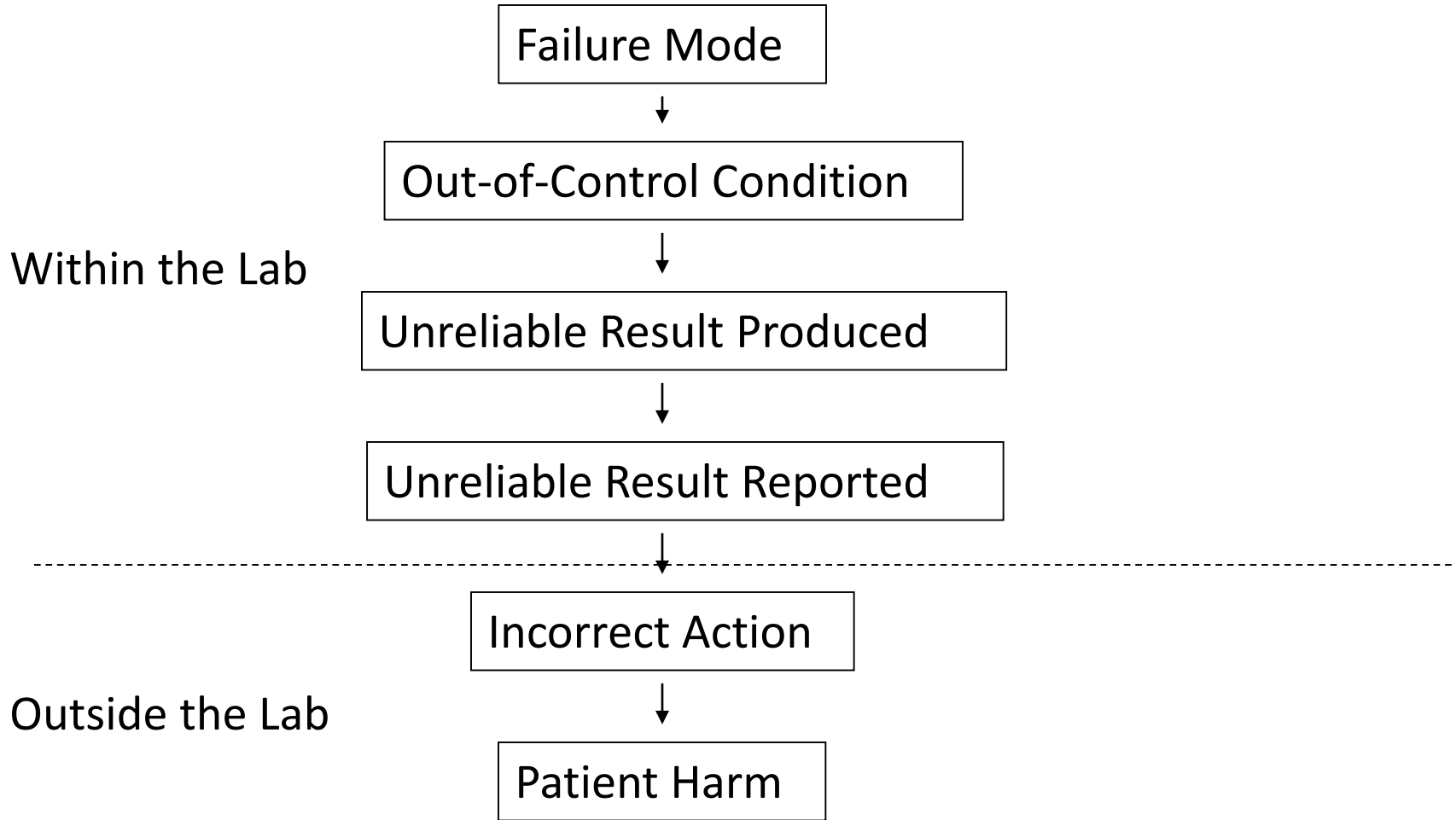
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- The quality of a patient result depends on the difference between the correct concentration and the value reported by the laboratory.
- If this difference is greater than some defined allowable error limit then we define the results unreliable.
  
- All results contain measurement error
- When the process is in-control, few results with the measurement error are unreliable
- When an out-of-control condition exists, additional error is added so a higher percentage of patient results are unreliable

# Sequence of Events Leading to Patient Harm

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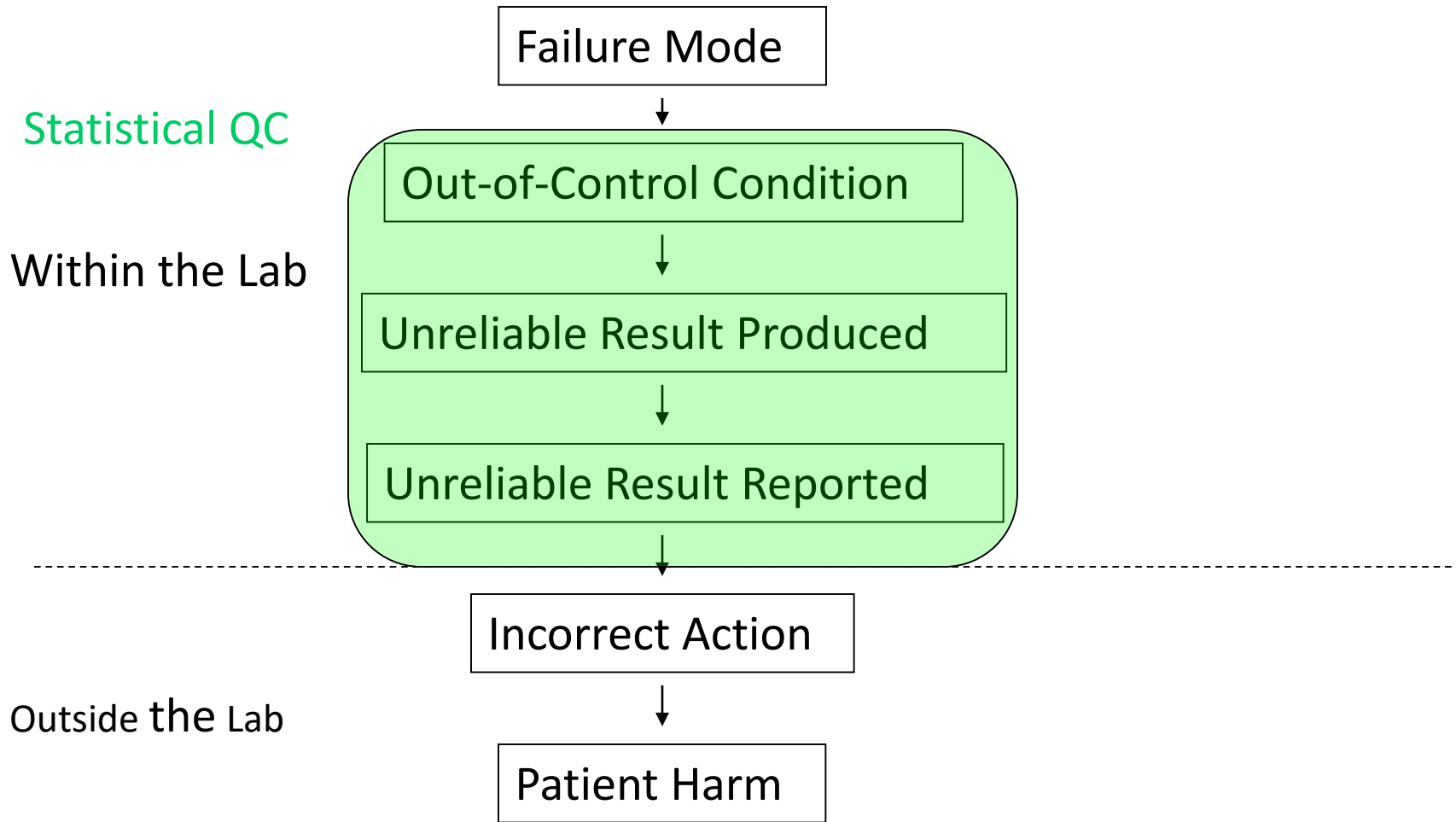
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# Sequence of Events Leading to Patient Harm

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# Goal

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## ➤ Design Statistical Quality Control

- Detect Persistent out-of-control conditions that affect multiple patient samples
- Reduce the number of unreliable patient results reported
- Focus is on minimizing the patient risk.

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