# Medicine Shortages – Causes and Approaches to Improvements Clinical Needs/Risks Assessment

EAHP Academy Seminar

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# Conflict of Interest

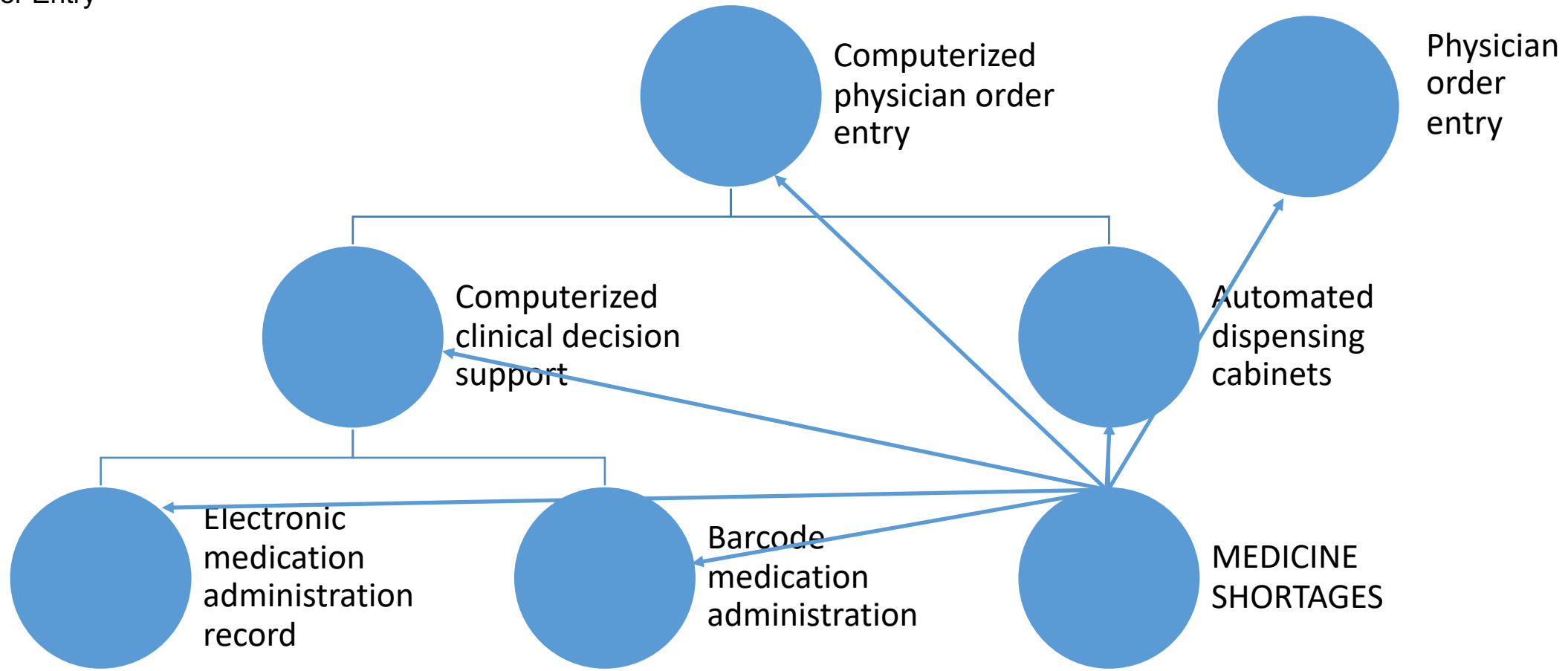
- Nothing to disclose

# Outline

- Medicine shortages - prescription and administration
- Prospective risk assessment
- Healthcare Failure Mode and Effect Analysis (HFMEA)
- Prioritization (First risk- First needs)
- Implications to real healthcare settings and an initial analysis of the results

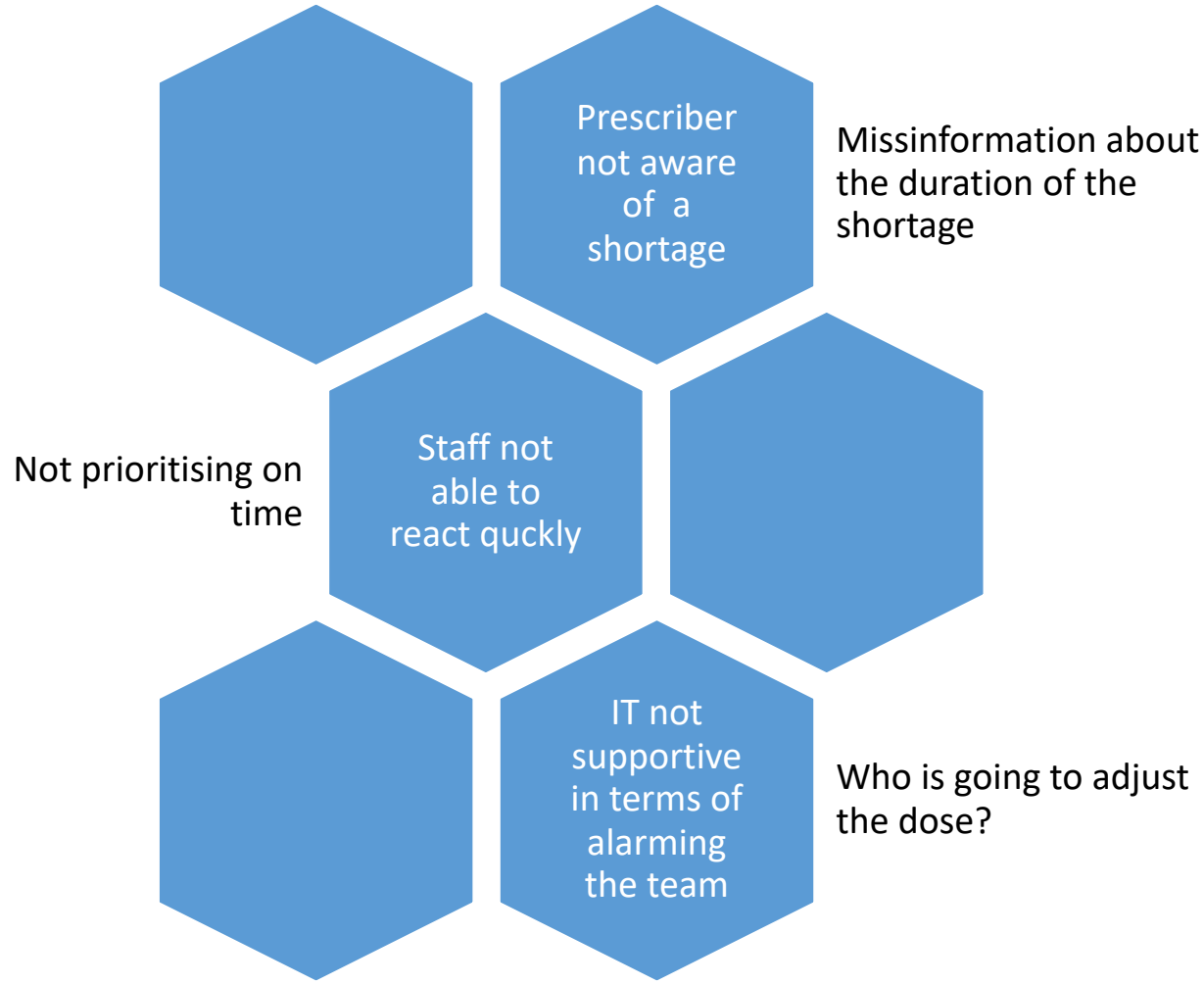
# POE and CPOE Hospital

* Physician Order Entry / Computer Physician Order Entry

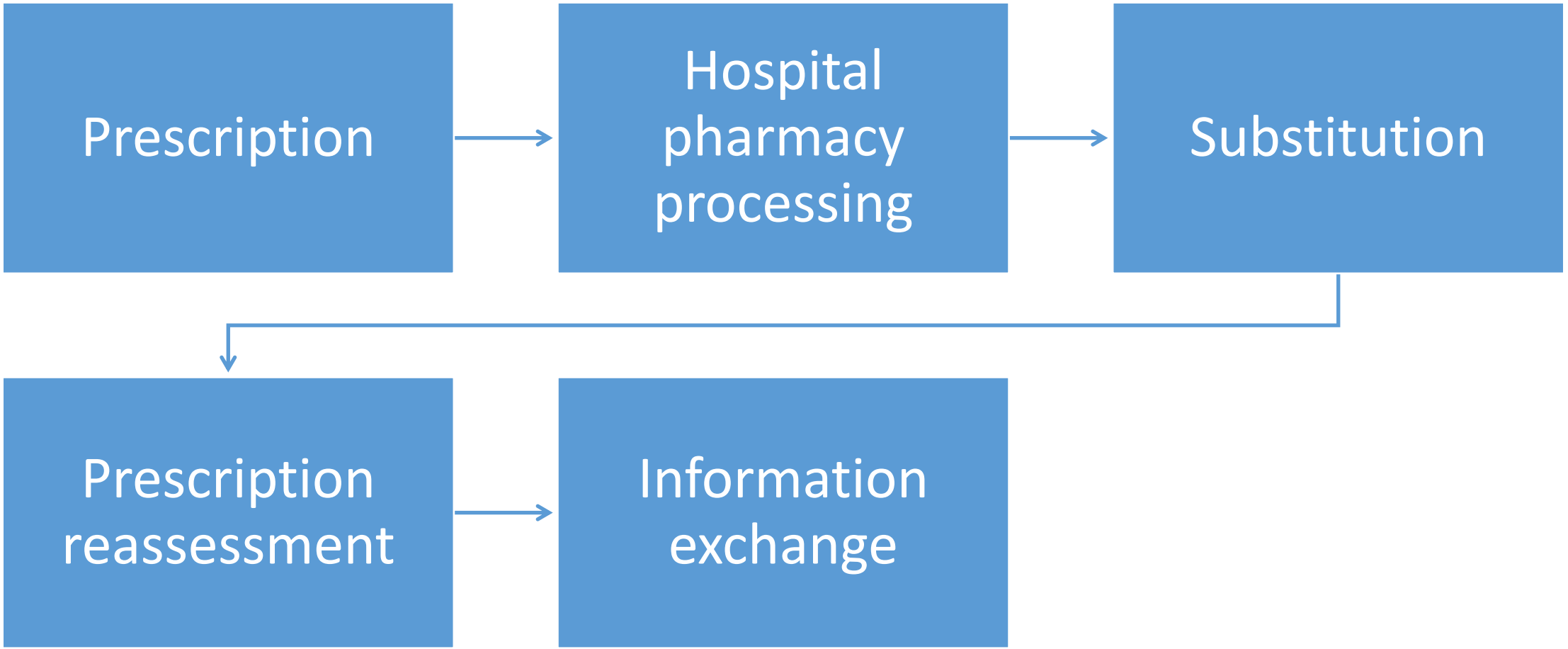



Rodriguez-Gonzalez CG, Martin-Barbero ML, Herranz-Alonso A, et al. Use of failure mode, effect and criticality analysis to improve safety in the medication administration process, J Eval Clin Pract. 2015 Aug;21(4):549-59.

# Implications to Real Healthcare Settings Risks and Hazards



# The Flow of Information



# Proactive Risk Assessment

1) Reduce the likelihood of patient harm
2) Seek the best solution in times of medicine shortages

# Why Risk Assessment?

- Proactively detect risks that could cause patient harm
- Describe and rate risks based on probability and severity
- Prioritise detected risks
- Propose actions to reduce risks
- Simulate processes using the proposed actions aiming at reducing risks

DeRosier J, Stalhandske E, Bagian J P. et al Using health care failure mode and effect analysis: the VA National Center for Patient Safety's prospective risk analysis system. Jt Comm J Qual Improv 2002 May;28(5):248-67, 209.

# Risks Associated with Medicine Shortages

- Incorrect  dosage of the substitute medicine prescribed
- Improper administration of the substitute medicine
- New drug-drug interactions not reviewed
- Onset effects not properly assessed - no information on treatment-effect delays
- Adverse effect profiles not reviewed

Canadian Pharmacists Association. Drug Shortages: A Guide for Assessment and Patient Management. Canadian Pharmacists Association: 2010. PDF. <http://pharmacists.ca/cpha-ca/assets/File/cpha-onthe-issues/DrugShortagesGuide.pdf>
Institute for Safe Medication Practices Canada. The Systems Approach to Quality Assurance for Pharmacy Practice: A Framework for Mitigating Risk. ISMP Canada, 2012.

# Prospective Risk Analysis

Common in:

- Chemotherapy
- Blood transfusions
- Drug prescription
- Compounding parenteral nutrition
- Drug distribution systems
- Continous drug infusions
- Dialysis
- Drug administration analysis

Uncommon in other areas.
Particularly drug shortages

Van Tilburg CM, Leistikow IP, Rademaker CMA, Bierings MB, van Dijk ATH. Health care failure mode and effect analysis: a useful proactive risk analysis in a pediatric oncology ward. Quality & Safety in Health Care. 2006;15(1):58-63.
Castro Vida MÁ, Martínez de la Plata JE, Morales-Molina JA, et al. Identification and prioritisation of risks in a hospital pharmacy using healthcare failure mode and effect analysis Eur J Hosp Pharm 2017;0:1–6.
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# Prospective Risk Assessment

- Critical evaluation of the processes involved for medicine substitution in shortages
- Causes of failure modes detected which may lead to adverse events coming from the prescription and administration of medicines
- Prioritise interventions that need to be implemented to provide adequate medicine substitution according to failure modes

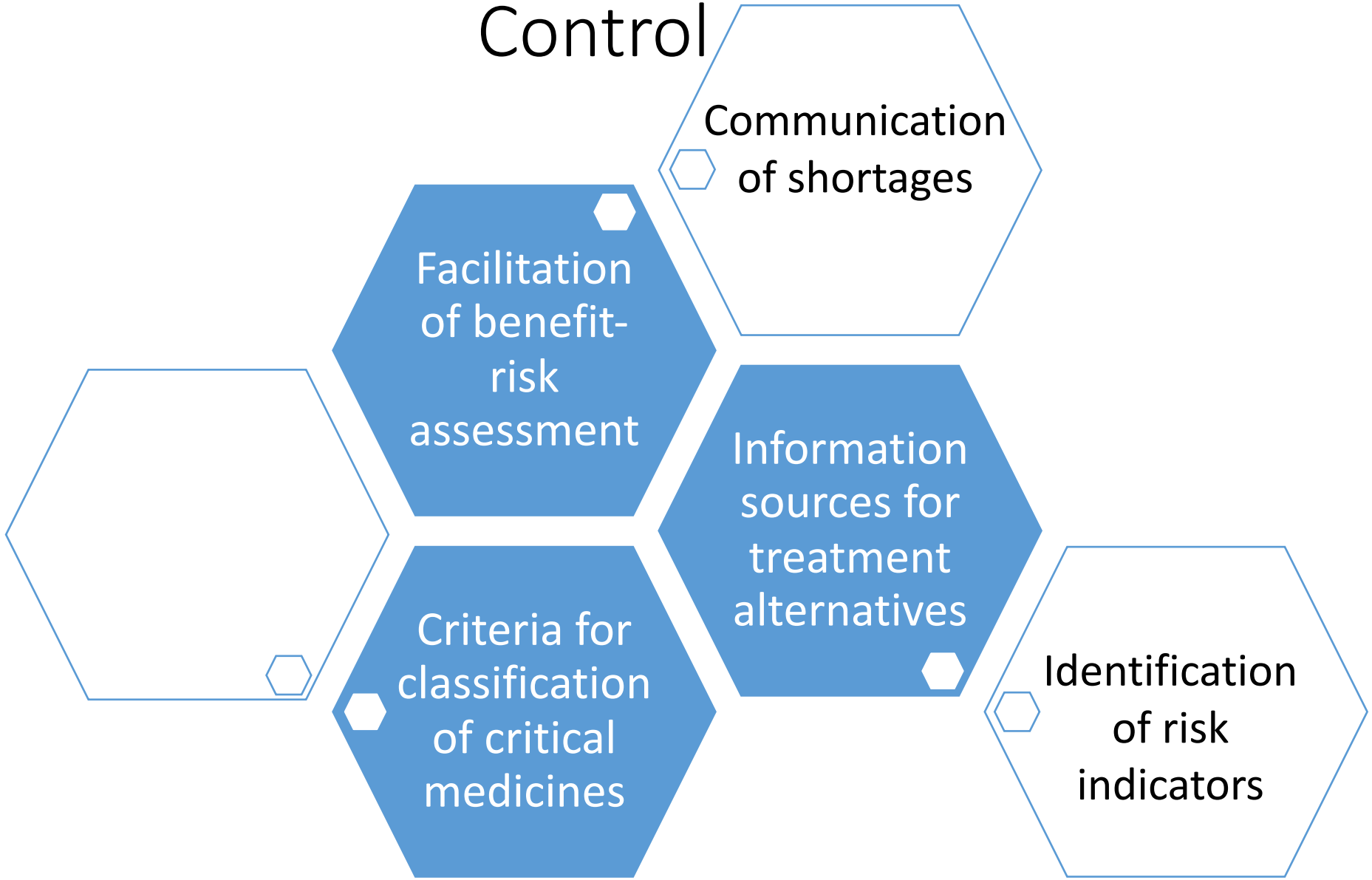
Rodriguez-Gonzalez CG, Martin-Barbero ML, Herranz-Alonso A, et al. Use of failure mode, effect and criticality analysis to improve safety in the medication administration process, J Eval Clin Pract. 2015 Aug;21(4):549-59.

# Treatment Second.
# Risk Assessment First.

- The healthcare setting in question
- How healthcare services are organized and provided
- IT infrastructure
- Communication channels - multidsiciplinary cooperation

DeRosier J, Stalhandske E, Bagian J P. et al Using health care failure mode and effect analysis: the VA National Center for Patient Safety's prospective risk analysis system. Jt Comm J Qual Improv 2002 May;28(5):248-67, 209.

# Proactive Medicine Shortage Management via Risk Control




PDA, Technical Report No. 68 (TR 68), Risk-Based Approach for Prevention and Management of Drug Shortages, PDA, 2015.

# Risk Assessment-Clinical Needs Assessment

- Clinical need to manage risks
- Replacement / alternative risks
- Internal support and external communication

# The Parenteral Drug Association (PDA) Technical Report 68


PDA, Technical Report No. 68 (TR 68), Risk-Based Approach for Prevention and Management of Drug Shortages, PDA, 2015.

# Medicine Shortage Prevention and Response Plan Risk-Triage Model

1

Categorise medicine

2

Risk Management

& Control measures

3

Register

PDA, Technical Report No. 68 (TR 68), Risk-Based Approach for Prevention and Management of Drug Shortages, PDA, 2015.

# Risk Register of Medicine Shortages

| Generic name | Potential shortage risk | Risk source | Affected internal area | Initial risk level | Risk indicators | Intended risk-control measures | Expected risk level after corrective measures | Responsible party | Status |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |

PDA, Technical Report No. 68 (TR 68), Risk-Based Approach for Prevention and Management of Drug Shortages, PDA, 2015.

# Risk-triage Model

- Identify the risk level for the patient based on the availablity of an alternative medicine and its therapeutic use

| Risk | Therapeutic Use of Products | Availability of Alternatives | Likelihood of Shortage |
|---|---|---|---|
| High | Life supporting or life sustaining | No Alternatives Available | High likelihood of shortage |
| Medium | Acute short term or chronic long term | Alternative Products Available: Similar Therapy | Moderate likelihood of shortage |
| Low | Other indications | Exact Product Available but in Other Presentations | Low likelihood of shortage |

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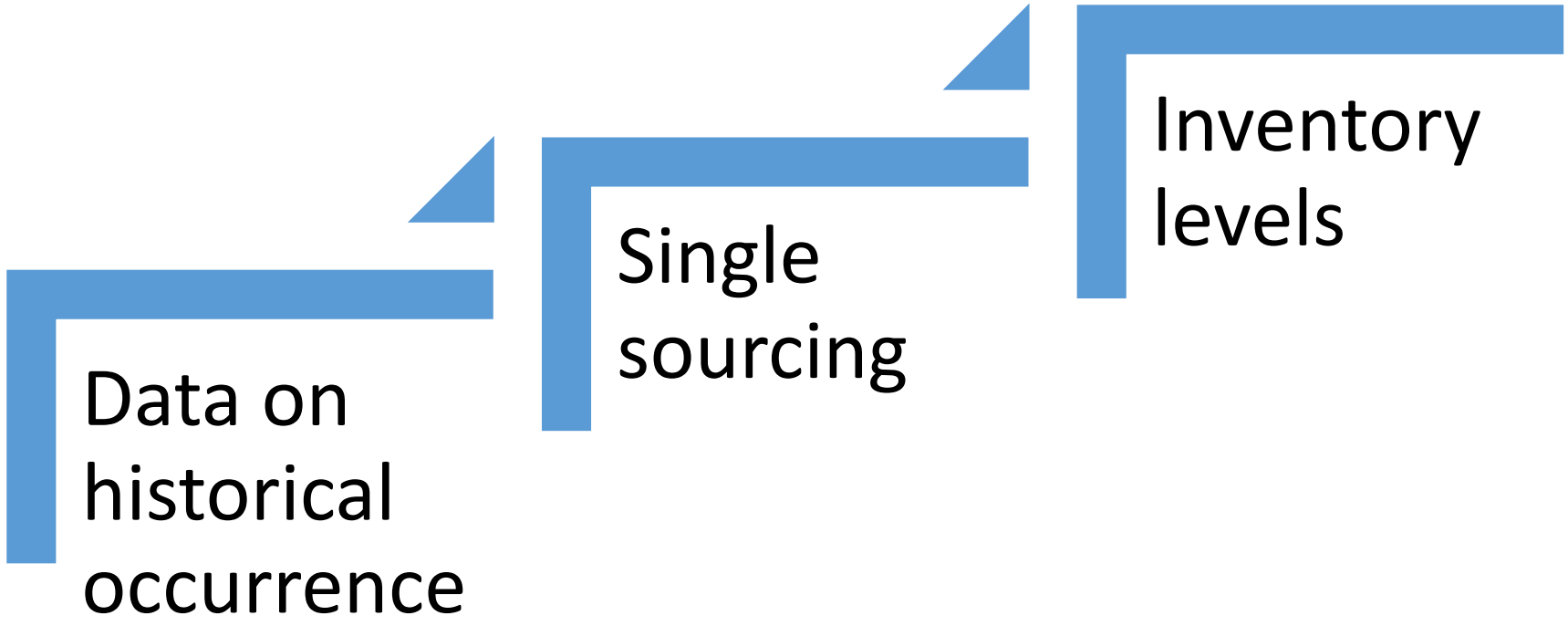
# Risk-triage Model

- Determine the likelihood of a medicine shortage for a particular medicine

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# Risk-triage Model

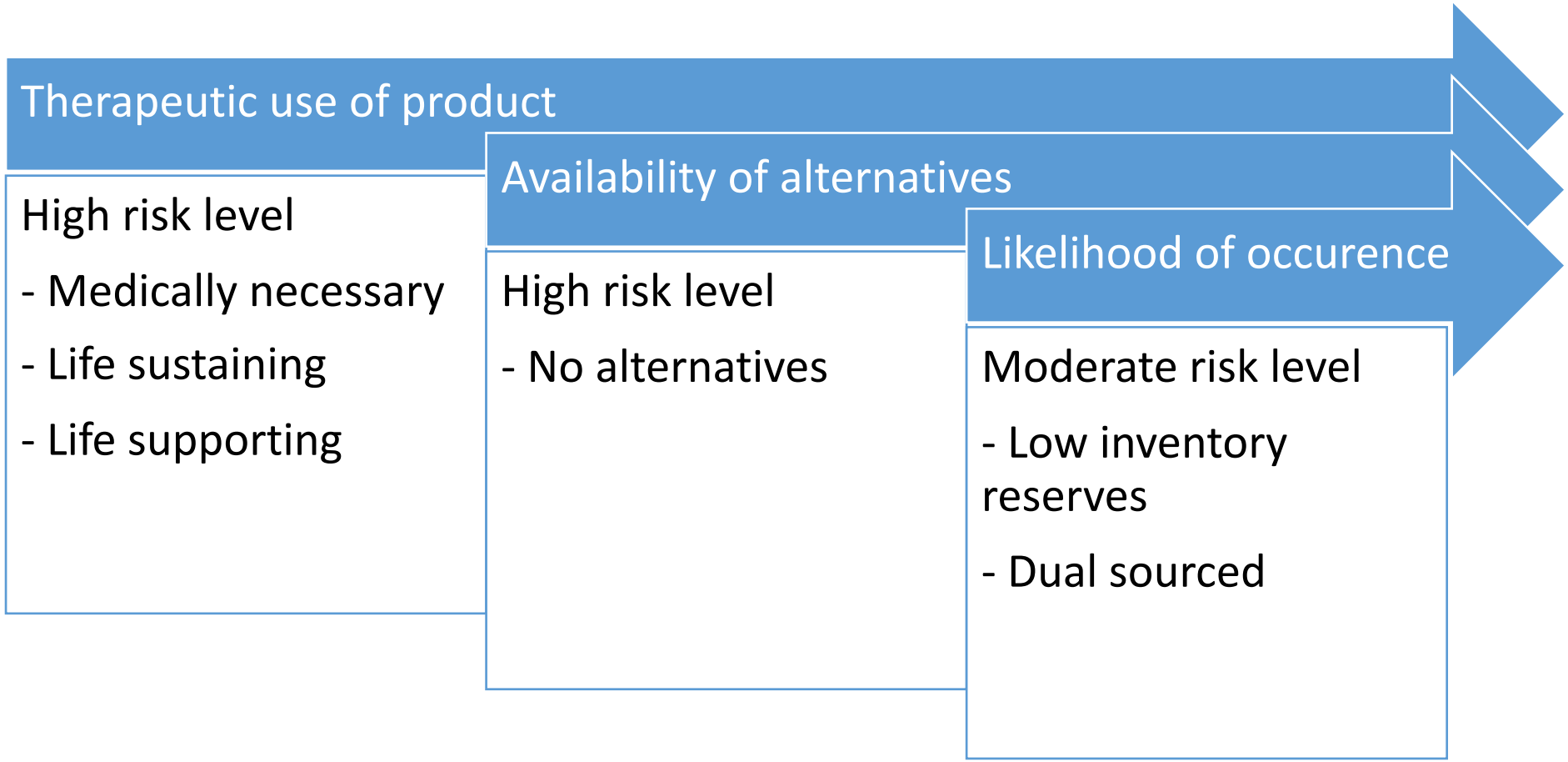
- Establish the risk-priority level based on the projected impact to the patient and the likelihood of a medicine shortage

**2. At each risk level consider the likelihood of a drug shortage**
**3. Define priority**

| Therapeutic Use & Consequences if Product not Available | | Likelihood of Shortage | | |
|---|---|---|---|---|
| | | **High** | **Moderate** | **Low** |
| | **Risk Level A** | **Risk Priority Level 1** | **Risk Priority Level 1** | **Risk Priority Level 2** |
| | **Risk Level B** | **Risk Priority Level 1** | **Risk Priority Level 2** | **Risk Priority Level 3** |
| | **Risk Level C** | **Risk Priority Level 2** | **Risk Priority Level 3** | **Risk Priority Level 3** |

PDA, Technical Report No. 68 (TR 68), Risk-Based Approach for Prevention and Management of Drug Shortages, PDA, 2015.

# Basic Example



# Risk-triage Model

- Plan and implement risk control measures

# Risk Assessment and Management

- Practitioner input
- Watch list
- Early identification
- Assessments based on existence and availibility

TGA, Management and Communication of Medicine Shortages in Australia – A New Protocol for Australian Product Sponsors, the Therapeutic Goods Administration and supply chain stakeholders, TGA, 2018.

# Medicines Watch List

- Antibiotics, antifungals and antivirals
- Antidotes and treatments for poisonings
- Emergency and Critical Care
- Vaccines
- Specific Immunoglobulins
- Anticonvulsants
- Obstetrics

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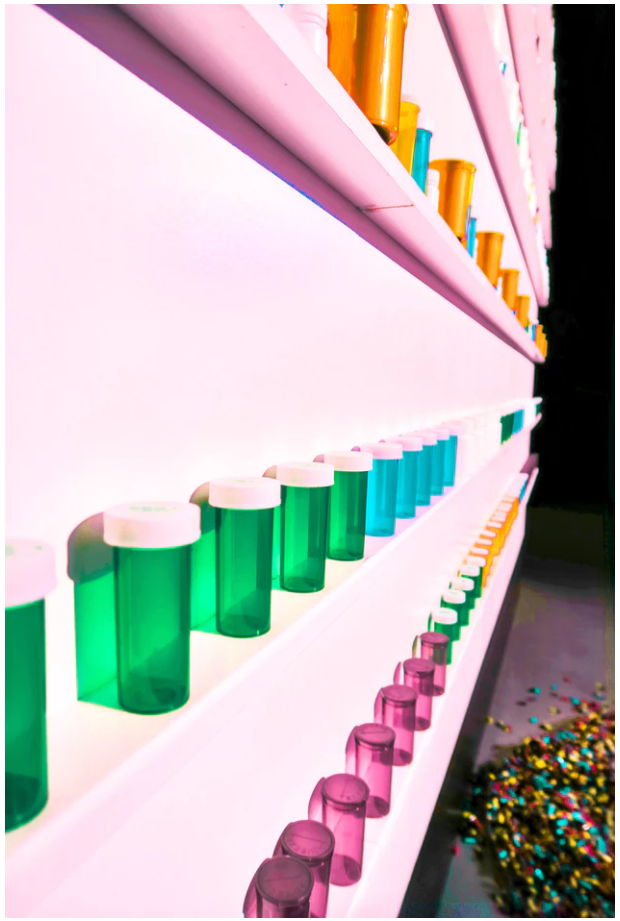
# How do we Assess and Verify?

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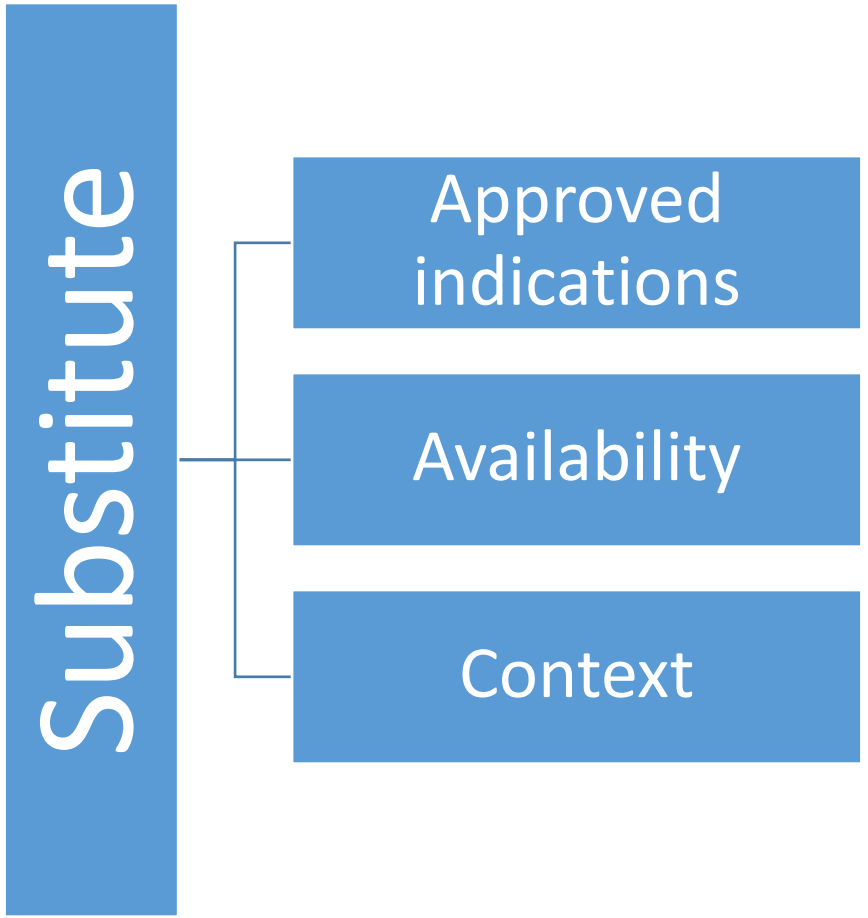
# Medicine Substitute

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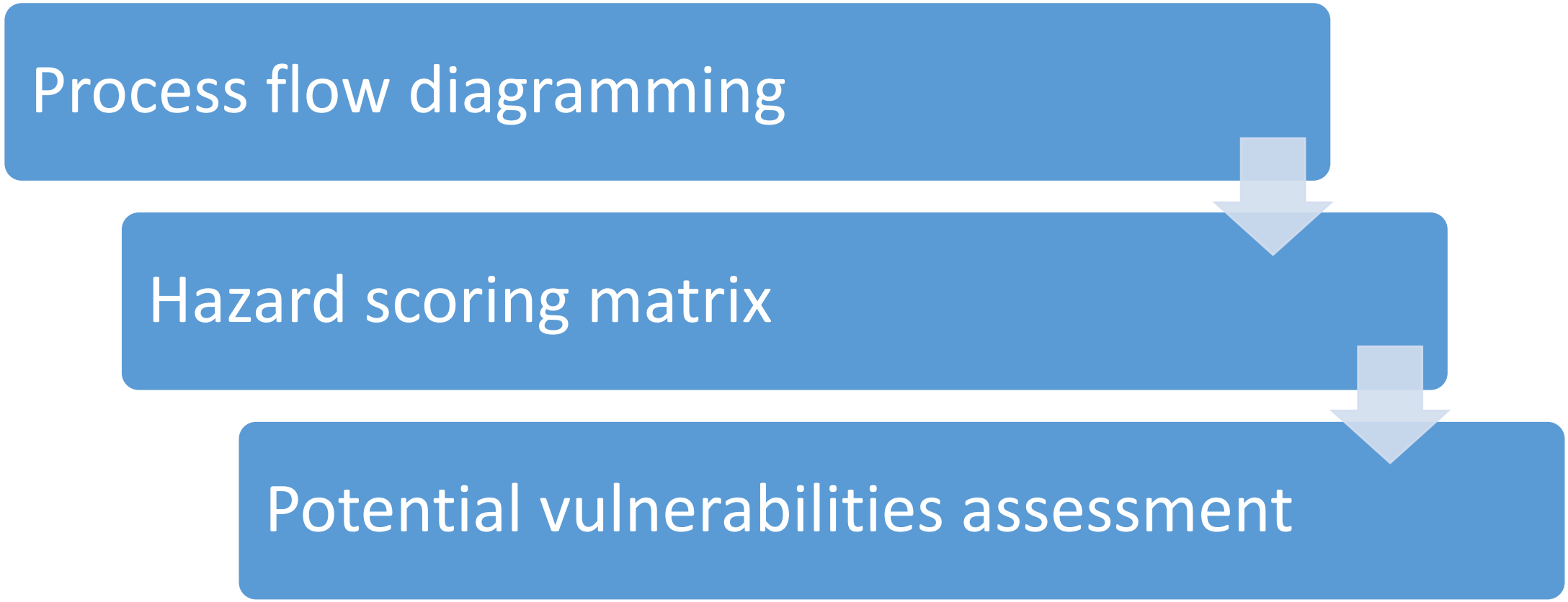
# Proactive Risk Assessment Models

- Failure Mode Effect Analysis (FMEA)
- Healthcare Failure Mode Effect Analysis (HFMEA)
- Operational Risk Management (ORM)
- Hazard Analysis and Critical Control Point (HACCP)
- Root Cause Analysis (RCA)

# Is the HFMEA Merely an Academic Exercise?

# Healthcare Failure Mode Effect Analysis (HFMEA)

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# Healthcare Failure Mode Effect Analysis (HFMEA)

- HFMEA analyzes a process:
- Precisely
- In a stepwise matter
- Can encounter failure modes which do not qualify as high risk
- The HFMEA team can still give recommendations for these non-high risk failure modes

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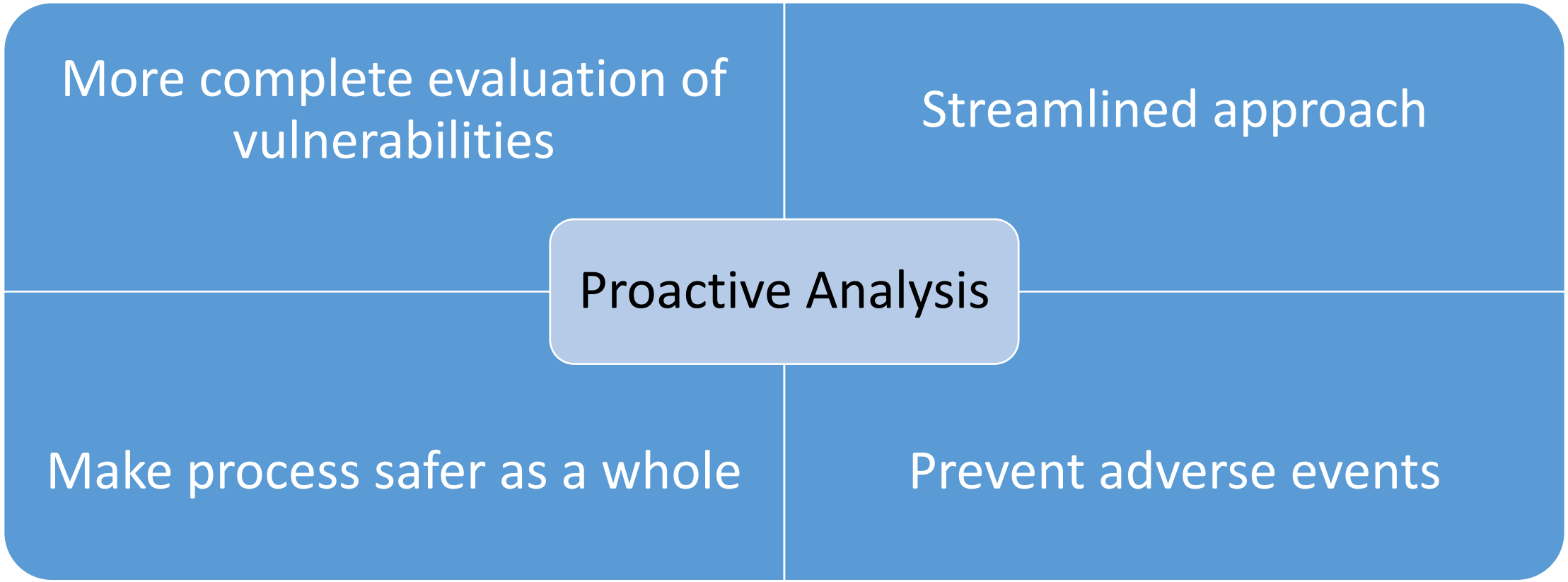
# Healthcare Failure Mode Effect Analysis (HFMEA)

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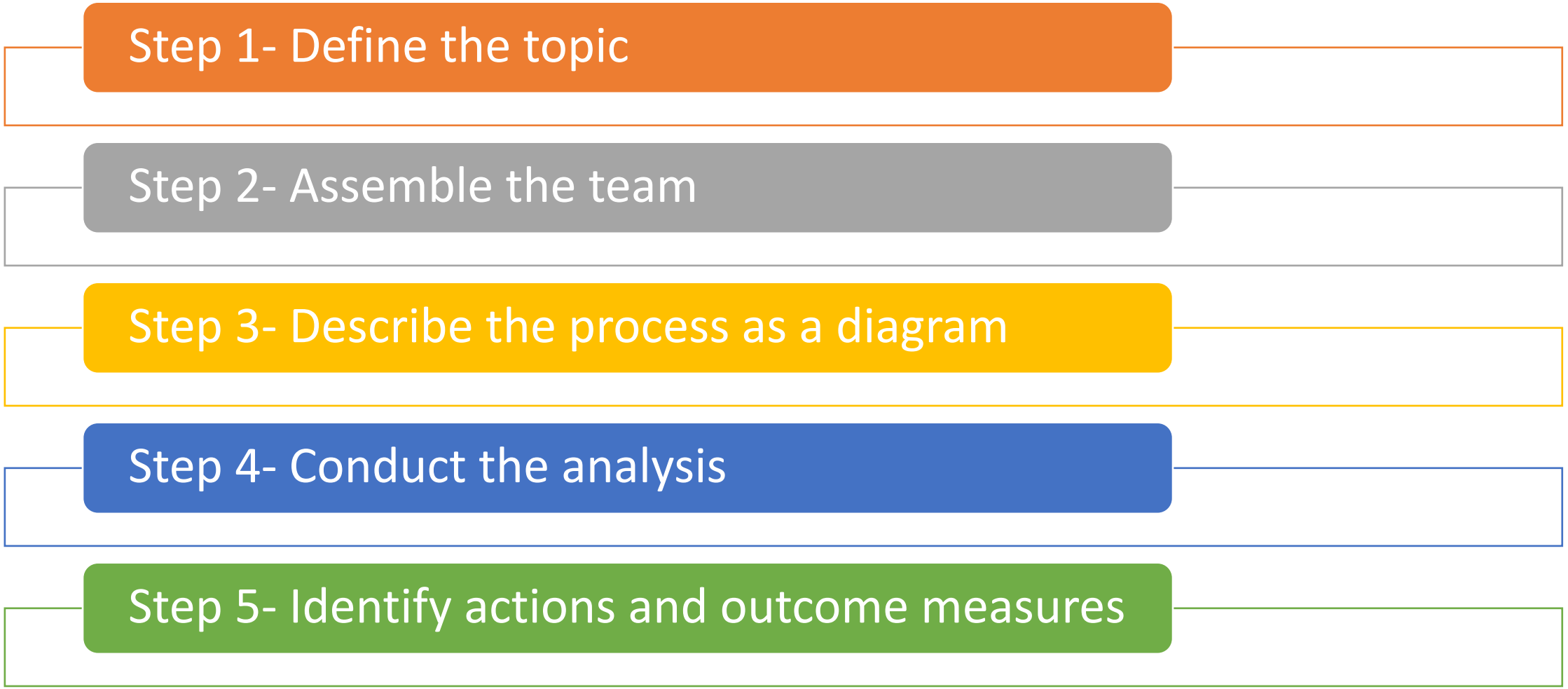
# HFMEA as applied to Several Hospitals Accross Europe

- Is the HFMEA a valid proactive tool to evaluate a circumscribed healthcare process like prescription up to and including administration of reserve antibiotic in the hospital wards/inpatient setting with a high detection rate of potential adverse events?

?

# HFMEA Steps




DeRosier JM and Bagian JP, Proactive Risk Assessment Healthcare Failure Mode Effect Analysis Process, A cognitive aid and guidebook for the HFMEA process, Centre fo Healthcare Engineering & Patient Safety University of Michigan, 2017.

# Step 1 Define the Topic


DeRosier JM and Bagian JP, Proactive Risk Assessment Healthcare Failure Mode Effect Analysis Process, A cognitive aid and guidebook for the HFMEA process, Centre fo Healthcare Engineering & Patient Safety University of Michigan, 2017.

# 5-6 Primary Process Steps

Avoid problem statements

Show proactive way to minimise risks

NOT “Preventing inapropriate medicines substitution during a medicine shortage”

BUT “Providing adequate and optimal medicine substitution during a medicine shortage”

DeRosier JM and Bagian JP, Proactive Risk Assessment Healthcare Failure Mode Effect Analysis Process, A cognitive aid and guidebook for the HFMEA process, Centre fo Healthcare Engineering & Patient Safety University of Michigan, 2017.

# Step 2 - Assemble the Team

DeRosier JM and Bagian JP, Proactive Risk Assessment Healthcare Failure Mode Effect Analysis Process, A cognitive aid and guidebook for the HFMEA process, Centre fo Healthcare Engineering & Patient Safety University of Michigan, 2017.

# Step 3 - Describe the Process as a Diagram

Identify all subprocesses

Create a new flow diagram accordingly

Assign failure modes, faliure causes and detect effects

- Describe failure modes-WHAT COULD GO WRONG?
- Describe failre mode causes-WHY IT WOULD GO WRONG?

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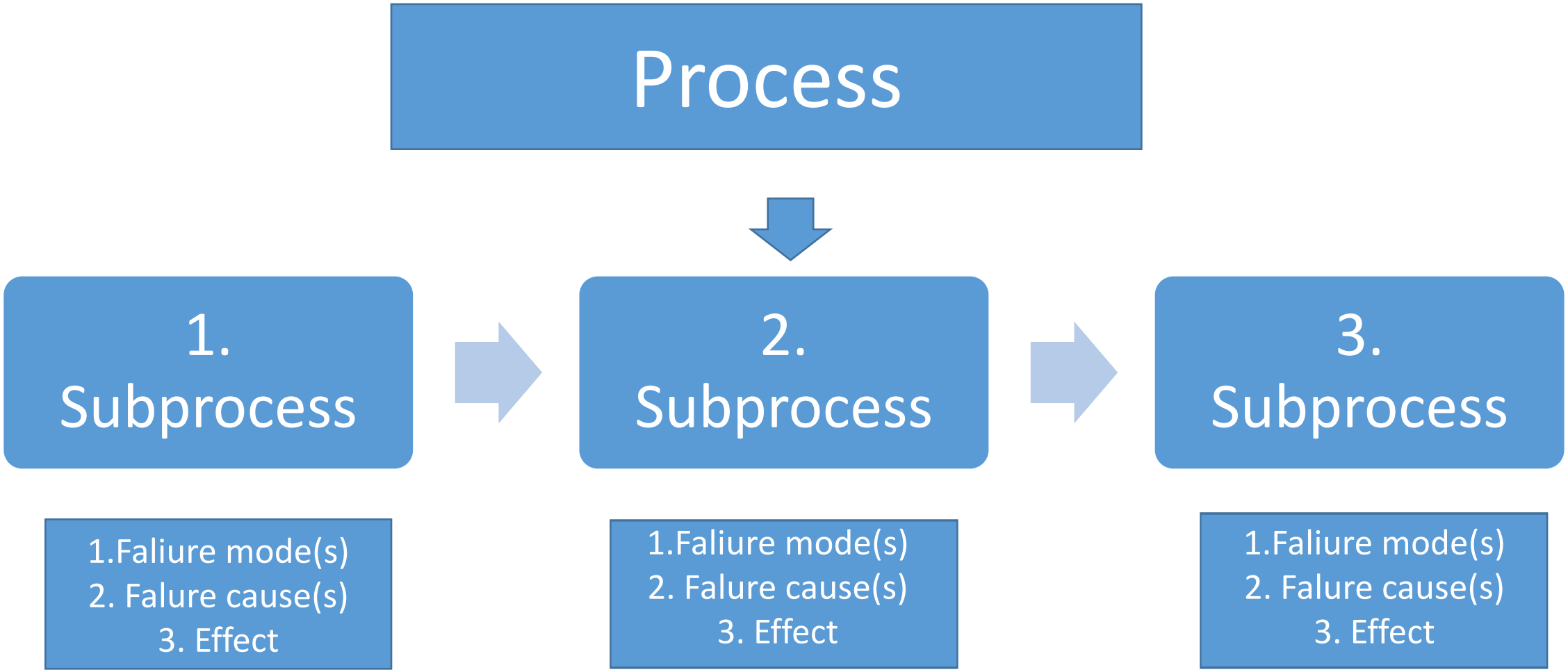

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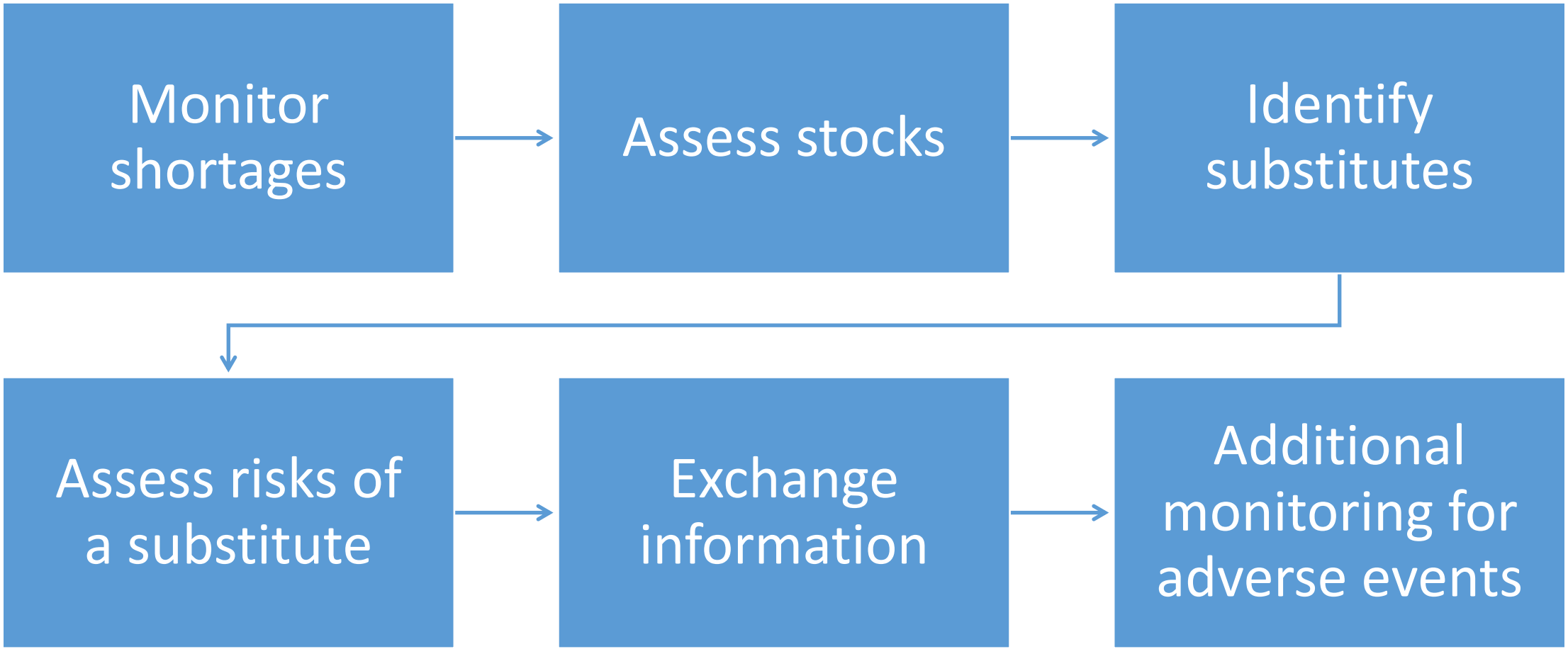

# Step 4 Conduct a Hazard Analysis

- List failure modes, causes and effects
- Determine severity and probability
- Use hazard scoring matrix
- Use the Decision tree for analysis
- Propose actions
- Recalculate the scores

DeRosier JM and Bagian JP, Proactive Risk Assessment Healthcare Failure Mode Effect Analysis Process, A cognitive aid and guidebook for the HFMEA process, Centre fo Healthcare Engineering & Patient Safety University of Michigan, 2017.

# Severity and Probability

| Severity | |
|---|---|
| Catastrophic event | Major event |
| Patient Outcome: Death or permanent loss of function (sensory, motor, physiologic, or intellectual) | Permanent lessening of bodily functioning (sensor, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients |
| Moderate event | Minor event |
| Increased length of stay or increased level of care for 1 or 2 patients | No injury, nor increased length of stay nor increased level of care |

| Probability | |
|---|---|
| Frequent | Likely to occur immediately or within a short period (may happen several times in one year) |
| Occasional | Probably will occur (may happen several times in 1 to 2 years) |
| Uncommon | Possible to occur (may happen sometime in 2 to 5 years) |

# HFMEA Scoring Matrix

| Probability | | Severity | | | |
|---|---|---|---|---|---|
| | | Catastrophic (4) | Major (3) | Moderate (2) | Minor (1) |
| | Frequent (4) | 16 | 12 | 8 | 4 |
| | Occasional (3) | 12 | 9 | 6 | 3 |
| | Uncommon (2) | 8 | 6 | 4 | 2 |
| | Remote (1) | 4 | 3 | 2 | 1 |

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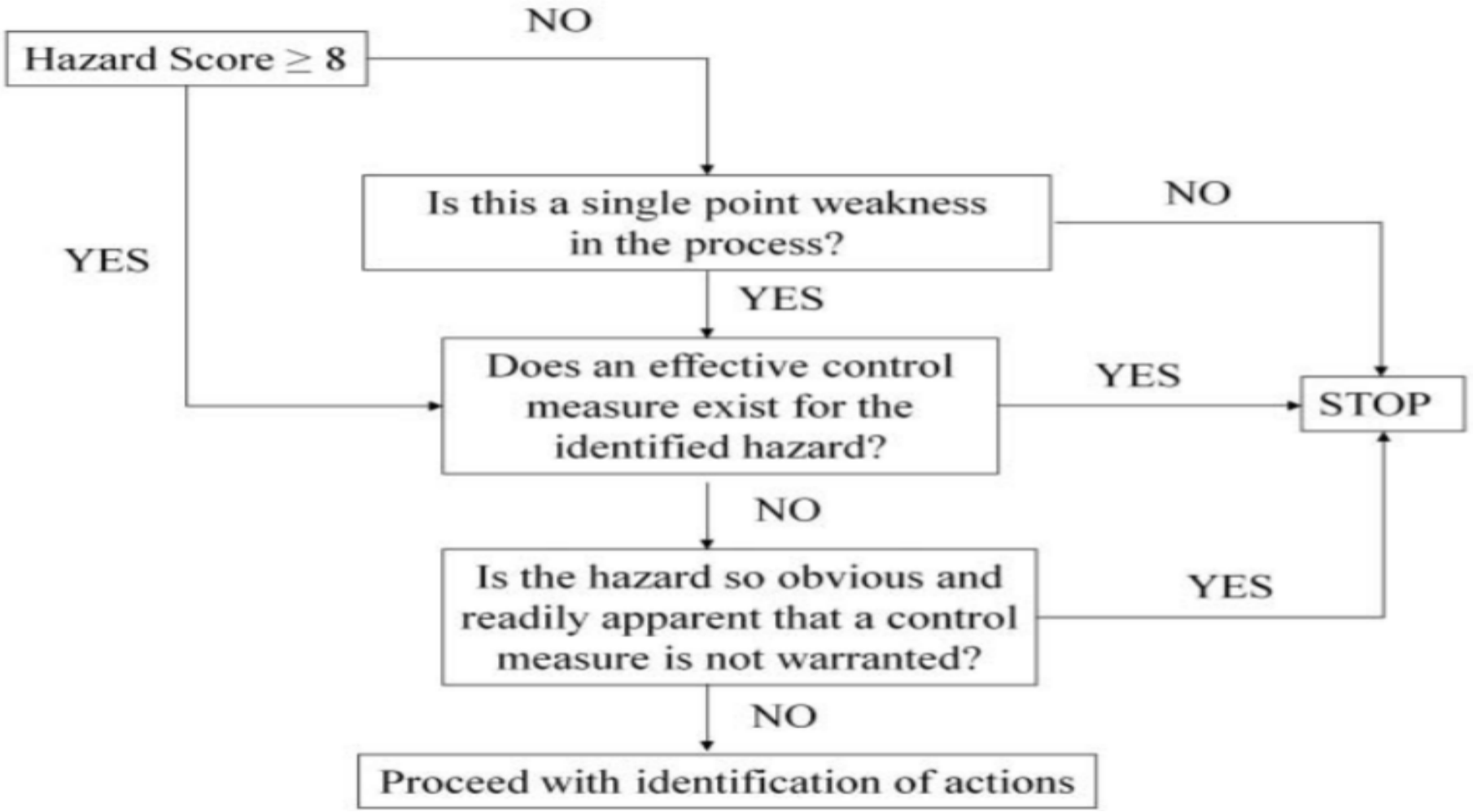
# HFMEA Decision Tree

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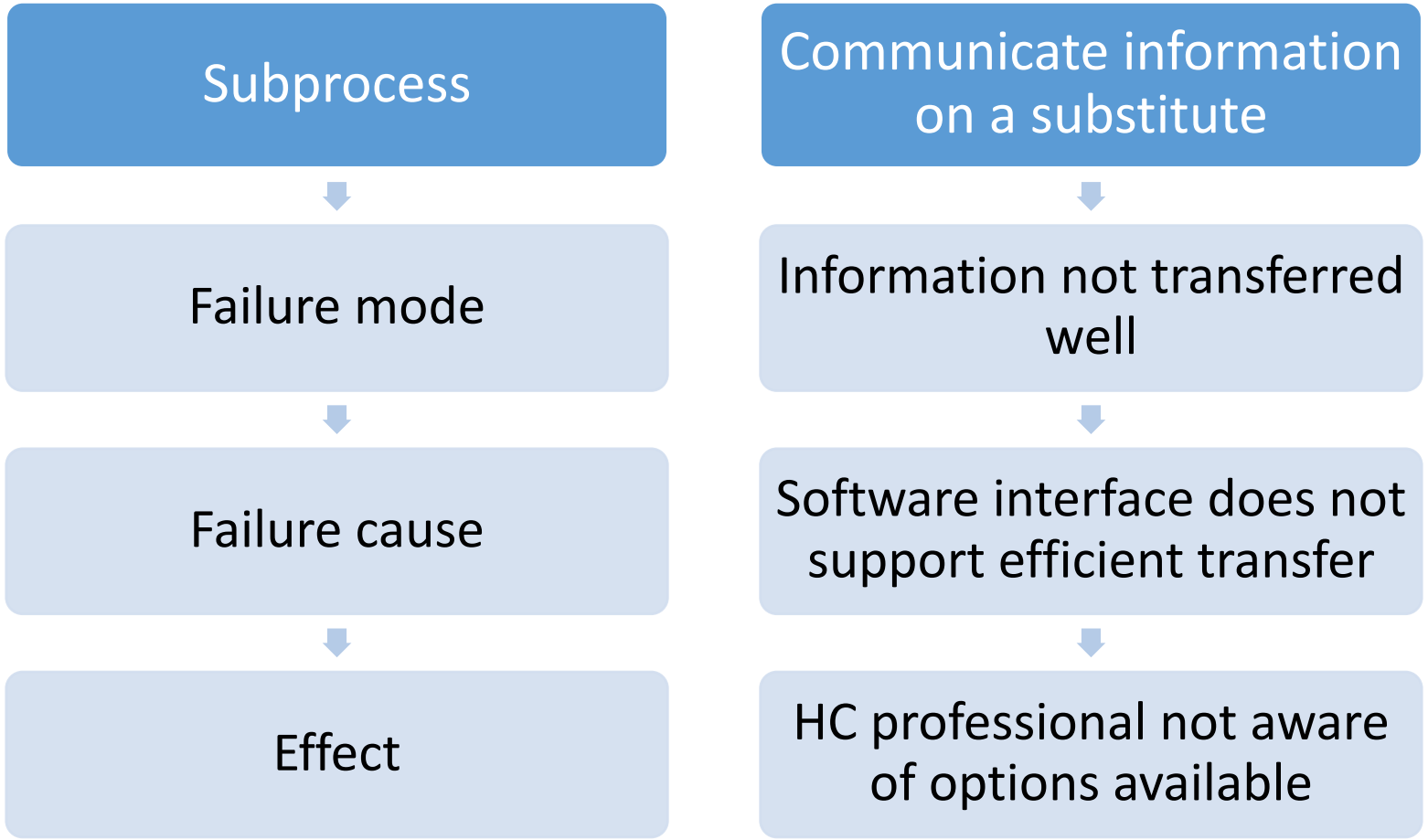
# Healthcare Settings

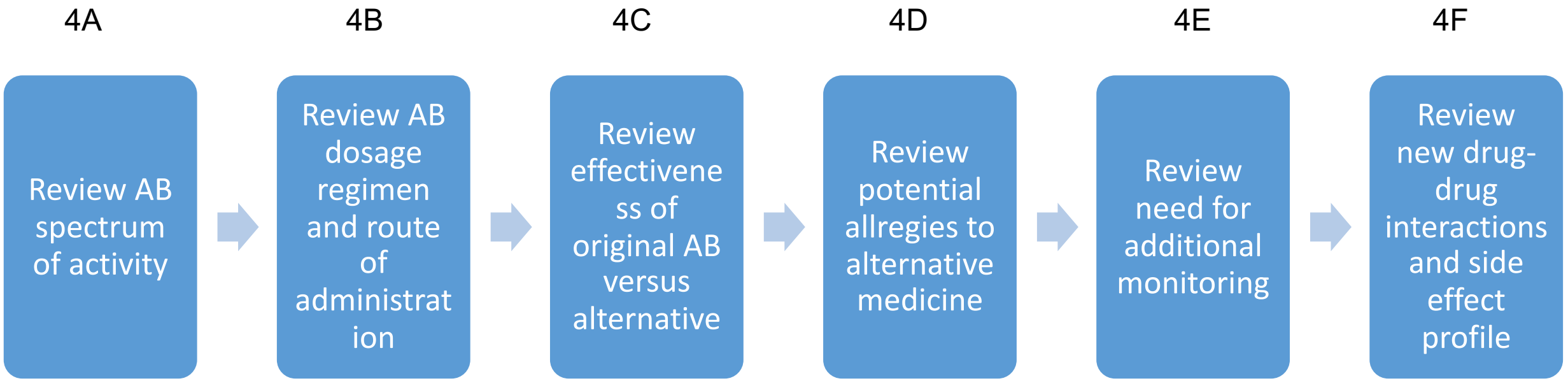
| A | B | C |
| --- | --- | --- |
| • 8 Failure Modes<br>• 38 Failure Mode Causes | • 13 Failure Modes<br>• 33 Failure Mode Causes | • 10 Failure Modes<br>• 18 Failure Mode Causes |

# Example HFMEA Key Words



# Antibiotic Substitution-Research Site A

## What to check and in what order



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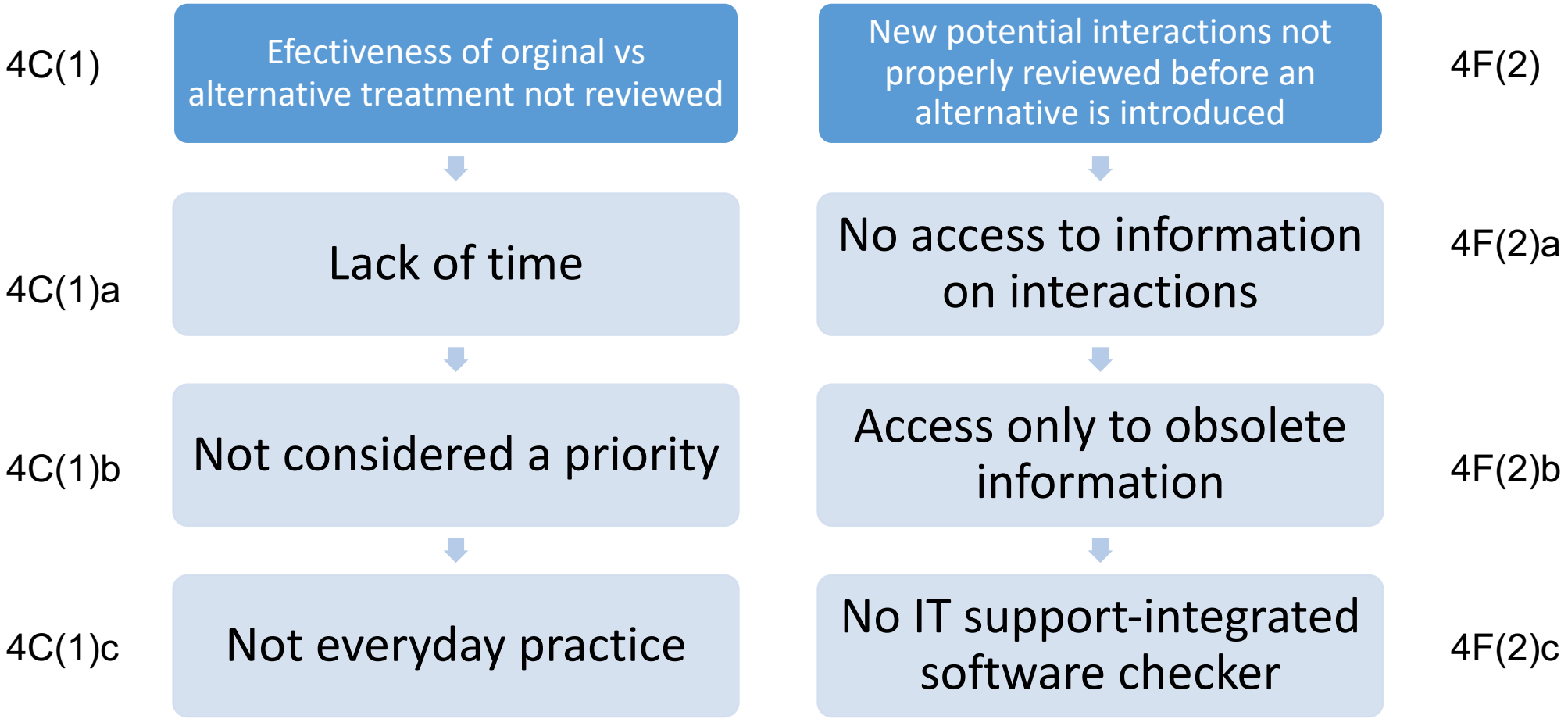


# Proposed Actions-Research Site A

## Provide

Online access and sufficient data on AB spectrum of activity

IT support at the ward/pharmacy

## Purchase

software (Lexi-Comp) and receive software PIM-Check

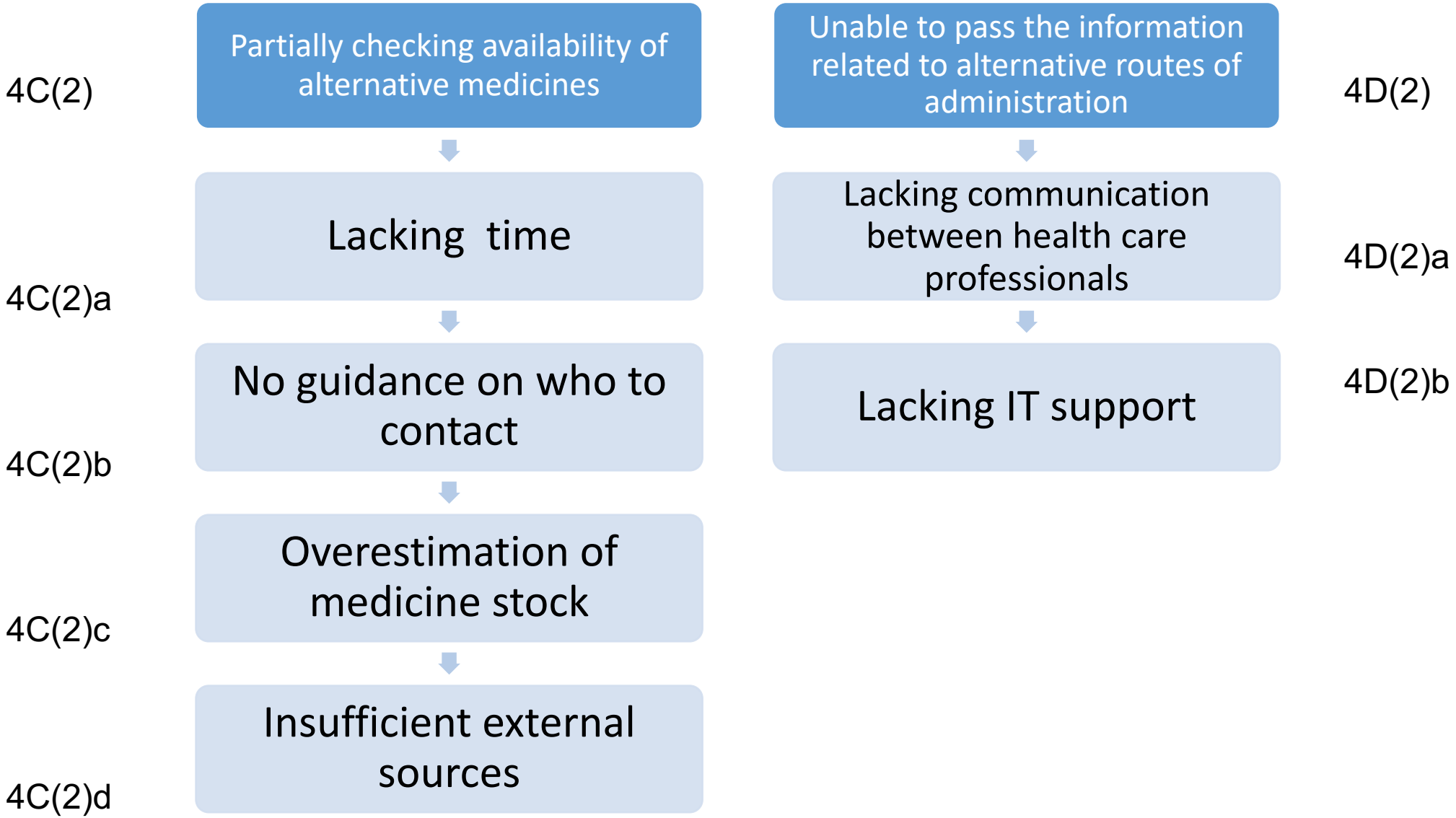
Archive obsolete paper literature to be replaced by up-to-date online resources on AB spectrum of activity

# Antibiotic Substitution-Research Site B

## What to check and in what order

| 4A | 4B | 4C | 4D | 4E | 4F |
|---|---|---|---|---|---|
| Patient's medical record. Assess criticalness of the medicine prescribed including allergies, needs | Product characteristics (SmPC) of alternative medicines based on antibacterial spectrum including the side effects profile | Availability of alternatives proposed/introduced to/by a physician | Necessity of the same administration of the antibiotic in shortage compared to the alternative | Appropriateness of substitute according to pharmacoeconomic (PE) aspects | Establish proper communication among HC professionals to introduce an alternative |

# Antibiotic Substitution-Research Site B



# Proposed Actions-Research Site B

## Provide

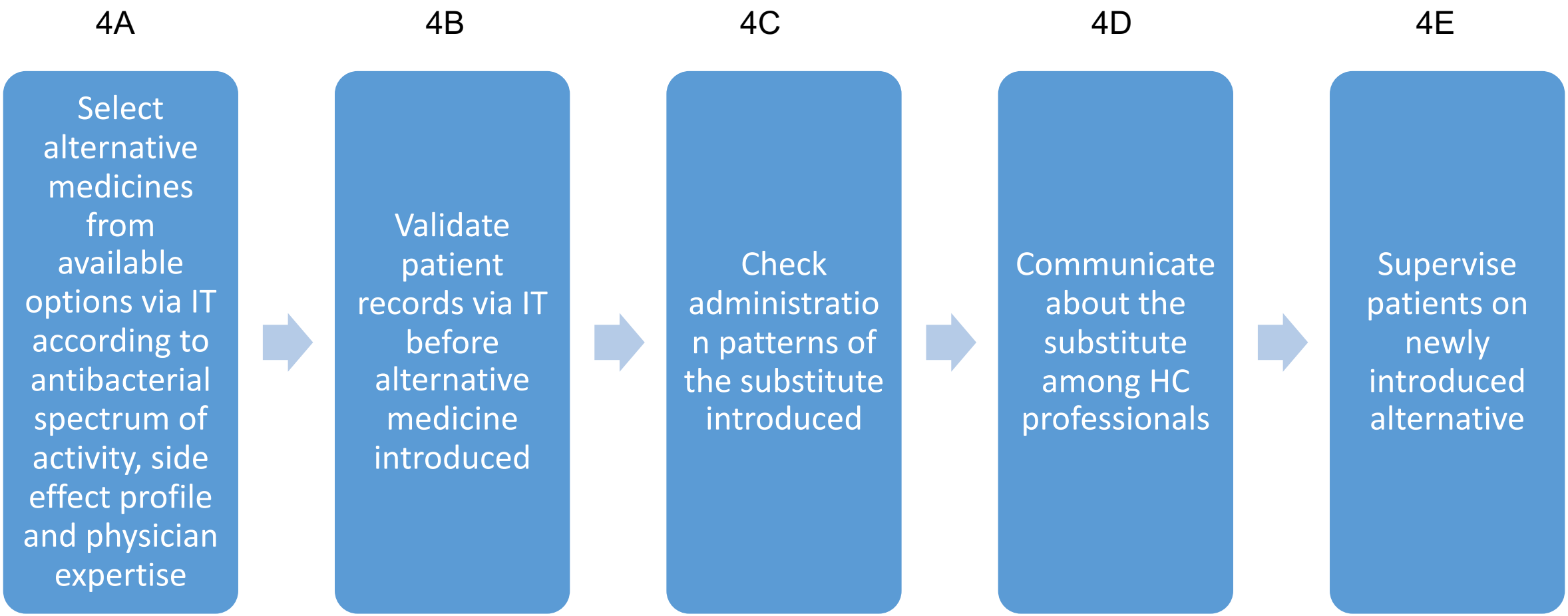
- IT support at ward/pharmacy
- SOPs for gathering information/daily ward stock assessment
- Internal/external protocols of communication

## Purhcase

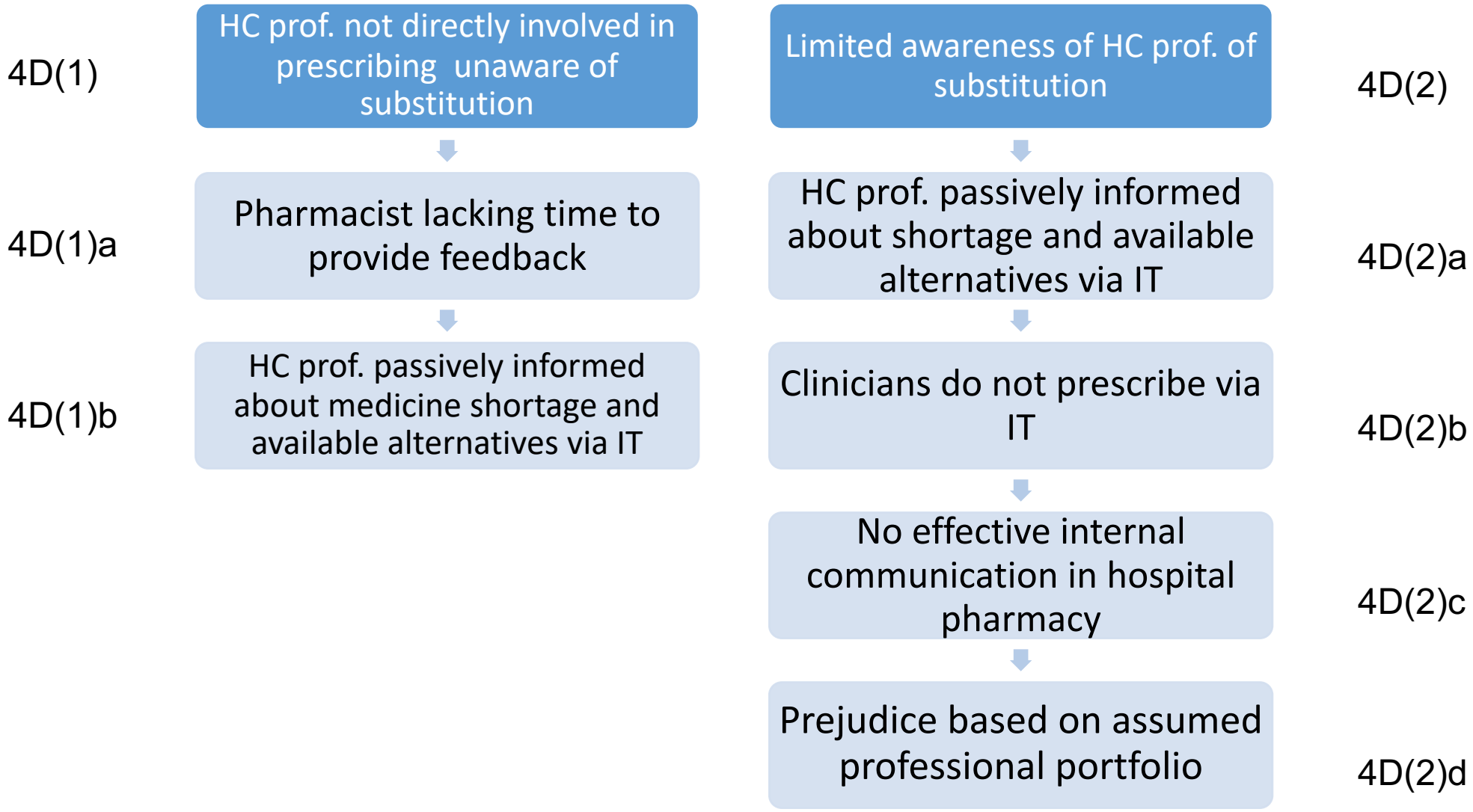
- Software Lexi-Comp
- Receive free software PIM-Check
- Intensify multidsciplinary collaboration

# Antibiotic Substitution-Research Site C

## What to check and in what order



# Antibiotic Substitution-Research Site C



# Proposed Actions-Research Site C

## Provide

- IT support regarding administration patterns
- Full supervision of contracted staff by senior staff
- Efficient less time consuming communication
- IT which actively cross-check lab data

## Prioritise

Define list of medicines for which validation is a necessity

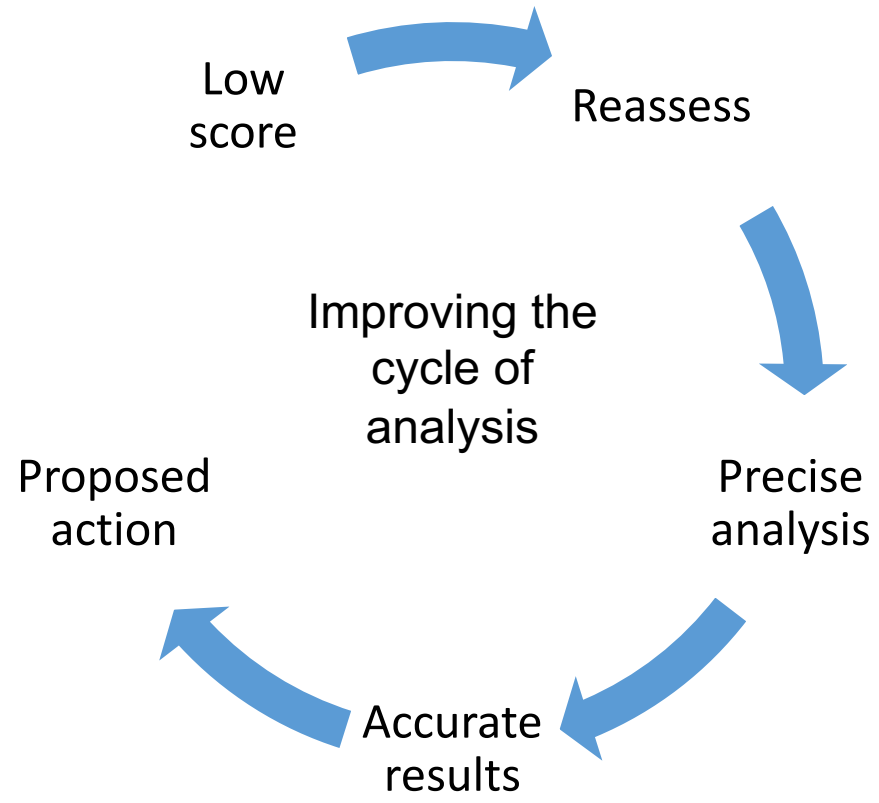
Define group of fragile patients for supervision

# Practical Implications of HFMEA

- Identifying and prioritise risks in hospital pharmacies
- Preventing chemotherapy errors
- Preventing risk to patients and medical practitioners using radiology medical devices in hospitals
- Testing surgical instrument sterilization in response to positive biological indicators
- Evaluating selected risk processes of the emergency surgery department

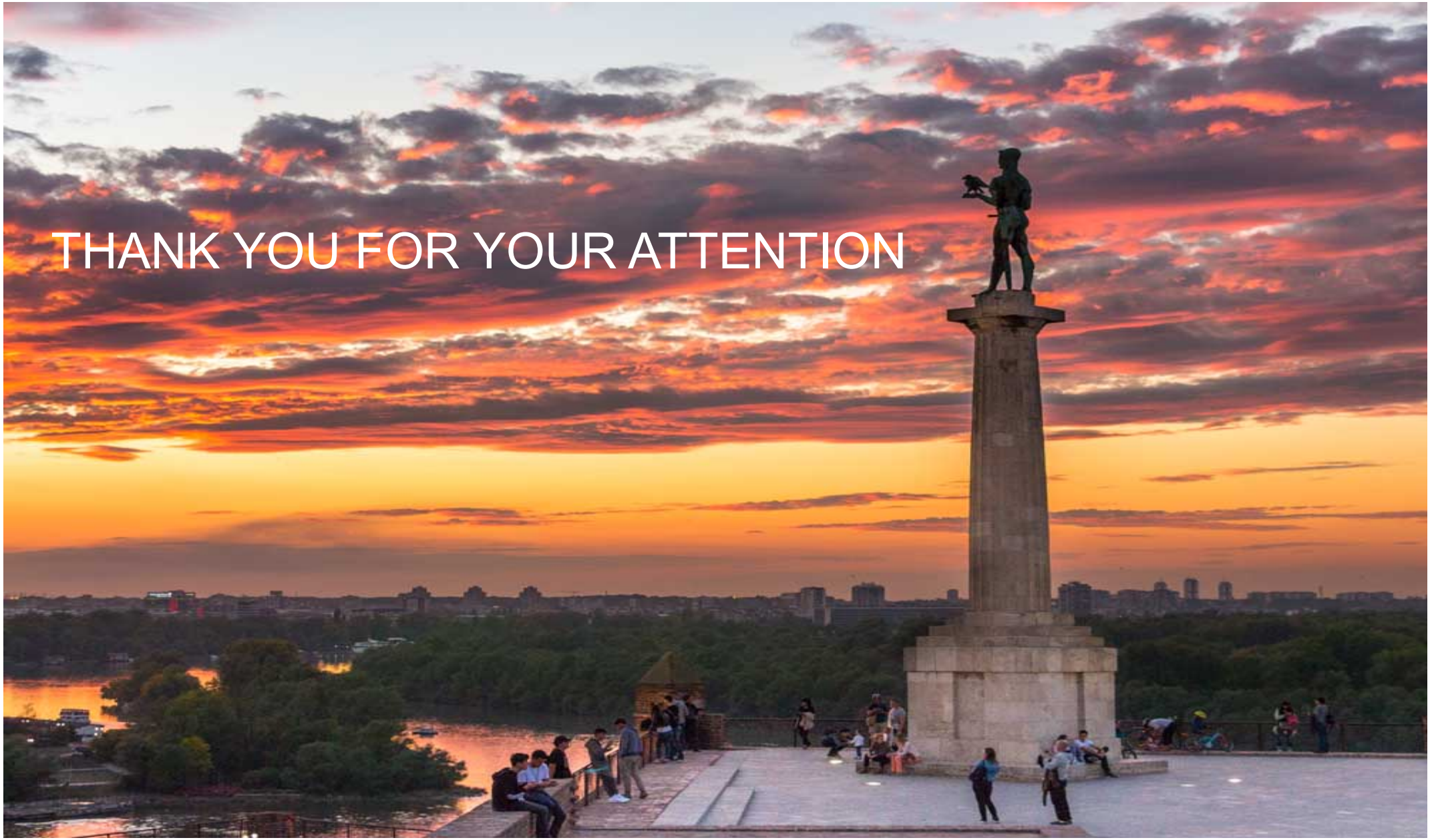
# Prioritization Depends on the Context

- High hazard scores for FM require quick measures
- Lower hazard scores (below 8) must be reasseed as HFMEA methodology provides a more precise analysis of the process



# Key Messages

- Using the HFMEA only for one process is feasible
- Be aware of potential frustration among team members due to the effort required for the HFMEA
- Do not immediately eliminate low hazard score failure modes prior to discussion within the team
- When proposing actions to control or eliminate failure modes, be aware of the real constraints posed by healthcare settings and the feasibility of each proposed action
- Think of how your medicine substitution system works


THANK YOU FOR YOUR ATTENTION