Human Factors in Barrier Thinking in Healthcare

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Barrier Thinking in Healthcare

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The importance of “Barriers” in healthcare

Never Events Policy and Framework.

NHS Improvement. (Jan 2018)

Never Events:

*“..Serious Incidents that are wholly preventable because guidance or safety recommendations that provide **strong systemic protective barriers** are available…and should have been implemented by all healthcare providers”.*

Strong systemic protective barriers:

“.. successful, reliable and comprehensive safeguards or remedies”.

“The importance, rationale and good practice use of relevant barriers should be fully understood by and robustly sustained throughout the system, from suppliers, procurers, requisitioners, training units to frontline staff”.

Content

Barrier Management concepts in High Hazard industries

- Bowtie Analysis
- Barrier quality criteria
- Issues with current practice

Examples of Bowtie Analysis applied to healthcare

1. Primary care “Never Events”
2. Human error in Radiation Oncology

NHS Education (Scotland) Guidance

- Bowtie Analysis for Healthcare practitioners

Common approaches to proactive risk analysis

“Functional Safety”

- Failure Modes and Effects Analysis (FMEA)
- Fault Tree Analysis (FTA)
- Hazard and Operability Studies (HAZID/HAZOP)
- Probabilistic Risk Assessment (PRA)
- Layers of Protection Analysis (LOPA)
  - Safety Integrity Levels (SIL)
- Process Hazard Analysis (PHA)
- Human Reliability Analysis (HRA)

What can go wrong?
How can system components fail?
How could failures escalate?
How can failures be prevented?

Assume linear model of accident causation.

Socio-technical systems approaches

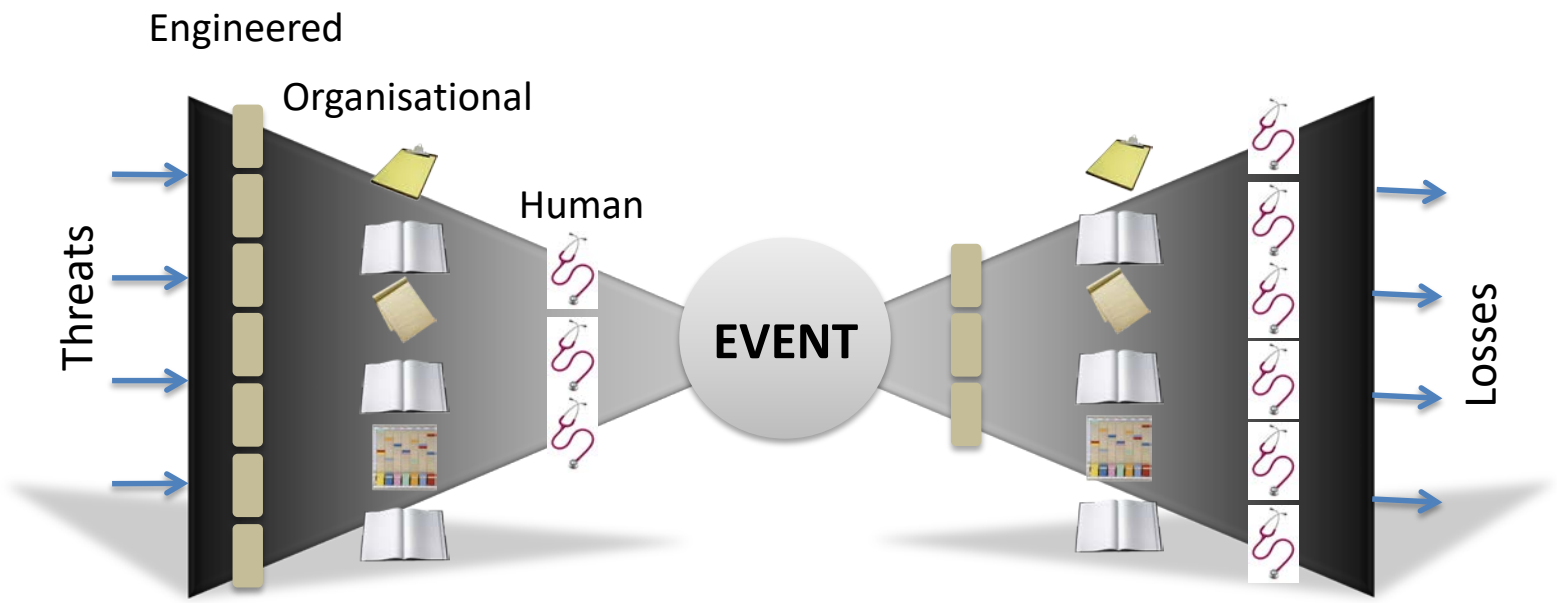
- Functional Resonance Analysis Method (FRAM)
- Systems-Theoretic Process Analysis (STPA)

Challenge assumptions of linear accident causation.

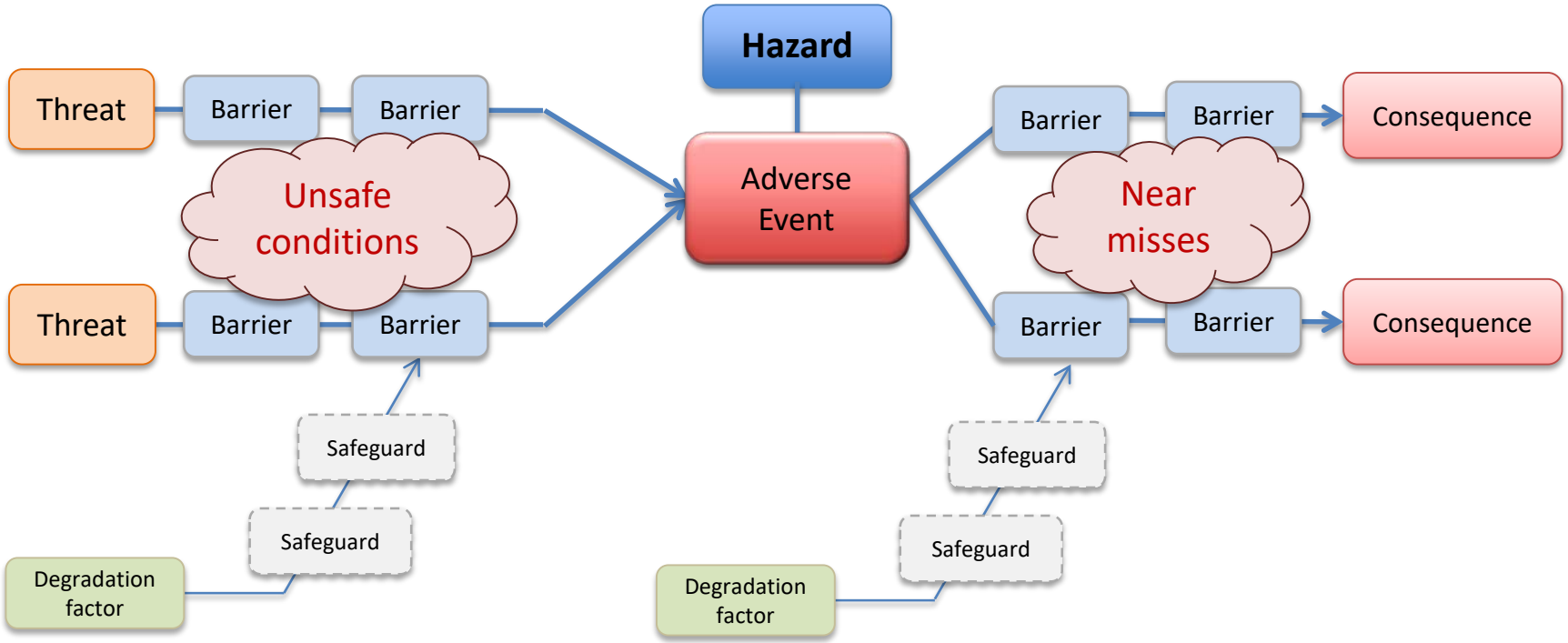
Bow-tie Analysis

Focuses on what needs to go right.
Understand how controls fail and how to assure them
Independent of failure and escalation mechanisms.

Conceptual Barrier Model



Bowtie Analysis



- Critical Equipment
  - Physical structures or equipment that support a control.
- Critical Activities
  - Human tasks necessary to assure the integrity of structural or equipment controls.
- Critical Positions
  - Roles responsible for the performance of Critical Activities.

Benefits of Bowtie Analysis in healthcare

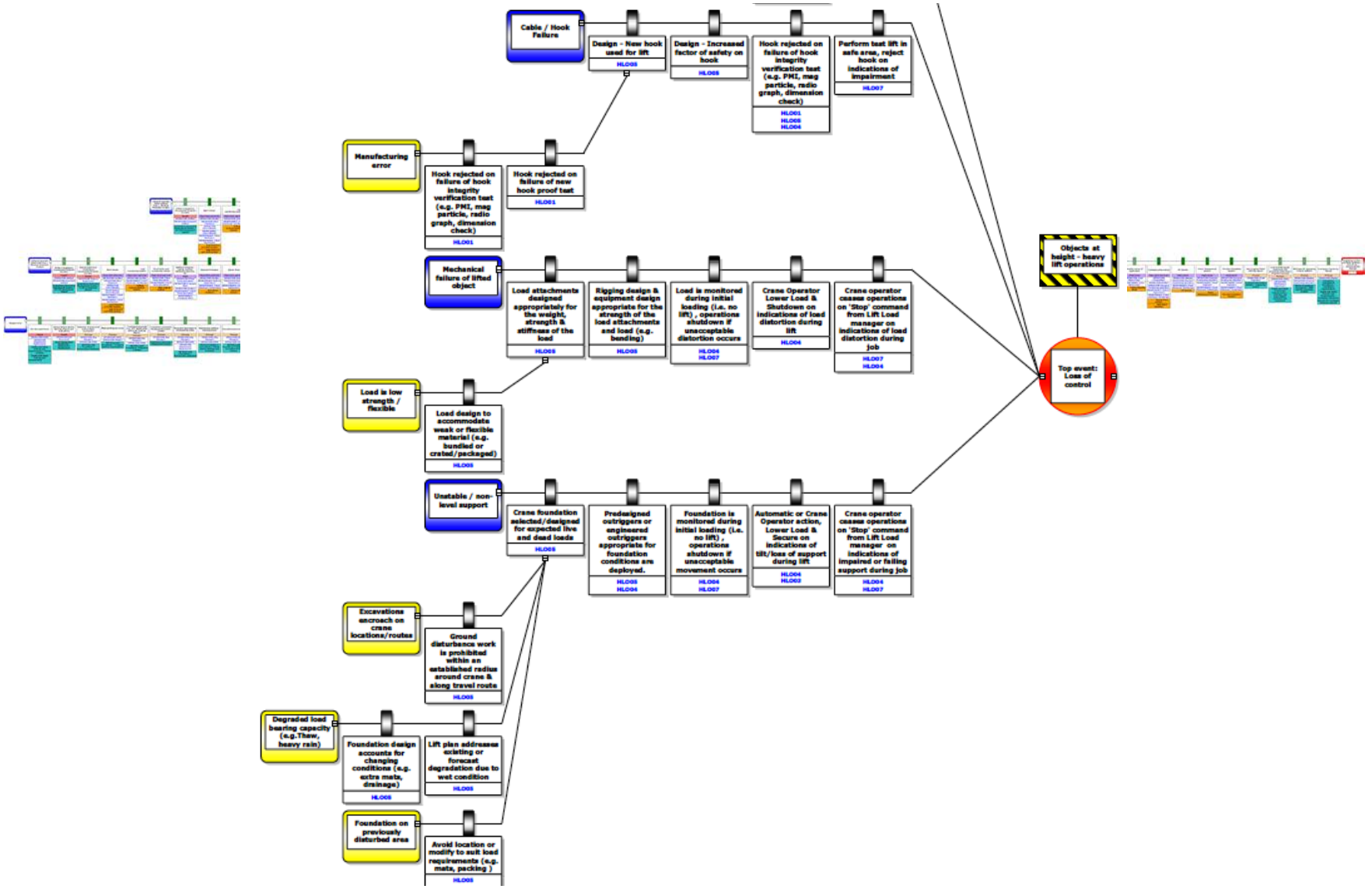
1. Improved awareness of the controls against adverse events;
2. Understanding of the quality and effectiveness of those controls;
3. Understand how controls fail, and how to protect against failure;
4. Identify where responsibility for control performance lies.
5. Recognise how different stakeholders contribute to control failure.

What goes wrong?

- Being seduced by the apparent simplicity of the method
- Jumping into drawing diagrams too early

- Lack of clarity of the Hazard / Adverse Event
- Too many “Barriers”
  - Not using barrier quality criteria
  - Not distinguishing between “Barriers” and “Safeguards
- Locating the adverse event too far to the right
- Treating human error as a Threat
  - It is a Degradation Factor

Too many Barriers!



The nature of Barriers

- Capable of blocking the threat on its own
  - Provided it functions as expected.
- Can be Passive or Active
- Active barriers must be able to: Detect, Decide and Act.
  - Often relies on individual Elements to achieve the three functions.

- The decision to call a control a “Barrier” will often be subjective:
  - Declaring a “Barrier” implies a commitment to allocate time and effort to ensuring the barrier is in place and effective
    - It requires a “Barrier Management Plan”

Barrier quality criteria

1. Ownership
   Somebody knows they are responsible for its existence and performance
2. Traceable
   To Management System
3. Specific
   To the threat/event
4. Effective
   Capable – if everything else fails - of blocking the threat
5. Independent
   A single failure should not be able to defeat more than one control
6. Capable of being Assured
   Evidence that it is in place and functioning as intended

“Key Safeguards”

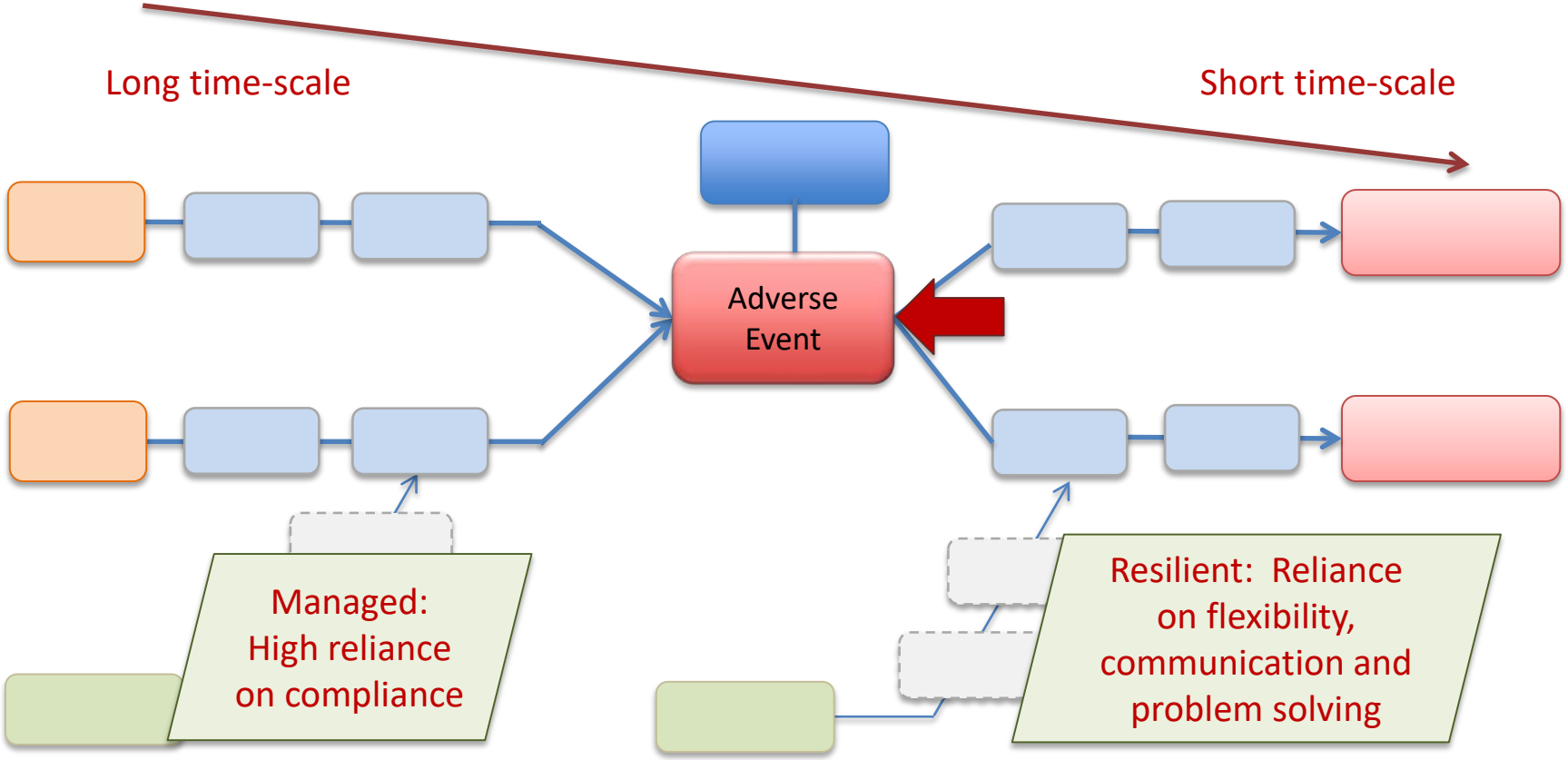
There are few genuine full “Barriers” in healthcare

- There is a high reliance on “Safeguards”
- Barriers can be designed-in to protect against misuse of equipment.

“Key Safeguards”

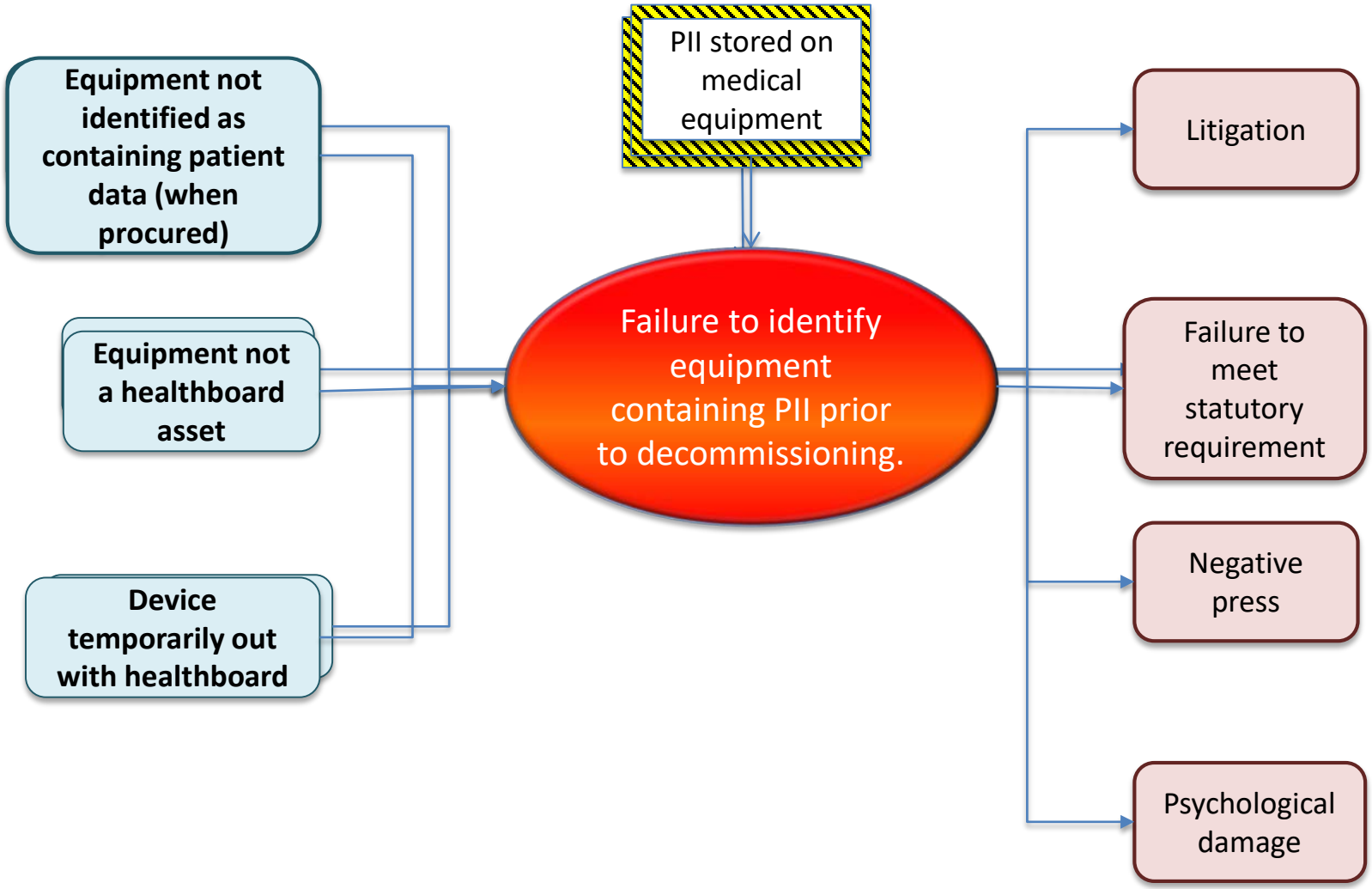
- Controls that cannot satisfy the conditions to be declared as “Barriers”
- But nevertheless must be relied on
  - Are more important than other “Safeguards”
- Require special effort and attention
  - Included in the Barrier Management Plan
  - Recognition that they are inherently less robust.

Locating the Adverse Event



Labels/ alerts	Cross-checks	A&E	ICU
£	£	££	£££

Example of Adverse Event too far to the right



Example 1: Bowtie Analysis in primary care

McLeod, R. W. and Bowie, P. (2018) '*Bowtie Analysis as a Prospective Risk Assessment Technique in Primary Healthcare*'. Policy and Practice in Health and Safety. May

1 day workshop

- 4 GPs
- 2 Practice Managers
- 2 Patient Safety researchers

Top Event = "Never Event"

- *Prescribing systemic oestrogen-only hormone replacement therapy for a patient with an intact uterus*
- 37/501 (7%) GPs estimate it to have occurred at least once in the previous year
- 29% estimate likely to occur in the next five years in their practices.

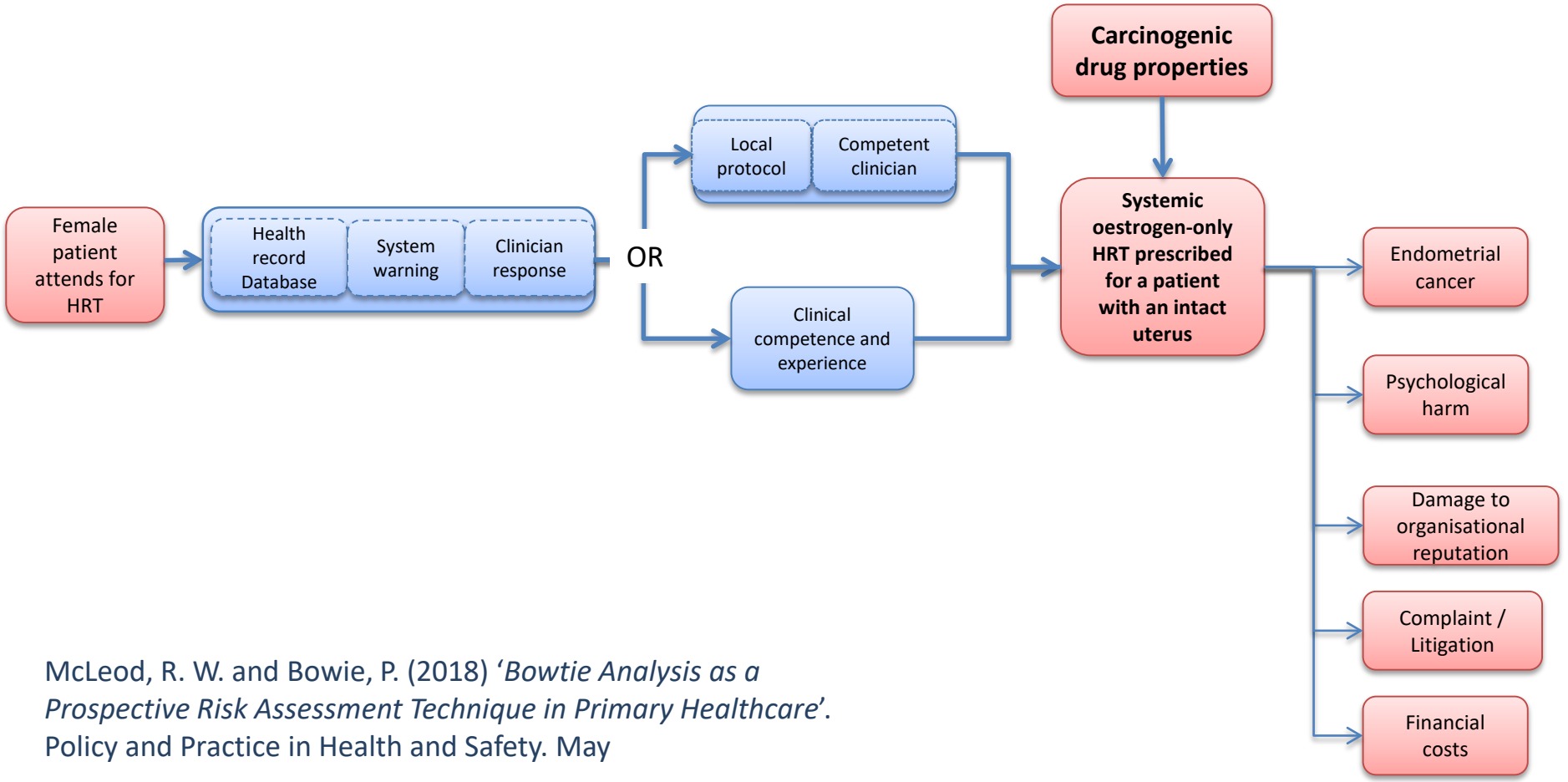
Suggested controls included;

- Electronic health records
- Pharmacy review of prescriptions
- Prescriber knowledge and experience
- Formal cross check by GP colleague
- Protocol / policy / procedures
- Formulary
- Patient knowledge
- Regular review of patient records

Are any of these Barriers?

Key Safeguards?

Example 1: Bowtie framework for a “Never Event”



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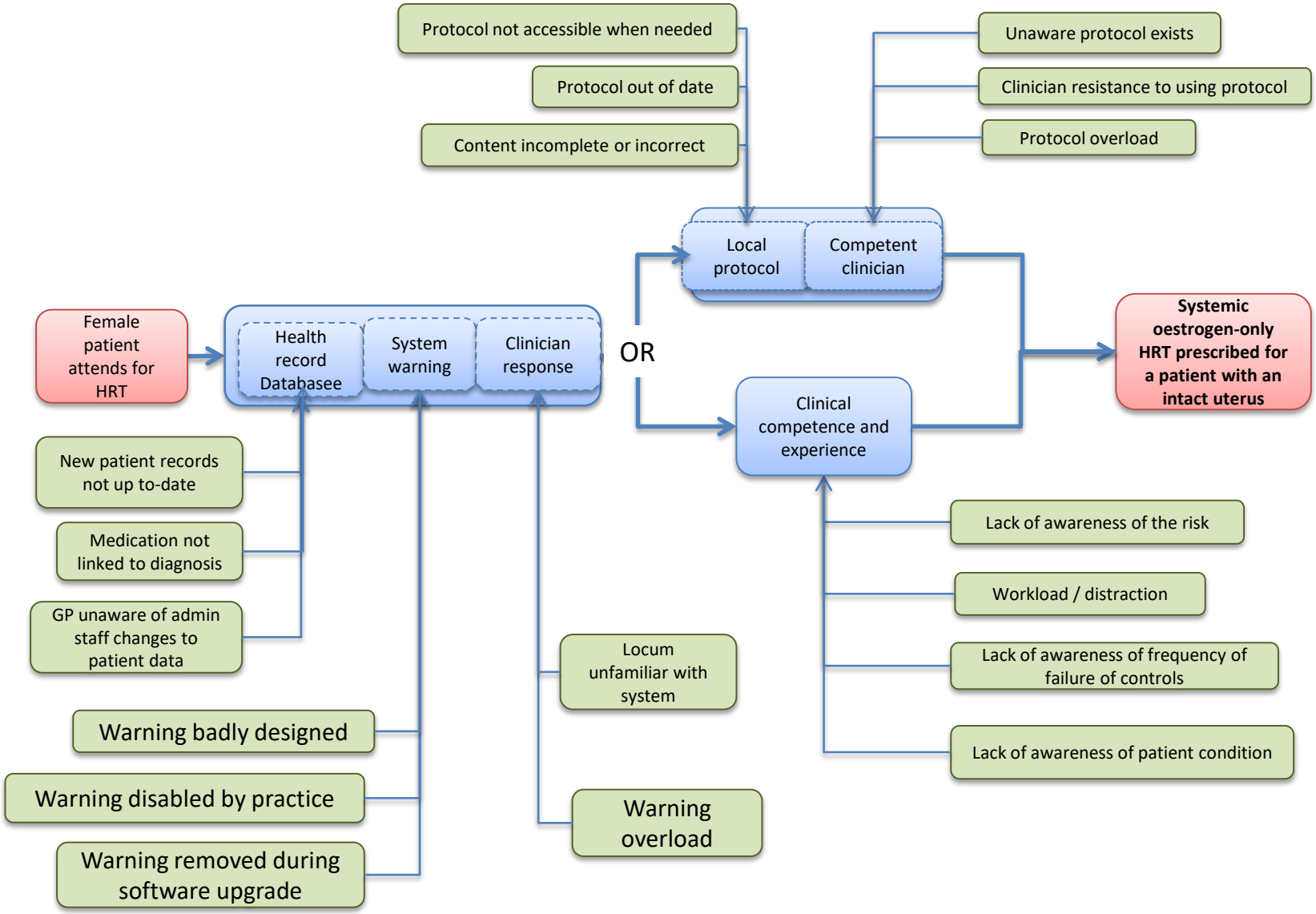
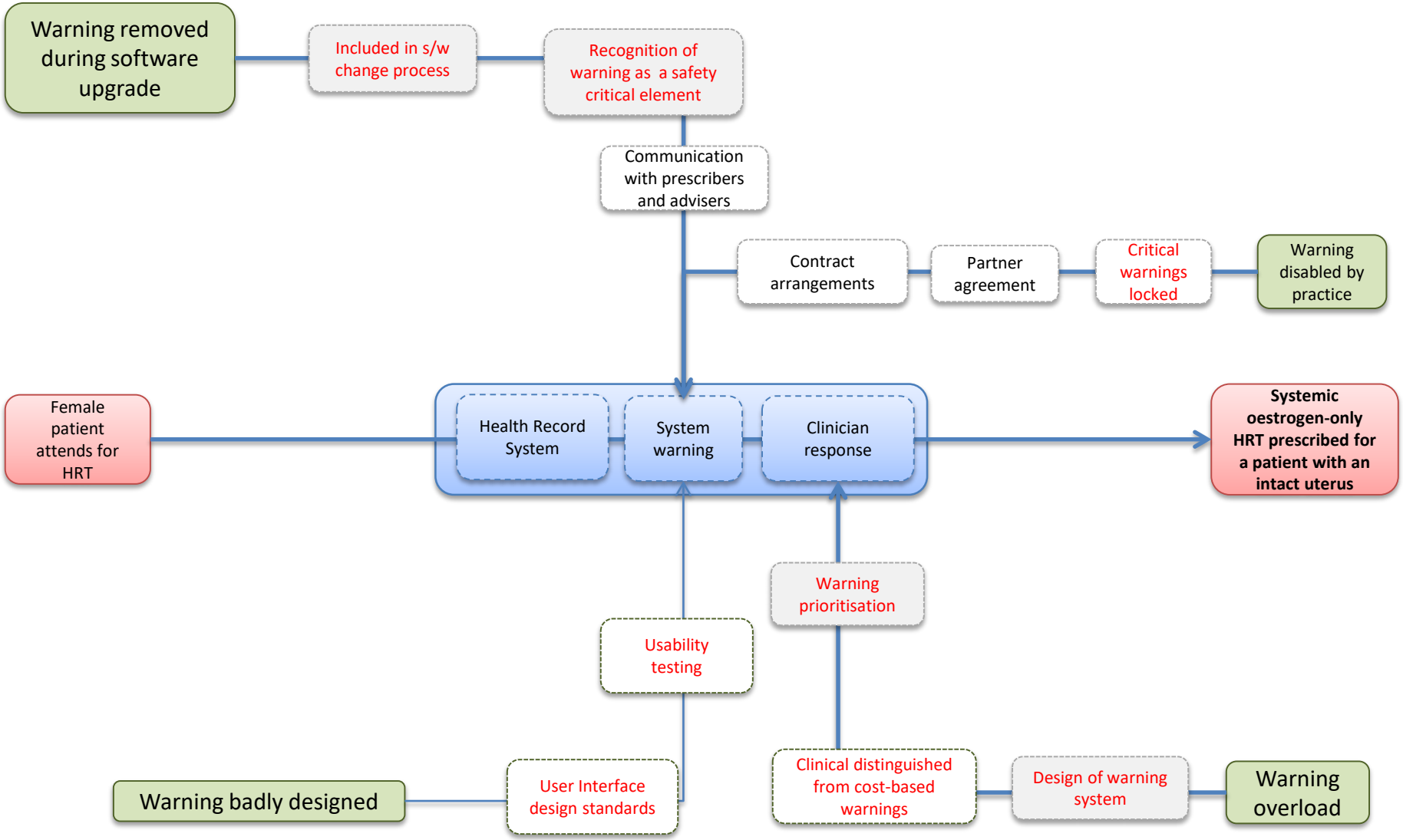
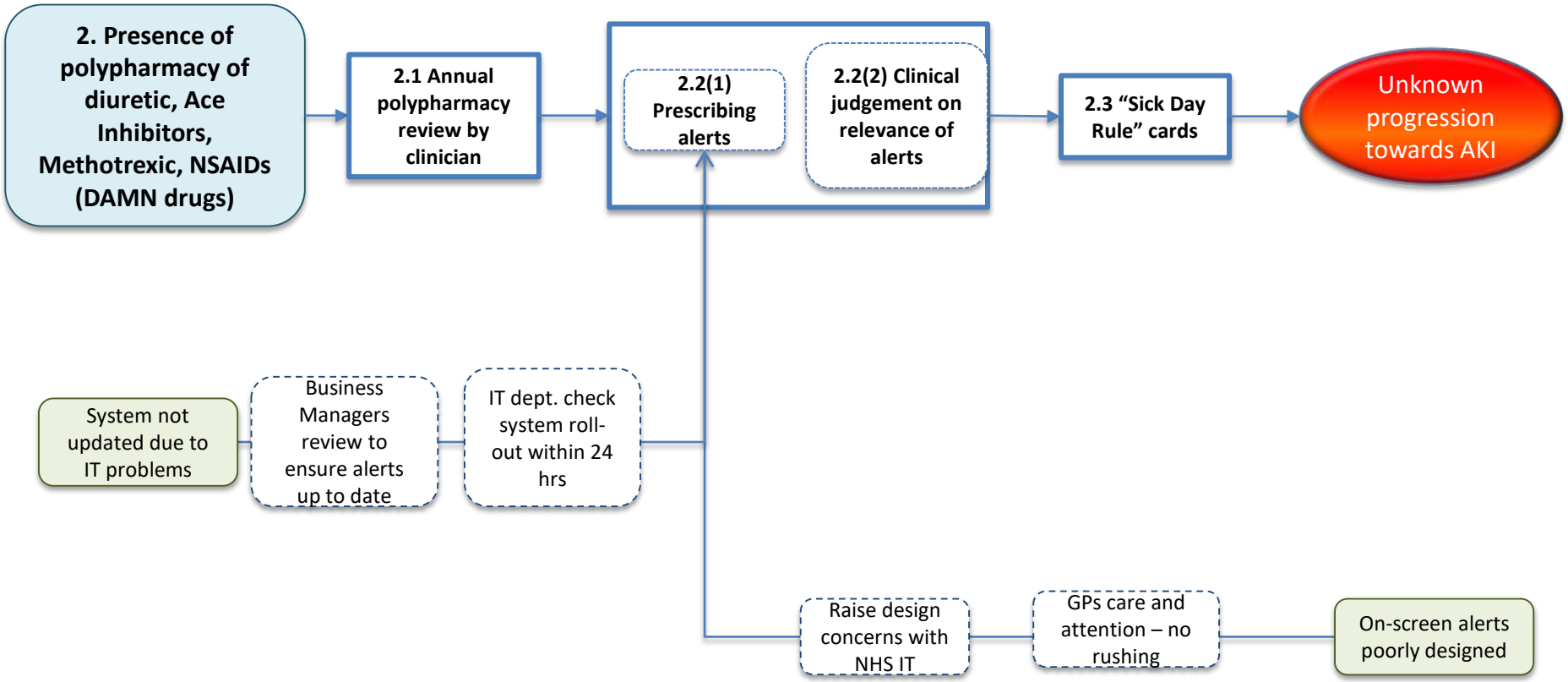
“Never Event” barrier degradation factors



Safeguards against barrier degradation



Unknown progression towards AKI



Example 2: Bowties in Radiation Oncology

Mullins, et al. (2019) '*Human Error Bowtie Analysis to Enhance Patient Safety in Radiation Oncology*'. Practical Radiation Oncology. **9**, 465-478

- Collaborative study between University of North Carolina, University of Michigan and Ohio State University
- Explored potential use of Bowtie Analysis for understanding human errors that defeat controls in Radiation Therapy
  - Used concept of ***Layered Bowties*** to examine human error as a degradation factor for main controls.
- Adverse Event = Site Set-up errors
- Data from voluntary incident reporting systems used to examine effectiveness of controls against human error in RT care path.

$$\text{Control Effectiveness} = \frac{\text{N (Control caught the error)}}{\text{N (Opportunities for control to catch the error)}}$$

RT Care-path

Mullins, et al. (2019) '*Human Error Bowtie Analysis to Enhance Patient Safety in Radiation Oncology*'. Practical Radiation Oncology. **9**, 465-478

Patient Assessment

1.00	Attending, Resident, or APP reviews pertinent medical records (pathology report, imaging and outside records)
1.01	Attending decides to treat and determines urgency as applicable
1.02	Attending, Resident, or APP discusses patient case at Tumor Board as applicable (evaluation of other Tx modalities: chemo, surgery)
1.03	Patient checks in for consult
1.04	Admin verifies patient ID at check-in
1.05	RN takes patient vital signs
1.06	RN completes nursing assessment, including 3Ps (information on pregnancy, pacemaker, prior radiation)
1.07	RN provides patient education
1.08	RN communicates with ancillary services as applicable (social work, nutrition, speech, CCP, pain team, smoking cessation, etc.)
1.09	RN documents nursing assessment in EPIC and Mosaiq
1.10	Attending, Resident, or APP interviews, examines, assesses patient, determines intent to treat
1.11	Attending, Resident, or APP consents patient
1.12	Attending, Resident, or APP orders follow-up apt, CT sim, labs, imaging, or special procedures
1.13	Attending, Resident, or APP enters documentation, meaningful use, billing into electronic medical record (EMR)
1.14	Attending reviews and approves documentation, meaningful use, billing entered into EMR
1.15	Attending , Resident, or APP defines and enters diagnosis and clinical staging into EMR

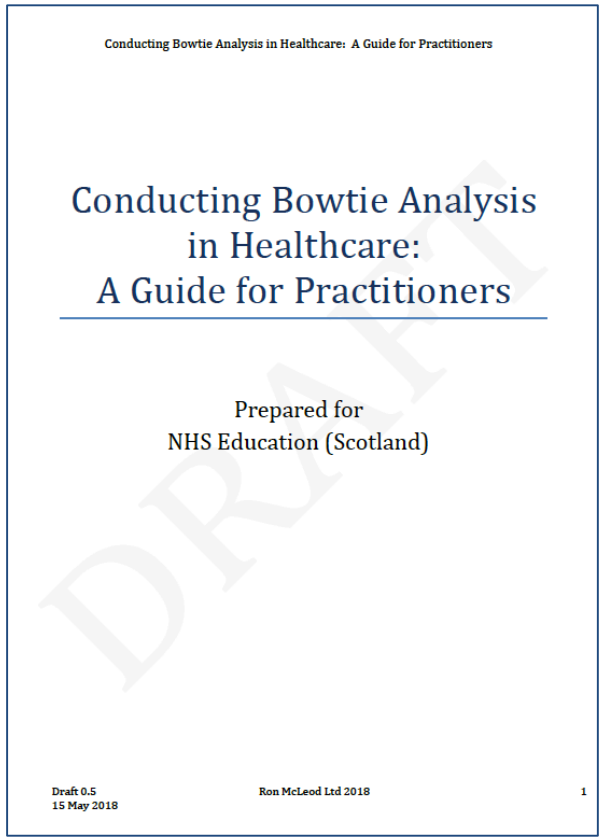
Legend

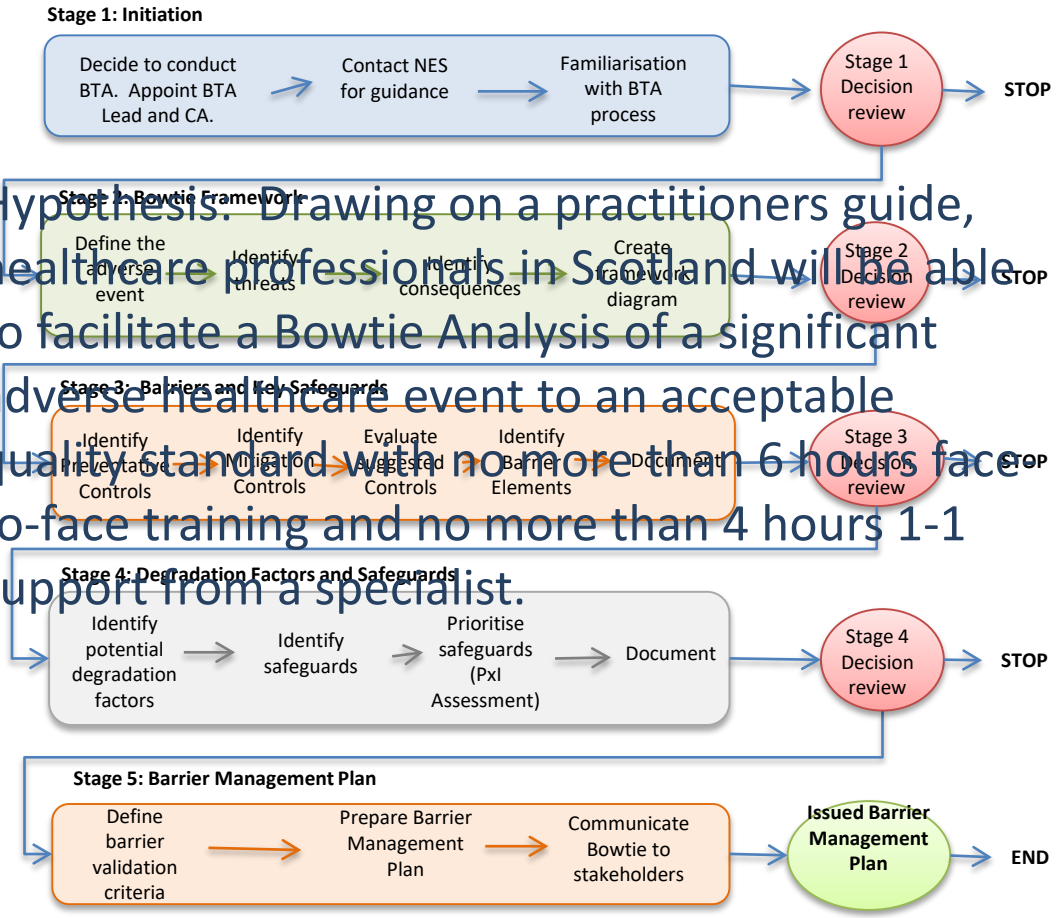
APP: Advance Practice Practitioner
RN: Registered Nurse
3Ps: History of prior RT, current pregnancy, or current pacemaker placement.
CCSP: Certified Cancer Support Program

Analysis of controls against human error in RT

Control	Type	Ownership	Traceable	Auditable	Specific	Indep'ent	Effective
Threat 1: Conflicting bladder information							
Physics pre-treatment checklist	Safeg'd	✓	✓	✓	✓	✓	1 / 5
MD reviews and approves setup	Safeg'd	✓	✓	✓	✓	X	0 / 4
MD day/week image review	Safeg'd	✓	✓	✓	✓	X	0 / 4
Physics weekly chart check	Safeg'd	✓	✓	✓	✓	✓	4 / 4

NES Guidance: Bowtie Analysis for Healthcare Practitioners





Hypothesis: Drawing on a practitioners guide, healthcare professionals in Scotland will be able to facilitate a Bowtie Analysis of a significant adverse healthcare event to an acceptable quality standard with no more than 6 hours face-to-face training and no more than 4 hours 1-1 support from a specialist.

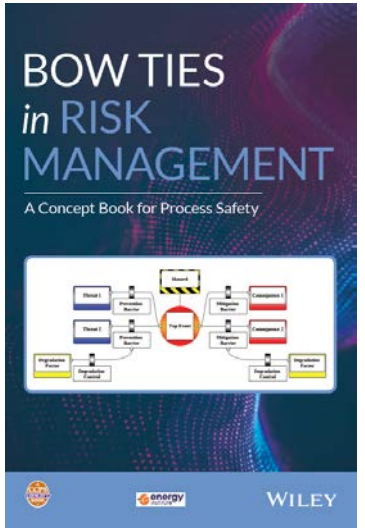
Summary and Take-aways

- Healthcare relies on many Controls to protect patient safety
  - "layers of protection"…"protective measures"..."checks and balances"..."safeguards"…"safety critical elements"
- Controls can be of different types, depending on the protection provided;
  - "Barriers"; "Key Safeguards', "Safeguards".
  - Technical; Operational; Organisational
  - There are few full "Barriers" in healthcare.
    - Though there should be many protecting against errors using equipment
- Bowtie Analysis offers a powerful and accessible means of understanding and assuring the Controls relied on in healthcare.
  - Understanding how good those controls really are;
  - Understanding how they fail, and how to protect against failure;
  - Knowing where responsibility for the performance of controls lies;
  - Recognising how different stakeholders can contribute to control failure.
- Customisation is needed when applying BTA to healthcare.
  - Don't be seduced by the apparent conceptual simplicity
  - Don't jump into drawing diagrams too early –
    - Take time to think and understand the risk space.
    - Barrier quality criteria discriminate between Barriers, Key Safeguards and Safeguards
- Bowtie Analysis can be used both prospectively (in planning and design) and retrospectively (in incident investigations)

Bowtie Analysis – Industry Best Practice

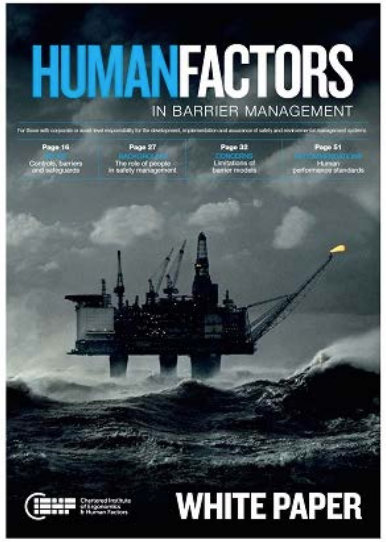
Centre for Chemical Process Safety (CCPS)/ Energy Institute (EI)

- Concept Book: “Bowties for Risk Management”



Chartered Institute of Ergonomics and Human Factors (CIEHF)

- White paper: “Human Factors in Barrier Thinking”
- www.ergonomic.org.uk



Thank you for your attention

Any Questions?

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