



# Drug errors and the law

Robin Ferner

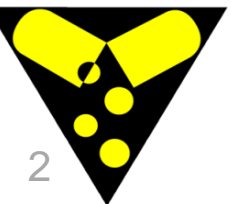
University of Birmingham



# Fact

Edinburgh is west of Bristol

- **Edinburgh**       $3^{\circ} 13' W$
- **Bristol**             $2^{\circ} 35' W$



# What is an error?

An **error** occurs when an action is intended but not performed

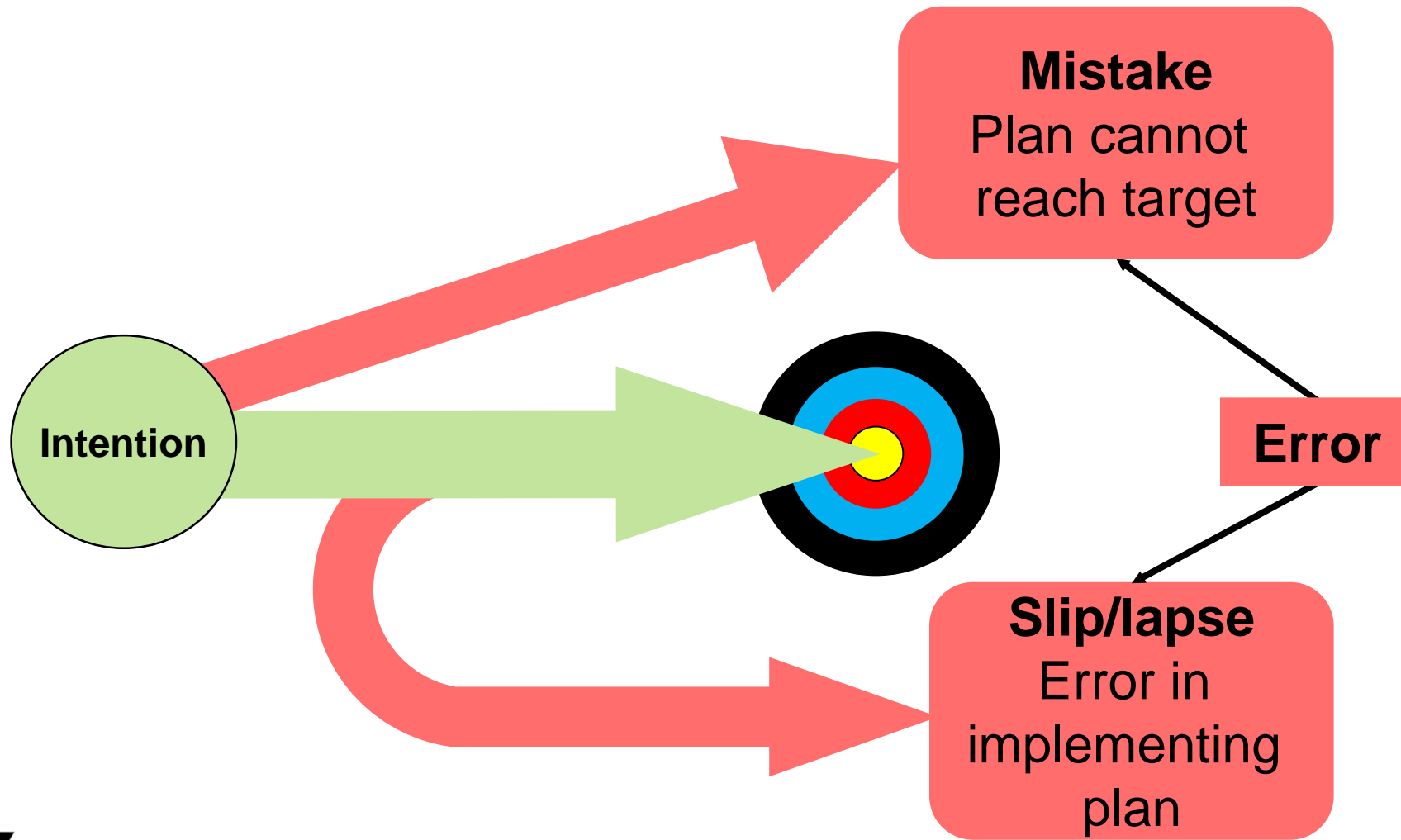
Unintentional

A **violation** is a conscious act that contravene accepted rules

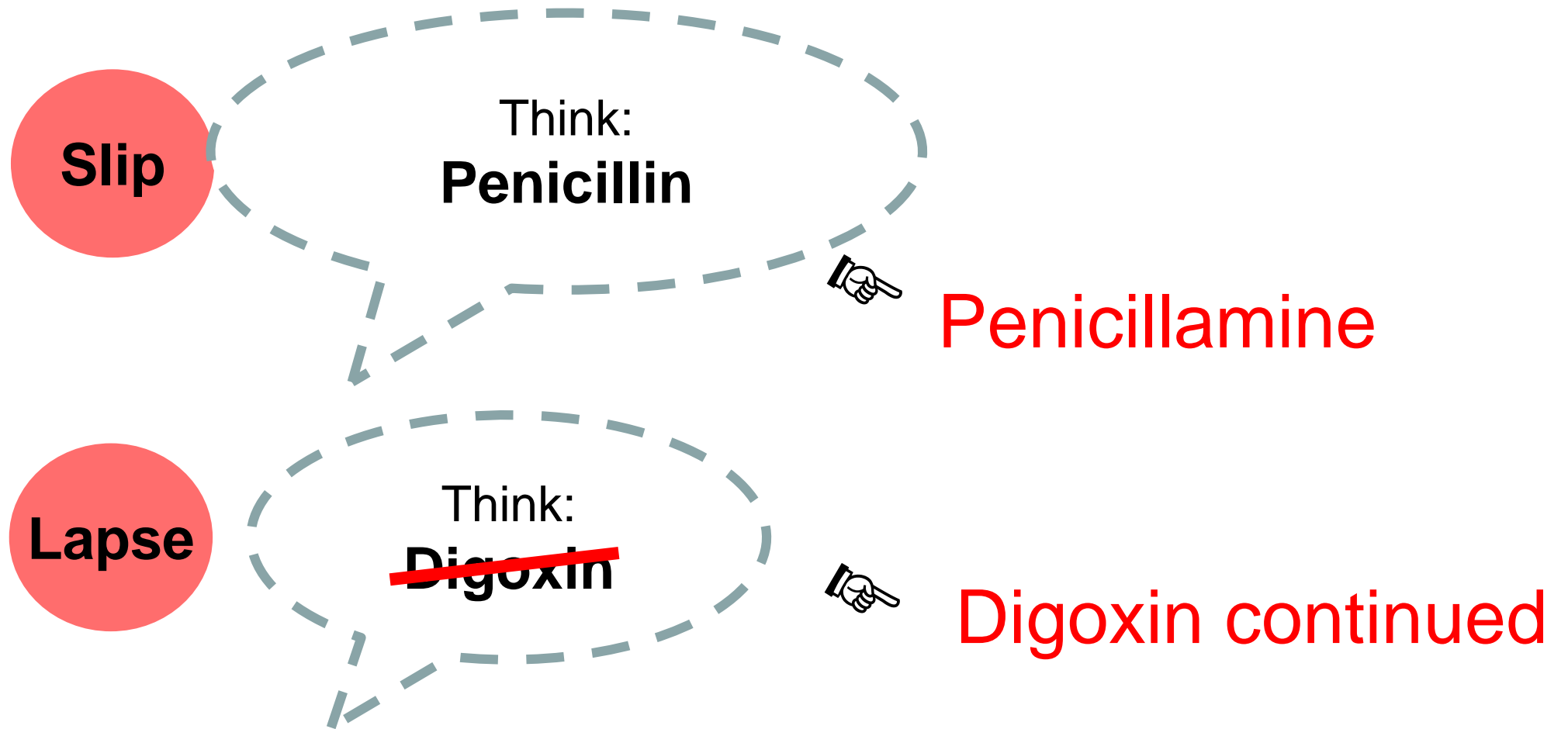
Intentional

James Reason *Human Error* 1990

# We all make errors



# Slips and lapses: skill-based errors



# Mistakes: knowledge-based errors

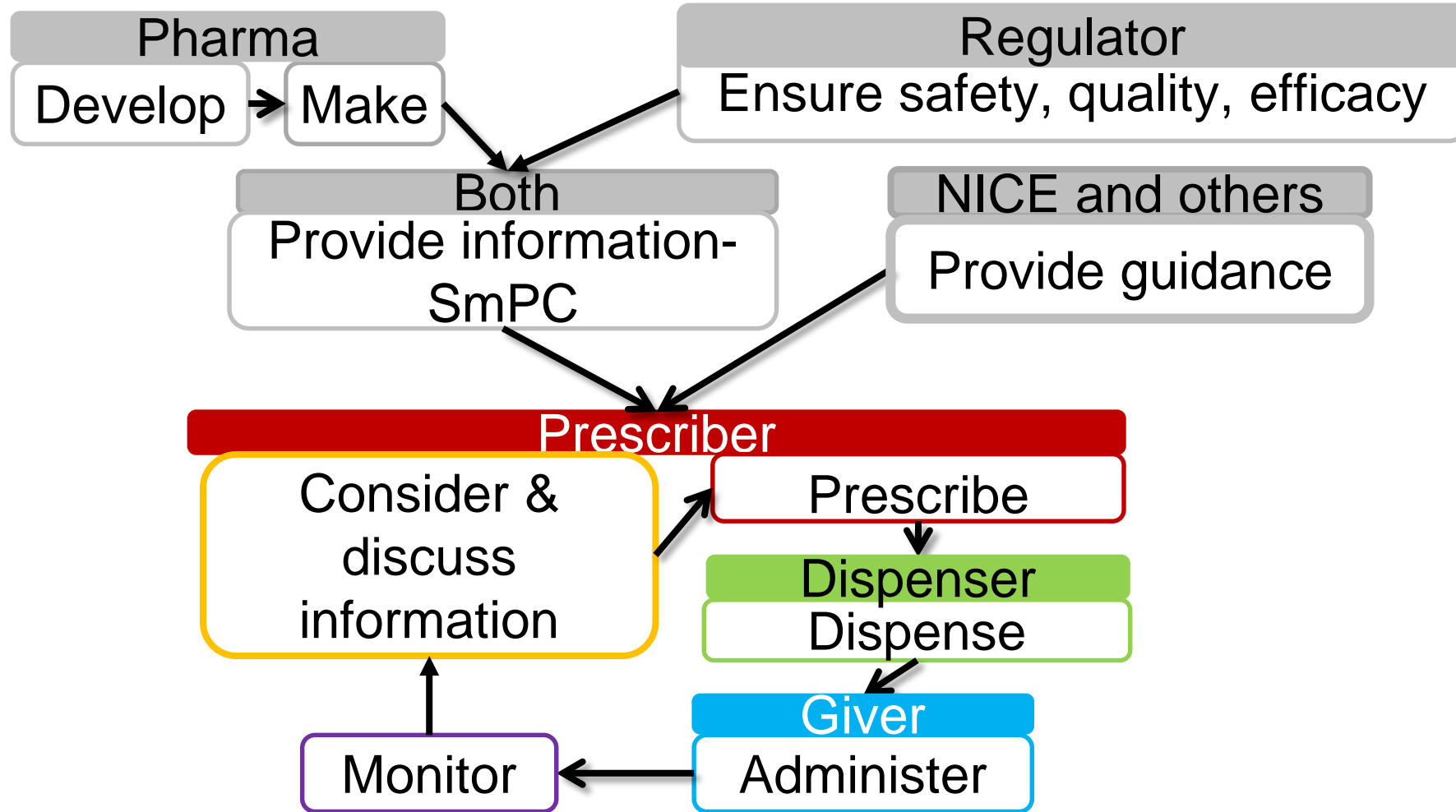
**Mistake**

Tamsulosin



‘Tamsulosin hydrochloride should not be given in combination with strong inhibitors of CYP3A4 (e.g. ketoconazole) in patients with poor metaboliser CYP2D6 phenotype.’

# Scope for medication errors



Pharma

Regulator

# Read the label

Report of three children with eye injuries from superglue

‘reported frequently since 1982 when superglue was repackaged into ophthalmic style dropper bottles’

Chloramphenicol  
Eye Drops BP



INSTANT NAIL GLUE  
COLLE A ONGLE



# Negligence: a clinician's understanding

## The principal actors

**IN THE HIGH COURT OF JUSTICE**  
**QUEEN'S BENCH DIVISION**

**CLAIM No. HQ22Q33R**

**BETWEEN:**

**JOHN FREDERICK SMITH**

**Claimant**

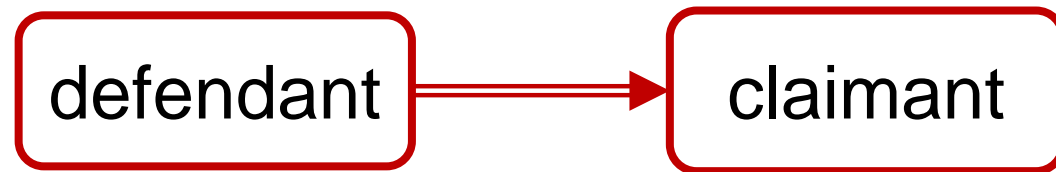
**and**

**HOLISTIC HEALTHCARE NHS TRUST**

**Defendant**

# Negligence: a clinician's understanding

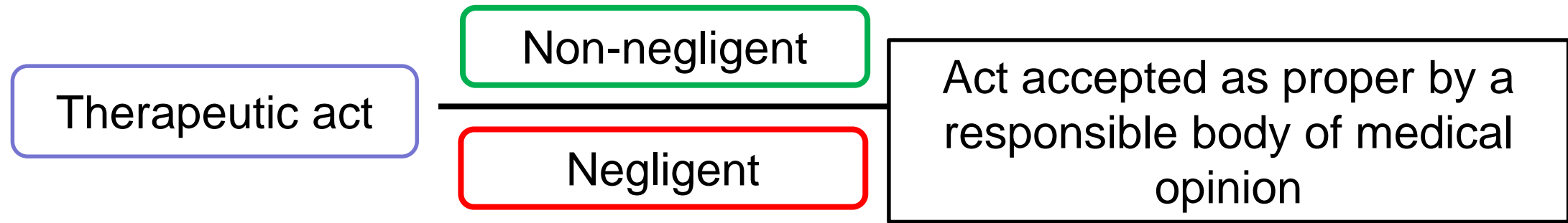
1. Does the defendant owe the claimant a duty of care?



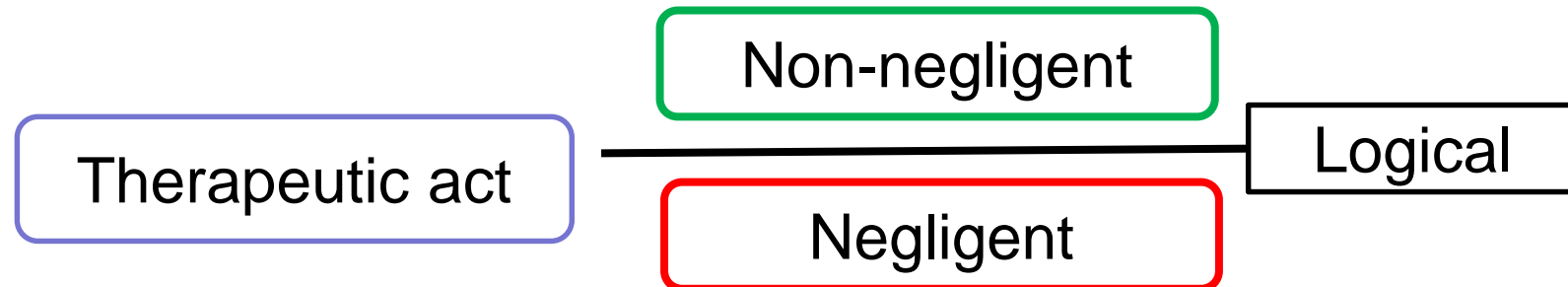
# Negligence: a clinician's understanding

Was the therapeutic act negligent?

2. Was the act below an acceptable standard? (Bolam)

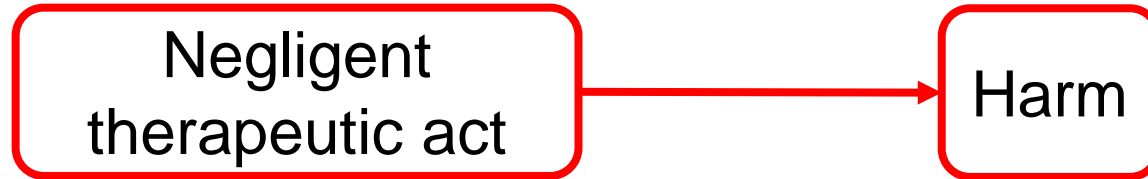


2a. Or illogical (Bolitho)

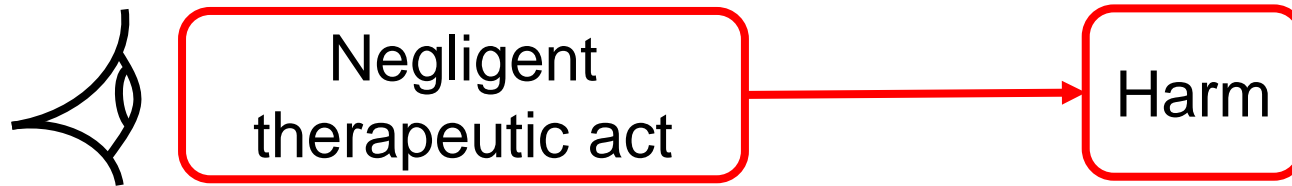


# Negligence: a clinician's understanding

3. Did the act cause the harm?



4. Was harm foreseeable?



# Homicide: a clinician's view

The act of one person causes the death of another

(Medical) errors are involuntary

But even involuntary homicide can be a crime



# Was fatal act a crime?

Only if it was negligent, and  
‘[his or her] negligence or incompetence... showed  
such disregard for life and safety as to amount to a  
crime against the state.’

R -v- Bateman 1925

Conduct was ‘truly exceptionally bad’

R -v- Misra 2004

Must be proven beyond reasonable doubt

The jury decide whether the conduct is criminal

# 19<sup>th</sup> century manslaughter

Causation 1856 R -v- Dr Snape

re Death of Daniel Dolley, 65

an insane mole catcher

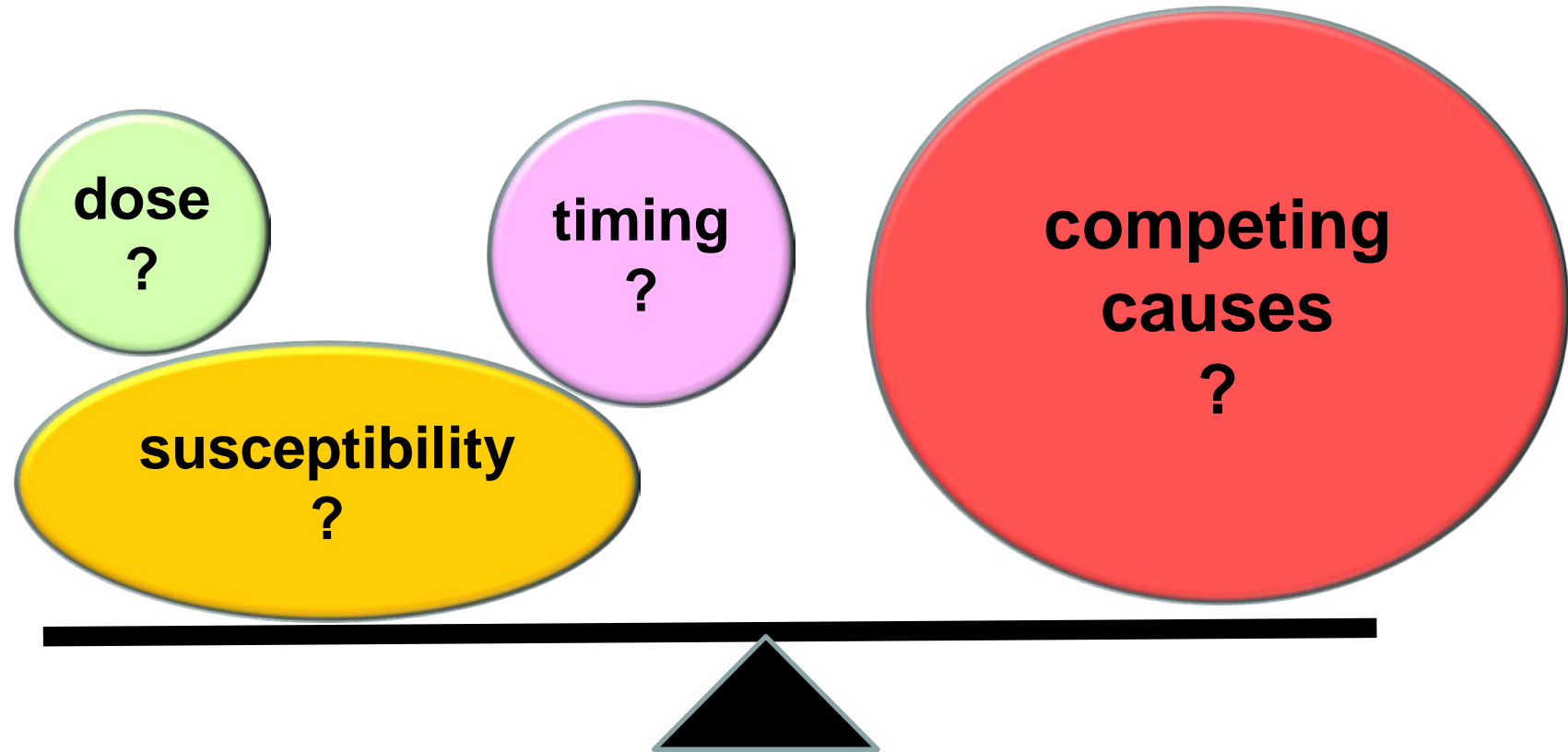
Cold shower for 28 min: 618 gallons of water

Then tartar emetic

Died shortly afterwards

Grand jury: acquitted (?natural causes)

# Causation for clinical pharmacologists





# 21<sup>st</sup> century manslaughter

Foreseeability: an obvious risk of death Dr JR 2016

12-year-old ♂

Fatigue for months; diarrhoea; deferred appointment; death

Expert: 'I would have to go and assess to see if it was life-threatening'

Court of Appeal: no case to answer

# 21<sup>st</sup> Century manslaughter (with drugs)

Guilty of manslaughter

Dr RK nitrous oxide in dental surgery

Dr FM intrathecal vincristine

Dr NS OOH GP three-fold morphine overdose

Dr PR adrenaline against advice

Dr MS morphine for migraine

'Doctor's errors led to death of patient'

GP who killed grandmother spared jail

Doctor guilty of killing intensive care patient

# Protection against errors: finding them

- Spontaneous reporting
- Audit
- Methodical investigation

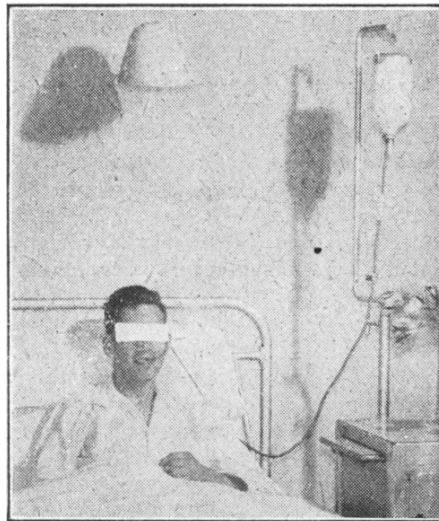
If you don't recognize possible errors,  
you can't protect against them



# Protection: designing errors out

Design systems that

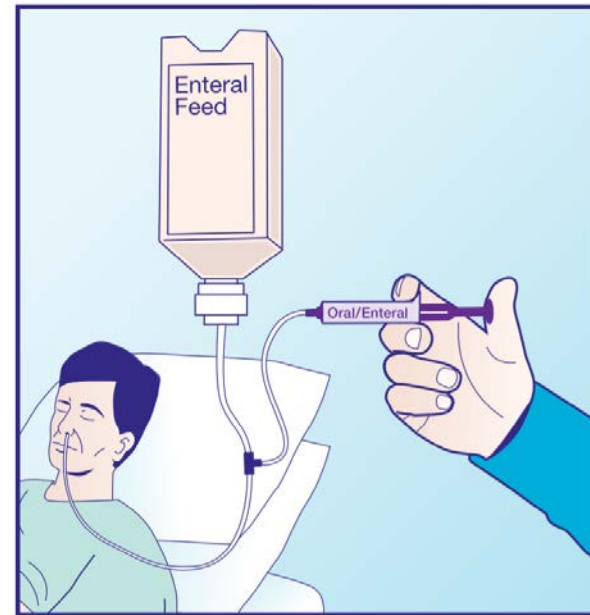
- reduce the likelihood of human error
- mitigate its consequences



## INADVERTENT INTRAVENOUS INFUSION OF MILK

J. R. WALLACE      R. W. PAYNE  
A. J. MACK  
*Victoria Infirmary, Glasgow G42 9TY*

CONTINUOUS INTRAGASTRIC MILK DRIP  
IN TREATMENT OF UNCOMPLICATED  
GASTRIC ULCER



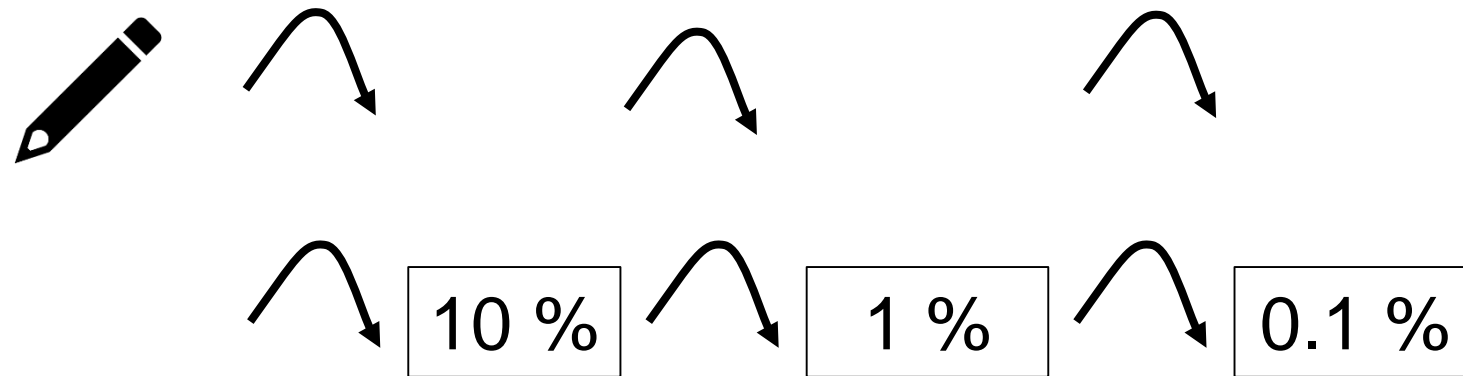
Doll R. *Lancet* 1956; 270: 70-3

Wallace *Lancet* 1972: 299: 1264-6



# Protection: 'An inspector will detect 90% of errors'

So check each step



# The choice

Criminalize  
Hide error  
Leave faults

Deterrence

Retribution

Improvement

Report  
Investigate  
Mitigate

Public interest

