LIGHTS, CAMERAS, ACTIONS
Developing a readiness and quality management framework for Biocontainment

Dr Jaimie Henry

ACIPC Internation Conference – November 2024

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Declarations and Acknowledgments

- No conflicts to declare

- This work produced in collaboration with the NSW Biocontainment Centre team:
  - Dr Patricia E Ferguson
  - A/Professor Matthew O'Sullivan
  - Dr Nicole Gilroy
  - A/Professor Mary Wyer
  - Ms Jaisa Kuriakose

  - Ms Kathryn Green
  - Mr Jimmy Ng

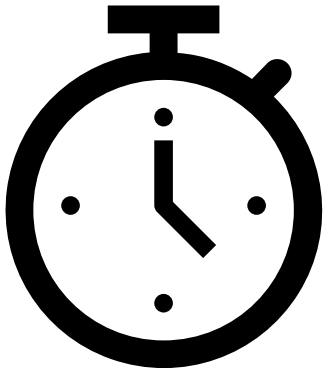
What does it mean to be ready?

The only thing worse than not being ready

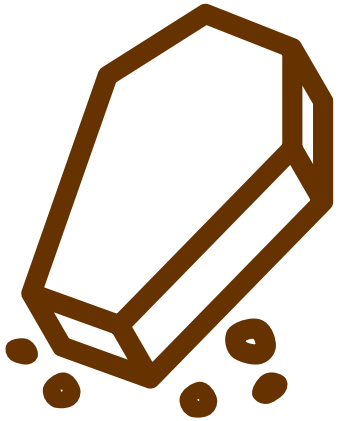
is not being ready when everyone else *thinks* you're ready…

What are High Consequence Infectious Diseases and why do they matter?

Acute



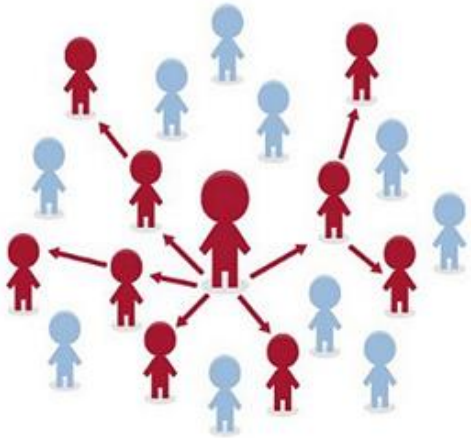
High case-fatality rate



Limited prophylaxis or treatment

Difficult to rapidly recognize/detect

Spreads quickly, especially nosocomial



Requires an enhanced individual, population and system response to ensure it is managed effectively, efficiently and safely.

☛ laboratory diagnosis ☛ clinical management ☛ Public Health

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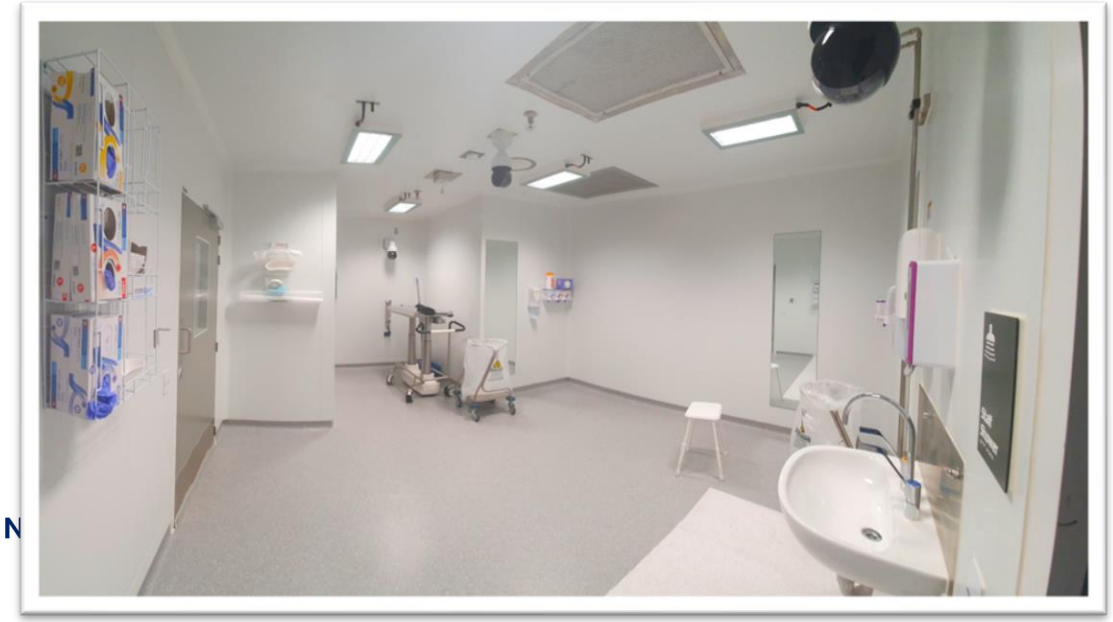
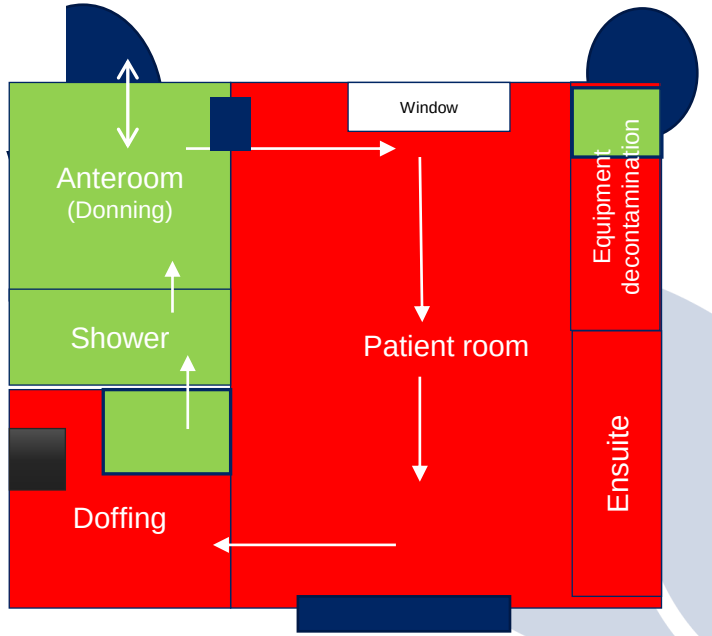
Biocontainment





Autoclaves and Cat A Waste Removal

Dual HEPA filtered, sequential negative pressure air handling

Intensive Care capable

Specialist PPE

16 hours

8 hours

High training commitment

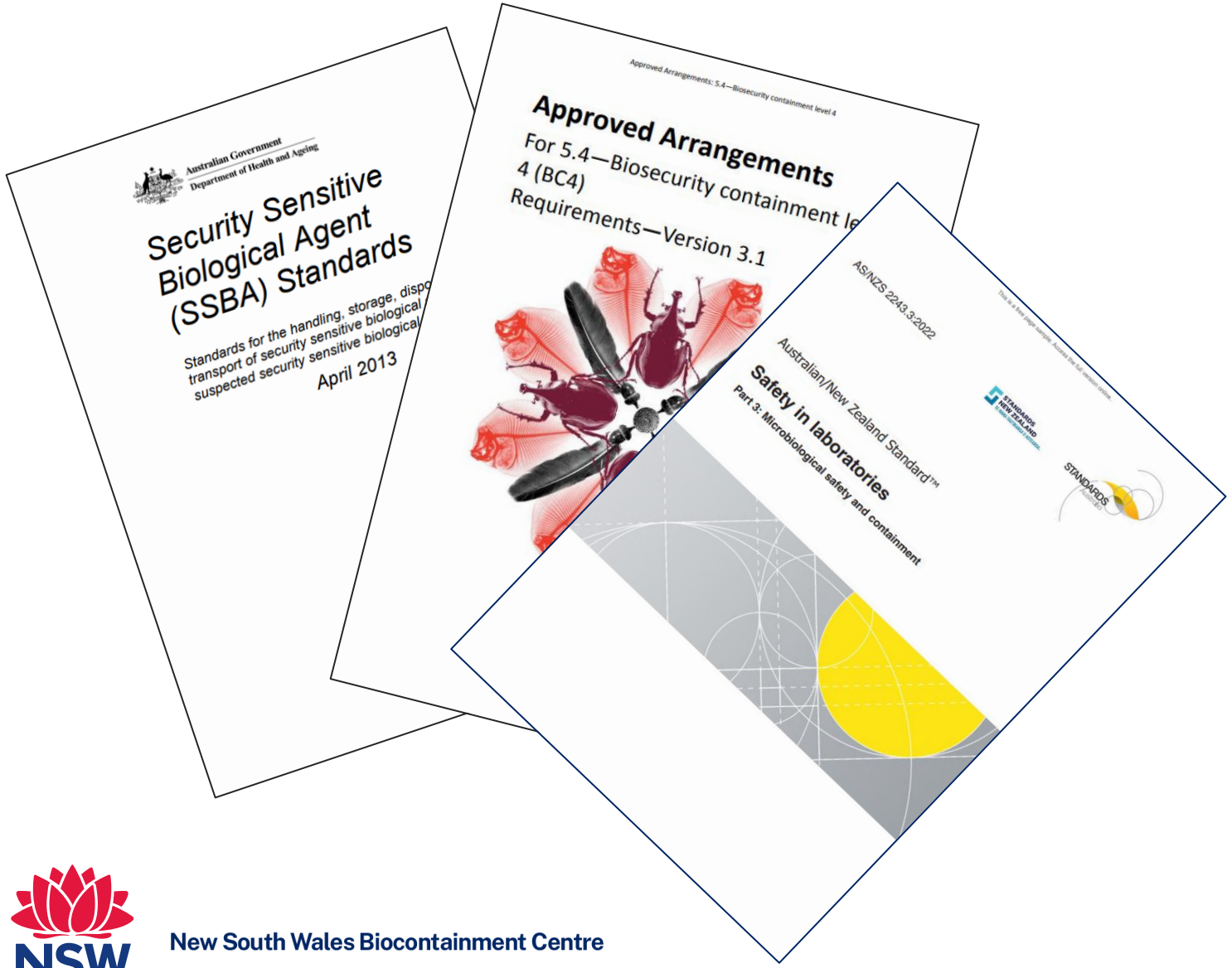
Effluent management plant

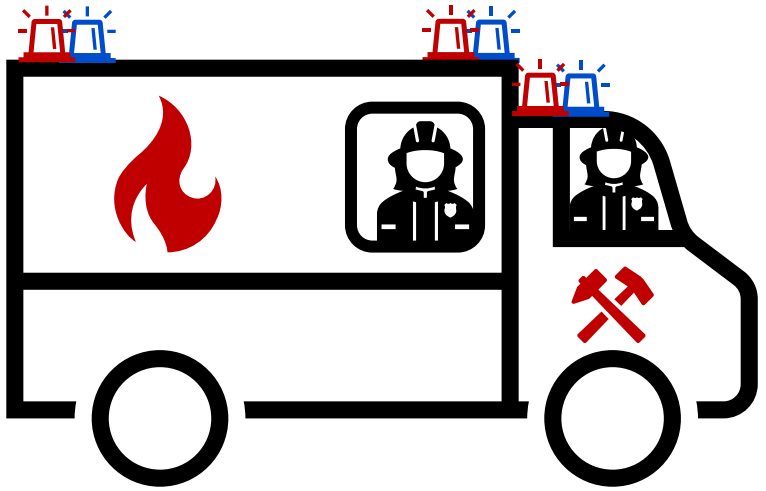
Why are we any different?

	Nuclear Power	Fire & Rescue	Biocontainment
Staff group	Defined, permanent, specialist Predictable	Defined, permanent, specialist Predictable	Defined, rotational, quasi-specialist? Unpredictable
Baseline level of activity	Continuous – all components are continually active	Intermittent but frequent	Minimal
Regulatory pressure	Extreme	High	Unclear
Perspective on abnormal events	Highly averse – avoid at all costs	Highly receptive – respond as default	Hope for best, plan for worst
Threat reflexivity	Threat specific – many (most) outcomes predicted	Threat agnostic, unpredictable	Threat agnostic but generally predictable
Environmental complexity	Extreme	Unknown, likely high	High

Threats to readiness – why do we need assurance?

Challenges of assurance





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What are the key, unique drivers of this system?

Define the model – the “stress test”

What are failure modes and the priority targets?

FAILURES

CONTROLS

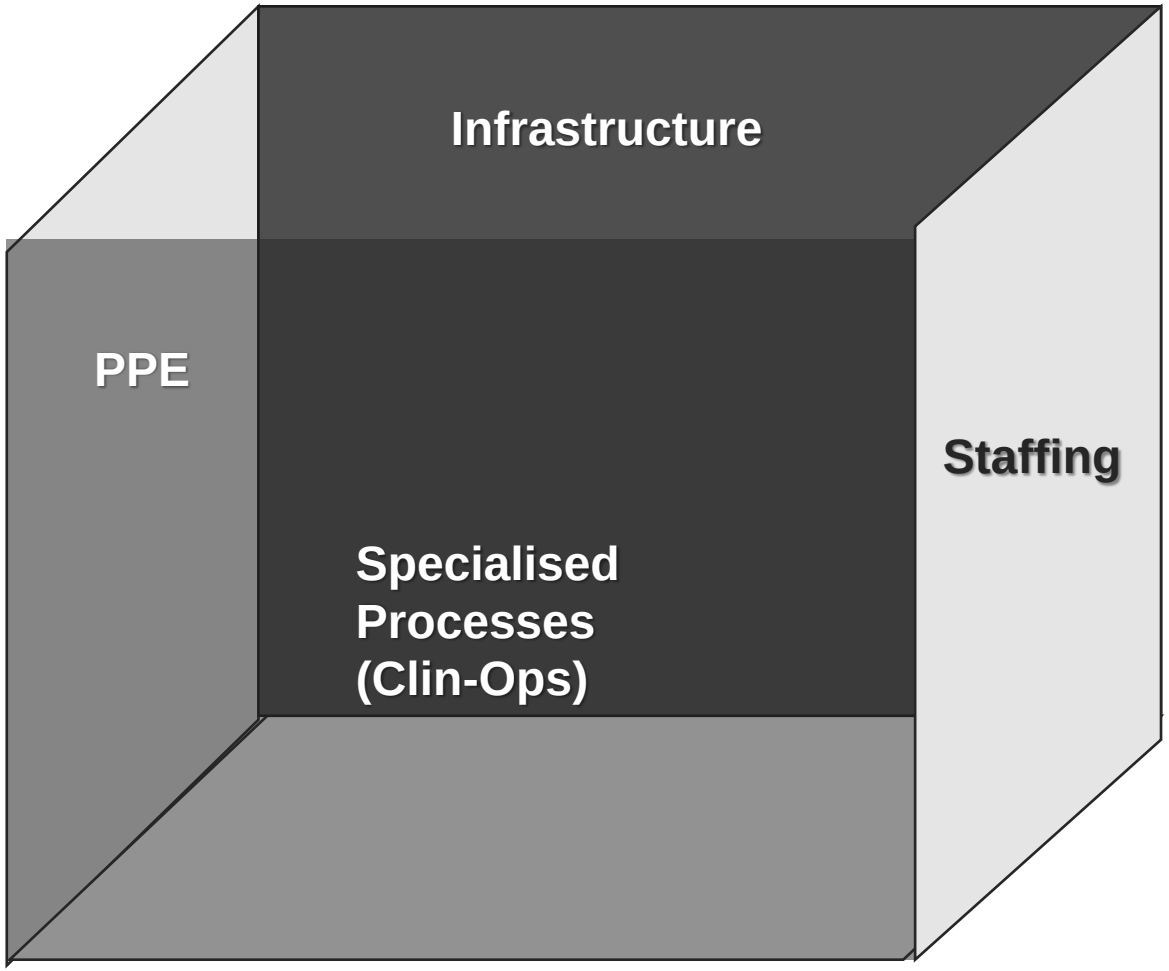
What level of visibility or control exists?

- **Standard development**

Development of “Readiness Controls”

Development of “confirmatory Readiness Assurance”

Four Walls of Biocontainment – the “Critical Domains”



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Developing “Readiness Controls”

Assurance of readiness

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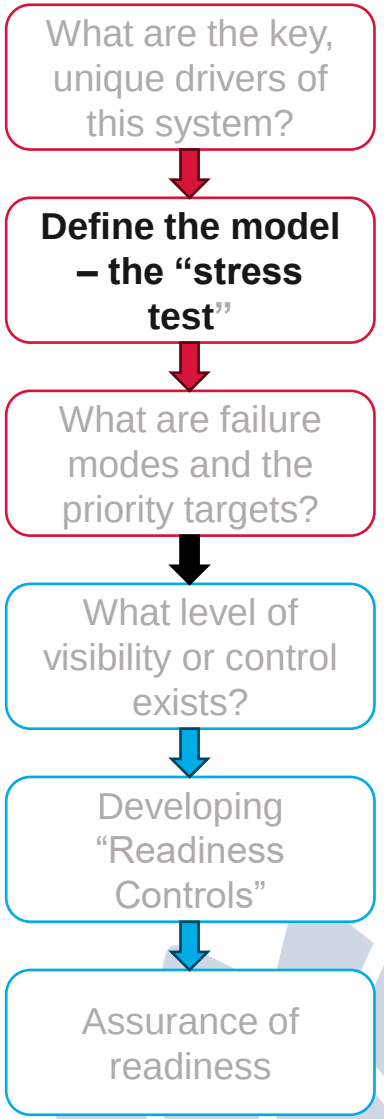
The stress test model

- An **adult** patient, **with confirmed viral haemorrhagic fever**, critically ill, **ventilated**

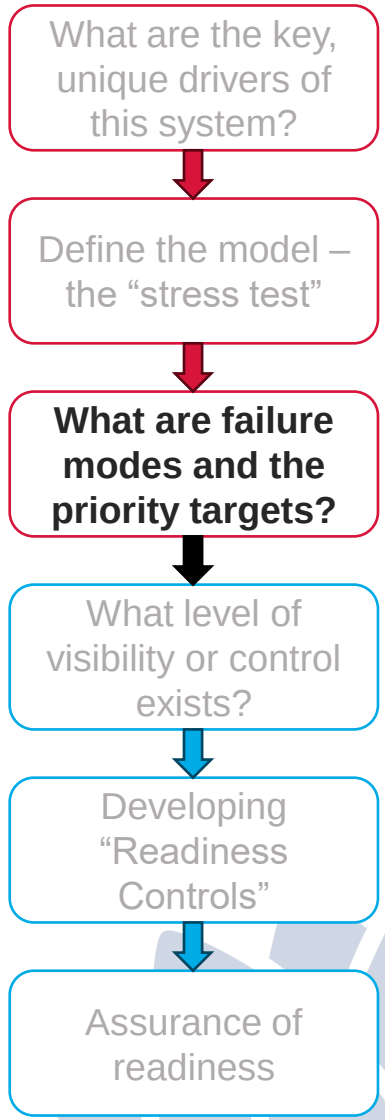
- **Summary of model:**
  - Hour 0: arrival and unloaded from EpiShuttle
  - Hour 2: Electrolyte and acid-base derangements
  - Hours 4-6: Extensive GI losses, minor bleeding
  - Hour 9: Arterial line
  - Hour 9-11: Respiratory distress (APO); High flow nasal cannula
  - Hour 15: Intubation, mechanical ventilation
  - Hour 17: CVC insertion
  - Hour 19: Bowel management system
  - Hour 21: Rapid atrial fibrillation



Four questions

Staffing	PPE	Infrastructure	Clinical/Ops
Are there sufficient, appropriately skilled clinical staff?	Is the stockpile of PPE sufficient and adequate to care for a critically ill patient?	Does the infrastructure prevent biocontainment failure?	Can we provide the clinical critical care procedures necessary?

Failure of biocontainment



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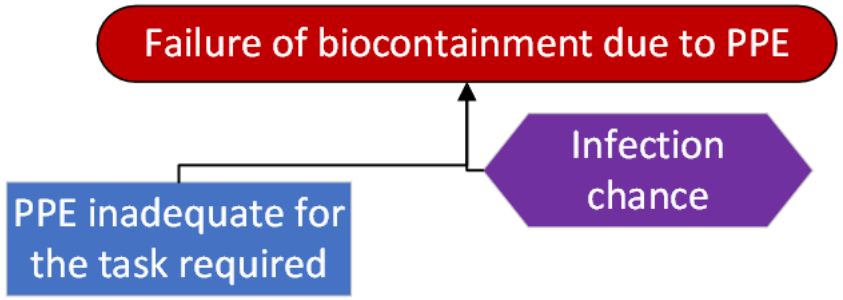
Fault Tree Analysis: PPE



OR

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FAULT

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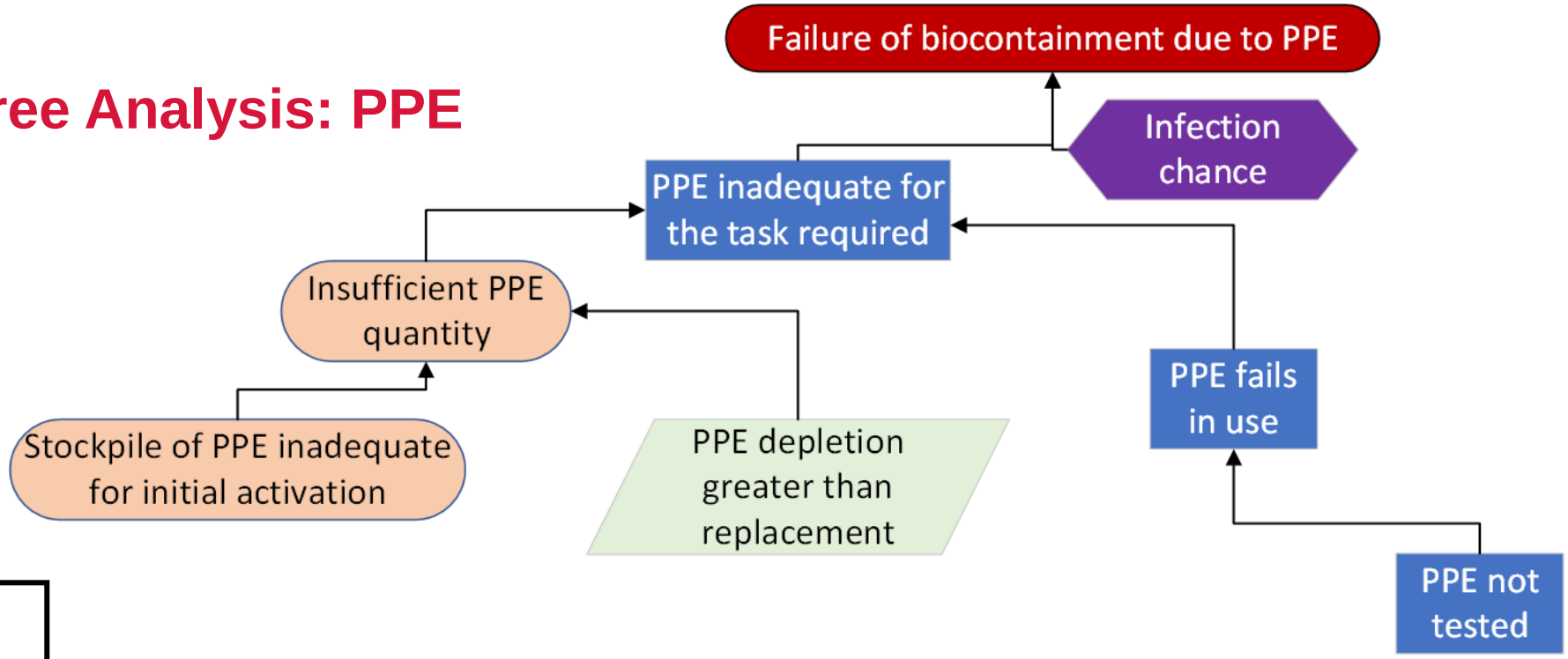

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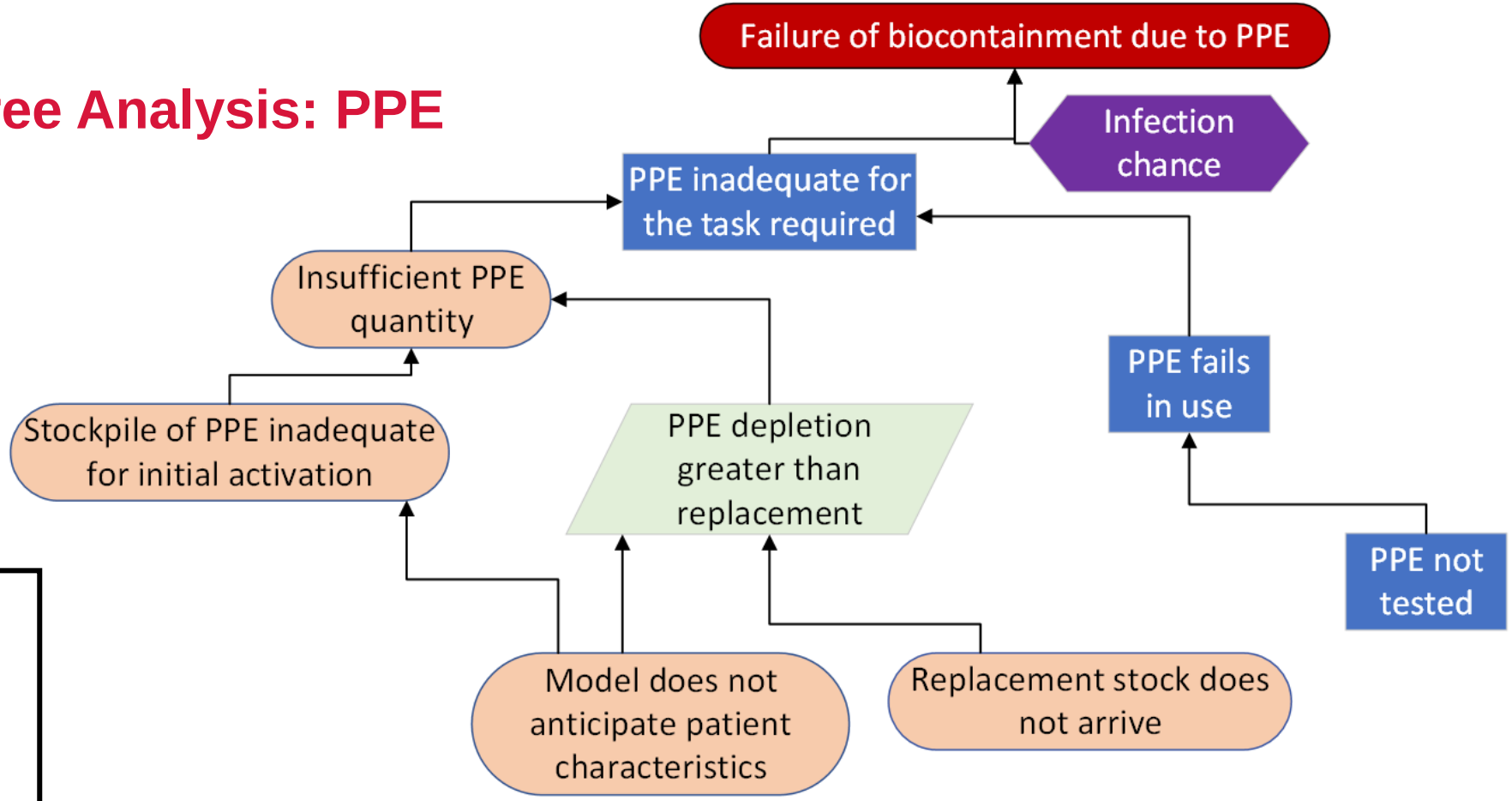

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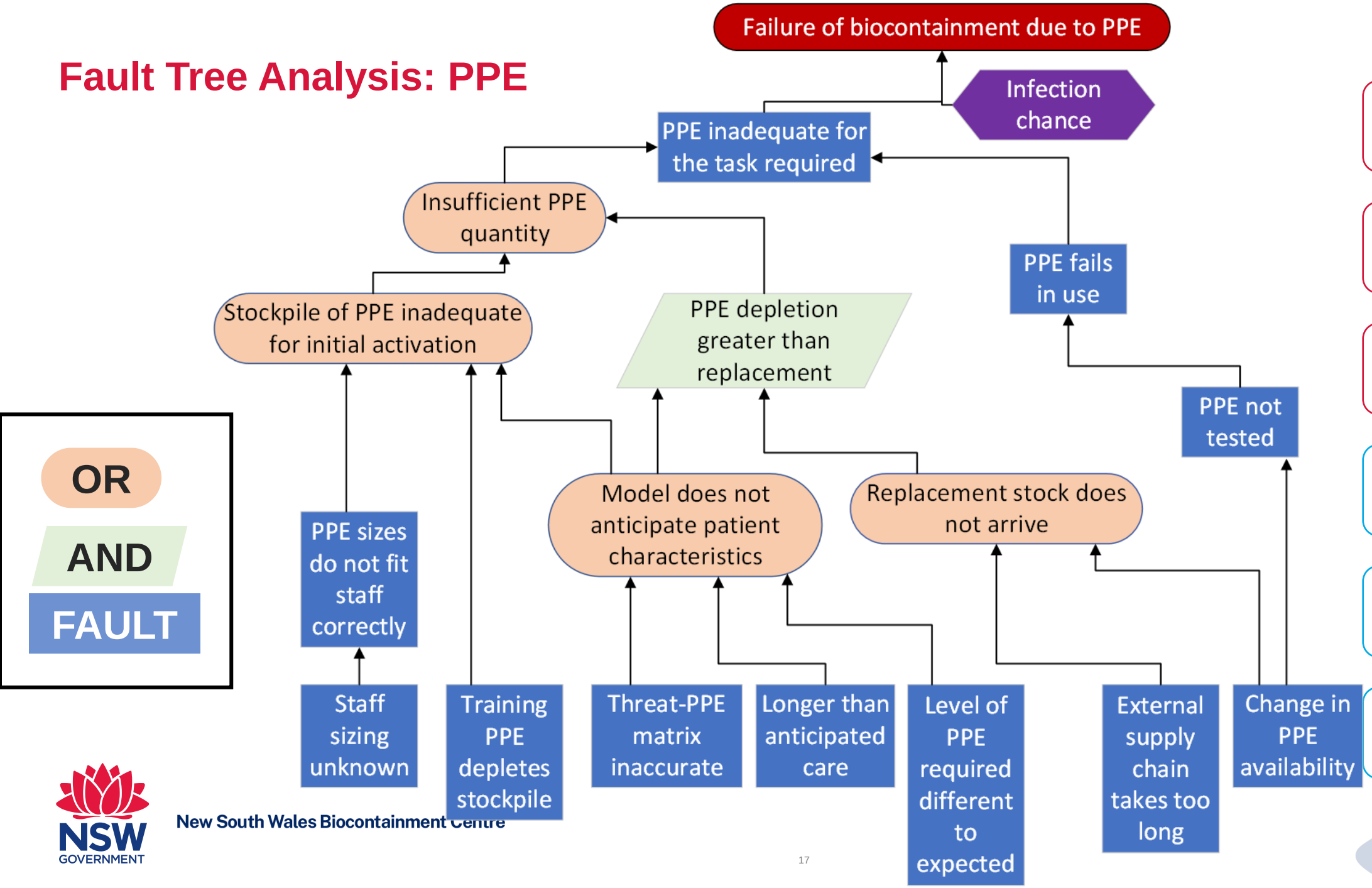
Fault Tree Analysis: PPE



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What are failure modes and the priority targets?

Example Failure Modes and Effects Analysis: PPE

Function	Requirement	Potential Failure Mode
PPE	PPE fit for purpose	PPE fails in use
	Sufficient quantity of PPE	PPE stockpile inadequate at activation
		PPE depletion greater than replacement

Top Priority Risks

Staff	PPE	Infrastructure	Clin Ops
Trained staff unavailable for duty	Staff sizing inadequate	HVAC failure	Specialised procedures not adapted for HCID/NBC
Trained staff have incorrect skillset	Repletion of PPE inadequate (PPE supply chain vulnerable)	Sewage plant failure/flood	Medications not available at short notice
	Model does not reflect PPE usage		PPE affects procedure safety or efficacy
	Training PPE depletes stockpile		

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Implementing the Readiness Management Framework

Failure analyses → **What level of visibility or control exists?**

PPE

- **PPE modelling**

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PPE Burn Calculator

Box 1: Instructions

- This page summarises the total number of units (i.e. quantities ordered such as boxes) required for each combination of PPE level
- The quantity provided is for 24 hours of care for ONE patient, provided the assumptions in Box 3 are true
- Staff are categorised as arbitrary sizes small/medium/large - these are generic size ranges of people, and do not match names to e.g. glove sizes
- Tabs are explained in Box 2 below
- Editing is locked to prevent errors on the formulas however the following is possible:

Patient interactions updates can be edited according to the instructions on that sheet
To calculate burn for a different PPE level change the drop down lists on "PPE per patient interaction" for all relevant interactions (i.e. for all Level 3- change all drop down "Level" options to "3")
Glove and PAPR sizing assumptions can be edited on the "Burn calculator" sheet
New PPE ensemble can be created - follow the guide below in Box 4 (advanced users/admin access required)

Box 2: Sheets

PPE supply quantities
- Used to identify the number if individual items per supply quantity e.g. box; can be updated if brand or supply unit changes

PPE per patient interaction
- The total number of PPE items for various PPE ensembles
- Adding PPE ensembles is possible with admin access (advanced)

Patient interaction
- Based on the assumed number of interactions for a given patient
- Default assumptions in Box 3
- Can be edited or added to as required

Burn calculator
- Automatically calculates the burn rates based on information provided
- Replicates outcome of supplies required to the summary box on this page

Box 4: To create a new PPE ensemble (advanced users)

Ordering requirement			
NB Check special calculations boxes on Burn calculator sheet (PAPR/gloves/respirators)			
Calculations provided for the following PPE/24 hours:	Level 2 0	Level 3 29	PAPR 0
Item	**Units required**	**Brand name**	
Face shield	0	CKF5003	
Surgical flange hood	1		
Surgical gown - L	1		
Surgical gown - XL	2		
Surgical gown - XXL	1		
Respirator	0		
PAPR Mask	32		
Biohood	32		
Bio exhalation filter	3		
Mask exhalation adapter	7		
HEPA filter unit - bauble	11		
Booties - Universal	2		
Booties - XL	1		
Orange Long Cuff (Inner) - M	1		
Orange Long Cuff (Inner) - L	1		
Orange Long Cuff (Inner) - XL	1		
Outer (surgical) gloves	2		
Doffing pull down gloves (contaminated zone) - M	1		
Doffing pull down gloves (contaminated zone) - L	1		
Doffing pull down gloves (contaminated zone) - XL	1		
Doffing gloves (clean zone) - M	1		
Doffing gloves (clean zone) - L	1		
Doffing gloves (clean zone) - XL	1		
Steriplus filter	#REF!		

Box 3: Default assumptions

Patient
- A worst case scenario: the patient is critically ill, requires central and arterial a intubation and remains mechanically ventilated
- Staff work 2 hour shifts with a patient, and remain in room for this whole peri
- The patient requires 2 hourly pressure area care (PAC), requiring two staff an at the 2 hour changeover
- Twice per 8 hour shift (In addition to above) a second nurse is required to atte a staff assist
- A medical officer reviews the patient at bedside once per 8 hour shift, and att once each shift for a hypothetical "urgent review"

Staff and PPE
- Glove sizes are normally distributed i.e. 68% of the population fall 1 SD aroun (so majority are medium) and 18% either side (small/large): *this can be adjuste sheet*
- Glove size determines the other PPE size and scale together - e.g. smallest glo smallest gown and bootie size
- A 10% error calculation is added to all PPE to provide a safety margin (except
- A 20% error added to all gloves to provide a safety margin (larger margin due size variability)
- All PPE quantities are round UP to the nearest whole number or unit (therefo not always match across columns)
- PAPR mask special caclulations are based on the observed fitting of PAPR mas NBC personnel as of 17/05/2024

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Steriplus filter	#REF!		

Implementing the Readiness Management Framework

Failure analyses → **What level of visibility or control exists?**

Infrastructure

- **Smokestick evaluations**

Implementing the Readiness Management Framework

Failure analyses → **What level of visibility or control exists?**

ClinOps

- **Clinical Modelling**

An **adult** patient, **with confirmed viral haemorrhagic fever**, critically ill, **ventilated**

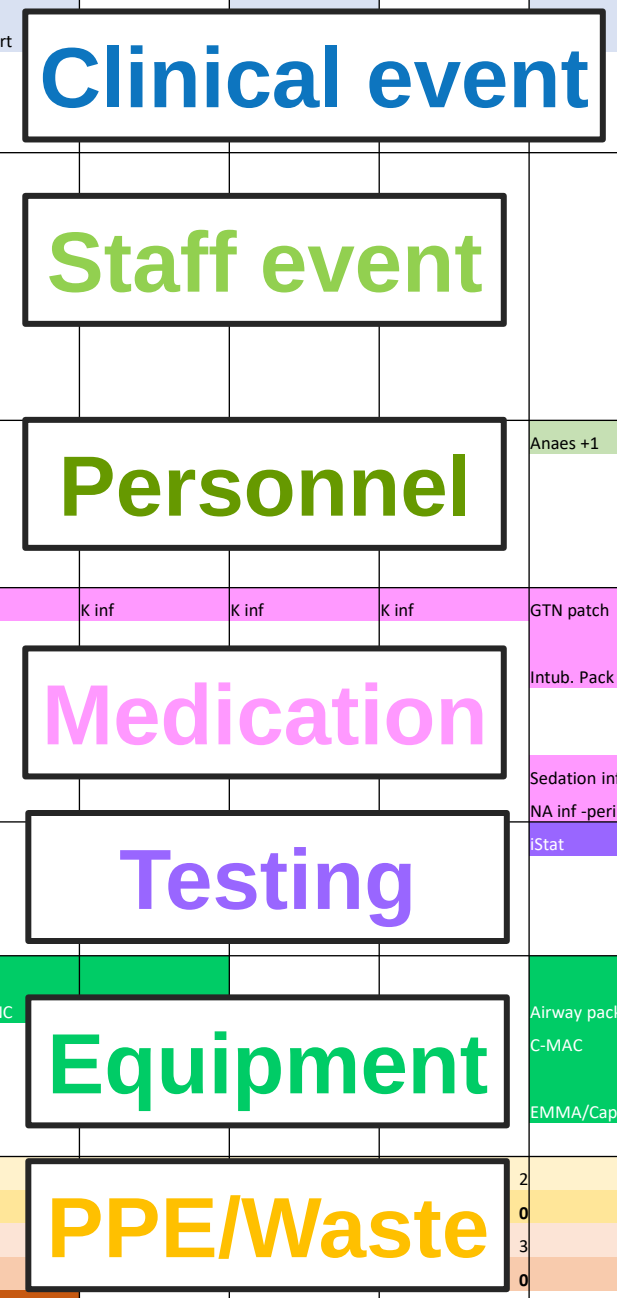
What does this severe EVD look like over a 24-hour period?

How do we care for the clinical situation usually?

What do we need to do to deliver this care within Biocontainment?

Hour	0	1	2	3	4	5
Clinical Events	Transfer to NBC EpiShuttle Unload Low BP	IVC	Low K+ Low Na Lac high pH low	Tachy	Vomiting Diarrhoea ++	Diarrhoea ++
Staff Events	Shift change - nursing Shift change - medical				ICU activate Staffing shift	
Personnel	NSW Amb +1	NSW Amb -1			ICU Cons +1 K7b -2 ICU RN +3	
Medications	IVF bolus	Antibiotic	K inf IVF bolus	K inf	K inf	K inf

Hour	10	11	12	13	14	15
Clinical Event		Dyspnoea HFNC start	IVC	Hypoxic		APO
Staff Events						
Personnel						Anaes +1
Medications		K inf	K inf	K inf	K inf	GTN patch Intub. Pack Sedation inf NA inf -perip
Testing						iStat
Equipment		Vent HFNC				Airway pack C-MAC EMMA/Capno
PPE Level	2					2
PPE Quantity	0					0
PPE Level	3					3
Quantity	1					0
Waste	Autoclave	Autoclave				



Implementing the Readiness Management Framework

Failure analyses → What level of visibility or control exists? → **Developing "readiness controls"**

PPE

- **Stocktake "Red-Amber-Greens"**

PPE Category	Brand Name	In stock (UNITS)	Use by	Days available (Level 2)	Days available (Level 3)
Biohood	HALO Biohood	180	Oct-2023	30	5
Steriplus filter	Steriplus filter	3	May-2025		
Steriplus filtercase	Exhalation Valve Filter case Steriplus	11	Feb-2025		
flat filter for motor unit	Particulate filter - flat filter for motor unit	10			
HEPA filter unit - bauble	Halo biohepa P3/TM3 - bauble filter for motor unit	77	Jul-2025	38	7
Bio exhalation filter	Bio Exhalation filters - round mushroom	10	May-2025	10	3
Mask exhalation adapter	Halo bio mask exhalation adaptor (blue nose)	51		25	7
PAPR mask	Cleanspace 3 half mask - Small	10		1	0
PAPR mask	Cleanspace 3 half mask - Medium	27		4	0
PAPR mask	Cleanspace 3 half mask - Large	19		3	0
Surgical gown - XXL	Medline gowns- XXL 150cm long - long	11	Dec-2027	11	11
Surgical gown - XL	Medline gowns - XL 130cm long - medium	15	Dec-2025	7	7
Surgical gown - L	Medline gowns - Large 120cm long - short	6	Dec-2026	6	6
Surgical flange hood	Tyvek hoods	2		2	2
Respirator	Trident Masks one size	1			
Respirator	Halyard - small masks	5			
Respirator	Halyard - regular masks	3			
Respirator	3M Aura N95	1			
Respirator	Cocoon N95/P2 mask	2			
Booties - Universal	Booties - Universal size	25		12	12
Booties - XL	Booties - XL size	12		12	12
Face shield	Face shields - PPE	1		1	
Goggles	Goggles - PPE	4			
Imperveious gown - Yellow	Imperveious gown - Yellow	3			
Thumb hook gowns- blue	Thumb hook gowns- blue	0			
Doffing gloves (clean zone) - XL	wall mount cuff first short cuff gloves - Incontrol XL (clean zone)	7		7	7
Doffing gloves (clean zone) - L	wall mount cuff first short cuff gloves - Incontrol L (clean zone)	7		7	7
Doffing gloves (clean zone) - M	wall mount cuff first short cuff gloves - Incontrol M (clean zone)	7		7	7
Doffing pull down gloves (contaminated zone) - XL	cuff first short cuff gloves - Incontrol XL (doffing)	3		3	3
Doffing pull down gloves (contaminated zone) - L	cuff first short cuff gloves - Incontrol L (doffing)	18		18	18
Doffing pull down gloves (contaminated zone) - M	cuff first short cuff gloves - Incontrol M (doffing)	9		9	9
Orange Long Cuff (Inner) - M	Medium - long cuff orange gloves - Nitril	0		0	0
Orange Long Cuff (Inner) - L	Large - long cuff orange gloves - Nitril	19		19	19
Orange Long Cuff (Inner) - XL	XL - long cuff orange gloves - Nitril	3		3	3
Outer (surgical gloves)	Surgical gloves - Protexis size 6	3		3	1
Outer (surgical gloves)	Surgical gloves - Protexis size 6.5	1		1	0
Outer (surgical gloves)	Surgical gloves - Protexis size 7	2		2	1
Outer (surgical gloves)	Surgical gloves - Protexis size 7.5	3		3	1
Outer (surgical gloves)	Surgical gloves - Protexis size 8	2		2	1

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Implementing the Readiness Management Framework

Failure analyses → What level of visibility or control exists? → **Developing "readiness controls"**

PPE

- **Training PPE burns**

Implementing the Readiness Management Framework

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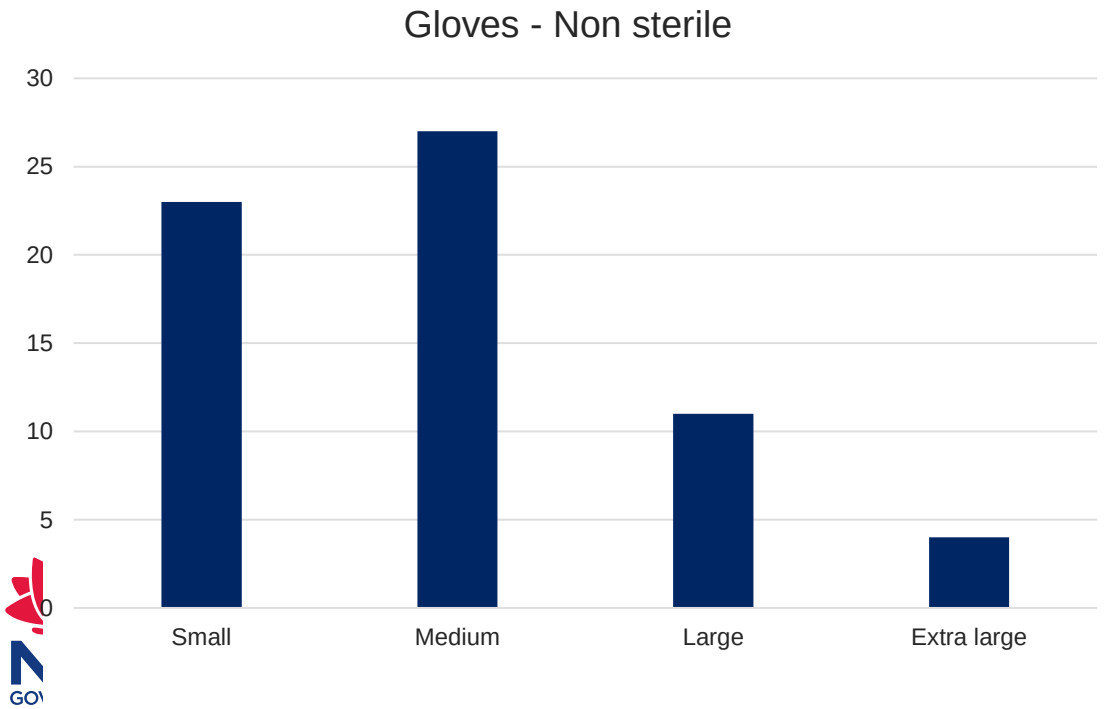
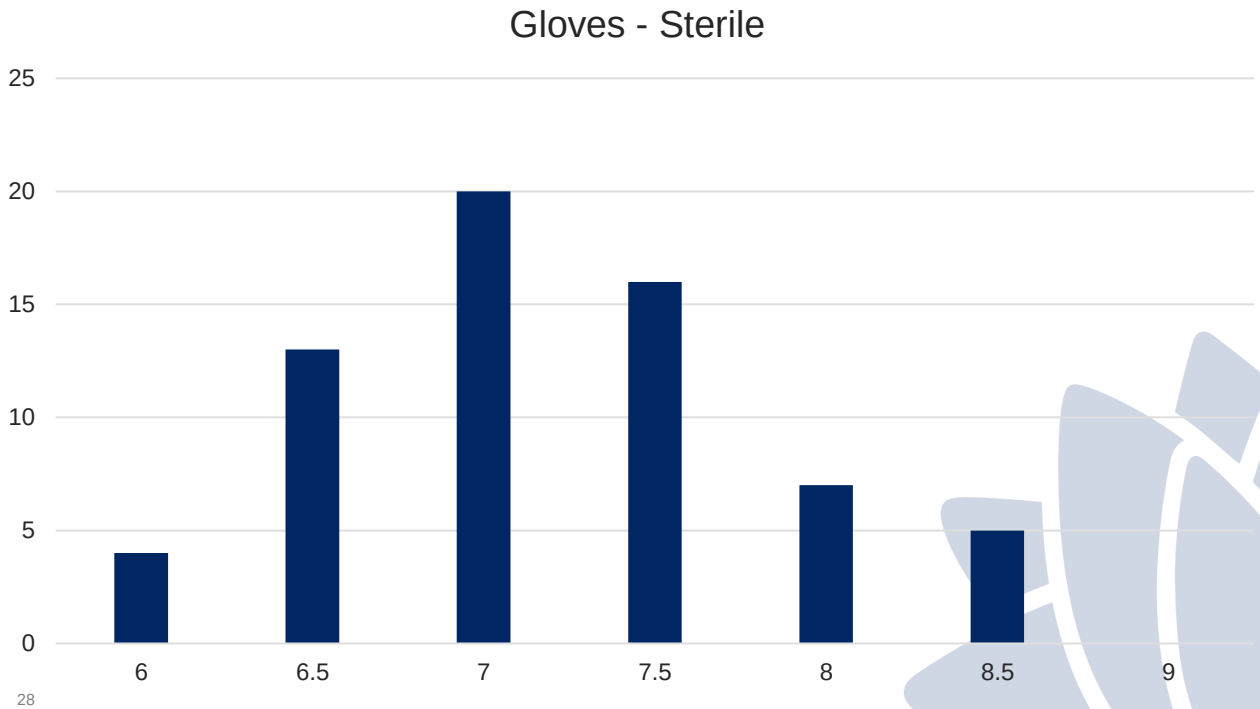
PPE

- **Sizing calculator**





Implementing the Readiness Management Framework

Failure analyses → What level of visibility or control exists? → Developing "readiness controls"

ClinOps

- **Protocol evaluation**

Implementing the Readiness Management Framework

Staffing

- Prospective drills

PPE

- Simulation
- Tabletops

Infrastructure

- Leak tests and verifications
- Simulations
- Assurance checklists

ClinOps

- Simulations
- Unexpected event drills

The Readiness Management Framework

	Staff	PPE	Infrastructure	Clin Ops
Standard	International consensus Simulation	Health protection and local threat assessment Modelling	Local expertise AS 2243.3 International consensus	Case reports Simulation studies "All hazards approach"
Exploratory Readiness Assurance				
Readiness Controls				
Confirmatory Readiness Assurance				

COMPLEXITY

RELIABILITY

Practice Points

- Embrace the “tragedy of the un-commons” – model for the worst possible outcome
- Clinicians need to step outside of usual practice zones to achieve buy-in from non-clinical stakeholders
- Accept complexity alongside a **relentless** focus on failure – over-simplification is dangerous
- *Usual* processes do not work in *unusual* environments – but they can be ”hacked” to provide valuable tools

Thank you

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