Model-based Mechanical Ventilation:
A road trip from concept to randomized controlled trial

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BMS 2015
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Road Trip Experience

Doghouse Diaries "We juggle bears."

Outline

1. *Introduction*
2. *Mechanical ventilator settings*
3. *The need of model-based mechanical ventilation*
4. *Experimental and clinical trials*
5. *Preparation for the randomised controlled trial*
6. *Commencement and challenges*
7. *Final thoughts*

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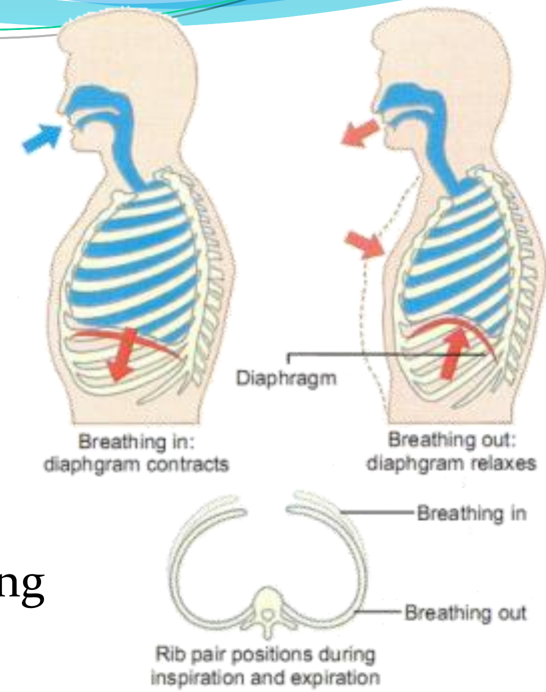
1. Introduction

Introduction

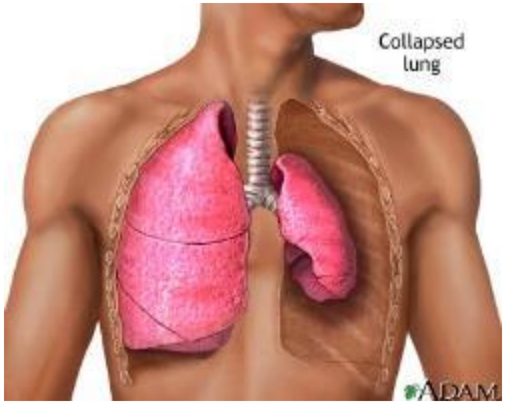
The Human Lung

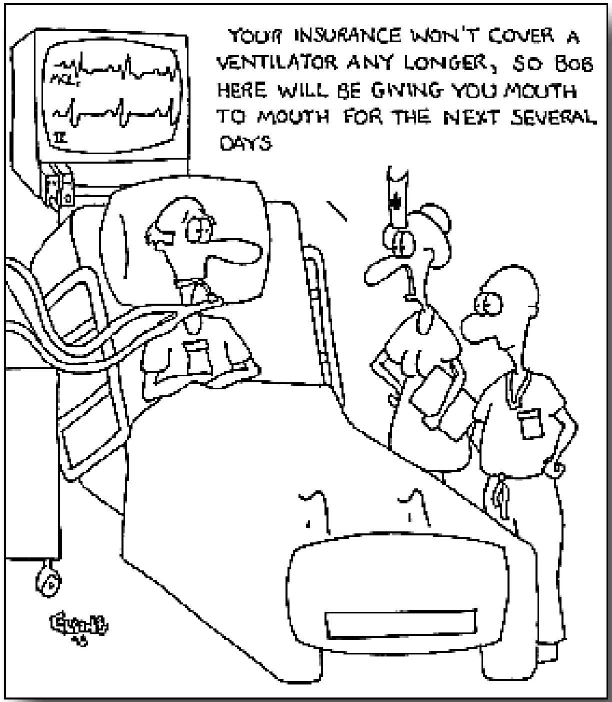


- Primary function of the human lung
  - Ventilation and Perfusion (in other words… breath)
  - Ventilation: Transport of surrounding air into the lung
  - Perfusion: Gas exchange in the alveoli and alveoli capillaries
- Acute Respiratory Failure (ARF)
  - Impaired lung functions
  - Essentially, the patient was not able to breath properly and/ or not getting enough oxygen
  - Pneumonia, sepsis, trauma, near drowning etc

Acute Respiratory Distress Syndrome (ARDS)

- 1965 – Ashbaugh
- Affecting up to 30% of ICU patients
- Mortality up to 30~60%
- Significant cost in treatment (~$1500/day extra)





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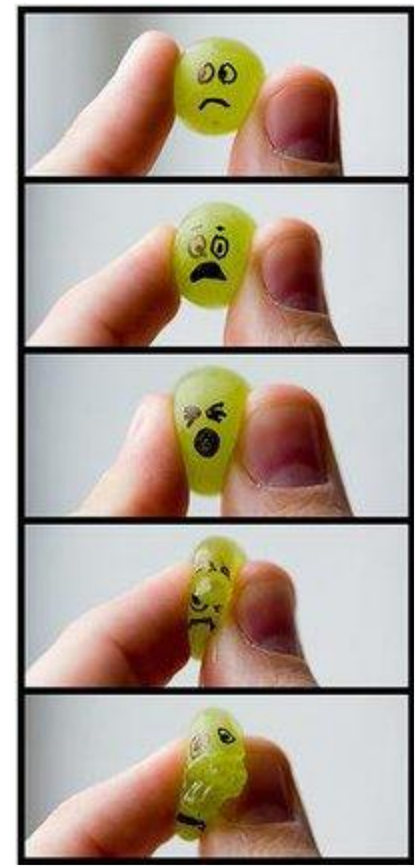
Acute Respiratory Distress Syndrome (ARDS)

- 1965 – Ashbaugh
- Affecting up to 30% of ICU patients
- Mortality up to 30~60%
- Significant cost in treatment
- Collapse lung (Collapse Alveoli)

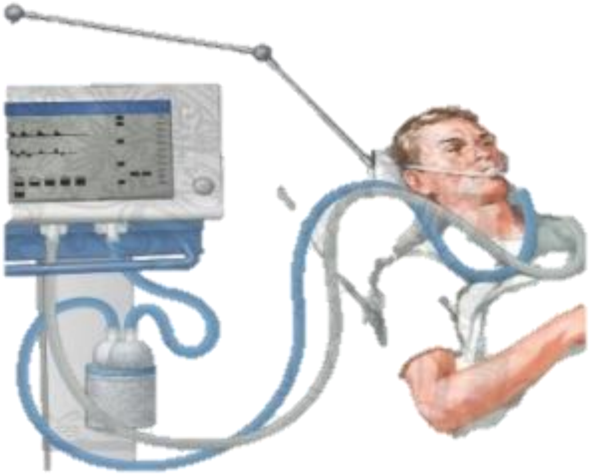


Acute Respiratory Distress Syndrome (ARDS)

- 1965 – Ashbaugh
- Affecting up to 30% of ICU patients
- Mortality up to 30~60%
- Significant cost in treatment
- Collapse lung

- Fluid Build-up, Inflammation, Lost of Surfactant in the Alveolar, Alveolar Collapse, Gas Exchanged Impaired
- Stiffer, Smaller, Baby Lung

Ventilator



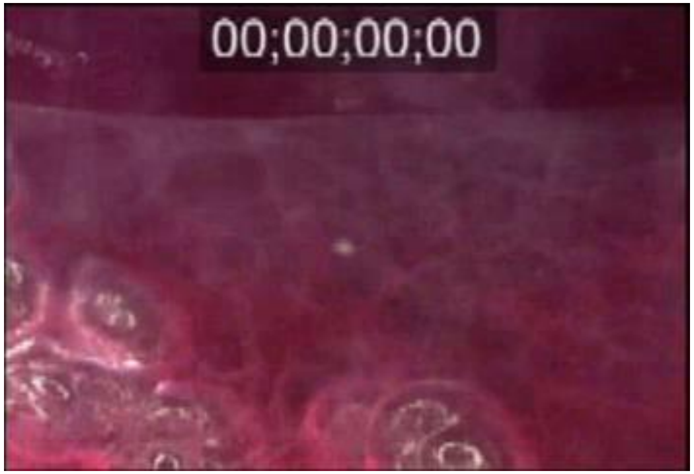
2. Ventilation

1. Introduction

Human Lung, Respiratory Failure and Mechanical Ventilation

Mechanical Ventilation

- Mechanical Ventilation (MV) provides breathing support for the ARF/ ARDS patients
- MV delivers a supply of oxygen using positive pressure
- Some settings in a mechanical ventilator
  - **Fraction of Inspiration Oxygen (FiO_2)**
  - **Positive End Expiratory Pressure (PEEP)**
  - **Tidal Volume**



3. The need of Model-based method to select PEEP

2. Ventilation
PEEP

1. Introduction
Human Lung, Respiratory Failure and Mechanical Ventilation

Problems

- “Humans are horribly variable” (Dickson et al, 2014)

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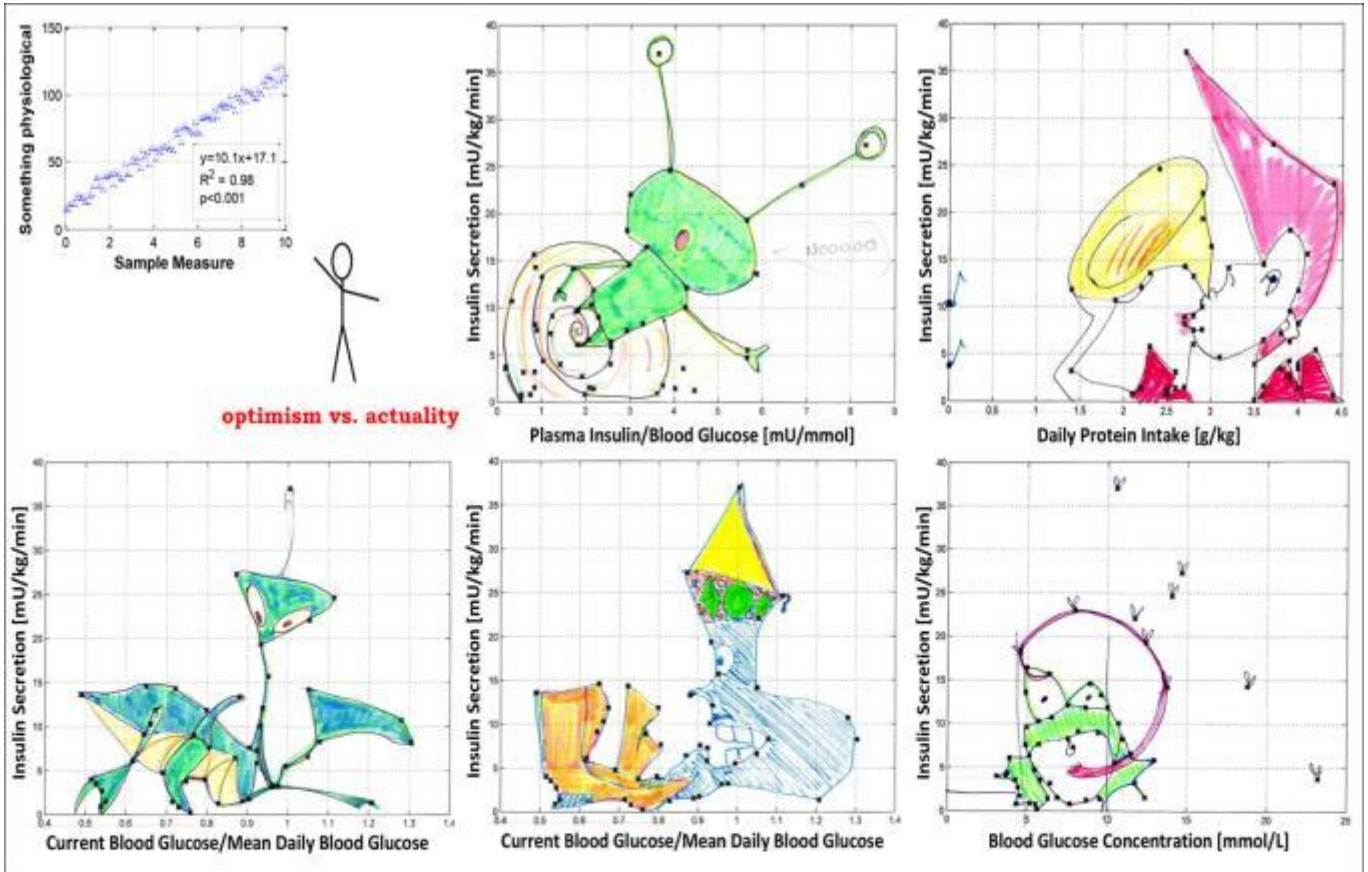
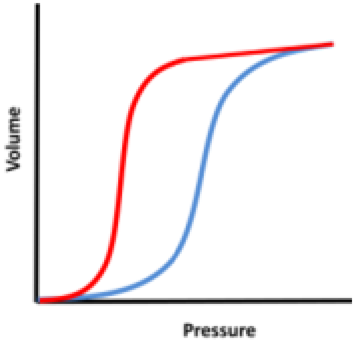
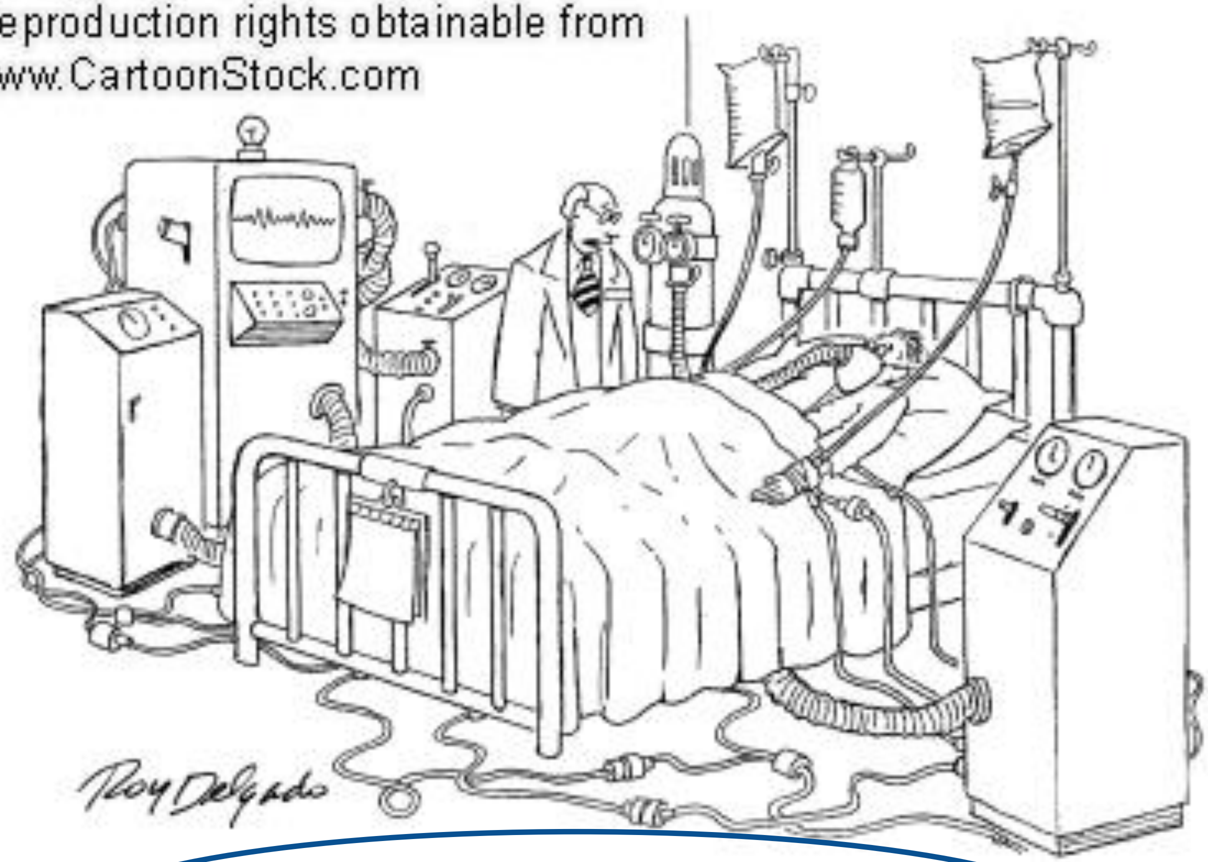


Humans are horribly variable: The problem of variability in physiological measurement and modelling.

The Need of Model-based mechanical ventilation

- "Humans are horribly variable" (Dickson et al, 2014)
- Disease and response is patient-specific
- Clinicians rely on intuitions and experience to set MV (**PEEP**)
  - Relatively little non invasive assessment method to assess lung condition





" You could go home tomorrow, but it will take the plumber three days to disconnect you. "

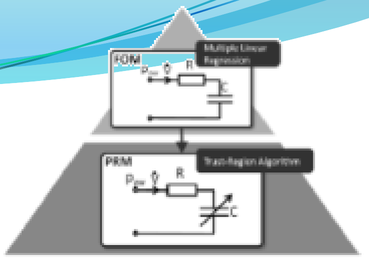
- A need of a non-invasive method to individualise MV
- Model-based Mechanical Ventilation
  - **Capture patient-specific condition and response to MV setting**
  - **Develop metric to aid clinical decision making**

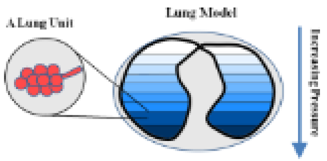
- Improve the quality of care
  - Setting MV in a consistent fashion
  - Improve care, reduce MV dependency, reduce mortality

"If you want a second opinion, I'll ask my computer."

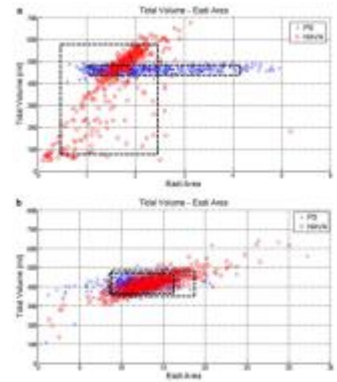
Model-based Mechanical Ventilation

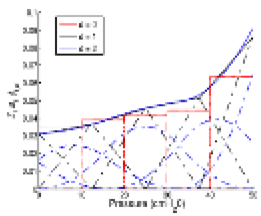
Here are some models and metrics that I have worked on…

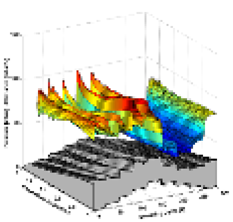


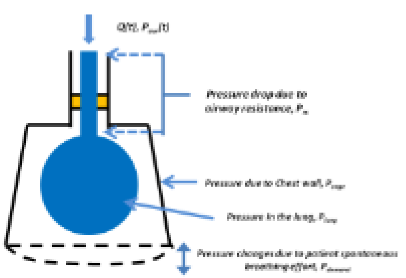


- **Minimal Model, Gaussian Distribution model**
  (Sundaresan et al., 2009, 2010, Chiew et al., 2012, Redmond et al. 2014)
- **Functional Residual Capacity Estimation**
  (Sundaresan et al., 2010, Mishra et al., 2013, van Drunen et al., 2013)
- **Pressure Recruitment and Multi Compartment Models**
  (Schranz et al., 2011, Docherty et al., 2013)
- **Patient-Ventilator Interaction, Asynchrony Analysis**
  (Moorhead et al., 2012, Chiew et al., 2013)
- **Expiratory Time Constant Model**
  (van Drunen et al., 2013)
- **Time-Varying Elastance Model**
  (van Drunen et al., 2013, Chiew et al., 2014)
- **Airway Branching Model**
  (Damanhuri et al., 2014)
- **Nonlinear Auto Regressive Modelling**
  (Langdon et al., 2015)









Lets only work on Single Compartment Lung Model

$$P_{aw}(t) = R_{rs} * Q(t) + E_{rs} * V(t) + P_o$$

4. Experimental and Clinical Trials

3. The need of Model-based method to select PEEP

2. Ventilation
PEEP

1. Introduction
Human Lung, Respiratory Failure and Mechanical Ventilation

Experimental and Clinical Trials

Simulate ARDS in Animals

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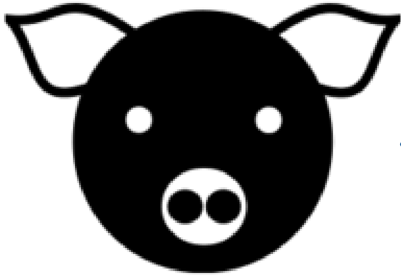
1. Animal



2. Ventilator

3. Computer Platform

Airway Pressure Flow data

Induce ARDS through:

4A. Oleic Acid

4B. Saline Lavage

Other of methods inducing ARDS in animal models

- **Endotoxin**
- **Smoke/ burn**

Ballard-Croft C, Wang D, Sumpter LR, Zhou X, Zwischenberger JB: **Large-Animal Models of Acute Respiratory Distress Syndrome.** *The Annals of Thoracic Surgery* 2012, **93:**1331-1339

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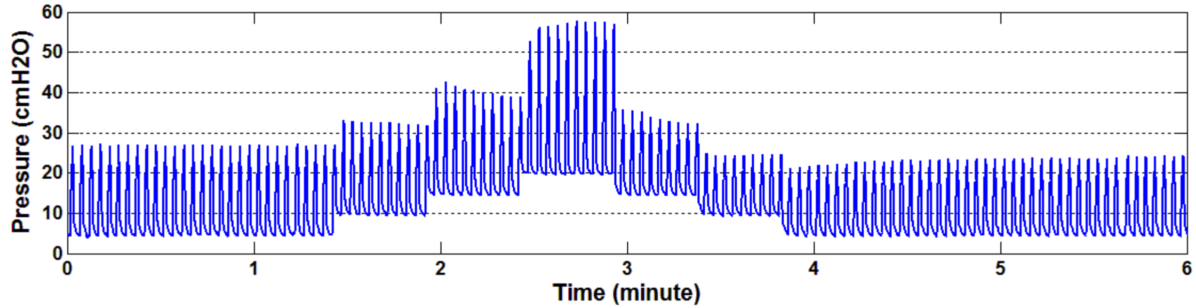
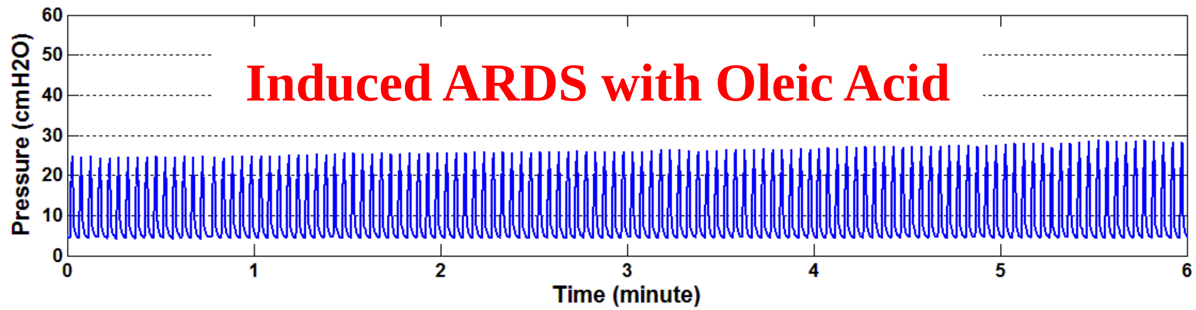
Experimental Phases

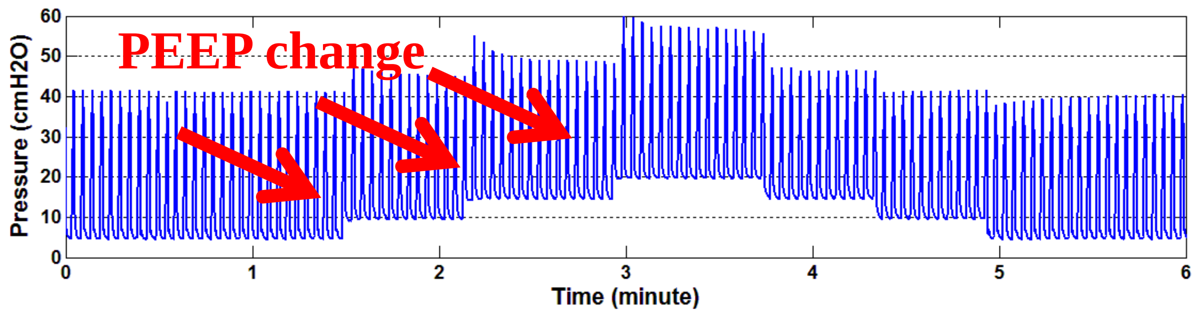
Phase 1 – Staircase recruitment manoeuvre (SRM) during healthy



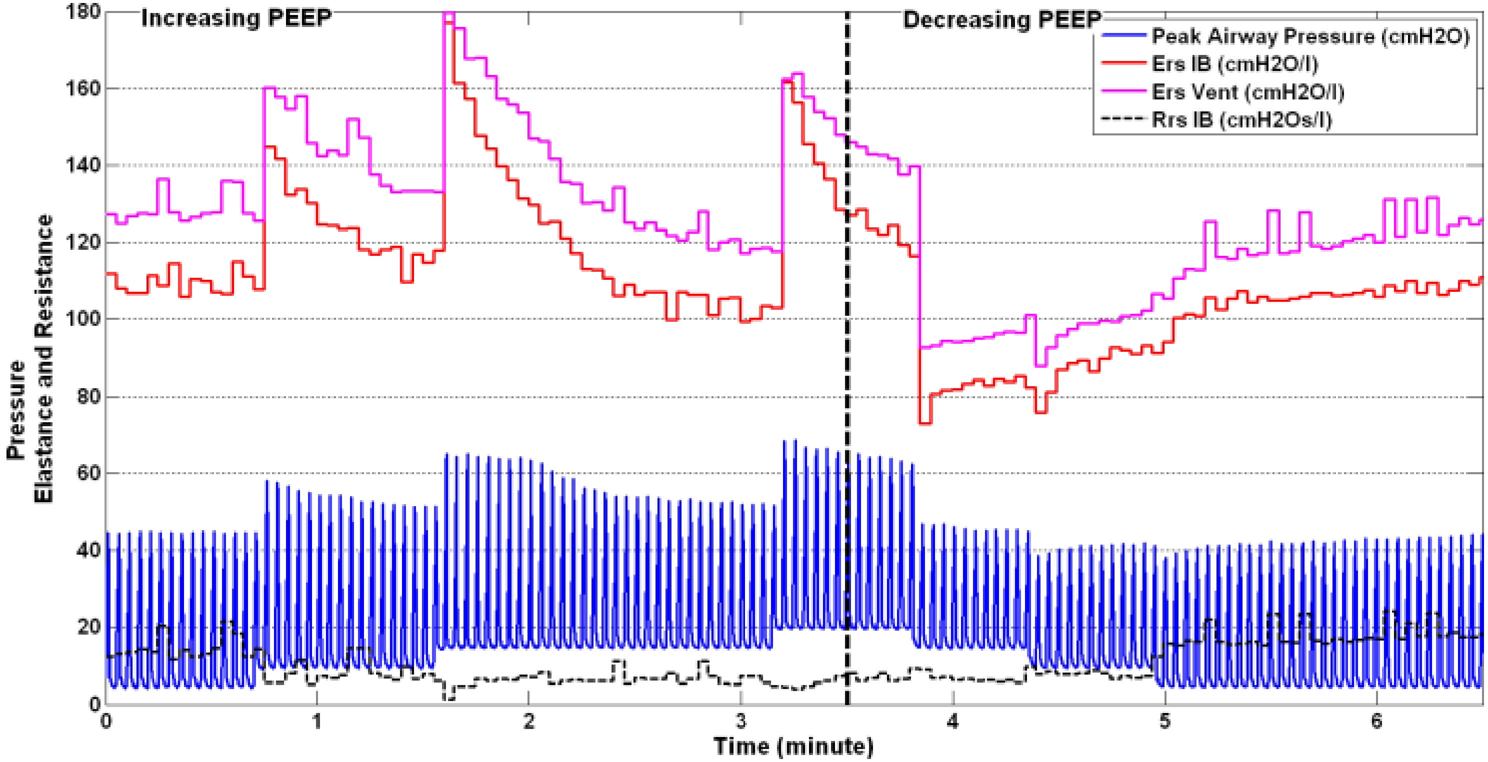
Phase 2 – Progression



Phase 3 – Staircase recruitment manoeuvre during ARDS



Phase 3



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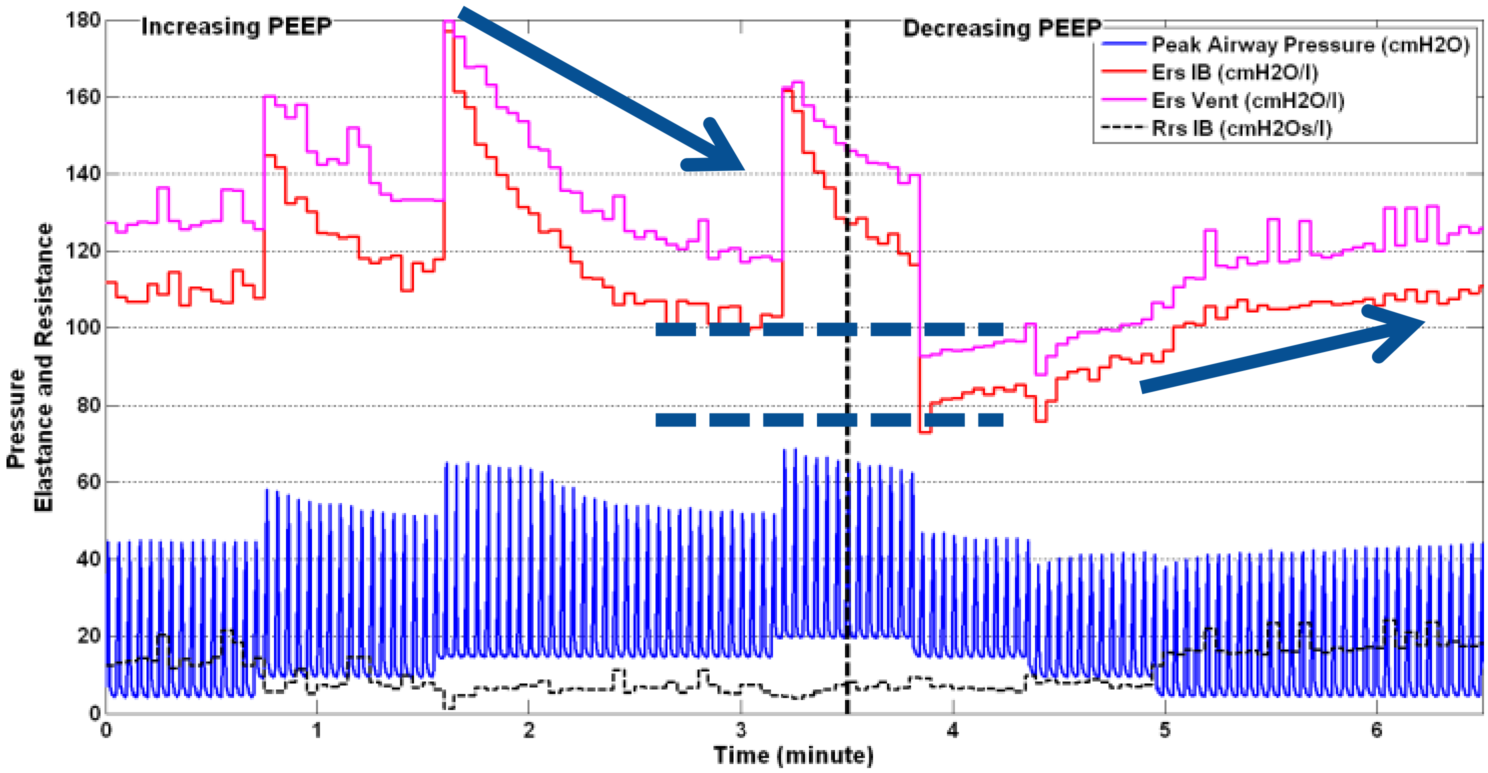
Phase 3



Increasing PEEP
Decreasing PEEP
Peak Airway Pressure (cmH2O)
Ers IB (cmH2O/l)
Ers Vent (cmH2O/l)
Rrs IB (cmH2Os/l)
Pressure
Elastance and Resistance
Time (minute)
0
20
40
60
80
100
120
140
160
180
0
1
2
3
4
5
6

Phase 3

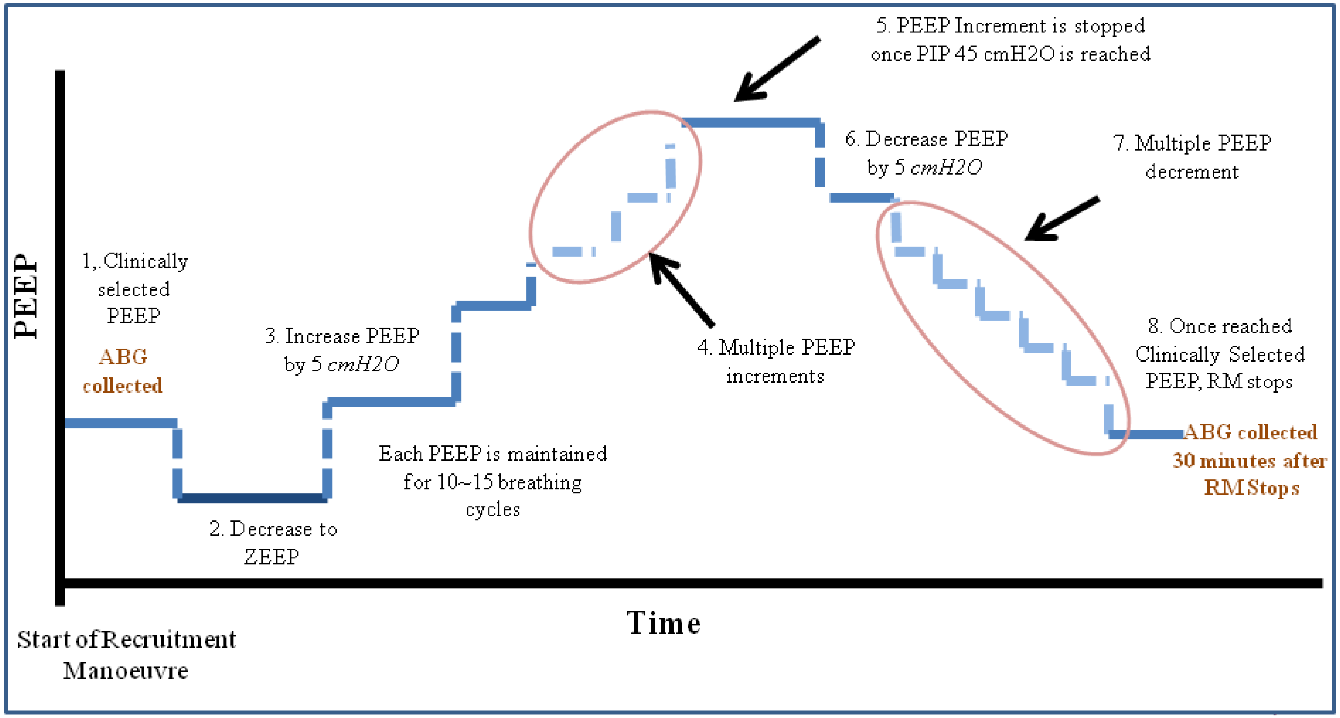

recruitment
Increasing PEEP
Decreasing PEEP
Peak Airway Pressure (cmH2O)
Ers IB (cmH2O/l)
Ers Vent (cmH2O/l)
Rrs IB (cmH2Os/l)
Alveoli collapse
recruitment resulting in lower elastance
Pressure
Elastance and Resistance
Time (minute)
180
160
140
120
100
80
60
40
20
0
0
1
2
3
4
5
6

Findings

- Respiratory elastance (E_{rs}) can be used as an **indicator** for recruitment and overdistension.
- **PEEP can be set at minimal Elastance to maximise recruitment while minimising the risk of overdistension**
- **Monitoring Elastance continuously provides information the on patients disease state progression**

Clinical Studies

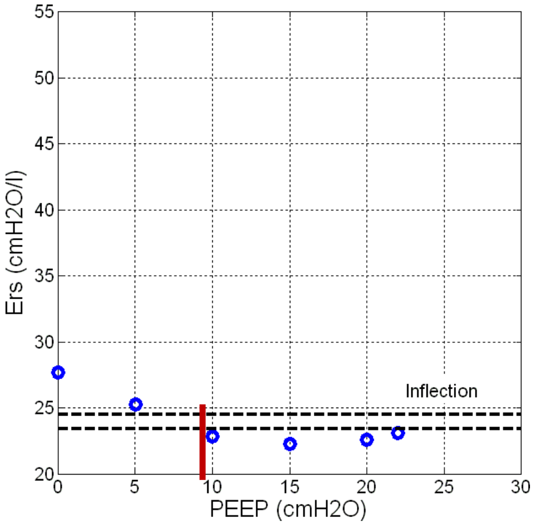
- Christchurch Hospital intensive care unit
- 10 + 15 ARDS patients
- Perform a Recruitment Manoeuvre (PEEP change)
- Respiratory System Elastance with PEEP



Examples – Variable PEEP with Respiratory Elastance

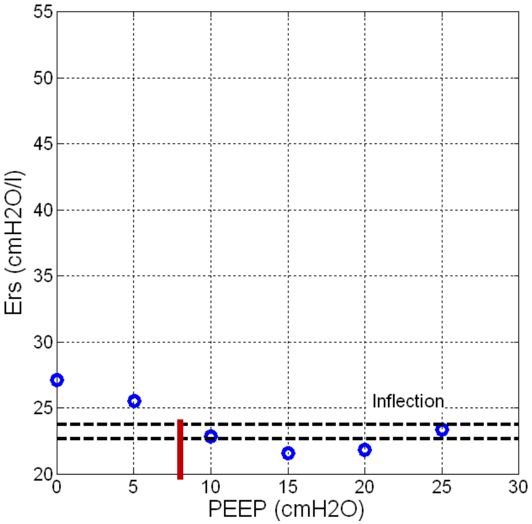
Pt 2:
(Trauma)

Minimal Elastance PEEP = 15cmH2O



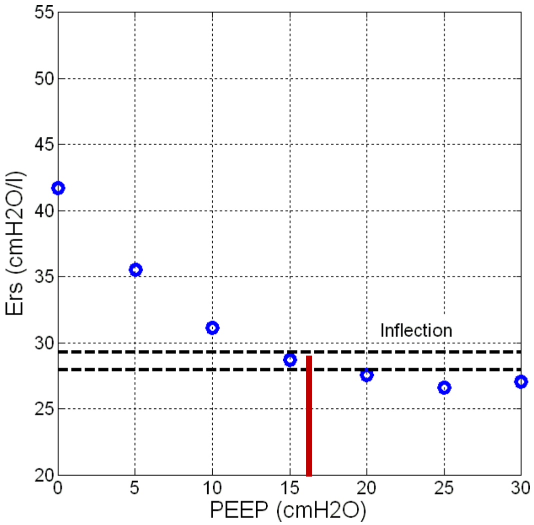
Pt 6:
(Intra-abdominal sepsis, CHF)

Minimal Elastance PEEP = 15cmH2O



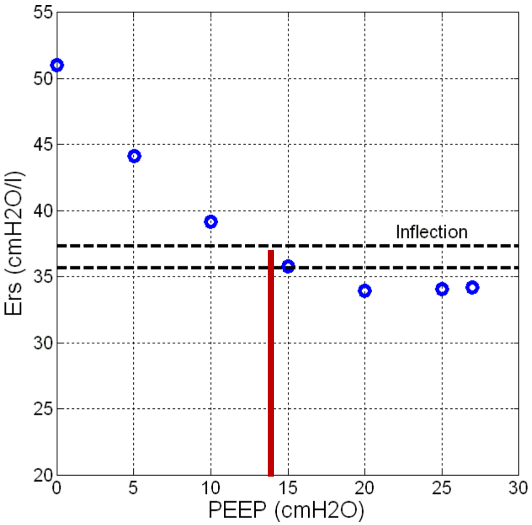
Pt 8:
(Aspiration)

Minimal Elastance PEEP = 25cmH2O



Pt 10:
(Legionnaires, COPD)

Minimal Elastance PEEP = 20cmH2O



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Some research with minimal Elastance

- Suter P, Fairley B, Isenberg M: **Optimum End-Expiratory Airway Pressure in Patients with Acute Pulmonary Failure.** *N Engl J Med* 1975, **292:**284-289.
- Suarez-Sipmann F, Bohm SH, Tusman G, Pesch T, Thamm O, Reissmann H, Reske A, Magnusson A, Hedenstierna G: **Use of dynamic compliance for open lung positive end-expiratory pressure titration in an experimental study.** *Crit Care Med* 2007, **35:**214 - 221.
- Carvalho A, Jandre F, Pino A, Bozza F, Salluh J, Rodrigues R, Ascoli F, Giannella-Neto A: **Positive end-expiratory pressure at minimal respiratory elastance represents the best compromise between mechanical stress and lung aeration in oleic acid induced lung injury.** *Critical Care* 2007, **11:**R86.
- Lambermont B, Ghuysen A, Janssen N, Morimont P, Hartstein G, Gerard P, D'Orio V: **Comparison of functional residual capacity and static compliance of the respiratory system during a positive end-expiratory pressure (PEEP) ramp procedure in an experimental model of acute respiratory distress syndrome.** *Critical Care* 2008, **12:**R91.
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- Carvalho AR, Bergamini BC, Carvalho NS, Cagido VR, Neto AC, Jandre FC, Zin WA, Giannella-Neto A: **Volume-Independent Elastance: A Useful Parameter for Open-Lung Positive End-Expiratory Pressure Adjustment.** *Anesthesia & Analgesia* 2013, **116:**627-633
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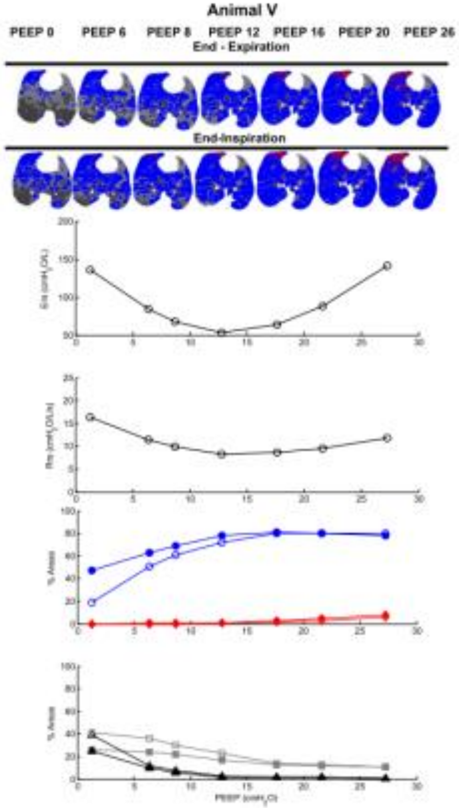

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4. Experimental and Clinical Trials

1. Experimental Animal Trials: Oleic Acid, Lavage
2. Clinical Trials: Observational, pilot, etc

3. The need of Model-based method to select PEEP

5. Preparing for RCT

2B. Ventilation
PEEP

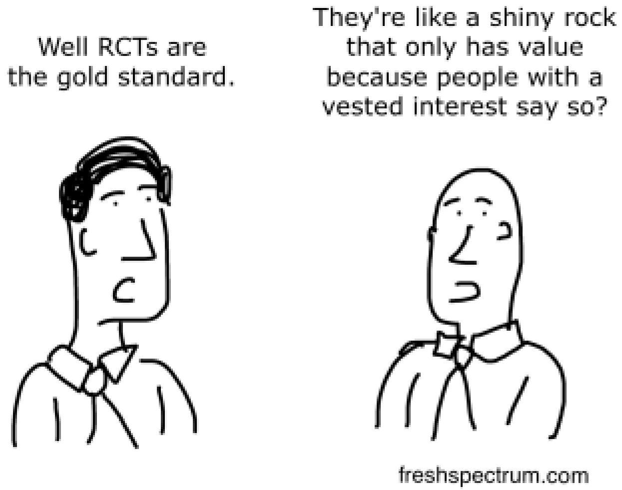
1. Introduction
Human Lung, Respiratory Failure and Mechanical Ventilation

Preparation for Randomised Controlled Trial

Randomized controlled trial:

A study in which people are allocated at random to receive one of several clinical interventions.

- identify factors that influence the effects of the intervention
- understand the processes through which an intervention influences change



CURE RCT

- Clinical Utilisation of Respiratory Elastance

CURE

Clinical Utilisation of Respiratory Elastance

- Using real-time breath-to-breath respiratory system elastance to guide mechanical ventilation PEEP selection, based on minimum elastance-PEEP concept.
- Compared to standard practice

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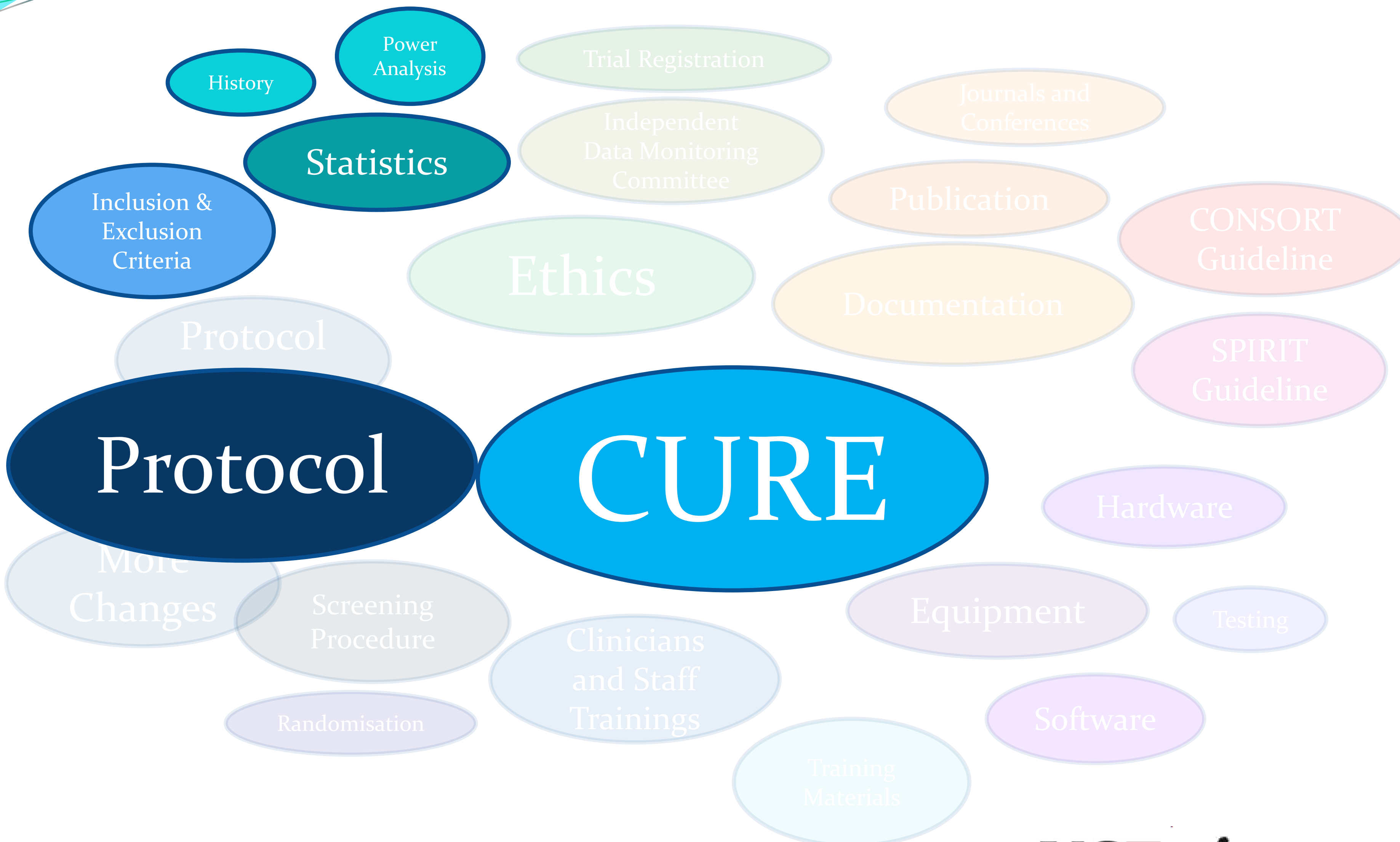
History
Power Analysis
Trial Registration
Journals and Conferences
Statistics
Independent Data Monitoring Committee
Publication
Inclusion & Exclusion Criteria
CONSORT Guideline
Ethics
Documentation
Protocol
SPIRIT Guideline
Protocol
CURE
Hardware
More Changes
Screening Procedure
Equipment
Testing
Clinicians and Staff Trainings
Randomisation
Software
Training Materials

Designing the study and clinical protocol

- We need to know our target patient group.
- What are the sample size?
  - What are the Primary and Secondary Outcomes.
    - Blood oxygenation, Length of mechanical ventilation, mortality etc



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Christchurch ICU Record

- ICU admission record from 2011 to 2013 were analysed
- Of the 3907 patients admitted, 2921 patients (75%) required MV, and 2534 (65%) patients were invasively ventilated.

Christchurch ICU Record

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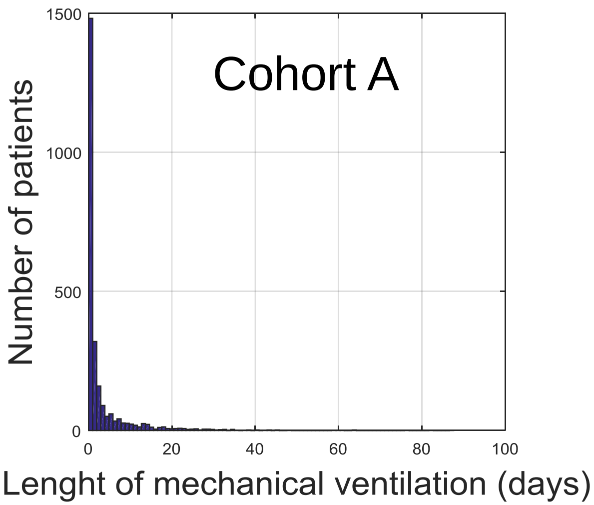
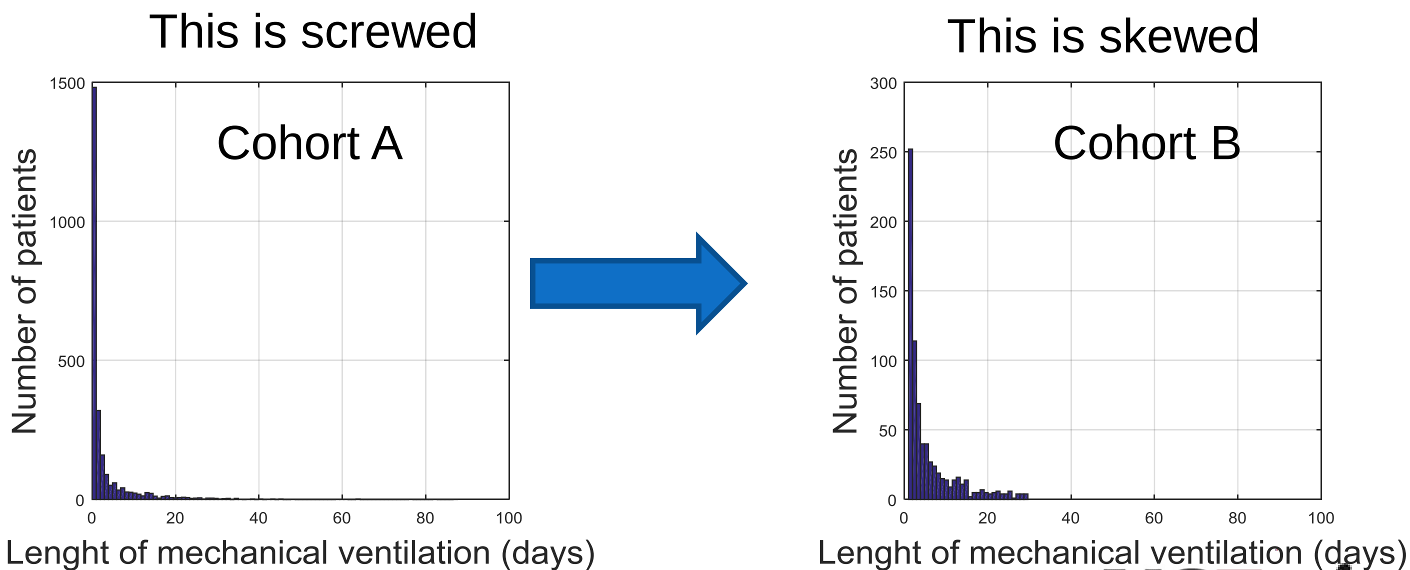
- Of the 3907 patients admitted, 2921 patients (75%) required MV, and 2534 (65%) patients were invasively ventilated.
- But the distribution of length of mechanically ventilation is skewed.



Christchurch ICU Record

- ICU admission record from 2011 to 2013 were analysed
- Of the 3907 patients admitted, 2921 patients (75%) required MV, and 2534 (65%) patients were invasively ventilated.
- But the distribution of length of mechanically ventilation is skewed.
- It is important to target the cohorts that is likely to benefit for the trial.



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Protocol

CURE

Hardware

More Changes

Screening Procedure

Equipment

Testing

Clinicians and Staff Trainings

Randomisation

Software

Training Materials

Designing the study and clinical protocol

- We need to know our target patient group.
- What are the sample size?
  - What are the Primary and Secondary Outcome.
    - Blood oxygenation, Length of mechanical ventilation, ventilator free days, $EtCO_2$
- Clinical protocol has to be feasible and not burdensome to current clinical practice
  - When should we titrate PEEP?
  - How often should we titrate PEEP?
  - What about other settings?

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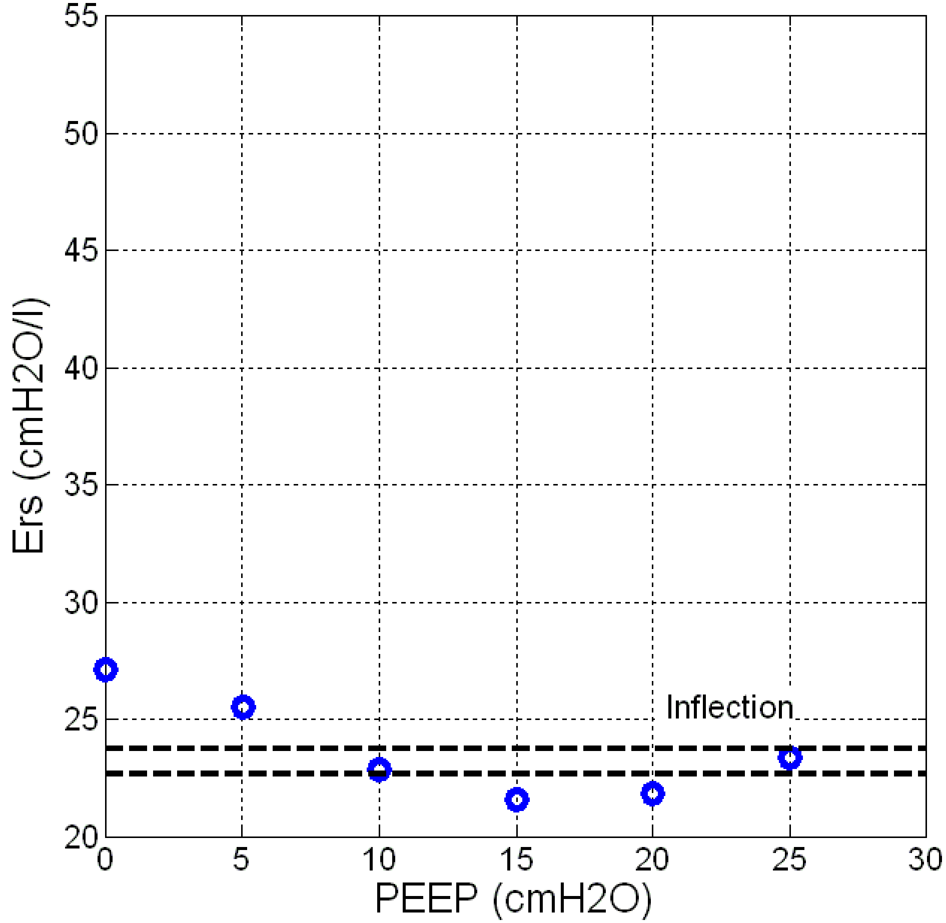
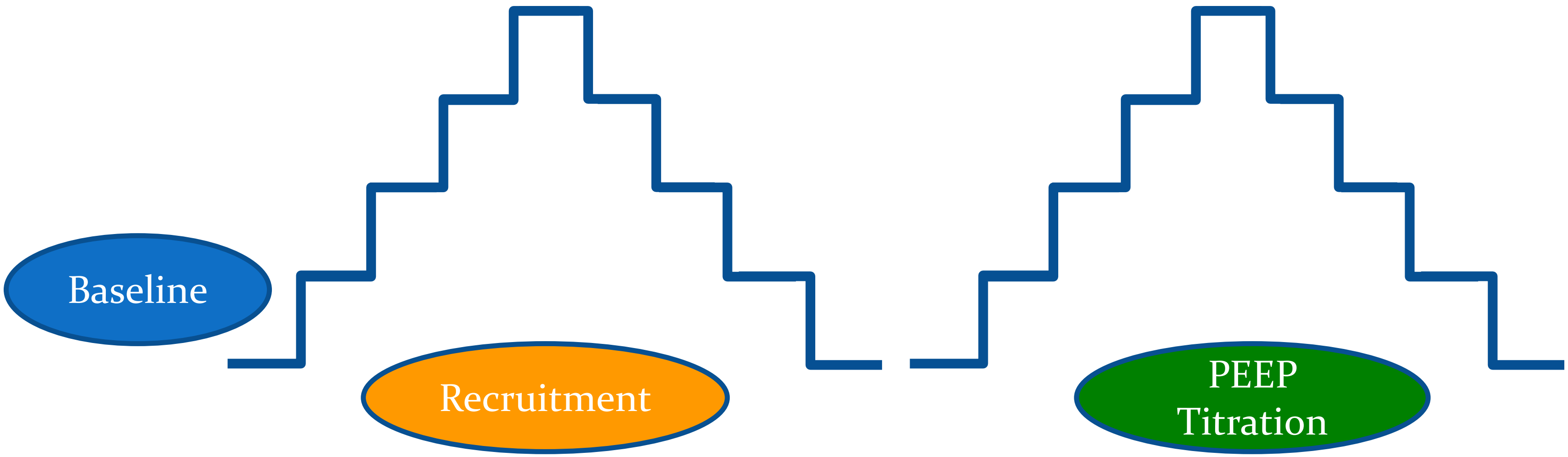
Finding Minimal Respiratory System Elastance PEEP

- Minimal Elastance (Maximum Compliance) was observed at PEEP 15cmH2O

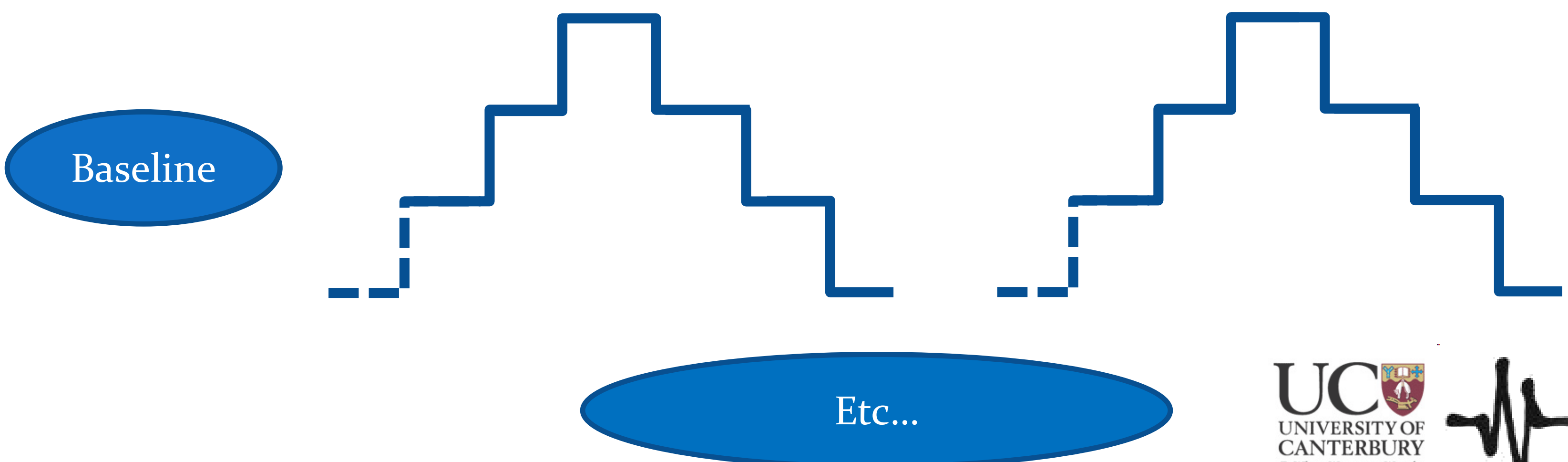


Maximum Recruitment Manoeuvre

- During the start of the trial



PEEP Adjustment and Monitoring Procedure Every 6 hours



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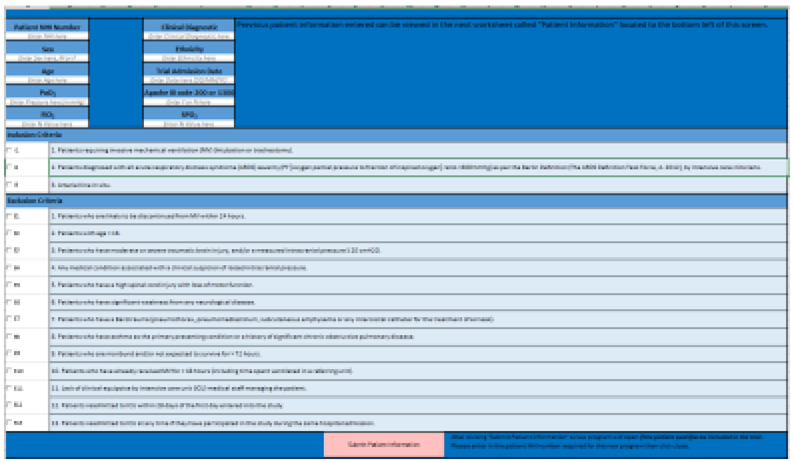
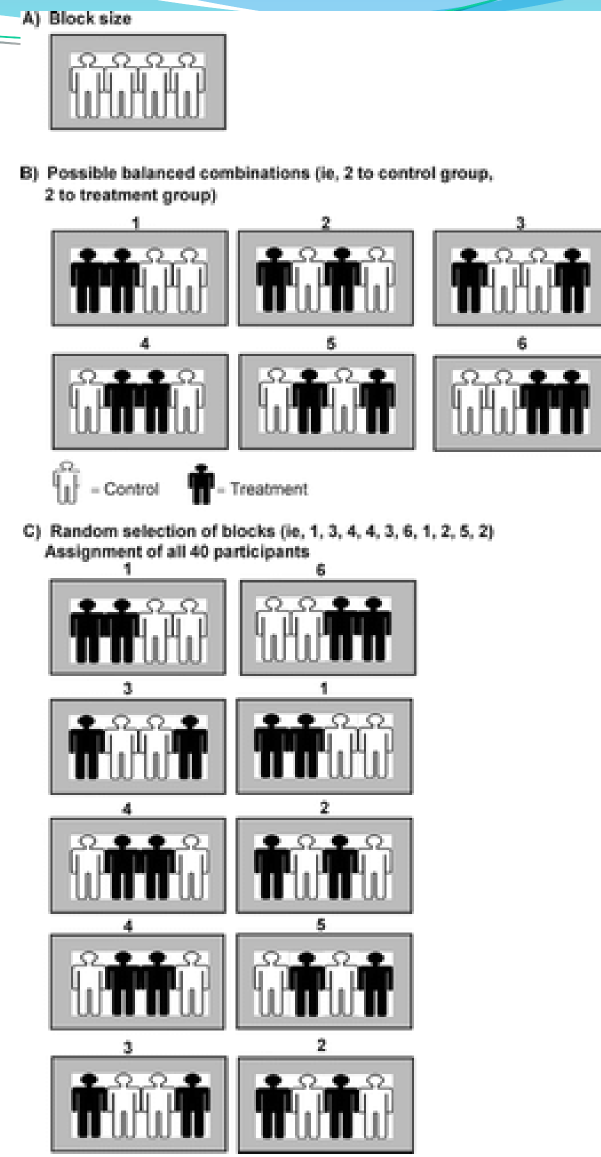
Screening and Randomisation

- Eligibility
- Block Randomisation (Random block size)
- Web-based, letter based etc…





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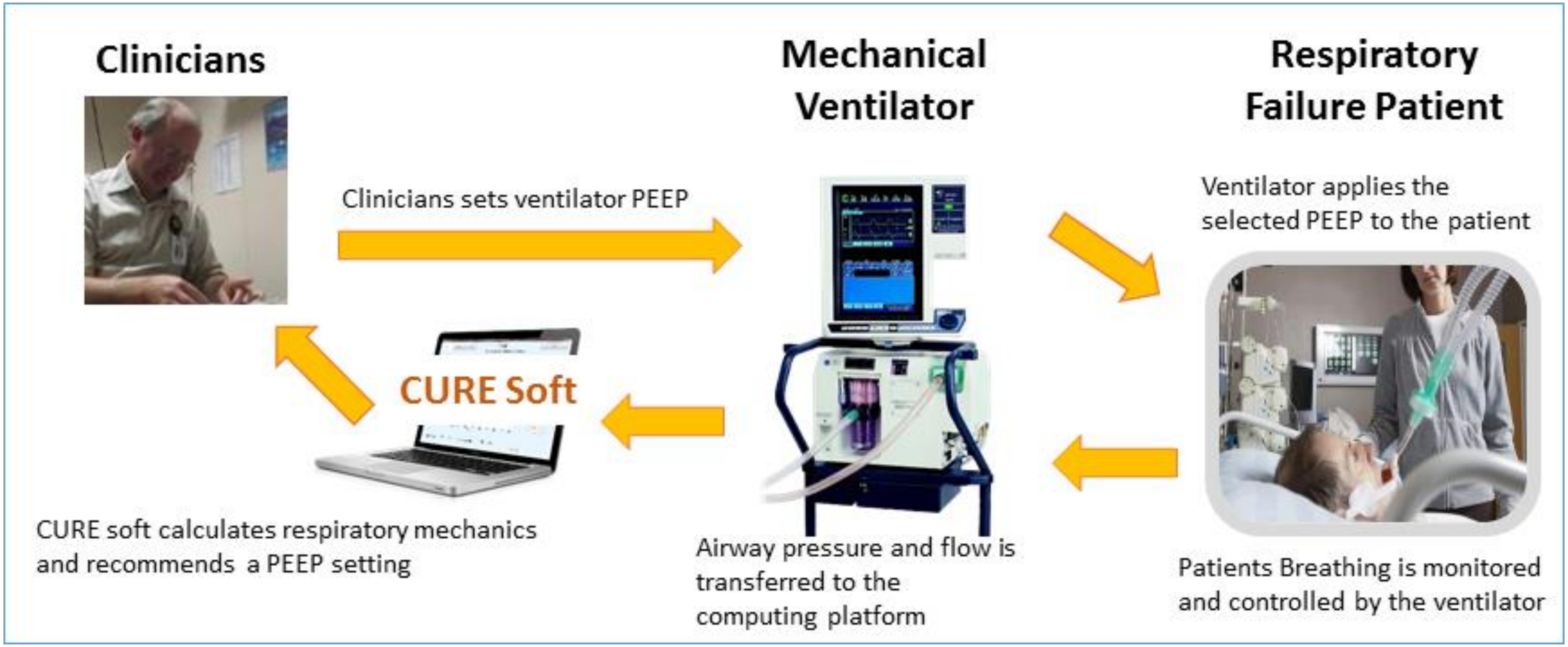
Equipment
Testing
Clinicians and Staff Trainings
Software
Randomisation
Training Materials

CURE Implementation



Equipment

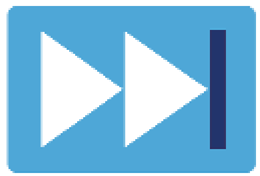
Software – CURE Soft

2012:
CURE Soft
Matlab version 1.0


User Experience
Design

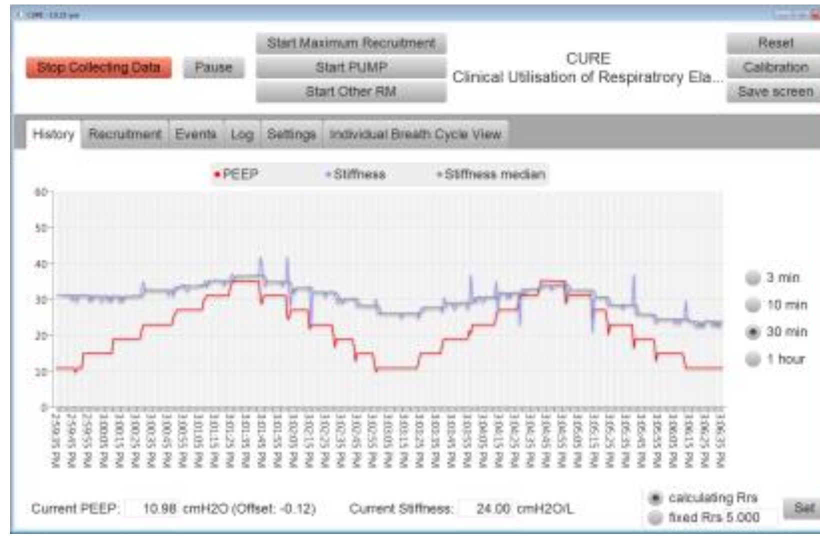
Equipment

Software – CURE Soft



n = i-iterations

2012:
CURE Soft
Matlab version 1.0

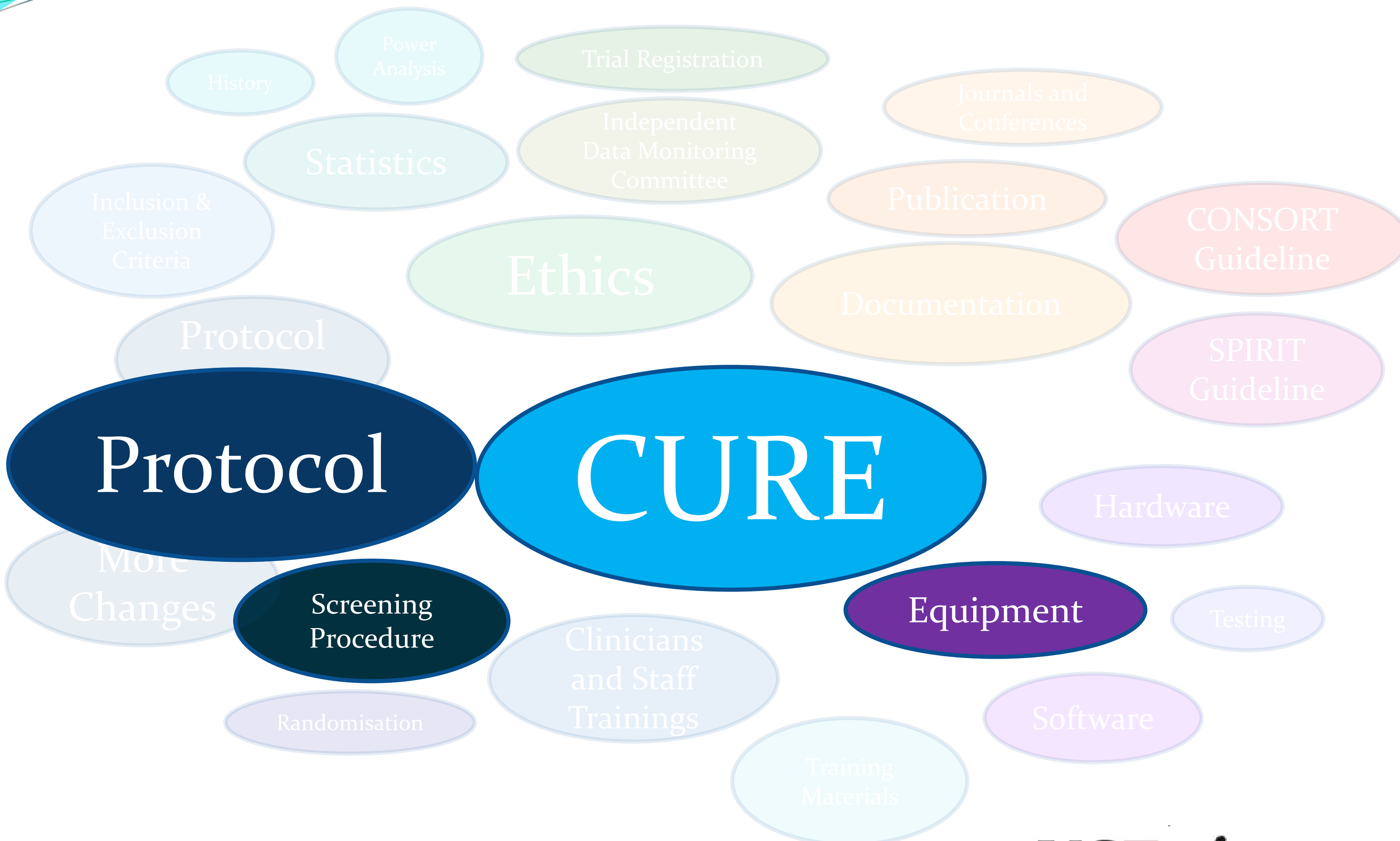


2015 :
CURE Soft
JAVA version 1.0.22 pre beta 9

Equipment

CURE Soft System:
Consist of a Gechic Touchscreen monitor and Next Unit of Computing (NUC) unit for data processing

Mounting Support for CURE Soft:
Consist of stainless steel brackets and holders



History
Power Analysis
Trial Registration
Journals and Conferences
Statistics
Independent Data Monitoring Committee
Publication
Inclusion & Exclusion Criteria
CONSORT Guideline
Ethics
Documentation
Protocol
SPIRIT Guideline
Protocol
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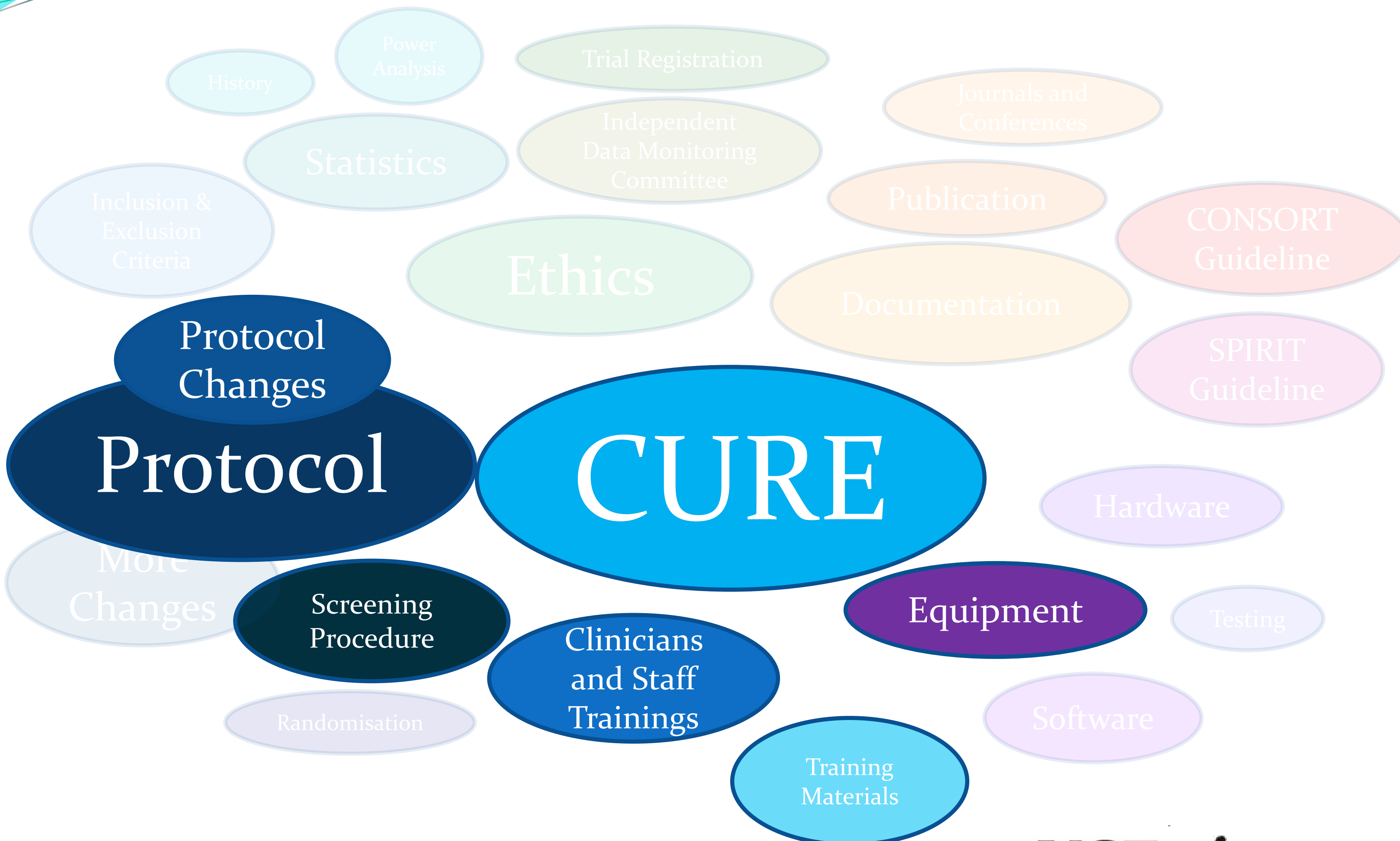

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Trial Registration
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SPIRIT Guideline
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Testing
Software

Ethics and Clinical Trial Registration

- Local ethics committee
- Independent data monitoring committee (Data safety)
- Clinical trial registry

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Independent Data Monitoring Committee

Inclusion & Exclusion Criteria

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Documentation Guideline

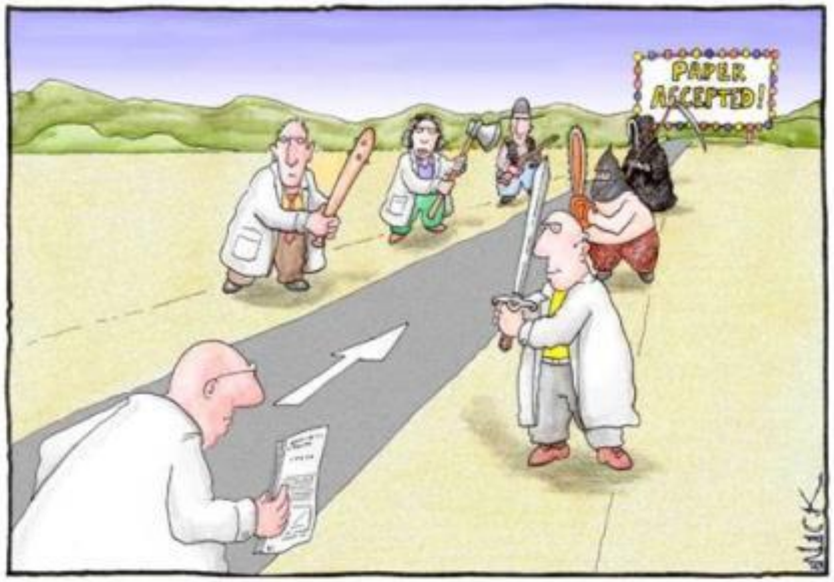
- SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials)
  - http://www.spirit-statement.org/

"Sure, it's a great invention, but does it comply with all government guidelines?"

Documentation Guideline

CONSORT
TRANSPARENT REPORTING of TRIALS

- CONSORT (Consolidated Standards of Reporting Trials)
  - http://www.consort-statement.org/consort-2010



Most scientists regarded the new streamlined peer-review process as "quite an improvement."

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Repository

4. Experimental and Clinical Trials

1. Experimental Animal Trials: Oleic Acid, Lavage
2. Clinical Trials: Observational, pilot, etc

3. The need of Model-based method to select PEEP

5. Preparing for RCT

1. Statistical analysis
2. Documentation
3. Staff Trainings
4. Randomisation and Logging
5. Repository… etc

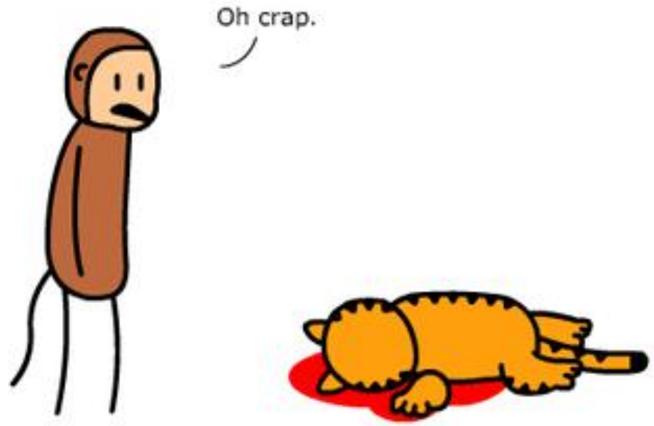
2B. Ventilation
PEEP

6. Commencement and Challenges

1. Introduction
Human Lung, Respiratory Failure and Mechanical Ventilation

Challenges in Mechanical Ventilation RCT

- What is the best Protocol?
- What is good MV?
- Equipment implementation?
- Adaptation?



Curiosity killed the cat.

1. Introduction

Human Lung, Respiratory Failure and Mechanical Ventilation

2B. Ventilation

PEEP

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6. Commencement and Challenges

1. Equipment implementation
2. Asynchrony and Spontaneous breathing
3. Change of protocol
4. Adaptation

7. Final thoughts

Final Thoughts

- RCT is where your work should be heading
- Do I think model-based mechanical ventilation will work?
  - Yes and…
  - No. Too many co-founding factors that can effect quality of MV.
- Can we solve MV issue?
  - Maybe not all at once, but we wish to open a path to standardise patient-specific MV in a consistent fashion.
- We need human resources.

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Human Lung, Respiratory Failure and Mechanical Ventilation

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There are still lots to do

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1. Introduction

Human Lung, Respiratory Failure and Mechanical Ventilation

2. Ventilation

PEEP

Perfusion

FiO2

Other

Respiratory Rate, I:E Ratio, Minute Ventilation etc

3. The need of Model-based method to select PEEP

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2. Clinical Trials: Observational, pilot, etc

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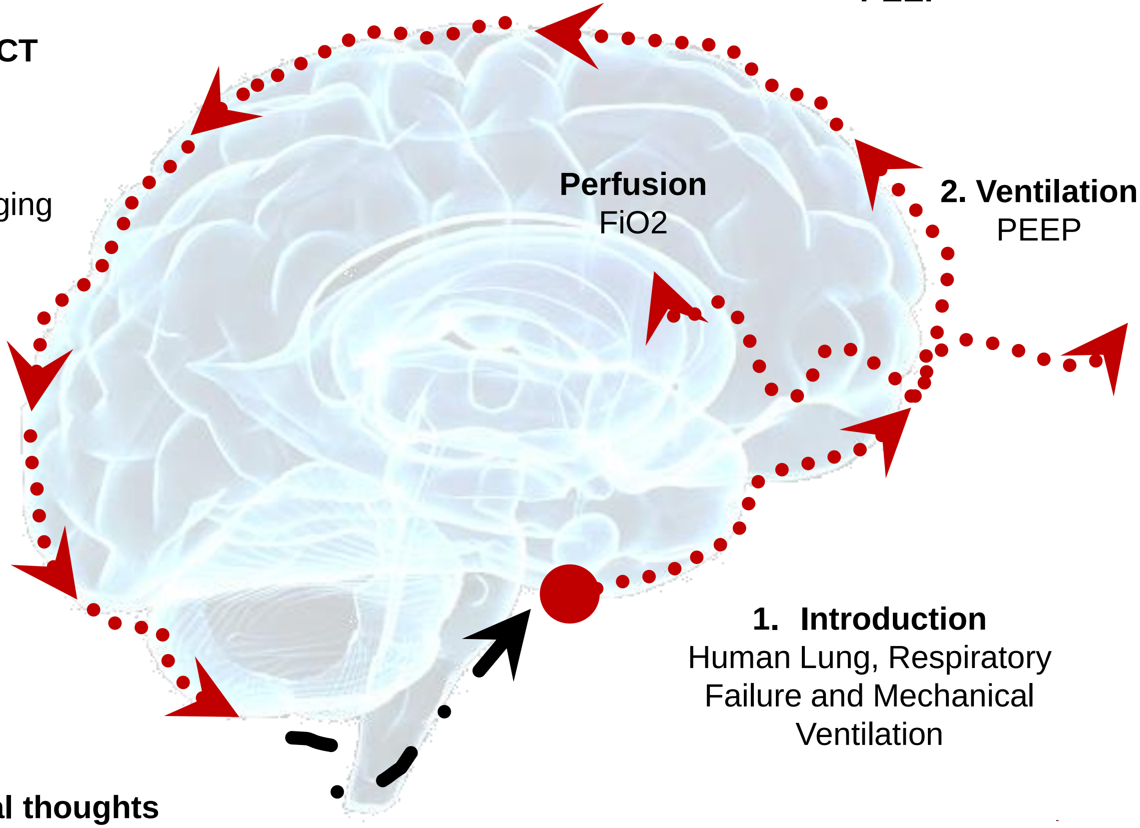

2. Ventilation
PEEP

Other
Respiratory Rate, I:E Ratio, Minute Ventilation etc

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Human Lung, Respiratory Failure and Mechanical Ventilation

7. Final thoughts
There are still lots to do

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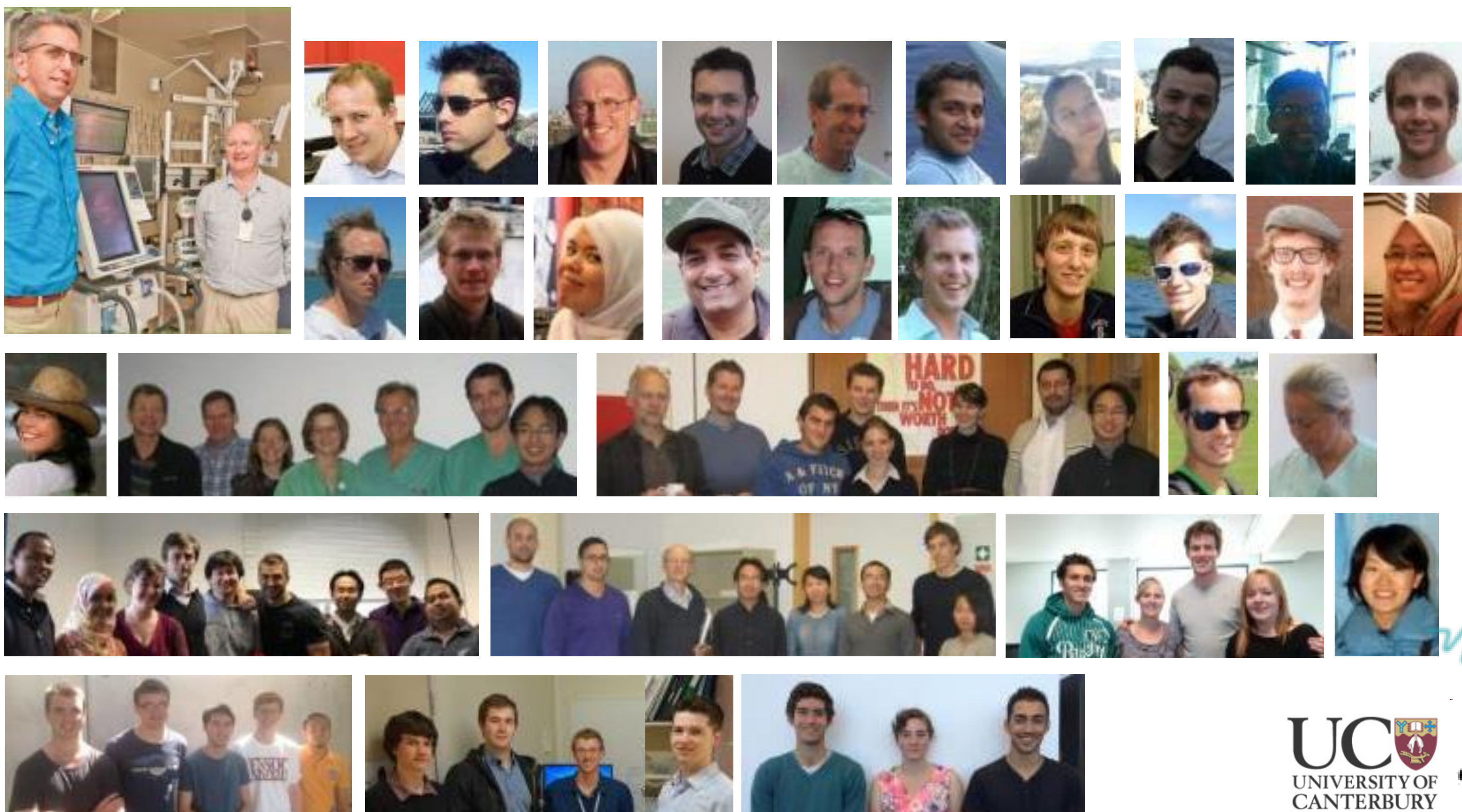
Acknowledgement

- Centre of Bioengineering (University of Canterbury, New Zealand)
- GIGA Cardiovascular Science (University of Liege, Belgium)
- Swiss-Belgium NAVA ventilation Research Group (Belgium, Switzerland)
- Institute of Technical Medicine (Furtwangen University, Germany)



Université de Liège

GIGA

HOCHSCHULE FURTWANGEN UNIVERSITY HFU

ITeM

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תודה
Dankie Gracias
Спасибо شكراً Merci Takk
Köszönjük Terima kasih
Grazie Dziękujemy Dėkojame
Ďakujeme Vielen Dank Paldies
Kiitos Täname teid 谢谢

Thank You

Tak
感謝您 Obrigado Teşekkür Ederiz
감사합니다
Σας Ευχαριστούμ ขอบคุณ
Bedankt Děkujeme vám
ありがとうございます
Tack

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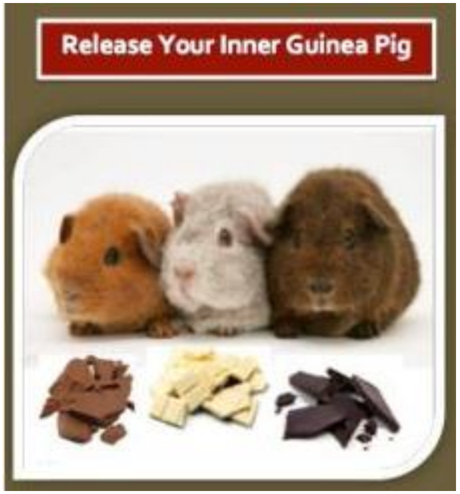
Others

- Exploring new ideas and Look for other ideas
- Not knowing… could be good for generating ideas
  until you found out someone did the work



- Ventilation model does not directly link to patient outcome or quality of the delivered MV
  - Develop the relation of respiratory mechanics progression with patient-specific outcome.
  - PaO_2, SPO_2, Mortality, LoMV
- Perfusion Model. Setting FiO_2 which link to PaO_2 and SpO_2 are may be a solution. We need to adapt this model to clinical practice

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Models and metrics…

- All models are ‘wrong’ because of limitations
- All models are ‘correct’ because of assumptions

- **Engineers**: Physiological Model →

More parameters → Less parameters →

More parameter → …

→ Optimal… what is optimal?

"If you want a second opinion, I'll ask my computer."

- **Clinicians**: Physiological Model → As long as it works (will be better if I can understand)

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Surrogates of Good Mechanical Ventilation

- Survival: 28-day mortality
- Organ failure free days
- Ventilator Dependency
  - Length of mechanical ventilation
  - Ventilator free days
  - Weaning time
- Oxygenation
  - Partial Pressure of Arterial Oxygenation (PaO2)
  - Oxygen Saturation SaO2 or Oxygen Saturation measured SpO2 (Desaturation events)
- Asynchronous index (?)
- Respiratory Mechanics (?)

Blackwood B et al, **How Outcomes Are Defined in Clinical Trials of Mechanically Ventilated Adults and Children.** *American Journal of Respiratory and Critical Care Medicine* 2014, **189:**886-893.

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Acknowledgement

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