STUDY PROTOCOL: EMERGENCY LUNG-PROTECTIVE VENTILATION IMPLEMENTATION STRATEGY

Short title: The ELVIS project

Lay description: A small number of patients who are brought to the emergency department need a general anaesthetic. This lets us help them by keeping their airway open, improve their oxygen levels and breathe for them on a mechanical ventilator. Some of these patients have injured or severely diseased lungs. In these patients, a protective ventilator setting (small volumes of breath at lower pressures) reduces rates of death and time on a ventilator. Other patients have normal lungs initially, but are at risk of developing lung disease whilst on a ventilator. The use of the same protective ventilator settings on these patients can reduce the development of severe lung disease, including infections and lung collapse.

Currently, the ventilator settings in our emergency department are set by the bedside, treating clinician. These may not always be with protective settings.

We aim to improve the quality of our care of our ventilated patients by optimising ventilator settings and increasing the frequency by which protective settings are used. This will be done by implementing a guideline (called ELVIS) designed to prompt clinicians and bed-side nursing staff to set the ventilator to patient-specific, protective values whilst promoting frequent reassessment of these targets and adjusting settings on a regular basis to meet the patients needs. This guideline has been developed by both Intensive Care and Emergency Medicine specialists.

The ELVIS guideline will be used on all ventilated patients in the emergency department, unless the clinician believes an alternate method is safer based on their underlying lung disease. For example, asthmatic patients do not need a protective strategy and will not have the guideline used.

Most ventilated patients are transferred from the emergency department to the intensive care unit. These protective ventilator settings will be continued in intensive care.

This study aims to compare clinical data, ventilation settings and outcomes of patients ventilated according to the ELVIS guideline to those who were ventilated during the subsequent two years (2015-2016).

Study investigators:

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Background: Endotracheal intubation and mechanical ventilation are utilised in severely injured and critically ill patients who present to the Emergency Department (ED). There is a significant body of evidence demonstrating that lung protective ventilation strategies (tidal volumes of 6-8mL/kg of ideal body weight and plateau pressures of <30cmH_2O) decrease mortality and increase the number of ventilator free days in patients with acute lung injury (ALI) and acute respiratory distress syndrome (ARDS)[1-5].

Mechanically ventilated patients in the ED often have no features of ALI or ARDS at the time of intubation (ie. non-injured lungs). They are however at high risk for developing ventilator-induced lung injury (VILI) through various mechanisms including interventions such as blood transfusion, general anaesthesia and surgery or coinciding pathology such as sepsis, trauma or brain injury[6]. The implementation of lung protective ventilation strategies in this population can decrease the development of ARDS, pulmonary infection and atelectasis but not in-hospital mortality[6-11]. Evidence suggests that lung protective ventilation is uncommon in the ED, regardless of ALI status[12-14]. Furthermore, only a minority of ventilated patients actually have adjustments made to their ventilation whilst still in the ED[13-14].

Currently, ventilation strategies in our Emergency Department are non-standardised and are largely dependent upon the treating clinician. The frequency with which lung protective ventilation is utilised remains unknown and is currently under investigation by way of a retrospective audit.

This study aims to review the data and observations following the implementation a mechanical ventilation care bundle *(Appendix A)* including a lung-protective ventilation strategy (ELVIS) guideline designed to prompt the treating emergency medicine clinician and nursing staff to optimise their ventilation strategy for their intubated patients in line with current accepted lung-protective ventilation practices.

Methods: The ELVIS guideline is a quality improvement initiative designed by Emergency Medicine and Intensive Care physicians and approved for implementation by Executive members of both departments. It will be introduced as a quality improvement initiative to senior medical staff (specialist Emergency Physicians and senior registrars), Clinical Nurse Educators and resus-trained nurses via formal in-services. Implementation will take place once 75% of these staff have been educated and signed off for use.

Following the implementation of ELVIS, all patients aged ≥16 years, who are mechanically ventilated in emergency department (with the exception of those excluded by clinician discretion, eg. asthma) will have their ventilation strategy optimised by the ELVIS guideline. Prospective data will be collected on all mechanically ventilated patients to ensure quality improvement outcomes are being reached.

Regular audits (1-3 monthly) will be also be performed to assess for compliance and safety with this initiative. Staff feedback and satisfaction surveys will also be obtained during this period.

Following a twelve month trial period, clinical data will be formally reviewed to establish the effectiveness of this strategy including patient demographics, intubation details, physiological observations, ventilation parameters, blood gas results and rates of ventilator-associated pneumonia and acute lung injury. This data will be collated and compared to our current, pre-ELVIS ventilation practices (2015-16 data). All analyses will be supervised by a senior biostatistician. Normally distributed outcomes will be reported as means (SD) and non-normal data will be reported as medians (IQR). Categorical data will be reported as count and proportions. A two-sided p-value of 0.05 will be considered statistically significant. Multivariable logistic regression with propensity score adjustment will test the hypothesis that ED lung-protective ventilation decreases the incidence of pulmonary complications.

Objectives:

Primary:
To measure the percentage of mechanically ventilated patients who receive a lung protective strategy in the emergency department following implementation of the ELVIS guideline and compare this to rates of lung protective ventilation that occurred prior to this implementation.

Secondary:
To measure the percentage of patients receiving lung-protective ventilation who develop pulmonary complications (eg. atelectasis, pneumothorax or ventilator-associated pneumonia) during their hospital stay, and compare this to rates that occurred prior to this implementation.

To measure the percentage of patients receiving lung-protective ventilation who reach their predetermined physiological targets (oxygenation and ventilation).

To measure the percentage of patients receiving lung-protective ventilation who reach acute lung injury or acute respiratory distress syndrome criteria during their hospital stay, and compare this to rates that occurred prior to this implementation.

To measure the total ventilator days and hospital length of stay in patients receiving lung-protective ventilation and compare this to durations that occurred prior to this implementation.

Study design: This is a prospective, observational cohort study. As this study aims to report the outcomes of a quality improvement intervention designed to bring current daily practice in line with current accepted lung-protective ventilation practices, a before-and-after observational study is most appropriate.

Study setting: A single-centre study, set in the Emergency Department and Intensive Care Unit of Liverpool Hospital, Sydney.

Study duration:
Study protocol completion: May 2017
LNR submission: May 2017
Ethical approval: June 2017
Training of medical staff: June 2017
Study commencement: June 2017 (*pending Ethics approval*)
Recruitment closes: n/a (ongoing data analysis, based on quality improvement)
Data analysis complete: July 2018
Write-up complete: September 2018.
Submission: December 2018.

Study population:

Recruitment process:
All mechanically ventilated patients in the emergency department will entered into this study. The ELVIS guideline will be applied to all patients aged 16 years or older who do not meet any of the exclusion criteria. Excluded patients will also be followed as a component of the quality improvement initiative and for ongoing data analysis.

Inclusion criteria:
Mechanically ventilated patients
(including those intubated prehospital).
Age ≥16 years

Exclusion criteria:
Age < 16 years
Underlying clinical condition or lung pathology not conducive to lung-protective ventilation.

Potential for risk, burden or benefit:
This quality improvement initiative aims to bring mechanical ventilation practices in line with those scientifically proven to have a reduction in morbidity and mortality in patients with acute lung injury and acute respiratory distress syndrome. It also aims to carry this ventilation strategy to at-risk patients where it is known to reduce rates of acute lung injury. As such, there are no foreseeable risks to these participants.

These patients may potentially benefit from the ventilator improvements mentioned above.

Informed consent, confidentiality and privacy:

A waiver of participant consent is sought as this is a prospective quality improvement initiative, where the participants will be de-identified and their privacy maintained.

This study is completely non-invasive in that it uses demographic, physiological and patient stay data which is measured routinely as part of their clinical care. There is no additional interventions to patient care deviating from standard practice. There is no change in the use of their data, nor is there data collected which is extra to that used in routine patient assessment and management.

In the current study, the maximum level of intervention is the collection of data concerning patients who present with critical illness or injury to the Liverpool Hospital Emergency Department (ED). These data are necessary solely to investigate illness or to guide ongoing clinical care for patients presenting to the ED and transitioning to the Intensive Care Unit (ICU) at Liverpool Hospital. Identifiers will be used to collect data on demographics, investigations and outcomes; once these data are linked to the clinical data collected as part of routine ED and ICU assessment and management, the patients will be de-identified and data stored with patients allocated a unique study number. The ability to re-identify patients from these data will then not exist.

There is no risk to the rights, privacy or professional reputation of carers, health professionals and/or institutions as the study solely concerns the impact of a single clinical intervention which is used ubiquitously, and has no intent to identify individual clinicians or carers, nor to use the data as commentary on the institutions concerned.

Data management and storage:

Data will be stored in the Principal Investigator's office, in the Emergency Department, Liverpool Hospital. Once case and patient data are identified and linked, a unique linkage key will be generated for each set of linked data, and identifiers removed. Information will be stored in electronic form (REDCap database, Vanderbilt University). REDCap (Research Electronic Data Capture) is a secure, browser-based, metadata-driven, electronic data capture software designed by Vanderbilt University. The licensing for REDCap for this study is via the South Western Sydney Clinical School of the University of New South Wales, with data stored behind a firewall.

This database will be stored on the Principal Investigator's computer and will not be shared or distributed in any way, other than to the project investigators. As stated above, a unique linkage key will be generated for each set of linked data, each comprising records from the Emergency Department Information System, physiological and pathology data from ED and hospital records, and outcome data from inpatient clinical notes and Hospital Information System, and AORTIC registry database for ICU-admitted patients. Once linkage is achieved between the data, all identifying details will be removed.

From this point all analyses will be carried out on the de-identified dataset, and access to the prior identified data will only be available to the Principal Investigator for the purposes of security; i.e. if loss of de-identified data occurred due to computer malfunction, the database should be able to be rebuilt based on the original information. Once the de-identified database is complete, all identifiable data stored within the project database will be erased. This will, of course, not affect the original patient records and health information, which are stored in the standard fashion.

This information will be stored for 15 years, in keeping with the NHMRC Australian Code for the Responsible Conduct of Research Practice, Section 2. Magnetic media will be erased before being discarded, and all data will be removed from the drives to the new system. Simply deleting files does not remove data from a disc, therefore the most secure method to prevent the accidental disclosure of information will be used, by reformatting the hard disc.

Data monitoring: Regular audits (1-3 monthly) will be be performed to assess for safety with ventilation and compliance with this initiative. Staff feedback and satisfaction surveys will also be obtained during this period. Following a twelve month trial period, clinical data will be formally reviewed and compared to our current, pre-ELVIS ventilation practices (2015-16 data). If there is any adverse event, the principle investigator will inform the Human Research and Ethics Committee. If there is a serious adverse event, this notification will occur within one working day.

Ethical considerations: This study will occur as part of the participants' care within the emergency department, and it is not anticipated that any specific ethical issues will arise. All clinical care will be provided in a tertiary emergency department or intensive care unit. It will be performed by senior registrars or consultant physicians from each speciality.

Dissemination of results: It is intended that the results of the study will be published in a peer-reviewed journal, and will also be submitted for presentation at any relevant conferences.

Budget: This study will be run using no additional budget. Emergency physicians and registrars will complete study duties within their normal clinical duties or clinical support time.

References:

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APPENDIX A.

MECHANICAL VENTILATION CARE BUNDLE

Date	
Time	
Patient MRN	

This bundle is aimed at patients requiring intubation and mechanical ventilation in the ED.

Please find enclosed:

- RSI checklist
- Airway registry form
- Mechanical ventilation care set
- Ventilation observation chart
- Fluid order
- Drug chart

A tape measure and ideal body weight (IDW) nomogram will be available in each resus bay.

INCLUSION CRITERIA:

Mechanically ventilated patients (included patients intubated prehospital)

Aged ≥16 years

EXCLUSION CRITERIA:

Age < 16 years

Clinician discretion whereby lung protective ventilation not safe/appropriate
eg. asthma/bronchospasm, severe acidosis, toxicological needs
If so please complete the box below.

	Please tick	Document reason for clinical exclusion
Clinical Exclusion	☐	

****** please affix patient label to ELVIS Project register ******

LUNG PROTECTIVE MECHANICAL VENTILATION GUIDELINE

Measure patient height (cm): _____

Calculate IDW (kg): _____
(*see attached nomogram*)

VENTILATION

Calculate V_T - Target 6mL/kg IBW: _____ mL
- Acceptable: 6-8mL/kg IBW

Check Plateau Pressure <30cmH_2O: ☐
(please specify if other limit used:_____ cmH_2O)

Set RR:_____ (breaths/min)
(*suggest 20-25, titrate to achieve pCO_2/pH goals*)

pCO_2 target: _____mmHg **pH target: >7.3**

For patients with excessive V_T (>12mL/kg) or spontaneous breaths over prescribed rate:
- **Review V_T and RR settings.**
- **Consider increasing sedation, additional analgesia or use of NMB.**

OXYGENATION

Set PEEP:_____ cmH_2O (*suggest ≥5cmH_2O*)

Consider 8-10cmH_2O in BMI>30, severe hypoxia or APO.

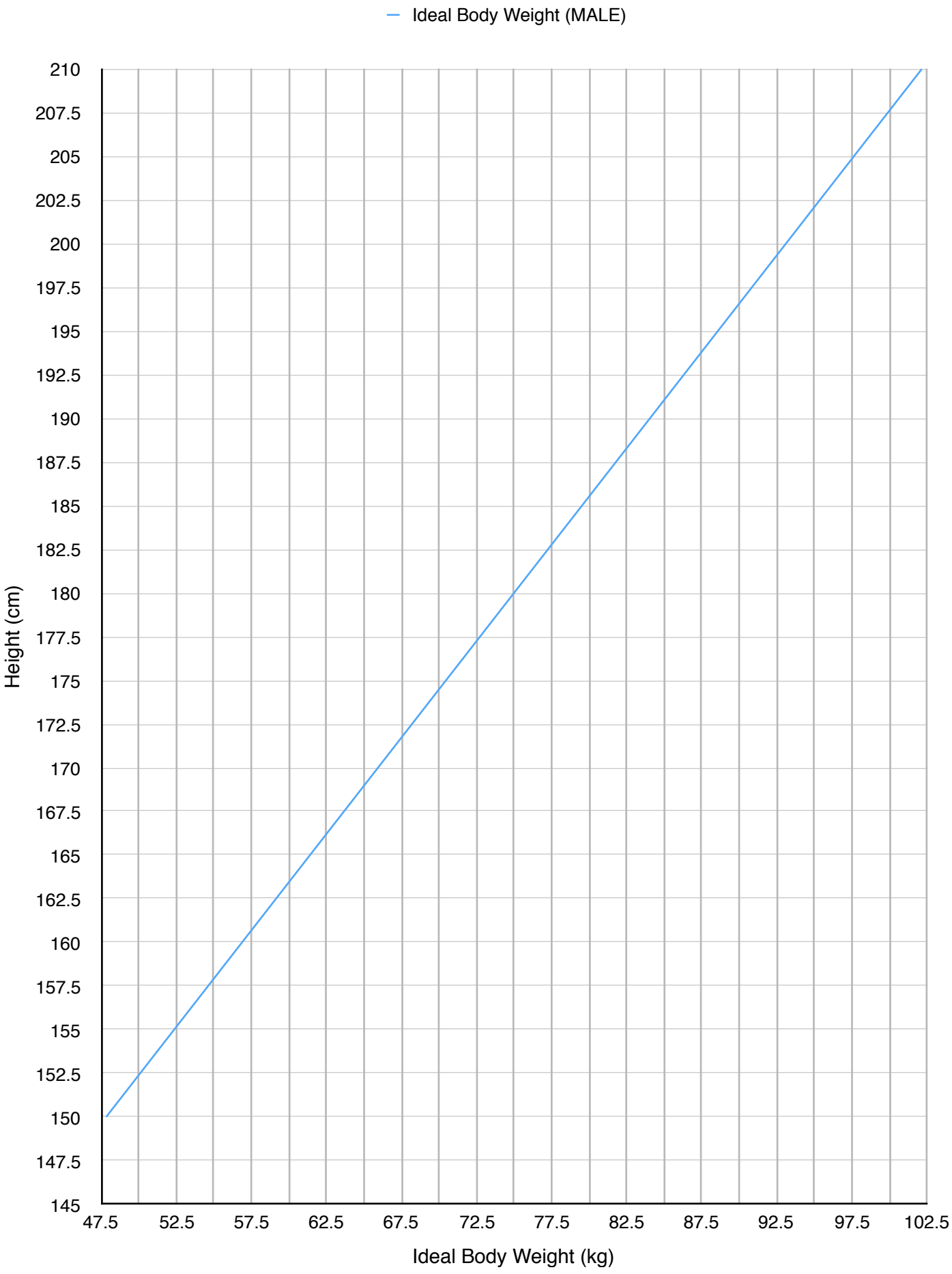
Titrate FiO_2:_____
Aim to achieve SpO_2 targets below.

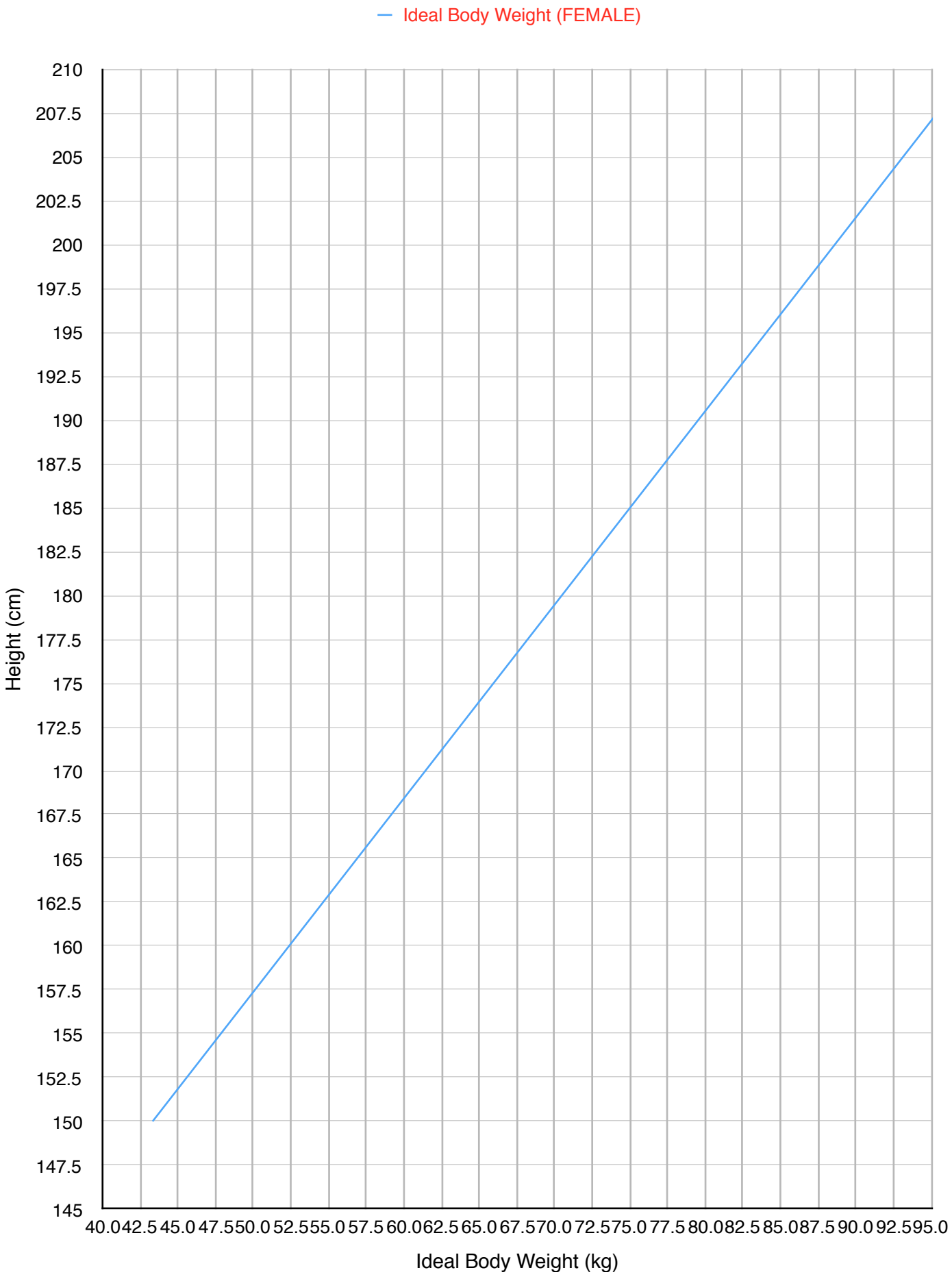
Target SpO_2 (please circle):

88-92% 94-98%

For refractory hypoxia, refer to Emergency Action Checklist (attached).

Prescribe ongoing sedation	
Consider further muscle relaxation where indicated	
Check cuff pressure (20-30cmH_20)	
Head-up *or* bed-tilt unless contraindicated	
NG/OG tube sited	
Post-intubation ABG (consider placement of arterial line)	


Ideal Body Weight (MALE)
Height (cm)
210
207.5
205
202.5
200
197.5
195
192.5
190
187.5
185
182.5
180
177.5
175
172.5
170
167.5
165
162.5
160
157.5
155
152.5
150
147.5
145
47.5
52.5
57.5
62.5
67.5
72.5
77.5
82.5
87.5
92.5
97.5
102.5
Ideal Body Weight (kg)


Ideal Body Weight (FEMALE)
Height (cm)
210
207.5
205
202.5
200
197.5
195
192.5
190
187.5
185
182.5
180
177.5
175
172.5
170
167.5
165
162.5
160
157.5
155
152.5
150
147.5
145
40.0 42.5 45.0 47.5 50.0 52.5 55.0 57.5 60.0 62.5 65.0 67.5 70.0 72.5 75.0 77.5 80.0 82.5 85.0 87.5 90.0 92.5 95.0
Ideal Body Weight (kg)

REFRACTORY HYPOXIA
EMERGENCY ACTION CHECKLIST

1. Notify Intensive Care.

You may require their ventilator or expedited transfer to ICU.

2. Titrate PEEP.

Incremental increase in PEEP above 10cmH_2O.
Watch for associated hypotension (consider fluid bolus or vasopressors).
(ARDSnet PEEP/FiO_2 table below for reference.)

OXYGENATION GOAL: PaO_2 55-80 mmHg or SpO_2 88-95%
Use a minimum PEEP of 5 cm H_2O. Consider use of incremental FiO_2/PEEP combinations such as shown below (not required) to achieve goal.

Lower PEEP/higher FiO2

FiO_2	0.3	0.4	0.4	0.5	0.5	0.6	0.7	0.7
PEEP	5	5	8	8	10	10	10	12

FiO_2	0.7	0.8	0.9	0.9	0.9	1.0
PEEP	14	14	14	16	18	18-24

3. Trial of recruitment manoeuvres.

Manual ventilation with BVM & PEEP valve (titrated up to 20cmH_2O)
Repeated inspiratory hold (20-30sec) with PEEP set to 20cmH_2O
(Caution hypotension)

4. Detect & correct “DOPES” causes.

Dislodged or displaced Endotracheal Tube or cuff
Obstructed Endotracheal Tube (e.g. mucous plugging, blood in tube)
Pneumothorax
Equipment failure (Ventilator, tubing)
Stacking of breaths (incomplete exhalation in Asthma or COPD)

5. Consider ventilator setting adjustment.

AutoFlow: trial off
Check I:E settings
Tolerate higher PAW in Bariatric patients
Consider reduction in PEEP (single lung pathology, pulmonary HTN)