Ventilator Associated Pneumonia: developing consensus for a pragmatic 'clinical surveillance' definition and measuring current incidence in Australian and New Zealand intensive care units

Research protocol and data dictionary

Abbreviations

APACHE	Acute Physiology and Chronic Health Evaluation
BMI	Body mass index
CICM	College of Intensive Care Medicine
CT	Computerised tomography
FiO_2	Fraction of inspired oxygen
HDEC	Health and Disability Ethics Committees (New Zealand)
ICU	intensive care unit
MRI	Magnetic resonance imaging
MRO	Multi-resistant organism
NEAF	National Ethics Application Form (Australia)
NHMRC	National Health and Medical Research Council (Australia)
PEEP	Positive end expiratory pressure
P/F ratio	Ratio of partial pressure of arterial oxygen to fraction of inspired oxygen (PaO_2/ FiO_2)
SIRS	Systemic inflammatory response syndrome
SOFA	Sequential Organ Failure Assessment
VAP	ventilator associated pneumonia
WCC	White cell count

Universally used definitions

Intensive care unit	Any department overseen by an intensive care clinician (i.e. intensivist or anaesthetist)
Intensive care clinician / physician	A specialist medical doctor; an intensivist or anaesthetist (staff specialist).
Mechanical ventilation	The provision of respiratory support or mandatory ventilation invasively via an artificial airway (e.g. endo/nasotracheal tube or tracheostomy tube

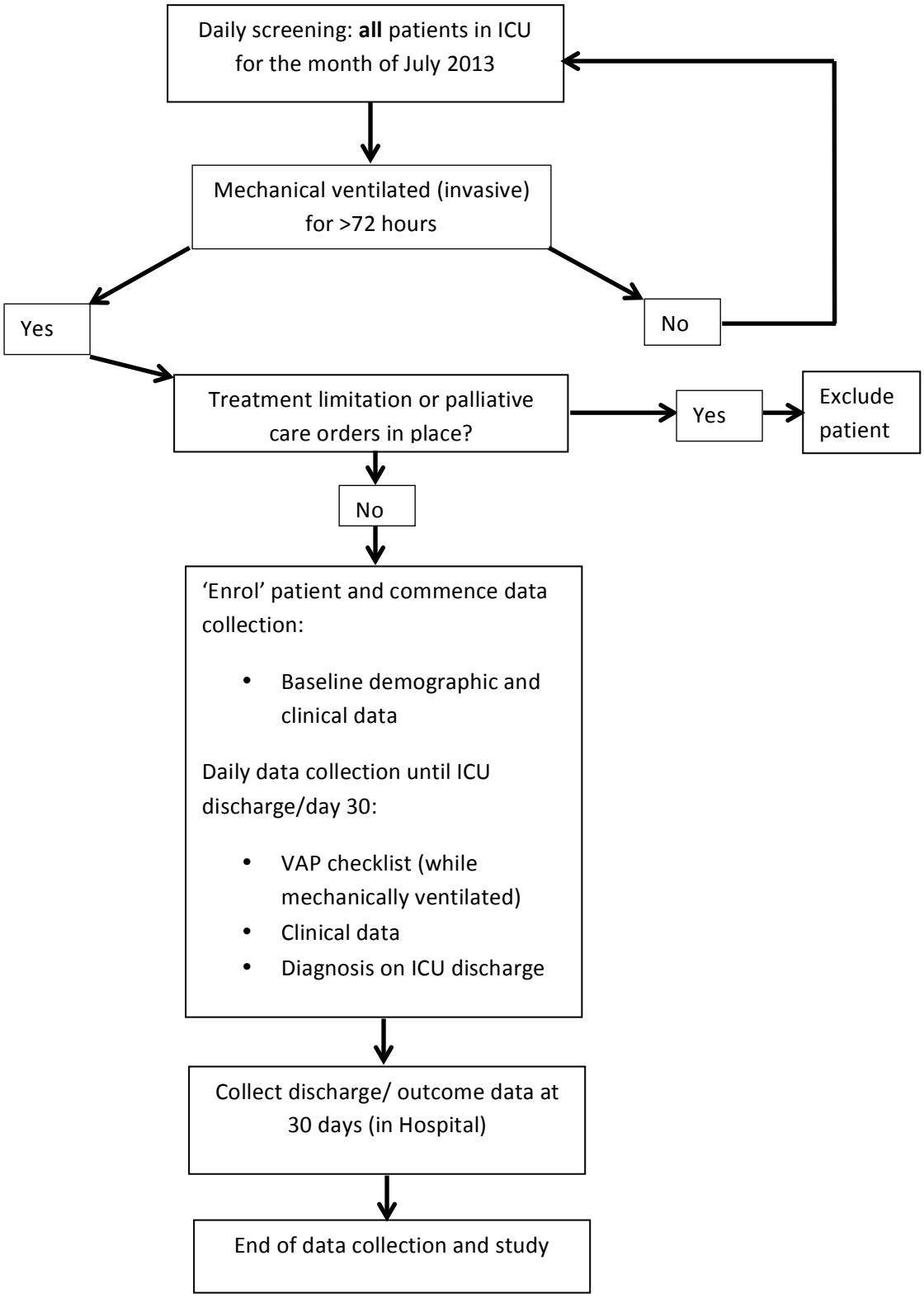

Figure 1. Schematic representation of screening/ data collection

Eligibility criteria

All adult patients who are:

- Age >16 years
- Mechanically ventilated for >72 hours (that is a contiguous period of a minimum mechanical ventilation time of >12 hours per 24 hours for 3 consecutive days)
- Patients who are readmitted to ICU in the month of the audit will be re-enrolled in the study.

Exclusion criteria

Patients who have treatment limitation orders or are receiving palliative care at the time of enrolment are excluded.

Daily screening

We have provided template forms for screening. Screen all patients for eligibility and track patients who are receiving mechanical ventilation each day. Please note patients may be enrolled more than once as this is a survey (observational) design study.

At the end of the study (the 30 day period) provide the total number of patients screened, enrolled and who were excluded, there are data entry fields for this purpose in the web-based database. Keep all screening records in a secure location until the project officer informs you that they may be destroyed.

Screening log instructions

No.	Question	Definition or explanation of question
No.		• You may use this field to number the patients screened consecutively in order to more easily reconcile the total number screened.
S1	Patient initials & gender M/F	• Enter the patient's initials in the format **FML** (**F**irst, **M**iddle, **L**ast). 1st letter of the given, **M**iddle and **L**ast/family name. • If no middle name, use the first and last initial • Gender M= male and F= female • Data is used to track eligible patients
S2	Date of birth dd/mm/yyyy	• Use full date format i.e. dd/mm/yyyy • Use estimated age if date of birth is not known • If the age is unknown and there is any doubt the patient is not 16 years old **DO NOT** collect data
S3 S3a	Date first screened Total (cumulative) number screened	• Record all patients' details who are receiving mechanical ventilation • This is the date that the patient is reviewed for possible enrolment in the study and will assist in keeping track of patients and reconciling the number of patients screened • You can use this field to record and reconcile the number of patients screened at the end of the study (30 days) as numbers will be entered into the study database.
S4	Eligibility check	• Tick the boxes when the eligibility criteria apply • To assist you record the date of intubation/commencement of mechanical ventilation. Mechanical ventilation includes all

		modes (spontaneous and mandatory) • To be eligible the period of mechanical ventilation must be a contiguous 72 hours (**a minimum time of 12 hours mechanical ventilation per 24 hours for 3 consecutive days**)
S5 S5a S5b S5c	Excluded Palliation Treatment limitations Total (cumulative) number excluded	• Tick the boxes for the relevant exclusion criteria that apply • Consult health care records to check for descriptors of medical orders for palliative care • Consult health care records to check for descriptors of treatment limitations/orders e.g. 'do not escalate mechanical ventilatory support', 'ceiling' doses of vasoactive medications • You can use this field to record and assist reconciling the number of patients excluded at the end of the study (30 days) as the numbers will be entered into the study database.
S6 S6a	Date eligible/excluded Total number enrolled	• Record the date that the patient was excluded from or eligible for the study • You can use this field to record and assist reconciling the number of patients enrolled at the end of the study (30 days) as the numbers be entered into the study database.
S7	Study no. if enrolled	• Number the patients consecutively as they are enrolled using the study unit number provided as the prefix and the patient number e.g. patient number one enrolled in unit number five would be allocated the study number: 05-001. • Record the enrolment in the enrolment log.

Enrolment

If there are no exclusion criteria adult patients (>16 years) are enrolled when they have received >72 hours of contiguous mechanical ventilation (≥12 hours per 24 hours over the past 3 days), irrespective of mode. The need for informed consent was waived by the Ethics Committees. To avoid unnecessary burden and concern patients should **not** be approached about enrolment in this study.

Enrolment log instructions

The enrolment log must be kept separate from any data screening or data collection forms/files (in a locked filing cabinet and a separate locked office to the data collection materials). The enrolment log has been designed as a study master index to assist you to track data collection and patient location and to ensure that data collection is complete.

No.	Question	Definition or explanation of question
E1	Study No.	• Number the patients consecutively as you enrol them. The ICU study number allocated by the VAP project officer is used to prefix the patient's study number e.g. patient number one enrolled in unit number five would be allocated the study number: 05-001. • Patients can have more than one study number, one for each separate ICU admission. One of the preliminary questions of the baseline data collection form requests information regarding ICU re-admission.
E2	Date of birth	• Use full date format i.e. dd/mm/yyyy • If the age is unknown and there is any doubt the patient is not

		yet 16 years **DO NOT** collect data
E3	Patient initials	• Enter the patient's initials in the format **FML** (**F**irst, **M**iddle, **L**ast). 1st letter of the given, Middle and Last/family name. • If no middle name, use the first and last initial
E4	Date enrolled	• Use full date format i.e. dd/mm/yyyy
E5	Date discharged from ICU	• Use full date format i.e. dd/mm/yyyy
E6	Date ICU data collection complete	• Use full date format i.e. dd/mm/yyyy
E7	Date 30 day follow-up complete	• Use full date format i.e. dd/mm/yyyy
E8	Data required/comments	• Use this field to record any data that is outstanding and as an aide memoir

Site specific data collection

When you log into the study web-based database for the first time please respond to the two queries about the CICM level of your ICU and the details of any ventilator associated pneumonia prevention programme in your ICU.

Level of ICU [tick one]	• Record the level of the ICU in which you work according to College of Intensive Care Medicine (CICM) criteria (**Appendix I**) • Tick (one) the appropriate CICM level 1, 2 or 3
Ventilator pneumonia prevention programme in your **unit** [tick all that apply]	Tick any of the prevention strategies that apply in your unit • Routine mouth care with chlorhexidine if this part of practice (any concentration of chlorhexidine) • Head of bed elevation ≥45° (if there are concerted efforts/policy to ensure that patients are positioned in an upright position most of the time) • Subglottic suction endotracheal/tracheostomy tubes if these tubes are used routinely
Number of beds in your ICU	Please state the number of beds available for patient treatment in your ICU (if the ICU is a mixed HDU/ICU please provide the total number of beds)
Specialities treated	Please tick all the specialities that are treated in your ICU • Cardiothoracic surgery • Renal medicine • Multitrauma • Spinal cord injury • Neurosurgery • Burns • Haematology/oncology • Liver disease
Number of patients screened	• Please insert the total number of patients screened at the conclusion of data collection
Number of patients excluded	• Please insert the total number of patients excluded from data collection at the conclusion of data collection (and indicate how many were receiving palliative care and had treatment limitations)
Number of patients enrolled	• Please insert the total number of patients enrolled

Data collection at enrolment (baseline)

Collect baseline data from the time of the current ICU admission or at enrolment (please follow the instructions provided). Information from the health care records and laboratory and radiology reports should be all that is required for data collection.

Baseline Form instructions

Ensure the patient's initials and study number are written in the top right hand corner of the forms

No.	Question	Definition or explanation of question
1. Admission data		
B1.01	Hosp Admission date	• Record the date of **this** Hospital admission • Use full date format i.e. dd/mm/yyyy
B1.02	ICU Admission date	• Record the date of this ICU admission (each ICU admission will be treated as a different episode and readmissions will be taken into account in the analysis) • Use full date format i.e. dd/mm/yyyy
B1.03	ICU Admission time	• Enter the time the patient was admitted to the ICU using the 24 hour clock format
B1.04	From where was the patient admitted into ICU? [tick one, only one can be chosen]	Select ONE response that corresponds with the source of admission to your ICU: • Emergency Department = from the Emergency Department at **your** hospital • Hospital wards = any **ward** in **your** hospital, including day care facilities (but not including an ICU, CCU or HDU if they are overseen by an intensive care clinician) • Transfer from another ICU **within your** hospital = any other ICU **within** your hospital (specialised ICU, CCU or HDU) • Transfer from another ICU **from outside your** hospital = transfer from an ICU from **another** hospital • 'ICU' is defined as any department overseen by an intensive care clinician • Transfer from another hospital = transfer from any area in another hospital **except** an ICU • Theatre (operating) following **emergency** surgery = from operating theatre or recovery ward following surgery that was required **immediately** to correct a life threatening situation • Theatre (operating) following **elective** surgery = from operating theatre or recovery ward following any surgery that is NOT defined as 'emergency' from within your hospital N.B. the Angiogram suite or cardiac catheter laboratory are **not** the Operating Theatre –document as a ward transfer.
B1.05	Is this a readmission into ICU during the same hospital admission?	• Circle 'Y', 'Yes', if a patient was treated in your ICU during this hospital admission, was transferred to another area within the hospital and then re-admitted to your ICU
B1.06	If 'yes', record the ICU length of stay for previous admission to ICU	• Please consult the health care records for the previous ICU admission (IF it was during this hospital admission) and record the length of ICU stay in 'chart' days.
B1.07	If 'yes', was the patient	• Circle Y for 'yes' if the patient was intubated with an

	intubated during the previous ICU admission?	endo/nasotracheal tube or/and a tracheostomy tube (do **not** include oropharyngeal tube) • Circle N for 'no' if the patient was not intubated with a tracheostomy tube or an endotracheal tube
B1.08	If the patient was intubated, record the duration of mechanical ventilation	• Consult the health records to calculate the duration of ventilation for the previous ICU admission (**if** this admission was during the current hospital admission) in days that is the number of days the patient received >12 hours of invasive mechanical ventilation in a 24 hour period. • Record the number of days the patient received invasive mechanical ventilation i.e. via a tracheostomy tube or an endotracheal /nasopharyngeal tube. For patients who were 'weaned' from mechanical ventilation and received intermittent episodes of ventilation record the number of days the patient received >12 hours of invasive mechanical ventilation in a 24 hour period.
B1.09	Diagnosis necessitating this ICU admission [please select from Data Dictionary]	• Select **one** of the diagnostic codes from the APACHE III diagnostic code list (**see Appendix II**) • If a patient was admitted to your ICU directly from the Emergency Department, a ward, another ICU or another hospital, you MUST select a NON-OPERATIVE diagnostic code – code numbers < 1200 • If a patient was admitted to your ICU directly from OT, you MUST select a POST-OPERATIVE diagnostic code – code numbers >1200
2.	General information	
B2.01	Gender	• Select the appropriate box corresponding to patient's legal gender • This is the gender listed on the birth certificate
B2.02	Age in years	• Please insert an age (estimated) if the date of birth is unknown (however if you suspect the patient is not yet 16 years old do NOT collect data)
B2.03	Weight	• Enter the patients weight in kilograms – If weight is measured in pounds please use conversion calculator (http://www.metric-conversions.org/weight/pounds-to-kilograms.htm) • Weight may be measured, documented in the medical records, obtained from the patients relative or estimated by clinicians • If the last recorded weight is thought to be significantly inaccurate to the patient's current weight, provide the best estimate of weight • Weight will be used to calculate body mass index (automated in the study database)
B2.04	Height	• Enter the patients height in metres – If height is measured in feet/inches please use conversion calculator (http://www.metric-conversions.org/length/feet-to-meters.htm) • Height may be measured, documented in the medical records, obtained from the patients relative or estimated by clinicians

		• Height will be used to calculate body mass index (automated in the study database)
3.	Severity of illness and pre hospital health status	
B3.01	Total APACHE II score on admission to ICU	• To derive the APACHE II score, use the APACHE II Worksheet (**Appendix III**) or record the score provided by the data manager in your ICU • This is an admission APACHE II score (derived from values in the 24 hours first 24 hours of admission). Please use any available values from the pre-ICU medical records, 24 hours prior to admission e.g. Emergency Department charts, OT charts, ambulance charts, ward charts etc. to derive score If medical records are not available because the patient was not under medical care prior to their ICU admission, please use any available values 24 hours prior to admission to derive the score • Please use the definitions and methods your unit has adopted to collect data for the AORTIC database
B3.02	From the APACHE II which of the Chronic health categories did the patient fulfil [tick all that apply]	• Select all that apply: 1. None 2. Liver 3. Renal 4. Cardiovascular 5. Respiratory 6. Immunocompromised
B3.03	Charlson co-morbidities index	• Tick all chronic health conditions that apply for this patient's prehospital health status (see **Appendix IV**). • A drop down menu is provided; the database will automatically calculate the total score
B3.04	Excessive intake of alcohol	• Circle Y for 'Yes' if there are notations in the health care records that the patient ingested an excess amount of alcohol in the 4 week period prior to this ICU admission. • Excess amount of alcohol is defined as more than 28 standard drinks per week for a male and 14 standard drinks for a female. • Circle N for 'No' if there is no evidence in the health care records that the patient ingested an excess amount of alcohol.
B3.05	Smoking history (no. of pack years)	• Examine the health care records for notations about the patient's smoking habits and use this to calculate the number of pack years • A pack year is defined as twenty cigarettes smoked every day for one year. As people vary their smoking habits calculation of pack years is difficult. This website may help you: http://smokingpackyears.com/ (the calculator can be dragged and dropped onto your desktop, there are no restrictions on its use and its reliability has been extensively checked)
4.	Study enrolment	
B4.01	Date of eligibility	• Record the date on which the patient became eligible to be enrolled i.e. received 72 hours (3 days) of mechanical ventilation (i.e.≥12 hours of mechanical ventilation each 24 hours period in the preceding 3 days)

		• Use full date format i.e. dd/mm/yyyy

Daily data collection in ICU (only)

Collect data for this form from the time date of enrolment each day. Information from the health care records and laboratory and radiology reports should be all that is required for data collection. **No** additional tests or investigations (over and above the tests already performed for the patient) must be ordered to complete data collection –this is an observation study requiring the documentation of information which is already available.

- Daily data collection includes all ICU data from enrolment i.e. day 3 of mechanical ventilation
- Each day is the 24 hours of your site chart day
- In the web-based database start a new form for each day
- On the paper form - A separate column is used for **each** study day
- Study day 1 is day of enrolment up to the end of your ICU chart day. Day 1 will always be less than 24 hours. You may find it easier to collect data the day after each study day i.e. perform data collect for study day 1 on day 2.

Sometimes you may be asked for total data recorded in a study day e.g. antimicrobials administered. At other times you may be asked for the most abnormal value recorded e.g. highest heart rate.

Intensive care (ICU) is defined as any department overseen by an intensive care clinician (i.e. intensivist or anaesthetist), therefore 'ICU discharge' is defined as when a patient is discharged to any department NOT overseen by an intensive care clinician. N.B. If a patient has been "booked out" of ICU, however due to a lack of hospital ward beds they physically remain in the ICU, then the patient is still defined as an ICU patient and daily data is still to be collected.

If a patient is discharged from ICU, complete data collection for that day up to the time of ICU discharge e.g. If a patient is physically discharged to the ward at 08:00hrs, collect data from the start of your ICU flowchart day to 08:00hrs

If a patient dies in the ICU, complete data for that day up to the time of death and also complete Day 30 Discharge-Outcome forms e.g. If a patient dies at 08:00hrs, collect data from the start of your ICU flowchart day to 08:00hrs. The last day of a patient's ICU stay may be less than 24 hours (due to ICU discharge or death).

If a patient is readmitted to ICU during the current hospital stay, treat the next ICU admission as a separate episode and enrol them again (i.e. allocate another study number to them).

Continue daily data collection up to 30 days, ICU discharge or death (whichever is soonest) regardless of the type of respiratory support the patient is provided (i.e. even if the patient is extubated).

Daily data collection form instructions

Ensure the patient's initials and study number is written in the top right hand corner of the forms.

No.	Question	Definition or explanation of question
D1.01	Study day	• Enter the study day number. • Number the day of enrolment '1'

		• Day 2 begins at the beginning of your next flowchart day • This field has been added to each sheet of the daily data collection forms to reduce the chance of errors during data collection
D1.02	Study day date	• Enter the date in dd/mm format • Day 1 will be the date of enrolment • This field has been added to each sheet of the daily data collection forms to reduce the chance of error during data collection
2. VAP checklist (**Appendix V**)		
Only complete this section if the patient has received invasive mechanical ventilation >12 hours in the 24 hours of this chart/study day		
D2.01	P/F ratio≤ 300mmHg	• Deterioration in gas exchange over 24 hours in the **absence of cardiogenic pulmonary oedema or exacerbation of existing pulmonary disease such as asthma** • To calculate the P/F ratio = PaO_2mmHg/FiO_2 e.g. If PaO_2 = 80mmHg and FiO_2 = 0.4, P/F ratio is 200 (in which case circle 'Y', for 'yes' P/F ratio ≤ 300mmHg over the past 24 hours) • You may use SaO_2 if an arterial gas is not available i.e. SaO_2 / FiO_2 • Circle 'Y', for 'yes' hours if there is one SaO_2 or PaO_2 measurement in which the P/F ratio is ≤ 300mmHg over the past 24 hours
D2.02	Sputum changes	• Recognising that this is a subjective judgement please check the health care records for notations which refer to 'A change in sputum characteristics, increased volume, or colour changes (yellow or green)'. • Circle 'Y', 'yes' if you find new descriptions/documentation which indicates that the quality and quantity of sputum has changed
D2.03	New CXR infiltrates	• Check the health care records or radiological reports for descriptions which indicate the occurrence of '**New** localised or diffuse infiltrates on a single Chest X-ray (not explained by cardiogenic pulmonary oedema or pulmonary disease)' • Other descriptions which indicate the presence of **new** CXR infiltrates are new/progressive/worse diffuse/widespread infiltrates, consolidation, homogenous opacity, showing, density • Descriptions which include terms that were not used in the previous chest X ray report (and are indicative that the Chest X ray has changed) include: patchy, diffuse, localised and bilateral (when they were unilateral before)
D2.04	Inflammatory response	• Circle Y for 'yes' **≥ 1** of the following is present (in the absence of immunocompromise): 1. New and persistent (24 hours) elevated body temperature ≥38°C (or >37.5°C if concurrent anti-inflammatory medication administration). Note the

		temperature recordings from which ever method is standard in your ICU. 'new and persistent' elevated body temperature , means more than one recording over the past 24 hours 2. White cell count ≤4 or ≥12 cells 10^9/L for the past two days 3. Elevated serum inflammatory markers: C-reactive Protein (>100mg/L) or Procalcitonin (>2.5ng/L) for a single blood test in the past 24 hours (if preformed) • The definition of 'immunocompromise' for the purposes of this Checklist is that a person's immune system is incapable of working at full capacity. This can be caused by hereditary or genetic defects, end stage renal failure, diabetes, cirrhosis, cancer, medications e.g. steroids, chemotherapy, radiotherapy, post transplantation medications, HIV, leukemia and autoimmune disease. It does **not** apply to the 'neutropenic' patient where the number of neutrophils is significantly depressed usually as a result of chemotherapy.
D2.05	Microbial growth	• Retrieve the microbiology report and circle 'Y' for 'yes' if there is microbial growth in the sputum. Microbial growth in the sputum refers to the presence of white cells or microbes in the sputum in sufficient numbers: ○ Neutrophils or polymorphonuclear cells in the sputum which may be indicative of infection that is '**>25 neutrophils per low power field'** or equivalent i.e.' ++ to +++ polymorphs' or '+3 polymorphs' ○ Alternatively if the laboratory in your hospital does not report white cell counts in sputum use descriptions of the presence of microbes. Circle 'Y' for 'yes' for descriptors such as '>6 per high power field [name microbe]' or '++ [name microbe]' or identification of microbe(s) and/or recommendation by the microbiologist for the administration of an antimicrobial(s) for example, 'This isolate is sensitive to [name of antimicrobial] and related antimicrobials [name of antimicrobials]' and 'Growth of [name of microbial] has been isolated'.

3 Clinical status		
D3.01 SOFA	Respiration (value) Coagulation (value) Liver (value) Cardiovascular (value) CNS (value) Renal (value)	• Please refer to **Appendix VI** for directions on how to calculate the Sequential Organ Failure Assessment (SOFA) and the scores for each organ system. • Please write the values for each organ system beside the respective organ system. The overall SOFA score will be automatically calculated by the database if you enter a value for each organ system (please insert 0 if the score is zero). • We are collecting this information in order perform multivariate analyses on contributing factors for the development of VAP (e.g. Respiration value)
D3.02 SIRS	1. Core temperature >38 °C or <36 °C 2. Heart rate >90 beats/min 3. Respiratory rate >20/min 4. WCC >12 or <4 x 10^9/L or >10% immature neutrophils	• There may be some repetition here with the VAP checklist (apologies). • Circle 'Y' for 'Yes' if the patient had any of the following at **any** time on this day of the study o a core temperature <36.0°C or >38.0°C o a heart rate of >90 beats per minute at **any** time o a respiratory rate >20/min o WCC >12 or <4 x 10^9/L or >10% immature neutrophils • The presence or absence of SIRS will be automatically recorded by the database – simply click 'yes' or 'no' for the presence of the SIRS criteria in each row • Systemic inflammatory response syndrome (SIRS) will be a factor explored in multivariate analysis of the risk factors for VAP
D3.03 Serum inflammatory marker levels	Procalcitonin level (if test performed) [record in ng/L]	• **Only** record this data if a test is performed (this research is observational and does **not** require additional investigations to be ordered/performed)
	C reactive protein level (if test performed) [record in mg/L]	• **Only** record this data if a test is performed (this research is observational and does **not** require additional investigations to be ordered/performed) • Serum inflammatory maker levels will be used in a multivariate analysis to explore predictors of a diagnosis of VAP
D3.04 Clinician diagnosed VAP	Has an intensive care clinician documented a diagnosis of ventilator associated pneumonia in the health care records?	• On enrolment (i.e. day 1 of the study) if a medical doctor recorded a diagnosis of VAP in the patient's health care records in the previous 24 hours (i.e. the patient is considered to have VAP on enrolment) circle 'Y' for 'Yes' • Circle 'Y' for 'Yes' if an intensive care clinician (intensivist or anaesthetist staff specialist) recorded a diagnosis of VAP in the patient's health care records on this day of the study. Circle 'N' for 'No' if there is no record of clinician diagnosed VAP. • Each new episode of VAP should be recorded i.e. if you circle 'Y' for 'Yes' on study day 3 on subsequent days you

		should circle 'N' for 'No' until a new occurrence is recorded by a medical doctor in the health records in which you should circle 'Y' for 'Yes' on the day it was recorded.
4 Support and treatments		
D4.01	Breathing spontaneously? (if 'N' got to question D4.02)	• Circle 'Y' for 'Yes' if the patient was breathing spontaneously **without** the assistance of a mechanical or non-invasive ventilator for >12 hours (total) over the past 24 hours. If the patient was not ('N') breathing spontaneously for the majority of time during this day of the study go to question D4.02.
	Oxygen therapy [record FiO_2]	• Record the FiO_2 for >12 hours for this study day • To assist you here are some FiO_2 values for 3 oxygen delivery devices: o Nasal Cannulae ▪ 1L pm = 24% i.e. 0.24 ▪ 2L pm = 28% i.e. 0.28 ▪ 3L pm = 32% i.e. 0.32 ▪ 4L pm = 36% i.e. 0.36 o Hudson Oxygen Mask ▪ 5 – 6L pm = 40% i.e.0.40 ▪ 6 – 7L pm = 50% i.e. 0.50 ▪ 7 – 8L pm = 60% i.e. 0.60 o High Concentration Mask ▪ 8 – 12L pm = 60 – 80% i.e. 0.60 - 0.80 o Partial Re-breathing Bag ▪ 8 – 12L pm = 60 – 80% i.e. 0.60 - 0.80 o Non-Rebreathing Bag ▪ 8 – 12L pm = 90 – 99% i.e. 0.90-0.99
D4.02	Non-invasive ventilation	• Circle 'Y' for 'Yes' if the patient received non-invasive ventilation (NIV) of any type (e.g. CPAP, BiPAP, High Flow Nasal Prongs) for >12 hours (total) for this day of the study • This will provide valuable data about whether NIV is a risk factor for VAP and will be used in the multivariate analysis to explore the risks/contributing factors for VAP
D4.03	Artificial airway in situ	• Circle 'Y' for 'Yes' if the patient had an artificial airway of **any** type in situ for >12 hours (total) for this day of the study • This will provide data about the duration of time the patient has an airway in situ and will be used in the multivariate analysis to explore the risks or contributing factors for VAP
D4.04	Type of tube	• Circle one of the options if the patient had an artificial airway in situ for >12 hours total for this day of the study o oET = oral endotracheal tube o nET = naso endotracheal tube o trach = tracheostomy

D4.05	Mechanical (invasive) ventilation?	• Circle 'Y' for 'Yes' if the patient received invasive mechanical ventilation of **any** type for >12 hours (total) for this day of the study (Now answer question D04.06).
D04.06 Invasive mechanical ventilator settings	Mode (for >12 hours in past 24 hours) [circle one only]	• If you answered 'Y' for D4.05 circle one option which represents the main mode of mechanical ventilation i.e. for >12 hours (total) the patient received for this day of the study: o Mand = any mandatory mode in which the majority of breaths do not have to triggered by patient effort e.g. pressure control, controlled o Spont = any mode which relies on the patient to trigger the ventilator for ALL breaths e.g. pressure support o Mixed = any mode which is a combination of a mandatory and spontaneous mode e.g. synchronised intermittent mechanical ventilation used with a low mandatory respiratory rate settings i.e. <8bpm • Information on specific modes of mechanical ventilation have not been requested because there is extensive variability in their use and terms used. The important information is whether the patient received mechanical ventilation and if this was a mandatory/controlled or spontaneous mode, the level of PEEP and the amount of oxygen
	PEEP in $cmHO_2$	• Record the highest level of positive end expiratory pressure (in $cmHO_2$)used on this study day
	FIO_2	• Record the fraction of inspired oxygen used for the majority of time (i.e. >12 hours) on this study day
D4.07	Renal replacement therapy (any)	• Circle 'Y' for 'Yes' if the patient received **any form** of renal replacement therapy for **any duration** on this day of the study
D4.08	Cardiac assist device (any)	• Circle 'Y' for 'Yes' if the patient received support from **any form** of cardiac assist device e.g. IABP for **any duration** on this day of the study
Four fields (D4.09 – D4.12) have been provided for recording the antimicrobials the patient received on this study day. Use one field per antimicrobial – the order in which they are recorded is not important		
D4.09 – D4.12 Antimicrobials	Type [circle one]	• Circle one type of antimicrobial per field o AF = antifungal o AB = antibiotic o AV = antiviral
	Area of body infected or prophylaxis [write the name] (drop down menu provided)	• Check the health care records for notations about the rationale for the administration of the antimicrobial. • Write the name of the area of the body infected or if this was for prophylaxis. A list is provided (alphabetical order) in a drop down menu in the database to ease data entry (**Appendix VII**)

		• The administration of antimicrobials will be one of the factors included in multivariate analysis to explore the risk factors for VAP and outcomes of patients with a diagnosis of VAP
	Name of antimicrobial	• Write the name of the antimicrobial here. There is an extensive list provided (alphabetical order) in a drop down menu in the database to ease data entry (**Appendix VII**)
	Daily dose [in mg]	• Record in milligrams for the entire 24 hour period
	Day no. (of antimicrobial treatment)	• Record the day number that the antimicrobial has been administered
D4.13	Administered H_2 antagonists?	• Circle 'Y' for 'Yes' if any H_2 antagonist (e.g. ranitidine, cimetidine, famotidine, nizatidine) was administered on this study day
5 Investigations [complete this section if investigations were performed over the past 24 hours]		
D5.01 Radiology [write the body part(s) imaged] (drop down menu provided in the database)	CT MRI Xray Angiogram Other	• Write the main body area / region imaged using the radiological investigations listed. • More than one type of radiological investigation can be recorded per study day • A full list of body parts is provided in a drop down menu in the database (**Appendix VIII**)
D5.02 Invasive [write the body part(s) explored] (drop down menu provided in the database)	Exploratory operation Endoscopy Biopsy Other	• Write the main body area investigated invasively using the procedures listed. • More than one type of investigation can be recorded per study day. • A full list of body areas is provided in a drop down down menu in the database (**Appendix VIII**)
D5.03 Sputum sample	How was the sputum sample obtained? [circle one]	• Complete D5.03 if a sputum sample was sent for formal analysis on this study day. Circle one of the following: o Scope = bronchoscope (BAL or suction) o ET = suction via endotracheal tube o Trach = suction via tracheostomy tube • This data will be used to explore the sensitivity of different sampling methods in diagnosing pneumonia.
	What investigations were performed? [circle one]	• Please circle one of the following: o Cyto = cytology o Micro = microbiology
	What type of microbe (s) was reported? [circle all that apply if reported]	• Please circle all that apply: o Vir = virus o bact = bacteria

		○ fung = fungus ○ pseud = pseudomonas
	Name of the microbe [write the name(s)] (a drop down menu provided)	• Write the name(s) of the microbe(s) here. • A drop down menu is provided in the database (**Appendix IX**). • This data will be used to identify the microbes commonly associated with a diagnosis of VAP
	Colonisation or infection?	• Circle one of the following: ○ Col = colonisation (circle this if the microbiology report indicates that the microbe is colonising rather than causing infection in the patient) ○ Inf = infection (circle this if the microbiology report indicates that the microbe is causing infection rather than colonising the patient) • It is possible that the patient may be infected with one microbe and colonised with another. Please circle 'inf' if this is the case
	If reported name(s) the antimicrobial the microbe(s) is sensitive to [write the name] (drop down menu provided)	• Write the name of the antimicrobial that the microbiologist recommends or the report suggests the microbe is sensitive to. There is an extensive list provided (alphabetical order) in a drop down menu in the database to ease data entry (**Appendix VII**)
D5.04 Blood sample (micro)	From where was the sample obtained? [circle all that apply]	• Complete D5.04 if a blood sample was sent for microbiology reporting on this study day. Circle one of the following: ○ CVC = central venous catheter. Circle this if the blood was taken from a CVC of **any** type or site ○ art = arterial catheter. Circle this if the blood was taken from an arterial line (**any** site) ○ perph = peripheral. Circle this if the blood was taken from a newly inserted peripheral IV catheter or by a 'stab'
	What type of microbe (s) was reported? [circle all that apply if reported]	• Circle the type of microbe that was reported in the microbiology report: ○ Vir = virus ○ bact = bacteria ○ fung = fungus ○ pseud = pseudomonas
	Name of the microbe(s) [write the name] (drop down menu provided)	• Write the name of the antimicrobial that the microbiologist recommends or the report suggests the microbe is sensitive to. There is an extensive list provided (alphabetical order) in a drop menu in the

		database to ease data entry (**Appendix VII**)
	Colonisation or infection?	• Circle one of the following: o Col = colonisation (circle this if the microbiology report indicates that the microbe is colonising rather than causing infection in the patient) o Inf = infection (circle this if the microbiology report indicates that the microbe is causing infection rather than colonising the patient) • It is possible that the patient may be infected with one microbe and colonised with another. Please circle 'inf' if this is the case
	If reported name the antimicrobial the microbe(s) is sensitive to [write the name] (drop down menu provided)	• Write the name of the antimicrobial that the microbiologist recommends or the report suggests the microbe is sensitive to. There is an extensive list provided (alphabetical order) in a drop down menu in the database to ease data entry (**Appendix VII**).
D5.05 swabs and other cultures (micro)	From where was the sample obtained? [write the body fluid/area swabbed] (drop down menu provided)	• Complete D5.05 if a body fluid sample or swab was sent for microbiology reporting on this study day. • Write the name of the body area / region swabbed or body fluid sample • A drop down menu is provided (**Appendix X**)
	What type of microbe(s) was reported? [circle all that apply if reported]	• Circle the type of microbe that was reported in the microbiology report: o Vir = virus o bact = bacteria o fung = fungus o pseud = pseudomonas
	Name of the microbe(s) [write the name(s)] (drop down menu provided)	• Write the name of the antimicrobial that the microbiologist recommends or the report suggests the microbe is sensitive to. There is an extensive list provided (alphabetical order) in a drop down menu in the database to ease data entry (**Appendix VII**)
	Colonisation or infection?	• Circle one of the following: o Col = colonisation (circle this if the microbiology report indicates that the microbe is colonising rather than causing infection in the patient) o Inf = infection (circle this if the microbiology report indicates that the microbe is causing infection rather than colonising the patient) • It is possible that the patient may be infected with one microbe and colonised with another. Please circle 'inf' if this is the case

	If reported name the antimicrobial(s) the microbe(s) is sensitive to [write the name(s)] (drop down menu provided)	• Write the name of the antimicrobial that the microbiologist recommends or the report suggests the microbe is sensitive to. There is an extensive list provided (alphabetical order) in a drop down menu in the database to ease data entry (**Appendix VII**)
D5.06 Site of infection	D5.06 Site of infection Is there documentation (by a Staff Specialist –any speciality) in the health care records of a site of infection (or strong suspicion of infection) on this study day? [tick all that apply]	
	Pulmonary Intra-abdominal Blood Skin Urinary IV catheter CNS Gut Endocarditis Other	• Consult the health care records for documentation by an experienced medical doctor of a site of infection (or strong suspicion of infection) and tick the site that is documented as the most likely source/site • Samples of body fluid or wound swabs do not always 'grow' microbes as antimicrobials are often administered before the samples are taken. Therefore this data will be used in the interpretation of analyses to explore the association between signs of inflammatory response and treatments (antimicrobials)

Data collection (outcome and discharge status) at 30 days (in hospital)

Please track the patients while they remain in hospital and document their **in-hospital status at 30 days**. There is **no** requirement to contact the patient in the community. **Ethical approval has not been provided for investigators to contact patients. Please do not contact patients or their families for the purposes of this study.** Record the ICU discharge date and the hospital discharge date. If the patient dies in hospital record the approximate cause of death and up to four underlying causes of death. The data will be used to explore the risks of mortality associated with a diagnosis of VAP and the contribution a diagnosis of VAP has to mortality.

Discharge/Outcome data collection form instructions

1. Outcome and discharge status at 30 days (in-hospital outcomes only)		
O1.01	Was the patient ALIVE at day 30? [if 'yes' go to O1.05, 'no' go to O1.02]	•
O1.02	Date of death	• Record using full date format dd/mm/yyyy
O1.03	Where did the patient die? [circle one]	• Circle 'ICU' if the patient died while in ICU (recall ICU is defined as any department overseen (could be a HDU) by an intensive care clinician (i.e. intensivist or anaesthetist), therefore 'ICU discharge' is defined as when a patient is discharged to any department NOT overseen by an intensive care clinician. N.B. If a patient has been "booked out" of ICU, however due to a lack of hospital ward beds they physically remain in the ICU, then the patient is still defined as an ICU patient and daily data

		must still be collected • Circle 'ICU' if the patient died while on 'transfer' or during an intervention/investigation in another department (e.g. operating theatre, radiology) if they were still under the care of the ICU clinician • Circle 'hospital ward' if the patient died when they were **no** longer under the care of the intensive care clinician (i.e. intensivist or anaesthetist) **and** physically located outside of ICU i.e. circle 'Hospital ward' if the patient is officially discharged from ICU and has physically moved out of ICU • HDU **not** overseen by an ICU clinician is classified as 'Hospital ward'
O1.04 causes of death	Proximate cause of death [circle only one]	• Tick one option from the list of proximate causes of death /select one option from the drop down menu • Record (tick/select) the primary diagnosis that is identified as the main cause of death in the medical records, post mortem report or death certificate • "Cardiopulmonary arrest" is not considered a cause of death. Please specify the cause that led to the cardiopulmonary arrest e.g. arrhythmia, shock etc. • An option 'Coroner's case (not able to access records)' is provided. It would be greatly appreciated if all efforts could be made to collect data related to cause of death. Please **only** tick/select this option if the records cannot be located at the end of the entire study period (i.e. the chief investigators have announced the imminent closure of the web-based database for data entry)
	Underlying cause(s) of death (if known) [circle **up to** 4]	• Tick up to four (4) options from the list of underlying causes of death/ Select up to four (4) options from the down menu • Record (tick/select) the underlying disease processes or diagnoses that existed **at the time of death** and identified as being connected with the proximate cause of death
O1.05	ICU discharge date	• Record the date (dd/mm/yyyy) the patient was discharged from **your** ICU i.e. regardless of whether they are transferred to an ICU in another hospital • Do not record the date if the patient is discharged to another ICU in your facility – Daily data collection should continue until their discharge to the ward/death/30 days • The ICU admission and discharge dates will enable automatic calculation of ICU length of stay
O1.06	Duration of mechanical ventilation	• Chart days (>12 hours in any 24 hours) • Record the number of days the patient received invasive mechanical ventilation i.e. via a tracheostomy tube or an endotracheal /nasopharyngeal tube. For patients who were 'weaned' from mechanical ventilation and received intermittent episodes of ventilation record the number of days the patient received >12 hours of invasive mechanical ventilation in a 24 hour period.

O1.07	Hospital discharge date	• Enter the date the patient was discharged from **your** hospital regardless of whether the patient was transferred to another acute hospital • The hospital admission and discharge dates will enable automatic calculation of hospital length of stay
O1.08	Location discharged to..	• Circle one only: o Home = their usual home or a relative/friend's abode o Hospital = transfer to another hospital (public or private) o Rehab = rehabilitation (any facility that provides rehabilitation if the patient stays overnight) o nursing home = a facility other than one of the above which provides nursing care o other o Unknown. Please only circle/select this option if it is not possible to find the information from hospital sources

Data entry

We recommend that data are entered into the study web-based database as soon as possible after the data are collected in paper form. Unique log-in and passwords will be provided for the research officer at each site. Please keep these details in a secure place and do not give them to others.

Data management

Please store screening and enrolment logs in a secure location separate from daily collection forms. Please do not destroy the screening and enrolment log forms until the VAP project officer gives instructions for you to do this. We also recommend that you keep paper copies of the Baseline, Daily Collection and Discharge Outcome forms until the conclusion of the study. When the VAP project officer contacts you to tell you that data collection is complete and advises you that the paper forms can be destroyed please shred them in a commercial grade shredder.

Data monitoring (checking)

Please ask a colleague (experienced nurse or medical doctor) to perform a random check on 10% (i.e. 2 patients) of your data collection for section 2 (VAP checklist) of the daily collection form. Please resolve/correct any inaccuracies using consensus. (For example you may differ in your opinion about the content of the chest X ray report and your responses to D2.03.) You do not need to report the number of corrections made. The VAP project officer will check the database every 3-4 days for trends in patient data which appear unusual and for changes which are sudden or unexpected and contact you for verification and corrections.