The Fluid Translation of Research into Practice Study (Fluid TRIPS)

DATA DICTIONARY

ANZICS Clinical Trials Group

Advocate for intensive care throughout Australia and New Zealand

THE GEORGE INSTITUTE for Global Health

General Information

The aim of Fluid TRIPS is to conduct a prospective assessment of fluid resuscitation practice in ICU patients in as many countries as possible worldwide to:

1. document current practice in fluid resuscitation
2. determine if there are identifiable patient characteristics that influence choice of fluid
3. determine whether there are identifiable regional or national variations in choice of resuscitation fluid that are not explained by patient characteristics
4. compare the results to the same data collected in 2007 from SAFE TRIPS

Explanations for the completion of each question are provided. Each number in the left hand column refers to the question number on the data form.

If you have other questions, please contact your site principal investigator or Ms Maryam Correa fluidtrips@georgeinstitute.org.au .

Study day

The study day is the 24-hour period corresponding to the chart day at your institution for the date of 30th April, 21st May, 11th June, 16th July, 20th August, 17th September or 15th October, 2014. For example:

- **If your unit keeps charts from 0000 hours to 0000 hours (midnight to midnight) and you are participating on the May study date, then your study day is from 0000 hrs on May 21st to 2359 hrs on May 21st.**
- **If your charts are from 1200 hours to 1200 hours (midday to midday) and you are participating on the May study date, then your study day is from 1200 hrs on May 21st to 1159 hrs on May 22nd.**
- **If your charts are from 0800 hours to 0800 hours then your study day is from 0800 hrs May 21st to 0759 hrs May 22nd.**

Inclusion criteria

All patients who are in the ICU during the study day who are 16 years or older and receive fluid resuscitation (definition on page 5).

This includes all the patients who are already present at the start of the study day and every patient admitted to the ICU during the study day.

Forms to be filled in

There are several forms on the website at http://www.georgeinstitute.org.au/projects/fluid-translation-of-research-into-practice-study-fluid-trips . These include the:

- Study protocol
- Data dictionary (this document)
- Patient log - TO BE FILLED OUT FOR **ALL PATIENTS WHO MEET THE INCLUSION CRITERIA** AND ARE IN THE ICU FOR ANY PART OF THE STUDY DAY
- Bedside form – TO BE FILLED OUT AT THE BEDSIDE BY NURSING STAFF FOR EACH RESUSCITATION EPISODE DURING THE STUDY DAY
- Case Report Forms (CRFs) and Unit Survey (see below)

Case Report Forms:

- Unit Survey: TO BE FILLED OUT ONCE ONLY FOR EACH ICU. INCLUDE **ALL PATIENTS** IN THE ICU FOR ANY PART OF THE STUDY DAY (≥ 16 years old).

CRFs 1-4 ARE TO BE COMPLETED FOR **ONLY THOSE PATIENTS RECEIVING RESUSCITATION FLUIDS** ON THE STUDY DAY:

- CRF 1: ICU Admission Data
- CRF 2: Baseline Data
- CRF 3: Fluid Resuscitation
- CRF 3a: Additional Fluid Resuscitation
- CRF 4: Day Summary

The patient log and bedside form are to be kept securely at the participating hospital. These forms contain identifiable information and **must not** be sent to The George Institute. However, should data checks be requested these forms will allow you to match patient study numbers to hospital records.

Please transcribe the data once collected into the electronic CRF (eCRF). **You will be sent details of the URL and password**. Keep the original paper documentation as your record. If it is not possible for you to enter data into the eCRF then, once complete, all the case report forms need to be photocopied.

The originals are to be sent by mail (with all patient identifiers masked and only the patient study ID visible) to:

Ms Maryam Correa
Critical Care and Trauma Division
The George Institute for Global Health
PO Box M201 Missenden Rd
Sydney NSW 2050 Australia

The photocopies should be kept securely at the participating hospital, we will notify you once the originals are received at The George Institute.

Abbreviations

ABP	Arterial blood pressure
APACHE	Acute physiology and chronic health evaluation
ARDS	Acute respiratory distress syndrome
BP	Blood pressure
CCU	Coronary care unit
CPAP	Continuous positive airway pressure
CVP	Central venous pressure
ECMO	Extracorporeal membrane oxygenation
GCS	Glasgow Coma Score
HDU	High dependency unit
HR	Heart rate
RRT	Renal replacement therapy
ICP	Intracranial pressure
ICU	Intensive Care Unit
INR	International Normalised Ratio
MAP	Mean arterial pressure
NIPPV	Non-Invasive Positive Pressure Ventilation
PCWP	Pulmonary capillary wedge pressure
PAOP	Pulmonary artery occlusion pressure
SIRS	Systemic inflammatory response syndrome
SOFA	Sequential Organ Failure Assessment
$ScvO_2$	Central venous oxygen saturation
SvO_2	Mixed venous oxygen saturation

GENERAL ADVICE	
Unit Survey	• Complete the Unit Survey ONCE per ICU for the chosen study day. When recording the total number of patients in the ICU, include **EVERY** patient in the ICU during the study day ≥ 16 years old. This includes every patient already on the unit and those admitted to the unit during the study day, regardless of whether or not they receive fluid resuscitation.
Fluid resuscitation patients: **Forms 1, 2, 3, 4**	• Only complete Forms 1, 2, 3 and 4 for patients who receive fluid resuscitation in the ICU during the study day. Fluid resuscitation is defined as: 1. A bolus of crystalloid 2. A crystalloid infusion of 5mL/kg/hour or greater for one or more hours 3. A colloid bolus 4. Any colloid by infusion
Country ID:	Your country has been allocated a 3-digit number by the Coordinating Centre. Contact your site principal investigator or email Ms Maryam Correa fluidtrips@georgeinstitute.org.au if you do not know your country ID.
Hospital ID:	Your hospital has been allocated a 3 or 4-digit number by the Coordinating Centre. Contact your site principal investigator or email Ms Maryam Correa fluidtrips@georgeinstitute.org.au if you do not know your hospital ID.
Patient ID:	• Each patient at your site is to be allocated a 3-digit patient number by you. The first patient enrolled at your hospital will be 001, the second will be 002 and so on. Please keep a record at your site which identifies each patient by their patient number- use the patient log form for this. This record MUST NOT be sent to The George Institute, The George Institute will identify data by the country, hospital and patient ID only.

UNIT SURVEY: THIS FORM SHOULD BE COMPLETED ONCE PER ICU	
General tips	• Complete the Unit Survey ONCE per ICU for the chosen study day. • The total number of patients in the ICU (question 0.02) should include all patients in the ICU during the 24-hour study period, regardless of whether or not they received fluid resuscitation.

No.	Question	Definition or explanation of question	Comments
Country ID		Your country has been allocated a 3-digit number by the Coordinating Centre. This number will be the same for every form completed at all hospitals in your country.	This is the unique study number that identifies which country the form is from.
Hospital ID		Your hospital has been allocated a 3 or 4-digit number by the Coordinating Centre. This number will be the same for every form you complete at your hospital.	This is the unique study number that identifies which hospital the form is from.
0.01	Date	Enter the date of the study day using the following format e.g. 30/04/2014 for 30th April 2014.	
0.02	Total ICU patients	Record the total number of patients in the ICU on the study day ≥ 16 years old. This total should include: o every patient already on the unit and all of those admitted to the unit during the 24-hour study period. o patients who receive fluid resuscitation and patients who do not receive fluid resuscitation during the study day.	This will enable precise calculation of the prevalence of fluid resuscitation on the chosen study day.
0.03-0.23	Fluid availability	For each fluid type listed, select 'Y' if it is available for use in your ICU. Select 'N' if it is not available in your ICU.	

0.24	Access to cost information	Select 'Y' if any clinical staff working in your ICU have access to information on the cost of fluid preparations used in the ICU (i.e. the price paid by the hospital to purchase the fluid preparation). Then proceed to the next question (question 0.25). Select 'N' if cost information is not available. If no cost information is available, the form is finished.	These data will assist in undertaking a cost analysis of fluid used for resuscitation globally.
0.25	Primary currency	Indicate the primary currency used for fluid costs. If there are multiple currencies used, specify the most commonly used currency. Example: USD $, EUR €	
0.26-0.46	Unit cost and unit volume	For each of the fluids listed, provide the unit cost where cost information is available. Provide costs in the primary currency specified in question 0.25. In addition to the cost amount, indicate the unit volume in mL that this cost applies to. For example, where the price of a 1000mL bag of saline is $6, indicate unit cost = 6, unit volume = 1000	
0.47	Source of cost information	Indicate where the cost information given in questions 0.26-0.46 was obtained from. Select all that apply. If 'other' is selected, please specify the source.	

FORM 1 – ICU ADMISSION DATA: THIS FORM SHOULD BE COMPLETED FOR ALL PATIENTS THAT RECEIVE FLUID RESUSCITATION	
General tips	• **This form is only to be completed for those patients receiving fluid resuscitation** • Fluid resuscitation is defined on page 5 of the data dictionary • Form 1 should be completed for every patient in the ICU during the study day who receives fluid resuscitation. This includes all patients already on the unit and all of those admitted to the unit during the study day who receive fluid resuscitation at any time during the 24-hour study period.

No.	Question	Definition or explanation of question	Comments
Country ID		Your country has been allocated a 3-digit number by the Coordinating Centre. This number will be the same for every form completed at all hospitals in your country.	This is the unique study number that identifies which country the form is from.
Hospital ID		Your hospital has been allocated a 3 or 4-digit number by the Coordinating Centre. This number will be the same for every form you complete at your hospital.	This is the unique study number that identifies which hospital the form is from.
Patient's Study ID		The individual patient number will be 001 for the first patient enrolled at your hospital, 002 for the second patient enrolled, 003 for the third patient etc.	This is the unique study number that, together with the country and hospital numbers, identifies the patient.
1.01	Patient's sex	Select the patient's legal gender as **M** (male) or **F** (female)	
1.02	Is the patient pre-menopausal?	Select 'Y' if the patient is a woman of child bearing age (16-49 years old) unless there is documented evidence of menopause, hysterectomy or surgical sterilisation. Select 'N' if the patient is ≥ 50 years old or if there is evidence of menopause, hysterectomy or surgical sterilisation.	This question is included as hydroxyethyl starch is contraindicated in patients who are pregnant.

No.	Question	Definition or explanation of question	Comments
1.03	Pregnancy excluded	Select 'Y' if negative pregnancy test OR if the patient is breastfeeding.	This question is included as hydroxyethyl starch is contraindicated in patients who are pregnant.
1.04	Age	Enter the patient's age on the study day in whole years.	
1.05	ICU admission date	Enter the date the patient was admitted to your ICU using the following date format e.g. 01/04/2014 for 1st April 2014. This date must be before the end of your study day (e.g. on or before 30 April 2014).	All patients already in your ICU at the start of the study day and all patients admitted to your ICU during the study day will be included if the patient received fluid resuscitation during the 24-hour study period.
1.06	From where was patient admitted to the ICU	Select the response that corresponds with the source of admission to your ICU. Only one box should be selected. • 'Accident and Emergency' = the A&E at *your* hospital • 'Hospital Floor' = any WARD in your hospital, including day care facilities but not including an ICU, • 'Transfer from other ICU' = any other ICU from within your hospital or an ICU from another hospital • 'Transfer from another hospital' = transfer from any area in another hospital except an ICU • 'Operating theatre following emergency surgery'. Emergency surgery is defined as surgery that the patient needed immediately due to physiological instability that was potentially life threatening. • 'Operating theatre following elective surgery' = from operating theatre or recovery ward following any surgery that is NOT defined as 'emergency'.	The definition of emergency surgery is taken from the original APACHE II study data dictionary.
1.07	Patient been in YOUR ICU during THIS admission	Select 'Y' if the patient has had a previous admission episode in your ICU during this hospital admission Select 'N' if the patient has not previously been in your ICU during this hospital admission.	

No.	Question	Definition or explanation of question	Comments
1.08	Post-operative admission to ICU	Select 'Y' if patient was admitted DIRECT from the operating theatre or the recovery room and go to question 1.09 Select 'N' if the patient was not admitted directly from the operating theatre or recovery room and go to question 1.10	
1.09	Primary post-operative diagnosis	Choose the single most important reason for ICU treatment from this list of **POST-OPERATIVE** diagnoses. Only **ONE** *primary* diagnosis can be selected. The diagnosis leading to this ICU admission does not necessarily have to be the same diagnosis that led to the hospital admission e.g. A patient admitted for investigation of chronic anaemia who then goes on to have an emergency bowel resection for a bleeding colonic neoplasm would be classed as: POSTOPERATIVE / Gastrointestinal / Neoplasm. 'Neoplasm' should be selected in this case rather than 'Bleeding' as it is a more specific diagnosis that led to the ICU admission.	
1.10	Primary medical diagnosis	Choose the single most important reason for ICU treatment from this list of **MEDICAL** diagnoses. Only **ONE** *primary* diagnosis can be selected. The diagnosis leading to this ICU admission does not necessarily have to be the same diagnosis that led to the Hospital admission e.g. a patient admitted for elective cholecystectomy who survives a cardiac arrest on the ward would be classed as MEDICAL / Cardiovascular / Cardiac Arrest. It is the cardiac arrest that led the patient to be admitted to the ICU, not the cholecystectomy.	

FORM 2 – BASELINE DATA: THIS FORM SHOULD BE COMPLETED FOR ALL PATIENTS THAT RECEIVE FLUID RESUSCITATION	
General tips	• This form is only to be completed for those patients receiving fluid resuscitation. • Fluid resuscitation is defined on page 5 of the data dictionary. • The fluid given should be in addition to that which is required for nutrition or "maintenance" fluids. • All variables used to answer questions 2.11-2.12 on this form are from the 24 hours prior to the FIRST fluid resuscitation episode

No.	Question	Definition or explanation of question	Comments
2.01	Patient's weight	Enter patient's weight in kilograms. Weight may be measured, documented in medical records, obtained from patient or relative questioning or visually estimated.	The patient's weight will be used to calculate the amount of fluid given per kg. A useful source for patients' weight may include dietician notes.
2.02	Weight estimated or known	Select 'ESTIMATED' if the patient's weight was obtained by asking relatives or the patient or visually estimated. Select 'KNOWN' if the patient's weight was documented in the medical record.	
2.03	Hospital admission due to trauma	Select 'Y' if the primary hospital admission diagnosis is trauma of any kind, including burns. Go to question 2.04. Select 'N' if the patient was not admitted to hospital due to trauma. Go to question 2.11.	
2.04	Trauma criteria – injury by mechanical forces	Select 'Y' if there is a history of blunt or penetrating bodily injury caused by mechanical physical forces or 'N' if there is no mechanical injury.	These data are requested so that patients admitted to hospital because of trauma with or without traumatic brain injury can be prospectively defined for sub group analysis at the end of the study.
2.04	Trauma criteria – primary admission diagnosis of burns	Select 'Y' if the primary ICU admission diagnosis is burns and go to question 2.05 or 'N' if the patient does not have burns **OR** burns are not the primary ICU admission diagnosis and go to question 2.06.	

No.	Question	Definition or explanation of question	Comments
2.05	Percentage body area of burns	Enter percentage as proportion out of 100 to nearest whole number e.g. burns to 10% of the body surface area should be coded as 10.	
2.06	Last GCS prior to sedation	Enter the last GCS score prior to the patient receiving sedation, including sedation given pre-hospital. For information on how to calculate the GCS, see Appendix 1.	
2.07	GCS recorded or estimated	Select 'RECORDED' if the GCS was documented in the patient record or 'ESTIMATED' if the GCS was obtained from a description of the patient's neurological state.	
2.08	Cranial CT	Select 'Y' if a cranial computerised tomography (CT) scan was performed prior to ICU admission. Go to question 2.09 Select 'N' if CT scan was not performed and go to question 2.11	
2.09	Trauma criteria – Abnormality on cranial CT	Select 'Y' if there was any abnormality on a cranial CT scan that was deemed consistent with an acute traumatic brain injury. Select 'N' if the CT results were not consistent with acute traumatic brain injury.	These data are requested so that patients admitted to hospital because of trauma with or without traumatic brain injury can be prospectively defined for sub-group analysis at the end of the study.
2.10	Trauma criteria- Intracranial haemorrhage on cranial CT	Select 'Y' if there is any intracranial haemorrhage (extradural haemorrhage/subdural haemorrhage/subarachnoid haemorrhage/intraparenchymal haemorrhage or haemorrhagic contusion) reported or visible on cranial CT scan that is attributed to trauma.	

No.	Question	Definition or explanation of question	Comments
2.11	Sepsis at Baseline	Select 'Y' only if the patient has a defined focus of infection AND TWO (2) systemic inflammatory response syndrome [SIRS] criteria in the 24 hours prior to the first resuscitation episode Select 'N' if these criteria are absent A "defined focus of infection" is indicated by either (i) An organism grown in blood or sterile site **OR** (ii) An abscess or volume of infected tissue (e.g. pneumonia, peritonitis, vascular line infection, soft tissue, etc). The 4 SIRS criteria are: 1. Core temperature >38°C or <36°C (core temperature is rectal, central line, or tympanic). If oral or axillary temp is used, add 0.5°C to the measured value. Hypothermia <36°C must be confirmed by core temperature only. Use the most deranged value recorded in the 24 hours before the first fluid resuscitation episode. 2. Heart rate >90 beats/minute. If patient had an atrial arrhythmia, record the ventricular rate. If patients have a known medical condition or are receiving treatment that would prevent tachycardia (for example, heart block or beta blockers), they must meet two of the remaining three SIRS criteria. Use the most deranged value recorded in the 24 hours before the first fluid resuscitation episode. 3. Respiratory rate > 20 breaths per minute or a $PaCO_2$ < 32 mmHg or mechanical ventilation for an acute process. Use the most deranged respiratory rate or $PaCO_2$ recorded in the 24 hours before the first fluid resuscitation episode. 4. White blood cell (WBC) count of >12 x 10^9/L or < 4 x 10^9/L or > 10% immature neutrophils (band forms). Use the most deranged value recorded in the 24 hours before the first fluid resuscitation episode.	Positive cultures are NOT required. A defined focus of infection may be indicated by chest x-ray changes and a clinical picture consistent with infection or by peritonitis reported on a surgical operation record or other clinical indicators of a defined focus of infection. These data are requested so that we can prospectively identify patients with sepsis. For question 2.11 select 'Y' only if the patient has a defined focus of infection **AND** two SIRS criteria.

No.	Question	Definition or explanation of question	Comments
2.12	ARDS at baseline	Select 'Y' if the patient has met all 4 criteria for ARDS. Select 'N' if ANY of the 4 criteria are NOT met. The 4 ARDS criteria are: 1. Timing Onset is within one week (7 days) of a known clinical insult or new or worsening respiratory symptoms 2. Chest imaging Bilateral opacities evident on chest radiograph or CT scan taken in the 24 hours prior to the first fluid resuscitation episode, not fully explained by effusions, lobar/lung collapse or nodules. If these opacities are present in only ONE of two lungs this criterion is **NOT** met. If the patient has had one lung removed and the opacities are present in the remaining lung, this criterion IS met. If no chest radiograph or CT scan is available from the 24 hours prior to fluid resuscitation, the criterion is **NOT** met. 3. Origin of oedema Respiratory failure not fully explained by cardiac failure or fluid overload. Need objective assessment (e.g. echocardiography) to exclude hydrostatic oedema if no risk factor present. 4. Oxygenation* $PaO_2/FiO_2 \leq 300$mmHg with PEEP or CPAP ≥ 5cm H_2O (this may be delivered non-invasively) at any time within the 24 hours prior to fluid resuscitation. If no blood gas is available or the ratio is greater than 300mmHg, the criterion has **NOT** been met. PaO_2/FiO_2 ratio: aterial oxygen pressure / concentration of inhaled oxygen *If altitude is higher than 1000m, apply correction factor: [PaO_2/FiO_2 x (barometric pressure/760)]	The ARDS definition is taken from the Berlin Definition: The ARDS Definition Task Force, JAMA, 2012, 307(23): 2526-2533 These data are requested so that we can define patients with Acute Respiratory Distress Syndrome (ARDS) prospectively for sub-group analysis at the end of the study. ALL 4 criteria at question 2.12 MUST be present for the full definition of ARDS AT BASELINE to be met.

No.	Question	Definition or explanation of question	Comments
2.13	Severity of disease score	Select 'Y' if a severity of disease score was calculated for this patient on admission for example an APACHE II or SAPS II score. Then proceed to question 2.14. Select 'N' if a severity of disease score was not calculated for the patient on admission, then go to question 2.16.	
2.14	Name of score used	Specify the name of the severity of disease score calculated on admission for this patient.	
2.15	Severity of disease score value	Provide the value of the severity of disease score named in question 2.14.	
2.16	Chronic health points score	Refer to Appendix 2 for the chronic health points worksheet, a component of the APACHE II score. To calculate the chronic health points score, first decide if the patient meets any of the criteria provided on the worksheet for a history of severe organ insufficiency or immunocompromised state. If there is no history, assign 0 points. If there is a history, assign points depending on whether the patient is a non-operative emergency admission or an emergency post-operative admission (5 points) OR a post-operative admission following elective / planned surgery (2 points). Enter this score (0, 2 or 5 points) at question 2.16.	
2.17	Chronic health points	If the patient had a history of organ insufficiency or immunocompromised state, select 'Y' or 'N' for each category of chronic health conditions the patient met (liver, renal, cardiovascular, respiratory and immunocompromised). You can select more than one category.	

FORM 3 – FLUID RESUSCITATION: THIS FORM SHOULD BE COMPLETED FOR ALL PATIENTS THAT RECEIVE FLUID RESUSCITATION	
General tips	• **This form is only to be completed for those patients receiving fluid resuscitation**. • To be completed for the first 3 episodes of resuscitation. For more than 3 episodes use Form 3A. • Resuscitation episodes defined as an hour during which a patient receives a BOLUS of either crystalloid or colloid to increase or maintain intra-vascular volume. If a fluid bolus is given over a period longer than one hour, then begin a new resuscitation episode for the second hour. Resuscitation episodes are defined by time, NOT by the fluid administration. Where two fluid boluses are given in one hour, these are treated as a single episode. Each additional hour where a fluid bolus is received is a new resuscitation episode. • Resuscitation episodes defined as the first hour of a colloid infusion or the first hour of a crystalloid infusion of 5mL/kg/hour or more. Where fluid resuscitation is given as either a continuous colloid infusion or a continuous crystalloid infusion of 5mL/kg/hour or more, take the first hour of the infusion as the resuscitation episode and complete the resuscitation episode data for that hour. The remaining volume of the infusion should be recorded on Form 4. • For more than 3 episodes, use Form 3A. You can use as many copies of Form 3A as necessary to document every episode of fluid resuscitation the patient received during the study day. Form 3A is almost identical to Form 3 except for question 3.01 and you will need to enter the number of the episode e.g. 4, 5 etc. into the spaces indicated.

No.	Question	Definition or explanation of question	Comments
3.01	Total fluid resuscitation episodes	Indicate the total number of fluid resuscitation episodes received by this patient across the 24-hour study period. Fluid resuscitation episodes are defined above. Please note question 3.01 differs for Form 3A.	
3.02	Time of resuscitation	Enter the time in hours and minutes of the start of each fluid resuscitation episode using the 24-hour clock e.g. 5pm is entered as 17:00.	
Indications for fluid resuscitation episode: Select either 'Y' or 'N' for each indication, for each episode; more than one reason may be chosen.			
3.03	Hypotension	Please choose 'Y' if an unacceptably low blood pressure contributed to the decision to give the fluid bolus.	
3.04	Increasing inotrope or vasopressor requirements	Please choose 'Y' if increasing doses or persistently high doses of inotrope vasopressor medications such as adrenaline (epinephrine), noradrenaline (norepinephrine), dobutamine, milrinone, vasopressin, or dopamine contributed to the decision to give the fluid bolus.	
3.05	Low CVP	Please choose 'Y' if an unacceptably low CVP contributed to the decision to give the fluid bolus.	
3.06	Low PCWP	Please choose 'Y' if an unacceptably low PCWP (pulmonary capillary wedge pressure) or PAOP (pulmonary artery occlusion pressure) contributed to the decision to give the fluid bolus.	

No.	Question	Definition or explanation of question	Comments
3.07	Tachycardia	Please choose 'Y' if an unacceptably high heart rate contributed to the decision to give the fluid bolus.	
3.08	Low urine output	Please choose 'Y' if an unacceptably low urine output contributed to the decision to give the fluid bolus.	
3.09	Low measured cardiac output via invasive haemodynamic monitoring	Please choose 'Y' if an unacceptably low measured cardiac output contributed to the decision to give the fluid bolus as assessed by an intravascular technique used to diagnose low cardiac output e.g. a pulmonary artery catheter or other thermodilution/dye indicator technique or waveform analysis of arterial tracing.	
3.10	Low measured cardiac output via echocardiographic findings	Please choose 'Y' if an unacceptably low measured cardiac output as assessed by an echocardiography technique contributed to the decision to give the fluid bolus e.g. pulse wave Doppler of lateral ventricle outflow tract.	
3.11	Low intravascular volume as assessed by echocardiography	Please choose 'Y' if an unacceptably low intravascular volume contributed to the decision to give the fluid bolus, as diagnosed using an echocardiographic technique e.g. inferior vena cava diameter.	
3.12	Clinical signs of poor peripheral perfusion	Please choose 'Y' if poor peripheral perfusion contributed to the decision to give the fluid bolus.	
3.13	Low $S_vO_2/S_{cv}O_2$	Please choose 'Y' if an unacceptably low $S_vO_2/S_{cv}O_2$ contributed to the decision to give the fluid bolus.	
3.14	Ongoing bleeding	Please choose 'Y' if ongoing bleeding contributed to the decision to give the fluid bolus.	
3.15	Other ongoing fluid loss	Please choose 'Y' if ongoing fluid losses other than bleeding contributed to the decision to give the fluid bolus.	
3.16	Unit protocol or standing orders	Please choose 'Y' if the fluid bolus was given based on a unit protocol or standing order.	
3.17	Increasing or persisting acidosis or lactate	Please choose 'Y' if Increasing or persisting acidosis or lactate contributed to the decision to give the fluid bolus.	
3.18	Positive Straight Leg Raise Test	Please choose 'Y' if temporary passive elevation of a limb (and its effect on haemodynamic indices) contributed to the decision to give the fluid bolus.	

No.	Question	Definition or explanation of question	Comments
3.19	Abnormal indices of Systolic Pressure Variation or Stroke Volume Variation	Please choose 'Y' if systolic pressure or volume variation contributed to the decision to give the fluid bolus e.g. variation of greater than 10%.	
3.20	Other? Specify	Please choose 'Y' if other features contributed to the decision to give the fluid bolus Please specify what those features or characteristics were.	
3.21	Who decided choice of fluid for resuscitation episode?	Select 'Y' for the option corresponding to the staff member responsible for the choice of fluid for this resuscitation episode: • ICU doctor • Surgical doctor • Medical doctor **If you choose one of the above, go to question 3.22.** **If you choose one of the below, go straight to question 3.23.** • Nurse acting independently • Nurse following unit protocol • Other	

No.	Question	Definition or explanation of question	Comments
3.22	Level of doctor choosing fluid type	For the ICU, surgical or medical doctor selected in 3.21, what is the doctor's level? Enter 'Yes' to ONE of the following only (for each resuscitation episode): • Specialist/consultant/attending - Doctor who has completed Advanced Training in Intensive Care and/or applicable Board or College Registration. • Registrar/ Fellow / Senior Trainee – Doctor who is undertaking Advanced Training in Intensive Care and/or applicable Board or College Registration. • Resident/HMO/Junior Trainee – Doctor who has more than one year of post graduate experience but has not yet entered advanced training in their specialty. • Intern/House Officer – Junior doctor who has less than one year of post-graduate experience.	
Questions 3.23 to 3.41 are designed to collect the data that was available to the prescribing clinician at the start of the resuscitation episode. The values entered should be the last available prior to the resuscitation episode. For parameters such as heart rate and blood pressure the values are likely to be from the hour preceding the episode. For other parameters such as laboratory values the last available value may be from some hours before the resuscitation episode and may even be from during or before a previous resuscitation episode – these values should still be recorded if they are less than 24 hours old and they are the last value available before the resuscitation episode. If a parameter has been measured once and then followed by several resuscitation episodes before being measured again, please record the value for all the subsequent resuscitation episodes until a new value for that parameter is available.			
3.23	SOFA score-respiration	Enter the one digit SOFA score for respiration for each resuscitation episode. A SOFA worksheet is available in Appendix 3. Use the last available arterial blood gases prior to the resuscitation episode commencing.	
3.24	SOFA score - cardiovascular	Enter the one digit SOFA score for cardiovascular for each resuscitation episode. A SOFA worksheet is available in Appendix 3.	
3.25	Renal replacement therapy	Select 'Y' if renal replacement therapy (RRT) was being used at the start of this fluid resuscitation episode or 'N' if renal replacement therapy was not used	RRT refers to any form of artificial renal support including intermittent or continuous haemodialysis and / or haemofiltration
3.26	Mechanical ventilation	Select 'Y' if the patient is receiving any form of POSITIVE pressure ventilation via an endotracheal tube or tracheostomy / tracheotomy or mask.	'Y' includes NIPPV. It does NOT include CPAP delivered by mask or CPAP without positive inspiratory pressure via an endotracheal tube or tracheostomy / tracheotomy.
3.27	ECMO	Select 'Y' if the patient is receiving extracorporeal membrane oxygenation (ECMO) at the start of this fluid resuscitation episode or 'N' if ECMO was not used.	ECMO refers to any extracorporeal technique of providing either cardiac or respiratory support oxygen to patients with cardiac or respiratory failure.

No.	Question	Definition or explanation of question	Comments
3.28	ICP monitor	Select 'Y' if the patient had intracranial pressure monitoring in situ at the start of this episode or 'N' if the patient did not have ICP monitoring at the start of this episode.	
3.29	ICP (mmHg)	Enter the ICP reading in mmHg from the start of this fluid resuscitation episode. Where a value is not available at the start of the episode, use the value closest to, but before, the start of the episode. Select 'N/A' if the patient does not have an ICP monitor.	
3.30	Heart rate (bpm)	Please record the most recent heart rate in beats per minute (bpm) recorded on the ICU chart prior to each fluid resuscitation episode. If the patient has an atrial arrhythmia or is being paced (atrial and/or ventricular), please record the ventricular rate.	If the HR has not been recorded in the preceding 24 hours please write 'N/A' on the paper CRF (and select 'Not Available' in the eCRF).
3.31	MAP (mmHg)	Please record the mean arterial pressure (MAP) in mmHg recorded on the ICU chart in the hour prior to each fluid resuscitation episode. If there is no MAP recorded in the hour preceding the resuscitation episode, record the SBP and DBP in Q 3.32 and 3.33 respectively. If there is MAP, SBP or DBP, record the most recent MAP or SBP/DBP available.	If the MAP has not been recorded in the preceding hour and the most recent BP is a SBP and DBP please write 'N/A' on the paper CRF (and select 'Not Available' in the eCRF) for the MAP.
3.32	Systolic ABP (mmHg)	If the MAP has been recorded in the last hour enter the MAP for Q3.31 and indicate 'Not Available' for the SBP. If there is no MAP recorded in the last hour and the last SBP prior to the resuscitation episode is after the last MAP prior to the resuscitation episode, enter the most recent Systolic blood pressure in mmHg.	If the most recently recorded BP is a MAP please write 'N/A' on the paper CRF (and select 'Not Available' in the eCRF) for the SBP.
3.33	Diastolic ABP (mmHg)	If the MAP has been recorded in the last hour enter the MAP for Q3.31 and indicate 'Not Available' for the DBP. If there is no MAP recorded in the last hour and the last DBP prior to the resuscitation episode is after the last MAP prior to the resuscitation episode, enter the most recent Diastolic blood pressure in mmHg.	If the most recently recorded BP is a MAP please write 'N/A' on the paper CRF (and select 'Not Available' in the eCRF) for the DBP.
3.34	CVP (mmHg)	Enter the most recent CVP in mmHg recorded on the ICU chart prior to each fluid resuscitation episode. Where no value is available since the previous resuscitation episode, carry the previous value forward, as it is the most recent value available. Only record a CVP measurement if it was recorded in the 24 hours prior to the resuscitation episode. If no central catheter was in situ or a CVP measurement is not available for the 24 hours prior to the resuscitation episode, indicate 'Not Available'.	If the CVP has not been recorded in the preceding 24 hours please write 'N/A' on the paper CRF (and select 'Not Available' in the eCRF).

No.	Question	Definition or explanation of question	Comments
3.35	PCWP (mmHg)	Enter the most recent Pulmonary Capillary Wedge Pressure in mmHg. Where no value is available since the previous resuscitation episode, carry the previous value forward, as it is the most recent value available. Only record a PCWP if it was recorded in the 24 hours prior to the resuscitation episode. If no pulmonary artery catheter was in situ or no value is available for the 24 hours prior to the resuscitation episode, indicate 'Not Available'.	If the PCWP has not been recorded in the preceding 24 hours please write 'N/A' on the paper CRF (and select 'Not Available' in the eCRF).
3.36	Creatinine (µmol/L)	Enter the most recent Cr in µmol/L taken prior to each fluid resuscitation episode. If the Cr is measured in mmol/L, convert to µmol/L by multiplying by 1000. Where no value is available since the previous resuscitation episode, carry the previous value forward, as it is the most recent value available. Where a value has not been recorded in the 24 hours prior to the resuscitation episode, indicate 'Not Available'.	If the creatinine has not been measured in the preceding 24 hours please write 'N/A' on the paper CRF (and select 'Not Available' in the eCRF).
3.37	Bilirubin (µmol/L)	Enter the most recent bilirubin in µmol/L taken prior to each fluid resuscitation episode. Where no value is available since the previous resuscitation episode, carry the previous value forward, as it is the most recent value available. Where a value has not been recorded in the 24 hours prior to the resuscitation episode, indicate 'Not Available'.	If the bilirubin has not been measured in the preceding 24 hours please write 'N/A' on the paper CRF (and select 'Not Available' in the eCRF).
3.38	Base excess	Enter the most recent base excess taken prior to each fluid resuscitation episode. Where there was a base deficit, indicate 'Not Available'. Where no value is available since the previous resuscitation episode, carry the previous value forward, as it is the most recent value available. Where a value has not been recorded in the 24 hours prior to the resuscitation episode, indicate 'Not Available'.	If the base excess has not been measured in the preceding 24 hours or if there is a base deficit please write 'N/A' on the paper CRF. Note- units used on CRF (mEq/L and mmol/L) are equivalent so either can be used.
3.39	Base deficit	Enter the most recent base deficit taken prior to each fluid resuscitation episode. Where there was a base excess, indicate 'Not Available'. Where no value is available since the previous resuscitation episode, carry the previous value forward, as it is the most recent value available. Where a value has not been recorded in the 24 hours prior to the resuscitation episode, indicate 'Not Available'.	If the base deficit has not been measured in the preceding 24 hours or if there is a base excess please write 'N/A' on the paper CRF. Note- units used on CRF (mEq/L and mmol/L) are equivalent so either can be used.

No.	Question	Definition or explanation of question	Comments
3.40	Lactate (mmol/L)	Enter the most recent lactate in mmol/L taken prior to each fluid resuscitation episode. Where no value is available since the previous resuscitation episode, carry the previous value forward, as it is the most recent value available. Where a value has not been recorded in the 24 hours prior to the resuscitation episode, indicate 'Not Available'.	If the lactate has not been measured in the preceding 24 hours please write 'N/A' on the paper CRF (and select 'Not Available' in the eCRF).
3.41	Serum Albumin (g/L)	Enter the most recent serum albumin in g/L taken prior to each fluid resuscitation episode. Where no value is available since the previous resuscitation episode, carry the previous value forward, as it is the most recent value available. Where a value has not been recorded in the 24 hours prior to the resuscitation episode, indicate 'Not Available'.	If the serum albumin has not been measured in the preceding 24 hours please write 'N/A' on the paper CRF (and select 'Not Available' in the eCRF).
3.42	Urine output (mL)	Record the volume of urine output for the last complete hour (mL/hr) period charted on the ICU chart immediately prior to the commencement of resuscitation fluid infusion. For example, if the fluid resuscitation episode began at 13:40 and the urine output was last recorded at 13:00 for the hour 12:00 – 13:00, then record the hourly output for 12:00 – 13:00. If no urine output was recorded on the patient's chart for the hour prior to fluid resuscitation, indicate 'Not Available'.	If no urine output was recorded on the patient's chart for the hour prior to fluid resuscitation, please write 'N/A' on the paper CRF (and select 'Not Available' in the eCRF).
3.43	Total fluid output (mL)	Record the total fluid output for the complete hour prior to the beginning of the fluid resuscitation episode. For example, if the fluid resuscitation episode began at 13:40 and the total fluid output was last recorded at 13:00 for the hour 12:00 – 13:00, then record the hourly output for 12:00 – 13:00. If no fluid output was recorded on the patient's chart for the hour prior to fluid resuscitation, indicate 'Not Available'.	If no fluid output was recorded on the patient's chart for the hour prior to fluid resuscitation, please write 'N/A' on the paper CRF (and select 'Not Available' in the eCRF).

No.	Question	Definition or explanation of question	Comments
3.44-3.58	Fluid type and volume- crystalloids	For each type of fluid given, record the volume delivered in mLs for each fluid resuscitation episode **ACCORDING TO THE INSTRUCTIONS ON PAGE 16**.	
3.59-3.73	Fluid type and volume- colloids	For each type of fluid given, record the volume delivered in mLs for each fluid resuscitation episode **ACCORDING TO THE INSTRUCTIONS ON PAGE 16**.	

FORM 3A – ADDITIONAL FLUID RESUSCITATION	
General Tips	• If the patient has more than three fluid resuscitation episodes, record the additional episodes on Form 3A. Use as many copies of 3A as needed to capture all fluid resuscitation episodes across the 24-hour study period. • Enter the episode number where applicable throughout the form e.g. enter 'Episode 4' for the fourth fluid resuscitation episode where indicated (Episode __) • Questions in Form 3A are identical to those in Form 3, with the exception of question 3.01. For 3.01 in Form 3A, please record the fluid resuscitation episode number.

FORM 4 – DAY SUMMARY: THIS FORM SHOULD BE COMPLETED FOR ALL PATIENTS THAT RECEIVE FLUID RESUSCITATION

General Tips	• **This form is only to be completed for those patients receiving fluid resuscitation**. • This form is to record total input and output volumes of fluid for the 24 hours of the study day

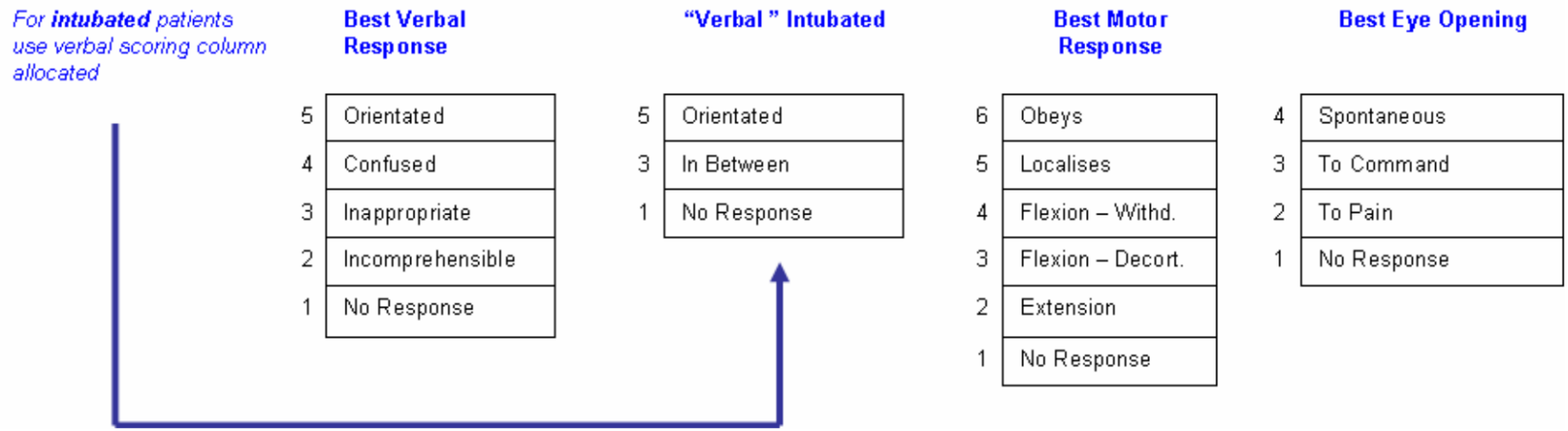
No.	Question	Definition or explanation of question	Comments
4.01	Fluid resuscitation infusion received	Select 'Y' if the patient received a fluid resuscitation **infusion** that lasted for more than one hour during the 24-hour study period. Then proceed to question 4.02. Select 'N' if the patient did not receive such an infusion, then proceed to question 4.19.	
4.02-4.11	Infusion totals-crystalloids	For each fluid type, enter the volume given by infusion EXCEPT the first hour of the infusion which should be recorded on Form 3 or 3A. See the CRF and page 16 of the Data Dictionary for further explanation. For crystalloids other than those listed, write the type of crystalloid in the space provided and record the volume given EXCEPT the first hour of the infusion which should be recorded on Form 3 or 3A (questions 4.09-4.11).	
4.12-4.18	Infusion totals-colloids	For each fluid type, enter the volume given by continuous infusion EXCEPT the first hour of the infusion which should be recorded on Form 3 or 3A. See the CRF and page 16 of the Data Dictionary for further explanation. For colloids other than albumin or 6% HES, write the type of colloid in the space provided and record the volume given EXCEPT the first hour of the infusion which should be recorded on Form 3 or 3A (questions 4.16-4.18).	

No.	Question	Definition or explanation of question	Comments
4.19	Fluid input	Enter the total volume (mL) of fluid input for the study day. This should include any non-resuscitation fluids, enteral nutrition and parenteral nutrition, plus the fluid used for each fluid resuscitation episode recorded on Form 3, 3a and 4.	This includes all resuscitation and non-resuscitation fluid
4.20	Fluid output	Enter the total volume (mL) of fluid output for the study day. Please record the total fluid output (such as urine, drainage from wounds, NG aspiration, stomal drainage or vomit) in mLs that is produced and recorded in the study day.	Do not add 'insensible loss' to this volume, or if 'insensible loss' is normally added on the ICU chart, please delete this amount before entering the output volume into the CRF.

APPENDIX 1

GCS Calculation

To obtain a GCS, add together the best verbal response score, the best motor response score and the best eye opening score. For intubated patients, use the "verbal" intubated score in place of the best verbal response score. The minimum score is 3 and the maximum score is 15.



APPENDIX 2

APACHE II Severity of Disease Classification- Chronic Health Points

C. CHRONIC HEALTH POINTS			
If patient has history of severe organ system insufficiency or is immuno–compromised, assign points as follows:	**Points**	**DEFINITIONS:** Organ insufficiency or immuno-compromised state must have been evident **prior** to this hospital admission and conform to the following criteria:	
		LIVER	Biopsy proven cirrhosis & documented portal hypertension (PH); episodes of upper GI bleeding due to PH; or prior episodes of hepatic failure/encephalopathy/coma
☐ **a**. for non-operative or emergency post-operative patients	**5**	**RENAL**	Receiving chronic dialysis
		CARDIOVASCULAR	New York Heart Association Class IV - Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort increases.
☐ **b**. for elective post-operative patients	**2**	**RESPIRATORY**	Chronic restrictive, obstructive or vascular disease resulting in severe exercise restriction (i.e. unable to climb stairs, perform household duties); or documented chronic hypoxia, hypercapnia, 2^{o} polycythemia, severe pulmonary hypertension (>40mmHg) or respiratory dependency
		IMMUNOCOMPROMISED	Patient has received therapy that suppresses resistance to infection, eg. immuno-suppression, chemotherapy, radiotherapy, long term or recent high dose steroids, or has a disease sufficiently advanced to suppress resistance to infection (e.g. leukaemia, lymphoma, AIDS)

APPENDIX 3 **SOFA Score Worksheet**

ORGAN SYSTEM	0	1	2	3	4	9	Organ scores
Respiration PaO_2 / FIO_2 (in mmHg)	>400	301 - 400	201 – 300 (with respiratory support*) <301 (without respiratory support*)	101 - 200 (with respiratory support*)	≤ 100 (with respiratory support*)	Variable not measured	
(in kPa)	>53.2	40.0 – 53.1	26.7 – 39.9 (with respiratory support*) <40.0 (without respiratory support*)	13.4 – 26.6 (with respiratory support*)	≤ 13.3 (with respiratory support*)		
Coagulation Platelets (x 10^9 / L)	>150	101 - 150	51 - 100	21 - 50	≤ 20	Variable not measured	
Liver Bilirubin (mg / dl)	< 1.2	1.2 – 1.9	2.0 – 5.9	6.0 – 11.9	> 12.0	Variable not measured	
(µmol / L)	<20	20 - 32	33 - 101	102 - 204	>204		
Cardiovascular Hypotension	MAP > 70 mmHg	MAP < 70 mmHg	dopamine ≤ 5.0 (doses are given in µg / kg / minute)	dopamine 5.0 – 15.0 (doses are given in µg / kg / minute)	dopamine > 15.0 (doses are given in µg / kg / minute)	Variable not measured	
			or any dose dobutamine	or epinephrine ≤ 0.1	or epinephrine >0.1		
			or any dose milrinone or any dose levosimendan	or norepinephrine ≤ 0.1 or any dose vasopressin or any dose metaraminol or any dose phenylephrine	or norepinephrine >0.1		
Renal Creatinine (mg / dl)	< 1.2	1.2 – 1.9	2.0 – 3.4	3.5 – 4.9	> 5.0	Variable not measured	
(µmol/l)	< 110	110 – 170	171 – 299	300 – 440	> 440		
OR Urine output				or < 500 ml / day	or < 200 ml / day		

*Respiratory support is defined as any form of invasive or non-invasive ventilation including mask CPAP or CPAP delivered through a tracheostomy / tracheotomy or endotracheal tube.