PARAMEDIC Data Management and Monitoring Plan

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This data management and monitoring plan will be used in accordance with:

- WCTU SOP 15 (Data Management)
- WCTU SOP 18 (Risk Assessment and Monitoring)
- WCTU SOP 30 (Electronic Data Security)
- PARAMEDIC Statistical Analysis Plan

Aims: To outline data entry, data cleaning, data checking and monitoring procedures at WCTU and Sites.

To check that data entry error rate for the primary outcome is ≤1% and for the secondary outcome/for all other variables is ≤5%

Also to determine inaccurate, incomplete or unreasonable data and then improve the quality through correction of detected errors and omissions. This will include format checks, completeness checks, logic checks, limit checks, review of the data to identify outliers or other errors, and assessment of data in primary and secondary outcomes. Where errors are found, data will be corrected and staff will be retrained as needed.

This plan is divided into three parts:

1. **Data entry**
2. **Data cleaning, data checking and monitoring at WCTU**
3. **Data checking (Source Data Verification) and monitoring at Sites**

Data entry

Please refer to the following files for the most up-to-date Data Collection and Data Entry procedures: M:\Emergency Care Trials\PARAMEDIC\PlansProcessesIssues\PARAMEDIC CTU Manual\8. Data collection\

-Working Procedure Data entry_CRF01 and CRF02

-Working Procedure Data entry_Follow Up

-Working Procedure Research Fellows

2. Data Cleaning, data checking and monitoring at WCTU

All data checking will be undertaken by a person who did not originally enter the data. Data cleaning includes checking for missing data, data queries, monthly/quarterly data checks and validation checks. This cleaning will be done prior to data checking (as per SOP 15).

2.1 New Data Clerks

For new Data Entry Clerks working on the trial the TC will perform a 100% data check of the first 50 CRFs entered (to include a mix of different cases i.e eligible, non-trial vehicle, non resusc, excluded). Any errors will be discussed with the Data Entry Clerk and further training will be given if required, and corrected on the database.

2.2 Checks during *Data Entry*

As data is entered, any missing data fields or confusing information is added to the individual Trust query lists straight away - see data query procedure in M:\Emergency Care Trials\PARAMEDIC\Plans, processes, issues\PARAMEDIC CTU Manual_In Progress\8. Data collection\Working Procedure Data entry

This is emailed to Research Fellows/Officers at each ambulance service every 2 weeks. The Data Clerk will highlight on the CRF, with post-it notes, the information that needs to be queried with the Research Fellow/Officer. Once the information has been obtained/clarified the post-it note will be removed and the database and CRF will be amended as appropriate. Changes to CRF's are made in a different coloured pen, initialled and dated.

Reports detailing cases where LUCAS was not used in the LUCAS arm are sent to the research fellows at the beginning of each month automatically form the database. The research fellows then follow up with crews involved to find out the reason for non use. Reports are also sent where LUCAS used is blank (control and LUCAs arm) to find out from crews if it was used or not.

2.3 Checks on entered data for CRF01

Before the end of recruitment, data on paper CRFs will be checked by someone in the trial team other than the person who entered the data, against data entered on the database. This is specifically to check for errors which could result in:

- misclassification of eligibility
- errors relating to the primary/secondary outcomes

Only data from eligible participants will be checked, due to the large amount of data collected. 10% of eligible cases per ambulance service will be randomly selected (using the RAND function in Excel), and all fields on CRF01 will be checked for data entry validation. The number of fields that are completed on each CRF01 vary according to patient scenario, therefore error rates will be calculated based on how many fields should have been completed for each case.

An Excel spread sheet has been set up to record errors and calculate error rates for these scenarios.

<<spreadsheet and link here>>

It should be noted that Q7b and Q7bvii relate to the primary outcome for the patient, therefore once the 10% of cases have been checked a further calculation of error for these two fields will be made which should not exceed 1%. If it does, then a further 10% of cases will be selected and only these two fields will be checked. If the error rate is still >1% once 20% have cases have been checked, the TMG will discuss further actions.

For data not relating to the primary outcome: If there is >5% error in data entry for the 10% of cases checked, a further 10% of cases will be selected for all fields to be checked. If the error rate is still >5% this will again be discussed by the TMG.

2.3.1 On-going Quarterly logic/data checks

The following data queries are also run monthly through a query report in reporting tool (PARAMEDIC/Data Queries/Quarterly checks).

- Where 'identified through' is blank
- If other resource 1st on scene, check who witnessed arrest and whether CPR/defib given
- Cases where bystander CPR was given but not resuscitated by EMS
- Check stations and start dates
- Cases where patient declared deceased at ED but no comments (death is usually confirmed in comments)
- Consistency of hospital names
- Review of non compliance reasons to be re-categorised
- Review of comments for eligible and non-eligible cases (to detect DNARS, futility and rigor mortis cases, mortal staining, trauma, ROSC before EMS arrival, short resusc, in-hospital which should be excluded)
- Where initial rhythm is 'unknown'
- Cases where arrest was witnessed but no bystander CPR given

If any queries arise these are added to the query list and dealt with as per procedure for handling data queries (See M:\Emergency Care Trials\PARAMEDIC\PlansProcessesIssues\PARAMEDIC CTU Manual\8. Data collection\)

2.3.2 On-going Monthly logic/data checks

The following data queries are also run monthly through a query report in reporting tool (PARAMEDIC/Data Queries/Monthly checks).

- Where 'at scene' and 'at patient' times are missing
- Where patient 'gender' is blank
- Where 'location' is blank
- Where location of arrest is 'ambulance' will check station is correct
- Where location of arrest is 'ambulance' and 'witnessed by EMS?' is blank
- Where reason for no resuscitation is missing (ineligible cases only)

- Where resuscitation information is missing (Rhythm, Drugs, Intubated, LMA)
- Where 'other resource 1st on scene?' is blank
- Where 'bystander CPR before EMS arrival' is blank
- Where 'witnessed' is blank
- Where 'witnessed by bystander/EMS/non-EMS' is blank
- Where 'defib before EMS arrival' is blank
- Where 'CPR stop time' is missing
- Where destination and handover times are missing
- Where marked as 'ineligible' but case was eligible
- Where 'rhythm' is blank
- Check status deceased but death recorded is blank

If any queries arise these are added to the query list and dealt with as per procedure for handling data queries (See M:\Emergency Care Trials\PARAMEDIC\PlansProcessesIssues\PARAMEDIC CTU Manual\8. Data collection\)

A log will be kept of cases where data will never be known such as gender, times (e.g CPR stop time).

At the end of the recruitment aetiology other and location other will be reviewed and re-categorised if needed. Aetiology will be reviewed by a clinical person.

2.4 Checks on data entered on database for CRF02

2.4.1 Primary Outcome

The primary outcome (see table 1) is checked by several sources (MRIS, GP, SCR, Hospital) and therefore does not require further source verification checks. 100% of the information returned by MRIS is cross checked against the database. Before the end of recruitment we will double check 10% of cases matched on MRIS for data entry errors, to make sure Date of Death matches the database.

Some notes to be aware of when checking data entry for CRF02:

- Death information will come in from multiple sources. If data from MRIS clashes with existing data i.e DOB, gender, then go with existing data (after double checking paper CRF02 and source data). If MRIS provides additional information i.e DOB, NHS number when it was missing in the database, this information should be used. If there is a discrepancy between the date of death from MRIS or the SCR then the date from MRIS will be inputted, but any discrepancies will be logged in the 'comments' field. Where DoD is not known on CRF01 and also not available from MRIS, date of death may be recorded from another source e.g GP or hospital.

- The WMAS "CPI" (Clinical Performance Indicator) reports also provide outcome data but this source has been known to be incorrect. Therefore if there is a death showing on this report, it will not be recorded on the database until concurrent information from other sources is received.

- To date, "location of death" is mostly left blank unless the patient was known to have died in hospital. This will be discussed by the TMG prior to analysis.

- "Death recorded = no" is only selected when a patient has been written to i.e. when sufficient checks have been made to verify the patient's status. Therefore conflicts may exist temporarily between paper CRF02 and the database.

For cases where a match is not found on MRIS, a review will take place of how death was established (if deceased) and if any further checks are needed e.g if the registrar was the only source of death information. Details of the sources that are checked are recorded on the database. See also Working Procedure for Follow-Up (Section 1).

2.4.2 Monthly logic checks

Three reports have been set up for checking outcome data on a monthly basis:

- Status is "deceased" but "death recorded" = blank
- Check status for 'transported to hospital' = no and 'declared deceased at ED' = yes
- Date of death and date of cardiac arrest to be checked if the report shows "-" (minus) days or "364-6" days, which could mean typo in the dates entered.

  If the date of death is recorded as before the date of cardiac arrest, the CRF will be double checked incase of a data entry error. If the DoD on the CRF matches the database, the original source of death information will be double checked.

As data is entered, any missing data fields or confusing information is added to the individual Trust query lists straight away - see section 1.2.

2.4.3 Other data on CRF02

All CRF02 data that does not relate the primary outcome is checked against what is entered on the database on an ongoing basis. Where a hospital check is done information about discharge dates maybe entered in the comments, a report will be run to check and move any dates into the "discharge date field". Patient addresses are also double-checked on an ongoing basis via 192.com and GPs before letters are sent to patients. Therefore this data will not be checked further as part of monitoring procedures.

2.5 Crew names/training details

A report query has been set up which pulls out a list of names/crew numbers in the database that only have a generic station (e.g West Midlands) to check if they should have been trained and assigned to a trial station. We will also run a report to check for duplicate names i.e the same person entered twice. The results of the reports will be sent to Research Fellows to find out if these crew have been trained. These checks will be done at least once before the end of recruitment.

We will also cross check a proportion (at least 10%) of names and corresponding training dates in the database against the training logs sent to us to check data entry is correct. Any errors will be corrected on the database and discussed with the Data Clerk, with further training of the Data Clerk if necessary.

2.6 Inbuilt database validation

The database contains inbuilt validation to ensure critical data is not missing and data is logical – details of this can be found in the FRS (M:\Emergency CareTrials\PARAMEDIC\11.Data\Database\New Database\FRS)

1.12.7 Validation/Range checks

The trial statistician will conduct range and validation checks to see if variables are in the expected range, as well as to assess completeness and whether dates are consecutive etc. (See table 2 and Statistical Analysis Plan)

2.8 Follow-up Questionnaires

2.8.1 Data Checking at WCTU (data entered on database against paper forms)

10% of follow-up questionnaires from each ambulance service will be randomly selected and double checked against what is entered on the database. Errors will be recorded on a spreadsheet (see section 1.3). If the error rate is found to be >5% a further 10% of questionnaires will be randomly selected and checked. Any errors will be amended on the database accordingly.

Any missing data from follow-up questionnaires identified after the visit is complete/questionnaire is received in the post will not be chased as it would not be appropriate to contact patients for this reason.

2.9 Oversight arrangements

2.9.1Trial Management Group

Composition: Project staff, Investigators involved in the day-to-day running of the study. Please refer to the protocol for a current list of staff and Investigators.

Frequency: Monthly

Reason: Responsible for the day-to-day running of the study

2.9.2 Trial Steering Committee

Composition: Independent clinicians and trialists, lay representation, Investigators, Independent Chair

Frequency: Face to face meetings will be held at regular intervals determined by need but not less than once a year.

Reason: To provide overall supervision of the trial and ensure that it is being conducted in accordance with the trial protocol, principles of Good Clinical Practice and the relevant regulations.

2.9.3 Data Monitoring and Ethics Committee

Composition: Independent experts with relevant clinical research, and statistical experience. DMC meetings will also be attended by the Chief Investigators (for non-confidential parts of the meeting) and the trial statistician.

Frequency: every 6 months

Reason: To advise the trial steering committee as to whether there is evidence or reason why the study should be amended or terminated based on recruitment rates or safety and efficacy.

2.9.4 Investigators Meetings

The Investigators team will meet regularly throughout the trial, either face to face, by teleconference of through other means of communication.

Reason: These meetings will be to discuss set up, progress and close out of the trial.

2.9.5 Teleconferences with Ambulance Services

Frequency: at least quarterly

Who: Trial Co-ordinator, Trial Administrator, Lead Investigator (from Trial team); Lead Paramedic Research Fellow, Principal Investigator, other key contacts within the ambulance service.

Reason: To update on recruitment and compliance, and discuss any issues that arise.

3. Data Checking at Sites

3.1 Data Checking CRF01 against source

For source data verification, only the allocation i.e call sign and outcome fields (transported to hospital, CPR stopped, ROSC any time) will be checked at source by the Research Fellows, as many other fields are interpreted data which cannot be verified.

A spreadsheet consisting of case number, arrest date and station of 10% of eligible cases (randomly selected) from each ambulance service will be sent electronically to the Research Fellows. The Research Fellows will not be given the data that is already recorded in the database. They will be instructed to check data at source (i.e CAD/PRFs), not their CRF copies. We will compare this to what we've received previously (paper CRF01 and on the database). Any discrepancies will be discussed with the relevant Research Fellow to try and ascertain why there is an error. If the error rate is >5% within the ambulance service, a further 10% of cases will be randomly selected and checked by the Research Fellows at source. If the error rate is still >5% this will be discussed by the TMG to decide further actions.

Cases where there was uncertainty as to the eligibility of the patient (for example where two ambulances were first on scene simultaneously), will be looked at on a case by case basis.

3.1 Monitoring Plan

3.2.1 Site Master File

Site Master Files will be checked remotely before the end of the trial using the site file checklist:

<<**Site File Checklist** link here>>

To ensure they are up-to-date and contain all essential documents according to the Site Master File index (see SOP 11), sites will be asked for the latest version number they hold of each document. Any missing documents will be sent to sites to be filed in the Site File.

2.2.2 Site visits

The trial coordinator visited each Trust in the early stages of recruitment to check the consistency of staff training and answer any questions about the protocol, device or research in general. These visits are listed on the "Site Visit Log" .

A final site visit will be carried out for each participating ambulance service trust to answer any questions on source data verification checks and Site Master File documents. No data checking or file checking will take place on these visits but particular attention will be given to storage of documents ready for archiving. A monitoring letter and report will be sent to sites after this visit.

3.2.3 Consent forms

As part of monitoring, consent forms will be checked by the Research Nurse to ensure they are completed correctly for every participant that agreed to be followed-up. The forms will be checked as they are received, and 100% of consent forms will be checked at the end of the study. If consent forms are not correctly completed, patients will not be contacted to complete another form as it would not be appropriate given the nature of the patient group but a file note will be written to explain any discrepancies.
Names of the trial team signing consent forms will be checked by the Research Nurse or Trial Administrator to make sure they are on the relevant ambulance services' delegation logs.

3.2.4 Training records

It is the participating ambulance service trust's responsibility to ensure competency assessment forms have been completed for each member of staff trained on LUCAS. This will not be monitored by CTU.

3.2.5 Device Tracking

A database is held at CTU to log when devices are sent to the Research Fellow, when they are put on the ambulance and when they are moved e.g to physio control. We also track when a device has been serviced, but rely on being told by the Research Fellows where devices are. Therefore this will not be formally monitored by WCTU.

3.2.6 Adverse Events

Any reported faults or incidents with the devices are recorded on Adverse Events forms – at monitoring visits we will confirm that all original Adverse Event documents are kept in the Site Master File. If they are not, copies will be sent out to sites to be filed.

Responsibility for tracking devices and logging faults stays with the Ambulance Services. The Ambulance Services report any faults to the Trial Co-ordinator on a CRF05 which is the reviewed and signed off by the Chief Investigator.

At the end of the trial, we will reconcile which devices are with each Trust against our records of device location.

3.2.6 Vehicle Tracking

Research fellows send periodic reports of vehicle lists for their allocated area. This will not constitute part of monitoring carried out during the trial. Reports of vehicle location are primarily for checking vehicle randomisation balance in case of the need to randomise or re-randomise vehicles.

Table 1. Outcome measures

	Outcome	Source(s)	Acceptable error rate
Primary	Survival to 30 days	CRF01 (Q7b, Q7bvii) CRF02 (Q9) MRIS GP contact Hospital Registrar Summary Care Record	≤1%
Secondary	Survived event (sustained ROSC) with spontaneous circulation until admission and transfer of care to medical staff at receiving hospital	CRF01 (Q7bvi)	5%
	Survival to hospital discharge	CRF02 (Q7)	5%
	Survival to 3 and 12 months	CRF02 (Q9) MRIS GP contact	5%
	SF12 and EQ5D at 3 and 12 months	Follow-up	5%
	Neurologically intact survival to 3 months	Follow-up	5%
	MMSE at 12 months	Follow-up	5%
	HADS at 12 months	Follow-up	5%
	PCL-C at 12 months	Follow-up	5%
	Hospital length of stay	ICNARC/HES	5%
	Intensive care length of stay	ICNARC/HES	5%
Other data fields	CRF01	All other fields on CRF01	5%

Table 2. Checklist for the Validation Checks for PARAMEDIC TRIAL

Please note PART 2 Q5 onwards is only needed for eligible patients so will be blank for excluded cases.

Please note that only the grey shaded questions on CRF01 required for non-trial vehicles so all other questions in PART 1 and PART 2 will be blank.

		Check	Variables on database
PRIMARY OUTCOME	Date of death	Greater than DOB< Cardiac arrest date< date of death If transport to hospital=no, declared deceased = yes, DoD = date of cardiac arrest	
		999 call time is close to midnight, DoD might be next day?	
	Status	If status=deceased, death recorded=yes	
SECONDARY OUTCOMES	ROSC at any time	No missing data	
	Survival to hospital discharge	Date of hospital discharge >Date of hospital admission; Date of hospital discharge missing then date of death not missing;	
	Intensive care stay	Date of entry ICU < end of ICU If ICU missing then date of death not missing	
	Survival to 3 months	Every patient to have a status at 3 months (alive, death, withdrew or not reached and in the study)	
	Survival to 12 months	Every patient to have a status at 12 months (alive, death, withdrew or not reached and in the study)	

PROCESS DATA/OUTCOMES	Age	Date of cardiac arrest - DOB >0	Pcd_CardiacArrestDate -pat_DOB
		For eligible patients age >18	
		If DOB missing (unknown) then approx. age not missing; Approx. age > 18	
	Gender	Not missing (coded as 1 (male), 2 (female))	
	Pregnant	For eligible patients, patient not pregnant (1 – pregnant, 2- not pregnant)	
	Date of Cardiac Arrest date	Less than date of death (if died); Greater than DOB	tsc_date of death - Pcd_CardiacArrestDate Pcd_CardiacArrestDate -pat_DOB
	Response time	(At scene -999 Call time) >0	pcd_AtScene –pcd_CallTime
	Resusc time	At scene – CPR stop time >0	
	Time to hospital (1)	Time of arrival to hospital – time of EMS arrival at scene	Pcd_DestinationTimeCAD – pcd_AtScene
	Time to hospital (2)	Time of arrival to hospital – Time left scene	Pcd_DestinationTimeCAD – pcd_LeftScene
	At patient time	At patient time > at scene time	Pcd_pat – pcd_AtScene
	Resuscitation attempt by EMS	If no: then one or more of the following has to be complete: (i) incompatible with life; (ii) DNAR or expected death; (iii) futility	

	Aetiology	If aetiology = 'others' then specify is non-missing	
	Location	If location = 'others' then specify is non-missing	
	Witness/Bystander	If 'witness' = 'yes', then one or more of the following should be ticked: (i) bystander, (ii) EMS or (iii) Non- EMS healthcare	
	Bystander CPR/ defib	Non missing	
	Compliance	If LUCAS used =N, then one of the following has to be complete: (i) TBC, (ii) protocol confusion, (iii) patient too big, (iv) not trained, (v) crew decision, (vi) patient too small, (vii) forgot, (viii) no device, (ix) device failure, (x) others	
		If 'others' then 'specify' not missing	
	Initial rhythm	No missing data	
	Drugs given	No missing data	
	Intubated	No missing data	
	LMA/Supraglottis device	No missing data	
	Transport to hospital	If transport to hospital is 'no' then CPR stopped completed	
		If transport to hospital is 'yes' then (i) Time left scene completed;	

		(ii) hospital name completed; (iii) destination time (CAD) completed; (iv) hand over time completed.	
	Status at handover	No missing data	
	Patient declared deceased	No missing data	
	Other resource	Not missing	
	Region	Check station, call sign and crew are all from same region	
	Duplicate cases	Per region check for same cardiac arrest date and case number	
FOLLOW UP	Health related quality of life (EQ 5D and SF-12)	No missing item data and range checks	
	Mental Mini State examination	No missing item data and range checks	
	HADS scale	No missing item data and range checks	
	Post Traumatic Stress	No missing item data and range checks	