THE DEVELOPMENT AND VALIDATION OF A SCORING SYSTEM TO ASSESS POST-OPERATIVE MORBIDITY FOLLOWING CARDIAC SURGERY: THE CARDIAC POST-OPERATIVE MORBIDITY SCORE (C-POMS)

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DECLARATION

I, Julie Sanders, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

STUDY CONCEPT

The concept of the study was conceived by Professor Michael Mythen.

PROTOCOL

I designed the study protocol, under the supervision of Professor Hugh Montgomery (UCL) and Professor Sir Bruce Keogh (formerly UCL and UCLH). Contributions were also made by a Protocol Development Group (PDG), established specifically for this purpose. I invited the PDG members and convened and chaired the meetings.

DATA COLLECTION AND DATA MANAGEMENT

I undertook all the patient screening, consenting, data collection, data entry, data cleaning and data management processes.

RESULTS

I developed the tool and tested the reliability and validity of it under the supervision of Professor Jan Van der Meulen (Royal College of Surgeons of England Clinical Effectiveness Unit) and Dr John Browne (University of Cork). I invited the Expert Panel members and convened and chaired the meetings.

I established the collaboration with the London Chest Hospital.

ACKNOWLEDGEMENTS

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Professor Jan Van der Meulen and Dr John Browne: For their expert guidance on the developmental and validation phases of this work.

Professor Monty Mythen: For giving me the opportunity to conduct this work and for his continued support.

PDG and Expert Panel: For their expertise and for giving up your time so generously.

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Patients: This work is indebted to the patients who agreed to participate.

Last, but certainly not least, I would like to thank my wonderful family, not only for their love and support and but also their understanding and patience, particularly in the final writing up phase.

ABSTRACT

INTRODUCTION

Low post-operative death rates after cardiac surgery make mortality an inadequate outcome measure. As post-operative morbidity is more common, its measurement would be more sensitive. Accurate identification and quantification might also allow its aetiology to be addressed. The nine domain Post-Operative Morbidity Survey (POMS)[1] is the only prospective tool for standardised morbidity measurement in general surgical patients. I sought to develop and validate such a tool (cardiac- or C-POMS) for cardiac surgery.

METHODS

Development: Morbidity was prospectively assessed in 450 cardiac surgery patients on post-operative days 1, 3, 5, 8 and 15 using POMS criteria and cardiac-specific variables (from an expert panel). Other morbidities were noted as free-text and included if prevalence >5%, missingness <5% and mean expert-rated severity-importance index score >8.
Reliability/validity: assessed by expert panel review, using Cronbach's alpha (internal consistency) and linear regression to test the ability of C-POMS to predict length of stay (LOS).
Clinical utility: assessed by multi-professional teams at two hospitals.

RESULTS

Development: Following item-reduction, C-POMS resulted in a 13 domain model.
Reliability/validity: Internal consistency (>0.7) on D3-D15 permits use of C-POMS as a summative score of total morbidity burden. Mean C-POMS scores were 3.4 (D3), 2.6 (D5), 3.4 (D8) and 3.8 (D15). Patient LOS was 4.6 (p=0.012), 5.3 days (p=0.001) and 7.6 days (p=0.135) longer in patients with (compared to without) morbidity on D3, D5, D8 and D15, respectively. For every unit increase in C-POMS summary score subsequent LOS increased by 1.7 (D3), 2.2 (D5), 4.5 (D8) and 6.2 (D15) days (all p=0.000). ***Clinical utility***: Demonstrated by C-POMS now being routinely collected at two hospitals.

CONCLUSIONS

C-POMS is the first validated tool for identifying total morbidity burden post cardiac surgery. C-POMS identifies considerable morbidity in these patients and may assist in modelling causation and in identifying preventative and therapeutic targets.

SUMMARY OF OUTPUTS

DIRECTLY ASSOCIATED WITH PhD

Clinical

- The resulting model (C-POMS) has been accepted as a routine data collection tool for all patients undergoing cardiac surgery and transcatheter aortic value implantation (TAVI) at the Heart Hospital, UCLH NHS Trust, London, UK.
- The London Chest Hospital, Barts and the London NHS Trust, London, UK agreed to collect C-POMS on all patients undergoing cardiac surgery (April 2011). C-POMS will be incorporated into their existing database. Together, we intend to make the combined C-POMS model and computerised program available to other centres.
- The London Chest Hospital and the Heart Hospital have agreed to collaborate and share anonymised C-POMS data to give greater power to further analysis (for example, exploring the predictors of C-POMS) and also for cross-unit comparisons.

Publications

Sanders J, Keogh BE, Van der Meulen J, Browne JP, Treasure T, Mythen MG, Montgomery HE. The development of a post-operative morbidity score to assess total morbidity burden after cardiac surgery. *Submitted Journal of Clinical Epidemiology (20th June 2011).*

Conference abstracts

- **Sanders J**, Keogh BE, Van der Meulen J, Browne J, Treasure T, Mythen M, Montgomery HE. The development and validation of a model to assess total morbidity burden after cardiac surgery. *Society of Cardiothoracic Surgery*. 2011 (oral presentation in opening surgical session of the conference)
- **Sanders J**, Keogh BE, Van der Meulen J, Browne J, Treasure T, Mythen M, Montgomery HE. The development and validation of a model to assess total morbidity burden post cardiac surgery. *European Society of Cardiology*. 2011(poster presentation)

Invited sessions

- **Sanders J.** Conducting research: How to get started, carry it out and get published. *Society of Cardiothoracic Surgery. Plenary session*. March 2008.

Other presentations

- **Sanders J**. The Cardiac Post-Operative Morbidity Survey (C-POMS): The Pilot study. *UCL/UCLH Nursing and Midwifery Research Day 2006* (oral presentation).

RELATED/RELEVANT OTHER OUTPUTS SINCE PhD REGISTRATION

The following are related outputs. Those marked with ** contain data collected within this PhD work.

Publications

- **Sanders J**, Patel S, Cooper J, Berryman J, Farrar D, Mythen M and Montgomery HE. Duration of red-cell storage is associated with post-operative length of stay and new renal complications following surgery. Transfusion 2011; *E-published 12.05.2011. Doi: 10.1111/j.1537-2995.2011.03170.x*
- **Sanders J**, Toor I, Yurik T, Keogh BE, Mythen M and Montgomery HE. Tissue oxygen saturation and outcome after cardiac surgery. American Journal of Critical Care 2011; March. 20(2):138-145.**
- **Sanders J**, Skipworth J, Cooper J, Brull D, Humphries SE, Mythen M, Montgomery HE. Duration of preceding hypertension is associated with prolonged length of intensive care unit stay. International Journal of Cardiology 2010; *E*-published 31.12.2010: http://dx.doi.org/10.1016/j.ijcard.2010.12.011.
- **Sanders J**, Hawe E, Brull DJ, Hubbart C, Lowe GDO, Rumley A, Humphries SE, Montgomery HE. Higher IL-6 levels but not IL6 -174G>C or -572G>C genotype are associated with post-operative complication following coronary artery bypass surgery (CABG). Atherosclerosis 2009; 204(1): 196-201

Conference abstracts

- **Sanders J**, Patel S, Cooper J, Berryman J, Farrar D, Mythen M, Montgomery HE. Duration of red-cell storage is associated with post-operative length of stay and new renal complications following cardiac surgery. *Network for the Advancement of Transfusion Alternatives (NATA) 2010 (poster presentation).***
- **Sanders J**, Patel S, Cooper J, Berryman J, Farrar D, Mythen M, Montgomery HE. Duration of red-cell storage is associated with post-operative length of stay and new renal complications following cardiac surgery. *SCTS 2010 (oral presentation).***
- **Sanders J**, Toor I, Yurik T, Smith A, Keogh BE, Montgomery HE, Mythen M. Tissue oxygen saturation during cardiac surgery is associated with post-operative recovery. *ESICM 2008* (oral presentation). **
- **Sanders J**, Toor I, Yurik T, Smith A, Keogh BE, Montgomery HE, Mythen M. Tissue oxygen saturation during anaesthesia and cardiac surgery and its association with ICU outcome. *Association of Cardiothoracic Anaesthetists 2008 (oral presentation).***
- **Sanders J**, Martin D, Smith A, Keogh B, Mutch M, Montgomery H, Hamilton M, Mythen M. Tissue oxygen saturation during anaesthesia, cardiopulmonary bypass and intensive care stay for cardiac surgery. *International Symposium on Intensive Care and Emergency Medicine 2008* (poster presentation).**

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ABBREVIATIONS

Abbreviation	Explanation
ABG	Arterial Blood Gas
ACEI	Angiotensin Converting Enzyme Inhibitor
AMI	Acute Myocardial Infarction
APACHE	Acute Physiology and Chronic Health Evaluation
ASO	Arteriosclerosis Obliterans
AVR	Aortic Valve Replacement
BIPAP	Bi-level Positive Airway Pressure
BMI	Body Mass Index
BP	Blood Pressure
BPM	Beats Per Minute
CABG	Coronary Artery Bypass Graft
CCSC	Canadian Cardiovascular Society Classification
CDMR	Cochrane Database of Methodological Reviews
CDR	Clinical Data Repositiory
CHB	Complete Heart Block
CHF	Chronic Heart Failure
CI	Chief Investigator
COPD	Chronic Obstructive Pulmonary Disease
CPAP	Continuous Positive Airway Pressure
CPB	Coronary Pulmonary Bypass
C-POMS	Cardiac Post Operative Morbidity Survey
CRD	Centre for Reviews and Dissemination
CRP	C-Reactive Protein
CRF	Case Report Form
CTT	Classical Test Theory
CV	Cardiovascular
CVA	Cerebro-Vascular Accident
CVI	Content Validity Index
CVP	Central Venous Pressure
CXR	Chest Xray
DIB	Difficulty in Breathing
DVT	Deep Vein Thrombosis
ECG	Electrocardiogram
EF	Ejection Fraction
FiO_2	Fraction of Inspired Oxygen
GCS	Glasgow Coma Score
GI	Gastrointestinal
HES	Hospital Episode Statistics
Hb	Haemaglobin
HR	Heart Rate

IABP	Intra-aortic Balloon Pump
ICU	Intensive Care Unit
IDC	In-Dwelling Catheter
IDDM	Insulin Dependent Diabetes Mellitus
IHD	Ischaemic Heart Disease
IM	Intra-muscular
INR	International Normalised Ratio
IRS	Item Reduction Strategy
IRT	Item Response Theory
IV	Intra-venous
K	Potassium
LLL	Left Lower Lobe
LMS	Left Main Stem
LOC	Loss of Consciousness
LV	Left Ventricular
LVEF	Left Ventricular Ejection Fraction
MAP	Mean Arterial Pressure
MI	Myocardial Infarction
MRSA	Methycillin Resistant Staphyloccocus Aureus
MVR	Mitral Valve Replacement
Na	Sodium
NBM	Nil By Mouth
NG	Naso-Gastric
NICOR	National Institute for Clinical Outcomes Research
NIDDM	Non-Insulin Dependent Diabetes Mellitus
NRR	National Research Register
NYHA	New York Heart Association
O_2	Oxygen
OT	Occupational Therapy
PA pressure	Pulmonary Artery Pressure
PACS	Picture Archiving and Communication System
PAS	Patient Administration System
PATS	The Patient Analysis Tracking System
PCA	Patient Controlled Analgesia
PCI	Primary Coronary Intervention
pCO_2	Partial pressure of carbon dioxide
PDA	Personal Digital Assistant
PDG	Protocol Development Group
PI	Principle Investigator
pO_2	Partial pressure of oxygen
POMS	Post Operative Morbidity Survey
POSSUM	Physiologic and Operative Severity *Score* for the enUmeration of

	Mortality and Morbidity
PR	Per Rectum
PROMS	Patient Reported Outcome Measures
PTCA	Percutaneous Transluminal Coronary Angioplasty
PVD	Peripheral Vascular Disease
PW	Pacing Wire
RBC	Red Blood Cell
RIND	Reversible Ischaemic Neurologic Deficit
ROC	Receiver Operating Curve
RR	Respiratory Rate
Rx	Treatment
SaO2	Saturation of Oxygen (arterial blood)
SBCc	Arterial blood gas bicarbonate concentration
SBEc	Arterial blood gas base deficit level
SBP	Systolic Blood Pressure
SCTS	Society of Cardiothoracic Surgery
SI	Severity Importance (score)
SOB	Shortness of Breath
SOFA	Sequential Organ Failure Assessment *Score*
TAVI	TransCatheter Aortic Valve Implantation
TIA	Transient Ischaemic Attack
TPN	Total Parenteral Nutrition
U and E	Urea and Electrolytes
UK	United Kingdom
UO	Urine Output
USA	United States of America
UTI	Urinary Tract Infection
VSD	Ventricular Septal Defect
WCC	White Cell Count

1 INTRODUCTION

1.1 INTRODUCTION

Open heart surgery was first performed in 1952 in the United States of America (USA)[2]. However, cardiac surgery was initially infrequently performed due to the high risk of mortality. Surgery became more frequent, particularly in the United Kingdom (UK), with the subsequent development of the heart-lung machine in 1953[2]. This was considered safe to use with hypothermia on patients in 1960. The advantages were that slower flow rates could be induced, the operative fields were dry enabling increased visual inspection and that greater time allowances for completing the procedure were provided[3]. Outcome measurement following cardiac surgery has been recorded in the UK for a period of nearly 35 years since the introduction of the UK national cardiac registry in 1977. At this time, 11,602 patients had heart surgery with a mortality rate of 9.8%[4]. Currently, more than 25,000 patients have heart surgery each year in the UK with a mortality rate of approximately 2%[5]. However, whilst mortality rates have declined, cardiac surgery is still associated with significant morbidity and hospital length of stay.

The aim of this chapter is to explore the available evidence surrounding outcome measurement, and in particular morbidity outcome measurement, in patients undergoing cardiac surgery in the period leading to the commencement of this study. Firstly, the debate surrounding mortality and morbidity outcome measurement will be addressed. Secondly, the work of the national and international cardiac surgery societies in post-operative outcome measurement, both now and in the future, will be reviewed. Thirdly, I will critically evaluate the existing literature relating to pre-operative risk assessment scores for post-operative morbidity outcome in patients undergoing cardiac surgery, particularly exploring the definitions of post-operative morbidity being utilised. Finally, I will explore morbidity measurement within other medical disciplines.

1.2 MORTALITY VS MORBIDITY OUTCOME MEASUREMENT

Mortality is the most commonly cited cardiac surgery outcome variable[6]. This is because mortality is clearly an undesirable outcome, can be unequivocally defined[7, 8] and is easily measured[8, 9, 10]. However, post-operative death has become increasingly infrequent[11], (currently 2% for isolated coronary artery bypass graft (CABG) surgery[5]), rendering mortality an insensitive general outcome measure or indicator of quality of care or performance[12].

Post-operative morbidity, being more common than mortality, may be a more valid end-point[13], but only if inherent limitations such as subjectivity and imprecision[14] can be overcome. Surrogate markers of morbidity have been used (for example, length of intensive care unit (ICU) stay, length of post-operative stay), but although objective and readily available, are limited in their usefulness as they do not account for non-medical causes of prolonged stay (for example, bed availability on the ward or delay in discharge related to social, rather than medical, factors). Since 31% of general surgical patients[15] have been found to remain hospitalized for non-medical reasons, the use of surrogate markers should be used cautiously. Additionally, these

markers provide no indication of the type or frequency of conditions contributing to the prolonged length of stay, limiting their usefulness in relation to risk assessment and optimization of care to reduce post-operative morbid conditions.

It has further been suggested that mortality and morbidity should be considered independently since post-operative complication rate does not correlate well with mortality rate[16, 17] and hospital characteristics associated with higher quality of care were associated with lower mortality rates but higher complication rates[16]. Additionally, pre-operative risk prediction models for mortality (Parsonnet[18], EuroSCORE[19] and Pons[9]) significantly underestimate post-operative morbidity[6].

For all these reasons, although mortality has been the standard measure of quality of care to date[20], morbidity is now recognised as a complementary and independent component of quality of care. However, standardised and uniformly applied definitions are required[14].

1.3 OUTCOME MEASUREMENT AFTER CARDIAC SURGERY

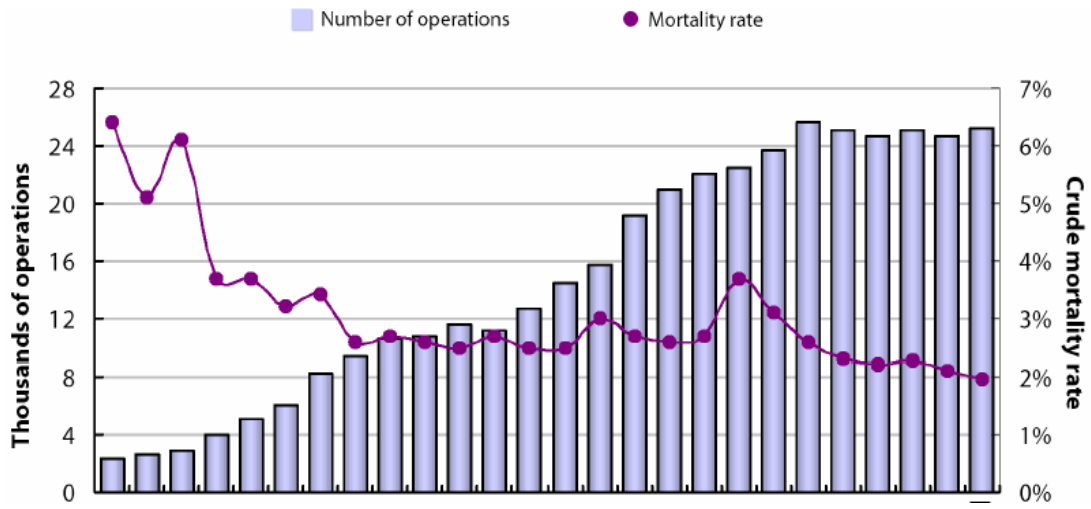
1.3.1 United Kingdom

Investigation of outcome after cardiac surgery in the UK has been primarily driven and implemented by the Society of Cardiothoracic Surgery of Great Britain and Ireland (formerly the Society of Society of Thoracic and Cardiovascular Surgeons of Great Britain and Northern Ireland) (SCTS). To date, this has focused almost entirely on in-hospital mortality.

1.3.1.1 Mortality

Lead by Sir Terence English in 1976[21], the SCTS initiated a cardiac surgery register in 1977 for all National Health Service (NHS) units to voluntarily and anonymously submit their cardiac surgery activity data and 30 day mortality. Analysis within the first few years indicated a significant decline in mortality despite the increasing numbers of operations being performed[4], a trend which has continued to be observed (Figure 1-1).

Figure 1-1: Activity and mortality trends for isolated surgery (N=386,745) from 1977 to 2003[5]. This figure was obtained from the SCTS.



However, the main limitation of the register was the lack of ability to adjust results by case-mix. This was resolved through the establishment of the cardiac surgery database project in 1994, and ultimately the national SCTS database in 1996 by Professor Sir Bruce Keogh, which generated a more comprehensive dataset comprising pre-operative, operative and post-operative information. This enabled national risk-adjusted in-hospital mortality analysis on all operative groups, on which the five published audit reports between 1999 and 2004[5, 22, 23, 24, 25] are based.

1.3.1.2 Morbidity

Three post-operative outcome variables (re-operation, new post-operative stroke and new haemofiltration/dialysis post-operatively) were included in the first SCTS database in 1996 and these remained the same until a decision to revise the dataset in 2003. However, in the latest audit report[5], the results for re-operation for post-operative bleeding were reported for the first time, albeit in only 21 hospitals due to missing or unsuitable data. The dataset revision is yet to go live and thus the changes, if any, to national morbidity outcome reporting are as yet unreported.

1.3.2 International

Many national cardiac surgical registers were established in Europe during the 1990's including those in France, Belgium, Norway, Israel, Sweden, Germany, Denmark, Portugal and the Czech Republic, with varying degrees of detail collected. Where outcome data has been obtained this is usually restricted to 30 day mortality, and in some instances hospital length of stay. The European Cardiac Surgical Register (ECSUR), funded by the European Association for Cardiothoracic Surgery (EACTS), aimed to centralise cardiac surgical data from many European countries[26]. In the year following inception of data collection (1997-1998) data were obtained from 30 countries, including national data from the UK, Norway and Belgium[26]. However, the ECSUR minimum dataset, utilised by some countries, does not include any outcome data

variables. Although no further information is currently available from the year 2000, it appears that the aim is to negotiate with other countries to make additional information available in order to undertake European comparisons[26].

In comparison, the STS (Society of Thoracic Surgeons) national database, established in 1990, is the largest database in America. In addition to mortality outcome variables, the STS database includes 24 post-operative complications (Table 1-1). These are primarily severe complications (for example, cardiac arrest, re-operation, central neurological deficit, coma >24 hours and multi-system failure), but some considered to be less serious (for example, urinary tract infection, transient neurological deficit, new atrial fibrillation (AF) or atrial flutter) are also included.

Table 1-1: Post-operative complications in the STS dataset V2.52.1 (9th April 2004)

Post-operative complication	
Bleed/tamponade	Pneumonia
Re-operation	Renal failure
Peri-operative MI	New dialysis
Deep sternal wound infection	Dissection iliac/femoral arteries
Infection in harvest site	Limb ischaemia
Septicaemia	New heart block requiring permanent pacemaker
Urinary Tract Infection (UTI)	Cardiac arrest
Central neurological deficit >72hrs	Anticoagulation complication
Transient neurological deficit	Fluid in pericardial space
Coma >24hrs	GI complications
Pulmonary insufficiency requiring ventilation	Multi-system failure
Pulmonary embolism	New AF or atrial flutter

Furthermore, efforts are underway between ECSUR and STS to create an international adult cardiac surgical dataset to enable international comparisons and the adoption of a world-wide standard[27]. However, details of the minimum dataset (including those relating to post-operative morbidity variables) are not publically available.

1.4 MORBIDITY OUTCOME AFTER CARDIAC SURGERY

The Bristol Royal Infirmary Inquiry Final Report (recommendation 108) and the Department of Health Adverse Events Consultation Document (recommendation 7) emphasised the immediate need for basic research to investigate the incidence and nature of adverse events leading to significant morbidity in the post-operative period[28, 29]. Without a validated standard by which to assess morbidity, it remains impossible to investigate the mechanisms which might underlie morbidity and to accurately assess the impact of therapeutic or systematic interventions on such morbidity. Thus, the following literature review was undertaken with the primary aim of identifying any existing validated tools for the assessment of post-operative morbidity following cardiac surgery.

1.4.1 Aim

To identify and critically evaluate the existing evidence regarding the development and validation of pre-operative risk assessment scores for post-operative morbidity in patients undergoing cardiac surgery.

This will enable:

- the identification of the definitions of post-operative morbidity following cardiac surgery
- the identification of the incidence of post-operative morbidity following cardiac surgery
- the identification of clinically applicable pre-operative risk assessment scores for predicting post-operative morbidity following cardiac surgery. Such pre-operative risk scores could be used to assess their predictive ability of a newly-defined post-operative morbidity tool.

1.4.2 Methods

1.4.2.1 Time-frame

The literature review was conducted in July 2004.

1.4.2.2 Centre for Reviews and Dissemination framework

The basic framework for conducting systematic reviews from the Centre for Reviews and Dissemination[30] was utilised (Phases 0-7).

STAGE I - PLANNING THE REVIEW
Phase 0: Identification of the need for a review
Phase 1: Preparation of a proposal for a systematic review
Phase 2: Development of a review protocol

STAGE II - CONDUCTING THE REVIEW
Phase 3: Identification of research
Phase 4: Selection of studies
Phase 5: Study quality assessment
Phase 6: Data extraction and monitoring progress
Phase 7: Data synthesis

1.4.2.3 Inclusion criteria

Three methodological quality filters were utilised to determine inclusion of studies into the literature review:

a) Study population: The study population was defined as an adult population undergoing any form of cardiac surgery (excluding transplantation).
b) Data collection tool: Only methodologies that constructed a pre-operative risk assessment tool were included. Those concentrating solely on intra-operative and/or post-operative variables were excluded.
c) Outcomes: Valid outcomes were mortality and morbidity. Both mortality and morbidity definitions were taken as the definitions presented in the paper. There were no exclusions on the basis of the definition of either outcome.

Furthermore, inclusion was limited to those publications available in the English-language for ease of interpretation. However, since English is the language required by internationally recognised journals, it was considered that this would not be a significant limiting factor to identifying the appropriate studies. Papers were not excluded on the basis of sample size, year of study or study design (retrospective or prospective).

1.4.2.4 Searching for eligible papers

In addition to publication databases (the National Centre for Biotechnology Information (NCBI), Entrez retrieval system (PubMed) and the Web of Science ISI Citation Databases) sources of ongoing and recently completed studies (The National Research Register, The Cochrane Library of Systematic Reviews) were also interrogated to identify eligible papers.

1.4.2.4.1 The National Research Register

The National Research Register (NRR) is a database of ongoing and recently completed research projects funded by, or of interest to, the UK's National Health Service (NHS). It consists of The NRR Projects database (115,152 records from 350 organisations from 2000-March 2004), The MRC Clinical Trials Directory (180 records), The Centre for Reviews and Dissemination (CRD) Register of Reviews (806 records) and Abstracts of Cochrane Reviews (1964 records).

1.4.2.4.2 The Cochrane Library of Systematic Reviews

The Cochrane Collaboration, founded in 1993, is an international, non-profit and independent organisation containing The Cochrane Database of Systematic Reviews (3,440 records), The Database of Abstracts of Reviews of Effectiveness (4,645 records), The Cochrane Controlled Trials Register (405,580 records), The NHS Economic Evaluation Database (13,828 records), Health Technology Assessment Database (3,848 records) and the Cochrane Database of Methodological Reviews (CDMR) (18 records). All databases are regularly updated, evidence-based and contain both published and unpublished work.

1.4.2.4.3 PubMed and Web of Science ISI Citation Databases

The indexing services utilised were the National Centre for Biotechnology Information (NCBI) Entrez retrieval system (PubMed 1966-) and the Web of Science ISI Citation Databases (1945-). NCBI Entrez PubMed is a text-based search and retrieval system that includes MEDLINE (National Library of Medicine bibliographic database covering medical, nursing, dentistry, and pre-clinical science disciplines). In addition to access to MEDLINE's 4,600 biomedical journals published from 71 countries and containing 11 million citations, PubMed provides over 14 million citations dating back to the 1950's, out-of-scope citations, citations that precede the date that a journal was selected for MEDLINE indexing and some additional life science journals. The Science Citation Index Expanded is a multidisciplinary database covering the journal literature of the sciences. It indexes more than 8,400 major journals from over 3000 publishers in 60 nations across 164 scientific disciplines and contains a current total of 17 million records, with all cited (backward and forward) references captured. As of January 1991 it contains

searchable, full-length, English-language author abstracts for approximately 70% of the articles in the database.

Since the search 'morbidity scores' produced a significant number of potential papers in PubMed, combinations of keywords were utilised. The title combinations employed were based on preliminary reading and the keywords associated with this study. Table 1-2 highlights the searches undertaken in June 2004.

Table 1-2: Initial keyword searches. Values in bold are those where all titles/abstracts were read and assessed for relevance.

Keywords	Pubmed: limits			NIHR	Cochrane Collaboration (all databases)
	None	Title/ abstract word	Title word		
Morbidity scores	13,026	2,350	**30**	**5**	**10**
Risk prediction score	1,033	796	**16**	0	0
Cardiac surgery score	**277**	580	**11**	0	0
Cardiac surgery risk score	**143**	285	**4**	0	0
Preoperaive risk; cardiac surgery	**33**	**94**	**33**	0	0
Risk prediction score; cardiac surgery	**18**	**30**	0	0	0

However, very few potential studies were identified through the NRR or Cochrane Collaboration and hence additional, broader keyword searches were undertaken to ensure optimal study capture (Table 1-3).

Table 1-3: Additional keyword searches conducted in NRR and the Cochrane Collaboration. Values in bold are those where all titles/abstracts searched for relevance.

Keyword	NRR	Cochrane Collaboration
Cardiac	3,578	15,425
Cardiac surgery	554	1,891
Cardiac surgery morbidity	0	0
Cardiac surgery risk	0	0
CABG	**251**	1,020
CABG morbidity	0	**1**
Surgery morbidity	**4**	**20**
Surgery outcome	**15**	**72**

Thus, overall the study titles and abstracts of the 1,067 potential eligible records identified through the keyword searches (all records highlighted in bold in Tables 1-2 and 1-3), were scrutinised in order to identify relevant studies fulfilling the review inclusion criteria.

1.4.2.4.4 Backward citation tracking

The bibliographies of all relevant papers identified and retrieved were manually searched for additional relevant papers.

1.4.2.4.5 Forward citation tracking

Using the Science Citation Index, papers that had subsequently cited the relevant papers identified from the keyword literature search were reviewed. References which had not been previously identified from the primary or backward citation searches were recorded.

1.4.2.4.6 Repeat backward and forward citation searches

Backward and forward citation searches were conducted on all papers identified from the previous backward and forward citation tracking.

1.4.2.5 Literature analysis

Data extraction utilised a modified Ganong framework[31] encompassing descriptive issues (title, author, date), methodological issues (type of study, study characteristics, sample, data collection tool, validity/reliability), analysis (methods, results) and study evaluation (strengths, limitations, conclusions). Non-quantitative analysis of extracted data were undertaken.

1.4.3 Results

1.4.3.1 Number of studies

In total, 20 relevant studies were identified from the following sources: The NRR 0 (0%), The Cochrane Collaboration 0 (0%) PubMed 10 (50.0%); backward citation 6 (30.0%); forward citation 4 (20.0%). Full-text articles were retrieved on all studies (100%). Table 1-4, Table 1-5 and Table 1-6 show the results of the backward and forward citation searches.

Table 1-4: Backward and forward citation searches from relevant papers identified through the initial PubMed search (new references appear only once - therefore duplicated new references not repeated if found in more than one paper).

Paper identified through pubmed search and availability	Backward citation: No of references cited	Backward Citation: No of new references identified	Backward Citation: Potential new references identified	New score identified? If yes, state	Forward Citation: No of times cited	Forward Citation: No new references identified	Forward Citation: Potential new references identified	New score identified? If yes, state
Parsonnet et al 1989[18]	81	6	Edwards et al 1988[32]	No.	220	16	Lippmann et al 1997[38]	No
			Wright et al 1987[33]	No			Martinez-Alario et al 1999[39]	No.
			Junod et al 1987[34]	No.			Daly et al 1993[40]	No.
			Hlatky et al 1988[35]	No.			Reed et al 2003[41]	No.
			Horst et al 1987[36]	No.			Schoepf et al 2002[42]	No.
			Scott et al 1985[37]	No.			Wagener et al 2001[43]	No.
							Pons et al 1997[9]	No.
							Junger et al 2002[44]	No.
							Wyse et al 2002[45]	No.
							Duncan et al 1995[46]	No.
							Pliam et al 1997[47]	No.
							Dupuis et al 1998[48]	No.
							Daley et al 1994[49]	No.
							Simchen et al 2000[50]	No.
							Geraci et al 1993[11]	**Yes. Own score**
							Immer et al 2000[51]	No.
Higgins et al 1992[52]	35	2	Kennedy et al 1980[53]	No.	353	2	Baretti et al 2001[55]	No
			Paiement et al 1983[54]				Smith et al 1996[56]	No
				No.				
Tuman et al 1992[57]	24	1	Hammermeister et al 1990[58]	No	89	5	Wong et al 1999[59]	**Yes. Own score**
							Heijmans et al 2003[60]	No.
							Cortina et al 1998[61]	No.
							Pinna-Pintor et al 2002[62]	No

Tu et al 1995[63]	20	0	-		148	0	-	
Kurki and Kataja 1996[64]	23	1	Marshall et al 1994[65]	No	41	1	Wouters et al 2002[66]	**Yes. Own score.**
Higgins et al 1997[67]	27	3	O'Connor et al 1992[68]	No.	41	0	-	
			Hattler et al 1994[69]	**Yes. Uses STS model**				
			Orr et al 1995[70]	No.				
Staat et al 1999[7]	28	1	Magovern et al 1996[71]	**Yes. Own score**	6	0	-	
Dupuis et al 2001[72]	39	2	Urzua et al 1981[73]	No.	14	0	-	
			Pons et al 1998[74]	No.				
Huijske et al 2003[75]	24	4	Bernstein et al 2000[76]	No.	0	0	-	
			Bridgewater et al 1998[77]	No.				
			Pitkanen et al 2000[78]	**Yes. Own score**				
			Stoica et al 2002[79]	No				
Janssen et al 2004[80]	10	1	Kurki et al 2001[81]	No.	0	0	-	

Table 1-5: Relevant papers identified from backward citation searches from review papers identified from PubMed. New references appear only once - therefore duplicated new references are not repeated if found in more than one paper.

Paper identified through backward/forward citation	Backward citation: No of references cited	Backward Citation: No of new references identified	Backward Citation: Potential new references identified	New score identified? If yes, state	Forward Citation: No of times cited	Forward Citation: No new references identified	Forward Citation: Potential new references identified	New score identified? If yes, state
Tremblay et al 1993[82]	26	1	Grover et al 1990[83]	No.	19	0	-	
Roques et al 1995[84]	17	0	-		20	0	-	
Eagle et al 1999[85]	0	0	-		70	1	Reed et al 2003[86]	No.
Fortescue et al 2001[87]	28	0	-		2	1	-	

Table 1-6: Backward and forward citation searches from relevant papers identified through backward and forward citation searches of papers identified on Pubmed or from review papers (new references appear only once - therefore duplicated new references s not repeated if found in more than one paper).

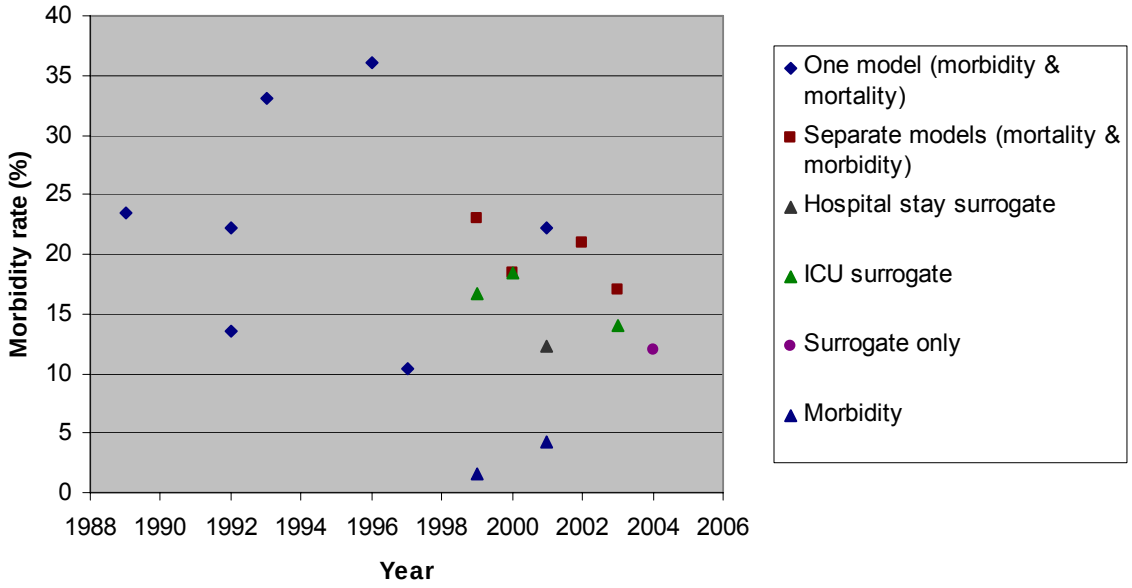
Paper/Score identified through backward/forward citation	Backward citation: No of references cited	Backward Citation: No of new references identified	Backward Citation: Potential new references identified	New score identified? If yes, state	Forward Citation: No of times cited	Forward Citation: No new references identified	Forward Citation: Potential new references identified	New score identified? If yes, state
Geraci et al 1993[11]	29	0	-	-	51	0	-	-
Hattler et al 1994[69]	15	0	-	-	29	0	-	-
Magovern et al 1996[71]	20	0	-	-	42	0	-	-
Wong et al 1999[59]	33	0	-	-	34	0	-	-
Pitkanen et al 2000[78]	20	0	-	-	7	0	-	-
Wouters et al 2002[66]	11	0	-	-	1	0	-	-

1.4.3.2 Identification of the definitions of post-operative morbidity

The analysis of the pre-operative risk assessment models for post-operative morbidity following cardiac surgery is summarised in Table 1-7, with the full version available in Appendix 1.

Of the 20 pre-operative risk predictive models identified, 10 models specifically defined morbidity and mortality separately but included all outcomes in developing one model[11, 18, 52, 57, 63, 67, 71, 72, 82, 84] and 5 models included death within their definition of morbidity[7, 64, 69, 80, 87]. Only 5 models defined mortality and morbidity separately and constructed separate models for each[59, 66, 75, 78, 85]. Increased ICU stay[59, 63, 75, 78, 80] and increased hospital stay[18, 63, 64, 71, 72] were used as surrogate measures for morbidity with 4 models solely using these definitions for measuring post-operative morbidity[18, 63, 64, 80]. The definition of morbidity used by year of study publication is summarised in Figure 1-2 highlighting that the earlier models included mortality and morbidity in one model with a trend towards separating mortality, morbidity and morbidity surrogate models appearing more recently.

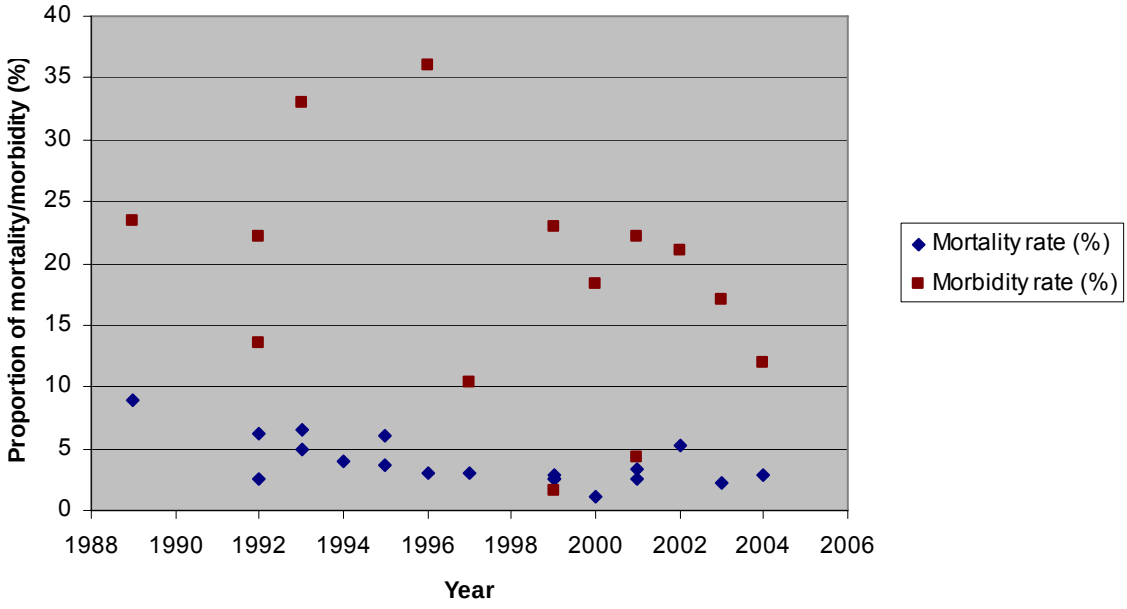
Figure 1-2: Definition of post-operative morbidity by year of study publication. (Some models used more than one definition and appear more than once).



1.4.3.3 The incidence of post-operative morbidity

As detailed in Table 1-7, the reported incidence of post-operative morbidity varies from a minimum 4.3%[87] to a maximum 36%[71]. The wide range of reported morbidity rates (Figure 1-3) probably reflects the diverse definitions of morbidity used.

Figure 1-3: Mortality and morbidity rates observed in studies developing pre-operative risk assessment scores for morbidity outcome following cardiac surgery.



While the Fortescue model includes mortality, others including mortality have much higher incidences of morbidity 12.0%[80] and 23.0%[7]. However, they report similar mortality rates of 2.8%[80] and 2.5%[7]. Overall, definitions including surrogate measures of morbidity report a lower incidence of morbidity with 16.7%[59] to 20.0%[78] remaining in ICU for >2days and 12%[80] to 14%[75] >3days.

1.4.3.4 Clinically applicable pre-operative risk assessment scores

Although the majority of models include variables that are readily attainable in routine clinical care, the Magovern score is the only score with a wide definition of morbidity, including major and minor categories, that also does not include mortality[71]. The full score is reported with definitive cut-offs differentiating between different levels of risk and the predictive power of the model for their defined morbidities is strong.

Table 1-7: Summary of pre-operative risk prediction scores for morbidity outcome in patients undergoing cardiac surgery (Full version available in Appendix 1).

Primary author	Year	Country	Method	Year (data)	Sample	Sample size	Outcome morbidity definitions	Mortality rate (%)	Morbidity rate (%)
Parsonnet[18] Parsonnet score	1989	USA	Retrospective	1982-1987	Open-heart surgery	Development: 3,500; Validation: 300	**Operative mortality:** any death occurring within 30days of surgery **Post-operative complications**: Not stated **Length of hospital stay**: Not stated	8.9	23.5
Higgins[52] Cleveland Clinical Severity Score	1992	USA	Retrospective development; Prospective validation	1986-1988	CABG	Development: 5,051; Validation: 4,069	**Mortality** Not stated **Morbidity**: MI, IABP, mechanical ventilation >3 days, neurological deficit, oliguric or anuric renal failure, Serious infection	2.5	13.5
Tuman[57] Canadian Model	1992	Canada	Prospective			Development: 3,156; Validation 394	**Morbidity** :The presence of one or more of the following categories of complications: Cardiac, Pulmonary, Renal, Infectious, Neurologic **Operative mortality**:intra-operative death or death within 24hrs of surgery. Death after this period was defined as post-operative mortality.	6.2	22.2
Geraci[11]	1993	USA	Retrospective	1985-1986	CABG	2,213	**Mortality**: Death within 30days of admission. **Non-fatal adverse event**: New MI by ECG, Cardiorespiratory arrest, New CHF by CXR, Acute graft failure New onset thromboembolism, New onset stroke, Coma, Mechanical ventilation >48hrs,	6.6	33.0

							Wound infection, Bacteraemia, Acute renal failure (1st time dialysis or rise in creatinine to 442mmol/l), More than 6 units of blood or packed red blood cells, Unplanned return to surgery		
Tremblay[82] The Montreal Heart Institute Risk Assessment Classification	1993	Canada	Retrospective development; Prospective validation	Development: 1980; Validation 1988-1990	Cardiac surgery	Development: 500; Validation 2,029	**Mortality**: Postoperative mortality during hospitalisation (1980 and 1990 populations) **Length of stay in post-operative ICU** (1990 population) Not stated **Length of postoperative hospitalisation** (1990 population) Not stated	3.4 (1980) 4.9 (1990)	NS
Hattler[69] STS Model 2	1994	USA	Prospective	1991-1993	CABG	728	**Mortality** Not stated **Morbidity:** Included: Re-operative bleeding, Perioperative MI Infection (mediastinal, septicaemia), Stroke (permanent/transient) Ventilator >5days, Renal failure (no dialysis) Dialysis required, Heart block (permanent), Cardiac arrest, Anticoagulant complication, Tamponade, Gastrointestinal complication, Multisystem failure, In-hospital mortality	3.98	NS
Roques[84] Ontario Province Risk Score (French	1995	France	Prospective	1993	Cardiac surgery	7,181	**Mortality** Not stated **Mortality/severe morbidity**: Reoperation for thoracic wound infection, Perioperative MI, Duration of intubation >48hrs, Severe infection, Reoperation with CPB, Low	6.0	NS

Score)							cardiac output, Cardiac massage, Low limb ischaemia, Ventricular arrhythmia, Renal failure, Stroke, Gastro-duodenal, hemorrhage, Insertion of IABP		
Tu[63] Tu Score	1995	Canada	Retrospective	Development: 1991-1992; Validation 1992-1993	Cardiac surgery	Development: 6,213; Validation 6,885	**Mortality** In-hospital mortality **Very long ICU LOS** >6days **Very long post-op LOS** >17days	3.7	NS states LOS
Kurki[64] CABDEAL Score	1996	Finland	Retrospective	1990-1991	CABG	386	**Prolonged hospital stay** >12 days because of adverse events, transfer to another hospital for treatment of complications or death during hospital stay	NS	NS
Magovern[71]	1996	USA	Retrospective	Development: 1991-1992; Validation: 1993-1994	CABG	Development: 1,567; Validation: 1,235	**Outcome**: mortality or morbidity during the hospitalisation only. **Mortality :** Death at any time during the hospital stay **Morbidity:** An unexpected post-operative complication, major or minor, which resulted in the increase consumption of hospital resources owing to the required treatment. Full definitions of each major and minor complication stated. *Major:* cardiovascular failure, respiratory failure, acute renal failure, permanent cerebral deficit, major wound infection, pulmonary embolus, surgical intervention after CABG *Minor:* Temporary central nervous system deficit, acute renal insufficiency, atrial arrhythmias, ventricular arrhythmias, superficial wound	3.8 (Development) 3.0 (Validation)	16 (major); 36 (minor)

							infection, respiratory insufficiency, pleural effusion, pneumothorax, systemic sepsis, gastrointestinal bleeding, post-operative mediastinal bleeding.		
Higgins[67]	1997	USA	Prospective	1993-1995	CABG (alone or combined)	Development: 2,793; Validation: 2,125	**Morbidity** :The presence of one or more of the following during hospitalisation: Cardiac complication, prolonged ventilatory support, CNS complication, renal failure, serious infection, death. **Mortality** : All deaths during hospitalisation for the operation, regardless of length of stay.	3.1	10.4
Eagle[85] ACC/AHA Practice Guidelines	1999	USA		1996-1998	CABG	7,290	**Mortality**: I-hospital mortality **CVA** : New focal neurological event persisting at least 24hrs. **Mediastinitis:** During index admission defined as a positive deep culture and/or Gram stain and/or radiographic findings indicating infection and requiring re-operation.	2.93	1.58 (CVA); 1.19 (mediastinitus)
Staat[7]	1999	France	Retrospective	1996	CABG	679	**Severe morbidity**: Mortality or one of the following 10 non-fatal adverse events: Low cardiac output, IABP, MI Mechanical ventilation >48hrs, Serious pneumonia, Other serious infections, Acute renal failure, Excessive bleeding, Unplanned return to surgery, CNS complication	2.5	23.0
Wong[59]	1999	Canada	Prospective	1995	CABG	885	**Delayed extubation**: >10hrs **Prolonged ICU LOS**: >48hrs **Mortality**: Death occurring within 30 days of hospital or during hospital stay	2.6	NS states LOS

Pitkanen[78]	2000	Finland	Retrospective development; Prospective validation	Development: 1992-1996; Validation 1998-1999	Cardiac surgery	Development: 4,592; Validation: 821	**Morbidity (overall)** : 1 or more of the following: Haemodynamic problems (inotropic support, IABP), mechanical ventilation >24hrs, serious gastrointestinal complications, anuria, stroke multi-organ failure, resternotomy due to other cause than excessive bleeding, sepsis, pneumonia, mediastinitis, psychosis or remarkable confusion, readmission to the ICU or complicated clinical situation at discharge to another hospital. **Morbidity:** Length of ICU stay >2days. **Mortality**: Death occurring within 30 days from the operation.	2.0 (Development) 1.1 (Validation)	22.0 (Development) 18.4% (Validation)
Dupuis[72] Cardiac Anaesthesia Risk Evaluation Score (CARE)	2001	Canada	Prospective	Development: 1996-1998; Validation 1998-1999	Cardiac surgery	Development: 2000; Validation: 1,548	M**ortality:** In-hospital death **Morbidity**: Complications in one or more of the following categories: cardiovascular, respiratory, neurological, renal, infectious, any other. **Length of stay:** If no morbidity data, prolonged post-operative LOS used as a surrogate.	3.4	20.7 (Development); 22.2 (Validation)
Fortescue[87] QMMI Score	2001	USA		1993-1995	CABG	Development: 6,237; Validation: 3,261	**Major adverse outcome**: Any of the following: Death, Renal failure, MI, Cardiac arrest, Stroke, Coma	2.5	4.3
Wouters[66] CORRAD Score	2002	Netherlands	Retrospective	Development: 1998; Validation:	CABG	Development: 653; Validation: 969	**Early mortality**: hospital mortality and cardiac-related mortality within the 6 month follow-up period. **Morbidity**: hospital mortality and also the	5.6 (Development); 5.3 (Validation)	19.1 (Development); 21 (Validation)

				1999-2000			following complications resulting in a prolonged hospital stay: ventilatory support > 3days, sternal wound, nephrological, neurological, pulmonary, gastrointestinal, vascular problems		
Huijskes[75] Amphia Score	2003	Netherlands		1997-2001	CABG and/or valve surgery	7,282	**Mortality:** In-hospital mortality **Major adverse cardiac event** (MACE): in-hospital death or peri-operative MI or VT/VF **Extended length of stay**: intensive care length of stay of at least 3 days or in-hospital death.	2.3	17
Janssen[80]	2004	Netherlands	Retrospective	2000-2001	CABG	888	**Prolonged length of stay in ICU:** longer than 3 days. Indications for prolonged length of ICU stay were: Prolonged ventilation, Low cardiac output defined as need for inotropic support and a cardiac index <2.2l/min per m^2, Need for Swan ganz-catheter	2.8	12 (LOS)

1.4.4 Discussion

This review has identified that no consistent definition of post-operative morbidity has been used (for example, Higgins et al[52], Magovern et al[71], Wouters et al[66]). Furthermore, some included death within the definition (for example, Staat et al[7], Fortescue et al[87]) and some defined morbidity using surrogate markers such as increased ICU (for example, Tu et al[63], Janssen et al[80]) or post-operative stay (Parsonnet et al[18], Magovern et al[71], Dupuis et al[72]). Since such varied definitions are used, it is unsurprising that such a range in morbidity rates are reported - from 4.3%[87] to 40%[71]. As highlighted previously, post-operative complication rate does not correlate well with mortality rate[16, 17], and although the Parsonnet score[18] is widely used in clinical practice for post-operative mortality risk assessment, its usefulness in assessing morbidity risk has been questioned[72, 88].

The literature review identified 5 models that constructed morbidity models separately from mortality[59, 66, 75, 78, 85]. Of these, 2 models defined morbidity using a more general perspective[66, 78]. However, neither model reported the origin of the definitions used. Furthermore, the Pitkanen pre-operative risk score was not sensitive in predicting morbidity. This was considered to be due to the morbidity definition: generalisation of morbid events as opposed to considering an isolated morbid event, a limitation also echoed by Wouters and colleagues[66]. Furthermore, the subjectivity of morbidity definition and their impact relating to treatment choices and length of stay is highlighted[66].

Overall, the Magovern score, despite including mortality within the morbidity definition, has the most well-defined morbidity outcome encompassing major and minor definitions. The inclusion of minor morbidity explains the increased morbidity rate in comparison with other studies. Furthermore, the pre-operative risk assessment model contains easily attainable clinical variables with high predictive ability of subsequent post-operative morbidity. However, as with the Pitkanen and Wouters models, the origin of the morbidity outcome definitions in undefined and the study was only conducted in patients undergoing isolated CABG.

1.4.5 Conclusion

This review has demonstrated the diversity associated with attempting to measure morbidity which can lead to imprecise measurement and monitoring of events[14]. Despite the limitations of the tools identified, no model is used in the UK for the assessment of post-operative morbidity after cardiac surgery.

1.5 MORBIDITY ASSESSMENT IN OTHER SURGICAL DISCIPLINES

Due to a lack of tools for general post-operative morbidity assessment in patients undergoing cardiac surgery, methods used by other surgical disciplines were explored. As with cardiac surgery, studies in post-operative morbidity have generally been restricted to specific post-operative complications (for example infection, cardiac morbidity) or surrogate markers (for example length of

hospitalisation). However, the Post-Operative Morbidity Survey (POMS)[1] is the only published, prospective tool for assessing the incidence and pattern of post-operative morbidity in orthopaedic, urological, vascular, gynaecological and general surgical patients. POMS is a nine domain survey (Table 1-8) completed on all participants remaining in hospital on post-operative days 5, 8 and 15.

Table 1-8: Post-Operative Morbidity Survey[1]

Morbidity type	Criteria
Pulmonary	The patient has developed a new requirement for oxygen or respiratory support
Infectious	Currently on antibiotics and/or has had a temperature of >38°C in the last 24 hours
Renal	Presence of oliguria < 500ml/24hours, increased serum creatinine (>30% from pre operative level); urinary catheter in situ for non surgical reason
Gastrointestinal	Unable to tolerate an enteral diet for any reason including nausea, vomiting and abdominal distension
Cardiovascular	Diagnostic tests or therapy within the last 24 hours for any of the following: 1) new MI or ischaemia, 2) hypotension (requiring fluid therapy >200ml/hr or pharmacological therapy, 3) atrial or ventricular arrhythmias, 4) cardiogenic pulmonary oedema, thrombotic event (requiring anticoagulation).
Neurological	New focal neurological deficit, confusion, delirium or coma
Haematological	Requirement for any of the following within the last 24 hrs: packed erythrocytes, platelets, fresh-frozen plasma, or cryoprecipitate
Wound	Wound dehiscence requiring surgical exploration or drainage of pus from the operation wound with or without isolation of organisms
Pain	New postoperative pain significant enough to require parenteral opioids or regional analgesia

At study inception, POMS was being validated at University College London Hospitals, NHS Trust, London, UK by Grocott and colleagues who additionally collect POMS data on post-operative days 1 and 3.

1.6 OVERALL SUMMARY AND CONCLUSIONS

Examination of the work of the SCTS in the UK, of other cardiac surgery societies internationally, and of the available published literature has highlighted that there is no uniformly applied definition of post-operative morbidity following cardiac surgery nor method for its measurement. The STS in the USA collects the greatest range of data relating to post-operative morbid events which is collectively reported but not at the patient level. The only instrument for post-operative morbidity assessment, at the patient level, is the POMS tool for general surgical patients[1]. Thus, the

development of a tool, similar to POMS but specifically designed for the identification and quantification of post-operative morbidity following cardiac surgery, is indicated.

1.7 THESIS PLAN

My thesis aim was thus to develop and validate a tool, the Cardiac Post-Operative Morbidity Survey, (C-POMS), for the identification and quantification of post-operative morbidity after cardiac surgery.

The 'route-plan' of the work undertaken is described below. However, Figure 2-1 in the methods chapter shows the overall architecture in more detail.

Chapter 2: Methods
This chapter describes the aims and objectives of the thesis and the main study methods, including the pilot study.

Chapter 3: Data quality
This chapter examines the necessity of strategies for maximising data quality and undertaking data quality assessments, which informs the error prevention strategies and data cleaning strategies undertaken in this study. The results on data uniqueness, accuracy, completeness, consistency and validity of the study data are reported.

Chapter 4: Results I: Pilot study
Chapter 4 reports the results of the pilot study. These results informed changes to be made to the main study protocol in terms of routine data collection items which are also indicated in this chapter.

Chapter 5: Results II: Baseline characteristics
The inter-rater reliability test results, screening and recruitment characteristics and participant baseline characteristics are reported in this chapter. The baseline characteristics include demographic, pre-operative, intra-operative, immediate ICU and outcome characteristics of the participants of the main study.

The following three results chapters are closely related and follow a process through model development, reliability and validity testing of the model and assessment of its use in clinical practice.

Chapter 6: Results III: C-POMS development
This chapter begins by examining the background to health indices model development exploring the theoretical background (psychometric and clinimetric theory; classical test theory and item-response theory), construction frameworks (the McMaster Framework[89] for constructing a health

indices) and item reduction strategies. The methods undertaken for developing C-POMS are then described and the results of each phase are reported. The resulting model is shown, while the discussion relating to the components of the final model being included in chapter 9.

Chapter 7: Results IV: C-POMS reliability and validity testing

The aim of this chapter is to assess the reliability and validity of the C-POMS tool. Firstly, the need for validity testing is examined. Then the specific aims and objectives of the content validity, reliability and construct validity testing are stated and the methods utilised, and results, for each are detailed. The strengths and weaknesses of the reliability and validity methods undertaken are evaluated and whether the results indicate if sufficient reliability and validity has been obtained is discussed.

Chapter 8: Results V: Clinical utility of C-POMS

The final results chapter focuses on the clinical utility of the C-POMS tool, both at an individual patient level and also as a potential tool to be administered to all patients undergoing cardiac surgery. Thus, the aims of this chapter are to identify and quantify post-operative morbidity as defined by C-POMS, to determine if C-POMS provides benefit over POMS in defining and quantifying post-operative morbidity in cardiac surgical patients and to explore the utility of C-POMS in clinical practice with multi-disciplinary clinical teams. The methods and results are reported and discussed.

Chapter 9: Discussion

This chapter aims to bring together the overarching discursive elements concerning this work. Firstly, an update on the work of the SCTS, international cardiac registries and the literature from the commencement of the study are considered to conclude on the current appropriateness of C-POMS. The use of C-POMS as a morbidity outcome measure is then discussed, particularly exploring the C-POMS morbidity rate with morbidity rates reported in the literature, the independently predictive domains of subsequently length of stay and the newly derived domains. Consideration is also given to the uses of C-POMS ranging from the individual patient level to unit level and a national perspective, and to the limitations and strengths of C-POMS as a tool in addition to the methodological strengths and weaknesses of the study. Finally, future work is highlighted.

2 STUDY METHODS

2.1 INTRODUCTION TO CHAPTER

The aim of this chapter is to detail the aims and objectives of the work undertaken and to describe the methods utilised for the main study and pilot study data collection. To aid clarity of how this work progressed from inception to completion, a summary figure is included which details the process undertaken and where each key aspect is reported within this document.

2.2 AIMS AND OBJECTIVES

2.2.1 Aims

The overall aim is to explore in-hospital morbidity outcome in patients undergoing cardiac surgery

The specific aims are:

1. To develop and validate a scoring system to assess in-hospital post-operative morbidity in patients undergoing cardiac surgery.

2. To describe and quantify in-hospital post-operative morbidity experienced following cardiac surgery.

2.2.2 Objectives

The objectives are to:

1. Develop and validate a cardiac POMS (C-POMS) from the components of the original POMS and cardiac-specific indices determined by an expert panel.

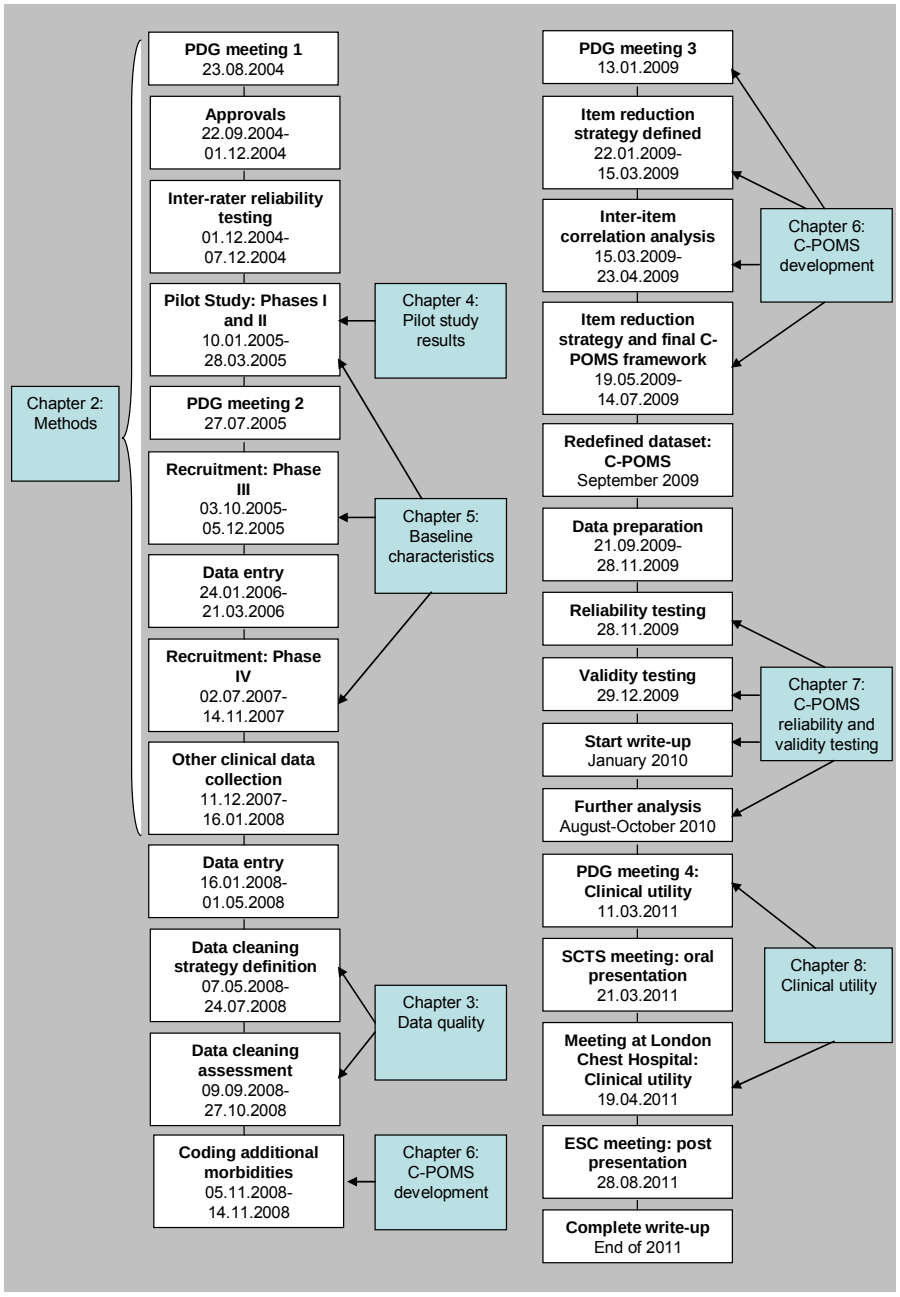
2. Explore the applicability of POMS in describing and quantifying post-operative morbidity in patients undergoing cardiac surgery

3. Assess the utility of a post-operative morbidity survey in the description of in-hospital morbidity following cardiac surgery

2.3 ROUTE-MAP

Figure 2-1 details the process of work undertaken in working towards the aims and objectives of this study, highlighting the chapter in which the steps are specifically described or discussed.

Figure 2-1: Route-map of work undertaken



2.4 MAIN STUDY METHODS

2.4.1 Ethics committee approval and study registrations

This study was registered with UCL Data Protection on September 24th 2004 (reference Z6364106 Section 19, Research: medical research), received UCLH Research and Development approval on October 13th 2004 (reference 04/0165) and ethics approval from The Joint UCL/UCLH Committees on the Ethics of Human Research (Committee Alpha) on December 1st 2004 (reference 04/Q0502/73). Table 2-1 details the relevant Ethics amendments submitted.

Table 2-1: Ethics committee amendments

Number	Reason for amendment	Date approved	Included in thesis
1	Addition and removal of clinical data items following the pilot study	25.07.2005	Yes
2	The measuring of oxygen saturation levels using near-infra red spectroscopy on a sub-section of the cohort	Full submission required	Separate study conducted
3	Genetics sample collection	03.08.2006	No
4	Extension of study	26.04.2007	Yes
5	Additional retrospective variables for blood storage study	15.07.2008	No
6	1-year mortality data from the NHS Information Centre	15.07.2008	No

2.4.2 Protocol Development Group

A Protocol Development Group (PDG) was established to provide expert clinical opinion on the protocol throughout this study. Membership of the PDG included fifteen representatives from cardiac nursing, surgery, intensive care and anaesthesia, and also included representatives from the original POMS study[1]. Table 2-2 provides a brief overview of the meetings undertaken.

Table 2-2: Schedule of PDG meetings

Meeting	Date	Purpose of meeting
1	23.08.2004	Development of cardiac specific variables for inclusion in data collection
2	27.07.2005	Presentation of pilot study results, to discuss the additional morbidities, review variables for ongoing data collection
3	13.01.2009	Presentation of completed recruitment, present data quality assessments, to discuss the additional morbidities, discussion relating to item-reduction
4	11.03.2010	Presentation of results, to discuss clinical utility of C-POMS

The output of meeting 1 is detailed in section 2.4.5.2.

2.4.3 Study design

This study is a prospective, single-site (The Heart Hospital, UCLH NHS Foundation Trust, London, UK), observational cohort study. All the cardiothoracic consultant surgeons were approached prior to the study commencement and each provided written agreement that their patients could be approached for participation in this study.

2.4.4 Participants

2.4.4.1 Inclusion and exclusion criteria

Patients undergoing any form of cardiac surgery (for example, coronary artery bypass grafting (CABG), valve surgery, CABG plus valve, aortic root replacement) were eligible for the study. Patients under 18 years of age, undergoing emergency surgery (inadequate time to obtain informed consent), undergoing cardiac surgery for a grown-up congenital heart condition (complicated and sub-set specific co-morbidities), unable to give informed consent (severe mental illness or handicap, difficulties in understanding English language) and those involved in a clinical intervention trial (due to influencing patient outcome) were excluded. Furthermore, those who died within five days of surgery were also excluded in order that morbidity could be considered separately from factors affecting mortality in the immediate post-operative period.

2.4.4.2 Identification, recruitment and informed consent

All participants were screened and recruited from either the bi-weekly cardiothoracic pre-admission clinics or on admission to hospital (usually the day prior to surgery). Patients coming into hospital for surgery were identified through weekly operating timetables and through liaison with the Bed Management team and the operating theatre and surgical staff. Written informed consent was obtained from each patient who agreed to participate and participants were re-consented if more than two weeks had lapsed between the clinic date and admission to hospital. Agreement to participate was documented in the medical notes.

2.4.4.3 Sample size

Using a sample size calculator from Creative Research Systems (http://www.surveysystem.com/sscalc.htm), based on a population of approximately 40,000 patients undergoing cardiac surgery annually in the UK and a 95% confidence level, a sample size of 450 patients is required to detect a specific morbid event/variable occurring in 5% of the patients (CI±2%).

2.4.5 Data variables

2.4.5.1 POMS framework

The morbidity types and individual criteria as detailed within POMS[1] were collected (Chapter 1,Table 1-8). In participants with pre-operative morbidities present, the presence of the post-operative morbidity in any of the post-operative days was only coded as ‘not new’ if exactly the same as in the pre-operative category. For example, in these participants if the morbidity was more severe (nasal spec pre-op and CPAP post-op) or identified by a different criteria (GI: pre-op nausea only; post-op vomiting only) the morbidity was coded as ‘new’

2.4.5.2 Cardiac specific data variables

The PDG (meeting 1, Table 2-2) made the following recommendations:

a) the POMS framework (Table 2-3)

Table 2-3: PDG recommendation on additional data items relating to each POMS domain.

POMS domain	PDG recommendations for additional data collection
Pulmonary	▪ Is the patient intubated and ventilated? Y/N ▪ Is the patient on CPAP, BIPAP, O2 mask, nasal specs? Specify which ▪ How much? ▪ Record RR ▪ Record FIO_2 or SaO_2
Infectious	▪ Treatment (antibiotics) Y/N ▪ Is treatment routine/non-routine
Renal	▪ Is the patient currently receiving any renal replacement therapy? Y/N ▪ If yes, state:_____ ▪ Add space for post-operative creatinine level on all post-operative days.
Gastrointestinal	Prior to *'unable to tolerate enteral diet (oral or tube feed)*' add ▪ Is the patient receiving nutritional support? Y/N ▪ Specify TPN/NG feed ▪ Is additional nutritional support due to GI disturbance? Y/N In *'is the patient experiencing nausea, vomiting or abdominal disturbance? On anti-emetics?*' specify which contributes to the scoring of the morbidity.
Cardiovascular	For each of the outcomes (new MI, Ischaemia or hypotension, atrial or ventricular arrhythmias, cardiogenic shock or non-routine anticoagulation) add in ▪ Specify diagnostic test: ▪ Diagnosis following diagnostic test: ▪ Treated: Y/N ▪ Specify treatment: Under atrial and ventricular arrhythmias add in: ▪ Presence of *any* rhythm disturbance? Y/N ▪ Paced? Y/N ▪ Specify rhythm ▪ Treated? Y/N ▪ Specify treatment Need to specify use of inotropes Y/N
Neurological	Specify between new confusion, delirium, focal deficit or coma.

Haematological	State the number of units of each used Add Aprotinin and dose (indication of post-operative bleeding)
Wound	To *'has the patient experienced wound dehiscence requiring surgical exploration or drainage of pus from the operation wound with or without isolation of organisms?*' add ▪ Specify surgical intervention or drainage ▪ Isolation of organism? Y/N state ▪ Additional treatment? After *'has the patient experienced wound dehiscence requiring surgical exploration or drainage of pus from the operation wound with or without isolation of organisms?*' add ▪ Has the patient experienced any wound complications? Y/N ▪ If yes, specify whether sternal, L arm, R arm, L leg, R leg ▪ Swab taken? Y/N ▪ Isolation of organisms? Y/N state:
Pain	Change to: Has the patient *required* parenteral opioids or regional analgesia? Specify method of medication of administration (PCA/Epidural/IV/IM)

b) additional assessments at each time-point: ambulation assistance (wheelchair, zimmer frame, walking sticks etc), DVT (has the patient undergone a diagnostic test for suspected DVT in the last 24 hrs or has the patient received treatment for suspected DVT in the last 24 hrs?)
c) pre-operative assessment: Magovern score[71] as identified from literature review, Parsonnet score[18] and EuroSCORE[19] as used in clinical practice and POSSUM (physiological component only)[90] data variables
d) intra-operative assessment: anaesthetic agents, cardioplegia method, circulatory arrest time, aortic cross clamp time, cardiopulmonary bypass details (used, time and temperature)
e) theatre/ICU interface variables: APACHE II[91] and SOFA score (Sequential Organ Failure Assessment 1996,[92]) variables
f) first recorded after 30 minutes stabilisation period: ventilator settings, arterial blood gas (ABG) results, BP, HR, temperature, MAP, CVP, urine output, fluids, level of inotrope use, drainage (mediastinal/pleural), intubation grade.
g) other outcome measures: extubation time, hours ventilated, return to theatre, length of ICU stay, post-operative length of stay, total hospital length of stay, delayed discharge and reason.

2.4.5.3 Other clinical data

Pre-operative risk factors and relevant medical history, intra-operative details and post-operative outcome variables were extracted from the SCTS national audit minimum dataset, collected

routinely on all patients undergoing cardiac surgery at the Heart Hospital, by dedicated Information Nurses. Full details of the variables can be found in the SCTS data definition table (Appendix 2).

2.4.5.4 Participant interviews

To ensure that full coverage of all aspects of post-operative morbidity were identified, participants were asked at each time-point how they were feeling and to report all symptoms, regardless of their perception of severity, and any factors they felt were affecting or influencing their recovery. Responses that identified morbidities not encapsulated within the POMS framework were recorded as free-text.

All participant interviews were conducted at a time convenient to the patient, in either a single or double patient room to provide a significant amount of privacy to discuss the symptoms/difficulties the patient may be experiencing post-operatively.

2.4.5.5 Outcome variables

The primary outcome measure which C-POMS will be validated against is post-operative length of stay.

2.4.5.6 Data definitions

Data definitions of all variables and normal clinical parameters can be found in Appendix 2.

2.4.5.7 Data collection

2.4.5.7.1 Reliability study

To ensure reliability and consistency in POMS coding, prior to commencement of data collection an inter-rater reliability study was undertaken with the data collector for the POMS validation study conducted at UCLH[93]. During December 2004, 20 in-patients participating in the POMS validation study had repeat data collection on one of their post-operative time-points, excluding D1 as D1 data were not collected in the validation study.

2.4.5.7.2 Time-points and time-frame

Morbidity data were collected pre-operatively and on post-operative days 1 (D1), 3 (D3), 5 (D5), 8 (D8) and 15 (D15) if the participant remained an in-patient, as per the POMS protocol[1].

Data collection commenced on January 10th 2005 and was conducted in phases, due to the time commitment required, through to completion on November 14th 2007.

2.4.5.8 Data collection tools

All data were obtained from a) NHS electronic information systems: PAS (administrative and demographic data); CDR (blood results); PACS (radiographic data), PATS (SCTS data), b) the medical or nursing notes/charts, c) the patient, using a standardised Case Report Form (CRF):

- V1 Sept 2004: Completed after PDG meeting 1

- V2 March 2005: Revised version after review of clinical variables Phase I pilot study
- V3 July 2005: Revised version after completion of pilot study (after PDG meeting 2)

2.4.5.9 Data collector

The SCTS data were collected by the Heart Hospital Information Nurses. All other data were collected by myself.

2.4.5.10 Data custodian

Professor Hugh Montgomery (as Chief Investigator (CI)/supervisor) and myself as the study Principle Investigator (PI) were named data custodians for this study.

2.4.5.11 Data security and storage

A pseudoanonymised system was required to enable ongoing data collection. At time of recruitment, participants were allocated a unique study number by which all clinical data collection was labeled. All CRFs and the study enrolment register (only place where patient name is recorded with the allocated study number) were stored in a locked metal filing cabinet within a locked office at UCL with access only allocated to the CI and PI. All electronic data were stored on a double password protected database within a locked office at UCL, with access restricted to the PI. Patient identifiable information was stored separately from all other data, and only linkable through database manipulation.

2.4.6 Ethical considerations

This study was conducted under the Principles of the Declaration of Helsinki[94]. In accordance with ethical principles as stated by American Nurses Association[95], and in addition to those already detailed (Right to privacy and dignity: section pt interviews 4.1.5.4; Right to anonymity and confidentiality: section Data security 4.1.6.6), the other principle ethical principles relevant to this study are:

2.4.6.1 Right to self determination

Patients must not feel coerced into participating in the study. Thus, particular emphasis was given during recruitment on not having to take part, being able to withdraw at any time, without giving a reason and that the decision to take part or not will not affect their care and management in any way.

2.4.6.2 Right to fair treatment

All participants were treated equally during the study, there were no payments or reimbursements made and there were no unequal distributions of risk between patients by participating in the study.

2.4.6.3 Right to protection from discomfort and harm

There were no anticipated risks to the participant or researcher by participating in this study.

2.4.7 Statistical methods

All analyses were performed using SPSS V13. The Kappa statistic was utilised to establish the measure of agreement between the two raters. For the baseline descriptors of patients, categorical and continuous variables were analysed using basic descriptive analysis: frequencies and mean, minimum, maximum and standard deviation, as appropriate.

2.5 PILOT STUDY

2.5.1 Aim

The purpose of the pilot study was to

a) explore the initial applicability of POMS in describing and quantifying post-operative morbidity following cardiac surgery
b) confirm the routine data collection variables required for the main study.

2.5.2 Methods

The pilot study emulated the study design, participants (excluding sample size), data variables, data collection (excluding reliability study and time-frame) and ethical considerations of the main study design, detailed in section 2.4.

2.5.2.1 Sample size

The pilot study consisted of a pre-determined sample size of 100 participants, which was deemed to be clinically appropriate by the PDG (meeting 1).

2.5.2.2 Time frame

The pilot study was conducted in two phases: a review of the routine data variables in the first fifty patients (Phase I) resulting in a revised CRF (V2 March 2005) for the remaining fifty patients (Phase II).

2.5.2.3 Data collection Phase II

Retrospective clinical data on the Phase I participants was obtained in order to complete routine clinical data following Phase I review. Additionally, retrospective review of all chest x-ray reports using PACS on all patients was completed to ensure accurate identification of pneumothoraces, pulmonary oedema, left lower lobe (LLL) collapse and pleural effusions requiring drainage.

2.5.2.4 PDG review

The PDG met post completion of the pilot study (meeting 2, Table 2-2) to evaluate the free-text additional morbidities (occurring in ≥5% of participants) from a clinical perspective to decide which were to be included as standard data items on the C-POMS CRF.

2.5.2.5 Statistical methods

All analysis was conducted in SPSS (V12.1). The baseline descriptor analysis methods were identical to those used in the main study (section 2.4.7)

2.5.2.5.1 Analysis of free-text entry

Any symptoms/items identified to occur in more than 5% of patients were considered for inclusion in C-POMS. Each morbidity identified through free-text data entry was entered into the Microsoft Access database into separate fields for every patient. Thus, a patient with four additional post-operative morbidities on day 1 and two on day 3 would have four free-text fields for day 1 and two for day 3. Each free-text field was sorted into ascending order to identify each type of morbidity. A new data table comprising of all patients and the identified morbidities was completed (where 1=yes for the presence of the morbidity at any point during the post-operative period). The frequency of each morbidity was then calculated. To identify the time-point specific frequency of each morbidity, each morbidity was allocated a code and the frequency of the code in each of the morbidity fields was calculated for each day.

2.5.2.5.2 Acceptability and item frequency

This was determined by examining distributions for item response frequencies and item non-response, at all time-points. Items with less than 5% completion were considered poorly performing and therefore redundant, items. Items with less than 5% frequency were retained if considered by the PDG to have substantial clinical significance. Items occurring in more than 5% of patients were included in the final C-POMS data collection tool.

3 DATA QUALITY

3.1 INTRODUCTION TO CHAPTER

The validity of the conclusions reached depends on the quality of the data[96, 97].Thus, this chapter explores the concept of data quality, describes the methods used to devise and implement a data quality strategy and reports the data quality results of the data collected in the main study.

3.2 INTRODUCTION TO DATA QUALITY

All studies, no matter how well designed or implemented, have to deal with errors from various sources[98]. However, while 'quality' data are not necessarily 'perfect' data[99] a lack of quality control can be detrimental to analysis and conclusions[97]. Therefore, the validity of the conclusions reached depends partly on the accuracy of the data[96]. Data quality issues can arise due to application errors, human errors and deliberate manipulations[100] and can be either random or systematic[101]. Both error types can occur during data collection and data management but often can be identified and corrected[96]. Furthermore, multi-source datasets that require matching are vulnerable to naming and structural conflicts and also overlapping, contradicting and inconsistent data[102, 103]. However, little guidance exists in the peer-reviewed literature on how to set up and carry out data quality strategies in an efficient way[98] and regulations and guidelines do not address minimum acceptable data quality levels for clinical trial data[104]. Furthermore, since the majority of publication retractions are due to research error or inability to reproduce results[105], the growing importance of Good Clinical Practice guidelines and regulations[98] and the recommendation from the statistical societies that the description of data cleaning be a standard part of reporting statistical methods[106], greater emphasis on data quality in clinical studies is being made.

The importance of a data quality strategy for this study is evident. Since the data quality process is unique for each study and particular to the data being analysed[102], the development of a data quality strategy specific to this study is required. Thus, this chapter will detail the development (from exploration of data quality and data quality strategies in the literature), implementation and reporting of a data quality strategy applied to the data in this study.

3.3 AIMS

The overall aim is to ensure a valid dataset containing minimal errors is produced.

The specific aims and objectives are to:

1. Develop a data quality strategy
    a. Explore the literature for existing methods and strategies
    b. Design a data quality strategy based on current evidence

2. Implement the data quality strategy
3. Report and assess the results of the study's data quality
    a. Report the data cleaning and screening procedures used
    b. Report the sources and assessed adequacy of the data

3.4 EXPLORATION OF THE LITERATURE ON DATA QUALITY

3.4.1 Defining data quality

Data quality is a continuous and dynamic process of the operational checks to verify that clinical data are generated, collected, handled, analysed and reported accurately[96, 107]. High levels of data quality are achieved when information is valid for the use for which it is applied[99, 108]. A review of the literature highlighted the components of data quality as detailed in Table 3-1. Other components identified were structure[109], value distribution[109], representativeness[110], integrity, cleanliness and correctness[100], where correctness and accuracy were stated as individual components. However, these components were ill-defined.

3.4.2 Data quality strategies

Data quality strategies comprise error prevention and data cleaning processes. Error-prevention strategies reduce many problems but cannot eliminate them and therefore data cleaning deals with data problems once they have occurred[98, 99]. Known approaches to error prevention are detailed in Table 3-2.

Table 3-1: Components of data quality

Component	Reference	Definition	Measurement
Uniqueness	Orli 1996[99], Geiger 2007[109]	• The ability to establish the uniqueness of a data record (and data key values) • addresses the validity of the keys	Quickly compare the number of records with distinct instances of the primary key
Timeliness	Orli 1996[99], Geiger 2007[109]	The extent to which a data item or multiple items are provided at the time required or specified. A synonym for currency, the degree to which specified values are up to date	
Accuracy	Orli 1996[99], Dongre 2004[100], Geiger 2007[109], Bethell 2001[110]	▪ The measure or degree of agreement between a data value (or set of values) and a source assumed to be correct and a qualitative assessment of freedom from error ▪ addresses the correctness of the data	A quick assessment can quickly see if you have numeric fields where they don't belong, negative values for a field that should only have positive values, future dates for past events and other data that is obviously incorrect. While it is possible to spot some accuracy problems quickly, others may require verification against known values
Completeness	Orli 1996[99], Dongre 2004[100], Geiger 2007[109], Bethell 2001[110]	▪ The degree to which values are present in the attributes that require them ▪ addresses whether or not the field has a value	This is quickly detected by looking at the percent null. Additionally, an examination of frequently occurring values (e.g., 1/1/1900 as a date) may indicate that the operational system inserted a default value for a null condition. Understanding the completeness of fields that may be used as a selection criterion in the data warehouse is crucial to ensure that when a user looks at data segmented by that criterion, all of the expected data is provided
Consistency	Orli 1996[99], Dongre 2004[100],	Data are maintained so they are free from variation or contradiction. The measure of the degree to which a set of data satisfies a set of constraints	
Validity	Orli 1996[99]	The quality of the maintained data is rigorous enough to satisfy the acceptance requirements of the classification criteria. A condition where the data values pass all edits for acceptability, producing desired results.	

Table 3-2: Error prevention strategies (Roberts et al 1997[96], unless otherwise stated)

	Error prevention strategy
Data collection and coding	1. If existing records are being used (lab value sheets) then the sequence on the CRF should follow the sequence of the existing record. This helps to minimize systematic errors in data collection 2. Once data collection has begun, data should be coded soon after so that errors or questions can be corrected or subjects remeasured. 3. Coding should be present on CRF so the coder doesn't have to go between the form and a code book. Use of embedded coding instructions also facilitates data checking because data can be checked simultaneously with data entry. 4. There are coding schemes that also simplify later analysis. For example, dichotomous variables can be code as 0 and 1 to avoid recoding the variable 5. To minimize error coding should be performed by one person and checked by another. 6. Data collection points requiring calculations (eg mean BP) can be easily performed by a computer to avoid calculation errors on the part of the data collector.
Data entry	7. When assigning variable names to items that make up a scale, using the same 2 or 3 letters to start the variable names will ensure they appear sequentially in the list of variable names in the statistical software. 8. Hand-held computers can be used to eliminate the need for a paper record. This reduces the frequency with which the data can be manipulated and hence reduces the chance of error entering the data. 9. Appropriate design of the database schema and integrity constraints as well as of data entry applications are required[103]. 10. All tools should be designed with data entry efficiency in mind. Blocks of data items then a space will likely minimize misreading and incorrect key strokes because the values to be entered can be chunked[111]. 11. Data errors are minimized when record lengths are kept short and multiple records per case are used. Thus an ID number is required[111]. 12. Can set up the ranges of values to be identified while the file is set up, thus entry of out of range data is prevented. 13. Using optical scanning technology[112]. Although this technology reduces introduction of errors into data files it does not compensate for recording incorrect data on the instrument[113] and does introduce possible transcription errors. 14. Stats packages like SPSS can have a programme written to fill in logistical responses to questions and to skip items that are not relevant. 15. If data cleaning starts at same time as data collection, systematic errors can be identified.

Data cleaning is the process of detecting, diagnosing and editing/removing faulty data[98]. The goal is to obtain a set of data that contains a minimum of errors resulting from human factors in coding and data entry[114]. Data cleaning can also be used to determine the extent of error, where in the process the errors occurred, and whether the errors are systematic or random[96].

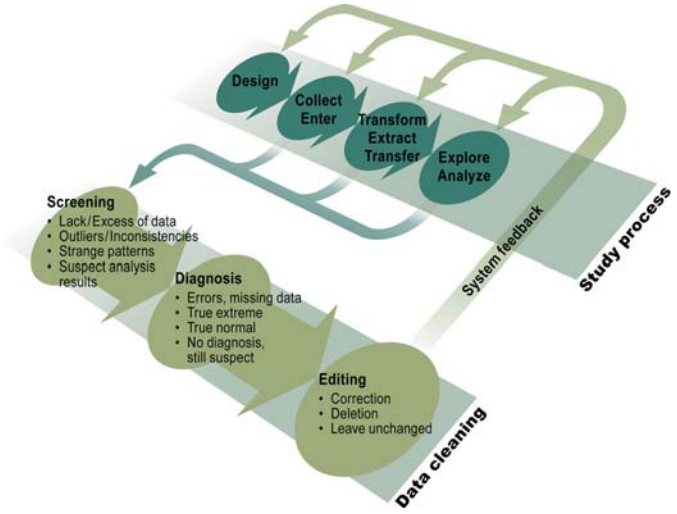
Data cleaning is a time-consuming exercise which requires a sound methodological strategy[100]. In addition to some practical data cleaning techniques (Table 3-3), a search of the literature identified three data cleaning frameworks[98, 99, 103], with Geiger[115] and Wright[116] describing the data profiling and error analysis components only, respectively.

Table 3-3: Data cleaning techniques

	Data cleaning techniques
Roberts et al 1997[96]	1. The raw data should be copied into a data file for computation and analysis so if computational errors or computer problems the raw data remains unchanged. 2. Personnel who know the data well are instrumental in identifying potential errors and can be essential in resolving them 3. Data should be entered twice into 2 separate files which can then be compared to identify inconsistencies 4. Random samples of subjects can be drawn and the data entered compared with that on the CRF. If multiple instruments for data collection are used, random samples should be drawn for each instrument to ensure thorough checking. 5. Each data collectors work should be checked
Dongre 2004[100]	6. Examination of listings of the records: visual inspection of fields for the appropriateness of the content and the correctness of the value. 7. Frequency distributions: Prior to doing them the researcher determines the upper and lower limits for the variables. Also identifies illegitimate values (eg. Those as fractions when should be whole numbers) 8. Cross tabulations: when certain combinations of variables are illegitimate. 9. Examination of entire record: examines a sample of records. Must make 2 decisions. The first is to determine the number of error-containing records that will be accepted before all records can be verified. The second is to determine the size of a sample of records that should be drawn and verified. 10. Multiple entry: constructing 2 duplicate data sets for comparison. Discrepant records are then verified against the original forms and the appropriate corrections made. Is more efficient for large data sets (>250 records).
Hayes 2004[102]	11. Descriptive analysis: identify missing information, incorrect coding, outliers and misaligned data. These findings precipitate checks against the original hard copy – time consuming element. 12. Double verification of entered data 13. Random checks of individual subjects against original: Use cross-tabulations to show impossible or unlikely combinations.
Suter 1986[111]	14. Scatterplots highlight suspicious combinations of values. 15. Double entry for double checking 16. Handling missing data: leave blank (code as missing in SPSS). 17. Recoding variables (computing) to create new variables can introduce errors. Frequency distributions on recoded and computed variables should always be inspected for errors.

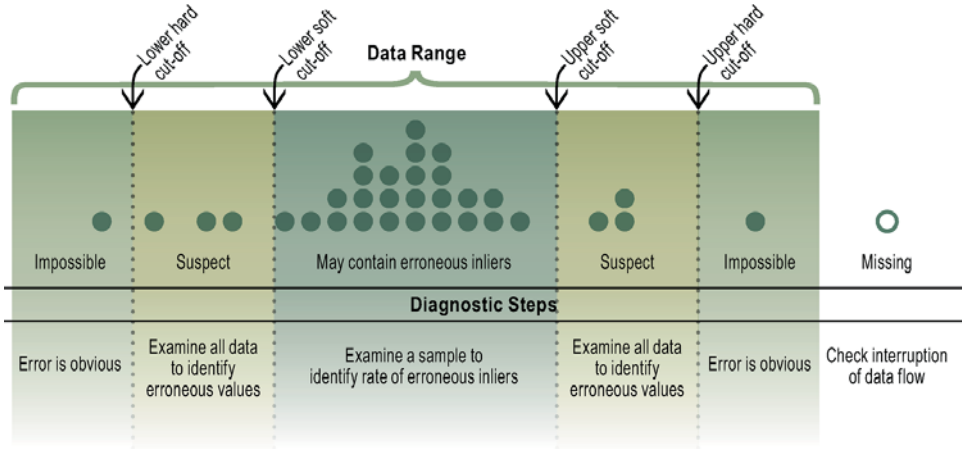
The Rahm and Do model[103] deals exclusively with computational data cleaning. However, while Orli[99] highlight the need for individual projects to deal with existing data and the processes that causes those errors, only Van der Broeck 2005[98] comprehensively includes data quality as a continuous process from study design to completion, although is branded as a data cleaning framework (Figure 3-1).

Figure 3-1: Van der Broeck 2005[98] Data cleaning framework



The screening, diagnosis and editing steps can be initiated at any stage during the study process but do rely on insight into the sources and types of errors at all stages of the study. As detailed in Figure 3-1, the screening phase is to identify four types of potential error. The data range identified, and the diagnostic steps required (Figure 3-2) aim to provide clarity of the true nature of the potential error identified. Finally, the editing phase involves deciding how to deal with the error, either to correct, delete or leave unchanged. The general rules for the editing phase are that a) impossible values should never be left unchanged but should be deleted if the correct value cannot be obtained, b) for biological measurements some within-subject variation should be considered acceptable, c) additional individual and group investigation may be required for true extreme values and values that are still suspect after the diagnostic phase.

Figure 3-2: Data range in screening and diagnostic steps required to clarify diagnosis[98].

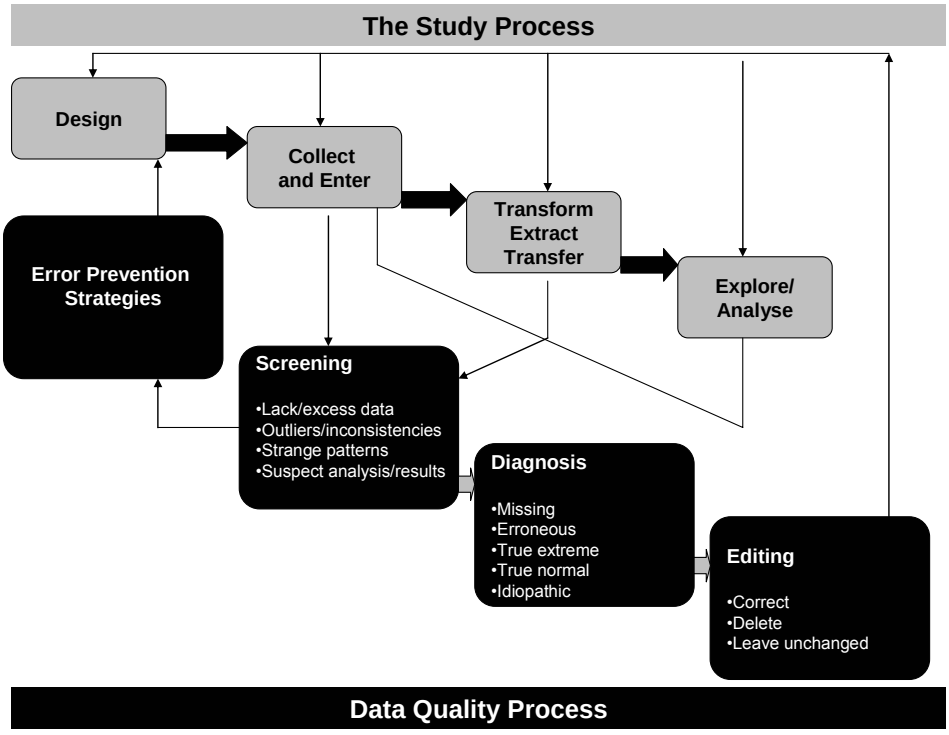


3.5 METHODS

3.5.1 Design

A modified Van der Broeck[98] framework (Figure 3-1) was utilised incorporating specific practical strategies from a variety of other sources (Figure 3-3).

Figure 3-3: Data quality strategy



3.5.2 Time-points

Error prevention strategies were employed at the Design and Collect/enter phase following completion of the Pilot study. Some data cleaning occurred at the Collect/enter phase at the end of pilot phases I and II (uniqueness, accuracy of coding, completeness: not reported here) with the most extensive data cleaning being commenced at the end of all data entry following completion of Phase IV recruitment. Subsequent data errors noted during the Explore/Analyse steps of the study process were also noted, diagnosed and treated.

3.5.3 Error prevention strategy

The error prevention strategies 1-4 and 6-12 detailed in Table 5.2 were employed within the Design and Collect/enter I steps of the study process. Strategies 13 and 14 were not appropriate as optical scanning techniques were not utilised in the study and Microsoft Access (not SPSS) was used for data storage, respectively. Strategy 5 was also not applicable as I was a lone researcher, resulting in strategy 15 not being able to commence at start of data collection, but was delayed until the end of Phase I of the pilot study data collection. Furthermore, while in accordance with strategy 3 most coding was present on the CRF, some coding of free-text fields (for example, additional morbidities, pre-operative medications) occurred at the end of the pilot study which was as the earliest opportunity, as suggested within strategy 2. The CRF was designed with variables blocked in accordance to flow of data collection (administrative information, pre-operative information, intra-operative information and post-operative days in date order) and, within that, sources of data collection (for example, all drugs grouped together for collection from the drug chart). The database mirrored the data collection flow with each time-point entered into a separate data entry table to ease data entry and minimise errors (strategies 9-11). Additionally, data validation rules were constructed in the database, where appropriate, in accordance with strategy 12.

3.5.4 Data cleaning strategy

3.5.4.1 Screening

To identify 3 of the 4 types of potential errors (lack/excess of data; outliers/inconsistencies; strange patterns), exploration of the components of data quality (Table 3-1) was undertaken using the strategies 3-17 (excluding 5) detailed in Table 3-3. Strategy 5 was not relevant since there was only one data collector, and the assessment of timeliness was not applicable as all data were collected at the appropriate times. The suspect analysis errors are detailed in section 5.3.3.4. All tasks were conducted in Microsoft Access through frequency distributions and data query functions and all assessments were done in the order indicated below, as each had the potential to affect the next.

a) Uniqueness

The distinct instances of the primary key (unique study identifier) was assessed in each of the data tables within the database by ensuring the correct frequency of records were present and whether duplicates of the primary key existed (Microsoft Access 'Find duplicates query wizard')

b) Accuracy

The accuracy of the data was assessed individually for each data variable within each data table. Pre-defined quality criteria were that all clinical variables and blood results would be considered within acceptable range if within two-times the upper/lower normal range, as defined by centre norms (Appendix 2). Visual assessments included that the type of information in the field was correct, of expected length (decimal places or characters) and that the information was within the expected range (either coding range or clinically reasonable). Those considered suspect or impossible were indicated to establish diagnosis.

Using a random number generator in Microsoft Excel, (where column A is the patient number between 1-464 (=FLOOR(1+A$1*RAND(),1), column B is section in C-POMS (=FLOOR(1+B$1*RAND(),1) and where F9 refreshes the list) 10 participants were identified for each data table for multiple entry (one repeat data entry by data enterer), 5 for the examination of the entire record and 10 for random checks between the CRF and database entries.

c) Completeness

The completeness of the data was assessed for each data variable within each data table individually. For variables attributable to an indicator field, data completeness was related to the indicator field and not the dataset overall. Incompleteness was defined as the percentage null or coded as not stated (not stated in medical notes) or missing (missing in CRF). The residual incompleteness was defined as overall incompleteness (include not stated/not done) not only dataset incompleteness. The pre-defined quality criteria was that 0% incompleteness should be attempted for all variables, thus all variables above this threshold were subject to re-exploration.

d) Consistency

Consistency assessments were undertaken in variables where it was possible:

a) Unique identifier across all data tables
b) Dates across all post-operative data tables from day of operation. For example DODay1-DOOP should be 1, DODay3-DOOP should be 3
c) Neurological history: consistency between C-POMS and SCTS data
d) Pulmonary disease history: consistency between C-POMS and SCTS data
e) C-POMS coding of categories:
    I. The coding of each variable within each category was checked.

II. Each post-operative day compared against pre-operative coding for each variable to ensure consistency in coding for morbidity 'new' or 'not new'. Exception to this rule was 'ischaemia/MI' in the cardiovascular category and the haematological category

e) Validity

The representativeness of the population characteristics of those who did and did not participate in the study was assessed. Cross tabulation for categorical variables and comparing means of continuous variables in SPSS was conducted. Statistical significance was taken at the $p<0.05$ level. The results of all the data quality assessments were considered by the PDG (meeting 3) to determine if the data were 'fit for purpose'.

3.5.4.2 Diagnosis

A 2-tier level to confirm diagnosis was employed on all variables indicated as potential errors. Firstly all suspect, impossible or missing variables were checked in the CRF and, if not resolved, the medical records were then examined. A diagnosis of missing, erroneous (incorrect/wrong) true extreme, true normal (prior expectation was incorrect), idiopathic (unknown) was applied to all indicated potential errors.

3.5.4.3 Editing

Prior to any data editing, a copy of the raw data was saved as a separate file, as per strategy 1 (Table 3-3). The treatment plan options were correcting, deleting and leaving unchanged. Pre-defined quality criteria are that any missing values subsequently identified are corrected, true extreme and true normal values are left unchanged and idiopathic errors are deleted and then become a missing value.

3.5.4.4 Suspect analysis/results

These data errors, their diagnosis and treatment, were identified during data analysis.

3.6 RESULTS

3.6.1 Uniqueness

Each data table had the required number of records and were without duplicate unique study identifiers.

3.6.2 Accuracy

Of the 1234 data fields, 138 (11.2%) were assessed as having potential inaccuracies affecting 532 entries of which 259 (48.7%) were erroneous, 251 (47.2%) were true extreme and 21 (3.9%) were true normal. The true extreme and true normal values were left unchanged and 5 (1.9%) of the erroneous values were deleted as subsequently diagnosed as idiopathic. The remaining erroneous

values were corrected. Summary details for the accuracy assessments in each data table are detailed in Table 3-4.

Table 3-4: Summary of accuracy assessment results. Values are n(%).

Table	% pre-screening potential inaccuracy (mean)	Erroneous (n=259 entries)	True extreme (n=251 entries)	True normal (n=21 entries)
Admin	0.004	1 (0.4)	2 (0.8)	1 (4.8)
Pre-operative	0.18	99 (38.2)	20 (8.0)	2 (9.5)
Intra-operative	0.04	33 (12.7)	15 (6.0)	0 (0.0)
C-POMS D1	0.10	28 (10.8)	2 (1.2)	0 (0.0)
C-POMS D3	0.09	18 (6.9)	38 (15.1)	0 (0.0)
C-POMS D5	0.05	5 (1.9)	27 (10.8)	0 (0.0)
C-POMS D8	0.13	28 (10.8)	61 (24.3)	0 (0.0)
C-POMS D15	0.10	0 (0.0)	73 (29.1)	0 (0.0)
Outcome	0.24	26 (10.0)	0 (0.0)	0 (0.0)
SCTS	0.13	21 (8.1)	13 (5.2)	18 (85.7)

The accuracy assessments also highlighted that some fields required further coding (Additional DOOP comments, Other infusions, D1 comments, DC services comments) and that some fields were redundant (pre-operative creat >50% in the pre-operative table, as irrelevant pre-operatively; wound culture treatment on D3, D5, D8 and D15 in the C-POMS tables, as will be defined within antibiotic field in the infectious POMS domain.)

3.6.2.1 Multiple entry

Overall, 81 (6.9%) of fields in the dataset had discrepancies (Table 3-5). Sixty-eight (84.0%) of those fields had errors in one pair of entries, 8 (9.9%) had errors in 2 pairs of entries, 2 (2.5%) had errors in 3 pairs of entries and 3 (3.7%) had errors in all 5 pairs.

Table 3-5: Summary of multiple entry errors

Table	Total number of fields	Fields with errors n(%)
Admin	19 (not incl NHS no)	0 (0)
Pre-operative (including C-POMS)	225	6 (2.7)
Intra-operative	172	11 (6.4)
C-POMS D1	143	7 (4.9)
C-POMS D3	142	17 (12.0)
C-POMS D5	152	7 (4.6)
C-POMS D8	151	15 (9.9)
C-POMS D15	150	14 (9.3)
Outcome	23	4 (17.4)
Total	*1177*	*81 (6.9)*

Table 3-6 details the specific results. Thirty-four (38.3%) and 40 (49.4%) of the errors were attributed to the first and second entry, respectively, with 4 (4.9%) of errors being attributable to either entry and in 3 (3.7%) where the fields in the whole dataset need re-examination (D1 wound drain, D1 wound complication, D1 assisted ambulation type). These errors were attributable to incorrect value/code/data entry errors (n=36, 44.4%; 3.0% of all variables), an incorrect indicator field code (n=20, 24.7%), data being obtained from different source (not CRF) (n=13, 16.0%), field introduction after pilot study/change in data collection during study (n=5, 6.2%) and the presence of mixed results within field (n=4, 4.9%).

Errors attributed to the first entry were examined individually in the database. Eleven (32.4%) were already corrected within the database from data cleaning efforts. 23 (67.6%) remained inaccurate and were changed in the database of which 20 (58.8%) were erroneous inliers and 3 (8.8%) were changed from missing.

3.6.2.2 Examination of entire records

Examination of the entire record of CP161, CP261, CP271, CP319, CP361 detected no errors.

3.6.2.3 Random checks

Examination of records CP100 (pre-operative data), CP106 (CPOMS D1 and D8), CP165 (intra-operative data), CP282 (C-POMS D3 and D5) and CP454 (administrative and outcome data) detected no errors. C-POMS D15 data were not checked as no numbers were generated for participants still an inpatient on D15.

Table 3-6: Detailed results of discrepancies detected during multiple entry

Table	Field	Error (number of pairs)	Discrepancy check	Reason for discrepancy	*First entry errors checked in database
Pre-operative	DOpreopCXR	1 (CP313)	Error on 2nd entry	Data from different source (not on CRF)	
	COPD	2 (CP056, CP313)	CP056: **Error on 1st entry** CP313: Error on 2nd entry	Incorrect code	Already changed in database
	Pre albumin	1 (CP056)	Error on 2nd entry	Incorrect value	
	H2 agonsist	1 (CP207)	**Error on 1st entry**	Not routine variable in 1st entry. Coded at end of study	Already changed in database through data cleaning methods
	Other2 state dose	1 (CP207)	Error on either	Monday dose stated in entry 1 and combined weekly dose coded on entry 2	
	Other3 state drug	1 (CP207)	Error on either	Too many drugs to enter	
Intra-operative	Anaes room time	1 (CP377)	Error on 2nd entry	Data from different source (not on CRF)	
	Anaes start	1 (CP377)	Error on 2nd entry	Data from different source (not on CRF)	
	Enter theatre	1 (CP377)	Error on 2nd entry	Data from different source (not on CRF)	
	Skin prep	1 (CP377)	Error on 2nd entry	Data from different source (not on CRF)	
	Op end	1 (CP377)	Error on 2nd entry	Data from different source (not on CRF)	
	Leave theatre	1 (CP377)	Error on 2nd entry	Data from different source (not on CRF)	
	PORR vent or ext	1 (CP125)	Error on 2nd entry	Incorrect code	
	Temp (1st)	1 (CP125)	**Error on 1st entry**	Incorrect value (coding Fields for first entries changed to 1st and highest during study).	Changed in database to correct entry
	Temp (high)	2 (CP123, CP125)	**Both: Error on 1st entry**	Incorrect value (coding Fields for first entries changed to 1st and highest during study)	Changed in database to correct entry
	D1 heart rhythm	1 (CP377)	Error on 2nd entry	Incorrect coding	
	D1 heart rhythm other	1 (CP377)	Error on 2nd entry	Error related to incorrect code in indicator field	
C-POMS D1	D1 Oxy Supp?	1 (CP212)	**Error on 1st entry**	Incorrect code	Changed in database to correct entry
	D1 Renal new	1 (CP212)	Error on 2nd entry	Incorrect code	
	D1 IV frusemide	1 (CP082)	Error on 2nd entry	Incorrect code	
	D1 creat >30%	3 (CP212, CP273,	Error on 2nd entry	Data from different source (not on CRF)	

		CP423)			
	D1 wound drain	5		To check whole dataset	
	D1 wound compl	5		To check whole dataset	
	Assisted ambulation type	5		To check whole dataset	
C-POMS D3	D3 ward transfer	1 (CP021)	**Error on 1st entry**	Incorrect code	Changed in database to correct entry
	D3 How much oxy?	2 (CP021, CP027)	Both: Error on 2nd entry:	Incorrect value	
	D3 Fragmin	1 (CP021)	Error on 2nd entry	Incorrect code	
	D3 Frusemide	1 (CP098)	Error on 2nd entry	Incorrect code	
	D3 creat >30%	2 (CP242, CP349)	Both: Error on 2nd entry	Data from different source (not on CRF)	
	D3 hypotension	1 (CP349)	**Error on 1st entry**	Incorrect code	Changed in database to correct entry
	D3 Hypo new?	1 (CP349)	**Error on 1st entry**	Error related to incorrect code in indicator field	Changed in database to correct entry
	D3 Hypo test	1 (CP349)	**Error on 1st entry**	Error related to incorrect code in indicator field	Changed in database to correct entry
	D3 Hypo diag	1 (CP349)	**Error on 1st entry**	Error related to incorrect code in indicator field	Changed in database to correct entry
	D3 Hypo treated	1 (CP349)	**Error on 1st entry**	Error related to incorrect code in indicator field	Changed in database to correct entry
	D3 Hypo Rx	1 (CP349)	**Error on 1st entry**	Error related to incorrect code in indicator field	Changed in database to correct entry
	D3 Arrhy treated	1 (CP021)	Error on 2nd entry	Incorrect code	
	D3 Assisted ambulation	1 (CP021)	Error on 2nd entry	Incorrect code	
	D3 Assisted ambul new?	1 (CP021)	Error on 2nd entry	Error related to incorrect code in indicator field	
	D3 Assisted ambul type	1 (CP021)	Error on 2nd entry	Error related to incorrect code in indicator field	
	D3 Hypotension (fluid)	1 (CP027)	**Error on 1st entry**	Pilot study: Field introduced after pilot study and data merged at end of study	Already changed in database through data cleaning methods
	D3 Hypotension comments	1 CP027)	**Error on 1st entry**	Error related to incorrect code in indicator field	Already changed in database through data cleaning methods
C-POMS D5	D5 How much oxy?	1 (CP181)	**Error on 1st entry**	Incorrect code	Already changed in database through data cleaning methods

	D5 state inotropes	1 (CP181)	**Error on 1st entry**	Incorrect code	Already changed in database through data cleaning methods
	D5 Wound culture	1 (CP181)	Error on 2nd entry	Data from different source (not on CRF)	
	D5 Wound culture results	1 (CP181)	Error on 2nd entry	Error related to incorrect code in indicator field	
	D5 Social reasons	1 (CP127)	Error on 2nd entry	Incorrect code	
	D5 Other medical	1 (CP255)	**Error on 1st entry**	Incorrect code	Changed in database to correct entry
	D5 Other medical state	1 (CP255)	**Error on 1st entry**	Error related to incorrect code in indicator field	Changed in database to correct entry
C-POMS D8	D8 ward transfer	2 (CP032, CP043)	**Both: Error on 1st entry**	Incorrect value	Changed in database to correct entry
	D8 How much oxy?	1 (CP043)	Error on 2nd entry	Incorrect value	
	D8 SaO2	1 (CP349)	Error on 2nd entry	Incorrect value	
	D8 wound complication	1 (CP281)	**Error on 1st entry**	Incorrect code	Changed in database to correct entry
	D8 Pul oed/anticoag	1 (CP032)	Error on 2nd entry	Data from different source (not on CRF)	
	D8 Pul oed/anticoag new?	1 (CP032)	Error on 2nd entry	Error related to incorrect code in indicator field	
	D8 Pul oed/anticoag test	1 (CP032)	Error on 2nd entry	Error related to incorrect code in indicator field	
	D8 Pul oed/anticoag diag	1 (CP032)	Error on 2nd entry	Error related to incorrect code in indicator field	
	D8 Neuro state	1 (CP032)	**Error on 1st entry**	Incorrect code	Changed in database to correct entry
	D8 Neuro comments	1 (CP032)	**Error on 1st entry**	Error related to incorrect code in indicator field	Changed in database to correct entry
	D8 Assisted ambulation type	1 (CP032)	**Error on 1st entry**	Incorrect code	Changed in database to correct entry
	D8 IV Frusemide	1 (CP043)	**Error on 1st entry**	Pilot study: Field introduced after pilot study and	Already changed in database through

	given			data merged at end of study.	data cleaning methods
	D8 IV Frusemide comment	1 (CP043)	**Error on 1st entry**	Error related to incorrect code in indicator field	Already changed in database through data cleaning methods
	D8 INR	1 (CP349)	**Error on 1st entry**	Field introduced after pilot study and data merged at end of study.	Changed in database to correct entry
	D8 Periph oed	1 (CP349)	**Error on 1st entry**	Field introduced after pilot study and data merged at end of study.	Changed in database to correct entry
C-POMS D15	D15 SaO2	1 (CP128)	**Error on 1st entry**	Incorrect value	Changed in database to correct entry
	D15 wound site	1 (CP154)	**Error on 1st entry**	Incorrect code	Changed in database to correct entry
	D15 Wound culture	1 (CP154)	Error on 2nd entry	Data from different source (not on CRF)	
	D15 Wound culture result	1 (CP154)	Error on 2nd entry	Error related to incorrect code in indicator field	
	D15 intol type ent diet	1 (CP154)	Error on 2nd entry	Incorrect value	
	D15 Dysrhythm treated	1 (CP418)	**Error on 1st entry**	Incorrect value	Already changed in database through data cleaning methods
	D15 Dysrhtyhm Rx	2 (CP264, CP418)	**Both: Error on 1st entry**	CP418: Error related to incorrect code in indicator field CP264: Incorrect text (Data in wrong field)	Already changed in database through data cleaning methods
	D15 Hypertension Rx	1 (CP154)	**Error on 1st entry**	Incorrect code	Already changed in database through data cleaning methods
	D15 Hypertension comments	1 (CP154)	**Error on 1st entry**	Error related to incorrect code in indicator field	Already changed in database through data cleaning methods
	D15 INR	1 (CP156)	Error on 2nd entry	Incorrect code	
	D15 Incr wt	1 (CP156)	Error on 2nd entry	Incorrect code	
	D15 Incr wt comments	1 (CP156)	Error on 2nd entry	Error related to incorrect code in indicator field	
	D15 Other medical	1 (CP128)	**Error on 1st entry**	Incorrect code (not reason for delayed discharge)	Changed in database to correct entry

	D15 Other medical comments	1 (CP128)	**Error on 1st entry**	Error related to incorrect code in indicator field	Changed in database to correct entry
Outcome	Dest from ICU	1 (CP006)	Error on 2nd entry	Data from different source (not on CRF)	
	DC services	3 (CP006, CP060, CP189)	CP006: Error on 2nd entry CP060: Error on 2nd entry CP189: **Error on 1st entry**	CP006: Field introduced after pilot study and collected retrospectively thus data from different source (not on CRF) CP060 and CP189: Incorrect coding	
	DC DN	2 (CP006, CP060)	CP006: Error on 2nd entry CP060: Error on 2nd entry	CP006: Field introduced after pilot study and collected retrospectively thus data from different source (not on CRF) CP060: Error related to incorrect code in indicator field	
	DC SS	2 (CP006, CP060)	CP006: Error on 2nd entry CP060: Error on 2nd entry	CP006: Field introduced after pilot study and collected retrospectively thus data from different source (not on CRF) CP060: Error related to incorrect code in indicator field	

3.6.3 Completeness

Prior to data cleaning, the mean incompleteness of the dataset was 2.8%, reducing to 1.4% post-cleaning (Table 3-7). All data tables had over 93% completeness post-cleaning, with admin, intra-op, C-POMS D1-D15 all exhibiting over 99% completeness. Overall, 52.8% and 77.9% of variables were 100% and >99% complete, respectively pre-cleaning, increasing to 67.7% and 90%, respectively post-cleaning. The SCTS database was the poorest performing with overall incompleteness of 6.8% and only 30.4% of variables with 100% completeness and 48.2% of variables with >99% completeness while 7 of the other 9 data tables exhibited >99% completeness in more than 92% of variables post-cleaning.

Table 3-7: Summary of data completeness

	Descriptives (mean% ± SD)		**Variables with 100% completeness**		**Variables with >99% completeness**	
	Screen	**Post-cleaning**	**Screen**	**Post-cleaning**	**Screen**	**Post-cleaning**
Admin	0.2 ±4.8	0.18 ± 4.8	17 (85.0)	17 (85.0)	19 (95.0)	19 (95.0)
Pre-op	2.5 ± 6.6	2.23 ± 6.4	133 (59.1)	151 (67.1)	189 (84.4)	194 (86.2)
Intra-op	1.1 ± 5.5	0.9 ± 5.5	78 (45.3)	94 (54.7)	155 (90.1)	159 (92.4)
CPOMS D1	2.6 ± 6.5	0.4 ± 1.1	72 (50.3)	81 (56.6)	119 (83.2)	134 (93.7)
CPOMS D3	2.9 ± 6.9	0.8 ± 3.4	69 (48.6)	94 (66.2)	118 (83.1)	133 (93.7)
CPOMS D5	3.0 ± 8.1	1.0 ± 5.7	85 (55.9)	126 (82.9)	125 (82.2)	142 (93.4)
CPOMS D8	2.4 ± 6.1	1.0 ± 4.6	88 (58.3)	94 (62.3)	121 (80.1)	140 (92.7)
CPOMS D15	2.4 ± 6.1	1.0 ± 4.6	90 (60.0)	144 (96.0)	90 (60.0)	144 (96.0)
Outcome	3.1 ± 11.8	2.7 ± 11.2	14 (60.9)	17 (73.9)	16 (69.6)	19 (82.6)
SCTS	7.8 ± 18.9	6.8 ± 19.2	6 (10.7)	17 (30.4)	8 (14.3)	27 (48.2)
All	*2.8 ± 7.8*	*1.4 ± 6.5*	*652 (52.8)*	*835 (67.7)*	*960 (77.9)*	*1111 (90.0)*

Despite some records exhibiting significant amounts of residual incompleteness (Table 3-8), no records were deleted since only sections of the data, and not the whole record, were affected in each case.

Table 3-8: Records with high residual incompleteness

Study number	Reason	Table	Residual missing in indicator field n(%)
CP004	No anaesthetic chart, ICU charts for DOOP/D1 in notes	Intra-op CPOMS D3	39 (42.4) 40 (66.7)
CP035	No D1 ICU chart	Intra-op	12 (13.0)
CP059	Notes not received	Intra-op	11 (12.0)
CP065	Notes received but no notes pertaining to this admission	CPOMS D8	52 (77.6)
CP122	Notes received but no ICU/drug charts	CPOMS D1	22 (36.1)
CP123	Notes not received	CPOMS D1	20 (32.8)
CP196	Obs chart missing in medical notes	Pre-op	5 (5.6)
CP215	Notes not received	Pre-op CPOMS	5 (5.6)
CP238	No D1 ICU chart in notes	Intra-op, CPOMS D1	18 (19.6) 51 (83.6)
CP245	Notes received but no notes for that day (? Transferred o/n)	CPOMS D5	11 (16.4)
CP297	Drug related fields only as no drug charts and medical notes not received	Pre-op	31 (34.4)

Cause of death, days ventilated and circulatory arrest time, all variables from the SCTS database, had 100%, 41.6% and 99.1% incompleteness, respectively and ASA (intra-operative table) had 55.3% missing data. Thus, each was deleted from analysis.

3.6.4 Consistency

3.6.4.1 Unique identifier

With the exception of the administrative table, complete consistency across all tables was identified with the unique study number. The administrative table contained the 14 participants who gave consent to participate but did not complete the study.

3.6.4.2 Dates throughout all data tables

Complete data consistency of dates was observed on D8, with <1% error identified at all other post-operative time-points (Table 3-9). All errors were erroneous and corrected, thus resulting in 100% consistency on all days.

Table 3-9: Date inconsistencies on post-operative data time-points from day of operation.

Table	Screen (% inaccurate)	Diagnosis	Treatment plan	Comments
C-POMS D1 (n=450)	0.4	Erroneous	Correct	CP180 (DOOP) CP439 (DODay1): Correct from CRF. Corrected from CDR
C-POMS D3 (n=450)	0.2	Erroneous	Correct	CP180: Corrected DOOP from CDR
C-POMS D5 (n=426)	0.7	Erroneous	Correct	CP012, CP224: Corrected from CRF. CP180: Corrected DOOP from CDR,
C-POMS D8 (n=181)	0.0	Erroneous	Correct	
C-POMS D15 (n=48)	0.2	Erroneous	Correct	CP385: Correct from CRF. Corrected from CDR.

DOOP = Date of operation; DODay1 = date of D1; CDR = Clinical Data Repository; CRF = Case Report Form.

3.6.4.3 Neurological history

A neurological history was recorded in 32 (7.1%) participants in C-POMS and 31 (6.9%) in SCTS. Agreement was observed in 28 participants (87.5%) while there were 4 (12.5%) participants identified that had a neurological history identified in C-POMS but not SCTS and 3 (9.4%) that had a neurological history recorded in SCTS but not C-POMS (Table 3-10). The medical notes of each of the 7 discrepancies were requested but were unavailable. Thus, it was concluded that those in C-POMS but not SCTS would remain in the database as there was enough information for the entry to be valid and unlikely to be due to data entry. However, those in SCTS but not C-POMS were not added since without verification from the medical notes there was insufficient information not to exclude data entry error. Furthermore, there was sufficient confidence in the C-POMS data collection to be assured that it ws unlikely those cases were missed.

Table 3-10: Consistency between C-POMS and SCTS data collection of neurological history

	C-POMS database	Checked with medical notes	SCTS database	Checked with medical notes
Those with neurological history in C-POMS but not SCTS (to check medical notes)	CP039: slight TIA 10yrs ago CP364: L cortical infarct 2002 CP384: ?? TIA CP402:TIA 3yrs ago, complete recovery	CP039: medical notes not received CP364: medical notes not received CP384: medical notes not received CP402: medical notes not received	-	
Those with neurological history in SCTS but not C-POMS (to check medical notes)	-	-	CP038: TIA or RIND CP186: TIA or RIND CP221: CVA with full recovery	CP038: medical notes not received CP186: medical notes not received CP221: medical notes not received

3.6.4.4 Pulmonary disease

A history of pulmonary disease was recorded in 62 (13.8%) participants in C-POMS and 45 (10%) in SCTS. All those identified within SCTS were observed in C-POMS. Of the 17 identified in C-POMS but not SCTS, 6 were erroneous data entries and were corrected.

3.6.4.5 POMS coding of categories

Erroneous errors were detected in POMS coding on D1 (0.7%), D3 (1.6%), D5 (2.4%), D8 (1.1%) and D15 (1.1%) (Table 3-11). All treatment plans were to correct, which were implemented leaving no residual POMS coding errors.

3.6.5 Validity

Overall, those participating in the study were significantly older with a higher percentage of Caucasians and hypertensive patients in comparison to those who didn't participate in the study (Table 3-12). Those in C-POMS also had a lower EuroSCORE with lower mean ICU and post-operative length of stay. When comparing the characteristics of those who did and did not participate in the CPOMS study during each of the recruitment phases (Table 3-13) there were no significant differences during phase I and II. During Phase III there were significantly more Caucasians in the study and a lower mean EuroSCORE was observed overall in the study group. During Phase IV again there were more Caucasians, more hypertensives and more single procedure surgery than those not in the study with an overall reduced mean length of ICU stay in the study group.

On review of the data quality strategy and results, the PDG deemed sufficient face validity was observed that the data did accurately represent the data aimed to be collected, with sufficient accuracy for decision making to be made on this data.

Table 3-11: Consistency of POMS domain coding

	Pre-operative		CPOMS D1		CPOMS D3		CPOMS D5		CPOMS D8		CPOMS D15	
	Screen (n)	**Comments**	**Screen (n)**	**Comments**	**Screen (n)**	**Comments**	**Screen (n)**	**Comments**	**Screen (n)**	**Comments**	**Screen (n)**	**Comments**
Pulmonary	**13**	Correct	**449**	Correct	**303**	Correct	**113**		**50**	CP002: corrected to 'not new'	**14**	Correct
Supplementary oxygen	13	Correct	373	Correct	**303**	CP159 corrected to 'new'	113	CP199 corrected coding of type of suppl	50	CP419, CP443: checked but correct	14	Correct
Infectious	**12**	Correct	376	Correct	**109**	Correct	**154**	CP258: Corrected coding. CP168: Corrected to new	**99**	CP168: corrected to 'new'. CP397: Corrected coding as antibiotics present (99 to 100)	**28**	Correct
Antibiotics	11	Correct	376	CP063 changed to 'not new'	109	CP062 corrected to 'new'	152	Correct	100	Correct	28	Correct
Temperature	1	Correct	19	Correct	21	Correct	5	Correct	2	Correct	1	Correct
Renal	**12**	Correct	**44**	CP429 corrected	**154**	CP297: corrected coding	**67**	Correct	**45**	Correct	**18**	Correct
Oliguria	6	Correct	11	CP004, CP386: Checked but correct	15	Correct	11	Correct	4	Correct	1	Correct
Creatinine	NA	Correct	26	Correct	56	Correct	25	Correct	21	Correct	5	Correct

Catheter	4	Correct	448	CP429 as missing in renal	142	Correct	61	Correct	33	CP263: not coded as 'not new' as pre-op catheter not a long-term catheter	13	Correct
RRT	7	Correct	8	Correct	11	CP004: corrected from 'no' to 'missing'	12	Correct	5	Correct	1	Correct
Gastrointestinal	**10**	Correct	**230**	Correct	**112**	Correct	**93**	CP058: Corrected coding	**38**	Correct	**8**	Correct
Nausea	7	Correct	224	Correct	92	Correct	75	Correct	31	CP107: corrected to 'not new'	5	Correct
Vomiting	2	Correct	80	Correct	21	Correct	11	Correct	2	Correct	0	Correct
Abdominal distension	1	Correct	1	Correct	20	Correct	22	CP158, CP235, CP285, CP446: Corrected to 'new'	8	Correct	7	4 not new: all erroneous and corrected
Cardiovascular	**66**	Correct	**223**	Correct	**196**	Correct	**184**	Correct	**104**	Correct	**28**	Correct
Ischaemia/MI	9	Correct	15	Correct	4	Correct	0	Correct	0	Correct	0	Correct
Hypotension	1	Correct	132	Correct	37	Correct	15	Correct	5	Correct	5	Correct
Arrhythmias	38 (corrected to 42 after post-op	Correct	93	32 checked: all correct	152	CP106, CP123, CP341: Corrected	162	CP295, CP420, CP422: Corrected to	86	Correct	25	CP013: corrected to 'new'

	checks)					pre-op coding		‘not new’				
Pulmonary oedema/anticoag	53	Correct	44	Correct	60	Correct	56	Correct	41	CP273: check Factor V Laden	8	Correct
Neurological	**1**	Correct	**69**	Correct	**80**	Correct	**45**	Correct	**27**	Correct	**8**	Correct
Focal deficit	0	Correct	2	Correct	6	Correct	7	Correct	7	Correct	2	Correct
Confusion	1	Correct	35	Correct	25	Correct	18	Correct	14	Correct	5	Correct
Delirium	0	Correct	27	Correct	44	Correct	17	Correct	4	Correct	0	Correct
Coma	0	Correct	2	Agitated = 3	1	Agitated = 4	1	Agitated = 2	1	Agitated =1.	4	Correct
Haematological	**2**	Correct	**67**	Neither pre-op in this group	**12**	Correct	**6**		**8**		**4**	Correct
RBC	1	Correct	63	Correct	11	Correct	6	Correct	8	Correct	4	Correct
Platelets	1	Correct	3	Correct	1	Correct	0	Correct	0	Correct	0	Correct
FFP	0	Correct	10	Correct	0	Correct	0	Correct	0	Correct	0	Correct
Cryoprecipitates	0	Correct	2	Correct	0	Correct	0	Correct	0	Correct	0	Correct
Wound	**0**	Correct	**449**	Correct	**11**	Correct	**7**	Correct	**12**	Correct	**11**	Correct
Surgical	0	Correct	1	Correct	0	Correct	2	Correct	3	Correct	0	Correct
Drainage	0	Correct	449	Correct	11	Correct	7	Correct	11	Correct	11	Correct
Pain	**2**	Correct	**430**	CP036, CP038: checked but correct	**9**	Correct	**11**	Correct	**9**	Correct	**3**	Correct

Table 3-12: Comparison of patients who did and did not participate in the study. Values are n(%) unless otherwise stated.

	In C-POMS (n=450)	Not in C-POMS (n=298)	p
Age (mean/years)	66.5	64.1	0.01
Gender (female)	93 (20.7)	77 (25.8)	0.06
Ethnicity - Caucasian	384 (86.1)	198 (74.4)	0.001
- Asian	39 (8.7)	37 (13.9)	
- Black	16 (3.6)	19 (7.1)	
- Other	7 (1.6)	12 (4.5)	
Hypertension	332 (73.8)	196 (66.7)	0.02
Diabetes	105 (23.3)	68 (23.0)	0.49
Smoking - Current	49 (10.9)	37 (12.6)	0.51
- Ex	250 (55.6)	151 (51.4)	
- Never	151 (33.6)	106 (36.1)	
LVEF - Good	327 (74.1)	206 (71.8)	0.72
- Fair	90 (20.4)	62 (21.6)	
- Poor	24 (5.4)	19 (6.6)	
EuroSCORE (mean)	4.2	5.0	0.00
Op Type - CABG	301 (66.9)	178 (60.5)	0.06
- AVR	61 (13.6)	34 (11.6)	
- MVR	11 (2.4)	14 (4.8)	
- CABG + AVR	37 (8.2)	23 (7.8)	
- CABG + MVR	1 (0.2)	4 (1.4)	
- AVR and MVR	3 (0.7)	6 (2.0)	
- CABG +AVR+MVR	2 (0.4)	2 (0.7)	
- Other	34 (7.6)	33 (11.2)	
ICU LOS (mean/nights)	2.1	2.8	0.05
Post-op LOS (mean/days)	9.6	10.5	0.27

Table 3-13: Comparing patients that did and did not participate in the study in each of the three recruitment phases. Values are n(%) unless otherwise stated.

	Phase I and II (n=230)			Phase III (n=180)			Phase III (n=338)		
	In C-POMS (n=100)	Not in C-POMS (n=130)	p	In C-POMS (n=100)	Not in C-POMS (n=80)	p	In C-POMS (n=250)	Not in C-POMS (n=88)	p
Age (mean/years)	66.9	64.1	0.07	66.5	63.8	0.17	66.3	64.4	0.18
Gender (female)	23 (23.0)	30 (23.1)	0.56	26 (26.0)	27 (33.8)	0.17	44 (17.6)	20 (22.7)	0.18
Ethnicity – Caucasian	85 (86.7)	94 (76.4)	0.19	90 (90.0)	49 (74.2)	0.01	209 (84.3)	55 (71.4)	0.02
- Asian	7 (7.1)	19 (15.4)		8 (8.0)	8 (12.1)		24 (9.7)	10 (13.0)	
- Black	3 (3.1)	7 (5.7)		2 (2.0)	6 (9.1)		11 (4.4)	6 (7.8)	
- Other	3 (3.1)	3 (2.4)		0 (0.0)	3 (4.5)		4 (1.6)	6 (7.8)	
Hypertension	75 (75.0)	95 (73.6)	0.47	71 (71.0)	47 (59.5)	0.07	186 (74.4)	54 (62.8)	0.03
Diabetes	22 (22.0)	31 (24.0)	0.42	18 (18.0)	17 (21.3)	0.36	65 (26.0)	20 (23.0)	0.34
Smoking – Current	11 (11.0)	19 (14.7)	0.15	9 (9.0)	5 (6.3)	0.56	29 (11.6)	13 (15.1)	0.62
- Ex	64 (64.0)	66 (51.2)		54 (54.0)	39 (49.4)		132 (52.8)	46 (53.5)	
- Never	25 (25.0)	44 (34.1)		37 (37.0)	35 (44.3)		89 (35.6)	27 (31.4)	
LVEF – Good	66 (67.3)	85 (67.5)	1.0	68 (69.4)	61 (77.2)	0.44	193 (78.8)	60 (73.2)	0.34
- Fair	24 (24.5)	31 (24.6)		23 (23.5)	15 (19.0)		43 (17.6)	16 (19.5)	
- Poor	8 (8.2)	10 (7.9)		7 (7.1)	3 (3.8)		9 (3.7)	6 (7.3)	
EuroSCORE (mean)	4.1	4.6	0.24	4.0	5.1	0.02	4.2	5.5	0.00
Op Type – CABG	72 (72.0)	87 (68.5)	0.82	65 (65.0)	45 (56.3)	0.51	164 (65.6)	46 (52.9)	0.01
- AVR	11 (11.0)	9 (7.1)		13 (13.0)	13 (16.3)		37 (14.8)	12 (13.8)	
- MVR	3 (3.0)	7 (5.5)		1 (1.0)	2 (2.5)		7 (2.8)	5 (5.7)	
- CABG + AVR	6 (6.0)	12 (9.4)		9 (9.0)	4 (5.0)		22 (8.8)	7 (8.0)	
- CABG + MVR	0 (0.0)	1 (0.8)		1 (1.0)	3 (3.8)		0 (0.0)	0 (0.0)	
- AVR and MVR	1 (1.0)	1 (0.8)		2 (2.0)	2 (2.5)		0 (0.0)	3 (3.4)	
- CABG +AVR+MVR	1 (1.0)	1 (0.8)		1 (1.0)	0 (0.0)		0 (0.0)	1 (1.1)	
- Other	6 (6.0)	9 (7.1)		8 (8.0)	11 (13.8)		20 (8.0)	13 (14.9)	
ICU LOS (mean/nights)	2.0	2.3	0.47	2.4	3.0	0.53	2.0	3.4	0.02
Post-op LOS (mean/days)	9.8	9.4	0.79	10.1	11.3	0.49	9.4	11.5	0.10

3.7 DISCUSSION

3.7.1 Summary of findings

The aim of a data quality strategy is to ensure that the data collected are valid for the purpose to which they are intended and of sufficient quality to minimise the impact of any errors on the study results[98]. The implementation of a data quality strategy has highlighted that the data collected for this study has: a) complete uniqueness across all data tables, b) only five data entries were deleted due to erroneous, but unverifiable values, c) >99% completeness in >92% variables, with only 1.4% incompleteness overall, d) <1% consistency error relating to dates in the data flow and high levels of consistency with the SCTS dataset in other clinical variables e) demonstrated overall representativeness with those patients who didn't participate in the study, following consideration of the study's exclusion criteria: the observed lower EuroSCORE, mean ICU and post-operative length of stay and more single procedure surgery in patients participating in the study can be explained by the inclusion of only non-emergency surgery. All those undergoing emergency surgery, by definition, have a higher level of pre-operative risk, would be expected to have more complicated surgery and are likely to require longer in ICU and hospital. Thus, while the development and implementation of a data quality strategy has highlighted that the data remains imperfect, undertaking the process has improved the accuracy (identified 259 erroneous data entries and corrected 254 (98.6%) of them) and completeness (decreased overall from 2.8% to 1.4%, alerted to records and fields with high levels of residual incompleteness) of the data. Furthermore, the erroneous inliers identified would have remained undetected without the accuracy (in particular the multiple entry and random examination) and consistency (specifically pulmonary disease and POMS coding) assessments.

3.7.2 Random and systematic errors

As highlighted by Barhyte and Bacon[114], most errors are due to human factors in coding and data entry, which was evident in this study. Most of the errors were random[101] and attributable to genuine errors in these processes. However, there were some systematic errors due to design discrepancies that were also emphasised through data quality assessments. For example, some medications, highest temperature, and ward were added after the pilot study and not available on all patients retrospectively and there was recoding of 'creatinine >30% pre-operative value' and also the overall renal domain on each post-operative day from missing (if blood sample not taken) to no morbidity).

3.7.3 Missing data

Missing data poses a threat to a study's validity[117]; as the percentage of missing values increases, so too does the level of potential bias[118], particularly if the missingness is completely not at random[119]. The missingness in this study is, in the majority, missing completely at random. However, what is considered an acceptable level of missingness is undetermined and is context specific[120]. Thus, some judgments relating to which values are missing and what their expected impact on the results may be are required[117]. While missing baseline data do not usually lead to

bias[121], missing outcome data will, unless only a few observations are missing or unless values are missing completely at random[119]. Complete case analysis is appropriate when missingness is completely random, it does reduce the statistical power of the study[118] and is generally not acceptable as the primary approach to data analysis on exploratory studies[122]. Furthermore, analysis of only observed data can in itself produce a biased result[123]. In this study, following recoding of the creatinine and renal POMS variables, missing outcome data is minimal in the POMS tables, although a little higher in the SCTS table. Although sensitivity analysis is recommended when a substantial proportion of missing outcome data is apparent[124] for complete assurity of non-bias, a sensitivity analysis comparing those with and without missing values could be conducted when using these variables. However, in accordance with the strategies for addressing missing data[119], variables with many missing values were deleted (ASA, cause of death, days ventilated and circulatory arrest time).

3.7.4 Strengths and weaknesses

Although little guidance exists on what to include in[114] and how to conduct a data quality strategy[98], a specific strength is that not only has a systematic approach been employed to both minimise errors and increase data quality through a structured data cleaning framework, but that a transparency of the methods used, error types and rates, and decision rules applied during the editing phase have been detailed, in accordance with current recommendations[98]. Furthermore, consistent with the American Statistical Association guidelines[106], these processes and results have been reported. Secondly, as proposed in the literature[96, 107, 109], a proactive and continuous approach to data quality has been employed, including error prevention strategies incorporated at study design, early preliminary data quality assessments at completion of the pilot study to identify systematic and random problems early and also accounting for problem identification through preparation for and conducting analysis[111].

However, as it is impossible to ensure 100% quality data[99] and since the data quality process is unique to each study[102] it is inevitable that limitations, either due to the nature of the data or the strategy employed, exist. In this study three main limitations have been identified. Firstly, there was a distinct lack of predefined quality expectations and validity criteria on which to assess the data quality assessment results. A hospital setting is considered an uncontrolled environment exhibiting a high degree of subject and environmental variability resulting in a increased likelihood of errors in data collection[96]. Additionally, there is a lack of published guidance on the minimum acceptable data quality levels for clinical data[104] and a distinct lack of data quality reporting in the literature[98]. Thus, there were no standards on which to base defining any realistic or appropriate quality objectives[99] or validity acceptability criteria[98]. Consequently, no specific quality objectives were set (only that as near to 100% accuracy, completeness, uniqueness and consistency as possible be attained) and validity criteria were based purely on face validity and subjective assessment by the PDG. Whilst this was less than scientific a lack of experience in this area dictated this an

appropriate starting point. Since none of the key data items (POMS criteria) exhibited a high level of residual incompleteness, inaccuracy or inconsistency in coding, and those errors that were identified were corrected, further decision-making on the quality of the data were not warranted. Had significant issues relating to data quality been highlighted, then, retrospectively, validity criteria judgments would have been required.

Secondly, despite it being recommended that data coding be performed by one person and checked by another to minimise errors, and that data cleaning be started at the same time as data collection so as to reduce systematic errors[96], this was not done since it was only possible for data collection and entry to be undertaken by one person. Additionally, although adequate numbers of skilled human resources should be available for collecting and maintaining data[125], it is also imperative that personnel involved in the data are involved in identifying and resolving errors[96]. Thus, while this provides further indication that a data quality strategy was necessary, it also illustrates not only the required trade-off between optimum requirements and rate-limiting practicalities but also that this strategy was appropriate: the person most knowledgeable of the study data conducted the data quality assessments, diagnosis and treatment.

Finally, the use of a single-person strategy resulted in a significant amount of time being devoted to the implementation of the data quality programme. While the STS[126] reported 15% of time was spent on data cleaning, approximately 18% of time was required overall in this study. More time-efficient strategies could have been considered, for example a) establishing critical and non-critical errors (those requiring and not requiring cleaning)[100], b) prioritisation of critical errors[98], c) the use of hand-held computer to eliminate the need for a paper record and reducing the potential for data entry error[96], d) the use of automated as well as manual data cleaning techniques[100] and e) the use of computer with built-in mechanisms to check completeness and validity continuously[125]. While the former strategies (a-c) would have been beneficial, the latter (d-e) are outside the scope and expertise of this PhD (although some validation rules were applied to some variables), and are more properly assigned to larger studies where difficulties exist in maintaining procedures[102]. Nevertheless, in this study the majority of data cleaning could only be done manually, and this is a time consuming process[102]. Despite error prevention strategies being employed in order to assist in minimising the amount of data cleaning necessary, substantial time was still required and thus time was the most expensive resource of this process in this instance. In the vast majority of other studies this will be a monetary expense and thus data cleaning, and utilising the most effective and efficient strategies, becomes a due consideration for study resources[103].

3.8 CONCLUSION

Despite the time-commitment involved, developing and implementing a data quality strategy increased the accuracy and completeness of the data, reducing potential analysis bias and improving the validity of the data.

4 RESULTS I: PILOT STUDY

4.1 INTRODUCTION TO CHAPTER

This chapter reports the results of the pilot study, including the screening and recruiting figures and participant baseline characteristics. The applicability of POMS to cardiac surgical patients in the pilot study is assessed and the changes required for the main study are highlighted.

4.2 TIMEFRAME

Phase I and Phase II were conducted between 10th January 2005 – 9th February 2005 (50 patients) and 7th March 2005 – 28th April 2005 (50 patients), respectively.

4.3 PARTICIPANTS: SCREENING AND RECRUITMENT

In total, 230 patients underwent cardiac surgery of whom 124 patients (54%) were screened for the study and 106 patients (46%) were missed. The breakdown of reasons why patients were missed are detailed in Table 4-1.

Table 4-1: Reasons why patients were missed for screening (n=106). Values are n(%).

Reason	Number of patients (%)
Monday surgery	46 (43.4)
General researcher unavailability	44 (41.5)
Saturday surgery	7 (6.6)
Sunday surgery	3 (2.8)
Theatre list changed overnight	1 (0.9)
Patient not on original theatre list	1 (0.9)
Theatre list not confirmed	1 (0.9)
Emergency surgery	1 (0.9)
Late transfer from NHS general hospital (1st on list)	1 (0.9)
Not required as had 100 patients for pilot at that time	1 (0.9)

Of the 124 patients that were screened, 104 (84% of those screened and 45% of total population) gave consent to participate and 100 patients completed the study. The breakdown of reasons why the 20 patients who were screened did not participate, and why the 4 patients who consented but did not complete the study are detailed in Table 4-2 and Table 4-3, respectively.

Table 4-2: Reasons why patients who were screened but did not participate in the study (n=20). Values are n(%).

Reason	Number of patients (%)
Declined to participate	8 (40.0)
Participating in an intervention study	5 (25.0)
Unable to consent (lack of English and no translation available)	3 (15.0)
Too anxious to provide informed consent	2 (10.0)
Emergency surgery	1 (5.0)
Inappropriate (drug abuser)	1 (5.0)

Table 4-3: Reasons why patients who gave consent did not complete the study (n=4). Values are n(%).

Reason	Number of patients (%)
Surgery cancelled (1x leg wound, 1x lack of ITU beds)	2 (50.0)
Died on return to theatre on day of surgery	1 (25.0)
No longer appropriate for surgery	1 (25.0)

4.4 PARTICIPANT BASELINE CHARACTERISTICS

4.4.1 Pre-operative and surgical details

Of the 100 participants 77% were male, the majority were White British, and the mean age was 67 years. Five percent had cardiac surgery previously, 74% underwent elective surgery and overall participants had a medium operative risk (mean EuroSCORE 4.12). A summary of the pre-operative and operative details are shown in Table 4-4. Data completeness was >93% in all variables except liver disease (92%) and pre-operative temperature (74%).

Table 4-4: Baseline characteristics of the study population (n=100). Values are stated as n, or mean, range and standard deviation (SD).

Variable	Frequency/ % or mean	Range	SD
Medical history			
Non-cardiac history			
Neurological dysfunction**	6		
Pulmonary disease	10		
Liver disease	0		
GI	14		
Renal*	5		
Hypothyriodism	6		
Varicose veins	17		
Immunosuppresive medication	0		
Cardiac history			
Previous MI	37		
Previous PCI	6		
Congestive cardiac failure	13		
Cardiogenic shock	0		
Atrial arrhythmia	8		
Symptoms			
NYHA class – I	21		
- II	42		
- III	26		
- IV	7		
CCSC score – 0	22		
- I	17		
- II	28		
- III	18		
- IV	11		
Cardiac risk factors			
Smoking -Current	11		
-Ex	63		
-Never	25		
Hypertension	74		
Hypercholesterolaemia	84		
Diabetes	21		
Family history of IHD	50		
Examinations and investigations			
Number of diseased vessels – 0	16		
- 1	6		

- 2	20		
- 3	56		
LMS >50% stenosis	21		
LV function – Good (≥50%)	66		
-Fair (30%-49%)	23		
-Poor (<30%)	8		
Cardiomegaly	3		
Systolic blood pressure (mean/mmHg)	133.8	90.0-183.0	18.2
Heart rate (mean/bpm)	68.6	48.0-133.0	13.4
Respiratory rate (mean/breathspm)	18.9	10.0-27.0	2.8
Oxygen saturation (mean/%)	97.4	94.0-100	1.6
Temperature (mean/^{0}C)	36.4	36.0-38.0	0.4
Height (mean/cm)	169.4	144.0-197.0	10.37
Weight (mean/kg)	78.9	46.0-127.0	16.0
BMI (mean/kg/m^2)	27.5	18.5-38.8	40.62
Glasgow coma score (mean)	15	15-15	0.0
Creatinine (mean/umol/l)	96.9	46.0-321.0	36.3
Urea (mean/mmol/l)	6.6	3.0-14.0	2.5
Potassium (mean/mmol/l)	5.0	3.3-48.0	4.4
Sodium (mean/ mmol/l)	138.0	128.0-148.0	3.4
Haemaglobin (mean/g/dl)	13.5	9.2-16.2	1.5
White cell count (mean/x10^9/l)	7.8	3.1-14.5	2.1
Albumin (mean/g/l)	43.3	32.0-51.0	3.7
Pre-operative risk assessment			
Parsonnet score (mean)	11.0	0.0-33.0	8.1
EuroSCORE (mean)	4.1	1.0-10.0	2.68
POSSUM score (physiological component) (mean)	19.2	12.0-40.0	
Operation details			
Surgical procedure – CABG	73		
- AVR	11		
- MVR	3		
- CABG + AVR	6		
- AVR + MVR	1		
- CABG + AVR +MVR	1		
- Other	5		

*Renal: no patients require dialysis; **neurological dysfunction: 2 patients with CVA, 4 patients with TIA;

4.4.2 Outcome characteristics

Table 4-5 shows the outcome characteristics. Data completeness was >94% in all variables except number of hours ventilated (89%) and discharge services required (71%) due to incompleteness of reporting in the medical notes.

The mean length of ventilation was 5.8 hours (3 participants were extubated in theatres while waiting for a bed to become available on ICU) with participants spending an average of 2 days on ICU and 9.8 days in the operating hospital. Fourteen percent of patients were transferred to an NHS hospital and overall the average length of post-operative hospital stay was 12.2 days. However, the most commonly observed outcome was a ventilation of 5.0 hours, one night spent on the ICU, a post-operative stay of 5.0 days in the operating hospital, with this increasing to 6.0 days when including the additional hospital stay of patients transferred to another NHS hospital. In total, two participants died.

Table 4-5: Outcome characteristics. (n=100). Values are stated as n, or mean, mode, range and standard deviation (SD).

	Frequency/mean	Mode	Range	SD
Length of ventilation (hours)	5.8	5.0	0.0-22.0	2.5
Length of ICU stay (nights)	2.0	1.0	0.0-11.0	1.9
Return to theatre	3			
Readmitted to ICU	7			
Length of hospital stay (HH) (days)	9.8	5.0	3.0-123.0	13.1
Discharge destination – home	83			
- NHS hospital	14			
- Convalescence home	1			
- Other (died)	2			
Total length of post-operative hospital stay (days)	12.3	6.0	4.0-176.0	22.1
Discharge services	32			
In-hospital death	2			

4.5 APPLICABILITY OF POMS TO CARDIAC SURGERY PATIENT

4.5.1 POMS framework

All patients were in-hospital on post-operative days 1 and 3 with 95%, 33% and 10% remaining an in-patient on post-operative days 5, 8 and 15, respectively. The frequency of each POMS morbidity type is shown in Table 4-6.

Table 4-6: Frequency of original POMS items in C-POMS population. Data is 100% complete. Values stated as n (new morbidity).

POMS morbidity type	Frequency of items					
	Pre-op (n=100)	D1 (n=100)	D3 (n=100)	D5 (n=95)	D8 (n=33)	D15 (n=10)
Pulmonary	2	100 (100)	56 (56)	25 (25)	8 (8)	4 (4)
Infectious	3	81 (78)	21 (18)	28 (27)	16 (16)	6 (6)
Renal	2	100 (100)	30 (30)	14 (13)	9 (9)	6 (6)
Gastrointestinal	5	48 (47)	20 (17)	17 (16)	8 (8)	2 (2)
Cardiovascular	10	48 (45)	36 (33)	36 (31)	20 (17)	8 (6)
Neurological	0	16 (16)	18 (18)	9 (9)	6 (6)	2 (2)
Wound complication	0	100 (100)	0 (0)	0 (0)	3 (3)	2 (2)
Haematological	0	10 (10)	0 (0)	0 (0)	2 (2)	1 (1)
Pain	2	95 (93)	3 (1)	5 (3)	2 (1)	1 (0)

While there were no patients in hospital on D15 that did not have at least one POMS morbidity criteria present, 34.7% of patients on D5 and 9.1% of patients on D8 remained in-hospital on these days but had no POMS-defined morbidity. However, over a third of these patients did remain in hospital for a medical reason. Table 4-7 identifies the reasons for patients remaining in hospital on D5 and D8, when no POMS-defined morbidities were present.

Table 4-7: Reasons for remaining in hospital when no POMS morbidity present. Values are n(%).

	Post-operative D5 (n=95)	**Post-operative D8 (n=33)**
No POMS-defined morbidity	33 (34.7)	3 (9.1)
Discharge planned for today	11 (31.7)	1 (33.3)
Social reasons	2 (6.1)	0 (0.0)
Equipment needed at home	0 (0.0)	0 (0.0)
Mobility (ongoing physio/occupational therapy needs)	6 (18.2)	1 (33.3)
Institutional failure (transport not booked/out-patient appointment not arranged)	0 (0.0)	0 (0.0)
Delayed discharge (lack of bed/rehab)	3 (9.1)	0 (0.0)
*Other medical reason:	12 (36.4)	1 (33.3)
Hypertension	*1 (3.0)*	
ACEI commenced	*1 (3.0)*	
Discharge planned for next day	*3 (9.1)*	
Uncontrolled diabetes	*3 (9.1)*	
Increased INR	*2 (6.1)*	*1 (33.3)*
Awaiting haematological out-patient review	*1 (3.0)*	
Due to extra post-op respiratory requirements	*1 (3.0)*	
Increased weight	*2 (6.1)*	
Awaiting echocardiography	*2 (6.1)*	
Pleural effusion awaiting drainage (INR)	*1 (3.0)*	

4.5.2 Additional morbidities identified by free text

In total there were 73 additional morbidities identified that were not captured within POMS (Appendix 3), with 20 occurring in ≥5% patients (Table 4-8).

Table 4-8: Additional morbidities not captured by the POMS occurring in ≥5% patients. Values n(%).

	Frequency					
Morbidity	**All patients (n=100)**	**D1 (n=100)**	**D3 (n=100)**	**D5 (n=95)**	**D8 (n=33)**	**D15 (n=10)**
Blood sugar control (actrapid infusion/uncontrolled diabetes)	97 (97)	88 (88)	26 (26)	11 (11.6)	4 (12.1)	3 (30.0)
Potassium supplements	83 (83)	73 (73)	22 (22)	13 (13.7)	3 (9.1)	1 (10.0)
IV Furosemide (stat/infusion)	41 (41)	36 (36)	6 (6)	5 (5.3)	2 (6.1)	1 (10.0)
Magnesium supplements	34 (34)	27 (27)	9 (9)	2 (2.1)	0 (0.0)	0 (0.0)
Salbutamol or atrovent nebs	29 (29)	18 (18)	15 (15)	7 (7.4)	3 (9.1)	1 (10.0)
Hypertension	27 (27)	19 (19)	10 (10)	7 (7.4)	0 (0.0)	0 (0.0)
Chest drains remain insitu	17 (17)	17 (17)	1 (1)	0 (0.0)	1 (3.0)	0 (0.0)
Inotropic support	17 (17)	16 (16)	3 (3)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension (fluid/omit medication/drink)	15 (15)	10 (10)	9 (9)	3 (3.2)	0 (0.0)	0 (0.0)
*Pleural effusion	15 (15)	1 (1)	7 (7)	10 (10.5)	0 (0.0)	0 (0.0)
LLL collapse	13 (13)	11(11)	0 (0)	1 (1.1)	0 (0.0)	0 (0.0)
Constipation	11 (11)	0 (0)	5 (5)	6 (6.3)	2 (6.1)	0 (0.0)
Untherapeutic INR	9 (9)	0 (0)	1 (1)	6 (6.3)	5 (15.2)	1 (10.0)
Diarrhoea	8 (8)	0 (0)	3 (3)	3 (3.2)	2 (6.1)	0 (0.0)
Low Hb (ferrous sulphate)	7 (7)	0 (0)	2 (2)	4 (4.2)	2 (6.1)	1 (10.0)
Peripheral oedema	6 (6)	1 (1)	1 (1)	2 (2.1)	2 (6.1)	2 (20.0)
Blurred vision/visual disturbances (not delirium)	5 (5)	0 (0)	3 (3)	1 (1.1)	1 (3.0)	0 (0.0)
Increased weight (medical treatment)	5 (5)	0 (0)	2 (2)	4 (4.2)	0 (0.0)	0 (0.0)
Pneumothorax	5 (5)	4 (4)	2 (2)	1 (1.1)	0 (0.0)	0 (0.0)
Sputum spec/productive cough	5 (5)	3 (3)	3 (3)	2 (2.1)	0 (0.0)	0 (0.0)

Of the 20 morbidities, 5 (25%) did not corresponded to an existing POMS morbidity type. These were blood sugar control, chest drains *in situ*, untherapeutic INR, peripheral oedema and increased weight requiring medical treatment. This suggests that new morbidity domains are required to accurately describe and quantify post-operative morbidity following cardiac surgery. All the 15 (75%) additional morbidities that could be corresponded to an existing POMS morbidity type, contributed independently to their morbidity type (Table 4-9). For example, of the 73 patients requiring potassium supplements on D1, only 33 (78.8%) already had a cardiovascular morbidity, as defined by POMS. If any of the morbidities were not contributing to the morbidity type and were reflecting a criterion already measured, then all the percentages over each of the post-operative days would be 100. However, since each of the additional morbidity were found to be contributing above and beyond that already measured within POMS, modification to the existing POMS criteria may be required.

4.6 CONFIRMING THE ROUTINE DATA COLLECTION ITEMS FOR THE MAIN STUDY

Review of the routine data collection variables following Phase I was conducted with study supervisors and the PDG reviewed all pilot data results at meeting 2 on 27th July 2005.

4.6.1 Routine data items

Following completion of Phase I of the pilot study a review was undertaken of the routine data variables being collected, resulting in V2 (March 2005) of the CRF. The amendments agreed are detailed in Table 4-10.

Table 4-9: The contribution of the additional morbidities to the corresponding POMS morbidity type. Values n(%).

		Frequency								
Morbidity	**Corresponding POMS category**	**D1 (n=100)**	**POMS category already present (D1)**	**D3 (n=100)**	**POMS category already present (D3)**	**D5 (n=95)**	**POMS category already present (D5)**	**D8 (n=33)**	**POMS category already present (D8)**	**D15 (n=10)**	**POMS category already present (D15)**
Potassium supplements	CV	73	33 (78.8)	22	12 (54.5)	13	8 (61.5)	3	2 (66.7)	1	1 (100)
IV Frusemide (stat/infusion)	Renal	36	36 (100)	6	4 (66.7)	5	3 (60.0)	2	1 (50.0)	1	1 (100)
Magnesium supplements	CV	27	9 (33.3)	9	7 (77.8)	2	0 (0.0)	0	-	0	-
Salbutamol or atrovent nebs	Pulmonary	18	18 (100)	15	14 (93.3)	7	5 (71.4)	3	2 (66.7)	1	1 (100)
Hypertension	CV	19	8 (42.1)	10	2 (20.0)	7	4 (57.1)	0	-	0	-
Inotropic support	CV	16	2 (12.5)	3	1 (33.3)	0	-	0	-	0	-
Hypotension (fluid/omit medication/drink)	CV	10	5 (50.0)	9	4 (44.4)	3	1 (33.3)	0	-	0	-
*Pleural effusion	Pulmonary	1	1 (100)	7	6 (85.7)	10	5 (50.0)	0	-	0	-
LLL collapse	Pulmonary	11	1 (100)	0	-	1	1 (100)	0	-	0	-
Constipation	GI	0	-	5	2 (40.0)	6	2 (33.3)	2	0	0	-
Diarrhoea	GI	0	-	3	3 (100)	3	2 (66.7)	2	1 (50.0)	0	-
Low Hb (ferrous sulphate)	Haem	0	-	2	2 (100)	4	0 (0.0)	2	1 (50.0)	1	0 (0.0)
Blurred vision/visual disturbances (not delirium)	Neuro	0	-	3	0 (0.0)	1	0 (0.0)	1	1 (50.0)	0	-
Pneumothorax	Pulmonary	4	4 (100)	2	2 (100)	1	0 (0.0)	0	-	0	-
Sputum spec/productive cough	Pulmonary	3	3 (100)	3	2 (66.7)	2	1 (50.0)	0	-	0	-

Table 4-10: Data collection amendments following Phase I

Data Table	Change
Admin	▪ Add if participating in intervention trial ▪ State date of transfer and transferring hospital
Pre-operative	▪ Exclude duplication of fields (creatinine and haemaglobin) ▪ Add list of co-morbidities ▪ Add NYHA class: easier that waiting for it in SCTS database ▪ Add date of blood results: for quality assessments
Intra-operative and immediate post-op	▪ Collect surgiserve data: from sheets in theatre not database: unable to get response from database owner ▪ Add any other medications given ▪ Remove estimated blood loss: not recorded in theatre as too complicated due to CPB ▪ Add tick boxes for operation performed: for ease of documentation ▪ Add type of valve inserted, if appropriate: mechanical or tissue ▪ Add whether participant was intra-operatively paced ▪ Add free-text space for other comments ▪ Add 12 hour summary for blood loss, urine output, total fluid, sedation score, potassium/magnesium supplements ▪ Add list of infusions, doses and time started and discontinued.
C-POMS D1-15	▪ Pulmonary: record highest level of support required during the course of the day ▪ Renal: record furosemide treatment separately as free-text. ▪ Pain: do not record routine medications unless participant remaining in hospital due to pain.
Outcome	▪ Add destination from discharge from ICU ▪ Add post-operative day of discharge from ICU and hospital ▪ Add discharge services as a tick-box field

It was decided not to include separate sections for blood test results, medications or referrals as routine data collection variables since any abnormalities/requirements outside the norm would be picked up either within the POMS domains, or can be recorded separately in the free-text if contribute to a prolonged period of hospitalisation.

There were no changes to the routine data variables following completion of Phase II.

4.6.2 POMS

Although, wound complications and haematological complications on D3 and D5 were present in <5% of the participants, it was agreed that no redundancy of items was to occur following the pilot study so as to permit full exploration of the applicability of POMS in the main study.

4.6.3 Additional morbidities

The PDG reviewed the 20 additional morbidities confirming whether or not each additional morbidity should be a routine data collection item for the main study (Table 4-11).

Table 4-11: PDG decision on inclusion of additional morbidity present in ≥5% patients as routine data item.

To include as routine data collection	Not to include as routine morbidity items (reason)
Treatment for blood sugar control	Potassium supplements (not morbidity or indicative of morbidity on own)
IV furosemide for low urine output	Magnesium supplements (not morbidity or indicative of morbidity on own)
Hypertension	LLL collapse (all patients have some degree of this, thus non-discriminatory)
Chest drains *in situ* beyond day 1	Constipation (if severe enough to be a morbidity patient will experience nausea and/or abdo distension in GI category)
Inotropic support	Low Hb (not severe enough to be morbidity. If severe will require blood transfusion and be picked up by haematological category)
Hypotension (fluids/omit medication)	Sputum specimen/productive cough (not morbidity on own. If becomes a morbidity will be picked up in respiratory or infectious categories).
Pleural effusion requiring drainage	Diarrhoea (if severe enough to be a morbidity patient will experience abdominal distension in GI category)
Untherapeutic INR	Salbutamol nebulisers (not a morbidity in own right)
Peripheral oedema	
Blurred vision/visual disturbances	
Increased weight (requiring treatment)	
Pneumothorax – note presence and severity	

4.7 CONCLUSION OF THE PILOT STUDY

The PDG concluded it was appropriate to conduct the full study. Furthermore, it was indicated that the pilot study participants data could be included in the main study since few protocol changes occurred as a result of the pilot study.

5 RESULTS II: BASELINE CHARACTERISTICS

5.1 INTRODUCTION TO CHAPTER

This chapter reports the baseline characteristics of the main study.

5.2 INTER-RATER RELIABILITY

Rater comparisons for 6 participants on D3 and 9, and 2 on D5, D8 and D15, respectively identified excellent agreement on 5 POMS domains (Table 5-1). Kappa statistics for the cardiovascular, neurological, wound complication and haematological domains was not generated since there were no events identified by either rater.

Table 5-1: Inter-rater comparisons of POMS data collection

POMS domain	Kappa	p
Pulmonary	0.77	0.00
Infectious	1.00	0.00
Renal	0.80	0.00
Gastrointestinal	0.79	0.00
Cardiovascular	-	-
Neurological	-	-
Wound complication	-	-
Haematological	-	-
Pain	1.00	0.00

5.3 SCREENING AND RECRUITMENT CHARACTERISTICS

5.3.1 Timeframe

Phase I and Phase II were conducted between 10th January 2005 and 9th February 2005 and 7th March 2005 – 28th April 2005, respectively. Phase III was conducted between 3rd October 2005 and 3rd December 2005 while Phase IV was completed between 2nd July and 15th November 2007.

5.3.2 Participants: screening and recruitment

During all the study phases 748 patients underwent cardiac surgery of whom 520 (69.5%) were screened and 464 (89.2%) subsequently consented to participate (Table 5-2). The majority of patients (55.6%) were recruited during Phase IV which had the highest percentage of patients seen compared to Phases I/II and III (83.1% v 53.9% v 63.9%, respectively), highest screening to recruitment rate (91.1% v 83.9% v 90.4%) and the lowest withdrawal rate (2.4% v 3.8% v 3.8%).

Table 5-2: Recruitment summary of each phase of data collection.

	Phase I and II (n=100)	Phase III (n=100)	Phase IV (n=250)	Overall (n=450)
No of cardiac surgery cases	230	180	338	748
No of participants missed	106	65	57	228
No of participants screened	124	115	281	520
*% patients seen**	*53.9%*	*63.9%*	*83.1%*	*69.5%*
No participants recruited	104	104	256	464
Screening to recruitment rate	*83.9%*	*90.4%*	*91.1%*	*89.2%*
No participants completed study	100	100	250	450
Withdrawal rate	*3.8%*	*3.8%*	*2.4%*	*3.0%*

The majority of patients that were missed was due to researcher unavailability, particularly in relation to Monday surgery in Phase I/II where patients require consenting on a Sunday if not pre-consented in pre-admission clinic (Table 5-3). Overall, 21 (9.2%) missed patients were missed due to hospital operational reasons (changes to operation list, late transfer from other hospital).

Table 5-3: Reasons why patients were missed (n=228). Values are n(%).

Reason	Phase I and II (n=106)	Phase III (n=65)	Phase IV (n=57)	Overall (n=229)
Monday surgery	46 (43.4)	23 (35.4)	-	69 (30.1)
Break in recruitment/ researcher unavailability	37 (34.9)	31 (47.7)	41 (71.9)	110 (48.0)
Weekend surgery	17 (16.0)	1 (1.5)	-	18 (7.9)
Patient not on list/list changes	3 (2.8)	4 (6.2)	2 (3.4)	9 (3.9)
Emergency case	1 (0.9)	-	8 (13.8)	9 (3.9)
Late transfer and 1st on op list	1 (0.9)	5 (7.7)	6 (10.3)	12 (5.2)
Not required (100 in pilot)	1 (0.9)	-	-	1 (0.4)
Not known	-	1 (1.5)	-	1 (0.4)

Of the 56 patients that were screened but did not participate, 64.3% declined to participate while 8.9% were already involved in an interventional trial (Table 5-4). Some judgments were required on the appropriateness of obtaining informed consent in 10 (17.9%) cases, resulting in non-inclusion in the study.

Table 5-4: Reasons why patients who were screened did not participate (n=56). Values are n(%).

Reason	Number of patients (%)
Declined to participate	36 (64.3)
Unable to consent	8 (14.3)
Participating in an intervention study	5 (8.9)
Late transfer and 1st on operation list	2 (3.6)
Researcher decision	1 (1.8)
Didn't want to sign consent form	1 (1.8)
Not appropriate to approach	1 (1.8)
Operation list changed	1 (1.8)
Emergency operation	1 (1.8)

Of the 464 patients who gave consent to participate, 14 patients (3.0%) did not complete the study because they no longer fulfilled the inclusion criteria: 6 (42.9%) died within 5 days of surgery, 7 (50.0%) did not undergo surgery and 1 (7.1%) participated in an intervention trial post consenting to C-POMS (Table 5-5). No participants withdrew their consent.

Table 5-5: Reasons patients who gave consent did not complete the study (n=14). Values are n(%).

Reason	Number of patients (%)
Died within 1 week of surgery	6 (42.9)
Surgery suspended	2 (14.3)
Surgery cancelled: too high risk	2 (14.3)
Surgery cancelled and not done within study time-frame (pilot study)	2 (14.3)
Took part in an intervention study post-recruitment	1 (7.1)
Patient refused surgery	1 (7.1)

5.4 PARTICIPANT BASELINE CHARACTERISTICS

5.4.1 Demographic characteristics

Of the 450 participants completing the study, 357 (79.3%) were male and the mean age was 66.5 years (range 19-91). The majority were White British (384, 86.1%), with 39 (8.7%), 16 (3.6%) and 7 (1.6%) of Asian, Black or other background, respectively. Three hundred and twernty-three (71.8%) were admitted from home while 117 (26.0%) were admitted from another NHS hospital and 10 (2.2) from another source.

5.4.2 Pre-operative characteristics

Table 5-6 details a summary of the participants' pre-operative baseline characteristics (full version in Appendix 4: Pre-operative baseline and immediate post-operative characteristics). While 17 (3.8%) had a history of CVA and 7 (1.6%) had a history of renal dialysis, 149 (33.1%), 36 (8.0%) and 19 (4.0%) had a previous MI, PCI and cardiac surgery, respectively. 105 (23.3%) were diabetic and the majority were ex-smokers (250, 55.6%), hypertensive (306, 68.0%) with hypercholesteraemia (347, 77.1%) and were overweight (mean BMI 28.5 kg/m^2). However, only 277 (61.6%), 104 (23.1) 24 (5.3%) were on a statin, nitrate and ACE inhibitor, respectively. Although the majority had triple vessel disease (245, 54.4%) and a good LVEF (327, 72.7%), 80 (17.8%) had no coronary disease and a poor LVEF was observed in over 5%. Overall, participants were of moderate mortality risk (mean EuroSCORE and Parsonnet score 4.2 and 11.3, respectively).

Table 5-6: Pre-operative baseline characteristics (n=450). Values are n(%) or mean, range and standard deviation (SD) as appropriate.

	Frequency/mean	Range	SD
Medical history			
Non-cardiac history			
Cerebrovascular disease	32 (7.1)		
- CVA	17 (3.8)		
Renal	12 (2.7)		
- Dialysis	7 (1.6)		
Cardiac history			
History of previous MI	149 (33.1)		
Number of previous MIs – 1	119 (79.9)		
- 2	30 (20.1)		
Previous PCI	36 (8.0)		
Re-operation	19 (4.2)		
Number of previous operations -1	16 (3.6)		
-2	3 (0.7)		
Symptoms			
NYHA Class -I	116 (25.8)		
- II	207 (46.0)		
- III	102 (22.7)		
- IV	23 (5.1)		
CCSC – 0	86 (19.1)		
- I	93 (20.7)		
- II	114 (25.3)		

- III	85 (18.9)		
- IV	44 (9.8)		
Cardiac risk factors			
Smoking – Current	49 (10.9)		
- Ex	250 (55.6)		
- Never	151 (33.6)		
Hypertension	306 (68.0)		
Hypercholesteraemia	347 (77.1)		
Diabetes	105 (23.3)		
Current medication			
ACEI	24 (5.3)		
Beta Blocker	219 (48.7)		
Nitrate	104 (23.1)		
Statin	277 (61.6)		
Examination and Investigation			
Number of diseased vessels -0	80 (17.8)		
- 1	36 (8.0)		
- 2	80 (17.8)		
- 3	245 (54.4)		
LVEF – Good (≥50%)	327 (72.7)		
- Fair (30%-49%)	90 (20.0)		
- Poor (<30%)	24 (5.3)		
Potassium (mmol/L)	4.4	3.3-6.3	0.4
Sodium (mmol/L)	139.6	128.0-148.0	3.2
Haemaglobin (g/dL)	13.3	7.9-17.3	1.6
White cell count (x10^9L)	1.13	1.0-4.0	0.4
Creatinine (mmol/L)	99.9	46.0-838.0	66.2
Systolic blood pressure (mmHg)	133.3	90.0-212.0	19.0
Heart rate (bpm)	69.5	44.0-150.0	13.9
Respiratory rate (breaths/min)	19.2	10.0-30.0	2.1
Temperature (^{o}C)	36.5	36.0-38.0	0.4
BMI (kg/m^2)	28.5	18.3-62.9	5.6
Pre-operative risk assessment			
Parsonnet	11.3	0-37	8.1
EuroSCORE	4.2	1-14	2.8

POSSUM	19.5	12-40	5.0

5.4.3 Intra-operative characteristics

315 (70%) of participants had elective surgery with 77 (17.1%) having multi-procedure surgery (Table 5-7). Cardiopulmonary bypass (CPB) was used in 418 (92.9%) of cases and lasted on average 79.5 minutes. In those having a valve replacement, a tissue value was implanted in the majority of cases. RBC, platelet and FFP transfusions were required in 37 (8.2%), 9 (2.0%) and 10 (2.2%), respectively requiring up to 5, 2 and 6 units, respectively. Approximately a quarter of participants required enoximone, vasoconstrictors and tranexamic acid with nearly all participants receiving intra-operative antibiotics. Only 1 participant (0.2%) had an intra-operative balloon pump inserted.

Table 5-7: Intra-operative characteristics (n=450). Values are n(%) or mean, range and standard deviation (SD) as appropriate.

	Frequency/mean	Range	SD
Intra-operative details			
Operative priority – Elective	315 (70.0)		
Operation performed - CABG	301 (66.9)		
-AVR	61 (13.6)		
-MVR	11 (2.4)		
-CABG + AVR	37 (8.2)		
-CABG + MVR	1 (0.2)		
-AVR + MVR	3 (0.7)		
-CABG + AVR + MVR	2 (0.4)		
-Other	34 (7.6)		
Mechanical valve	65 (14.4)		
Total number of grafts	2.7	1.0-5.0	0.9
- SVG	1.8	0.0-4.0	0.8
- arterial	0.9	0.0-3.0	0.3
CPB used	418 (92.9)		
Length of CPB (mins)	79.5	0.0-314.0	35.9
Length of aortic cross clamp (mins)	51.33	0.0-226.0	25.2
Operation length (mins)	224.5	105.0-515.0	54.1
Intra-operative medication			
RBC	37 (8.2)		
- number of units (mean/patient)	2.0	1.0-5.0	0.9
Platelets	9 (2.0)		
- number of units (mean/patient)	1.2	1.0-2.0	0.4
FFP	10 (2.2)		
- number of units (mean/patient)	0.6	1.0-6.0	1.5
Cryoprecipitate	0 (0.0)		
Aprotinin	155 (34.4)		
Enoximone	121 (26.9)		
Inotropes	51 (11.3)		
Vasoconstrictors	124 (27.6)		
Tranexamic acid	119 (26.4)		
Antibiotics	421 (93.6)		
IABP	1 (0.2)		

5.4.4 Immediate ICU characteristics

A summary of the participants' characteristics during the immediate post-operative period through to D1 are detailed in Table 5-8 (full details in Appendix 4: Pre-operative baseline and immediate post-operative characteristics). In the first 12 hours following surgery 100 (22.2%), 35 (7.8%) and 38 (8.4%) required RBC (mean 1.9 units), platelet (mean 1.3 units) and FFP (mean 3.1 units) transfusions, respectively. The mean drainage was 485.6mls (maximum 3035mls) with 52 (11.6%) requiring aprotinin. As would be expected almost all participants received GTN, actrapid, propofol and morphine infusions with 133 (29.6%) and 139 (30.9%) requiring some inotropic or vasodilator support, respectively. Overall, haemodynamic variable means were within expected parameters, almost three quarters were in sinus rhythm, 131 (29.1%) required pacing and mean temperature increased from 35.8 to 36.9^{o}C during this period.

Table 5-8: Immediate ICU characteristics (n=450). Values are n(%) or mean, range and standard deviation (SD) as appropriate.

	Frequency/mean	Range	SD
Immediate post-operative medication			
RBC	100 (22.2)		
- number of units (mean/patient)	1.9	1.0-9.0	1.6
Platelets	35 (7.8)		
- number of units (mean/patient)	1.3	1.0-5.0	0.8
FFP	38 (8.4)		
- number of units (mean/patient)	3.1	1.0-11.0	2.1
Cryoprecipitate	0 (0.0)		
Aprotinin	52 (11.6)		
Enoximone	62 (13.8)		
Inotropes	71 (15.8)		
Vasoconstrictors	139 (30.9)		
Morphine	437 (97.1)		
Propofol	441 (98.0)		
GTN	422 (93.8)		
Actrapid	444 (98.7)		
Immediate post-operative measurements and examinations (12 hrs)			
Heart rhythm* - Sinus rhythm	321 (71.3)	,	
Paced	131 (29.1)		
Total drainage (ml)	485.64	70.0-3035.0	366.1
Heart rate (bpm)	87.5	50.0-180.0	14.7
Systolic blood pressure (mmHg)	138.7	70.0-188.0	19.3

Diastolic blood pressure (mmHg)	61.8	35.0-100.0	9.9
Respiratory rate (bpm)	12.2	8.0-26.0	1.7
First temperature (^{o}C)	35.8	32.0-38.0	0.9
Highest temperature (^{o}C)	36.9	36.0-38.0	0.4
CVP (mmHg)	14.8	3.0-29.0	3.7
MAP (mmHg)	85.0	60.0-130.0	10.3
Day 1 medication			
RBC	63 (14.0)		
- number of units (mean/patient)	1.4	1.0-5.0	0.7
Platelets	3 (0.7)		
- number of units (mean/patient)	1.0	1.0-1.0	0.0
FFP	10 (2.2)		
- number of units (mean/patient)	2.3	1.0-4.0	1.1
Cryoprecipitate	2 (0.4)		
- number of units (mean/patient)	10.0	10.0-10.0	0.0
Aprotinin	6 (1.3)		
Enoximone	68 (15.1)		
Inotropes	53 (11.8)		
Vasoconstrictors	93 (20.7)		
Furosemide	25 (5.6)		
Morphine	423 (94.0)		
Propofol	38 (8.4)		
GTN	400 (88.9)		
Actrapid	438 (97.3)		
Day 1 examinations			
Drains out	381 (84.7)		
Heart rhythm* - Sinus rhythm	289 (64.2)		
Heart rate (bpm)	90.6	30.0-190.0	17.3
Systolic blood pressure (mmHg)	142.2	90.0-215.0	19.2
Diastolic blood pressure (mmHg)	63.5	42.0-100.0	9.9
Respiratory rate (breathspm)	22.4	10.0-47.0	5.0
Temperature (^{o}C)	37.1	35.6-38.6	0.5
CVP (mmHg)	16.1	0.0-30.0	4.6

*Heart rhythm was taken as that reported by ICU nursing staff

The day following surgery only slightly less participants required inotropic (26.9%) or vasodilator support (20.7%) although 25 (5.6%) required furosemide infusion. The proportion of participants in

sinus rhythm and atrial fibrillation decreased and increased, respectively, and the mean of all haemodynamic parameters increased on D1 in comparison to day of surgery but remained within expected clinical limits.

5.4.5 Outcome characteristics

Overall, participants stayed on ICU for an average of 3 days (but most commonly 1 day) with 31.6% discharged from ICU to a monitored bed (Table 5-9). 23 (5.1%) and 16 (3.6%) participants returned to theatre and ICU, respectively. On average, participants remained in the operating hospital for 9.6 days with the vast majority being discharged home (382, 84.9%) and with 27.5% of those requiring discharge services. Fifty-five (12.2%) participants were transferred to another NHS hospital increasing the average length of total post-operative hospital stay to 11 days. However, the most frequently observed length of stay was 5.0 days in the operating hospital and 6.0 days when including additional stay at other NHS hospitals for patients who were transferred. Four patients died in the operating hospital, and a further 2 patients died in the hospital they were transferred to. Thus, the overall in-hospital mortality rate was 1.3%.

Table 5-9: Outcome characteristics (n=450). Values are n(%) or mean, range and standard deviation (SD) as appropriate.

	Frequency/ mean	Mode	Range	SD
Length of ventilation (hours)	9.8	5.0	0.0-1152.0	57.7
Length of ICU stay (days)	3.0	1.0	1.0-29.0	2.6
Destination from ICU				
-Acute coronary ward (cardiology monitored bed)	69 (15.3)			
-3rd Floor (cardiothoracic ward, monitored bed)	73 (16.2)			
-3rd Floor (cardiothoracic ward)	154 (34.2)			
-4th Floor (cardiothoracic ward)	140 (31.1)			
-Other	14 (3.1)			
Return to theatre	23 (5.1)			
Readmitted to ICU	16 (3.6)			
Length of hospital stay (HH) (days)	9.6	5.0	3.0-123.0	10.6
Discharge destination – home	382 (84.9)			
- NHS hospital	55 (12.2)			
- Convalescence home	9 (2.0)			
- Other (died)	4 (0.9)			
Total length of post-operative hospital stay (days)	11.2	6.0	4.0-176.0	15.4
Discharge services	105 (23.3)			
- District nurse	68 (64.8)			
- Social services	11 (10.5)			
- Other	26 (24.8)			
In-hospital death	6 (1.3)			

5.5 DISCUSSION

With the exception of patients <18 years of age and patients undergoing emergency or GUCH surgery, all patients undergoing cardiac surgery were eligible for inclusion in this study. Such inclusiveness was intended to ensure the full range of potential morbidities, which might vary with factors such as patient risk or surgical procedure, would be identified so that bias (and ultimately over- or under-representation of the scope or prevalence of post-operative morbidity) could be avoided. Furthermore, if C-POMS development is based on a population representative of the UK cardiac surgical population, this will enhance it's generalisability and role in clinical and research practice.

This is evaluated in the following text where the degree to which the study population is representative of current national data (where possible) is addressed. In addition, some key areas raised by the results, the limitations and strengths of the recruitment process, and the data collection process are discussed.

5.5.1 Representativeness of study population

The study population was similar to the UK cardiac surgery population with respect to gender, age, proportion of diabetics and proportion of isolated CABG operations (SCTS data: 80% male, mean age 63years, 21.8% diabetic, 68.5% CABG [5]). A higher average Parsonnet (11.3 v 7) and EuroSCORE (4.2 v 3.4) was observed in my study compared to that observed nationally[(5)], a finding likely to be attributable to the fact the SCTS data relate to mean scores for isolated CABG patients and this study includes all cardiac surgery (except emergency cases). All the mean pre-operative measures were generally within normal clinical range except for a low white cell count (1.13 vs normal range 3.0-10.0 $x10^9$/L), creatinine at the upper normal limit (99.9 vs normal range 49-112 umol/L) and an elevated BMI in the 'overweight' category (28.5 vs normal range 18.5-25 kg/m^2). However, given that 46.9% of patients undergoing cardiac surgery in the UK are classified as overweight[(5)], this is not an unusual finding.

The in-hospital mortality rate is lower in the study (1.3% v 2% for isolated CABG, 4.2% isolated valve, 7.2% CABG and valve) than reported in the UK 2003 national data[(5)] and the re-operation rate (5.1%) is similar (3.0-3.5% for isolated CABG and 5% for isolated valve and mixed CABG and valve surgery). However, Keogh and colleagues only reported re-operation for bleeding while all causes are included in the study. Average post-operative length of stay is slightly higher than reported in 1999 data (9.6 days v 9.0 days)[(5)] but considerably higher if the patient being transferred from the operating hospital to another NHS hospital is taken into account (11.2 days). Thus, the post-operative length of stay reported nationally appears to underestimates total length of post-operative stay.

5.5.2 Factors that may influence morbidity outcome

Non-white patients undergoing cardiac surgery have similar in-hospital mortality[(127)], but have a poorer post-operative course with longer hospital stay than White patients[(128)]. Since the vast majority of the study population were of White British background (86.1%), specific morbidities reported by patients from other ethnic backgrounds potentially may be under-represented in this study. Furthermore, ethnicity may be a confounder in future post-operative morbidity and hospital length of stay comparisons with hospitals with considerably more ethnic diversity.

Pre-operative statin[(129)] and beta-blocker[(130)] use has been reported to decrease complications after cardiac surgery, and the effect of ACE inhibitors for left ventricular dysfunction in patients with cardiovascular disease on outcome is well-reported[(131, 132)]. Thus, medication use may play an

important role in morbidity after cardiac surgery. Overall, the proportion of patients receiving a pre-operative statin and beta-blocker appeared lower than would be expected (61.1%, 48.7%, respectively) given the National Service Framework (NSF) targeted that 80-90% of patients with an MI to be on a statin and beta-blocker by 2002[133]. Of the study participants with a previous MI, 66.4% were on a statin, 56.4% were taking a beta-blocker and 25.5% were taking both. Similarly, 16.7% of participants did not have any surgery for coronary artery disease and when exploring only CABG patients, 70.5% of patients were receiving statin therapy. Considering coronary risk as defined by the Sheffield tables[134] it would be expected that all cardiovascular patients should probably be on a statin.

Only a small proportion of patients (7.1%) had surgery conducted without extracorporeal circulation (off-CPB), which is considerably lower than the 17% undergoing off-CPB surgery in the UK[5]. Off-CPB surgery, when compared to on-CPB surgery (with extracorporeal circulation) is associated with fewer in-hospital complications and reduced hospital stay[135, 136]. This is an area of comparison that can be made using C-POMS once it has been developed and validated.

5.5.3 Limitations and strengths of the recruitment and data collection process

A limitation of this study is that recruitment of participants occurred in four phases over three years. This could introduce distortion since patients were not recruited consecutively and that clinical practices may have changed during the course of the study. Although phase IV of participant recruitment had the highest proportion of available patients screened (83.1%), this proportion was relatively modest overall (69.5%). This was solely due to researcher availability as a consequence of this being a single-researcher study. The limitations of this have already been discussed in the data quality chapter (Chapter 3, section 3.7.4). Also, as explored in the previous chapter, the overall representativeness of the patients recruited into the study, compared to those that were not, was good. Differences that were observed can, in part, be explained by the exclusion of emergency surgery patients. However, the overall representativeness of the baseline characteristics of the study population compared with those not participating in the study and compared with UK statistics is indeed a study strength. Other strengths include the excellent inter-rater agreement of the POMS data collection and that no participants withdrew consent from the study.

5.6 CONCLUSION

Despite the recruitment limitations, the study population appears representative of the UK cardiac surgical population. Ethnicity, medication use and off-CPB surgery are areas for potential comparison following final development and validation of the C-POMS tool.

6 RESULTS III: C-POMS DEVELOPMENT

6.1 INTRODUCTION TO CHAPTER

This aim of this chapter is to explore the theoretical background to developing health measurement tools; to describe the methods utilised to develop C-POMS and to report the results of each phase of the process, resulting in the final C-POMS model.

6.2 INTRODUCTION

6.2.1 Background to model development: Psychometrics and Clinimetrics

Health outcome measures can be developed within psychometric or clinimetric theory. Table 6-1 provides a summary of each approach. Psychometric theory primarily refers to the measurement of a single psychological phenomenon using multiple items[137], while clinimetric tools aim to measure multiple constructs within a single index[138]. Opinion is divided as to whether psychometrics and clinimetrics are indeed isolated phenomena[139, 140] or whether clinimetrics is merely a sub-section of psychometrics[138]. However, since the approach undertaken does influence which items are included in a model[141, 142, 143], the choice of approach undertaken is important.

Most measurement scales in psychometric theory are developed and validated using classical test theory (CTT)[144, 145] although item-response theory (IRT) methods are being used on a rapidly increasing basis[146]. While both CTT and IRT aim to '*measure a single attribute by means of several variables that are related to but do not have influence on the construct (indicator variables)*'[145, p9] both have their advantages and disadvantages (Table 6-1). Despite IRT being considered the more favourable approach[147], it is much more mathematically complex. Current opinion is that they should be viewed as complementary approaches[148] since little difference has been observed following comparison[143, 149].

In contrast, the clinimetric approach measures multiple constructs within a single index, may include causal variables, is constructed with emphasis on what patients and clinicians consider to be important and describes or measures symptoms, physical signs and other distinctly clinical phenomena in clinical medicine[150] (Table 6-1). The most widely known example of a clinimetric index is the Apgar score[151], where the rating of the presence or absence of five clinical signs (heart rate, respiratory effort, reflex irritability, muscle tone and color) are noted to evaulate newborn infants. It has also been suggested that clinically important items should be included in a disease-specific measure, irrespective of their statistical associations[141]. Juniper et al[141] identified that three items of greatest importance to patients would have been excluded from the Asthma Quality of Life questionnaire if they had only used psychometric methods and that not all the items derived through psychometric methods made clinical sense. Thus, in clinical research, psychometric methods without clinimetric integration may give misleading results[152]. Such perspectives lend to the argument that clinimetrics is, therefore, not a unique entity but a subset of psychometrics[138].

Table 6-1: Comparison of psychometric theory (CTT and IRT) with clinimetric theory. Sources: [12, 139, 145, 146, 148, 147, 149, 150, 153].

	Psychometric theory		Clinimetric theory
	Classical Test Theory (CTT)	**Item Response Theory (IRT)**	
Principles	▪ Unidimensional scale with multiple items that are substantially correlated to each other ▪ The theoretical value of the construct can be measured through components which are closely related to it ▪ Individuals are able to distinguish between different grades of intensity, to which a numeric value (score) is assigned ▪ The sum of the scores (total score) represents the construct's value plus random error ▪ Has circular dependency in that the quality of the measure is dependent on the response sample and the respondent scores are dependent on the quality of the items making up the measure. ▪ Primary emphasis is on items as a group, thus often referred to as scales	▪ The scale items only assess one trait (scale is unidimensional) ▪ The probability of answering any given item positively is independent of that of answering any other item positively ▪ There are essentially 4 unidimensional models characterised by the number of parameters in the model.	▪ Multidimensional indexes ▪ Indexes or rating scales designed to describe or measure a variety of clinical phenomena: symptoms, progression of illness, co-morbidities, functional capacity, reasons for medical decisions, for example ▪ Include clinical phenomena that are observed, judged and decided by clinicians ▪ Combines different symptoms and characteristics ▪ Constructed on what the patients or clinicians consider to be important ▪ May include causal variables
Validation	Mainly based on correlation (scaling assumptions, internal consistency, reproducibility and construct validity)	Based on logit 'which represents the transformation of probability values in a linear continuum. The relationship between the individual's ability and the underlying trait is represented by a curve, typically s-shaped'.	Construct validity of tool, in the absence of a gold standard, relies on the acceptance or rejection of hypotheses, which can be subjective
Advantages	▪ Principles are easy to understand	▪ High reliability and consistency of the	▪ Clinical data is essential for evaluation of

	▪ Statistic measures require little mathematical knowledge and are widely available ▪ Based on relatively weak assumptions that are easy to meet with real data and modest sample sizes ▪ The underlying model fits certain types of instruments fairly well, for example, a scale that adds together the scores from items designed as roughly equivalent indicators of a common underlying principle ▪ The individual items do not need to be optimal: items that relate only modestly to the underlying variable can be used successfully by having many of them	selected items ▪ Data furnished on an interval level of measurement ▪ Measurement error is more accurately adjusted for ▪ Sample independence ▪ A diversity of generalised IRT linear models and statistical methods exists, with the models being dependent on the item-response options (dichotomous or polytomous) ▪ Provides context and meaning to score change as opposed to the aggregate score from the CTT approach	patient care strategies where randomised controlled trials are inappropriate ▪ Unlike statistical indexes, the major contributions are clinical phenomena to diagnostic and therapeutic procedures
Limitations	▪ Presumed random distribution of the error ▪ Independence of the error of the true value ▪ Homogenous contribution of items to the final score ▪ Impossibility of testing person ability and item difficulty separately Statistics describing items and ratings are sample-dependent ▪ Scales are often long and items often seem quite similar	▪ Difficulty in understanding its postulates ▪ Complex methodology which requires large samples, training in analysis and specific statistical programs ▪ In practice the independence of the sample is not always confirmed ▪ It is not appropriate for causal variables and complex latent traits	▪ Clinical data are often considered ‘too soft’ compared to scientific evidence ▪ There are no standardised methods or procedures for identifying clinical information obtained from observation, conversation or decision-making practices

6.2.2 Model development framework

The McMaster Framework 1985[89], updated in 1992[154] following publication of Feinstein's 1987 book, is the most comprehensive and commonly cited methodological framework for constructing and assessing health indices providing frameworks for discriminative, predictive and evaluative instruments (Appendix 5: The McMaster Framework for discriminative, predictive and evaluative tools[89]). All three measures have item selection, item scaling, items reduction, reliability, validity and responsiveness steps, differing only in their step definition. C-POMS by design and function is a discriminative instrument. Table 6-2 details the step definitions for discriminative instruments.

While item selection was detailed in section 2.4.5 and the determination of reliability and validity is detailed in the following chapter, this chapter details the item scaling and item reductions steps undertaken to enable production of a proposed C-POMS model.

Table 6-2: McMaster Framework for discriminative instruments[89,154]. Text in italics refers to 1992 updates.

Step in framework	Step definition for 'discriminative instrument'
Item selection	▪ Tap important components of the domain ▪ Universal applicability to respondents ▪ Stability over time
Item scaling (ie, options available for answering each question) *Response options*	Short response sets which facilitate uniform interpretation (dichotomous responses are appropriate for a discriminative instrument)
Item reduction	Internal scaling or consistency Comprehensiveness and reduction of random error vs respondent burden *Delete redundant items (high inter-item correlations)* 1. Choose items based on item frequency and importance 2. Look at discriminative ability of each of the items – those items to which most or all of the respondents give similar or identical answers are of no use 3. Idiosyncratic items must be excluded 4. Identify and exclude items in which most of the between person variance is accounted for by other factors
Determination of reliability *Reproducibility*	Large and stable inter-subject variation: correlation between replicate measures *Signal: between subject differences (validity)* *Noise: within subject differences (measurement error: random and systematic error)* *Signal to noise ratio: reliability measured by reliability coefficient*
Determination of validity	Cross-sectional construct validity: relationship between index and external measures at a single point in time (Content and construct validity are appropriate for discriminative instruments)
Determination of responsiveness	Not relevant

6.2.3 Item reduction strategies

The utility of C-POMS being administered routinely in clinical practice is reliant on it not being burdensome in terms of time and complexity[155, 156, 157] while retaining its measurement properties[158] and rigor[157]. Thus, application of an appropriate item-reduction strategy (IRS) is paramount. Whether theoretically based in psychometrics or clinimetrics there are many methods for item reduction. While the McMaster Framework for discriminative instruments[89]

provides some indication of process, the specific methods have to be determined. Previous clinical studies have used a variety of methods including Rasch or alternative methods of statistical modelling[159, 160, 161], item importance and frequency as determined by patient and/or expert ratings using Likert scales[162], patient rankings of severity and importance[142], content validity index assessment by clinician judgment using Likert scale[163], patient questionnaires and subsequent correlation of scores[164] and mixed-method approaches[143, 165]. These mixed-method approaches used a combination of factor analysis, item frequency and expert review[165] and inter-item correlations, factor analysis and Rasch analysis[143]. Therefore, overall, there is little uniformity in IRS approaches applied to clinical studies.

This purpose of this chapter is to detail the item scaling and reduction processes undertaken and the results which culminate in the production of the C-POMS model.

6.3 METHODS

6.3.1 Overall theoretical theory and methods

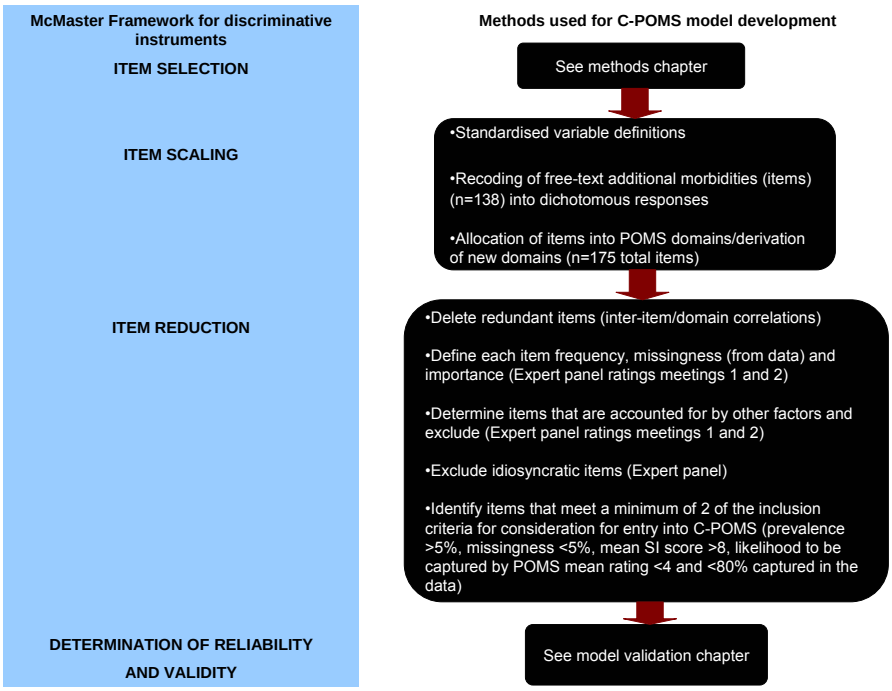
6.3.1.1 Theoretical approach

Although C-POMS contains attributes of CTT, the clinimetric approach is employed since it encompasses clinical opinion as well as statistical assessment.

6.3.1.2 McMaster Framework for discriminative instruments

A summary of the process undertaken for these steps in the McMaster framework are indicated in Figure 6-1. The terms additional morbidity and item are used synonymously throughout this chapter.

Figure 6-1: Summary of the methods undertaken in relation to the McMaster Framework for discriminative instruments.



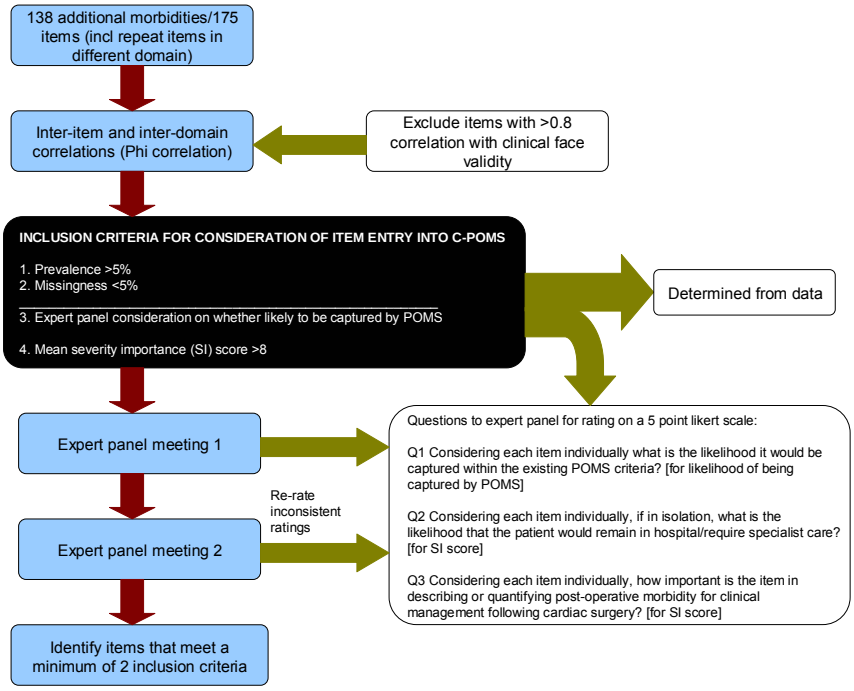
6.3.2 Item scaling

As previously indicated, POMS items have standardised definitions and are indicated by either a present or absent (ie dichotomous) response. Thus, re-coding of the 138 additional morbidities from free-text to a dichotomous present/absent response for each participant on each post-operative day was undertaken. Each additional morbidity/item was allocated to a corresponding POMS domain and/or a newly derived domain. This lead to some of the morbidities being allocated to more than one domain and hence increased the number of items under consideration from 138 to 175.

6.3.3 Item reduction

The 175 items identified underwent an item reduction strategy (IRS) process as indicated in Figure 6-2.

Figure 6-2: Item reduction strategy process



6.3.3.1 Delete redundant items

A correlation matrix of all 138 additional morbidities against each other plus POMS categories was conducted (10,143 correlation) using Phi correlation (both variables are dichotomous). A correlation of >0.8 was imposed for consideration for the deletion of an item, based on the clinical face validity of the association.

6.3.3.2 Item selection criteria

Following deletion of redundant items, the item selection criteria for potential entry into C-POMS was defined as:

- Prevalence >5%
- Missingness <5%
- Consideration on whether likely to be captured by POMS: mean rating <4 and <80% likely to be captured by POMS domain.
- Mean severity-importance (SI) score >8

It was decided *a priori* that a minimum of two criteria had to be met for consideration into C-POMS. Section 6.3.3.3 defines the methods applied for each of these inclusion criteria.

6.3.3.3 Item selection criteria methods

6.3.3.3.1 Inclusion criteria for potential entry into C-POMS

The prevalence and missingness criteria were derived from gold standard psychometric principles[166] and previous application[167, 168] and were calculated from the data. Consideration of whether the item is likely to be captured by POMS was taken from both Expert Panel opinion and the data. An Expert Panel independently rated the following question for each item on a 5 point Likert scale (1=<20%, 2=20-40%, 3=40-60%, 4=60-80%, 5=>80%):

- Question 1: Considering each item individually what is the likelihood it would be captured within the existing POMS criteria?

The mean rating of ≤4 and the likelihood that <80% of the item was captured by the corresponding POMS domain (i.e. the percentage of occasions in which the item was captured by another criterion within the item's corresponding POMS domain) were both required for the item to be considered for inclusion into C-POMS.

The SI score is the most popular clinimetric method for item reduction[169] and has been used extensively to develop variety of health outcome measures. For example, in quality of life[162] and critical care[163] outcomes. The SI score is based on the ratings of patients or clinicians of both the severity and importance of each item under consideration for inclusion into the health outcome tool. For C-POMS, the mean SI score was calculated from responses from an Expert Panel to the following questions, members of which independently rated each item on a 5 point Likert scale (1=none, 2=a little, 3= moderately, 4=a lot, 5=extremely):

- Question 2: Considering each item individually, if in isolation, what is the likelihood that the patient would remain in hospital/require specialist care?
- Question 3: Considering each item individually, how important is the item in describing or quantifying post-operative morbidity for clinical management following cardiac surgery?

A SI score per item per rater was calculated as the sum of the rating for severity (question 2) and the rating for importance (question 3)[142]. A mean SI score was calculated.

The consistency of the ratings for each question and for each item was examined. An item was reconsidered/re-rated by the expert panel when the range of ratings across raters bridged the 1-3 or 4-5 boundary.

6.3.3.3.2 Expert panel

A minimum of five raters is recommended for an expert panel rating items on a Likert scale[170]. Thus, a five-member expert panel was convened consisting of Consultant Cardiothoracic Surgeons (2) and Anaesthetist (1), a Consultant Intensivist (1) and the database lead for the SCTS/Clinical Director for the National Institute for Clinical Outcomes Research (NICOR) (1). These individuals were invited to participate to give a balance of clinical expertise from surgery, anaesthetics, intensive care and also from a national data perspective. As previously stated, the three questions were applied to each additional morbidity and independently rated each on a 5 point Likert scale. Consistent with the Delphi Method[171], the questionnaires were completed anonymously and underwent controlled feedback whereby a second expert panel meeting was convened to re-rate and discuss specific items that had shown poor agreement from raters following the initial rating process.

6.4 RESULTS

6.4.1 Item scaling

All items were re-coded successfully and allocated to POMS and/or new domains as detailed in Appendix 6: Categorisation of additional morbidities/items into POMS and/or new domains.

6.4.2 Item reduction

6.4.2.1 Delete redundant items: inter-item/domain correlations

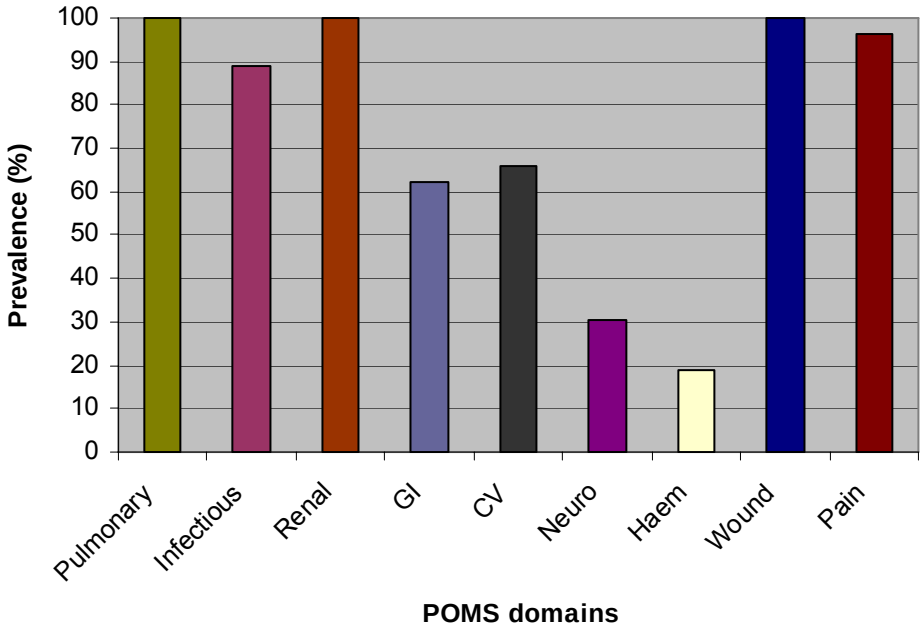
Three correlations with r value >0.8 were identified (bronchoscopy v haemothorax =1.0; decreased heart rate v pus from tooth = 1.0; eye infection v aortic dissection = 1.00). None hold face validity of being correlated. Repeat correlations with the 138 additional morbidities with the overall prevalence (excluding post-operative D1) were conducted. No correlations >0.8 were identified. Overall, no items were deleted due to item redundancy.

6.4.2.2 Item frequency and importance

6.4.2.2.1 Item frequency and missingness

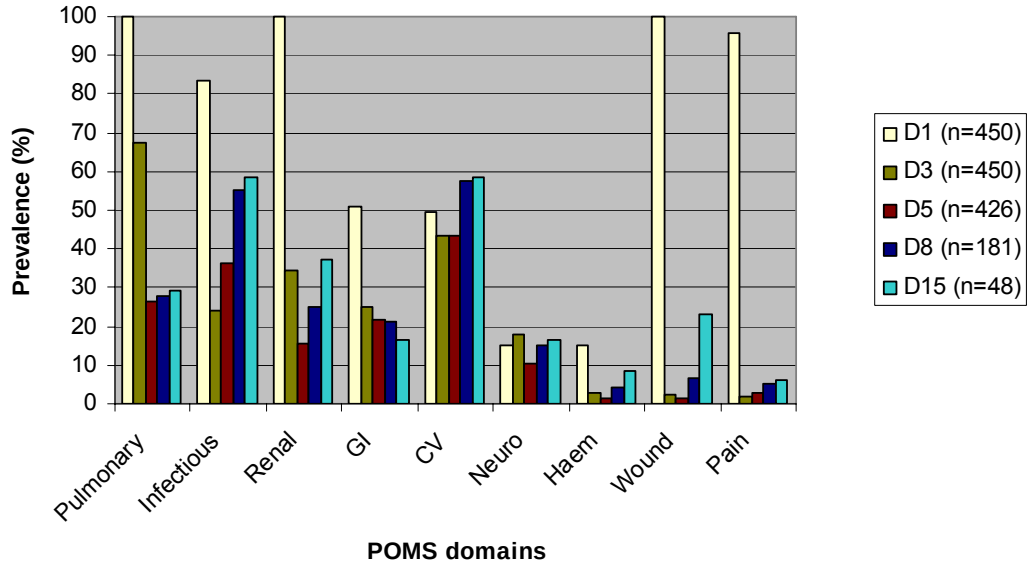
Figure 6-3 shows that that all POMS domains have overall prevalence of >5%.

Figure 6-3: Prevalence of POMS domains



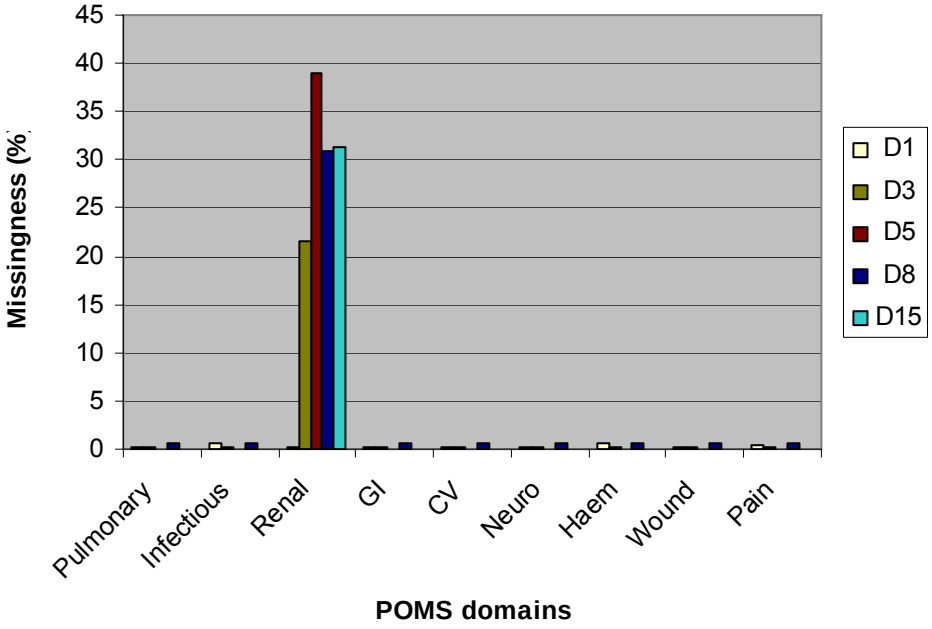
However, the haematological, wound and pain domains have <5% prevalence on D3 (2.7%, 2.4% and 2.0%, respectively) and D5 (1.4%, 1.6% and 2.6%, respectively) with only the haematological domain having <5% prevalence on D8 (4.4%) (Figure 6-4).

Figure 6-4: POMS domain prevalence by post-operative day



Renal is the only POMS domain with missing data in >5% patients on post-operative days 3-15 (Figure 6-5), which is wholly attributable to creatinine levels not being measured on these days for all patients. In all other domains missingness is ≤0.2%.

Figure 6-5: Percentage missingness of each POMS domain on each post-operative day.



There were 20 additional morbidities captured by free-text data collection (thus level of missingness is not indicated for these items) occurring in >5% of the study population (Table 6-3).

6.4.2.3 Item importance

6.4.2.3.1 Captured within POMS

Of the 175 additional morbidity items, 63 (36.0%) could not be assigned to a POMS domain and thus were excluded from this specific analysis. Of the remaining 112 items that were assigned to a corresponding POMS domain, 56 (50.0%) were inconsistently rated by the expert panel and only 15 (26.8%) matched the data, ie had a mean rating of <4 and <80% captured by the other criteria within the corresponding POMS domain. Due to the overall lack of consistency, all 112 items were collectively re-considered by the expert panel at the second meeting having access to both the initial mean rating and the percentage captured by the other criteria within the corresponding POMS domain (Table 6-3).

This discussion process by the expert panel led to two decisions:

- Redefine the POMS pain domain definition to replace the word 'new' with 'unexpected/continuing/escalated beyond day 5' and also to remove 'regional analgesia' as not applicable to cardiac surgery.
- Redefine the POMS neurological domain definition to remove the word 'focal'. This will enable lack of coordination, drowsy/slow to wake, poor swallow, blurred vision, sedated and changing loss of consciousness to be automatically included within the domain.

These changes mean that out of the 175 additional items under consideration, 36 (20.6%) are accounted for in the change of POMS pain domain definition and a further 7 (4.0%) from redefining the POMS neurological domain.

6.4.2.3.2 Mean SI scores

Mean SI scores were calculated for each item. However, 60/175 (34.3%) and 54/175 (30.9%) items did showed poor agreement between raters for question 2 and question 3, respectively. The 39 items having inconsistent ratings for both questions were returned to the expert panel for collective re-rating and subsequent recalculation of the SI score. The final mean SI scores for all items are included in Table 6-3.

Table 6-3: Summary of the item-reduction strategy results for each inclusion criteria for all additional morbidities (n=175). The shaded cells indicate those that satisfy the inclusion criteria.

	Inclusion criteria	Prevalence	Mean SI score	Unlikely to be captured in CPOMS		
		Frequency (prevalence)		a) Likelihood of being in POMS (data)	b) Likelihood of being in POMS (mean Q1 rating)	Unlikely to be captured by POMS
POMS/potential new category	Additional morbidity	Inclusion >5%	Inclusion >8	Inclusion <80%	Inclusion <4	Expert panel collective decision
Anticoag	Bleeding with Rx	1 (0.2)	9.6	NA	-	-
Anticoag	Clotting coagulopathy	1 (0.2)	9.2	NA	-	-
Anticoag	Platelet abnormalities	4 (0.9)	7.4	NA	-	-
Anticoag	Untherapeutic INR	102 (22.7)	8.2	NA	-	-
Blood sugar	Blood sugar treatment	438 (97.3)	8.2	NA	-	-
Blood sugar	Previous diabetic ulcers	1 (0.2)	4.6	NA	-	-
CV	Inotropes	113 (25.1)	10.0	92.9	5.0	No
CV	Hypotension (meds/fluid)	49 (10.9)	9.0	71.4	3.8	Yes
CV	K abnormalities	7 (1.6)	8.2	85.7	2.2	No
CV	PW remain insitu	11 (2.4)	6.8	63.6	3.0	Yes
CV	Tamponade ?echo	1 (0.2)	10.0	100	4.6	No
CV	Lactate abnormalities	1 (0.2)	9.0	100	3.4	No
CV	Hypertension	104 (23.1)	7.0	64.4	1.8	Yes
CV	Cold extremities	1 (0.2)	6.8	100	2.4	No
CV	Aortic dissection?	1 (0.2)	10.0	100	4.2	No
CV	Pericardial effusion	1 (0.2)	8.6	100	2.6	No
CV	Large heart on CXR	1 (0.2)	6.8	100	2.2	No
CV	Vasovagal	2 (0.4)	5.8	100	2.6	No
CV	Dizzy	12 (2.7)	5.8	83.3	2.8	No
CV	Tamponade ?theatre	1 (0.2)	10.0	100	5.0	No

CV	HR decreased	1 (0.2)	8.4	100	3.6	No
CV	Pericarditis?	1 (0.2)	9.0	100	4.0	No
Death	Death		7.33	NA	-	-
Gen pain	pain around ears	2 (0.4)	4.6	NA	-	-
Gen pain	Swollen knee	2 (0.4)	5.0	NA	-	-
Gen pain	R pleural chest pain	1 (0.2)	7.4	NA	-	-
Gen pain	Kidney pain	1 (0.2)	6.0	NA	-	-
Gen pain	Pain in foot	1 (0.2)	4.8	NA	-	-
Gen pain	Wound tightness	1 (0.2)	3.4	NA	-	-
Gen pain	Ileostomy pain	1 (0.2)	4.8	NA	-	-
Gen pain	Shoulder pain	12 (2.7)	4.6	NA	-	-
Gen pain	Headache	5 (1.1)	4.6	NA	-	-
Gen pain	Pericarditis	1 (0.2)	9.2	NA	-	-
Gen pain	General pain	9 (2.0)	4.6	NA	-	-
Gen pain	Wound pain	19 (4.2)	6.2	NA	-	-
Gen pain	Back pain	6 (1.3)	4.6	NA	-	-
Gen pain	Sore throat	27 (6.0)	4.4	NA	-	-
GI	Ischaemic bowel	3 (0.7)	10.0	66.7	5.0	No
GI	PR Bleed	3 (0.7)	8.6	100	2.2	No
GI	Gastric reflux	1 (0.2)	5.6	100	2.2	No
GI	Incontinence	9 (2.0)	7.0	55.6	1.6	Yes
GI	GI bleed	4 (0.9)	9.8	100	3.8	Yes (although captured not identified specifically)
GI	Constipated	19 (4.2)	4.4	73.7	1.6	No (normal to get constipated after surgery)
GI	Stomach ache	2 (0.4)	7.4	50	2.8	Yes
GI	NBM for procedure	13 (2.9)	7.25	53.8	2.2	No (NBM is not a morbidity)
GI	Decreased appetite	13 (2.9)	4.6	92.3	2.8	No
GI	Indigestion	2 (0.4)	5.0	100	2.2	No
GI	Diarrhoea	51 (11.3)	8.2	76.5	2.0	Yes
GI	NG tube	10 (2.2)	9.0	90	3.8	Yes

Hypovol	CVP/Fluid challenge	1 (0.2)	9.4	NA	-	-
Hypovol	UO decreased	66 (14.7)	9.2	NA	-	-
Hypovol	Thirsty	17 (3.8)	4.4	NA	-	-
Hypovol	Na abnormalities	7 (1.6)	8.4	NA	-	-
Hypovol	Positive fluid balance	4 (0.9)	6.4	NA	-	-
Hypovol	Overfilled	4 (0.9)	8.0	NA	-	-
Hypovol	IV fluids/hydration	8 (1.8)	9.4	NA	-	-
Hypovol	U and E abnormalities	14 (3.1)	8.6	NA	-	-
Infectious	UTI	1 (0.2)	6.8	100	3.4	No
Infectious	Pyrexia <38	5 (1.1)	6.0	40.0	-	Yes (but debated)
Infectious	Fungal infection under breast	1 (0.2)	4.2	100	1.8	No
Infectious	Eye infection	1 (0.2)	6.4	100	2.8	No
Infectious	WCC/CRP abnormalities	18 (4.0)	8.6	66.7	3.6	Yes
Infectious	?MRSA +VE	4 (0.9)	7.0	100	2.8	No
Infectious	Abscess	3 (0.7)	9.2	100	4.2	No
Infectious	Infected venflon site	10 (2.2)	7.0	77.8	2.8	No
Infectious	Hot/sweaty	20 (4.4)	8.0	60.0	3.6	No
Infectious	Shivery	1 (0.2)	8.8	100	4.0	No
Infectious	Shingles	1 (0.2)	7.2	100	2.8	No
Infectious	Pus from tooth	1 (0.2)	6.6	100	2.6	No
Infectious	Oral thrush	2 (0.4)	4.6	50.0	2.4	No
Liver	Decreased liver function	2 (0.4)	8.8	NA	-	-
Liver	ALT increased	1 (0.2)	8.0	NA	-	-
Liver	Vitamin B	1 (0.2)	4.0	NA	-	-
Misc	Increased sense of smell	1 (0.2)	2.4	NA	-	-
Misc	Nose bleed	1 (0.2)	4.6	NA	-	-
Misc	Daxamethasone (?why given)	1 (0.2)	6.4	NA	-	-

Misc	Collapse (no obvious cause)	3 (0.7)	9.0	NA	-	-
Misc	Nicotine patches	2 (0.4)	2.6	NA	-	-
Misc	Femoral line	2 (0.4)	8.4	NA	-	-
Mobility	OT assistance	1 (0.2)	6.2	NA	-	-
Mobility	Fall	7 (1.6)	8.4	NA	-	-
Mobility	Mobility encouragement	27 (6.0)	3.8	NA	-	-
Neuro	Cerebral irritation	4 (0.9)	9.8	100	4.4	Included automatically following new neuro definition
Neuro	Lack of coordination	6 (1.3)	8.4	33.3	4.2	Included automatically following new neuro definition
Neuro	Weird dreams	37 (8.2)	2.8	35.1	1.2	No
Neuro	Blurred vision	61 (13.6)	6.6	34.4	3.0	Included automatically following new neuro definition
Neuro	Panic attack	5 (1.1)	3.8	60	1.8	No
Neuro	Dizzy	12 (2.7)	6.5	8.3	2.0	No
Neuro	Changing LOC	1 (0.2)	10.0	100	4.6	Included automatically following new neuro definition
Neuro	Pressure in head	1 (0.2)	5.0	0	2.0	No
Neuro	Tinnitus	1 (0.2)	3.8	0	1.8	No
Neuro	Sedated	32 (7.1)	8.2	53.1	2.8	Included automatically following new neuro definition
Neuro	Insomnia	3 (0.7)	2.8	100	1.4	No
Neuro	Depression	1 (0.2)	5.0	100	2.0	No
Neuro	Drowsy/slow to wake	11 (2.4)	9.4	45.5	3.8	Included automatically following new neuro definition
Neuro	Poor swallow	4 (0.9)	8.0	50.0	3.4	Included automatically following new neuro definition
Neuro	Feels weak/tired	1 (0.2)	6.0	33.3	1.3	Yes
Overload	Peripheral oedema	368 (81.8)	7.2	NA	-	-
Overload	Increased weight	14 (3.1)	6.2	NA	-	-
Overload	Overfilled	4 (0.9)	8.0	NA	-	-
Overload	Whole body oedema	6 (1.3)	9.0	NA	-	-
Pain	General pain	9 (2.0)	4.8	0	2.0	Included automatically following new pain definition
Pain	Wound tightness	1 (0.2)	4.0	0	1.8	Included automatically following new pain definition
Pain	Kidney pain	1 (0.2)	7.4	0	3.0	Included automatically following new pain definition

Pain	Pericarditis	1 (0.2)	9.2	0	3.6	Included automatically following new pain definition
Pain	R pleural chest pain	1 (0.2)	8.2	0	3.2	Included automatically following new pain definition
Pain	Stomach ache	2 (0.4)	6.0	0	2.6	Included automatically following new pain definition
Pain	Sore throat	27 (6.0)	3.8	9.1	1.6	Included automatically following new pain definition
Pain	Ileostomy pain	1 (0.2)	6.0	0	2.2	Included automatically following new pain definition
Pain	Swollen knee	2 (0.4)	5.4	0	2.0	Included automatically following new pain definition
Pain	Back pain	6 (1.3)	4.4	0	2.0	Included automatically following new pain definition
Pain	Pain from chest drains	2 (0.4)	6.4	0	3.2	Included automatically following new pain definition
Pain	Headache	5 (1.1)	4.4	0	2.4	Included automatically following new pain definition
Pain	Pain around ears	2 (0.4)	5.4	0	2.4	Included automatically following new pain definition
Pain	Shoulder pain	12 (2.7)	4.4	0	2.2	Included automatically following new pain definition
Pain	Pain in foot	1 (0.2)	4.8	0	2.2	Included automatically following new pain definition
Pain	Wound pain	19 (4.2)	7.6	25.0	2.8	Included automatically following new pain definition
Pulmonary	Bronchoscopy	1 (0.2)	8.0	100	4.0	No
Pulmonary	Pneumothorax	15 (3.3)	9.6	90.9	4.0	No
Pulmonary	Surgical emphysema	5 (1.1)	9.2	100	4.0	No
Pulmonary	Pleural effusion	59 (13.1)	9.2	94.6	4.0	No
Pulmonary	Saline/other nebs	210 (46.7)	7.75	87.5	4.0	Yes (include nebulisers within the definition)
Pulmonary	DIB/pain from chest drains	2 (0.4)	7.8	0	3.0	No
Pulmonary	Haemothorax	1 (0.2)	9.2	100	4.0	No
Pulmonary	Phrenic nerve palsy	1 (0.2)	7.2	100	3.0	No
Pulmonary	SOB after medication	1 (0.2)	7.8	0	3.4	No
Pulmonary	Ventilation difficulties	1 (0.2)	9.4	100	5.0	No
Pulmonary	Chest physio	3 (0.7)	7.8	66.7	3.0	Yes
Pulmonary	Reintubated	4 (0.9)	9.4	100	5.0	No
Pulmonary	Aspiration Pneumonia	1 (0.2)	9.8	100	5.0	No
Pulmonary	Respiratory acidosis	1 (0.2)	9.6	100	4.6	No
Pulmonary	Hiccups	3 (0.7)	3.2	66.7	1.2	No

Renal	Haematuria	4 (0.9)	7.8	75.0	2.2	No
Renal	Lactate abnormalities	1 (0.2)	9.4	100	2.6	No
Renal	IV Frusemide	191 (42.4)	9.6	92.9	4.0	No
Renal	Polyuric	14 (3.1)	8.8	84.6	3.0	No
Renal	Na abnormalities	7 (1.6)	8.6	50.0	2.4	Yes
Renal	IDC bypassing	3 (0.7)	7.6	100	2.4	No
Renal	UO decreased	66 (14.7)	9.4	100	4.2	No
Renal	K abnormalities	7 (1.6)	9.4	83.3	2.8	Yes (add as requiring treatment)
Renal	Phosphate infusion (low)	5 (1.1)	8.6	50.0	2.0	Yes
Renal	Increased BE	4 (0.9)	9.0	100	3.0	No
Renal	U and E abnormalities	14 (3.1)	9.2	78.6	3.8	Yes
Renal	ATN	3 (0.7)	10.0	100	5.0	No
Renal	Cramps	1 (0.2)	4.8	0	1.4	No
Renal	Kidney pain	1 (0.2)	7.4	0	2.4	No
Renal	Prostate problems	3 (0.7)	5.5	33.3	2.25	No
Renal	Urinary retention	8 (1.8)	8.6	87.5	3.0	No
Renal	UTI	1 (0.2)	8.2	100	2.4	No
Renal	Incontinence	9 (2.0)	6.0	55.6	1.8	Yes
Review	Aortic dissection?	1 (0.2)	9.2	NA	-	-
Review	For review	35 (7.8)	6.6	NA	-	-
Review	Tamponade ? Echo	1 (0.2)	9.6	NA	-	-
Review	For investigation/procedure	23 (5.1)	7.4	NA	-	-
Review	WCC/CRP abnormalities	18 (4.0)	8.2	NA	-	-
Review	Rtn to theatre	6 (1.3)	9.4	NA	-	-
Review	D1 post-procedure	33 (7.3)	6.5	NA	-	-
Review	D2/3 post procedure	13 (2.9)	6.0	NA	-	-
Review	Bronchoscopy	1 (0.2)	8.4	NA	-	-
Review	Tamponade ? Theatre	1 (0.2)	9.6	NA	-	-

Review	Pericarditis?	1 (0.2)	9.2	NA	-	-
Review	NBM for procedure	13 (2.9)	7.6	NA	-	-
Skin	Itchy	1 (0.2)	5.2	NA	-	-
Skin	Severe bruising	2 (0.4)	6.2	NA	-	-
Skin	Iodine burns	2 (0.4)	7.4	NA	-	-
Skin	Rash	3 (0.7)	5.6	NA	-	-
Skin	Blisters	1 (0.2)	5.4	NA	-	-
Skin	Allergic reaction	1 (0.2)	7.6	NA	-	-
Wound	Chest drains	449 (99.8)	7.6	100	1.8	No
Wound	Wound pain	19 (4.2)	6.0	25.0	2.6	Yes
Wound	Chest support insitu	2 (0.4)	5.2	0	2.4	Yes
Wound	Wound tightness	1 (0.2)	4.0	0	1.8	No
Wound	Sternal click	1 (0.2)	6.0	0	2.6	No
Wound	Numbness of donor site	17 (3.8)	3.2	16.7	1.4	No
Wound	Return to theatre	6 (1.3)	10.0	100	3.2	No

There were 21 rating inconsistencies for question 2: 18 items had 1 rater inconsistency, 2 items had considerable disagreement and 1 item had a high level of missing ratings. For the 18 items with 1 rater inconsistencies, a mean SI score excluding the inconsistent rating, was re-calculated. No items met the inclusion criteria (>8) initially and then had SI <8 following recalculation (ie dropped out after recalculation) but 3 items had a mean score of <8 initially and then had an SI >8 following recalculation (Table 6-4).

Table 6-4: Differences in mean SI score (affecting inclusion into C-POMS) following exclusion of rating not in agreement with other raters.

Item	Mean SI score	Recalculated mean SI (excluded out of range rater)	Expert panel review
DIB/pain from chest drains	7.8	8.25	Collate all
Kidney pain	7.4	8	pain items
Right pleural chest pain	7.4	8	

* DIB: difficulty in breathing

For the remaining 3 items with question 2 rating inconsistencies, a collective re-rating by the expert panel was undertaken and a revised mean SI score was calculated (Table 6-5)

Table 6-5: Collective re-rating by the expert panel for question 2 on items with initial rating inconsistencies.

Item	Re-rating of Q2 by expert panel	Recalculated mean SI score
Prostate problems	1	5.5
Constipated	1	4.4
Feels weak/tired (delaying discharge)	5	6.0

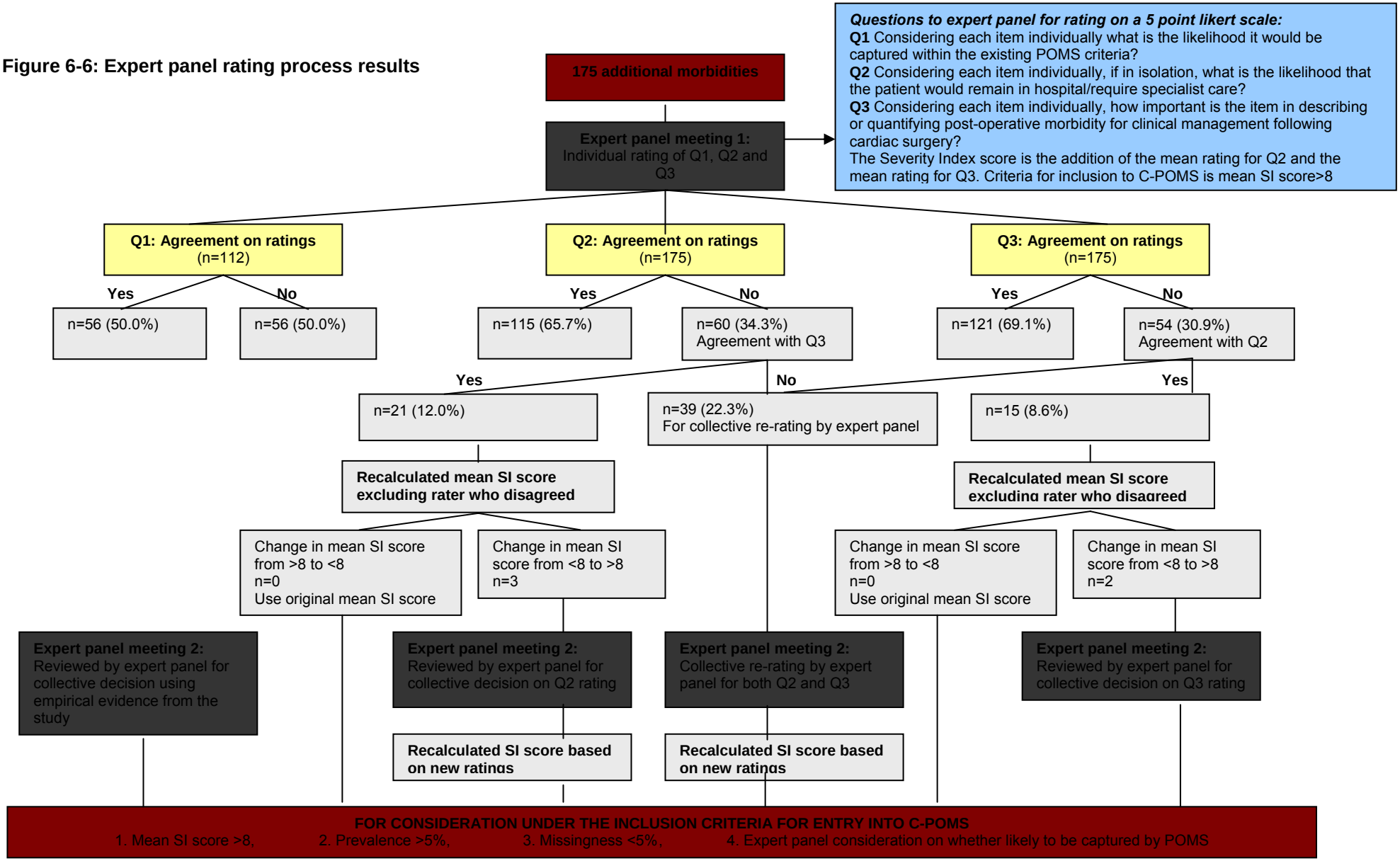
There were 15 items that only had rating inconsistencies in question 3. Following the recalculation of the mean SI score, excluding the inconsistent rating, no items dropped out of potential inclusion into C-POMS (initial mean SI score >8 initially and <8 after re-calculation), but 2 items changed from <8 to >8 (ie potentially to add in) (Table 6-6). The expert panel decided that shortness of breath after medication and chest physiotherapy should be exclude and included for consideration into C-POMS, respectively.

Table 6-6: Items changing SI score inclusion status from inconsistent ratings

Item	Mean SI score	Recalculated mean SI (excluded out of range rater)	Expert panel review
Short of breath after medication	7.8	8.5	Exclude
Chest physiotherapy	7.8	8.25	Include

Figure 6-6 provides a summary of the results of the expert panel rating process.

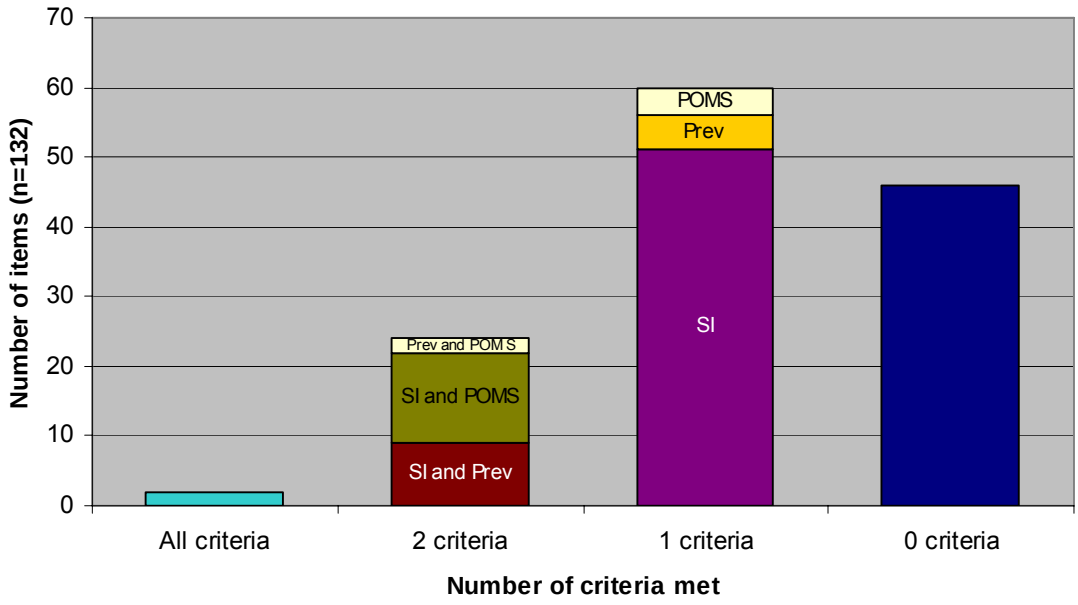
Figure 6-6: Expert panel rating process results



6.4.3 Item reduction and C-POMS inclusion criteria

Table 6-3 summarises the results of the inclusion criteria for all 175 items. Overall, of the 175 additional morbidity items, 43 (24.6%) were removed following re-definition of the POMS neurological (7 items) and pain (36 items) domains during the second expert panel meeting. Of the 132 remaining items, 18 (13.6%) had a prevalence of >5%, 21 (15.9%) were judged as unlikely to be captured within POMS and 75 items (56.8%) had a mean SI score of >8. Figure 6-7 shows the distribution of number of the items meeting the criteria for consideration into C-POMS.

Figure 6-7: The frequency of items meeting all, 2, 1 or none of the inclusion criteria following the item reduction process



Thus, there were 26 items meeting the minimum standard of meeting 2 or more criteria. Decreased urine output and potassium abnormalities requiring treatment were present under 2 domains and thus one of each was made redundant to prevent duplication of data collection. Table 6-7 summarises the 24 items for inclusion into C-POMS.

Table 6-7: Summary of the 24 items for inclusion into C-POMS.

New morbidity criteria	Overall prevalence (inclusion criteria >5%)	Mean SI score (inclusion criteria >8)	Likelihood of being captured in POMS (mean Q1 score) (inclusion criteria <4)	Number of inclusion criteria met	Comments
Pulmonary					
Pleural effusion requiring drainage	59 (13.1)	9.2	4.0	2	
Chest physio	3 (0.7)	7.8	3.0	2	
Infectious					
WCC/CRP level requiring review	18 (4.0)	8.6	3.6	2	
Renal					
IV Furosemide	191 (42.4)	9.6	4.0	2	
Decreased UO	66 (14.7)	9.2	NA	2	
Urinary incontinence	9 (2.0)	6.0	1.6	2	Included faecal incontinence in IRS
Serum K (K abnormalities)	7 (1.6)	9.4	2.8		
Gastrointestinal					
NG tube	10 (2.2)	9	3.8	2	
GI Bleed	4 (0.9)	9.8	3.8	2	
Diarrhoea	51 (11.3)	8.2	2.0	3	
Cardiovascular					
Inotropic therapy	113 (25.1)	10.0	5.0	2	

Pacing wires	12 (2.7)	6.8	3.0	2
Hypotension	49 (10.9)	9.0	3.8	3
Hypertension	104 (23.1)	7.0	1.8	2
Haematological				
Untherapeutic INR	102 (22.7)	8.2	NA	2
Wound complication				
Chest drains	449 (99.8)	7.6	1.8	2
Wound pain	19 (4.2)	6.0	2.8	2
Endocrine (new domain)				
Blood sugar management	438 (97.3)	8.2	NA	2
Electrolyte (new domain)				
Sodium	7 (1.6)	8.4	2.4	2
Potassium	7 (1.6)	9.4	2.8	2
Urea	14 (3.1)	9.2	3.8	2
Phosphate	5 (1.1)	8.6	2.0	2
Review (new domain)				
Further review	3 (8.2)	6.6	NA	
Investigation or procedure	23 (5.1)	8.4	NA	2

6.4.4 The C-POMS tool

The C-POMS model with morbidity type and criteria definitions is stated in Table 6-8. C-POMS includes all POMS morbidity types and definitions in addition to the 24 items identified through the IRS, resulting in modified POMS domains and three new domains. As indicated previously, (Methods chapter section 2.4.5.2), ambulation was requested as a routine data collection domain by the PDG and thus inclusion was mandatory. No amendments to the domain criteria were recommended by the expert panel. Furthermore, in addition to C-POMS all non-C-POMS related reasons for delayed discharge on D5, D8 and D15 are to be documented as part of routine C-POMS data collection (Table 6-9), as also decided by the PDG.

Overall, C-POMS can be used as crude presence/absence of each of the morbidity types or detailed collection of individual definition items. Each is documented as a new morbidity or an escalating morbidity from pre-operative assessment.

Table 6-8: Final tool: C-POMS morbidity types and definitions

Morbidity type	C-POMS criteria
Pulmonary	Presence of one or more of the following: ▪ New requirement for oxygen or respiratory support (including nebuliser therapy or request for chest physiotherapy on or after D5); ▪ pleural effusion requiring drainage
Infectious	Presence of one or more of the following: ▪ Currently on antibiotics ▪ has had a temperature of >38°C in the last 24 hours ▪ has a white cell count/CRP level requiring in-hospital review or treatment
Renal	Presence of one or more of the following: ▪ Presence of decreased urine output requiring intervention (including IV furosemide), ▪ increased serum creatinine (>30% from pre operative level); ▪ urinary catheter in situ; ▪ new urinary incontinence; ▪ serum potassium abnormalities* requiring treatment
Gastrointestinal	Presence of one or more of the following: ▪ Unable to tolerate an enteral diet for any reason including nausea, vomiting and abdominal distension; ▪ the presence of a nasogastric tube; ▪ diagnosis of a gastrointestinal bleed; ▪ presence of diarrhoea
Cardiovascular	Presence of one or more of the following: ▪ The use of inotropic therapy for any cardiovascular cause; ▪ the presence of pacing wires (on or after D5) and/or requiring temporary or new permanent pacing**; ▪ diagnostic tests or therapy within the last 24 hours for any of the following: 1) new MI or ischaemia, 2) hypotension

	(requiring fluid therapy, pharmacological therapy or omission of pharmacological therapy 3) atrial or ventricular arrhythmias***, 4) cardiogenic pulmonary oedema, thrombotic event (requiring anticoagulation), 5) hypertension (pharmacological therapy or omission of pharmacological therapy)
Neurological	New neurological deficit (including confusion, delirium, coma, lack of coordination, drowsy/slow to wake, poor swallow, blurred vision, sedated, changing loss of consciousness)
Haematological	Presence of one or more of the following: ▪ Untherapeutic INR requiring pharmacological therapy or omission of pharmacological therapy; ▪ Requirement for any of the following within the last 24 hrs: packed erythrocytes, platelets, fresh-frozen plasma, or cryoprecipitate
Wound	Presence of one or more of the following: ▪ Wound dehiscence requiring surgical exploration or drainage of pus from the operation wound with or without isolation of organisms; ▪ presence of chest drains; ▪ wound pain significant enough to require continuing or escalating analgesic intervention
Pain	Postoperative pain significant enough to require parenteral opioids and/or continuing or additional analgesia.
Endocrine	New or additional requirements for blood sugar management
Electrolyte	*Electrolyte (including sodium, urea, phosphate) imbalance requiring oral or intravenous intervention (NB not including potassium as included in Renal category)
Review	Remaining in hospital for further review, investigation and/or procedure
Assisted ambulation	A new or escalated post-operative requirement for mobility assistance (including wheelchair, crutches, zimmer frame, walking sticks, or assistance)

*Where abnormalities refer to the local clinical ranges.

**Protocol development group (PDG) meetings prior to collection of data requested identification of pacing (temporary or new permanent). Thus, added to CV category.

Table 6-9: Non-C-POMS related reasons for delayed discharge on D5, D8 and D15 which the PDG decided should also be routine data collection in C-POMS on these days.

Non-morbidity reason for delayed discharge	POMS criteria (UCLH validation study)	C-POMS criteria
Delayed discharge	Where POMS is '0' but the patient remains in hospital, state the reason for lack of discharge:	Where C-POMS is '0' but the patient remains in hospital, state the reason for lack of discharge:
	Social reasons	Social reasons
	Equipment at home	Equipment at home
	Mobility (ongoing physo and OT needs)	Mobility (ongoing physo and OT needs)
	Institutional failure (transport not booked, OPA or follow-up not arranged)	Institutional failure (transport not booked, OPA or follow-up not arranged)
	Delayed discharge (lack of rehab or other bed)	Delayed discharge (lack of rehab or other bed)
	Discharge planned for today	Discharge planned for today
	Other medical reason	Other medical reason

7 RESULTS IV: C-POMS RELIABILITY AND VALIDITY

7.1 INTRODUCTION TO CHAPTER

This chapter will describe the aims, methods and results of the reliability and validity testing of the C-POMS tool.

7.2 INTRODUCTION: THE NEED FOR MODEL VALIDATION

Validity refers to whether an instrument measures what it purports to measure[166]. There are several methods of validity assessment which are undertaken by a process of hypothesis testing: content validity, construct validity and criterion validity. Content validity, 'the degree to which the elements of an assessed instrument are relevant to and representative of the targeted construct for a particular assessment purpose'[172 p238], is a component of construct validity. Construct validity is 'the degree to which an assessment instrument measures the targeted construct'[172 p239] and is assessed in the absence of an existing gold standard by which to compare the instrument (criterion validity). As a gold standard for post-operative morbidity in cardiac patients does not exist, construct validity testing of C-POMS is required. Since clinical judgments are influenced by the construct validity of an instrument[172] construct validation is an essential process in the development of C-POMS.

The importance of the use of a conceptual framework in instrument development has been highlighted[173]. As stated previously, the McMaster Framework for discriminative instruments[89, 154] has been used in the development of C-POMS and the validation steps as set out by this framework will be described in this chapter. Furthermore, the most commonly cited content validity framework[172] will also be used to assess the content validity of C-POMS.

7.3 AIMS

The aim of this chapter is to assess the reliability and validity of C-POMS. The objectives are to assess the:

a) Content validity of C-POMS using the Haynes et al content validity framework[172]
b) Internal consistency of C-POMS to determine if C-POMS can be used as a summary score to denote total morbidity burden
c) Construct validity of C-POMS by testing the following hypotheses:
   I. C-POMS predicts post-operative length of stay
   II. Existing pre-operative risk assessment scores (EuroSCORE, Parsonnet score and Magovern score) predict C-POMS
   III. C-POMS domain frequencies are higher in patients with greatest post-operative risk

IV. No participants will remain in hospital with a C-POMS score of zero and that no participants will be discharged home with a C-POMS score of ≥1 on D5, D8 and D15

and to

V. Determine the independent predictive power of each domain on subsequent length of stay.

7.4 METHODS

7.4.1 Model development framework

As detailed in the previous chapter, the model development framework being utilised for the development and validation of C-POMS is the McMaster Framework published in 1985[89] and updated in 1992[154] for discriminative instruments. The framework steps relating to model validation are detailed in Table 7-1.

Table 7-1: Validation steps of the McMaster Framework for discriminative instruments[89, 154]

Step in framework	Step definition for 'discriminative instrument'
Determination of reliability	Large and stable inter-subject variation: correlation between replicate measures
Reproducibility	*Signal: between subject differences (validity)*
	Noise: within subject differences (measurement error: random and systematic error)
	Signal to noise ratio: reliability measured by reliability coefficient
Determination of validity	Cross-sectional construct validity: relationship between index and external measures at a single point in time
	(Content and construct validity are appropriate for discriminative instruments)

7.4.2 Content validity

The procedure and sequence of assessing content validity was conducted using the Haynes et al content validity framework[172] (Table 7.2).

Table 7-2: Haynes et al content validity framework[172]

Steps in the framework: Procedure and sequence of content validation
1. Specify the construct(s) targeted by the instrument
a) Specify the domain of the construct
(i) What is to be included
(ii) What is to be excluded
b) Specify the facets and dimensions of the construct
(i) Factors of the construct to be covered
(ii) Dimensions (e.g. rate, duration and magnitude)
(iii) Mode (e.g. thoughts and behaviours)
(iv) Temporal parameters (response interval and duration of time sampling)
(v) Situations
2. Specify the intended functions of the instrument (e.g. brief screening, functional analysis and diagnosis)
3. Select assessment method to match targeted construct and function of assessment
4. Initial selection and generation of items from:
a) rational deduction
b) clinical experience
c) theories relevant to the construct
d) empirical literature relevant to the construct (e.g. studies on construct validity of potential items)
e) other assessment instruments (e.g. borrowing items from other instruments that have demonstrated validity)
f) suggestions from experts
g) suggestions from target populations
5. Match items to facets and dimensions
a) use table of facets to insure coverage (include all relevant dimensions, modes, temporal parameters and situations)
b) generate multiple items for each facet
c) insure proportional representation of items across facets (i.e. the relative number of items in each facet should match the importance of that facet in the targeted construct)
6. Examine structure, form, topography and content of each item
a) appropriateness of item for the facet of construct
b) consistency and accuracy, specificity and clarity of wording and definitions
c) remove redundant items
7. Establish quantitative parameters
a) response formats and scales
b) time-sampling parameters (sampling intervals and durations)
8. Construct instructions to participants

a) match with domain and function of assessment instrument

b) clarify: strive for specificity and appropriate grammatical structure

9. Establish stimuli used in assessment (e.g. social scenarios, and audio and visual presentations) to match construct and function

10. Have experts review the results of methods 1-3 and 5-9

a) quantitative evaluations of construct definition, domain, facets, mode and dimensions

b) quantitative evaluation of the relevance and representativeness of items and stimuli

c) quantitative evaluation of response formats, scales, stimuli, situations, time-sampling parameters, data reduction and aggregation

d) match of an instrument attributes to it's function

e) qualitative evaluation: suggested additions, deletions and modifications

11. Have target population sample the results: review quantitative and qualitative evaluation of items, stimuli and situations

12. Have experts and target population sample re-review the modified assessment instrument

13. Perform psychometric evaluation and contingent instrument refinement: criterion-related and construct validity, and factor analysis.

7.4.3 Reliability: Reproducibility

Due to the nature of the study, repeat measure analysis was not appropriate, since morbidity issues would change over time. Additionally, since this study was conducted by one person, there was no available person to undertake inter-rater reliability testing of the final C-POMS tool.

7.4.4 Reliability: Internal consistency

The extent to which the C-POMS tool comprises a scale that measures the same underlying construct was calculated using Cronbach's alpha[174]. The minimum standard to indicate a sufficient level of homogeneity among the domains to regard the survey as a scale was taken as 0.70[175]. Descriptive statistics (minimum, maximum, median and standard deviation) were used to describe the resulting summary scores for each post-operative day that demonstrated at least the minimum standard for homogeneity.

7.4.5 Construct validity

7.4.5.1 C-POMS summary score and subsequent length of stay

The frequencies of those with and without C-POMS defined morbidity on each post-operative day were calculated. The predictive validity of C-POMS on subsequent post-operative length of stay was explored using a) univariate analysis using t-tests to compare the mean subsequent length of post-operative stay between those with and without -CPOMS defined morbidity, b) linear regression to test the predictive ability of C-POMS summary score on subsequent post-operative length of stay.

7.4.5.2 The ability of EuroSCORE, POSSUM and Magovern score to predict C-POMS summary score

Linear regression was performed to determine the predictive ability of EuroSCORE, POSSUM and Magovern scores on C-POMS summary score for each post-operative day.

7.4.5.3 Domain level analysis: Are C-POMS domain frequencies higher in patients with greatest risk of post-operative morbidity?

The Chi-square statistic was used to determine if C-POMS domains frequencies were higher in patients with greatest risk of post-operative morbidity as defined by EuroSCORE, the physiological component on POSSUM and the Magovern score. Categorisation of low and high risk of each of the pre-operative risk assessment scores was divided at the median score within the dataset. Thus, for EuroSCORE the median score was 4.0 (low risk = 0-4; high risk = 5-14), the physiological component on POSSUM the median score was 18 (low risk = 12-18, high risk = 19-40) and the Magovern score the median score was 5.0 (low risk = 0-5, high risk 6-18).

7.4.5.4 Remaining in hospital with a C-POMS score of zero and those discharged home with a C-POMS score of ≥1

The frequency of the social, organisational and/or medical reasons for remaining in hospital on D5, D8 and D15 when C-POMS is '0' but the patient is still an in-patient was examined. Additionally, the frequency and reasons why participants with a C-POMS score ≥1 who are discharged on these days was also explored.

7.4.5.5 Multivariate analysis: Independent predictive power of each domain on subsequent length of stay.

Multivariate linear regression analysis was performed to determine the independent strength of each C-POMS domain on subsequent length of stay for each post-operative day.

In all statistical tests statistical significance was taken at $p<0.05$ level.

7.5 RESULTS

7.5.1 Content validity

Table 7-3 shows the process undertaken for each of the McMaster framework steps.

Table 7-3: Process undertaken for each of the content validity steps

Steps in the framework: Procedure and sequence of content validation	Details within C-POMS
1. Specify the construct(s) targeted by the instrument 1. Specify the domain of the construct (i) What is to be included (ii) What is to be excluded b. Specify the facets and dimensions of the construct (i) Factors of the construct to be covered (ii) Dimensions (e.g. rate, duration and magnitude) (iii) Mode (e.g. thoughts and behaviours) (iv) Temporal parameters (response interval and duration of time sampling) (v) Situations	**Construct:** survey of in-hospital post-operative morbidity in patients undergoing adult cardiac surgery **a) Domain**: in-hospital post-operative morbidity (i) Included: All morbidity requiring treatment or extending hospital stay (ii) Excluded: any morbidity leading to death within 5 days of surgery **b) Facets and dimensions** (i) Factors: POMS framework dimensions, new dimensions as identified by prospective research (ii) Dimensions: POMS framework dimensions on post-operative days 1, 3, 5, 8 and 15 (iii) Mode: see 'factors' (iv) Temporal parameters: NA (v) Situations: NA
2. Specify the intended functions of the instrument (e.g. brief screening, functional analysis and diagnosis)	1. Identify and quantify post-operative morbidity burden in patients undergoing cardiac surgery
3. Select assessment method to match targeted construct and function of assessment	See methods chapter **1-3 REVIEWED BY EXPERT PANEL PRE-STUDY**
4. Initial selection and generation of items from: a) rational deduction b) clinical experience c) theories relevant to the construct d) empirical literature relevant to the construct (e.g. studies on construct validity of potential items) e) other assessment instruments (e.g. borrowing items from other instruments that have demonstrated validity) f) suggestions from experts g) suggestions from target populations	a) Rational deduction: Based on clinical experience/observation b) clinical experience: C-POMS study c) Theory: POMS. No others d) Literature review: Pre-op risk assessment models for post-operative morbidity e) Other assessment instruments: POMS f) Suggestions from experts: PDG meetings/Expert panel review g) Suggestions from target populations: Patient interviews in C-POMS study **REVIEWED BY EXPERT PANEL PRE-STUDY, POST PILOT STUDY AND POST STUDY (PRELIMINARY RESULTS)**
5. Match items to facets and dimensions a) use table of facets to insure coverage (include all relevant dimensions, modes, temporal parameters and situations) b) generate multiple items for each facet c) insure proportional representation of items across facets (i.e. the relative number of items in each facet should match the importance of that facet in the targeted	For morbidities identified outside of POMS framework: a) Group items relating to domain: group according to POMS domain or construct new dimensions as appropriate b) Ensure newly developed domains contain multiple items c) NA: Domains generated according to item generation results and not predetermined

construct)	d) NA: each dimension given equal importance
6. Examine structure, form, topography and content of each item a) appropriateness of item for the facet of construct b) consistency and accuracy, specificity and clarity of wording and definitions c) remove redundant items	See item-reduction strategy detailed in model development chapter **REVIEWED BY EXPERT PANEL POST PILOT STUDY AND POST-STUDY**
7. Establish quantitative parameters a) response formats and scales b) time-sampling parameters (sampling intervals and durations)	a) Defined by POMS framework and PDG/Expert panel pre-study b) Modified parameters in POMS study (post-operative D1, D3, D5, D8 and D15) to also include a pre-operative assessment: PDG/Expert panel questioned usefulness of D1 but kept in study design to accurately assess usefulness/clinical discriminative usefulness on D1 **DEFINED BY EXPERT PANEL PRE-STUDY AND REVIEWED POST PILOT STUDY**
8. Construct instructions to participants a) match with domain and function of assessment instrument b) clarify: strive for specificity and appropriate grammatical structure	Instructions to participants: NA Instructions to data collector (single): ▪ Standardisation of data variable definitions: Data definition tables for each variable constructed ▪ Standardisation of data collection: Standardised CRF constructed **DEFINED PRE-STUDY, REVIEWED MID PILOT STUDY AND BY EXPERT PANEL AT END OF PILOT STUDY**
9. Establish stimuli used in assessment (e.g. social scenarios, and audio and visual presentations) to match construct and function	NA: no need to additional stimuli and data collected by experienced research nurse and a simple checklist for data collection is being used with clear definitions for each variable
10. Have experts review the results of methods 1-3 and 5-9 a) quantitative evaluations of construct definition, domain, facets, mode and dimensions b) quantitative evaluation of the relevance and representativeness of items and stimuli c) quantitative evaluation of response formats, scales, stimuli, situations, time-sampling parameters, data reduction and aggregation d) match of an instrument attributes to it's function e) qualitative evaluation: suggested additions, deletions and modifications	Expert panel to review a) – e) pre-study, end of pilot study, end of data collection (preliminary results) *In addition:* ▪ Administrative burden: length of tool; ease of completion; number of assessment points[173]/Utility assessment of instrument[176]
11. Have target population sample the results: review quantitative and qualitative evaluation of items, stimuli and situations	**UNDERTAKEN AS THE PILOT STUDY**
12. Have experts and target population sample re-review the modified assessment instrument	**REVIEWED BY EXPERT PANEL POST PILOT STUDY. EXPERT PANEL REVIEWED FINAL MODEL.**

13. Perform psychometric evaluation and contingent instrument refinement: criterion-related and construct validity.	Criterion validity Most powerful method but no gold standard is available and thus unable to assess Construct validity As detailed in this chapter

7.5.2 Reliability: Internal consistency

The frequencies of those with and without C-POMS defined morbidity on each post-operative day are shown in Table 7-4.

Table 7-4: Frequencies of those with and without C-POMS defined morbidity (n=450). Values are stated at n(%).

Post-operative day	Without C-POMS	With C-POMS	Missing data
D3	35 (7.8)	412 (91.5)	3
D5	57 (13.4)	367 (86.1)	1
D8	9 (2.0)	171 (94.4)	1
D15	0 (0.0)	48 (100)	0

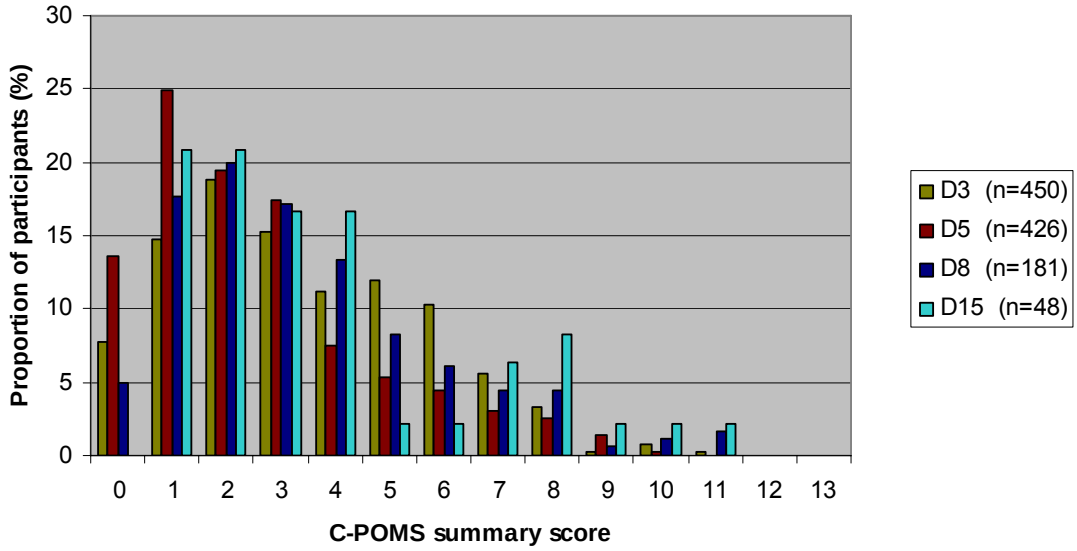
Excluding D1, C-POMS has sufficient internal consistency (>0.7) on D3, D5, D8 and D15 such that a summary score for each C-POMS post-operative day can be calculated (Table 7-5).

Table 7-5: Internal consistency of C-POMS

Post-operative day	Internal consistency
D1	0.19
D3	0.67
D5	0.66
D8	0.69
D15	0.74

For C-POMS, a summary score was then calculated for each participant for post-operative days 3, 5, 8 and 15. Figure 7-1 shows the frequency of each summary score 0-13 on each post-operative day.

Figure 7-1: C-POMS summary score frequencies.



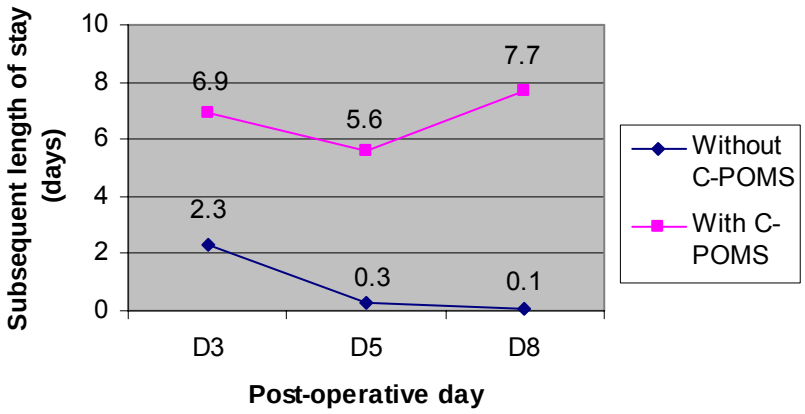
Overall, the mean C-POMS scores for D3, D5, D8 and D15 were 3.4, 2.6, 3.4 and 3.8, respectively. The maximum score of any participant was 11 on D3, D8 and D15 and 10 on D5 which was observed in one participant on D3, D5 and D15 and 3 (1.7%) on D8. The score with the highest frequency was 2 on D3 (18.8%) and D8 (19.9), a score of 1 for D5 (24.9%) and on D15 the same highest frequency was observed for a score of 1 and 2 (20.8%). No C-POMS recorded morbidity was identified in 7.8% on D3, 13.6 on D5, 5.0% on D8 and no participants on D15.

7.5.3 Construct validity

7.5.3.1 C-POMS summary score and subsequent LOS

Those with C-POMS-defined morbidity on post-operative D3, D5 and D8 remain in hospital for an additional 4.6 (p=0.012), 5.3 days (p=0.001) and 7.6 days (p=0.135), respectively, when compared to those without (Figure 7-2). There were no patients without C-POMS defined morbidity on D15.

Figure 7-2: The mean length of post-operative length of stay between those with and without C-POMS defined morbidity (n=450).



For every unit increase in C-POMS summary score there is a 1.7, 2.2, 4.5 and 6.2 day increase in subsequent length of stay on post-operative D3, D5, D8 and D15, respectively (Table 7-6).

Table 7-6: Subsequent length of stay per unit increase in C-POMS summary score

	Subsequent length of stay (days)	p	95%CI
D3 (n=450)	1.7	0.000	1.284-2.099
D5 (n=426)	2.2	0.000	1.770-2.640
D8 (n=181)	4.5	0.000	2.711-4.268
D15 (n=48)	6.2	0.000	4.004-8.351

7.5.3.2 EuroSCORE, POSSUM and Magovern score

Table 7-7 shows the ability of EuroSCORE, POSSUM and Magovern scores to predict C-POMS summary score on each post-operative day. The ability to predict C-POMS summary score is only small in all measures on D3 and D5 and additionally with EuroSCORE on D8. On D3 for every unit increase in EuroSCORE, POSSUM and Magovern score there was a 0.32, 0.17 and 0.17 increase in C-POMS summary score, respectively (all p=0.000) while on D5 a 0.23, 0.14 and 0.15 increase in C-POMS summary score is observed for each of the scores, respectively (all p=0.000).

Table 7-7: Predictive power of EuroSCORE, POSSUM and Magovern scores on C-POMS summary score.

	Level of predicting C-POMS summary score	p	95%CI
EuroSCORE			
D3 (n=450)	0.32	0.000	0.245-0.384
D5 (n=426)	0.23	0.000	0.161-0.303
D8 (n=181)	0.19	0.003	0.065-0.320
D15 (n=48)	0.04	0.743	-0.187-0.260
POSSUM			
D3 (n=450)	0.17	0.000	0.127-0.206
D5 (n=426)	0.14	0.000	0.103-0.183
D8 (n=181)	0.06	0.061	-0.003-0.126
D15 (n=48)	0.03	0.651	-0.100-0.158
Magovern			
D3 (n=450)	0.18	0.000	0.104-0.233
D5 (n=426)	0.15	0.000	0.083-0.211
D8 (n=181)	0.12	0.057	-0.003-0.213
D15 (n=48)	0.10	0.393	-0.138-0.341

7.5.3.3 Domain level analysis:

Tables detailing the full results are detailed in Appendix 7: C-POMS domain level analysis..

7.5.3.3.1 EuroSCORE

With the exception of the infectious domain, the frequency of each domain was higher in those with greatest surgical risk as defined by EuroSCORE. Significant differences were observed on D3 (64.0% vs 80.8%, p=0.000) and D5 (30.3% vs 46.7%, p=0.001) in the pulmonary domain and on D3, D5 and D8 in the renal (D3: 24.7% vs 54.6%, p=0.000; D5: 12.7% vs 24.2%, p=0.003; D8:18.8% vs 35.6%, p=0.013) and cardiovascular (D3: 46.1% vs 60.4%, p=0.002; D5 42.6% vs 57.7%, p=0.002); D8: 50.0% vs 73.0%, p=0.002) domains. While assisted ambulation was significantly higher in those with predicted higher risk on all days (D3: 33.5% vs 63.7%, p=0.000; D5: 17.2% vs 41.8%, p=0.000; D8: 27.5% vs 46.0%, p=0.013; D15: 12.5% vs 53.1%, p=0.011), significant gastrointestinal (24.0% vs 38.5%, p=0.001) and endocrine (25.8% vs 37.2%, p=0.007) differences were observed on D3 only.

7.5.3.3.2 POSSUM

With the exception of wound complication domain, the frequency of each domain was higher in those with greatest risk as defined by POSSUM. A significant difference was observed on both D3

and D5 in the pulmonary (D3: 62.2% vs 79.3%, p=0.000; D5: 26.7% vs 48.5%, p=0.000), renal (D3: 19.4% vs 51.4%, p=0.000; D5: 8.1% vs 26.7%, p=0.000), cardiovascular (D3: 44.1% vs 59.6%, p=0.002; D5: 38.8% vs 57.9%, p=0.000), endocrine (D3: 22.5% vs 39.2%, p=0.000; D5: 7.6% vs 14.4%, p=0.039) and assisted ambulation (D3: 28.8% vs 63.5%, p=0.000; D5: 16.2% vs 39.1%, p=0.000) domains. Assisted ambulation also had a significantly higher frequency in those with greater risk on D15 (13.3% vs 50.0%, p=0.023) while the infectious domain only observed a significantly higher frequency in those with higher risk on D8 (68.3% vs 50.0%, p=0.025).

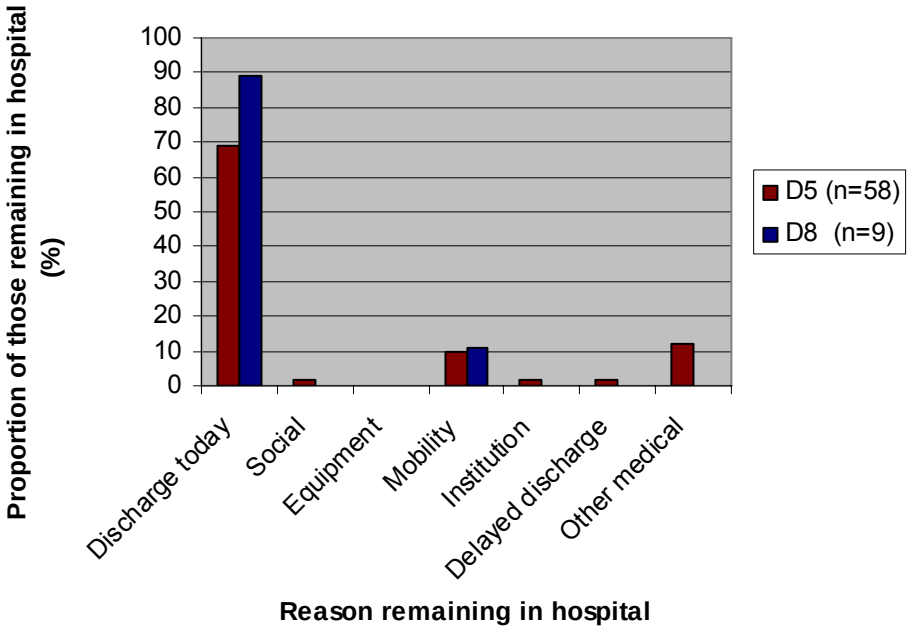
7.5.3.3.3 Magovern score

In those with greatest risk of post-operative morbidity, as defined by the Magovern score, higher frequencies were not observed in at least two C-POMS domains on each post-operative day. These were neurological and wound domains on D3, haematolgical and wound complication domains on D5, infectious, haematological, wound complication and electrolyte domains on D8 and infectious, and haematological and wound complications on D15. However, none were statistically significant. All other domains did have a higher frequency in those with greatest risk on all post-operative days. Those with a significant difference were pulmonary, renal, cardiovascular, endocrine and assisted ambulation on D3 (63.6% vs 79.9%, p=0.002; 22.3% vs 47.0%, p=0.000; 46.2% vs 60.4%, p=0.011; 19.6% vs 39.3%, p=0.000; 32.8% vs 58.4%, p=0.000, respectively) and D5 (28.0% vs 45.6%, p=0.001; 8.9% vs 27.2%, p=0.000; 45.2% vs 57.1, p=0.042; 3.6% vs 15.6%, p=0.000; 13.2% vs 42.2%, p=0.000, respectively), with renal and assisted ambulation on D8 (renal: 9.4% vs 33.3%, p=0.002; assisted ambulation: 21.2% vs 42.3%, p=0.014) and pulmonary and assisted ambulation on D15 (pulmonary: 9.1% vs 47.4%, p=0.049; assisted ambulation: 0.0% vs 36.8%, p=0.029).

7.5.3.4 Remaining in hospital with a C-POMS score of zero and those discharged home with a C-POMS score of ≥1

There were 58 out of the 426 in-patients on D5 (13.6%) and 9 out of 181 (5.0%) in-patients on D8, that had a C-POMS score of ‘0’. There were no in-patients with a C-POMS score of ‘0’ on D15. As shown in Figure 7-3, the majority of the participants were discharged on D5 and D8 (42/58 (72.4%) and 8/9 (88.9%), respectively). Of those remaining in hospital (16 on D5 and 1 on D8), social and organisational factors delayed discharge for 9 (56.3%) on D5 and in 1 (100.0%) on D8.

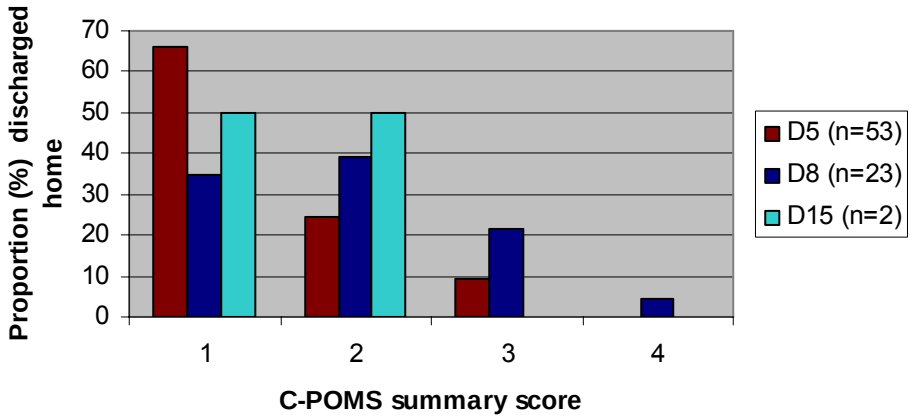
Figure 7-3: Reasons for non-discharge in participants with a C-POMS score of 0.



However, while C-POMS encompassed all the medical reasons for remaining in hospital on D8, 7 of the 58 participants (12.1%) with a zero C-POMS score on D5, remained in hospital for a medical reason. These reasons were increased weight requiring treatment (2), 'discharge planned for tomorrow' (2), peripheral oedema requiring observation (1) and increased blood sugar measurement (but no additional treatment prescribed) (1). One participant refused to go home.

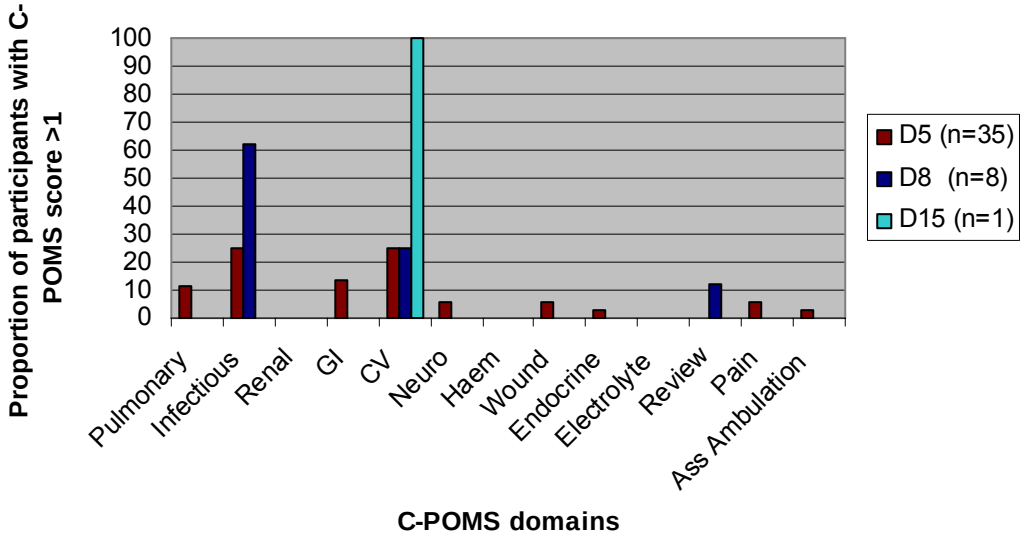
Overall, on D5, D8 and D15, 55/426 (12.9%), 26/181 (14.4%) and 6/48 (12.5%) participants, respectively, with a C-POMS score of ≥1 were discharged from the hospital where the surgery was undertaken. Of those, 2/55 (3.6%) on D5, 2/26 (7.7%) on D8 and 4/6 (66.7%) on D15 were either transferred to another NHS hospital or discharged to a convalescence/nursing home. One participant with a C-POMS score of 5 died on D8. The remaining participants were discharged home. There were 53/426 (12.4%), 23/181 (12.7%) and 2/48 (4.2%) participants with a C-POMS score of ≥1 that were discharged home on D5, D8 and D15, respectively. Figure 7-4 shows the proportion of participants with each summary score by discharge day.

Figure 7-4: The proportion of participants that were discharged home while having a C-POMS score of ≥1.



Of the participants with a C-POMS score of 1 (Figure 7-5), the majority discontinued the treatment they were receiving (oxygen supplementation, antibiotics, pacing wires were removed), or were prescribed medications to be taken on discharge (antibiotics, pain (wound) medication, anti-emetics (GI)). There were no participants with a score of 1 that was attributable to a renal, haematological or electrolyte domain morbidity.

Figure 7-5: C-POMS domains that were present in participants that were discharged home while having a C-POMS score of 1.



The combinations of domains present for those discharged home with a C-POMS score of 2, 3 or 4 are shown in Table 7-8.

Table 7-8: C-POMS domains and criteria present for participants that were discharged home with a C-POMS score of 2, 3 or 4.

	Frequency		
C-POMS score 2	**D5**	**D8**	**D15**
Pulmonary (O_2) + Infection (antibiotics)	3	1	
Infection (antibiotics) + CV (arrhythmia)	1		
Infection (antibiotics) + GI (nausea)	1		
Infection (antibiotics) + Ambulation (sticks)	1		
Infection (antibiotics) + Pain	1		
GI (diarrhoea) + CV (arrhythmia)	1		
GI (nausea) + CV (arrhythmia)	2		
GI (abdominal) + Neurological (blurred vision)	1		
CV (arrhythmia) + Neurological (confusion)	1		
Neurological (delirium) + Pain (continued)	1		
Pulmonary (O_2 and nebs) + CV (paced)		1	
Infection (antibiotics) + CV (pulmonary oedema)		1	
CV (paced and pulmonary oedema) + Haematological (INR)		1	
CV (arrhythmia) + Renal (abnormal potassium level)		1	
Infection (antibiotics) + Haematological (INR)		1	
CV (arrhythmia) + Neurological (blurred vision)		1	
GI (nausea and diarrhoea) + CV (arrhythmia)		1	
GI (vomiting) + Endocrine		1	
Renal (creatinine) + CV (paced and arrhythmia)			1
C-POMS score 3			
Pulmonary (O_2 and nebs) + Infection (antibiotics) + GI (nausea)	1		
Pulmonary (pleural effusion) + Infection (antibiotics) + GI (abdominal)	1		
Pulmonary (O_2 and nebs) + Infection (antibiotics) + CV (arrhythmia)	1		
Infection (antibiotics) + CV (arrhythmia) + Haematological (INR)	1	1	
GI (nausea) + Endocrine + Review (further review)	1		
Infection (antibiotics) + GI (diarrhoea) + Electrolyte (sodium)		1	
Infection (antibiotics) + GI (nausea and abdominal) + Endocrine		1	
Infection (antibiotics) + CV (paced, arrhythmia, pulmonary oedema) + Haematological (INR)		1	
Infection (antibiotics) + GI (nausea) + CV (arrhythmia)		1	
C-POMS score 4			
Pulmonary (O_2) + Infection (antibiotics) + CV (pulmonary oedema) + assisted ambulation (walking sticks)		1	

Overall, there were 29 domain-criteria combinations, with only 2 combinations occurring in more than one participant. The wound complication morbidity type was the only domain not to be present in any participant.

7.5.3.5 Multivariate analysis

Five domains on D3 were independently predictive of subsequent length of stay (Table 7-9). Those with, renal, gastrointestinal, neurological, haematological and wound complications have an additional 3.0, 2.2, 2.5, 3.2 and 8.4 days in hospital (post D3) than patients without those morbidities, regardless of whether or not they have other types of morbidity.

Table 7-9: Independent predictive strength of each C-POMS domain on D3 (n=450).

D3: C-POMS domains	Adjusted difference in subsequent length of stay (days)	p	95%CI
Pulmonary	1.1	0.358	-1.236-3.415
Infectious	1.5	0.175	-0.670-3.661
Renal	**3.0**	**0.015**	**0.583-5.503**
Gastrointestinal	**2.2**	**0.034**	**0.175-4.310**
Cardiovascular	-0.1	0.960	-2.181-2.073
Neurological	**2.5**	**0.026**	**0.309-4.765**
Haematological	**3.2**	**0.032**	**0.271-6.150**
Wound complication	**8.4**	**0.001**	**3.658-13.237**
Pain	-2.9	0.403	-9.610-3.868
Endocrine	0.8	0.487	-1.478-3.097
Electrolyte	-1.7	0.589	-7.977-4.535
Review	3.4	0.222	-2.067-8.869
Assisted ambulation	1.2	0.351	-1.278-3.589

On D5 the pulmonary, renal, neurological, pain and endocrine domains were independently predictive of subsequent length of stay (post D5) with an extra 2.3, 3.9, 5.4, 3.7 and 3.5 days in hospital, respectively, for those with these morbidities than those without them (Table 7-10).

Table 7-10: Independent predictive strength of each C-POMS domain on D5 (n=426).

D5: C-POMS domains	Adjusted difference in subsequent length of stay (days)	p	95%CI
Pulmonary	**2.3**	**0.048**	**0.017-4.643**
Infectious	0.6	0.535	-1.389-2.670
Renal	**3.9**	**0.013**	**0.837-7.007**
Gastrointestinal	0.5	0.634	-1.650-2.708
Cardiovascular	0.8	0.465	-1.304-2.850
Neurological	**5.4**	**0.000**	**2.370-8.351**
Haematological	1.5	0.273	-1.168-4.128
Wound complication	1.2	0.633	-3.769-6.194
Pain	**3.7**	**0.039**	**0.189-7.302**
Endocrine	**3.5**	**0.040**	**0.157-6.915**
Electrolyte	5.4	0.101	-1.071-11.953
Review	-0.6	0.737	-4.835-3.101
Assisted ambulation	1.7	0.202	-0.925-4.353

Three domains on D8 are independently predictive of subsequent length of stay (Table 7-11). Those with renal, haematological or wound complications, compared to those who do not, have an additional 6.5, 5.7 and 24.7 days (post D8), respectively, in hospital.

Table 7-11: Independent predictive strength of each C-POMS domain on D8 (n=181).

D8: C-POMS domains	Adjusted difference in subsequent length of stay (days)	p	95%CI
Pulmonary	1.2	0.602	-3.393-5.839
Infectious	2.4	0.194	-1.246-6.095
Renal	**6.5**	**0.015**	**1.299-11.791**
Gastrointestinal	2.5	0.252	-1.813-6.870
Cardiovascular	-1.8	0.382	-5.863-2.259
Neurological	3.4	0.200	-1.826-8.679
Haematological	**5.7**	**0.01**	**1.382-10.084**
Wound complication	**24.7**	**0.000**	**16.056-33.280**
Pain	-1.8	0.652	-9.566-6.002
Endocrine	2.7	0.435	-4.038-9.342
Electrolyte	3.4	0.453	-5.535-12.355
Review	0.8	0.800	-5.287-6.843
Assisted ambulation	1.8	0.440	-2.802-6.411

There were four domains that were independently predictive of subsequent length of stay on D15 (Table 7-12). Those with renal, pain and electrolyte morbidities had an additional 10.7, 77.4 and 74.1 days in hospital than those that did not have those morbidities. Those with an endocrine morbidity on D15 had 15.1 days less in hospital than those without the morbidity.

Table 7-12: Independent predictive strength of each C-POMS domain on D15 (n=48).

D15: C-POMS domains	Adjusted difference in subsequent length of stay (days)	p	95%CI
Pulmonary	4.1	0.413	-6.075-14.415
Infectious	6.8	0.126	-2.030-15.673
Renal	**10.7**	**0.049**	**0.063-21.357**
Gastrointestinal	2.7	0.623	-8.521-14.002
Cardiovascular	-7.3	0.111	-16.284-1.766
Neurological	-1.6	0.793	-13.889-10.700
Haematological	1.8	0.709	-8.128-11.822
Wound complication	5.2	0.356	-6.095-16.460
Pain	**77.4**	**0.000**	**45.917-108.989**
Endocrine	**-15.1**	**0.034**	**-28.908-1.235**
Electrolyte	**74.1**	**0.000**	**43.265-104.840**
Review	0.7	0.925	-13.750-15.091
Assisted ambulation	8.3	0.124	-2.406-19.092

Overall, C-POMS defined morbidity explains 16.5%, 22.3%, 43.1% and 82.0% of the variance in subsequent length of post-operative stay on D3, D5, D8 and D15, respectively.

7.6 DISCUSSION

7.6.1 C-POMS defined morbidity and increased length of stay

As hypothesised, participants with C-POMS defined morbidity remained in hospital longer than those who did not have C-POMS defined morbidity on D3 (+ 4.6 days), D5 (+ 5.3 days) and D8 (+ 7.6 days), while no participants were without C-POMS defined morbidity on D15. Thus, those without C-POMS-defined morbidity on D3 had on average a further 2.3 days in hospital, while those without C-POMS-defined morbidity on D5 and D8 were likely to be discharged on D5 and D8, respectively. This shows that the C-POMS model does appear to exhibit construct validity when comparing the length of subsequent stay in those with and without C-POMS defined morbidity.

7.6.2 C-POMS summary score

C-POMS also demonstrated sufficient internal consistency to be used as a summary score on D3, D5, D8 and D15. While a score of 1 or 2 was observed in the majority of participants on each day, a score of 6 or more was observed in approximately 20% of participants on D3, D8 and D15 with 2.8% and 4.2% experiencing morbidity in 10 or more C-POMS domains on D8 and D15, respectively. This substantial burden of morbidity has implications not only for the patient but for the clinical service since a 1.7, 2.2, 4.5 and 6.3 day increase in subsequent length of stay per unit increase in C-POMS on D3, D5, D8 and D15, respectively, was identified. However, this will be

discussed in further detail later (section 9.5.6). The finding that C-POMS did not have sufficient internal consistency on D1 to be used as a summary score is unsurprising due to the extent of routine requirements in the immediate post-operative period (for example, supplementary oxygen support, administration of antibiotics, urinary catheter insitu, chest drains insitu, assisted ambulation) that would register a minimum C-POMS score of 5 for all patients on D1. This is consistent with the original POMS[1] and POMS validation study[93] that do not report D1 results for this reason.

7.6.3 Association of pre-operative risk assessment scores on C-POMS

EuroSCORE, POSSUM and Magovern score were only modestly associated with C-POMS summary score on D3 and D5 and with EuroSCORE only on D8. Such a result is consistent with what would be anticipated from any of the three instruments due to their limitations and the lack of an overall gold standard. EuroSCORE is a pre-operative risk assessment tool for post-operative mortality. Since complication rate does not correlate well with mortality rate[16, 17] and pre-operative risk prediction models for mortality significantly underestimate post-operative morbidity[6], greater prediction of C-POMS was not expected. The POSSUM score is used to predict post-operative morbidity risk but the morbidity complications included in devising the morbidity risk were arbitrarily set and then categorised to those having a complicated or uncomplicated recovery[90]. Furthermore, it was developed and validated on patients undergoing general surgery only. In contrast, the Magovern score was developed and validated on cardiac surgical patients with a number of well-defined major and minor morbidity outcomes. Although this score was developed in a single site and was unvalidated at time of publication, greater prediction of C-POMS was anticipated. Potential reasons for not observing this are that construct validity can vary across populations and since Magovern's sample consisted of CABG only patients, was conducted in the USA, and developed and validated 10 years prior to C-POMS, strong associations perhaps cannot be expected. However, the most likely explanation is that although the Magovern score used a number of well-defined morbidities to construct their pre-operative risk assessment score, the morbidities were not similar enough to those included in C-POMS, for the Magovern score to be able to accurately predict C-POMS.

As hypothesised, C-POMS domain frequencies are higher in patients with greatest post-operative risk as defined by EuroSCORE (except infectious), POSSUM (except wound complication) and Magovern score (except neurological, wound, haematological, infection and electrolyte domains on certain days). Since EuroSCORE contains pre-operative pulmonary disease, renal dysfunction and cardiovascular conditions, it is unsurprising that significant differences were observed in the frequency of the pulmonary, renal and cardiovascular domains. This also applies to the POSSUM physiological score (which includes pulmonary, renal, cardiovascular and infection items and it was in these domains that a significantly higher frequency was observed in those with greatest surgical risk) and the Magovern score (significantly higher frequency in pulmonary, renal, cardiovascular and endocrine domains with items relating to these domains within the model).

7.6.4 New derived C-POMS domains

Of the new domains in C-POMS, endocrine (D3 EuroSCORE and D3, D5 POSSUM and Magovern score) and assisted ambulation (all days EuroSCORE and Magovern score, D3, D5 and D15 POSSUM) were also significantly higher in the higher surgical risk groups. In patients undergoing isolated CABG, the proportion of diabetics has increased by 33% between 2001 and 2008[25] with diabetes being a recognised risk factor for poorer outcome amongst patients undergoing cardiac surgery. Diabetics have a greater mortality rate (1.9% v 1.3 %)[25], a longer ICU[177] and post-operative stay (9.7days v 8.2 days)[25] and a significantly higher incidence of post-operative delirium, peri-operative stroke, renal dysfunction, sternal instability/infection and post-operative reintubation[177]. While 21% of patients undergoing non-cardiac surgery have undiagnosed diabetes[178], the proportion for those undergoing cardiac surgery is unknown. However, such patients will also contribute to those who exhibit endocrine domain morbidity post-operatively. Despite diabetes/endocrine function not being included in EuroSCORE or POSSUM, diabetic status does feature in the Magovern and Parsonnet[18] scores. Assisted ambulation, on the other hand, is only included within the neurological dysfunction definition within EuroSCORE as 'neurological dysfunction severely affecting ambulation or day-to-day functioning'. Interestingly, although both EuroSCORE and Magovern include cerebrovascular disease in their models the C-POMS neurological domain was not observed to have significantly higher frequencies in those with greatest surgical risk. This is possibly due to the different definitions used by EuroSCORE (stated above) and Magovern score ('focal brain injury documented by scan with a permanent functional deficit') compared with the C-POMS definition, which includes more transient neurological morbidities in addition to the permanent neurological morbidities.

7.6.5 Domains independently predictive of post-operative stay

Overall, nine of the thirteen C-POMS domains (five domains on D3 (renal, GI, neurological, haematological, wound) and D5 (pulmonary, renal, neurological, pain, endocrine), three on D8 (renal, haematological, wound) and four on D15 (renal, pain, endocrine, electrolyte)) independently predicted subsequent length of stay. Furthermore, the renal domain was independently predictive of subsequent length of stay at all post-operative time-points. While the results themselves are unsurprising, as these physiological complications are well documented in terms of prolonging hospital stay, this gives some assurance that the definitions used within C-POMS are producing expected results. The interesting aspect lies in that different domains independently predict subsequent length of stay on different post-operative days. There may be scope to further analyse this to ascertain if the presence of certain domains, or combinations of domains, in the early post-operative period lend to a particular subsequent post-operative recovery path. Currently, the possibility of this is being explored with Professor John Shawe-Taylor, Head of the Department of Computer Science at UCL.

7.6.6 Extent to which C-POMS explains length of stay

It was found that C-POMS-defined morbidity explained the variance in subsequent length of post-operative stay by 16.5%, 22.3%, 43.1% and 82.0% on D3, D5, D8 and D15, respectively. Thus, other factors not accounted for within C-POMS are influencing post-operative length of stay, particularly on D3 and D5. Four such influences might be suggested. Firstly, C-POMS does not assess patients every day and therefore some short-lived morbidities may not be identified or tracked. Secondly, human factors (doctor/nurse preferences, simple mistakes, minor delays) may also have some part in explaining the variance. Thirdly, not all morbidities may be accounted for in C-POMS. There were 7 (12.1% of those remaining in hospital on D5 with a C-POMS score of 0) with a C-POMS score of zero that remained in hospital due to a morbidity not identified by C-POMS, but none on D8. Finally, non-medical reasons are also likely to contribute to increased length of stay, since between 31%[15] and 53.9%[93] of general surgical patients have been found to be hospitalised for non-medical reasons. In this study it was found that 9 participants on D5 and 1 on D8 remained in the hospital they underwent surgery due to social or organisational reasons, indicating that while early discharge planning is still indicated, fewer patients remained in hospital due to social or organisational factors in this study.

Conversely, it was found that 12.4%, 12.7% and 4.2% of participants that were in hospital on D5, D8 and D15 were discharged home with C-POMS-defined morbidity on those days. If C-POMS were a perfect measure of morbidity it would be expected that no patients would be discharged with any C-POMS defined morbidity. However, no instruments will measure a health-related concept with 100% accuracy and anomalies will always be present. For example, in terms of mortality prediction, the additive EuroSCORE has been found to underestimate[179], the Parsonnet score has been found to over estimate[180] and both scores have been found to discriminate well overall between favourable/non-favourable outcome but not on individual predictions[62]. Furthermore, the predictive ability of EuroSCORE has been reported as an area under the receiver curve of between 0.7-0.8[62, 181], indicating a fair test but not perfect which would produce an area under the receiver curve of 1. Other considerations are that the presence of some morbidity is acceptable to be discharged home with (for example, antibiotics for an infection, anti-emetics for nausea, anti-arrhythmics for an arrhythmia) or that there is potentially some degree of unrequired treatment in hospital on those days (for example, a significant proportion of participants were receiving oxygen supplementation of the day of discharge).

7.6.7 Limitations and strengths of the validation process

The limitations in the validation process are threefold. Firstly, the C-POMS summary score was derived on the basis of the internal consistency, as measured using Cronbach's alpha, reaching the minimum acceptable standard of internal consistency, as described by Nunnally 1978[175]. Not only was this minimum standard only just met but the definition itself has been contested despite it being commonly accepted and widely used. Such criticisms include the lack of rationale for defining 0.7 as

the minimum[182, 183] and that a greater number of items can artificially increase Cronbach's alpha when no substantial consistency exists between items[183, 184]. In light of these criticisms, it has been suggested that the minimum standard should not be used as a definitive rule but that researcher discretion be applied[183]. Furthermore, it is also recognised that high alpha coefficients in a newly developed model may reflect the inclusion of redundant items[185]. Since inter-item correlations were conducted to delete redundant items prior to testing the internal consistency, such items are not likely to be enhancing the alpha coefficient in C-POMS and thus the internal consistency identified for C-POMS is likely to reflect the best estimate of it's reliability. Secondly, although indicated within the McMaster Framework as a necessary step in the validation of a health indices[154], the reliability/reproducibility step was not able to be conducted in this study. This was due to the lack of available personnel that could have undertaken inter-rater reliability testing. Additionally, test-retest reliability could not be conducted due to the changes that would occur in the participant morbidity profile once enough time had elapsed for such testing to be repeated. This could only have been achieved if the repeat data had been obtained retrospectively from the participant medical records. Since C-POMS is intended as a prospective model true results would potentially not be obtained. However, reliability/reproducibility testing would be an essential training step prior to data collection in the clinical setting if adopted as a routine data collection tool. Finally, although C-POMS currently exhibits construct validity, content validity decreases over time as new data and theories evolve[170]. Thus, future construct validity assessments will be necessary which will potentially identify a need for revisions to C-POMS in order for it to remain an appropriate measure of post-operative morbidity[172]. Methods to do this include the calculation of a content validity index (CVI) of each item[170, 186] or for the overall instrument[170]. However, calculating the CVI in the validation of C-POMS was unnecessary since part of C-POMS construction was based on expert panel judgments on the severity and importance of the morbidity items for inclusion into the model.

There are also several strengths of this validation process. Conceptual frameworks were used[173], which included recommended content validation methods[172] that assessed both the overall instrument as well as each individual facet[166]. Furthermore, sufficient data were collected to permit determination of the reasons for delayed discharge when participants remained in hospital when having no C-POMS defined morbidity. This enabled further exploration of the construct validity of C-POMS and also provides useful clinical information with regards to organisational and social issues related discharge planning.

7.7 CONCLUSION

C-POMS has sufficient internal consistency to be used as a summative score to denote total morbidity burden on post-operative D3, D5, D8 and D15 and also appears to exhibit construct validity, as assessed by pre-defined hypotheses.

8 RESULTS V: CLINICAL UTILITY OF C-POMS

8.1 INTRODUCTION TO CHAPTER

For C-POMS to be adopted within the clinical environment, the case must be made that no existing tools adequately address the phenomenon under consideration[173] and that C-POMS has clinical utility[163]. This chapter will explore both concepts in relation to C-POMS by presenting the results of C-POMS in quantifying post-operative morbidity, comparing C-POMS and POMS as morbidity outcome tools in patients undergoing cardiac surgery, and exploring the clinical utility with multi-professional teams at 2 cardiac surgical centres.

8.2 INTRODUCTION TO THE CLINICAL UTILITY OF C-POMS

Although a plethora of outcome measurement instruments exist[12], the POMS tool is the only prospective tool for the description and quantification of post-operative morbidity identified in the literature (chapter 1 section 1.4). My pilot data (chapter 4) indicate that POMS may underestimate post-operative morbidity in patients undergoing cardiac surgery and certainly, the generalisability of POMS to cardiac surgery patients remains unclear[93]. Furthermore, multifactorial models are generally poorly integrated into clinical practice[72] due to their complexity and requirement on clinical variables that are not readily attainable[57, 72] making them impractical to use. Nonetheless, whilst efforts were made to try to maintain simplicity, the clinical utility of C-POMS (in terms of length and ease of completion[173]), both on an individual patient level and as a tool to be administered for all patients undergoing cardiac surgery, requires assessment.

8.3 AIMS

a. To quantify post-operative morbidity after cardiac surgery using the C-POMS tool
b. To determine whether C-POMS does provide benefit over POMS in defining and quantifying post-operative morbidity in cardiac patients, by
    i. assessing the construct validity of POMS on the study population
    ii. comparing the results of C-POMS (chapter 7) and POMS
c. To explore the utility of C-POMS in clinical practice, by
    i. exploring the potential use of C-POMS as a routine data collection tool with the PDG (described chapter 2 section 2.4.2)
    ii. obtaining the opinions of others at the 2011 annual scientific meeting of the SCTS, following presentation of the results.

8.4 METHODS

8.4.1 Quantifying post-operative morbidity using C-POMS

The proportion of participants with the presence of each C-POMS domain and criteria, on each post-operative day, was calculated.

8.4.2 Applying POMS to the study population

The internal consistency and construct validity analysis applied to C-POMS, as detailed in the model validation chapter, were applied to POMS.

8.4.3 To explore the utility of C-POMS in clinical practice

The utility of C-POMS in clinical practice was explored through a variety of meetings:

- with the PDG,
- at the London Chest Hospital, London, UK.

8.5 RESULTS

8.5.1 Quantifying post-operative morbidity using C-POMS

The proportion of participants with the presence of each C-POMS domain is shown in Figure 8-1. The full breakdown of the proportion of participants with the presence of each C-POMS criterion is shown in Table 8-1.

Figure 8-1: Proportion of participants with the presence of each C-POMS domain.

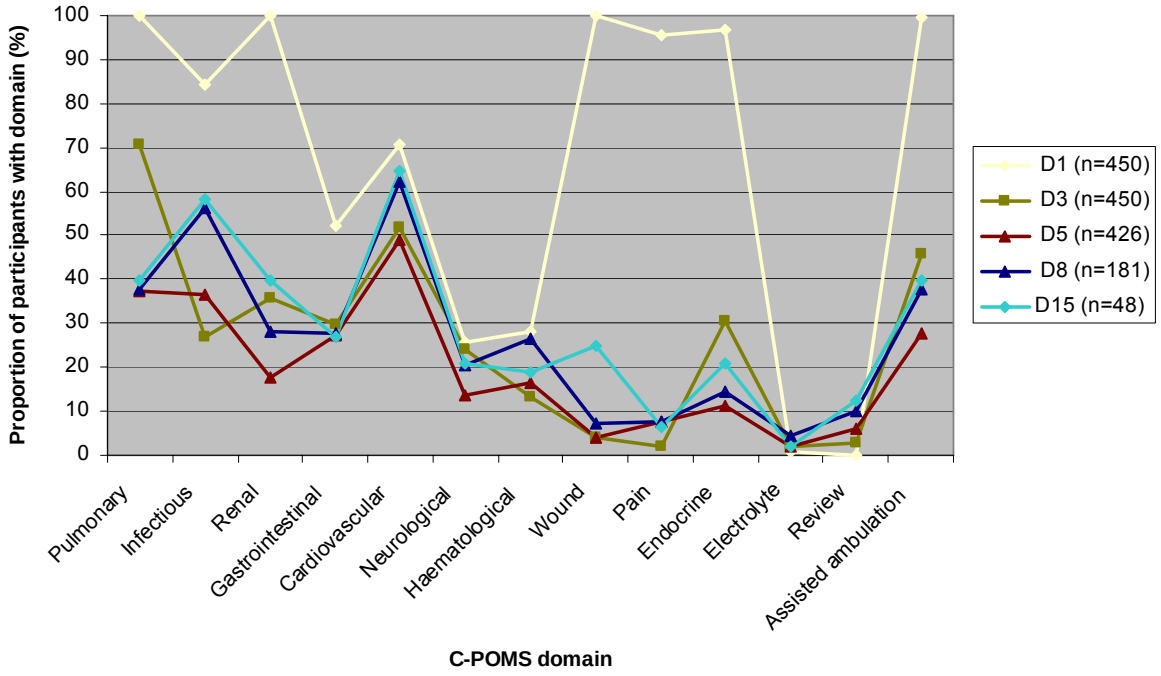


Table 8-1: Proportion of patients with each C-POMS criteria. Values are n(%). Criteria defining the morbidity types are not mutually exclusive.

Morbidity type and criteria	Post-op D1 (n=450)	Post-op D3 (n=450)	Post-op D5 (n=426)	Post-op D8 (n=181)	Post-op D15 (n=48)
Pulmonary	**449 (99.8)**	**318 (70.7)**	**159 (37.3)**	**68 (37.6)**	**19 (39.6)**
Supplementary oxygen or support	449 (99.8)	304 (67.6)	139 (32.6)	64 (35.4)	19 (39.6)
Pleural effusion requiring drainage	4 (0.9)	14 (3.1)	38 (8.9)	12 (6.6)	1 (2.1)
Infectious	**380 (84.4)**	**121 (26.9)**	**155 (36.4)**	**102 (56.4)**	**28 (58.3)**
Antibiotics	376 (83.6)	109 (24.2)	152 (35.7)	100 (55.2)	28 (58.3)
Pyrexia (>38^{0}C)	19 (4.2)	21 (4.7)	5 (1.2)	2 (1.1)	1 (2.1)
WCC/CRP level requiring review	0 (0.0)	9 (2.0)	5 (1.2)	6 (3.3)	0 (0.0)
Renal	**449 (99.8)**	**160 (35.6)**	**75 (17.6)**	**51 (28.2)**	**19 (39.6)**
Decreased urine output	207 (46.0)	53 (11.8)	31 (7.3)	14 (7.7)	6 (12.5)
Creatinine >30% pre-op)	26 (5.8)	56 (12.4)	25 (5.9)	21 (11.6)	10 (20.8)
Urinary catheter insitu	448 (99.6)	142 (31.6)	61 (14.3)	33 (18.2)	13 (27.1)
Urinary incontinence	0 (0.0)	4 (0.9)	3 (0.7)	3 (1.7)	0 (0.0)
Serum K level requiring treatment	1 (0.2)	0 (0.0)	1 (0.2)	2 (1.1)	3 (6.3)
Gastrointestinal	**235 (52.2)**	**134 (29.8)**	**116 (27.2)**	**50 (27.6)**	**13 (27.1)**
Nausea	223 (49.6)	92 (20.4)	75 (17.6)	31 (17.1)	5 (10.4)
Vomiting	79 (17.6)	21 (4.7)	11 (2.6)	2 (1.1)	0 (0.0)
Abdominal distention	6 (1.3)	20 (4.4)	22 (5.2)	8 (4.4)	8 (16.7)
NG tube	10 (2.2)	20 (4.4)	18 (4.2)	12 (6.6)	7 (14.6)
GI bleed	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	1 (2.1)
Diarrhoea	0 (0.0)	22 (4.9)	21 (4.9)	9 (5.0)	2 (4.2)
Cardiovascular	**318 (70.7)**	**233 (51.8)**	**208 (48.8)**	**113 (62.4)**	**31 (64.6)**

Inotropic therapy	111 (24.7)	31 (6.9)	7 (1.6)	3 (1.7)	0 (0.0)
Paced	114 (25.3)	42 (9.3)	30 (7.0)	21 (11.6)	6 (12.5)
Pacing wires	NA	NA	9 (2.1)	1 (0.6)	1 (2.1)
MI or ischaemia	15 (3.3)	4 (40.9)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension	142 (31.6)	58 (12.9)	26 (6.1)	9 (5.0)	6 (12.5)
Atrial or vent arrhythmia	93 (20.7)	152 (33.8)	162 (38.0)	86 (47.5)	25 (52.1)
Cardiogenic pulmonary oedema	44 (9.8)	60 (13.3)	56 (13.1)	41 (22.7)	8 (16.7)
Hypertension	82 (18.2)	22 (4.9)	16 (3.8)	4 (2.2)	1 (2.1)
Neurological	**116 (25.8)**	**108 (24.0)**	**58 (13.6)**	**37 (20.4)**	**10 (20.8)**
Confusion	35 (7.8)	26 (5.8)	18 (4.2)	15 (8.3)	5 (10.4)
Delirium	29 (6.4)	44 (9.8)	19 (4.5)	4 (2.2)	0 (0.0)
Focal deficit	2 (0.4)	6 (1.3)	7 (1.6)	7 (3.9)	0 (0.0)
Coma	2 (0.4)	1 (0.2)	1 (0.2)	1 (0.6)	1 (2.1)
Agitated	8 (1.8)	10 (2.2)	0 (0.0)	3 (1.7)	0 (0.0)
Lack of coordination	6 (1.3)	3 (0.7)	4 (0.9)	0 (0.0)	0 (0.0)
Drowsy/slow to wake	7 (1.6)	1 (0.2)	0 (0.0)	1 (0.6)	2 (4.2)
Poor swallow	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.6)	0 (0.0)
Blurred vision	26 (5.8)	23 (5.1)	8 (1.9)	5 (2.8)	0 (0.0)
Sedated	16 (3.6)	8 (1.8)	6 (1.4)	8 (4.4)	2 (4.2)
Changing level of consciousness	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.6)	0 (0.0)
Haematological	**127 (28.2)**	**59 (13.1)**	**70 (16.4)**	**48 (26.5)**	**9 (18.8)**
Untherapeutic INR	70 (15.6)	49 (10.9)	65 (15.3)	40 (22.1)	5 (10.4)
RBC	63 (14.0)	11 (2.4)	6 (1.4)	8 (4.4)	4 (8.3)
Platelets	3 (0.7)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
FFP	10 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Cryoprecipiate	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Wound complication	**449 (99.8)**	**19 (4.2)**	**17 (4.0)**	**13 (7.2)**	**12 (25.0)**
Surgical exploration	1 (0.2)	0 (0.0)	2 (0.5)	3 (1.7)	0 (0.0)
Drainage	449 (99.8)	11 (2.4)	7 (1.6)	11 (6.1)	11 (22.9)
Chest drains	449 (99.8)	10 (2.2)	6 (1.4)	4 (2.2)	0 (0.0)
Wound pain	18 (4.0)	8 (1.8)	10 (2.3)	2 (1.1)	1 (2.1)
Pain	**430 (95.6)**	**9 (2.0)**	**33 (7.7)**	**14 (7.7)**	**3 (6.3)**
Endocrine	**436 (96.9)**	**137 (30.4)**	**48 (11.3)**	**26 (14.4)**	**10 (20.8)**
Electrolyte	**4 (0.9)**	**10 (2.2)**	**9 (2.1)**	**8 (4.4)**	**1 (2.1)**
Na	1 (0.2)	0 (0.0)	3 (0.7)	4 (2.2)	0 (0.0)
Urea	0 (0.0)	9 (2.0)	6 (1.4)	4 (2.2)	1 (2.1)
Phosphate	3 (0.7)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Review	**0 (0.0)**	**13 (2.9)**	**25 (5.9)**	**18 (9.9)**	**6 (12.5)**
Clinical review	0 (0.0)	9 (2.0)	15 (3.5)	10 (5.5)	4 (8.3)
Investigation or procedure	0 (0.0)	4 (0.9)	10 (2.3)	8 (4.4)	3 (6.3)
Ambulation	**448 (99.6)**	**205 (45.6)**	**118 (27.7)**	**68 (37.6)**	**19 (39.6)**
Wheelchair	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Crutches	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Zimmer frame	0 (0.0)	5 (1.1)	10 (2.3)	10 (5.5)	3 (6.3)
Walking sticks	0 (0.0)	10 (2.2)	17 (4.0)	8 (4.4)	6 (12.5)
Bedbound	29 (6.4)	78 (17.3)	40 (9.4)	27 (14.9)	10 (20.8)
With assistance	418 (95.9)	99 (22.0)	44 (10.3)	19 (10.5)	3 (6.3)
Attached to equipment	0 (0.0)	13 (2.9)	7 (1.6)	4 (2.2)	0 (0.0)

Overall, D1 is a poor discriminator in 7 domains (pulmonary, infectious, renal, wound complication, pain, endocrine and ambulation) primarily due to routine care requirements. For example, oxygen supplementation and the presence of a urinary catheter are standard on D1, hence pulmonary and renal domains are present in 99.8% of participants. The highest level of morbidity on D3 was observed in the pulmonary domain (70.7%), on D5 and D8 in the cardiovascular domain (48.8% and 62.4%, respectively) and on D15 in the infectious domain (58.3%). Unsurprisingly, the proportion of participants requiring further review increased steadily over the post-operative stay (D3 2.9%, D5 5.9%, D8 9.9% and D15 12.5%). GI complications were seen in just over a quarter of patients on D3-D15, mainly attributable to nausea on D3-D8, and abdominal distention and the presence of an NG tube on D15. For the other domains, the criteria that considerably contributed to each were supplementary oxygen (pulmonary), antibiotic use (infectious), urinary catheter in situ (renal), MI/ischaemia (D3) and atrial/ventricular arrhythmias (D5-D15) (cardiovascular), untherapeutic INR (haematological), drainage (wound complication), urea abnormalities (electrolyte), clinical review (review) and with a requirement for assistance with mobilisation/bedbound (ambulation). The proportion of the presence of the neurological domain criteria were much more spread, although confusion and delirium did contribute to at least half of the identified neurological domain morbidity.

8.5.2 Applying POMS to the study population and comparison with C-POMS

8.5.2.1 Internal consistency

The frequency of those with and without POMS-defined morbidity on each post-operative day is shown in Table 8-2.

Table 8-2: Frequency of those with and without POMS-defined morbidity. Values are stated at n(%).

Post-operative day	Without POMS	With POMS	Missing data
D3 (n=450)	58 (12.9)	390 (86.7)	2 (0.4)
D5 (n=426)	110 (25.8)	316 (74.2)	0 (0.0)
D8 (n=181)	21 (11.6)	159 (87.8)	1 (0.6)
D15 (n=48)	4 (8.3)	44 (91.7)	0 (0.0)

As expected, since all POMS domains and criteria were included in C-POMS, there were fewer participants with POMS-defined morbidity on each post-operative day. Conversely, that means that on each post-operative day a greater proportion of in-patient participants (up to 25.8% on D5) had no-recorded morbidity.

Only D15 for POMS shows minimum level of internal consistency (≥0.7) (Table 8-3).

Table 8-3: Internal consistency of POMS.

Post-operative day	POMS
D1	0.07
D3	0.49
D5	0.56
D8	0.63
D15	0.66

For POMS, a summary score was then calculated for each participant for post-operative D15 only. Table 8-4 shows the frequency of each summary score.

Table 8-4: POMS summary score frequencies. Value n(%).

Score	Frequency
0	4 (8.3)
1	14 (29.2)
2	13 (27.1)
3	4 (8.3)
4	4 (8.3)
5	3 (6.2)
6	3 (6.2)
7	3 (6.2)
8	0 (0.0)
9	0 (0.0)

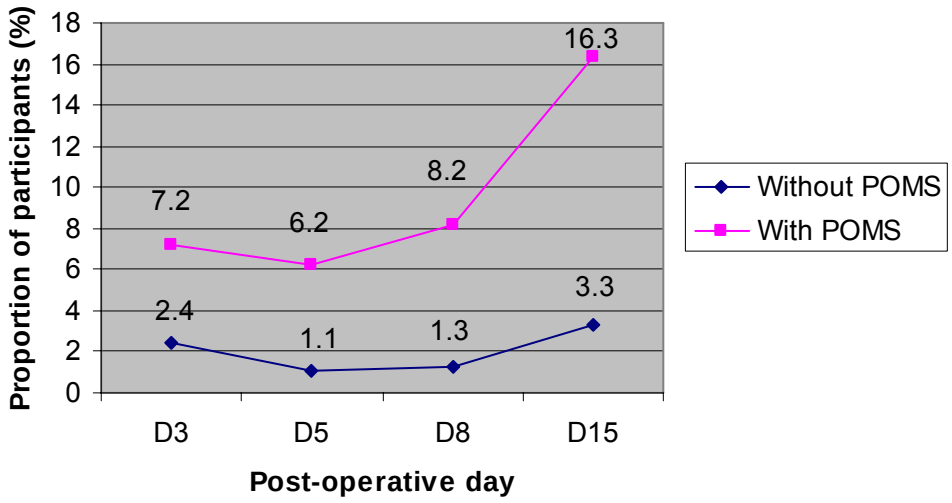
The maximum POMS score of any participant was 7, with the highest frequency of participants having one recorded morbidity. The mean score was 2.5 and there were 8.3% of participants with no POMS-defined morbidity.

8.5.2.2 Construct validity

8.5.2.2.1 POMS summary score and subsequent LOS

Participants with POMS-defined morbidity on post-operative D3, D5 and D8 remain in hospital for an additional 4.8 (p=0.001), 5.1 days (p=0.000) and 6.9 days (p=0.047), respectively, compared to those without such morbidity on those days (Figure 8-2). No significant difference was observed between those with and without POMS-defined morbidity on D15 (p=0.296).

Figure 8-2: Subsequent length of post-operative stay comparing those with an without POMS defined post-operative morbidity.



For every unit increase in POMS summary score on D15 there is an 8.2 day (95% CI 5.223-11.213, p=0.000) increase in subsequent length of stay.

8.5.2.2.2 EuroSCORE, POSSUM and Magovern score

Table 8-5 shows that EuroSCORE, POSSUM and Magovern scores do not predict POMS summary score on D15. A negative relationship between EuroSCORE and POSSUM with POMS summary score on D15 is observed (for every unit increase in EuroSCORE or POSSUM there is a 0.03 or 0.20 decrease in POMS summary score, respectively) while for every unit increase in Magovern score a statistically non-significant 0.013 increase in POMS score is observed.

Table 8-5: Predictive power of EuroSCORE, POSSUM and Magovern scores on POMS summary score.

	Level of predicting POMS summary score	**p**	**95%CI**
EuroSCORE			
D15	-0.03	0.684	-0.198-0.131
POSSUM			
D15	-0.20	0.676	-0.116-0.076
Magovern			
D15	0.013	0.889	-0.174-0.200

8.4.1.1.1 Domain level analysis:

Tables detailing the full results are detailed in Appendix 8: POMS domain level analysis..

8.5.2.2.2.1 EuroSCORE

The frequency of each domain was higher in those with greatest surgical risk as defined by EuroSCORE with the exception of the infectious domain on D3, D5 and D8, the cardiovascular domain on D3 and D15, the wound complication domain on D8 and D15 and the neurological and haematological domains on D15. Significant differences were observed on D3 in the pulmonary (79.9% vs 59.2%, p=0.000), renal (50.0% vs 23.6%, p= 0.000), gastrointestinal (32.4% vs 19.9%, p=0.003) and haematological domain (4.9% vs 1.1%, p=0.017), on D5 in the pulmonary (36.3% vs 19.3%, p=0.000), renal (22.0% vs 11.1%, p=0.003) and cardiovascular domain (51.6% vs 36.9%, p=0.003) and on D8 in the cardiovascular domain only (65.0% vs 48.8%, p=0.034). However, on D3 the highest frequency of cardiovascular morbidity as defined by POMS was observed in those with lowest pre-operative risk as defined by EuroSCORE (53.6% vs 50.0%, p=0.026) and there were no significant differences observed on D15.

8.5.2.2.2.2 POSSUM

The frequency of each domain on D3 and D5 was higher in those with higher risk as defined by the POSSUM physiological score and significantly higher on both days in the pulmonary (D3: 77.9% vs 42.3%, p=0.000; D5: 36.1% vs 17.1%, p=0.000), renal (D3: 50.5% vs 36.1%, p=0.003; D5: 24.8% vs 6.2%, p=0.000) and cardiovascular domains (D3: 50.5% vs 36.1%, p=0.003; D5: 50.5% vs 34.8%, p=0.001) and in the neurological domain on D3 only (22.1% vs 14.1%, p=0.033). A higher frequency was observed in those with greatest risk in all domains on D8 and D15, with the exception of the cardiovascular domain (D15), wound complication domain (D8 and D15) and the infectious domain (D8 and D15) which was significantly different on D8 (66.7% vs 49.1%, p=0.037).

8.5.2.2.2.3 Magovern score

A higher frequency of each domain was observed in those with greatest risk as defined by the Magovern score with the exception of the pulmonary and neurological domains on D3, infectious, and wound complications domains on D8 and the infectious, gastrointestinal, cardiovascular and haematological domains on D15. Significant differences were observed in the renal domain on D3, D5 and D8 (45.0% vs 21.7%, p=0.000; 25.2% vs 7.1%, p=0.000; 28.2% vs 9.4%, p=0.014, respectively), pulmonary domain on D5 and D15 (36.7% vs 17.9%, p=0.000; 36.8% vs 0.0%, p=0.029, respectively) and also on D3 although the higher frequency was observed in the lower risk group (55.3% vs 44.7%, p=0.000).

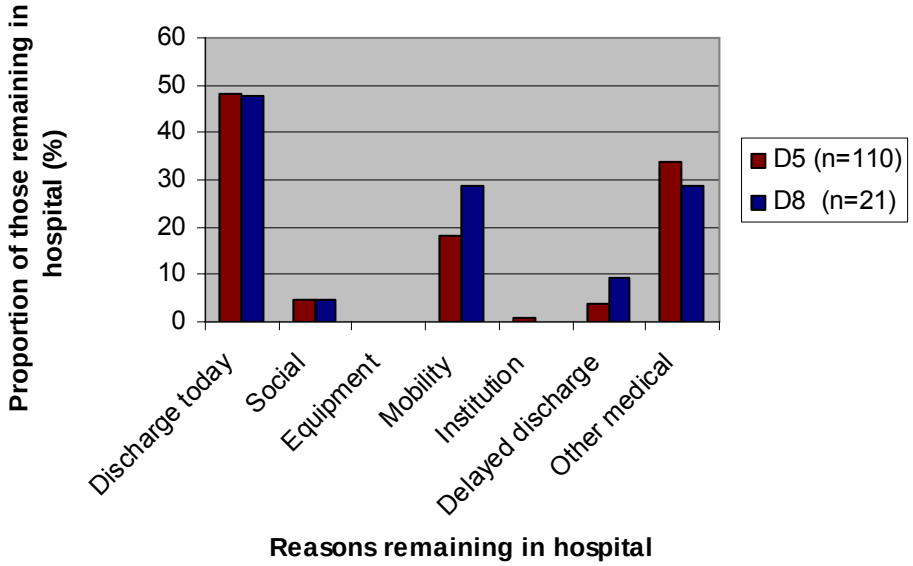
8.5.2.3 Remaining in hospital with a POMS score of zero and those discharged home with a POMS score of ≥1

On D15, there were 4 (8.3%) participants that had a POMS score of zero but remained in hospital. One participant was discharged to a nursing home on D15 while 3 participants were transferred on D16, D20, D22 to their local hospitals, having a total length of hospital stay of 18 days, 21 days and

57 days, respectively. Conversely, on D15 2 (4.2%) participants were discharged home with a POMS score of ≥1. One participant scored 1 (cardiovascular domain) and 1 participant scored 2 (cardiovascular and renal domains).

Due to the lack of sufficient internal consistency to calculate a POMS summary score on D5 and D8, comparisons can only be made in those with and without POMS-defined morbidity. It was observed that of those with no POMS-defined morbidity 110 (25.8%) and 21 (11.6%) remained in hospital on D5 and D8, respectively. The reasons for remaining in hospital are detailed in Figure 8-3.

Figure 8-3: Reasons for non-discharge in participants with no POMS-defined morbidity.



Furthermore, 42 (9.9%) and 21 (11.6%) of participants were discharged home on D5 and D8, respectively, that were suffering from some POMS-defined morbidity.

8.5.2.4 Multivariate analysis

Three domains on D3 were independently predictive of subsequent length of stay (Table 8-6). Those with renal, haematological and wound complication morbidities as defined by POMS have an additional 3.8, 10.1 and 11.8 days in hospital (post D3) than participants without those morbidities.

Table 8-6: Independent predictive strength of each POMS domain on D3.

D3: POMS domains	Adjusted difference in subsequent length of stay (days)	95% CI	P
Pulmonary	2.1	-0.028-4.243	0.053
Infectious	2.0	-0.166-4.140	0.070
Renal	**3.8**	**1.638-6.038**	**0.001**
Gastrointestinal	1.5	-0.599-3.633	0.160
Cardiovascular	0.076	-1.906-2.058	0.940
Neurological	1.6	-0.898-4.000	0.214
Haematological	**10.1**	**4.165-16.048**	**0.001**
Wound complication	**11.8**	**5.464-18.122**	**0.000**
Pain	-4.395	-11.198-2.408	0.205

On D5, the pulmonary, renal and neurological domains are independently predictive of subsequent length of stay (post D5) with an extra 3.8, 5.9 and 5.6 days in hospital, respectively, for those with these morbidities than those without them (Table 8-7).

Table 8-7: Independent predictive strength of each POMS domain on D5.

D5: POMS domains	Adjusted difference in subsequent length of stay (days)	95% CI	p
Pulmonary	**3.8**	**1.249-6.345**	**0.004**
Infectious	0.7	-1.356-2.689	0.517
Renal	**5.9**	**2.774-8.958**	**0.000**
Gastrointestinal	0.6	-1.713-2.817	0.632
Cardiovascular	0.5	-1.538-2.446	0.654
Neurological	**5.6**	**2.425-8.761**	**0.001**
Haematological	-0.1	-8.126-7.895	0.977
Wound complication	10.9	2.625-19.215	0.10
Pain	7.2	1.050-13.414	0.22

Three domains are independently predictive of subsequent length of stay post D8 (Table 8-8).Those with renal, haematological and wound complications, as defined by POMS, have an additional 5.9, 32.2 and 21.5 days in hospital, respectively, when compared to those participants where these morbidities were not observed.

Table 8-8: Independent predictive strength of each POMS domain on D8.

D8: POMS domains	Adjusted difference in subsequent length of stay (days)	95%CI	p
Pulmonary	-0.4	-5.104-4.245	0.856
Infectious	2.6	-0.573-5.865	0.106
Renal	**5.9**	**1.289-10.586**	**0.013**
Gastrointestinal	1.4	-2.448-5.297	0.469
Cardiovascular	-0.5	-3.683-2.704	0.762
Neurological	4.5	-0.174-9.266	0.059
Haematological	**32.2**	**23.531-40.908**	**0.000**
Wound complication	**21.5**	**13.251-29.757**	**0.000**
Pain	1.6	-7.197-10.299	0.727

On D15, the pulmonary and pain domains were independently predictive of subsequent length of stay with an additional 22.2 and 46.8 days in hospital, respectively, when compared to those without these morbidities on D15 (Table 8-9)

Table 8-9: Independent predictive strength of each POMS domain on D15.

D15: POMS domains	Adjusted difference in subsequent length of stay (days)	95%CI	p
Pulmonary	**22.2**	**7.403-37.026**	**0.004**
Infectious	4.5	-6.673-15.668	0.420
Renal	2.2	-12.020-16.498	0.752
Gastrointestinal	12.4	-5.082-29.796	0.159
Cardiovascular	-4.3	-15.337-6.810	0.440
Neurological	-1.1	-15.554-13.453	0.884
Haematological	-3.7	-21.825-14.372	0.679
Wound complication	8.7	-7.357-24.673	0.280
Pain	**46.8**	**9.787-83.906**	**0.015**

Overall, POMS-defined morbidity explains the variance in subsequent length of post-operative stay by 16.8%, 21.7%, 55.1% and 62.4% on D3, D5, D8 and D15, respectively.

8.5.3 To explore the utility of C-POMS in clinical practice

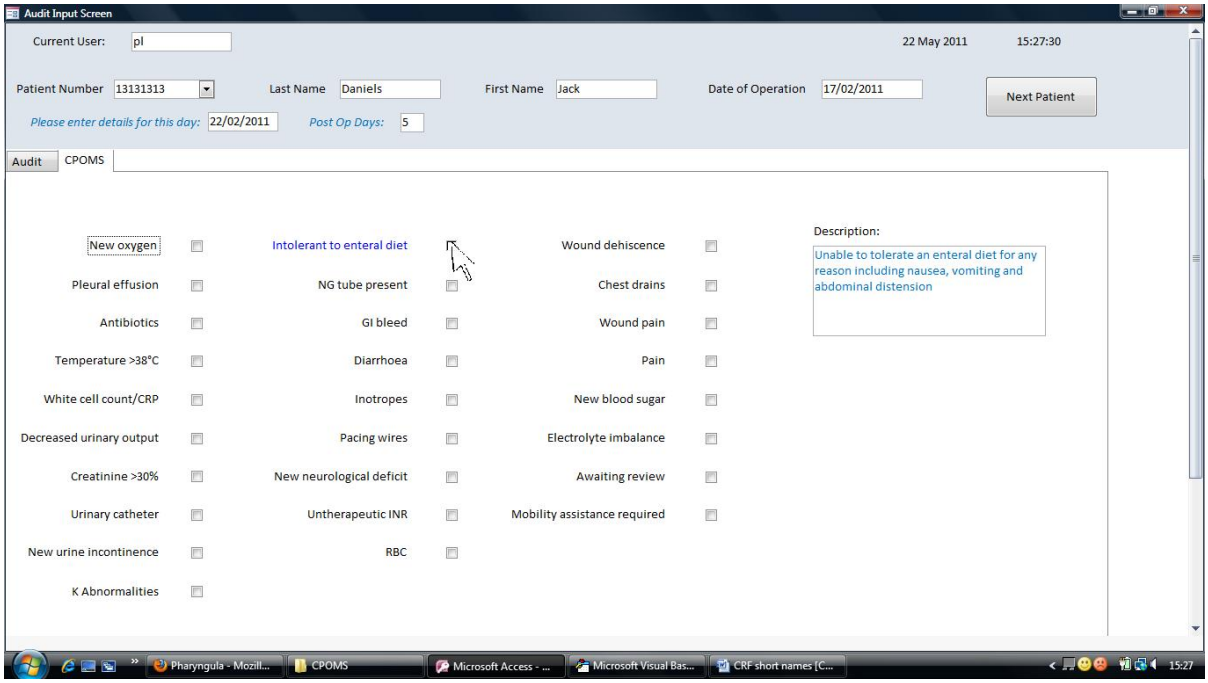
8.5.3.1 The PDG

The PDG thought C-POMS was fundamentally useful. The PDG recognised the potential of C-POMS in the hospital, departmental and individual quality profile and as a patient outcome measure, where the identification of the presence and frequency of each domain is as useful as using the overall score. It was agreed that C-POMS should be a routine data collection tool at the Heart Hospital, and thus the discussion mainly focused on how this could be achieved. Consideration was given to data collection personnel, data quality, database management and the longer-term sustainability of the routine collection of C-POMS data on all cardiac surgical patients. For this long-term strategy it was suggested that the Hospital Directors would need to be persuaded of the usefulness of the tool in order to gain support, and in particular, funding for a dedicated data collector. To achieve this, it is necessary to provide evidence of C-POMS being successfully integrated into clinical practice, with demonstrable application. Thus, in the short-term it was agreed that the data would be collected by the Senior House Officer allocated to audit each week and to ease the administrative burden, data would be entered directly onto a PDA (Personal Digit Assistant), supported through departmental funds. Data quality would be overseen by Dr Andrew Smith, who would lead on this initiative at the Heart Hospital. Support was formally given by the Heart Hospital Clinical Director and work is currently underway to commence data collection in the near future.

8.5.3.2 London Chest Hospital, London, UK.

Following my oral presentation at the SCTS 2011 meeting, discussion was initiated with representatives from the London Chest Hospital, who have developed a Microsoft Access database to collect ICU outcome data. For example, on a daily basis and for each patient, if a patient is considered by the Consultant to be following a routine recovery trajectory then no data are collected. For patients not considered not to be following a normal post-operative course, the reasons for this assessment are selected from a defined list. Furthermore, the database programme provides summary data ‘at the click of a button’. It was agreed that a pilot study merging the C-POMS tool onto the London Chest Hospital database and to commence data collection at the London Chest Hospital, led by Dr Alex Shipolini, would be advantageous. Initial work on adding C-POMS to the database is underway, with Figure 8-4 showing a screen shot of the progress made thus far.

Figure 8-4: Screenshot of C-POMS database.



8.5.3.3 The Heart Hospital and London Chest Hospital collaboration

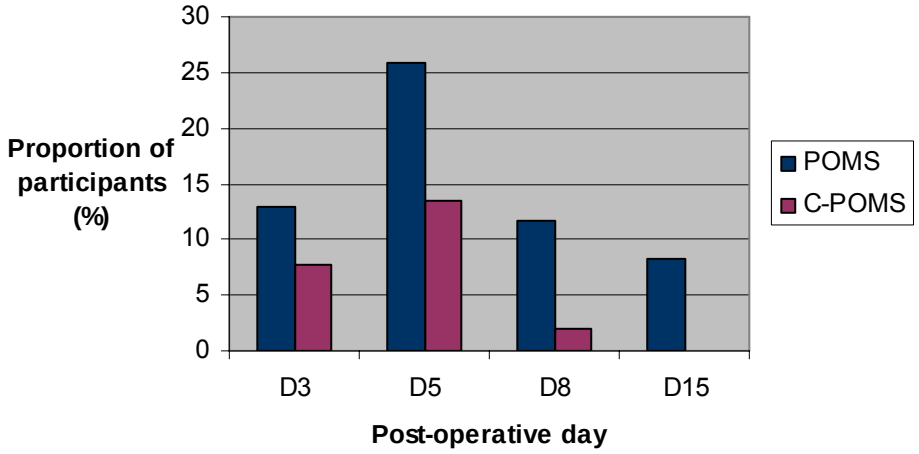
Discussions concluded that the London Chest Hospital would be happy to collaborate with the Heart Hospital and provide them with a copy of the database so that data is collected identically at each site. Furthermore, it was agreed that anonymised merged data from both sites would be used for analysis, particularly in relation to determining pre-operative risk factors of C-POMS.

8.6 DISCUSSION

8.6.1 Applying POMS to cardiac patients

Comparison of the results from the construct validity of C-POMS (chapter 7) and POMS (this chapter) suggests that the POMS has noticeably less construct validity than C-POMS when applied to patients undergoing cardiac surgery. Firstly, as summarised in Figure 8-5, there are considerably more participants without POMS defined morbidity remaining in hospital than C-POMS defined morbidity on D3, D5, D8, and D15.

Figure 8-5: Proportion of participants without POMS and C-POMS-defined morbidity.



Furthermore, whist those without POMS-defined morbidity on D15 remained in hospital due to non-medical reasons, POMS failed to capture all relevant morbidity on D5 and D8, with 33.6% and 28.6%, respectively, remaining in hospital for a medical reason. In contrast, C-POMS captured all the morbidity in 87.9% and 100% of in-patients on D5 and D8, respectively. Secondly, while C-POMS had sufficient internal consistency on D3, D5, D8 and D15 to be used as a summary score, POMS only exhibited sufficient internal consistency on D15. As expected, due to the proportion of medical reasons for remaining in hospital not accounted for in POMS, the comparison of C-POMS and POMS summary scores on D15 highlights that fact since C-POMS has a higher mean summary score (3.8 vs 2.5) and higher maximum score (11 vs 7). However, although there was no predictive power of EuroSCORE, POSSUM or Magovern score on D15 POMS summary score, this was also true for D15 C-POMS summary score, despite a small predictive ability being observed from the three pre-operative risk assessment scores on the other assessment days. Thirdly, while similar results were observed between POMS and C-POMS in the domain level analysis for the domains observed in both models, significant differences were also observed in the newly constructed endocrine and assisted ambulation C-POMS domains across EuroSCORE, POSSUM and Magovern score. Fourthly, the domains that were independently predictive of subsequent length of stay using POMS and C-POMS tools were the same for D8 (renal, haematological and wound complication) and similar for D3 (renal, haematological and wound complications), D5 (pulmonary, renal and neurological) and D15 (pain). Additionally, the following C-POMS domains were also being independently predictive: Gastrointestinal (D3), neurological (D3), pain (D5), endocrine (D5, D15), renal (D15) and electrolyte (D15). Finally, whilst C-POMS- and POMS-defined morbidity explain similar variance in subsequent length of stay on D3 (16.5% vs 16.8%) and D5 (22.3% vs 21.7%), C-POMS-defined morbidity explains considerably more of the variance than POMS-defined morbidity on D15 (82.0% vs 62.4%) but less on D8 (43.1% vs 55.1%).

While POMS alone exhibits some features of being a useful tool in describing and quantifying post-operative morbidity in cardiac surgery patients, POMS does appear to underestimate post-operative morbidity in cardiac patients and has considerably less construct validity than C-POMS. However, POMS domains and criteria were deliberately retained within the C-POMS model in order to benefit from the advantages of both generic and disease-specific instruments in the clinical environment. This allows the use of POMS as a generic tool that permits comparison across different patient populations[166]. For example, POMS has been used and validated in urological, orthopaedic and general surgery patients[93], while the cardiac-specific amendments included to create C-POMS provide the greater specificity of a condition specific instrument[187]. This has use in assessing changes over time[188], accurately predicting outcomes and utilization of health services[189].

8.6.2 Clinical utility of C-POMS

One of the most useful aspects of C-POMS when compared to POMS is the ability to use it as a summary score on D3, D5, D8 and D15, compared with only D15 for POMS. Summary scales provide an easy method of scoring and are readily interpretable[173]. The Heart Hospital and London Chest Hospital recognised the usefulness of this characteristic and the potential such a tool provides in morbidity measurement after cardiac surgery. Both hospitals agreed to use C-POMS as a routine data collection tool for post-operative morbidity and to collaborate by analyzing anonymised joint data. Furthermore, if other hospital sites were interested in using C-POMS the package of C-POMS on the pre-developed database would be offered. Overall, there was considerable enthusiasm for piloting C-POMS in clinical practice at these sites and to work collaboratively. Thus, at this early stage, C-POMS has been well received within the cardiac surgical profession. Further analysis of this will occur over time as the pilot data is collected, and if other surgical units come on board. Ultimately, if C-POMS continues to be well received and its usefulness demonstrated, the aim would be for C-POMS data collection to be included in the SCTS dataset in all UK cardiac surgical centres.

8.7 CONCLUSION

C-POMS has greater construct validity and more appropriately identifies and quantifies post-operative morbidity than POMS after cardiac surgery. C-POMS has been evaluated favorably from a clinical perspective with efforts now underway to introduce C-POMS as a routine data collective tool at two hospitals.

9 DISCUSSION

9.1 INTRODUCTION TO CHAPTER

This chapter aims to bring together the overarching discursive elements concerning this work. However, a summary of the work undertaken will first be provided. This will be followed by an update on the work conducted by the SCTS, international cardiac registries and the literature since commencement of the study. The use of C-POMS as a morbidity outcome measure will be discussed, as will the limitations and strengths of C-POMS as a tool, the methodological strengths and weaknesses of the study and potential future work. Finally, the overall conclusions reached from this work will conclude the chapter.

9.2 SUMMARY OF THESIS

Post-operative morbidity, being more common than mortality, may be a more valid outcome measure. However, there has been very little emphasis placed on morbidity outcome measurement after cardiac surgery, both nationally and internationally. Primarily this is due to the difficulty in defining post-operative morbidity thus making its measurement difficult. However, morbidity is now recognised as a complementary and independent component of quality of care. Despite this, the POMS tool[1] is the only published prospective tool for assessing the incidence and pattern of post-operative morbidity in orthopaedic, urological, vascular, gynaecological and general surgical patients. Hence, the aims and objectives of this thesis were to:

- Develop and validate a system (C-POMS) to describe and quantify in-hospital post-operative morbidity in patients undergoing cardiac surgery,
- Explore the applicability of POMS in describing and quantifying post-operative morbidity in patients undergoing cardiac surgery and
- Assess the utility of a post-operative morbidity survey for the description of in-hospital morbidity following cardiac surgery.

9.2.1 Development of C-POMS

The development of C-POMS was established using clinimetric principles through prospective data collection of 450 patients undergoing cardiac surgery between 2005-2007. Data collection comprised POMS criteria, cardiac specific indices determined by a PDG and free-text for morbidities not captured by the POMS criteria and was collected on D1, D3, D5, D8 and D15, if they remained an in-patient on those days. Analysis of the free-text identified 175 additional morbidities that went through an item reduction process using inter-item and inter-domain correlations, and an inclusion criteria of: prevalence >5%, missingness <5%, a mean severity-importance score ≥8 and expert panel consideration of whether the item would be identified by a POMS criteria. POMS criteria and Items that met at least two of the criteria were considered for entry into C-POMS. The result was a 13 domain tool.

9.2.2 Reliability and validity testing of C-POMS

Reliability testing of C-POMS demonstrated sufficient internal consistency to be used as a summary score to denote total morbidity burden on D3, D5, D8 and D15. The mean C-POMS score for D3, D5, D8 and D15 was 3.4, 2.6, 3.4 and 3.8, respectively and for every unit increase in C-POMS summary score there is a 1.7 (D3), 2.2 (D5), 4.5 (D8) and 6.2 (D15) day increase in subsequent length of stay (all p=0.000). Due to lack of a gold standard, construct validity was assessed through the testing of 5 hypotheses. The key findings were that those with C-POMS-defined morbidity on post-operative D3, D5 and D8 remain in hospital for an additional 4.6 (p=0.012), 5.3 days (p=0.001) and 7.6 days (p=0.135), respectively, when compared to those without. There were no patients without C-POMS defined morbidity on D15. Existing pre-operative risk assessment scores (EuroSCORE, POSSUM and Magovern) only had a small predictive ability to predict C-POMS summary score. However, higher C-POMS domain frequencies were observed in those with greatest surgical risk, as defined by these scores, in all but the infectious (EuroSCORE) and wound complication (POSSUM) domains. Overall, C-POMS-defined morbidity explains the variance in subsequent length of post-operative stay by 16.5%, 22.3%, 43.1% and 82.0% on D3, D5, D8 and D15, respectively. Potentially, social and organisational factors may also contribute to variations in length of post-operative stay. Of those patients remaining in hospital with a C-POMS score of zero, social and organisational factors accounted for 100% of reasons on D8 and 56.3% on D5, while only 7 (12.1%) remained in hospital for a medical reason not captured by C-POMS on D5. Overall, nine of the thirteen C-POMS domains (renal, GI, neurological, haematological, wound on D3, pulmonary, renal, neurological, pain, endocrine on D5, renal, haematological, wound on D8 and renal, pain, endocrine, electrolyte on D15) independently predicted subsequent length of stay with between 2.2 to 77 extra days in hospital. Thus, C-POMS appears to exhibit construct validity, as assessed by pre-defined hypotheses.

9.2.3 The applicability of POMS to cardiac surgical patients

In exploring the applicability of POMS to cardiac surgical patients, POMS appears to underestimate the post-operative morbidity experienced. Furthermore, POMS only exhibited sufficient internal consistency to be used as a summary score on D15 where for every unit increase in POMS summary score on D15 there was an 8.2 day (95% CI 5.223-11.213, p=0.000) increase in subsequent length of stay. However, EuroSCORE, POSSUM and Magovern scores do not predict POMS summary score on D15 and less domains than C-POMS exhibited the highest frequency in those with greatest risk as defined by these score. Furthermore, POMS failed to capture all relevant morbidity on D5 and D8.

9.2.4 The utility of C-POMS in clinical practice

The utility of C-POMS in clinical practice was considered by the PDG at the Heart Hospital and also the London Chest Hopsital and both thought that C-POMS was fundamentally useful for hospital,

departmental and individual quality profiles and as a patient outcome measure. Both have agreed to use C-POMS as a routine data collection tool, and have agreed to collaborate, sharing anonymised data, for analysis purposes. The London Chest Hospital currently collect data electronically using a purpose-built database to which they are adding the C-POMS data fields to. This database will be shared with the Heart Hospital, and potentially other hospitals who are interested.

9.3 UPDATE: UK, INTERNATIONAL AND LITERATURE

9.3.1 UK update

Although the SCTS are leading on outcome measurement compared with other countries[190] and other medical disciplines, since this study started the focus has remained primarily on mortality. In response to recommendation 155 (outcomes of Trust, units and consultant team should be available to the public) of the Bristol Royal Infirmary report[28], the SCTS have published mortality rates at the hospital level and whether the mortality standard (defined as crude mortality within 99.99% CIs of the national mean for isolated coronary artery surgery[5] was achieved at the named consultant surgeon level. However, while the debate continues as to the appropriateness of publishing named surgeons' results[25, 191], the choice currently rests with the individual unit[192].
In terms of morbidity, there has been some consideration of morbidity outcome since this study commenced. The revision of the SCTS dataset, which went live in April 2010, contained additional post-operative outcome measures which included return to theatre, deep sternal wound infection, new post-operative neurological dysfunction and new haemofiltration/dialysis post-operatively. However, data incompleteness for post-operative complications is considerably higher than for operative risk stratification variables (15% vs <5%, respectively), although this is declining[192].
Currently, morbidity is of particular interest following the publication of Darzi's 2008 report 'high quality care for all'[193] as it is recognised that alone mortality is an inadequate quality indicator[57].

9.3.2 International update

It has been challenging to identify international changes that have occurred since this study commenced. Although the first and 2nd EACTS database reports appear not to be publically available, the third report in 2007[194] contains data from 260 hospitals in 22 countries. However, the outcome data reported (post-operative length of stay and mortality) is presented only as aggregate data and not by country. Similarly, in the 4th 2010 report which referred to over 1 million patients from 366 hospitals in 29 countries, epidemiological data, mortality (2.2% for isolated CABG) and post-operative length of stay (median 7 days, range 5-11 days) only are reported[195]. Nevertheless, the ultimate aim of this database is to measure quality of care across the whole patient pathway[196].
Furthermore, since updates relating to the progress of the international STS-ECSUR database have not been reported, calls for an international database remain[197]. However, the Belgian National Cardiac Surgical Register are expanding the dataset from 1st January 2012 to include 4 post-operative complications (re-operation, new post-operative stroke, new post-operative dialysis and multi-system failure using STS definitions), while the Swedish national register has included quality

of life measures since 2005. Additionally, revisions to the STS database in relation to post-operative morbidity outcome have also occurred. From January 2011 the STS database contains 49 variables related to post-operative events with new post-operative complications including paralysis, pleural effusion requiring drainage, aortic dissection, laryngeal nerve injury and an 'other' category for complications not defined within the dataset.

9.3.3 Update from the literature

At the start of this work there was no standardised definition of post-operative morbidity or method for its measurement in cardiac surgery patients. To assess whether this remains true, an update on the literature review was conducted using the same methods, excluding backward citation tracking, as detailed previously (section 1.4.2). The forward citation search of the pre-operative risk assessment scores identified through the literature review was conducted in September 2010, while the keyword searches were conducted July 2011. Since the initial review, the NRR has been archived (October 2007) and only contains records up to September 2007. Furthermore, both PubMed and the Cochrane Library now contain considerably more records, with over 20 million citations and over 28,000 contributors from more than 11 countries, respectively.

A total of 734 forward citations since 2004 were identified from the 20 pre-operative risk assessment models for post-operative morbidity identified in the literature review. Figure 9-1 details the number of forward citations identified from each of the pre-operative risk assessment models. The abstract/record details of each forward citation was assessed for relevance.

Figure 9-1: Number of forward citations since 2004 of the pre-operative risk assessment models for morbidity identified in the literature review.

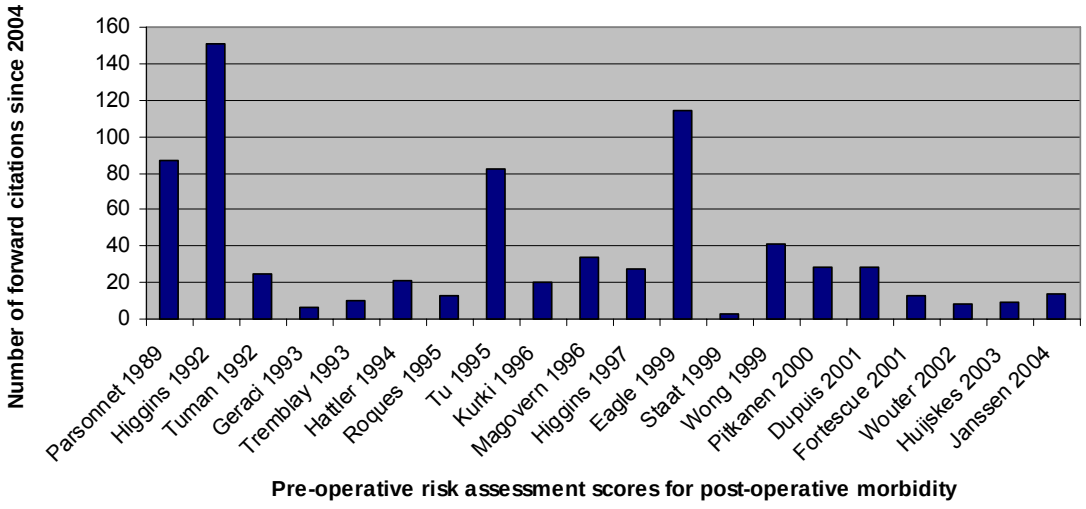


Table **9-1** details the number of papers that were identified through the keyword searches. The abstracts of those highlighted in bold were assessed for relevance.

Table 9-1: Keyword searches for literature review update.

Keywords	PubMed (limit to title word)	NIHR archive	Cochrane Library (all databases) (limit to title, abstract and keyword)
Morbidity score	**67**		**67**
Risk prediction score	**102**		**119**
Cardiac surgery score	**48**		**2**
Cardiac surgery risk score	**20**		**1**
Preoperaive risk; cardiac surgery	**64**		**2**
Risk prediction score; cardiac surgery	**2**		**4**
Cardiac	144,681	1,560	**144**
Cardiac surgery	12,699	6,760	**43**
Cardiac surgery morbidity	**123**	1,786	**14**
Cardiac surgery risk	792	3,106	**28**
CABG	973	**18**	**11**
CABG morbidity	**9**	**214**	**2**
Surgery morbidity	857	1,284	**167**
Surgery outcome	3,476	2,184	567

As identified in the original literature review, models were identified that only explored a particular post-operative event (for example, renal complications[198, 199, 200] or post-operative bleeding[201]), defined morbidity by using a surrogate marker (ICU LOS)[202, 203], or were based exclusively on mortality outcome[204]. However, four new models of pre-operative risk assessment of overall post-operative morbidity were identified. Both Biagioli and colleagues[205] and Cevenini and colleagues[206] used Higgins et al[52] definition of morbidity, which included death, while the Syntax score defined morbidity as cardiovascular events[207] only. Finally, the Toronto Risk score[208] was established to assess risk for post-operative adverse events, defined as death, MI, low cardiac output syndrome, post-operative renal failure, stroke or deep wound infection.

Since the commencement of the work on C-POMS, the Post-operative Quality Recovery Scale has been published[209]. This was developed principally in general surgical patients, although 5% of patients did undergo cardiac surgery. It is a six domain (physiology, nociceptive, emotional, activities of daily living, cognitive and overall patient perspective) tool comprising a mix of patient-reported outcomes and researcher-led tests, in all but the physiological domain. The variables are collected pre-operatively, at a time when anaesthesia is no longer required (T0), at 15 and 40

minutes after T0, on D1 and D3 after surgery and at 3 months after surgery. However, the authors recognise that for cardiac surgery, the earlier time-points may not be appropriate and that the scale is also limited by the burden of undertaking the tests, preferably by one dedicated person. Although, like C-POMS, the PQRS tool is a multi-dimensional tool to assess post-operative recovery, they are very different instruments in relation to content, with the PQRS not containing easily or readily available variables. Nevertheless, the PQRS tool may be a useful as a complementary tool to C-POMS, particularly in relation to patient-reported outcomes and should be explored further.

Thus, overall, this literature update revealed that there continues to be no standardised definition of post-operative morbidity or method for its measurement in patients having cardiac surgery. Despite the development of the PQRS scale, it is not possible to compare it with C-POMS in the study population due to the variables that comprise the scale . Therefore, C-POMS remains relevant with the nearest tool to compare with continuing to be POMS.

9.3.4 Conclusions

Following review of the progress on post-operative morbidity outcome measurement since commencement of this work, it is apparent that in the continued absence of a standardised method to measure morbidity outcome, a place for C-POMS is still apparent.

9.4 C-POMS AS A MORBIDITY OUTCOME MEASURE

9.4.1 C-POMS vs. POMS

As already discussed (section 8.6.1 and section 9.2.3) POMS appears to underestimate post-operative morbidity in cardiac surgery patients and has noticeably less construct validity than C-POMS when applied to this patient group. In brief:

- POMS failed to capture all relevant morbidity on D5 and D8 while C-POMS captured all the morbidity in 87.9% and 100% of in-patients, respectively.
- While C-POMS had sufficient internal consistency to be used as a summary score on D3, D5, D8 and D15, POMS only exhibited sufficient internal consistency on D15
- Although C-POMS and POMS defined morbidity explained a similar variance in subsequent length of stay on D3 (16.5% v 16.8%) and D5 (22.3% v 21.7%), C-POMS defined morbidity explained considerably more of the variance than POMS defined morbidity on D15 (82.0% v 62.4%).

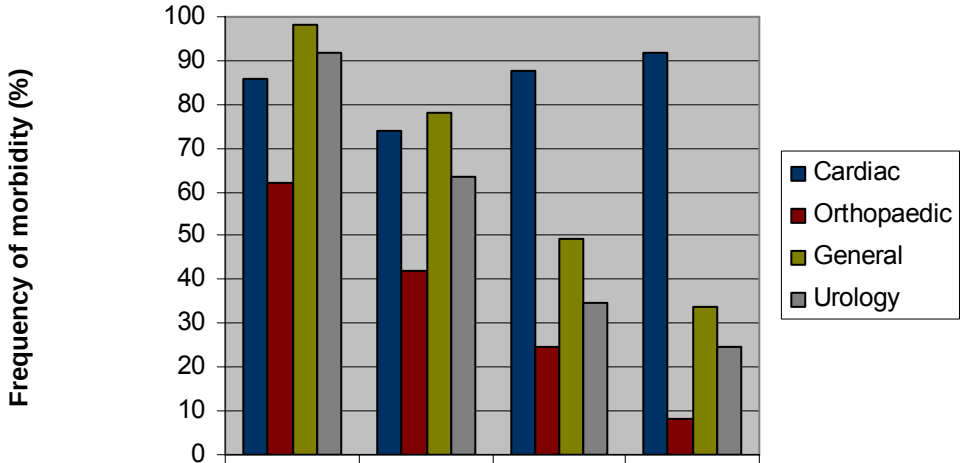
Thus, the cardiac-specific amendments included to create C-POMS appear to provide the greater specificity of a condition specific instrument[187].

9.4.2 Comparing morbidity rate with the existing literature

The frequency of morbidity reported is affected by the definition of morbidity used[7, 11]. As highlighted in section 1.4.4, the diverse methods previously used to define morbidity makes

comparisons of morbidity rates difficult. In these studies the incidence of morbidity ranged from 4.3%[87] to 36%[71] compared with 92.2%, 86.4%, 95% and 100% on D3, D5, D8 and D15, respectively, by C-POMS. This difference in morbidity prevalence is likely to be attributable to C-POMS assessing total morbidity burden while other studies limited their definition to consist of only major/specific complications, surrogate markers of morbidity or included mortality within the morbidity definition. Since C-POMS retains the properties of POMS, comparison of POMS in cardiac patients with other published in reports in other surgical populations[93] is possible (Figure 9-2).

Figure 9-2: Comparison of morbidity rates using POMS criteria across different patient populations. Orthopaedic, general and urology figures obtained from Grocott et al 2007[93].



	D3	D5	D8	D15
Cardiac	86	74.2	87.8	91.7
Orthopaedic	62.2	41.9	24.6	8.3
General	98	78.2	49.5	33.7
Urology	91.8	63.3	34.7	24.5

Post-operative day

As shown in Figure 9-2 above, patients having cardiac surgery have less POMS-defined morbidity than general or urology patients on D3, similar levels to those seen in general surgical patients on D5, but considerably more than that in all the other patient groups on D8 and D15. Overall, orthopaedic surgical patients have the least POMS-defined morbidity on each post-operative day. Exploring this in terms of domain frequencies highlights that for orthopaedic patients the most common POMS-defined morbidities are pulmonary and pain on D3 and infection on D5, D8 and D15, while for general surgical patients GI complication is the most prevalent on all post-operative days (Table 9-2). Renal and infection domains on D3, GI on D5 and D8 and infection on D15 have the highest frequency for urology patients while for cardiac patients the most common domains are pulmonary on D3, CV on D5, and both infection and CV on D8 and D15. Thus, while infection is a main course of morbidity in all surgical groups, cardiac patients have the lowest infection and pain

rates on D3 of all surgical groups. They also have considerably less GI POMS-defined morbidity than general or urology surgical populations and the lowest level of haematological complications on D3 but highest on D8. However, cardiac patients have the highest level of POMS-defined cardiovascular and neurological morbidity on all post-operative days and in all domains except GI on D15.

Table 9-2: Comparison of POMS domain frequencies in different surgical populations.

	D3				D5			
	Orthopaedic	General	Urology	Cardiac	Orthopaedic	General	Urology	Cardiac
Pulm	30.1	58.4	36.7	67.3	7.3	19.8	22.4	26.5
Infect	26.6	43.6	59.2	25.1	21.5	28.7	36.7	36.2
Renal	24.9	39.6	53.1	34.2	8.7	21.8	30.6	15.7
GI	20.1	92.1	51.0	24.9	15.9	65.3	40.8	21.8
CV	0.7	3.0	2.0	43.6	1.4	4.0	2.0	43.2
Neuro	1.7	3.0	0	17.8	0.7	2.0	0	10.6
Wound	1.7	0	0	2.7	5.5	1.0	2.0	1.4
Haem	7.3	4.0	16.3	2.4	2.4	2.0	2.0	1.6
Pain	30.8	58.4	49.0	2.0	4.2	24.8	20.4	2.6
	D8				**D15**			
	Orthopaedic	General	Urology	Cardiac	Orthopaedic	General	Urology	Cardiac
Pulm	2.4	12.9	8.2	27.6	1.7	5.9	6.1	29.2
Infect	14.5	18.8	14.3	55.2	7.6	11.9	16.3	58.3
Renal	2.8	5.9	10.2	24.9	1.0	3.0	4.1	37.5
GI	7.3	37.6	18.4	21.0	1.0	25.7	10.2	16.7
CV	0.3	1.0	0	57.5	0	1.0	0	58.3
Neuro	0.3	0	4.1	14.9	0	0	0	16.7
Wound	5.9	6.9	4.1	6.7	2.4	6.9	4.1	8.3
Haem	1.0	1.0	0	4.4	0.3	0	0	22.9
Pain	1.4	10.9	2.0	5.0	0.7	5.9	2.0	6.3

Abbreviations: Pulm=pulmonary, Infect=infection, GI=gastrointestinal, CV=cardiovascular, Neuro=neurological, Haem=haematological

Overall, this comparison provides a new insight into post-operative morbidity across different surgical groups and highlights that different surgical groups do exhibit different morbidity events post-surgery and in different frequencies. In particular, cardiac patients have higher levels of morbidity than other surgical groups, despite POMS underestimating post-operative morbidity in

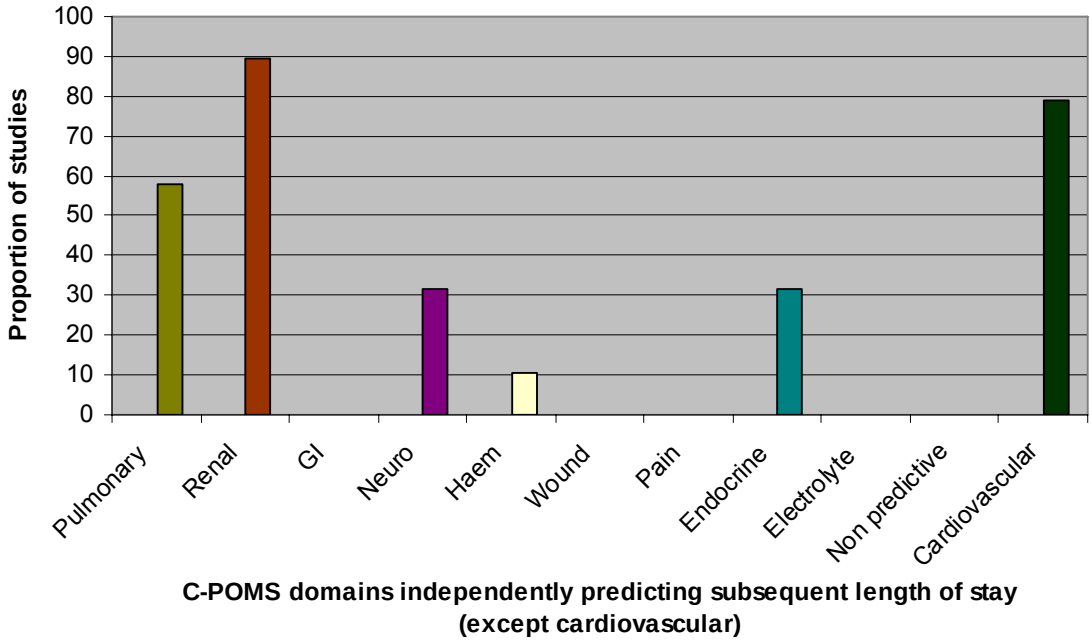
comparison to C-POMS. In the future such information may potentially have use in planning and delivering health services and in a hospital quality report (see section 9.5.6)

9.4.3 Independently predictive domains of subsequent length of stay

As shown in chapter 7 section 7.5.3.5, nine of the thirteen domains were independently predictive of subsequent length of stay on at least one post-operative day: Pulmonary (D5), renal (D3, D5, D8, D15), gastrointestinal (D3), neurological (D3, D5), haematological (D3, D8), wound complications (D3, D8), pain (D5, D15), endocrine (D5, D15) and electrolyte (D15). Direct comparisons with existing literature unfortunately cannot be made as there are no other post-operative morbidity assessment tools with which to compare. Nevertheless, the independent predictive nature of these domains, with the exception of GI, pain and electrolyte, is unsurprising as these physiological areas have previously been shown to be pre-operatively predictive of ICU LOS and post-operative morbidity (Chapter 1 section 1.4.3.2) in cardiac surgical patients. Pre-operative renal predictors of ICU LOS include LVEF and a history of renal dysfunction[210, 211, 212, 213], while pulmonary predictors include a history of pulmonary disease[80, 213, 214] and NYHA class[210]. Additionally, neurological predictors include a history of cerebrovascular disease[210] with diabetes also being associated with ICU LOS[210, 211]. ICU LOS is also independently predicted by receiving any red blood cell (RBC) transfusion[215, 216] while for patients newly started on warfarin, untherapeutic INR delays hospital discharge in 30%[217]. Furthermore, post-operative deep sternal wound infections is associated with significantly increased hospital length of stay[218, 219]. However, in contrast, pain has been found not to increase ICU LOS[220], and no studies were found that identified gastrointestinal or electrolyte complications as predictors of post-operative stay in cardiac surgical patients.

The findings in the literature review (chapter 1 section 1.4.3.2) similarly show that areas within these physiological domains pre-operatively predict post-operative morbidity, despite the diverse definitions of morbidity utilised. Figure 9-3 summarises the proportion of studies in the literature review (all variables detailed in Appendix 1) that contain areas in each of the domains that were independently predictive of subsequent length of stay in C-POMS, with the exception of the cardiovascular domain.

Figure 9-3: The proportion of studies identified in the literature review that contain areas of the domains in C-POMS found to be independently predictive of subsequent length of stay.



The cardiovascular domain was not independently predictive on any post-operative day. This was unexpected given that pre-operative cardiac-related factors such as rhythm disturbances[80, 221], MI[213, 222] and hypertension[211] are known to be predictive of increased length of ICU stay, and 78.9% of the pre-operative risk assessment tools for post-operative morbidity in the literature review contained cardiovascular variables (Figure 9-3, above) . However, it is likely that the cardiovascular domain was not independently predictive of subsequent length of stay due to the overall high proportions of participants experiencing a cardiovascular morbidity. It is possible that sub-analysis of this domain may identify that individual criteria are predictive of subsequent length of stay, as suggested in the literature.

9.4.4 New domains

9.4.4.1 Assisted ambulation

Assisted ambulation, defined as 'a new or escalated post-operative requirement for mobility assistance (including wheelchair, crutches, zimmer frame, walking sticks, or 'assistance'), was requested by the PDG as a routine data collection variable prior to commencing the study. Assisted ambulation was present in 99.6%, 45.6%, 27.7%, 37.6% and 39.6% on D1, D3, D5, D8 and D15, respectively, and mobility-related issues were the reason for non-discharge in 18.2% on D5 and 28.6% of patients with no POMS-defined morbidity. Thus, mobility at a reduced pre-operative capacity has been identified in a considerable proportion of patients, delaying discharge and hence increasing hospital costs. Possible causes of this reduced mobility capacity are acquired muscle weakness in the ICU[223], neurological impairment, worsened cardiac output and/or general confounders (difficult to walk with catheter/drains/attached to cardiac monitor). However, whatever

the reason, mobility is still a useful marker of patient recovery and since in-hospital mobility following cardiac surgery has only been included as an outcome measure in only a few studies (for example, Izumi et al 2010[224]), the inclusion of this domain in C-POMS has merit. Furthermore, assisted ambulation fits well within the clinimetric principle by which C-POMS was developed since clinimetrics by definition can include such clinical phenomena such as functional capacity ailments[150].

9.4.4.2 Review

The newly generated 'review' domain is defined as 'remaining in hospital for further review, investigation and/or procedure' and was present in 0.0%, 2.9%, 5.9%, 9.9% and 12.5% on D1, D3, D5, D8 and D15, respectively. While this domain could be criticised for being more a measure of system failure than morbidity, the inclusion of reasons for medical decisions, as in the 'review' criteria, is a legitimate characteristic of clinimetric measures[150]. Furthermore, such judgmental decisions are a routine feature of clinical practice that are rarely measured[150]. If patients require further investigations or procedures that are necessary prior to discharge, the 'investigation and/or procedure' criteria can be a measure of system failure (delay due to organisational factors) and morbidity (delay due to medical reasons), both of which will prolong time to discharge. Subsequent analysis of the individual criteria will distinguish between the two reasons and provide useful information for clinical management.

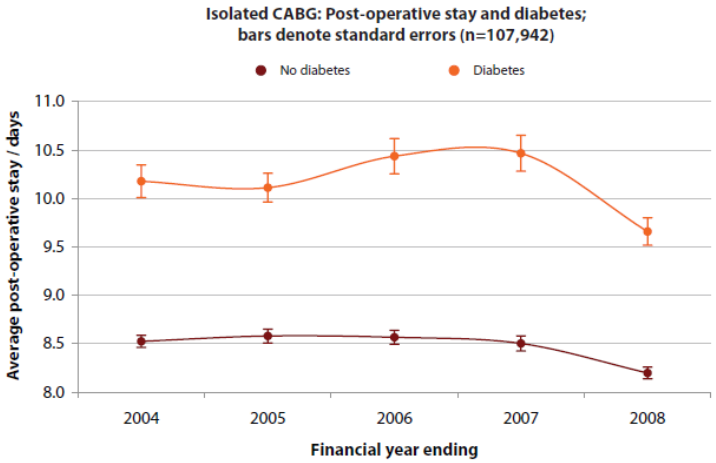
9.4.4.3 Electrolytes

Patients undergoing cardiac surgery are at high risk of developing electrolyte depletion[225], a risk factor for a range of clinical symptoms including arrhythmias[226, 227], respiratory complications and muscle weakness[228]. In this study, electrolyte disturbances were defined as an imbalance (depletion and elevation) in serum electrolyte concentrations (including sodium, urea, phosphate but not potassium as included within renal domain) requiring oral or intravenous intervention' and overall were observed in 0.9% on D1, 2.2% D3, 2.1% D5, 4.4% D8 and 12.5%on D15. Individually, sodium, urea and phosphate imbalances were observed only in 1.6%, 3.1% and 1.1% of participants, respectively, but all had a mean severity-importance (SI) score (defined within chapter 6 section 6.3.3.3.1) of greater than 8 and were considered by the expert panel not likely to be captured within the POMS criteria. Thus, overall the inclusion of electrolyte abnormalities was attributable to the ratings of the expert panel, providing an example of how clinically important items should be included in a disease-specific measure, irrespective of their statistical associations[141]. Furthermore, this domain was found to be independently predictive for subsequent length of stay on D15 (74.1 extra days, p=0.000, 95%CI 43.265-104.840) providing statistical justification for the inclusion of the domain in C-POMS.

9.4.4.4 Endocrine

The proportion of diabetic patients undergoing isolated CABG surgery has increased from 18% to 24% between 2001 and 2008 (p<0.001) ([25]). Furthermore, diabetic patients have an increased length of hospital stay, currently an additional 1.5 days, than non-diabetic patients (Figure 9-4[(25)]).

Figure 9-4: Post-operative length of stay in diabetic and non-diabetic patients undergoing isolated CABG[(25)]. This figure was obtained from the SCTS.



However, poor glycaemic control following surgery is associated with increased mortality and morbidity (including MI, infection, renal and pulmonary complications) in both diabetics and non-diabetics[(229, 230, 231)]. Furthermore, 48.2% of patients with poorly controlled post-operative blood glucose and 68.5% of patients with moderately controlled post-operative blood glucose being pre-operatively defined as non-diabetic. In the C-POMS study, although the incidence of diabetes was 23.3%, the proportion of non-diabetics requiring blood sugar management was 96.8%, 19.7%, 4.6%, 6.2% and 16.7% on D1, D3, D5, D8 and D15, respectively. Additionally, the presence of this domain was an independent predictor of subsequent length of stay on D5 (3.5 extra days, p-0.04, 95%CI 0.157-6.915) and D15 (-15.1 days, p=0.034, 95%CI -28.908-1.235). Thus, a domain that notes new or additional requirements for blood sugar management in both diabetic and non-diabetic patients is clinically useful.

9.5 USES OF C-POMS

9.5.1 Standard outcome measure for post-operative morbidity following cardiac surgery

Since C-POMS is the only validated measure of post-operative morbidity following cardiac surgery, C-POMS can be used as a standard outcome measure to describe and quantify post-operative morbidity and total morbidity burden. Once applied as a standard outcome measure C-POMS might thus have use in identifying those at greatest risk of post-operative morbidity, in guiding clinical decision making, as a prognostic indicator, in quality assurance (audit and performance/quality of care indicator) processes, in the optimising the utilisation of health services and in cost analysis.

9.5.2 Identifying those at risk of post-operative morbidity

Risk factors associated with C-POMS- (and C-POMS summary score-) defined post-operative morbidity, and those which might be causal, can be sought. Since risk assessment can change from the pre-operative period to that immediately following surgery, factors associated with pre-operative risk and then subsequent risk on arrival on ICU should be explored[67]. This would aid patient group and individual risk stratification[64] and permit new therapeutic or preventative strategies to be implemented to specifically address the risk factors identified.

9.5.3 Clinical decision making and informed consent

Although the ability to predict mortality following surgery is important to patient and their families it is an incomplete method for assessing surgical outcome[71]. It has been reported that four times as many patients undergoing cardiac surgery were concerned about surgery-related stroke rather than death and that 80% wanted to be informed of all the risks associated with having the operation[232]. Furthermore, the General Medical Council guidance on obtaining patient consent states that patients should be told about 'less serious side effects and complications'[233]. The identification of risk factors for total morbidity burden and the associated prediction of subsequent length of stay can be used for improved pre-operative risk assessment and information provision for patients and their families.

9.5.4 Prognostic indicator

Potentially, C-POMS summary score could be used as a prognostic indicator for longer-term morbidity and particularly within the first year of surgery. However, while this is an area we are exploring (see section 9.8.2), currently there is a lack of information on morbidity outcome beyond initial hospitalisation period. Thus, further work in this area is required for C-POMS to be used in this way.

9.5.5 Quality assurance

9.5.5.1 Clinical audit

The C-POMS tool provides a framework by which changes in post-operative morbidity over time (level and type; following interventional strategies and processes; in unit and between centres) can be measured. The assessment of such changes over time highlights the potential use of C-POMS as a performance indicator/quality of care assessment tool at individual, departmental and institutional levels.

9.5.5.2 Performance indicator/quality of care assessment tool.

Quality of care as a concept in the NHS is not new. However, Lord Darzi's 2008 report 'high quality care for all' emphasised the need to bring clarity to quality, to measure and publish quality performance and to recognise and reward quality[193]. This led to the establishment of the National

Quality Board in 2009 to drive the quality agenda throughout the NHS. Since little correlation has been found between quality of care and mortality[234], it is now acknowledged that mortality is only one aspect of overall healthcare quality[235] and consequently alone is an inadequate quality indicator[57, 236]. Thus, morbidity outcome, along with clinical process evaluation[236, 237], has become important in this quality initiative. Since C-POMS offers clarity of definition and a tool for the measurement of post-operative morbidity, C-POMS has potential use as a tool in the quality assessment of cardiac surgery at both departmental and institutional level. If C-POMS data could be collected nationally, or in a number of diverse institutions, a national reference for comparing morbidity results between centres could be created[52]. The publication of such quality assessment is likely to have particular usefulness in the assessment of the future procurement of cardiac surgical services by GPs and by patients in an era of patient choice. The Bristol Royal Infirmary Inquiry recommendation 153 states that performance indicators should be understandable by the public as well as by the healthcare profession[28]. C-POMS as a summary score and by morbidity domain are likely to be understandable to the lay person due to its simplicity. Nevertheless, formal lay person review would be required prior to publication. Furthermore, since there is also a professional responsibility to monitor surgical performance[238], and especially with the introduction of revalidation for doctors in late 2012[239], C-POMS could also be utilised for individual quality performance assessment/evidence of practice.

9.5.6 Utilisation of health services

C-POMS has potential use in decisions relating to the utilisation of health services. As highlighted in chapter 7 section 7.5.2, a C-POMS summary score of 6 or more was observed in approximately 20% of participants on D3, D8 and D15 with 2.8% and 4.2% experiencing morbidity in 10 or more C-POMS domains on D8 and D15, respectively. This is a considerable amount of morbidity and has implications for the clinical service since a 1.7, 2.2, 4.5 and 6.3 day increase in subsequent length of stay per unit increase in C-POMS on D3, D5, D8 and D15, respectively, was identified. Since post-operative morbidity increases length of hospitalisation it obstructs patient through-put[80]. Using C-POMS summary score to predict subsequent length of stay might thus help in modelling (and better managing) patient flow. Furthermore, once pre-operative predictors of C-POMS-defined morbidity are determined, services for those at high risk can be planned accordingly. Conversely, following exploration on whether C-POMS summary score predicts post-operative morbidity following the initial hospitalisation period, rehabilitation and follow-up services could be determined and tailored accordingly.

9.5.7 Cost analysis

Increased length of stay caused by post-operative morbidity has considerable economic importance due to the greater utilisation of resources required[71, 240]. This is particularly pertinent for extended ICU stays since ICU is the most expensive clinical area[80]. Although EuroSCORE can predict direct hospital costs[241], unsurprisingly it a poor predictor of total hospital costs[242]. Thus, while C-POMS

can be used in calculating total hospital resource utilisation, pre-operative and post-surgical risks for C-POMS should provide a more accurate mechanism for predicting hospital costs.

9.6 LIMITATIONS

9.6.1 Generalisability

C-POMS was designed specifically to describe and quantify morbidity following cardiac surgery. Therefore, C-POMS is unlikely to be generalisable to other surgical populations. However, the inclusion of the POMS domains and criteria does permit comparison of the POMS components with general, urological and orthopaedic surgery populations, in which POMS has been validated[93]. In such circumstances the limitations of POMS in cardiac patients would need to be considered. The applicability of POMS to other surgical populations is currently unknown.

C-POMS was developed within one institution and may only reflect the population on which it is based[243]. For example, patient demographics, disease acuity and incidence of co-morbidities[71] as well as organisational factors such as intensivist-model ICUs[244, 245] can influence outcome and differ across institutions. Thus, the validity of C-POMS in other cardiac surgical centres is required. Currently, this is underway at the Heart Hospital and The London Chest Hospital. However, it is anticipated that C-POMS will be widely applicable since the case-mix is similar in many centres, and the study population characteristics remain comparable to the characteristics of cardiac surgical patients in the UK (see section 9.6.4).

9.6.2 Methodological and data considerations

The limitations relating to internal consistency and reliability methods have been discussed previously in chapter 7 section 7.6.7.

9.6.2.1 Inclusion of symptoms and interventions

C-POMS could be criticised for including symptoms (for example, wound pain criteria; the pain domain) which, by their subjective nature, will vary in intensity between patients[173]. While this would have greater influence in quality of life assessments, the aim of C-POMS is to identify only whether the morbidity is present or absent. However, using symptoms within a clinimetric approach is appropriate since clinimetrics is defined by the use of symptoms in addition to pathophysiologic findings, disease status and severity to measure a clinical phenomena[150]. Furthermore, the pain domain was found to have construct validity and was an independent predictor of subsequent length of stay on D5 and D15.

C-POMS could also be criticised for including interventions (for example, supplementary oxygen, pleural effusion requiring drainage, urinary catheter *in situ*) for two reasons. Firstly, an intervention assumes a level of severity. This is masked in the initial post-operative days, especially D1, by

routine treatments that become documented as 'morbidity' (for example, antibiotic use, urinary catheter *in situ*, new or additional requirements for blood sugar management). As highlighted in chapter 6 section 6.4.2.2.1, on D1 pulmonary, renal, wound, pain, endocrine and assisted ambulation domains showed almost 100% prevalence. Since C-POMS only had sufficient internal consistency to be used as a summary score on D3, D5, D8 and D15 it does reduce the influence this will have in C-POMS since all routine interventions would be expected to be discontinued by D3. However, C-POMS could be introduced on other post-operative days, and this should be considered on D2 where only escalated interventions above the routine protocol may need to be recorded. Secondly, the inclusion of interventions does assume competency of the institution to correctly recognise and treat morbidities[93]. As acknowledged in chapter 7 section 7.6.6, human factors (doctor/nurse preferences, simple mistakes, and minor delays) are inevitably going to contribute to some degree in the variance. However, it is possible that those hospitals recording the lowest morbidity levels provide a lower standard of care. Comparison of C-POMS on early post-operative days with routine care pathways would assist in establishing the effect of this potential bias.

9.6.2.2 'Lost' data

C-POMS was developed on data collected on D1, D3, D5, D8 and D15 and thus some transient morbidities would not have been identified on intervening days and fluctuations could not be tracked. The administrative burden of C-POMS may prevent daily completion depending on the infra-structure at each site. For example, the Heart Hospital will not collect C-POMS data daily until an electronic system for data collection is established, whereas The London Chest Hospital have such a system already established and hence will collect C-POMS daily there.

Additionally, when continuous or discrete variables are changed into binary data, some information can be lost[7]. However, this is a necessary compromise when attempting to develop as simple as possible and clinically usable tool.

9.6.3 Validity and reliability

There is no gold standard by which to assess the criterion validity of C-POMS, and validity assessment of discriminative instruments thus relies on construct validity[89]. Although C-POMS currently exhibits construct validity, content validity decreases over time due to the dynamic nature of construct definitions and content validity[172]. Thus, future construct validity assessments will be necessary which will potentially identify a need for revisions to C-POMS in order for it to remain an appropriate measure of post-operative morbidity[172]. Methods to do this include the calculation of a content validity index (CVI) of each item[170, 186] or for the overall instrument[170]. However, calculating the CVI in the validation of C-POMS was unnecessary since part of C-POMS construction was based on expert panel judgments on the severity and importance of the morbidity items for inclusion into the model. Furthermore, since content validity is conditional for the targeted

population[246] this reinforces C-POMS as condition-specific tool unlikely to have generalisability to other surgical populations.

9.6.4 Clinical utility

Data collection for this study started in 2005, and thus considerable time has evolved since this study was commenced. However, compared to the UK cardiac surgery population[25], the population on which C-POMS was developed remains representative in terms of gender (female: 19.3% vs 20.7%), age (66 years vs 66.5 years), the proportion of patients returning to theatre (4.9% vs 5.1%) and in mortality rate (1.5% vs 1.3%). The fact that C-POMS population remains representative is useful when introducing C-POMS as a tool into clinical practice.

Since this study was conducted, some changes have occurred that are of interest. Firstly, the proportion of patients undergoing off-CPB isolated CABG has stabilised at 17% in the UK[25], compared with 7.1% in this study. Since off-CPB surgery has since been shown to be associated with lower morbidity and reduced hospital stay[247], additional analysis comparing C-POMS-defined morbidity outcome between patients having surgery on- and off-CPB could now be explored. Secondly, further research evidence is now available suggesting that medications do affect outcome following cardiac surgery. Pre-operative statin use has been shown to enhance recovery after cardiac surgery[248], particularly for all-cause mortality, atrial fibrillation and stroke[249] while a combination of statin and beta-blockers have been shown to protect against stroke after CABG[250]. However, there was no effect of pre-operative statins on MI or renal failure[249]. Thirdly, although in-hospital mortality appears not to be affected by ethnic background, non-whites have been found to have a longer hospital stay[251]. Thus, it may be useful to undertake further analysis to determine if there are ethnicity differences in C-POMS-defined morbidity outcome.

Since multifactorial models are generally poorly integrated into clinical practice[72] due to their complexity[57, 72], the routine use of C-POMS in clinical practice is reliant on it not being burdensome in terms of time and complexity[155, 156, 157] while retaining its measurement properties[158] and rigor[157].To assist ease of completion the presence or absence of each domain can be recorded without presence or absence of the individual criteria being documented to enable the summary score to be calculated and each variable is readily available. Furthermore, consideration of the resources required and of the personnel available to obtain the data is required. Since recommendation 145 of the Bristol Royal Infirmary Inquiry report[28] suggests that participation in audit should be mandatory for all healthcare professionals providing clinical care, there should be sufficient resources available. However, in practice the reverse if often true. Nevertheless, two London hospitals have considered C-POMS and have concluded that the benefits of using C-POMS outweighs any administrative burden. Future assessment of the practicalities of using C-POMS in clinical practice in these sites will be reviewed.

9.7 STRENGTHS

9.7.1 Methodological strengths

9.7.1.1 Comprehensive frameworks

As discussed in chapter 7 section 7.2, it is important to use a conceptual framework for credible instrument development[173]. Three frameworks were utilised in the development and validation of C-POMS: A modified Van den Broeck framework[98] was used to minimise data errors and improve data quality; C-POMS was developed utilising the McMaster Framework for constructing and assessing health indices[89, 154] for discriminative instruments; and a content validation framework[172] was also employed to maximise content validity.

9.7.1.2 Collaborations

A considerable strength of this work has been the multi-professional collaboration and input obtained at various stages of the process, which is recommended when adopting the clinimetric approach to serve the needs of both clinical research and clinical practice[12]. The PDG (membership detailed in chapter 2 section 2.4.2) has met 4 times to review and comment on the development, progress and evaluation while the expert panel (membership detailed in chapter 6 section 6.3.3.3.2) was formed for the item reduction strategy and content validity processes. Furthermore, methodological and statistical advice for the model development and validation was sought from experts in the field of health outcome measurement and clinimetrics.

9.7.1.3 Data quality

The validity of the conclusions reached does depend partly on the accuracy of the data[96]. A particular strength of this study is that despite a lack of guidance in the literature regarding development and implementation[98] and the minimal acceptable data quality levels for clinical data[104], a comprehensive and systematic data quality framework was devised and implemented. This process identified >99% completeness in >92% variables, with only 1.4% incompleteness overall, that 98.6% of erroneous inliers identified were rectified, there was <1% consistency error and there representativeness with those patients who didn't participate in the study, following consideration of the study's exclusion criteria. Thus, although it is not possible to ensure 100% quality data[99], there is considerable confidence in the quality of the data used in this study. Furthermore, consistent with the American Statistical Association guidelines[106], these processes and results have been reported, for complete transparency.

9.7.2 Multi-dimensional nature of C-POMS

C-POMS is multi-dimensional in that it measures multiple constructs within a single index, which is a key feature of the clinimetric approach[137]. The advantage of this is that the summary score does then reflect the total morbidity burden as defined by C-POMS. One of the most useful aspects of C-POMS is the ability to use as a summary score on D3, D5, D8 and D15. Although multifactorial

indexes are generally poorly integrated into clinical practice[72], summary scales provide an easy method of scoring are readily interpretable[173], and are commonly used in clinical practice.

9.7.3 Clinical utility

Thus far, C-POMS has been evaluated favourably from a clinical perspective. As highlighted in sections chapter 8 section 8.5.3 and section 9.2.4 of this chapter, both the Heart and London Chest Hospitals agree that C-POMS is fundamentally useful and have agreed to use C-POMS as a routine data collection tool. Further review will occur through the implementation processes at each site.

9.8 FUTURE WORK

9.8.1 Validate in other cardiac centres

As highlighted in section 9.6.1, an important element of future work is the determination of the validity of C-POMS in other cardiac surgical centres. Since the quality of the performance of the instrument depends on the expertise of those using the tool[12], training, inter-reliability testing and ongoing support would need to be provided. As stated previously, this is currently in progress at the Heart Hospital and The London Chest Hospital. Ultimately, if C-POMS does exhibit sufficient validity in other institutions, a subsequent aim would be the incorporation of C-POMS domains into the national SCTS dataset for collection at all 55 cardiac surgical centres in the UK.

9.8.2 Prognostic studies

Since in-hospital audit underestimates morbidity in the post-operative period[252], and 3-year mortality is significantly higher in cardiac surgery patients with major morbidity after sugery[253], extension of follow-up beyond the initial hospitalization is indicated. Ethics committee approval has been received to obtain hospital episode statistics (HES) data for readmission (diagnosis and procedures) to any hospital within England and Wales and to National Statistics for mortality data, within the first year following surgery. Additionally, work to identify pre-operative risk factors for post-operative morbidity (see section 9.8.3) could also include the determination of risk factors for the presence of morbidity in the year following surgery.

Morbidities are indicators not only of quality of care but of quality of life[57]. When considering longer-term morbidity rehabilitation, absence from symptoms[84] and patient reported outcome measures (PROMS)[193] could also be considered.

9.8.3 Pre-operative risk assessment for total morbidity burden following cardiac surgery

Unsurprisingly, the pre-operative risk assessment EuroSCORE, POSSUM and Magovern scores poorly predicted total morbidity burden as defined by C-POMS summary score. Thus, pre-operative variables that may predict post-operative total morbidity burden, as defined by C-POMS summary score, or those domains with greatest frequency/predictive ability for subsequent length of stay

should be explored. As stated in section 9.5.2, such prediction of post-operative complications has use in patient group and individual risk stratification , optimising available resources[64] and identifying those patients that could be fast-tracked for early discharge[71]. However, subsequent risk prediction assessed at time of arrival on ICU should also be examined since morbidity prognosis at this time may differ from the pre-operative assessment[67] due to anaesthetic and intra-operative factors. Such analysis might also identify targets for therapeutic intervention such that post-operative morbidity is also mitigated.

9.8.4 Comparison of POMS components with other patient populations

One of the most promising uses of discriminative instruments is to quantify the burden of illness across different populations[89]. As stated previously, the inclusion of POMS domains and criteria within C-POMS does permit comparison with other patient populations where POMS has been validated. Thus, a collaboration is currently underway to directly compare the results of this study in cardiac patients within the urological, general and orthopaedic surgery patients in the Grocott et al study[93]. Further comparison may also be occur when the paediatric version of POMS has been completed at Great Ormond Street Hospital, London and if possible, assessment of the applicability of C-POMS within a grown up congenital heart surgery (GUCH) population would also be of interest.

9.8.5 Update C-POMS

As stated in chapter 7 section 7.6.7, due to the dynamic nature of construct definitions and content validity[172], revisions to C-POMS may become necessary in order for it to remain an appropriate measure of post-operative morbidity. Thus, future research has to include re-assessment of the validity of C-POMS to describe and quantify post-operative morbidity following cardiac surgery.

9.9 CONCLUSIONS

C-POMS is the first validated tool for identifying total morbidity burden post cardiac surgery. In clinical practice C-POMS can primarily be used as a standard outcome measure to describe and quantify post-operative morbidity and total morbidity burden. In this study, considerable C-POMS-defined morbidity was observed in these patients which lends C-POMS to potentially useful in identifying those at greatest risk of post-operative morbidity, in guiding clinical decision making, as a prognostic indicator, in quality assurance (audit and performance/quality of care indicator) processes, in the optimising the utilisation of health services and in cost analysis.

Historically, the diversity associated with attempting to measure morbidity, lead to imprecise measurement and monitoring of events. C-POMS provides a standardised definition and measurement tool for total morbidity burden after cardiac surgery. The use of C-POMS would permit morbidity to be considered independently of mortality in quality of care assessment in cardiac

surgical patients. Since clarity, measurement and the publication of quality performance is a key perspective of the NHS currently, such potential usage of C-POMS in this way is very timely.

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APPENDICES

Appendix 1: Pre-operative risk prediction scores for morbidity outcome patients undergoing cardiac surgery.

Study/Score	Sample/Method	Outcome measure/Follow-up	Pre-operative variables in model (with scores in bold)	Results/Comments
Parsonnet Score Parsonnet V et al (1989). A method of uniform stratification of risk for evaluating the results of surgery in aqcuried heart disease USA	Univariate and multivariate logistic regression analyses were performed on data from 3,500 consecutive open-heart surgery procedures selected retrospectively from an existing database (1982-1987). The odds ratio of each variable on outcome was calculated with those significant entering the additive model. 17 factors met the criteria and were analysed for an association with operative mortality and a second model was constructed. The 2 models were compared by regression analysis to test the validity of the additive univariate model. 300 earlier cases from the same database were then tested retrospectively by summation of all the risk-scores applicable to each case. The total score was compared with the actual outcome. The scores were tabulated by people not concerned directly with the outcome. Scores tested	**Operative mortality:** defined as any death occuring within 30days of surgery Mean predicted operative mortality was 10.4%. Mean observed operative mortality was 8.9% **Post-operative complications**: 824 (23.5%) had post-operative complicatioin **Length of hospital stay**: Not stated	*Variable* — *Score* Female **1** Morbid obesity (>1.5x ideal weight) **3** Diabetes (unspecified type) **3** Hypertension (SBP >140mmHg) **3** EF Good (>50) **0** Fair (30-49) **2** Poor (<30) **4** Age (yr) 70-74 **7** 75-79 **12** >80 **20** Reoperation - first **5** - second **10** Preoperative IABP **2** Left ventricular aneurysm **5** Emergency surgery following PTCA **10** Or catheterisation complications Dialysis dependency (PD or Haemo) **10** Catastrophic states **10-50** Other rare circumstances **2-10** Valve surgery -mitral **5** -PA pressure >60mmHg **8** -Aortic **5** - Pressure gradient >120mmHg **7**	The mean predictive operative mortality was 10.4%. The mean observed operative mortality was 8.9%. Correlation of univariate and multivariate models was 0.85. Operative mortality in surgery subgroups resembled that of all groups combined. The differences were not statistically different. Correlation also between pre-operative score and length of stay and non-fatal complications. Excluded many variables that were too subjective, for example, NYHA classification, CPB time, use of LIMA etc. **Roques et al (1995):** Assessed predictive value of score on French population. Seven risk factors were not predictive according to multivariate analysis and thus does not recommend it's use in France **Gabrielle et al (1997):** Assessed the parsonnet and SUMMIT (modified parsonnet) in french surgical population. Showed that parsonnet had moderate predictive value and the modified version was too complex. **Lawrence et al (2000):** Parsonnet score was a good predictor of ICU stay<24hrs, post-operative complications and in-hospital

	prospectively in 4 institutions.		CABG at time of valve surgery **2**	death. **Wynne-Jones et al (2000):** Found Parsonnet score overpredicted mortality and included variables not associated with mortality. **Dupuis et al (2001):** Parsonnet score failed to calibrate for morbidity. **Vanagas et al (2003):** Parsonnet score over-predicted mortality in lithuanian population
Cleveland Clinical Severity Score Higgins et al (1992). Stratification of morbidity and mortality outcome by pre-operative risk factors in coronary artery bypass patients. A clinical severity score. USA	Retrospective analysis of 5051 patients to identify risk factors (out of 29 variables) associated with perioperative morbidity and mortality. Model validation consisted of 4069 prospectively recruited patients undergoing CABG between July 1st 1986 to June 30th 1988 in Cleveland Clinic Foundation. ORs were calculated to measure the degree of association. Factors significant to at least p<0.10 were used in logistic regression analysis. Potential interactions were evaluated. Forward step-wise regression models were developed to determine effects of pre-op factors on outcome and included only factors that were significant p<0.05. The goodness of fit of the model was evaluated using	**Mortality** No definition given 126 (2.5%) died **Morbidity** defined as MI, IABP mechanical ventilation >3 days, neurological deficit oliguric or anuric renal failure Serious infection. 680 (13.5%) morbidity	*Variable* *Score* Emergency case **6** Serum creatinine >141 and <167 **1** >168 **4** Severe LV Dysfunction **3** Re-operation **3** Operative mitral valve insufficiency **3** Age >65 and <74yrs **1** >75yrs **2** Prior vascular surgery **2** COPD **2** Anaemia (haematocrit <0.34) **2** Operative aortic valve stenosis **1** Weight <65kg **1** Diabetes, on oral or insulin therapy **1** Cerebrovascular disease **1**	Mortality and distribution of severity score differ significantly between the 2 groups, with increased numbers of higher-risk patients (>5) in the validation group. The morbidity rate was lower than the CI of the predicted rate in 4 of the 9 severity score categories. The Homer-Lemeshow goodness-of-fit test comparing observed and expected events by deciles of risk also showed lack of fit (p<0.001). There was good agreement between the predicted and observed mortality rates in each severity score category. The Hosmer-Lemeshow test showed overall agreement (p=0.3) between observed and expected events. The cut-off point that yielded the largest combined sensitivity and specificity was a clinical score of 6 for mortality (Sensitivity 67.5%, specificity 86.2%, positive predictive value 11.1%, negative predictive value 99.0%) and 4 for morbidity (Sensitivity 62.5%, specificity 73.2%, positive predictive value 26.7%,

	Hosmer-Lemeshow x^2 statistic.				negative predictive value 92.6%). **Kurki et al (2002):** CABDEAL has the highest predictive value for morbidity compared with EUROScore and Cleveland models., while EuroSCORE and Cleveland better for mortality.
Canadian Model Tuman et al (1992). Morbidity and duration of ICU stay after cardiac surgery. A model for pre-operative risk assessment	Prospective study on 3,156 patients undergoing cardiac surgery in Chicago. Univariate analysis determined factors predictive of morbidity and used to construct model. 17 variables included and 15 were significant and 11 independently predictive. The validation group consisted of 394 prospective patients.	**Morbidity** was defined as the presence of one or more of the following categories of complications: Cardiac Pulmonary Renal Infectious Neurologic 700 (22.2%) morbidity **Operative mortality** was defined as intra-operative death or death within 24hrs of surgery. Death after this period was defined as post-operative mortality. 197 (6.2%) died	*Variable* Emergency surgery Age 65-74yrs >75yrs Renal dysfunction Age of previous MI 3-6mo <3mo Female Reoperation Pulmonary hypertension Cerebrovascular disease Multivalve or CABG/valve CHF LV dysfunction	*Score* **4** **1** **2** **2** **1** **2** **2** **2** **2** **2** **1** **1** **1**	Low risk (0-5): Predicted probability (95%CI) 14.6 (14.3-14.8); observed morbidity 14.7%, p=0.99 Increased (6-9): Predicted 34.4 (33.8-35.0), observed 30.6%, p=0.49 High (>10): Predicted 61.0 (59.4-62.5), Observed 52.9%, p=0.62.
Geraci et al (1993) Predicting the occurrence of adverse events after coronary artery bypass surgery	Retrospective data on 2213 Medicare patients >65yrs undergoing bypass surgery between January 1985 and June 1986 in Alabama, Arizona, Indiana,	**Mortality** was defined as death within 30days of admission. 145 (6.6%) died.	*Variable* Intercept History of CABG Emergent CABG History of COPD	*OR(95%CI)* **0.31** **2.8** (2.0-4.0) **2.3**(1.6-3.3) **2.0**(1.3-2.8)	The C statistic of the model is 0.64 and the Hosmer-Lemeshow statistic was 9.15 (NS) indicating acceptable fit of the model to the data. Approximately 25% of patients in lowest 4 deciles experienced adverse events

USA	New York, Pennsylvania, Utah and Wisconsin were extracted from MedisGroups software by trained chart extractors. Data included 250 key clinical findings representing patient history, physical examination, laboratory tests, pathologic examination, radiologic examination from admission. Entrance required presence of one of following ICD-9 codes: 36.10 – 36.16, 36.19, 36.20 and 36.30. Adverse events defined as serious post-operative complications potentially related to quality of care, resulting in a high likelihood of increased morbidity, subsequent intensive therapy or prolonged hospital stay (defined by literature review and expert opinion). Statistical analysis included descriptive statistics, regression models (forward selection stepwise) the C statistic (measure of explanatory power of logistic model) and Hosmer-Lemeshow statistic (goodness-of-fit). Database split in half and model developed for each and tested with other half using $R(^2)$. All variables from either model were used as candidates in	**Non-fatal adverse event** was defined as: New MI by ECG (3.0%) Cardiorespiratory arrest (5.3%) New CHF by cxr (15.0%) Acute graft failure (0.3%) New onset thromboembolism (0.4%) New onset stroke (1.8%) Coma (2.6%) Mechanical ventilation >48hrs (3.9%) Wound infection (0.8%) Bacteraemia (0.6%) Acute renal failure (1st time dialysis or rise in creatinine to 442mmol/l) (1.7%) More than 6 units of blood or packed red blood cells (9.6%) Unplanned return to surgery (4.9%) Rate of one or more adverse events was 33.0% (n=730).	Infiltrate on xray **1.8**(1.1-3.1) Pulse>110bpm **1.8**(1.1-3.0) Age (10yr incr >65) **1.6**(1.3-2.0) Urea nitrogen >10.7mmol **1.5**(1.1-2.1) AMI at admission **1.4**(1.0-1.8) History of MI **1.3**(1.1-1.5) Male **0.9**(0.7-1.1) 1 or 2 vessel disease **0.8**(0.6-1.0)	compared with just over 50% in the highest 2 deciles. Post-operative occurrence of adverse events was modestly associated with severity of illness at admission thus suggest could be marker of sub-optimal care.

	stepwise logistic regression model applied to whole database.				
The Montreal Heart Institute Risk Assessment Classification Tremblay et al (1993). A simple classification of the risk in cardiac surgery: the first decade. Canada	500 patients from 1980 study were included to define and establish risk classification. A further 2029 consecutive patients undergoing cardiac surgery (range of surgery) were prospectively studied (November 1988 to November 1990). Risk factor data were collected (LV function, unstable angina, recent MI, age, BMI, emergent surgery, systemic disturbances.) Full definitions of each were given. All patients were prospectively classified as normal, increased or high risk of early death during hospitalisation according to the number of risk factors present. Statistical analysis included: ANOVA, Chi Squared, Z proportion.	**Mortality** was defined as postoperative mortality during hospitalisation (1980 and 1990 populations) 17 (3.4%) died in 1980 set 100 (4.9%) died in 1990 set **Length of stay in post-operative ICU** (1990 population) Not stated **Length of postoperative hospitalisation** (1990 population) Not stated	*Risk factors* Poor left ventricular function Unstable angina or recent MI Evidence of heart failure Advanced age Obesity Emergent surgery Reoperation Other severe and uncontrolled systemic disturbances *Patient classification* Normal risk = no risk factor Increased risk = 1 risk factor High risk = >2 risk factors		Mortality, number of days in ICU and number of days in hospital all increased with increasing number of risk factors (p=0.0001 in all). Changes in surgery and practice between datasets which may have influenced results.
STS Model 2 Hattler et al (1994). Risk stratification using The Society of Thoracic Surgeons Program USA	728 patients undergoing CABG only within 2 year period ending in October 1993. Data collection as per STS database on standardised forms and discharge charts reviewed by 2 nurse practitioners. Morbidity and length of stay were extracted from the STS database. Short-term follow-up attained through clinic visits or telephone	**Mortality** Definition not given. Predicted mortality was 6.94% Observed mortality was 3.98% (n=29) **Morbidity** Included:	*Mortality* Morbid obesity Time from failed PTCA to CABG <6hrs Prior MI<21days Cardiogenic shock Preop IV nitrates Preop inotropic agents NYHA class IV Non-elective procedure	*Risk ratio* **4.6** **6.6** **3.4** **8.9** **3.1** **5.1** **3.0** **5.0**	Significant difference between the predicted and observed mortality (p<0.005). Number of complications and length of hospital stay was linear with increasing predicted risk.

	contact with patient or GP. A questionnaire was used to determine NYHA class and patient's subjective assessment of own condition.Statistical methods included univariate analysis and multivariate step-wise logistic regression to determine independent risk factors, significance taken at p<0.05. The model was used to examine the effect of multiple risk factors to patient survival. The model uses a modification of the Bayesian algorithm and was validated using set/test approach.	Re-operative bleeding, Perioperative MI Infection (mediastinal, septicaemia) Stroke (permanent/transient) Ventilator >5days Renal failure (no dialysis) Dialysis required Heart block (permanent) Cardiac arrest Anticoagulant complication Tamponade Gatrointestinal complication Multisystem failure In-hospital mortality Morbidity rate not stated	Preop IABP **5.8** Ejection fraction <0.30 **3.6** *Morbidity* Morbidity was assessed according to the STS predicted risk intervals (0-5%, 5-10%, 10-20%, 20-30%, >30%) **Mean no of complications per patient**: 0.27, 0.71, 1.07, 2.12, 3.00, respectively. **%patients having complications**: 16.78, 34.92, 42.71, 76.47, 66.67, respectively. **Length of hospital stay**: 10.48, 12.94, 13.85, 23.60, 25.54, respectively	
Ontario Province Risk Score (French Score) Roques et al (1995) Quality of care in adult heart surgery: proposal for a self-assessment approach based on a French multicentre study. France	Prospective study of 7,181 consecutive patients undergoing adult cardiac surgery (type not stated) between January and April 1993 from 42 French centres. 108 parameters were collected regarding pre-operative risk factors, surgical procedure and post-operative course (mortality, post-operative events, ICU length of stay, overall post-operative stay and transfer to another hospital). Statistical methods included univariate analysis, 2 multivaraiate	**Mortality** Not specifically defined. Overall mortality rate was 6% but in 2 sub-centres was 4.1% **Mortality/severe morbidity** was defined as: Reoperation for thoracic wound infection Perioperative MI Duration of intubation >48hrs Severe infection Reoperation with CPB Low cardiac output	*Variable* *Weighting index* Age 70-74 **3** Age 75-79 **4** Age >80 **5** Acute renal failure (creat >200umol/l) **5** Renal failure (on dialysis) **6** Ejection fraction (30-50%) **2** Ejection fraction (<30%) **5** Saphenous vein graft only **2** Reoperation **2** Tricuspid surgery **4** Valve + CABG **2** *Critical situations:* MI<48hrs **4**	Predictive accuracy of score appeared better than Parsonnet score for mortality alone (ROC 0.75 v 0.65, p=<0.0001). The ROC was 0.74 for the French score on mortality/severe morbidity. For mortality the predictive value of French score was better in CABG group than valve group (ROC 0.72 v 0.69).

	logistic regression analyses (mortality and mortality/severe morbidity), ROC curves (Hanley's method) for the accuracy and predictive value of scoring systems overall and in 2 subsets (CABG and valve) (between 0.5-0.7 is low accuracy, 0.7-0.9 is a useful test)	Cardiac massage Low limb ischaemia Ventricular arrhythmia Renal failure Stroke Gastro-duodenal hemorrhage Insertion of IABP Severe morbidity rate not stated	Ventricular tachy/fibrillation Preoperative intubation Transplantation Post MI VSD Acute aortic dissection Pulmonary embolectomy Risk groups divided into: Score <2 Score 2-3 Score 4-6 Score >6	**4** **10** **9** **8** **13** **15**	
Tu Score Tu et al (1995). Multicentre validation of a risk index for mortality, intensive care unit stay and overall hospital length of stay after cardiac surgery. Canada	13,098 patients undergoing cardiac surgery from 9 institutions from April 1st 1991 to March 31st 1992 (derivation group: 6213 patients) and April st 1992 to March 31st 1993 (validation group: 6885 patients). All information obtained from the PACCN database of all patients undergoing cardiac surgery in Ontario.	**In-hospital mortality** Overall 3.7% mortality rate **ICU LOS** Overall mean LOS was 3.2 days **Post-op LOS** Overall mean LOS was 10.6 days **Very long ICU LOS was >6days** Patient numbers not stated **Very long post-op LOS was defined as >17days.** Patient numbers not stated	*Variable* Age <65 **65-74** >75 Female LVEF Grade 1 Grade 2 Grade 3 Grade 4 Type of surgery CABG only Single valve Complex Urgency of surgery Elective Urgent Emergency Repeat operation (yes)	*Score* **0** **2** **3** **1** **0** **1** **2** **3** **0** **2** **3** **0** **1** **4** **2**	Areas under the ROC curve for the risk index were 0.75, 0.67 and 0.71 for mortality, very long ICU LOS and very long post-op LOS predictions in the derivation set and 0.75, 0.66 and 0.69 for the validation group. The index predicted mortality significantly better that the very long post-op LOS (P<0.05) in both groups.
CABDEAL Score	Retrospective study.	**Prolonged hospital stay**	*Variable*	*Score*	The sensitivity of the model was 56% and the

Kurki and Kataja (1996) Preoperative prediction of postoperative morbidity in CABG Finland	386 consecutive CABG patients in 1990 and 1991 in Helsinki. Preoperative data were collected: demographic, NHYA class, ECG, past medical history, priority of operation, cardiac catheterisation data, co-morbidity factors. In total 21 pre-operative variables were collected.	defined as >12 days because of adverse events, transfer to another hospital for treatment of complications or death during hospital stay. Morbidity or mortality rate not stated	Creatinine (> 111) **2** Age (>70) **1** BMI (>28) **1** Diabetes **2** Emergency operation **2** Abnormal ECG **1** Lung disease **1**	specificity 77%. The model gave 69 false-positive and 39 false-negative results at the score. The higher the risk score the greater the risk of increased morbidity and the better the specificity. **Kurki et al (2002):** CABDEAL has the highest predictive value for morbidity compared with EUROScore and Cleveland models., while EuroSCORE and Cleveland better for mortality.
Magovern Model Magovern et al (1996). A model that predicts morbidity and mortality after coronary artery bypass graft surgery USA	All patients undergoing cardiothoracic surgery from July 1991 have data (including 170 preoperative, 50 procedural and 100 post-operative variables) collected prospectively for the Allegheny General Hospital's cardiothoracic database (standard definitions included). 1567 consecutive patients undergoing CABG only between July 1st 1991 and December 31st 1992 (test group) and 1235 between January 1st 1993 and April 30th 1994 (validation group) were analysed. The association of 125 preoperative variables were analysed. Statistics included univariate and forward step-wise regression, chi-squared, Fisher Exact Test, Students t test, Hosmer-Lemeshow statistic, ROC,	Outcome was defined as mortality or morbidity during the hospitalisation only. **Mortality** Death at any time during the hospital stay Mortality was 3.8% and 3.0% in the test and validation group, respectively. **Morbidity** An unexpected post-operative complication, major or minor, which resulted in the increase consumption of hospital resources owing to the required treatment. Full definitions of each major and minor complication stated.	*Variable* *Clinical risk score* Cardiogenic shock **7** Emergency operation **5** Urgent operation **4** Catheterisation induced coronary closure **4** Severe LV dysfunction (LVEF <30%) **4** Age >75yrs **3** Cardiomegaly **2** PVD **2** Chronic renal insufficiency (creat >1.9) **2** Age 70-74yrs **2** IDDM **2** NIDDM **1** Low BMI **1** Female gender **1** Reoperation **1** Age 65-69yrs **1** Anaemia **1** Cerebrovascular disease **1** COPD **1**	The predicted versus observed morbidity and mortality fell within the 95%CI. The predictive power of the model for morbidity was 0.82 and 0.86 for mortality (area under ROC).

	Odds ratio. The clinical risk score was devised using the independent predictors of morbidity and mortality from the logistic regression model and assigned points. ROC characteristics were used to verify the predictive accuracy of the model in the validation group.	*Major:* cardiovascular failure, respiratory failure, acute renal failure, permanent cerebral deficit, major wound infection, pulmonary embolus, surgical intervention after CABG *Minor:* Temporary central nervous system deficit, acute renal insufficiency, atrial arrhythmias, ventricular arrhythmias, superficial wound infection, respiratory insufficiency, pleural effusion, pneumothorax, systemic sepsis, gastrointestinal bleeding, post-operative mediastinal bleeding. Major and minor complication was 16% and 36% in the test group and 12% and 40% in validation group.	Albumin <4.0mg/dl **1** Renal dysfunction (creatinine 1.5-1.9) **1** Elevated blood urea nitrogen (>29mg/dl) **1** Congestive heart failure **1** Atrial arrhythmia **1** Total number of points is 50 but maximum score is 37. **Mortality** *Points %Predicted* Low 0-4 0.2 Average 5-8 2 Moderate 9-11 6 High 12-18 30 Extremely High 19+ 95 **Morbidity** *Points %Predicted* Low 0-2 20 Moderate 3-5 50 High 6-8 74 Extremely High 9+ 93		
Higgins et al (1997) Higgins et al (1997). ICU admission score for predicting morbidity and mortality risk after coronary artery bypass grafting.	Prospectively collected data on 4,918 consecutive patients undergoing CABG (alone or combined) between January 1st 1993 and March 31st 1995. Data from the first 15 months (n=2,793) was used to develop the model and	**Morbidity** was defined as the presence of one or more of the following during hospitalisation: Cardiac complication, prolonged ventilatory support, CNS complication, renal failure,	*Pre-operative factors* Small body size (BSA <1.72m2) **1** Prior heart operation - one **1** - two or more **2** History of op or angioplasty for PVD **3** Age >70yrs **3** Pre-operative creatinine >1.9mg/dl **4**		The ROC C-statistic reflecting mortality for the logistic regression mortality and clinical models were 0.86 and 0.87, respectively, which were not statistically different. For morbidity it was 0.82, 0.80, respectively (p=0.02). For isolated CABG a C-statistic for mortality and morbidity was 0.87 and 0.82,

	data from the next 12 months (n=2,125) was used to validate the mode. Separate analysis was also conducted on CABG only patients (n=2,035; 73% of the developement group). Data collection reliability was tested by comparing the data with chart review of a random subset. For each variable 98-100% agreement was found. Over 100 risk factors identified from literature, clinical experience and own work were collected. The association of each factor with morbidity and mortality was evaluated. Factors significant ($p<0.05$) and had at least 2% prevalence were entered into multiple logistic regression model (58 variables). Two models were developed; one each for mortality and morbidity. The number of terms allowed in the models was limited to 10% of the number of outcome events. The goodness-of-fit of each final logistic model was tested using Hosmer-Lemeshow X^2 statistic. ROC curves were generated to measure and compare the accuracy of the models. C-statistic values closer to 1.0 indicate	serious infection, death. In total population morbidity rate was 10.4% **Mortality** included all deaths during hospitalisation for the operation, regardless of length of stay. Total population mortality rate was 3.1%.	Pre-operative albumin <3.5mg/dl **5** *Intra-operative factors* CPB time >160mins **3** Use of IABP after CPB **7** *ICU admission physiology* A-a gradient >250mmHg **2** Heart rate > 100 beats per min **3** Cardiac index <2.1.min^{-1}.m^{-2} **3** CVP >17mmHg **4** Arterial bicarbonate <21mmol/l **4**		respectively. Using the clinical model, the observed outcomes fell within the 95%CI predicted by the developmental set.
USA					Applying the clinical model to patients in the validation set produced C-statistics of 0.85 for mortality and 0.82 for morbidity. Hosmer-Lemeshow goodness-of-fit determined all logistic and clinical models calibrate well.

	better discrimination by the model.							
ACC/AHA Practice Guidelines Eagle et al (1999). ACC/AHA guidelines for coronary artery bypass graft surgery: Executive summary and recommendations. USA	Based on 7,290 patients undergoing isolated CABG surgery between 1996 and 1998	**Mortality** defined as in-hospital mortality Mortality rate was 2.93% **CVA** defined as new focal neurological event persisting at least 24hrs. CVA rate was 1.58% **Mediastinitis** during index admission defined as a positive deep culture and/or Gram stain and/or radiographic findings indicating infection and requiring re-operation. Mediastinitis rate was 1.19%	*Mortality score*		*CVA*	Peri-operative risk		
			score			Total score	Mortality%	CVA%
			Age 60-69	**2**	**3.5**	0	0.4	0.3
			Age 70-79	**3**	**5**	1	0.5	0.4
			Age >80	**5**	**6**	2	0.7	0.7
			Female sex	**1.5**		3	0.9	0.9
			EF <40%	**1.5**	**1.5**	4	1.3	1.1
			Urgent surgery	**2**	**1.5**	5	1.7	1.5
			Emergency surgery	**5**	**2**	6	2.2	1.9
			Prior CABG	**5**	**1.5**	7	3.3	2.8
			PVD	**2**	**2**	8	3.9	3.5
			Dialysis or creat >2	**4**	**2**	9	6.1	4.5
			COPD	**1.5**		10	7.7	>6.5
						11	10.6	
						12	13.7	
						13	17.7	
						14	>28.3	
Staat et al (1999) Severe morbidity after coronary artery surgery: development and validation of a simple predictive clinical score. France	Retrospectively collected 43 pre-operative and 4 intra-operative clinical variables for 679 consecutive patients undergoing CABG between 1st January and 3rd Decemeber 1996 in one French institution. Variables were decided on literature review, discussion with participating physicians and available data.	**Severe morbidity** was defined as mortality or one of the following 10 non-fatal adverse events: Low cardiac output IABP MI Mechanical ventilation >48hrs Serious pneumonia Other serious infections	*Variable*		*Score*	For the validation group, the area under the ROC curve was 0.65. With a threshold score of 2 the sensitivity was 63% and specificity 75%. The positive predictive value was low at 23.8% and the negative predictive value was high (88.0%).		
			Symptomatic right heart failure		**7**			
			Ventricular arrhythmias		**4**			
			Reoperation (CABG)		**4**			
			COPD		**3**			
			BMI <24		**2**			
			ST changes on pre-op ECG		**2**			

		Acute renal failure Excessive bleeding Unplanned return to surgery CNS complication 17 (2.5%) operative mortality 156 (23.0%) severe morbidity Mean ICU LOS 2.8 days Mean hospital LOS 13.5 days			
A New Cardiac Risk Score Wong et al (1999). Risk factors of delayed extubation, prolonged length of stay in the intensive care unit and mortality in patients undergoing coronary artery bypass graft with fast-track cardiac anaesthesia Canada	Prospective study of 885 consecutive patients undergoing CABG (following the fast-track anaesthesia protocol and standard surgical procedure) between April to November 1995 in 1 hospital. Data collection included pre-operative, intra-operative, post-operative and outcome variables (all stated) collected by anaesthetists and research nurses. Statistical methods included univariate analysis, multiple stepwise logistic regression models. A model was developed for each outcome measures. An integer score between 1 and 6 was given based on the odds ratio and clinical considerations for each risk factor identified from logistic regression model. The models and scores were validated using bootstrap	**Delayed extubation** (>10hrs) Medium time 7hrs 25% >10hrs **Prolonged ICU LOS** (>48hrs) Median time 1 day 16.7% >48hrs **Mortality** (death occurring within 30 days of hospital or during hospital stay). 23 (2.6%) died.	*Variable* **Delayed extubation** Age>75yrs Age 61-75yrs Female gender Excessive bleeding (post) IABP (post) Inotropes (post) Atrial arrhythmia (post) **Prolonged ICU LOS** Age >75yrs Age 61-75yrs MI Female gender Renal insufficiency (post) IABP (post) Inotropes (post) Atrial arrhythmia (post) Excessive bleeding (post) **Mortality** Left ventricle grade 4	*Score* **3** **2** **2** **6** **6** **2** **2** **4** **2** **3** **3** **6** **6** **4** **4** **3** **5**	No significant differences between area under ROC curve between the logistic regression and clinical risk scores. No significant differences between the observed and predicted outcomes at various clinical risk score ranges.

	techniques. Area under ROC curve was used to assess the predictive performance of the models and scoring.		Emergency surgery **4** Female gender **3**	
Pitkanen Model Pitkanen et al (2000). Intra-institutional prediction of outcome after cardiac surgery: comparison between a locally derived model and the EuroSCORE. Finland	Retrospective analysis of 4592 patients who underwent cardiac surgery (excluding those done off-CPB) between January 1st 1992 and December 31st 1996 and prospectively on 821 consecutive patients between September 1st 1998 and May 31st 1999. Data were collected by 2 investigators. Mortality data were obtained from Statistics Finland. Compared with EuroSCORE. Predictive models were developed by logistic regression. 3061 patients from retrospective sample were randomised to a derivation database and validated on the remaining sample and in the prospective sample. A model for each outcome was developed using univariate analysis, backward stepwise logistic regression analysis. P<0.005 formed the final predictive model. Model calibration was determined using Hosmer-Lemeshow goodness-of-fit statistic. The discrimination abilities	**Morbidity (overall)** was defined as 1 or more of the following: Haemodynamic problems (inotropic support, IABP), mechanical ventilation >24hrs, serious gastrointestinal complications, anuria, stroke multi-organ failure, resternotomy due to other cause than excessive bleeding, sepsis, pneumonia, mediastinitis, psychosis or remarkable confusion, readmission to the ICU or complicated clinical situation at discharge to another hospital. Overall morbidity was 22.0% and 18.4% in the retrospective and prospective databases, respectively. **Morbidity:** Length of ICU stay >2days.	*Variable* *OR(95%CI)* **Morbidity** Age yrs **1.04(1.03-1.06)** Female gender **1.32(1.05-1.65)** NYHA class **1.29(1.10-1.51)** Previous stroke **1.90(1.09-3.29)** Number of previous MIs **1.32(1.16-1.51)** Diuretic use **1.35(1.04-1.74)** Renal failure (creat>120) **2.42(1.09-5.38)** LVEF **0.99(0.98-0.99)** Pulmonary rales **1.68(1.02-2.76)** CABG only **0.52(0.36-0.75)** UAP and ongoing MI **8.09(1.56-42.1)** Combined CABG and valve **1.73(1.16-2.60)** Combined AVR and MVR **4.57(1.47-14.2)** Emergency operation **2.08(1.14-3.80)** **ICU LOS>2days** Age yrs **1.04(1.02-1.06)** Female gender **1.62(1.18-2.21)** NHYA class **1.49(1.18-1.87)** Diabetes **1.57(1.11-2.24)** Previous stroke **3.61(1.95-6.70)** ASO in lower limbs **1.67(1.05-2.65)** Previous inferior MI **1.84(1.27-2.66)**	There was a difference in the calculated risk between the retrospective and prospective databases. The validation databases were not different with regard to expected risk of ICU LOS>2days. All 3 predictive models calibrated well, with the exception of the morbidity model (Hosmer-Lemeshow p value for retrospective data p=0.002, the others in the region of p=0.4). Discriminate abilities of the model compared with EuroSCORE with similar, except for morbidity. In the prospective database EuroSCORE was higher among non-survivors than survivors, with morbidity than without and among those with ICU LOS>2days compared with <2days. This model and EuroSCORE appeared equally accurate in predicting adverse outcome, but not morbidity.

	assessed by area under ROC curve. Comparison with EuroSCORE in outcome states used non-parametric tests.	Mean ICU LOS was 1.9 and 1.4 days for the retrospective and prospective databases, respectively. **Mortality** was defined as death occurring within 30 days from the operation. Mortality was 2.0% and 1.1% in the retrospective and prospective databases, respectively.	Diuretic use **1.51(1.08-2.12)** LVEF **0.98(0.97-0.99)** CABG only **0.32(0.23-0.45)** UAP and ongoing MI **4.06(1.09-15.1)** Emergency operation **2.61(1.35-5.03)** **Mortality** Age yrs **1.09(1.04-1.13)** NYHA class **1.37(1.17-1.59)** Diabetes **2.14(1.12-4.12)** Number of previous MIs **1.54(1.14-2.07)** LVEF **0.98(0.96-0.99)** CABG only **0.30(0.16-0.57)** AVR, MVR and CABG **4.98(1.19-20.7)** Emergency operation **4.33(1.78-10.5)**	
Cardiac Anaesthesia Risk Evaluation Score (CARE) Dupuis et al (2001). A clinically useful predictor of mortality and morbidity after cardiac surgery Canada	Prospective observational study of 3,548 consecutive patients undergoing a cardiac surgical procedure at Ottawa Heart Institute. Split into reference group (2000 patients between November 12 1996 and March 18th 1998) and validation group (1,548 patients between March 19th 1998 and April 2nd 1999). CARE score was designed to resemble the ASA physical staus classification.	M**ortality** defined as in-hospital death Reference and validation group mortality rate both 3.4% **Morbidity** defined as complications in one or more of the following categories: cardiovascular, respiratory, neurological, renal, infectious, any other. -If no morbidity data, prolonged post-operative LOS used as a surrogate.	1. patient with a stable cardiac disease and no other medical problem. A non-complex surgery is undertaken 2. Patient with stable cardiac disease and one or more uncontrolled medical problems. A non-complex surgery is undertaken 3. Patient with any uncontrolled medical problem and in whom a complex surgery is undertaken 4. Patient with any uncontrolled medical problem and in whom a complex surgery is taken 5. Patient with chronic or advanced cardiac disease for whom cardiac surgery is undertaken as a last hope to save or improve life E. Emergency: surgery as soon as diagnosis is made and operating room is available Can have scores 1-5 or 3E, 4E, 5E	Areas under ROC curve were 0.791 +/- 0.067 and 0.740 +/- 0.024 for the prediction of morbidity and mortality, respectively. Compared all analyses with the Parsonnet score and Tuman classification. All risk models had acceptable calibration in predicting mortality and morbidity, except Parsonnet which failed to calibrate for morbidity.

		Ref grp morbidity rate 20.7% Validation grp morbidity rate 22.2% Ref grp prolonged LOS 10.2% Validation grp prolonged LOS 12.3% Ref grp mean post-op LOS 8.8 days Validation group mean post-op LOS 9 days.			
QMMI Score Fortescue et al (2001). Development and validation of a clinical prediction rule for major adverse outcomes in coronary bypass grafting. USA	All patients undergoing CABG only without additional procedure between August 1993 to October 1995 in 12 large tertiary care centres. The 9,498 patients were divided randomly into 2 mutually exclusive subsets of episodes: the derivation set (6,237) and validation set (3,261). Considered 27 pre-operative factors. Data obtained prospectively through patient interviews and retrospectively through the medical notes. Data collection benchmarking was performed by comparing with the Uniform Hospital Discharge Data Set. Factors considered potential predictors of major adverse outcomes included correlates of morbidity and mortality published in	**Major adverse outcome** defined as any of the following: Death Renal failure, MI Cardiac arrest Stroke Coma Death Each patient counted only once in the analyses regardless of total number of adverse outcomes. Mortality rate 2.5% In total 408 (4.3%) morbidity rate In derivation set 6.5% had one or more adverse	*Variable* *Score* Pre-CABG creatinine >3.0mg/dl **12** Age >80yrs **11** Cardiogenic shock **10** Emergent operation **9** Age 70-79 yrs **8** Prior CABG **7** EF <30% **6** History of liver disease **6** Age 60-69yrs **5** Pre-op creatinine 1.5-3.0mg/dl **5** Stroke or TIA **4** EF 30-49% **3** History of COPD **3** Female gender **3** History of hypertension **2** Urgent operation **2**		The mean total risk score of those with and without a major adverse outcome was 18.0 +/- 8.5 and 11.3 +/- 6.6 points, respectively. Calibration of the model using Hosmer-Lemeshow goodness-of-fit test was good. ROC curve areas were 0.77 for death, 0.71 for renal failure, 0.75 for coma, 0.68 for stroke, 0.72 for cardiac arrest and 0.67 for MI. In the validation set the ROC curve areas were 0.74, 0.75, 0.74, 0.70, 0.68 and 0.64 in above categories, respectively.

	previous analyses and other variables suggested by members of the Consortium. Variables studied included ischaemic heart disease stage, cardiac anatomy and function, other conditions and risks prior to surgery, and therapy received before surgery. Variables that showed significant correlation ($p<0.05$) were then entered into a step-wise regression analysis. Factors with $p<0.05$ were retained. The resulting independent correlates were used to develop the clinical prediction rule. After assigning a value to each variables each patient was given a total score. Discriminatory performance of the model was internally validated between the 2 groups using area under ROC	outcomes.			
CORRAD Score Wouters et al (2002) Preoperative prediction of early mortality and morbidity in coronary bypass surgery The Netherlands	?retrospective study The development set was the first 653 patients undergoing CABG in 1998. Validation set 1 contained 503 patients undergoing CABG in 1999. Validation set 2 contained 466 patients undergoing CABG in 2000. Pre-, per- and post-operative data obtained from CORRAD database (variables stated). All	Follow-up was 180 days (6 months post-surgery) **Early mortality** defined as hospital mortality and cardiac-related mortality within the 6 month follow-up period. Development set: 5.6% (n=32)	*Early mortality* Sex Age Hypertension Lung disease Reoperation Operative status Ventricular function *Morbidity*	*B-coefficient* **0.71** **0.67** **0.62** **1.0** **0.9** **0.7** **0.67**	Area under ROC for early mortality was 0.81 (development) 0.77 (validation 1), 0.73 (validation 2), 0.67 (Parsonnet in validation 1), 0.67 (Parsonnet in validation 2), 0.70 (EuroSCORE in validation 1) and 0.68 (EuroSCORE in validation 2). Area under ROC for morbidity was 0.73 (development) 0.62 (validation 1) and 0.69 (validation 2). Score sensitivity and specificity was 0.46

	follow-up was 6 months post-surgery. Statistical methods included univariate analysis (odds ratios and chi-squared) to identify risk factors, multiple logistic regression analysis for independent risk factors. Non-significant variables eliminated from the model one at a time. The weight attributed to each variable was obtained from the logistic regression B-coefficients. The area under ROC was used to assess discrimination between mortality and morbidity for all datasets. Low and high risk groups were then defined. Score was compared with parsonnet and EuroSCORE for the validation sets.	Validation 1: 5.7% (n=29) Validation 2: 4.8% (n=21) **Morbidity** was registered in the case of hospital mortality and also the following complications resulting in a prolonged hospital stay: ventilatory support > 3days, sternal wound nephrological neurological pulmonary gastrointestinal vascular problems Development set: 19.1% (n=108) Validation 1: 26% (n=131) Validation 2: 16% (n=75)	Age **0.45** Diabetes **0.62** Hypertension **0.80** Kidney disease **1.06** Lung disease **0.60** Reoperation **0.84** Operative status **1.13** Ventricular function **0.54** Hospital stay for the 1999 and 2000 sets was 7.1 and 7.3 days respectively for low risk (<2) patients and 13 and 12 days for high risk patients (>2).		(82/186) and 0.86 (673/783), respectively. The predictive value for morbidity was 0.42 (82/195) and for no-morbidity 0.87 (673/777). Rates of mortality and morbidity between low risk (<2) and high risk (>2) patients was statistically significant (p,0.05). The hospital stay between predicted high and low risk groups is statistically significant (p<0.05).
Amphia Score Huijskes et al (2003). Outcome prediction in CABG and valve surgery in the Netherlands: development of the Amphiascore and it's comparison with the EUROScore	7282 patients undergoing CABG and /or valve surgery between January 1997 and December 2001. Collected demographic, morbidity, cardiac status and indication/intervention variables pre-operatively.	1. **in-hospital death**. 171 (2.3%) died 2. **Major adverse cardiac event** (MACE) defined as in-hospital death or peri-operative MI or VT/VF 1224 (17%) MACE 3. **Extended length of stay** (ELOS) defined as intensive care length of stay of at least 3 days or in-hospital death.	***In hospital death*** Age, per 5 yrs over 60, **1** Female **1** Creatinine level (150-200) **3** Poor LVEF **2** Prior cardiac surgery **4** MI within last 24hrs **5** Emergency procedure **3** Combined CABG/Mitral valve **4**		The MACE and ELOS models was less predictive than the in-hospital death model. Good correlation with the EUROScore - complete agreement in 72%, partial agreement in 93%, Kappa=0.37, weighted Kappa 0.51. Only included pre-operative factors and increased cross-clamping time, increased operative use of blood products, lower intraoperative diastolic blood pressure and

		1001 (14%) ELOS	***MACE***		intraoperative electrocardiographic ST-T
			Age	**1**	chages are factors influencing post-op MI.
The Netherlands			Extracardiac arteriopathy	**2**	
			Pulmonary hypertension	**2**	
			MI>30days	**2**	
			Prior cardiac surgery	**6**	
			MI within last 24hrs	**9**	
			Emergency procedure	**3**	
			Cobmined CABG/AVR	**5**	
			Combined CABG/MVR	**6**	
			ELOS		
			Age	**1**	
			Female	**2**	
			Neurological dysfunction disease	**2**	
			Creatinine level (150-200)	**4**	
			Haemoglobin (80-90%)	**1**	
			Poor LVEF	**4**	
			Pulmonary hypertension	**3**	
			Prior cardiac surgery	**4**	
			MI within last 24hrs	**4**	
			Failed PCI	**3**	
			Emergency procedure	**3**	
			Critical pre-operative state	**3**	
			Combine CABG/AVR	**2**	
			Combined CABG/MVR	**6**	
Janssen et al (2004) Preoperative prediction of prolonged stay in the intensive care unit for coronary bypass	888 patients undergoing CABG only between January 2000 and December 2001 in the University Medical Centre. Pre-, per- and post-operative data extracted from	**Prolonged length of stay** in ICU was defined as longer than 3 days. Indications for prolonged length of ICU stay were:	Variables	Odds Ratio	Area under ROC was 0.68 for prolonged length of ICU stay. The observed risk compared well with predicted risk. The specificity and sensitivity of the prognostic test was 99% (95%CI 98.4-99.6) and 9%
			Lung disease (Y/N)	**2.46**	
			No sinus rhythm (Y/N)	**4.60**	
			Mild valve pathology (Y/N)	**0.30**	
			Reoperation (Y/N)	**4.00**	

surgery The Netherlands	CORRAD database (stated). Statistical methods included univariate analysis, Fisher's exact test (which variables contributed to prolonged ICU length of stay), odds ratios, multiple logistic regression analysis (independent risk factors), odds ratios (used as estimates of risk) and step-wise logistic regression (prognostic value of variables). P<0.05 was taken as statistically significant for entry into prognostic model. ROC curve was calculated was used to measure the prognostic value of these variables. A score was then calculated as a linear function of the variables included and the predicted probability of prolonged length of stay determined. Probability of >40% was the cut-off for constructing a prognostic test.	Prolonged ventilation Low cardiac output defined as need for inotropic support and a cardiac index <2.2l/min per m^2 Need for Swan ganz-catheter. 104 (12%) had a prolonged length of stay. Mean ICU stay was 2.2±5.1 days with a median of 1 day (range 0-79days). Hospital mortality was 2.8%.	No elective operation (Y/N) **4.01** Off-pump procedure (Y/N) **0.20** The S-Score was calculated for each patient using the logistic regression coefficients and the distribution and predicted probabilities for those with and without prolonged ICU length of stay were calculated. Low risk: 5% Intermediate risk: 15% High risk: 30% Very high risk: >40%	(95%CI 4-14), respectively. The positive predictive value was 60% (95%CI 36-84) and the negative predictive value was 89% (95%CI 87-91).

Appendix 2: Data Definition Tables.

- All the tables are below are constructed in the order in which the variables appear on the CRF and in the data entry tables.
- An indicator field is where completion of subsequent fields are dependent on answering 'yes' in the indicator field. In all instances, subsequent fields follow directly after the indicator field.
- In the field name/variable column prefixes are used to identify variables that are repeated at different time-points. Pre- is pre-operative, IO is intra-operative, PO is within the first 12 hours post-op and D1, D3, D5, D8 and D15 are post-operative days 1, 3, 5, 8 and 15, respectively.
- In the code in database column the code 3 for 'not stated' means variable not found from source by the data collector. A code of -1 for 'missing' indicates the variable has been missed by the data collector.
- Consistency in coding: 1=yes, 2=no, 3=not stated, -2=not done or not stated and -1=missing/NA. Mainly numerical fields where possible. Consistency in text fields due to one data collector/enterer.

Admin table

Field name/Variable	Definition	Type of field	Code in database
Study number	Unique identifier	Text	As stated
Hosp no	Participant hospital number	Text	As stated
NHS no	Participant unique NHS number	Text	As stated, -1=missing
Incl in Pilot II	Included in pilot study	Number	1=yes, 2=no, -1=missing
Consultant	Consultant surgeon	Text	Initials stated
DoRecruit	Date of recruitment into study	Date	As stated, 01/01/2001 if missing
Incl criteria met?	Were all inclusion criteria met?	Number	1=yes, 2=no, -1=missing
DOB	Participant date of birth	Date	As stated, 01/01/2001 if missing
Age	Participant age (yrs)	Number	As stated, -1=missing
Gender	Participant gender	Number	1=male, 2=female, -1=missing
Ethnicity	Participant ethnicity, participant defined	Text	As stated, blank if missing
Ethnicity code	Recode of participant ethinicity	Number	1= Causasian, 2=Asian, 3=Black, 4=Other, -2=not stated
Postcode	Participant's home postcode	Text	As stated, in AA1 1BB format

DoAdm	Date of admission to Heart Hospital	Date	As stated, 01/01/2001 if missing
Home or transfer	Indicator code: Source of admission	Number	1=home, 2=transfer, 3=other, -1=missing
State other adm method	State other admission method if 3 in indicator code	Text	As stated, blank if missing
Tranferring hospital	State transferring hospital, if 2 in indicator code	Text	As stated, blank if missing
DoAdm Transfer hosp	Date of admission to transferring hospital, if 2 in indicator code	Date	As stated, 01/01/2001 if missing
Private patient?	Was the participant a private patient?	Number	1=yes, 2=no, -1=missing
Compl study?	Indicator field: Did the participant complete the study?	Number	1=yes, 2=no, -1=missing
DODiscont	Date of discontinuation in study, if no in indicator field	Date	As stated, 01/01/2001 if missing
Reason for discont	Reason for discontinuation, if no in indicator field	Number	1= not fulfill incl crit, 2=pt request to withdraw, 3= invest judgement, 4=pt death, 5=non-compliance, 6=lost to f-up, 7=other
Explanation	Further explanation for discontinuation in study, if no in indicator field	Text	As stated, blank if missing/NA
Genetics sample received?	Was a DNA sample received from the retrospective sampling?	Number	1=yes, 2=no, -1=missing.
Genetics consent (prospective)	Was consent for prospective genetics study given?	Number	1=yes, 2=no, -1=missing.
Fit for discharge validation	Was the participant included in the 'fit for discharge' validation?	Number	1=yes, 2=no, -1=missing.
Other trial participation	Indicator field: Did the participant take part in another trial?	Number	1=yes, 2=no, -1=missing
State trial	State the trial, if yes in indicator field	Text	As stated, blank if missing/NA
Trial control or treat	State whether the participant was a control or treatment subject, if yes in indicator field	Text	As stated, blank if missing/NA
Admin comments	Any other admin comments	Text	As stated, blank if no other comments

Pre-operative table

Field name/Variable	Definition	Type of field	Code in database
Study number	Unique identifier	Text	As stated
Hosp number	Participant hospital number	Text	As stated
Cardiogenic shock	**Magovern indicator field:** Cardiogenic shock present. Defined as systolic blood pressure <50mmHg and a cardiac index <2.0l/min/m^2 and evidence of peripheral hypoperfusion.	Number	1=yes, 2=no, -1=missing
Catheter coronary closure	**Magovern indicator field:** Catheter induced coronary closure. Defined as iatrogenic coronary occlusion or dissection secondary to a diagnostic	Number	1=yes, 2=no, -1=missing

	catheterisation or angioplasty, or both, that requires heart surgery within 24 hrs.		
DOpreopCXR	Date of pre-op chest x-ray	Date	As stated, 01/01/2001 if missing
Cardiomegaly	**Magovern indicator field:** Cardiomegaly present. Defined as enlarged heart as determined by chest radiography or echocardiography	Number	1=yes, 2=no, 3=not stated, -1=missing/report missing
Cardiomegaly state on CXR report	Definition of cardiomegaly on chest-x-ray report, if yes in indicator field	Text	As stated, blank if missing
Reoperation	**Magovern indicator field:** Has the participant had any previous cardiac surgery?	Number	1=yes, 2=no, -1=missing
No prev op	Number of previous cardiac surgeries, if yes in indicator field	Number	As stated, -1=missing
Doprevop	Date of previous surgery, if yes in indicator field	Date	As stated, 01/01/2001 if missing
Prev op state	State the previous operation, if yes in indicator field	Number	1= CABG, 2=AVR, 3=MVR, 4=CABG+AVR, 5=CABG+MVR, 6=AVR+MVR, 7=CABG+MVR+AVR,8=other, -1=missing/not stated
Cerebrovasc disease	**Magovern indicator field:** Cerebrovascular disease present. Defined as history of transient ischaemic attack, embolic stroke or non-embolic stroke and/or angiographic evidence of internal carotid stenosis >50%.	Number	1=yes, 2=no, -1=missing
COPD	**Magovern indicator field:** Chronic obstructive pulmonary disease present. Defined as pulmonary disease that results in functional disability or requires bronchodilator therapy and/or results in abnormal spirometry as defined by a forced expiratory volume in 1s <75% of that predicted.	Number	1=yes, 2=no, -1=missing
Atrial arrhyth	**Magovern indicator field:** History of atrial arrhythmia, defined as atrial fibrillation, flutter or tachycardia.	Number	1=yes, 2=no, -1=missing
State arrhyth	State atrial arrhythmia, if yes in indicator field	Text	As stated, blank if missing
CVA	Has the participant ever had a stroke?	Number	1=yes, 2=no, -1=missing
TIA	Has the participant ever had a transient ischaemic attack	Number	1=yes, 2=no, -1=missing
State CVA/TIA	State any additional information related to CVA/TIA	Text	As stated, blank if no further details/missing
Pre Albumin	**Magovern indicator field:** Pre-operative albumin level (mg/dl). Low serum albumin defined as <4.0 mg/dl.	Number	As stated, -2, not done, -1=missing
Hypertension	SCTS definition: Identifies if the patient has hypertension defined as	Number	1=yes, 2=no, -1=missing

	receiving treatment or dietary advice or if blood pressure has been recorded greater than 140/90mmHg on two occasions, or lower if on medication.		
State hypertension	State any additional information related to hypertension	Text	
Liver disease	Has the participant ever had or currently has liver disease?	Number	1=yes, 2=no, -1=missing
GI bleeding	Has the participant ever had or currently have GI bleeding?	Number	1=yes, 2=no, -1=missing
State GI bleeding	If yes above, state type of bleeding	Text	
Dialysis	Does the participant have a current requirement for dialysis?	Number	1=yes, 2=no, -1=missing
Immunosuppressants	Is the participant currently taking immunosuppressant medication?	Number	1=yes, 2=no, -1=missing
NYHA class	Class I: patients with no limitation of activities; they suffer no symptoms from ordinary activities. Class II: patients with slight, mild limitation of activity; they are comfortable with rest or with mild exertion. Class III: patients with marked limitation of activity; they are comfortable only at rest. Class IV: patients who should be at complete rest, confined to bed or chair; any physical activity brings on discomfort and symptoms occur at rest.	Number	Class as stated, -1=missing
ACEI	Indicator field: Is the participant currently taking ACE Inhibitor medication?	Number	1=yes, 2=no, -1=missing
ACEI state drug	State the ACE inhibitor taking, if yes in indicator field	Text	As stated, blank if missing
ACEI state dose	State the dose (mg) of the ACE inhibitor taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
AntiArrh	Indicator field: Is the participant currently taking anti-arrhythmia medication?	Number	1=yes, 2=no, -1=missing
AntiArrh state drug	State the anti-arrhythmic taking, if yes in indicator field	Text	As stated, blank if missing
AntiArrhy state dose	State the dose (mg) of the anti-arrhythmic taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
Anticoag	Indicator field: Is the participant currently taking anticoagulation medication?	Number	1=yes, 2=no, -1=missing
Anticoag state drug	State the anticoagulant taking, if yes in indicator field	Text	As stated, blank if missing
Anticoag state dose	State the dose of the anticoagulant taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
Antiplatelets	Indicator field: Is the participant currently taking anti-platelet medication?	Number	1=yes, 2=no, -1=missing
Antiplatelets state drug	State the anti-platelet taking, if yes in indicator field	Text	As stated, blank if missing
Antiplatelets state dose	State the dose (mg) of the anti-platelet taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
BBlock	Indicator field: Is the participant currently taking beta blocker medication?	Number	1=yes, 2=no, -1=missing

BBlock state drug	State the beta blocker taking, if yes in indicator field	Text	As stated, blank if missing
Bblock state dose	State the dose (mg) of the beta blocker taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
CCB	Indicator field: Is the participant currently taking calcium channel blocker medication?	Number	1=yes, 2=no, -1=missing
CCB state drug	State the calcium channel blocker taking, if yes in indicator field	Text	As stated, blank if missing
CCB state dose	State the dose (mg) of the calcium channel blocker taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
Diuretic	Indicator field: Is the participant currently taking diuretic medication?	Number	1=yes, 2=no, -1=missing
Diuretic state drug	State the diuretic taking, if yes in indicator field	Text	As stated, blank if missing
Diuretic state dose	State the dose (mg) of the diuretic taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
Nitrate	Indicator field: Is the participant currently taking nitrate medication?	Number	1=yes, 2=no, -1=missing
Nitrate state drug	State the nitrate taking, if yes in indicator field	Text	As stated, blank if missing
Nitrate state dose	State the dose (mg) of the nitrate taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
PCA	Indicator field: Is the participant currently taking potassium channel activator medication?	Number	1=yes, 2=no, -1=missing
PCA state drug	State the potassium channel activator taking, if yes in indicator field	Text	As stated, blank if missing
PCA state dose	State the dose (mg) of the potassium channel activator taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
Statin	Indicator field: Is the participant currently taking statin medication?	Number	1=yes, 2=no, -1=missing
Statin state drug	State the statin taking, if yes in indicator field	Text	As stated, blank if missing
Statin state dose	State the dose (mg) of the statin taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
H2agonists	Indicator field: Is the participant currently taking H_2 agonist medication?	Number	1=yes, 2=no, -1=missing
H2agonists state drug	State the H_2 agonist taking, if yes in indicator field	Text	As stated, blank if missing
H2agonists state dose	State the dose (mg) of the H_2 agonist taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
PPI	Indicator field: Is the participant currently taking proton pump Inhibitor medication?	Number	1=yes, 2=no, -1=missing
PPI state drug	State the proton pump inhibitor taking, if yes in indicator field	Text	As stated, blank if missing
PPI state dose	State the dose (mg) of the proton pump inhibitor taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
AngioII	Indicator field: Is the participant currently taking angiotensin II receptor agonist medication?	Number	1=yes, 2=no, -1=missing

AngioII state drug	State the angiotensin II receptor agonist taking, if yes in indicator field	Text	As stated, blank if missing
AngioII state dose	State the dose (mg) of the angiotensin II receptor agonist taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
Thyroid	Indicator field: Is the participant currently taking thyroid medication?	Number	1=yes, 2=no, -1=missing
Thyroid state drug	State the thyroid taking, if yes in indicator field	Text	As stated, blank if missing
Thyroid state dose	State the dose of the thyroid taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
Asthma	Indicator field: Is the participant currently taking asthma medication?	Number	1=yes, 2=no, -1=missing
Asthma state drug	State the asthma medication taking, if yes in indicator field	Text	As stated, blank if missing
Asthma state dose	State the dose of the asthma medication taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
Pain meds	Indicator field: Is the participant currently taking analgesic medication?	Number	1=yes, 2=no, -1=missing
Pain state drug	State the analgesic taking, if yes in indicator field	Text	As stated, blank if missing
Pain state dose	State the dose (mg) of the analgesic taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
Diabetic	Indicator field: Is the participant currently taking diabetic medication?	Number	1=yes, 2=no, -1=missing
Diabetic state drug	State the diabetic medication taking, if yes in indicator field	Text	As stated, blank if missing
Diabetic state dose	State the dose of the diabetic medication taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
Alpha adreno block	Indicator field: Is the participant currently taking alpha-adrenoceptor blocking medication?	Number	1=yes, 2=no, -1=missing
Alpha adreno state drug	State the alpha-adrenoceptor blocker taking, if yes in indicator field	Text	As stated, blank if missing
Alpha adreno state dose	State the dose (mg) of the alpha-adrenoceptor blocker taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
Other lipids	Indicator field: Is the participant currently taking other lipid medication?	Number	1=yes, 2=no, -1=missing
Other lipids state drug	State the other lipid taking, if yes in indicator field	Text	As stated, blank if missing
Other lipids state dose	State the dose (mg) of the ACE other lipid taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
Other HBP drugs	Indicator field: Is the participant currently taking other anti-hypertensive medication?	Number	1=yes, 2=no, -1=missing
Other HBP state drug	State the other anti-hypertensive taking, if yes in indicator field	Text	As stated, blank if missing
Other HBP state dose	State the dose (ug) of the other anti-hypertensive taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing
Other1 (1-6)	Indicator field: Is the participant currently taking any other medication?	Number	1=yes, 2=no, -1=missing
Other1 state drug (1-6)	State the other medication taking, if yes in indicator field	Text	As stated, blank if missing
Other1 state dose (1-6)	State the dose of the other medication taking, if yes in indicator field	Number	As stated, -2=not documented, -1=missing

DOpre-op values	Date pre-op data collected from	Date	As stated, 01/01/2001 if missing
DOpre-op bloods	Date of pre-op blood results	Date	As stated, 01/01/2001 if missing
Age value	Participant age	Number	As stated, -1=missing
Age score	**POSSUM indicator field:** Age score according to POSSUM criteria	Number	1=<=60, 2=61-70, 4=>71, -1=missing
Pre-op SBP value	Systolic blood pressure (mmHg)	Number	As stated, -1=missing
Pre-op SBP score	**POSSUM indicator field:** Systolic blood pressure score according to POSSUM criteria	Number	8=<=89, 4=90-99, 2=100-109, 1=110-130, 2=131-170, 4=>171, -1=missing
Pre-op HR value	Pre-op heart rate (bpm)	Number	As stated, -1=missing
Pre-op HR score	**POSSUM indicator field:** Heart rate score according to POSSUM criteria	Number	8=<=39, 2=40-49, 1=50-80, 2=81-100, 4=101-120, 8=>121, -1=missing
Pre-op GCS value	Pre-op Glasgow coma score	Number	
Pre-op GCS score	**POSSUM indicator field:** GCS score according to POSSUM criteria	Number	1=15, 2=12-14, 4=9-11, 8=<=8, -1=missing
Pre-op urea value	Pre-op urea (mmol/l)	Number	As stated, -1=missing, 2=haemolysed
Pre-op urea score	**POSSUM indicator field:** Urea score according to POSSUM criteria	Number	1=<=7.5, 2=6-10, 4=10.1-15, 8=>=15.1, -1=missing, 2=haemolysed/Not done
Pre-op K value	Pre-op serum potassium (mmol/l)	Number	As stated, -1=missing, -2=haemolysed
Pre-op K score	**POSSUM indicator field:** Potassium score according to POSSUM criteria	Number	8=<=2.8, 4=2.9-3.1, 2=3.2-3.4, 1=3.5-5.0, 2=5.1-5.3, 4=5.4-5.9, 8=>=6.0, -1=missing, -2=haemolysed/not done
Pre-op Na value	Pre-op serum sodium (mmol/l)	Number	As stated, -1=missing, -2=not done
Pre-op Na score	**POSSUM indicator field:** Sodium score according to POSSUM criteria	Number	8=<=125, 4=126-130, 2=131-135, 1=>=136, -1=missing, -2=not done
Pre-op Hb value	**Magovern indicator field:** Pre-op haemoglobin (g/dl)	Number	As stated, -1=missing, -2=not done (sample underfilled)
Pre-op Hb score	**POSSUM indicator field:** Haemaglobin score according to POSSUM criteria	Number	8=<=9.9, 4=10-11.4, 2=11.5-12.9, 1=13-16, 2=16.1-17, 4=17.1-18, 8=>=18.1, -1=missing, -2=not done (sample underfilled)
Pre-op WCC value	Pre-op white cell count ($x10^9$/l))	Number	As stated, -1=missing, -2=not done (sample underfilled)
Pre-op WCC score	**POSSUM indicator field:** White cell count score according to POSSUM criteria	Number	4=<or=3000, 2=3100-3999, 1=4000-10000, 2=10100-20000, 4=>=20100, -1=missing, -2=not

			done (sample underfilled)
Pre-op ECG score	**POSSUM indicator field:** ECG score according to POSSUM criteria	Number	1=Normal, 4=AF and rate 60-90/min, 8=Any other abnormal rhythm or >5 ectopics/min, Q wave or ST/T wave changes, -1=missing
Pre-op cardiac status	**POSSUM indicator field:** Cardiac status score according to POSSUM criteria	Number	1=No failure, 2=Diuretic, digoxin, anti-anginal or antihypertensive therapy, 4=Peripheral oedema, warfarin therapy, borderline cardiomegaly, 8=Raised JVP or cardiomegaly on CXR, -1=missing
Pre-op respiratory status	**POSSUM indicator field:** Respiratory score according to POSSUM criteria	Number	1=No dyspnoea, 2=Dyspnoea on exertion or mild obstructive changes, 4=dyspnoea limiting patient to one flight of stairs or moderate chronic obstructive changes on CXR, 8=dyspnoea at rest or fibrosis or consolidation on CXR, -1=missing
POSSUM score	Total POSSUM score	Number	Calculated total of all POSSUM score, -1=missing/incomplete variables

The pre-op C-POMS variables are also collected and entered within this table. The details of these variables are found within the C-POMS tables.

Intra-operative data table

All data items with the D1 prefix are considered within the full 24 hours of post-operative day 1.

Field name/Variable	Definition	Type of field	Code in database
Study number	Unique identifier	Text	As stated
Hosp No	Hospital number	Text	As stated
DOOP	Date of operation	Date	As stated, 01/01/2001 if missing
DOOpDay of Wk	Day of the week of the operation	Text	As stated, blank if missing
Op performed	Indicator field: Identifies the operation performed	Number	1= CABG, 2=AVR, 3=MVR, 4=CABG+AVR, 5=CABG+MVR, 6=AVR+MVR, 7=CABG+MVR+AVR, 8=other, -1=missing
State other op	State other type of operation if 8 in the indicator field	Text	As stated, blank if missing/NA
Total no of grafts	State total number of grafts if indicator field includes CABG	Number	As stated, -1=missing

No of SVG	Include total number of saphenous veins used, if indicator field includes CABG	Number	As stated, -1=missing
No arterial grafts	Include total number of arterial grafts used, if indicator field includes CABG	Number	As stated, -1=missing
Tiss or mech valve	State whether a tissue or mechanical valve is used, if the indicator field includes any valve surgery	Number	1=Tissue, 2=mechanical, 3=not stated, -1=missing
ASA	Class 1: Healthy patient, no medical problems; Class 2: Mild systemic disease; Class 3: Severe systemic disease, but not incapacitating; Class 4: Severe systemic disease that is a constant threat to life; Class 5: Moribund, not expected to live 24 hours irrespective of operation	Number	As stated, -2=not stated, -1=missing
Anaes room time	Time arrived in anaesthetic room	Time	As stated, 00:00:00 if missing
Anaes start	Time anaesthetic started	Time	As stated, 00:00:00 if missing
Enter theatre	Time entered theatre	Time	As stated, 00:00:00 if missing
Skin prep	Time skin preparation started	Time	As stated, 00:00:00 if missing
Op end	Time operation ended	Time	As stated, 00:00:00 if missing
Leave theatre	Time left theatre	Time	As stated, 00:00:00 if missing
Op duration	Total duration of operation (mins)	Time	As stated, 00:00:00 if missing
Anaes agents	Identify type of administration of anaesthesia	Number	1=IV, 2=Gaseous, -1=missing
IO RBC	Indicator field: Received red cells	Number	1=yes, 2=no, 3=not stated, -1=missing
IO RBC units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
IO Platelets	Indicator field: Received platelets	Number	1=yes, 2=no, 3=not stated, -1=missing
IO Platelets units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
IO FFP	Indicator field: Received fresh frozen plasma	Number	1=yes, 2=no, 3=not stated, -1=missing
IO FFP units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
IO cryo	Indicator field: Received cryoprecipitates	Number	1=yes, 2=no, 3=not stated, -1=missing
IO cryo units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
IO Aprotinin	Indicator field: Received aprotinin	Number	1=yes, 2=no, 3=not stated, -1=missing
IO Aprotinin dose	State dose (mu), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
IO Enoximone	Indicator field: Received enoximone	Number	1=yes, 2=no, 3=not stated, -1=missing
IO Enoximone dose	State dose (ug/kg/min), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
IO Inotropes used	Indicator field: Received inotropes	Number	1=yes, 2=no, 3=not stated, -1=missing

IO Inotrope state	State inotrope, if yes in indicator field	Number	1=dopamine, 2=dobutamine, 3=isoprenaline, 4=dopexanine, -1=missing
IO Inotrope highest dose	State highest dose (ug/kg/min), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
IO Vasocon	Indicator field: Received vasoconstrictors	Number	1=yes, 2=no, 3=not stated, -1=missing
IO Vasocon state	State vasoconstrictor, if yes in indicator field	Number	1=nor adrenaline, 2=phenylephrine, 3=metaraminol, -1=missing/NA
IO Vasocon highest dose	State highest dose (ug/ml/min), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
IO IABP	Identify whether the patient required intra-operative aortic balloon pump	Number	1=yes, 2=no, 3=not stated, -1=missing
IO Tranexamic acid	Indicator field: Received tranexamic acid	Number	1=yes, 2=no, 3=not stated, -1=missing
IO Tran acid dose	State dose (g), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
IO ABs	Indicator field: Received antibiotics	Number	1=yes, 2=no, 3=not stated, -1=missing
IO ABs state	State antibiotics and dose, if yes in indicator field	Text	As stated, blank if missing/NA
IO Others	State any other medications given intra-operatively, and dose	Text	As stated, blank if NA. If more than one separated by a comma.
IO Comments	State any other intra-operative comments	Text	As stated, blank if NA. If more than one separated by a comma.
FiO_2	First value on ICU: FiO_2 (l)	Number	As stated, -2=not stated, -1=missing
pH	First value on ICU: pH level	Number	As stated, -2=not stated, -1=missing
pCO_2	First value on ICU: : partial pressure carbon dioxide (kPa)	Number	As stated, -2=not stated, -1=missing
pO_2	First value on ICU: partial pressure oxygen (kPa)	Number	As stated, -2=not stated, -1=missing
SBCc	First value on ICU: SBCc (mmol/l)	Number	As stated, -2=not stated, -1=missing
SBEc	First value on ICU: base deficit level (mmol/l)	Number	As stated, -2=not stated, -1=missing
K	First value on ICU: potassium level (mmol/l)	Number	As stated, -2=not stated, -1=missing
Na	First value on ICU: sodium level (mmol/l)	Number	As stated, -2=not stated, -1=missing
Glu	First value on ICU: glucose level (mmol/l)	Number	As stated, -2=not stated, -1=missing
Hb	First value on ICU: haemaglobin (g/dl)	Number	As stated, -2=not stated, -1=missing
PO RBC	Indicator field: Received red cells	Number	1=yes, 2=no, 3=not stated, -1=missing
PO RBC units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
PO Platelets	Indicator field: Received platelets	Number	1=yes, 2=no, 3=not stated, -1=missing
PO Platelets units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
PO FFP	Indicator field: Received fresh frozen plasma	Number	1=yes, 2=no, 3=not stated, -1=missing

PO FFP units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
PO cryo	Indicator field: Received cryoprecipitates	Number	1=yes, 2=no, 3=not stated, -1=missing
PO cryo units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
PO Aprotinin	Indicator field: Received aprotinin	Number	1=yes, 2=no, 3=not stated, -1=missing
PO Aprotinin dose	State dose (mu), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
PO Aprotinin end	State time aprotinin was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
PO Enoximone	Indicator field: Received enoximone	Number	1=yes, 2=no, 3=not stated, -1=missing
PO Enoximone dose	State dose (ug/kg/min), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
PO Enoximone end	State time enoximone was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
PO Inotropes used	Indicator field: Received inotropes	Number	1=yes, 2=no, 3=not stated, -1=missing
PO Inotropes state	State inotrope, if yes in indicator field	Number	1=dopamine, 2=dobutamine, 3=isoprenaline, 4=dopexanine, -1=missing/NA
PO Inotrope highest dose	State highest dose (ug/kg/min), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
PO Inotrope end	State time inotrope was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
PO Vasocon	Indicator field: Received vasoconstrictors	Number	1=yes, 2=no, 3=not stated, -1=missing
PO Vasocon state	State vasoconstrictor, if yes in indicator field	Number	1=nor adrenaline, 2=phenylephrine, 3=metaraminol, -1=missing
PO Vasocon highest dose	State highest dose (ug/ml/min), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
PO Vasocon end	State time vasoconstrictor was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
PO Frusemide	Indicator field: Received frusemide infusion	Number	1=yes, 2=no, 3=not stated, -1=missing
PO Frusemide dose	State dose (mg/hr), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
PO Frusemide end	State time frusemide was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
PO Morphine	Indicator field: Received morphine	Number	1=yes, 2=no, 3=not stated, -1=missing
PO Morphine dose	State dose (mg/hr), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
PO Morphine end	State time morphine was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
PO Propofol	Indicator field: Received propofol	Number	1=yes, 2=no, 3=not stated, -1=missing
PO Propofol dose	State dose (mg/hr), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
PO Propofol end	State time propofol was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
PO GTN	Indicator field: Received GTN	Number	1=yes, 2=no, 3=not stated, -1=missing
PO GTN dose	State dose (mg/hr), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
PO GTN end	State time GTN was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA

PO Actrapid	Indicator field: Received actrapid	Number	1=yes, 2=no, 3=not stated, -1=missing
PO Actrapid dose	State dose (iu/hr), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
PO Actrapid end	State time actrapid was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
PO SNP	Indicator field: Received SNP	Number	1=yes, 2=no, 3=not stated, -1=missing
PO SNP dose	State dose (mg/hr), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
PO SNP end	State time SNP was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
PO other infusions	State any other infusion, dose and time commenced and discontinued.	Text	As stated, blank if NA. If more than one separated by a comma.
12hr Gelo	Total gelofusin given in first 12 hrs post surgery (mls)	Number	As stated, -1=missing
12hr IVI	Total intravenous fluid given in first 12 hrs post surgery (mls)	Number	As stated, -1=missing
12hr input	Total fluid input given in first 12 hrs post surgery (mls)	Number	As stated, -1=missing
12hr urine	Total urine output in first 12 hrs post surgery (mls)	Number	As stated, -1=missing
12hr drainage	Total chest drain drainage in first 12 hrs post surgery (mls)	Number	As stated, -1=missing
Highest sedation score	Highest sedation score (Bloomsbury) in first 12 hrs post surgery	Text	As stated, blank if missing
Lowest sedation score	Lowest sedation score (Bloomsbury) in first 12 hrs post surgery	Number	As stated, -1=missing
Total K+	Total potassium supplements given in first 12 hrs post surgery (mmol)	Number	As stated, -1=missing
Total MgSO4	Total magnesium supplements given in first 12 hrs post surgery (mmol)	Number	As stated, -1=missing
PO Heart Rhythm	Indicator code: Worst heart rhythm in first 12 hrs post surgery	Number	1=SR, 2=ST, 3=SB, 4=AF, 5=other, -1=missing
PO Heart rhythm other	State any other heart rhythm if answer 5 in indicator field	Text	As stated, blank if missing/NA
PO Paced	Identify whether receiving pacing (temporary or permanent)	Number	1=yes, 2=no, 3=not stated, -1=missing
PO HR	Highest heart rate in first 12 hrs post surgery (bpm)	Number	As stated, -1=missing
PO SBP	Highest systolic blood pressure in first 12 hrs post surgery (mmHg)	Number	As stated, -1=missing
PO DBP	Diastolic blood pressure corresponding to highest systolic blood pressure in first 12 hrs post surgery (mmHg)	Number	As stated, -1=missing
PO RR	Indicator field: Highest respiratory rate if ventilated. If not ventilated highest respiratory rate in first 12 hrs post surgery (bpm)	Number	As stated, -1=missing
PO RR vent or ext	Identify whether respiratory rate in indicator field is ventilated or extubated	Number	1=ventilated, 2=extubated, -1=missing
Temp (first)	Temperature on arrival to ICU (^{o}C)	Number	As stated, -1=missing, -2=Not done
Temp (highest)	Highest temperature in first 12 hrs post surgery (^{o}C)	Number	As stated, -1=missing
Intubation grade	State the intubation grade Class I: the vocal cords are visible; Class II: the vocals cords are only partly visible; Class III: only the epiglottis is seen;	Number	As stated, -2=not done/documented, -1=missing

	Class IV: the epiglottis cannot be seen.		
CVP	Highest CVP in first 12 hrs post surgery (mmHg)	Number	As stated, -1=missing
MAP	Highest mean arterial pressure in first 12 hrs post surgery (mmHg)	Number	As stated, -1=missing
Additional DOOP comments	State any additional comments relating to first 12 hrs post surgery	Text	As stated, blank if NA. If more than one separated by a comma.
DODay1	Date of post-operative day 1	Date	As stated, 01/01/2001 if missing
D1 Heart Rhythm	Indicator code: Worst heart rhythm	Number	1=SR, 2=ST, 3=SB, 4=AF, 5=other, -1=missing
D1 Heart rhythm other	State any other heart rhythm if answer 5 in indicator field	Text	As stated, blank if missing/NA
D1 Paced	Identify whether receiving pacing (temporary or permanent)	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 HR	Highest heart rate (bpm)	Number	As stated, -1=missing
D1 SBP	Highest systolic blood pressure (mmHg)	Number	As stated, -1=missing
D1 DBP	Diastolic blood pressure corresponding to the highest systolic blood pressure (mmHg)	Number	As stated, -1=missing
D1 RR	Highest respiratory rate (bpm)	Number	As stated, -1=missing
D1 Temp	Highest temperature (^{o}C)	Number	As stated, -1=missing
D1 CVP	Highest CVP (mmHg)	Number	As stated, -1=missing, -2=Not stated
D1 RBC	Indicator field: Received red cells	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 RBC units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
D1 Platelets	Indicator field: Received red cells	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Platelet units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
D1 FFP	Indicator field: Received red cells	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 FFP units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
D1 cryo	Indicator field: Received red cells	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 cryo units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
Drains out 1	Indicator field: identify whether chest drains were removed on post-operative day 1	Number	1=yes, 2=no, 3=not stated, -1=missing
TODR	Time of chest drain removal, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
D1 Aprotinin	Indicator field: Received aprotinin	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Aprotinin dose	State dose (mu), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
D1 Aprotinin end	State time aprotinin was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
D1 Enoximone	Indicator field: Received enoximone	Number	1=yes, 2=no, 3=not stated, -1=missing

D1 Enoximone dose	State dose (ug/kg/min), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
D1 Enoximone end	State time enoximone was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
D1 Inotropes used	Indicator field: Received inotropes	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Inotropes state	State inotrope, if yes in indicator field	Number	1=dopamine, 2=dobutamine, 3=isoprenaline, 4=dopexanine, -1=missing/NA
D1 Inotrope highest dose	State highest dose (ug/kg/min), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
D1 Inotrope end	State time inotrope was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
D1 Vasocon	Indicator field: Received vasoconstrictors	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Vasocon state	State vasoconstrictor, if yes in indicator field	Number	1=nor adrenaline, 2=phenylephrine, 3=metaraminol, -1=missing/NA
D1 Vasocon highest dose	State highest dose (ug/ml/min), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
D1 Vasocon end	State time vasoconstrictor was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
D1 Frusemide	Indicator field: Received frusemide infusion	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Frusemide dose	State dose (mg/hr), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
D1 Frusemide end	State time frusemide was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
D1 Morphine	Indicator field: Received morphine	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Morphine dose	State dose (mg/hr), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
D1 Morphine end	State time morphine was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
D1 Propofol	Indicator field: Received propofol	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Propofol dose	State dose (mg/hr), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
D1 Propofol end	State time propofol was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
D1 GTN	Indicator field: Received GTN	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 GTN dose	State dose (mg/hr), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
D1 GTN end	State time GTN was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
D1 Actrapid	Indicator field: Received actrapid	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Actrapid dose	State dose (iu/hr), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
D1 Actrapid end	State time actrapid was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
D1 SNP	Indicator field: Received SNP	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 SNP dose	State dose (mg/hr), if yes in indicator field	Number	As stated, -2=not stated, -1=missing/NA
D1 SNP end	State time SNP was discontinued, if yes in indicator field	Time	As stated, 00:00:00 if missing/NA
D1 other infusions	State any other infusions received during post-operative day 1, the dose	Text	As stated, blank if NA. If more than one separated

	and the time commenced and discontinued.		by a comma.
D1 comments	State any other comments relating to post-operative day 1	Text	As stated, blank if NA. If more than one separated by a comma.

C-POMS data table

These variables are collected pre-operatively and post-operatively on days 1, 3, 5, 8 and 15 where the participant is still an in-patient. The data from each post-operative day is stored in different tables. D1 Chair (whether the participant sat in a chair on post-operative day 1) is the only variable included on day 1 only. All data items are considered within the full 24 hours of that day.

In code in database column, 'not applicable' is abbreviated to NA.

Field name/variable	Definition	Type of field	Code in database
Study number	Unique identifier	Text	As stated
Hospital number	Hospital number	Text	As stated
D1 inpt?	Is the participant an in-patient	Number	1=yes, 2=no, 3= not stated, -1=missing
DODay1	Date of post-op D1	Date	As stated, 00/00/2001 =missing
D1 Ward	Indicator field: Highest dependency ward on this day	Number	1=ITU, 2=HDU, 3=ACW, 4=3rd fl monitoring bay, 5=3rd floor, 6=4th floor, 7=other
D1 Ward other	State other ward, if answered 7 in indicator field	Text	As stated, blank if missing/NA
D1 ward transfer	Indicator field: Was the participant transferred to another ward?	Number	1=yes, 2=no, 3= not stated, -1=missing
D1 transfer to	Which ward was the participant transferred to, if yes to above.	Number	1=ITU, 2=HDU, 3=ACW, 4=3rd fl monitoring bay, 5=3rd floor, 6=4th floor, 7=other
D1 How much oxy?	Highest number of litres of oxygen received	Number	As stated, -1=missing
D1 RR	Highest respiratory rate (bpm)	Number	As stated, -1=missing, -2=not done
D1 FiO2	Highest FiO2 (%)	Number	As stated, -1=missing, -2=not stated
D1 SaO2	Lowest SaO2 (%)	Number	As stated, -1=missing, -2=not done
D1 temperature	Highest temperature (^{o}C)	Number	As stated, -1=missing, -2=not done
D1 wound complication	Iindicator field: Is a wound complication present?	Number	1=yes, 2=no, 3= not stated, -1=missing
D1 wound site 1	State the wound site with the complication, if yes in indicator field.	Number	1=sternum, 2=left leg, 3=right leg, 4=left arm, 5=right arm, 6=sacrum, 8=other/combination, -1=missing
D1 wound site 2	State the wound site with the complication, if yes in indicator field and more	Number	1=sternum, 2=left leg, 3=right leg, 4=left arm,

	than 1 wound complication		5=right arm, 6=sacrum, 8=other/combination, -1=missing
D1 wound site other	State other wound site with complication, if not covered by coding	Text	As stated, blank if missing/NA
D1 wound site compl	State the type of complication of the wounds, if yes to above.	Text	State type and details of wound complication
D1 Abs	Indicator field: Received antibiotics	Number	1=yes, 2=no, 3= not stated, -1=missing
D1 Abs new?	Is this a new requirement (compared to pre-op), if yes in indicator field?	Number	1=yes, 2=no, -1=missing/NA
D1 state Abs	State the antibiotic(s) and dose(s) received, if yes in indicator field	Text	As stated, blank if missing/NA
D1 antiemetic	Indicator field: Received antiemetic(s)	Number	1=yes, 2=no, 3= not stated, -1=missing
D1 antiemetic new	Is this a new requirement (compared to pre-op) if yes in indicator field?	Number	1=yes, 2=no, -1=missing/NA
D1 state antiemetic	State the antiemetic(s) and dose(s) received, if yes in indicator field	Text	As stated, blank if missing/NA
D1 Inotropes	Indicator field: Received inotropes	Number	1=yes, 2=no, 3= not stated, -1=missing
D1 state inotropes	State the inotrope(s) and dose(s) received, if yes in indicator field	Text	As stated, blank if missing/NA
D1 RBC	Indicator field: Received red cells	Number	1=yes, 2=no, 3= not stated, -1=missing
D1 RBC units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
D1 Platelets	Indicator field: Received platelets	Number	1=yes, 2=no, 3= not stated, -1=missing
D1 Platelets units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
D1 FFP	Indicator field: Received fresh frozen plasma	Number	1=yes, 2=no, 3= not stated, -1=missing
D1 FFP units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
D1 cryo	Indicator field: Received cryoprecipitates	Number	1=yes, 2=no, 3= not stated, -1=missing
D1 Cryo units	State number of units, if yes in indicator field	Number	As stated, -1=missing/NA
D1 Aprotinin	Indicator field: Received aprotinin	Number	1=yes, 2=no, 3= not stated, -1=missing
D1 Aprotinin dose	State dose, if yes in indicator field	Text	As stated, 3= not stated, -1=missing/NA
D1 Pain	**POMS indicator field:** New postoperative pain significant enough to received parenteral opioids or regional analgesia	Number	1=yes, 2=no, 3= not stated, -1=missing
D1 Pain new?	Is this a new requirement (compared to pre-op), if yes in indicator field?	Number	1=yes, 2=no, 3= not stated, -1=missing/NA
D1 Analgesia type	Identify which form of administration the analgesia was given, if yes in indicator field	Number	1=PCA, 2=epidural, 3= IV, 4=IM, 5=PO, -1=missing/NA
D1 Analgesia state	State the analgesia and dose given, if yes in indicator field	Text	As stated, blank if missing/NA
D1 Fragmin	Indicator field: Received fragmin	Number	1=yes, 2=no, 3= not stated, -1=missing
D1 Fragmin dose	State fragmin dose, if yes in indicator field	Number	As stated, 3= not stated, -1=missing/NA
D1 Creat	Serum creatinine level (mmol/l)	Number	As stated, -2= not done, -1=missing

D1 Wound culture	Indicator field: Was a wound culture taken?	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 wound culture results	Wound culture results, if yes in indicator field	Text	As stated, blank if missing/NA
D1 wound culture rx	State treatment given in light of wound culture results, if yes in indicator field and positive culture obtained.	Text	As stated, blank if missing/NA
D1 Pulmonary	**POMS indicator field:** Has the participant developed a new requirement for oxygen or respiratory support	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Pulmonary new?	Is this a new requirement (compared to pre-op), if yes in indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 intub and vent?	Is the participant intubated and ventilated, if yes in indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 oxygen suppl?	Identify type of supplementary oxygen received, if yes in indicator field	Number	1=cpap, 2=bipap, 3=bird, 4=mask, 5=nasal specs, 6=none, 7=AQP, -1=missing/NA
D1 Infectious	**POMS indicator field:** Received antibiotics and/or has had a temperature of >38°C in the last 24 hours	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Infectious new?	Is this a new requirement (compared to pre-op), if yes in indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Renal	**POMS indicator field:** Presence of oliguria < 500ml/24hours, increased serum creatinine (>30% from pre operative level); urinary catheter in situ for non surgical reason	Number	1=yes, 2=no, -2=creatinine not done, -1=missing
D1 renal new?	Is this a new requirement (compared to pre-op), if yes in indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Oliguria	Indicator field: Presence of oliguria < 500ml/24hours	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 oliguria new?	Is this a new requirement (compared to pre-op), if answered yes to indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 creat >30%	Increased serum creatinine (>30% from pre operative level)	Number	1=yes, 2=no, -2=not done, -1=missing
D1 urine cath	Indicator field: Urinary catheter in situ for non surgical reason	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 urine cath new?	Is this a new requirement (compared to pre-op), if yes to indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 RRT	Indicator field: Received renal replacement therapy	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 RRT state	State the type of renal replacement therapy received, if yes in indicator field	Text	As stated, blank if missing/NA
D1 nutrition support	Indicator field: Received nutritional support	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 nutrition support state	Identify the type of nutritional support received, if yes in indicator field	Number	1= NG feed, 2=TPN, 3=not stated, -1=missing/NA
D1 nutrition support new?	Is this a new requirement (compared to pre-op), if yes in indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 GI dist	Is nutritional support given due to gastrointestinal disturbance, if yes in indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 intol ent diet	**POMS indicator field:** Unable to tolerate an enteral diet for any reason	Number	1=yes, 2=no, 3=not stated, -1=missing

	including nausea, vomiting and abdominal distension		
D1 intol type ent diet	Identify the type of enteral diet intolerant of, if yes to indicator field	Number	1=oral, 2=NG feed, 3=TPN, 4=not stated, -1=missing/NA
D1 nausea	Indicator field: Unable to tolerate an enteral diet due to nausea	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 nausea new?	Is this a new symptom (compared to pre-op), if yes to indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 vomiting	Indicator code: Unable to tolerate an enteral diet due to vomiting	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 vomiting new?	Is this a new symptom (compared to pre-op), if yes in indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 abdo dist	Indicator field: Unable to tolerate an enteral diet due to abdominal distension	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 abdo dist new?	Is this a new symptom (compared to pre-op), if yes in indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 CV	**POMS indicator field**: Diagnostic tests or therapy within the last 24 hours for any of the following: 1) new MI or ischaemia, 2)hypotension (requiring fluid therapy >200ml/hr or pharmacological therapy, 3) atrial or ventricular arrhythmias, 4) cardiogenic pulmonary oedema, thrombotic event (requiring anticoagulation).	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 CV new?	Is this a new symptom (compared to pre-op), if yes in indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 new MI	Indicator field: Diagnostic tests or therapy within the last 24 hours for new MI or ischaemia,	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 MI test	State MI or ischaemia test, if yes indicator field	Text	As stated, blank if missing/NA
D1 MI diagnosis	State MI or ischaemia diagnosis, if yes in indicator field	Text	As stated, blank if missing/NA
D1 MI treated	Indicator field: Identify whether MI or ischaemia was treated, if yes in indicator field	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 MI rx	State treatment for MI or ischaemia, if yes in indicator field	Text	As stated, blank if missing/NA
D1 Hypotension	Indicator field: Diagnostic tests or therapy within the last 24 hours for hypotension (requiring fluid therapy >200ml/hr or pharmacological therapy	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Hypo new?	Is this a new symptom (compared to pre-op), if yes in indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Hypo test	State hypotension test, if yes in indicator field	Text	As stated, blank if missing/NA
D1 Hypo diagnosis	State hypotension diagnosis, if yes in indicator field	Text	As stated, blank if missing/NA
D1 Hypo treated	Indicator field: Identify whether hypotension was treated, if yes in indicator field	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Hypo Rx	State treatment for hypotension, if yes in indicator field	Text	As stated, blank if missing/NA

D1 Arrhythmias	Indicator field: Diagnostic tests or therapy within the last 24 hours for atrial or ventricular arrhythmias	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Arrhythmias new?	Is this a new symptom (compared to pre-op), if yes in indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Arrhy test	State arrhythmia test, if yes in indicator field	Text	As stated, blank if missing/NA
D1 Arrhy diagnosis	State arrhythmia diagnosis, if yes in indicator field	Text	As stated, blank if missing/NA
D1 Arrhy treated	Indicator field: Identify whether arrhythmia was treated, if yes in indicator field	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Arrhy rx	State arrhythmia treatment, if yes in indicator field	Text	As stated, blank if missing/NA
D1 Pul oed/anticoag	Indicator field: Diagnostic tests or therapy within the last 24 hours for cardiogenic pulmonary oedema, thrombotic event (requiring anticoagulation).	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Pul oed/anticoag new?	Is this a new symptom (compared to pre-op), if yes in indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Pul oed/anticoag test	State pulmonary oedema/thrombotic event test, if yes in indicator field	Text	As stated, blank if missing/NA
D1 Pul oed/anticoag diag	State pulmonary oedema/thrombotic event diagnosis, if yes in indicator field	Text	As stated, blank if missing/NA
D1 Pul oed/anticoag treated	Indicator field: Identify whether pulmonary oedema/thrombotic event was treated, if yes in indicator field	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Pul oed/anticoag Rx	State pulmonary oedema/thrombotic event treatment, if yes in indicator field	Text	As stated, blank if missing/NA
D1 Dysrhythm	Indicator field: Identify whether a dysrhythmia was present	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 paced	Iindicator field: Identify whether pacing was required (internal or external)	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Dysrhythm/underlying	State dysrhythmia and/or underlying rhythm if yes in either above indicator fields	Text	As stated, blank if missing/NA
D1 Dysrhythm treated	Indicator field: Identify if treatment received, if yes to dysrhythm indicator field	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Dysrhythm Rx	State treatment received if yes in indicator field	Text	As stated, blank if missing/NA
D1 Neuro	**POMS indicator field:** New focal neurological deficit, confusion, delirium or coma within the last 24 hrs?	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Neuro new?	Is this a new symptom (compared to pre-op), if yes in indicator field?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Neuro state	Identify type of neurological deficit, if yes in indicator field	Number	1=confusion, 2=delirium, 3=focal deficit, 4=coma, 5=agitated/violent, -1=missing/NA

D1 Neuro comments	State additional comments relating to neurological deficit, if yes in indicator field	Text	As stated, blank if missing/NA
D1 Wound compl	**POMS indicator field:** Wound complication present: Wound dehiscence requiring surgical exploration or drainage of pus from the operation wound with or without isolation of organisms	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Wound surg	Wound dehiscence requiring surgical exploration with or without isolation of organisms	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Wound drain	Wound dehiscence requiring drainage of pus from the operation wound with or without isolation of organisms	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Haematol	**POMS indicator field**: Requirement for any of the following within the last 24 hrs: packed erythrocytes, platelets, fresh-frozen plasma, or cryoprecipitate	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Assisted ambulation	Requirement for any assistance with ambulation?	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Assisted ambul new?	Is this a new symptom (compared to pre-op)?	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Assisted ambul type	State the type of ambulation assistance required, if yes to above.	Number	1=wheelchair, 2=unaided, 3= crutches, 4=zimmer, 5=not stated, 6=walking sticks, 7=bedbound, 8=with assistance, 9=attached to equip, -1=missing/NA
D1 In chair	Identify whether the participant sat in the chair day 1 after surgery	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 DVT diag or test	Indicator field: Diagnostic tests or therapy within the last 24 hours for a deep vein thrombosis	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 DVT rx	Identify whether any treatment was administered for deep vein thrombosis, if yes in indicator field	Number	1=yes, 2=no, 3=not stated, -1=missing/NA
D1 Blood sugar control	Received treatment for blood sugar control (additional to regular requirements)	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Blood sugar control comment	State the type and dose of treatment, if yes to above	Text	As stated, blank if missing/NA
D1 IV Frusemide given	Received IV Frusemide	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 IV frusemide comment	State the type and dose of treatment, if yes to above	Text	As stated, blank if missing/NA
D1 Hypertension Rx	Received treatment for hypertension (additional to regular requirements)	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Hypertension Rx comments	State the type and dose of treatment, if yes to above	Text	As stated, blank if missing/NA

D1 Chest drains	Chest drains in situ	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Chest drains comments	State any additional information, if yes to above	Text	As stated, blank if missing/NA
D1 Inotrope support	Received inotrope support	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Inotrope comments	State the type and dose of treatment, if yes to above	Text	As stated, blank if missing/NA
D1 Hypotension (fluid)	Received treatment for hypotension (fluid <200mls/hr or medications omitted)	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Hypotension comments	State the type and dose of treatment, if yes to above	Text	As stated, blank if missing/NA
D1 Pleural eff	Drains insitu for pleural effusion	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Pleural eff comments	State details on drain site, drainage, time of removal	Text	As stated, blank if missing/NA
D1 INR	Received treatment for untherapeutic INR	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 INR comments	State the type and dose of treatment and INR level, if yes to above	Text	As stated, blank if missing/NA
D1 Periph oed	Presence of peripheral oedema	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Periph oed comments	State the site and type and dose of treatment (if any), if yes to above	Text	As stated, blank if missing/NA
D1 Blurred vision	Presence of blurred vision	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Blurred vision comments	State any details relating to above	Text	As stated, blank if missing/NA
D1 Incr wt	Received treatment for increased weight	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Incr wt comments	State the type and dose of treatment, if yes to above	Text	As stated, blank if missing/NA
D1 Pneumothorax	Presence and/or treatment of pneumothorax	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Pneumothorax comments	State details of pneumothorax and treatment, if yes to above.	Text	As stated, blank if missing/NA
D1 Other morbidity 1 (1-7)	Indicator field for whether any other morbidities experienced not covered within these fields	Number	1=yes, 2=no, 3=not stated, -1=missing
D1 Other comments (1-7)	State any other morbidity	Text	As stated, blank if NA. If more than one separated by a comma.

For post-operative days 5, 8 and 15 the following fields are also collected in relation to delayed discharge at the end of the C-POMS data table.

Field name/variable	Definition	Type of field	Code in database
D5 POMS=0	**Indicator field:** All POMS indicator fields entered as no (to define other reasons for delayed discharge)	Number	1=yes, 2=no, 3= not stated, -1=missing/NA
D5 Social reasons	Delayed discharge due to social reasons	Number	1=yes, 2=no, 3= not stated, -1=missing/NA
D5 Equipment	Delayed discharge due to equipment needed at home	Number	1=yes, 2=no, 3= not stated, -1=missing/NA
D5 Mobility	Delayed discharge due to mobility (ongoing physiotherapy or occupational	Number	1=yes, 2=no, 3= not stated, -1=missing/NA

	therapy needs)		
D5 Institution	Delayed discharge due to institutional failure (transport not booked, no out-patient appointment or follow-up arranged)	Number	1=yes, 2=no, 3= not stated, -1=missing/NA
D5 Delayed dc	Delayed discharge due to lack of rehab or other bed	Number	1=yes, 2=no, 3= not stated, -1=missing/NA
D5 DC today	Discharged today	Number	1=yes, 2=no, 3= not stated, -1=missing/NA
D5 Other medical	Delayed discharge due to any other medical reason (not covered in C-POMS criteria)	Number	1=yes, 2=no, 3= not stated, -1=missing/NA
D5 Other medical state	State medical reason for delayed discharge	Text	As stated, blank if missing/NA
D5 Other comments	State any other comments relating to delayed discharge	Text	As stated, blank if NA. If more than one separated by a comma.

Outcome data table

Field name/Variable	Definition	Type of field	Code in database
Study number	Unique identifier	Text	As stated
Hosp No	Hospital number	Text	As stated
DOAdmICU	Date of admission to ICU	Date	As stated, 01/01/2001 if missing
DODcICU	Date of discharge from ICU	Date	As stated, 01/01/2001 if missing
Dcicu post-op day	Post-operative day discharged from ICU	Number	As stated, -1=missing
Dest from ICU	Indicator code: Ward destination following discharge from ICU	Number	1=ITU, 2=HDU, 3=ACW, 4=3rd floor monitoring bay, 5=3rd floor, 6=4th floor, 7=other
Dest ICU other	State other destination if 7in indicator code	Text	As stated, blank if missing/NA
DODCphysio	Post-operative day of discharge from physiotherapist	Number	As stated, -2=not known, -1=missing
DOHospDC	Date of discharge from Heart Hospital	Date	As stated, 01/01/2001 if missing
DCPost-op day	Post-operative day on day of discharge	Number	As stated, -1=missing/NA
Dcday of wk	Day of the week discharged on	Text	As stated, NA if not applicable
DC destination	Indicator field: Destination of discharge (home, other NHS hospital (state NHS gen (state hospital), convalescence, RIP if died)	Text	As stated, blank if missing
DODC Tr Hosp	Date of discharge from transferred to hospital, if transfer indicated in indicator field	Date	As stated, 01/01/2001 if missing/NA
DOD Needs indicator field	Date of death Needs indicator field	Date	As stated, 01/01/2001 if missing/NA Needs indicator field

In-hosp death	Indicator field: Identify whether participant died during course of overall admission for surgery	Number	1=yes, 2=no, -1=missing/NA
Cause of death	State course of death as documented in medical notes, if yes to indicator field	Text	As stated, blank if missing/NA
DC services	Indicator field: Required services were required on discharge	Number	1=yes, 2=no, 3=not stated, -1=missing
DC DN	Required district nurse on discharge, if yes in indicator field	Number	1=yes, 2=no, 3=not stated, -1=missing
DC SS	Required social services on discharge, if yes in indicator field	Number	1=yes, 2=no, 3=not stated, -1=missing
DC services other	State if required other services on discharge	Text	As stated, blank if missing/NA
DC services comments	State any additional comments regarding discharge services	Text	As stated, blank if no other comments
Outcome comments	State any additional outcome comments	Text	As stated, blank if NA. If more than one separated by a comma.
Total post-op LOS	Total post-operative length of stay. Includes length of stay in local hospital if transferred from Heart Hospital		

SCTS data table

Magovern variables highlighted as such where they are included in the dataset purely for the Magovern model.

Variables from SCTS database are collected according to SCTS definitions

Field name/Variable	Definition	Type of field	Code in database
Study number	Unique identifier	Text	As stated
Hosp no	Hospital number	Text	As stated
Diabetes (rx)	Identified the type of management, if any, for diabetes	Text	As stated, blank if missing
Diabetes	Recode of diabetes management	Number	1=yes (all types of treatment), 2=no (non-diabetic), -1=not stated/missing
Smoking	Cigarette smoking history. Never: has never smoked cigarettes; Ex: has smoked one or more cigarettes per day in the past but not within the last month; Current: regularly smokes one or more cigarette per day or has smoked in the last month	Text	As stated, blank if missing
Smoking code	Recode of smoking	Number	1=current, 2=ex, 3=never, -1=not stated/missing
History of pulmonary disease	Pulmonary medical history. No: no history of pulmonary disease; COAD/Emphysema: participant requires medication for chronic pulmonary	Text	As stated, blank if missing

	disease or FEV1 less that 75% predicted value. Venous pO_2 <600mgHg, pCO_2 >50mmHg; Asthma: intermittent or allergic reversible airway disease treated with bronchodilators or steroids		
Hx Pul Dis code	Recode of pulmonary	Number	1=yes, 2=no, -1=not stated/missing
Renal (e/p)	Renal medical history. No: No history of renal disease and creatinine <200umol/l on admission; Functioning transplant: functioning renal transplant irrespective of creatinine; Creatinine >200umol/l: creatinine >200umol/l at the time of surgery; Acute renal failure: acute renal failure within 6 weeks of surgery necessitating any form of dialysis up to the time of surgery; Chronic renal failure: chronic renal failure on regular dialysis	Text	As stated, blank is missing
Renal	Recode of renal	Number	1=yes, 2=no, -1=not stated/missing
Neurological dysfunction (e/p)	Indicator code: History of neurological disease affecting ambulation or day-to-day functioning.	Text	As stated, blank if missing
Neuro hx	Recode of neurological dysfunction	Number	1=yes, 2=no, -1=not stated/missing
History of neurological disease	CVA with full recovery, No history of neurological disease, TIA or RIND.	Text	As stated, blank if missing
GI tract	Gastrointestinal medical history. No: no history of GI problems; Peptic ulcer: previous surgery, medical treatment or current treatment for known peptic ulceration.	Text	As stated, blank if missing
GI Hx	Recode of GI tract	Number	1=yes, 2=no, -1=not stated/missing
Hypercholesteraemia	A history of serum cholesterol of greater than 5.0mmol or lower if on treatment	Number	1=yes, 2=no, -1=not stated/missing
Family history of IHD	Does the patient have a family history of ischaemic heart disease?	Number	1=yes, 2=no, -1=not stated/missing
Hypertension	Identifies if the patient has hypertension defined as receiving treatment or dietary advice or if blood pressure has been recorded greater than 140/90mmHg on two occasions, or lower if on medication.	Number	1=yes, 2=no, -1=not stated/missing
Extracardiac arteriopathy	Indicates if the patient has a history of peripheral vascular disease (PVD). Defined as history or evidence of aneurysm or occlusive peripheral vascular disease or carotid disease, including aortic aneurysm, previous aorto-iliac or peripheral vascular surgery, or reduced or absent peripheral pulses and/or angiographic stenosis of more than 50%. Includes femoral or carotid bruits as evidence of PVD.	Number	1=yes, 2=no, -1=not stated/missing

Parsonnet score (PATS)	Total parsonnet score	Number	1=yes, 2=no, -1=not stated/missing
EuroSCORE (additive)	Total additive EuroSCORE	Number	1=yes, 2=no, -1=not stated/missing
Operative priority	Operative status. Elective: routine admission from the waiting list. The procedure can be deferred without risk; Urgent: patients who have not been scheduled for routine admission from the waiting list but who require surgery on the current admission for medical reasons. They cannot be sent home without surgery; Emergency: unscheduled patients with ongoing refractory cardiac compromise. There should be no delay in surgical intervention irrespective of the time of day; Salvage: patients requiring CPR en-route to the operating theatre or prior to anaesthetic induction.	Number	1=Elective, 2=urgent, 3=emergency, 4=salvage, -1=missing
Ejection fraction category	Left ventricular function (EF). Good: EF of 50%; Fair: EF 30-49%; Poor: EF <30%	Text	As stated, blank if missing
EF code	Recode of ejection fraction category	Number	1=good, 2=fair, 3= poor, -1=missing
PPM	The patient has any type of pacemaker (temporary or permanent)	Number	1=yes, 2=no, -1=not stated/missing
CCSC	Canadian Cardiovascular Society score for angina. CCS Class I - ordinary physical activity such as walking, climbing stairs does not cause angina. Angina occurs with strenuous, rapid or prolonged exertion at work or recreation. CCS Class II - Slight limitation of ordinary activity. Angina occurs on walking or climbing stairs rapidly, walking uphill, walking or stair-climbing after meals, or in cold, or in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions. CCS Class III - Marked limitations of ordinary physical activity. Angina occurs on walking one to two blocks on the level and climbing one flight of stairs in normal conditions and at a normal pace. CCS Class IV - Inability to carry on any physical activity without discomfort - anginal symptoms may be present at rest.	Number	0=none, 1= Class 1, 2=Class 2, 3=Class 3, 4=Class 4, -1=not stated/missing
NYHA	New York Heart Association dyspnoea status (see pre-op table for definitions)	Number	1=Class 1, 2= Class 2, 3= Class3, 4=Class 4, -1=not stated/missing
Extent of coronary disease	The number of major vessels (LAD, Cx, RCA system) with >50%	Text	As stated, blank if missing

	narrowing in any angiographic view (excludes left main stem)		
No Dis Vessels	Recode of extent of coronary disease	Number	0=normal, 1=single vessel disease, 2=double vessel disease, 3=triple vessel disease, -1=not stated/missing
LMS>50%	Left main stem stenosis of >50% diameter is present observed in any angiographic view	Number	1=yes, 2=no, -1=not stated/missing
Height (cm)	Participant height (cms)	Number	As stated, -1=not stated/missing
Weight (kg)	Participant weight (kg)	Number	As stated, -1=not stated/missing
BMI	**Magovern indicator field: kg/m^2.** Body mass index calculated from height and weight.	Number	As stated, -1=not stated/missing
CCF	**Magovern indicator field:** Documented history of or treatment for heart failure and/or clinical evidence of heart failure (S3 gallop, jugular venous distention, pleural effusion, pulmonary oedema, peripheral oedema or radiographic evidence of interstitial oedema)	Number	1=yes (current), 2=no (never), 3=In past, -1=not stated/missing
Cardiogenic shock	Patient in shock prior to operation. BP<100mmHg, pulse >100bpm, patient cool, clammy, or requiring inotropes, intra-aortic balloon pump or CPS to support circulation.	Number	1=yes, 2=no, -1=not stated/missing
Heart rhythm	Pre-op arrhythmia within two weeks prior to surgery. Normal: patient in sinus rhythm; Atrial fibrillation/flutter: Demonstrable, chronic or paroxysmal atrial fibrillation or flutter; Complete Heart Block: no association of p waves to QRS complexes or pacing system in place; VF/VT: sustained VF/VT requiring cardioversion or IV medication (i.e. amiodarone infusion). Recoded from SCTS text field.	Number	1=normal sr, 2=atrial arrhythmia, 3=ventricular arrhythmia, 4=CHB/pacing, -1=not stated/missing
No of Prev MI's	Number of previous Q-wave myocardial infarctions	Number	0=none, 1=one, 2=two or more, -1=not stated/missing
Previous PCI	Identifies whether the patient has undergone percutaneous coronary intervention in any hospital on this hospital admission	Number	1=PCI >24hrs before op, previous admission, 2=no, 3=failed, -1=not stated/missing
Cardioplegia method	Method of cardioplegia used stating solution (blood/crystalloid), temperature (cold/warm), infusion mode (antegrade, retrograde), timing (intermittent/continuous)	Text	As stated, blank if missing 1=antegrade, 2=antegrade, intermittent, warm blood, 3=antegrade, intermittent, cold blood, 4= antegrade cold blood, 5= antegrade, retrograde,

			intermittent cold blood, 6=antegrade, intermittent blood, -1=missing
Circulatory arrest time	Circulatory arrest time (mins)	Number	As stated, -1=not stated/missing
XC time	Cumulative aortic cross clamp time (mins)	Number	As stated, -1=not stated/missing
CPB?	Cardiopulmonary bypass used for part or all of the procedure	Number	1=yes, 2=no, -1=not stated/missing
CPB time	Cumulative cardiopulmonary bypass time (mins)	Number	As stated, -1=not stated/missing
Extubation time	Time of extubation	Text	Date and time as stated, blank if missing
Hours ventilated	Total number of whole hours ventilated, if less than 24 hours	Number	As stated, blank if missing
Days ventilated	Total number of whole days ventilated, if more than 24 hours	Number	As stated, blank if missing
Rtn theatre?	Indicator code: Did the patient have to return to theatre	Number	1=yes, 2=no, -1=not stated/missing
Rtn theatre reason	If yes above, the reason for return to theatre	Text	As stated, blank if missing
Stay on ICU (nights)	Total length of stay on the intensive care unit, whole number of nights	Number	As stated, -1=not stated/missing
Readmitted ICU	Was the patient readmitted to ICU	Number	1=yes, 2=no, -1=not stated/missing
Post-op stay (days)	Total length of post-operative stay in the Heart Hospital, whole number of days	Number	As stated, -1=not stated/missing
Total hospital stay (days)	Total length of hospital stay from admission to discharge	Number	As stated, -1=not stated/missing
Patient status	Indicator field, Patient status at discharge (alive or dead)	Text	As stated, blank if missing
Cause of death	If indicated dead above, the cause of death as stated in the medical notes.	Text	As stated, blank if missing/NA

New variables

Field name/Variable	Definition	Type of field	Code in database	Details
Pulmonary	**C-POMS indicator field:** New requirement for oxygen or respiratory support (including nebuliser therapy, or request for chest physiotherapy on or after D5); pleural effusion requiring drainage	Number	1=yes, 0=no, -1=missing	New C-POMS definitions
SupplO2	New requirement for oxygen or respiratory support (including nebuliser therapy, or request for chest physiotherapy on or after D5)	Number	1=yes, 2=no, 3= not stated, -1=missing	
Nebs	New requirement for nebuliser therapy	Number	1=yes, 2=no, 3= not stated, -1=missing	
Chest physio	New request for chest physiotherapy on or after D5	Number	1=yes, 2=no, 3= not stated, -1=missing	

Pleuraleff	pleural effusion requiring drainage	Number	1=yes, 2=no, 3= not stated, -1=missing
Infectious	**C-POMS indicator field:** Currently on antibiotics and/or has had a temperature of >38°C in the last 24 hours and/or has a white cell count/CRP level requiring in-hospital review or treatment	Number	1=yes, 0=no, -1=missing
Temp38	a temperature of >38°C in the last 24 hours	Number	1=yes, 2=no, 3= not stated, -1=missing
WCCorCRP	white cell count/CRP level requiring in-hospital review or treatment	Number	1=yes, 2=no, 3= not stated, -1=missing
Renal	**C-POMS indicator field:** Presence of decreased urine output requiring intervention (including IV frusemide), increased serum creatinine (>30% from pre operative level); urinary catheter in situ; new urinary incontinence; serum potassium abnormalities* requiring treatment	Number	1=yes, 0=no, -1=missing, -2=creatinine not done and no other renal morbidity present
DecrUO	Presence of decreased urine output requiring intervention (including IV frusemide)	Number	1=yes, 2=no, 3= not stated, -1=missing
Urineincontinence	New urinary incontinence	Number	1=yes, 2=no, 3= not stated, -1=missing
Kabnorm	Serum potassium abnormalities* requiring treatment	Number	1=yes, 2=no, 3= not stated, -1=missing
GI	**C-POMS indicator field:** Unable to tolerate an enteral diet for any reason including nausea, vomiting and abdominal distension; the presence of a nasogastric tube; diagnosis of a gastrointestinal bleed; presence of diarrhoea	Number	1=yes, 0=no, -1=missing
NGtube	The presence of a nasogastric tube	Number	1=yes, 2=no, 3= not stated, -1=missing
GIbleed	Diagnosis of a gastrointestinal bleed	Number	1=yes, 2=no, 3= not stated, -1=missing
Diarrhoea	Presence of diarrhoea	Number	1=yes, 2=no, 3= not stated, -1=missing
CV	**C-POMS indicator field:** The use of inotropic therapy for any cardiovascular cause; the presence of pacing wires (on or after D5) and/or requiring temporary or new permanent pacing**; diagnostic tests or therapy within the last 24 hours for any of the following: 1)	Number	1=yes, 0=no, -1=missing

	new MI or ischaemia, 2) hypotension (requiring fluid therapy, pharmacological therapy or omission of pharmacological therapy 3) atrial or ventricular arrhythmias, 4) cardiogenic pulmonary oedema, thrombotic event (requiring anticoagulation), 5) hypertension (pharmacological therapy or omission of pharmacological therapy)		
Inotropes	The use of inotropic therapy for any cardiovascular cause	Number	1=yes, 2=no, 3= not stated, -1=missing
Pacingwires	The presence of pacing wires (on or after D5)	Number	1=yes, 2=no, 3= not stated, -1=missing
Hypotension	hypotension (requiring fluid therapy, pharmacological therapy or omission of pharmacological therapy	Number	1=yes, 2=no, 3= not stated, -1=missing
Wound	**C-POMS indicator field:** Wound dehiscence requiring surgical exploration or drainage of pus from the operation wound with or without isolation of organisms; presence of chest drains; wound pain significant enough to require continuing or escalating analgesic intervention	Number	1=yes, 0=no, -1=missing
Woundpain	Wound pain significant enough to require continuing or escalating analgesic intervention	Number	1=yes, 2=no, 3= not stated, -1=missing
Neuro	**C-POMS indicator field**: New neurological deficit (including confusion, delirium, coma, lack of coordination, drowsy/slow to wake, poor swallow, blurred vision, sedated, changing loss of consciousness)	Number	1=yes, 2=no, 3= not stated, -1=missing
Confusion	The presence of confusion	Number	1=yes, 2=no, 3= not stated, -1=missing
Delirium	The presence of delirium	Number	1=yes, 2=no, 3= not stated, -1=missing
Focal deficit	The presence of focal deficit	Number	1=yes, 2=no, 3= not stated, -1=missing
Coma	The presence of coma	Number	1=yes, 2=no, 3= not stated, -1=missing
Agitated	The presence of agitation	Number	1=yes, 2=no, 3= not stated, -1=missing
Lackofcoord	The presence of lack of coordination	Number	1=yes, 2=no, 3= not stated, -1=missing

Drowsy	The presence of drowsiness	Number	1=yes, 2=no, 3= not stated, -1=missing
Poorswallow	The presence of poor swallow	Number	1=yes, 2=no, 3= not stated, -1=missing
Blurredvision	The presence of blurred vision	Number	1=yes, 2=no, 3= not stated, -1=missing
Sedated	The patient has received sedation	Number	1=yes, 2=no, 3= not stated, -1=missing
ChangingLOC	The presence of changing loss of consciousness	Number	1=yes, 2=no, 3= not stated, -1=missing
Haematol	**C-POMS indicator field:** Untherapeutic INR requiring pharmacological therapy or omission of pharmacological therapy; Requirement for any of the following within the last 24 hrs: packed erythrocytes, platelets, fresh-frozen plasma, or cryoprecipitate	Number	1=yes, 0=no, -1=missing
Electrolyte	**C-POMS indicator field:** Electrolyte (including sodium, urea, phosphate) imbalance requiring oral or intravenous intervention (NB not including potassium as included in Renal category)	Number	1=yes, 2=no, 3= not stated, -1=missing
Sodium	Sodium imbalance requiring oral or intravenous intervention	Number	1=yes, 2=no, 3= not stated, -1=missing
Urea	Urea imbalance requiring oral or intravenous intervention	Number	1=yes, 2=no, 3= not stated, -1=missing
Phosphate	Phosphate imbalance requiring oral or intravenous intervention	Number	1=yes, 2=no, 3= not stated, -1=missing
Review	**C-POMS indicator field**: Remaining in hospital for further review, investigation and/or procedure	Number	1=yes, 2=no, 3= not stated, -1=missing
Further review	Remaining in hopital for further review	Number	1=yes, 2=no, 3= not stated, -1=missing
Investigation/procedure	Remaining in hospital for an investigation or procedure	Number	1=yes, 2=no, 3= not stated, -1=missing
All these new variables will be prefixed with D1, D3, D5, D8 and D15 for the			

corresponding post-operative day				
CPOMS0 *All POMS indicator fields became prefixed with D1POMS, D3POMS, D5POMS, D8POMS and D15POMS for the corresponding post-operative day*	**Indicator field:** All C-POMS indicator fields entered as no (to define other reasons for delayed discharge)	Number		
D3Score	C-POMS summary score on postoperative D3 of all C-POMS domains whereby each domain is coded 1 for present and 0 for absent	Number	As stated (between 0-13), -1=missing	C-POMS summary score also calculated for D5, D8 and D15
D3Renal2	Recode of C-POMS Renal domain for post-operative D3: whereby -2=creatinine not done and no other renal morbidity present recoded to 'no morbidity'	Number	1=yes, 0=no, -1=missing	New C-POMS Renal definition also recoded for D5, D8 and D15
D3Score2	Revised C-POMS summary score on postoperative D3 following recoding of the Renal domain	Number	As stated (between 0-13), -1=missing	Version 2 of the C-POMS summary score also calculated for D5, D8 and D15
D3LOS	Subsequent post-operative length of stay (in days) from post-operative D3		As stated, -1=missing	Also calculated for D5, D8 and D15
D3noCPOMS	Where no C-POMS domains are present at all.		1=no CPOMS, 0=C-POMS present	Also calculated for D5, D8 and D15
Euroscoregrps	Euroscore categorised into groups whereby a score of 0-2 is a low risk, 3-5 is a medium risk and 6+ is a high risk.		1= low risk, 2=medium risk, 3=high risk	
Euroscore2grps	EuroSCORE categorised into high (5-14) and low (0-4) risk groups	Number	1=high risk, 0=low risk, -1=missing	
POSSUM2grps	POSSUM score categorised into high (19-40) and low (12-18) risk groups	Number	1=high risk, 0=low risk, -1=missing	

MagCardiogenicscore	Magovern score for cardiogenic shock: systolic blood pressure <90mmHg or mean systemic blood pressure <50mmHg and a cardiac index <2.0 L/min per m^2 and evidence of peripheral hypoperfusion.	Number	If present, score 7
MagOPpriorityscore	Magovern score for operative priority: a) Emergency: operation performed immediately to prevent death. The patient is having an acute event that is refractory to all other appropriate forms of therapy and is haemodynamically unstable, b) Urgent: operation performed to reverse or stabilise a deteriorating clinical condition. These patients are already receiving support with an IABP, inotropic medications, nitroglycerine or heparin, or a combination of these. These operations are done 24 to 48hrs from the onset of the acute event precipitating the symptoms.	Number	Emergency: If present, score 5 Urgent: If present, score 4
MagCathClosurescore	Magovern score for catheter coronary closure: Iatrogenic coronary occlusion or dissection secondary to a diagnostic catheterisation or angioplasty, or both, that requires heart surgery within 24hrs.	Number	If present, score 4
MagEFscore	Magovern score for ejection fraction: LVEF <30%	Number	If present, score 4
MagAgescore	Magovern score for age	Number	≥75yrs score 3, 70-74yrs score 2, 65-69yrs score 1
MagCardiomegalyscore	Magovern score for cardiomegaly: Enlarged heart as determined by chest radiography or echocardiography	Number	If present, score 2
MagPVDscore	Magovern score for peripheral vascular disease: Claudication, ischaemic rest pain, prior peripheral vascular surgery, absent lower extremity pulses, inability to insert an IABP from the groin and/or a non-invasive vascular test showing >50% obstruction of the lower extremity vasculature.	Number	If present, score 2
MagCreatininescore	Magovern score for renal dysfunction: a) renal insufficiency: History of chronic renal disease or serum creatinine ≥1.9mg/dl, or both, b) renal dysfunction: serum creatinine 1.5-1.9mg/dl.	Number	a) present, score2 b) present, score1
MagDiabetesscore	Magovern score for diabetes: a) insulin-dependent diabetes mellitus: Diabetes that has been treated with insulin before the surgical procedure, b) non-insulin-dependent diabetes: Diabetes that has been treated with oral hypoglycaemic agents before the surgical procedure.	Number	a) present, score 2 b) present, score 1
MagBMIscore	Magovern score for body mass index: Low body mass index ≤24kg/m^2.	Number	If present, score 1
MagGenderscore	Magovern score for gender	Number	Female score 1

MagReopscore	Magovern score for re-operation: Any prior cardiac surgery	Number	If present, score 1	
MagAnaemiascore	Magovern score for anaemia: Haemoglobin ≤12.5g/dl and ≤11g/dl for males and females, respectively, or the need for pre-operative blood transfusion.	Number	If present, score 1	
MagCOPDscore	Magovern score for chronic obstructive pulmonary disease: Pulmonary disease that results in functional disability or requires bronchodilator therapy and/or results in abnormal spirometry, as defined by a forced expiratory volume in 1 second, <75% of that predicted.	Number	If present, score 1	
MagCVDscore	Magovern score for cerebrovascular disease: History of TIA, embolic stroke or non-embolic stroke, and/or angiographic evidence of internal carotid stenosis >50%.	Number	If present, score 1	
MagAlbuminscore	Magovern score for albumin: Low serum albumin <4.0mg/dl	Number	If present, score 1	
MagUreaN2score	Magovern score for blood urea nitrogen: Blood urea nitrogen >29mg/dl.	Number	If present, score 1	
MagCCFscore	Magovern score for congestive cardiac failure: Documented history of or treatment for heart failure and/or clinical evidence of heart failure, as defined by an S_3 gallop, jugular venous distention, pleural effusion, pulmonary oedema, peripheral oedema or radiographic evidence of interstitial oedema (flash pulmonary oedema excluded).	Number	If present, score 1	
MagAtrialarrhyscore	Magovern score for atrial arrhythmia: Prior admission or out-patient treatment for atrial fibrillation, flutter or tachycardia.	Number	If present, score 1	
Magovernscore	Magovern total score (maximum 37)	Number	As stated, -1=missing	
Magovernscore2	Magovern score divided into high (6-18 (max score in study)) and low (0-5) risk groups	Number	1=high risk, 0=low risk, -1=missing	
NoPOMSD3	Where no POMS domains are present at all.		1=no POMS, 0=POMS present	Also calculated for D5, D8 and D15
D15POMSscore	POMS summary score on postoperative D15 of all POMS domains whereby each domain is coded 1 for present and 0 for absent	Number	As stated (between 0-9), -1=missing	POMS summary score also calculated for D5, D8 and D15

Normal clinical ranges at study site

	Units	Normal range
Albumin	g/L	34-50
Creatinine	umol/L	49-92
Haemaglobin	g/dl	11.5-15.5
Internationalised Normal Ratio (INR)	NA	1.0-2.0
Potassium	mmol/l	3.5-5.1
Sodium	mmol/l	135-145
Urea	mmol/l	1.7-8.3
White cell count	$X10^9$/L	3.0-10.0

MAP: 70-100mmHg

CVP 2-6mmHg

Arterial Blood gas values

pH	7.35-7.45
pCO2	4.7-5.9kPa
pO2	11-13 kPa
cBase	+3 - -3 mmolL
HCO3	21-28 mmol/L
Hb	11.5-15.5 g/dl
K+	3.5-5.1 mmol/L
Chloride	98-107 mmol/L
Na+	135-145 mmol/L
Glu	5-7 mmol/L
Lactacte	0.2-0.8 mmol/L

Venous Blood Gas Values

pH	7.35-7.45
pCO2	5.6-6.7 KPa
pO2	5.0-5.6 KPa

others as for ABG above

Venous blood

Urea	1.7-8.3 mmol/L
Potassium	3.5-5.1 mmol/L
Sodium	135-145 mmol/L
Creatinine	49-92 umol/L (Female); 66-112 umol/L (Male)
Albumin	34-50 g/L

Haemoglobin	11.5-15.5 g/dl (Female); 13.0-17.0 g/dl (Male)
White cell count	3.0-10.0 $x10^9$/L

Haemodynamic variables

SBP	<140 mmHg (pre-surgery), <120mmHg (post surgery)
DBP	<85 mmHg (pre-surgery), <70 mmHg (post surgery)
HR	60-100 bpm
Respiratory rate	12-20 bpm
SaO2	96-100%
CVP	
MAP	80-100
Actual body temperature	36.5-37.2 ^oC

Appendix 3: Additional morbidities not captured within POMS in the pilot study.

Morbidity	All patients (n=100)	Frequency at post-op day 1 (n=100)	Frequency at post-op day 3 (n=100)	Frequency at post-op day 5 (n=95)	Frequency at post-op day 8 (n=33)	Frequency at post-op day 15 (n=10)
Blood sugar control (actrapid infusion/uncontrolled diabetes)	97	88	26	11	4	3
Potassium supplements	83	73	22	13	3	1
IV Frusemide (stat/infusion)	41	36	6	5	2	1
Magnesium supplements	34	27	9	2	0	0
Salbutamol or atrovent nebs	29	18	15	7	3	1
Hypertension	27	19	10	7	0	0
Chest drains remain insitu	17	17	1	0	1	0
Inotropic support	17	16	3	0	0	0
Hypotension (fluid/omit medication/drink)	15	10	9	3	0	0
*Pleural effusion	15	1	7	10	0	0
LLL collapse	13	11	0	1	0	0
Constipation	11	0	5	6	2	0
Untherapeutic INR	9	0	1	6	5	1
Diarrhoea	8	0	3	3	2	0
Low Hb (ferrous sulphate)	7	0	2	4	2	1
Peripheral oedema	6	1	1	2	2	2
Blurred vision/visual disturbances (not delirium)	5	0	3	1	1	0
Increased weight (medical Rx)	5	0	2	4	0	0
Pneumothorax	5	4	2	1	0	0
Sputum spec/productive cough	5	3	3	2	0	0
Miscellaneous – changes in medication ?reason	4	0	1	4	0	0
NG tube free drainage	4	4	1	0	1	0
NBM for procedure	4	1	0	1	2	0
Propofol infusion	4	3	1	0	0	0
ATN	3	0	2	0	1	0
Fall	3	0	2	1	0	0
Fluid therapy (clinically dry)	3	1	1	1	0	0
MRSA +ve/eradication	3	3	3	3	1	1
Poor nutrition	3	0	2	0	2	1
Urinary	3	0	2	1	1	0

dribbling/incontinence/retention						
Reintubated	3	2	1	0	2	0
Surgical emphysema	3	2	2	1	1	0
Cellulitis	2	0	1	1	1	0
Fluid overload	2	2	0	0	0	0
Increased wound pain	2	0	1	1	0	0
Low urine output (filling)	2	1	0	0	0	0
Oral thrush	2	0	1	1	0	0
Paracetamol for pyrexia (low)	2	0	1	1	0	0
Slow coordination	2	1	1	0	0	0
Adrenaline infusion	1	0	1	0	0	0
Anxiety attack	1	0	1	0	0	0
Awaiting ICD insertion	1	0	0	0	1	0
Behaviour out of character	1	0	0	1	0	0
Blood cultures (+ve)	1	1	0	0	0	0
Calcium resonin for resistant hyperkalaemia	1	0	0	0	1	0
Cerebral irritation	1	1	0	1	0	0
Chest pain	1	1	0	0	0	0
Cramps	1	0	1	0	0	0
Depression	1	0	1	0	0	0
Femoral line insitu	1	0	1	1	1	0
Fluid restriction	1	1	1	0	0	0
GI bleed	1	0	0	0	0	1
Increased platelets	1	0	0	1	0	0
Ischaemic injury to bowel	1	0	0	0	1	0
Left arm weakness	1	1	0	0	0	0
Low CVP (fluid)	1	1	0	0	0	0
Mild cognitive impairment	1	0	0	0	1	0
NaCl supplements	1	0	0	1	0	0
Paracetamol IV	1	1	0	0	0	0
Pericardial effusion	1	0	0	1	0	0
Pericarditis	1	1	0	0	0	0
Phosphate infusion	1	0	1	0	0	0
Phrenic nerve palsy	1	0	0	0	1	0
Polyuric	1	0	1	0	0	0
Poor respiratory function	1	0	1	0	0	0
Poor swallowing	1	1	0	0	0	0
PPM insertion	1	0	0	0	0	1
Previous diabetic ulcers oedematous	1	0	0	1	0	0
Rash	1	0	1	0	0	0
Sedation and insertion of vascath	1	0	1	0	0	0
Sore throat (simple linctus)	1	1	1	0	0	0
Tremor	1	0	0	1	0	0

UTI	1	0	0	1	0	0

Appendix 4: Pre-operative baseline and immediate post-operative characteristics

Pre-operative baseline characteristics (n=450). Values are n(%) or mean, range and standard deviation (SD) as appropriate.

	Frequency/mean	Range	SD
Medical history			
Non-cardiac history			
Cerebrovascular disease	32 (7.1)		
- CVA	17 (3.8)		
COPD	56 (12.4)		
Liver disease	1 (0.2)		
GI history	51 (11.3)		
- Bleeding	18 (4.0)		
Renal	12 (2.7)		
- Dialysis	7 (1.6)		
Hypothyroidism	21 (4.7)		
Varicose veins	65 (14.4)		
Immunosuppressants	1 (0.2)		
Cardiac history			
History of previous MI	149 (33.1)		
Number of previous MIs – 1	119 (79.9)		
- 2	30 (20.1)		
Previous PCI	36 (8.0)		
Re-operation	19 (4.2)		
Number of previous operations -1	16 (3.6)		
-2	3 (0.7)		
Congestive heart failure	102 (22.7)		
Cardiogenic shock (current)	1 (0.2)		
Permanent pacemaker	8 (1.8)		
Atrial arrhythmia (current)	43 (9.6)		
Symptoms			
NYHA Class -I	116 (25.8)		
- II	207 (46.0)		
- III	102 (22.7)		
- IV	23 (5.1)		
CCSC – 0	86 (19.1)		

- I	93 (20.7)
- II	114 (25.3)
- III	85 (18.9)
- IV	44 (9.8)
Cardiac risk factors	
Smoking – Current	49 (10.9)
- Ex	250 (55.6)
- Never	151 (33.6)
Hypertension	306 (68.0)
Hypercholesteraemia	347 (77.1)
Diabetes	105 (23.3)
Family history of IHD	239 (53.1)
Current medication	
ACEI	24 (5.3)
Antiarrhythmic	24 (5.3)
Anticoagulant	52 (11.6)
Antiplatelet	260 (57.8)
Beta Blocker	219 (48.7)
Calcium Channel Blocker	102 (22.7)
Diuretic	112 (24.9)
Nitrate	104 (23.1)
Potassium channel activators	40 (8.9)
Statin	277 (61.6)
H2 agonist	8 (1.8)
PPI	96 (21.3)
Angiotensin II inhibitor	45 (10.0)
Thyroid medication	26 (5.8)
Asthma medication	32 (7.1)
Pain medication	27 (6.0)
Diabetic medication	72 (16.0)
Alpha adreno blockers	23 (5.1)
Other lipid medication	11 (2.4)
Other hypertension medication	3 (0.7)
Examination and Investigation	
Heart rhythm* – Sinus rhythm	379 (84.2)
- Atrial arrhythmia	37 (8.2)

- Ventricular arrhythmia	2 (0.4)		
- Paced/CHB	6 (1.3)		
Number of diseased vessels -0	80 (17.8)		
- 1	36 (8.0)		
- 2	80 (17.8)		
- 3	245 (54.4)		
LMS >50%	93 (20.7)		
Extracardiac arteriopathy	42 (9.3)		
Catheter coronary closure	0 (0.0)		
LVEF – Good	327 (72.7)		
- Fair	90 (20.0)		
- Poor	24 (5.3)		
Cardiomegaly	57 (12.7)		
Albumin (g/L)	43.7	19.0-52.0	3.9
Urea (mmol/L)	6.9	2.0-26.0	2.6
Potassium (mmol/L)	4.4	3.3-6.3	0.4
Sodium (mmol/L)	139.6	128.0-148.0	3.2
Haemaglobin (g/dL)	13.3	7.9-17.3	1.6
White cell count (x10^9L)	1.13	1.0-4.0	0.4
Creatinine (mmol/L)	99.9	46.0-838.0	66.2
Systolic blood pressure (mmHg)	133.3	90.0-212.0	19.0
Heart rate (bpm)	69.5	44.0-150.0	13.9
Glasgow Coma Score	15	15.0-15.0	0.0
Respiratory rate (breaths/min)	19.2	10.0-30.0	2.1
Temperature (^{o}C)	36.5	36.0-38.0	0.4
Height (cm)	168.9	131.0-197.0	9.6
Weight (kg)	81.3	44.0-158.0	16.9
BMI (kg/m^2)	28.5	18.3-62.9	5.6
Pre-operative risk assessment			
Parsonnet	11.3	0-37	8.1
EuroSCORE	4.2	1-14	2.8
POSSUM	19.5	12-40	5.0

* *Heart rhythm was taken as that reported by medical staff on the patient's integrated care pathway

Immediate ICU characteristics (n=450). Values are n(%) or mean, range and standard deviation (SD) as appropriate.

	Frequency/mean	Range	SD
First ABG on ICU			
FiO_2	0.96	0.4-1.0	
pH	7.4	7.2-7.5	0.06
pCO_2 (kPa)	5.3	3.0-9.0	0.8
pO_2 (kPa)	18.0	2.9-47.8	7.2
SBCc (mmol/L)	22.1	-4.2-93.7	4.9
SBEc (mmol/L)	-1.7	-10.3-99.8	7.7
K (mmol/L)	4.1	3.0-6.9	0.4
Na (mmol/L)	139.3	110.0-162.0	2.9
Glucose (mmol/L)	6.1	1.0-13.1	1.7
Hb (g/dl)	9.7	6.0-14.4	1.6
Immediate post-operative medication			
RBC	100 (22.2)		
- number of units (mean/patient)	1.9	1.0-9.0	1.6
Platelets	35 (7.8)		
- number of units (mean/patient)	1.3	1.0-5.0	0.8
FFP	38 (8.4)		
- number of units (mean/patient)	3.1	1.0-11.0	2.1
Cryoprecipitate	0 (0.0)		
Aprotinin	52 (11.6)		
Enoximone	62 (13.8)		
Inotropes	71 (15.8)		
Vasoconstrictors	139 (30.9)		
Frusemide	6 (1.3)		
Morphine	437 (97.1)		
Propofol	441 (98.0)		
GTN	422 (93.8)		
Actrapid	444 (98.7)		
SNP	18 (4.0)		
Immediate post-operative measurements and examinations (12 hrs)			
Intubation grade – 1	330 (73.3)		
- 2	69 (15.3)		

- 3	30 (6.7)		
Heart rhythm* - Sinus rhythm	321 (71.3)	,	
- Sinus tachycardia	54 (12.0)		
- Sinus bradycardia	21 (4.7)		
- Atrial fibrillation	19 (4.2)		
- Other	34 (7.6)		
Paced	131 (29.1)		
Total gelofusin (ml)	1318.9	0.0-3150.0	585.1
Total IVI (ml)	846.5	50.0-2417.0	209.2
Total input (ml)	2802.3	746.0-9766.0	827.7
Total urine output (ml)	1339.15	0.0-3280.0	531.2
Total drainage (ml)	485.64	70.0-3035.0	366.1
Lowest sedation score	-3	-5--2	0.7
Total K supplements (mmol)	53.5	0.0-200.0	35.9
Total MgSO4 supplements (mmol)	0.6	0.0-30.0	3.5
Heart rate (bpm)	87.5	50.0-180.0	14.7
Systolic blood pressure (mmHg)	138.7	70.0-188.0	19.3
Diastolic blood pressure (mmHg)	61.8	35.0-100.0	9.9
Respiratory rate (bpm)	12.2	8.0-26.0	1.7
First temperature (^{o}C)	35.8	32.0-38.0	0.9
Highest temperature (^{o}C)	36.9	36.0-38.0	0.4
CVP (mmHg)	14.8	3.0-29.0	3.7
MAP (mmHg)	85.0	60.0-130.0	10.3
Day 1 medication			
RBC	63 (14.0)		
- number of units (mean/patient)	1.4	1.0-5.0	0.7
Platelets	3 (0.7)		
- number of units (mean/patient)	1.0	1.0-1.0	0.0
FFP	10 (2.2)		
- number of units (mean/patient)	2.3	1.0-4.0	1.1
Cryoprecipitate	2 (0.4)		
- number of units (mean/patient)	10.0	10.0-10.0	0.0
Aprotinin	6 (1.3)		
Enoximone	68 (15.1)		
Inotropes	53 (11.8)		
Vasoconstrictors	93 (20.7)		
Furosemide	25 (5.6)		
Morphine	423 (94.0)		

Propofol	38 (8.4)		
GTN	400 (88.9)		
Actrapid	438 (97.3)		
SNP	7 (1.6)		
Day 1 examinations			
Drains out	381 (84.7)		
Heart rhythm* - Sinus rhythm	289 (64.2)		
- Sinus tachycardia	66 (14.7)		
- Sinus bradycardia	12 (2.7)		
- Atrial fibrillation	47 (10.4)		
- Other	33 (7.3)		
Heart rate (bpm)	90.6	30.0-190.0	17.3
Systolic blood pressure (mmHg)	142.2	90.0-215.0	19.2
Diastolic blood pressure (mmHg)	63.5	42.0-100.0	9.9
Respiratory rate (breathspm)	22.4	10.0-47.0	5.0
Temperature (^{o}C)	37.1	35.6-38.6	0.5
CVP (mmHg)	16.1	0.0-30.0	4.6

*Heart rhythm was taken as that reported by ICU nursing staff

Appendix 5: The McMaster Framework for discriminative, predictive and evaluative tools[89]

	Discriminative	Predictive	Evaluative
Function	to distinguish between individuals or groups on an underlying dimension when no external criterion or gold standard is available for validating these measures	To classify individuals into a set of pre-defined measurement categories. When a gold standard is available, either concurrently or prospectively, to determine whether individuals have been classifed correctly.	To measure the magnitude of longitudinal change in an individual or group on the dimension of interest
Item selection	▪ Tap important components of the domain ▪ Universal applicability to respondents ▪ Stability over time	Statistical association with criterion measure	▪ Tap areas related to change in health status ▪ Responsiveness to clinically significant change
Item scaling	Short response sets which facilitate uniform interpretation	Response sets which maximise correlations with the criterion measure	Response sets with sufficent graduations to register change
Item reduction	▪ Internal scaling or consistency ▪ Comprehensiveness and reduction of random error vs respondent burden	Power to predict vs respondent burden	Responsiveness vs respondent burden
Reliability	Large and stable intersubject variation: correlation between replicate measures	Stable inter and intra-subject variation: chance corrected agreement between replicate measures	Stable intersubject variation: insignificant variation between replicate measures
Validity	Cross-sectional construct validity: relationship between index and external measures at a single point in time	Criterion validity: agreement with criterion measure	Longitudinal construct validity: relationship between changes in index and external measures over time
Responsiveness	Not relevant	Not relevant	Power of the test to detect a clinically important difference

Appendix 6: Categorisation of additional morbidities/items into POMS and/or new domains

POMS domains

Pulmonary

Pleural effusion
Pneumothorax
Surgical emphysema
Saline/other nebs
DIB/pain from chest drains
Reintubated
Aspiration pneumonia
Respiratory acidosis
Chest physiotherapy
Ventilation difficulties
SOB after medication
Bronchoscopy
Phrenic nerve palsy
Hiccups
Haemothorax

Infectious

Infected venflon site
Abscess
MRSA +ve
WCC/CRP abnormalities
Eye infection (from CPAP)
Pyrexia (<38^{o}C)
Fungal infection under breast
Oral thrush
UTI
Pus from tooth
Shingles
Hot/sweaty
Shivery

Haematological

Renal/ Metabolic

IV furosemide
Polyuric
Na abnormalities
IDC bypassing
UO decreased
K abnormalities
Haematuria
U and E abnormalities
Prostate problems
Incontinence
Kidney pain
UTI
Cramps
Increased base excess
Phosphate infusion - low phosphate
Lactate abnormalities
Urinary retention

Gastrointestinal

NG tube
GI bleed
Constipated
Stomach ache
NBM for procedure
Decreased appetite
Indigestion
Diarrhoea
Incontinence
Ischaemic bowel
Gastric reflux
PR Bleed

Cardiovascular

Hypertension
Inotropes
Hypotension
K abnormalities
PW remain insitu
Tamponade ?echo
Aortic dissection?
Pericarditis?
HR decreased
Tamponade ?theatre
Dizzy
Vasovagal
Large heart on CXR
Pericardial effusion
Lactate abnormalities
Cold extremities

Wound complications

Chest drains
Wound pain
Chest support in situ
Wound tightness
Sternal click
Numbness of donor site
Rtn to theatre (4 for bleeding, 1 rewire, I wire removal)

Neurological

Blurred vision
Weird dreams
Cerebral irritation
Lack of coordination
Panic attack
Depression
Changing LOC
Dizzy
Tinnitus
Sedated
Insomnia
Poor swallow
Drowsy/slow to wake
Pressure in head
Feels weak/tired

Pain

Shoulder pain
Pain around ears
Headache
Pain from chest drains
Back pain
Wound pain
Stomach ache
General pain

Ileostomy pain
Wound tightness
Pain in foot
Kidney pain
R pleural chest pain
Swollen knee
Sore throat
Pericarditis

POTENTIAL NEW DOMAINS

Blood sugar management

Blood sugar

Previous diabetic ulcers

Anticoagulation

Untherapeutic INR

Platelet abnormalities

Clotting coagulopathy

Bleeding with treatment

Hypo/hypervolaemia

Thirsty

Na abnormalities

UO decreased

Positive fluid balance

Overfilled

U and E abnormalities

IV fluids/dehydration

CVP/fluid challenge

Clinical review/intervention

D1 post-procedure

NBM for procedure

WCC/CRP abnormalities

For investigation/procedure

D2/3 post procedure

For review

Tamponade ?echo

Aortic dissection?

Pericarditis?

Tamponade ?theatre

Bronchoscopy

Rtn to theatre

Mobility

Mobility encouragement

Occupational therapy assistance

Fall

Death

General pain

Shoulder pain

Pain around ears

Headache

Back pain

Wound pain

General pain

Ileostomy pain

Wound tightness

Pain in foot

Kidney pain

Right pleural chest pain

Swollen knee

Sore throat

Pericarditis

Liver function

Decreased liver function

ALT increased

Vitamin B

Fluid overload

Peripheral oedema

Increased weight

Whole body oedema

Overfilled

Skin complaint

Blisters

Rash

Itchy

Iodine burns

Allergic reaction

Severe bruising

Miscellaneous

Increased sense of smell

Nose bleed

Collapse (no obvious cause)

Dexamethasone – reason for given not documented in medical notes

Potential to delete as not morbidities

Nicotine patches

Femoral line

Appendix 7: C-POMS domain level analysis.

Euroscore

C-POMS domain frequencies in those with high and low risk of post-operative mortality (EuroSCORE) on D3. Values shown are for the presence of the C-POMS morbidity and are n(%). Data available in 449/450

D3: C-POMS domains	EuroSCORE: low risk (n=267)	EuroSCORE: high risk (n=182)	p
Pulmonary	171 (64.0)	147 (80.8)	**0.000**
Infectious	75 (28.1)	46 (25.3)	0.291
Renal	66 (24.7)	94 (51.6)	**0.000**
Gastrointestinal	64 (24.0)	70 (38.5)	**0.001**
Cardiovascular	123 (46.1)	110 (60.4)	**0.002**
Neurological	63 (23.6)	45 (24.7)	0.434
Haematological	29 (10.9)	30 (16.5)	0.057
Wound complication	9 (3.4)	10 (5.5)	0.194
Pain	4 (1.5)	5 (2.7)	0.278
Endocrine	69 (25.8)	68 (37.2)	**0.007**
Electrolyte	3 (1.1)	7 (3.8)	0.058
Review	5 (1.9)	8 (4.4)	0.103
Assisted ambulation	89 (33.5)	116 (63.7)	**0.000**

C-POMS domain frequencies in those with high and low risk of post-operative mortality (EuroSCORE) on D5. Values shown are for the presence of the C-POMS morbidity and are n(%).

D5: C-POMS domains	EuroSCORE: low risk (n=244)	EuroSCORE: high risk (n=182)	p
Pulmonary	74 (30.3)	85 (46.7%)	**0.001**
Infectious	92 (37.7)	63 (34.6)	0.542
Renal	31 (12.7)	44 (24.2)	**0.003**
Gastrointestinal	59 (24.2)	57 (31.3)	0.123
Cardiovascular	104 (42.6)	105 (57.7)	**0.002**
Neurological	31 (12.7)	27 (14.8)	0.569
Haematological	34 (13.9)	36 (19.8)	0.114
Wound complication	10 (4.1)	7 (3.8)	1.000
Pain	19 (7.8)	14 (7.7)	1.000
Endocrine	22 (9.0)	26 (14.4)	0.090
Electrolyte	3 (1.2)	6 (3.3)	0.180
Review	15 (6.1)	13 (7.1)	0.679

Assisted ambulation	42 (17.2)	76 (41.8)	**0.000**

C-POMS domain frequencies in those with high and low risk of post-operative mortality (EuroSCORE) on D8. Values shown are for the presence of the C-POMS morbidity and are n(%).

D8: C-POMS domains	EuroSCORE: low risk (n=80)	EuroSCORE: high risk (n=100)	p
Pulmonary	24 (30.0)	44 (44.0)	0.064
Infectious	49 (61.2)	53 (53.0)	0.292
Renal	15 (18.8)	36 (35.6)	**0.013**
Gastrointestinal	19 (23.8)	31 (31.0)	0.317
Cardiovascular	40 (50.0)	73 (73.0)	**0.002**
Neurological	13 (16.2)	24 (24.0)	0.265
Haematological	18 (22.5)	30 (30.0)	0.310
Wound complication	6 (7.5)	7 (7.0)	1.000
Pain	6 (7.5)	8 (8.0)	1.000
Endocrine	12 (15.0)	14 (14.0)	1.000
Electrolyte	3 (3.8)	5 (5.0)	1.000
Review	7 (8.8)	11 (10.9)	0.803
Assisted ambulation	22 (27.5)	46 (46.0)	**0.013**

C-POMS domain frequencies in those with high and low risk of post-operative mortality (EuroSCORE) on D15. Values shown are for the presence of the C-POMS morbidity and are n(%).

D15: C-POMS domains	EuroSCORE: low risk (n=16)	EuroSCORE: high risk (n=32)	p
Pulmonary	4 (25.0)	15 (46.9)	0.213
Infectious	12 (75.0)	16 (50.0)	0.127
Renal	4 (25.0)	15 (46.9)	0.213
Gastrointestinal	2 (12.5)	11 (34.4)	0.170
Cardiovascular	10 (62.5)	21 (65.6)	1.000
Neurological	3 (18.8)	7 (21.9)	1.000
Haematological	5 (31.2)	4 (12.5)	0.138
Wound complication	6 (37.5)	6 (18.8)	0.178
Pain	1 (6.2)	2 (6.2)	1.000
Endocrine	4 (25.0)	6 (18.8)	0.712
Electrolyte	0 (0.0)	1 (3.1)	1.000
Review	1 (6.2)	5 (15.6)	0.648
Assisted ambulation	2 (12.5)	17 (53.1)	**0.011**

POSSUM Physiological Component

C-POMS domain frequencies and post-operative mortality and morbidity risk on D3. Values shown are for the presence of the C-POMS morbidity and are n(%). Data available on n=435/450.

D3: C-POMS domains	POSSUM: low risk (n=227)	POSSUM: high risk (n=208)	p
Pulmonary	142 (62.6)	165 (79.3)	**0.000**
Infectious	60 (26.4)	56 (26.9)	0.914
Renal	44 (19.4)	107 (51.4)	**0.000**
Gastrointestinal	61 (26.9)	69 (33.2)	0.173
Cardiovascular	100 (44.1)	124 (59.6)	**0.002**
Neurological	52 (22.9)	52 (25.0)	0.653
Haematological	24 (10.6)	31 (14.9)	0.195
Wound complication	10 (4.4)	8 (3.8)	0.814
Pain	4 (1.8)	4 (1.9)	1.000
Endocrine	51 (22.5)	82 (39.2)	**0.000**
Electrolyte	2 (0.9)	6 (2.9)	0.161
Review	6 (2.6)	7 (3.3)	0.781
Assisted ambulation	65 (28.8)	132 (63.5)	**0.000**

C-POMS domain frequencies and post-operative mortality and morbidity risk on D5. Values shown are for the presence of the C-POMS morbidity and are n(%). Data available on n=412/426.

D5: C-POMS domains	POSSUM: low risk (n=210)	POSSUM: high risk (n=202)	p
Pulmonary	56 (26.7)	98 (48.5)	**0.000**
Infectious	74 (35.2)	76 (37.6)	0.682
Renal	17 (8.1)	54 (26.7)	**0.000**
Gastrointestinal	56 (26.7)	56 (27.7)	0.825
Cardiovascular	82 (39.0)	117 (57.9)	**0.000**
Neurological	25 (11.9)	30 (14.9)	0.389
Haematological	30 (14.3)	35 (17.3)	0.420
Wound complication	9 (4.3)	7 (3.5)	0.800
Pain	14 (6.7)	17 (8.4)	0.577
Endocrine	16 (7.6)	29 (14.4)	**0.039**
Electrolyte	2 (1.0)	5 (2.5)	0.276
Review	12 (5.7)	16 (7.9)	0.436
Assisted ambulation	34 (16.2)	79 (39.1)	**0.000**

C-POMS domain frequencies and post-operative mortality and morbidity risk on D8. Values shown are for the presence of the C-POMS morbidity and are n(%). Data available on n=174/181

D8: C-POMS domains	POSSUM: low risk (n=60)	POSSUM: high risk (n=114)	p
Pulmonary	20 (33.3)	44 (38.6)	0.513
Infectious	41 (68.3)	57 (50.0)	**0.025**
Renal	11 (18.3)	38 (33.0)	**0.051**
Gastrointestinal	13 (21.7)	34 (29.8)	0.285
Cardiovascular	35 (58.3)	73 (64.0)	0.512
Neurological	10 (16.7)	26 (22.8)	0.432
Haematological	18 (30.0)	30 (26.3)	0.598
Wound complication	5 (8.3)	8 (7.0)	0.767
Pain	4 (6.7)	10 (8.8)	0.774
Endocrine	6 (10.0)	19 (16.7)	0.265
Electrolyte	3 (5.0)	5 (4.3)	1.000
Review	4 (6.7)	14 (12.2)	0.305
Assisted ambulation	17 (28.3)	49 (43.0)	0.071

C-POMS domain frequencies and post-operative mortality and morbidity risk. Values shown are for the presence of the C-POMS morbidity and are n(%). Data available on n= 45/48.

D15: C-POMS domains	POSSUM: low risk (n=15)	POSSUM: high risk (n=30)	p
Pulmonary	3 (20.0)	14 (46.7)	0.110
Infectious	11 (73.3)	15 (50.0)	0.203
Renal	5 (33.3)	13 43.3)	0.748
Gastrointestinal	3 (20.0)	9 (30.0)	0.722
Cardiovascular	10 (66.7)	18 (60.0)	0.752
Neurological	3 (20.0)	7 (23.3)	1.000
Haematological	3 (20.0)	6 (20.0)	1.000
Wound complication	5 (33.3)	7 (23.3)	0.496
Pain	1 (6.7)	2 (6.7)	1.000
Endocrine	2 (13.3)	7 (23.3)	0.695
Electrolyte	0 (0.0)	1 (3.3)	1.000
Review	1 (6.7)	5 (16.7)	0.647
Assisted ambulation	2 (13.3)	15 (50.0)	**0.023**

Magovern score

C-POMS domain frequencies and post-operative morbidity risk on D3. Values shown are for the presence of the C-POMS morbidity and are n(%). Data available on n=333/450.

D3: C-POMS domains	Magovern score: low risk (n=184)	Magovern score: high risk (n=149)	p
Pulmonary	117 (63.6)	119 (79.9)	**0.002**
Infectious	45 (24.5)	40 (26.8)	0.705
Renal	41 (22.3)	70 (47.0)	**0.000**
Gastrointestinal	43 (23.4)	48 (32.2)	0.084
Cardiovascular	85 (46.2)	90 (60.4)	**0.011**
Neurological	46 (25.0)	32 (21.5)	0.516
Haematological	25 (13.6)	21 (14.1)	1.000
Wound complication	7 (3.8)	3 (2.0)	0.521
Pain	2 (1.1)	5 (3.4)	0.250
Endocrine	36 (19.6)	59 (39.3)	**0.000**
Electrolyte	3 (1.6)	5 (3.3)	0.475
Review	5 (2.7)	4 (2.7)	1.000
Assisted ambulation	60 (32.8)	87 (58.4)	**0.000**

C-POMS domain frequencies and post-operative morbidity risk. Values shown are for the presence of the C-POMS morbidity and are n(%). Data available on 315/426

D5: C-POMS domains	Magovern score: low risk (n=168)	Magovern score: high risk (n=147)	p
Pulmonary	47 (28.0)	67 (45.6)	**0.001**
Infectious	58 (34.5)	51 (34.7)	1.000
Renal	15 (8.9)	40 (27.2)	**0.000**
Gastrointestinal	38 (22.6)	46 (31.3)	0.097
Cardiovascular	76 (45.2)	84 (57.1)	**0.042**
Neurological	18 (10.7)	21 (14.3)	0.392
Haematological	30 (17.9)	23 (15.6)	0.652
Wound complication	7 (4.2)	6 (4.1)	1.000
Pain	9 (5.4)	15 (10.2)	0.136
Endocrine	6 (3.6)	23 (15.6)	**0.000**
Electrolyte	1 (0.6)	5 (3.4)	0.101
Review	9 (5.4)	10 (6.8)	0.641

Assisted ambulation	22 (13.1)	62 (42.2)	**0.000**

C-POMS domain frequencies and post-operative morbidity risk. Values shown are for the presence of the C-POMS morbidity and are n(%). Data available on 130/181

D8: C-POMS domains	Magovern score: low risk (n=52)	Magovern score: high risk (n=78)	p
Pulmonary	14 (26.9)	33 (42.3)	0.094
Infectious	30 (57.7)	43 (55.1)	0.857
Renal	5 (9.4)	26 (33.3)	**0.002**
Gastrointestinal	12 (23.1)	22 (28.2)	0.548
Cardiovascular	29 (55.8)	56 (71.8)	0.090
Neurological	7 (13.5)	19 (24.4)	0.179
Haematological	15 (28.8)	22 (28.2)	1.000
Wound complication	4 (7.7)	6 (7.7)	1.000
Pain	2 (3.8)	7 (9.0)	0.314
Endocrine	3 (5.8)	11 (14.1)	0.159
Electrolyte	2 (3.8)	1 (1.3)	0.565
Review	5 (9.4)	9 (11.5)	0.780
Assisted ambulation	11 (21.2)	33 (42.3)	**0.014**

C-POMS domain frequencies and post-operative morbidity risk. Values shown are for the presence of the C-POMS morbidity and are n(%). Data available on 30/48

D15: C-POMS domains	Magovern score: low risk (n=11)	Magovern score: high risk (n=19)	p
Pulmonary	1 (9.1)	9 (47.4)	**0.049**
Infectious	8 (72.7)	10 (52.6)	0.442
Renal	2 (18.2)	8 (42.1)	0.246
Gastrointestinal	2 (18.2)	4 (21.1)	1.000
Cardiovascular	7 (63.6)	13 (68.4)	1.000
Neurological	1 (9.1)	4 (21.1)	0.626
Haematological	3 (27.3)	3 (15.8)	0.641
Wound complication	5 (45.5)	4 (21.1)	0.225
Pain	0 (0.0)	2 (10.5)	0.520
Endocrine	1 (9.1)	5 (26.3)	0.372
Electrolyte	-	-	-
Review	1 (9.1)	2 (10.5)	1.000
Assisted ambulation	0 (0.0)	7 (36.8)	**0.029**

Appendix 8: POMS domain level analysis.

EuroSCORE

POMS domain frequencies in those with high and low risk of post-operative mortality (EuroSCORE) on D3. Values shown are for the presence of the POMS morbidity and are n(%). Data available in n=449/450.

D3: POMS domains	EuroSCORE: low risk (n=267)	EuroSCORE: high risk (n=182)	p
Pulmonary	**158 (59.2)**	**145 (79.7)**	**0.000**
Infectious	69 (25.8)	44 (24.2)	0.740
Renal	**63 (23.6)**	**91 (50.0)**	**0.000**
Gastrointestinal	**53 (19.9)**	**59 (32.4)**	**0.003**
Cardiovascular	**105 (53.6)**	**91 (50.0)**	**0.026**
Neurological	43 (16.1)	37 (20.3)	0.260
Haematological	**3 (1.1)**	**9 (4.9)**	**0.017**
Wound complication	3 (1.1)	8 (4.4)	0.057
Pain	4 (1.5)	5 (2.7)	0.496

POMS domain frequencies in those with high and low risk of post-operative mortality (EuroSCORE) on D5. Values shown are for the presence of the POMS morbidity and are n(%).

D5: POMS domains	EuroSCORE: low risk (n=244)	EuroSCORE: high risk (n=182)	p
Pulmonary	**47 (19.3)**	**66 (36.3)**	**0.000**
Infectious	92 (37.7)	62 (34.1)	0.476
Renal	**27 (11.1)**	**40 (22.0)**	**0.003**
Gastrointestinal	47 (19.3)	46 (25.3)	0.155
Cardiovascular	**90 (36.9)**	**94 (51.6)**	**0.003**
Neurological	22 (9.0)	23 (12.6)	0.265
Haematological	1 (0.4)	5 (2.7)	0.088
Wound complication	3 (1.2)	4 (2.2)	0.467
Pain	5 (2.0)	6 (3.3)	0.540

POMS domain frequencies in those with high and low risk of post-operative mortality (EuroSCORE) on D8. Values shown are for the presence of the POMS morbidity and are n(%).

D8: POMS domains	EuroSCORE: low risk (n=80)	EuroSCORE: high risk (n=100)	p
Pulmonary	17 (21.2)	33 (33.0)	0.095
Infectious	49 (61.2)	51 (51.0)	0.178
Renal	14 (17.5)	31 (30.7)	0.056
Gastrointestinal	15 (18.8)	23 (23.0)	0.582
Cardiovascular	**39 (48.8)**	**65 (65.0)**	**0.034**
Neurological	9 (11.2)	18 (18.0)	0.294
Haematological	1 (1.2)	7 (7.0)	0.078
Wound complication	6 (7.5)	6 (6.0)	0.768
Pain	3 (3.8)	6 (6.0)	0.733

POMS domain frequencies in those with high and low risk of post-operative mortality (EuroSCORE) on D15. Values shown are for the presence of the POMS morbidity and are n(%).

D15: POMS domains	EuroSCORE: low risk (n=16)	EuroSCORE: high risk (n=32)	p
Pulmonary	2 (12.5)	12 (37.5)	0.098
Infectious	12 (42.9)	16 (50.0)	0.127
Renal	3 (18.8)	15 (46.9)	0.068
Gastrointestinal	1 (6.2)	7 (21.9)	0.240
Cardiovascular	10 (62.5)	18 (56.2)	0.763
Neurological	3 (18.8)	5 (15.6)	1.000
Haematological	2 (12.5)	2 (6.2)	0.592
Wound complication	6 (37.5)	5 (15.6)	0.144
Pain	1 (2.1)	2 (4.2)	1.000

POSSUM (Physiological component)

POMS domain frequencies and post-operative mortality and morbidity risk on D3. Values shown are for the presence of the POMS morbidity and are n(%). Data available in n=435/450

D3: POMS domains	POSSUM: low risk (n=227)	POSSUM: high risk (n=208)	p
Pulmonary	**131 (42.3)**	**162 (77.9)**	**0.000**
Infectious	55 (24.2)	53 (25.5)	0.824
Renal	**40 (17.6)**	**105 (50.5)**	**0.000**
Gastrointestinal	52 (22.9)	56 (26.9)	0.374
Cardiovascular	**82 (36.1)**	**105 (50.5)**	**0.003**
Neurological	**32 (14.1)**	**46 (22.1)**	**0.033**
Haematological	5 (2.2)	6 (2.9)	0.764
Wound complication	4 (1.8)	6 (2.9)	0.530
Pain	4 (1.8)	4 (1.9)	1.000

POMS domain frequencies and post-operative mortality and morbidity risk on D5. Values shown are for the presence of the POMS morbidity and are n(%). Data available on n=412/426.

D5: POMS domains	POSSUM: low risk (n=210)	POSSUM: high risk (n=202)	p
Pulmonary	**36 (17.1)**	**73 (36.1)**	**0.000**
Infectious	74 (35.2)	75 (37.1)	0.758
Renal	**13 (6.2)**	**50 (24.8)**	**0.000**
Gastrointestinal	48 (22.9)	41 (20.3)	0.551
Cardiovascular	**73 (34.8)**	**102 (50.5)**	**0.001**
Neurological	16 (7.6)	27 (13.4)	0.075
Haematological	2 (1.0)	4 (2.0)	0.441
Wound complication	2 (1.0)	4 (2.0)	0.441
Pain	5 (2.4)	6 (3.0)	0.768

POMS domain frequencies and post-operative mortality and morbidity risk on D8. Values shown are for the presence of the POMS morbidity and are n(%). Data available on n=174/181.

D8: POMS domains	POSSUM: low risk (n=60)	POSSUM: high risk (n=114)	p
Pulmonary	16 (26.7)	31 (27.2)	1.000
Infectious	**40 (66.7)**	**56 (49.1)**	**0.037**
Renal	11 (18.3)	32 (27.8)	0.198
Gastrointestinal	11 (18.3)	25 (21.9)	0.695
Cardiovascular	34 (56.7)	66 (57.9)	0.874
Neurological	7 (11.7)	19 (16.7)	0.503
Haematological	2 (3.3)	6 (5.3)	0.716
Wound complication	5 (8.3)	7 (6.1)	0.754
Pain	3 (5.0)	6 (5.3)	1.000

POMS domain frequencies and post-operative mortality and morbidity risk on D15. Values shown are for the presence of the POMS morbidity and are n(%). Data are available on n=45/48.

D15: POMS domains	POSSUM: low risk (n=15)	POSSUM: high risk (n=30)	p
Pulmonary	2 (13.3)	11 (36.7)	0.165
Infectious	11 (73.3)	15 (50.0)	0.203
Renal	4 (26.7)	13 (43.3)	0.341
Gastrointestinal	2 (13.3)	5 (16.7)	1.000
Cardiovascular	10 (66.7)	15 (50.0)	0.352
Neurological	2 (13.3)	6 (20.0)	0.699
Haematological	1 (6.7)	3 (10.0)	1.000
Wound complication	5 (33.3)	6 (20.0)	0.464
Pain	1 (6.7)	2 (6.7)	1.000

Magovern score

POMS domain frequencies and post-operative morbidity risk on D3. Values shown are for the presence of the POMS morbidity and are n(%). Data available on n=333/450.

D3: POMS domains	Magovern score: low risk (n=184)	Magovern score: high risk (n=149)	p
Pulmonary	**108 (55.3)**	**149 (44.7)**	**0.000**
Infectious	40 (21.7)	40 (26.8)	0.303
Renal	**40 (21.7)**	**67 (45.0)**	**0.000**
Gastrointestinal	38 (20.7)	35 (23.5)	0.595
Cardiovascular	74 (40.2)	74 (49.7)	0.096
Neurological	34 (18.5)	25 (16.8)	0.773
Haematological	3 (1.6)	5 (3.4)	0.475
Wound complication	3 (1.6)	3 (2.0)	1.000
Pain	2 (1.1)	5 (3.4)	0.250

POMS domain frequencies and post-operative morbidity risk on D5. Values shown are for the presence of the POMS morbidity and are n(%). Data available on n=315/426.

D5: POMS domains	Magovern score: low risk (n=168)	Magovern score: high risk (n=147)	p
Pulmonary	**30 (17.9)**	**54 (36.7)**	**0.000**
Infectious	58 (34.5)	51 (34.7)	1.000
Renal	**12 (7.1)**	**37 (25.2)**	**0.000**
Gastrointestinal	31 (18.5)	37 (25.2)	0.170
Cardiovascular	70 (41.7)	72 (49.0)	0.213
Neurological	13 (7.7)	18 (12.2)	0.190
Haematological	2 (1.2)	2 (1.4)	1.000
Wound complication	1 (0.6)	2 (1.4)	0.600
Pain	1 (0.6)	5 (3.4)	0.101

POMS domain frequencies and post-operative morbidity risk on D8. Values shown are for the presence of the POMS morbidity and are n(%). Data available in n=130/181.

D8: POMS domains	Magovern score: low risk (n=52)	Magovern score: high risk (n=78)	p
Pulmonary	10 (19.2)	22 (28.2)	0.301
Infectious	30 (57.7)	42 (53.8)	0.721
Renal	**5 (9.4)**	**22 (28.2)**	**0.014**
Gastrointestinal	9 (17.3)	18 (23.1)	0.511
Cardiovascular	28 (53.8)	50 (64.1)	0.276
Neurological	5 (9.6)	14 (17.9)	0.215
Haematological	0 (0.0)	3 (3.8)	0.274
Wound complication	4 (7.7)	5 (6.4)	1.000
Pain	2 (3.8)	4 (5.1)	1.000

POMS domain frequencies and post-operative morbidity risk on D15. Values shown are for the presence of the POMS morbidity and are n(%). Data available in n=30/48.

D15: POMS domains	Magovern score: low risk (n=11)	Magovern score: high risk (n=19)	p
Pulmonary	**0 (0.0)**	**7 (36.8)**	**0.029**
Infectious	8 (72.7)	10 (52.6)	0.442
Renal	1 (9.1)	8 (42.1)	0.100
Gastrointestinal	2 (18.2)	2 (10.5)	0.611
Cardiovascular	7 (63.6)	12 (63.2)	1.000
Neurological	1 (9.1)	4 (21.1)	0.626
Haematological	1 (9.1)	0 (0.0)	0.367
Wound complication	5 (45.5)	3 (15.8)	0.104
Pain	0 (0.0)	2 (10.5)	0.520