HOW TO COLLECT THE DATA

Contents:

Intraoperative Data collection (Appendix 1 – Patient Data Collection form):

Dates of data collection:
Collect data during a locally agreed weekday 48 hour period between Monday 21st November and Friday 2nd December.

Location of data collection:
Please consider the various different recovery units/ PACUs that may be present in your hospitals (main, day case etc) and ensure data is collected from all sites.

- *Note from the pilot study: by looking at the theatre lists, you can anticipate when the patients will be coming out of theatre and target different recovery units as needed.*

How to collect intraoperative patient data:

1) Record data for each patient meeting the inclusion criteria. Each intraoperative dataset should take approximately 10 minutes to complete.

   Table 1, below, answers some common questions and provides detail on the inclusion and exclusion criteria:

Inclusion criteria	
Criterion	Detail
Age ≥65 years old	
General anaesthesia or regional anaesthesia either alone or in combination	What constitutes regional anaesthesia? • Any regional block technique. • However, for study data to be collected the anaesthetist must also be present for intra-operative management and record BP values. If the anaesthetist simply delivers the block and is then no longer involved in intra-operative management (e.g. many eye blocks) and/ or no blood pressure data is recorded, the case should be omitted. What is not regional anaesthesia? • Topical anaesthesia • Local anaesthetic infiltration by the surgeon during the case.
Emergency or elective surgery	All surgical procedures Interventional radiological procedures including: • Endovascular procedures: TAVI, EVAR, TEVAR, hybrid repairs • Neuroradiology: aneurysm coiling etc This does not include electroconvulsion therapy (ECT) or coronary angioplasty procedures.

Exclusion criteria	
Criterion	Detail
Sedation alone	Conscious sedation, where the sedation is performed by the interventionalist e.g. endoscopy If sedation is used in combination with regional anaesthesia the case should be included.
Cardiopulmonary bypass	Any procedure using cardiopulmonary bypass

2) Record intraoperative data on the paper Case Report Forms (CRF) titled '*RAFT iHypE - Appendix 1 & 3 - Patient Data Collection Form*'. Data can be obtained from the below sources whilst patients are in the recovery room post-operatively:

a) The paper anaesthetic chart
b) Electronic anaesthetic records:
c) NB. Intraoperative blood pressure data should not be collected in real-time in the operating theatre.

3) To ensure that the primary outcome measures are not biased, intraoperative BP data should not be recorded on the CRF by the team giving the anaesthetic.

4) No identifiable information should be written on the CRF, however you must ensure you are able to link the intraoperative data with the outcome data collected at 30 days after surgery. Please use a locally agreed pseudonomysation code. This code should not be transferred outside of the local hospital. An example is shown in table 2, however you may use your own:

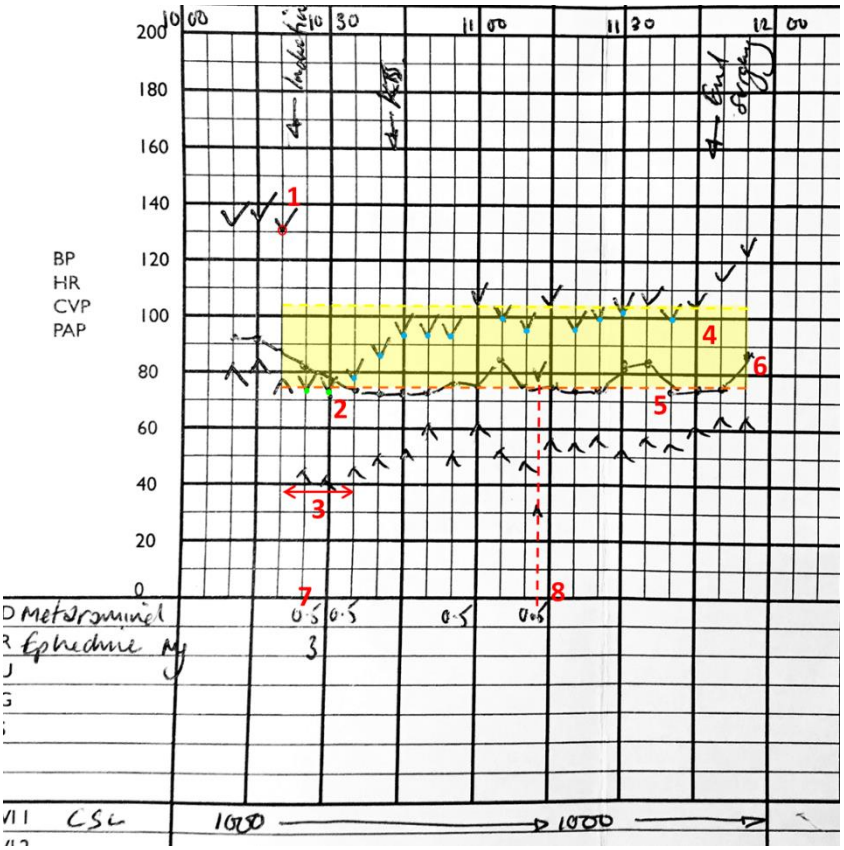
Example	
Fred Smith, 2nd patient on the list in theatre 5 on local study day 1.	Example codes: D1 5.2 or D1 T5 P2 or similar

Table 2: example of pseudoanomysation code

5) Table 3: How to complete the boxes in Appendix 1 – Patient data CRF:

		Item	Detail
1	Patient	Gender	–
		Age	–
		Comorbidities	Please record from the anaesthetic chart only. • Cerebrovascular disease: past history of TIA or stroke documented • Chronic Kidney Disease: Stage 1-4 CKD documented • Heart failure: left, right or biventricular failure documented. • Ischaemic heart disease: past history of angina, myocardial ischaemia, coronary stents or bypass grafting documented.
		Anti-hypertensive Medications	Please record from the anaesthetic chart only. Dose is not required.
		ASA score	If this is not recorded, please do not calculate it yourself,
2	Surgery	NCEPOD Urgency	See appendix 2 below for guidance
		Surgical speciality	For joint procedures, please use 'other' and specify
		Operative severity	See appendix 3 below for guidance
		Cancer surgery	–
		Procedure where hypotension may be requested by surgeon?	• Examples include maxillofacial surgery, middle ear surgery, functional endoscopic sinus surgery, spinal surgery, major orthopaedic surgery and prostatectomy. • This should be based on your assessment, please do not ask the anaesthetist as this may affect their survey answers.
3	Anaesthesia	Seniority	Record the grade of the most senior anaesthetist in theatre.
		Number	As a local research team, please count the number of anaesthetists providing anaesthetic care to patients aged 65 or older (who would therefore be eligible to complete the anaesthetist survey). The trainee lead will be asked to provide this denominator information on REDCap.
		Induction	If it is clearly recorded that the patient had either a co-induction (inhalational and intravenous) please tick both.
		Maintenance	If it is clearly recorded that the patient received both a Propofol IVI and inhalational maintenance, please tick both boxes.
		Regional block	What counts as regional block? See above.
4	Blood Pressure	Data source	–
		Intra-operative monitoring	–
		Pre-operative BP Source	If taken from a letter, please use the most recent letter. If taken from the ward observations chart: please use the most recent value prior to surgery.

	Pre-induction BP	The BP documented prior to induction of anaesthesia. If more than one BP is documented prior to induction, please record the last value before anaesthesia is induced. See figure 1 If no pre-induction BP is recorded on the anaesthetic chart, please tick the box stating not recorded.
	Lowest intra-op BP & duration	The lowest systolic BP recorded on the anaesthetic chart and its associated diastolic BP value. Please do not calculate the mean arterial pressure. See figure 1 Duration: we have defined this as, "the period of time that the preceding and following systolic BPs remain within 5mmHg of the single lowest systolic BP value". See figure 1. Please document greater than 5min accuracy where able.
	Hypotension Timing	Refers to the lowest intra-operative BP. • If the surgery lasts less than 30 minutes, please record the timing as being within the first 30 minutes after induction. • If the surgery lasts 30-60 minutes, please record the lowest intra-op BP as being within either the first 30 or last 30 minutes of surgery
	Duration of systolic hypotension	This refers to the cumulative time spent with a systolic BP at one of the described ranges. Please see figure 1, items 4 and 5. If pre-induction BP is not recorded on the anaesthetic chart, please use the most recent ward or pre-operative value to calculate the percentage reduction.
	Duration of surgery	Please record as the total duration of BP recordings after induction of anaesthesia to the last recording on the chart. See figure 1, item 6.
5 Vasopressor use	On vasopressor infusion pre-op?	–
	Vasopressor total dose used intraoperatively	Calculate from the cumulative number of boluses given. Please do not attempt to calculate the total dose given from a vasopressor infusion unless the total dose administered is clearly documented.
	Vasopressors given as infusion intra-op?	–
	BP value immediately preceding vasopressor use	Record the systolic and diastolic BP value immediately preceeding each bolus dose of vasopressor or a vasopressor infusion starting. See figure 1, items 7 and 8.
6	How many surgical procedures took place on the day of data collection?	Total: As a team please record the number of procedures that took place in each 24 hour period of the study. The trainee lead will be asked to provide the total number of procedures that took place at your site over the 48 hours study period on REDCap. ≥65 years old: please record the number of ≥65 year olds who were operated on during the 48 hours study period. The trainee lead will be asked to provide the total number of procedures that took place in ≥65s at your site.



1. The pre-induction BP is 130/78mmHg. Please use the tip of the 'V' (circled in red) to identify the BP value.
2. The lowest intra-operative BP (74/41mmHg). It occurs in the first 30 minutes of the procedure.
3. The duration of the lowest blood pressure period (three 5 minute epochs with systolic BPs within 5mmHg (pre and post) of the lowest value = 15 minutes in total).
4. The yellow shaded area represents 20.0-40.0% below the pre-induction SBP (104mmHg – 78mmHg). The cumulative duration of systolic BP's in this range (denoted by blue dots) is eleven 5 minute epochs, totaling 55 minutes.
5. The orange hyphenated line represents >40.1% below the pre-induction SBP. The cumulative duration below this is two 5' epochs (denoted by green dots), totaling 10 minutes.
6. The 'duration of surgery' (taken as the duration time from the first BP recording after induction of anaesthesia to the last recorded value) is the shown by the duration of the yellow shaded area, nineteen 5 minute epochs, totaling 95 minutes.
7. 1st hypotensive triggering vasopressor use.
8. 5th hypotensive episode, here recorded in between normal 5 minute monitoring (see red hyphenated line), triggering vasopressor use.

Figure 1: a worked example

Patient information and opt-out:
This is a non-consenting study. However the study will be advertised by posters in pre-operative clinics and waiting areas – please ensure this happens as early as possible prior to data collection. Ordinarily, data may be collected, however if a patient or their carer asks for more information, please provide them with a copy of '*RAFT iHypE - Information Sheet - Patient - v2.2 07.08.16*' and offer them the opportunity to discuss the project with the local lead.

If the individual wishes to opt out, respect their request without question. Inform them that this will not affect their current or future care.

Storage of data
You will need to store the data collected on the "Appendix 1 – patient data collection form" securely until collecting the outcome data.

All information for the trial must be held securely and treated as strictly confidential according to NHS policies. Paper case report forms (CRFs) must be stored in a locally arranged secure location, typically a drawer or filing cabinet in a locked anaesthetic consultants office accessed by key or swipe card.

Anaesthetist Data collection (Appendix 2 – Anaesthetist Data Collection form):

How to collect anaesthetist data:
This part is crucial to the goal of the study, please do not omit. Additionally, it will count towards NIHR accruals (your hospital will get paid for you collecting and uploading this data).

1) Ask the anaesthetist whose patient(s) have been included in the study to complete the anaesthetist survey ('*RAFT iHypE - Appendix 2 - Anaesthetist Survey Data Collection Form*'). Provide each

individual with a copy of the anaesthetist information sheet (*RAFT iHypE - Information Sheet - Anaesthetist - v2.1 14.07.16*).

2) If more than one anaesthetist was present in theatre (e.g. a consultant and trainee), give a survey form and information sheet to each individual clinician.

3) Each anaesthetist should only be surveyed once, even if they have more than 1 patient enrolled in the study, to ensure their views are not over-represented in the results.

4) If a patients surgery spans a handover period (for example at 0800 or 2000hrs on the emergency list), please survey both anaesthetic teams.

5) Reassure the clinician that completion will take less than 5 minutes and will not (and cannot) be linked to their patients intraoperative or outcome data.

6) Encourage them to complete it promptly and return it to you at their earliest convenience. On the day is ideal.

7) Please do not distribute the anaesthetist survey to every clinician in your department or survey medical students.

Outcome Data collection (Appendix 3 – Outcome Data Collection form):

How to collect the outcome data:
At 30 days after surgery, collect outcomes data from your hospitals electronic data system. Use your local identifier number to link the correct intraoperative blood pressure data to the correct outcomes.

1) Mortality: in hospital mortality at 30 days.
   a) Can be obtained from the discharge summary, patient administration system or electronic record.
   b) If the patient was discharged alive and has not returned to your hospital and died within the 30 day period, please record them as alive for the purposes of this study (we are not seeking Hospital Episode Statistics data).
   c) Record the number of days after surgery death occurred. The day of surgery is day 0.

2) Renal injury:
   a) Document the pre-operative creatinine value closest to surgery (µmol/L)
   b) Document the highest post-operative creatinine value within 7 days of surgery (µmol/L).
   c) If no values were recorded for one or both, please leave them blank.

3) Stroke:
   a) Search your trusts radiology image viewing system for a post-operative Computed Tomography (CT) scan of the brain/ head that was completed within 7 days of surgery.
   b) Tick the ‘yes’ box on the CRF if there is a report confirming the presence of an ischaemic stroke.
   c) If no CT brain/ head was performed within 7 days of surgery, please tick the ‘no CT performed’ box.

4) Cardiac injury:
   a) Document whether there was a rise in the cardiac enzyme concentration within 7 days of surgery that is above the reference range for your trust.

b) If no cardiac enzyme test was performed within 7 days of surgery, please tick the 'no cardiac enzyme test performed' box.

Why have we stated 'cardiac enzyme' rather than 'troponin'? Although most NHS trusts will use troponins, some may use other tests. We are interested in a rise above locally applied the reference range.

Once the data is collected:

Upload the data to RAFT:

Input the completed data to REDCap from an NHS desktop computer using the links in the e-mail you receive from Anaesthesia.Audit. You will be asked to provide your unique investigator number and GMC number for each dataset you upload. This is so that we can contact you if we have a question about the dataset.

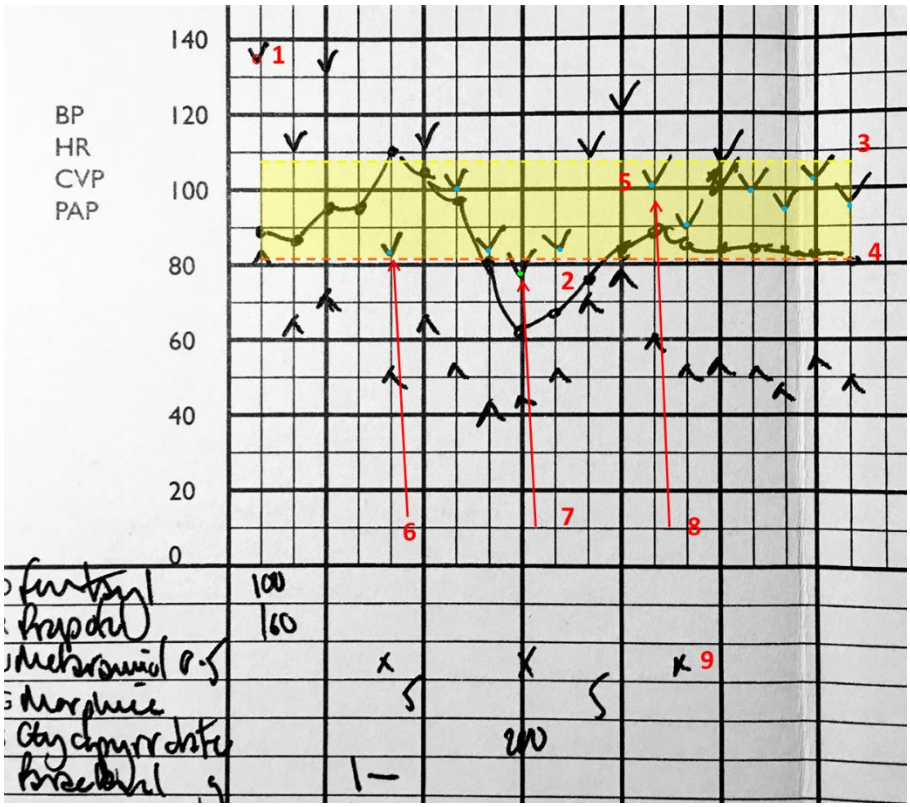
1) Anaesthetist Survey: Please upload the anaesthetist survey data as soon as it is collected.

2) Patient intraoperative and outcome data: must be uploaded at the same time i.e. once 30 day outcome data has been collected.

3) All data must be uploaded via REDCap **before 14/01/2017**, otherwise it will not be included in the analysis.
   - *Why this timeline? As a portfolio registered study, we are required to report our recruitment numbers to the National institute of Health Research (NIHR). This information has to be submitted by 31/01/2016. Therefore we are allowing you 2 weeks to upload the data and us (RAFT) 2 weeks to enter the data into the Central Portoflio Management System.*

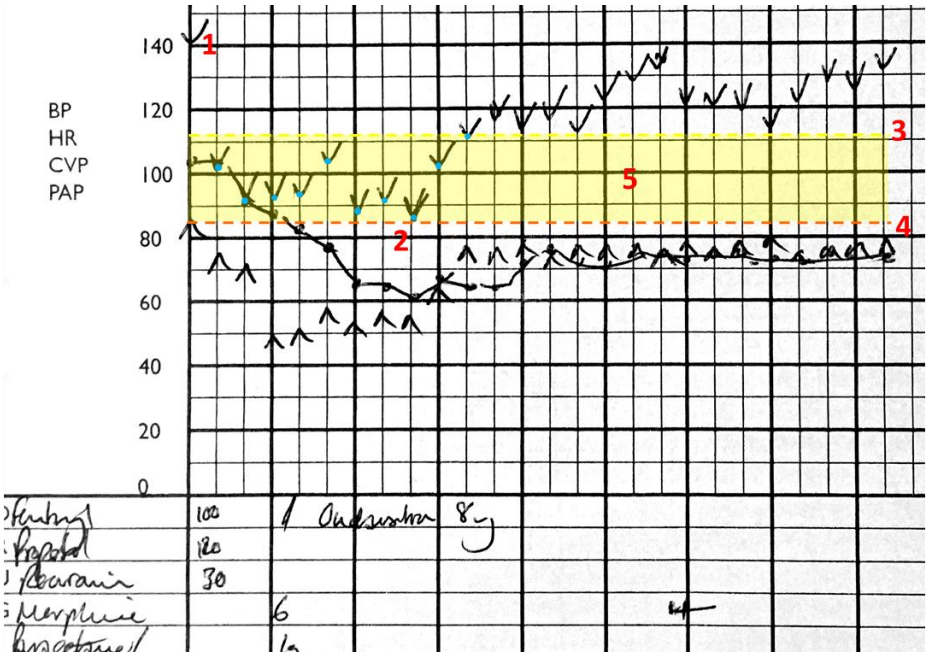
Appendix 1 – Example cases

Example 1



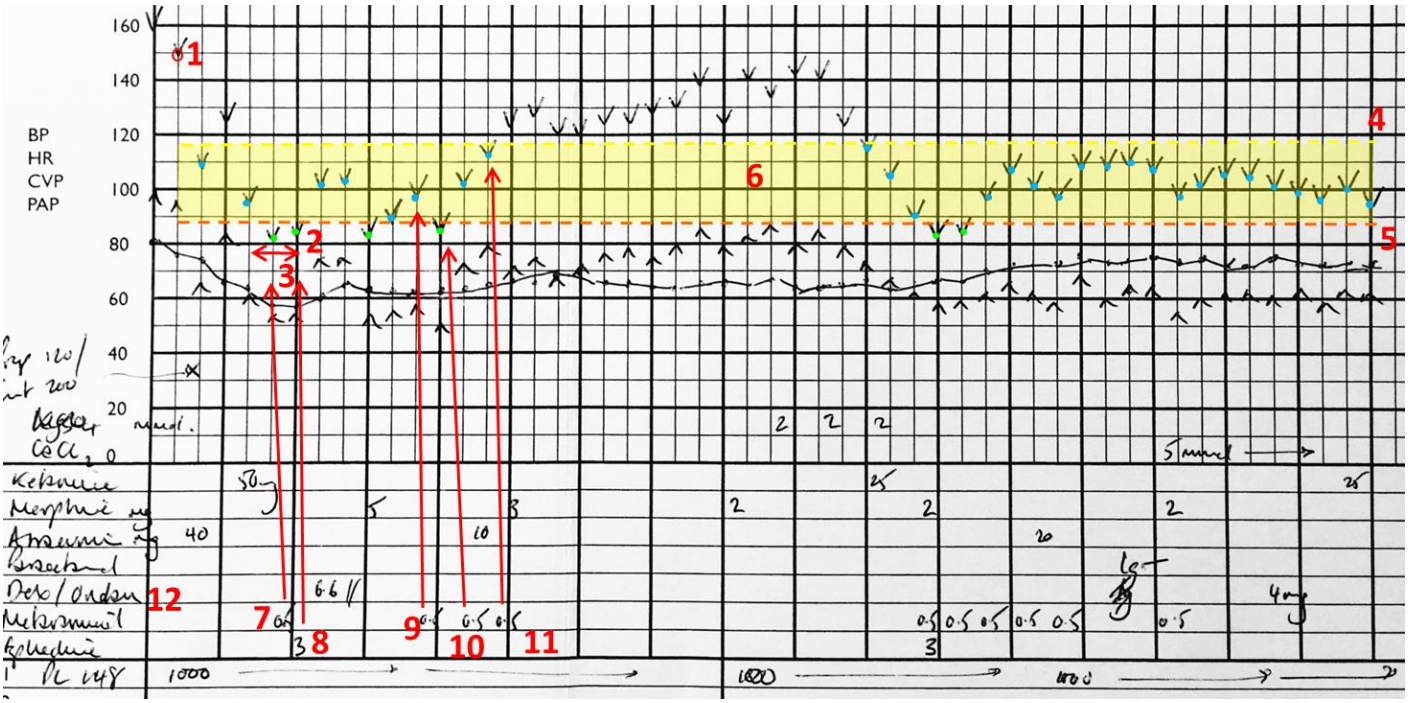
1. The pre-induction BP is 135/82mmHg.
2. The lowest intra-operative BP (77/44mmHg). In this example, the lowest blood pressure period lasts just one 5 minute epoch. It occurs in the 'middle' period of surgery.
3. The yellow shaded area below the hyphenated yellow line represents 20.0-40.0% below the pre-induction SBP (108mmHg – 81mmHg). The cumulative duration of systolic BP's in this range (denoted by blue dots) is ten 5 minute epochs, totaling 50 minutes.
4. The cumulative duration below the orange hyphenated line (>40.1% drop from pre-induction SBP) is one 5 minute epoch (also the lowest BP, denoted by green dots), totaling 5 minutes.
5. The 'duration of surgery' is the shown by the duration of the yellow shaded area, eighteen 5 minute epochs, totaling 90 minutes.
6-8. The 1st to 3rd hypotensive episodes triggering vasopressor use (arrowed).
9. Total dose of metaraminol in this case is 1.5mg.

Example 2



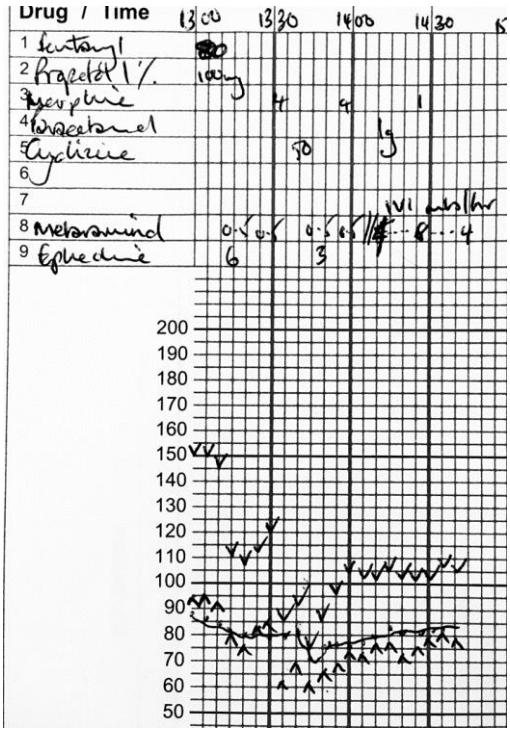
1. The pre-induction BP is 141/84mmHg.
2. The lowest intra-operative BP (86/46mmHg). In this example, the lowest blood pressure period lasts just one 5 minute epoch. It occurs in the middle period of surgery.
3. The yellow shaded area below the hyphenated yellow line represents 20.0-40.0% below the pre-induction SBP (112mmHg – 84mmHg). The cumulative duration of systolic BP's in this range (denoted by blue dots) is ten 5 minute epochs, totaling 50 minutes.
4. The orange hyphenated line represents >40.1% below the pre-induction SBP. There are no BP values below this threshold.
5. The 'duration of surgery' is the shown by the duration of the yellow shaded area, twenty five 5 minute epochs, totaling 125 minutes.

Example 3



1. The pre-induction BP is 148/84mmHg. In this case, as in fig. 1, the last value before induction of anaesthesia is used.
2. The lowest intra-operative BP (82/54mmHg). In this example, the lowest blood pressure period lasts for two 5 minute epochs. It occurs in the first 30 minutes.
3. The duration of the lowest blood pressure period is 10 minutes (two 5 minute epochs).
4. The yellow shaded area below the hyphenated yellow line represents 20.0-40.0% below the pre-induction SBP (118mmHg – 88mmHg). The cumulative duration of systolic BP's in this range (denoted by blue dots) is twenty eight 5 minute epochs, totaling 140 minutes.
5. The cumulative duration below the orange hyphenated line (>40.1% drop in systolic BP) is six 5 minute epochs, totaling 30 minutes (denoted by green dots).
6. The 'duration of surgery' is fifty 5 minute epochs, totaling 250 minutes.
7-11. The 1st to 5th hypotensive episodes triggering vasopressor use respectively, 82/54, 84/53, 89/55, 85/49 and 90/62.
12. Total dose of metaraminol used in this case is 5mg and ephedrine 3mg.

Example 4 – test



1. What is the pre-induction BP?
2. What is the lowest intraoperative BP?
3. How long does the lowest intraoperative BP episode last for?
4. In what section of the case does the lowest intraoperative BP occur?
5. How long is the case?
6. What is the total duration with systolic blood pressure values in the 20.0 – 40.0% drop range?
7. What is the total duration with systolic blood pressure values in the ≥40.1% drop range?
8. What BP values trigger vasopressor use?
9. What is the total dose of vasopressors used?
10. Is an infusion of vasopressor used? If so, what are the maximum and minimum infusion rates? How long does the infusion last for?

The answers are on the following page.

Answers:

1. 145/92
2. 75/62
3. One 5 minute epoch (5 minutes)
4. The middle (it occurs at 35 minutes).
5. 90 minutes (eighteen 5 minute epochs)
6. Fourteen 5 minute epochs, therefore 70 minutes
7. Three 5 minute epochs, therefore 15 minutes
8. 1st: 110/80, 2nd 112/84, 3rd 75/62, 4th 105/75. In this example, 2 doses of vasopressor (ephedrine and metaraminol) were triggered by the same BP value.
9. 2mg metaraminol and 9mg ephedrine as boluses
10. An infusion of metaraminol is started. The maximum infusion rate is 8mls/hr, the minimum infusion rate is 4mls/hr. The infusion lasts for 35 minutes (seven 5 minute epochs).

Appendix 2 – NCEPOD Urgency

Table from the NCEPOD Revised Classification of Intervention, 2004

Code	Category	Description	Target time to theatre	Expected location	Example Scenarios	Typical procedures
1	Immediate	Immediate (A) life-saving or (B) limb or organ-saving intervention. Resuscitation simultaneous with surgical treatment.	Within minutes of decision to operate	Next available operating theatre – "break-in" to existing lists if required	• Ruptured aortic aneurysm • Major trauma to abdomen or thorax • Fracture with major neuro-vascular deficit • Compartment syndrome • Acute myocardial infraction (AMI)	• Repair of ruptured aortic aneurysm • Laparotomy/ thoracotomy for control of haemorrhage • Fasciotomy • Coronary angioplasty
2	Urgent	Acute onset or deterioration of conditions that threaten life, limb or organ survival; fixation of fractures; relief of distressing symptoms.	Within hours of decision to operate and normally once resuscitation completed	Day time "emergency" list or Out-of-hours emergency theatre (including at night)	• Compound fracture • Perforated bowel with peritonitis • Critical organ or limb ischaemia • Acute coronary syndromes (ACS) • Perforating eye injuries	• Debridement plus fixation of fracture • Laparotomy for perforation • Coronary angioplasty
3	Expedited	Stable patient requiring early intervention for a condition that is not an immediate threat to life, limb or organ survival	Within days of decision to operate	Elective list which has "spare" capacity or Day time "emergency" list (not at night)	• Tendon and nerve injuries • Stable & non-septic patients for wide range of surgical procedures • Retinal detachment	• Repair of tendon and nerve injuries • Excision of tumour with potential to bleed or obstruct • Coronary angioplasty
4	Elective	Surgical procedure planned or booked in advance of routine admission to hospital	Planned	Elective theatre list booked & planned prior to admission	• Encompasses all conditions not classified as immediate, urgent or expedited.	• Elective AAA repair • Laparoscopic cholecystectomy • Varicose vein surgery • Joint replacement • Coronary angioplasty

Appendix 3 – Surgical Severity

There is no widely accepted or validated system for grading the physiological stress caused by surgical procedures. The table below, whilst not exhaustive, provides some examples to guide the iHypE data collector when assessing the severity of the surgical procedure..

Table adapted from:

- NICE Clinical Guideline 3: Preoperative Tests (2003)
- ESC/ESA Guidelines on non-cardiac surgery: cardiovascular assessment and management. *European Heart Journal* 2014; **35**; 2383–2431
- Glance LG, Lustik SJ, Hannan EL, Osler TM, Mukamel DB, Qian F et al. The Surgical Mortality Probability Model: derivation and validation of a simple risk prediction rule for noncardiac surgery. *Ann Surg* 2012; **255**: 696–702. Details available from appendices.

Grade		Examples
1	Minor	• Drainage of a breast abscess • Eye surgery • Superficial surgery e.g. removal of skin lesion • Dental surgery • Minor gynaecological surgery e.g. hysteroscopy
2	Intermediate	• ENT: Tonsillectomy/ adenotonsillectomy • General: repair of inguinal hernia, rectal/ anal surgery • Laparoscopic abdominal surgery: cholecystectomy, appendectomy, hernia repair • Ortho: arthroscopy • Vascular: Excision of varicose vein(s) of leg
3	Major	• Gynaecology: Total abdominal hysterectomy • Open abdominal surgery (laparotomy): bowel, gastric, liver and pancreatic surgery • Urology: Endoscopic resection of prostate (TURP) • ENT: Thyroidectomy • Vascular: endovascular repair of aneurysm, peripheral vascular surgery, including amputations • Spinal surgery, including lumbar discectomy
4	Major +	• Cardiac: all surgery • ENT: Radical neck dissection • General: Oesophagectomy, pelvic/ abdominal exenterations, perforated abdominal viscus • Neurosurgery: Intracranial neurosurgery • Ortho: total joint replacement • Thoracic: pulmonary resection • Vascular: aortic surgery