

# THE LANCET

## **Supplementary appendix**

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

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## APPENDIX

### Surgical risk scores provided to study centres

This list has been developed to guide centres when allocating a surgical risk score at randomisation. It is a comprehensive list of surgical procedures, each has been allocated a risk score of low, medium or high. High risk surgery is excluded from the TAPS trial. Allocation of surgical risk for procedures NOT listed here are to be done using the PI's clinical judgement, or referred to the Medical Expert.

<b>TAPS SURGICAL RISK SCORES</b>			
<b><u>Surgery Type</u></b>	<b><u>High Risk</u></b>	<b><u>Medium Risk</u></b>	<b><u>Low Risk</u></b>
<b>General</b>			
Biliary Surgery		Medium	
Cholecystectomy and exploration of common duct		Medium	
Colostomy		Medium	
Gastrostomy		Medium	
Hepatectomy	High		
Ileostomy		Medium	
Laparotomy		Medium	
Liver Biopsy		Medium	
Mastectomy		Medium	
Oesophagectomy	High		
Oesophagogastrectomy	High		
Partial Gastrectomy		Medium	
Splenectomy		Medium	
Total Gastrectomy		Medium	
Vagotomy +/- drainage		Medium	
<b>Endocrine</b>			
Adrenalectomy		Medium	
Parathyroidectomy		Medium	
Partial Pancreatectomy		Medium	
Thyroidectomy		Medium	
Whipples procedure	High		
<b>Transplantation</b>			
Bone Marrow Harvest			Low
Kidney transplant		Medium	
<b>Colo-Rectal Surgery</b>			
Intra-abdominal - colectomy		Medium	
Rectopexy		Medium	
Rectum - pouch; resection/excision		Medium	
<b>Vascular Surgery</b>			
Amputation of limb		Medium	
Aorto-femoral bypass	High		
Aorto-iliac endarterectomy	High		
Axillo-pop bypass		Medium	
Bifemoral bypass		Medium	
Endarterectomy (HIGH if carotid/vertebrobasilar)		Medium	
Fem-pop bypass		Medium	
Infra-renal aneurysm		Medium	
Sympathectomy		Medium	
Thoracic Aortic Aneurysm	High		
<b>Cardiothoracic Surgery</b>			
Angioplasty	High		

Aortic Valve Replacement (AVR)	High		
Coronary Angioplasty	High		
Coronary Artery Bypass Graft (CABG)	High		
Excision of mediastinal mass	High		
Hiatus Hernia ( <b>HIGH in infant</b> )		Medium	
Lobectomy	High		
Mitral Valve Replacement (MVR)	High		
Oesophageal Resection	High		
Pneumonectomy	High		
Re-do AVR	High		
Re-do CABG	High		
Re-do MVR	High		
Sternal deformity	High		
Thorabdominal excision retroperitoneal malig tumour	High		
Thoractomy	High		
Thymectomy	High		
<b>Paediatric Cardiac</b>			
Artrial Septal defect ( ASD)	High		
Blalock Shunt ( simple < 6 years old)	High		
Coarctation < 2 years old	High		
Coarctation 2 - 7 years old	High		
Coarctation 8-15 years old	High		
Other Bypass cases ( eg transposition)	High		
Paed ventricular aneurysm	High		
Patent ductus arteriosus (PDA)	High		
Pulmonary artery banding	High		
re-do Blalock for > 6 years old	High		
Re-dos	High		
Unifocalisation	High		
Ventricular septal defect (VSD)	High		
<b>Neurosurgery</b>			
A-V malformations	High		
Craniectomy	High		
Cranioplasty	High		
Craniotomy	High		
Disc Surgery		Medium	
Laminectomy		Medium	
Meningioma	High		
Perpherial Nerve Surgery		Medium	
Posterior fossa exploration	High		
Shunt procedures	High		
Spinal decompression	High		
Vascular ( eg aneurysm)	High		
<b>Orthopaedics</b>			
Acetabular shelf reconstruction		Medium	
Arthroscopy (shoulder/knee)		Medium	
Bone graft from iliac crest		Medium	
Core decompression of hips		Medium	
Foot or ankle surgery			Low
Incision drainage and curettage of tibia & humerus			Low
Internal fiaxtion of tibia or fibula		Medium	
Intramedullary femoral nail		Medium	

Osteotomy (long bone)		Medium	
Pelvic osteotomy		Medium	
Postop tibia reaming for osteomyelitis			Low
Removal of cervical rib		Medium	
Removal of metal work ( including femoral nail)		Medium	
Repair of Fractured neck of Femur		Medium	
Revision of finger fracture			Low
Revision of Total Hip replacement		Medium	
Revision of total knee replacement		Medium	
Scarf osteotomy 1st metatarsal			Low
Scoliosis Surgery	High		
Soft tissue tumour resection		Medium	
Spinal Fusion (simple)		Medium	
Spinal Fusion complex		Medium	
Total Elbow replacement		Medium	
Total Hip replacement		Medium	
Total Knee replacement		Medium	
<b>Urology</b>			
Augmentation cystoplasty		Medium	
Bladder neck surgery		Medium	
Bladder tumour removal		Medium	
Colpal suspension		Medium	
Cystectomy	High		
Cystoscopy urethral dilation		Medium	
Cystourethrectomy		Medium	
Impospadias repair		Medium	
Nephrectomy		Medium	
Nephropylolithotomy		Medium	
Percutaneous nephrolithotomy (PCNL)		Medium	
Prostatectomy -TURP ( <b>HIGH if radical</b> )		Medium	
Pyelolithotomy		Medium	
Renal biopsy			Low
Urethroplasty		Medium	
Urethrolithotomy		Medium	
<b>Obstetrics</b>			
ERPC			Low
Hydatidiform mole		Medium	
Hysterectomy ( abdominal or vaginal)		Medium	
LSCS (Caesarian)		Medium	
LSCS for placenta praevia		Medium	
Myomectomy		Medium	
Pelvic extenteration		Medium	
Radical Oophorectomy		Medium	
Radical Vulvectomy		Medium	
Sterilisation		Medium	
Termination of Pregnancy			Low
<b>Maxillofacial</b>			
Bicoronal flap	High		
Bimaxillary osteotomy		Medium	
Craniofacial Surgery	High		
Microvascular		Medium	
Neck Dissection		Medium	

Parotidectomy		Medium	
<b>ENT</b>			
Adenoidectomy & myringotomy			Low
Adenoidectomy & SMD inferior turbinates			Low
Adenoidectomy & submucous diathremy of interior turbinates			Low
Adenoidectomy			Low
Adenoido-tonsillectomy		Medium	
ENT: insertion of stents			Low
Tonsillectomy		Medium	
<b>Eye Surgery</b>			
Trauma/Reconstruction/Orbital surgery		Medium	
Cataract/Virectomy/Retinal surgery			Low
<b>Miscellaneous</b>			
Dental surgery			Low
Drainage of abscess			Low
Excision burns scars			Low
Excision of lipoma			Low
Excision of lymph nodes			Low
Hernia repair (inguinal/umbilical)			Low
Lymph node biopsy			Low
PICC line insertion			Low
Portocath removal/insertion			Low

## Transfusion Alternatives Preoperatively in Sickle Cell Disease (TAPS) Randomised Controlled Trial

### List of Clinically Important Complications:

#### TRANSFUSION RELATED

**101 Acute haemolytic transfusion reaction:** fever and other symptoms/signs within 24 hours of transfusion. Confirmed by fall in Hb,  $\pm$  rise in LDH, positive crossmatch.\*

**102 Acute hyperhaemolysis:** haemolytic reaction to blood with no evidence of auto allo-Antibody.\*

**103 Febrile non-haemolytic reaction:** rise in temperature of  $> 1.0^{\circ}\text{C} \pm$  rigors, during or within 24 hours of transfusion.

**104 Delayed transfusion reaction:** fever and other symptoms/signs of haemolysis more than 24 hours after transfusion. Confirmed by fall in Hb, rise in bilirubin, positive DAT and new RBC alloantibodies not detectable pre-transfusion Red cell alloimmunisation alone (development of antibody without positive DAT or evidence of haemolysis) are excluded.

**105 Anaphylactic/severe allergic reaction:**

1051 Anaphylactic reaction, severe hypotension with one or more of: rash, respiratory symptoms, oedema and abdominal pain.\*

1052 Severe allergic reaction: a reaction during or within 24 hours of transfusion, characterised by respiratory symptoms, widespread urticaria and/or angioedema.\*

**106 Transfusion related acute lung injury (TRALI):** acute dyspnoea with hypoxia and bilateral pulmonary infiltrates during or within 6 hours of transfusion, not due to circulatory overload or other likely cause.\*

**107 Post transfusion purpura:** Thrombocytopenia typically within 12 days after transfusion of red cells, associated with presence in patient of antibodies directed against HPA systems.\*

**108 Transfusion transmitted infection:** viral, bacterial, prion, parasitic. Confirmed by NHSBT investigations.\*

**109 Graft Versus Host Disease (GVHD):** development of fever, rash, liver dysfunction, diarrhoea and pancytopenia within typically 1-6 weeks of transfusion without apparent cause.\*

**110 Fluid overload:** dyspnoea with signs or left ventricular failure, raised CVP, tachypnoea.

#### SICKLE RELATED

**201 Acute painful crisis:** Pain not of surgical origin lasting longer than 24 hours, (generally affecting bones, joints or muscles, including paralytic ileus) and requiring opioid analgesia. Specifically, only pain for which there is no other explanation and is described by the patient as typical for their sickle cell crisis.

**202 Central Nervous System event:** A decline in neurological status accompanied by neurological findings e.g. seizure, coma, transient ischaemic attack or stroke.

**203 Acute chest syndrome:** A new pulmonary infiltrate associated with respiratory signs and symptoms.\*

**204 Priapism:** Painful penile erection lasting more than 4 hours.\*

**205 Renal Complication:** New renal insufficiency, with an increase in creatinine levels 30% above baseline or more. (if dialysis required then \*)

**301 INFECTION RELATED:** The need for a new prescription for antibiotic treatment. This can mean either a completely new prescription, an increase in dose, or extension of prophylaxis (surgical). (If septic shock then \*)

#### SURGERY RELATED

**Adverse peri-operative events occurring in Operating Room (OR) or post anaesthesia care unit (PACU)/Recovery Room**

**401 Intraoperative blood loss:** Blood loss exceeding 10% of blood volume.

**402 Cardiovascular events:** Cardiac arrest or circulatory insufficiency/de novo myocardial infarction or ischaemia, hypotension or hypertension requiring ongoing treatment, arrhythmias requiring treatment.\*

**403 Respiratory events:** Bronchospasm or laryngospasm/respiratory distress requiring treatment/hypercapnia  $\text{pCO}_2 > 7\text{KpPa}$ /hypoxia  $\text{SpO}_2 < 90\%$ /difficult intubation/oesophageal or endobronchial intubation/pulmonary

oedema.

**404 Others:** Allergic reaction/anaphylactic shock/residual paralysis/drug error/temperature < 35°C or > 38°C, malignant hypothermia.

**Post-operative events related to surgery**

**405 Deep venous thrombosis:** proven by doppler USS or venogram.

**406 Pulmonary embolism:** confirmed by a VQ or CTPA scan.\*

**407 Wound complication:** Wound dehiscence or infection requiring surgical intervention or drainage of pus, or causing prolongation of hospital stay.

**408 Post-operative bleeding:** requiring re-operation or on-going volume replacement in addition to normal maintenance fluids.

**409 Cardiovascular complications:** de novo myocardial infarction or ischaemia/hypotension (requiring intervention)/arrhythmia/cardiogenic pulmonary oedema. **(if septic shock then \*)**.

**410 Gastrointestinal complication:** unable to tolerate enteral feeds > 24 hours post surgery for any reason (including nausea and vomiting or abdominal distension).\*

**\* These events meet the definition of a Serious Adverse Event (SAE) for reporting as both a clinically important complication and an SAE. Other clinically important complication events (eg Acute Painful Crisis) to be reported as SAEs depending on their clinical severity.**