EDITED BY
TJUN TANG
ELIZABETH O'RIORDAN
STEWART WALSH

SECOND EDITION

Cracking the Intercollegiate General Surgery FRCS Viva

A REVISION GUIDE

CRC Press
Taylor & Francis Group

Cracking the Intercollegiate General Surgery FRCS Viva

A Revision Guide

Second Edition

Edited by

Tjun Tang, MD, FRCS(Gen), FAMS
Associate Professor & Senior Consultant
Vascular and Endovascular Surgeon
Department of Vascular Surgery
Singapore General Hospital, Singapore
Duke NUS Graduate Medical School, Singapore

Elizabeth O'Riordan, MBChB, FRCS, PhD, PG Dip (Oncoplastic Surgery)
Retired Consultant Oncoplastic Breast Surgeon

Stewart Walsh, MSc, MCh, FRCS (Gen)
Established Professor of Vascular Surgery &
Consultant Vascular Surgeon
National University of Ireland (NUI)
Galway, Ireland

CRC Press
Taylor & Francis Group
Boca Raton London New York

CRC Press is an imprint of the
Taylor & Francis Group, an **informa** business

Second edition published 2021
by CRC Press
6000 Broken Sound Parkway NW, Suite 300, Boca Raton, FL 33487-2742

and by CRC Press
2 Park Square, Milton Park, Abingdon, Oxon, OX14 4RN

First edition published by CRC Press 2013

CRC Press is an imprint of Taylor & Francis Group, LLC

Library of Congress Cataloging–in–Publication Data
[Insert LoC Data here when available]

ISBN: 9780367565237 (hbk)
ISBN: 9780367179427 (pbk)
ISBN: 9781003098171 (ebk)

For Nicole, the most supportive, loving and understanding wife, and to Ellie and Leo, who give me the greatest joy in life.

Tjun Tang

For Dermot, who has stood by me through everything with unwavering love, support and understanding.

Elizabeth O'Riordan

For Serena, who put up with it all from the beginning.

Stewart Walsh

The most important thing is to try and inspire people so that they can be great in whatever they want to do…We all have self-doubt. You don't deny it, but you also don't capitulate to it. You embrace it…Dedication sees dreams come true.

Kobe Bryant (1978–2020)
NBA basketball player

If you cannot do it, practice until you can do it. If you can do it, then practice till you can do it perfectly. If you can do it perfectly, then practice until you can do it perfectly every time. Efforts do not always result in better performance. But, I don't want any of you to hesitate on trying harder. The mere action of trying hard will benefit your lives. By putting in effort, trying hard in practices, we, as a person and as an athlete, grow to become a better person for the society. Failure or not depends on perspective of people. Failure is not the opposite of success, but a part of it. If you do not fail, you might not notice a lot of things.

Yuzuru Hanyu
Japanese Figure Skater considered the greatest men's singles figure skater of all time
2-time Olympic Champion

Contents

Foreword from the First Edition

This is no question a high hurdle. But it's not something that cannot be done.

Lou Lamoriello

This observation was made about hockey but could equally be applied to the FRCS examination. 'The exit exam' sits in the mind of every surgeon throughout his or her final years of training. It is the last hurdle, the ultimate professional examination on the road to independent practice as a consultant surgeon. It is the surgical profession's final opportunity to ensure that the trainees reach the standards and calibre expected of consultant surgeons in the United Kingdom and Ireland. It was never meant to be straightforward.

For many exit FRCS candidates, it is often a number of years since they have been in an examination situation. Undergraduate and postgraduate medical education has changed radically over the past decade. Increasingly, FRCS candidates may have little or no experience of the 'viva voce' that forms a major component of the exit exam and which was the bread and butter of exams in my day. These examinations seek not only to evaluate the candidate's knowledge of various surgical topics but also to test the candidate's reasoning and decision-making skills through the use of multiple clinical scenarios. Patients are no longer passive recipients of our knowledge and wisdom and come prepared to their consultation armed with information gleaned from the Internet and prepared to interrogate the unwary practitioner. The 'viva voce' is not only an integral part of the examination, but also serves to prepare candidates for life as independent consultant surgeons.

The contributors to this book have all taken and passed the Intercollegiate FRCS in General Surgery in the past 5 years. They have not produced a textbook but instead have sought to provide a guide to approaching the viva for those yet to take the examination. By the time of the exit exam, candidates have many competing pressures compared to the MRCS earlier in training. Families, mortgages and 'getting that job' all add to the stress for candidates. Hopefully, by providing some advice on how to tackle the myriad of topics that may come up in the vivas, this book will go some way towards reducing the stress.

Dr Stansfield, an anatomist at the Royal College of Surgeons, sent my generation of surgeons off to their exams with the rejoinder, 'I don't wish you luck, I wish you justice'; reading this book will ensure justice is delivered.

The Lord Ribeiro Kt, CBE, FRCS

From the Editors

We wish to thank all the new contributors to this book, without whom this project would not have been possible. Surgery has moved forward since our time in training and we have learnt a great deal by embarking on this second journey together. We acknowledge the previous authors to the First Edition who made this adventure possible in the first place. We would like to thank Mervin, a hard-working and conscientious final year medical student from Yong Loo Lin Medical School, Singapore, for helping with the administrative aspects of putting together the second edition. It has been a real team effort and thank you all for giving up your time to help our trainees make it through their most difficult hurdle in their professional career.

As Admiral William H. McRaven said in his 'Make Your Bed' commencement address to new graduates at the University of Texas, Austin, US in 2014:

> *For the boat to make it to its destination, everyone must paddle. You can't change the world alone – you will need some help – and to truly get from your starting point to your destination takes friends, colleagues, the good will of strangers and a strong coxswain to guide them.*
>
> *If you want to change the world, find someone to help you paddle.*

Thank you for paddling together to make this project a reality.

Tjun Tang
Elizabeth O'Riordan
Stewart Walsh

Editors

Tjun Tang, MA, MB, BChir, MD, FRCS(Gen), FAMS, graduated from Queens' College in Cambridge, UK and qualified from Addenbrooke's Hospital, Cambridge in 2000 with a Distinction in Surgery. He was trained on the higher surgical training programme in East Anglia, UK and was awarded his Doctorate of Medicine (MD) by the University of Cambridge in 2009 for research into carotid plaque inflammation. Just after completion of surgical training in late 2012, he was awarded a prestigious Cook British Society of Endovascular Therapy (BSET) fellowship and undertook further endovascular training at Leicester Royal Infirmary, UK followed by a senior postgraduate fellowship at the Prince of Wales Hospital in Sydney, Australia. He has dual accreditation in both general and vascular/endovascular surgery.

After four successful years of practice as a consultant in vascular and endovascular surgery at Changi General Hospital, he took up a post at Singapore General Hospital to focus on building a portfolio of academic vascular and endovascular interests, including international randomised-controlled trials and endovascular device evaluation. He passionately believes that clinical research can only improve the quality of care for his patients. He has active subspecialty clinical interests in diabetic foot salvage, superficial and deep venous surgery and renal access. His research interests focus on endovenous surgery and outcome modelling in vascular surgery and he has published widely on these subjects. He has over 200 peer-reviewed publications. Regionally, he has helped run multiple endovascular lower limb revascularisation workshops, serves as an expert proctor for superficial and deep endovenous surgery devices and is a regularly invited speaker at regional and international vascular meetings. He is a Fellow of both the Royal College of Surgeons of England and Royal College of Physicians and Surgeons of Glasgow and is a MRCS Examiner for the Royal College of Surgeons of England. He serves on a number of editorial boards of peer-reviewed international journals.

Elizabeth O'Riordan, MBChB, PhD, FRCS(Gen), graduated from the University of Wales College of Cardiff in 1998 and did her basic surgical training in South Wales. She spent four years researching the molecular genetics of human thyroid cancer and was awarded a PhD from Cardiff University in 2006. She then moved to East Anglia to complete five years of higher general surgical training before being awarded a prestigious National Oncoplastic Fellowship at the Royal Marsden Hospital, London, in 2011. During her fellowship, she began a postgraduate MS in oncoplastic surgery with the University of East Anglia. Miss O'Riordan was appointed as a consultant oncoplastic breast surgeon at Ipswich Hospital, England, in 2012.

She was diagnosed with breast cancer in 2015, followed by a local recurrence in 2018 which led to her retiring as a surgeon. She now widely publishes and talks internationally

about her experiences as a cancer surgeon and patient. She is the co-author (under her married name of O'Riordan) of *The Complete Guide to Breast Cancer: How to Feel Empowered and Take Control* (Vermilion 2018). She has peer reviewed for the *European Journal of Surgery* and the *British Journal of Surgery.* She is a Fellow of the Royal Colleges of Surgeons of England and Edinburgh.

Stewart Walsh, MSc, MCh, FRCS, is currently the established professor of vascular surgery at NUI Galway, Ireland and a consultant vascular surgeon at Galway University Hospital. He qualified from University College Dublin in 1997. Following basic surgical training in north-west England, he completed a Master of Science degree at the University of Liverpool in 2002 and was appointed as a specialist registrar on the East of England surgical training rotation. From 2005 until 2007, he carried out research work at Addenbrooke's Hospital and the University of Cambridge, leading to a Master of Surgery Degree. After he finished training as a vascular and endovascular surgeon in 2010, he was appointed as associate professor of surgery at the University of Limerick before moving to Galway in 2014.

His research interest focuses on the perioperative care of major vascular surgery patients and the management of venous ulcers, utilising comparative-effectiveness methodology to evaluate current and potential interventions. He has over 150 peer-reviewed journal publications. In 2013, he was appointed as an editor with the Cochrane Peripheral Vascular Diseases Group. He is a Fellow of the Royal College of Surgeons of Edinburgh.

Contributors

Alastair Brookes, FRCS(Gen)
Consultant
Colorectal and Paediatric Surgery
Walsall Manor Hospital
Walsall, United Kingdom

Yiu-Che Chan, MBBS, BSc, MD, FRCS(Eng), FRCS(Gen)
Associate Professor
Division of Vascular and Endovascular Surgery
University of Hong Kong Medical Centre
Hong Kong

Edward Choke, PhD, FRCS(Gen)
Senior Consultant
Vascular & Endovascular Surgery
Sengkang General Hospital
Singapore

Chris Collins, PhD, FRCS(Gen)
Consultant
Department of Upper Gastrointestinal Surgery
Galway University Hospital
Galway, Ireland

Emma E Collins, BMedSci, BMBS, FRCS(Gen)
Consultant
Endocrine Surgery
Leeds Teaching Hospitals NHS Trust
Leeds, United Kingdom

John Davidson, BMedSci, BM, BS, FRCA, DICM, FFICM
Consultant
Anaesthesia and Intensive Care Medicine
Freeman Hospital
Newcastle upon Tyne, United Kingdom

Rebecca Fish, MBChB, BSc, FRCS(Gen), PhD
Honorary Clinical Lecturer and Senior Clinical Fellow
Advanced Laparoscopic and Colorectal Cancer Surgery
Leeds Teaching Hospitals NHS Foundation Trust
Leeds, United Kingdom

Fung Joon Foo, BMedSci(Hons), BMBS(Nottingham), MSc, FRCSEd
Consultant
Colorectal Surgery
Sengkang General Hospital
Singapore

Avinash Gobindram, FRCA, PgCert
Senior Consultant
Department of Anaesthesia and Surgical Intensive Care
Changi General Hospital
Singapore

Brian KP Goh, MBBS, MMed, MSc, FRCSEd, FAMS
Adj Professor and Senior Consultant
Hepato-Pancreato-Biliary and Transplant Surgery
Singapore General Hospital
Singapore

Jennie Grainger, FRCS, DRCOG, MBChB, BSc(Hons)
Consultant
Colorectal and General Surgery
Countess of Chester Hospital
Chester, United Kingdom

Aisling Hogan, MB, BCh, BAO, MD, FRCS(Gen)
Consultant
Department of Colorectal Surgery
University Hospital Galway
Galway, Ireland

London Lucien Ooi Peng Jin, MBBS, MD, FRCSEd, FRCSG, FCSHK(Hon)
Professor and Senior Consultant
Hepato-Pancreato-Biliary and Transplant Surgery
Singapore General Hospital
Singapore

Alex Joseph, MBBS, MD, FRCA
Senior Consultant
Department of Anaesthesia and Surgical Intensive Care
Changi General Hospital
Singapore

Doireann Joyce, MB, BCh, BAO, MRCS, MCh, PhD
Specialist Registrar
Vascular Surgery
Tallaght University Hospital
Dublin, Ireland

Hussein Khambalia, BMBS, PhD, FRCS
Consultant
General and Transplant Surgery
Manchester Royal Infirmary, Manchester Foundation Trust
Manchester, United Kingdom

Thomas Konig, BSc(Hons), MBBS, FRCS(Gen), RAMC
Consultant
General, Vascular and Trauma Surgery
Royal London Hospital, Barts Health NHS Trust
Defence Medical Services
London, United Kingdom

Andrew Clayton Lee, MBBS, MSc, MS, FRCSEd, FAMS
Consultant
Breast & General Surgery
Andrew Lee Breast Clinic
Gleneagles Medical Centre
Singapore

Mervin Nathan Lim HH
Medical Student
Yong Loo Lin School of Medicine
National University of Singapore
Singapore

Aoife Lowery, PhD, FRCS
Associate Professor & Consultant
Breast, Endocrine and General Surgery, Discipline of Surgery
Lambe Institute
National University of Ireland
Galway, Ireland

Frank McDermott, FRCS, MD
Consultant
Colorectal Surgery
Royal Devon & Exeter NHS Foundation Trust
Exeter, United Kingdom

Zia Moinuddin, PhD, FRCS
Consultant
Transplant and Endocrine Surgery
Department of Renal and Pancreas Transplantation
Manchester Royal Infirmary
Manchester, United Kingdom

Animesh JK Patel, MA, MB BChir(Cantab), LLM, FRCS(Plast)
Consultant
Plastic and Reconstructive Surgery
Addenbrooke's Hospital
Cambridge University Hospitals NHS Foundation Trust
Cambridge, United Kingdom

Gaural Patel, MBChB, BA(Hons), FRCS
Consultant
Oncoplastic Breast and General Surgery
Milton Keynes University Hospital, NHS Foundation Trust
Milton Keynes, United Kingdom

Georgina SA Phillips, BSc(Hons), MBBS, MRCS
Registrar
Plastic Surgery
Chelsea and Westminster Hospital
London, United Kingdom

Rajkumar Rajendram, AKC, BSc(Hons), MBBS(Dist), MRCP(UK), EDIC FRCP(Ed), FRCP(Lon)
Consultant
Department of Medicine
King Abdulaziz Medical City
Ministry of National Guard – Health Affairs
Riyadh, Saudi Arabia

Karen Randhawa, MBChB, FRCS (Urol), MFST (Ed), FECSM
Consultant
Urology & Andrology
Altnagelvin Hospital, Western Health & Social Care Trust
Belfast, United Kingdom

Lucy Kate Satherley, BSc, MBBCh, PgCert, PhD, FRCS
Consultant
Breast Surgery
University Hospital Llandough
Cardiff, United Kingdom

Steve Schlichtemeier, MS, FRACS
Visiting Clinical Fellow
Department of Colorectal Surgery
University Hospitals of Derby and Burton NHS Foundation Trust
Derby, United Kingdom

Chelliah R Selvasekar, MD, FRCSEd(Gen), MFSTEd, PgCert(Med Ed), MBA
Consultant
General, Colorectal, Laparoscopic and Robotic Surgery
The Christie NHS Foundation Trust
Manchester, United Kingdom

Choon Sheong Seow, MD, FRCS, FAMS
Adj Professor, Senior Consultant and Director
Colorectal Service
Ng Teng Fong General Hospital
Singapore

Vishal G Shelat, FRCS, FAMS, FEBS, Hesperis Diploma in Organ Transplant(ECOT), MCI(NUS)
Clinical Senior Lecturer and Consultant
Hepato-Pancreato-Biliary Surgery
Tan Tock Seng Hospital
Singapore

CJ Shukla, BSc, MBBS, PhD, FRCS(Ed)
Consultant
Urology
Western General Hospital
Edinburgh, Scotland, United Kingdom

Prit Anand Singh, MBBS, FRCA, EDRA, MSc (Pain Med), FFPMRCA
Consultant
Department of Anaesthesia and Surgical Intensive Care
Changi General Hospital
Singapore

William Speake, DM, FRCS
Consultant
Department of Colorectal Surgery
University Hospitals of Derby and Burton NHS Foundation Trust
Derby, United Kingdom

Paul Sutton, PhD, MRCS
Specialty Trainee
General Surgery
Health Education North West
University of Liverpool
Liverpool, United Kingdom

Yew-Wei Tan, FRCS(Paediatric Surgery)
Consultant
Paediatric Surgery
Evelina London Children's Hospital
Guy's and St Thomas' Hospital NHS Foundation Trust
London, United Kingdom

Tjun Tang, MD, FRCS(Gen), FAMS
Senior Consultant
Vascular and Endovascular Surgery
Singapore General Hospital
Singapore

Nicola C Tanner, MBBS, FRCS(Gen)
Consultant
Department of Upper GI and General Surgery
Northampton General Hospital
Northampton, United Kingdom

Samson Tou, MS, FRCS(Gen), M.MinInvSu
Honorary Associate Professor and Consultant
Colorectal Surgery
University Hospitals of Derby and Burton Foundation Trust
Derby, United Kingdom

Thomas Tsang, FRCS
Honorary Consultant
Paediatric Surgery
Jenny Lind Children's Hospital
Norfolk & Norwich University Hospital
Norwich, United Kingdom

David van Dellen, MD, FRCS(Eng)
Consultant
Transplant and General Surgery
Manchester Royal Infirmary
Manchester, United Kingdom

Colin Walsh, PhD, MRCPI, MRCOG, FRANZCOG
Consultant
Obstetrics & Gynaecology
Royal North Shore Hospital
Sydney, Australia

Stewart Walsh, MSc, MCh, FRCS
Established Professor
Vascular Surgery
National University of Ireland
Galway, Ireland

John Wang, MD, FACS
Senior Consultant
Vascular & Endovascular Surgery
A.V.E Clinic
Mount Elizabeth Medical Centre
Singapore

Julian Wong, FRCS
Senior Consultant & Head
Division of Vascular & Endovascular Surgery
National University Hospital
Singapore

Ting Hway Wong, MB BChir(Cantab), MPH(John Hopkins), FRCSEd
Senior Consultant
General Surgery
Singapore General Hospital
Singapore

Teo Jin Yao, MBBS, FRCSEd, MMed
Consultant
Hepato-Pancreato-Biliary and Transplant Surgery
Singapore General Hospital
Singapore

Contributors from the First Edition

Jithesh Appukutty, MD, MRCA
Department of Anaesthetics
West Suffolk Hospital NHS Trust
Bury St Edmunds, Suffolk, England

Elizabeth Ball, MBChB, PhD, FRCS
Consultant Oncoplastic Breast Surgeon
Ipswich Hospital NHS Trust
Ipswich, Suffolk, England

Amy E Burger, FRCS
Consultant Oncoplastic Surgeon
Queen Elizabeth Hospital King's Lynn NHS Trust
King's Lynn, England

Edward Courtney, MBChB, FRCS
Consultant Colorectal and General Surgeon
Royal United Hospital Bath
Combe Park, Bath, England

John Davidson, BMedSci, BM, BS, FRCA, FFICM
Consultant Intensive Care Medicine and Anaesthesia
Freeman Hospital
Newcastle upon Tyne, England

Sue K Down, PhD, FRCS
Consultant Oncoplastic Breast Surgeon
James Paget University Hospital
Gorleston-on-Sea, Great Yarmouth
Norfolk, England
and
Honorary Senior Lecturer
University of East Anglia
Norwich, England

Naheed Farooq, FRCS, BSc(Hons), PGCME
Senior Upper GI fellow
Cambridge University Hospitals NHS Foundation Trust
Cambridge, England

Saurabh Jamdar, MD, FRCS
Consultant Hepatopancreatobiliary Surgeon
Manchester Royal Infirmary
Manchester, England

Nicole Keong, MPhil, FRCS
Consultant Neurosurgeon
National Neuroscience Institute
Tan Tock Seng Hospital
Singapore

Ashish Lal, FRACS
Consultant General Surgeon
Mid-Western Regional Hospital
Dooradoyle, Limerick, Ireland

Jeffrey Lordan, BSc, MBBS, PhD, FRCS
Post-CCT Fellow in Hepatopancreatobiliary Surgery
Royal Marsden NHS Foundation Trust
London, England

Pankaj Mishra, MRCS, MS, MCh
Clinical Fellow in Paediatric Surgery
Norfolk and Norwich University Hospital NHS Trust
Norwich, England

Zia Moinuddin, MBBS, MRCS
Specialist Trainee (Transplant and General Surgery)
Department of Renal and Pancreas Transplantation
Manchester Royal Infirmary
Manchester, England

Dermot O'Riordan, MBBS, FRCS
Consultant General Surgeon and Medical Director
West Suffolk Hospital NHS Trust
Bury St Edmunds, Suffolk, England

Dimitri Pournaras, PhD, MRCS
Specialist Trainee General Surgery
West Suffolk Hospital NHS Trust
Bury St Edmunds, Suffolk, England

Manel Riera, MD, FRCS
Consultant Upper GI Surgeon
Shrewsbury and Telford Hospital NHS Trust
Shrewsbury, Shropshire, England

CJ Shukla, PhD, FRCS
Consultant Urological Surgeon
Western General Hospital
Edinburgh, Scotland

Vinodkumar Singh, FRCA, MRCP, FFICM, MD
Department of Anaesthetics
West Suffolk Hospital NHS Trust
Bury St Edmunds, Suffolk, England

Rajesh Sivaprakasam, MPhil, FRCS
Locum Consultant Transplant Surgeon
St George's Healthcare NHS Trust
London, England

Tjun Tang, MA (Hons), MD, FRCS
Consultant Vascular Surgeon and Endovascular Surgeon
Changi General Hospital
Singapore

Gillian Tierney, DM, FRCS
Consultant in General Surgery and Coloproctology
Department of Colorectal Surgery
Royal Derby Hospital
Derby, England

Samson Tou, MS, FRCS, M.MinInvSu
Consultant Colorectal Surgeon
Department of Colorectal Surgery
Royal Derby Hospital
Derby, England

Andy Tsang, MD, FRCS
Consultant Upper GI Surgeon
Peterborough and Stamford Hospitals NHS Trust
Peterborough, Cambridgeshire, England

Thomas Tsang, FRCS
Consultant Paediatric Surgeon
Norfolk and Norwich University Hospital NHS Trust
Norwich, England

Janice Tsui, MD, FRCS
Senior Lecturer/Consultant Vascular Surgeon
UCL Division of Surgery and Interventional Science
Royal Free Vascular Unit
London, England

David van Dellen, MD, FRCS
Consultant Transplant and General Surgeon
Department of Renal and Pancreas Transplantation
Manchester Royal Infirmary
Manchester, England

Colin Walsh, PhD, MRCOG, MRCPI
Subspecialty Fellow
National Maternity Hospital
Dublin, Ireland

Stewart Walsh, MSc, MCh, FRCS
Associate Professor of Surgery and Consultant Vascular Surgeon
University Hospital Limerick
Dooradoyle, Limerick, Ireland

Michael Wu, BPharm, BMBS
Vascular Surgery Registrar
Box Hill Hospital
Melbourne, Australia

Introduction

Congratulations on passing the first part of the FRCS exam. This book will guide you through the second part.

STRUCTURE

Section 2 is the clinical component of the examination which takes place over 2 days, and you will be allocated to start with either the clinical or the viva. If you start with the viva, then the clinicals are held on the morning of the second day, and you finish at lunchtime. If you start with the clinical, these are held on the afternoon of the second day, with the vivas on the third day. The format is as follows:

Clinicals:

1 × General Surgery Clinical (2 × 10 minutes cases & 1 × 20 minutes case)

1 × Special Interest Clinical (2 × 10 minutes cases & 1 × 20 minutes case)

Orals:

4 × 30 minutes oral examinations as follows:

1. Emergency Surgery/Trauma/Critical Care Oral (clinical topics with discussion of published evidence supporting practice)
2. General Surgery Principles and Clinical Practice Oral (including applied anatomy, physiology and pathology)
3. Special Interest Surgery – Clinical Practice Oral (clinical topics with discussion of published evidence supporting practice)
4. Special Interest Surgery – Basic principles (applied anatomy, physiology and pathology, 15 min) and Academic Foundation (15 min)* Oral
   (A* Academic Foundation: candidates will be given 30 minutes to read 1 paper in their nominated Special Interest)

Interpretation of radiographs may be included in any of the orals.

The vivas are scored from 4 to 8. A score of 6 is a pass. Both examiners score you for each question. You need to average 6 or more for every question/patient to pass. It is an aggregate score, so you can fail one section but make up for it with a highly scoring question. Beware about getting a score of 4. This could indicate unsafe practice and could lead to you being reported to the Deanery.

To score a 6 and above you need:

6	• The candidate demonstrated competence and confidence in the diagnosis and clinical management of patients	• Competent knowledge and judgement of common problems • Essential points mentioned • Instils confidence • No major errors • Logical approach to difficult problems	• **Q:** Answers competence questions correctly • **A:** Methodical approach to answers; has insight • **P:** Requires minimal prompting	• Appropriate introduction • Appropriate examination of either sex • Considerate examination • Shows respect • Responds to patient/ carer

(*Continued*)

7	• The candidate demonstrated ability and confidence above the level of competence	• Ability to prioritise • Comfortable with difficult problems • Good decision-making/demonstrated good level of higher order thinking/ provided supporting evidence and familiar with literature	• **Q:** Answer difficult questions correctly • **A:** Demonstrates clear thinking process to difficult questions and answers. • **P:** Fluent responses without prompting	• Gains patient confidence quickly • Good awareness of patient's reaction • Puts patient at ease quickly
8	• The candidate demonstrated ability and confidence very significantly above the level of competence	• At ease with higher order thinking • Flawless knowledge plus insight and judgement • Had an understanding of the breadth and depth of the topic, and quoted from literature • High flyer • Strong interpretation/ judgement	• **Q:** Stretches examiners-answers questions at advanced level • **A:** Confident, clear, logical and focused answers • **P:** No prompting necessary	• Exceptional communication/ relationships with patient/carer

Note: [**Q:** questions **A:** answers **P:** prompting]

SURGICAL VIVAS

The first thing to do is to read the ISCP syllabus (https://www.iscp.ac.uk/curriculum/surgical/surgical_syllabus_list.aspx). It is over 300 pages long, and any topic on the syllabus can be covered in the exam. You therefore need a very broad range of knowledge to pass, rather than depth of knowledge.

It is important to prepare early for the exam. You will not be given confirmation of your exam date until 4–6 weeks before, so it is best to have a discussion with your consultant at the start of your placement and medical staffing to allow confirmation of leave at short notice.

Ideally, you should be able to talk for 3–4 minutes on every topic. The examiners only have 5 minutes per question, and some of this will be taken up with them asking the question and you thinking.

The examiners have a list of points to cover for each topic, starting with a very basic level of knowledge for a pass, and then the questions become more difficult, to enable you to score a 7 or an 8.

You are likely to have most of the basic knowledge already just from training as a surgeon and being on call. The level of detail for the most part is MRCS level, but that does include quite detailed physiology for the critical care section.

The key to passing is to answer the questions as a consultant, not as a trainee. Examiners want to know what *YOU* would do if you saw the patient in clinic or on a post-take ward round, or the decision *YOU* would make in an MDT. The answer to every decision-based

question should start with, 'I would…' – NOT 'you could/the options are/my consultant would….' Do not refer every difficult scenario to a colleague. This is a general surgery exam, and you are meant to be able to cope with these things as a consultant. If you were by yourself in a small DGH, what would you actually do to control a difficult laparotomy? You may not have the surgical expertise (e.g. if you are a breast trainee), but you should know the principles of trauma surgery and how to get out of trouble safely. Having said that, you should know when to refer patients out once stabilised e.g. common bile duct injury repair but say who you would refer to and what you would expect them to do.

For the subspecialty vivas, you will need a more detailed level of knowledge. This includes anatomy, physiology, embryology and pathology, as well as NICE (the National Institute for Health and Care Excellence) guidelines, Cochrane reviews, other national guidelines and key papers and trials that have changed practice. You will pick up a lot from your own MDTs, and these meetings are a good time to practise interpreting radiological imaging and become familiar with the current chemotherapy trials.

The examiners are unlikely to give you any feedback during the questioning. This can be difficult, especially if you are used to getting nods and sounds of encouragement from colleagues when practising. You must remember that you can aggregate marks. Therefore, if you have a bad question, take a breath, and start again. You have to be able to pick yourself up. Remember that, with no feedback from the examiners, you may not have done as badly as you think.

There is a definite halo effect, and a good first impression will go a long way. You want to sound and act like a colleague, not a terrified candidate (internal brown trousers, external calm). Dress smartly but comfortably, smile, keep your head up and make eye contact. Take a few seconds to think and to compose your answer before you actually start speaking. Be honest, get to the point (don't waffle) and if you know your subject then carry on without prompting, dropping in evidence e.g. 'based on the CRASH-2 trial I would…'. Present your best practice within your and the NHS's limitations and be your patient's advocate.

We have listed some of the books we found useful in the bibliography. It is not essential to buy the entire Core Companion series. They can be a little out of date by the time they are published. We would recommend reading the *Core Topics in General and Emergency Surgery* book and your own subspecialty book as a starting point. If your institution subscribes to ClinicalKey, they are all on there. However, you will need quite detailed physiology and critical care knowledge, over and above the ATLS (advanced trauma life support) and CCrISP (care of the critically ill surgical patient) manuals. *Life in the Fast Lane* is a good up-to-date and evidence-based website that covers most critical care and trauma scenarios. *Schein's Common Sense Emergency Abdominal Surgery* book is also a must-read to help you through the emergency viva.

APPLIED ANATOMY VIVA

This section applies to the international conjoint examinations where there is a separate surgical anatomy section, but in the intercollegiate exam these type of questions are part of the viva that also includes physiology and pathology.

This section requires you to be able to describe surgical anatomy relevant to most commonly encountered surgical procedures. You might be asked to sketch or draw the anatomy of a specific area (e.g. Calot's triangle for laparoscopic cholecystectomy or the inguinal canal for hernia repair) as a starting point for discussion. You do not need to be an artist for this but it is good to practise drawing the anatomy based on the common surgical procedures. Common follow-on questions will be about what possible

complications can occur and what steps can be taken during surgery to avoid these complications (e.g. for Calot's triangle, it will be to discuss bile duct injuries especially with relation to anatomical variations, and the laparoscopic principles that need to be followed to avoid injury).

ACADEMIC VIVA

This should be one part of the exam when it is relatively easy to score highly, as you have the papers in front of you. You need to practise reading and reviewing a paper in 25 minutes, giving yourself an extra 5 minutes per paper to make notes. You should read the last 6 months' worth of the key journals in your subspecialty.

During the reading time, other candidates may enter and leave the room. You are spaced quite close to the person next to you. Some candidates will be talking to themselves, so you need to get used to working in a noisy room with distractions. You are given pencils, markers and the papers. You can take your own pencils, pens and highlighters in with you. It is also worth taking a watch so that you can more easily keep track of time.

A good starting point is to flick through the paper to see how many tables and graphs you need to analyse. The examiners will have had the papers for a couple of weeks, so they will be a lot more familiar with the data than you are. Then, read the abstract and the conclusions. Often, the author critiques his or her own paper in the discussion and also explains missing patients or data. This can save time flicking back and forth through the methods and results sections looking for excluded patients and the reasons for this. Look for sources of bias and be prepared to explain them. You will naturally develop your own method for reading a paper with practice.

You then need to practise making notes on the paper. Some candidates use red and green pens to highlight good and bad points; others find this distracting and just use a pencil to star the relevant points. Finally, practise giving a 5–10-minute summary of the paper. The list of points to cover is included in the academic section of the book. Some examiners will let you talk for 5–8 minutes without interrupting, whilst others will keep butting in every 30 seconds or so. This can be very distracting because you never get into a rhythm, and you need to practise with colleagues so that you can cope with both examining styles.

The end point to get across is whether the paper would change your own practice. A lot of non-academic surgeons worry about this station the most, but this is purely designed to assess your interpretation of the medical literature and how it applies to your clinical practice. You are not critiquing a paper for a journal club; you are critiquing it as a surgeon reviewing the evidence. You may be asked if you would publish it. And remember that your examiner may have written the paper you are about to critique.

CLINICALS

These stations often scare candidates the most, but currently these should be thought of as mini-vivas. With only 5 minutes to see, examine and talk to a patient, there is not a lot of time to do a full formal examination. Most of the time you will be asked to look at a scar/examine a lump/take a history, and then the examiners will show you scans or start a discussion about the patient's surgical history and proposed treatment. You may also be asked to counsel a patient or consent them for a procedure.

You should be able to interpret basic CT scans of the abdomen and pelvis, MRIs, angiograms, ERCPs, mammograms – the images that you would request during a normal clinic and when on call.

Remember that you may be taken to see patients from other subspecialties in your general exam (that includes breast and transplant patients). It is therefore worth trying to get to a couple of clinics and MDTs outside your own subspecialty in the weeks before the exam to refresh yourself. There are often lots of skin lesions, varicose veins, neck lumps and patients with rare diseases who turn up at every clinical exam. We have listed useful books to read in the bibliography at the back of the book.

HOW TO PASS THE EXAM

Passing this exam is all about technique. People who fail usually do not do so because of lack of knowledge. The exam is a bit like a game, and you need to learn how to play it. As we mentioned earlier, you have to sound like a consultant giving an opinion. It is all very well to quote 10 papers' worth of evidence, but if you cannot make a decision, then you are not ready to become a consultant.

You must also be safe in your answers. When several options are available to treat a patient in your viva, start with the most widely practised option that has the greatest evidence base. You can then talk about new techniques and the pros and cons, but you do not want to come across as a maverick. It is also unwise to get into an argument with your examiner.

Discuss the exam with your consultants. They will be happy to treat post-take ward rounds as viva sessions, and will question you over the operating table. This experience is often invaluable as it gets you used to answering questions in a structured way and vocalising your thoughts. It is worthwhile attending clinics outside your subspecialty to allow you to examine patients with signs that may well come up in the clinical. Your day job can be used as 'mock exams' and provide constant learning opportunities, practising examination technique, concise history taking and communication skills. Arrange viva sessions with other specialties to help with things outside your subspecialty – this may include anaesthetics and intensivists for the critical care viva.

There are several courses available, and if you can afford it, they can be invaluable. It is very helpful to be put under pressure in a viva situation before the exam and to make the mistakes on the course, instead of on the day. It is also useful to hear how other candidates answer questions (write down the questions and key points in the answer) and to see how much you improve over the duration of the course. Courses can book up quite quickly once the Part A results become available. Some will only run at certain times of the year. Course availability will therefore depend on what time of the year you are taking the exam, with some courses only running in January. Book early as some courses have two tiers of training – full participation versus observation only. Masterclass and subspecialty update meetings can be useful to bring you up to date and focus on the latest relevant 'hot' topics.

Keep in touch with candidates in other groups who got asked different questions and practise together or over the internet, e.g. Skype or FaceTime – just organising your thoughts to say an answer out loud is helpful and the person listening can advise on how you come across and whether you miss anything important. Nearer the time organise viva practise with senior trainees who have recently taken their exam. Podcasts can also be a useful revision tool which you can listen to during your commute to work, or when you have a short break in your busy on call. Listening to a topic for 30 minutes can be as useful as reading a book chapter.

This is a selection of available viva revision courses:

- Edinburgh, Scotland – FRCS Viva Preparation Course
- Les Arps, France – Alpine FRCS Course (http://www.surgicalcourses.org.uk/courses/alpine-frcs)
- Liverpool, England – Intensive FRCS Part III Course (https://www.liverpool.ac.uk/translational-medicine/departmentsandgroups/molecular-and-clinical-cancer-medicine/fcrs-course/)
- Llantrisant, Wales – Practice Course for Clinical and Viva Examination in FRCS (Gen Surg)
- London, England – Whipps Cross Higher Surgery Course
- Manchester, England – The Christie FRCS Exit Exam Course in General Surgery

FINAL PREPARATION

Travel in good time of your exam, preferably arriving the day before if possible to avoid stressing on the day. If you can afford it, stay in a nice hotel that is not too far from the exam venue, rather than the cheapest one available. We know that the exam is already expensive before you add on the cost of courses, books and travel. But a decent hotel can make a huge difference to your preparation. Ask the receptionist when you book the hotel to find you a room in a quiet part of the hotel and take earplugs if you are a light sleeper. Tell him or her that you are sitting an important exam. You do not want a room by a lift overlooking the back streets where the nightclubs empty at 1 a.m.

Be aware that if you are staying at the exam venue the examiners will be at breakfast/in the jacuzzi/at the bar so mind what you say!

Pack travel-proof clothes or make sure they are presentable once you've unpacked. Book a taxi in advance to get to the exam venue and make sure it's the right one (some locations use more than one hospital for the clinicals).

On the day of the exam, all candidates will be briefed by the chair of the Intercollegiate Specialty Board in General Surgery. Don't be late to the briefing as they will go through the logistics of how the exam will take place for your sitting, housekeeping issues and when to expect the results. Try and relax. This is your time to show the examiners what you know. Dress for the part. This is your time to shine and show what you know, so dress smartly and comfortably. Try your outfit on prior to the exam to ensure it still fits and that you feel comfortable. For the clinical you will need to be bare below the elbows and use alcohol gel provided, as if on a ward.

On the day, you may find taking music and headphones helps to distract you from hearing other candidates talking whilst you are waiting. However, sometimes it can be helpful to know what questions have been asked of other candidates. Beware though, as not all candidates get the same questions so it may hamper your perception of what the examiners are asking you. Try not to spend your last hour beforehand flicking through books and pages of notes. Everyone does it, but it rarely helps you in the exam.

Smile at the examiners and answer in a structured fashion. Be enthusiastic. The examination hall is noisy and busy. Try not to let this distract you. Speak clearly. You will be given a notebook and pencil which can be used to make notes on the question, or draw diagrams if needed.

It is important to have an opinion on key issues and if possible back those up with evidence from key papers, especially within your subspecialty. Guidelines, landmark papers and position statements are useful to know to back up your answers where possible.

During the clinical, be respectful towards patients and try to establish an early rapport. Introduce yourself properly and remember to say please and thank you. Use alcohol gel before and after patient contact.

The results are usually emailed to you within 2 weeks of the exam. After the exam, candidates often say it's a fair exam and that they feel they weren't asked anything unreasonable. Remember, it's designed for a new consultant starting out and is about patients that could present to your clinic or your on call.

INTERNATIONAL FRCS AND OTHER CONJOINT EXAMINATIONS

Whilst the Intercollegiate Fellowship Exams are the required examination standards for the UK, the Royal Colleges also conduct the International FRCS for those outside the UK, with some Colleges also conducting conjoint examinations with surgical colleges and training authorities in other countries. The structure of these examinations mirror closely the Intercollegiate Examinations with quality assurance provided by the partnering Royal College. The information and tips provided in this book will be useful for candidates sitting for these examinations, but candidates are also advised to check with the relevant Examinations Boards to understand the format of examinations and the requirements necessary to sit for those.

Good luck!

Tjun Tang
Stewart Walsh
Elizabeth O'Riordan
Gaural Patel
Jennie Grainger
Lucien Ooi

Taylor & Francis
Taylor & Francis Group
http://taylorandfrancis.com

1 Academic Viva

Doireann Joyce and Stewart Walsh

ACADEMIC VIVA – HOW TO REVIEW A PAPER

Abstract

- Does the abstract accurately reflect the content of the paper?

Introduction

- Has the background of the study been given appropriately?
- Is the aim of the study clearly stated?
- What was the hypothesis?

Methodology

- Was there selection bias by the authors?
- What patients were excluded from the study?
- Were the patients included in the study representative of the patients encountered in general surgical practice?
- Are the methods appropriate?
- If it is a randomised study, was a power calculation used?
- What information is required to undertake a power calculation?
- Was the end point valid?
- Was the difference sought in the study of clinical relevance?

Results

- Are the results well set out?
- Was statistical analysis appropriate or needed?
- Are all patients accounted for?
- What is type I or type II error?
- What is sensitivity/specificity?
- Can you explain the forest plots/ROC curves?
- Have the results been presented in a biased way?
- Is follow-up adequate?
- Are significant complications excluded from the analysis?

Discussion

- Are the results discussed fairly and compared to what is known in the literature?
- What are the novel observations?
- Are you aware whether the topic is covered in existing guidelines or published papers?
- Are the conclusions supported by the data presented?
- What are the healthcare issues?

Final summary

- You can give this at the beginning or the end, depending on the examining style.
- Summarise it in five or six sentences.
- Pick out the good and bad points.
- Form an opinion – is it good/average/bad?

- Decide whether it will change your practice.
- How would you have designed the study differently?
- If you were the editor, would you publish it?

BASIC STATISTIC DEFINITIONS

Mode

- Most common value in a data set.

Median

- Middle value in a data set.

Mean

- Sum of all values/number of values.

Standard deviation

- Describes degree of data spread about the mean
- square root of the variance (only with parametric data)
- 1 SD = 68% observations; 2 SD = 95% observations.

Standard error (SE)

- Standard deviation (SD) of the sample mean.

Confidence interval (CI)

- Measure uncertainty in measurements.
- Width of the CI = precision of estimate.
- 95% CI = range in which 95% of population lies.
- CI that includes 0 is not significant.
- The larger the sample is, the smaller the variability, and the more likely the results are true.
- When quoted alongside a ratio (e.g. relative risk, odds ratio), an interval including 1 is not significant.
- When comparing two groups, if the CI of each group does not overlap, this is a significant result.

Prevalence

- Proportion of population with disease at a given time point.

Incidence

- Rate of occurrence of new cases over a period of time.

Odds

- Number of times an event is likely to occur/number of times it is likely not to occur.
  - Odds of having a girl = 1/1 = 1

Odds ratio (OR)

- Odds of having the disorder in the experimental group relative to the odds in favour of having the disorder in the control group.
  - OR = 1: no effect
  - OR >1: higher chance of disease in exposed group

Risk

- Probability of something happening.
- Number of times that an event is likely to occur/total number of events possible.
  - Risk of having a girl = 1/2 = 50%

Absolute risk

- Incidence rate of outcome in the group.

Relative risk (RR)

- Experimental absolute risk/control absolute risk:
  - RR = 1 – no risk difference
  - RR >1 – greater risk with the exposed factor
  - RR <1 – factor is protective

Number needed to treat

- Number of subjects that must be treated for one extra person to experience a benefit.

Hazard

- Instantaneous probability of an end point event.
- Degree of increased and decreased risk of a clinical outcome due to a factor.

Hazard ratio

- Comparison of hazard between two groups:
  - >1: Factor increases the chance of the outcome.
  - <1: Factor decreases the chance of the outcome.

Null hypothesis

- Any difference between the study groups is chance.

P-value

- Probability of results given a true null hypothesis.
- <0.05: Result due to chance is less than 1 in 20.
- Threshold for statistical significance.

Type I error (alpha)

- False positive.
- Null hypothesis is rejected when it is true.
- Due to bias, confounding variables.

Type II error (beta)

- False negative.
- Null hypothesis is accepted when it is false.
- Due to a sample size that is too small.

Intention-to-treat analysis

- All the patients are included in the analysis, regardless of whether they completed the study. If not accounted for, it leads to attrition bias.
- Dropouts increase the chance of a type I or II error.

Power

- Ability to detect a true difference in outcome between each arm.
- Probability that a type II error will not occur.
- The larger the sample size, the greater the power.
- Power of 0.8 = 80% probability of finding a significant difference, if one existed, having excluded the role of chance.
- Power = 1 – Type II error (beta – arbitrarily set at 0.2).

Sensitivity

- True-positive rate:
  - Proportion of subjects with the disorder who will have a positive result.
  - SnNout: highly sensitive test – negative result will rule out the disorder.

Specificity

- True-negative rate:
  - Proportion of subjects without the disorder who will have a negative result.
  - SpPin: highly specific test – positive result will rule in the disorder.

Clinical end point

- Measurement of direct outcome (e.g. mortality, disability).

Surrogate end point

- Outcome used as substitute for clinically meaningful end point.
- Believed to be predictive but cannot guarantee relationship.

Composite end point

- Combines several measurements into an algorithm – overcomes underpowering:
  - Primary end point – health parameter measured in all subjects to detect a response to treatment.
  - Secondary end point – other parameters measured in all subjects to help describe effects of treatment.

Validity

- Extent to which a test measures what it is supposed to measure.

Reliability

- How consistent a test is in repeated measurements.

BIAS

Selection bias

- Recruitment of unrepresentative sample population.
- Sampling bias – introduced by researchers.
- Response bias – introduced by study population.

Observation bias

- Result of failure to classify or measure the exposure or outcomes correctly.

Attrition bias

- Number of dropouts differs significantly in the different arms.
- Those left at the end may not be representative of the original study sample.

Confounding factors

- Confounder is associated with exposure but not a consequence of exposure.
- It is also associated with outcome, independent of exposure.
- For example, coffee (exposure), ischaemic heart disease (outcome), smoking (confounder).
- Not due to bias (cannot be created).
- Must be identified so you can take measures to eliminate.
- Control confounding factors with matching and randomisation, and at the time of analysis by stratification, standardisation and statistical adjustment (multivariate analysis).

COHORT STUDIES

What is a cohort study?

- This is an observational study in which a group of people without a certain condition are followed over time to establish the incidence of the condition of interest.
- The study design also allows identification and evaluation of potential risk factors for development of the condition of interest.
- In the hierarchy of evidence, cohort studies lie beneath randomised-controlled trials (RCTs) because they are more vulnerable to bias.
- They are also more likely to be influenced by confounders.
- The cohort is a group of people who share a certain characteristic.
- Three comparison or control groups are possible: the general population, a selected subgroup within the study cohort or a group who has not been exposed to the postulated risk factors for the condition under investigation.
- Cohort studies may be prospective or retrospective.
- The key difference with other study designs is that the exposure status is always assessed before the outcome status.

If randomised trials are superior, what purpose do cohort studies serve?

- Cohort studies are extremely useful as a means of proving a causative link between a putative risk factor and disease.
- The key feature is that the cohort is identified before the development of the disease in question and then followed over time.
- These cohort studies provide strong circumstantial evidence of causality though definitive confirmation may require more focussed experimental trials.
- Prospective cohort studies have the advantage of reducing recall error as data are all collected as the study progresses.

What are the advantages of cohort studies?

- They can clearly demonstrate an appropriate temporal relationship between exposure and disease development.
- This makes it easier to ascribe the outcome to the exposure.
- Cohort studies allow direct estimation of incidence rates in both exposed and unexposed groups.
- Multiple outcomes can be assessed in the same study (e.g. the Million Women Study).
- They provide insight into the latent period or incubation period for communicable and non-communicable diseases.
- They can be used to study exposures that are relatively uncommon.

What are the disadvantages?

- They often need a large sample size to ensure enough cases are captured to allow meaningful analysis, particularly for rarer conditions.
- Long follow-up periods are necessary.
- Frequent re-evaluations of exposure are required.
- Outcomes must be determined as they develop.
- Some of these disadvantages can be offset by using a retrospective cohort design but this is then vulnerable to recall and other biases.
- Portions of the cohort may be lost to follow-up, which may then introduce bias into the results.

- Outcomes may be misdiagnosed or misallocated, particularly if diagnostic criteria or technology changes in the course of the study.
- Outcome assessment is vulnerable to diagnostic suspicion bias (i.e. if the investigator strongly believes that the exposure causes the disease, he or she may be more inclined to reach diagnoses in the exposed population).

CONSORT AND PRISMA

What is the CONSORT statement?

- CONSORT (consolidated standards of reporting trials) is a set of recommendations for papers reporting the results of randomised clinical trials.
- The first version was published in 1996, the latest in 2010.
- The document is regularly updated as new evidence regarding clinical trial design and conduct emerges.
- It provides a framework to evaluate the quality of randomised clinical trials.

What guidance does the statement provide?

- The 2010 version provides a 25-item checklist and a template participant flow diagram.
- The checklist provides guidance for each section of the paper: title, abstract, introduction, methods, results, discussion and other information.
- The current checklist can be downloaded at www.consort-statement.org.

What is the PRISMA statement?

- The PRISMA (preferred reporting items for systematic reviews and meta-analyses) statement is a set of evidence-based guidelines intended to improve the quality of reports of systematic reviews.
- Originally called the QUOROM statement, it was renamed in the 2009 update.
- In addition to providing a guide for researchers undertaking systematic reviews, it can be used as a framework to critique reports of such reviews.
- Like CONSORT, PRISMA provides an itemised checklist providing guidance for each section of the paper together with a template flow diagram to describe the identification and inclusion/exclusion of trials/studies in the review.
- The current checklist can be downloaded at www.prisma-statement.org.

ACADEMIC IMPACT

What ways do you know to evaluate the impact of academic work?

- Can be direct or indirect.
- Direct measures include numbers of citations, impact factor (IF) of journals published in, *h*-index and patents obtained.
- More indirect measures include invitations for expert advice, participation in expert bodies and citations in support of major specialty guidelines.
- Journal IFs and *h*-index are widely used to evaluate individual academic performance but this is very controversial and not recommended by the Higher Education Funding Council for England, the Research Assessment Exercise or the National Science Foundation.

What is an IF?

- IF is used as a measure of a particular journal's relative importance in its field.
- In general, the higher the IF, the more significant the journal.
- The IF is calculated by taking the number of citations obtained by the particular journal in a given year for articles published in the preceding two years and dividing it by the total citable items published during those two years (e.g. citable items published in the *Journal of Hallux Surgery* in 2010 and 2011 were cited 100 times in 2012. There were citable items during 2010 and 2011, therefore the 2012 IF is 2).

How valid is the IF as an index of importance?

- Discipline-dependent as some disciplines tend to cite faster than others; thus, it is unreliable when comparing journals across disciplines.
- It is calculated using an arithmetic mean, which is statistically inappropriate, as citations are not normally distributed, instead tending to be left-skewed.
- Journal rankings based on IF only moderately correlate with journal rankings based on expert survey.
- IF can be influenced by deliberate editorial policies (e.g. publishing the most significant papers early in the year to maximise time to accrue citations).

Are you aware of any other bibliometrics similar to IF?

- Immediacy index is the number of citations in a given year divided by the number of articles published.
- Cited half-life is the median age of articles cited in Journal Citation Reports each year.

What is the *h*-index?

- A simple metric which provides a guide to an individual researcher's impact in their field.
- Calculated by ranking the individual's publications in order of citation counts, starting with the most cited publication.
- The *h*-index is the rank of the paper at which the position in the ranking equals the citation count.
- For example, Dr Smith has 50 publications with citation counts ranging from 0 to 30. Ranked in order of citation count, Dr Smith's first 19 publications have citation counts of 30 each, paper 20 in the ranking has a citation count of 20 while paper 21 in the ranking has a citation count of 19. Dr Smith's *h*-index is 20.
- It provides a measure of both the number of publications and the number of times each has been cited.
- Does not necessarily reflect the quality of the work.
- Can be influenced by factors such as multiple authorship, career stage and excessive self-citation.

LEVELS OF EVIDENCE

What are levels of evidence?

- Levels of evidence are widely used to provide an index of the strength of evidence for a particular recommendation in evidence-based medicine.

- Differing levels are defined for evidence of interventions and evidence of diagnostic ability.
- The Oxford taxonomy is commonly used for studies of interventions.

Can you outline the Oxford system for studies of interventions?

- 1a Systematic reviews (with homogeneity) of randomised clinical trials
- 1b High-quality individual RCTs with narrow CIs
- 1c All-or-none RCTs
- 2a Systematic reviews (with homogeneity) of cohort studies
- 2b Individual cohort study or low-quality RCTs
- 2c Outcomes research and ecology studies
- 3a Systematic reviews (with homogeneity) of case–control studies
- 3b Individual case–control study
- 4 Case series, poor-quality cohort or poor-quality case–control studies
- 5 Expert opinion

Do you know of any alternatives?

- The National Institute for Health and Care Excellence (NICE) and the Scottish Intercollegiate Guidelines Network (SIGN) recommend an alternative classification.
- The advantage of this system is that it provides guidance as to which levels of evidence should not be used to form the basis of a recommendation.
- Levels are ranked from 1 to 4 with various sublevels.

Can you explain the SIGN system?

- 1++: High-quality meta-analyses, systematic reviews of RCTs or RCTs with a very low risk of bias
- 1+: Well-conducted meta-analyses, systematic reviews of RCTs or RCTs with a low risk of bias
- 1−: Meta-analyses, systematic reviews of RCTs or RCTs with a high risk of bias (should not be used as a basis for a recommendation)
- 2++: High-quality systematic reviews of case–control or cohort studies; high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high likelihood that the relationship is causal
- 2+: Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
- 2−: Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal (should not be used as the basis for a recommendation)
- 3: Non-analytic studies (e.g. case series, case reports)
- 4: Expert opinion, formal consensus

META-ANALYSIS

What is a meta-analysis?

- The Cochrane collaboration defines meta-analysis as the use of statistical methods to combine results of individual studies.

- Meta-analysis allows investigators to determine a more precise estimate of treatment effect.
- Meta-analysis is applied to studies of interventions, most often RCTs.
- Meta-analytical techniques may also be applied to studies of diagnostic techniques and epidemiological studies.[1]

What is a systematic review?

- A systemic review is a secondary research study in which a literature review is conducted according to a strict protocol in order to identify all studies relevant to the question under consideration.
- They often include attempts to identify and obtain data from unpublished studies relevant to the question at hand.
- Rigorous inclusion and exclusion criteria are applied in order to ensure that no selection bias occurs with respect to study eligibility.
- They should be conducted in accordance with the current PRISMA guidelines (www.prisma-statement.org).

Do systematic reviews and meta-analyses provide a high level of evidence?

- Systematic review and meta-analysis of high-quality, homogenous RCTs currently constitute the pinnacle of the hierarchy of evidence, ranked as level 1a evidence in the Oxford taxonomy.

What elements comprise a good systematic review/meta-analysis?

- It should have a well-constructed, relevant, clinical question, ideally expressed in PICO terms: population, intervention, controls and outcomes.
- Objective inclusion and exclusion criteria should be defined at the outset.
- The key outcomes should also be explicitly defined in the review protocol.
- The review should use a structured search strategy in order to identify all relevant studies, ideally both published and unpublished.
- Where necessary, efforts should be made to obtain missing but relevant data from published papers to avoid propagating publication bias.
- Data should be extracted by two or more observers independently using a prepared extraction pro forma.
- An assessment of the validity of the eligible studies must be included.
- Outcome measures should be standardised and defined in advance.

Do you know any commonly used pooled outcome measures in meta-analyses?

- Continuous variables (e.g. length of stay) are usually pooled in the form of a weighted mean difference.
- Categorical variables (e.g. death) are often combined in the form of a pooled odds ratio for intervention studies and a risk ratio or relative risk for epidemiological studies.

What are the advantages of meta-analysis compared to traditional literature reviews?

- Meta-analysis controls for between-study variation.
- The result can be generalised to the study population.
- It allows an evaluation of whether bias exists in the literature.
- It has greater statistical power to detect an effect than a single study would.

- It provides a more reliable synthesis of the available literature, allowing clinicians to cope with information overload.
- By combining results from several studies, it is less likely to be influenced by local factors peculiar to single institutions.

Are there any disadvantages to meta-analyses?

- Pooling results from several small studies may not reliably predict the results of a single large study. Some meta-analyses have later been contradicted by large, well-conducted RCTs.
- If the source studies are poorly designed, the meta-analysis will produce unreliable results.
- They are vulnerable to publication- and agenda-driven bias.

What is publication bias and how is it tested for?

- Studies with positive results are more likely to be published than those with negative results.
- Consequently, meta-analyses restricted to published studies only may produce an exaggerated effect-size estimate as the unpublished studies with negative results are missing.
- Publication or other bias is detected using a funnel plot.
- A funnel plot exploits the observation that in small studies, effect-size estimates should vary quite a lot while, in larger studies, the variability should be much less.
- Consequently, a plot of effect-size estimate against sample size would be expected to form an inverted funnel.
- An asymmetric funnel suggests an absence of studies, usually small, negative studies.
- This is usually due to publication bias, though it could also arise from selection or agenda-driven bias on the part of the meta-analysts.

Why do a meta-analysis? Why not simply add up the results of all the individual studies?

- This is known as the pooling participants approach and is not considered a valid approach.
- Mixing participants from different studies and calculating a simple effect-size estimate negates the effects of randomisation.
- It also gives equal weighting to all results, rather than taking account of more precise results from larger studies.
- A meta-analysis avoids these pitfalls by calculating an effect-size estimate for each individual study and then assigning a weight to each study based upon the sample size to generate an overall summary effect-size estimate.

Can you explain how to interpret a forest plot?

- Meta-analysis data are presented in a format called a forest plot or meta-view.
- On the left side of the plot, the studies that are included in the analysis are listed along with the year in which they were published or a reference.
- The next column usually shows the number of patients that were involved in the treatment group or control group.

- The area on the right shows the results. The central line is known as the line of no effect, where there was no difference in outcome between treatment and placebo groups.
- Anything on the left of this line (unity) favours treatment, anything to the right favours control.
- Each study is shown by the point estimate of the odds ratio, which is represented by a square proportional to the weight of the study, and a 95% confidence interval for risk ratio, represented by extending lines.
- The summary odds ratio and 95% confidence intervals by random effects calculations are represented by a diamond.

What is the difference between fixed effects and random effects models in a meta-analysis?

- The random effects assumption is that the individual-specific effects are uncorrelated with the independent variables. The fixed effects assumption is that the individual-specific effects are correlated with the independent variables.

PARAMETRIC AND NON-PARAMETRIC STATISTICAL TESTS

What are parametric tests?

- They are based on assumptions about the shape of the distribution and form of distribution of the characteristic being tested in the population.
- Parametric tests require the population characteristics to have a normal (i.e. Gaussian) distribution.
- An example of a simple parametric test would be the Student's *t*-test.

What are non-parametric tests?

- These tests do not rely on assumptions about the distribution of the characteristic in the underlying population.
- There is less scope for erroneous or improper use of non-parametric tests compared to the parametric equivalents.
- An example of a simple non-parametric test is the Mann–Whitney *U*-test.
- Non-parametric tests can be used to compare inherently subjective data (e.g. pain scores).
- Non-parametric tests are widely used to study data that take on a ranked order (e.g. patient preferences regarding four different types of postoperative analgesia).

Why not always just use a non-parametric test, if it makes no assumptions about the underlying data?

- Non-parametric tests have two drawbacks compared to their parametric equivalents.
- Firstly, they are less statistically powerful, which means that there is a smaller probability that the test will tell us that two variables are related when they are, in fact, related to each other.
    - Consequently, non-parametric tests require a slightly larger sample size to achieve the same power as their parametric equivalents.
- The other main drawback is that results of non-parametric tests are less easy to interpret.

TABLE 1.1
Statistical Tests Used to Analyse a Given Data Set

	Categorical	Non-normal Compare median	Normal Compare mean
One sample	Chi^2	Wilcoxon's signed-rank test	One-sample *t*-test
Two groups, unpaired	Chi^2 (unpaired)	Mann–Whitney	*t*-test
Two groups, paired	McNemar's test	Wilcoxon's matched pairs	*t*-test
More than two groups, unpaired	Chi^2	Kruskal–Wallis ANOVA	ANOVA
More than two groups, paired	McNemar's test	Friedman's test	ANOVA

Abbreviation: ANOVA, analysis of variance.

- They also tend to rely on ranking the values in the data set rather than using the actual data.

What tests should be used for categorical, non-normal and normal data?

- See Table 1.1.

POWER

What do you understand by the term 'power' in medical studies?

- It is the measure of the ability of the study findings to conclude that an observed effect really occurred, rather than simply being the result of inaccurate observations or experimental error.
- It is related to the sample size. Generally, the larger the sample size is, the greater the study's power to detect increasingly small differences.
- Large studies may detect small differences that reach statistical significance but are of dubious clinical significance.

Explain the difference between clinical and statistical significance.

- Statistical significance indicates that the study findings are not likely to have occurred by chance alone.
- This differs from clinical significance, which is the clinical importance or meaning of the findings.
- Large studies may find tiny differences between patient groups that reach statistical significance but are unlikely to have any great clinical significance.
- Conversely, small studies may identify large clinical differences between patient groups that fail to reach statistical significance, but would be of great clinical importance if true, warranting further, larger studies with adequate power.

How do you undertake a power calculation for an RCT?

- This should involve assistance from an experienced clinical trials statistician.

- Realistic data regarding the proportion of patients with the outcome of interest in the control group will be required as a baseline.
- An assumption then has to be made about the expected effect size of the intervention under investigation.
- Generally, the larger the effect-size estimate is, the smaller the number of patients required in each arm of the trial.
- However, large effect sizes may be unrealistic.
- This, in turn, may result in the incorrect conclusion that the intervention has no effect.
- Numbers needed in each arm of the trial are determined using precalculated tables for the common statistical tests.

What do you understand by the term *stratification*?

- Stratification is a method of ensuring an equal distribution of key confounding factors between the arms of a randomised trial.
- It avoids relying on chance to produce an even distribution of these key confounders.
- Stratification is particularly useful in small trials, which are particularly vulnerable to an uneven distribution of key confounders occurring by chance.
- For example, in a pilot trial of vitamin C for prevention of contrast-induced nephropathy, participants were stratified according to baseline eGFR <60 or >60 (i.e. baseline renal impairment). Separate randomisation schedules were prepared for each of these two groups to ensure that they were evenly distributed between the arms of the trial.

RANDOMISATION

What is an RCT?

- This type of study design permits comparison of two or more possible interventions.
- Participants enrolled in the study are randomly allocated to one or the other treatment arm.
- Apart from the intervention being tested, all other care received by the participants should be intrinsic to the treatments being studied.
- Properly conducted and reported RCTs provide level 1b evidence of treatment efficacy.

What are the advantages and disadvantages of randomised trials?

- A key advantage is that randomisation should minimise the risk of introducing bias, especially allocation bias, into the study by balancing both known and unknown prognostic factors between the arms of the trial.
- Properly conducted trials have high internal validity (i.e. a causal relationship between two variables is demonstrated).
- A causal relationship can be inferred provided that the supposed cause precedes effect in time, the cause and effect are related and there is no other potential explanation for the observed cause–effect relationship.
- The results of RCTs can be combined in systematic reviews to provide level 1a evidence of a treatment's efficacy, thus guiding healthcare policy.
- While internal validity is often very good, external validity is often limited.
- External validity is the extent to which the trial findings can be applied outside the setting of the actual trial (i.e. the generalisability of the trial findings).

- The external validity may be affected by the physical location of the trial, exclusion criteria that render the trial population different or more selected than the general population, the use of outcome measures infrequently used in clinical practice and inadequate adverse event reporting.
- Time and cost are two other frequent limitations. The time taken to conduct a good-quality trial often renders the results of limited interest as medical technology has progressed in the time taken to perform the trial. Large-scale trials are expensive to run.
- It is often difficult to continue trials for the time necessary to obtain long-term follow-up data.
- Trials often tend to focus on one narrow area of the patient's condition and thus may not be reflective of a complex medical situation.

What are the different phases of randomised trials?

- Randomised trials may be conducted at various phases in the translational cycle of a new intervention.
- **Phase 0** trials are exploratory, first-in-human trials, usually with a small number of participants (typically less than a dozen). Phase 0 trials are used in drug development to test new compounds at an early stage using subtherapeutic doses to see if the drug behaves in humans as expected from preclinical studies.
- **Phase 1** trials aim to determine primarily whether an intervention is safe and also whether it has any beneficial effect. They usually involve between 20 and 100 healthy volunteers.
- **Phase 2** trials are conducted in larger groups of up to about 300 patients after safety has been established in a phase 1 trial. A **phase 2A** trial aims to establish dosing requirements whilst a **phase 2B** study aims to establish efficacy.
- **Phase 3** trials are large, multicentre RCTs which aim to evaluate the efficacy of a new intervention in clinical practice. They are complex, expensive and time consuming but provide robust evidence of efficacy.
- **Phase 4** trials are conducted after an intervention has been licensed for routine clinical use. They are also referred to as post-marketing surveillance.

What do you understand by intention to treat as opposed to per-protocol analysis in a randomised trial?

- Intention-to-treat analysis is a comparison of the treatment groups that includes all patients as originally allocated after randomisation.
- This is the recommended method in superiority trials to avoid any bias.
- Per-protocol analysis is a comparison of treatment groups that includes only those patients who completed the treatment originally allocated. If done alone, this analysis leads to bias.
- In non-inferiority trials, both intention-to-treat and per-protocol analysis are recommended. Both approaches should support non-inferiority.

RANDOMISATION TECHNIQUES

What types of randomised trials are you aware of?

- Randomised trials may be classified by trial design, of which there are four main types:

- In parallel-group trials, participants are randomly assigned to a group and all members of that group then receive or do not receive an intervention.
- In crossover trials, each participant receives the intervention then does not receive the intervention in a random sequence over time.
- Factorial trials are used when there are several elements to the intervention under investigation. Participants are randomly assigned to groups with differing combinations of the intervention elements.
- In a cluster trial, pre-existing groups of participants are randomised en masse to receive one intervention or another (e.g. entire wards are randomised to use a new or old type of hand-wash).

What methods are available to randomise patients taking part in trials?

Randomisation may be simple, restricted or adaptive.

- *Simple randomisation* is commonly used. It is similar to coin tossing and is good at avoiding selection bias. The main disadvantage is that it may result in an imbalanced distribution of key confounders, particularly in small trials. Generally, simple randomisation is used only in trials with a planned recruitment of >200 participants.
- *Restricted randomisation* is used in smaller trials. This may include block sizes with specified randomisation ratios (e.g. blocks of eight participants with a 3:1 ratio would lead to six participants being assigned to one arm and two to the other). Restricted randomisation is often combined with stratification, in which separate randomisation schedules are prepared for use in participants according to the presence or absence of a key confounding variable (e.g. diabetes in studies of contrast nephropathy).
- *Random allocation* is a special type of restricted randomisation in which entire blocks of patients are allocated to one or an other arm of the trial. The major disadvantage is that it can lead to loss of allocation concealment and subsequent selection bias unless multiple random block sizes are used.
- *Adaptive randomisation* is used relatively infrequently. The most common example is randomisation by minimisation. With this approach, the chance of a participant receiving a certain treatment varies depending upon the allocation of the preceding treatment. It is another method of ensuring an even distribution of key potential confounders in small trials. However, it suffers from the disadvantage that only the first allocation is truly random and as time goes on it becomes vulnerable to selection bias.

What is allocation concealment?

- Allocation concealment refers to the procedures used to ensure that the trial assignment of the next recruited participant remains unknown before successful recruitment of the patient.
- Successful allocation concealment is considered critical to minimising selection bias in the trial.
- Various methods are available including sequentially numbered opaque sealed envelopes, sealed containers, pharmacy randomisation or central randomisation.
- Ideally, randomisation should be undertaken by a third party not involved in the recruitment or care of the patient. This helps preserve allocation concealment.

How does allocation concealment differ from blinding?

- *Allocation concealment* is the method used to prevent clinicians working out the trial allocation of the next participant, thus influencing their decision as to whether or not to recruit the next eligible patient.
- *Blinding* refers to the intervention under investigation. In a blinded study, combinations of the clinicians, patients and outcome assessors are unaware of whether the patient has received one intervention or another.
- *Allocation concealment* should always be used but blinding is often not feasible or possible.

REGRESSION ANALYSIS

What is meant by regression analysis?

- A statistical technique which aims to model the relationship between multiple variables.
- In medicine, it is most often used to identify and control for the effect of possible confounding variables in an experiment.
- It is frequently applied in case series aiming to compare non-randomised cohorts.
- Occasionally, it is used in randomised trials if random chance has created an imbalance in key confounders, though this is unlikely in large, properly designed trials.
- Regression analysis may also be used for prediction and is essential in the development of risk prediction models in surgery such as POSSUM and VBHOM.

What types of regression analysis do you know?

- Linear regression – the dependent variable (the outcome) is continuous.
- For example, a cohort of vascular surgery patients receives aspirin, clopidogrel or dipyridamole preoperatively and we wish to determine whether any of the three increase blood loss measured in millilitres.
- Linear regression using the amount of blood loss as the dependent variable will evaluate the possible effect of each of the three antiplatelets on blood loss.
- Logistic regression – the dependent variable is categorical (i.e. a yes or no variable).
- If the data held on blood loss in our vascular surgery cohort were simply recorded as >1 l or <1 l, logistic regression would be used to evaluate the influence of the different antiplatelets.
- Cox regression – the influence of multiple variables on survival is evaluated.
- Cox regression is generally only used under the expert guidance of a statistician as it relies upon multiple complex assumptions.

What are the limitations of regression?

- It is based upon assumptions about which variables should be entered at the start. Incorrect assumptions will lead to flawed models and the selection criteria for including/deleting variables, especially in stepwise models, are controversial.
- In surgical series, the models are often applied to small cohorts. The models then lack sufficient power to tease out the relationship between competing variables, which are erroneously determined to be 'independent' of each other.

- As a rule of thumb, in order to construct an adequately powered model, there should be at least 10 patients with the outcome of interest for each of the candidate variables entered into the model. For example, if you read a report of a regression analysis of factors influencing complications following colorectal surgery, 10 variables were entered into the model but there were only 50 patients with a complication. The model is likely to be underpowered.

ROC CURVES

What are ROC curves?

- They are receiver operating characteristic curves.
- An ROC curve is a graphical plot which illustrates the performance of a test as its threshold of discrimination varies. The test must have a threshold value above which a positive result is returned, and vice versa.
- The curve is generated by plotting the fraction of true positives out of all the positives against the fraction of false positives out of the negatives at various thresholds.
- It is a trade-off between sensitivity and specificity.

How do you interpret ROC curves?

- The ROC curve is drawn based on the true-positive rate and false-positive rate.
- The best possible prediction method would have a sensitivity of 100% (i.e. no false negatives) and 100% specificity (i.e. no false positives).
- This would be plotted on the curve as coordinates 0,1, which would lie in the upper left corner of the ROC space.
- The better the test is, the closer it will lie to the upper left corner of the ROC space.
- A test that is performing no better than random chance will yield a point along a diagonal line running from the bottom left to the top right of the ROC space. This is called the line of non-significance.

What does the area under the curve (AUC) mean?

- The area under the ROC curve is a summary statistic that is used to summarise the performance of the test at various thresholds.
- A perfect test would have an AUC of 1.0 but, in reality, this is never attained.
- A poorly performing test would have an AUC of 0.5 or less.
- The AUC is sometimes also referred to as the c-statistic.
- In medicine, a test with a c-statistic of 0.8 or greater is considered to have good discrimination.
- Values of 0.6−0.8 are considered to indicate moderate discrimination and anything below 0.6 is poorly discriminating.

SCREENING TESTS

What is screening?

- Screening is a population-based strategy which aims to identify disease before it is clinically obvious, thus allowing earlier and hopefully more effective treatment.
- The overall aim is to reduce disease-related mortality.
- Screening tests differ from other tests in that they are generally performed in apparently healthy people.

What criteria need to be fulfilled to justify a screening test?

- A test must be available with reasonable sensitivity.
- A test must be available with reasonable specificity.
- The disease must be a significant public health problem (i.e. sufficiently common to justify screening).
- The test must be acceptable to the population at large (i.e. not overly invasive or inconvenient).
- The test must carry minimal risks.
- The test should be economically viable.
- An effective treatment must be available for the target disease of the screening exercise. It is probably not ethical to screen for incurable disease.
- There should be a latent period between the establishment of the disease process and clinical presentation.
- Sufficient facilities and resources must exist to allow treatment of those individuals who screen positive for the disease under consideration.

What types of screening do you know?

- Broadly, there are two types of screening:
  - *Universal* screening screens an entire population defined by a certain characteristic (e.g. all men between 65 and 67 years of age for abdominal aortic aneurysm).
  - *Case selection* is more focused screening in which only members of the population with certain risk factors are selected for screening (e.g. all men between 65 and 67 years of age with a smoking history for abdominal aortic aneurysm).

Explain what is meant by sensitivity and specificity.

- Sensitivity provides a measure of the proportion of a group with a condition that the test detects as positive (e.g. clinical examination for abdominal aortic aneurysms is positive in about 50% of patients with an aneurysm, therefore clinical examination has a sensitivity of 50%).
- Sensitivity is calculated by dividing the number of true positives (number of patients with a positive test and a positive condition) by the sum of the true positives plus the false negatives (number of patients with a negative test but positive condition).
- Specificity is a measure of the ability of a test to correctly classify an individual as disease-free.
- Specificity is calculated by dividing the number of true negatives by the true negatives plus the false positives.
- Note that sensitivity does not take account of indeterminate test results.
- Sensitivity relates to the ability of a test to detect positive results.
- Specificity relates to the ability of a test to detect negative results.

What are the disadvantages of screening?

- There is a risk of false positives (i.e. the screening test suggests the person has the disease when he or she actually does not). This may lead to unnecessary anxiety or treatment.

- Conversely, there is a risk of false negatives (i.e. the test fails to detect the disease in a person with the condition), resulting in misplaced reassurance and possibly delayed treatment.
- Screening exposes large numbers of people to tests who ultimately do not require any form of treatment.
- If the disease detected is at an advanced, incurable stage, the screening simply prolongs stress and anxiety without affecting the ultimate prognosis.

STATISTICAL ERROR

What are the types of statistical error?

- There are type 1 and 2 errors.
- Statistical testing depends upon a null hypothesis which the test aims to accept or reject (e.g. blue-eyed men are no more likely than brown-eyed men to have abdominal aortic aneurysms).
- Type 1 and 2 errors can occur if the null hypothesis is erroneously accepted or rejected.

What is meant by a type 1 error?

- When the null hypothesis is actually true but is accidentally rejected, this results in an erroneous conclusion. In the example of the blue-eyed and brown-eyed men, a type 1 error would involve a conclusion that eye colour did influence AAA risk when, in fact, no such relationship exists.
- In simple terms, a type 1 error occurs when we fail to recognise a falsehood.
- The rate of type 1 errors usually equals the significance level of the test.
- At the 5% significance level, the investigator accepts that 1 in 20 tests will result in an erroneous rejection of the null hypothesis.

What is meant by a type 2 error?

- A type 2 error occurs when the null hypothesis is false but is not rejected. In the example of eye colour and AAA risk, a type 2 error would occur if there was, in fact, a connection between blue eyes and AAA risk but the null hypothesis (that no such relationship exists) was not rejected.
- In simple terms, type 2 errors occur when we fail to recognise the truth.
- The rate of type 2 errors relates to the power of the test.
- A statistical test can either reject a null hypothesis (i.e. prove it to be false) or fail to reject a null hypothesis (i.e. not prove it to be false). However, a statistical test can never prove the null hypothesis to be true.

What is a type 3 error?

- A type 3 error is said to occur when the null hypothesis is correctly rejected, but the effect is attributed to the wrong cause.
- For example, the null hypothesis regarding eye colour and AAA is correctly rejected but the investigators incorrectly attribute the difference to eye colour when, in fact, another difference (e.g. smoking) exists between the groups.

How can you avoid type 1 errors?

- Reducing the amount of acceptable error reduces the chances of a type 1 error.
- Type 1 errors tend to be viewed as more serious than type 2 and thus more important to avoid.

- In practice, reducing the chance of a type 1 error means reducing the level at which significance is assumed from 5% to 1% or lower.
- Reducing the risk of a type 1 error does involve a converse increase in the risk of a type 2 error.

SUBGROUP ANALYSES

What is a subgroup analysis?

- Subgroup analysis is the term applied to searching for a pattern within a subset of subjects in a study. It may be encountered in every study design but tends to be seen most frequently in large randomised trials.
- Large studies aim to assess general, representative patient populations, but clinical decision-making often relies on individual patient characteristics, thus providing an impetus for analysis of particular subgroups with particular characteristics of interest.
- The broad aim is to determine whether the treatment effect observed in the whole trial population differs in magnitude in selected subsets of interest.
- Ethically, such analysis can be justified as identifying patient subsets who are unlikely to benefit and may suffer harm as a result of an intervention that, in their case, is likely to be futile.
- Conversely, it may allow for the identification of patients in whom a particular treatment may be beneficial, despite failing to demonstrate a significant benefit in the principle trial.
- The term is used equivocally, sometimes referring to analysis of effect-size estimates within subgroups (subgroup analysis) or between subgroups (interaction analysis).[2]

How would you assess the quality of a subgroup analysis?

- Use DARA: design, analysis, reporting, applicability.
- Design: Is there a rational indication for the subgroup analysis, was it predefined or suggested post hoc, was the subgroup small, did the original power calculation take account of subgroup analysis, was randomisation stratified for subgroup variables and were subgroup definitions based on pre-randomisation patient characteristics?
- Analysis: Were interaction tests used, were the tests adjusted to account for multiple comparisons and were the subgroups checked for an even distribution of prognostic factors?
- Reporting: Did the authors report all the subgroup analyses or just a few, does the overall discussion remain largely focused on the overall treatment effect or is there undue emphasis on particular subgroups, are the subgroup analyses reported as relative risk reductions?
- Applicability: Is the observed subgroup effect clinically relevant, is it observed consistently across other similar studies?

What problems can you think of with subgroup analyses?

- Sometimes they are performed and designed post hoc, when the main trial has not yielded the expected or desired result. This may lead to distortions in the trial manuscript, as authors emphasise the subgroup analyses and gloss over the main results.

- They are often underpowered and can be vulnerable to type 2 errors, resulting in erroneous conclusions about treatment efficacy.
- If the subgroup analysis was not planned from the outset, and randomisation possibly stratified accordingly, there may be an imbalance of key prognostic factors between the subgroups, resulting in faulty conclusions about treatment effects.

SURVIVAL ANALYSIS

What is survival analysis?

- Survival analysis is a branch of statistics which considers comparisons of time-to-event data.
- It can be applied to any event but is frequently encountered in the analysis of time to death or recurrence in cancer patients.
- The analysis depends on well-defined events occurring at specific times.
- Generally, survival analysis can only be applied to events which only occur once.

What is censoring?

- Censoring is a technique used in survival analysis to account for missing data.
- If the occurrence of the event of interest is not known for a particular participant in the analysis, his or her data are censored at the date of last contact.

What is a Kaplan–Meier curve?

- A Kaplan–Meier curve is a form of survival analysis widely used in medical research.
- It can be used to measure the fraction of patients living a certain time following treatment (overall survival).
- It may also be used to measure time to the development of a particular study end point such as disease recurrence (disease-free or recurrence-free survival) or progression (progression-free survival).
- A key advantage is that the technique can take account of patients who are censored due to losses to follow-up.
- By convention, censored patients are indicated by a tick on the plot at the time point at which they were censored.[3]

How do you compare two Kaplan–Meier curves?

- The curves are often compared using the log-rank test.
- This is a non-parametric test which is used when the data are skewed (often the case in survival data) and when some data are censored.
- If there are no censored data (unlikely in medical research), the Wilcoxon rank-sum test can be used as an alternative.
- The test involves computing the expected and observed events in each group at each observed event time.
- The log-rank test gives equal weight to each event regardless of when it happened; the Peto test applies a greater weighting to earlier events.

What information should be presented with Kaplan–Meier curves to allow adequate interpretation?

- Definition of patients (T-stage, treatment groups, etc.) and study groups with dates of enrolment.

- The actual number of patients in each group at the start of the analysis together with revised numbers at reasonable time intervals along the curves. These numbers should be presented with 95% confidence intervals.
- Definitions of events and censoring.
- Median follow-up time and method of calculation.
- Numbers of missing data and losses to follow-up in each group, together with information on how these issues were handled.
- Results of a test statistic (e.g. log-rank test if appropriate).

How far should the plot extend?

- Theoretically, the plot can extend as far as the last point of contact with the last patient, but this results in wide confidence intervals and consequently much uncertainty at the far right of the plot due to small numbers.
- Conventionally, the plot should be curtailed when <20% of patients remain under follow-up.

REFERENCES

1. Panesar SS, Bhandari M, Darzi A, Athanasiou T. Meta-analysis: A practical decision making tool for surgeons. *Int J Surg (London, England)* 2009;7(4):291–296.
2. Dijkman, B, Kooistra B, Bhandari M. Evidence-Based Surgery Working Group. How to work with a subgroup analysis. *Can J Surg* 2009;52(6):15–522.
3. Bollschweiler E. Benefits and limitations of Kaplan–Meier calculations of survival chance in cancer surgery. *Langenbeck's Arch Surg/Deutsche Gesellschaft Chirurgie* 2003;388(4):239–244.

2 Breast Surgery

Gaural Patel, Lucy Kate Satherley, Animesh JK Patel, and Georgina SA Phillips

ADVANCED BREAST CANCER

A 48-year-old premenopausal woman who underwent WLE and axillary sampling 8 years previously presents with a new lump deep to the scar and palpable axillary nodes. Describe your initial management.

- Take a history – duration of new symptoms, associated symptoms (e.g. weight loss, bone pain, breathlessness), details about previous breast cancer treatment and pathology.
- Complete a triple assessment.
- Perform an examination – including supraclavicular fossae, liver, lungs and vertebra.
- Request imaging – mammograms, ultrasound (for breast and axilla) with core biopsy of lump and core biopsy or fine-needle aspiration [FNA] of nodes.
- Request details of previous breast cancer treatment, previous imaging and pathology slides for review in MDT.

Core biopsies confirm recurrent invasive lobular cancer, grade 2, ER Allred score 8/8, HER2 positive on fluorescent in situ hybridisation (FISH). Imaging shows a 25-mm mass, with several suspicious axillary lymph nodes. She previously underwent radiotherapy and took tamoxifen for 5 years. What further investigations would you recommend?

- Blood tests – FBC, U&Es, Ca, LFTs, CEA, cancer antigen (CA)15-3
- Staging CT (chest, abdomen, pelvis)
- Isotope bone scan – to look for metastatic deposits in long bones and skull
- If recurrence not visible on mammography, MRI may be of value in assessing the contralateral breast

Staging CT shows metastatic nodules in both lungs and involved internal mammary nodes. What systemic treatments would you suggest?

- I would suggest ovarian suppression (LH−RH agonist, e.g. goserelin or surgical ablation) with tamoxifen (as >1 year since therapy ceased) or an aromatase inhibitor (after ovarian suppression has been achieved).
- Chemotherapy (especially if symptomatic from distant metastases) consists initially of anthracyclines (risk of cardiomyopathy; cannot be repeated). If disease progression on anthracyclines, offer first-line docetaxel, second-line vinorelbine or capecitabine.
- Trastuzumab is given in combination with a taxane. Because of the associated cardiac toxicity, avoid use with anthracyclines; monitor cardiac function

(MUGA/echo). Continue as single agent whilst disease is responsive. If brain metastasis develops (trastuzumab does not cross the blood–brain barrier), continue trastuzumab and treat mets with surgery/radiotherapy
- Pertuzumab may be given in combination with trastuzumab and docetaxel (NICE Guidelines 2018)
- If relapse occurs with trastuzumab, I would consider lapatinib in combination with capecitabine.

Is there a role for primary surgery?

- It is used for local control (e.g. fungating tumours).
- Discuss the role of axillary clearance at MDT; give only further prognostic information because patient is already being offered chemotherapy; this would prevent axillary recurrence in the future.
- There is a possible survival advantage in removing primary disease.
- Postoperative complications can delay systemic treatment, resulting in a worse prognosis.

Five months later, she develops severe lower back pain. A repeat isotope bone scan confirms an isolated vertebral body metastasis. What treatment can you offer?

- Bisphosphonates (you should know the oral and intravenous preparations)
  - Inhibit osteoclast activity
  - Decrease bone resorption
  - Reduce the risk of further skeletal morbidity (metastases, fractures, etc.), reduce bone pain and treat malignant hypercalcaemia
  - Side effects – renal impairment and osteonecrosis of the jaw, possible increased risk of oesophageal cancer with oral bisphosphonates – should be taken with water on an empty stomach, then patient needs to remain upright for 60 min with no further oral intake
- Pain control with simple non-steroidal anti-inflammatory drug (NSAID) analgesia (e.g. diclofenac) or external beam radiotherapy (single fraction, 8 Gy)
- Systemic therapy regime changed due to disease progression (i.e. switch from tamoxifen to AI, from AI to exemestane)

AXILLARY MANAGEMENT IN BREAST SURGERY

How do you manage the axilla in a woman with invasive breast cancer?

- Axillary status remains of vital importance for providing prognostic information and guiding adjuvant treatment.
- I would complete a preoperative triple assessment – clinical examination, imaging and FNA/core biopsy of any suspicious nodes.
- Ultrasound provides the best assessment of axillary lymph nodes – all patients with invasive breast cancer should have preoperative axillary ultrasound examination and biopsy if indicated.
  - Ultrasound features of suspicious nodes include round rather than elliptical shape, increased size, absence of the fatty hilum, and a thickened/irregular/eccentric cortex measuring more than 3 mm.