

13 Surgical audit and research

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AUDIT AND SERVICE EVALUATION

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Clinical audit is a process used by clinicians who seek to improve patient care. The process involves comparing aspects of care (structure, process and outcome) against explicit criteria and defined standards. Keeping track of personal that a surgeon's own performance is monitored continuously and can be compared with a national data set to ensure compliance with agreed standards. Involvement in active audit processes is also an essential component of revalidation for the individual surgeon in the UK. If care falls short of the guidance standard being compared against, some change in the way that care is organised should be proposed. This change may be required at one of many levels. It might be an individual who needs training or surgical equipment that needs replacing. At times, the change may need to take place at the team level. Sometimes, the only appropriate action is change at an institutional level (e.g. a new antibiotic policy), regional level (provision of a tertiary referral centre) or, indeed, national level (screening programmes and health education campaigns). There are two main types of audit in common practice – single site/local audits and multisite regional, national or international audits. Both are designed to improve the quality of care. In an ideal world local audits might identify needs closest to the patient, which can then be further investigated in multisite larger scale audits. For example, hospital topics are often identified at departmental morbidity and mortality meetings, where issues relating to patient care are discussed. The reporting process might identify a possible national issue, and a national or international audit could be designed to be delivered by local surgical teams. Audits are formal processes that require a structure. The following steps are essential to establish an audit cycle: 1 Define the audit question in a multidisciplinary team. 2 Identify the body of evidence and current standards. 3 Design the audit to measure performance against agreed standards based on strong evidence. Seek appropriate advice (local audit department in the UK) and ensure institutions have agreed to undertake the audit. 4 Measure over an agreed interval. 5 Analyse results and compare performance against agreed standards. 6 Undertake gap analysis: a if all standards are reached, reaudit after an agreed interval; b if there is a need for improvement, identify possible interventions such as training, and agree with the involved parties. 7 Reaudit. A new type of audit that has developed significant traction in surgery over recent years is the 'multicentre snapshot audit', whereby many collaborators across multiple hospitals prospectively collate anonymised patient-level data for a specific condition, presentation or intervention over a short time period of normally around 6–8 weeks. This allows exploration of differences in patients, techniques and management across the cohort to identify areas of practice variability that may result in apparent differences in outcome. These studies Archibald Lemman Cochrane, 1909–1988, Director of the UK Medical Research Council Epidemiology Unit, Cardiff, UK, after whom the Cochrane Collaboration is named. tive research is needed. Key advantages of these snapshot audits are their easy accessibility and the fact that they can be conducted at almost zero cost, so they can be an

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How to review a journal article and determine • its value

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Surgical practice has been considered an art: ask 50 surgeons how to manage a patient and you will probably get 50 different answers. There is so much clinical information available that no surgeon can know it all. Evidence-based surgery is a move to find the best ways of managing patients using clinical evidence from collected studies. It was estimated that sufficient evidence to justify routine myocardial thrombolysis for heart attacks was available years before the randomised clinical studies that finally made it clinically acceptable; no one had gathered all the available information together. Centres such as the Cochrane Collaboration have been collecting randomised trials and reviews to provide up-to-date information for clinicians. The Cochrane Library presently includes a database of systematic reviews, reviews of surgical effectiveness and a register of controlled trials. The BJS has been collecting surgical randomised trials on its website archive for 20 years (www.bjs.co.uk). As evidence accumulates, it is expected that this will gradually smooth out the differences between clinicians as the best way of managing patients becomes more obvious. Collecting published evidence together and analysing it often requires reviews of multiple randomised designed to interpret multiple findings and synthesise the - results of multiple studies.

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tice, engaged thousands of surgical trainees and their consultant mentors and created an active network of research active clinicians at many hospitals across the world. In the UK, trainee collaboratives have, to date, developed at least 10 RCTs and been awarded competitive grant funding worth over £8 /uni00A0 million. The model has also extended to medical student collaboratives (STARSurg), and all 42 medical schools in the UK now have an active network student research collaborative. More recently, similar research collaboratives have also formed, utilising the established core principles, in non-surgical specialities such as anaesthetics, gastroenterology and elderly care. All of these collaborative groups work on a principle of complete inclusivity – any interested person is very welcome to get involved in the collaborative; both in existing projects and in suggesting new ideas. People can join at any stage from medical student to consultant. Anyone interested in surgical research should seek out their local or national surgical research collaborative group and get involved. FORMING A TEAM

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tice, engaged thousands of surgical trainees and their consultant mentors and created an active network of research active clinicians at many hospitals across the world. In the UK, trainee collaboratives have, to date, developed at least 10 RCTs and been awarded competitive grant funding worth over £8 million. The model has also extended to medical student collaboratives (STARSurg), and all 42 medical schools in the UK now have an active network student research collaborative. More recently, similar research collaboratives have also formed, utilising the established core principles, in non-surgical specialities such as anaesthetics, gastroenterology and elderly care. All of these collaborative groups work on a principle of complete inclusivity – any interested person is very welcome to get involved in the collaborative; both in existing projects and in suggesting new ideas. People can join at any stage from medical student to consultant. Anyone interested in surgical research should seek out their local or national surgical research collaborative group and get involved. FORMING A TEAM

One of the most common reasons for the failure of an otherwise good research project is failure to involve others. Only the smallest single-centre project can be delivered by an individual researcher working alone; almost any project worth doing will need a team to deliver it. This team can bring the necessary skills and experience to help bring the project to fruition but also, and perhaps more importantly, it can provide the momentum required to keep pushing a project through to completion when the inevitable hurdles are met. There may be local colleagues who form a natural team for a project, perhaps with the oversight of an experienced trainer or mentor. Another solution can be to get involved in a collaborative research group. Surgery has led the way with collaborative research working over recent years. The first trainee-level research collaborative in the UK was formed in 2008 when a group of surgical trainees who shared the same frustrations around the challenges of conducting high-quality research while engaged in a full-time training programme came together to create the West Midlands Research Collaborative (WMRC). The premise was simple: to create and conduct prospective research projects that simultaneously collate data from across all of the members' units and to take advantage of the rotation of trainees' postings between units to ensure project longevity and thus enable longer term outcome collection. By achieving a critical mass of engaged members in these projects, the collective momentum ensured completion even if individuals were unable to personally contribute in a consistent manner because of examinations, family life or busy clinical periods. Such research collaboratives can be most effective in undertaking two key types of study: (i) simple randomised controlled trials (RCTs) and (ii) multicentre snapshot audits (see Audit and service evaluation). The first RCT undertaken by the WMRC was the ROSSINI trial, which explored the clinical effectiveness of a simple wound-edge protection device in reducing wound infections after abdominal surgery. A network of trainees mobilised 21 units for the trial and together they completed the trial 2 months ahead of schedule, having randomised 760 patients over a 23-month

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FURTHER READING

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IDENTIFYING A RESEARCH TOPIC

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Research is designed to generate new knowledge and might involve testing a new treatment or regimen. Once an idea has been formed, or a question asked, it needs to be transformed into a hypothesis. It is helpful to approach surgeons who regularly publish articles and who have a special interest in the subject area being considered. As ideas are suggested, it is important to consider whether the question posed really matters. Spending time refining the question (hypothesis) is probably the most important part of the process. Choosing the wrong topic can lead to many wasted hours. Once a topic has been identified, it is also important not to rush into the study. The worst possible outcome is to find at the end of a long arduous study that the research has already been performed or that the chosen methodology did not support investigation of the primary/secondary outcomes. The first port of call for information is the Internet (with assistance as needed from a medical librarian). Current articles about the proposed research should be retrieved; review articles and meta-analyses can be particularly helpful. It is very important to learn how to do an accurate and efficient search as early as possible. Collections of reviews are available – the Cochrane Collaboration brings together evidence-based medical information and is available in most libraries. Once information on the subject has been obtained and the relevant literature identified, it is important that these are carefully perused. It is not sufficient to just read the abstract! Further information is given in Table 13.1. An excellent source of ideas where research is needed can come from reviewing high-quality national guidelines such as those produced by the UK National Institute for Health and Care Excellence (NICE) on a particular area of interest, many of which include a section beneath the headline guidance being made on ‘recommendations for research’. This section is populated after the currently available evidence for an intervention or treatment has been reviewed by the expert team and found lacking. Designing a research project to cover one or more of these agreed areas can be easily justified to both funders and clinicians alike. Finally, there is an increased number of Priority Setting Partnerships across all aspects of surgery, including those formally undertaken by the James Lind Alliance and by others run by surgical associations and their patient-partner groups. These partnerships consist of patients, carers, healthcare professionals and organisations or charities representing people with the particular condition. They focus on identifying and prioritising research gaps or important specific questions for which additional new research is needed to answer them. Again, creating research projects in these areas is likely to be well received; sometimes such studies are also prioritised for funding support. It is also helpful to seek support from specific networks set up to support health research. In the UK, the National Institute for Health Research (NIHR) runs the Research Design Service (RDS), which provides free and confidential advice on research design, writing funding applications and obtaining public engagement in research for all researchers. There are also a number of training courses available in research methodology and application.

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Introduction

INTRODUCTION

Surgeons are innovators and a key aspect of a surgical career is to constantly adapt, tweak and improve surgical techniques and treatments to provide the best outcomes for those under our care. In addition, few others in the hospital use more technology or devices on a day-to-day basis than surgeons. It is therefore beholden upon all surgeons to be able to critically evaluate both our individual performance and the impact of adaptations in techniques, devices and treatment pathways on the individual and collective outcomes of our patients. Involvement in research and audit activities will form a stable cornerstone within a long and successful surgical career. The aim of this chapter is to outline both how to undertake a successful audit cycle and how to design and conduct a surgical research study. Key aspects associated with enhanced chances of a successful project are discussed, including how collaboration with others can be crucial. Large numbers of clinical papers appear in the surgical literature every year. Many are flawed, and it is important that a surgeon has the skills to examine publications critically. The best way to develop a critical understanding of the research and audit undertaken by others is to perform studies of one's own. The hardest part of audit and research is writing it up, and the hardest article to write is the first. This chapter contains the information required to write a surgical paper and to evaluate the publications of others.

Learning objectives

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To understand: The planning and conduct of surgical audit and • research How to write up a project
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ONLINE RESOURCES

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AcoRD: <https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research> CLAHRC: <https://clahrcprojects.co.uk/about> Clinical Evidence: www.clinicalevidence.com Cochrane Library: www.cochrane.org/index.htm Concordat to Support Research Integrity: <https://ukrio.org/revised-concordat-to-support-research-integrity-published> Consolidated Standards of Reporting Trials: <http://www.consort-statement.org> Data Archive: <http://www.data-archive.ac.uk> Eudract database: <https://www.clinicaltrialsregister.eu> European Code of Conduct: <https://allea.org/wp-content/uploads/2017/05/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017.pdf> GafREC: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees> Health Research Authority: <http://www.hra.nhs.uk> Integrated Research Application System: <https://www.hra.nhs.uk/about-us/committees-and-services/integrated-research-application-system> ISRCTN: <http://www.isrctn.com> MHRA: <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency> National Institute for Health and Care Excellence (NICE): <https://www.nice.org.uk> NHS England audits: <https://www.england.nhs.uk/clinaudit> REDCap: <https://projectredcap.org> Scottish Intercollegiate Guideline Network (SIGN): www.sign.ac.uk Singapore Statement on Research Integrity: <https://wcrif.org/guidance/singapore-statement> Vascular Society: <http://www.vascularsociety.org.uk> ONLINE RESOURCES

AcoRD: <https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research> CLAHRC: <https://clahrcprojects.co.uk/about> Clinical Evidence: www.clinicalevidence.com Cochrane Library: www.cochrane.org/index.htm Concordat to Support Research Integrity: <https://ukrio.org/revised-concordat-to-support-research-integrity-published> Consolidated Standards of Reporting Trials: <http://www.consort-statement.org> Data Archive: <http://www.data-archive.ac.uk> Eudract database: <https://www.clinicaltrialsregister.eu> European Code of Conduct: <https://allea.org/wp-content/uploads/2017/05/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017.pdf> GafREC: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees> Health Research Authority: <http://www.hra.nhs.uk> Integrated Research Application System: <https://www.hra.nhs.uk/about-us/committees-and-services/integrated-research-application-system> ISRCTN: <http://www.isrctn.com> MHRA: <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency> National Institute for Health and Care Excellence (NICE): <https://www.nice.org.uk> NHS England audits: <https://www.england.nhs.uk/clinaudit> REDCap: <https://projectredcap.org> Scottish Intercollegiate Guideline Network (SIGN): www.sign.ac.uk Singapore Statement on Research Integrity: <https://wcrif.org/guidance/singapore-statement> Vascular Society: <http://www.vascularsociety.org.uk>

PRESENTING AND PUBLISHING AN ARTICLE

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There is no point in conducting a research or audit project and then leaving the results unreported. Even when results are negative, they are worth distributing; no project if properly conducted is worthless. Under-reporting of negative outcomes causes a systematic bias in the literature in favour of positive trials. Most studies do not provide dramatic results, and few surgeons publish seminal articles. The key to both presentation and publication is to decide on the message and then aim for an appropriate forum. Big important randomised studies or national audits merit presentation at national or international meetings and publication in international journals. Small observational studies and audits Alejandro R Jadad Bechara, b.1963, Canadian-Colombian physician, University of Toronto, ON, Canada. - - are more often accepted for presentation at regional meetings and for publication in smaller specialist journals. Help and - advice from clinicians familiar with presentation and publica - tion are invaluable at this stage. The most important piece of advice is to follow accurately the instructions for journal sub - mission. Most international meetings will accept presentations eagerly (especially by poster) as this increases the attendance at a conference. Most surgeons publish research in peer-reviewed journals. The work that is submitted is checked anonymously by other surgeons before publication. If in doubt about whether to sub - mit to a journal, many editors will give advice about the suit - ability of an article for submission to their journal. It is usually free to publish in surgical journals since the cost of refereeing and editing is borne by the journal subscriber. A second model of publication is becoming mor e prevalent: open access, in which the author pays. This ensures that all research is visible to anyone, by pushing the costs of the editorial process onto the - study budget. It may well become standard in future. Convention dictates that articles are submitted in IMRAD form: introduction, methods, results and discussion. Increas -

(CONSORT) checklist for authors. Heading Subheading Descriptor Title Identify as randomised trial Abstract Structured format Introduction Prospectively de /f_i ned hypotheses, clinical objective Protocol Methods Study population Intervention, timing Primary and secondary outcome Statistical rationale Stopping rules Assignment Unit of randomisation Method: allocation schedule Masking (blinding) Results Participant /f_l ow Trial pro /f_i le, /f_l ow diagram and follow-up Analysis Estimated effect of intervention Summary data with appropriate inferential statistics Protocol deviation Comment Speci /f_i c interpretation of study Sources of bias External validity General interpretation From the CONSORT statement: Journal of the American Medical Association 1996; 276: 637-9.

face of scientific publication and, in the next decade, these restrictions on style may disappear. For now, the IMRAD for mat remains inviolable. The length of an article is important: a paper should be

as long as the size of the message. Readers of large randomised multicentre trials need to know as much detail about the study as possible; reports on small and simple trials should be brief.

Introduction . This should always be short. A brief background of the study should be presented and then the aims of the trial or audit outlined.

Methods . The methodology and study design should be given in detail. It is important to identify potential biases. New techniques or investigations should be detailed in full; if they are common practice or have been described elsewhere, this should be referenced instead of described.

Results . Results are almost always best shown diagrammatically using tables and figures. Results shown in the form of a diagram need not then be duplicated in the text.

Discussion . It is important not to repeat the introduction or reiterate the results in this section. The study should be interpreted intelligently and any suggestions for future studies or changes in management should be made. It is prudent not to indulge in flights of fantasy or wild imagination about future possibilities; most journal editors will delete these. Recently, a standard format for the discussion section has been promoted, and journals such as the *BMJ* are keen that authors use it.

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PRESENTING AND PUBLISHING AN ARTICLE

There is no point in conducting a research or audit project and then leaving the results unreported. Even when results are negative, they are worth distributing; no project if properly conducted is worthless. Under-reporting of negative outcomes causes a systematic bias in the literature in favour of positive trials. Most studies do not provide dramatic results, and few surgeons publish seminal articles. The key to both presentation and publication is to decide on the message and then aim for an appropriate forum. Big important randomised studies or national audits merit presentation at national or international meetings and publication in international journals. Small observational studies and audits are more often accepted for presentation at regional meetings and for publication in smaller specialist journals. Help and advice from clinicians familiar with presentation and publication are invaluable at this stage. The most important piece of advice is to follow accurately the instructions for journal submission. Most international meetings will accept presentations eagerly (especially by poster) as this increases the attendance at a conference. Most surgeons publish research in peer-reviewed journals. The work that is submitted is checked anonymously by other surgeons before publication. If in doubt about whether to submit to a journal, many editors will give advice about the suitability of an article for submission to their journal. It is usually free to publish in surgical journals since the cost of refereeing and editing is borne by the journal subscriber. A second model of publication is becoming more prevalent: open access, in which the author pays. This ensures that all research is visible to anyone, by pushing the costs of the editorial process onto the study budget. It may well become standard in future. Convention dictates that articles are submitted in IMRAD form: introduction, methods, results and discussion. Increasingly,

(CONSORT) checklist for authors.

Heading	Subheading	Descriptor	Title
Identify as randomised trial			
Abstract	Structured format	Introduction	Prospectively defined hypotheses, clinical objective
Protocol	Methods	Study population	Intervention, timing
Primary and secondary outcome			Statistical rationale
Stopping rules	Assignment	Unit of randomisation	Method: allocation schedule
Masking			

(blinding) Results Participant flow Trial profile, flow diagram and follow-up Analysis
Estimated effect of intervention Summary data with appropriate inferential statistics Protocol
deviation Comment Specific interpretation of study Sources of bias External validity General
interpretation From the CONSORT statement: Journal of the American Medical Association 1996;
276: 637-9.

face of scientific publication and, in the next decade, these restrictions on style may disappear. For now, the IMRAD format remains inviolable. The length of an article is important: a paper should be as long as the size of the message. Readers of large randomised multicentre trials need to know as much detail about the study as possible; reports on small and simple trials should be brief.

Introduction . This should always be short. A brief background of the study should be presented and then the aims of the trial or audit outlined.

Methods . The methodology and study design should be given in detail. It is important to identify potential biases. New techniques or investigations should be detailed in full; if they are common practice or have been described elsewhere, this should be referenced instead of described.

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(CONSORT) checklist for authors. Heading Subheading Descriptor Title Identify as randomised trial Abstract Structured format Introduction Prospectively defined hypotheses, clinical objective Protocol Methods Study population Intervention, timing Primary and secondary outcome Statistical rationale Stopping rules Assignment Unit of randomisation Method: allocation schedule Masking (blinding) Results Participant flow Trial profile, flow diagram and follow-up Analysis Estimated effect of intervention Summary data with appropriate inferential statistics Protocol deviation Comment Specific interpretation of study Sources of bias External validity General interpretation From the CONSORT statement: Journal of the American Medical Association 1996; 276: 637-9.

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PROJECT DESIGN

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Why do the study? Will it answer a useful question? Is it practical? Can it be accomplished in the available time and with the available resources? Will the project bene /f_i t from collaboration to increase numbers or make best use of high-technology equipment? What /f_i ndings are expected? What are the research governance requirements? What are the ethical issues? What impact could it have? Type of study De /f_i nition Observational Evaluation of condition or treatment in a de /f_i ned population Retrospective: analysis of past events Prospective: contemporaneous collection of data Case-control Series of patients with a particular disease or condition compared with matched control patients Cross-sectional Measurements made on a single occasion, not looking at the whole population but selecting a small similar group and expanding results Longitudinal Measurements taken over a period of time, not looking at the whole population but selecting a small similar group

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Regulatory approvals

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Interventional clinical or device trials are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. Researchers are encouraged to use an existing and established international register such as ISRCTN or ClinicalTrials.gov to ensure that the public is aware of a trial before recruitment of the first participant. Trials involving sites specifically in EU countries must be registered in the EU Clinical Trials Register. Trials should be registered before applying to the MHRA for a clinical trial authorisation via the MHRA submissions portal and researchers must ensure that the registry is kept up to date and trial results are uploaded in the appropriate timeframe. This can be a complicated and trying process, and support should be sought from the investigators' employing institution. Editors of the major surgical journals now agree that all clinical trials should have been registered before an article relating to a trial can be published. All studies undertaken with NHS patients and/or carers will need HRA Approval and confirmation of capacity and capability from NHS sites. Studies involving animals require approval from statutory licensing authorities. In the UK this is the Home Office. Animal research should be based on ARRIVE guidelines (Animal Research: Reporting of In Vivo Experiments). Regulatory approvals

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that enhances the integrity of the study and includes requirements for sponsorship by an institution to ensure the following: peer review, independent ethics review, compliance with data protection principles, financial probity, dissemination and management of intellectual property. Sponsorship is defined by the HRA as the individual, company, institution or organisation that takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research. The sponsor takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting (<https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/#sponsor>).

SUNRRISE: Single Use Negative pressure site infection following Multicentre, prospective undergoing emergency RCT (minimum 25 general surgical units) Sample size calculation: 90% power to detect reduction of SSI at 30 days from 25% to 15% Predicted attrition rate of 20% 420 SUNPD Figure 13.1 SUNRRISE trial: protocol summary and recruitment flowchart. Permission is granted by Birmingham Clinical Trials Unit, University of Birmingham, UK. RCT, randomised controlled trial; SSI, surgical site infection; SUNPD: single-use negative-pressure dressing.

SUNRR

that enhances the integrity of the study and includes requirements for sponsorship by an institution to ensure the following: peer review, independent ethics review, compliance with data protection principles, financial probity, dissemination and management of intellectual property. Sponsorship is defined by the HRA as the individual, company, institution or organisation that takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research. The sponsor takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting (<https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/#sponsor>).

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Sample size

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Calculating the number of patients required to perform a satisfactory investigation is an important prerequisite to any study. An incorrect sample size is probably the most frequent reason for research being invalid. Often, surgical trials are marred by the possibility of error caused by the inadequate number of patients investigated. none (false positive). /uni25CF Type II error. Benefit is missed when it was there to be found (false negative). Calculating the number of patients required in the study can overcome this bias. Unfortunately, it often reveals larger number of patients is needed for the study than can possibly be obtained from available local resources. This usually means expanding enrolment by running a multicentre study – which has the added benefit of improving the external validity of findings. More patients will need to be randomised than the final sample size to take into account patients who die, drop out or are lost to follow-up; this is known as the attrition rate. A longer time from trial entry to primary outcome assessment will result in an increased attrition rate of participants. The following is an example calculation for a study to recruit patients into two groups. In order to calculate a sample size, it is now common practice to set the level of power for the study at 90% with a 5% significance level. This means that, if there is a difference between study groups, there is a 90% chance of detecting it. Based on previous studies, realistic expectations of differences between groups (i.e. the magnitude of the effect seen from utilising the intervention under study), according to the best available evidence, should be used to calculate the sample size. The formula below uses the results of a reduction in event rate from 30% to 20% (e.g. a new treatment expected to reduce the complication rate such as wound infection from 30% = r to 20% = s).
$$\frac{[r(100 - r) + s(100 - s)] \times 9 \times 2}{(r - s)^2}$$

$$[30(100 - 30) + 20(100 - 20)] \div 9 \times 2 = 333$$
 needed in each group

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