

PROJECT DESIGN

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During the first phase, it is important to keep in the mind some important questions (Summary box 13.1). Summary box 13.1 Questions to answer before undertaking research /uni25CF /uni25CF /uni25CF /uni25CF /uni25CF /uni25CF /uni25CF There are many di ff erent types of scientific study . The design used depends on the study . Time spent carefully design ing a potential project is never wasted. An RCT is regarded as one of the best methods of scientific research; however, much surgical practice has been advanced through other di ff erent types of study suc h as those listed in Table 13.2 . For example, testing a new type of operation often requires a pilot study to assess feasibility , which is then followed by a formal RCT . The introduction of innovative surgical techniques may require novel handling, and recommendations have been made by the IDEAL collaborators (see Further reading). Research can be qualitative or quantitative. Quantitative research allows hard facts to speak for themselves. A medical condition is analysed systematically using hard, objective end Pierre-Alain Clavien , contemporary , Professor of Surgery , Zurich, Switzerland. Daniel Dindo , contemporary , surgeon, Zurich, Switzerland. - - - points such as death or major complications, which should be clearly defined. For example, surgical complications are now classified using the Clavien–Dindo system. In qualitative research, data often come from patient narratives, and the psychosocial impact of the disease and its treatment are anal - ysed; for example, narratives from patients with breast cancer. These kinds of data are often collected using quality-of-life measurements. A variety of di ff erent quality-of-life question - naires exist to suit several di ff erent clinical situa tions. Much of the best research is both quantitative and qualitative. Recently , the importance of outcomes from the patient’s perspective has been emphasised: patient-re ported outcome measures (PROMs) are now an important component of the evaluation of surgical procedures. Research should be focused according to institutional, national and international strategies. As finances for health care are always limited, it is important to consider including a cost-benefit analysis in any major area of research so that the value of the proposed intervention or change in treatment - can be assessed. The NIHR provides the framework through which the Department of Health maintains and manages the research, research sta ff and research infrastructure of the National Health Service (NHS) in England.

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

and expanding results Experimental Two or more treatments are compared. Allocation to treatment groups is under the control of the researcher Randomised Two or more randomly allocated treatments Randomised Includes a control group with standard controlled treatment

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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 benefit from collaboration to increase numbers or make best use of high-technology equipment? What findings are expected? What are the research governance requirements? What are the ethical issues? What impact could it have? Type of study Definition Observational Evaluation of condition or treatment in a defined 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 and expanding results Experimental Two or more treatments are compared. Allocation to treatment groups is under the control of the researcher Randomised Two or more randomly

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