How to Practice Academic Medicine and Publish from Developing Countries?

A Practical Guide

Samiran Nundy
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Foreword

When I became an assistant editor at the *BMJ* in 1979 and began to process scientific papers submitted to the journal it was extremely unusual to see, let alone publish, a paper from a low-income country. I remember being surprised by high-quality papers coming from Bangladesh, a country that Henry Kissinger called a 'basket case'. Those papers came from the International Centre for Diarrhoeal Disease Research, Bangladesh, which I learned later was a creature of the Cold War and might cruelly be called a 'branch office of Johns Hopkins'.

Years later, in 2013, I became the chair of the board of what was by then called icddr,b. The centre has now published major vaccine trials led by Bangladeshi scientists in the *New England Journal of Medicine* [1], and I was privileged to be on the steering committee of a major trial, also published in the *New England Journal of Medicine*, of a system for managing hypertension in rural Pakistan, Bangladesh, and Sri Lanka led by scientists from those countries [2]. A few weeks ago, I was delighted to see a major trial of the polypill for the prevention of cardiovascular disease led from India and also published in the *New England Journal of Medicine* [3].

High-quality research relevant to the needs of low-and-middle-income countries is much commoner than 40 years ago, and China has become a scientific leader. But, as the editors of this book describe in the introduction, there is still not nearly as much good research as there should be from the part of the world that carries most of the disease burden. Even worse, the medicine practiced in some of these countries is disconnected from research and teaching and driven more by profit than what is best for patients and the population. I have Indian friends who are terrified of seeing a cardiologist for fear that they will be given treatments they do not need.

I agree with the editors' diagnosis that 'the main reasons for our having sunk into this deep morass is not because we are poor but because we have not intelligently examined, evaluated and investigated how we could use our own resources more effectively. We have tended to blindly follow what is being done in richer countries instead of trying to provide healthcare to our population which is accessible, affordable and, most importantly, appropriate even if this means deploying and working with informal healthcare providers'.

Other people's research can be valuable, but it can never be as valuable as your own—addressing the problems that matter to your people with relevant methods and the tools you have. And we know that the very act of researching brings improvement, and (as I know to my cost) you can never learn about research from reading about it: you need to do it.

I have never quite understood why people in low-and-middle-income countries would want to replicate the health systems of high-income countries. Not only are those systems not relevant to the needs and circumstances of the low-and-middle-income countries, but the systems in high-income countries are increasingly unaffordable and unsustainable and not meeting the needs of their own populations.

Health systems in high-income countries were developed decades ago and were designed to respond to the infectious disease and trauma that were then the main causes of suffering and death. Those problems could be cured, but the non-communicable disease is now the main cause of suffering and death. Such a disease cannot be cured and needs a different approach.

Non-communicable disease is now also the main cause of morbidity and mortality in low-and-middle-income countries (apart from some sub-Saharan countries, but even there it will soon be the main cause). The epidemiological transition happened very fast in low-and-middle-income countries: in Bangladesh, non-communicable disease caused about 10% of deaths in 1986 but nearer 80% by 2006 [4]. I spent years working with 11 centres in low-and-middle-income countries that were doing research, building capacity and advising on policy in relation to non-communicable disease. We envisioned what a better system in low-and-middle-income countries might look like—with an emphasis on public health, the social determinants of health, prevention, primary care, and patient empowerment and widespread use of evidence-based guidelines [5]. (Such guidelines were developed by academics in the centre in South Africa as part of a package that allows good primary care where doctors are few or unavailable [6].)

We should have said more about the use of technology. Most people in low-and-middle-income countries, even some of the poorest, now have mobile phones, which has meant that people can communicate without having to connect every house by wires, as happened with terrestrial phone systems in high-income countries. Low-and-middle-income countries can in this way 'leapfrog' over a stage that was needed in high-income countries, and the same can be done for health—not least by using mobile phones to provide access to care. Similarly, health systems in low-and-middle-income countries might create health record systems where patients, not health care providers, own and control the records. Health systems in high-income countries are just beginning to recognize the importance and inevitability of giving patients ownership and control of their records. (I have a conflict of interest here as I am the chair of Patients Know Best, a company that gives patients in Britain and some other countries control of their records and data.)

Health systems in high-income countries are actually sickness systems, and low-and-middle-income countries would be wise to concentrate more on health. Only a small part of health comes from the health system, but politicians, citizens, and even many health professionals seem unaware of the fact. Consequently, health and health care are treated as if synonymous. Those countries that currently have poorly developed health systems have the opportunity to build systems that pay more attention to health than health care, as indeed was the case in many traditional and ancient health systems. Physicians to Chinese emperors were paid only if the emperor was well.

Such developments in health and health systems can be achieved only through research conducted in low-and-middle-income countries by researchers from those countries. And, I suggest, we need a new way of doing science, and researchers in low-and-middle-income countries should take the lead. I have recently been part of a discussion on the future of the UK Academy of Medical Sciences, and people are advocating a new way of doing science that will be much more transdisciplinary and global with more involvement of citizens. A broader range of methods will be needed together with a greater willingness to bring together different kinds of studies and data to reach conclusions. Without curiosity-driven research being neglected, there might be more emphasis on research that brings social benefit. Implementation of research findings will become as important as discovery, and the hierarchy of science that ranks genetics above social science will disappear.

Secondary aspects of the new science might be universal data sharing, greater transparency throughout the research process, immediate open access to all research, and the final abandoning of publications and the place of publication as the main way to measure academic success. In addition, scientific integrity (and its dark twin, misconduct) will be taken much more seriously as will the commitment to explaining science and how it works to the public.

As part of the debate over the future of the Academy there has been discussion on priorities, and two of the priorities that are widely advocated—climate change and inequalities—are even more relevant to low-and-middle-income countries than to high-income ones. It is a huge global injustice that most of the greenhouse gases that are causing climate change have been produced in high-income countries, but the resulting harm will be experienced most in low-and-middle-income countries. A third of Bangladesh, already a densely crowded country, is set to disappear under water, and temperature increase and drought will reduce crop yields in many low-and-income countries, forcing people to migrate. Health academics must pay attention to climate change, which will mean forming new unfamiliar research partnerships with climate, agricultural, social, and political scientists.

Academics must also recognize the huge role that inequalities in wealth, income, education, and opportunity play in health. The COVID-19 pandemic has brutally illustrated the importance of inequality, in both high- and low-and-middle-income countries. Most low-and-middle-income countries have greater inequality within the countries than do high-income countries. Health researchers in some high-income countries, including Britain, have done a good job of measuring and describing the harm to health from inequalities but have done less well in reducing the harm. Researchers in low-and-middle-income countries have an opportunity to do better.

The world faces considerable problems, and what is clear is that research and teaching will be essential in tackling those problems. It is also clear that the research and teaching must be undertaken by researchers and teachers within countries, producing responses and using methods that are right for their countries. This book will be a great aid to researchers and teachers. The result should be better health and sustainable health systems. The opportunities are greater than the problems.

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Richard Smith was an editor at the BMJ from 1979 to 2004, and from 1991 to 2004 he was the editor-in-chief of the BMJ and the chief executive of the BMJ Publishing Group. From 2006 to 2015, he was the director of the UnitedHealth part of the UnitedHealth/National Heart, Lung, and Blood Institute Centers of Excellence programme, and from 2013 to 2018 he was the chair of icddr,b [formerly the International Centre for Diarrhoeal Disease Research, Bangladesh]. He is now the chair of the UK Health Alliance on Climate Change, the Lancet Commission on the Value of Death, the Point of Care Foundation (which works to humanise health care), and Patients Know Best. He blogs regularly for the BMJ.

Conflict of Interest: RS's current positions are all unpaid, but he has equity in Patients Know Best, which he mentions in the Foreword.

Richard Smith

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Samiran Nundy, Atul Kakar, Zulfiqar A. Bhutta

Why This Book?

For all our working lives we have been constantly reminded how healthcare in developing countries is both challenging and substandard. The usual arguments are the lack of resources, the overwhelming numbers of poor patients who arrive at our hospitals with advanced disease, physicians who have been inadequately trained in models of care unsuited and irrelevant to our settings. Of late this list has been augmented by consideration of profit-driven private medical colleges where there is very little teaching, there is also competition from droves of unqualified informal healthcare providers, little monitoring and accountability of the quality of services provided and, of course, ubiquitous corruption.

Some of us who initially trained and taught in Western countries, and subsequently made careers out of working in low-and middle-income countries, have now come to the conclusion, albeit rather late, that the main reasons for our having sunk into this deep morass are not because we are poor but because we have not intelligently examined, evaluated and investigated how we could use our own resources more effectively. We have tended to blindly follow what is being done in richer countries instead of trying to provide healthcare to our population which is accessible, affordable and, most importantly, appropriate even if this means deploying and working with informal healthcare providers. We need to work out local solutions to our local problems and task sharing is one such example of innovation for reaching poor and marginalized populations.

Even to do this we do not know where and how to start. We maintain abysmally poor medical records—a GP consultation is often over in 5 min (often less), after which the patient is given a prescription for a drug on a piece of paper without documenting any history or tentative diagnosis. For instance, to a patient who probably has a viral fever, many doctors would blatantly prescribe a cocktail of antimalarials, antibiotics, and even occasionally steroids, in the hope that something might work. Such poor documentation is by no means restricted to general practice, in many hospitals, there are few standardized records of how many patients are seen by a doctor, what their diagnoses are, what treatment they have been given, and what happens to them afterwards. Thus, without any data to fall back upon we often have little information on the prevalence and distribution of key diseases in our countries, as is evident in the recent COVID-19 crisis across South Asia. There is no inventory of the resources which are available to tackle the problems and poor audit and information on outcomes of the treatment these patients receive.

We feel that the time has come to revamp our approach to common problems in our region and this major change can be affected if we start practicing true Academic Medicine in letter and spirit. By Academic Medicine, we do not mean doing basic laboratory research or sophisticated care in only specialized teaching hospitals or research institutes, but use the expression in its intent to examine and evaluate the results of the medical care our patients receive, the training we provide our budding doctors and what they achieve not only in their day-to-day practice but also in research and publications. They should also be encouraged to investigate ways by which their practice and care might be improved fully utilizing local resources, no matter how limited. To do this we must not shun but make full use of modern technology which is now widely available such as electronic tools and the internet to record, retrieve and analyse what our problems are.

The fact that research done in South Asia is poor both in quantity and quality has been well documented. It was well documented almost two decades ago that some 90% of the 70 billion dollars spent annually worldwide on medical research continue to target diseases that affect only 10% of the world's population (the so-called 10–90 gap) [1]. This situation has only improved marginally and many of the key advances in research on tropical diseases or diseases of the poor continue to be the result of research spearheaded by western investigators, perhaps reflecting the availability and flow of funding. By one evaluation only 8% of cited papers originated in tropical countries [2] and additionally, of the 579 so-called 'academic' medical institutions in India, 57% had not published a single indexed article between 2005 and 2014 [3].

More recently the private sector, controlled by large corporate houses, has become the dominant provider of health care catering to 80% of the population and being solely profit driven is not interested in academic activities. The underfunded public institutions have inadequate infrastructure, entrenched staff irrespective of the quality of performance, promotions which are often not based on merit or achievement but time bound and based on seniority and external influences. There is little credit given to clinical or academic achievement and, of course, there is constant political interference.

What is to be done? As this compilation of articles suggests, we need to identify key limitations and problems in our health care system, make changes in our educational system to make it more relevant to the needs of our nations. We need to focus on context-relevant medical education and encourage both undergraduate and graduate students to think originally rather than memorize facts. This must be linked to the monitoring of the quality of medical care our patients are receiving and identification of gaps that exist and finally, we need to evaluate the results of these interventions, i.e., practice true Academic Medicine in both letter and spirit.

We realize that our submissions may ruffle some feathers with indignant protests that we have generalized and not considered the successes of many leading institutions and academics in health care in South Asia. We make no excuses for creating ripples in otherwise still and stagnant waters as we think that change is needed and soon. Some 10 years after the publication of the acclaimed Lancet Commission on Health Professional Education for the twenty-first century, tangible progress in this

regard in a region housing almost a sixth of the world's population is both slow and inconsistent [4]. Our aim has been simply to provide a 'guide' on how the young dedicated men and women work in low-and middle-income settings in general, and South Asia in particular, can make our health systems and population health outcomes better by using the resources available to us more effectively. Some 75 years after the publication of the landmark reports of the Bhore Commission, many of the intransigent challenges and health care inequities need a radical solution, and this is a humble step in that direction by improving the practice of academic medicine.

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Contents

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Samiran Nundy was a medical undergraduate in Cambridge and Guy's Hospital London and then trained in medicine and later in surgery at Guy's, Addenbrooke's Cambridge, the Hammersmith and the Massachusetts General Hospital in Boston. He has taught at the Universities of Cambridge, London, and Harvard and returned to the All India Institute of Medical Sciences, New Delhi, India in 1975 where he eventually became Professor and Head of the department of Gastrointestinal Surgery. He left AIIMS in 1996 to start the Surgical Gastroenterology and Liver Transplantation department at Sir Ganga Ram Hospital, New Delhi. Dr. Nundy's clinical and research interests are in the surgical management of diseases of the liver, bowel, and pancreas, the quality of Indian medical research and publications, electronic medical records, and disseminating health information to laypeople via books, television, and the web. He has written or edited 37 books and authored 236 research papers. He helped in lobbying for and drafting the Transplantation of Human Organs Act 1995. He has edited *The National Medical Journal of India, Tropical Gastroenterology, the Indian Journal of Medical Ethics*, *DoctorNDTV.com,* and the web application *Doctor Raxa* and has served on 24 journal editorial boards including the *British Medical Journal* and *The Bhutan Health Journal*. He was till recently the Dean of the Ganga Ram Institute for Postgraduate Medical Education and Research, is the editor-in-chief of *Current Medicine Research and Practice*, co-chairman (with Prof. Zulfiqar A. Bhutta) of the editorial board of the *BMJ South Asia,* and is on the board of trustees of Sir Ganga Ram Hospital. He has recently been appointed Adviser to the Governor of Meghalaya on how to improve health services in that state and is also the President of AIIMS, Rishikesh, India.

Zulfiqar A. Bhutta is the Inaugural Robert Harding Chair in Global Child Health and Inaugural Ibn Sina Scholar in Global Child Health at the Hospital for Sick Children, Canada and co-Director of SickKids' Centre for Global Child Health, Canada. He is also the Founding Director of the Centre of Excellence in Women and Child Health and the Institute of Global Health and Development at Aga Khan University, across its campuses in South Central Asia, East Africa and United Kingdom. He holds adjunct professorships at universities including Johns Hopkins University, George Washington University and the London School of Hygiene & Tropical Medicine. Dr. Bhutta is a Distinguished National Professor of the

Government of Pakistan, co-Chair of the Maternal and Child Health oversight committee of WHO EMRO, Chairman of the Coalition of Centres in Global Child Health, and a leading voice for health professionals supporting integrated maternal, newborn and child health globally. Dr. Bhutta leads large research groups in Toronto, Karachi, and Nairobi with special interests in scaling up evidence-based, community setting interventions and implementation of RMNCAH&N interventions in humanitarian contexts. His work with community health workers influenced maternal and newborn outreach programs for marginalized populations internationally and his group's work with the WHO and PMNCH is guiding essential global intervention policies for women, children, and adolescents. Dr. Bhutta obtained his MBBS from the University of Peshawar, Pakistan, and his PhD from the Karolinska Institute, Sweden. He is a fellow of the Royal College of Physicians, the Royal College of Pediatrics and Child Health, American Academy of Pediatrics and the National Academy of Sciences, USA. In 2020, he was awarded the honour of Fellowship of the Royal Society, United Kingdom. He was awarded the Roux prize in October 2021, the highest global award for the use of evidence to impact global public health.

Atul Kakar is a graduate from the University College of Medical Sciences, University of Delhi, India and has done his post-graduation in internal medicine, Diplomat of National Board. He has been awarded MRCP and FRCP from the Royal College of Glasgow. He is an alumnus of the Ganga Ram Institute of Postgraduate Medical Education and Research, New Delhi, India. Currently, he is the Vice-Chairman and Teaching Coordinator of the department of internal medicine, Sir Ganga Ram Hospital, New Delhi. He has also done EULAR certification course in rheumatic diseases and is the Secretary of the Delhi Rheumatology Association. His area of interest besides rheumatology includes HIV medicine. Dr. Kakar has been awarded the eminent National Board of Examination (NBE) Alumnus Award, Dr. K.C. Mahajan Award for Best Academician and Smt Pawan Kumari Jain Oration Award for the Best Physician by the Delhi State Chapter of Associations of Physicians of India. He is the examiner for the Royal College of Physicians & Surgeons, Glasgow, National Board of Examination, and Khesar Gyalpo University of Medical Sciences, Bhutan. Dr. Kakar has written and edited many books, has 130 publications in national and international journals. He has been involved with many clinical drug trials as the Principal Investigator for rheumatoid arthritis, osteoporosis, and amyloidosis. He is currently the Editor of *Current Medicine Research and Practice*.

Part I

Introduction

Academic Medicine and the Social Determinants of Health

1

Social accountability is achieved through a structured and purposeful partnership in action between the educational institution and the wider health structures existing in the community, area or region it serves.

—Boelen C, Pearson D, Kaufman A, Rourke J, Woollard R, Marsh D, et al. Producing a socially accountable medical school: AMEE Guide No. 109. Medical Teacher. 2016;38(11):1078–1091

1.1 What Is Academic Medicine?

The term academic medicine has evolved over generations. While historically academic medicine was synonymous with formal medical education [1], the past few decades have seen it being recognized as a domain where members, in addition to a transfer of knowledge, must demonstrate a culture of sustained and applicable research.

However, while the focus primarily remains on 'teaching, research, and service' [2] in clinical medicine and tertiary care, academic medicine must expand to include primary health care, public health and, importantly, the social and physical environments that impact them [2].

1.2 What Are the Social Determinants of Health?

The World Health Organization defines social determinants of health as, "*the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces and systems include*

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Fig. 1.1 The intersection of the five key factors that can contribute to health inequalities. (Source: United Nations Sustainable Development Group. Leaving No One Behind: A UNSDG Operational Guide for UN Country Teams. UNSDG; 2019)

economic policies and systems, development agendas, social norms, social policies, and political systems" [3].

These could include social, physical, and economic risk factors that further up the causal chain can influence health of populations (Fig. 1.1). Their effects in an individual can extend through the prenatal period, along the life course contributing to a range of health inequities leading to mortality, morbidity, and even suboptimal growth and development outcomes in children. These health inequities are typically inequalities attributable to the external environment and are largely unavoidable for the individuals concerned. Poverty and its intergenerational transfer are the underlying determinants for much of the global health inequity. Household food insecurity, limited access to health care, suboptimal living conditions, and lack of resources all contribute to health inequalities. Similarly, educational achievement, women's empowerment, religion, and gender, can all affect health outcomes. Geographical disparities in health are often a consequence of governance, discrimination, economic status, and access to services. Conflict, migration, and natural disasters are also critical social determinants that can create adversities in the living condition and health services, increasing the risk of disease and death. Many also allude to the political and commercial determinants of health; we have largely focused on social determinants of health as they underpin many of the sustainable development goals.

1.3 How Can Physicians Help Address Social Determinants of Health?

The role of physicians in helping circumvent and address social inequities in the population can extend from the patient–doctor interaction to a broader community-based role. Identifying underlying social challenges, providing support to a patient, and helping them access appropriate social services are some of the immediate steps a physician can take. At the next level, the physician can ensure their practice or facility operates in an equity-sensitive manner and facilitates access to services for

the underprivileged or marginalized communities. These could include subsidized services, special outreach camps, or on-site counsellors. In addition, physicians can extend their role beyond their facilities into the community by supporting and implementing collaborative community-based interventions that would help achieve equitable health outcomes in the local population.

Conducting research and generating evidence could influence policy change and advocate for better services. Given their clinical expertise and knowledge, physicians are placed uniquely in a community to help avert and tackle these, often hidden, underlying social reasons for poor health. However, they cannot work in isolation; they must collaborate with multiple sectors to ensure equitable solutions are found. Most importantly, none of this could be achieved without the necessary ambition and initiative to intervene and improve the community's environment and health.

1.4 What Are Boyer's Principles of Academic Scholarship?

In 1990, Ernest Boyer challenged the status quo by presenting an alternate, broader approach to higher education, as compared to the traditional 'teaching versus research' path [4]. He suggested that academic scholarship should encompass more than just research, publishing articles and teaching. He proposed scholarship to be considered a more dynamic and non-linear process where the interrelated scholarships of discovery, integration, application, and teaching could cover the full scale of academic work.

What do the scholarship of discovery; the scholarship of integration; the scholarship of application; and the scholarship of teaching mean? To put it simply the *scholarship of discovery* refers to the process of research and investigation. Next, the *scholarship of integration* underscores the significance of linking knowledge gained to a larger context and 'across disciplines' [4]. The *scholarship of application* is seemingly a self-explanatory term. However, Boyer cautioned *not* to perceive it as a 'one-way street' where knowledge always has to come before application and practice [4]. *Teaching* is a scholarship that focuses on knowledge transfer and student learning.

1.5 What Can Be the Role of Academic Medicine in Addressing Social Determinants of Health?

Globally, medical schools have typically focused on learning and research with the sole purpose of building clinical knowledge and skills. Despite decades of studying subjects such as community medicine or population-based care, with scattered content on determinants of health, the commitment and role of physicians in addressing health inequities remain limited. An enormous gap in the medical curricula exists with the focus being on acquisition of medical knowledge without an emphasis on

health disparities and inequities. Recognizing pervasive health inequalities as well as developing the skills and approaches to addressing them would be an essential competency for any physician trainee in the run-up to the Sustainable Development Goals (SDGs).

However, experience indicates that the mere acquisition of knowledge of social determinants of health and their impact on communities is not enough for trainees to realize their social responsibility [5]. The integration of social determinants of health within the curriculum must be accompanied by an effort to equip the trainees with the right attitude and tools to address these disparities, to the point when they believe that they are not just clinicians who treat sick people, but rather occupy a distinctive position in the community where they are able to address these inequities in a far more effective manner than others.

We feel that the Boyer's principles of academic scholarship would be relevant and valuable tools for effective 'teaching' of social determinants of health and health inequities as part of academic medicine.

1.6 Boyer's Principles of Academic Scholarship, Academic Medicine, and Social Determinants of Health

While the medical curriculum may touch upon or cover social determinants of health and health inequities in some form, self-reported competence, and practice of physicians in addressing social determinants of health remains low [6]. Importantly, as described in surveys, physicians with reported higher levels of competence and involvement were from low-resource backgrounds or had experience working in such settings or in primary care clinics. The common theme noticed was that real-life practical experience is key in ensuring higher awareness, better attitude, and competence amongst physicians for identifying and addressing health inequities and social determinants. On the flip side, only practical experience alone would not be sufficient. If that were the case physicians in low- and middle-income countries would be the most competent in promoting health equity and addressing the underlying social causes of ill health.

Academic medicine must adopt a multidimensional, transformative approach for training future physicians in social determinants of health. For this incorporating *discovery*, the first of the scholarship principles, is important for emphasizing implementation research in health inequities and needs assessment in communities. While research and investigation are critical to the subject [3], the scholarship of *integration* is imperative. Educating trainees on social determinants with simplistic curricul a without providing the perspective on how these inequalities and determinants practically affect health of communities would be pointless. Unless the trainees can grasp the importance of community surroundings, social and economic influences, and cultural sensitivity, their ability to tackle these inequalities would be limited. Academic medicine must main strong ties with public health systems to ensure knowledge, science, and implementation find a way to be integrated with active student and trainee experience within those communities, as much as possible.

The principle of *application* would include the community engagement component where learning from the community and identifying the social and structural determinants of health would be key. Thus, application could be part of the learning process as well as a consequence of the knowledge gained. *Teaching* is the last link which focuses on knowledge transfer and can aid in building the trainee's communication skills and attitudes which are essential in identifying social and health equity challenges.

1.7 What Is the Way Forward?

Strengthening academic medicine especially in LMICs must remain a priority. Promotion of academic research, strong ties with public health systems, innovative solutions to enhance access to information and building linkages between academic institutions in developing countries and academic centres in high-income countries are sustainable actions to improve inventive academic medicine and, ultimately, promote health equity. *The Education of health professional for the 21st century: a global independent Commission* identified transformative learning and interdependent education as key to developing responsive, patient-, and population-centred health systems that can advance equity in health [7] (Fig. 1.2). Thus, the focus should be on learning which creates leaders, who are not only professional or researchers, but rather change agents who can identify and address health disparities.

The 2030 Agenda for Sustainable Development vows 'leaving no one behind'. Achieving equity for the most vulnerable groups has been identified as a key domain for achieving the health and health-related SDGs [8]. The role of academic

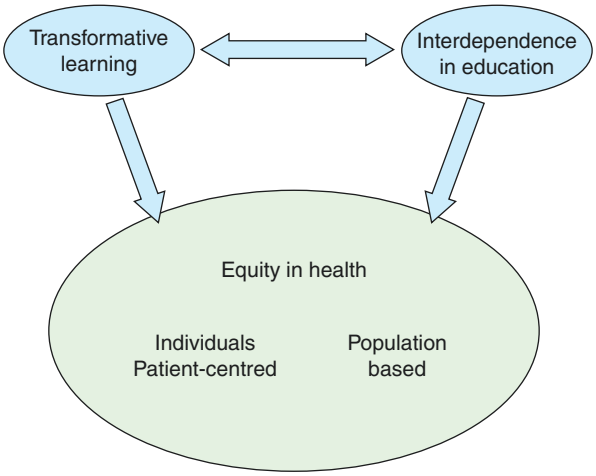

Fig. 1.2 Vision for the future of academic medicine. (Source: Frenk J, Chen L, Bhutta Z, Cohen J, Crisp N, Evans T, et al. Health professionals for a new century: transforming education to strengthen health systems in an interdependent world. The Lancet. 2010;376(9756):1923–1958)

medicine and trained physicians is thus central to achieving equitable health outcomes for all, with an 'endeavour to reach the furthest **behind** first' [9].

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Part II

Background

Why Should We Publish Papers?

2

To get to know, to discover, to publish—this is the destiny of the scientist

—Francois Arago, French Mathematician, Physicist and Astronomer (1786–1853)

2.1 What Is Academic Medicine?

Academic medicine traditionally includes three principal pursuits, i.e., educating doctors and biomedical scientists, discovering the causes and cures of illness, and using knowledge to improve patient care. Teaching, research, and service are the triad of academic medicine (Fig. 2.1). It has also been described as 'the capacity of the system for health and health care to think, study, research, discover, evaluate, innovate, teach, learn, and improve' [1].

2.2 What Are the Duties of a Doctor in an Academic Institution?

An academic doctor plays many roles like clinician, teacher, administrator, mentor, examiner, and researcher during his or her lifetime (Fig. 2.2). However, his/her most important role is patient care followed by teaching and finally research. Thus, research and publication are important aspects of academic medicine but combining academics with patient care are two full-time jobs that many physicians are unable to pursue.

As a clinician, the first priority is to treat a patient's illness. This involves the science as well as the art of practicing medicine. A clinician in an academic institution should follow the highest standards and guidelines for practice so that his/her

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_2

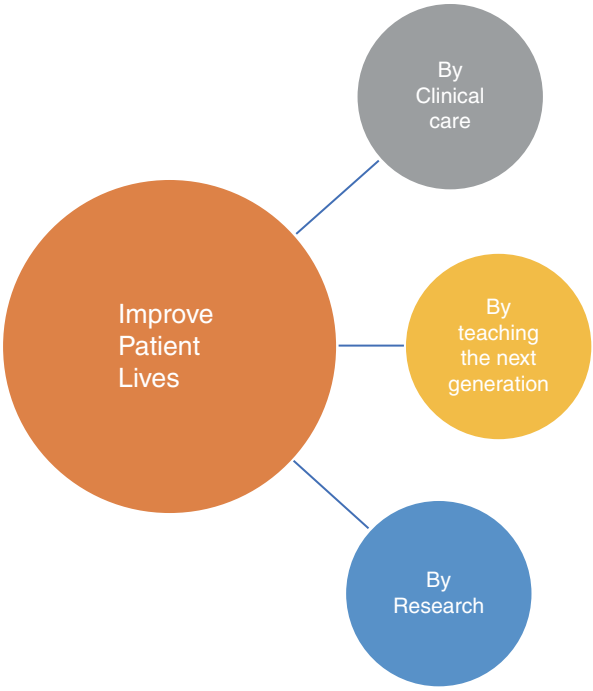

Fig. 2.1 Components of academic medicine

Fig. 2.2 Role of an academic doctor

students can imbibe these qualities. The clinical care of patients is taxing, especially in private hospitals where patients are more demanding than they are in public institutions.

Academics provides a physician multiple roles like the opportunity to teach the next generation of doctors, provide comprehensive care to patients, and opportunities for research. As a teacher, he or she may be involved in lectures, case presentations, journal clubs, and topic discussions. However, his/her greatest quality should be a passion for teaching. Being a physician in an academic institution also has a major impact on medical students who look upon their teachers as examples to follow. Anne Beal of the Commonwealth Fund stated that 'medical school faculty set research agendas, influence medical education and yet serve as role models for the recruitment and retention of students' [2].

2.3 Is Publication in Medical Journals a New Phenomenon?

'The purpose of research is to publish'—Michael Faraday English Physicist and Chemist (1791–1867)

Scientific publication began in 1660 with the *Journal de Scavans* in France and the *Philosophical Transactions of the Royal Society of London*. Henry Oldenburg was the first appointed secretary, i.e., editor, in charge of managing the 'correspondence' between the Society and the rest of the scientific world (Fig. 2.3) [1]. Since then there has been an exponential surge in publications in the field of medicine, the number of articles have increased and so have the journals which now may number more than 30,000. The main role of medical research articles has always been to inform other doctors and the general public about the progress of science. However,

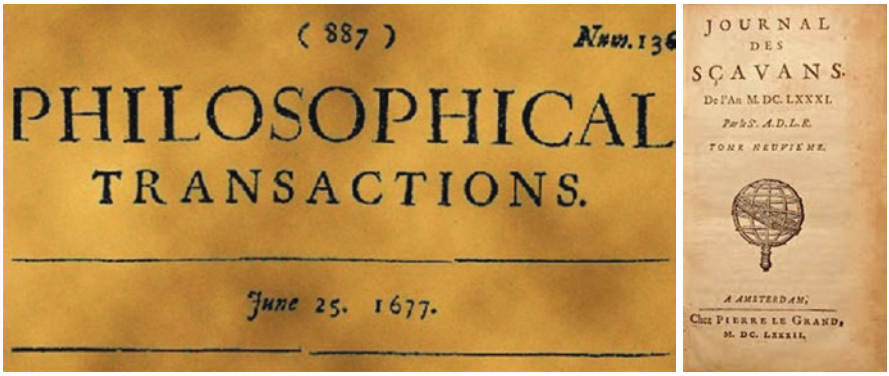

Fig. 2.3 Image of the cover of the first medical journal

in the current competitive academic environment, more articles are probably published so that authors can gain colleague approbation and faculty promotion.

2.4 What Are the Main Reasons for Publications?

These are disseminating the progress of knowledge, personal credit, gaining recognition for a department or institution, and improving patient care. Moe et al. have likened publication to a 'golden egg'. They suggest that the reasons for publication can be summarized in a 'SULTAN pyramid' (amplified below)—to acquire a degree forming the base of the pyramid (Fig. 2.4) [3].

- **S**—Study requirement for obtaining degrees like Doctor of Medicine or Master of Surgery (MD/MS), Diplomate of the National Board of Examinations (DNB), or Doctor of Philosophy (PhD).
- **U**—Requirement for higher faculty posts in academic institutions, salary hikes, or to improve career prospects.
- **L**—Long-term sustainability of an academic career—called 'tenure' in America.
- **T**—Achieving a position like a departmental head, dean, and director.
- **A**—Advancement of health, education, and economic policies.
- **N**—Name and fame in society and among one's family and colleagues.

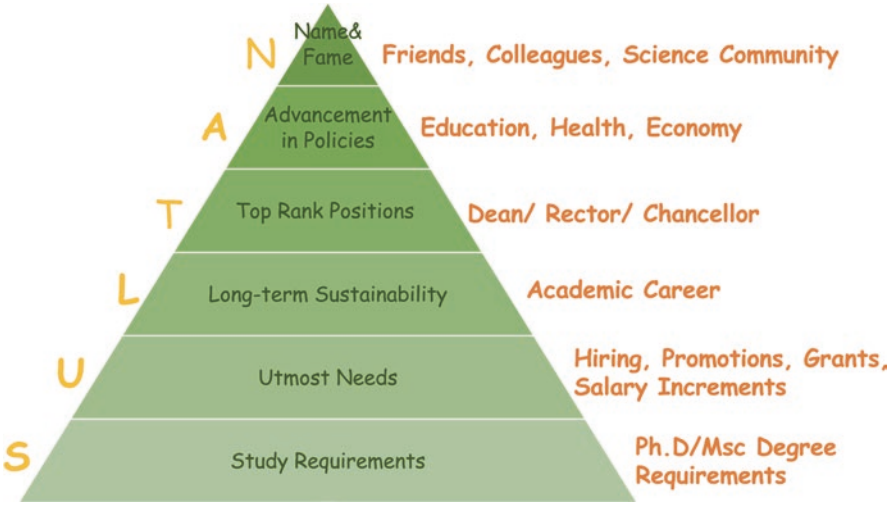

Fig. 2.4 Why we should publish?

2.5 Are There Any Other Reasons for Publications?

Some mention that the main reason why we publish is to improve our Curriculum Vitae and fulfilling criteria for recruitment [4]. The main advantage of publication therefore can also be to further one's career [5].

To the above, we would also like to add a financial reason. In this triad of name, fame, and money, we feel the maximum gain is in personal growth from being a nonentity to an author, from being an ordinary person in a crowd to a leader, to whom people will look for help. You will also become more confident on the professional front and get more referrals from your colleagues.

Publication also increases collaboration between different institutions, which may also involve some injection of finances [6]. You will get an opportunity to travel to present your work in various conferences here and abroad and meet the leaders in your field.

2.6 Does Publishing Negative Studies Also Give You Fame?

Sharing negative results does not mean making a good story out of a bad one, that the results are less important, or that they should remain unpublished [7]. But the reality is that if the results of a scientific paper are negative it will be difficult to find acceptance of your submission by a journal editor. However, some of the most important publications in academic medicine have a negative outcome.

2.7 Fraudulent Publication and the Case of Dr. John Darsee?

John Darsee was a physician and investigator who had a long list of publications in leading journals. He seemed, on the surface, to be having a successful career in the field of research in cardiology and a former administrator described him to be 'one of the most remarkable young men in American Medicine'. At the age of 33 years, Darsee was offered a faculty position at the Harvard Medical School in Boston but the trajectory of his career quickly began to collapse when one day his colleagues caught him juggling with the data in a study on heart attacks. There was subsequently an enquiry against him which found scientific delinquency on a large scale. He was punished by being expelled from his institution, banned from receiving any grant money for ten years and all his manuscripts were withdrawn from the medical literature. He eventually expressed regret for publishing 'inaccuracies and falsehoods' [8]. The Darsee syndrome is named after him reflects the state of how doctors are pressurized to 'Publish or Perish'.

This happened in 1970. However, since then the pressure to publish continues to lead to the fabrication of data. Recently during the present COVID pandemic two papers published in reputed journals were retracted which were based on 'doubtful' data which were untraceable. These were 'Cardiovascular Disease, Drug Therapy, and Mortality in COVID-19' in the *New England Journal of Medicine* [9] and 'Hydroxychloroquine or Chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis' in the Lancet [10]. Both happened in the early part of 2020 [11]. Although, the publication is necessary as an academic physician you should always follow the highest ethical standards in all your activities—patient care, teaching, and research.

2.8 Conclusions

- Academic medicine involves patient care, teaching, research, and publication.
- We publish to get degrees, acquire fame, share knowledge, and get faculty promotions.
- Both positive or negative results help to build knowledge.
- Unethical practices should be strictly avoided as they can ruin careers and lead to much harm.

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3 Overcoming the Initial Barriers to Publication and the Role of the Mentors?

Leaders become great, not because of their power, but because of their ability to empower others

—John Maxwell, American Author (1947–)

3.1 What Is India's Contribution to the World's Medical Publications?

Although India has 1.3 billion inhabitants, which is 17.7% of the world's population, it contributes only1.6% of all the articles to the medical literature (1998–2008) [1, 2]. The top two countries with the largest number of scientific publications are the United States and China. The other countries that are at the top after they are the United Kingdom, Japan, and Germany (Fig. 3.1). There is, however, a large difference between the number of papers published by America and other top countries. Although India ranked among the top 20 countries based on the number of publications from 2008 to 2012 [2]. It produced much fewer papers than the world's leading nations.

3.2 Are the Numbers of Publications from India Increasing?

There are three large data systems that have studied the publications from India over the last 10 years [3–5]. These have been based on Scientometric analyses [3, 5], which aim to provide a quantitative characterization of scientific activity. Table 3.1 shows that although the total numbers of research papers have varied in the three studies (possibly because two different databases were used). Gupta et al. concluded that the annual publication growth rate had increased by 11.6% between 1999 (3930) and 2008 (10,381) [3].

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_3

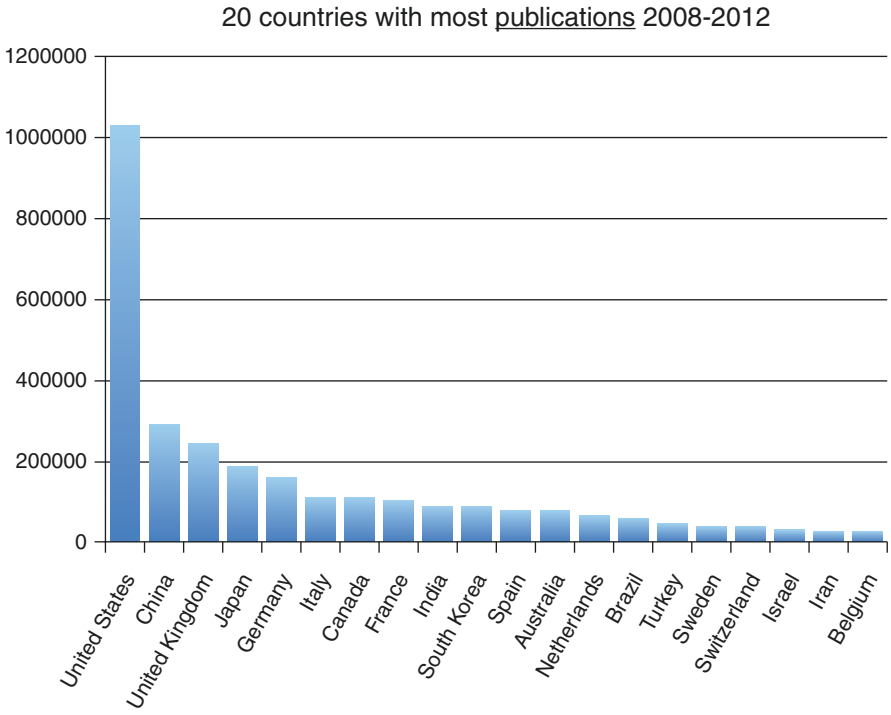

Fig. 3.1 Twenty countries with most publications (Reference for citation: Xu Q, Boggio A, Ballabeni A. Countries' Biomedical Publications and Attraction Scores. A PubMed-based assessment – Scientific Figure on Research Gate. F 1000 Research. 2015 H)

Table 3.1 Medical research output from India

Authors	Gupta et al. [3]	Ray et al. [4]	Chaman Sab et al. [5]
Date of paper	2011	2016	2018
Period studied	1999–2008	2005–2014	2005–2014
Number of publications	657,345	101,034	29,153
Database used	Scopus	Scopus	Web of Science
H index	97	–	71

3.3 Is Quantity or Quality More Important in Publications?

Although there is evidence that it is better to publish papers than not publish at all Indian scientists publish papers that are generally of a poor quality, i.e., they are not included in respected indexing systems and therefore rarely cited [3–5]. We need to upscale our research activities to investigate systematically the problems that occur in our own country rather than perform copycat investigations based on Western publications. However, this is not to say that we should shun Western collaboration

because there is much to learn from their experience and there is also evidence that such joint efforts receive more citations [6].

3.4 Should Faculty and Students from All Medical Colleges Publish Papers. Does this Not Detract from Patient Care and Teaching?

There is evidence to suggest that medical institutions which have done more research provide better patient care and by disseminating their knowledge attract the best students and faculty in a country [7]. Indeed the US experience seems to support this. During the early twentieth century, the state of American medical education was similar to what we have in India today. There were a large number of medical colleges producing substandard doctors. The Carnegie Foundation then sent Abraham Flexner to Germany and the UK where medical education standards were higher. Based on the influential 'Flexner report' of 1917 the number of medical colleges in the USA was drastically reduced and it was recommended that their research

output be assessed to be a surrogate marker of the quality of the training they were imparting [8]. More than one hundred years later this report still forms the basis of the American medical education system. Although it has been commented that 'teacher and student chased each other down the fascinating road of research, forgetful of those wider interests to which a hospital must minister' research and clinical care should fuse together for the better prosperity of patients as well as the institution [9].

According to a recent study published on the research output of 579 medical teaching institutions in India 57% had not published a single paper between 2005 and 2014, which was included in the Scopus indexing system. Four Indian medical colleges, i.e., the All India of Medical Sciences, New Delhi, the Post Graduate Institute for Medical Education and Research, Chandigarh, Christian Medical College, Vellore, and the Sanjay Gandhi Institute of Medical Sciences, Lucknow were responsible for a quarter of the total number. Only 25 institutions produced more than 100 papers per year and their contribution to overall publication output was 40.3% [4].

It has also been found that 88 medical colleges that received research grants from the Indian Council of Medical Research (ICMR) did not publish any papers at all. Only 10% of projects funded by the ICMR ended in the publication in indexed journals [10]. In 2002, in another study, the ICMR concluded that out of 158 medical colleges, 27 did not have any publication at all, and 29 had only one paper [1]. Clearly there is a large disparity in India, between the best medical institutions which produce some papers and the large majority which publish very little or nothing at all.

3.5 How Much Does the Private Sector Contribute Towards Research?

The private sector provides almost 80 percent of the outpatient and 60 percent of the inpatient care in India. It is also emerging as an alternate medical education hub with more than 470 private medical colleges all over the country. Unfortunately, the primary aim of most private institutions is to make money for their owners and shareholders through student fees and patients' fees and therefore they do not invest in research that will eat into their profits. Yet despite this, there are some, mainly not-for-profit hospitals, which generate a reasonable number of publications (Fig. 3.2). The top three being the LV Prasad Eye Institute in Hyderabad (1202), Sir Ganga Ram Hospital in New Delhi (1067), and the PD Hinduja National Hospital in Mumbai (677) [4]. However all these institutions are very far behind similar ones in the USA like the Massachusetts General Hospital in Boston and the Mayo Clinic which over the same period produced 46,3011 and 37,633 papers respectively.

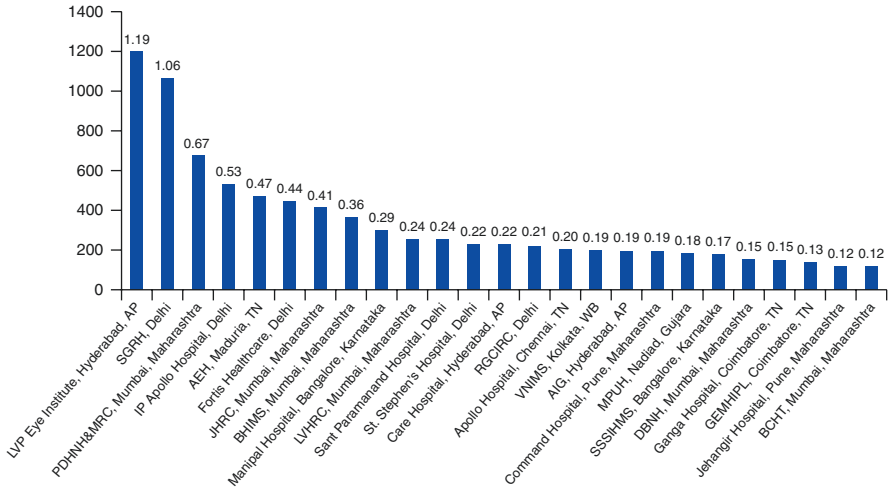

Fig. 3.2 Distribution of the number of publications by the hospitals from private sectors in India

3.6 Is the Recent Medical Council of India (MCI) Rule Linking Publications to Faculty Promotion the Main Reason for the Surge in Publication Numbers?

The MCI was established in 1956 with the main objective of maintaining uniform standards of medical education in India. These state that medical professors are the planners and builders of the future of students and have a fundamental role in shaping their careers [11, 12].

Many amendments in regard to the appointment and promotion of medical teachers have been declared under the 'Minimum Qualifications for Teachers in Medical Institutions Regulations, 1998' to its last version of 'amendments up to June 8, 2017'. These consist of two main criteria, firstly teaching experience and then comes research publication. The second criterion is regarded to be the passport for an eventual professorship.

According to a circular in 2015, a medical teacher should possess certain requirements in regard to his or her publications, i.e., to be either the first or second author (later amended to the corresponding author) in a publication in journals that are included in six indexing agencies—Scopus, PubMed, Medline, Embase/Excerpta Medica, Index Medicus, and Index Copernicus. The circular also states that only original research papers would be considered.

A Professor should have published 4 papers, an Associate Professor 3, and an Assistant Professor 2 papers.

3.7 Can We Expect India's Unique Health Issues to Be Solved By the Developed World?

There are many health problems which are largely 'Indian'. These include the big five communicable diseases like tuberculosis, malaria, diarrhoeal diseases (including cholera), AIDS, and acute respiratory infections. Among the non-communicable disease that are now common and increasing in prevalance are diabetes, cancer, cardiovascular diseases, and blindness. There are some diseases that are also largely unique to our region like leprosy, filariasis, sanitation-induced illness, Kyasanur Forest disease, and Nipah virus infection. Among the non-communicable diseases, cancers and diabetes occur at a younger age than in Western populations. For all these local problems, we need local solutions which is only possible if we do research [12–15].

Unfortunately, many of the solutions to our health problems have been found by expatriates working here or in laboratories abroad. Some examples of expatriates as well as Indians working in India, contributing to landmark research are as shown in Table 3.2

3.8 What Are the Various Barriers to Quality Publication Output from India?

There are several reasons proferred for our low research output which are considered to be barriers. They include [1, 12]:

- Lack of time
- Lack of financial support
- Lack of attitude and aptitude
- Lack of a team to support research
- The perception that research is a 'fancy' activity and an unnecessary waste of time
- Lack of adequate training in research methodology

3.9 How Can a Clinician Take Out Time from His/Her Schedule for Publication?

The two important responsibilities for a physician are patient care and teaching. The former takes up most of a doctor's time. In addition, there are administrative responsibilities that are given to him or her from the institute. Thus for him to take out time for research he needs to cut down from his 'leisure' time. Dedication and interest are a must for this commitment [1, 4].

Table 3.2 Major contributors to landmark Indian research (India and overseas)

Expatriates working in India	
1. Folly TLF (1798)	The medical skills of the Malabar doctors in Tranquebar, India (1798)
2. McCarrison, Major General Sir Robert (1878–1960)	Nutrition, goitre, cretinism, Nutrition Research Laboratory
3. Ross, Ronald (1857–1932)	20 August 1987, Secunderabad, Ross made the landmark discovery of transmission of malaria by the Anopheles mosquito; Nobel prize in Medicine in 1902
4. Esdaile, James (1831)	The 'Apostle of Mesmerism in India'
5. Fayrer, Sir Joseph (1824–1907)	Treatment of snakebite, in India. Physiological effects of the venom of poisonous snakes (Thanatophobia of India, 1872)
6. O'Shaugnessy, Dr. William Brooke (1809–1889)	Modernized treatment of cholera, introduced cannabis to Western medicine, laid the first telegraph system in Asia
7. Russell Dr. Patrick (1727–1805)	*The Natural History of Indian Serpents*
8. Annesley-James (1828)	*Diseases of India* vols. 1,2; Cholera and other tropical diseases. 1828
9. Carter, Henry Vandyke (1831–1897)	Drawings for the famous textbook *Gray's Anatomy*. Work on leprosy, actinomycosis, relapsing fever etc.
10. Swain, Clara A (1912)	First medical missionary to the women of the orient
11. Brand, Paul (1914–2003)	Surgery for the reconstruction of hands damaged by leprosy
12. Scudder, Ida (1870–1960)	Founded the Christian Medical College and Hospital. Saved lives of countless women who might have died during labour
Indians working in India	
1. Furdoonji, Dr (Miss) Rupa Bai (1885)	World's first qualified lady anaesthetist
2. Nath, Indira (1938)	Indian immunologist. Mechanisms underlying immune unresponsiveness in man, reactions, and nerve damage in leprosy
3. Brahmachari, Rai Bahadur Sir Upendranath (1873–1946)	Synthesized Urea-Styibamine in 1922; effective treatment for Kala-azar
4. De, Sambhunath (1915–1985)	Discovered the cholera toxin; successfully demonstrated the method of transmission of *Vibrio cholera*
5. Bose, Jagdish Chandra (1858–1937)	Plant neurobiology
6. Chopra, Ramnath (1882–1973)	Indian pharmacopoeia. Books include 'Indigenous drugs of India', 'Glossary of medicinal plants of India', and 'Poisonous plants of India'
7. Venkataswamy, Govindappa (1918–2006)	Aravind eye hospital
8. Sethi PK (1927–2008)	Jaipur foot
9. Bawaskar, Himmat (1983)	Scorpion, snake bites, medicine in rural India
10. Chatterjee, Asima (1917–2006)	Periwinkle derived alkaloids having anti-cancer properties
11. Vaidya, Vidita (2000)	Neurophysiology and stress-associated psychopathology
12. Mukerji, Mitali (1967)	Human genomics and personalized medicine
13. Mukhopadhyay, Subhash (1931–1981)	India's first test-tube baby in 1978

Suggested by Dr. Sunil Pandya, Neurosurgeon, Mumbai

3.10 Do Our Institutes Lack the Infrastructure for Research and Publication?

Some research requires dedicated space, computers, Wi-Fi connections, manpower in terms of artwork specialists, statisticians, and reliable Internet access to medical journals and all these facilities are not present in many Indian medical institutions. However, there are examples of many major discoveries that have been made by enthusiasts in poor countries in the absence of adequate infrastructure. These include Dr Dennis Burkitt who described lymphoma in Uganda. Thus, proving the point that 'wherever there is a will there is a way'. Other discoveries that have helped developing countries, in particular, are using blue light to treat neonatal jaundice, praziquantel to treat schistosomiasis, the hepatitis B vaccine, a rapid malaria test for diagnosis, and the female condom.

3.11 Do We Need Finances to Start Writing for Publication?

Once there is a will very little financial support is necessary to publish papers and although some open access and 'predatory' journals have started charging large sums for this. They are best avoided. In other instances publication fees for open access in leading journals can be supported by funding bodies or research grants.

Clinical trials or laboratory-based research require manpower and reagents that are the main source of expenditure. If the research proposal is promising, one can apply for funding from the ICMR, Department of Biotechnology, the Department of Science and Technology in India, or even the National Institutes of Health in the USA and many other sources both here and abroad.

3.12 Do We Have an Attitude Towards or an Aptitude for Research?

Attitude is an option or behaviour about research whereas aptitude is a flair for it. Whereas the former can be acquired the latter is natural. Workshops and incentives can help in changing the behaviour of doctors for publication as is being demonstrated in China.

3.13 What Is the Role of a Mentor in Publication?

A mentor is a teacher who can help students to understand research methodology and do hand-holding and act as a role model during the initial phase of projects. There is, however, a shortage of these individuals in most developing countries [16, 17]. It has been suggested that our medical education should be research oriented, we should strive to improve the quality of medical faculty in colleges, try to decrease load of patients so that adequate care can be given. Besides this hand-holding by

premier research institutes to upscale the research activities in medical college is also recommended [18, 19].

The best tips for improving our research output are:

- Educating students on the benefits of research.
- Providing incentives in the form of financial rewards for publication.
- Encouraging students to network with other researchers.
- Holding frequent, well-publicized regular research meetings and updates.
- Conducting medical writing and editing workshops.
- Encouraging students to attend scientific conferences and learn how the mentors present.
- Regarding our Medical Records as a source of treasure.
- Balancing the faculty's clinical and research commitments.

3.14 Conclusions

- There are many barriers preventing initial publication which include a lack of time, lack of infrastructure, and the lack of attitude for research.
- Despite all the bottlenecks, India still figures in the top 20 countries according to its research output.
- A mentor is a person who can handhold for the initial publication and shows the road forwards.
- Both attitude and aptitude need to be developed for doing research.

- We have a large number of patients for undertaking research and our spectrum of disease is different from that seen in the West. For local problems, we need local solutions which can only be done if we do research.

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When Should We Start Doing Research and Publishing Papers?

4

Publication is a vital science. It is actually contributing to the world's store of knowledge

—Stephen Lock, Former Editor, BMJ (1929–)

4.1 Is Research Methodology Taught in the Undergraduate Syllabus?

Although basic statistical concepts are covered during the Preventive Medicine posting in the majority of medical schools in India there is no attention paid to research. However, globally many leading universities encourage their undergraduates to do research. A classic example of this was in 1923 when Charles Best was an undergraduate at the University of Toronto, he together with Banting and Mcleod, discovered insulin. Banting shared the Nobel Prize money that he was subsequently awarded with his student Best. Another Nobel laureate, Alan Hodgkin, won the Nobel Prize in 1972 for his work on nerve transmission that he had begun as an undergraduate in Cambridge, England.

Medical colleges should be the institutions where the greatest amount of research takes place. Even if the undergraduate does not do it, he or she should be inspired to do research by following the examples of his/her post-graduate seniors and faculty. At the post-graduate level, writing a thesis has been made compulsory by many medical councils in this country but, as everyone knows, it is a chore, usually copied from someone else's work and rarely published [1].

There are now more than 542 teaching medical institutions in India producing 79,798 medical graduates. However, there is practically no research activity and 91.2% of interns have no research skills at all [2]. Fifty-seven percent of these institutions had published not a single paper that was indexed between 2005 and 2014. This is probably true of most developing countries. One of the indices for ranking

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universities worldwide is on the basis of their research output and very few from developing countries are included in the top 200 positions.

4.2 What Is the Brain Drain?

The brain drain is a term that describes the relocation and loss of a skilled worker such as a doctor, nurse, or scientist who leaves the country of his/her birth to move to a more developed nation in pursuit of a better quality and standard of life. This also generally means a higher remuneration, exposure to a progressive skilled environment, and a more stable political situation where there is less corruption (Fig. 4.1) [3]. Data suggest that close to 90% of the brain drain for physicians were to just five nations: the USA, UK, Australia, Canada, and Germany [4]. The main contributor nations are from Asian countries, i.e., India, Pakistan, and Sri Lanka. The migration process starts immediately after receiving an MBBS degree or a PhD. However doctors who have migrated can still play a big role in the upliftment of the country of

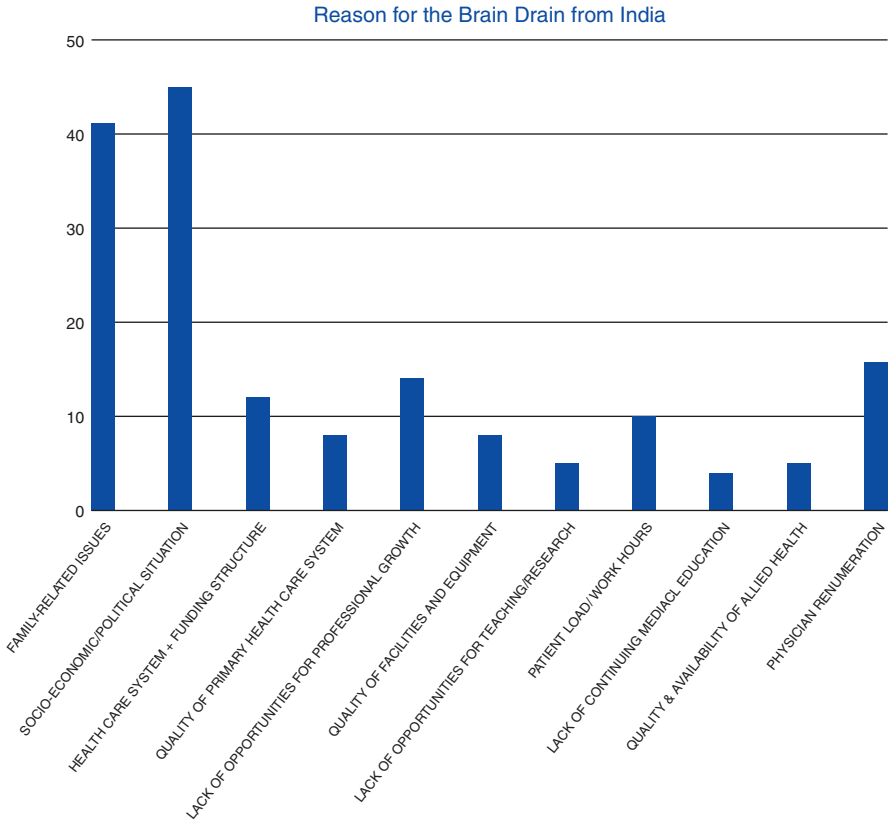
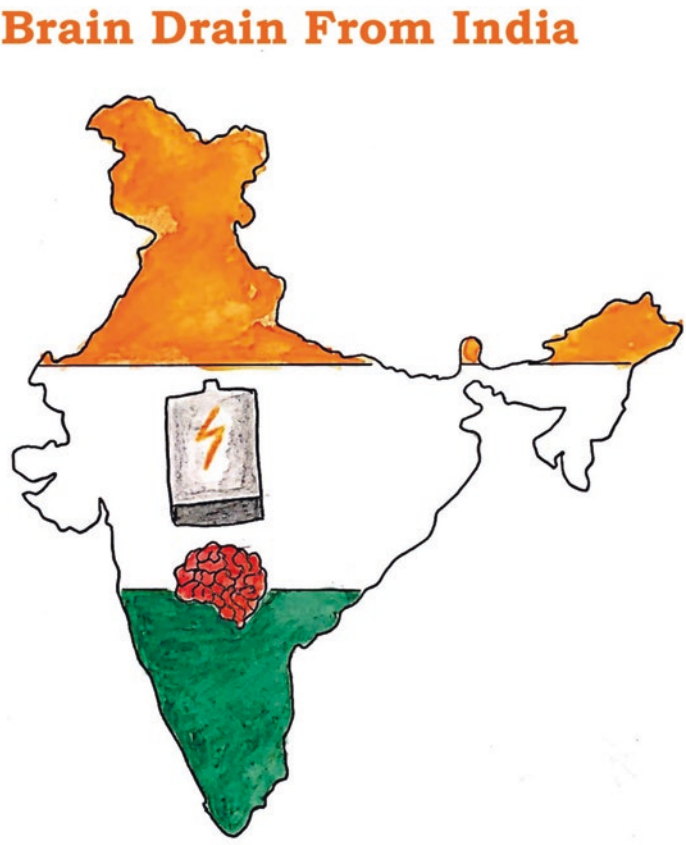


Fig. 4.1 Reasons for the brain drain from India

their birth by doing collaborative research or by teaching students. This may be a way how a brain drain can be converted to a 'brain gain'. There are many associations of doctors which have been formed in the USA and UK precisely with these objectives. India has the largest diaspora in the world. Although the brain drain decreases the research output from the country of origin it can be an opportunity to foster collaboration and improve the research of the host country.



In 2015, India had the largest "diaspora" in the world at 16 million people

4.3 Is an Internship a Good Time To Do Research?

In one study half of the interns (54.2%) stated that internship was not the appropriate time for the exposure to research, as their priority during the internship was to study for entrance examinations to post-graduate courses [2]. However, data from the Netherlands suggest that as students have different types of incentives, interests and determinations the best time to position the research-related internship in a medical programme should be flexible and should be not only *after*, but also *before* the clinical clerkships [5].

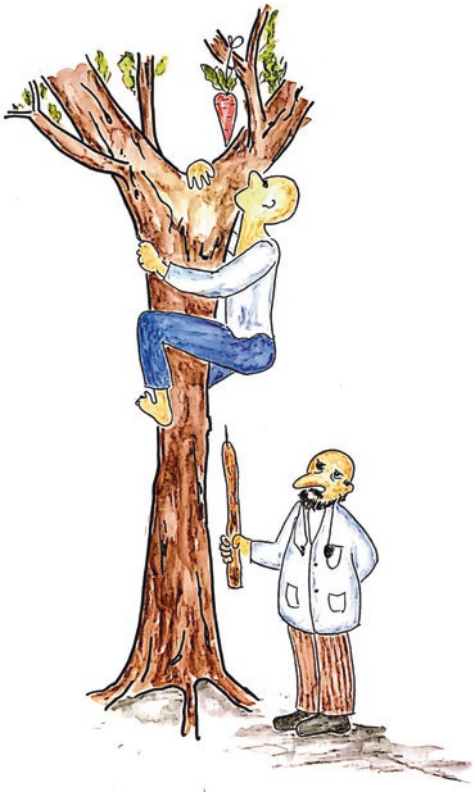
4.4 What Are the Requirements of Research During Post-Graduation?

The basic requirement for post-graduation or super specialization for various degrees like MD, MS, MCh, DM is writing a dissertation or thesis. Such dissertation is also needed for the FCPS in Pakistan and Bangladesh. It is considered to be a passport to sit for the exit examination. Although there are at least 22,000 theses produced every year very little of the output gets converted into a final publication anywhere.

The University Grants Commission currently requires PhD scholars to publish at least one manuscript in a peer-reviewed journal and present two papers at conferences or seminars before they submit their doctoral theses for assessment. Such rules are not there for Master's degrees [6]. The conversion rate of a dissertation to a research manuscript is low and was reported only in about one-third of PhD students [1]. The last 10 years data has also shown a declining trend in the conversion of theses to papers.

4.5 How Can We Increase the Student-Based Research Activities in Our Country?

The two main ways to increase research activity are to use the 'carrot and stick' approach.



Carrot

1. Catch them young—start research during the MBBS course and add marks in the final examination and for selection in post-graduate courses depending on the number and quality of papers published.
2. Give incentives for research at the post-graduate level in selection for faculty appointments.
3. Give awards for theses that get converted into peer-reviewed publications.
4. Faculty promotions should be based on the number and quality of research papers published and their journal impact factors.
5. Link research publications with academic benefits like funding and attending conferences abroad.
6. Provide financial rewards for papers published in prestigious journals following the successful examples of China and other countries.
7. Explain to selectors and administrators how research publication benefits patient care, institution attractiveness to students and faculty, and the image of the college abroad.

Stick

1. Insist that post-graduates publish at least one research paper in an indexed journal before being awarded a degree
2. Base faculty promotions on research publications—20 for Professor, 10 for Associate Professor, and 5 for Assistant Professor.
3. Start a 'Tenured Faculty' system depending on the continuing publications of an individual. If they do not reach a specified standard he or she should be asked to leave.

4.6 Are There Any Journals That Publish Papers Directed Mainly at Students?

These include the *Student BMJ*, *International Journal of Medical Students*, *American Medical Student Journal*, *Medical Student Journal*, and *Medical Student Research Journal*. Also, many journals have a special section for students mainly authored by trainees.

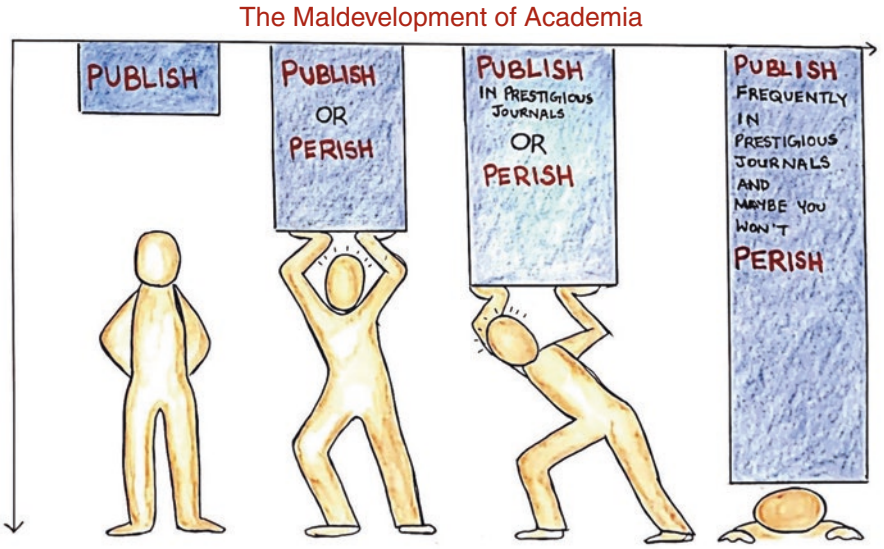
In a recent publication, the problems with student medical journals were discussed at length. These included low impact factors, a poor peer review process, lack of visibility in PubMed and other indexing systems, and the low quality of articles [7]. Despite these shortcomings student research should be encouraged not only in these student-friendly journals but also in mainstream publications [8].

All types of articles may be published in student journals ranging from original articles, case reports, letters to the editor, book reviews, commentaries, and images. Not all of them need to be contributed only by student authors.

The *Yale Journal of Biology and Medicine* is one of the oldest student journals and is also indexed in MEDLINE. It also publishes three theme-based issues in a year [9].

4.7 How Can We Increase Our Research Output After Post-Graduation?

As a senior resident applying for a post of Assistant professor in an academic institution you will need publications. The same is true for further promotion. 'Publish or perish' has become an international watchword that increases the quantity but not the quality of paper writing [10]. This burden and the resulting upsurge in the number of publications has, unfortunately, led to 'unethical practices and wasteful research'. It has also been stated that the Indians are all about quantity but not quality [11]. The gold standard of research should be such that in ten years the guidelines or treatment suggested in a publication become incorporated into textbooks [11]. Our suggestion is that linking research to salaries may be the biggest boost to output.



4.8 Conclusions

- You should encourage your residents to pursue scholarly activities such as research and publication.
- Research for post-graduate students is often confined to getting a degree. It is only a passport to appear in examinations.
- The brain drain in doctors is related to migration for a better quality of life and many migrate after post-graduation to build academic careers. This should be taken as an opportunity by us for collaborative research.
- The carrot and stick approach may be a good way to increase a nation's biomedical research output.

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Does Research Improve Patient Care?

5

You can have data without information, but you cannot have information without data.

—Daniel Keys Moran, American Science Fiction Writer (1962–)

5.1 Are Patient Care and Clinical Research Related Activities?

Patient care and research are complementary. If you do research it helps you to become a better clinician. The first step in doing clinical research is to formulate a research question [1]. The sequence of events which helps in studying gaps in knowledge comes from regularly reading published scientific papers which in turn are based upon the data generated by others. Patients are living teachers and each one teaches us something new.

The mind of a clinician should always be curious to know what the deficiencies are in current knowledge while pursuing practice. A major excitement in medicine is the working up of undiagnosed cases. These cases are like solving a jigsaw puzzle where the physician puts in each piece of evidence to make a pattern and solve a mystery. Another challenging area is to treat patients who have 'grey' illnesses, i.e., those whose management has not been described in any published books or guidelines.

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5.2 How Can One Blend Research with Practice?

Practicing physicians have been involved in clinical research for many years. It is usually said that 'The gap between research and health care practice can be reduced by the immersion of the researcher in the practice environment' [2]. Initially, research was limited to collecting data or performing retrospective analyses of such data and describing case reports or case series. Recently, scientific techniques have exploded with many new types of study design, such are randomized controlled trials, metanalyses, quality of life investigations, and translational medicine research. The average doctor needs to be taught how to carry out research as this is usually not covered in their curriculum. He needs to be trained how to write research protocols, what the types of study design are, how analyses including metanalyses are done, and basic statistics. Till he/she receives such hands-on training on how to do research he/she may have to just limit research activity to gathering retrospective data and not venture into new and exciting research paths.

5.3 How Should I Start Research in My Institution?

You first need to build synergy between your clinical and research teams. The clinical team should have a consultant and associates, residents, and nurses whereas the research team should include a research coordinator and a statistician. You will also require a computer and Internet access. Finally, you must have the will to persist till you reach your goal and then to write up the results well. You may not start by being proficient in medical writing but this skill can be developed over time by sheer persistence. Another key principle is to find a good and helpful mentor who can help you navigate through this exciting journey.

5.4 What is Evidence-based Medicine?

Evidence-based medicine is the meticulous, clear, judicious, and reasonable use of current, best evidence in making clinical decisions about the care of individual subjects. Evidence-based medicine integrates clinical experience, scientific information, and patients' values for treating a disease [3] (Fig. 5.1).

The concept of evidence-based medicine is not new. The first record of this is from the year 1192–1250 AD, when the Emperor Frederick II who ruled Rome, Sicily, and Jerusalem showed his interest in this type of experiment. He showed the effect of exercise on digestion using the knights. He gave them identical meals and then one was sent for hunting and the other was restricted to bed. Several hours later he killed both of them to examine the residue in the gastrointestinal tract. The inactive one had the greater stomach residue. The experiment was evidence based but definitely not a good example to emulate!

The effect of bloodletting on humans was also studied based on a randomized trial by Jan Baptista Van Helmont in the seventeenth century. He divided the poor

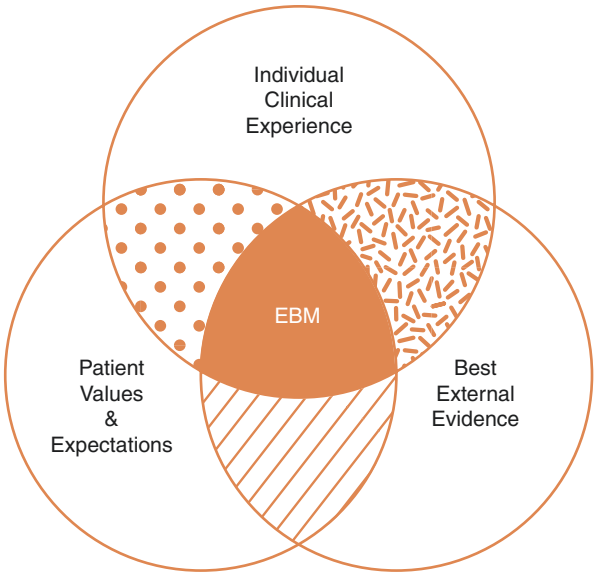

Fig. 5.1 Evidence-based medicine: integration of clinical experience, patient values, and expectations and best external evidence

population into sample sizes between 200 and 500 by casting lots. While one group had a phlebotomy, the other was left alone. The number of funerals was recorded in both the groups. However, in the nineteenth century when Pierre Charles Alexendrae Louis introduced the concept of statistical analysis for the treatment of medical outcomes he showed that bloodletting did not change the outcome of disease. Despite this the practice of bloodletting did not change for many years.

James Lind, a Scottish physician will be given the credit for conducting the first documented experimental trial in medical history, by administrating citrus fruits to treat scurvy. He conducted the trial on a naval ship in 1747 by giving oranges and limes to half of the sailors affected by scurvy and not to the others, and recorded their progress and outcomes in detail. Those who were given citrus fruits recovered from scurvy and those who were given did not. Lind concluded that there was something in the fruit (later shown to be Vitamin C), which prevented scurvy [4].

Now the Cochrane Library synthesizes the best evidence on individual medical problems and publishes authoritative and widely read systematic reviews and summaries of the results [5, 6].

5.5 How Can Research Data Be Incorporated into Clinical Practice?

Previously reading medical journals used to involve going to library and reading printed papers. However, this has now changed tremendously with the advent of the Internet and most information is widely and easily available through laptop, computers, iPads, and even smartphones. This has revolutionized medical education and research and we will discuss this in detail in a subsequent chapter [7].

5.6 What are the Limitations of Medical Care in Developing Countries?

The expenditure on health care in developing countries is very small. There are many reasons for this but their low Gross Domestic Product (GDP) is probably the single most important factor. Most developing nations spend about 1–2% of their GDP on health care compared with the USA that spends 18% of a much larger GDP [8]. What is expected from us in our resource-constrained settings is to provide a high quality of health care to our population, which is accessible, affordable, and appropriate. For this we need to be guided by evidence on how to do this which is relevant to us and this can only be obtained by doing research into our own problems.

5.7 How Can Commonly Available Data Help in Research?

Developing countries generally have large populations. If we collect basic data on the common diseases, we will find them to be very different compared to those in the Western countries. Data collection on a common condition like hypertension has helped us realize its prevalence in a younger age group here [9, 10], diabetes mellitus type 2 in India is associated with a low BMI [11]. The common sites of cancers are in the mouth and cervix [12, 13], and rheumatoid arthritis is more common than we previously thought [14]. Using this data, we can plan strategies for diagnosis, treatment, and prevention.

5.8 What is Health Outcomes Research?

Health outcome studies are those which link the treatment or intervention given to a patient and its end result (outcome) (Fig. 5.2) [15]. These studies let us know what works and what does not. These studies can easily be done from good medical

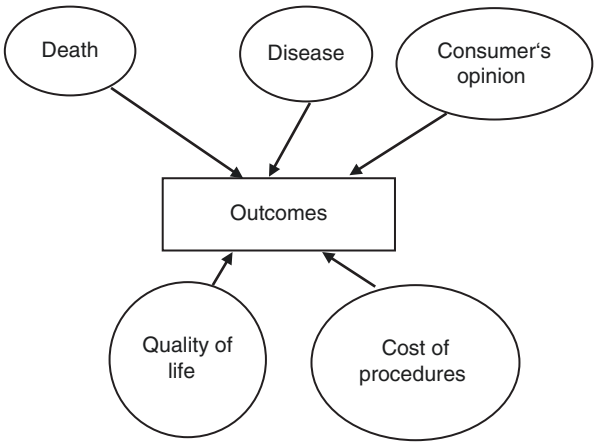

Fig. 5.2 Factors affecting health outcomes

records, clinical audit, and the databases of insurance companies. They can guide us towards correct interventions and decisions, to compare whether the medical facilities available match performance and can help uncover deficiencies. These studies are on safety, efficacy, effectiveness, equality, timeliness, system responsiveness, and are patient centric.

5.9 How is Research Perceived among Doctors?

The way we perceive research has also to be changed. It is usually thought that research is 'experimental and dangerous' for patients. It's safety aspects and patient-centric approach need to be highlighted. The benefits of the research can be exemplified by the following. A large study was conducted in England between 2001 and 2008 involving more than 200,000 patients with colorectal cancer. In patients who participated in the trial the post-operative mortality was significantly less ($p < 0.001$) and also there was improved survival ($p < 0.001$) than in those who did not. Another interesting finding is that even patients who are not enrolled in clinical trials had better outcomes in hospitals that are active in research than in those who are not [16]. In another systematic review and metanalysis on women's health issues of 11 obstetric and 10 gynaecological studies, participation in a clinical trial consistently improved patient outcomes [17].

5.10 Conclusions

- Research and patient care are related activities. Increasing research involvement improves patient care.
- Simple data collection can lead to us to discover how we might help patients better.
- It is easy to blend patient care and research by learning simple research methodologies.
- Health outcomes research measures the value of a particular course of therapy and helps in decision-making.
- Practicing evidence-based medicine improves the quality of treatment patients receive and the most competent clinicians are those who keep abreast of what is the best current evidence by comprehensive and systematic literature searches while treating their patients.

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The Status of Biomedical Research in Some Developing Countries

6

6.1 What Is a 'Developing Nation'?

The International Monetary Fund (IMF) and the United Nations (UN) have both defined developing nations but depend on the country itself to declare whether or not it is still not developed. The Human Development Index (HDI) is easier to understand and is a comparative measure of four parameters—life expectancy, literacy, education, and standards of living for regions worldwide. Countries fall into four broad categories based on their HDI: very high (for developed countries), high

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and medium (for developing countries), and low (for least developed countries). Alternative classification exists based on the Gross Domestic Product which can classify countries into high- medium-, and low-income group. In this article we will use the HDI criteria of 2019 for our discussion [1].

Developing countries have a common set of problems. These include the lack of availability of clean drinking water, poor sanitation, poverty, pollution, low levels of education, poor economic growth, poor funding for health care, and common poverty-related illnesses. All these contribute to the health outcomes of their inhabitants.

We will discuss the health issues with reference to three developing regions:

- Latin America
- Africa
- Asia

6.2 Which Continent Produces the Largest Number of Research Papers?

According to data from 2008 to 2012, the total number of publications worldwide during this period was almost four million, excluding review publications and this number had nearly doubled when compared to the years 1993–1997 (Fig. 6.1). America produces the largest number (35.5%), followed by Europe (33.7%) and

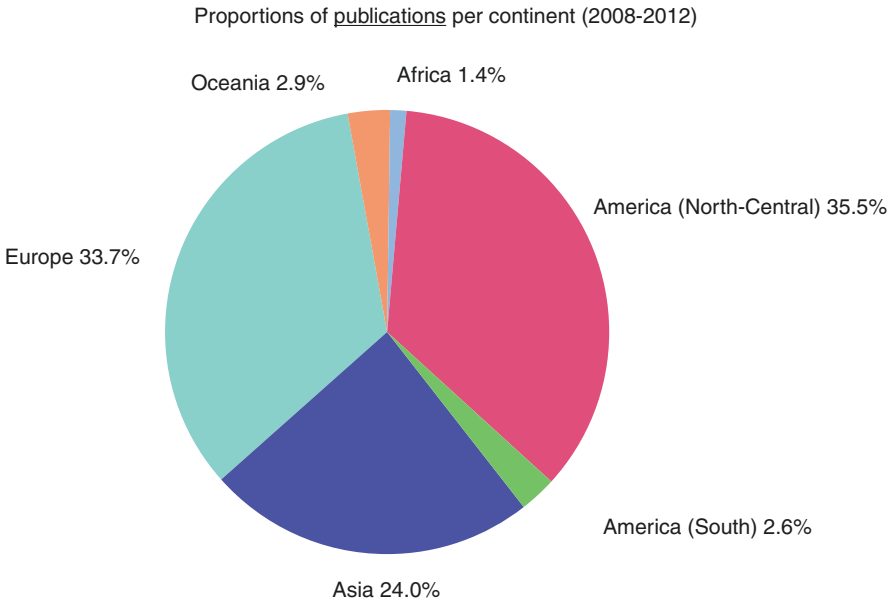

Fig. 6.1 Global data on publications (Xu et al. 2014)

Asia (24%) (for this data, the publications from Russia and Turkey were equally divided between Asia and Europe).

6.3 Latin America

6.3.1 How Can the Developing Nations from Latin America Be Divided?

Latin America can be divided into three regions, i.e. South America, Mexico, Central America, and the Caribbean islands.

Developing countries of South America with a High Development Index
Bolivia
Brazil
Colombia
Ecuador
Paraguay
Peru
Uruguay
Venezuela

Mexico and central America
Medium Development Index
El Salvador
Guatemala
Honduras
Nicaragua
High Development Index
Mexico
Panama

Caribbean islands
High Development Index
Barbados
Cuba
DominicanRepublic
Guyana
Jamaica
Trinidad
Tobago.

Low Development Index
Haiti

6.3.2 Has There Been a Recent Increase in Biomedical Research from Latin America?

Over a 10-year period (2000–2010), Latin America has had a growth of more than 9% per year in its scientific output, which has resulted in a nearly 70% increase in its share of global manuscripts but it was just under 4.4% of the world's annual output of scholarly papers. Among the various developing regions, South America's research is growing and is becoming more visible. The citation impact for Latin America has been improving by 1.6% per year for the above period but is still less than the world's average [2] (Fig. 6.2).

6.3.3 In Which Field Has Latin America Progressed?

In certain areas of science, Latin America's stake in global scientific manuscripts is substantial. For example, in Dentistry and for Biological Sciences it is 10% and 11%, respectively. These areas of medicine have increased considerably together with their citation impact. For dentistry, it was 1% per year which is very close to the world's average, which was 0.97 in 2010. For the years 2000–2010, it was 3% per year for the Biological Sciences [2] (Fig. 6.3).

6.3.4 Who Are the Regional Leaders Among the Latin American Nations?

Latin America is composed of numerous states of diverse sizes, histories, and economies. The three Latin American republics with strong research outputs are Brazil,

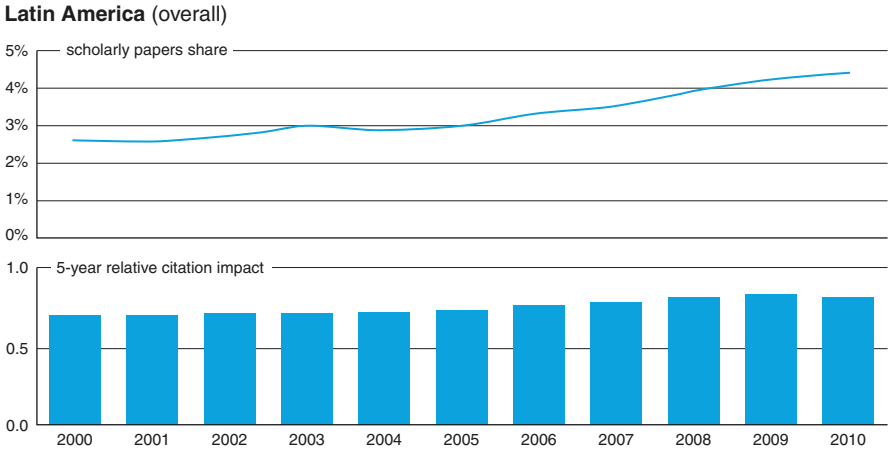

Fig. 6.2 Latin America's number of manuscripts over one decade and the citation index. (Source: Scopus)

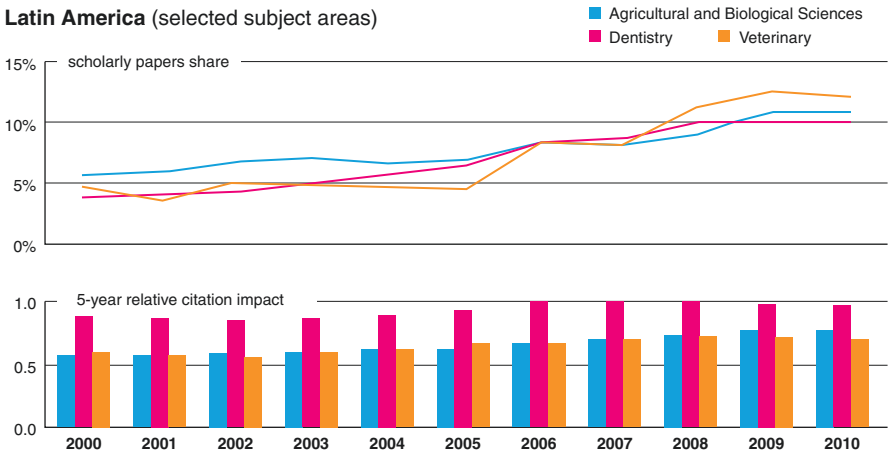

Fig. 6.3 The number of manuscripts in various fields of sciences and the citation index. (Source: Scopus)

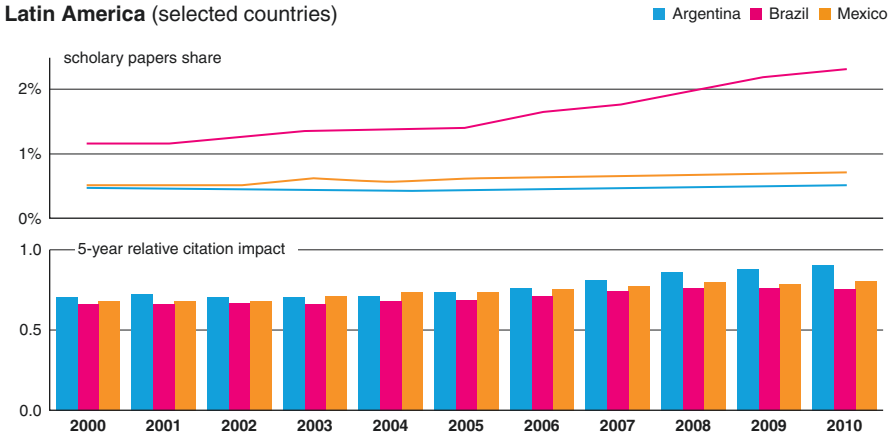

Fig. 6.4 Annual share of total scientific paper from Argentina, Brazil, and Mexico and the citation index. (Source: Scopus)

Mexico, and Argentina [2]. Of these, Argentina has a higher HDI compared to the other two [1]. The citation impact has also improved for all these countries (Fig. 6.4). Brazil also had the largest number of papers on dentistry in this region and is the only nation in the entire continent that spends more than 1% of its GDP on research and development. In the last 20 years, the quantity of research has increased fivefold (Scopus 2013).

6.3.5 Is There Any Data from the Medium Development Index Countries?

These include Cuba, Ecuador, Bolivia, Nicaragua, and the Honduras [3]. All these countries have similar economies and according to Scopus there has been a rapid surge in research output across the region. Cuba has more prominent and visible areas of research in basic sciences (pharmacology, toxicology, pharmacy, biological sciences, chemistry, biochemistry, genetics, and microbiology) and agriculture compared to the other countries.

6.3.6 Are There Any Specialties That Are Producing More Papers?

For the period 2003–2013, the most productive areas for publication included Public Health, Infectious Diseases, Surgery, Neurology, and Cardiovascular Medicine. The most high-volume countries were Brazil, Mexico, and Argentina and those having a greater impact and more international collaborations were from Peru, Puerto Rico, and Argentina. The most productive and visible fields, were Oncology, Cardiology, and Infectious Diseases [4].

6.3.7 What Is the Reason for the Low Visibility of Latin American Journals?

Although the total scientific research from South America grew from 2% of the global share in 1996 to 4% in 2012 the papers are published in the native languages and are therefore not widely accessible. According to the Thomson Institute for Scientific Information (ISI) (which includes only the most reputed scientific publications and is one of the ways of assessing the value and visibility of a journal the countries with the highest number of ISI journals in Latin America are Brazil, Chile, Mexico, and Colombia. Brazil and Chile are the countries with the largest increase in ISI-indexed journals language other than in English but their visibility was low [5] (Table 6.1).

Table 6.1 Language distribution of publications from Latin America

Total journals	Medical journals	Native language only	English only	Bilingual
Brazil	139	33	1	12
Chile	49	3	3	0
Mexico	43	6	3	1
Colombia	23	1	0	0
Argentina	21	6	3	0
Venezuela	14	4	0	0
Ecuador	1	1	1	0
Total	290	54	11	13

6.3.8 What are the Other Reasons for the Low Scientific Output from Latin America?

Many bright young scientists continue to leave Latin America for developed countries. The reasons are [6, 7]:

- Firstly, South America invests less in research compared to other developed nations. Most research allowances in Latin America are provided by Governmental organizations. They are often inadequate and range from $5000 to $40,000/ year. This is very low compared to the grants provided by developed nations.
- Secondly, a career in science is poorly paid, most medical physicians are better off chasing a clinical practice rather than participating in research, even if it is part time.
- Thirdly, to publish a manuscript in a high-impact journal, a publication fee of $3400–5000 is sometimes required in open access publications. These journals offer fee discounts if the scientist is based in a HINARI country (the world's lowest-income countries as defined by the World Bank). Therefore, several Latin American experts prefer to publish their scientific papers in journals that do not charge for publication.

6.3.9 Are Open Access Journals the Way Forward for Latin America?

The scientific community of Latin America is slowly appreciating that publishing online will provide it an exposure to academics and more extensive audiences. In this way, with open access to journals, books, and all kinds of manuscripts from nations where the cost of posting a printed version overseas was more expensive than printing a book or journal. Many countries are now opting to change over to Open Access for publicly funded research. Many public universities and government organizations are also insisting on this. This is also known as 'plan S'. Many feel that open access publishing is the way forward for scientific publications from developing nations [8].

6.4 Africa

6.4.1 How Can One Divide Africa's Nations into Various Regions?

Africa can be divided into five large areas, i.e. north, west, east, central, and south.

North Africa

High Development Index

Algeria Egypt

Libya Tunisia

Greater Sahara

Medium Development Index

Morocco

Low Development Index

Sudan

Central Africa

Medium Development Index

Cameroon Equatorial Guinea

Sao Tome and Prinicipe

Low Development Index

Central African Republic

Chad Congo

High Development Index

Gabon

East Africa

Medium Development Index

Democratic Republic ofthe Congo

Kenya

Low Development Index

Burundi Comoros

Djibouti Eritrea

Ethiopia Madagascar

Rwanda Somalia

Uganda

United Republic of Tanzania

South Africa

High Development Index

Mauritius
South Africa

Medium Development Index

Angola Namibia
Zimbabwe

Low Development Index

Botswana Lesotho
Malawi Mozambique
Zambia

West Africa

Medium Development Index

Cabo Verde Guinea
Mauritania

Low Development Index

BeninGuinea Guinea-Bissau
Liberia Mali
Niger Nigeria
Senegal Burkina Faso
Gambia Ghana
Sierra Leone Togo
Côte d'Ivoire

6.4.2 Is It True That Africa's Research Output Has Increased?

Yes, in a Scopus-based analysis published in 2013, Africa has doubled its research output over a decade (1996–2012). This was a positive sign for Africa and at the same time its world's share also increased from 1.2% to 2.3% of the world's scientific publications [9] (Fig. 6.5)

6.4.3 What Are the Factors Contributing to This Promising Trend?

There are many factors that have contributed to the surge in African research output [10, 11]. These include:

- Augmented money for research.
- Substantial changes in strategies.

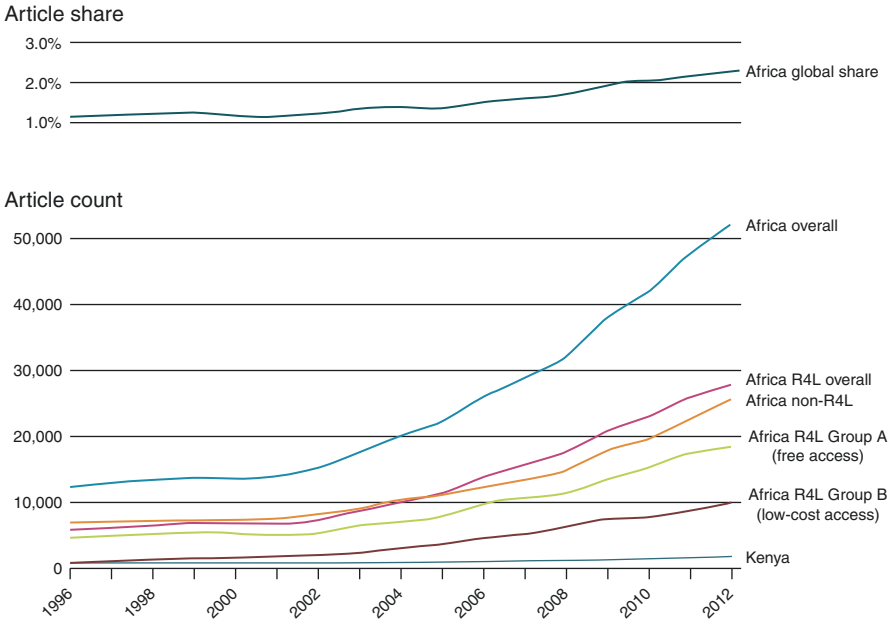

Fig. 6.5 Increase in Africa's research output

- Enhanced research infrastructure (human and physical).
- Availability of journals that are open access or free.
- Peer-reviewed literature that can be accessed free or at a low cost.

6.4.4 What Could Be the Key Contributor to This Promising Growth?

A public–private partnership called the 'Research4life' programme has been one of the contributing forces towards the increase in scientific papers. It includes more than 200 publishers and many associations which have provided free access to 6000 institutions in over 100 countries to scientific papers, books, and databases [2].

6.4.5 What Is the African Index Medicus?

This gives access to information published in or associated with Africa. This also encourages local publishers to publish scientific manuscripts. This has been possible due to the technical backing of the World Health Organization. Very few African

health and biomedical information sources are included in the global leading databases and there is a treasure of untapped material in books, reports, and manuscripts which can be accessed [12].

6.4.6 Are There Any Countries That Are Leading?

In southern Africa, the leader is South Africa with 47,000 manuscripts published during 1999–2008. In the north, Egypt is the main country with 30,000 papers published over the same period, and Nigeria dominates the central region with more than 10,000 publications. These three nations dominate again when the data are broken down into areas of research, with South Africa publishing the most papers in clinical medicine and most other life sciences (e.g. microbiology, immunology, and neuroscience) [13].

In a research paper, biomedical analysis was done for the most productive countries in West Africa for over 10 years (2005–2014). Nigeria, Ghana, Senegal, Burkina Faso, and Mali had the highest number of publications [14].

6.4.7 What Are the Top Diseases for which Research Is Going On in Africa?

Recent data published by Elsevier, stated that in HIV/AIDS-related research, for the period 2014 to 2018, South Africa was the third-highest global producer of papers. In another analysis, from 2003 to 2011, bibliometric assessment of sub-Saharan scientific search output was studied on 'poverty related and neglected infectious diseases'. For the period 2007–2011, African countries produced 10% of the world's share on infectious diseases. Tuberculosis, HIV/AIDS, Malaria, Hydatid diseases, Sleeping sickness, Leprosy, Kala Azar, and Schistosomiasis were those which were studied. With the help of European trial partnerships, African countries were able to increase the quality and quantity of papers and were able to publish in high-impact factor journals [15].

6.5 Asia

Asian countries can be divided into three regions:

- East Asia
- South Asia
- West Asia

6.5.1 East Asian Countries According to the Human Development Index

EAST ASIA
High Development Index
China Philippines
Indonesia Malaysia
Thailand
Medium Development Index
Viet Nam Myanmar
Laos Cambodia
Low Development Index
Papua New Guinea

SOUTH ASIA
High Development Index
Sri Lanka
Maldives
Medium Development Index
Bangladesh
India
Nepal
Pakistan
Low development index
Afghanistan

WEST ASIA
High Development Index
Jordan
Lebanon
Medium Development Index
Iraq
Low Development Index
Yemen
Syrian Arab Republic

6.5.2 What Is the Research Output from South Asian Countries?

An analysis of the research output of eight countries of south Asia—India, Afghanistan, Bhutan, Sri Lanka, Pakistan, Nepal, Bangladesh, and Maldives is available—two with a high HDI (Sri Lanka, Maldives), four with a medium HDI (Bangladesh, Nepal, India, and Pakistan) and one with a low HDI (Afghanistan) and has been examined recently. The analysis was carried out over a 5-year period, i.e., from 2012 to 2017 [16]. The quantity and quality (as judged by the h Index) of publication was highest for India, followed by Sri Lanka and Nepal (Fig. 6.6). Unfortunately, these figures are very much lower than the h indices from the developed countries (e.g., the USA and the UK). The authors concluded that despite a recent increase in numbers, the overall quality and quantity of scientific output was still low in south Asia. This was not related to their HDI because Indian institutes outnumbered those from other countries. This finding is in contrast with studies reported from the Gulf Cooperation Council and ASEAN countries where they found that the research output of a country was directly related to its economic development [17].

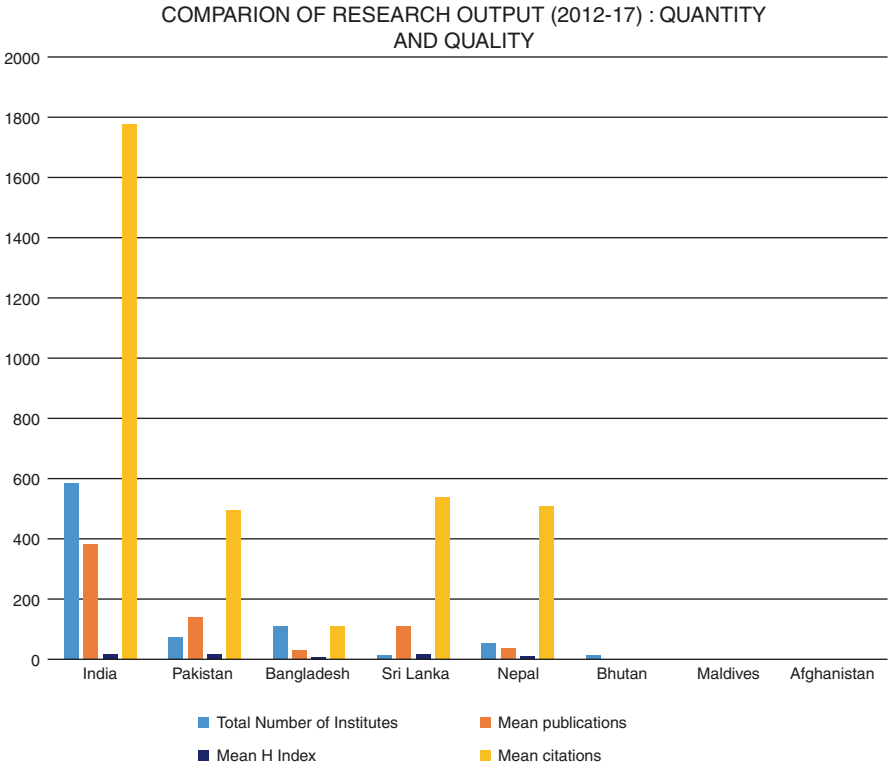

Fig. 6.6 Quality and Quantity of research from South Asian countries (2012–2017)

6.5.3 Can India Be the Leader in South Asian Health Care Over the Coming Years?

India has the capacity to overcome many health challenges because although it is a poor country it has a large mass of trained, English speaking doctors some of whom have been trained in the best medical institutes in this country and abroad. India has eradicated smallpox and polio. It has a population of many phenotypes and genotypes and has produced a number of important publications on Kala-Azar [18], Tetanus [19], Takavasu's Disease [20], Oral rehydration solution [21], Pulse polio programme [22], and sickle cell anaemia [23].

It is also the largest producer of generic drugs and exports antiretroviral, anticancer medicines, and vaccines to most of the world [24, 25, 26].

6.5.4 Among All the Developing Countries Where Does India Stand in Medical Research?

A scientometric research assessment of 16 developing nations was published in 2018 [27]. If that data is reanalyzed using the 2019 definition for developed and developing countries, it would exclude Argentina, Chile, Indonesia, Iran, Philippines that all have a high HDI. The other 11 countries can be reclassified into developing countries (Table 6.2). Although India had a sizeable number of publications their quality, as judged by the number of citations they receive, is low. The data from Panama shows that even with small numbers the citation index of that small country's papers is high.

Table 6.2 Modified data for Scientometrics research of eleven developing countries (2009–2013)

	Countries	Papers	Citation index[a]	Papers from general internal medicine	Citation index[a]	Papers from non-internal medicine	Citation index[a]
High development index	Brazil	180,944	0.97	3465	1.51	41,270	1.0
	Cuba	4251	0.94	318	0.83	697	0.97
	Mexico	52,977	1.02	3684	1.50	5861	1.08
	Panama	1622	1.39	56	8.83	159	1.39
	Venezuela	5980	0.94	391	1.08	855	1.21
	Peru	3673	1.32	479	1.75	1095	1.12
Medium development index	India	239,072	0.99	13,798	1.08	26,232	0.85
	Pakistan	2691	1.24	3314	1.47	1808	1.09
	Kenya	6186	1.21	854	1.58	2054	1.11
	Columbia	15,276	1.27	1061	1.60	2292	1.17
Low development index	Nigeria	11,495	0.95	1683	1.54	2425	0.79
	World	6,787,816	1.0	747,244	1.0	1,191,990	1.0

[a]Mean observed citation rate/mean expected

6.5.5 Is Collaborative Work on Research the Way Forward for All Developing Countries?

Collaboration is now seen as an important activity for the progress of science. It improves research and is now considered essential [28]. In the last decade many large-scale collaborative projects have been commissioned in Medicine, Diabetes, Oncology, Rheumatology, Molecular biology, and Genetics. Collaboration increases the number of co-authors and the citation index and increases the productivity of scientists as well. Collaboration in itself is thought to be a reflection of success for the investigator. Collaboration is beneficial to all, especially to young scientists.

In a study where six leading journals were studied for collaboration and citation index it was found that there was a correlation between the number of authors of manuscripts and the frequency of articles cited. Investigators who were open to collaborations produced superior manuscripts with higher impact factors [29].

With the available data, it seems the best way to do scientific work in developing countries is to seek help and guidance from our colleagues abroad [27].

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Part III

How to Plan a Study?

How to Think of a Research Question?

7

The art and science of asking questions is the source of all knowledge

—Thomas Berger, American Novelist (1924–2014)

7.1 What Is a Research Question?

A research question is the central theme of a scientific experiment around which everything revolves. It is a probing statement for which an answer is required. If the research question is not clear at the beginning the whole research becomes questionable and doubtful. Thus, formulating a question is the critical step towards biomedical research [1]. The research question is a signpost that indicates the direction of a study [2] and is based on the gaps in our knowledge.

7.2 What Are the FINER Criteria?

FINER is an acronym which help us to formulate a good research question [3]. Its expanded form is given below:

F—Feasible

- It is a technique that is possible to use.
- There are enough patients with this illness.
- Financially the project is possible.
- The outcome can be measured.
- The sample size will not be a problem.
- The scope of the study is not too vast.

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_7

I—Interesting
- Getting the answer to the study will be intriguing.
- The study is of interest to your peers.
- It may interest the funding agencies.
- Will help your community.

N—Novel
- The study confirms previously done results.
- Disproves earlier studies.
- Is an extension of previously done experiments.

E—Ethical
- The study complies with the Institutional Review Board's requirements.
- It safeguards the interests of patients.
- There is confidentiality and anonymity of the participants.
- There will be benefits from this study?
- The risk is minimal?

R—Relevant
- It will be useful in day-to-day practice.
- It will be useful for patient care.
- It will be useful to formulate health care policy.

7.3 Some Consider the FINER 'MAPS' to Be a More Complete Acronym. What Does MAPS Stand For?

The word MAPS stand for:

- **M—**Manageable
- **A**—Appropriate
- **P—**Publishable
- **S—**Systematic

7.4 How Do We Break Down a Research Question?

PICOT is the commonest method used to do this into five components [4]:

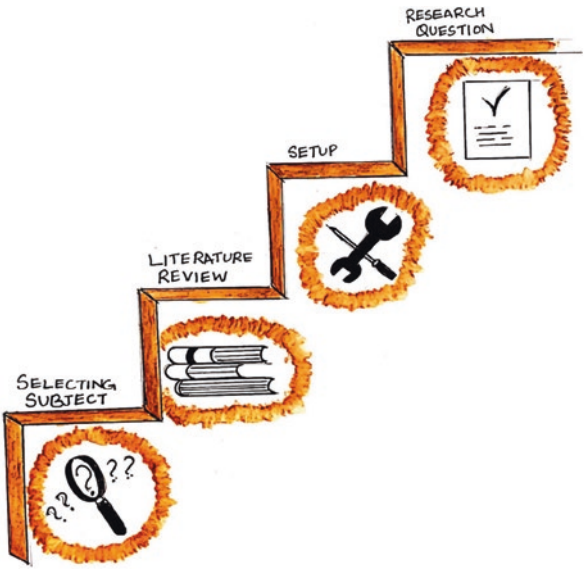
- P—Population/disease (i.e., age, gender, ethnicity, with a certain disorder).
- I—Intervention or variable of interest (exposure to a disease, risk behaviour, prognostic factors).
- C—Comparison (could be a placebo or business as usual as in no disease, absence of risk factor, prognostic factor).

- O—Outcome (risk of disease, the accuracy of a diagnosis, rate of occurrence of an adverse outcome).
- T—Time it takes to demonstrate an outcome (for how long were the participants observed?).

An example of a research question is given to the understanding of a concept. Supposing you are planning to do research on *The role of hydroxychloroquine in preventing COVID-19 in health care workers*. We will need to break down this into various components:

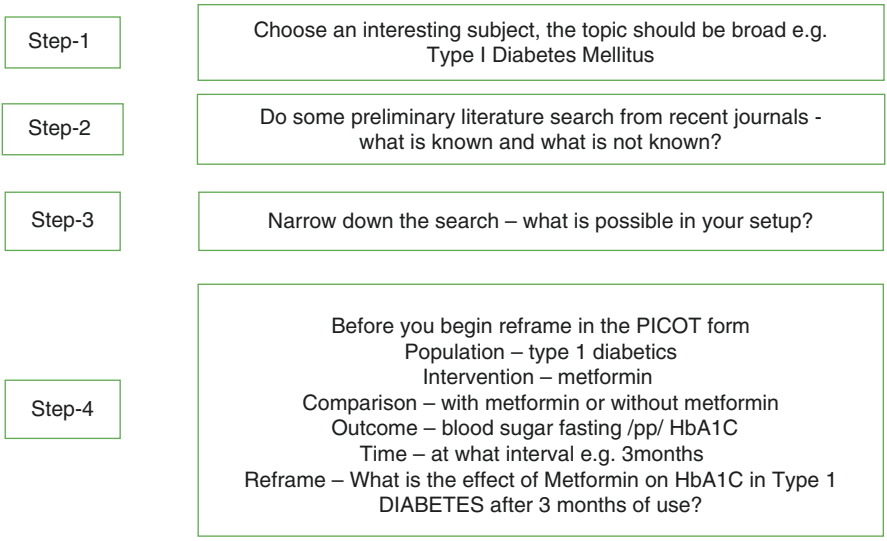
- Population—Health care worker
- Intervention—Hydroxychloroquine 400 mg once a week
- Comparison—Health care workers who receive placebo
- Outcome—Health care workers who eventually develop COVID-19
- Time—6 weeks.

The research question should be framed in a question format. In the above example, it should be 'Can hydroxychloroquine (400 mg) administered once weekly for 6 weeks protect health care workers against COVID-19 infection?



7.5 What Are the Steps for Framing a Research Question?

The basic steps for formulating a research question are given below [5]:



7.6 What Are the Examples of Bad Research Questions?

A bad research question is often not in the PICOT format and has missing information. Table 7.1 describes few research question which are incomplete and how to formulated the suggested questions.

Table 7.1 Examples of bad research questions

Research	Missing information	Suggested question
Study of Telemedicine during the lock down period	It is just a statement, there is no question	What is the patient satisfaction after a telemedicine consultation during the lockdown period?
Does consumption of cinnamon help in lowering lipids?	How much cinnamon? At what interval is a repeat study planned and on which subjects?	Is the lipid profile altered after the consumption of cinnamon powder 3 gm per day for 2 months in non-diabetic subjects?
Clinico-pathological study of small intestinal tumours	Bad research, there is no question	Are the clinico-pathological characteristics of small intestine tumours different in India and western countries?
Are artificial sweeteners good for health?	A more specific question is required	What is the effect of Stevia, an artificial sweeter, on men who have recurrent migraine?

7.7 Conclusions

- A good question is the backbone of research and any further steps should be initiated after formulating this.
- The acronym "FINER/MAPS suggests how a research question should be assessed.
- The research question should be written in the PICOT format for easy understanding.

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What Are the Types of Study Design?

8

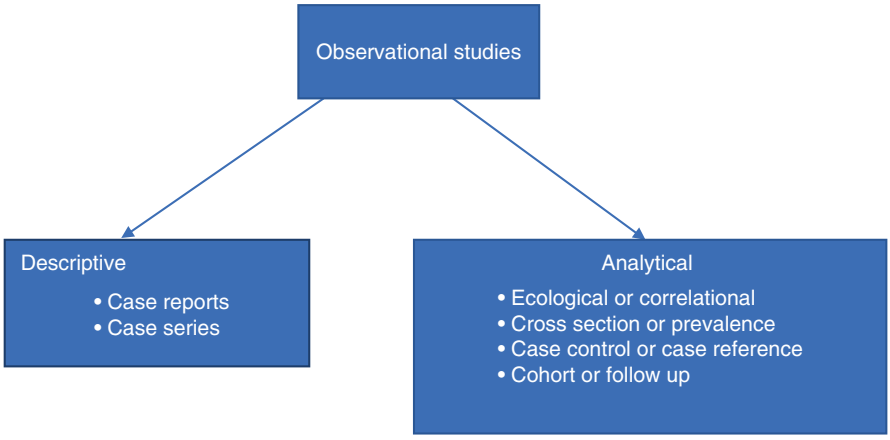
8.1 What Are the Various Types of Clinical Study Designs?

The quality, reliability, dependability, and publishability of a study depend on its design. A clinical study design includes the preparation of trials, experiments, and observations in research involving human beings. The various types of study designs are depicted in Fig. 8.1.

8.2 What Are the Types of Observational Studies?

Broadly there are two types of observational studies, i.e.:

- Descriptive.
- Analytical.



"Education without application is just entertainment."
Tim Sanders, American author and speaker (1959-)

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_8

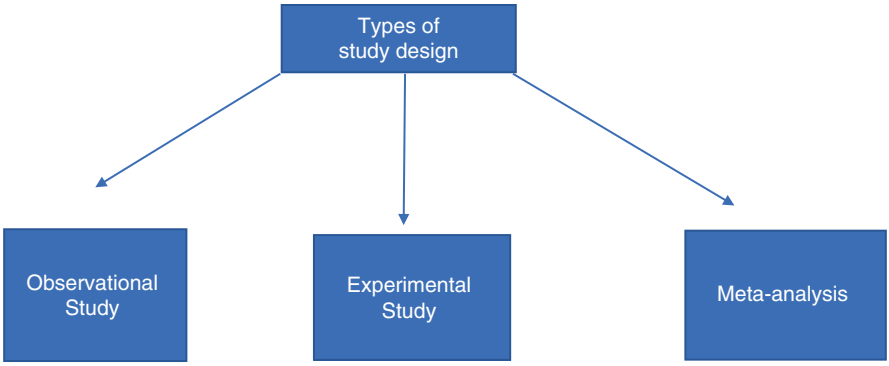


Fig. 8.1 A study can be classified into three major groups: observational, experimental, and meta-analysis

8.3 What Is a Descriptive Study?

This kind of study deals with observing the distribution of a given phenomenon. It generally deals with a time, place, and person distribution [1, 2].

The procedures involved in a descriptive study include:

- Definition of the population to be studied.
- Naming of the illness.
- Describing the disease by time, place, and person.
- Quantification of the disease outcome.
- Comparing this with known parameters.

The advantages of a descriptive study:

- Provides information regarding the extent of the disease load.
- May suggest a clue to its aetiology.
- Provides background data for planning.
- Contributes to research by describing the illness in relation to time, place, and persons.

Examples of descriptive studies include:

Case reports 1. Profound neutropenia in a patient with COVID-19.

2. Multiple Renal Abscesses in a Horseshoe Kidney

Case series 1. Gastrointestinal manifestations in COVID-19: A review of 30 cases.

2. Long-Term Follow-Ups of Relapses after Surgery for Astrocytoma

8.4 What Is Analytical Epidemiology?

The objective of this kind of study is to test a hypothesis and includes specific subjects of interest. There are four distinct types of investigations:

- Ecological.
- Cross sectional.
- Case control.
- Cohort.

8.5 What Are Ecological Studies?

These are observational studies often used to measure the prevalence and incidence of disease, particularly when the disease is rare, and are quite easy to conduct. The other advantage is that they are usually retrospective in nature. In them, there should be only one exposure in the population. An example of such a study would be to compare the prevalence of rheumatoid arthritis in Delhi and Manipur. This data is usually extracted from large databases which may have been used for other purposes and thus are not always reliable. Ecological studies are generally economical and serve as a preliminary point for hypothesis generation [2].

8.6 What Is a Case–Control Study?

This compares a population with a certain medical condition with another group of people who do not have the disease but are otherwise similar to the study population.

The basic steps include:

- Proper selecting cases and controls.
- Matching of cases with controls.
- Measuring the exposure.
- Analyzing and interpreting the results.

Case–control studies are inexpensive and frequently used kind in epidemiology. Their design allows the study of a rare illness. The preliminary data help to learn what is already known about the association between the risk factors for the disease. The measure of interest is the calculation of the odds ratio. These are also retrospective studies that cannot calculate prevalence and are usually used for rare diseases. They can also be nested within longitudinal studies but given their retrospective nature, can be prone to recall bias [3].

An example of such a study is the occurrence of cervical cancer in patients who have received Human Papillomavirus vaccine in childhood. Figure 8.2 is an example of a case–control study design and how to calculate the odd's ratio.

8.7 What Is a Cohort Study?

A cohort study is done on a group of people who are followed up over many years—for instance, to determine how often a certain disease occurs. It is performed to obtain evidence to support the existence of an association between a suspected cause and disease (Fig. 8.3).

Types of cohort study:

- Prospective cohorts.
- Retrospective cohorts.
- Combination of prospective and retrospective cohorts.

Elements of a cohort study:

- Collection of study patients.
- Procuring data on exposure.
- Study of comparison groups.
- Review visits.
- Final data analysis.

These studies can help in calculating point prevalence or period prevalence. Prospective cohort studies are the 'gold standard for observational research'.

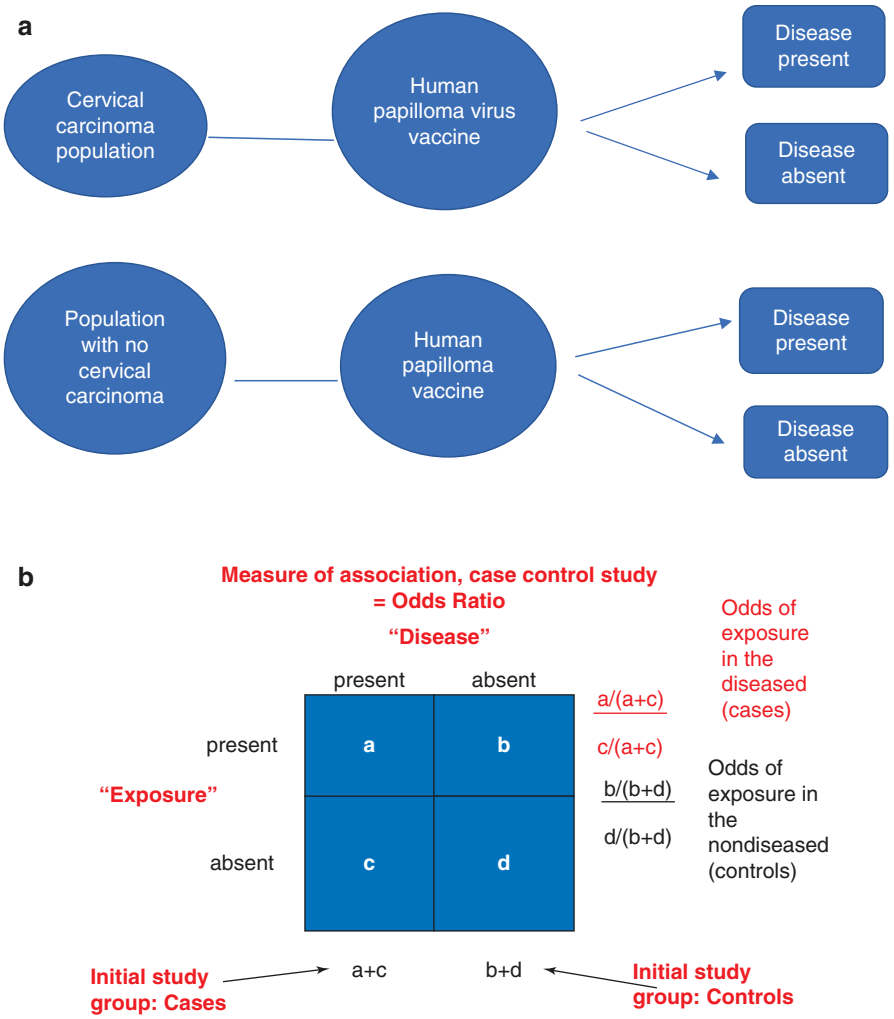


Fig. 8.2 (**a**, **b**) Case–control study and calculation of odds ratio

8.8 What Are Cross-Sectional Studies?

These are also retrospective and study the prevalence of a disease. They are economical and easy to conduct. An example of a cross-sectional study design would be enrolling participants who are either current alcohol consumers or have never consumed alcohol, and are being assessed whether or not they have liver-related issues. The studies assess both exposure and outcome at a single point in time. Figure 8.4 shows an example of this [3, 4].

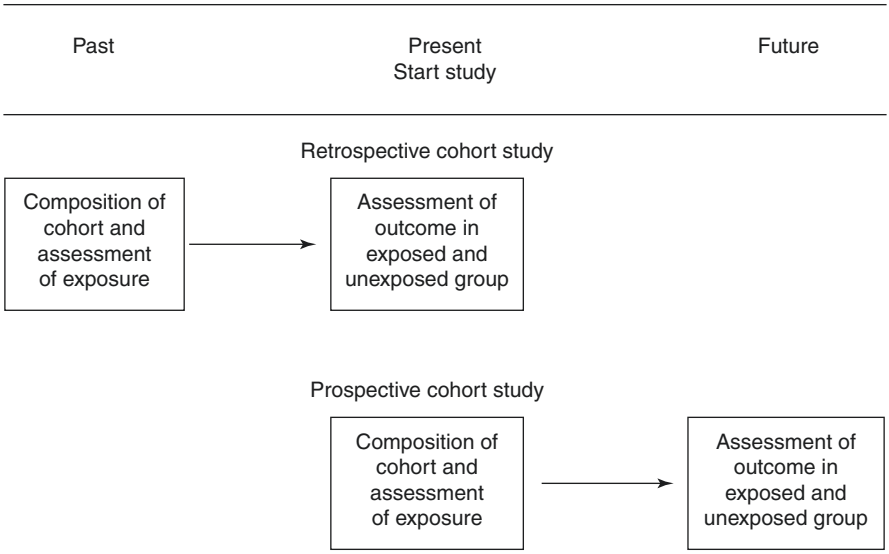


Fig. 8.3 Depicts both a retrospective and a prospective cohort study

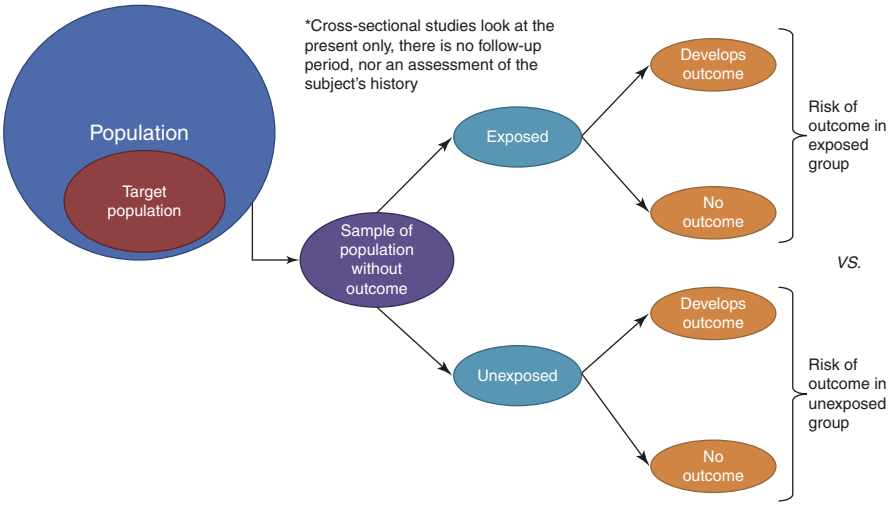


Fig. 8.4 Cross-sectional study

8.9 What Is an Experimental Study Design?

This has a similar approach to a cohort study except that it is carried out under direct control of an investigator. The aim is to provide systematic proof of either aetiological or risk factors of the disease the modification of which can control it. Epidemiological and interventional research studies include three elements:

1. Definition and measure of exposure in two or more groups.
2. Measure of disease outcome(s) in the same groups.
3. Statistical comparison made between groups to assess potential relationships between the exposure and outcome, all of which are defined by the researcher.

8.10 What Is a Randomized Controlled Trial?

This is a study performed to avoid any bias while testing for the efficacy of, e.g., a drug. The study population is randomly divided into two groups, of which one receives the drug under study and the second group receives a placebo and acts as the control group. The experiment may be blinded, which means that any information which may influence the participant is withheld while the trial is ongoing or maybe double blinded in which the information is withheld from both the subject and the investigator [5].

The basic steps of a randomized control trial (RCT) include:

- Writing a protocol.
- Selecting a normal and experimental population.
- Randomization.
- Intervention in the study group and placebo.
- Follow up.
- Measuring the outcome of interest.

8.11 Design of a Randomized Control Trial (Fig. 8.5)

8.12 What Are the Standards of Research and Reporting?

There are many available guidelines on study design, execution, and how it needs to be reported in the final manuscript. This improves the quality of a research paper and allows results to be presented in a systematic manner for a sound conclusion to be drawn. Table 8.1 mentions some important reporting formats and their websites.

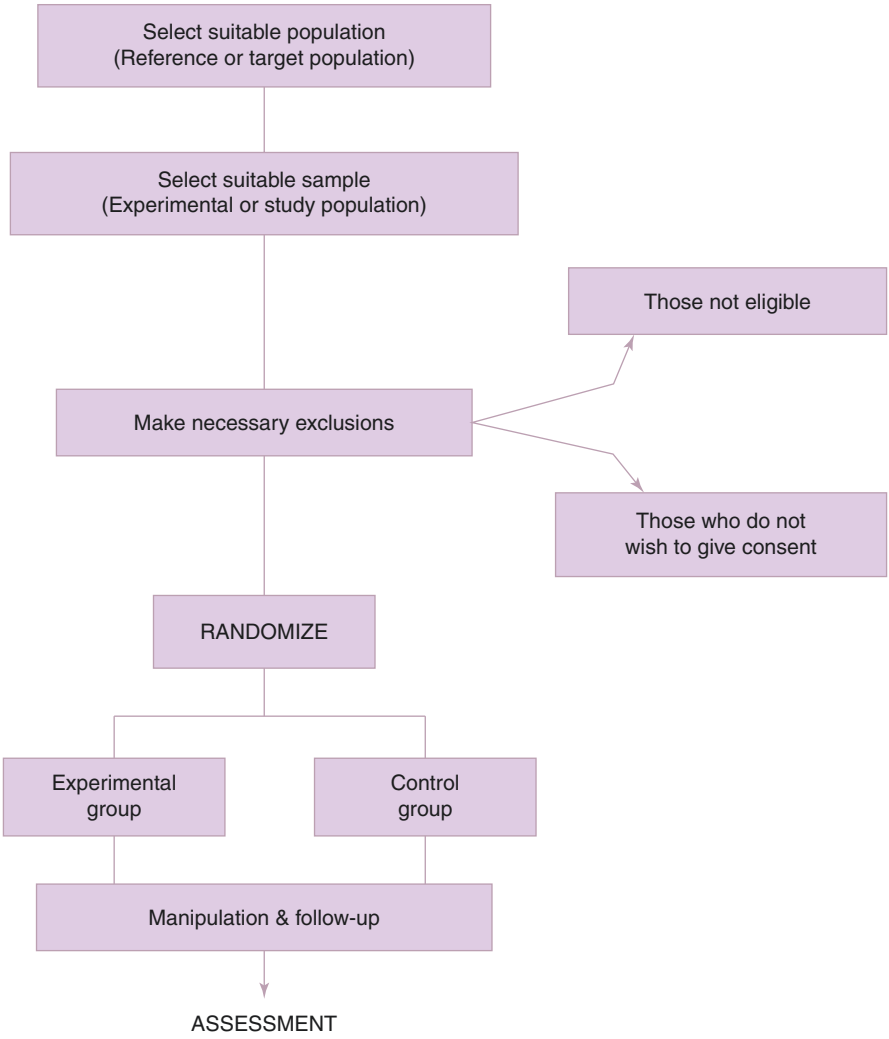


Fig. 8.5 Randomized control trial

Table 8.1 Published standards for study design and reporting

Study design	Abbreviation	Website
Randomized controlled trials [6]	CONSORT	http://www.consort-statement.org/downloads
Systematic reviews [7]	PRISMA	http://www.prisma-statement.org/
Observational studies [8]	STROBE	https://www.strobe-statement.org/home
Case reports [9]	CARE	https://www.care-statement.org/
Qualitative research [10]	COREQ	https://academic.oup.com/

8.13 Conclusions

- Formulating a study design is the most important part of the planning stage of clinical research. It is an indispensable part of new drug discovery.
- Basic research is also called experimental and done in genetics, biochemistry, and physiology. Studies on drug properties are also included in this.
- Clinical studies can be interventional or non-interventional. Interventional studies are done on surgery, chemotherapeutic agents, devices, or drugs.
- A rare disease is best investigated by a case–control study and rare exposures by cohort studies.
- A retrospective study is based on historical data, which may be obtained from past records. In prospective studies the data are collected after the work has begun.
- Observational studies are divided into descriptive and analytical studies.
- In cohort studies, two or more groups are selected on the basis of their exposure to a drug or environmental exposure and then followed up for outcome.
- The evidence collected from randomized controlled trials is of good quality. They allow a proper evaluation of a drug. More recently adaptive designs allow for greater flexibility and pragmatic randomized trials.

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How to Calculate an Adequate Sample Size?

9

The determination of an adequate sample size is a prerequisite for any research programme. A study concluded on the basis of a smaller sample size than required is termed an 'underpowered study' and its reliability is questionable. Such a study may lead to faulty conclusions and consequent waste of resources. On the other hand, a study with a larger sample size than required may enhance its reliability but unnecessarily consumes expensive resources, takes a long time, and may even put the subjects to various health hazards. Thus, the researcher should look for an adequate sample size that can serve the purpose of this study.

Determining the sample size in a research study is a challenging task. It depends primarily on the objectives of the study and how they are achieved with statistical support. These objectives may be descriptive as well as analytical in nature and accordingly the determinants of sample size will vary. The determinants of sample size mainly include the available basic information associated with the population parameters to be estimated or statistically tested such as the expected values of the mean, proportion, strength of association, correlation and regression coefficients, odds ratio, relative risk, hazard ratio, sensitivity, specificity, accuracy, AUC, standard deviation, and effect size. Other determinants include the level of precision with which a parameter is estimated along with the level of confidence, significance level, and statistical power for testing the significance of the null hypothesis. The sample size calculation literature comprises a large number of formulae suited to different study designs because different study designs need different formulae for the calculation of the sample size. Thus, for calculating the adequate sample size, the formula best suited to the study design should be used.

Several free as well as commercial software/calculators are available that can help in the calculation of sample size for various study designs. These provide us a minimum theoretical sample size required to meet a specific objective.

A sample is a small proportion of a large population. On the basis of the sample, we tend to study the characteristics of the population as a whole and draw inferences about the population. Since our inferences are based on the data of the sample, the size of the sample, and how it is drawn is crucial for assessing the population

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characteristics or parameters. A biased sample may not give us a true picture of the parameters. A biased sample or nonrandom sample sometimes called a non-representative sample is the one that does not ensure that each item of the intended population has been given an equal chance (probability) of inclusion. Sampling bias can lead to a systematic over- or underestimation of the population parameter(s) and the conclusions drawn may be erroneous. The present write up discusses, in brief, the essentials of sample size determination, especially for those who are new to this subject.

9.1 What Should the Sample Size Be for a Research Study?

A research study generally comprises descriptive as well as analytical objectives. A clear distinction between the two is that an analytical objective requires testing the significance of a hypothesis, whereas a descriptive one does not. For example, 'estimating the prevalence of a particular disease in northern India' or 'estimating the diagnostic accuracy of a diagnostic tool' are descriptive objectives, whereas 'comparing the efficacies of two or more drugs', 'testing correlation between two attributes' etc. are analytical objectives. A study with descriptive objectives simply estimates the parameters of a population (population means, prevalence/proportion, sensitivity, specificity, accuracy etc.) with a certain level of confidence (normally 95%). Whereas, a study with analytical objectives, compares statistically a parameter with some constant value; or compares two or more parameters. Thus, prior to the beginning of an analytical study, we set a null hypothesis and the corresponding alternative hypothesis. A null hypothesis (H_0) is a statement that we set without any prejudice and look for statistical evidence against this, if any. For example, the statements—'Two drugs have the same effect', 'There is no effect', 'There is no relationship between the two variables' are null hypotheses. Contrary to this, an alternative hypothesis (H_1) is a statement that says—'Two drugs differ in their effects' or 'There is an effect' or 'There is a relationship between two variables'. Thus, for determining the overall sample size for a study, we should identify what parameters need to be estimated and what to be tested for statistical significance, so that appropriate formulae can be used for calculating the sample size for a specific objective. The sample size required for the study should be either based on the primary objective or the objective which gives the maximum sample size. In addition to this, we need to enhance the theoretically determined minimum sample size in view of the possible attrition of subjects who drop out from the study or are lost to follow up.

9.2 How to Calculate the Sample Size in a Descriptive Study?

As mentioned above, when our objective is to estimate, say the prevalence of a disease in a cross-sectional study or diagnostic accuracy of a new modality or the mean effect of a treatment etc., we need the following inputs for calculating the sample size [1]:

- ***Confidence level*:** Confidence level is the most important component in estimating the population's true value with a confidence interval and refers to the percentage of all possible samples that can be expected to include the true value. We have to specify the desired level of confidence, say 90%, 95%, or higher 99%. The higher the confidence level, the larger will be the sample size (the next chapter deals with the details on confidence levels and intervals). The corresponding *Z*-value (standard normal variate) for the confidence level required in the formula is automatically taken by the sample size calculators. However, for the benefit of the readers, we give the following table that gives different confidence levels and their corresponding *Z* values:

Confidence level(%)	*Z*-value
90	1.645
95	1.960
99	2.576

- ***Precision or margin of error*:** Different samples from the same population give different estimates of the true value. This phenomenon in statistics is known as 'sampling fluctuations'. Thus, we aim to estimate the true value (prevalence, mean, accuracy etc.) with some margin of error or precision. Precision is just the opposite of the margin of error and measures the reliability in the estimation. The lower the margin of error, the higher will be the precision of the estimate. But an estimate with a higher precision requires a larger sample size [2]. Level of precision is subjective and depends upon the nature of the project as well as the requirement of the researcher. In some studies, a margin error of 5% is optimal, whereas it may be too high for studying a prevalence of a population that has a low prevalence of 6% only. With a high margin of error (low precision), the requirement of a sample size will be lower but our confidence interval will be wider. Studies with wider confidence intervals are not generally acceptable and are rejected by reputed journals.

  There are two terms associated with the margin of error known as 'absolute precision' and 'relative precision'. In absolute precision, we specify the exact value of the margin of error or the absolute uncertainty in the parameter to be estimated. For example, if we are estimating the prevalence of disease and give 3% as the absolute precision/margin of error, then the prevalence will be estimated with an uncertainty of 3% on either side of the estimate. Similarly, we can specify absolute precision for estimating a mean by giving the exact value, say 2 or 5 units. Most of the sample size calculators ask for the absolute precision. However, some calculators/software/formulae may ask for the relative precision. For example, a researcher wants to calculate a sample size for estimating a disease prevalence (9%) with a relative precision of 5%. Then the margin of error will be five percent of the prevalence (9%), i.e., 0.45%. Here 0.45% or 0.0045 (converted to proportion) is the absolute precision, which is ultimately used in

the formula. Similarly, we can calculate the relative precision for estimating the mean parameter.

- ***Expected proportion(percentage) for categorical data*:** This is the basic input for calculating the sample size and is the expected value of the parameter (prevalence, accuracy etc.) and is taken from the previously published studies. This value is either entered as a proportion or percentage depending upon the software or calculator. The margin of error or precision discussed earlier should be decided on the expected value used for the calculation of sample size.
- ***Expected mean/variability (standard deviation)*:** The expected mean and standard deviation are required for estimating the mean effects. The expected mean is used to determine the absolute precision and the standard deviation is used as such in the sample size calculation formula. Standard deviation is a measure of the variability of the population and affects the sample size. The higher the variability (SD), the larger will be the sample size provided the other inputs remain the same.

9.2.1 Example 1: How to Calculate the Sample Size for Estimating the Prevalence of a Disease?

The following simple formula is used for calculating the minimum sample size in a cross-sectional study for estimating the prevalence or a proportion:

$$n \geq Z^2.p\left(1-p\right)/d^2 \tag{9.1}$$

where n is the sample size, Z is the value of standard normal deviation corresponding to the level of confidence. For a 95% confidence level, the value of Z is 1.96 and for 90%, it is 1.645. p is the expected prevalence expressed in proportion and this value is taken from the published study(s), which resemble your study. In case, if there is no such study reported in the literature, one can conduct a pilot study with a smaller sample size to have an idea of the expected value. The value estimated from the pilot study is then used for calculating the sample size. d is the absolute precision also called the margin of error. Let us calculate the required sample size for estimating the prevalence of a disease which has been reported as 20%(0.2) with an absolute precision of 3%(0.03) and for a confidence level of 95%. The required sample size using the above formula (9.1) is 683. However, if we reduce the confidence level to 90%, the sample size reduces to 482.

9.3 Does My Sample Size Change When Sampling Is Done from a Finite Population?

Formula (9.1) by Cochrane is applicable when the sampling is done from a large population. When the population is finite or smaller, the sample size calculated by the said formula (9.1) needs adjustment as shown below:

$$n_{adj} = Nn / \left(N + n - 1\right) \tag{9.1.1}$$

where n_{adj} is the adjusted sample size, N is the finite population size, and n is the sample size calculated by the Cochran's formula (9.1). If we assume the population size is 1000, adjusted sample sizes in the abovesaid example reduce from 683 to 407 and 482 to 326.

9.3.1 Example 2: How to Calculate the Sample Size for Estimating the Mean of an Attribute?

The following formula is used for calculating the minimum sample size for estimating the mean with a specified precision:

$$n \geq Z^2 \sigma^2 / d^2 \tag{9.2}$$

where Z and d are explained as above, and σ is the expected value of standard deviation. One may ask a question, 'from where shall I get the value of standard deviation when I have not even started the project?' The value of the standard deviation is taken from the earlier similar studies published by other researchers in the past. It may be possible that you may not get a study which matches yours. In that case, the value of standard deviation is calculated by conducting a pilot study with a very small sample size and using the estimated mean and standard deviation value for calculating the size of the samples.

Let us calculate the required sample size for estimating the mean HDL cholesterol of a particular community whose expected value is 40 mg/dL with a relative precision of 10% of the mean. Here, we have to first determine the absolute precision as required by the formula (9.2). The absolute precision (d) is 4 (40×10/100 = 4) units. Using this precision of 4, standard deviation (σ) of 10, and confidence level of 95% (Z = 1.96), formula (9.2) gives a sample size of 24.

9.3.2 Example 3: How to Calculate the Sample Size for Estimating the Sensitivity and Specificity of a Diagnostic Test?

The following formulae can be used:

$$n_{Sens} \geq Z^2 .Sens\left(1 - Sens\right) / \left(d^2 .Prev\right) \tag{9.3}$$

$$n_{Sps} \geq Z^2 .Sps\left(1 - Sps\right) / \left(d^2 .\left(1 - Prev\right)\right) \tag{9.4}$$

where n_{Sens} is a sample size for sensitivity, n_{Sps} is a sample size for specificity, Z = 1.96 for 95% significance level, *Sens* is the expected sensitivity, *Sps* is the expected specificity, d is the margin of error and *Prev* is the expected prevalence of the disease. Let us calculate the sample size for estimating the sensitivity of a test

whose expected sensitivity is 90% and the prevalence of the disease is 30%. Suppose we want to estimate the sample size with a precision of 4% and at a confidence level of 95%, formula (9.3) gives a sample size of 721 subjects.

9.3.3 How to Calculate the Sample Size in an Analytical Study?

In the analytical mode, we are in a null hypothesis significance testing mode, e.g., we may like to test whether the two prevalences differ significantly or not [3]. Other examples may include testing the statistical significance of the correlation coefficient or odds ratio, testing the equality of two diagnostic accuracies or two means etc. Calculation of sample size in an analytical study requires probabilities associated with the incorrect rejection of null and alternative hypotheses when they are true in addition to other basic information. These probabilities are commonly known as alpha(α) and beta(β) errors. Let us understand these errors. Suppose we want to compare the effects of two drugs, we test the null hypothesis against the alternative hypotheses as follows:

- Null Hypothesis(H_0): Two drugs have the same effect
- Alternative Hypothesis(H_1): Two drugs differ in their effects

During hypothesis testing, we find statistical evidence against the null hypothesis. When we find evidence against the null hypothesis as indicated by the *p*-value being less than 0.05, we reject the null hypothesis and conclude that the two drugs differ in their effects. The following two errors become associated while testing the hypothesis:

- **Alpha error:** The probability of falsely rejecting the null hypothesis when it is true is also known as a Type-I error or significance level or false positive error. This probability is generally kept at 5% or sometimes 1%. The error occurs when the two drugs have the same effect but we prove they have different effects. The following table gives the *Z* values for the one- and two-tailed tests for different significance levels.

Significance level (Alpha error)	*Z*-value (Two-tailed test)	*Z*-value (One-tailed test)
10%	1.645	1.282
5%	1.960	1.645
1%	2.576	2.330

- **Beta error (Power):** The probability of falsely rejecting the alternative hypothesis when it is true is also known as a Type-II error or beta error or false-negative error. This error occurs when the drugs differ in their effects but we prove they

do not. Beta error is the opposite of the alpha error. This error (probability) is generally kept at 20%. The power of the statistical test depends on this error and is equal to 100 minus the beta error. In case of a 20% beta error, the power of the test is 80%.

These errors cannot be excluded but can be reduced. Sample size is drastically affected by these errors. Therefore, the minimum acceptable levels of these errors are set in advance prior to the beginning of a project and for estimating the sample size. In addition to these errors the following inputs are also required for determining the sample size:

- **Proportion(s)/Means/Variability (Standard deviations):** This is the basic information required for the calculation of a sample size.
- **Effect size:** Some of the software/calculators ask for the effect size for calculating the sample size. For example, G*Power uses effect size for calculating the sample size. We may directly input the effect size into G*Power or can calculate it with the basic information fed to the software package. Effect size is a standardized measure of the strength or magnitude of an effect. For example, the effect size for the difference between two independent means using the Student *t*-test is the difference between means divided by the pooled standard deviation. Similarly, there are effect sizes for differences of proportions between two groups; correlation and regression coefficient, ANOVA; odds and hazard ratio, coefficient of determination etc. Cohen gives a table of effect size (ES) indexes and their values for small, medium, and large effects. For example, for testing the difference of two independent means, a value of ES index 0.2 is considered a 'small', 0.5 a 'medium', and 0.8 a 'large' effect. For correlation coefficient, the effect size index is the correlation coefficient(*r*) itself and is considered a 'small' when it is 0.1, a 'medium' 0.3, and 'large' at 0.5. Effect size severely affects the sample size. The lower the effect size, the higher will be the sample size.
- **Two-tailed/one-tailed test:** Sample size depends on the way we test the null hypothesis. By default, most of the software/calculators provide the two-tailed test. A two-tailed test allows testing on both sides. For example, if our null hypothesis is that the mean is equal to 20, then a two-tailed test will test in both directions, i.e., if the mean is significantly greater than 20 and if the mean is significantly less than 20. In a one tailed-test, we see the relationship only in one direction and test if the mean is greater than 20 or the mean is less than 20. The sample size will be lower for a one-tailed compared to a two-tailed test for a given level of power.
- **Sample size ratio:** When we are comparing two groups, software/calculator asks to input the ratio of sample sizes of the two groups. Enter 1 if you want an equal sample size in each group, otherwise, enter the integer number more than 1 depending upon the availability of subjects in each group. This is required, especially for case–control studies.

9.3.4 Example 3: How to Calculate the Sample Size for Comparing Two Proportions(Prevalence)

Suppose we want to calculate the sample size to compare the accuracy of the deformity correction of the ortho SUV frame and the Taylor Spatial frame whose expected values (proportions) are 85.1% (P_1) and 91.1% (P_2), respectively. The minimum required sample size to test the null hypothesis of 'no difference in deformity correction' against the alternative hypothesis 'there is a difference in deformity correction' with a statistical power ($1-\beta$) of 80% and a significance level (α) of 5% is 456 for each procedure. The following formula is used to calculate the sample size:

$$n \geq \left[\left(Z_{1-\alpha/2}\sqrt{2P(1-P)}\right) + Z_{1-\beta}\left\{\sqrt{P_1(1-P_1)} + \sqrt{P_2(1-P_2)}\right\}\right]^2 / \left(P_1 - P_2\right)^2$$

where $P = (P_1+P_2)/2$;
$Z_{1-\alpha/2} = 1.96$ (5% significance level)
$Z_{1-\beta} = 0.84$ (Z value for 80% power or 20% Type-II error)
The above formula can be used for comparing sensitivities or specificities as well.

9.3.5 Example 4: How to Calculate the Sample Size for Comparing Two (Unpaired) Means in Two Populations?

Suppose an investigator is interested in comparing the efficacies of two diet programmes for reducing LDL cholesterol, the following formula can be used for calculating the sample size for each group:

$$n \geq \left[Z_{1-\alpha/2} + Z_{1-\beta}\right]^2 .\left[\sigma^2{}_1 + \sigma^2{}_2\right] / \left[M_1 - M_2\right]^2$$

where $Z_{1-\alpha/2} = 1.96$ (For 5% significance level)
$Z_{1-\beta} = 0.84$ (For 80% power)
$M_1 = 165$ (mean of LDL cholesterol of Group1)
$M_2 = 155$ (mean of LDL cholesterol of Group2)
$\sigma_1 = 13.2$ (Standard deviation of Group1)
$\sigma_2 = 12.1$ (Standard deviation of Group2)
The formula gives a sample size of 27 for each group.

9.3.6 Example 5: How to Calculate the Sample Size for Comparing Two Paired Means?

Suppose we are interested in studying the change in behavioural effect following an intervention on the same subjects using pre-test and post-test designs. Here pre- and post-observations are paired. The following formula can be used for estimating the sample size for comparing paired means:

$$n \geq \left[Z_{1-\alpha/2} + Z_{1-\beta} \right]^2 / d^2 + Z^2_{1-\alpha/2} / 2$$

where $Z_{1-\alpha/2} = 1.96$ (For 95% confidence level)

$Z_{1-\beta} = 1.282$ (For 90% power)

d is the effect size = difference of means/ SD

SD = Standard deviation of difference of means = sqrt ($\sigma^2_1 + \sigma^2_2 - 2.r.\ \sigma_1.\sigma_2$)

σ_1 is the standard deviation(pre)

σ_2 is the standard deviation(post)

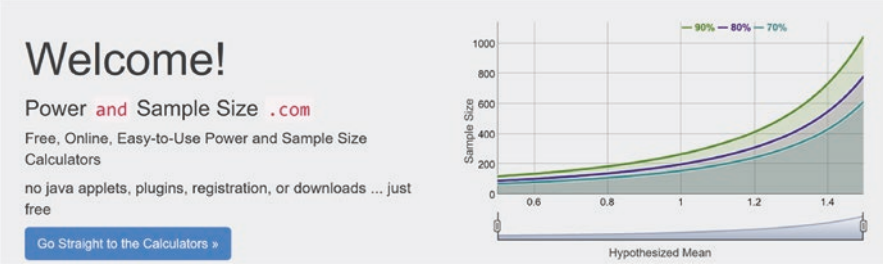
r is the correlation coefficient between pre- and post-values which is generally not known. In that case, we may assume $r = 0.5$ for calculating the sample size.

9.4 Which Are the Free Websites/Software/Apps for Sample Size Calculation?

The following are some of the free websites available on the net for calculation of sample sizes for clinical trials and conducting surveys:

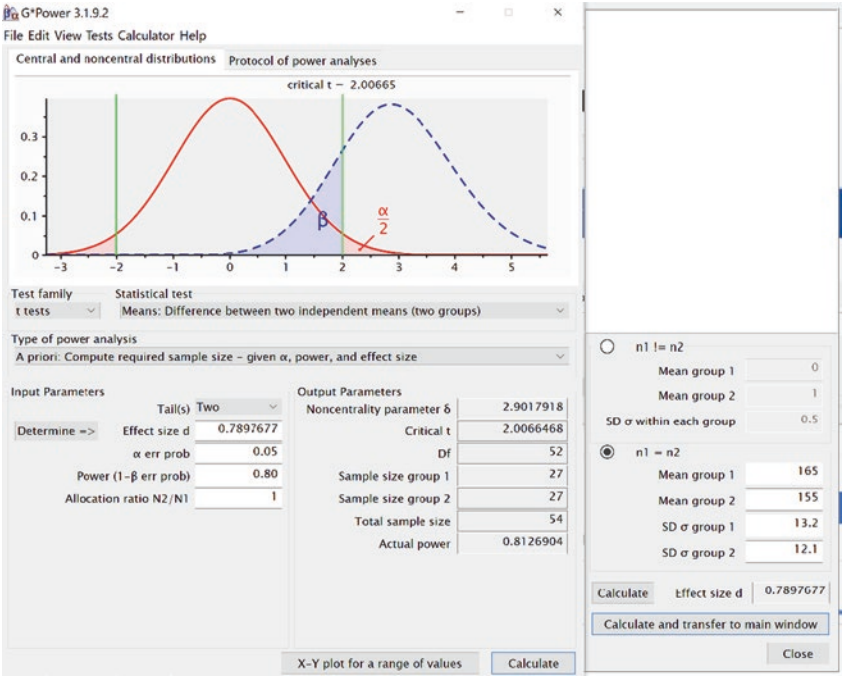
1. **Power and Sample Size: http://powerandsamplesize.com/**

   This online site hosts a number of sample size calculators for testing means, proportions, odds ratios, and Cox PH. Calculators also have the provision to test the said parameters in superiority, noninferiority, and equivalence mode.



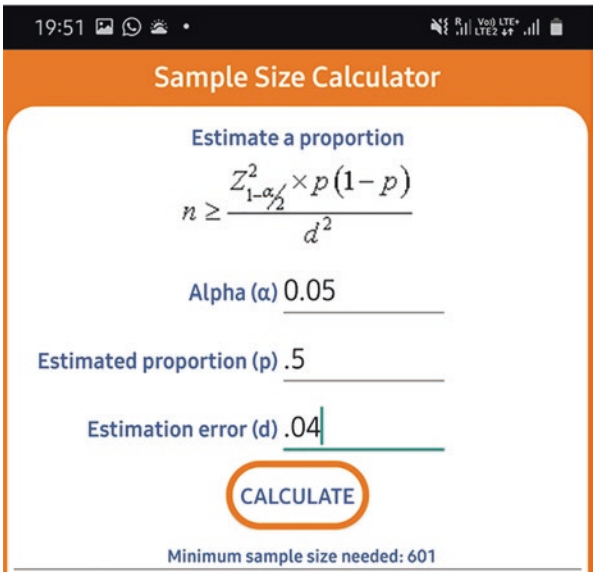
2. **G*Power: https://gpower.software.informer.com/3.1/**

   G*Power is a free downloadable software. It is a powerful tool and includes a large number of programmes for calculating sample sizes for different scenarios. It can do statistical power analyses for many different t tests, F tests, χ^2 tests, z tests, and some exact tests. G*Power can also be used to compute effect sizes and to display graphically the results of power analyses. Below is the snapshot for calculating sample size for testing the difference between two independent means. Here the software first determines the effect size which is transferred to the main window for calculation of the sample size.



3. **Statistics and Sample Size App: https://play.google.com/store/apps/details?id=thaithanhtruc.info.stat**

This app downloadable from the Google play store is a handy tool to calculate sample size for scientific studies as well as doing basic statistics. It can be used for estimating a proportion in a large and finite population, mean, correlation coefficient, sensitivity, and specificity. Sample size for comparing two proportions (paired and unpaired), two means (paired and unpaired), and multiple means. In addition to this it can be used for case–control, cohort, and survival studies to some extent. Below are the snapshots of the Statistics and Sample Size app for android phones.



4. **UCFS-Sample Size Calculators: https://www.sample-size.net/**
   The online website provides useful calculators for sample size calculation for analytic and descriptive studies for clinical researchers.
5. **Sealed envelope: https://www.sealedenvelope.com/power/**
   The website is suited for determining sample size for superiority, noninferiority, equivalence trials with binary as well as continuous outcomes.
6. **OpenEpi: https://www.openepi.com/SampleSize/**
   The website can be used for calculating sample size for proportion, unmatched case–control, Cohort/RCT, mean difference.
7. **R software: https://cran.r-project.org/bin/windows/**
   R is a free downloadable software and contains useful programs for calculation of sample sizes. It is mainly suited for advanced users who have skills to write and execute the programmes.

9.5 Which Are Commercial Software Available for Sample Size Calculation?

1. **Power and Sample Size (PASS) software: https://www.ncss.com/software/pass/**
   PASS is a powerful tool for power and sample size calculation. PASS software provides sample size tools for over 965 statistical tests and confidence interval scenarios. It is an extremely user-friendly software tool for power analysis and sample size estimation for testing statistical hypotheses of varying nature in clinical, pharmaceutical, and medical research settings. It includes powerful modules namely—'group sequential design' and 'conditional power' for power

analysis and sample size estimation for carrying out interim analysis of the experimental trials. PASS 2020 is the latest version of the software.

2. **Adaptive clinical design software (nQuery): https://www.statsols.com/nquery-adapt/adaptive-clinical-trials**
   nQuery sample size software includes a whole module dedicated to adaptive clinical trials and is suited for researchers dealing with adaptive clinical trial designs.
3. **SAS: https://www.sas.com/en_in/home.html**
   SAS is a general statistical software package and can be used for calculating sample size and power using its programming language.

9.6 How Can I Determine Sample Sizes for Diagnostic Test Studies?

Hajian-Tilaki discusses a number of formulae for sample size estimation as well as for testing the sensitivity/specificity, likelihood ratio, and accuracy (AUC) of diagnostic tests. The paper also gives readymade tables of sample sizes for descriptive and diagnostic studies.

9.7 Summary

Sample size calculation has become a necessity from the ethical and methodological points of view in any research proposal. An underpowered study may fail to detect the treatment effect due to an inadequate sample size, whereas an overpowered study may lead to a waste of resources or may put unnecessarily greater numbers of subjects at risk. Hence, an adequate sample size is required to draw definitive conclusions from a study. Sample size estimation is a large subject and requires in-depth training and expertise, especially when the researcher deals with a complicated study design. A number of software/calculators are available for the calculation of power and sample size. The task becomes easier if the researcher understands the terms associated with these software/calculators/formulae prior to sample size estimation.

Suggested Reading

1. Chow SC, Shao J, Wang H, Lokhnygina Y. Sample size calculations in clinical research. 3rd ed. Chapman & Hall/CRC Biostatistics Series; 2019.
2. Cohen J. A power primer. Psychol Bull. 1992;112:155–9.
3. Faber J, Fonseca LM. How sample size influences research outcomes. Dental Press J Orthod. 2014;19:27–9.

Understanding Medical Biostatistics

10

Variation is a law of nature that makes this universe beautiful. In healthcare, two human beings, though genetically similar, may not respond equally to the same drug. The same drug may also have a varying response and become ineffective in an individual over a period of time. When we look at a population of individuals, variations are so prominent that no two individuals are ever exactly alike. There may be several factors for these variations among individuals which include those which are due to biological, genetic, environmental, or ecological effects [1]. Variations also occur when we sample these individuals. Moreover, variability in the observers themselves may also contribute to variations in assessment. These variations are bound to occur whatever may be the reasons and consequently lead to uncertainties in clinical practice, identification of risk factors, and policy planning.

Statistics is the science that manages these uncertainties and helps in minimizing their impact on decisions. Medical biostatistics manages uncertainties in fields related to medicine and health. It comprises a large number of statistical tools/methods such as descriptive and inferential statistics, associations and relationships, diagnosis, prediction and forecasting, assessment of risk and survival analysis, studies and experimental designs and sampling and survey methodology. We discuss here some of the basic concepts of medical biostatistics in the form of questions and answers to make this subject interesting and easy to implement in day-to-day clinical research.

10.1 Understanding the Basics of Biostatistics

We begin by explaining what are data, variables, the types of variables and then go on to statistics.

"If your experiment needs a statistician, you need a better experiment."Ernest Rutherford British Physicist (1871–1937).

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_10

10.1.1 What Are Data?

Data are a set of related raw information. For example, the data may be the demographic information about patients such as their age, gender, medical condition, and diagnosis. The raw information cannot be used as such, and require statistical methods for better understanding and interpretation. The word 'statistics' is generally used together with data and refers to the results of data analysis.

10.1.2 What Is a Variable?

A variable is a characteristic whose values vary. For example, the serum cholesterol, creatinine, height, weight, age, and the colour of eyes and skin of subjects vary from individual to individual and hence they are variables. Variables are measured on different scales of measurement depending on their nature.

10.1.3 What Are the Different Scales of Variable Measurement?

There are four scales that are used for measuring variables.

Nominal/Qualitative/Categorical Nominal variables, also called qualitative/categorical, consist of categories/classes, e.g., colour of eyes (blue, grey, black), status of health (healthy or unhealthy), and type of cancer (benign or malignant). A nominal variable with two categories is called a binary variable and polytomous if it has more than two categories. Nominal data can also assign numeric codes to categories, e.g., healthy =1, unhealthy =2. However, no mathematical manipulations (addition, subtraction, multiplication, and division) can be done on these numeric codes.

Ordinal Ordinal data are ordered or ranked data. For example, pain score (1—low, 2—moderate, 3—severe), intelligence level (1—poor, 2—average, 3—sharp), satisfaction level (1—highly dissatisfied, 2—dissatisfied, 3—neutral, 4—satisfied, 5—highly satisfied) are scored on an ordinal scale. In an ordinal scale we can say $1 > 2 > 3 > 4 > 5$. But we cannot add or subtract these numbers. In other words, we cannot say that the difference between 2 and 1 is equal to 4 and 3. Ordinal variables cannot be used for calculating mean and standard deviations. However, we can use the median or mode for ordinal data to measure the central tendency.

Interval Interval scales are numeric which show both order and direction. We can add or subtract these numbers but cannot multiply or divide them. Interval scales do not have a true zero point. We can measure mean, median and mode, etc., and calculate the dispersion. Examples include age in years (1, 2, 3, 4…), time of each day, or temperature in Celsius or Fahrenheit. In interval scales, we cannot calculate ratios. We cannot say 60 degrees C is twice as hot as 30 degrees. However, we can calculate the exact difference between the two values.

Ratio The Ratio scale is a quantitative scale and has a true zero, unlike the interval scale. Here the ratio of two measurements has a meaning interpretation. For example, a weight of 60 kg is twice as heavy as a weight of 30 kg. Examples of ratio scale variables include body weight, height, and creatinine levels. Ratio scales do not have a negative number. All mathematical manipulations can be done on ratio scale variables.

10.1.4 What Is the Likert Scale?

The Likert scale was developed by Rensis Likert for psychometric assessment such as opinions, beliefs, and attitudes on a variety of items. Likert scales include 4-, 5-, 7-, and 9-point scales to assess the response of the subjects through a questionnaire containing a number of items. The first scale, i.e., a 4-point scale is also called a 'forced-scale' as it does not give an option to the respondent to stay neutral in his opinion. The others are odd-numbered point scales where the respondent can exercise this option.

An example of a 4-point scale can be the feedback of trainees on items such as course material and quality of contents. Responses on a 4-point scale can be—excellent, good, average, and poor. The difficulty with the 4-point scale is that the respondent is forced to answer when he has no opinion. This drawback distorts the results. On many occasions, a respondent might not answer the item.

Examples of a 5-point scale for assessing the satisfaction level regarding the nursing services provided by a hospital can be as follows:

10.1.4.1 Example 1

1. Highly dissatisfied.
2. Dissatisfied.

3. Cannot say (Neutral).
4. Satisfied.
5. Highly satisfied.

10.1.4.2 Example 2

1. Very poor.
2. Poor.
3. Average.
4. Good.
5. Excellent.

The other example could be an opinion about the implementation of some medical policy.

10.1.4.3 Example 3

1. Strongly disagree.
2. Disagree.
3. Neutral.
4. Agree.
5. Strongly agree.

A 7-point or 9-point scale includes more options so that options from strongly disagree to strongly agree are equally spaced and convey meaning to the options. The following is the 7-point scale example:

10.1.4.4 Example 4

1. Strongly disagree.
2. Disagree.
3. Somewhat disagree.
4. Neutral.
5. Somewhat agree.
6. Agree.
7. Strongly agree.

A 9-point scale has 9 options and the middle point 5 is the neutral point where the respondent neither agrees nor disagrees. However, the 5- and 7-point scales are commonly used as the 9-point scale becomes somewhat complicated due to the higher number of classes and maybe confusing to a respondent.

10.1.5 What Are Descriptive and Inferential Statistics?

The study of statistics can be broadly classified into two categories - descriptive and inferential statistics. Descriptive statistics organizes and summarizes data so that it gives some meaning to it. Descriptive statistics comprises the most basic

components of statistics such as *proportions*, measures of *central tendency*, measures of *variability* or spread of the data and *graphical representation* (bar diagrams, pie charts, scatter plots, etc.). Measures of central tendency provide the central or average value of the data, whereas measures of variability or spread focus on the dispersion of values in the data set.

Inferential statistics arrive at conclusions about a population based on sample data drawn from the population. Inferential statistics includes a large number of statistical tools such as probability distributions (Normal, Poisson, Student-t, F, Chi-square distributions), testing of hypotheses, correlation and regression analyses, analyses of variance, etc.

10.1.6 What Is a Measure of Central Tendency and What Are the Various Measures of Central Tendency, Their Merits and Demerits?

When we have data containing a large number of values, the first question that comes to mind is 'Can we find a single value which can best describe our data rather than handling lots of numbers?' The single value or the representative value is called the central tendency or central location of the data. There are a large number of measures of central value in statistics. However, mean, median, and mode are common measures. Below we discuss these measures in detail.

10.1.6.1 Mean

The mean, also known as the arithmetic mean (AM) or average, is the most commonly used statistic. It is the average of all values, is simple to compute, and has several good statistical properties. However, the mean may not be an appropriate choice, particularly when the data has extreme values/outliers or has a skewed distribution. Also, the mean cannot be used for data scored on an ordinal scale such as intelligence, honesty, and pain score.

10.1.6.2 Median

The median is the central value in the data arranged either in an ascending or descending order. It is the appropriate choice for skewed (asymmetric) data. It can also be used when data is scored on an ordinal scale such as intelligence score and satisfaction level. Unlike the mean which is severely affected by extreme values, the median is not affected by the extreme values and is preferred over the mean. In the medical field, hospital stay (number of days) is generally skewed data as most patients stay for a few days and only a few have a longer stay. Here the median seems to be a more appropriate choice compared to the mean.

10.1.6.3 Mode

The mode is not as commonly used as the mean or median and is the value in the data which occurs most frequently. Systolic and diastolic blood pressure, i.e., 120/80 is perhaps the most common example of a mode as most normal human

beings have this level of blood pressure. It is simple to understand, easy to locate, and like the median unaffected by extreme values, but has several demerits. The mode is not based on all observations as it ignores all values except the one which has the maximum frequency. It is inappropriate for bimodal or multimodal data and is not considered to be a good measure of a central value.

10.1.6.4 Example

The following is the age (years) distribution of 15 subjects. Let us calculate the mean, median, and mode of the data.

Data	10, 1, 2, 15, 10, 14, 13, 9, 9, 10, 11, 10, 5, 6, 6
Arranged data	1, 2, 5, 6, 6, 9, 9, 10, 10, 10, 10, 11, 13, 14, 15
Mean (divide the sum of 15 observations by 15)	8.73
Median (eighth observation in the arranged data)	10
Mode (observation with maximum frequency)	10

Let us see how the extreme value affects the mean and not the median. In the above data set if the data value 15 is replaced by 95 by mistake or otherwise, the mean increases to 14.07 whereas the median remains the same.

10.1.6.5 Less Frequently Used Measures

In addition to the mean, median, and mode the statistical literature also includes several less frequently used measures such as the harmonic, geometric, truncated, interquartile, midrange, midhinge, and trim mean which are rarely used except in specific conditions.

10.1.7 What Is Dispersion or Variability in a Data Set and How Is It Measured?

Measures of central tendency such as the mean, median, etc. focus on a central value that can describe the data but they do not give any idea how the values in the data set are scattered or dispersed. For example, consider two data sets having four values in each - data set-I: 0,25,75,100 and data set-II: 48,51,52,49. Surprisingly both the data sets have the same value for the mean, i.e., 50. But if we look at the values in the data set-I, the values are highly dispersed and away from the mean, whereas they are much closer in data set-II and to the mean value as well. Thus, with measures of central tendency alone, we will not be able to understand the distribution of the data accurately and we have to have a measure that understands the spread or variability among the data values. Below, we discuss the various measures of dispersion.

10.1.7.1 Range

The Range (R) is the simplest measure and provides a broader idea of the dispersion. It is the difference between the maximum and minimum values of a data set. For example, the range for the data set-I mentioned above is 100 and for the set-II is 4. Thus, there is a high level of dispersion in set-I compared to set-II. The major drawback of this dispersion measure is that it is based on only two values (minimum and maximum) and ignores all the other values which lie between these two.

10.1.7.2 Interquartile Range

The Interquartile range (IQR) also known as the midspread, middle 50% or H-spread describes the middle 50% of the values when placed in order from the lowest to the highest. It is the difference between the third and first quartile. The first quartile is the value in the data set that has 25% of the values below it. The median is the middle value and is also known as the second quartile. The third quartile holds 25% of the data values above it. The IQR is preferred over the range (R) and is used for constructing boxplots to visualize the spread and identify outliers.

10.1.7.3 Standard Deviation

The Standard deviation ($\boldsymbol{\sigma}$), also called the root mean square deviation, is the most popular and commonly used measure for describing the variation in a data set. Unlike the range and interquartile range, the standard deviation is based on all the values and measures the variation from the mean value. The formula for calculating the standard deviation is:

$$\sigma = \sqrt{\frac{\sum \left(x_i - \mu \right)^2}{N}}$$

where $\boldsymbol{x}_{\mathrm{i}}$ is each value of the population, $\boldsymbol{\mu}$ is the population mean, and $\mathbf{N}$ is the population size.

The above formula is used for calculating the population standard deviation when the data is considered a population. However, while calculating the sample standard deviation, the divisor is $n-1$, where n is the sample size.

The standard deviation measures squared deviations of all the data values from the mean and is the most reliable measure of dispersion. It is rigidly defined and difficult to compute. However, it is the least affected by the sampling fluctuations. The square of the standard deviation is called the variance.

10.1.7.4 Median Absolute Deviation

When our data is skewed, the median is the appropriate measure of average and the median absolute deviation (MAD) should be preferred over the standard deviation for measuring the dispersion. MAD is the median of the absolute deviations from the median.

$$\mathrm{MAD} = \mathrm{median}\left(\left| x - \mathrm{median}\left(x \right) \right| \right).$$

Table 10.1 Calculation of MAD

x	x-median	|x-median|
40	−4	4
40	−4	4
44	0	0
46	2	2
46	2	2
45	1	1
39	−5	5
80	36	36
11	−33	33

Note: When our data is symmetrical, we should prefer the mean as the measure of central tendency and standard deviation (SD) as the measure of dispersion. However, when it is skewed or has extreme values, we should prefer the median as a measure of central tendency and the IQR or median absolute deviation (MAD) as the dispersion measure

Let us calculate MAD for the data (40,40,44,46,46,45,39,80,11) (Table 10.1). Follow these steps:

- Step 1: Arrange the data in an ascending order: 11,39,40,40,44,45,46,46,80.
- Step 2: Choose the middle value (5th) as the median: 44.
- Step 3: Subtract the median from each value and calculate its absolute value as shown in the following table.
- Step 4: Arrange |x-median| in an ascending order and find the middle value (5th): 0,1,2,2,4,4,5,33,36. Here the MAD is 4. However, the mean and standard deviations for this data are 43.44 and 16.49, respectively. The standard deviation is very high as it is affected by the extreme values (11,80). However, the mean (43.44) is closer to the median (44).

10.1.8 What Is Meant by the Distribution of Data?

The distribution of data shows how often each value or values in the intervals occur in the data. The following graph shows how the age (years) of the patients is distributed. The height of the bar gives the count (frequency) of the patients lying in an interval (Fig. 10.1). The distribution shows that the highest number of patients (14) have ages between 41 and 51 followed by 9 who are between 31 and 41 years.

The subject of statistics includes a large number of theoretical distributions such as Binomial, Beta, Cauchy, '*F*', Geometric, '*t*', Inverse-Normal, Normal, Negative-Binomial, Poisson, and Uniform. However, the Normal distribution is the most common. These are also called probability distributions.

10.1.9 What Is a Normal Distribution Curve?

A normal distribution curve is bell-shaped and symmetrical where the mean, median, and mode are equal (Fig. 10.2). It is also called a Gaussian distribution and most of the large populations in nature follow this pattern. A standard normal

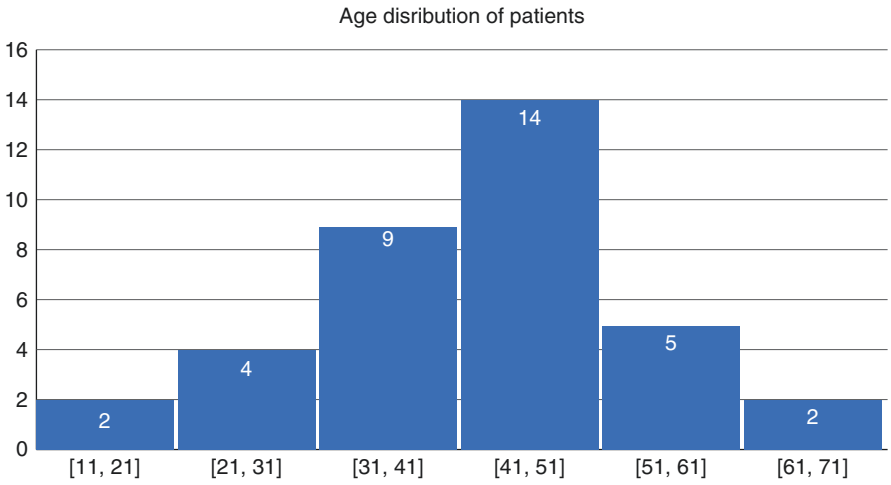


Fig. 10.1 Age distribution of Patients

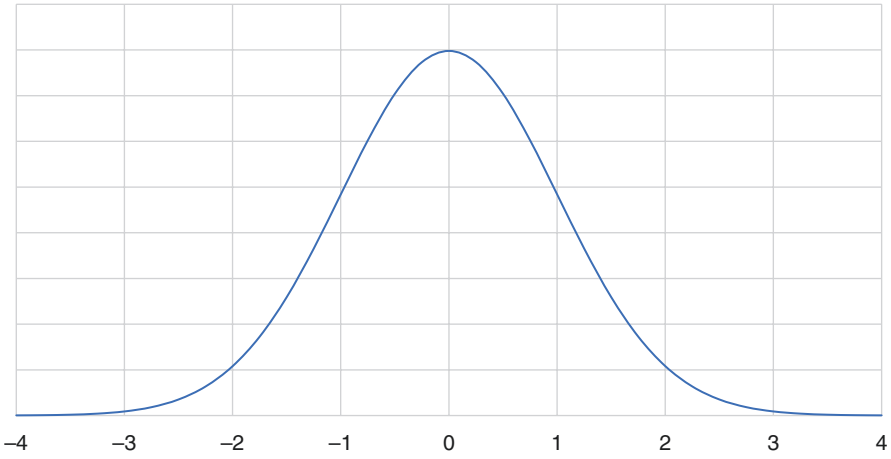


Fig. 10.2 Normal distribution curve

distribution curve has a mean of 0 and a standard deviation of 1. A normal distribution curve has a skewness of 0 and kurtosis 3.

10.1.10 What Is Skewness and What Are Its Implications?

When we plot the data, it may not give a perfect symmetric curve. The lack of symmetry about the mean is generally known as skewness. The curve can be negatively skewed with a longer tail on the left or positively skewed on the right side as shown in the following figures. Skewness indicates a direction and deviation from normality. A normal curve is symmetrical and has a skewness of zero. However, the converse is not necessarily true, i.e., a curve having a skewness of zero may not

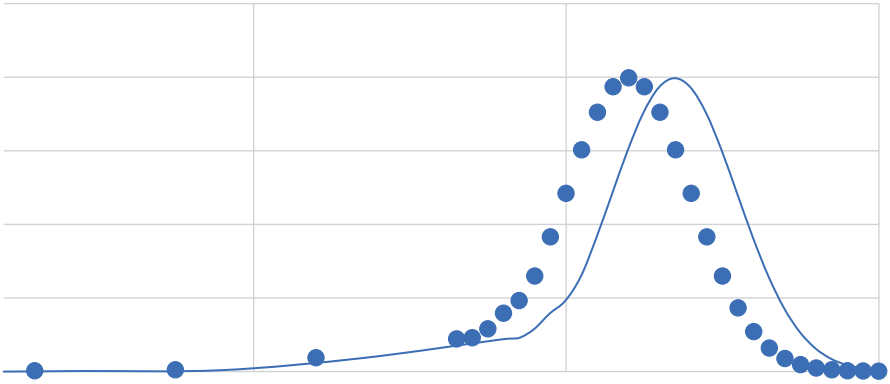


Fig. 10.3 Positively skewed curve

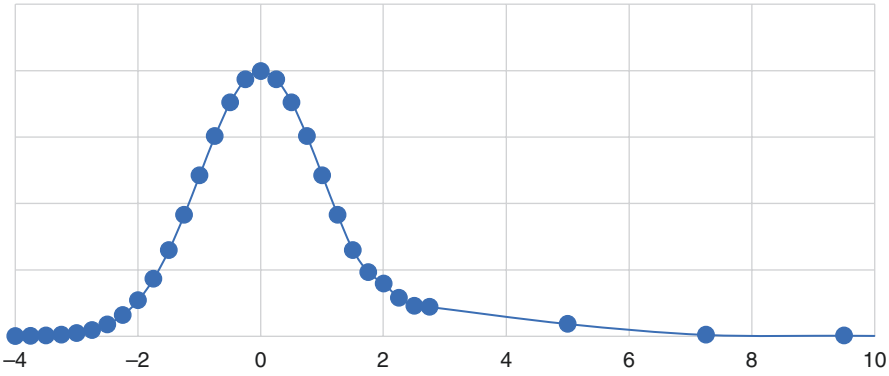


Fig. 10.4 Negatively skewed curve

necessarily be symmetrical. Figures 10.3 and 10.4 give positively (longer tail on the right) and negatively (longer tail on the left) skewed curves.

10.1.11 What Is a Kurtosis and What Are Implications?

Kurtosis is a measure of the peakedness in a curve. A normal curve is known as a mesokurtic curve, which has a moderate peak and a kurtosis of 3. A Leptokurtic curve is a high peaked curve with a low kurtosis (<3), has a lower spread of the data indicated by the lighter tails and lacks outliers (Fig. 10.5). A Platykurtic curve has a high kurtosis (>3), has a wider spread of the data with heavier tails, and may include outliers. From the kurtosis number, one can get a clear visualization of the spread of the data.

Curves are classified as follow:

- Platykurtic (Kurtosis <3.0).
- Mesokurtic (Kurtosis =3.0).
- Leptokuric (Kurtosis >3.0).

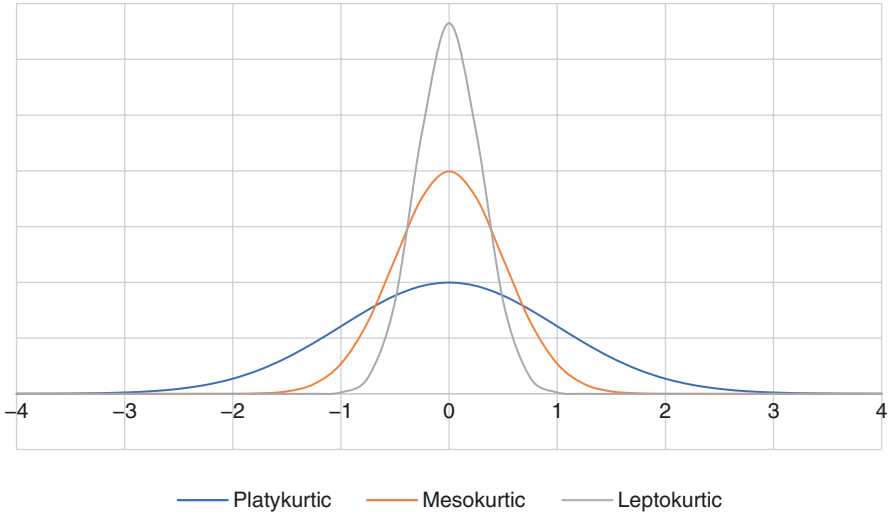


Fig. 10.5 Curves with varying kurtosis levels

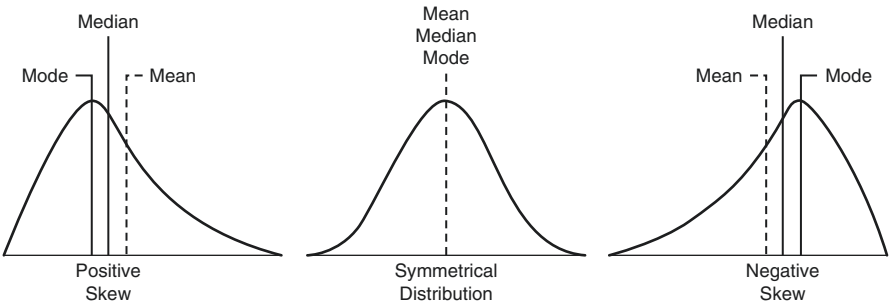


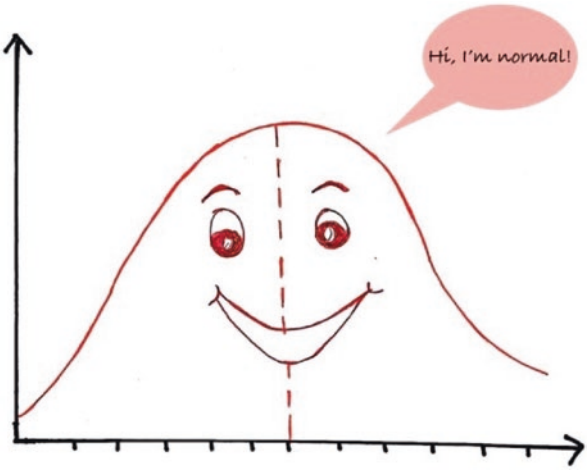
Fig. 10.6 Showing Mean, Median, and Mode with respect to skewness

10.1.12 Is There Any Relationship Between Skewness and the Three Measures of Central Tendency (Mean, Median, and Mode)?

Most textbooks show a general relationship between the skewness and three measures as shown below (Fig. 10.6):

- *Normally distributed data: Mean = Median = Mode*
- *Positively skewed data: Mean > Median > Mode.*
- *Negatively skewed data: Mean < Median < Mode.*

However, the latest findings contradict the above relation/ship in the case of positively skewed data of adult residents across US households where the mean was found to be less than the median and mode [2].



10.1.13 What Is an Outlier in a Data Set?

Before data are subjected to analysis, they are examined and cleaned. We may unexpectedly get very high or low or both values in the data which severely affect results and interpretation. An outlier in a data set is a value that is located at an abnormal distance from most of its values. The minimum or maximum or both values are often outliers but not always. One can think of a value in normally distributed data that is three or more standard deviations away from either side of the mean. According to Maddala, 'An outlier is an observation that is far removed from the rest of the observations'. [3] Outliers are extreme observations and may impact the analysis and lead to misleading interpretation and inferences, if proper precautions are not taken. There are a number of methods available in the literature for detecting and handling outliers.

10.1.14 Why Do Outliers Occur?

Some of the common causes for outliers are:

- Variability in the population and sampling fluctuations.
- Malfunctioning of the instruments, measurements, and human errors.
- Sampling from a highly asymmetric distribution.
- Error in data transmission or transcription.
- Mixing of two distributions.

10.1.15 How Can We Detect Outliers?

The statistical literature supports a number of methods (graphical and model based) for the detection of outliers in a dataset. However, the Box and Whiskers plot is the

most commonly used in descriptive statistics and is based on quartiles. In a boxplot an outlier is a value that is less than the Q_1–1.5(IQR) or greater than Q_3 + 1.5(IQR), where Q_1 and Q_3 are the first and third quartile; IQR is the interquartile range and is equal to Q_3-Q_1. Figure 10.7 shows the Box and Whisker plot of data showing 25, 20, 19.5, and 1 as outliers.

10.1.16 How Should We Handle Outliers?

There are a number of methods available in the literature for identifying and handling outliers. Aguinis reviews and discusses best-practice recommendations for defining, identifying, and handling outliers [4]. The subject of handling outliers is not as simple as it looks. The simplest method is to correct the wrong value or to drop the records containing the outliers. Dropping the records introduces the bias in the results and we suggest the readers to refer to the recommendations of the said paper before deleting the outlier.

10.1.17 What Is Data Heaping?

Data heaping or rounding is a measurement error that arises from an intentional coarsening of the data. Heaped data includes exact and rounded-off values. If the heaping occurs at random, then it does not pose any problem. However, this is not usually so and results in misleading inferences about the parameters of the population if it is ignored. The most common example of data heaping is self-reported income and age from the retrospective data. Statistical literature includes several methods to overcome and handle the heaping of data.

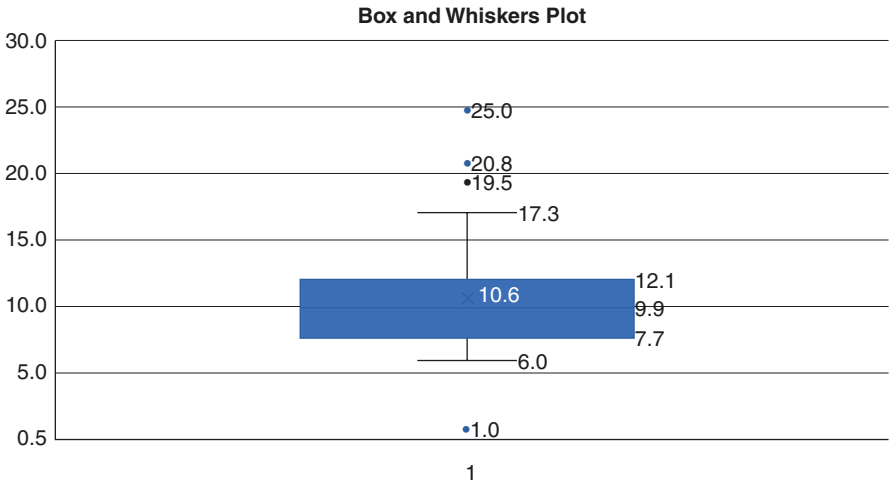


Fig. 10.7 Box and Whiskers plot

10.1.18 What Is the Difference Between a Parameter and an Estimate?

A parameter is a characteristic, say mean, proportion, etc. of a population. It is also called the true value of the population, whereas an estimate is the characteristic of a sample that predicts the true value on the basis of sample data. For example, if we measure the height of all Indian adult males and calculate its mean, it will be a true value and is called the parameter. But measuring the height of an entire population is not feasible and is also an expensive proposition. Thus, we try to estimate the true population value on the basis of a small sample. However, if we calculate the mean on the basis of a sample, it will be an estimate which may or may not be equal to the parameter (true mean) as different samples give rise to different estimates. We try to estimate the true value precisely with some degree of confidence (normally 95%) and with lesser sampling fluctuations or narrow confidence intervals. When we estimate a parameter, we report a confidence interval along with the estimate.

10.1.19 What Are Inferential Methods?

The most important component of biostatistics is inferential statistics which includes a large number of statistical methods which help in testing hypotheses and drawing inferences about the population parameters based on the sample data. Inferential methods are often used to compare differences between a treatment group and a prespecified value or between different treatment groups. Inferential statistics can tell us with a certain degree of confidence, whether the difference between the two groups is a true difference or it is likely due to chance outcomes as a result of sampling fluctuations (different samples resulting in different estimates). Based on a single sample, inferential statistics can also suggest the probable value of a population parameter (mean or proportion) lying in the range popularly known as the confidence interval. These methods are different for qualitative variables than for quantitative ones.

They also vary further depending upon the sample size or sampling distribution. It has been theoretically established that when the sample size is large, the distribution pattern of the mean/proportion tends to be Gaussian (normal having a bell-shaped curve). Thus, when the sample size is large and the distribution is Gaussian (normal) we use parametric inferential methods, otherwise we use non-parametric methods.

10.1.20 What Are Inferential Methods for Proportions?

Inferential methods for proportions are commonly used for calculating confidence intervals as well as for testing differences between statistics which are estimated on the basis of proportions such as the prevalence of a disease, odds ratio (OR), relative risk (RR), sensitivity, and specificity. These methods also include equivalence tests

(superiority, equivalence, noninferiority) for testing whether the two groups are essentially equivalent and whether the difference, if any is medically relevant. These methods generally use the Z-test, Chi-square test, likelihood ratio test, Fisher Exact test, and McNemar test. Users have to be cautious about these tests because of their limitations. The chi-square test is suited for large sample sizes whereas the Fisher Exact test can be used with small sample sizes for a 2×2 classification. A sample is considered large enough for using the chi-square test if the expected counts in every cell are 5 or more. The McNemar test is used for matched-pair proportions and is mainly used in pre-post designs. Except for the Z-test, all the above-said tests are non-parametric and do not require the assumption of normality.

10.1.21 What Are Inferential Methods for Means?

10.1.21.1 Parametric Methods

A large number of parametric inferential methods are available for testing the difference of means between groups when the sample size is large and the underlying distribution of the study variable follows a Gaussian pattern. Thus, the normality assumption is tested before going for the analysis. These methods include Student unpaired and paired t-tests for comparing two means or a mean with a specified value one way and two-way ANOVA, Repeated measure ANOVA, etc. The Analysis of variance (ANOVA) is a technique for comparing three or more means and uses the F-test for testing the null hypothesis of the equality of means. Repeated measures ANOVA is the equivalent of the one-way ANOVA, but for related groups, and is the extension of the Student paired t-test.

10.1.22 What Are Post Hoc Tests?

ANOVA is used when we want to test differences in the means among three or more groups. ANOVA uses Fisher's F-test to do this. If the p-value corresponding to the F-test is less than the threshold (0.05) then we reject the null hypothesis of equality of all means and look for which pairs of means differ significantly. The F-test does not tell which pairs of means differ. Post hoc tests are applied to test individual pairs. The tests are –Bonferroni, Tuckey, Dunnett, Scheffe, Fisher's LSD, Newman-Keul, and Dunkan. They are an integral part of ANOVA for making multiple comparisons. The Bonferroni and Tuckey tests are the most used in the medical field.

10.1.23 What Are the Assumptions of the Student *t*-test?

The Student t-test is the most commonly used for comparing a mean with a prespecified value (constant) or two unpaired means. The assumption for a t-test is that the measurement applied to the data collected follows a continuous numeric scale (e.g., body weight, cholesterol level) or an ordinal scale, such as the scores

for an IQ test. The Student t-test assumes that the values within each group should be independent and the means normally distributed. The test also requires homogeneity of variance (i.e., the standard deviations of the samples are approximately equal).

10.1.24 What Are the Tests Used for Testing the Normality of the Data?

Many statistical procedures such as t-tests, linear regression analysis, discriminant analysis, and Analysis of Variance (ANOVA) require assumptions of normality. If this is not present the inferences drawn may not be reliable and valid. There are three common methods for assessing normality. These are graphical methods (histograms, boxplots, Q-Q plots), numerical methods (skewness and kurtosis) and formal normality tests – the Shapiro–Wilk test, Kolmogorov–Smirnov test, Lilliefors test, and the Anderson–Darling test. A standard statistical software package has all three tests to assess normality. One can have an idea of the normal curve from the histogram of the data. If the curve is bell shaped, the data seems to follow a normal distribution. Skewness measures the lack of symmetry and a normal curve has a value of zero. A larger negative value means the curve is negatively skewed and a larger positive value, positively skewed. Kurtosis measures the peakedness of the curve. A normal curve has a kurtosis of three. If the kurtosis is greater than three then the curve will have a high peak and flatter tails. If it is less than three, the curve will have a low peak. However, to be more specific, data can be tested for normality using formal tests. Results of a simulation study [5] show that the Shapiro–Wilk test is the most powerful normality test, followed by the Anderson–Darling, Lilliefors and Kolmogorov–Smirnov tests. However, the power of all four tests is still low for a small sample size. If the p-value of the test is less than 0.05, the data does not follow the Gaussian pattern or does not have a normal distribution.

10.1.25 What Should We Do If the Normality Assumption Fails?

If the data fails for normality, we should first apply the appropriate transformations (log, square root, reciprocal, arcsine, etc.) for transforming the data to normal and then apply the test. If the transformation does not help, we should go for the corresponding non-parametric test.

10.1.25.1 Non-Parametric Methods

Non-parametric methods are distribution-free methods and particularly used when the normality assumption fails. These methods can be applied when the data is ordinal or the sample size is small. They may not be as efficient as parametric tests when the data is normally distributed. Table 10.2 shows the parametric and their corresponding non-parametric tests for comparing two or more groups.

Questions and answers related to testing of hypotheses:

Table 10.2 Parametric and non-parametric methods

Number of groups	Parametric	Non-parametric
Two	Unpaired student t-test	Mann–Whitney U test
Two	Paired student t-test	Wilcoxon signed-rank test
More than two	ANOVA	Kruskal–Wallis

10.1.26 What Are the Null and Alternative Hypotheses?

A null hypothesis is a statement about the population(s) saying such as there is 'no effect' of a factor or 'no association' between two attributes or 'no difference' in characteristics (mean, efficacy, accuracy) in the population. The null hypothesis eliminates any prejudice or presumption with respect to a population. Whereas an alternative hypothesis is a contrasting statement that says, 'there is an effect' or 'there is an association' or 'there is a difference' among the populations. The alternative hypothesis is what we might believe to be true or hope to be true.

For example, we want to compare the efficacies of two drugs using the Student t-test we can set the hypothesis as follow:

- Null Hypothesis (H_0): There is no difference in the efficacy of drug A and B.
- Alternative Hypothesis (H_1): The drugs differ in their efficacy.
- Alternative Hypothesis (H_1): Drug A has a higher efficacy than B.
- Alternative Hypothesis (H_1): Drug A has a lower efficacy than B.

In case when we want to test the association, we set the hypothesis as follow:

- Null Hypothesis (H_0): There is no association (correlation coefficient = 0).
- Alternative Hypothesis (H_1): There is an association (correlation coefficient $\neq 0$).

We can also set the two hypotheses as follows:

- Null Hypothesis (H_0): Prevalence of a disease (p) ≤ 0.20.
- Alternative Hypothesis (H_1): Prevalence of a disease (p) > 0.20.

When there are several means to be tested using ANOVA, the hypotheses are written thus:

- Null Hypothesis (H_0): $\mu_1 = \mu_2 = \mu_3 = \mu_4 = \mu_5$
- Alternative Hypothesis (H_1): $\mu_1 \neq \mu_2 \neq \mu_3 \neq \mu_4 \neq \mu_5$

10.1.27 What Errors Do We Make While Testing a Hypothesis?

Testing a hypothesis is commonly known as the null hypothesis significance testing (NHST) where we find the evidence against the null hypothesis using various statistical tools such as the Student *t*-test, F-test, and Z test. If the evidence is strong enough ($p < 0.05$) we reject the null hypothesis in favour of an alternate hypothesis. Since all statistical significance testing is based on a fairly small single sample that is associated with fluctuations, errors are bound to creep into the testing process.

Two kinds of errors known as type-I and II occur while testing a hypothesis. For example, if in reality, two drugs have the same efficacy but on the basis of the *p*-value, we prove that they are different this is called the type-I error or alpha error. Let us consider the other situation where in reality the drugs differ but we are showing that they are not. This is called the type-II error or beta error. We define these errors more precisely as follows:

- Type-I error: Probability of rejecting a true null hypothesis is also known as an Alpha(α) error or false-positive. This probability is generally kept at 5% or sometimes 1% and this level is called the significance level.
- Type-II error: The probability of not rejecting the false null hypothesis is also known as the Beta(β) error or false negative. This probability is generally kept at 20%.

10.1.28 What Is the Relationship Between Type-I and Type-II Errors and Power?

The Type-I error is the probability of a false-positive result and is conventionally kept below 0.05 (5%). If we reduce this error, the Type-II error increases and consequently, the power of the test decreases. Thus, the lower the level of significance, the lower is the power. The main disadvantage with a low-powered statistical test is that it is difficult to reject the false null hypothesis. Such a test may not permit us to recommend a drug even if it is better than the control.

10.1.29 What Is the Power of a Statistical Test?

The power of a statistical test is the probability of rejecting the null hypothesis when the alternative hypothesis is true and is equal to 1-β. It is the probability of detecting significant differences. For example, an investigator sets a power of 80%. This will enable him or her, to observe an effect of that size or larger in his study 80 times out of 100. Increasing the sample size enhances the power. With high power, even the smaller differences in populations can be detected.

10.1.30 What Is a Confidence Level and Confidence Interval?

The confidence level is a measure of uncertainty associated with a *sampling method*. The higher the confidence level, the lower is the uncertainty. Suppose we want to estimate the population mean. We draw a random sample and calculate the mean. If we repeat this process 100 times, we may get different values of the mean because of sampling fluctuations. Suppose we also compute the interval estimate for each sample along with the sample means. Some interval estimates would include the true population mean and some would not. A 95% confidence level means that we

would expect 95% of the interval estimates to include the population mean. This does not mean there is a 95% probability that the population mean is in the interval estimate.

The confidence interval is a range of plausible values in which we are fairly sure our unknown true value (for example, mean, proportion) lies. The confidence interval is always associated with the confidence level. The width of the confidence interval is indicative of the reliability of the estimate. The narrower the interval, the higher is the reliability. For a given confidence level, the confidence interval depends upon variability (standard deviation) as well as sample size. If the standard deviation is high or sample size is low, the confidence interval will be wider. We can use the following formula for calculating the lower and upper limits of the confidence interval of a mean:

$$\text{Lower limit of confidence interval is } \bar{X} - Z\alpha/2 \times \left[\sigma/\sqrt{n}\right].$$

$$\text{Upper limit of confidence interval is } \bar{X} + Z\alpha/2 \times \left[\sigma/\sqrt{n}\right].$$

where

$\bar{X}$ = Mean, σ = Standard deviation, Z = Standard score, α = Confidence level.

For a 90% confidence level(α) the value of Z is 1.645, for 95%, 1.96 and for 99%, 2.576.

Example: The sample data (10, 1, 2, 15, 10, 14, 13, 9, 9, 10, 11, 10, 5, 6, 6) has a mean of 8.73 and a sample standard deviation is 4.06. Using the above confidence interval formula, the 95% confidence interval of the mean is 6.68–10.79. Half of this interval width (2.05) is called the margin of error or precision.

10.1.31 What Are One- and Two-Tailed Tests?

While calculating the sample size to test a hypothesis, the researcher must specify whether the researcher is using a one- or two-tailed test. A one-tail alternative hypothesis test is a one-sided test. For example, drug 'A' is better than 'B' or drug 'A' is inferior to 'B'. A two-tail alternative hypothesis test is a two-sided test. For example, drugs 'A' and 'B' differ. If we do not have any idea about the performance of the drugs, we should choose the two-tail test; otherwise, we can use a one-tail test. The advantage of a one-tail test is that it requires a smaller sample size for testing the significance compared to a two-tail test.

10.1.32 What Is the *p*-value?

The *p*-value is the most frequently used inferential statistics for testing a null hypothesis. The *p*-value developed by Sir Ronald Fisher almost a century ago is highly controversial and is generally misunderstood by researchers. It is the probability of an observed or more extreme result assuming that the null

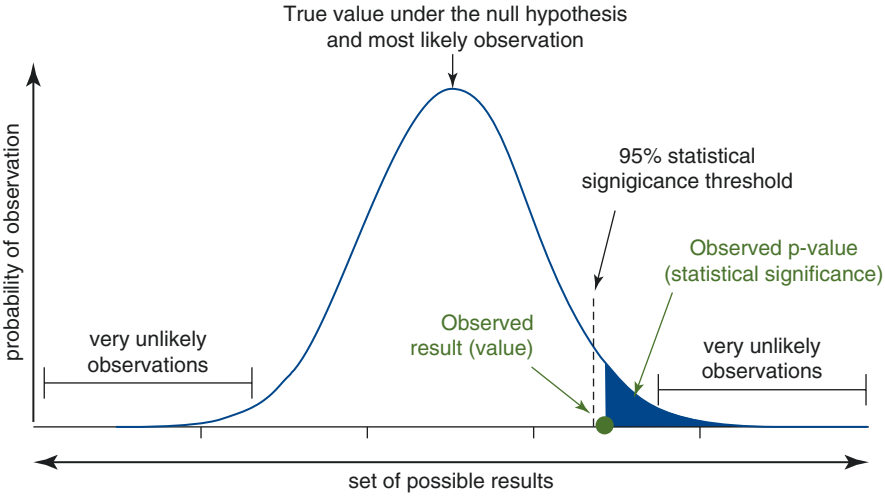


Fig. 10.8 A normal probability distribution curve. Figure Downloaded from the Internet

hypothesis is true. For example, if a researcher wants to test whether a new drug is better than an old one, he applies the *t*-statistic and gets a '*t*-value' of say 2.0. Then he looks for the probability of getting a result of 2.0 or more ($t \geq 2.0$). This value which is shown under the blue area in Fig. 10.8 is the probability and is called the *p*-value.

The *p*-value is automatically calculated by the software. If this is found to be less than or equal to the significance level (usually $p = 0.05$), we have a strong evidence against the null hypothesis and can reject the null hypothesis. However, rejecting the null hypothesis does not imply that it is false. Similarly, when the $p > 0.05$ it is incorrect to say there is 'no effect' or that the 'null hypothesis is true'. When $p \leq 0.05$, the safer inferential statement we can make is that there is at most a 5% probability that our results are compatible with the null hypothesis. The ASA's recent interpretation of the *p*-value clearly says, '*p*-values can indicate how incompatible the data are with a specified statistical model'.

10.1.33 What Are the Most Common Misinterpretations of the *p*-value?

(i) The *p*-value is the probability that the null hypothesis is true when $p > 0.05$.
(ii) 1-minus the *p*-value is the probability that the alternative hypothesis is true.
(iii) When $p > 0.05$, the null hypothesis is false or should be rejected.
(iv) When the *p*-value >0.05 there is no effect.
(v) A statistically significant result is also medically important.

10.1.34 What Is the New Interpretation of the *p*-value by the American Statistical Association (ASA)?

The *p*-value suggested by Fisher has now been interpreted by the American Statistical Association (ASA) [6] as 'Informally, a *p*-value is the probability under a specified statistical model that a statistical summary of the data (e.g., the sample mean difference between two compared groups) would be equal to or more extreme than its observed value'. If the *p*-value is less than the threshold (0.05), then there is a strong evidence against the null hypothesis.

10.1.35 What Are the Six Principles Suggested by the American Statistical Association (2016) on *p*-values?

1. '*p*-values can indicate how incompatible the data are with a specified statistical model'.
2. '*p*-values do not measure the probability that the studied hypothesis is true, or the probability that the data were produced by random chance alone.
3. 'Scientific conclusions and business or policy decisions should not be based only on whether a *p*-value passes a specific threshold'.
4. 'Proper inference requires full reporting and transparency'.
5. 'A *p*-value, or statistical significance, does not measure the size of an effect or the importance of a result'.
6. 'By itself, a *p*-value does not provide a good measure of evidence regarding a model or hypothesis'.

10.1.36 Is a Very Low *p*-Value Indicative of a Large Effect Size?

A low *p*-value is not indicative of the effect size (difference between two proportions or means), i.e., that it will be very large. The *p*-value is sample size dependent. Even a very small observed difference turns out to be statistically significant if the sample sizes are large. According to the ASA guidelines inferences should not be simply drawn on the basis of *p*-value alone.

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Applying Biostatistics in Medical Research

11

11.1 What Is the Difference Between a Retrospective and a Prospective Study?

A retrospective study is based on information collected in the past, say about a disease that has already occurred and the study aims to investigate its association with the risk factors or exposure, for example, studying the association between lung cancer and those who smoke. The most common example of a retrospective study is a case–control study. However, all retrospective studies are not case–control ones. Retrospective studies are relatively inexpensive, easy to perform, and require less time to draw inferences from data. Their major disadvantage is that the investigator has to depend on the available information which has been collected and maintained in the past by others and maybe incomplete or lacking in some aspects, like confounding factors.

Unlike a retrospective study which looks backwards, a prospective study looks forwards and is conducted over a period of time in a cohort of subjects and attempts to study the relationship of outcomes with respect to specific exposures or risk factors. A prospective study may consist of studying the relationship between maternal anaemia and gestation. Here the outcome is observed with respect to different levels of haemoglobin. Prospective studies are relatively expensive and time-consuming as the disease or the outcome occurs after the beginning of the study, but are considered to be better than retrospective studies in the hierarchy of evidence.

11.2 What Is a Cross-Sectional Study?

Unlike retrospective and prospective study designs, a cross-sectional study examines and collects data at a single point in time. A cross-sectional study provides the current status, say the prevalence of a disease and other associated factors of a population.

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_11

11.3 What Is a Longitudinal Study?

A cross-sectional study collects data on individuals at a single point in time, whereas a longitudinal study collects data on the same individuals at different points in time. For example, a cohort of individuals is compared over time for a specific outcome. The Framingham Heart Study is one of the most well-known longitudinal studies and has been conducted over the last 50 years [1].

11.4 What Is a Case–Control Study?

In a case–control study subjects with and without a medical condition (disease) are investigated for exposure in the past. Cases who have a specific medical condition, say lung cancer and a control group without lung cancer. Case–control studies are usually, but not exclusively, retrospective. Cases and controls are individually checked for suspected risk factors or past exposure which are likely to cause the medical condition. The potential relationship between the suspected risk factor and the disease is examined by generally arranging the data of the counts in a 2×2 table and computing the odds ratio. In case–control studies, the odds ratio (OR) is the valid measure to assess the risk and not the relative risk (RR).

11.5 What Is a Randomized Controlled Trial?

A randomized controlled trial (CRT) is a scientific experiment where the investigator wants to compare the response of two or more treatments/drugs or interventions. Subjects are allocated randomly to different groups to reduce bias. Those in the control group are assigned a 'placebo' or 'no intervention' or 'the existing intervention' whereas the other groups called test groups or experimental groups are assigned the new intervention. Randomized trials can include more than one treatment group or even more than one control.

11.6 What Is a Cluster Randomized Trial?

The cluster randomized trial is a relatively new study design. Cluster randomized trials are now commonly used to evaluate public health, health policy, and health system interventions. In cluster designs, clusters are randomly allocated to groups and have several advantages over individual randomization in terms of implementation costs or administrative convenience. Readers may refer to a paper by Moberg and Kramer [2] for a better understanding of these designs and their applicability.

11.7 What Is an Equivalence, Superiority, or a Noninferiority Trial?

A superiority trial aims to test the superiority of one treatment over another in a randomized controlled trial. For example, we want to know whether a new drug is better in increasing the high-density lipoprotein (HDL) levels compared to the existing one. Superiority is established if the response improves by some predetermined, called superiority, margin. The null and alternative hypotheses in a superiority trial are specified as follows:

We set the null hypothesis (H_0) that the response of the new drug is equal to or less than the existing one by a margin (δ) and look for evidence against it in favour of the alternative hypothesis (H_1).

$$H_0 : \mu_1 - \mu_0 \leq \delta$$
$$H_1 : \mu_1 - \mu_0 > \delta$$

where $\delta \geq 0$ is the superiority margin.

An equivalence trial aims to test that the two treatments are 'not too different' with respect to some characteristics. Here the 'not too different' is a specified margin that is clinically unimportant. For example, if a difference of 2% or less in efficacy is irrelevant from the clinical perspective, an equivalence trial tests for a difference of a 2% margin using a two-tailed statistical test.

The hypotheses of an equivalence trial can be specified as follow:

$$H_0 : |\mu_1 - \mu_0| \geq \delta$$
$$H_1 : |\mu_1 - \mu_0| < \delta$$

where $\delta > 0$ is the tolerance margin.

A noninferiority trial aims to show that the new regimen is 'not (much) worse' than the existing or standard regimen by more than a specified margin. Noninferiority trials are conducted where the new regimen has the potential to be at least as effective as the standard regimen but is cost-effective or more convenient. The hypotheses of noninferiority trial can be specified as follow:

$$H_0 : \mu_1 - \mu_0 \leq -\delta$$
$$H_1 : \mu_1 - \mu_0 > -\delta$$

where $\delta \geq 0$ is the margin of clinical significance.

11.8 Questions and Answers related to Sampling Methods

11.8.1 What Are the Common Methods of Random Sampling?

There are a large number of methods in statistics that are used for selecting a random sample. The most common and widely used is simple random sampling. However, below we discuss some of the other methods as well.

Simple Random Sampling (SRS) Simple random sampling is a method where each member of a population is given an equal chance(probability) to be included in the sample. The sample is selected on the basis of random numbers. Simple random sampling appears to be easy but is sometimes difficult to implement as it requires the availability of a sampling frame, i.e., a list of all the sampling units in the target population. Preparing this is an exhausting exercise, particularly when the list is large. Even, if we are able to do so, the SRS does not ensure that the different segments of the population are adequately represented in the sample.

Stratified Random Sampling In stratified random sampling, the population is first divided into different homogeneous strata based on some criteria, say age, income, sex, BMI, or disease followed by selecting a simple random sample from each stratum. Compared to SRS, stratified sampling gives a more adequate representation to one or more subgroups of interest.

Multistage Random Sampling Multistage random sampling is the most preferred sampling design, particularly when the population size is very large and spread over a large area, say all over a state. Here the sampling is done in stages by selecting a sample of districts called the primary stage units, followed by sampling blocks from the selected districts and villages from the selected blocks; and finally subjects from the selected villages. This is the most preferred sampling design followed in large-scale surveys and requires less effort in developing the sampling frame.

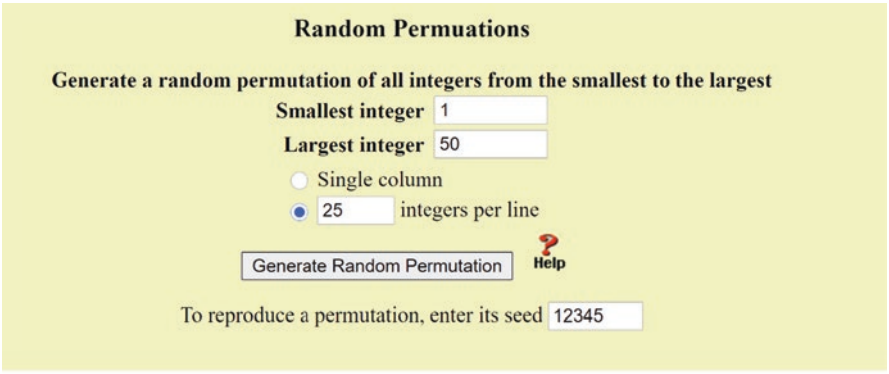
Cluster Random Sampling A cluster is a group of subjects who are located in close proximity and easy to administer for survey purposes. In cluster sampling, clusters are the primary units and sampling is done on the clusters. In stratified sampling, a random sample is drawn from each of the strata, whereas in cluster sampling only the selected clusters are sampled. A major advantage of cluster sampling is that the cost is reduced by the increased sampling efficiency, whereas stratified sampling increases the precision.

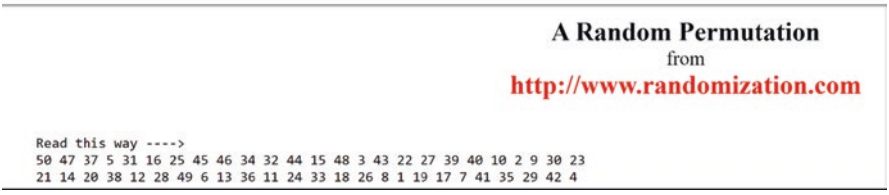
Systematic Random Sampling Systematic random sampling selects the first element randomly and the other units are automatically included on the basis of the sampling interval (every kth unit). Simple random sampling is easy to execute, particularly in a hospital. Every kth patient visiting the clinic can be included in the sample once the first patient is chosen randomly. However, systematic random sampling yields biased estimates.

In addition to the above commonly discussed methods of random sampling, there are others such as probability proportional to size sampling, area sampling, inverse sampling, sequential sampling, and nonrandom methods of sampling (purposive or convenience).

11.8.2 How to Perform Randomization in Real Research Settings?

Randomization is a prerequisite for conducting any experimental trial and helps in eliminating bias by randomly allocating subjects/units to different interventions/stimuli. Randomization provides the chance that the two or more than two groups are at par in terms of unseen heterogeneity prior to intervention. Normally, a randomized controlled trial (RCT) includes a group of subjects who do not receive any intervention or receive a placebo and is called the control group. The other group is the 'intervention' or the 'test' group receiving the treatment. If an experiment is to be performed on 50 subjects with 25 each in the intervention and the control group, we can assign subjects to either of the groups with the help of random numbers. Readers may refer to the website www.randomization.com or use R-software with little coding for drawing random numbers. Following is the output of the website for selecting 50 random numbers for the two groups:





11.8.3 What Are the Determinants of an Adequate Sample Size for a Research Study?

Determination of a sample size is a prerequisite for any research programme and will primarily depend on the objectives of the study as well as how statistically those objectives are to be answered. A study may have a single or multiple objectives. Further, an objective may be 'descriptive' or 'analytical' in nature. Determinants for the calculation of sample size mainly include the available basic

information associated with the study such as the mean, standard deviation, proportion and effect size in addition to general statistical information such as confidence level, significance level (type-I error), and the power of the study (1 minus type-II error). This basic information is taken from the related studies published in the past. For more details on how to calculate sample size please see the chapter on '*How to calculate an adequate sample size'* in this book.

11.9 Questions and Answers Related to the Diagnostic Ability/Validity of a Test

11.9.1 What Is the Sensitivity and Specificity of a Test?

In medical diagnosis, the terms sensitivity and specificity are often used to assess the ability of an alternative test against a gold standard to identify the positive and negative cases correctly. Sensitivity is the ability of a test to correctly identifying positive cases out of those who have the disease, whereas specificity is the ability to correctly identify negative cases out of those who do not have the disease. Sensitivity is also called the true-positive rate and specificity the true negative rate. For example, if a test correctly identifies 85 positive cases out of 100 cases who have the disease, its sensitivity is 85%. If the test correctly identifies 95 negative cases out of 100 who do not have the disease, its specificity will be 95%. Let us discuss the results of the identification of gold standard and alternative tests conducted on 700 subjects which are arranged in the following table:

	Gold standard test		
Alternative test	Positive	Negative	Row total
Positive	400 (TP)	30 (FP)	430
Negative	100 (FN)	170 (TN)	270
Column total	500	200	

In the above table, the gold standard tests that disease is present in 500 and absent in 200 subjects (see column totals). However, the alternative test confirms that the disease is present in 430 and absent in 270 subjects (see row totals). There is a disagreement between the two tests. Had there been no disagreement between the results of two tests, an alternative test would have been as accurate as the gold standard. Let us further analyze critically the results of the alternative test. The alternative test says that the disease is present in 400 and not in the remaining 100 subjects. These 400 subjects are true-positives (TP) and 100 are false negatives (FN). Similarly, if we examine the negative cases which are 200 as identified by the gold standard, the alternative test says that there is no disease in 170 and the remaining 30 subjects have the disease. These 170 subjects are true negatives (TN) and 30 are false positives (FP). If there were no false positives and negatives, the alternative

test would be as good as the gold-standard test. Below we describe various diagnostic, predictive, and accuracy parameters of the alternative test.

Sensitivity is the true-positive rate (TPR) = 100 × TP/(TP + FN) = 100 × 400/(400 + 100) = 80%. Sensitivity is also called Recall in information retrieval.

$$\text{False negative rate}\left(\text{FNR}\right) = 100 - \text{sensitivity} = 100 - 80 = 20\%$$

Specificity also called the true negative rate (TNR) = 100 × TN/(TN + FP) = 100 × 170(170 + 30) =85%

$$\text{False positive rate}\left(\text{FPR}\right) = 100 - \text{specificity} = 100 - 85 = 15\%.$$

$$\text{Positive predictive value}\left(\text{PPV}\right) = 100 \times \text{TP} / \left(\text{TP} + \text{FP}\right) = 100 \times 400 / \left(400 + 30\right) = 93\%$$

$$\text{Negative predictive value}\left(\text{NPV}\right) = 100 \times \text{TN} / \left(\text{TN} + \text{FN}\right) = 100 \times 170 / \left(170 + 100\right) = 63\%$$

11.9.2 What Are Positive and Negative Predictivities?

The sensitivity and specificity of a test are indicators of its validity and do not measure its diagnostic value which is obtained in terms of predictivities. Let us analyze the results of the alternative test in the above table to understand the predictivities of the test. The test has labelled 430 subjects as positive cases. However, out of 430, only 400 have been correctly labelled, whereas 30 have been labelled wrongly. Similarly, the test has labelled 270 subjects as negative cases. However, out of 270, only 170 cases have been labelled correctly and the other 100 wrongly. Here the alternative test could label 93% of the positive cases correctly and 63% of the negative cases. The predictivity of a test is the ability to correctly label the tested cases. The positive predictivity of the test is its ability to correctly label the subjects 'positive' who test positive. Negative predictivity is correctly labelling the subjects 'negative' who test negative. Predictivities are also called post-test probabilities and measure the utility of the test in correctly identifying or excluding the disease. However, the major drawback with the predictivities is that they are disease-prevalence dependent. If disease prevalence or prior probability of disease is known we should use the formula for PPV and NPV which involves sensitivity, specificity, and prevalence. PPV is directly proportional to the prevalence of a disease. In the above-said example, if we increase the proportion of subjects having a disease, PPV will increase and NPV may fall. If the disease is rare, positive predictivity will be very low. However, sensitivity and specificity do not depend upon the prevalence. Thus, the calculation of predictivities should be done for a study that includes the correct proportion of diseased and non-diseased subjects to be tested. It would be appropriate to report predictivities along with sensitivity-specificity in a cross-sectional study. However, for case–control studies sensitivity-specificity should be calculated.

11.9.3 What Are Likelihood Ratio Tests?

Likelihood ratios are other measures that combine both sensitivity and specificity for interpreting diagnostic tests. The advantage of likelihood ratio tests is that they do not depend upon the prevalence of a disease. Likelihood ratio positive (LR+) is the ratio of a true-positive rate (TPR) and a false-positive rate, whereas likelihood ratio negative (LR−) is the ratio of the false-negative rate (FNR) and true negative rate (TNR). LR+ gives the odds of having a disease in relation to not having the disease when the test is found to be positive. When LR+ is 10, then the odds a person has a disease are 10:1 when he is tested positive. The higher the LR+, higher is the likelihood of having a disease. LR− is the reverse of LR+. An LR− of 0.1 means that the odds a person has a disease are 1:10 when he is tested negative. It has been shown that if we know the pretest probability (prevalence), say on the basis of earlier records or symptoms, a value of 10 or more of LR+ and 0.1 or less of LR− indicates that the test is extremely good. If a test has LR+ and LR− equal to 1 then the test has no diagnostic value.

$$\begin{aligned}\text{Likelihood ratio positive}\left(\text{LR}+\right) &= \text{Sensitivity} / 100 - \text{Specificity}) = 80 / \left(100 - 85\right) = 5.33\\ &= \text{TPR} / \text{FPR} = 80 / 15 = 5.33\end{aligned}$$

$$\begin{aligned}\text{Likelihood ratio negative}\left(\text{LR}-\right) &= \left(100 - \text{Sensitivity}\right) / \text{Specificity} = 20 / \left(85\right) = 0.235\\ &= \text{FNR} / \text{TNR} = 20 / 85 = 0.235\end{aligned}$$

11.9.4 What Is a Diagnostic Odds Ratio?

$$\text{Diagnostic odds ratio}\left(\text{DOR}\right) = \left(\text{LR}+\right) / \left(\text{LR}-\right) = 22.67.$$

A Diagnostic odds ratio (DOR) is the ratio of positive and negative likelihoods. DOR measures the effectiveness of a diagnostic test. DOR ranges from 0 to infinity. In a test with a 50% sensitivity and specificity, the DOR has a value of 1, with 90% it is 81 and with 99% it is 9801. A higher value of DOR is considered to give a better performance.

11.9.5 What Is the Accuracy of a Diagnostic Test?

The accuracy of the test is the ability of the test to correctly label the positive and negative cases.

Accuracy = (TP + TN)/*N*, where *N* is the number of subjects tested.

11.9.6 What Is a Receiver Operating Characteristic (ROC) Curve?

The ROC curve is a graphical plot between the true-positive rate (Sensitivity) and false-positive rate (1-Specificity) for various threshold settings of the predicting variable (Fig. 11.1). ROC curves are frequently used in medical research and help in predicting the binary outcome, i.e., having two states only, 'Yes' or 'No', 'Positive' or 'Negative'. For example, we may be interested in predicting the coronary heart disease (CHD) outcome on the basis of a threshold level of LDL or making suicide prediction on the basis of a threshold level of post dexamethasone suppression test (DST) plasma cortisol. In both examples, the predictor variable is quantitative and the outcome is binary. The ROC curve is useful for locating an optimal threshold point on the curve to the least diseased and non-diseased subjects. The optimal cut-off point on the curve is where the sum of sensitivity and specificity is maximal. It is at the upper left corner on the curve. The area under the curve (AUC) is a measure of the diagnostic accuracy or discriminative ability and is used for comparing two or more medical tests for assessing the same outcome. A test that gives a higher AUC is considered to be better. A test with an AUC of 1 is a perfect

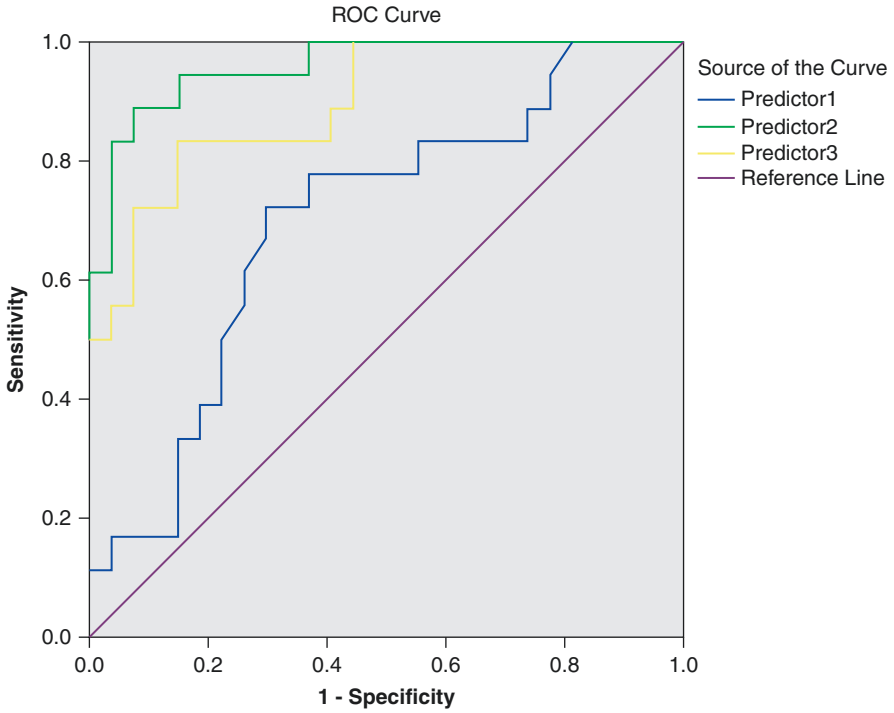


Fig. 11.1 ROC curve (Example)

Table 11.1 Showing AUC, cut-off value, sensitivity, and specificity of three predictors

Predictor variable	AUC	Cut-off value	Sensitivity (%)	Specificity (%)
Predictor1	0.699	17.55	77.8	63.0
Predictor2	0.959	182.01	83.3	96.3
Predictor3	0.897	1222.56	83.3	85.2

test. Below we give the ROC curves of three predictors, their AUCs, cut-off values, sensitivities, and specificities for predicting a binary outcome using SPSS. Predictor2 has the highest value of AUC, i.e., 0.959 among the three predictors and is thus the strong predictor, whereas predictor1 is the week predictor (Table 11.1).

11.10 Questions and Answers Related to Relative Risk, Odds Ratio (OR), and Hazard Ratio

11.10.1 What Is Meant by the Relative Risk (RR), Odds Ratio (OR), and Hazard Ratio (HR)?

The medical literature commonly uses three measures for assessing risk namely relative risk (RR), odds ratio (OR), and hazard ratio (HR). All these are measures that look for the association of an event (e.g., occurrence of cancer, recurrence of a disease, survival/mortality, etc.) under two contrasting conditions. For example, these two conditions can be exposure versus non-exposure, treatment versus non-treatment, or surgery versus conservative treatment. All three risk measures provide some idea of the comparative risk under different conditions and are sometimes misunderstood and interchanged. They are known as relative measures of association. There are also methods based on absolute measures of association such as Risk difference, Rate difference, and Number needed to treat [3]. These absolute methods are less frequently used and have their own merits and demerits. Generally, there is confusion among the researchers which relative measure should be used.

The following points may help:

Odds ratio (OR) is a measure of association between exposure and an outcome. It is simply the ratio of two odds under two conditions, i.e., odds of having the disease under exposure and non-exposure. The Odds ratio is generally used for assessing risk in case–control studies. Below we discuss the risk of developing lung cancer who have exposure to smoking with the help of a hypothetical case–control study. We calculate the odds ratio using the data in the following table which includes 30 cases and 1170 controls from two populations (Table 11.2).

Here the odds of having lung cancer under exposure are 1:9 and under non-exposure 1:99. Odds ratio which is the ratio of these two odds, i.e., 1/9 divided by 1/99 and is equal to 11. Odds ratio of greater than 1 implies that there is an increased occurrence of lung cancer among those who smoke compared to those who do not. Or we can say smoking has an association with lung cancer. If the odds ratio is equal to 1, exposure has no role in the development of lung cancer. If the odds ratio is less than 1, exposure plays a protective role.

Table 11.2 Observed count and probabilities

Lung cancer				
		Case	Control	Odds
Smoking	Yes	20	180	20/180 = 1/9
	No	10	990	10/990 = 1/99

Relative risk (RR) is the ratio of two probabilities and is generally calculated when we study the outcome for two groups, for example, recurrence of cancer among patients of two cohorts where patients of one cohort receive a new drug and the other gets an old drug. Unlike case–control studies where we have two samples—one pertains to 'cases' and the other to 'controls', in cohort studies, samples pertain to two groups and enable us to estimate the probabilities of outcome for each group correctly. Thus, we should calculate relative risk (RR) rather than odds ratio where we can calculate probabilities of outcome for each group. Relative risk or risk ratio is usually calculated in prospective study designs, e.g., cohort studies or RCTs.

Let us calculate the relative risk for a hypothetical example of two groups of women who drink and who do not drink drawn randomly from two populations. We follow both groups for a period of 10 years to observe the occurrence of liver disease. Here we assess the relative risk of developing the disease between the two groups. Relative risk is the probability ($\pi 1$) of developing liver disease in women who drink divided by the probability ($\pi 2$) who do not.

Liver disease				
		Yes	No	Total
Drinking	Yes	80 (0.16)	420 (0.84)	500
	No	10 (0.02)	490 (0.98)	500

$$\mathrm{RR} = \pi 1 / \pi 2 = 0.16 / 0.02 = 8$$

Thus, the relative risk of developing liver disease among females who drink is 8 times higher than those who do not. The following important points should be kept in mind while estimating odds ratio, relative risk, and hazard ratio; and effect sizes:

The odds ratio (OR) may or may not be equal to the relative risk (RR) depending upon the probabilities of outcome in the two groups. For the above-discussed case–control study, the OR is 11 and RR is 10. However, it is wrong to calculate the relative risk here as we cannot estimate the probabilities of outcome in the exposure and non-exposure groups as samples have not been drawn accordingly from the populations which had exposure and the others which did not. However, in the second example, we can estimate the probabilities under exposure and non-exposure. The odds ratio and relative risk are related together as shown below [4].

- Odds ratio is equal to relative risk if probabilities of outcome are equal in two groups (exposure and non-exposure).
- Odds ratio is greater than the relative risk if the probability of outcome in the exposure is higher than that of non-exposure.

- Odds ratio is lower than the relative risk if the probability of outcome in the exposure is lower than that of non-exposure.
- OR and RR are bound to differ, if there is a difference between the two probabilities. However, the odds ratio is close to the relative risk, if the probabilities of the outcome are small [5].

Odds ratio (OR) does not change even if the ratio of number of cases versus controls changes. However, relative risk (RR) changes [6]. For example, if the cell count in the above table increases from 180 to 360 and other cell count from 990 to 1980, the odds ratio remains the same, i.e., 11, but the RR changes from 10 to 10.5.

In an RCT or cohort study, we can calculate the odds ratio; however, the odds ratio only approximates the risk ratio if the outcome is rare or if the odds ratio is close to 1 [3].

Hazard ratio (HR) is the ratio of two hazard rates with respect to two conditions, say treatment and control, and is useful when the risk varies with respect to time. The term hazard ratio is often used interchangeably with the term relative risk ratio. However, the major difference between the two is that hazard ratio is estimated in a time-to-event analysis. Relative risk studies the cumulative risk over an entire study period with a defined endpoint and is usually calculated at the end of the study. Whereas, hazard ratio gives the instantaneous risk at some point of time or some time interval. The Cox regression model is generally used to estimate the hazard ratio and for drawing time to event curves. Cox regression investigates the effect of several variables in the occurrence of an event over a period of time. If the hazard ratio is greater than 1, then the predictor is associated with increased risk, and if less than 1, it is protective.

The following table gives a classification based on effect sizes (estimates of risk parameters) suggested by Oliver and co-workers [7] for various risk measures (Table 11.3).

11.10.2 What Is the Kaplan–Meier Curve?

The Kaplan–Meier (KM) curves are commonly used in clinical and basic research for estimating the probability of survival at different intervals of time (Fig. 11.2). It generally compares two cohorts, for example—one following a new treatment and the other existing regimen. One can easily infer from the curves which treatment

Table 11.3 Association measures, classification, and effect size

Association measure	Classification	Effect size
Relative risk, odds ratio, hazard ratio, rate ratio, and mantel–Haenszel odds ratio (for equal group allocation)	• Small. • Medium. • Large.	• 1.22 • 1.86 • 3.00
Odds ratio for a non-rare event	• Small. • Medium. • Large.	• 1.32 • 2.38 • 4.70.

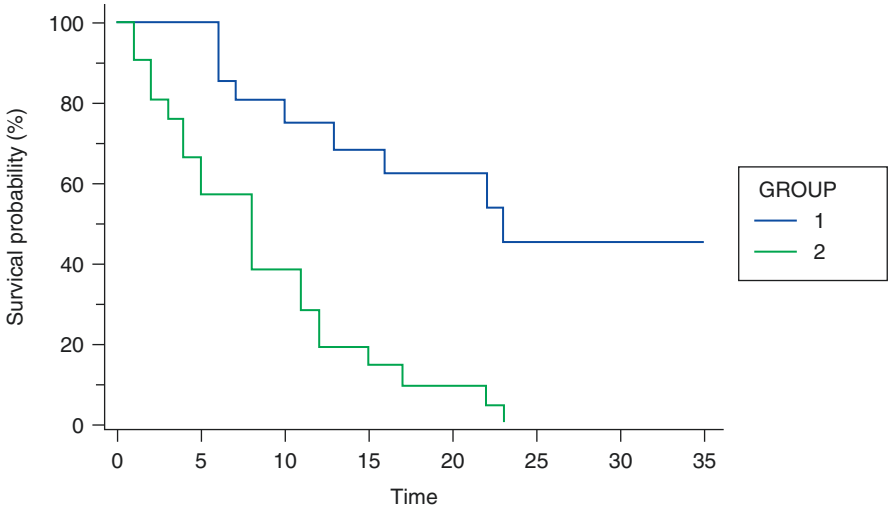


Fig. 11.2 Example of a Kaplan–Meier curve

prolongs survival or what is the status of survival in the two groups. Here the cohort B doing better than that of A in terms of survival. Group B has a median survival (50%) time of 23 months whereas A has 8 months.

Censored data can substantially affect the KM curve, but have to be included when fitting the model. Censoring of data is common in survival analysis and is a form of missing data either due to nonoccurrence of the event of interest during the study period or the subject has left the study prior to the occurrence of the event. Kaplan–Meier curves consider the impact of one factor at a time and ignore other confounding factors. Here the predictor variable is categorical such as surgery vs conservative treatment, new regimen vs existing regimen. Figure 11.2 gives Kaplan–Meier curves showing the survival probability (%) with respect to time for the two groups.

11.10.3 What Is the Cox Proportional: Hazards Model?

The Cox Proportional—Hazards model is essentially a regression model and assesses simultaneously the effect of several risk factors (predictors) on the survival time of the patients. These predictors are also known as covariates or confounding factors in the regression model which are not taken into consideration in Kaplan–Meier curves or the Log Rank test. The effect of any factor (predictor) is estimated by the hazard ratio (HR) which is the exponential of the regression coefficient. If the HR > 1 then the factor increases the hazard and is a risk factor, and if the HR < 1, it reduces the hazard and is a good prognostic factor. However, if HR = 1, the factor has no effect.

11.11 Questions and Answers Related to Association, Agreement and Correlation and Regression Analysis

11.11.1 What Is the Difference Between Association and Correlation?

In medical studies, the word 'association' and 'correlation' between two attributes/variables are frequently used and often interchanged. In ordinary language, they may carry the same meaning but statistically, they do not. Association refers to the general relationship and is normally used for studying the relationship between two nominal/categorical/ordinal attributes whereas correlation refers to a linear relationship between two quantitative attributes. Thus, when we want to ascertain whether CKD is linked to diabetes or hypertension, it is an 'association' as both the attributes are nominally scored as 'Yes' or 'No'. In the other example of body weight and cholesterol level, both the attributes are numeric and the relationship has to be assessed through a correlation coefficient. The relationship between two quantitative variables can even be non-linear as well such as curvilinear or exponential.

11.11.2 How Can I Test the Association Between Two Nominal Attributes?

The most commonly used test to study the association between two nominal attributes is the Pearson Chi-square statistic which can be used for a 2 × 2 or higher classification ($m \times n$ classification, m categories for the first attribute and n for the other). Statistical Package for Social Sciences (SPSS) gives four tests under the Chi-square included under the crosstab module for testing the independence of nominal/ordinal attributes. These are - Pearson Chi-square, Chi-square with the Yates continuity correction, Likelihood ratio, and Fisher Exact tests. Normally, there is confusion about which test should be used for drawing conclusions, particularly when different tests give contrasting results. The following points will help in taking a decision:

1. If there is a 2 × 2 contingency table, i.e., two categories for each variable, the best choice is Fisher's exact test. Compared to the Pearson Chi-square test, Fisher's test is even suited for small samples.
2. For a higher contingency table (for example, 2 × 3 or 3 × 4 etc.), use Pearson Chi-square if at least 80% of the cells have expected counts of more than 5, otherwise use the Maximum Likelihood Ratio Chi-square test.
3. One should prefer the Fisher Exact test over the Yates' continuity correction method used for small sample sizes.

11.11.3 How Can I Assess the Strength of an Association?

The above-discussed methods help us to find whether there is a significant association or not between the two categorial attributes. If the *p*-value is less than 0.05, conclude that there is a likelihood of an association. However, the *p*-value does not tell us whether the association is 'weak' or 'strong'. Cramer's V is the most useful statistical method used for testing the strength of an association when Chi-square is found to be significant. The Phi(φ) statistic is used for assessing the strength for a 2×2 contingency table whereas the Cramer's V is used for classification larger than 2×2 tables.

11.11.4 How Can I Study the Relationship Between Two Quantitative Attributes?

When we want to study the relationship between attributes that have been measured on a continuous numeric scale, we cannot use chi-square statistics. For example, we may be interested in studying the relationship between age and height of school-going children, body weight and cholesterol level or maternal age and anxiety. For such attributes, we assess the relationship through the Pearson correlation coefficient which ranges from −1 to +1. Minus one (−1) is a perfect negative relationship and plus one (+1) is a perfect positive relationship. Zero (0) correlation coefficient implies two attributes are independent. One of the limitations of the Pearson correlation coefficient is that it assesses the linear or straight relationship between the two variables. It cannot assess a non-linear or monotonic relationship (curvilinear, exponential, or polynomial). Thus, it is always advisable to draw the scatter plot of the data points and visually explore the relationship before calculating the correlation coefficient. The major limitation of the correlation coefficient is that the two variables should be jointly normally distributed. The correlation coefficient is also severely affected by the outliers in the data.

11.11.5 What Are Cohen's Guidelines for Assessing the Strength of a Correlation?

Cohen's 1992 guidelines [8] can be used to assess the strength of a linear relationship. If the effect size, i.e., correlation coefficient is from 0.1 to less than 0.3, it is categorized as 'small', 0.3 to less than 0.5 'medium'; and 0.5 and above 'large'.

11.11.6 How Can I Study a Relationship When My Attributes Are Ordinal?

For ordinal attributes/variables such as pain score, satisfaction level, MELD score, or intelligence level, we cannot use the Pearson correlation coefficient which

assumes the variables to be normally distributed. For such variables, we can either use Kendall's Tau or Spearman's Rank correlation. However, Spearman's correlation coefficient is more widely used and is appropriate for ordinal as well as continuous variables. Similar to Pearson's correlation coefficient, it ranges from −1 to +1. A typical example for a Spearman correlation coefficient could be to assess whether or not the income level is related to the educational level.

It is worth mentioning here that Pearson's correlation coefficient is highly sensitive to outliers (extreme values) and may give an unexpected result; therefore, extra precaution should be taken for the outliers (extreme values) before calculating the coefficient. However, Spearman's coefficient is more robust to outliers than is Pearson's coefficient.

11.11.7 What Do We Mean by Agreement Between Observers, Raters, and Diagnostic Tests?

Agreement is the degree of concordance between two or more sets of assessments or measurements. For example, two or more observers, raters, or diagnostic tests assess a subject for a particular characteristic. They may or may not agree with their assessment. While making a diagnosis, a standard test may diagnose a 'benign' condition whereas an alternative test may diagnose 'malignancy'. Agreement can be assessed for nominal, ordinal as well as numeric measurements.

11.11.8 How Can I Assess the Agreement for Binary, Nominal, and Ordinal Measurements?

Cohen's kappa and Fleiss' kappa coefficients are used for assessing the agreement between two (or more) tests/raters/observers. Cohen's kappa (κ) can be used for assessing the agreement between two raters with two or even more than two categories of observations. For example, a two-category observation can be either 'Yes' or 'No' for a particular characteristic and a three-category observation, say regarding the diagnosis can be 'Benign' or 'Doubtful' or 'Malignant'. Kappa is used mostly to assess how close the agreement is to one rather than how far it is from 0. The following table can be used for assessing the strength of agreement:

Kappa	Strength of agreement
<0.3	Poor
0.3–0.5	Fair
0.5–0.7	Moderate
0.7–0.9	Good
>0.9	Excellent

Cohen's kappa is used for studying the agreement between two raters, whereas Fleiss' kappa is used when there are more than two raters. The Fleiss kappa, however, is a multi-rater generalization of Scott's pi statistic.

11.11.9 How Can I Assess Agreement When the Measurements Are Numeric?

Cohen's and Fleiss' kappa are used when the measurements are either ordinal or categorical/nominal. However, when the measurements are numeric, these methods cannot be used. For example, we may be interested in assessing the agreement between two different methods which measure the haemoglobin levels of a number of patients. For such numeric measurements, two methods are available for assessing agreement—the Intra-class correlation coefficient and the Bland–Altman plot. The intra-class correlation coefficient lies between 0 and 1. Zero indicates no agreement, whereas one indicates perfect agreement. The Bland–Altman plot provides a graphical display of agreement between the two methods or techniques with 95% limits of agreement.

11.11.10 What Are Regression Methods?

Regression methods are extensively used in medical research for predicting the outcome based on one (or more) independent variables commonly known as predictors or regressors. The outcome variable is known as the dependent variable. For example, we may use a regression method for predicting the birth-weight of full-term babies with the weights of their fathers and mothers as predictors. A regression model can be written as follow:

$$\text{Simple regression model}: Y = \beta_0 + \beta_1 X_1$$
$$\text{Multiple regression model}: Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 \ldots\ldots\ldots \beta_n X_n$$

where Y is the dependent variable, X_1, X_2, X_3 … are independent variables, and β_0, β_1, β_2, β_3 …… are regression coefficients. The sign and magnitude of a regression coefficient indicates the role of the corresponding variable in predicting the outcome.

Regression methods are generally used in making a prediction as well as in understanding the relative contribution or role of various factors in predicting the response or outcome. If the regression model/equation involves one dependent and only one independent, it is called simple regression; and one dependent and two or more independents, multiple regression. If the number of dependents is greater than one, then it is in the domain of multivariate regression.

11.11.11 How Can I Test the Performance of the Regression Model?

When we develop a regression model, we want to be sure that that the developed model accurately predicts the outcome. We judge the performance or goodness of fit of the regression model on the basis of the multiple correlation coefficient (R^2) which ranges from 0 to 1. A model is considered to be good when it contains a small number

of regressors (independent variables) but gives a sufficiently large value of R^2. When the number of predictors is large, computer algorithms are available with statistical packages which help in selecting the statistically significant variables. Forward selection, backward elimination, and stepwise are the common algorithms for selecting the variables. However, most studies in medicine use linear regression models. Sometimes the nature of the relationship is that linear models miserably fail to explain the variation in dependent variables and give a low value of R^2. In that case, curvilinear and non-linear regression models can be tried which are being increasingly used in the medical field. However, all precautions should be taken that the regression model includes the relevant variables before going for non-linear models.

11.11.12 How Can I Assess the Relative Importance of Predictors in a Regression Model?

A multiple regression model may include a number of predictors and one may be interested to know the relative importance of these in predicting the outcome. For example, one may like to know the relative importance of these variables which have been measured in different units. Bodyweight is measured in kilograms or grams whereas body height in centimetres or metres. When our aim is to assess the relative importance of such independent variables, standardized coefficients should be used. Comparing unstandardized coefficients of independent variables that have different units of measurement is rather like comparing apples and oranges. Therefore, most statistical packages provide a table of regression results which includes unstandardized regression coefficients as well as standardized regression coefficients (Beta coefficients).

It is worth mentioning here that interpreting standardized coefficients for individual variables is cumbersome compared to unstandardized ones. The unstandardized coefficient of any predictor indicates the amount of change in the response for a unit change in that factor, holding other predictors constant. However, standardized coefficients (Beta) are interpreted as the standard deviation change in the response variable when the predictor is changed by one standard deviation, holding all other predictors constant.

11.11.13 What Is a Serious Problem in Regression Analysis?

Multicollinearity is a problem in regression analysis and occurs when the predictor variables which are assumed to be independent are correlated among themselves. For example, when we want to predict body fat with the help of skinfold thickness at the triceps, mid-arm, and thigh, the three predictor variables are highly correlated among themselves. These highly correlated variables tend to enhance the standard errors of the coefficients, leading to unreliable and unstable estimates of regression coefficients. Increased standard errors, in turn, means that coefficients for some independent variables may be found to be statistically insignificant, though, in reality, they were not. In the presence of multicollinearity, when we add or delete a

predictor variable, the regression coefficients change dramatically. However, it should be noted that if our aim is to make predictions then multicollinearity is not a serious concern.

11.11.14 How to Detect and Handle Multicollinearity?

The simplest way to detect multicollinearity is to calculate pairwise correlation coefficients of all the predictor variables. Pairs of predictors which have very high correlation coefficients are likely to result in multicollinearity. Remove either of the correlated predictors and fit the regression model with the remaining predictors. After doing so, you may notice some of the predictors which were earlier not significant, have now become significant.

The more reliable method to detect collinear predictors is to examine the variance inflation factor (VIF) of each predictor. SPSS gives the option to calculate the VIF of a predictor. If this is greater than or equal to 5, then it is considered collinear and needs attention. There are several ways in the literature to handle multicollinearity. These are some of the methods to do this:

- Increase the sample size to avoid occurrence by chance. Increasing the sample size may reduce the collinearity.
- Use stepwise regression analysis to choose the best subset having the highest *R*-squared value.
- Remove predictors with high variance inflation factors (VIF) and fit the regression model with the remaining predictors.
- Modify the existing predictors by making use of the information from prior research. For example, in a regression model which uses the height and weight of subjects that happen to be highly associated, we may take the ratio of the said predictors, i.e., BMI as a single predictor.

11.11.15 What Is Logistic Regression?

Logistic regression analysis has been extensively applied in medical research for predicting the categorial outcome. For example, predicting the outcome (survival/mortality) based on the pre-, intra-, and post-operative variables following GI surgery. Logistic regression studies the relationship between the outcome (dependent variable) which is a categorical/ordinal variable; and independent predictors which are a mixture of quantitative, categorical, and ordinal variables. The dependent variable of a binary logistic regression has two categories (yes or no, benign or malignant cancer, recurrence or non-recurrence of cancer, survival or mortality), whereas multinomial logistic regression has more than two (polytomous).

$$\text{Simple logistic regression equation} : \ln\left(\pi / 1-\pi\right) = \beta_0 + \beta_1 X_1$$

$$\text{Multiple logistic regression equation} : \ln\left(\pi / 1-\pi\right) = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 .. \beta_n X_n$$

The probability

$$\pi = 1/\left[1+\exp\left(-\beta_0+\beta_1X_1+\beta_2X_2+\beta_3X_3..\beta_nX_n\right)\right]$$

where $\ln(\pi/1-\pi)$ is the logit of the probability (π) and lies between $-\infty$ and $+\infty$, ($\pi/1-\pi$) represents odds for a positive response in the subjects and β_is are logistic coefficients.

Logistic coefficients are similar to regression coefficients. However, most of the software packages also give exponentiated coefficients along with regression coefficients. The exponential of a regression coefficient is called the odds ratio and more specifically adjusted odds ratio. If odds ratio for a variable is statistically greater than one, it is considered to be a risk factor and less than one, a protective or prognostic one. When the odds ratio is one, it does not play any role.

11.11.16 How to Test the Adequacy of the Logistic Model?

A number of methods such as pseudo R^2, generalized R^2, likelihood ratio, and Wald statistics are available to which can test the adequacy or goodness of fit of the logistic model. However, log-likelihood ($-2\ln L$) is commonly used and has a better appeal [1]. If the model is a perfect fit $-2\ln L$ is equal to 0 and for worst fit it is 1. A Nagelkerke pseudo R^2 resembles ordinary R^2. It ranges from 0 to 1, and the best fit model has a value of 1. Some software such as SPSS provide the Hosmer–Lemeshow test, which tests the null hypothesis that the model is an adequate fit. If p is found to be <0.05, there is an evidence against the null hypothesis or the model indicates a lack of fit.

11.12 Summing Up

We have discussed the essentials of most of the commonly used biostatistical tools in the form of questions and answers and provided an overview of these tools with cautionary notes so that readers need to be vigilant in applying them. Choosing an inappropriate tool may sometimes lead to severe consequences. We have apprised readers of the most important but controversial inferential tool, i.e., the p-value which is frequently misunderstood and misinterpreted.

Biostatistics includes an ocean of statistical tools and techniques. However, we have discussed the most commonly used in day-to-day research. There are more techniques, especially suited for advanced medical researchers. These techniques simultaneously consider several variables, such as multivariate multiple regression, path analysis, multivariate analysis of variance (MANOVA), discriminant functions, factor and cluster analysis, etc. Techniques are also available to study similarity and dissimilarity among the DNA sequences and for better understanding the genetic variation at the DNA or protein level. It is difficult to cover all the aspects of biostatistics in a single chapter. We hope the contents of the chapter will enable the students in applying appropriate statistical tools while pursuing their research protocols.

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Writing the Research Proposal: The Art and the Science

12

Research is to see what everybody else has seen, and to think what nobody else has thought

—Albert Szent-Györgyi, Hungarian Biochemist (1893–1986)

No Research without Action, No Action without Research

—Kurt Lewin, German-American psychologist (1890–1947)

12.1 What Is a Research Proposal?

A research proposal is a document containing details about the research which is to be undertaken. It should be self-contained and start with a fundamental enquiry related to the research questions(s) and the hypothesis (es) on which it is based. The objectives and key questions are the fundamental pillars of a research proposal and formal grant application.

A study protocol, often used for clinical trials, is a document that describes the objectives, elucidates the methodology, ethical considerations (consent process) as well as the overall execution template to guide the research [1]. Journals dedicated to studying protocols also encourage publication of research protocols prior to the wrap-up and conclusion of studies to encourage transparency and avoid duplication of research.

A research proposal can be in a free form or follow a suggested format, usually prescribed by the science funding body or organization. In general, a proposal format includes:

- The Title
- Abstract

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_12

- Background and Rationale
- Aims and Objectives of the study
- Details of the Research Question
- Methodology
- Ethical considerations
- Details of the primary investigator, co-investigator. Internal and external collaborators.
- Estimated Budget

12.1.1 The Title

The title should be composed of key substantive words, which may include the characteristics and geographical location of research, the sample population as well as a hint of the result. The title may at times be interrogative.

For example, the title of this study protocol—*Study protocol of a cluster randomized controlled trial to evaluate the effectiveness of a system for maintaining high-quality early essential newborn care in Lao PDR* [2]. conveys the study design, i.e., the cluster randomized trial, the purpose of the research and also the study population and site of the research.

Many grant organizations have specific requirements for space and characters for titles, so ensure conformity with those.

12.1.2 Abstract

Some organizations require an abstract or an executive summary at the beginning of the research proposal. This is a brief precis and description of your research project, background, methods, and analytical plan.

12.1.3 Background and Rationale

What is already known about this research area? Have there been any previous studies already addressing this issue? Many research funding bodies expect the investigators to cite a systematic review related to the subject area, typically the most credible review available on the subject. The literature review ought to highlight why the research question being addressed in the project is important.

12.1.4 Aims and Objectives of the Research

The primary goals of the research study are described in terms of its aims and objectives. Aims are general and broad statements that state the intent of the researchers and what they hope to achieve, while objectives are more specific that describe the path to achieving those aims.

Aims and Objectives are encouraged to follow the SMART criteria:

- **Specific—**Precision about what is going to be done
- **Measurable—**Outcomes clearly defined
- **Attainable—**Can be possibly achieved and not overly ambitious
- **Realistic—**Possible in the presence of available resources, e.g., finances, time, and manpower
- **Time Constrained—**Bound by time

12.1.5 Details of the Research Question

The PICOT format (**P**opulation, **I**ntervention, **C**ontrol or comparison group, **O**utcome of disease, **T**ime, or **T**ype of study) helps to frame a good research question.

12.1.6 Methodology

The Methodology section follows the background and literature review so should organically follow through with a recapitulation of your research question, the related scholarly research available, and your own aims and objectives [3].

This section attempts to answer the 5 W and One H questions—Who, What, When, Where, Why and How.

This section should be written carefully in full detail in such a way that anyone who reads it can replicate the experiment; if it is a new statistical model that you propose, you should be able to apply it to your own dataset. This section is like a road map that helps the investigator to navigate the planned study and should be written in the future tense. The methodology section should not just state the methods chosen, but should appropriately justify why it was selected based on sound scholarly research. It should also discuss the limitations in the proposed methods and compromises made based on existing constraints, for example, the choice of sampling and the inclusion and exclusion criteria. This section should include the following details [3]:

12.1.6.1 Study Area/Location

This subsection states the institutional and departmental affiliation or the site where the research is to be conducted. If it is clinical research, data on the patient enrolment area, patient catchment area and patient recruitment area, and whether they were from the outpatient or inpatient departments.

In other instances, with population-based research, the study population may be a community, region, or even a larger population aggregate, comprising the universe of the study from which subjects will be recruited.

12.1.6.2 Study Population

The enrolment should always be according to a pre-defined population. The inclusion and exclusion criteria to be used for the study should also be mentioned in this section.

For example, 'to study the prevalence of lymphoma in Sjogren's syndrome', the inclusion will include all known cases of Sjogren's syndrome and those with a histologically confirmed diagnosis of lymphoma. The exclusion criteria will be lymphoma associated with HIV, hepatitis B and C viral infections, or due to other causes.

12.1.6.3 Sample Size

The number of cases to be recruited into the study should be stated here. The formula that is intended to be used to derive the sample size should also be included as well as the statistical power, the expected prevalence of the disease, or the shift in outcome if relevant. Recent statistical software has made this step much easier so the statistical software employed for these calculations, e.g., EPI INFO should be mentioned.

12.1.6.4 Study Design

The designs are broadly experimental or observational and may utilize primary or secondary data. Differences between both are tabulated in Table 12.1 [4].

Table 12.1 Differences between primary and secondary data sources

Points	Primary data	Secondary data
Meaning	Data collected by researcher himself	Data collected by other people
Originality	Original or unique information	Not original or unique information
Adjustment	Does not need adjustment, is focused	Needs adjustment to suit actual aim
Sources	Surveys, observations, experiments	Internal records, govt. published data etc.
Type of data	Qualitative data	Quantitative data
Methods	Observation, experiment, interview	Desk research method, searching online etc.
Reliability	More reliable	Less reliable
Time consumed	More time consuming	Less time consuming
Need of investigators	Needs team of trained investigators	Does not need a team of investigators
Cost-effectiveness	Costly	Economical
Collected when	Secondary data is inadequate	Before primary data is collected
Capability	More capable to solve a problem	Less capable to solve a problem
Suitability	Most suitable to achieve objective	May or may not be suitable
Bias	Possibility of bias exist	Somewhat safe from bias
Collected by	Researcher or his/her agents	Persons other than who collects primary data
Precaution to use	Not necessary	Quite necessary

12.1.6.5 Study Duration

The date of initiation and expected completion date are mentioned. The study can start only after the institutional board gives ethical clearance.

12.1.6.6 Methodology of the Trial

In this section, the step-by-step approach of the study is described. It could begin with patient recruitment and the patient consent approval process and could be followed by a description of the physical examination and a systemic examination to be carried out. It should include whether there are tests to be done in the intervention and the length of period after which any change in the intervention will be studied.

12.1.6.7 Outcome of the Disease

This is the most important consequence of the study. Mention what change you are expecting during the experiment. For any disease, the outcome can be:

- Complete recovery
- Incomplete recovery
- Death

There may also be disease-specific outcome measures like in rheumatology one can use a visual analogue scale, ESR, CRP, Disease Activity Score (DAS), Simplified Disease Activity Index, and Clinical Disease Activity Index.

12.1.6.8 Data Collection

The data collected may be qualitative or quantitative. A protocol for data collection which incorporates and satisfies the requirements of Good Clinical Practice (GCP) should be included. For example, in a study around the effect of pomegranate juice on lipid profile and type 2 diabetes, the systolic and diastolic blood pressures, and the lipid profile of the patients were measured at baseline and end-line following 12–14 h of fasting (5).

Furthermore, a data analysis plan, a data quality assurance plan, a statistical plan, and a contingency plan for missing and spurious data should also be discussed.

12.2 What Are Study Designs?

Experimental studies are further divided into randomized controlled trials or non-randomized trials. The observational studies are of four types, cohort studies, case–control studies, cross-sectional, and ecological studies (Fig. 12.1).

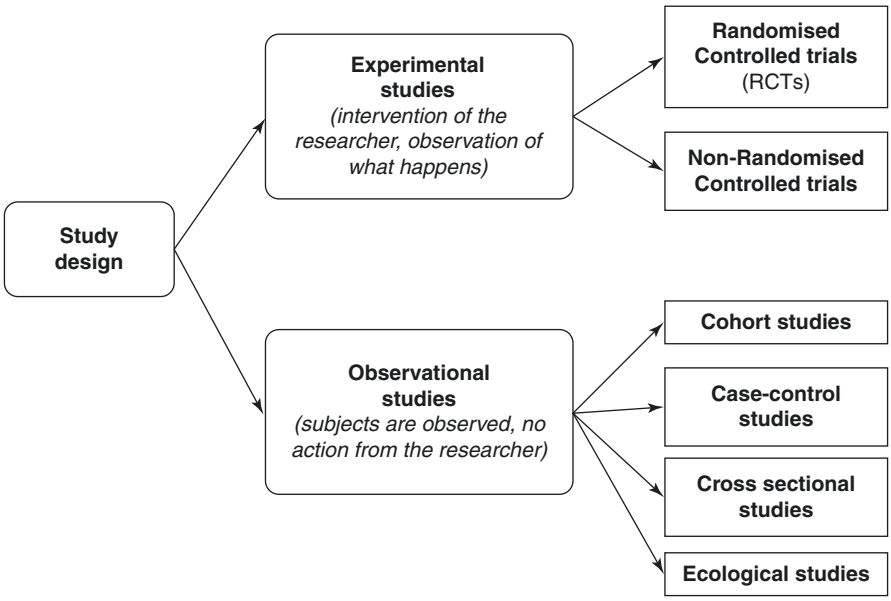

Fig. 12.1 Overview of types of study design

Table 12.2 Types of interventions

Intervention	Examples
Using a specific drug	Using iron tablets in adolescent girls in school in one subset of the population
Using a vaccine	Administration of quadrivalent influenza vaccines in one group of elderly residents of an old age home
Use of a dietary supplement	Use of fenugreek seeds in one group of patients for weight loss in morbid obesity
Performing a test	Performing retHb for predicting the response of iron supplementation in one subset of a population
Using a new surgical technique	Use of robotic techniques for gastric bypass surgery
An educational tool	Use of pictures and flash cards for nurses for segregation of biomedical waste into waste bins of different colours

12.3 What Is an Intervention?

The intervention can be in the form of treatment using a drug, vaccine, or even a dietary supplement, the use of a diagnostic or therapeutic procedure or the introduction of an educational tool (Table 12.2).

12.4 What Are the Various Type of Trials with Interventions?

There are various types of intervention-based trials that are listed below:

- **Randomized controlled trials**
  In this, a patient in one arm of the trial gets the intervention and the others get the placebo or the standard of care. Randomized Controlled Trials are considered the gold standard in clinical research, and evidence generated is considered to be the highest in the hierarchy of evidence.
- **Nonrandomized trials**
  In this, the intervention is given only to some participants, e.g., those who can afford the drug or vaccine and the others get standard care.
- **Interventional studies without concurrent controls**
  If a new drug is to be given in a particular condition to a study population, historical controls are used (Fig. 12.2).
- **Pre- and post-intervention study**
  An example is the use of an educational tool applied in a specific population - the change is noted before and after the intervention.
- **Factorial studies**
  In this, two or more interventions are examined and their effects are studied collectively and separately.

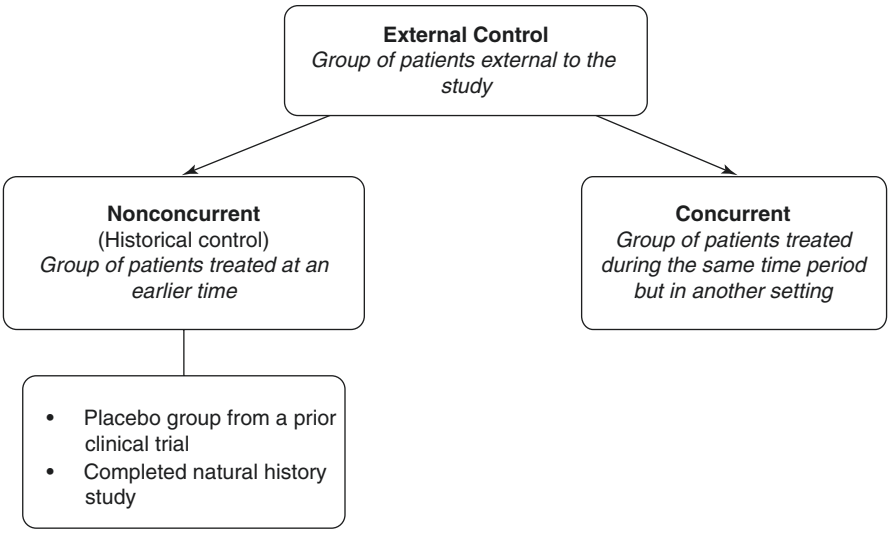

Fig. 12.2 Study with external controls

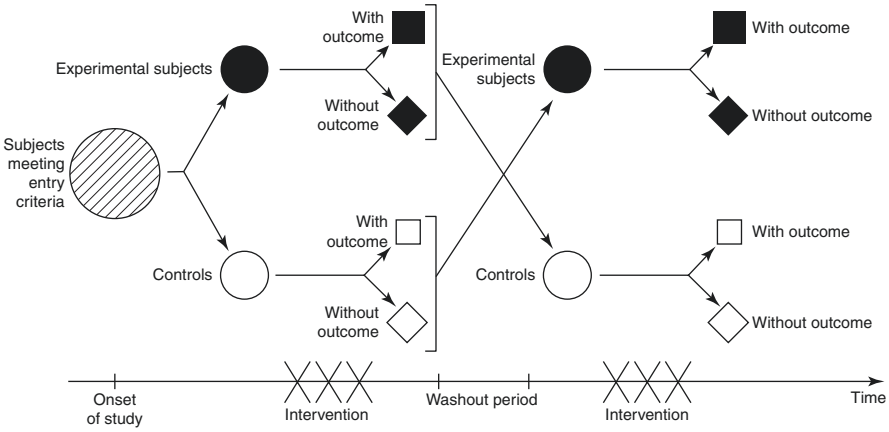

Fig. 12.3 RCT crossover design

- **Crossover studies**

  Each patient is given one type of intervention and then after a predefined time a washout period is instituted where controls and experimental subjects are swapped and then given the other trial intervention (Fig. 12.3).
- **Cluster randomization trials**

  The intervention in a single person may be easy to apply but once the trial is done on a community it requires to be studied in a cluster of the population. Units of randomization are clusters, and not individuals. By design, they are large and complex studies but more definitive in terms of health population and systems research.

  In the cluster randomized trial in Matiari and Hala in Sindh Pakistan (Fig. 12.4), clusters were allocated to intervention and control groups through stratified randomization. The intervention package included health promotive

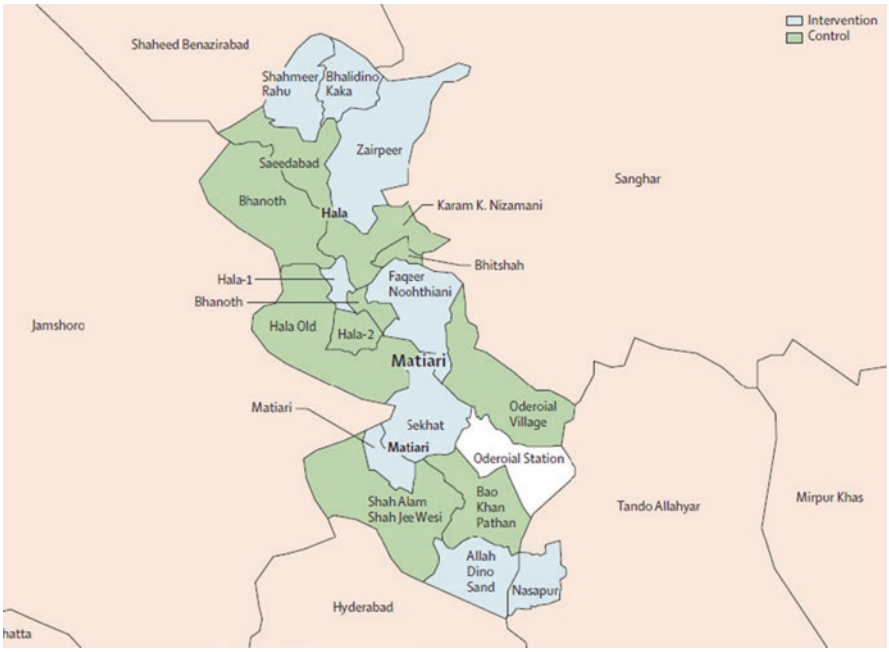

Fig. 12.4 Cluster randomized trial in Matiary and Hala in Sindh Pakistan

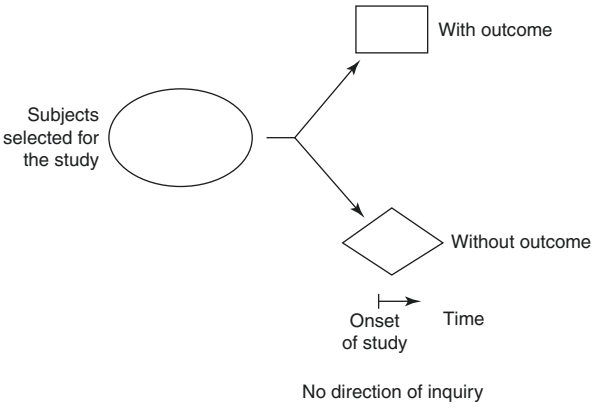

Fig. 12.5 Cross-sectional study (Basic design)

MNCH activities through community healthcare workers and this RCT. Neonatal mortality rate was lower in intervention clusters at 43.0 deaths per 1000 live births and 49.1 per 1000 in control groups (RR 0.85, 0.76–0.96; $p = 0.02$) [5].

12.4.1 Observational Studies

12.4.1.1 Cross-Sectional Study

These studies represent data collected over a defined period of time, and are often used to calculate the prevalence of a certain disease or condition (Fig. 12.5).

However, a major limitation is that they do not help establish causality due to unknown temporality. They are also vulnerable to recall error and response bias when questions about the past are assessed.

12.4.1.2 Cohort Studies

This study design is longitudinal in nature and involves following a group of participants who have a particular characteristic in common, for example, they may all be in the same geographical region or in a particular occupation (Fig. 12.6). The study involves following them prospectively and studying associations between exposure and outcome.

12.4.1.3 Case–Control Studies

By definition, case studies are observational and retrospective. Also known as 'case-referent studies'. They are observational because they compare patients who have the disease or outcome of interest (cases) with patients who do not have the disease

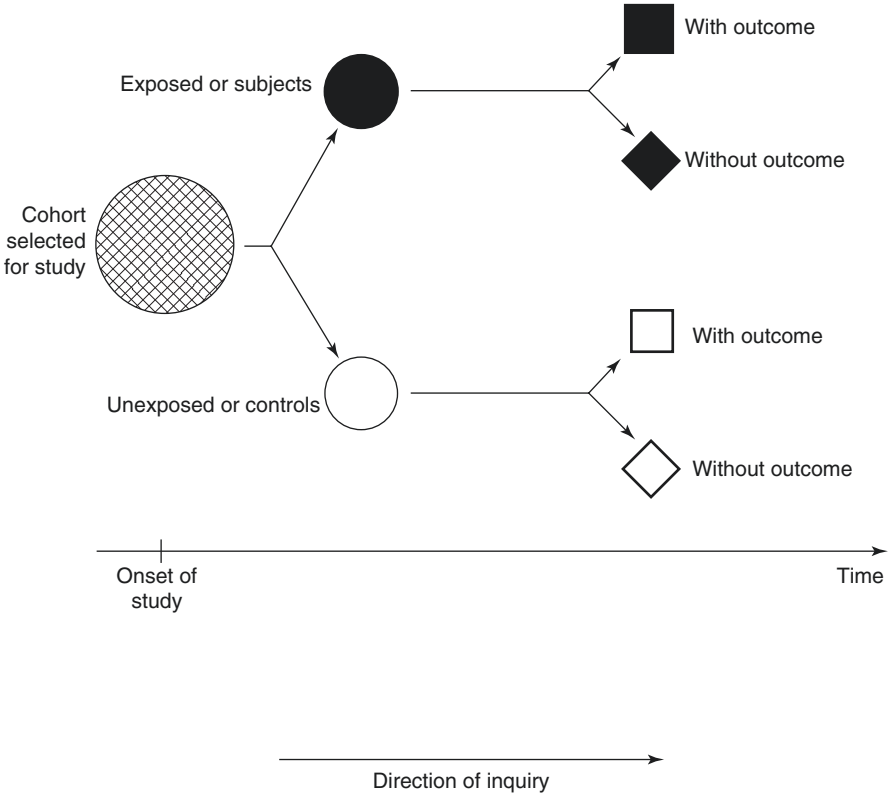

Fig. 12.6 Cohort study (Basic design)

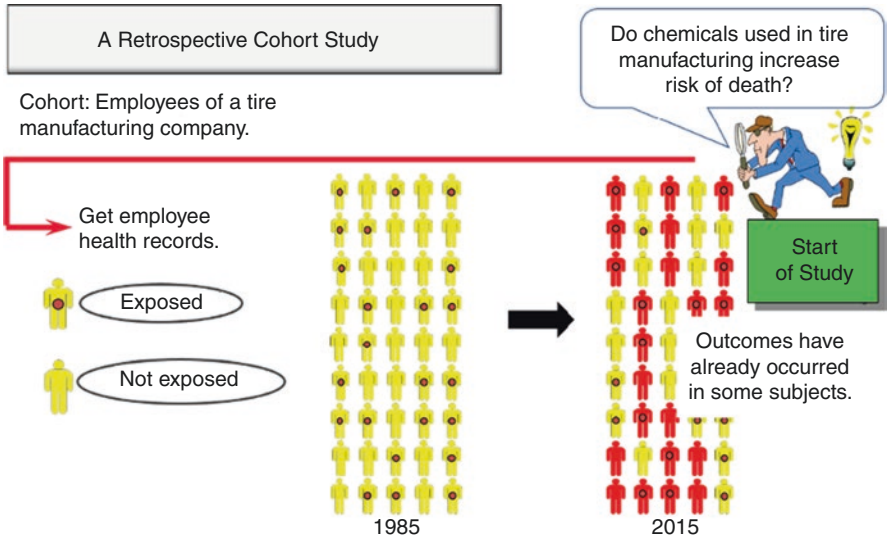

Fig. 12.7 Retrospective study

or outcome (controls) and look back retrospectively to compare how frequently the exposure to a risk factor is associated with the disease (Fig. 12.7).

Case–control studies are observational because no intervention is attempted and no attempt is made to alter the course of the disease. The goal is to retrospectively determine the exposure to the risk factor of interest from each of the two groups of individuals: cases and controls. These studies are designed to estimate odds.

12.4.1.4 Ecological Studies

Ecological studies the association between exposure and disease, but the unit of observation is a community or even a broader regional area such as a country. The ecological study design is relatively cheaper as it often utilizes published population-level statistics such as mortality and morbidity estimates.

12.5 What Are the Ways to Do Randomization?

12.5.1 The Methods of Randomization in a Clinical Trial

Blinding refers to keeping trial subjects, doctors, and trial-related persons or data collectors unaware of the allocated intervention to eliminate bias.

Various methods of randomization are used:

1. Simple randomization—Using techniques like a pack of cards, flipping of a coin (even—control, odd—treatment), or throwing dice (e.g., below and equal to 3—control, over 3—treatment) can be used.

2. Random allocation is done using random number tables.
3. Block randomization—This method is designed to randomize subjects into groups.
4. Stratification randomization—This is a two-stage procedure where the first randomization is done according to clinical features which may influence the outcome and in the second a particular treatment is given to that arm.
5. Minimization—The aim of minimization is to minimize the imbalance between the number of patients in each treatment over a number of factors.

12.6 What Are Other Considerations Before Conditional Trial?

12.6.1 Ethical Considerations

IRB approval must be discussed and the data collection protocol's adherence to the World Medical Association Declaration of Helsinki on Ethical Principles for Medical research involving Human Subjects should be discussed.

12.6.2 Clinical Trial Registration

Clinical trials are registered mainly to avoid publication bias and selective reporting. In addition, clinical trial registries serve to increase transparency and access to clinical trials for the public. There have been recently much efforts to increase standardization of registration of clinical trials with the WHO aim to 'achieving consensus on both the minimal and the optimal operating standards for trial registration'. The largest and most frequently used repository of trials is ClinicalTrials.gov, run by the United States National Library of Medicine (NLM). Others include Australian New Zealand Clinical Trials Registry (ANSCTR), the International Standard Randomised Controlled Trial Number in the UK, and the Clinical Trials Registry in India.

12.6.3 Details of Primary Investigator, Co-Investigator, Internal and External Collaborators

Rich and salubrious scholarship is obtained through active collaborations between multiple centres of research. Individual and institutional collaborations should be listed.

12.6.4 Budget

This is an estimation of the expenses which are likely to be incurred during the study period. It should include travel costs, costs of reagents, instrumentation,

special software, and manpower. Each cost should be justified and if the research is expected to run for several years, the inflation cost should also be added.

12.7 What Are the Various Extramural Source of Funding for Doctors for a Research Project?

Usually, there are two mechanisms for grants, i.e., sole-source grants commissioned grants for pre-qualified organizations, and competitive grants. Sole source grants are non-competitive with contractual arrangements whereas competitive grants are managed through call for proposal where individuals or organizations are required to go through a competitive process. The various funding agencies are given below. Besides the government authorities, many speciality associations also offer funding for MD, DM projects. Many universities and colleges have travel grants for students who present papers in national or international conferences. The details and age limits and inclusion criteria need to be checked on their websites (Table 12.3).

Table 12.3 Various funding agencies in India and Pakistan

Agency	Details	Website
Department of Biotechnology (DBT)	The department is under the Ministry of Science and Technology It was established in 1986 gave motivation to the development of the field of modern biology and biotechnology in India Covers funding for basic research and for Vaccines, Diagnostics, new Drug Development, Human Genetics and Genome Analysis, Stem Cell Biotechnology	www.dbtindia.gov.in, www.btisnet.gov.in, www.dbtindia.gov.in/organisation/nodal.htm
University Grants Commission (UGC)	Universities have been the centres of research University and college teachers need to be supported to meet this requirement For medical major and minor projects	www.ugc.ac.in
Higher Education Commission (HEC)	HEC offers numerous grants and challenges to assist researchers financially	https://www.hec.gov.pk/english/services/RnD/Pages/Research-Grants.aspx
Pakistan Science Foundation (PSF)	PSF offers grants to universities and other R&D organizations, both for projects on an individual basis or to group of scientists	http://www.psf.gov.pk/researchSupport.aspx
Pakistan Health Research Council (PHRC)	Offers grants in health and disease reach to guide policy decisions	https://phrc.org.pk/research-grant.html
Indian Council of Medical Research (ICMR)	Have various schemes like Ad-hoc Research Schemes, Senior / Junior Fellowships, or Emeritus Medical Scientist Scheme Financial assistance to MD/MS/DM/MCH thesis programme Grant-in-aid for organizing Seminars / Symposia /Work shops	www.icmr.nic.in

12.8 Conclusions

- The application for study proposal should be well-structured and free from any grammatical and scientific errors.
- Not all research projects receive funding.
- For protocol and research grants, the methodology should be written in the future tense.
- Use references in this section for the definition of various terms related to your study.
- Write comprehensively describing minute details of the experiment.

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Ethics in Research

13

13.1 What Are Ethics, Medical Ethics, and Bioethics?

Ethics is a set of moral principles of 'what is right?' and 'what is wrong?' or, in simple words, 'what is good and what is bad?' When the same principles are applied to medicine, the subject is called medical ethics. It is expected that a doctor should act in a particular way and follow certain rules. Medical ethics are professional standards for physicians. Bioethics is a branch of medical ethics and deals with complex issues like euthanasia, transplant medicine, genetic medicine, assisted reproduction therapy, human cloning, and medical genomics. Medical ethics and bioethics concepts are guides for physicians and to ensure patient safety.

"Wrong is wrong even if everyone is doing it. Right is right even if no one is doing it." William Penn, American writer, (1644–1718).

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_13

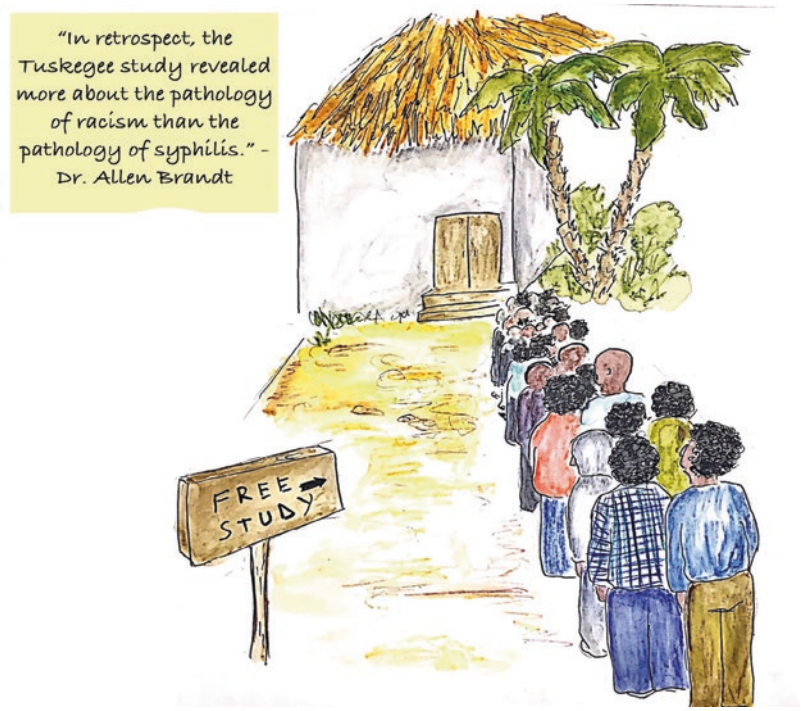
13.2 What Is the History of Medical Ethics?

Hippocrates is considered to be the father of medicine (as well as medical ethics) and enunciated what is now known as the Hippocratic oath around the fifth century BC, which most graduating doctors are required to take even today. In China, Confucius, the great philosopher, enunciated the concepts of ethics [1]. In 1947, after the Second World War a landmark court in Nuremberg, Germany which was investigating the atrocities of Hitler and the Nazis enunciated the Nuremberg Code which has now served as the foundation of modern-day ethics. This was followed in 1949, by the Geneva Declaration and subsequently, in 1964, there was a Declaration of Helsinki that modified the ethical code. 1n 1996, the International Conference on Harmonization of Technique Requirement and Good Clinical Practice Guidelines were published (ICH GCP) [2] involving 13 core principles which all investigators follow today.

In India, the history of medical ethics goes back to the Indus Valley civilization. Ayurveda is an ancient science and two of its manuscripts the 'Charak Samhita' and 'Shushrut Samhita' provide guidelines on ethical practice. More recently, in 2017, the Indian Council of Medical Research enunciated a set of guidelines on medical ethics which we will discuss later.

13.3 What Are the General Principles of an Ethical Clinical Trial?

These are based upon protecting the patients' rights, safety and ensuring his or her willingness to participate. The notorious Tuskegee study on Negro (African-American) males who had syphilis and were left untreated to observe the natural course of the disease was a landmark where no medical ethical principles were followed. It was supposed to last for 6 months but continued for 40 years (1932–1972) [3]. Although the drug penicillin, which could have cured them, was discovered in 1947, the trial patients were not given it or even informed about its existence. They were just given food, free treatment, and a burial [3]. Other studies which were unethical were done by the Nazis during the Second World Ward and in some of these they observed the physiological effects of immersing prisoners in ice-cold water. The Nuremberg code was a direct result of such gruesome experiments.



13.4 What Are the Principles of Medical Ethics?

The four principles are Autonomy, Beneficence, nonmaleficence, and Justice (Fig. 13.1).

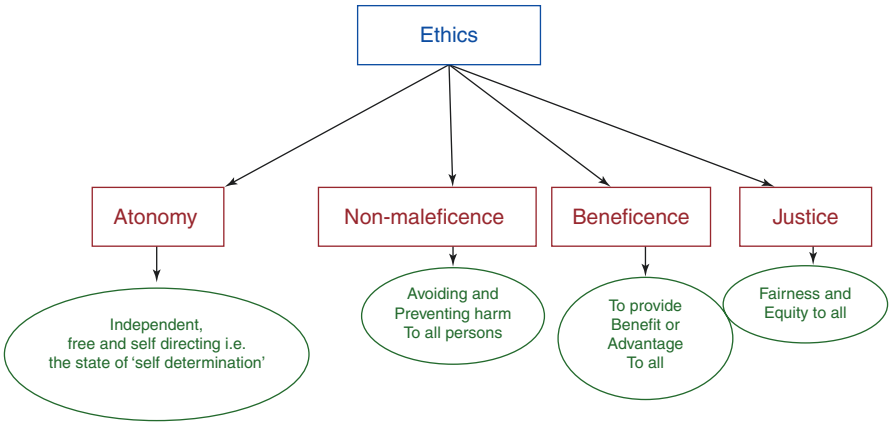


Fig. 13.1 Basic principles of Ethics

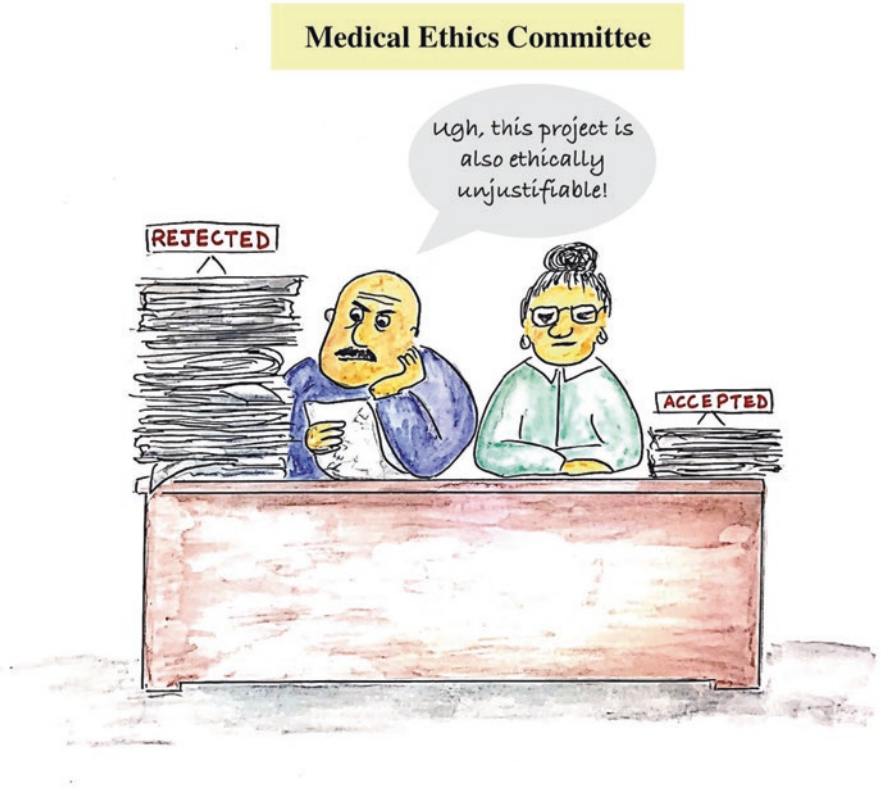
- *Autonomy* means patients should have a choice on whether they want to participate in a study [4]. They also have the right to information on the purpose of the clinical trial the right to withdraw midway, and also the right to know about the details of the drug used in the clinical trial. After stopping the trial, the patient has the right to be on an approved standard of care.
- *Beneficence* is derived from the Latin word meaning 'good deed'. It is to perform an act of 'charity, mercy, and kindness' with the strong implication of doing good to others including doing what is one's moral duty [5].
- *Nonmaleficence* means 'to do no harm'. Thus, the trial should benefit the participant rather than harm them. The principle of nonmaleficence supports the following rules—do not kill, do not cause pain or suffering, do not incapacitate, and do not cause offence [6].
- *Justice.* The fruits of the research should be for all sections of society and benefit the rich and poor equally. Each patient should be treated on his or her merit and need [6].

13.5 What Are the Duties of Ethics Committees?

Research is an important method of advancing medical knowledge but, at the same time, those who do research should not violate human rights. Every institution which does research should have an ethics committee which is a heterogeneous group of individuals whose aims are to monitor all research projects involving humans so that they are being done in the right way and on the right patients. They ensure patient safety and have the right to accept, modify, reject and stop any trial [7]. They should also look at the risk-to-benefit ratio to the participants and to their safety. Their specific duties are to:

- Review the scientific soundness of the trial.
- Accept or reject the proposed trial.

- Ensure the safety of the patient.
- Ensure the well-being of all the participants.
- Ensure travel reimbursements for the participants.
- Debar any group or individual which does not follow ethical principles.



13.6 What Is an Institutional Review Board (IRB)?

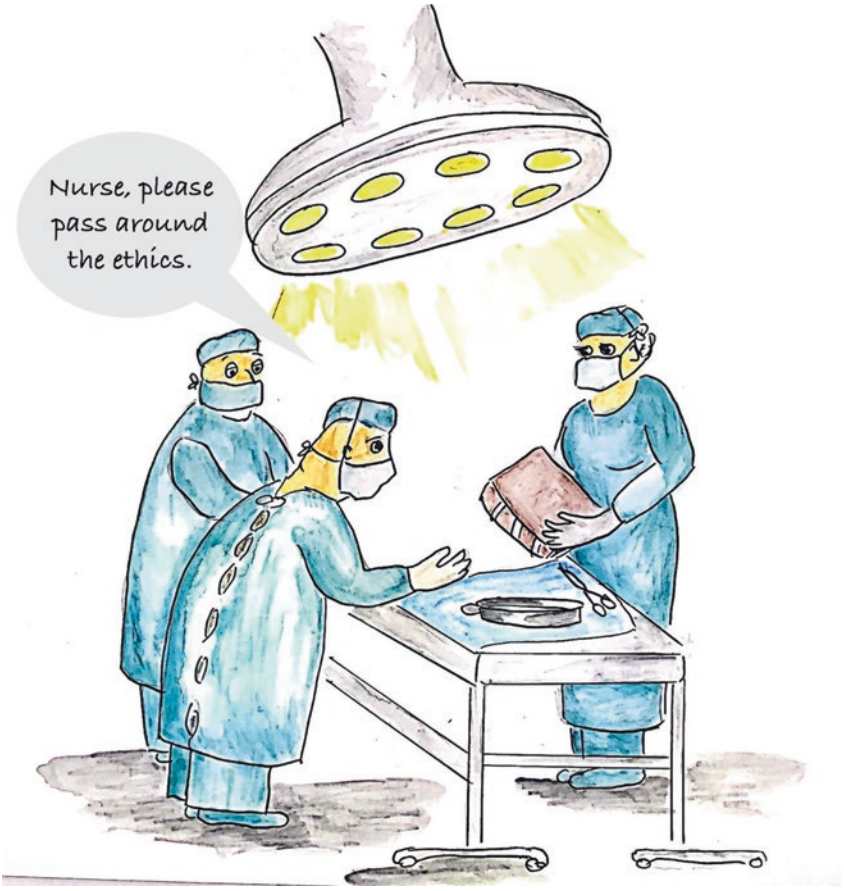
Sometimes an Ethics Committee is called an IRB which consists of members who ensure human safety during trials. There should be at least 5 members, according to good clinical practice, 7 according to the schedule Y of the Act, and 8–12 according to the Indian Council of Medical Research (ICMR) [8]. The members should be from different fields, one from civil society, one lawyer, one social worker, one basic medical scientist, one clinician, and one philosopher. It should have a Chairperson who is usually from outside and a Secretary from within the institution in which the project is proposed to take place. It must also include a woman. The quorum should be complete while addressing any issue. The IRB requires registration from the Central Drugs Standard Control Organization (CDSCO) and its registration requires renewal after every 3 years [9]. All records related to trials should be kept with the IRB for at least 3 years after their completion.

13.7 Which Documents Are Required to be Submitted to the Ethics Committee for Approval?

The list includes the following:

- Protocol of the trial.
- Any amendments related to the trial.
- Consent form given to the subjects.
- Investigators' details.
- Curricula vitae of the investigators.
- The Clinical Trial Agreement (CTA).
- Insurance papers that are site specific.
- Regulatory approval letter from the Drugs Controller (DCGI).
- Any advertisements related to the trial.
- Proof of travel reimbursements to the participants.
- Data collection form.

Besides these, the committee may ask for any other paper which is related to the trial.



13.8 What Happens in Case an Adverse Effect Occurs in a Clinical Trial?

All investigators are required to send regular recruitment-related updates, trial-related protocol deviation, report side effects, and serious adverse effects. In case a patient has any adverse effects, the primary investigator/sponsor should inform the ethics committee and treat the patient. The trial should be accompanied by insurance which covers any hospitalization or death. In case of death or serious adverse effect, the patient or his family needs to be awarded compensation based on a specified formula (Table 13.1) [10].

A serious adverse effect is defined by the Central Drugs Standard Control Organization as: [8]

- Death.
- Hospitalization of the participant in case the study was being conducted as an out-patient.
- Prolongation of hospitalization in case the study was being conducted on an in-patient.
- Persistent or significant disability or incapacity.
- A congenital anomaly or birth defect.
- Life-threatening condition.

The Drugs Controller General of India has issued a directive mentioning that any trial injury or death should be compensated by the sponsor. A compensation formula has already been proposed by the Independent Expert Committee for clinical trial-related death (Table 13.1).

13.9 What Is Medical Research Misconduct?

The Primary Investigator is the principal person who leads the research team. He or she needs to act in a way that is not influenced by his sponsors, pharmaceutical companies, or his peers. Research misconduct includes the following:

- Construction/making-up of data intentionally.
- Recording/reporting of fabricated data.
- Manipulating the research content.
- Omitting/suppressing data or results in the analysis.
- Overlooking scientific data without statistical justification.
- Plagiarism—'stealing of ideas' or using other authors' language for publication.

Table 13.1 Computation formula in case of adverse effect

$$\text{Compensation} = \frac{B \times F \times R}{99.37}$$

where,
B = Base amount (i.e., 8 lakhs)
F = Factor depending on the age of the participant (based on Workmen's Compensation Act)
R = Risk factor depending on the seriousness and severity of the disease, presence of comorbidity, and duration of disease of the participant at the time of enrolment in the clinical trial between a scale of 0.5 and 4 as under:

i. 0.50: Critically ill patient (expected survival not more than 6 months)
ii. 1.0: High-risk patient (survival expected between 6 and 24 months)
iii. 2.0: Moderate-risk patient
iv. 3.0: Mild-risk patient
v. 4.0: Healthy volunteers or participants of no risk.

However, in case of 90% expected mortality or more within 30 days, a fixed amount of Rs. 2 lakhs should be given.
In view of the above, a committee was constituted to work out a formula to be followed to determine the amount of compensation in case of clinical trial-related injury (other than death).
Serious adverse event causing permanent disability to the participant
The committee arrived at a conclusion that the amount of compensation to be paid in case of 100% disability should be 80% of the compensation which would have been due for payment to the nominee(s) in case of death of the participant. The amount of compensation for disability which is <100% will be calculated based on the presence of actual percentage disability. Accordingly, the committee arrived at the following formula:

$$\text{Compensation} = \frac{D \times 80 \times C}{100 \times 100}$$

D =Disability percentage
C = Compensation amount for payment to the participant's nominee(s) in case of death of the participant
Serious adverse event causing congenital anomaly or birth defect
The committee opined that the compensation in such cases should be a lump-sum amount such that if that amount is kept by way of fixed deposit or alike, it should bring a monthly interest amount which is approximately equivalent to half of the minimum wage of the unskilled worker (in Delhi). The committee noted that this aspect was duly considered while fixing Rs. 8 lakhs as the base amount for determining the amount of compensation in case of SAE resulting in death. Hence, the committee decided that the quantum of compensation in such cases of SAE should be half of the base amount as per the formula for determining the compensation for SAE resulting in death.
Serious adverse event causing life-threatening disease
The committee arrived at the following formula.

$$\text{Compensation} = N \times W$$

where,
N = Number of days for a life-threatening situation requiring medical care, irrespective of days of hospitalization
W = Minimum wage per day of the unskilled worker (in Delhi)
Reversible serious adverse event in case it is resolved
Compensation = $2 \times W \times N$.
where,
W =Minimum wage per day of the unskilled worker (in Delhi)
N = Number of days of hospitalization

13.10 Is Consent Important in Doing Research?

Written Informed Consent is a very important document that is required to be signed before starting or enrolling a patient. It means that the patient is willing to participate in the study. This document is signed by the patient who is explained about the risks, benefits, and side effects of the drug being tested. This is applicable for all adults of more than or equal to 18 years of age. If a child is involved in the study and has not attained legal age this is called 'assent'. This information can be given to the patient verbally or in the form of a written document or both. Figure 13.2 explains the need for three important aspects for taking consent [10].

Informed consent form must include the following:

- A declaration stating that it is research.
- Explaining the purpose of the study in simple language and how it will be done.
- Information about the probable duration of the involvement and the number of times the subject will be called for data collection.
- What benefits might accrue to the patient /subjects or to the community with the results expected from the research.
- Any predictable risks, distress, or awkwardness to the subject from participation in the trial.
- The level at which the privacy of the records will be maintained.
- Imbursement/reimbursement for subjects and accompanying relatives depending on the type of study.

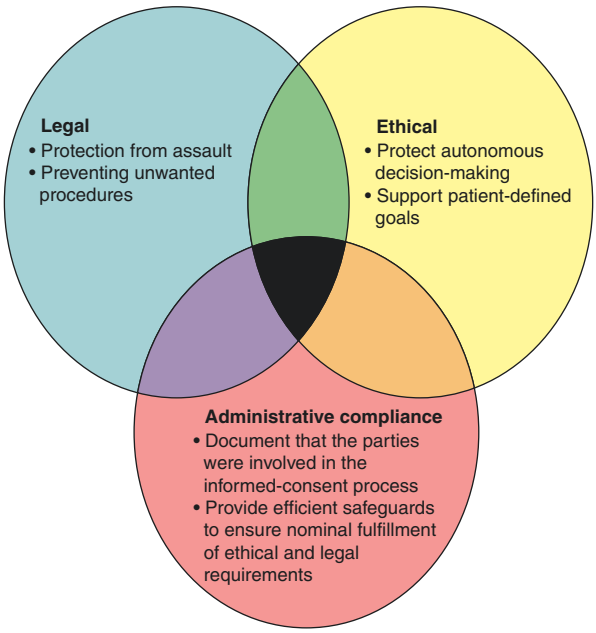


Fig. 13.2 Purpose of informed consent

Table 13.2 Ways to enhance informed consent

Simplification of informed conset documents
Assessment of patient comprehension
Use of printed brochure, information sheets
Use of multimedia and audio-video presentations
Extended discussions with patients
Use of decisional aids to help patients inn decision-making

- Free treatment and/or reimbursement of the subject for research-related injury and/or harm.
- Liberty of the subject to participate and/or withdraw from the trial at any time without consequence.
- Trial-related information of the Principal Investigator and other members of the team and of the Chairperson and Secretary of the IRB.

In addition, the following information may also be required depending on the type of study:

- Any different drugs/measures which may be beneficial to the participant.
- If there is a likelihood that the trial could lead to any defamation of the subject.
- Indemnification coverage if any, for research-related to serious adverse effects (SAE).
- Time for which the sample will be stored and used for secondary purposes.
- If the biological tissue will be shared with other researchers.
- Potential strategies to enhance the informed consent process.

13.11 What Are the Ways to Enhance the Informed Consent Process?

The various ways to enhance informed consent have been listed in Table 13.2. The process of consent should be voluntary, comprehensive, and informative. Additional audio-visual aids and printed sheets can help in decision-making [11].

13.12 Conclusions

- Ethics is an important aspect of the medical profession.
- The principles of ethics are autonomy, beneficence, nonmaleficence, and justice.
- Consent is an act of voluntary agreement between the patient and doctor.
- Consent is in simple language which the participant can understand. It gives details of treatment, possible side effects, and benefits to the patient.
- Compensation is given if there are adverse events in a clinical trial.

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Part IV

How to Write an Original Research Paper?

Who Should Be An Author?

14

"A writer is someone for whom writing is more difficult than it is for other people."

Thomas Mann, German Novelist (1875–1955)

14.1 Who Is an Author?

An author is a person who creates a manuscript or paper. He is the one who initiates the process of crafting the document. He is also called a writer, a person who begins the process or plan or an idea [1]. Before venturing into the authorship of biomedical research, one should know if one is entering 'a sweet fruit of inspiration' or drifting 'towards a bitter fruit of the trade' [2]. Stephen Lock has summed up authorship as not being 'a bread ticket; it is an intellectual responsibility'. Incidence of inappropriate authorship even in Cochrane reviews has increased [3].

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_14

14.2 Who Can Become an Author?

Various journals have different criteria for defining 'who can be an author'. However, the majority now use the standard definition as given by the International Committee of Medical Journals (ICMJE) Editors, formerly called the 'Vancouver group'. The criteria for being an author included in this are related to study design, conception of the idea, data analysis, drafting of the manuscript, and final approval of the paper [4]. In 2013, a new version of this recommendation added as mandatory criteria—a declaration of conflict of interest, responsibility of the corresponding author, deciding who can become an author before the paper is conceived, and giving precision to the study question [5]. In addition to being accountable for the publication work, an author should be able to identify which co-authors are responsible for the other specific parts of the publication. These criteria as given in Table 14.1.

Table 14.1 Defining the role as an author (ICMJE recommendation)

The authorship be based on the following criteria: 1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work AND 2. Drafting the work or revising it critically for important intellectual content AND 3. Final approval of the version to be published AND 4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

14.3 Who Can We Acknowledge in a Scientific Paper?

Any person who has not qualified as an author but has contributed intellectually to the study can be acknowledged. These may include people who have arranged for funding, generally supervised the research activities and administration, provided typing assistance, and done technical editing, language editing, or proofreading. The ICMJE encourages written permission from acknowledged individuals 'because acknowledgment may imply endorsement'. The acknowledgement is usually placed at the end of the conclusion section.

14.4 Who Are Lead Authors and Co-authors?

A lead author is also called the first/principal author and is the one who conducts the investigation as well as writes and edits the document. The co-author is someone who collaborates with the lead author and contributes to the work in the text [6].

14.5 What Is the Corresponding Author?

The corresponding author is the guarantor of the study, who communicates with the editors on behalf of the other authors. He is usually the senior most and is responsible for his team. He is a bridge between the authors and the journal. The functions of the corresponding author are [5]:

Being

- Responsible for the manuscript as it passes through the entire publication process
- The chief contact between the journal and co-authors
- Responsible for guaranteeing that all authors have reviewed and approved the final version of the paper prior to submission
- The author who uploads the paper for online submission and for peer review
- Responsible for dealing with communications from the journal (e.g., decision letters, reviewers' reports)
- Responsible for ethics committee approval and clinical trial registration
- Available throughout the submission and peer-review process to respond to editorial queries
- Available after publication to respond to critiques of the work
- Available to cooperate with any requests from the journal for data or additional information should questions about the paper arise after publication

14.6 What Are the Types of Inappropriate Authorship?

There are three types of inappropriate authorship. They are called guest authorship, gift authorship, and ghost authorship [7–9]. Sometimes, the 'guest and gift' are also referred to as 'honorary authors' as there is very little difference between them [10, 11].

The problem with including these authors is that the integrity of the work becomes questionable and it may also have an adverse effect on whether or not the submission is accepted. Honorary authorship is totally unethical and dilutes the credits which an honest writer should be getting. Articles with over five authors are more likely to have 'honorary authors' than those with three or fewer authors [12].

14.7 What Is a Gift Author?

Gift authorship is given to any senior in the department, chair of an organization, institutional head, or head of department. This person has not contributed to the conception of the manuscript but the junior fellow includes his name as a 'mark of respect'. Such passive noncontributors should not be included in the list of authors.

14.8 What Is a Guest Author?

Usually, an influential person whose name is included in an attempt to make the journal editor biased towards publication.

14.9 What Is a Ghost Author?

Ghost authors are very common in some research work especially clinical trials. These are of three types:

- The name of a junior faculty member is omitted on purpose when the major work might have been done by him, thus robbing him of authorship credit.
- In the second type, the manuscript was prepared by a person only for financial gain and this person did not want this name to be included in the paper.
- The third type is the writer of a manuscript who is employed by a company which, e.g., sponsors a drug trial to get financial gain but whose name is not included in the list of authors.

14.10 Are These Inappropriate Authors Common in the Scientific World?

Inappropriate authorship is becoming very common globally and its reported prevalence is estimated to be 9–60% in different studies. Shah et al. reported the ugly side of research in India and reported the prevalence of honorary authorship to be 20.9% in India. The World Association of Medical Editors (WAME) labels ghostwriting to be a 'dishonest and unacceptable' act [15]. Table 14.2 depicts this data.

14.11 What Are the Other Types of Authorship Misconduct?

Coerced author: In this, the senior faculty forces his junior colleague to include his name in the research work. This senior researcher may have contributed absolutely nothing to the research findings [17–19].

Mutual support authorship: This act of bestowing authorship is carried out by mutual cooperation and agreement by authors to include each other's names in scientific manuscripts to achieve higher credits [16, 17].

Table 14.2 Prevalence of inappropriate authorship

Author	Type of publication	Prevalence rates
Moswatt et al. [3]	Cochrane review article authors	39%-Honorary authors
		9%-Ghost authors
Flanagin et al. [13]	Review articles	26%-Honorary authors
Shah et al. [14]	Leading Medical and Dental	20.9% Honorary
	Institutes in India	
Ghajarzadesh [15]	Asia data	32.17%-Gift
Bates et al. [12]		JAMA, BMJ
	Annals of Internal Medicine	60%-Honorary author

Duplicate authorship: This is an act of publishing identical manuscripts in more than one journal with different headings to increase the number of publications in the curriculum vitae [17, 20].

Forged authorship: In this, the author is unaware of his name being included. He has not taken part in the research or manuscript writing, reviewing, or drafting, but is awarded a place in authorship without his knowledge or consent to increase the chances of the paper being accepted by a peer-reviewed journal [21].

Orphan authorship: These are the authors who had contributed considerably to the work, but are omitted from the list of authors of the manuscript [21].

Denial of authorship: This is a dreadful form of authorship abuse in which a paper of research work carried out by others is submitted to a journal without providing the credit to core searchers in the form of an authorship and acknowledgement [17, 22].

14.12 What Is CRediT?

This means contributor Roles Taxonomy (CRediT). It is based on 14 different criteria and will permit authors to provide information on the author's individual contributions to the manuscript. Few of the important aspects are Conceptualization, Data Curation, Formal Analysis, Funding Acquisition, Validation, Visualization, Writing—Original Draft Preparation, Writing—Review & Editing. Each of these has a stated definition and helps to classify the authors according to various duties [23, 24].

14.13 How Does One Decide Authorship Issues in Multicentre Trials?

When a large, multicentre group has conducted the work the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fulfil the criteria for authorship defined above and editors should ask for individuals to complete the contribution of each one and also fill up a conflict-of-interest disclosure forms. The corresponding author should clearly indicate the preferred citation sequence. The Acknowledgements should be spelled out at the time of submission [5].

14.14 Who Settles the Dispute Post Publication of Authorship?

When authorship disputes arise after publication, most current guidelines recommend that the authors work out the disputes between themselves. But this is unlikely to occur because there are often large power disparities between team members and institutions (e.g., universities, funding agencies) are unlikely to have authority over all team members [25].

14.15 What Is Retraction Watch?

RetractionWatch.com is a public website launched in 2010. It gives information about articles which have been retracted and the possible reasons. There have been more than 700 cases where manuscripts have been withdrawn due to authorship problems [26].

14.16 What Is the Responsibility of a Journal Regarding Authorship?

The journals should spread awareness about authorship criteria so that potential writers do not default [11]. Table 14.3 mentions few steps that journals can take.

14.17 What Are Remedial Measures for Authorship Abuse?

These can be grouped into non-judicial or judicial measures. The non-judicial measures are withdrawing the paper and black listing the authors [2]. For the judicial approach a person can use various sections of the Indian penal court like section 62, section55 and section 63. Journals can also take these actions according to ICMJE [5].

Several actions are possible:

1. To serve a notice that a paper has been ghostwritten, along with the names of the responsible companies and the submitting author
2. To make the authors' academic institution aware of this incident
3. To identify the commercial companies involved in such an act
4. To provide specific names if contacted by the popular media or government organizations
5. To share their experiences on the World Associations of Medical Editors (WAME) Listserve and in other forums.

Table 14.3 What measures journals can take to prevent guest authorship?

Providing directions to authors regarding authorship criteria by listing them in their "Instructions to Authors'
Pledging allegiance to the authorship criteria provided by the ICMJE
Requiring each author to sign that he or she fulfils the authorship criteria
Requiring authors to commit that no one who satisfies authorship criteria has been excluded and no one who does not qualify as an author has been included
Declaration from all authors about the exact contribution made to the conduct of the research and in preparation and finalization of the manuscript
Keeping the number of authors permitted to a pre-set number

14.18 How Many Co-authors Should There Usually Be in a Research Paper?

It is not the number of authors but the quality of the paper that is the most important factor. If the author has significantly contributed to the manuscript his name should be included. In 1981, the maximum number of authors on any paper indexed by Clarivate Analytics was 118. In 2006, this number was 2500, which in the next 2 years reached 3000 authors for a paper. Currently, a physics paper holds the record for the largest number of authors, i.e., 5154 authors for a single paper [27].

Persons or groups who have aided the research study but whose contributions do not justify being authors may be listed under such headings as 'participating investigators' or 'clinical investigators'. These people should give written permission to be acknowledged, because readers may argue their endorsement of the data and conclusions [28].

14.19 What Is the Meaning of Shared First Co-author?

Shared co-first authorship is defined as 'two or more authors who have worked together on a publication and contributed equally. This equal contribution is often indicated in the fine print of a published paper or in an investigator's curriculum vitae'. A few journals publish the manuscript mentioning shared co-authorship in the description of the author's contribution. For example, Gastroenterology mentions up to two co-first authors by printing their names in bold letters in the reference section but not in the body of the manuscript. There is no uniform format for a citation for the first co-author [29].

14.20 Conclusions

- Authors are fully responsible for the intellectual content of the manuscript. The International Committee of Medical Journals (ICMJE) recommends that authorship be based on certain fixed criteria.
- Persons who have helped in the technical work should be acknowledged at the end of the manuscript.
- Authorship should not be granted based on seniority or experience but should be earned by working on the manuscript and given only to persons who deserve it.
- The corresponding author should certify that all authors have fulfilled the required standards for authorship and prepare a brief write-up describing the contribution of each to the manuscript.
- Ghostwriting is emerging as a big problem in medical publications and needs to be addressed.

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How to Write an Abstract?

15

Research is formalized curiosity. It is poking and prying with a purpose.

—Zora Neale Hurston, American Author, Anthropologist and Filmmaker (1891–1960)

15.1 What is an Abstract?

An abstract is a crisp, short, powerful, and self-contained summary of a research manuscript used to help the reader swiftly determine the paper's purpose. Although the abstract is the first paragraph of the manuscript it should be written last when all the other sections have been addressed.

An abstract is usually a standalone document that informs the reader about the details of the manuscript to follow. It is like a trailer to a movie, if the trailer is good, it stimulates the audience to watch the movie. The abstract should be written from scratch and not 'cut –and-pasted' [1].

15.2 What is the History of the Abstract?

An abstract, in the form of a single paragraph, was first published in the Canadian Medical Association Journal in 1960 with the idea that the readers may not have enough time to go through the whole paper, and the first abstract with a defined structure was published in 1991 [2]. The idea sold and now most original articles and reviews are required to have a structured abstract. The abstract attracts the reader to read the full manuscript [3].

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_15

15.3 What are the Qualities of a Good Abstract?

The quality of information in an abstract can be summarized by four 'C's. It should be:

- C: Condensed
- C: Clear
- C: Concise
- C: Critical

15.4 What are the Types of Abstract?

Before writing the abstract, you need to check with the journal website about which type of abstract it requires, with its length and style in the 'Instructions to Authors' section.

The abstract types can be divided into:

1. Descriptive: Usually written for psychology, social science, and humanities papers. It is about 50–100 words long. No conclusions can be drawn from this abstract as it describes the major points in the paper.
2. Informative: The majority of abstracts for science-related manuscripts are informative and are surrogates for the research done. They are single paragraphs that provide the reader an overview of the research paper and are about 100–150 words in length. Conclusions can be drawn from the abstracts and in the recommendations written in the last line.
3. Critical: This type of abstract is lengthy and about 400–500 words. In this, the authors' own research is discussed for reliability, judgement, and validation. A comparison is also made with similar studies done earlier.
4. Highlighting: This is rarely used in scientific writing. The style of the abstract is to attract more readers. It is not a balanced or complete overview of the article with which it is published.
5. Structured: A structured abstract contains information under subheadings like background, aims, material and methods, results, conclusion, and recommendations (Fig. 15.1). Most leading journals now carry these.

15.5 What is the Purpose of an Abstract?

An abstract is written to educate the reader about the study that follows and provide an overview of the science behind it. If written well it also attracts more readers to the article. It also helps the article getting indexed. The fate of a paper both before and after publication often depends upon its abstract. Most readers decide if a paper is worth reading on the basis of the abstract. Additionally, the selection of papers in systematic reviews is often dependent upon the abstract.

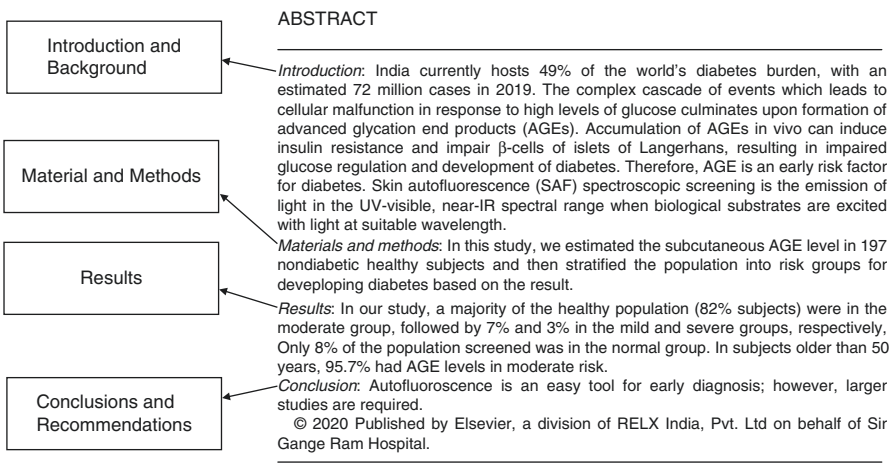


Fig. 15.1 Example of a structured abstract (with permission editor CMRP)

15.6 What are the Steps of Writing an Abstract?

An abstract should be written last after all the other sections of an article have been addressed. A poor abstract may turn off the reader and they may cause indexing errors as well. The abstract should state the purpose of the study, the methodology used, and summarize the results and important conclusions. It is usually written in the IMRAD format and is called a structured abstract [4, 5].

I: The introduction in the opening line should state the problem you are addressing.

M: Methodology—what method was chosen to finish the experiment?

R: Results—state the important findings of your study.

A: And

D: Discussion—discuss why your study is important.

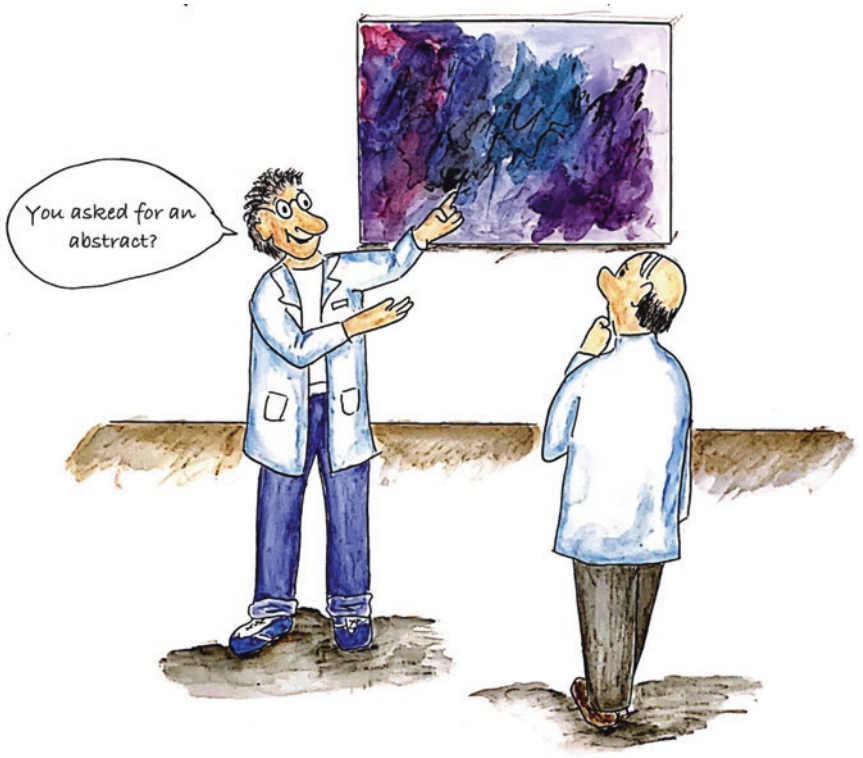
Mention the following information:

- Important results with the statistical information (*p* values, confidence intervals, standard/mean deviation).
- Arrange all information in a chronological order.
- Do not repeat any information.
- The last line should state the recommendations from your study.
- The abstract should be written in the past tense.

15.7 What are the Things to Be Avoided While Writing an Abstract?

15.7.1 Do Not

- Cut and paste information from the main text
- Hold back important information
- Use abbreviations
- or include
- Tables or Figures
- Quotations
- Generalized statements
- References
- Arguments about the study



15.8 What are Key Words?

These are important words that are repeated throughout the manuscript and which help in the indexing of a paper. Depending upon the journal 3–10 key words may be required which are indexed with the help of MESH (Medical Subject Heading).

15.9 How is an Abstract Written for a Conference Different from a Journal Paper?

The basic concept for writing abstracts is the same. However, in a conference abstract occasionally a table or figure is allowed. A word limit is important in both of them. Many of the abstracts which are presented in conferences are never published in fact one study found that only 27% of the abstracts presented in conferences were published in the next five years [6].

Table 15.1 gives a template for writing an abstract.

15.10 What are the Important Recommendations of the International Committees of Medical Journal of Editors?

The recommendations are [7]:

- An abstract is required for original articles, metanalysis, and systematic reviews.
- A structured abstract is preferred.

Table 15.1 Content of the abstract writing

Section	Details
Background	1–2 lines of background material to focus the significance of the study query/hypothesis: • What is the known data? • What is the knowledge gap?
Study postulate	What the study was planned to discover?
Experimental details	Study design (e.g., observational, interventional), randomization, blinding, placebo control, criterion standards for diagnostic tests
	Setting: Outpatient department, hospitalized patient, community-based data
	Materials/subjects/participants: • The resources studied • The details of participants (number, sex) • Selection criteria—inclusion and exclusion • Intervention—drug, surgery, procedure, test • Outcome of interest
Results	Choose the most important results that answer the research question
Importance of the findings	A sentence that declares the results, recommendations, inferences, or speculations based on the answer

- The abstract should mention the purpose of the scientific study, how the procedure was carried out, the analysis used, and principal conclusion.
- Clinical trials should be reported according to the CONSORT guidelines.
- The trials should also mention the funding and the trial number.
- The abstract should be accurate as many readers have access only to the abstract.

15.11 Conclusions

- An Abstract should be written last after all the other sections of the manuscript have been completed and with due care and attention to the details.
- It should be structured and written in the IMRAD format.
- For many readers, the abstract attracts them to go through the complete content of the article.
- The abstract is usually followed by key words that help to index the paper.

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How to Choose a Title?

16

A title should predict the content of a paper, should be interesting, reflect the tone of writing, and contain important keywords so that it can be easily located.

16.1 Why is the Title So Important in Biomedical Research?

'What's in a name? That which we call a rose by any other name would smell as sweet' is a famous quote from Shakespeare's play 'Romeo and Juliet'. However, in biomedical research, the title or name of the article is without any reservation the most important part of the paper and the most read part in the journal. The title is the face of the research and it should sum up the main notion of the experiment/research in such a way that in the fewest possible words one can summarize the facts of the paper and attract the reader as well. 'Being concise, precise, and meticulous is the key' for planning a title [1].

The title should not be very lengthy and also it should not contain several unnecessary words, e.g., 'A Study to Investigate the safety and efficacy of Hydroxychloroquine in subjects who are infected with COVID-19 during the pandemic' contains many extra words and could be easily replaced by 'Safety and efficacy of Hydroxychloroquine during the COVID-19 pandemic'. Besides this, a title that is too petite or brief would not convey what the paper is all about. For example, 'COVID depression' does not provide the necessary information to the readers of the paper.

The title thus has two functions, first to help the scientific sites to index the academic paper, and second, it acts like a billboard or advertisement to sell the paper.

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_16

16.2 What Parameters Help to Formulate a Suitable Research Paper Title?

Time should be spent in planning the title. Editors often reject an article based on its title [2]. Typically, principal investigators and their coinvestigators should select the title accurately so that it captures the central ideal of the research. Devoting time to the title can help writers to relook at the main purpose of the study and also reconsider if 'they are drifting off on a tangent while writing'. There are many adjectives to describe the title of a medical paper and these include 'simple, direct, accurate, appropriate, specific, functional, interesting, attractive/appealing, concise/brief, precise/focused, unambiguous, memorable, captivating and informative' [2–4]. The following information is important while designing the title.

- The aim of the research project.
- The type of the study.
- The methodology used in the project.
- PICOT: population/problem, intervention (test, drug or surgery), control/comparison and time.

16.3 How to Plan Effective Titles in Academic Research Papers?

Although the title appears on the top of the article, it should be written only after the abstract has been written and finalized. There are five basic steps for writing the title. After doing this exercise, one should jot down two or three options and then choose wisely which is the best for your paper. Titles are typically arranged to form a phrase, but can also be in the form of a question. The grammar should be correct and one should capitalize all the first words. In academic papers, a title is rarely followed by an exclamation mark. Ideally, the 'title' should be 'descriptive, direct, accurate, appropriate, interesting, concise, precise and unique' [1].

- Step 1: Write scope of the study and the major hypothesis in a point format.
- Step 2: Use current nomenclature from the manuscript or keywords and dependent and independent variables.
- Step 3: Break down the study into the various components of PICOT.
- Step 4: Frame phrases that give a positive impression and stimulate reader interest.
- Step 5: Finally organize and then reorganize the title (Fig. 16.1).

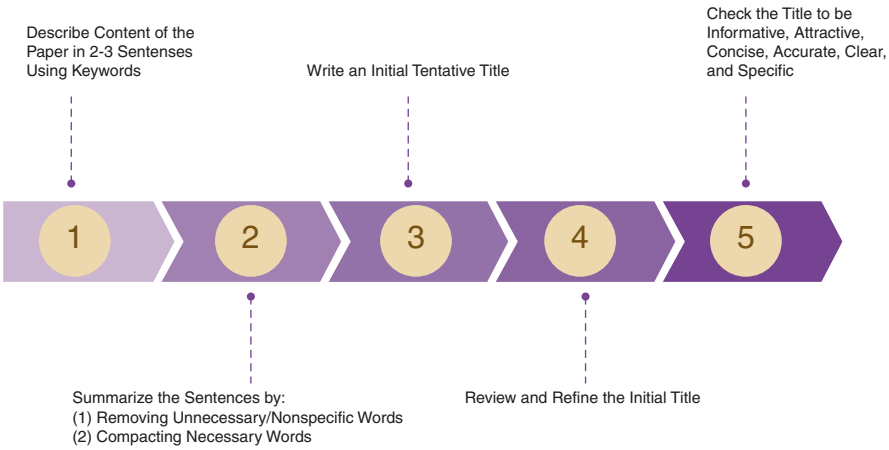

Fig. 16.1 Steps to frame title

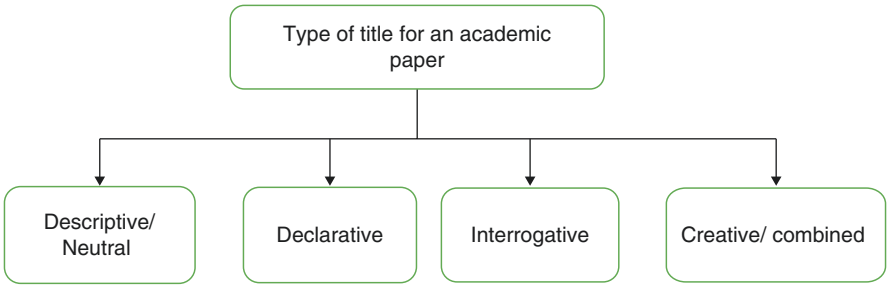

Fig. 16.2 Type of title for an Academic paper

16.4 What Things Should Be Avoided in the Title?

One should avoid the following.

- Avoid using abbreviations and symbols in the title.
- Limit the word count to 10–15.
- Do not include 'study of', 'analysis of', or a similar assembly of words.
- Avoid using unfamiliar jargon not used in the text.
- The title should not be misleading.
- Amusing titles may be taken less seriously by readers and maybe cited less often [2, 5].

16.5 What are the Types of Titles for an Academic Paper?

Classically three types of titles have been described in the literature, i.e., descriptive, declarative, or interrogative. The fourth category which is Creative is also called the combined type. The details are given in Fig. 16.2.

16.5.1 Descriptive or Neutral Title?

This has the vital components of the research paper, i.e., information on the subjects, study design, the interventions used, comparisons/control, and the outcome. It is the PICOT style of a title but does not disclose the observations, results, or conclusions [4, 6]. The descriptive title is based on multiple keywords and provides an opportunity for the reader to decide about the results in an unbiased matter. This type of title is usually preferred in original articles and is also more read and cited as compared to the other types [6, 7]. Examples are given in Table 16.1.

16.5.2 Declarative Title

The title provides the main results of the study and decreases inquisitiveness and thus should be avoided. A few examples are cited in Table 16.2.

Table 16.1 Examples of descriptive titles

Title	Comments
A randomized, active- and placebo-controlled, three-period crossover trial to investigate short-term effects of the dipeptidyl peptidase-4 inhibitor linagliptin on macro- and microvascular endothelial function in type 2 diabetes [8]	Type of study: randomized, cross over Population: Diabetic Time: 3 months Outcome: macro−/microvascular complications Intervention: DPP4 inhibitor—Linagliptin
A Randomized, Controlled Trial of Liraglutide for Adolescents with Obesity [9]	Type of study: randomized Patient characteristics: obesity Intervention: Liraglutide
Effect of an Inactivated Vaccine Against SARS-CoV-2 on Safety and Immunogenicity Outcomes Interim Analysis of 2 Randomized Clinical Trials [10]	Type of study: randomized clinical trial Intervention: SARS-CoV-2 vaccine (inactive) Outcome: it provided short term safety and immunogenicity data

Table 16.2 Example of declarative titles

Title	Comments
Absence of HIV Infection in Blood Donors with Indeterminate Western Blot Tests for Antibody to HIV-1 [11]	The title suggests that if the HIV test is indeterminate HIV-1 by Western blots there are rare chances for HIV in blood donor
Reduced Bone Mass in Daughters of Women with Osteoporosis [12]	The result is evident from the title that daughters of patients suffering from osteoporosis have low bone density
Improved Light-Microscopic Detection of Microsporidia Spores in Stool and Duodenal Aspirates [13]	The conclusion can be drawn that spores of Microsporidia can be picked by in the stool and Duodenal Aspirates by an improved Light-Microscopic detection method

16.5.3 Interrogative Title

In this, the title ends with a question mark which increases the reads and the downloads. When the title is in the form of a query it dramatizes the subject and the readers become inquisitive. A few examples are cited in Table 16.3.

16.5.4 Creative Phrase/Combined Type of Title

This title is used for editorials or viewpoints. Sometimes it can be used in original articles but in such cases, there is the clubbing of an informative with a creative phrase. Usually, the informative part is the main and the creative is the minor part of the title. The latter gives a punch. Both can be separated by a colon or hyphen (Table 16.4).

Table 16.3 Examples of interrogative titles

Tiles	Comments
Anorectal Carcinoid Tumours: Is Aggressive Surgery Warranted? [14]	For malignant tumours aggressive surgery is usually warranted. The title leaves the reader doubtful if this is indicated in carcinoids
Hepatic Vein Embolization for Safer Liver Surgery Insignificant Novelty or a Breakthrough? [15]	The title is in the form of question which increases the curiosity of the readers
Dyslexia—Is it a disease? [16]	A common disorder of spelling and reading
To immunosuppress: whom, when, and how? That is the question with COVID-19 [17]	In the era of COVID-19, the article talks about how to treat autoimmune diseases

Table 16.4 Examples of creative titles

Title	Type of publication
Good for Us All [18]	JAMA publishes a 'Piece of My Mind' series devoted to telling stories about the joys, challenges, and hidden truths of practicing medicine in the modern era
Old wine in a new bottle [19]	English phrase which means an old idea that has been repackaged. The article is an editorial
A tale of two kidneys—how long can a kidney transplant wait? [20]	The title of this original article is a combination of an interrogative title along with an English phrase
Pain, panic, and panting—the reality of 'shortness of breath' [21]	This is a combination of informative and creative writing
When I Use a Word … Clowns [22]	This title leaves us in suspense about what the article is about

16.6 What is a Short-running Title?

Many journals will ask for a short running title that is published on the top of each page. The requirements for this, e.g., the word count should be checked with the journal.

16.7 Conclusions

- The title provides the most important information which helps in indexing and also attracts readers.
- The word count for the title should be less than 16.
- There are four types of title descriptive, declarative, interrogative, and creative. The majority of original articles have a descriptive title.
- There are five basic steps that you need to follow when designing a title. They start with writing the hypothesis and finish with a phrase that can hold the attention of the reader.

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How to Write the Introduction to a Scientific Paper?

17

I once had a professor tell a class that he sifted through our pile of essays, glancing at the titles and introductions, looking for something that grabbed his attention. Everything else went to the bottom of the pile to be read last, when he was tired and probably grumpy from all the marking. Don't get put at the bottom of the pile, he said.

Anonymous

17.1 What is the Importance of an Introduction?

An Introduction to a scientific paper familiarizes the reader with the background of the issue at hand. It must reflect why the issue is topical and its current importance in the vast sea of research being done globally. It lays the foundation of biomedical writing and is the first portion of an article according to the IMRAD pattern (**I**ntroduction, **M**ethodology, **R**esults, **a**nd **D**iscussion) [1].

It provides the flavour of the article and many authors have used phrases to describe it for example—'like a gate of the city' [2], 'the beginning is half of the whole' [3], 'an introduction is not just wrestling with words to fit the facts, but it also strongly modulated by perception of the anticipated reactions of peer colleagues', [4] and 'an introduction is like the trailer to a movie'. A good introduction helps captivate the reader early.

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_17

17.2 What Are the Principles of Writing a Good Introduction?

A good introduction will 'sell' an article to a journal editor, reviewer, and finally to a reader [3]. It should contain the following information [5, 6]:

- The known—The background scientific data
- The unknown—Gaps in the current knowledge
- Research hypothesis or question
- Methodologies used for the study

The *known* consist of citations from a review of the literature whereas the *unknown* is the new work to be undertaken. This part should address how your work is the required missing piece of the puzzle.

17.3 What Are the Models of Writing an Introduction?

These are:

1. The Problem-solving model

First described by Swales et al. in 1979, in this model the writer should identify the 'problem' in the research, address the 'solution' and also write about 'the criteria for evaluating the problem' [7, 8].

2. The CARS model that stands for **C**reating **A** **R**esearch **S**pace [9, 10].

The two important components of this model are:

- Establishing a territory (situation)
- Establishing a niche (problem)
- Occupying a niche (the solution)

In this popular model, one can add a fourth point, i.e., a conclusion [10].

17.4 What Is Establishing a Territory?

This includes: [9]

- Stating the general topic and providing some background about it.
- Providing a brief and relevant review of the literature related to the topic.
- Adding a paragraph on the scope of the topic including the need for your study.

17.5 What Is Establishing a Niche?

Establishing a niche includes:

- Stating the importance of the problem.
- Outlining the current situation regarding the problem citing both global and national data.
- Evaluating the current situation (advantages/ disadvantages).
- Identifying the gaps.
- Emphasizing the importance of the proposed research and how the gaps will be addressed.
- Stating the research problem/ questions.
- Stating the hypotheses briefly.

Figure 17.1 depicts how the introduction needs to be written. A scientific paper should have an introduction in the form of an inverted pyramid. The writer should start with the general information about the topic and subsequently narrow it down to the specific topic-related introduction.

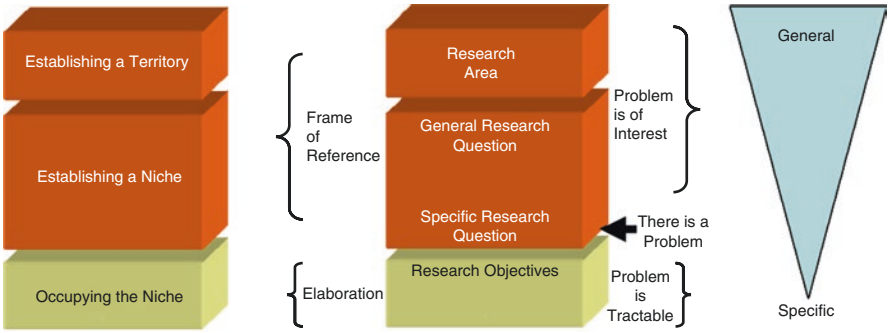

Fig. 17.1 Flow of ideas from the general to the specific

17.6 What Does Occupying a Niche Mean?

This is the third portion of the introduction and defines the rationale of the research and states the research question. If this is missing the reviewers will not understand the logic for publication and is a common reason for rejection [11, 12]. An example of this is given below:

Till date, no study has been done to see the effectiveness of a mesh alone or the effectiveness of double suturing along with a mesh in the closure of an umbilical hernia regarding the incidence of failure. So, the present study is aimed at comparing the effectiveness of a mesh alone versus the double suturing technique along with a mesh.

17.7 How Long Should the Introduction Be?

For a project protocol, the introduction should be about 1–2 pages long and for a thesis it should be 3–5 pages in a double-spaced typed setting. For a scientific paper it should be less than 10–15% of the total length of the manuscript [13, 14].

17.8 How Many References Should an Introduction Have?

All sections in a scientific manuscript except the conclusion should contain references. It has been suggested that an introduction should have four or five or at the most one-third of the references in the whole paper [15].

17.9 What Are the Important Points Which Should be not Missed in an Introduction?

An introduction paves the way forward for the subsequent sections of the article. Frequently well-planned studies are rejected by journals during review because of the simple reason that the authors failed to clarify the data in this section to justify the study [16, 17]. Thus, the existing gap in knowledge should be clearly brought out in this section (Fig. 17.2).

The following points are important to consider:

- The introduction should be written in simple sentences and in the present tense.
- Many of the terms will be introduced in this section for the first time and these will require abbreviations to be used later.
- The references in this section should be to papers published in quality journals (e.g., having a high impact factor).
- The aims, problems, and hypotheses should be clearly mentioned.
- Start with a generalization on the topic and go on to specific information relevant to your research.

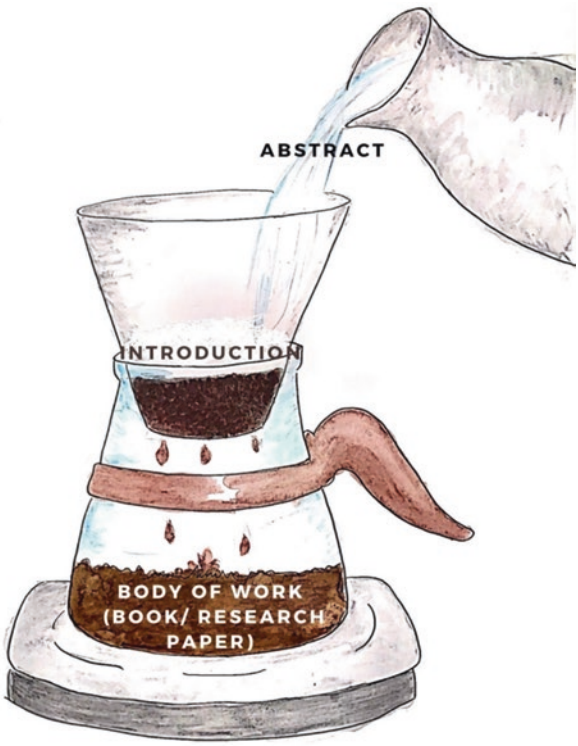

Fig. 17.2 How should the abstract, introduction, and discussion look

17.10 Example of an Introduction

Stratification of Risk Groups for Developing Diabetes among Healthy Non-Diabetic Population using Skin Autofluoroscence Spectroscopic Screening (From editor CMRP with permission)

Introduction

The prevalence of diabetes in India has remained at 11.8% in the last four years, according to the National Diabetes and Diabetic Retinopathy Survey report released by the health and family welfare ministry. [1] The chronic hyperglycaemia in diabetes is associated with long-term complications like retinopathy, nephropathy and neuropathy. Multiple pathogenic processes are involved in the development of diabetes, these range from autoimmune destruction of the pancreatic β-cells with subsequent insulin deficiency to abnormalities that resultin resistance to the physiological action of insulin. [2]

The autofluorescence (AF) is a widespread phenomenon which operates due to the presence of intrinsic biomolecules acting as endogenous fluorophores in the tissues of the human body. The relationship of these endogenous fluorophores with morpho-functional properties of the body, which are influencing their AF emission features, provides an outstandingly powerful resource for the direct monitoring of the biological substrate condition. [3]

AGE estimation gives a measure of long-term cumulative metabolic stress and it acts as a mechanism for the “metabolic memory” observed in diabetes. We studied Skin Autofluoroscence Spectroscopy as a screening method for estimating subcutaneous accumulation of AGE and quantified it to analyse the risk for diabetes in a non diabetic population.

Risk of developing diabetes have been vividly studied in the past and have been defined in many studies, such as the ones by Yanling et al [4], Belloui et al [5] at international level and by J Aravinda [6] in India itself. The results have been more or less similar in expressing that BMI, age and family history have been significant predisposing risk factors for developing

17.11 Conclusions

- An Introduction is a brief account of what the study is about. It should be short, crisp, and complete.
- It has to move from a general to a specific research topic and must include the need for the present study.
- The Introduction should include data from a literature search, i.e., what is already known about this subject and progress to what we hope to add to this knowledge.

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How to Do a Review of the Literature?

18

"Research is creating new knowledge."

Neil Armstrong, American Astronaut, (1930–2012)

18.1 Why Is Reviewing the Literature Important?

In scientific writing, whether it is a research paper, thesis, or dissertation, it is important to investigate a problem that has not been tackled before—that is, to fill a gap in the current knowledge. The first question an editor or reviewer asks after seeing a submission is 'Why did the authors do the work, is the subject original?'

Thus, the aim of a review of the published literature is to explore and subsequently discuss key published material relating to your topic and research questions. This is to show your understanding and awareness of how your research might add to what is already known about the subject. A review of the literature is another area in scientific writing which should also be relevant, precise, and concise [1, 2].

In a review, you are expected to identify and group together similar studies that are relevant to your research question or topic and compare, contrast and evaluate all of them. Some studies may look similar to what you have done or intended to do but once you read the full text you may find that either the population was different, e.g., it was Western, or the intervention or technique to do the test was different. You should highlight these differences in the review.

18.2 What Are Five Crucial Steps for Reviewing the Literature?

For a good review of the literature, the following steps are recommended:

- Step 1 Frame a research question and plan a literature search.
- Step 2 Decide which search engine to use.

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_18

- Step 3 Record, preferably electronically, and review the search results.
- Step 4 Identify how the topic has evolved over a period of time.
- Step 5 Highlight the gaps in the knowledge which need to be filled.

18.3 What Is a Good Literature Search?

The most important part of the review is a good literature search. A good search should seek out both the established facts that have been published in journals and books and deduce logical inferences drawn from evidence-based medicine [1]. Limit your research generally to the past 10 years but you should not miss a landmark study outside this period. Try and include only relevant articles because those unrelated to your subject will only serve to make your publication bulky and boring to read.

18.4 What Are 'Keywords'?

These are usually nouns or short phrases using which the important concepts presented in a paper can be identified [3]. For example, in case you plan to write a paper on the role of hydroxychloroquine to prevent COVID-19 infection among health care workers, the keywords will be 1) COVID-19, 2) Hydroxychloroquine, and 3) Health care workers.

18.5 What Are 'stop' Words?

These are superfluous words that need to be removed before doing a literature search in various search engines to make the search more effective [4]. A list of these is given in Table 18.1.

Table 18.1 Stop words

A	About	Again	All	My
Also	Almost	Although	Always	He
An	And	Any	Are	Him
As	At	It	Itself	Are
Made	Mainly	Might	Most	Do
These	They	This	Those	Who
Thus	To	Upon	Use	What
Used	Various	Very	Was	When
Were	I	Me	Myself	Whom
She	Her	Hers	Which	This

Table 18.2 Various search engines

Wikipedia	WebMD
Google	Google scholar
IndMed	PubMed
Thomson Reuters	EMBASE
CINAHL	World Health Organisation
CABI	Cochrane Library
Index Copernicus	Online e-databases
Approved dissertations	Ongoing trials, data and from e-portals

18.6 Which Are the Various Search Engines That I Might Find Useful?

There are multiple literature sources include online databases like PubMed and MEDLINE from the USA's National Library of Medicine, Thomson Reuters, EMBASE, CINAHL, the HINARI programme of the WHO, CABI, Google Scholar, Cochrane Library, Index Copernicus, and Indian Medlars [1].

Apart from online databases, data can be collected from books, approved dissertations, ongoing trials, World Health Organisation data, and from e-portals (Table 18.2).

18.7 What Is Wikipedia?

This is an English language encyclopaedia that is accessible, free online, and contains more than 6 million articles. Most of the articles are informative but a few contain inaccuracies mainly because their authenticity has not been verified by expert reviewers. Those who run the site, which we believe has its uses, always mention where an article may be prone to error. For medical writing, it is a site that should be used with some caution [5].

18.8 Is the Google Search Engine Useful?

Google is the most frequently used website in the world and in 2018 captured 69% of the share of all the search engines in the United States. This was followed by Google Images (22.03%) and Yahoo, Bing, Amazon, Twitter, Pinterest, and others [6].

Although it provides results quickly it also provides unnecessary information which is difficult to distinguish and discard. It is best used with caution when doing scientific research. Fig. 18.1 shows that a simple search for 'Gastrointestinal Bleeding' took only 0.78 sec but yielded 34,700,000 results which were obviously impossible to scan.

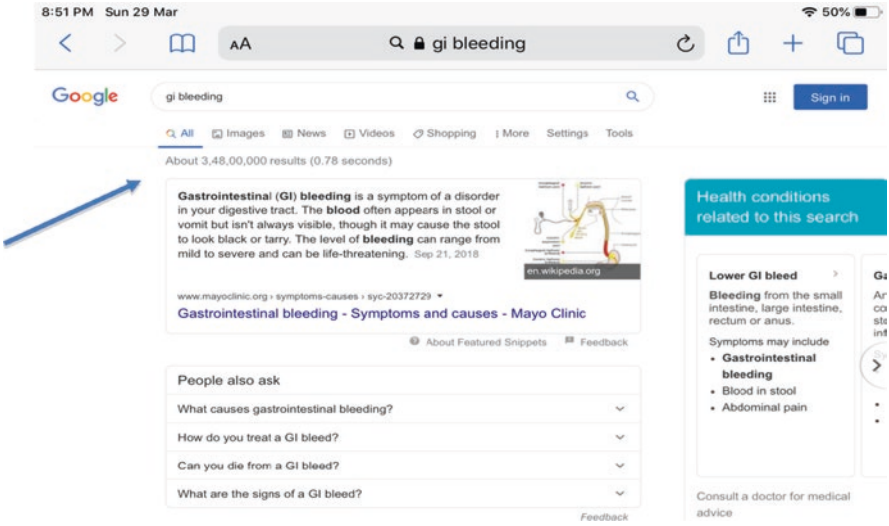

Fig. 18.1 Screenshot depicting a search for gastrointestinal bleeding. Took 0.78 sec and had 34,700,000 results

Tang et al. state that 'Google is not primarily a medical search engine but doctors and patients use it continually for their internet searches related to illnesses and health'. However, 'When used properly, the internet empowers both patients and doctors and may improve the quality of care'. [7].

18.9 How Useful Is PubMed as a Search Engine?

We would recommend that you use PubMed as your main search engine for scientific writing. It consists of 30 million articles that have been published (print and online) from journals that have been carefully chosen as having met some exacting scientific and presentation standards and are thereby 'indexed'—a prized attribute. These are on Medicine, Dentistry, Healthcare systems, and Preclinical research. It is free to use with the US National Library of Medicine (NML) maintaining its papers related to health. Its online presence is in the form of MEDLINE. PubMed is the search interface for MEDLINE as well as other NLM resources, making it the primary source now for the biomedical literature [8].

PubMed also has a facility called 'My NCBI' to save multiple search papers, filter your search, and send you the results by email. You can also refine your search from dates to years and also select the article type. However, you should remember that it may take 3–6 months for a paper to appear on PubMed after it is published.

Using PubMed you can access citations, abstracts and some full-text articles on the life sciences and biomedical topics. For more effective use of PubMed, we recommend using the YouTube video or a short instruction clip on the web site via the link http://www.nlm.nih.gov/services/pubmed.html.

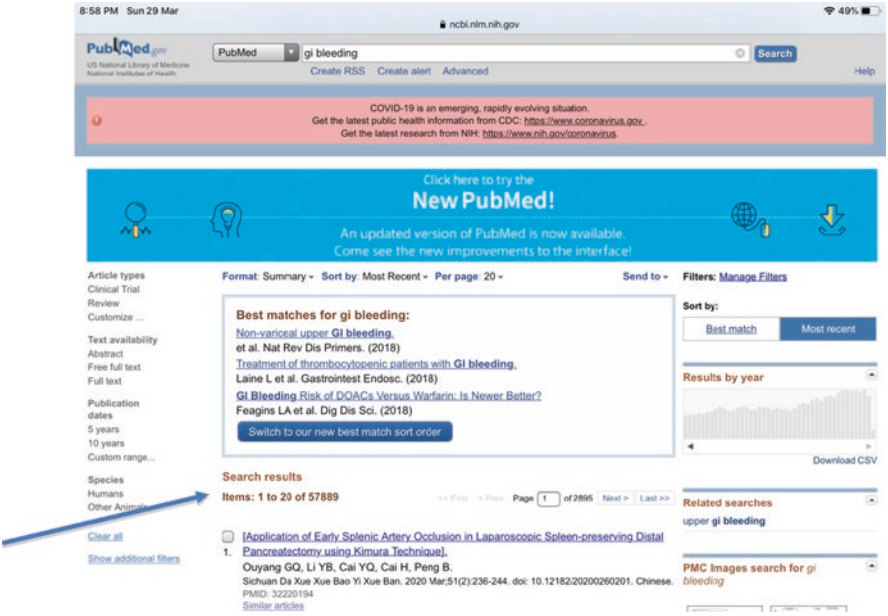

Fig. 18.2 PubMed research on Gastrointestinal Bleeding

Figure 18.2 shows an example of a search on Gastrointestinal Bleeding which yielded 57,889 papers—much less than what Google found.

18.10 What Are MeSH Words?

MeSH stands for Medical Subject Headings. Using MeSH words, you can enhance the accuracy and effectiveness of your search of the literature on PubMed. The link appears on the right of the screen under More Resources (Fig. 18.3). MeSH terms are labels allocated to each scientific item in Medline in order to describe what the article is about. The National Library of Medicine staff with training as 'indexers' look at each new manuscript added to Medline and assign to it about 10–12 labels that best describe the content of the article. MeSH terms are official words or phrases selected to represent particular biomedical concepts. This strict rule results in more efficient searches [9].

MeSH terms are organized into a hierarchy called the MeSH tree. For instance, if you were to search for lymphoma, you would see 134 subtypes along with definitions like lymphoma, non-Hodgkin's lymphoma, ocular lymphomas, lymphoma mantle cell, etc. and you will then need to pick the types that interest you to conduct a more effective literature search. This is time-saving by restricting the absolute number of titles and increase the number of relevant titles which you need to read.

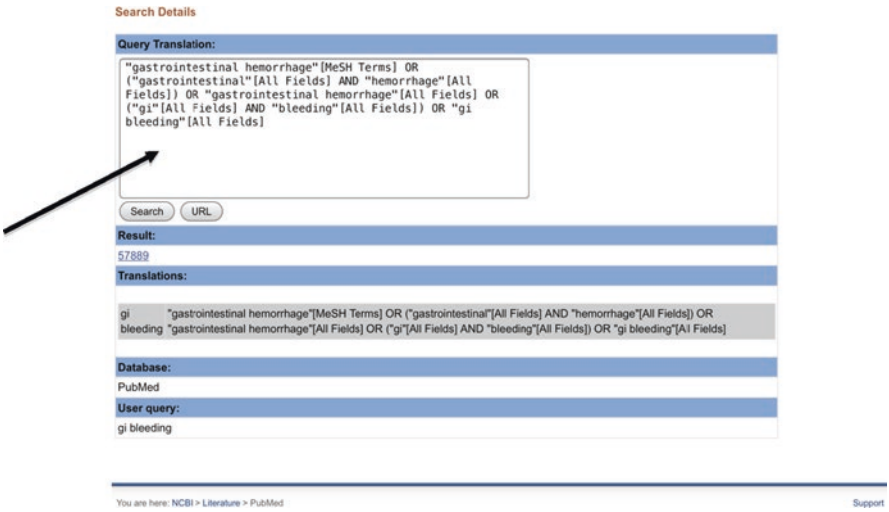

Fig. 18.3 MESH terms for Gastrointestinal Haemorrhage

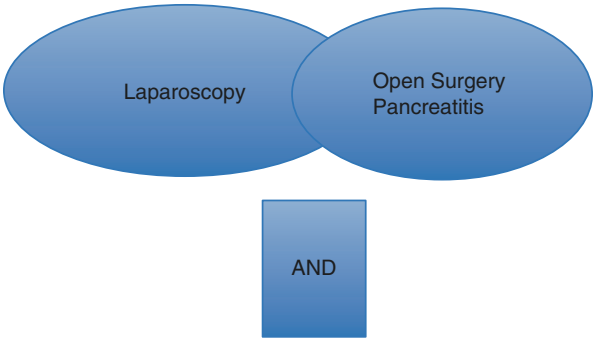

Fig. 18.4 Example of the Boolean word 'AND'

18.11 What Are Boolean Operators?

Boolean Operators are simple words (AND, OR, NOT, or AND NOT) used as combinations to eliminate keywords in a search. This provides more intensive and productive results. They save time and effort by removing inappropriate hits that need to be scanned before they are discarded [10].

AND—means both terms must be used in a search. For example, in research 'Is laparoscopic or open surgery better in patients with pancreatitis' (Fig. 18.4).

OR—means either term (or both) will be in the search document. An example of this is laparoscopy or open surgery in acute pancreatitis (Fig. 18.5).

NOT—this means the first term is looked for, and the other word is not important for the search. In the above example, it may mean but laparoscopy not open surgery in acute pancreatitis (Fig. 18.6).

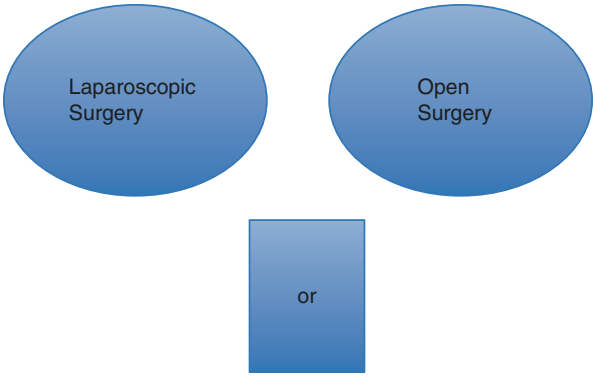

Fig. 18.5 Example of the Boolean word 'OR'

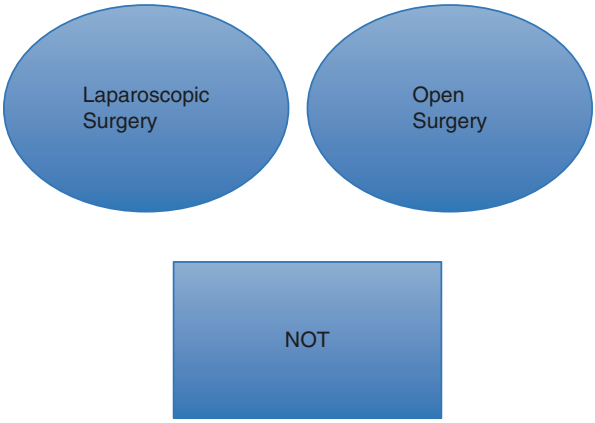

Fig. 18.6 Example of the Boolean word 'NOT'

18.12 What Is PubMed Central?

PubMed Central is different from PubMed as it provides complete access to scholarly articles for both reading and downloading. It was launched in the year 2000 and provides full-text of biomedical and life sciences journal articles. Almost all the scientific content of PubMed Central is included in MEDLINE (91%). With the launch of PubMed Central, the percentage of PubMed records indexed in MEDLINE has slowly decreased and that of PMC content increased (Fig. 18.7) [11].

Much of the content in PMC is contributed by journals that are not indexed (included) in Medline or are open access journals. PubMed does give access to some journals through PMC (Fig. 18.8).

Fig. 18.7 Percentage content of Medline and PubMed Central

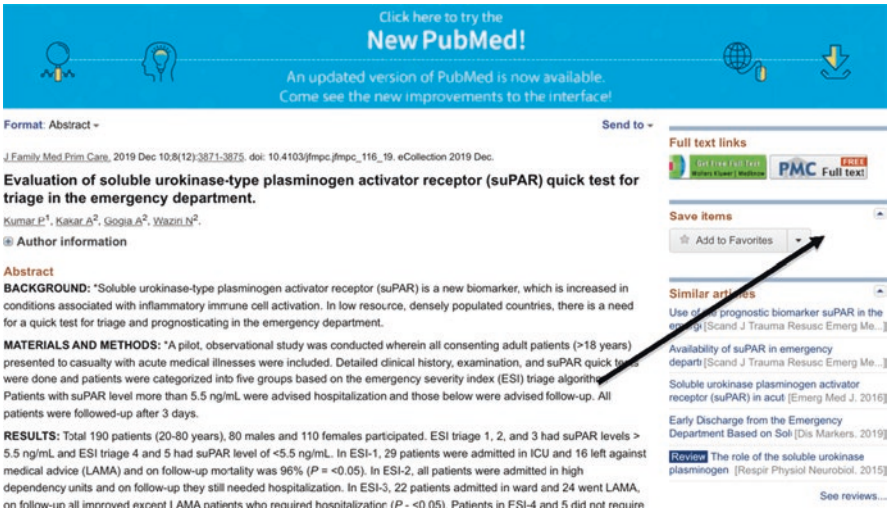

Fig. 18.8 Free access to full journal from PubMed

18.13 What Are the Cochrane Reviews?

These are extensive systematic reviews and meta-analyses performed by chosen experts who are generally leaders in the field. They organize medical research findings to facilitate evidence-based choices about health interventions involving health professionals, patients, and policymakers. They can be Intervention reviews, Diagnostic test accuracy reviews, Methodology reviews, Qualitative reviews, and Prognosis reviews.

Health care and health policies can benefit from an interventional review. A review of the diagnostic accuracy of a test can help us decide whether or not to use

it. A methodology review studies clinical trials and how they were reported, whereas an aprognostic review addresses the outcome related to trials. Meta-analysis in a Cochrane review measures the benefit and harm from many trials which meet certain standards and whose results are combined. The Cochrane reviews are also peer-reviewed and indexed in PubMed. The articles are somewhat lengthy, but often offer an abstract for you to read. A Cochrane review is generally very authoritative and helps health workers to make rational clinical decisions [12, 13].

18.14 What Is IndMed?

This is an Indian biomedical journal base that covers 78 journals and provides online access to full-text Indian journals within this country and abroad. It can be accessed by http://indemed.nic.in., which is free of cost and is peer-reviewed. The journals in this database are from 1985 onwards. This project is funded by the Indian Council of Medical Research (ICMR) under the 'National Databases of Indian Medical Journals'. In a study to evaluate the coverage of Indian medical journals, it was found that IndMed was one of the most important contributors to a certain national database, as the coverage of Indian literature in Medline was not comprehensive and visible [14].

"Which are the various search engines that I might find useful?"

18.15 What Are some Data Portals Maintained by Publishers and Search Engines?

EMBASE (ExcerptaMedica) is a large multipurpose biomedical and pharmacological bibliographic database of the published literature.

ScienceDirect contains articles on science, technology, and medical research. It contains 12 million articles from 3500 academic journals and 34,000 eBooks.

Google Scholar is a search engine that should be used often by the scientific community as it is a collection of a large number of articles, theses, books, and abstracts. Google Scholar also covers non-English sources, technical reports, conference presentations, and institutional repositories. The database is also a citation index; this means that you can search the number of times the article has been cited by other authors. The other advantage of Google Scholar is that it is easy to use and also covers the 'grey' literature like conference proceedings.

Its drawbacks are that it sometimes misses important articles, its content changes constantly, and sometimes includes material that has not gone through a peer-review process.

18.16 What Is Scopus?

This is the world's largest database and includes cited articles, journals, books, and conference proceedings They are all peer-reviewed. It is easy to use and includes more than 36,377 titles. It is maintained by Elsevier and includes citations from top licenses, social sciences, and related medical fields.

18.17 What Is Index Copernicus (ICI)?

ICI is a journal indexing base that has been in existence for almost 20 years. The indexation is based on a hundred criteria but the process of evaluation is free of charge. The index Copernicus is valuable for scientific journal publishers to increase their impact factor.

18.18 Can Online Portals for Clinical Trials Be Accessed?

The information can be obtained from the clinical trials registry—ctro.nic.in/clinicaltrials. The website is free and all the trials need to be registered in this portal. All postgraduate theses should be registered at this site [15].It provides publications in the form of a clinical trial register of the India bulletin and also about how to plan clinical trials in India, strengthening the ethics in clinical research, and updating the clinical trials registry in India.

18.19 What Is the Information and Library Network (INFLIBNET)?

The INFLIBNET is a centre in Gandhinagar and is an autonomous inter-university centre under the University Grants Commission. It contains a digital library of more than 15,000 core peer-reviewed journals and a number of bibliography citations and databases. The site promotes higher education e-resources and has many e-journals. The various e-resources include biochemistry, biological sciences, biotechnology, criminology, education, microbiology, which may be relevant to medical practice. Government-aided colleges can access this through their libraries.

18.20 Conclusions

- Navigating through the jungle of information now available is a difficult task. It involves browsing through research papers, reading the information provided, and critically analyzing the facts which may be useful for your research.
- PubMed and PubMed Central are the main indexing sites we recommend. Other important databases like Google Scholar, Embase, Science Direct, and Scopus should also be explored.
- An effective way to use PubMed can be learned by using the YouTube video on this subject.
- A comprehensive review of the literature will help you to write a good Introduction and Discussion.

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How to Write the Material (Patients) and Methods Section

19

The method of science is logical and rational; the method of the humanities is one of imagination and sympathetic understanding.

Andrew Louth British Theologian (1944–…).

19.1 What Should be Included in the Material and Methods Section?

In this segment, you should describe exactly and in detail how you did the study so that the readers will be able to (Fig. 19.1):

- Assess how the research was done.
- How they might repeat the study, if they wish to do so [1].

You must mention 'what', 'how much', 'how often', 'where', 'when' and 'why' clearly to provide a step-by-step tutorial for your reader. It may not be possible to provide all the technical details while writing this section for a print journal, but these may perhaps be included in an online version of the article.

James Provenzale, in an editorial for American Journal of Roentgenology, stated, 'One of the more common reasons for rejection of a manuscript is that the reviewers cannot fully understand how the study was conducted' [2]. Many journals have page limits for the Materials and Methods section so we would suggest that only important steps should be included. Journals nowadays do provide an electronic access for their articles and all the extra information describing the methodology and results in detail can go into the supplementary online file. Most journals will also ask for clearance from an ethical committee or an Institutional Review Board (IRB) for studies involving human subjects and this should be recorded here.

In summary

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_19

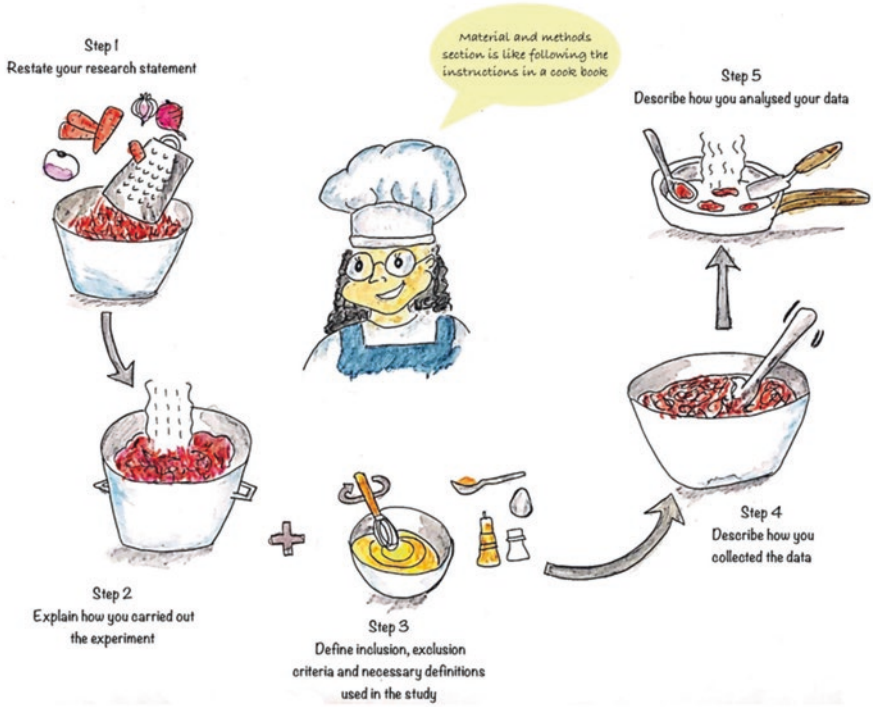

Fig. 19.1 The section should be like following the instructions in a cookbook

- Step-1 Restate your research statement
- Step-2 - Explain how you carried out the experiment
- Step-3 define inclusion, exclusion criteria and necessary definitions used in the study
- Step-4 Describe how you collected the data
- Step-5 describe how you analysed your data

19.2 What Are the Important Steps that Should be Followed?

The Material (or preferably Patients if it is a clinical study) is defined as any subjects, matter, investigations, chemicals, drugs or devices which have been included.

The Methods has been defined as the 'particular procedures for accomplishing or approaching something'.

Describe which experimental animals, patients, volunteers or control subjects will be included. For a drug mention how the drug was taken and through which route it was administered stating the name of the source and the supplier in brackets. For immunological tests the technique used and the name of the manufacturer should be mentioned. The reagents used should also be mentioned in this section. For a surgical technique describe how it was different from a standard one in some detail [3].

We would recommend a five-step approach for writing this section for a journal. Open this section by stating the research question you wish to answer. Then mention how many patients were screened for the study, the number of patients who fulfilled the criteria for inclusion and how many were excluded. A CONSORT (Consolidated Standards of Reporting Trials) flow chart may be a useful guide at this stage (Fig. 19.2).

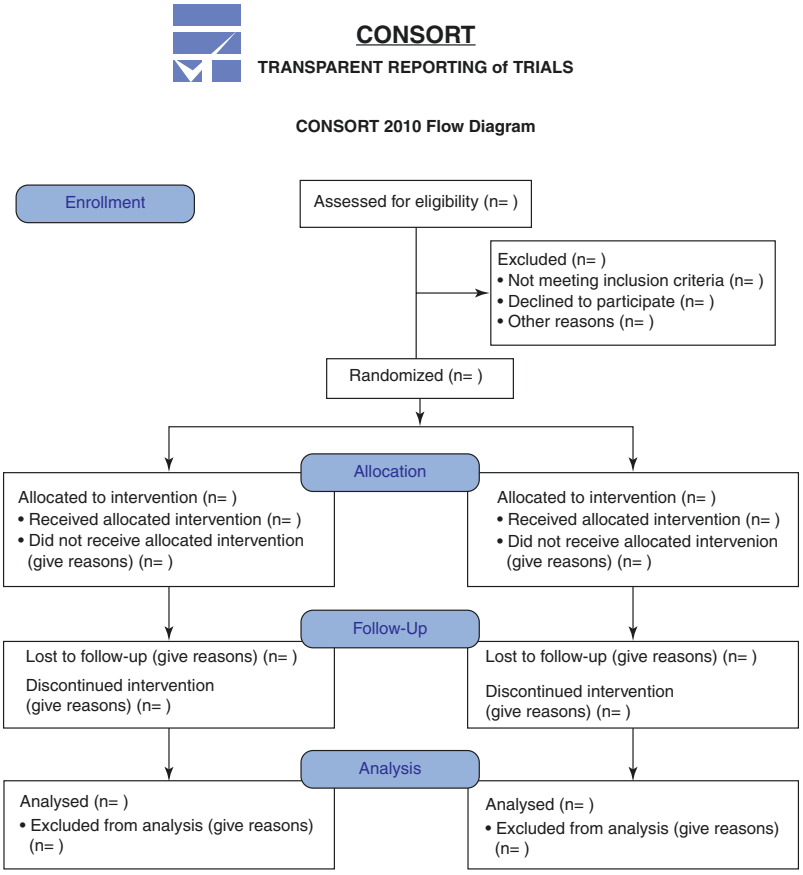

Fig. 19.2 CONSORT Flow chart

19.3 In Which Tense Should the Methodology Be Written?

All the methodology should be written in the past tense preferably in an active voice [4]. According, to this you should use verbs like 'investigated', 'evaluated' or 'performed'. Recently, terms showing the ownership of the investigation as 'we performed', 'we evaluated', 'we implemented' have taken priority. The communication to the reader should be clear and there should not be any cluttered thought. This section should be written in simple English and should be comprehensive.

19.4 What Are the Points Which Should Not be Missed in Methodology Section in a Biomedical Research Paper?

These include:

- Date of initiation and termination.
- Inclusion and exclusion criteria.
- Outcome measure with the definitions.
- Statistics used.
- Type of study design.

19.5 What Are the Common Errors Seen in this Section?

- Many authors write this section as a set of instructions but what is required is a description of the experiments.
- Mingling the results with the methods. Results should be discussed and analyzed in a subsequent section.
- Including explanatory information and background—save these for the discussion section.
- In this section include information relevant to the reader and minute details such as who helped to set up the experiment or who helped to input the data are not relevant. Many journals provide links for supplemental information which is available online but not in the print version.
- Writing the pros and cons of the technology used to study the experiment in this section. This should be done in the discussion section.

19.6 Conclusions

- Include in this section 'What was done, how it was done, how the data was collected, and how the data was analyzed'.
- Organize your methodology as what was the first step and then what were the subsequent steps.

- Avoid writing stories in the methodology when the same can be conveyed in a flow chart.
- Describe in detail the statistics used in the study.

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How to Write Results?

20

Progress is made by trial and failure; the failures are generally a hundred times more numerous than the successes; yet they are usually left unchronicled.

William Ramsay, Scottish Chemist (1852–1916)

20.1 What Is the Difference between Observations and the Results of an Experiment?

Observations are usually tabulated, graphed, or charted after conducting a study. The interpretation of the observations is called the results.

To understand the difference between the two, we are citing an example below:

Experiment—To study the seropositivity of COVID-19 antibodies in ten hot spots in Delhi.

Observations—Blood tests for IgG antibodies against COVID-19 were done in 26,127 patients. Table 20.1 depicts the number of samples screened in each hot spot, the total number which were positive and the number of males who were positive.

However, while submitting for publication a better way to represent the above data would be by Table 20.2.

20.2 Results

1. The seropositivity rate in the community was found to be 40.3% for COVID-19 antibodies and ranged from 2.7 to 98.8%. The minimum positivity rate was seen in hot spot number 6 and the maximum in number 10.
2. The seropositivity rate for males in the community was 25.5%.

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_20

Table 20.1 Observations on community transmission of COVID-19 in hot spots in Delhi

Hotspot code	Population	Positive samples	Positive male
Area 1	5235	1346	999
Area 2	2345	124	52
Area-3	1689	47	39
Area4	1392	1100	112
Area-4	1389	119	103
Area-5	1450	1145	796
Area-5	1289	56	50
Area-6	1190	32	29
Area -7	1899	185	170
Area-8	5696	3233	2347
Area9	2359	1123	1092
Area-10	1348	1251	789

Table 20.2 Community transmission in COVID hot spots in Delhi

Hotspot code	Population screened	Positive rate Percentage	Seropositivity in males Percentage
Area 1	5235	25.7	19.1
Area 2	2345	5.3	2.2
Area-3	1689	2.8	2.3
Area4	1392	79.0	8.0
Area-4	1389	8.6	7.4
Area-5	1450	79.0	54.9
Area-5	1289	79.0	3.9
Area-6	1190	2.7	2.4
Area -7	1899	9.7	9.0
Area-8	5696	56.8	41.2
Area9	2359	47.6	46.3
Area-10	1348	92.8	58.5
	26,127	40.3	25.5

20.3 What Should Be Included in the Results?

In this section, you should include all the data in the form of tables, charts, graphs, and figures [1]. Then analyze this data explaining its meaning in sentences. The results should provide information on how the data was collected and the participants recruited. Secondary outcomes and subgroup analyses should be also included. Like in the example the COVID antibody titre might be mentioned if it was recorded.

There is no one way to represent the results but graphic representation is probably the easiest to understand [2]. In case a graph is self-explanatory, we should avoid duplication of the same data in a tabular form. Most journals have a limitation on the number of tables and figures that can be submitted and the manuscript should be adjusted according to their requirements. One size does not fit all and graphic representation may need to vary from manuscript to manuscript. Fig. 20.1 shows the commonly used various ways to represent the results, i.e., from line graphs, bar charts, pie diagrams, and histograms.

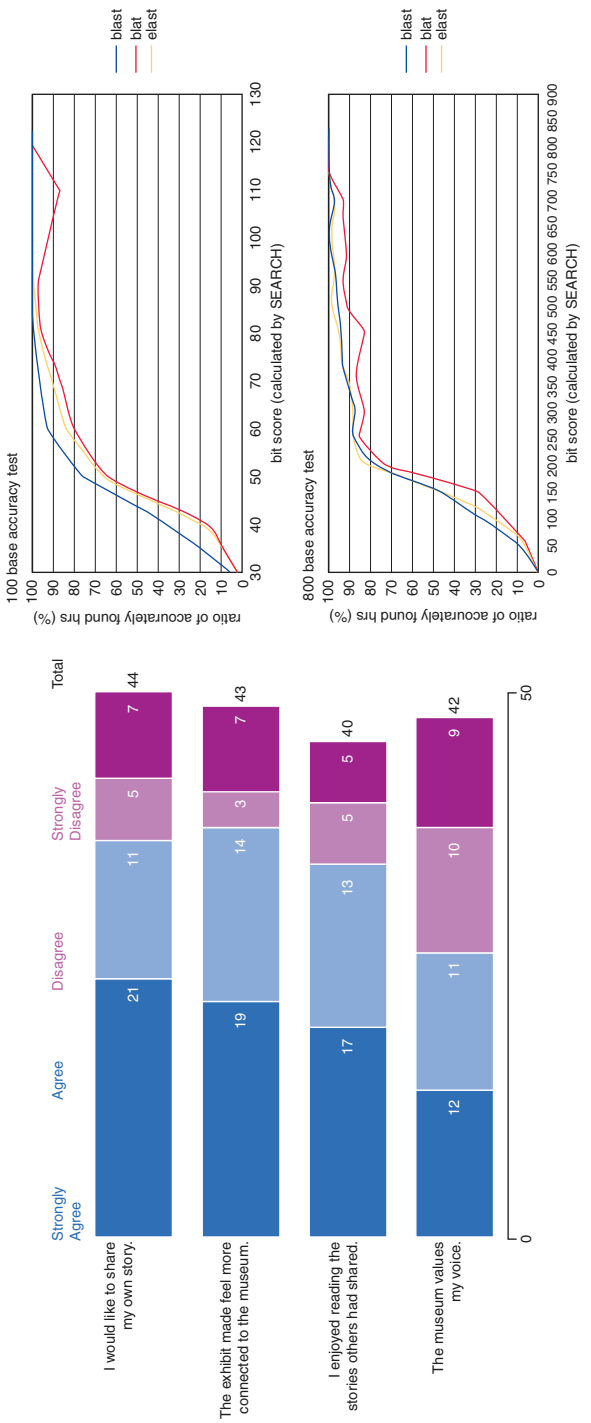
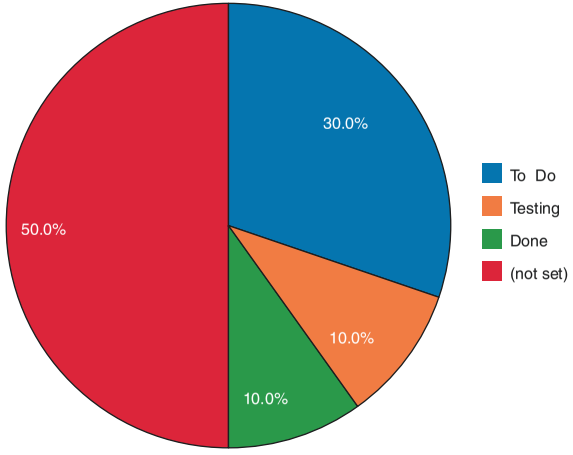
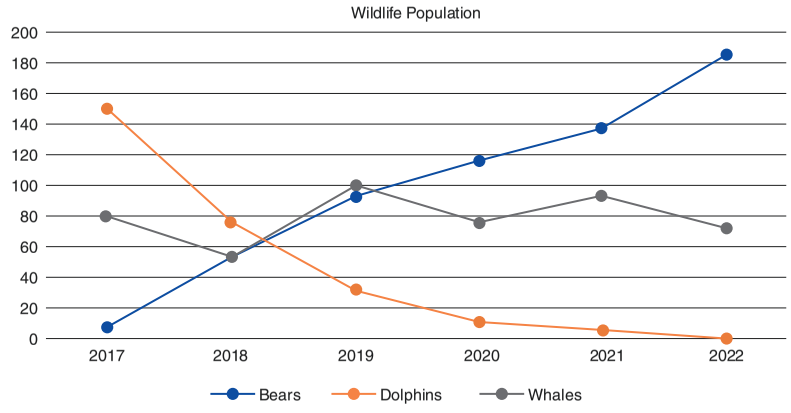


Fig. 20.1 Various ways of displaying results





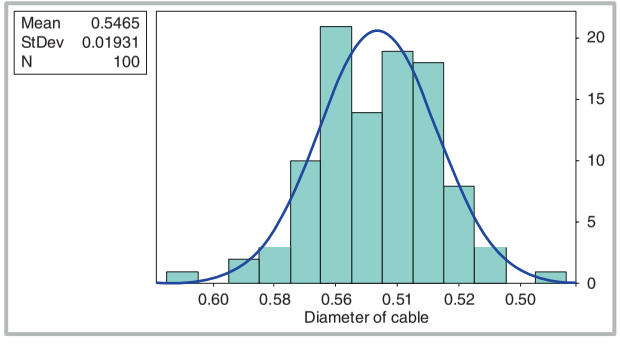


Fig. 20.1 (continued)

20.4 What Are the Ten Steps for Presenting the Results?

- **Step 1:** Organize your draft in such a way that it gives maximum communication to the readers. Frame simple sentences to achieve this [3].
- **Step 2**: Start with an opening sentence that restates the research questions.
- **Step 3:** Follow this by the number of patients screened, number enrolled, and who were included and excluded.
- **Step 4:** State the principal findings.
- **Step 5:** All Tables and Figures should be numbered according to the order in which they appear in the manuscript. All tables should have a descriptive caption on the head. The figures and tables should require a minimum amount of explanation in the results or discussion section.
- **Step 6:** Check for the language and scientific mistakes and revise your draft constantly to achieve the best results. Make sure that the graphs and figures are all correct and no values of the observations have been wrongly copied.
- **Step 7**: Refer to the Instructions to Authors given on the journal website about this section. Read about how many graphs and figures are allowed to represent the results. This will help you to reframe the manuscript according to their guidelines.
- **Step 8:** Include all the positive as well as the negative results which are statistically significant.
- **Step 9**: Make sure that the results section jells with the other sections and does not look like a stand-alone piece. Check for grammar and tense at this stage. All results have to be reported in the past tense [3].
- **Step 10:** Any data which have not been mentioned in the results section cannot be discussed later. If there are too many results then try and categorize them further into subheadings.

20.5 What Is the Role of Statistics in the Results Section?

Most papers now need to include statistical analyses in their results section. This has been discussed in greater depth elsewhere in this volume. John Shaw Billings (1838–1913), the eminent American Librarian, said that ‘Statistics are somewhat like old medical journals, or like revolvers in newly opened mining districts. Most men rarely use them, and find it troublesome to preserve them so as to have them easy of access; but when they do want them, they want them badly’.

20.6 Conclusions

- The main goal of a medical article is to display the results. Both the positive and significantly negative ones need to be mentioned.
- The organization of this section requires a stepwise approach.
- Visual aids, like graphs, figures, tables, pie charts, and histograms usually make the results easier to comprehend.

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How to Write the Discussion?

21

That then is the first draft and you should never think of having fewer than six drafts

Stephen Lock, BMJ editor in chief (1929–…)

21.1 What Is the Importance of the Discussion?

Many authors, and editors, think this is the most difficult part of a paper to write well and have described it variously to be the 'narrating the story of your research', 'the movie or the main scientific script' and the 'proof of the pudding'. The idea of a discussion is to communicate to the readers the importance of your observations and the results of all your hard work. In this section, you are expected to infer their meaning and explain the importance of your results and finally provide specific suggestions for future research [1, 2]. The discussion places the outcome into a larger context and mentions the implications of the inferences for theoretical and practical purposes [3].

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_21

21.2 How Should I Structure the Discussion Section?

There are three major portions for the discussion of a manuscript.

The first paragraph should baldly state the key findings of your research. Use the same key concept you gave in the introduction. It is generally not necessary to repeat the citations which have already been used in the Introduction. According to the 'serial position effect', themes mentioned at the beginning and end of a paragraph are more likely to be remembered than those in the middle [1]. However, one should remember that the discussion should not look like a second introduction, and all the ancillary information which has been previously cited should not be repeated [4].

For example, in a paper on the 'Role of sulfasalazine in the Chikungunya arthritis outbreak of 2016', the review may start with, 'Our key findings suggest that chikungunya arthralgia is a self-limiting disorder. Persistent arthritis was recorded in only 10% of the affected population and in those who received sulfasalazine, clinical improvement both in tender and swollen joints, was recorded in 95% of the subjects'.

The middle portion should consist of the body of the discussion. This section interprets the important results, discusses their implications and explains how your data is similar to or different from those that have been published previously.

Discuss in fair detail studies supporting your findings and group them together, against those offering a different perspective (e.g., Western experience, smaller numbers, non-randomized studies, etc.). An explanation should be offered on how your work is similar to others or how it is different from the others. This should be followed by a review of the core research papers. The results should now be divided thematically and analyzed. The discussion should also contain why the study is new, why it is true, and why it is important for future clinical practice [4–6].

For the above research mention the clinical features, patterns of joint involvement, how long arthritis persisted, and any role of disease-modifying agents. Have any other researchers found different findings under the same circumstances.

The final paragraph should include a 'take home message' (about one or two) and point to future directions for investigation that have resulted from this study.

The discussion can be concluded in two ways:

- By again mentioning the response to the research question [5, 7]
- By indicating the significance of the study [2, 4]

You can use both methods to end this section. Most importantly you should remember that the last paragraph of the discussion should be 'strong, clear, and crisp' and focus on the main research question addressed in the manuscript. This should be strengthened by the data which clearly states whether or not your findings support your initial hypothesis [1, 5, 8–10].

21.3 What Are the General Considerations for Writing a Discussion? [3, 10, 11]

- Start the discussion with the 'specific' problems and move to the 'general' implications (Fig. 21.1).
- The discussion should not look like a mass of unrelated information. Rather, it should be easy to understand and compare data from different studies.
- Include only recent publications on the topic, preferably from the last 10 years.
- Make certain that all the sources of information are cited and correctly referenced.
- Check to make sure that you have not plagiarized by using words quoted directly from a source.

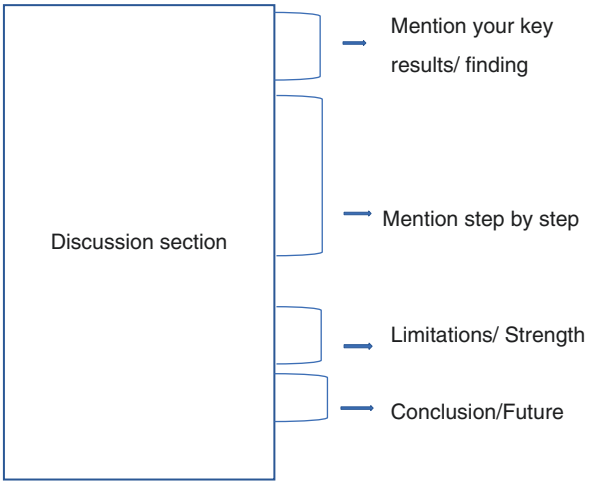

Fig. 21.1 How a discussion should look. First arrow—Mention your key results/findings; Second arrow—Discuss your results with their explanations\step by step; Third Arrow—Enumerate your studies limitations and strengths; Last arrow—Suggest future directions for investigation

- The written text written should be easily understood, crisp, and brief. Long descriptive and informal language should be avoided.
- The sentences should flow smoothly and logically.
- You need not refer to all the available literature in the field, discuss only the most relevant papers.

21.4 Discussion Is Not a War of Words

21.5 How Long Should the Discussion in the Manuscript Be?

Most journals do not mention any limits for discussion as long as it is brief and relevant (Fig. 21.2). As a rule, 'The length of the discussion section should not exceed the sum of other parts-introduction, materials and methods, and results'. [3] In any good article, the discussion section is 3–4 pages, 6–7 paragraphs, or approximately 10 paragraphs, and 1000–1500 words [1, 5, 8, 12].

21.6 What Should Be Written in the Conclusion Section?

The conclusion is the last paragraph and has the carry-home message for the reader. It is the powerful and meaningful end piece of the script. It states what change has the paper made to science and it also contains recommendations for future studies.

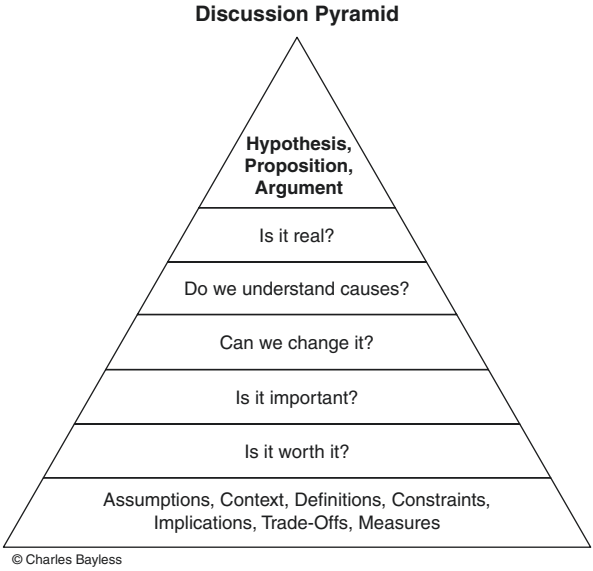

Fig. 21.2 Discussion pyramid

21.7 Conclusions

- Discussion is not a stand-alone section, it intertwines the objectives of the study with how and what was achieved.
- The major results are described and compared with other studies.
- The author's own work is critically analysed in comparison with that of others.
- The limitations and strengths of the study are highlighted.

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How to Cite Other Papers and Add References?

22

There are two important things about the references; firstly, you should have read them and secondly, they should be retrievable.

Jane Smith Deputy Editor BMJ (1952–…).

22.1 What Does Citation Mean?

Citation means acknowledging and documenting the source of information that has been used in a study [1]. Citations are given in the text of the manuscript to be prepared. There are three common ways to cite an article which are given below.

For example

'The first and most important lesson is that we have to devise Indian solutions to Indian problems. Portal hypertension surgery has been largely given up in western countries because of its poor results in patients with cirrhosis'.

If you are citing this text you have to insert a number at the end of the text or in superscript. Another, older, system is to mention the authors' names in brackets at the end of the text.

First method—The first and most important lesson is that we have to devise Indian solutions to Indian problems. Portal hypertension surgery has been largely given up in western countries because of its poor results in patients with cirrhosis [1] or (1).

Second method—The first and most important lesson is that we have to devise Indian solutions to Indian problems. Portal hypertension surgery has been largely given up in western countries because of its poor results in patients with cirrhosis [1].

Third method—The first and most important lesson is that we have to devise Indian solutions to Indian problems. Portal hypertension surgery has been largely given up in western countries because of its poor results in patients with cirrhosis (Nundy 2018).

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_22

As you must have realized that citation does not provide complete details of the source but a link to where this information has been accessed. Do not add any degrees or institutional affiliations for the author. For more than one author use et al. (Nundy et al.). For theses and publications, the first two are usually preferred. At the end of the text, i.e., after the Conclusions of the manuscript, the complete reference is given.

22.2 What Are References?

A reference provides complete details about the article's author(s), the journal in which it was published, the year it was published, the volume, and page numbers. The article can also be from a website, book, or thesis. The references are cited in the text in the serial order of their appearance and the same order is then followed for the reference list at the end. The references can also be given in alphabetical order or by year of publication. There are different types of reference systems that need to be followed according to a journal's requirements [1]. It is expected that the authors have read the references and include only accurate information in the manuscript.

22.3 What Is the Advantage of Providing References and Citations?

The advantage is that it acknowledges and gives due credit to authors who have conducted the original work. It also lets the readers check if more details are required from the referred paper. In addition, on seeing the references you can know how extensive has been literature search. It also protects you from plagiarism charges [2].

22.4 What Are the Various Referencing Styles?

Some common and widely used citation styles are listed below. The Vancouver style is now generally used for the majority of journals. The first two will be discussed in the latter part of the chapter.

- Vancouver.
- Harvard.
- Chicago—16th edition.
- American Psychological Association—6th edition.
- Modern Language Association.
- Turabian—8th edition.
- National Library of Medicine.
- Institute of Electrical and Electronics Engineers.

There are other styles that are not common but are still required in some places:

- American Chemical Society.
- Australian Guide to Legal Citation.

- American Medical Association.
- Council of Science Editors/Council of Biology Editors.

22.5 What Is the Vancouver Style for Referencing?

To arrive at a consensus on a uniform format for biomedical manuscripts a meeting of the International Committee for Medical Journal Editors was held in Vancouver, Canada in 1978 in which they proposed the Uniform Requirements for Manuscripts Submitted to Biomedical Journals.

22.6 What Are the General Rules for Citation and Referencing in the Vancouver Style?

The general rules for citation are:

- A number is given to each citation in a superscript format.
- If one needs to cite the same source again and again in the manuscript, the same number will be used as cited elsewhere.
- No degrees or affiliation are added to the cited authors.
- If there is more than one author add et al. after the first author's name. et al.' is written in italics which means 'and others'.

The general rules for the list of references are:

- Listed all the references in a numerical order, in the same order as they were cited in text.
- Use a new page and title it 'List of references'.
- Use Arabic numerals (1, 2, 3, 4, 5, 6, 7, 8, 9).
- Abbreviate journal titles in the style used in the National Library of Medicine (NML) catalogue [3].
- Be consistent with your referencing style across the document.

22.7 How to Write Authors' Names in the Vancouver Style?

Vivek Sharma is written as Sharma V and Anuj Kumar Verma is written as Verma AK.

How to write authors' name in the reference list

One author—Sharma V

Two authors—Sharma V, Verma AK

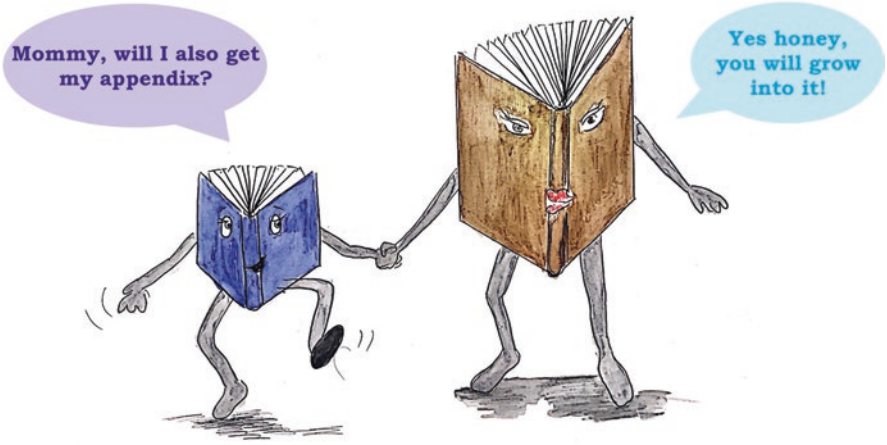
Up to 6 authors—Sharma, V, Verma A, K, Soni P, S, Chawla A, K, Singh, Singh P

More than 6 authors—mention the names of the first six authors as in the original paper and then add et al., e.g., Sharma V, Verma AK, Soni PS, Chawla AK, Singh P, et al.

22.8 How Do you Write the journal's Name in the Vancouver Style?

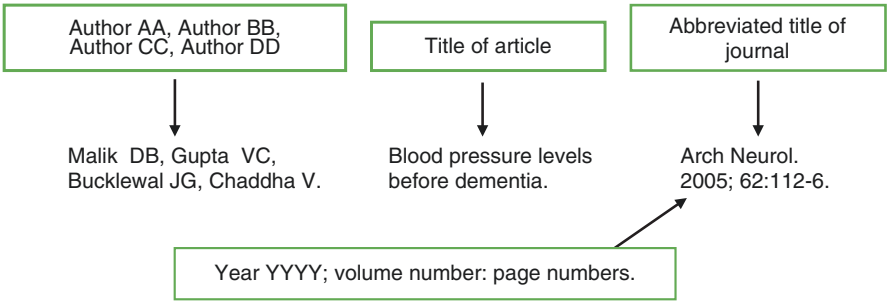
Use standard abbreviations for the journal which can be check at NML catalogue [3]. Some examples are given below.

Original name	NML abbreviation
The New England Journal of Medicine	N Engl J Med
Annals of the Rheumatic Diseases	Ann Rheum Dis
American College of Epidemiology	Am Epidemiol
BMJ Surgery, Interventions, & Health Technologies	BMJ Surg Interv Health Technol
General Psychiatry	Gen Psychiatr
Journal of Neurology, Neurosurgery &Psychiatry Research	J Neurol Neurosurg Psychiatry Res
American Journal of Obstetrics & Gynecology	Am J Obstet Gynecol
Current Opinion in Gynecology and Obstetrics	Curr Opin Gynecol Obste
Global Journal of Pediatrics &Neonatal Care	Glob J Pediatr Neonatal Care



22.9 How Should the References in the Vancouver Style Be Finally Listed?

- Article with 1 to 6 authors.



- For articles which more than 6 authors.

Same as above till six authors and then add et al

Lal AH, Amari JD, Johan IM, Chadha J, Sharma CL, Manan RJ, et al. Magnetic resonance cholangiopancreatography accurately detects common bile duct pathologies. J Am Coll Surg. 2005 ;2020(6):869-75.

Some journals require the issue number

- From electronic journals.

Shankar L, Tughak S. A study of research output from nurses in India from 2010-2020. J Nurs Scholarsh [Internet]. 2020 [cited 2020;43(1):89-96. Available from: http://search.proquest.com.ezproxy.lib.monnor.edu.au/docview/858241255?accountid=12528

Author AA, Author BB. Title of article. Abbreviated title of Journal [Internet]. Date of publication YYYY MM [cited YYYY Mon DD]; volume number (issue number): page numbers. Available from: URL

- Reference from a book.

Kakar A, Nundy S. HIV/AIDS-test and treat.1st edition. New Delhi: Jaypee publishers:2018 pp 212.

Author AA. Title of book. # edition [if not first]. Place of Publication: Publisher; Year of publication. Pagination.

- Reference from a chapter in a book.

Raveendran R, Wattal. C. Diagnosing Tuberculosis and Non tuberculosis Mycobacterium disease. In:Kakar A, Nundy S. HIV/AIDS-test and treat.1st edition. New Delhi: Jaypee publisher:2018. pp 95-.111.

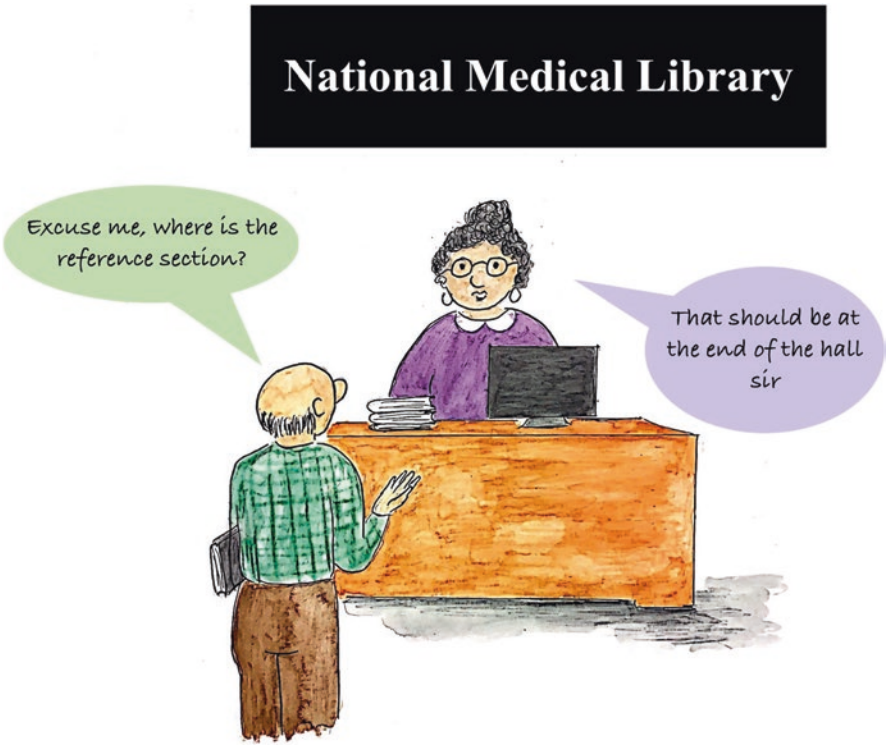
Author AA, Author BB. Title of chapter. In: Editor AA, Editor BB, editors. Title of book. # edition. Place of Publication: Publisher; Year of publication. p. [page numbers of chapter].

22.10 What Is a DOI?

The digital object identifier (DOI) is a unique identifier given to an article and should be listed in the references where it is available. This is usually provided if the journal style requires it and is placed at the end after the URL source:

Kumari P, kumar JD, Bhora RH . The effect of smoking on joint replacement surgery. Indian J Sports Med [Internet]. 2020 Dec [cited 2013 Feb 19];40(12):2872-8. Available from: http://ajs.sagepub.com/content/40/12/2872 DOI: 10.1177/0363546512458223

DOI number



22.11 What Is the Harvard System of Referencing?

This type can be used for journals, books, and e-portals [4]. This style is sometimes used in the United Kingdom and in Australia.

For a citation in the manuscript only the last name (surname) of the author is used; the authors' names and year of publication are not separated by a comma (,).

- For example, one author (Sharma 2020).
- For two authors (Sharma & Verma 2020).
- For three authors (Sharma et al. 2020).

Detailed references are listed on a separate page at the end of the document

- Each reference ends with a full stop (.).
- There is a double line spacing between each entry.
- Vivek Sharma is written as Sharma V and Anuj Kumar Verma is written as Verma AK.
- Thus, this can be referred.
  - For one author—Sharma V 2020, Corona virus infection and Rheumatoid arthritis. Indian J Arthritis.
  - For two authors—Sharma V, Verma AK 2020, Corona virus infection and Rheumatoid arthritis. Indian J Arthritis.
  - For up to 5 authors—Sharma, V, Verma AK, Soni PS, Chawla AK, Singh PK 2020, Corona virus infection and Rheumatoid arthritis. Indian J Arthritis.

Finally, the references in the Harvard style for a paper will look like the following.

Author. (Year)Title of the paper, Journal, volume (issue), pages.

The references in Harvard style from a book will be as given below.

Author. (Year)Chapters title. In: Editor. Name of book.
Edition, page number.

22.12 What Is a Reference Manager?

Reference Managers are software packages intended for authors of academic manuscripts to organize and sort their references [5]. Reference Managers are typically 'plugged in' directly to the researcher's word processing software or web browsers. By introducing a code associated with a given reference, such a manager will create and organize the references in the style required by the journal.

Citations can be inserted in the manuscript using the following methods:

- Manually—using software that comes standard with any Microsoft Word© package.
- Online resources.
  - Web of Science or Worldcat.
  - Free online search tools (e.g., Google Scholar, arxiv, IEEE Xplore, or PubMed.
  - Social collaboration networks for researchers (e.g., Mendeley Web, Zotero, or CiteULike.

The advantages are that you can change the style of the reference or change the number without much problem**.**

Many sites like PubMed Central help you to download the citation directly.

22.13 Conclusions

- A citation is acknowledging the work done by the original author and a reference is citing the source.
- The Vancouver and Harvard styles are the two most commonly used for medical writing.
- The references are usually placed at the end of the article.
- It is expected that the authors should have read all the references and the information provided is complete.
- It is best to keep an electronic record of all papers which have been cited till the article is published.

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How to Add Illustrations?

23

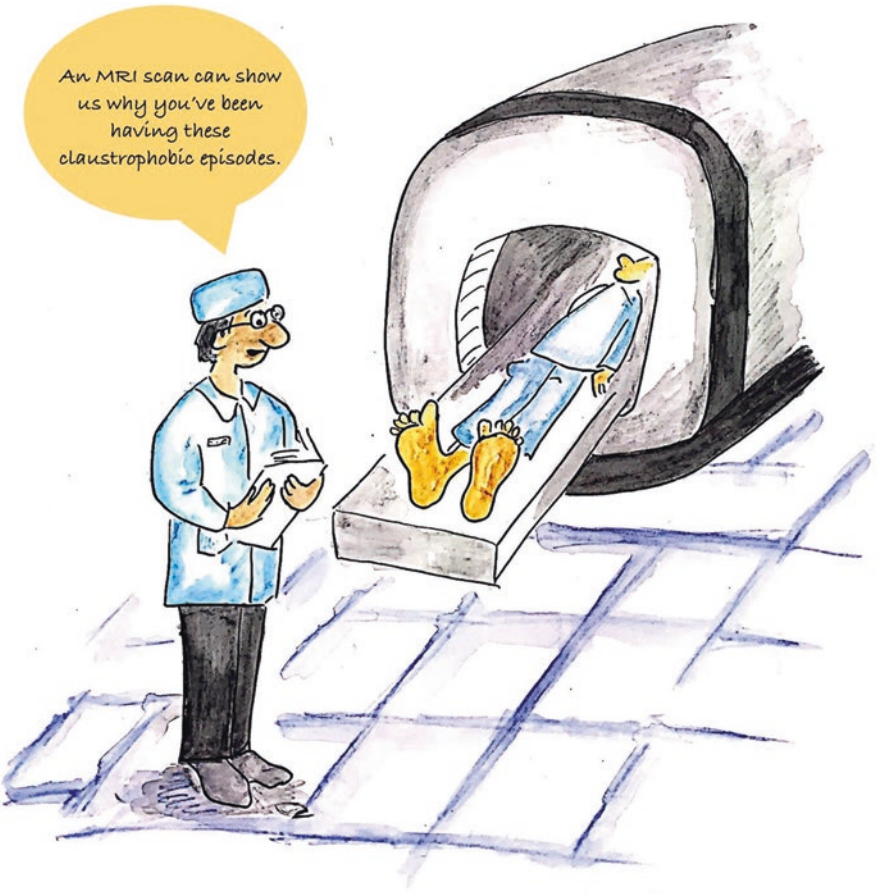
One picture is worth a thousand words.

Fred R. Barnard, English illustrator (1846–1896).

23.1 Why Is it Important to Add Illustrations to your Manuscript?

Adding illustrations to a research paper makes the manuscript more readable and attractive. As compared to text-only adding visual aids like radiological images (X-rays, ultrasounds, CT, PET or MRI scans), pathological material (gross tissues, cytopathology, histopathology) using new medical tools or kits which support your diagnosis improves the comprehension and recall for the reader [1]. Illustration is also an effective way of communication both for the doctor and also for the patient [2].

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_23



23.2 How Do Illustrations Help in Teaching?

Illustrations help in teaching students the subjects of anatomy, physiology, general surgery, pathology, radiology and neurosurgery [3]. For cardiology also learning through photos of echocardiography, angiography and endoultrasound helps in learning [4]. A doctor who is an artist also understands what needs to be shown in an illustration. The grasping power of the student also increases tremendously. Medical students depend a lot on illustrations to learn anatomical facts and supplement the knowledge given in their textbooks. Often, an illustration transmits pertinent fact or useful information much more successfully than words. They 'tell a story' through their drawings. For surgical disciplines especially learning through illustrations aids surgical technique. Thus, the use of illustrations is an integral aspect of teaching, learning, and communication.

23.3 What Medium Can be Used for Representation of Art in Medicine?

The commonest is the use of clinical or radiological photographs which are easy to capture using smartphones. They are handy and the illustrations are quite clear. Histopathological slides require special techniques to take images. A line diagram can be drawn with the help of a pencil or fibre tip black pen. For making posters, one can use poster colours or coloured pens. Nowadays creating digital illustrations are also possible. They are fast, easy to edit, and take less time. Newer digital tools like the Apple iPad, laptop, or Mac Pro can be also useful. Adobe illustrator and photoshop help to edit illustrations [5].

23.4 Can Illustrations be Submitted to Journals for Publication?

Many leading journals like the BMJ and NEJM accept images as a separate type of publication under the heading 'Images in Medicine' or 'image quiz'. However, the images should have the following qualities—they should be:

- Clear.
- Rare.
- Sharp.
- Uniquely educative.
- Having a good reproduction.

The image can be submitted either as a PowerPoint presentation or saved in the TIFF, JPEG, or EPS formats. The accompanying text should be saved as a Word document about 150–200 words long. This usually allows a maximum of two authors and not more than five references. No abstract is usually required.

23.5 What Are the Ten Important Unsaid Rules for Adding Illustrations to your Manuscript?

The important key ten points for adding images for the biomedical manuscript are given below [5, 6].

1. Add a picture that enhances the knowledge in the paper. Always cover the eyes. Many journals will ask for extra consent from patients if you are showing a clinical photograph. Figure 23.1 shows a 3D printed face mask.
2. Crop the image and, remove the date, name and all personal information from the photograph. The chest-X-ray on the left looks much better after cropping. However, do not crop so much that the pathology becomes unclear and one cannot make out which organ is being shown as shown in Fig. 23.2.

Fig. 23.1 New 3D printed design of a face shield to protect from COVID-19

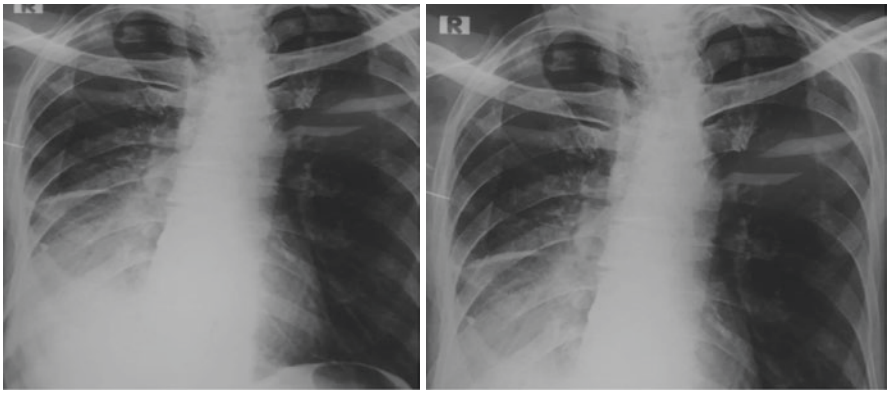


Fig. 23.2 Chest X-ray revealing right-sided lower zone opacity with fluid in the fissure

3. Add legends to illustrations. A Description or a Caption about the picture should always be included, otherwise one cannot focus upon what needs to be highlighted (Figs. 23.3 and 23.4) [1].
4. Avoid using abbreviations in the legend to the illustration.
5. **Allot** serial numbers to all figures and add a description of the photo in the text [6, 7].
6. Use arrows to show what you are highlighting. Figure 23.5 shows a muscle biopsy in patient with dermatomyositis.
7. You may show pictures before and after therapy to depict the improvement after treatment. Figure 23.6a and 23.6b depicts a pneumothorax in a patient with AIDS before and after treatment.
8. Make separate files for photographs in jpg or JPEG formats for submission.

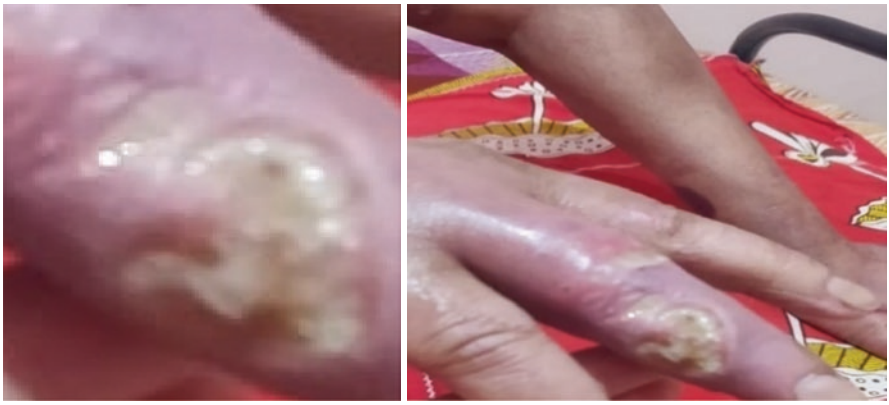


Fig. 23.3 Depicts Staphylococcal dactylitis in a diabetic patient

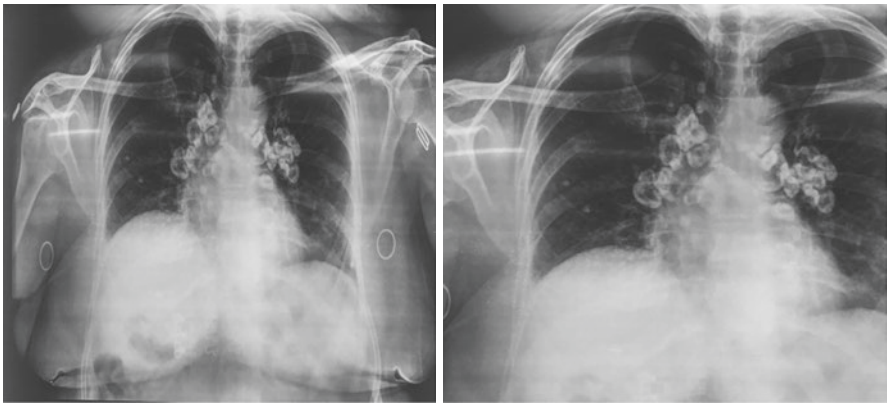


Fig. 23.4 Multiple calcified lymph nodes in a patient with Sarcoidosis

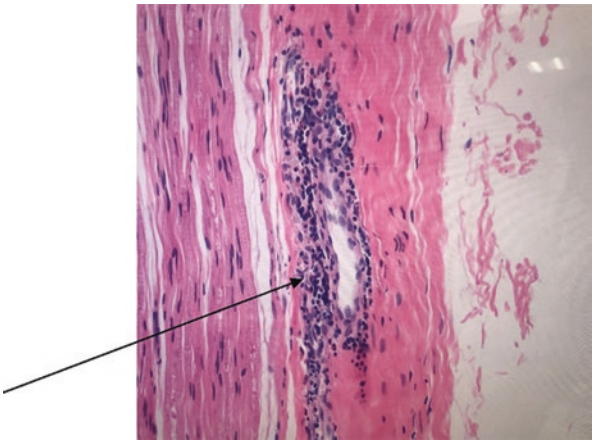


Fig. 23.5 Arrow points to perivascular infiltrates in a patient with Dermatomyositis

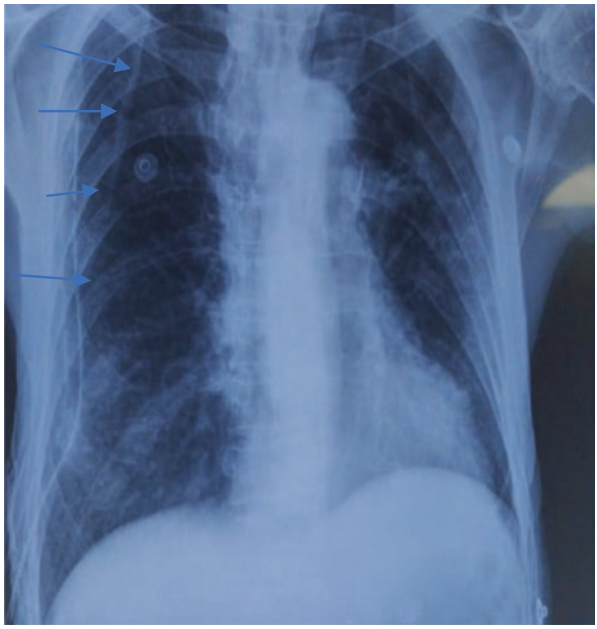


Fig. 23.6a Shows arrows pointing to the collapsed lung in a pneumonia

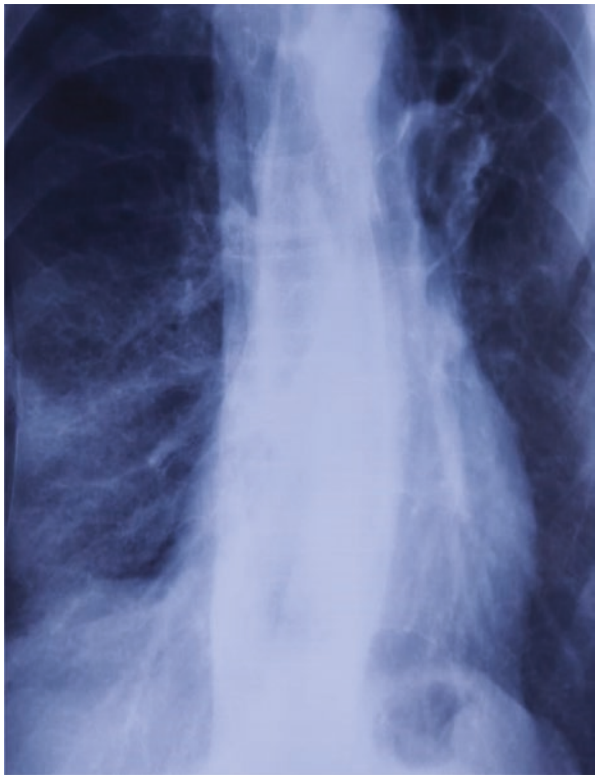


Fig. 23.6b The lung collapse has improved after chest tube insertion

9. Read the instructions to authors before preparing your manuscript regarding how many illustrations you are allowed to include.
10. Use cartoons or hand diagrams to supplement the understanding of the pathology.
11.

23.6 Conclusions

- When words alone are not enough, an image may be needed to explain a scientific process or promote clarity.
- Medical illustrations can help to demonstrate surgical techniques and simplify the burden of a complicated text.
- A good illustration helps to tell a story. Images are effective tools in medical education.

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How to Check for Plagiarism?

24

Copying from one it's plagiarism, copying from two it's research.

Wilson Mizner, American playwright, raconteur and entrepreneur (1876–1933).

24.1 What Is Plagiarism?

The word 'Plagiarism' has been derived from the Latin word 'Plagiare' which means 'to kidnap or abduct'. In scientific literature, it means the 'wrongful appropriation' and 'stealing and publication' of another author's 'language, thoughts, ideas, or expressions' and depicting it as one's own creative work. Plagiarism amounts to academic untruthfulness and a breach of journalistic integrity [1].

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_24

24.2 Why Is Plagiarism So Rampant in India?

There are many reasons why plagiarism is common in India. There is the compulsory thesis before the final postgraduate examination which students need to finish in time so they find the 'cut and paste' technique to be a convenient shortcut to writing the manuscript or even doing the research. The other reason is that they have never attended research methodology workshops where plagiarism is discussed. They do not know that plagiarism is a serious offence that can be punished with suspension or expulsion from their institution in other countries. The unfamiliarity with the English language, lax checking by their supervisors and an absence of punishment are other reasons for this. Plagiarism reflects the poor standards of our medical publications [2]. However, it is also a global phenomenon and not unique to India [3].

24.3 What Action Can Be Taken Against you if your Manuscript Is Found to be Plagiarized?

All types of plagiarism can attract disciplinary action which may range from removing the published paper, legal and monetary repercussions and academic and professional damage to your reputation. All good journals and many universities check the manuscripts for this through online checking systems which are now widely available. We should have a 'zero tolerance policy' for such acts.

24.4 Does Plagiarism Apply Only to Written Text?

No, this statement is not true as plagiarism applies to text in manuscripts as well as images, clinical photographs, tables, graphs, and pictorial data.

24.5 Is There a Gazette of India Notification on Plagiarism?

Yes**,** the University Grants Commission (UGC) has a regulation, dated 31 July 2018 regarding promotion in academic institutions and on the prevention of plagiarism. It defines 20 terms like plagiarism, author, academic integrity, script, source, etc. It also describes a penalty for a plagiarized thesis and dissertation. It also mentions that all students should submit a soft copy of their theses or dissertations to some central information and library centre [4].

24.6 What Is the UGC's Classification of Plagiarism?

In 2018, it classified plagiarism in educational institutions into various levels. If similarity is less than 10%, no action is taken. However, if the level of plagiarism increases above this, the action given below is recommended [4, 5].

- Level 1—10–40% similarity. No marks or credits shall be awarded for the plagiarized script. The revised manuscript should be re-submitted within 6 months.
- Level 2—40–60% similarity. No marks or credits shall be awarded for the plagiarized script. The student is entitled to resubmit the revised script after 1 year but not exceeding 18 months.
- Level 3—above 60% similarity. No marks or credits shall be awarded for the plagiarized script. Registration for the course itself is cancelled.

24.7 What Are the Sections in Articles which Are Excluded from Plagiarism Checks?

The areas which are excluded are: [4].

- Quoted statements (quoted work can be reproduced with all the necessary permissions).
- References/Bibliography.
- Table of Contents.
- Preface/Acknowledgements.
- Standard symbols/Generic terms.

24.8 What Do Words Quote, Paraphrase and Similarity Mean?

A quote is using or repeating the same words as in the original text. If this is done it should appear under inverted commas. For example, Hippocrates stated 'I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous'.

A Paraphrase is rewriting the original idea in our own words. While doing paraphrasing the central concept or the meaning of the text is not changed.

Similarity is copied text and is like the original text. The original and the text written are exactly the same.

24.9 What Are the Various Types of Plagiarism? [6–8]

1. Total or Complete Plagiarism

   This depicts a severe form of plagiarism. In this, the investigator passes off someone else's script or study as his own, and submits it under his own name.
2. Direct Plagiarism

   Direct or verbatim plagiarism is a type of complete plagiarism when one section of the text is copied rather than the whole text.

3. Self- or Auto-plagiarism
   Auto-plagiarism, also known as self-plagiarism or duplication, happens when authors reuse sizeable portions of their previously published work without attribution.
4. Paraphrasing plagiarism
   This is the most common type of plagiarism seen among students. It involves the use of the original author's manuscript after making some minor changes in the sentences and creating a new article.
5. 'Cut and paste' plagiarism
   This type of plagiarism is becoming common among students because of the easy accessibility of scientific information on the internet.
6. Mosaic/patchwork plagiarism
   Mosaic plagiarism may be difficult to detect because it interposes someone else's a few sentences or paragraphs within the text.
7. Accidental Plagiarism
   This can be either intended or unintended. Even for this, there is no excuse and the consequences are often the same.

24.10 How Can we Check for Plagiarism?

Many sites are now available - free or paid. Grammarly©, Whitesmoke©, Prewriting aid©, Duplichecker©, Plagarism © Check.org©C, Quetext ©, small SEO plagiarism checker©, copytext©, viper©, checkforplagiarism.net©, Wordpress Plugin©, Plagium©, etc.

24.11 How Does a Plagiarism Report Appear?

Once a check is done, the report looks similar to the Fig. 24.1. The lines and sentences which have been copied are highlighted in various colours as is the source from which it has been copied.

24.12 How Much Plagiarism Is Usually Allowed for a Paper to Be Accepted?

When it is an original paper, the author should aim at zero plagiarism. However, in many journals, a similarity of up to 15% is allowed. For a chapter in a book, this limit is about 5% and in a thesis, less than 10% is accepted.

Fig. 24.1 Review in an article with 92% plagiarism, along with the sources (published with permission editor—Current Medical Research and Practice)

24.13 What Is the Difference between Plagiarism and Copyright Infringement?

Plagiarism is claiming credit for a work you did not do or using someone else's work without proper attribution.

Copyright infringement is a broad term covered under the law. In this, an author uses someone else's work without obtaining their permission.

24.14 What Are the Five Rules for Avoiding Plagiarism?

- Plan to finish your project well in time before submission.
- Recognize the concept behind the manuscript you need to cite.
- Never do 'copy–paste'; it seems to be a shortcut but eventually it takes double the time to correct the mistakes.
- Use your own language to build up the manuscript.
- Use an online plagiarism device to check before final submission.

24.15 Conclusions

- Plagiarism is a type of research delinquency that consists of copying someone else's work or idea without giving him proper credit.

- Plagiarism extends not only to the text but also to tables, charts and pictures.
- An awareness about the risks of plagiarism is low among the students and researchers in developing countries.
- To avoid the copy–paste culture, students should be instructed to read articles completely and carefully and then write a paper in their own words.

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How to Improve the Language and Syntax in Medical Writing?

25

The ideal of communication is that a clear message goes straight from the writer's brain into the reader's brain. However, it very rarely does go in a straight line because there are distractions. These distractions cause the message to meander about and generally cloud what you are trying to say.

William Whimster, British Pathologist (1934–1997).

25.1 What Is the Importance of Using Correct English in a Medical Paper?

Although India is the second-largest country in the world where the English language is spoken, we often use it incorrectly and tend to be verbose. When it comes to writing skills, we use convoluted phrases and complex words when simple ones would do. A medical paper does not need to be written in theatrical or Shakespearean English. We should express ourselves using short words and simple sentences which convey to a reader why we did the study, how we did it, what the results were and whether they are important, what is known about the subject and what your paper adds. Often, even if your article contains good science it may be rejected by Western journals because you did not state clearly what you wanted to convey. We need to improve not only our scientific endeavours but also our writing skills to be accepted for publication in the world's best journals.

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_25

25.2 What Are the Common Challenges Faced by Developing World Authors with Regard to Writing English?

One of our major problems is that English is not the mother language for most of us [1]. We think in our native languages and then convert into English and this makes the final product a bit difficult to understand. However, we cannot get away from the fact that English is the medium of writing which is required by nearly all medical journals. The global demand for English is constantly increasing because it removes the barriers to scientific communication. Helps disseminate knowledge and improves the visibility of your work [2].

Another problem which we face is that English communication skills are never discussed in medical college courses or in any research methodology workshops. This has to be addressed urgently and it has been proposed that English writing should be integrated into science programmes in non-English speaking countries as it is the language used in 95% of all cited articles [3].

25.3 What Is the Fate of a Poorly Written Manuscript?

Once received at the editorial office if the script does not comply with basic language standards, it may be rejected outright. Most leading journals have to deal with many more submissions than they can cope with and will not waste time trying to correct those written in bad English. Some others who may be more charitable may send the article for peer review, where the referee is unlikely to look upon it favourably if it is written badly [4].

25.4 Are There Any Words in English Which Sound Alike but Have Different Meanings?

English cannot be learned overnight especially if it is not your mother tongue [5]. There are some words that sound alike but have different meanings. These words are called 'Homophones' (Table 25.1).

25.5 What Is Redundancy?

Redundancy means the use of extra or excessive use of unnecessary words. These include repeating information in the written manuscript, tables and Figs. A common form of redundancy occurs when a writer lines up 2 or 3 synonyms in the same sentence. The meaning may be clear even after the use of the first word. An example of this is using 'accurate, exact, and precise' in one sentence whereas it can be replaced by any of one word.

Table 25.1 Confusing words in the medical literature

Word	Meaning
ABDUCT ADDUCT	To move away from a position parallel to the median axis. To move towards a position parallel to the median axis
ADVISE ADVICE	To give counsel to; offer an opinion or suggestion An opinion or recommendation offered as a guide to action, conduct
ABERRANT APPARENT	Wandering or deviating from the normal; abnormal. Visible, obvious, evident.
EFFECT AFFECT	As a result of Influence
PRINCIPLE PRINCIPAL	Fundamental fact or assumption Head of teaching Institute or school
ACCESS AXIS	Admittance; 'access to' A real or imaginary straight line going through a structure around which it revolves, or would turn if it could revolve
ANURESIS ENURESIS	Inability to urinate; total lack of urine Bedwetting.
HYPOPHYSIS HYPOTHESIS	Pituitary gland A theory that appears to explain certain phenomena
CITE SIGHT	To quote; to relate an incident Vision
PERFUSE PROFUSE	To flow or spread, such as blood or lymph Lavish, extravagant, bountiful.

Table 25.2 Roundabout words

Original	Suggestion
The authors	we
The majority of	most
In a routine manner	Routinely
In order to	to
For the purpose of	for

25.6 What Are Roundabout Words?

Roundabout words are ways in which as many words as possible are used when one or two will do. Table 25.2 represents some examples of these. The problem with using roundabout words is that they increase the word count of an abstract or text when more important information needs to be conveyed. Writing succinctly is another important aspect of language skills.

Examples.

Original: 'The experiment, which was just published, highlights numerous challenges of importance'.

Suggested revision: 'The recently published study highlighted several important challenges'.

Table 25.3 Examples of Indianisms

Indianism	Correct English
Are you having a paper?	Do you have a paper?
Let us discuss about the results	Let us discuss the results
What is the good name of author?	What is the author's name
I myself will do the experiment	I will conduct the experiment
I will start the experiment at 9 am in the morning	I will start the experiment at 9 am
The entrance of the lab is from backside	The entrance of the laboratory is from the back

25.7 What Are Some Examples of Indianisms?

Indianisms refer to terms or phrases which are typical of Indian English and refer to the way a sentence has been designed as if it was directly translated from an Indian language. Some examples of common Indianisms are in Table 25.3.

25.8 What Is a Thesaurus?

A Thesaurus is a book that lists words or groups of related concepts or synonyms. It is very useful to refer to when writing a paper and is available on Microsoft Word. All you have to do is to highlight the word, right click and then select the synonyms [6].

25.9 What Is Hedging?

In biomedical research, it is sometimes necessary to be careful in one's statements to distinguish between known facts and purported claims. This is commonly known as 'hedging'. Hedging is encouraged in scientific writing as it uses non-commital or vague statements [7].

- **Introductory verbs**—seem, tend, look like, appear to be, think, believe, doubt, be sure, indicate, suggest.
- **Certain lexical verbs**—believe, assume, suggest.
- **Modal adverbs**—possibly, perhaps, conceivably.
- **That clauses**—It could be the case that…, it might be suggested that…, there is every hope that….

25.10 What Is Syntax?

Syntax is the 'arrangement of words and phrases to create well-formed sentences in a language'.

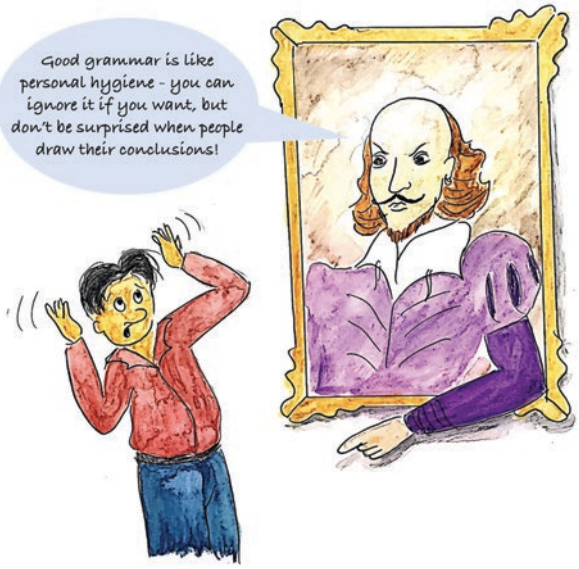
Examples:

Wrong syntax—The handwashing technique with soap in COVID-19 and also alcohol-based sanitizers is described.

Correct syntax—The technique for handwashing using soap or alcohol-based sanitiser for preventing COVIV-19 is described.

25.11 In What Tense Should an Article Be Written?

If it is a project report or protocol it should be written in the *future* tense [8]—'we will conduct the study under all aseptic conditions' or 'laparoscopy will be performed in all emergency obstructed hernias during this trial'. Once the work is completed and you are writing the article you should use the *past* tense. It should now be written as 'we conducted the study under all aseptic conditions' or 'during the trial laparoscopic repair was done in all patients with obstructed hernias'.



25.12 Are There any Online Grammar Correction Sites?

Yes, there are. Grammarly software can be downloaded and is useful for checking spelling, grammar and also for plagiarism. Writers from non-English speaking countries can also be helped by using Ref-n-write website. Sci flow is an online portal that helps in improving writing skills and has citations as well [9–11].

25.13 Can External Editing Agencies Help in Improving Language?

Many authors whose native language is not English are using these services. However, there are many ethical issues involved. These agencies help the author with queries from the editor, revising the manuscript and, at times, unfortunately providing the wrong data. These agencies also provide the authors and editors with fake peer reviews accounts which help in publication.

Besides this many physicians hire professional authors to help in their publications and it is estimated that medical writing is the fourth most commonly outsourced clinical service.

25.14 What Are the General Instructions for Using the English Language in a Research Paper?

1. Use simple sentences (containing words of less than three syllables) with no flowery words.
2. Write short paragraphs starting with a central theme and end with a link sentence to the next paragraph.
3. Make sure ideas flow smoothly one after the other.
4. Use grammar and spellchecking tools which are available online. Misspelled words annoy editors.
5. Revise the manuscript at least five times and get it looked at by two knowledgeable and experienced colleagues.

25.15 Conclusions

- A good scientific content but poorly written English is a source of distraction to editors.
- Construct short readable sentences and avoid tortuous ones.
- Use the past tense if your experiment has already finished.
- Use commas carefully as extra commas can change the meaning of a sentence.

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Part V

How to Write Other Journal Articles?

How to Write an Editorial?

26

Editorial writers enter after battle and shoot the wounded

Neil Goldschmidt, American Businessman and Politician (1940–…)

26.1 What Is an Editorial?

An Editorial is defined as an opinion or a view of a member of the editorial board or any senior or reputed faculty written in a journal or newspaper. The statement reflects the opinion of the journal and is considered to be an option maker. If you have been asked to write an editorial it means that you are an expert on that topic. Editorials are generally solicited.

26.2 How Is the Topic for an Editorial Chosen?

This is decided by the members of the editorial board and is usually related to important work which is about to be published in the journal. If you are invited to write an editorial on a topic of your choosing you should preferably write one on a general or public health problem that might interest a wide readership [1].

26.3 What Should be the Contents of an Editorial?

It has been said that 'Editors, by and large, are reticent people, with a magnified sense of their own importance. Well, this may hurt some, but before they jump at our throats, let us clarify that we belong there as well'. The editorial should not look like an introduction to an original article or a self-glorifying piece of fiction.

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_26

Editorial writing has been compared to a double-edged sword, you can be apolitical and pragmatic but at the same time dogmatic in your views. The majority of editorials provide the readers a balanced view of the problems raised in a particular research paper and place them in a wider context. But there is no harm in going to extremes if the data supports your view. However, you should not mock the paper's authors [2].

26.4 What Is the Basic Information Required for Writing an Editorial?

First, read the paper for which the editorial has been asked again and again. Do a literature search and critically analyze the strengths and weaknesses of the study. Read about how and why other authors came to similar or different conclusions. Discuss whether or not the findings are important [3].

An editorial should be brief, about one to two pages long, but it should be powerful. The language should be a combination of good English and good science. The writing can be 'embellished by language but not drowned in it'. While a good editorial states a view, it does not force the reader to believe it and gives him the liberty to form his own opinion.

26.5 What Are the Steps Involved in Writing an Editorial?

These are:

- Choose a topic intelligently.
- Have a catchy title.
- Declare your stance early.
- Build up your argument with data, statistics and quotes from famous persons.
- Provide possible solutions to the problem.
- Follow a definite structure consisting of an introduction, a body that contains arguments and an end with a tailpiece of a clear conclusion. It should give the reader a chance to ponder over the questions and concerns raised.

26.6 What Are the Types of Editorial?

Editorials can be classified into four types. They may:

1. ***Explain or interpret***: Editors use this type of editorial to explain a new policy, a new norm or a new finding.
2. ***Criticize:*** this type of editorial is used to disapprove of any finding or observation.
3. ***Persuade:*** These encourage the reader to adopt new thoughts or ideas.
4. ***Praise:*** These editorials admire the authors for doing something well.

26.7 What Is the Purpose of an Editorial?

An editorial is a personal message from the editor to the readers. It may be a commentary on a published article or topic of current interest which has not been covered by the journal. Editorials are also written on new developments in medicine. They may also cover non-scientific topics like health policy, law and medicine, violence against doctors, climate change and its effect on health, re-emerging infectious diseases, public interventions for the control of non -communicable diseases and ongoing epidemics or pandemics [4].

26.8 What Are the Instructions for Writing Editorials in Major Journals?

Many editorials written by in-house editors or their teams represent the voice of the journal. A few journals allow outside authors to write editorials. The details for these suggested by some of the leading journals are given in Table 26.1.

26.9 What Is a Viewpoint?

A Viewpoint is a short article that focuses on some key issues, cutting-edge technology or burning topics or any new developments in the field of medicine. It can be a 'personal opinion' or any piece of information, which gives the author's perspective on a particular issue, supported by the literature. Viewpoints can also be unencumbered by journal policy. The normal length of viewpoints can flexible. The BMJ, for instance, also allows viewpoints to be written by patients.

Viewpoints may share a few common features with commentaries, perspectives and a focus which is a brief, timely piece of information. It is like a 'spotlight' that contains information on research funding, policy issues and regulatory issues

Table 26.1 Details about Editorial

Journal	Word limit	Instructions
British Medical Journal	800	• Editorials are usually commissioned • They no longer accept unsolicited editorials • Topic should be of current interest • It should be evidence based • Should interest an international audience • Authors with financial ties to industry are not generally invited
New England Journal of Medicine	750	• Offers commentary and analysis on a current-issue NEJM article. • Maximum of one figure or table • Up to ten references

whereas a commentary is an in-depth analysis of a current matter which can also include educational policy, law besides any other seminal issue.

26.10 Conclusions

- An editorial is written to provide a crisp, concise overview of an original article. It is generally deemed to be an honour to be asked to write an editorial.
- One needs to follow the general instructions for writing editorials for a particular journal.
- It should have an objective and the flow of ideas should be clear.

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How to Write a Letter to the Editor?

27

Great writers experience their dreams. They put them on paper, where others can read about them.

Ellen J. Barrier, American author (……)

27.1 What Is the Purpose of a Letter to the Editor?

Most journals have a section called 'Letters to the Editor', the purpose of which is to obtain feedback from the readers on an article regarding whether they have a different interpretation of the results, wish to provide constructive comments or clarify any missing links in the piece [1, 2]. This is usually in the form of a short communication and written in response to original articles, case reports or reviews. The editors prefer this type of communication to be sent online initially as it is quicker and for the person who writes such a letter it is an additional publication when it is printed.

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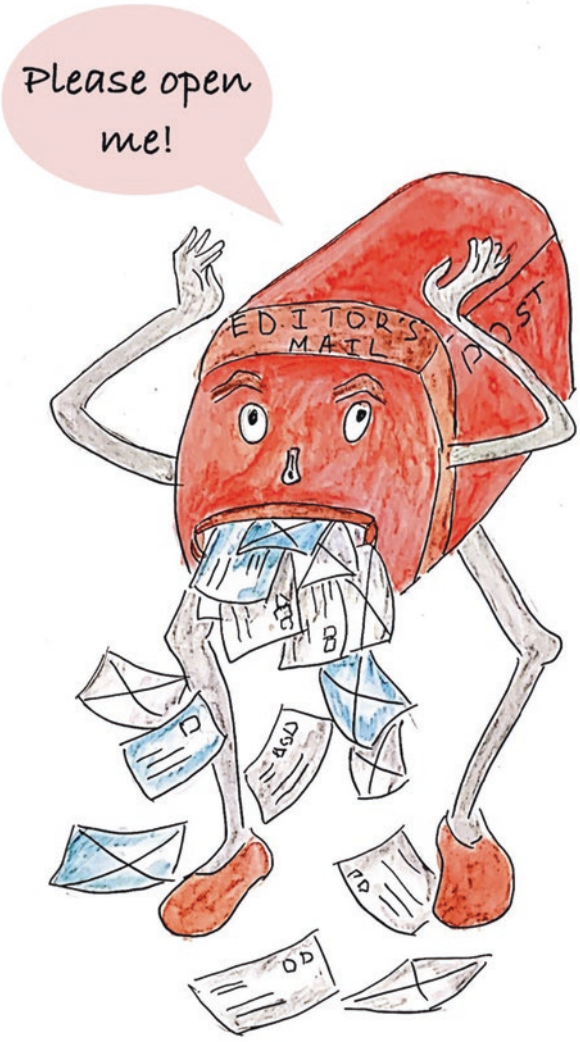

27.2 How Is a Letter to the Editor Published?

Generally, all articles published in reputed journals have been carefully peer-reviewed. However, occasionally, confusing data are still published which have been overlooked by the editors. In this situation, a reader sends a letter to the editor indicating his opinion about the manuscript. Once the editorial office decides that the letter is relevant it sends this to the corresponding author of the article. Both the letter and the author's reply are then published in a subsequent edition of the journal. The International Committee of Medical Journal Editors recommends that the letter and its answer should be published together [3]. Besides, some

MEDLINE-indexed journals print these letters with their responses under the title of original articles to avoid them escaping the attention of their readers.

27.3 What Are the Types of Letters to the Editor?

There are two types: [1]

1. The common variety—a commentary on previously published material in the journal. The comment can be positive or negative. It may also give suggestions, feedback on any data which has been missed or is lacking in the manuscript.
2. Uncommon variant—this piece of information is new for the journal and may include general comments on health care, patient-related policies or the quality of the journal.

27.4 What Are the Practical Tips for Writing a Letter to the Editor?

The letter should be short and should have a clear purpose [4]. Table 27.1 provides an overview.

Table 27.1 Overview of letter to the editor

Purpose	To provide missing information to the authors
Title	Crisp and informative
Word count	*For Letters in response to an article published* • up to 175 words • Must be received within three weeks after publication of the article *For letters not in response to an article published* • up to 400 words • title, references are not counted in both categories • no abstract is required
Authors	May be signed by up to three authors
References	May include up to five references and one figure or table • no need to give acknowledgments in the correspondence section.
How do we start?	Dear Editor, We read the original article entitled 'Medical Treatment for gallstones' by Ak et al. published in the April issue of your journal. We want to congratulate the authors for this informative article and make some suggestions.
Avoid	Being rude Mentioning general information Repeating the text of the original article Giving your personal opinion Making personal remarks against the author
Include	Evidence-based opinion A clear message Have a one-line conclusion

27.5 Conclusions

- Letters to the editor are of two types, in response to scientific information published in the journal or to provide new information.
- The larger number of letters received the greater is the popularity of the journal.
- After journal clubs students should be encouraged to write letters to the editors about any information in an article they find that is missing or unclear.

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How to Write a Case Report?

28

> To become an academic expert takes years of studying. Academic experts are experts in how and what others have done. They use case studies and observation to understand a subject.
>
> Simon Sinek, American Author (1973–)

28.1 What Are the Various Types of Medical Publications?

The various types of medical publications include:

- Original articles
- Review articles
- Letters to the editor
- Commentaries
- Case reports
- Personal communications
- Students' page
- Images

28.2 What Is the Importance of a Case Report in the Medical Literature?

Case reports are either based on a rare disease or a rare manifestation of a common disease. They can also highlight an unusual clinical situation or a non-conventional treatment. For many authors, it is the first exposure to the world of publication [1]. According to Vandenbroucke, 'Good case reporting demands a clear focus, to make explicit to the audience why a particular observation is important in the context of existing knowledge' [2].

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_28

Case reports used to be one of the sections in prominent journals and came with a clear message. However, many journals are now removing them to achieve a higher impact factor as case reports are not cited [3]. However, there is often a lot to learn from a case report about a new idea that can pave the way towards future research [4, 5]. Notwithstanding that in the medical hierarchy they are thought to provide a very low quality of evidence (Fig. 28.1) [6].

28.3 How Do We Write a Case Report?

A case report should tell a good story. While writing it you need not follow the IMRAD format of introduction, methodology, results and discussion (Table 28.1). The title should be brief, catchy and informative. The CARE guidelines for case reports can help writers with writing and also with the checklist [6].

28.4 What Are the Qualities of a Good Case Report?

A good case report should have quality, novelty, exceptional interest, conciseness, may be about rare disorder and relevant to medical practice. It may provide new information which can be developed into a hypothesis for further testing.

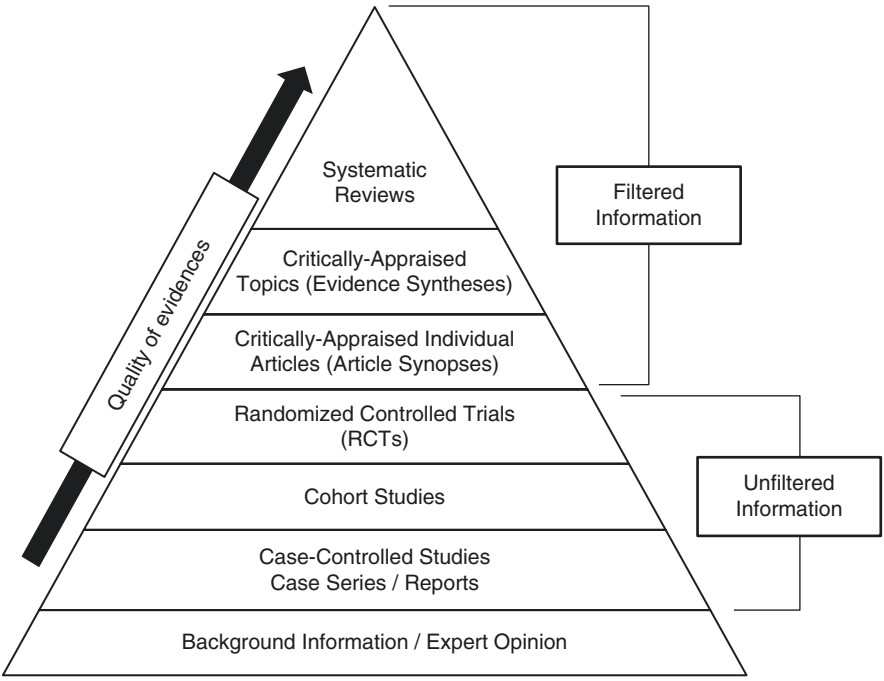

Fig. 28.1 Hierarchy of medical publications

Table 28.1 How to write a case report?

Abstract	An unstructured abstract is sometimes required of about 100 words It should highlight the new data or ideas presented or pose a clinical problem Provide 3–5 keywords (helps in electronic searching)
Introduction	Include in this section what is new. New disease, new manifestation, new laboratory report, new treatment or rare disease, common disease with a rare manifestation
Case history	Describe the case, include the clinical impression or differential diagnosis, laboratory tests & treatment and follow up
Images	Clinical images (radiological or pathological are most important)
Discussion	Highlight what is usual, learning points What is unique in your case, compare with previous reports Lessons learned from managing such a patient
Conclusion	One single paragraph, take-home points
References	Only relevant ones, some journals allow up to 10
Informed consent	A few journals require this, CARE guidelines have added a patient's perspective in this list
Appendices	If necessary

28.5 What Are the Limitations of Case Reports?

Case reports may have many scientific restrictions. Some of these are listed below:

1. No generalizations can be made based on a single case report of a disease and few inferences can be drawn for managing such cases in the future [7].
2. Case reports highlight success stories in 90% [8]. Very few doctors report their failures and few editors are likely to publish these.
3. They do not generate any epidemiological data.
4. 'Anecdotal fallacy' is the term used to describe overinterpretation or misinterpretation of data associated with case reports [9].
5. The data are retrospective and sometimes based on recall.

28.6 Are There Any Journals Which Publish Only Case Reports?

There has been a surge in the number of case reports offered for publication and to cope up with this demand some publishers, mainly for commercial considerations, have introduced many journals which only publish case reports. [10] The citation index of the majority of them is less than 1. Some of these are listed in Table 28.2.

Table 28.2 Journals which accept case reports

Journal	Website
Journal of Medical Case Reports	https://jmedicalcasereports.biomedcentral.com
American Journal of Case Reports	https://www.amjcaserep.com/
BMJ Case Reports	https://casereports.bmj.com/pages/
Journal of Radiology Case Reports	https://www.radiologycases.com/
Epilepsy and Behaviour Case Reports	https://www.journals.elsevier.com/epilepsy-and-behaviour-case-reports
Gynaecologic Oncology Reports	https://www.journals.elsevier.com/gynecologic-oncology-reports
Journal of Surgical Case Reports	https://academic.oup.com/jscr
Journal of the American Academy of Dermatology	https://www.jaad.org/
De Gruyter's Case Reports in Perinatal Medicine	https://www.degruyter.com/view/journals/crpm/
Indian Journal of Case Reports	https://www.journalonweb.com/ijcr/
Case Reports in Medicine	https://www.hindawi.com/journals/crim/

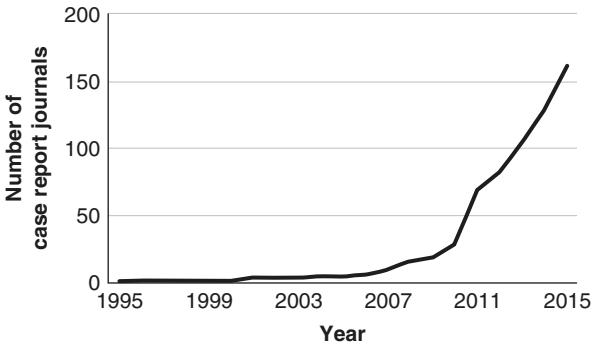

Fig. 28.2 Number of case report journals

28.7 What Are the Reasons That the Number of Case Reports Is Increasing?

Between 1946 and 1976, case reports accounted for 38% of all articles published in three premier journals, i.e., Journal of the American Medical Association, the Lancet, and the New England Journal of Medicine [11]. From 1971 to 1991, there was a reduction in the number of case reports published in these journals who began to publish more randomized controlled trials and systemic reviews which carried more scientific credibility [12]. After 1991, there was a surge of case reports submitted and published globally mainly to fulfil academic requirements for promotion and prestige. In 2016, there were more than 160 journals that published only case reports [10]. Figure 28.2 shows the increase in the number of journals that only publish case reports.

28.8 Conclusions

- Descriptions of interesting and rare cases are sometimes accepted by some journals but there are few prestigious publications that carry case reports.
- Case reports provide a low quality of evidence but if their message is clear they can provide their readers information about a new test or treatment.

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Systematic, Scoping and Narrative Reviews

29

29.1 What Is a Systematic Review?

A Systematic Review is an attempt to distill the essence of a large number of studies in medicine by first asking a research question and then first identifying and later synthesizing carefully chosen studies of a high quality which might provide the answers. A more precise definition is 'a summary of the medical literature that uses explicit and reproducible methods to systematically search, critically appraise and synthesise the results of multiple primary studies related to each other by using strategies to reduce bias and random errors' [1].

In 1979, Archibald Cochrane, a Scottish doctor, proposed: 'It is surely a great criticism of our profession that we have not organised a critical summary, by specialty or subspecialty, adapted periodically, of all relevant randomised controlled trials'. Cochrane was one of the founding fathers of evidence-based medicine (Fig. 29.1). He highlighted and advocated the importance of critically summarizing the findings of research studies and designated the systematic review as a method of providing such a summary. This ultimately led to the development of the Cochrane Collaboration in 1993 [2]. The findings of systematic reviews are now widely used for clinical decision-making and have become integral towards the development of sound clinical practice guidelines and recommendations. In fact, they now occupy the summit of the pyramid for the quality of evidence.

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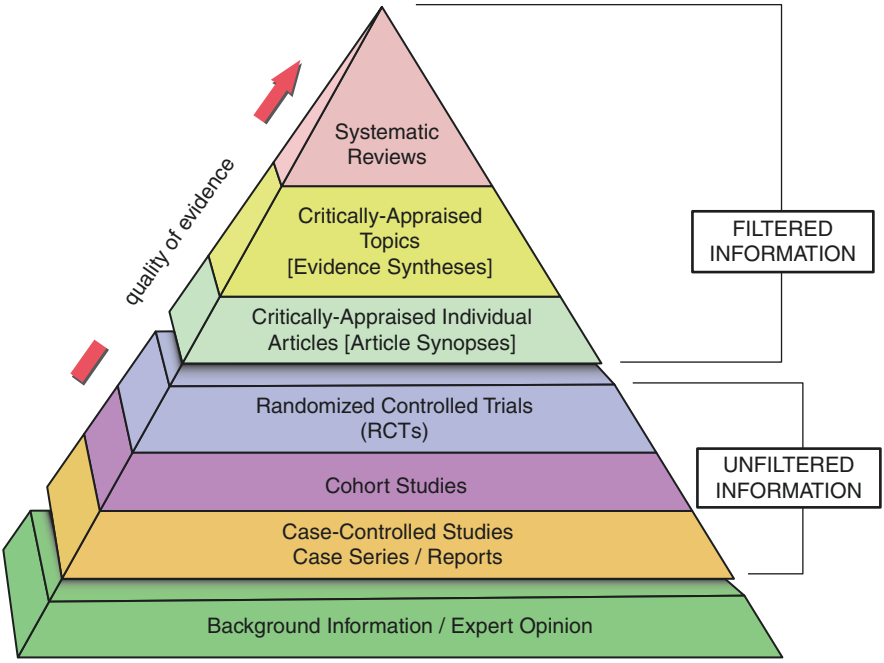

Fig. 29.1 Shows the quality of evidence from various types of research papers

29.2 How Is a Systematic Review Done?

It is done using the following steps:

Step 1—Defining the research question clearly and formulating criteria for which reports to include.

Searching for and selecting these studies and collecting their data. This will involve a review of all the available databases and citation indexes like the Web of Science, Embase, PubMed and others using different search technologies or even artificial intelligence-based tools. Each study should conform to the PRISMA (Preferred Reporting Items for Systemic Reviews and Meta-Analyses) guidelines or the standards of the Cochrane Collaboration [3].

The PRISMA guidelines (Fig. 29.2) are steps that depict the flow of information through the different phases of a systematic review. It maps out the number of records identified, included and excluded, and the reasons for exclusions.

Step 2—Assess their risk of bias. The review should use an objective and transparent approach for collection and synthesizing the data to minimize bias.

Step 3—Analyse the data and undertake a meta-analysis. This may involve using complex statistical methods and the more data that is analyzed the more confident we can be of the result.

Step 4—Write conclusions. Present the results and summarize the findings. Interpret the results, draw conclusions and suggest a message.

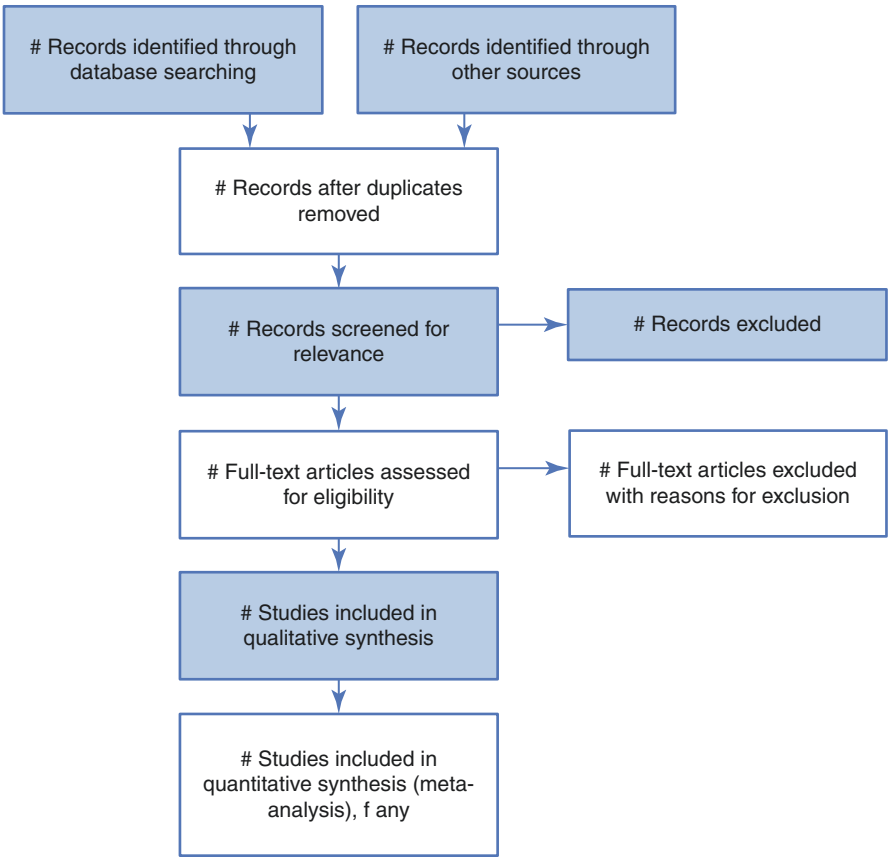

Fig. 29.2 PRISMA guidelines

29.3 Why Is a Systematic Review Useful?

Many clinical decisions are guided by published studies but, unfortunately, there are now too many to choose from for a busy clinician. These studies often vary in their design, methodological quality, population involved and the intervention or condition considered. To take a rational clinical decision involves trying to reconcile the results of studies that provide different answers to the same question. Because it is often impractical for readers to track down and read all of the primary studies, systematic review articles are an important source of summarized evidence on a particular topic [4, 5].

29.4 What Are Its Weaknesses?

Most systematic reviews focus on a single question when more than one may be relevant in a particular situation, e.g., the best treatment for variceal bleeding in a developed country may be endoscopic sclerotherapy but not in a person in a

developing country who is poor, has good liver function and does not have access to sophisticated medical facilities. In him or her a portosystemic shunt operation and a one-time procedure may be the more appropriate.

Then search strategies are often not provided in detail, the selection of studies may be biased, and only the positive results may reach publication. It also takes about 6 months to complete a single systematic review [6, 7].

29.5 What Is a Meta-Analysis? How Does It Differ from a Systematic Review?

A meta-analysis is a summary of data collected from multiple sources by collating it and helping to frame guidelines. While a systematic review includes the entire process of collecting, reviewing and presenting all available evidence, a meta-analysis only refers to the statistical technique of extracting and combining the data to produce a summary [7, 8].

29.6 What Are Scoping and Narrative Reviews? How Do They Differ from a Systematic Review?

A Scoping review is a preliminary assessment of the potential size and scope of the available research literature. It aims to identify the nature and extent of research evidence (usually including ongoing research) and present an overview of a potentially large and diverse body of literature pertaining to a broad topic. In contrast, a systematic review attempts to collate empirical evidence from a relatively smaller number of studies pertaining to a focused research question.

A Narrative review is the type first-year college students often learn as a general approach. Its purpose is to identify a few studies that describe a problem of interest. Narrative reviews have no predetermined research question or specified search strategy, only a topic of interest. They are not systematic and follow no specified protocol. No standards or protocols guide the review. Although the reviewers will learn about the problem, they will not arrive at a comprehensive understanding of the state of the science related to the problem [9, 10]. No strict rules are there for narrative review and can be done using the keywords.

29.7 Conclusions

- A Systemic review gives a comprehensive and complete plan and search approach to study a topic of interest. This reduces the bias by recognizing, assessing and creating all relevant studies on a particular topic.
- Systematic reviews can be ambiguous, not helpful, or even harmful when data are incorrectly handled.

- A Meta-analysis involves using statistical methods to create the data from several studies into a single quantitative study.
- Outcomes from a meta-analysis may help to estimate the effect of treatment or risk factors for disease, or other outcomes.

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Part VI

After the Paper Is Written

To Which Journal Should You Submit Your Article?

30

Medicine is a science of uncertainty and an art of probability
William Osler, Canadian physician (1849–1919)

30.1 What Are the Various Types of Journals?

Medical journals help physicians to upgrade their knowledge. Beside education, they also contain news and views about the profession and provide a forum for doctors to debate other issues. Journals are an amalgamation of clinical medicine, basic science and popular journalism and can be divided into two major categories based on the content they publish:

- **General Medical—**These journals publish manuscripts on many different subjects in each volume and thus have a variety of articles. Examples of these are The New England Journal of Medicine, The Lancet, The BMJ and The National Medical Journal of India and Current Medicine of Research & Practice (CMRP).
- **Specialty—**These journals publish articles related to a single speciality only. Examples of these are the American Journal of Obstetrics and Gynaecology, Anaesthesia, Gastroenterology, Circulation and the British Journal of Surgery.

30.2 Which Are the Oldest Running Medical Journals?

The history of scientific journals goes back to 1665 when the Royal Society in England published the Philosophical Transactions of the Royal Society. In the same year, the 'Journal des Savants' (Scholars) appeared in France [1].

Currently, the oldest running medical journals are 'The New England Journal of Medicine' which has been published continuously for over 200 years, 'Lancet' which is being published since 1823, The BMJ from 1840. In India, the 'Indian Journal of Medical Research' is being published since 1913 and is the oldest journal.

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30.3 How Frequently Are Journals Published?

A journal can be published annually (Journal of Medical Research and Innovation), semi-annually (International Journal of Advanced Medical and Health), quarterly (International Journal of Medicine), bimonthly (Annals of Family Medicine, Academic Paediatrics), monthly (Indian Journal of Clinical Medicine), semi-monthly, biweekly or weekly (The BMJ, The New England Journal of Medicine, The Lancet).

30.4 Are There Any MCI- or UGC-approved Journals for Publication in India?

The MCI and University Grants Commission (UGC) have approved lists of journals publication which may be considered for recruitment, promotion and career advancement in universities and colleges. These are listed on their websites [2].

30.5 What Is a Peer-Reviewed Journal?

Most leading medical journals are 'peer reviewed', i.e., the articles submitted to them are sent for scrutiny and approval to two or three other experts in the same field before a manuscript is accepted. This is done to ensure their quality and their suitability for publication. In most cases, the reviewers are 'blinded', i.e., do not know who the authors of the paper are, so that the manuscript succeeds or fails on its own merit, not the reputation of the author [3].

Peer review helps in improving the standard and quality of journals. However, the process has been criticized (by a disgruntled minority) as 'slow, expensive, ineffective, something of a lottery, prone to bias and abuse, and hopeless at spotting errors and fraud' [4].

30.6 What Are Predatory Journals?

Predatory journals accept all articles submitted to them, do not send them for peer review and print quickly. They are money-making enterprises that charge huge fees. There has been a surge of these recently. They are viewed as predatory because academics are deceived into publishing in them for the sake of adding to their CVs, although they may be aware that the journal is of poor quality and fraudulent. They actively solicit articles by haranguing and attracting gullible young academicians. It is estimated that there may be more than 10,000 predatory journals and 60% of articles published in predatory journals receive no citations over the 5-year period following publication. Predatory publishing is perhaps a manifestation of the 'publish or perish' phenomenon with authors willing to pay [5–7]. More than 80% of

predatory journals have origins in India. They are prompt to publish and in a few instances, the article may appear online in 2 days [8, 9].

30.7 What Are Open Access Journals?

Open access is a practice through which biomedical manuscripts are distributed online, free of cost to readers as well as for downloading. One of the major advantages of this type of publication is an increased visibility of the paper [10]. It is thought to be the best solution for the majority of developing countries. In 2003, the philosophy of open access was defined in the 'Berlin declaration on open access to knowledge in the science and humanities'. The names of the open access journals can be accessed on the website DOAJ [11, 12]. The various types of open access are:

1. Golden route—they are provided open access by the publishers. They may ask the authors for processing charges which can be paid by either the author or the institute to which he or she belongs.
2. Hybrid route—there is a subscription charge for the journal, the articles are free for the readers but processing charges are taken from the authors. Many journals are following this route.
3. Green route—in this, the author needs to deposit the entire text to a trusted repository and the full text can then be read and downloaded according to that database.

4. Diamond route—this model is fully funded by the library and there are no author processing charges.
5. The major issue with open access journals is the cost of publishing. While some offset some of these costs from authors from low-income countries, others do not and hence this cost can be prohibitive for some of them (between 2000 and 4000 dollars per article). More recently some funders will pick up these charges but only if budgeted in international grants.

30.8 What Are e-Journals?

Most reputed journals publish print and electronic versions for each issue. If the publication is in an electronic format on the Internet alone, it is called an e-journal. Many readers find electronic journals to have several advantages over traditional printed journals. They help in searching, downloading, storing and sharing the articles.

However, the new MCI guidelines specify that publications in most e-journals will not be considered for promotion. This guideline is probably a response to the propagation over the past years of predatory journals, which are almost exclusively among e-journals [13].

30.9 How Should an Author Choose a Journal to Which to Submit His Manuscript?

Submitting a manuscript to an unsuitable journal is a common error and can cause journal editors to reject the document without even sending it for peer review. Choose a journal that matches your scientific research. Some of the factors you should consider are:

- Look at the content of the journal—basic research or clinical work?
- Which audience do you need to target-general physicians or specialists?
- What is the type of article you need to publish?
- What is the reputation of the journal?
- What is the interval between submission, acceptance and publication?
- Would you prefer an open-access journal and are you ready to pay the author processing charges?
- Publishing in a peer-reviewed journal and indexed journal is difficult at the first attempt but if your work is really good go for these first.

30.10 Conclusions

- There are criteria requirement by the Medical Council of India regarding which journal to publish for promotion in an academic institution.
- Submission to a journal by matching your article with the journal type.
- E-journals are usually thought to have poor scientific content compared to print publications.

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Publication Algorithm

31

Publication is a marathon, not a sprint. Writing the book is only the start.
Jo Linsdell Marketeer (1980–)

31.1 Through What Stages Does a Paper Pass Before It Is Published?

There is a famous proverb by Sir Francis Bacon, 'reading makes a full man; conference a ready man; and writing an exact man'. The first two are still easy to achieve but for the last, there are many barriers. It is a fact that only 10–30% of science research is published in journals [1]. A first-time publication is associated with fear and excitement for the author but it is the role of his mentor to guide him or her closely and make it an enjoyable experience (Fig. 31.1).

After authors have uploaded their manuscript, there are two processes that are involved. They include:

1. Review process.
2. Production process.

31.2 What Is the Review Process?

The review process includes manuscript checking by the editors for quality and plagiarism, (discussed in Chap. 26), formatting according to the journal's style and type of article, which has been covered separately and summarized in Table 31.1 (the details of the peer review process and authorship issues are discussed elsewhere in this volume).

Registration of clinical trials and protocols in the case of systematic reviews are now required by many journals. This can be done through the Clinical Trial Registry website (http://ctri.nic.in/Clinicaltrials/login.php).

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_31

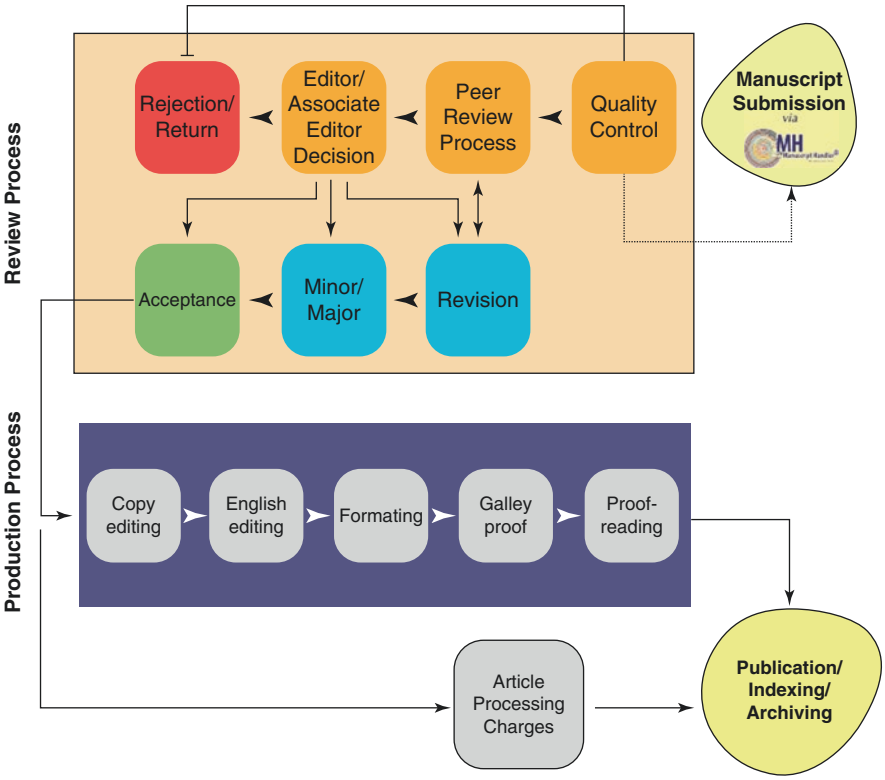


Fig. 31.1 An overview of the road to publication

Table 31.1 The structure of the research article

a. Research articles generally follow the IMRAD format (introduction, methods, results and discussion).
b. Reviews can be similarly structured but there is flexibility.
c. Systematic reviews are now quite structured.
d. Comments/Viewpoints/Editorials.
e. Case Reports- IMRAD format.
f. Letters to the Editor.
(d, e and f are discussed elsewhere in this volume)

Before publication it is expected that ethical clearance has been obtained from a board, the basic experimental work has been completed and the results are available. You started with an idea or a research question on a topic of interest from, for example, your thesis. Review the relevant literature and think about whether you can produce one or more publications based on this thesis (e.g., one review and one original article). Do not make salami papers, i.e., thinly sliced publications from the same material. It is easy to detect this as they all carry the same hypothesis and the same methodology [2]. Do not procrastinate after the first thought.

A suggested algorithm is given in Fig. 31.2.

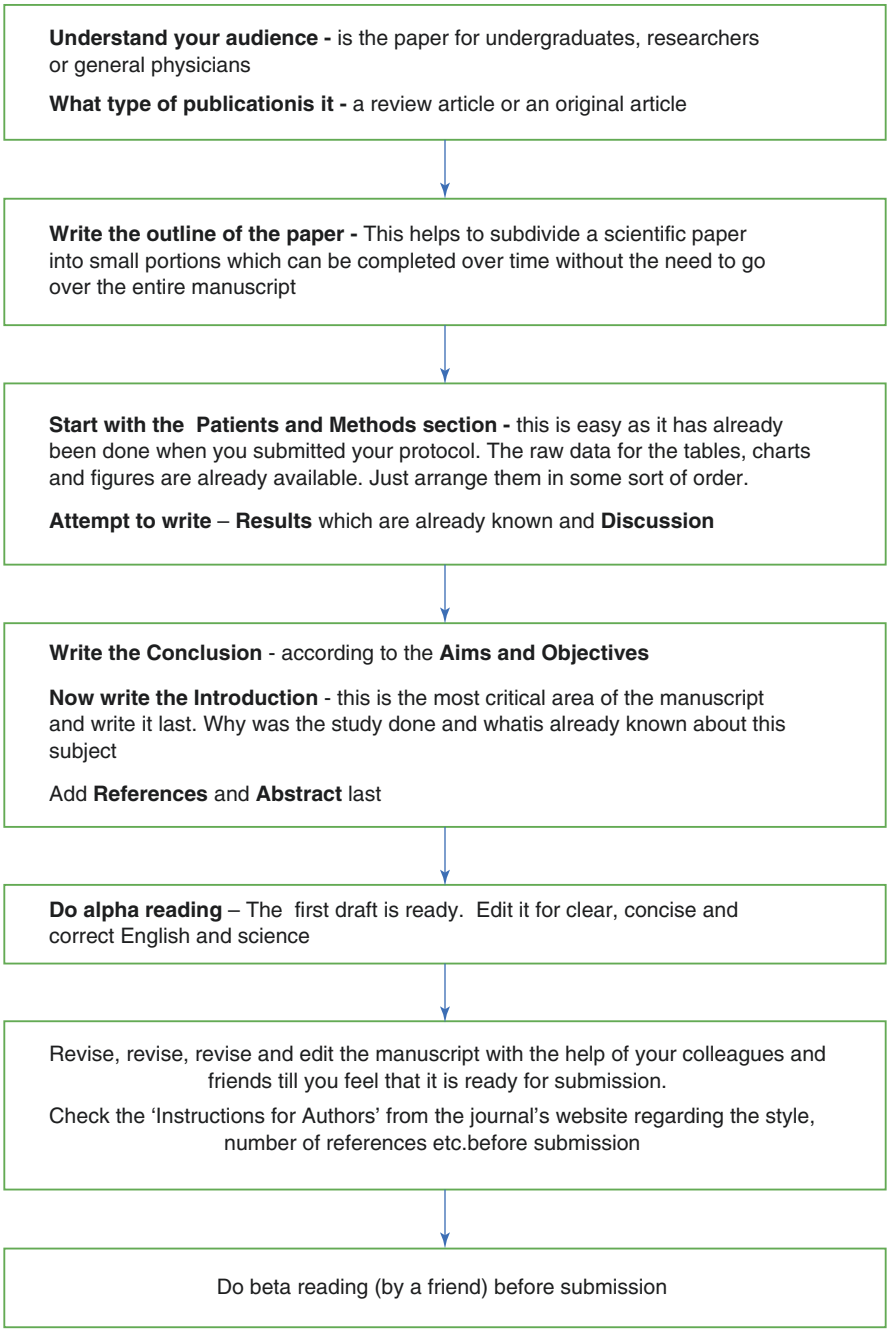


Fig. 31.2 Journey towards the submission of a manuscript

An alpha reader is someone who will inspire you and give you a genuine and honest option to get onto the next stage of revision. Your alpha reader could be your mentor or any physician who has experience in writing and editing medical papers. A beta reader may be a friend or a family member who can tell you which portions of the paper are weak and which portions are not easily understood. He can opine on the issues that have become invisible to you during your numerous rounds of revisions.

31.3 What Are the Requirements for a Manuscript at the Time of Submission?

You need to create an account with some basic information on the journal site and keep all this information handy before online submission.

- Covering letter—A manuscript will be reviewed for possible publication with the understanding that it is being submitted to that particular journal alone at that point in time and has not been published anywhere, simultaneously submitted, or already accepted for publication elsewhere. Include why you chose this particular journal and what is interesting and unique about your paper.
- Ethics clearance—many journals now ask for this in the case of original articles involving human subjects. Can be submitted separately or referenced within the paper.
- A file containing the full manuscript needs to be uploaded. Some journals require an XML, HTML or pdf format.
- File containing tables and clinical photographs.
- During submission, the contributor is requested to provide the names of two or three qualified reviewers who have had experience in the subject of the submitted manuscript, but this is not mandatory.
- If it is an animal study, the experiment should be done according to 'The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving animals'.
- Information on conflicts of interest.
- Information on funding.

31.4 What Happens to the Manuscript After Submission?

The submission of the article should be done to a journal according to its relevance to the topic and subject area and its standing (Impact Factor, Open access, etc.). You should avoid 'predatory' journals. A guide on how to choose Journal has been discussed in another chapter (Fig. 31.3).

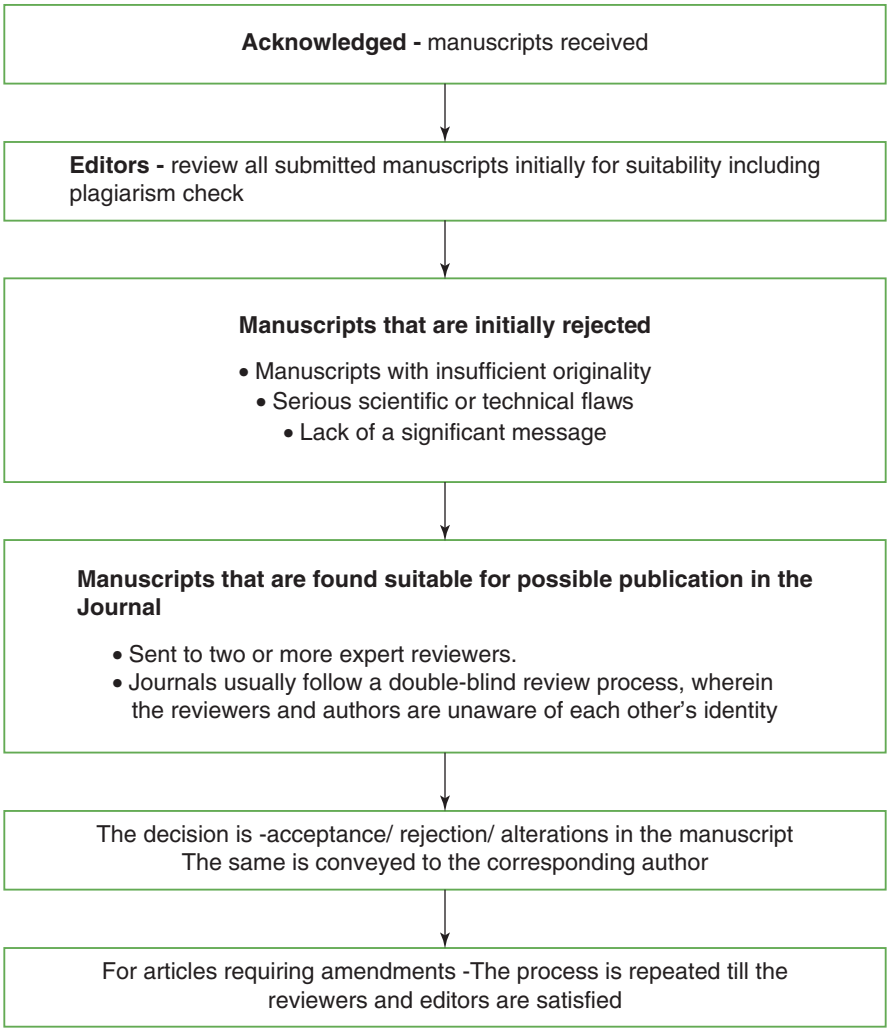
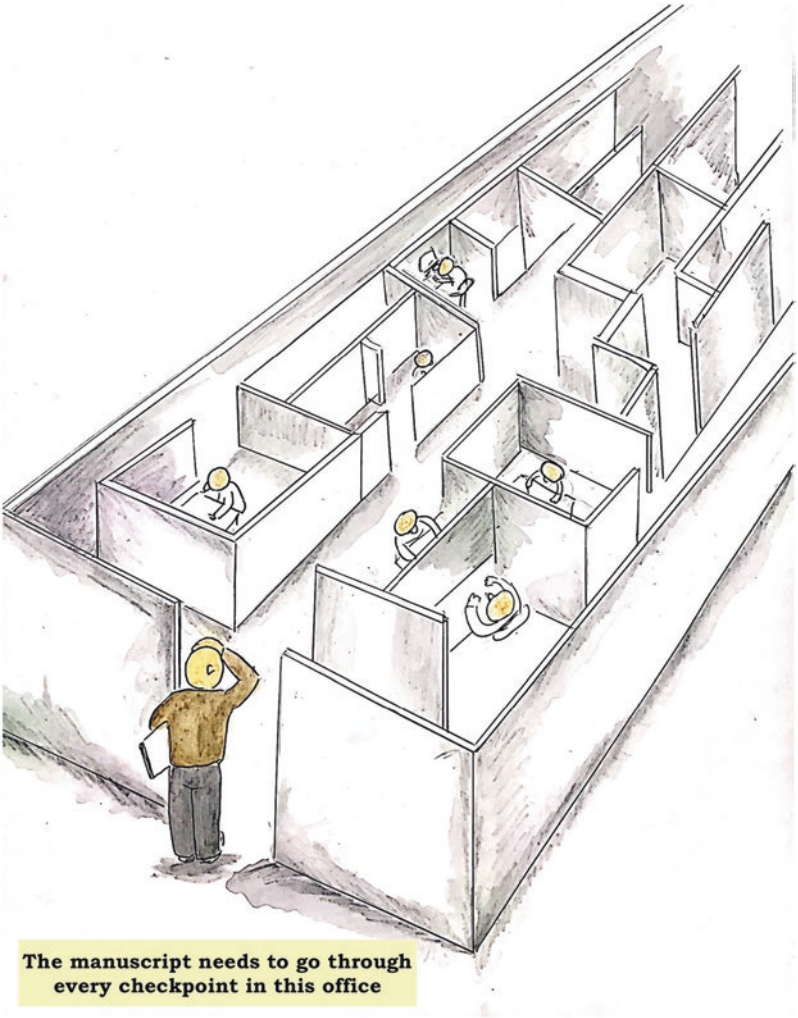


Fig. 31.3 Shows the series of events that can happen after submission



The Editor is the focal point with whom the reviewer or author interacts**.** The responsibilities of the Editor, Author and Reviewer are listed below [3]:

Editor
- Assigns reviewers for manuscripts.
- Forwards the reviewers' comments to the corresponding author.
- Makes the final decision on whether the article should be published.

Author
- Responds to the reviewers' and editors' comments.
- Corresponds with the editor and co-authors.

Reviewers
- Accepts the offer to review the assignment.
- Provides feedback on the manuscript to the editors (Fig. 31.4).

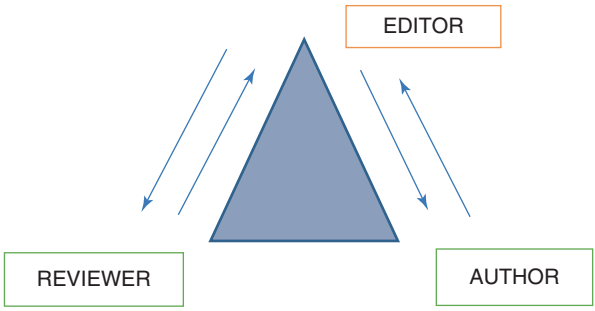


Fig. 31.4 Direction of workflow

Table 31.2 Details of peer review process

R	Read the Reviews	Read the editor's and reviewers' comments Understand what is required from the review Note the things on which they agree and on which they disagree
E	Emote	Hope, despair, anger, frustration and, less often, happiness may be common after reading the referee's comments Discuss these with your close friends but not with the editor
A	Arrange the Reviewer Comments	Organize the document into clusters of concerns
P	Pass Responsibility	Distribute small portions of the work to be done to each co-author
R	Revisit the Manuscript	Reread the manuscript many times with the reviewers' comments in mind.
E	Evaluate the comments	Categorize the comments into three bins Critical-Most important Contestable-required us to consider seriously Tangential-beyond the scope of the paper
W	Write Responses	Write the answer to the queries from the reviewer using additional data
A	Argue among yourselves—Play Devil's Advocate!	Argue amongst yourselves Revise your manuscript according to the reviewers' comments
R	Rewrite the Manuscript	'Writing from scratch' approach enables us to take a holistic view
D	Direct the reviewer's attention to the responses	Respond without being rude
S	Submit the revised manuscript and responses, pointwise, to the reviewer	Wait for the comments again

31.5 What Is the Role of the Peer Reviewer of a Manuscript?

The details of the peer review process have been discussed elsewhere. The peer reviewer assists the journal by critically reading and analyzing the manuscript and provides an independent evaluation to the editor about the worth of a paper (Table 31.2). Through constructive feedback, he helps the authors to publish their

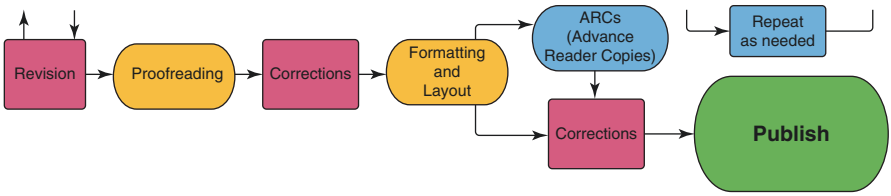


Fig. 31.5 Publisher's flow chart

work. The mnemonic REAP REWARDS stands for how to get the maximum benefit from the reviewer's comments [4].

31.6 What Is the Production Process?

This is a series of events that happen after acceptance (Fig. 31.5). These include copy editing, English language editing, galley proofs and proof editing.

In proof editing the manuscripts accepted for publication are edited by laypersons before publication for the following:

- Grammar, punctuation.
- Print style.
- According to the format of the journal.
- Page numbering.
- Running title of the article.

The page proofs are then sent to the corresponding author. The entire process of submission of the manuscript to the final decision and sending and receiving proofs is completed online.

Proof editing is different from content editing in which the article's scientific content is added or deleted and copy editing in which the sentences are polished.

31.7 What Is a Copyright Form?

Upon acceptance of an article, the authors will be sent an e-mail to fill a form regarding the copyright agreement. This allows the publishers to reproduce the manuscript for circulation within their institutions. Permission from the publisher is required for resale or distribution outside the institution (Fig. 31.6).

31.8 Why Do Journals Take Such a Long Time to Publish a Paper?

The time to print after submission can be divided into three sections:

1. From submission to peer review.
2. From peer review amendments to the corresponding author's resubmission.

Copyright Transfer Form

Title of the paper: _____

The authors hereby transfer all copyrights in and to the manuscript named above in all forms and media, now or hereafter known, to the Current Medicine Research & Practice effective if and when the paper is accepted for publication in the *Current Medicine Research & Practice*. The authors reserve all proprietary right other than copyright, such as patent rights.

Everyone who is listed as an author in this article should have made a substantial, direct, intellectual contribution to the work and should take public responsibility for it.

This paper contains works that have not previously published or not under consideration for publication in other journals.

Corresponding author _____ _____ _____
Name Signature Date

Authors:

Name	Signature	Date
Name	Signature	Date
Name	Signature	Date
Name	Signature	Date
Name	Signature	Date
Name	Signature	Date
Name	Signature	Date

(This form must be signed by all authors in order as appeared in the article, and should be returned to the editorial office.)

Fig. 31.6 Copyright form with permission from Editors CMRP

Table 31.3 Average time taken to publish after acceptance

Journal name	Average time to publish after acceptance
Circulation	77 days
Stem cell	10 days
Cell	Up to 3 weeks
Cellular and molecular life sciences	2 months
BMJ group of journals	About 3 weeks
Biology	Within 4 weeks
American Journal of Human Genetics	Around 8 weeks
PLoS Medicine	6–8 weeks
PLoS biology	Within 6 weeks

3. From final acceptance to publishing.

The first two periods are due to the journal processing the manuscript but the second interval is due to the authors. The process of peer review is slow and also involves two independent individuals. Also, journals try to publish articles of common interest first and about what the readers want. They are called ‘fasttrack’ articles. This is decided by the editors and they would, for instance, during the corona pandemic prefer to publish an article on COVID over one on the epidemiology of diabetes. Some journals publish the average time on their website after acceptance [5]. Examples of these are given in Table 31.3.

In a retrospective study to assess the speed of publication in General Medical Journals a total of 18 journals (whose impact factors ranged from 1.1 to 19.7) and which published 781 papers were studied. It was found that the mean submission to acceptance time was 123 days, acceptance to publication time was 68 days and submission to publication time was 224 days [5]. In another article it was suggested that journals with higher impact factors had longer acceptance and publication times. This could be related to their larger workloads [6].

31.9 What Is Epub Ahead of Print Mean?

'Epub ahead of print' means that the article is being published electronically before it is available in print. Digital Object Identifier (DOI) helps to link the full text and citations for such articles. Very recently a 'preprint server' was started by Yale University and The BMJ called 'MedRxiv'. This service is for academic manuscripts that have not undergone the process of peer review and have not yet been published. The authors can post papers and receive feedback even before journals review and accept or reject them [7].

31.10 Conclusions

- There are two main processes involved in publication, i.e., reviewing and production.
- The review process is long and involves checking for formatting, plagiarism and assessment by peers.
- Peer review adds value to a paper and maintains the standard of the journal.
- The production process after a paper is accepted may be lengthy because a paper has to undergo various checks before publication.
- The acceptance to publication time varies from journal to journal.
- Copyright forms need to be completed by the authors after acceptance.
- Epub is printing of a manuscript electronically before its printed version. MedRxiv is a new service for preprints.

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How to Do a Peer Review?

32

"The Nobel laureate for literature of this year has said that an author can do anything as long as his readers believe him.A scientist cannot do anything that is not checked and rechecked by scientists of this network before it is accepted."

Sune Bergström, Swedish Biochemist (1916–2004).

32.1 What Is Peer Review?

Peer review is a process in which a paper's validity, originality and academic content are checked prior to publication in a good journal. In other words, it is 'evaluation of work by one or more people with similar competencies'. The people who carry out this work are called reviewers or referees [1].

The science in a manuscript should be good enough for it to be published. Bad science even with good statistics should not be accepted. The peer-review process is also called the 'art of trashing a paper' as it has been said that 99% of scientific literature belongs to the waste paper bin [2]. In 1979, Dr. Stephen Lock, the editor of the British Medical Journal wrote, 'few things are more dispiriting to a medical editor than having to reject a paper based on a good idea but with irremediable flaws in the methods used'.

32.2 How Is a Peer Review Process Initiated?

After a paper has been submitted, the editors have the first read and check if the manuscript is suitable for the journal. Only if they feel that the science in the article is worth publishing does it undergo the process of peer review (Fig. 32.1).

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_32

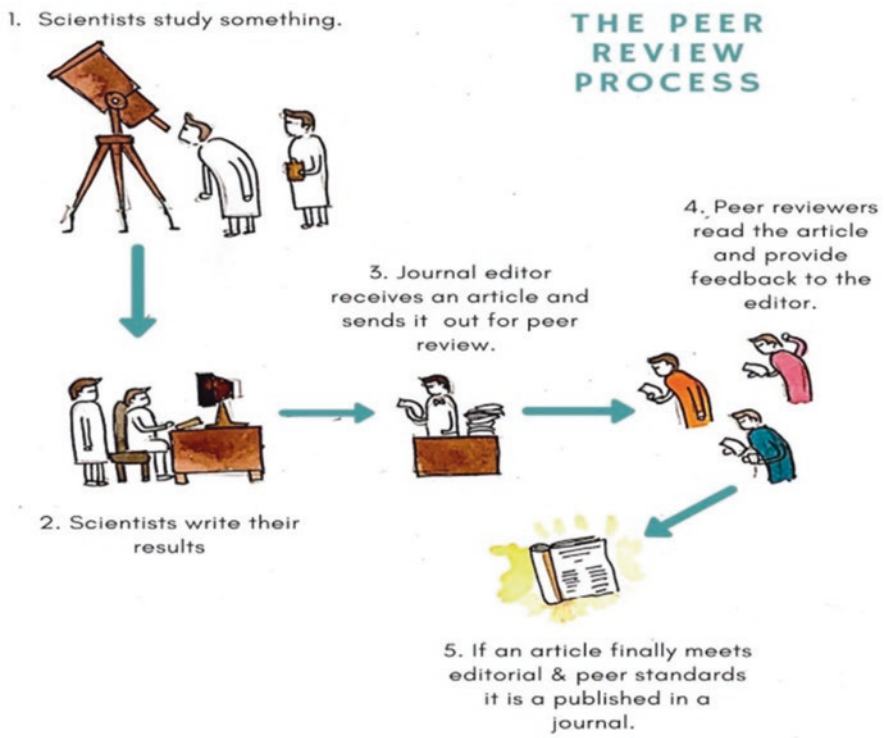

Fig. 32.1 The peer review process

32.3 What Are the Qualities of a Good Peer Reviewer?

The reviewer is like a traffic policeman who regulates the science in a journal. He becomes involved in peer review due to his academic and altruistic bent, to improve his curriculum vitae, to be involved in editorial work and to be informed about the field of research before anyone else. He should be aware of the journal's style and stance. An editor often takes the help of the expertise of the members of his editorial board for the peer review process.

The qualities of a good reviewer are:

- To give a judicious and professional review.
- To critique the science in the manuscript.
- To review the article in the stipulated time.
- To suggest changes that might improve the quality of the paper.
- To give a balanced judgement on whether the paper should be accepted, revised or rejected.
- He should have the ability to express complex ideas simply.

Referees who have a sound grasp of epidemiology and statistics are sometimes more likely to produce good reviews. Also, those who spend a longer time over their

task tend to produce better reviews [3]. An interesting study suggested that reviewers who had a lower academic or professional status provided a better analysis of manuscripts than those of higher status possibly because they were less busy and being invited to do this task by a reputed journal added to their academic credentials. They were also less likely to refuse to review. If they were less than 40 years old they were also likely to produce more useful comments [4].

A reviewer is not expected to correct poor English grammar or syntax which can be done by the editorial team or the publishers. They can help by underlining sentences or paragraphs and writing 'rephrase', 'unclear' or 'unsubstantiated'.

32.4 What Are the Types of Peer Review Process?

The process can be a single, double- or even triple-blind review or an open review process [5, 6].

Single-blind peer review—this is the commonest type of review in which the names of the authors are concealed from the reviewer. The concealed identity allows for neutral decisions as a reviewer will not be influenced by the names or institutions of the authors. The only concern is that if the reviewer is also from the same specialty, he may delay the process, to give himself a chance to publish earlier. Occasionally, a referee may sometimes use his concealment to be unnecessarily critical or harsh when judging an author's work.

Double-blind peer review—in this both the referee and the author are concealed from each other. There are several advantages of this model. Author concealment restricts the reviewer's bias and a more authentic opinion may be given. Manuscripts written by respected professional colleagues or famous authors can be considered on the basis of their merit rather than the person's standing in the profession. However, often the reviewer's or author's identity cannot be concealed as there is some mention of him in the methodology section, or it becomes obvious from the style of writing or the scientific content.

A triple-blind review is a process in which the reviewers as well as the authors are unknown to the editor. The submitted articles are processed and handled in such a way as to minimize any potential bias towards the author(s). However, this is a complicated process compared to a double-blind review. There is also the possibility that the editor and/or reviewers may correctly opine the author's identity from their style of writing or the methodology used in the investigation.

Open review is a general term for many different models directed at better transparency during the peer review process. The most common type of open review is when both the referee and author are known to each other. Other types of open peer review consist of the publication of the referees' names on the article's printed page. The ultimate degree of openness would be the publication of the peer review data together with the article, the peer review reports (signed or anonymous) along with the authors' and editors' responses alongside the article and publication of the manuscript after opening a discussion forum to the readers along with comments (named or anonymous). Open review has gained impetus since the late 1990s, with the decision of the British Medical Journals (BMJ) to publish both reviewers' names and reviews [7].

32.5 What Are the Top Ten Causes Why a Paper Gets Rejected?

The peer review process is slow but is necessary to keep up the standard of the journal. The top causes for rejection during the process are enumerated below: [8, 9].

1. The research question is not clear or buried somewhere or not mentioned in the manuscript.
2. The main scientific issue has not been addressed properly.
3. The work submitted is not original or a duplication of the work of others and does not add to scientific knowledge.
4. The study design is not appropriate.
5. The sample size is not adequate for any statistically significant results.
6. The methodology for the study is not appropriate.
7. The statistical methods used are not appropriate or have been calculated wrongly.
8. The conclusions drawn are unreasonable or unjustifiable.
9. There is a conflict of interest, the study is sponsored and it seems that the sponsor will benefit from publication.
10. The manuscript is badly written and there are both major scientific and grammatical mistakes.

32.6 What Are the Top Ten Tips for Doing a Good Peer Review?

These are easy to remember:

1. **Respond quickly to offers to review**
   Read the abstract and full text once and you will be able to judge if this is in your area of interest. Be swift to respond to the call given by the editors.
2. **Show Honesty**
   If you are also working on a similar subject to the paper in question, do inform the editorial about this conflict of interest.
3. **Know the Scope of the journal**
   Once the manuscript is in your hand be aware of the journal's style, editorial policy and article presentation.
4. **Give constructive suggestions**
   It is easy to find loopholes in someone else's work. Even if you are rejecting the manuscript give constructive feedback to authors so that they can improve their paper.
5. **Assign sufficient time for the review**
   The comments on the review should not be made in haste. It is always better to spend time to review the manuscript.
6. **Number your feedback comments**
   It is easier for the editors if comments are mentioned in a pointwise fashion.

7. **Focus on the science in the manuscript**
   While reviewing, analyze the science in the manuscript. If the English and syntax are wrong, just mention this in the comments rather than pointing out each mistake.
8. **Read the aims of the study and check if they have been met**
   Reading aims and conclusions gives a good idea about what new information the manuscript has added.
9. **Check the statistics**
   Editors always welcome reviewers who have a strong statistical background and comment on the sample size and other analytical calculations.
10. **Praise the authors for something novel**
    If the paper has extraordinary findings and is well written it is always best to bring this to the notice of the editors. Do not forget to praise the authors for their work.

32.7 What Are the Guidelines for Peer Reviewers from the Committee on Publication Ethics (COPE)?

These guidelines are given below: [10].

Initial step: The reviewer should read the main file, supplementary file and also policy statement of the journal. In case there is something missing or any clarification is required the reviewer should not contact the author directly.

Confidentiality: The information gathered from reviewing should not be used by the referee for his own advantage. Do not involve anyone else in the review of a manuscript, without first obtaining permission from the journal The names of any persons who have helped with the review should be included so that they are associated with the manuscript in the journal's records and can also receive due recognition for their efforts.

Bias and competing interests: It is important to remain impartial by thoughts related to the nationality, religious or political beliefs, gender or other characteristics of the authors, origins of a paper or by commercial considerations. If during the process the reviewer feels a competing interest to evaluate the manuscript, to inform the journal office.

Suspicion of ethics violations: If the reviewer feels that there has been wrongdoing with respect to research, ethics and publication he needs to inform the journal office or editors. This should also include similarity in publication, data manipulation or if ethical standards have not been followed.

Transferability of peer review: For this, one needs to understand the term 'portable or cascading peer review'. Here the publishing house has a policy for transferring a peer reviewer's comments to other journals in the publisher's portfolio and after permission this can be done.

32.8 Does Training Help in Improving the Peer Review Process?

Logically, the answer should be yes. Having workshops and standardization should help to improve the peer review. In a systematic review and meta-analysis, it was suggested that as compared with the standard peer review process, training did not improve the quality of a peer review report. Also, the use of a checklist did not improve the quality of the final manuscript. However, adding a statistical peer reviewer improved the quality. It was also concluded that blinded peer reviews did not affect the quality of the report or the rejection rate [11].

There has been recently a checklist which has been suggested for the peer-review process [12]. The 20 items to assess peer-review (PR) report quality included in the survey. Few sites also give details about how to peer review the manuscript, how to write peer review report and how-to read manuscript for peer review (Table 32.1). These include plos.org/resources/for-reviewers, https://authorservices.wiley.com/, https://researcheracademy.elsevier.com/ and https://masterclasses.nature.com/

Table 32.1 Twenty-point checkpoints for peer reviewers

Labels	Items to assess PR report quality
Relevance	The reviewer comments on the relevance of the study
Originality	The reviewer comments on the originality of the study
Interpretation results	The reviewer comments on the interpretation of study results
Strengths and weaknesses (general)	The reviewer comments on the general strengths and weaknesses of the study
Strengths and weaknesses (methods)	The reviewer comments on the strengths and weaknesses of the study methods
Statistical methods	The reviewer comments on the appropriateness of the statistical methods
Methodological quality	The reviewer comments on the methodological quality (internal validity) of the study
Applicability and external validity	The reviewer comments on the applicability and external validity of the study results
Presentation and organization	The reviewer comments on the presentation and organization of the manuscript
Adherence to reporting guidelines (RG)	The reviewer comments on the adherence of the manuscript to the reporting guideline
Structure of reviewer's comms.	The reviewer's comments are structured and organized
Clarity	The reviewer's comments are clear and easy to read
Constructiveness	The reviewer's comments are constructive
Detail/thoroughness	The reviewer's comments are detailed and thorough
Objectivity	The reviewer's comments are objective
Fairness	The reviewer's comments are fair
Support by evidence	The reviewer's comments are evidence based
Knowledgeability	The reviewer knows and understands correctly the content of the manuscript
Tone	The reviewer uses a courteous tone
Timeliness	The reviewer completes the PR report on time

32.9 What Is the Future of the Peer Review System?

Like all other processes, the peer review process has also been subjected to criticism. Peer review has often been thought to be an unappreciated job [13, 14]. The lack of motivation and commitment for doing such time-consuming work remains a challenge [15]. Both non-financial [16] and financial incentives have been suggested to improve peer reviewing. The non-financial approach includes giving a subscription to the journal, publishing names on websites, giving a certificate and also providing free and non-limited access to scholarly sites to digital libraries like Scopus, UpToDate, etc.

The financial approach is giving cash for reviewing. The money which is generated from the article processing charges can be shared with the reviewer [17, 18]. Many feel that this would make publication into a business model. However, we agree with payment because since the only person who is earning money from a printed paper is the publisher the time has come for reviewers to be paid and given more recognition for their expertise and effort (Table 32.2).

32.10 What Is a Preprint? What Are the New Developments in Preprints?

A preprint or ahead of print is a full draft of a scientific manuscript that is shared widely in the public domain before it has been certified by the peer-reviewed process. Most preprints are given a digital object identifier (DOI) so that they can be cited in other research papers. In the traditional publication system, the manuscript is sent to two or three reviewers before publication. With a preprint, other scientists can notice the manuscript early and any theoretical flaws pointed out early [19].

Very recently a 'preprint server' was started by Yale University and The BMJ called 'MedRxiv'. This service is for academic manuscripts that have not undergone the process of peer review and have not yet been published. The authors can post papers and receive feedback even before journals review and accept or reject

Table 32.2 Future of peer review system

Traditional approach	Suggested approach
Gatekeeping to scientific content published in journal	No gatekeeping function but only teamwork and productive criticism
Quality control difficult to measure	Quality control achieved based on consensus
Private and choosy review within a closed system	Self-organized reviewer and open system
Limited peer review exclusively to 2–3 people	Open participation, with semi-automated review matching
No incentives for reviewer Entry into editorial board based on board's decision and knowledge High rate of refusal to review	Incentive for reviewer based on performance Entry based on reputation in the scientific community More persons to be enrolled for the process of peer review

them. This is a good development as it allows an open feedback process. Many science journals like Physics and the New England Journal of Medicine ask if this service has been used as it improves the science of the final paper submitted to the journal.

This has been an important way of sharing information during the COVID pandemic, although at times readers and journalists have not distinguished between non-peer-reviewed and peer-reviewed research. Many of the COVID-19-related manuscripts were found to be imperfect when posted on MedRxiv (Fig. 32.2) [20].

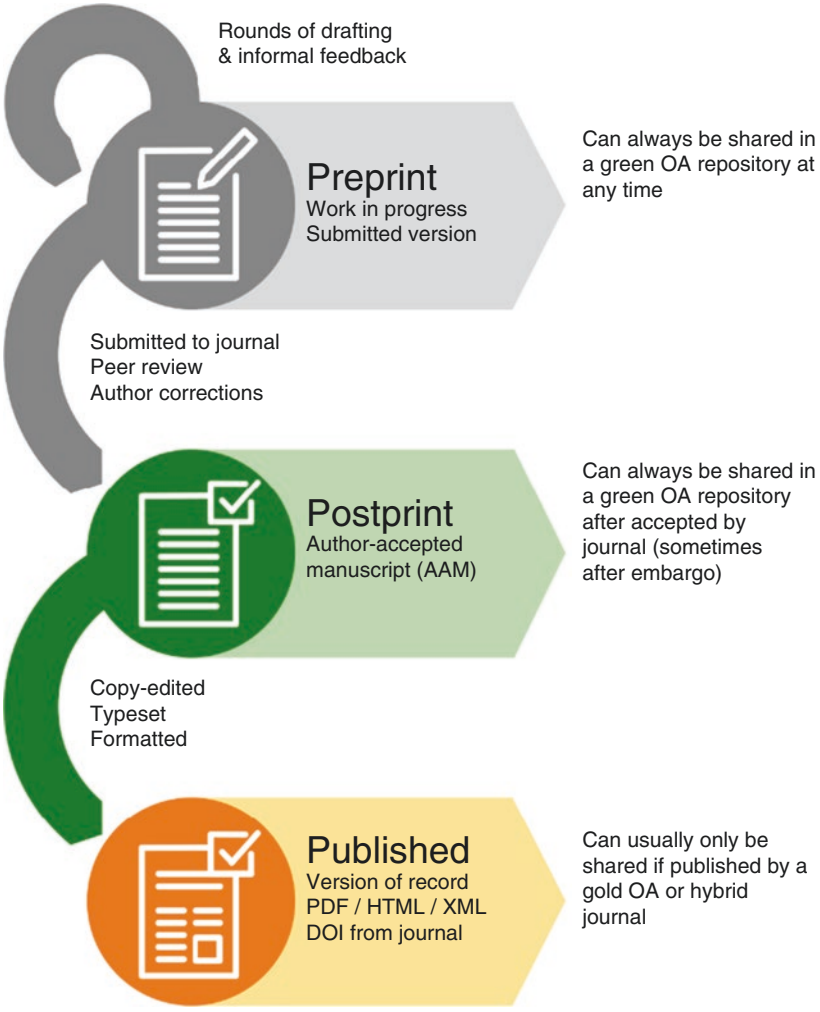

Fig. 32.2 Article publication algorithm

32.11 Conclusions

- The peer review process is a regulatory process for assessing papers that have been offered for publication in a journal.
- Reviewers are like gatekeepers who control the entry of scholarly information.
- The process of peer review has a hierarchical order, i.e., from authors submitting the papers to a journal, to editors forwarding the paper to a reviewer, from the reviewer to the editor and finally the editors passing judgement.
- Preprints increase the visibility of a scientific paper even before the peer review process.

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How to Handle Rejection?

33

Every time I was rejected for something good, I was actually being redirected to something better

Steve Maraboli, American Author and Motivational Speaker (1975–)

33.1 What Are Reasons for the Outright Rejection of a Manuscript?

The most important reason for immediate rejection is that the authors have not complied with all the necessary requirements of the journal. The submission of auxiliary documents that are necessary (ethics, conflict of interest) may have not been sent. The Editor in charge first looks at the title and the topic of the research [1, 2]. When he feels that it may not have much interest to his readers, the paper can be directly sent back at this level.

There are many explanations for why the paper is rejected without a detailed peer reviewers' analysis. These include:

- The manuscript may be out of the scope of the journal and not appropriate for its audience.
- The paper may contain no hypothesis or a weak hypothesis.
- The manuscript may contain too much basic research which may not interest clinicians.
- The paper may have bad methodology, the sample size may not be adequate and the statistical analysis incorrect.
- There is a discordance of the affiliations between the authors and institutes.
- Conflict of interest not declared.
- Ethics committee permission not taken.
- No informed consent from subjects.
- Case reports not important enough for scientific literature.

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_33

- The journal may have published a similar manuscript recently or is in the process of publishing one.
- There is plagiarism of language and ideas.

33.2 What Are the Reasons for Rejection After the Peer Review Process?

Only those manuscripts that survive the initial editorial inspection are sent for reviewers' opinions. This diminishes the load of papers on reviewers. Hence, expert commentators can focus and give time to do a detailed critical scrutiny of a good-quality paper [1–3]. The reasons for refusal to publish at this stage are as follows (Fig. 33.1):

- The scientific content lacks precision of thought.
- Data are inadequate, and the methodology section has irreparable deficits.
- Advice to authors has not been followed properly.
- The photographs are of low resolution, and tables are too complex and are not comprehensible.
- Discussion and conclusions do not answer the research question posed in the manuscript.
- There is an inconsistency between the statements made in the different sections of the paper.
- The reviewers feel that the authors have not edited the work enough to improve the presentation of the data.
- References are not according to the journal's style.
- There are mistakes in syntax and grammar.

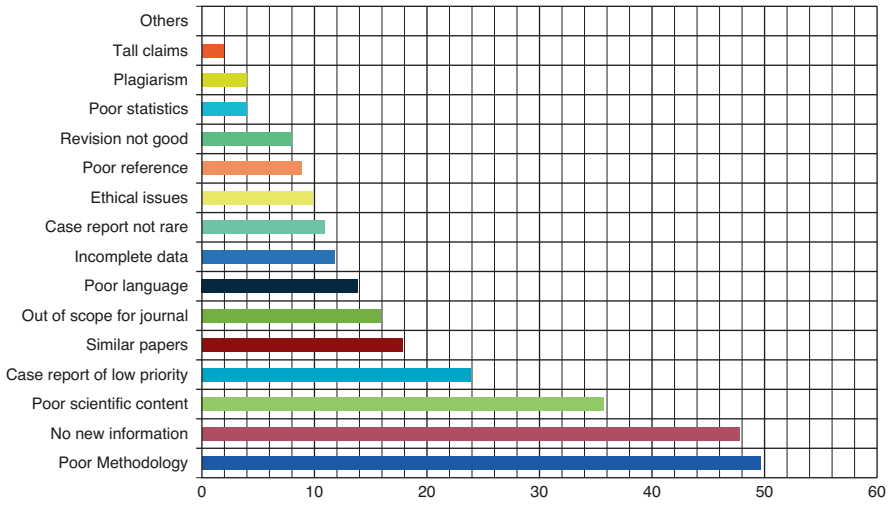

Fig. 33.1 An audit of reasons for rejection [1]

33.3 What Should You Do After Rejection?

The rejection rate of the leading journals varies from 80 to 95% [1]. It does not always mean that the manuscript is poorly written but that it is often not suitable for that journal. Look for the comments by the reviewers, improve the article and resubmit it to some other journal. If the reviewer has commented that the sample size is too small then you need to continue your work till you achieve an adequate number. Rejection is common so do not get disheartened and continue to improve the manuscript till you succeed in getting it accepted somewhere [4].

33.4 What Are Few Tips for Coping with Rejection?

- Do not feel dejected, it is a very common phenomenon.
- Read the comments of the referee and act on those.
- Resubmitting the paper to the same journal is usually not advisable.
- Check the formatting before submitting to a new journal.
- *Match* the paper with the journal's style.
- If the data is inadequate, continue the work till you reach an adequate sample size.

33.5 Conclusions

- Rejection of an article is a very common phenomenon. It should be taken as a step towards improvement.
- Peer review of an article is done when the editors feel it is worth processing the article further.
- Resubmission should be done soon to another journal after incorporating all necessary suggestions for improvement.

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Bibliometrics

34

Scientific quality is hard to define, and numbers are easy to look at.

But bibliometrics are warping science—encouraging quantity over quality.

Rinze Benedictus, Dutch Professor of Structural Integrity.

Bibliometrics is a statistical number obtained after a biomedical publication. It is a score that is given to a medical paper which reflects the impact of the research in science. It can also be used for medical books, websites, conference proceedings and policy documents. In simple terms, it is a measure of the impact of research [1]. It is traditionally used by librarians and currently researchers use it for:

- Providing evidence of the impact of their research output in their curriculum vitae when applying for jobs, promotion or research funding
- Investigating new or emerging areas of research
- Finding potential research collaborators
- Choosing in which journals to publish their research

34.1 What Are the Various Bibliometric Scores?

Traditionally, the academic success of a doctor was determined by the number of papers he or she published in any journal and this was later changed to papers published in peer-reviewed journals. As academia progressed there was a need to have a yardstick so that rather than only quantity, the quality of the papers became important. This led to the use of certain scores like the impact factor and h-index. However, with the widespread use of social media, new generation scores have evolved. There

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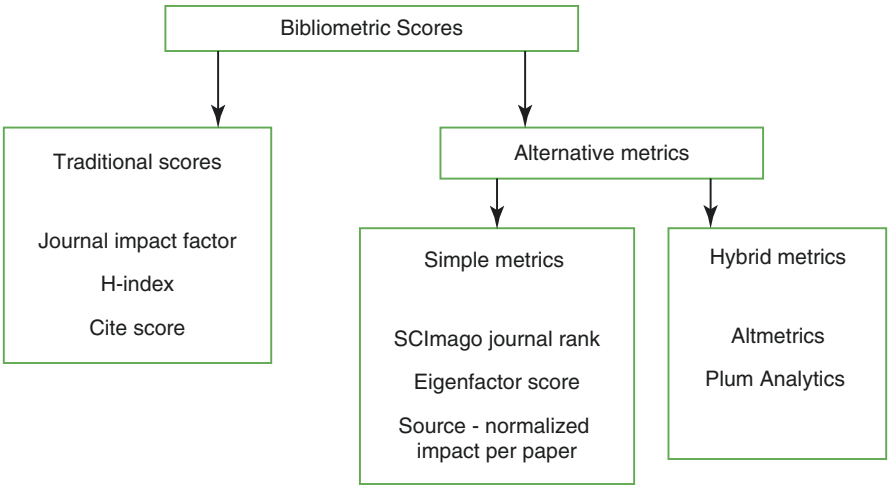


Fig. 34.1 Various bibliometric scores

are now more than two dozen bibliometric scores available. These scores can be classified into two broad categories (Fig. 34.1):

1. **Classical or traditional scores**—These are based on the number of citations each article gets and are well known to the majority of us. Examples are of this are the Impact factor of a journal, the H-index and citation score
2. **Alternative metrics**—With medical research increasing many new metrics like SCImago (SJR), the Eigenfactor score (ES), the source-normalized impact per paper (SNIP) called simple metrics or hybrid metrics such as Altmetrics and Plum analytics have evolved. These take into consideration newer factors like the number of downloads, social media mentions and post-publication reviews. These scores have their own strength and limitations and will be discussed later [2]

34.2 What Does Citation Mean?

Citation is the bibliographic acknowledgment of a previously published article [3]. The number of times an article has been quoted is its citation index [4]. In other words, the index is a process that allows us to track the use of an idea by other authors and is a measure of a paper's importance.

Citation establishes the informational 'ancestry' or 'hierarchy' of a particular idea as it is expressed in the literature. This ancestry is to be cited by the author of the current manuscript. For example, if an original paper on the 'Role of endoscopy in patients with fatty liver' contains 12 citations, each of these 12 references can work as potentially referable facts to support the text mentioned in any future article.

Careful and accurate citation helps the authors of the original paper gain respect and acknowledgment. It also helps to develop a network between the original and

new researchers. Citation indexing has many advantages as it excludes the need for intellectual indexing and overcomes language barriers and is highly effective, reliable and quick [5]. However, according to one survey, approximately 44% of all published papers are never cited. Thus, if you manage even a single citation you are in the top 56% in your field and with 10 or more citations you have reached the top 24% of the most cited works worldwide. If you get 100 citations you are in the top 1.8% [6].

34.3 How Is the Citation Index Calculated?

The Citation Index counts the number of times an article has been cited by other authors over a certain time period to judge the impact of its publication. The caveat, however, is that there is no single citation site that gathers such information and stores such data on published manuscripts. For a complete analysis of the impact of a manuscript, the authors require help from many different sites which carry this information and include The Web of Science, Scopus and Google Scholar [7].

What Citation Indexing does is to record a 'heading or title' for each reference or 'citation' that these current authors make in their journal articles and trace it back to each previously published article or book. In short, they keep a database of all the published articles and match them via pre-designed algorithms to locate when a previously published work is mentioned in a new study, as a reference.

34.4 What Is The Journal Impact Factor?

The journal impact factor is calculated by Clarivate analytics once in three years and depicts the performance of the journal in the previous 2 years.

The impact factor of a journal is a Scientometric índex that measures the intellectual influence of that journal and is calculated from the data of the total number citations achieved by it for papers published in it, in the preceding 2 years. It was initially used by librarians to decide whether or not to purchase a journal but is now used as a tool for judging the quality of a journal since it only uses data from the recent past. Thus, it is often used to rank the relative importance of a journal within its domain; journals with higher impact factors are often deemed to be more important than those with lower ones. The Impact Factor is calculated in any given year, as the frequency of citations, received in that year, of manuscripts published in that journal during the two preceding years, divided by the total number of 'citable items' printed in that journal during the 2 preceding years [1, 2, 7, 8].

For example, the 2020 IF for a journal is calculated as follows:

- a = the number of times articles published in 2018–2019 were cited in indexed journals during 2020
- b = the number of articles or reviews published in 2018–2019
- Impact factor = a/b

The articles which are not included in the denominator are editorials, letters to editors, medical news, obituaries, rectification notices and meeting abstracts. Thus, original articles and reviews are the most important for journals in calculating their impact factors.

34.5 What Are the Limitations of the Impact Factor?

Garfield first proposed the concept of the Impact Factor in 1955 in a paper published in the journal 'Science' [9]. Subsequently, Thompson Reuters divided manuscripts into non-citable (editorials, letters to editors, medical news, obituaries, rectification notices, meeting abstracts, biographical items) and citable items. The problems with the impact factor are that when non-citable items are cited, they are counted in the numerator, but excluded from the denominator thus increasing its value. These citations from non-citation papers are called 'free lunches' [10, 11]. It was found that the impact factor of the Lancet was reduced by almost 40% when just counting citations of the citable items, and Nature's Impact factor would be reduced by some 30% by including letters. Thus, the numerators and denominators are important. For calculation of the impact factor and a little change in any one of them can cause substantial variations [12].

The impact factor provides a general understanding of a journal without giving importance to individual articles. Also, journals that are not in English have a low impact factor, especially if the title, abstract and keywords are not in English [13]. Many articles have multiple authors and with this, there are chances that if their own work is cited the impact factor will be high [14, 15].

34.6 What Are the Recommendations of the World Association of Medical Editors (WAME) on the Impact Factor?

The impact factor is broadly viewed by authors and academic institutions as a measure of a journal's standing and also has usefulness in the authors' career in academic medicine. However, the impact factor can be pretentious by a number of features unrelated to journal quality, including self-citation by a journal, publication timing, and types of articles published. The following recommendations have been made by the WAME: [16].

- 'More research is needed to evaluate the impact factor and other measures of journal and article quality'
- 'Journal editors should look beyond the impact factor as a summary statistic and present other indicators of journal visibility, such as circulation, number of published articles, and the distribution of the citations. Such demographics of a journal should be regularly published to inform journal readers and authors'.

- ‘Journal editors have the responsibility to educate their readers, authors, administrators, and their scientific community in general about the impact factor and its relevance, as well as about other measures of journal and article quality’.

34.7 What Is Self-citation?

A self-citation is a quotation to a manuscript written by the author earlier which is quoted by him or herself in a fresh manuscript on the same topic.

Although it is not considered unethical to have self-citations, extreme self-citation is unethical. Examples of this are that there are more than one hundred thousand researchers in the world who have self-citations from more than 50% of their own work or citations from their co-authors, with the median self-citation rate being 12.7%. From India, Sundarapandian Vaidyanathan is famous for self-citation. He has received 94% of his citations from himself or his co-authors up to 2017 [17].

Table 34.1 Impact Factors of some important Indian Medical Journals

S. no.	Name	Impact factor
1	Indian Journal of Dermatology, Venereology and Leprology	3.03
2	Neurology India	2.708
3	Indian Journal of Dermatology	1.411
4	Indian Journal of Medical Research	1.251
5	Indian Journal of Pharmacology	1.040
6	Indian Journal of Gastroenterology	0.92
7	Journal of Postgraduate Medicine	0.855
8	Indian Journal of Pathology and Microbiology	0.529
9	Indian Journal of Cancer	0.429
10	Indian Journal of Sexually Transmitted Diseases and AIDS	0.42
11	Indian Journal of Community Medicine	0.39
12	Indian Journal of Nephrology	0.38
13	Journal of Cytology	0.311
14	Medical Journal of the Armed Forces of India	0.28
15	Indian Journal of Radiology and Imaging	0.28
16	Indian Journal of Medical and Paediatric Oncology	0.27
17	National Medical Journal of India	0.64
18	Indian Journal of Plastic Surgery	0.25
19	Journal of the Association of Physicians of India	0.20
20	Indian Journal of Medical Sciences	0.1

34.8 What Are the Impact Factors of the Top Indian Journals?

There are many Indian journals some of which are specialty based and others for a general readership. The aim of all these medical journals is to disseminate new scientific knowledge among physicians, clinicians and researchers so as to improve the patient that is imparted. The exact number is not known but an estimate is that there are about two hundred. The impact factor for the top 20 Indian medical journals is given in Table 34.1. Unfortunately, all are rather low.

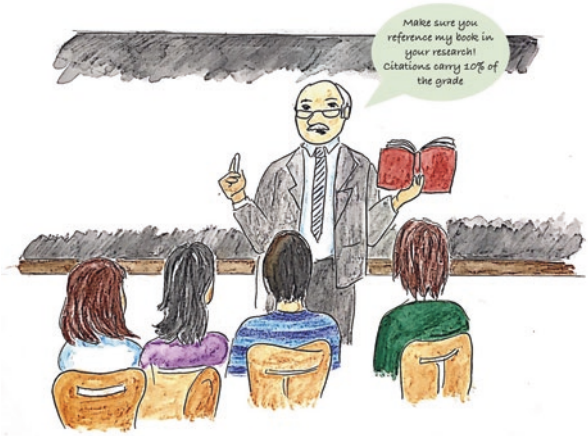
34.9 What Are the Impact Factors of Some Important International Medical Journals?

PubMed includes more than thirty thousand journals and PubMed Central has approximately two thousand journals listed in their databases. Every year, several new journals on all medical specialties are being added. Journals are published either by well-established academic institutions and societies or private organizations (Table 34.2).

A manuscript published in a journal with a high impact factor carries great prestige not only for the authors but their departments and institutions as well.

Table 34.2 Impact factors of the top five international journals

S. no.	Name	Impact factor
1	The New England Journal of Medicine	70.670
2	The Lancet	59.102
3	The Journal of the American Medical Association	51.273
4	The British Medical Journal	27.604
5	Annals of Internal Medicine	19.315



34.10 Should We Publish in a Journal with a High Impact Factor?

The impact factor of a journal usually, but not always, reflects the quality of a manuscript and its acceptance among readers [14, 15]. However, it is now so widely used as a guide for academic promotion, etc. that there has been some criticism of its dominance. For instance, the National Health and Medical Research Council an Australia-based research funding agency is against using the impact factor. The San Francisco declaration in 2020 concluded that one should not judge a journal just by looking at its impact factor as it does not reflect the quality of all the papers in the journal. They recommend:

- Removing the use of journal-based metrics, such as journal Impact Factors, in funding, appointment, and promotion considerations
- Evaluating research on its own qualities rather than on the basis of the journal in which the research is published
- Using the opportunities provided by online publication (such as relaxing unnecessary limits on the number of words, figures, and references in articles, and exploring new indicators of significance and impact).

34.11 What Is the h-index?

The h-index is also known as the 'Hirsch index' and was introduced in 2005. The 'h-index' is an author-level metric that attempts to measure both the productivity and citation impact of the publications of a scientist or scholar. It is a more specific method of finding the impact of a scientist using citation analysis which measures not only the quality but also the quantity of his publications. For example, if a researcher has an h-index of 10 it means that he has published at least 10 papers for which they have received at least 10 citations [2, 17].

The h-index for an author is thus a score that measures the productivity and citation impact of the publications by a scientist. An h index of 20 is good, 40 is outstanding and 60 is truly exceptional (Table 34.3).

Table 34.3 Generalizations of the h-index, according to Hirsch

h-index	Number of years in a career as a scientist (scientific age)	Characterization of the scientist
20	20	Successful
40	20	Outstanding (likely to be found only at the top universities or major research laboratories)
60	20	Truly unique individuals
90	30	

34.12 What Are Strengths and Limitations of h-index?

The h-index is easy to calculate. It combines the research output and impact factor [18]. However, it cannot be used as a measure to compare two investigators in different fields of medicine, as there is field-related variation and also citation pattern. The h-index is considered to be a more accurate performance of research than the impact factor. The young investigator has a disadvantage because with time both research output and impact will change with time. The h-index is a better marker as it combines impact factor and research output that the other indices use which depend on a single parameter like the total number of citations or citation per paper. The h-index does not look into various co-authors and gives equal credit to all of them. It excludes poorly cited articles but it does not exclude self-citation. This could lead to an inflated h-score. Senior faculty are likely to have better h-indexes as their research performance will get better with time.

Many versions of the h-index have been used to overcome its limitations. However, none of them are perfect. The G-Index is another marker that considers the citation for top publications of the author; however, it is not widely accepted [2]. The e-index attempts to differentiate between researchers with similar h-indexes [19].

34.13 In Which Journal Should You Preferably Publish Your Work: Indian Or International?

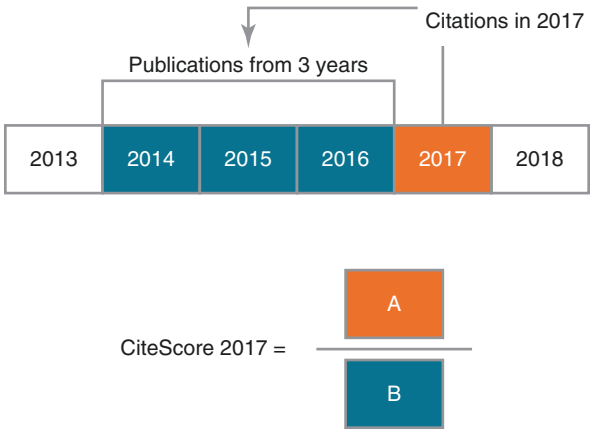
It is a common tendency for Indian researchers to try and get their work published in international journals rather than in Indian journals because it reaches a wider audience and commands more prestige—even among Indian selection bodies.

This practice demoralizes a researcher because not only is it difficult to get accepted but there is a certain bias against articles from developing countries as generally being of poor quality and not being relevant to the majority of the journal's readers. Repeated rejections also cause long delays in publication.

However, till the quality of our own journals improves we will have to aspire towards what is best.

34.14 What Is the Cite Score (CS)?

The cite score is the average number of citations that a biomedical manuscript received over the last 3 years. This score was started by Elsevier Publishers in 2016. In contrast to the impact factor, this score is given to all cited articles including editorials, letters to editors, conference papers and other articles indexed by Scopus. Elsevier believes that the cite score provides a comprehensive, transparent view of the journal [20].



34.15 What Is the Scimago Journal Rank (SJR)?

This was developed from the Scopus database by Elsevier. SJR is calculated by.

The Weight value based on the subject field and Quality and Reputation of the journal. This overcomes the problems of specialties that have a smaller number of experts. This score takes into account the citations which an article has received in the last 3 years. It uses an algorithm to handle self-citation and the overall score calculation is complex is open access and available free online at www.scimagojr.com. India is among the top ten countries and the only developing country included if the Scimago Journal Rank (SJR) is used. The average citation parameters are listed in Table 34.4 [2, 21].

34.16 What Is Eigen factor Metrics?

The Eigenfactor metrics give two scores called Eigenfactor score and article influence score. It calculates the number of times the article has been cited in the last 5 years. It is relatively a new metric and is a paid score. In simple words, Eigenfactor is basically a measure of how many people read the journal and think its contents are important. Eigenfactor also takes into account self-citation. Usually, the Eigenfactor score is combined with other scores [2, 22].

Table 34.4 Top ten countries with high Scimago Journal Rank

Country	Documents	Citable documents	Citations	Self-citations	Citations per document	H index
United States	12,839,607	11,339,587	339,229,687	151,101,326	26.42	2386
China	6,589,695	6,469,704	61,658,138	35,288,321	9.36	884
United Kingdom	3,715,590	3,145,039	89,357,199	20,051,057	24.05	1487
Germany	3,222,549	2,964,814	70,371,678	16,909,011	21.84	1298
Japan	2,893,614	2,762,245	48,232,916	12,366,873	16.67	1036
France	2,249,498	2,084,654	48,364,784	9,918,365	21.5	1180
Italy	1,881,818	1,708,800	37,430,348	8,584,150	19.89	1030
Canada	1,877,183	1,684,334	45,766,661	7,875,702	24.38	1193
India	1,873,277	1,741,868	18,243,852	6,215,206	9.74	624
Australia	1,489,730	1,315,978	32,118,547	6,519,905	21.56	1001

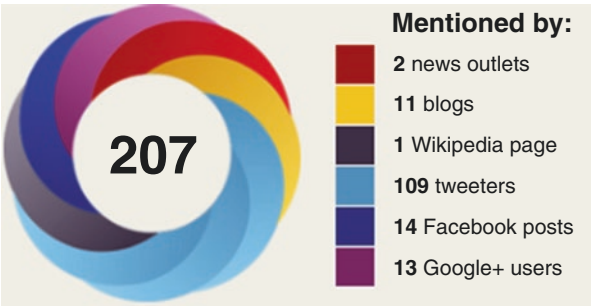


Fig. 34.2 Altmetrics donut

34.17 What Is Altmetrics?

Altmetrics takes into account the digital attention which an article receives. There is a mechanism to track and prevent self-citation. It can also track repeated posts by the same person. All non-journal sources like social media, Wikipedia, blogs and mainstream news are used. It is represented by a colourful donut (Fig. 34.2). The scores can be checked using the website Altmetric.com. the only drawback of this score is that social attention does not necessarily mean a good quality article. The data coverage started in 2011, older articles are not covered by this score [2, 23].

34.18 What Is the Plum X Metric?

This was founded in 2012 but was acquired by Elsevier in 2017. It is integrated with Scopus PlumX Metrics, providing insights into the ways people interact with individual pieces of research output (articles, conference proceedings, book chapters, and many more) in the online environment. Examples include: when research is mentioned in the news or is tweeted about. Collectively known as PlumX

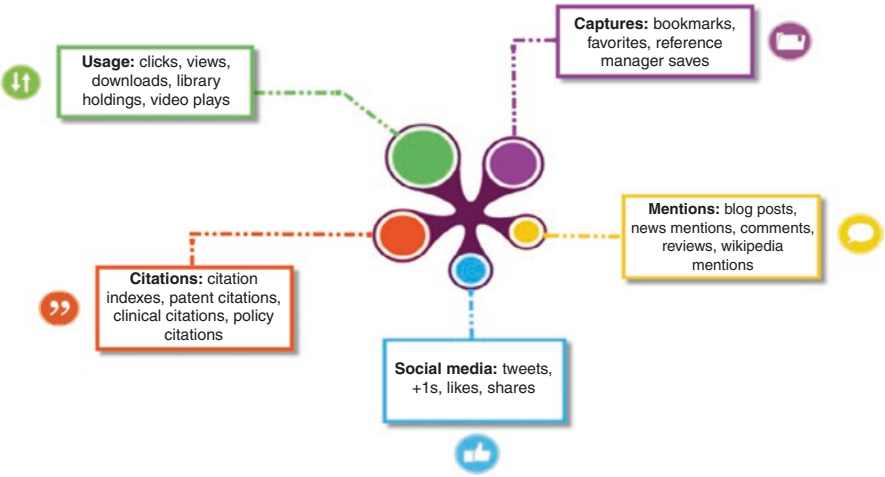


Fig. 34.3 PlumX Metrics

Metrics, these metrics are divided into five categories to help make sense of the huge amounts of data involved and to enable analysis by comparing like with like (Fig. 34.3) [2, 24].

34.19 What Is ORCID?

It is Open Researcher and Contributor's Identification. It is given at the time of registration and submission of an article online. This helps to track all articles with the same number and also tracks the article's responses on social media [25].

34.20 Conclusions

- Once an article has a PubMed citation it means that it is MEDLINE-indexed, manuscripts deposited in PMC and also in the NCBI Bookshelf.
- The impact factors of Indian journals are very much lower than those of international journals.
- The h-index is calculated for the authors' most cited papers and the number of citations that they have received in other publications.
- Bibliometric scores are required by universities and other academic institutions for the promotion and also for research funding
- The newer scores like Eigenfactor score, PageRank index, source normalized impact per paper, plum analytics and Altemetrics are new generation indexes.

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Part VII

What Else You Should Know About Publication?

Is Medical Publishing Lucrative?

35

For many doctors the achievement of a published article is a tedious duty to be surmounted as a necessary hurdle in a medical career.

—Richard Asher, British Physician (1912–1969)

35.1 Can a Doctor Pursue a Full-Time Career as a Writer?

In many developed nations, medical writing and editing is a well-established career path for doctors who are interested in publication. It is not possible, at present, to make a living doing this in India. However, with the increasing number of publications (in print and on the electronic media), medical books, promotions of drugs and devices, and writing designs for drug trials the requirement for medical writers is increasing [1].

Authors generally do not get paid for publication in a peer-reviewed journal. In fact, you may be expected to pay the publisher if it is an open access journal, i.e., it is freely available to readers on the net. The amount may vary from journal to journal and could be from one thousand rupees to ten thousand rupees. Journal publishers justify charging this reasoning that it makes their publications cheaper by helping to offset some of their costs of reviewing, editing, and printing and, moreover, some agencies, like the National Institutes of Health in the USA, insist that the publication of their funded research is in open access journals.

However, if you publish a book you may get some money from writing it in the form of a 'royalty'. Debut writers can expect to receive 5–7.5% of its selling price but if you are recognized as an authority on the subject or already a renowned name in the field this percentage can reach 15% [2]. The percentage rises depending on who the publisher is and how successful the author's previous books have been. Earlier, there was no tax on royalty—it was exempted under the sales tax. However,

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now a Goods and Services Tax (GST) of 12% is applicable on author royalties. In another model, the publishers pay a lump sum as a fee for writing a book.

35.2 Should Indian Researchers Pay to Get Their Work Published?

Many writers are turning towards open access journals for publication of their work. These journals provide full text articles which can be read and downloaded by anyone but the author needs to pay a fairly substantial amount for the privilege [3]. The advantage of open access publication is its easy visibility and early appearance of your work. There are about 540 Open Access journals in India. They include some from various government bodies like the Indian Council of Medical Research, Council of Scientific and Industrial Research, National Institute of Science Communication and Information Resources, Defence Scientific Information and Documentation Centre and Indian Council of Agricultural Research.

35.3 Do Any Countries Give Researchers Cash Incentives for Publication in Peer-Reviewed Journals?

Yes, China is the most well known for this practice. Figure 35.1 shows the amount paid in dollars to the first author by the Chinese authorities for publication in various journals. The amount can range from ten to nearly fifty thousand dollars. The

	2008	2009	2010	2011	2012	2013	2014	2015	2016
Nature, Science	$26,212	$26,006	$25,781	$25,365	$33,990	$36,658	$38,908	$43,783	$43,783
PNAS	$3,156	$3,025	$3,353	$3,443	$3,664	$3,619	$3,751	$3,513	$3,513
PLOS One	$1,096	$1,086	$1,035	$994	$991	$915	$941	$984	$984
MIS Quarterly	$2,613	$2,570	$2,553	$2,654	$2,876	$2,861	$2,992	$2,938	$2,938
JASIST	$1,737	$1,758	$1,741	$1,887	$2,066	$2,303	$2,435	$2,488	$2,488
Journal of Documentation	$1,082	$1,087	$1,042	$1,111	$1,167	$1,265	$1,329	$1,408	$1,408
Library Hi Tech	$781	$775	$726	$741	$740	$768	$795	$783	$783
LIBRI	$650	$644	$577	$560	$538	$509	$517	$484	$484

* All the amounts are full amount (in USD) awarded to the first author

Fig. 35.1 Cash paid in dollars by the Chinese authorities from 2008 to 2016 for publication in various science journals [4]

highest amount is given for publication in the journals 'Science', 'Nature', or the 'Journal of the Association for Information Science and Technology'. For publications in the last journal, the author gets a cash incentive equal to the annual salary of a newly hired Professor and if the article is published in 'Nature' or 'Science', whose journal Impact Factors are 43 and 41, respectively, which means each article has been cited in subsequent publications 43 and 41 times in the next two years (the Impact Factor of an Indian journal, the Indian Journal of Medical Research is 2.0) the cash incentive is up to 20 times the annual salary of a university professor [4, 5]. China has more than a thousand universities which are classified into a 3-tier system. In 1990, they started a project 211 to strengthen about one hundred educational institutions which were classified as tier 1. According to this, the tier 1 universities were given 70% of the national funding so that they could publish research papers.

Other countries are now adopting this practice of giving cash as incentives and these include two in the Gulf region, i.e., Saudi Arabia and Qatar as well in southeast Asia—Malaysia and Taiwan.

In India, the GMR Institute of Technology in Andhra Pradesh has also started paying authors (details available at www.gmr.it.org facilities, perks (Fig. 35.2) [6]. However, a cash incentive for publications has not been perceived to be a good idea by the Western scientific world who felt it hurts both an individual and scientific society [7]. Whether or not it would be good for India is a moot point but we suggest, given the current abysmal state of Indian medical research and publication, that it might be well worth trying.

35.4 Does Collaborative Research Get More Funding for the Researcher?

Yes, collaborative research work has two objectives; firstly, to improve the quality of research by getting help from more experienced colleagues and secondly to attract more funds from wealthier countries. The top five countries with whom

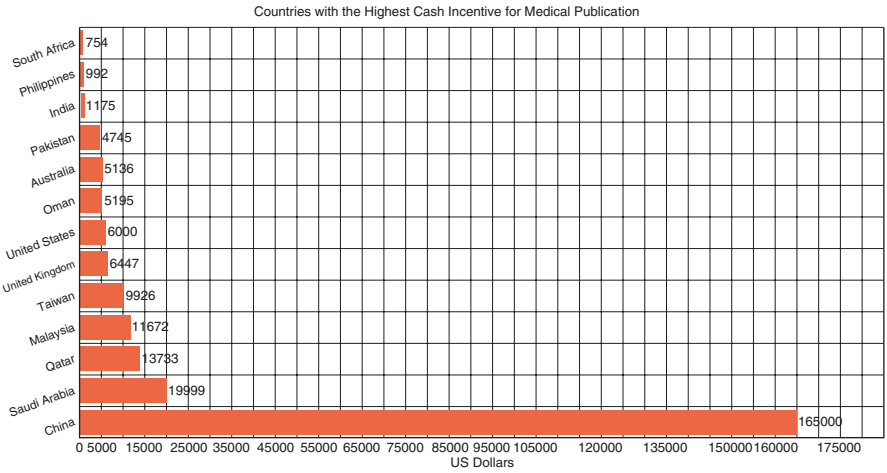

Fig. 35.2 Cash bonus for publication global data [5]

Indian doctors collaborated in publication between 1999 and 2008 were the USA (46.85%), the UK (21.61%), Australia (7.48%), Canada (6.39%), and Japan (6.05%). China appeared in the 11th position (2.8%). Over the next 10 years, a publication by Chaman et al. (2009–2018) mentioned that the USA remained the number one partner in collaboration (31.18%) but, surprisingly, China jumped to the second position during this decade (14.35%) [8, 9].

35.5 How Do Publishers Earn?

Medical publishing is generally a financial venture and many organizations like Elsevier, the Oxford University Press, Wolters Kluwer, and Springer Nature are the leaders in this field. Once a contract is signed by the organization or institute that wishes to start or continue an existing journal and the publisher a fairly substantial sum of money is exchanged. Over and above this, the publisher charges the association according to the number of copies printed. The publishers also gain from the journal's advertisements, subscriptions (personal or institutional), Internet downloads, and from reprints. A proportion of this money is returned to the institution according to the contract. It is estimated that science publishing had made US$9.4 billion profit from 'about 1.8 million English language papers each yielding a revenue of about $5000 to the publisher' [1]. With an annual return on investment of about 40% journal publishing is perhaps more lucrative for investors than the pharmaceutical sector. [9, 10]

35.6 Conclusions

- Publication should be considered as an academic activity rather than an activity to earn money.
- The article processing charge (APC), is a fee that authors need to pay to open access journals for publication.
- Some countries offer money for publication. China is the number one country on this list.
- Publishers earn substantial amounts of money from subscriptions to the journal, downloading of articles, or publication of books.

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How to Start a New Medical Journal?

36

To strive with difficulties, and to conquer them, is the highest human felicity.

—Samuel Johnson, English Essayist (1709–1784)

36.1 Why Should We Start a Medical Journal?

A medical journal encourages research and promotes publication from the institution which publishes it [1]. Many of the best academic institutions abroad and in India publish medical journals, e.g., the Mayo Clinic (Mayo Clinic Proceedings) in the USA and the All India Institute of Medical Sciences (The National Medical Journal of India).

36.2 What Are the Ten Most Important Steps Before Starting a Journal?

Starting a journal is a major commitment and cannot be done alone. It requires teamwork with like-minded people. Most of the editorial work is honorary and only people interested in academics should be entrusted to take this on. The editorial and working committee of the journal require determination, time commitment, and passion to produce a journal of high quality.

The important steps before thinking of starting a new journal are [2]:

- **Step-1** Understand the need for starting a new journal. It could be a new field, a journal based on an unusual theme or a hospital-based multi-speciality journal.
- **Step-2** Appoint an Editor, who will lead the team and will be responsible for the scientific content published.
- **Step-3** Then appoint a Working Committee from within the local talent and representing many different specialties. These dedicated people should hold weekly meetings initially to work on the logistics for launching the journal.

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- **Step-4** Invite an Editorial Board of approximately sixteen well-known physicians who would be willing to help. There should be at least eight from abroad.
- **Step-5** Ask for a dedicated office, computer, Internet access, and start designing a website.
- It is useful to have an 'Editorial Assistant' who receives and checks manuscripts, sends them to reviewers, and interacts with the publisher.
- **Step-6** Work on a name for the journal. The name should be catchy, concise, and reflect what the expected contents will be. The title should be attractive, informative, unusual, and perhaps unique. Not 'Proceedings of the …' but 'Quality Health care in the Himalayan Foothills'.
- **Step-7** Work on getting a good publisher. This is a major task and in medicine the top publishers are Springer Nature Publishing, Oxford University Press, Taylor & Francis Publishing, Wolters Kluwer, and Elsevier.
- **Step-8** Call for papers. To get manuscripts will be difficult initially as the journal will not be indexed. Depend on the local institutional talent, your friends and acquaintances here and abroad, and subsequently through online advertisements and displaying it in major conferences.
- **Step-9** Try and produce a 'world class' journal from the first few issues which should influence decision makers in science.
- **Step-10** Register the journals on various portals like a web of science, PubMed, and Scopus to disseminate knowledge about journals and articles published.

36.3 What Kind of Articles Should We Publish? How Do We Plan a Table of Contents?

The Editorials should first be written by the Editor, e.g., 'Why this Journal?' Later they should be invited, and discuss general topics or comment on papers published in that particular issue. We believe that the editorials should be signed.

The next section should be on Original Articles; initially requested from friends, faculty, and students preferably from other institutions on basic, clinical, and paraclinical sciences. They should all be sent for peer review to two or three experts one of whom should be foreign.

Review articles should be commissioned from known authorities and although sent for review but should generally be accepted.

Then should follow Short Reports, Selected Summaries (precis and commentary on articles published elsewhere), a section for General Practitioners and Students, reports of Clinicopathological Conferences, a Speaking for Myself or Medicine and Society Section and perhaps a profile of a great medical man or institution here or abroad. There should be a special section on 'Letters to the Editor'.

36.4 What Are the General Guidelines for Publishing the Journal?

Always start a journal using peer reviewers. This not only improves the quality of articles published in the journal but also it is standing among the scientific community. Few general instructions are [3]:

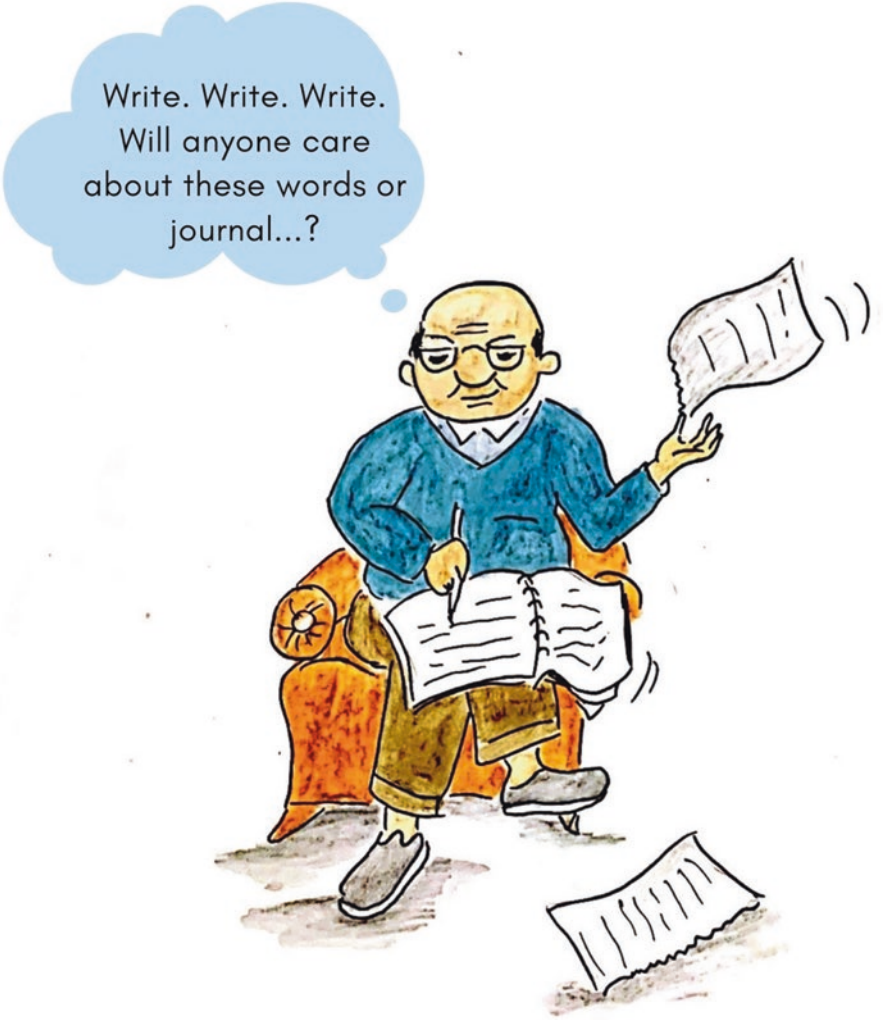
- Insist on Quality, Class, and Excellence in the article published.
- The number of pages per issue should be at least 48 pages and thereafter in multiples of four.
- The Cover should have a simple design perhaps displaying the table of contents.
- Choose good quality paper, have a two-column layout, and make provision to have both black and white and colour illustrations (Fig. 36.1).

Fig. 36.1 Simple cover of Medical Journal with table of contents (with permission of editor CMRP)

- Choose a good printing press for the paper copy and post the online issue on your website.
- Apply for an International Standard Serial Number (ISSN). This is an eight-digit unique number given to all journals by the Registrar of Newspapers of India.

36.5 What Discussions Should We Have with the Publisher When Planning a Journal?

Discuss the general layout of the journal and the paper's quality. The other things to be discussed are its format, whether it is open access or closed, free online, or requiring a subscription. Also, discuss revenue sharing between the institution and publisher from subscriptions and also from advertisements. Decide the frequency of publication, i.e., monthly, bimonthly, or quarterly.



36.6 What Should Be the Agenda for Weekly Working Task Force Meetings?

The members of the working task force are the main people who will run the journal. They should be responsible for:

- Sending letters of invitation for articles to potential authors-constantly and regularly.
- The whole process of submitting articles, receiving them, sending to reviewers to accept, modify or reject, making an editorial decision to accept, forwarding to the printer, checking the PDFs can all be done using an Editorial Manager software programme.
- Try and maintain a high standard of content, layout, and quick decision-making on the submissions.
- Ensure that the journal is published and always comes out on time. The online version should always be followed by a print version.
- After 2 years of regular publication apply for indexing to Medline.

36.7 What Are the Challenges Which the Journal May Face During Its Initial Days?

It is usually believed that if a journal is able to survive for two years it may be able to exist for the long term. The major challenges which the journal may face in the future are [4, 5]:

1. Financial crises—the start of a journal requires a good amount of seed money and then there are recurring costs of printing per issue and also the cost of manpower in running the office. The open access model where the authors pay processing fees and subscriptions and advertisements can be the three sources of income for the journal.
2. Inability to get good content scientific articles. There is a vicious cycle that till the journal is indexed it may not be able to get quality articles. Till then all the articles that are received by the journal may have to be raised to better quality by the working committee.
3. Inability to get indexed with different scientific portals.
4. Poor English is also encountered in many manuscripts, especially when it is from non-English speaking countries.
5. Reluctance to do peer review is a process that is very time consuming.

36.8 Conclusions

- Starting a new journal is a difficult task and sustaining it is even more difficult.
- It is not a one-man show and requires a team effort. One of the pre-requisites is to include a competent experienced, hardworking, and enthusiastic editorial team.
- A major hurdle for the journal is to be indexed with different agencies. Once this is done the journal may be able to survive and flourish.

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Part VIII

How to Project Your Work Further?

How to Present a Poster in a Conference?

37

If you can't make it good at least make it look good.

—Bill Gates, American Software Developer (1955–)

37.1 What Is the Importance of a Poster Presentation?

Once your scientific experiment has finished you need to tell the world about its importance [1]. The usual ways are by writing a manuscript and sending it to a peer-reviewed journal, by giving a slide presentation at a conference or by the way of a poster presentation at a conference. There are usually workshops held in conferences about how to publish papers. However, little consideration is paid to how to present a good poster. This is also a common method of presenting your work, at a conference and needs to be given importance [2].

37.2 How to Start Preparing for a Poster Presentation?

The making of a poster starts with the acceptance of the abstract by the scientific committee of the conference. They will then separate the papers according to the importance of the subjects into those selected for oral presentations or traditional poster presentations. This letter of acceptance is the first step from which the journey to prepare the poster begins [3].

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37.3 What Are Important Facts to Know Before You Start a Poster Presentation?

You should learn some preliminary facts about poster presentations before starting your project. These include [4]:

- About 30% of posters are cluttered or 'sloppy'.
- About 20% have fonts that are too small to read from a distance.
- In about 38% the research question cannot be located after a one-minute survey.

There is another interesting fact called the '10 ×10 rule for poster presentations', i.e., the average attendee spends only 10 seconds to scan the poster as he/she strolls in from a distance of 10 feet. It is imperative therefore that the poster should be eye-catching and attract a potential reader to come close to it. Thus, poster making combines both the science and the art of scientific presentations [5].

37.4 What Are the Stages of a Poster Presentation?

The stages are the planning of the contents, organizing the data, drafting, and finally printing the poster. The final endorsement comes during the interaction with the audience as to how well you have been able to 'sell' your work and defend it at the same time.

The various steps for poster presentation are described below:

37.4.1 Step 1: Planning

Simplicity is the key mantra for a poster. A person does not spend more than a few seconds gazing at the poster, so there should be a minimum of clutter and a maximum of graphics.

1. The information provided by the conference organizers is vital at this stage. They usually specify details such as the poster size, poster number and on which day, place, and time it may be displayed.
2. Go through the abstract and make sure it contains all the necessary information.
3. Check all the data and tables and figures.
4. There are many paid and unpaid sites that provide templates for poster presentations (Table 37.1). The ideas may be borrowed from them but be creative and use your own ideas as well.

Table 37.1 Paid/free sites for poster template

Free sites for poster template	Paid sites for poster template
https://www.freepik.com	https://graphicriver.net
https://www.postermywall.com	https://in.pinterest.com
https://pngtree.com/poster-templates	https://www.canva.com

37.4.2 Step 2: Organization of the Poster

A poster has been compared to the story of a movie. It should contain the setting of the main plot (research question), methods, climax (results), and the ending (conclusions). Figure 37.1 shows how to organize a poster into various heading.

37.4.3 Step 3: Printing of the Poster

Before this stage, it is always better to show a draft of the poster to a friend or senior colleague who has more experience. Their inputs at this stage can be very useful.

There are two types of papers available for printing. Glossy paper is expensive but it is durable. There is glare as the light reflection can make it difficult to see the poster from a particular angle. There is, however, better resolution of clinical photographs, histopathology, and radiology illustrations. In comparison matte paper does not reflect light, is more economical but less durable, and also provides less resolution for illustrations [2].

37.5 How Should the Material Be Placed in the Poster?

A poster has three main components [5, 6]:

- Main text
- Illustrations such as statistical graphs, flow diagrams, and photographs

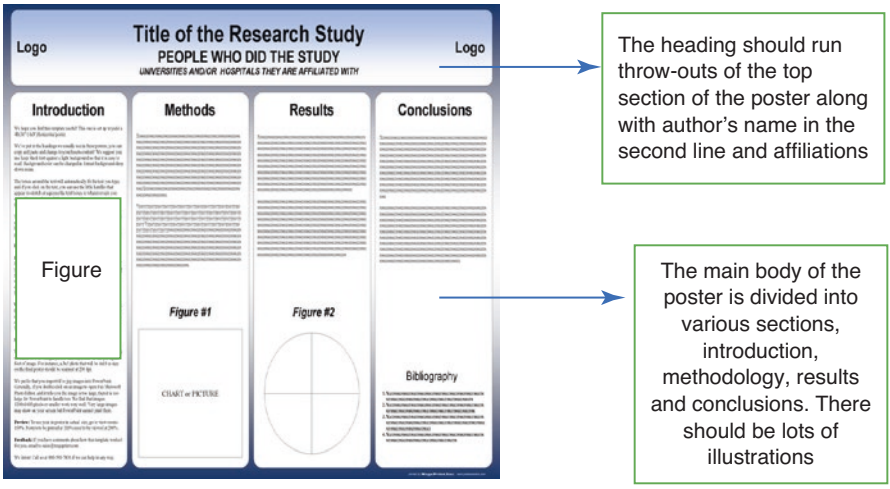


Fig. 37.1 Organization of the poster

37.6 Background

Make a plan for the poster and fix a space for each component [7].

- The heading appears in the uppermost part of the poster. The title should be readable from at least 2 metres away. The names of the authors and their affiliations should also come under the heading [4].
- Introduction should be brief and should be 3 to 5 lines and appear at the upper left portion of the poster.
- Research question, aims, methodology, and results need to be placed subsequently. Do not repeat any data. If possible, use more space for tables and results.
- Illustrations are important components of a poster and add life to it.
- The conclusions should appear at the lower right portion of the poster.

37.7 What Should Be the Font Size of the Text in a Poster?

- The main content of the poster should be made double-spaced with a left-sided justification.
- A text with its left side even and right side jagged is easiest to read.
  - The font size is important. Posters should be legible from a distance of about 2 metres [8].
- In general, use font sizes proportional to the subheading in the poster.
  - The title should have the largest font and should be bold and at least 72 points.
  - The subheading is the next largest and should be at least 48 points and bold.
  - The text of the body font should be at least 24 points.
- Both landscape or portrait layouts are good for a text poster.
- You need to be consistent in using fonts. Only one type should be used throughout the poster.
- Bold headings stress importance. The other ways of doing this are by highlighting or underlining, or using different colours. A text in italics is difficult to read from a distance.

37.8 What Should Be the Word Count in a Poster?

The success of a poster is directly related to the 'clarity of the illustrations and tables and viewing a poster should be a visual feast'. [2] The total word count of the poster text should be between 300 and 800 words. More important than the word count are the illustrations. A self-explanatory graph should govern the poster. The text should supplement the photographs wherever possible. Less text is better, be innovative in the poster, in the placement of the text, and a light background stands out (Fig. 37.2).

Effect of smoking in young males on complete blood counts.

ABC……..The Ganga Ram Institute of Postgraduate Medical Education and Research, Sir Ganga Ram Hospital

Fig. 37.2 Word count in a poster

37.9 How Should the Poster Background Look?

The choice of a background colour depends on the presenter. Softer pastels or greys look fine. They can be easily viewed for a long time and are also ideal for graphics and photographs. Dark backgrounds should be avoided, as the graphics do not stand out against them. Backgrounds with a graded texture make a poster look too busy.

37.10 What Are the Important Considerations While Making a Poster?

- Graphic illustrations should be visible easily from a minimum 2 metres. Do not use more than 3 colours in a poster.
- Avoid photographs less than 5 × 7 inch as they may be difficult to see.
- All figures should have legends.
- All photographs should be at least 300 dpi for clarity and good resolution.
- Cropping all unwanted details from photographs helps to depict what you want to show.
- Having a thin outline around photographs, helps them to look prominent.
- The colour of graphs should match with the poster.
- Do not use copyright images for poster presentation.

37.11 What Are the Limitations of Posters?

The poster presentation occurs in a calmer environment than an oral presentation. It also encourages much more individual interaction between the author and viewer than an oral presentation. However, it has many drawbacks. Firstly, the reach of posters is limited to a few delegates compared to an oral presentation. Secondly, the interaction may need to be repeated many times with different attendees. Thirdly, any routine or inconsistent conclusions cannot be debated in a group.

37.12 How Should You Store and Transport a Poster?

The packing and carriage can be done in cardboard tubes or plastic rolls. Identification details should also be mentioned on the tube to recover it if it gets lost. If the poster is to be reused then using a thick quality of paper with lamination along with a box will increase its life.

37.13 How Should You Display the Poster?

Although the organizers usually provide pins or tape at the conference venue, it is always better to carry these with you. Also, carry a few A4 printouts for distribution.

37.14 What Happens During the Interaction?

The interaction during a poster presentation is a better way of communication than an oral presentation as it is only between two individuals. The time for displaying the poster and for interaction is usually given in the letter of acceptance. If the scientific content of the paper is good then the poster is shortlisted for a special poster tour. There is often an award given to the best poster for its overall content, aesthetics, and interaction of the author with the referee.

37.15 What Are the Types of Poster Presentations?

By convention, a poster has to be printed on paper. However, the demand for an electronic poster format is increasing in many conferences. The e-poster is inexpensive, it saves paper, is quicker, has better colours, and is easy to carry. It uses the PowerPoint format or multimedia, which is more versatile. The impact of an e-poster is greater as 3D animation and surgical technique videos can be loaded and it is visually appealing. This has revolutionized poster sessions as science has become more colourful and vivid. In this COVID era the majority of conferences except for posters are in the e-format. Smartphones and tablets are new generation devices that have paved the way towards the electronic format of poster presentation.

Examples of good and bad posters are shown in Figs. 37.3 and 37.4.

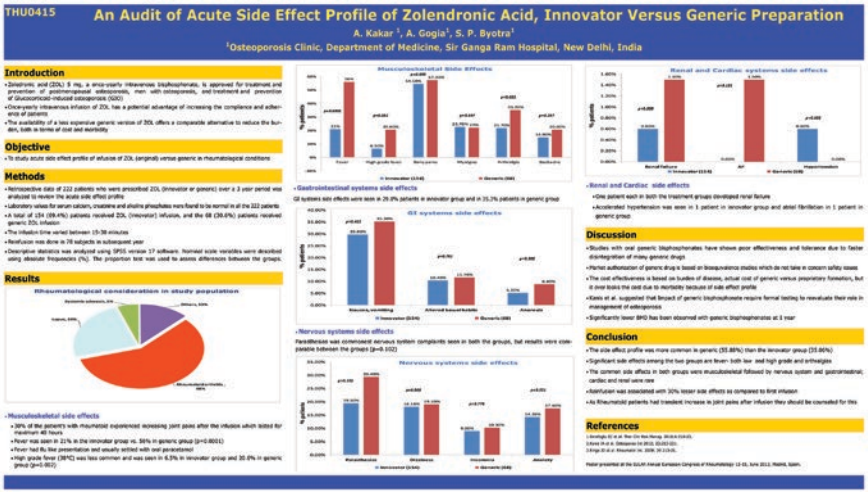
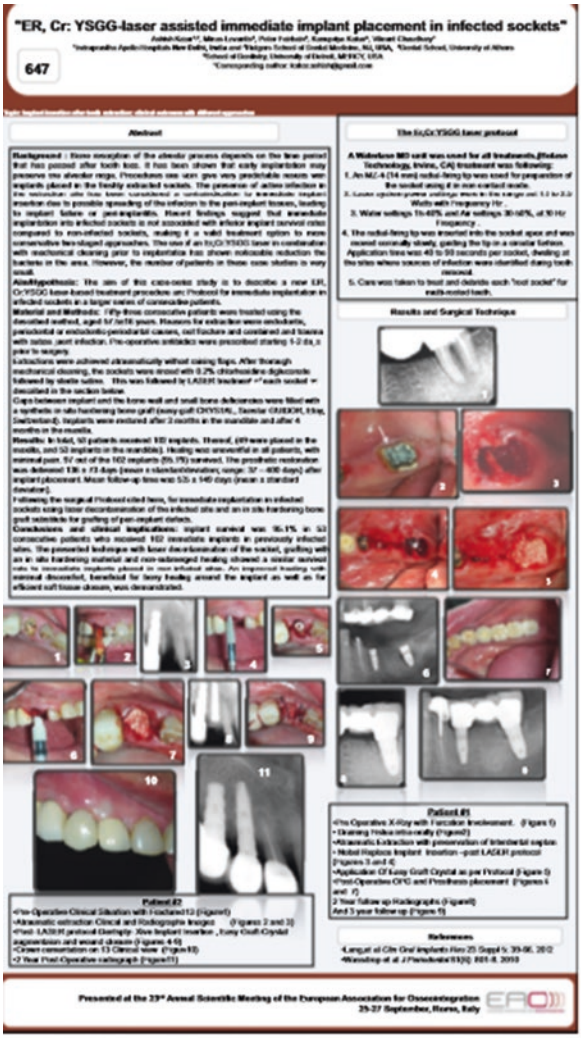


Fig. 37.3 Balance of text with graphs


"ER, Cr: YSGG-laser assisted immediate implant placement in infected sockets"

647

Abstract

Background

Aim/Hypothesis

Material and Methods

Results

Conclusions and clinical implications

The Er,Cr:YSGG laser protocol

Results and Surgical Technique

Patient #1

Patient #2

References

Presented at the 23rd Annual Scientific Meeting of the European Association for Osseointegration

Fig. 37.4 Too much data, balance between text and figure is missing

37.16 Conclusions

- A poster presentation is a combination of art and science.
- It is an effective way to communicate scientific work.
- It has many stages like planning, organization, printing, and transportation.
- The interaction session with the viewer is important during the display and may yield new ideas.
- The e-posters are a new and powerful technique being used in many conferences.

- Analyse study data
- Short list important / interesting observations and material illustrations, graphs, charts, photographs
- Read details about poster presentation from conference web site

- Title: Most important 'Be innovative'
- Author and affiliation
- Introduction – brief outline
- Problem: what is the scientific question to be tested?
- Methods and material – brief discription, use algorithm, flow chart
- Results: outcome measures
- Conclusion: summary
- References (minimum)
- Acknowledgement
- Contact information

- Decide general lay out and placement of text and graphics
- Colour scheme
- Font
- Material: paper / flexi paper

- Cardboard roll / Storage box
- Lamination of paper roll

Fig. 37.5 Flow chart of how to proceed with a poster

37.17 What Are the Various Steps in Making a Poster?

The various steps are given in Fig. 37.5.

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How to Give an Oral Presentation?

38

The first 30 seconds and the last 30 seconds have the most impact in a presentation.

—Patricia Fripp, American author

38.1 Planning

An oral presentation is a form of communication, where you impart and then exchange information with your audience. This can be either one-way, a didactic, or two-way called a Socratic or a Dialectic presentation. There are many forms of oral presentation and you should find out where and when you are required to speak [1]. The National Training Laboratory in Maine, USA has suggested a 'cone' of learning or learning 'pyramid'. In this, they have found that the most effective way of learning is through teaching others. Most students remembered only 10% of the material given in books but remembered 90% of the facts they learned when they had to teach others [2] (Fig. 38.1).

- **The Lecture** is an old way of teaching and by convention called the 'chalk and talk' method. The talk needs to be prepared carefully but it is thought to be an ineffective way of imparting knowledge. The flow of ideas and organization of a lecture is an art. It is usually taken by a qualified person. In this, there is passive learning of the attendees as it is a one-way communication. The number of people in a lecture should be around 30 and its duration should be 15–20 minutes. In a lecture during a conference, the number of participants can vary from 50 to 1000.
- **Symposium**—This consists of a series of lectures usually on a single selected topic. Each speaker gives a brief presentation, there is no discussion between the speakers during the presentation and finally the chairman summarizes the talks.

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_38

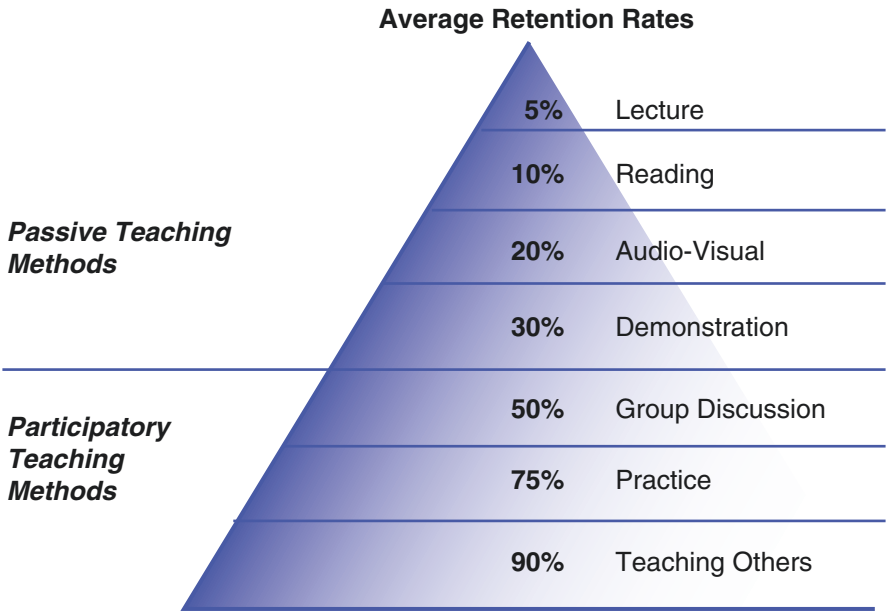

Fig. 38.1 Retention rate of various teaching methods adapted from National Training Laboratories, Bethel, Maine, USA

People who speak in symposia are experts in the field and all talks are delivered in a single day.

- **Group discussion or Round table talk**—In this, there is a face-to-face discussion between a group of people of usually 6–12 members who sit around a table. The leader initiates the talk and the other members give their opinions. Most round table sessions are fairly structured and require attention to time management and content, with intermittent audience participation.
- **Workshop—**This is a series of lectures in a smaller group. There is an interaction between the members but it is usually at a local level.
- **Seminar—**This is a half to full-day discussion on a particular topic with about 30–40 participants.
- **Debate—**This is an increasingly popular format utilized in larger meetings with two speakers discussing controversy and arguing for either side. This can be through formal presentations or interactive discussions.

All these teaching activities can now be virtual and recent circumstances have indicated that this might be the 'new normal'. Physicians need to be accustomed to this as it may be the way forward for medical education.

38.2 Does the Success of an Oral Presentation Depend on the Audience?

This is generally true and a presentation works if:

- The audience feels the need for the information.
- Is enthusiastic.
- The subject is applicable to their clinical practice.
- Its content is clear and easy to grasp.
- There is active audience participation.
- Multiple ways of presentation are used, i.e., PowerPoint slides and videos.

38.3 What Is a Powerful Oral Presentation?

A powerful oral presentation can be summarized with 5 C's

- Contains **C**rucial information
- There is a Clear style of presentation
- Confidently delivered
- With Concise data
- The delivery is Creative and Clever

38.4 What Are the Steps You Should Take Before an Oral Presentation?

An oral presentation can be divided into:

1. A Pre-Presentation stage
2. The Presentation
3. The Post-presentation stage [3–5]

In the Pre-Presentation stage:

- It is important to check the venue and equipment. It is always better to arrive on time, load the presentation, and recheck it in the preview room to see if the presentation is in order. You should also check with the organizer whether there is double projection, because this requires a lot of coordination and rehearsal.
- Check the podium and make a mental picture of how much of the area of the podium and dais you will use during the presentation. Currently, many people follow the TED (Technology, Entertainment, Design) format where there is no podium and they use the entire stage for the talk. For this type of presentation, you should be a seasoned public speaker. Body language is important in this.

- Find out about your target audience—general physicians, a mixed group of doctors, a specialty group, or the lay public. However, if it is a speciality lecture the content should cater only to specialists.
- You should be appropriately dressed—properly and professionally.
- It is always better to email the presentation in case there is a hitch in your pen drive function at the last minute.
- Before planning the presentation, go through the programme of the conference as many of the topics in the session might have been covered by someone else. So, those aspects should be omitted from your talk.
- The preparation time for your lecture, whether it is 10 min or 30 min long is the same as you need to review all the relevant literature before the presentation. The shorter the talk the more difficult it is to condense and give a powerful performance.
- 'Rehearse, rehearse and rehearse' are the three most important mantras for a flawless delivery.

38.5 How to Deliver an Oral Presentation?

Making a presentation is a skilful art, which has to be learned over years. Richard Leech, a medically qualified actor, stated that 'Lecturing is like Acting, where you have to a tell a tale to the audience but it is more difficult than acting because you have to write the script as well'. You cannot inherit the ability to give a good lecture—it comes with repeated practice and as you lecture more you become more confident of speaking in public.

A presentation has two important components, i.e., its content and style.

The content can be further divided into introductory slides, the main text, and conclusions.

The Introduction is the most powerful part of the presentation. There are various models that have been suggested for an introduction slide.

- The expected introduction would be to greet the audience and start reading the slides. However, this approach although considered polite, is benign, boring, and lacks power and passion.
- Model 1–2-3 consists of, step 1 to greet the audience, step 2 pause, and step 3 is to make an attention-grabbing statement or relate a story that is linked to the presentation.

The opening few slides should make the audience believe that you are the best person to deliver this lecture and also it has important content for them (WIIFM—What's in it for me?). In case the chairperson has not introduced you it would be relevant to provide some personal and professional information in the first few slides. Typically, the introduction should take 2–3 minutes or 10–15% of your allotted time. This is also the time you will take to establish a relationship with your audience.

Thus, the introduction slides are:

- The first contact with the audience and they set the tone for the rest of the lecture.
- An opportunity to grab the audience's attention.
- You can start by asking a question or pose a hypothesis to the audience.

The main body of the talk should be divided into 3–4 subheadings and each subheading should have a learning and take-home message to reduce the monotony and increase (Fig. 38.1) the learning. The content of the presentation should also contain the purpose of the talk. Although information repeated is important for learning, unnecessary facts are usually boring. You should use diagrams, charts, cartoons, tables, and photos to decrease the written parts.

You should use varied modes of presentation which may include PowerPoint slides, clips of videos, or discuss real-world scenarios. These make the presentation more interesting.

The Conclusions can take up the last few slides and rather than re-stating the same sentences try to find new and easily understood words.

As for the style of the presentation, it should be bold and exude confidence.

The other qualities are:

- Maintain calm—Many people get anxious when it comes to an oral presentation. Mild anxiety increases the androgenic drive which makes the presentation more exciting, however, if you have moderate-to-severe anxiety it may manifest as jitteriness and you may fumble. Sometimes deep breathing exercises can help to allay symptoms of anxiety. Do not take any drugs before the presentation.

- Rehearse your presentation. This has two advantages—you can do time management and you can speak with clarity on all the important slides. You should not read out the slide but use it as a point of reference to dilate on the subject. Under all circumstances, DON'T read your slides!
- You should not be nervous, shuffle, fidget, and fumble once you are on stage. Even if you are anxious, like a good actor you should not show it.
- A boring presentation can be judged by the non-verbal communication during it. The audience will see how many people are sleeping, busy on their cell phones and how many are learning and taking notes.
- During the presentation, you should have eye contact with the audience and not with the slides.

38.6 What Should Be Done in the Post-Presentation Period?

You should invite questions. Do not be afraid to answer questions because you as a presenter have more knowledge about the subject than the audience [5]. The questions can be answered by saying 'thank you, it was an intelligent question'. The answer to the question should be brief and should not be the signal to launch a second presentation.

The questions after the lecture can be divided into *irrelevant*. For which you need to be polite in answering, *profound* to which you can regret that there is a lack of time and the person can interact with you during the break or might be *challenging* and requires inputs from the house. You can ask for a show of hands or a debate on such challenging questions.

38.7 What Should Be the Speed of the Presentation?

The newsreaders on the media speak at 120–130 words per minute. You need to practice this. If you speak very fast the information is not grasped. In the case of an international talk, you need to speak slowly as language and pronunciation may be a problem for the audience [6].

38.8 Should You Take Short Pauses During a 30-Minute Talk?

You should not take a pause or stop the presentation as it becomes boring for the audience. There is an attention curve that is maximum in the first few minutes of the lecture and then during the last portion of the lecture (Fig. 38.1). However, in case the lecture is lengthy, you can change the tone of your voice or show a visual aid rather than pause. In general, avoid lectures exceeding 30 min and as a general principle, try not to exceed one slide per minute.

Fig. 38.2 Example of good studies

How to write an Introduction?

- It is critical in any protocol
- It familiarizes the readers with the background of the issue at hand
- It must reflect why the issue is topical
- Its current importance in the vast sea of research being done globally

Fig. 38.3 Example of bad studies

End para of introduction

Till date no study has been done to see the effectiveness of fascial interposition alone or effectiveness of double ligation of seminal vesical cut end of the vas without fascial interposition for this low incidence of failure rate. So, present study is aimed at comparative effectiveness of fascial interposition with double ligation of the seminal vesical cut end of the vas and effectiveness of double ligation of seminal vesical cut end of vas only without fascial interposition.

38.9 What Kind of Slides Should There Be?

The background of the slide should be such that the information written is clear; traditionally a light colour with black writing is recommended. There should be no more than 6–8 lines in a slide with not more than 8 words in a line and with proper alignment. No detailed sentences are required while making the slide [7, 8]. Examples of good and bad slides are shown in Figs. 38.2 and 38.3.

38.10 What Are the Ten Steps Towards a Robust PowerPoint Presentation?

Delivering PowerPoint presentation requires skill in public speaking. Below we summarize the six steps for a power-packed presentation [9].

- **Step 1**—Know what are goals of your presentation. Is it to educate the audience on a naïve subject or to update existing knowledge?
- **Step 2**—Know your audience. It is usually said that one size does not fit all and similarly your audience may be heterogenous and your aim will be to give all of

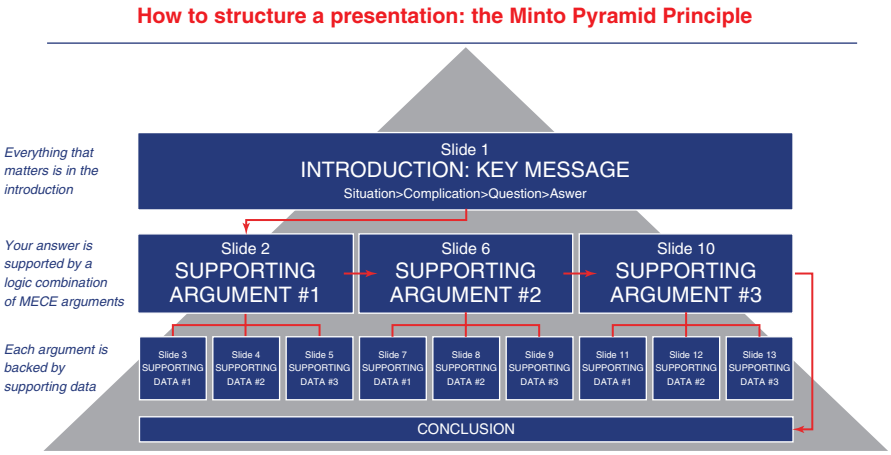

Fig. 38.4 The Minto Pyramid

them a basic level of information. Each time there is a new audience your slides should change accordingly.

- **Step 3**—Prepare an outline of your talk. Each topic can be subdivided into small topics and try to focus on 3–4 subpoints in your presentation.
- **Step 4**—Build up your subpoints. Work on the 'pyramidal' approach to build up your presentation (Fig. 38.4).
- **Step 5**—know the layout, designs, and background available. Few of the layouts and background designs are shown (Fig. 38.5).
- **Step 6**—Your PowerPoints slides should be perfect. Use a font which is legible, a background colour which is soothing, and a template which suits your presentation.
- **Step 7**—Follow the 5/5/5 rule that is not more than five words in line, not more than five lines per slide, and no more than five text slides in a row.
- **Step 8—**Adjust the number of slides according to the time allowed. For a five-minute presentation about 5–6 slides are recommended.
- **Step 9**—The slide design should match the audience and ambience.
- **Step 10**—Use graphs, photos, and other visual aids to decrease the monotony.

38.11 What Is the Conclusion for an Oral Presentation?

- Conclude by recapitulating what you have said in your slides. Why did you do this study, How did you do it, what results did you get and what is your 'take home' message.
- An Oral presentation is a powerful way of communication with the audience. It should be presented clearly and with confidence.

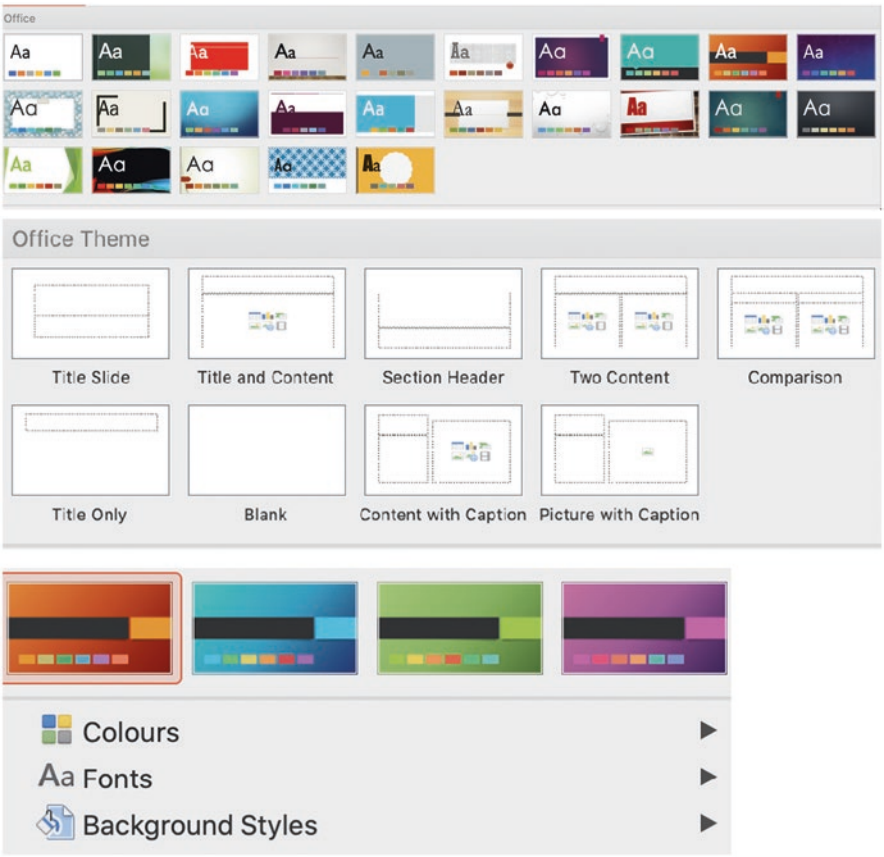

Fig. 38.5 Some designs available

- The Stages of an oral presentation include the pre-presentation preparation, podium presentation, and post-presentation period. An Oral presentation is an art that is learnt with time.
- The Slides for an oral presentation should follow the 5 × 5 rules.

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Part IX

Education, Planning and Execution

Bedside Teaching in Developing Countries

39

To study the phenomena of disease without books is to sail an uncharted sea, whilst to study books without patients is not to go to sea at all.

—Sir William Osler, Canadian Physician, 'Father of Modern Medicine' (1849–1919)

39.1 How Has the Concept of Bedside Teaching Evolved?

The patient's bedside has been compared to a platform where budding doctors get an opportunity to actively engage, learn, and acquire new skills. It provides the best in-person professional environment for young medical graduates, staff physicians, and fellows to translate their theoretical knowledge into practical skills. The concept of human learning has been based on the evolution of varying theories of behaviourism, cognitivism, and constructivism [1]. Human psychology trains itself by constructive analysis of the varying experiences in day-to-day learning; in other words, exploring old information through the discovery of new information. This phenomenon has been termed as the 'spiral learning' by Bruner [2] a concept that is reinforced in bedside teaching. This emphasizes active participation in teaching by the mentee/learner, which is the 'new normal' for a didactic teaching format (Fig. 39.1). The importance of bedside teaching dates back to the fifteenth century, when Sylvius (1614–1672), a renowned French practitioner, voiced his thoughts on teaching on rounds [3]. He believed in the concept of daily teaching by asking questions about the various clinical signs and symptoms and inquiring from the students regarding their observations, thoughts, and perceptions relating to patient care. It has been shown by studies that the history contributes to deriving 56% of the diagnosis [4] and a comprehensive physical examination can provide 70%.

Some of the strategies used to ensure adequate teaching through ward rounds and bedside clinics are as follows [5]:

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_39

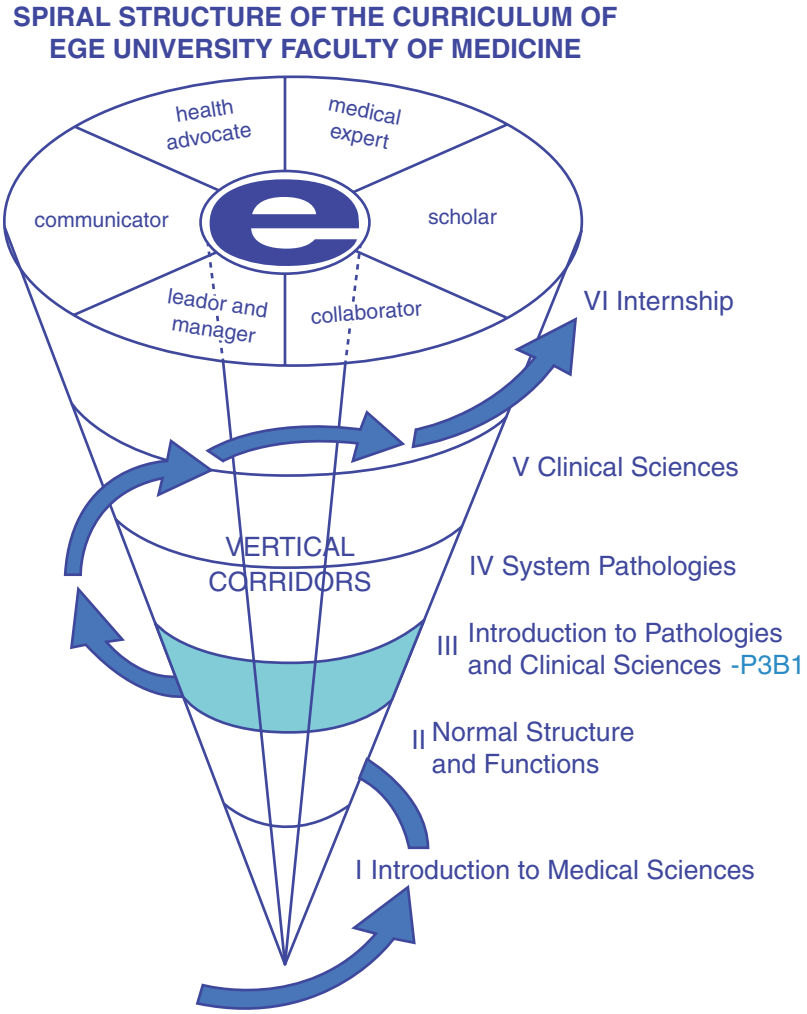


Fig. 39.1 Example of spiral learning

- ***Generating interesting questions***: The concept of guiding superficial to conceptual learning occurs when the student/resident is fired with questions by the house staff/consultant on the rounds, which would essentially make the latter think 'out of the box'. This would mean establishing a connection between the theoretical facts with its twists in medical practice.

  For example:

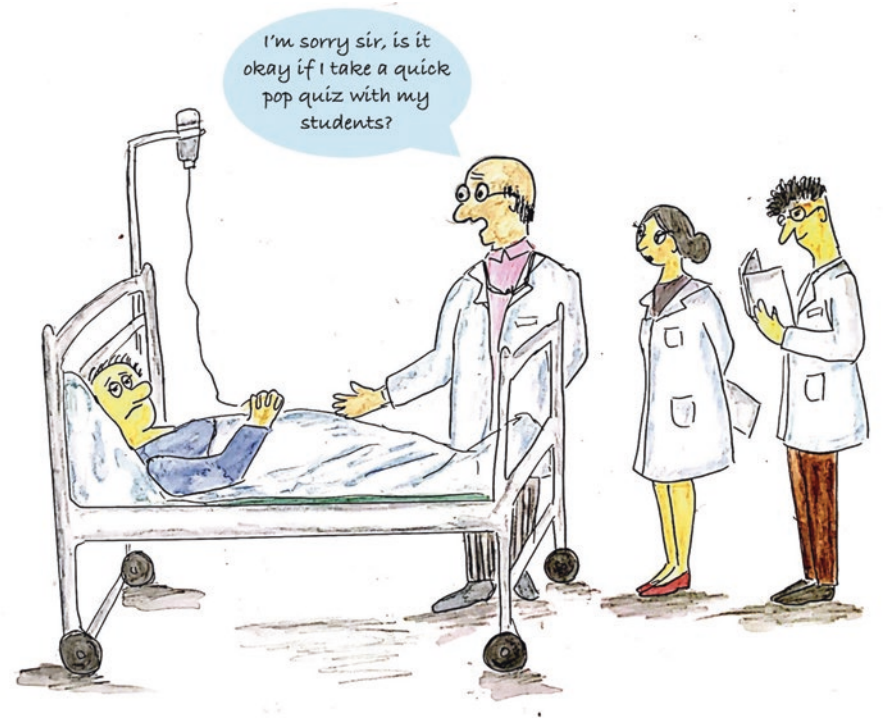
  – Why does blood appear black on ultrasonography? (Ans: Because it does not generate an echo).

- ***Making 'connections'***: Establishing connections between medical phenomena and general day-to-day practical learning ensures remembering facts for a long time without having to cram them. The onus lies with the mentor (consultant), who can explain to the students complex techniques and physiological phenomena in a simplified manner by drawing parallels from day-to-day life.

  Examples:
  - Explaining the decrease in intravascular volume associated with hypotension: Comparing the same with leaking plumbing pipes in a household that lead to a decrease in the water pressure and flow.
  - Teaching the effect of a change in bed position on central venous pressure (CVP): Taking the example of a see-saw → when one end goes down, the other end goes up → in other words, when the bed is low, CVP is falsely high and vice versa.
- ***Demonstrating contrasting features on rounds****:* This is most useful when teaching important clinical signs.

  Examples:
  - Auscultation of heart sounds: Differentiating the heart sounds based on the characteristics is better grasped when demonstrated on the patient than learning the same by memorizing from the book. This is a more than 200-year-old technique described in the medical literature [6].
  - Demonstrating the amount of free fluid in peritoneal cavity → by demonstrating the fluid thrill (a large amount of fluid), shifting dullness (moderate), and puddle sign (minimum fluid).
- ***Questioning based on hierarchy****:* Asking a question to the team composed of the undergraduate students, interns, house staff, registrars, and the consultant. The aim is to circulate the question in the team from the junior to the senior most in the round, to generate the most refined answer.

  Example: What is Courvoisier's law? (The most acceptable response would be the law stated 'verbatim': *In a jaundiced patient if the gall bladder is palpable, it is seldom due to stone disease* vs *If the gall bladder is palpable with jaundice, stone disease is unlikely* vs *Jaundice with a palpable gall bladder is not due to stone disease*).
- ***Grooming up strategies****:* Bedside teaching, besides being a platform also plays an important role in the grooming of the young house staff. Paying attention to detail, learning the value of punctuality, enhancing communication skills with the patients, and above all being humble and grounded are some of the other attributes learned through regular bedside rounds. This builds up the skills such as interpersonal communication, rapport building, and gaining a patient's confidence; attributes that cannot be learned through textbook reading.



39.2 What Are the Various Models of Bedside Teaching?

- ***The three-domain model of the best bedside teaching practices:***
  Suggested by Janicik and Fletcher in 2003 [7], the model emphasizes.
  - Attending to patient comfort: patiently listening to the complaints, counselling about the disease in detail; avoiding technical language, and providing an encouraging disclosure.
  - Focused teaching: diagnose the patient, diagnose the learner, target the teaching, and provide constructive feedback, in private.
  - Group dynamics: aims to keep the group active and attentive during the entire session.
- ***Patient-based models:***
  Doshi and Brown in 2005 [8], suggested the following patient-based models for effective bedside teaching:
  - Role modelling: Trainee shadowing a senior clinician and learning by emulating the techniques and nuances of the former.
  - Patient-centred model: Allocating patients/beds to a set of trainees, who would be responsible for monitoring their progress from the beginning to the end of their hospital stay.

  - Reporting-back model: Reporting the observations and progress of the patients by the trainee to the mentor.
  - Direct observation: Observation and assessment of the trainee's progress by the mentor directly on a day-to-day basis.
  - Case conference: Presenting a case by the trainee to a wider audience of mentors.
- ***Five-Step microskills model:***
  Proposed by Neher et al. in 1992 [9], this five-step model composed of simple, discrete teaching microskills for effective bedside teaching:
- Asking for commitment, probing for an underlying reason, teaching of general rules, reinforcing what has been done, and working on the mistakes. These five elements constitute the five steps of the microskills model.
- ***Trialogue—A model of interaction between three groups of players:***
  The three groups of players are composed of teachers (clinicians), learners, and patients [10]. The trialogue model focuses on the interaction between these three groups with varying principles, background, and expectations. This enables the clinical teachers to ensure the active engagement of the trainees/learners in the clinical decision-making at the bedside, while simultaneously catering to the needs of the patients and addressing their concerns at the same time.

39.3 What Are the Types of Bedside Teaching?

Smith et al. proposed two methods of bedside teaching and compared the same with a control group, when examining the cardiovascular system: Demonstration and Practice (DP) and collaborative discovery (CD) [11].

- **DP group**: One or a few of the trainees demonstrate the clinical sign in front of the group of trainees and mentors. The mentor would then correct the same and refine it further to show the correct technique to the group.
- **CD group**: All the trainees perform demonstration of a clinical skill and report their findings to the mentor. The latter would analyze the same neutrally and point out the errors and the lacunae to the group and would eventually arrive at a consensus to standardize the examination technique. Subsequent to this, the trainees would perform the examination again.

Both the techniques of bedside teaching have been shown to be equally effective in imparting the knowledge of the clinical examination to the trainees. However, Smith et al. had evaluated the skills using an OSCE (Objective Structured Clinical Examination). There was an increase in the learned skills observed in both the groups: 12% for the DP and 10% for the CD. However, compared to the control group, the CD group demonstrated a 5% increase in the finding of key clinical aspects [11].

39.4 What Is the Current Status of Bedside Teaching in Developing Countries?

According to the reports by Peters et al., the practice of an ideal bedside teaching has decreased from 75% of all the clinical training in 1960s to 8–9% in the current era [12]. According to the amendments by the Medical Council of India in 2017, the graduate medical education curriculum should focus on training students towards taking the responsibilities of physicians of first contact [13]. The theory lectures alone would be incomplete if not complemented with regular bedside teaching and ward rounds with case presentations. In India, the Indian medical graduates get their first-hand experience of dealing with patients during their compulsory one-year internship after completion of their MBBS. During that period, they get the experience of taking decisions in the emergency as well as outpatient department under the supervision of the house staff and the registrars. However, the teaching curriculum during the final two years of MBBS (clinical subjects) focuses on priming the students to get a practical experience of interacting with the patients and formulating the clinical diagnosis and approach to further management. Bedside teaching focuses primarily on the skills of a good history taking, arriving at a differential diagnosis, correlating the theoretical knowledge of paraclinical subjects at devising an approach towards the patient management, exposure to bedside procedures (intravenous cannulation, blood transfusion, insertion of a nasogastric tube, Foley's catheterisation etc.) and assimilating all the above knowledge to approach a clinical case as an independent physician.

However, there are certain hindrances to conducting proper bedside teaching as well. The most important reasons cited for the gradual decline in bedside teaching worldwide are time constraints due to the pressure to see more patients with increased record keeping and also the worry about patient comfort and privacy during the sessions of teaching [14]. In India, the hospitals are mostly divided into the public sector (government funded) and private sector. The former includes the medical colleges and the latter include the teaching hospitals (mostly involved in postgraduate medical education only). The biggest hindrance towards bedside teaching in the public sector has been the lack of accountability of the senior faculty members towards conducting ward rounds, leaving the same mostly at the discretion of the house staff and the registrars (who are usually overworked). The hindrances in the private sector hospitals have been a lack of incentive for the faculty to conduct regular bedside teaching (where most faculty have their busy OPD schedules and are not paid for their academic roles) and also the concern regarding the patient comfort and privacy during the bedside teaching sessions. Factors such as the greater reliance on technology such as sophisticated radiological investigations to arrive at a diagnosis without spending much time on arriving at a diagnosis based on clinical findings have been also contributory towards the decline in the trend of regular bedside teaching. For example, when asked about identifying the possibility of right-sided pleural effusion in a patient with dyspnoea, the 'knee jerk' response by the trainee would be to order a Chest X-ray or Ultrasound examination, instead of considering bedside percussion or auscultation. With increase in the

technological armamentarium of the clinician, there is a decline in the importance of basic bedside clinical tests that would help arrive at a diagnosis. Even for diseases like acute appendicitis, where 98% of the diagnosis relies on bedside clinical findings, the first-line approach is to order for an ultrasonography of the right iliac fossa or a CT scan of the abdomen (especially in private sector hospitals). Another important factor that has come into play in 2020 is the COVID-19 pandemic that has led to a widespread disruption of the regular teaching curriculum in all medical institutions and hospitals. With lockdown of the teaching institutions being imposed to minimize social contact, there has been a major shift in the modes of undergraduate teaching. Newer platforms such as e-learning through Zoom, and Microsoft meetings are being used to conduct lectures. Virtual case scenarios are being discussed with clinical signs being demonstrated on dummies on a cyber platform. Even examination patterns have shifted from bedside discussion of cases and evaluation to OSCE (mainly being conducted through the display of virtual cases on a computer screen) and clinical case simulations. Even though, these have been the only possible measures that could be taken to ensure an uninterrupted flow of classes, the importance of learning the nuances of bedside clinical signs cannot be undermined in any medical teaching curriculum.

In a study by Holla et al., the following factors were identified by the medical and surgical faculty as the hindrances to a smooth bedside teaching [15]:

- Bigger group sizes in smaller arenas.
- Increased workload of the faculty (administrative/research) and house staff (high patient load).
- Language barrier for the students (especially in India, with different languages in different states).
- Shorter length of patient stays in hospitals.
- Lack of patient cooperation.
- Interruptions due to phone calls, visitors, noise in the wards.
- Lack of an incentive for the faculty to take dedicated bedside classes.
- Miscellaneous (students not following decorum, lack of infrastructure in the ward such as viewing boxes).

39.5 What Are the Ways Forward?

Some of the ways suggested to overcome the decline of bedside teaching are as follows:

- ***Compulsory allocation of time for bedside teaching with detailed planning:***
  The clinical postings composed of nearly 2–3 hours of the curriculum in undergraduate teaching during the pre-final and the final professional years in India. However, effective bedside teaching usually gets limited to only half an hour to 45 minutes. This could be improved by prior allocation of a faculty or registrar to this duty for a particular day, well in advance, so that one particular

faculty member is responsible for conducting the teaching. The teaching method should be patient-centric instead of a theoretical discussion in the demonstration room. The expectations by the faculty should be kept realistic and a gradual step-by-step escalation of skills by the students should be aimed at.

- ***Ensure patient comfort:***

  Even though it has been speculated and observed by many that bedside teaching might cause discomfort to most patients, a study by Nair et al. reported that contrary to this belief, most patients report to be benefitted from bedside teaching by understanding their own problems [16]. Having said that, basic etiquette by the clinician cannot be undermined. Emphasizing the importance of taking consent from the patient prior to the examination, introducing himself to the patient prior to initiating the encounter, lateral conversation (without breaching professionalism) for good rapport building, keeping medico-legal pre-requisites in mind (especially when examining a female patient or doing a genito-urinary/breast/rectal examination) are some of the important points that need to be re-emphasized during every session of bedside teaching.

- ***Focused approach by the teacher and the student:***

  Bedside discussions of cases are highly prone to tangential detours. This usually stems from over inquisitiveness of the student (who feels the urge to know everything in one day) or an irrational approach by the mentor (who derives a pleasure asking 'out of the context' questions to the student). The remedy to this problem is by strategizing the goal of the class in advance. A checklist of the 'must-to-do' signs/manoeuvres/techniques should be formulated, and the teacher should make sure that these have been achieved by the students at the end of the class. An ideal bedside teaching should make the students learned and more conceptual in their clinical approach and not leave them confused with garbled facts and figures difficult to comprehend and recall.

- ***Integration of case-based learning (CBL):***

  A study by Kulkarni et al. in 2019 reported highly positive results by integration of case-based learning strategies to bedside clinics [17]. Their study reported a high level of motivation among the students by this approach (88%). Authors such as Dubey et al. and Nair et al. reported similar results by showing 74–98% motivation among the students to learn using additional resources by this approach [18, 19]. An interesting way to make bedside teaching more interesting is framing case scenarios and allowing the students to solve them similarly in the way they would as clinicians sitting in the out-patient department. This approach is similar to the pattern followed by the United States Medical Licensing Exam (USMLE) in their final step 3 (Clinical Case Simulators). For example:

  Case: A 50-year-old lady comes to the Emergency Room with fever and severe pain in her right hypochondrium.

  Approach:

  Step 1: Overall assessment of the patient → vital signs, state of hydration.

  Step 2: Focused clinical examination → eliciting Murphy's sign; Rebound tenderness

Step 3: Next line investigation → Total leucocyte count, Ultrasonography of the abdomen

Step 4: Prepare the patient for lap/open cholecystectomy based on the fitness and other laboratory parameters

39.6 Conclusion

- Bedside clinical teaching is an open arena to translate theoretical learning into a practical application for budding clinicians.
- The importance of the clinical approach by taking a meticulous history and attention to detail in assessing the physical signs cannot be undermined in the light of the recent greater dependence on the ancillary tools of investigation such as CT scans, MRI.
- Bedside teaching will provide a strong foundation pillar to a future clinician and should therefore be an indispensable component of every undergraduate and postgraduate medical curriculum.

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E-Learning in the Developing World

40

There is an abundance of data available in the digital world and if it is harnessed effectively and correctly it can provide terrific insights.

—Gian Fulgoni, British Market Research Consultant (1948–)

40.1 Introduction

Medicine is a changing field and so is the art of teaching medicine. To cope up with technology and science is a major challenge. We all have been trained by conventional classroom teaching, which includes seminars, demonstrations, and bedside clinics but should now be aware of e-learning, blended learning, use of smartphones and tablets, webinars, telemedicine, and tele-education. There is a lot of medical content in the social media (Facebook, Twitter, and LinkedIn), which is very easy to access. This chapter gives an overview of how electronics have changed the way we practice, keep our records, learn, and teach.

40.2 What Is Distance Learning in Medical Education?

Distance learning has long been associated with education. It was in this form that correspondence courses were first offered by a few universities and other educational institutions. The learning modules were sent to the students by post. This was associated with a learning delay mainly due to the use of postal services and sometimes the module was lost in transit. Recently using electronic media or e-learning has taken over the transmission. It is rapid and learning is also easier as there is more information using different media [1] (Table 40.1).

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_40

Table 40.1 Compares the differences between the two types of learning

	Classroom learning	e-Learning
Distribution of handouts/prints	Yes	Yes
Library access	Both to print and electronic	Electronic
Downloading modules in mobile/tab/iPad	No	Yes
Face-to-face lecture	Yes	No
Record seminar/lecture	Yes	Yes
Formative assessment	Yes	Possible
Summative assessment	Yes	Yes
Feedback about lecture asking question or queries	Yes	Through chat box
Structured teaching	Yes	Yes

40.3 Do All Institutions Offer Online Career Enrichment Courses?

Many institutions offer online courses on various subjects. These courses are for a short duration and the fee has to be deposited at the time of registration. They are career enrichment courses and you need to have a basic degree before enrolling in them. Some of the well-accepted medical courses are run by the Mayo Clinic [2], Harvard Medical School [3], The European League Against Rheumatism [4], Stanford Medicine [5], and Johns Hopkins University [6]. Although the physician needs to register at a particular time of year with a stipulated fee, they are very popular in Asia as the degree is from a reputed Institution.

Many online free portals offer academic courses that are getting well accepted among the younger generation. One of the sites is the Massive Open Online Course (MOOC) [7]. The basic content in them is free but more advanced information requires a nominal payment.

40.4 What Are the Advantages of an Online Education?

It is usually thought that medicine cannot be taught without examination of patients. William Osler, a Canadian physician who taught in the Johns Hopkins Medical School and is considered to be the father of modern medicine had stated, 'He who studies medicine without books sails an uncharted sea, but he who studies medicine without patients does not go to sea at all'.

With an online course, the world becomes your classroom. There are many advantages of online education. Technology will play a major role in the education of our next generation [8] although Niels Bohr said, 'Prediction is very difficult, especially about the future'. But we need to be ready for the future by upscaling our infrastructure for online technology. The following are clear advantages of online teaching:

- Flexibility in learning hours.
- Reduced cost as there is no commuting time.

- Opportunity to do networking.
- A subject can be explained in detail with the need for experienced teachers.
- Easy to attend.

40.5 What Is Blending Learning?

The boundaries between distance learning and classroom learning are getting blurred. The proliferation of information and communication technology in education is going to be the next boom. Blending learning is an educational method which combines online education with an opportunity to interact with a traditional place-based classroom. It is also called hybrid learning and both components are complementary to one another (Fig. 40.1).

Digital medicine has helped blending learning to reach a new level and digital education includes didactic lectures, group, or panel discussions. It has been observed that with the use of digital technology the attendance of students has improved, student evaluation can also be done and the progress of students can be monitored as well.

In a systematic review done on medical students to compare the traditional classroom learning to digital learning, there was no difference between the two types but blended digital education was more effective than traditional learning [9]. In another meta-analysis there was no difference between the two forms of education methods. However, the investigators could not come to a conclusion about students' attitudes and student satisfaction in this study [10].

40.6 What Is a Webinar?

The word 'Webinar' is a combination of 'web' and 'seminar'. A webinar is like an oral presentation with the exception that the event is held on the World Wide Web, which is attended exclusively by a single online viewer. The presenter and attendee do not need to travel and can attend the webinar from home. This distinguishes it from a webcast, which also needs the presence of physical viewers. Other words used as substitutes for webinars are web event, online seminar, webcast, web lecture, and virtual event (Fig. 40.2).

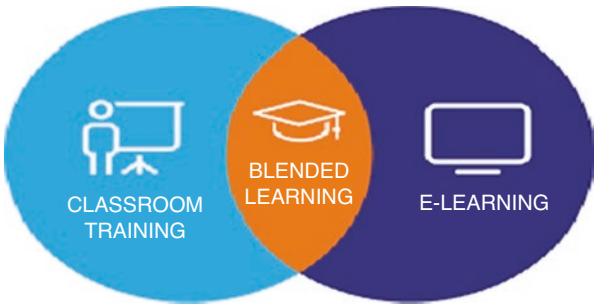

Fig. 40.1 Types of learning

Fig. 40.2 Screenshot of webinar in process

Participants view webinars by using their personal computers, Macs, tablets or smartphones, and they can see and hear the speaker who is addressing them. A webinar offers an effective way of communication: where the presenter can reach out to a large group from a single location. Hence, a webinar offers various interactive opportunities to ask queries, have opinion polls, carry out surveys and chat with other participants.

It is the latest form of educational tool and can reach out a large audience in a short span of time. It is also quick and replaces the normal method of giving lectures. As the COVID-19 pandemic becomes widespread, all major conferences across the globe are being cancelled and replaced by webinars. In a study done in five continents over a webinar, it was found that it was well accepted by all the attendees as a source of continuous medical education (CME) [11].

40.7 What Are the Ten Golden Rules for Conducting a Webinar?

Ten rules have been suggested for conducting webinars and these are listed below [12]:

1. Identify the organizing team. There should be dedicated staff who work on all the logistics, planning, and communication for hosting and take the major load of work (Fig. 40.3).
2. A webinar that is based on a single theme is better accepted by the audience.
3. Have a checklist for tracking the work and responsibilities.
4. Plan a poster for the webinar.
5. Plan the timing of the webinar—one should remember that time zones differ between countries when planning to attract a larger audience from some of them.

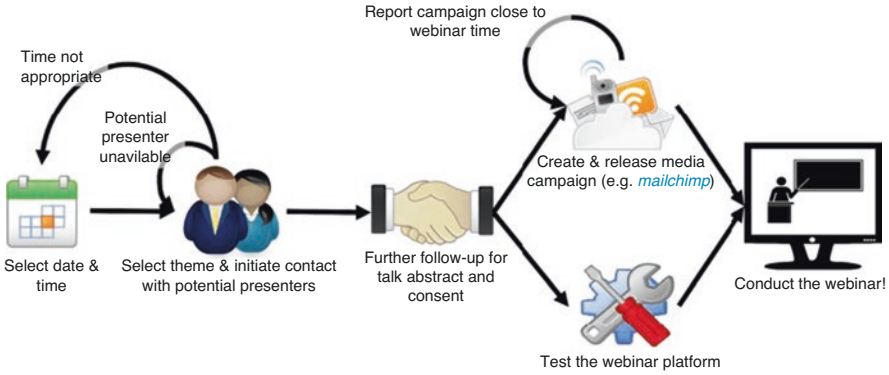

Fig. 40.3 How a webinar works?

6. Use a friendly webinar platform. Those commonly used are Zoom, Microsoft, blue jeans, GoToMeeting, Adobe Connect, Vidyo, and Google hangouts. Also, consider how many can attend on each platform.
7. The choice of the presenter should be good and he or she should be an expert in the field.
8. Advertise it well on social media and also by emailing the information to potential participants.
9. Allocate a time to each speaker and also for the question and answer sessions.
10. Have a dry run one day prior to or on the same day but much before the meeting to fix any technical issues which may arise.

40.8 What Are the Important Features of Various Platforms for a Webinar?

There are many webinar platforms and include Zoom, Google Meet, and WebEx. The meeting can be planned according to some salient features. Since video conferences are no longer limited to desktops and laptops, both Google Meet and Zoom are available for mobile devices based on Android and iOS. These virtual fields are dynamic and the platforms are constantly upgrading to give better services (Table 40.2).

Table 40.2 Comparison of Zoom and Google Meet

Features	Google Meet	Zoom
Availability	Web, android, iOS	Mac OS, Windows, Android, iOS
Direct web access	Yes	No
Participants limit	100	100
Meeting time limit	60 minutes (unlimited until Sept. 30)	40 minutes
Multiple participants on a single screen	Yes	Yes
Screen sharing	Yes	Yes
Recording support	No	Yes

40.8.1 Zoom

- Can be accessed from any device.
- App needs to be downloaded.
- Can allow one hundred participants free and up to fifty thousand after subscription.
- The first 40 minutes of the virtual meeting is free but the meeting can be extended by paying.
- Up to forty-nine participates can be seen on the screen at one time.
- Has a facility for a small breakout sub-meeting.
- Registration of participants is easy with email.
- Live streaming on social media is possible.
- Muting and unmuting can be done by the speaker.
- The proceedings can be recorded.
- Participants can ask questions to the speaker and even polling can be done.
- Recently concerns about security issues were raised while using this.

40.8.2 Google Meet

- Has a very low learning curve as compared to Zoom.
- Has no time for interaction and after September 2020 it will be free for sixty minutes.
- Has encryption of the video and recordings, and it prohibits anonymous users from entering calls.
- Can presently host up to two hundred and fifty people.
- Can show up to sixteen participants in one screen.
- No waiting room for participants as they can join early.
- Only one person at a time can share their screen.

40.8.3 Jio Meet

- Allows from one to one hundred participants like the Zoom Video Conferencing App.
- The main advantage is that it has no time limit for meeting for a conference. The free call can last for as long as 24 hours uninterrupted.
- The entry to the meeting is password protected like Zoom.
- There is a waiting room for security purposes.
- Participants can send text and voice messages, files, and images to one another.

40.8.4 Microsoft Team

- Fully integrated with office 365
- No time limit for a call
- No waiting rooms
- Recording in cloud and screen sharing possible
- Can be accessed from any electronic device
- Instant messaging possible

40.9 Can Textbooks and Journals Also Be Accessed Electronically?

In the current era, there is a trend towards the demise of published textbooks and medical journals. All leading medical journals are also published electronically. Medical journals have been compared to 'telephone directories' as they are dull. It is easy to scan an electronic copy and you can know what information is useful. The information can be accessed from smartphones, tablets, or laptops which are more handier.

Many journals allow downloading of full text and an e-library is getting more popular. One of the important and popular sites is the ERMED Consortium an Electronic Resources in Medicine site maintained by the National Medical Library of India. Members are divided into Level-I and Level-II on the basis of a number of end-users in different institutes. High-quality 242 online e-journals are available for students or researchers. There is 24×7 instant online access to multiple users and no restrictions on downloads and printing. The other e-portals have been listed in the chapter on 'How to do a review of the literature'. These include INFLIBNET a centre in Gandhinagar and an autonomous inter-university centre under the University Grants Commission. It contains a digital library of more than 15,000 core peer-reviewed journals and a number of bibliography citations and databases. INDMED is an Indian biomedical journal base that covers 78 journals and provides online access to full-text Indian journals within this country, and abroad.

40.10 What Is the Medical Infodemic?

An excessive amount of information about medical problems which spreads rapidly without any reliable source is called a medical infodemics. During this COVID-19 pandemic, the information on multiple issues have been disseminated in public without any reliable sources.

WhatsApp is popular and convenient in medical education. Current published literature suggests it may also be effective as a medical learning tool. It can be a useful and handy tool for medical students and primary care physicians provided the source is authentic.

40.11 Can Teaching Occur Using a YouTube Video?

YouTube is the second most accessed social media site after Facebook. YouTube has the potential to fill literacy gaps and can present data in innovative ways that allow even illiterate people to learn. It is increasingly being used as a podium for publicizing health-related information. However, the contents of the site are not peer reviewed and there is no authenticity regarding the information which may be misleading, or containing unsubstantiated work which the creator wants to publish on a social platform. Many pharmaceutical companies sponsor videos, which describe new drugs or vaccines. There are no set scores regarding how to judge the content of videos, and determine the reliability of the video's sources of information except by seeing the number of 'likes' for the video [13–15].

40.12 How Can Smartphones Be Used for Medical Education?

Mobile apps are software programmes that run on smartphones. They can also be accessories that attach to smartphones or other mobile communication devices, or a combination of accessories and software. Smartphones are like mini computers and ninety percent of doctors use them [16]. Because one can access medical literature via the Internet or WIFI, the publication on medical apps has increased in PubMed over the last few years (Fig. 40.4). In addition, one can download Medical apps for iPhones or Android devices. These apps help in patient diagnosis, calculating scores, clinical decisions, and also to look for drug interactions. The names of a few important apps are given below [17]. However, there are a few legal and non-legal requirements for the development of apps. As data is required to be stored in someplace (for instance in a cloud) it should be not be should for research purposes. Many apps also require personal information which needs to be protected. The Food and Drugs Administration (FDA) of America also has a policy for mobile apps [18]. Health-related apps have arrived and they have a definite role in the treatment of diseases in all fields of medicine. Apps are also available to patients for control of diabetes and mental health and are commonly used Table 40.3).

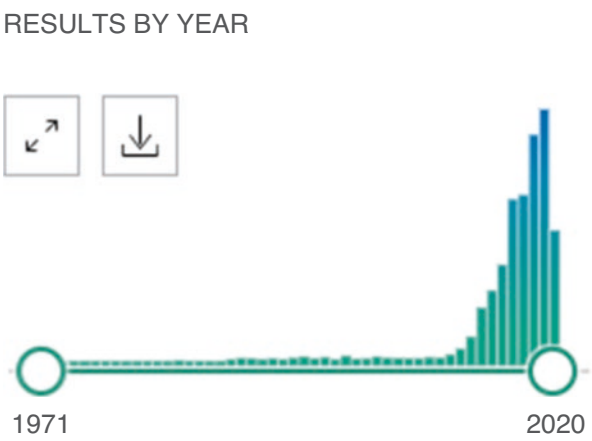

Fig. 40.4 The number of medical publications on apps has increased tremendously over the last few years

Table 40.3 Commonly used medical apps

Apps	Details of charges/ phone compatibility	Features
Medscape	Free Android, iPhone	• Most downloaded medical app. • Medical literature can be downloaded from 34 different health fields • Gives a clinical reference section about drug safety guidelines on common conditions • Videos and tutorials on various procedures and education activities for students
Medpage Today	Free iPhone	• Medical news service for Doctors • Partnered with Thomson-Reuters Healthcare • Contains drug monographs • Information on disease pathology • Also delivers free CME/CE credits at your fingertips
3D4Medical	Free to $19.99 iPhone	• Helps to navigate the body using 3D technology • Operators can rotate, cut, zoom have superior/ inferior views • Excellent source for anatomical animations • Can help patients to understand the various views
Muscle Trigger Point	$2.00 Android, iPhone	• Has hundred trigger points for over seventy muscles
Visual DX	Free Android, iPhone	• Contains a digital medical image library of more than ninety thousand peer-reviewed images
AHRQ ePSS	FreeAndroid, Blackberry, iPhone, Windows	• Assists primary care clinicians in identifying the screening, counselling, and preventive medication services
Airstrip Cardiology	Free with Airstrip software download	• Mobile transmission of ECG • Helps cardiologists to make clinical decisions
Airstrip Cardiology	Free Android, iPhone	• Outlines in Clinical Medicine • Medical Calculator • Drug Dosing Tool • Medical Alert
BNF and BNF children	Android, iPhone iPad free in the UK only	• Contains British national formulate • Developed for NHS UK health care professionals • Clinical content updated regularly • Has drugs, treatment protocols, drug interactions, medical devices, and wound care
Tox base	£6.99 outside the UK iOS and Android	• Contains toxicology database of the UK and antidote • Register using NHS for free use necessary • Does not require internet

Table 40.3 (continued)

Apps	Details of charges/ phone compatibility	Features
MD Calc	Free iPhone, iPad, and iPod touch	• Works offline and in limited connection settings • Gives scoring and calculations for commonly used conditions such as: • Atrial Fibrillation Stroke Risk • Creatinine Clearance (Cockcroft-Gault Equation) • Wells' Criteria for Pulmonary Embolism • MELD Score (Model For End-Stage Liver Disease) • Calcium Correction for Hypoalbuminemia • SIRS, Sepsis, and Septic Shock Criteria • Corrected QT Interval • DVT score
Figure 1	15 dollars Android	• Viewers can see many real-world teaching cases from many specialities • Easy communication with each other, seven from remote or isolated locations • Has received appreciation from doctors of 170 countries • Rare and interesting cases can also be discussed

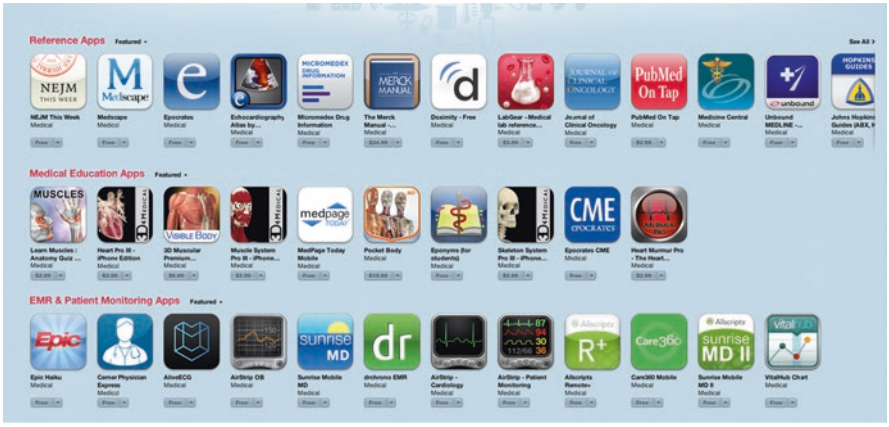

Fig. 40.5 Apps for health care professionals

In a study of 328 apps (175 Android and 153 iOS) seventy-three percent were developed by the software industry and only a minority of them were codeveloped by health care professionals or academia (Fig. 40.5). The most prevalent specialty was diabetes (23 apps). Only 7 apps focused on mental health, but their content was easily understood and had the highest prevalence of an educational component. The most prevalent features were reminders, symptom trackers, and an ability to share

data with a family member or doctor. We have highlighted the features which we considered to be innovative and listed some practical suggestions for future development [19].

40.13 Conclusions

- Nelson Mandela stated that 'Education is the most powerful weapon which you can use to change the world'. However, in the present day scenario, it can be said that technology is the most powerful weapon which we can use to change the world.
- Blended teaching is the next generation teaching method, which is a combination of classroom teaching and online teaching.
- Webinars, medical apps, and YouTube are part of the new technology. The first two have scientific content which can be moderated, however, the contents of YouTube are dependent on the person uploading the video.

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Developing Learning Objectives and Evaluation: Multiple Choice Questions/Objective Structured Practical Examinations

41

Examinations are formidable even to the best prepared, for the greatest fool may ask more than the wisest man can answer.

—Charles Caleb Colton, English, author, philosopher and eccentric (1780–1832)

41.1 Why Must We Develop Assessment Methods?

The practice of medicine depends on qualified doctors who strive to achieve and maintain appropriate knowledge, skills, and attitude. Competent doctors are the need of the hour and hence tests of clinical competence, which allow a decision to be made about whether or not a doctor is fit to practice are in demand. This demand poses a challenge for all involved in medical education. Therefore, assessment and evaluation of medical trainees play important roles in choosing good doctors.

Assessment promotes learning and for this assessment needs to be educational, formative, and also summative. Students learn from the assessment process and receive feedback on which they build their knowledge and skills. Wass et al. pragmatically describe assessment to be the most appropriate engine on which the curriculum is harnessed. They feel assessment should not only aim at certification and exclusion but also influence the learning process [1].

Neufeld and Norman have listed key measurement issues that should be addressed when designing assessments of clinical competencies [2].

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Key Issues that underpin any test

Key Issues	Description
Summative/formative	Be clear on the purpose of the test.
Blueprinting	Plan the test against the learning objectives of the course or competencies essential to the speciality.
Validity	Select appropriate test formats for the competencies to be tested. This action invariably results in a composite examination.
Reliability	Sample adequately. Clinical competencies are inconsistent across different tasks. Test length is crucial if high-stakes decisions are required. Use as many examiners as possible.
Standard setting	Define endpoint of assessment. Set the appropriate standard—eg, minimum competence—in advance.

To assess skill, knowledge, and attitude in medicine, a combination of assessment techniques is always required. Selecting an assessment technique not only depends on measuring students' performance but also needs to address issues like cost, suitability, and safety. These play a major role in inter-institutional variations in selecting assessment methods and success [3].

41.2 Are Objective Assessment Methods Reliable and Valid?

Reliability measures the reproducibility or consistency of a test. It is affected by examiner judgments, types of cases, nervousness of candidates, and test conditions. Two important aspects of reliability are inter-rater reliability and inter-case (candidate) reliability. Inter-rater reliability measures how consistent different examiners are in rating candidates' performance. The use of multiple examiners improves interrater reliability [4]. Intercase reliability which measures consistency of candidate performance across different cases is the most important aspect of testing clinical competence. Multiple sampling across many cases improves intercase reliability as compared to candidates assessed on a single case (Fig. 41.1). Clinical skill testing has now moved to the multicase format with increasing use of assessment techniques like the objective structured clinical examination (OSCE). OSCE consists of multiple tasks in multiple stations with sufficient testing time which helps achieve adequate intercase reliability. Length also plays a critical role in determining reliability [5].

Validity determines if a test actually succeeds in testing the competencies that it is designed to test. As valid measures of clinical competence are absent, Miller introduced the concept of pyramid of competence (Fig. 41.2). It is a conceptual model outlining issues involved in analyzing validity.

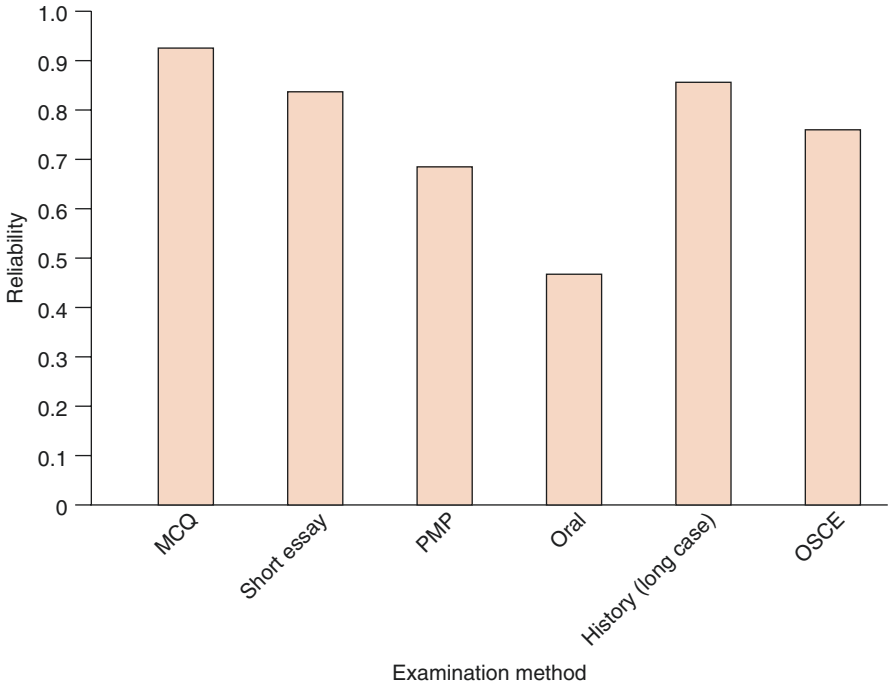

Fig. 41.1 Reported reliability when 4 h testing times are used for different test formats (MCQ = multiple-choice examination; PMP = patient management problem; OSCE = objective structured clinical examination)

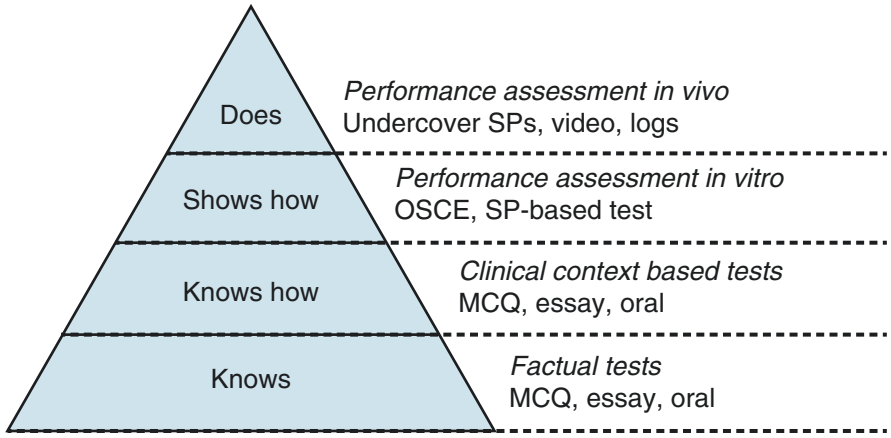

Fig. 41.2 Miller's pyramid of competence (SP = simulated patients; OSCE = objective structured clinical examination; MCQ = multiple-choice questions)

All facets essential for clinical competence are covered by the pyramid. The base of the pyramid represents the knowledge components of competence: knows (basic facts) followed by knows how (applied knowledge). These are easily assessed by

written tests of clinical knowledge like multiple-choice questions. Assessment of competency of a qualifying doctor needs evaluation of more important facet which is 'shows how'. It evaluates behavioural function which involves hands-on demonstration. Ultimate valid assessment of clinical competence is to test a doctor's actual performance, which involves assessing the summit of the pyramid using modalities like OSCE [6].

41.3 Is Traditional Assessment Inferior to Objective Assessment?

Medical education facilitates learning and encourages acquiring factual knowledge, improving professional skills and developing skills of application like critical reflection, problem solving, and reasoning. Until recently assessments of medical students depended on traditional methods like essay type questions and long case/viva voces, which typically required students to memorize large amounts of content without needing to apply it.

Unfortunately what and how a student learns depends on how he/she thinks will be assessed. And the use of traditional assessment methods leads a student to memorize and reproduce factual information in order to get a good grade and much of this information is forgotten within a week. It also relies on the assessment by examiners with different teaching experiences that leads to increased subjectivity and reduced reliability of the examination [7].

The merits and demerits of traditional assessment methods can be summarized as follows [8]:

Merits

- Global judgement of the skills of the student.
- No compartmentalization of the clinical skills to be judged.
- Less time consuming.
- Less effort in organization and conduction of the examination.
- More interaction between examiners and examinees.

Demerits

- Biased system hence less valid and reliable.
- Lacks the structure and uniformity to be used as an assessment tool.
- Affective skills like communication, history taking are not judged.
- Requires experienced faculty for the judgement of student's performance.

These limitations have led to a search for an objective, structured, and unbiased assessment tool that is reliable and valid. Objective assessment methods like multiple-choice question's (MCQ's), objective structured practical examination (OSPE), and objective structured practical examination (OSPE) have helped address these issues and have now largely replaced traditional assessment methods.

41.4 Multiple-Choice Questions (MCQs): What, Why, and When?

Multiple-Choice Questions (MCQs) have now become the most widely applicable, useful and accepted type of objective assessment. They help assess all important facets of educational outcomes which are knowledge, understanding, judgement, and problem solving. Introduced in medical education since the 1950s, MCQs have now become well established as a reliable examination tool in assessments of both undergraduate and post-graduate students. The MCQ which has become synonymous with objective evaluation and consists of questions for which there is a prior agreement on what constitutes the correct answers [9].

MCQs are reliable and easy to score. They also help in wide sampling of knowledge in a limited time. Through a short and time-efficient examination, the length and breadth of any topic are assessed. The beauty of this assessment method is that, apart from the recall of isolated facts, it also helps to assess taxonomically higher-order cognitive processing such as interpretation, synthesis, and application of knowledge [10]. Apart from reliability MCQs are also discriminatory, reproducible, and cost effective. There is a general consensus that rather than using MCQs as a sole method of examination it can be used alongside other evaluation methods to broaden the range of skills to be assessed in medical education [11].

Even though considerable effort goes into framing MCQs, their high objectivity helps in the immediate release of results as they can be marked by any person or machine. They also allow easy collection and analysis of raw data and also comparisons with past performances. Another advantage is their ability to assess a large number of candidates easily and making use of computers [12, 13].

Medical teachers are often faced with the challenging task of constructing good MCQs that test higher-order thinking skills. Unfortunately, they often have little or no experience or training in constructing MCQs. Preparing a good MCQ is difficult and time consuming. Most institutes now emphasize on faculty development programmes that concentrate on MCQ construction and implementation.

41.5 How to Design a Good MCQ?

MCQs can be prepared in different patterns. Commonly used formats are 'one correct answer', single or one best response, 'true or false' and 'multiple true or false', 'matching', and the 'extended matching questions or items types [14]. Single best options are the most common format of MCQs which are widely used and accepted.

Before preparing an MCQ one must consider objectives that need to be sampled and areas to be tested. Learning outcome also needs to be determined before sampling to ensure the high validity of the test. Another important issue to be addressed is learning objectives which the learners are expected to achieve. Learning objectives can be formulated to SMART an acronym representing goals that are specific, measurable, attainable, realistic, and time bound [15–17].

Benjamin Bloom was an educational psychologist who divided what and how we learn into three separate domains of learning [18]:

1. Cognitive domain—related to thinking/knowledge (K).
2. Affective domain—related to feeling/attitudes (A).
3. Psychomotor domain—related to doing/skills or practice (P).

In 1956 he also published a taxonomy of cognitive learning, described as a hierarchy of (i) knowledge, (ii) comprehension, (iii) application, (iv) analysis, (v) synthesis, and (vi) evaluation. After nearly four decades in 2001, the last 2 taxonomies were revised to (v) evaluation and (vi) creation (Fig. 41.3) [19].

MCQs designed to test knowledge (lower-level learning) would not be appropriate to test competence for objectives that reflect analysis (higher-level learning). Importance of skill and knowledge objectives should be provided in the educational

Revises Blooms' Cognitive Taxonomy			
Creating	Level-VI	Higher order learning	Higher level, not suitable for MCQs
Evaluating	Level-V		Higher order learning that can be tested with MCQs
Analyzing	Level-IV		
Applying	Level-III		
Understanding	Level-II	Lower order learning	Lower order learning is what mose MCQs target
Remembering	Level-I		

Fig. 41.3 Suitability of testing revised Bloom's cognitive taxonomic level learning by MCQs

programmes and measurable objectives should allow the assessment of achievement of the same [20].

41.6 What Needs to Be Done to Construct MCQs?

The first step for conducting MCQs is to have a blueprint also known as a test specification table. It is a guide that helps create a balanced examination and consists of a list of competence and topics that need to be tested. Three important contents of a good blueprint are:

1. Content/objectives to be tested.
2. Questions that design to test the content/objective.
3. Learning domain and levels of testing.

It is a three-dimensional chart where the placement of each question and the content area is represented. It provides a solid foundation on which test activity is developed. It offers an evidence for content validity and also makes assessment more meaningful [21, 22].

MCQs need to have good grammar, appropriate punctuation, and avoid spelling errors. One must also minimize the time required to read each item. Basically, an MCQ consists of a stem or a lead-in question which is followed by 4–5 answers or options. The option which matches the key in a MCQ is best called 'the correct answer' and the other options are called the 'distracters'. An ideal question is one that can be answered by 60–65% of the tested population. One must avoid unintended cues like making correct answers longer than the distracters. The instructions to answer these questions should be clear and uniform [23, 24].

A good distracter should be inferior to the correct answer but at the same time should also be plausible to a non-competent candidate. All options should contain facts and have a varying degree of acceptance. Only one answer should be correct and should match the examiner's key. Commonly asked questions include the most appropriate, most common, least harmful, or any other feature which is at the uppermost or lowermost point in a range. The options need to be homogenous in both content and length. Options like always, never, completely, all of above, and none of the above should be avoided. Preparing appropriate distracters is challenging and needs a lot of effort [25].

Well-constructed MCQs aim at testing the application of medical knowledge (context-rich) rather than just the recall of information (context-free). Context-rich questions stimulate the thinking process, and represent the candidate's problem-solving ability better than context-free questions. Practical problems encountered in clinical practice should be assessed rather than assessing knowledge of trivial facts or obscure problems rarely seen. MCQs should aim at making testing both fair and consequentially valid. MCQs should strategically evaluate important content and clinical competence [23, 26].

41.7 Can Objective Structured Clinical Examination (OSCE) and Objective Structured Practical Examinations (OSPE) Replace the Traditional Viva Voce?

Medical education has undergone a paradigm shift towards a more competency-based system and as a corollary, competency-based medical assessment. The Objective Structured Clinical Examination (OSCE) and its derivative the Objective Structured Practical Examination (OSPE) have been introduced as measures of competence, which avoid many biases associated with the conventional methods.

Harden et al. were the first to describe OSCE in 1975. OSCE /OSPE assesses clinical or practical competencies in a methodical, objective, and time-orientated manner with direct observation of the student's performance during planned clinical or test stations. The third level of Miller's pyramid 'shows how' is assessed. The student is evaluated on the performance of specific skill sets in a controlled setting [6, 27, 28].

The traditional examination focuses more on global performance rather than a student's clinical competency. It mainly addresses the 'knows' and 'knows how' aspects of Miller's pyramid of competence. Evaluation is often subjective, biased, monotonous, and inadequate in evaluating the overall performance of the student. Other attributes like attitude, communication skills, interpersonal skills, ethical issues, and professional judgements are not tested. Also, the need to understand core topics and develop problem-solving skills is not covered by traditional assessment methods. Another drawback is the variation of the examiner's subjectivity which in turn reduces the reliability of the examination. It has been seen that subjectivity reduces the correlation coefficient between marks given to the same student to as low as 0.25. This affects scoring and results in dissatisfaction among both the examiners and examinees. Also, traditional methods lack a proper feedback process which is essential to improve one's skills [7, 29].

41.8 How to Conduct OSCE and OSPE Assessments?

Conducting an OSCE or OSPE requires considerable effort and preparation. Here too the first step of planning is designing a blueprint of the structured checklist for observed and unobserved stations based on Bloom's taxonomy. An examiners' and students' instruction manuals also should be considered while designing a blueprint. Checklists of clinical procedures, manuals, and standard answers need to be checked and validated by senior faculty members and medical educators [18].

Based on requirements the number of OSCE/OSPE station is decided. Apart from knowledge, the stations should also focus on evaluating communication, psychomotor, and clinical skills. The stations also need to be designed with difficulty

levels ranging from 'must know' to 'desirable to know' to 'nice to know' sections. Stations can be either question and answer stations or procedure stations. Ideally, a procedure station should be followed by a question and answer station pertaining to the previous procedure. At procedure stations, students are expected to perform a focused history or examination on standardized patients. Other focused tasks like interpreting X-rays, electrocardiograms, and microscopic slides also can be evaluated. About 3–5 min are allotted for each station and it is recommended to have a few rest stations in between. Adequate time is given between stations to facilitate student movement [30].

Marking in OSCE/OSPE is relatively simple. Every examiner has a previously agreed-upon checklist of items with assigned points. The student is marked based on each piece of predetermined key information obtained or physical manoeuvre performed. A Likert-like scale ranging from 1 to 5 can also be used to grade overall efficacy. The final score is based on a compilation of marks obtained at different stations and the overall score [31].

Debates regarding the reliability and validity of OSCE/OSPE have been put to rest through multiple studies [31–33]. van der Vleuten and Swanson have recommended a few steps to improve reliability like using checklists, having standardized patients to maximize reproducibility, increasing hands-on skill stations, and maximizing testing time to 3–4 h [34].

The merits and demerits of objective testing using MCQs or OSCE/OSPE can be listed as follows [8]:

Merits

- With comprehensive blueprinting cognitive, psychomotor domains, and high order thoughts can be effectively examined.
- OSPE/OCSE help assess affective domain skills like history taking, communication.
- Competence-based assessment.
- Good teaching-learning tool with appropriate feedback.
- Less experienced faculty members can be incorporated for assessment.
- All the students are asked similar types of questions hence assessment is less biased.

Demerits

- Blueprinting of the syllabus, validation of the comprehensive checklist is tedious and time consuming.
- Administration and conduction of an MCQ-based examination or OSCE/OSPE is time consuming and laborious, money and resource intensive.
- There is less interaction between the examiner and examinee.
- Limited scope of questions.
- Constant need to innovate and develop MCQ, OSPE, and OSPE banks to prevent repetition.

41.9 Conclusion: Where are We and Where Do We Need to Go?

- The primary concern of medical education is clinical performance measurement which remains elusive.
- Even though traditional assessment methods have been replaced by more objective evaluation systems like MCQs, OSCEs, and OSPEs with studies showing a significant correlation between the two, but a gold standard for such comparisons still does not exist.
- Creation of a competency-based curriculum and appropriate tools to evaluate that curriculum is the need of the hour.
- The literature supports the role of these objective modalities in the evaluation of knowledge, skill, and competency. One can conclude that combining objective assessment methods with traditional methods along with direct observation in the clinical setting has the potential to become the gold standard to measure a physician's competence.

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How to Prepare a Lecture?

42

> The secret of getting ahead is getting started. The secret of getting started is breaking your complex overwhelming tasks into small manageable tasks, and then starting on the first one.
>
> Mark Twain, American writer and humorist (1835–1910)

Lectures are an economical and effective way to convey information to large groups of participants. They can provide an overview of a difficult topic or different perspectives on a subject. They can be used to provoke thought and deepen understanding. Lectures can be used to give structure to the students' reading or to cover material not easily found in textbooks. When lectures are delivered well, the lecturer motivates the students and can become an inspirational role model [1].

Delivering a good lecture is like an artistic theatre performance, with the lecturer playing the leading role. So just as with acting, the lecture delivery must be well planned, thoroughly rehearsed, and properly timed [2].

A lecture is an organized oral presentation of subject matter often augmented by visual aids.

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_42

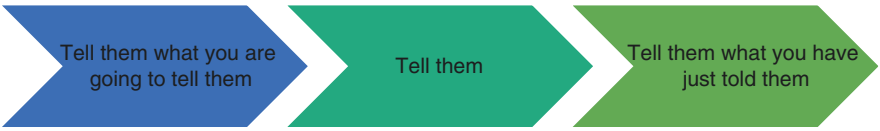

Fig. 42.1 Schema for lecture flow

42.1 Planning the Lecture

Know your subject and have a good command of what you have to talk about. Then know your audience, their background, needs, and prior knowledge.

Lectures can be taken as a feature film and with an identifiable beginning, middle, and end. Structuring the lecture this way makes it easier for the audience to follow and also provides a framework for preparing the flow of the lecture [3] (Fig. 42.1).

If your lecture is part of a series, it is good to know the content of the other lectures particularly those just before and after yours to avoid repetition.

42.2 Preparing the Lecture

Just like success in decorating or culinary skills, successful lecture delivery is characteristically dependent on its preparation. If you prepare appropriately for a lecture, delivering it is easier [4].

The essential ingredients for the preparation of a lecture are:

- Knowing the purpose of the lecture—formulate the learning objectives.
- Content.
- Organization.
- Preparation of audiovisual aids.

42.3 Developing the Lesson Plan

Lesson planning is the crucial step to make life easier in delivering a lecture. Although it requires patience, discipline, reflection, and time, however, the payoff is boundless: a clearly organized lecture that is easy for you to deliver, and for your audience to follow.

A lesson plan is the sketch of a sequence of activities engaged in by both the lecturer and the audience to achieve the desired objectives together with a schedule for the lesson and a list of instructional resources. The quality of planning affects the quality of results. For the lecturer it is important to consider the three basic elements when planning a lecture; the introduction (bridge-in, objectives, pre-assessment), the body (participatory learning), and the conclusion (post-assessment and summary). This structure is often referred to as the **BOPPPS** model [5, 6] (Fig. 42.2).

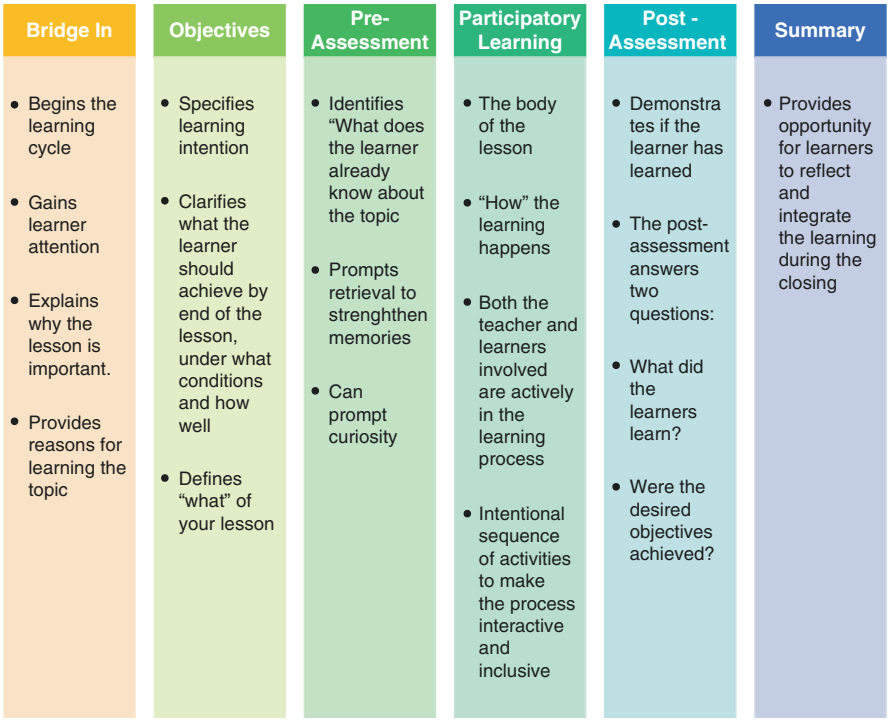

Fig. 42.2 The BOPPS Model

42.4 How to Deliver a Good Lecture? [7]

- Actively engage students in the learning process. Students' engagement is a vital part of the learning from a lecture. Various techniques can be used to make lectures more interactive and engaging (Fig. 42.3).
- Provide a supportive, trusting, and non-threatening environment in which the audience positively enjoys learning.
- Take into account how much the audience already knows about the subject being delivered and structure the lecture accordingly.
- Spell out the objectives of the lecture and focus on outcomes so that the audience is clear about what it needs to attain.
- Think about how best to use your tone of voice, emphasis, repetition, body language, and facial expression to achieve the best results.
- Humour, planned and spontaneous, can be an excellent way to relieve the stress and monotony during a lecture. It can be achieved by comical pictures, funny anecdotes, and succinct jokes appropriate to the subject.
- At the end of the lecture summarize the main points. Indicate that you have finished and be ready to answer questions.
- Seek the audience's feedback about the lecture and change practice according to what they say.

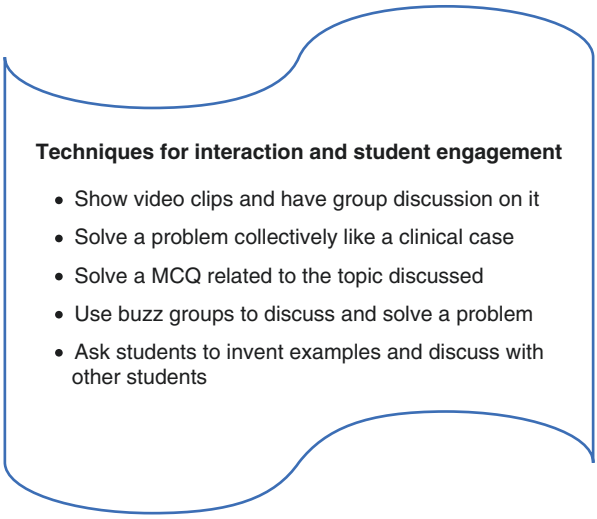

Fig. 42.3 Making lectures interactive and engaging

42.5 Do's for Preparing a Good Lecture [8]

42.5.1 Content—How Much and What

- When starting preparation for the lecture, remember **'less is more'**.
- If using slides it is suggested to allow 1.5–2 min per slide, so do not have 80 slides for a 30-min talk. If using other means dwell on a point enough to make it clear to all participants.
- The assumption is that at any given time during the lecture 20% of the audience will have their attention elsewhere so put the most important points, at the beginning and end of the lecture when their attention is at its maximum.
- Avoid technical terms and jargon as much as possible. If you must introduce an acronym or an unfamiliar technical term, clearly define it the first time you use it.
- Use simple, common language with short words and sentences. If using slides just have enough text on each slide to remind you what to say. The best example of this technique is the 'newspaper headlines' where one has to use clear, direct, and engaging language due to the limited space to communicate ideas.
- If using slides keep them simple to minimize the work of the audience in figuring out what is being said so they will pay more attentive to the ideas in the lecture.
- The use of analogies or examples makes the material more interesting. If possible, relating it to personal experience makes the relevance of the material clearer. Use anecdotes and humour whenever the opportunity arises.

42.5.2 Adding Pictures

- For technical content, talk that is entirely in pictures can convey the message in an excellent manner. Once this is done then adding one or two words per slide will clarify the content further (Figs. 42.4 and 42.5).
- The images should be clearly labeled and annotated.
- If a graph is used the axes must be properly labelled. You will be intimately familiar with your graph or image, but your audience will be seeing it for the first time. They will need orientation, so take them on a guided tour, explaining the axes, annotations, and major features.

42.5.3 Fonts

Everything written on a slide should be readable, including subtitles, annotations, and labels. Use a font that is easy to read. Sans-serif fonts are better for slides than serif fonts. Too many different fonts in a slide or a presentation can be distracting, so limit to one or two. The font size should not be less than 20 points that can be seen by everyone in the room.

Fig. 42.4 Newspaper headline

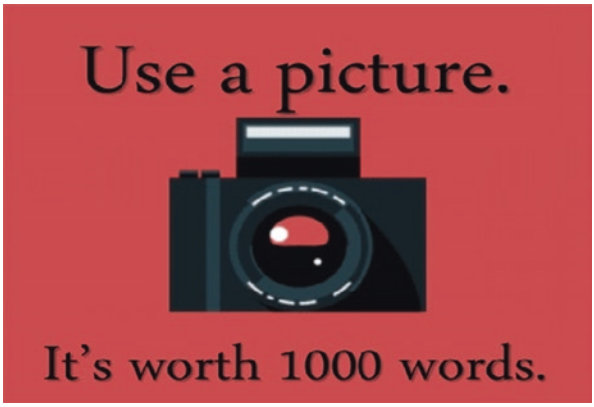

Fig. 42.5 Advantage of using picture

42.5.4 Colour Scheme

Black text on a white background or white text on a blue background, makes the slides easily readable. However, blue slides in a dark room can induce sleep.

Varying the colour and font size to emphasize points can also make the text more interesting to look at. Colour schemes that do not have much contrast, such as red on blue or black on blue, are difficult to read and cause the audience to tire.

The slides should look neat, with the same background template and the same font throughout. Using bullet points and avoiding spelling mistakes are also very important.

42.5.5 Handouts

Provide copies of the text and figures used in the lecture, either as printed handouts or as web files. It is good to provide references as well. This will make the audience pay full attention to the lecture instead of writing down notes.

42.5.6 Introduction

A good introduction raises an audience's interest in the lecture and establishes the lecturer's authority to give the talk. To ensure that your lecture gets off to a solid start, write a brief description of yourself and your talk, which can be used by the person who introduces you (Fig. 42.6).

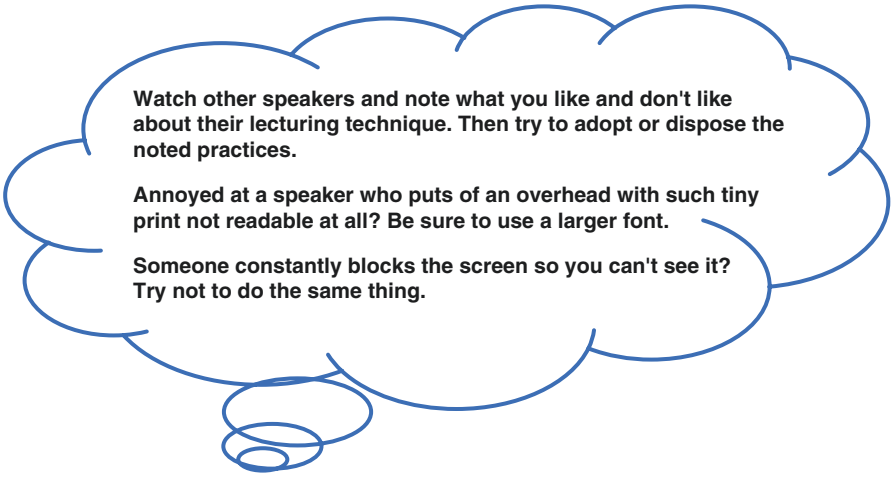

Fig. 42.6 Tips for preparing a good lecture

42.5.7 Contextual Learning

Connecting lectures to the real world broaden learning possibilities by changing the focus from recall to application.

42.5.8 Duration of a Lecture

- The usual standard length of a lecture period is 60 min, with approximately 45 min speaking and a 15-min question and answer period.
- The optimal attention span for an audience is approximately 20 min.
- Breaking down the lecture into smaller units, of 20 min can help in keeping the participants engaged with the lecture.

42.6 Don’ts in Preparing a Lecture

42.6.1 Busy Slides

Do not put too much information on an individual slide. Do not write whole sentences next to bullet points. The audience should be listening to the lecture, rather than reading on the screen.

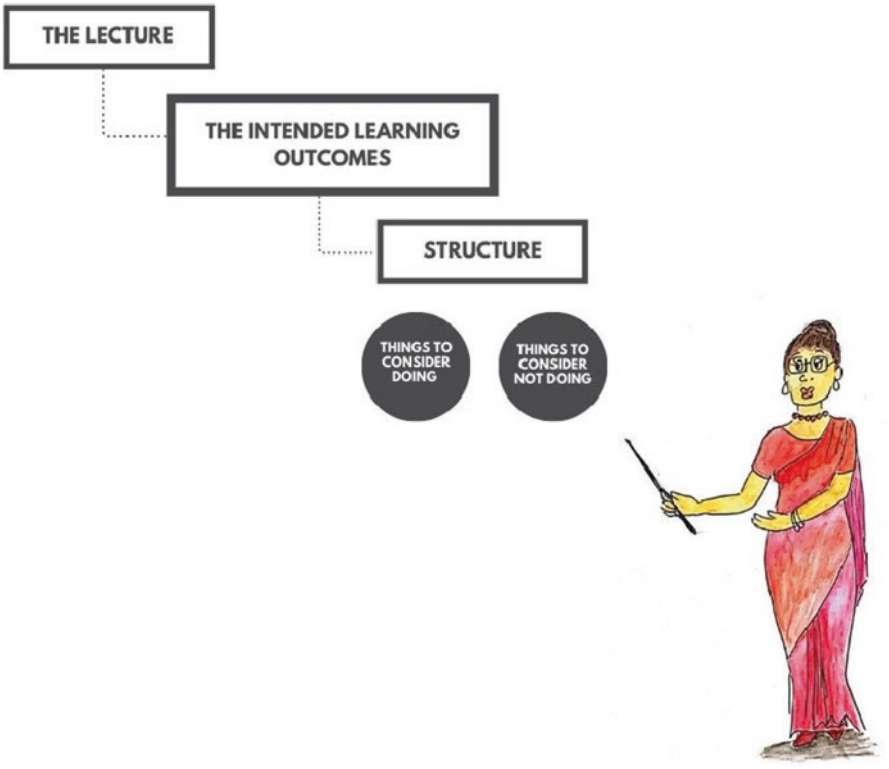

Fig. 42.7 Poorly designed slide

A slide should not be overloaded with images, graphs, or complex tables. This will cause loss of concentration and confusion for the audience.

Do not go beyond the allotted time.

Excessive animation may cause distraction so avoid it. Keep animations subtle and simple and use only to augment a specific idea that needs reinforcement (Fig. 42.7).

Do not introduce every bullet point piecemeal, reserve this for times when it gives added importance.

42.7 Conclusions

- The success of a lecture is proportional to the time spent in planning and preparation.
- Delivering a good lecture is all about connecting with the audience.
- Make a lecture interactive whenever you can and allow time for questions.
- Keep the lecture simple—stick to key facts but do not try to cram too much in.
- Never let a lecture overrun.
- Develop your lecture skills by practicing and by acting on feedback.

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The Why and How of Problem-Based Learning?

43

> Probably the most important skill that children learn is how to learn. … Too often we give children answers to remember rather than problems to solve. This is a mistake.
>
> Roger Lewin, American Anthropologist and Writer (1974–)

43.1 Origins of Problem-Based Learning—An Era of Transformation

In 1966, the faculty of medicine at McMaster University started conceptualizing medical education, which subsequently led to the evolution of what is known as '*The McMaster Philosophy*' [1]. Strong emphasis was placed on the discrete capacities of the student physician rather than having a store of knowledge. Dr. Burrows, at McMaster, explored the reasoning capabilities of both medical students and expert practitioners and found that students learned more effectively through problem situations. In 1969, the learning experiences were transformed from traditional, i.e., fact memorization, to problem-based learning at McMaster University [2].

43.2 Why Problem-Based Learning?

Problem-based learning has been popularly used in the medical curriculum with the principal aim to engage the learner in the process of learning by using a problem [3]. It is not simply the opportunity to solve problems, but rather an opportunity where solving problems is the focus or starting point for students' learning (Fig. 43.1) [4].

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_43

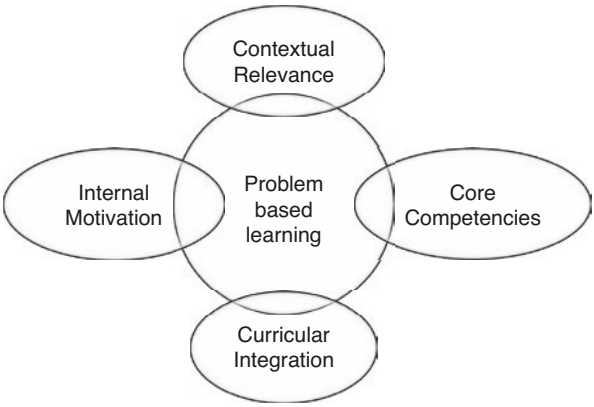


Fig. 43.1 Facets of problem-based learning

Advantages of PBL

- The problem is structured around common clinical cases. This adds strong contextual relevance to PBL as the students get the opportunity to apply critical thinking and problem-solving skills to real-life problems. It also eliminates irrelevant information which increases the cognitive load on students [5].

  Example: '**Part 1**—*Mrs. Khan brought her 15-month- old baby to the clinic with a history of recurrent loose stools since the last few months. Every time the child ate, he passed watery, sometimes mucus containing stools. There was no associated history of vomiting or diarrhoea. ……..pause for discussion……*.**Part 2**—*Mrs Khan is a 30-year old lady. She has 4 children. Her husband works on daily wages. She stitches ladies' dresses at home. They live in a kutcha house……pause for discussion…….* **Part 3**—*The baby was born by Dai assisted delivery at home at full term. He was breast fed till 8-months and then gradually started on diluted goat milk, rusk and rice. He has not received any vaccination*.'
- A well-structured problem facilitates learning critical thinking and problem-solving skills. Working with peers also provides the opportunity to learn the core competencies of teamwork and communication. PBL also serves the purpose to assess the aforementioned competencies.
- PBL rests around the core principles of adult learning. The students take the responsibility for their own learning and progress. This helps in internally motivating them towards the process of learning, having a key impact on metacognition.
- It is a vital education strategy that offers horizontal and vertical integration between various concepts of basic sciences and along with clinical sciences.

43.3 Teaching and Learning: Pedagogy Versus Adult Learning

Roles	Pedagogy	Adult learning
Teacher	– Seen as an *Expert.* – Direct the learning (what to learn, how to learn, and when to learn).	– *Facilitates* the learning process. – Manages the group dynamics and supports and challenges the student's learning.
Learner	– Passive recipient. – Dependent on external motivations(e.g., appreciation). – No prior experience/lacks the support to utilize the past experiences. – The focus is on memorization.	– Creates the learning experience based on the students' needs. – Self-directed, responsible for his/her own learning. – Internally motivated. – Rich prior experiences which have a key role in learning. – The focus is on developing concepts.
	Example: Traditional lectures	*Example: Problem-based learning*

43.3.1 How to Develop PBL?

As problem-based learning revolves around a problem, crafting a good problem is vital to the learning process [6].

Context	Problems simulating real life tend to motivate the learner. The learner invests himself in not only solving the problem but also in the application of concepts to real life.
Learning outcomes	This is the purpose behind the problem, i.e., what do you want your learner to attain out of the whole learning experience. A problem may have one or more learning outcomes, depending upon the duration of PBL.
Prior knowledge	A good case helps the learner to establish new knowledge while stimulating the previous experiences relevant to the same context.
Peer interaction	The learners interact with one another in the quest for a solution. A good case provides an opportunity for discussion, which gives birth to unique ideas.
Gaps and Cues	A good case has pre-identified gaps coupled with thought-provoking cues which prevent the learner to distract from key learning outcomes.

43.4 Characteristics of a Good Case for PBL

A PBL case composed of the following components (Fig. 43.2):

1. Problem—*The Case*

   The case is developed by a group of people (content specialist and educational expert). The group discusses the intended learning outcomes (ILOs) and drafts events relevant to each outcome. Real-life facts and evidences available in

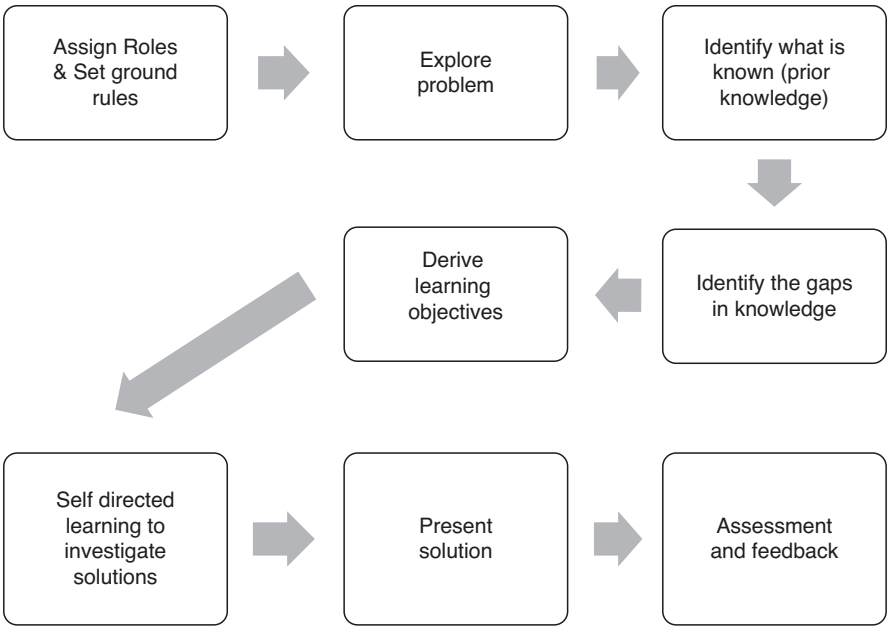


Fig. 43.2 The process of problem-based learning

the literature help in creating the ILO and the events. The case has established triggers in the form of patient age, gender, residence, occupation, ethnic background, sociocultural background etc. The triggers have cues (problems) which direct the learning process. The learning outcomes are not shared with students. The case is structured with a logical flow in such a way that students identified their learning needs themselves.

2. Facilitator Guide

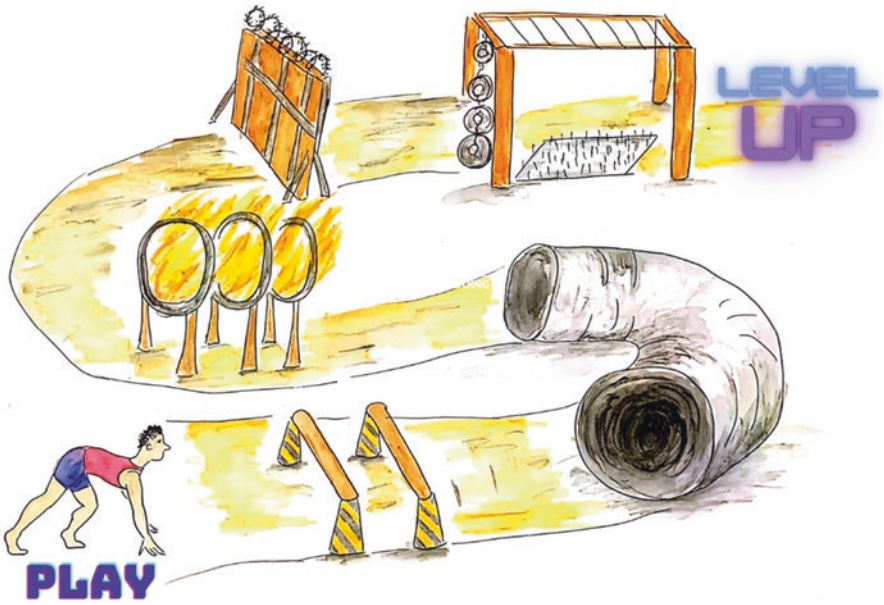
   Each case is accompanied by a facilitator guide, also developed by the case developer. The guide provides the facilitator the information regarding the ILOs, details relevant to each ILOs, and the pertinent resources (e.g., reading material) for tutors.

3. Assessment Rubrics:

   Assessment is imperative to improve the quality of learning process [7]. PBL has embedded assessment that focuses on how well the students have attained the learning outcomes, how much the facilitator supported the group dynamic and process of inquiry and how well the problem was structured to generate the inquiry and discussion.

43.4.1 PBL—*The Process*

43.4.2 Facilitating PBL



1. Maintaining the group dynamics is one of the key expectations from PBL facilitators, i.e., to see if every individual fairly contributes in proposing solutions. At the same time, facilitators also make sure that appropriate time is invested on each learning objectives [3, 7].
2. The facilitators also serve to stimulate the process of problem-based learning by challenging student's thinking towards aspects that need consideration.
3. PBL facilitators act as guides to students during the process of developing scientific reasoning and critical thinking. The facilitators should not propose solutions themselves or serve as direct source information unless they see that the resources have already been exhausted by students.
4. Certain personal qualities of facilitators, such as communicating with the students, creating a non-threatening environment where unique ideas float and an empathetic attitude seem to be important in promoting student learning.
5. There is a natural tendency of content experts as facilitators to complicate the flow of learning and problem solving; therefore the literature supports facilitators who are trained for PBL facilitation with no content expertise.

43.5 What are the Limitations of PBL?

- Problem-Based Learning is found to have a promising impact (long and short term) as compared to the traditional curriculum on selective competencies, e.g., critical thinking, problem solving, and teamwork. Current evidence does not show a significant effect of PBL curricula on clinical/patient-related outcomes [8–10].
- Despite an obvious overlap between PBL competencies and graduate attributes, PBL is little used in residency programmes [11]. One reason could be that these programmes have their roots embedded in the clinical context and traditional schools of thought do not support the learning of patient-based skills using only problems.
- The sociocultural perspective in Asia regarding teacher-centeredness, i.e., seeing the teacher as the centre of expertise makes it far more challenging to implement the student-centred PBL-based approach [12].
- Authentic assessment is required to evaluate the effectiveness of problem-based learning.
- An effective PBL requires a significant amount of time to develop and implement problem-based learning [13].
- Effective problem solving requires more time by the student, which is sometimes not possible due to concomitant curricular activities.
- PBL facilitation requires holistic training of faculty members on the principles of small group teaching and learning.

43.6 Conclusions

- The evidence supports problem-based learning over the traditional curricula in developing competencies related to problem solving, critical thinking, teamwork, and communication.
- A group of content and education experts develop problems around intended learning outcomes.
- A good PBL case stimulates prior knowledge, has more than one solution and is relevant to real life for future applications.
- PBL facilitators have to be experts in maintaining group dynamics and act as a stimulus towards inquiry.

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How to Conduct a Journal Club?

44

It is astonishing with how little reading a doctor can practice medicine, but is not astonishing how badly he may do it

William Osler, Canadian Physician, 'The Father of Modern Medicine' (1849–1919)

44.1 What Is the Importance of Having Journal Clubs?

Reading journals usually starts when you are a postgraduate and a journal club forms an important part of your curriculum. A journal club is a meeting that should be attended by all faculty and trainees. Your mentor will decide which journal articles you should get ready to present and discuss.

There is an interesting story of the origin of the words 'journal club'. Sir James Paget, a surgeon in St. Bartholomew's Hospital in London, was the first person who started reading journals regularly with his students in a baker's shop near the hospital gate. Since then there is usually a snack available at all journal club meetings (this also increases the attendance).

After postgraduation, your interest in reading journals usually diminishes unless you are in an academic institution or preparing a talk for some conference. For a busy practitioner, the reprints from journals handed over as a promotional activity by pharmaceutical representatives may often be the only source of enhancing his/her knowledge. This is a highly biased method with a blatantly commercial intent.

The reasons why you should read journals regularly are: [1, 2].

- It is a form of Continuing Medical Education even for experienced staff who may not be active academically.
- To gain knowledge about recent advances in a particular area of medicine and link this evidence to practice.
- When you are in difficulties about what to do in a particular clinical situation.
- To learn about the application of a new test which has been recently introduced.
- To guide your research.

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_44

- To help towards an oral presentation in a conference or a workshop.
- To learn about a new treatment when a patient gets sick.
- To boast of your recently acquired knowledge in the doctors' mess.
- To generate a publication in the form of a letter to the editor when an original article is discussed.

44.2 Which Kind of Articles Should Be Discussed in a Journal Club?

John Naisbit said that 'we are drowning in information but starved for knowledge'. There has been a proliferation of scientific knowledge and the number of medical journals is constantly increasing. Although the exact number of medical journals and articles published each month is not known and maybe 35,000 it is estimated that every 20 minutes one article is being included in some indexing system.

You should choose an article to discuss which describes a new technique, test, treatment option, or suggests a change in guidelines for your practice. After reading the article quickly you should ask yourself whether what is published is:

New—Is it original?

True—Are the conclusions justified based on the basis of the information provided?

Is it important—Will it influence medical practice in your hospital, your country, or the rest so the world?

Should you change—The way you are currently practicing.

Some journals also carry a box that asks—What is already known about this subject and what does this paper add?

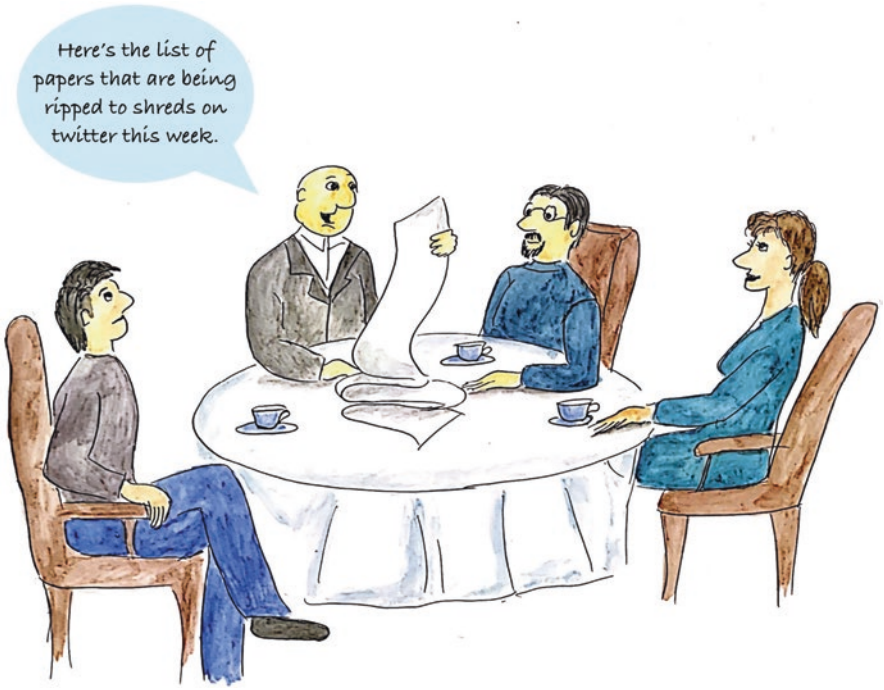
The types of articles published in a journal can be divided into *primary* literature which consists of original research papers, epidemiological data, case series, keynote addresses from conference proceedings, editorials, and letters to the editors. *Secondary* literature includes review articles, metanalyses, guidelines, book reviews, systematic reviews, and commentaries. Both are important for journal clubs. Whereas the former provides new information the latter summarises it concisely and in a way that is easy to assimilate.

Currently, there are more than 200 Indian medical journals that should also be discussed in journal clubs as they provide a perspective on health care in our country. All 'landmark' papers whether national or global should be discussed in a journal club.

44.3 What Is the Order for a Journal Club Discussion? [3]

- The authors' names and affiliations.
- What is the impact factor of the journal?
- Read the research question and how it has been addressed in the article. Dissect it in the PICOT style. Discuss the study design and how randomization was done.

- Discuss the study population and the inclusion and exclusion criteria.
- Discuss the results and examine whether statistics have been used correctly and effectively.
- The Discussion section should be clear on the authors' supportive statements about their research.
- What future directions are suggested by the article's findings?
- Can the research be replicated in our country?
- What is the take-home message from the paper?
- And again, what was known about this subject previously and what the study adds.



44.4 How Do You Choose an Article for a Journal Club?

Fig. 44.1 gives a suggestion of how to look for an article.

44.5 What Are the Future Prospects of Journal Clubs?

Electronic or e-journal clubs have been suggested to be a way forward both in the developed and in the developing world. Their many advantages include reaching out to a larger audience who are in many different institutions, better interaction, more scientific discussion, and more critical evaluation of an article. Twitter-based

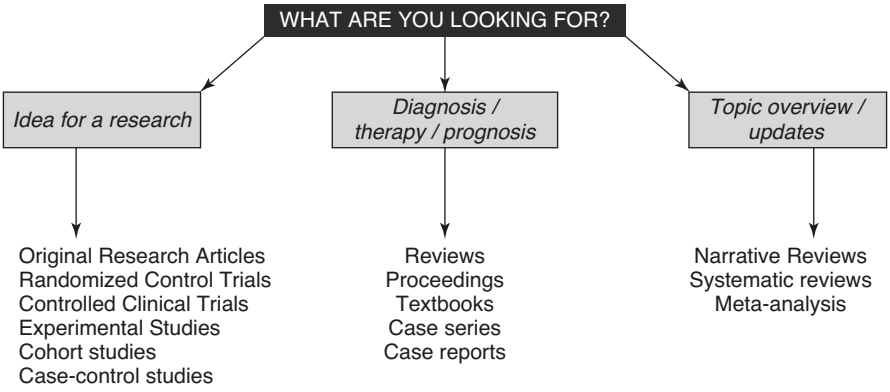


Fig. 44.1 How to look for an article?

journal clubs have also been started. The first e-journal club has been started in the field of mental health in India. All aspects of the journal including the methodology, the strength, weaknesses, and how to critically discuss the journal are discussed [4, 5].

This we feel is the way forward.

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Part X

Other Topics

Medical Records

45

'By computerising health records, we can avoid dangerous medical mistakes, reduce costs and improve care'—George W. Bush, former US President (1946–)

45.1 What Are Medical Records?

The term of Medical Records is vast and vaguely defined. It encompasses, but is not necessarily limited to, the admission sheet, history sheet, progress of a patient as well as the charts of his or her vital parameters, intake–output data, medications given, referrals, and discharge summary. Medical certificates, birth certificates, Medico-legal case sheets also fall into this purview.

There is a lack of uniformity in the dimensions defined and encompassed by medical records in the literature.

45.2 Is There a Legal Basis for Medical Records?

In the USA, Medical Records refer to all communications related to a patient's physical or mental state that is recorded in any form and are maintained for diagnosis or treatment. These include medical records that are prepared by providers other than health professionals as well. However, they exclude material that is prepared in connection with utilization review, peer review, or quality assurance activities, irrespective of whom they are prepared by. They also do not include recorded telephone as well as radio calls to and from a publicly operated emergency dispatch office relating to requests for emergency services or reports of suspected criminal activity. The exceptions to this are communications that are recorded in any form or medium between emergency medical personnel and medical personnel regarding diagnosis or treatment. These inclusions and exclusions are pursuant to particular sections of their legal system.

S. Nundy et al., *How to Practice Academic Medicine and Publish from Developing Countries?*, https://doi.org/10.1007/978-981-16-5248-6_45

Analogous to that reference, medical records are acceptable in a court of law in India as per Sect. 3 of the Indian Evidence Act, 1872 amended in 1961. Amendment of the Consumer Protection Act (1986) in 1993 brought doctors under its purview following the landmark decision of the Honourable Supreme Court. Even its current version (most recently amended in 2019) does not specifically state what is included or excluded in Medical records. However, the onus of proving dereliction of service is on the consumer stressing the paramountcy of accurate, complete, and detailed records.

45.3 What Are the Types of Medical Records?

The WHO Medical Records manual enlists four major sections of medical records that include (Fig. 45.1):

- *Administrative*: Demographic and socioeconomic data.
- *Legal*: Such as consent.
- *Financial.*
- *Clinica*l: Whether Inpatient/Outpatient; Elective/Emergency with relevant medical details.

Inpatient records can be in the form of:

– A History sheet/Emergency room admission record: which contains the patient's presenting complaints, duration along with details of symptoms, description of

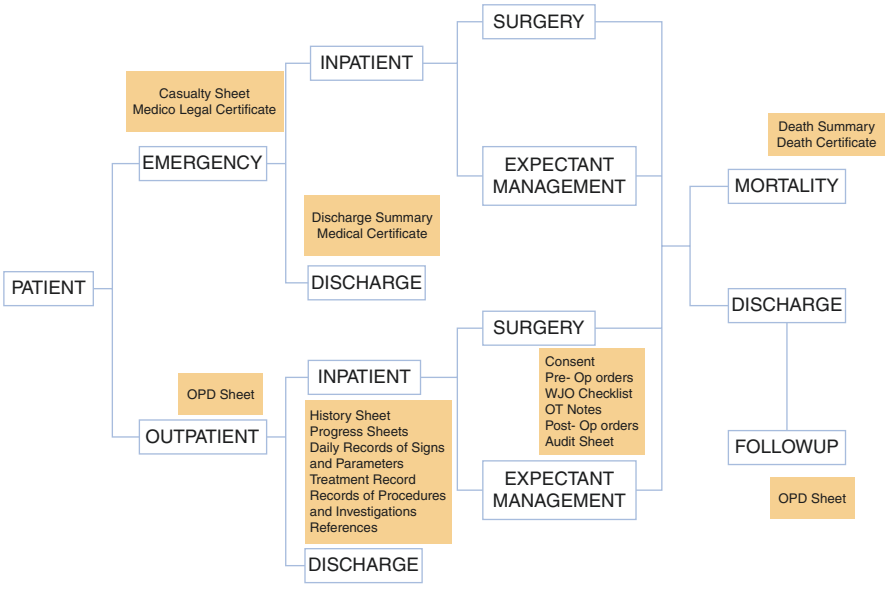


Fig. 45.1 Classification of inpatient and outpatient records

signs, a provisional diagnosis, a record of investigations already done as well as those ordered along with a plan of treatment.
– Progress Sheets: These contain relevant information on the inpatient's clinical course in the hospital as well as parameters monitored and interventions carried out. Our routine clinical practice is recording it in the 'SOAP' format.

- *Subjective*: Symptoms.
- *Objective*: Signs.
- *Assessment*: Overall.
- *Plan*: of further investigations and treatment.

Besides the patient's complaints, the progress sheet must mention the post-operative day and procedure for patients that have undergone surgery.

– Operative and Post-operative notes: Essential components of the record of surgical patients are the detailed operative findings and steps of the procedure. It is useful to have a structured template that is followed in every patient which includes preoperative diagnosis, indications for operation, findings, procedure (in numbered consecutive steps), and post-operative instructions.
– Referrals: These form an important go-between for comprehensive patient management. Coordinated care with clear and crisp communications chronologically documented with relevant information provided and subsequent advice is crucial.

Each of these documents must be duly titled with the Patient's Name, Date, Bed, Ward, and who the case is seen by. They have no standing unless duly signed with a legibly written name and designation underneath.

– Discharge Summary: Arguably this is the single most important document of the health/illness a patient possesses, a status earned for its succinct comprehensiveness. As the name suggests it collates details of the course in the hospital in an abbreviated format ensuring meticulous documentation of the relevant information.

Formulation of minimum data sheets of each subdivision with features that reflect the identity of the assessee and assessor, time of assessment, enable the risk assessment of morbidity, and mortality with an objective score, are not only easy to record manually as well as electronically, but also improve clinical care.

45.4 Are There Standards for Compliance for Medical Records?

The National Center for Quality Assurance (NCQA), a not-for-profit organization in the USA that accredits health plans has developed a Healthcare Effectiveness Data and Information Set. It gives guidelines for medical record keeping. These consist

of 21 points of which 6 are considered core elements (comorbidities, allergy, diagnosis, treatment, past history, and risk from procedures).

The National Accreditation Board for Hospitals (NABH) in India, provides standards for Information Management in the hospitals it accredits. Management of hospital information systems, as well as all modalities of information communicated to staff, patients, visitors, and the community in general, are included. Among the 7 standards it specifies in the fifth edition published in April 2020, it stresses on processes, accuracy, continuity of care, security of data, and information as well as their retention and retrievability. There is also a required review of medical records.

45.5 What Is the Clinical Importance of Medical Records?

Medical records are a repository of objective documented experience that can be extrapolated as tools for teaching, a basis for billing, and links to maintain continuity of care during follow up whether in the same or different institution by the same or a different practitioner. They are crucial to enable proper healthcare service delivery. Well-managed medical records allow smooth functioning and reduce the chances of human error. They are indispensable for audit and essential for research. In developing countries, where the majority of patients are poor and a significant proportion illiterate, they provide unambiguous insight into events that have transpired in previous encounters.

An Italian study by Poscia et al. [1] that aimed to investigate the correlation between the level of implementation of clinical governance dimensions and the quality of medical records along with the extent to which it could promote quality improvement in the context of a large Teaching Hospital found clinical governance influences health care quality, even in terms of the quality of medical records. It reiterates that well-kept medical records may be considered a surrogate marker of good clinical governance.

45.6 What Is the Administrative Importance of Medical Records?

The use of medical records surpasses current clinical practice and gains even more value in posterity. They are indispensable to medico-legal and malpractice suits where they have equal standing in defence and incrimination of health care providers and institutes. It is the legal liability of health care institutions to keep and maintain in standardized format indoor patient medical records for at least 3 years in India. In the USA, it is 6 years as per HIPPA (the Health Insurance Portability and Accountability Act), The Canadian Medical Protective Association recommends 10 years though it varies from jurisdiction to jurisdiction; Similarly, England requires retention up to 10 years after death and electronic records must not be destroyed.

Medical records are often perceived as the reflection of the standard of care provided by the health care institute.

Ethical and meticulously detailed record-keeping form the cornerstone of resilient health systems. They even provide the epidemiological data on which national health policy as well as health expenditure may be based.

45.7 How Do Medical Records Facilitate Research and Audit?

Record keeping is integral to both Research and Audit. For research, whether retrospective or prospective, meticulous record of patient's demographic and clinical data is imperative. For meaningful retrospective research, only meticulously maintained clinical records may yield patterns that can help improve practice. For instance, to evaluate intra-operative parameters that may significantly contribute to leaks in pancreatico-jejunal anastomoses in a centre correlation can only be demonstrated if data such as the texture of the pancreas, size of its duct, size, and location of the lesion, vascular anatomy, anastomotic technique, size and type of suture used etc. are diligently documented. Similarly, the first step in Audit is reviewing one's own practice which is almost entirely hinged ongoing through past records. Also, to complete the audit cycle with re-audit, any demonstrable change is contingent on that change reflecting in records. Reviewing mortality files in regular mortality meets can help identify preventable deaths. Similarly, regular audits can help identify near misses. All of these together contribute to evidence-based and improved clinical care.

Digitalization of medical records has made Audit and Research significantly less cumbersome. Patient data is available a click away. Furthermore, maintaining data on spreadsheets allows one to use filters to specify research parameters. Also, if considered at the onset and planned, they even improve data portability.

Most national and international standards for maintaining and accrediting EMRs include a mandatory review of records.

45.8 How Are Medical Records Maintained?

Medical Records may be recorded both in an electronic or paper format. Most health care organizations tend to use a combination of both.

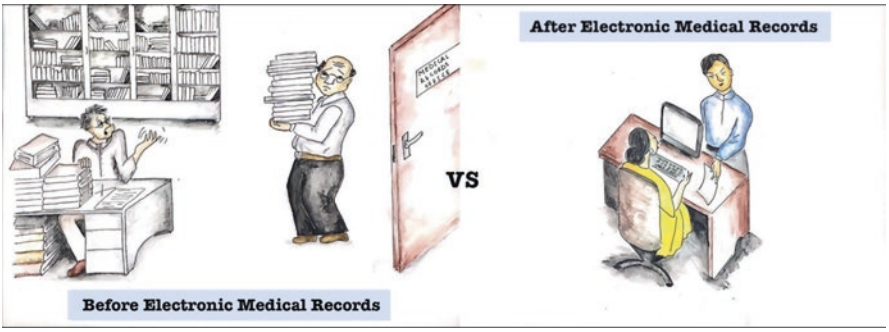
Paper records are traditional and widely kept. The responsibility and accountability are clearly allocated with the roles of data entry operators, doctors, and staff nurses defined.

The single largest value of electronic medical records (EMR) is in promoting transparency, followed by, perhaps immeasurable but definitely welcome, impact of legibility.

EMR directly improves retrievability and follow-up of patients.

Indirectly electronic records promote improved clinical governance, mitigating not only pilferage and fabrication but also human error.

Electronic medical records can be stored in various forms including a simply scanned copy of paper documents. Most hospitals utilizing electronic medical records have a specially designed software (Hospital Information System; HIS). In a study affiliated with the Australian Institute of Health Information conducted in four Saudi hospitals [2] collected information directly from different categories of health care professionals. It enumerated, validated, and ranked 10 benefits of an HIS—(1) Improved information access, (2) Increased health care professionals' productivity, (3) Improved efficiency and accuracy of coding and billing, (4) Improved quality of health care, (5) Improved clinical management (diagnosis and treatment), (6) Reduced expenses associated with paper medical records, (7) Reduced medical errors, (8) Improved patient safety, (9) Improved patient outcomes, and (10) Improved patient satisfaction.



45.9 How Are Electronic Medical Records (EMR) Different from Paper Records?

When comparing Electronic records with paper records, electronic ones score in ease of retrieval, perusal, maintaining continuity, uniformity as well as storage. They also allow performance analysis besides audit.

When its advantages are extrapolated beyond logistics, EMR simplifies and increases the feasibility of research with keyword searches, data at one's fingertips which can be easily transferred, sorted, and processed. These also improve legal standing with digital footprints that are time and date stamped and verifiable.

The switch from paper to digital can be slow, inconvenient, and nagging; the initial transition is marred by a lack of familiarity with both hardware and software, but the period is brief and worth the initial investment in training, hardware, software, and personnel. The benefits become self-evident in a very short time.

Paper records retain their significance in feasibility of recording even in remote areas, familiarity, and freedom from risk to intangible threats like technical glitches, viruses, and hacking. However, their universality is challenged by the concept of 'cloud' databases that allow information to be accessed from anytime anywhere in real time.

45.10 Why Is Medical Record-Keeping Important in Developing Countries?

A wealth of data already exists in the developing world, a direct corollary of the heavy burden of disease and difficult access to healthcare as well as a paucity of resources—health related and otherwise. The challenge remains in leveraging systems so crutches can become strengths. One of the advantages of EMRs is to link direct patient care processes within the information systems in health care delivery with the information systems at the level of government initiatives and international programmes. This can expedite improvement in health indicators with real-time access to data and its monitoring and evaluation. Digitalization in health care is here to stay. EMRs are already widely adopted in the developed world and their benefits are self-evident. Databases developed, centralized or institutional, have not only enabled authentic research and publication but demographic and disease-related information can guide national health policies, enable institutions, states, and nations to develop risk assessment models that are specific and applicable to their regional population. The major technical challenges in the adoption of EMR in developing countries include poor system security as well as a lack of backups for power, data, and technical support.

45.11 What Are the Challenges to Adoption of EMR in Developing Countries?

The Global Observatory for eHealth (GOe) has been set up by the World Health Organisation with the intent to examine the implementation of eHealth in the Member States along with the benefits of adopting information and communication technologies to health care services. A survey by the GOe found most patient data are collected on paper in spite of the high costs, limited usefulness, and inefficiencies though worldwide, a lot of countries collect aggregate health data in electronic formats at the national level. Countries in the upper-middle-income and high-income (World Bank groups) have greater adoption of EMR than those in the lower groups. Only a limited number of countries report widespread use of electronic formats and communications. These mostly include high-income countries with advanced information and communication technology infrastructure along with a workforce most of which have received advanced education. In these countries, electronic transmission use is similar to electronic capture rates which could be indicative of the adoption of interoperable systems to communicate electronic data. There is widespread availability of mobile telephone communications technology. This is an important asset that can stimulate the deployment of electronic patient health information. Many countries have adopted standards for data interoperability and have national plans for implementation. Developing economies such as Brazil, China, and India are beginning to incorporate EMRs into their health systems. However many factors still hinder their widespread adoption in other economies. For example, in sub-Saharan Africa, cost of the procuring and maintaining EMR, inadequate power supply, and Internet access form major hurdles.

45.12 What Are the Technological Advances in Medical Record Keeping?

The practice of telemedicine has seen an exponential rise and the guidelines of practice have been rolled out already. This is also coupled with the increasing proportion of surgical procedures carried out using minimal access technology and hence available video recordings. With a rise in the number of medico-legal cases, there is also a trend towards video recording the patient's consent as well as important briefings regarding surgery—the procedure, its complications as well as alternatives. Besides widely available cellular phones with cameras, a lot of records are available in the form of photos or videos. There are many systems in use now. EPIC, a privately owned healthcare software company, founded in Wisconsin, United States is quite popular in North America as well as the UK. There are also other, even cheaper models. In a study conducted in Boston [3], aimed at understanding how clinicians utilize image uploading tools in a home-grown EMR system, general surgery was amongst the departments uploading the most clinical images. The recommendations from that publication include training on when to consider adding photos to the record, how to take good clinical photos, and policies for uploading and protecting images. They also address the quandary regarding the protection of photos taken using a personal smartphone during transfer. Their hospital has developed a CliniCam, an iOS mobile application for taking clinical photographs and securely uploading those images onto the patients' medical records. Similar to this, there is an Indian application and web-based software 'Raxa' available for iOS as well as android that is being used by our department. It can store patient's demographic data, imaging investigations as well as daily patient progress. The information stored is accessible to health care providers as well as patients.

With the digitization of records, vast volumes of data are available and this is going to increase with the passage of time. The use of big data in health analytics, especially in the fields of improvement of the quality of care for a whole population, predicting new epidemics, and ensuring equal access to care for everyone has tremendous potential. A case study in Morocco [4] concluded while adopting electronic medical records, considering the adoption of a framework based on big data storage and processing technologies to attain high-performance potential descriptive, predictive, or prescriptive analytics can be incorporated easily to get valid significant insights from the EMR data.

45.13 What Is the Future of Medical Record Keeping in South Asia?

Most South Asian Countries have begun adopting Electronic Medical Records, however, the adoption is neither uniform nor universal. There is a centrally driven mandate in countries such as India, China, and Pakistan to not only digitalize medical records but also improve integration and connectivity. Despite its economic progress, most regions of China have EMRs developed in an uncoordinated manner.

A case study [5] published in 2019 explored bottlenecks of data integration and recommended the adoption of a multi-stakeholder participation in data collection followed by establishment of standards for information and an audit mechanism. In Pakistan, a legislation governing the use of the national Electronic Health Record system came into being in 2013. In India, the Electronic Health Record standards were last updated in 2016 and Telemedicine practice guidelines rolled out in 2020; in part expedited by the COVID-19 Pandemic. All of this is in line with the National Digital Health Mission and NITI Aayog's proposal of 'National Health Stack' with the goal of developing digital health records for all citizens by 2022. The pandemic has also seen momentum build-up for improving adoption of Health Information System and EMR in Bangladesh. In a paper [6] out of Sri Lanka researching gaps in national EMR implementation pointed out the current EMR implementations in public sector (non-profit organizations) has provided significant cost benefits. It also pointed towards the limited scientific research on EMRs, issues related to data ownership, private and security, need for furthering data analytics and underscored the importance of national policy for successful implementation of countrywide digital system.

EMRs have been around for a while now, albeit in a fragmented manner. As identified, the questions of Data security and Privacy, even ownership still need to be addressed more rigorously in all of these countries. For example, in India, the Right to Privacy is recognized as a fundamental right and the guidelines are that health care practitioners protect the confidentiality of their patients under the IMC regulations, IT Act 2000, SPDI Rules 2011, and other data protection laws as applicable. The Electronic Health Record Standards 2016 are important guidelines that are relevant to data protection. However there are still lacunae and loopholes that may be exploited such as even though consent is necessary for a telemedicine consultation, there is no specification requiring consent for processing, storing, and transferring patient's medical records and health information.

45.14 How Can One Maintain Records in a Department?

Even though not encouraged specifically, maintaining patient files is integral to the clinical training of doctors (Fig. 45.2). A well-written history and a comprehensive physical examination are taken as a mark of competence in residents and regularly updated progress sheets, as a reflection of their responsible attitude towards patient care. Despite the central role it plays, the teaching in this sector is informal and more of an oral tradition than dedicated practice. With rising importance due to growing number of litigations as well as the advent of EMRs, record keeping is becoming increasingly demanding. Medical record keeping is growing as a branch of its own with increasing admissions and electronic record keeping, becoming more effort intensive. Where patient sheets continue to be maintained by clinicians, their storage, duplication, or scribing them into electronic systems is increasingly being taken over by data entry operators. Familiarity and a basic knowledge of medical terms, procedures, and legal requirements, as well as structure is important.

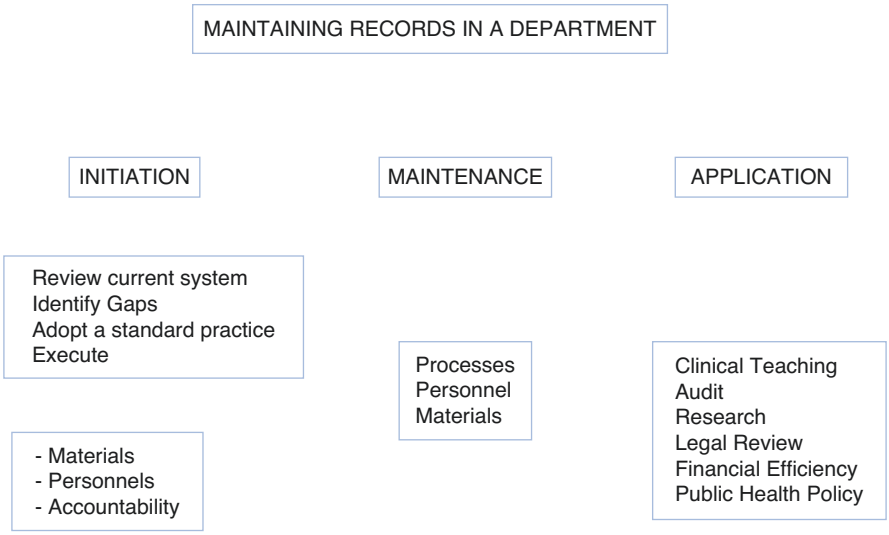


Fig. 45.2 Maintaining medical records: An overview

There are around 21 paramedical colleges in India offering Medical Record Technology courses. The number of medical colleges in India offering MBBS is 529 (National Health Profile 2019).

45.14.1 Initiation

Medical records are a byproduct of clinical care of the patient and communication between the doctor–patient as well as doctors with other doctors and doctors with paramedical staff about the patient.

The key role they play requires attitude revision to treat them as an integral part of clinical care.

The first step to improving surgical record keeping would be an audit of one's current practices, choosing a standard to comply/developing one's own minimum data sets and identifying gaps.

It is also important to identify materials and personnel recruited, their roles and responsibilities for execution as well as assigning accountability to enable compliance and re-audit to complete the cycle.

Materials:

- Clinical sheets and Charts.
- Discharge summaries.
- Operative Notes and Details.
- Histopathology Reports.
- Videos/Photographs.

– Mortality and Morbidity Data.
– Audits/Annual Reports.
– Hospital Information System/Computer with software such as Word/Pages/Excel/Numbers etc.

Personnel:

– Number.
– Designation.
– Roles and Responsibilities.

Accountability:

– Head: Oversight.
– Consultants: Regular checks/countersign.
– Residents: Clinical Details.
– Nurses: Emergency (Treatment and Vital charts, Admission/Discharge/Transfer statistics), Ward (Files, Monitoring and Treatment Charts) OT (Record of cases, specimens, special events);
– Paramedical Staff: Data entry/duplication/storage.
– Institute: Medical Records Department.

45.14.2 Maintenance

Once adopted, the aim is to inculcate it in daily routine practice so the process becomes continuous. Most important aspect to prevent fractures is to retrain as the department cycles with turnover of new personnel, especially residents. Datasets and processes pinned on the department notice board/duty room/ward are helpful. Accountability and review which may be in the form of regular audits also boost improved record keeping.

45.14.3 Application

The effort-intensive nature of meticulous record-keeping merits it contributes to patient care and improved clinical service as well be of benefit to health care professionals.

Maintaining detailed records of not only patient data, but also their laboratory investigations, imagining studies etc. can aid retrospective meaningful research as well as audit, especially into perceived errors or mortality and even help identify near misses. Increased adoption Health information systems and EMR has made this conveniently feasible as it facilitates linking across platforms (laboratory services, radiology, pharmacy etc.)

Minimum data sets improve resident training, completeness of records facilitates research and audit coupled with former two facets improve clinical service benefiting the department as well as the patient.

45.15 Conclusion

Medical records are pivotal to clinical care delivery. Digitalization is the way forward and facilitates improved Clinical Teaching, Audit, Research, and Legal Review. Big data generated can also facilitate better financial efficiency and guide Public Health Policy.

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Clinical Audit

46

Surgery without audit is like cricket without keeping the score.

—Hugh Brendon Devlin, British Surgeon (1932–1998)

46.1 What is a Clinical Audit?

Audit literally means 'official inspection of an organization's data or finances, typically by an independent body'. While most audits relate to financial matters, medical audits are used by health care professionals to evaluate, estimate, and improve the care of their patients in an organized way. These can be internal or external. Medical audit provides a systemic feedback to health authorities about the quality of medical care that was being given. With the help of audits, doctors learn about what they have been practicing, comparing their results with other benchmarks, and thus changing their practice to improve its effectiveness [1].

In audits, a comparison is made between the patient care being given and standard protocols. An audit encourages the use of the best clinical practices to provide important feedback to doctors and policymakers from previous experience [2].

46.2 Is Medical Audit a New Concept?

The first documented audit was conducted by Florence Nightingale in 1853 who measured the death rate in a hospital during the Crimean war. This was reduced from 40% to 2% by applying simple hygienic measures [3]. Medical audit is now compulsory in most western countries but its practice is rare in developing nations largely due to a lack of awareness, lack of commitment, and also due to the absence of adequate medical records. The other reason for its absence are that it is perceived as a threat to clinical freedom.

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Clinical audits have existed in some form or another for over 100 years in developed countries. In these countries, there are specific laws for health care units, doctors, and paramedics. The focus of clinical audits in the developed world is on patient outcome measures. There are deliberate efforts to improve patient care and many Quality Improvement programmes are used for this. In the UK, the National Health Service has a special audit system called 'The National Clinical Audit and Patient Outcomes Programme' and in America, the 'American College of Surgeons National Surgical Quality Improvement Program (ACS *NSQIP*)' is a validated, risk-adjusted, outcomes-based programme to measure and improve the quality of surgical care.

46.3 What are the Types of Audit?

An audit can be based on different determinants of the quality of care [4]. They include:

- The infrastructure of the institution—Beds available in the wards or intensive care units, number of operation theatres, nurse–patient ratio, qualified personnel etc.
- Patient-related activities—Quality control of check-in or checkout procedures, checklists for surgical procedures, records and note keeping, audit on infection control guidelines, prescription, pharmacy, sentinel events etc.
- Patient outcome audit—Recovery parameters and complication rates, mortality audits etc.

46.4 What is the Difference between Audit and Research? Does Audit Help in Research?

Research and clinical audit both have many similarities in terms of starting with a question and ending with answers. The answer in research is to a hypothesis whereas in audit it is to change clinical practice. Both require collection of data on patients and both depend on methodology to reach meaningful conclusions and both improve patient care [5]. The standard of data collection is important in both. If audit findings are published most people would ask for ethics appraisal. However, despite many similarities there are differences between the two activities (Table 46.1).

46.5 What is the Debate around Clinical Audit?

Any audit checks the line of treatment provided by a health care unit against standard lines of management within and outside an institution [6]. The basic requirement for such an audit to happen is to have internal reference points to say that this is the norm. The concerns over clinical audit are [7, 8]:

Table 46.1 Audit versus research

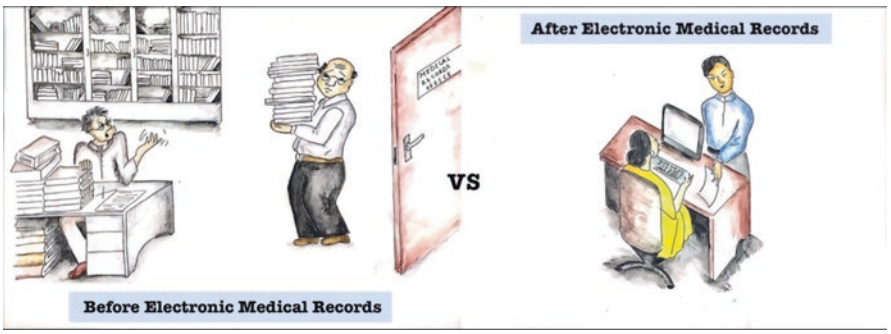
Medical audit	Health outcomes research
Audit is a systematic review of the medical care given to patients to identify whether we can improve patient outcomes	Research is a systematic investigation that aims at increasing knowledge
In audit no experiment is done	In research experiments are done on patients or healthy volunteers
No new drugs or procedures are tested	New drugs or procedures may be tested on suitable subjects
Does not involve patients travelling to a health care unit except for regular follow up	Patients may be required to travel to the health Centre according to a fixed protocol
In case there is more than one treatment available for a disease the patient has the choice	Strict criteria are used for treatment allocation and usually patients do not have a choice
The aim is improvement of the existing system by comparing audit results with accepted standards	The aim is to test a hypothesis and add new knowledge

There may be a number of different factors which influence a patient's admission to a hospital which may not entirely depend on the quality of care available but also health insurance and affordability. In addition, medical practice is often faced with challenging or life-threatening cases and in them, it may not always be possible to follow 'standard' protocols for treatment. Thus, audit should not be a fault-finding exercise and is, therefore, best done by agencies who understand the complexities of patient care.

46.6 What are the Advantages and Disadvantages of Audit?

Many clinicians who practice audit feel that it helps them improve professionally, improves communication among various disciplines and various levels of personnel involved and encourages good data keeping and research. Good audit improves patient care and provides professional validation for the health care provider.

However, many think it to be a waste of time and that it detracts from patient care. Most physicians are unwilling to criticize their colleagues and may also refuse to accept externally imposed standards of care, and perceive audit to be a professional threat. A further serious objection, especially in developing countries where the resources are so limited, is that a strict audit may curb professional creative freedom, restricting practice to a prescribed policy and discourage innovation [9].



46.7 What is the Audit Cycle?

The audit cycle has three major components of planning, audit, and action. These components can be studied by five basic steps:

1. *Preparation*: For this, we need to think of a topic that has a high priority for the hospital. For instance, in the Department of Internal Medicine, we can choose to do an audit on the demographic data of patients we admit with HINI infection, the treatment we offered to those with accidental poisoning, complications occurring during community-acquired pneumonia or to study the mortality of patients admitted with acute pancreatitis.
2. *Selection criteria*: We need to define the criteria for inclusion in the audit report. The mortality data may be of inpatients or the 30- or 90-day post-operative mortality. We can record and grade according to the widely used classification of post-operative complications described by Clavien and Dindo [10], which makes comparisons between different centres easier.
3. *Measuring the level of performance*: The data collected is analyzed and also compared with set standards. In case the accepted standards of care have not been met we should explain why this was so.
4. *Making improvements*: This involves presenting the results and discussing them with colleagues in our institution and elsewhere. We should use the results to develop an action plan, specifying what needs to be done, how it will be done, who is going to do it, and by when.
5. *Maintaining improvements*: This follows the preceding stages of the audit, to determine whether the schedules have been effective, or whether further improvements are needed. The audit/re-audit process goes on till there is improvement and thus it is called the 'audit cycle' or 'audit spiral'. This cycle is the most important step in the whole process to progress and show efficacy in the area of interest. For example, if the mortality of COVID patients admitted to the intensive care unit was found to be 15% against the internationally accepted figure of 5% we need to find why this was so and rectify the same.

   The audit cycle is diagrammatically depicted in Fig. 46.1.

46.8 What is the Status of Clinical Audit in India?

In a recent paper published in Current Medicine Research and Practice the authors mentions about the dismal status of medical audit in our country [11]. They also state that the pressure to conduct an audit is absent here. In one of the nation's premier super-specialty hospitals in Hyderabad, it was found in a survey although 86% of doctors thought that conducting audits was important not a single department was doing it.

In 1962, a committee headed by Dr. A. Lakshmanaswami Mudaliar submitted its report which emphasized the importance of medical audit [12]. In 2005 the NABH, which restructures the functions of hospitals at all levels, imposed audit processes to measure the improvement in the quality of care they provided. However, the

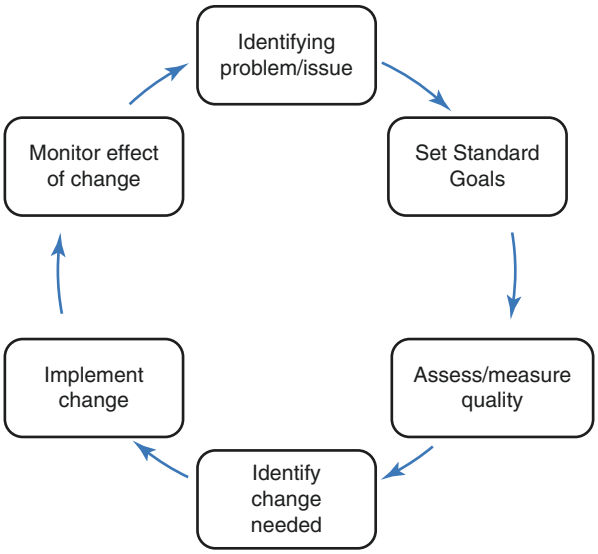


Fig. 46.1 Audit cycle

problem with the NABH is that only 600 facilities are under its supervision and it has been able to popularize the concept of clinical audit in very few of them.

Presently Ayushman Bharat, funded by the Government of India accounts for almost one-third of all health insurance expenditure in India. A number of states such as Andhra Pradesh, Tamil Nadu, Karnataka, Maharashtra, and Gujarat have instituted programmes where treatment is available in the private sector [13]. While this has led to an influx of funds into health care, there has been no increase in clinical audits or the use of accreditation mechanisms. Most state governments are focusing on the structural indicators of patient care like the availability of well-equipped operation theatres, qualified staff etc. Such indicators are concrete; easy to understand and evaluate. What is problematic is that there is no clear established relationship between good infrastructure and good clinical outcomes. As this data is lacking even in the best institutes it is difficult to say that these private hospitals are offering better patient outcomes than public hospitals.

There is, however, one exception to the above and that is the state of Maharashtra which has partnered with a public sector insurance company, the National Insurance Company. In 2013, they launched an appraisal tool for empanelment of hospitals using all three indicators—structure, process, and outcome. This tool included 85 standards to evaluate health care facilities. These indicators were grouped into nine separate chapters, namely: (1) Human resources, (2) Infrastructure, and Facilities (3) Infection Control, (4) Medication Monitoring, (5) Patient Medical Records, (6) Standard Operating Protocols, (7) Quality of Patient Care, (8) Transparency in Pricing, and (9) Patient Satisfaction Indices. The appraisal tool is being used till today in running the scheme.

The audit report of each hospital in the state should also be available.

46.9 Conclusions

- A health care unit that integrates regular audits with clinical work in its curriculum can led to continuous improvement. An audit has a positive impact on patient outcomes.
- The simple exercise of comparing practice with protocol-based standard therapy, encourages practitioners to comply with protocols. The recording of a patient's history and the examination seems to be a simple exercise but if done properly can lead to improvements in patient care.
- Conducting a clinical audit, builds up a large database that is available for corrective action.
- Establishing whether the protocols have been followed in all conditions, can provide protection to healthcare providers against negligence.
- Collection of data helps in creating transparency which bonds a trust relationship between a patient and a doctor.
- All these factors will help in building a future universal health care system.

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Clinical Drug Trials

47

47.1 What Is a Clinical Drug Trial?

This is a procedure to evaluate the efficiency and safety of a drug or medical device by monitoring its effects on participants. The research is usually done when a molecule is thought to be useful for treating humans. Thus any trial requires a triad of:

- The new molecule, or the device.
- The participants or volunteers.
- Doctors, research scientists, and coordinators.

A new drug is defined as a medication that has not been previously used in humans to treat a particular disease or has not been given a license to be used for that illness or is in the form of a fixed drug combination containing two or more drugs and has not been approved [1].

47.2 What Are the Advantages and Disadvantages for a Patient Who Is Enrolled in a Trial?

A trial is undertaken on subjects on a voluntary basis and after an informed consent form has been signed.

The benefits are:

- The patient gets a new treatment before it is available to the general public.
- He plays an active role in the health care system.
- The investigators provide better and more vigilant monitoring with more frequent health check-ups.
- By participating he/she may be helping other patients with the same illness to get better treatment for their health problems in the future.
- Access to support groups and resources becomes easier.

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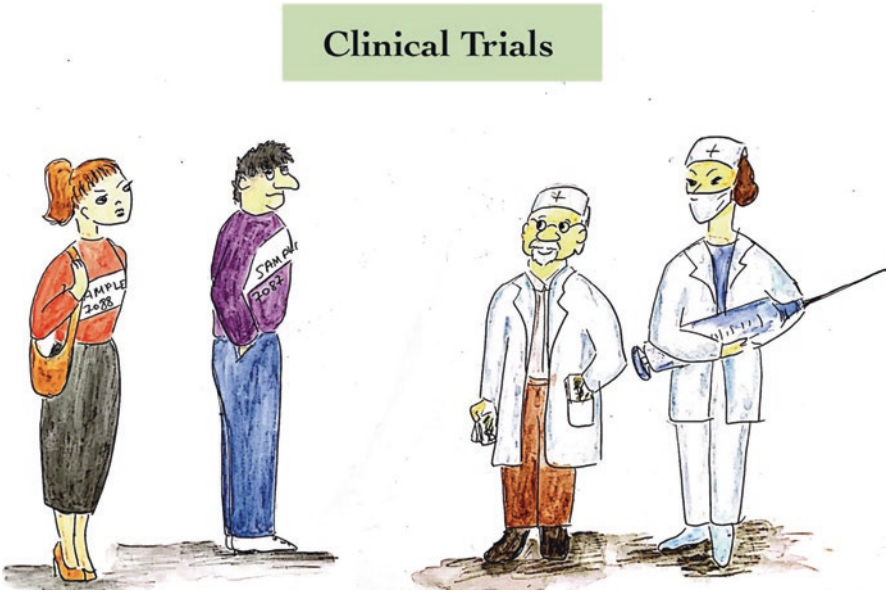
The disadvantages are:

- The new therapy may cause serious adverse effects.
- It may not work, or it may not be better than the standard of care.
- The patient can be part of the placebo rather than the treatment group.
- There can be inconvenience from the frequent medical visits and blood tests.



47.3 What Are the Various Stages of a Clinical Trial?

These are the:

- Preclinical trial
- Phase 0
- Phase 1
- Phase 2
- Phase 3
- Phase 4 (Fig. 47.1)

It has been estimated that it takes approximately 15 years to convert a small molecule in a laboratory into a life-saving drug and finally getting approval to market it [2].

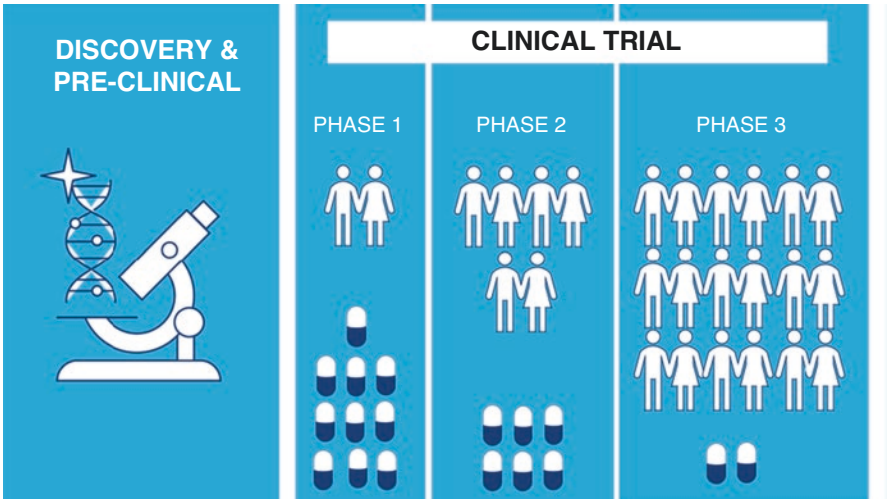


Fig. 47.1 Stages of clinical trials

Pre-clinical trial—In this phase drugs are tested in non-human subjects (in vitro and in vivo only), to gather data about their efficacy, toxicity, and pharmacokinetics. During this phase, the dose is unrestricted.

Phase 0—In this phase, a very small sub-therapeutic dose of the drug is tested in a small number (about 10) of subjects to assess for pharmacokinetics, pharmacodynamics, and particularly its bioavailability and half-life in humans.

Phase I—In this phase, a larger number of healthy volunteers (20–100) are administered sub-therapeutic doses but increasing amounts of the drug to assess its therapeutic dose range.

Phase II—In this phase, therapeutic doses of the drug are administered to a larger group of patients (100–300) to assess its efficacy and safety.

Phase III—Usually conducted by both clinical researchers or physicians. In this phase, therapeutic doses of the drug are administered to (300–1000) patients for assessing its efficacy, safety, and side effects.

47.4 What are Phase IV and Post-marketing Studies (PMS)?

Formerly, there was some vagueness in the definition and requirements for Phase IV and PMS. In 2019, New Rules, have differentiated the requirements for conducting Phase 4 and post-marketing surveillance studies for new drugs (Table 47.1).

In the New Rules, 2019, Phase IV studies would include investigations related to drug–drug interactions and dose–response or safety studies. In these, the ethical aspects for protection of the rights, safety, and well-being of the trial subjects will be followed as per the regulatory provisions. It also includes compensation for clinical trial-related injury or death and good clinical practice guidelines [3].

Table 47.1 Difference between Phase IV and Post-marketing studies from regulations perspective

	Phase IV	PMS
Approval required from Clinical licensing authority	Approval—only for a new drug and not for an old drug	
Drugs to be provided in a study	Yes	Discretion of the applicant
Design	As per study protocol design	As per prescribing information
Compensation	Applicable	Not applicable

Post-marketing Surveillance Studies are conducted with a new drug under approved conditions of its use. The regulatory provisions and guidelines applicable for the clinical trial of a new drug are not applicable when a drug has already been approved for marketing.

47.5 Is the Real-World Data the Same as Post-marketing Surveillance?

Although both are observational or non-interventional studies each has very different data. When a drug comes into the market it has already undergone a randomized controlled trial under strict conditions but when the drug actually reaches a market in the real world the situation may be very different. This type of study gives more value to already available data and is called real-world data. These studies are longer than the clinical trials and the data is collected by pharmaceutical companies or insurance authorities [4].

47.6 Is India a Potential Hub for Clinical Trials?

India has all the resources to do clinical trials. The reasons for this, include the large naive population with varied characteristics and multiple ailments, along with numerous high-level tertiary care facilities. Along with this, the cost of trials is lower compared to Western nations, there are high enrolment rates, greater patient agreement, and lower maintenance [5]. Thus these advantages are:

Investigators

(i) Many specialists and subspecialists.
(ii) The medium of instruction during training is English.
(iii) More than 7 lakh English speaking doctors.
(iv) Treatment guidelines are as per the western literature.
(v) A large number of subjects are compliant.

Patient Population

(i) Huge population who are therapy naive.
(ii) Large patient pool has acute or chronic diseases.

(iii) Many patients have lifestyle-related disease.
(iv) Many patients with cancer and HIV/AIDS—both common area for research.

Clinical Research Infrastructure

(i) Over 542 training medical institutions.
(ii) 79,855 medical graduates per year
(iii) 739,024 hospital beds
(iv) 60,000 diagnostic laboratories
(v) Many scientists and engineering graduates.
(vi) Computer savvy biomedical health workers.
(vii) Good air/surface transport facilities across country.

IT Support

(i) Highly developed.
(ii) High-quality digital connectivity.

47.7 What Is the Status of Clinical Trials in India?

The journey of clinical trials in India has been a roller coaster [3, 5, 6]. The ups and downs are related to the regulatory authorities. Recently the number of trials has been on the rise and this has been described as the 'golden period'. The new Drugs and Clinical Trials Rules (2019) have promoted clinical research in our country. The data below shows that between 2000 and 2107 [7] India was in the top ten countries in research and innovation (Table 47.2).

Table 47.2 Top 10 countries in clinical research

Country		↓ Documents	Citable documents	Citations	Self-Citations	Citations per Document	H index
1		United States	13817725	11986435	384398099	168230420	27.82
2		China	7454602	7229532	78201759	44817420	10.49
3		United Kingdom	4039729	3347117	102878206	22808209	25.47
4		Germany	3515309	3151775	81454056	19404148	23.17
5		Japan	3074206	2895478	54130480	13573127	17.61
6		France	2437589	2203243	55858552	11260558	22.92
7		India	2128896	1946730	22218913	7526767	10.44
8		Italy	2072168	1840490	43760942	10035285	21.12
9		Canada	2037509	1796688	52825596	8841600	25.93
10		Australia	1638743	1423945	37937045	7501967	23.15

47.8 Should We Be Conducting Clinical Trials in India?

There are many diseases/syndromes, which are still not curable or treatable. Diseases like autoimmune disorders, amyloidosis, various cancers, certain infections caused by antibiotic-resistant organisms still need extensive clinical research and drug trials. A decrease in the ability to conduct these trials due to multiple factors inhibits the growth of science and human progress. There is a need to consolidate efforts to improve awareness about the general safety of clinical trials among both doctors and the lay public. This can be done by:

1. Informing patients with data about the safety of previous trials.
2. Maintaining detailed records and data of patients.
3. Holding awareness programmes among doctors at multiple levels, to convince them about the safety of clinical trials.

Along with these measures, there we need to keep a strict watch on their quality and their ethical standards.

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Ethics in Genetic Research

48

48.1 Why this Chapter?

The reader must be wondering about the need for this chapter in a book on pursuing academic medicine in developing countries, as the authors did when asked to write it. The foremost reason is that informing readers about ethics in a predominantly unethical world is not out of place. It is a reminder of the inherent good in man. Secondly, genetics, which was considered a luxury in developing countries has in recent years assumed importance in clinical practice. The completion of the project on the sequencing of the human genome also provided the impetus for the development of faster and cheaper sequencing technology, which came to be known as the next generation sequencing (NGS). To illustrate, the Human Genome Project (HGP) took 13 years to complete at a cost of US $2.7 billion (US contribution). It involved the sequencing of 3 billion base pairs. The same could be carried out in a few days for US 1500 in 2016 [1]. Indeed Hennekam and Bieseker (2012) have called NGS as 'the most powerful diagnostic tool developed in medicine since the roentgenogram. Its value and utility in clinical medicine will be enormous' [2]. Numerous perplexing disorders were unravelled by NGS, and in many patients it resulted in life-saving therapy, ushering in the era of precision medicine. Medical therapy, from a position of 'one size, fits all' changed to "the right size for each patient.

Secondly, genetics deals with DNA—the very stuff of life. Using genetic techniques we can manipulate DNA—alter it, duplicate, or delete it, or correct the errors that led to disease in the first place. It thus has tremendous power which can also be misused. It is now well-known that every disease has both a genetic as well an environmental component, although the contribution of the two factors varies, depending upon the disorder (Fig. 48.1). For example, in infectious diseases, the environmental component is greater while the genetic component is small. On the other hand diseases such as β-thalassemia have a greater genetic component while the environmental component is small. In the middle are disorders such as diabetes mellitus, coronary artery disease, hypertension etc. with almost equal contributions from both the factors.

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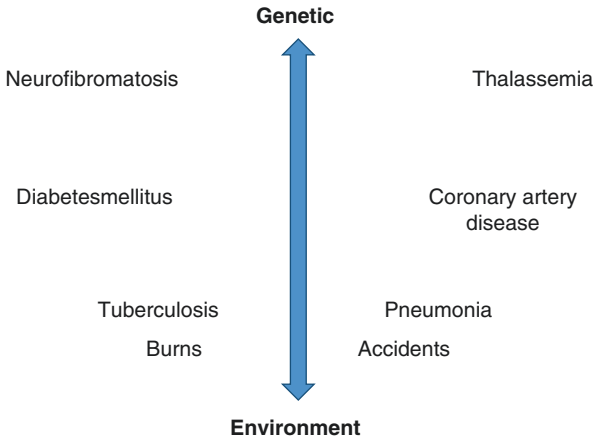

Fig. 48.1 Interaction of genes and environment

The implementation of widespread immunization programs, improvements in sanitation, and increase in incomes has led to significant control of infectious, nutritional, and parasitic disorders, and this, in turn, has resulted in the emergence of genetic disorders as important causes of morbidity and mortality. The WHO recommended that once the infant mortality rate falls below 40 (per 1000 births) the need for genetic services begins to be felt [3]. The developing world is now faced with a double burden—of infectious as well that of non-communicable disorders. Controlling the latter requires not only a change in the lifestyle and the 'environment' but also recognizing that genetic alterations have played a significant role in causing these disorders. The developing countries have a heavy load of genetic disorders as they have many communities that practice consanguineous marriages which increases the incidence of autosomal recessive disorders [4]. Cancer is also on the increase leading to genetic studies for delineating predisposition to cancer as well as the use of genetic markers in therapy.

48.2 Why Be Concerned about Ethics in Genetic Research?

Historically, genetics has been blamed to have been used as a tool for eugenics through prenatal diagnosis and termination of the pregnancy if the foetus was abnormal. Others have tried to create designer babies, or attempted to clone some individuals to generate 'perfect humans'. These misguided attempts to improve the human race have been frowned upon by the majority of people. As the cost of performing tests has come down this has led to mushrooming of genetic laboratories at times offering tests of questionable utility. The developing countries have lagged in enacting suitable legislation in controlling these laboratories to ensure the quality of the tests. Strict guidelines are needed so that genetic tests are performed adhering to ethical and professional guidelines, and create some mechanism to enforce these guidelines.

48.3 What Activities in Genetic Research Demand Special Attention to Ethical Principles?

Activities that require special attention are genetic testing which is of many types, genetic counselling, prenatal diagnosis, assisted reproductive technologies, manipulation of embryos and genes, and clinical trials for new therapies. The ethical problems arising in some of these will be discussed separately.

48.4 What are the Core Ethical Principles Worth Adhering to?

Most nations accept the following as core principles of medical ethics: respect for patient autonomy, beneficence (doing good), non-maleficence (avoiding harm), and justice (fairly balancing burdens and benefits across society). Of these, respect for autonomy has acquired a position of primary importance [5]. The conflicts arise because the law lays down the limits for the autonomy of the individual. Autonomy is not absolute and has to be within the law of the land. For example, currently, the law in India lays down that no termination of pregnancy can be carried out beyond 20 weeks of gestation. If a pregnant woman learns that the foetus has Down syndrome (that leads to mental retardation) at 22 weeks of pregnancy and wants an abortion the law does not permit this. It is apparent that the core principles are global but the action has to be as per local conditions.

The doctor is governed by the five core principles and has to work within the bounds of medical ethics (the Hippocratic Oath). The patient has to respect the culture, religion, the society, and the family norms; but above all is the law (Fig. 48.2).

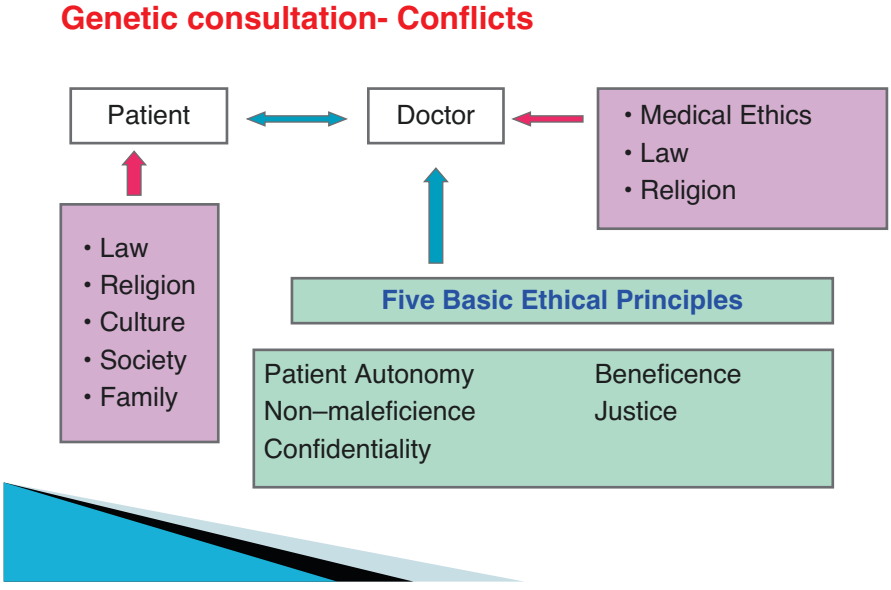

Fig. 48.2 Factors influencing actions of the doctor and the patient, and the core principles of ethics

48.5 What are the Types of Genetic Tests, their Utility, and the Ethical Concerns Raised by their Performance and Reporting?

Due to the cost of the genetic tests coming down as a result of next generation sequencing technology they are offered widely in India and are rapidly being set up and provided in other developing countries. Genetic testing may be done for diagnostic or research purpose [6]. Most commonly it is for diagnosis of a suspected genetic disorder in a symptomatic patient, which is similar to common tests in symptomatic patients, e.g., glucose testing in a case of diabetes mellitus. In such cases, it can be argued that consent is implicit in the patient coming to get the test done, and special consent may not be required. However, there is one big difference—the DNA can be used not only to diagnose a particular disease in an individual but also other disorders. It can also point to the occurrence of the disease in the family. Secondly, the leftover DNA can be utilized for the diagnosis of various genetic disorders or genetic predisposition to other characteristics. Therefore, it is advisable to obtain consent even in those subjects wanting a genetic test for diagnostic purposes The testing may be to make a prenatal or preimplantation genetic diagnosis, situations that have their ethical issues. It may be done in an asymptomatic individual to diagnose a disease before symptoms appear, or predictive testing in a young person for a disorder that occurs later in life, such as Huntington disease or Alzheimer's disease. In many countries, newborn screening tests are performed to detect disorders before they have caused serious problems or disorders that may lead to disability or death. Most hospitals require a formal consent for newborn screening as often this is mandated by the State or the Government, although the couple is given the chance to opt-out of the test if they wish. Lastly, in forensic genetic testing DNA can be used to identify persons from some remains of their tissues such as hair, blood, or semen at the scene of the crime. The test results may impact employment, insurance, or health coverage so that confidentiality of the results is of prime importance. The doctor or the laboratory cannot reveal the results of the test to the relatives without the permission of the patient unless the disorder involves a threat to life, and preventive measures can be undertaken.

48.6 What is the Revolution that Genetic Tests are Going Through?

The human genome project marked the complete sequencing of the human genome. This saw the sequencing technologies achieve unprecedented speed and at the same time reduce tremendously the cost. This was called next generation sequencing (NGS) and propelled the performance of genetic testing to unimaginable heights. Genetic tests that would earlier cost US 2000 to the US $3000 could now be done for the US $300. Instead of sequencing one gene, we could sequence a panel of genes varying from 10 to 1000 or more, the exome (all the protein-producing genes)

and even the whole genome (which including the non-coding DNA—the introns). This has led to the adoption of NGS in everyday practice in India in several fields, paediatric, adult, neurology, and haematology—literally in every field. A new era of precision medicine has dawned. Equally, changes have taken place in cytogenetic tests and karyotyping has mostly been replacing by microarray studies which can delineate much smaller changes in the chromosomes.

48.7 Ethical Issues in Next Generation Sequencing (NGS)

Exome or whole-genome yields a vast amount of information about the genes to be tested as well as other genes. Significant changes in the gene relevant to the phenotype have of course to be disclosed. What about changes detected in other genes? There is a consensus of the genetic societies that patients should be informed about changes in genes of high clinical importance such as that led to breast cancer or heart disease. List of these genes for which incidental findings should be disclosed has been generated. Another ethical issue associated with NGS data is that the patient has a right not to know the incidental findings, and such wishes should be respected. Disclosure of some results raises several sensitive human rights issues, such as the possibility of discrimination and social stigma for obtaining health or life insurance or employment [7]. Therefore confidentiality of the results is important. USA has enunciated in 2008 the Genetic Information Nondiscrimination Act (GINA) that forbids discrimination on genetic data [8], but such a law does not exist in most developing countries. In India, insurance companies even refuse health insurance or reimbursement of expenses if the disease in a person is of genetic origin. Another ethical issue is that the results may reveal information about other family members in addition to the person who is tested, and have to be handled with care. A common situation is the vast number of DNA variants that are revealed and need to be classified for pathogenicity. Despite the best efforts of the scientist's many variants remain classified as of unknown significance (VUS). At times the pathogenic variants may not be identified. All these limitations should be explained in the pre-test counselling session.

48.8 How Essential are Pre-and Post-Test Genetic Counselling?

In all genetic tests, it is good practice to provide pre-test and post-test counselling. This is especially so for prenatal tests or those that are complex or that have serious import such as for predisposition to cancer. In all such cases, the purpose and utility of the test should be explained to the patient, especially its limitations. The patient needs to be told about the cost and reliability of the test. In the post-test counselling session, the results are explained, with their interpretation, the options available, and implications for the patient and family members.

48.9 What Ethical Concerns Arise in Informed Consent for Genetic Tests?

It is essential to have consent for the genetic test to be performed from the subject being tested. The contents of the consent are very similar to the one employed in a medical test, albeit with some differences that raise ethical issues [6]. Commonly the genic laboratories store the DNA leftover after performing the test. This is used in an anonymized fashion for standardization or performance of tests to generate data for other research studies. So the consent form must specify what will be done with the DNA after the performance of the test. Will it be destroyed or used for anonymized tests for research? The ethical committees do not like to give bracket permission to store leftover DNA and perform any type of genetic research so that the investigator has to specify the nature of further testing that will be performed.

The biggest ethical issue that is faced while obtaining informed consent in developing countries is how to explain complex genetic issues to persons with little knowledge of science. One tries to be as simple as possible but even that may be beyond the comprehension of people who have very little knowledge of scientific principles. Another common misunderstanding the patients in developing countries have is that the research being done will provide treatment for the disorder that has eluded the patient so far. The scientist must remain ethical and should not provide any false promises that the results of the research will provide treatment for the patient's problems unless this happens to be true.

In general, informed consent can only be given by adults who are competent to make medical decisions for themselves. For children and others who are unable to make their own medical decisions (such as people with impaired mental status), informed consent can be given by a parent, guardian, or another person legally responsible for making decisions on that person's behalf. This is similar to consent for another medical test.

In developing countries, the language of communicating with a patient can be a barrier. Most doctors are fluent in the English language but in India and other developing countries, the patient may not understand English. The patient may understand the language of his ethnic group which the physician does not know of. A good translator is then required to make informed consent meaningful. Does the translator faithfully convey the purpose and procedure of the research study is always a moot point?

Acknowledgement that the person who is being tested has had the opportunity to discuss the test with a healthcare professional with the individual's signature, and that of a witness is essential. Verbal consent can never be accepted. Informed consent is not a contract, so a person can change his or her mind at any time after giving initial consent, and an ethical scientist will honour the wish of the patent. Informed consent from children or vulnerable groups does not have any special ethical concerns when performed for genetic research. This is similar to research in other subjects.

48.10 Informed Consent from Tribal Communities?

In developing counters there are many tribal groups and these are often subjects of research by medical anthropologists for genetic research or epidemiologic studies, and by medical geneticists for sickle cell disease and other haemoglobinopathies or other rare disorders. The tribal communities represent groups as they were before being 'civilized' and adopting modern habits and mores. These tribal communities often do not know written English or Hindi [9]. They cannot even sign their name and often their thumb impression is taken on the consent form. In the past, their thumb impression has been misused for purposes other than those explain to them, and in this way, their lands have been taken away fraudulently. When scientists approached them for research in sickle cell disease tribals are often reported as saying 'our lands have been taken away in the past and now you want to take our blood'. They are thus very suspicious of giving signatures or thumb impressions. Some anthropologists have suggested that their consent may be recorded on video. Often it is necessary to first convince their leader before the tribal people with agreeing to give a blood sample or sputum. It is the experience of the authors that scientists with good intentions usually do not have difficulty in getting consent from the tribals, who can easily judge what is good for them.

48.11 What are the Ethical Issues in Predictive Testing?

Predictive genetic tests are performed on subjects who are at risk of developing a genetic disorder based on their family history. This is termed as pre-symptomatic genetic testing when used to find out whether a person, who is currently asymptomatic, is carrying the mutation that causes disease. For example, if a child has Wilson disease and the mutations are known one may test the other siblings to find out if they are at risk of developing the disease. If they are positive for the mutation, treatment can be initiated to present the symptoms/complications of the disease. Another type of predictive testing is when it is performed for disorders for which no therapeutic intervention is available, e.g., Huntington disease, spinocerebellar ataxia, Alzheimer's disease, and other disorders of adult-onset. The subjects to be tested are in an ethical dilemma, should they get tested or take their chance. If they test positive, knowing that they may suffer from the disease in future, may cause depression and occasionally lead to suicide. If they do not have the mutant gene then this would mean they will not suffer from the disease and neither will their children be at risk. In India more people seem to opt for testing, the reason being that many live in a joint family system which provides a sort of buffer against bad news, and provides support. In developing countries many patients who are suffering themselves want their children to be tested for the reason that the child's life can be planned and the future career be decided accordingly. Generally, testing of children is permitted only if some therapy is available, not otherwise. The major reason for this is to let the child grow up and then decide for himself. As mentioned earlier this personal autonomy is less of an issue in India and other developing countries.

The issue of 'the right not to know' does get applied in developing countries too. Consider the situation where the grandfather has an adult-onset autosomal dominant disorder and his asymptomatic 'at-risk' progeny is married and the wife is pregnant. Such a person may like the foetus to be tested but not the person himself or herself. We do carry out such tests to honour the wishes of the individual.

48.12 What are the Ethical Issues in Genetic Counselling?

Genetic counselling involves providing necessary information to the patient with a genetic disease to cope with the disorder in the family and take informed decisions. In the West, it is customary and essential that the information be provided in a non-directive way and let the patient decide what should be done in a particular situation. In developing countries, non-directive counselling is very difficult to follow. Most patients when informed that they must make the decision on their own, albeit after getting the necessary information, appear uncomfortable, and will ask the doctor 'what would you do in my place'. I was once confronted with the statement 'doctor that is why we came to you, so you would tell us the right course of action to be followed'. In developing countries, most children—preschool, school, and college—are guided by the parents—what to wear, what to study, and whether to go to a movie. The children are not trained to take independent decisions. So in real-life situations or genetic counselling, they find it hard to decide on the action to be pursued. In such situations, the counsellors often say 'what others might do in your sort of situation'.

Another important principle followed in genetic counselling is the autonomy of the patient in choosing a particular course of action. The patient should be provided with the necessary information and should be given the autonomy to choose the course of action that is appropriate for his/her situation. One has to remember that this autonomy is not absolute, it is limited by what the law allows, or what the society permits. This is particularly applicable in prenatal diagnosis when a person would like to know the sex of their child (which is not permitted by law) or would like to terminate an affected foetus beyond the legally permitted gestation.

48.13 What is an Ethical Issue in Prenatal Diagnosis?

Prenatal diagnosis is easily accepted in developing countries such as India because it is a means for ensuring that a normal baby will be born. The expense of bringing up a baby with abnormalities and disabilities has to be borne from out-of-pocket expenses by the family, and most couples would like to avoid this. However, there are many ethical issues in prenatal diagnosis. The foremost in India is that the law forbids disclosure of sex of the foetus, as well as the performance of any test that may reveal the sex of the foetus. The doctor in charge of the foetal medicine specialist or the ultrasonologist has to maintain a register of every patient they see and certify that the sex of the foetus was not determined and not disclose to the patient.

For which disorders prenatal diagnosis can be permitted is an ethical question and the answer varies in different countries. In developing countries, prenatal diagnosis is sought for many disorders that may not form the basis of prenatal diagnosis in the West. The reason for this is that the socio-burden of having a child with a genetic disease is high. To illustrate, in India patients desire prenatal diagnosis for deafness or albinism as the burden of rearing an affected child is sufficient to persuade them to go for prenatal diagnosis. Another example is biotin deficiency. This causes seizures, deafness, and mental retardation. However, if the treatment is initiated before the onset of symptoms the patient remains normal. In Japan, they carry out newborn screening for biotic deficiency and treat in the presymptomatic stage and prenatal diagnosis is not performed. In India and other developing countries, couples at risk go for prenatal diagnosis for biotin deficiency as there are no newborn screening programmes for this disorder.

It is advisable to do a pre-test and post-test counselling in the presence of both partners. However, in developing countries, there is discrimination against women in many spheres and activities, who get a greater proportion of the blame for 'bad luck' issues such as having no babies or having babies with abnormalities. So the genetic counsellor has to be very careful in the presence of X-linked disorders (haemophilia A or Duchenne muscular dystrophy) in a family. Counselling is often sought by the at-risk woman accompanied by her parents or relatives. In such families very often the boy's side has not been told about the presence of X-linked disease. We, therefore, accede to the wishes of the at-risk woman and her family and do not disclose the information to the in-laws.

The disclosure of results of prenatal diagnosis in X-linked disease is also problematic due to the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act [10], which forbids the disclosure of sex of the foetus. The laboratories report that the foetus is affected or unaffected. However, if the foetus is female the family wants to know if the foetus is a carrier or not. They desire not to have a girl who is a carrier due to the difficulties they encounter in arranging her marriage. Although a female carrier in most X-linked disorders is free of disease, this is unacceptable to them because of their own experiences and hassles they have to go through. However, the staff of the genetic centre have to follow the law of the land, because of the stiff penalties for disclosing the sex of the foetus.

48.14 Is Research on Embryos Permitted?

Many people have moral and religious objections to the use of human embryos for research. In USA, Federal funds cannot be used for any research that creates or destroys embryos. However, many bioethicists and scientists believe that research using embryos is important for various reasons, as scientific questions about human biological processes in embryos need to be answered, as long as the embryos are not used for reproductive purposes [11]. Some countries have already allowed research on non-viable embryos (those that would not result in a live birth), while others have approved research studies on viable embryos.

48.15 What are the Ethical Issues in the Genomic Editing of Embryos?

The discovery and use of CRISPR CAS 9 have highlighted the ethical debate of genome editing [12]. The common consensus is that editing of the germline human genome should not be permitted at present. The story of the two Chinese doctors who attempted germ-line editing, though for the noble cause of stopping the spread of HIV, is a reminder that one should abstain from germ-line editing, as the Chinese scientists were sent to jail. This may continue until the chance of introducing a change in the wrong place (off-target) is eliminated. Until that time preimplantation genetic diagnosis (PIGD) may be resorted to. Gene editing can indeed address issues not tackled by PIGD, e.g., when both the partners are homozygotes for an autosomal recessive disorder such as sickle cell disease. There is a total consensus by almost all countries that genome editing for purposes of enhancement of certain qualities should be forbidden. However, the moot point of how much right the parents have o interfering with embryos and foetuses will always remain. There is also the concern that genome editing will only be accessible to the wealthy and will increase existing disparities between the rich and the poor.

48.16 What Do the ICMR Guidelines Say about Ethical Practice in Genetic Research?

There are many international guidelines and documents on this topic, such as those issued by the UNESCO Bioethics committee, WHO [13], CIOMS, HUGO, European Commission, and Nuffield Bioethics Council. India is one of the few developing countries where guidelines exist for genetic service and research (Sect. 10) and for biobanking (Sect. 11) issued by the Indian Council of Medical Research entitled 'National Ethical Guidelines for Biomedical and Health Research involving Human Participants' [14]. It mentioned that a thin line exists between genetic testing for service and research, and both may be considered together. Some of the important clauses are as follows: For routine testing written informed consent may not be required, and the institutional policy for these tests may be followed. It emphasizes that the harm caused by genetic testing and research may be psychosocial, and that stigmatization and discrimination should be avoided at all costs. Confidentiality of information is critical. Breaking of families by information such as the revelation of non-paternity or carrier status for X-linked disease should not be disclosed. The commercial benefit accruing from samples collected from a group requires some return of benefit to the group. One should ensure that for samples collected for commercial purposes no coercion or inducement is used. Somatic cell gene therapy is permitted while germline therapy is not permitted. It does not forbid direct-to-consumer marketing of genetic tests but emphasizes that the results should be given out by a physician who is knowledgeable in these tests.

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