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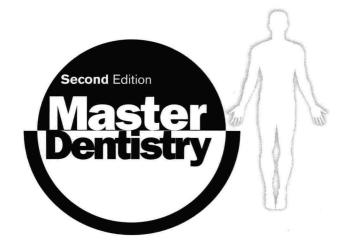
口腔颌面外科学、影像学、病理学与口腔内科学 Oral and Maxillofacial Surgery, Radiology, Pathology and Oral Medicine

(第2版)

Paul Coulthard Keith Horner Philip Sloan <u>Elizabeth D Theake</u>r







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Preface

This book is written for clinical students, undergraduate and postgraduate, as an aid to understanding clinical dentistry. Our purpose is to present our specialties in an integrated patient-focused way. The disciplines of oral and maxillofacial surgery, oral and maxillofacial radiology, oral and maxillofacial pathology and oral medicine have been brought together to provide an understanding of clinical problems. We have therefore worked together to compile chapters, although we have each taken a lead in coordinating particular chapters (Paul Coulthard chapters 1,3,4,6,8,9; Keith Horner chapters 2,5,7,15,16; Philip Sloan chapters 10,11,12,13; and Elizabeth Theaker chapter 14). This new edition has been thoroughly updated since the publication of the earlier popular text and has an introductory chapter about evidence-based practice that we believe is important for clinicians to understand. This book deals primarily with those clinical problems that would traditionally come under the 'surgical and medical umbrella'.

We did not presume to trespass into other areas of dentistry; these are dealt with in the accompanying volume of this series – *Master Dentistry 2: Restorative Dentistry, Paediatric Dentistry and Orthodontics*, edited by Peter Heasman. We hope that the format is fresh and stimulating with ample opportunity for readers to test their knowledge.

Whilst this book will act as a core text for undergraduates approaching final examinations, it will also be useful for dental students at any stage of the course who want to expand their knowledge. Postgraduates approaching professional examinations such as MJDF should find the book particularly appropriate.

Paul Coulthard Keith Horner Philip Sloan Elizabeth Theaker 2008

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Introduction



Using this book

Philosophy of the book

This book brings together core text from the traditional subject areas of oral surgery, oral medicine, oral pathology and radiology to help readers to organise their knowledge in a useful way to solve clinical problems. We believe that this core text of knowledge is essential reading for university undergraduate final examination success and will also be of help to graduates undertaking vocational training, their trainers and those preparing for postgraduate professional examinations such as the MJDF in the UK or international equivalent. This book will also be helpful as a reference for those undertaking university higher degrees such as MSc and specialist clinical training.

During your professional education, you will be gaining knowledge of oral surgery, oral medicine, oral pathology and radiology and also developing your clinical experience in these areas of dentistry. You may, however, be anxious to know how much you should know to answer examination questions successfully. The aim of this book is to help you to understand how much you should know. However, we also believe that learning is for the purpose of solving clinical problems rather than just to pass examinations and we, therefore, hope to help you to develop understanding. To ensure examination success, you will need to integrate knowledge and experience from different clinical areas so that you can solve real clinical problems. If you aim to do this, then you will be able to cope with the simulated ones in examinations.

You are required to be competent to practise dentistry on graduation and this requirement is directly related to how to be successful in the Finals examinations. Your examiners will wish you to demonstrate to them that you will make sensible and safe decisions concerning the management of your patients. So demonstrate that to them! Your clinical judgement may not be based on a lot of experience but it will be sound if you stick to basic principles. Ensure that you can take a logical, efficient history from a patient and that you are confident in your clinical examination. You will be required to use your findings together with your knowledge and the results of appropriate investigations to reach a diagnosis and suggested treatment plan. Various aspects of this process are examined in different ways but to be successful in final university and postgraduate examinations you must appreciate that there is a difference between learning and understanding. Being able to regurgitate facts is not the same as applying knowledge and will not help your patients.

It is important that you understand what you would be expected to know and manage for your particular working situation. We have, therefore, been explicit about the knowledge and skills required of those graduates working in primary care and the areas that you need to know about but do not need to understand to the same degree. There is often confusion about the role-play in an examination, and candidates attempt to avoid further questioning by stating that they would refer the patient to a specialist rather than manage them themselves! In reality, there are clearly some things that you must know and others that you need only to be aware of; it is important to know when to refer. However, even if you are not working in a hospital environment you need to be able to explain to your patient what is likely to happen to them. For instance, if a patient experiences intermittent swelling associated with a salivary gland, then you will need to refer the patient to hospital for investigation but you also need to be able to give your patient an idea about the most likely pathosis and management. Also, when deciding that your patient requires general anaesthesia for their treatment, you need sufficient knowledge to make an appropriate sensible referral and to provide the relevant information for your patient even though you will not be providing the anaesthesia.

Layout and contents

We have presented the text in a logical and concise way and have used illustrations where appropriate to help understanding. Principles of diagnosis and management are explained rather than stated and where there is controversy, this is described. The contents cover the broad areas of subjects of relevance to oral surgery, oral medicine, oral pathology and radiology but are approached by subject area rather than by clinical discipline. We deliberately present an integrated approach, as this is more helpful when learning to solve clinical problems. The artificial boundaries of specialities do not assist the clinician learning to deal with a patient's problems.

Many of the answers to the questions in the self-assessment sections present new information not found in the text of the chapter so to get the most out of this book, it is important to include these assessment sections. While it may be tempting to go straight to the answers, it would be more beneficial to attempt to write down the answers before turning to them, or at least think about the answers first.

Approaching the examinations

The discipline of learning is closely linked to preparation for examinations. Give yourself sufficient time. Superficial memorising of facts may be adequate for some multiple choice examinations but will not be adequate when understanding is required. Spending time to acquire a deeper knowledge and understanding will not only get you through the examination but will have long-term use solving real problems in clinical practice. It is useful to discuss topics with colleagues and your teachers. Talking through an issue will let you know very quickly whether or not you understand it, just as it will in an oral examination!

This book alone will not get you through an examination. It is designed to complement your lecture notes, your recommended textbooks, past examination papers and your clinical experience. Large reference textbooks are of little use when preparing for examinations and should have been used to supplement your notes and answer particular questions during the course. Short revision guides may have lists of facts for cramming but will not provide sufficient information to facilitate any understanding and will not be enough for finals and postgraduate examinations. Medium-sized textbooks recommended by your teachers will, therefore, be the most useful. This book will help to direct your learning and enable you to organise your knowledge in a useful way.

The main types of examination

Make sure that you are familiar with the examination style and look at past examination papers if possible.

Multiple choice questions

Multiple choice questions (MCQs) are usually marked by computer and are seen to be a good method of examining because they are objective, but they do not often check understanding. They do require detailed knowledge about the subject. Be sure to read the stem statements carefully as it is possible to know the answer but not score a point because you misunderstand the question. Calculate in advance how much time you have for each question and check that you are on schedule at time intervals during the examination. Find out if a negative marking system is to be used, such that marks are lost for incorrect answers, as this will determine whether it is worth a guess or not when you do not know the answer.

Extended matching items

Extended matching items (EMIs) are thought to be valuable in assessing both the level and application of knowledge. They may be based around a theme, such as a diagnosis, a set of investigations or a symptom or sign. Identify the theme, then carefully read the introductory 'lead in'

statement. Note that an option to be matched with each vignette or case may be used once, more than once or not at all. On occasions when more than one option could be correct, choose the best option available.

Short notes

Do not waste time writing irrelevant text. Short note questions are marked by awarding points for key facts. While layout is always important to allow the examiner to identify these facts easily, a logical approach is less important than for an essay. Give each section of the question the correct proportion of time rather than spending too long on one part in an attempt to get every point. It is more efficient to get the easiest points down for every question rather than all for one part and none for another.

Essays

Answer the number of essays requested. It is dangerous not to answer a question at all and many marking systems will mean that you cannot pass even if you answered another question rather well. Quickly plan your answer so that you can present a logical approach. The use of subheadings will guide your examiner through the essay, indicating that you have an understanding of the breadth of the question and score you points on the way. A brief introduction to set the scene will produce a good impression. Describe common factors first and rare things later. Try to devote a similar amount of text to each aspect of the answer. Maintain a concise approach even for an essay. Finish the essay with a conclusion or summary to draw together the threads of the text or describe the clinical importance.

Vivas

The viva is probably the most anxiety inducing of all types of examinations. It can be very difficult to know how well or not you are doing, depending on the attitude of the examiners. The examiners usually begin with general questions and then move on to requests for more detailed information and continue until you reach the limit of your knowledge. It is useful to have pre-prepared initial statements on key subjects, which might include a definition and a list of causes or types of pathology. This can help you to be articulate at the start of the viva until you settle into things.

There is frequently more than one answer to a question of patient management and it is not wrong to state this in an examination. To explain that a particular area is not well supported by scientific evidence and describe the alternative views will be respected and appreciated. Students are often advised to lead the direction of the viva, but in practice this may be difficult to do. In reality, the examiner may insist that you follow rather than lead. Remain calm and polite and do not hold back on showing off what you know.

Evidence-based practice



1.1	Decision making	;
1.2	Randomised controlled trials	
1.3	Other research methods	3
1.4	Systematic reviews	
1.5	How to read a paper	
1.6	Clinical practice guidelines	

Overview

Evidence-based medicine and dentistry is not new but is not always well understood. It is a way of thinking that should permeate every aspect of clinical practice. This chapter describes this philosophy, provides an overview of its components, and provides an approach on how to make best use of the scientific literature and the benefits of evidence-based medicine.

1.1 Decision making

Learning objectives

You should:

- know what influences clinical decisions
- understand what evidence-based practice is
- understand the advantages and limits of using an evidence-based approach to practice.

Clinical decision making is influenced by many factors, including expert opinions, experience, expectations, financial constraints and political pressures, in addition to research evidence.

Evidence-based medicine is the explicit and judicious use of current best evidence to guide health-care decisions. It integrates this best research evidence with clinical expertise and patient values. The aim of evidence-based medicine is to optimise clinical outcomes and quality of life for patients.

This approach may be used for individual patients, or for planning and purchasing care for groups of patients. Patients will benefit if their clinician is abreast of the latest data but he or she also needs to be able to take a good history, carry out a good examination, and have an understanding of the patients' values and preferences.

Evidence-based medicine

Best research evidence

When working with patients there is a constant need to seek information before making a clinical decision and professionals need to develop the habit of learning by inquiry so when confronted with a clinical question they can look for the current best answer as efficiently as possible. It can be difficult to find the current answer in a large database such as MEDLINE with over ten million references and a specialised database such as the Cochrane Library or Best Evidence can be a better place to start. Best-evidence resources are growing in number and are accessible as never before.

Best research evidence is clinically relevant research from basic science and clinical research. It either validates previously accepted diagnostic tests, preventive regimens and treatments, or replaces them with new ones that are more powerful, more accurate, more effective and safer. The strength of evidence from various study designs is shown in Figure 1.

Do not look at promotional brochures, which often contain unpublished material and ignore anecdotal 'evidence' such as the fact that a dental celebrity is using the product. Do not accept the newness of a product as an argument for changing to it as the opposite might have good scientific argument.

Clinical expertise

Clinical expertise is the ability to use clinical skills and past experience to rapidly identify each patient's unique oral health state and diagnosis, their individual risks and benefits of potential interventions and their personal values and expectations.

Patient values

Patient values are the unique preferences, concerns and expectations each patient brings to a clinical encounter and which must be integrated into clinical decisions if they are to serve the patient. It is usual practice for the clinician to describe the diagnosed condition or disease to the patient and then describe the treatment available together with the harms that the treatment may potentially cause. To determine the patient values, the clinician could go on to ask the patient to make a value judgement about these two, that is, which is worse and by how much. The patient may need to think about this or discuss with family members. The clinician may also describe the outcomes of forgoing or accepting treatment. For example, when the consultation concerns the removal of a lower wisdom tooth, the clinician may ask the patient to compare the distress caused by the pericoronitis with the anticipated distress of temporary pain and swelling and possible altered sensation. The patient should also take into account the likelihood of future episodes of pericoronitis if they forgo surgery.

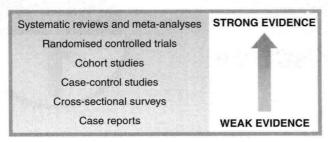


Fig. 1 Strength of evidence from some research designs.

Benefits and limitations of evidence-based medicine

The aim of evidence-based medicine is to improve clinical outcomes for patients and there is plenty of evidence that this is the case. One example is that myocardial infarction survivors who are prescribed aspirin or beta-blockers have lower mortality rates that those who aren't prescribed these drugs. Another example would be the benefit of using streptomycin for pulmonary tuberculosis as demonstrated by the historic Medical Research Council trials. These are generally regarded as the first of the modern randomised controlled trials.

The randomised controlled trial provides the underlying basis for evidence-based medicine and the number of trials is growing exponentially with more than 150000 listed by the Cochrane Library. However, there are limitations to evidence-based medicine. There is a shortage of consistent scientific evidence, difficulties in application of research evidence to individual patients, and barriers to the practice of high-quality care. Some clinicians misunderstand the philosophy of evidence-based medicine and incorrectly believe that it means a loss of clinical freedom, or that it ignores the importance of clinical experience and of individual values.

1.2 Randomised controlled trials

Learning objectives

You should:

- know what a randomised controlled trial is
- understand what the components of a trial are
- have knowledge of the different types of trial
- understand the importance of minimising bias in trials.

Randomised controlled trials may be used to compare health screening, diagnostic and preventative strategies in addition to different treatments. They are recognised to be one of simplest yet most powerful and revolutionary clinical research tools that we have. People are allocated at random to receive one of several clinical interventions, and comparisons are made (Fig. 2).

Components of the randomised controlled trial

 The patients who take part in the trial are referred to as 'participants' or the study population. Participants don't have to be ill as the study can be conducted in healthy volunteers or members of the general public.

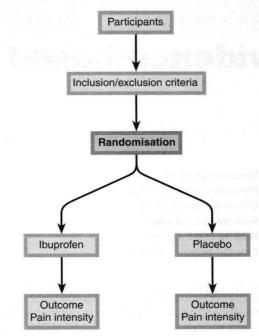


Fig. 2 Illustration of randomised controlled trial method.

- The investigators are those that design the study, administer the interventions, and analyse the results.
- One of the interventions is usually regarded as the standard of comparison or 'control', hence the name randomised *controlled* trial, and the group of participants who receive the control are known as the 'control group'. The control may be conventional treatment, placebo or no treatment.
- Outcomes are measures, so randomised controlled trials are regarded as quantitative studies. They compare two or more interventions and so are regarded as comparative studies. Case-series studies may also be quantitative but do not include comparisons among groups.

Randomisation and allocation concealment

Random allocation means that all participants have the same chance of being assigned to each of the study groups. This ensures that the groups are balanced for the disease severity or other predictors of prognosis and not biased. The randomisation should be concealed from the clinicians who entered patients into the trial so they don't know which treatment the patient will receive, otherwise they may consciously or unconsciously distort the balance of the groups being compared.

The best method for allocation to study group is to use random-number tables or computer-generated sequences. Some investigators report using 'odd or even' birth year or hospital number but there may be problems with these 'quasi-randomisation' methods. The investigator may subvert the allocation because he or she knows which group the patient will be in and the study results could be biased as the groups are not properly balanced. For example, if comparing different surgical techniques for the removal of wisdom teeth, it would be important to have an equal mix of simple and difficult cases in the different groups and not

all the simple cases in one group and all the difficult cases in another. If the groups are kept as similar as possible at the start of the study then it will be easier to isolate and quantify the impact of the intervention.

Blinding

Ideally all patients and clinicians involved in the trial should be blind to the intervention so that all groups are treated equally apart from the experimental treatments that are being compared. If this isn't the case then the study may be biased by patients who report symptoms, and clinicians who interpret them, influenced by their hunches and opinions about the anticipated treatment effectiveness. It is, however, not always possible to blind all trials. In surgical trials, for example, the surgeon will be aware of which technique of the alternatives he or she is using, but it may be feasible to have clinicians other than the operating surgeon, who are blind to the study group, carrying out the postoperative assessments. This would be described as a single-blind trial.

A trial is described as 'double-blind' when both the participants and the investigator are blind to the intervention. Some trials require a double-dummy. This may be the case, for example, in an oral medicine trial when two or more mouthrinse interventions need to look and taste the same. The double-blind, double-dummy randomised controlled trial can also be useful when, for example, a drug in tablet form is to be compared with a drug in injection form. Participants in one of the study groups would receive a tablet containing the active drug together with an injection of placebo, and the other study group would receive a placebo tablet with an injection of the active group.

A study is described as 'triple-blind' when the statistician who is analysing the data is blind to the identification of the study group in addition to the investigator and participants.

Completeness of follow-up

All patients entered to the study should be accounted for at its conclusion. Ideally no patients should be lost to follow-up because these patients could have had outcomes that would affect the conclusions of the study. They may have dropped out because of an adverse outcome. One way of dealing with the data where there are patients who have been lost is to assign the worst-case outcome to all of those lost to follow-up. However, some consider that a loss of more than 20% is unacceptable.

Sample size calculation

A clinical trial should be large enough to have a high chance of detecting, as statistically significant, a benefit from the treatment. Many trials are too small to be sure that no benefit exists. The authors may conclude that the intervention had no benefit but if they had calculated in advance the appropriate sample size, and recruited more participants, then they may have observed an effect.

Inclusion and exclusion criteria

The criteria used to determine who can enter the trial and who should be excluded shouldn't be too restrictive. If they are restrictive then the conclusions can only be used to guide decisions for the narrow group of patients who also fit the criteria.

Estimate of effect

The estimate of effect or treatment effect is the relationship observed between the intervention and outcome. There are various methods available to describe the results in clinically useful ways, including the risk ratio and a number needed to treat to benefit. The risk ratio is the ratio of the risk in the intervention group to the risk in the control group. A risk ratio of one indicates no difference between comparison groups. The number needed to treat to benefit (NNT) is an estimate of how many people need to receive a treatment before one person would experience a beneficial outcome. The NNT for 1g oral paracetamol compared to placebo to achieve at least 50% relief of severe or moderate pain after surgery is about 3.8. Ibuprofen at 400 mg compared to placebo has an NNT of 2.4 and is therefore a more effective oral analgesic.

The confidence interval (CI) provides a measure of the precision or uncertainty of study results for making inferences about the population of patients. As CIs indicate strength of evidence about quantities such as treatment benefit, they are of particular relevance to practitioners of evidence-based medicine.

Different types of randomised controlled trial Efficacy and effectiveness

Efficacy refers to whether an intervention works in people who receive it. In an efficacy trial the investigators completely control the administration of the intervention given to the participants. Surgical trials comparing different surgical techniques are efficacy trials. Trials investigating analgesics for pain control after wisdom tooth surgery are often efficacy trials too, when patients are usually kept on the study premises so that investigators can ensure that the study medication is taken properly. Even if participants go home a high compliance is expected and will usually be aided by contacting the participants by telephone to prompt this.

Effectiveness refers to whether an intervention works in people to whom it has been offered. These effectiveness trials try to evaluate the effects of an intervention in a similar environment to that found in usual clinical practice. The inclusion criteria are likely to be less strict as the intention is to mimic the real world. Participants may accept or refuse the intervention, which is likely to already have a proven efficacy.

Phase I, II and III trials

Trials designed for evaluation of new drugs are described as Phase I, II and III trials. Following the investigation of safety and potential efficacy in animal studies, the first human trials are conducted. These are known as Phase I studies and are carried out with healthy volunteers as participants and focus on safety and establishing the appropriate dose level. These are followed by Phase II studies that investigate efficacy of the chosen dose or a dose range. Participants will be patients who have a condition requiring the drug, for example, pain after surgery, requiring an

analgesic. Phase III studies are effectiveness studies comparing the new drug with an existing similar drug.

Once the new drug has been approved for marketing, there is likely to be a phase of monitoring. This phase is sometimes called a Phase IV trial, although it is not a randomised controlled trial but rather a survey.

Parallel, cross-over and split-mouth design

When participants are exposed to only one of the study interventions, for example a new analgesic or placebo, the study is described as a parallel trial or trial with parallel group design. An alternative design, used less frequently, is when the participant is given one intervention followed by another in random order, that is, each participant receives both interventions. This is called a 'cross-over' trial. This has been used for comparing patient satisfaction after provision of a conventional denture versus an implant-retained denture. Participants are randomised to receiving a conventional denture, or implant-retained denture. Then after an evaluation period, those with the conventional denture receive dental implants and a new or modified denture. Those participants with implants have the abutments only removed, so that the soft tissues heal over the implants (implants are allowed 'to sleep'), and then have a conventional denture made. In this way patients can experience both interventions and report their satisfaction in a better way.

In a split-mouth design each patient acts as his or her own control. The different treatment options are carried out on different sides of the mouth. The advantage of this type of design is that the influence of host-related factors, such as general health, age, or oral hygiene, on the interventions are reduced. The split-mouth design could not be used for the comparison of two mouthrinses as the effect of each could not be limited to one side or the other but is excellent for procedural treatments such as placement of dental implants. The intervention is randomised to the right or left side of the patient's mouth.

Bias and assessment of randomised controlled trials

Bias

Bias in health-care research refers to any process or factor that causes the results of a trial to deviate away from the truth. It usually occurs unconsciously rather than because the investigators are making a deliberate attempt to falsify the conclusions. Bias can be introduced at any stage, in the planning, conducting or analysis of a trial. A bias known as 'selection bias' is described when patients are entered into a trial such that the groups are not properly balanced. For example, an investigator may believe that a new implant system is better than an existing one but is anxious that it may not actually work so well for the more complex cases. If the clinician has prior knowledge as to which implant group a particular patient will be in, then he or she may present study information in such a way to the complex patients that they are discouraged from entering the trial altogether when they were due to enter the new implant system group. This should not occur if the randomisation and allocation procedure is good.

Bias can also occur in the publication and dissemination of trials. Authors are more likely to submit and editors are known to be more likely to accept papers for publication when the findings are positive. This is referred to as 'publication bias'. It would be helpful if high-quality trials were published irrespective of the direction of their findings.

Assessing the quality of RCTs

Not all published trials are perfect and so if you want to be confident about the conclusions drawn from a trial in guiding your clinical decision making, then the quality of the paper should be assessed. The degree to which the trial has been designed, conducted and analysed well is described as the 'internal validity' of the trial. The precision and extent to which it is possible to generalise the results of the published trial to other settings is known as the 'external validity'. There are various assessment tools available to determine the quality, although these are likely to be modified as needed. It may, for example, be important to know that a trial comparing different analgesics for pain after wisdom tooth surgery was blinded properly. However, blinding of participants would not be important in a trial comparing lingual nerve protection with no protection during wisdom tooth surgery when measuring postoperative tongue sensation as the patient is unlikely to introduce bias. It is necessary therefore to consider what parts of any assessment tool are important and relevant to the research question being asked.

The outcomes measured should be meaningful and provide direct information about benefit or harm. Outcome measures may be described as 'true' and 'surrogate' outcomes. A 'true' outcome provides unequivocal evidence of tangible benefit for the patient. An example in a dental implant trial would be the presence or absence of a functioning implant-supported prosthesis. A 'surrogate' outcome is a predictor of the true outcome. In the dental implant trial, the number of surgical visits required or the presence of plaque, bleeding of probing, or radiographic marginal bone changes, would be described as surrogate outcomes.

Outcomes should be reliable, reproducible, easily quantifiable and affordable.

1.3 Other research methods

Learning objectives

You should:

know other types of clinical study design.

A multicentre double-blind placebo controlled trial is not the only way to answer a therapeutic question. There are some questions that cannot be answered by randomised controlled trials usually because it would be inappropriate for the investigator to influence the aetiology or natural history of the disease. For example, we believe from observational studies that dental implant osseointegration is significantly impaired in patients who smoke, thus reducing implant success. It would not be ethical to randomise patients to smoking and non-smoking groups and so a randomised controlled trial cannot be undertaken. We must be content with observational studies. Similarly it may not be feasible to study an intervention that may not show effects for many years because of the difficulty in funding and high drop-out.

Also, some things are so obvious that there doesn't need to be a randomised controlled trial. There has never been a randomised controlled trial to show that defibrillation of the heart in ventricular fibrillation saves more lives that doing nothing, or to demonstrate that antibiotics are beneficial in treating pneumonia.

Cohort studies

In a cohort study, two or more groups of individuals are selected on the basis of difference in their exposure to a particular agent and followed up to determine how many in each group develop a particular disease or other outcome.

The evidence that there is a causal, rather than coincidental, link between smoking and ill health was produced by the world-famous cohort study that followed up 40 000 British doctors divided into four cohorts (non-smokers and light, moderate and heavy smokers). The authors published their 10-year interim results in 1964, which showed a substantial excess in both mortality from lung cancer and all-cause mortality in smokers with a 'dose–response' relation. They went on to publish 20-year and 40-year results, with an impressive 94% follow-up, that confirmed the dangers of smoking.

Case-control studies

Case-control studies like cohort studies are usually concerned with the aetiology of a disease rather than its treatment. Patients with a particular disease are 'matched' with controls in the general population. Data are collected (from medical records or by asking the individuals) about past exposure to a possible causal agent for the disease.

Cross-sectional surveys

In a cross-sectional survey, data are collected from a representative sample of subjects or patients by interview, examination or some other means. The collection is at a single time point, although this may be in the past when this is commonly extracted from the medical records. Most surveys do not have a comparison or control group but rather, internal comparisons are made.

Case reports

A case report describes in detail the history of a single patient to illustrate a rare condition, treatment or adverse reaction to treatment. Whilst considered to be relatively weak in the hierarchy of clinical evidence, they are useful to highlight to colleagues a new development or important observation that would otherwise be lost in a clinical trial.

A case report was used to highlight a doctor's observation of two newborn babies in his hospital that had absent limbs and that both mothers had taken a new drug in early pregnancy called thalidomide.

1.4 Systematic reviews

Learning objectives

You should:

- · know what a systematic review is
- understand the importance and use of systematic review.

A systematic review uses a predefined methodology to bring together randomised controlled trials on a similar topic, which have been systematically identified, appraised and summarised to give a summary answer. The methods used include steps to minimise bias in all parts of the process: identifying relevant studies, selecting them for inclusion, and collecting and combining their data. Reviews aim to minimise standard error by amassing very large numbers of individuals. They may include statistical methods for combining the results of individual studies called 'meta-analysis'. Systematic review of the effects of health care is the most powerful and useful evidence available for decision making.

Cochrane Collaboration

The Cochrane Collaboration is an international organisation that aims to help people make informed decisions about health, by preparing, maintaining and ensuring the accessibility of rigorous, systematic and up-to-date reviews (and where possible, meta-analysis) of the benefits and risks of health-care interventions. The collaboration consists of an international network of researchers, physicians, dentists and other health-care professionals. Since its creation in 1993, the Cochrane Collaboration has undergone an unprecedented growth and has such potential to influence decision making that it has been described as a rival of the Human Genome Project in its implications for modern medicine. The main product is the electronic Cochrane Library, which contains four databases. Cochrane reviews represent the highest level of evidence on which to base clinical treatment decisions. The typical components of a review are shown in Box 1.

Box 1 Components of a Cochrane systematic review

- Background
- Objectives
- Criteria for considering studies for this review
- Types of studies
- Types of participants
- Types of interventions
- Types of outcome measures
- Identification of studies for inclusion
- Search strategy
- Databases searched
- Any language restrictions
- Any unpublished studies
- Study selection
- Quality assessment
- Data collection and analysis
- Main results
- Discussion
- · Reviewers' conclusions for practice and research.



Fig. 3 Cochrane Collaboration logo.

In many meta-analyses, 'non-significant' trials contribute to a pooled result that is statistically significant. A famous example of this is a pooling of seven trials of the effect of giving steroids to mothers who were expected to give birth prematurely. Only two of the trials showed a statistically significant benefit (in terms of survival of the infant) but the improvement in precision (that is, the narrowing of the confidence intervals) in the pooled results, shown by the narrower width of the diamond compared to individual lines, demonstrates the strength of the evidence in favour of this intervention. This meta-analysis showed that infants of mothers treated with steroids were 30% to 50% less likely to die than infants of control mothers. The results are typically displayed in a graph called a forest plot that makes it easy for the reader to see the amount of variation between the results of the studies, as well as an estimate of the overall result of all the studies together. The forest plot from this review has been adopted as the logo for the Cochrane Collaboration (Fig. 3).

A more recent systematic review in 2005 based on 139 studies showed that there was 'no credible evidence' that the vaccine against measles, mumps and rubella was involved in the development of either autism or Crohn's disease.

1.5 How to read a paper

Learning objectives

You should:

understand the importance of critical appraisal.

The medical and dental literature is vast and growing rapidly, so the reader should be clear about why he or she is reading to avoid getting lost. Reasons may include keeping up-to-date, to find an answer to a specific clinical question or to undertake research. There are many poorquality studies published, so once the reader has identified papers of potential interest, it is important to assess their methodological quality or 'critically appraise', and note their clinical applicability.

Appraisal questions

When seeking to provide the best possible care for patients, clinicians need to know what works, what doesn't and how

Box 2 Appraisal questions generally applicable to all types of research methods

- Are the aims clear?
- Was the sample size justified?
- Are the chosen outcomes meaningful?
- · Are the measures used valid and reliable?
- Are the statistical methods described?
- Do the numbers add up?
- Was the statistical significance assessed?
- What do the main findings mean?
- Do the main findings address the aims?
- How do the results compare with other papers?
- Are there implications for clinical practice?

to distinguish between the two. When reading a paper it is useful to ask particular questions (see Box 2) but remember that it is easier to criticise the research of others than to undertake a perfect piece of research oneself.

CONSORT

The CONSORT (Consolidation of the Standards of Reporting Trials) statement was published in 1996 by a group of biostatisticians, clinical epidemiologists and journal editors to help authors with the reporting of randomised clinical trials for publication in journals. The statement consists of 22 items on a checklist (Table 1) and flow diagram (Fig. 4).

Many journals, including the *British Dental Journal*, *JAMA*, *British Medical Journal* and *The Lancet*, require that papers submitted reporting randomised controlled trials should adhere to the recommended presentation. The intention is that this initiative will improve the quality of RCTs and their reporting in publications.

1.6 Clinical practice guidelines

Learning objectives

You should:

- know what clinical guidelines are
- understand the advantages and limits of guidelines.

Guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. Their purpose is to make evidence-based clinical standards explicit and accessible so that a decision in the clinic or at the chairside will be easier and more objective. Guidelines have two components: an evidence summary, and detailed instructions on how to apply to the patient. They can also be used as a standard for assessing professional performance, to delineate the division of labour, for example, between primary care (general practice) and secondary care (hospital), to educate patients and professionals about current best practice, and to improve the cost-effectiveness of health services.

Valid guidelines create their evidence components from systematic reviews of all the relevant worldwide literature.

Table 1 CONSORT checklist of items to be included when a randomised trial is reported

Paper section	Item	Description
Title & Abstract	1	How participants were allocated to interventions (e.g., 'random allocation', 'randomised', or 'randomly assigned').
Introduction		
Background	2	Scientific background and explanation of rationale
Methods		4
Participants	3	Eligibility criteria for participants and the settings and locations where data were collected
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered
Objectives	5	Specific objectives and hypotheses
Outcomes	6	Clearly defined primary and secondary outcome measures
Sample size	7	How sample size was determined
Randomisation –	8	Method used to generate the random allocation sequence
Sequence generation		
Randomisation -	9	Method used to implement the random allocation sequence clarifying
Allocation concealment		whether the sequence was concealed until interventions were assigned
Randomisation -	10	Who generated the allocation sequence, who enrolled participants and
Implementation		who assigned the participants to their groups
Blinding	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to the group assignment
Statistical methods	12	Statistical methods used to compare groups for primary outcomes
Results		
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome.
Recruitment	14	Dates defining the periods of recruitment and follow-up
Baseline data	15	Baseline demographic and clinical characteristics of each group
Numbers analysed	16	Number of participants in each group
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval).
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.
Adverse events	19	All important adverse events or side-effects in each intervention group
Discussion		the region of the state of the
Interpretation	20	Interpretation of the results taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.
Generalisability	21	Generalisability (external validity) of the trial findings
Overall evidence	22	General interpretation of the results in the context of current evidence

However, guidelines may also use less robust evidence. Each recommendation should be tagged with the level of evidence on which it is based and the recommendation can then take this into account (Table 2).

Problems with guidelines

Health-care managers tend to welcome guidelines more than many clinicians who may distrust them. The concern is that in the absence of best evidence, guidelines may be produced anyway using poor evidence such as 'expert opinion' and the clinician may feel under pressure to adhere to these. Guideline development usually involves a small number of individuals with a consequent limited range of views and skills, so it is important that the recommendations are evaluated and modulated by external review and comment and tested in the field in which they are to be implemented.

Clinical guidelines have also been criticised for inhibiting innovation and preventing individual cases from being dealt with discretely and sensitively.

Also, nationally developed guidelines may not reflect local needs, or those developed in primary care may not reflect secondary care and vice versa. Some may consider that they may lead to an undesirable shift in balance of power between purchasers and providers, and may be perceived to be politically motivated.

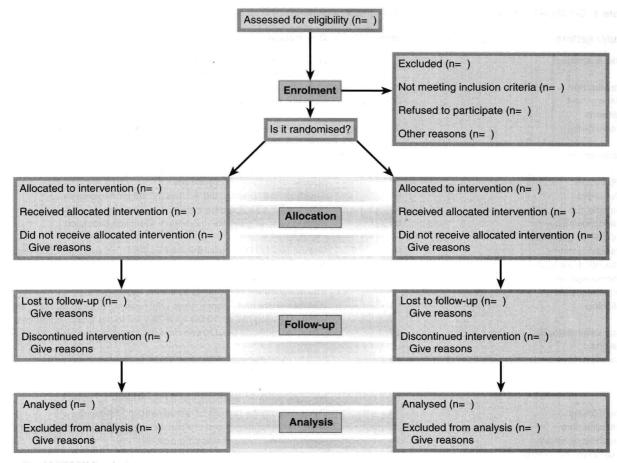


Fig. 4 The CONSORT flowchart.

Table 2 Levels of evidence and grades of recommendations for therapies

Grade of recommendation	Level of evidence		
Α	1a	Systematic reviews of randomised controlled trials	
Α	1b	Individual randomised controlled trial with narrow confidence interval	
Α	1c	All or none	
В	2a	Systematic reviews of cohort studies	
В	2b	Individual cohort study and poor quality randomised controlled trial	
В	2c	'Outcomes' research	
В	За	Systematic reviews of case-control studies	
В	3c	Individual case-control study	
C	4	Case series and poor quality cohort and case-control studies	
D	5	Expert opinion without explicit critical appraisal	

Assessing patients



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Overview

This chapter describes the basic principles of assessing a dental patient. A history should include significant medical and social facts as well as the dental problem. An initial extraoral examination covers both the visual appearance of the patient and features such as swellings and nerve dysfunction. Once these aspects are completed, the intra-oral examination will attempt to identify any lumps or swellings and to differentiate these into dental and non-dental origins. Features such as ulcers and motor or sensory nerve dysfunction will also be noted before the detailed examination of the troublesome tooth or teeth. The physical examination of the teeth is described. Specific investigations must be chosen for their suitability both in terms of the usefulness of the results and the medicolegal aspects of their use. For example, both HIV testing and the use of X-rays have implications beyond the results that they provide. The relative merits of the various investigations are described.

2.1 History

Learning objectives

You should:

- understand what information should be elicited in history taking
- develop a questioning style that is consistent, thorough and obtains the most information.

A full and accurate history is of paramount importance in assessment of a patient. In some cases, the history may provide the diagnosis while in the remainder it will give essential clues to the nature of the problem. The approach to history taking needs to be tailored to the type of complaint being investigated.

It is important to have a systematic approach to taking a history. A consistent series of questions will avoid inadvertently missing an important clue. Use 'open' rather than 'closed' (those usually eliciting a yes/no response) questions wherever possible to avoid leading the patient. Record the patient's own responses rather than paraphrasing. The history will cover:

- · the complaint
- the history of the complaint
- past dental history
- social and family history
- medical history.

The complaint

'What is the problem?' Record the patient's symptoms. If there are several symptoms make a list, but with the principal problem first.

History of the complaint

'When did the problem(s) start?' Identify the duration of the problem. Also remember to ask whether this is the first incidence of the problem or the latest of a series of recurrences.

Past dental history

'Do you see your dentist regularly?' Establish whether the patient is a regular or irregular attender. Obtain a general picture of their treatment experience (fillings, dentures, local and general anaesthetic experience).

Social and family history

Just a few questions about yourself.' The importance of recording such basic details as the age of the patient is self-evident. Other factors such as marital status and job help to gain a picture of the patient as a person rather than a mere collection of symptoms. Occupation can have direct relevance to some clinical conditions but may also reveal aggravating factors such as physical or psychological stress. Record alcohol consumption (units per week) and smoking. Family history may be relevant in some instances, for example in some genetic disorders such as amelogenesis imperfecta.

Medical history

'Now some questions about your general health.' This is obviously important. Some medical conditions may have oral manifestations while others will affect the manner in which dental treatment is delivered. Even if the patient volunteers that they are 'fit and healthy' when you say you are going to ask them a few medical questions, you must persist and enquire specifically about key systems of the body:

- cardiovascular (heart or chest problems)
- respiratory (chest trouble)
- · central nervous system (fits, faints or epilepsy)
- allergies

- current medical treatment: a negative response should be further confirmed by asking whether the patient has visited their general practitioner recently
- current and recent drug therapy
- past medical history: previous occurrences of hospitalisation or medical care
- bleeding disorders
- history of rheumatic fever
- history of jaundice or hepatitis
- any other current health problems: a negative response can be confirmed, with a final 'so you are fit and well?'.

See Chapter 3 for a more detailed discussion of the medical aspects of dental care.

2.2 Extra-oral examination

You should:

- know how to palpate lymph nodes
- be able to identify and assess swellings, sensory disturbance and motor disturbances
- understand what to look for based on the history.

Like history taking, examination necessitates a systematic approach. As a general rule, use your eyes first, then your hands to examine a patient. Start with the extra-oral examination before proceeding to examine the oral cavity.

Take time to look at the patient. This may seem obvious but will identify swellings, skin lesions and facial palsies. Facial pallor may indicate anaemia, or that the patient may be about to faint. This process of observation will start while you are taking the history.

Visual areas would cover:

- general patient condition
- symmetry
- swellings
- lips/perioral tissues.

Palpation would cover:

- lymph nodes
- temporomandibular joint (TMJ)
- salivary glands
- problem-specific examination.

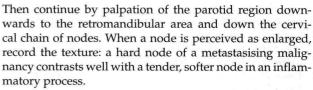
Lymph node examination

The major lymph nodes of the maxillofacial region and neck are shown in Figure 5. The submental, submandibular and the internal jugular nodes (jugulo-digastric and jugulo-omohyoid node being the largest) are of particular importance because these receive lymph drainage from the oral cavity. Examination of the nodes should be systematic, although the order of examination is not critically important. To palpate the nodes, the examiner should stand behind the patient while he/she is seated in an upright position. Use both hands (left hand for the left side of the patient etc.). A common sequence would be to start in the submental region, working back to the submandibular nodes then further back to the jugulo-digastric node (Fig. 5).



- Submandibular
- Preauricular
- Postauricular
- Occipital
- Jugulo-digastric
- Jugulo-omohyoid
- Mid jugular
- Midposterior cervical
- Lower jugular
- k Lower posterior cervical

Fig. 5 Principal lymph nodes in the head and neck. The dotted lines indicate the outline of the sternocleidomastoid muscle.



Temporomandibular joint

A detailed examination of the TMJ is probably only needed when a specific problem is suspected from the history. Details of examination of this joint and the associated musculature is given in Chapter 15.

Salivary glands

As with the TMJ, examination of the salivary glands is only required when the history suggests this is relevant. Chapter 13 describes the examination of the major salivary glands.

Problem-specific examination

The examination will be made in the light of the symptoms reported by the patient but the examiner may detect swelling, sensory or motor disturbance that the patient has not noticed.

Swelling/lump

The procedure for examination of a swelling or a lump must encompass a range of observations:

- anatomical site
- shape and size
- single or multiple
- surface texture/warmth
- tenderness
- fluctuation
- sensation/pulsation.

Consistency can be informative, ranging from the soft swelling of a lipoma, through 'cartilage hard' pleomorphic adenomas and 'rubbery hard' nodes in Hodgkin's disease to the 'rock hard' nodes of metastatic malignancy. Tenderness and warmth on palpation usually indicates an