Rational Diagnosis and Treatment

Evidence-Based Clinical Decision-Making
Fourth Edition

Peter C. Gøtzsche
Consultant Physician, Director of The Nordic Cochrane Centre
Rigshospitalet, Copenhagen, Denmark

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Preface

'The aim of this book is to show that work at the bedside can present just as great an intellectual challenge and yield even more satisfaction than work in the laboratory. Clinical reasoning can be as rigorous and as logical as that in any other academic discipline. True, the information on which decisions are based contains many elements of uncertainty, but measurement of uncertainty can replace personal and intuitive experience so that reasons for a decision become explicit and subject to analysis'. This is a quotation from the foreword by Professor J. E. Lennard-Jones, MD, FRCP, to the first edition of this book, which was published in 1976.

The book was written to promote the principles of what is now called evidence-based medicine, which at that time was slowly gaining ground. Most clinicians knew little of the methodological details of, for instance, the randomized clinical trial and many were baffled even by those simple statistical expressions, such as P-values and confidence intervals, which increasingly found their way to the medical journals. Since that time much has changed. What was then new is now well accepted and regarded as something which ought to be taught at every medical school. A textbook, however, is still needed, and, therefore, I decided to publish a new edition of the book.

I am deeply indebted to Professor Emeritus Henrik R. Wulff, MD, who wrote the first two editions of this book and with whom I rewrote the third edition that came out in 2000. I have now revised the book again, taking into account the developments since its third edition, but the aim is the same. It presents an analysis of the foundation of the clinician's decisions when he or she faces the individual patient, and although it stresses the importance of stringent scientific thinking it does not ignore the human aspects of clinical work. It emphasizes the importance of clinical research, but the methodological intricacies are viewed from the perspective of the clinician who wishes to make rational diagnostic and therapeutic decisions, not from the point of view of the researcher.

The Danish edition of the book is part of the curriculum for medical students at the University of Copenhagen, and I hope that the updated English edition may be used for undergraduate teaching at other medical schools. I also hope that it will find its place in the continued education of medical practitioners.

Peter C. Gøtzsche, MD, MSc
Consultant Physician
Director of The Nordic Cochrane Centre
Rigshospitalet, Copenhagen

Peter C. Gøtzsche studied at the University of Copenhagen, Denmark, and at the universities in Uppsala and Lund, Sweden. He graduated as a scientist in biology and chemistry in 1974 and as a physician in 1984. He worked in the drug industry from 1975 till 1983, mainly with clinical trials and regulatory affairs, and as a clinician at hospitals in Copenhagen till 1995. In 1993, when Sir Iain Chalmers in Oxford, UK, founded The Cochrane Collaboration, Peter Gøtzsche established The Nordic Cochrane Centre. He has lectured in Theory of Medicine at the University of Copenhagen since 1988. His research is mainly clinically oriented and his thesis from 1990 is about bias in drug trials. He is a specialist in internal medicine.

Introduction

> *It is at the bedside we commence our labors and at the bedside we terminate them.*
>
> *Knud Faber*[1]

Medical students work their way through books on anatomy, physiology, microbiology, paediatrics, surgery and many other subjects; they have to read thousands of pages and to assimilate a multitude of facts mostly for one purpose, the practice of medicine.

Somewhere along the road the students must also be taught how to utilize all this theoretical knowledge for making the right diagnostic and therapeutic decisions, and this lesson is learnt on the wards and in the out-patient departments. We talk about clinical medicine, and the word clinical is derived from Greek *kline* = bed.

Theoretical knowledge is important and bedside teaching will always be indispensable, but nevertheless something is missing. I shall try to explain this by a number of examples.

The medical student may be shown a patient with a palpable liver and a serum aminotransferase level above normal, and the importance of these findings is discussed. That is useful, but sometimes the student is not taught to what extent physical findings are subject to inter- and intra-observer variation, how the normal range for a laboratory test is calculated, and what is understood by normality. Therefore, he may not be sufficiently critical when later he evaluates the clinical picture of one of his patients.*

* Anonymous persons are labeled 'he' in chapters with even numbers and 'she' in chapters with odd numbers.

The student may also see a patient with changed bowel habits who had a positive test for faecal occult blood, which led to further investigations and a diagnosis of colonic cancer. However, he may not know the difference between nosographic and diagnostic probabilities and the importance of the disease prevalence and the clinical spectrum, and, therefore, he will be unable to discuss the value of a diagnostic test. Later on, he may subject his patients to unnecessary diagnostic investigations and misinterpret the results.

Further, the student may see a patient with an acute attack of bronchial asthma and he may also observe that the attack quickly subsides when the patient is treated with a β-agonist. That may enhance the student's confidence in drug therapy, but his confidence may be exaggerated, if he has been taught nothing about the fallacies of uncontrolled experience. The asthma attack might have subsided anyway. Most of those drugs which are used today will be replaced by others within a few years, and the doctor who has not been schooled in critical thinking may well expose his patients to new, ineffective or even harmful treatments.

These examples show that the teaching of clinical medicine as a master–apprentice relationship has its limitations. The apprentice learns to imitate the decisions of the master but he does not learn to assess the basis for the decisions. In contemporary medicine many clinical decisions have such far-reaching consequences that, apart from bedside experience, medical students and doctors must be well acquainted with the theoretical foundation of clinical decision-making and the results of clinical research. The clinician who bases his decisions on the best available clinical evidence from systematic research and integrates this knowledge with his clinical expertise and the patients' preferences is practicing so-called 'evidence-based medicine'.[2]

Clinical decision theory, however, is not a well-defined discipline. Clinical reasoning is extremely complex and the thought processes leading to diagnostic decisions are not well understood. It is also difficult to get a good grasp of the knowledge which does exist since it must be pieced together from articles in journals of epidemiology, biostatistics, medical ethics and other specialized fields, as well as from a number of useful treatises.[2–19]

It is also important to realize that clinical medicine belongs both to the natural sciences and the humanities, and in this book I shall distinguish between the scientific and the humanistic aspects of clinical decisions. We shall deal mostly with the scientific aspect when we discuss the decision process, i.e. how the clinician makes his observations in the individual case, interprets the data and then endeavours to act as rationally as possible combining this information and his knowledge of the results of clinical research. But I am very much aware of the fact that the two aspects of clinical medicine are inseparable, and the

book also comprises a chapter on the humanistic aspect, i.e. the understanding of the patient as a fellow human being and the analysis of the ethical aspects of the case.

The examples from the history of medicine that are interspersed in the text illustrate that clinical practice, to a much greater extent than is realized by most clinicians, is influenced by the ideas and traditions of previous generations of doctors. The lessons from history may help us to avoid repeating the mistakes of our predecessors. I have sought some primary sources, but most of the information comes second-hand through standard works on medical history.

In some of the chapters, clinical research methods are discussed in some detail, but the book has not been written for those who are actively engaged in, for instance, the assessment of new diagnostic and therapeutic methods. I only wish to guide the consumers of medical literature who have to be critical when they consider the practical consequences of the research of others. The busy clinician should remember that some knowledge of research methodology is a great time-saver as it enables the reader of medical journals to skip all those papers where the methods are obviously inadequate.

Critical reading requires some knowledge of biostatistics, but the reader need not have any prior knowledge of that topic. I only wish to introduce basic statistical reasoning and to show that the statistician's approach to clinical problems is closely linked to common sense and rational decision-making. A survey among Danish doctors revealed that their knowledge of fundamental statistical concepts (including P-values, standard errors and standard deviations) was so limited that they could not be expected to draw the right conclusions from those calculations that are reported in most medical papers. They realized themselves that this was an important problem.[20] There is no reason to believe that the situation is any better in other countries.

Although the book is not intended as a primer for researchers I hope to show on the following pages that there is a great need for clinical research both at hospitals and in general practice. Much of the research done today, also by clinicians, is laboratory-oriented and aims at exploring the causes and mechanisms of disease. Acquisition of that kind of knowledge is indispensable, also from a clinical point of view, as it may lead to the development of new diagnostic and therapeutic methods, but, before they are accepted, these new methods must be assessed critically in practice. Good clinical research can only be carried out by experienced clinicians, and research at the bedside presents as big an intellectual challenge as work in the laboratory and deserves the same respect.

I shall briefly present the structure of the book. In Chapter 1 the clinical decision process is compared to a flow chart. The first step is the collection of

information, and the formal characteristics of the different kinds of data are discussed. This discussion continues in Chapter 2, which deals with the reliability and relevance of the clinical data. In Chapter 3 the disease classification, which is indispensable for recording clinical knowledge and experience, will be viewed from a historical, a theoretical and a practical perspective.

The diagnostic decision is discussed in Chapter 4. If the truth of the diagnosis can be established by independent means, it is possible to determine the efficacy of a diagnostic test. In other cases the true diagnosis remains concealed, and it then has little meaning from a logical standpoint to discuss whether a diagnosis is true or false.

The diagnosis is only a means to select the best treatment, and the next two chapters deal with the treatment decision. Chapter 5 explains what can be learned from previous generations of doctors, and the randomized clinical trial, which is the logical consequence of that lesson, is discussed in some detail in Chapter 6.

In Chapter 7 clinical medicine is viewed as a humanistic discipline, and the ethical aspects of clinical decisions is considered. Chapter 8 deals with research methods and biostatistics and is meant as a guide for readers of medical journals.

I hope that the detailed Index at the end of the book will prove helpful when those who use it for teaching purposes wish to find examples and information about specific topics.

Peter C. Gøtzsche

1

The Foundation of Clinical Decisions

Decision-making is ... something which concerns all of us, both as the makers of the choice and as sufferers of the consequences.

Lindley[21]

And what does 'outgrabe' mean? Well, 'outgribing' is something between bellowing and whistling, with a kind of sneeze in the middle: However, you'll hear it done, maybe – down in the wood yonder – and when you've once heard it you'll be quite content ...

Lewis Carrol in 'Through the Looking-Glass'

A person who feels ill will usually seek medical advice, and the doctor, having listened to her patient's complaints, will make those decisions which, to the best of her knowledge, will help the patient most. This sequence of events is not new. If a patient at the beginning of the thirteenth century had developed an acute fever, the physician would have prescribed some medicinal herb. White benedicta (blessed thistle) might have been the choice, because this herb was said to possess great healing powers when it was taken on an empty stomach and when Pater Noster and Ave Maria were recited three times.[22] If the incident had taken place 600 years later the doctor might have made a diagnosis of pneumonia using the newly invented stethoscope, and would probably have ordered blood letting, customary dietary measures and blistering (induced by dried, pulverized Spanish fly).

The situation today is just the same, except that the doctor has a choice between many more investigations and treatments, and that the decision may

have much greater influence on the course of the disease, and, therefore, on the future life of the patient. The decision to treat a patient suffering from pneumonia with penicillin may ensure her survival when otherwise she might have died, and the decision not to do a lumbar puncture in a febrile patient may lead to her death from meningitis, although she could have been saved.

The clinical decision process

It is not so simple, however, that all positive decisions are beneficial and that all negative decisions – omissions – are harmful. All active treatments can produce harm (otherwise, they wouldn't be active) and many diagnostic procedures (e.g. liver biopsies and endoscopic examinations) are unpleasant and may cause complications. The clinician must carefully consider the consequences of her actions, both for the individual patient, and, as we shall discuss later, for the health service as a whole.

The clinical decision process is complex, but may be illustrated by a simple flow chart (Fig. 1.1). When contact between patient and doctor has been established, the data collection begins (Step 1). The doctor interrogates the patient, does a physical examination and asks for appropriate blood tests, X-ray examinations etc. When the examinations are concluded, the clinician assesses the data that have been collected and tries to make a diagnosis (Step 2). To do this she uses her *nosographic* knowledge, i.e. her knowledge of the manifestations of different diseases (nosography = disease description, derived from Greek *nosos* = disease).

A diagnosis may be more or less certain, and the clinician has to ask herself whether or not the diagnosis is sufficiently well founded to proceed to treatment (Step 3). If the answer is 'no', the process returns to Step 1 and the investigations continue. If the answer is 'yes' the clinician proceeds to Step 4.

At this point she must once again draw on her nosographic knowledge, this time of the prognosis of the disease and the effect of different treatments. She chooses the treatment that is considered likely to help the patient most, and if the patient progresses as expected, the process comes to an end (Step 5).

This presentation is, of course, greatly simplified and frequently the decisions proceed in a different way. Sometimes the patient does not respond to treatment as expected, and the diagnosis must be revised; and sometimes it is necessary to institute treatment before the final diagnosis is made, as, for instance, in cases of haemorrhagic shock when treatment is started before the site of the bleeding is known. The flow chart also ignores the fact that in chronic diseases clinicians

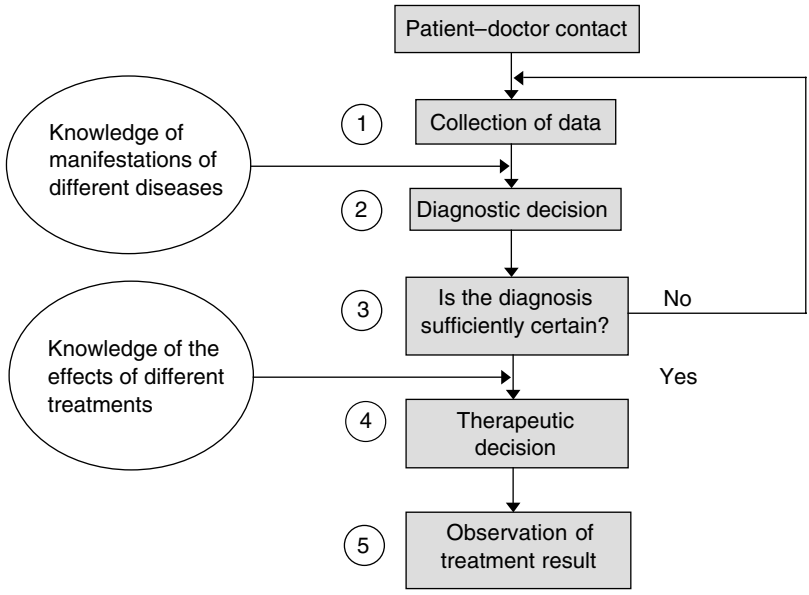

Fig. 1.1 Flow chart illustrating the clinical decision process.

must consider the long-term effects of their treatments, and the presentation does not take into account that doctors concern themselves not only with treatment, but also with prophylaxis.

Therefore, the flow chart in Fig. 1.1 is by no means universally valid, but it may serve as a framework for a systematic analysis of the decision process.

Clinical reasoning may be *deductive* or *empirical*. Clinicians reason deductively when they base their treatment decisions on deductions from theoretical knowledge of disease mechanisms and the mechanism of action of different drugs, whereas they reason empirically when their decision is based on experience that has been gained from the treatment of other patients. When a clinician recommends a β_2-agonist for the treatment of asthma, her reasoning is deductive if she argues that the symptoms are caused by bronchoconstriction and that β_2-agonists decrease this. Her reasoning is empirical, however, if she recommends steroid inhalations because randomized trials have shown a good and sustained effect with little harm.

Deductive and *empirical* reasoning constitute the scientific component of clinical decision-making (if we use the word scientific in its narrow sense, i.e. 'pertaining to the natural sciences'), but added to this is the humanistic

component which comprises reasoning based on an *understanding* of the patient as a fellow human being, and *ethical* reasoning based on ethical norms (see Chapter 7). Thus, clinical decision-making is a synthesis of four types of reasoning.

Clinical data

A house physician at a medical unit reports to a registrar that she has just seen a new patient who presents with a red and swollen left lower leg and tenderness of the calf. The registrar accepts the suggestion that anticoagulant treatment is instituted in order to prevent progression of the surmised deep venous thrombosis. However, another houseman who has also seen the patient objects. It is true that the leg is red and swollen, but the demarcation of the erythema is sharp, the affected skin is raised compared with the adjoining normal skin, and the patient has a small ulceration on the foot. The registrar now correctly diagnoses erysipelas and changes the treatment to penicillin. The example illustrates the well-known danger involved when decisions are made by a doctor who has not examined the patient herself. Both diagnosis and treatment depend on the collected data and no amount of professional knowledge can compensate for incorrect information. Therefore, it is not possible to attempt an analysis of diagnostic and therapeutic decision-making until the information that is used for the decisions has been analysed in detail, but unfortunately this analysis is hampered by the fact that many of the terms that we generally use are vague and ill defined.

In this book I shall use the term *clinical data* to denote all those data about the individual patient which are relevant for the decision process, and collectively these data are said to constitute the patient's *clinical picture*. Consequently, the clinical data in this wide sense comprise both the data recorded at the bedside (symptoms and signs), i.e. the truly clinical data, and the results of laboratory investigations, i.e. the so-called paraclinical data. Further, the clinical data (and the clinical picture) include negative findings, such as 'the lack of neck stiffness' in a febrile patient.

I shall use the following definitions of the different types of clinical data:

- *Subjective symptoms*. These are the sensations noted by the patient (e.g. pain, clouded vision and dizziness) and the patient's mood (e.g. depression and anxiety).

- *Objective symptoms.* This term signifies all observations made by the patient or the relatives concerning the patient's body and its products, e.g. swollen ankles, blood in the urine or an epileptic attack.
- *Physical signs.* These comprise all those observations that are made by the doctor during the physical examination, e.g. a cardiac murmur, swollen lymph nodes or jaundice. Some of the recorded 'signs', such as tenderness, dysaesthesia or loss of central vision of one eye, fall into a special group. They are subjective symptoms that are only noticed by the patient during the physical examination, and they may appropriately be called *provoked symptoms.*
- *Paraclinical data.* They include all laboratory results, and the results of all examinations not done by the clinician herself, such as blood analyses or radiological and histological findings. Paraclinical data may be either *descriptive*, e.g. the shadow on a chest X-ray, or *quantitative,* e.g. the blood glucose concentration.

The patient's record will also contain other data that may be of paramount importance, e.g. information about occupation, family life, previous illnesses, medication, smoking, drinking and other habits.

The erysipelas case illustrated that incomplete or unreliable information may easily lead the decision process astray, and it is worthwhile considering how the clinical data come to the clinician's attention. We may for this purpose distinguish between three types of data:

1. The symptoms that make the patients seek medical advice;
2. The data that are revealed by the routine questioning and the routine investigation of the patient;
3. The data that are the results of diagnostic tests that are carried out to confirm or exclude various diagnostic possibilities.

The first type of data may be labelled the *iatrotropic symptoms* (from Greek *iatros* = doctor and *trope* = turn).[3] They are the subjective and objective symptoms that make the patient turn to her doctor as opposed to the non-iatrotropic symptoms which are only disclosed during the taking of the history. In the same way one may distinguish between iatrotropic and non-iatrotropic cases of a disease. A patient who sends for a doctor because of a high temperature and who, during history taking admits having epigastric pain, may represent an iatrotropic case of pneumonia and a non-iatrotropic case of duodenal ulcer.

Non-iatrotropic cases may also be diagnosed during a routine medical 'check-up' or at mass screening for some disease, e.g. tuberculosis.

Iatrotropic symptoms are of particular importance as they usually represent that problem which the doctor, in the eyes of the patient, has to solve, and they ought to be given particular prominence, especially in hospital notes. Nowadays it is not rare in hospital practice that the investigations bring some unexpected findings to light which then lead to further investigations along a side-track. After a while the whole staff is interested in, say, the immunoglobulin pattern, and nobody remembers why the patient was admitted. Only on the day on which the patient is discharged will she say, 'But you have not done anything about my backache!'. The advanced specialization of hospital departments invites the occurrence of such incidents. If a patient presents a complex clinical picture, the subspecialized physician may more or less consciously emphasize those clinical data which pertain to her own field of interest, whereas the remaining data are treated more lightly.

A symptom may become iatrotropic for a number of reasons. One patient with abdominal pain may ask to see her doctor because she is afraid of cancer while somebody else with the same complaint may be worried about losing her job, and in other cases the reason for the visit is not directly related to the symptoms. The patient may have felt a lump in the breast which she dares not mention, but hopes that the doctor will find, or she may have problems at work or at home which made her contact her doctor on the pretext of some mild symptom, which under normal circumstances she would have accepted. Personal problems of any kind may lower the *threshold of iatrotropy*.

The second type of data are recorded routinely from all patients. In hospital practice they comprise answers to standard questions during history taking, the results of the ordinary physical examination and some simple paraclinical tests, such as haemoglobin determination and urine analysis. The routine history taking and examination are to a large extent determined by tradition and from time to time they must be brought up to date. It is no longer necessary in some countries to ask all elderly patients whether they have had rheumatic fever or diphtheria, but it is important to ask detailed questions about their social network and their living conditions. Perhaps the dangers of working with organic solvents would have been detected earlier if the notes contained more routine information about occupation and working conditions.

The third type of data are those collected during the diagnostic process, which begins as soon as the iatrotropic symptoms have been recorded. The clinician will, for instance, ask a jaundiced patient if she has had abdominal pain and or if she has travelled abroad, and such specific questions may well

be likened to diagnostic tests, which aim at confirming or excluding different diagnostic possibilities. In other words, the process passes through the loop in the flow chart (Fig. 1.1) many times already during the taking of the history.

Scales of measurement

Clinical data have many characteristics that are not peculiar to medicine, and I shall now consider the classification of data in general terms, using nonmedical examples. There are three levels of measurement scales:[23] the nominal scale, the ordinal scale and the interval scale.

At a music lesson, a recording of a short passage from an orchestral work is played and the children are asked to identify the solo instrument at a particular moment. Each child is asked to indicate her reply on a list of all the instruments of the orchestra. Such a list, which is used to classify qualitative observations in a series of named categories, is called a *nominal scale*, which, from a formal point of view, must fulfil three conditions. Firstly, each category or class must be well defined, and we shall see later that this requirement in particular causes great difficulties in clinical medicine. Secondly, the classification must be exclusive, meaning that no observation must belong to more than one category, and thirdly the classification must be exhaustive, which means that all observations to be classified must belong to one of the categories. It is often possible to reduce a nominal scale to fewer classes. In the present example one might have used four classes (strings, woodwind, brass and percussion) or even two classes ('stringed instruments' and 'other instruments'). A scale consisting of only two classes is called a *binary scale*.

Observations may be more refined. In 1806 the British admiral Sir Francis Beaufort constructed a scale for the measurement of wind force. The scale, which consists of 13 classes, is shown in Table 1.1. This is an example of an *ordinal scale*, and although it must have formed the basis for important decisions in the course of history, it has its limitations. We may take it for granted that a Force 10 is greater than, say, a Force 8, and that a Force 3 is greater than a Force 1, but we must not presuppose that the difference between Force 10 and Force 8 is the same as the difference between Force 3 and Force 1. That was revealed (as shown in Table 1.1) when it became possible to measure the wind force in m/s. To measure on an ordinal scale is like using an unevenly stretched elastic tape measure, and therefore it makes little sense calculating the 'mean windforce'. An ordinal scale may also be reduced to a binary scale, which would be the case if we only distinguished between 'windy weather' and 'calm weather'.

Table 1.1 Beaufort scale of wind force. Specifications for use on land. The numbers in brackets indicate the wind force in m/s.

0. *Calm.* Smoke rises vertically (0–0.2).
1. *Light air.* Direction of wind shown by smoke drift, but not by wind wanes (0.3–1.5).
2. *Light breeze.* Wind felt on face; leaves rustle; ordinary wane moved by wind (1.6–3.3).
3. *Gentle breeze.* Leaves and small twists in constant motion; wind extends light flag (3.4–5.4).
4. *Moderate breeze.* Raises dust and loose paper; small branches are moved (5.5–7.9).
5. *Fresh breeze.* Small trees in leaf begin to sway; crested wavelets form on inland waters (8.0–10.7).
6. *Strong breeze.* Large branches in motion; whistling heard in telegraph wires; umbrellas used with difficulty (10.8–13.8).
7. *Moderate gale.* Whole trees in motion; inconvenience felt in walking against wind (13.9–17.1).
8. *Fresh gale.* Breaks twigs off trees; generally impedes progress (17.2–20.7).
9. *Strong gale.* Slight structural damage occurs (chimney pots and slates removed) (20.8–24.4).
10. *Whole gale.* Seldom experienced inland; trees uprooted; considerable structural damage occurs (24.5–28.4).
11. *Storm.* Very rarely experienced; accompanied by widespread damage (28.5–32.6).
12. *Hurricane.* Disastrous results (>32.6).

The *ranking* of data also provides measurements on an ordinal scale. School children may, for instance, be ranked from the top to the bottom of the form according to their proficiency, but once again one cannot assume that the difference between the proficiency of, say, numbers 5 and 6, is the same as that between numbers 6 and 7.

The *interval scale* represents the highest level of measurement. Weighing an object on a balance or the wind force in m/s may serve as examples. In these cases the scale is continuous and the interval, which is constant along the scale, is chosen to suit the precision of the measuring instrument. It may be 1 g for an ordinary letter balance and much less for an analytical balance. Interval scales may also be discontinuous (discrete). The number of patients in a ward may be 27 or 28, but not 27.5.

Usually, an interval scale is also a *ratio scale*. For instance, an object weighing 28 g is twice as heavy as an object weighing 14 g. Only measurements on a scale with an arbitrary zero point form an exception. Water having a temperature of 28 °C is not twice as warm as water having a temperature of 14 °C.

Measurements on an interval scale may be reduced to an ordinal or a binary scale. We may, for instance, measure objects in grams, but for some purposes we may confine ourselves to distinguishing between very heavy, heavy and light