1.6 Clinical decision- making 26 Timothy E.A. Peto

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ESSENTIALS Clinicians make decisions at every stage of the patient pathway. In routine practice complex decisions are often made rapidly using ‘intuition’ or common sense, but this can lead to suboptimal man- agement plans. Clinical decision analysis is a way of formalizing the logical process behind decision-making, and when combined with evidence from medical research is described as the practice of evidence-based medicine. Clinical decision analysis consists of five discrete steps: (1) con- structing the ‘decision tree’—structuring the problem so that alter- native courses are defined; (2) estimating the probability of each possible outcome; (3) assigning a relative value or utility to each potential outcome; (4) calculating the best alternative using the decision tree model; (5) performing a set of sensitivity analyses, which provides insight into which values are the most critical to a decision. In practice, most clinicians do not have the time, intellectual en- ergy, or training to perform a formal clinical decision analysis and they tend to use short cuts and go for the ‘safe’ decision which is suitable for the ‘average patient’ and often in keeping with guidelines for local practice. However, clinicians who follow the logical process of clinical decision analysis find it easier to live with the uncertainty of an inexact science and subjective wishes of the patient. Good understanding of the decision tree and use of sensitivity analyses allow clear documentation of the reasoning behind each decision that is made. This approach provides the tools to help make the right decision for each patient, free from the artificial constraints of clinical guidelines. Introduction Clinical decision-making is an essential skill required to practice medicine, yet the process of clinical decision-making is often rushed. Complex decisions can be made rapidly using ‘intuition’ or common sense, based on a combination of information derived from theor- etical knowledge and personal experience. This intuitive approach alone, although it saves the busy clinician valuable time, may lead to suboptimal treatment plans. The discipline of ‘clinical decision analysis’ has, therefore, evolved to formalize the logical process be- hind decision-making. When combined with evidence from med- ical research to make decisions, this is described as the practice of ‘evidence-based medicine’. Clinical decision analysis is used by national clinical and public health services. In practice, this mean that clinical decision aids are widely available as guidelines, both national and local. Government guidelines often also include cost-benefit or economic analysis to decide which treatments to fund. However, as every patient is dif- ferent, it is helpful to understand how guidelines should be adapted to tailor treatment for individual patient needs. Ideally the patient should also play an active role in decision-making. This is called ‘shared decision-making’. In this chapter we set out the principles of clinical decision-making and give guidance as to how it can be applied by the busy clinician in routine practice. Clinical context Clinicians make decisions at every stage of the patient pathway. Typical decisions made for a patient attending a hospital emergency department are summarized in Table 1.6.1. 1.6 Clinical decision-making Timothy E.A. Peto and Philippa Peto Table 1.6.1 Typical decisions made for a patient attending a hospital emergency department Decision node Choice Decision to admit to hospital Admit or send home? Medical Investigations Which tests? Diagnosis Which diagnosis? Treatment plan Which treatment? Resuscitation plan For cardio-pulmonary resuscitation? Management of incidental findings To investigate further or not? Discharge plan When and where to? Discussion with relatives How much do you tell them? These points are called ‘decision nodes’ in decision theory. The most critical decisions are made at points on the pathway where some of the consequences may be irreversible.

1.6 Clinical decision-making 27 Analysis Clinical decision analysis consists of five discrete steps which can be performed at each decision node (see Fig. 1.6.1): 1. Constructing the ‘decision tree’; structuring the problem so that alternative courses are defined The different possible management choices need to be defined and the different possible outcomes, good and bad, need to be listed for each. In decision analysis terminology, this is referred to as con- structing a ‘decision tree’. To busy clinicians, this may seem trivial but is critical because the omission of important treatment options or outcomes may lead to a suboptimal management plan. For instance, for any clinical treatment decision, failure to consider a ‘no intervention’ option could result in an unnecessary poor out- come for the patient. 2. Estimating the probability of each possible outcome For each possible outcome, the probability of that outcome needs to be estimated. While past experience and the expert opinion of colleagues may be an attractive source of information, a system- atic review of the evidence produces a more unbiased estimate of probabilities. Where little evidence is available, a range of plausible probabilities using expert opinion should be made which will allow a sensitivity analysis to be made for the final decision. These might be available in published guidelines and the uncertainty can be cap- tured by the level of evidence quoted. 3. Assigning a relative value or utility to each potential outcome The most challenging, and more subjective step, is to assign utility to each outcome. The purpose is an attempt to compare the rela- tive importance of different outcomes. A variety of different metrics have been proposed including quality adjusted life years, disability adjusted life years or monetary value of health cost. All such metrics will provide a numeric value for each outcome that are then easily compared to show the optimum outcome. For example, death is usually awarded value 0, disease free life awarded 1, and morbidity such as side effects from chemotherapy would be awarded a value between 0 to 1, depending on perceived severity. To create an individualized decision analysis requires the patient to express their personal views about different outcomes. This is ‘shared decision-making’. For guidelines which have been con- structed nationally, or for cost-effective analyses, groups of patient representatives are asked to provide the patient’s perspective. One problem with this approach is that the relative utility as- signed by doctors may be different from that assigned by a par- ticular patient. The patient's views may also be in conflict with their own family. In addition, personal views may change with time as the understanding of each outcome changes and anxieties are allayed or fuelled. The decision to discuss every outcome with a patient is in itself a decision. Judgement is required to decide whether the psychological distress that may be caused by such a discussion is justified by the benefit of assigning a personalized utility to each outcome. For instance, the discussion of resuscitation with a relatively well patient for whom cardiorespiratory arrest is an unlikely event might in itself cause unnecessary distress. Table 1.6.2 shows examples of common unfavourable outcomes. These outcomes may be differently valued by doctor and patient, re- sulting in differing assumptions of the relative utility of each. 4. Calculating the best alternative using the decision tree model For each management plan chosen, the probability and utilities chosen are used to produce a combined numerical value. The values can then be easily compared to determine the best possible outcome for that pa- tient. In some cases, the utilities assigned by the medical practitioner may be so different from those chosen by the patient that the practi- tioner is unwilling to proceed with the identified management plan. Sometimes a change in clinician might be required before a decision can be made which will be acceptable to the patient (see Fig 1.6.1a). 5. Performing a set of sensitivity analyses A sensitivity analysis explores how outcomes vary depending on making changes to the probability or utility values. This is par- ticularly helpful when there is uncertainty over the probabilities of different outcomes or when there are differing views on the util- ities, such as where the patient is themselves unsure as to their own views. Sensitivity analysis provides insight into which values are the most critical to a decision. Sometimes it is found that a particular decision is robust even when there are major differences of opinion on a particular probability or utility (see Fig 1.6.1b). For example, the precise probability of bleeding makes little difference to the Table 1.6.2 Examples of common unfavourable outcomes Adverse outcome to patient Examples Death Significant adverse events Stroke Amputation Unnecessary surgical intervention End stage renal failure Seizure ITU admission Readmission to hospital Prolonged hospital stay Psychological distress Fear of possible future morbidity Hypochondria Unnecessary frequent emergency department attendance Drug side effects Bleeding Anaphylaxis Immunosuppression Public health implications Spread of TB Road accident Pregnancy outcome Fetal or maternal death Fetal or maternal morbidity Social consequences Loss of job Loss of driving licence Breakdown of trust within a family Adverse outcome to doctor Guilt Complaint from angry patient Litigation or fear of litigation Loss of professional reputation Loss or fear loss of licence to practice

 decision to anticoagulate a patient following a life-threatening pul- monary embolus. Decision-making in clinical practice In practice, clinicians do not have the time, intellectual energy, or training to perform a formal clinical decision analysis and they tend to use short cuts and go for the 'safe' decision, which is suitable for the 'average patient' and often in keeping with guidelines for local practice. Clinical decisions are often made heuristically, using 'intuition' which is a combination of pattern recognition and personal ex- perience, to come to a rapid conclusion regarding the most likely best outcome. Unfortunately, intution is not reliable and can lead to suboptimal outcomes. Utility Expected value (Probability x utility for each outcome) Overall value for
each decision 1 0.5 x 0.8 x 1 = 0.4 0.98 0.5 x 0.2 x 0.98 = 0.098 0 0.5 x 0.1 x 0 = 0 0.6 0.5 x 0.8 x 0.6 = 0.24 0.7 0.5 x 0.1 x 0.7 = 0.035 0.7 BKA BKA AKA Death Recovery with limp Full recovery Foot saved (a) 0.5 0.5 0.8 0.2 0.1 0.1 0.8 Infection not controlled Antibiotics Infected fractured ankle 0.7 Decision node: amputate or give antibiotics BKA – Below knee amputation AKA – Above

knee amputation Total for ‘give antibiotics’ 0.773 Total for ‘amputate’ 0.7 Immediate amputation better (b) Probability of antibiotics saving leg Overall value of utilities 0 0.2 0.4 0.6 0.8 1 BKA antibiotics 1 0.9 0.8 0.7 0.6 0.5 Antibiotics better Sensitivity analysis Fig. 1.6.1 (a) Decision tree showing the possible outcomes of a case of a seriously infected compound fracture of the ankle following a decision to either amputate immediately or give antibiotics with the hope of saving the leg but with the risk of mortality from infection. Blue square represents the decision node; green circles show different possible outcomes following the decision with the assigned probability of the outcome documented on the branches. The triangles represent the final outcomes with the utility shown alongside. The calculations showing the expected values for each outcome and the overall values for each decision is also shown. (b) Sensitivity analysis showing how changes in the assigned probability of antibiotics saving the leg affects the overall values of amputation versus antibiotics. The original calculation estimated that antibiotics would prevent amputation in 50% of cases. The red line shows that amputation is the preferred option only if antibiotics prevents fewer than 33% of cases. The sensitivity analysis can also be altered to reflect changes in utility awarded to each outcome which could also impact on the decision. Adapted from Lee A, et al. for the EBM Teaching Scripts Working Group (2009). Tips for Teachers of Evidence-based Medicine: Making Sense of Decision Analysis Using a Decision Tree. J Gen Intern Med, 24, 642–8.

1.6 Clinical decision-making 29 Most clinicians informally use the ‘decision tree’ but often without being aware that they are doing so, and can easily be swayed by per- sonal bias which may distort their perception of probabilities. For example, a physician who has recently seen a patient die from an undiagnosed subarachnoid haemorrhage is much more likely to perform a diagnostic lumbar puncture even when the clinical indi- cation is negligible. To introduce a more systematic approach, ensuring use of best available evidence, guidelines are widely available. National guide- lines summarize best available evidence to clarify the probabilities for common clinical outcomes. Local guidelines are then created to ensure that local clinicians are also aware of the subjective utility value for each outcome to the department. In order to make the best possible decision for an individual pa- tient, the clinician needs to be aware that the utility to the depart- ment may be at odds with the utility to the patient. This is where shared decision-making is critical. Shared decision-making, where the doctor and patient are both involved in making the decision, is well documented to lead to the best patient outcomes and greater patient satisfaction. There are two main reasons why the departmental guideline might not be followed: 1. Objective factors which alter the assumed probabilities for each outcome: a. Diagnostic uncertainty b. Specific physical factors for a particular patient c. No relevant guideline or limited evidence base 2. Subjective factors altering the utility allocated for each outcome. a. Patient would like to be supported not to follow guideline for personal reason Clearly, if the physician has a personal reason to fear a particular outcome, this can affect their own assignment of utility, but this must be recognized as subjective and should not be allowed to influ- ence the final clinical decision. Case studies Comparison of two possible treatments A 60-year-old man presents with a badly infected compound fracture of the left ankle. The infection is not only threatening to destroy the ankle itself, but is spreading proximally and the septic complications are potentially life-threatening. The options are either to perform a below-knee amputation immediately or to perform surgical debride- ment followed by antibiotic treatment to save the leg. Although the second option offers a chance of complete recovery, it is associated with a substantial risk of infection that spreads leading to below-knee amputation or possible an above-knee amputation, or even death. Even if conservative management with debridement plus antibiotics is successful, there is still a chance of minor longterm disability. A decision tree is drawn and, after discussion with the patient, util- ities are assigned to each of the possible outcomes (see Fig 1.6.1a). A sensitivity analysis is performed (see Fig 1.6.1b) which shows that immediate amputation is only indicated if the chance of antibiotics working is less than 33%. After discussion with colleagues it was de- cided that antibiotics had a better than 33% chance of working and therefore the patient was treated conservatively. (Case study based from A. Lee et al. for the EBM Teaching Scripts Working Group (2009). Tips for Teachers of Evidence-based Medicine: Making Sense of Decision Analysis Using a Decision Tree. J Gen Intern Med, 24(5), 642–8.) Variations in utility a. A 70-year-old man, living alone since the death of his wife 6 months ago, is admitted at 7 pm with acute onset of haema- temesis and melaena and blood pressure 160/100, pulse 140 bpm, and haemoglobin 82. He is resuscitated with IV fluids and given 4 units of blood after which his haemoglobin is 102 and his pulse rate settles to 88 bpm. ECG showed sinus tachycardia and chest X-ray and all other blood tests were normal including clotting. He is usually well with no past medical history but has recently taken nonsteroidal anti-inflammatory medication for knee pain. He regularly exercises by walking his dog. The following morning, he is haemo-dynamically stable but the medical team plan for him to stay in hospital for a repeat blood test and endoscopy to reduce the risk of further bleeding. The patient becomes very agitated and states that he feels perfectly all right now and needs to go home immedi- ately. The consultant's view is that the patient is at high risk for fur- ther bleeding with possible life-threatening complications and local hospital policy is that severe gastrointestinal bleeds require inpatient endoscopy with at least 24 h observation as an inpatient in order to reduce the hospital readmission rates. On discussion, the consultant establishes that the patient's main concern is to get home to look after his elderly dog who requires daily medication with regular painkillers and will be suffering without his owner. Finally, a compromise is reached as the patient agrees to come in to hospital daily for review and blood tests with clear understanding of the risks to his own health if he bleeds again while alone at home. The patient did not want to die but was prepared to take a mod- erate risk in order to look after his dog. The main risks and the patient's views were clearly recorded in the notes to explain the ra- tionale behind the decision. This case illustrates the different utility accorded by each party to a particular outcome, in this case rapid discharge home. Clear com- munication can help make a decision that both doctor and patient are happy with. b. A 60-year-old woman is referred with a new diagnosis of acute myeloid leukaemia. She has successfully gone into remission fol- lowing chemotherapy and is told that the median life expectancy is 5 years. She is given the option to have a bone marrow transplant from her sister which will give her a 50% chance of total cure but a 15% chance of dying immediately as a consequence of the trans- plant. Her daughter is due to give birth next month. The doctors advise immediate transplantation, with enforced 6-week hospital stay to maximize her overall chance of survival. However, the patient values short-term life as she wants to see her new grandchild and therefore decides not to go ahead with the transplant immediately but requests a six month delay, despite the risk that the leukaemia will progress. Variation in probability of clinical events A 32-year-old woman presents with rapidly deteriorating kidney function. Her estimated glomerular filtration rate is now down

 to 14, from baseline more than 60, one month before. She has a history of systemic lupus erythematosus (SLE) for which she takes regular painkillers and low-level immunosuppression. The differential diagnosis includes analgesic nephropathy or lupus nephritis requiring immediate immunosuppression. Standard procedure would be to stop the nonsteroidal anti-inflammatory drugs (NSAIDs) and perform a renal biopsy to confirm the diagnosis.

However, the patient announces that she is a lifelong Jehovah's witness and would decline blood transfusion under any circumstances. The possible adverse events following a kidney biopsy include bleeding requiring transfusion and possible death. In this case, because the patient is not willing to have the routine treatment for bleeding, the probability of more serious consequences of bleeding, such as death, is much higher. It is essential, therefore, to perform a new decision analysis reflecting the uncertainties of the diagnosis and the increased risks of performing the renal biopsy, in order to make a rational management plan. Conclusion Clinicians who follow the logical process of clinical decision analysis find it easier to live with the uncertainty of an inexact science and subjective wishes of the patient. Good understanding of the decision tree and use of sensitivity analyses allow clear documentation of the reasoning behind each decision. This approach provides the tools to help make the right decision for each patient, free from the artificial constraints of clinical guidelines. FURTHER READING Barry MJ, Edgman-Levitan S (2012). Shared decision making— pinnacle of patient-centered care. N Engl J Med, 366, 780–1. Charles C, Whelan T, Gafni A (1999). What do we mean by partner- ship in making decisions about treatment? BMJ, 319, 780–2. Cooper N, Frain J (eds) (2016). ABC of clinical reasoning. Wiley Blackwell BMJ Books, Oxford. Croskerry P (2013). From mindless to mindful practice—cognitive bias and clinical decision making. N Engl J Med, 368, 2445–8. Elstein AS, Schwartz A (2002). Clinical problem solving and diag- nostic decision making: selective review of the cognitive literature. BMJ, 324, 729–32. Elwyn G, et al. (1999). Towards a feasible model for shared decision making: focus group study with general practice registrars. BMJ, 319, 753–6. Rodriguez-Osorio CA, Dominguez-Cherit G (2008). Medical decision making: paternalism versus patient-centered (autonomous) care. Curr Opin Crit Care, 14, 708–13. Sondhi M, et al. (2005). DEALE-ing with lung cancer and heart failure. Med Decis Making, 25, 82–94. Weinstein MC, Feinberg HV (1980). Clinical decision analysis. Saunders, Philadelphia, PA.

SECTION 2 Background to medicine Section editors: John D. Firth, Christopher P. Conlon, and Timothy M. Cox
