The Thinker's Guide
to

Clinical Reasoning

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Based on
Critical Thinking Concepts and Tools

The Foundation for Critical Thinking

Introduction
Why a Thinker's Guide to Clinical Reasoning?

Clinical reasoning can be defined as thinking through the various aspects of patient care to arrive at a reasonable decision regarding the prevention, diagnosis, or treatment of a clinical problem in a specific patient. Patient care includes history taking, conducting a physical exam, ordering laboratory tests and diagnostic procedures, designing safe and effective treatment regimens or preventive strategies, and providing patient education and counseling.

Obviously, the clinician should be well grounded in biomedical and clinical sciences and skillful at gathering clinical data from a patient before engaging in the process of clinical reasoning. This guide does not address the knowledge and skills required to competently gather and interpret clinical data. Rather, the guide is intended to help clinicians take the next step, which is determining the best course of action to take based on what is known or what can reasonably be hypothesized from clinical data. So, it isn't enough to have a strong background in the biomedical sciences or to possess excellent clinical knowledge, nor to know how to conduct a history and physical exam on a patient, or even to know how to formulate a differential diagnosis given the signs, symptoms, and test results of a patient. In addition to all of this, there is still a need to think critically about all the important information pertaining to a particular case and to formulate or synthesize a rational plan of action. In short, clinical reasoning requires critical thinking skills, abilities and traits which are often not taught in schools and colleges for the health professions.

Skilled clinicians systematically analyze their thinking by targeting the elements of clinical reasoning and evaluate their thinking through application of intellectual standards to those elements. These clinicians also develop and routinely exhibit intellectual traits or dispositions of mind. When these foundations of critical thinking – the elements of reasoning, intellectual standards, and intellectual traits – are made explicit and deeply understood, the clinician has explicit intellectual tools useful for

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examining, assessing and improving thought. This guide introduces the clinician to these foundations and offers examples of their application to the field.

It is important to note that there are numerous problems in clinical practice that go beyond the scope of this guide, including:

1. the mistakes in medical reasoning which lead to death or other adverse consequences.
2. the overspecialization within medical fields that often leads to fragmented care and lack of integration across specialities.
3. the overreliance of traditional medicine on prescription medications in dealing with medical problems rather than alternative potential therapies.
4. the general failure within traditional medicine to acknowledge and appropriately use effective alternative medical approaches (which is connected with the failure to integrate the best ideas within traditional medicine with the best ideas within alternative medicine).
5. the failure to emphasize prevention over "cure."
6. the medical decisions being determined primarily by the vested interests of clinicians.
7. the influence pharmaceutical companies have on prescribing habits.

This guide focuses on a framework for critical thinking relevant to all domains of human thought and is specifically focused on clinical reasoning. The suggestions and conclusions herein are consistent with the suggestions and conclusions found in the works of prominent thinkers in the clinical fields, including Joy Higgs, Mark Jones, Jerome Kassirer, John Wong, Richard Kopelman, Daniel Pesut, Joann Herman, Kathryn Montgo, Eileen Gambrill, Jerome Groopman and Milos Jenicek.

Though this guide includes some significant examples within the field of medicine, given its limited nature, it does not include the many field-specific contributions to clinical reasoning from medicine, nursing, pharmacy, dentistry, veterinary medicine, and other health related fields. Moreover, we are not attempting to provide specific procedures for clinical reasoning, but only broad principles that must be contextualized by the user. For exemplification purposes, we have focused primarily on diagnosis and treatment. The guide is intended to detail and exemplify clinical reasoning as a mode of thought. Thus the principles illuminated in it should be integrated within the context of clinical reasoning – for the purpose of both teaching and practice at all levels. Finally, due to its nature, we have not attempted to link the principles in this guide to current or classical philosophical orientations within general argumentation, reasoning and decision making.

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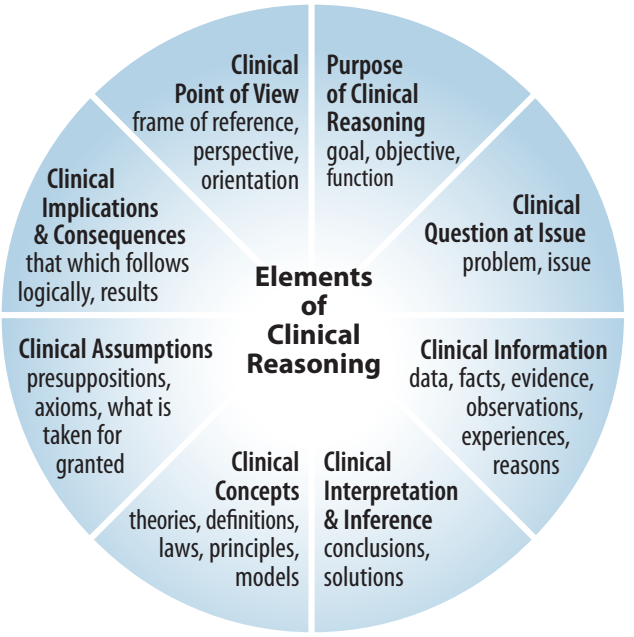
The Elements of Clinical Reasoning

The elements of clinical reasoning that appear in the diagram below provide the basis for analyzing the structures present in all thinking. *Whenever we think, we think for a purpose within a point of view based on assumptions leading to implications and consequences. We use concepts, ideas, and theories to interpret data, facts, and experiences in order to answer questions, solve problems, and resolve issues.*

Each of these structures has implications for the others. If you change your purpose, for example, you change your questions and problems. You are then forced to seek new information and data. And this changes the implications and consequences of your conclusions and decisions.



Used With Sensitivity to Universal Intellectual Standards

Clarity → Accuracy → Depth → Breadth → Significance
Precision ↓
Relevance Fairness

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A Checklist for Clinical Reasoning

1) All clinical reasoning has a PURPOSE.

- Can you state your purpose clearly?
- What is the objective of your clinical reasoning?
- Does your reasoning focus throughout on your clinical goal?
- Is your clinical goal realistic?

2) All clinical reasoning is an attempt to figure something out, to settle some QUESTION, to solve some PROBLEM.

- What clinical question are you trying to answer?
- Are there other ways to think about the question?
- Can you divide the question into sub-questions?
- Is this a question that has one right answer or can there be more than one reasonable answer?
- Does this question require clinical judgment rather than facts alone?

3) All clinical reasoning is based on ASSUMPTIONS.

- What assumptions are you making? Are they justified?
- How are your assumptions shaping your point of view?
- Which of your assumptions might reasonably be questioned?

4) All clinical reasoning is done from some POINT OF VIEW.

- What is your point of view? What insights is it based on? What are its weaknesses?
- What other points of view should be considered in reasoning through this problem? What are the strengths and weaknesses of these viewpoints? Are you fairmindedly considering the insights behind these viewpoints?

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A Checklist for Clinical Reasoning (cont.)

5) All clinical reasoning is based on DATA, INFORMATION, and EVIDENCE.

- To what extent is your reasoning supported by relevant data?
- Do the data suggest explanations that differ from those you have given?
- How clear, accurate, and relevant are the data to the clinical question at issue?
- Have you gathered data sufficient to reach a valid conclusion?

6) All clinical reasoning is expressed through, and shaped by, CONCEPTS and THEORIES.

- What key concepts and theories are guiding your clinical reasoning?
- What alternative explanations might be possible, given these concepts and theories?
- Are you clear and precise in using clinical concepts and theories in your reasoning?
- Are you distorting ideas to fit your agenda?

7) All clinical reasoning contains INFERENCES or INTERPRETATIONS by which we draw CONCLUSIONS and give meaning to data.

- To what extent do the data support your clinical conclusions?
- Are your inferences consistent with each other?
- Are there other reasonable inferences that should be considered?

8) All clinical reasoning leads somewhere, that is, has IMPLICATIONS and CONSEQUENCES.

- What implications and consequences follow from your reasoning?
- If we accept your line of reasoning, what implications or consequences are likely?
- What other implications or consequences are possible or probable?

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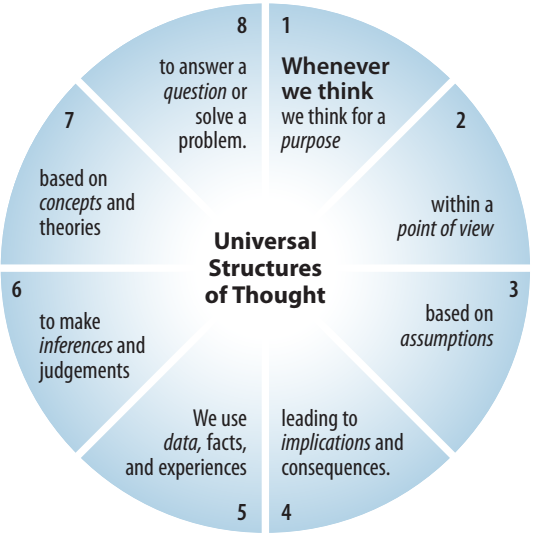
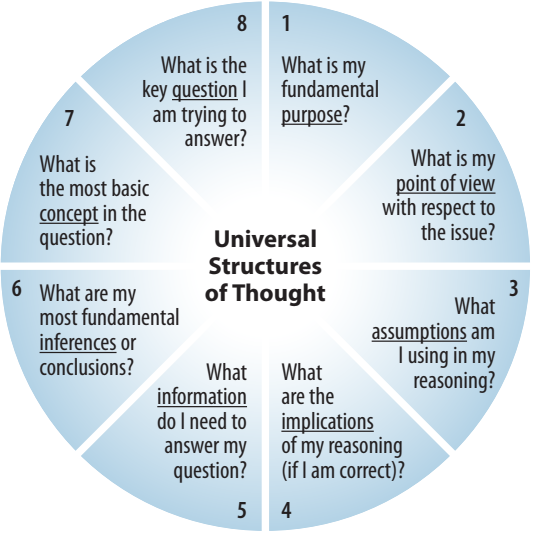
To Analyze Thinking, Identify and Question its Elemental Structures





Note: When we understand the structures of thought, we ask important questions implied by these structures.

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Analyzing the Logic of a Clinical Case Through the Elements of Reasoning

A 53 year old man complains of severe pain in his left big toe for the past 2 days. The patient has a past medical history of two episodes of acute gouty arthritis in the past 3 months, hypertension for 10 years, and dyslipidemia. He is currently receiving a thiazide diuretic for his high blood pressure, atrovastatin for his high cholesterol, and one aspirin tablet daily to prevent heart attacks. Laboratory studies revealed a serum urate concentration of 10mg/dL and a very high urinary urate concentration. The patient's blood pressure is 130/80 mmHg. A positive diagnosis of acute gouty arthritis was confirmed by taking a sample of the patient's synovial fluid taken from the affected joint and examining it under a polarizing microscope.

Purpose:

To treat the acute attack and to prevent recurrent attacks.

Questions

1. What is the most effective way to treat this patient's acute attack?
2. What is the most effective way to prevent recurrent attacks in this patient?
3. What adjustments, if any, need to be made to this patient's other medications?

Assumptions

1. Colchicine will not work in this case.
2. Baby aspirin will not significantly increase serum urate concentrations.
3. Traditional medicine has the best answers in a case like this, so we don't need to consider alternative therapies.

Points of View

1. A conservative approach would be to treat the acute attack and discontinue the thiazide diuretic because it increases serum uric acid concentration and therefore the propensity for recurrent attacks.
2. A more aggressive approach would be to initiate preventive therapy irrespective of the decision to continue or discontinue the diuretic.

Information

1. Either colchicine or a non-steroidal anti-inflammatory agent can be used to treat acute attacks.
2. Colchicine's effectiveness diminishes 48 hours after onset of pain.
3. Either probenecid or allopurinol can be used to prevent recurrent attacks.
4. Probencid increases urinary uric acid excretion.
5. A further increase in urinary uric acid could cause the development of kidney stones.

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6. Diuretics and adult doses of aspirin increase serum urate concentrations.
7. Other medicines that do not increase serum urate concentration can be used to control the patient's blood pressure.

Concepts

1. Gout
   - acute gouty arthritis
   - recurrent gouty arthritis
   - nephrolithiasis
2. Hypertension
   - traditional approaches
   - alternative approaches
3. Heart Attack Prevention
   - low dose aspirin
   - cholesterol management

Interpretation/Inference

1. The clinical data indicate a positive diagnosis of acute gouty arthritis.
2. Since the patient has a relatively high risk of recurrent events, preventive therapy with allopurinol should be initiated.
3. The patient's antihypertensive therapy should be switched from thiazide to another agent that will not increase serum urate concentration.
4. Baby aspirin should be continued since it is unlikely that a small dose of aspirin will increase serum urate substantially.

Implications and Consequences

1. Failure to treat the acute attack with an agent that will be effective even after 24 hours of the onset of pain will result in the unnecessary continuation of severe pain.
2. By not initiating preventive therapy, there is a high likelihood that the patient will experience repeated attacks given his history and clinical condition.
3. If probencid is used to prevent recurrent attacks, the patient will be placed at a high risk of developing kidney stones because probenecid increases uric acid excretion.

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Universal Intellectual Standards Essential to Sound Clinical Reasoning

Universal intellectual standards are standards which must be applied to thinking whenever one is evaluating the quality of reasoning about a problem, issue, or situation. To think critically one must have a command of these standards. While there are a number of universal standards, we focus here on some of the most significant:

Clarity

Could you elaborate further on that point? Could you express that point in another way? Could you give me an illustration? Could you give me an example?

Clarity is a gateway standard. If a statement is unclear, we cannot determine whether it is accurate or relevant. In fact, we cannot tell anything about it (except that it is unclear) because we don't yet know what it is saying.

Accuracy

Is that really true? How could we check that? How could we find out if that is true? What evidence is there to support the validity of your clinical thinking?

A statement can be clear but not accurate, as in "Most creatures with a spine weigh more than 300 pounds."

Precision

Could you give me more details? Could you be more specific?

A statement can be both clear and accurate, but not precise, as in "The solution in the beaker is hot." (We don't know how hot it is.)

Relevance

How is that connected to the question? How does that bear on the issue?

A statement can be clear, accurate, and precise, but not relevant to the question at issue. If a person who believed in astrology defended his/her view by saying "Many intelligent people believe in astrology," their defense would be clear, accurate, and sufficiently precise, but irrelevant to clinical reasoning.

Depth

How does your answer address the complexities in the question? How are you taking into account the problems in the question? Are you dealing with the most significant factors?

A statement can be clear, accurate, precise, and relevant, but superficial (that is, lacks depth). For example, the statement "Just Say No", which is often used to

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discourage children and teens from using drugs, is clear, accurate, precise, and relevant. Nevertheless, it lacks depth because it treats an extremely complex issue, the pervasive problem of drug use among young people, superficially. It fails to deal with the complexities of the issue.

Breadth

Do we need to consider another point of view? Is there another way to look at this question? What would this look like from the point of view of a conflicting theory, hypothesis or conceptual scheme?

A line of reasoning may be clear, accurate, precise, relevant and deep, but lack breadth (as in a well-reasoned argument from either of two conflicting theories which ignores insights into the conflicting theory).

Logic

Does this really make sense? Is this consistent with what we know about this issue or problem?

When we think, we bring a variety of thoughts together into some order. When the combination of thoughts is mutually supporting and makes sense in combination, the thinking is "logical." When the combination is not mutually supporting, is contradictory in some sense, or does not "make sense," the combination is "not logical." In clinical reasoning, new conceptual schemes become working hypotheses when we deduce from them logical consequences which can be tested by experiment. If many of such consequences are shown to be true, the theory (hypothesis) which implied them may itself be accepted as true.

Significance

Is this the most important problem to consider? Is this the central idea to focus on? Which of these facts are most important?

When dealing with a complex issue it is essential to consider relevant variables. But some are more significant than others. The most significant variables should be considered first. Secondary relevant variables come next in order of importance.

Fairness

Do I have a vested interest in this issue? Am I representing the viewpoints of others in a way that is fair and balanced?

We naturally think from our own perspective, from a point of view which tends to privilege our position. Fairness implies the treating of all relevant viewpoints alike without reference to one's own feelings or interests. Because we tend to be biased in favor of our own viewpoint, it is important to keep the standard of fairness at the forefront of our thinking. This is especially important when the situation may call on us to see things we don't want to see, or give something up that we want to hold onto.

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Clarity	Could you elaborate further? Could you give me an example? Could you illustrate what you mean?
Accuracy	How could we check on that? How could we find out if that is true? How could we verify or test that?
Precision	Could you be more specific? Could you give me more details? Could you be more exact?
Relevance	How does that relate to the problem? How does that bear on the question? How does that help us with the issue?
Depth	What factors make this a difficult problem? What are some of the complexities of this question? What are some of the difficulties we need to deal with?
Breadth	Do we need to look at this from another perspective? Do we need to consider another point of view? Do we need to look at this in other ways?
Logic	Does all this make sense together? Are we taking a reasonable approach to the problem? Does what you say follow from the evidence?
Significance	Is this the most important problem to consider? Is this the central idea to focus on? Which of these facts are most important?
Fairness	Do I have any vested interest in this issue? Am I sympathetically representing the viewpoints of others?

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The Application of Clinical Reasoning to Patient Care

History Taking

A careful history of a patient's presenting signs and symptoms, current medical conditions, previous surgeries, illnesses or medical problems, use of medications, vitamins, and supplements, lifestyle behaviors, and perceptions of health and disease is rarely achieved skillfully and comprehensively. One explanation for this is that clinicians feel rushed to see as many patients as they can, and so they conduct a cursory or abbreviated history. In some clinical settings, a rapid, highly focused history is appropriate, as is in the case when a patient presents to the emergency room complaining of severe chest pain. Another explanation, however, is that history taking is not always guided by careful, critical thinking. As each piece of information is gathered during history taking, the clinician should assess the information by asking the following types of questions:

1. Is the patient being *clear* and *accurate* in his or her description of what is or has taken place? Or, do I need to ask more questions to *clarify* what the patient is reporting?
2. Am I gathering the information *relevant* to figuring out the problem(s) being experienced by the patient?
3. What else do I need to know to identify more *precisely* what the problem or issue is or how to solve the problem?
4. As I listen to what the patient is reporting, what fundamental concepts do I need to think through to formulate a reasonable hypothesis (or draw an inference) as to what the problem might be?
5. If I think I know what the problem might be, how can I test my hypothesis? In other words, what laboratory studies and diagnostic procedures do I need to order?

Another important aspect of history taking is close observation. The body language of a patient is almost as important as what the patient articulates, or it may be irrelevant. Facial expressions, nervous tics, stroking a beard, scratching the head, leg swinging, leg pumping, repeated rubbing the ends of an arm rest, staring at the floor, wringing the hands may communicate the state of mind, nervousness, anxiety, fear, sadness, exaggeration, and even deceit or untruthfulness. The clinician making observations of body language draws certain inferences that require critical inquiry. In some instances what is being observed merely reflects a patient's timidity or uneasiness due to the circumstances and surroundings. In such a case as this, it is, of course, important to help the patient feel more relaxed

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and comfortable so that the history the patient gives is clear, accurate, and relevant. In other instances, the clinician infers that the outward behavior of the patient is indicative of depression, anxiety, panic disorder, hypochondria, or even drug-seeking behavior. The ability to make good clinical observations comes with years of experience and reflective thinking. In any case, the clinician must be careful not to infer beyond what is actually implied. And in many cases, what is "meant by" body language cannot be accurately inferred.

History taking is guided by hypotheses formulated as the history unfolds. Before formulating a final conclusion, initial hypotheses must be carefully considered and thought through. An initial hypothesis is based on the relevant information: patient's age, gender, known risk factors, and chief complaint (the reason the patient is seeking medical attention), and so forth. Consider, for example, a 40 year old woman who complains of shortness of breath and who is on birth control pills, has a history of heavy menses, and smokes. This initial information would generate possible hypotheses of anemia, pulmonary embolus, asthma, lung cancer, and heart disease.

To test a hypothesis, a series of questions are posed either to elicit information that supports or refutes the hypothesis. For example, if a patient complains of chest pain, the clinician will ask a series of questions to determine the likelihood that the chest pain is due to coronary artery disease (a reasonable hypothesis based on the patient's symptom or chief complaint). These questions would be directed at finding out the nature of the pain (sharp, dull, squeezing), whether or not the pain radiates (up into the jaw, down the left arm), the duration of the pain, what provokes the pain, and what relieves the pain. If the answers to these questions do not support the hypothesis that the patient's chest pain is due to coronary artery disease, the line of questioning shifts toward identifying other possible causes of chest pain, such as indigestion, gallbladder problems, pulmonary embolism, rib inflammation, or even anxiety.

The purpose of taking a history is to elicit accurate pieces of information that contribute to the problem-solving process. After considering information obtained from questioning a patient about his or her symptoms, the clinician draws either an inference that the patient has a specific problem or has one of several possible problems. In the latter case, the physical exam and various diagnostic procedures will be used to narrow the list or determine the actual problem. Every step in this

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process requires careful clinical reasoning. Alternative inferences (of disease) must be entertained. Assumptions regarding the patient's ability to articulate accurately the history of illness have to be examined along with assumptions made based on patient demographics and other known medical problems. The implications of ordering certain diagnostic procedures have to be weighed, the possible consequences of treating, or failing to treat, appropriately the underlying problem have to be considered. And the patient's point of view must be ascertained.

If it were possible to quantitate the relative importance of each aspect of making a diagnosis, history taking would probably be in the range of 70% to 80%.

Physical Examination

After history taking comes the physical examination. The clinician is looking for physical signs either to confirm or rule out inferences made while taking the patient's medical history. The approach to the physical examination can be thorough (i.e., a complete physical), in which case unexpected findings and additional problems may be identified, or highly focused, where the intent is to search for findings that either confirm or rule out clinical impressions. In either case, careful, analytical thinking is necessary in order to reach an accurate diagnosis or to construct a differential diagnosis (a list of possible clinical problems), which then requires further inquiry. Even before one begins to conduct a physical examination, it is imperative to run through the elements of thought with a series of questions. For example,

1. What is the purpose of this physical examination? Is it to confirm or rule out impressions or is it to determine if problems may be contributing to or coexisting with the presumptive underlying problem?
2. What specific questions need to be addressed while conducting the physical examination?
3. What information do I need to gather in order to answer the key questions?
4. What assumptions am I making even before I begin the physical examination (in other words, what am I taking for granted)? Do these assumptions need to be questioned for *justifiability*?
5. What basic pathophysiologic concepts do I need to use in my thinking as I conduct the physical exam?

Then during and after the physical examination, it is important to grapple with questions like:

1. What inferences do I draw from the physical examination? How do these relate to my prior impressions or inferences (based on the medical history)?

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2. If I reason to conclusion X, what implications are likely to follow? If I reason to conclusion Y, what implications are likely to follow?
3. Am I certain enough of my tentative conclusion (diagnosis) to start treatment now or should I order additional tests or procedures to gather more information before making a final decision? What are the *important* consequences of starting treatment if the diagnosis is correct? What are the *important* consequences of starting treatment if the diagnosis is incorrect? What are the consequences of delaying treatment if the presumptive diagnosis is correct?
4. What additional information or data are needed to make an *accurate* clinical decision?
5. What points of view are being considered in deciding what exactly needs to be done to reach a final clinical decision (inference) in this case? Am I missing any *important relevant* viewpoints?
6. Am I missing *important relevant* information such as the patient's age, social status, family support, financial capability, patient's input?
7. Do I need to refer this patient to a specialist for a more comprehensive and skillful work-up?

The physical examination includes four major components: inspection, palpitation, percussion, and auscultation. The information obtained from conducting each part of the physical must then be assessed using intellectual standards. The following questions are examples of applying intellectual standards to the physical examination:

1. Have I been *accurate* in observing physical signs that may indicate the presence of a particular condition or several possible conditions?
2. Have I gathered all the *relevant* information for making a diagnosis?
3. Is my auscultatory technique *precise* enough to detect an abnormality if abnormality is actually present?
4. Have I been *thorough* enough to identify abnormalities, or is there something more that needs to be done to be certain?
5. Have I *clearly* stated the findings I made during the physical exam?
6. Have I documented all the *significant* physical findings?
7. Are the findings from the physical examination *consistent* with the impressions formed during the history taking? Is it all making sense? Are my conclusions *logical*?

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Ordering Laboratory Tests and Diagnostic Procedures

Based on the history and physical examination, the clinician constructs a list of possible diagnoses (if the patient is presenting with a new sign or symptom), or an objective assessment and plan (if the patient is returning for a follow-up visit for an existing clinical problem). Clinical laboratory tests are usually ordered to strengthen or confirm the assessment of the patient's condition and occasionally to arrive at a particular diagnosis. For example, if anemia is suspected based on the patient's history and physical examination, a complete blood count is obtained to determine if indeed the patient suffers from some kind of anemia as evidenced by a low hemoglobin and hematocrit. Other tests would then be ordered to ascertain what specific type of anemia the patient has developed. For example, a low serum iron and elevated iron binding capacity would indicate an iron deficiency anemia as opposed to a folic acid deficiency anemia.

Diagnostic tests are ordered to confirm or rule-out a particular diagnosis. Before choosing a diagnostic test, the clinician needs to address the following questions:

1. What assumptions are being made regarding the need to pursue a particular diagnosis or the need for more than one test to confirm a specific diagnosis? (What am I taking for granted in this case?)
2. What is the purpose of the diagnostic test? Is it to confirm a presumptive diagnosis or is it to rule-out a diagnosis in order to narrow the list of possible causes of the patient's signs and symptoms?
3. If the purpose is to confirm a diagnosis, what is the best diagnostic test?
4. If the purpose is to rule-out a diagnosis, what is the best diagnostic test?
5. What information do I have regarding the sensitivity and specificity of the diagnostic test that I have chosen? In other words, how *accurate* is the test in detecting disease if the disease in question is present (sensitivity)? And how certain can I be that the patient does not have the disease in question if the test is negative (specificity)?
6. What are the false-positive and false-negative rates associated with the diagnostic test?
7. What are the implications and consequences of a true-positive test, a false-positive test, or a false-negative test?
8. And, finally, how does my perspective on what to do about a positive or negative diagnostic test differ or agree with the patient's perspective? For example, if the patient has made up her mind that treatment of the disease is not worth the cost or possible side effects, or if the patient has decided to aggressively pursue treatment regardless of the cost or consequences, then either I have to change my perspective or try to convince the patient to change hers.

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Diagnosis

As stated earlier, the diagnosis of a clinical problem can often be made on the basis of the patient's history and/or physical exam. However, in most cases a diagnostic test will be needed either to confirm or rule out a particular diagnosis. It is therefore imperative to understand the properties of a diagnostic test to know how to interpret a test result.

The fixed properties of a diagnostic test relate to its sensitivity and specificity.

		Disease	
		Present	Absent
Diagnostic Test	Positive	True Positive	False Positive
	Negative	False Negative	True Negative

The sensitivity of a diagnostic test is the proportion of subjects with the disease who have a positive test for the disease. Sensitivity = True Positive Rate /True Positive Rate + False Negative Rate. A highly sensitive diagnostic test is used when there is an important penalty for missing a disease or to rule out a disease when the test is negative, since a negative test would be unlikely in an individual with the disease.

The specificity of a diagnostic test is the proportion of subjects without the disease who have a negative test. Specificity = True Negative Rate/ True Negative Rate + False Positive Rate. A highly specific test is used when a false positive test can harm a patient physically, emotionally, or financially or to rule in a disease when the result is positive since, a positive test would be unlikely in an individual without the disease.

Once the results of a diagnostic test are known, the question arises as to how predictive are the results. In other words, if the test is positive, what is the probability that the diagnosis in question is present (i.e., the positive predictive value)? And, if the test is negative, what is the probability that the disease in question is absent (i.e., the negative predictive value)?

The predictive value of a test depends on its sensitivity and specificity.

The more sensitive a test, the better will be its negative predictive value, i.e., the more confident one can be that a patient with a negative test does not have the disease.

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The more specific a test, the better will be its positive predictive value, i.e., the more confident one can be that a patient with a positive test has the disease.

The positive predictive value = True Positive Rate / True Positive +False Positive Rate. The negative predictive value = True Negative Rate/ True Negative + False Negative Rate.

While sensitivity and specificity are fixed properties of a diagnostic test, predictive values are influenced by prevalence. As prevalence of a disease approaches 0%, the positive predictive value approaches 0%. And, as prevalence of a disease approaches 100%, the negative predictive value approaches 0%.

Given a diagnostic test that is 80% sensitive and 90% specific, what is its predictive value when prevalence is 50% in 1000 patients tested?

		Disease		
		Present	Absent	
Diagnostic Test	Positive	400 (TP)	50 (FP)	
	Negative	100 (FN	450 (TN)	
		500	500	1000

The positive predictive value = 400/400+50 or 90% and the negative predictive value = 450/450+100 or 82%. If the prevalence was 10% instead of 50%, then the positive predictive value would drop to 47% and the negative predictive value would increase to 98%.

Another useful property of a diagnostic test is the likelihood ratio. The likelihood ratio expresses the odds that a given level of a diagnostic test would be observed in a patient with (as opposed to one without) the presumptive disorder.

The likelihood ratio for a positive test = TP rate/FP rate (Sensitivity/1-specificity). The likelihood ratio for a negative test = FN rate/TN rate (1-sensitivity/specificity)

The true positive rate = TP/TP+FN; the false positive rate = FP/FP+TN.

The false negative rate = FN/FN+TP; the true negative rate = TN/TN+FP.

Likelihood ratios (LR) can be used to convert pretest odds to posttest odds by the equation: pretest odds X LR = posttest odds, where odds = the probability of event / (1-probability of event). To convert odds back to probability, probability = odds/1+odds.

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To illustrate the utility of likelihood ratios consider the following case scenario:

A 45 y/o woman with a 1 month history of chest pain has a pretest probability of coronary artery disease of 1% (pretest odds =.01/.99 or .01:1) based on previously validated sets of clinical data. A careful history reveals that the chest pain is substernal, radiates down the left arm, is brought on by exertion, and is relieved by rest.

Given this particular history, the estimated likelihood ratio for coronary artery disease in a woman is known to be 120 (that is to say that this history is 120 times more likely to come from a female patient with coronary artery disease than from a woman without coronary heart disease). This then raises her probability for coronary artery disease from 1% to 55% (posttest odds =.01:1 X 120 = 1.2:1; probability of coronary artery disease = 1.2/2.2 = 55%).

She then undergoes a treadmill exercise tolerance test (ETT) which shows a 2.2mm ST segment depression in several chest leads on her EKG. The likelihood ratio of this ETT result in a woman has been calculated to be 11. Now her probability for coronary artery disease rises to 93% (posttest odds = 1.2 X 11 = 13.2:1; probability of coronary artery disease= 13.2/14.2 = 93%). A more detailed discussion on the diagnostic test can be found in *Clinical Epidemiology: The Essentials*, 4th edition by Robert Fletcher and Suzanne Fletcher.

Treatment

Once a diagnosis has been made, the next step in clinical care is to decide what if anything will be used to treat the problem. Again, the same elements of reasoning must be applied to the case. The following checklist for clinical reasoning can be used:

1. What is the explicit purpose of treatment? Is it to bring about a cure or prescribe palliative therapy, such as alleviating pain in a patient with incurable cancer? Or, is it needed to control a clinical abnormality like high blood pressure or prevent complications of a disease? Is the purpose of treatment to slow down or stop disease progression or simply to manage the disease to alleviate symptoms?
2. Given alternative ways to treat the patient's condition, which treatment is the most effective as indicated by evidence-based information and data? Which treatment is associated with the least number of side effects? Which treatments may be contraindicated (i.e., irrelevant) given the patient's underlying physiologic condition and concomitant medical problems? Are some alternative treatments more cost-effective than others, and how *accurate* are the data for making this judgment?
3. Have I identified and do I clearly understand the relevant pathophysiologic concepts of the disease. Can I explain how alternative therapies will interact

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with underlying pathophysiologic mechanisms to produce a desired and optimal therapeutic outcome?

4. What will be the consequences of implementing therapy with a particular intervention? Is it possible that treatment will do more harm than good? How long should treatment be continued to achieve the best possible results? What are likely consequences if the patient does not adhere to the prescribed regimen? Will the new treatment interact with an existing therapy in such a way as to cause significant harm to the patient?
5. How will I know if the treatment is safe and effective? What parameters should be used to assess treatment outcomes? What variables should be monitored to identify or prevent adverse treatment effects? What should be the starting point for treatment and on what bases should adjustments be made?
6. What assumptions am I making about the desired treatment outcome? Are there possible differences in treatment outcomes based on age, race, gender, genetics, or underlying physiologic and pathophysiologic characteristics of the patient?
7. From whose perspective(s) are treatment decisions being made? What are the patient's perceptions of their illness and the proposed treatment? How will that affect compliance with the medical regimen and outcomes? What strategy needs to be employed to achieve proper understanding of the illness, treatment, and good adherence behavior? What can be done to help the patient who may not be able to afford the treatment?

These are just some of the questions the clinician should grapple with. The elements of reasoning help guide the thinking by formulating appropriate questions. Similarly intellectual standards can be targeted to discipline one's clinical reasoning. For example, I might ask:

Am I *clear* on just what the problem is and the alternative solutions? Or, do I need to define the problem more *precisely* and further explore the evidence in support of one treatment over another?

How *precisely* does the treatment target the problem or how likely is the treatment to favorably alter the underlying pathophysiologic mechanisms of the disease?

How can I ensure that this treatment regimen is the most *logical* considering the severity of the patient's problem, the need to make adjustments for age, physiologic abnormalities or concomitant conditions?

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How *relevant* is the treatment given what is known about the patient's physiologic and pathophysiologic condition, prognosis, and level of commitment and motivation?

What are some of the *complexities* of the treatment that need to be considered? Have we dealt with the problem and treatment in sufficient *detail* to ensure optimal results?

Do we need to consider any other *relevant* points of view in the management of the patient? In other words, should we refer the patient to a specialist for re-evaluation and consultation?

Does the proposed treatment make sense (is it *logical?*) given the severity of the patient's illness, prognosis, likelihood of developing complications, and natural history of the illness?

How *significant* is the problem? Is it self-limiting? Can it lead to further morbidity or mortality?

Am I recommending treatment based on good medical ethics and reasoning? Or am I being influenced by outside forces or my own particular bias or financial gain?

Treatment decisions are made on the basis of both scientific evidence and logic. In some cases the decision will be to avoid treatment, either because there is no effective treatment for the disease, treating the disease may cause more harm than good, the disease is self-limiting and doesn't require intervention, or the seriousness of the disease does not warrant treatment. In the latter case, it may be more prudent to wait until the disease progresses before initiating therapy. Whatever decision is made, it should be supported by good clinical evidence that treatment is efficacious, safe and effective, and it should make sense given relevant patient variables and the underlying pathophysiologic condition of the patient.

The efficacy and safety of a particular treatment is best determined by the evidence obtained from a randomized controlled trial (RCT). A RCT is an investigation in which groups of individuals are randomly assigned to receive an experimental intervention or a control intervention (placebo or standard therapy). Patient selection criteria and proper randomization help achieve comparability between the two groups. To be properly randomized, each subject must have an equal chance of being assigned to the experimental group or control group. Subjects are followed prospectively over a finite period of time during which specific outcomes are measured with equal intensity in both groups. Differences in outcome are evaluated by appropriate statistical tests to determine significant differences. It is also important to assess any clinically significant differences irrespective of statistical significance. An inadequate sample size may explain why no statistical difference was observed even when a clinically relevant difference between the two treatments occurs.

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As mentioned, a RCT is used to determine whether or not a particular treatment works compared to either a placebo (inert substance) or standard treatment. However, the subjects who participate in RCTs are not always representative of all patients to whom a treatment might be administered. Eligibility criteria for patients in a RCT are usually designed to achieve homogeneous groups of patients who are healthy, except for the condition being treated, and who are unlikely to experience an adverse effect as a result of other underlying co-morbid diseases or physiologic impairments. Therefore, clinical studies designed to measure the therapeutic effectiveness of alternative treatments are also needed to make sound clinical judgments regarding the treatment of individual patients. These studies answer the question: Does the treatment work compared to alternative treatments in patients who may or may not have co-morbid diseases and compromised physiologic conditions, such as renal function impairment? In other words, will the treatment work in normal practice (as opposed to does it work under highly controlled settings)?

In addition to investigating the evidence of a treatment's safety, efficacy, and effectiveness, there is also a need to determine the logic of a given treatment based on the underlying pathophysiology of the illness or disease and the various mechanisms by which treatment produces either positive results or adverse events. This type of critical inquiry integrates what we know about the cause and effects of a clinical problem with what we know about the benefits and risks of treatment.

To illustrate this type of clinical reasoning, consider a patient who presents for the first time with a diagnosis of type 2 diabetes mellitus. When this patient is seen by her clinician she is exhibiting all the signs and symptoms of poorly controlled diabetes and is found to have a fasting blood sugar of 210 mg/dL and hemoglobin A-1C level of 10%. We know in a patient like this there are two underlying pathophysiologic mechanisms that are working in tandem. One causes impaired insulin secretion and the other causes decreased insulin sensitivity. Among the oral agents used to treat type 2 diabetes mellitus are sulfonylureas that increase insulin secretion and metformin and the glitazones that increase insulin sensitivity. In order to effectively manage this patient's diabetes, combination therapy (a sulfonylrea plus metformin or a glitazone) would be indicated. That takes care of the benefit side of the treatment equation, but what about the risk side? If the patient also has impaired kidney function, then the clinician should avoid the use of metformin since it may lead to the development of lactic acidosis which may be fatal.

For more information on how to apply scientific evidence to treatment decision-making, we refer you to *Evidence-based Medicine: How to Practice and Teach EMB*, 3rd edition by Sharon Straus, W. Scott Richardson, Paul Glasziou, and R. Bryan Haynes.

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Reasoning Through a Clinical Case

A 51 year old man complains of coughing up blood, shortness of breath, and difficulty in breathing. He first noticed these symptoms about 2 months ago. He smokes one pack of cigarettes per day and was told that his blood pressure was a "little high." He is otherwise well and takes no medications, but he is worried about his health. His father had a heart attack and died at the age of 52. A complete physical examination is normal except for a blood pressure of 150/96. His pre-clinic blood work was also normal including a serum cholesterol of 180mg/dL and a fasting blood glucose of 100mg/dL.

As you think about this patient, what questions come to your mind that, when effectively answered, enable you to better understand the patient's condition and how to approach the treatment of this patient?

Consider these possible questions:

1. What is the probability that this patient has lung cancer?
2. What diagnostic tests would provide the greatest utility in ruling in or ruling out cancer?
3. How likely is it that this patient's condition will worsen?
4. What are this patient's risk factors for lung cancer?
5. How long can this patient expect to live if he in fact has lung cancer?
6. What would be the best course of action to take in treating this patient?
7. Will risk factor reduction and treatment of his disease improve the quality and quantity of his life?
8. What caused this patient to develop his condition?

Important questions such as these enable the clinician to think through relevant issues like the diagnosis, risk factors, prognosis, treatment, prevention, and causation of disease and what can be done to treat or prevent disease or reduce the likelihood of disease complications.

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Analyzing the Logic of an Article, Essay or Chapter

One important way to understand an essay, article or chapter is through analyzing the parts of the author's reasoning. Once you have done this, you can evaluate the author's reasoning using intellectual standards (see pages 11-13). Here is a template to follow:

1) The main **purpose** of this article is _____. (Here you are trying to state, as accurately as possible, the author's intent in writing the article. What was the author trying to accomplish?)

2) The key **question** that the author is addressing is _____. (Your goal is to figure out the key question that was in the mind of the author when he/she wrote the article. What was the key question addressed in the article?)

3) The most important **information** in this article is _____. (You want to identify the key information the author used, or presupposed, in the article to support his/her main arguments. Here you are looking for facts, experiences, and/or data the author is using to support his/her conclusions.)

4) The main **inferences** in this article are _____

_____

(You want to identify the most important conclusions the author comes to and presents in the article).

5) The key **concept**(s) I need to understand in this article is (are) _____. By these concepts the author means _____ _____. (To identify these ideas, ask yourself: What are the most important ideas that you would have to know to understand the author's line of reasoning? Then briefly elaborate what the author means by these ideas.)

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6) The main **assumption**(s) underlying the author's thinking is (are) _____ (Ask yourself: What is the author taking for granted [that might be questioned]? The assumptions are generalizations that the author does not think he/she has to defend in the context of writing the article, and they are usually unstated. This is where the author's thinking logically begins.)

7a) If we accept this line of reasoning (completely or partially), the **implications** are _____. (What consequences are likely to follow if people take the author's line of reasoning seriously? Here you are to pursue the logical implications of the author's position. You should include implications that the author states, and also those that the author does not state.)

7b) If we fail to accept this line of reasoning, the **implications** are _____. (What consequences are likely to follow if people ignore the author's reasoning?)

8) The main **point(s) of view** presented in this article is (are) _____. (The main question you are trying to answer here is: What is the author looking at, and how is he/she seeing it? For example, in this thinker's guide we are looking at clinical reasoning and seeing it as requiring one to understand and routinely apply the elements of reasoning when thinking through clinical problems and issues).

If you understand these structures as they interrelate in an article, essay or chapter, you should be able to empathically think within the author's reasoning. These are the eight basic structures that define all reasoning, the essential elements of thought.

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Analyzing the Logic of an Article: An Example

On pp. 30-31 you will find an analysis of the following brief article. Use the template on pp. 26-27 to work through the logic of this article before reading our specimen analysis.

Drug-Eluting versus Bare Metal Stents for the Treatment of Coronary Artery Stenosis*

Two drug-eluting stents were approved by the FDA in 2003 for use in patients with coronary artery disease. Before drug-eluting stents were available, bare metal stents were used to correct for coronary artery stenosis. By the end of 2004, drug-eluting stents were used in nearly 80% of patients.

Initial approval of the two drug-eluting stents was based on the results of randomized, controlled trials that showed superiority of drug-eluting stents over bare metal stents up to 1 year after implantation. Shortly after drug-eluting stents were approved, reports of late stent thrombosis began to appear. This complication can lead to restenosis, which may result in myocardial infarction or even death.

In 2006, the results of a large study suggested that between 7 and 18 months after implantation, the rates of nonfatal myocardial infarction, death from cardiac causes, and angiographically documented stent thrombosis were higher with drug-eluting stents than with bare metal stents. Over the next 6 months, the two manufacturers of the drug-eluting stents issued 19 press releases touting the effectiveness of their devices and never mentioned the potential risk of late thrombosis.

Other studies presented conflicting results, some showing an increased risk of death or myocardial infarction with drug-eluting stents and others showing no difference in mortality between patients with drug-eluting stents and bare metal stents.

Upon further investigation into these studies, two important factors emerged as possible explanations for the conflicting results including differences in the characteristics of patients and coronary lesions. Drug-eluting stents were approved for use in patients with newly diagnosed coronary lesions and without additional serious medical conditions, like those studied in

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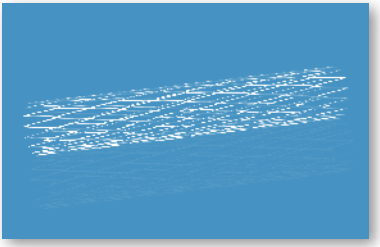
the clinical trials that led to FDA approval. However, since FDA approval was granted, more than 60% of drug-eluting stents have been implanted in patients with complex conditions (such as multi-vessel disease or acute myocardial infarction) or with complex lesions. These should be considered as off-label use.

On-label use of drug-eluting stents is associated with a persistent, long-term (>3year) reduction in the need for repeated revascularization (another stent, angioplasty, or clot dissolving therapy), without increasing the rates of mortality or myocardial infarction. Therefore, the risk of thrombosis associated with drug-eluting stents does not outweigh their advantages over bear metal stents in reducing the rate of repeated revascularization procedures.

On the other hand, off-label use of drug-eluting stents is associated with increased risk of both early and late stent thrombosis, as well as death and myocardial infarction. For this reason, patients who receive drug-eluting stents should be placed on extended (at least 12 months) antiplatelet therapy as an added measure of protection against stent thrombosis. More studies are needed to determine if extended antiplatelet therapy will improve the overall outcome of drug-eluting stents in patients with multi-vessel disease or concomitant serious medical conditions.

(Adapted from two articles that appeared in the New England Journal of Medicine, March 2007, pages 981-987)*



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ISBN 978-0-944583-42-5
Item #564m