Opening the black box of clinical judgment—an overview

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In all advanced healthcare systems, medical decision making depends on cognitive inputs from highly trained doctors. Yet those cognitive inputs fall short of what the practice of medicine requires. The reason is that doctors are expected to do the impossible—firstly, to recall and process complex information reliably under severe time constraints, and then to identify the decisions that patients would make for themselves were they fully informed. The inevitable outcome is that doctors' decisions too often cannot be justified in light of available knowledge, medical risk, cost, benefit, or patients' desires.

Summary points

Medical decision making requires combinatorial analysis to comprehend patients' uniqueness and avoid harmful, unnecessary trial and error

Combinatorial analysis combines numerous, simple, inexpensive observations, tests, and procedures on a patient with medical knowledge to identify all individually relevant options, and the pros and cons of each for the patient

The apparent difficulties of a combinatorial approach—gathering comprehensive data and linking it with the medical knowledge base—are avoidable when properly designed software tools are habitually used

The actions of caregivers and the medical knowledge they use must be subject to effective feedback, which requires medical records with a problem oriented structure

New systems are needed not only to improve cognitive inputs to medical decision making but also to improve manual and procedural inputs to assure the skilful execution of decisions

Such reforms would expand the roles of patients and have large implications for medical science, medical education, health care regulation, and the economics of care

The impossible is expected of doctors because we are socialised to rely on their acquired knowledge and cognitive abilities. But cognitive psychology has shown that the human mind normally functions by oversimplifying and filtering complex information. In contrast, modern electronic tools, if properly designed, can empower the mind to systematically consider all available details and their possible combinations. A new division of intellectual labour in medicine is therefore possible—a division between electronic tools that retrieve and process information, and users who apply judgment and values to arrive at medical decisions.

Using information tools in every encounter with patients is essential to harvest the fruits of medical science effectively. Medical science has given us an enormous array of inexpensive, simple, safe tests, observations, and procedures. Yet solutions potentially available from these sources may not be recognised, or the needed data may not be gathered at all, because of the limitations of the human mind. Medical decision making may thus be crippled at its very first stage—that of identifying relevant options and their pros and cons for the patient. In turn, the next stage, deciding among the options, can easily fail. The outcome is wasted resources and needless risks, delays, and harm to patients.

A case in point

Consider the following example, described in a 1996 *New England Journal of Medicine* article.[1] A 15 year old girl experienced excessive fatigue, shortness of breath, weight loss, and amenorrhoea for months. Her initial physical examination revealed mild hypotension and multiple, deeply pigmented naevi (moles), but her examination and history were generally unremarkable. Test results were normal except for some borderline readings. The girl was admitted to a teaching hospital several times with additional symptoms of distress. Summarising her condition, the article states, "the unfortunate child described here suffered from weakness, breathlessness, abdominal pain, nausea, vomiting, diarrhea, weight loss, and severe malnutrition. Examination never disclosed any findings other than tachycardia, mild hypotension and dehydration.''

No diagnosis was established for months. Many consulting specialists subjected this girl to what the article described as "dozens of blood tests, immunologic studies, endoscopies, scans, other radiographic tests, and biopsies." In their perplexity, and influenced by a false positive test result that suggested emetine poisoning, the doctors became suspicious that psychiatric problems or child abuse might somehow account for the girl's condition.

Then further blood tests revealed abnormal concentrations of serum electrolytes. Investigation soon narrowed the possibilities down to Addison's disease, a potentially fatal insufficiency of adrenocortical hormones. The girl's doctors began hormone replacement therapy, and she rapidly improved. "Fortunately, the patient survived not only her illness but the myriad tests and treatments administered before the telltale electrolyte levels revealed the correct diagnosis. Fortunately as well, this happened just in time." The article acknowledges, however, that diagnostic failures of this magnitude are all too common.

"Disaster lurks when a patient has a life threatening disease that not only is rare but also presents with either atypical or nonspecific symptoms and signs. In patients with diseases that fit this description, vastly excessive testing and numerous attempts to treat putative diagnoses are the rule. We can be certain that in such instances some patients die because the correct diagnosis is never entertained and that even after an autopsy the mystery often persists."[1]

Yet, Addison's disease was readily identifiable in the early stages of this girl's care. A careful literature review would have revealed that among the signs and symptoms characteristically appearing with Addison's disease are fatigue, hypotension, weight loss, and unusual pigmentation. These were observed in the initial examination, and other clues to the disease were observed within two weeks, including abdominal pain, nausea, dehydration, vomiting, and a serum sodium concentration that on its face was borderline and in the context of dehydration should have been interpreted as below normal (hyponatraemia). ''In retrospect, the diagnosis seems obvious," the article acknowledges. "Fatigue, weakness, dehydration and hypotension are classic manifestations of Addison's disease. A rare diagnosis that is obvious in retrospect, however, is often not so obvious prospectively." In this case, "Addison's disease did not make the [differential diagnosis] list until it was nearly too late to save the child's life.''

To make the diagnosis earlier, the girl's doctors needed to focus on their patient's individual combination of symptoms and signs, ascertaining the possibilities suggested by that combination. Instead, their approach was backwards, focusing not on detailed patient data but on general knowledge about large populations. As the article explains: "the clinician usually begins a diagnostic investigation by considering (and excluding) the most common diagnoses. As these most common diagnoses become less likely, many less common diagnoses are considered.'' Yet, what diagnoses are common or uncommon depends on what population one examines. In the general population, Addison's disease is indeed uncommon. But that fact is wholly irrelevant to the population of people with the combination of excessive fatigue, low blood pressure, unusual pigmentation, gastrointestinal symptoms, and hyponatraemia, because for them Addison's disease is far more common than in the general population.

Had the girl's doctors recognised even some of those clues to Addison's disease, they immediately could have watched for other clues or carried out the tests needed to confirm or rule out the disease. The only barrier to an earlier diagnosis was the doctors' cognitive inability to couple the readily available findings on their patient with medical knowledge.

The solution is apparent—routine use of computer software to recognise linkages between medical knowledge and data relating to a particular patient. Without the aid of software, expert clinicians viewed the clinical findings on this girl as "atypical and nonspecific"; with properly designed software, even lay people could recognise that the girl's combination of findings was quite typical and highly specific.

But recognising such linkages between patient data and medical knowledge depends on what data are selected as inputs to the software. This selection of inputs is critical, and must itself be guided by software. Medicine imposes on practitioners rigorous demands concerning the nature, scope, and sequence of inputs to the decision making process. Satisfying those demands consistently is not within the capacities of even the most talented and exacting doctors, given the mind's limitations and the time constraints of most medical practice.

Using the combinatorial approach

Medicine needs a far stronger foundation than the fallible minds and habits of overburdened, ill equipped doctors. Diagnosis of a symptom such as fatigue, for example, must always begin with a predefined work up based on the best medical knowledge—a comprehensive set of simple, safe, inexpensive findings that, in combination, best identify the diagnostic possibilities and discriminate among them. Similarly, treatment decisions must always begin with a predefined set of carefully chosen findings that, in combination, best identify available treatments for the patient's condition and the factors relevant to selecting among them (for example, their side effects and interactions with the patient's other conditions and treatments). This combinatorial approach—as distinguished from probabilistic reasoning or rigid, "if-then" algorithms—accounts for individual variation among patients while avoiding arbitrary variation arising from providers' idiosyncracies. It thereby permits further investigation and decision making to proceed on a fully informed, cost effective basis.

Doctors fail to use a combinatorial approach for two reasons. Firstly, routine collection of comprehensive data is too time consuming and expensive to be practical if doctors have a heavy case load. Secondly, their unaided minds cannot effectively couple comprehensive data with the enormous medical knowledge base under real world time constraints. Both those problems, however, can be dealt with by software tools designed to implement a combinatorial approach. This conclusion is based on more than 15 years of practitioners' use of ''knowledge coupling" software developed by LLW and his colleagues at PKC Corporation. Available for a broad and increasing range of medical problems, this software (table 1) guides physicians, other caregivers, and patients themselves in efficiently collecting comprehensive data. Then it instantly identifies linkages between that data and the medical knowledge base, presenting users with diagnostic or therapeutic options and the pros and cons of each, based on the patient's individual characteristics.[2–6]

Equipping providers with software tools to enable a combinatorial approach, however, is not enough. More is needed to address three constraints that are inherent in complex cases. Firstly, these cases involve large volumes of patient data and multiple caregivers who must comprehend those data efficiently and coordinate their actions over time. Secondly, caregivers apply medical "knowledge" in the form of fallible, incomplete generalisations that often diverge from the realities of unique, individual patients. Thirdly, complex cases involve uncertain choices and difficult trade offs that are inherently personal to patients. Expert caregivers cannot know what decisions patients would make for themselves, yet patients cannot make those decisions unless presented with individually relevant medical information.

Table 1 Knowledge coupling software modules ("couplers") currently available. Source: PKC Corporation

Coupler sets	*Use*
Screening	For complete health history, mental health screening, wellness, physical examination, and laboratory screening
Senior assessment and disease management	To support care planning, case management, disease prevention, OASIS (outcomes and assessment information set) reporting, and patient education for senior and disabled populations
Occupational health	To equip providers to identify and manage work related injuries, exposures, and disease, as well as to navigate the complex rule sets surrounding specific work environments
Behavioural care	For assessing potential behavioral manifestations of medical problems, supporting the determination of DSM-IV diagnosis, and guiding patient-provider strategies for disease management
Chronic disease management	For managing conditions such as diabetes, chronic obstructive pulmonary disease, asthma, depression, hypertension

Table 1 *continued*

Individual problem-knowledge couplers

Disease management:
- Acne vulgaris
- Anaesthesia: preoperative screening*
- Angina, stable
- Anxiety disorders
- Asthma
- Atrial fibrillation - new onset*
- Benign prostatic hyperplasia
- Carpal tunnel syndrome
- Contraception
- COPD - chronic obstructive pulmonary disease
- Dementia
- Depression: management and guidance
- Diabetes mellitus
- Gallstones*
- GERD - gastro-oesophageal reflux disease
- Heart failure due to LV dysfunction
- Hyperlipidaemia or dyslipidaemia
- Hypertension
- Hypertension, malignant and other hypertensive crises
- Male erectile dysfunction
- Menopause - disease management
- Obesity
- Parkinson's disease
- Otitis media with effusion in children*
- Pressure ulcers*
- Smoking cessation
- Substance use disorders
- Suicidal thinking and behavior*

Diagnostic/disease management:
- Asthma attack: assessment and management*
- Chest pain I*
- Kidney stone (known): type of stone and its management*
- Tinnitus (noise in the ear or head)*

Diagnostic:
- Acute abdomen*
- Anaemia
- Anxiety, panic, and phobias
- Chest pain II *
- Depressed feelings, fatigue, apathy
- Diarrhoea
- ECG interpretation*
- Hand and wrist
- Headache
- Heart sounds abnormal (initial evaluation)*
- Haematuria*
- Hypercalcaemia*
- Hypertension
- Itching of unknown origin (pruritis)
- Jaundice*
- Knee problem
- Knee problem due to acute trauma
- Low back, buttock and/or leg pain, acute
- Male erectile dysfunction
- Memory loss and confusion
- Obesity or unexplained weight gain*
- Personality problems*
- Psychotic-like or bizarre behaviour, thinking, perception*
- Rhinitis chronic*
- Shoulder problem*
- Sleep problems*
- Substance use disorders
- Swallowing problems (dysphagia)
- Syncope (fainting)*
- Upper respiratory complaints, acute
- Urinary incontinence
- Urinary problems, female (dysuria, urgency, etc)
- Urticaria/angio-oedema
- Vaginal bleeding abnormal*
- Vertigo and dizziness
- Vomiting not easily explained in an adult or older child*
- Vulvar and vaginal problems (itch, discharge, pain)

Other:
- History: comprehensive screening for mental health problems
- History: screening to discover patient's problems - complete health history
- Laboratory screening - guidance regarding interpretation of indicated lab tests
- Periodic health evaluation - yearly update of patient problem list
- Physical exam: screening to discover patient's problems
- Senior assessment - functional assessment and improved management for seniors
- Travel preparation
- Wellness and health: assessment and guidance - complete health risk assessment

*Beta version.

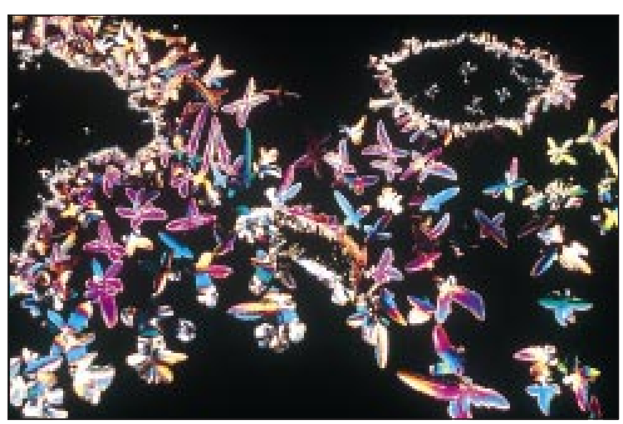
Further reforms in decision making needed

Working within these constraints successfully requires, in addition to software tools, two further reforms in medical decision making. Firstly, medical records must be rigorously maintained in electronic form with a structure that permits rapid comprehension, reliable monitoring, and meaningful outcome studies. The structure required is that data and the recording of provider actions be organised around a complete list of the patient's problems.[2 7–12] Unless care is fully documented in a problem oriented manner, neither the actions of providers nor the medical knowledge that they apply are subject to rigorous feedback. And systems without feedback loops run out of control.

Secondly, when uncertainty exists, patients themselves must become the primary decision makers, and thus a source of effective feedback. Patients can assume that role with properly designed software and medical records, because those tools provide them with individually relevant information. Patients can then engage in informed dialogue with providers to decide on the care of their own bodies and minds.

Execution of decisions

Although patients need not be dependent on physicians for medical decision making, they are necessarily dependent on physicians and other caregivers for skilful execution of many decisions. And patients are necessarily dependent on third parties to assure that caregivers and health care institutions execute decisions skilfully. Yet in this domain, as in decision making, we find that inputs from clinical workers and institutions—their manual skills, techniques, and systems—are of variable and uncertain quality. Medicine has many virtuoso performers, but their achievements are largely individual. Healthcare institutions function without the standards and systems needed to assure that decisions are executed skilfully by all practitioners. Assuring quality in this domain demands reform of two kinds. Firstly, individual caregivers should be awarded credentials periodically, not permanently, on the basis of demonstrated skills. Knowledge should not be a basis for "credentialing," because information tools are superior to the human mind as a device for retrieving and processing knowledge.[13] Secondly, healthcare institutions must put in place



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People without this hormone, cortisol, may develop Addison's disease

Table 2 Concepts of reform in medical practice

Function	*Problem area*	*Old approaches*	*New approaches*
	Basis for decision making	*The mind of the educated doctor*	*Software tools and patients' choices*
Medical decision making	Structuring and recording the decision process	Broad discretion for doctors' "clinical judgment"; manual medical records varying in structure and completeness	Defined, explicit structure for doctors and others; complete electronic medical records with a problem oriented structure
Execution of decisions	Individual performance	Educational credentialing and apprenticeships, certifying general knowledge and skill	Credentialing based on periodic demonstrations of actual competence in discrete skills
	System performance	Individual responsibility for errors	Improvements in the system to support individual performance

standards and systems designed to protect against error and enhance performance of individual caregivers.[14–16]

Table 2 summarises these reforms in medical practice. Bringing about these reforms would have large implications for medical science, medical education, health care regulation, and the quality and economics of care, as discussed in the complete version of this paper (available on the *BMJ* website). Here we observe simply that without the elementary reforms we have described, little progress will occur in medical outcomes for patients and economic outcomes for society. Profound disorder in the connections between patient care and medical knowledge means that the conditions for progress do not yet exist. Organised improvement in outcomes cannot occur until we adopt new tools and approaches to improve inputs by clinical workers in the domains of skill and knowledge.

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The views expressed do not necessarily represent the views of Groom Law Group or any of its clients.

Competing interests: LLW is president and shareholder at PKC Corporation, which develops and markets software described in this articles. LLW is the father of LW.

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