HSPI The Open Access Publisher

JCMHS ISSN 2833-5333 JOURNAL OF COMMUNITY MEDICINE AND HEALTH SOLUTIONS

Clinical Trial

Limits of Diagnostic and Treatment Protocols in Medical Practice

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Submitted: April 10, 2025
Approved: April 21, 2025
Published: April 22, 2025

How to cite this article: Buta MG, Oltean IA. Limits of Diagnostic and Treatment Protocols in Medical Practice. J Community Med Health Solut. 2025; 6(1): 034-038. Available from: https://dx.doi.org/10.29328/journal.jcmhs.1001055

Making a medical decision is the result of a mental (cognitive) process that selects a certain course of medical action from among several possible alternatives.

If making decisions based on logic is essential in medicine, under special circumstances (time pressure, uncertainties, high stakes, team constraints), specialists tend to make intuitive decisions without considering all possible alternatives.

Making a robust medical decision

A robust decision involves the adequate management of ambiguity, after the elimination of uncertainties that can be ruled out in the light of existing information.

To the question of how a clinician, faced with a specific problem, can make a robust decision, the answer is the following: he will use all the knowledge he has accumulated during his professional training as well as all the experience he has. In the modern age, where the pace of scientific discoveries has become extremely fast, this conduct is no longer sufficient and effective [1].

Article 21 of the Medical Code of Ethics specifies:

The doctor will have a constant and permanent concern for finding out, in any way, including through forms of continuous medical education, the latest medical discoveries, procedures and techniques assimilated and accepted by the medical community [2].

One of the options available to the doctor is the use of the Internet. Ex.: *Entering the phrase "medical guidelines" provides a number of 184,000,000 references within 0.27 seconds by searching on yahoo.com* [2].

There is an enormous amount of information regarding the field of health care that an interested person would not be able to sift through effectively. The academic community is working to systematize this information according to its value, validity and utility in medical practice.

This is done by:

a. systematization of specialized literature;

b. consensus documents;

c. medical practice guidelines

Guidelines in clinical practice

Guidelines are "*Systematically developed statements that medical practitioners use to make appropriate decisions in specific clinical circumstances*" (U.S. Institute of Medicine). They are the step by which scientific evidence is transferred into the field of medical practice. Modern guidelines are based on the examination of scientific evidence, and are part of the paradigm of "*evidence-based medicine*" [3].

The questions that are asked are the following:

- How to choose among several guides that address the problem we want to solve?
- How can we choose between the recommendations made by different guides, when these recommendations are not identical, or are even contradictory?

! Due to the constant increase in guidelines in medical practice, many of them of questionable quality, the scientific community is trying to promote a methodology that allows the development of guidelines with increased validity and consistency.

The validity of a guideline refers to its ability, when implemented, to improve the effects on the patient's health within the limits of acceptable costs. Validity is tested by how the scientific evidence is identified, summarized

and incorporated into the recommendations made by the guideline.

Development of a "*de novo*" guide

The most difficult stage, which requires a large consumption of resources, is the review of research in the field and the grading of the results of this research, which unfortunately are not all relevant.

We wonder if these efforts are accessible to all countries?

Two authors from Denmark state in an article published in 2004 that, for small countries (such as the Nordic countries), this task would be impossible to solve in terms of human and financial resources. What can we say about the poorer countries in Eastern Europe, including Romania [4]?

In the development of the guidelines, data provided by organizations specialized in the systematic search of scientific records and their grading are used. Such methodology is provided by the *Scottish Intercollegiate Guideline Network (SIGN)*, which is an international network, representing 51 countries and 104 organizations working to develop a consensus on minimum standards for the development of principles. *SIGN* has developed a guideline designed to ease and standardize the work of those involved in the development of guidelines in clinical practice [5].

AGREE Instrument provides 23 key items, grouped into 6 domains, intended to assess the quality of a guideline, among which items 8 - 14 refer to the process of collecting and synthesizing information and the link between the grading of robust information and the grading of the strength of recommendations formulated in the guideline [6].

A necessary quality of a valuable guide is to propose in concrete terms, *a continuous renewal of recommendations* according to the new discoveries of science.

In a study of principles by the American Agency for Research on Patient Care Quality, it was found that impactful new discoveries usually appeared within 2 years of their publication. The average survival time of a principle is 5.5 years, which implies their review within this time frame.

The principles of approaching a clinical problem may differ among different groups of experts *Ex: "Currently, there are numerous treatment schemes for diabetic ketoacidosis, at first glance very different from each other, but all of which must have some common objectives: correction of hypovolemia, hydroelectrolytic restoration, correction of metabolic acidosis, insulin substitution"* [7].

Schema discrepancies occur at:

1. Correction of metabolic acidosis in terms of the bicarbonate dose administered and the PH value at which the administration begins.
2. Time of insulin administration: from the first hour of treatment or after the first hour of rehydration.
3. Insulin routes of administration: intramuscular or intravenous.
4. Administration rate: bowls or continuous infusions.
5. Glucose solutions used: blood sugar < 500 mg%, < 300 mg%, < 250 mg%.

In the absence of an ideal therapeutic scheme, the experience of the clinician speaks for itself.

Adaptation of guidelines

No guideline, however valuable, can be fully applied in all medical facilities in the world.

Cultural, legislative and organizational differences between countries lead to legitimate changes in recommendations, even if the scientific evidence base is the same. These differences relate to the accessibility of diagnostic and treatment means, the organization of medical services, cultural beliefs and values, patient preference and population characteristics.

Translating a guideline into another language, essential for the implementation of the guideline, is a form of cultural adaptation.

Adaptation strategies of guidelines

1. PGEAC (The Practice Guideline Evaluation and Adaptation Cycle) proposes a 10-step approach for adapting a guideline, which leads to three alternatives: [8].

a. Adoption of a guide with all recommendations.

b. Adopting a guideline while retaining some recommendations and removing those that lack strong evidence or cannot be adopted locally.

c. Adopting the best recommendations from multiple guidelines and adopting them for inclusion in a new guideline.

2. WHO proposes a strategy aimed at a division of efforts between central and local bodies [9].

3. The recommendations made and endorsed by WHO will be made accessible to WHO centres in the 192 member countries where they will be adapted according to:

a. Local needs (prevalence of the disease, risk factors, health status of the population).

b. Availability of resources.

c. Factors that could modify the expected effects (resistance of the microbial flora).

d. Relative value of benefits

Ex: Implementation of the nosocomial infection control program.

Local protocols

Based on the recommendations in the guideline, local protocols can be formulated, targeting a small number of simple, effective and robust key elements that are more easily accepted by doctors and patients.

The large number of recommendations formulated by a medical practice guideline can generate confusion among users, making it difficult to implement. However, the clinician must not forget that a guide is not a "*cookbook*", and does not offer recipes applicable in all possible situations [10].

In the introduction to the "*Guidelines for the management of patients with hospital-acquired pneumonia associated with mechanical ventilation*" from the USA, it is stated: "*This guideline was not created with the intention of replacing clinical judgment, but rather to provide an institutional framework for the care of patients. Individual clinical situations can be complex, and the judgment of a knowledgeable physician, who has all the information concerning the patient at hand, is essential in making the optimal decision for clinical care"* [11].

We exemplify these elementary and fundamental statements that must be the basis of the therapeutic approach of any patient, through two clinical observations of infants with Dg. Severe diarrheal disease with SDA 10%:

Case 1: Patient M.E, 3 months, W = 5200 g, naturally fed, in the period of growth and development called "*physiological immunological gap*", has had diarrheal stools for 5 weeks, which led to the alteration of the general condition

Dg: Acute gastro-enterocolitis with SDA10%;

Repeated coprocultures were negative. Biologically, IgG agammaglobulinemia, hypo IgA, hypo IgM was found.

Case 2: SME patient, 2.2 months, W = 5800 g, artificially fed, in the period of growth and development called "*physiological immunological gap*":

Dg: Acute gastroenterocolitis with SDA 10% caused by rotavirus and adenovirus infection;

Biologically it was found: hypo IgG.

Treatment: Despite the treatment according to the existing protocols: antibiotic therapy, antidiarrheal medication (probiotics, silicates, antisecretory agents, zinc, etc.), diet regimen, the evolution was unfavorable in both cases until the introduction of treatment with IGIV 500 mg/kg, which led to a cure in a few days.

Conclusion: The 2 clinical observations of acute Gastro-enterocolitis argue for the need for immunological exploration and adequate substitutive treatment with immune globulin in the event of immune deficiency.

This conduct is not provided for in the diagnostic and treatment protocols.

Ethical dilemmas in the Emergency Department

Case 1: A.I., 14 years old, female, presented to Paediatrics Emergency Department brought by ambulance, unaccompanied, with a clinical picture of compensated hemorrhagic shock, secondary to an abdominal trauma due to a sledding accident (SBP > 90 mmHg, AV 135/min, Hb 8.5 g/dl).

Dg.: *Abdominal trauma due to sledding accident. Compensated hemorrhagic shock. Spleen rupture*.

Treatment: Volemic resuscitation and intention to administer preoperatively in Emergency Room Rh negative O (I) Erythrocyte Mass (patient accepting this).

Evolution: In the meantime, the girl's father arrives, who for religious reasons (Jehovah's witness) refuses the transfusion under his signature, with the assumption of responsibility, although he was informed that without the transfusion the patient may die. The patient is urgently transferred to the Children's Surgery Service, with a view to surgical intervention. The father again refuses under his signature, the transfusion of MER/whole blood, this time iso-group, iso-Rh, writing a statement according to which, if the patient is transfused, he will sue the hospital. The Police were notified, who in turn notified the Prosecutor's Office. The patient was taken to the room for emergency splenectomy, without administration of blood or MER.

Postoperative: Patient intubated, mechanically ventilated, in compensated hemorrhagic shock (SBP > 90 mmHg, AV – 130 - 140/min, Hb 5.5 g/dl).

The father still refuses the transfusion, although law enforcement threatens to open a criminal case in the event of death. The pastor of the religious community is contacted, who introduces himself and gives a dispensation, according to which the patient could be transfused with MER iso-group, iso-Rh. In the end, the evolution of the case was favorable.

Case 2: L.A, 4 ½ years old, male, is brought by ambulance to the Paediatrics Emergency Department, accompanied by his father by transfer from a city hospital.

Dg: *Medium-risk minor TCC. Concussion. Sutured right parietal contusion wound. Refusal of tetanus prophylaxis (declaratively, the child was not vaccinated).*

Treatment: After ruling out post-traumatic intracranial lesions, toileting the wound, but refusing, under the father's signature, the anti-tetanus vaccination, the patient is sent for supervision to the Paediatric Neurology Clinic, where he is discharged cured.

Evolution: About 2 weeks after this episode, the patient

returns to UPU Paediatrics, with the suspicion of Dg. *Tetanus*, which is later confirmed.

Case 3: P.M, 3 months old, male presented to Paediatrics Emergency Department, brought by his parents from home for a 3-day history of fever, diarrheal stools, vomiting and loss of appetite.

Dg.: *Acute gastroenterocolitis. SDA IInd degree*

The parents refuse under their signature the installation of an i.v. catheter, the collection of biological samples and the admission of the patient to the hospital. In the Pediatrics Emergency Department, a prescription is issued and medical advice is given.

Parents seek "*another opinion*" from a homeopathic doctor, following his advice. The infant is brought to the Emergency Department after 2 days, with gasps, cardio-respiratory arrest, that fortunately responds to resuscitation maneuvers. He is later transferred to the Intensive Care department, from where after extubation he is sent to the Pediatric Neurology clinic for the evaluation of possible neurological sequelae secondary to cardio-respiratory arrest.

Medical malpractice - legal coordinates

The problem of medical malpractice arises when a doctor (or other health care professional) deviates from the standards of the profession, thereby causing harm to the patient.

Liability for malpractice is based on proving negligence and a causal link between the negligent medical act and the damage claimed by the patient: erroneous diagnosis, delay in initiating treatment, inadequate treatment.

Lawyers may refer to nationally accepted "*medical principles*" in malpractice lawsuits, arguing that doctors who failed to follow such principles without good reason would be negligent. Malpractice claims in this category are debatable due to the fact that the principles represent the multiplicity of a situation, which tends to be different from one case to another, therefore not being standardized as valid for the entire community. Arguments: biological differences in drug metabolism, immune response, genetic endowment, comorbidities, available resources, etc.

The principles are suggestions for care, not rules for care. In evaluating the allegedly prejudicial medical act, the rule is used: "*A doctor will not be held liable if, in the exercise of his judgment, he followed a therapeutic attitude supported by a considerable number of recognized and respected professionals in the given field of competence*." The doctor does not have the obligation of the result, but he has the obligation of choosing the means, that is, he must always justify his choices and acts, depending on what is considered to be the good practice of the moment. Jurisdictions, however, are very receptive to patients' claims regarding informed consent, even if a medical error of diagnosis and treatment cannot be imputed [12].

The legal basis for the use of diagnostic and treatment guidelines in our legislation, article 655 of the Health Reform Law, which states:

"(1) *In providing medical assistance/health care, the medical staff is obliged to apply the therapeutic standards, established by practice guidelines in the respective specialty, approved at the national level, or, in their absence, the standards recognized by the medical community of the respective specialty.*

(2) *The Romanian College of Physicians will develop and submit to the Ministry of Public Health for approval the therapeutic standards, established by practice guidelines at the national level, until the entry into force of this title*."

Reporting to the therapeutic guidelines also becomes necessary in the context of litigation generated by allegations of malpractice.

For the forensic doctor who prepares the expertise required by justice, but also for the specialized referring doctor, the therapeutic protocols mark the limit between the correct medical act *vs.* the improperly rolled one. In this way, we try to achieve a high degree of objectivity. This reference to the therapeutic standards sometimes becomes subjective, being conditioned by the referent's personal assessment and his vision of the correct attitude in the case at hand.

Many times, however, the referent (especially the one with great experience and professional prestige) refers in his evaluation to his own activity, forgetting the rule mentioned above, according to which the standard of appreciation must be that of a good doctor and not of an exceptional doctor.

In situations where there are no "*practice guidelines in the respective specialty, approved at the national level*", there is a tendency to refer to the existing guidelines in other states; The interpretation becomes even more difficult, because most of the time there is no consensus between the guidelines applicable in different countries and the question obviously arises "*Which of these guidelines prevails, which is better and which should have been applied by the respondent doctor?*"

A question to which justice expects a clear, "*black or white*" answer, which cannot always be given.

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