Patient Care and Medical Decision-Making

STANDARDS OF CARE AND TREATMENT GUIDELINES

In 2011, the Institute of Medicine (IOM) defined clinical practice guidelines as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options". Clinical guidelines enable practice of evidence-based medicine (EBM)[1].

Adherence to the recommendations in clinical practice guidelines enhance quality of care by reducing likelihood of adverse events. By standardizing care, they also reduce variations in clinical practice. A survey of 3,098 general practitioners (GPs) was conducted in Germany between April and August 2020. A little over half (52%) of those surveyed held a positive attitude towards guidelines. The outcomes of compliance to guidelines were an increase in evidence-based approach (69%), standardization of diagnosis and treatment (62%) and decrease in overprovision or underprovision of care (57%). Sixty-seven percent of the GPs opined that abiding by the guidelines sharpened their clinical skills, while 62% felt that guidelines positively impacted quality of care[2].

Guidelines should be[1]:

- Developed using the best available scientific evidence,
- Developed by a multidisciplinary panel using consensus methods,
- Well disseminated, and
- Updated from time to time incorporating latest evidence.

Clinical guidelines developed by renowned professional bodies can be relied upon and may be used in medical negligence cases[3]. However, physicians are not legally obligated to follow guidelines. If they are not applicable to some patients, then doctors may choose not to follow the recommendations provided therein. However, they must justify any deviation from the guidelines[4]. The reasons for not following the recommendations must be duly recorded in the patient's medical record[5].

"The standard of care is the benchmark that determines whether professional obligations to patients have been met"[6]. Failure to provide treatment that is consistent with the standard of care is liable for negligence. The standard of care and degree of care are not synonymous. The standard of care is similar in all patients, the degree of care differs. This means that a GP and a specialist have to meet the same standard of care, but the degree of care provided by them is not the same. "The specialist is expected to exercise the ordinary skill of his speciality and not that of the GP"[7].

The Supreme Court has defined medical negligence in the case of Jacob Mathew vs. state of Punjab and Anr on 5 August, 2005 as follows:

"*The essential components of negligence, as recognised, are three: 'duty', 'breach' and 'resulting damage', that is to say:*

- *The existence of a duty to take care, which is owed by the defendant to the complainant;*
- *The failure to attain that standard of care, prescribed by the law, thereby committing a breach of such duty; and*
- *Damage, which is both causally connected with such breach and recognised by the law, has been suffered by the complainant (Para 1.23). If the claimant satisfies the Court on the evidence that these three ingredients are made out, the defendant should be held liable in negligence (Para 1.24).*"

Liability in negligence is unassailable if all the three can be established on the preponderance of probabilities (civil lawsuit) or beyond reasonable doubt (criminal prosecution). The onus of proving negligence lies on the complainant. It is just not enough to allege a breach of duty; it has to be conclusively proven that the injury occurred "directly" on account of the action of the doctor.

The Bolam test has been traditionally used to assess two main issues of medical negligence – the standard of care as required by the law and whether the doctor accused of medical negligence has complied with that standard of care.

In Jacob Mathew v. State of Punjab, the Supreme Court of India has observed: *"A simple lack of care, and error of judgment or an accident, is not proof of negligence on the part of a medical professional. So long as a doctor follows a practice acceptable to the medical profession of that day, he cannot be held liable for negligence merely because a better alternative course or method of treatment was also available or simply because a more skilled doctor would not*

have chosen to follow or resort to that practice or procedure which the accused followed. When it comes to the failure to taking precautions what has to be seen is whether those precautions were taken which the ordinary experience of men has found to be sufficient; a failure to use special or extraordinary precautions which might have prevented the particular happening cannot be the standard for judging the alleged negligence. So also, the standard of care, while assessing the practice as adopted, is judged in the light of knowledge available at the time of the incident, and not at the date of trial. Similarly, when the charge of negligence arises out of failure to use some particular equipment, the charge would fail if the equipment was not generally available at that particular time (that is, the time of the incident) at which it is suggested it should have been used."

Errors can be made in an Emergency even by Experts and may not Amount to Negligence

In Martin F. D'Souza vs. Mohd. Ishfaq on 17 February, 2009, the cases Supreme Court of India has observed: *"The higher the acuteness in an emergency and the higher the complication, the more are the chances of error of judgment …."*

Medical Accident is not Negligence

In Jacob Mathew v. State of Punjab, the Supreme Court of India has observed: *"Mere accident is not evidence of negligence."* The order also clarifies that the difference of opinion or error of judgment cannot be termed negligence, also adverse reactions or medical accidents cannot be classified under medical negligence.

"Not Getting Cured" is not Negligence

In Jacob Mathew v. State of Punjab, the Supreme Court of India has observed: "*Simply because a patient has not favourably responded to a treatment given by a physician or a surgery has failed, the doctor cannot be held liable per se by applying the doctrine of res ipsa loquitur.*"

Error of Judgment is not Negligence

In Jacob Mathew v. State of Punjab, the Supreme Court of India has observed: "*An error of judgment on the part of a professional is not negligence per se.*"

Wrong Diagnosis does not Amount to Medical Negligence

In the matter of Vinod Jain vs. Santokba Durlabhji Memorial Hospital & Anr (Civil Appeal No. 2024 of 2019 Arising out of SLP(C) No. 32721/2017, dated February 25, 2019), the Supreme Court upheld the order of the National Consumer Disputes Redressal Commission (NCDRC), which had held that the case "would at best be a case of wrong diagnosis, but not medical negligence".

"Deviation from normal practice is not necessarily evidence of negligence. To establish liability on that basis, it must be shown:

1. *That there is a usual and normal practice;*
2. *That the defendant has not adopted it; and*
3. *That the course adopted is no professional man of ordinary knowledge skill would have taken had he been acting with ordinary care."*

In the judgment in Kusum Sharma & Ors vs. Batra Hospital and Medical Research Centre & Ors on 10 February, 2010, the Supreme Court observed that *"while deciding whether the medical professional is guilty of medical negligence following well known principles must be kept in view.*

I. *Negligence is the breach of a duty exercised by omission to do something which a reasonable man, guided by those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do.*

II. *Negligence is an essential ingredient of the offence. The negligence to be established by the prosecution must be culpable or gross and not the negligence merely based upon an error of judgment.*

III. *The medical professional is expected to bring a reasonable degree of skill and knowledge and must exercise 4 (1968) 118 New LJ 469 5 (supra) a reasonable degree of care. Neither the very highest nor a very low degree of care and competence judged in the light of the particular circumstances of each case is what the law requires.*

IV. *A medical practitioner would be liable only where his conduct fell below that of the standard so far reasonably competent practitioner in his field.*

V. *In the realm of diagnosis and treatment there is scope for genuine difference of opinion and one professional doctor is clearly not negligent merely because his conclusion differs from that of other professional doctor.*

VI. *The medical professional is often called upon to adopt a procedure which involves higher element of risk, but which he honestly believes as providing greater chances of success for the patient rather than a procedure involving lesser risk but higher chances of failure. Just because a professional looking to the gravity of illness has taken higher element of risk to redeem the patient out of his/her suffering which did not yield the desired result may not amount to negligence.*

VII. Negligence cannot be attributed to a doctor so long as he performs his duties with reasonable skill and competence. Merely because the doctor chooses one course of action in preference to the other one available, he would not be liable if the course of action chosen by him was acceptable to the medical profession.

VIII. It would not be conducive to the efficiency of the medical profession if no doctor could administer medicine without a halter round his neck.

IX. It is our bounden duty and obligation of the civil society to ensure that the medical professionals are not unnecessarily harassed or humiliated so that they can perform their professional duties without fear and apprehension.

X. The medical practitioners at times also have to be saved from such a class of complainants who use criminal process as a tool for pressurizing the medical professionals/hospitals particularly private hospitals or clinics for extracting uncalled for compensation. Such malicious proceedings deserve to be discarded against the medical practitioners.

XI. The medical professionals are entitled to get protection so long as they perform their duties with reasonable skill and competence and in the interest of the patients. The interest and welfare of the patients have to be paramount for the medical professionals."

CLINICAL DECISION-MAKING AND EVIDENCE-BASED MEDICINE

Evidence-based medicine has been the cornerstone of clinical decision-making for several years now. It is defined as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." EBM is an amalgamation of up-to-date research and clinical decision-making leading to better patient outcomes. It also takes into consideration patient's values such as autonomy and what is available and affordable for a particular patient.

While knowledge undoubtedly aids in accurate clinical decision-making, experience makes the process more efficient. "EBM should be used to guide, and not replace, clinical decision-making"[8].

There are two stages in clinical reasoning[9].

- **Early stage:** Developing one or more diagnostic hypotheses.
- **Verification stage:** Testing the hypotheses generated and confirming the final diagnosis.

The dual process theory of cognition is an interplay of two systems of thinking. One which is intuitive, fast and almost unconscious thinking, called "system 1 thinking", while the other is slower, analytical and effortful thinking called "system 2 thinking". Both systems of thinking are implicated in both stages of clinical reasoning[9]. This dual system also applies to decision-making in clinical medicine[10].

Clinical Decision-making Checklist[9]

Taking the history	Ordering investigations
Performing the physical examination	Formulating a diagnosis
Generating a differential diagnosis	Documenting decisions

The process of confirming a diagnosis entails the following steps[10]:

- **Information gathering:** "It is a capital mistake to theorize before one has data", said Sherlock Holmes. Appropriate information must be gathered from the history, physical examination, including laboratory/imaging investigations before reaching to a conclusion. One should stay alert so as to not miss findings on history and physical examination that may turn out to be significant.
- **Hypothesis generation:** A list of differential diagnoses corresponding to the patient's illness is worked out.
- **Hypothesis testing and reflection:** The hypothesis that is generated must be examined and discarded, if appropriate.

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Treatment of Post-Kidney Transplant Osteoporosis

Denosumab is effective in increasing bone mineral density (BMD) and reducing fracture risk in kidney transplant recipients with osteoporosis, according to a retrospective study from Italy published May 10, 2024 in the journal *Calcified Tissue International*[1]. It was also safe with no significant adverse effects attributable to it on kidney function or graft survival.

The study objective was to evaluate the long-term effectiveness of denosumab in improving BMD in kidney transplant recipients with osteoporosis and compare these outcomes with those not receiving any treatment for osteoporosis. BMD was measured at the femoral neck, lumbar spine and hip using dual-energy X-ray absorptiometry scans at baseline and at regular intervals during follow-up.

The study included 46 patients who had received a kidney transplant and had osteoporosis. Denosumab was administered subcutaneously in the dose of 60 mg/6 months to this study group of 23 patients. They were matched 1:1 with a group of 23 age- and sex-matched untreated kidney transplant recipients, which acted as the control group. All patients were given oral cholecalciferol and calcium supplementation. Data on serum creatinine, alkaline phosphatase (ALP), 25-hydroxyvitamin D and parathyroid hormone (PTH) were also collected. The primary outcome was changes in the BMD at 4 years.

In the denosumab-treated group, there was a significant increase in BMD from baseline, with an average increase of 9.0% at the lumbar spine. The total hip BMD increased by an average of 3.8%. On the other hand, there was a significant decrease in BMD at all sites in the untreated group. The lumbar spine and total hip BMD decreased by an average of −3.0% and −6.3%, respectively. The differences in percent BMD changes between the denosumab-treated and untreated groups were statistically significant at all measured sites. “Similar results were found for the respective Z-scores”, state the authors.

In the denosumab-treated group, ALP serum levels significantly decreased from baseline. The between-group difference in ALP changes was statistically significant. Both groups maintained normal levels of PTH and 25-hydroxyvitamin D. No significant differences in serum creatinine levels, incidence of hypocalcemic events and acute graft rejection rates were observed between the denosumab-treated and untreated groups.

These findings suggest that denosumab is a beneficial treatment for osteoporosis in kidney transplant recipients, contributing to improved bone health and potentially reducing the risk of fractures. It was also safe in terms of kidney function and graft survival. This supports the consideration of denosumab as a standard viable treatment option in managing osteoporosis in this group of patients, alongside calcium and vitamin D supplementation.

Reference

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