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UNRAVELING MEDICO-LEGAL LITIGATION IN INDIA: MEDICAL NEGLIGENCE

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DIAGNOSTIC ERRORS:

Defining diagnostic errors in primary care involves the correct and timely identification of patients' health problems, which relies on the expertise of healthcare providers and available resources. However, the complexity of clinical presentations and the high number of patients seen in primary care make it a high-risk area for errors. A diagnostic error occurs when a diagnosis is missed, delayed, or incorrect[2]. This can take various forms, such as overlooking a condition despite evident symptoms, providing the wrong diagnosis, or not communicating abnormal test results to the patient. These errors can occur at different stages of the diagnostic process, from initial assessments to follow-up and communication. Diagnostic errors represent missed opportunities to provide accurate and timely diagnoses based on available evidence. They can result from cognitive or system-related factors. To avoid hindsight bias, it is essential to identify evidence of omission or commission at the time the error occurred. Defining diagnostic errors in primary care involves the accurate and timely identification of patients' health problems, which heavily relies on the expertise of healthcare providers and the resources available to them. However, the intricate clinical presentations and the high patient volume in primary care create a high-risk environment for errors. A diagnostic error occurs when a diagnosis is either missed, delayed, or incorrect. These errors can manifest in various ways, such as overlooking a condition despite clear symptoms, providing an inaccurate diagnosis, or failing to communicate abnormal test results to the patient. Such errors can happen at any stage of the diagnostic process, from initial assessments to follow-up and communication. Diagnostic errors signify missed opportunities to provide precise and

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[2] Graber ML, Franklin N, Gordon R. Diagnostic error in internal medicine. Arch Intern Med. 2005;165(13):1493-9. (Last accessed on 11.07.2023 at 11.00 am).

timely diagnoses based on the available evidence[3]. They can stem from both cognitive and system-related factors[4]. To avoid hindsight bias, it is crucial to identify evidence of omission or commission at the specific time the error occurred.

Causes of diagnostic errors : Key factors

The diagnostic process is susceptible to errors in various aspects. Studies investigating diagnostic errors often reveal several root causes in each case. These causes may include cognitive errors, such as failing to properly synthesize available evidence or misusing physical examination or test data. In fact, evidence suggests that cognitive errors can be identified in over half of the cases involving diagnostic errors. Additionally, system flaws can contribute to diagnostic errors due to issues with communication or care coordination, problems with accessing medical record data, and insufficient access to specialists. A study conducted in a developed country found that process breakdowns were most frequently associated with the patient-practitioner clinical encounter (79%), followed by referral problems (20%), patient-related factors (16%), follow-up and tracking of diagnostic information (15%), and performance and interpretation of diagnostic tests (14%). Interestingly, almost half of all diagnostic errors involved more than one of these processes. The breakdowns in the patient-practitioner encounter were primarily related to problems with history-taking (56%), examination (47%), or ordering diagnostic tests for further evaluation (57%)[5].

The following factors can cause diagnostic process errors:

1. **Care coordination:** Delays in consultations, misplaced test findings, or insufficient patient care documentation can all result in mistakes.
2. **Follow-up:** Poor follow-up might impede the development of diagnostic impressions and lead to the loss of chances for a precise diagnosis.
3. **Healthcare affordability:** Delaying or neglecting necessary medical care may result from prioritizing other fundamental requirements or from inability to afford healthcare.

[3] Singh H, Giardina TD, Meyer AND, Forjuoh SN, Reis MD, Thomas EJ. Types and origins of diagnostic errors in primary care settings. JAMA Intern Med. 2013;173(6):418-25. (Last accessed on 11.07.2023 at 11.22 am).
[4] Singh H, Meyer and Thomas EJ. The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations. BMJ Qual Saf. 2014;23(9):727-31. (Last accessed on 11.07.2023 at 11.32 am).
[5] https://apps.who.int/iris/bitstream/handle/10665/252410/9789241511636-eng.pdf

4. **Healthcare provider education:** Diagnostic accuracy can be impacted by inadequate training, particularly when clinical reasoning is not stressed enough, as well as by flaws in certification and license standards.
5. **Resources for health informatics are accessible:** Healthcare professionals may struggle to get essential information if they have limited access to health informatics resources, such as the internet or medical information, especially in rural locations.
6. **Culture:** Diagnostic errors may be influenced by punitive environments that hinder collaboration and learning, as well as physician-centric systems that downplay teamwork. Some patients might feel more comfortable receiving care in a passive manner.
7. **Human factors and cognitive problems:** Errors in the diagnostic process can be caused by interruptions, disruptions, and the disorder of information in the work environment and systems[6].

Overall, it seems that the most common types of hazardous diagnostic mistakes in primary care include missed diagnoses of cancer, infections, and cardiovascular disease. These are each briefly discussed in turn.

CANCER:

In many nations around the world, cancer has a large economic impact. Cancer diagnosis that is postponed is dangerous and expensive. It can be difficult to diagnose cancer, in part because many tumours might present to primary care doctors with vague symptoms. However, initiatives to promote diagnosis through screening may unintentionally result in the identification of tumours that are benign or dangerous and may not require severe treatment.

INFECTIONS:

Both more dangerous diseases and self-limiting infections frequently have diagnostic blunders. Antibiotics are sometimes used unnecessarily because viral illnesses are frequently misinterpreted as bacterial infections. The lack of specificity in crucial

[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779963/

symptoms like fever might make malaria diagnosis challenging[7]. The failure to apply fundamental diagnostic tools, including microbiology or imaging, and incorrect interpretation of test results may result in the misdiagnosis of nearly 10% of tuberculosis cases[8]. Pediatric pneumonia, diarrheal dehydration, and malaria diagnoses are frequently subpar on a global scale[9].

A CARDIOVASCULAR CONDITION:

A delayed diagnosis of cardiovascular problems can happen in both children and adults, which could impair clinical results. When modest premonitory symptoms are ignored or neglected in primary care, errors may result. It is necessary to correctly diagnose and treat risk factors or predisposing illnesses, such as diabetes, hypertension, and excessive cholesterol levels, in order to identify those for whom primary or secondary prevention is required.

PAEDIATRICS:

The almost 7 million children who pass away each year worldwide, primarily from preventable causes, may be affected by misdiagnoses[10]. There is not much information available, though, about pediatric misdiagnosis. Meningitis, gastroenteritis, pneumonia, appendicitis, sepsis, and cancer were common illnesses that led to claims in children[11].

CONSENT AND INFORMED CONSENT: EXAMINING THE IMPORTANCE OF PATIENT AUTONOMY:

Prior patient consent is required by hospitals and doctors:

[7] Leslie T, Mikhail A, Mayan I, Cundill B, Anwar M, Bakhtash SH, et al. Rapid diagnostic tests to improve treatment of malaria and other febrile illnesses: patient randomised effectiveness trial in primary care clinics in Afghanistan. BMJ. 2014;348:g3730. (Last accessed on 11.07.2023 at 12.00 pm).
[8] Szczuka I, Pawlicka L, Kus J, Leowski J, Roszkowski K. Analysis of diagnostic errors and recommendations of diagnostic procedures in bacteriologically negative pulmonary tuberculosis. PneumonolAlergol Pol. 1998;66(1-2):17-23. (Last accessed on 11.07.2023 at 12.10 pm).
[9] Liu L, Johnson HL, Cousens S, Perin J, Scott S, Lawn JE, et al. Global, regional, and national causes of child mortality: an updated systematic analysis for 2010 with time trends since 2000. Lancet. 2012;379(9832):2151-61 (Last accessed on 11.07.2023 at 12.10 pm).
[10] Levels and trends in child mortality, estimates developed by the UN inter-agency group for child mortality estimation. New York: United Nations Children's Fund; 2014. (Last accessed on 11.07.2023 at 12.15 pm).
[11] Wallace E, Lowry J, Smith SM, FaheyT. The epidemiology of malpractice claims in primary care: a systematic review. BMJ Open. 2013;3(7):e002929. (Last accessed on 11.07.2023 at 12.15 pm).

Patients must give consent before they are utilized for a multitude of purposes, such as diagnosis, treatment, organ transplant, research, disclosure of medical information, instruction, and medico-legal ones. For pathological post mortems, medico-legal post mortems, organ transplants (for legal heirs), and disclosure of medical information involving deceased patients, consent is required. There are various ways to grant consent:

Express Consent: It may be given verbally or in writing, but written consent has stronger probative value. Consent that is implied can be deduced from a patient's actions. Without being overtly stated, tacit permission is acknowledged. Courts have determined that consent from family members, combined with the written endorsement of two doctors, is sufficient to safeguard a patient's interests. Surrogate Consent: Given by family members.

In contrast to proxy consent, which is granted on behalf of the patient, advance consent is provided in advance by the patient. It is preferable to obtain permission that has been fully informed of all potential dangers and negative effects.

Getting Informed Consent and Its Importance:

The need of gaining informed permission was underlined by a famous case, **Samira Kohli vs. Dr. Prabha Manchanda and Ors. (2008)**[12]. According to the court's decision, implied consent does not apply to more involved surgeries when performing diagnostic or surgical treatments. Without a medical emergency, consent must be secured from responsible adults, and choices made on behalf of patients should never be taken without proper consent. Any procedure for which consent is not obtained is seen as an illegal intrusion into the patient's body. The Consumer Protection Act (CPA) covers medical professionals and hospitals.

The Indian Medical Association v. V.P. Shanta and Ors. (1995)[13]case established that the medical industry is covered by the Consumer Protection Act, 1986. This ruling eliminated any uncertainty by establishing that all patients, even those receiving free care, are customers as long as they pay for any additional medical services. The court understood that even with adequate care and treatment, a small proportion of patients would not respond well, and ex gratia payments should not be made to medical staff members. In several significant cases, the National Commission has also accepted the likelihood of hospital deaths occurring without wrongdoing.

[12] I (2008) CPJ 56 (SC)
[13] III (1995) CPJ 1 (SC)

The following five conditions must be met in order to gain informed consent for medical operations or research: The patient or subject must meet the following requirements:

a) they must be able to understand and make decisions;
b) they must receive full disclosure of all material information;
c) they must comprehend the information revealed;
d) their decision must be voluntary; and
e) they must consent to the intended action.

With recommendations to create a set of rules that respect the cultural norms of other countries, these strongly ingrained western requirements have encountered some pushback. It has been suggested that there should be a core set of human rights that are upheld worldwide, regardless of changes in surface elements, in order to defend the universal applicability of the five conditions. One of these basic rights is the right to self-determination, which forms the basis of the informed consent theory.

Since competency is the primary prerequisite for informed consent, determining incompetence is essential. The patient's incapacity to articulate a preference or choice, appreciate their condition and its repercussions, and rationally consider significant life decisions are frequently the basis for accepted standards for determining incompetent.

A patient's previously indicated preferences or autonomous judgments should be respected in situations where they become incompetent. A surrogate decision-maker is necessary for non-autonomous individuals as well as patients who were competent in the past but are now incapable. The surrogate may apply a best interests standard, which compares risks and benefits to decide what would benefit the patient most overall, or a substituted judgment standard, which is based on what the patient would want in the current situation.

Using "substituted interests" is a useful and advantageous solution when the surrogate is unsure of the patient's preferences or when the patient's choices have not kept up with scientific advancements. As mentioned by Snyder and Sulmasy[14] in their informative paper, this strategy entails taking the patient's genuine values and interests into account while making the choice.

[14]Sulmasy DP, Snyder L. Substituted interests and best judgments: an integrated model of surrogate decision making. JAMA. 2010 Nov;304(17):1946–7. https://doi.org/10.1001/jama.2010.1595[PubMed]0098-7484

MISDIAGNOSIS AND DELAYED DIAGNOSIS: IMPACT ON PATIENTS AND LEGAL IMPLICATIONS IN INDIA:

With far-reaching effects for patients and medical professionals, misdiagnosis and delayed diagnosis remain serious problems in the Indian healthcare system. More information on the effect on patients and the legal ramifications in India may be found here:

Patient's Experience:

a) **Patient Suffering:** Patients may experience prolonged suffering as a result of misdiagnosis and delayed diagnosis, if their medical conditions go untreated or are not properly managed.
b) **Disease Progression:** Delays in diagnosis can cause diseases to advance, which can make treatment more challenging and perhaps lower the likelihood of success.
c) **Psychological Effect:** Due to ambiguity regarding their health issues and the need for more tests or treatments, patients may experience emotional anguish and worry.
d) **Financial Burden:** Patients may have many tests and treatments before receiving a correct diagnosis, which can lead to excessive medical expenses as a result of misdiagnosis and delayed diagnosis.
e) **Loss of Productivity:** Patients who suffer from chronic sickness or disabilities brought on by a delayed diagnosis may experience a loss in productivity.

Occurrence and Root Causes:

a) **Restricted Access to Advanced Diagnostic Facilities:** Diagnostic difficulties are caused by restricted access to advanced diagnostic equipment and medical specialists in many parts of India.
b) **Doctor-patient ratio:** India has a severe doctor shortage, which increases the workload for healthcare professionals and raises the possibility of incorrect diagnoses.
c) **Lack of Awareness:** Patients may be unaware of their medical concerns or put off seeking care, which can prevent early diagnoses from occurring.

Legal repercussions:

a) **Medical Negligence Claims:** Hospitals and healthcare providers may be held liable for damages suffered by patients as a result of delayed or incorrect diagnoses.

b) **Compensation:** Paying compensation to the injured patient may be mandated by a court if it determines that a hospital or healthcare provider was careless in making their diagnosis.

c) **Disciplinary Actions:** If a healthcare professional is proven to have committed medical negligence, regulatory organizations like the Medical Council of India (MCI) may initiate disciplinary action against them.

Case Studies:

A case of misdiagnosis involving a patient who received needless therapies after receiving a false cancer diagnosis in Rajasthan in 2019 came to light. The patient's family reported the hospital for medical malpractice. In another instance, a woman in Tamil Nadu underwent surgery to remove a fictitious tumour following a false positive diagnosis. The family complained to the consumer court and requested compensation.

Considering Expert Testimony:

Expert medical testimony is vital in determining whether the healthcare provider acted carelessly and violated the standard of care in medicolegal situations involving misdiagnosis and delayed diagnosis.

Observations for Development:

a) **Strengthening Medical Education:** Increasing medical education and training can help healthcare practitioners become more adept at making diagnoses.

b) **Access to healthcare:** Access to specialized healthcare services in rural places can be improved with the use of telemedicine and remote consultations.

c) **Improved Patient Education:** Teaching patients the value of prompt medical advice and the early identification of symptoms can help with early diagnosis.

It is critical to understand that, despite healthcare professionals' best efforts, misdiagnosis or delayed diagnosis may happen because medical practice is a complicated discipline. Nevertheless, ongoing initiatives to enhance patient education, medical awareness, and access to cutting-edge diagnostic tools can aid in lowering such occurrences and enhancing patient outcomes.

CONFIDENTIALITY:

A doctor's demand for privacy is not just mandated by an ethical or moral norm. There is also a therapeutic perspective. Without privacy, a patient would put off disclosing facts they deemed embarrassing or humiliating. A patient would not believe the doctor as a result. As a result, the patient's care would suffer because the doctor would not have access to all the information necessary to manage the patient. Therefore, a doctor is required to maintain patient information's confidentiality.

Exceptions in Maintaining Confidentiality:

A registered doctor shall not reveal patient's secret that he gained during the treatment except under the following circumstances:

a) In a court of law, as directed by the presiding judge. when there is a significant and clearly defined risk to a specific person or community.
b) In the event of Notifiable Illnesses.
c) Only those healthcare personnel who need to know about the patient's treatment are given access.
d) To the patient's friends and immediate family only if withholding the information could endanger them.
e) Only report it to public authorities if it has to do with infections.
f) A licensed physician is not permitted to expose or publish a patient's images or case reports in any medical journals or media that could reveal the patient's identify without the patient's agreement. If the patient's name is kept a secret, consent is not required.
g) Insurance provider, place of employment, or health care management.

Avoiding Common Errors in Confidentiality Maintenance:

a) No competent adult should ever divulge their confidential information to their parents, husband, or wife.
b) Only with the patient's explicit agreement may medical records be given to another physician or facility.
c) The blood donor's identity should not be made public
d) The hospital staff must make sure that no other person receives access to patient information.

Privacy in the context of medicolegal cases:

Medical-legal reports have occasionally been used as evidence by law enforcement agencies like the police. The doctor-patient relationship is not appropriate in these circumstances. Therefore, without the patient's permission, the report may be forwarded to the proper authority. However, it is also required to maintain the confidentiality of medicolegal reports.

a) Medical-legal reports are not required to be shared with anybody but the requesting legal authority; this includes neither the patient nor the victim.
b) A clear written agreement from the asking authority is essentially required for anyone other than the seeking authority to get medicolegal reports.
c) the requirement by law to disclose privileged and confidential information in court.
d) Confidential information differs significantly from privileged information.
e) Without the owner's express written authorization, no one may divulge privileged information, not even in court. Confidential information is that which is privileged.
f) Though not all privileged information is confidential.

The Indian Evidence Act of 1872 states that only two types of information are confidential between a lawyer and a client, as well as between a husband and wife.

a) A doctor called as a witness in a legal proceeding cannot assert a privilege not to divulge private information provided by the patient. A doctor must now comply with court demands to divulge private information.
b) The doctor is not legally responsible to the patient for disclosing such private information in such circumstances.

Details Regarding Dead Patients:

Before providing information on a deceased patient to an insurance company or TPA, the doctor should obtain consent from the patient's executor or heirs. Doctors have a moral and legal obligation to do this.

- **No Overly Detailed Disclosures Are Allowed**

  The doctor or hospital must make sure that there is no excessive disclosure of information that is likely to be confidential in nature when information is disclosed to

other parties, with or without the patient's consent. Only those who need to know must be provided with pertinent and necessary information.

- **How HIV patient confidentiality is preserved:**
  a) Doctors are required to maintain a higher level of confidentiality with patients with AIDS or HIV.
  b) HIV positive diagnoses must be kept private. Doctors should refrain from making patient identities public.
  c) Such patients' medical records must be kept segregatedly. Only other healthcare professionals and the patient's sexual partner should have access to their medical information, and even then, only on a need-to-know basis as they are most likely to interact with them.
  d) Without receiving official confirmation, the patient's sero-positive status should not be disclosed to his or her sex partner. Only after receiving the patient's written consent can information be provided.
  e) Prior to informing the patient's sexual partner of their HIV/AIDS status, doctors should first attempt to persuade the patient to do so willingly. The doctor is required to tell the patient's sexual partner about their HIV status if the patient declines to do so. This medical practice is protected by the law.

If the diagnosis is provisional and not final, though, is unclear. Obtaining the patient's consent to disclose this fact is the best course of action in such a circumstance. Not telling a patient after a tentative diagnosis is equivalent to endangering the patient's sexual partner.

A doctor's obligation to their patients:

Since the time of Hippocrates, maintaining patient anonymity has been a cornerstone of medical ethics. Physicians have a duty to fulfil this obligation. According to the Hippocratic Oath, "I will keep to myself, considering such things shameful to be spoken about, whatever I may see or hear regarding the life of men during the course of the treatment or even outside of the treatment.[15]"

[15] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3032388/

The World Medical Association's Geneva Declaration states, "I will respect the secrets which are confided in me, even after the patient has passed away.[16]"

The WMA Declaration on Patients' Rights states[17]:

Even after a patient has passed away, all identifiable information on their health state, medical condition, diagnosis, prognosis, and course of treatment must be kept private. Particularly, the descendants might be entitled to information that would warn them of the health hazards they face.

a) Only the patient's express consent or situations where it is expressly permitted by law may allow for the disclosure of confidential information. Unless the patient has expressly consented, information can only be disclosed to other healthcare providers on a strictly "need to know" basis.
b) All individually identifiable patient data must be protected. The information's security needs to match the way it is being stored. Additionally, human chemicals that can be used to deduce personally identifiable information must be secured.

According to the WMA Declaration, there are some exceptions to the need to maintain confidentiality. Doctors, nurses, research facility workers, students, and others need access to a patient's medical information in order to properly care for the person as well as for students to learn about and practice medicine. There is a need for mediators to promote communication when patients and carers speak different dialects .It is necessary to provide others with knowledge about patients who lack the capacity to make therapeutic decisions on their own so they can act in their best interests and provide for them. The cause of death is frequently disclosed to the patient's family by the doctor; however, these disclosures should be kept to a minimum, and anyone with access to confidential information should be reminded not to share it unless it is absolutely necessary for the patient or their descendants to do so. Privacy is violated to meet legal requirements. For instance, many jurisdictions have legislation requiring the mandatory notification of patients with specified diseases, those who are deemed unfit to drive, and anyone who are suspected of abusing children.

Transparency and Privacy:

[16] https://www.wma.net/policies-post/wma-declaration-of-geneva/
[17] https://social.un.org/ageing-working-group/documents/tenth/Inputs%20NGOs/WMA_UN%20palliative%20care%20WG_final.pdf

In many domestic laws, the concept of "privacy" is primarily used to refer to the basis of the fiduciary relationship between a patient and a doctor. The Indian Medical Council Act of 1952, notably section 20(A) of the Act, which lays down the code of ethics that a doctor must always abide by, serves as the foundation for this fiduciary relationship, which arises from a fair expectation of mutual trust between the doctor and his patients. Informational privacy (such as confidentiality, anonymity, and data security), physical privacy (such as modesty and bodily integrity), associational privacy (such as intimate sharing of illness, death, and recovery), proprietary privacy (such as self-ownership and control over personal identifiers, genetic information, and body tissues), and decisional privacy (such as a patient's right to informed consent) are just a few examples of the complex issues surrounding privacy in healthcare. National standards for ethical conduct in scientific and health research involving human subjects. A person's right to privacy is their ability to decide how, by whom, and with whom their personal information is collected, maintained, and shared. The researcher, study team, or organization has a duty of confidentiality to the participant in order to safeguard the information that has been given to them. It also entails a promise to safeguard information against unauthorized access, use, disclosure, alteration, loss, or theft.

The researcher must uphold rigorous and absolute confidentiality of the research-related data of participants and the community, and participants must be made aware of any potential restrictions. Prospective participants must be made aware that while every attempt will be made to maintain confidentiality and preserve privacy, in some cases it may not be practical to do so. The privacy of the persons should be protected in any publication resulting from research by ensuring that their images or any other material that could expose their identity is not released without their prior agreement. Certain details, such as HIV status, sexual orientation, such as lesbian, gay, bisexual, and transgender (LGBT), genetic information, or any other sensitive details, may be delicate and should be protected to avoid stigmatization and/or prejudice. Encrypting or anonymizing personal information is crucial when conducting research with biological samples or medical records/data that have been gathered, and this helps to restrict access to both the samples and the records.

The Ethics Committee may authorize the disclosure of a participant's or community's data under certain specific conditions, such as when a court has issued specific orders, when there is a threat to an individual's or group's safety that would take precedence over privacy rights, when there are other serious adverse events (SAEs) that must be reported to the relevant

regulatory authority, etc. When a patient was diagnosed with HIV, the doctor might not have violated either the rule of confidentiality or the patient's right to privacy because the woman the patient was likely to marry was prevented from contracting the disease in time by the disclosure, or else she would have been exposed to it had the marriage taken place and been consummated.

X vs. Hospital Z[18]:

X filed a lawsuit against Hospital Z, claiming that they had violated his right to privacy by telling his fiancée that he was HIV-positive. Doctors have an ethical and moral duty to uphold confidentiality because it is the foundation of the doctor-patient relationship. Medical workers must likewise uphold confidentiality, according to the 2002 Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations. The RTI Act's Section 8(1)(e), which permits the refusal of third parties' medical records, serves as additional support for this.

Raghunath Raheja v the Maharashtra Medical Council[19]:

The Maharashtra Medical Board and the State of Maharashtra have been given instructions by the court in its order, and it has been noted that hospitals or doctors cannot claim any secrecy or confidentiality regarding copies of the case papers relating to the patient, and that they must be made available to him upon request after payment of the customary fees.

Radiological & Imaging Association v Union of India[20]:

After careful consideration of the facts, it was decided that neither the patient's right to privacy nor the doctor's duty of secrecy had been violated. Furthermore, it was noted that the public interest must limit or restrict the right to privacy and that it should follow each PNDT rule's provision.

Mr SurupsinghHrya Naik v. State of Maharashtra[21], 23 march, 2007

The Medical Council Code of Ethics and the Right to Information Act of 2005 were in question in this case. In this instance, it was investigated whether it would be against the right to privacy to make the health records public under the Right to Information Act. As a result,

[18] (2003) 1 SCC 500
[19] AIR 1996 Bom 198
[20] WRIT PETITION NO. 797 OF 2011
[21] AIR 2007 Bom 121

in this instance, the Medical Council Code of Ethics can be superseded by the Right to Information Act. The rules and precedents governing medical negligence in many nations are illustrated by these few examples. However, the fundamental concepts of responsibility, openness, and patient-centred care are universal[22]. The specific legal requirements and standards of care may differ depending on the jurisdiction.

Sharda v Dharmpal[23]:

A husband claimed that his wife had a mental illness in order to apply for divorce. The spouse was had to go through a medical checkup in order to prove this fact. She argued that doing so against her will would be a violation of her personal freedom. The Court decided that the lack of such information would make it impossible to render a conclusion on the case's facts after stating that the "right to privacy" is not an absolute right.

Z v Finland[24]:

The publication of a woman's medical records—revealing her HIV status—during the trial of her spouse for the rape of other women was deemed a violation of her rights and freedom by the European Court of Human Rights.

The Tarasoff Case, **Tarasoff v. Regents of the University of California[25]:**

A therapist failed to alert possible victims of her patient's aggressive intentions in the Tarasoff case. After the patient killed a lady, the victim's family filed a lawsuit against the university and the therapist. The court found that if mental health doctors think their patient poses a severe threat of violence, they have a duty to defend possible victims. This obligation may call for alerting legal enforcement or warning possible victims. The "duty to warn" or "duty to protect" doctrine in mental health law was founded by this decision.

MEDICAL NEGLIGENCE:

Medical negligence is a legal term that describes a scenario in which a healthcare provider or professional violates their duty of care to a patient, causing the patient harm or injury. The

[22] Subrahmanyam BV. Allahabad, India: Law Publishers; 2011. Medical Jurisprudence and Toxicology; pp. 651–75.
[23] AIR 2003 SC 3450,
[24] (1998) 25 EHRR 371 97/10
[25] 17 Cal. 3d 425

respondent in the matter of **Poonam Verma v. Ashwin Pateland others**[26] held a diploma in homoeopathic medicine, and he gave certain allopathic medications to a patient who had a high fever. The patient was then moved to a nursing home, where he passed away. The respondent was found responsible by the court because he was licensed to practice homoeopathy but not under the allopathic system, and because his activities constituted medical malpractice. Also defined by the Supreme Court is "medical negligence."

a) There are many different ways that medical malpractice can happen, such as erroneous or delayed treatment, misdiagnosis, and failure to give necessary care.
b) Medical negligence is typically regarded as a civil wrong, and plaintiffs may seek compensation for damages such as medical expenses, lost wages, and pain and suffering.
c) To establish medical negligence, the plaintiff must show that the healthcare professional or provider violated their duty of care by failing to provide a standard of care that a reasonably competent professional would have provided in similar circumstances.

Medical negligence is when a medical professional or healthcare provider fails to give a patient the proper treatment, which leads to harm or injury. various jurisdictions may have various standards of care and legal requirements for demonstrating negligence, and legal rules governing medical negligence vary from one jurisdiction to another.

The supreme court made the following observations regarding medical malpractice: An "offense" is negligence. When a doctor first enters the field of medicine, they have a responsibility to use reasonable caution and skill. A medical professional's implied pledge to utilize a fair, reasonable, and competent level of skill is referred to this.

Here are some instances of medical malpractice:

a) incorrect medication administration.
b) carrying out the incorrect or unsuitable kind of surgery.
c) failing to offer sound medical counsel.
d) keeping a sponge, bandage, or other foreign object inside the patient's body following surgery.

[26] 1996 AIR 2111,

Indian cases:

a) **Bolam v. Friern Hospital Management Committee (1957)[27]:** This case established the reasonable man test, which states that a doctor is not negligent if they acted in accordance with a practice that is accepted as appropriate by a responsible body of medical opinion.

b) **Spring Meadows Hospital v. Harjol Ahluwalia (1998)[28]:** This case established that medical facilities can also be held accountable for medical malpractice perpetrated by their personnel and that these facilities must have adequate measures in place to guard against and address medical errors.

c) **Jacob Mathew v. State of Punjab (2005)[29]:** In this case, the Supreme Court of India ruled that even if a medical procedure was carried out correctly, a practitioner might still be held accountable for medical negligence if they neglected to explain to the patient the dangers and treatment options.

International Case Laws:

a) **Roe v. Ministry of Health (1954)[30]:** This case in the United Kingdom created the tenet of res ipsa loquitur, or "the thing speaks for itself," which is Latin for "the thing speaks for itself." According to this theory, a plaintiff can prove negligence in a medical negligence lawsuit by demonstrating that the defendant had control over the event that led to the harm or injury and that it would not have happened without carelessness.

b) **Canterbury v. Spence (1972)[31]:** This case in the US introduced the idea of informed consent, which mandates that medical professionals must advise their patients of the advantages and drawbacks of a procedure as well as any available alternatives before getting their approval to proceed.

c) **Rogers v. Whitaker (1992)[32]:** In this Australian case, the court determined that a physician could be held accountable for failing to disclose a material risk to a patient,

[27] [1957] 1 WLR 582
[28] 1998(2) SCALE 456 (SC)
[29] AIR2005SC3180; (2005)6SCC1; 2005CriLJ3710
[30] [1954] 2 All ER 131
[31] 464 F.2d. 772, 782 D.C. Cir. 1972
[32] (1992) 175 CLR 479

even if the risk was negligible, and that the patient had the right to make an educated decision about their course of treatment based on all available information.

THE ESSENTIALS OF MEDICAL MALPRACTICE:

The legal criteria that must be met in order to prove medical negligence are referred to as the "essentials of medical negligence." The following are the main aspects of medical negligence, but they differ slightly from nation to nation:

- **Obligation to care :** Medical personnel are legally obligated to treat their patients with a specific standard of care under the concept of duty of care. What a reasonably prudent healthcare expert would do in the same or similar situations serves as the basis for determining this standard of care. A duty of care violation could occur from failing to uphold this standard of care.

  e.g., A patient with acute chest pain attends the emergency room of a hospital. The on-call medical practitioner has a responsibility to give the patient the best standard of care possible, which includes doing a complete assessment, requesting the required tests, and administering the right treatments. A healthcare provider may violate their duty of care to the patient if they fail to deliver this level of care.

  In the 2015 case of **Montgomery v. Lanarkshire Health Board**[33], a patient who was pregnant was not made aware of the dangers of vaginal delivery and thus incurred injuries while giving birth. The healthcare provider had violated the patient's right to enough information in order for her to make an educated decision regarding her care, the court said. The patient-centred care principle, which calls for healthcare providers to give patients enough information to make knowledgeable decisions about their treatment, was established by this case.

- **Breach of duty:** The healthcare professional or provider must have failed to give the necessary care or treatment or must have done so at a level below what is reasonable for a competent professional in their area.

  The Supreme Court ruled in the case of **Dr. Laxman Balkrishna Joshi vs. Dr.Trimbak Bapu Godbole and Others**[34] that a doctor has specific obligations and

[33] [2015] UKSC 11
[34] 1969 AIR 128, 1969 SCR (1) 206

that any violation of those obligations might subject him to legal liability for medical malpractice. A acceptable standard of care is expected of doctors, one that has been established for their profession.

- **Causation:** The duty violation must have resulted in the patient's harm or injury or at least contributed to it. This indicates that if the healthcare provider or professional had given appropriate care or treatment, the harm or injury would not have happened.
- **Damages:** Due to the healthcare provider's or healthcare professional's breach of duty, the patient must have actually suffered harm or injury. This damage or hurt could be material, psychological, or pecuniary.

In the case of **Calcutta Medical Research Institute v. Bimalesh Chatterjee**[35], it was decided that the complaint had the burden of demonstrating the absence of negligence and a lack of service.

The plaintiff must demonstrate that each of these conditions was true in order to establish medical negligence. A medical expert who can attest to the level of care, the obligation breached, and the cause of the harm or injury is typically required for this. A thorough investigation and analysis of the facts and evidence are required to establish if medical negligence has happened. It is vital to keep in mind that not every unfavourable medical outcome is the consequence of medical carelessness.

The Supreme Court ruled in **Kusum Sharma v. Batra Hospital**[36] that a doctor frequently chooses a procedure with a higher element of risk when, in doing so, he genuinely feels that it will increase the patient's prospects of success. If a doctor took a bigger risk to relieve the patient's pain and it did not work, it might not be considered medical malpractice.

In the case of **Jasbir Kaur v. State of Punjab**[37], a newborn infant was discovered missing from its hospital bed. The young toddler was discovered bleeding and close to the bathroom sink. The hospital's administration said that the boy had been hurt when a cat took him away. The hospital administration was found to have been careless and to have not exercised due caution. Consequently, a settlement of Rs. 1 lakh was granted.

RES IPSA LOQUITUR RULE:

[35] I(1999) CPJ 13 (NC)
[36] Civil Appeal No 1385 of 2001
[37] AIR 1995 P H 278

The Latin proverb "Res Ipsa loquitur" means "The Thing Speaks for Itself." Res Ipsa loquitur is a legal theory that permits a plaintiff to demonstrate a breach of duty and negligence in the context of medical negligence proceedings without specific proof of the healthcare provider's actions or inactions. Instead, the claimant can depend on the fact that the patient's pain or injury is proof enough of carelessness. In a lawsuit involving medical negligence, the plaintiff must establish the following in order to use the Res Ipsa loquitur principle:

a) The patient's hurt or injury was caused by something within the control of the healthcare provider or provider;
b) The patient made no contribution to the injury or harm in any way; and
c) The injury was of a type that does not typically occur in the absence of negligence.
d) The onus of proving that the healthcare provider was not negligent transfers to the defendant if the plaintiff is successful in establishing these criteria, at which point the court may conclude that the healthcare practitioner was negligent.

In some circumstances of medical negligence, res ipsa loquitur is not relevant, and the courts frequently interpret it differently. However, it can be a potent weapon for plaintiffs who have experienced harm or injury as a result of medical negligence, especially in situations when obtaining direct proof of the conduct or omissions of the healthcare provider is challenging.

a) **Scott v. London and St. Katherine Docks Co. (1865)[38]:** This decision created the English common law's res ipsa loquitur rule. The court ruled that the burden of proof shifts to the defendant in situations when an injury occurred under circumstances that suggest carelessness and the defendant had sole control over the instrumentality that produced the injury.
b) In the case of **Ybarra v. Spangard (1944)[39]**, a patient who had undergone surgery awoke with damage to his shoulder and arm. The patient was unable to pinpoint the precise origin of his injuries, although numerous medical professionals worked on the operation. The defendants had sole control over the patient and the surgical tools, the court ruled after applying the res ipsa loquitur principle, and the injuries were of a nature that was unusual in the absence of negligence. As a result, the court decided that the defendants now had to provide evidence that they were not careless.

[38] [1865] 3 H&C 596
[39] 25 Cal.2d 486

c) **SuvanantKongkam v. Santa Clara County Superior Court (2004):** A patient in this case underwent surgery and awoke with a dislocated jaw. The patient was unable to pinpoint the precise cause of the injury, but the court used the res ipsa loquitur principle to rule that the defendant had sole control over the patient and the surgical equipment used in the procedure and that the injury was of a type that does not typically happen in the absence of negligence. As a result, the court decided that it was now the defendant's responsibility to establish their lack of negligence.

d) **Sarojini Ramaswamy v. Sri Gokulam Hospital and Medical Research Ltd. (2014)[40]:** This case involved a surgery patient who experienced problems that ultimately resulted in her death. The patient's family was unable to pinpoint the precise cause of the injury, but the court used the res ipsa loquitur principle to rule that the defendant had sole control over the patient and the surgical equipment used in the procedure and that the injury was of the type that does not typically happen in the absence of negligence. As a result, the court decided that it was now the defendant's responsibility to establish their lack of negligence.

DEFENCES:

a) According to Section 80 of the Indian Penal Code, 1860, a conduct that occurs by accident or bad luck, without criminal knowledge or intent, while a lawful act is being performed in a legal manner using legal means and with due care and caution, is not a crime.

b) According to Section 81 of the Indian Penal Code, 1860, it is not illegal to do something if it is done in good faith and without any malicious intent in order to prevent further harm from being done to a person or his property.

c) According to Section 88 of the Indian Penal Code, 1860, no one can be charged with a crime if they act in good faith for the benefit of others and do not intend to injure anyone, even if there is a risk involved and the patient has provided their explicit or implied agreement.

NEGLIGENCE OF DUTY:

[40] Writ Petition (civil) 514 of 1992

Failure to uphold one's responsibility of care to a patient is referred to as dereliction of duty. Dereliction of duty happens when a healthcare provider violates the level of care that is expected of them in the context of medical negligence, harming or injuring the patient as a result.

a) The failure of a healthcare provider to uphold their responsibility of care to a patient is referred to as dereliction of duty in law.
b) The ethical and legal duty of care requires healthcare practitioners to treat patients with a specific quality of care.
c) When a healthcare worker violates this standard and causes harm or injury to the patient, it is called dereliction of duty.

Failure to diagnose a medical illness, inaccurate or inappropriate treatment, prescription errors, failing to monitor a patient's status, and failing to send a patient to a specialist when necessary are a few examples of dereliction of duty in the healthcare industry.

Depending on the particulars of each instance, it is possible to determine if a healthcare provider has violated their duty of care. A surgical error or pharmaceutical overdose are two situations when the breach might be immediately apparent. To ascertain whether the medical expert performed in accordance with the proper standard of care in other situations, expert testimony may be necessary. One instance of a healthcare professional failing in their role is a medication error. When a medical professional prescribes, administers, or distributes the incorrect medication, the incorrect amount, or the incorrect route of administration, pharmaceutical errors may occur. These mistakes may cause the patient great injury, even death. When a pharmaceutical error occurs, the healthcare provider's duty of care to the patient may have been violated. Any damage or injury brought on by the pharmaceutical error may be the responsibility of the medical expert.