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RESEARCH ARTICLE

Medical negligence in cases decided by the National Consumer Disputes Redressal Commission: A five-year retrospective review.

SANJAY SUKUMAR

Abstract

Background: *There has been a gradual increase in disputes between doctors and patients in the healthcare system over the years. The aim of this review was to determine the speciality-wise prevalence of medical negligence in cases decided by the National Consumer Disputes Redressal Commission (NCDRC) and the factors responsible for it.*

Methods: *A total of 253 cases of medical negligence decided by the NCDRC from 2015 to 2019 were reviewed and categorised with respect to the number of cases compensated, the speciality involved, the compensation payout for the specialities involved, and the nature of the error leading to negligence.*

Results: *Among the cases analysed, negligence was identified in 135(53%) cases. Of these, the incidence of negligence was highest in surgery [37(27%)], followed by obstetrics and gynaecology (OBG) [29(21%)]. The highest compensation payouts were Rs 1.38 crore and Rs 1.1 crore in the paediatrics and OBG specialties, respectively. The common errors were lack of skill/care in the treatment of the patient [62(36%)] and failure to maintain accurate medical records [38 (22%)].*

Conclusion: *The study of adverse events in healthcare practice can improve the quality of patient care, and steps can be taken to reduce such events. Many adverse events are preventable by improving the skill/care in treatment and meticulous record keeping.*

Author: **Sanjay Sukumar** (sanjss@yahoo.co.in), Additional Professor, Department of Forensic Medicine, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry 605 006 INDIA.

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Keywords: *medical negligence, closed claim files, medical malpractice, litigation, consumer protection, patient safety*

The Consumer Protection Act, 1986 (COPRA) was passed to protect consumers' interests, and state bodies were established to deal with consumer problems, conflicts and grievances, and to ensure that these disputes were resolved at the earliest. All doctors and hospitals that charge for their service (including hospitals that give partial free service), are covered under COPRA.

The onus of proving negligence lies on the complainant. The essential components of negligence are: duty owed to the patient, breach of the said duty and consequential damage [1,2,3]. Deficiency of service means "any fault, imperfection, shortcoming, or inadequacy in the quality, nature, and manner of performance which is required to be maintained by or under any law for the time being in force or has been undertaken to be performed by a person in pursuance of a contract or otherwise in relation to any service" [3].

Public awareness of medical negligence is growing in India. Hospital managements are increasingly facing complaints regarding their facilities, standards of professional competence, and the appropriateness of their therapeutic and diagnostic methods [4]. These complaints give rise to many medical malpractice claims accompanied by financial liability [5].

Retrospective studies of hospital case records in the United States and Australia have shown a substantial number of adverse events, defined as unintended injuries caused by medical management rather than the disease process [6]. However, error prevention and error management for better healthcare are largely feasible goals [7].

Previous review studies of retrospective records in several countries have shown that 2.9% to 16.6% of patients in acute care hospitals experience one or more adverse events (AEs), of which 4.5–20.8% of the AEs have resulted in the patient's death [8]. Approximately 30 to 50% of such AEs are judged to be preventable [8-12].

An important objective for those concerned with medical malpractice and quality of care is preventing iatrogenic injury. The first step in prevention is to develop a better understanding of such injuries, their types, and causes [13].

The principle that studying adverse events can yield information that helps to improve quality in healthcare and elsewhere is well established. Since individuals learn much from their own mistakes, it is reasonable to assume that organisations can also learn a great deal from examining their own errors [14].

To date, a few publications have offered physicians an assessment of their risk of being sued and the nature of such suits, or have identified what criteria exist to predict a successful or unsuccessful outcome [15].

This review was carried out to determine the specialty-wise occurrence of medical negligence and its outcome in cases decided by the National Consumer Disputes Redressal Commission (NCDRC). The focus is on the number of negligence cases filed in that speciality, how many were successful, the average compensation payout, and the factors responsible for medical negligence.

Methods

A total of 253 cases of medical negligence decided by the NCDRC from 2015 to 2019 were analysed from a public database obtained from the periodical *Consumer Protection Judgments*. The case judgments were scrutinised and categorised with respect to the number of cases in which compensation was awarded, the speciality involved, the compensation payout for the specialities involved, and the nature of error leading to negligence or deficiency in service. The nature of error was categorised under the following: lack of skill/care, deficient medical records, deficient preoperative evaluation, deficient postoperative care, failure to diagnose, delay in referral, delay in treatment, lack of infrastructure, wrong diagnosis, delay in diagnosis, wrong treatment, failure to take a specialist opinion, and miscellaneous errors. The data was analysed in Microsoft Excel spreadsheet and presented in tables.

Ethics committee approval

Exemption from review was approved by the Institutional Ethics Committee as all data were obtained from public records.

Results

Table 1 displays the specialities associated with the highest number of claim cases. The majority of the cases (73, 29%) were from surgery. Negligence was proved in 135 (53%) cases, with surgery (37, 27%) topping the list. The conviction rate was quite high in anaesthesiology (13, 10%).

Table 2 displays the speciality-based distribution of compensation payout. The highest compensation was claimed in surgery (Rs 10 cores). The highest single payouts were Rs 1.38 crore and Rs 1.1 crore in paediatrics and in obstetrics and gynaecology (OBG), respectively. The highest average payout was Rs 13.78 lakhs in anaesthesiology.

Table 3 displays the nature of error leading to litigation and Annexure 1 [available online only] gives examples of various errors. The most common was lack of skill/care (62, 36%) in the patient's treatment. Along with other errors, it is followed by deficient medical records (38, 22%), deficient preoperative/treatment care (12, 7%), failure to diagnose (12, 7%), delay in treatment (4, 2%), lack of infrastructure (6, 3%), delay in referral (3, 2%), and miscellaneous deficiencies (9, 5%).

Table 1: Specialty-wise distribution based on compensation awarded

Speciality n (%)	Compensation awarded	Compensation not awarded	Total
Surgery	37(27)	36(31)	73(29)
OBG	29(21)	25(21)	54(21)
Medicine	14(10)	29(25)	43(17)
Orthopaedics	14(10)	14(12)	28(11)
Anaesthesiology	13(10)	3(3)	16(6)
Ophthalmology	5(4)	7(6)	12(5)
Paediatrics	5(4)	1(1)	6(2)
ENT	4(3)	1(1)	5(2)
Radiodiagnosis	3(2)	2(2)	5(2)
Radiotherapy	3(2)		3(1)
Blood bank	2(1)		2(1)
Pathology	1(1)		1(1)
Others	5(4)		5(2)
Total	135	118	253

OBG: Obstetrics and gynaecology; ENT: Ear, Nose and Throat.

Discussion

It is necessary to understand the frequency, seriousness, and causes of medical errors to improve patient safety [16]. Adverse events are important to healthcare organisations, because of their impact on patients, for the insights they can provide into the quality of healthcare, and the opportunity for improvement [14].

In this study, the common errors found in the patients' treatment were lack of skill/care (37%), deficient preoperative/treatment care (11%), failure to diagnose (7%) and delay in referral (2%). These AEs are avoidable and can be achieved by better coordination and communication among healthcare providers. Lack of infrastructure (3%) is also a cause for concern; many hospitals and nursing homes

Table 2: Speciality-based distribution on compensation payout.

Speciality (Rs.)	Highest compensation claimed	Highest compensation payout	Average compensation payout
Surgery	10,00,00,000	47,00,000	8,37,837
OBG	8,50,00,000	1,10,00,000	9,97,166
Medicine	5,00,00,000	15,65,000	4,95,400
Orthopaedics	7,36,00,000	20,00,000	7,10,266
Anaesthesiology	3,58,00,000	47,00,000	13,78,300
Ophthalmology	2,00,00,000	50,00,000	-
Paediatrics	1,00,00,000	1,38,00,000*	-
ENT	1,96,00,000	10,00,000	-
Radiodiagnosis	50,00,000	16,80,000	-
Others	80,00,000	10,00,000	-

OBG: Obstetrics and gynaecology; ENT: Ear, Nose and Throat.

**The compensation amount claimed was not available in this case.*

did not have intensive care (ICU) facilities and round the clock ambulance services. Many of these AEs are preventable to some extent [6,9,10,], and effective interventions can improve patient safety.

More than half the cases (53%) studied resulted in financial compensation being awarded. As stated earlier, surgery and OBG gave rise to more complaints of negligence [17,18]. There were multiple layers of failure in these two departments. For example, not performing proper preoperative tests, lack of skill and care in treatment and deficiency in maintaining medical records. The payout rate for anaesthesiology errors was very high because anaesthetic complications usually lead to death or severe disability. In most specialities, the ratio of cases awarded compensation was higher than that of rejected claims. An exception was general medicine, where the payout rate was relatively low, because in many cases, the patient was brought in an extremely debilitated condition, and the chances of survival were narrow despite adequate treatment.

Deficient medical records are a cause for concern. In some cases, the medical records were found missing for various reasons. The National Commission, in many cases concerning deficient medical records, states that "poor records mean poor defence, no records mean no defence". Not taking proper informed consent, especially not mentioning the risks involved in a procedure, was viewed as a deficiency in service. There may be valid reasons why doctors do not explain in detail the diagnosis, the treatment planned, or the expected prognosis to the patient. However, not providing such information to patients violates their rights [19].

In some cases, even when found not guilty of medical negligence, the practitioners or hospital were found guilty of deficiency in service. Some of the reasons were: not maintaining proper medical records, deficient consent forms, and inadequate infrastructure (no ICU/Neonatal ICU, lack of staff etc.). Under the "Others" category, practising modern medicine without a valid degree, amounted to negligence due to lack of skill/care, but the average payout

Table 3: The number and percentage in association between speciality and nature of error

Nature of error n (%)	Surgery	OBG	Medicine	ORTHO	ANES	OPHTH	PEDS	ORL	Radio	Others	RT	BB	PATH	Total
Lack of skill/care	14(23)	15(24)	5(8)	4(6)	9(15)	2(3)	2(3)	2(3)		5(8)	3(5)	1(2)		62(36)
Deficient medical records	11(29)	9(24)	2(5)	5(13)	3(8)	3(8)		3(8)	1(2)			1(3)		38(22)
Deficient post-operative care	7(39)	4(22)	1(6)	4(22)		2(11)								18(11)
Deficient pre-operative evaluation	7(58)	2(17)		1(8)	2(17)									12(7)
Failure to diagnose	1(8)	3(25)	2(17)	4(33)					2(17)					12(7)
Delay in referral	1(33)		1(33)		1(34)									3(2)
Delay in treatment	3(75)			1(25)										4(2)
Lack of infrastructure	1(17)	4(67)					1(16)							6(3)
Wrong diagnosis		1(100)												1(1)
Delay in diagnosis							1(100)							1(1)
Wrong treatment			1(100)											1(1)
Failure to take a specialist opinion	1(25)	2(50)						1(25)						4(2)
Miscellaneous	3(33)	1(11)	3(33)				1(11)						1(11)	9(5)
Total	49	41	15	19	15	7	5	6	3	5	3	2	1	171

OBG: Obstetrics and gynaecology; Ortho: Orthopaedics; ANES: Anaesthesiology; OPHTH: Ophthalmology; PEDS: Paediatrics; ORL: Otorhinolaryngology; Radio: Radiodiagnosis; Others: no valid degree to practice modern medicine; RT: Radiotherapy; BB: Blood bank; PATH: Pathology.

was low even though treatment was administered by unqualified personnel.

In this review, case examples of adverse events due to lack of skill/care which are likely preventable are as follows:

- Wrong blood transfused resulting in Rh sensitisation of the patient, leading to the death of the foetus in subsequent pregnancies.
- Endoscopic papillotomy (EPT) was performed even though the patient was suffering from pancreatitis, leading to severe pancreatitis causing fatal complications. The procedure should have been done after the pancreatitis was cured.
- The patient underwent an abdominal repair mesh operation, complained of pain during follow up. A second opinion revealed two surgical mops in the abdomen.
- Administration of syntocinon to induce labour beyond 24 hrs and delay in conducting caesarean section led to foetal distress, causing spastic cerebral palsy with quadriparesis.
- The patient underwent medical termination of pregnancy and tubectomy. Postoperatively, she developed abdominal pain and was referred to another centre. She was diagnosed with uterine and terminal ileal perforation with faecal peritonitis, and four corrective procedures were performed to repair the defect. Negligence was established in not following a reasonable degree of skill/care in operating.
- An infant diagnosed with septicaemia was administered an IV drip in the right hand. A few hours later, the fingers of the right hand turned blue, and the parent was reassured that there was nothing to worry about. The child was discharged the next day with advice to use conservative measures to treat the right hand. A second opinion was taken, and a Doppler study revealed no blood flow in the palmar arch and the right hand's digital arteries. Gangrene had set in, and the hand had to be amputated.
- The patient underwent an appendectomy operation and died a few hours after the procedure. An autopsy revealed a tear in the ileocecal junction and the right lobe of the liver with multiple haematomas in the lateral wall of the abdominal cavity with 1000ml of blood. There was a failure to determine the cause of the intra-abdominal haemorrhage and a failure to apply reasonable skill and care in operating.
- In an attempt to put a central venous line (CVL), the jugular vein was injured, leading to haemothorax, and thoracotomy was performed. The consent form did not specifically mention the CVL procedure and its complications. The National Commission observed that the CVL procedure had caused life-threatening complications; hence, it cannot be considered an ordinary procedure. Consent was mandatory.
- The patient underwent a corrective procedure for a dislocated lens. The pain continued to persist after the operation and was conservatively treated. A second opinion revealed that the new lens was implanted without removing the dislocated lens, which led to damage to the retina. Implantation of a new lens without extracting the subluxated lens was contraindicated.
- The patient suffered a fracture of the left side of the mandible and right clavicle. She was put on a ventilator through a tracheostomy tube (TT) and underwent a procedure to fix the jaw under general anaesthesia. Two days after the operation, the TT was replaced with nasotracheal intubation (NI). There was perforation of the trachea at the subglottic level during NI. This led to permanent loss of speech and restricted head movements. There was no satisfactory explanation to justify replacing the TT with NI as the patient was doing fine with TT.
- The patient underwent a thoracotomy. On recovery, his voice was hoarse, and he could barely speak. A second opinion was sought and it revealed posterior subluxation (partial dislocation) of the left arytenoid cartilage along with vocal cord palsy. This probably occurred due to wrong instrumentation during intubation. The intubation by a double-lumen tube needs a lot of experience and expertise. A trainee had done the instrumentation instead of an experienced anaesthetist who was available at the time. This amounted to a breach in the duty of care.
- A child was suffering from penile phimosis and underwent circumcision at the hospital. Soon after the procedure, he developed respiratory distress due to choking on his vomit, a known complication of anaesthesia, leading to mental disability. There was a failure to take adequate precautions against this.
- A nurse administered atracurium leading to the patient's death. It should have been administered only by, or under, the direct supervision of an anaesthetist.

There is low awareness among health workers of patient safety incidents, and there is no robust mechanism for reporting such incidents [20]. The reduction of adverse events involving negligence will require an increased emphasis on education, improved dissemination and enforcement of practice guidelines that might be effective [13].

Increased use of electronic medical records is another strategy for guarding against communication breakdowns. This approach would improve the care team's access to necessary information across all settings, from pre-operative to post-operative [21].

The frequency, seriousness, and causes of medical errors can also be acquired by analysing data collected through error-reporting systems to improve patient safety. These systems may be internal or external to healthcare institutions and can be made voluntary or mandatory [16].

Also, the patient's perspective ought to be a key component of any quality improvement strategy in patient safety. Some improvements in quality from the patient's perspective include access to care, responsiveness and empathy, good communication, clear information provision, appropriate treatment, relief of symptoms, improvement in health status and, above all, safety and freedom from medical injury [22].

Further studies like these [23,24] should be encouraged to identify AEs, thereby improving the overall quality of patient care. Another practical implication in the study of AEs is to consider its use for medical education. These incidents can be used to educate medical students, residents and faculty about patient safety issues. This could increase doctors' awareness of these situations and reduce the number of errors [25]. A course on patient safety should be made mandatory at undergraduate and postgraduate levels of medical education.

Limitations

Since the study was based on the review of judgements of the NCDRC, all obtained information was limited to those documents. Sorting out terminologies for adverse events proved to be complicated. A few cases where an appeal has been made in the Supreme Court may face a different outcome.

Conclusion

Patient safety is crucial to high-quality healthcare. The study of adverse events in healthcare practice can improve the quality of patient care, and take steps to reduce such events. Many adverse events are preventable by improving the skill/care in treatment, improving communication with patients and meticulously maintaining medical records.

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Statement of similar work: *None.*

Downloadable supplementary files (available online only):

1. Consumer court cases in medical negligence

2. Flowchart of cases included and excluded from the study

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RESEARCH ARTICLE

Association of funding and conflicts of interest on outcomes reported in published studies of Covid-19

SNEHALATA GAJBHIYE, CHAITALI CHINDHALORE, ASHISH GUPTA, GANESH DAKHALE

Abstract

Background: *An outbreak of the Covid-19 has led to substantial mortality globally. The entire world is carrying out studies to understand the pathophysiology, clinical features, diagnosis and treatment of Covid-19. We investigated the possible association of type of funding, corporate or academic, and conflict of interests on the outcomes reported in clinical trials on Covid-19.*

Methods: *Studies containing the keywords "clinical trial" AND "Covid 19" or "Corona" were located by a search on PubMed published between September 2019 to August 2021. Filters were used to select only papers in the English language and on "humans". The data were analysed using descriptive statistics and the Chi-square test.*

Results: *We found a significant association between the existence of a conflict of interest and reporting of a positive outcome (X^2 value = 18.751, $p<0.001$). We also found a significant association between industry funding and reporting of a positive outcome (X^2 value = 18.041, $p<0.001$).*

Conclusion: *We conclude from this study that the presence of conflict of interest and pharmaceutical industry funding is associated with reporting a positive outcome.*

Keywords: *PubMed, pandemic, clinical trials, industry funding, conflict of interest*

Introduction

In late December 2019, a disease outbreak due to a novel coronavirus began in Wuhan China and quickly spread across the globe. The epidemic was declared a pandemic by the World Health Organization (WHO) on March 12, 2020 [1]. Globally, as of Feb 2023 , it is found to have caused seven hundred million confirmed cases and over six million deaths worldwide [2]. Numerous pharmaceutical companies and academic institutes began racing to find effective therapies for the treatment and prevention of SARS-CoV-2 across the world, including in India. Worldwide, several therapies received regulatory approval comprising antiviral remdesivir, remdesivir plus baricitinib, dexamethasone, convalescent plasma, bamlanivimab and the fixed-dose combination of casirivimab plus imdevimab [3,4]. Also, several vaccines got regulatory approval from different countries and have been administered across the globe. Despite these developments, effective treatment options for Covid-19 remain limited. The large quantity of clinical data being generated, a wide spectrum of disease presentations, and rapid mutations presented a critical need for analysing the data generated from an ethical point of view.

Several non-Covid studies in the literature have demonstrated an association between funding from pharmaceutical companies and the presentation of positive findings [5, 6,7]. There are also studies in the non-Covid area which have shown an association between conflicts of interest (COI) and the presentation of positive findings [6,7]. A huge number of studies have been published during the pandemic. Available evidence suggests that the methodological quality of studies on Covid-19 is poor [8]. According to Jung et al, Covid-19 clinical studies have a

Authors: **Snehalata Gajbhiye** (corresponding author — dr.ssborkar@aiimsnagpur.edu.in), Assistant Professor, Dept of Pharmacology AIIMS Nagpur, Nagpur 441108, Maharashtra, INDIA; **Chaitali Chindhalore** (drchaitali@aiimsnagpur.edu.in), Assistant Professor, Dept of Pharmacology AIIMS Nagpur, Nagpur 441108, Maharashtra, INDIA; **Ashish Gupta** (dr.ashish1489@gmail.com), Senior Resident, Dept of Pharmacology AIIMS Nagpur, Nagpur 441108, Maharashtra, INDIA; **Ganesh Dakhale** (gndakhale@aiimsnagpur.edu.in), Professor and Head, Dept of Pharmacology AIIMS Nagpur, Nagpur 441108, Maharashtra, INDIA.

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