

Review Article

Negligence without a patient: medical negligence in clinical trials in India and the comparative study of South Korea and Australia

Abhinav Kuchipudi*, Aditi Jani

Faculty of Law, GLS University, Ahmedabad, Gujarat, India

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*Correspondence:

Abhinav Kuchipudi,

E-mail: abhinav23721998@gmail.com

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ABSTRACT

Clinical research has migrated toward low- and middle-income countries, and India became a leading host before consent failures and participant deaths triggered a regulatory reckoning in 2013. The injured trial participant occupies an awkward position in medical negligence law: the intervention is experimental, its risks are by design incompletely known, and no settled standard of care governs the researcher's conduct. This study compares three jurisdictions. India, a common-law system, has adopted statutory no-fault compensation; South Korea, a civil-law system, relies on regulatory approval and indemnity insurance; Australia, a common-law system, is shaped by a landmark judicial standard and subsequent civil-liability reform. India's obligation requires sponsors to compensate trial-related injury without proof of fault, reaching injuries only associatively connected with a trial, making its principle the most protective in form. South Korea channels protection through institutional review boards and indemnity insurance, leaving the standard of care to malpractice litigation. Australia combines notification-based approval with a court-determined standard derived from *Rogers v Whitaker*, tempered by the customary-practice defence and supplemented by health complaints commissions. No jurisdiction performs well on compensation certainty, standard-of-care clarity and access to justice at once. The comparison supports three reforms for India: a defined standard of care, an independent compensation authority, and a clarified relationship between the no-fault remedy and the civil claim.

Keywords: Medical negligence, Clinical trials, Research-related injury, No-fault compensation, Informed consent, Comparative law, India, South Korea, Australia

INTRODUCTION

The geography of clinical research has shifted. Multinational trials have moved toward low- and middle-income countries, drawn by larger and cheaper patient populations and by regulatory environments that once promised speed over scrutiny.^{1,2} India became emblematic: a 2005 amendment to the Drugs and Cosmetics Rules opened the country to contract research, and registered trials rose sharply.³ Expansion was shadowed by consent failures among poor and mentally ill participants, deaths that regulators could not account for, and compensation paid only sporadically.⁴

Those reports exposed a question the ordinary law of medical negligence answers poorly. A person injured in a trial is not a patient in the conventional sense: the intervention is experimental, its risk profile deliberately unknown, and the participant has consented to that uncertainty. Harm may occur where the investigator followed the protocol exactly and disclosed every known risk. The building blocks of negligence, namely duty, breach, causation and damage, become unstable. Was the standard of care that of the treating physician or the competent researcher? Does valid consent extinguish the claim or merely redistribute risk? When the injury was unforeseeable, is there a wrong to litigate at all?

The participant's claim resists classification. Analysed as ordinary clinical negligence, the researcher is judged by the standard of a competent physician, too generous where the protocol was breached and too harsh where an approved protocol predictably produced harm. Analysed as product liability, it founders because harm usually arises from a lawful use of a product still under investigation, not a defect in a finished good. Neither analogy captures serious injury from a trial conducted flawlessly under a protocol no one could have known was dangerous.

The three jurisdictions answer these questions differently. India has chosen a statutory path, imposing since 2013 a no-fault compensation obligation on sponsors for trial-related injury or death, independent of proof of negligence.⁵ Australia retains a fault-based tort standard but has given it distinctive content through the High Court's rejection of medical paternalism in *Rogers v Whitaker*, and has reshaped the surrounding litigation environment through the reforms following the Ipp Report.⁶ South Korea, a civil-law jurisdiction, addresses participant protection chiefly through regulatory approval, institutional review and mandatory indemnity insurance, while the substantive law of negligence evolves through its Supreme Court's case law.^{7,8}

Comparative practice offers two candidates for the standard against which a researcher's conduct is judged. The customary-practice standard, associated with *Bolam v. Friern Hospital Management Committee*, holds a professional not negligent if acting in accordance with a practice accepted as proper by a responsible body of professional opinion. The judicial standard leaves the court to decide what reasonableness requires, without deference to professional consensus. Each carries risk: a customary-practice standard may shelter researchers behind the norms of an industry with an interest in rapid recruitment, while a judicial standard may impose the wisdom of hindsight about genuinely unknown risks.⁹

The compensation architecture matters as much as the standard. A fault-based tort system requires the participant to prove negligence and causation and to bear litigation's cost, a heavy burden where the causal mechanism is obscure and the defendant commands better evidence. A no-fault scheme compensates defined injuries without proof of fault, trading moral judgment for speed and predictability.¹⁰ An insurance-and-approval model channels compensation through mandatory indemnity cover and prior regulatory scrutiny, leaving the substantive claim to the general law. This paper compares the three structures and asks which best protects the participant, deters careless research, and gives the injured person a realistic route to redress.

METHODS

The study adopts functional comparative legal analysis. Rather than compare rules in isolation, it asks how each

legal order responds to the same social problem, the injured research participant, treating doctrinal differences as alternative institutional solutions. The materials are of three kinds: primary instruments, including India's Drugs and Cosmetics Act 1940 and New Drugs and Clinical Trials Rules 2019, South Korea's Pharmaceutical Affairs Act, Medical Devices Act and Bioethics and Safety Act, and Australia's Therapeutic Goods Act 1989 and National Statement on Ethical Conduct in Human Research; leading judgments, including *Swasthya Adhikar Manch v. Union of India* and *Jacob Mathew v. State of Punjab* in India, decisions of the Supreme Court of Korea, and *Rogers v. Whitaker* in Australia; and scholarly and policy commentary in medical, health-policy and legal journals.

The jurisdictions were selected to cover the principal institutional alternatives. India represents a common-law system that has adopted an express statutory compensation scheme for research injury. South Korea represents a civil-law system whose protection of participants is primarily prospective, through approval and insurance, with the standard of care developed in case law. Australia represents a common-law system that produced a distinctive judicial standard of care and later reworked the surrounding litigation environment by statute. Comparing them isolates the effect of the compensation model from that of the legal family.

The analysis applies six dimensions uniformly: the principal instruments governing trials, the approval pathway, the locus of ethical review, the compensation model, the standard of care, and the enforcement mechanism together with the practical accessibility of redress. It is confined to interventional trials of drugs and biologicals, the domain in which the three jurisdictions developed their most distinctive responses; broader biomedical research appears only where the regulatory architecture requires. The study is doctrinal and documentary: it reports the law and its scholarly evaluation, and does not measure the incidence of research injury or the outcomes of individual claims.

RESULTS

The Indian framework

From liberalisation to scandal

India's engagement with contract research accelerated after the 2005 amendment to the Drugs and Cosmetics Rules, which streamlined approvals.³ The Drugs and Cosmetics Act 1940 and Schedule Y provided the formal framework, supplemented by Indian Council of Medical Research guidelines; trial registration became mandatory in 2009 and expert committees were created to evaluate applications.³ The apparatus lagged behind the volume of research. Parliamentary scrutiny uncovered lax standards in approval and authorisation, and the National Human Rights Commission concluded that regulatory controls were largely ineffective.¹¹ Consent had been obtained improperly from vulnerable groups, including mentally ill

patients recruited without adequate authorisation, and deaths in trials far exceeded those regulators attributed to them.³

The 2013 amendments and the new drugs and clinical trials rules 2019

Two responses defined the modern framework. Amendments to Schedule Y in 2013, introduced amid public-interest litigation, mandated registration of ethics committees, made audio-visual recording of informed consent compulsory, and established that sponsors must provide compensation and free medical care for injury or death arising from a trial.^{12,13} The obligation was not confined to injuries caused by negligence but extended to injuries connected with the trial whether or not the connection was causal in the ordinary sense, a feature that distinguishes India from fault-based systems and even from other no-fault regimes.⁵ The New Drugs and Clinical Trials Rules 2019, notified as G.S.R. 227(E), consolidated the amendments, set out a compensation formula for death and serious injury, and for the first time brought non-drug biomedical and health research within a unified framework alongside drug trials.¹² They completed the transformation of a regime organised around product approval into one organised around the protection of the participant.

The no-fault compensation regime

India's compensation regime is the most protective of the three in formal terms. Where a participant dies or is injured, the sponsor must pay compensation and bear the cost of medical care, and the obligation reaches injuries merely associated with the trial as well as those caused by it.⁵ Before 2013 sponsors set compensation themselves, and families of participants who died in trials between 2005 and 2012 received only a fraction of what the later formula contemplated.⁴ The 2013 amendments and the 2019 Rules introduced a structured scale, with the maximum for death capped at a specified figure and free medical management required in every case of trial-related injury.⁴ Because wrongfulness need not be proved, a participant who can establish that injury arose out of a trial recovers without litigating the researcher's competence, which addresses the evidentiary asymmetry that pervades research injury. India also treats injuries unrelated to the research but suffered during the trial as compensable in certain circumstances, an approach few other systems have matched.⁵

Judicial analysis: the Supreme Court and the standard of negligence

The defining judicial moment was *Swasthya Adhikar Manch v. Union of India*, decided on a public-interest writ petition by a health-rights organisation.¹³ The petitioners alleged widespread malpractices in trials by government, non-government and independent investigators, and inadequate compensation for harmed participants.¹³ The Supreme Court directed the

government to supply comprehensive information about ongoing trials, halted new trial approvals until a monitoring mechanism was in place, and pressed for stronger participant protection.^{3,4} The litigation supplied the impetus for the 2013 amendments and established that the conduct of clinical research is a matter of constitutional concern. A second line of authority governs the substantive standard: in *Jacob Mathew v. State of Punjab* the Supreme Court held that a physician may be prosecuted for criminal negligence only after a credible opinion from a competent medical authority, and that criminal liability requires gross negligence or recklessness rather than a mere error of judgment. The consumer-protection jurisdiction offers a parallel civil route, though vulnerable patients rarely invoke it because of cost, delay and deference toward clinicians.¹⁴

Assessment of the Indian framework

Three criticisms recur. The first is definitional: pre-2013 rules permitted trial requirements to be relaxed where doing so served the public interest, and the absence of a settled definition invited discretionary relaxation and regulatory arbitrage.³ The second concerns ethics committees, where conflicts of interest and the subordination of lay members persisted even after the 2013 reforms required a proportion of members to be unaffiliated with the sponsoring institution.¹² The third is the effect on research volume: the stringent compensation obligation, documentation burden and uncertainty surrounding approvals contributed to a marked decline in trials hosted in India after 2013¹, as sponsors moved studies to jurisdictions with lighter obligations.^{11,2} A separate critique concerns the evidence base for Indian approvals, with studies of approved fixed-dose combinations finding reliance on limited and sometimes unpublished data.¹⁵ Empirical research on Indian clinical-research ethics remains skewed toward measuring knowledge rather than understanding recruitment, consent and the experience of injury.¹²

The South Korean framework

Statutory architecture

South Korea protects participants through a layered statutory scheme rather than a single code. The Pharmaceutical Affairs Act governs approval and conduct of trials of medicinal products, the Medical Devices Act performs the equivalent function for devices, and the Bioethics and Safety Act, enacted in 2004 following controversy over Korean stem-cell research, provides the overarching framework for research involving human subjects.^{7,16} The Ministry of Food and Drug Safety is the approval authority, and Korean Good Clinical Practice, modelled on ICH-GCP, sets the conditions for trials.⁷

National registration is provided by the Clinical Research Information Service, a primary registry of the WHO International Clinical Trials Registry Platform.¹⁷ The state has also invested in research infrastructure,

establishing the Korea National Enterprise for Clinical Trials.¹⁸

Ethical review and indemnity insurance

Institutional review boards are the principal site of protection, reviewing the protocol, consent form and compensation arrangements.¹⁹ Early empirical work found significant variation: only about a third of surveyed boards made sponsor indemnity insurance compulsory, most academic institutions had no indemnifying policy at all, and the majority reviewed only monetary payment while a significant minority reviewed no compensation whatever.¹⁹ The financing of participant injury proceeds mainly through insurance rather than a state fund, sponsors being expected to carry clinical-trial insurance covering medical expenses and indemnity, though a policy indemnifying medical expense may not extend to the legal liabilities a participant might enforce.¹⁹ Alongside this, Korea operates a public no-fault scheme in a neighbouring field: the National Vaccine Injury Compensation Program, introduced in 1995, compensates adverse events following vaccination without proof of fault, and its pandemic administration illustrated both the value of a state-backed scheme and the difficulty of applying a strict causality test.²⁰ It is not a research-compensation scheme, but it shows a willingness to socialise the cost of injuries from interventions with public-health purposes, an approach not extended to the general run of trials.

Judicial and doctrinal analysis

Because the substantive law of negligence is judge-made, the standard of care in research injury develops through ordinary malpractice litigation rather than research-specific doctrine. Korean courts analyse medical liability within the civil-law framework of the Civil Code, where the physician's duty is reasonable care measured against a competent practitioner exercising ordinary skill, and the burden of proof follows general principles rather than participant-protective presumptions.⁸ Two features illuminate its operation. First, doctrine develops through systematic study of decided cases: analysis of judgments involving complex regional pain syndrome showed that many claims succeeded in part, that sums awarded fell far below those claimed, and that courts distributed the burden of proof according to the difficulty of establishing causation, often disadvantaging the patient.⁸ Second, the standard attends to the boundary of lawful practice: in anaesthesia the Supreme Court has held that procedures reserved to physicians may not be performed by others, and a study of recorded disputes showed that a large proportion of injuries were avoidable had the proper standard been applied.²¹ The dispute-resolution landscape has also evolved, with legislation in 2011 creating a rapid recovery system intended to divert medical claims from litigation toward structured resolution.²² Research on consent found decisions shaped by trust in the physician-investigator and a limited understanding of the distinction between research and treatment, so that the formal

completeness of the consent document does not guarantee the substantive autonomy the doctrine assumes.²³

Assessment of the South Korean framework

The Korean model is regulatory and prospective. It prevents injury by controlling entry to research and requiring insurance against the consequences, leaving the injured participant to the general law when prevention and insurance fail. A clear approval pathway, a public registry and improved research infrastructure are its strengths. Its weaknesses follow from the same design. Because the standard of care develops in ordinary malpractice litigation, the trial participant must litigate the same issues of breach and causation as any patient, facing the same evidentiary difficulties. Insurance protects against the sponsor's insolvency but not against the difficulty of establishing that a compensable injury occurred, and the absence, outside the vaccine programme, of a general no-fault scheme for research injury means that the most vulnerable participants, those in academic studies without sponsor indemnity, may have no realistic remedy at all.¹⁹

The Australian framework

The regulatory framework

Australia regulates trials through the Therapeutic Goods Act 1989 and its associated schemes, supplemented by a national ethical framework. A trial using an unapproved therapeutic good may proceed by the Clinical Trial Notification scheme, where the sponsor notifies the regulator and substantive scientific and ethical review is carried out by a human research ethics committee, or by the Clinical Trial Exemption scheme, provided for in section 19 of the Act, where the regulator itself reviews the data and grants approval. The distinction is structural: notification locates scrutiny in the ethics committee, exemption in the regulator. The ethical standard for both is the National Statement on Ethical Conduct in Human Research, which sets out requirements for consent, risk assessment and the composition and operation of ethics committees. The architecture distributes responsibility: the regulator controls the supply and use of unapproved goods, the ethics committee controls ethical conduct, and the general law of negligence governs the consequences of injury. Australia thus lacks a research-specific compensation statute of the kind India adopted, and does not rely on mandatory indemnity insurance as the principal protection of participants in the way Korea does.

The standard of care: from Bolam to Rogers and back

Australia's most distinctive contribution is its treatment of the standard of care. In *Rogers v. Whitaker* the High Court declined to follow the English customary-practice standard and held that the adequacy of a warning about risk is a question for the court, not the medical profession, deciding that a practitioner breaches the duty

of care by failing to warn of a material risk, being a risk to which a reasonable person in the patient's position would attach significance. The decision placed the patient's informational interests at the centre of the duty and made the court the ultimate arbiter of reasonableness. It was extended in *Rosenberg v. Percival*, where the Court applied the same approach to diagnosis and treatment while cautioning against the distorting effect of hindsight.

The subsequent reshaping of Australian negligence law narrowed *Rogers's* practical reach. Following concerns that the cost and availability of medical indemnity insurance had become unsustainable, the Ipp Report of 2002 recommended a package of reforms enacted in the state and territory Civil Liability Acts.⁶ Those statutes capped damages, shortened limitation periods, restricted claims to significant injuries and required mediation. Most significantly, they reinstated a version of the customary-practice defence: under provisions such as sections 5O and 5P of the Civil Liability Act 2002 of New South Wales, a professional who acts in accordance with a practice accepted by a significant body of peers is not negligent unless the court considers that practice irrational. The reforms moved Australia part of the way back toward *Bolam*, though the defence generally does not extend to the duty to warn, where *Rogers* continues to govern.

For research injury, the effect is a standard that is court-determined in principle but substantially deferential in operation. The participant must prove a departure from practice that no significant body of professional opinion would accept, or show that the accepted practice was irrational, unless the complaint is inadequate warning, where the *Rogers* standard applies directly.

Compensation and the alternatives to litigation

Australia has no general no-fault compensation scheme for treatment or research injury; the fault-based tort action is the default, and the absence of a no-fault pathway has been noted in policy discussion of injury compensation.²⁴ Several features temper that default. Professional indemnity insurance is compulsory for Australian doctors, and hospitals are vicariously liable for the negligence of employed practitioners, so the defendant in most claims is an institution or insurer rather than an individual.²⁵ Empirical analysis of the largest

Australian cohort of doctors showed that the proportion named in a negligence claim declined over the study period, that the overwhelming majority of claims settled out of court on confidential terms, and that the reforms of the previous two decades reduced claim volume.²⁵

Alongside the courts, health complaints commissions in each state and territory receive and investigate complaints, are free to use and do not require legal representation, and can provide explanations, apologies, corrective action and monetary payments.²⁶ They coexist with the civil-liability system, and plaintiffs' lawyers commonly await a complaint's outcome before deciding whether to bring a negligence claim.²⁶ Their remedial range is broader than tort's, though research suggests they frequently fail to deliver what complainants seek, an expectations gap between what injured parties want and what the process provides.²⁶ A parallel regulatory pathway exists through the national health-practitioner regulation scheme and systematic review confirms that complaints and claims concentrate among a minority of practitioners and are associated with identifiable vocational and psychosocial characteristics rather than clinical specialty alone.²⁷⁻²⁹

Assessment of the Australian framework

Australia's strength is the clarity and integrity of its standard of care. *Rogers v. Whitaker* established that the duty to warn of material risk is not a matter on which the profession may set its own benchmark, and the doctrine has proved durable in the disclosure context even after the civil-liability reforms. The weakness is that of fault systems generally: the participant must prove breach and causation, in the face of the confidentiality attending settlements of most claims and the practical barriers of cost and delay. The reforms that reduced claim volume also reduced the accessibility of the tort system, and the institutional alternatives that might fill the gap do not in practice deliver the remedies complainants seek.²⁶

Comparative findings

Table summarises the comparison across six dimensions: approval pathway, ethical review, compensation model, standard of care, enforcement and access to justice.

Table 1: Comparison of clinical-trial regulation and liability in India, South Korea and Australia

Dimension	India	South Korea	Australia
Principal instruments	Drugs and Cosmetics Act 1940; Schedule Y; New Drugs and Clinical Trials Rules 2019	Pharmaceutical Affairs Act; Medical Devices Act; Bioethics and Safety Act 2004	Therapeutic Goods Act 1989; NHMRC National Statement
Approval pathway	Central regulator (CDSCO) approval with expert committees	Ministry of Food and Drug Safety approval; KGCP/ICH-GCP	CTN notification (ethics-led) or CTX/CTA approval (regulator-led)

Continued.

Dimension	India	South Korea	Australia
Ethical review	Registered ethics committees; audio-visual consent; ICMR guidelines	Institutional review boards; protocol, consent and compensation reviewed	Human research ethics committees under the National Statement
Compensation model	Statutory no-fault sponsor liability, including related injuries; structured scale	Sponsor indemnity insurance; civil claim for injury; state no-fault scheme only for vaccines	Fault-based tort; compulsory professional indemnity; complaints commissions
Standard of care	Tort standard; criminal liability requires gross negligence (<i>Jacob Mathew</i>)	Civil-law reasonable-care standard developed in malpractice litigation	Court-determined standard (<i>Rogers v Whitaker</i>), partly restored to peer practice by Civil Liability Acts
Access to justice	Statutory scheme, consumer forums and criminal complaint; barriers remain	Litigation and mediation; evidentiary burden disadvantages participants	Tort plus complaints commissions; most claims settle confidentially

Compensation: form against operation

On paper India is the most protective: its statutory obligation requires compensation for trial-related injury without proof of fault and reaches injuries bearing only an associative connection with the trial, a reach neither Korea nor Australia matches.²⁵ In operation the contrast narrows. Whether an injury is trial-related is administratively contested, and the sponsor, who controls the evidence, is also the party against whom the claim is made. Australia's tort system is slower and less certain for the individual but is embedded in a mature litigation and insurance infrastructure, and Korea's insurance model at least secures a solvent defendant. India's scheme is the boldest in principle and the least settled in execution.

Standard of care and deterrence

The three systems place the standard of care in different hands. India's criminal law is deliberately protective of practitioners, requiring gross negligence for prosecution, while its civil law has not developed a research-specific standard. Korea's courts develop the standard case by case within the civil-law tradition, the burden of proof resting on the claimant. Australia has gone furthest in articulating the content of the duty, though the civil-liability reforms reintroduced a qualified deference to accepted practice. Deterrence, likewise, is not a single quantity. India's stringent obligation is associated with a decline in hosted trials, which reduces participants' exposure to risk but deprives the population of research benefits; Korea's insurance-and-approval model keeps volume high at the price of leaving the injured participant to litigate; Australia's tort reforms reduced claim volume and cost, at a possible cost to accessibility for the seriously injured.^{1,2,11,25,26}

Access to justice

Access to justice favours the statutory model in principle, because a no-fault scheme removes the need to prove negligence, and favours mature litigation and complaints systems in practice, because they provide institutions

through which a claim can be pursued. India's scheme offers a right without, in many cases, a workable procedure; the consumer-forum route is little used by the vulnerable participants most exposed to research risk.¹⁴ Korea's mediation mechanism offers a middle path, but its application to research injury is untested.²² Australia's complaints commissions offer free, accessible processes but frequently fail to deliver the remedies injured parties seek.²⁶

DISCUSSION

The comparison sustains one broad conclusion: participant protection is achieved not by any single instrument, whether a compensation statute, an insurance policy or a judicial standard, but by their alignment. India has the most protective instrument and the least aligned system, and three reforms follow.

The first is a defined standard of care for research injury. India's courts have concentrated on the regulation of trials rather than the adjudication of the harm they cause, and have not articulated what negligence by a researcher means. The clarity Australia achieved in *Rogers v. Whitaker* offers a model. A research-specific standard would distinguish departure from an approved protocol, which is objectively assessable, from the unforeseen materialisation of a disclosed risk, which is not.

The second is an independent compensation authority. India's no-fault principle is undermined by the sponsor determining the initial assessment of causation and quantum. An independent body, drawing on the experience of the Australian complaint's commissions and the administrative machinery of Korea's vaccine-injury programme, could determine contested claims at lower cost and with greater consistency than litigation, while a defined scale and an appeal to a court would avoid the expectations gap that limits the commissions.^{20,26} The third is a clarified relationship between no-fault compensation and civil liability. India's statute does not remove the participant's tort claim, and the interaction is unsettled. Korea's insurance model and

Australia's indemnity arrangements both presuppose that the civil claim survives alongside the protection, and India could adopt the same structure explicitly: no-fault compensation for defined injuries, assessed by the independent authority, without prejudice to a civil action for negligence. Clarity here would address the principal uncertainty sponsors cite when they relocate trials, without weakening the protection that makes the Indian regime distinctive.

These reforms are modest by design. The Indian framework already contains the most participant-protective principle of the three, and the task is to make it effective rather than replace it. The comparative evidence suggests that the failure of protective regimes is rarely a failure of principle; it is a failure of the machinery through which the principle is delivered.

The study has limitations. It is doctrinal and documentary, confined to interventional trials of drugs and biologicals, and does not measure the incidence of research injury or the outcomes of individual claims. Comparative legal scholarship in Korea and Australia is thinner than in India, so those jurisdictions rest more heavily on primary instruments and medical-legal literature than on dedicated legal commentary. The reform proposals are reasoned from institutional experience rather than tested empirically, and their calibration would require consultation with regulators, sponsors and participant advocates.

CONCLUSION

The injured participant in a clinical trial exposes a gap in the law of medical negligence that no single doctrine fills cleanly. India, South Korea and Australia have each responded in ways reflecting their legal traditions and political histories. India, shocked into reform by litigation and scandal, adopted a statutory no-fault compensation obligation that is the most generous of the three in terms and the most uncertain in operation. South Korea, a civil-law jurisdiction, built a regulatory and insurance-based system that prevents injury prospectively and leaves compensation to the general law and the contract of indemnity.

Australia, shaped by a landmark judicial decision and then by a political reaction to the cost of litigation, produced the clearest standard of care and the most institutionally developed alternatives to the courtroom, at the price of accessibility for the injured. On the measures that matter most to the participant, no jurisdiction performs well on all three. India performs best on compensation in principle and worst on redress in practice; Australia performs best on the standard of care and is constrained on compensation; Korea performs best on preventing injury and least well on compensating those nonetheless harmed. The lesson is that participant protection is achieved not by any single instrument but by their alignment, and India, which has the most protective

instrument and the least aligned system, has the clearest reform agenda.

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REFERENCES

1. Aguilera B, DeGrazia D, Rid A. Regulating international clinical research: an ethical framework for policy-makers. *BMJ Glob Health*. 2020;5(5):e002287.
2. Limaye D, Langer JM, Rühling T, Fortwengel G. A critical appraisal of clinical trials conducted and subsequent drug approvals in India and South Africa. *BMJ Open*. 2015;5(8):e007304.
3. Chowdhury N. Poor definitions threaten drug trial safety in India. *Nat Med*. 2013;19(1):15.
4. Jayaraman K. India's top drug regulator. *Nat Med*. 2014;20(8):802-5.
5. Lemey G, Larivière Y, Matuvanga Zola T, Maketa V, Matangila J, Mitashi P, et al. Algorithm for the support of non-related (serious) adverse events in an Ebola vaccine trial in the Democratic Republic of the Congo. *BMJ Glob Health*. 2021;6(6):e005726.
6. Kessler DP, Summerton N, Graham JR. Effects of the medical liability system in Australia, the UK, and the USA. *Lancet*. 2006;368(9531):240-6.
7. Park HW. Effect of Bioethics and Safety Act in medical research. *J Korean Med Assoc*. 2013;56(8):665-75.
8. Shin S, Jang SG, Min K, Lee W, Kim SY. The legal doctrine on the liability of physicians in medical malpractice lawsuits involving complex regional pain syndrome. *J Korean Med Sci*. 2018;33(9):e46.
9. Herring J. Consistent clinical research standards benefit patients around the world. *Nat Med*. 2011;17(9):1036.
10. Kamalo P, Manda-Taylor L, Rennie S. Translating ethics guidelines on compensation for research-related injuries into policy in low-income countries: lessons learnt from Malawi. *BMJ Glob Health*. 2017;2(Suppl 2):1.
11. Sullivan R, Badwe RA, Rath GK, Pramesh CS, Shanta V, Digumarti R, et al. Cancer research in India: national priorities, global results. *Lancet Oncol*. 2014;15(6):e213-e222.
12. Paramasivan S, Davies P, Richards A, Wade J, Rooshenas L, Mills N, et al. What empirical research has been undertaken on the ethics of clinical research in India? A systematic scoping review and narrative synthesis. *BMJ Glob Health*. 2021;6(5):e004729.
13. Roy Chaudhury R, Mehta D. Regulatory developments in the conduct of clinical trials in India. *Glob Health Epidemiol Genom*. 2016;1:e4.
14. Tiwari SS, Desai PN. Unproven stem cell therapies in India: regulatory challenges and proposed paths forward. *Cell Stem Cell*. 2018;23(5):649-52.

15. Evans V, Roderick P, Pollock AM. Adequacy of clinical trial evidence of metformin fixed-dose combinations for the treatment of type 2 diabetes mellitus in India. *BMJ Glob Health*. 2018;3:e000263.
16. Hahm KH, Lee I. Biomedical ethics policy in Korea: characteristics and historical development. *J Korean Med Sci*. 2012;27 Suppl:S76-81.
17. Choi EK, Kim MJ, Lim NK, Park HY. Review of the registration in the Clinical Research Information Service. *J Korean Med Sci*. 2016;31(1):1-8.
18. Choi YJ, Beck SH, Kang WY, Yoo S, Kim SY, Lee JS, et al. Knowledge and perception about clinical research shapes behavior: face-to-face survey in Korean general public. *J Korean Med Sci*. 2016;31(5):674-81.
19. Kim OJ, Park BJ, Sohn DR, Lee SM, Shin SG. Current status of the institutional review boards in Korea: constitution, operation, and policy for protection of human research participants. *J Korean Med Sci*. 2003;18(1):3-10.
20. Kang CR, Choe YJ, Yoon SJ. COVID-19 vaccine injury compensation program: lessons learned from a review of 10 implementing countries. *J Korean Med Sci*. 2024;39(13):e121.
21. Roh WS, Kim DK, Jeon YH, Kim SH, Lee SC, Ko YK, et al. Analysis of anesthesia-related medical disputes in the 2009-2014 period using the Korean Society of Anesthesiologists database. *J Korean Med Sci*. 2015;30(2):207-13.
22. Park JY. Social recognition of medical accident. *J Korean Med Assoc*. 2011;54(10):1000-2.
23. Choi IS, Choi EY, Lee IH. Challenges in informed consent decision-making in Korean clinical research: a participant perspective. *PLoS One*. 2019;14(5):e0216889.
24. Helps C, Leask J, Barclay L, Carter S. Understanding non-vaccinating parents' views to inform and improve clinical encounters: a qualitative study in an Australian community. *BMJ Open*. 2019;9(5):e026299.
25. Bradfield OM, Bismark M, Scott A, Spittal M. Medical negligence claims and the health and life satisfaction of Australian doctors: a prospective cohort analysis of the MABEL survey. *BMJ Open*. 2022;12(5):e059447.
26. Bismark MM, Spittal MJ, Gogos AJ, Gruen RL, Studdert DM. Remedies sought and obtained in healthcare complaints. *BMJ Qual Saf*. 2011;20(9):806-10.
27. Veness BG, Tibble H, Grenyer BF, Morris JM, Spittal MJ, Nash L, et al. Complaint risk among mental health practitioners compared with physical health practitioners: a retrospective cohort study of complaints to health regulators in Australia. *BMJ Open*. 2019;9(12):e030525.
28. Austin EE, Do V, Nullwala R, Fajardo Pulido D, Hibbert PD, Braithwaite J, et al. Systematic review of the factors and the key indicators that identify doctors at risk of complaints, malpractice claims or impaired performance. *BMJ Open*. 2021;11(8):e050377.
29. Bradfield OM, Bismark M, Scott A, Spittal M. Vocational and psychosocial predictors of medical negligence claims among Australian doctors: a prospective cohort analysis of the MABEL survey. *BMJ Open*. 2022;12(6):e055432.

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