The Safety of Medical Devices: Adverse Event Figures and the Patient's Trust

News context: the investigative report of 6 November 2026 | **Published:** 7 November 2026

Mains: GS-II: Health, transparency and regulatory accountability | **Prelims:** MvPI, IPC, CDSCO and RTI



Original symbolic image: pcsmantra.com

Why in the News

An investigative report published on 6 November 2026, based on figures that emerged under the Right to Information, has raised questions about the safety monitoring of medical devices. According to the report, the Indian Pharmacopoeia Commission (IPC) made available data on **9,373 serious adverse events** received and reviewed since 2020. In the year 2020 there were 808 such reports; in 2025 there were 2,176. These numbers should not be understood as the real rate of device failure among patients, or as final proof of a device defect in every case.

There are two main questions: after information of harm is received, how effective is the safety improvement, and how much information should a patient get while respecting commercial confidentiality?

What Are Medical Devices and Adverse Events

Medical device: an instrument used in the identification, monitoring or treatment of disease, such as stents, catheters, syringes, ventilators and implants. Their risks and conditions of use differ.

Adverse event: an event connected with the use of a device in which a patient or user has suffered harm or a safety concern has arisen. A report being filed is an initial safety signal. Later investigation may bring out a device fault, wrong use, a lapse in procedure or another cause.

Serious event: a case tied to outcomes such as death, a threat to life, prolongation of hospitalisation or serious disability. Ordinary adverse events and serious events are separate categories; the figures of the two cannot be interchanged.

How Monitoring Happens in India

Materiovigilance means collecting safety signals related to medical devices, assessing them and taking measures to prevent harm. The Health Ministry approved the launch of the Materiovigilance Programme of India (MvPI) on **6 July 2015**. The IPC has been its national coordination centre since 2018.

- **Collection of reports:** hospitals, health workers, manufacturers and other informed persons can report a device-related event. The IPC's reporting form gathers details of the device, the event, the outcome and the reporter.
- **Analysis:** repeated signals, severity and possible causes are examined. A single incomplete report and several confirmed events do not carry the same evidentiary weight.
- **Regulatory action:** the Central Drugs Standard Control Organisation (CDSCO) plays the role of the national regulator. Connecting the information received from the monitoring system to the necessary regulatory decisions is important.

What the Rising Number of Reports Shows

More reports can be a sign of more harm, but better monitoring, the participation of more centres and awareness about reporting can also raise the number. So, without bases such as the total sales of devices, the number of devices in use, patients' conditions and the completeness of reporting, the real risk rate cannot be derived.

The investigative report also mentioned 14,584 ordinary medical-device adverse events in the financial year 2024-25. This number is of a different time period and category from the 2025 figure for serious events. Adding them to derive any new total would be wrong.

Confidentiality Versus Public Interest

According to the report, details relating to the manufacturer and brand were not made public on grounds of commercial confidentiality and uncertainty about the cause. This raises a genuine question of balance. Presenting an unconfirmed report as a final verdict of fault would be improper, but holding back all safety-related information can also weaken the patient's informed choice and independent research.

A useful option: identity-protected data, the event's severity, the device's category, the status of the investigation and the outcome of action can be published separately. The public portal should also make clear whether a report is suspected, under investigation, or its cause has been confirmed.

Way Forward

- **Facility at the hospital level:** simple reporting, staff training and information to the patient about the event.
- **From investigation to action:** monitoring of the time between a signal being received, the investigation being completed and safety advice being issued.
- **Transparent data:** identification of duplicate reports, clear mention of time periods, and figures with the usage base.
- **The patient's safety:** clear communication of regulatory action, corrective measures and, when necessary, the process of recalling a device. No patient should take a decision to change their treatment or an implanted device on the basis of this article.

Importance for the Exam

This subject connects **public health, regulatory capacity, RTI and consumer protection**. In the Mains, it is useful to explain not merely the number of accidents, but the relationship between safety signals, determination of cause, public interest and accountability.

Mains Practice Question

How can a balance be made between commercial confidentiality and the patient's safety in monitoring the adverse events of medical devices? Discuss with reference to India's regulatory system. (250 words, 15 marks)

Answer Outline

Introduction: Connect device safety with the quality of treatment and the citizen's right to health.

Main Body: State the separate roles of MvPI, IPC and CDSCO. Discuss under-reporting, uncertainty of cause and the lack of public data. Explain the justification of confidentiality and the balance with public interest; do not treat a report as proven device fault.

Conclusion: Place the need for identity-protected transparency, time-bound investigation and risk-based regulation.

Sources

- The RTI-based investigative report of 6 November 2026
- IPC: India's materiovigilance programme
- IPC: medical device adverse event reporting form
- IPC: guide to digital reporting