INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

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Review Article

A PRISMA 2020–Compliant Systematic Review: KAP Studies conducted on Healthcare Professionals, Students and Consumers about Medical Device related Adverse Events in Indian Hospital settings

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ARTICLE INFO

Published: 19 Jun. 2026
Keywords:
Materiovigilance, Medical Device Adverse Events, MvPI, KAP Study, Patient Safety, India, MDAE Reporting, PRISMA
DOI:
10.5281/zenodo.20759483

ABSTRACT

Background: Materiovigilance Materiovigilance - post-market surveillance of adverse events associated with medical devices - is an important component of patient safety in India in the form of the Materiovigilance Programme of India (MvPI). Underreporting continues to be a challenge although it was introduced in 2015. This is because the knowledge, attitude, and practice (KAP) environment of various stakeholders are important to the enhancement of MvPI. **Objectives:** The objectives of the study are to compile the published KAP evidence on materiovigilance in India among healthcare professionals, students (medical and pharmacy), consumers, and other stakeholders and to establish gaps, enablers, and barriers to MDAE reporting. **Methods:** A system review that is PRISMA 2020 compliant was carried out. Without any date restrictions, the electronic databases were searched (PubMed, Google Scholar, Scopus, DOAJ). Research that had reported KAP of materiovigilance by any population in India in validated questionnaire-based designs were eligible. The inclusion criteria were the fifteen studies (n= 3,260 participants). Analysis of data collection and appraisal of quality was done through a standardized form based on the Joanna Briggs Institute (JBI) checklist in cross-sectional studies. **Results:** In the studies included, the level of MvPI knowledge at baseline was unanimously low (range: 1455%), and the majority of participants expressed knowledge that medical devices are associated with adverse events (>80%). The necessity of MDAE reporting always had a positive attitude (60-95%), but the actual practice of reporting was very low (2-25%). The critical obstacles were the absence of an organized training, the inability to work with the MDAE reporting forms, time limitations, fear of legal actions, and the institutional culture.

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

The educational interventions resulted in considerable changes in KAP scores ($p<0.001$ in pre- and post-studies).
Conclusions: There is a critical knowledge practice gap in the materiovigilance ecosystem of India. Although positive attitudes have a foundation, specific curricula integration, specialized professional training, simplified bilingual reporting instruments, and strong institutional backing is badly required to make MvPI work at the grassroots level.

INTRODUCTION

1.1 Background and Rationale

There is a large range of medical instruments, equipment, implants, software, and in vitro reagents used in the delivery of modern healthcare. Ranging in sophistication between a basic glucometer and an intricate cochlear implant and cardiac stent, these devices touch the patient and, therefore, their post-market safety surveillance is not negotiable. Medical device safety is a patient safety priority that the World Health Organization (WHO) has identified as being globally of importance, thus highlighting the importance of an effective materiovigilance system. The Drug Controller General of India (DCGI) launched Materiovigilance Programme of India (MvPI) on July 6, 2015 on the behalf of the Ministry of Health and Family Welfare, the headquarters of which is the Indian Pharmacopoeia Commission (IPC), Ghaziabad. The program operates through a network of Medical Device Adverse Event Monitoring Centres (MDMCs) and mandates the collection, monitoring, and reporting of adverse events through the standardized Medical Device Adverse Event (MDAE) Reporting Form. India's Medical Devices Rules 2017 (amended 2020) further strengthened the regulatory framework, requiring manufacturers, importers, and distributors to report serious MDAEs within stipulated timelines. Despite this infrastructure, underreporting of MDAEs is a pervasive challenge in India, as it is globally. The cornerstone of any effective surveillance system is the knowledge, attitude, and practice (KAP) of its stakeholders. Healthcare professionals are the primary observers and reporters of MDAEs, while students represent the future workforce, consumers are direct device users, and manufacturers have post-market obligations. Characterizing KAP across these groups in the Indian context is therefore vital for evidence-based policy intervention.

1.2 Review Objectives

This systematic review aimed to:

- Systematically synthesize published KAP evidence on materiovigilance in India across all stakeholder categories
- Quantify knowledge levels, attitudinal profiles, and reporting practices related to MDAEs
- Identify common barriers and facilitators to MDAE reporting
- Assess the impact of educational interventions on KAP outcomes
- Generate evidence-based recommendations for strengthening MvPI implementation

2. Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 standards were followed in conducting this study. The PICo (Population, Interest, Context) framework was used to formulate the review question, and the protocol was created in advance.

2.1 Eligibility Criteria

Inclusion Criteria: (1) Original research articles (observational cross-sectional, pre-post interventional, or quasi-experimental designs); (2) Conducted entirely in India or among Indian

healthcare settings; (3) Reporting data on knowledge, attitude, and/or practice related to materiovigilance or MDAE reporting; (4) Targeting any stakeholder population including physicians, nurses, pharmacists, pharmacy students, medical students, interns, postgraduate residents, consumers, or manufacturers; (5) Published in peer-reviewed journals in English; (6) Any year of publication.

Exclusion Criteria: (1) Review articles, editorials, letters, conference abstracts without full data; (2) Studies outside India or primarily addressing pharmacovigilance without distinct materiovigilance focus; (3) Studies with insufficient KAP data for extraction; (4) Duplicate publications from the same dataset.

2.2 Information Sources and Search Strategy

Systematic electronic database searches were conducted in PubMed/MEDLINE, Google Scholar, Scopus, Directory of Open Access Journals (DOAJ), and Indian Citation Index. The search employed combinations of the following Medical Subject Headings (MeSH) and free-text terms: "materiovigilance," "medical device adverse event," "MDAE," "MvPI," "knowledge attitude practice," "KAP," "medical device surveillance," "India," "medical device reporting." Reference lists of included articles and key journals (IJBCP, JCDR, Perspectives in Clinical Research, NJPPP) were hand-searched. No date or language restriction was applied.

2.3 Study Selection

Using the eligibility criteria, two independent reviewers screened titles and abstracts; conflicts were settled by a third reviewer or by consensus. The whole texts of research that might qualify were obtained and evaluated. The PRISMA 2020 flow diagram (Figure 1) details the selection procedure.

2.4 Data Extraction

A data extraction form was standardized and the following were the major items that were captured: First author, year, journal, study design, setting, state/region, type of participant, sample size, data collection tool, domains assessed (K/A/P), key quantitative KAP findings, barriers identified, educational outcome of the intervention, and author conclusions.

2.5 Quality Assessment

The methodological quality of the included research was assessed using the JBI Critical Appraisal Checklist of Cross-Sectional research (11 criteria) and the JBI checklist of Quasi-Experimental Studies (when it comes to interventional research). All but one study was rated as low quality, moderate, and high.

2.6 Synthesis Approach

Because of high levels of heterogeneity in population of participants, questionnaire measures, and outcome measures among the included studies, formal meta-analysis was not undertaken. A narrative synthesis was done, synthesizing proportions and ranges of data, and the themes were clustered around: (1) areas of knowledge, (2) attitudinal patterns, (3) rates of practice and reporting, (4) barriers, (5) interventional outcomes, and (6) population-specific profiles.

3. Study Selection — Prisma 2020 Flow

Figure 1 below presents the systematic search and selection process. A total of 15 primary studies were ultimately included in this review.

PRISMA Phase	Details
Identification	Records from databases (PubMed, Google Scholar, Scopus, DOAJ, ICI): ~180 records. Additional records via reference and hand searching: ~25. Total identified: ~205
Screening	Records after removal of duplicates: ~170. Records screened on title/abstract: ~170. Records excluded (irrelevant, non-Indian, non-materiovigilance focus): ~130. Full texts assessed for eligibility: 40.
Eligibility	Full texts excluded (n=25): Reviews/letters (n=8), insufficient KAP data (n=9), non-India studies (n=5), pharmacovigilance only (n=3). Studies meeting all criteria: 15.
Included	15 primary studies included in narrative synthesis. Total participants across studies: approximately 3,260.

4. Characteristics Of Included Studies

Table 1 presents the bibliographic and methodological characteristics of all 15 included studies. Together they span 2022–2025, cover 11 Indian states, and collectively enrolled approximately 3,260 participants representing postgraduate residents, MBBS interns, medical students, pharmacy students, consultant physicians, surgeons, nursing staff, pharmacists, physiotherapists, dentists, and consumers.

Table 1: Characteristics and Key Findings of Included Studies (n=15)

Ref	Author (Year)	Journal/ State	Design/ Population	N	Knowledge Findings	Attitude Findings	Practice Findings
S1	Polillan GR et al. (2025)	Educacion Medica Tamil Nadu	Cross-sectional PG Students	73	54.79% adequate	60.27% positive	76.71% good; 23.28% reported
S2	Bangal N et al. (2025)	IJLBPR Maharashtra	Pre-post interventional UG Medical Students (2nd year)	94	Before: 14.8% aware of MvPI; After: 96.8%	Before: 84%; After: 97.8% (MD can cause AEs)	Before: 7.4% trained; After: 78.7%
S3	Kulkarni M et al. (2025)	NJPPP Karnataka	Cross-sectional PG Residents	200	66.5% knew CDSCO; gaps in MvPI specifics	96.5% agreed reporting essential; 95% said mandatory	22.5% reported; 45 knew MDAE form
S4	Singh AV (2025)	IJDRA Uttar Pradesh	Cross-sectional Consumers (OPD/IPD patients)	76	Low; majority unaware of MvPI	Majority recognized importance of reporting	Only 9 out of 76 reported; barriers: lack of knowledge (n=37), doubt about impact (n=22)

S5	Deolekar P et al. (2025)	SJHRA Maharashtra	Cross-sectional Surgeons	149	70.5% knew about MDAE; 75.2% knew who can report; 57% knew NCC	82.4 (mean±SD) attitude score; 86.1% agreed HCPs should report	48.3% encountered MDAE; 25.5% reported; 19.5% received training
S6	Modi K et al. (2023)	JCDR Gujarat	Cross-sectional Medical Doctors	174	Moderate; gaps in MDAE classification knowledge	94.25% willing to report future MDAE	71.83% time constraints; low reporting rates; 48.27% learned device use
S7	Tavethia J et al. (2024–25)	IJP Gujarat	Cross-sectional Healthcare Workers (Doctors + Paramedical)	370	Doctors avg 5.7/10; Paramedical avg 3.76/10; 21.08% knew reporting centers	85.49% doctors willing to report future; 84.34% paramedical	25.1% doctors could name reporting center; language barriers noted
S8	Sojitra B et al. (2024)	Cureus Gujarat	Cross-sectional HCPs (Consultants, Residents, Nurses)	215	62.79% identified MvPI; 87.44% knew risk-based classification	93.95% agreed devices cause AEs; 79% knew all reporting methods	64.19% noticed MDAE; only 27.91% reported; 79% knew reporting methods
S9	Selvam S et al. (2024)	IJBCP Tamil Nadu	Cross-sectional HCPs (Tertiary Care)	220	Gaps in other reporting sources beyond MvPI	76.81% felt MvPI teaching mandatory; 169/220 supported hospital reporting center	104/220 trained; 75/220 had seen reporting form; low actual reporting
S10	Saranraj K, Usha Kiran P (2024)	IJBCP TN + AP	Cross-sectional Medical Professionals (MBBS + PG + Faculty)	496	57.3% knew device classification; 41.9% knew NCC for MvPI	93.5% willing to report MDAEs	12.1% reported; 16.1% trained; 22.2% seen reporting form

S11	Panchal YN et al. (2022)	NJPPP Gujarat	Cross-sectional Surgeons	156	56.4% knew device classification basis	87.2% said HCPs responsible to report; 94.7% agreed reporting improves safety	77.6% never reported; gaps in knowledge of reporting channels
S12	Binu KM et al. (2025)	SJMPS Karnataka	Pre-post interventional HCPs (Mixed: Physio, Pharm, Nurses, Doctors, Dentists)	307	Before: 21.5% knew device classification; After: 92.83% (p<0.001)	Before: 55.7% knew who can report; After: 89.25% (p<0.001)	Before: 16.6% seen MDAE form; After: 91.2% (p<0.001)
S13	Dharman D et al. (2025)	IJOPP Kerala	Cross-sectional Pharmacy Students	118	75.42% aware of classification system; gaps in category details	89.83% agreed devices cause AEs; 92.37% believed reporting necessary	65.25% never seen MDAE form; 80.51% not attended workshops; 80.51% never reported
S14	Dr Sathiyanathan et al. (2025)	EEJPH Karnataka	Cross-sectional Medical Interns	120	76.7% knew device classification; 76.7% knew reporting system	90% agreed HCPs responsible to report; 92.5% said reporting should be compulsory	35% encountered MDAE; 64.2% never trained; 63.3% never seen reporting form
S15	Sushma HK et al. (2025)	IJMPR Karnataka	Cross-sectional Mixed HCPs (Nurses, Interns, PGs, Consultants)	100	82% aware of MvPI concept; 77% knew ADR system; only 22% knew who can report	86% agreed devices cause AEs; 81% felt reporting is not an extra burden	Only 2% reported; 68% unfamiliar with MDAE form; 9% involved in device discussion

Abbreviations: PG = Postgraduate; UG = Undergraduate; HCP = Healthcare Professional; K = Knowledge; A = Attitude; P = Practice; MvPI = Materiovigilance Programme of India; MDAE = Medical Device Adverse Event; N = Number of

Population; TN + AP = Tamil Nadu + Andhra Pradesh

RESULTS

5.1 Overview of Included Studies

The 15 included studies were published between 2022 and 2025. Geographically, studies were conducted across 11 Indian states: Gujarat (4 studies), Karnataka (3), Tamil Nadu (2), Maharashtra (2), Kerala (1), Andhra Pradesh (1 combined with TN), Uttar Pradesh (1), and 1 multi-state study. Study designs were predominantly cross-sectional observational (n=12) with two pre-post educational intervention studies (S2, S12) and one quasi-experimental design. Total enrolled participants across studies: approximately 3,260. Types of participants included postgraduate medical residents (4 studies), mixed healthcare professionals (4 studies), MBBS interns (1 study), undergraduate medical students (1 study), pharmacy students (1 study), surgeons (2 studies), consumers (1 study), and combined group of HCPs (1 study). Self-administered structure questionnaires were used in all studies. Sample sizes ranged from 73 (S1) to 496 (S10).

5.2 Knowledge Domain

5.2.1 Awareness of Materiovigilance Programme of India (MvPI)

The weakest area of all 15 studies was always the knowledge of the MvPI and the composing elements. The pre-intervention awareness of MvPI by name is as low as 14.8% (S2), postgraduates 55.41). In S3, 2/3 of postgraduates were aware that CDSCO was the regulator, but considerable numbers mixed up MCI or USFDA with the responsibility of MvPI. There was awareness among the mixed HCPs in S15 of the existence of the concept of materiovigilance and of the availability of an ADR reporting system on medical devices in India, but the level of operational knowledge was superficial. The year of the MvPI introduction (2015) and the IPC as the National Coordinating Centre were not remembered well: out of S10 (496 medical professionals in Tamil Nadu and Andhra Pradesh), only 41.9% of them correctly recognized IPC as the National Coordinating Centre. In S8 (215 HCPs, Gujarat), the correct identification of MvPI as the current program was 62.79% and the relatively high rate can be explained by the tertiary teaching hospital and the presence of an active MDAE monitoring center.

5.2.2 Knowledge of Medical Device Classification

One of the areas of common knowledge assessment was the risk-based classification of medical devices (Categories A, B, C, D under MDR 2017). However, the correct answers were 56.4 percent (S11, surgeons) to 87.44 percent (S8). Issues with S10 included 57.3% of the respondents being aware of classification as a risk-based method, and 41.1% being able to identify the categories of devices. One of the most difficult specific items within the studies was that of identifying Category C devices: in S1, they identified category C at 67.12 percent correct, and in S5 (only) 49.7 percent correct. These results demonstrate that the risk stratification principle is moderately well-understood, but the knowledge of granular classification is absent.

5.2.3 Knowledge of Who Can Report and How

There was a mixed nature in the understanding of reporter eligibility. Under S3, two in five (133 out of 200; 66.5%) postgraduates were aware that hospital technology managers and other healthcare professionals can report but a widespread

awareness that anyone having direct or indirect information on the devices can report was low. In S8, 167/215 (77.67%) correctly made the inclusive reporter eligibility. In S15, 22% of respondents were aware of who is to report MDAEs. Among S14 (interns), 76.7% had the correct knowledge of the reporting system. HCPs in tertiary institutions, which are parts of MvPI networks (S8: 79% knew all reporting methods), were more likely to know the reporting modalities than those in a community or peripheral setting. The lack of familiarity with the actual MDAE reporting form was a recurrent finding across the studies, with S10 (22.2% saw the form), S13 (pharmacy students, 65.25% had not seen the form) and S14 (interns, 63.3% had not seen the form) all reporting this.

5.3 Attitude Domain

5.3.1 Belief that Medical Devices Can Cause Adverse Events

Near-universal agreement existed across studies that medical devices can cause adverse events (range: 84–96.5%). In S1, 59.46% held a positive attitude toward MDAE reporting. S3 reported 95% acknowledged that medical devices could cause adverse events, and 96.5% believed reporting was essential. In S5 (surgeons), the mean attitude score was 82.4 ± 10.5, with 86.1% agreeing that HCPs bear a responsibility to report. In S14 (interns), 90% agreed that reporting every MDAE is an HCP's responsibility, and 92.5% felt reporting should be compulsory.

5.3.2 Willingness to Report and Perceived Responsibility

Attitudinal willingness to report in future was high: in S10, 93.5% were willing to report; in S6 (Gujarat doctors), 94.25% were willing. In S12 (pre-post study, Karnataka), pre-intervention attitudes about MvPI training need were at 78% agreeing and improved to near-universal post-intervention. Notably, in S5, surgeons who had actually reported MDAEs had significantly higher attitude scores (mean 82.4 ± 10.5) compared to non-reporters (77.1 ± 11.2; p=0.024), confirming the attitude–behaviour link.

5.3.3 Curriculum Integration Attitudes

A strong consensus emerged across studies that materiovigilance should be integrated into undergraduate and postgraduate medical and pharmacy curricula. In S1, the majority of postgraduates agreed upon inclusion of materiovigilance in UG/PG curriculum. In S2 (pre-post study), 84% pre-workshop believed MDAE reporting should be included in induction programs; post-workshop this rose to 97.8% (p=0.00024). In S9 (Chennai HCPs), 76.81% felt MvPI should be taught in detail to HCPs. In S13 (pharmacy students), 92.37% believed reporting adverse events associated with medical devices is necessary.

5.4 Practice Domain

5.4.1 Actual MDAE Reporting Rates

The most striking and consistent finding across all 15 studies is the profound gap between positive attitudes and actual reporting behaviour. Reported MDAE reporting rates ranged from a mere 2% (S15, mixed HCPs Karnataka) to 25.5% (S5, surgeons). In S10 (496 medical professionals across TN and AP), only 12.1% had ever reported an MDAE — despite 93.5% expressing willingness to report. In S11 (Gujarat surgeons), 77.6% had never reported despite 94.7% agreeing that reporting improves patient safety. In S3 (200 postgraduates), only 22.5% had actually reported despite 96.5% believing it was essential.

The most representative population-level finding comes from S7 (370 healthcare workers, Gujarat), where the average knowledge score for doctors was 5.7/10 and for paramedical staff 3.76/10, and overall reporting rates remained very low, underscoring systemic deficiencies.

5.4.2 Familiarity with MDAE Reporting Form

Familiarity with the MDAE reporting form was uniformly low at baseline across all studies. In S1, only 20.54% had seen the reporting form. In S8, only 27.91% of the 64.19% who had noticed adverse events actually reported them. In S14, 63.3% of interns had not seen the reporting form. Post-educational intervention data from S12 showed dramatic improvement: from 16.6% to 91.2% familiarity with the MDAE form ($p<0.001$). In S2, post-workshop 100% of students were aware of the MDAE form compared to some pre-workshop.

5.4.3 Training in MDAE Reporting

Formal training in how to report MDAEs was received by a minority of participants in all baseline cross-sectional studies: 16.1% in S10, 19.5% in 5, 21.91% in S1, 35.8% in 14. After intervention in S2, trained participants rose from 7.4% to 78.7%. In S12, knowledge of who can report improved from 55.7% to 89.25% post-training ($p<0.001$).

5.5 Barriers to MDAE Reporting

Barriers identified across studies were categorized into individual, institutional, and systemic dimensions:

5.5.1 Individual-Level Barriers

Lack of knowledge about MvPI, reporting procedures, and the MDAE form was the most commonly cited individual barrier. Fear of litigation or punitive consequences was highlighted in S6 and S7, with the recommendation that educational campaigns clarify that reports cannot serve as the basis for legal action against reporters. Perceived futility — doubts about whether reports lead to action — affected both HCPs and consumers (S4: n=22 cited this barrier). Cognitive overload and time constraints in clinical settings were prominent in S6 (71.83% of doctors cited time constraints).

5.5.2 Institutional-Level Barriers

Absence of a hospital-level materiovigilance reporting culture, lack of institutional support, and absence of MDAE reporting centers in smaller hospitals were consistently cited. In S9, 169/220 HCPs supported establishing MDAE reporting centers in every hospital — suggesting recognition of this gap. Many institutions lacked a designated materiovigilance officer or coordinator.

5.5.3 Systemic and Tool-Related Barriers

The MDAE reporting form itself was identified as a barrier in S7 (Gujarat): the form was a lengthy five-page document available only in English, making it inaccessible to multilingual healthcare workers and patients. Absence of simple digital reporting platforms and lack of regional language materials further limited engagement.

Consumer-specific barriers (4) included: lack of knowledge about MvPI (n=37), doubts about report impact (n=22), unfamiliarity with reporting channels, and language barriers.

5.6 Consumer Perspective

Study S4 uniquely addressed consumer reporting — an understudied population in materiovigilance literature. Among 76 consumers enrolled from OPD/IPD settings at AMU, Aligarh, the majority had encountered adverse events related to medical

devices either themselves or in their surroundings, yet only 9 individuals had ever reported. Primary barriers were lack of knowledge about MvPI (n=37) and doubts about whether reports would have any tangible impact (n=22). The study recommended public awareness campaigns, multilingual/multilingual reporting mechanisms, and social media-based MvPI engagement to empower consumer participation.

5.7 Educational Interventions

Two studies evaluated the effect of structured educational interventions on materiovigilance KAP. S2 (Bangal N et al., Maharashtra, 2025) conducted a pre-post workshop study with 94 second-year MBBS students. Post-workshop, awareness of MvPI rose from 14.8% to 96.8% (~0 p-value); awareness of who can report MDAE improved from 69.1% to 97.8%; and training experience increased from 7.4% to 78.7%. S12 (Binu KM et al., Karnataka, 2025) enrolled 307 multi-professional healthcare workers; post-educational intervention, knowledge of device classification improved from 21.5% to 92.83%, awareness of all reporters from 55.7% to 89.25%, and MDAE form familiarity from 16.6% to 91.2%, all with $p<0.001$. These results compellingly demonstrate that targeted education produces rapid, statistically significant, and clinically meaningful KAP improvements.

5.8 Population-Specific Summary

The stakeholder analysis indicates the different KAP profiles:

Postgraduate Resident: Intermediate level of baseline knowledge (4955%), high level of positive attitude (6096%), and low level of actual reporting (2223%). Close desire to take part in materiovigilance campaigns. More clinical experience latter senior PGs were more adherent to practice.

MBBS Interns: Good-moderate knowledge on classification and reporting systems (76.7%), and very positive attitudes (90% supported HCP responsibility), but very low training and reporting rates (35% had experienced MDAE, only a few had reported). Represent early training high-yield targets.

Medical Students (Undergraduate): The level of understanding of the specifics of MvPI is very low (14.8%), though very receptive to educational intervention (near-universal improve after workshop). There is the greatest potential benefit of curriculum integration.

Pharmacy Students: Attitudinal results were reasonably high (8992%), however 6580% had not actually viewed the MDAE form and had never reported. This is a serious loophole considering that pharmacists are the important reporters.

Surgeons: MDAEs were found in high proportions in surgeons; 4870% of the surgeons exposed to medical devices reported, and the reporting rates were 2526. Technical MDAE classification information was very scanty. Correlated reporting was also significant with knowledge and attitude scores ($p<0.05$) indicating that knowledge alone is not all that is needed without practice enablers.

Wide cadres' variation (Multi-Cadres): Mixed Healthcare Professionals. The physicians performed higher in terms of knowledge compared to the paramedical employees. Dentists, physiotherapists and nurses were less aware of the baseline. The most drastic improvements were experienced in multidisciplinary educational programs.

Consumers: Low awareness and maximum obstacles. Literary underrepresentation; unique investigation (S4) showed that the knowledge of MvPI is almost completely missing when a practical reporting is involved. One of the large gaps in the system of materiovigilance in India.**5.9 Summary of KAP Proportions by Population Type**

Table 2: Pooled KAP Summary by Stakeholder Category

Stakeholder Category	Knowledge (% adequate/aware)	Attitude (% positive/willing)	Practice (% reported MDAE)
PG Medical Residents	49–67% (baseline)	60–96%	~22–23% (ever reported)
MBBS Interns	~77% (classification)	90–92%	<5% (ever reported)
UG Medical Students	15% (pre) → 97% (post)	84% (pre) → 98% (post)	<10% → 78%+ (post-training)
Pharmacy Students	~75% (classification)	89–92%	<5%; 80% never reported
Surgeons	56–71%	82–87%	25–26%
Mixed HCPs (Physicians)	55–63% (avg score 5.7/10)	85–95%	12–28%
Paramedical/Nursing	~38% (avg score 3.76/10)	~85%	<10%
Consumers	<20%	Moderate (recognized importance)	~12% (9/76)

DISCUSSION

6.1 The Knowledge–Practice Chasm

The main conclusion of this systematic review is the dramatic and steady gap between the knowledge and perception of Indian healthcare stakeholders on the matter of materiovigilance and their practice. Although most of the participants in all 15 studies recognized that medical equipment could result in adverse events (>80-95%), and were willing to report MDAE in future (>85%), actually the rates of MDAE reporting was often less than 30% and less than 2% in a number of studies. This attitude practicing gap is not peculiar to India, but global studies support it. In India, however, it is exacerbated by organizational weaknesses, such as the complexity of the MDAE reporting form, language barrier, and absence of institutional reporting facilities, which have turned an attitude difference into an institutional safety hazard.

In the literature, this gap is explained by: (a) insufficient training in the reporting process; (b) lack of familiarization with MDAE form; (c) fear of litigation; and (d) the lack of reporting culture in institutions. Notably, two of the interventional studies (S2, S12) indicate that specific knowledge items can be bridged through a combination of targeted educational programs quickly and dramatically with post-intervention KAP improvement of 70-80 percentage points.

6.2 Population-Specific Considerations

It is concerning that even pharmacy students who are supposed to study drug and device regulation reported to MDAE at very low rates (80% never reported, 65% never saw the form), since their role of gatekeeping in this aspect is critical to device safety. Practical training on materiovigilance of drugs should be urgently included in the pharmacy curriculum in India. In the same vein, the lack of knowledge of consumers (S4) is consistent across the board, indicating nearly nonnon-existent

public communication regarding MvPI, even ten years after the program has been in existence. Great performance of surgical specialists in terms of knowledge and attitude dimensions (S5, S11) is not surprising because they are highly exposed to medical devices every day. Nonetheless, the awareness of technical classification (Category A-D), particular MDAE criteria and reporting channels was low even in the group of surgeons, and the actual reporting was less than 26 percent. The statistically significant difference in the KAP scores between surgical reporters and non-reporters (S5: knowledge p=0.018, attitude p=0.024, practice p=0.001) supports that the statistically significant improvement in KAP would equally result in statistically significant improvement in practice.

6.3 Geographic and Institutional Heterogeneity

The baseline awareness of MvPI also generally reported higher rates of baseline awareness of MvPI and more frequent encounters with MDAE in studies carried out at institutions themselves (e.g., Mysore Medical College in S3; the hospital in S8) designated as MDMCs than in non-MDMC hospitals. It indicates that it is the proximity to the reporting infrastructure itself that enhances awareness itself, which could indicate an effective network-effect argument in favor of developing MDMC designation. On the other hand, the non-MDMC studies (e.g., community hospitals in S7) provided the data that even physicians working in the non-MDMC settings scored below 60% in terms of their knowledge, which highlights the fact that outreach is urgently required outside of the current nodes of the MvPI network.

6.4 Comparison to Global Materiovigilance KAP Literature

Although direct comparisons are restricted by the heterogeneity of instruments, worldwide sources on the topic of medical device vigilance are a consistent finding on the obstacles to such actions: lack of knowledge, the complexity of forms, time restrictions, and fear of lawsuits. Similar under-reporting effects are observed in studies in Australia (Kingston et al.), EU and the United States. The difficulty of India lies in the size of their healthcare system, language and the fact that the regulatory system is yet to be fully developed and, therefore, context-specific solutions are necessary.

6.5 Limitations of This Review

There are a number of limitations that have to be realized. To start with, the 15 studies included in the article employed heterogeneous questionnaires containing different numbers of items, scoring rubrics, and outcome definitions, which does not permit formal meta-analytic pooling. Second, self-administered questionnaires were used in all studies and this involved social desirability and recall bias. Third, the publication bias might have given preference to the studies realized in tertiary academic centers where there is an active pharmacology service, which could have overestimated awareness. Fourth, several studies used convenience sampling, limiting generalizability. Fifth, with the exception of two studies (S2, S12), all designs were cross-sectional, precluding causal inference about factors that drive practice improvement.

7. Recommendations

7.1 Curriculum Integration

Materiovigilance should be formally incorporated into MBBS and BPharm/PharmD curricula with dedicated modules covering: (a) MvPI structure and IPC-NCC role; (b) MDAE classification criteria; (c) hands-on training with the MDAE reporting form; (d) case-based exercises using

real-world device adverse events. The revised MCI/NMC and PCI undergraduate curricula should mandate materiovigilance as a distinct competency. Given the demonstrated effectiveness of workshops (S2, S12), even single-session educational interventions can produce dramatic KAP improvements, suggesting that resource-light implementation is feasible.

7.2 Professional Continuing Education

State Medical Councils and hospital credentialing bodies should include materiovigilance CME credits as part of annual learning requirements. Specialty societies (e.g., Association of Surgeons of India, Indian Society of Critical Care Medicine) should develop specialty-specific MDAE reporting guidelines and conduct periodic sensitization programs. In-service training for nurses, physiotherapists, and paramedical staff — who had the lowest baseline knowledge scores — is particularly urgent.

7.3 Simplification of Reporting Infrastructure

The current five-page MDAE reporting form should be replaced or supplemented with a shorter digital reporting interface. The MvPI smartphone application should be promoted more aggressively and made available in all 22 scheduled languages of India. IPC should consider pre-populating form fields from hospital electronic health records to reduce the documentation burden. Reporting should be integrated into hospital quality management systems and hospital management software.

7.4 Consumer Awareness

The existing MvPI communication plan is almost entirely targeting healthcare workers. It requires an independent consumer-facing initiative - through social media, Jan Aushadhi Kendras, ASHA workers, patient advocacy organizations and patient information leaflets in local languages. Easy reporting features (e.g., reporting through SMS, consumer helpline) ought to be created. Clinicians and other healthcare professionals must take the initiative to educate persons using devices on the need to report unfavorable occurrences.

7.5 Institutional and Regulatory Enablers

The hospital must have the center of materiovigilance with nominated officers of MDAE. Institutional policies covering good-faith reporters along with clear non-punitive reporting policies should serve to alleviate the fear of litigation as a barrier. The CDSCO and IPC are to increase the MDMC network beyond the existing metropolitan and academic center agglomerations. Frequent reports on the effectiveness of MDAE trends at the national level and the corresponding regulatory responses would serve as an illustration of the worth of reporting, which would cover the barrier to reporting called the doubt about impact identified in S4.

7.6 Research Agenda

Future studies should consider: (a) multi-centre KAP research (large scale) using standard validated measures to facilitate meta-analysis (b) longitudinal research on changes in KAP over time; (c) qualitative research on deeper contextual barriers; (d) research on the manufacturers and importers - missing in the existing literature; (e) economic research on under-reporting burden; and (f) implementation science research on the feasibility of educational interventions.

CONCLUSION

This PRISMA 2020-conformance systematic review of 15 KAP studies (n 1460 participants) on materiovigilance in India indicates that this is a

field in a crossroads. Ten years after the release of MvPI, the level of awareness about the program among the Indian healthcare stakeholders, including postgraduate residents and surgeons, pharmacy students and consumers, is far from ideal, and the actual rates of adverse event reporting are dismal (226) in spite of the widely positive attitudes toward the concept of reporting. Such ignorance-practice disparity is posing a danger of nullifying the intended role of MvPI and causing potentially avoidable harms associated with the device to go unnoticed and unresolved. Although the evidence base is still immature and heterogeneous in method, it is converging consistently upon practice solutions: there should be a targeted educational program, resulting in rapid and dramatic changes in KAP; integration of the curriculum must start at the undergraduate level; consumer involvement, which is often overlooked, must be actively removed; and even systemic obstacles such as the complexity of forms, language, and fear of litigation must be actively dismantled. The evolving medical device market of India, which is estimated to reach USD 50 billion by 2030, and the large number of patients in the country further predisposes the need to have a solid materiovigilance system, which is not only desirable but also a moral and regulatory necessity. Taken together, the articles discussed here form an action plan: to educators, to introduce materiovigilance into each healthcare curriculum, to hospital administrators, to establish reporting cultures, to regulators, to streamline reporting systems, to the general population, to be enabled as active contributors to the safety monitoring of devices. With the positive experience of the first ten years of MvPI, India has an infrastructure to build on, and the chance to become an example of material vigilance in the developing world.

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HOW TO CITE: Dr. C. Dhandapani*, Yuvanraj L., R. M. Padma Priya, A PRISM 2020–Compliant Systematic Review: KAP Studies conducted on Healthcare Professionals, Students and Consumers about Medical Device related Adverse Events in Indian Hospital settings, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 6, 5000-5014. https://doi.org/10.5281/zenodo.20759483