

Breaking barriers: a study on knowledge, attitudes, and practices of Materiovigilance among healthcare workers in Central India

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ABSTRACT

Background: Materiovigilance (Mv) plays a crucial role in patient safety, as medical device adverse events (MDAE) and its reporting and monitoring will help to ensure safety of patient. Healthcare professionals' awareness and participation, however, remain suboptimal despite implementation of Mv program of India (MvPI) in 2015. An in-depth understanding of their knowledge, attitudes and practices (KAP) is key to bridging gap between policy and practice.

Methods: This was an observational, cross-sectional study using a survey on Google Forms sent through social networks. The survey comprised 22 questions related to KAP regarding Mv. Survey responses were obtained from healthcare professionals in Central India. Data were analysed to identify trends and gaps in awareness and engagement.

Results: The 344 out of 500 doctors, Postgraduate residents responded, yielding a response rate of 68.8%. A total of 91.8% accepted adverse event caused by medical devices, and 82.5% accepted that it is responsibility for healthcare professionals to report the events. Despite of having encountered adverse events related to medical device in practice 73.8%, a minor proportion, 25.6%, reported adverse events, while 85.5% showed willingness to report.

Conclusions: Preliminary findings suggest limited awareness among healthcare professionals about MvPI and its reporting protocols. A significant gap exists in their knowledge and practices, underscoring the need for targeted awareness campaigns and training to enhance reporting of MDAEs.

Keywords: Materiovigilance, MvPI, Medical device adverse events, Knowledge attitudes and practices, Healthcare professionals, Patient safety

INTRODUCTION

In the current era of healthcare, the design, use, and reliance on medical gadgets have increased exponentially. From simple thermometers to implanted neurostimulators and prosthetic heart valves, these devices are currently used in all stages of medical intervention, including diagnostic, therapeutic, supportive, and rehabilitative.

The range of hazards connected to their use increases in tandem with their sophistication. This new reality calls for a methodical, analytical, and watchful framework to track device-related hazards, a field known as Mv.^{1,2}

Many medical devices come to market with little long-term safety data because of the shorter clinical evaluation cycles and smaller patient samples, in contrast to pharmaceuticals, whose pharmacodynamics and pharmacokinetics are thoroughly investigated throughout the pre-marketing period.^{3,4} Post-marketing surveillance becomes essential in such a situation. However, historically, pharmacovigilance has taken precedence over device safety, with delayed signal detection and underreporting resulting in avoidable patient harm.⁵

Globally, strong frameworks like Canada's Vigilance Program, Europe's EUDAMED database, and the FDA's medical device reporting (MDR) system have been models

for device-related vigilance. Global regulatory requirements for Mv were harmonized in 2011 with the creation of the international medical device regulators forum (IMDRF).^{6,7} In addition to enabling prompt device recalls, these systems act as sentinel data sources for manufacturers looking to enhance design, usability, and risk communication.⁹

In India, however, journey of Mv has been gradual and fraught with infrastructural, educational and regulatory inertia. Until 2017, medical devices were ambiguously governed under Drugs and Cosmetics Act, 1940, without specificity that devices warrant. Medical devices rules 2017 progressive step in aligning India's regulations with international norms, introducing risk-based classification, quality standards and reporting obligations.^{9,10}

To operationalize post-market surveillance, the *MvPI* was initiated on July 6, 2015, by the Drug Controller General of India and is currently coordinated by the Indian Pharmacopoeia Commission (IPC). The program seeks to develop a nationwide network of Medical Device Adverse Event Monitoring Centers (MDMCs), harmonize reporting forms, conduct root cause analyses, and facilitate regulatory action through the Central Drugs Standard Control Organization (CDSCO).^{11,12}

Despite this strategic blueprint, ground-level data suggest a worrisome gap in the uptake of Mv. Multiple KAP studies across tertiary healthcare institutions and private surgical practices have revealed a paradox high awareness of device-associated risks but an alarmingly low rate of adverse event reporting. In a multicentric study in Gujarat, while 71.8% of respondents were aware of reporting systems, only 9% had ever reported incident.¹³ Similarly, in a national institute-based survey, although over 92% acknowledged possibility of device-related complications, merely 20.13% had taken action to report such events.¹⁴

A crucial point is brought up by these findings: why does this inertia continue in spite of institutional frameworks and legislative mandates? A number of obstacles have been noted:

Insufficient training

Even in elite institutions, the majority of medical practitioners lack awareness of the procedural facets of MDAE reporting.

Fear of legal action or administrative retaliation

Reporters may worry about professional repercussions if they lack legal protection.

Lack of system transparency or instant feedback

After a report is submitted, there is frequently no feedback loop to recognize its value, which lowers the incentive for further reporting.

Infrastructure constraints

Real-time documentation and analysis are challenging in non-urban hospitals due to the lack of biomedical engineering departments or specialized vigilance officers.^{5,11,15}

In addition, structural limitations such as a fragmented supply chain, a lack of integrated electronic health records, and excessive outpatient and surgical loads frequently affect device users in India, including surgeons, anesthetists, nurses, and technicians. Instead of being viewed as a therapeutic obligation in such a setting, Mv is usually seen as an administrative burden.¹⁶

But this perception needs to shift. The legitimacy of India's domestic Mv system is crucial for international licensing, safety standards, and worldwide export compliance as the country grows its medical device manufacturing industry under the "Make in India" push. Beyond regulatory optics, moral motivation is just as strong: every defect that goes unreported represents lost chance to save next patient.¹⁷

Incorporating Mv into undergraduate and graduate medical, dentistry, and nursing programs is crucial going forward. Incentives for institutional reporting performance, public awareness campaigns, anonymous digital reporting platforms, and mandatory continuing medical education (CME) modules are desperately needed. Additionally, the integration of AI into national-level dashboards and signal identification has the potential to transform trend surveillance and predictive analytics.¹

As a result, Mv needs to be rethought as a sentinel that protects the integrity of medical intervention rather than just a regulatory checklist.

METHODS

This KAP study was conducted at RKDF medical college hospital and research center, Bhopal, from September 2024–December 2024, among physicians, postgraduate residents and MBBS students involved in medical device usage. The study's objective was to assess their Mv-related knowledge, attitudes, and behaviors.

Using online platforms, convenience sampling was used to select participants, who included licensed clinicians from both public and private institutions. Clinical professionals and administrative workers who did not work with medical devices were not included; participation required free consent and direct engagement with the devices. To ensure participant autonomy and anonymity, informed consent was obtained electronically and ethical approval was acquired from the institutional ethics committee.

Data collection instrument

Based on previously approved Mv KAP tools, a structured, self-administered questionnaire was created in English and

tailored to the Indian healthcare environment. There were two sections on the questionnaire:

Section 1

Professional and demographic details, such as age, sex, title, specialization, years of clinical experience, and previous training in Mv.

Section 2

The 22 items measuring KAP in relation to Mv knowledge: Ten multiple-choice questions that test a fundamental comprehension of adverse event identification, regulatory procedures, and Mv principles. Correct answers received a score of 1, while incorrect or "don't know" answers received a score of 0.

Attitude and practice

Twelve questions total; six use a 4-point Likert scale (Strongly agree, Agree, Disagree and Strongly disagree) to gauge attitudes toward Mv, and six use yes/no responses to gauge self-reported practices around reporting unpleasant events.

Before receiving final ethical clearance, the questionnaire was improved in pilot research involving thirty clinicians. In order to maximize response rates, the survey was distributed electronically via social media, institutional emails, and professional WhatsApp groups. Follow-up reminders were also sent out.

Statistical analysis

Data analysis was performed using IBM SPSS Statistics (version XX). Descriptive statistics summarized participant characteristics and KAP responses. Knowledge scores were categorized into poor, moderate, and good levels. Associations between demographics and KAP outcomes were analyzed using chi-square and t-tests for continuous variables, with significance set at the p value < 0.05 .

RESULTS

Demographic characteristics

The survey included 344 healthcare professionals in total. Most respondents (43%) were between the ages of 26 and 30, with those between the ages of 31 and 40 coming in second (39.5%). Other age categories showed a preponderance of early- to mid-career physicians, including those aged 21-25 years (6.4%), 41-50 years (9.3%), 51-60 years (1.2%), and 61-70 years (0.6%).

Regarding professional designation, the majority of participants (41.3%) were postgraduate students, followed by MBBS medical officers (23.8%) and faculty and consultants (34.9%). Because all of the respondents are

actively involved in patient care, including medical devices, this respondent profile guaranteed a representative sample across various levels of clinical responsibility and expertise.

Assessment of knowledge

A well-crafted 10-item questionnaire covering important aspects of Mv, such as device classification, regulatory oversight, adverse event reporting procedures, and required reporting dates, was used to assess the knowledge domain of this study. With a maximum possible score of 10, each correct response was worth one point. With a mean knowledge score of 3.70 ± 1.57 , the participants showed a noticeably poor understanding of fundamental Mv concepts and procedures.

Within the cohort of 344 respondents, 57.6% correctly identified the risk-based classification of medical devices, whereas only 38.4% recognized devices categorized under the highest risk, class D. Awareness of the MvPI was observed in merely 34.9% of participants, with 29.1% correctly identifying the IPC as the national coordinating authority. Although 68.6% understood that adverse event reporting can be performed by any healthcare professional, awareness of critical reporting timelines for serious adverse events was alarmingly low at 20.3%. Furthermore, a scant 16.3% could accurately distinguish between reportable and non-reportable adverse events, underscoring significant deficits in the regulatory knowledge.

Statistical analysis revealed no significant difference in mean knowledge scores across different professional designations ($p=0.074$), indicating uniformly low awareness levels irrespective of clinical experience or role. These findings emphasize the pressing need for comprehensive educational programs and institutional support to elevate Mv literacy among healthcare practitioners in Madhya Pradesh, thereby fortifying patient safety frameworks and regulatory adherence.

Assessment of attitude

The present study meticulously evaluated participants' attitudinal orientation toward Mv through a six-item Likert-scale-based instrument. This instrument was structured to assess domains such as perception of harm, ethical responsibility, regulatory compliance, and educational needs in the context of medical device surveillance. The results elucidate a broadly affirmative attitudinal trend among respondents, reflecting a latent readiness to engage with Mv systems, contingent upon appropriate institutional scaffolding.

Despite their therapeutic value, medical devices can occasionally injure patients, according to an astounding 91.8% of respondents (33.7% strongly agree and 58.1% agree). Any effective Mv framework must start with this

understanding since risk awareness comes before all types of regulatory vigilance and reporting practices.

In reference to the ethical and professional obligation to report, 82.5% of participants (36% strongly agreed, 46.5% agreed) said that reporting adverse occurrences associated to devices should be the direct responsibility of healthcare providers. This group's propensity for responsibility shows a mature professional attitude and points to the possibility of institutional or regulatory reporting requirements being accepted soon.

When asking whether reporting should be required, 80.8% of respondents (36.6% strongly agreed and 44.2% agreed) supported the notion that adverse event reporting ought to be made mandatory and not optional. This perspective underlines necessity for India's healthcare system to shift toward a more legally codified and enforcement-oriented approach to Mv and consistent with global best practices.

A high level of regulatory consciousness is also demonstrated by the vast majority of respondents (91.9%) who stated that promoting adverse event reporting will significantly enhance patient safety and the caliber of medical devices. This agreement draws attention to the possible influence of reporting systems on subsequent events, including post-market surveillance, device recalls, and the creation of policies.

Additionally encouraging was the readiness to report: 85.5% of participants said they would report an adverse event if they had one, indicating an intent-to-act that can be used with the help of enabling technologies including feedback systems, in-hospital nodal officers, and digital reporting platforms.

Lastly, 94.2% of respondents agreed, with 43.6% strongly agreeing, that systematic training in Mv is necessary. This realization highlights a significant weakness in the current platforms for CME and healthcare curricula. Although there is awareness, frontline doctors may still lack operational knowledge and hands-on confidence, according to the demand for upskilling.

Assessment of practice

Six structured questions centered on clinical encounters, reporting behavior, regulatory familiarity, and procedural abilities were used in this study to evaluate healthcare worker's practical implementation of Mv.

Just 120 individuals (34.6%) out of 344 respondents said they had at least one experience during clinical practice where a medical device caused injury or an adverse event. However, 88 participants (25.6%) acknowledged that they have in fact reported such events, a much smaller percentage. Despite the existence of observable incidents, this disparity reveals a critical underreporting trend, suggesting either procedural inertia or a lack of systemic encouragement.

Only 126 participants (36.6%) indicated that they were familiar with the MvPI, suggesting that practitioners generally are not aware of the national regulatory framework. Inadequate training further exacerbated this ignorance: just 92 respondents (26.7%) had ever been formally trained on how to report adverse events connected to medical devices.

In terms of operations, the difference became even more: only 100 respondents (29.1%) said they knew how to correctly fill out the official medical device adverse event reporting form, and only 104 participants (30.2%) had ever seen it. When taken as a whole, these numbers highlight a troubling disconnect between clinical accountability and actual practice.

In conclusion, even though one-third of respondents have personally experienced negative outcomes brought on by medical devices, the great majority do not have the knowledge, resources, or self-assurance required to meet their reporting requirements. Urgent measures are required to close this practice gap, including requiring seminars for in-service physicians, institutionalizing Mv modules in postgraduate training, and strengthening regulatory accountability systems in Madhya Pradesh's public and private healthcare systems.

Table 1: Demographic characteristics of participants, (n=344).

Demographic characteristics	Categories	N
Age (in years)	21-25	22 (6.4%)
	26-30	148 (43%)
	31-40	136 (39.5%)
	41-50	32 (9.3%)
	51-60	4 (1.2%)
	61-70	2 (0.6%)
Designation	MBBS medical officer	58 (16.9%)
	Post graduate	142 (41.3%)
	Faculty/consultant	120 (34.9%)
	Nursing staff	16 (4.7%)
	Pharmacist	8 (2.3%)

Table 2: Knowledge regarding Mv among participants.

Knowledge	Correct	Incorrect
1. How are medical devices categorised into classes in India?	198 (57.6%)	146 (42.4%)
2. Which medical device falls under Category D in India?	132 (38.4%)	212 (61.6%)
3. What is the name of the program currently used in India to monitor adverse events related to medical devices?	120 (34.9%)	224 (65.1%)
4. Who is eligible to report adverse events caused by medical devices in India?	236 (68.6%)	108 (31.4%)
5. Which organisation is the National Coordination Centre for monitoring adverse events related to medical devices in India?	100 (29.1%)	244 (70.9%)
6. Which of the following adverse events does not require reporting?	56 (16.3%)	288 (83.7%)
7. What methods are available in India for reporting adverse events related to medical devices?	96 (27.9%)	248 (72.1%)
8. Which adverse event should be reported?	146 (42.4 %)	198 (57.6)
9. Which of the following is NOT a partner organisation of the MvPI?	132 (38.4%)	212 (61.6%)
10. Within what time frame must a serious adverse event caused by a medical device be reported in India?	70 (20.3%)	274 (79.7%)

Table 3: Attitude towards Mv.

Attitude	N
1. Do you think medical devices can sometimes cause harm to patients?	Strongly agree 116 (33.7%)
	Agree 200 (58.1%)
	Disagree 18 (5.2%)
	Strongly disagree 10 (2.9%)
2. Should medical professionals take responsibility for reporting every adverse event caused by a medical device?	Strongly agree 124 (36%)
	Agree 160 (46.5%)
	Disagree 36 (10.5%)
	Strongly disagree 24 (7%)
3. Do you feel reporting medical device-related adverse events should be a compulsory practice?	Strongly agree 126 (36.6%)
	Agree 152 (44.2%)
	Disagree 52 (15.1%)
	Strongly disagree 14 (4.1%)
4. Do you believe that encouraging the reporting of such events can make healthcare safer for patients?	Strongly agree 134 (39%)
	Agree 182 (52.9%)
	Disagree 20 (5.8%)
	Strongly disagree 8 (2.3%)
5. Would you personally report an adverse event caused by a medical device?	Strongly agree 118 (34.3%)

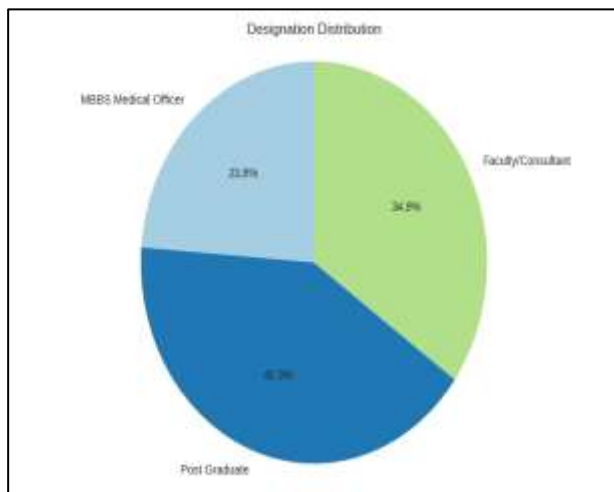


Figure 1: Designation distribution.

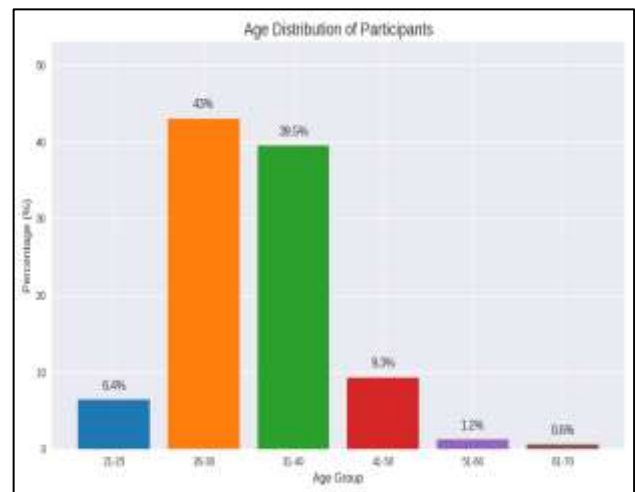


Figure 2: Age distribution of participants.

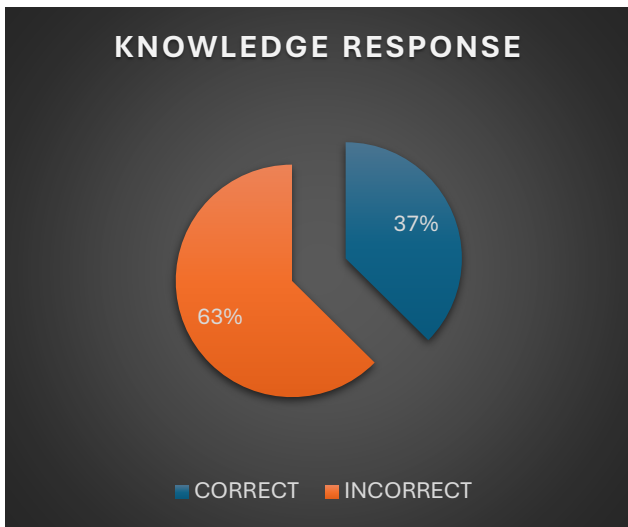


Figure 3: Knowledge response of participants.

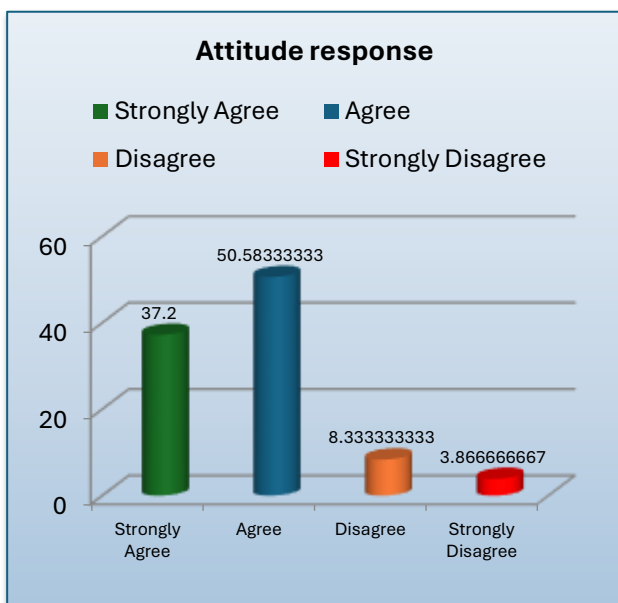


Figure 4: Attitude towards Mv.



Figure 5: Practice of Mv among participants.

DISCUSSION

The purpose of this study was to assess Central Indian healthcare professional’s KAP regarding Mv. The results show a startling discrepancy between clinical practice reporting behaviors, positive attitudes toward vigilance, and awareness of the risks associated with medical devices. Even while most respondents agreed that adverse events can occur from medical devices and that it is their ethical duty to report them, actual reporting procedures were found to be less than ideal. According to earlier Indian and international studies on Mv and pharmacovigilance, there is a persisting knowledge-practice gap that is reflected in this.^{13,14}

All professional groups had consistently poor knowledge scores, which was one of the survey’s most alarming findings. Even though the MvPI has been in place for almost ten years, fewer than one-third of those surveyed knew about it, its coordinating body, or the official case reporting form. This suggests that institutional sensitization, training opportunities, and information distribution are still woefully insufficient. On the other hand, more robust Mv frameworks, like the EU’s EUDAMED database or the FDA’s MDR system in the US, have effectively combined training, reporting platforms, and feedback channels to guarantee greater compliance among medical technicians. The relatively new approach in India still seems to be having trouble getting enough traction in routine clinical practice.^{12,15}

The attitudinal findings, however, are encouraging. Nearly 92% of participants acknowledged the potential of Mv to enhance patient safety, and over 85% expressed willingness to report adverse events. Furthermore, the widespread consensus for mandatory training and obligatory reporting points to a strong latent readiness among physicians, which can be harnessed through systematic interventions. This aligns with other studies highlighting that healthcare professionals are generally not resistant to vigilance systems; instead, their inaction stems primarily from lack of knowledge, procedural clarity, and absence of operational channels rather than from apathy or disregard.^{13,14}

In terms of practice, the results demonstrate how structural and educational barriers hinder real-time reporting.¹⁷ While more than one-third of the respondents had directly encountered adverse events from medical devices, only a quarter took action to report them. Several reasons may explain this gap. First, a lack of training in adverse event form completion prevents physicians from converting intent into practice. Only 30% of respondents had even seen the reporting form, suggesting that operational tools are not widely circulated or taught. Second, the absence of immediate feedback or visible institutional support may reduce motivation to report, echoing common concerns that reporting systems often function as “black boxes.”¹⁷ Finally, cultural and administrative barriers, such as fear of punitive action or

medico-legal consequences, may exacerbate underreporting, a problem already well-documented in pharmacovigilance in India.

The implications of these findings are twofold. At the policy level, there is an urgent need to re-emphasize the MvPI infrastructure by ensuring its visibility and usability at the hospital level. Designating Mv officers within institutions, integrating reporting dashboards into electronic medical records, and creating simplified mobile applications could drastically reduce procedural friction. International experience demonstrates that digital tools with real-time feedback significantly improve reporting compliance.^{12,15} At the educational level, incorporation of Mv modules into undergraduate and postgraduate curricula, hands-on workshops, and mandatory CME sessions are pivotal. This study's finding that over 94% of participants demand structured training underscores the necessity of curriculum-based reforms, which would gradually normalize device surveillance as a professional duty rather than an optional administrative task.¹⁵

The study has consequences for the expanding medical device sector in India as well. In addition to protecting patients, strengthening Mv reporting also improves regulatory legitimacy, builds global confidence in devices made in India, and lowers financial losses related to recalls. A reliable monitoring system will be essential to attaining worldwide competitiveness in the "Make in India" framework. If deliberate interventions are implemented, a similar trajectory for Mv is possible, drawing parallels with pharmacovigilance, where India went from reporting very little to becoming one of the top contributors to the WHO Uppsala Monitoring Centre database.¹⁷

Lastly, it is important to recognize some of the current study's shortcomings. Selection bias may have been created by the use of online surveys and convenience sampling, which favored younger, tech-savvy doctors, especially postgraduate residents. As a result, there is still minimal generalizability across all healthcare professional levels, including nurses and biomedical engineers. Additionally vulnerable to recollection and social desirability bias are self-reported responses. However, the results show significant patterns that draw attention to the structural resistance that keeps Central India from adopting the best Mv practices.¹⁴

Overall, Madhya Pradesh's healthcare workers have good attitudes about Mv, but they don't know much about the MvPI framework or real reporting procedures. This emphasizes how urgently organized educational initiatives, institutional accountability, and the incorporation of easily navigable reporting systems are needed. In addition to improving patient safety, closing this knowledge-practice gap will improve India's reputation in the world of medical device oversight.

This study has certain limitations that should be acknowledged. It's possible that selection bias was created by the use of convenience sampling and online data collecting, favoring younger and more tech-savvy medical personnel. The accuracy of stated practices may have been impacted by the inherent recall and social desirability biases in self-reported replies. The results of the study can't be applied to other healthcare settings in India because it was only carried out in one area. Multidisciplinary perspectives on Mv procedures were further hampered by the limited participation of technical workers, biomedical engineers, and nurses. Additionally, causal inferences are not possible due to the cross-sectional design. It is advised that future multicentric, longitudinal research use objective reporting data in order to produce stronger and more broadly applicable evidence.

CONCLUSION

This study highlights a glaring discrepancy in Central Indian healthcare workers' knowledge, perspectives, and behaviors regarding Mv. The MvPI and its working procedures were not well understood by the majority of respondents, despite the fact that they acknowledged the dangers of medical devices and indicated a desire to report adverse occurrences. As a result, underreporting has persisted. To close this knowledge-practice gap, the results emphasize the critical need for curricular integration, organized training, and easy-to-use reporting tools. In addition to protecting patient safety, enhancing Mv is crucial for maintaining regulatory credibility and helping India's medical device sector meet international standards.

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