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Self-Reported Awareness, Attitudes and Barriers Related to Dental-Device Materiovigilance: A Cross-Sectional Survey

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Abstract:

- ***Background:***

Materiovigilance supports the monitoring of adverse events related to medical devices. Dental clinicians and trainees may encounter device-related problems, yet may not know how to report them. This survey described self-reported awareness, attitudes, and perceived barriers related to materiovigilance in dentistry, with questions referring to India's Materiovigilance Programme of India (MvPI).

- ***Methods:***

We conducted a descriptive analysis of an exported cross-sectional questionnaire dataset. The export contained 218 submissions. We included the 211 submissions with an affirmative consent response and excluded seven for which affirmative consent was not recorded. We report item-specific counts and percentages using the number of non-missing responses as each denominator. We did not calculate a response rate because the number invited was unavailable. The export did not document the sampling frame, recruitment method, survey setting, eligibility criteria, or instrument validation.

- ***Results:***

Among 211 consented submissions, 209 included gender and professional-status data. Of these, 168 (80.4%) were from undergraduate students, 22 (10.5%) from postgraduate students, and 19 (9.1%) from faculty. Median age was 23 years (interquartile range, 22–25; 205 parseable records). Ninety of 205 respondents (43.9%) reported awareness of the term materiovigilance; 53/201 (26.4%) reported awareness of the MDAE reporting form; and 42/186 (22.6%) said they knew exactly how to report an event through formal channels. A perceived lack of adequate reporting information or training was reported by 132/203 (65.0%). A total of 145/203 (71.4%) agreed or strongly agreed that adverse-event reporting should be included in undergraduate dental curricula. Immediate access to reporting forms was reported by 40/204 (19.6%).

- ***Conclusions:***

In these consented survey submissions, self-reported familiarity with practical reporting mechanisms was limited, while support for curricular inclusion was common. These descriptive findings identify potential education and access priorities but cannot establish population prevalence, actual reporting competence, or causal relationships. The number of unique individuals is uncertain because the source export contains repeated account identifiers. Study setting, recruitment, ethics-review information, and other design details require author confirmation.

- ***Reporting:***

The manuscript is structured around the STROBE recommendations for cross-sectional studies [1]. PRISMA 2020 is not applicable because no systematic review was conducted; the questionnaire export cannot support a PRISMA search or study-selection flow [2].

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I. INTRODUCTION

Medical-device surveillance depends in part on identifying and reporting adverse events after devices enter clinical use. India's Materiovigilance Programme of India (MvPI) was launched in 2015, with the Indian Pharmacopoeia Commission serving as the programme's National Coordination Centre. The programme describes its purpose as monitoring medical-device safety and facilitating adverse-event reporting [3]. The official Medical Device Adverse Event reporting form is designed for healthcare professionals as well as manufacturers, importers, and distributors. Its instructions list submission routes that include email, postal submission, and a telephone helpline [4].

Dental care involves materials and devices that may fail, cause complications, or be associated with an adverse reaction. Recognizing a potential event is only one step: clinicians also need to identify whether an event is reportable, locate the correct route, and understand what information to provide. A survey that asks about knowledge, confidence, access, and training can help identify perceived gaps, although self-reported awareness is not the same as demonstrated knowledge or reporting behaviour.

This study describes responses to a questionnaire concerning dental-device materiovigilance, including awareness of MvPI-related reporting, perceived training and access, prior exposure to possible adverse events, and attitudes toward education and reporting. The survey export did not contain a stated protocol or prespecified hypotheses; the objective is therefore descriptive.

II. METHODS

- *Study design and setting* this was a cross-sectional questionnaire survey, as indicated by the single-time-point response format and variables in the supplied export. Timestamp metadata in the CSV spans 8 July to 16 September 2026 (GMT+5:30). The survey platform, geographic and institutional setting, recruitment channels, sampling frame, eligibility criteria, and date on which data collection closed were not supplied and must be confirmed by the study authors. The questions refer to MvPI and Indian device-safety arrangements, but the export does not establish that all participants were located in India.
- *Participants and consent,* the dataset contained 218 submissions. The consent field contained "Yes" for 211 submissions and was blank for seven. We included only submissions with an affirmative consent response. The export contains repeated account identifiers. Because the study team did not provide a prespecified duplicate-detection rule or respondent linkage procedure, we did not attempt to deduplicate records. Therefore, the analytic count represents consented submissions and may not equal the number of unique people. No invitation denominator was available, so a participation or response rate could not be calculated.
- *Questionnaire and variables,* The questionnaire included demographic fields and items about awareness of the term materiovigilance, the relevant Indian regulatory authority, device risk classification, the

Medical Device Adverse Event (MDAE) form, device categories, and reporting routes. It also asked about perceived training gaps, curriculum inclusion, patient-safety benefits, expected feedback, responsibility for reporting, prior exposure to a possible device-related complication, access to reporting forms, reluctance to report, and previous participation in targeted training.

The export did not include the complete questionnaire as administered, a scoring protocol, evidence of instrument validation, or a prespecified definition of adequate knowledge. Accordingly, we analysed each item separately and did not create a composite knowledge or attitude score. Responses describe participants' perceptions and are not treated as objective tests of knowledge or as statements of legal responsibility.

- *Data processing and statistical analysis* We restricted analysis to submissions with affirmative consent. For each survey item, we calculated the frequency and percentage for each recorded response, using non-missing responses to that item as the denominator. Missing item responses were not imputed. Percentages may not sum to 100 because of rounding Age was entered as free text. For descriptive summarization, we extracted the first integer from each entry and retained values from 18 through 100 years. This yielded 205 parseable ages; the median and interquartile range are reported. The "years in practice" field contained heterogeneous entries, including years of study, calendar years, free-text descriptions, and non-numeric answers. We did not calculate a summary for that field. No inferential testing or subgroup modeling was performed because the export supplied no prespecified analysis plan and the objective was descriptive.
- *Reporting guidance* We used the STROBE cross-sectional checklist to structure reporting [1]. PRISMA 2020 is intended for reporting systematic reviews and related evidence syntheses [2]. No review search, eligibility screening, or study synthesis was performed for this survey manuscript; a PRISMA flow diagram and PRISMA compliance claim would therefore be inappropriate.

III. RESULTS

Submission flow and participant characteristics Of 218 records in the export, 211 had affirmative consent recorded and were included; seven with no recorded affirmative consent were excluded. Item nonresponse ranged from five to 25 among the 211 included submissions. The formal reporting-channel question had the most missing responses (25/211, 11.8%). Among submissions with demographic data, 137/209 (65.6%) recorded female gender and 72/209 (34.4%) male gender. Professional status was undergraduate student for 168/209 (80.4%), postgraduate student for 22/209 (10.5%), and faculty for 19/209 (9.1%). Among 205 parseable age entries, median age was 23 years (interquartile range, 22–25; range, 20–60). The practice-years field was not

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summarized because its entries were not consistently interpretable.

- *Awareness and reporting knowledge* Ninety of 205 submissions (43.9%) reported awareness of the term materiovigilance. Seventy-eight of 204 (38.2%) reported that they could identify the relevant regulatory authority, and 83/204 (40.7%) reported knowing about dental-device risk classification. Awareness of the MDAE form was reported by 53/201 (26.4%). Although 109/205 (53.2%) reported knowing which dental materials fall under the medical-device category, only 54/204 (26.5%) reported awareness of the official helpline or portal asked about in the questionnaire.

For a separate item about formal reporting channels, 42/186 respondents (22.6%) said they knew exactly how to report an event. Fifty-eight (31.2%) said they were aware but unsure of the exact process, and 86 (46.2%) said they were not aware of formal channels. The questionnaire's wording about a "helpline number or digital portal" does not cover every route listed on the official MDAE form, so this item should be interpreted as a response to that wording rather than a complete audit of knowledge of all official routes [4].

- *Attitudes, experience, and perceived barriers* A total of 145/203 submissions (71.4%) agreed or strongly agreed that adverse-event reporting should be included in the undergraduate dental curriculum. A perceived lack of adequate information or training was reported by 132/203 (65.0%). On whether reporting improves patient safety, 123/205 (60.0%) agreed or strongly agreed, 42 (20.5%) were neutral, and 40 (19.5%) disagreed or strongly disagreed. Sixty-six of 204 respondents (32.4%) reported having encountered a patient with a possible dental-material or device-related reaction or complication; 39 (19.1%) selected "Maybe." Only 40/204 (19.6%) reported immediate and free access to an MDAE form at their clinic or hospital, while 124 (60.8%) reported no access and 40 (19.6%) selected "Maybe." Forty three of 202 (21.3%) reported having refrained from reporting because of legal concerns or lack of understanding; a further 46 (22.8%) selected "Maybe." Previous participation in targeted materiovigilance workshops or continuing-dental-education programmes was reported by 54/206 (26.2%).

Table 1 Responses to Survey Items Among Submissions with Affirmative Consent. Percentages Use the Item-Specific Non-Missing Denominator. Wording is Shortened for Readability; Response Categories Follow the Export.

Survey domain (shortened item)	Valid n	Response distribution, n (%)
Awareness of the term *materiovigilance*	205	Yes 90 (43.9); No 115 (56.1)
Identify Indian regulatory authority	204	Yes 78 (38.2); No 126 (61.8)
Know device risk classification	204	Yes 83 (40.7); No 121 (59.3)
Aware of MDAE form under MvPI	201	Yes 53 (26.4); No 148 (73.6)
Know which dental materials are medical devices	205	Yes 109 (53.2); No 96 (46.8)

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Aware of official helpline or portal	204	Yes 54 (26.5); No 150 (73.5)
Include reporting in undergraduate curriculum	203	Strongly agree 69 (34.0); Agree 76 (37.4); Neutral 48 (23.6); Disagree 10 (4.9)
Perceive inadequate reporting information/training	203	Yes 132 (65.0); No 41 (20.2); Unsure 30 (14.8)
Reporting improves patient safety	205	Strongly agree 34 (16.6); Agree 89 (43.4); Neutral 42 (20.5); Disagree 13 (6.3); Strongly disagree 27 (13.2)
Expect feedback after an event report	203	Yes 115 (56.7); Maybe 44 (21.7); No 44 (21.7)
Healthcare professional has primary reporting obligation	202	Yes 103 (51.0); Maybe 47 (23.3); No 52 (25.7)
Encountered possible device/material complication	204	Yes 66 (32.4); Maybe 39 (19.1); No 99 (48.5)
Immediate/free access to reporting form	204	Yes 40 (19.6); Maybe 40 (19.6); No 124 (60.8)
Refrained from reporting due to legal concerns/limited understanding	202	Yes 43 (21.3); Maybe 46 (22.8); No 113 (55.9)
Awareness of formal channels and reporting process	186	Not aware 86 (46.2); Aware but unsure of process 58 (31.2); Knows exactly how 42 (22.6)
Prior targeted workshop/CDE participation	206	Yes 54 (26.2); Maybe 20 (9.7); No 132 (64.1)

IV. DISCUSSION

In this dataset, the most consistent pattern was a gap between broad recognition of some device-related concepts and familiarity with practical reporting. About two in five submissions reported awareness of the term materiovigilance or the relevant authority, while roughly one in four reported awareness of the MDAE form or official helpline/portal. Fewer than one in four respondents who answered the formal-channel item said they knew exactly how to report.

These are self-reports, not demonstrations of competence, and the study cannot establish whether respondents would successfully identify or submit a report in practice. Perceived educational need was common. Nearly two-thirds reported inadequate information or training, and more than seven in ten supported curriculum inclusion. Fewer than one in three reported previous targeted training. These findings point to practical opportunities for dental education: teach how to recognize a potentially reportable event, where to find the current form, which reporting route is available, and what information to record. Because the survey did not test an educational intervention, it cannot show that any particular training approach would improve reporting.

Access may be a separate obstacle. Only about one in five respondents reported immediate, free access to an MDAE form in their clinic or hospital. The official programme form is intended for healthcare professionals and lists multiple reporting options, including email, postal submission, and a helpline [4].

The survey item asked about a helpline or portal, however, so the low reported awareness may reflect limited knowledge, question wording, or both. Future questionnaires should distinguish awareness of the form, knowledge of each submission route, ability to locate the current contact details, and prior submission experience.

A substantial minority reported a possible prior complication, while around one in five said they had refrained from reporting because of legal concerns or limited understanding. The form itself states that submission does not constitute an admission of causation and that reporter and patient identities are protected [4]. This information could be

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incorporated into education, but the present survey did not establish whether legal concern caused non reporting or whether participants had seen or understood the form's disclaimer. Responses about whose "primary obligation" it is to report are perceptions and should not be interpreted as a legal conclusion.

- *Strengths and limitations* the dataset includes responses across awareness, attitudes, perceived access, and prior experience, and the consent filter and item-specific denominators make the descriptive calculations transparent. However, several limitations constrain interpretation. The recruitment method, setting, eligibility rules, and invitation denominator are unknown. The sample is dominated by undergraduate students, and there is no basis for assuming it represents dental professionals or students beyond these submissions. Non-probability selection and self-selection may have influenced responses.

The export contains repeated account identifiers, so the number of unique participants is uncertain. We retained consented submissions without deduplication because no defensible rule was supplied. A few identical answer profiles were also present; identical answers alone are insufficient evidence that submissions are duplicates. The survey instrument's validation and scoring are undocumented, and the items rely on self-report. Missingness varied by item, and the practice-years field was too inconsistent to analyse.

Finally, the instrument may conflate distinct reporting routes, and the cross-sectional descriptive design cannot support causal or temporal conclusions.

V. IMPLICATIONS

The results support evaluating a practical, curriculum-linked materiovigilance module and improving visibility of current reporting forms and contact routes in dental training and care settings. Any future evaluation should use a validated or piloted instrument, include a practical knowledge task, prespecify eligibility and sampling, document unique participants and duplicate handling, and record whether training changes knowledge or reporting behavior. Those are recommendations for future study, not effects demonstrated by this dataset.

VI. CONCLUSION

Among 211 submissions with affirmative consent recorded, respondents commonly perceived a training gap and supported undergraduate curricular coverage of adverse event reporting. Self-reported awareness of the MDAE form and exact reporting process was lower, and reported access to forms was limited. These findings are exploratory and submission-level. They should not be generalized to a wider population until recruitment, setting, unique-participant counts, ethics documentation, and instrument characteristics are confirmed.

DECLARATIONS REQUIRING AUTHOR COMPLETION

- Consent: The export records affirmative consent for 211 included submissions; [confirm consent wording, how it was obtained, and whether consent was required before survey access].

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