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KNOWLEDGE, ATTITUDE, AND PRACTICE OF PHARMACOVIGILANCE AND ADVERSE DRUG REACTION REPORTING AMONG HEALTHCARE PROFESSIONALS AT A TERTIARY CARE TEACHING HOSPITAL IN SOUTHERN RAJASTHAN: A CROSS-SECTIONAL QUESTIONNAIRE-BASED STUDY

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ABSTRACT

Background: Adverse drug reactions (ADRs) contribute substantially to hospital admissions, prolonged stay, and avoidable mortality. The Pharmacovigilance Programme of India (PvPI), coordinated by the Indian Pharmacopoeia Commission (IPC), Ghaziabad, depends on spontaneous reporting by healthcare professionals. Persistent under-reporting suggests that gaps in knowledge, attitude, and practice (KAP) remain an unsolved barrier. The objective is to assess baseline knowledge, attitude, and practice regarding pharmacovigilance and ADR reporting among interns, postgraduate (PG) residents, and clinical faculty at a tertiary care teaching hospital in Rajsamand, and to identify the principal reasons for under-reporting.

Materials and Methods: A cross-sectional, questionnaire-based study was carried out from November 2023 to January 2024 at Ananta Institute of Medical Sciences and Research Center, Rajsamand, before a sensitisation Continuing Medical Education (CME) session. A pre-validated, structured 15-item questionnaire derived from the PvPI pre-test instrument was administered to 180 participants (60 interns, 70 PG residents, and 50 clinical faculty) selected by convenience sampling. Items covered six knowledge, five attitude, **and four practice domains.** Responses were entered into Microsoft Excel and analysed using SPSS v.25; group differences were tested with the chi-square test, with $p < 0.05$ considered statistically significant.

Results: Of 180 distributed questionnaires, 168 were returned (response rate 93.3%). Correct definition of pharmacovigilance was given by 78.0% of participants, but only 39.3% correctly identified the IPC, Ghaziabad as the National Coordination Centre of PvPI; 41.7% wrongly believed it was located at AIIMS, New Delhi. The Central Drugs Standard Control Organisation (CDSCO) was correctly identified as the regulatory body by 56.0%. Although 92.3% agreed ADR reporting improves patient safety and 90.5% considered it a professional obligation, only 38.7% had ever reported an ADR; 56.0% had witnessed an ADR during clinical posting. The leading cited reasons for non-reporting were unawareness of an institutional ADR monitoring centre (38.4%), uncertainty about the reporting procedure (32.7%), and the perception that reporting is time-consuming (18.5%). Faculty scored higher than PG residents and interns on knowledge items (mean correct responses 3.9 vs 3.1 vs 2.4 out of 5; $p < 0.001$), whereas interns expressed greater willingness to participate in future training.

Conclusion: A favourable attitude toward pharmacovigilance coexists with a marked deficiency in factual knowledge and reporting practice. The findings argue for routine integration of pharmacovigilance into the undergraduate Competency-Based Medical Education (CBME) curriculum, hands-on PG training, and a visible institutional ADR monitoring centre with a clear reporting workflow.
Keywords: Adverse drug reaction, Pharmacovigilance, PvPI, KAP study, Medical education, CBME, ADR reporting, Tertiary care hospital.

INTRODUCTION

Drug therapy is rarely free of risk. Even after a medicine has cleared regulatory approval, it continues to interact with a population that is far broader and more heterogeneous than any pre-marketing trial can capture.[1-3] The patients who fill clinic waiting rooms after a drug is launched have variable genetics, multiple comorbidities, polypharmacy, and patterns of use that researchers seldom anticipate.[3-8] Spontaneous monitoring of adverse drug reactions (ADRs), or pharmacovigilance, was developed to bridge this gap between the controlled world of clinical trials and routine clinical use.[1,2]

The World Health Organization defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.[1,9-13] The discipline gathered scientific and political weight after the thalidomide tragedy of the early 1960s, which exposed the need for systematic post-marketing surveillance and prompted the WHO Programme for International Drug Monitoring in 1968.[2,14-18] Today the Uppsala Monitoring Centre (UMC), Sweden, holds VigiBase, the global ADR database to which more than 150 member countries contribute.[2,19-24]

In India, the Pharmacovigilance Programme of India (PvPI) was launched on 14 July 2010 by the Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare [4]. The National Coordination Centre (NCC) was shifted from AIIMS, New Delhi to the Indian Pharmacopoeia Commission (IPC), Ghaziabad in April 2011, and was designated a WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services in 2017.[4] The PvPI now operates through more than 700 ADR Monitoring Centres (AMCs) attached to medical colleges, autonomous institutes, and corporate hospitals across the country.[4]

Despite this expanding architecture, India contributes a disproportionately small share to VigiBase.[4] Several Indian studies have documented the same paradox: a positive attitude toward ADR reporting is rarely matched by actual reporting behaviour.[5,6,10,12] Hardeep et al. found that more than 60% of clinicians in a North Indian teaching hospital were unaware of how to report an ADR.[5] Dass and colleagues, in a study of clinicians and postgraduate residents, observed satisfactory knowledge (61.8%) and attitude (70%) but poor practice (under 50%).[6] More recently, Raikar et al. reported that medical students and staff had stronger theoretical knowledge while nursing personnel were more active participants in ADR awareness programmes, suggesting an interesting dissociation between cognitive and applied competencies.[7]

The reasons for under-reporting are not merely cognitive. Lack of dedicated time, ambiguity about which reactions to report, doubt over causality, and absence of feedback after reporting have all been described as real-world deterrents.[6,11,12] Importantly, for the first time the National Medical Commission's Competency-Based Medical Education (CBME) framework now embeds pharmacovigilance within the pharmacology curriculum, 2023 (PH1.50, PH1.52), making it the duty of every medical college to train competent reporters.[9] A baseline assessment of where exactly the gaps lie is therefore the first step in any meaningful curricular response.

Against this background, the present cross-sectional study was undertaken at a tertiary care teaching hospital in western India to evaluate the existing knowledge, attitude, and practice of pharmacovigilance and ADR reporting among interns, PG residents, and clinical faculty, and to identify the principal reasons for under-reporting. The findings were intended to guide a subsequent structured CME and to inform institutional pharmacovigilance policy.

MATERIALS AND METHODS

Study design and setting: This was a cross-sectional, questionnaire-based, observational study conducted in the Department of Pharmacology at Ananta Institute of Medical Sciences and Research center, Rajsamand, Rajasthan, India. The study formed the baseline (pre-test) phase of a planned educational intervention on pharmacovigilance organised under the auspices of the institutional ADR Monitoring Centre. Data were collected over a period of approximately ten weeks, between November 2023 and January 2024.

Study population: Three groups of healthcare professionals were eligible: (a) clinical interns rotating through medicine, surgery, paediatrics, and obstetrics; (b) postgraduate residents (junior and senior, MD/MS) of clinical and pre/para-clinical departments who were involved in patient care or therapeutic decision-making; and (c) clinical faculty (Assistant Professors, Associate Professors, and

Professors) of departments that prescribe drugs. Nursing staff and pharmacy personnel were excluded to keep the sampled population homogeneous. Participants who had attended any formal pharmacovigilance training programme in the preceding six months were also excluded.

Sample size and sampling: With an estimated proportion of healthcare professionals having adequate KAP of approximately 50%,[6,7] a 95% confidence level (Z = 1.96), and an absolute precision of 8%, the minimum required sample size was calculated using the formula $n = Z^2 \times p (1-p) / d^2$ as 150. Allowing for an anticipated non-response rate of 20%, the target was raised to 180 participants. Participants were recruited by convenience sampling from departmental ward rounds, faculty meetings, and PG academic sessions.

Study tool: The study tool was a structured, pre-validated 15-item questionnaire adapted from the PvPI pre-test instrument circulated under the Indian Pharmacopoeia Commission, Ghaziabad. The questionnaire contained three domains:

Knowledge (Q1-Q6, six items): Definition of pharmacovigilance, definition and types of ADR, professional responsibility for ADR reporting, location of the National Coordination Centre, and the regulatory body of ADR reporting in India.

Attitude (Q7-Q11, five items): Belief that ADR reporting is a professional obligation, perceived necessity of ADR reporting, perceived effect on patient safety, opinion on hospital-based ADR monitoring centres, and need for detailed pharmacovigilance teaching.

Practice (Q12-Q15, four items): Awareness of an institutional pharmacovigilance committee, having seen an ADR during clinical posting, having ever reported an ADR, reasons for non-reporting, and awareness of the post-reporting workflow.

Each item carried four response options (a-d), with a single best answer or a categorical response. The questionnaire was content-validated by three senior faculty of the Department of Pharmacology and pilot-tested on 15 participants who were excluded from the main study. Cronbach's alpha for internal consistency was 0.74, indicating acceptable reliability.

Data collection: Printed copies of the questionnaire were distributed in person before a planned pharmacovigilance CME session held at the institute on 22 November 2023. Participants were given 10 minutes to complete the form anonymously and were not permitted to consult any reference material. Demographic details (age, sex, designation, years of clinical experience) were collected on the same form. Written informed consent was obtained from every participant before form distribution. Forms returned with more than two unanswered items were treated as incomplete and excluded from analysis.

Operational definitions: A response was scored as correct only when it matched the WHO/PvPI standard answer. For knowledge items, the proportion of correct responses was calculated. For attitude items, an affirmative response was taken as a positive attitude. For practice items, the proportion of participants reporting the desired practice was calculated.

Ethical considerations: The study protocol was approved by the Institutional Ethics Committee, (Ref. No.: [AIMS & RC/IEC/2019/010A], dated [26/04/2019]). Confidentiality was maintained by avoiding any personal identifier on the questionnaire. Participation was voluntary and unremunerated.

Statistical analysis: Data were entered into Microsoft Excel 2019 (Microsoft Corp., Redmond, WA, USA) and analysed using IBM SPSS Statistics version 25 (IBM Corp., Armonk, NY, USA). Categorical variables were summarised as frequencies and percentages, and continuous variables as mean ± standard deviation. Differences between the three professional groups (interns, PG residents, faculty) were tested using the chi-square test, with Fisher's exact test applied for cells with an expected count below five. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Of the 180 questionnaires distributed, 168 fully completed forms were returned, giving a response rate of 93.3%. Eight forms were excluded because of missing answers in more than two items, and four were withdrawn by participants who later disclosed prior pharmacovigilance training. The final analytic sample comprised 58 interns, 64 PG residents, and 46 faculty members. Demographic details of the participants are summarised in [Table 1].

Table 1: Demographic profile of the study participants (n = 168).

Variable	Interns (n=58)	PG residents (n=64)	Faculty (n=46)
Age in years, mean ± SD	23.4 ± 1.2	28.6 ± 2.4	38.9 ± 6.7
Male, n (%)	32 (55.2)	38 (59.4)	31 (67.4)
Female, n (%)	26 (44.8)	26 (40.6)	15 (32.6)
Clinical experience in years, mean ± SD	0.4 ± 0.2	3.5 ± 1.8	12.4 ± 6.1
Before six month PV training, n (%)	4 (6.9)	11 (17.2)	18 (39.1)

Knowledge of pharmacovigilance and ADR: Knowledge scores varied widely across the three groups. The definition of pharmacovigilance was correctly identified by 78.0% of all participants, but the proportion fell to 50.0% when respondents were asked to recall the six types of ADR (A-F classification). The most striking deficit was in identifying the National Coordination Centre of PvPI: only 39.3% of all participants correctly named the IPC, Ghaziabad, while 41.7% wrongly believed it

was located at AIIMS, New Delhi, a distractor that closely matches the original launch site of PvPI in 2010. The Central Drugs Standard Control Organisation (CDSCO) was identified as the regulatory body by 56.0% of respondents. Faculty consistently outperformed PGs and interns on every knowledge item, and the difference was statistically significant ($p < 0.001$) [Table 2].

Table 2: Knowledge of pharmacovigilance among healthcare professionals (n = 168).

Q.	Item	Correct response	Interns n=58	PG n=64	Faculty n=46
1	Definition of pharmacovigilance	Detection, assessment, understanding & prevention of adverse effect	39 (67.2%)	52 (81.3%)	40 (87.0%)
2	General definition of ADR	All of the above	36 (62.1%)	48 (75.0%)	39 (84.8%)
3	Number of types of ADR (A-F, six types)	6 types	18 (31.0%)	28 (43.8%)	29 (63.0%)
4	Healthcare professional responsible for ADR reporting	All of the above (doctor, nurse, pharmacist)	46 (79.3%)	57 (89.1%)	44 (95.7%)
5	Location of NCC-PvPI	IPC, Ghaziabad	13 (22.4%)	26 (40.6%)	27 (58.7%)
6	Regulatory body of ADR in India	CDSCO	25 (43.1%)	38 (59.4%)	31 (67.4%)

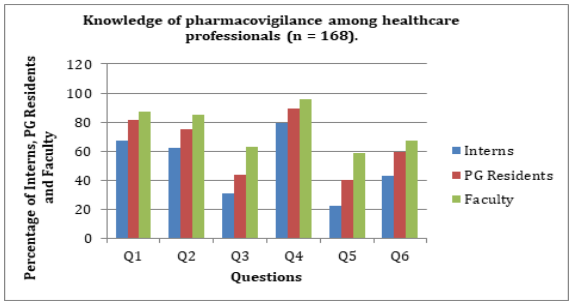

Figure 1: Comparison of Knowledge Regarding Pharmacovigilance and ADR Reporting among Interns, PG Residents, and Faculty Members

Attitude toward pharmacovigilance

In contrast to knowledge, attitude scores were uniformly high. Across all three groups, more than 90% of respondents agreed that ADR reporting is necessary, that it improves patient safety, and that pharmacovigilance should be taught in detail to healthcare professionals [Table 3]. The lowest figure, though still encouraging, was for the question on whether an ADR monitoring centre should exist in every hospital (overall 86.3%). Differences between the three groups did not reach statistical significance for any of the attitude items ($p > 0.05$).

Table 3: Attitude toward pharmacovigilance among healthcare professionals (n = 168).

Q.	Item	Desired response	Interns	PG	Faculty
7	ADR reporting is a professional obligation	Yes	50 (86.2%)	60 (93.8%)	44 (95.7%)
8	ADR reporting is necessary	Yes	55 (94.8%)	63 (98.4%)	46 (100%)
9	ADR reporting will increase patient safety	Yes	52 (89.7%)	60 (93.8%)	43 (93.5%)
10	ADR monitoring centre should be in every hospital	Yes	47 (81.0%)	56 (87.5%)	42 (91.3%)
11	Pharmacovigilance should be taught in detail to healthcare professionals	Yes	57 (98.3%)	63 (98.4%)	45 (97.8%)

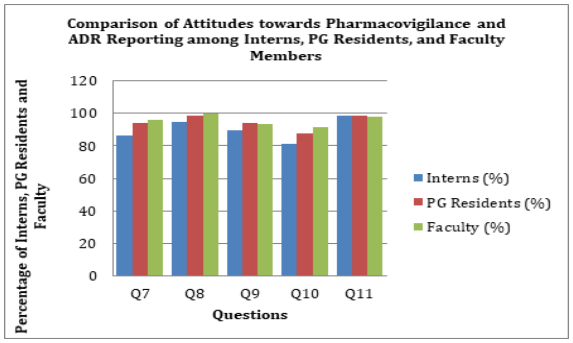

Figure 2: Comparison of Attitudes towards Pharmacovigilance and ADR Reporting among Interns, PG Residents, and Faculty Members

Practice of ADR reporting: The practice profile told a different story. Only 56.0% of all respondents had ever witnessed an ADR during their clinical work, and of these only 38.3% (36 of 94) had ever reported the event through any formal channel. The faculty group was the most active reporter (55.9%), reflecting longer clinical exposure and greater institutional familiarity. Awareness of an institutional pharmacovigilance committee or ADR monitoring centre showed a clear hierarchy: 29.3% of interns, 48.4% of PGs, and 69.6% of faculty (Table 4). Awareness of the post-reporting workflow (what happens to a report after it leaves the AMC) was poor across the board (36.3% overall).

Table 4: Practice of ADR reporting among healthcare professionals (n = 168).

Q.	Item	Desired response	Interns	PG	Faculty
12	Awareness of an institutional pharmacovigilance committee	Yes	17 (29.3%)	31 (48.4%)	32 (69.6%)
13a	Have witnessed an ADR during clinical posting / practice	Yes	21 (36.2%)	39 (60.9%)	34 (73.9%)

13b	Of those who saw an ADR, ever reported it (n=94)	Yes	4/21 (19.0%)	13/39 (33.3%)	19/34 (55.9%)
15	Aware of what happens after ADR is reported to AMC	Yes	12 (20.7%)	24 (37.5%)	26 (56.5%)

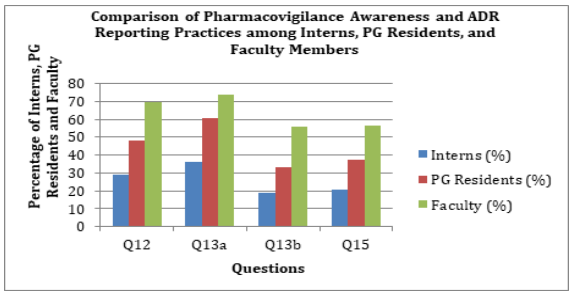

Figure 3: Comparison of Pharmacovigilance Awareness and ADR Reporting Practices among Interns, PG Residents, and Faculty Members

Reasons for under-reporting

Of the 168 participants, 130 (77.4%) had never filed an ADR report. When asked to choose all applicable reasons, half of the non-reporters (50.0%) cited unawareness of an institutional ADR monitoring center, and 42.3% admitted that they did not know how to fill the ADR form. Time pressure was cited by 23.8%, and a small fraction (6.9%) feared medico-legal consequences [Table 5].

Table 5: Reasons cited by participants for not reporting ADRs (n = 130, multiple responses permitted).

Reason cited (Q14, multiple-response among non-reporters, n = 130)	Frequency (n)	Percentage (%)
Not aware of the presence of an ADR monitoring centre	65	50.0
Did not know how to report an ADR	55	42.3
ADR reporting perceived as time-consuming	31	23.8
Believed reporting only the duty of pharmacist	18	13.8
Uncertain about drug-event causality	22	16.9
Fear of medico-legal implications	9	6.9

Composite KAP scores by professional category

Mean (± SD) knowledge scores out of a maximum of six were 2.4 ± 1.1 for interns, 3.1 ± 1.3 for PGs, and 3.9 ± 1.0 for faculty (one-way ANOVA, $F = 26.5$, $p < 0.001$). Mean attitude scores (out of five) were uniformly high across the three groups (4.5 ± 0.6, 4.7 ± 0.5, and 4.7 ± 0.5 respectively, $p = 0.07$). Mean practice scores (out of four), in contrast, were poor for all groups but lowest among interns (1.0 ± 0.8) compared with PGs (1.7 ± 1.1) and faculty (2.5 ± 1.2) ($p < 0.001$). The widening gap from knowledge to practice supports the view that information alone does not produce reporting behaviour.

DISCUSSION

This study evaluated the baseline KAP of pharmacovigilance among interns, PG residents, and clinical faculty at a tertiary care teaching hospital in Rajsamand and revealed three findings that are both consistent with the existing Indian literature and clinically actionable.[5-7,10,12,15-20,23]

First, attitude is not the bottleneck. More than nine in ten respondents in every category agreed that ADR reporting is a professional obligation, will improve patient safety, and should be taught in greater detail.[5-7,10,12-20,23] The figure is comparable to the 93% reported by Dass et al. for the same belief among clinicians and PGs in Andhra Pradesh,[6] and to the 97% reported by Raikar et al. among medical staff in Karnataka.[7] Indian healthcare professionals appear to have absorbed the moral case for pharmacovigilance; they simply have not been given the operational tools to act on it.[11,12,23]

Second, knowledge gaps are concentrated in operational facts rather than in conceptual understanding. The definition of pharmacovigilance was familiar to most participants, but the location of the National Coordination Centre, the regulatory body of ADR reporting, and the six-type classification of ADRs were not.[1-4,9] The same pattern was reported by Dass et al., where only 25.3% of respondents could correctly identify the location of the National Pharmacovigilance Centre,[6] and by Hardeep et al., who noted that more than 60% of clinicians did not know how to file a report.[5] The persistence of this finding across geography and time suggests that the operational dimension of pharmacovigilance is not being delivered alongside the conceptual content.[10,12,15-20]

Third, and perhaps most important, the gap between attitude and practice is wide. Although 92% of our respondents endorsed reporting in principle, only 38% of those who had seen an ADR had ever reported one, and 50% of all non-reporters cited unawareness of the institutional ADR monitoring centre as the reason.[5,6,10,12,16-18,23] This mirrors the 'KAP gap' described in earlier Indian work, in which knowledge and attitude scores hover around 60-70% but practice rarely crosses 50%.[6,7,10] A favourable attitude is necessary but not sufficient: the visible infrastructure of a working AMC, an accessible reporting form, and a feedback loop that closes the reporting circuit are equally important.[11,12,21,24]

Several explanations have been proposed for this gap. Hazell and Shakir, in a systematic review, estimated that the median under-reporting rate of ADRs across clinical settings is 94%, with the dominant drivers being lethargy, ignorance, indifference, and diffidence.[11] Indian studies have added context-specific reasons: workload, lack of an established AMC, absence of feedback, and the perception that a

single report will not change practice.[10,12,15-18] Our finding that only 36.3% of participants knew what happens to a report after it reaches the AMC is consistent with this last point.[12,13] People rarely sustain a behaviour whose consequences they cannot see.[11,21]

The differential performance of the three groups also deserves comment. Faculty members had the highest knowledge and practice scores, an expected result given their longer clinical experience and greater exposure to institutional processes.[16-18] PG residents occupied a middle position, and interns scored lowest on every domain except attitude.[15-17] Raikar et al. reported a comparable hierarchy, although in their study nursing professionals showed superior practice despite weaker theoretical knowledge, an observation we could not test because nursing personnel were excluded from our sample.[7] Interns are arguably the most important target for pharmacovigilance training: they will spend the next three to five decades prescribing, and habits forged in the first months of clinical responsibility tend to persist.[9,14]

These findings carry direct implications for medical education. The NMC's CBME framework already lists pharmacovigilance and ADR reporting as core competencies (PH1.50 to PH1.52).[9] Translating these competencies into actual reporting behaviour will require: (i) integration of pharmacovigilance into early clinical postings, with a structured small-group session demonstrating the PvPI form and the Vigiflow online platform.[4,9,24] (ii) a designated ADR monitoring centre in every teaching hospital that is visible, signposted, and reachable through more than one channel (paper form, mobile app, WhatsApp helpline),[4,21,24] (iii) periodic CMEs and hands-on workshops as recommended by John et al. and Rajesh et al,[13,14] and (iv) a feedback mechanism that closes the loop by sharing periodic AMC bulletins and signal detection updates with the reporters.[11,21,24]

Strengths and limitations

The principal strength of the study is the inclusion of three professional groups with widely differing levels of clinical experience, which allowed an internal benchmark for comparing KAP across the training continuum.[16,18,23] The response rate (93.3%) was higher than that typically reported for paper-based surveys in Indian academic settings.[15,17,19] Pilot testing and content validation strengthened the reliability of the instrument.[19,20,22]

The limitations are familiar to questionnaire-based KAP research.[18-20,23] The study was conducted in a single tertiary care institution; generalisability to district hospitals, primary care centres, and private practice is therefore limited. Convenience sampling carries an inherent risk of selection bias, especially toward more academically engaged participants.[18,20]. Self-reported practice is vulnerable to social desirability bias; actual reporting rates may be even lower than those declared.[11,12] Finally, the design was cross-sectional, and causal inferences about determinants of reporting behaviour cannot be drawn.[22,23] A subsequent pre-/post-test interventional study with a follow-up of actual ADR reports filed at the institutional AMC is currently being planned to address these gaps.[13,14]

CONCLUSION

Healthcare professionals at our tertiary care teaching hospital in Rajsamand hold a uniformly favourable attitude toward pharmacovigilance, but their factual knowledge and reporting practice lag behind. Operational facts (location of the National Coordination Centre, classification of ADRs, identity of the regulatory body) and the visibility of an institutional ADR monitoring centre were the most important deficits. Bridging the KAP gap will require integration of pharmacovigilance into the CBME-aligned undergraduate curriculum, structured PG and intern training, and a clearly signposted institutional reporting workflow with feedback to the reporter. Without these, the well-meaning attitude documented in this study will continue to dissipate before it can reach VigiBase.

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