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Assessing Pharmacovigilance Knowledge, Attitudes, Practices and the Clinical spectrum of Adverse Drug Reactions among Healthcare Professionals at a Tertiary Care Teaching Hospital in Jaipur, India: A Two-Phase Observational Study

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ABSTRACT

Background: Spontaneous reporting of adverse drug reactions (ADRs) by healthcare professionals (HCPs) remains the backbone of the Pharmacovigilance Programme of India (PvPI), yet persistent under reporting continues to limit the reliability of national drug safety data.
Objectives: To assess the knowledge, attitudes, and practices (KAP) of HCPs regarding pharmacovigilance and ADR reporting, and to characterise the clinical spectrum, causality, severity, and preventability of ADRs documented at a tertiary care teaching hospital in Jaipur, Rajasthan.
Materials and Methods: The study had two phases. Phase 1 was a cross-sectional online KAP survey of physicians and nurses (372 complete responses) using a 43-item pretested questionnaire. Phase 2 was a prospective, hospital-based observational study of 137 confirmed ADRs collected between February 2019 and May 2020 through combined active and spontaneous surveillance. Causality was assessed with both the WHO-UMC criteria and the Naranjo algorithm, severity with the Hartwig and Siegel scale, and preventability with the modified Schumock–Thornton criteria. Categorical associations were tested with the Chi-square test and expressed as crude odds ratios (ORs) with 95% confidence intervals (CIs).
Results: Out of 372 respondents, 132 (35.48%) encountered the term pharmacovigilance for the first time through the survey itself. Although 260 (69.89%) had observed an ADR in practice, only 174 (46.77%) had ever filed a report. Previous use of the official reporting form

(OR 8.34, 95% CI 4.05–17.18; p < 0.001) and formal pharmacovigilance training (OR 4.12, 95% CI 2.31–7.35; p < 0.001) showed the strongest associations with reporting. Among the 137 ADRs, antimicrobials (41.61%) and NSAIDs (27.74%) were the leading causative classes, and cutaneous reactions predominated. Half of the reactions (69/137, 50.36%) were judged definitely or probably preventable; 121 (88.32%) patients recovered completely and no deaths occurred.

Conclusions: A wide gap separates ADR detection from ADR reporting in this setting. Structured training embedded in medical and nursing curricula, simpler digital reporting channels, and targeted monitoring of high-risk drug classes such as antimicrobials and NSAIDs offer practical routes to narrow it.

Key words: Adverse drug reaction; India; knowledge attitude practice; pharmacovigilance; preventability; underreporting

INTRODUCTION

The World Health Organization (WHO) defines an adverse drug reaction (ADR) as a noxious and unintended response to a drug that occurs at doses routinely used in humans for the prevention, diagnosis, or treatment of disease **[1]**. ADRs sit among the leading causes of iatrogenic harm: they prolong hospital stay, raise treatment costs, and in some patients prove fatal **[2]**. A recent cross-sectional analysis of 5,707 urgent admissions found that 5.0% were caused by ADRs, with polypharmacy and age above 65 years as independent risk factors **[3]**. In older adults the burden is heavier still; a systematic review and meta-analysis reported that roughly one in six hospitalised older patients experiences a significant ADR, most of them preventable **[4]**.

India launched the Pharmacovigilance Programme of India (PvPI) in 2010 to build a national system for drug safety surveillance, and the network of ADR monitoring centres has grown steadily since **[5]**. The programme, however, depends on spontaneous reports from clinicians, and underreporting remains its central weakness. A systematic review estimated that more than 90% of ADRs go unreported worldwide **[6]**, and a meta-analysis of Indian studies found that 55.6% of surveyed health professionals were unaware that the PvPI existed **[7]**. The reasons are well documented: ignorance of reporting procedures, diffidence about causality, fear of consequences, and the simple friction of paperwork **[8]**. A large multicentre survey confirms that these barriers persist even where attitudes toward reporting are positive **[9]**, and Indian hospital surveys report the same pattern **[10]**.

Education changes behaviour. Cluster-randomized trials have shown that structured educational outreach can multiply spontaneous reporting rates several-fold, and that the effect can be sustained with periodic reinforcement **[11,12]**. On the regulatory side, the PvPI has standardised spontaneous reporting and expanded its toolkit with a national helpline and a mobile application to lower the barrier to reporting **[13,14]**. Whether these measures have reached the ordinary prescriber and staff nurse is a separate, empirical question.

The clinical face of the problem also deserves attention. Reviews from both developed and developing countries identify antimicrobials, NSAIDs, and cardiovascular agents as the classes most often implicated in ADR-related hospital contact **[15]**, and a substantial share of these reactions is preventable **[16]**. In Indian hospital series, cutaneous reactions ranging from benign maculopapular rash to Stevens–Johnson syndrome form the largest single clinical category **[17]**. Large prospective and database studies from the United Kingdom show that the population-level burden of ADR-related admissions has changed little over two decades **[18,19]**, and meta-analytic data confirm the particular vulnerability of the elderly **[20]**.

This study was planned with two linked objectives: first, to measure the knowledge, attitudes, and practices of physicians and nurses toward pharmacovigilance and ADR reporting; and second, to describe the clinical profile, causality, severity, and preventability of ADRs documented prospectively at a tertiary care teaching hospital in Jaipur. Reading the two datasets together allows the human and clinical dimensions of pharmacovigilance to be examined side by side in one institutional setting.

MATERIALS AND METHODS

Study design and setting

A two-phase study was conducted at Government RDBP Jaipuria Hospital, a 500-bed tertiary care teaching hospital in Jaipur, Rajasthan, India (Figure 1). Phase 1 was a cross-sectional KAP survey of healthcare professionals; Phase 2 was a prospective, observational, hospital-based ADR monitoring study. The Institutional Ethics Committee approved both phases, and the study followed Indian Council of Medical Research guidelines. Informed consent was obtained from all survey participants and from all patients (or their guardians) in the observational phase.

Phase 1: KAP survey of healthcare professionals

A structured, self-administered questionnaire was assembled after reviewing validated instruments in the published literature, and refined by a focus group of ten healthcare professionals. The final instrument contained 43 items in four domains: demographic and professional details; knowledge of pharmacovigilance and ADR reporting; attitudes toward reporting; and self-reported practices with perceived barriers. The survey was hosted on the Survey Monkey platform and circulated over three months (June to August 2017) to physicians and nurses through the local Indian Medical Association branch, the Trained Nurses Association of India, and professional social media networks. Participation was voluntary and anonymous. Of 380 individuals who opened the survey, 372 submitted complete responses and were analysed.

Phase 2: Prospective ADR monitoring study

Between February 2019 and May 2020, all inpatients and outpatients receiving pharmacological therapy at the study hospital were eligible; moribund patients and cases of intentional poisoning or drug abuse were excluded. A dual surveillance strategy combined active ward-based monitoring by clinical pharmacologists, in the Medicine, Surgery, Pediatrics, Dermatology, Psychiatry, ENT, and Orthopedics wards, with stimulated spontaneous reporting through ward drop-boxes, telephone, or e-mail. For every suspected ADR, a case report form captured patient demographics, clinical history, suspected drug details, description of the reaction, treatment given, and outcome. After causality screening, 137 confirmed ADRs entered the final analysis.

Each reaction was assessed by trained assessors. Causality was determined with both the WHO-UMC criteria **[21]** and the Naranjo algorithm **[22]**, with discrepancies resolved by consensus; both classifications are reported. Severity was graded on the Hartwig and Siegel scale **[23]**, preventability on the modified Schumock–Thornton criteria **[24]**, and reaction type according to the Rawlins–Thompson classification **[25]**.

Statistical Analysis

Data from both phases were compiled and analysed in Epi Info version 7 (CDC, Atlanta, USA). Categorical variables are summarised as frequencies and percentages, and continuous variables as mean ± standard deviation. Associations between categorical variables (Phase 1 reporting behaviour and its correlates) were tested with the Pearson Chi-square test, or Fisher's exact test where any expected cell count was below five, and are expressed as crude odds ratios (ORs) with 95% confidence intervals (CIs). No multivariable regression was performed; accordingly, all reported associations are univariable and are described as associations rather than independent predictors. A two-

sided p <0.05 was considered statistically significant.

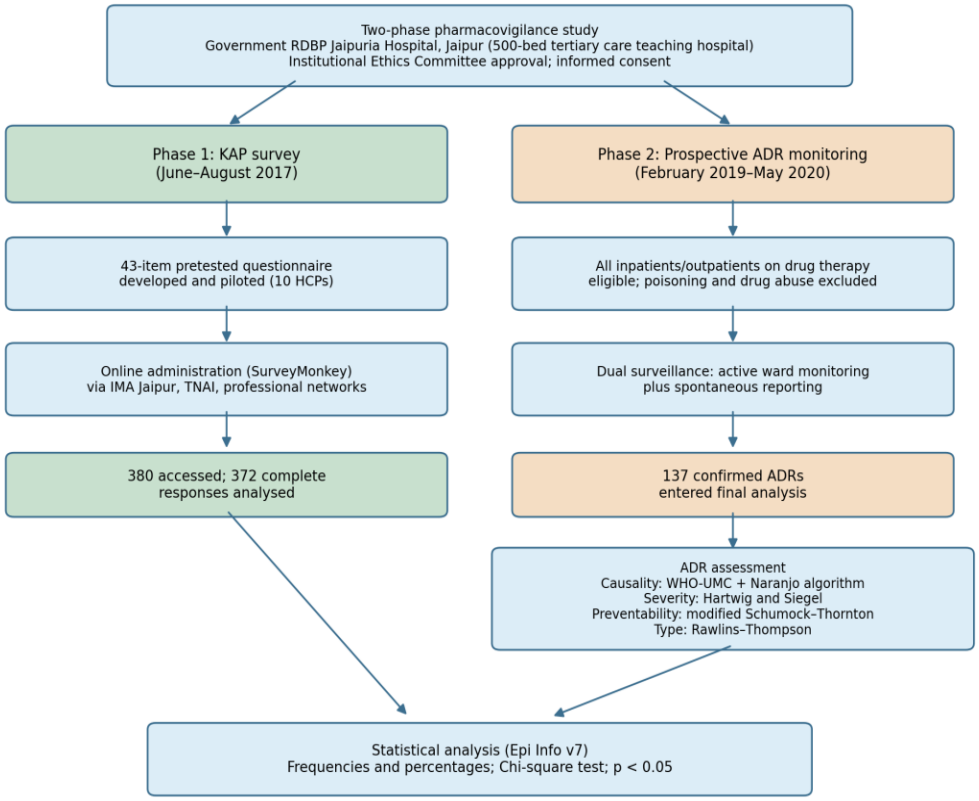

Figure 1. Flow diagram of the two-phase study design: the KAP survey of healthcare professionals (Phase 1) and the prospective hospital-based ADR monitoring study (Phase 2).

RESULTS

Phase 1: Survey of healthcare professionals

Of 380 professionals who opened the survey, 372 (97.89%) completed it. Physicians formed the majority of respondents, followed by nurses, most of them working in government and teaching hospitals. The single most striking finding concerned basic awareness: 132 respondents (35.48%) met the term pharmacovigilance for the first time in the survey itself. Only 71 (19.09%) had learned of it through formal training or continuing education, 69 (18.55%) during their student years, and 49 (13.17%) at conferences or scientific meetings (Table 1). When asked where they turn for drug-safety information, respondents pointed overwhelmingly to self-directed digital resources: internet search engines (228, 61.29%) and peer-reviewed journal articles (208, 55.91%) led the list, with package inserts (135, 36.29%) used as a bedside reference. Textbooks (93, 25.00%) and industry material (81, 21.77%) trailed well behind (percentages exceed 100% because multiple responses were permitted).

The gap between observation and action was wide. Of 372 respondents, 260 (69.89%) had encountered at least one ADR in practice, yet only 174 (46.77%) had ever submitted a formal report, and when reports were filed they went more often to pharmaceutical companies than to the national pharmacovigilance centre or an institutional contact person. On univariable analysis, several factors were significantly associated with having reported (Table 2). The strongest association was with previous use of the official reporting form (OR 8.34, 95% CI 4.05–17.18; $\chi^2 = 46.9$, df = 1; $p < 0.001$), followed by formal pharmacovigilance training (OR 4.12, 95% CI 2.31–7.35; $\chi^2 = 24.8$; $p < 0.001$); specialist qualification, prior exposure to pharmacovigilance

concepts, regular reading of ADR literature, and clinical trial experience were each also significantly associated (all $p < 0.01$). Because no multivariable model was fitted, these are associations rather than independent predictors. The commonest stated reasons for not reporting were uncertainty over whether an event qualified as an ADR, confusion about where and how to report, difficulty accessing forms, administrative hurdles, and lack of time.

Table 1. Pharmacovigilance awareness, information sources, and reporting behaviour among 372 healthcare professionals.

Domain	Category	n (%)
First source of awareness of the term "pharmacovigilance"	Through the present survey	132 (35.48)
	Formal training or continuing education	71 (19.09)
	Undergraduate or postgraduate studies	69 (18.55)
	Conferences and scientific meetings	49 (13.17)
	Other sources (industry, colleagues, media)	51 (13.71)
Preferred source of ADR information (multiple responses permitted)	Internet search engines	228 (61.29)
	Peer-reviewed journal articles	208 (55.91)
	Package inserts	135 (36.29)
	Textbooks	93 (25.00)
	Industry brochures and representatives	81 (21.77)
Reporting behaviour	Encountered ≥1 ADR in practice	260 (69.89)
	Ever submitted a formal ADR report	174 (46.77)

ADR: adverse drug reaction. Percentages for information sources sum to more than 100% because multiple responses were permitted; all other percentages use 372 as the denominator.

Table 2. Factors associated with ever having submitted an ADR report (univariable analysis, n = 372).

Factor	Crude OR (95% CI)	χ^2 (df = 1)	p-value
Previous use of the official reporting form	8.34 (4.05–17.18)	46.9	<0.001
Formal pharmacovigilance training	4.12 (2.31–7.35)	24.8	<0.001
Specialist qualification	2.18 (1.34–3.55)	9.06	0.002
Prior exposure to pharmacovigilance concepts	2.57 (1.56–4.23)	13.9	<0.001
Regular reading of ADR literature	1.98 (1.21–3.24)	7.42	0.006
Clinical trial experience	2.34 (1.28–4.28)	7.86	0.005

OR: odds ratio; CI: confidence interval; df: degrees of freedom. Crude ORs from 2 × 2 tables; Chi-square (or Fisher's exact) test. No multivariable regression was performed, so these are univariable associations.

Phase 2: Clinical profile of adverse drug reactions

All percentages in this section are calculated from the 137 confirmed ADRs unless otherwise stated. The series showed a modest male predominance (76, 55.47%). Adults aged 21–40 years contributed the largest share (46, 33.58%), but the burden was spread across the adult lifespan, with 36 (26.28%) in the 41–60 group and 34 (24.82%) above 60 years. The Department of Medicine generated the most reports (58, 42.34%), followed by Dermatology (41, 29.93%), a pattern consistent with the predominance of drug-induced skin reactions (Table 3, Figure 2).

Antimicrobials were the leading causative class (57, 41.61%), with NSAIDs second (38,

27.74%) and anticonvulsants third (12, 8.76%). Cutaneous reactions dominated the clinical picture: maculopapular rash (32, 23.36%), urticaria (24, 17.52%), and pruritus (17, 12.41%) together accounted for more than half of all presentations. Gastrointestinal symptoms made up 15 cases (10.95%). Serious cutaneous reactions also occurred, including seven cases of Stevens–Johnson syndrome (5.11%) and five of angioedema (3.65%).

Causality was concordant between the two scales. On the WHO-UMC criteria, most reactions were probable (65, 47.45%) or possible (54, 39.42%), with 18 (13.14%) certain; on the Naranjo algorithm, 67 (48.91%) were probable, 54 (39.42%) possible, and 16 (11.68%) definite, and no reaction was classed as doubtful. Severity was moderate in two-thirds of cases (93, 67.88%), mild in 35 (25.55%), and severe in 9 (6.57%). Sixty-nine of the 137 reactions (50.36%) were judged definitely (12, 8.76%) or probably (57, 41.61%) preventable. Type A (augmented, dose-related) reactions predominated on Rawlins–Thompson typing (98, 71.53%), in keeping with the high preventability figure. Outcomes were favourable overall: 121 patients (88.32%) recovered completely, nine (6.57%) recovered with sequelae, seven (5.11%) showed no improvement at last follow-up, and there were no deaths (Table 3).

Table 3. Demographic, clinical, and pharmacological characteristics of the 137 adverse drug reactions documented in the prospective phase.

Characteristic	Category	n (%)
Gender	Male	76 (55.47)
	Female	61 (44.53)
Age group (years)	≤20	21 (15.33)
	21–40	46 (33.58)
	41–60	36 (26.28)
	>60	34 (24.82)
Reporting department	Medicine	58 (42.34)
	Dermatology	41 (29.93)
	Pediatrics	18 (13.14)
	Surgery	12 (8.76)
	Others	8 (5.84)
Causative drug class	Antimicrobials	57 (41.61)
	NSAIDs	38 (27.74)
	Anticonvulsants	12 (8.76)
	Others	30 (21.90)
Clinical presentation	Maculopapular rash	32 (23.36)
	Urticaria	24 (17.52)
	Pruritus	17 (12.41)
	Gastrointestinal symptoms	15 (10.95)
	Stevens–Johnson syndrome	7 (5.11)
	Angioedema	5 (3.65)
	Others	37 (27.01)
Causality (WHO-UMC)	Certain	18 (13.14)
	Probable	65 (47.45)
	Possible	54 (39.42)
Causality (Naranjo)	Definite	16 (11.68)
	Probable	67 (48.91)
	Possible	54 (39.42)
Severity (Hartwig and Siegel)	Mild	35 (25.55)
	Moderate	93 (67.88)
	Severe	9 (6.57)
Preventability (modified Schumock–Thornton)	Definitely preventable	12 (8.76)
	Probably preventable	57 (41.61)
	Not preventable	68 (49.64)

Reaction type (Rawlins–Thompson)	Type A	98 (71.53)
	Type B	13 (9.49)
	Unclassified	26 (18.98)
Outcome	Complete recovery	121 (88.32)
	Recovery with sequelae	9 (6.57)
	No improvement at follow-up	7 (5.11)
	Fatal	0 (0.00)

ADR: adverse drug reaction; NSAIDs: nonsteroidal anti-inflammatory drugs; WHO-UMC: World Health Organization–Uppsala Monitoring Centre. All percentages use 137 as the denominator; within each characteristic, categories sum to 137 (100%).

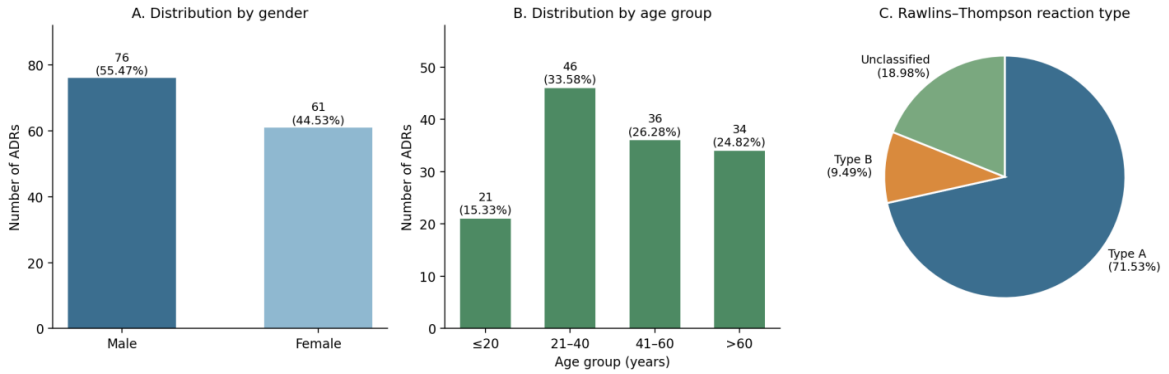

Figure 2. Distribution of the 137 adverse drug reactions by (A) gender, (B) age group, and (C) Rawlins–Thompson reaction type.

DISCUSSION

Two findings anchor this study. First, one in three practicing physicians and nurses had never heard the word pharmacovigilance before completing our survey, and fewer than half of those who had witnessed an ADR had ever reported one. Second, half of the ADRs documented prospectively at our hospital were preventable, and the two drug classes responsible for about 69% of them (antimicrobials 41.61% and NSAIDs 27.74%) are among the most heavily and often loosely prescribed medicines in Indian practice. The problem, in other words, is not rare or exotic reactions escaping detection; it is common, predictable reactions escaping the reporting system.

The awareness deficit we observed fits the national picture. Bhagavathula and colleagues, pooling 28 Indian studies, found that 55.6% of health professionals did not know the PvPI existed and that 74.5% had never reported an ADR [7]. Indian hospital surveys report persistent knowledge gaps among doctors and nurses despite broadly positive attitudes [10], and a large multicentre survey describes an almost identical pattern of willing but untrained professionals [9]. That so many respondents in our sample first encountered the concept through the survey itself points to a curricular failure rather than an attitudinal one: drug safety is simply not taught early enough, or reinforced often enough, to become part of routine clinical thinking.

The information-seeking behaviour of our respondents suggests where the remedy should be built. Search engines and journal articles were their first ports of call, well ahead of textbooks and industry material. Reporting systems that live inside the digital tools professionals already use, such as electronic prescribing platforms, hospital information systems, and the PvPI mobile application [14], are therefore more likely to succeed than paper forms that must be located, filled, and dispatched. The association analysis reinforces this: previous use of the reporting form was associated with roughly eight-fold higher odds of having reported, and formal training with four-fold higher odds. Both are modifiable. Cluster-randomized trials have already shown that educational outreach produces large and sustained gains in spontaneous reporting [11,12].

The clinical profile of our ADR series matches Indian and international experience. Antimicrobials and NSAIDs lead most hospital-based series from developing countries [15], and cutaneous reactions form the largest clinical category in Indian data, as they did here [17]. The predominance of Type A reactions, which are dose-related and pharmacologically predictable, is consistent with the finding that half of our cases were preventable, in line with meta-analytic estimates of preventable ADR-related harm [16]. The practical implication is direct: antimicrobial stewardship, rational analgesic prescribing, and structured medication review would eliminate a substantial fraction of the ADR burden at hospitals like ours, without any new technology at all. Large studies from other health systems tell the same story from a different angle; the burden of ADR-related admissions has stayed stubbornly flat for two decades despite better drugs and better monitoring [3,18,19], and the elderly remain disproportionately affected [4,20].

Taken together, the two phases suggest that underreporting in this setting is less a motivation problem than a structural one, layered from undergraduate curricula upward. A two-pronged response follows naturally. Pharmacovigilance should enter medical and nursing education early and be revisited across professional life, so that reporting becomes a reflex rather than an afterthought. At the same time, the mechanics of reporting should be folded into existing digital habits, supported by trained institutional contact persons, constructive feedback on submitted reports, and recognition for quality reporting. Widening active reporting responsibility beyond physicians to nurses, midwives, and pharmacists, each with tailored training, would multiply the number of eyes on the problem.

Limitations

Several limitations deserve mention. The two phases were separated in time, and the survey used convenience sampling through professional networks, so respondents may not represent all HCPs in the region; self-reported practice is also prone to social desirability bias. The reporting associations are univariable, with no adjustment for confounding, and the wide confidence intervals reflect the modest number of reporters, so they should be read as associations, not causal or independent predictors. The observational phase was conducted at a single centre, and without a defined denominator of drug-exposed patients we cannot estimate ADR incidence. Causality and preventability judgements, although made with validated scales and by consensus, retain an element of subjectivity. Finally, the later months of the observational period coincided with the onset of the COVID-19 pandemic, which may have altered both prescribing patterns and reporting behaviour.

CONCLUSION

This two-phase study documents a wide gap between the detection and the reporting of adverse drug reactions at a tertiary care teaching hospital in Jaipur. A third of surveyed professionals were unfamiliar with pharmacovigilance itself, and practical obstacles, not indifference, kept most observed reactions out of the reporting system. On the clinical side, antimicrobials and NSAIDs caused the large majority of documented ADRs, most reactions were cutaneous and of moderate severity, and half were preventable. Embedding pharmacovigilance in health-professional curricula, simplifying and digitising the reporting pathway, and targeting stewardship at high-risk drug classes are the interventions most likely to convert this hospital's detection capacity into usable national safety data. Prompt recognition and management remain rewarding: nearly nine of every ten affected patients in this series recovered completely.

Declaration

Ethical Approval: The study was approved by the Institutional Ethics Committee, and

the study was conducted in accordance with ICMR National Ethical Guidelines. Informed consent was obtained from all survey participants and from patients or their guardians in the observational phase. (RUHS-CMS/Ethics Committee/2019/01 Date: 05/02/19)

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