Research Article

From Contact To Conduct: Pharmacist Counselling, Safety Awareness and Safe Use Behavior Among Over-The-Counter Medicine Users in India – A Cross-Sectional Analysis

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ABSTRACT

Background: Safe self-medication depends on a chain that runs from professional contact at the point of supply, through the content of counselling and the patient's awareness, to everyday conduct such as reading labels and seeking timely medical review. Few Indian over-the-counter (OTC) studies examine where this chain weakens.

Objective: To quantify the contact, content, comprehension, conduct cascade among OTC users in India, to measure the gap between safety awareness and safe-use practice, and to test whether pharmacist counselling is associated with safety outcomes.

Methods: A cross-sectional survey of 200 adult OTC users (18–75 years) was conducted using a structured questionnaire. Proportions were reported with Wilson 95% confidence intervals (CIs); gaps between proportions with Newcombe intervals; associations with Pearson chi-square tests and Cramér's V. Upper 95% confidence limits and sensitivity power were used to bound null findings, and Holm and Benjamini–Hochberg procedures were applied across 81 safety-domain tests.

Results: Pharmacist contact was almost universal (95.0%), and 69.0% received dosage counselling, but only 43.0% received side-effect counselling and 38.5% interaction counselling. Side-effect awareness (78.0%) far exceeded always reading labels (21.5%; gap 56.5 percentage points, 95% CI 47.7–63.8) and always checking expiry dates (28.5%). None of 11 tests linking pharmacist consultation or counselling with decision or safety outcomes was significant (all $V \leq 0.17$; upper 95% limits ≤ 0.22). All 57 respondents who reported an adverse drug reaction (ADR) belonged to the side-effect-aware group (36.5% vs 0%, $p<0.001$). Doctor consultation was triggered only by treatment failure, side effects or severe or persistent symptoms, and 53.5% reported delaying consultation. Of 81 tests, 5 were nominally significant and 2 survived multiplicity correction (education with dosage–duration knowledge; side-effect awareness with ADR).

Conclusion: In this sample, the OTC safety chain narrows sharply after dosage advice and again between awareness and conduct. Safe-use deficits were not confined to any demographic group. Interventions should deliver structured side-effect, interaction and referral counselling at the point of supply and convert awareness into habits such as label reading, rather than rely on general awareness messages.

Keywords: over-the-counter medicines, pharmacist counselling, medication safety, knowledge practice gap.

1. INTRODUCTION

Over-the-counter (OTC) medicines are a core element of self-care, and the World Health Organization has long linked responsible self-medication to the advisory role of the pharmacist (1). In India the regulatory, safety and economic aspects of OTC supply remain contested (2), and the reported prevalence of self-medication is high and variable; a pooled analysis of Indian studies estimated a mean prevalence of about 54%, with individual studies ranging from roughly 8% to 92%, and familiarity with the medicine was a major reason for self-medicating (3). Safe self-medication is not a single behaviour. It depends on a sequence of links: a professional exchange at the point of supply, the content of that exchange, the patient's resulting awareness, and the conduct that follows, such as reading the label, checking the expiry date, avoiding duplicate ingredients and seeking medical review when symptoms persist. Much of the Indian literature describes prevalence and demographic determinants; fewer studies ask where along this sequence protection is lost. Reviews show that communication during OTC consultations can be improved by targeted interventions (4), that pharmacists' information gathering and counselling in minor-ailment management vary widely in low- and middle-income settings (5), and that the evidence for pharmacist-provided non-dispensing services in such settings is of low certainty (6). Pharmacists are considered well placed to promote optimal analgesic use (7), and a structured counselling approach has been developed to engage consumers in the wise use of OTC medicines (8). Studies of community pharmacies elsewhere have nevertheless documented deficiencies in routine counselling (9). We therefore examined the OTC safety

chain as a four-stage cascade: contact (consulting a pharmacist), content (what counselling is actually received), comprehension (what the patient knows) and conduct (what the patient does). The objectives were to (i) quantify attrition across these stages; (ii) quantify the gap between awareness and safe-use practice; (iii) test whether pharmacist consultation and counselling are associated with decision-making and safety outcomes, and bound the effect sizes that the data can exclude; (iv) examine whether safe-use deficits cluster in particular demographic groups; and (v) re-appraise statistical significance across the whole safety-domain test battery under multiplicity correction.

2. METHODOLOGY

Design and participants. A cross-sectional, survey-based study was conducted in India among adults (18–75 years) with prior experience of OTC medicine use. Stratified random sampling was used to represent different age, gender, socio-economic and geographic groups. The sample size of 200 exceeded the minimum of 196 calculated for 95% confidence and a 7% margin of error. Data were collected by face-to-face interviews and online survey platforms after written or digital informed consent. The study was approved by the Institutional Ethics Committee.
Instrument and variables. A structured questionnaire, developed from the literature and previously validated tools and piloted before use, captured the variables analysed here. Contact: frequency of pharmacist consultation (never, rarely, sometimes, always). Content: receipt of dosage, side-effect and drug-interaction counselling (yes/no). Comprehension: side-effect awareness and drug-interaction awareness (aware/not aware) and dosage–duration knowledge (adequate/inadequate). Conduct: medicine-label reading (never, rarely, sometimes, always) and expiry-date checking (never, sometimes, always). Outcomes: experience of an adverse drug reaction (ADR), reuse of previous prescriptions (never, sometimes, frequently), use of multiple OTC medicines, and delayed medical consultation (all self-reported). Trusted information source, trigger for doctor consultation and purchase source were single-response items. Socio-demographic variables were age group, gender, education, occupation, monthly income and residence.
Relationship to a companion paper. The respondents are the same as those in a companion manuscript (Ahlawat and Sharma), which addressed prevalence, socio-demographic determinants of drug selection, education and dosage duration knowledge, a multivariable model of multiple OTC use, and online pharmacy use. The present paper addresses different questions: the counselling cascade, the awareness practice gap, bounded null effects of counselling, reactive consultation behaviour, and multiplicity-adjusted reappraisal.
Statistical analysis. Counts and chi-square statistics were taken from the study's SPSS output; the additional quantities below were computed from these summary statistics in Python (SciPy). Proportions are reported with Wilson 95% CIs (10). Differences between proportions are reported with Newcombe hybrid-score intervals (11); because the same respondents answered both items, these unpaired intervals are conservative. Associations were tested with Pearson's chi-square and expressed as Cramér's V. For non-significant counselling tests, the upper 95% confidence limit of V was obtained by inverting the non-central chi-square distribution. Sensitivity analysis gave the smallest effect (Cohen's w) detectable with 80% power at n=200 (12). Distributions of single-response items were compared with uniform expectation by goodness-of-fit tests. The side-effect awareness × ADR table was reconstructed from reported percentages and tested with Fisher's exact test. Across the family of 81 safety-domain tests (socio-demographic × knowledge and safety behaviors, 54 tests; counselling × outcomes, 11; knowledge × behaviour, 16), p-values were adjusted by the Holm (13) and Benjamini–Hochberg (14) procedures. Significance was set at two-sided α=0.05.

3. RESULTS

3.1 Respondents

The mean age was 36.8 years (SD 14.4; range 18–75); 54.0% were female; 48.0% lived in urban, 29.0% in semi-urban and 23.0% in rural areas; and 71.5% held a graduate or higher qualification.

3.2 The contact-content comprehension -conduct cascade

Pharmacist contact was near-universal: 95.0% consulted a pharmacist at least rarely, 76.5% sometimes or always, and 28.0% always. Protection narrowed at the content stage. Dosage counselling was received by 69.0%, but side-

effect counselling by only 43.0% and interaction counselling by 38.5% (Table 1). Relative to dosage counselling, this was a fall of 26.0 percentage points for side effects (95% CI 16.3–35.0) and 30.5 points for interactions (95% CI 20.9–39.3). Comprehension was higher than counselling would suggest (side-effect awareness 78.0%, interaction awareness 57.0%, adequate dosage–duration knowledge 67.0%), but conduct was low: only 21.5% always read labels and 28.5% always checked expiry dates; 25.0% never read labels and 36.5% never checked expiry dates.

Table 1. The OTC safety cascade (N=200)

Stage	Indicator	n	% (95% CI)
Contact	Consults pharmacist at least rarely	190	95.0 (91.0–97.3)
Contact	Consults sometimes or always	153	76.5 (70.2–81.8)
Contact	Always consults	56	28.0 (22.2–34.6)
Content	Dosage counselling received	138	69.0 (62.3–75.0)
Content	Side-effect counselling received	86	43.0 (36.3–49.9)
Content	Interaction counselling received	77	38.5 (32.0–45.4)
Comprehension	Side-effect awareness	156	78.0 (71.8–83.2)
Comprehension	Interaction awareness	114	57.0 (50.1–63.7)
Comprehension	Adequate dosage–duration knowledge	134	67.0 (60.2–73.1)
Conduct	Always reads label	43	21.5 (16.4–27.7)
Conduct	Reads label sometimes or always	90	45.0 (38.3–51.9)
Conduct	Always checks expiry date	57	28.5 (22.7–35.1)
Conduct	Checks expiry sometimes or always	127	63.5 (56.6–69.9)
Outcome	Experienced ADR	57	28.5 (22.7–35.1)
Outcome	Reused previous prescription (at least sometimes)	132	66.0 (59.2–72.2)
Outcome	Used multiple OTC medicines	102	51.0 (44.1–57.8)
Outcome	Delayed medical consultation	107	53.5 (46.6–60.3)

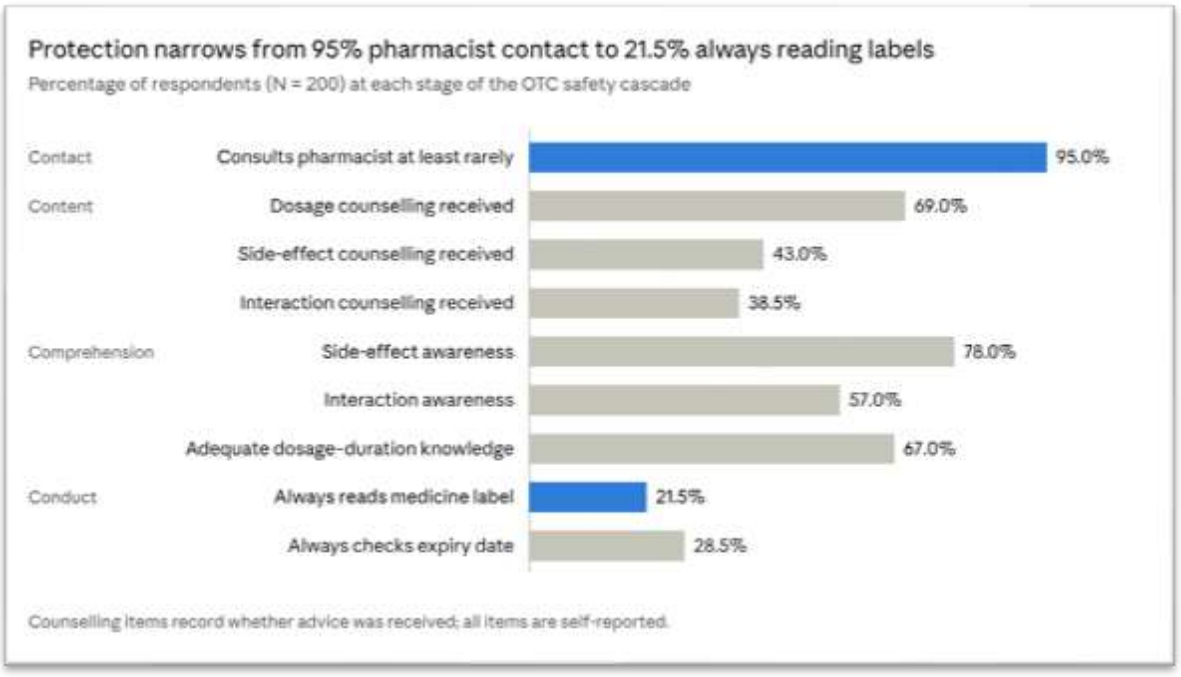


Figure 1. The OTC safety cascade. Blue bars mark the two endpoints discussed in the text (pharmacist contact and consistent label reading); grey bars show the intermediate content and comprehension indicators.

3.3 The awareness–practice gap

Awareness exceeded consistent practice in every pairing examined (Table 2). The largest gap was between side-effect awareness and always reading labels (56.5 points, 95% CI 47.7–63.8). Side-effect awareness (78.0%) and interaction awareness (57.0%) were also higher than the proportions who reported receiving the corresponding counselling (43.0% and 38.5%; differences 35.0 and 18.5 points).

Table 2. Gaps between proportions (percentage points; Newcombe 95% CI, conservative)

Comparison	Gap	95% CI
Side-effect awareness − always reads label	56.5	47.7–63.8
Side-effect awareness − always checks expiry	49.5	40.4–57.3
Dosage–duration knowledge − always reads label	45.5	36.3–53.5
Dosage–duration knowledge − always checks expiry	38.5	29.0–47.0
Interaction awareness − always reads label	35.5	26.2–43.9
Side-effect awareness − side-effect counselling received	35.0	25.7–43.4
Interaction awareness − interaction counselling received	18.5	8.7–27.8

3.4 Pharmacist consultation and counselling showed no detectable association with outcomes

No test of pharmacist consultation or counselling against decision-making or safety outcomes was significant (Table 3). For the six two-by-two or two-by-three counselling-to-outcome tests, observed V ranged from 0.005 to 0.050, and the upper 95% confidence limits ranged from 0.095 to 0.172. For the five consultation-frequency tests, observed V ranged from 0.035 to 0.170 and upper limits did not exceed 0.216. All Holm-adjusted p-values were 1.00. With n=200, the smallest effect detectable with 80% power was w≈0.20 for a 2×2 table and w≈0.22–0.28 for tables with 2–9 degrees of freedom (w≈0.30–0.39 after Bonferroni-type correction for 81 tests). Moderate associations were therefore excluded, but small ones were not.

Table 3. Pharmacist consultation and counselling versus outcomes

Predictor	Outcome	χ^2 (df)	p	V	Upper 95% limit of V
Consultation frequency	Pharmacist-recommendation influence	2.430 (3)	0.488	0.110	0.216
Consultation frequency	Brand preference	4.828 (6)	0.566	0.110	0.160
Consultation frequency	Purchase source	8.522 (9)	0.482	0.119	0.149
Consultation frequency	Trusted information source	17.267 (12)	0.140	0.170	0.200
Consultation frequency	Previous-experience influence	0.245 (3)	0.970	0.035	0.044
Dosage counselling	Prescription reuse	0.501 (2)	0.778	0.050	0.157
Dosage counselling	Multiple OTC use	0.245 (1)	0.620	0.035	0.172
Side-effect counselling	ADR	0.024 (1)	0.877	0.011	0.127
Side-effect counselling	Multiple OTC use	0.106 (1)	0.745	0.023	0.155
Interaction counselling	ADR	0.115 (1)	0.734	0.024	0.157
Interaction counselling	Multiple OTC use	0.006 (1)	0.937	0.005	0.095

3.5 Side-effect awareness and ADR experience

Side-effect awareness was strongly associated with ADR experience ($\chi^2(1)=22.49$, V=0.335). All 57 respondents who reported an ADR were in the aware group: 57/156 (36.5%, 95% CI 29.4–44.3) versus 0/44 (0%, 95% CI 0–8.0) among the unaware (Fisher's exact $p=6.6\times10^{-8}$). Side-effect counselling, by contrast, showed no association with ADR (Table 3).

3.6 Reactive consultation and fragmented trust

Respondents named four triggers for consulting a doctor: lack of improvement (28.0%), side effects (25.5%), severe symptoms (24.5%) and persistent illness (22.0%); these did not differ from an equal split ($\chi^2(3)=1.48$, p=0.687). Every trigger was a reaction to failure or deterioration, and 53.5% (95% CI 46.6–60.3) reported having

delayed consultation. Trusted information sources were similarly dispersed: pharmacist 22.5% (95% CI 17.3–28.8), doctor 22.0%, family or friends 21.0%, internet 20.0% and advertisements 14.5% ($\chi^2(4)=4.15$, p=0.386). Purchase sources were also evenly spread (hospital pharmacy 30.5%, online 26.0%, supermarket 22.0%, local pharmacy 21.5%; $\chi^2(3)=4.20$, p=0.241).

3.7 Distribution of deficits across demographic groups

Of 54 tests relating six demographic variables to side-effect awareness, interaction awareness, label reading, expiry checking, dosage–duration knowledge, ADR, prescription reuse, multiple OTC use and delayed consultation, three were nominally significant: education with dosage–duration knowledge ($\chi^2(4)=58.76$, V=0.54), occupation with dosage–duration knowledge ($\chi^2(5)=11.82$, V=0.24) and occupation with expiry checking ($\chi^2(10)=20.00$, V=0.22). No demographic variable was associated with label reading, awareness of side effects or interactions, or any of the four risk outcomes.

3.8 Multiplicity-adjusted reappraisal

Across 81 tests, five reached p<0.05 unadjusted (Table 4). After Holm and Benjamini–Hochberg adjustment, only education × dosage–duration knowledge and side-effect awareness × ADR remained significant. The association of dosage–duration knowledge with multiple OTC use (unadjusted p=0.012) did not survive adjustment as a bivariate test (Holm p=0.957; BH q=0.327); its adjusted multivariable estimate is reported separately in the companion paper.

Table 4. Nominally significant associations and multiplicity adjustment (m=81)

Association	χ^2 (df)	V	Raw p	Holm p	BH q
Education × dosage–duration knowledge	58.76 (4)	0.54	<0.001	<0.001	<0.001
Side-effect awareness × ADR	22.49 (1)	0.34	<0.001	<0.001	<0.001
Dosage–duration knowledge × multiple OTC use	6.29 (1)	0.18	0.012	0.957	0.327
Occupation × expiry checking	20.00 (10)	0.22	0.029	1.000	0.592
Occupation × dosage–duration knowledge	11.82 (5)	0.24	0.037	1.000	0.604

4. DISCUSSION

A cascade that narrows after dosage advice. Almost every respondent had some contact with a pharmacist, yet the content of that contact was uneven. Dosage advice reached about seven in ten respondents, whereas side-effect and interaction advice reached fewer than half. This pattern is consistent with reports of incomplete counselling in community pharmacies elsewhere (9) and with the variable counselling practices described across low- and middle-income settings (5). It suggests that pharmacist contact, which is often used as an indicator of safe self-care, overstates the protection actually delivered. Brief structured approaches, such as the counselling model developed for OTC users in Taiwan (8) and interventions that improve OTC consultation communication (4), offer templates for closing the gap, although their transferability to Indian retail pharmacies has not been tested here.

Awareness is not conduct. High self-reported awareness coexisted with low consistent practice, and the gaps were large and statistically clear. A plausible explanation is that awareness is declarative, whereas label reading and expiry checking are habits that compete with familiarity: where patients treat a recurrent complaint with a remembered product, the perceived need to check is low. This fits the finding that familiarity with the medicine is a leading reason for self-medication in India (3). Messages that raise awareness without prompting a specific action at the moment of purchase are therefore unlikely to close the gap on their own.

Counselling and outcomes: absence of evidence, bounded. We found no association between consultation or counselling and any outcome, but this should not be read as evidence that counselling is ineffective. The counselling items recorded only whether advice was received, not its quality, comprehension or follow-through; people with complicated needs may seek more counselling (confounding by indication); and all outcomes were self-reported. The bounding analysis adds information that p-values alone do not: associations of moderate size (V above roughly 0.2) are unlikely, but small effects of the kind often produced by brief interventions cannot be excluded in a sample of 200. Larger samples, measures of counselling quality, and prospective or interventional designs are needed. The overall evidence for pharmacist services in low- and middle-income countries is itself of low certainty (6).

Learning through harm? Every respondent who reported an ADR was side-effect aware, whereas none of the unaware did, yet receiving side-effect counselling was unrelated to ADR. Because the data are cross-sectional, awareness may follow the reaction rather than precede it. One hypothesis, which this study cannot test, is that for many users side-effect awareness is acquired through experiencing harm and not through counselling received beforehand. If so, anticipatory counselling at the first purchase of a product class would have the most to add. A prospective design that records awareness before and after a first ADR could test this directly.

Reactive escalation and dispersed trust. The four reasons given for consulting a doctor were all responses to failure or deterioration, and more than half of respondents reported delaying consultation. Trust was spread almost evenly across pharmacists, doctors, family, the internet and, to a lesser degree, advertisements. Together these results portray self-medication as a reactive pathway with no single dominant guide, which strengthens the case for point-of-sale prompts that state explicitly when to stop self-treating and see a doctor.

Deficits are not demographically concentrated. Only education (for dosage duration knowledge) and, tentatively, occupation differed across groups; no demographic factor distinguished label readers, ADR reporters, prescription re-users, multiple-medicine users or those who delayed consultation. Given the detectable-effect limits, demographic differences of small to moderate size may exist, but the findings do not support narrowly targeting educational campaigns at a particular demographic group on the basis of these data. Universal, pharmacy-based measures appear more defensible.

Statistical caution. Of 81 tests, only two retained significance after correction. Findings such as the occupation associations should be regarded as exploratory. Reporting adjusted and unadjusted results together lets readers judge which findings are robust.

Strengths and limitations. Strengths include a single instrument covering all four cascade stages, explicit interval estimates, effect sizes and a pre-stated multiplicity strategy. Limitations are the cross-sectional design; self-reported, mostly binary measures of counselling, awareness and behaviour; a modest sample of 200 collected partly online, which may favour more literate and connected respondents; and the derivation of intervals, effect sizes and adjustments from summary statistics rather than person-level data. The awareness-versus-practice and counselling-versus-awareness gaps compare items answered by the same respondents, so the unpaired intervals are conservative approximations. The side-effect awareness × ADR table was reconstructed from percentages. Single-item awareness measures were not validated against observed knowledge.

5. CONCLUSION

In this sample of Indian OTC users, pharmacist contact was nearly universal but counselling content narrowed from dosage to side effects and interactions, and awareness translated poorly into label reading and expiry checking. Counselling was not detectably associated with safer outcomes, although only moderate or larger effects could be excluded. Safe-use deficits were broadly distributed across demographic groups, and most nominally significant associations did not survive multiplicity correction. Practical priorities are structured side-effect, interaction and referral counselling at the point of supply, prompts that turn awareness into habits such as reading the label, and prospective studies that measure counselling quality and outcomes.

Ethical approval and consent to participate:

This study did not involve animal or human subjects. No ethical approval is required.

Consent for publication:

All authors read and approved the final version of the manuscript.

Competing interests:

The authors have no relevant financial or non-financial interests to disclose.

Funding:

The authors declare that no funds, grants were received during the preparation of this manuscript.

Data availability:

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Author Contributions (CRediT Statement)

Payal Ahlawat: Conceptualization, Methodology, Data curation, Formal analysis, Investigation, Writing – original draft, Writing – review & editing, Visualization, and Project administration.

Aditya Sharma: Supervision, Methodology, Validation, Writing – review & editing, and Project administration.

Both authors have read and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

Authorship Declaration

All authors have made substantial contributions to the conception, design, data acquisition, analysis, and interpretation of the work. All authors were involved in drafting the manuscript or revising it critically for important intellectual content. All authors have approved the final version of the manuscript and agree to be accountable for all aspects of the work, ensuring the accuracy and integrity of the research.

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