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UNDER-REPORTING OF ADVERSE DRUG REACTIONS AMONG COMMUNITY PHARMACISTS: REASONS AND REMEDIES

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Abstract

Spontaneous reporting of suspected adverse drug reactions is the backbone of post-marketing drug safety surveillance, yet most reactions are never reported. This short narrative review summarises published evidence on why community pharmacists under-report and what has been tried to change it, and it presents no new survey data. It covers the scale of under-reporting, knowledge, attitudinal, practical and system-level barriers, and remedies such as education, simpler reporting routes, feedback, regional centres and patient reporting. Studies from many countries point to similar barriers, and educational and organisational interventions can raise reporting. Most evidence comes from self-reported surveys and short-term interventions, and long-term effects on report quality remain poorly documented.

1. INTRODUCTION

Before a medicine is licensed, it has usually been given to a few thousand people for a limited time under closely controlled conditions. That is enough to show efficacy and to detect common adverse effects, but it cannot reveal reactions that occur in one patient in many thousands, that appear after years of use, or that arise mainly in groups left out of trials, such as older people, children, pregnant women and patients taking many other drugs [1, 2, 3]. Adverse drug reactions (ADRs) are also costly. In hospital

studies they account for a substantial share of admissions, can be fatal, and national

surveillance of emergency visits shows that many occur in the community [4, 5, 6].

Regulators therefore rely on spontaneous reporting to watch drugs once they are on the market. A health professional or patient who suspects that a drug has caused harm sends a short report to a national centre, where reports are collected, assessed and examined for patterns. The method is inexpensive, covers every drug and the whole population, and has been responsible for identifying many serious reactions that trials missed [7, 8]. Its great weakness is that it depends entirely on someone choosing to report. Where few people do, rare signals are slow to appear, and the numerator for any calculation of risk is only a fraction of the true count [9, 10].

Community pharmacists are well placed to contribute. They see patients who have not been admitted to hospital, they are asked about symptoms that may be drug-related, they dispense repeat prescriptions and over-the-counter products, and they know the full list of medicines a person takes. In many countries they are among the most accessible health professionals. Yet in most reporting systems their contribution is small compared with that of doctors or hospital pharmacists, and in some countries it is close to nothing [11, 12, 13]. Understanding why, and what can be done about it, is the subject of this review.

This short review draws on published surveys, case-control studies, intervention trials and reviews, and it reports no new data. It considers first the evidence on how much under-reporting there is, then the reasons given by pharmacists and other professionals, and then the remedies that have been proposed or tested. Most of the evidence concerns professionals in general, with a smaller body specific to community pharmacists, so the review draws on both and says which is which where the difference matters. Evidence on remedies is thinner still, and much of it was gathered in hospital or physician populations before being applied, by analogy, to community practice [9, 14, 15].

Terminology also varies between countries and sometimes within them. Some systems accept reports only on defined forms from registered professionals, others invite reports from anyone, and a few allow pharmacists to submit reports on behalf of patients. The wording of the legal duty differs as well, from an obligation to report serious reactions to a general encouragement to report anything suspected. These differences influence both the number of reports and the interpretation of survey results, and they should be borne in mind when findings from one country are applied to another [12, 16, 17].

A few definitions help to avoid confusion. An ADR is a noxious and unintended response to a drug at doses normally used for treatment, while an adverse event is any untoward occurrence during treatment, whether or not caused by the drug. Pharmacovigilance reports are by nature suspicions, not proofs, and reporters are not expected to establish causality; that is the task of the assessing centre. Many of the barriers discussed below arise because professionals think they must be certain before they report, a belief that runs against the logic of the system [2, 3, 8].

2. SCALE OF UNDER-REPORTING

One of the better-designed estimates compared hospital records with the national system in Sweden and found that the large majority of serious reactions had never been reported [9]. The figure is a rough guide, not a precise constant. Rates varied with the method of estimation, the country, the type of reaction and the group of professionals studied. Serious and well-known reactions are reported more often than minor or unexpected ones, and reporting of reactions to newly marketed drugs is better than for old products, a pattern that has been seen repeatedly [9, 14, 18].

Estimating under-reporting is itself difficult, and the methods explain much of the spread in published figures. Some investigators compare the number of reports received with the number of reactions found by reviewing medical records, others ask professionals how many reactions they have seen and how many they reported, and others compare reports with prescribing data for a drug known to cause a specific reaction [9, 18]. Each approach has weaknesses, including incomplete records, recall bias and

uncertainty about what counts as a reportable reaction. A study on a hospital medical unit in Britain, for example, found that only a small fraction of the reactions meriting notification had been reported [18]. The data should be read as showing a big gap, not as measuring it precisely [9, 14].

Surveys of professionals give a similar picture from the other side. A survey of community pharmacists in Mumbai, India, explored their knowledge, attitudes and practice of reporting in a setting where formal pharmacovigilance was still developing [19]. A Swedish survey of hospital doctors found that many had seen ADRs that they thought worthy of report but had not reported them [20]. Italian practitioners showed gaps in knowledge about the reporting system, and a study of American doctors in the 1980s found that many did not know which reactions to report or did not report because they believed the drug was already known to be safe [21, 22].

Pharmacists as a group have been studied in several countries. In Norway, pharmacists as a profession contributed a modest share of all reports, and the quality of their reports was similar to that of other reporters, which suggests that the problem lies in quantity and not in competence [11]. The Dutch and several other European systems have received a larger share of reports from pharmacists than the systems of many other countries, showing that the profession can be a major source when conditions allow [12]. International comparisons indicate large differences in the role given to pharmacists by law and tradition [12, 16].

Non-prescription medicines are a particular blind spot. A person with a reaction to an over-the-counter analgesic, cold remedy or herbal product has often not seen a doctor at all, and the pharmacist may be the only professional who hears about it. Such reactions are rarely captured by reporting systems built around prescribers, and surveys of patients suggest that people seldom volunteer them to anyone unless asked [23, 24]. Because many serious reactions, from gastrointestinal bleeding to liver injury, can follow the use of products sold without prescription, the absence of community pharmacists from the reporting base leaves a real gap in the picture that regulators receive [2, 3].

The picture in community pharmacy specifically comes largely from surveys in individual countries. In a Spanish region, community pharmacists reported few suspected reactions despite regular contact with patients, and under-reporting was associated with knowledge and attitudinal factors [15]. Surveys in Nigeria, Saudi Arabia and the United States describe a similar situation: pharmacists who were aware of the concept of pharmacovigilance but who rarely reported, or who did not know how the system worked [25, 26, 27]. Differences between countries in the legal duty to report and in the visibility of the system explain part of the variation.

Under-reporting matters for different reasons in different settings. In high-income countries it delays recognition of signals and weakens estimates of frequency, because the proportion of reactions that are reported may differ between drugs and over time, particularly after publicity [7, 8, 10]. In low- and middle-income countries the problem is more basic, since many systems are young and under-resourced, and medicines are sold and used in ways that make reactions difficult to detect or link to a drug [28]. Pharmacists, who are often the first and sometimes the only professional a patient sees, could have an even greater role there.

3. REASONS FOR UNDER-REPORTING

The reasons why professionals do not report have been studied for several decades, and the results have been remarkably consistent. Early surveys of doctors in England pointed to complacency, fear of litigation, ignorance of the scheme, diffidence about doubtful associations and indifference, which came to be known as the seven deadly sins of non-reporting [29]. Later systematic work has recast these as knowledge, attitudes and practical or system factors, and has added structural barriers such as the absence of feedback [14]. The reasons identified in the literature for community pharmacists are collected in table 1, together with the remedies discussed in the next section, and

their distribution is shown in fig. 1.

Table 1: Reasons for under-reporting by pharmacists and remedies reported in the literature

Barrier or remedy	Published evidence	Ref.
Not knowing where or what to report Knowledge gap	Many pharmacists were unsure of the reporting route or of which reactions to report	[15, 26, 27]
Belief that only safe drugs are marketed Attitude	Complacency and the assumption that serious reactions must already be known reduced reporting	[22, 29]
Uncertainty about causality Attitude	Hesitation to report doubtful associations or events with several possible causes	[15, 30]
Lack of time and workload Practical barrier	Cited in nearly every survey, especially in busy community pharmacies	[15, 31]
Forms and reporting route Practical barrier	Paper forms and remote centres made reporting slower and less likely	[13]
No feedback from the centre System factor	Absence of acknowledgement or learning from reports discouraged repeat reporting	[30]
Role not defined in the system System factor	Reporting by pharmacists varied with the legal and professional role given to them	[12, 16]
Educational programmes Remedy	A cluster-randomised trial in physicians and attitude-based design raised reporting	[32, 33]
Regional centre support Remedy	Regional visits, training and an online reporting link were followed by increased reporting	[34, 35]
Patient reporting Remedy	Patient reports were useful and added information; awareness limited uptake	[23, 24, 36]

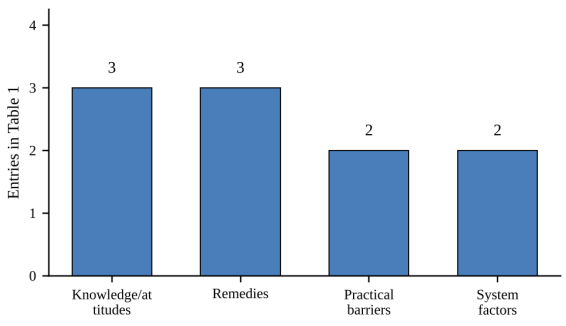


Fig. 1: Number of entries in table 1 by group of barrier or remedy

Knowledge comes first. Many pharmacists do not know that they may report, where to send a report, which reactions are worth reporting or what information is needed [15, 26, 27]. Some believe that only serious reactions matter and that anything already listed in the product information is not worth reporting, although reports of known reactions help to define frequency and risk factors. Knowledge gaps are often greater for newer systems and for patient-facing channels, and they seem to be most pronounced among pharmacists without postgraduate training in clinical pharmacy or pharmacovigilance [21, 25, 37].

Attitudes carry at least as much weight as knowledge. A survey of health professionals in Nepal found that limited knowledge of pharmacovigilance went with little practice of reporting [37], whereas a case-control study in doctors found that attitudes, not only knowledge, separated those who reported from those who did not [38]. Typical attitudes include a belief that only safe drugs reach the market, so that serious reactions must be rare and already known, diffidence about reporting a doubtful association, and fear of being blamed or sued [22, 29]. Some pharmacists see reporting as the doctor's job, an attitude reinforced when the pharmacist has little contact with the prescriber [39].

Uncertainty about causality deserves separate mention, because it is one of the most frequently cited reasons. Pharmacists, like other reporters, hesitate to submit a report when the link between drug and event is unclear, when several medicines were taken at once or when the reaction might be due to the underlying illness [15, 30]. This hesitation conflicts with the purpose of the system, which is to collect suspicions. Educational messages that tell professionals explicitly that they do not need to be certain, and that a report does not imply blame, address the barrier directly and have been part of successful interventions [32].

Pharmacists face some barriers that differ from those of doctors. They usually see the patient after the prescriber and often lack access to the diagnosis, laboratory results or clinical notes that would help to judge whether a symptom is drug-related [13, 39]. Many see their role as supplying the right

drug in the right way, with clinical monitoring belonging to the prescriber. In surveys, pharmacists have described reluctance to question the doctor's choice of drug by reporting a reaction to it, and some noted that patients return to the doctor and not the pharmacy when a reaction occurs, so the pharmacist never learns of it [13, 31].

Practical barriers are equally important in a busy pharmacy. Lack of time is mentioned in nearly every survey, along with the need to search for and complete a form, to obtain further information from the patient or doctor and to do so while customers wait [15, 31]. Unlike a hospital pharmacist, the community pharmacist often works alone or with technicians, with no protected time for non-dispensing tasks and no financial reward for reporting. In Britain, hospital pharmacists listed the same barriers as did their community colleagues, though they had more access to patient records and to clinical colleagues [13], and a survey of pharmacists in India found comparable gaps in knowledge and practice [39].

System factors form a third group. A report that disappears into a national database without acknowledgement gives the reporter little reason to try again, and pharmacists frequently mention the absence of feedback or learning from their reports [30]. Forms may be hard to find, hard to complete or available only on paper, while the reporting centre may be remote from everyday practice. Where pharmacists are not formally included in the legal framework, or where reporting is not part of the standard of practice, the activity is optional and tends to be dropped when the day is busy [12, 13, 16].

Personal and workplace characteristics have been examined, with mixed findings. Training in pharmacovigilance and previous experience of reporting predicted later reporting in several studies, whereas age, sex and years in practice showed inconsistent relationships [15, 25]. Pharmacists in chain stores sometimes reported less than independent owners, and those with a professional or employer expectation to report did more, though the data are patchy. The inconsistent findings may reflect real differences between health systems as well as the weakness of cross-sectional surveys, which can show association but cannot establish what causes pharmacists to start reporting [15, 26, 37].

Patients add another dimension. People who have a reaction often talk first to the pharmacist, to whom they bring questions about symptoms, but the conversation may end with advice and without a report [23, 24]. The pharmacist may judge the reaction minor, may not recognise a drug as the cause, or may not know that patients themselves can now report in many countries. The reaction of the patient to the system also matters, since patients who see no response from their pharmacist are less likely to raise the matter again. Understanding how reactions are communicated in the pharmacy is a research need that surveys of knowledge alone do not meet [24, 36].

Surveys also reveal that willingness to report is not the same thing as reporting. Many pharmacists who said they would report a serious reaction had not done so in the preceding year, and stated intentions were higher than recorded behaviour [25, 26]. In a study based on a model of planned behaviour, American pharmacists' intention to report serious events was shaped by their own attitudes, by the views of colleagues and by their sense of control over the process, which suggests that a good attitude has to be matched by the means to act on it [25]. Self-report always carries the risk of social desirability bias. Direct observation of what pharmacists do, for example by auditing reports submitted from a sample of pharmacies, would be a stronger design than any questionnaire.

4. REMEDIES

Education is the remedy most often proposed and the one with the best trial evidence. A distance-learning programme in pharmacovigilance for clinicians in the United Kingdom, linked to educational credits, was followed by a rise in Yellow Card reports from participants [32]. The same group had identified the factors that influence reporting in a model centred on the professional and used the model to design workshops [33]. Although these programmes

mainly involved doctors, their logic applies to pharmacists, and similar attitude-based content has been recommended for them [33, 37].

Education works best when it addresses attitudes as well as facts. Lectures on the definition of an ADR and the use of a form change knowledge but leave deterrents such as fear of blame untouched. More effective programmes use case discussion, reassure participants that suspicion is enough, explain how a report is used, and repeat the message over time [32, 33]. For pharmacists, undergraduate teaching can introduce pharmacovigilance as a part of professional practice, and continuing education can follow for those already working. Evidence for long-term retention is limited, since most evaluations measure reporting over months rather than years [34, 35], and the few comparisons of training methods, such as those among general practitioners in the Netherlands, have been retrospective [40].

Making reporting easier is the second approach. Short forms, electronic reporting from within the dispensing software, a telephone line or a mobile application reduce the time required, and reports can be pre-populated with information already in the pharmacy record [34]. Pharmacists in hospitals have benefited from simplified forms and from the presence of a local pharmacovigilance officer who helps to fill them in [34]. In community practice, integration with the existing software and the removal of duplicate data entry is probably the most promising practical change, though this has been evaluated less systematically than education [16, 34].

Feedback and local support are strongly associated with sustained reporting. The French PharmacoMIP pilot linked hospitals to a regional pharmacovigilance centre, with visits, training and prompt responses to reports, and recorded a clear increase in reporting over two years [34]. A Portuguese hospital study placed a hyperlink to the online reporting form on the clinical intranet, and the number of spontaneous reports rose afterwards [35]. Regional centres allow face-to-face contact and personal feedback, which addresses the sense of reporting into a void [34].

Patient reporting offers a different route around some of the barriers. Many countries now accept reports from patients directly, and studies indicate that patient reports are of good quality, add information about the experience of a reaction and often concern reactions that professionals under-report [17, 23, 24]. Evaluations of the British Yellow Card scheme found that patients could contribute meaningful reports and that awareness was the main limiting factor [36]. Pharmacists have a natural role in telling patients about this option and in helping them to complete a report, which shifts effort from the professional to the patient without losing the pharmacist's clinical input [17, 24].

Prompts at the point of care could prove more useful than general campaigns. A pharmacist who dispenses a newly marketed drug, or who is asked about a symptom that follows a recent change of medicine, is in a good position to ask whether the patient has had a problem. Dispensing software can flag drugs under additional monitoring and offer a reporting link, while a standard question at the counter, such as whether anything about the medicine has troubled the patient, would turn an incidental conversation into a more systematic one [16, 34]. These ideas follow from the barriers identified in surveys, though they have not been tested widely in community pharmacies.

Organisational and professional incentives deserve consideration. In several countries pharmacists are formally recognised as reporters, and professional bodies include pharmacovigilance among expected duties [12, 16]. Feedback in the form of regular bulletins, recognition of reporters and inclusion of reporting in continuing-education credits are inexpensive ways to signal that the task is valued. Payment for individual reports is rarely used and may encourage low-quality submissions; the experience from some countries is that professional recognition and ease of use matter more than money [12, 13, 39]. Legal protection for good-faith reporters removes the fear of litigation cited so often [22, 29].

Community pharmacists can also act as detectors in structured services. Medicines

use reviews, new-medicine consultations and adherence support all bring the pharmacist into extended conversation with patients about how they are getting on with treatment, and such conversations frequently uncover reactions that explain poor adherence [23, 24, 26]. Where such services are paid, they give a natural opportunity and a time slot for pharmacovigilance. Some health systems have begun to link them explicitly to reporting duties. The literature on whether this raises reporting is limited, but the logic is sound and the cost of testing it is small [17, 24].

Developing countries face special constraints and also special opportunities. In many settings pharmacists dispense a large share of medicines directly to the public, sometimes without a prescription, which puts them in the front line of detection [28]. Reporting systems may be new, funding thin and public awareness low, so a programme that includes pharmacists from the start, builds on local networks and uses simple tools stands the best chance of success. International programmes have supported such efforts, though sustained national funding remains the deciding factor [27, 28]. Pharmacy associations can act as natural partners in training and promotion.

5. LIMITATIONS AND FUTURE DIRECTIONS

The literature on under-reporting has several limitations of its own. Most studies are surveys, which measure what professionals say and not what they do, and response rates are often modest, so respondents may be those with more interest in the subject [19, 20, 26]. Intervention studies are fewer, usually run over short periods, and rarely compare the quality of reports before and after, although a rise in the number of reports is only useful if the reports contain enough information to be assessed [11, 32, 35]. Studies specific to community pharmacists remain few in comparison with those on doctors [15, 37, 38].

Report quality is a second concern. Reports from pharmacists in Norway were found to be of similar quality to those from other health professionals, but completeness varied, and reports often lacked data on outcome, dechallenge or concomitant medicines [11]. A larger flow of poorly documented reports could overload assessors and add noise to signal detection without adding information [7, 41]. Programmes aimed at community pharmacists therefore need to teach what a good report contains as well as encouraging more of them, and centres need the capacity to follow up promptly when a report is incomplete [8, 11].

Several knowledge gaps follow. We know little about the cost-effectiveness of different interventions, about whether effects last, and about how the barriers vary between countries with different pharmacy practice [12, 16, 34]. Few studies have followed the full chain from a pharmacist's suspicion to an actual report to a regulatory decision. Evidence on how community pharmacists handle reactions to over-the-counter and herbal products is particularly sparse, although these are the products most often sold without professional supervision [24]. Qualitative work, which can explore the reasoning behind a decision not to report, has been underused [39].

The survey instruments themselves deserve scrutiny. Knowledge, attitude and practice questionnaires differ from study to study, many were developed locally without validation, and responses on a Likert scale can reflect a wish to appear conscientious [25, 26, 27]. Comparing one country's score with another's is therefore of doubtful value. A shared, validated instrument, translated and tested across settings, would allow a proper comparison of the barriers reported by community pharmacists and would make it easier to see whether interventions change attitudes in the way their designers intend [14, 15, 37].

Confidentiality is occasionally raised by pharmacists as a worry, and it deserves a clear answer in training. Reports to national centres are handled under strict rules, patient identity is protected, and most systems ask for only initials, age and sex. Explaining this openly removes a barrier that is rarely recorded in surveys but surfaces in qualitative interviews, where pharmacists voice concern about passing on details of a person's health without consent [2, 8]. Clear national guidance on data protection and on patient information in

reports would help, and so would a short statement in the pharmacy that tells customers how the system works.

Future work should combine education with practical change and be evaluated with proper designs. Randomised or stepped-wedge trials of integrated interventions, such as training plus a reporting button in the dispensing software plus feedback, would show which components matter and how much they cost [32, 34, 35]. Outcomes should include the quality and clinical value of reports, not only their number, and follow-up should last at least one or two years. Patient-reported data and linkage of pharmacy records to reporting could also open new ways to measure under-reporting directly [17, 23].

A last consideration is the relationship with policy. Where regulators define a role for pharmacists in pharmacovigilance, provide training and guarantee feedback, rates of reporting by pharmacists are higher [12, 16]. Where the role is unstated, even well-motivated individuals are unlikely to carry the burden alone. Professional bodies, regulators and employers share responsibility for creating conditions in which a busy community pharmacist can send a report in a couple of minutes and learn something from the result [12, 27]. That, rather than any single educational course, is probably the sustainable answer.

It would be wrong to expect that fixing under-reporting alone solves the problem of drug safety. More reports bring more noise, including coincidental events and reports of poor quality, and the statistical methods that screen reports need to deal with this [7, 8, 10]. Reporting is the first step in a chain that includes expert assessment, communication of findings back to prescribers and pharmacists, and regulatory action. Without the later steps a high reporting rate would be wasted. Strengthening the system as a whole and the reporting link in particular is therefore the realistic objective [2, 3].

6. CONCLUSION

The evidence reviewed here suggests that under-reporting by community pharmacists is large, long-standing and driven by a consistent set of causes. Gaps in knowledge, attitudes such as complacency and uncertainty about causality, lack of time, awkward reporting routes and the absence of feedback appear in surveys from many countries [9, 14, 15, 29]. Because the same reasons emerge across settings, they are unlikely to be accidents of local culture, and solutions found in one country can often be adapted for another [12, 16].

Remedies with the best support combine education that deals with attitudes, simpler reporting integrated into pharmacy workflows, regional or local support with prompt feedback, and recognition of the role of patients [23, 32, 34, 35]. The weakest part of the evidence is the long-term effect on the number and quality of reports, and trials of integrated programmes in community pharmacy are still needed [17, 27, 33]. Until then, regulators and professional bodies can act on the existing evidence by making reporting easy and visibly valued.

7. ABBREVIATIONS

ADR-Adverse drug reaction, WHO-World Health Organization, OTC-Over the counter, FDA-Food and Drug Administration

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Nil

9. AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

10. CONFLICT OF INTERESTS

Declared none

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