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KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AMONG HOSPITAL NURSES

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Abstract

Nurses administer medicines and observe their effects, yet they contribute few spontaneous reports of adverse drug reactions (ADRs). This narrative review summarises published evidence on the knowledge, attitudes and practice of pharmacovigilance among hospital nurses, drawing on surveys of nurses and of doctors and pharmacists where nursing data are thin; it reports no new data. Awareness of ADRs is generally good, but knowledge of reporting systems and of what to report is limited. Attitudes are positive in principle, though fear, uncertainty and workload discourage action. Educational interventions have raised reporting in other professions, whereas trials in nurses are lacking, and the weaknesses of self-reported survey data limit firm conclusions.

1. INTRODUCTION

Every medicine that reaches the market has been tested in a limited number of people for a limited time, and what remains unknown at the point of licensing is often more than what is known. Pharmacovigilance, defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem, is the system that fills that gap after approval [1]. Its raw material is the individual report, usually made by a health professional who notices that something unexpected has happened to a patient. The quality of a national system therefore depends on the people at the bedside, and on whether they know how, when and why to report [2, 3].

Nurses are the largest group of health professionals in most hospitals and the group closest to the patient at the point when a drug is given. They prepare and administer

medicines, observe the response, and are usually the first to see a rash, a fall in blood pressure or a change in behaviour. Yet reports from nurses make up a small share of spontaneous reports in many countries [4, 5]. This review asks what published surveys and commentaries say about the knowledge, attitudes and practice of pharmacovigilance among hospital nurses, and how those findings compare with other professions. It reports no new data and is not a survey of any particular hospital.

Knowledge, attitude and practice (KAP) studies are the usual tool for this question. A questionnaire asks respondents what they know about adverse drug reactions (ADRs) and reporting systems, how they feel about reporting, and whether they have actually reported. Such studies are quick, cheap and easy to compare, which explains why they have been done in dozens of countries [6, 7, 8]. They also have well-known limits, which are discussed near the end of this article [9]. Evidence specific to nurses is thinner than that for doctors and pharmacists, so findings in other professions are used here where they help to explain nurses' behaviour [10, 11, 12].

2. THE NURSE IN THE PHARMACOVIGILANCE SYSTEM

The burden that pharmacovigilance addresses is not small. A meta-analysis of earlier observational studies put the share of hospital admissions related to adverse drug reactions at roughly 5%, with wide variation between settings and definitions [13]. A study of in-patient episodes in a UK teaching hospital found that a substantial minority were complicated by an ADR, with consequences for the length of stay [14]. An American study of hospitalised patients attached a longer stay and a substantial extra cost to adverse drug events, although how much of the excess belongs to the event itself is hard to settle [15]. Wards are therefore settings in which reactions are common, and the people who work on them are positioned to notice them [13, 14].

It helps to be precise about what counts as a reportable event. An ADR is generally taken to be an appreciably harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product [16]. Reactions are often divided into those that are predictable from the pharmacology of the drug and those that are idiosyncratic or immunological, and the second group is the one most likely to be discovered only after marketing [17]. A serious reaction is one that is fatal, life-threatening, disabling, or that requires or prolongs hospitalisation, as set out in the ICH standards used by regulators [18]. Seriousness describes the outcome for the patient, not the clinician's certainty about the cause, and a nurse need not decide on the cause before reporting [16, 18].

Medication errors and ADRs overlap, and nurses sit at the end of the medication-use process. Lesar and colleagues, in a study of prescribing errors in a teaching hospital, found that many arose at the ordering stage from gaps in drug and patient information, and that nurses and pharmacists intercepted a considerable share of errors before they reached the patient [19]. Earlier work on error in medicine had already argued that such failures usually point to weak systems, not to careless individuals [20]. Administration, monitoring and patient education are the nurse's tasks. The same professional who catches an erroneous dose may also be the one who notices that a patient has developed a cough after starting an ACE inhibitor or a skin eruption after an antibiotic [19].

Spontaneous reporting systems, such as the Yellow Card scheme in the United Kingdom, are the main method for detecting rare and unexpected reactions after marketing, and they rely on voluntary reports from clinicians and, increasingly, patients [2, 3]. Their weakness is under-reporting. A French analysis of reporting rates found that only a small fraction of the serious reactions expected to occur reached the national spontaneous reporting system [21]. Pilots in which nurses reported directly to spontaneous systems, carried out in Ireland and the United Kingdom, suggested that their reports were practicable and informative, though the numbers were small [4, 5]. Reports from patients have also been welcomed in several countries, suggesting that wider participation can add useful information, and nurses are often the people patients ask about it [22].

3. KNOWLEDGE OF PHARMACOVIGILANCE

Studies of knowledge usually test three things: whether respondents have heard of the national reporting system, whether they know what should be reported, and whether they know how to report. Surveys of doctors and pharmacists in Europe, the Middle East, Africa and Asia show a recurring pattern, in which awareness of the concept of ADRs is high but detailed knowledge of the system is weak [6, 7, 11, 12, 23]. Many respondents do not know where to find a reporting form, or that reports need not be restricted to serious or new reactions. A survey of community pharmacists in Turkey reported a similar pattern, with positive attitudes but little actual reporting [24].

Nursing education adds its own twist. Pharmacology is taught in most nursing curricula, but the teaching of pharmacovigilance as a professional duty is much less consistent, and many nurses qualify without ever having completed a report form. A pharmacy student survey in Malaysia likewise found that understanding of pharmacovigilance concepts and reporting channels was limited, which suggests that the problem begins early in training [25]. Where nurses have been studied directly, the picture is much like the one for other professions, namely general awareness, vague ideas about what counts as reportable and unfamiliarity with the local reporting process [4, 5, 26].

The most commonly misunderstood area is the threshold for reporting. Surveys in physicians and pharmacists show a belief that only serious or unlabelled reactions are worth reporting, and that a reaction should be reported only when the causal link is certain [8, 10, 27]. This misunderstanding runs counter to the purpose of the system, which is to collect suspicions so that patterns can be recognised by those who see the aggregate data [2, 3]. Causality algorithms and preventability scales exist to support later assessment by reviewers, and the person making the first report is not expected to do that work [28, 29].

Experience and setting influence knowledge, although in unexpected ways. Surveys of physicians in Germany and of hospital pharmacists in the United Kingdom found that knowledge of the national system was uneven even among senior staff, and that years in practice did not guarantee familiarity with the reporting scheme [10, 11]. Respondents who had been taught about the scheme during training, or who worked in units with a pharmacovigilance contact, tended to know more [10, 11]. This suggests that knowledge is acquired through exposure and instruction, not simply through clinical experience, a point that should apply as much to nurses as to doctors [10, 11, 30].

4. ATTITUDES TOWARDS REPORTING

Attitudes are generally positive when measured on paper. Large majorities in European surveys agreed that reporting ADRs is a professional obligation and that it contributes to patient safety [6, 7]. The same studies reveal a gap between belief and behaviour. A case-control study of physicians in Portugal linked non-reporting to attitudes, and the reasons for silence included ignorance of what to report, diffidence about doubtful cases, complacency about the safety of marketed drugs and lack of time [31]. Many of these map neatly onto the barriers that later surveys found, which speaks to how durable they are [31, 32].

Fear and uncertainty affect nurses in particular. A qualitative study of hospital staff in Iran, using a theoretical domains framework, found that workload, lack of time, uncertainty about the causal link and fear of blame or of being held responsible for a medication error all discouraged reporting, along with the perception that reporting made no difference [26]. A Swedish survey of physicians likewise found that many did not report because the reaction seemed well known or minor [8]. In nursing, a hierarchical ward culture can add to the sense that raising a drug-related concern is somebody else's duty, or that it might reflect badly on a colleague who prescribed or dispensed the drug [26, 32].

Professional attitudes can be influential in their own right. A Spanish study of physicians' attitudes to voluntary reporting found that attitudes, such as diffidence and

the belief that a reaction was already known, mattered alongside knowledge [30]. That work indicated that knowledge and attitudes both predicted behaviour, and an intervention in Catalonia showed that structured training could shift behaviour [30, 33]. For nurses, attitudes towards reporting are likely to depend on whether feedback is given and whether their role in reporting is valued by the institution [4, 32].

Local culture decides how safe it feels to raise a concern. Leape's account of error in medicine argued that most failures arise from weaknesses in systems, not from individual carelessness, and that a punitive response discourages the open reporting that safety improvement needs [20]. That message has been slow to reach ward practice. Nurses who have seen colleagues blamed for an error are understandably cautious about documenting any event linked to a drug, whether an error or a true reaction, and this caution shows up in survey answers as fear of consequences [20, 26]. Reframing reports as information for the system may weaken that reflex [20, 32].

Incentives and feedback also matter. Staff who never hear what happened to a report, or who receive only a formal acknowledgement, may conclude that it was not worth the time, and experience from systems that give feedback suggests that responsiveness encourages more reporting [5]. Anonymous or non-punitive reporting, protection against blame and recognition from managers are often proposed as ways to improve attitudes, though evidence for their independent effect is sparse. Experience in hospital incident-reporting programmes suggests that a visible response to the first few reports can change staff expectations of the whole system [26, 32]. Vallano and colleagues, who surveyed hospital clinicians about the obstacles to reporting, identified attitudes such as diffidence and complacency alongside gaps in knowledge, and proposed practical solutions [32].

5. REPORTING PRACTICE

Practice is the weakest leg of the KAP triad. In surveys, the proportion of respondents who have ever submitted an ADR report is usually far lower than the proportion who say they approve of reporting, often a third or less [6, 7, 11, 27]. Nurses are no exception. Early work in Ireland and the United Kingdom showed that nurses could and did report, and that their reports could carry useful clinical detail, but the volume was small compared with the number of nurses employed [4, 5]. Findings from the main sources are collected in table 1, and the entries are grouped by theme in fig. 1.

Table 1: Selected published evidence on pharmacovigilance knowledge, attitudes and practice relevant to nurses

Source or study type	Reported finding	Ref.
Hospital admissions meta-analysis	Around one admission in twenty was related to an adverse drug reaction in a meta-analysis	[13]
In-patient episodes UK teaching hospital	A substantial minority of episodes were complicated by an ADR, with longer stays	[14]
Reporting-rate analysis France	Only a small fraction of expected serious reactions were reported spontaneously	[21]
Determinants of under-reporting	Ignorance, diffidence, complacency and lack of time recur as reasons for silence in a physician case-control study	[31]
Qualitative study hospital staff	Workload, uncertainty about causality and fear of blame discouraged reporting	[26]
Nurse reporting pilots	Nurses' reports were practicable and informative, though few in number	[4, 5]
Pharmacist surveys	Positive attitudes but limited knowledge of reporting procedures	[10, 12, 23, 34]
Physician surveys	Reporting limited by belief that only serious or certain reactions matter, and by lack of time	[6, 7, 8, 11, 27]
Community pharmacists Turkey	Positive attitudes towards reporting but little reporting in practice	[24]
Drug-utilisation intervention physicians	Intervention was followed by higher ADR reporting	[33]
Review of training several professions	Educational interventions raised reporting across settings	[35]

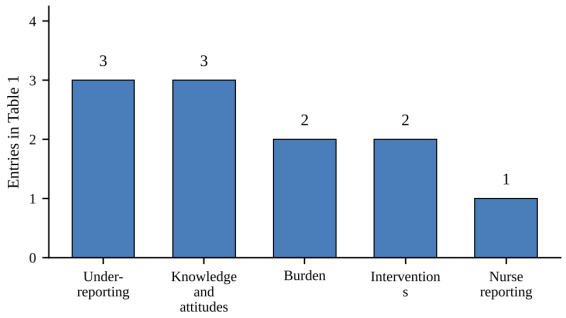


Fig. 1: Number of entries in table 1 by theme

Why practice lags is clear from the barrier studies. Nurses report being short of time, uncertain whether a reaction is caused by the drug, unsure which form to use, and worried that a report might lead to criticism [26, 32]. Hospital systems often send an incident report for a medication error through a local safety channel that does not feed the national pharmacovigilance centre, so a reaction that was documented locally may never be reported externally [2, 3]. This separation between local incident reporting and national spontaneous reporting is a structural reason why a nurse may be an active reporter within the hospital and invisible in the national database [3, 19].

The quality of the reports is also a concern. Reports from clinicians are valuable only if they include the suspect drug, dose, date of onset, outcome and relevant history, and these details are often incomplete in busy wards [2, 3]. Nurses record the timing of doses and symptoms accurately, which gives them a strong claim to supply good-quality information, particularly the timing of onset relative to administration [4, 5]. In addition, nurses are well placed to describe dechallenge and rechallenge, as they see what happened when a drug was stopped. This information is central to causality assessment, so the contribution they can make is greater than their reporting numbers imply [28, 29].

What counts as a valid report is simpler than many staff assume. International standards describe four minimum elements for an individual case report, namely an identifiable patient, an identifiable reporter, a suspected medicinal product and a suspected adverse event [18]. Anything else, including the diagnosis, laboratory results and the outcome, improves the usefulness of the report but is not a condition for submitting it. If nurses understood that a short report with these four elements is acceptable, one of the barriers to reporting, the feeling that one needs to be sure and to have all the details, could fall away [18, 32]. Many national forms now make this explicit.

Patients have started to report directly in several countries, which changes the nurse's role. Experience from the Netherlands showed that patient reports contained information not found in professionals' reports, notably about the effect of reactions on daily life [22]. A nurse who explains to a patient how to report and who supports a report from a patient who has had an unusual reaction is therefore adding to the system, even without writing the report themselves [22]. Counselling about side effects at discharge or in outpatient clinics offers a natural moment to introduce this idea, and a leaflet that names the reporting route is a low-cost way to support it [22].

6. EDUCATION AND SYSTEM INTERVENTIONS

Education is the most-tested remedy. A Catalan intervention sent physicians information built on local drug-utilisation data, and their reporting of ADRs rose afterwards [33]. A systematic review of educational interventions concluded that training, especially when interactive and repeated, improved reporting across several health professions, though the studies differed in design and many were small [35]. No equivalent trial has been done specifically in nurses, so the extent to which these results transfer is uncertain, although there is no obvious reason why nurses should respond differently [33, 35].

Content matters as well as method. Training that explains the purpose of the system, shows how rare reactions are discovered, uses concrete examples of drugs withdrawn after spontaneous reports and gives practical instruction on how to fill in the form appears more effective than brief reminders [2, 3, 35]. Training that corrects the belief that only serious or certain reactions should be reported addresses the most common misunderstanding found in the surveys [8, 10, 27]. Short, repeated sessions at ward level,

and the inclusion of pharmacovigilance in basic nursing curricula and in competence frameworks for continuing education, are sensible practical measures [25, 35].

System changes can make reporting easier. Electronic forms embedded in the clinical record, a single local contact for queries, and designated pharmacovigilance champions on each ward have been suggested as ways to reduce the effort involved [26]. Hospital pharmacists can act as a bridge, since they usually have better knowledge of the system, and surveys suggest they are willing to support colleagues [10, 12, 23]. Regulators can help by giving direct feedback and by recognising reports from nurses as valid, which several countries now do [4, 5]. Few of these measures have been formally evaluated in nursing [26, 35].

Evaluation of interventions needs to be more careful than it has been. Many studies of training measure only knowledge scores immediately afterwards, which says little about later behaviour, and few follow reporting rates for a year or more [35]. The Catalan study is unusual in using reports to the regional centre as its outcome, which is easy to count but cannot show the quality of the reports [33]. Future nursing studies should count reports submitted, assess their completeness with a simple scoring tool, and record whether the nurse or someone else wrote the report, since each of these measures answers a different question about impact [29, 33, 35].

Some measures aim to alter the climate rather than the process. A non-punitive stance towards reporting, leadership that visibly values safety reports and routine discussion of reports at ward meetings are mentioned by many authors as supporting a reporting culture [26, 32]. They are also cheap. The strongest evidence for changing behaviour still comes from structured education, and combined strategies using training and workflow changes seem more promising than either on its own. Because climate measures are harder to evaluate, they are seldom tested in trials, so their effect on nurses is inferred from general patient-safety experience and not from pharmacovigilance studies [33, 35].

7. LIMITATIONS AND FUTURE DIRECTIONS

This review inherits the limits of the KAP method. Self-reported practice overstates actual behaviour, because respondents tend to give socially acceptable answers, and knowledge scores depend on how the questions were worded and scored [9]. Questionnaires differ widely, so percentages from different studies cannot be pooled or ranked safely. Much of the evidence comes from doctors and pharmacists, and findings in nurses are extrapolated in places. The review is also narrative and selective, and studies from some regions and languages are probably missing [21, 32]. Readers should treat the patterns described as plausible and consistent, not as precise estimates.

Better evidence would come from several directions. Studies that compare actual report counts from wards with survey answers would show how far stated behaviour reflects practice [9, 21]. Trials of educational and system interventions specifically in nurses, with reporting rates and report quality as outcomes, are needed [33, 35]. Qualitative work could clarify how ward hierarchy and shared responsibility affect decisions to report [26]. Consistent, validated questionnaires would allow comparison between countries and over time, and the inclusion of patient reporting in nurse education would reflect changes in practice [9, 22]. For hospitals, local audit of ADR reports by ward and profession is a simple place to begin [2, 3].

8. CONCLUSION

The published literature suggests that hospital nurses are well placed but under-used contributors to pharmacovigilance. They see reactions first, and early pilots show that they can report them in a useful way [4, 5]. The main weaknesses are in knowledge of the reporting system and of what is worth reporting, and in practice, where attitudes that favour reporting rarely turn into reports [6, 7, 11]. Barriers such as lack of time, fear of blame and uncertainty over causality are widely documented and appear to be shared across professions and countries [26, 31, 32].

Practical steps follow from this. Nursing curricula and continuing education should

teach pharmacovigilance as a professional duty with worked examples and hands-on form completion, and hospitals should make reporting easy and safe by linking local incident systems to the national scheme [26, 35]. Rigorous trials in nurses and better survey instruments are needed before firm claims can be made [9, 33]. Until then, a reasonable working assumption is that what has helped doctors and pharmacists will help nurses as well, provided that their circumstances are taken into account [10, 33, 35].

9. ABBREVIATIONS

ADR-Adverse drug reaction, KAP-Knowledge, attitude and practice, WHO-World Health Organization, ICH-International Council for Harmonisation, ACE-Angiotensin-converting enzyme

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11. AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

12. CONFLICT OF INTERESTS

Declared none

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