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# Adverse Drug Reactions, Nursing and Policy: A Narrative Review

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**Abstract**

Medicines' management is a priority in healthcare delivery, but weaknesses in the monitoring and management of Adverse Drug Reactions (ADRs) cause unplanned hospital admissions, financial burdens on healthcare systems, patient discomfort, morbidity, and mortality. This paper suggests policies and strategies that would help nurses minimise and manage ADRs to prescription medicines. The literature was searched for strategies to promote nurses' engagement with monitoring patients for potential ADRs. This narrative review opens the discussion by exploring the potential for nurse policy makers to address this hiatus in care. Recognition, amelioration and reporting of ADRs are important components of safe care, areas where nurses could make important contributions through collaboration in policy development, healthcare reform and enhanced nursing practice. Minimising ADRs necessitates paying sufficient attention to their recognition and prevention. Healthcare providers, particularly nurse leaders, need to commit to strategies to identify and address any adverse consequences of treatments, including ADRs: the axiom *primum non nocere* (first, do no harm) should be applied to all healthcare delivery. The application of structured nurse-led medicines' monitoring in practice depends on the collaboration of all healthcare professionals, co-ordinated by nurses. Incorporation of strategies to identify and ameliorate preventable ADRs into routine work will require the support of policy makers.

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## ABBREVIATIONS

ADRs: Adverse Drug Reactions; HSC: Health Service Commissioner for England; FDA: Food and Drug Administration; WWADR: nurse-administered West Wales Adverse Drug Reaction; OTC: Over-The-Counter; IT: Information Technology; EU: European Union

## INTRODUCTION

### Patient safety and adverse drug reactions

Monitoring the safety of prescribed medicines, or pharmacovigilance, requires appreciation of the underpinning science and the interventions needed for the assessment, detection, and prevention of adverse drug reactions (ADRs) and medicine-related problems [1]. ADRs are an important cause of iatrogenic harm, and most are preventable [2,3]. Failure to monitor patients is a greater problem than poor prescribing, and enhanced patient monitoring will prevent many of problems related to ADRs [4-10].

Medicines' management should be a priority for healthcare organisations, but weaknesses in the monitoring and management of ADRs have been noted [11,12]. Of the ten cases, nine fatal, of substandard care in hospitals and ambulatory care highlighted by the Health Service Commissioner for England (HSC) (2011) [13], two were attributable to failure to monitor prescribed medicines. For example, an 84 year old man with a history of Parkinson's disease was prescribed 10mg olanzapine, and rapidly lost muscle control (described as a ragdoll) and the ability to eat or drink. He became dehydrated and died of pneumonia. The assessors found no records of vital signs, fluid balance, physical health checks or care planning.

Approximately 50% of secondary care ADRs occurs during the first five days of hospitalization [14]. Even ADRs considered non-serious or non-life-threatening, such as xerostomia, constipation, or incontinence [15] have significant impact on an individual's quality of life and require amelioration and intervention [16]. However, social media rarely report such mundane ADRs, preferring to focus on dramatic but rare ADRs [17].

ADRs have significant impact on patients and the resources of health services. ADRs are responsible for 5-8% of UK unplanned hospital admissions [18], 20.8% of preventable emergency re-admissions within one year of discharge [19], 4-6% of UK

hospital bed occupancy [2], and unnecessary morbidity [20,21]. ADRs cost the UK's health services £1-2.5bn ($1.43-3.575bn, €1.3-3.3bn) annually [22], and account for 8% of the USA's total healthcare spend, estimated at $213bn (£149.6bn, €195bn), due mainly to the 10 million additional hospitalisations [23]. The costs of adverse drug events can be substantial, estimated at $6,000–$9,000 for each event, due to increased length of hospital stay [16,24]. In France, ~1% of all emergency calls are ADR related; half of these calls are classified as serious, and most commonly involve antithrombotics or insulin [25].

## Management of ADRs

Management of ADRs is integral to patient safety [26]. Insufficient attention has been paid to identifying ADRs and no appropriate method has been universally adopted and applied to monitor and manage ADRs in clinical practice [27]. Traditionally, doctors prescribe, pharmacists dispense and nurses administer medicines. Although the roles of some nurses and pharmacists have expanded, the task of monitoring patients for potential ADRs is not assigned to any one profession (Figure 1) [28]. Teamwork and involvement of all stakeholders in safety initiatives will facilitate development of more integrated and useable systems that will prevent errors [29], including preventable events relating to suboptimal monitoring, where potential known adverse effects do not receive due attention [30], for example failure to check postural hypotension in patients prescribed diuretics or antihypertensives [31].

Barriers to ADR monitoring and management include: patient non-adherence (accidental, deliberate, informed or uninformed); healthcare providers' workloads; unfamiliarity with/ ignorance of ADRs; uncoordinated care; lack of standardized monitoring systems; and communication failures [32,33].

The negative effects on patients' health, and the burden ADRs place on healthcare systems, require effective policies and strategies to manage the challenge of ADRs. Nurses around the world have a crucial role in the provision of safe pharmacotheraphy [34], healthcare reform, and improving nursing practice through policymaking [35].

## ADR Management: a policy vacuum

This narrative review explores the contributions of nursing to monitoring and managing ADRs. English language work relating to "adverse drug reactions" (as a MeSH entry term), nursing (as nurs*) and "monitoring" was identified from PubMed and the Cochrane library, using these as keywords in titles and abstracts. Hand searches of journals and reference lists yielded additional material. Few relevant publications, and fewer clinical trials, were identified. Therefore, this narrative review also draws on qualitative and descriptive studies, experience and the wider literature. The international literature highlighted the need for: a commonly understood working definition of ADRs; agreed curricula for pre- and post-registration education; strategies to enhance nurses' involvement in managing ADRs; embedding structured medication monitoring systems into practice; application of information technologies; and central roles for nurse leaders in co-ordination and policy development. As with all narrative work, any inferences drawn by readers are logical or theoretical, rather than statistical.

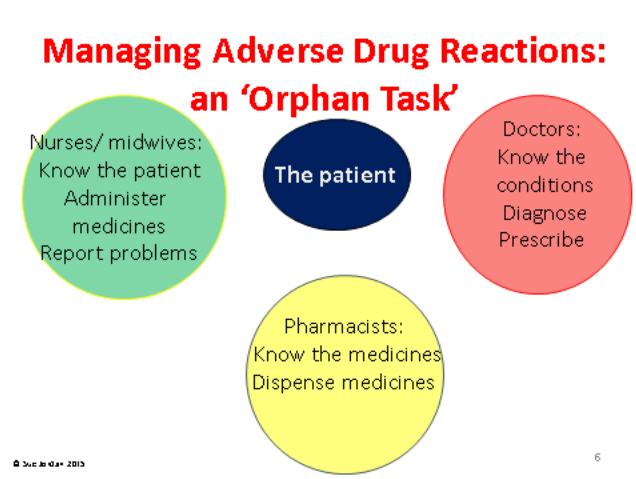


**Figure 1** Monitoring patients for potential ADRs
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## Towards an operational definition of ADRs

A standardised definition of an ADR is needed before the impact of interventions on the reduction of ADRs can be assessed and common problems, such as incontinence, falls, xerostomia, or failure to breastfeed, are recognised as ADRs [36,37]. The U.S. Food and Drug Administration (FDA) promotes the reporting of serious adverse events that may be related to medicines, but there is less encouragement to report adverse events that are not life-threatening [38]. The definitions from recognised experts (Table 1) are couched in general terms, and are not related to individual patients to help practitioners recognise ADRs and relate patients' signs and symptoms to medicines administered.

Distinguishing subtle or ill-defined ADRs from symptoms of illness or ageing is not always easy, and common problems, such as incontinence, constipation, postural hypotension or confusion, may have multiple aetiologies, such as ageing, dehydration, diuretics, antihypertensives, or mental health medicines [44]. Therefore, effective interventions to minimise ADRs need to take a person-centred, holistic approach, and measure outcomes on comprehensive lists of potential ADRs based on reviews, formularies and manufacturers' data sheets, since amelioration of problems is more important to patients than aetiology [15, 28,45].

## ADRs and nurse education

The knowledge and attitudes of healthcare professionals are reflected in their management of ADRs [46]. Healthcare providers' knowledge may be insufficiently detailed to ensure patient safety, prescribe appropriate therapeutic regimens (where licensed), and assess the effects of prescribing [47,48]. Consequently, timely recognition of ADRs may not be acheived [49,14]. Educational interventions, such as case histories of ADRs [4], can increase awareness of ADRs and pre-existing risk factors, such as hypersusceptibility to "allergic" reactions, age, polypharmacy, and co-morbid renal, hepatic or cardiac conditions, that may impair drug distribution, metabolism and elimination [50,51].

**Table 1:** Definitions of Adverse Drug Reactions (ADRs).

| Definition | Provenance | Comments |
|---|---|---|
| *A response to a medicinal product* which is noxious and unintended. This includes adverse reactions which arise from:*<br>*The use of a medicinal product within the terms of the marketing authorisation*<br>*The use outside the terms of the marketing authorisation, including overdose, off-label use, misuse, abuse and medication errors*<br>*Occupational exposure*<br>*EU (2010) [39], European Medicines Agency (2013) [40]*<br>*Medicinal product is the portmanteau term used in the European Union (Directive 2001/83/EC3, Article 1(2)) [41], defined as: *Any substance or combination of substances presented as having properties for treating or preventing disease in human beings.* | The European Union (EU) from the earlier WHO documents | This leaves terms such as 'noxious' and 'unintended' undefined and thus open to interpretation [43]. Causality. An event is considered a possible ADR if there a reasonable possibility of a causal relationship between a suspected medical product and an occurrence (an adverse event). |
| *An adverse drug reaction (ADR) is any untoward and unintended response in a patient or investigational subject to a medicinal product* which is related to any dose administered; serious ADRs are those which result in death, life-threatening conditions, persistent or significant disability or incapacity, hospitalization, prolonged hospitalization, congenital anomalies* (International Conference on Harmonisation [ICH], 1996) [42]. | Good Clinical Practice guidelines for the conduct of research. | Participants in trials are very closely observed. Attribution is arbitrated by clinical experts, usually the Data Monitoring Committee for the trial. Neither this close observation nor relevant expertises are available in routine care. |
| *An appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, usually predicting hazard from future administration and warranting prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product* [43,15]. The term 'side-effects' is reserved for dose-related and therapeutically-unrelated adverse drug reactions. | Editor of leading textbooks in the field. | Attribution is arbitrated by clinical experts. There is a risk that common problems will be attributed to ageing or the underlying condition, and not remediated. |

Note to table: Several looser definitions of ADRs exist, which has led to inconsistencies in identifying and reporting incidents [36].
EU: European Union

ADR recognition and reporting is an essential pre-requisite for the management of medication-related issues [52], and pharmacovigilance and ADR reporting, emphasising collaboration between healthcare professionals and patients, should be incorporated into both undergraduate and continuing professional development programmes [53-56]. Although both physicians and nurses know how to report ADRs, more nurses than physicians report to pharmacovigilance centres, attributed to nurses' greater awareness of professional accountability [14,57-59]. Under–reporting of ADRs is a persistent problem, variously attributed to: inability or lack of knowledge to identify mild or moderate ADRs; fear of being questioned; procrastination; lack of time; bureaucratic reporting methods; uncertainty that the adverse event is attributable to a prescription medicine; and the common notion that prescribed drugs are mainly safe and have no adverse effects [46].

## Monitoring ADRs

Inadequate monitoring affects more patients than poor prescribing [5,6,8,10,60]. ADR monitoring and reporting programmes identify and minimise preventable ADRs, while helping professionals to deal with ADRs efficiently [26]. However, some primary care physicians undertake medication review only if offered suitable financial incentives, including an upfront payment of £350 (US$ 538, 411 Euros) [61], and evidence from pharmacist-led interventions remains equivocal [5,62,63]. We did not identify systematic reviews on nurse-led initiatives, but nurse-led monitoring and intervention is an effective, low cost, low risk and convenient strategy for both service users and professionals, with potential for cost savings and increased quality and safety of care [15]. Nurse-led patient monitoring is one important strategy to minimize the problems attributed to ADRs. ADR monitoring and reporting systems do not replace clinical knowledge and experience, but they unite information on signs and symptoms of ADRs in a succinct, formal assessment, and, in accompanying guidelines, suggest solutions to problems that could be related to prescribed medicines [15,45,64]. A series of observational studies and randomised controlled trials indicated that structured nurse-led medicines' monitoring addresses problems related to ADRs, improve prescribing and pain management and focus attention on patients' perceptions and reports of adverse events [15,28,64-67]. The nurse-administered West Wales Adverse Drug Reaction (WWADR) Profiles were successfully used by nurses within their normal work routines [15,45,64,67]. They offer a thorough and detailed check-list for potential medication-related harms, the risk of over-ascertainment being outweighed by the detection of potentially treatable problems of equivocal aetiology. They provide data trails that ensure effective communication, minimise scope for error or acts of omission, and reduce the risk that time pressures and knowledge deficits affect care standards [15,67]. Problems identified are addressed by nursing care, including health promotion advice, or passed to pharmacists or prescribers with appropriate urgency, adding patient feedback to the medication chain (Figure 2). Self-medication, including medicines purchased over-the-counter(OTC), formerly prescribed medicines without a current physician recommendation or medicines taken above recommended doses can cause ADRs. Collecting full details (including doses) on all medicines from all prescribers, OTC and herbal products, is integral to ADR Profiling and patient safety [68-70]. Nurse-led prescribing initiatives may offer an opportunity for guideline-driven monitoring of adverse events to be incorporated into scheduled patient reviews [36].

While there are widespread concerns regarding over-medication [18], untreated and under-treated conditions are equally common in primary care [71], and detailed ADR

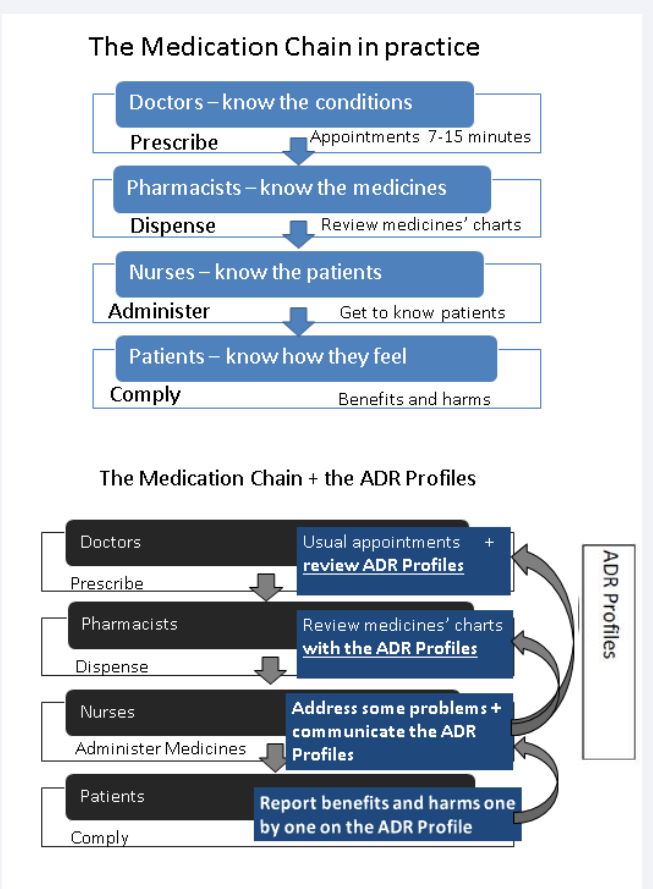


**Figure 2** How the West Wales ADR Profiles bring Feedback to the medication chain
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monitoring also identifies problems, such as pain and gastro-intestinal ulceration, that could be ameliorated by new prescriptions [15].

## Nurse-led management of ADRs

Identification and management of drug-related events are complex and socially contingent processes involving erudite clinical and academic judgments and inter-professional collaboration [36]. A multi-disciplinary healthcare team therefore offers an effective approach for the promotion of safe medication practice [24]; however, medicines' support needs to be pro-actively sought in settings such as care homes [72].

Since nurses are the professionals most closely involved in direct patient care and spend most time with patients, they are best placed to identify adverse drug reactions [73]. Nurses should be encouraged to increase their involvement and accept responsibility for routinely reporting ADRs [73], but to prepare nurses for this requires educational support and structure, as offered by ADR monitoring Profiles with guidelines [15,67]. Such strategies offer leadership opportunities to nurses, placing them as the central professionals liaising between patients and their pharmacists, prescribers, dentists, opticians, and occupational therapists, to ensure that ADRs are identified and resolved as soon as they occur [74,75].

## Information technology

A systematic review of the application of information technology (IT) to prevent medication errors indicates that IT interventions are effective [76]. ADRs may be reduced and patient safety enhanced by electronic recording systems with information on ADRs [27,77-81]. Tracking ADRs over time and medication chart reviews might be combined in software designed to screen ADRs from signs and symptoms identified from nurses' observations based on personalized screening lists generated by the software [27,82].

Online databases have been designed to receive reports of ADRs and collect related information to support post-marketing safety surveillance programs for all approved drug and therapeutic biologic products. For instance, Med Watch is the FDA's programme for reporting serious reactions, product quality problems, therapeutic failure, and product use errors with human medicinal products. Healthcare professionals and patients are encouraged to report serious ADRs *via* online systems [83]. While the application of computerised systems to improve the safety of patient care has been growing in healthcare systems around the world, largely driven by the need to prevent medication errors, policy informed nursing leadership is needed to encourage individual nurses to utilise these applications.

## Nursing leadership in medicines' monitoring: unoccupied professional territory

The dearth of nurse managers or leaders with a special interest in pharmacotherapeutics impacts negatively on ADR monitoring and prevention [26]. Much could be gained by nurse leaders promoting a culture of evidence-based practice in medication monitoring. Nurse leadership could guide strategic planning and policy development to transform practice and improve quality and safety of care through: application of practice guidelines; modification, simplification and incentivising of ADR reporting; and assistance and feedback to nurses to augment the monitoring and management of ADRs [84]. Currently, all professionals, patients, their families, and friends are empowered to report ADRs to the regulatory authorities, but there is no compulsion. Neither is there any obligation to monitor patients for ADRs, although many guidelines recommend appropriate laboratory tests. This offers a key opportunity for nurses to develop their roles [28]. Designation of dedicated nurses to act as 'ADR advocates' and link with a specified prescriber or pharmacist, would promote monitoring and prevention of ADRs [32].

Effective interventions to monitor ADRs require nurses' collaboration, as they hold key information about patients' care, wellbeing, and medicines' administration and can detect and report ADRs before problems escalate or persist and detract from quality of life. Nurses tend to underestimate patients' ADRs, particularly xerostomia, pain and sedation [85]. Therefore, Profiles would benefit many patients or their carers by engaging them in the identification of drug-related events and obtaining their perspectives on potential problems. ADR Profiles as structured checklists of possible ADRs compiled by nurses should

be completed ahead of schedule appointments and reviewed with prescribers and pharmacists (Figure 2) [15].

## CONCLUSION

Many ADRs could be prevented by improved medication monitoring. Optimal management of ADRs in healthcare systems requires nurses to accept professional responsibility to identify and describe problems and to bring them to the attention of prescribers. Most ADRs are preventable, but are dependent on healthcare providers' attitudes, knowledge and skills, and timely recognition and reporting. These barriers would be overcome by formalised collaboration and nursing leadership in safety initiatives. Policy makers and nurse administrators have the opportunity to develop, apply and mandate structured medication monitoring systems.

### Implications for nursing policy and practice

Nurses' roles in safe medication practice require support and direction from policies that set standards to incorporate monitoring and reporting ADRs into nurses' job specifications, local and national audits and the care homes' inspectorates. Management of ADRs requires a comprehensive working definition of ADRs to promote a standardised, structured approach to medication surveillance, and we suggest an inclusive definition of problems reported in the literature. 'First, do no harm' – *primum non nocere'* – is the founding principle of modern medicine and "Prudent Healthcare" [29,86,87]. Healthcare leaders need to maintain ethical values in practice and decision-making and encourage providers to incorporate such values into sustainable practice, respecting patients' humanity, dignity and safety [88].

Embedding medicines' monitoring into policy and practice will require regular audit with external validation at clinic, practice, hospital or regional level. Trials of nurse-led medicines' monitoring have demonstrated short-term gains, but further research is needed to identify factors promoting and thwarting sustainability and long-term impact.

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