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DISCUSSION PAPER

Nurses as adverse drug reaction reporting advocates

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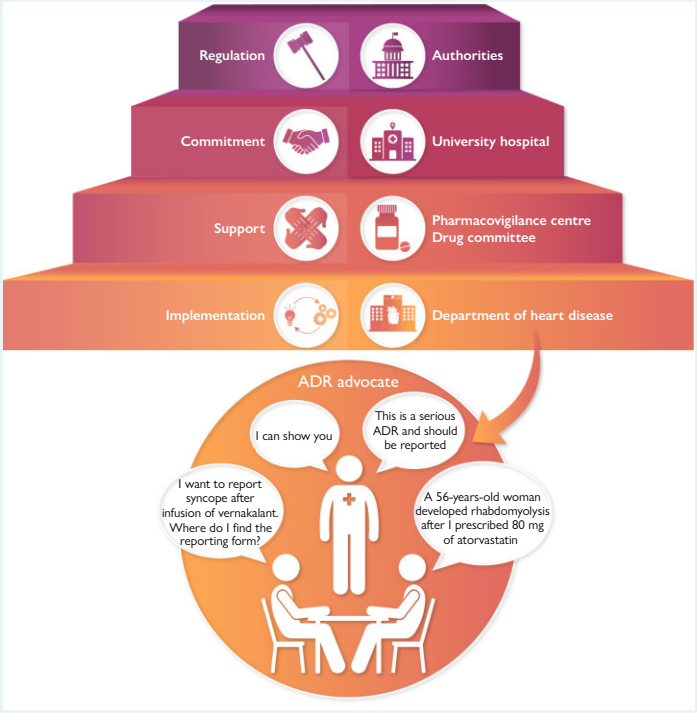
Adverse drug reactions (ADRs) is a challenge in modern healthcare, particularly given the increasing complexity of drug therapy, an ageing population, rising multimorbidity, and a high patient turnover. The core activity of detecting potential ADRs over the last half century has been spontaneous reporting systems. A recent Norwegian regulation commits healthcare professionals other than physicians and dentists to report serious ADRs. In this discussion paper, we share our preliminary experience with a training programme using nurses as ADR advocates to stimulate ADR reporting among the clinical staff in a hospital department.

Central Illustration



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Nurses as adverse drug reaction (ADR) reporting advocates participating in pharmacovigilance (PV) at the Department of Heart Disease, Haukeland University Hospital, Bergen, Norway. The department is a 'lighthouse' (inspiring other departments) in PV in the hospital, and cooperates with the drug committee and the regional PV centre. Commitment is achieved through the department manager and the medical director in the hospital. In addition, a new national regulation commits healthcare professionals other than physicians and dentists to report serious ADRs.

Keywords Nurses • Adverse drug reactions • Training programme • Pharmacovigilance • Cardiovascular drugs

Highlights

- Nurses are involved in direct patient care, and are in a unique position to suspect, identify, and detect adverse drug reactions.
- Nurses as adverse drug reaction advocates require a training programme.
- A training programme in a hospital department increases adverse drug reaction reporting.

Adverse drug reactions

According to the World Health Organization, an adverse drug reaction (ADR) is a response that at any dose or exposure is noxious and unintended.[1] ADRs are associated with considerable clinical and economical costs, and account for ~3.5% of hospital admissions. Furthermore, the percentage of hospitalisations that end in a fatal ADR are reported to be between 0.25 and 0.5%.[2] Excess medical costs attributable to an ADR has been estimated to $6.000–$9.000 (about 6.000–9.000 EUR), due to increased length of hospital stay.[3] ADR reporting is a core activity of pharmacovigilance (PV), which allows post-marketing monitoring of drugs used in a clinical setting and enables detection of new, rare, or serious ADRs. Under-reporting of ADRs is a major issue among healthcare professionals, estimated to exceed 90%.[4] This is concerning, as a high rate of under-reporting can postpone detection of new ADRs and endanger patient safety. Importantly, a particular challenge is the limited information on rare and very rare ADRs when a new drug is marketed.[5]

Cardiovascular drugs and adverse drug reactions

Cardiovascular drugs are commonly associated with ADRs.[6] Patients with cardiovascular diseases are particularly vulnerable to ADRs due to comorbidity and advanced age. A systematic review found that cardiovascular and diabetes drugs were most often responsible for ADRs that resulted in hospitalizations.[7] European Society of Cardiology guidelines recommends combination of several drugs in treatment of cardiovascular diseases, and polypharmacy is prevalent.[8] Additional drug therapy to already established pharmacotherapy can also become necessary when these patients are admitted to hospital for interventions such as percutaneous coronary intervention or surgical procedures. However, use of multiple drugs can lead to drug interactions with further risk of ADRs.[9] This suggests that increased awareness of ADR reporting among healthcare professionals caring for patients who use cardiovascular drugs could improve drug safety.

Nurses and adverse drug reaction reporting

Nursing leadership in PV, including ADR reporting, is based on the fact that nurses are the healthcare professionals most closely involved in direct patient care and spend most time with the patients. Furthermore, nurses prepare and administer most drugs and are therefore in a unique position to suspect, identify, and report ADRs. However, leadership is dependent on nurses accepting new roles and policy makers embedding monitoring and managing ADRs as a formal requirement in nurses' patient monitoring.[10] In March 2007, a legislative amendment was issued in Sweden compelling nurses to report all suspected ADRs to the national PV system. A retrospective study reviewed all individual ADR reports from 2005 and 2010 identified in the national database, the Swedish Drug Information System (SWEDIS).[11] The overall ADR reporting by nurses did not appear to increase after the change in reporting legislation. The proportion of serious and/or unlabelled ADRs reported by nurses did however appear to increase during the same period. Taken together, the data suggest that further proactive measures should be considered in order to involve nurses in the reporting of suspected ADRs. Furthermore, the inclusion of nurses in PV programmes, a relatively recent development, may increase the number of reports, especially of those that add new ADR information within the PV system.[11]

Barriers

A review found that a common challenge in PV is under-reporting of ADRs, and this also includes nurses.[12] Among the explanations put out for this widespread underestimation of PV by nurses, the authors suggest that there are at least two important points to underline: (i) the limited awareness by nurses of their key professional role in PV and (ii) nurses' own beliefs that they have inadequate pharmacology knowledge to identify an ADR.[12] These suggestions are corroborated by a recent systematic review which investigated nurses' knowledge, attitudes, and practice towards ADR reporting and the associated barriers.[13] The review found 23 studies published in English from 2010 to 2020. Despite that two-thirds of nurses encountered ADRs in their clinical practice, only 21% had experience with ADR reporting. Lack of knowledge and training was reported to be the most significant barrier that influenced ADR reporting.[13] Furthermore, an integrative review found that nurses are not fully aware of their role in ADR reporting.[14] Although nurses have a positive attitude towards ADR reporting, their knowledge and skills in these practices were not at a suitable level of competence.[14] Similar barriers to ADR reporting have been reported in studies of physicians and pharmacists.[5] The suggestion of further proactive measures to involve nurses in the reporting of ADRs is important.[11] New legislation or regulations are not sufficient to improve PV among new groups of healthcare professionals.

Table 1 Adverse drug reaction reporting before and after the training programme

Year	Adverse drug reaction	Suspected drug	Reported by
Before implementation of programme			
2019	Immune-mediated adverse reaction, visual disturbance, throat discomfort, runny nose, symptoms of pleuritis, feeling sick	Alirocumab	Physician
	Anaphylactic shock, cardiac arrest (fatal)	Piperacillin/tazobactam	Physician
After implementation of programme[a]			
2020	Hypoglycaemia, transcription medication error, prescribed overdose	Insulin degludec/liraglutide	Nurse
	Headache (stabbing pain), head spinning, visual disturbance	Diazepam	Nurse
2021	Rash, pruritus	Amiodarone, levothyroxine	Nurse
	Supine dyspnoea, chest pressure (diaphragm)	Ticagrelor	Nurse
	Rash, pruritus, dyspnoea, general body pain, swelling of hands, swelling face	Metoprolol, clopidogrel	Nurse
	Hyponatraemia, atrioventricular block third degree	Dapagliflozin	Nurse
	Anaphylaxis	Ephedrine, heparin, ketorolac	Nurse
	Non-ST-segment elevation myocardial infarction, nausea, vomiting, chest pain aggravated	Sodium picosulphate/magnesium oxide/citric acid	Nurse
	Destructive thyroiditis	Amiodarone	Physician
	Cerebral haemorrhage (fatal)	Tenecteplase, clopidogrel, enoxaparin	Physician
	Dyspnoea, productive cough, haemoptysis, chest pain, pulmonary oedema, cardiopulmonary arrest, cerebral infarction, myocardial infarction, takotsubo cardiomyopathy, apical ventricular hypokinesia, ejection fraction decreased, acute heart failure (fatal)	Anagrelide	Physician
	Anaphylaxis, dyspnoea, pruritus, swelling, erythema, hypotension, loss of consciousness, cyanotic	Sulphur hexafluoride	Physician
	Ventricular extrasystoles/tachycardia/fibrillation, cardiac arrest	Flecainide	Physician

[a]The first training sessions to become an ADR advocate took place in March 2020. However, in reality, implementation of the programme did not commence until February 2021 due to higher work demands for nurses in 2020 because of the ongoing pandemic. Notice that adverse drug reactions are termed according to Medical Dictionary for Regulatory Activities (MedDRA; https://www.meddra.org/).

Nurses as adverse drug reaction reporting advocates

On 1 January 2020, a new legislative regulation established the Norwegian Adverse Drug Reaction (NorADR) Registry as a national health registry. In addition, the regulation committed all healthcare professionals involved in patient care to report serious ADRs. Until then, only physicians and dentists had been legally compelled to report serious ADRs in Norway. Thus, we developed a training programme to promote awareness of ADRs and the spontaneous reporting system. *Central Illustration* shows the concept of a nurse acting as an ADR advocate, stimulating ADR reporting among the clinical staff in a hospital department. Training to become an ADR advocate include an e-learning course (how to recognize an ADR) combined with lectures (why PV is important) and practicing ADR reporting (how to report and what happens with the report). In Norway, electronic reporting forms are preferred for ADR reporting, and have been available for medicinal products excluding vaccines since November 2018, and for vaccines since October 2020. As NorADR Registry is a national health registry, information can be shared and enriched with data from other registries, which enable more detailed studies of ADRs and help to improve patient safety. Healthcare professionals can report ADRs without obtaining patient consent. All healthcare professionals filing ADR reports through this system will receive feedback from the regional medicines information and PV centre, including a causality assessment and what is known of the suspected ADR according to current literature. A test version of the electronic reporting form is made available in the training programme, so that the ADR advocates can practise filing dummy reports. During training, the importance of ADR reporting as a component of patient safety and quality of care is highlighted. This includes discussions around the limited number of humans involved in clinical trials prior to drug approval, and the limited drug safety evidence when a drug is marketed.[5,15] The possibility to keep track of ADRs of commonly used drugs in a hospital department, and to initiate local ADR studies to improve quality in daily patient care, are suggested. Hereby, the staff may obtain increased ownership to ADR reporting, and the departments are more likely to experience that the benefits outweigh the burden of such practice.

Adverse drug reaction resource group

Based on the experience with ADR reporting among nurses in Sweden[11] and the current knowledge of barriers to participation in PV,[5,10–14] we established an ADR resource group to ensure continuity and development of the training programme and general awareness of PV and ADR reporting. The ADR resource group included a cardiovascular nurse and PhD candidate (T.R.P.) from the Department of Heart Disease, an ADR responsible pharmacist (L.M.A.) and a senior

consultant (J.S.), both from the Regional Medicines Information and Pharmacovigilance Centre (RELIS Vest), and the leader of the hospital drug committee (T.K.B.), all members from Haukeland University Hospital, Bergen, Norway. The Department of Heart Disease was chosen as a model department for the training programme, since cardiovascular drugs are commonly associated with ADRs.[6–9] We planned to establish nurses as ADR reporting advocates based on the concept described above (*Central Illustration*) with a particular focus on knowledge, training, commitment, and continuity. The programme was gradually implemented through a series of meetings with the Department of Heart Disease in 2020–21, but activity was postponed by the COVID-19 pandemic. Nurses were trained by the ADR responsible pharmacist, and training included practical experience with ADR reporting (reporting forms and instructions). The department manager, the hospital drug committee, and the medical director approved the programme and ensured commitment to the project. Continuity is maintained through regular meetings in an ADR resource group that includes all local ADR advocates, representatives from the local PV centre (RELIS), and the leader of the hospital drug committee. RELIS is responsible for national PV through close cooperation with the Norwegian Medicines Agency, and the programme allows for local pharmacoepidemiology projects through systematic collection of ADR reports and ADR studies of commonly used drugs. At Haukeland University Hospital, the Department of Heart Disease is now a 'lighthouse department' with nurses from different wards as ADR advocates promoting drug safety.

Results

In our meetings with and training of nurses as ADR advocates, we specifically addressed that lack of pharmacology knowledge to identify an ADR is not necessarily a limiting factor. Nurses' ability to observe a patient, and be suspicious of ADRs, was highlighted. Furthermore, many of the nurses were unfamiliar with the spontaneous ADR reporting system, and they did not know that their profession was perceived as important in post-marketing surveillance of drugs. Training as ADR advocates, who facilitate reporting by other nurses and health care professionals in the department, was important to render the role more attractive and less laborious. A typical remark by the nurses in the first meetings was: 'how do I find the time for this?'. The risk of ADRs with use of cardiovascular drugs, and the utility of the programme for patient safety was elaborated. In *Table 1*, we compare reporting of ADRs from nurses and physicians from the department before and after implementation of the programme. The table shows a promising increase in total ADR reports, and an increase in reporting by nurses in particular.

Prospects

Nurses as ADR advocates stimulating reporting among colleagues in a hospital department is an exciting idea at our university hospital. We hope this description could be used as an inspiration in nursing and nursing leadership. Hopefully, our description of a 'lighthouse department' could inspire other departments to find ADR advocates based on their preferences. This could ensure more formal commitment and incentives to ADR advocates and departments that prioritize this type of quality work in hospitals. Nurses from the ADR resource group have already presented the programme to nurses in other departments in the hospital, and at national meetings. Our preliminary experience with nurses as ADR advocates indicates that they are motivated and increasingly aware of the value of detecting and reporting ADRs. A result may be that the nurses become more confident in discussing ADRs with both colleagues and patients. Increased awareness and knowledge of ADRs may again contribute to safer working practices and decreasing preventable or recurrent ADRs.[16] Hence, our programme may be a promising step towards improved drug and patient safety.

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Conflict of interest: The Authors declare that there is no conflict of interest.

Data availability

The data underlying this article cannot be shared publicly for the privacy of individuals that participated in the study and we do not have ethics approval to share the data.

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