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A SURVEY ON ASSESSING THE KNOWLEDGE, ATTITUDE, AND PRACTICE AMONG PHARMACIST TO ADVERSE DRUG REACTION RELATED ASPECTS IN SOUTERN PARTOF KERALA

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Abstract:

A response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiologicalfunction· Pharmacist can play an important role in ADR monitoring and reporting. It would beworth to assess their knowledge and behaviour in drug safety related aspects. Eighty-one pharmacists in the southern part of Kerala were consented in this study. A questionnaire was prepared to investigate the knowledge, attitude and practice of pharmacist regarding ADR reporting and distributed to the identified pharmacist.

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INTRODUCTION:

The World Health Organization (WHO) defines an ADR as 'a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function' [(1)]. Pharmacist can play an important role in ADR monitoring and reporting. It would be worth to assess their knowledge and behaviour in drug safety related aspects [(2)].

All medicines with the ability to produce a desired therapeutic effect also have the potential to cause unwanted adverse effects [(1)]. There is no need to prove a pharmacological mechanism for any noxious response. Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality worldwide. Spontaneous (yellow card) reporting of ADRs remains the most widely used and cost-effective surveillance system and is the cornerstone of safety monitoring of drugs in clinical practice. It detects previously unrecognized adverse reactions and identifies risk factors that pre-dispose to drug toxicity and investigates causality. In addition to identifying drug safety problems, it helps to facilitate risk-benefit judgments and comparisons within therapeutic categories [(3,4).] Intrinsic factors such as knowledge, attitude and practice can help in understanding the relationship of pharmacists with patients and other healthcare professionals and formulating strategies to encourage pharmacists to report ADRs.

A few studies carried out in India have shown poor knowledge, attitude, and deficient practices involving ADR reporting among prescribers and healthcare professionals, mainly physicians [(5,6,7)]. A very few studies into the reasons that impact the knowledge, attitude, and practice of pharmacist with regard to ADR reporting. This study was conducted to analyse the knowledge, attitude, practice (KAP) related to ADR reporting among the pharmacist in southern part of Kerala. Our study explores the views of pharmacist about KAP of ADR reporting.

Medicinal substances are used because of their ability to affect biological processes in the body. Using such substances always carries a certain risk of unwanted or unintended effects.The readiness of the patient and healthcare provider to use a medication depends on the extent of the expected benefit. Accordingly, patients and health professionals who advice patients needto know as precisely as possible the frequency and magnitude of the risks involved in medical treatment, as well as the magnitude and duration of the expected beneficial effects. Every occasion that a patient is exposed to a new medicinal product is a unique situation, and we can never be certain exactly what will happen. We can learn from previous experience when patients under similar conditions have been exposed to the same or a similar medicine.

CLASSIFICATION OF ADVERSE DRUG REATION:

Traditionally, ADRs are classified into two categories: type A and type B reactions. TypeA (augmented) reactions are usually the exacerbation of the pharmacological effects of a drugand are thus dose-dependent. An example is insulin-induced hypoglycaemia. These reactionsare usually predictable due to the known pharmacology of a drug and are thus preventable.Although the incidence of type A reactions is high, they are generally associated with less morbidity and mortality. Because of their high incidence, the public health impact is large.

Type B (bizarre) reactions are hypersensitivity reactions and are not dose-dependent. An example is a penicillin induced hypersensitivity reaction. These reactions are often not predictable and preventable in the individual case (unless the patient has a known history of this type of reaction). This type is associated with high morbidity and mortality but its occurrence in the clinical setting is low.

Type C (continuing) reactions are diseases that occur at a higher frequency among exposed patients than those unexposed, although the exact mechanism is unknown. One example is the higher frequency of cardiovascular events among patients exposed to the COX-2 inhibitor rofecoxib compared with an unexposed control group [(8)].

Type D (delayed) reactions, become apparent sometime after the use of a medicine. Thetiming of these may make them more difficult to detect. An example is leucopoenia, which can occur up to six weeks after a dose of lomustine.

Type E (end of use) reactions are associated with the withdrawal of a medicine. An example is insomnia, anxiety and perceptual disturbances following the withdrawal of benzodiazepines.

Type F (failure) reactions occur when the expected responds to treatment is not achieved.

PHARMACOVIGILANCE AND EPIDEMOLOGICAL METHODS IN ADR DETECTION

The inherent weaknesses of pre-marketing studies mean that post-marketing surveillance of medicines is essential to detect previously unnoticed adverse effects of treatment. The science of this process is called pharmacovigilance and has been defined as 'thestudy of the safety of marketed drugs under the practical conditions of clinical use in large communities. Pharmacovigilance is concerned with the detection, assessment and prevention of adverse effects or any other possible drug-related problems, with the ultimate goal of achieving rational and safe therapeutic decisions in clinical practice.

SPONTANEOUS REPORTING:

Pharmacovigilance uses multiple methods, but the following will focus on spontaneous reporting systems. Spontaneous reporting systems collect data about suspected ADRs in a central database. Cases are not collected in a systematic manner, but accumulate through reportssubmitted spontaneously by people who make a connection between a drug and a suspected drug-induced event. In the UK, the spontaneous reporting scheme is the Yellow Card scheme. In some countries reporting is a voluntary activity, in others reporting is a legal requirement. There is no evidence that such a requirement increases reporting rates. Spontaneous reporting has a number of advantages. It is relatively cheap to administer, can follow a product throughout its life and can also accept reports to over-the-counter medication and herbal treatments. Such schemes are, however, passive surveillance systems, which rely on the ability of health professionals to recognise possible ADRs and to distinguish these from symptoms related to underlying disease. It is important to emphasise that only a suspicion of a

causal link between a drug and an adverse event is required, not confirmation of the association. One disadvantage of spontaneous reporting systems is their inability to quantify the risk. Such systems supply a numerator (the number of reports), but estimates of the incidence of reactions cannot be made because the population exposed to the drug cannot be ascertained accurately. Furthermore, only a minority of reactions are reported. Spontaneous reports are, however, an important form of evidence leading to drug withdrawals and are crucial for hypothesis generation.

Signal detection: A signal can be described as a possible causal relationship between an adverse event and a drug, which was previously unknown. One useful analogy for signal detection in a spontaneous reporting database is to think of a radio signal, which is disguised by the background radio 'noise'.

Statistical methods of signal generation can be thought of as methods of tuning in to capture the radio signal from the background noise. Statistical approaches scan the data accumulated through spontaneous reports for 'drug–adverse event pairs' that are disproportionately present within the database as a whole. Such calculations can be run automatically by modern computer systems, providing the opportunity to scan large databasesfor potential signals of new ADRs. Only rarely will a signal provide such strong evidence that

a restriction on use of the drug or its withdrawal is immediately required.

However, while these mathematical approaches do develop hypotheses and give the illusion of an objective estimate of risk, they are not conclusive in themselves. A signal could be due to causes other than the drug. Confounding factors such as particular groups of patientsbeing 'channelled' into receiving a drug can influence reporting. Similarly, reports may be received and analysed by a varied set of people with differing levels of understanding, competence, training, experience and awareness. There is also a tendency for reporting rates to be higher with newly introduced drugs, while articles in the media, regulatory action and even legal cases can provoke reporting of particular reactions. For that reason, the strength of the signal also depends on the quality of the individual spontaneous reports.

Causality assessment: The assessment of whether a drug is responsible for a suspected ADR is of great importance in both the regulatory environment and within the pharmaceutical industry. Reporters to spontaneous reporting schemes are requested to submit suspected ADRs and such reports contain variable levels of information. For example, since re-challenge with the suspected drug is often ethically unacceptable, very few reports contain such information.

As already noted, while a safety signal can arise from the accumulation of reportedcases of the event in a database, causality assessment of individual cases may influence the subsequent decision-making process. However, often causality is difficult to prove in pharmacovigilance and a high degree of suspicion may be all that is necessary for regulatoryaction.

One of the most common methods of causality assessment in use is unstructured clinicalassessment, also known as global introspection. Expert review of clinical information is undertaken and a judgement is made about the likelihood of the reaction being due to drug exposure. The assessment of complex situations, often with missing information, is open to variation between different assessors and studies have shown marked disagreement between experts. The WHO international monitoring centre uses global introspection for case assessment, assigning standardised causality categories to suspected ADRs.

A number of alternative methods of assessing causality have been developed using standardised decision algorithms in an attempt to increase objectivity and reduce assessor bias.

One of those most commonly used to assess causality is the Naranjo algorithm. This uses a questionnaire and points are added or taken away based on the responses to each question, such as 'Did the adverse reaction reappear when the drug was re-administered?' Thetotal score is then used to place the assessed reaction on the following scale: definite, probable, possible or doubtful. Algorithms may be less open to the effects of confounding variables, such as underlying disease states or concomitant drugs, but variation in assessor judgements still occur.

YELLOW CARD SYSTEM:

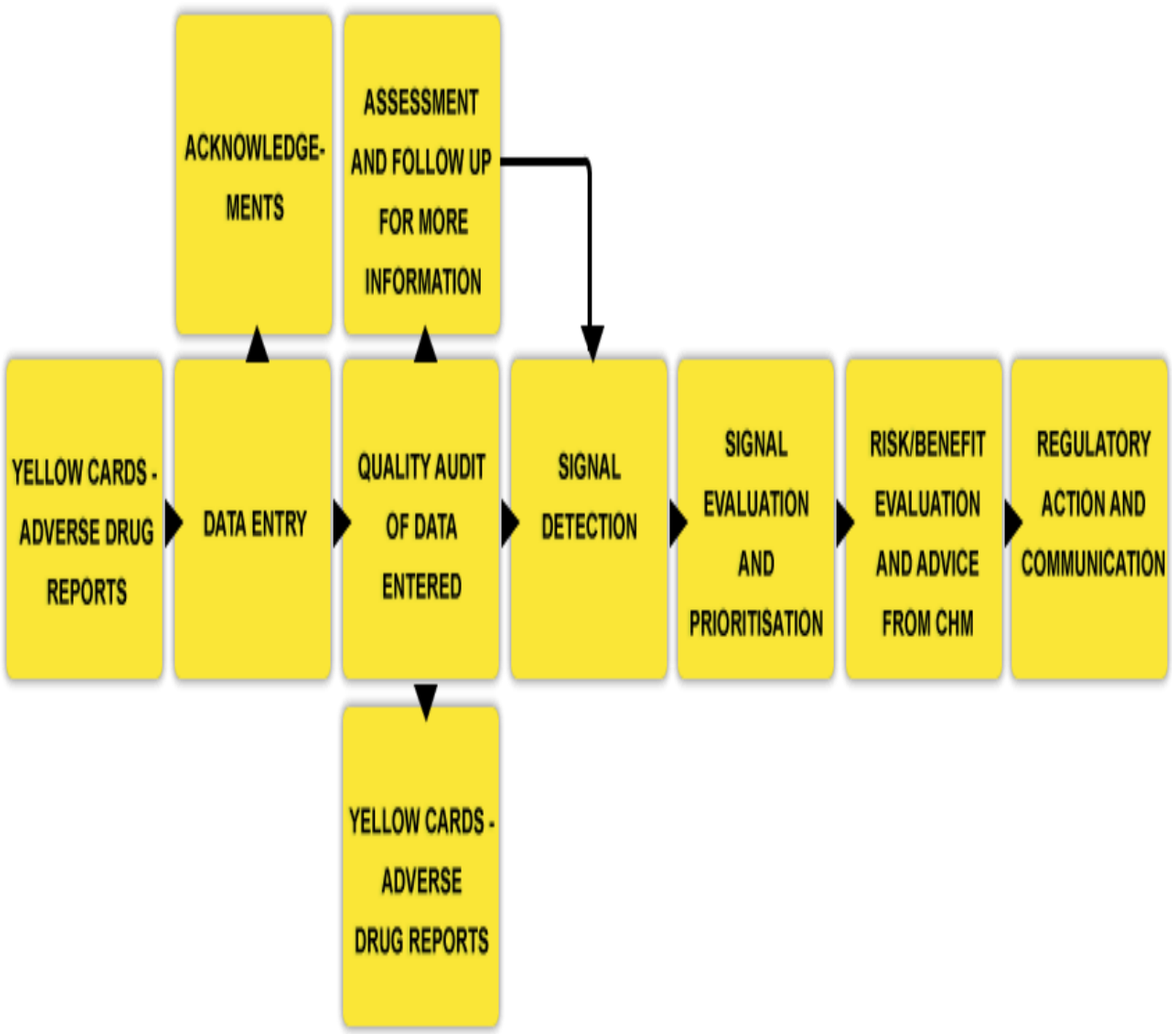
The UK's Yellow Card Scheme was established in 1964 following the thalidomide tragedy. The Scheme is operated by the Medicines and Health care Products Regulatory Authority (MHRA). Health care professionals and coroners can submit reports of suspected ADRs using a Yellow Card (found in the British National Formulary) or using an on-line form (http:// www.yellowcard.gov.uk). An association between the medicine and the event does not have to be confirmed. A suspicion is sufficient for a report to be submitted. The MHRA request that all serious suspected ADRs are reported by health care professionals concerning established medicines (drugs and vaccines). For newer drugs and vaccines, all suspected ADRs should be reported, even if minor events. Newer medicines under intensive surveillance are identified with an inverted black triangle symbol in product information and standard prescribing texts. Black triangle status is generally maintained for at least 2 years, but the period varies, depending on how much information is obtained about a product's continued safety. All suspected ADRs occurring in children should be reported even if the medicine has been used off-label.

Information from Yellow Card reports is entered into a database, suspected reactions are categorised using the internationally accepted Medical Dictionary for Regulatory Affairs (MedDRA) and the resultant signals generated by the combined reports are then assessed for causality. Where there is a valid signal which may be an ADR, further work may be required to assess the association further. This could involve requesting further details from reporters, contacting manufacturers, reviewing the literature or conducting pharmacoepidemiological studies. The MHRA estimates that about 40% of the safety signals investigated by the Agency are generated from spontaneous reports.

When new ADRs are identified and an association confirmed, the MHRA may take action in the form of changes to the Summary of Product

Characteristics (SmPC) and/ or the patient information leaflet (PIL), restricting usage or withdrawing marketing authorisation for the medicine. Withdrawal of marketing authorisation or change in use requires that prescribersand suppliers be informed immediately, but such information is also usually publicised in the media; hence, patients are often aware of these actions and may present with requests for information and advice.

Unfortunately, spontaneous reporting systems, including the Yellow Card Scheme, suffer from severe under-reporting. A systematic review estimated this to be between 82% and98% (Hazell and Shakir, 2006). There are a variety of reasons for this, including lack of certainty that the medicine caused the symptom, but it is important to emphasise that such certainty is not required. There is also no requirement to provide the patient's name or contact details, only those of the actual reporter; hence, confidentiality, also cited as a reason for underreporting, is no longer an issue. Furthermore, the MHRA have systems in place to check for duplicate reports covering the same incident, thereby eliminating concern about two people submitting reports about the same event in a given patient.



COHORT STUDIES:

Cohort studies are prospective pharmacoepidemiologic studies that monitor a large group of patients taking a particular drug over a period of time. Ideally such studies compare the incidence of a particular adverse event in two groups of patients, those taking the drug of interest and, another group, matched for all important characteristics except the use of the drug. These studies can indicate the relative risks associated with the adverse event in people exposed to the drug being studied.

CASE- CONTROL STUDIES:

Case–control studies compare the extent of drug usage in a group of patients who have experienced the adverse event with the extent of usage among a matched control group who aresimilar in potentially confounding factors, but have not experienced the event. By comparing the prevalence of drug taking between the groups, it may be possible to identify whether significantly more people who experienced the event also took a particular drug.

AIM:

To assess the knowledge, attitude and practice among pharmacist to adverse drug reaction related aspects.

OBJECTIVES:
Present investigation is designed to evaluate the impact of pharmacist's educational intervention on ADRs and pharmacovigilance program of India (PvPI) among pharmacists inSouthern part of Kerala.

METHODOLOGY:

STUDY DURATION:
The study was conducted for a period of 6 months.

STUDY SITE:
The study was conducted in Sree Krishna College of Pharmacy and Research Centre,Parassala.

STUDY SETTING:
Study was conducted among pharmacist in southern part of Kerala.

STUDY DESIGN:
A prospective observational study of ADR will be conducted among pharmacist in southern part of Kerala.

STUDY PROCEDURE:
It is a prospective study of ADR conducted for a period of 6 months among pharmacist in southern part of Kerala. A written informed consent is taken from pharmacist about ADR reporting. All information relevant to the study was collected from direct interview with pharmacist. The demographic characters, knowledge, attitude and practice of pharmacist is documented in the proforma.

A structured interview with pharmacist was conducted by using Questionnaire to elicit information about ADR. In this study a survey was conducted to assess the knowledge, attitude and practice among pharmacist to ADR related aspects.

The knowledge, attitude and practice were assessed by using suitably designed questionnaire prior to survey. The questionnaire that contains total 29 questions, 10 from knowledge part,10 from attitude part, 4 from practice part and 5 questions from barriers of adverse drug reaction. The knowledge, attitude, practice and barrier part contain YES/NO questions.

SAMPLE SIZE:
The proportion of knowledge. Practice and attitude among pharmacists to the adverse drug reaction is assumed to be 70% with a precision of 15% of the assumed proportion. The significant level is 5% and the power of the test is 80%. The Cochran's formulae for the samplesize

$$\text{Sample Size } n = \frac{Z_{\alpha * P * q}^{2}}{d^2}$$

P- Assumed proportion =.70 d-Precision=15% of the assumedproportion70%=0.10
Z_{α} -5% level of significance -1.96

$$\text{Sample Size} = \frac{(1.96)^2 * .70 * .30}{(0.10)^2} = 81$$

A total of 81 sample is requires for the study.

RESPONSES OF PHARMACIST TOADVERSE DRUG REACTION DEMOGRAPHIC DETAILES:

AGE : GENDER : M / F
QUALIFICATION: PROFESSION:

KNOWLEDGE ASSESSMENT:

1. Do you know what are ADRs? Yes:
   No:
2. Are you aware about the national pharmacovigilance programme?

   Yes: No:

3. Do you know the nearest pharmacovigilance centre located from your working place?

   Yes: No:

4. Do you believe all drugs available in market are safe?

   Yes: No:

5. Do you know which organisation is responsible for collecting and monitoring ADR in India?

   Yes: No:

6. Do you know which type of ADRs are usually reported?

   Yes: No:

7. Do you know when ADRs should be reported?

   Yes: No:

8. Do you worry about legal problems while thinking about ADR reporting?

   Yes: No:

9. Are you conscious about the drug that can harm the pregnant women?
Yes: No:

10. Do you feel that patient confidentiality should be maintained while reporting ADR?

Yes: No:

ATTITUDE ASSESSMENT:

1. Do you think reporting ADR is a pharmacist's duty?

Yes: No:

2. Have you ever noticed /experienced of an ADR in patient?

Yes: No:

3. Do you think proper ADR reporting and monitoring will benefit the patient?

Yes: No:

4. Do you support ADR reporting by patients instead of pharmacist?

Yes: No:

5. Do you think pharmacist is the right person to assist physician in reducing ADR?

Yes: No:

6. Do you think serious ADRs encourage pharmacists to report it to the relevant authorities?

Yes: No:

7. Do you feel that you need assistance in the area of ADR?

Yes: No:

8. Are you trained to report ADRs?Yes:
No:
9. Do you have free access to ADR reporting form?

Yes: No:

10. Did you receive feedback from ADR monitoring centres:
Yes: No:

PRACTICE ASSESSMENT:

1. Do you know how to report ADR?

Yes: No:

2. Do you know where to obtain the ADR forms?

Yes: No:

3. Have you ever observed a suspected adverse drug reaction?

Yes: No:

4. Have you reported any suspected ADR to any of the reporting and monitoring centres?

Yes: No:

BARRIERS OF ADVERSE DRUG REACTION:

1. Did not know that ADRs needs to be reported?

Yes: No:

2. Did not know pharmacists can report?

Yes: No:

3. Did not know how to report?

Yes: No:

4. Did not know how to get the reporting forms?

Yes: No:

5. Did not feel that ADR reporting would benefit?

Yes: No:

CONCLUSION:

A survey was conducted among pharmacist using questionnaires; the knowledge attitude and practice of pharmacist about adverse drug reaction was assessed.

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