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GAINING INSIGHT INTO PATIENTS MEDICATIONS AND THEIR SELF-REPORTED EXPERIENCE OF ADVERSE DRUG REACTIONS: A CROSS SECTIONAL STUDY IN THE EMERGENCY DEPARTMENT

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ABSTRACT: Aim: To gain an insight into patients medications and their experience of self-reported adverse drug reactions. **Methods:** A cross sectional study was conducted in the Emergency Department of a teaching hospital in the Midlands, United Kingdom from February to March, 2012.The study included patients aged 16 or over and currently on treatment with one or more medications. All patients were questioned on their medication history, indications for their medicines and experience of any adverse drug reactions with their medicines. **Results:** Of the 341 patients assessed, data from 85 patients was not complete and therefore was not included in the analysis. 256 (75%) of patients were included in the study. 103(40%) patients reported using over the counter medications, mainly paracetamol and non-steroidal anti-inflammatory drugs. 52 (20%) of the patients did not know the reason for taking their medications and 116 (45%) patients were unaware of the adverse effects of their medications. 79 adverse drug reactions were recorded in 62 (24%) patients with 17 patients suffering from multiple reactions. Lack of prior knowledge about potential ADRs (R^2 0.025, p = 0.002) was found to be an independent predictor of adverse drug reaction reporting. **Conclusions:** Information from 25% of the patients about their medicines was unavailable which highlights some of the challenges in obtaining accurate medication history. Provision of effective communication to patients about their medications can help in obtaining an accurate medication history that may lead to a reduction in the occurrence of preventable adverse drug reactions.

INTRODUCTION: Adverse drug reactions (ADRs) impose a major clinical and cost burden on acute hospital services [1]. The World health organization defines ADR as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modifications of physiological function" [2].

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There is a major interest in whether better medication reconciliation may help to reduce medication errors that may be associated with potential ADRs [3]. Medication reconciliation requires up to date and accurate lists of medications taken by a patient [4]. The process should account for any changes or discrepancies in patients' medications and must ensure that these changes have been effectively communicated to the patients or carers [4].

Although evidence suggests that medication reconciliation does not have an impact on mortality [5], it can significantly reduce medication discrepancies [6] and can reduce the risk of adverse drug event related visits to hospitals [7]. Medication reconciliation since December 2007 has been an expected part of

clinical care in the National Health Service (NHS) in the United Kingdom (UK) [8]. However, the process of medication reconciliation can be challenging in a high risk area such as the Emergency Department (ED) where patients are acutely unwell, and where decisions on medications are particularly important. Patients' lack of knowledge about their medications [9 - 11] may also act as a barrier in implementing the process of medicines reconciliation which in turn could increase the incidence of ADRs and compromise medication safety.

There is limited evidence to suggest a relationship between lack of patient's knowledge about their medications and the incidence of ADRs [12]. Therefore, the aim of this study was to gain an insight into patients' knowledge about their medicines and their experience of self-reported ADRs through the process of medicines reconciliation.

MATERIALS AND METHODS: A questionnaire based study was conducted in the ED of a large teaching hospital in the Midlands in February and March 2012. The study was conducted for a period of three weeks including both weekdays and weekends.

Study Development: A Structured, 15 - item questionnaire was developed by a team of 5 researchers (two medical consultants, a pharmacist and two medical students) using the format and style of some of the questions from those in the yellow card reporting form for health care professionals [13].The questionnaire was modified to include specific questions to assess the knowledge of patients about their medications and awareness about their adverse effects.

All patients were questioned on indications for their medicines, awareness of potential adverse effects, OTC and herbal use, history of ADRs in the last three months and lifestyle. The questionnaire was piloted on a small number of patients attending the ED of the hospital. Patients were allowed to seek the assistance of a relative, friend or carer to assist them in completing it.

Ethical Approval: The study was approved by the audit committee of the hospital. As this study was an audit based study, the research and development office of the hospital advised that ethical approval was not required. Prior consent was obtained from the patients before data collection. All information collected from the patients was kept strictly confidential. The procedures for handling, processing, storage and destruction of the data complied with the Data Protection Act 1998.

Study Participants: The study included patients aged 16 or over, male or female, currently on treatment with one or more medications including OTC medications and who were attending the ED of the hospital with an acute medical presentation. Patients were included in the study based on their ability and willingness to participate. Patients were eligible to take part if they were either taking prescribed or OTC medications at the time of the study or had taken these medications in the last three months. Recruitment of patients in the study was limited to patients who could read and write English. This was done to avoid the possibility of interpreter bias. Patients were not included if they were under 16 years of age, pregnant or too unwell to participate. Patients were asked to complete the questionnaire after they had been booked in by the triage nurses and were waiting to be seen by the doctors/nurses.

Statistical Analysis: Statistical analysis was performed with SPSS (IBM version 22). Summary descriptive statistics were generated from the questionnaire data using SPSS. Fisher's exact test was used to explore the association between patients' knowledge about their medicines and incidence of self-reported ADRs. A step-wise multivariable linear regression analysis was undertaken to explore the influence of various explanatory or independent variables including age, gender, BMI, ethnicity, medical conditions, number of medicines used by patients, smoking, intake of alcohol, awareness of reasons of medication use and prior warnings about ADRs on the incidence of ADRs as the dependent variable.

RESULTS: A total of 341 patients were assessed during the study. 256 (75%) of patients were included in the study (age range was 17 - 96, 122 were male). Of the 341 patients assessed, data from 85 patients was not complete and therefore was not included in the analysis (22 were not taking medications and 59 were not well enough to

participate). The number of current medicines, including OTC use, ranged from 1 - 12.

All patients were questioned on indications for their medications and awareness of potential adverse effects. A total of 52 (20%) of the patients did not know the reason for taking their medications and 116 (45%) patients were not aware of the adverse effects of their medications. When warnings were recalled, these were said to be from the GP or a package insert. Only eight patients recollected specific advice from a community pharmacist. 103 (40%) patients reported using OTC medications, mainly paracetamol and NSAIDs. In one patient, no tablets had been renewed in the previous four months.

79 ADRs were recorded in 62 (24%) patients with 17 patients suffering from multiple ADRs. In three patients, an ADR was the cause of their current acute medical presentation. Reported ADRs included rash, dizziness, wheeze, constipation, GI bleeding/ulceration and severe myalgia (cipro-floxacillin). **Table 1** presents examples of some of the drugs associated with ADRs reported by patients.

TABLE 1: EXAMPLES OF SOME OF THE DRUGS ASSOCIATED WITH ADRS REPORTED BY PATIENTS

Age (Yrs)	Gender (M/F)	No. of medicines used	No. of ADRs	Medicines involved	Prior warning about side effects
43	F	4	1	Trastuzumab	Yes
85	F	5	2	Amloidipine, Doxycycline	No
85	F	5	1	Co-codamol	No
64	M	12	2	Penicillin, aspirin	No
29	M	1	1	Codeine	Yes
85	M	6	2	Aspirin, bisoprolol	No
63	M	1	1	Warfarin	No
28	F	5	1	Tramadol	Yes
72	F	2	1	Simvastatin	No
19	F	2	1	Erythromycin	No
56	M	1	1	Aspirin	No

Antibiotics (chiefly penicillin) were responsible for 15 ADRs, followed by ten due to opioid analgesics (codeine or tramadol) and nine caused by NSAIDs. Other classes of medications contributing to ADRs were statins, anti-coagulants, calcium channel blockers, diuretics and anti-psychotic medications. An important risk factor for reporting ADR was identified: not recalling prior warnings about possible ADRs (odds ratio 12.2, 95 % CI 4.7 - 30.6, $p< 0.001$).

Multiple Linear Regression Analysis: Prior awareness about potential ADRs of medications was found to have a weak but statistically significant linear association with the incidence of self-reported ADEs (R^2 0.025, $p = 0.002$). None of the other variables showed any significant association with ADRs recalled by patients.

DISCUSSION: In this study, information from a number of patients was either unavailable or limited that indicates the challenges in capturing information about medicines from high risk patients. OTC use of medications was common in patients and GP prescription lists do not provide information on what may potentially be important unrecognized OTC use of these drugs. This study has also highlighted prevalence of recalled ADRs and suggests that lack of knowledge about medications and their adverse effects may possibly be associated with increased incidence of self-reported ADRs.

Previous work has reported that medication lists produced in the ED are not accurate [10]. In this study, information from 25% of the study group on their medicines was either unavailable or limited. Although family members were present to interpret, they were only aware of or able to obtain partial information about their relatives' medications. Incomplete medication histories at the time of admission have been reported to be responsible for at least 27% of prescribing errors [14].

115 (45%) of patients did not bring their medications with them. Additionally, it was found that only 32 (13%) patients brought a list of their medications to the hospital. This finding is consistent with the findings of a previous study where 17 % of patients brought a list or their actual

medications with them to the ED [15]. Patients have sub optimal knowledge about their medication history [16] and may not have the desired literacy to maintain or communicate a list of their current medicines [17]. Research has indicated that transfer of patients between different interfaces of care such as admission and discharge is the most common source of medication errors and possible adverse drug events [18 - 20].

Family members or carers of patients can be a useful source of information on patients' medication history and their support should be utilized in obtaining medication history of patients at the time of admission to hospital. By the time patients are admitted to hospital, their relatives or carers may have left the hospital. However, incomplete or inaccurate history provided by family members can be a risk factor for errors in medication reconciliation [21].While it is important to recognise and acknowledge that information on medications is being gathered from laypeople including patients or family members, healthcare professionals including doctors, nurses and pharmacists must make efforts to educate patients as well educated patients can better manage their medications post hospital discharge [22].

OTC in general and analgesic use was common in this study with 67 (26%) of patients reported using OTC paracetamol and 43(17%) reported using OTC ibuprofen. Such common use of OTC medicines has also been reported in a recent systematic review of 72 studies [23]. GP prescription lists do not provide information on what may potentially be important unrecognized OTC use of these drugs. Such unrecognized use of OTC NSAIDs may trigger or exacerbate medical conditions such as GI ulcers; intrinsic asthma; heart failure; blood pressure control and renal impairment.

79 ADRs were reported by 62 (24%) of the patients who participated in this study. A high prevalence of ADRs has also been reported by patients in a recent study where (44%) of the patients experienced a serious possible ADRs [24]. Reported ADRs by patients in this study included rash, dizziness, gastrointestinal bleeding and wheezing. Antibiotics (chiefly penicillin) were responsible for 15 ADRs reported by patients, followed by ten due to opioid analgesics (codeine or tramadol) and nine caused by NSAIDs. All these medication classes contributing to the incidence of most ADRs reported in this study have also been named among the medications most frequently involved in serious adverse events in a study carried out by a working group associated with Danish Medicines Agency's network "Prevention of Medication Errors" [25].

Nearly half of the study population in this study did not recall any prior warnings about potential ADRs. This finding seems to correlate with the results of a survey by the Picker Institute (2007) which reported that only 58 % of primary care patients who were prescribed new medicines in 2006 were given enough information about the potential adverse effects from medications [26]. Female patients seem to have a greater risk of developing an ADR than male patients [27]. The increased susceptibility of females towards developing an ADR was also confirmed in this study where more than half (56%) of the patients who reported an ADR were females.

Although it is believed that medication reviews and patient counselling provided by pharmacists can provide ways to improve identification and prevention of ADRs [28], this impact is not reflected in the findings of this study. In this study, only 8 patients recalled such warnings. This highlights a major challenge for pharmacists and suggests that despite frequent interaction of pharmacists with patients, patients seem to lack knowledge about their medications. More work is needed to establish how health professionals and pharmacists in particular can ensure that education of patients about their medicines is more effective, and whether this will reduce the incidence of preventable ADRs.

This study has few limitations. Although this study suggested possible association between the incidence of ADRs and the lack of knowledge about medicines by patients; such association could have been explained by the risk of confounding. Another limitation of the study was the lack of an independent verification of the information provided by patients on their medications and history of ADRs. Thus a patient could have listed their medications incorrectly or could have stated incorrectly that they knew the reason of taking their medications.

CONCLUSION: This study highlights some of the challenges in obtaining accurate medication history from high risk patients. Provision of effective communication to patients about their medications can help in obtaining an accurate medication history that may lead to a reduction in the occurrence of ADRs.

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