Review of Adverse Drug Reaction Enquiries

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Introduction
An adverse drug reaction (ADR) is any undesirable experience that has happened to the patient while taking a drug and is suspected to be caused by the drug. ADRs can negatively impact patients, including loss of confidence in healthcare treatment and reduction in quality of life.(1) They significantly burden the NHS, accounting for 1 in 16 hospital admissions and 4% of the hospital bed capacity.(2) Enquiries regarding ADRs to the Medicines Information service at Guy’s and St Thomas’ NHS Foundation Trust (GSTT) account for approximately 12.5% of all enquiries (157/1254). This paper presents this pilot study to explore what types of ADR enquiries are received and the impact MI currently has on patient safety, care and outcomes in answering patient-centred adverse effects enquiries.

Aim of Study
To determine the impact of the advice from Medicines Information on patient safety, care and outcomes in answering patient-centred ADR enquiries.

Methods
A retrospective review of ADR enquiries was carried out. Enquiries regarding ADRs were retrieved from the electronic enquiry recording database, MiDatabank starting at 1/1/2014 and continuing until 100 ADR enquiries were found (resulting in the end date 17/4/2014). A rating scale for patient care and outcomes and patient safety used in a previous study was adapted for use in this study.(3) The data obtained from each ADR enquiry were categorised according to ADR enquiry type, severity and seriousness of reaction, impact on patient safety, patient care and outcomes, if a referral was made and where referred, yellow card needed and if completed. Definitions of terms used and answer options within categories were created where necessary.

Definitions and Rating Scales

Retrospective: enquiry about a potential adverse effect that has already occurred
Suspective: enquiry about a potential adverse effect that is occurring at present
Prospective: adverse effect has not occurred but could do in the future

Severity:
mild: no symptoms, transient
moderate: reaction significant but not reached its maximum potential
high: reaction has reached its maximum potential
unknown: no enough information to determine severity
n/a: does not apply as enquiry is prospective
E.g. nausea is mild, moderate is vomiting blood is high.

Seriousness:
The categories for classifying seriousness of reactions were: no symptoms, mild discomfort, uncomfortable, nuisance, everyday activities affected, emergency/urgent care required, hospitalisation, life-threatening, fatal. Adapted from a previously used scale. (4)

Patient Safety Impact
Negative: Unhelpful advice given/Adverse effect more likely to occur/Adverse effect occurred
None: Advice given was for information only. No prevention of adverse effect.
Positive: Helpful advice given/Adverse effect potentially avoided or avoided

Patient Care and Outcomes Impact
Negative: Negative impact on care provided or outcome
None: Advice was given for information only
Positive: Positive impact on care provided or outcome / Treatment/avoidance of a life-threatening condition / Appropriate referral made / Likely improvement in patient care or outcomes due to information/advice provided

Patient Care: Any benefit to the patient as a result of decisions made about their health treatment by healthcare professionals. E.g. this could include the initiation, cessation or choice of appropriate treatment.

Outcome: The result or visible effect of an event, intervention or process; any change in a person’s state of health after a period of treatment, ideally improvement in symptoms or resolution of a problem.

Yellow Card for Suspected Adverse Drug Reactions
MHRA website guidelines were used to determine need for yellow cards.

References
1. MHRA Guidance and Adverse Drug Reactions