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MHRA/UKMi MiDatabank Yellow Cards Project

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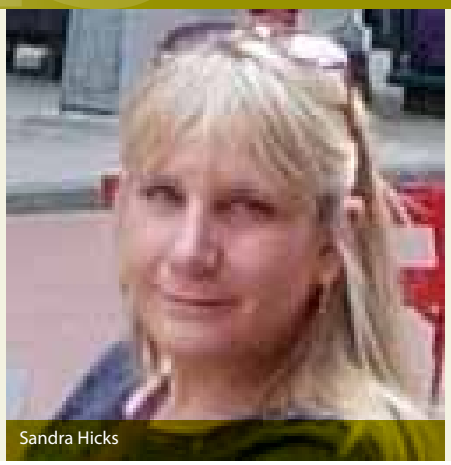
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Summary

Can hospital Medicines Information Pharmacists increase the electronic reporting of Yellow Cards? Our feasibility project sets out to investigate this question, plus impact upon workload. We also want to assess the quality of Yellow Card reporting, using the new Adverse Drug Reaction (ADR) Input function in the database MiDatabank version 3 (v3). This project is a collaboration between three organisations: – the Medicines and Healthcare products Regulatory Agency (MHRA), CoAcS the developers of MiDatabank, and UKMi. MiDatabank is the enquiry database used in all UK hospital Medicines Information centres and in some Medical Information departments within the Pharmaceutical Industry. Wessex Drug & Medicines Information Centre at Southampton are leading the project, which involves 5 Medicines Information pilot centres in total. The data collection period runs for 3 months, from 1st September to 30th November, 2010. Data analysis is to be performed in December. So this article aims to give an overview of the rationale and setting-up of the project.

Introduction & rationale

It is well recognised that one of the main problems with the spontaneous reporting system for adverse drug reactions (ADRs) ie. the Yellow Card (YC) scheme, is underuse. Even in European countries such as Spain and Italy, where ADR reporting is compulsory for healthcare professionals, under-reporting is a problem[1]. This may be because no practical mechanism of enforcement has yet been developed. If busy healthcare professionals are to submit reports voluntarily, they are only likely to do so if the process is straightforward. So development of mechanisms for automatic, systematic capture of ADRs is required[2].

The Wessex Drug and Medicines Information Centre (WDMIC) is based at Southampton University Hospitals NHS Trust. It was recently granted research funding from the MHRA, to test a new Adverse Drug Reaction (ADR) function in the enquiries database 'MiDatabank'[3]. This will enable generation and submission of an electronic yellow card via MiDatabank. The project is currently being piloted, and if successful, it will be rolled out to the rest of the UKMi network in 2011.

Method

This is a service evaluation research project to be conducted over one year. The initial phase of setting-up the project involved testing and re-design of the database. A sample of 20 test ADR enquiries were entered into MiDatabank version 3. This was to become familiar with the system and identify any workflow issues. A small in-house assessment, found that time taken to enter Yellow Card data into the ADR Input fields took between 4 – 8 minutes, depending upon numbers of drugs the

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patient was taking. In the next phase all of the pilot study participants were trained.

Then MiDatabank v3 was installed at five pilot sites (3 local centres, and 2 regional).

The data collection phase will run for three months starting on 1st September and finishing on 30th November 2010. UKMi centres answer thousands of clinical enquiries about medicines every year and many of these are concerned with patient safety. During the data collection phase, all ADR enquiries received in each pilot centre will be assessed against the MHRA's criteria for reporting a Yellow Card. So this includes all reactions to Black Triangle drugs and vaccines even if mild, any ADRs in children and finally all serious reactions for established drugs and vaccines[4]. If they meet the criteria, then an electronic YC generated via MiDatabank will be submitted to the MHRA.

This feasibility project involving 5 pilot centres aims to evaluate:

- **whether the quantity of YC submissions to the MHRA is increased**
- **if quality of submitted YC data is acceptable**
- **impact upon MI Pharmacists' workload**
- **if MHRA follow-up of data is enhanced via MI Pharmacists (MIPs)**
- **extent of contribution to patient safety**

The last phase of the project will involve constructing a best practice guide, standard operating procedures, and any changes to the MiDatabank database to allow for national roll out.

Results

Results will be analysed in December 2010 - this will involve:

- **quantitative assessment of YC reports from the five participating UKMi centres in the study, before and after introducing MiDatabank reporting**
- **quantitative assessment of impact upon MIPs' workload**
- **qualitative analysis of MIPs' perceptions of feasibility of this method of YC reporting in a busy MI Centre, plus likes and dislikes about the new function in MiDatabank v3.**

Discussion

The practicalities of implementing this method of electronic YC submission on a national basis will be explored. It's envisaged that MI Pharmacists' workload will not increase significantly, but this will add further value to the MI Service in terms of improved patient safety.

There is also an industry-specific version of MiDatabank version 3, called 'MiDatabank i' which enables the compulsory reporting of ADRs. For further information please contact CoAcS via **http://www.midatabank.com/MiiiDatabankiii.aspx**

For further information on the pilot study, please contact Sandra Hicks at **s.hicks2@nhs.net**

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