The Precise Observation System for the Safe Use of Medicines (POSSUM): An Approach for Studying Medication Administration Errors in the Field

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Abstract. Medication administration errors (MAEs) in hospital are frequent and significantly more likely to result in serious harm to patients than other medication error types. Many interventions have been proposed in order reduce MAEs and the amount of harm associated with these errors. A major limitation in assessing the effectiveness of these interventions has been the lack of robust measures for assessing changes in MAEs and associated harms. Drawing upon extensive foundational research we have developed a robust approach and data collection software to be applied in direct observational studies of nurses to allow measurement of changes in MAE rates. We report how this approach is being applied in a large stepped-wedge cluster randomised controlled trial to assess the effectiveness of an electronic medication management system to reduce MAEs in a paediatric hospital.

Keywords. Medication administration errors, nurses, electronic health records, safety, evaluation

1. Introduction

An ever increasing number of interventions has been designed to target the medication administration process with the aim of reducing errors and adverse drug events (ADEs). These interventions have ranged from nurses wearing “Do not interrupt” vests, isolation zones for preparation of medications free from distractions, to pre-programmed smart pumps and bar-coding technology.\cite{1; 2} Assessing the effectiveness of these interventions to reduce both medication administration errors (MAEs) and ADEs is reliant upon robust methods for measuring these outcomes both before and after intervention implementation. To date, there has been an over-reliance upon proxy outcome measures and voluntary incident reporting data, which are recognized as having significant limitations.\cite{3; 4} Unlike the capture of prescribing errors, which can be identified by auditing written medication charts retrospectively, MAEs need to be captured in real-time. Direct observation of medication administration is thus the most appropriate approach, but comes with several methodological challenges. The most
significant is how to capture detailed drug-related information quickly, accurately and in a standardized way. We aimed to develop a valid and reliable method for conducting direct observational studies of medication administration processes in order to identify errors and subsequently the harm associated with those errors. This paper describes our approach, the specialized data collection software which has been developed and the application of this tool in a large stepped-wedge cluster randomized controlled trial (SWCRCT) to evaluate changes in MAE rates following the introduction of an electronic medication management system.

2. Direct Observation of Nurses and the Development of the Precise Observation System for the Safe Use of Medicines (POSSUM) Data Collection Tool

In direct observational studies of nurses, observers must observe nurses through all the preparation and administration stages and record details to reflect what was actually administered to the patient. This information is then compared against a patient’s medication chart to determine whether the patient received the drug as ordered or whether there was an error in the administration process. Observational studies which rely upon the recording of information on paper are significantly limited in terms of the level of detail which can be collected given the pace at which medication processes are performed. Information technology is ideally suited to support such data collection allowing greater standardization and speed of data collection. Drawing upon extensive foundational observational work[5-8] we identified the multitude of work processes involved in the preparation and administration of medicines in hospitals, and the temporal relationships between these processes. While policy and procedure manuals may set out a step by step linear process, in reality the medication process has a level of fluidity in which nurses adapt the sequence of tasks for both efficiency and safety. For example, rather than preparing one drug for one patient, nurses may arrange several patients’ medications in the medication room and then sequentially administer those medicines. Further, studies have consistently demonstrated that nurses receive a high rate of interruptions during the medication preparation and administration process.[7] These interruptions have been shown to increase both the risk and severity of errors.[9] Thus a data collection tool designed to support direct observational studies of nurses performing medication administration must equally have flexibility in terms of the way and order in which data are collected and have the capacity to capture contextual factors such as interruptions and multi-tasking which may impact error rates.

An early prototype of the POSSUM tool was developed on a Personal Digital Assistant (PDA) and applied in a large study in which over 4000 drug administrations were observed and error rates calculated.[8-10] That experience demonstrated the approach is feasible and acceptable to nurses. However, there was a need to develop a more sophisticated tool which would also allow greater flexibility in terms of being able to specify different data collection items for different studies. Thus we set out to develop an updated tool using an Android platform.

2.1. Design Elements of POSSUM and Data Collection Process

The core elements of the drug administration process to be captured include, drug name, constituent parts if assembled, dose, strength, and route given. To improve recording efficiency, observers are able to enter the first couple of letters of a drug name (brand
or generic) and a drop-down list of possible drugs appears (Fig 1). Similarly, available doses associated with specific drugs are built into the database and appear as a list from which observers can select (Fig 2). Greater details are required for specific administration routes, e.g., intravenous medications and subcutaneous injections (Fig 3).

Figure 1. Drug name selection  Figure 2. Dose selection  Figure 3. Selection of drug route

Specific procedures viewed as critical to patient safety, are able to be recorded in POSSUM. These include, e.g., whether nurses correctly identify patients prior to administering medications, wash their hands, and comply with drug double-checking procedures if required (Fig 4). For any particular POSSUM study up to 15 procedures may be added. The first data item entered for a new drug administration is time stamped. Each of the procedures is also time-stamped when checked and thus the sequence of these procedures can be ascertained. When a drug is given to a patient the ‘Drug given’ button is checked by the observer and also time stamped (Fig 4). This allows for calculation of the overall time taken for one administration. Each drug prepared for administration signifies a drug event. Multiple drug events may be live at the same time in the POSSUM tool, e.g., a nurse may prepare multiple drugs for a patient. Further, it is possible to have drug events relating to different patients active at the same time, e.g., a nurse may prepare drugs for two patients at the same time. To manage multiple drug events the POSSUM tool allows observers to switch between these as shown in Fig 5. At the commencement of a study nurses are briefed about the purpose and invited to participate. Demographic details and nurses’ characteristics, such as years of clinical experience and position, are recorded. This allows investigation of possible associations between, for example, years of clinical experience and MAE rates. These nurse details are added to the POSSUM database. Before the commencement of an observation session, the observer will record the name of the nurse they will be observing for that session from a drop down menu (Fig 6). At the end of the observation session when the data are uploaded from the tablet computer to the database on the server, all nurses’ names are removed and a unique unidentifiable code attached to protect the identity of data relating to individual nurses.

2.2. Assessment of MAEs

Following observations, patients’ medication charts are obtained and reviewed. Using the ‘review’ module within POSSUM, a researcher is guided through a series of steps in order to compare observational data with that contained on the record to identify
MAEs, e.g., does the drug name, dose, strength, that was observed to be given match the information on the patient’s chart? The potential and actual severity of any MAEs identified are then rated by an expert panel.

3. Application of POSSUM in the field

In April 2016 we will commence the use of POSSUM in a stepped-wedge cluster randomized controlled trial (SWCRCT) [11] to evaluate the effectiveness of an electronic medication management system in a paediatric hospital in Sydney, Australia. In this SWCRCT, the intervention will be delivered sequentially, one week apart, to the eight study wards which have been randomized to receive the intervention. In each week of the study, trained observers will be positioned on all eight wards and record information on a minimum of 50 drug administrations. This will continue through the study and result in observation and review of > 5200 drug events. In the initial data collection week, none of the wards will have the intervention and all will have the intervention eight weeks later. Inter-rater reliability will be assessed prior to and during the study. Analyses will include calculation of MAE rates per administration, by type and severity (potential and actual ADEs), before and after electronic medication management system introduction. The relationships between nurse characteristics, compliance with procedures, contextual factors and MAE rates will be assessed.

4. Conclusion

Despite continued concerns regarding the high rates of MAEs in hospitals there has been little substantive progress in terms of their reduction and we still have surprisingly limited research evidence of risk factors or the effectiveness of the many interventions which have been applied to this problem.[2; 12; 13] Information technology has been hailed as potentially one of the greatest contributors to improving medication safety and the efficiency of the medication process. Information technology may also assist in addressing one of the most significant barriers to improving the research evidence-base by providing researchers with the capacity to collect standardized, accurate and reliable
data during direct observational studies of nurses undertaking medication administration. We have identified no other publications describing such tools.

POSSUM has been developed following extensive field research and testing. By using this approach it is possible to test the effectiveness of interventions specifically designed to reduce MAEs and harm. Further, the data generated allows identification of factors which may be associated with higher error rates, e.g., the extent to which nurse experience is associated with MAE rates. There are many safety procedures, embedded within nursing practice, yet which have limited supporting evidence. A good example is the use of double-checking. Existing evidence for this procedure is scant, yet it is resource intensive.[14] In our study we will assess whether double-checking by nurses is associated with MAE rate. Further, our approach recognises the disruptive environment in which nurses must operate. The order of processes may shift, nurses will be interrupted and often required to multi-task. POSSUM captures this information, and thus provides the opportunity to gain new insights into how these factors may impact upon both safety and efficiency. The greatest strength of POSSUM is the standardization of the data collection process allowing comparisons of data over time, and between studies, not previously possible. This however does not negate the need for rigorous observer training and the need to obtain a high level of inter-rater reliability prior to commencing any study.

References

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Preface

The European Federation for Medical Informatics (EFMI) Association is the leading organisation in medical informatics in Europe as a federation of national societies of 30 countries. EFMI is organized as a non-profit organization concerned with the theory and practice of information science and technology within health and health science in a European context. The objectives of the EFMI are:

- To advance international co-operation and dissemination of information in medical informatics at the European level;
- To promote high standards in the application of medical informatics;
- To promote research and development in medical informatics;
- To encourage high standards in education in medical informatics;
- To function as the autonomous European Regional Council of IMIA.

This year is a special year for EFMI as it celebrates its 40th anniversary; the Federation was founded in 1976. Therefore, different special events have been organized including several conferences, workshops and special issues in journals. In view of this special year for EFMI also the Medical Informatics Europe (MIE) conference, one of EFMI’s top conferences, is organized in a special way.

Considering the complexity and interrelation of the health domain and as a sign of the long-lasting collaboration of major societies in the field a special joint conference was set up that unites the conferences of the German Association for Medical Informatics, Biometry and Epidemiology (GMDS), the German Society for Epidemiology (DGEpi), the International Epidemiological Association – European Region and the European Federation for Medical Informatics (EFMI). The societies involved have longstanding experience in integrating the disciplines of medical informatics, biometry, epidemiology and health data management. The collaboration will not only offer a unique opportunity for integration but also strengthen each of the disciplines involved both on a national and international level.

The event is organized under the common umbrella of HEC2016 by the motto of ‘Health – Exploring Complexity: An Interdisciplinary Systems Approach’, which took place in the city of Munich in Germany from August 28th to September 2nd.

The title points to the joint effort of all societies involved to rethink their approaches and to signal the need to move on from silo thinking by exploring the complexity of health together although from different perspectives. Complex systems often involve heterogeneous objects and multifaceted interactions. The health domain is recognized to be particularly complex; hence, we need to identify models that are able to integrate all the various aspects. We need to find new ways for collaboration of different scientific disciplines as well as for establishing comprehensive methodological approaches. The HEC2016 conference is a step forward.

The current volume supports this effort by documenting the results of this event. The HEC2016 received 833 contributions from 47 countries.
We would also like to take the opportunity to express our gratitude to all who contributed to this proceeding as well as to the success of this important event by submitting their contributions, reviewing them and by sharing their expertise and time.

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