Current status of the monitoring of medication practice

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Medication practice encompasses the processes of prescribing, dispensing, preparing, administering, and monitoring the clinical effects of medicines. The mission for hospital pharmacy services is to ensure the safe, effective, and economic uses of medicines. Medication practice measures monitor one or more of these elements.

Outcome measures providing quantitative data related to the outcomes of health-system performance are the hardest to develop and use in practice. Voluntary medication-error reporting systems provide qualitative information about negative or unsafe outcomes, but the quantitative use of medication error reports should be used with great caution because only a small percentage of incidents will be reported. Trigger tools have recently been developed to enable adverse drug events to be more easily identified and provide a quantitative outcome measure of medication practice. Because outcome measures are difficult to develop and implement in practice, process and structural measures are frequently used to measure medication practice.

Measures for unsafe use and negative outcomes of medication are usually used before measures of safe and effective use. Product-defect and adverse-drug-reaction reporting systems comprise the basic elements of pharmacovigilance worldwide. Hospitals and hospital pharmacy services should monitor for incidents of this type, manage the risks locally, and share these data with national and regional pharmacovigilance reporting systems where available.

The development of medication practice measures is linked with the development of hospital pharmacy practice. Where practice is confined to the hospital pharmacy department, then measures will reflect this (e.g., measuring dispensing errors).

Where hospital pharmacy practice has developed to provide services outside the pharmacy department, a more comprehensive set of measures can be developed. This usually involves recording pharmacist clinical interventions intended to modify medication therapy for individual patients. These interventions are usually intended to improve medicine safety, clinical effectiveness, and cost-effectiveness outcomes. Advanced clinical pharmacy practice provides further opportunities to measure more definitive health care outcome data, such as clinical mortality; morbidity; and disease-specific clinical-effectiveness measures.

Like other aspects of health care monitoring, medication use in a hospital can be monitored in terms of structures, processes, and outcomes.1

Structural measures

Structural measures provide qualitative information regarding the environment (hospital infrastructure, culture, systems, policies, procedures, and activities) required for provision of quality health care. Structure measures typically require yes/no answers and provide a snapshot of the organizational environment at a particular point in time. It is assumed that compliance with structural measures results in improved health outcomes; however, there may not be robust evidence to support these assumptions. Structural measures are usually monitored by external quality assessment or self assessment.

External quality assessment (EQA). Many countries have voluntary and statutory mechanisms for periodic EQA, or accreditation of health care organizations against defined standards.2 EQA programs have four key components:3

• They are based on written and published standards.
• Reviews are conducted by professional peers.
The American Society of Health-System Pharmacists (ASHP) have developed a best practice self-assessment tool.\textsuperscript{10,11} The tool consists of 125 questions and statements describing standards of practice. Each question is weighted for relative importance so that the user can obtain an overall score. As incremental improvements are made in practice and operations, organizations are recommended to resurvey to evaluate improvements in the overall score.

The International Pharmaceutical Federation have developed \textit{Guidelines for Good Pharmacy Practice and for Good Pharmacy Practice in Developing Countries}, which can also be used for self-assessment.\textsuperscript{12,13}

\underline{Process measures}

Process measures provide quantitative data regarding the impact or effectiveness of systems, policies, and procedures and can monitor changes over time when measured repeatedly. Where process measures are evidence-based, it is assumed that improved performance results in improved health outcomes. Process measures for different hospitals can be used to help institutions compare their medication practice performance with other hospitals and services. This is called benchmarking. Benchmarking has been defined as “a continuous process of measuring products, services, and practices against an organization’s toughest competitors or groups renowned as leaders.”\textsuperscript{14} Added to this definition should be the evaluation (relative to the competitors) of the outcomes of the products, services, and practices in order to learn what might be improved. Benchmarking is a tool for identifying and reducing variations in practices and the resulting outcomes.\textsuperscript{15}

The New South Wales Therapeutic Advisory in Australia published \textit{Indicators for Quality Use of Medicines in Australian Hospitals} in 2007.\textsuperscript{16} Thirty measures were developed in six practice areas:

- Antithrombotic therapy,
- Antibiotic therapy,
- Medication ordering,
- Pain management,
- Continuity of care, and
- Hospital wide medication management policies.

The Healthcare Commission in England has developed medicine-management measures for acute hospitals in order to enable hospital pharmacy departments to benchmark their performance.\textsuperscript{17} Three groups of measures were developed—patient focus, clinical focus, and efficiency and capability.

Benchmarking methods have been used for a wide range of medication practice topics such as comparative costs and use of antimicrobials;\textsuperscript{18} identifying cost-reduction opportunities by diagnosis-related groups;\textsuperscript{19} comparing dispensing rates;\textsuperscript{20} and clinical pharmacy services, collaborative drug management, medication errors, and pharmacy technology.\textsuperscript{21}

National and international surveys of hospital pharmacy practice enable the comparison of medication practice in an individual hospital with national and international comparitors. ASHP conducts a survey on different aspects of pharmacy practice in hospital settings each year. Topics surveyed include prescribing and transcribing, dispensing and administration, and monitoring and patient education.\textsuperscript{22-24} A survey of hospital pharmacy service provision in Australia has been conducted.\textsuperscript{25} The European Association of Hospital Pharmacists conducted international surveys of hospital pharmacy practice in Europe in 2000 and 2005.\textsuperscript{26} A survey of hospital pharmacists activities outside of the United States was reported in 2007.\textsuperscript{27}

\underline{Outcome measures}

Outcome measures provide quantitative data related to the outcomes of health system performance (e.g., morbidity, mortality, satisfaction...
with health care). Currently, there are few useful and valid outcome measures that can be directly related to medication practice and hospital pharmacy services. This is an important area for future research.

Historically, clinicians have relied primarily on traditional biomedical measures, such as the results of laboratory tests, to determine whether a health intervention is necessary and whether it is successful. Researchers have discovered, however, that when they use only these measures, they miss many of the outcomes that matter most to patients. Hence, outcomes research also measures how people function and their experiences with care (Table 1).28

Some outcomes instruments have focused on describing how individuals rate their overall health. General health surveys, such as the Short Form-36, are now used in research studies, population surveys, and some health plans to assess patients’ overall level of functioning. A comprehensive analysis of outcomes and effectiveness research has been conducted by the Agency for Health Care Policy and Research, the Lewin Group.29, 30

**Pharmacist’s clinical interventions**

Analyses of hospital pharmacists’ clinical interventions on medication can provide both process and outcome data. A systematic review of published literature on the effects of interventions by clinical pharmacists on processes and outcomes of care in hospitalized adults was conducted by Kaboli et al.31 Peer-reviewed, English-language articles were identified from January 1, 1985, through April 30, 2005. Three independent assessors evaluated 343 citations. Inpatient pharmacist interventions were selected if they included a control group and objective patient-specific health outcomes. Type of intervention, study design, and outcomes (e.g., adverse drug events); medication appropriateness; and resource use were abstracted.

Thirty-six studies met inclusion criteria, including 10 evaluating pharmacists’ participation on rounds, 11 medication reconciliation studies, and 15 on drug-specific pharmacist services.

The addition of clinical pharmacist services in the care of inpatients generally resulted in improved care with no evidence of harm. Interacting with the health care team on patient rounds, interviewing patients, reconciling medications, and providing patient discharge counselling and follow-up all resulted in improved outcomes, such as reduced adverse drug events or medication errors; improved medication adherence, knowledge, and appropriateness; and shortened hospital length of stay.

Two staffing variables were found to be associated with reduced mortality: (1) number of pharmacy administrators per 100 occupied beds and (2) number of clinical pharmacists per 100 occupied beds.

Published economic evaluations of clinical pharmacy interventions have been reviewed by De Rijdt et al.32 Cost-saving clinical pharmacy interventions were found to comprise a small percentage of clinical pharmacy interventions, but they generated substantial savings. Clinical pharmacy interventions reduced preventable adverse drug events and prescribing errors, yielding savings related to cost avoidance. Interventions relating to antibiotic therapy lowered costs of care without adversely affecting clinical outcomes. The results of cost–benefit analyses suggested that general clinical pharmacy interventions are associated with cost savings. Most economic evaluations of clinical pharmacy interventions suffered from a number of methodological limitations relating to the absence of a control group without clinical pharmacy interventions, limited scope of costs and outcomes, focus on direct health care costs only, exclusion of pharmacist employment cost, use of intermediate outcome measures, exclusion of health benefits, and absence of incremental cost. In addition to the literature on process and outcome measures for pharmacist clinical interventions in the United States, there is a growing body of international literature on this topic.33-41

**Advanced clinical pharmacy practice**

Bond and Raehl42 reviewed data from 14 hospitals in the United States with clinical pharmacy services that were compared with data from hospitals without these services. Levels of hospital pharmacist staffing were also compared. A multiple regression analysis, controlled for severity of illness, was used. Seven clinical pharmacy services were associated with reduced mortality rates: (1) pharmacist-provided drug use evaluation, (2) pharmacist-provided in-service education, (3) pharmacist-provided adverse drug reaction management, (4) pharmacist-provided drug protocol management, (5)

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**Table 1. Examples of Outcomes and Associated Indicators**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Indicator</th>
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<tbody>
<tr>
<td>Mortality</td>
<td>Infant death rate</td>
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<tr>
<td>Physiological variable</td>
<td>Blood pressure</td>
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<tr>
<td>Clinical event</td>
<td>Stroke</td>
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<tr>
<td>Symptom</td>
<td>Difficulty breathing;</td>
</tr>
<tr>
<td>Health function</td>
<td>Short-form 36 or 36-item health survey</td>
</tr>
<tr>
<td>Patient experience</td>
<td>Consumer assessment of health-plans survey</td>
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pharmacist participation on the cardiopulmonary resuscitation team, (6) pharmacist participation on medical rounds, and (7) pharmacist-provided drug admission histories.

Advanced clinical pharmacy practice is the specialization of a specific area of medication practice in which the pharmacist takes direct clinical responsibility for the use of specific medicines and/or works very closely with the clinical teams to optimize the safety, clinical effectiveness, and cost effectiveness of therapeutic care. There are many examples of these types of services and the types of measures from the world literature.43–55.

Measuring harms from medicines

Harms from medicines are often described as adverse drug events and can arise from both medication errors and adverse drug reactions. The most widely used definition of a medication error is the one adopted by the U.S. National Coordination Council for Medication Error Reporting and Prevention in 1998 which states: “A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.”56

Medication errors should not be confused with adverse drug reactions. An adverse drug reaction is a response to a drug that is noxious and unintended, and occurs at doses normally used for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.57 Bates et al.58 has developed a model to help better define patient safety incidents involving medicines.59

From this model, it is clear that not all medication errors are adverse drug events or have the potential to cause adverse drug events.

Only a few studies have examined overall adverse drug events in hospital inpatients. Prospective studies reported adverse-drug-event frequency ranging from 2.4 to 6.5 events per 100 admissions in the United States.60-63 The frequency of adverse drug events in European studies varied between 2.1% and 21.5% for inpatients at internal medicine wards.63

The Council of Europe Committee of Experts on Pharmaceutical Questions established the Expert Group on Safe Medication Practices to review medication safety and to prepare recommendations to specifically prevent adverse events caused by medication errors in European health care.64 The report was published in 2007 and recommended that:

- All health care organizations should establish medication-errors-reporting systems as a component of or to complement patient safety incident-reporting systems recommended by the World Health Organization World Alliance for Patient Safety (2005).
- Nationally recognized focal points for safe medication practices should be established in a way that is collaborative and complementary to pharmacovigilance systems, that is based on a national system for reporting medication errors, and that analyzes causes and disseminates information on risk reduction and prevention.

The International Pharmaceutical Federation published a report in 2008 on national and local medication-error-reporting systems used in different countries.65 An international network for medication safety has been set up to link national reporting centers (www.intmedsafe.net).

Trigger tools

Although medication-incident-reporting systems provide useful qualitative data on adverse outcomes from medication practice, they do not provide robust quantitative data.

Trigger tools use triggers, or sentinel words, in clinical records to identify and measure adverse drug events. This approach uses very specific triggers that may identify serious harm; not benign errors or innocent mistakes. Triggers include the use of drug antidotes, certain abnormal laboratory values, and abrupt stop orders. The triggers initiate a more detailed review of the patients’ clinical record to determine whether a adverse drug event has occurred.

Each month, 10–20 randomly selected clinical records of discharged inpatients are reviewed using trigger-tool methods. Each clinical record is reviewed by two clinical reviewers. The trigger tool detects clues for adverse drug events that are then confirmed or excluded by detailed review of the clinical record. Using this method, the median adverse drug events per 1000 doses of medicines dispensed can be measured each month.66,67

In 2006, Cohen et al.68 implemented a range of initiatives intended to reduce the rate of adverse drug events in a community hospital in the United States. Median adverse drug events per 1000 doses of medication dispensed declined significantly from 2.04 to 0.65. The severity of reported medication events also declined.

Measuring dispensing error, medicine product defects, and adverse drug reactions

The most fundamental of pharmacy services provides a dispensing service to supply medicines to patients. Measuring dispensing errors data provide information on how the safety of these services can be improved and it one of the first measures that pharmacy services should introduce.69-74

Pharmacovigilence reporting systems identify and manage inci-
Adverse drug reactions are the fourth to sixth largest causes of mortality in the United States. The percentage of hospital admissions caused by adverse drug reactions in some countries is approximately 10%. Some countries spend up to 15–20% of hospital budgets dealing with complications from medicines. There is very limited information about adverse drug reactions in developing countries. Pharmacovigilence is needed in every country as there are differences in the occurrence of adverse drug reactions and other drug-related problems because of differences in diseases and prescribing practices, genetics, diet, traditions, medicine manufacturing processes, medicine distribution and use (e.g., indication, dose, availability), and traditional and complementary medicines.

Adverse-drug-reaction-reporting systems can help to manage harms from medicines at local, regional, national, and international levels.

In 2004, Temple et al. reviewed adverse-drug-reaction reports for pediatric patients in a U.S. hospital over a six-year period. There were 0.85 adverse drug reactions per 100 admissions and 20.7% of those were preventable. An adverse-drug-reaction reporting program for medical wards in an Indian hospital was coordinated by a clinical pharmacist over a nine-month period. The overall adverse-drug-reaction occurrence rate was 9.8%. The majority of incidents (61%) were not predictable and not potentially preventable. In another study in an Indian hospital, 1.14% of the hospitalized patients, and 0.012% of the outpatients were found to have experienced an adverse drug reaction.

Baniasadi et al. described how an adverse-drug-reaction reporting system was developed in a teaching hospital in Iran by a clinical pharmacist and clinical pharmacologist. In another Iranian hospital, of the 1000 admissions studied, 11.5% of the adverse drug reactions were caused by drug-related problems—81% as a result of medicine-therapy failure and 18% as a result of adverse drug reactions.

**The global continuum in monitoring medication practice**

Measures for hospital pharmacy services are usually developed in the following order: costs (e.g., costs of pharmacy staff and medicines purchased and supplied), workload (e.g., number of prescriptions dispensed and medicines supplied), and quality (e.g., quality and safety of medicines and medication practice).

It is important to develop quality and safety measures at the same time as measures for cost and workload. Reductions in costs and increases in workload should not be at the expense of quality and safety.

The role of the hospital pharmacist is often described as ensuring safe, effective, and economic use of medicines. This can be translated to mean monitoring that the right patient receives the right medicine in the right dose by the right route of administration at the right time.

Measurement of medication practice ranges between monitoring the quality and safety of the medicine product through the accuracy of the dispensing practice in the pharmacy to more comprehensive measures of medication use, including prescribing, dispensing, preparing, administering, and monitoring therapeutic outcomes in all clinical areas of the hospital.

The initial focus for measurement is often to measure unsafe use and negative outcomes of medication in order to better understand and minimize harms to patients.

Medication-product defect and adverse-drug-reaction-reporting systems comprise the basic elements of pharmacovigilance worldwide. Hospitals and hospital pharmacy services should monitor for incidence of this type and share this information with national pharmacovigilance reporting systems where available.

Medication-error-incident-reporting systems provide a simple method to describe actual harm or potential harm from medication use. However, these reporting systems provide a poor quantitative measure. Use of trigger-tool methodology can help identify and measure adverse drug events. As both practice and measurement develop, measuring positive outcomes and to what extent therapeutic outcomes have been achieved become major focal points alongside measuring negative outcomes. A common method of measurement for hospital pharmacists is to record their clinical interventions and classify these interventions to medication safety, clinical effectiveness, and cost effectiveness outcomes. Advanced clinical pharmacy practice provides other methods to measure more definitive health care outcome data, such as clinical mortality; morbidity; and disease-specific, clinical-effectiveness measures.

The literature on measuring medication practice is still not very extensive, especially outside of the United States, which reflects the state of development of hospital pharmacy practice.
of medication practice is still considered a research activity and is not considered an integral part of a hospital pharmacist’s day job. An important professional goal in the future is to establish the idea that routine measurement of medication practice is considered an integral part of the safe delivery of health care.

**Conclusion**

During the Global Conference on the Future of Hospital Pharmacy, eight consensus statements were developed to encompass measuring medication practice. Using Donabedian’s model, structural, process, and outcome measures for medication practice were developed. These measures can be matched to the level of pharmacy practice operating in hospitals from basic practice to more advanced level practice (Table 2).

**References**


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**Table 2. Measures for Medication Practice Within the Continuum of Pharmacy Practice**

<table>
<thead>
<tr>
<th>Measurement Type</th>
<th>Basic</th>
<th>Intermediate</th>
<th>Advanced</th>
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<tbody>
<tr>
<td>Outcome</td>
<td>Reporting and learning systems for harms from medicines</td>
<td>Use of trigger tools to identify harms from medicines</td>
<td>Clinical pharmacy services to optimize therapeutic outcomes and provide mortality, morbidity, disease-specific, and quality-of-life data</td>
</tr>
<tr>
<td></td>
<td>Cost of medicines used</td>
<td>Cost of inpatient episode or diagnosis-related groups</td>
<td></td>
</tr>
<tr>
<td>Process</td>
<td>Reporting and learning systems for defective medicines, dispensing errors, and use of medicines in hospital formularies</td>
<td>Reporting and learning systems for harms from medicines</td>
<td>Benchmarking with comparable institutions</td>
</tr>
<tr>
<td></td>
<td>Pharmacy clinical interventions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structural</td>
<td>External accreditation for pharmacy services</td>
<td>External accreditation for medication practice</td>
<td>External accreditation of advanced clinical pharmacy services</td>
</tr>
<tr>
<td></td>
<td>Self-assessment of pharmacy services</td>
<td>Self-assessment of medication practice</td>
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**Notes:**

- Table 2 provides a summary of measures for medication practice within the continuum of pharmacy practice.


Clinical hospital pharmacy services and clinical pharmacist staffing have been associated with reduced adverse drug reactions and mortality rates in patients. At the core of this lies the understanding that pharmacists are requisite to making the goal of access to and rational use of essential medicines a reality.

Hospital pharmacists comprise up to 25% of the work force, and hospital pharmacy is often the second-largest sector employing pharmacists. There are marked inequalities in the distribution of the pharmacy work force worldwide, with pharmacy personnel being particularly scarce in sub-Saharan Africa. The ratio of the pharmacy work force (pharmacists and pharmacy technicians) to population varies widely between regions, from 0.8 per 10,000 population in the African region to 5.4 per 10,000 population in the Americas. Less is known about the prevalence of pharmacy technicians, assistants, and related midlevel cadres, and there is greater variation in their training and regulation.

Unless planned for, changing demographics in the pharmacy work force, such as increases in the female work force, increasing part-time employment, and the retirement of the baby-boomer generation, will exac-