Current status of medicines procurement

EVA OMBAKA


Procurement is an important part of efficient drug management and supply and is an important procedure for all levels of health care institutions. An effective procurement process ensures the availability of the right drugs in the right quantities, available at the right time, for the right patient and at reasonable prices, and at recognizable standards of quality. Thus, procurement is not simply the act of buying but encompasses a complex range of operational, business, information technology, safety and risk management, and legal systems, all designed to address an institution’s needs. Specifically, individuals involved in medicines procurement must determine, accredit, and monitor appropriate supply sources; evaluate suppliers’ performance; choose a buying strategy or approach; monitor drug delivery; assess clinical and use outcomes; and evaluate new products and the drug market. Successful hospital procurement is also a collaborative process, involving people with skills in purchasing, finance, management, clinical and nursing specialties, pharmacy, quality control, and even the end user: the patient.

Given the impact of procurement activities on the operation and effectiveness of a hospital, it is essential that these activities be performed by qualified staff with high professional and ethical standards and using sound procedures anchored in appropriate policies and regulations. Experience has shown that an effective procurement process is one in which efforts are made at all times to have a transparent and corruption-free process and use good procurement practices. Efforts must also be made to contain costs through regular review of procurement models and approaches, monitor prices, and keep records of sourcing, and use a variety of information to make informed decisions. Attention must be paid to safety, the quality of products and processes, the monitoring of external and internal environment, and the use of appropriate technology and available tools.

If information is the lifeblood of procurement, then financing is the engine that drives it. Thus, ensuring adequate financing for the procurement of pharmaceuticals is an important part of medicines procurement.

Pharmacists involved in hospital procurement of medicines, whether directly or indirectly, must be knowledgeable about medicines as well as the interacting issues and the many stakeholders who can potentially affect the process or who may have legal responsibility.

General overview

Procurement is one of several elements of the drug management cycle. But since medicines represent a large part of a hospital’s expenditures, ranging from 5% to 12% in developed countries to as much as 40% in developing countries, procurement is a critical activity of any institution.

Procurement is a complex process involving many stakeholders who can affect it or whose work can be markedly changed by it. Many issues must also be addressed if the provision of equitable, quality, and efficient pharmaceutical care is to occur. In this paper, procurement in the hospital setting has been taken to have several stakeholders who, while interested in the general equity and quality-efficient outcomes, have a specific interest in one or more aspects of procurement. Therefore, successful hospital procurement must also address their specific needs. The key tasks can be grouped into several classifications.

Transparency. The high market value of pharmaceutical products means that the procurement of these products is prone to unethical practices such as theft and corruption. Though such practices are common around the world, a number of factors predispose developing countries to higher risks. It is estimated that...
in some countries, up to two thirds of all hospital medicines are “lost” through poor procurement practices, including corruption and fraud. Unsafe medical products can also enter the hospital with potentially serious health consequences. Any pharmaceutical procurement must therefore be done in a manner that ensures transparency and a corruption-free process.

In addition, a hospital is often the buying legal entity, and the pharmacist or procurement officer is delegated the responsibility to oversee the process. Transparency and adequate reporting builds trust and ensures that the relationship between implementers and governance organizations are mutually supportive.

Cost containment. In all countries, limited resources or increasing drug expenditure and good business ethics dictate that the procurement of pharmaceuticals receives special attention to contain costs and purchase to maximum effectiveness. A number of procurement methods are used according to needs, ranging from individual institutions shopping around to a variety of pooled or group procurement options. The choice is determined by a number of internal and external factors.

Ready access to price information at the local and global levels and market surveillance can improve the procurement department’s ability to negotiate good prices. Various sources are available for providing price information and methodologies for reference pricing and should form a resource base for hospital procurement teams.

Technical capability. The various stakeholders at the hospital level have expectations that drugs will be available at all times, at the lowest cost, and be of acceptable quality and efficacy and that patients will receive all their medicines in a timely and appropriate manner. The skills needed are wide and complex and form some of the key tasks of pharmacists in hospital settings. Because of the shortage of pharmacy personnel, especially in developing countries, innovative methods need to be put in place to ensure that such technical knowledge is available.

Implementation of operational principles of good pharmaceutical procurement. When procurement is conducted without a systematic process, it often leads to unacceptable outcomes. The operational principles of a good procurement process are the backbone of any medicines procurement. These principles ensure the selection of the most cost-effective essential drugs to treat commonly encountered diseases and that the quantification, supplier selection, delivery schedules, product availability, quality, and supplier performance are correct and properly monitored.

Purchasing for safety. Patient safety is recognized as a priority for health care organizations and is receiving increased attention. Purchasing for safety should therefore be a guiding principle for medicines procurement. Information for the process can be gained through a thorough understanding of situations likely to lead to high rates of medication errors. Procurement staff should familiarize themselves to these and use the available tools and procedures to assess the risk potential of products. A system of staff training, incentives, and systematic supervision and monitoring may be necessary to ensure that these and other procurement duties are completed.

Adhering to an appropriately selected drug list. Procurement must be based on the hospital’s formulary or national drug list prepared by an appropriate body, such as a multidisciplinary hospital drugs and therapeutics committee. Similarly, systematic management and assessment of drug use should be conducted using clinical judgment. The selection process can be affected by changes in the drug market. Strategies such as donations and seeding trials can disturb the selection and the transparency of the procurement processes.

Timely and accurate information. Information is the lifeblood of procurement and is needed at every stage if the procurement process is to be optimal. Timely and accurate information exchange is necessary among staff and among procurement trading partners. Thus, maintaining an up-to-date inventory and management information system and ensuring the use of the data are critical for productivity, effectiveness, and efficiency in the institution. This aids in the effort to control costs and helps the hospital to ensure that enough supplies are at hand and that stock-outs are minimized.

Records and documentation can be kept in a number of ways. Human error can be reduced and data processing improved by the use of telecommunication and computer technologies, which should be introduced when available and appropriate.

Ensuring quality products. The increasing number of substandard, counterfeit, and contaminated drugs are an issue of concern. In addition to quality-assurance activities that are conducted by individuals involved with procurement, each hospital should develop and implement its own internal quality-assurance system. A number of methods are available for use at the hospital level to check on drug quality, and an investigation into and investment in some of these would be of benefit.

Proper budgeting and financing. Adequate financing is necessary for successful procurement and careful quantification, and planning will ensure that the pharmacy can request adequate funding to procure the necessary medicines.

Pharmaceutical procurement in hospital settings: Literature review

Pharmaceutical procurement is a complex process that involves many
steps and many stakeholders. It is also conducted within national and institutional policies, rules, regulations, and structures that may hinder or support the overall efficiency of the procurement process. An effective procurement process at any level must ensure that four strategic objectives are achieved: the procurement of the most cost-effective drugs in the right quantities, the selection of reliable suppliers of high-quality products, procurement and distribution systems that ensure timely and undisturbed deliveries, and processes that ensure the lowest possible total costs.1

Procurement in hospitals is the responsibility of the pharmacist or pharmacy staff, though skills beyond basic pharmacy are also required.2,3 In order to arrive at consensus statements that are appropriate for the hospital drug procurement, nine issues (described above) have been taken as key areas of attention: (1) transparency, (2) cost containment, (3) technical capability, (4) operational principles of good pharmaceutical procurement, (5) purchasing for safety, (6) ensuring appropriate selection, (7) timely, accurate and accessible information, (8) ensuring quality products, and (9) proper budgeting and financing. These respond to the specific needs of the key stakeholders in the hospital setting (Table 1).

Transparency

Medicines represent a large part of the hospitals’ budget, ranging from 5% to 15% in developed countries and countries in transition3-5 and from 40% to 60% in developing countries, often representing the largest health expenditure after staff salaries.6-8 Studies have shown that procurement is one of the areas most prone to corruption in the health sector.9,10 The high market value of medicines contributes to this.11 Though common in many regions around the world, the lack of strong regulatory authority or an inability to enforce regulations, low staff remunerations, poor procedures, and inadequate payment practices predispose developing countries to higher risks of corruption.7,12 It is estimated that in some countries, up to two thirds of all hospital medicines are “lost” through poor procurement practices, including corruption and fraud.6,8 In addition to drug loss, corruption can lead to unsafe medical products entering the hospital with potentially serious health consequences. Loss of credibility and clients’ confidence in the services of a hospital are serious outcomes of corruption and may also erode the hospital’s resource base.

There are a number of steps that hospitals can take to increase drug procurement transparency, thus promoting cost-effectiveness and increasing equity to access to those in need. In Chile, the creation of an electronic bidding system and the use of the Internet for information dissemination, in a process that involved the stakeholders, enabled hospitals to determine fair practices and prices and achieve significant savings.11 This and other reports show that transparency can be increased through participation of all stakeholders, setting evaluation criteria in advance, addressing efficiency and capacity gaps, regular monitoring and external audits, ensuring different procurement functions and responsibilities (i.e., selection, quantification, product specification, preselection, and adjudication of suppliers) are divided among different individuals or committees, and establishing good incentive structures that foster ethical behavior.1,13

Cost containment

Many times in developing countries, pharmaceuticals must compete for limited resources. Even in wealthier countries, increasing drug expenditures14,15 and good business ethics dictate that the procurement of medicines receives special attention

| Table 1. Stakeholder Interest in Procurement in the Hospital Setting |
|-----------------|-----------------|-----------------|
| Stakeholder | Primary Interest | Corresponding Consensus Statement(s) from Global Conference |
| General public | Transparency, equity, environment | 1, 5 |
| Government | Legal, address health needs of population, professionalism | 1, 7 |
| Owners | Efficiency, effectiveness | 2, 5, 8, 9 |
| Hospital administration | Cost containment, reputation | 2, 5 |
| Suppliers and manufacturers | Confirmed business, payments on time | 10 |
| Pharmacy | Quality, continuity in availability | 4, 5, 6, 8, 11 |
| Stores | Order, appropriate facilities | 4, 5, 11 |
| Clinicians, prescribers, pharmacists | Clinical outcome | 3, 7 |
| Nursing staff | Ease of administration | 3 |
| Patients | Ease of use, positive health outcome and price (if paying) | 1, 3 |
| Payers (e.g., insurance) | Prices | 2, 3 |
to contain costs while maximizing effectiveness. A number of procurement methods are therefore used in different contexts according to needs, including shopping around or tendering, contracting out, or pooled or group procurement. Significant savings have been observed with pooled procurement. In their report, Huff-Roussell and Burnet reported a saving of over 50% during their first procurement cycle. Savings trends and efficiency have led to the establishment of group procurement in many countries, including Kenya, Uganda, England, Togo, India, Thailand and New Zealand. The choice is determined by a number of factors, including market situation of each product (e.g., single-sourced or multisourced, local or imported, nature of the medicines, delivery imperatives), the size of the order, availability of manufacturers locally, available human resources, hospital ownership (public, for profit, or not for profit), geographical issues, and national policies and regulations. It is therefore important to understand the national and local situation and to select a model that is appropriate for the hospital or the context.

Regardless of the method selected, ready access to price information, at the local and global levels, is important. Accessing pharmaceutical price data and market surveillance can improve the procurement department’s ability to negotiate good prices. A number of regularly updated price resources are available, which also provide information on methodologies for reference pricing. These include the United Nations Children’s Fund (UNICEF), Management Sciences for Health (MSH), World Health Organization (WHO) Regional Office for Africa, Health Action International, Pharmaceutical Management Agency of New Zealand, Pharmaceutical Benefits Scheme of Australia, and Médecins Sans Frontières publications. These documents, often available free of charge, should be a valuable addition to the procurement team’s resource base.

Technical capability

Hospital administrators and the clinical, nursing, and pharmacy staff expect that medicines will be available at the least total cost at all times, that they will be of acceptable quality and efficacy, and that patients will receive all their medicines in a timely and appropriate manner. Thus, medicines procurement is about not only providing timely and effective supply of medicines to patients but also ensuring that institutional, clinical, and pharmacy objectives are achieved. Karr, while defining the role of pharmacist in procurement, points out that the skills needed are many and complex and include an understanding of not only pharmacy but issues pertaining to operations, business and management; information technology; safety and risk management; and laws and regulations. In a recent global survey of pharmacists’ tasks, purchasing and being involved in formulary decisions were noted as some of the key tasks of pharmacists in hospital settings. However, in many developing countries there is a severe shortage of pharmacists. Many procurement tasks are therefore carried out by pharmacy technicians or nonpharmacy staff. Innovative measures, including supervised task shifting, need to be implemented to ensure that the technical knowledge is available.

Implementation of operational principles of good pharmaceutical procurement

Good procurement practices are the backbone of any successful procurement. Although there are many steps in the procurement process, these have been made easy to follow through a number of publications. One of the best known is the document developed and endorsed by the Interagency Pharmaceutical Coordination Group, involving the pharmaceutical advisers of UNICEF, the United Nations Population Fund, WHO, and the World Bank. This key guide introduces the four strategic procurement objectives and twelve operational principles for good pharmaceutical procurement, which can be reviewed and adapted to fit different situations. Other relevant materials include “Practical Guidelines on Pharmaceutical Procurement for Countries With Small Procurement Agencies” and Managing Drug Supply. Part of procurement is being able to address the short- or long-term unavailability of drugs, situations that have been increasing in frequency and severity. The ASHP Guidelines on Managing Drug Product Shortages and the joint UK Department of Health and the British Generic Manufacturers Association guidelines, which describe the factors contributing to drug product shortages and recommend general processes for inventory management in preparing for and working through shortage situations, are also available for procurement teams. Other proactive hospital techniques to address failure to deliver drugs ordered may include the addition of penalty clauses in contracts.

The main aim of efficient procurement and distribution procedures is to select the most cost-effective essential drugs to treat commonly encountered diseases, quantify an institution’s needs, pre-select potential suppliers, manage procurement and delivery, ensure good product quality, and monitor the performance of suppliers and the procurement system. If procurement is conducted without a systematic process, it can lead to a lack of access to appropriate drugs, wastage of resources (e.g., overstocked items expiring on the shelves), the purchase of low-quality products, or failure to achieve intended clinical outcomes. To ensure
this systematic approach, hospitals should review, adapt, and adopt the available tools for their own internal procurement procedures. To ensure that all those involved in procurement are aware of these principles, standard operating procedures must be developed, accompanied by emphasis on accurate record keeping and regular reviews.

Purchasing for safety

Patient safety is recognized as a priority for health care organizations and is receiving more and more attention.\(^46,47\) Purchasing for safety should therefore be a guiding principle (i.e., procuring presentations and formulations of medicines that are approved for use in the formulary and designed to promote safe practices).\(^48,49\) There are many situations that are likely to lead to high medication errors and which the products would need to undergo risk assessment as part of the procurement process. They include products whose manufacturer is unknown or have poor history, new generic products, a product known to be associated with problems, parallel import products, injections requiring specialized labeling, and products in a high-risk therapeutic category (e.g., anticoagulants).\(^48\) A more complete list and tools and procedures for assessing inherent risk potentials of products have been developed in the United Kingdom\(^50\) and Canada.\(^51\)

Adhering to an appropriately selected drug list

Procurement must be informed by drug selection. The pharmacy and therapeutics committee must identify the drugs to be purchased based on most up-to-date evidence. Pharmacists’ role in the committee is crucial.\(^1\) The process of drug selection is also facilitated in many cases by the availability of a national essential drugs list or the use of the WHO model list of essential medicines\(^52\) or more-specific lists, such as those for reproductive health and for children.\(^52,53\)

In addition, systematic management and assessment of drug expenditures (and hence the procurement budget) must be ensured by regular study of the drug market and the various factors affecting it, such as drug development, drug utilization, drug costs, new drug entry into the market, entry of generics products, and other trends in health care as they occur both locally and internationally. These factors can affect the current clinical judgment and therefore the selection process.\(^15,16,20,34,55\)

Control must also be exercised to eliminate seductive strategies, such as donations and seeding trials, which may not only introduce unselected drugs on the list but also disturb the transparent procurement processes.

Timely, accurate, and accessible information

Information is the lifeblood of procurement and is needed at every stage if the procurement process is to be optimal.\(^55-57\) Costs and procurement inaccuracies are reduced by timely and accurate information exchange among the staff of the institution and between staff and the supplier (i.e., the procurement trading partners). Keeping accurate records and documentation of all activities provides the basis for this information. In this way, the pharmacy staff and the administration have information necessary for decision-making. Access to quality data is also necessary for the quantification process, the outcome of which is used for the hospital and the national health information system.\(^58\) Experience has shown that proper drug inventory, monitoring, and control can identify bottlenecks in the hospital system beyond the pharmacy.\(^59,60\)

The data can be stored in a number of ways, ranging from simple

<table>
<thead>
<tr>
<th>Activity</th>
<th>% Respondents Indicating Necessity of Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Computer in pharmacy</td>
<td>% in Scope of Current Practice</td>
</tr>
<tr>
<td>Access to Internet</td>
<td>9.8</td>
</tr>
<tr>
<td>Group purchasing</td>
<td>6.9</td>
</tr>
<tr>
<td>Temporary medicines</td>
<td>28.6</td>
</tr>
<tr>
<td>Store and tracking for recall system</td>
<td>2.4</td>
</tr>
<tr>
<td>Hospital works within formulary or essential medicines list</td>
<td>1.2</td>
</tr>
<tr>
<td>Pharmacist on formulary decision</td>
<td>0</td>
</tr>
<tr>
<td>Policy on use of medicine samples</td>
<td>20.2</td>
</tr>
<tr>
<td>Policy on use of investigational medicines</td>
<td>21.4</td>
</tr>
</tbody>
</table>
### Table 3. Examples of Continuum of Practice in Procurement Practices

<table>
<thead>
<tr>
<th>Procurement Principle</th>
<th>Procurement Activities at Various Levels of Pharmacy Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Basic</strong></td>
<td><strong>Intermediate</strong></td>
</tr>
<tr>
<td><strong>Transparency</strong></td>
<td>Functions and responsibilities managed by committee(s); documentation (manual or computer) of all activities</td>
</tr>
<tr>
<td><strong>Cost containment</strong></td>
<td>Procure only drugs on hospital formulary or national drug list; use available national and international pharmaceutical price data; use joint pooled or group procurement</td>
</tr>
<tr>
<td><strong>Technical capability</strong></td>
<td>Technicians under supervision perform procurement functions</td>
</tr>
<tr>
<td><strong>Implementation of operational principles of good pharmaceutical procurement</strong></td>
<td>Copies of available guidelines in the institutions and adopted for facility; work conducted according to written SOPs</td>
</tr>
<tr>
<td><strong>Purchasing for safety</strong></td>
<td>Procure drugs only on national or hospital formulary</td>
</tr>
<tr>
<td><strong>Ensuring appropriate selection</strong></td>
<td>Functioning hospital P&amp;T committee with at least clinical, nursing, financial and pharmacy personnel overseeing procurement; VEN used to select priorities</td>
</tr>
<tr>
<td><strong>Timely and accurate information</strong></td>
<td>Use of paper-based documentation and data analyzed</td>
</tr>
<tr>
<td><strong>Ensuring quality products</strong></td>
<td>Procurement only from approved hospital or national drug list and suppliers that are known to provide high-quality products; physically check on receipt of all products with a formal user-friendly system of reporting of poor product quality (e.g., simple reporting forms)</td>
</tr>
<tr>
<td><strong>Proper budgeting and financing</strong></td>
<td>Apply business principles with careful quantification and planning irrespective of funding source; order only quantities that can be accommodated in within storage, transport capacity and financial resources available; proper bookkeeping</td>
</tr>
</tbody>
</table>

*SOPs = standard operating procedures, P&T = pharmacy and therapeutics, VEN = vital, essential, and nonessential, DDD = defined daily dose, ABC = ABC inventory system, DU = drug utilization, UN = United Nations, ICH = International Conference on Harmonisation, PIC = Pharmaceutical Inspection Convention.*
paper forms to electronic forms.\textsuperscript{61} Human error can be reduced and data processing improved by the use of new telecommunication technologies, including electronic systems,\textsuperscript{62} which should be investigated and introduced in the procurement process when available and appropriate to the situation.

**Ensuring quality products**

Although quality is one of the key components in the operational principles of good pharmaceutical procurement, it is highlighted here because of the increasing problem of counterfeit and substandard medicines on the market. Although the extent of counterfeit is difficult to quantify, WHO reported an average detection of more than four incidents daily for 2007, a 10-fold increase from 2006.\textsuperscript{63} Other reports estimated a global prevalence of 1% in developed countries, up to 30% in developing countries, and as much as 50% for Internet-based sales.\textsuperscript{64,65} Substandard, counterfeit, and contaminated drugs cause wastage of resources and can pose serious health risks.\textsuperscript{66} Quality assurance in procurement is therefore an integral part of all key activities (i.e., prequalification of products and suppliers during purchasing, storage, and distribution). But more can be done. Each hospital should develop and implement its own internal quality-assurance system, guided by guidelines and technical details specified in national or international agencies, such as WHO’s interagency guidelines.\textsuperscript{67} Depending on the level of sophistication, personnel training, and resources available, a number of methods to check on drug quality are available for use at the hospital level. These include visual inspection, colorimetry, refractometry, thin-layer chromatography, and the use of minilabs. Hospitals can also “link up” with centers with the ability to check quality with high-performance liquid chromatography and other forensic techniques.\textsuperscript{68}

**Proper budgeting and financing**

Adequate financing is necessary for successful procurement. Drug-financing mechanisms include public financing (i.e., government budget), health insurance, user fees, donor financing, and development loans.\textsuperscript{6,28,69-72} Each of these has limitations and, depending on how the hospital is funded, will affect pharmaceutical procurement. The drug procurement managers should therefore be familiar with funding mechanisms. Revolving drug funds (RDFs) or earmarked or designated funds have been used in drug procurement, sometimes with success. Unfortunately, experience has shown that RDFs face a number of problems, which leads to insufficient recovery of funds to replenish the supplies.\textsuperscript{73,74} All these point to the importance of addressing drug procurement financing using business principles, careful quantification and planning, and an agreed-upon mechanism to ensure that funds are available when needed.

Keeping these issues in mind, the finding of the International Pharmaceutical Federation survey show that there is much to be done (Table 2).\textsuperscript{3}

**Pharmaceutical procurement in the hospital setting: Continuum of practice**

While acknowledging that the above principles of good procurement should be applicable at all levels, it is also true that the availability of resources (material and human) to make these possible is not equal in every country or hospital. Therefore, it will be necessary for institutions to perform that which is possible as they strive toward higher levels of performance. Examples of levels of the continuum are as shown in Table 3.

A number of tools and guidelines have been developed that allow procurement staff at different levels to conduct their activities in confidence and to know what next steps to take.\textsuperscript{1,3,6,8,10,73-78} Using these, hospitals can gauge their own level and be able to carry out procurement services without compromising quality, efficiency, or safety. The consensus statements build on these principles and tools.

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Medicines procurement


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