Upholding Ethical Standards: The Crucial Role of Pharmacists in Drug Selection, Decision-Making, and Procurement Processes

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Introducing a new drug into hospital clinical practice can certainly be overwhelming. This process is typically managed by a Pharmacy and Therapeutic Committee (PTC). The PTC formulates policies regarding the evaluation, selection, monitoring, diagnosis, and therapeutic application of medications, medication-related products, and medication delivery devices [1]. Additionally, the PTC participates in performance improvement activities related to the procurement, prescribing, dispensing, administering, and monitoring of medications [2]. Comprised of physicians, pharmacists, nurses, and other health professionals involved in the medication use process, the PTC serves as a body that advises the medical staff and the organisation's administration on policies for the safe and effective use of drugs [3].

Evaluating medications for inclusion in the formulary is one of the responsibilities of the PTC [1]. The evaluation process should be structured and evidence-based, following a clear and comprehensive approach. The committee should receive impartial information that thoroughly reviews and analyzes the available evidence in scientific literature. This evaluation process should promote unbiased consideration of clinical and care delivery information, while facilitating effective communication. The ultimate goal is to contribute to positive patient outcomes, and ensure the safe and efficient ordering, dispensing, administration, and monitoring of medications. The decisions made by the PTC should aim to enhance patient care outcomes throughout the entire continuum of care, including access to medications after discharge.

The PTC’s main responsibility is to create an evidence-based list of approved medications and related products for use within the organization. They must also regularly update and maintain this formulary while promoting the rational, clinically appropriate, safe, and cost-effective utilization of medications through guidelines, protocols, and other means. The committee continuously and impartially assesses, evaluates, and chooses medications to add or remove from the formulary. The formulary itself is based on the most reliable clinical evidence available and incorporates the current professional judgment of medical staff, pharmacists, and other healthcare experts. When deciding which items to include, the committee should objectively evaluate their economic, clinical, and humanistic outcomes and avoid making decisions based solely on financial considerations [4]. When considering a medication for inclusion in the formulary, the committee should identify any potential safety issues and ensure that these concerns are appropriately addressed if the medication is added to the formulary or used within the health system.

Other than that, the PTC should aim to reduce unnecessary duplication of drugs with similar characteristics, such as drug type, entity, or product. By optimizing the selection of drug entities and products offered by the pharmacy, significant benefits can be achieved in terms of patient care and finances. These benefits are further enhanced by utilizing generic equivalents, which are drug products that the United States Food and Drug Administration (US FDA) considers identical or equivalent and therapeutic equivalents, which are drug products that may differ in composition or basic drug entity but are deemed to have similar pharmacological and therapeutic effects [5,6]. It is the responsibility of the PTC to establish policies and procedures that regulate the dispensing of generic and therapeutic equivalents [7].

Even though it may sound simple, introducing a new drug is deceptively challenging. The committee must ensure that the procurement and drug selection processes are cost-effective, transparent, and ethical. It appears that the decision-making process is vulnerable to unethical practices, so it is imperative to instill trustworthiness, fairness, equity, and sincerity in all personnel to maintain system efficiency, thereby preventing bribery and pilferage. Undoubtedly, the inclusion of the new drug in the drug formulary will benefit hospital clinical practice. It will enhance access and availability to a core list of well-proven and cost-effective medicines, outline the necessary steps for physicians before prescribing specific medications, and also serve as a cost-saving measure [8]. Yet, the drug selection process is at risk of unethical practices if moral values and ethical principles that serve as a guide to prevent unethical behavior are not made a priority by the committee.

A Framework for Good Governance in the Public Pharmaceutical Sector, which was published by the Pharmaceutical Service Division, Ministry of Health, Malaysia, highlighted that conflict of interest (COI) has become the driving force behind unethical practices. This is consistent with the previous literature, which found that the influence and financial relationships with industry on decision-making within PTC have been widely reported [9,10]. COI occurs when the professional judgment of an individual or the primary mission of an institution is unreasonably influenced by secondary interests, such as personal or financial gain [11]. COI within the PTC poses a risk to the objective of making cost-effective decisions. With a limited range of drugs being considered, decisions may be influenced by the vested interests of the involved parties rather than being solely evidence-based. Hence, COI can influence the selection of medications to be included in formularies. Therefore, individuals or organizations involved in decision-making committees should be mandated to establish a code of conduct that outlines their responsibilities through selflessness, integrity, objectivity, accountability, openness, honesty, and leadership.

When a request is made by a consultant, specialist, or pharmacist to add a new drug, the requester should disclose their affiliation or relationship with a drug manufacturer to ensure that the PTC can assess the request's objectivity [12]. At this stage, the committee is vulnerable to collusion and manipulation from pharmaceutical companies. Pharmaceutical companies are liable for selecting drugs and creating the Proforma for doctors without considering factors such as budget, drug necessity, morbidity, and disease burden [13]. In addition to that, sales representatives will approach the requesters with freely given samples of drugs, resulting in indiscriminate use. Bribery actions may also be accompanied by incentives, gifts, and sponsorships such as holiday trips, conferences, or seminars. The company will aggressively promote the products as part of their marketing strategies to achieve sales targets.

While awaiting international regulatory approval for the new drugs, which may be delayed, the applications will undergo a thorough review as part of the PTC decision-making process. This review will assess the drug's efficacy, safety, and cost-effectiveness, and formulate recommendations. At this stage, the committee is susceptible to bribery, collusion, and manipulation. Sales representatives may exert pressure to expedite the process, influence the PTC's final decision, and aggressively promote the drug through sample distribution. COI can result in biased acceptance of non-evidence-based literature to support products, along with the possibility of fabricating or omitting clinical data on the product's safety, quality, and efficacy. These actions can lead to an inappropriate selection process. The decision-making and drug selection process by the PTC should not be influenced by pharmaceutical companies with vested interests, favouritism, bias towards a particular company, political or management pressure, or monetary bribes. Ethically, the committee's decision-making must be guided by factors such as disease prevalence, sufficient evidence of efficacy and safety, comparative cost-effectiveness within the same therapeutic category, consideration of available treatment facilities, personnel experience, and alignment with evidence-based recommendations.

Procurement can give rise to various ethical concerns, such as bribery, kickbacks, and COI [13]. These matters hold significant implications, as they can foster corruption and result in severe consequences. From an ethical standpoint, procurement should adhere to Treasury instructions, be guided by end-user and drug pattern usage, prioritize the availability of operating funding, and obtain the "best value for money." At this stage, the PTC or drug purchasers face vulnerability to pressure from pharmaceutical sales representatives, who may prioritize expediting purchases without considering drug usage or movement patterns in the hospital. Their intention may be driven by meeting monthly or quarterly sales targets rather than the hospital's best interests. Ethically, procurement should only involve products that are approved by the US FDA, registered and listed in a national or institutional formulary, and free from any influence of COIs, pressure, bribery, collusion, or manipulation by pharmaceutical companies.

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ISSUE 06/2024

JUNE 2024

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