Medicine Development

What's my responsibility?

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The seemingly endless commercials for medications caused me to consider how medicines are developed and monitored in clinical practice. The process of medication development does not end when the drug is released on the market, and clinical nurse specialists can take a more active role in ensuring medication safety across time. In clinical practice, many clinical nurse specialists may feel far removed from the process of medicine development, yet there are certain aspects of the process that relate to day-to-day care delivery that have implications for clinical nurse specialists.

Medicine development is a highly regulated process designed to protect the public and ensure the quality, safety, and efficacy of medications when they are introduced on the market. The basic 5-step process is as follows: (1) discovery and development conducted by researchers to identify potential drug compounds, (2) preclinical research conducted in laboratories and animals to determine whether compounds are safe to test in humans, (3) clinical research conducted in phases to evaluate safety in healthy humans (phase I) and efficacy in those with the target disease (phases II and III), (4) Food and Drug Administration (FDA) review to determine medicine approval for consumer use, and (5) FDA post-market surveillance to gain insight into medication performance in the real world (http://www.fda.gov/ForPatients/Approvals/Drugs/default.htm). The FDA provides oversight of this process including review of product information and research data before medications are distributed to the public. This carefully monitored development process results in prescribing information that assists healthcare providers to deliver safe care. Information about dosing, side effects, adverse effects, and medication administration result from the drug development process. Interestingly, an estimated 50% of new drugs coming to the market have serious adverse effects not detected during clinical trial phases.[1] Detecting these adverse effects in the post-market period relies on the expert assessment of patients' symptoms and knowledge of their medications, and the clinical nurse specialist is ideally positioned to support these efforts.

Once medications are approved for use in the public, the FDA continues to monitor for drug-related problems, ensures drug quality in the manufacturing process, and monitors the medication information and advertising distributed to the public (http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405579.htm). This post-market surveillance is where patients and healthcare providers can voluntarily report adverse events. Keep in mind that not all adverse effects may be known and included in the initial medication prescribing information, which is why post-market surveillance is critical. In evaluating patient symptoms in clinical practice, consider that medications may be an etiology and develop a differential diagnosis related to medications if there is a

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suspected relationship between the patients' symptoms and current medications. Symptom evaluation can be accomplished by coordinating a case review with physicians and pharmacists in situations where there is a high potential of an adverse event related to medication. Report suspected adverse events through the FDA's MedWatch program. This program allows health professionals and consumers/patients to voluntarily report observed or suspected adverse events resulting from prescription and over-the-counter medications, including medications administered in a hospital or outpatient setting (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home). As listed on the reporting Web site, adverse events that can be reported through the MedWatch program include problems with human medical products, serious adverse effects, product use errors or quality problems, and therapeutic failures. Reporting this information ensures new medication safety information is communicated to the healthcare provider community to improve the quality of patient care (http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm090385.htm). For more details about what should and should not be reported through the MedWatch program, visit http://www.fda.gov/Safety/MedWatch/default.htm.

Clinical nurse specialists can stay current on new medication information by accessing and using the most current FDA medication guides. Many medications come with FDA-approved paper handouts known as medication guides. Drug manufacturers develop medication guides, and this content and information format is governed by federal regulation and regulated by the FDA (21CFR 208; http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=208&showFR=1). Current medication guides are available at http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm. Clinical nurse specialists should educate nurses and patients about known side effects and adverse effects of new medications. Medication guides can be used when teaching both nurses and patients about medications. Be aware that medication information can be updated when new side effects or adverse effects are identified, which requires staying up-to-date about what is new and changing in the medication marketplace.

Evidence from some clinical trials is reported through the FDA's Drug Trials Snapshots program. This resource is designed to better inform consumers and can be used to help providers and patients make decisions about prescribing medications. Trials Snapshots permit the user to evaluate differences among sex, race, and age groups of participants in clinical trials. This information, along with other clinical decision-making criteria, can be useful in promoting a dialogue about the benefits and risks of medications based on the knowledge of people participating in clinical trials. This resource is available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm412998.htm.

Clinical nurse specialists, as practice leaders and clinical role models, have a responsibility to engage in the long process of medication development starting with having a better understanding of the drug development process. Clinical nurse specialists can help identify adverse effects and contribute to improving medication safety by being more aware of and engaging in existing mechanisms for providing feedback to the FDA. Furthermore, clinical nurse specialist responsibility includes ensuring patients receive the most up-to-date medication information and partnering with patients and other healthcare providers to monitor for adverse events to improve the safety monitoring of medications in the post-market period of drug development. Helping to introduce safe, effective new medications is every clinician's responsibility.

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Reference

1. Lehne RA. Chapter 3: drug regulation, development, names and information. In: Lehne RA, ed. *Pharmacology for Nursing Care*. 7th ed. St Louis, MO: Saunders Elsevier; 2013:15–24.