

Medical Devices in Pharmacy Practice

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Agenda

- Describe the role of the FDA in medical device approval and quality monitoring
- Describe the roles of pharmacists and pharmacy technicians in the education of patients regarding medical devices associated with medication therapies for optimal medical outcomes
- Recognize opportunities in your own practice setting to improve medication therapies associated with medical devices

Optimizing Medication Therapy with Devices

What are examples of devices that
impact medication therapy?

Devices and Medication

- Blood Glucose Monitors
- Anticoagulation Self Testing (PT/INR CoaguChek)
- Inhalation Devices
- Blood Pressure Cuffs
- Injector Devices (especially those designed for certain diseases)
- Mechanical Ventilation and optimization of drug delivery
- Infusion Pumps
- Orthopedic Implants
- Drug-eluting Stents
- Antibiotic-Impregnated Cements
- Eye Drop Assistive Devices
- Devices that look like Drugs (hyaluronic acid, Caphasol, Xclair, etc.)
- Electronic Medication Compliance Devices (vibrating watches, pill timers, microchips with implantable antenna wireless communication)
- The FDA's definition of medical devices range from simple tongue depressors, bedpans, and thermometers, to complex programmable pacemakers with micro-chips. Devices are a \$300 billion dollar global market.

The FDA's Role with Medical Devices

- The FDA regulates the sale of medical device products (including diagnostic tests) in the U.S. and monitors the safety of all regulated medical products.
- In the U.S., the FDA regulates the sale of medical device products. Before a medical device can be legally sold in the U.S., the person or company that wants to sell the device must seek approval from the FDA. To gain approval, they must present evidence that the device is reasonably safe and effective for a particular use.
- The FDA monitors the ongoing safety and efficacy of regulated marketed devices through the MedWatch, the FDA Safety Information and Adverse Event Reporting Program.

Medical Device Classification

- Device classification depends on the intended and indicated uses
- Class I, II, and III listing
- 510(k)-premarket submission-at least as safe and effective and substantially equivalent, to an already legally marketed device
- PMA (pre-market approval)
- Exempt

www.fda.gov

- New device approvals
- Databases for previously approved devices
- 501(k) cleared products
- Description of FDA's role in fostering better medical devices
- Devices that have been recalled
- Initiative focused on home use devices
- Information on the infusion pump initiative and risk reduction strategies, along with examples of reported infusion pump problems
- Information on "user Interface design" issues

Where you do submit a medical device product problem?

- Online <https://www.accessdata.fda.gov/scripts/medwatch/>
- By telephone 1-800-FDA-1088
- By Fax 1-800-FDA-0178
- By mail FDA
Center for Devices and Radiological Health
Medical Device Reporting
P. O. Box 3002
Rockville, MD 20847-3002

On the FDA site what is MAUDE?

- MAUDE data represents reports of adverse events involving medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since 1996
- The on-line search allows you to search this database information on medical devices which may have malfunctioned or caused death

What is the FDA MedSun program?

- The Medical Product Safety Network (MedSun) improves the FDA's understanding of problems with the use of medical devices so that the FDA, healthcare facilities, clinicians, and manufacturers can better address safety concerns.
- The MedSun Web page is a newsletter-based website which provides monthly updates about timely issues. This is a free subscription available at:
https://service.govdelivery.com/service/subscribe.html?code=USFDA_65

What is HomeNet

- HomeNet is a specialty subnetwork within MedSun focused on the collection and sharing of information about potential and actual adverse events associated with medical devices used in the home

What is an example of the FDA monitoring program in action?

- The Food and Drug Administration officials are "moving to tighten their oversight of medical devices, including one of the most ubiquitous and problematic pieces of medical equipment," the infusion pump. Approximately **"two million infusion pumps are used in hospital and clinical settings, and hundreds of thousands more are used by" home-bound patients who need their medication, insulin, morphine, or cancer treatments delivered intravenously. Yet, "over the last five years, the agency says it has received reports of 710 patient deaths linked to problems with the devices."**
- In fact, there were 87 recalls between 2004 and 2009, 14 of which were prompted by potentially life-threatening issues, according to the [Wall Street Journal](#) (4/23, Dooren). Apparently, the most frequent problem involved something referred to as "key bounce." There have been instances when a healthcare worker enters one number into the key pad, but it is actually recorded twice, which may cause the release of too much medication. "When I punch 10 digits in my cell phone...I don't get 11 or 22, and we should have that same expectation for infusion pumps...said," Jeffrey Shuren, the director of the FDA's device division.
- Shuren added that, "in one instance, a nurse wanted to set an infusion pump to deliver 20 mL/h of heparin to a patient, but accidentally entered two zeroes instead of one, which infused the patient with 200 mL/h of the blood thinner," [MedPage Today](#) (4/23, Walker) reported. **After 56,000 such "reports of infusion pump malfunction" were received, "Shuren said the agency decided the 'old approach isn't working." So, instead of "dealing with individual device makers as safety problems emerge," the FDA "is beefing up its premarket approval requirements for manufacturers of infusion pumps."**

What resources are available to assist your patients?



How much information is available?



What are other optional sites?



Where can you and your patients go for blood glucose meter information?

- <http://www.diabetes.org/>
 - Read about the latest advances in blood glucose meters in *Diabetes Forecast's* "Consumer Guide 2010."
 - Go directly to a PDF of currently available blood glucose meters.

Home is where the heart is: A call for greater use of home blood pressure monitoring

- Blood pressure control up in US; many still suffer
Last Updated: 2010-05-25 16:36:52 -0400 (Reuters Health)

By Julie Steenhuysen

CHICAGO (Reuters) - About half of the 65 million people in the United States who have high blood pressure now have it under control, up from 27 percent two decades ago, U.S. researchers said on Tuesday.

But the overall rate of Americans who have high blood pressure has not changed in recent years, reflecting the need for better prevention efforts, they wrote in the Journal of the American Medical Association (JAMA).

The Institute of Medicine earlier this year declared high blood pressure, or hypertension, a "neglected disease" that costs the U.S. health system \$73 billion a year.

It is the second-leading cause of death in the United States.

Blood Pressure Monitoring

- <http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/HighBloodPressureToolsResources/High-Blood-Pressure>

What is the AHA recommendation for healthy blood pressure?

This chart reflects blood pressure categories defined by the American Heart Association.

Blood Pressure Category	Systolic mm Hg (upper #)		Diastolic mm Hg (lower #)
Normal	less than 120	and	less than 80
Prehypertension	120 - 139	or	80 - 89
High Blood Pressure (Hypertension) Stage 1	140 - 159	or	90 - 99
High Blood Pressure (Hypertension) Stage 2	160 or higher	or	100 or higher
Hypertensive Crisis (Emergency care needed)	Higher than 180	or	Higher than 110

Which number is more important, top (systolic) or bottom (diastolic)?

- AHA statement:
- Typically more attention is given to the top number (the systolic blood pressure) as a major risk factor for cardiovascular disease for people over 50 years old. In most people, systolic blood pressure rises steadily with age due to increasing stiffness of large arteries, long-term build-up of plaque, and increased incidence of cardiac and vascular disease.

Where do I find more details on BP Measurement?

- Recommendations for Blood Pressure Measurement in Humans and Experimental Animals
<http://hyper.ahajournals.org/cgi/content/full/45/1/142>
- **Suggested Values for the Upper Limit of Normal Ambulatory Pressure**
 - Optimal Normal Abnormal
 - Daytime <130/80 <135/85 >140/90
 - Nighttime <115/65 <120/70 >125/75
 - 24-Hour <125/75 <130/80 >135/85

Devices to help administer medications



Discussion regarding our roles with patients and medical devices

- Medication delivery
- Medication compliance
- Medication monitoring
- Medical device safety
- Medical device educational provider
- Device preservation through medication compliance
- Medication delivery with devices on the market