The Dynamics of Pharmaceutical Care: ENRICHING PATIENTS' HEALTH

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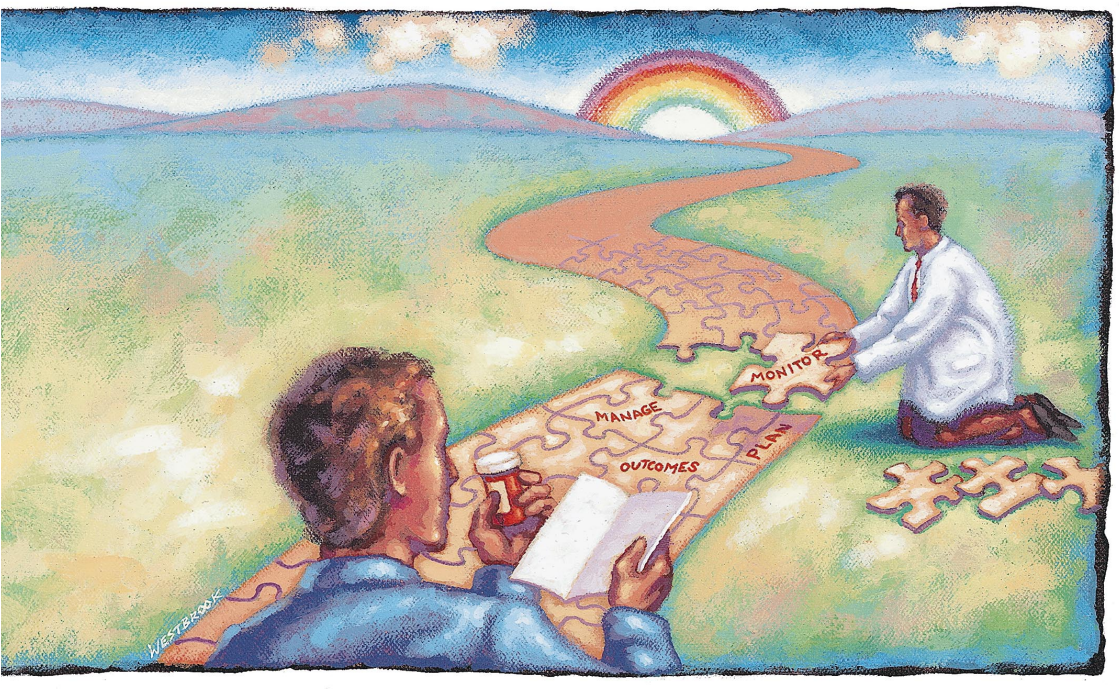
Pharmacy-Based Bone Mineral Density Testing

Monograph 16



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APhA

Dear Colleague:

The role of the pharmacist in the United States health care system needs to be focused on the delivery of pharmaceutical care—improving the quality of medication use. To assist pharmacists in developing the skills necessary to do this, the American Pharmaceutical Association, with the support of Merck & Co., Inc., has developed the *Dynamics of Pharmaceutical Care: Enriching Patients' Health* continuing education series.

The *Dynamics of Pharmaceutical Care: Enriching Patients' Health* series is built upon the foundation of the former Value Added Services Series.

This issue explores the implementation of pharmacy-based bone mineral density (BMD) testing to identify individuals who are at increased risk of fracture. Osteoporosis, the most common human bone disease, has become well recognized as a major public health problem in the United States. The advent of small, portable, and accurate bone densitometers has created a range of opportunities for pharmacists to conduct on-site or mobile BMD testing services. Pharmacy-based BMD testing can provide a valuable public service by helping to identify individuals who have low bone mass, allowing preventive and treatment strategies to be implemented before fractures occur.

Our goal for this ongoing series is to illustrate the basics of pharmaceutical care delivery and provide pharmacists with concrete guidance in developing professionally rewarding practices focused on improving patient outcomes.

Sincerely,

John A. Gans, PharmD
Executive Vice President
American Pharmaceutical Association

David G. Miller, RPh
Director, Pharmacy Affairs
Merck & Co., Inc.

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Pharmacy-Based Bone Mineral Density Testing

Growing awareness of the impact of osteoporosis and the importance of early detection have created new opportunities for pharmacists to provide bone mineral density testing.

By Wendy Munroe Rosenthal

Program Preview

Osteoporosis, the most common human bone disease, has become well recognized as a major public health threat in the United States. Just as high blood cholesterol is a risk factor for heart attack and stroke, osteoporosis is a major and silent risk factor for fractures, leading to more than 1.5 million fractures annually in the United States.[1–3]

An increasingly important focus of osteoporosis management is the early detection and prevention of this disease. This strategy has become feasible largely because of recent innovations in diagnostic technology that allow early detection of bone loss, before fractures occur. Through the use of bone mineral density (BMD) testing, health care providers can identify individuals who are at increased risk of fracture and reduce their risk through lifestyle interventions and pharmacologic therapy.

The advent of small, portable, and accurate bone densitometers has created a range of opportunities for pharmacists to conduct on-site or mobile BMD testing services. This article provides an overview of bone densitometry and presents practical information on issues to consider when establishing a pharmacy-based BMD testing service.

Why Should Pharmacists Provide BMD Testing?

In the past few years, BMD devices have become increasingly compact, easy to operate, and accurate. The refinement of this technology has allowed pharmacists to conduct BMD testing within a defined scope. In addition to the potential benefits of this service for patients, BMD testing can be professionally and financially rewarding for pharmacists.

Public awareness of osteoporosis has increased dramatically in recent years through direct-to-consumer advertising by the pharmaceutical industry and numerous articles on the subject in the lay press. Growing recognition of the medical, psychosocial, and economic impact of osteoporosis has heightened consumers' interest in BMD testing. According to the recent National Institutes of Health (NIH)-sponsored Consensus Development Conference on Osteoporosis Prevention, Diagnosis, and Therapy, 10 million Americans have osteoporosis and an additional 18 million have low bone mass, placing them at high risk for debilitating or fatal fractures.[2] Moreover, the number of individuals with osteoporosis is expected to rise substantially as the baby boom generation enters midlife. By one estimate, the number of hip fractures and their associated costs could more than triple by the year 2040.[3]

Learning Objectives

After reading this monograph, the pharmacist should be able to:

- **State the reasons why pharmacists provide bone mineral density (BMD) testing services.**
- **Define bone mineral density.**
- **Name and compare the two major technologies used to measure BMD.**
- **Define the World Health Organization criteria for the diagnosis of osteoporosis.**
- **List criteria for identifying candidates for BMD testing, as defined by the National Osteoporosis Foundation.**
- **Describe regulations that must be followed when operating dual energy X-ray absorptiometry devices.**
- **Discuss factors to consider when selecting a BMD device.**
- **Discuss potential sources of reimbursement for BMD testing.**

For pharmacists, BMD testing offers an opportunity to diversify and expand pharmaceutical care services beyond the more common offerings of asthma, diabetes, and immunization. In the experience of many pharmacists who provide BMD testing, most consumers are willing to pay out-of-pocket for this service, although in some cases third party reimbursement may be available.

A BMD testing service also can serve to anchor a comprehensive program of pharmaceutical care services for the prevention and treatment of osteoporosis. Such services may include education on lifestyle modifications to reduce the risk of bone loss and counseling on appropriate use of dietary supplements and medications. BMD testing may also provide companion sales opportunities, especially for calcium supplements and vitamin D products. The National Osteoporosis Foundation (NOF) recommends that all patients be advised to receive an adequate daily intake of calcium and vitamin D.[3] However, the typical American diet provides less than half the daily recommended amount of calcium.[3]

Benefits and Limitations of BMD Testing

Bone mass or density is defined as the amount of mineral (predominantly calcium) contained within a specific amount of bone. BMD is usually expressed in grams per square centimeter (g/cm^2) of the area scanned. BMD measurements have been shown to correlate highly with the strength or load-bearing capacity of the hip and spine. BMD has an inverse relationship with the risk of fracture: as BMD decreases, fracture risk increases exponentially.[3] Low bone mass is the single most accurate predictor of fracture risk.

Bone densitometry has revolutionized the management of osteoporosis by allowing clinicians to detect low bone mass before fractures occur, enabling a preventive approach to therapy. The use of bone mass measurement to predict fracture risk is considered as valuable as cholesterol testing or blood pressure measurement to assess the risk of heart attack or stroke.[3,4] In addition to predicting risk of fracture, BMD testing can be used to establish a diagnosis of osteoporosis and to monitor changes in bone density due to medical conditions or therapy.

Although BMD measurement is a good way to identify individuals at risk of fracture, the technology has several limitations. First, BMD results do not reveal the cause of bone loss. Also, although low BMD is an important contributor to bone fragility and fracture, it is not the sole factor. BMD results do not provide information on bone microarchitecture or other properties of the bone matrix that may contribute to fracture risk. These other bone qualities are poorly understood and cannot be objectively assessed at present. Because of these limitations, BMD measurements must be combined with a complete medical history and clinical evaluation to establish a diagnosis of osteoporosis. The diagnosis of osteoporosis should not be based solely on BMD values.

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Physicians are responsible for the diagnosis of osteoporosis. The pharmacist's primary role is to help identify individuals who are at risk of osteoporotic fractures and to work collaboratively with other health care providers to help reduce patients' risk. This role should be kept in mind when pharmacists discuss BMD values with their patients.

Technologies for Measuring BMD

Devices for measuring BMD use either X-ray or ultrasound technology. Dual-energy X-ray absorptiometry (DEXA), which is the most widely used and thoroughly studied BMD measurement technology, is considered the gold standard. This method is based on the principle that bone absorbs photons (generated by an X-ray tube) in proportion to the calcium density in the bone. These devices compute a numeric value for BMD by determining the difference in the number of photons entering and emerging from the body part imaged. The higher the bone density, the more photons are absorbed and the fewer emerge.

DEXA systems are "dual energy" because they emit two X-ray beams: one at higher energy and one at lower energy to account for soft-tissue absorption. The computer program provided with the device performs the calculations to determine the BMD value.

Quantitative ultrasound (QUS) is a recently developed, radiation-free technique to measure BMD.[5] QUS measures broadband ultrasound attenuation (BUA) and the speed of sound (SOS) through the measured site, determining the loss in acoustic energy that results. Normal bone has a higher BUA and SOS than osteoporotic bone. The BUA and SOS values reflect the elasticity and strength of bone, and BMD is estimated from these measurements.

Another important distinction between the available devices is the body site imaged. Two major categories of machines are available based on the skeletal site measured: central and peripheral devices.

Central devices can measure any skeletal site, with the hip and spine being most common. The advantage of central devices is their ability to study multiple skeletal sites. Their primary disadvantages are their cost and lack of portability.

Hip fractures have particular clinical significance because of their associated morbidity, mortality, and cost. Approximately 10% to 20% of women sustaining a hip fracture die within the first year, 25% are confined to long-term care, and only one third regain their prefracture level of independence.[3] For this reason, the hip is considered an ideal site to measure BMD.

Peripheral devices measure only peripheral bones. Peripheral DEXA (pDEXA) devices use the same X-ray based methodology as central DEXA but measure BMD at sites such

as the hand, distal radius (wrist), and most commonly, the calcaneus (heel). The introduction of peripheral devices has made BMD testing in the pharmacy much more feasible. These devices offer the advantages of lower cost and portability. Their primary drawback is their lack of versatility, with each device able to measure only one, or possibly two, skeletal sites.

The NIH Consensus Panel has noted that while DEXA and QUS technologies are both helpful in predicting fracture risk, no standards exist to compare the efficacy, value, or cost of the different testing modalities.[2] Also, the clinical trials that have evaluated drug therapies for osteoporosis have used DEXA to determine the entry criterion. Therefore, it is uncertain whether the results of these trials can be generalized to patients diagnosed using QUS technology. In general, QUS devices are not considered as precise as DEXA, because QUS does not directly measure the amount of mineral in bone but, rather, measures ultrasound variables to predict fracture risk.[3] However, according to NOF the two technologies appear to predict fracture risk equally well.[3] All currently available BMD assessment methods are considered to be reliable in predicting risk of fractures.[3]

Peripheral BMD devices are primarily used to detect low bone mass and predict future fracture risk. However, some QUS devices (for example, the Achilles Express) and the pDEXA devices also are approved to monitor long-term changes in BMD, such as those associated with aging, disease progression, or response to therapy. Usually, however, clinicians rely on central DEXA measurements to help establish the diagnosis of osteoporosis and for ongoing patient monitoring.

Certain patients who have normal BMD values with peripheral testing may need further evaluation using a central device.[6] For example, patients who have significant risk factors for osteoporosis, such as those who use long-term glucocorticoids or have a history of fragility fractures, may benefit from further assessment through central DEXA. Table 1 describes these individuals.

Table 1.
Patients with Normal Peripheral BMD Results Who May Need Central BMD Testing

- Postmenopausal women not on estrogen who would consider drug therapy if indicated.
- Patients at high risk for hip fracture (such as maternal history of osteoporosis, weight <127 lb, or smoker).
- Patients taking medications associated with bone loss (such as glucocorticoids or long-term heparin).
- Patients with conditions associated with low bone mass (such as hyperparathyroidism, malabsorption, or hyperthyroidism).
- Patients with a history of fragility fracture.

BMD = bone mineral density.

Source: Reference 6.

Interpreting BMD Measurements

Most BMD devices provide the following information on the scan reports:

- *Raw BMD value*. This value reflects the grams of bone mineral, predominantly calcium, in the area measured, generally expressed in g/cm^2. Although these raw values are not used to establish a diagnosis of osteoporosis, they are preferred for use in patient monitoring. Raw BMD values are generally used to compare an individual's measurements over time to assess the effects of pharmacologic interventions or to determine the rate of continued bone loss due to disease progression.
- t *score*. *t* scores are generally considered the most clinically relevant values obtained with BMD testing and are used in the diagnosis of osteoporosis. This value describes the patient's bone mass compared with the mean peak bone mass of a normal young adult, sex-adjusted reference population. The difference between the patient's score and the norm is expressed as a standard deviation (SD) from the mean. The young adult mean and SD are derived from a group of healthy individuals aged 20 to 35 years. This population is considered to have peak bone mass (the maximum bone mass accumulated during young adult life). This comparison with an "ideal" population highlights the true magnitude of a patient's bone loss. Although QUS and DEXA devices measure different qualities of bone, both types of machines report a *t* score.
- z *score*. The *z* score is similar in concept to the *t* score, except that the mean BMD and SD for a healthy age-matched population are used as the reference values. Although not as relevant as the *t* score, *z* score values less than the age-matched reference population can serve as a red flag for bone loss, indicating the need for further clinical evaluation.

In 1994 the World Health Organization (WHO) proposed diagnostic guidelines for osteoporosis based on *t* scores obtained using central DEXA devices (see Table 2).[7] According to the WHO definition, osteoporosis is present when the *t* score is at least –2.5 SD. This level was selected based on epidemiologic data showing that more than 50% of individuals who had already sustained a fracture were at or below this level of BMD. For each SD that BMD is below the mean for the young normal population, the fracture risk approximately doubles.

Table 2.
WHO Criteria for the Diagnosis of Osteoporosis

Category	Criteria
Normal	BMD ≤1 SD below average peak young adult
Osteopenia	BMD >1 SD but <2.5 SD below average peak young adult
Osteoporosis	BMD ≥2.5 SD below average peak young adult
Severe osteoporosis	BMD ≥2.5 SD below average peak young adult and fragility fracture

BMD = bone material density; SD = standard deviation; WHO = World Health Organization.

Source: Reference 7.

The WHO criteria provide clinicians with an objective value for the diagnosis of osteoporosis, ideally before a fracture occurs. It is important to recognize that fracture risk represents a continuous gradient. That is, there is no distinct cutoff point in the *t* scores below which all patients will sustain fractures or above which fractures will not occur. In addition, the criteria allow for the diagnosis of osteopenia (low bone mass).

It is also important to remember that these values should not be used as the sole determinant of treatment decisions. Other pertinent patient information, such as medical history and lifestyle, must be considered in the interpretation and clinical application of these measurements. When measuring more than one skeletal site (for example, the hip and spine), the lower BMD value should be used to define risk.

The WHO criteria were based on BMD measurements using central DEXA imaging of the hips of postmenopausal white women. However, in clinical practice, the WHO criteria also are used to define diagnostic thresholds at other skeletal sites, for other technologies, and for diverse populations, such as men, children, and various ethnic groups. Pharmacists should be aware that this extrapolation of the WHO criteria has not been rigorously studied and is not supported by sound scientific evidence.

Who Should Be Tested?

As a general rule, BMD testing should be considered in patients of any age or either sex only when the results will influence a clinical decision. NOF has helped to define more clearly who should receive BMD testing, stating that the decision to test should be based on the individual's risk profile for osteoporosis[3] (see Tables 3 and 4).

The Health Care Financing Administration (HCFA) also has developed a set of criteria to identify candidates for testing. The federal Bone Mass Measurement Act authorizes Medicare coverage for "qualified individuals" who fall into at least one of the five categories listed in Table 5.[8]

Some clinicians advocate testing between the ages of 20 to 35 years to determine an individual's peak bone mass. In women, the test could then be repeated around menopause (which occurs at an average age of 50 years), when accelerated bone loss results from declining estrogen levels. This approach would establish a woman's baseline BMD value for future comparison and allow early identification of potential problems.

Men, who lose bone more gradually as they grow older, should also consider testing. In the past few years, the problem of osteoporosis in men has become more widely recognized. Approximately 1 in 8 men over age 50 years has osteoporosis, and more than 5 million men in the United States are affected by or at risk for the disease.[9] Although clear guidelines for BDM testing in men are not available, testing may be valuable in older men (age 75 or older) or in those with significant risk factors for osteoporosis, such as long-term glucocorticoid use or hypogonadism.

From a practical perspective, however, population-based screening of BMD is not currently recommended.[2] Because the value and cost-effectiveness of mass screening have not been established, an individualized approach to identifying candidates for testing is preferred, based on each patient's risk profile. Pharmacists also should bear in mind that the use of X-ray devices is contraindicated during pregnancy.

Table 3.
Risk Factors for Osteoporosis and Fractures

Nonmodifiable factors
- Advanced age
- Dementia
- Female sex
- Personal or family history of fracture
- White or Asian race

Modifiable factors
- Alcoholism
- Cigarette smoking
- Estrogen or testosterone deficiency
- Inadequate dietary calcium
- Physical inactivity
- Low body weight

Source: Reference 3.

Testing Procedure

Each BMD device operates differently, and users should always adhere to the specific procedure for each machine. However, some general guidelines apply, regardless of the device in use. First, the nondominant foot or arm is the preferred site for BMD testing. The dominant appendage tends to have higher BMD values because of increased use and weight-bearing exercise. Also, avoid measuring skeletal sites that are affected by arthritis or previous fracture. Increased calcification in these skeletal areas can produce higher BMD values, potentially leading to an underestimation of the patient's fracture risk.

Use of BMD Tests for Patient Monitoring

As stated earlier, one of the uses of BMD testing is to monitor changes in bone mass over time. Important goals of monitoring are to determine the patient's response to therapy and to provide feedback that can be helpful in improving adherence to treatment regimens. Generally, central skeletal sites (the hip or spine) are preferred for monitoring purposes because these sites consistently demonstrate the greatest magnitude of change in the shortest period of time.[6] It is unclear why peripheral skeletal sites are less responsive to therapy. Any changes in measured BMD over time must be within the precision error of the device.

Usually, an interval of at least 1 to 2 years is needed to determine bone gain or loss with BMD testing. An exception to this rule lies in the case of long-term glucocorticoid therapy. Because these drugs can induce rapid skeletal wasting, patients who receive glucocorticoid regimens equal to or greater than prednisone 7.5 mg daily should have a baseline BMD measurement followed by repeat testing every 6 to 12 months during the first 1 to 2 years of therapy.[10]

When evaluating an individual's serial BMD values, it is critical to compare only results that have been obtained using the identical BMD device at the same skeletal site. BMDs obtained from one device are not interchangeable with measurements derived from other machines or taken at other skeletal sites. This variability reflects differences in the rates of bone loss at different skeletal sites, variation in the reference populations used to calculate values, and technical differences between devices. Currently, the reference databases used by the major manufactures vary with the devices. A universal database is needed that would become the gold standard with which all measurements from all devices could be compared.

Table 4.

National Osteoporosis Foundation Recommendations for Who Should Receive BMD Testing

- All postmenopausal women less than 65 years who have one or more additional risk factors for osteoporosis.
- All women 65 years or older, regardless of additional risk factors.
- Postmenopausal women who present with fractures.
- Women considering therapy for osteoporosis, if BMD results would facilitate decision.
- Women who have been on hormone replacement therapy for prolonged periods.

BMD = bone mineral density.

Source: Reference 3.

Table 5.

HCFA Definition of "Qualified Individuals" for Medicare Coverage of BMD Testing

- An estrogen-deficient woman at clinical risk of osteoporosis as determined by a physician-based medical history and other findings.
- A patient with vertebral abnormalities as demonstrated by X-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.
- A patient receiving glucocorticoid therapy equivalent to or greater than prednisone 7.5 mg daily for more than 3 months.
- A patient with primary hyperparathyroidism.
- A patient being monitored to assess efficacy of an FDA-approved osteoporosis drug therapy.

FDA = Food and Drug Administration; HCFA = Health Care Financing Administration.

Source: Reference 8.

Implementing BMD Testing

Before deciding to provide BMD testing, pharmacists should carefully investigate any state regulations that may affect provision of this service. They also should research and compare the various options in BMD testing devices and the customer service plans offered by major manufacturers (see Table 6). A sound marketing plan and a feasible strategy for obtaining reimbursement are also critical to the success of a BMD testing service.

Regulatory Considerations

A multitude of regulations govern the provision of X-ray–based BMD testing to the public. Many of these regulations involve safety precautions, because the pDEXA devices use X-ray technology. Although these devices emit negligible levels of radiation (significantly lower than that associated with standard dental X-rays), they are governed by state laws and regulations. In most states, the regulation of X-ray devices is under the jurisdiction of the department of public health or the office of radiation control.

Specific regulations vary from state to state, but typically address such issues as ownership, transportation, and operation of X-ray devices. Pharmacists must be fully informed of all regulations before implementing a BMD testing service and remain up-to-date with any changes in these laws after introducing a testing service. Due diligence in this regard is a necessity to ensure regulatory compliance and avoid potential liability or other legal problems. Table 7 provides a general overview of state regulations that typically pertain to pDEXA devices.

Selecting Equipment

In general, peripheral devices have been preferred for use in community pharmacies because of their lower cost and smaller size. In the past several years, the options have

Table 6.
Major Manufacturers of Peripheral BMD Devices

Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730
800-343-9729
www.hologic.com

Norland Medical Systems, Inc.
106 Corporate Park Drive
White Plains, NY 10604
914-694-2285
www.norland.com

Lunar Corporation
726 Heartland Trail
Madison, WI 53717
888-795-8627
www.lunarcorp.com

Schick Technologies, Inc.
31-00 47th Avenue
Long Island City, NY 11101
888-818-4BMD
www.schicktech.com

Table 7.
State Regulations for Peripheral BMD Testing Devices

Although specific regulations that govern BMD testing vary widely from state to state, the following types of requirements are typical:

- *Machine registration and fees.* Most states require that the device be registered upon or after installation, and certain states have additional requirements. The registration is generally for a limited period of time (typically, 1 to 3 years) and is associated with a nominal fee.
- *Operator requirements.* The requirements for equipment operators range from none to requiring a Certified Radiological Technician (CRT) to having a permit requiring specific certification and training of the operator (limited scope license). This regulation may present a challenge for pharmacists, depending on the specifics of the particular state regulation.
- *Inspection and renewal.* Post-installation surveys by a state-appointed or approved inspector may be required and reinspection at set intervals also may be mandated. Fees are generally associated with this process.
- *Shielding requirements.* Although most states only require that the manufacturer's specifications be followed, some specify additional shielding requirements.
- *Ordering regulations.* Many states require that X-ray procedures be ordered by a physician. One way pharmacists can work within this regulation is to obtain a standing order from a physician. However, some states do not allow standing orders but require an individual prescription for each patient.
- *Machine transportation across state lines.* Some states require that notice be given to a state agency before transporting X-ray equipment into the state. This may or may not be an issue for the pharmacist, depending on the intended use of the device.

BMD = bone mineral density.

expanded. Many pharmacists choose QUS devices, because X-rays are not used and therefore costs are lower and the devices are subject to fewer regulatory requirements. Table 8 provides general information on some currently available QUS and pDEXA devices.

A major consideration in device selection is the skeletal testing site. Osteoporotic fractures occur primarily at the wrist, spine, and hip, although any skeletal site can be affected. Although the hip is considered the ideal site to measure, this procedure requires central DEXA scanning, which is not feasible in most pharmacies.

Another consideration in site selection is the bone composition at various locations. The body has two types of bone: trabecular and cortical. Trabecular bone is the spongy, latticework tissue located primarily in the middle of bone and at the end of the long bones. Cortical bone forms the dense outer layer of bone. The ratio of trabecular and cortical bone varies in the bones throughout the body (Table 9). Due to its increased surface area, trabecular bone is significantly more metabolically active than cortical bone. Because changes in trabecular bone occur more rapidly over time and with therapeutic interventions, changes may be seen earlier at these sites than in cortical sites. Therefore, highly trabecular sites may be preferable for monitoring response to drug therapy.

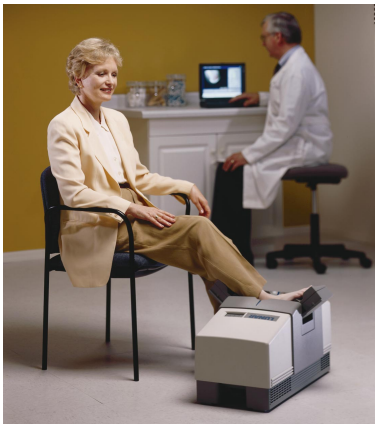
Currently available peripheral devices measure three skeletal sites: the wrist, hand, or heel. Physicians may have a "preferred" testing site based on their experience and personal opinion. Before choosing a specific BMD testing device, pharmacists may wish to survey physician opinion leaders in their communities to determine whether a preference exists for a particular site.

Other important considerations in device selection include:

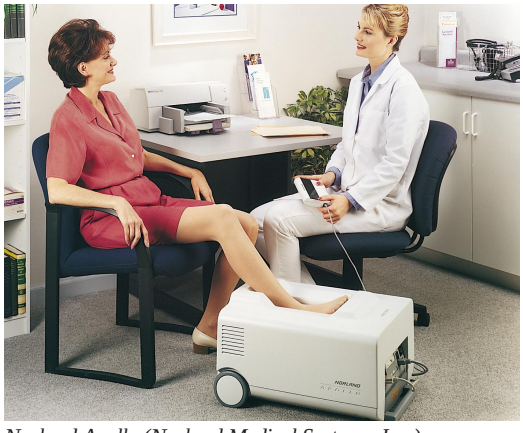
- *Ease of use*. Pharmacists should compare the testing procedures for the various devices. Each step introduces a potential source of human error, so machines requiring the fewest manipulations are generally the most desirable. Also consider the procedure for positioning the body part in the device. Proper placement is essential in

Sahara Clinical Bone Sonometer (Hologic, Inc.)

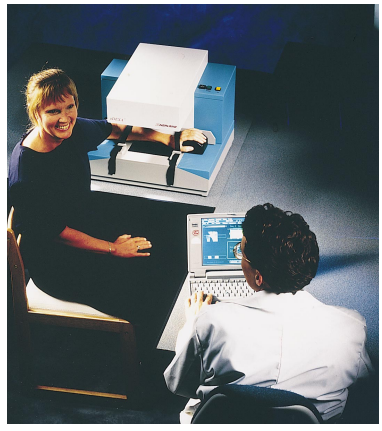
Achilles Express (Lunar Corp.)



PIXI (Lunar Corp.)



Norland Apollo (Norland Medical Systems, Inc.)



Norland pDEXA (Norland Medical Systems, Inc.)

Pharmacists who wish to implement BMD testing services can choose from a wide range of portable and accurate bone densitometers. These photos show a representative sampling of peripheral ultrasonometers (Sahara Clinical Bone Sonometer, Achilles Express) and peripheral DEXA devices (PIXI, Apollo, pDEXA). More information about these and other peripheral BMD testing devices can be found in Table 7 and by contacting the various manufacturers (Table 6).

Table 8.
Comparison of Selected Peripheral BMD Devices

QUS Devices	Achilles Express	McCue CUBA	Sahara
Manufacturer	Lunar	Norland	Hologic
Skeletal site	Heel	Heel	Heel
Scan time	1 minute	1 minute	1 minute
Size	22 lb	22 lb	22 lb
Reference population	White women	White men and women	White women
Components	Self-contained with internal microprocessor and printer	Scanner (computer and printer to be supplied by end-user)	Scanner with micro-processor and printer
Cost[a]	~$15,000	~$16,800	~$14,000
Comments	Gel; built-in carrying handle	Gel; comes with carrying bag	Gel

DEXA Devices	pDEXA	accuDEXA	PIXI	Apollo DEXA
Manufacturer	Norland	Schick	Lunar	Norland
Skeletal site	Forearm	Hand	Heel and forearm	Heel
Scan time	5 minutes	30 seconds	5 seconds	15 seconds
Size	59 lb	70 lb	70 lb	64 lb
Reference population	Females and males of various ethnic backgrounds	Females of various ethnic backgrounds and white men	White men and women	Women and men of various ethnic backgrounds
Components	Scanner, laptop computer and printer	Scanner with microcomputer Printer optional	Scanner, laptop computer, printer	Scanner, hand-held control console, printer
Cost[a]	~$19,900	~$16,000	~$26,000	~$19,900
Comments	Dry system; measures two sites at forearm: one mainly trabecular, the other mainly cortical	Dry system	Dry system; leave on sock or hose	Dry system; leave on sock or hose; wheels and retractable pull-handle

BMD = bone mineral density; DEXA = dual X-ray absorptiometry; QUS = quantitative ultrasound.

[a]Prices provided by manufacturer; actual costs may vary.

producing accurate results, and this procedure should be foolproof. Some devices require the use of a water bath or gel. Patients must remove their socks or hose, adding time and hassle to the testing procedure. Placing a disposable plastic bag over the foot allows the patient to wear their socks or hose when using the water bath. Check with the manufacturer to see if this type of aid can be used with the particular BMD device.

▲ *Size and portability*. Depending on the pharmacist's intended use of the device, these factors may or may not be a concern. Determine how much space is required to house and operate the device. Also consider the weight and ease of moving the machine. Some devices come with wheels and retractable handles or carrying cases

Table 9.
Bone Composition at Various Skeletal Sites

Bone	% Cortical	% Trabecular
Midradius	95	5
Heel	25	75
Femur neck	75	25
Finger	60	40
Lumbar spine	40	60

Source: Reference 4.

for transport between testing locations. This feature may be an important consideration for pharmacists who intend to implement a mobile testing service or who plan to transport the device among several pharmacies.

- *Cost*. In general, the purchase price for these devices ranges from $15,000 to $28,000, with QUS devices generally being less expensive than pDEXA machines. In some instances, suppliers may be willing to negotiate price. Also, manufacturers typically sell the devices at substantial discounts below their official list prices. When comparing costs, consider all of the necessary components. Some suppliers include the computer and printer in the price, while others require the end-user to supply these. Most companies also offer leasing options.
- *Cost per test*. This expense includes direct costs, such as the employees' time and the cost of supplies, such as gels, wipes to clean the device, and paper for the printout of results. Associated indirect costs that should be prorated include the cost of the device and related equipment (computer and printer), regulatory fees, and overhead.
- *Company support*. The type and scope of support services vary among suppliers. Determine how each supplier trains new customers on device installation, maintenance, and use. How do they support pharmacists in addressing the laws and regulations affecting the use of the device in their state? For example, if the state requires the operator to have a limited scope of service license, will the supplier provide the training necessary to meet the regulations? How do they handle malfunctioning equipment? Do they provide marketing and patient education materials? The importance of these considerations will vary among pharmacies, but should be factored into the decision-making process.

Marketing the Service

Developing a service plan to provide BMD testing calls for creativity and business acumen on the pharmacist's part. To generate a return on their investment, pharmacists need to provide multiple tests while minimizing time and expense. Therefore, one needs to invest considerable time and effort in identifying and establishing BMD testing opportunities. Promotional materials should focus on target populations who are at increased risk for osteoporosis, such as perimenopausal and postmenopausal women or patients receiving long-term glucocorticoid therapy.

On-site testing in the pharmacy is one of many possible testing venues. Another option is to offer BMD screening services for pharmacists in other communities. Other possible testing sites include:

- Health fairs (community and corporate)
- Health clubs and spas
- Local employers
- Physician offices
- Assisted living facilities
- Community centers for the elderly

Effective marketing is critical for success. Marketing materials should foster an awareness of the benefits of BMD testing among the public and other health care providers, who may refer patients to your testing service. Advertising and promotional efforts should also communicate the convenience and availability of your service. The specific method of marketing depends on budget considerations, the target audiences, and past experience with various forms of advertising. Newspaper advertising is often used to attract a broad base of individuals who are at risk for osteoporosis. For example, some communities publish local newspapers and magazines geared to active older adults, an important target market for BMD testing.

Some pharmacists offer BMD testing as an integral component of pharmaceutical care services for osteoporosis prevention and management. This approach emphasizes the pharmacist's patient care skills beyond mere screening and fosters the development of long-term relationships with patients. For example, a patient who receives a BMD test may return to the pharmacy on repeated occasions for other related services, such as small group classes on osteoporosis management and

Table 10.
Osteoporosis Resources

National Institutes of Health
Osteoporosis and Related Bone Diseases
National Resource Center
1232 22nd Street, NW
Washington, DC 20037-1292
800-624-BONE
www.osteo.org

National Osteoporosis Foundation
1232 22nd Street, NW
Washington, DC 20037-1292
202-223-2226
www.nof.org

risk reduction, a consultation on the appropriate use of calcium or other dietary supplements, and drug therapy counseling for hormone replacement therapy or other medications. Osteoporosis education materials for patients and health care professionals are available from the organizations listed in Table 10.

Marketing efforts also should be directed to physicians in the community. Marketing materials to physicians should emphasize the convenience of the service and describe any training or special qualifications of pharmacy staff in this area, such as participation in continuing education programs or the Osteoporosis Care Program, a certificate training program offered by the National Institute for Pharmacist Care Outcomes. Marketing materials to physicians also should describe the collaborative aspects of the service. For example, patients whose peripheral BMD tests indicate increased fracture risk should be referred to their physicians for further evaluation and an appropriate treatment plan. Physicians may likewise refer patients to a trusted pharmacist for a screening BMD test or for various pharmacy-based patient care services to reduce the risk of osteoporosis or improve outcomes of drug therapy.

Reimbursement

As with any business venture, the feasibility of BMD testing depends on adequate financial remuneration. Thus, a critical first step is to establish a fee schedule that allows for profit. Consider the cost of doing business and the "going rate" in the community for peripheral BMD testing. Nationwide, most pharmacists who offer this service charge between $25 and $50 per test. Another approach is to include BMD testing in a comprehensive package of patient care services for osteoporosis prevention and management and offer the test itself at no charge.

The most common source of reimbursement for peripheral BMD testing is out-of-pocket payment by consumers. Although pharmacists can make a good case for third party reimbursement in some instances, insurance coverage for BMD testing and the criteria for determining patient eligibility are highly variable. Most insurance companies that provide coverage have adopted the qualifications defined by HCFA, which are listed in Table 4.

To bill a third party, pharmacists must have a physician order for the BMD test and submit a HCFA 1500 form. When completing the HCFA 1500, use the Physician Current Procedural Terminology (CPT) code for the type of BMD testing device. The CPT code for pDEXA is 76076 and for QUS is 76977.

Conclusion

Pharmacy-based BMD testing is often overlooked in favor of diabetes or asthma management services as an entrée into pharmaceutical care. This service has several features that make it worthy of pharmacists' consideration. It is an opportunity to provide a valuable public service by helping to identify individuals who have low bone mass, allowing preventive and treatment strategies to be implemented before fractures occur. Public interest in BMD testing also is growing, and the number of individuals at risk of osteoporosis is projected to increase substantially in the next few years as the population ages. In addition, many patients are willing to pay pharmacists for BMD testing at the time of the service,[11] facilitating compensation. BMD testing has many appealing attributes and can add a new dimension to pharmacists' practice.

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Assessment Questions

Instructions: For each question, circle the letter on the answer sheet corresponding to the answer you select as being the correct one. Please review all your answers to be sure that you have circled the proper answer. There is only one correct answer to each question.

1. All of the following are reasons pharmacists would provide bone mineral density (BMD) testing *except:*
   a. Potential new source of revenue.
   b. Companion sales opportunity.
   c. Avoid the need to visit a physician for the diagnosis of osteoporosis.
   d. Diversify pharmaceutical care services.

2. Which of the following statements is *true* regarding BMD?
   a. BMD is defined as the amount of mineral contained within a specific amount of bone.
   b. BMD is usually expressed as mg/mL^2.
   c. BMD primarily measures the phosphorus content of the bone.
   d. BMD is inversely related to the strength of bone.

3. Which of the following is a limitation of BMD measurements?
   a. BMD accounts for only a portion of the fracture effect.
   b. BMD measurements expose the patient to large amounts of radiation.
   c. BMD tests only measure trabecular bone.
   d. There are no limitations.

4. Which of the following statements is *false* concerning quantitative ultrasound (QUS) devices?
   a. QUS devices only measure peripheral skeletal sites.
   b. QUS measures broadband ultrasound attenuation and the speed of sound waves through the site.
   c. QUS devices are generally less portable and more expensive than central dual-energy X-ray absorptiometry (DEXA) machines.
   d. QUS machines are not as tightly regulated as the X-ray–based devices.

5. Which of the following statements is *true* concerning X-ray–based BMD technology?
   a. X-ray–based BMD devices only measure the heel.
   b. Measured values indicate the elasticity and microarchitecture of bone.
   c. The technology measures the speed of X-rays through the site.
   d. X-ray–based BMD devices measure calcium in the bone.

6. Which of the following is *true* concerning central versus peripheral devices?
   a. Central devices are less expensive and more portable.
   b. Peripheral devices are considered the gold standard.
   c. All currently available BMD devices are considered good predictors of fracture risk.
   d. Peripheral devices are preferred for monitoring purposes.

7. Which skeletal sites do the peripheral BMD devices measure?
   a. Heel only.
   b. Heel or hand.
   c. Heel, hand, or forearm.
   d. Hip or spine.

8. The correct definition of the *t* score is:
   a. The grams of bone mineral in the area measured.
   b. The grams of bone mineral measured at trabecular skeletal sites.
   d. The bone mass of the patient compared with the mean peak bone mass of a healthy age-matched population.
   d. The bone mass of the patient compared with the mean peak bone mass of a normal young adult sex-adjusted reference population.

9. Which of the following statements is correct concerning the World Health Organization (WHO) diagnostic guidelines for osteoporosis?
   a. The patient must have a history of fracture to have a diagnosis of osteoporosis.
   b. The diagnostic guidelines apply equally well to all patient populations.
   c. Osteoporosis is present when the *t* score is at least –2.5 SD.
   d. Osteoporosis is present when the *t* score is >1 g/cm^2.

10. Based on the WHO criteria, osteopenia is a *t* score:
    a. Within 1.0 SD of the young adult mean.
    b. Greater than 1.0 SD but less than 2.5 SD below the young adult mean.
    c. 2.5 SD or more below the young adult mean.
    d. 2.5 SD or more above the young adult mean.

11. The WHO criteria were based on:
    a. Hip BMD measurements of postmenopausal white women using DEXA devices.
    b. Hip BMD measurements of white women and men over age 50 using DEXA devices.
    c. Hip BMD measurements of postmenopausal women of various ethnic backgrounds.
    d. Hip, spine, and heel measurements of postmenopausal white women.

12. According to the National Osteoporosis Foundation, BMD testing is recommended for which of the following populations?
    a. All women aged 55 and older.
    b. All women aged 60 and older.
    c. All women aged 65 and older.
    d. All women and men aged 65 and older.

13. Which of the following statements is *true* concerning the comparison of multiple BMD measurements for the same person?
    a. In general, measurements should not be repeated any more often than every 1 to 2 years.
    b. Measurements taken using different devices are comparable.
    c. Measurements taken at different skeletal sites in the same person are equivalent.
    d. BMD measurements are not to be used for patient monitoring.

14. Which of the following is *not* a risk factor for osteoporosis?
    a. Cigarette smoking.
    b. Estrogen deficiency.
    c. Obesity.
    d. Inadequate physical activity.

15. Which of the following statements is *false* regarding skeletal site selection for BMD testing?
    a. The nondominant arm or foot is the preferred site for BMD testing.
    b. Changes due to therapy are detected earlier in cortical bone sites.
    c. Pharmacists should avoid measuring sites of arthritis or previous fracture.
    d. The National Osteoporosis Foundation recommends the hip as the ideal site for BMD testing.

16. Which of the following best describes the recommended schedule for BMD testing in patients receiving long-term glucocorticoid therapy?
    a. BMD testing is not beneficial in this population.
    b. Baseline and every 6 to 12 months while taking glucocorticoids.
    c. Baseline and every 1 to 2 years while taking glucocorticoids.
    d. Begin testing yearly after 6 months of glucocorticoid therapy.

17. Peak bone mass is achieved at what age?
    a. 10-15 years.
    b. 15-25 years.
    c. 20-35 years.
    d. 35-40 years.

18. The single most accurate predictor of fracture risk in postmenopausal women is:
    a. Low bone mass.
    b. Postmenopausal status.
    c. Use of medications that decrease bone mass.
    d. Family history.

19. Which of the following best describes pharmacists' compensation for BMD testing?
    a. Most pharmacists are providing the testing for free.
    b. Most patients are paying out-of-pocket.
    c. Most pharmacists are billing private insurance companies.
    d. Most pharmacists are billing Medicare.

20. In the next 40 years, the number of hip fractures and their associated costs are projected to:
    a. Remain about the same.
    b. Decrease by 50%.
    c. Nearly double.
    d. More than triple.

Monograph 16

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