

## Evidence-based Practice Center Technical Brief

### Project Title: Whole-Body Vibration Therapy for Osteoporosis

#### I. Background and objectives

Osteoporosis is a disease of the skeletal system characterized by low bone mass and deterioration of bone tissue.<sup>1</sup> Osteoporosis is a significant public health problem that leads to increased bone fragility and an increased risk of bone fractures typically in the wrist, hip, and spine.<sup>1</sup> In an epidemiological study conducted in Switzerland, half of all fractures in women and 24 percent in men were considered to be osteoporotic.<sup>2</sup> In the United States, the estimated 1.5-million yearly osteoporotic fractures result in more than 500,000 hospitalizations, 800,000 emergency room visits, 2.6 million physician office visits, and 180,000 nursing home placements.<sup>1</sup> Hip fractures, in particular, have been shown to be associated with an increased risk of death.<sup>1</sup> Fractures can also cause pain, height loss, and functional disability, and individuals that suffer from a fracture are also at risk for other complications, such as pressure sores and pneumonia.<sup>1</sup> Osteoporosis affects 2 percent of men and 10 percent of women over the age of 50 in the U.S.<sup>3</sup> In addition, 49 percent of older women and 30 percent of elderly men in the U.S. have low bone density or osteopenia.<sup>3</sup> By 2020, approximately half of all elderly Americans will be at risk for fractures from osteoporosis or low bone mass.<sup>1</sup>

The U.S. Preventive Services Task Force recommends active screening for osteoporosis and early intervention to prevent bone fractures.<sup>4</sup> Current clinical guidelines recommend dietary and pharmacological interventions to treat osteoporosis and prevent bone fractures.<sup>5-9</sup> An increase of 1 standard deviation in bone mineral density in women would prevent 33 percent of hip fractures and 77 percent of vertebral fractures.<sup>10</sup> Despite proven effectiveness, these treatments may have low rates of long-term adherence. In addition, pharmacological interventions can result in adverse effects, commonly atypical fractures, renal toxicity, and osteonecrosis of the jaw.<sup>11-15</sup> Alternative therapies, including weight-bearing exercise, may also increase bone density<sup>16,17</sup> and are safer than medication. The U.S. Preventive Services Task Force encourages research on new alternative interventions that may have higher adherence rates and lower risks of side effects to help prevent osteoporosis.<sup>18</sup>

One possible intervention is whole-body vibration therapy.<sup>19-23</sup> Whole-body vibration was originally proposed as a means to build bone density for astronauts in space;<sup>24</sup> like other weight-bearing physical activities, it causes muscles and bones to work against gravity.<sup>3</sup> Recently, whole-body vibration has been considered to be a possible therapeutic intervention for increasing bone density in the elderly and others at risk for osteoporosis.<sup>19,25-30</sup>

How vibration therapy increases bone density is not well understood.<sup>31,32</sup> One hypothesis is that vibration signals are transmitted and amplified into bone tissue, directly activating mechanosensors in bone cells.<sup>33</sup> Animal studies demonstrated that vibration increases the anabolic (bone building) activity of bone tissue and increases bone

density.<sup>24,34-36</sup> Another hypothesis is that the effect of whole-body vibration is similar to other weight-bearing exercise<sup>37,38</sup> and improves muscle strength and power by increasing neuromuscular activation.<sup>39,40</sup> Human studies on healthy volunteers examined adaptive muscle strength and performance after vibration therapy and found that the effects were similar to those achieved with short-term resistance exercise.<sup>37,38</sup> Several studies show that whole-body vibration therapy improves muscle and bone circulation, increasing the supply of nutrients needed to build bones.<sup>20,41-44</sup>

Using vibration therapy to increase bone mass and decrease the risk of fractures has been discussed elsewhere in the literature,<sup>20-23,32,45-48</sup> including recommendations made by the International Society of Musculoskeletal and Neuronal Interactions.<sup>47</sup> To date, a description of the available evidence on vibration therapy for the various populations at risk of or with osteoporosis has never been summarized.

We aim to provide a description of the state of the science and an overview of the key issues related to the use of whole-body vibration therapy to improve bone density and treat osteoporosis, including modalities, standards, relevant patient populations, outcomes measured, and implications for future research. The scope of this report is confined to whole-body vibration platforms designed and marketed for prevention and treatment of osteoporosis. The scope of the report does not include exercise equipment with vibrating platforms intended for use in physical fitness or athletic regimens.

## II. Guiding Questions

1. *Describe the Existing Technology.*
  - a. What vibration modalities have been proposed or used in practice to treat osteoporosis?
  - b. What are the potential advantages and disadvantages of vibration therapy when compared to regular exercise and pharmacological treatments of osteoporosis in preventing osteoporotic fractures?
  - c. What are the potential safety issues and harms of vibration therapy when used to treat osteoporosis?
2. *Describe the Context in Which the Technology Is Used.*
  - a. What kinds of training, certification, and staffing are required for vibration therapy?
  - b. How are treatment sessions in clinical settings billed?
  - c. What is the current U.S. Food and Drug Administration (FDA) approval status of vibration therapy for osteoporosis?
  - d. What modifications of vibration platforms are in development?
3. *Describe the Current Evidence of the Technology.*
  - a. What are the inclusion and exclusion criteria of patients in therapeutic studies of vibration therapy for osteoporosis?
  - b. What modalities of vibration therapy for osteoporosis have been examined in therapeutic studies?

- c. What was the length, intensity, and frequency of each vibration therapy session, and what was the total duration of the vibration therapy intervention?
  - d. What primary and secondary outcomes and harms were examined?
  - e. What comparators were used to examine benefits and harms?
  - f. What was the length of followup to examine benefits and harms?
  - g. What were the methodological approaches or study designs used (i.e., randomized controlled trial, cohort, case control, etc.)?
4. *Identify the Important Issues Raised by the Technology.*
- a. What are the implications of reimbursement practices on accessibility?
  - b. What are the possible areas of confusion or potential harms from misuse in direct-to-consumer marketing and unsupervised consumer use?
  - c. What medical claims about effectiveness have been made, and how do they compare to what is available in the literature? What are the implications for third-party payers?
  - d. What are possible areas of future research?

Note: These questions may be modified over the course of the research as additional information is uncovered.

### III. Methods

We will integrate the information from the key informants and a systematic literature review into a single, cohesive review process. In particular, responses to questions 1, 2, and 4 will rely on information from key informants and published information about vibration technology, the applications of the technology, and the FDA-approval process. Responses to question 3 will be based on peer-reviewed, published studies that examined outcomes after whole-body vibration for osteoporosis.

#### 1. Data Collection.

##### A. Discussion With Key Informants.

We will identify relevant key informants for this technical brief, ensuring both balanced viewpoints and efficient data collection. We will include experts on whole-body vibration therapy and in the treatment of osteoporosis, and clinicians who use whole-body vibration therapy in their practices. We will also include public purchasers of healthcare, consumer advocates, and potential consumers. Representatives from device manufacturers will only be included as key informants if two or more firms with leading research and development staff have representatives available to provide a balanced view from competing perspectives. We will locate potential key informants from frequently listed and cited authors of relevant literature, Internet searches for possible candidates of relevant viewpoints, and nominations by other key informants. In cases where the Evidence-based Practice Center (EPC) staff is not able to identify a specific individual to represent a specific organization, we will invite the organization to nominate an individual. In cases where a key informant

has a potential conflict of interest but is still deemed to have a viewpoint or specific expertise critical to the technical brief, we will interview them separately from other key informants to avoid undue influence.

We will conduct semistructured interviews with the key informants to gather information on their opinions regarding whole-body vibration therapy for improved bone health. Listed below are examples of the types of questions that will be used in the key informant discussions. The key informants will receive invitation letters that will provide a brief description of the project and the key informant's expected role, and appropriate disclosure forms for conflicts of interest. Experts in the field will be convened by a group conference call. Clinicians and advocates may also be separately convened by a group conference call. Consumers will be interviewed separately. Summaries of calls will be circulated to participants for content confirmation.

*Questions for Third-Party Payers.*

- a. What information about whole-body vibration is most needed by payers?
- b. What criteria (clinical effectiveness, safety, FDA approval, market value, others) are the most critical when making payment coverage decisions for whole-body vibration?
- c. What kinds of research would be most useful to make evidence-based coverage decisions?
- d. What outcomes do payers take into consideration for coverage decisions?

*Questions for Osteoporosis Content Experts.*

- a. What are the criteria used to determine appropriate patient populations for whole-body vibration therapy?
- b. What are the potential advantages and disadvantages of vibration therapy when compared to regular exercise and pharmacological treatments of osteoporosis in preventing osteoporotic fractures?
- c. What modifications of vibration platforms are available in the U.S.? What modifications of vibration platforms are in development?
- d. What is the current FDA-approval status of vibration therapy for adults with osteoporosis?
- e. What kinds of training, certification, and staffing are required for vibration therapy?
- f. What type of research is needed most? What research designs are most likely to answer the important research questions?
- g. What outcomes are appropriate measures of the efficacy and effectiveness of vibration therapy?
- h. When should patient outcomes be measured (length of followup)?

*Questions for Clinicians, Patients, and Patient Advocates.*

- a. What has been your experience with whole-body vibration therapy?

- b. What information do clinicians and patients need to know to make informed decisions about whole-body vibration (effectiveness, safety, FDA approval, doctor recommendation, other)?
- c. What information do clinicians and patients need to know when to use alternative therapeutic options for osteoporosis?
- d. What is the measurement of successful treatment for osteopenia and osteoporosis?

## **B. Grey Literature Search.**

We will conduct a grey literature search of Federal Government Web sites (e.g., [www.medicare.gov](http://www.medicare.gov)) for current coverage and/or payment policies, the FDA Web site for approval reviews, and presentations of unpublished studies at scientific meetings. We will also search the Internet with different engines (e.g., Google Scholar, Scirus, LexisNexis) to obtain, for example, information on availability and other issues and controversies regarding vibration platforms. We will survey enrolling and ongoing clinical trials through [ClinicalTrials.gov](http://ClinicalTrials.gov). We will search the CSA Physical Education Index, the Web of Science<sup>®</sup>, and Medscape<sup>®</sup> databases to find studies that were presented in scientific meetings. We may also try to obtain coverage information for some major private insurers.

## **C. Published Literature Search.**

We will search for relevant articles on the use of whole-body vibration to treat patients with low bone density. We will include studies published in English of any sample size, any design (randomized controlled trial, controlled clinical trial, uncontrolled observational trial, and case reports and series) and studies that report any clinical outcome (e.g., bone density, bone mineral content, bone fractures).

We will search several databases: MEDLINE<sup>®</sup> via OVID and via PubMed<sup>®</sup>, the Cochrane Library, AMED, CINAHL, the CSA Physical Education Index, the Web of Science, PEDro, and Academic Search<sup>™</sup> Premier. Exact search strategies have been developed in consultation with the EPC librarian and guided by the Scientific Resource Center. We have developed an a priori search strategy based on relevant medical subject headings (MeSH) terms, text words, and a weighted word-frequency algorithm to identify related articles. The key informants may suggest additional sources for evidence.

For question 3, we will screen the abstracts against the following inclusion and exclusion criteria:

1. Healthy adults and children.
2. Market evaluations of whole-body vibration platforms.

We will retrieve and review full articles on eligible studies to determine final inclusion. We will repeat the literature search to identify literature published up to

February 2011 and to determine whether the new material provides additional information not previously covered in the report.

## 2. Data Organization and Presentation.

### A. Information Management.

Data from the published literature will be abstracted by using the standardized data-abstraction tool shown in Appendix 2. One reviewer will collect the data and assess the evidence against the inclusion and exclusion criteria. We will not abstract actual results from the studies.

Data from the published literature will be integrated with information from the grey literature and key informant discussions. Responses to questions 1 and 2 will be formed with information from published narrative reviews, information in the grey literature, and key informant discussions. Responses to question 3 will be based primarily on peer-reviewed, published literature and may be combined with some information gleaned from the grey literature (e.g. information from ongoing studies). Responses to question 4 will be informed by discussions with key informants along with information regarding the technology and the context within which it is used, and the existing research gathered to address questions 1–3.

### B. Data Presentation.

The data will be presented in narrative form (Q1, 2, and 4) and in evidence tables. We will summarize the evidence into summary tables/plots by population subgroup, vibration platform, study location, size and design, and examined outcomes.

*Proposed templates for summary tables.*

**Table 1. List of vibration therapy platforms that are available for home-based exercise and for exercise in clinical settings**

Vibration platform (brand and type)	Manufacturer	Status (fitness vs. medical device)	Characteristics of the device	Number of studies that tested the platform (references)

**Table 2. Distribution of the studies that examined the effects of vibration therapy by study design, sample size, characteristics of intervention (dose, amplitude, frequency, duration), and comparators**

Vibration platform	Vibration amplitude	Vibration duration	Study design	Sample size	Comparator

**Table 3. Distribution of the studies that examined vibration therapy in different populations**

Vibration platform	Country	Inclusion criteria-age, comorbidities	Exclusion criteria	Inclusion of men	Inclusion of minorities	Concomitant treatment for osteoporosis

**Table 4. Distribution of the studies that examined different outcomes after vibration therapy**

Vibration platform	Fracture (N RCTs/other studies)	BMD (N RCTs/other studies)	BMC (N RCTs/other studies)	Harms (N RCTs/other studies)	Quality of life	Other outcomes



## IV. References

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## V. Definition of Terms

### **Bone density:**

The amount of mineral (calcium phosphate) per square centimeter of bone. Bone mineral density values are calculated by using reference values for healthy young white women who are 20 to 29 years of age and are expressed in standard deviation (SD) units and reported as a T-score:

<b>Normal bone density:</b>	T-score >1 SD
<b>Osteopenia:</b>	T-score between -1 and -2.5
<b>Osteoporosis:</b>	T-score <2.5 SD
<b>Osteoporosis:</b>	reduction of bone mass without alteration in the composition of bone, leading to increased risk of fractures

### **Therapeutic vibration:**

Use of a continuing periodic change in displacement of the body or parts of the body with respect to a fixed reference point of the body position.

### **The intensity of whole-body vibration exercise:**

The frequency of oscillations per second (Hz/sec), or the amplitude of the vibration platform (displacement of the platform from a horizontal position in mm).

### **Vibration acceleration:**

The function of the frequency and amplitude ( $[\text{meter/second}]/\text{second}$ )

## VI. Summary of Protocol Amendments

## Appendix 1.

*Preliminary literature search.* We searched the MEDLINE, Cochrane Library, CINAHL, CSA Physical Education Index Web of Science, PEDro, and Academic Search Premier databases using the key words “whole body vibration,” “vibration,” and “osteoporosis.”

Software: Ovid Technologies, Inc. Email Service

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 Search for: 18 not 19

Results: 120

Database: Ovid MEDLINE(R) <1950 to August Week 4 2010>

Search Strategy:

- 
- 1 exp Vibration/tu [Therapeutic Use] (511)
  - 2 whole body.mp. (39402)
  - 3 1 and 2 (71)
  - 4 exp Muscle Strength/ (10075)
  - 5 exp "Recovery of Function"/ (19156)
  - 6 4 or 5 (28640)
  - 7 1 and 6 (27)
  - 8 3 or 7 (85)
  - 9 wbv.mp. (309)
  - 10 1 and 9 (36)
  - 11 8 or 10 (85)
  - 12 exp Muscle, Skeletal/ (165830)
  - 13 1 and 12 (65)
  - 14 11 or 13 (114)
  - 15 exp Physical Therapy Modalities/ (99436)
  - 16 1 and 15 (206)
  - 17 14 or 16 (278)
  - 18 limit 17 to (english language and humans and yr="2000 -Current") (127)
  - 19 limit 18 to (case reports or editorial) (7)
  - 20 18 not 19 (120)
  - 21 exp Osteoporosis/rh, th [Rehabilitation, Therapy] (2609)
  - 22 1 and 21 (14)

PubMed search strings

#

Search "Vibration/therapeutic use"[MAJR] Limits: Humans, Randomized Controlled Trial, English	68
Search "Vibration/therapeutic use"[MAJR] Limits: Humans, Journal Article, English	1287
Search "Vibration"[Mesh] Limits: Humans, Journal Article, English	6541
Search vibration AND osteoporosis Limits: Humans, Journal Article, English	71
Search vibration AND osteoporosis	119
Cochrane Library: Whole body vibration for preventing and treating osteoporosis (Protocol)	
CINAHL: 212 references	

## **Appendix 2.**

### ***Abstraction form.***

#### Publication Information

Author

Title

Year of publication

Journal

#### Research Design

Type of study design

#### P — Patient Population

Country of residence of patients

Inclusion criteria

Exclusion criteria

Number of patients in treatment group

Presence of men in treatment group (yes or no)

Presence of minorities in treatment group (yes or no)

Patients with comorbidities in treatment group (yes or no)

Patients with prior treatments for osteoporosis in treatment group (yes or no)

Patients receiving other treatments for osteoporosis in addition to vibration therapy during study (yes or no)

Patients receive vibration therapy in combination with other exercise (yes or no)

#### I — Intervention Characteristics

Therapy done in home or clinical setting

Type of vibration therapy

Manufacturer of vibration platform  
Vibration platform frequency  
Vibration platform magnitude  
Vibration platform amplitude  
Length of each vibration session  
Pattern of vibration session  
Frequency of vibration sessions  
Total time of vibration therapy intervention  
Compliance with intervention measured  
Length of follow-up

C — Comparison Group

Number of participants in comparison group

O — Outcomes

Bone mass density as outcome of interest (yes or no)  
Measures used to assess bone mass density  
Site of bone mass density measurement  
Bone mineral content as outcome of interest (yes or no)  
Measures used to assess bone mineral content  
Fracture as outcome of interest (yes or no)  
Measures used to assess fracture  
Quality of life as outcome of interest (yes or no)  
Measures used to assess quality of life  
Harms reported for treatment group  
Other outcomes