AMERICAN ORTHOPAEDIC ASSOCIATION

Own the Bone™

Providers & patients united for improved care.

Own the Bone™

A Quality Improvement Program

Preventing Future Fractures in Patients Sustaining Fragility Fractures by Identifying, Evaluating and Treating Osteoporotic Bones and Low Bone Mass

Protocol Date:	30 April 2009
Sponsor:	American Orthopaedic Association 6300 North River Road, Suite 505 Rosemont, IL 60018

Own the Bone™ Leadership

Steering Committee Members

Andrew D. Bunta, MD,
Own the Bone, *Committee Chair*
Northwestern University
Feinberg School of Medicine

Douglas R. Dirschl, MD
University of North Carolina
School of Medicine

Joseph M. Lane, MD
Hospital for Special Surgery

Clifford B. Jones, MD, FACS
Michigan State University

William B. Macaulay, Jr., MD
New York Presbyterian Hospital

Kyle J. Jeray, MD
Greenville Hospital System
University Medical Center

Marc F. Swiontkowski, MD
University of Minnesota

Laura L. Tosi, MD
Children's National Medical Center

Vincent D. Pellegrini, Jr., MD,
AOA President
University of Maryland

Debra Sietsema, PhD, RN, *Consultant*
Orthopaedic Associates of Michigan

Beatrice Edwards, MD, *Consultant*
Northwestern University
Feinberg School of Medicine

Lisa Shindle, APN, *Consultant*
Hospital for Special Surgery

Multidisciplinary Advisory Board Members

Douglas R. Dirschl, MD, *Multidisciplinary Advisory Board Chair*
University of North Carolina School of Medicine

Andrew D. Bunta, MD
Northwestern University Feinberg School of Medicine

Felicia Cosman, MD
Columbia University

Kristine Ensrud, MD, MPH
University of Minnesota

Jay S. Magaziner, PhD, MSHyg
University of Maryland

Lawrence G. Raisz, MD
University of Connecticut Health Center

Paula H. Stern, PhD
Northwestern University Feinberg School of Medicine

Marc F. Swiontkowski, MD
University of Minnesota

Nelson B. Watts, MD
University of Cincinnati

Coordinating Center: Clinipace
Phone: 919.224.8800
support@clinipace.com

Own the Bone™

A Quality Improvement Program

Participant Agreement

I have read and understand this protocol and agree that it contains the ethical, legal, and scientific information necessary to participate in this evidence-based quality improvement program (Program). I will personally oversee conduct of the Program as described herein and in the participating site agreement.

I will provide copies of this protocol as needed to all physicians and physician extenders (nurses, nurse practitioners, physician assistants, and other professional personnel) responsible to me who will participate in the Program. I will discuss the protocol with them to assure myself that they are sufficiently informed regarding the conduct of the Program. I am aware that this protocol may need to be approved by an appropriate Institutional Review Board (IRB) or Ethics Committee (EC) for my institution, prior to any data being submitted, and that I am responsible for verifying whether that requirement is to be met. I understand that it is my responsibility to ensure that the Own the Bone program is being carried out with the full awareness, consent, and approval of the Hospital Administration or Quality Improvement office. I agree to review medical information for data entered to my hospital's system to assure accuracy if Own the Bone requests verification of submitted information.

Signature

_____

Printed Name

Title

Date

_____

Institution

Table of Contents

1 Executive Summary

Poor bone health and osteoporosis are preventable and treatable conditions often with no warning signs until a fracture occurs. For many, the initial diagnosis occurs at the time of fracture. Patient sustaining fragility fractures have a high likelihood of subsequent (repeat) fractures.[1, 2,3,4]

Fragility fractures are not limited to patients with osteoporosis. In a large longitudinal observational study, the National Osteoporosis Risk Assessment, post-menopausal women with osteopenia had a 1.8-fold higher rate (95% CI, 1.49-2.18) of fragility fractures compared to women with normal bone mineral density.[5]

Own the Bone™ is an evidence-based quality improvement program for patients with fragility fractures. Own the Bone is designed to prevent future fractures in patients with current fragility fractures by increasing the application of current evidence-based guidelines set forth in the National Osteoporosis Foundation *Clinician's Guide to the Prevention and Treatment of Osteoporosis* and highlighted in the 2004 Surgeon General's Report on Bone Health and Osteoporosis[6,7]. The goals of Own the Bone are to assist clinicians in identifying, evaluating, diagnosing, and treating patients with poor bone health after a fracture and improving awareness of the fracture risk. In this program, adherence to evidence-based treatment guidelines is measured. Ultimately, Own the Bone endeavors to reduce the risk of secondary fragility fractures in participating patients.

Participation in Own the Bone facilitates patient education efforts by providing a downloadable library of patient education materials and promotes guideline-based care through the use of computerized reminders based on patient characteristics. Online submission of data is streamlined to minimize reporter burden (requiring the completion of an easy-to-use electronic case report form). Data submitted to the Own the Bone program is used to develop confidential benchmarking reports for hospitals to evaluate progress to goals and improve systems of care based on evidence-based guidelines.

Participating in Own the Bone requires the following:

- Identifying patients aged 50 and over presenting with a fragility/low energy fracture
- Screening, educating, and treating patients as appropriate
- Entering patient information into web-based quality initiative registry (Estimated data-entry time commitment is approximately 5 minutes per patient.)
- Maintaining a log of patients entered into the system
- Following up with patients after 60-90 days (via a letter or phone call) inquiring about compliance with program measures (This is a recommended step.)
- Recording responses to follow up questions into system.

Own the Bone was specifically developed to make the current evidenced-based guidelines easy to implement. By entering information in the web-based data registry, physicians, nurse practitioners and others can immediately quantify results and begin to see that the measures are positively affecting patient care.

2 Introduction

To focus attention on the importance of bone health on overall health and the quality of life, on March 27, 2002, US President George W. Bush declared the years 2002-2011 as the "Decade of the Bone and Joint."[8] The Bone and Joint Decade has evolved into a global, multi-disciplinary initiative targeting the care of people with bone and joint disorders.[9] The focus of the Bone and Joint Decade is the improvement of the quality of life as well as the advancement of the understanding and treatment of those conditions through research, prevention, and education. Sadly, the bone health status of Americans appears to be in jeopardy. Because there are often no warning signs of poor bone quality until a fracture occurs, many patients are not diagnosed in time to receive effective therapy during the early phase of the disease. According to a 2004 RAND Study, only 18% of patients received appropriate osteoporosis care after a fragility fracture. This evidence suggests that health care providers frequently fail to identify and treat individuals at high risk for osteoporosis even in patients who have already had a fracture.[10]

Fragility fractures are not limited to those meeting the formal definition of osteoporosis as defined by the World Health Organization. In post-menopausal women, Siris et al. (2001) found that osteoporosis was associated with a fracture rate approximately 4 times that of normal BMD (rate ratio, 4.03; 95% confidence interval [CI], 3.59-4.53) and osteopenia was associated with a 1.8-fold higher rate (95% CI, 1.49-2.18).[5] These findings were from a population of post-menopausal women participating in the National Osteoporosis Risk Assessment, a longitudinal observational study.

The US Surgeon General identified osteoporosis and fragility fractures as a major public health problem in the report, *Bone Health and Osteoporosis: A Report of the Surgeon General.*[7] The Surgeon General noted that "much of what could be done to reduce this burden is not being done today largely due to a lack of awareness of the problem and a failure to apply current knowledge." This significant gap between recognized, evidence-based therapies and actual clinical practice represents an opportunity to advance guideline-based care aimed at quality improvement through improved education, health promotion, future fracture prevention, osteoporosis-risk assessment, and monitoring of services.

Own the Bone has been developed to respond to this need. Own the Bone™ is an evidence-based quality improvement program for patients with fragility fractures. Own the Bone is designed to prevent future fractures in patients with a current fragility fracture by increasing the application of current evidence-based guidelines set forth in

the National Osteoporosis Foundation *Clinician's Guide to the Prevention and Treatment of Osteoporosis* and highlighted in the 2004 Surgeon General's Report on Bone Health and Osteoporosis.[6,7]

Own the Bone incorporates computerized reminders that promote the timely and appropriate care of these patients in accordance with the National Osteoporosis Foundation's evidence-based guidelines.[6] The data collected through the program will be analyzed to provide a better understanding of the patient demographics, risk factors, patient education efforts, and treatment recommendations that are made to patients who sustain fragility fractures. Feedback will be provided to participating hospitals, allowing them to track their rate of compliance with the guidelines, benchmark their performance against similar hospitals and program data on a national level, and focus on areas for improvement.

In 2005, the American Orthopaedic Association piloted Own the Bone at 14 institutions. The 10-month pilot was designed to document the ability of Own the Bone to improve patient care by increasing compliance with eight evidence-based management strategies for the treatment of bone health after a fragility fracture.[11] The pilot program documented statistically significant improvement in compliance with six of the eight evidence-based fracture care guidelines. There were two measures for which little improvement was documented. Fewer than 20% of patients had a BMD test ordered at the time of discharge. Similarly, osteoporosis pharmacotherapy was initiated in fewer than 30% of eligible patients. This finding was driven, in part, by the design of the pilot; therefore, a follow-up contact with the patient 60-90 days after enrollment has been added as a recommended, but not mandatory, action. After reviewing current science and lessons learned from the pilot study, changes have been made to the current program to help foster compliance among all the guidelines. The current Own the Bone program has two additional measures for a total of ten measures (section 5.1.2), and follow up is included as part of the program as a recommended step for hospitals.

Applying the principles of evidence-based medicine to osteoporosis management is highly important because of the morbidity and mortality associated with this condition. It is estimated that more than 1.5 million individuals suffer from an osteoporosis-related fracture each year, resulting in 800,000 emergency room encounters, 500,000 hospitalizations, and 2,600,000 physician office visits.[12] Measured in 2002 dollars, the direct cost of these fractures is in the neighborhood of $18 billion, with indirect costs due to lost productivity for patients and caregivers adding billions more to this figure.[13] Although few patients die from osteoporosis-related fractures, these fractures can lead to a downward spiral in physical and mental health that may result in death. In addition, it is projected that one of two females and one of four males will sustain a fragility fracture in their lifetime.

This major public health problem is only expected to get worse. The prevalence of osteoporosis is expected to increase for all ethnic groups. By 2020, one out of two

female Americans over the age of 50 is expected to have or be at risk for developing osteoporosis of the hip, and even more will be at risk for developing osteoporosis at other sites in the skeleton. Bone loss and fractures affect a large segment of the US population and can be prevented during all stages of life. Therefore, bone health is particularly amenable to population-based interventions such as the Own the Bone program. In addition, there is widespread lack of knowledge and awareness regarding bone disease prevention among health care providers and the public.

3 Goals of Own the Bone

The goals of the Own the Bone Program are to:

- Prevent future fragility fractures among persons with fragility fractures.
- Increase awareness about poor bone health and osteoporosis and among health care providers and patients.
- Provide a tool to clinicians to facilitate the implementation of guideline-based care for the diagnosis, prevention, and treatment of poor bone health and osteoporosis in appropriate patients.

4 Objectives of Own the Bone

Promoting the application of current knowledge about bone health is an important step toward reducing the burden of osteoporosis on patients, caregivers, and the health care system. Own the Bone focuses on increasing patient awareness of osteoporosis as a silent disease, recommending bone mineral density (BMD) testing in patients at risk for osteoporosis, and initiating appropriate interventions, ranging from pharmacologic therapy to counseling on exercise, vitamin D, calcium, alcohol consumption, smoking and fall prevention. These interventions are intended to decrease the risk of secondary fragility fractures. Communication and coordination with other health care providers is another key component of the program.

The primary objectives of Own the Bone are the following:

- Change physician and patient behavior to reduce the incidence of secondary fractures in patients with an identified fragility fracture;
- Implement a quality improvement process at centers that will be incorporated as routine clinical practice;
- Improve overall awareness of osteoporosis-related fractures while also improving the education and evidence-based management of fragility fracture patients;
- Increase recognition of the need to evaluate and treat osteoporosis after a fragility fracture;
- Close the treatment gap documented in the RAND and NCQA studies[14,15].

The Own the Bone program will provide hospitals with the tools to collect and interpret data on their management of patients at risk for osteoporosis, and will assist hospitals in identifying opportunities to improve patient management by providing access to quality

improvement tools. These tools are aimed at improving adherence to evidence-based guidelines for the prevention, diagnosis and management of osteoporosis.

An additional benefit of this program is the accumulation of a database of important variables reflective of osteoporosis care in this population. Analyses of this data will further characterize osteoporosis patients with fragility fractures and provide much-needed information on patient characteristics and risk factors, treatment patterns, and compliance with evidence-based recommendations after initiation of the program.

5 Study Design Overview

Own the Bone is a multi-center quality improvement initiative that will collect data benchmarking the application of evidence-based guidelines for the osteoporosis treatment of patients with fragility fractures including dissemination of patient educational materials and referral for BMD testing. The program is available to hospitals in the U.S. on a subscription basis.

To participate in Own the Bone, clinicians or their designates will be asked to

- Identify patients age 50 and over presenting with a fracture
- Screen, educate and treat patients for low bone mass and/or osteoporosis
- Maintain log of participating patients
- Follow up with patients regarding status of DXA and pharmacotherapy (Follow-up is a voluntary, but recommended, step.)
- Enter patient information into web-based system

The guidelines suggest BMD testing and initiation of pharmacotherapy, if indicated. However, according to the Own the Bone pilot study, these interventions may not be feasible in an acute care setting. Recognizing the difficulty in measuring adherence to BMD testing and initiation of pharmacotherapy in an acute care setting, the program has been updated with an additional step: a follow-up telephone contact with the patient. Since halting data collection after the acute care encounter results in a missed opportunity to document implementation of guidelines, centers are encouraged to track patients during the 60-90 day period after discharge to confirm BMD testing, therapy initiation and compliance with other treatment recommendations.

Reports generated from Own the Bone will provide data on educational, diagnostic, and therapeutic (prescribing) practices directed at patients with low bone mass and fragility fractures in the US and provide this information to the hospital centers for evaluation. Data collection will focus on both hospitalization information and discharge plans (i.e., medications, diagnostic tests, patient instructions, and recommendations to primary care provider). Each participating center will access reports through the online system providing both institution-specific and aggregate benchmarking data from similar, participating hospitals regionally and nationally. Reports will include both rate-based and description frequency reports documenting each center's adherence to Guidelines in the treatment of patients with fragility fractures. For each center, performance

indicators are benchmarked against the entire participating cohort of centers and subgroups based on geography or institution type. Own the Bone reports generated for Participating Sites can be printed or downloaded as an electronic file for use in hospital presentations and team meetings.

5.1 Description of Study Stages

5.1.1 Eligibility Assessment

Own the Bone will collect data regarding patients who meet the following criteria:

- Male or female
- Age 50 or older
- With a current fragility/low energy fracture (not including fingers and toes). A fragility fracture is defined as a low-energy fracture of the distal radius, proximal humerus, ankle, vertebrae or proximal femur (hip) that results from minimal trauma, such as a fall from a standing height.
- Patients with cognitive impairment, such as dementia, are encouraged to participate; for these patients, caregiver contact will be essential to maximizing the interventions performed and the data collected.

Ineligible patients are not entered into the Own the Bone system.

5.1.2 Enrollment and Follow-up

Data from eligible patients will be collected on an online case report form (CRF) accessed through the Own the Bone website. Patient information may be collected from the patient or family member, the patient's medical record, and the patient's treating physician. The CRF may be completed directly online by a clinician or designee. For convenience, paper CRF forms will be available (downloadable).

Guideline-based Measures

Own the Bone is targeting the following ten specific measures (unless contraindicated):

Nutrition Counseling

1. Calcium supplementation
2. Vitamin D supplementation

Physical Activity Counseling

3. Exercise, especially weight-bearing and muscle strengthening
4. Fall prevention education

Lifestyle Counseling

5. Smoking cessation (if needed)
6. Limiting excessive alcohol intake

Pharmacology

7. Pharmacology for the treatment of osteoporosis

Testing

8. Dual Energy X-Ray Absorptiometry (DXA) to test bone mineral density

Communication

9. Physician referral letter
10. Follow-up note and educational material to Patient

The CRF collects data for assessing the patient's osteoporosis risk in accordance with both the National Osteoporosis Foundation's Clinician's Guide and the World Health Organization's FRAX instrument .[1,16] In addition, the CRF will collect data to compute the major outcome measures characterizing participation in the Own the Bone Program.

The Own the Bone Program consists of:

- An online Case Report Form.
- Computerized reminders for National Osteoporosis Foundation Guideline-based recommendations for diagnosis and treatment of osteoporosis in fragility fracture patients.
- A downloadable library of customized patient education materials.
- Automated template communication to primary care physicians which include the patient's discharge information, osteoporosis testing, and management recommendations in accordance with the guidelines.
- Site-specific benchmarking reports for hospitals to assess and improve their systems of care based on evidence-based guideline recommendations and goals. Hospitals will have access to their own data and aggregated data will be blinded.

Schedule of Assessments

Table 1. Schedule of Own the Bone System Encounters

	Eligibility Screening	**Fracture or First Encounter**	**Follow-up or Hospital Discharge**
Review Eligibility Criteria	X		
Collect Data on			
Admission Information		X	
Demographics Characteristics		X	
Site of Fracture(s)		X	
Fracture Risk Factors		X	
Medications for Osteoporosis*		X	X
WHO FRAX Questions*		X	X
Co-morbidities		X	
BMD Testing*		X	X
Conduct Patient Education and Counseling*		X	X
Initiate/Recommend Osteoporosis Medications*		X	X
Document Discharge Status*		X	X

*May be conducted at time of fracture/first encounter *or* follow-up/hospital discharge.

5.2 Own the Bone Program Population

5.2.1 Number of Patients/Centers

The estimated enrollment for Own the Bone is 40 centers during the first year with the goal of immediate expansion to 100 centers in Year 2 and an unlimited number of centers thereafter. Each center is asked to enter data for all patients sustaining a fragility fracture on an ongoing basis.

6 Conduct of the Program

6.1 Ethical and Regulatory Considerations

Own the Bone will be conducted in compliance with this Protocol, the Site Agreement, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

6.2 Institutional Review Board

Hospitals/Physicians will have the option to follow patients whose data is contributed to Own the Bone for approximately 60 to 90 days after their fragility fracture. Own the Bone will request Data that does not include identifying characteristics such as name, address, etc. As such, data collected by Own the Bone will constitute a "Limited Data Set" as defined by the federal HIPAA statute and regulations. Own the Bone is a quality improvement program that does not require administration of any specific medications or medical procedures, and specific patient identifiers are not collected. Each center should evaluate the need to obtain Institutional Review Board (IRB) approval. This program may be eligible for expedited review by the applicable IRB.

Participating centers will assign a unique identifying number. This identification number will be kept in the medical record of the participating center. Patient names will not be entered into the Own the Bone database. Participating clinicians will keep a log of their patients names and identification numbers.

Each participating center will receive two unique user names and passwords allowing access to the data registry as well as to a portion of the Own the Bone web site for subscribers of Own the Bone.

7 Statistical Analysis

In the first year, it is expected that data related to 400 fracture patients from 40 centers around the U.S. will be contributed to Own the Bone. All patient data will be collected by hospital personnel using Tempo, a proprietary web-based program designed to support registry data collection and reporting. The Clinipace Reporting System (CRS) will provide real-time online reports where summary statistics for each question on the case report form will be made available to each site summarizing the site's own data. Each site will also have access to a global summary report for aggregate Case Report Form Results nationally. This report will allow each site to compare their demographics and

outcome measures to participating centers nationally. These aggregated reports will be blinded such that no site will be able to identify other participating sites.

In addition, the Own the Bone Steering Committee and Multidisciplinary Advisory Board will determine specific multivariate analyses of interest, such as incidence of specific fracture types by sex or race or incidence of bisphosphonate use by age. Statistical reports for these desired analyses will also be provided for each site by CRS, again allowing the sites to compare their specific results to the overall registry results.

The OTB Steering Committee and OTB Multidisciplinary Advisory Board will also have the opportunity to identify and respond to research questions of interest and to publish the results. Using these data, it will be possible to examine associations between type of fragility fracture and variable such as demographic characteristics, BMD score, medication use, and counseling. Clinipace will provide biostatistical and epidemiological consultation to work with the AOA designated experts to identify research questions of interest, to carry out needed analyses, and text to support the publication process.

7.1 Analysis Population

Analyses will be conducted on all available data. It is anticipated that some eligible patients will have missing data for various measures. Each site shall comply with the participation requirements regarding eligible patients as well as its own internal compliance requirements.

7.2 Primary Analysis

The primary analysis will be based on data collected from registration through clinician/center follow up for individual patients (approximately 60-90 days after fracture). Specifically, the Own the Bone program will compute the number and percentage of eligible patients who:

- Received patient education/counseling (if applicable and not contraindicated) on
    - Calcium intake requirements and supplementation
    - Vitamin D intake requirement and supplementation
    - Regular weight bearing and muscle strengthening exercise
    - Fall prevention
    - Smoking cessation
    - Limiting excessive alcohol consumption
- Have had BMD/DXA scanning performed or scheduled
- Have had pharmacologic therapy initiated for low bone mass
- Have had a letter (Physician Letter) sent to his/her physician discussing the patient's fracture, diagnosis of and/or risk for low bone mass or osteoporosis and recommending evaluation and treatment

- Have been given a letter (Patient Letter) discussing their diagnosis and/or risk for low bone mass or osteoporosis and recommending evaluation and treatment.

8 Data Management

Identification of fragility fracture patients will occur through prospective identification of patients as they enter the participating hospital-based healthcare system. Centers will enter patient data into a secure internet-based electronic data capture tool with a streamlined electronic case report form. The designated individual each center will access the system to enter and review data using an account consisting of a username and password. The database will be housed in a physically and logically secure computer system maintained in accordance with a written security policy. The system meets approved federal standards for the security of health information and is validated. The CRF will only include data that meets the definition of a "Limited Data Set" under HIPAA.

9 Confidentiality

AOA will maintain confidentiality of information submitted to Own the Bone as required by the accompanying Site Participation Agreement ("Agreement'). AOA will only use or disclose information as permitted by this Protocol and the Agreement. Subjects will be identified only by unique subject number in Own the Bone Program database and AOA will not have access to the subject number key.

10 Program Effectiveness Evaluation and Improvement

Program evaluation is essential to the success of a quality improvement initiative. AOA Own the Bone program staff will conduct periodic Program Effectiveness Evaluations examining data on program participation, barriers to participation, inefficiencies, and problematic areas. Data will be evaluated from user interviews; reviews of aggregate data (e.g., performance measures, participation metrics), and system data for review of missing data fields and accessibility issues. The OTB Steering Committee and OTB Multidisciplinary Advisory Board will make changes to the program and this Protocol as appropriate following Program Effectiveness Evaluations.

11 Assessment of Safety

The design of this program is overseen by OTB Steering Committee and OTB Multidisciplinary Advisory Board. However, AOA takes no responsibility for safety events that occur in any Participating Site or with respect to any patients. Each participating Site and treating physician is responsible for reporting adverse events in connection with their own internal policies and practices.

12 Data Retention

Patient data will be aggregated in the database for the duration of this program. Upon completion of the program, the data will be securely retained for a time period in keeping with the Site Agreement and this Protocol, and as advised by the oversight boards of this program.

13 Disclosures

Own the Bone was developed by the American Orthopaedic Association (AOA) in response to the epidemic of fragility fractures in the US population. The AOA believes that orthopaedic surgeons must play a role to ensure a coordinated multi-specialty approach to osteoporosis care in patients after a fracture. The AOA has sought and obtained funding for Own the Bone from a variety of sources: medical center subscriptions, company and organization sponsorship, and non-profit organizations. Initial funding has been provided by Amgen, The Alliance for Better Bone Health: Sanofi Aventis and P & G Pharmaceuticals, Eli Lilly and Company, Novartis Pharmaceuticals and Synthes North America. Since funding for this program will be continuously solicited, a complete and up-to-date list of sponsors will be maintained on the Own the Bone Web site. While biopharmaceutical manufacturers of drugs may contribute financially to this quality improvement program, Own the Bone will adhere to evidence-based guidelines as stated herein.

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Appendices

Appendix A. Case Report Form (See attached.)

Appendix B: Table of Abbreviations

Table of Abbreviations

BMD	Bone Mineral Density
CFR	Code of Federal Regulations
CRF	Case report form
DXA	Central Dual X-ray Absorptiometry
EC	Ethics Committee
e-CRF	electronic case report form
EDC	electronic data capture
ERC	ethics review committee
FDA	Food and Drug Administration
FRAX	Fracture Risk Assessment Tool
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
ICH	International Conference on Harmonization
IRB	Institutional Review Board
NCQA	National Committee for Quality Assurance
NOF	National Osteoporosis Foundation
WHO	World Health Organization

Acknowledgements

Own the Bone™ Pilot Program Design Committee

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Joseph A. Buckwalter, MD- Chair
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- **SUNY Buffalo School of Medicine, Buffalo, NY**
  Lawrence Bone, MD, Cathy Buyea, MS
- **Loyola University Medical Center, Chicago, IL**
  Victoria Davidson-Bell, CNP, Terry Light, MD, Steven Rabin, MD, Anthony Rinella, MDM
- **Northwestern University Feinberg School of Medicine, Chicago, IL**
  Andrew Bunta, MD, Beatrice Edwards, MD, Lidia Andruszyn, DNP, APN, CNP
- **Rush University Medical Center, Chicago, IL**
  Patricia Piasecki, RN, Walter Virkus, MD
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  Bob DeMarco, RN, Maria Fiallos, RN
- **Truman Medical Center, Kansas City, MO**
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- **University of Iowa Health Care, Iowa City, IA**
  J. Lawrence Marsh, MD, Tess Sommer, RN
- **University of Maryland School of Medicine, Baltimore, Maryland**
  Sandra Brinson, Vincent D. Pellegrini, MD, Elizabeth A. Streeten, MD
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