

# MedCAC Meeting

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# OSTEOPOROSIS

- About 25 million Americans affected
- Occurs 4 times more often in women than men
- One third of women over 65 will have spine fractures, and 15% of white women will have hip fracture
- 10-15% of patients die within 6 weeks of hip fracture
- Can be treated and prevented if discovered before major bone loss occurs



# NIH Osteoporosis and Related Bone Diseases ~ National Resource Center

**Mission:** Expand awareness and enhance knowledge and understanding of the prevention, early detection, and treatment of these diseases as well as strategies for coping with them.

**Research Opportunities:**

How to target educational materials?

How are they accepted by diverse populations?

Do they make a difference?



# Research Opportunities

- Clinical studies -- Who to treat? What to treat them with?
- Prevention-identify high risk persons
  - More evidence is needed to determine the most opportune time for bone density testing for both men and women
  - Larger cohorts of men and racial and ethnic minorities need to be studied with regard to all factors – genetic, environmental – to determine susceptibility and risk factors



# Research Opportunities - continued

- Identify markers predictive of fracture risk
- Predicting fracture risk using ultrasound and MRI – bone quality
- Identify genes that affect bone mass and can be targeted for development of new Osteoporosis therapies. E.g.: how does LRP5 function to simulate bone growth?



# Research Opportunities - continued

- What to treat them with?
  - Use of bone morphogenetic proteins (or other osteoinductive proteins) to stimulate fracture healing or bony fusions
  - Combination therapies –
    - Optimum regimen of Vitamin D and Calcium
    - low dose hormone therapy and alendronate
    - Parathyroid hormone and alendronate
    - Cholesterol lowering statin drugs
- Behavioral Studies related to nutrition and exercise



# Osteoarthritis (OA)

- 20.7 million Americans-Pain and Dysfunction
- Affects the cartilage (soft tissue) that covers the ends of bones
- Cartilage normally cushions and protects the bones
- When it breaks down bones rub on bones
- 80% of people with OA find their movements or activities limited



# The Osteoarthritis Initiative Research Resources

- **Goal**
  - Create research resources to aid in identification and evaluation of biomarkers as candidates for surrogate endpoints for OA
- **Approach**
  - Develop a prospective, natural history cohort
    - 4,800 participants at high risk for developing knee OA
  - Collect clinical and imaging data and biological specimens
- **Status**
  - Enrollment has been completed
    - 12 and 24 month follow-up visits are underway
  - First public data release has occurred ([www.oai.ucsf.edu](http://www.oai.ucsf.edu))
    - Clinical/exam data and documentation available for ~2000 subjects
    - Complete image sets for a random sample of 200 subjects
    - All images available for users who supply a 1-2 Terabyte hard drive





# Research Opportunities in Osteoarthritis

- **Understanding cartilage:**
  - The effects of SERMS (raloxifene) on joint cartilage
  - Effect if doxycycline on enzymes that destroy cartilage
  - The effect of Bisphosphonate (risedronate) on symptoms and pathophysiology
  - Tissue engineering
    - Cartilage Cell Replacement
    - Stem cell transplantation
    - Gene therapy – to inhibit enzymes that help break down cartilage



# Research Opportunities in Osteoarthritis Continued

- Identification of risk factors-Prevention
  - Behavior changes related to obesity; exercise patterns
  - Environmental exposures – such as to heavy metals
- Clinical trials –
  - treatment of pain
  - Exercise – how much is beneficial? How much is too much?
  - Effect of Vitamin D on Knee OA



# Knee OA

- Evidence Report from AHRQ – Knee OA

## Conclusions:

Osteoarthritis of the knee is a common condition. The three interventions reviewed (intra-articular viscosupplementation; Oral glucosamine, chondroitin in combination; and arthroscopic lavage or debridement), are widely used in the treatment of OA of the knee, yet the best available evidence does not clearly demonstrate clinical benefit. Uncertainty regarding clinical benefit can be resolved only by rigorous, multicenter RCTs.

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# Research Opportunities in Knee OA

- Research opportunities:
  - Developing less invasive surgeries and better joint prostheses.
  - Modifications of joint replacement devices, including partial replacement
  - Metal-on-metal total joint replacements
  - Procedures that may replace lost or damaged joint cartilage
  - Investigate the role of exercise in protecting the knee

# Back Pain

- One of society's most common medical problems affecting an estimated 8 out of 10 people.
- Conditions of concern: Spinal stenosis; disc herniation; degenerative spondylolisthesis



# Research Opportunities - Low Back Pain

- Compare the effectiveness of surgery versus non-surgical treatment for low back pain
- Identify the best treatments for certain low back pain patients – which treatments will work well on who and why?



# Research Opportunities - Low Back Pain Continued

- What causes disc degeneration – test the effectiveness of lumbar fusion, artificial discs, and other treatments for disc-derived pain
- Disc arthroplasty for degenerative disc disease of the cervical and lumbar spine



*Thank you*

