The Treatment and Management of Osteopenia & Osteoporosis

“Integrated Medical Approach”

The Family Care Center of Harrah, Inc.

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Board Certified ~ Family Practice
Nationally Certified ~ FirstLine Therapy
(Therapeutic Lifestyle Choices)
Clinical Professor @ Large OSU-HSC
Integrated Medicine Specialist
Nationally Certified “Center of Excellence”
27-years of Community Service

The Family Care Center of Harrah, Inc.

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Administrative Owner - FCC of Harrah
Masters in Healthcare Administration
Nationally Certified ~ Lifestyle Educator
Nationally Certified ~ Program Coordinator
27-Years Clinical Management Experience
Business Integration Specialists
FirstLine Therapy ~ TLC Associate
Integrated Medical Facility

FCC has incorporated a number of different treatment options for the resolution of any number of medical Problems and health issues presented today.

FCC of Harrah, Inc.:
  Family Practice ~ Full Service
  OMM ~ Extended Services
  Therapeutic Lifestyle Choices ~ FLT
  Functional Medicine

The Mission!
Building Stronger Bones

Q & A

1. Why would a PCP consider treating Osteopenia or Osteoporosis with a natural prescription?

- A. Fewer side effects
- B. Better outcomes
- C. The patients are requesting the option
- D. I like learning new things
- E. All of the above
Q & A

2. Which of the following is true about Osteoporosis?

- A. 44 million Americans estimated to have low bone mass
- B. Women generally lose 1-2% of bone per year during and after menopause
- C. Men do not ever lose bone mass
- D. Bone Mineral Density and Urinary Deoxypyridinoline levels are used to diagnose bone loss
- E. A, B, and D only

Q & A

3. Osteoporosis by definition?

- A. Disease of the bone that leads to an increased risk of fracture
- B. Bone Mineral Density is reduced
- C. Bone micro architecture is disrupted and the amount and variety of proteins in bone is altered
- D. Can be prevented with lifestyle changes and sometimes medications
- E. All of the above

Q & A

4. Prescriptions Medications that cause bone loss include?

- A. Steroids in all forms
- B. Proton Pump Inhibitors
- C. Overcompensated thyroid prescriptions
- D. SSRIs
- E. All of the above
Q & A

5. Diseases that cause bone loss include

- A. Depression
- B. Hyperthyroidism
- C. GERD treated with PPIs
- D. Diabetes
- E. All of the above

Osteoporosis Facts

- 44 million Americans estimated to have low bone mass
- Women generally lose 1-2% of bone per year during and after menopause
- Nearly 1/3 lose bone at a faster rate, 3-4%/yr.
- Characterized by decreased bone mass, increased bone turnover, and increased susceptibility to fracture
- Mostly diagnosed by low bone mineral density (BMD)
- Also diagnosed and managed by biochemical markers (BC) of breakdown products such as Type I Collagen Cross-links, (Deoxypyridinoline)

Osteopenia

Osteopenia is a condition where bone mineral density is lower than normal. It is considered by many doctors to be a precursor to Osteoporosis. However, not every person diagnosed with Osteopenia will develop osteoporosis.

Wikipedia (2010)
Osteoporosis

Osteoporosis is a disease of bone that leads to an increased risk of fracture. In osteoporosis the bone mineral density (BMD) is reduced, bone micro architecture is disrupted, and the amount and variety of proteins in bone is altered. Osteoporosis can be prevented with lifestyle changes and sometimes medication; in people with osteoporosis, treatment may involve both. Lifestyle change includes exercise and preventing falls; medication includes calcium, vitamin D, bisphosphonates and several others.

The Family Care Center of Harrah, Inc.

Osteopenia/Osteoporosis Management and Treatment Data Collection Program Outline.

Guidelines of the Data Collection...
* The Historic Foundation of Treatment of Osteoporosis in our practice
* Guidelines of the Data Collection
* Osteopenia and Osteoporosis – Basic Information
* Diseases that Cause Bone Loss
* Medications that Cause Bone Loss
* DPD Collection Protocols

Practice History

* Nearly 1,000 patients in the past 24 months with the diagnosis of Osteopenia and Osteoporosis.
* Treated and Managed associated fractures leading to painfully modified lives or loss of life.
* The treatment of Osteopenia and Osteoporosis has become very important to me.
* Family History – all my grandparents had Osteoporosis that disabled them and/or took their lives and my parents were next in line.
* Therefore, when bisphosphonates became available, the patients identified as appropriate candidates were screened on the most sensitive BMD testing equipment I could find in our area.

* Many were treated with bisphosphonates and/or selective estrogens receptor modulators and calcium 1200-1500 mg in two divided doses with vitamin D 1000 IU per day.

* As the treatment revolution (2004) continued a local pharmacist introduced me to a supplement that contained Calcium, Vitamin D, and Hydroxyapatite.

  * Vitamin D (as cholecalciferol) [600.00 IU]
  * Calcium (as MCHC) [604.00 mg]
  * Phosphorus (as MCHC) [137.00 mg]
  * MCHC [3036.00 mg]

* This supplement was incorporated in combination with the bisphosphonates. Patients that chose this course of treatment began to experience remarkable positive changes on their BMD Studies.

* Eventually, our society reported that many people on bisphosphonates were experiencing poor dental healing and mandibular bone loss. We made an intentional change from bisphosphonates to a CMC compound of Calcium, Vitamin D, and Hydroxyapatite combination only.

* The bone density studies were as good and often better than the studies with the bisphosphonates.

Guidelines of the Data Collection...

1. Documents for the patients in the study include;
   "Historic Foundation of Treatment of Osteoporosis in the FCC of Harrah, Inc."
   "Osteoporosis" Information from Your Health Care Provider
2. Baseline Bone Density Study.
3. Baseline DPD.
4. Instruction will be given for dosing of C-CMC following results of #2 and #3 above.
5. Instruction will be given after each DPD result.
6. If unable to follow instruction given #4 and #5, please explain why.
7. Please schedule appointments and expect reminder calls for all DPD testing.
8. Remember this is a data collection and consistency is necessary.
9. Remember this is a Data Collection and if you plan to discontinue we will need to know that you plan to discontinue and why.
11. Please report any improved symptoms.
Osteopenia and Osteoporosis Basic Information

DESCRIPTION
Loss of normal bone density, bone mass, and bone strength. Osteoporosis (porous bones) is a progressive disease that leads to increased thinning of bones and risk of fractures (broken bones). It occurs in both sexes, but is most common in women after menopause due to a decrease in the hormone estrogen. Estrogens protect against bone loss.

FREQUENT SIGNS AND SYMPTOMS
Osteoporosis does not cause pain, and there are usually no obvious symptoms. It is called a "silent" disease.
People don't realize they have osteoporosis until they fall and suffer a fracture, or a spontaneous fracture occurs to a shock-bone. Pain from fractures may be mild to severe. The pain may stop when the fracture heals or it may be chronic due to permanent bone damage.

CAUSES
Loss of bone mass and density occurs due to a decrease of calcium (a mineral) and other substances that are needed for maintaining bone strength. A number of risk factors can contribute to the decrease.

RISK INCREASES WITH
- Females; advanced age; Asian or white persons.
- Early menopause (either naturally or due to surgery).
- Lack of exercise (sedentary lifestyle).
- A broad range of diseases and drugs.
- Poor nutrition. Lack of calcium, protein, and vitamins.
- Women with a small body frame or are quite thin.
- Eating disorders (bulimia or anorexia).
- Family history of osteoporosis.
- Smoking.
- Excess alcohol use.
- Men with low testosterone levels.

PREVENTATIVE MEASURES
Preventative measures need to start at a young age.
Adequate calcium intake (1200 to 1500 mg a day) with milk and dairy products or calcium supplements.
Regular exercise, such as walking (which is weight-bearing, and is better for preventing osteoporosis).
Avoid risk factors such as alcohol and smoking.
Preventative drugs may be prescribed in high-risk cases.

EXPECTED OUTCOME
There is no cure for osteoporosis. Treatment (no matter what age) can help halt and may reverse some bone loss. Pain symptoms can usually be helped with drugs.

POSSIBLE COMPLICATIONS
- Falls and bone fractures, such as hip, spine and wrist.
- Severe, disabling pain.
- Deformed spinal column and bent back (sometimes called Dower hump). Loss of height.

Diseases that Cause Bone Loss

- Anorexia Nervosa
- Depression
- Multiple Myeloma
- Weight Loss
- Eating disorders
- Emphysema
- Diabetes mellitus
- Lymphoma
- Multiple sclerosis
- Poor diet
- Prostate cancer
- CVA
- Inflammatory Bowel Disease
- Blood & Bone Marrow Disorders
- Gastrointestinal Bypass Procedures
- Osteopenia and Osteoporosis Basic Information, cont...

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- Blood & Bone Marrow Disorders
- Gastrointestinal Bypass Procedures
Medications that can Cause Bone Loss

- Methotrexate
- Tamoxifen
- Heparin
- Lithium
- Antacids
- Antiseizure Medications
- Thyroid hormones ~ in excess
- Cancer Chemotherapeutic Drugs
- Cyclosporine A and FK506 (Tacrolimus)
- Glucocorticoids such as: Cortisone and Prednisone
- GnRH such as: Lupron and Zoladex
- Medroxyprogesterone Acetate for contraception ~ Depo-provera
- Aromatase inhibitors such as: Femara, Arimidex, Aromasin
- PPI's such as: Nexium, Prilosec, Prevacid
- SSRI's such as: Lexapro and Zoloft
- Thiazolidinediones such as: Actos and Avandia
- Thyroid hormones ~ in excess

DPD Data Collection Program

**DPD Collection Technique**

1. 1st or 2nd morning void.
2. Use conical cup to catch the specimen.
3. Transfer to 10cc tube and cap tightly (Small amount of urine is needed) Fill the tube 1/2 full (5cc) (An extra twist will prevent leaks)
4. Print on the identification label: name, date and time of urine collection
5. Affix the label to the tube

Submission of DPD Test

1. Complete the patient information section of the requisition form
2. State:
   - How long the patient has been using C-CMC?
   - First date of use of C-CMC?
   - How long they have taken it consistently?
   - Most recent date and time of use?
3. State the dosage: One or two packets per day
4. Use of prednisone?
5. Use of steroid nasal sprays?
6. Use of antacids (including Tums)?
7. Use of proton pump inhibitors (acid suppressors)?
8. Wrap tube in pink absorbent paper and place in zip lock bag for mailing
9. Affix prepaid lab address label to mailing envelope, seal and mail
DPD
Deoxypyridinoline

Also called D-Pyrilinks or Pyrilinks-D:

Is a crosslink of type I collagen present in bone which is excreted unmetabolized in urine and is a specific marker of bone resorption. It is measured in urine tests in patients when osteoporosis is suspected. (FDA Approved, April 1994. DPD was also used in clinical trials of bisphosphonates).

Post-Marketing Experience of Bisphosphonates

The following Adverse Reactions have been reported in post-marketing use:

Body as a Whole: hypersensitivity reactions including urticaria and rarely angioedema. Transient symptoms of myalgia, malaise, articularia and rarely, fever have been reported with FOSAMAX, typically in association with initiation of treatment. Rarely, symptomatic hypocalcemia has occurred, generally in association with predisposing conditions. Rarely, peripheral edema.

Gastrointestinal: esophagitis, esophageal erosions, esophageal ulcers, rarely esophageal stricture or perforation, and oropharyngeal ulceration. Gastric or duodenal ulcers, some severe and with complications have also been reported (see WARNINGS, PATIENT INFORMATION, and DOSAGE AND ADMINISTRATION).

Localised Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection with delayed healing, has been reported rarely (see PRECAUTIONS, Dental).

Musculoskeletal: bone, joint, and/or muscle pain, occasionally severe, and rarely incapacitating (see PRECAUTIONS, Musculoskeletal Pain); joint swelling; low-energy femoral shaft and subtrochanteric fractures. Nervous system: dizziness and vertigo.

Skin: rash (occasionally with photosensitivity), psoriasis, hyperpigmentation, rarely severe skin reactions, including Steven-Johnson syndrome and toxic epidermal necrolysis. Special Senses: rarely otitis, scleritis or episcleritis.
Post-Marketing Experience of **CMC**

The following **Side Effects** have been reported in post-marketing use:

* Decrease in DPD,
* Increase in BMD,
* Reduction Fine Lines & Wrinkles,
* Thicker Hair,
* Increase strength & Flexibility,
* Increased quality of Life,
* Total Musculoskeletal Strengthening

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**Fractures Associated with Osteoporosis**

_Jumped 55 Percent from 1995 to 2006_

“Osteoporosis is primarily a disease of elderly women: about 90% of those with injuries.”

July 21, 2009 - The hospitalization rate of patients admitted for treatment of hip, pelvis and other fractures associated with osteoporosis increased by 55 percent between 1995 and 2006. And, about 90 percent of these patients were senior citizens and almost all of these were women, according to the latest News and Numbers from the Agency for Healthcare Research and Quality.

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**Best assessment of fracture risk may be made by BMD along with Biochemical Marker of bone turnover.**

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*Bone Mass in Women*
**Preliminary Study Efficacy**  
*C- CMC*  
Osteopenia Clinical Study (Spector et al.)

Double blind, randomized placebo-controlled study  
- 136 (out of 184) women with Osteopenia  
  - T-score spine < -1.5  
- Placebo: 1000 mg Ca and 800 IU Vit D3  
- 3 active: Ca/Vit D3 plus 3mg Si, 6mg Si, 12mg Si as ch-OSA® liquid  
- 12 months supplementation  
- Parameters  
  - Markers of bone turnover = primary study objectives  
  - Bone mineral density (BMD)

**Parameters**

- Markers of bone turnover = primary study objectives  
- Bone mineral density (BMD)

**Conclusion**

- ch-OSA® increases procollagen marker  
- ch-OSA® increases bone mineral density in femur

Present Form of Treatment:

Currently we treat this patient population with a C-CMC which contains:
- Microcrystalline Hydroxyapatite Concentrate (MCHC),
- Calcium (as MCHC),
- Vitamin D3 (Cholecalciferol), and
- Silicon (as Choline-Stabilized Orthosilicic Acid),

which helps to improve the flexibility of our bones.

C-CMC

Supplement Facts

<table>
<thead>
<tr>
<th>Active Ingredients in MCHC: Bio-identical to Bone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral Complex (Hydroxyapatite) ✓</td>
</tr>
<tr>
<td>Calcium ✓</td>
</tr>
<tr>
<td>Phosphorous ✓</td>
</tr>
<tr>
<td>Trace Minerals ✓</td>
</tr>
<tr>
<td>Protein ✓</td>
</tr>
<tr>
<td>Biologically Active Growth Factors</td>
</tr>
<tr>
<td>Type I Collagen ✓</td>
</tr>
<tr>
<td>Bone Amino Acids ✓</td>
</tr>
<tr>
<td>Chondroitin Sulphate ✓</td>
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</tbody>
</table>
C-CMC  
Collagen – Complex Mineral Compound

MCHC, a superior, comprehensive bone support formula that undergoes proprietary standardized extraction from one of the world’s safest, most natural, premium sources of bone. This complex compound contains microcrystalline Hydroxyapatite, a crystalline calcium and phosphorous matrix in the ideal physiological ratio of 2:1; bioactive growth factors and type I collagen. Amino acids, glycosaminoglycans and a broad range of essential trace elements are also present with clinically tested ch-OSA®, which help to increase the number of collagen strands (posts) and thereby helps increase your bone mineral density (BMD).

The Vital “Vitamin D / Calcium” Interplay
Vitamin D regulates calcium and phosphate metabolism, controlling both the absorption and “distribution” of calcium. Vitamin D regulates the flux of phosphate between three target tissues: bone (storage), gut (absorption/excretion of non-absorbed) and kidney (excretion of absorbed). That’s why without sufficient vitamin D, bones can become thin, brittle, or malformed.

Optimize Calcium Absorption and Utilization Vitamin D3
21st Century Vitamin D Deficiency
Today’s lifestyle, worries about skin cancer and wrinkling, the wide use of sunscreen, and a poor diet puts people at risk for Vitamin D deficiency.

In fact, research shows that over 70 percent of women ages 51-70 and nearly 90 percent of women over 70 are not getting an adequate intake of vitamin D. Low levels of vitamin D are associated with reduced calcium absorption, bone loss, and increased risk of fracture.
Inside bone, calcium binds to Collagen

Less collagen = Less surface area for calcium to bind to
More collagen = More surface area for calcium to bind to

Use of Biochemical (BC) Bone Markers in the Management of Osteoporosis

- The higher the bone remodeling and bone loss rates, the greater the concentration of bone biochemical markers in urine or serum
- BMD is the best surrogate marker of fracture risk, however change in BMD during therapy is a poor predictor of fracture risk
- Decreases in BC markers can account for 40-70% of the observed anti-fracture efficacy
- Data suggest changed in BC markers during treatment can predict subsequent reductions in fracture risk independent of BMD
Tracking Methods Used

DPD ~ “Deoxypyridinoline” Urine Test (Aeron Labs)
A urine specific marker for bone resorption (bone density loss). A test greater than 6.5 indicated increased bone loss. As we gain experience and review more outcomes in our patient population our DPD lab value target has become closer to 4.0.

Following are the current Case Studies now into our 8th month of treatment and Data Collection with C-CMC.

Case Study #1
Female ~ 60 yrs
Osteoporosis
Treatment: C-CMC 1 pk qd (maintenance dose)

Reported Outcomes: ~ Patient Reported
- Increased Appetite/Weight Gain (8 lbs)
- Prefers C-CMC vs. Bisphosphonates
- Hair is thicker per stylists
BMD -3.3 Lumbar; -2.2 Hip

<table>
<thead>
<tr>
<th>Date</th>
<th>DPD</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/17/09</td>
<td>6.1</td>
<td></td>
</tr>
<tr>
<td>3/18/10</td>
<td>5.8</td>
<td>-18%</td>
</tr>
</tbody>
</table>

Case Study #2
Female ~ 73 yrs
Osteoporosis
Treatment: C-CMC 1 pk bid (Treatment Dose)
8/17/09

Lifestyle: Consumes Alcohol Daily
BMD 8/09, -2.9

<table>
<thead>
<tr>
<th>Date</th>
<th>DPD</th>
<th>% Change</th>
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<tbody>
<tr>
<td>8/17/09</td>
<td>10.6</td>
<td></td>
</tr>
<tr>
<td>9/17/09</td>
<td>11.9</td>
<td></td>
</tr>
<tr>
<td>10/20/09</td>
<td>12.4</td>
<td>+17%</td>
</tr>
</tbody>
</table>
Case Study #2
Female ~ 73 yrs
Osteoporosis
Treatment: C-CMC 1 pk bid (Treatment Dose) [8/17/09]
Lifestyle: Consumes Alcohol Daily
BMD 8/09, -2.9

<table>
<thead>
<tr>
<th>Date</th>
<th>DPD Rate of Bone Loss</th>
<th>% Change</th>
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</thead>
<tbody>
<tr>
<td>12/09/09</td>
<td>15.5</td>
<td></td>
</tr>
<tr>
<td>1/22/10</td>
<td>7.9</td>
<td></td>
</tr>
<tr>
<td>2/22/10</td>
<td>13.4</td>
<td>-21% Net</td>
</tr>
</tbody>
</table>

Case Study #3
Female ~ 63 yrs
Osteoporosis,
Treatment: C-CMC 1 pk bid (treatment dose)
Condition: Overcompensated Hypothyroidism, Low TSH [3/29/10]
BMD 3/5/09, -2.3 wrist, -1.4 lumbar/hip

<table>
<thead>
<tr>
<th>Date</th>
<th>DPD Rate of Bone Loss</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/07/09</td>
<td>8.0</td>
<td></td>
</tr>
<tr>
<td>12/03/09</td>
<td>10.7</td>
<td></td>
</tr>
<tr>
<td>01/22/10</td>
<td>10.3 – 11.2</td>
<td>-28.6%</td>
</tr>
</tbody>
</table>

Case Study #4
Female ~ 70 yrs
Treatment: C-CMC 1 pk qd (maintenance dose)
Condition: Hypothyroidism, Self-Dc's Thyroid Supplement 12/09 – general health declined until 3/5/10, Restarted Thyroid Supplement
Normal (H/O Osteopenia)
BMD 3/24/09, -0.7

<table>
<thead>
<tr>
<th>Date</th>
<th>DPD Rate of Bone Loss</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/15/09</td>
<td>5.5</td>
<td></td>
</tr>
<tr>
<td>03/08/10</td>
<td>3.7</td>
<td>-33.8%</td>
</tr>
</tbody>
</table>
Case Study #5

Female ~ 83 yrs
Osteopenia, Dx; L, Wedge Compression Fracture
Treatment: C-CMC 1 pk bid (Treatment Dose) 2 mths
1 pk qd (Maintenance Dose) 2/12/10
Reported Outcome: Reduced Pain
Condition: Total Knee 2/09, Hypothyroidism, NIDDM, T12 Compression Frx, Lumbbar Stenosis, Gout
BMD 8/24/09 0.2 Hip, 0.7 Femoral Neck, 0.9 Trochanteric Reg.

<table>
<thead>
<tr>
<th></th>
<th>08/20/09</th>
<th>11/02/09</th>
<th>02/02/10</th>
<th>% Change</th>
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<tbody>
<tr>
<td>DPD Rate of Bone Loss</td>
<td>7.0</td>
<td>6.1</td>
<td>4.4</td>
<td>-37.14%</td>
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</table>

Case Study #6

Female ~ 52 yrs
Osteoporosis
Treatment: C-CMC 1 pk bid (Treatment Dose)
Conditions: Early Menopause, Small Stature, Seizure Disorders, Depression, Post Menopausal
Lifestyle: Nicotine Dependent
Reported Outcomes: None Negative, Increases energy, Increased Endurance
BMD 09/03/09, -3.0

<table>
<thead>
<tr>
<th></th>
<th>09/04/09</th>
<th>03/10/10</th>
<th>% Change</th>
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<tbody>
<tr>
<td>DPD Rate of Bone Loss</td>
<td>12.1</td>
<td>4.9</td>
<td>-40.50%</td>
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C-CMC and DPD

<table>
<thead>
<tr>
<th>DAYS ON C-CMC</th>
<th>% Change In DPD</th>
</tr>
</thead>
<tbody>
<tr>
<td>CASE 1</td>
<td>-38%</td>
</tr>
<tr>
<td>CASE 2</td>
<td>+22%</td>
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<tr>
<td>CASE 3</td>
<td>+28.6%</td>
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</table>
## C-CMC and DPD

<table>
<thead>
<tr>
<th>DAYS ON C-CMC</th>
<th>% Change In DPD</th>
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<tbody>
<tr>
<td>CASE 4</td>
<td>120</td>
</tr>
<tr>
<td>CASE 5</td>
<td>120</td>
</tr>
<tr>
<td>CASE 6</td>
<td>80</td>
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</tbody>
</table>

## Summary

This summary is of the entire patient population who are currently taking part in our data collection, and their current progress.

- Total Number Improved & < 6.5 DPD: 34
- Total Number Condition Worsened: 12
- Total Number 1 Sample Only: 22
- Total Enter & Remained < 6.5 DPD: 3
- Total Entered and Remained < 7.0 DPD: 1
- Total Withdrawn: 21

## Summary Explanation

- **Total Number Condition Worsened**: 12
  - Cancer Related: 3
    - 1 taking Femora & only 1 C-CMC Pk per day
    - 1 takes Rituxan, Nasacort & Zegrid
    - Plus recent Hip Fracture
    - 1 Taking an excess of Acid Suppressors
    - Currently working up and preliminary findings show rectal squamous cell and 2 abdominal masses.
    - Not consistent [various reasons]
    - Some taking PPI's, SSRI's, Steroid Asthma inhalers: 3
    - HCG diet with 500 cal/day limit: 1
Summary Explanation

~ Reduced MCHC Component 2

~ Taking 1 C-CMC pk/day, SSRI, Prednisone (started Prednisone 3/10/10), Anticonvulsant 1

~ Stopped HRT due to recent Dx C.A.D. 1

~ Unknown 1

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Dexa Comparative Value

When considering the means by which to monitor these patients on a month to month basis we decided with the accuracy of testing, speed of results, as well as the cost factor difference it was appropriate to use the DPD testing exclusively. However, for an example we have data on a patient that reflects the positive relationship between DPD and Dexa values.

As DPD improve, Dexa scores also improve.

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Case Study

C-CMC @ 6 months/Deoxypyridinoline

Female; 65 yrs, osteoporosis, BMD improvement;

**DEXA - 3.7 to -2.8**

<table>
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<tr>
<th></th>
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<th>7/17/08</th>
<th>10/18/08</th>
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</tr>
</thead>
<tbody>
<tr>
<td>DPD: Rate of bone Loss</td>
<td>7.50</td>
<td>6.50</td>
<td>4.90</td>
<td>-24.62</td>
</tr>
</tbody>
</table>
Conclusion

In conclusion, taking into consideration adjustments made in dosage recommendation and outcome predictability, we are seeing significant changes in Bone Strength and Bone Growth by deceases in DPD Scores, as much as a 73% success rate in as little as 30-days in our patient population. We currently have approximately 125 patients in this program and have identified as many as 752 more that we are looking forward to treating with as much success. We have experienced 3,054 patient visits for these and related disease states since 1/1/08.

There is much more work ahead.

So....

Don’t let your patients get caught just sitting around as their bones weaken!

Fully Integrated Medicine

What if we applied an Integrated Medical Model to all the medical conditions of a patient?

Questions:

Is it practical to use an Integrated approach in this way?
Is it difficult to incorporate and Integration Medical Model?
Is it difficult to Manage?
Is it financially feasible to practice inside this model?
And: The Number One concern;
Is it more beneficial for the patient population as a whole?
Is it practical to use an Integrated approach in this way?

FCC of Harrah, Inc.:
Family Practice - Full Service
OMM - Extended Services
Therapeutic Lifestyle Choices - FLT
Functional Medicine

By evaluating the “tools” currently in your medical treatment tool box you simply “add” an TLC/FLT/FM tool to that collection of resources. As with any other form of treatment you must familiarize yourself with your choices per illness or disease state.

It's as easy as any other “Referral”, except as in our office, it's an "Internal Referral."

Is it difficult to incorporate and integration Medical Model?

The “Referral” or during your “Exam Time”

Once you've familiarized yourself with the choices per illness or disease state the process of initiating this as simple as referring the patient to one of two places:

An on staff person who works within the protocols of this program
OR
Simply choose an illness appropriate pharma-superior supplement or medical food. Treatment during your OV comes as your knowledge level grows concerning TLC/FLT/FM treatment options.

Currently, The FCC of Harrah utilizes some 250+ pharma-equivalent supplement of medical food in our TLC/FLT/FM Department which is managed by a National Certified Staff Member.

Therapeutic Lifestyle Choices - FLT
Functional Medicine

As directed by our Provider Core our Nationally Certified Director of this department works off of a set of protocols and within her certification as a Staff Lifestyle Educator.

Because this department operates under the oversight of Dr. Lacefield every Internal Referral for an Office Visit scheduled and performed by our Certified Lifestyle Educator is billed as an "Incident To Service" according to Medicare guidelines. This is likened to the oversight of a Physician who employs an extender whether it’s a PA or NP.

These OV’s are traditionally scheduled for 1 hour with the LE or staff member trained and assigned to this function. Forty-five minutes for the OV and 15 minutes for charting.

In order for this to be billed appropriately full vital signs and patient documentation is required – it is a patient visit (cpt 99214).
Is it difficult to Manage?

Because this type of treatment approach is simply an augmentation or addition to your current treatment options it requires very little to initiate.

- Create a new tab in chart for access or tracking purposes
- Develop and implement a modified “Routing Slip” or Super Bill
- Add appropriate line item to your Fee Schedule
- Start with one or two disease states
- Acquire appropriate staff training and certification of desired
- Develop your personal treatment protocols for your staff to follow

Is it financially feasible to practice inside this model?

Start up: Practice Integration Cost – Varies but unremarkable.

Additional OV’s alone…

<table>
<thead>
<tr>
<th>Year</th>
<th>PV</th>
<th>Gross Receipts (GR)</th>
<th>AGPP</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>168</td>
<td>$3,112</td>
<td>$54</td>
</tr>
<tr>
<td>2007</td>
<td>1365</td>
<td>$273,718</td>
<td>$219</td>
</tr>
<tr>
<td>2008</td>
<td>1767</td>
<td>$237,059</td>
<td>$156</td>
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<tr>
<td>2009</td>
<td>2899</td>
<td>$288,100</td>
<td>$111</td>
</tr>
<tr>
<td>2010</td>
<td>YTD</td>
<td>$142,781</td>
<td>$112</td>
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</tbody>
</table>

Estimated 2010 Totals:

<table>
<thead>
<tr>
<th>PV</th>
<th>GR</th>
<th>AGPP</th>
</tr>
</thead>
<tbody>
<tr>
<td>2659</td>
<td>$299,840</td>
<td>$145</td>
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</tbody>
</table>

Is it financially feasible to practice inside this model?

Additional Collections associated with pharma-equivalent pharma-superior supplement or medical food alone.

<table>
<thead>
<tr>
<th>Year</th>
<th>Collections</th>
<th>GR</th>
<th>AGPP</th>
</tr>
</thead>
<tbody>
<tr>
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<td>$49,091</td>
<td>$3,112</td>
<td>$52,203</td>
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<tr>
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<tr>
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<tr>
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<td>$480,922</td>
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<tr>
<td>2010</td>
<td>$142,781 YTD</td>
<td>$299,840</td>
<td>$486,370</td>
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</tbody>
</table>

These are Gross Numbers. Every office will have to apply their own Over Head percentage to determine true bottom line impact – Net Values. Professional Service Industry will run around 50% OH.
The **Number One** concern:
Is it more beneficial for the patient population as a whole?

Case Study #999
Male:
49 Years Old
Hypothyroidism, NIDDM, Hyperlipidemia, Vitamin D Deficiency

<table>
<thead>
<tr>
<th>Date</th>
<th>Weight</th>
<th>Blood Pressure</th>
<th>Glucose</th>
<th>HA1c</th>
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</thead>
<tbody>
<tr>
<td>3/1/10</td>
<td>347</td>
<td>158/100</td>
<td>223</td>
<td>10.1</td>
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<tr>
<td>4/1/10</td>
<td>327</td>
<td>130/80</td>
<td>140</td>
<td>7.6</td>
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<tr>
<td>6/1/10</td>
<td>307</td>
<td>128/78</td>
<td>148 (random)</td>
<td></td>
</tr>
</tbody>
</table>

Supplement – Treatment Plan
Pharma-Equivalent or better Supplement or Medical Food:
- Detox Meal Replacement
- CoQ10
- Cardiac Support
- Rx strength Vit D
- Kinase Receptor Enhancer
- Mitochondrial Kit
- Mineral Pack with Fish Oil
- Exercise
- Side Affects - None

Thank You!

Dr. Lacefield and I want to thank you for letting us share our experiences, patient outcomes and the positive affects that the Integrated Approach has offered our patient population.

We wish God’s best for you and your practice in this most interesting healthcare environment.

Contact Information:
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405/454/6058