

- My Practice: Really Unhealthy People & Really Healthy People
- Including Senior Skiers
- Over 1,000 people turn 65 every day in the US.



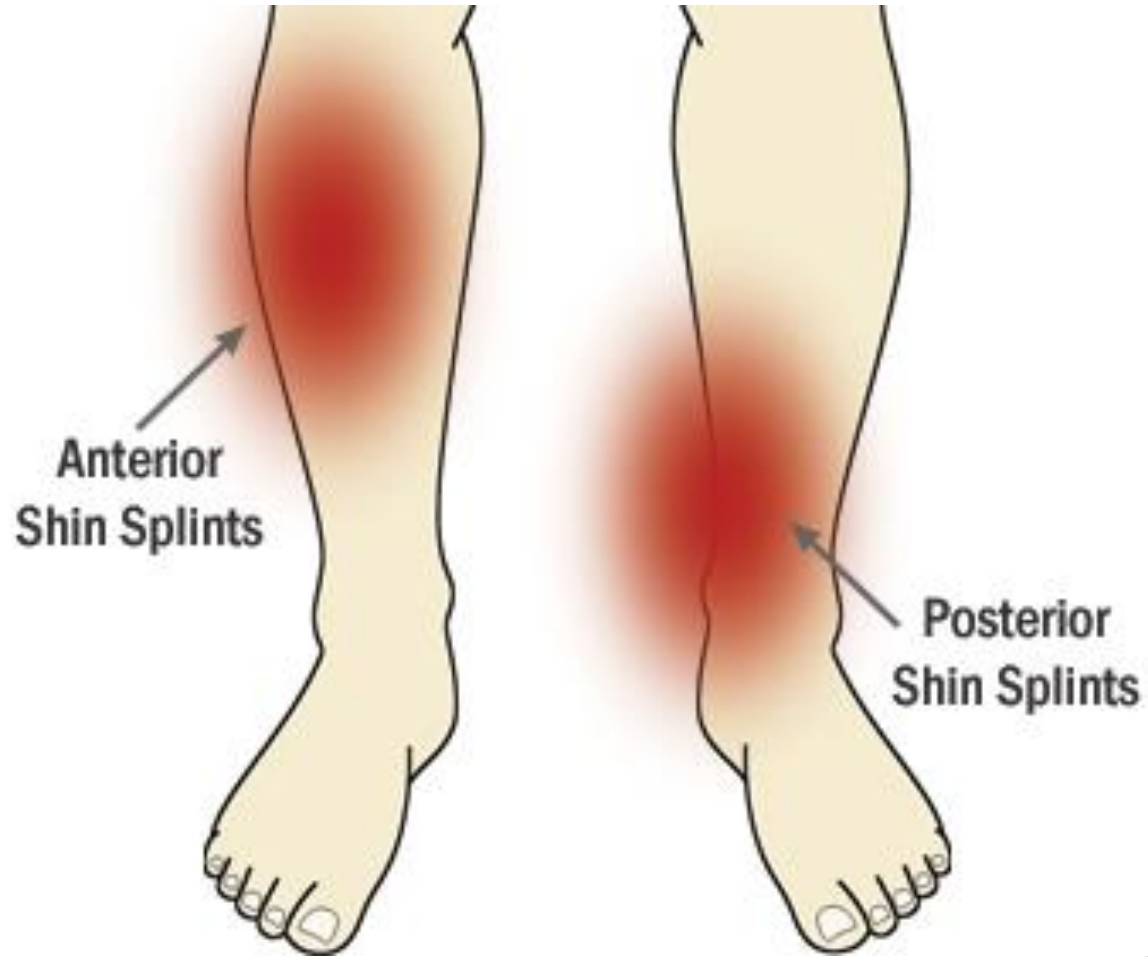
- How Do I make the most of my really healthy population when they get foot & Ankle Problems?

- They don't want surgery, they have a competition next Saturday!

Think about the options you currently have to offer a patient, whether on junior swim team, a runner, a high school basketball player hoping to get a scholarship, the tennis club coach, or a travel soccer kid hoping to be the next Olympic athlete from your state....

- You have a highly motivated, routinely active and competitive patient, coming with questions, wanting to try whatever will help them recover most rapidly. They want the safest treatments to stay active, fit and focus on returning to sports.

Or they've been training for the 100 mile Long Trail Ride over the mountains on their cycle too aggressively, without a balanced work out..
What are you going to do?



- How do we prevent this happening at the tennis club during Senior Singles Competition?.....

Achilles Rupture



Conventional aka Standard Medicine “ Western Medicine”

▶ Inflammation Treatment

▶ Anti-inflammatories

▶ R-I-C-E

▶ Steroids

▶ Injections : Dexamethasone

▶ Topical : Betamethasone

▶ Oral: methylprednisone

▶ IV: Prednisone

▶ Nonsteroidal Anti-inflammatories

▶ Injection: Ex: diclofenac

▶ Topical Ex: Diclofenac

▶ Oral: Ex: Ibuprofen

▶ Pain Treatment

Analgesics : Non opioid

Non aspirin NSAIDS

Aspirin

Acetaminophen

Opioid : narcotics

Anesthetics

▶ Topical: Ex: lidocaine

▶ Injectable : Ex: bupivacaine

▶ Gas: Halothane

▶ IV: Ketamine

Safety of What We do Every Day in “ Western Medicine”

- 70 Million NSAID Scripts in the US /year

30 Billion doses of OTC NSAIDS taken in the US / year

And they Read Headlines like these....

FDA Drug Safety Communication: FDA strengthens warning that non-aspirin non steroidal anti-inflammatory drugs (NSAIDs) can cause heart attacks or strokes...

*Can occur as early as the 1st week of use

*risk range: 10-50% increased risk depending on drug & dose.

100,000 hospitalizations NSAIDS as a factor & 16,000 deaths/ year

Poison Control handled 105,545 NSAID cases in 2014

1,352 Moderate Toxicity events (hospitalized) as only cause of event

85 Major toxic events as only cause of event, including death.

Ketorolac tromethamine (Toradol)

- Ketorolac tromethamine
- (NSAID) with μ receptor action, addictive.
- Indication: oral < 5 days (short-term) adults management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation treatment following IV or IM dosing of Ketorolac tromethamine, if necessary.
- Not for pediatric patients
- Limit total combined duration of use to < 5 days.

NOT indicated for minor or chronic painful conditions.

- Increasing dose > 40 mg/qd in adults has no increase in efficacy - only increases risk of serious adverse events.

What About the Corticosteroids?

An overview

- ▶ Corticosteroids: -decrease endogenous cortisol production via suppressing the hypothalamus-pituitary-adrenal axis.
- ▶ Methylprednisolone has cross-reactivity of its metabolites including the methylprednisone, methylprednisone acetate, 20 dihydroxy methylprednisolone, 20 dihydromethylprednisone.
- ▶ Doses cleared from the system in approximately 3-5 days.
- ▶ Serum level is not just injection- dose dependent:
- ▶ Injecting 80 mg in 1 knee has less than half the area under the curve as injecting 80 mg total as 40 mg ×2 knees. i.e. it is not the dose as much as how many locations that impact the serum level.
- ▶ But steroids thin skin and make us more susceptible to infections.. from tinea to yeast infections

So what are you going to do for these folks when they get tendinitis that won't go away? Steroids?

So they can get thin skin that bruises easily while they play volleyball? Or have to stay out of the pool and then get stiff from their arthritis?



Besides, how safe are the Corticosteroids?

- ▶ Safety and efficacy of long-term intra-articular steroid injections and osteoarthritis of the knee: A randomized, double-blind, placebo controlled trial.
- ▶ Triamcinolone acetonide 40 mg vs saline OA knee injection q 3 mo x 2 years, 68 patients.

No difference in space changes to knee, significant pain and stiffness and ROM difference between triamcinolone acetonide injection and saline injection.

- ▶ O.k, so they work. But they have side effects.

WOMAC index (pain scale) measured joint space changes on WB flouro XR semi flexed knee (radiograph)

J Raynaud, C Buckland-Wright, R Ward, D. Choquette, B. Haraoui, J. Martel- Pelletier, I Uthman, V. Khy, J.Tremblay, C. Bertrand, J. Pelletier

Arthritis and Rheumatology, volume 48, issued 2, February 2003 pages 370-377

Glucocorticoids adrenocortical steroid

- ▶ Crystalloid + Ionic mix
 - ▶ Betamethasone Sodium phosphate + betamethasone *acetate* injectable suspension (Celestone Soluspan)
 - ▶ Available in multiple strengths
 - ▶ May leave crystals in the injected site, like a depot, that dissolves after the 5 days.
 - ▶ Could lead to positive drug testing by WADA* for competitive athletes.
 - ▶ *World Anti-Doping Agency
- ▶ Ionic
 - ▶ Dexamethasone *phosphate*
 - ▶ Leaves no crystals in the injected area.

And how long do steroids stay in the system?

- ▶ Methylprednisolone acetate- 40 m/ml
- ▶ Serum methylprednisolone levels post intra-articular injection of methylprednisolone acetate evaluation.
- ▶ A 40 mg / knee injection had Peak serum level 2-12 hour post injection
- ▶ Dose increase corresponded to a higher serum dose concentration and higher peak concentration
- ▶ Oh, and Serum cortisol level suppressed for up to 1 week, all doses tested.

RD Armstrong, J English, T Gibson, J Chakraborty and V. Marks

Annals of the rheumatic diseases, 1981, 40, 571-574

Steroids 101

► Indications

- Allergic states
- Dermatological diseases, especially bullous dermatoses
- Endocrine disorders
- GI disorders (U.C)
- Rheumatic disorders, including RA and gout flares, synovitis of OA, tendonitis, bursitis.
- Dermatological problems with intra-lesional injections

Contraindication

Uncontrolled diabetes

Fungal infections, which can be exacerbated

Certain infections, including viral and Tb, cerebral malaria, and can decrease overall immune system ability to fight and localize infection.

OLYMPIC ATHLETE, Competitive amateur athlete



So why not be able to offer something else?

CAM = Complementary & Alternative Medicine- What are they?

Depends on who you ask....

- ▶ Wikipedia
- ▶ “ Alternative Medicine or Fringe medicine are practices claimed to have the healing effects of medicine but which are disproven, unproven, impossible to prove or are excessively harmful in relation to their effect; and where the scientific consensus is that the therapy does not, or can not, work because the known laws of nature are violated by it’s basic claims; or where it is considered so much worse than conventional treatment that it would be unethical to offer as treatment. “
- ▶ NIH
- ▶ “Alternative medicine is treatments that are used instead of standard medical treatments. One example is using a special diet to treat cancer instead of anticancer drugs that are prescribed by an oncologist.”
- ▶ “Complementary Medicine is treatments that are used along with standard medical treatments but are not considered to be standard treatments. One example is using acupuncture to help lessen some side effects of cancer treatment.”

Complementary & Alternative Medicine (CAM)

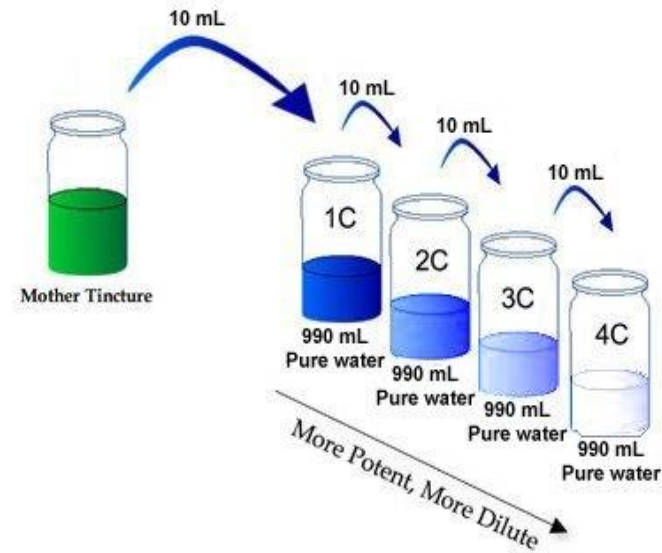
- ▶ When does it go from Alternative to mainstream?
- ▶ Example: Acupuncture is alternative Medicine, but now some insurers cover it
- ▶ Scientific Research validating / invalidating benefits
- ▶ Costs covered by insurers
- ▶ Costs covered by professional Athletic Teams



One Example of CAM: Homeopathy

- ▶ 1790, Dr. Samuel Hahnemann, founder of homeopathy.
- ▶ Disillusioned by harmful medical practices of the era, sought a gentler approach.
- ▶ The Principle of Similars = “Like Cures Like”
- ▶ An experiment with Peruvian bark, (& source of quinine):
 - He treated himself 2 x a day, & developed symptoms of malaria.
 - Ceasing treatment, symptoms resolved.
 - He theorized a small dose for a malaria sufferer might stimulate the body to fight the disease.
- ▶ Using Extremely dilute preparations of natural substances (plant, mineral, chemical) to stimulate the body’s self healing mechanisms.

Homeopathy



Homeo (similar)

pathos (illness/ suffering)

Believes the goal is enlisting the body's own regenerative capacity to restore health.

“The French refer to the body's “terrain” in the way we think of growing an organic garden...nourish the soil, water properly to allow the plant will grow”

Vs Western Medicine's thought: add chemical fertilizer and spray with pesticides to use chemistry / technology to kill pests to allow the plant to grow.

Homeopathy: how does it work?

Homeopathy quickly spread from Germany in 1790, and was in the US by 1820.

Dr. Hahnemann's work showed that for the sick, highly diluted remedies were less harmful, had fewer side effects, and were more effective. It was having success treating epidemics of the era.

During an 1849 Cholera epidemic in Cincinnati, 3% of homeopathic treated patients died, while 40-70% treated conventionally died.

As allopathic medicine organized, advanced, by the 1930's homeopathy nearly vanished in the US. In Europe, it continued to progress on a parallel track with allopathic medicine. The US revival started in the 1970's.

Hahnemann believed homeopathic remedies influenced the "Vital Force" - that which maintains health in a living system similar to Qi in China, prana in Ayurveda, but Western medicine has no similar concept.

However, as science has progressed, Physicists have shown water molecules have a tiny electromagnetic signal when they form specific structures within a highly dilute solution. NMR imaging tests reveal these water molecules and homeopathic solutions have similar subatomic activity. Saline does not.

Homeopathy: When does it work

- ▶ Homeopathy has since been subjected to RCT's with double blind, placebo controlled studies, through a number of different research teams in multiple countries, some trying to prove they are ineffective and then concluding that some are effective. In the US, we have a sub section of NIH devoted specifically to CAM research, including homeopathy.
- ▶ Statistically significant findings from properly conducted research trials were found for Seasonal rhinitis, post operative ileus, childhood diarrhea, Rheumatoid arthritis, fibromyalgia, mild influenza (not severe flu) allergic asthma and **ankle sprains**.
- ▶ What was found NOT to work: treating plantar warts, preventing illness onset.
- ▶ Two musculoskeletal ankle and foot homeopathic tinctures are Traumeel and Zeel.

Traumeel Active Ingredients

(quantities in microliters)

(a 2.2 ml ampule has 2,200 microliters)

- ▶ Aconitum napellus 1.32
- ▶ Arnica montana, radix 2.20
- ▶ Bellius perennis 1.10
- ▶ Belladonna 2.20
- ▶ Calendula officinalis 2.20
- ▶ Chamomilla 2.20
- ▶ Echinacea 0.55

Echinacea purpura 0.55

Hamamelis virginiana 0.22

Hepar Sulphuris calcareum 2.20

Mercurius solubilis 1.10

Millefolium 2.20

Symphytum officinale 2.20

INACTIVE INGREDIENTS:

Traumeel

► indications

- For the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms, such as pain.

► contraindications

- Known hypersensitivity to Traumeel or any of its ingredients
- **RELATIVE CONTRAINDICATIONS:**
- Pregnancy Category C, Some ingredients have been shown to be teratogenic in animal species when given in doses several thousand times the human dose.

Traumeel Mechanism of Action (still in research)

- ▶ In vitro studies show Traumeel decreases mast cell granulation (stabilizes mast cells)
- ▶ Reduces micro vascular leakiness in both number and area affected in a rat study.
- ▶ Decreases human T cells, monocytes and gut epithelial cell secretion of pro-inflammatory markers IL-1beta, IL=8 and TNF alpha, in both activated and resting cells.

Decreases tissue edema by synergistic activity of multiple ingredients.

Traumeel : MofA ct'd

Anti-inflammatory mechanism: produces Growth factor Beta in lymphocytes & does not affect granulocyte function or platelet adhesion in vitro (i.e. NOT the NSAIDS functional pathway of Cox -1 and Cox-2 inhibition + granulocyte and platelet adhesion inhibition)

Traumeel mechanism decreases pain of inflammation, accelerates the healing process by production of TGF- Beta, an inhibitory cytokine that suppresses the inflammatory production of IL-1 and TNF alpha, which then avoids them from turning on a nuclear factor that would rapidly activate the inflammatory process.

Traumeel research

- ▶ RCT, double blind, placebo from sports: controlled: 69 Acute ankle sprains treated with Traumeel ointment 7 times over 2 weeks, with compression bandages and electrotherapy. No pain with motion on day 10 and faster return to motion in the Traumeel group.
- ▶ RCT, double blind, placebo controlled: 73 patients: Traumeel solution injection for traumatic hemarthrosis knee, of 3 @ 2 ml injections, (and later joint puncture, to drain knee if needed) 13% of Traumeel went on to 2nd or 3rd, vs 25% placebo & 5.4% bloody punctate day 8 Traumeel vs 19.4% placebo group .measured success of therapy (circumference and motion) achieved on Day 8: 64% Traumeel and 36 % placebo & pain reduction to 0: 89% Traumeel and 64% placebo.
- ▶ Traumeel vs Diclofenac injectable for epicondylitis- not inferior effect, but decreased side effects profile and no drug- drug interactions. (increased safety profile).

Traumeel Research.. Does it Work?

- ▶ “Traumeel has shown comparable effectiveness to NSAIDs in terms of reducing symptoms of inflammation, accelerating recovery, and improving mobility, with a favorable safety profile.
- ▶ While continued research and development is ongoing to broaden the clinical evidence of Traumeel in acute musculoskeletal injury and to further establish its benefits, current information suggests that Traumeel may be considered as an anti-inflammatory agent that is at least as effective and appears to be better tolerated than NSAIDs.
- ▶ “ Traumeel - an emerging option to non steroidal anti-inflammatory drugs in the management of acute musculoskeletal injuries” Christian Schneider, Journal of General Medicine, 24 March 2011.

Zeel

► Indications

- As a mono-therapy, for the treatment of arthrosis/osteoarthritis, and/or rheumatic joint diseases and for the relief of symptoms such as pain and joint stiffness.

► contraindications

- Zeel® Injection Solution is contraindicated in patients with known hypersensitivity to Zeel® Injection Solution or any of its ingredients.

Zeel: Ingredients

▶ Active Ingredients:

- ▶ Lipoicum acidum 2.0 µl
- ▶ Arnica montana, radix 200.0 µl
- ▶ Cartilago suis 2.0 µl
- ▶ Coenzyme A 2.0 µl
- ▶ Dulcamara 10.0 µl
- ▶ Embryo totalis suis 2.0 µl

Funiculus umbilicalis suis 2.0 µl

Nadidum 2.0 µl

Natrum oxalaceticum 2.0 µl

Placenta suis 2.0 µl

Rhus toxicodendron 10.0 µl

Sanguinaria canadensis 3.0 µl

Sulphur 3.6 µl

Symphytum officinale 10.0 µl

Zeel: How does it work?

In vitro studies have indicated Zeel-mediated inhibition of the pathways involving the enzymes cyclooxygenase-1 and -2, and also the 5-lipoxygenase pathways, affecting levels of both eicosanoids and leukotrienes.

Zeel may reduce the main two classes of molecules responsible for arthritic pain and inflammation.

This is a more similar pathway to NSAIDs.

Regenerative Medicine

platelet growth factors : 1×10^6

- ▶ PRP
- ▶ Platelet Rich Plasma
 - ▶ Autologous donor, “it’s your own blood”
 - ▶ Venipuncture (Blood Draw)
 - ▶ Multiple providers of “ kits” for in office use to separate the platelets layer from the RBC’s and now, separate out granulocytes to decrease chance of inflammation,
 - ▶ Arthrex Angel, EmCyte Pure PRP II, Clear rPRP (Harvest/ Terumo) systems
- ▶ BMA vs BMC
- ▶ Bone Marrow Aspirate vs Concentrate
- ▶ Autologous Donor, “ Its your own Bone Marrow”
- ▶ Calcaneus donor site
- ▶ Multiple providers of kits: BMA vs BMC
- ▶ Retrieve from Globus, BMAC Harvest medical, Procure De Puy Synthes, Arthrex Angel, Wright Medical Biomet, Zimmer,, ...

PRP

Platelet Rich Plasma

- ▶ indications
 - ▶ Muscle strain
 - ▶ Tendonitis
 - ▶ Ligament sprain
 - ▶ Intra- Articular injuries
 - ▶ Arthralgia / joint pain
 - ▶ Arthritis (OA)
- ▶ contraindications
 - ▶ Cancer or currently in chemotherapy
 - ▶ Recent Corticosteroids treatment
 - ▶ Blood Clotting disorder
 - ▶ Platelet disorders
 - ▶ Skin disease
 - ▶ Infection, chronic or acute, including away from injection area
 - ▶ Fever

BMA Bone Marrow aspirate

▶ indications

- ▶ Severe osteoarthritis
- ▶ Osteochondral defects
- ▶ Early avascular necrosis
- ▶ Tendinopathies where pluripotential stem cells are needed.

▶ contraindications

- ▶ Cancer, including lymphoma
- ▶ Active anti-coagulation (Coumadin OR OTHERS)
- ▶ Infection
- ▶ Skin disease at the site

Prolotherapy

- ▶ Definitions:
- ▶ Prolotherapy is a technique that involves the injection of an irritant, usually a hyperosmolar dextrose solution, typically in the treatment of chronic painful musculoskeletal conditions.
- ▶ Indications: Chronic tendinopathies not responding to conservative care, including Achilles tendinosis.
- ▶ Research supports use of prolotherapy with a course of eccentric loading exercises for Achilles tendinopathy (chronic tendinosis) had better outcomes than either treatment alone.

Dextrose in Water (12.5-25%)

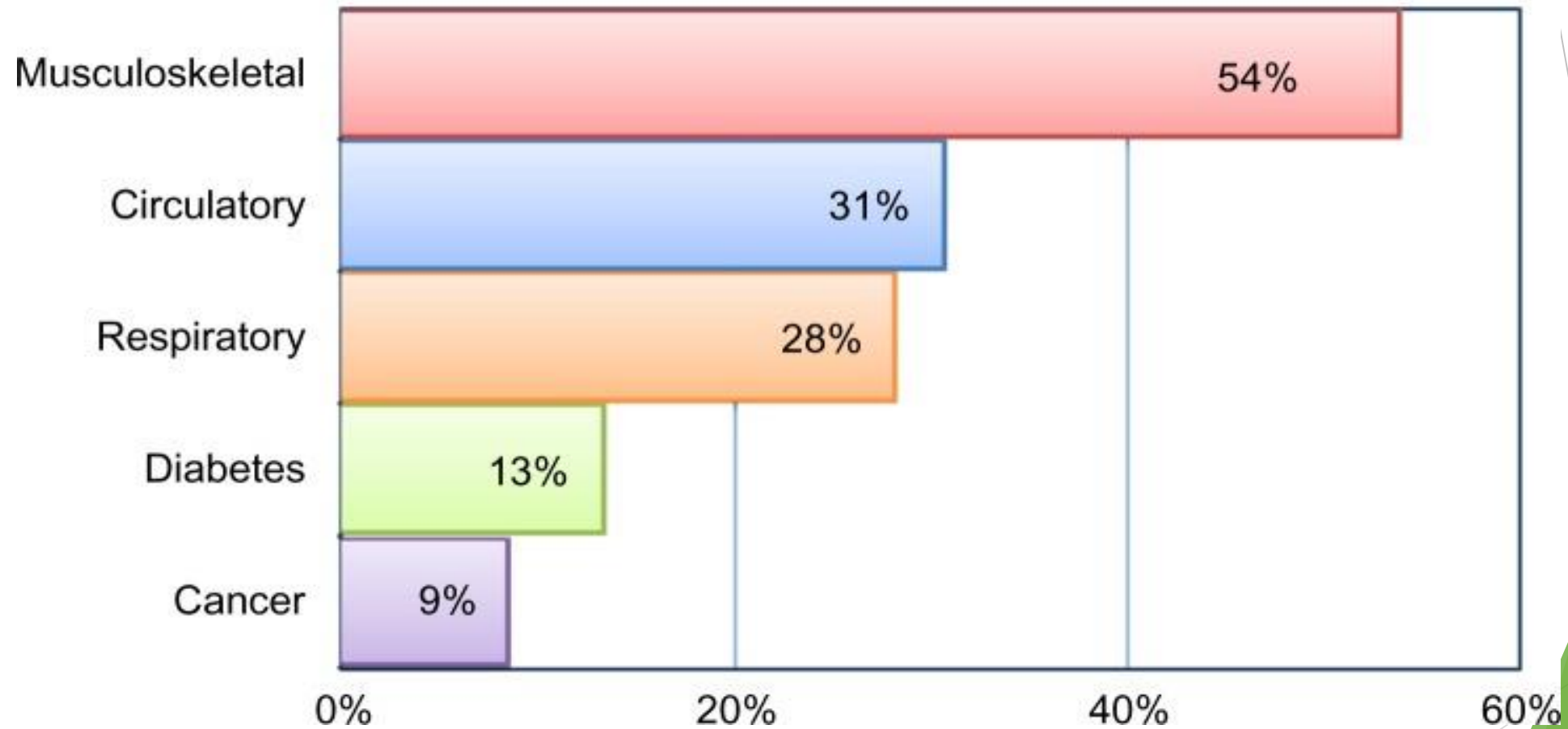
▶ indications

- ▶ Chronic tendinosis
- ▶ Chronic Plantar fasciosis
- ▶ Chronic OA
- ▶ Chronic Joint pain
- ▶ Chronic LBP
- ▶ Overuse tendinopathy

▶ contraindications

- ▶ Infection
- ▶ Acute Injury
- ▶ Acute Inflammation
- ▶ Cancer
- ▶ Collagen Vascular Diseases
- ▶ Genetic Collagen Defect Disease

Proportion of United States Population Reporting Chronic Medical Conditions, 2012



A word about Plantar fasciitis

- ▶ “Painful inflammatory process involving the plantar fascia causing pain on the underside of the heel. It is usually caused by overuse, injury or biomechanical abnormalities and may be associated with microtears, or fibrosis. It is usually a self-limiting condition. ” NICE guidelines 2013.
- ▶ “Conservative treatments including rest, analgesics, anti-inflammatory medication, use of orthotic devices, eccentric exercise, stretching and physiotherapy. Local injection of steroids, extracorporeal shock wave therapy and surgery to release the plantar fascia from the bone or to relieve muscular tightness are sometimes used for patients with refractory symptoms.”

Plantar Fasciitis and PRP & NIH

The NICE Guidelines: 2013 onset

- ▶ National Institute for Health and Care Excellent (NICE) Autologous blood injection for plantar fasciitis guidelines
- ▶ Evidence on Autologous blood injection for plantar fasciitis raises no major safety concerns.
- ▶ “Only used with special arrangements for clinical, government, consent and audit or research.”
- ▶ This clinician guideline is for providers desiring to treat plantar fasciitis with Autologous blood injection. It requires ensuring patient understands the uncertainty of efficacy, & has advised patient, in writing, of alternative treatments. The use of NICE’s information for the public is recommended.
- ▶ They review clinical outcomes of all patient’s treated by Autologous blood injection for plantar fasciitis.
- ▶ Trials must clearly describe patient selection, duration of symptoms, and any prior treatment. Outcomes must include specific measures of pain and function

consents

- ▶ Be clear
- ▶ Make certain your consent includes other options discussed, and for any experimental procedure, “cutting edge” cannot be the only description.
- ▶ I discussed treatments for the chronic plantar fasciitis that has not responded to standard therapy of _____ to date. I discussed an alternative of _____ which is considered experimental although there is scientific medical research to support the treatment in this manner.
- ▶ I offered the choice of _____
- ▶ Or _____ at this point in the treatment plan with a goal of _____
- ▶ Example: (decreased pain and improvement of symptoms)

Local Anesthetics: A word of caution...

- ▶ Effects on chondrocytes
 - ▶ Local anesthetics affect chondrocytes viability.
 - ▶ bupivacaine, Ropivacaine, lidocaine and mepivacaine are chondrotoxic in a time-dependent, concentration-dependent, and drug-dependent manner.
 - ▶ chondrotoxic and analgesic potencies do not directly correlate. Cellular death rates were higher in osteoarthritic compared with intact cartilage after local anesthetic treatment.
- ▶ Take Home Message
 - ▶ Ropivacaine treatment was less chondrotoxic than bupivacaine, lidocaine and mepivacaine exposure, including single dose exposure.

documentation

- ▶ PRP & BMA & Traumeel & Zeel
- ▶ Check with your malpractice provider for forms they prefer you use, for consent for PRP & BMA.
- ▶ It should have the words Experimental treatment for PRP & BMA / BMC & list alternative treatments considered a part of the “ Standard of care”.
- ▶ Have an ABN for both Medicare AND for private insurers, specifying the cost of treatment and clearly noting it is NOT covered by insurance.
- ▶ You may or may not get reimbursed
- ▶ 2013 NICE Guidelines: PRP
- ▶ PRP for plantar fasciitis has some extra rules, including you **MUST** note in the consent it is experimental.
- ▶ You must track the outcomes of your patients, like a research project would do, to determine if there is benefit or not.

documentation

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- ▶ Have an ABN for both Medicare AND for private insurers, specifying cost of treatment, and clearly noting it is NOT covered by insurance.
- ▶ You may or may not get reimbursed from Medicare for Traumeel or Zeel under the unlisted drug code. To get paid by private insurers, you will still need to list the NDC like any other FDA medication you inject.
- ▶ The injection (procedure) & office visit is covered for Traumeel and Zeel, when using for FDA approved indications.

▶ 2013 NICE Guidelines: PRP

- ▶ PRP for plantar fasciitis has some extra rules, including you **MUST** note in the consent it is experimental.
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Coding J 3490: Unlisted Drug Traumeel & Zeel

- ▶ J3490 unclassified Drug
- ▶ **J3490 Unclassified Drugs & Injections**
- ▶ For the drug with no assigned 'J' code, the name, strength of the drug (if applicable) and the actual dosage administered must be indicated on the CMS-1500 form in Block 19 or Block 24 (listed with the procedure code).
INCLUDE THE NDC codes
- ▶ J3490 & Medicare
- ▶ CMS Medicare offers two codes for unlisted drugs: J9999 Unclassified Chemotherapy Drugs and **J3490 Unclassified drugs** for others. The more commonly used unlisted drug code is J3490. With an unlisted drug code, it is needed to document the importance of trying this new drug and record it in the chart notes. If the physician tried listed drugs and they didn't work, you need to make sure the claim includes that information.

Coding PRP & BMA / BMC

- ▶ PRP has a new, experimental code
- ▶ “0232T—Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed
- ▶ (Do not report 0232T in conjunction with 20550, 20551, 20600-20610, 20926, 76942, 77002, 77012, 77021, 86965.)”

When **bone marrow aspiration** is performed alone, the appropriate **code** to report is **CPT code 38220**.

This is not the same as when it is for a biopsy, which is a different code.

Special equipment

- ▶ Diagnostic ultrasound
- ▶ Centrifuge

THANK YOU!

