AGENDA

State and Public School Life and Health Insurance Board

October 17, 2017

1:00 p.m.

EBD Board Room – 501 Building, Suite 500

I.	*Call to Order*	*Dr. John Kirtley, Stand-In Chair*
II.	*Approval of August 22, 2017 Minutes*	*Dr. John Kirtley, Stand- In Chair*
III.	*ASE-PSE August & September Financials*	*Marla Wallace, EBD Fiscal Officer*
IV.	*Benefits Sub-Committee Report*	*Shelby McCook, Board Member*
V.	*Quality of Care Report.*	*Izzy Whittington, Mike Motley, ACHI*
VI.	*Emerging Therapies.*	*David Harshfield, Morgan Pile, Regenerative Therapies*
VII.	*Emerging Therapies*	*Laura Trivette, MiMedx Group, Inc.*
VIII.	*Wellness Report*	*Chris Howlett, EBD Executive Director*
IX.	*Director's Report*	*Chris Howlett, EBD Executive Director*

Upcoming Meetings

November 21,2017, December 18, 2017, January 15, 2018

NOTE: All material for this meeting will be available by electronic means only

Notice: Silence your cell phones. Keep your personal conversations to a minimum.

STATE AND PUBLIC SCHOOL LIFE AND HEALTH INSURANCE BOARD MEETING MINUTES

175th meeting of the State and Public School Life and Health Insurance Board (hereinafter called the Board), met on October 17, 2017 at 1:00 p.m. in the EBD Board Room, 501 Woodlane, Suite 500, Little Rock AR 72201.

Date | *time* 10/17/2017 1:00 PM | *Meeting called to order by* John Kirtley, Stand-In Chair

Attendance

Members Present

Dr. Andrew Kumpuris
Shelby McCook
Katrina Burnett
Renee Mallory- Chair – Proxy – Robert Brech
Lori Freno-Engman – Proxy – Greg Rogers
Robert Boyd
Dr. John Kirtley
Carla Haugen
Janis Harrison
Chris Howlett, EBD Executive Director, Employee Benefits Division

Members Absent

Dr. Joseph Thompson – Vice Chair
Dr. Tony Thurman

OTHERS PRESENT:

Geri Bemberg, UAMS; Eric Gallo, Terri Freeman, Matt Turner, Marla Wallace, Shalada Toles, Laurie Fowler, Doris Brown, Jamie Levinsky, Rhoda Classen; EBD; Kristi Jackson, ComPsych; Eileen Wider, Securian/Minnesota Life; Andy Davis, Arkansas Democrat-Gazette; Marc Watts, ASEA; Sandra Wilson, Nina Reed, ActiveHealth; David Kizzia, AEA; Takisha Sanders, Jessica Akins, Health Advantage; Mike Motley, Elizabeth Whittington, Arlo Kahn, ACHI; Scott Yielding, DPAS; Jackie Baker, ASP; Robyn Keene, AAEA; John Vinson, APA; Wayne Whitley, Ronda Walthall, ARDOT; Greg Jones, MTI; Jan Bartlett, DFA; Treg Long, ACS; Suzanne Woodall, MedImpact; David Mason, Matt Larson, MiMedx; David Michael, Catapult; Jim Chapman, Abbvie; Dr. David Harshfield, Carl Keller, AIRM; Mark McElroy, House of Representatives; Seth Pinkerton; Sharon Jones, Phlecia Gillespie, DHS;

Approval of Minutes by: Dr. John Kirtley, Chair

Kirtley asked for a motion to approve the August 22, 2017 minutes.

Harrison motioned for adoption of the minutes. Haugen seconded; all were in favor.

Minutes approved.

Financials by: Marla Wallace, EBD Fiscal Officer

Wallace reported financials for August and September 2017.

For August PSE, four (4) weeks of medical and pharmacy claims were paid. FICA savings was $497,000 for the month. There was a net gain of $3.5 million for the month and a net gain of $42.2 million year-to-date. Other funding is higher due to some pharmacy rebates that came in for $421,000. There was $18 million added to the Catastrophic Reserve making the new total $58.5 million. Net assets available are $53.8 million.

For September PSE, five (5) weeks of medical and pharmacy claims were paid. The fifth week of claims for medical and pharmacy were $5.89 million. FICA savings was $510,000 for the month. There was a net loss of $419,000 for the month and a net gain of $41.74 million year-to-date. Net assets available are $52.94 million.

For ASE for the month of August, four (4) weeks of medical and pharmacy claims were paid. There was a net gain of $4.2 million for the month and a net gain of $39.3 million year-to-date. Other funding is higher due to some pharmacy rebates that came in for $618,000. There was $10 million added to the Catastrophic Reserve making the new total $30.3 million. Net assets available are $30.4 million.

For ASE for the month of September, five (5) weeks of medical and pharmacy claims were paid. The fifth week of claims for medical and pharmacy were $5.98 million. There was a net loss of $1.37 million for the month and a net gain of $37.9 million year-to-date. Net assets available are $29.1 million.

Benefits Sub-Committee Report by: Chris Howlett, EBD Executive Director

The following report resulted from a meeting of the Benefits Sub-Committee on October 6, 2017, with Claudia Moran presiding.

Topics Discussed:

- August and September Financials
- Regenerative Cellular Therapies
- MiMedx Presentations
- Wellness Options

April PSE-ASE Financials: Marla Wallace, EBD Fiscal Officer

Wallace reported the financials for September 2017.

Regenerative Cellular Therapy: Dr. David Harshfield, Jr M.D., M.S, & Carl Keller, CEO

Regenerative Medicine is now a first line treatment to avoid or delay pharmacological or surgical treatments. Regenerative therapies have learned to do pain control with glucose instead of narcotics and opioids. But, overall success of regenerative medicine is highly dependent on the overall health and psychological well-being of our patients including; comorbidities, pharmaceuticals and nutritional status. For now, we are going to have Centers of Excellence (COE) in El Dorado, Little Rock, and Fayetteville.

Key Points

Clinical Outcomes: IROM, with credentialed providers and certified protocols, provides safe, affordable and effective therapy resulting in improved healing and overall patient outcomes.

Financial outcomes: Lower costs to The State and Public School Life and Health Insurance Board, not only with avoidance of unnecessary pharmaceuticals and surgery but of complications, as well.

Quality of Life: IROM is not only financially beneficial, but allows patents a more rapid return to work and activities of daily living.

Treatment Acceptance: Increasing payer adoption of the use of regenerative and cellular medicine therapies, with Arkansas now playing a leadership role in the U.S.

MiMedx Presentation: Laura Trivette, Dr. David Mason, & Matt Larson

MiMedx® is a biopharmaceutical company developing, manufacturing and marketing regenerative biologics utilizing human placental allografts for multiple sectors of healthcare. MiMedx dHACM is the first human amnion/chorion dehydrated membrane to meet requirements of the United States Pharmacopeia (USP) monograph. The core material that is used to manufacture our product is the human placenta which is normally thrown away as human waste.

MiMedx Value Proposition

- Promotes Healing- Scientific data shows dHACM ability to draw stem cells toward the site to modulate inflammation, reduce pain and accelerate healing
- Proprietary PURION Process preserves 226+ different growth factors
- Superior Published Clinical Data - 6 Randomized Control Trials (RCTs) showing statistical significance
- Patient Safety – Terminal Sterilization
- Stem Cell Magnet - Scientific data shows dHACM ability to draw stem cells toward the site
- USP Monograph - Rigor in processes ensure consistent product quality
- Storage and Ease of use - Ambient conditions with 5-year shelf life

McCook motioned that we recommend to the board that they authorize the director to do whatever is necessary to develop the criteria for operational guidelines to begin a pilot program in 2018. Gardner seconded; all were in favor.

Motion Approved.

Wellness Options: Chris Howlett, EBD Executive Director

Howlett stated that our biggest struggle will be operationalizing the flu shot based on the timing that the flu shot is available and perimeters in which we would be designing the wellness program to capture that data and to be able to facilitate that. Howlett requested to the committee that EBD operationalize all the other components that were initially with the BMI, nicotine, and those components but take the flu shot with whatever operational means that we are having go out to be made 100% available at the time of interaction with our population as well as those that don't interact with the plan but go to the physician's office, can get the flu shot and be covered by the plan.

Keep the wellness components around the discount and those pieces; take the flu shot as an attestation, any mandate whatsoever and remove that and leave it from a voluntary standpoint and allow us to ramp up all the communication and education components and provide the services. Kissire motioned for this recommendation. Harrison seconded; all were in favor.

Motion Approved.

Board Comments:

McCook proposed a motion to adopt the motion that we remove the flu shot from the wellness requirements. Harrison seconded. All were in favor.

Boyd asked what the issue was with the flu shot.

Howlett stated that it was an attestation for the first year but moving forward into that would become historical practice. From one standpoint it was an attestation for the first year with the implication that it was going to be a defined requirement, and from an operational standpoint we have no way operationalize that function with the lookback period. So the request to make sure that we don't run into issues, tracking the membership and maintaining compliance, the recommendation was to made to make it an enhanced benefit that we could foster or provide at the time of the biometric collection.

Motion Approved.

Kirtley stated that the regenerative therapy motion will be tabled until after the presentations.

Quality of Care Committee Report by: Elizabeth Whittington, Mike Motley, ACHI

The following report resulted from a meeting of the Quality of Care Sub-Committee on October 10, 2017, with Margo Bushmiaer presiding.

Whittington reported on Choosing Wisely.

Choosing Wisely in Action

- Choosing Wisely was named in Act 1089 of 2017:
- "By the end of plan year 2017, the State and Public School Life and Health Insurance Board shall explore the evidence supporting opportunities for benefit modification information by:

  1. The Choosing Wisely Initiative;

  2. Emerging therapies; and

3. Therapeutic alternatives to invasive surgical procedures, such as regenerative injection therapy."

- Opportunity for EBD to utilize Choosing Wisely framework when assessing issues related to quality of care and benefit design
- States are using this initiative to uncover areas of wastefulness in their healthcare systems

Choosing Wisely Recommendation-

Nonspecific Low Back Pain (AAFP)

- Don't do imaging for low back pain within the first six weeks, unless serious conditions are present
- These include, but are not limited to:

–Severe or progressive neurological deficits

–When underlying conditions such as osteomyelitis (infection in a bone) are suspected

–Trauma

- Rationale: Imaging of the lower spine before six weeks does not improve outcomes, but does increase costs and increases the likelihood of surgery
- Low back pain can be addressed without imaging through pain management and/or physical therapy as first courses of action

Recommendation from QoC Subcommittee

1. Member education: Disseminate related education materials (from Choosing Wisely & Consumer Reports) in member newsletter and other outlets;

2. Provider outreach: Conduct targeted outreach to high-volume providers with higher rates of potentially wasteful imaging;

3. Prior authorization: Review existing EBD prior authorization criteria and work with vendor to refine criteria to more closely align with the Choosing Wisely recommendation.

Board Comments:

Harrison motioned to adopt the three suggested recommendations. Haugen seconded.

Kumpuris asked that mechanistically how would you do the prior authorizations. A great job has been done documenting two forces in healthcare that are hard to beat. First, the patients come in and they hurt and they want something done. Getting an MRI is getting something done. Second, the doctors are paid for doing something, not patting someone on the back and making them wait 6 weeks in pain. The prior authorization comes precariously close to practicing medicine. I would just like to know the mechanism of how we are going to do that.

Howlett responded that most condition states or things that would require a prior authorization presently have already defined criteria. This is suggesting that we review that and look at what would be aligned more closely to the Choosing Wisely recommendations. We would look at our vendor(s) to help align those with that recommendation.

Kumpuris stated that the first and second step are the right things to do but not take the third step because it is really hard to do correctly.

Kirtley responded that there is already PA criteria for MRI's right now. The only differences in the motion is just reviewing those to see if there is some mechanism to catch what would be perceived as egregious or unnecessary.

Howlett said that would realign the current PA criteria assuming that it could potentially be the issue. It could be that there is another mechanism that is weighing in on that.

Motley stated that the intent on number 3 was just to look at the prior authorization. Prior authorization would in part touch all three of these.

McCook questioned Kumpuris on if he would be willing to work with the Quality of Care and come up with an alternative. There may be an alternative that would not make the doctors feel that we are intruding too much but still control the costs.

Kumpuris stated that he would be glad to.

McCook suggests that if Dr. Kumpuris may have some ideas for Quality of Care that we might exclude that from today's vote until the next meeting.

Kumpuris made an amendment to the motion to embrace member education and provider outreach and wait on number three until we figure out how to do it. McCook seconded. All were in favor.

Amendment Approved.

Kirtley stated that with the amended motion on the floor to adopt numbers one and two.

Motion Approved.

Kumpuris would also suggest that ACHI get with Howlett to identify the outliers and think of a way to politely communicate with them that they are on the radar screen.

Howlett stated that the approach will be to meet with the ACHI team and look at the PA criteria for these and come back with that. We will also look at how we can provide some of the messaging which would fall in line with provider outreach. We would need to put that in proper confines and if you would be available, we can have you at the November Quality of Care meeting.

Kumpuris responded that he would be delighted.

Regenerative Cellular Therapy by: Dr. David Harshfield & Carl Keller

Regenerative Medicine is now a first line treatment to avoid or delay pharmacological or surgical treatments using the body's natural healing process.

Harshfield presented on how the Interventional Cellular Medicine Clinics work and what they do.

Kumpuris questioned is the American Association of Orthopedic Medicine (AAOM) or the Interventional Regenerative Orthopedic Medicine (IROM) accredited by the AMA or the American College of Physicians or any accrediting organization.

Harshfield stated that yes, the AAOM has been around for over 50 years. All of the coursework has been accredited by the ICME, so it would be accredited by the AMA.

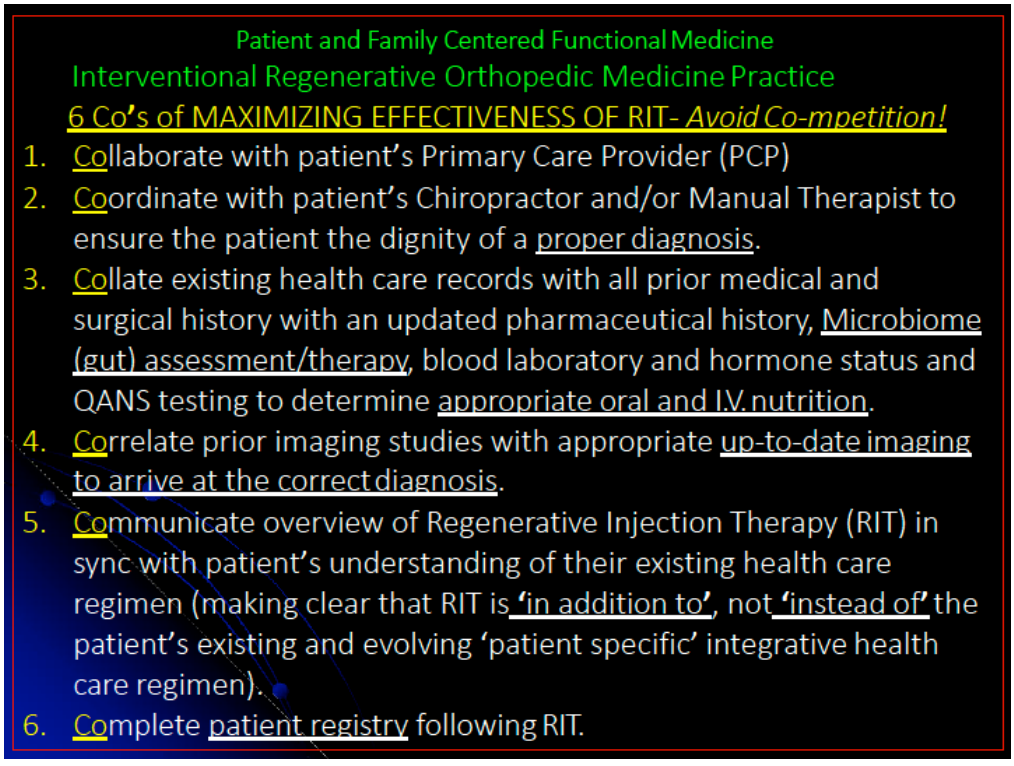
Kumpuris asked if the American Medical Association recognizes this organization like they do the Archeology of Cardiology.

Harshfield answered yes. The Interventional Cellular Medicine Society (ICMS) is an IRB apart from the larger government owned IRB. It's an independent organization but is overseen by the FDA. We are in communications with the state medical boards for the AOM for the therapies that we do.

Kumpuris stated that the reason he is asking is because the presentation says that you're teaching people by online courses. Kumpuris doesn't know of any American Medical Association or American College Physician training program that teaches by online courses.

Harshfield responded that he may have misstated. The information is available from the meetings so that if someone is not able to attend they can go online just like with the AMA.

Kumpuris stated that he knows of no organization accredited by the American College of Physicians that does online training like this.



The initial use is buffered glucose for pain control. It was known in 1863 and slipped under the radar until recently. A lot of pain is neuropathic pain caused by low glucose levels in the soft tissues. It can be relieved by a very shallow dextrose injection around a trigger point.

Boyd questioned on what the Board is supposed to be trying to do here.

Howlett stated that it is information that was presented from the Benefits meeting and arrived at a formal recommendation. What is different from the Benefits is that there were some requests for additional data from the Quality of Care committee. This is a combination of the two meetings that is being presented today.

Boyd reported that he is still confused as to what the Board is being asked.

Howlett answered that the initial ask was with the emerging therapies act that was put in place. This Board as well as the supporting subcommittees would explore any emerging therapy that could be done for this plan between now and the end of the year. It would be effective 1-1, as director, anything that the committee and/or Board approved; the EBD staff would have to operationalize that in terms of a pilot program. The ask would be what we would be considering towards emerging therapies and what's the will of the Board based on the evidence presented to initiate for me to operationalize a pilot program.

McCook stated that what we are trying to address is compliance with this law and educate ourselves on what the regenerative medicine is doing.

Kumpuris asked what the understanding of the pilot study is.

Howlett responded that this governing body would dictate the parameters that we would operationalize the pilot program in and around what products and/or services would be covered. EBD would have to operationalize how they would do that along with a full tracking, similar to the bariatric program. From that we would adopt the operational mechanisms to track that data and address the cost. This plan would set the potential for the reimbursement rates for those services. Some of the other additional items that came out of the Benefits are the qualifying the providers, the pricing, the cost, and areas of target or what we would address. Defining parameters around what we want to explore in the pilot is needed. Initially it was lower back, knees, neuropathy, and anything dealing with diabetes.

Kumpuris stated that the list of things just given is a hodge podge. All of the mechanisms of these are very, very different. For any kind of pilot study, you need to limit where it's done, who does it, and what you're doing, and you have to acquire very critical data to see if the efficacy justifies the cost. You can't have a list of 50 diagnoses and say we are going to treat all of them. You will get data that is uninterpretable. We have a precedent in this Board for what we're talking about right here and it's not exactly fixed but it's pretty close. My suggestion would be that this falls under the spectrum of orthopedics. I would suggest that we invite Dr. Larry Barnes, Head of the Orthopedic Department at UAMS, to come and give us his opinion as to what and how to do this. Before we embark on this we need to expand our database with someone from UAMS or in this specialty to talk to us.

McCook responded that he proposed the motion and there is a lot to figure out on it, but we have nothing. The information is going to have to be gathered and what you're going to treat. Secondly, the criteria for our vendors. The billing rates for different procedures. Criteria for who is going to qualify

for each disease that will be treated, all you have to figure out is everything. I agree with Dr. Kumpuris' suggestion to bring in Dr. Barnes. You have to start out by asking questions. It appears that this is dealing strictly with orthopedic issues according to the law.

Kirtley stated that the law has two requirements. One is that is 2017 by the end of the plan year and one that is July 2018. 2017 is that by the end of the plan year 2017 the State and Public School Life and Health Insurance Board shall explore the evidence supporting opportunities for benefit modification informed by the Choosing Wisely initiative emerging therapies and therapeutic alternatives to invasive surgical procedures such as regenerative injection therapy.

McCook questioned if that covers wound healing.

Howlett stated that the emerging therapies portion is where that would fall.

McCook reported that the point of his motion was that we have an act that we have to comply with. This office and the committees have a lot of work to do in getting information together. Next year there will be work to do based on that information.

Rep. Baltz spoke on behalf of the statute. What started all this was Rep. Baltz's wife had L4 and L5 bulging disks and was going to have to have surgery which would cost $35,000-$40,000. It was going to last 2 years with a 45% success rate and due to her degenerative bone disease she would be worse off. She was a candidate for the outpatient procedure. They came in and pulled her blood, plasma, and spun her stem cells out of it. They injected it back in at L4 and L5 vertebrae and within 10 days she started growing new cartilage. She is 5 years out and is pain free for $2000. We are just trying to help our folks that are in pain and also save money.

Boyd responded that going back to McCook's recommendation and what we are trying to accomplish here. It's not that Boyd doesn't want to hear the presentation but he is not sure it is getting further toward a decision today. Should we table this or vote on McCook's motion.

Howlett stated that once a decision is made, he may ask for qualifying questions to follow up how he might be able to provide what is voted on today.

McCook responded that all those things are not in his motion because it is impossible to sit here and cover all those things. Once a framework is started on this it will probably go back through the committees several times, but if we don't get started on it we are never going to be able to find out what we want to do or comply with the law. The motion is just a starting point.

Kumpuris stated that this is the future but the application of it has yet to be defined. I would strongly urge the Board to take a deep breath and understand that this is the future. We have to educate ourselves and patients and find the right providers. But before we do anything else, I would ask that we ask Dr. Barnes or a representative of UAMS Orthopedics to come and give us their opinion on this and help us set up a pilot program.

Haugen agreed with McCook to at least getting it moving forward and revamp the wellness committee to get these specific questions answered.

Howlett stated that he can bring a multitude of participants together. What do you want us to focus on; we have a head-to-toe application and Howlett needs a direction to explore.

McCook responded that joints and soft tissue related to orthopedics is the main thing emphasized in the law, so that's where we should start.

Kumpuris motioned to invite Dr. Barnes and/or representative of UAMS Orthopedics to come to our next meeting and discuss this matter further and help us focus in on where we are going. Boyd seconded. All were in favor.

Howlett questioned on if this was just Board or any of the Boards.

Kumpuris stated that he would defer to Dr. Barnes schedule. When you can get him, we will show up.

Motion Approved.

MiMedx Presentation by: Dr. David Mason & Matt Larson, MiMedx

MiMedx did not present due to needing appropriate orthopedic and wound healing specialists.

Wellness Report by: Chris Howlett, EBD Executive Director

Howlett would like to re-review the wellness recommendations with a few asks.

1. What is the pleasure of the Board to vote on the recommendation.
2. When it comes to the respective discount. What is the pleasure of the Board as far as that dollar amount? As far as next year it will remain the same as this year.

McCook reported that he thought that we approved it for next year, the amount and everything.

Howlett stated that he is speaking about plan year '19. For '18, everything will stay the same. This is the wellness that we would operationalize effective Nov. 1, unless we decide to start 1-1.

McCook asked when that decision has to be made.

Howlett responded that we would need to have that sometime soon, but my request is for today.

McCook stated that he is not for setting the amounts right now for what the requirements will be.

McCook motioned that we postpone the decision of the dollar amount incentive for insurance year '19 up until May '18. Boyd seconded. All were in favor.

Motion Approved.

Director's Report: by Chris Howlett, EBD Executive Director

As far as the chair for the Board, Howlett would like to make a request. Our current chair, Renee Mallory, is not able to fulfill her duties because of work and obligations. Howlett would like to make a request that not knowing where the Governor will stand with appointments and how it will play out, I need something solid. Howlett's recommendation is that Dr. John Kirtley can stand in through 6-30-

18. At that point, wherever we stand with positions on the Board with appointments, we have some stability.

McCook motioned that Dr. John Kirtley be inducted by acclimation to serve as chair until 6-30-18. Haugen seconded. All were in favor.

Motion Approved.

Dr. Kirtley asked for motion to adjourn. Harrison motioned to adjourn. Haugen seconded. All were in favor.

Meeting Adjourned.

Public School Employees (PSE) Financials - January 1, 2017 through August 31, 2017

	EMPLOYEE ONLY					EMPLOYEE + DEPENDENTS			
	ACTIVES	RETIREES	MEDICARE	TOTAL		ACTIVES	RETIREES	MEDICARE	TOTAL
BASIC	4038	452		**4490**		6040	586		**6626**
CLASSIC	23041	2228		**25269**		43245	2670		**45915**
PREMIUM	17783	775		**18558**		23476	835		**24311**
PRIMARY		65	11956	**12021**			131	13032	**13163**
TOTAL	**44862**	**3520**	**11956**	**60338**		**72761**	**4222**	**13032**	**90015**

REVENUES & EXPENDITURES

		Current Month	Year to Date (8 Months)
	Funding		
1	Per Participating Employee Funding (PPE Funding)	$ 7,818,846	$ 65,081,523
2	Employee Contribution	$ 9,613,289	$ 77,217,403
3	Department of Education $35,000,000 & $15,000,000 & Other Funding	$ 4,583,333	$ 54,425,758
4	Other	$ 1,099,429	$ 6,478,471
5	Allocation of Reserves	$ 3,792,121	$ 28,691,515
	Total Funding	$ 26,907,019	$ 231,894,670
	Expenses		
	Medical Expenses		
6	Claims Expense	$ 16,884,967	$ 123,939,332
7	Claims IBNR	$ -	$ (4,300,000)
8	Medical Administration Fees	$ 1,867,466	$ 13,816,437
9	Refunds	$ -	$ -
10	Employee Assistance Program (EAP)	$ 74,931	$ 622,207
	Pharmacy Expenses		
11	RX Claims	$ 4,047,472	$ 32,305,068
12	RX IBNR	$ -	$ 300,000
13	RX Administration	$ 180,856	$ 1,407,236
14	Plan Administration	$ 322,659	$ 3,542,838
	Total Expenses	$ 23,378,351	$ 171,633,118
15	Less DOE Allocation		$ (18,100,000)
16	**Net Income/(Loss)**	$ 3,528,668	$ 42,161,552

BALANCE SHEET

	Assets	
17	Bank Account	$ 18,936,158
18	State Treasury	$ 139,558,233
19	Receivable from Provider	$ -
20	Accounts Receivable	$ 4,982,041
21	Due from ASE	$ 421,908
	Total Assets	$ 163,898,340
	Liabilities	
22	Accounts Payable	$ 1,199
23	Due to ASE	$ -
24	Deferred Revenues	$ -
25	Due to Federal Government ($27 fee)	$ -
26	Health IBNR	$ 25,700,000
27	RX IBNR	$ 1,400,000
	Total Liabilities	$ 27,101,199
28	**Net Assets**	$ 136,797,141
	Less Reserves Allocated	
29	Premiums for Plan Year 1/1/17 - 12/31/17 ($5,760,000+$20,000,000 + $18,100,000 DOE)	$ (15,168,485)
30	Premiums for Plan Year 1/1/18 - 12/31/18 ($3,840,000 + $660,000)	$ (4,500,000)
31	Premiums for Plan Year 1/1/19 - 12/31/19 ($396,000)	$ (396,000)
32	Premiums for Plan Year 1/1/20 - 12/31/20 ($264,000)	$ (264,000)
33	Premium Assistance (FICA Savings)	$ (3,602,283)
34	Catastrophic Reserve (2017 $58,500,000)	$ (58,500,000)
35	**Net Assets Available**	$ 54,366,373

36 Fifth Week of Claims $

Public School Employees (PSE) Financials - January 1, 2016 through August 31, 2016

	EMPLOYEE ONLY				EMPLOYEE + DEPENDENTS			
	ACTIVES	RETIREES	MEDICARE	TOTAL	ACTIVES	RETIREES	MEDICARE	TOTAL
BASIC	3392	337		**3729**	5066	416		**5482**
CLASSIC	21931	2139		**24070**	40845	2594		**43439**
PREMIUM	18644	1008		**19652**	24382	1075		**25457**
PRIMARY		83	11163	**11246**		166	12164	**12330**
TOTAL	**43967**	**3567**	**11163**	**58697**	**70293**	**4251**	**12164**	**86708**

REVENUES & EXPENDITURES

		Current Month	Year to Date (8 Months)
	Funding		
1	Per Participating Employee Funding (PPE Funding)	$ 7,815,057	$ 64,782,914
2	Employee Contribution	$ 9,222,257	$ 74,262,507
3	Department of Education $35,000,000 & $15,000,000 & Other Funding	$ 3,181,818	$ 33,522,727
4	Other	$ 592,338	$ 5,091,514
5	Allocation of Reserves	$ 3,975,000	$ 31,800,000
	Total Funding	$ 24,786,470	$ 209,459,663
	Expenses		
	Medical Expenses		
6	Claims Expense	$ 16,689,049	$ 128,873,475
7	Claims IBNR	$ -	$ 2,000,000
8	Medical Administration Fees	$ 1,585,694	$ 13,111,411
9	Refunds	$ -	$ -
10	Employee Assistance Program (EAP)	$ 73,828	$ 613,970
	Pharmacy Expenses		
11	RX Claims	$ 3,700,481	$ 32,525,296
12	RX IBNR	$ -	$ (300,000)
13	RX Administration	$ 257,927	$ 2,179,252
14	Plan Administration	$ 390,828	$ 5,228,958
	Total Expenses	$ 22,697,807	$ 184,232,362
16	**Net Income/(Loss)**	$ 2,088,664	$ 25,227,301

BALANCE SHEET

	Assets	
17	Bank Account	$ 15,392,607
18	State Treasury	$ 109,089,802
19	Receivable from Provider	$ -
20	Accounts Receivable	$ 3,942,815
21	Due from ASE	$ 84
	Total Assets	$ 128,425,308
	Liabilities	
22	Accounts Payable	$ 2,889
23	Due to ASE	$ 177,363
24	Deferred Revenues	$ 303
25	Due to Federal Government ($27 fee)	$ 1,010,826
26	Health IBNR	$ 30,000,000
27	RX IBNR	$ 1,100,000
	Total Liabilities	$ 32,291,381
28	**Net Assets**	$ 96,133,927
	Less Reserves Allocated	
29	Premiums for Plan Year 1/1/16 - 12/31/16 ($9,600,000 + $20,000,000 DOE + 18,100,000 DOE)	$ (15,900,000)
30	Premiums for Plan Year 1/1/17 - 12/31/17 ($5,760,000)	$ (5,760,000)
31	Premiums for Plan Year 1/1/18 - 12/31/18 ($3,840,000)	$ (3,840,000)
33	Premium Assistance (FICA Savings)	$ (3,881,786)
32	Catastrophic Reserve (2016 $10,500,000)	$ (10,500,000)
34	**Net Assets Available**	$ 56,252,140

35 Fifth Week of Claims $0

Public School Employees (PSE) Financials - January 1, 2017 through September 30, 2017								
	EMPLOYEE ONLY					EMPLOYEE + DEPENDENTS			
	ACTIVES	RETIREES	MEDICARE	TOTAL		ACTIVES	RETIREES	MEDICARE	TOTAL
BASIC	4152	446		**4598**		6197	585		**6782**
CLASSIC	23353	2182		**25535**		43772	2617		**46389**
PREMIUM	17888	756		**18644**		23638	816		**24454**
PRIMARY		66	12010	**12076**			133	13088	**13221**
TOTAL	**45393**	**3450**	**12010**	**60853**		**73607**	**4151**	**13088**	**90846**

REVENUES & EXPENDITURES

		Current Month	Year to Date (9 Months)
	Funding		
1	Per Participating Employee Funding (PPE Funding)	$ 8,144,482	$ 73,226,005
2	Employee Contribution	$ 9,751,860	$ 86,969,263
3	Department of Education $35,000,000 & $15,000,000 & Other Funding	$ 4,583,333	$ 59,009,091
4	Other	$ 1,202,022	$ 7,680,494
5	Allocation of Reserves	$ 3,792,121	$ 32,483,636
	Total Funding	$ 27,473,819	$ 259,368,489
	Expenses		
	Medical Expenses		
6	Claims Expense	$ 20,434,202	$ 144,373,533
7	Claims IBNR	$ -	$ (4,300,000)
8	Medical Administration Fees	$ 1,716,661	$ 15,533,098
9	Refunds	$ -	$ -
10	Employee Assistance Program (EAP)	$ 77,611	$ 699,818
	Pharmacy Expenses		
11	RX Claims	$ 5,135,553	$ 37,440,621
12	RX IBNR	$ -	$ 300,000
13	RX Administration	$ 185,657	$ 1,592,893
14	Plan Administration	$ 343,181	$ 3,886,020
	Total Expenses	$ 27,892,864	$ 199,525,982
15	Less DOE Allocation		$ (18,100,000)
16	**Net Income/(Loss)**	$ (419,045)	$ 41,742,507

BALANCE SHEET

	Assets	
17	Bank Account	$ 13,844,016
18	State Treasury	$ 139,734,697
19	Receivable from Provider	$ -
20	Accounts Receivable	$ 5,796,768
21	Due from ASE	$ 311,692
	Total Assets	$ 159,687,174
	Liabilities	
22	Accounts Payable	$ 1,199
23	Due to ASE	$ -
24	Deferred Revenues	$ -
25	Due to Federal Government ($27 fee)	$ -
26	Health IBNR	$ 25,700,000
27	RX IBNR	$ 1,400,000
	Total Liabilities	$ 27,101,199
28	**Net Assets**	$ 132,585,975
	Less Reserves Allocated	
29	Premiums for Plan Year 1/1/17 - 12/31/17 ($5,760,000+$20,000,000 + $18,100,000 DOE)	$ (11,376,364)
30	Premiums for Plan Year 1/1/18 - 12/31/18 ($3,840,000 + $660,000)	$ (4,500,000)
31	Premiums for Plan Year 1/1/19 - 12/31/19 ($396,000)	$ (396,000)
32	Premiums for Plan Year 1/1/20 - 12/31/20 ($264,000)	$ (264,000)
33	Premium Assistance (FICA Savings)	$ (4,610,158)
34	Catastrophic Reserve (2017 $58,500,000)	$ (58,500,000)
35	**Net Assets Available**	$ 52,939,454

36 Fifth Week of Claims $5,979,856.20

Public School Employees (PSE) Financials - January 1, 2016 through September 30, 2016

	EMPLOYEE ONLY				EMPLOYEE + DEPENDENTS			
	ACTIVES	RETIREES	MEDICARE	TOTAL	ACTIVES	RETIREES	MEDICARE	TOTAL
BASIC	3507	335		**3842**	5243	412		**5655**
CLASSIC	22242	2101		**24343**	41421	2548		**43969**
PREMIUM	18782	975		**19757**	24613	1039		**25652**
PRIMARY		83	11191	**11274**		167	12198	**12365**
TOTAL	**44531**	**3494**	**11191**	**59216**	**71277**	**4166**	**12198**	**87641**

REVENUES & EXPENDITURES

		Current Month	Year to Date (9 Months)
	Funding		
1	Per Participating Employee Funding (PPE Funding)	$ 8,045,925	$ 72,828,839
2	Employee Contribution	$ 9,393,695	$ 83,656,202
3	Department of Education $35,000,000 & $15,000,000 & Other Funding	$ 3,181,818	$ 36,704,545
4	Other	$ 600,418	$ 5,691,932
5	Allocation of Reserves	$ 3,975,000	$ 35,775,000
	Total Funding	$ 25,196,856	$ 234,656,518
	Expenses		
	Medical Expenses		
6	Claims Expense	$ 18,648,776	$ 147,522,251
7	Claims IBNR	$ -	$ 2,000,000
8	Medical Administration Fees	$ 1,179,044	$ 14,290,455
9	Refunds	$ -	$ -
10	Employee Assistance Program (EAP)	$ 76,063	$ 690,033
	Pharmacy Expenses		
11	RX Claims	$ 4,873,829	$ 37,399,125
12	RX IBNR	$ -	$ (300,000)
13	RX Administration	$ 640,677	$ 2,819,929
14	Plan Administration	$ 416,904	$ 5,645,862
	Total Expenses	$ 25,835,293	$ 210,067,654
16	**Net Income/(Loss)**	$ (638,437)	$ 24,588,864

BALANCE SHEET

	Assets	
17	Bank Account	$ 6,163,588
18	State Treasury	$ 109,202,195
19	Receivable from Provider	$ -
20	Accounts Receivable	$ 8,444,515
21	Due from ASE	$ 1,573
	Total Assets	$ 123,811,871
	Liabilities	
22	Accounts Payable	$ 2,889
23	Due to ASE	$ 177,363
24	Deferred Revenues	$ 303
25	Due to Federal Government ($27 fee)	$ 1,010,826
26	Health IBNR	$ 30,000,000
27	RX IBNR	$ 1,100,000
	Total Liabilities	$ 32,291,381
28	**Net Assets**	$ 91,520,490
	Less Reserves Allocated	
29	Premiums for Plan Year 1/1/16 - 12/31/16 ($9,600,000 + $20,000,000 DOE + 18,100,000 DOE)	$ (11,925,000)
30	Premiums for Plan Year 1/1/17 - 12/31/17 ($5,760,000)	$ (5,760,000)
31	Premiums for Plan Year 1/1/18 - 12/31/18 ($3,840,000)	$ (3,840,000)
33	Premium Assistance (FICA Savings)	$ (4,365,745)
32	Catastrophic Reserve (2016 $10,500,000)	$ (10,500,000)
34	**Net Assets Available**	$ 55,129,745

35 Fifth Week of Claims $0

Arkansas State Employees (ASE) Financials - January 1, 2017 through August 31, 2017

	EMPLOYEE ONLY					EMPLOYEE + DEPENDENTS			
	ACTIVES	RETIREES	MEDICARE	TOTAL		ACTIVES	RETIREES	MEDICARE	TOTAL
BASIC	1582	47		**1629**		2505	65		**2570**
CLASSIC	1969	72		**2041**		3265	95		**3360**
PREMIUM	22510	2143		**24653**		38791	2700		**41491**
PRIMARY		214	9718	**9932**			445	12654	**13099**
TOTAL	**26061**	**2476**	**9718**	**38255**		**44561**	**3305**	**12654**	**60520**

REVENUES & EXPENDITURES

		Current Month	Year to Date (8 Months)
	Funding		
1	State Contribution	$ 14,532,280	$ 117,031,628
2	Employee Contribution	$ 8,084,057	$ 64,844,581
3	Other	$ 1,236,363	$ 11,371,535
4	Allocation of Reserves	$ 1,777,500	$ 14,220,000
	Total Funding	$ 25,630,201	$ 207,467,744
	Expenses		
	Medical Expenses		
5	Claims Expense	$ 13,659,620	$ 105,694,805
6	Claims IBNR	$ -	$ (2,300,000)
7	Medical Administration Fees	$ 1,281,997	$ 9,136,893
8	Refunds	$ 270	$ 3,705
9	Employee Assistance Program (EAP)	$ 55,092	$ 439,320
	Life Insurance	$ 79,353	$ 632,693
	Pharmacy Expenses		
11	RX Claims	$ 5,937,510	$ 50,144,539
12	RX IBNR	$ -	$ 300,000
13	RX Administration	$ 121,339	$ 931,782
14	Plan Administration	$ 280,030	$ 3,195,369
	Total Expenses	$ 21,415,210	$ 168,179,106
15	**Net Income/(Loss)**	$ 4,214,991	$ 39,288,638

BALANCE SHEET

	Assets	
16	Bank Account	$ 23,013,035
17	State Treasury	$ 96,298,229
18	Due from Cafeteria Plan	$ 5,561,503
19	Due from PSE	$ -
20	Receivable from Provider	$ -
21	Accounts Receivable	$ (367,866)
	Total Assets	$ 124,504,901
	Liabilities	
22	Accounts Payable	$ 3,143
23	Deferred Revenues	$ 3,780
24	Due to Cafeteria	$ 150
25	Due to PSE	$ 421,908
26	Due to Federal Government ($27 fee)	$ -
27	Health IBNR	$ 25,700,000
28	RX IBNR	$ 2,000,000
	Total Liabilities	$ 28,128,981
	Net Assets	$ 96,375,920
	Less Reserves Allocated	
29	Premiums for Plan Year 1/1/17 - 12/31/17 ($7,560,000 + $13,770,000)	$ (7,110,000)
30	Premiums for Plan Year 1/1/18 - 12/31/18 ($5,040,000 + $8,262,000 + $4,710,000)	$ (18,012,000)
31	Premiums for Plan Year 1/1/19 - 12/31/19 ($5,508,000 + $2,826,000)	$ (8,334,000)
32	Premiums for Plan Year 1/1/20 - 12/31/20 ($1,884,000)	$ (1,884,000)
33	Catastrophic Reserve (2017 $20,600,000)	$ (30,600,000)
34	**Net Assets Available**	$ 30,435,920

35 Fifth Week of Claims $

Arkansas State Employees (ASE) Financials - January 1, 2016 through August 31, 2016

	EMPLOYEE ONLY					EMPLOYEE + DEPENDENTS			
	ACTIVES	RETIREES	MEDICARE	TOTAL		ACTIVES	RETIREES	MEDICARE	TOTAL
BASIC	1302	39		**1341**		2147	54		**2201**
CLASSIC	1779	69		**1848**		2989	92		**3081**
PREMIUM	22740	2174		**24914**		39638	2799		**42437**
PRIMARY		213	9315	**9528**			435	12174	**12609**
TOTAL	**25821**	**2495**	**9315**	**37631**		**44774**	**3380**	**12174**	**60328**

REVENUES & EXPENDITURES

		Current Month	Year to Date (8 Months)
	Funding		
1	State Contribution	$ 14,702,184	$ 117,561,304
2	Employee Contribution	$ 7,880,195	$ 63,639,252
3	Other	$ 142,367	$ 9,194,272
4	Allocation of Reserves	$ 1,350,000	$ 10,800,000
	Total Funding	$ 24,074,746	$ 201,194,828
	Expenses		
	Medical Expenses		
5	Claims Expense	$ 14,757,836	$ 115,496,288
6	Claims IBNR	$ -	$ 3,300,000
7	Medical Administration Fees	$ 1,021,588	$ 8,694,702
8	Refunds	$ -	$ 265
9	Employee Assistance Program (EAP)	$ 54,313	$ 441,157
	Life Insurance	$ 78,180	$ 634,178
	Pharmacy Expenses		
11	RX Claims	$ 5,496,320	$ 50,123,760
12	RX IBNR	$ -	$ (100,000)
13	RX Administration	$ 184,306	$ 1,510,593
14	Plan Administration	$ 391,453	$ 4,030,751
	Total Expenses	$ 21,983,997	$ 184,131,693
15	**Net Income/(Loss)**	$ 2,090,750	$ 17,063,135

BALANCE SHEET

	Assets	
16	Bank Account	$ 8,358,214
17	State Treasury	$ 91,037,313
18	Due from Cafeteria Plan	$ 5,018,599
19	Due from PSE	$ 177,363
20	Receivable from Provider	$ -
21	Accounts Receivable	$ (563,221)
	Total Assets	$ 104,028,267
	Liabilities	
22	Accounts Payable	$ 1,253
23	Deferred Revenues	$ -
24	Due to Cafeteria	$ 28
25	Due to PSE	$ 84
26	Due to Federal Government ($27 fee)	$ 664,295
27	Health IBNR	$ 28,000,000
28	RX IBNR	$ 1,700,000
	Total Liabilities	$ 30,365,660
	Net Assets	$ 73,662,608
	Less Reserves Allocated	
29	Premiums for Plan Year 1/1/16 - 12/31/16 ($3,600,000 + $12,600,000)	$ (5,400,000)
30	Premiums for Plan Year 1/1/17 - 12/31/17 ($7,560,000 +13,770,000)	$ (21,330,000)
31	Premiums for Plan Year 1/1/18 - 12/31/18 ($5,040,000 + 8,262,000)	$ (13,302,000)
	Premiums for Plan Year 1/1/19 - 12/31/19 ($5,508,000)	$ (5,508,000)
32	Catastrophic Reserve (2016 $10,700,000)	$ (10,700,000)
33	**Net Assets Available**	$ 17,422,608

34 Fifth Week of Claims $0

Arkansas State Employees (ASE) Financials - January 1, 2017 through September 30, 2017								
	EMPLOYEE ONLY					EMPLOYEE + DEPENDENTS			
	ACTIVES	RETIREES	MEDICARE	TOTAL		ACTIVES	RETIREES	MEDICARE	TOTAL
BASIC	1591	46		**1637**		2520	63		**2583**
CLASSIC	1999	74		**2073**		3303	100		**3403**
PREMIUM	22466	2140		**24606**		38683	2691		**41374**
PRIMARY		211	9733	**9944**			439	12671	**13110**
TOTAL	**26056**	**2471**	**9733**	**38260**		**44506**	**3293**	**12671**	**60470**

REVENUES & EXPENDITURES

		Current Month	Year to Date (9 Months)
	Funding		
1	State Contribution	$ 14,554,092	$ 131,585,720
2	Employee Contribution	$ 8,080,017	$ 72,924,598
3	Other	$ 1,232,013	$ 12,603,548
4	Allocation of Reserves	$ 1,777,500	$ 15,997,500
	Total Funding	$ 25,643,622	$ 233,111,366
	Expenses		
	Medical Expenses		
5	Claims Expense	$ 17,764,235	$ 123,459,040
6	Claims IBNR	$ -	$ (2,300,000)
7	Medical Administration Fees	$ 1,094,424	$ 10,231,317
8	Refunds	$ 97	$ 3,802
9	Employee Assistance Program (EAP)	$ 55,184	$ 494,503
	Life Insurance	$ 79,633	$ 712,325
	Pharmacy Expenses		
11	RX Claims	$ 7,539,116	$ 57,683,655
12	RX IBNR	$ -	$ 300,000
13	RX Administration	$ 121,376	$ 1,053,158
14	Plan Administration	$ 359,579	$ 3,554,948
	Total Expenses	$ 27,013,643	$ 195,192,749
15	**Net Income/(Loss)**	$ (1,370,021)	$ 37,918,617

BALANCE SHEET

	Assets	
16	Bank Account	$ 18,917,986
17	State Treasury	$ 96,419,993
18	Due from Cafeteria Plan	$ 5,561,503
19	Due from PSE	$ -
20	Receivable from Provider	$ -
21	Accounts Receivable	$ 347,946
	Total Assets	$ 121,247,428
	Liabilities	
22	Accounts Payable	$ 3,143
23	Deferred Revenues	$ 3,780
24	Due to Cafeteria	$ 414
25	Due to PSE	$ 311,692
26	Due to Federal Government ($27 fee)	$ -
27	Health IBNR	$ 25,700,000
28	RX IBNR	$ 2,000,000
	Total Liabilities	$ 28,019,029
	Net Assets	$ 93,228,399
	Less Reserves Allocated	
29	Premiums for Plan Year 1/1/17 - 12/31/17 ($7,560,000 + $13,770,000)	$ (5,332,500)
30	Premiums for Plan Year 1/1/18 - 12/31/18 ($5,040,000 + $8,262,000 + $4,710,000)	$ (18,012,000)
31	Premiums for Plan Year 1/1/19 - 12/31/19 ($5,508,000 + $2,826,000)	$ (8,334,000)
32	Premiums for Plan Year 1/1/20 - 12/31/20 ($1,884,000)	$ (1,884,000)
33	Catastrophic Reserve (2017 $20,600,000)	$ (30,600,000)
34	**Net Assets Available**	$ 29,065,899

35 Fifth Week of Claims $5,893,256.33

Arkansas State Employees (ASE) Financials - January 1, 2016 through September 30, 2016

	EMPLOYEE ONLY					EMPLOYEE + DEPENDENTS			
	ACTIVES	RETIREES	MEDICARE	TOTAL		ACTIVES	RETIREES	MEDICARE	TOTAL
BASIC	1333	42		**1375**		2197	57		**2254**
CLASSIC	1792	67		**1859**		3001	89		**3090**
PREMIUM	22698	2164		**24862**		39544	2776		**42320**
PRIMARY		205	9348	**9553**			419	12220	**12639**
TOTAL	**25823**	**2478**	**9348**	**37649**		**44742**	**3341**	**12220**	**60303**

REVENUES & EXPENDITURES

		Current Month	Year to Date (9 Months)
	Funding		
1	State Contribution	$ 14,704,872	$ 132,266,176
2	Employee Contribution	$ 7,847,295	$ 71,486,547
3	Other	$ 142,629	$ 9,336,902
4	Allocation of Reserves	$ 1,350,000	$ 12,150,000
	Total Funding	$ 24,044,796	$ 225,239,624
	Expenses		
	Medical Expenses		
5	Claims Expense	$ 16,901,060	$ 132,397,348
6	Claims IBNR	$ -	$ 3,300,000
7	Medical Administration Fees	$ 1,137,747	$ 9,832,449
8	Refunds	$ -	$ 265
9	Employee Assistance Program (EAP)	$ 54,308	$ 495,465
	Life Insurance	$ 78,150	$ 712,328
	Pharmacy Expenses		
11	RX Claims	$ 7,142,223	$ 57,265,982
12	RX IBNR	$ -	$ (100,000)
13	RX Administration	$ 119,512	$ 1,630,105
14	Plan Administration	$ 249,727	$ 4,280,479
	Total Expenses	$ 25,682,727	$ 209,814,420
15	**Net Income/(Loss)**	$ (1,637,931)	$ 15,425,204

BALANCE SHEET

	Assets	
16	Bank Account	$ 5,174,781
17	State Treasury	$ 91,131,106
18	Due from Cafeteria Plan	$ 5,018,599
19	Due from PSE	$ 177,363
20	Receivable from Provider	$ -
21	Accounts Receivable	$ (451,304)
	Total Assets	$ 101,050,545
	Liabilities	
22	Accounts Payable	$ 4,846
23	Deferred Revenues	$ 4,292
24	Due to Cafeteria	$ 862
25	Due to PSE	$ 1,573
26	Due to Federal Government ($27 fee)	$ 664,295
27	Health IBNR	$ 28,000,000
28	RX IBNR	$ 1,700,000
	Total Liabilities	$ 30,375,868
	Net Assets	$ 70,674,677
	Less Reserves Allocated	
29	Premiums for Plan Year 1/1/16 - 12/31/16 ($3,600,000 + $12,600,000)	$ (4,050,000)
30	Premiums for Plan Year 1/1/17 - 12/31/17 ($7,560,000 +13,770,000)	$ (21,330,000)
31	Premiums for Plan Year 1/1/18 - 12/31/18 ($5,040,000 + 8,262,000)	$ (13,302,000)
	Premiums for Plan Year 1/1/19 - 12/31/19 ($5,508,000)	$ (5,508,000)
32	Catastrophic Reserve (2016 $10,700,000)	$ (10,700,000)
33	**Net Assets Available**	$ 15,784,677

34 Fifth Week of Claims $4,622,501

PROJECTED PAID CLAIMS AND EXPENSES BY MONTH

PSE

2017 August

Medical Claims

PROJECTED Monthly Amount	ACTUAL Monthly Amount	DIFFERENCE Monthly Amount	PROJECTED YTD Total	ACTUAL YTD Total	DIFFERENCE YTD Total
20,030,000	16,884,967	(3,145,033)	135,640,000	119,639,332	(16,000,668)

Note: IBNR decreased for Medical by $4,300,000

Pharmacy Claims

PROJECTED Monthly Amount	ACTUAL Monthly Amount	DIFFERENCE Monthly Amount	PROJECTED YTD Total	ACTUAL YTD Total	DIFFERENCE YTD Total
4,600,000	4,047,472	(552,528)	33,650,000	32,605,068	(1,044,932)

Note: IBNR increased for Pharmacy by $300,000

Expenses/Other

PROJECTED Monthly Amount	ACTUAL Monthly Amount	DIFFERENCE Monthly Amount	PROJECTED YTD Total	ACTUAL YTD Total	DIFFERENCE YTD Total
2,750,000	2,445,912	(304,088)	22,000,000	19,388,718	(2,611,282)

ASE

2017 August

Medical Claims

PROJECTED Monthly Amount	ACTUAL Monthly Amount	DIFFERENCE Monthly Amount	PROJECTED YTD Total	ACTUAL YTD Total	DIFFERENCE YTD Total
15,200,000	13,659,620	(1,540,380)	123,850,000	103,394,805	(20,455,195)

Note: IBNR decreased for Medical by $2,300,000

Pharmacy Claims

PROJECTED Monthly Amount	ACTUAL Monthly Amount	DIFFERENCE Monthly Amount	PROJECTED YTD Total	ACTUAL YTD Total	DIFFERENCE YTD Total
6,320,000	5,937,510	(382,490)	52,600,000	50,444,539	(2,155,461)

Note: IBNR increased for Pharmacy by $300,000

Expenses/Other

PROJECTED Monthly Amount	ACTUAL Monthly Amount	DIFFERENCE Monthly Amount	PROJECTED YTD Total	ACTUAL YTD Total	DIFFERENCE YTD Total
1,980,000	1,818,081	(161,919)	15,840,000	14,339,762.00	(1,500,238)

PROJECTED PAID CLAIMS AND EXPENSES BY MONTH

PSE

2017 September

Medical Claims

PROJECTED Monthly Amount	ACTUAL Monthly Amount	DIFFERENCE Monthly Amount	PROJECTED YTD Total	ACTUAL YTD Total	DIFFERENCE YTD Total
23,360,000	20,434,202	(2,925,798)	159,000,000	140,073,533	(18,926,467)

Note: IBNR decreased for Medical by $4,300,000

Pharmacy Claims

PROJECTED Monthly Amount	ACTUAL Monthly Amount	DIFFERENCE Monthly Amount	PROJECTED YTD Total	ACTUAL YTD Total	DIFFERENCE YTD Total
6,050,000	5,135,553	(914,447)	39,700,000	37,740,621	(1,959,379)

Note: IBNR increased for Pharmacy by $300,000

Expenses/Other

PROJECTED Monthly Amount	ACTUAL Monthly Amount	DIFFERENCE Monthly Amount	PROJECTED YTD Total	ACTUAL YTD Total	DIFFERENCE YTD Total
2,750,000	2,323,110	(426,890)	24,750,000	21,711,829	(3,038,171)

ASE

2017 September

Medical Claims

PROJECTED Monthly Amount	ACTUAL Monthly Amount	DIFFERENCE Monthly Amount	PROJECTED YTD Total	ACTUAL YTD Total	DIFFERENCE YTD Total
19,970,000	17,764,235	(2,205,765)	143,820,000	121,156,040	(22,663,960)

Note: IBNR decreased for Medical by $2,300,000

Pharmacy Claims

PROJECTED Monthly Amount	ACTUAL Monthly Amount	DIFFERENCE Monthly Amount	PROJECTED YTD Total	ACTUAL YTD Total	DIFFERENCE YTD Total
8,210,000	7,539,116	(670,884)	60,810,000	57,983,655	(2,826,345)

Note: IBNR increased for Pharmacy by $300,000

Expenses/Other

PROJECTED Monthly Amount	ACTUAL Monthly Amount	DIFFERENCE Monthly Amount	PROJECTED YTD Total	ACTUAL YTD Total	DIFFERENCE YTD Total
1,980,000	1,710,293	(269,707)	17,820,000	16,050,053.00	(1,769,947)

State and Public School Life and Health Insurance Board
Benefits Sub-Committee Summary Report

The following report resulted from a meeting of the Benefits Sub-Committee on October 6, 2017, with Claudia Moran presiding.

Topics Discussed:

- August and September Financials
- Regenerative Cellular Therapies
- MiMedx Presentations
- Wellness Options

April PSE-ASE Financials: Marla Wallace, EBD Fiscal Officer

Wallace reported the financials for September 2017.

Regenerative Cellular Therapy: Dr. David Harshfield, Jr M.D., M.S, & Carl Keller, CEO

Regenerative Medicine is now a first line treatment to avoid or delay pharmacological or surgical treatments. Regenerative therapies have learned to do pain control with glucose instead of narcotics and opioids. But, overall success of regenerative medicine is highly dependent on the overall health and psychological well-being of our patients including; comorbidities, pharmaceuticals and nutritional status. For now, we are going to have Centers of Excellence (COE) in El Dorado, Little Rock, and Fayetteville.

Key Points

Clinical Outcomes: IROM, with credentialed providers and certified protocols, provides safe, affordable and effective therapy resulting in improved healing and overall patient outcomes.

Financial outcomes: Lower costs to The State and Public School Life and Health Insurance Board, not only with avoidance of unnecessary pharmaceuticals and surgery but of complications, as well.

Quality of Life: IROM is not only financially beneficial, but allows patents a more rapid return to work and activities of daily living.

Treatment Acceptance: Increasing payer adoption of the use of regenerative and cellular medicine therapies, with Arkansas now playing a leadership role in the U.S.

MiMedx Presentation: Laura Trivette, Dr. David Mason, & Matt Larson

MiMedx® is a biopharmaceutical company developing, manufacturing and marketing regenerative biologics utilizing human placental allografts for multiple sectors of healthcare. MiMedx dHACM is the first human amnion/chorion dehydrated membrane to meet requirements of the United States Pharmacopeia (USP) monograph. The core material that is used to manufacture our product is the human placenta which is normally thrown away as human waste.

MiMedx Value Proposition

- Promotes Healing- Scientific data shows dHACM ability to draw stem cells toward the site to modulate inflammation, reduce pain and accelerate healing
- Proprietary PURION Process preserves 226+ different growth factors
- Superior Published Clinical Data - 6 Randomized Control Trials (RCTs) showing statistical significance
- Patient Safety – Terminal Sterilization
- Stem Cell Magnet - Scientific data shows dHACM ability to draw stem cells toward the site

- USP Monograph - Rigor in processes ensure consistent product quality
- Storage and Ease of use - Ambient conditions with 5-year shelf life

McCook motioned that we recommend to the board that they authorize the director to do whatever is necessary to develop the criteria for operational guidelines to begin a pilot program in 2018. Gardner seconded; all were in favor.

Motion Approved.

Wellness Options: Chris Howlett, EBD Executive Director

Howlett stated that our biggest struggle will be operationalizing the flu shot based on the timing that the flu shot is available and perimeters in which we would be designing the wellness program to capture that data and to be able to facilitate that. Howlett requested to the committee that EBD operationalize all the other components that were initially with the BMI, nicotine, and those components but take the flu shot with whatever operational means that we are having go out to be made 100% available at the time of interaction with our population as well as those that don't interact with the plan but go to the physician's office, can get the flu shot and be covered by the plan.

Keep the wellness components around the discount and those pieces; take the flu shot as an attestation, any mandate whatsoever and remove that and leave it from a voluntary standpoint and allow us to ramp up all the communication and education components and provide the services. Kissire motioned for this recommendation. Harrison seconded; all were in favor.

Motion Approved.

EBD Board Updates

Mike Motley, MPH
Assistant Health Policy Director

Elizabeth Whittington, MPA
Policy Analyst

ACHI
Arkansas Center for Health Improvement

October 2017

Choosing Wisely Initiative Background

Choosing Wisely In Action

- **Choosing Wisely was named in Act 1089 of 2017:**

- ***"By the end of plan year 2017, the State and Public School Life and Health Insurance Board shall explore the evidence supporting opportunities for benefit modification information by:***
  1. ***The Choosing Wisely Initiative;***
  2. ***Emerging therapies; and***
  3. ***Therapeutic alternatives to invasive surgical procedures, such as regenerative injection therapy."***

Source: Washington Health Alliance, "Less Harm. Less Waste. Choosing Wisely in Washington State," 2016

Choosing Wisely In Action

- **Opportunity for EBD to utilize Choosing Wisely framework when assessing issues related to quality of care and benefit design**

- **States are using this initiative to uncover areas of wastefulness in their healthcare systems**

- **<u>Washington Example</u>:**
  - **2016 reported determined 26% of patients in the state with upper respiratory infections were prescribed potentially unnecessary antibiotics**

Source: Washington Health Alliance, "Less Harm. Less Waste. Choosing Wisely in Washington State," 2016

Choosing Wisely In Action

- **Virginia Example:**
  - **Recent analysis of 44 low-value healthcare services revealed more than $586 million in unnecessary costs**
  - **Greatest amount of waste came from low-cost services**
  - **Preoperative lab testing for low-risk patients undergoing low-risk surgery accounted for half of unnecessary spending**

Source: Mafi, J., et. al. "Low-Cost, High-Volume Health Services Contribute The Most to Unnecessary Health Spending," Health Affairs, October 2017 vol. 36 no. 10, 1701-1704.

Choosing Wisely Recommendation: Imaging Tests for Low Back Pain

Choosing Wisely Recommendation-Nonspecific Low Back Pain (AAFP)

- **Don't do imaging for low back pain within the first six weeks, unless serious conditions are present**

- **These include, but are not limited to:**
  - **Severe or progressive neurological deficits**
  - **When underlying conditions such as osteomyelitis (infection in a bone) are suspected**
  - **Trauma**

Source: American Academy of Family Physicians, Choosing Wisely Recommendation-Lower Back Imaging.

Choosing Wisely Recommendations-Nonspecific Low Back Pain

- **Rationale: Imaging of the lower spine before six weeks does not improve outcomes, but does increase costs and increases the likelihood of surgery**

- **Low back pain can be addressed without imaging through pain management and/or physical therapy as first courses of action**

Source: Redd, S. Institute for Clinical and Economic Review Baseline Report-Choosing Wisely Recommendation Analysis: Prioritizing Opportunities for Reducing Inappropriate Care-Imaging for Nonspecific Low Back Pain.

Top 20 ASE/PSE Diagnoses: Potential to Impact Through Intervention 2016

Clinical Classification Category	Total Plan Paid	Unique Patients
Spondylosis; intervertebral disc disorders; other back problems	$14,694,262	16,614
Medical examination/evaluation	$14,383,565	75,200
Maintenance chemotherapy; radiotherapy	$12,005,758	731
Osteoarthritis	$9,859,450	7,026
Other screening for suspected conditions (not mental disorders or infectious disease)	$8,581,436	40,557
Coronary atherosclerosis and other heart disease	$8,278,458	6,724
Cancer of breast	$8,137,618	2,156
Other connective tissue disease	$5,624,911	16,647
Cardiac dysrhythmias	$5,590,183	6,877
Chronic kidney disease	$5,550,786	1,758
Residual codes; unclassified	$5,539,904	13,476
Septicemia (except in labor)	$5,486,604	656
Leukemia	$5,312,409	257
Immunizations and screening for infectious disease	$5,275,877	39,770
Complication of device; implant or graft	$5,208,682	1,268
Nonspecific chest pain	$5,148,580	8,580
Other nervous system disorders	$4,746,518	7,712
Diabetes mellitus with complications	$4,176,209	5,912
Other ear and sense organ disorders	$4,130,922	6,037

Known Consequences

- **Patients who received an MRI during the first month of diagnosis were eight times more likely to have surgery**
- **Five-fold increase in medical expenses**
- **No observed gains in recovery time as compared to patients undergoing no imaging**

Source: Webster, B., & Cifuentes, M., "Relationship of Early Magnetic Resonance Imaging for Work-Related Acute Low Back Pain with Disability and Medical Utilization Outcomes." *Journal of Occupational and Environmental Medicine*. 52(9):900-907, September 2010.

ASE/PSE Lower Back Imaging Analysis

Utilization Analysis

- 4,741 members were diagnosed with uncomplicated lower back pain within a one year period (October 2014—September 2015)

- 1,257 of those members had an imaging event within the first 4 weeks following diagnosis

- 27% of members with uncomplicated low back pain received potentially wasteful imaging

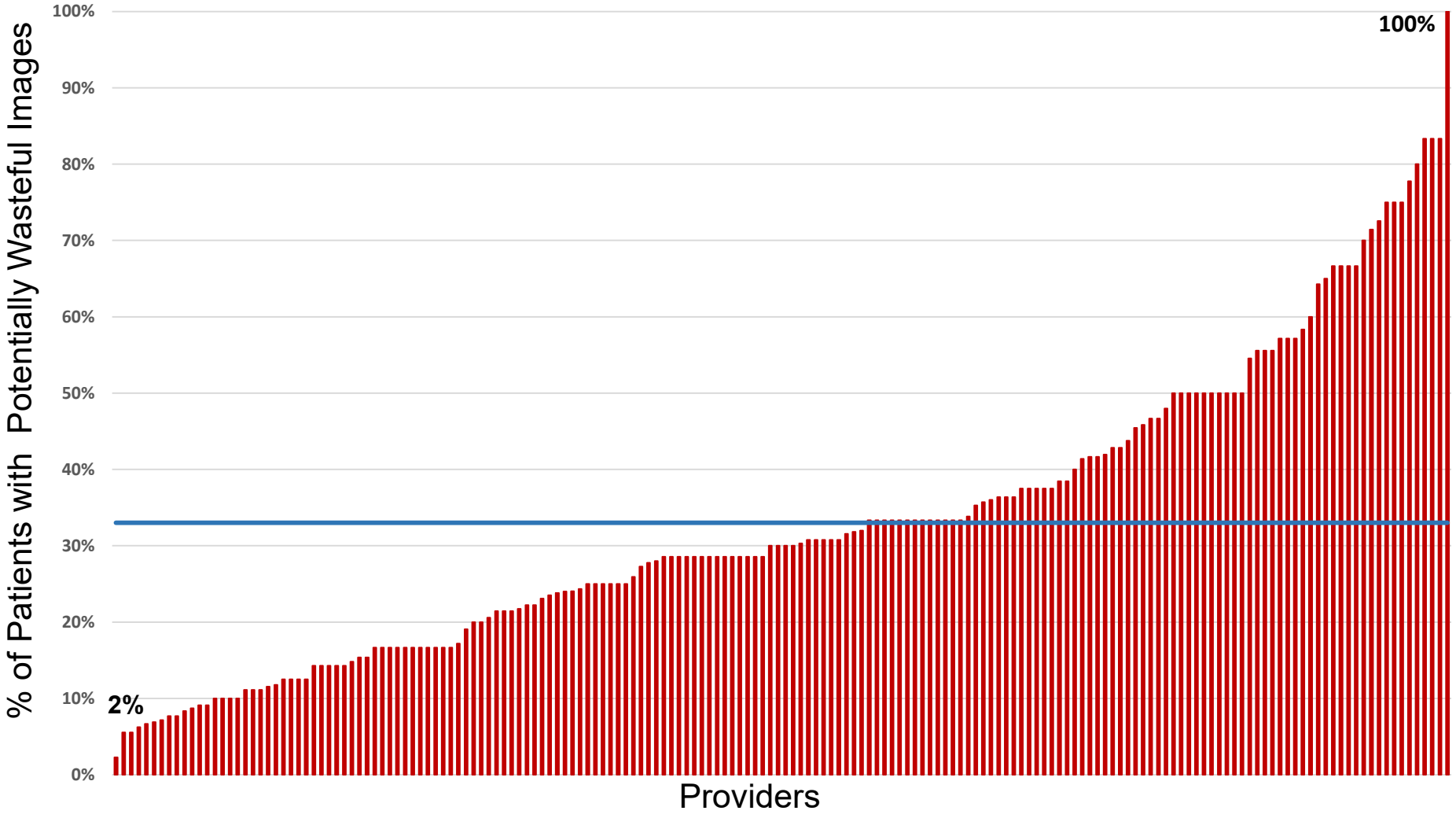
Surgery Analysis

- 8% of those who had imaging in the first four weeks of a diagnosis of uncomplicated back pain had subsequent back surgery
- Comparatively, 3% of those who did not receive imaging in the first four weeks had subsequent back surgery
- Patients who received imaging in the first 4 weeks were 2.6 times more likely to have surgery

Provider Analysis

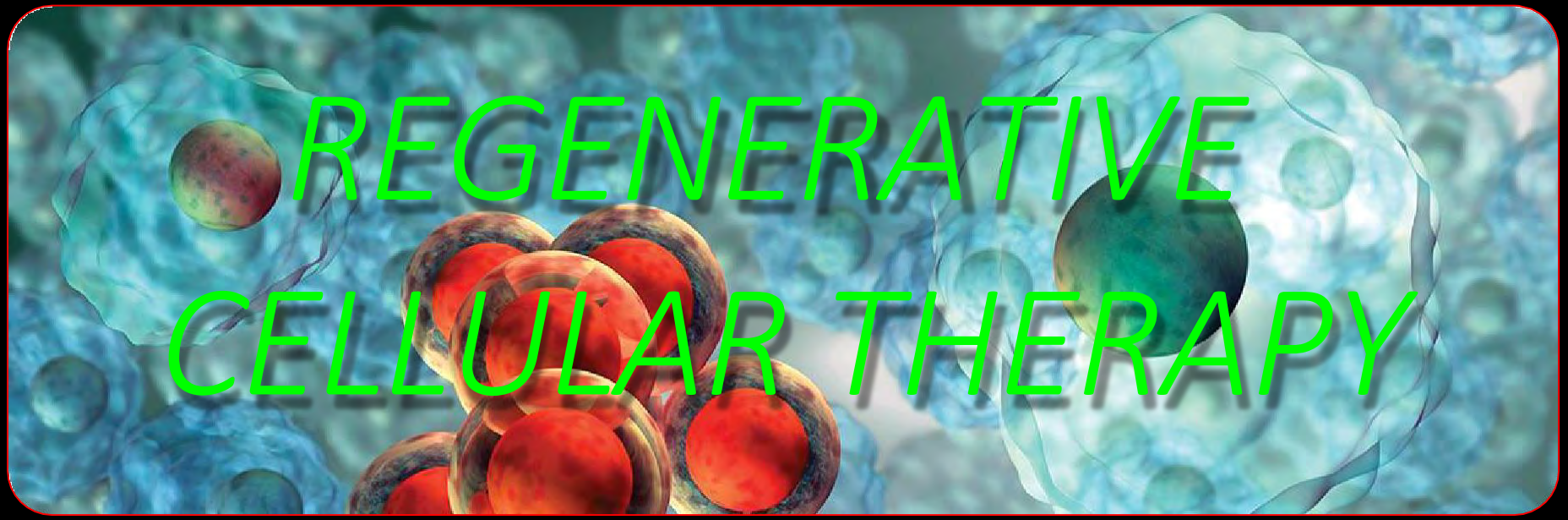
- 469 providers were included in this analysis (individuals or groups)
- 176 providers had at least 6 patients with uncomplicated low back pain within that year
- Following slide shows distribution of patients with potentially wasteful imaging

Potentially Wasteful Images by Providers (2014-2015)



Recommendation from QoC Subcommittee

1. **Member education: Disseminate related education materials (from Choosing Wisely & Consumer Reports) in member newsletter and other outlets;**
2. **Provider outreach: Conduct targeted outreach to high-volume providers with higher rates of potentially wasteful imaging;**
3. **Prior authorization: Review existing EBD prior authorization criteria and work with vendor to refine criteria to more closely align with the Choosing Wisely recommendation.**



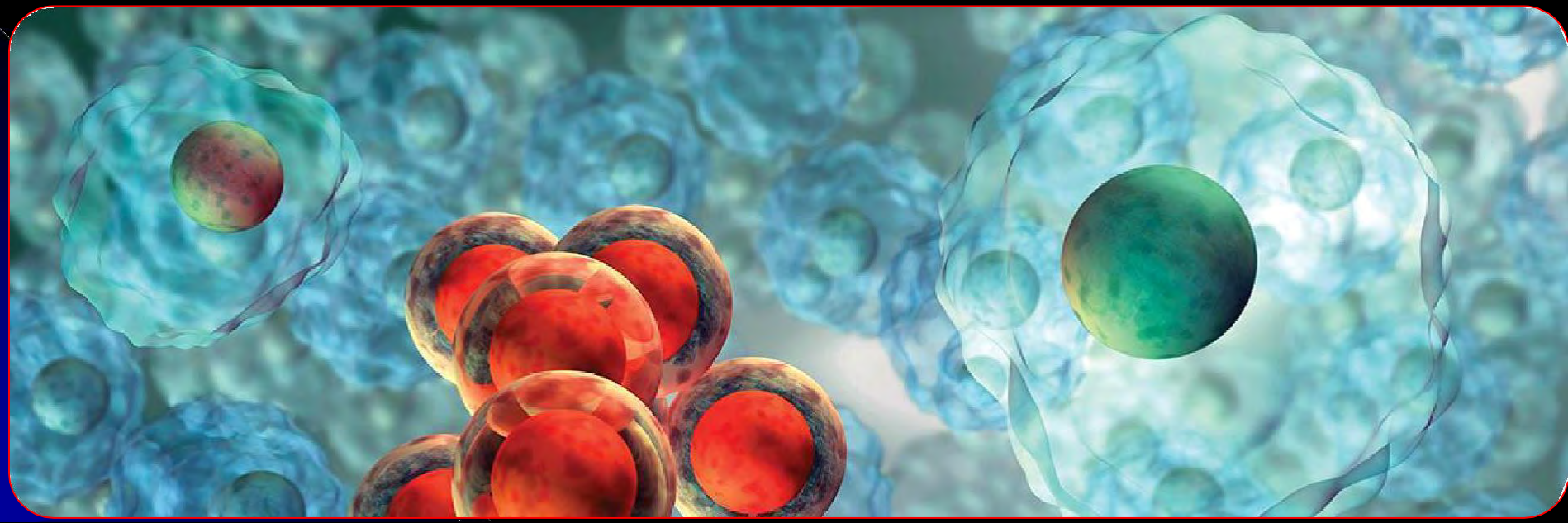
Regenerative Medicine is now a first line treatment to avoid or delay Pharmacological or Surgical treatments

October 17, 2017

Using the Body's Natural Healing Process

PRESENTATION

THE STATE AND PUBLIC
SCHOOL LIFE AND
HEALTH INSURANCE BOARD



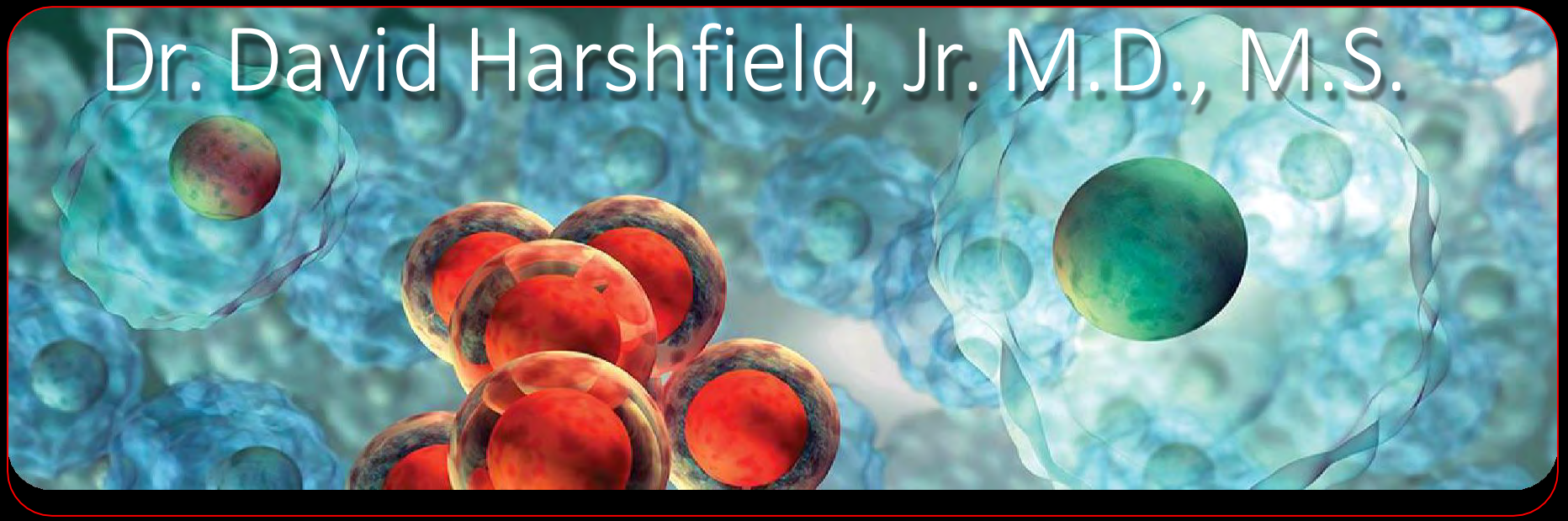
Dr. David Harshfield, Jr. M.D., M.S.

Born in Little Rock, Arkansas

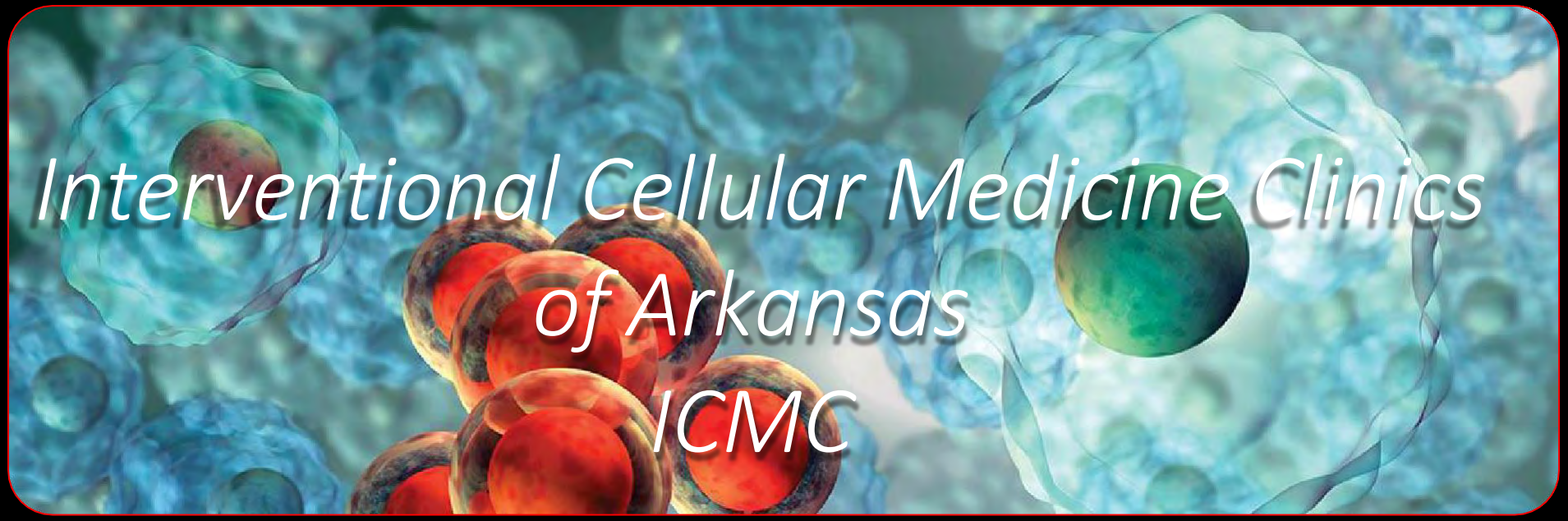
University of Arkansas for Medical Sciences

- Medical Doctorate in 1981, graduating with honors.
- Work in the Honor's Program during medical school pertained to stem cell therapy for the treatment of Diabetes resulted in a Masters Degree in Physiology and Biophysics.
- Board certified in Radiology in 1981

Dr. David Harshfield, Jr. M.D., M.S.



- Fellowships in:
  1. Angiographic and Interventional Radiology
  2. Musculoskeletal Radiology
- Director of Special Procedures at UAMS upon completing fellowship in 1982.
- Chairman of the Institutional Review Board (IRB) for the International Cellular Medicine Society (ICMS), as well as serving on the advisory board for the ICMS.
- Board of Directors for the American Association of Orthopedic Medicine (AAOM)



ICMC Physicians are Certified in IROM

(Interventional Regenerative Orthopedic Medicine)

through the AAOM

(American Association of Orthopedic Medicine)

Clinics are certified by the ICMS

(International Cellular Medicine Society).

Patient and Family Centered Functional Medicine

Interventional Regenerative Orthopedic Medicine Practice

6 Co's of MAXIMIZING EFFECTIVENESS OF RIT- *Avoid Co-mpetition!*

1. Collaborate with patient's Primary Care Provider (PCP)
2. Coordinate with patient's Chiropractor and/or Manual Therapist to ensure the patient the dignity of a proper diagnosis.
3. Collate existing health care records with all prior medical and surgical history with an updated pharmaceutical history, Microbiome (gut) assessment/therapy, blood laboratory and hormone status and QANS testing to determine appropriate oral and I.V. nutrition.
4. Correlate prior imaging studies with appropriate up-to-date imaging to arrive at the correct diagnosis.
5. Communicate overview of Regenerative Injection Therapy (RIT) in sync with patient's understanding of their existing health care regimen (making clear that RIT is **'**in addition to**'**, not **'**instead of**'** the patient's existing and evolving 'patient specific' integrative health care regimen).
6. Complete patient registry following RIT.

Patient and Family-Centered Integrated Functional Medicine

ICMC Services and Physicians are integral to a complete system of Care for EDB insureds:

Access

Communication

Assessment

Triage

Evaluation

Appropriate Regenerative Based Care

Tracking and Follow-up

Guidelines

Regenerative Injection Therapy (RIT)

Buffered 5% Dextrose (D5W)

plus

1. Platelet Rich Plasma (PRP),
2. Hematopoietic
3. Mesenchymal and/or
4. Amniotic Cellular Solutions

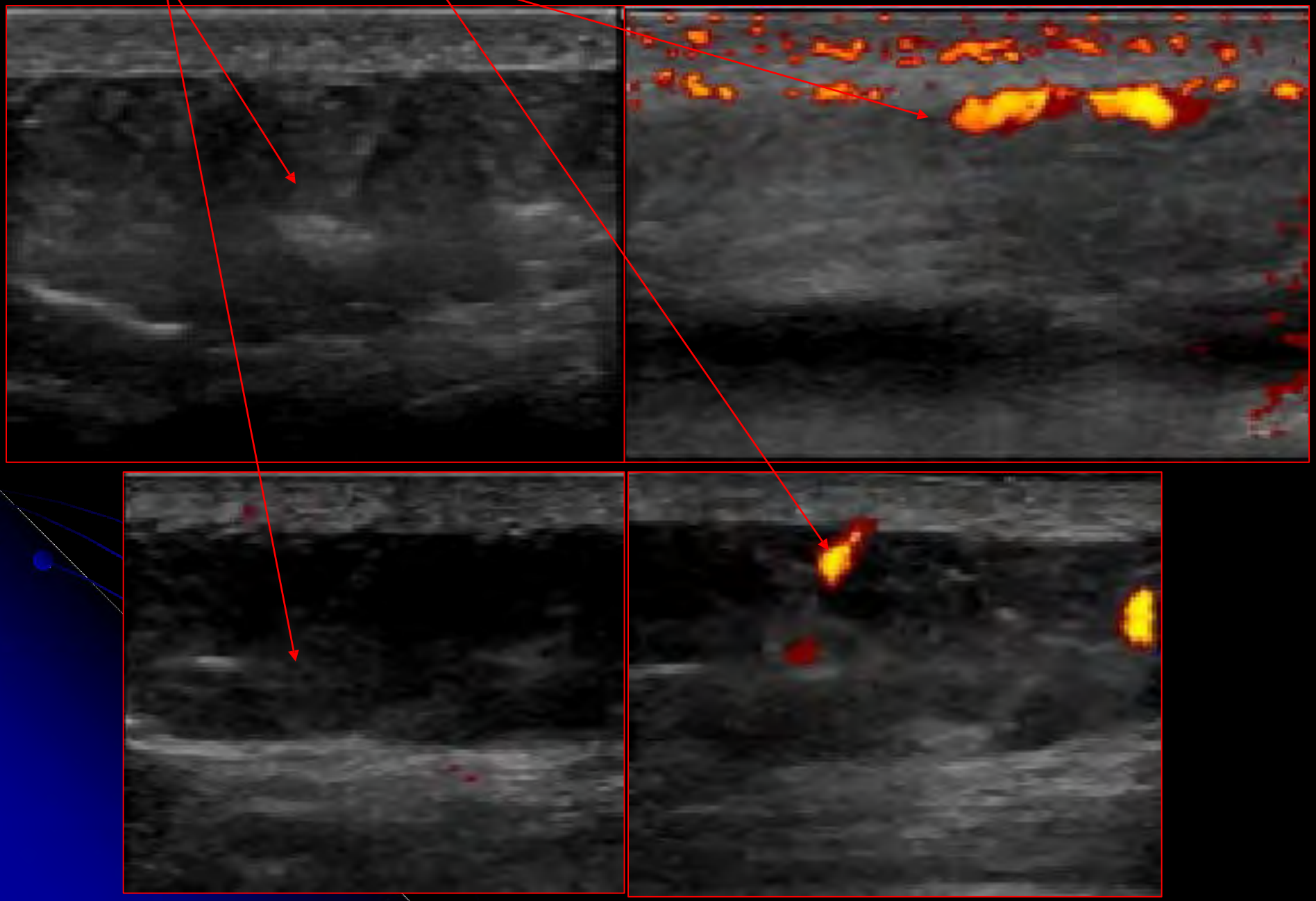
INJECTION METHOD

6 ml of 25% dextrose was injected in the knee via an inferomedial approach. (Solid circle) 15% dextrose was then injected in 0.5 ml aliquots in up to 3 areas using skin slide and redirection with each of up to 15 separate sites for a maximum of 22.5 ml. Areas emphasized included

1: Medial collateral ligament origin and insertion.

2. Pes anserine attachment.
3. Tibial tuberosity/patellar ligament insertion.
4. Medial and lateral coronary ligaments.
5. Superior patella at quads insertion, medial patella at retinacular attachments, and inferior patella and patellar ligament origin, and
6. Lateral collateral ligament origin and insertion

Before and 3 minutes after Perineural Injection Therapy with buffered 5% Dextrose



Biological Response of Severe Degenerative Arthrosis of the Knee to Serial 12.5% Dextrose Injections: A Radiographic and Pathological Assessment

Gaston Topol, M.D. PM&R, Rosario, Argentina
K. Dean Reeves, M.D. Clinical Associate Professor, PM&R, University of Kansas.
Leandro Podesta, M.D. Orthopedic Surgery, Rosario, Argentina
Lanny Johnson, M.D. Arthroscopic Pioneer, East Lansing, Michigan
David Robago, M.D. Department of Family Medicine,University of Wisconsin.
Tom Clark, D.C. Musculoskeletal Ultrasound Consultant, San Diego.

archives

AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

DISCUSSION AND CONCLUSION:
This scientific exhibit will provide the viewer with a comprehensive review of the challenges orthopaedic surgeons face in the nonoperative and operative management of an array of soft tissue disorders. Through illustrations and multimedia presentations, the exhibit will provide a guide to the different types of biologic agents available for soft tissue injuries, reviewing their contents, functions, production, delivery, and clinical applications. Although the data is still relatively scarce, the viewer comes away with a thorough understanding of the potential benefits of orthobiologic agents and sufficient education to begin the process of incorporating these agents into their own clinical practices.

Sports Medicine
Presented on Tuesday, March 14, 2017 7:00 AM

Author(s): **Hien Pham**, MD, EL MONTE, CA; **Kemjika Obinwanne Onuoha**, MD, Brooklyn, NY; **Maxwell Weinberg**, MD, Worcester, MA; **Laith M Jazrawi**, MD, New York, NY; **Eric Jason Strauss**, MD, Scarsdale, NY; **Michael J Alaia**, MD, New York, NY; **Kirk A Campbell**, MD, NY, NY;

INTRODUCTION:
Due to a combination of poor healing potential from a tenuous blood supply and progressive degeneration, orthopaedists continue to face challenges in managing ligamentous and tendinous pathologies throughout the body. For the same reasons, surgical management for common injuries such as rotator cuff tears, are marked by challenges in healing and high re-rupture rates. These obstacles highlight the interest in and propel the search for biologic agents that can boost host healing potential and stimulate native tissue regeneration. Biologic agents such as platelet rich plasma and stem cell therapies are promising tools that can be utilized in the treatment of soft tissue injuries throughout the musculoskeletal system.
METHODS:
Through posters and models, the anatomy, biology, and histology of healthy tendons and ligaments are reviewed and contrasted with their pathologic states. The role and utility of various orthobiologic agents including platelet rich plasma (PRP), and stem cell therapies will be thoroughly reviewed and illustrated.
RESULTS:
The production and medical delivery of orthobiologic treatments will be demonstrated through informative video presentations utilizing various clinical scenarios. Their clinical application will be highlighted in conjunction with a variety of common musculoskeletal soft tissue pathologies, including rotator cuff tears, lateral epicondylitis, anterior cruciate ligament reconstruction, patellar and Achilles tendonitis. Specific indications for utilizing each biologic agent will be outlined as well as current reported clinical outcomes of each.
DISCUSSION AND CONCLUSION:
This scientific exhibit will provide the viewer with a comprehensive review of the challenges orthopaedic surgeons face in the nonoperative and operative management of an array of soft tissue disorders. Through illustrations and multimedia presentations, the exhibit will provide a guide to the different types of biologic agents available for soft tissue injuries, reviewing their contents, functions, production, delivery, and clinical applications. Although the data is still relatively scarce, the viewer comes away with a thorough understanding of the potential benefits of orthobiologic agents and sufficient education to begin the process of incorporating these agents into their own clinical practices.

Disclosure: **H. Pham:** None; Submitted on: 06/01/2016; **K. Onuoha:** None; Submitted on: 04/14/2016; **M. Weinberg:** None; Submitted on: 05/30/2016; **L. Jazrawi:** Submitted on: 04/13/2016|Arthrex, Inc: Research support|Ferring Pharmaceuticals: Paid consultant|Mitek: Research support|Wolters Kluwer Health - Lippincott Williams & Wilkins: Publishing royalties, financial or material support|; **E. Strauss:** Submitted on: 04/04/2016|Arthrex, Inc: Paid presenter or speaker|Cartilage, Bulletin of the Hospital For Joint Diseases: Editorial or governing board|Jaypee Publishing: Publishing royalties, financial or material support|Joint Restoration Foundation: Paid consultant|Mitek: Paid consultant|NuTech: Research support|Omeros Inc., Dynasplint Inc.: Research support|Vericel: Paid consultant|; **M. Alaia:** None; Submitted on: 05/08/2016; **K. Campbell:** None; Submitted on: 05/17/2016;

Midwest Orthopaedics at RUSH
TEAM PHYSICIANS
Chicago Bulls & Chicago White Sox

OHSU HSS

Scientific Exhibit 73
Platelet-Rich Plasma in Orthopaedic Surgery: Where do we stand in 2017?

Nikolas Baksh M.D.[1], Charles P. Hannon M.D.[2], Rachel M. Frank M.D.[2], Jacqueline M, Brady M.D.[1], John G. Kennedy M.D. FRCS (Orth)[3], Scott A. Rodeo M.D.[3], Brian J. Cole M.D., M.B.A.[2]

[1]Department of Orthopaedic Surgery, Oregon Health Sciences University, Portland, Oregon

[2]Division of Sports Medicine, Department of Orthopaedic Surgery, Rush University Medical Center, Chicago, Illinois

[3]Department of Orthopedic Surgery, Hospital for Special Surgery, New York, New York

PRP & Ligament Injury

- Increases collagen content with increased gene expression of *COL1A1* and *COL3A1*
- Improves collagen organization
- Increases ligament cell viability, differentiation and expression of genes implicated in promoting ECM synthesis
- Ligaments (e.g. ACLs and MCLs) treated with PRP may have improved biomechanical properties (e.g. stiffness, max load to failure) compared to controls

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Chicago Bulls & Chicago White Sox
RUSH UNIVERSITY MEDICAL CENTER

PRP & Cartilage – Basic Science

- PRP increases chondrocyte proliferation & viability
- May also increase proteoglycan, glycosaminoglycan, and hyaluronic acid production, as well as type II collagen deposition
- Associated with increased MSC migration & chondrogenic differentiation
- Proposed systemic role within a joint by modifying levels of circulating catabolic cytokines
- Conflicting *in vivo* evidence on PRP's impact on healing of osteochondral defects, donor sites, and as an adjunct to cartilage restoration procedures
- In OA, PRP has been found to have a nociceptive & anti-inflammatory role that may modulate the disease

Platelet-Rich Plasma May Improve Osteochondral Donor Site Healing in a Rabbit Model
Smyth et al. *Cartilage 2015*

PRP & Osteoarthritis

- First FDA sanctioned RCT on PRP for OA recently published
  - PRP is safe and resulted in functional outcome scores that improved 78% from baseline compared to 7% in the placebo control group at 1 year
- Recent RCT by Cole et al. found PRP leads to lower pain scores and higher functional outcomes at 1 year compared to hyaluronic acid (HA)
- Current literature is varied in quality. Level of evidence ranges from Level I – Level IV
  - Many studies demonstrate improvement in PROs starting at 2 months and maintained at 12 months compared to controls
  - Unclear if multiple PRP injections, interval between injections, injection volume, number of spin cycles used to prepare PRP, and the use of an activating agent influence clinical outcomes

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Knee Arthrosis

- Osteoarthrosis (OA) is the most common joint disorder in the world.
- In Western populations it is one of the most frequent causes of pain, loss of function and disability in adults.
- Radiographic evidence of OA occurs in the majority of people by 65 years of age and in about 80% of those aged over 75 years.
- In the US it is second only to ischemic heart disease as a cause of work disability in men over 50 years of age.

Best Pract Res Clin Rheumatol. 2006 Feb;20(1):3-25

Editorials ***The evidence base for orthopaedics and sports medicine***

BMJ 2015; *350 doi: https://doi.org/10.1136/bmj.g7835 (Published 02 January 2015)*

Is the evidence-base for popular knee operations scandalously poor?

Orthopaedic surgeons and their patients will be disturbed to read that operations such as **arthroscopic meniscal surgery and anterior cruciate ligament (ACL) reconstruction are of no proven benefit. (1)**

1. L Stefan Lohmander, Ewa M Roos. The evidence base for orthopaedics and sports medicine. Scandalously poor in parts. BMJ 2015;350:g7835.

Effective Health Care

Three Treatments for Osteoarthritis of the Knee:

Clinician's Guide

EVIDENCE SHOWS LACK OF BENEFIT

This guide summarizes evidence on the effectiveness and safety of three treatments for osteoarthritis of the knee: use of the supplements glucosamine, chondroitin, or both combined; viscosupplementation (injection of hyaluronan into the knee); and arthroscopic lavage and debridement of the knee joint. The evidence evaluated comes primarily from comparisons of each treatment approach with a placebo. This guide does not address other treatments, such as exercise, physical therapy, pain medications, corticosteroid injections, or knee replacement.

Consensus and controversy.

- The most recent findings come from the Cochrane Collaboration.
- They examined data from seven studies of joint lavage involving almost 600 people and found little evidence that it reduced pain or improved function, even within a few months of surgery.

The 2012 Johns Hopkins Arthritis White Paper

Written by Drs. John Flynn and Carl Johnson from Johns Hopkins

Arthroscopic surgery for knee osteoarthritis? Just say no

For most patients with osteoarthritis of the knee, arthroscopic surgery offers little benefit.

Practice changer

Do not recommend arthroscopic surgery to adults with osteoarthritis of the knee. Treat knee pain with medical and physical therapy instead.[1,2]

Strength of recommendation

A: Based on 2 high-quality randomized controlled trials

Kirkley A, Birmingham TB, Litchfield RB, et al. A randomized trial of arthroscopic surgery for osteoarthritis of the knee. *N Engl J Med.* 2008;359:1097-1107.

Moseley JB, O'Malley K, Petersen NJ, et al. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. *N Engl J Med.* 2002;347:81-88.

tions to manage the symptoms. If these fall short in patients with more advanced disease, however, physicians often recommend an orthopedic surgery consult to consider surgical management.

Lavage and debridement: The (questionable) effects

Arthroscopic knee surgery involves lavage (to remove particulate material, such as cartilage fragments) and debridement (to smooth the articular surfaces). Theoretically, this widely used surgery reduces synovitis and improves joint motion, resulting in a decrease in pain and an improvement in function. But what does the latest research tell us?

Arthroscopic surgery for degenerative knee: systematic review and meta-analysis of benefits and harms

BMJ 2015; 350 doi: https://doi.org/10.1136/bmj.h2747 (Published 16 June 2015)

Conclusions:

- The small inconsequential benefit seen from interventions that include arthroscopy for the degenerative knee is limited in time and absent at one to two years after surgery.
- Knee arthroscopy is associated with harms.
- **Taken together, these findings do not support the practice of arthroscopic surgery for middle aged or older patients with knee pain with or without signs of osteoarthritis.**

Knee Arthroplasty Complications

In hospital complications after total joint arthroplasty.

Pulido L, Parvizi J, Macgibeny M, Sharkey PF, Purtill JJ, Rothman RH, Hozack WJ.
Rothman Institute of Orthopaedics at Thomas Jefferson University, Philadelphia, Pennsylvania, USA.

- Total joint arthroplasty is associated with numerous complications may present after elective arthroplasty. This study prospectively collected data on systemic and local in hospital complications after 15383 joint arthroplasties, which included 8230 total hip arthroplasties and 7153 total knee arthroplasties.
- In general, the incidence of complications was higher after knee arthroplasty, simultaneous bilateral surgery, and revision surgery.
- There were 22 (0.16%) deaths in this cohort.
- 486 major systemic complications:
    - the most common was pulmonary embolism (152),
    - followed by tachyarrhythmia (92) and
    - acute myocardial infarction (36).
- There were 109 major local complications, including:
    - 16 vascular injuries,
    - 29 peripheral nerve injuries,
    - 25 periprosthetic fractures, and
    - 18 dislocations.
- Total joint arthroplasty, despite its success, can be associated with serious and life-threatening complications. This study provides a baseline of complications that can occur after elective joint arthroplasty

By the year 2020, 59.4 million persons in the US will be affected by arthrosis, thus increasing chronic disability and costs by more than 25%.

Now is the time to make a difference.

Patient and Family Centered Functional Medicine
Interventional Regenerative Orthopedic Medicine Practice

func·tion·al med·i·cine

noun

medical practice or treatments that focus on optimal functioning of the body and its organs, usually involving systems of holistic or alternative medicine.
"you don't have to have a disease to benefit from functional medicine"

- The patient-centered medical home (PCMH) is the offspring of the Affordable Care Act that, among other things, mandates that going forward Primary Care physicians must acquire and store all patient electronic health records (EHR).
- An emerging 21st century intersection of industry, social healing and diverse practices is bringing about more compassionate, meditative and mindful medicine.

Patient and Family Centered Functional Medicine
Interventional Regenerative Orthopedic Medicine Practice

func·tion·al med·i·cine

noun

medical practice or treatments that focus on optimal functioning of the body and its organs, usually involving systems of holistic or alternative medicine.
"you don't have to have a disease to benefit from functional medicine"

- Health care is not just about what is being injected orjust about who is administering therapy to our patients.
- No question, the skill set of the administering physicians is extremely important.
- However, overall success of regenerative medicine is highly dependent on the overall health and psychological well being of our patients including; comorbidities, pharmaceuticals and nutritional status.

Does Age Affect Cellular Treatment Success?

- Not surprisingly, older patients do not do as well as younger patients with injection of their own cells.
- For example, hip arthritis patients younger than 55 years old are more likely to report improvement than older patients.
- Outcomes can be improved by bolstering the patient's immune system/gut health with I.V. and oral nutrition.

Regenerative therapies for Degenerative arthritis and Diabetic neurovascular therapy

- **Degenerative arthritis** is a challenging disease with limited treatment options, and has become the leading cause of disability in elderly people.
- **Diabetes** is growing at an epidemic rate in the United States. According to the Centers for Disease Control and Prevention (CDC), **nearly 30 million Americans have diabetes and face its devastating consequences.**

Regenerative therapies for Degenerative Arthritis and Diabetic neurovascular therapy

What is true nationwide is also true in Arkansas

- The bottom five states in Health care in the U.S. are in order Nevada, Arkansas, Texas, Mississippi and Oklahoma.

Regenerative therapies for Degenerative Arthritis and Diabetic neurovascular therapy

Emerging Therapies Act

3 Proposed study groups

1. Osteoarthritis (OA) of the Knee
2. Low back pain
3. Lower Leg & Diabetic extremity disease

Regenerative therapies for Degenerative arthritis and Diabetic Neurovascular therapy

Emerging Therapies Act

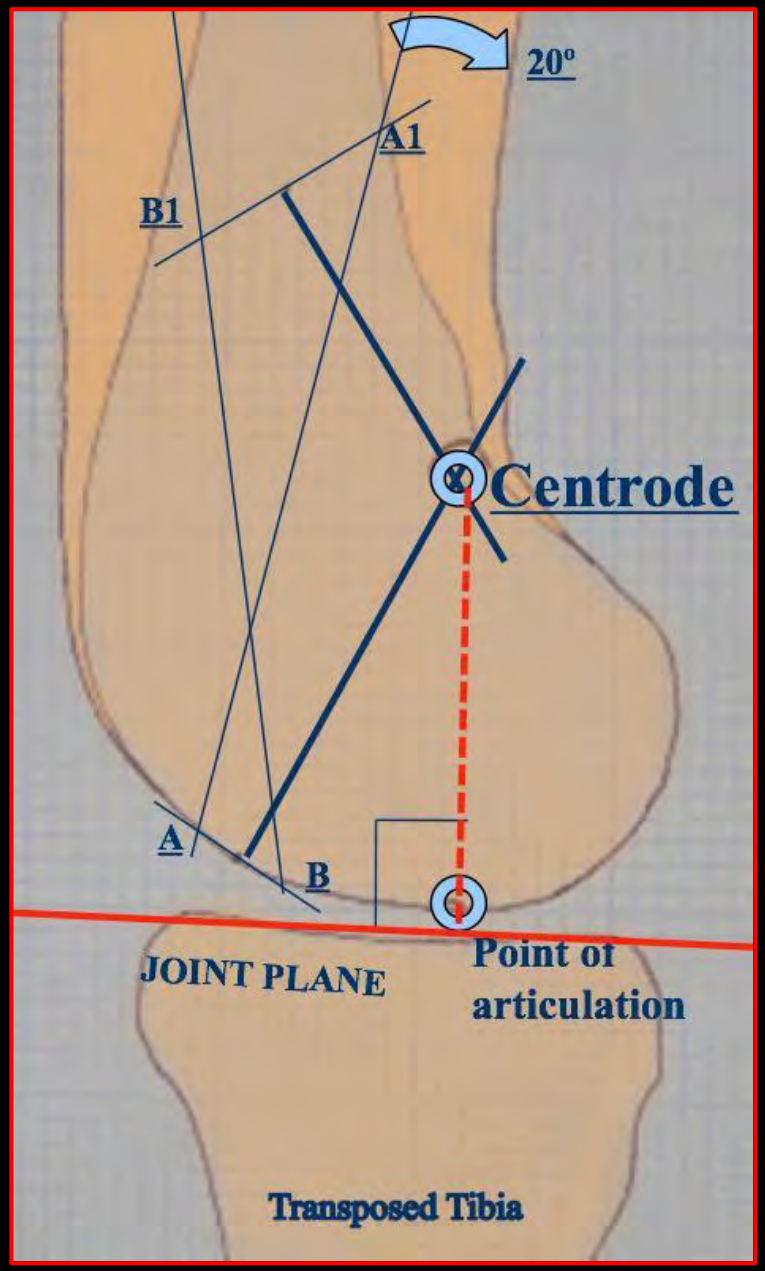
1. Degenerative Arthritis (DA) of the Knee

- Knee pain can be caused by a wide range of diseases or injury.
- Knee pain
  - Second most common cause of the chronic pain that affects over 100 million Americans.
  - Second most common musculoskeletal complaint that brings people to their physician.
- Degenerative arthritis is caused by incompetency of ligaments, the dense fibrous bands that connect bones to each other.

A Method to Measure, Confirm and Localize Joint Dysfunction and its Impact on Cartilage.

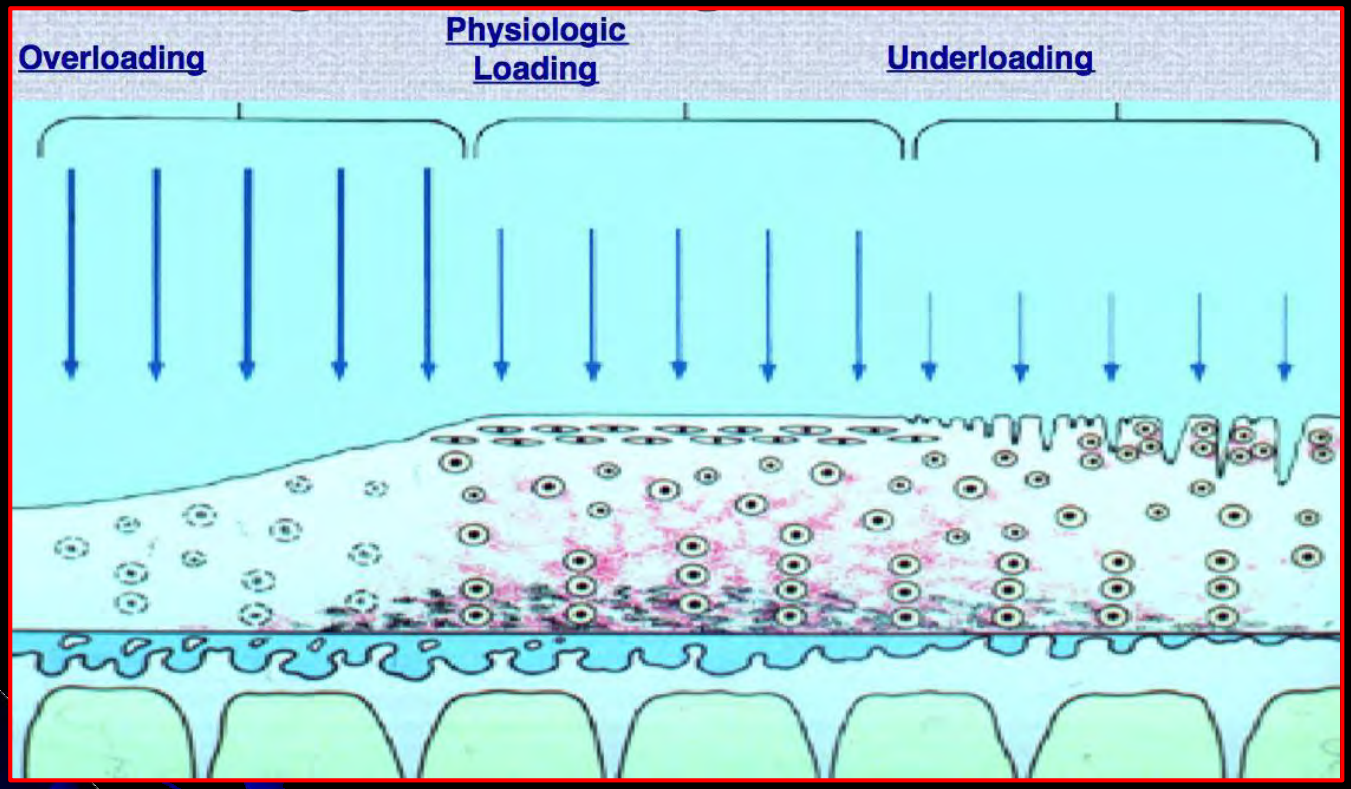
Authors: Ola Grimsby, PT, DMT, FFAAOMPT and David Harshfield M.D., M.S.

The lateral view of the knee shows the optimum axis of rotation, that depends on integrity of the cruciate and other key ligaments (static stabilizers of the knee).



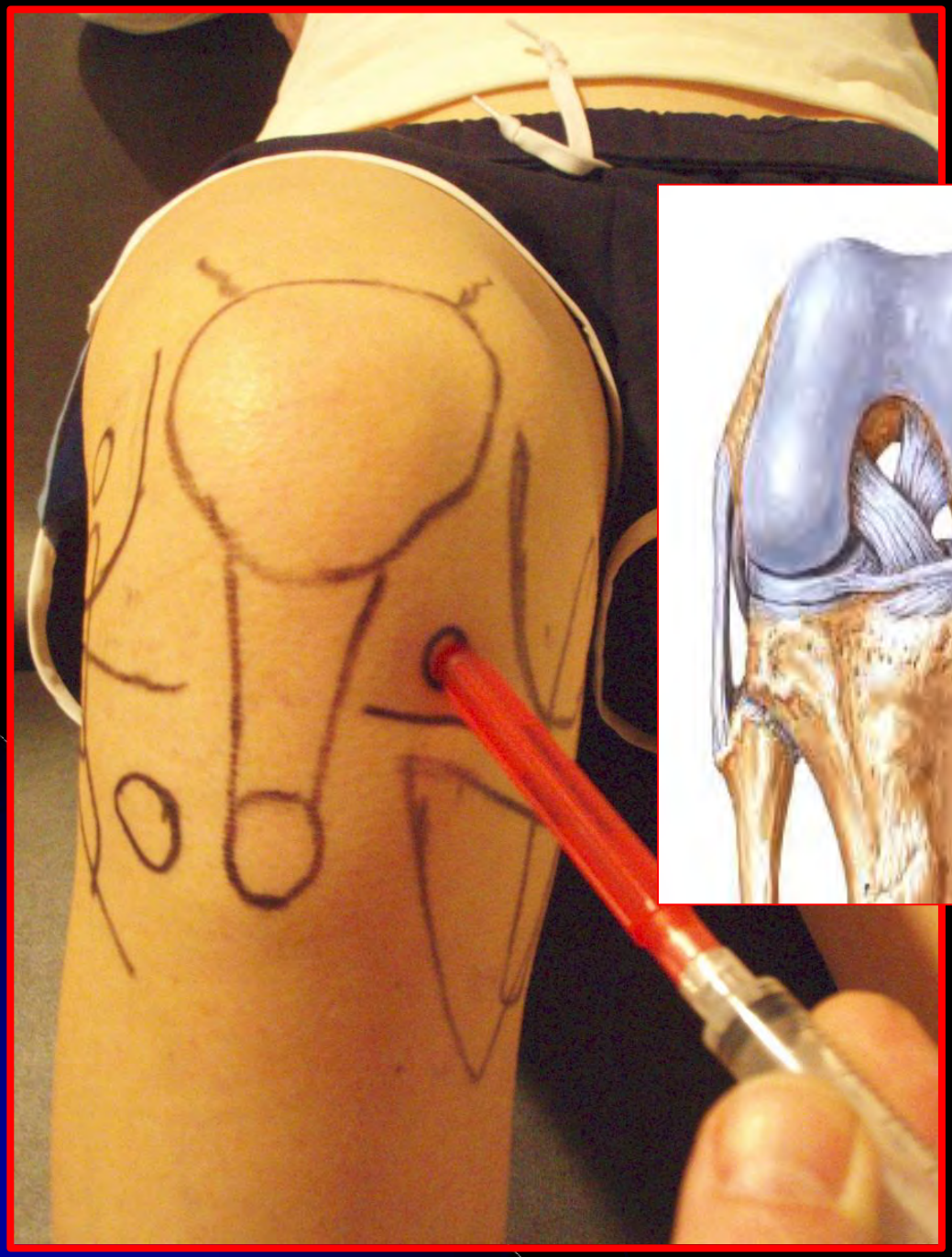
A Method to Measure, Confirm and Localize Joint Dysfunction and its Impact on Cartilage.

Authors: Ola Grimsby, PT, DMT, FFAAOMPT and David Harshfield M.D., M.S.



- Cartilage health is a "Goldilox" effect, in which load on the knee must be "just right" (not to much, but not too little either)
- The needed load depends on the integrity of the cruciate and other key ligaments (static stabilizers of the knee).

1. Articular "under load" is consequently reducing the cellular activity, causing shrinking of the matrix, reduced joint stability and secondary absorption of the tissue.
2. During static compression ("over load") we see an even more severe reduction in the cellular synthesis.
3. As cells die the reduction in matrix and joint dysfunction cause permanent degeneration.



Regenerative therapies for Osteoarthritis and Diabetic neurovascular therapy

Emerging Therapies Act

2. Low back pain

- 80% of us will get back pain at some time in our lives.
- In 2007 alone, about 27 million US adults aged 18 or older (11% of the total adult population) reported having back pain.
- Health economists have reported the annual cost of chronic pain in the United States is as high as $635 billion a year, which is more than the yearly costs for cancer, heart disease and diabetes combined.
- Individuals 18 and older to represent 210.7 million U.S. adults, with a mean health care expenditures per adult of $4,475.

Darrell J. Gaskin, Patrick Richard. The Economic Costs of Pain in the United States. *The Journal of Pain*, 2012; 13 (8): 715 DOI: 10.1016/j.jpain.2012.03.009

Centeno et al. J Transl Med (2017) 15:197
DOI 10.1186/s12967-017-1305-y

Journal of Translational Medicine

RESEARCH Open Access

Treatment of lumbar degenerative disc disease-associated radicular pain with culture-expanded autologous mesenchymal stem cells: a pilot study on safety and efficacy

Christopher Centeno[1,2*], Jason Markle[1], Eileen Dodson[1*], Ian Stemper[2], Christopher J Williams[1], Matthew Hyzy[1], Thomas Ichim[3] and Michael Freeman[2]

Abstract

Background: Degenerative disc disease (DDD) is a common cause of lower back pain with radicular symptoms and has a significant socioeconomic impact given the associated disability. Limited effective conservative therapeutic options result in many turning to surgical alternatives for management, which vary in the rate of success and also carry an increased risk of morbidity and mortality associated with the procedures. Several animal based studies and a few human pilot studies have demonstrated safety and suggest efficacy in the treatment of DDD with mesenchymal stem cells (MSCs). The use of bone marrow derived MSCs for the treatment of DDD is promising and in the present study we report on the safety and efficacy findings from a registry based proof of concept study using a percutaneous intradiscal injection of cultured MSCs for the management of DDD with associated radicular symptoms.

Methods: Thirty three patients with lower back pain and disc degeneration with a posterior disc bulge diagnosed on magnetic resonance imaging (MRI) met the inclusion criteria and were treated with culture-expanded, autologous, bone marrow derived MSCs. Prospective registry data was obtained at multiple time intervals up to 6 years post-treatment. Collected outcomes included numeric pain score (NPS), a modified single assessment numeric evaluation (SANE) rating, functional rating index (FRI), measurement of the intervertebral disc posterior dimension, and adverse events.

Results: Three patients reported pain related to procedure that resolved. There were no serious adverse events (ie. death, infection, or tumor) associated with the procedure. NPS change scores relative to baseline were significant at 3, 36, 48, 60, and 72 months post-treatment. The average modified SANE ratings showed a mean improvement of 68% at 3 years post treatment. FRI post-treatment change score averages exceeded the minimal clinically important difference at all time points except 12 months. Twenty of the patients treated underwent post-treatment MRI and 85% had a reduction in disc bulge size, with an average reduction size of 28% post treatment.

Conclusions: Patients treated with autologous cultured MSCs for lower back pain with radicular symptoms in the setting of DDD reported minor adverse events and significant improvements in pain, function, and overall subjective improvement through 6 years of follow-up.

*Correspondence: [redacted]
[redacted]
Full list of author information is available at the end of the article

BioMed Central

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J Transl Med. 2017 Sep 22; 15(1):197. doi: 10.1186/s12967-017-1300-y.

Treatment of lumbar degenerative disc disease-associated radicular pain with culture-expanded autologous mesenchymal stem cells: a pilot study on safety and efficacy.

Centeno C[1,2], Markle J[1], Dodson E[3], Stemper I[2], Williams CJ[1], Hyzy M[1], Ichim T[4], Freeman M[5].

Abstract

BACKGROUND:

Degenerative disc disea
socioeconomic impact
turning to surgical alter
morbidity and mortality
demonstrated safety ar
marrow-derived MSCs
findings from a registry
management of DDD w

METHODS:

Thirty-three patients wi
resonance imaging (MRI) met the inclusion criteria and were treated with culture-expanded, autologous, bone marrow-derived MSCs. Prospective registry data was obtained at multiple time intervals up to 6 years post-treatment. Collected outcomes included numeric pain score (NPS), a modified single assessment numeric evaluation (SANE) rating, functional rating index (FRI), measurement of the intervertebral disc posterior dimension, and adverse events.

RESULTS:

Three patients reported pain related to procedure that resolved. There were no serious adverse events (i.e. death, infection, or tumor) associated with the procedure. NPS change scores relative to baseline were significant at 3, 36, 48, 60, and 72 months post-treatment. The average modified SANE ratings showed a mean improvement of 60% at 3 years post-treatment. FRI post-treatment change score averages exceeded the minimal clinically important difference at all time points except 12 months. Twenty of the patients treated underwent post-treatment MRI and 85% had a reduction in disc bulge size, with an average reduction size of 23% post-treatment.

CONCLUSIONS:

Patients treated with autologous cultured MSCs for lower back pain with radicular symptoms in the setting of DDD reported minor adverse events and significant improvements in pain, function, and overall subjective improvement through 6 years of follow-up.

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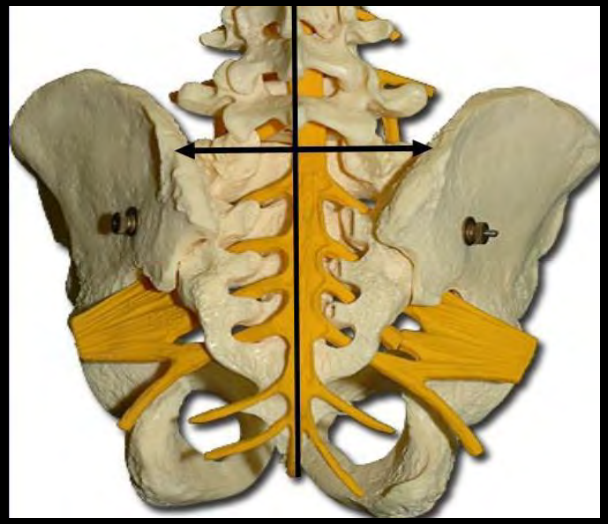
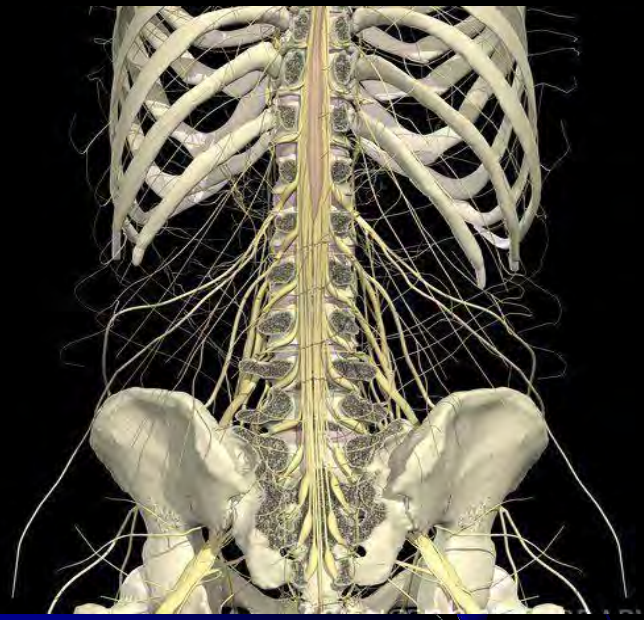
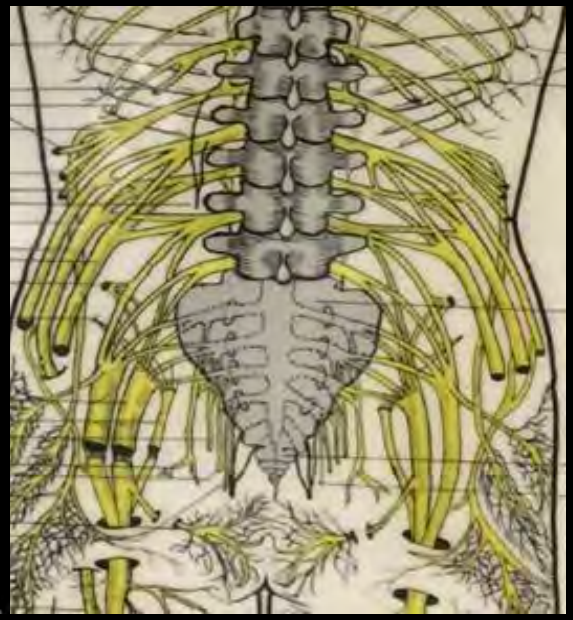
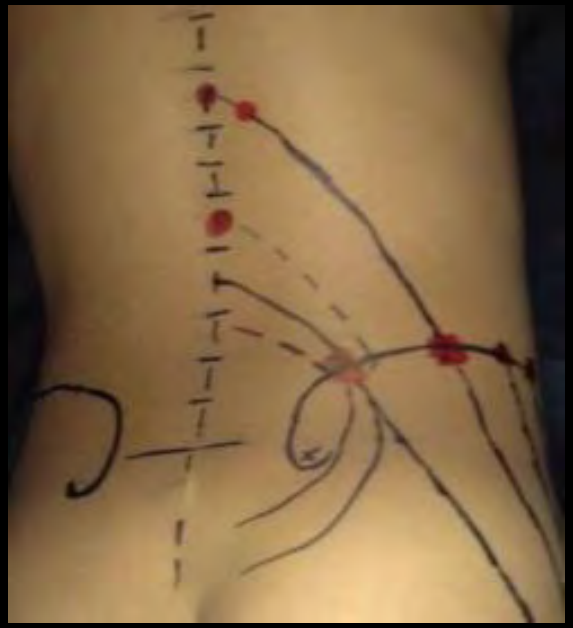
Patients treated with autologous cultured MSCs for lower back pain with radicular symptoms in the setting of DDD reported minor adverse events and significant improvements in pain, function, and overall subjective improvement through 6 years of follow-up.









Epidural steroid injections compared with gabapentin for lumbosacral radicular pain: multicenter randomized double blind comparative efficacy study

BMJ 2015; 350 doi: https://doi.org/10.1136/bmj.h1748 (Published 16 April 2015)

- Epidural steroid injections are the most commonly performed procedure for pain relief in the world.
- **Numerous controlled trials** have been performed to evaluate epidural steroid injections and drug treatment in people with low back pain, with review articles generally **reporting modest effects**.

REFERENCES:

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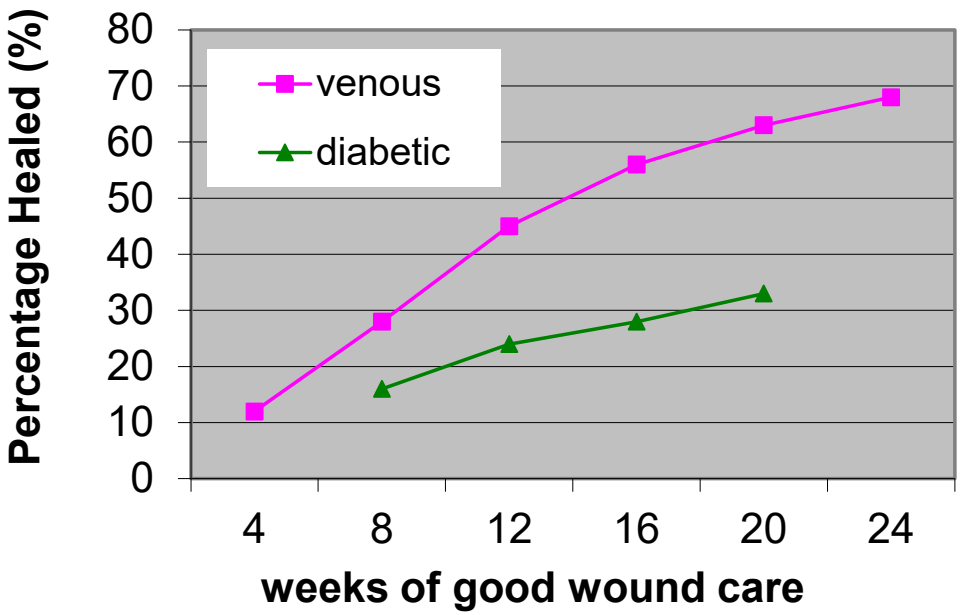
SPINE (Phila Pa 1976) 2011 (Feb 15); 36 (4): 320–331
2. Study Says Back Surgery Often Makes Things Worse
The Daily Hit ~ Oct 14, 2010
3. Back Surgery May Backfire On Patients In Pain
MSNBC.com ~ Oct 14, 2010
4. Why Do Spinal Surgery Rates Continue To Rise?
Chiro.Org Blog Editorial ~ April 10th, 2010
5. Findings from the: "United Kingdom Back Pain Exercise and Manipulation (UK BEAM) Randomised Trial"
British Medical Journal 2004 (Dec 11); 329 (7479): 1377
6. Painkiller Deaths Double In Ontario
Chiro.Org Blog ~ 12-08-2009

Regenerative therapies for Osteoarthritis and Diabetic neurovascular therapy

Emerging Therapies Act

3. Diabetes-
   - Total direct medical expenses for diagnosed and undiagnosed diabetes, prediabetes and gestational diabetes in Arkansas was over $2.3 billion.
   - In addition, another 1 billion spent on indirect costs from lost productivity due to diabetes.

Normal Healing Rates?



32% Venous ulcers not healed at 24 wks

67% Diabetic ulcers not healed at 20 wks

Kantor & Margolis, WOUNDS, Vol. 12, No. 6, 2000

FDA Critical Limb Ischemia (CLI) Trial

TREATMENT OF NO-OPTION CLI WITH A CONCENTRATE OF AUTOLOGOUS BONE MARROW CELLS

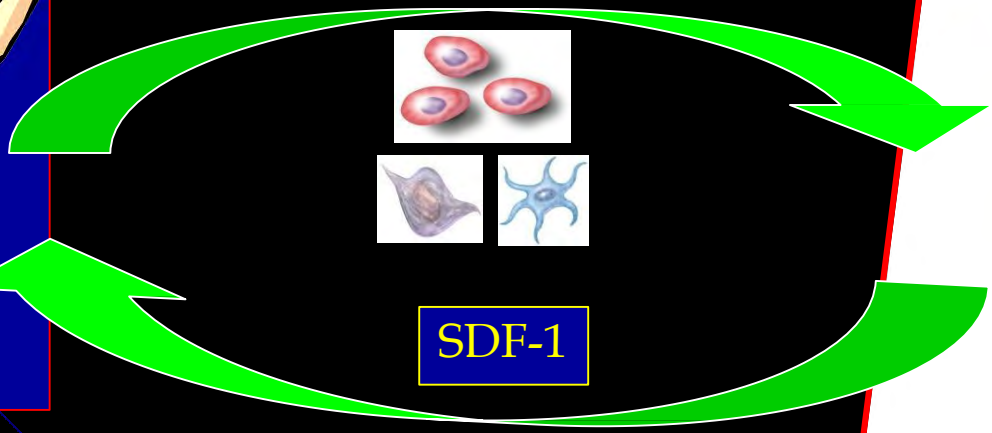
David L. Harshfield, Jr., M.D., M.S.
Co-Principle Investigator
Director of Interventional Radiology
MCSA Medical Center of South Arkansas

Director of Integrative Imaging
College of Integrative Medicine- coimed.org
Little Rock, Arkansas

Chairman of the Institutional Review Board (IRB)
International Cellular Medicine Society (ICMS)

NATURAL RESPONSE: BONE MARROW STEM CELLS ARE RECRUITED TO ISCHEMIC TISSUE

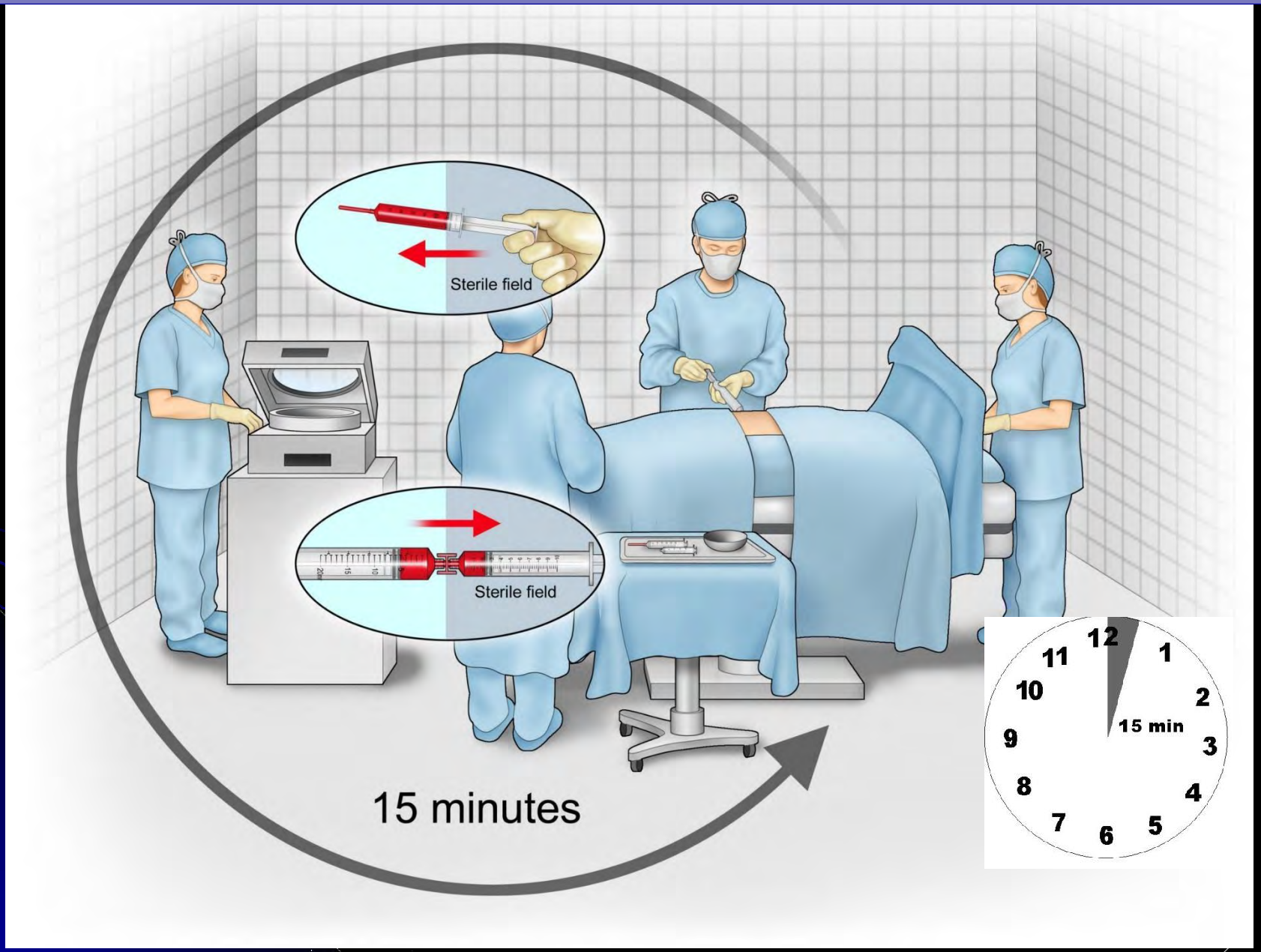
Ceradini, D, and Gurtner, G*; Trendsn Cardiovasc Med: 2005*



SDF-1 released from ischemic tissue recruits bone marrow cells

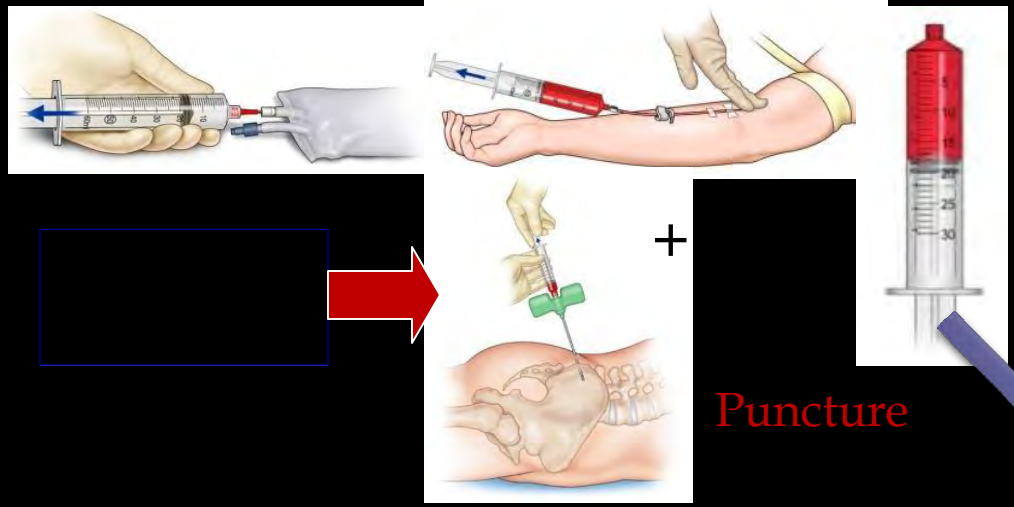
CONFIDENTIAL

Bone Marrow Aspirate Concentrate (BMAC) System: Facilitates Autologous Bone **Marrow** Therapy



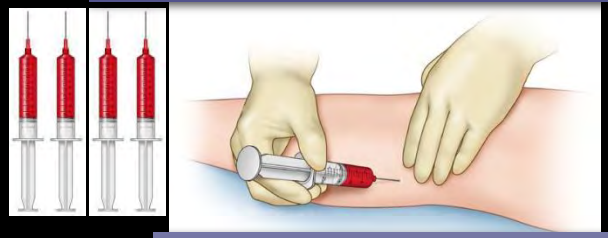
STUDY DESIGN: Randomized (2:1), Double Blind

PLACEBO



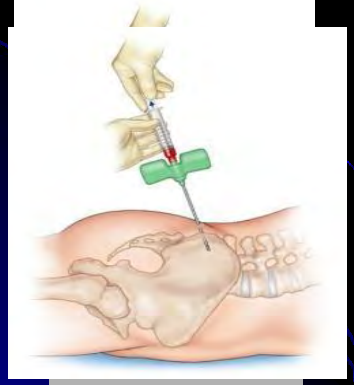
Puncture

INVESTIGATOR BLINDED TO INJECTATE



- 40 injections
- 1 mL per injection

BMAC GROUP



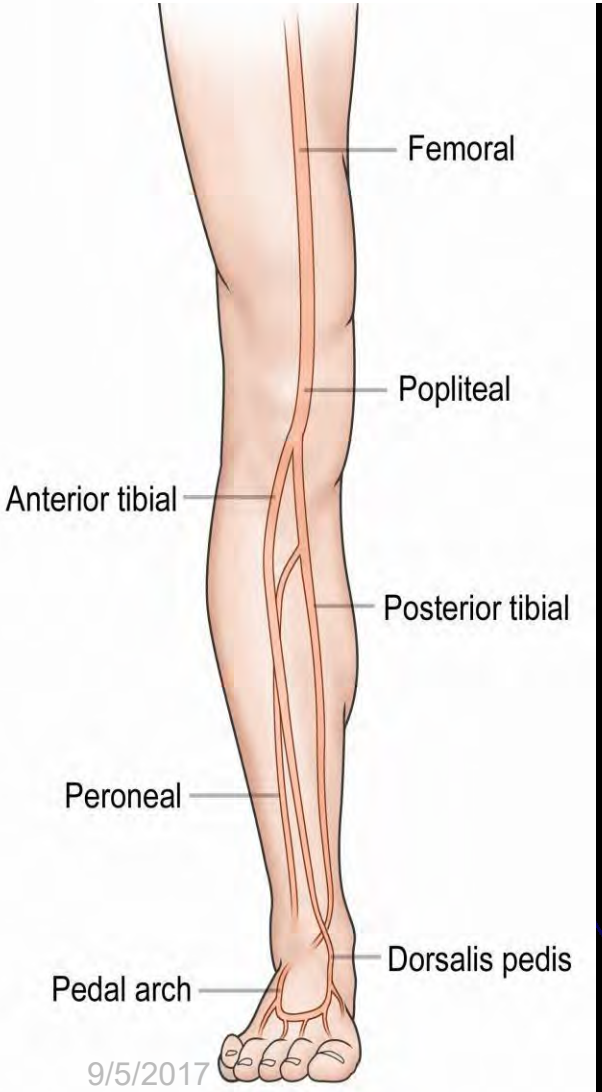
ASPIRATE

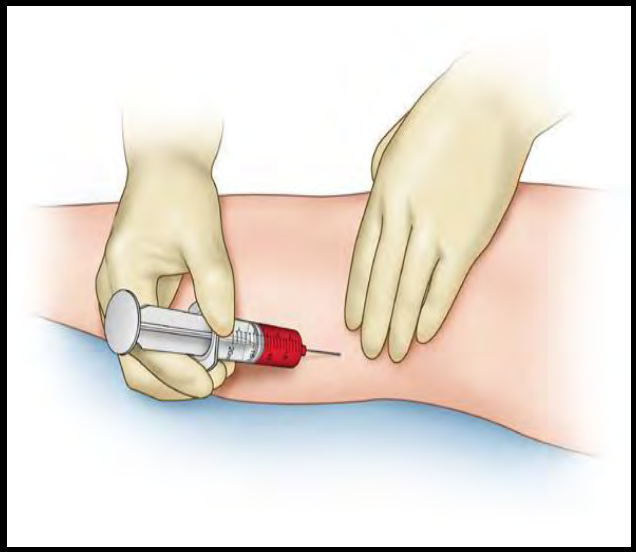
PROCESS

BMAC

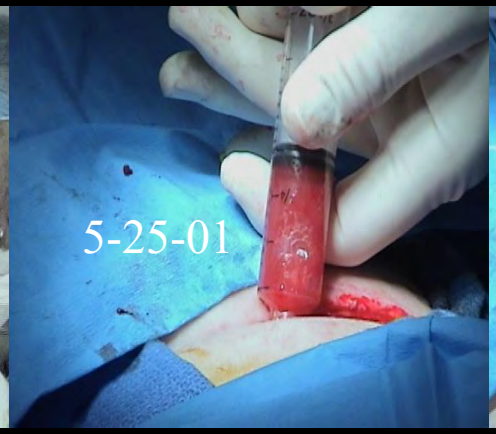
CONFIDENTIAL

Targeting the Delivery of BMAC





5-25-01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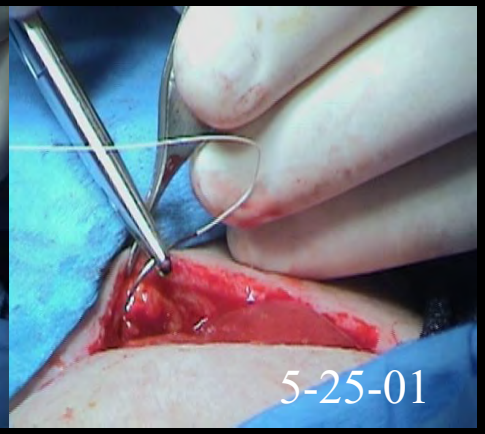

5-25-01

5-25-01

5-30-01

6-06-01
DAY #12

55 y.o. diabetic female with a chronic plantar-medial hallux interphalangeal ulcer. Osteomyelitis was confirmed in both the distal and proximal phalanges. Amputation was recommended by 3 different doctors. She refused and wanted to try the Autologous PRP. She healed and with no evidence of osteomyelitis.

35 Diabetic Foot Ulcers

	LENGTH WOUND PRESENT(wks)	(mm3) START VOL.	(mm3) END VOL.	WEEKS TO OUTCOME	# PROCEDURES REQUIRED
Averages*:	32.38	679.91	-0-	7.79	1.47
Fastest to heal:	24	48	-0-	0.71 (5 days)	1
Slowest to heal:	96	1360	-0-	22.71 (159 days)	5
	18	1496	-0-	22.71 (159 days)	1

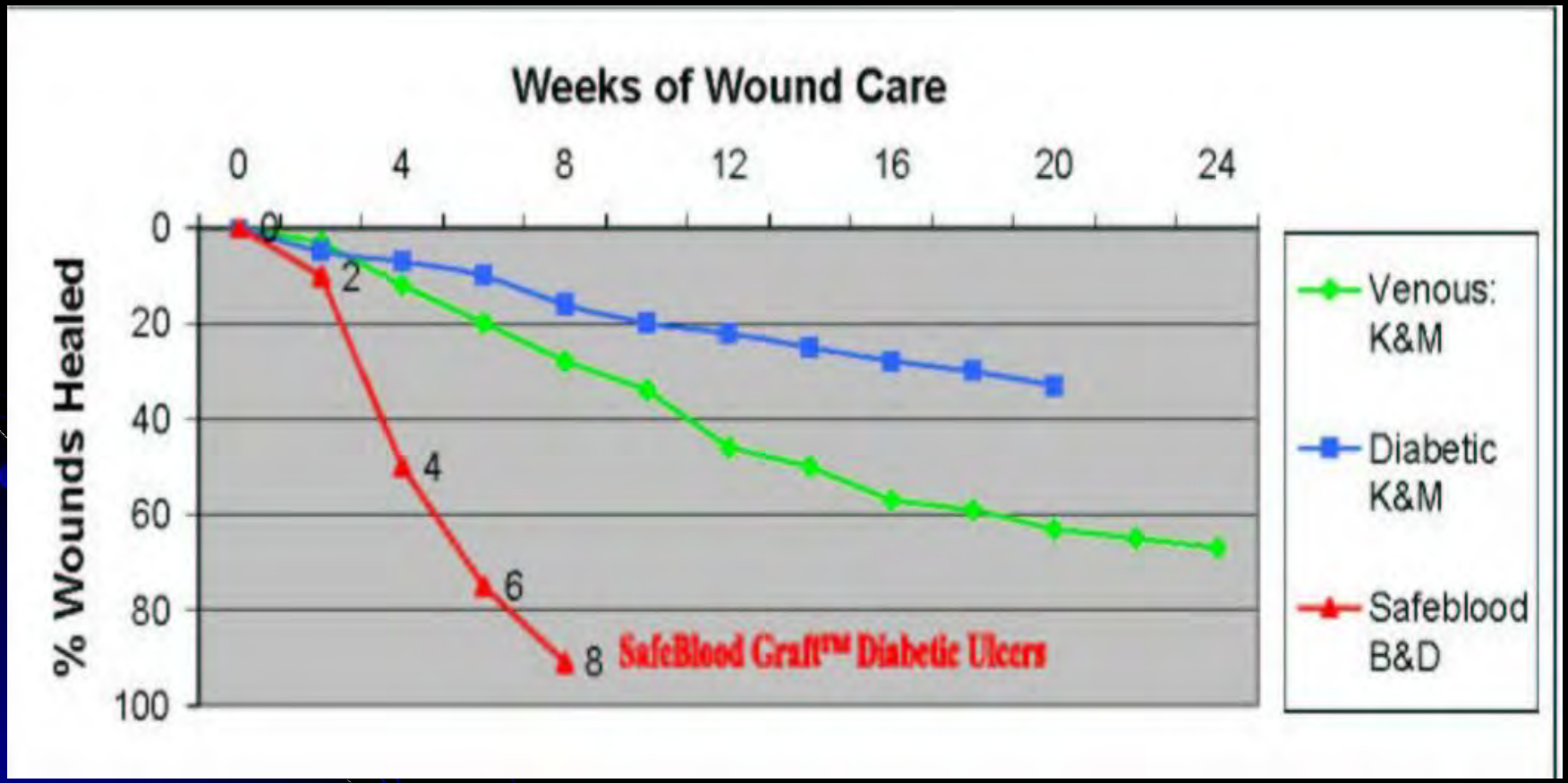
* Irrespective of Glucose levels, PVD status, Compliance.

Six Years of Unsuccessful Wound Care

THREE Brown Recluse Bites, Far right Tx with skin graft

Eight Weeks of Comprehensive Team Management

Regenerative Therapy vs. Standard Time to Close



Employer ABC	Diagnosis Code	Potential Surgical Encounter	Average Surgical Cost	Multi Site	Regenerative Costs	Patient Outcome
Workers' Comp	m66.211,m75.21,m65.811,m19	shoulder replacement	$ 52,000	No	$ 8,850	At 6 weeks patient reports significant improvement and is requesting full duty.
Workers' Comp	M17.12, S83.232D, M22.42	Knee Replacement	$ 43,000	No	$ 8,850	80-90% improvement at 6 weeks
Workers' Comp	M12.511 M75.01 M75.51 M75.	Rotator Cuff Surgery	$ 21,000	No	$ 7,500	n/a
Workers' Comp	M47.22 M50.32 M54.2 M79.1	Non-Surgical Spinal Repair	$ 21,800	No	$ 4,125	Recent Procedure. No results yet.
Workers' Comp	m47.817,m51.36,m54.5,m79.1	spinal fusion	$ 80,000	No	$ 4,125	Patient reports significant improvement at 6 weeks. No pain med.
Health	M17.0 M22.41 M22.42 M23.23	Bilateral Knee Replacement	$ 86,000	Yes	$ 7,570	80% improvement at 6 weeks and no pain at that time. Patient passed away May 2016.
Health	M47.26 M51.16 M48.06 M54.5	Laminectomy/Fusion	$ 81,000	No	$ 4,125	Minimal improvement at 1 month, however, patient was not attending PT regularly and had bronchitis for 3 weeks following procedure.
Workers' Comp	715.96 844.9 844.1	Knee Replacement	$ 43,000	No	$ 4,795	20% improvement at 1 year
Workers' Comp	s43.81,m19.011,s43.432d	rotator cuff repair	$ 25,000	No	$ 2,125	Patient reports no pain at 3 months. 40% improvement rating.
Health	M19.011 M25.511 M75.81 S43	Shoulder Surgery	$ 21,000	No	$ 7,500	Doing well at 2 weeks, PT going well.
Workers' Comp	M51.16 M47.816 M54.5	Laminectomy	$ 8,000	No	$ 4,125	n/a
Health	M19.031 M19.041 M25.531	Wrist Surgery	$ 5,600	No	$ 1,800	Pain free in wrist at 6 months, has minor pain in finger
Workers' Comp	M19.221 M67.823 M77.01	Arthroscopic Shoulder Repai	$ 21,000	No	$ 1,800	Recent Procedure
Health	M17.12 M22.42 S83.232A S83	Knee Replacement	$ 23,500	No	$ 8,798	Recent procedure
Workers' Comp	M17.0 M25.561 M25.562 S83.	Meniscal Repair/Laminectom	$ 98,000	Yes	$ 12,923	Just completed procedure
Workers' Comp	M17.11 S83.251D M22.41	Meniscal Repair	$ 18,000	No	$ 8,798	50-60% improvement at 10 weeks
Workers' Comp	S43.421D M19.211	Arthroscopic Shoulder Surge	$ 21,000	No	$ 1,800	80% improvement at 3 months
Health	M16.11 M25.852 M24.151	Hip Labral Repair	$ 25,000	No	$ 1,800	Left hip feeling well after 2 weeks
Health	G56.01 G56.02	Carpal Tunnel Surgery	$ 5,600	Yes	$ 2,450	Procedure completed on 3-31-16.
Health	M16.11 M25.511 M24.151	Hip Labral Repair	$ 25,000	No	$ 7,000	50% improvement at 6 weeks
Workers' Comp	m19.041,m66.841	hand tendon repair	$ 25,000	No	$ 6,741	procedure on 1/8/16
Workers' Comp	m47.26,m54.5,m53.2,m51.16,r	spinal fusion	$ 82,000	No	$ 3,676	procedure on 12/30/2015
Workers' Comp	m75.52,m19.012	shoulder repair	$ 21,000	No	$ 2,023	procedure on 12/1/2015
Workers' Comp	m19.012,m75.122	shoulder replacement	$ 52,000	No	$ 6,628	no complaints or concerns at 6 weeks
Workers' Comp	717.7,836.2,719.46	meniscal repair	$ 18,000	No	$ 8,908	patient reported no pain at 3 months post procedure
Workers' Comp	m17.5,m25.561,m17.31,s83.23	knee replacement	$ 43,000	No	$ 8,997	patient reported noticeable improvement at 2 weeks post procedure
Workers' Comp	m19.014,m19.042	bilat hand joint surgery	$ 25,000	Yes	$ 7,599	patients reported noticeable improvement at 2 weeks post procedure
Workers' Comp	840.9,840.6,726.12,840.4,715.	rotator cuff repair	$ 21,000	No	$ 1,408	no complaints or concerns at 3 months post procedure
Workers' Comp	840.4,840.6	rotator cuff repair	$ 21,000	No	$ 1,698	patient reports 50% improvement at 4 months post procedure
Workers' Comp	m25.562,715.96	knee replacement	$ 43,000	No	$ 10,427	patient reports that pain is decreasing and doing well at 3 months post procedure
Workers' Comp	715.96,836.2,m17.11	meniscal repair	$ 18,000	No	$ 10,363	no complaints or concerns at 3 months post procedure
Workers' Comp	715.94	Bilat carpal tunnel surgery	$ 25,000	Yes	$ 3,158	patient reports progressive improvement at 3 weeks
Workers' Comp	726.32	Tennis Elbow Surgery	$ 25,000	No	$ 2,000	n/a
Workers' Comp	m19.042	fusion surgery, arthrodesis	$ 25,000	No	$ 2,125	Patient reports slight improvement at 2 weeks.
Workers' Comp	726	Frozen Shoulder Surgery	$ 21,000	No	$ 2,000	75% improvement at 6 months.
Workers' Comp	M17.12 M22.42 S83.232D	Arthroscopic Knee Surgery	$ 21,000	No	$ 8,850	Minimal improvement at 6 weeks.
Workers' Comp	M54.5 M16.12 M25.552 M51.3	Hip Labral Repair	$ 39,000	No	$ 8,800	New procedure
Health	M17.11 M25.561 S83.221A M2	Knee Replacement	$ 24,854	No	$ 7,523	Doing well at 3 months. Mild pain while doing some physical activity. Happy with progress to date.
Health	836.2 715.96	Meniscal Repair	$ 7,875		$ 6,991	60 % improvement at 1 year. Only time he feels pain is when is doing longer runs or walks.
Health	M17.11 M25.561 M25.461 S83	Meniscal Repair	$ 7,875	No	$ 8,798	RK 80-90% improvement at 6 weeks. Continued improvement at 3 months. Happy with procedure.
Health	S33.6XXa S76.011a	Non-Surgical Muscle Repair	$ 19,000	No	$ 1,593	AN Recent Procedure
Health	M47.817 M47.816 M54.2 M50.	Laminectomy/Fusion	$ 48,056	No	$ 4,125	DV Slight improvement at 6 weeks
Health	M17.12 M25.562	Knee Replacement	$ 24,854	No	$ 7,523	Recent Procedure
Health	M47.817 M47.816 M54.2 M50.	Spinal Fusion	$ 48,056	No	$ 3,506	Recent Procedure
Health	M47.26 M48.06 M51.16 M50.3	Laminectomy	$ 48,056	No	$ 4,875	Recent Procedure
Health	M17.0 S83.231A S83.232A S8	Knee Replacement	$ 43,000	No	$ 11,100	Recent Procedure
Health	M76.891 M16.11	Hip Labral Repair	$ 21,953	No	$ 1,800	80-90% improvement at 6 weeks
Health	M77.11 M25.521	Elbow Surgery	$ 25,000	No	$ 1,800	New Procedure
Health	715.96,836.2,717.7,719.46,84	meniscal repair	$ 7,875	No	$ 2,000	patient reported 50% improvement at 6 months post procedure
Health	715.96,715.95,836.2,726.5,71	bilat knee replacement, bilat	$ 100,458	Yes	$ 9,847	patient's procedure was on 11/17/2015
Health	726.5,715.95	hip replacement	$ 25,375	No	$ 6,995	patient reported 90% improvement at 6 months post procedure
Health	715.95,840.7	hip labral repair	$ 21,953	No	$ 2,000	patient reported 80% improvement at 3 1/2 months
Health	836.2,715.96,717.7,726.64	bilat knee replacement, bilat	$ 50,078	Yes	$ 10,335	patient was 6 weeks post on 10/29/15
Health	836.2,715.96	bilat knee replacement	$ 49,708	Yes	$ 8,225	patient reports noticeable improvement at 3 months post procedure
Health	841.9	UCL reconstruction	$ 25,000	No	$ 2,000	patient reported no pain at 6 weeks post procedure
Health	726.32	arthroscopic elbow repair	$ 25,000	No	$ 2,000	patient reported 90% improvement at 31/2 months post procedure
Workers' Comp	S43.51XD S43.421D M75.22 M	Shoulder Surgery	$ 21,000	No	$ 2,125	Recent procedure
Workers' Comp	M19.011, M25.511	Soulder Surgery	$ 21,000	No	$ 7,500	n/a
Workers' Comp	m75.41,m25.511,m75.21	Shoulder impingement surger	$ 21,000	No	$ 2,125	Patient reports 70% improvement at 4 weeks.
Workers' Comp	M65.349, M65.339, M72.0, M6	Hand surgery	$ 25,000	No	$ 2,125	Slight improvement at 6 weeks
Workers' Comp	M77.01 S46.211	Elbow Surgery	$ 25,000	No	$ 2,125	Recent Procedure
Health	M70.62 M25.552 M67.854	Hip Labral Repair	$ 39,000	No	$ 1,800	Near complete resolution of pain at 6 weeks.
Health	M17.11 M22.41 S83.411D S83	Knee Replacement	$ 43,000	No	$ 8,850	Pain free with 100 improvement at 6 weeks.
Health	M19.021 M25.721 M77.11	Arthroscopic elbow repair	$ 25,000	No	$ 1,900	New procedure
Health	M72.2 M25.571	Plantar Fasciitis Repair	$ 3,500	No	$ 1,900	Doing well at 2 weeks.
Health	M17.12 M25.562 S83.412	Knee Surgery	$ 42,000	No	$ 9,315	New Procedue
Health	M17.0 M22.42 M23.232 M25.5	Knee Replacement	$ 43,000	No	$ 9,315	Left Knee doing better at 2 weeks post procedure
Health	M17.0 M25.561 M25.562	Knee Replacement	$ 43,000	No	$ 9,315	New Procedure

	A	B	C	D	E	F	G
1	Employer ABC	Diagnosis Code	Potential Surgical Encounter	Average Surgical Cost	Multi Site	Regenerative Costs	Patient Outcome
2	Workers' Comp	m66.211,m75.21,m65.811,m19.	shoulder replacement	$ 52,000	No	$ 8,850	At 6 weeks patient reports significant improvement and is requesting full duty.
3	Workers' Comp	M17.12, S83.232D, M22.42	Knee Replacement	$ 43,000	No	$ 8,850	80-90% improvement at 6 weeks
4	Workers' Comp	M12.511 M75.01 M75.51 M75.2	Rotator Cuff Surgery	$ 21,000	No	$ 7,500	n/a
5	Workers' Comp	M47.22 M50.32 M54.2 M79.1	Non-Surgical Spinal Repair	$ 21,800	No	$ 4,125	Recent Procedure. No results yet.
6	Workers' Comp	m47.817,m51.36,m54.5,m79.1	spinal fusion	$ 80,000	No	$ 4,125	Patient reports significant improvement at 6 weeks. No pain med.
7	Health	M17.0 M22.41 M22.42 M23.231	Bilateral Knee Replacement	$ 86,000	Yes	$ 7,570	80% improvement at 6 weeks and no pain at that time. Patient passed away May 2016.
8	Health	M47.26 M51.16 M48.06 M54.5	Laminectomy/Fusion	$ 81,000	No	$ 4,125	Minimal improvement at 1 month, however, patient was not attending PT regularly and had
9	Workers' Comp	715.96 844.9 844.1	Knee Replacement	$ 43,000	No	$ 4,795	20% improvement at 1 year
10	Workers' Comp	s43.81,m19.011,s43.432d	rotator cuff repair	$ 25,000	No	$ 2,125	Patient reports no pain at 3 months. 40% improvement rating.
11	Health	M19.011 M25.511 M75.81 S43.	Shoulder Surgery	$ 21,000	No	$ 7,500	Doing well at 2 weeks, PT going well.
12	Workers' Comp	M51.16 M47.816 M54.5	Laminectomy	$ 8,000	No	$ 4,125	n/a
13	Health	M19.031 M19.041 M25.531	Wrist Surgery	$ 5,600	No	$ 1,800	Pain free in wrist at 6 months, has minor pain in finger
14	Workers' Comp	M19.221 M67.823 M77.01	Arthroscopic Shoulder Repair	$ 21,000	No	$ 1,800	Recent Procedure
15	Health	M17.12 M22.42 S83.232A S83.	Knee Replacement	$ 23,500	No	$ 8,798	Recent procedure
16	Workers' Comp	M17.0 M25.561 M25.562 S83.2	Meniscal Repair/Laminectomy	$ 98,000	Yes	$ 12,923	Just completed procedure
17	Workers' Comp	M17.11 S83.251D M22.41	Meniscal Repair	$ 18,000	No	$ 8,798	50-60% improvement at 10 weeks
18	Workers' Comp	S43.421D M19.211	Arthroscopic Shoulder Surge	$ 21,000	No	$ 1,800	80% improvement at 3 months
19	Health	M16.11 M25.852 M24.151	Hip Labral Repair	$ 25,000	No	$ 1,800	Left hip feeling well after 2 weeks
20	Health	G56.01 G56.02	Carpal Tunnel Surgery	$ 5,600	Yes	$ 2,450	Procedure completed on 3-31-16.
21	Health	M16.11 M25.511 M24.151	Hip Labral Repair	$ 25,000	No	$ 7,000	50% improvement at 6 weeks
22	Workers' Comp	m19.041,m66.841	hand tendon repair	$ 25,000	No	$ 6,741	procedure on 1/8/16
23	Workers' Comp	m47.26,m54.5,m53.2,m51.16,m	spinal fusion	$ 82,000	No	$ 3,676	procedure on 12/30/2015
24	Workers' Comp	m75.52,m19.012	shoulder repair	$ 21,000	No	$ 2,023	procedure on 12/1/2015
25	Workers' Comp	m19.012,m75.122	shoulder replacement	$ 52,000	No	$ 6,628	no complaints or concerns at 6 weeks
26	Workers' Comp	717.7,836.2,719.46	meniscal repair	$ 18,000	No	$ 8,908	patient reported no pain at 3 months post procedure
27	Workers' Comp	m17.5,m25.561,m17.31,s83.231	knee replacement	$ 43,000	No	$ 8,997	patient reported noticeable improvement at 2 weeks post procedure
28	Workers' Comp	m19.014,m19.042	bilat hand joint surgery	$ 25,000	Yes	$ 7,599	patients reported noticeable improvement at 2 weeks post procedure
114	Health	M24.151 M24.251	Hip Replacement	$ 23,800	No	$ 8,033	Recent Procedure
115	Health	M17.0 M25.561 M25.562 M23.2	Arthroscopic Knee Surgery	$ 18,000	No	$ 8,850	Recent Procedure
116	Health	M17.0 M25.561 M25.562 M23.2	Arthroscopic Knee Surgery	$ 18,000	No	$ 8,850	Recent Procedure
117	Health	M17.12 S83.232A S83.412A S8	Knee Replacement	$ 24,854	No	$ 7,523	Recent Procedure
118	Health	M17.12 M22.41 S83.271A S83.	Knee Replacement/Plantar Fa	$ 23,500	Yes	$ 11,135	Recent Procedure
119	Health	M50.32 M54.12 M54.2 M48.02	Spinal Fusion	$ 81,000	No	$ 4,125	Recent Procedure
120	Health	M54.16 M54.5	Laminectomy	$ 8,000	No	$ 2,125	Recent Procedure
121	Health	M17.11 S83.272A S83.411A S8	Arthroscopic Knee Surgery	$ 49,000	No	$ 8,850	75% improvement at 6 weeks post-procedure.
122							
123				Total Sugical Cost		Total Cost	
124				$ 3,917,165		$ 674,874	
125							
126	Savings				**Savings**	$ 3,242,291	

Total Sugical Cost		Total Cost
$ 3,917,165		$ 674,874
	Savings	$ 3,242,291

PRP Therapy: Clinical Data

Patient	Beginning Volume CM	PRP Application CM	Week One CM	Week Two CM	Week Three CM	Week Four CM	Ending Volume CM	Volume Reduction %	PRP Cost x 3 Weeks	VAC Cost x 3 Weeks
1 Ha	252	10x9x2.8	?				0	100	688.44	1,967.13
2 BM	21	21x.5x2	15x.3x.4				1.8	92	688.44	1,967.13
3 BT	33.85	6.2x7.8x.7	6.3x8.3x.4	6.5x7x.2	6.8x7x.2		9.52	72	1,376.88	1,967.13
4 Ed	13.37	3.8x3.2x1.1	?				13.37	0	688.44	1,967.13
4 Fe	3.85	2.5x2.2x.7	2.2x2.3x.5				2.53	35	688.44	1,967.13
5 Fo	99.96	16.8x3.5x1.7	14.7x3.3x1	15.2x2.5x.8			30.4	70	688.44	1,967.13
6 GA #1	6.96	5.8x3.x.4	6x2.7x.1	5.8x2.5x.2			2.9	59	688.44	1,967.13
7 GA #2	0.09	.8x.4x.3	1x.4x.1	.6x.4x.1			0.024	74	688.44	1,967.13
8 Hb #1	1.4	1.9x1x.6	2.4x.6x0				0	100	688.44	WTD -BID
9 Hb #2	0.78	1.3x.6x1	1.1x.9x0				0	100		WTD -BID
10 Hb #3	0.3	1.1x.4x.7	.8x.7x0				0	100		WTD -BID
11 Hb #4	1.4	1x.5x2.8	.9x.7x1.5				0.94	33		WTD -BID
12 Hs #1	3.02	2.8x.6x1.8	1.9x.8x1	1.8x.9x.5	1.7x.8x1	1.7x.8x1	1.36	65	688.44	1,967.13
13 Hs #2	94.5	13.5x2.5x2.8	9x2.4x2.7	6x3x1.7	4.8x3x1	4.8x2.5x.7	8.4	92	688.44	1,967.13
14 Hm	28.5	3.8x7.5x?					0	100	688.44	1,967.13
15 Ha #1	54	10x3x1.8	9x2.8x1.8	5.3x1.3x.4	4.7x2x.5	4x1x.4	1.6	98	688.44	1,967.13
16 Ha #2	23.22	4.3x4.5x1.2	1.8x2.0x5.8	1x1.5x.6	1.5x.8x4	1x2x3	6	75	688.44	1,967.13
17 Ha #3	30	5x6x1	6.8x11x1	3.8x4.5x.7	4x4x.2	4x2x.1	0.8	98	688.44	1,967.13
18 Ha #4	0.56	.8x.5x1.4	1x.3x1	.7x.4x1.3	.4x.3x1.1		0.132	77	688.44	1,967.13
19 Th	11.61	4.3x9x.3	3.3x8x.2	1.5x6.7x.1			1.005	92	688.44	1,967.13
20 Me	0.45	2.5x1.8x.1	2.5x1.9x.1	1.7x.8x.1			0.136	70	688.44	1,967.13
21 Mi #1	27.82	10.5x5.3x.5	10.5x4.7x.3				14.8	47	688.44	1,967.13
22 Mi #2	5.21	4.7x3.7x.3	4.5x3x.2				2.7	49	688.44	1,967.13
23 RG	4.36	3.9X5.6X.2	4.7x5.6x.1	3.5x5.2x.2			3.64	17	688.44	1,967.13
24 BF	4347	13.5x46x7	13.5x42x5.5	10.7x44x5.8	10x43x3.6	8.7x37.4x2.7	878.52	80	688.44	1,967.13

PRP Therapy: Clinical Data

25 CC	1.05	3.5x.5x.6	2x.4x.6	1.9x.4x.4	1.9x.7x.2	2x.5x.2	0.2	81	688.44	1,967.13
26 FC #1	135.72	8.7x12x1.3	7.7x11x1	8.5x10x1.1	8x10x.4		32	76	688.44	1,967.13
27 FC #2	24.81	3.3x4.7x1.6	2.6x4x1.3	2.5x3.9x1.4			13.65	45	688.44	1,967.13
28 HD	63.6	5.3x6x2	3.8x5.7x1.5				32.49	49	688.44	1,967.13
29 Mc	10.16	6.2x4.1x.4	6.4x4.5x	6x6x.4	6x4.4x1	6.9x4x.6	16.56	-62	688.44	1,967.13
30 Mu	21.56	5.5x4.9x.8	5x5x.3	5.2x4.6x1		4x4x.2	3.2	86	688.44	WTD - BID
31 WG	1057.42	9.8x13x8.3	11.5x11.8x7.5	9x12x7			756	29	1,376.88	1,967.13
Beginning Volume	**6379.53**					**Ending Volume**	**1834.677**		**21,341.64**	**53,112.51**

Total Volume Reduction **71.25%**

VAC	53,112.51
PRP	21,341.64
Savings	**$31,770.87**

Total Cost Reduction **60%**

The total volume reduction is a cumulative total on the above patient population.

The total cost reduction is actual cost of PRP vs. projected cost of the VAC as estimated by Charlotte Martin WOCN.

These totals do not include nursing time which is generally 3 to 1 comparing VAC vs PRP.

Year 2014

Category:	Amount Paid (1)	Amount Paid (2)	Total Amount Paid
Superficial Ulcer	$ 10,975,190.55	$ 10,988,752.21	$ 21,963,942.76
Disorder of Knee's Articular Surface	$ 2,502,007.63	$ 3,396,545.05	$5,898,552.68
Lumbar/Low Back	$ 33,969,909.51	$ 33,004,371.63	$66,974,281.14
Lower Leg	$ 62,212.55	$ 155,728.63	$217,941.18
Other: Ulceration	$ 457,091.88	$ 443,089.03	$900,180.91
Plantar Fascitis	$ 3,863,864.53	$ 3,144,211.14	$7,008,075.67
Diabetic Foot Ulcer	$ 2,901,464.90	$ 3,097,735.37	$5,999,200.27
Complications Due to Diabetes	$ 7,782,001.82	$ 6,614,720.08	$14,396,721.90
Est. Total Spend for Catagories	$ 62,513,743.37	$ 60,845,153.14	$123,358,896.51
Regenerative Intervention Potential:	70%		$86,351,227.56
Estimated Costs of Regenerative Care	40%		$34,540,491.02
Projected Savings Net of Costs & Fees:			$51,810,736.53

Select
Specialty® Hospital

Carl Keller
Vice President
SafeBlood Technologies, Inc.
1100 North University Avenue
Little Rock, AR 72207

RE: The SafeBlood Graft protocol at Select Specialty in Little Rock

Dear Carl:

Select at St. Vincent has worked with SafeBlood since April of 2002 and I have personally experienced your commitment and efforts in serving our physicians and patients since 2004. During that time the coordinated efforts between our facility, physicians and SafeBlood have made a significant difference not only for many of our patients, but for our facility as well.

The SafeBlood Graft procedure and protocol consistently helps us to reduce and close chronic dehiscence, pressure ulcers, and wounds with which our patients have presented. In fact, under the direction of Dr. Holland, our wound care director, we are now regularly referred wound patients for treatment with the SafeBlood Graft who have not responded to other regimens or care.

By using your protocol we have experienced more rapid closure of deep, complicated or hard to treat wounds; fewer dressing changes and complicated nursing care, and a significant cost savings over the use of other prevalent chronic wound treatments or equipment.

In summary, we appreciate the professionalism and care you have shown our patients and staff, and would encourage our other facilities to consider implementing your protocol for their patients where appropriate. They are welcome to contact me, or I am sure that Dr. Holland would be happy to discuss his experience as well.

Sincerely,

Maureen Hanneken

Maureen Hanneken, MHA,
Chief Executive Officer
Select Specialty Hospital

#2 St. Vincent Circle 10th Floor Little Rock, AR 72205
Referral 501 661-4108 Fax (501) 603-9041
www.selectmedicalcorp.com

REGENCY HOSPITAL COMPANY

February 14, 2008

Charles Worden Jr., Vice President
Sales and Training Manager
SafeBlood Technologies, Inc.
1100 N. University Avenue
Little Rock, AR 72207

Dear Charles:

Regency Hospitals of Arkansas have been working with the SafeBlood graft since 2005. No other wound treatment modality has been as effective.

The SafeBlood graft procedure and protocol have been very successful in treating chronic ulcers, dehiscence and wounds that have been present for extended periods. The clinical outcomes our patients have received have been observed by physicians in several states and they are now referring their chronic non-healing wound patients to our facility for this procedure.

One of the more striking features of using the SafeBlood graft is the cost savings to the patient, hospital and third party payor. One study that we did showed a 60% cost savings over the use of conventional wound care related equipment. Our patients have experienced more rapid closure of their wounds and have been able to be discharged sooner.

The clinical team at Regency Hospitals of Arkansas along with SafeBlood has experienced phenomenal success in healing wounds that did not respond to any other treatment. We would be happy to discuss the clinical outcomes our patients have had with other case managers or third party payors.

Sincerely,

Mike McLean

Mike McLean, R.N.
Chief Executive Officer

MM/sr

1125 North College Avenue • Fayetteville, AR 72703 • Phone: (479) 713-7000 • Fax: (479) 713-7003

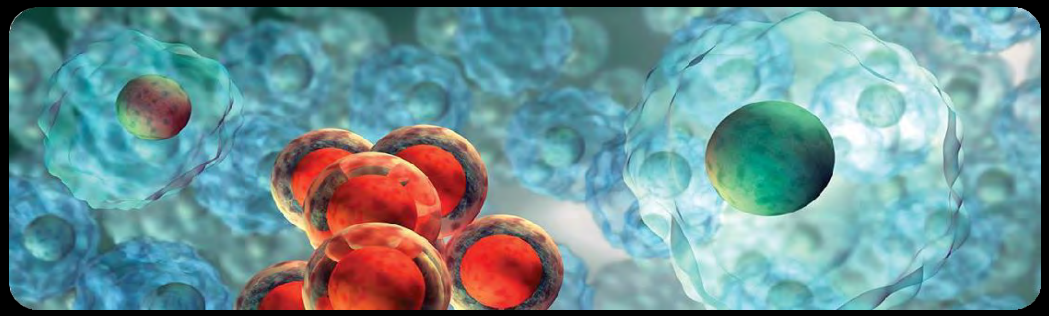
Key Points

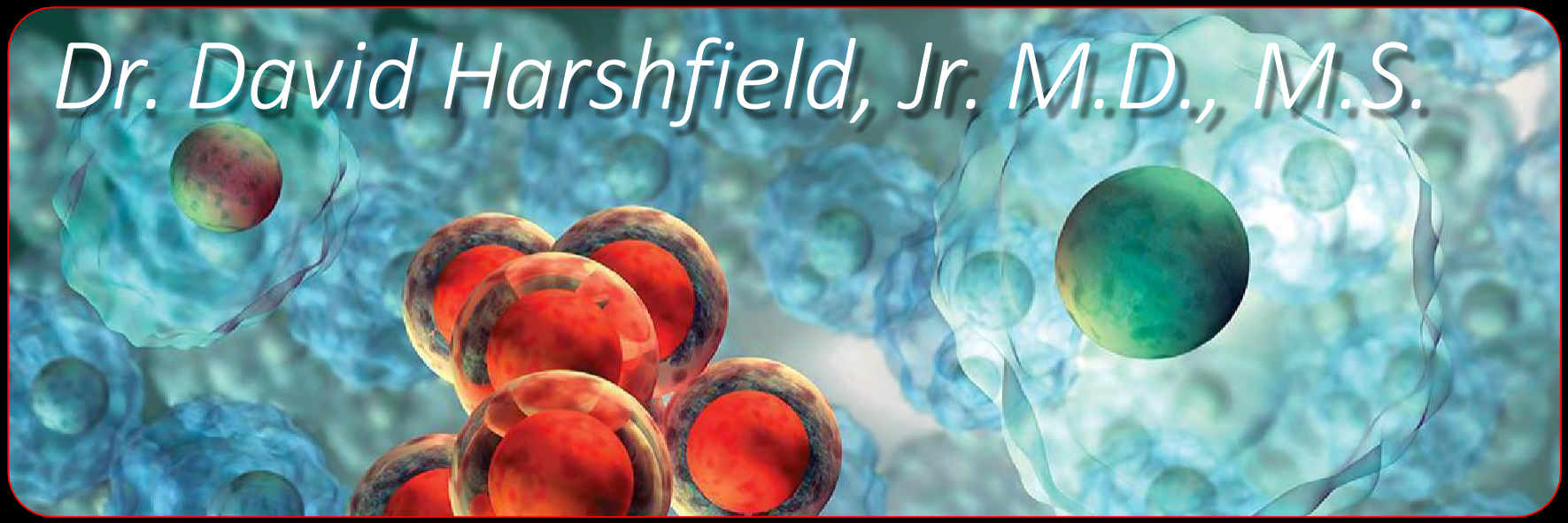
Clinical Outcomes: IROM, with credentialed providers and certified protocols, provides safe, affordable and effective therapy resulting in improved healing and overall patient outcomes.

Financial outcomes: Lower costs to The State and Public School Life and Health Insurance Board, not only with avoidance of unnecessary pharmaceuticals and surgery but of complications, as well.

Quality of Life: IROM is not only financially beneficial, but allows patents a more rapid return to work and activities of daily living and improved overall family dynamics.

Treatment Acceptance: Increasing payer adoption for the use of regenerative and cellular medicine therapies, with Arkansas now playing a leadership role in the U.S.





End of Presentation

D.L. Harshfield M.D., M.S.

- Board certified Radiologist with specialty training in NMSK, Ultrasound, Interventional Radiology and Cellular Medicine
- Director of the College of Integrative Medicine-coimed.org
- Member Board of Directors International Society for Cellular Medicine (ICMS)
- Chairman of the Institutional Review Board (IRB) of the ICMS
- Member Board of Directors American Association of Orthopedic Medicine (AAOM)
- Editor AAOM e-Journal

STATE AND PUBLIC SCHOOL LIFE AND HEALTH INSURANCE BOARD

OCTOBER 17, 2017

Meeting Objectives

Discover MiMedx as a leading Biopharmaceutical Company

Demonstrate value of patented differentiation that leads to positive patient outcomes

Dialogue regarding alignment with the Emerging Therapies Act Pilot

Discuss the merits of amniotic tissue based technology

MiMedx® Overview

MiMedx® is a biopharmaceutical company developing, manufacturing and marketing regenerative biologics utilizing human placental allografts for multiple sectors of healthcare.

"Innovations in Regenerative Medicine" is the framework behind our mission to provide physicians with products and tissues to help the body heal itself.

Literature shows amniotic membrane enhances healing:[1, 2, 3]

- ✓ Immunologically privileged
- ✓ Modulates inflammation
- ✓ Reduces scar tissue formation
- ✓ Contains essential growth factors

1,000,000 allografts distributed to date with **no adverse reactions** attributed to our products†

†As of September 1, 2017

>40 Peer Reviewed, Published Scientific and Clinical Studies

[1]Litwiniuk M1, Grzela T "Amniotic membrane: New concepts for an old dressing." Wound Repair Regen. 2014 Jul;22(4):451-6. (22)4. 2014 Jul. pp 451-6.
[2]Akle, C; Adinolfi, M; Welsh, K; Leibowitz, S; and McColl, I "Immunogenicity of Human Amniotic Epithelial Cells after Transplantation into Volunteers." The Lancet. (318)8254. 7 November 1981. pp 1003-1005.
[3]Parolini, O et alHuman Term Placenta as a Therapeutic Agent: From the First Clinical Applications to Future Perspectives, in Human Placenta: Structure and Development, Circulation and Functions. Pregnancy and Infants: Medical, Psychological and Social Issues Series. Nova Biomedical Books, 2010.

FDA Regulatory Classifications for Tissue, Cell Based Products, and Other

351 HCT/Ps (Human Cell Tissue/ Products)	Human Tissue (Allograft) or Cells	May be more than minimally manipulated, and/ or may or may not be for homologous use. Pre-market clearance or approval required. Requires FDA Current Good Manufacturing Practice (cGMP).
361 HCT/Ps (Human Cell Tissue/ Products)	Human Tissue (Allograft) or Cells	Minimally manipulated, intended for homologous use. No clearance or pre-market approval required. Requires FDA Good Tissue Practices (GTP)
510(k) Clearance	Medical Device (Example: decellularized human dermis, xenografts, collagen dressings, bovine filler)	Requires FDA Substantial Equivalence, shorter submission and less required verses PMA. Based on predicate device. Requires FDA Current Good Manufacturing Practice (cGMP)
Premarket Approval (PMA)	Medical Device (Example: human living skin substitutes, bone substitute)	Requires extensive FDA Pre-Market approval process, including comprehensive clinical trials. Requires FDA Current Good Manufacturing Practice (cGMP)
Biologic License Application (BLA)	Biological product (Example: Section 351 HCT/Ps, cell products, such as those containing hematopoietic progenitor cells, vaccines, and blood components)	Requires extensive FDA Investigational New Drug (IND) and BLA approval process, including comprehensive pre-clinical and clinical trials. Requires compliance to FDA Current Good Manufacturing Practice (cGMP)
New Drug Application (NDA)	(Example: living stem cells non-autologous, second degree relative, or autologous stem cells that are expanded in the laboratory)	Requires extensive FDA Investigational New Drug (IND) and BLA approval process, including comprehensive pre-clinical and clinical trials. Requires FDA Current Good Manufacturing Practice (cGMP)

United States Pharmacopeia Monograph

USP and the National Formulary (NF) are the public pharmacopeia standards for drug substances, dosage forms, compounded preparations, excipients, dietary supplements and medical devices.

- The "Tissue Human Amnion Chorion Membrane Dehydrated" USP Monograph outlines the definition of the products covered, as well as the specification, packaging, storage, and labeling requirements with which a product must conform. Validated tests, procedures for the tests, and acceptance criteria make up the specification.
- All products must have the stipulated strength, quality, and purity if they expect to conform to the requirements of this Monograph.

MiMedx dHACM is the first human amnion/chorion dehydrated membrane to meet requirements of the United States Pharmacopeia (USP) monograph.

Source: http://phx.corporate-ir.net/phoenix.zhtml?c=213465&p=irol-newsArticle&ID=2219390

Source of MiMedx PURION® Processed Amnion and Chorion Membranes

LIVE BIRTH Via Planned C-section

Microbiological and Viral Testing of Donor Tissue and Blood

purion® process

PURION® Processed Amnion/Chorion Grafts and injectables

MiMedx

MiMedx is a Biopharmaceutical Company with an Extensive Product Portfolio

Sheet dHACM:
Flagship bioactive Amnion/ Chorion grafts containing 226 proteins and growth factors with proven enhanced healing power

- Smaller wounds
- Various surgical applications
- As a barrier membrane

Micronized dHACM:
Same dHACM in an injectable configuration

- Smaller wounds
- Various surgical applications

Umbilical Cord Products:
Provide a protective environment for the healing process.

- Smaller wounds requiring a graft that can hold a stitch
- Longer site coverage timeframe
- When a thicker graft is needed for coverage/ padding

Placental Based:
Our NEW bioactive placental tissues containing Growth Factors found in PURION® Processed tissues that modulate the activity of the recruited cells to enhance healing **+** an extracellular matrix (ECM) that provides a scaffold for recruited cells to attach, populate, and proliferate.

- Larger and uneven surface areas >25cm^2
- NOT injectable

CLINICAL EFFICACY
PATIENT OUTCOMES

MiMedx

Diabetes in Arkansas:

We are focused on the 364,000 people in Arkansas who live with diabetes*

- Approximately 363,781 people in Arkansas, or 14.8% of the adult population, have diabetes.
- Every year an estimated 25,000 people in Arkansas are diagnosed with diabetes.
- People with diabetes have medical expenses approximately 2.3 times higher than those who do not have diabetes.
- Total direct medical expenses for diagnosed and undiagnosed diabetes, prediabetes and gestational diabetes in Arkansas was estimated at $2.3 billion in 2012.
- In addition, another $798 million was spent on indirect costs from lost productivity due to diabetes.

*American Diabetes Association
http://main.diabetes.org/dorg/PDFs/Advocacy/burden-of-diabetes/arkansas.pdf

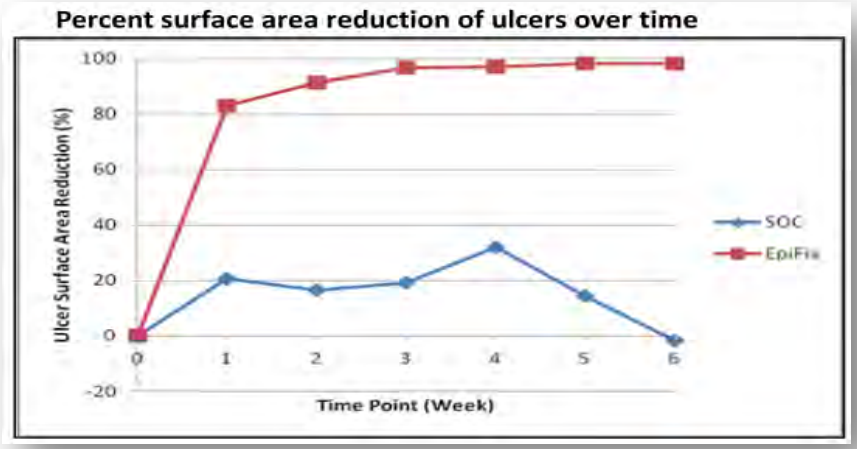
Diabetic Patients with Non-healing Wounds

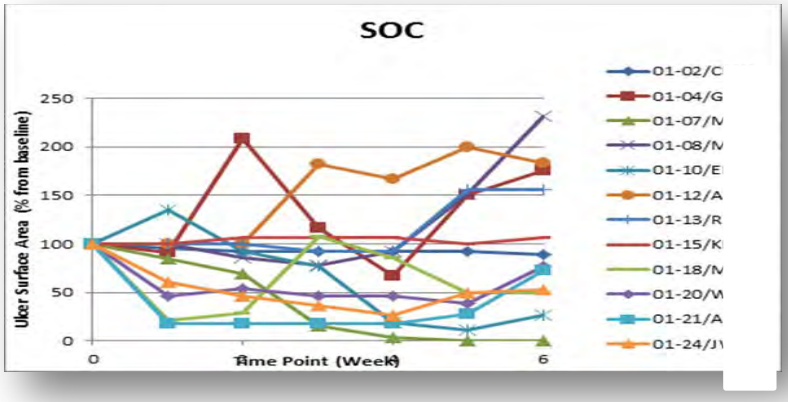
- Mean one year cost from a health care public payer perspective was $44,200 for diabetic foot ulcer (DFU), and $11,000 for leg ulcer (LU)[1]
- 33% of the cost of diabetes directly linked to the care of lower extremity complications[2,3]
- The majority of non-traumatic lower limb amputations can be avoided with education, monitoring and early treatment. [4]

[1]Chan; "Cost-of-illness studies in chronic ulcers: a systematic review." Journal of Wound Care Vol 26. No.4, April 2017
[2]Rogers LC, Lavery LA, Armstrong DG. The right to bear legs – an amendment to healthcare: How preventing amputations can save billions for the US health-care system. J Am Podiatr Med Assn 2008;98:3-5
[3]Driver VR, Lavery LA. The costs of the diabetic foot: The economic case for the limb salvage team. J Vasc Surg
[4]American Diabetes Association http://main.diabetes.org/dorg/PDFs/Advocacy/burden-of-diabetes/arkansas.pdf

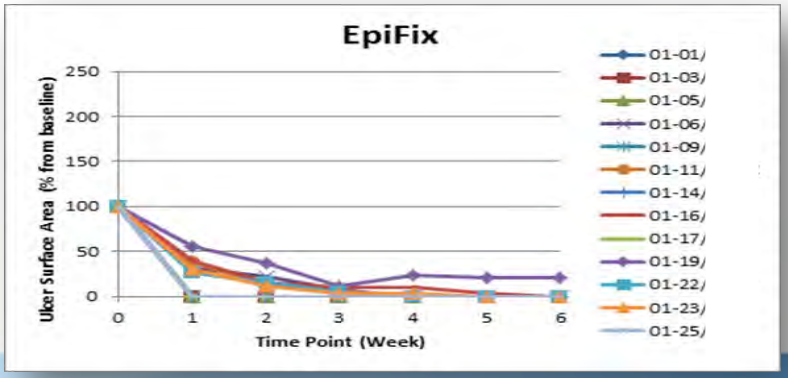
Diabetic Foot Ulcer Randomized Clinical Trial (RCT) Outcomes

- EpiFix® with Standard of Care vs. Standard of Care alone
- 92% healed in 6 weeks compared to 8% for control group
- Average of ***2.5*** grafts to closure





Ulcers healed	SOC (n=12)	EpiFix® (n=13)	P value
4 Weeks	0 (0%)	10 (77%)	<0.001
6 Weeks	1 (8%)	12 (92%)	<0.001

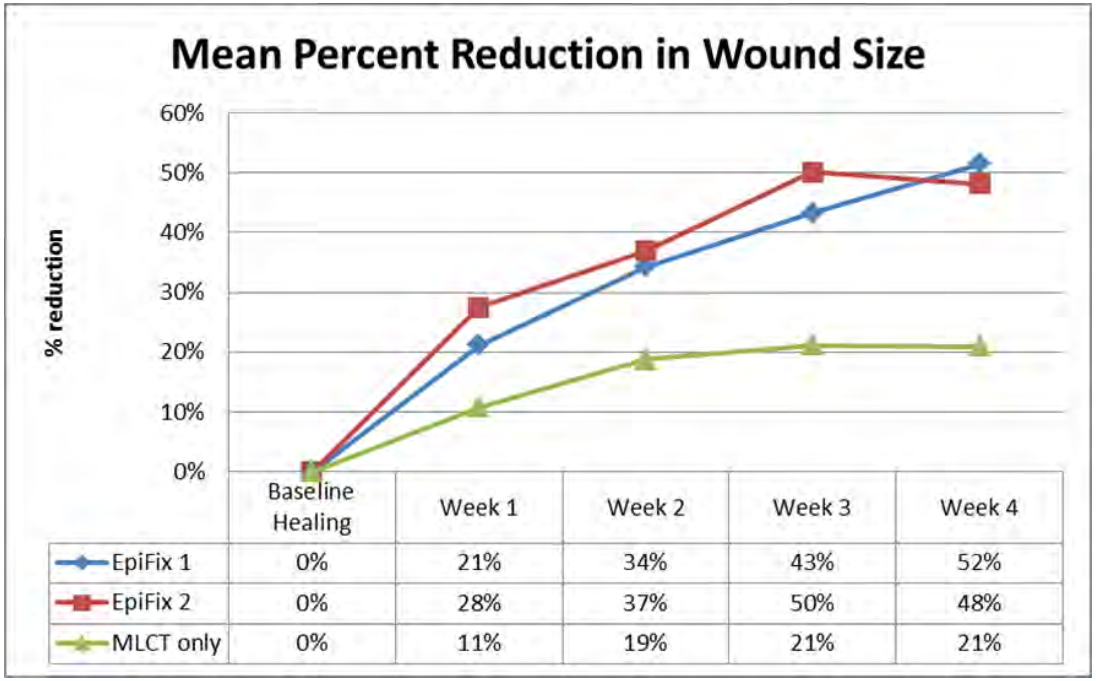


Zelen CM, Serena TE, Denozière G, Fetterolf DE. A prospective randomized comparative parallel study of amniotic membrane wound graft in the management of diabetic foot ulcers. Int Wound J. 2013 Oct;10(5):502-7.

MiMedx

Multi-Site RCT For Venous Leg Ulcer Wound

Study completed across 8 centers indicated that both one application and two applications are more effective than standard of care.



	Baseline Healing	Week 1	Week 2	Week 3	Week 4
EpiFix 1	0%	21%	34%	43%	52%
EpiFix 2	0%	28%	37%	50%	48%
MLCT only	0%	11%	19%	21%	21%

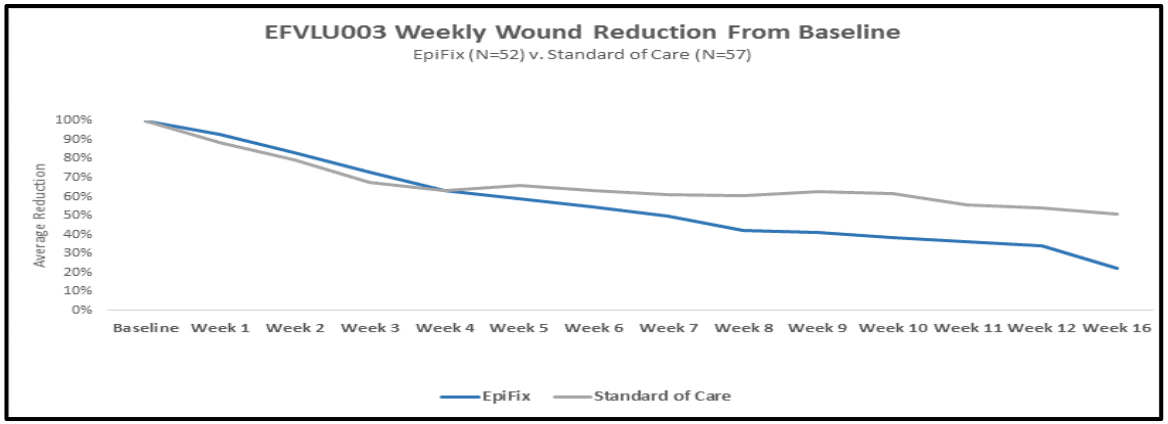
Mean percent reduction in wound size during the 4-week study period

Serena TE, Carter MJ, Le LT, Sabo MJ, DiMarco DT, and the EpiFix Study group. "A Multi-center Randomized Controlled Clinical Trial Evaluating the Use of Dehydrated Human Amnion/Chorion Membrane Allografts and Multi-layer Compression Therapy vs. Multi-layer Compression Therapy Alone in the Treatment of Venous Leg Ulcers." Wound Repair Regen. (22)6. November-December 2014. pp 688-693.

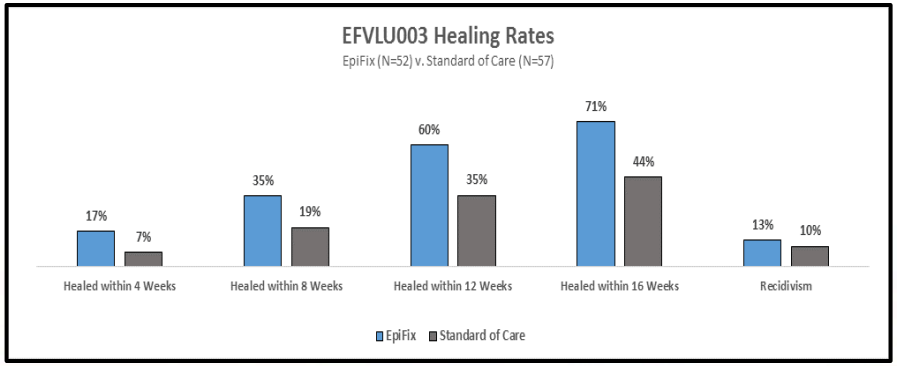
MiMedx

Venous Leg Ulcer Randomized Clinical Trial (RCT) Outcomes

- **EpiFix® with Standard of Care vs. Standard of Care (SOC) alone**
- **EpiFix healed 60% vs. SOC 35% at 12 weeks**
- **EpiFix healed 71% vs 44 % at 16 weeks**



Ulcers healed	SOC (n=57)	EpiFix® (n=52)	P value
12 Weeks	20 (35%)	31 (60%)	0.0128
16 Weeks	25 (44%)	37 (71%)	0.00625



" Bianchi, C, Cazzell s, Vayser D, Alexander M, Doslouglu H, Tovmassian G, " A Multi-Centre Randomised Controlled Trial Evaluating the Efficacy of Dehydrated Human Amnion/Chorion Membrane (EpiFix) Allograft for the Treatment of Venous Leg Ulcers." International Wound Journal doi:10.1111/iwj. 12843. 2017. pp 1 -9.

We believe using EpiFix in combination with existing Standard of Care treatments, can enhance the treatment and safe healing of chronic, non-healing lower extremity wounds.

Safety and Testing

Major Process Step	Criteria that Ensures Tissue Safety
Donor Screening	Performed per 21 CFR 1271 domestically.
Infectious Disease Testing	Negative results for all FDA approved and **CLIA Certified** tests that includes HIV, Hepatitis B and C, Syphilis, and Human T-cell lymphotropic virus (HTLV)
PURION® Process	A validated process with proven Bacterial/Spore reduction capabilities that range from 1.4 –5.6 Logs
Terminal Sterilization of all grafts	A validated process per **ISO 11137** standards providing at least a 10^{-6}SAL with irradiation dose monitoring linked to the release of every tissue distributed
Double sterile barrier product packaging	A validated process per FDA recognized **ASTM D4169** standards that ensures sterility is maintained post distribution

Completed Level I Studies

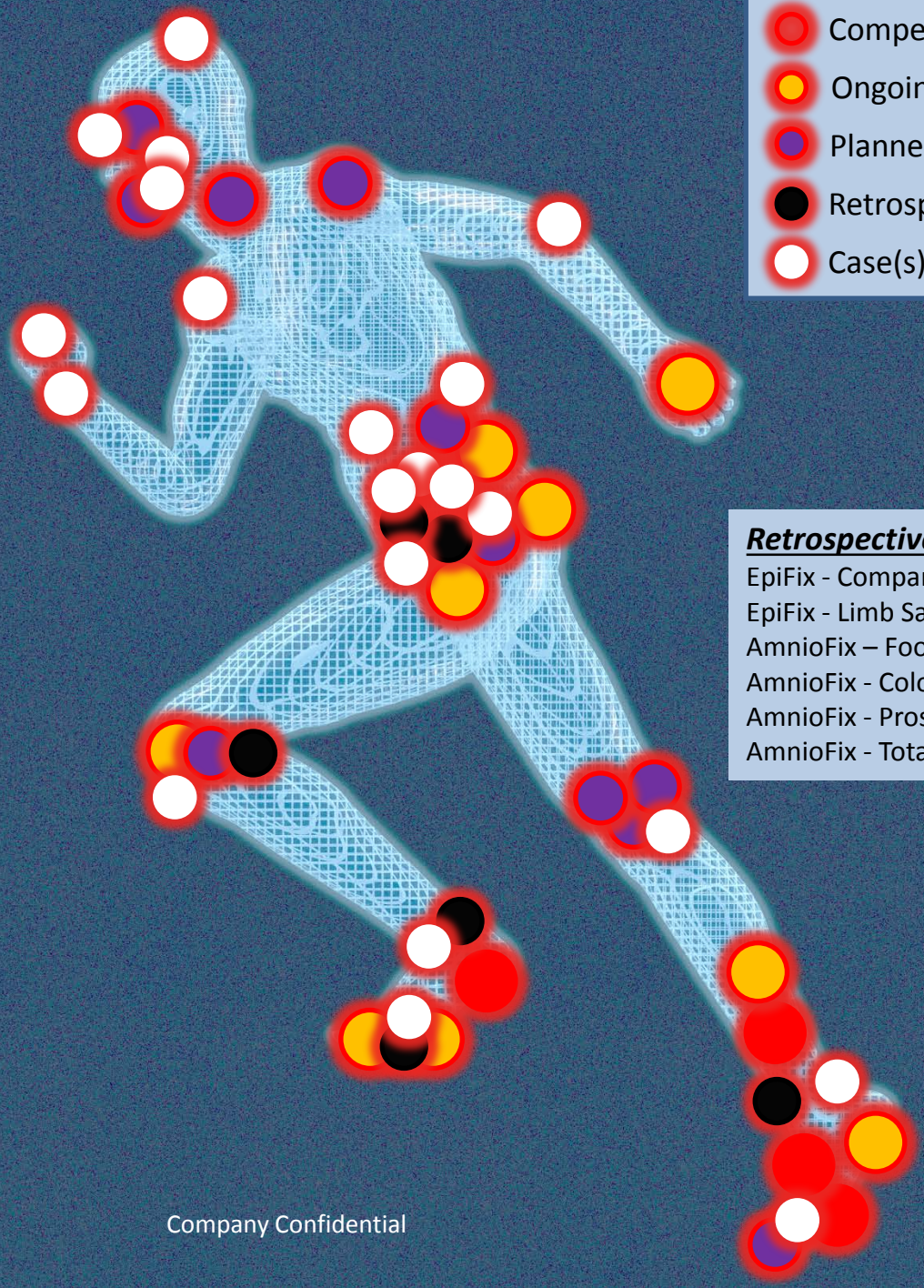
EpiFix® - Diabetic Foot Ulcer
EpiFix - Comparative DFU Study
EpiFix - Venous Leg Ulcer
AmnioFix® - Plantar Fasciitis

Ongoing Level I Studies

EpiFix - Diabetic Foot Ulcer
EpiFix - Pressure Ulcers
EpiFix - Venous Leg Ulcer
AmnioFix - Spine
AmnioFix - Prostatectomy
AmnioFix - Plantar Fasciitis
AmnioFix - Achilles tendonitis
EpiCord® - Diabetic Foot Ulcer
OrthoFlo® - Ortho Knee
EpiBurn® - Burns

Planned Level I Studies

EpiFix - Adult Facial Burns
EpiFix - Pediatric Facial Burns
AmnioFix - ACL Repair
AmnioFix - Head and Neck
AmnioFix - Partial Nephrectomy
AmnioFix - Knee OA
AmnioCord® - Hallux Rigidus
AmnioCord - Supraspinatus Repair
OrthoFlo - Early OA
OrthoFlo - Gluteal Tendinopathies
OthroFlo - Knee (1)
OrthoFlo - Knee (2)



Retrospective Studies

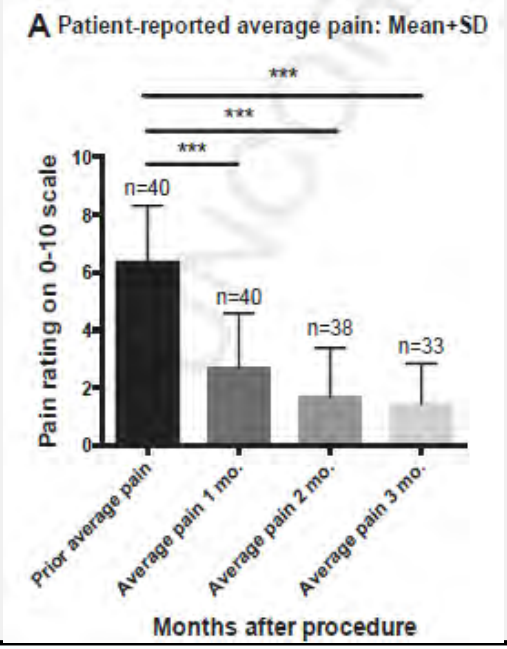
EpiFix - Comparative Effectiveness
EpiFix - Limb Salvage
AmnioFix – Foot and Ankle
AmnioFix - Colon Resection
AmnioFix - Prostatectomy
AmnioFix - Total Knee Arthroplasty

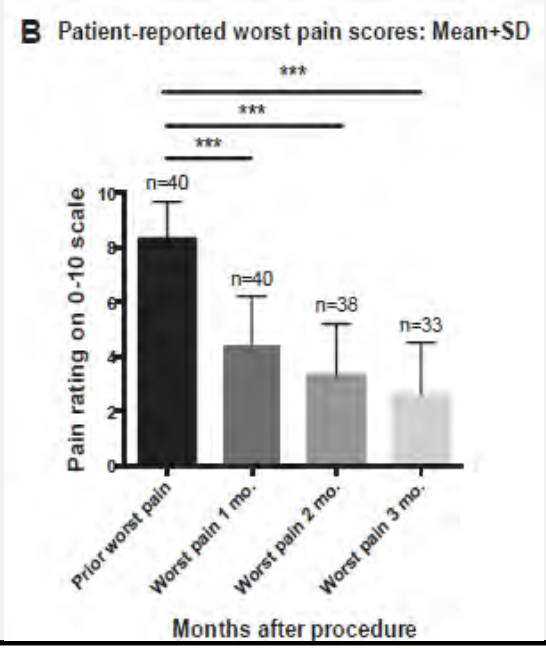
Company Confidential

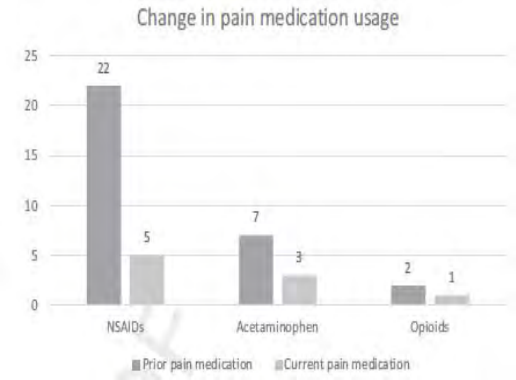
AmnioFix® Injectable Data

Multiple cases/studies completed or underway

Gellhorn and Han: ***The Use of Dehydrated Human Amnion/Chorion Membrane Allograft Injection for the Treatment of Tendinopathy or Arthritis: A case Series Involving 40 Patients****







*Physical Medicine and Rehabilitation. 2017 doi10.1016/j.pmrj.2017.04.011

SUMMARY

MiMedx Value Proposition

- ✓ **Promotes Healing** - Scientific data shows dHACM ability to draw stem cells toward the site to modulate inflammation, reduce pain and accelerate healing
- ✓ **Superior Published Clinical Data** - 11 Randomized Control Trials (RCTs) showing statistical significance
- ✓ **Proprietary PURION Process** preserves 226+ different growth factors
- ✓ **Patient Safety -** Terminal Sterilization
- ✓ **USP Monograph** - Rigor in processes ensure consistent product quality
- ✓ **Storage and Ease of use** - Ambient conditions with 5 year shelf life

THANK YOU