

TOP 10 QUESTIONS TO ASK WHEN CONSIDERING A STEM CELL PROCEDURE





Top 10 Questions to Ask When Considering a Stem Cell Procedure

Orthopedic stem cell providers are not all created equal. When making the decision to put all of your trust into a stem cell clinic and physician, it's important that you know the right questions to ask—and just as important that you know whether or not you're getting the right answers. Our top 10 questions to ask a stem cell clinic will help you scope out—based on questions orthopedic stem cell providers should be able to answer—what type of clinic has the greatest chance of accomplishing what you're paying them to do.

1. How much experience do you have?

Experience is everything in medicine. The more a surgeon or physician has practiced a particular skill, the better the outcome and the fewer the complications. For most surgical procedures, for example, surgeons will consider themselves competent after 20–50 procedures. They will not usually consider themselves an expert unless they have done a procedure two hundred times or more.

<u>Procedures that use stem cells to treat arthritis are no different</u>. Ask your physician how many stem-cell-based procedures of the type you need he or she has done.

Bait and Switch: Physicians at some clinics will talk about the number of procedures they've done that involve <u>PRP (platelet rich plasma)</u>; make sure your provider gives you the specific answer for stem-cell-based treatments. We have also seen new providers list the total number of surgical procedures they have performed (that did not involve stem cells).

2. What kind of data do you collect and report?

Where is the data? Stem cell treatments for arthritis are new: most doctors classify them as "investigational care," meaning that the techniques are not yet fully understood. That's not something that should scare you as a patient—after all these years, we still don't fully understand how aspirin works in the body—but it does mean that data should be collected by the clinic at all times. The data collected should go beyond a simple phone call after the procedure. Providers should want you to complete a questionnaire that will ask you about your pain level before and after the procedure, how well you can use the affected joint now that the procedure is finished, and whether there were any complications from the procedure.

Ask what information the clinic collects and where this information is located on their website. Investigational care results should be indexed in a <u>registry</u>, <u>which is an organized</u> <u>place to collect data on that specific procedure</u>. This registry allows other physicians to review the data and allows the medical community as a whole to improve its techniques and the practice of medicine.



Also ask if there are <u>any publications in medical journals regarding this specific procedure</u>. This is an area to be careful with as some less-scrupulous clinics may "borrow" the studies of other procedures that are not actually the same as the procedure they want to do on you, <u>such as using research on bone marrow stem cells instead of the fat stem cells</u> the clinic is actually using. If there is not a large amount of data for your particular procedure yet, ask <u>where you can read about their previous history with this procedure—the outcomes of both their successes and their failures</u>. Clinics that are involved with investigational care should post information from their registry about all of their patients, even those who didn't respond to the treatment.

In summary, it all comes down to one simple issue. Where on the clinic's website is the data that they have collected on this specific procedure? Where is the patient infographic that shows results? Where are the publications? By the way, you can find ours under the <u>"Research" tab on our website</u>.

3. What's your physician specialty?

Physician specialty matters. As a musculoskeletal specialist, I have in the past used Botox to treat a medical condition called dystonia. Sometimes, one of my female patients will ask me to perform a cosmetic Botox treatment. I probably could, but I won't because I'm not a cosmetic dermatologist or plastic surgeon, which means I don't have the specialized training these physicians go through to achieve the best results for their patients.

Medical specialties exist for a reason. I have thousands of hours of specific training in nonoperative orthopedics, and while I could certainly deliver a baby in an emergency, that's not my specialty. If something goes wrong with the delivery or there are complications, I would certainly do the best I can, but I don't have the specific training that an OB-GYN has. By the same token, while your plastic surgeon or family-care physician has thousands of hours of specific training in his or her specialty, this physician doesn't have the specific training or experience with orthopedic procedures in general or with orthopedic stem cell procedures specifically.

Specific training means better results. Ask your physician if he or she is board-certified in a specialty that is specifically trained to perform injection-based care into joints. <u>A</u> <u>board-certified physician who specializes in sports medicine, physical medicine, or</u> <u>interventional pain treatment has the specialized training and experience to do these</u> <u>procedures correctly.</u> While some orthopedic surgeons have undergone extra injectionbased training using guidance to perform these procedures, most have not. You would think that a surgeon should be able to perform a complex injection, but many still perform these procedures blind. If an orthopedic surgeon is performing the injection, make sure that he or she has extensive training in guided injections under ultrasound and/or fluoroscopy.



4. What cell source are you using?

Cell source is important. Stem cells are located in just about every part of our bodies, but not all stem cells are the same. The specific type of <u>stem cells that are used to treat</u> <u>knees</u>, <u>hips</u>, <u>shoulders</u>, <u>and ankles can be obtained from several sources—the most</u> <u>common sources are adipose tissue (the layer of fat we all have beneath our skin) and</u> <u>bone marrow</u>. For some issues, such as mild joint arthritis or a partial rotator cuff tear, the platelets found in blood can help, but for larger areas of involvement, the platelets in blood are usually not sufficient.

This leaves bone marrow and adipose as possible stem cell sources for joints and tissues that are more degenerated. Adipose stem cells may be able to help in orthopedic conditions, but in head-to-head studies with bone marrow stem cells, they are less able to repair joint tissue, like cartilage. Bone marrow is the best source of stem cells used to help cartilage health.

<u>"Amniotic stem cells"</u> have become an epic case of widespread consumer fraud. The problem? The vials of amniotic, placental, or fetal tissues being used by clinics offering this type of stem cell treatment don't contain any living cells (companies manufacturing these off-the-shelf products are required to actively kill all of the cells in them with gamma irradiation). That, however, hasn't stopped unscrupulous or less-than-knowledgeable clinics from claiming that the patient is getting injected with millions of live stem cells. Hence, any clinic claiming to use amniotic stem cells to treat orthopedic conditions should be avoided as they are really injecting a bunch of dead amniotic tissue.

When you talk with your provider, ask where he or she harvests the stem cells. If the physician only takes stem cells from fat (adipose stem cells), then the clinic you are in is not primarily focused on orthopedic issues or is not staying up-to-date with the science behind the procedures. There have been some less-reputable plastic-surgery and age-management clinics that are starting to offer stem cell treatments for orthopedic issues. These clinics only harvest stem cells from adipose because they aren't trained to perform stem cell harvesting from bone marrow.

5. What harvesting technique are you using?

Harvesting technique is critical. <u>Stem cells are removed from the body, or "harvested,"</u> <u>in several different ways.</u> The stem cells that are the most useful for orthopedic care are found in bone marrow. The methods used to harvest these cells are critical to the success of the procedure. <u>For fat stem cells, physicians use liposuction to harvest the stem</u> <u>cells.</u> The harvesting of stem cells from bone marrow requires a technique called bone marrow aspiration.

Bone marrow aspiration is a procedure that requires a great deal of experience. Because bone marrow is the richest source for stem cells that are the most useful for orthopedic issues, it is important to harvest, yet this is difficult without some form of imaging guidance. If your physician does not use some sort of imaging to guide his or her work (either fluoroscopy or ultrasound), there is a significant risk that he or she will aspirate blood with no stem cells instead of bone marrow with stem cells. Additionally, if a physician only harvests from a single spot (rather than multiple sites in the bone), the physician runs the risk of getting fewer stem cells, even if he or she does get bone marrow aspirate.



Also, make sure that you ask if the clinic uses a cell biology lab or a tool on-site to confirm that it has harvested actual stem cells (see number 6 for more).

6. Do you count the cell dose in the sample?

Dose in medicine is key. In stem cell therapy, the issue of whether you are getting enough cells to maximize the chance of a successful treatment is an epic fail on the part of most clinics.

After stem cells are harvested, they are processed to remove the less useful tissues and concentrate the fraction containing stem cells. They may also be cultured, which means that the stem cells are placed in an environment that encourages them to multiply.

We have seen a lot of clinics that offer <u>stem cell treatments where the cells are processed</u> <u>in bedside kits—small machines that centrifuge, or shake, the tissue to isolate a stem-cell-</u> <u>rich fraction.</u> The vast majority of clinics that use these bedside machines have no idea how much of what they inject back into you is actually stem cells because they can't count the cell content of the samples they're injecting.

As an example, <u>based on our dosing research</u>, <u>only about one in three to one in four older</u> <u>patients have enough stem cells to inject both knees</u>. Since we count the cells, we know who doesn't have enough. <u>In addition, since we use sophisticated stem-cell-harvest</u> <u>techniques</u>, we can adjust that procedure to obtain more cells. Compare that to a clinic <u>that has no idea how many cells you have or how many you need</u>. Are you willing to spend big bucks on a treatment and then flip a coin as to whether you have enough cells to treat all of your problems?

7. How do you make sure the stem cells are placed where they're needed most?

The stem cells must hit the bull's-eye. <u>Your physician must know how to accurately and</u> precisely inject your stem cells into the actual damaged or degenerated area to be optimally effective. Even being off by as little as an eighth of an inch may make the difference between a successful outcome or continued pain and dysfunction of the joint.

<u>Make sure your provider will use some form of imaging (fluoroscopy or ultrasound) to</u> <u>guide the injection.</u> Run away if the clinic is using a "blind" injection technique. In addition, make sure you know the difference between highly precise injections under guidance and being "in the neighborhood" is good enough. Or as I call it, the sharpshooter versus the shotgun approach.

Many clinics that do use guidance will place the cells anywhere they can easily reach in the joint (the shotgun). Other clinics will have advanced training on how to place cells in a specific structure (the marksman or sharpshooter). For example, in a shoulder, the shotgun approach is placing cells in the back part of the main joint under ultrasound or in the front part using fluoroscopy. However, the marksman has the advanced training using either or both technologies to place cells in the superior labrum where the biceps attaches.

Why pay for a blind injection or even a shotgun approach when you can have your cells precisely placed where they are needed most?



8. Are you using medicines or common additives that kill stem cells?

Some common medications and additives can kill stem cells. These come in three flavors: anesthetics, steroids, and other medications.

Many providers use local anesthetics to numb the area. However, the most common local anesthetics kill stem cells. Ask your provider if the medicines he or she is using come in contact with the stem cells. Sometimes this is unavoidable, but there's only one anesthetic that's safe for cells, an obscure OB-GYN anesthetic called ropivacaine (that's not commonly found outside of the baby-delivery area). If your provider is using lidocaine or bupivacaine/ Marcaine to numb the joint or other area, that's a problem. It also shows a lack of knowledge and sophistication with the procedure, which is problematic.

Steroid injections into joints are commonplace, but they regrettably kill cartilage and other cells when injected in the massive doses that are commonly used. In the same way that <u>steroid shots kill all local cells</u>, they will also kill stem cells. There should be at least 6-12 weeks of time separating a steroid injection from a stem cell injection. In addition, if the doctor does more steroid injections in his or her practice than PRP or stem cell injections, you may want to look elsewhere as that provider is sacrificing patient outcome for the convenience of a procedure that an insurer will cover. Finally, while milligram-dose steroid injections kill cells, specially compounded nanogram doses (one million times less), can help cells. However, outside of a few providers, 99.999% of doctors use the high-dose variety that kills cells.

Lastly, <u>many prescription medications have negative effects on stem cells</u>. We've developed a list based on years of observation on which medications make it harder for stem cells to propagate in culture. If a physician has no experience growing stem cells, he or she has no list of medications that you shouldn't take. This is despite the issue that staying on a prohibited medication likely reduces your chance of a successful procedure.

9. How sophisticated is your cell lab?

Level of lab sophistication matters. Most physicians' offices don't have an on-site lab, but even if they do, not all labs are equal. <u>A dedicated cell-biology lab will have equipment</u> <u>that a regular doctor's office simply does not need</u> because this equipment is absolutely vital to giving you the best possible outcome.

The first question to ask about the clinic's cell lab is if they use an "open" or "closed" system. A "closed" system keeps tissue samples in a germ-free environment, inside a clean hood. An "open" system exposes tissue samples to open air, where they are susceptible to being contaminated by bacteria in the air.

A dedicated cell-biology lab will also have devices that allow doctors to count cells. Cell biology labs also use air-quality checks, sterility checks of clean areas, and protective gear for the technicians in order to give the highest possible assurance that your stem cells will be protected from contamination.



10. What's your success rate, and am I a good fit?

Avoid hype about lack of complications, too-good-to-be-true success rates, and candidacy.

Even the best and most-successful clinics have patients who do not respond as well as can be hoped, and even the most careful physicians have patients who develop complications. Unfortunately, in the field of medicine, these things happen. <u>Physicians do absolutely</u> everything in their power to minimize these risks, and some aspects of patient care are beyond a physician's control.

Physicians or clinics that tell you they have a 100% success rate or close to it are, frankly, lying or rigging the numbers. Even the best stem cell clinics have a success and failure rate. Ask your stem cell provider what his or her success rate is for the stem cell procedure you are considering. If the provider's answer includes a frank discussion of the chances that the procedure will fail, then you have a physician who is being honest.

Every honest physician should also be able to tell you whether the procedure he or she is offering is a good fit for your particular condition. Every patient is not a good candidate for every procedure. Ask the question, "What percentage of patients have you turned away or told that they were a poor candidate for this procedure?" If you get a blank stare or silence, or if you believe the only test the physician uses to evaluate you for a stem cell procedure is your credit rating, run out of that office as fast as you can, and don't look back. In addition, ask what your candidacy rating is based on. Meaning does the clinic use its own registry data to see who is a good or bad candidate? Also, ask where can you find that data.

Knowing the top 10 questions to ask a stem cell clinic can make the difference between a successful and an unsuccessful treatment. There are qualified orthopedic stem cell providers out there, and unqualified ones. Hopefully, knowing what questions orthopedic stem cell providers should be able to answer will help you find the providers that can help you.

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