Reducing Bacterial Contamination of Cellular and Blood Products via Novel Needle Designs

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This is a brief summary describing the problem of bacterial contamination of cellular products and two novel methods designed to decrease its incidence.

The two main sources for cells in regenerative medicine and cell transplantation are peripheral vein blood draws and intra-osseous marrow extraction. The reported rate of contamination of the various types of stem cells ranges from 0.2% to more than 24%, averaging about 3% (Jacobs MR) (Kamble R) (Namdaroglu S). For HPCs sourced from peripheral blood (PB), the incidence of contamination is close to 2.1%. Rates of bacterial contamination of bone marrow-derived HPCs, are generally higher than PB-HPCs, reaching levels >3.5% (Honohan A).

Despite careful attention to sterile procedures, low-level contamination of hematopoietic stem cell components can occur. Bacteria from the skin flora (coagulase-negative Staphylococcus, Propionibacterium and Corynebacterium species) are the contaminants in approximately 90% of cases (de Medeiros CRFL).

The pathogenicity of skin flora is a complex topic. Let's take for example Cutibacterium Acnes. Cutibacterium (formerly known as Propionibacterium) species are nonsporulating, gram-positive anaerobic bacilli. P. acnes colonizes primarily sebaceous glands of hair follicles of human skin, but it may also be found in the mouth, nares, genitourinary tract, and large intestine. (Ackermann) In 2004, the whole genome of C.acnes was sequenced by Bruggemann et al. (Bruggemann H). They concluded the genome sequence clearly reveals many proteins involved in the ability of P. acnes to colonize and reside in human skin sites as well as a pronounced potential to survive a spectrum of environments. This capacity helps to explain the ubiquity of C. acnes and also its potential hazards, for example, the public health problems associated with Blood Bank contaminations. Although primarily recognized for its role in acne, C. acnes is an opportunistic pathogen, causing a range of postoperative and device-related infections. These include infections of the bones and joints, mouth, eye and brain. Device-related infections include those of joint prostheses, shunts and prosthetic heart valves. C. acnes may play a role in other conditions, including inflammation of the prostate leading to cancer, SAPHO (synovitis, acne, pustulosis, hyperostosis, osteitis) syndrome, sarcoidosis and sciatica (Perry A). McDowell et al. (McDowell A) demonstrated that some types of C. acnes appear to be commensural, while others have been found in human infections with some resistant to multiple antibiotics. C. acnes is able to invade mesenchymal

signaling cells (MSCs) inducing the potential transition of commensal C. acnes to an opportunistic pathogen in implant-associated infections (i.e. by increasing biofilm formation and resistance of macrophage phagocytosis) (Dubus M).

Contamination of cell cultures is not only frustrating, but is also very expensive both in time and loss of materials. (Vierck JL).

Contamination in a case of bone marrow transplantation is usually symptom free, however this may result in bacteremia with febrile illness (Stroncek DF) (Webb IJ) (Lazarus HM) (Namdaroglu S) as well as in septic shock (de Medeiros CRFL).

Infections resulting from skin commensals can be very dangerous in neutropenic patients and resistance has been increasing ie. among S. epidermidis (Lowder JN).

In the growing field of regenerative medicine, blood products such as platelet rich plasma (PRP), bone marrow and adipose tissue are now being used on a regular basis. Contamination of these cellular products is possibly the cause of severe complications. Two cases of spondylodiscitis (Subach BR) (Beatty NR) have been reported after intradiscal treatment with autologous cellular products. These infections may have serious sequelae, some requiring prolonged hospitalization, and some necessitating lumbar fusion surgery.

With the growing numbers of patients receiving cellular transplantation treatments as well as regenerative procedures, some involving culturing of cells prior to administration, it is more important than ever to prevent bacterial contamination of these products.

Up to 20% of skin bacteria are in the deeper layers of the skin and the pilo-sebaceous units, and these areas are untouched by antiseptics (Selwyn S) (Caldeira D). Additionally, contamination of the surface of the skin can occur immediately after disinfection, or an antiseptic may insufficiently eradicate certain pathogens from the needle site (Zubrod CJ) (Dumville JC). Therefore, despite adherence to the most stringent aseptic skin preparation techniques, a core of skin tissue with microbial flora may be introduced into a phlebotomy needle, infecting a cellular sample. In a cadaver study, it was noted that needle coring occurs often and could be a possible cause of post-injection septic arthritis (Xu C).

I am a specialist in the fields of regenerative medicine, internal medicine, pain management, physical medicine and rehabilitation , and headache management. I have performed in depth research on the needles in use and found that my two inventions are an improvement in the art, and that the ideas would be useful tools in medical

applications. There was a comprehensive study of the prior art of issued and pending patents, and it was determined that the ideas I have outlined are novel, and in our opinion patentable. Based on that research, I have patent pending status the United States for these novel designs.

I have designed a novel phlebotomy needle to decrease the incidence of contamination of blood samples. I have also designed a novel bone marrow biopsy needle to not only decrease the incidence of contamination, but to also increase ease of operation and to avoid possible fracture or other complications (Gladden K) (Bain BJ). I have patent pending status and I am looking for a strategic partnership to bring these improved needles to market.

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