

SERENAGROUP NEWSLETTER

Building the Nations Leading Wound Care Team

**THE NEED TO WORK
COOPERATIVELY
ACROSS DISCIPLINES
FOR HIGHER QUALITY
WOUND CARE**



THOMAS SERENA, MD, CEO

Investigators have partnered together to create cooperative groups in most fields of medicine, and in the first wound healing cooperative group formed under the aegis of the SerenaGroup Research Foundation (SGRF), a not-for-profit corporation based in Cambridge, MA, that has brought together nearly 100 clinical investigators in 60 sites across the globe to address inconsistencies and a lack of standardization in wound healing clinical trials.

Today, the SGRF Cooperative conducts numerous multi-center clinical trials solely within its network. Teamwork, progressive trial design, and technological advances in both data collection and analysis have revolutionized clinical trials in the areas of diabetic foot, venous leg and pressure ulcers, as well as in diagnostics and biomarkers.

The brainchild of a circle of thought leaders that first met in Cambridge in 2003, the Cooperative Group concept struggled for more than a decade. A breakthrough, though, arrived when I gathered a small collection of experienced researchers and began conducting clinical trials.

This group formed the nidus of the SGRF Cooperative. As clinicians, regulatory agencies and payors began to demand high quality trials, the SGRF Cooperative blossomed and, today, a central regulatory office manages ethics committee submissions for the sites. The burgeoning foundation drafts protocols, selects sites for trials, negotiates budgets and provides education for study coordinators and investigators.

In 2019 the SGRF Cooperative participated in clinical trials in all patient care settings, from the outpatient clinic to skilled nursing facilities. The research included Cellular or Tissue based Products for Wound Care (CTP), topical oxygen in diabetic foot ulcers, pharmaceutical investigations in venous leg ulcers, genetically modified tissues, biomarkers, wound imaging, biofilms, phototherapy and bacterial load in the ulcer bed. In addition, this year saw the SGRF Cooperative move from single device trials to studies evaluating a combination of multiple modalities. An equally robust slate of trials is planned for 2020.

The SGRF Cooperative's experience has led to the development of unique trial designs for diagnostics and biomarkers, much needed standardization for diabetic foot ulcer studies, and protocols that meet the reimbursement requirements for the Centers for Medicare Services.

The development of a cooperative group in the field of wound care has shown promise in enrolling patients in studies, supporting investigators and sites, improving trial design and raising the quality of research in wound healing.



Diabetes & Diet

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Tim Mayhugh,
National Safety
Director



A diet for diabetes simply means eating the healthiest foods in moderate amounts and sticking to regular mealtimes.

A diabetes diet is a healthy-eating plan that is naturally rich in nutrients and low in fat and calories. Key elements are fruits, vegetables and whole grains. In fact, a diabetes diet is the best eating plan for almost everyone.

Purpose

If you have diabetes, your doctor may recommend that you see a dietitian to help you develop a healthy eating plan. The plan helps you control your blood sugar (glucose), manage your weight and control risk factors for heart disease, such as high blood pressure and high blood fats. When you eat excess calories and fat, your body responds by creating an undesirable rise in blood glucose. If blood glucose is not kept in check, it can lead to serious problems, such as a dangerously high blood glucose level (hyperglycemia) and long-term complications, such as nerve, kidney and heart damage.

You can help keep your blood glucose level in a safe range by making healthy food choices and tracking your eating habits.

For most people with type two diabetes, weight loss can also make it easier to control blood glucose, while offering a host of other health benefits. If you need to lose weight, a diabetes diet provides a well-organized, nutritious way to reach your goal safely.

Diet Details

A diabetes diet is based on eating three meals a day at regular times. This helps your body more efficiently use the insulin it produces or acquires through a medication.

A registered dietitian can help you put together a diet based on your health goals, tastes and lifestyle. He or she can also talk with you about how to improve your eating habits; for example, by choosing portion sizes that suit the needs for your size and level of activity.

Recommended foods

Make your calories count with these nutritious foods:

- **Healthy carbohydrates.** During digestion, sugars (simple carbohydrates) and starches (complex carbohydrates) break down into blood glucose. Focus on the healthiest carbohydrates, such as fruits, vegetables, whole grains, legumes (beans, peas and lentils) and low-fat dairy products.
- **Fiber-rich foods.** Dietary fiber includes all parts of plant foods that your body can't digest or absorb. Fiber moderates how your body digests and helps control blood sugar levels. Foods high in fiber include vegetables, fruits, nuts, legumes (beans, peas and lentils), whole-wheat flour and wheat bran.
- **Heart-healthy fish.** Eat heart-healthy fish at least twice a week. Fish can be a good alternative to high-fat meats. For example, cod, tuna and halibut have less total fat, saturated fat and cholesterol than meat and poultry. Fish such as salmon, mackerel, tuna, sardines and bluefish are rich in omega-3 fatty acids, which promote heart health by lowering blood fats called triglycerides.

Avoid fried fish and fish with high levels of mercury such as tilefish, swordfish and king mackerel.

- **"Good" fats.** Foods containing monounsaturated and polyunsaturated fats can help lower your cholesterol levels. These include avocados, almonds, pecans, walnuts, olives, and canola, olive and peanut oils. But don't overdo it, as all fats are high in calories.



Electronic Clinical Documentation: Is yours a Van Gogh or a paint by the number?



Matt Schwyer, CPCO™, CHT-A, CHWS, UHMSDSA, CQO



Over the years we have seen many changes in the Advanced Wound Care space. In my opinion, the transition from paper documentation to Electronic Health Record (EHR) documentation being one of the largest--Be it good or bad.

Not long ago, we would spell everything out in the paper chart. Detailed SOAP notes were all the rage. And, complaining that we could not read the provider's handwriting would put some folks in a rage to the point that the Joint Commission published a standard citation, including penalties, on abbreviations in the medical record. The hospital had to have a policy and a plan for these abbreviations. Moving from paper to electronic was going to be the solution to all the inaccurate and illegible notes. Abbreviations!

All the above made sense and sounded like a great solution to the often-mentioned problems of illegible and sometimes completely inaccurate documentation, patient safety, and quality deliverables. But has it?

The success of the SerenaGroup Quality program is a nod to the data mining we have at our fingertips. The front-end work allowed us to establish that the right information was going in and the right information was able to be pulled out at the push of a button. However, I believe the next push for us as Providers, Clinicians, Hospitals and Company is to focus on the relevant clinical documentation in the EHR.

During a Pandemic, the requirements of the clinical documentation is what keeps me awake at night. Clearly, virtual presentations have their place and are effective to a point; However, one

without spot checks and in person support to review Internal audits, action plans, processes, and workflows. It is a form of accountability!

With Wound Expert and Intellicure we have been successful at getting all information to assure Medical Necessity, wound care goals, (soon debridement goals) into the records and we can audit off site. However, in hospitals that have their hospital-based EHR's, we have not been as successful in getting the elements expected to withstand an Audit and Audit Defense.

When do we find out there is an issue? When the hospital is selected for an audit. Then the fun begins: pieces of the painting are missing, such as Goals, Plans of Care, Re-Assessments. And then the Accountability question rears its ugly head.

Our world in Health Care and especially in wound care is ripe with Governmental audits: Post Payment Review (PPR), Revenue Audit Contractor (RAC), Unified Program Integrity Contractor (UPIC). Two things folks need to understand: the intensity and frequency of these audits has increased during the Pandemic and they have financial ramifications! Another, lesser-known fact is that "Data Analytics" drive these audits. Changes in practice patterns can trigger an Audit. All elements of medical necessity, goals, plans of care, orders, outside correspondences, treatment plans, treatment and procedure notes must be available in a succinct fashion. So, the question, is your clinical documentation a Van Gogh that can stand up to an Audit?

For the above reasons as a Compliance Officer, I expect all clinical documentation to look like a Van Gogh. Does yours? Not sure? Might we suggest, an in-person audit, and visit with your respective Information Technology team to get the elements into the record? Appropriate Clinical Documentation and Audit Defense allows the Wound Center to be a "Value Added" service line safeguarding and growing revenues for hospitals. Like a Van Gogh, which only appreciates in value over time.



SerenaGroup Education

SerenaGroup recognizes that the key to continued success with positive clinical outcomes is education. Education is provided through different platforms to ensure the tools are available to our centers. Topics for February Education included (but not limited to):

- Journal Club: Complications of Hyperbaric Oxygen Therapy
- HBO Safety: Chamber Maintenance
- Monthly Education: Strategies to promote patients adherence. Save a Treatment
- Roundtable Compliance Meeting
- Roundtable PD Meeting

Education is one of many key benefits to partnering with SerenaGroup. We are Building the Nation's Leading Wound Care Team.

The Advanced Wound Care Conference

May 7, 2021 | New Orleans, LA
for more information visit:
www.serenagroupinc.com



SerenaGroup Blue Star Winner



Andrea Sweeney, RN

Andrea saved a life; when her patient came into the wound care center, she recognized symptoms of a potential stroke and immediately took the patient to the ED where early intervention was performed. Patient recovered 100%!

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