SerenaGroup Newsletter

October 2020

SERENAGROUP MONTHLY UPDATE

ISSUE 32

Happy Retirement to Gay Smith!

Gay Smith announced her retirement September 1, 2020 from the Advanced Wound Center at Cleveland Clinic Akron General Medical Center. Gay has served as a secretary with the Hospital since 2009 and has worked with the inpatient units and the outpatient wound center. During that time, she has formed many friendships with many caregivers throughout the Hospital.

When people hear the news that she is retiring, they all have the same reaction, **"those are big shoes to fill."**

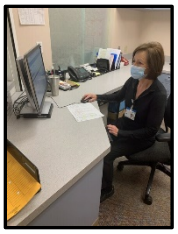
Gay's unparalleled dedication and attention to detail are evident to everyone she has interacted with over the years. Word quickly spread throughout the Hospital and it became impossible to not hear how much everyone will miss her and how happy they are for her to embark on her next journey.

Gay has undoubtedly spent years planning for this day making sure the timing was perfect. She is looking forward to improving her game of pickle ball with her husband, Jeff as well as spending time traveling to New York City, NY, and Austin, TX, to visit with her daughters; Katie and Jessie.

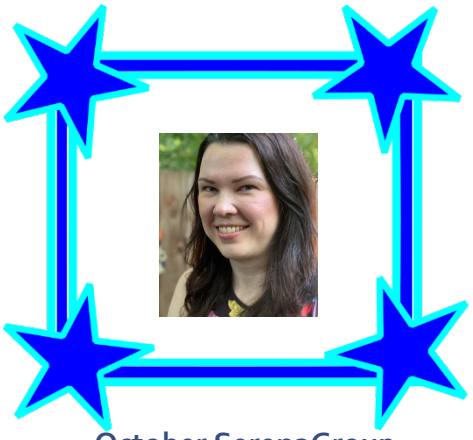
As her last day of work approached, there were mixed emotions throughout the department. Gay has formed a bond with every one of us and she will be truly missed. From her welcoming smile as we arrive to work to our team lunch breaks which will be seemingly bland without a well-timed joke or witty comment.

As we prepare to part, the only thing our team can say is **THANK YOU**. Thank you for setting high expectations for the clinic and making sure the day ran smoothly. Thank you for being there for our patients, and most importantly, thank you for being a wonderful friend and colleague to everyone at Akron General.

We would like to wish you the best of luck and many years of health and happiness in your retirement.



Congratulations!



October SerenaGroup Blue Star Winner

Laura Meyers, RN

"She is passionate about wound care and providing the optimal treatments to our patients. We can count on her for education to her peers & her patients" – *Ascension Dell Seton*

SerenaGroup® Centers are encouraged to recognize those around them who go above and beyond their job description. Recognizing hard work is a priority for SerenaGroup and we sincerely thank those who continue to be compassionate about their work in healing wound care and hyperbaric medicine patients.

The Rise of Diagnostics in the Treatment of Chronic Wounds

Guest Editor
Dr. Thomas E. Serena

Deadline
30 April 2021

Special Issue

Invitation to submit

Did I validate the order for that procedure?

Matt Schweyer, CQO

Recently, while auditing records, I noticed a pattern. To be compliant, we must have orders to start, deliver or continue to deliver care. There appears to be a pattern: initial orders are generated for HBOT; however, continuation orders are not written. Or if they are written, they are hard to find in the internal audits. Recently, an audit showed an initial order for twenty treatments; however, the patient had north of forty-five treatments. The prescription was completed in the record; however, there was no order to support the prescription of additional treatments. So, what might the impact be in this pattern?

Here are a few examples:

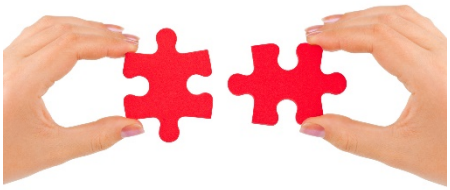
On treatment twenty-seven, patient is in the chamber, has a seizure, causes harm to himself. Without the order, clinicians are functioning outside of their scope, which could lead to problems! What problems?

An incident report is completed, the incident is investigated by the hospital Risk Management Department and a Risk Analysis completed. In the investigation, a complete review of the patient's medical record is performed. In the review, the orders are pulled and reviewed.

The order states, **twenty treatments at 2.4 ATA for ninety minutes of oxygen with two air breaks with appropriate time to travel to and from depth and reevaluate.** At the twentieth treatment, the patient is reevaluated and a decision to continue fifteen more treatments decided. However, at this reevaluation, orders were not written. And the next day, the patient continued treatments. What are the consequences of this action? Well, there are several! The RN and HBO Technologist are asked about workflow? Were orders checked prior to the procedure? What is the answer? Hopefully, that they reviewed the orders daily. However, if this were the case, how was the scenario allowed to play out with treatments rendered without orders? And, humbly, I would not want to be the staff members having to defend the decision to perform a procedure without an order!

Your hospital is under a Target Probe Educate (TPE) Audit. In the Additional Document Request (ADR) orders are reviewed. The order states twenty treatments; however, the patient has had more than twenty. What is the impact of this Escalation to Round Two of TPE. I would not want to be the Program Director who must meet with the Compliance Officer of SG and or the Hospital to discuss not having orders to carry out treatments.

Your hospital is audited by the insurance company that performs a Post Payment Review (PPR). Likewise, they pull the above order and the order substantiates twenty treatments. However, you have delivered twenty- seven. Obviously, seven w/o the order. What is the impact to the organization? Simple, they must pay back the money for the treatments that did not have an order. Again, who must meet with the CFO of the organization: The Program Director!



So, in conclusion, if it is determined the patient is going to continue HBOT at re-assessment, please review and ensure the provider places the order to continue HBOT in the order section of the Medical Record. The prescription, if indicated, must be completed as well. In doing this, we can ensure that we are performing best practices as it relates to the delivery of care & providing financial stewardship of the host organization, which is what sets SerenaGroup apart from other Wound Care management companies.

[1]New York Times, "Clinical Trials of Coronavirus Drugs are Taking Longer than Expected," Aug. 14, 2020
[2]U.S. Food & Drug Administration, Minorities in Clinical Trials Fact Sheet, May 23, 2019

How Virtual Clinical Trials Facilitate Wound Care Research During COVID-19

One of the many things interrupted by COVID-19 has been Clinical Trials.[1] And that is deeply impacting the healthcare system, from researchers to physicians to patients. Clinical research is vital to finding new ways to treat illness and disease and to ensure that patients have access to the best possible treatments for their conditions.

Recently, Net Health hosted a webinar with Thomas E. Serena, MD, founder and medical director of the Serena Group, and Nico O'Kuinghttons, vice president of Business Development for Clinical Trials for Tissue Analytics, a Net Health company, to explore this very topic. More specifically, how the current pandemic affects critical wound care research and how digital tools can be used to ensure this research continues.

Introducing Virtual Clinical Trials: The Serena Group is a global healthcare company with expertise in wound care research. Combined with Tissue Analytics' mobile wound and skin imaging and predictive analytics solutions, the two companies are at the forefront of the emerging virtual clinical trials marketplace. A virtual trial, or decentralized clinical trial, is defined as a clinical research study, in which one or all of the trial participants' visits do not occur in a traditional office setting, such as a clinic or hospital. Most virtual trials incorporate remote monitoring technology and are performed in the home via telehealth, with some conducted in hospitals, clinics, or nursing facilities.

Goals and Benefits of Virtual Trials: The goal of virtual trials is to remove barriers and provide greater access to potential trial participants. They offer a number of other benefits as well, including:

- Greater convenience for research participants as they don't have to travel to the wound clinic for a clinician to monitor their status and gather research data. Participants can remain in the comfort of their residence.
- Faster and increased study enrollment (because participation is so much more convenient).
- Better retention of subjects, as the ease of participation means fewer people drop out because of challenges getting to the clinic for check-ins, etc.

Yet another benefit of virtual trials is its ability to ensure greater diversity in the populations participating. Historically, racial and ethnic minorities in the United States are significantly under-represented in research.[2] This leads to the disenfranchisement of many populations who not only could benefit from participation in clinical trials, but whose data is vital to a robust research program.

Recognizing this need, the FDA has become very involved in stressing the need to ensure participant diversity. Virtual trials can significantly increase that participation for the reasons noted above.

The Role of Digital Tools: For success in the COVID-era, a research trial needs to incorporate the right tools. Specialty software applications can help monitor participants remotely, communicate information to and from the study participant, and provide education and encouragement. Digital tools offer a wide range of benefits for virtual trials; one of the most important is recruitment. Digital trial recruitment ensures:

- There are no geographical limitations for the study
- A more diverse patient group
- Access to additional care settings, such as patients in home care or Skilled Nursing Facilities (SNFs)

Digital solutions also expand participation opportunities by making it easier for caregivers and nursing staff to assist with the recruitment of patients. For example, with proper consent, a nurse at a skilled nursing facility can enroll patients that may be good candidates for a research study.

Enrolling in a virtual wound care clinical trial can be simple. Patients (or caregivers) can submit wound images and information through a mobile application for pre-screening to aid in the recruitment process. Images will show the size of a patient's wound, location, and other relevant information needed to appropriately screen trial candidates.

Components of Effective Programs: While there are many advantages to virtual clinical trials in wound care, it is important to have the right tools, resources and support. Those considering development of a virtual clinical trial should ensure their supporting software offers the following:

- Mobile wound imaging and analysis
- Cloud-based portal for participants and study authors
- Adherence to study timelines
- Real-time communications
- Digital tools that are simple for study participants to use

There are other considerations as well. For example, an essential component of effective clinical research is the ability to include alerts and reminders, effectively remind participants when it's time to change dressings, apply a therapy, turn on a device, etc.

Additionally, the FDA stresses the importance of Patient Reported Outcomes (PRO). With advances in wound care, researchers will want to pay special attention to gathering PRO insights. Once again, virtual clinical trials, when combined with digital tools can help make that happen.

The Future of Virtual Clinical Trials in Wound Care: With the ripples from COVID-19 set to continue for the immediate future, the need to develop and expand virtual clinical trials will continue. Through its technology, Tissue Analytics and its partners have the experience and tools needed to help organizations develop, recruit, implement, monitor and report on the full range of data necessary to conduct an effective research program.

How can you support Wound Care Research?

Here is a simple way to make that happen. When you shop on Amazon.com – always start at:

smile.amazon.com

Select SerenaGroup Research Foundation and Amazon will donate 0.5% of the price of your eligible AmazonSmile purchases.

While shopping for your favorite items, you will be helping develop new products and techniques through wound care research.

Dr. Serena gave two lectures at the Annual Mexican Wound Care Meeting – AMCICHAC last month. SerenaGroup continues to be part of International Wound Care Education & Leadership.


XIV CONGRESO INTERNACIONAL AMCICHAC ·2020· 10 - 12 de Septiembre
"14 años innovando, caminando a la excelencia"

Otorga la presente

CONSTANCIA

Dr. Thomas E. Serena

Por su participación como **Asistente** en el
XIV Congreso Internacional AMCICHAC *Online*
Ciudad de México, del 10 al 12 de septiembre de 2020.

Dra. Martha Alicia Zavala Aguirre PRESIDENTE
Dr. Gerardo Muñoz Jiménez COMITÉ CIENTÍFICO
Dra. Carolina Martínez Parra SECRETARIA
Dr. Jóse Alfredo Ponce del Carmen COMITÉ DE CONGRESO

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Valor curricular: 27 horas de Educación Continua

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