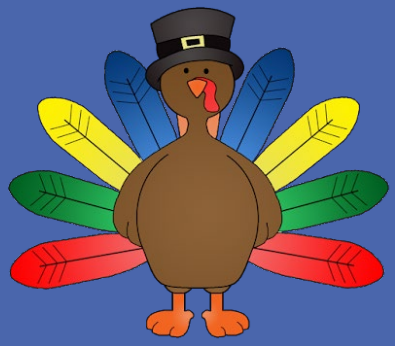

# SerenaGroup Newsletter



## November 2020

SERENAGROUP MONTHLY UPDATE

ISSUE 33

## SerenaGroup Journal Club

"Movember," the month of facial hair growth, celebrates men's health and raises funds for prostate cancer. Last month's pink theme increased awareness of breast cancer. These are great causes, although, the pandemic has already decreased my shaving frequency. Where is *Woundember* or *Augulcer*? Prostate and breast cancer have far better survival rates than our patients suffering from diabetic foot ulcers. We struggle to conduct clinical trials aimed at improving survival, while the oncologists have a blank check. I challenge all my fellow woundologists to help me raise awareness of the more than 10 million Americans suffering with nonhealing wounds. Please send me creative ideas.


In the interim, we have launched our journal club on the member's portal. The one silver lining in this pandemic is the improvement in technology and the ability of old men like me to use it. The journal club is on the Power Point platform with narration. Each month we will review an article that has implications for wound care practice. I have kept the length to 12-17 minutes. The October journal club reviewed our recently published FLAAG trial on identifying bacteria with fluorescence imaging. It is the most comprehensive trial on infection ever conducted in nonhealing wounds. November's presentation examines a real-world study on the frequency of debridement. In addition, we are releasing December's journal club early. It examines a randomized clinical trial published in *Lancet* on the use of hyperbaric oxygen therapy (HBOT) for radiation cystitis. This superb publication demonstrates that early intervention with HBOT leads to superior patient-centered outcomes in patients suffering from radiation cystitis. It is a must view.


If you have a topic you would like covered or if you want to record a session, please let me know. I welcome your feedback and look forward to your suggestions.

*– Dr. Tomas Serena*

### November SerenaGroup Blue Star Winner

Jessica Raub, RN

"She is a hard-worker and is dedicated to her job, staff and center. Jess wants nothing but the best for the patients that come to the Wound Healing Center and Hyperbaric Program."
*– Ascension Via Christi*

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**

## Post Payment Audits in Wound Care- *The CMS October Surprise*

***Matthew (Matt) Schweyer, CPCO™, CHT-A, CHWS, UHMSDSA***

As is typical in an election cycle, there tends to always be a surprise in October. In our Wound Care world, we were given a surprise in the form of additional auditing, which was initially announced on the WPs (Wisconsin Physician Services) GHA website. Specifically, it reads: CMS has authorized WPS to conduct **service specific post pay reviews.** Data analysis indicates potential problem areas regarding wound care services (CPT code 11042). In accordance with the WPS GHA Local Coverage Determination (LCD) L37228 Wound Care, we will conduct a medical review of these services. We expect the documentation to support the medical necessity of the current wound care plan.

For wound care services by a Physical Therapist (PT), we expect a written order from the referring physician specifying, prior to the procedure, the type of debridement required. Since the announcement by WPS, other CMS MAC providers have also been authorized to conduct these audits. Let us look at what is required to meet the elements of the LCD and audit.


To meet the requirements of the audit, the following must be in the Medical Record.

- Medical Necessity
- Plan of care including treatment goals and ongoing evidence of plan effectiveness
- Wound dimensions pre and post debridement
- Physician orders
- Physician progress notes
- Photographic documentation of wounds, if applicable
- Treatment records
- Advanced Beneficiary Notice of Noncoverage (ABN), if applicable
- Any additional documentation needed to support Medicare guidelines

SerenaGroup has a rigorous clinical documentation review and audits conducted by the Compliance/Quality/Reimbursement department. This measure is a not only Best Practice, it provides an additional layer of security for our host hospitals, providers, and others to ensure we are not gaming the system or worse, charging for services that are neither required nor meet Medical Necessity.


In closing, if your hospital receives an ADR (Additional Documentation Request), let them know that SG is here to assist & help them in the review process prior to submission of the ADR process. Those that have been involved with the TPE (Target Probe Educate) process should be aware of the success of our involvement. Lastly the audit and compliance assistance is a service the host hospital receives from SerenaGroup as part of the partnership.


**Results from 350-Patient FLAAG Trial Show MolecuLight Point-of-Care Imaging Improves Detection of High Bacterial Burden in Wounds Four-fold over Standard of Care Assessment**

*Study also Demonstrates that MolecuLight Fluorescence Imaging of Bacteria at Point-of-Care Resulted in Changes to Treatment Planning in 69% of All Patient Cases*

Toronto, CANADA – (September 29, 2020) MolecuLight Inc., the leader in point-of-care fluorescence imaging for real-time detection of bacteria in wounds, announced publication of results from the *Fluorescence Imaging Assessment and Guidance* ("FLAAG") clinical trial in *Advances in Wound Care*. This large prospective, multicenter, controlled clinical trial included 350 patients, across 14 U.S. outpatient wound care centers and 20 clinicians. The trial, independently led by Dr. Thomas E. Serena and his team at the SerenaGroup®, evaluated whether fluorescence imaging (MolecuLight ***i:X***) improves detection of high (>104 CFU/g) bacterial loads when used in combination with clinical signs and symptoms of assessment. The trial also examined how point-of-care information on bacterial presence and location impacted clinical treatment planning. The study, which included diabetic foot ulcers, venous leg ulcers, pressure ulcers and other chronic wounds, revealed that 82% of study wounds had high bacterial burden (>104 CFU/g). Use of the MolecuLight ***i:X*** fluorescence imaging device resulted in detection of 45% more wounds with high bacterial loads that wound have otherwise been missed by standard of care assessment of clinical signs and symptoms; these results were consistent across all wound types, study sites and clinicians. The objective, diagnostic information on bacterial load provided by fluorescence imaging changed clinical treatment planning in 69% of wounds and influenced wound bed preparation in 85% of study wounds. Most importantly, clinicians reported that use of fluorescence imaging improved patient care in 90% of study wounds.

"The FLAAG trial, one of the largest prospective clinical trials in wound care, demonstrated that clinical signs and symptoms are poor indicators of bacterial burden in chronic wounds", says Dr. Serena, Founder and Medical Director of The SerenaGroup® and Lead Investigator for the clinical trial. "Most of the wounds missed by standard of care in this study had alarmingly high bacterial loads, indicative of asymptomatic infection. Use of the MolecuLight ***i:X*** enabled earlier detection of bacterial burden in wounds that would have otherwise been missed by standard of care assessment; we saw this improvement in detection across all wound types. The information provided by fluorescence imaging had utility across in all aspects of wound care, influencing treatment planning and overall patient care. I believe that the MolecuLight ***i:X*** will quickly become a standard of care in wound care and play a pivotal role in antimicrobial stewardship in the wound clinic."

"As an investigator in this trial and a user of MolecuLight ***i:X*** in my routine clinical practice, I can attest to the clinical benefit that fluorescence imaging provides. Identifying the presence and location of significant bacteria facilitates optimal preparation and treatment of my patients' wounds enables me to quickly course correct a patient's treatment when needed. With this immediate diagnostic feedback on bacteria and infection available at point-of-care, I no longer need to wait for weeks to determine if treatments are effective", says Dr. Windy Cole, Director of Wound Care Research, Kent State University College of Podiatric Medicine. "The results of this robust clinical trial add to the large body of evidence from prior studies, including a study I previously published1 where I used fluorescence imaging of bacteria to guide debridement and select appropriate treatments that led to accelerated wound healing".

Up to 15% of Medicare beneficiaries had at least one type of wound or wound-related infection2, and the prevalence of chronic wounds continues to increase each year. Without objective methods to detect bacterial burden in wounds, wound healing stalls and inappropriate treatments are applied, further inflating these costs. "Results from this trial reveal the signification proportion of chronic wounds with high bacterial burden that are missed by standard of care assessment of clinical signs and symptoms," says Anil Amlani, CEO of MolecuLight Inc. "The results of this study show how use of point-of-care fluorescence imaging enables more accurate detection of bacterial burden in wounds. The diagnostic information provided by the device has the potential to fundamentally change the paradigm in wound care, leading to improved healing rates, reduced costs and improved patient outcomes".

The early results of this FLAAG trial were shared with the AMA and CMS, who, after a critical review of the large body of supporting clinical evidence, issued two CPT® codes (Category III) for physician work and facility payment for Hospital Outpatient Department (HOPD) and Ambulatory Surgical Center (ASC) settings through an Ambulatory Payment Classification (APC) assignment. These new codes were issued by AMA and CMS in recognition of the medical necessity of this MolecuLight fluorescence imaging procedure.

MolecuLight®

# HBO Update

### Monthly Briefing
### October 2020

While auditing an introductory hyperbaric training course the other day I heard mention on several occasions that the humidity level within the monoplace was always zero. This statement served to justify a requirement that patients should remove their contact lenses before each treatment. The stated basis for zero humidity was that incoming LOX sourced oxygen was dry.


This statement failed to account for the patient's ongoing respiratory and transcutaneous evaporative insensible moisture loss. Historically, our group had measured monoplace chamber relative humidity under varying conditions, namely changes in oxygen flow rates and differing patient body mass. RH was never zero, rather it was found to range from the low 20's to the high 60's. The lower the flow rate the higher the resulting RH. Experienced chamber operators may have observed RH levels so high on occasion that condensation occurred on the internal surfaces of the acrylic hull.

From a monoplace chamber fire safety perspective, one should aim for the higher of the above range. Dryer conditions tend to result in a higher risk of static electricity buildup, which can lead to dangerous electrostatic discharges if patients are not appropriately grounded. If patients complain of being cold while in the chamber this should prompt a reduction in oxygen flow, *not provision of a (another) blanket!* The 1996 monoplace chamber fire and explosion was an object lesson, in that combustible materials must be limited to the greatest extent possible. If patients complain of being too warm, titrate the oxygen flow higher. Do not simply default to the highest flow rate…comfort levels may be reached with only incremental increases.

I thought it useful to revisit this topic. Too commonly, oxygen flow is maintained at its highest rate, as a previous patient may have complained of overheating. When subsequent patients become too cold the default position may be to provide an additional blanket, or two.

***Consistent with the above, this would be considered F work! Don't do it.***

*Dick Clarke, President*

*National Board of Diving & Hyperbaric Medical Technology*

*(Permission Granted)*

NATIONAL BOARD OF DIVING & HYPERBARIC MEDICAL TECHNOLOGY


## How can you support Wound Care Research?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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.**

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