I. Title Page

Project Title: Improving Value of Care for Patients with Severe Stasis Dermatitis

Society name: Ohio Dermatological Association, Inc.

<u>Society Officers:</u> Linda S. Rupert, MD, President; Shannon C. Trotter, DO, President-Elect; Karl K. Kellawan, MD, Immediate Past President; Christine Jaworsky, MD, Secretary; Samia W. Borchers, MD, Treasurer; Cynthia K. Bartunek, Executive Director (retiring 12/31/15), Jill Hostetler, incoming Executive Director (January 1, 2016)

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<u>Brief summary</u>: We will explore the unmet needs of patients admitted to the hospital for severely inflamed skin of the lower legs, often described as 'bilateral cellulitis'. These patients usually have intractable lower extremity edema, stasis dermatitis and sometimes allergic contact dermatitis rather than an infectious process; readmission is common. We will create patient and provider education materials to align dermatological, home health, and other resources and measure reduction in hospital admission rate and length of stay.

II. Goals and Objectives:

1. Understand the unmet needs for stasis dermatitis care from the patient and provider perspective.

Access problem "What is": Severe stasis dermatitis is a multifactorial condition that can mimic "bilateral cellulitis". However, true bilateral cellulitis is exceedingly rare and in most cases, is a misdiagnosis. The diagnosis of cellulitis is based primarily on clinical appearance, sharing many features with severe stasis dermatitis. Objective measures for the diagnosis of cellulitis are rarely helpful, with low sensitivity and specificity rates for fever, leukocytosis, tachycardia, blood cultures, and imaging studies¹. Admissions for cellulitis and "bilateral cellulitis" in the United States are frequent, representing nearly 4% of all emergency admissions in 2010, with hospital stays averaging 5-7 days². Among the factors most highly associated with increased length of hospital stay in these patients, the top four include chronic edema, use of diuretics, elderly age, and living alone². These patients are likely to have severe lower extremity swelling, complicating stasis dermatitis, and the most difficulty managing their chronic health conditions. In a recent study of 145 patients admitted for cellulitis, it was found that 28% were incorrectly diagnosed with lower limb cellulitis, with venous stasis dermatitis being the most common diagnosis mistaken for cellulitis in 37% of cases³. This is costly to patients, providers, hospitals, and the healthcare system.

In outpatient and inpatient settings, internists frequently prescribe diuretics to reduce lower extremity edema without awarding the problem a comprehensive evaluation for underlying causes. This chronic condition requires ongoing treatment, in many forms, which must address the primary cause. Gradient compression is the most effective means to achieve relief, but longterm management with this form of treatment requires a breadth of knowledge on behalf of providers and patients. For providers for example, multi-layer bandages must be used during the acute phase to reshape and reduce the size of the limb, appropriate stocking compression grade and length must be chosen, and patients and potential caregivers should be educated on donning and doffing stockings, application aids, appropriate hosiery care, skin care, use of emollients, limb massage, and exercise^{4,5}. Additionally, this requires stockings not covered by many insurance plans. Many patients are non-adherent because they do not have a family member or home health aide to assist, or they do not understand the importance of stockings as a treatment for their disease. Providers may not have knowledge of who to contact to get patients assistance in these situations. As a result, the edema gets worse, and patients are admitted and readmitted to the hospital with relapsing "bilateral cellulitis" of the lower extremities.

"What could be": Using surveys and focus groups, we will explore both patient and provider perceptions of unmet needs. With this information, we will design educational materials to help align resources in a timely fashion and avoid admission when possible. For the patient, we anticipate some of these needs to include improved knowledge of the chronicity of their disorder, preventative measures that can be utilized at home, access to gradient compression stockings and application aids, access to caregivers or home health aides to assist with donning and doffing stockings, and hosiery care. For providers, we anticipate needs to include (but not be limited to) checklists for ruling out treatable causes of lower extremity edema, criteria for admission of patients with cellulitis with emphasis on "bilateral cellulitis", how soon to refer to more experienced colleagues or specialized practitioners (such as dermatology, vascular medicine, wound care, specialized nursing, and social work), and consolidated contact information for each of these groups to improve access to these resources and home health assistance for patients.

2. Design education for patients and providers to cue them when additional care is needed.

Access problem "What is": Patients are often admitted to the hospital for "bilateral cellulitis" despite the fact that most of these patients do not have true skin infections. Research studies from a dermatology perspective on this issue are lacking. Patients and providers may not even be aware of this misdiagnosis, as stasis dermatitis will improve with leg elevation alone during a hospital stay. As a result, we erroneously give intravenous antibiotics all of the credit for the condition's resolution. When it recurs, a history of "recurrent cellulitis" is added to the patient's chart, and the cycle is repeated.

Providers may also struggle with a lack of objective measures that can be used in the diagnosis of cellulitis and its severity, depending primarily on clinical appearance. A recent multi-national review article addressed the usefulness of laboratory testing and imaging studies in the diagnosis of cellulitis, using statistical measures as the basis for recommendations. The study came to the following conclusions: C-reactive protein (CRP) is a better indicator of bacterial infection than an elevated white blood cell count, but neither is clinically useful for diagnosis; blood cultures have true positive rates in the 2-4% range, do not alter outcomes whether positive or negative, and should be drawn only in patients with signs of systemic compromise; wound cultures should only be obtained from open cellulitis wounds; and imaging should only be considered when necrotizing fasciitis is a potential diagnosis or cellulitis is doubtful. Despite these results, these are routinely used tests in the diagnosis and management of presumed cellulitis.

Unnecessary admission and testing is expensive in many ways. For patients admitted to the hospital, standard treatment for cellulitis is IV antibiotics for a week or more. Prolonged bed rest in the hospital with potent antibiotics is problematic, especially for older patients. It puts them at risk for impaired mobility, deep venous thrombosis, nosocomial infections, particularly with *Clostridium difficile*, and is monetarily costly for all parties involved. Alternative diagnoses need to be considered. Allergic contact dermatitis, which is known to complicate stasis dermatitis, is one possibility. Patients can easily develop contact allergies to components of topical steroids and topical antibiotics prescribed in an attempt to treat dry, cracked, or fissured skin on an outpatient basis. However, many inpatient facilities do not have access to regular dermatological consultation, and local dermatologists may not have the appropriate patch tests or experience with patch testing to identify contact allergen in the setting of stasis dermatitis.

"What could be": Our patient education materials and toolkit will help patients know who to contact when their edema progresses, what they can do at home, when to go to the hospital, as well as information on financial and home care assistance as it relates to managing their chronic condition. Our provider education materials will assist providers with making the correct diagnosis, ordering appropriate testing, understanding when to consider admission, especially in cases of "bilateral cellulitis", involving specialty providers, and aligning assistance for patients. We hope to help providers when they feel stuck in their attempts to help patients manage this chronic condition, especially after the patient has already had multiple admissions. We also hope to provide both patients and providers with quick reference guides that they can use on a day-to-day basis as questions and complications arise.

3. Measure the value of services identified in steps 1 and 2.

We will track the number of patient admissions for antibiotics for "bilateral cellulitis" and length of stay at two different time points: (1) before and (2) after we execute provider education (resident didactic module, clinical decision support in the electronic health record, and contact

information guides for assistance groups). We will also track the number of readmissions and length of stay for patients at two time points: (1) before and (2) after patient education materials are implemented (prevention strategies, contact information guides, and improved access e.g. increased use of patch testing for inpatients). We will stratify patients who have been seen in wound care centers and those who have had patch testing and compare them to patients who have not, to help better understand the value of these services.

III. Project Design, Methods, and Evaluation Goals, timeline, and project design:

Goal #1: 3 months.

Understand the unmet needs for stasis dermatitis care from the patient and provider perspectives.

Our research nurse and resident physician will administer surveys to patients admitted to any of the ten regional hospitals in the University Hospitals Health System for "bilateral cellulitis". We plan to obtain a minimum of 50 surveys over 60 days. We will also administer surveys to the providers for these patients. With this information, we will identify obstacles to care such as understanding multiple mechanisms of disease as well as system issues such as criteria necessary to obtain home health care. In the final 30 days, we will hold two separate focus groups, one for patients and one for providers, to clarify questions that arise from the survey responses.

Goal #2: 6 months

Design education for patients and providers to cue them when additional care is needed.

We will create a toolkit for providers including (but not limited to) a checklist of items to consider to rule out treatable causes of lower extremity edema, criteria for diagnosis and admission, appropriate laboratory and imaging evaluation, as well as a list of resources for treatment and consultation. We will also design a resident didactic module addressing the above. For patients, we will create print and possibly web-based materials (as assessed from our needs survey) to help patients understand the chronicity of their disease, the rationale for certain treatments and tests, and to help them gain access to proper resources and preventative care items. The Case Medical Center television studio can also be used to record multimedia educational resources.

Goal #3: 12 months

Measure the value of services identified.

We will measure number of admissions and length of stay for L03.115 and L03.116 before and after we implement the educational resources for lower extremity inflammation. We will also stratify these measurements for patients who receive care in a wound care clinic and for those who are patch tested. Patients who receive patch testing at CMC will have results included in the existing patch test research database where they will be identified as a study cohort. We will also conduct a follow-up survey of patients and providers to determine if unmet needs are the same or different after our intervention.

Participants: University Hospitals Case Medical Center (CMC) has a Quality Institute and is associated with Case Western Reserve University School of Medicine which has a Clinical & Transitional Science Collaborative (CTSC). The principal investigator is an expert in allergic contact dermatitis and maintains a database for patch test results. We have a vascular medicine division as well as dermatology faculty interested in treatment of venous disease who will collaborate on this project.

Deliverables: All materials created by this grant will be in the public domain and shared with ODA members along with the assessment of value for these interventions. This includes patient and provider educational materials that are created in response to the needs assessment and outcomes measures including changes in admission rate and length of stay, and patient/provider needs which will likely be published in a peer reviewed journal.

IV. Project Timeline/Budget Timeline

Nov 2015: Submit IRB application (preparation budgeted, expect minimum 2

months to approval).

Jan 2016: Hire research nurse through December 2016.

Revise IRB submission if required.

Feb 2016: After IRB approval, begin patient/provider surveys of CMC inpatients. Apr 2016: Analyze survey results and schedule focus groups for May 2016.

Jun 2016: Plan patient and provider education materials.

Jul-Aug 2016: Prepare and pilot patient and provider educational materials. Sept 2016: Implement clinical decision aid in electronic health record.

Sept 2016: Flag ICD10 lower extremity cellulitis codes for provider receipt of tool kit

and optional telephone dermatological triage support to decide admission status (no admission, observation, or admission for IV

antibiotics).

Sept 2016- Continue implementation, monitor usage, make improvements based

Aug 2017: on feedback.

Summer 2017: Secure statistician effort for upcoming data analysis.

Sept 2017: Data analysis.

Oct 2017: Prepare manuscript for publication.

- V. Budget Upload
- VI. References
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 - 4. Lay-Flurrie K (2011). Use of compression hosiery in chronic oedema and lymphoedema. *Br J Nurs* 20(7): 418-422.
 - 5. Cooper G (2015). Compression therapy and the management of lower-limb lymphoedema: the male perspective. *Br J Community Nurs* 20(3): 118-124.
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- VII. Letter of Support for the project Upload