



Core Outcomes for Research in Lichen Sclerosus

Signs Domain

Working group progress:

Previous research completed by Sheinis and Selk (2018) identified a list of items for inclusion in a lichen sclerosis severity scale based on expert consensus using Delphi protocol. Patients surveyed also felt that these clinical signs were important in measuring disease severity (Green, Sheinis, Selk 2020). Lack of validity in severity scales for adult lichen sclerosis was demonstrated by Selk et al (2020) using this list of items, and identified a need for validated scales for future high-quality clinical trials. We are in the process of completing a systematic review to update the literature on signs used in previous clinical trials of genital lichen sclerosis in both males and females, as well as instruments used to measure them. Once a comprehensive list has been compiled, we will meet with our multidisciplinary steering group to form a consensus agreement on the most important clinical signs. Our goal is to have 3-4 clinical signs to incorporate into a core clinical outcome set for lichen sclerosis and potentially see how they can be measured if acceptable tools exist and if not, direct the development of these tools.



Dr Heidi Bentley
Clinical representative

Heidi is currently a Clinical Fellow in Vulvovaginal Health at the University of Toronto. She completed her residency in Obstetrics and Gynecology at the University of Manitoba and obtained her Medical Degree from Dalhousie University. Her interests are in vulvar dermatology, menopause and colposcopy. She is currently on the Board of Directors as Director-at-Large on The Society of Canadian Colposcopists. She is looking forward to transitioning to practice and to provide comprehensive gynecological care to her patients.



Dr Amanda Selk, MSc, MD,
FRCSC
Clinical representative

Amanda is an Associate Professor in the Department of Obstetrics and Gynaecology in Toronto, Canada. She is the clinical director of both the Colposcopy and Gynaecology Dermatology clinics at Women's College Hospital. She is past President of the North American branch of the International Society for the Study of Vulvovaginal Disease and is Co-Chair of the Social Media Committee ISSVD. She is past President of the Society of Canadian Colposcopists. She is on the Editorial Board of the Journal of Lower Genital Tract Disease and their social media editor. She has a MSc in health research methodology and a MHA. She cares for many patients with lichen sclerosus and has done research on developing lichen sclerosus disease severity measurement tools.



Dr Melissa Mauskar, MD
Clinical representative

Melissa is a Dermatologist and Associate Professor in the Departments of Dermatology and Obstetrics and Gynecology in Dallas, Texas. She is the Director of Genital Dermatology and Women's Health at UT Southwestern. Melissa is a fellow of the International Society of the Study of Vulvovaginal Diseases (ISSVD) and the Secretary General of the North American Chapter of the ISSVD. In addition to caring for patients with lichen sclerosus, she is active in clinical research and passionate about patient quality of life and health literacy initiatives. In 2021, she received a Women's Health Research Grant from the Dermatology Foundation to study cutaneous hormone landscapes and microbiomes in patients with vulvar lichen sclerosus. Melissa is the founder of the Vulvar Dermatoses Research Consortium (VDRC), an expansive group of healthcare practitioners and trainees in North America dedicated to advancing the field of vulvar dermatology.



Jaclyn Lanthier
Patient representative

Jaclyn is the face behind *The Lost Labia Chronicles*, which includes a blog, YouTube channel, and an eBook centering around vulvar Lichen Sclerosus. Jaclyn is passionate about disseminating evidence-based information and addressing mental and sexual health with Lichen Sclerosus. She is on the executive board of Lichen Sclerosus Support Network and spends much time in the LS online communities helping provide support to folks with LS. Jaclyn is 34 and was diagnosed at 31 (but symptomatic since she was 20) with vulvar Lichen Sclerosus. She works full-time as a data consultant and social media manager for an information services firm in Toronto, Canada. She did her Ph.D. in philosophy of neuroscience at Western University with a focus on the role of systematic review and meta-analyses for corroborating information about the mind-brain.

Author of *The Lost Labia Chronicles* @thelostlabiachronicles on Instagram and Facebook.

Secretary of the Board, Lichen Sclerosus Support Network.
www.lssupport.net



Suzanne von Seitzberg
Patient representative

Suzanne von Seitzberg is the founder and leader of the Danish Lichen Sclerosus Association, established in 2010. The organization provides crucial support to individuals affected by lichen sclerosus and lichen planus, as well as their families and caregivers, aiming to improve the quality of life for patients through invaluable support, information, and advocacy. Suzanne is also a passionate advocate for increased research into lichen sclerosus and lichen planus. Recognizing the urgent need for better treatments and a deeper understanding of these diseases, she champions efforts to advance scientific knowledge and foster collaboration among researchers, healthcare professionals, and stakeholders in Denmark and abroad.

Despite her professional role as a banking advisor, Suzanne volunteers for the Danish Lichen Sclerosus Association in her spare time. Diagnosed with lichen sclerosus in 2008, she actively educates herself on these conditions by attending medical conferences, enhancing her advocacy for patients.



Ione Bissonnette, CNM,
MSN
Clinical representative

Ione received her BS in Nursing degree from Columbia University in New York and her Masters in Midwifery degree from the University of Pennsylvania in Philadelphia. While practicing as a full-scope nurse midwife at Harvard Vanguard Medical Associates and Brigham and Women's Hospital in 1995, she met Dr Elizabeth G. Stewart, an OB GYN who later dedicated her career to caring for women with vulvovaginal disease. Dr Stewart is the author of [The V Book: a doctor's guide to vulvovaginal health](#). Ione apprenticed with Dr Stewart and later worked in her Vulvovaginal Specialty Service at Harvard Vanguard for eleven years, seeing many genital lichen sclerosus patients.

In 2005, she became the first Advanced Practice Clinician (Nurse) Fellow of the ISSVD (International Society for the Study of Vulvovaginal Disease). She has lectured on vulvar lichen sclerosus (2005), vaginal microscopy, pH and KOH in vulvovaginal care (2006), vulvar dermatoses (2008), vestibulodynia (2009), vulvovaginal diagnosis and treatment, (2009), vaginal atrophy (2012), and bacterial vaginosis (2012). She and Dr Stewart have initiated teaching sessions at Beth Israel Deaconess Medical Center's Ob Gyn Residency Program (affiliated with Harvard Medical School) (2015-2016).

In the interest of furthering education about vulvovaginal disease, Ione and Dr Stewart created a comprehensive, internet-based learning program www.vulvovaginaldisorders.org that is free to all, but intended primarily for anyone who sees (or will see) women with these problems. Their residency modules were derived from the learning program.



Dr Gudula Kirtschig, MD
Clinical representative

Gudula is a Consultant Dermatologist based in Germany and Switzerland. She studied medicine at Ulm University & Muenster University in Germany and has previously practiced dermatology in academic centres in Oxford, UK and Amsterdam, NL. She has a special interest in vulval skin disease, pregnancy associated skin disease and blistering skin conditions. Gudula has a strong research interest and her work has contributed towards the production of more than 100 peer reviewed scientific articles, national/international clinical guidelines, and patients' information leaflets. Together with more than 20 co-authors, she has edited a prize-winning book on vulval diseases. She works with the Cochrane skin group to deliver systematic reviews and sits on the oversight committees of clinical trials. Gudula is committed to excellence in clinical dermatology. She is a member of the Lichen Sclerosus PSP, the steering group to develop Core Outcome Sets (COS) for LS and was the lead-author on the European S3-guideline on Lichen sclerosus.



Dr Tanja Bohl, MBBS, FACD
Clinical representative

Dr Tanja Bohl is a dermatologist who works at Jean Hailes in Clayton where she is part of the specialist vulval clinic. She also works in private practice in Gippsland in Victoria.

She is President-Elect of the International Society for the Study of Vulvovaginal Disease, and Past President Australian and New Zealand Vulvovaginal Society (ANZVS).

Dr. Bohl is a leading authority on vulvovaginal health and a passionate advocate for women's health. She has dedicated her career to improving the lives of women through education, research, and clinical care.



Prof Catherine Leclair, MD
Clinical representative

Dr Catherine Leclair is currently a professor of OBGYN at Oregon Health & Science University in Portland, Oregon, USA. She is the Director for the Program in Vulvar Health, a specialty clinic serving the west coast of the United States. This program sees over 600 new and 1200 return patients annually and has research, clinical and educational goals. Additionally, the program includes 4 gynaecologists, 1 dermatologist, and on-site/off-site pelvic floor physical therapists and sexual health therapists. Dr. Leclair's career focus is in vulvovaginal health, with the goal to improve the physical and psychosexual health of women. With 25 years of experience, dozens of publications and present/past leadership positions, she serves as an expert in vulvovaginal diseases, especially for women and practitioners in the Pacific Northwest.



Dr Rosalind Simpson
Clinical representative

Rosalind works as a consultant dermatologist in Nottingham, U.K. and Associate Professor at the University of Nottingham. She is overall lead for the CORALS project. She studied at the University of Nottingham Medical School, U.K and completed a BMedSci degree in 2002 and BMBS degree in 2004. In 2008, Rosalind commenced Dermatology specialist training. She took time out of her training program to pursue a career in Academic Dermatology and completed a program of clinical research into vulvovaginal erosive lichen planus funded through the NIHR Doctoral Research Fellowship scheme. She has a research interest in trial methodology, especially for vulval skin disorders and rare conditions; diagnostic criteria development and selecting suitable outcome measures for clinical trials and clinical practice. Rosalind was lead for the Lichen Sclerosus Priority Setting Partnership (completed in 2018). She now leads the SHELLS (Establishing Effective Diagnostic Criteria for Lichen Sclerosus) and PEARLS (Proactive Against Reactive Treatment for Lichen Sclerosus) studies. Rosalind became a Fellow of the International Society for the Study of Vulvovaginal Disease ISSVD in 2011. She is Research Lead for the British Society for the Study of Vulval Disease.



Jan Kottner
Researcher

Jan obtained his master in Nursing Science and Education in 2007 after having worked as registered nurse in several hospital settings. Validation and reliability of pressure ulcer risk diagnoses and pressure ulcer classification, application of statistical process control methods in healthcare and epidemiology of care problems were topics of his PhD thesis and his postdoctoral qualification. In 2011, he became the Scientific Director of the Clinical Research Centre for Hair and Skin Science at the Department of Dermatology and Allergy at the Charité-Universitätsmedizin Berlin. Today, key research interests of Jan Kottner are skin and tissue integrity and preventive skin care with a special focus on skin physiology, skin barrier restoration and maintenance as well as efficacy of skin care interventions and pressure ulcer prevention. He has also special interests in evidence-based practice including systematic reviews, clinical trial design and conduct, and outcome development and validation. Since 2015, he works within Cochrane Skin-COUSIN and is involved in core outcome sets development in dermatology.



Prof Kim Thomas
Researcher

Kim is Co-Director of the Centre of Evidence Based Dermatology and Professor of Applied Dermatology Research. Her main research interests focus on conducting large, pragmatic randomised controlled trials to provide a better evidence-base for the prevention and treatment of skin disease.

In addition to the COS GLS initiative, she is an Executive Group member for the Harmonizing Outcome Measures for Eczema (HOME) initiative (www.homeforeczema.org), and is lead for the HOME Long-term Control Working Group. She also provides methodological support to other core outcome groups through the Cochrane Skin Core Outcomes Set Initiative (www.cs-cousin.org) and has helped to develop and validate a number of new outcome measurement instruments.

She has long been a supporter of patient and public involvement in research and has helped to run several skin-related Priority Setting Partnerships over the last 10 years.



Dr Martin Promm
Clinical representative

Martin works as a Consultant at the Department of Pediatric Urology in Regensburg, Germany. He studied at the University of Leipzig and the Technical University of Munich. After specialization in Urology, he subspecialized in Pediatric Urology and became Fellow of the European Academy of Paediatric Urology (FEAPU). Besides clinical and research work in congenital urogenital disorders (esp. bladder exstrophy-epispadias-complex) he is focusing in genital Lichen sclerosus in children. He has a research interest in the etiology, the long-term outcome and especially in therapy options in chronic course of this entity.
