SLE Discussion Topics

• The Path to Diagnosis
• Pathogenesis
• Impact on Patients: Mortality and Morbidity
• The Burden of Lupus
• Patient Support
The Path to Diagnosis
SLE Is an Autoimmune Disease That Primarily Affects Women of Childbearing Age

• SLE is a chronic, multisystem autoimmune disease characterized by:¹
  – Diverse clinical manifestations, which are the result of inflammation in affected organ systems²
  – Being potentially life threatening when major organs are affected¹
  – Waxing and waning disease activity¹

• SLE patient population:
  – Nine out of 10 cases occur in women,³ with the majority diagnosed between 15 and 45 years of age⁴
  – Tends to be more severe in men vs women⁵
  – More common and severe among nonwhite populations⁶-⁹*

*Nonwhite populations include those of African, Asian, Australian Aboriginal, Hispanic, and Native American descent.

A Range of Organ Systems May Be Involved

Musculoskeletal

Gastrointestinal

Skin

Heart and Lungs

Eyes and Mucous Membranes

Hematologic

Kidneys

Central Nervous System

Symptoms Are Highly Varied

- American College of Rheumatology (ACR) criteria were developed to classify patients diagnosed with SLE for research studies, not for clinical use\(^1\)
  - Four of 11 criteria must be met at any time in the patient’s history
- Additional symptoms indicating SLE may be evident upon presentation\(^1\)

<table>
<thead>
<tr>
<th>ACR SLE Classification Criteria(^1)</th>
<th>Some Additional Clinical Features of SLE</th>
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</thead>
<tbody>
<tr>
<td><strong>Cutaneous</strong></td>
<td><strong>Fatigue(^1,2)</strong></td>
</tr>
<tr>
<td>- Malar rash</td>
<td><strong>Unexplained fever(^1)</strong></td>
</tr>
<tr>
<td>- Discoid rash</td>
<td><strong>Myositis(^2)</strong> (muscle weakness)</td>
</tr>
<tr>
<td>- Photosensitivity</td>
<td><strong>Alopecia(^1,2)</strong> (hair loss)</td>
</tr>
<tr>
<td>- Oral ulcers</td>
<td><strong>Raynaud phenomenon(^1,2)</strong> (pale or purple fingers and toes)</td>
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<td><strong>Musculoskeletal</strong></td>
<td><strong>Vasculitis(^1,2)</strong> (inflamed blood vessels)</td>
</tr>
<tr>
<td>- Arthritis without deformed joints</td>
<td><strong>Nausea, vomiting(^1)</strong></td>
</tr>
<tr>
<td><strong>Cardiopulmonary</strong></td>
<td><strong>Peripheral neuropathy(^1)</strong></td>
</tr>
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<td>- Pleuritis or pericarditis (inflammation of lining of the chest cavity or heart)</td>
<td><strong>Sicca complex(^2)</strong> (dry mouth or eyes)</td>
</tr>
<tr>
<td><strong>Renal</strong></td>
<td><strong>Headache(^2,3)</strong></td>
</tr>
<tr>
<td>- Proteinuria or cellular casts (excess protein or cells in urine)</td>
<td><strong>Psychiatric disorders (eg, depression, anxiety)(^3)</strong></td>
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<td><strong>Neurologic</strong></td>
<td></td>
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<td>- Seizures or psychosis</td>
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<td><strong>Hematologic</strong></td>
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<tr>
<td>- Hemolytic anemia, leukopenia, lymphopenia, or thrombocytopenia (decreased red blood cells, white blood cells, or platelets)</td>
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<tr>
<td><strong>Immunologic</strong></td>
<td></td>
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<tr>
<td>- Antibodies to native DNA, Smith antigen (Sm), or phospholipid</td>
<td></td>
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<td>- Antinuclear antibodies (ANA)</td>
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Similarity and Overlap Between SLE Manifestations and Multiple Other Conditions

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<thead>
<tr>
<th>SLE Manifestation</th>
<th>Other Condition</th>
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<tr>
<td>Lupus arthritis</td>
<td>Fibromyalgia with positive ANA; rheumatoid arthritis</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>Idiopathic thrombocytopenic purpura</td>
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<tr>
<td>Positive ANA</td>
<td>Antiphospholipid antibody syndrome</td>
</tr>
<tr>
<td>Serositis</td>
<td>Undifferentiated connective tissue disease</td>
</tr>
<tr>
<td>Malar rash</td>
<td>Rosacea; polymorphous light eruptions</td>
</tr>
</tbody>
</table>


© 2013 American College of Rheumatology. Used with permission.

Reproduced with permission courtesy of the National Rosacea Society
Variability in Symptoms at Presentation and Over Time Can Result in Difficulty in Diagnosis

- Accurate diagnosis may take several years\(^1\)
- SLE may co-present with other autoimmune diseases\(^2\)
- Patients with SLE may present with different symptoms at different times\(^3\)
- No single test is sufficient to establish diagnosis\(^4\)
  - SLE should be suspected in patients with manifestations in \(\geq 2\) organ systems

In a study of 263 patients with presumptive SLE who were referred to an autoimmune disease center, 48% were ultimately diagnosed with a different disorder\(^5\)

# Patient Case Study: Clinical Perspective*

![Denise G., 26-year-old African American female](image)

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<td>Jan 20, 2011</td>
<td>Joint pain follow-up visit. X-ray indicates no erosion or subluxation. Patient reports all symptoms resolved</td>
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<tr>
<td>Aug 15, 2011</td>
<td>Rash on cheeks and nose</td>
<td>- Referred to dermatologist</td>
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<tr>
<td>Aug 22, 2011</td>
<td>Dermatologist report</td>
<td>- Diagnosed with rosacea</td>
</tr>
<tr>
<td>Feb 1, 2012</td>
<td>Patient presented with severe abdominal pain; reports occasional fever</td>
<td>- Referred to gastroenterologist</td>
</tr>
<tr>
<td>Feb 7, 2012</td>
<td>Gastroenterologist report</td>
<td>- Symptoms resolved prior to visit without intervention, possible inflammatory bowel disease</td>
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<td>Jul 16, 2012</td>
<td>Patient presented with severe Raynaud phenomenon</td>
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<td>Aug 9, 2012</td>
<td>Rheumatologist report</td>
<td>- SLE diagnosis</td>
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SLE diagnosis
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26-year-old African American female

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I felt so tired again today, even though yesterday I was fine!

My fever keeps coming and going.

Why can’t any of the doctors figure out what’s wrong with me?

My friends are starting to think it’s all in my head, and sometimes I would wonder if they’re right…

Why is this happening to me?

Patient perspective is for educational purposes only and represents hypothetical patient.
Pathogenesis
Multiple Factors Result in Systemic Immune Dysregulation Leading to SLE*

*Etiology is unknown, but factors presented here are thought to have major roles.

Immune Dysregulation Has Multiple Consequences

- Defective clearance mechanisms fail to remove cellular material exposed through normal apoptosis (cell death)\(^1\)
- Failure of normal immune checkpoints leads to loss of self-tolerance\(^2\)
  - Abnormal immune cells treat the body’s own cellular components like foreign pathogens and produce autoantibodies\(^1\)

Immune Dysregulation Has Multiple Consequences (cont)

• SLE is characterized by pathologic production of antibodies directed against self-antigens¹
  – Antinuclear antibodies are hallmark of disease
  – Abnormal activation of B and T cells

• Autoantibodies form immune complexes with self-antigen that get deposited in tissue²,³
  – Defective clearance mechanisms allow complexes to persist²,³

• Deposition of autoreactive B cells and immune complexes in tissues result in inflammation and can lead to organ damage²,³

• Damaged tissue stimulates additional immune response and inflammation, creating a vicious cycle of immune overactivity²-⁴

Numerous Factors Contribute to Underlying SLE Pathogenesis and Subsequent Organ Damage\textsuperscript{1,2}

Initiate Autoimmunity $\rightarrow$ Immune Dysfunction $\rightarrow$ Inflammation and Organ/Tissue Damage

**Genetic Susceptibility (Immune-Related)**

**Stimuli (eg, Environmental, Hormonal)**

**Immune Reactivity**

**Innate Immune System Activation**

**Adaptive Immune System Activation**

**Autoimmune Amplification**

**Brain**

**Lungs**

**Heart**

**Kidneys**

**Musculoskeletal System**

**Skin**

Cytokines

Autoantibodies

SLE Is a Chronic Disease With Higher Than Expected Mortality Rate

Estimated Rate of Death Compared to the Age-Matched General Population

Collaboration of the Systemic Lupus International Collaborating Clinics (SLICC) and the Canadian Network for Improved Outcomes in Systemic Lupus (CaNIOS) investigator groups (US, Canada, England, Scotland, Iceland, Sweden, South Korea). Death data were prospectively collected or acquired through probabilistic linkage to vital statistics registries. Expected deaths in the general population were determined by multiplying person-years at risk in the cohort by the geographically appropriate age-, sex-, and calendar-year period-matched mortality rates. Risk of death was assessed as a standardized mortality ratio, calculated as the observed number of deaths divided by the number expected in the general population. Duration of disease at time of enrollment was <2 years for most patients, and 90% of patients were female.


• Relative increase in mortality is highest in younger patients
Most Common Causes of Death in SLE Are Conditions Typically Associated With Aging¹

- Compared to the general population, mortality rates were estimated to be¹:
  - ~8x higher from renal causes
  - ~5x higher from infections
  - ~2x higher from heart disease
- Organ damage is one of the most important correlates with mortality²

![Most Common Causes of Death² (N=1255)*](chart.png)

*Cause of death was acquired through probabilistic linkage to vital statistics registries. It is possible that the primary cause of death when identified as "lupus" was actually another condition (eg, cardiovascular disease or infection), but the patient’s preexisting diagnosis of SLE may have led to this being listed as the cause of death.

One-Third of SLE Patients Accrue Permanent Organ Damage Within 5 Years of Diagnosis

Percentage of Patients With Permanent Organ Damage

<table>
<thead>
<tr>
<th>Year</th>
<th>N</th>
<th>Percent of Patients With SDI* ≥1</th>
<th>Mean Damage Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Year</td>
<td>232</td>
<td>10%</td>
<td>0.11</td>
</tr>
<tr>
<td>5 Years</td>
<td>232</td>
<td>33%</td>
<td>0.42</td>
</tr>
<tr>
<td>10 Years</td>
<td>232</td>
<td>51%</td>
<td>0.77</td>
</tr>
<tr>
<td>15 Years</td>
<td>143</td>
<td>55%</td>
<td>1.01</td>
</tr>
<tr>
<td>20 Years</td>
<td>75</td>
<td>65%</td>
<td>1.26</td>
</tr>
<tr>
<td>25 Years</td>
<td>6</td>
<td>100%</td>
<td>2.17</td>
</tr>
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Retrospective analysis of records for patients with ≥10 years of consistent follow-up presenting at the University College London Hospital SLE clinic. Year 0 represents time of diagnosis. Mean age at diagnosis was 31.2 years, 95% of patients were female, 72% were white, 14% were black, 10% were Asian (Indian), and 4% were “other.”

*The SDI (SLICC/ACR Damage Index) is a widely accepted scale that measures irreversible changes present for at least 6 months attributable to lupus, concomitant diseases, or treatment in 12 organ systems.

Patients Still Accrue Organ Damage Even With Low/Moderate Disease Activity

Disease Activity Over 5 Years of Follow-Up (N=298)

Percentage of Patients With Organ Damage Over 5 Years of Follow-Up (N=298)

Prospective analysis of patients in the SLICC cohort recruited within 15 months of diagnosis and followed annually for ≥5 years. Mean age at enrollment: 35.3 years; 87% female; 55% white, 12% black, 14% Asian, 16% Hispanic, 2% “other.” At enrollment, mean disease duration = 5.5 months; mean SLEDAI-2K score = 5.9.

*The SLEDAI-2K (SLE Disease Activity Index 2000) is a validated measure of global SLE disease activity.
†The SDI (SLICC/ACR Damage Index) is a validated measure of to assess damage in SLE.
Organ Damage May Be Subclinical in SLE Patients

Patients and Their Clinicians May Be Unaware As Organ Damage Accrues

**Bone Tissue Death**
- Osteonecrosis may be asymptomatic in SLE patients¹

53% of Osteonecrotic Hips May Be Asymptomatic¹

**Subclinical Cardiovascular Disease**
- Higher in SLE patients vs controls²,³
  - Prevalence of plaque in internal carotid artery is 3x higher
  - Inadequate blood-vessel dilation (endothelial dysfunction), a sign of early plaque formation, is twice as common

Organ Damage Can Result in Development of Chronic Diseases Usually Associated With Increased Age

1. Cardiovascular Disease
2. Osteoporosis
3. ESRD
4. Cognitive Impairment

ESRD = end-stage renal disease.
*Cognitive impairment involves dysfunction in the areas of complex attention, learning, memory, visual perception, and arithmetic. Impairment may involve specific domains or be global.
Cardiovascular Disease Can Be an Ongoing Issue for Patients With SLE

- Risks for coronary heart disease (CHD) and stroke are estimated to be significantly higher than in the general population

7.5x risk of CHD compared to age-matched controls

7.9x risk of stroke compared to age-matched controls
Incidence of Myocardial Infarction (MI) in Young, Premenopausal Women Is High

- Compared to the general population, rate of MI was higher in women with SLE overall
- Rate of MI is more than 50 times greater for women with SLE aged 35-44

Prospective analysis of the incidence of MI in 498 women with SLE. Cardiovascular incidence rates were compared to 2208 women of similar age participating in the Framingham Offspring Study, a prospective investigation of cardiovascular disease in the children of the 5209 men and women who participated in the original Framingham Heart Study. A comparison of MI rates was made over the same time period (1980-1993).

Osteoporosis Is a Major Concern for Patients With SLE

- Fracture risk is estimated to be significantly higher than in the general population.
Nephritis* Impacts the Majority of Patients As SLE Progresses

- Prevalence is higher in African Americans and Hispanics than in whites\(^1\); higher in men than in women\(^2\)
- Renal damage is one of the most important predictors of mortality for patients with SLE\(^3\)\(^4\)

ESRD=end-stage renal disease

*Lupus nephritis defined as (1) renal biopsy demonstrating WHO, class II-V histopathology; and/or (2) proteinuria ≥0.5 g/24 h or 3+ proteinuria attributable to SLE; and/or (3) one of the following features also attributable to SLE and present on 2 or more visits, done at least 6 months apart: proteinuria ≥2+, serum creatinine ≥1.4mg/dl, creatinine clearance ≤79ml/min, ≥10 red blood cells or white blood cells per high power field (HPF), ≥3 granular or cellular casts per HPF. Patients in whom other diseases (such as diabetes) might have explained abnormal urinary findings were excluded.

\(^1\)Patients were followed for a mean of 5.5 years, and up to 8 years.

\(^2\)Renal damage ascertained using the SLICC Damage Index (SDI) at last visit.

Involvement of cerebral microvasculature may result in diverse central nervous system syndromes. Neuropsychiatric Syndromes Affect From 37% to 80% of SLE Patients

**Most Common Manifestations**
- Cognitive dysfunction
- Headache
- Depression
- Anxiety

**Less Common Manifestations**
- Seizures
- Psychosis
- Movement disorders

*Definition of neuropsychiatric lupus included headache, per American College of Rheumatology criteria. Not all manifestations observed in SLE patients may be attributed to SLE.

†Cognitive dysfunction included difficulties in attention, concentration, memory, and visual perception.

## Patient Case Study: Clinical Perspective*

Cheryl M., 38-year-old white female

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<td>Renal biopsy indicates class III focal lupus nephritis</td>
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<td>Mar 16, 2009</td>
<td>Annual physical exam</td>
<td>Lab tests indicate hypertension, hyperlipidemia, and insulin resistance</td>
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<td>July 15, 2010</td>
<td>Continued edema, fatigue, headaches. Urine is foamy</td>
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<tr>
<td>Sept 24, 2010</td>
<td>Follow-up appointment: persistent proteinuria with hematuria, cellular casts, elevated serum creatinine. Urine is brown. Patient reports numbness in extremities, frequent vomiting</td>
<td>Diagnosed with end stage renal disease, placed on dialysis, added to kidney transplant list</td>
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This is supposed to be the prime of my life, but some mornings I wake up feeling like I’m 80 years old. I feel so weak since the last renal biopsy, and today I began writing my will. This is not where I expected to be at age 38!
The Burden of Lupus
Patients With SLE Have Impaired Function Affecting Multiple Aspects of Daily Life

- In a telephone survey of 829 patients with SLE:
  - Nearly all patients (91%) had ≥1 valued life activity affected by SLE
  - Almost half (49%) were unable to perform ≥1 valued life activity

Some of the Valued Life Activities Affected by SLE (N=829)

Prospective phone interview study of patients participating in the University of California at San Francisco Lupus Outcomes Studies. Valued life activity (VLA) disability was assessed using a scale rating the difficulty of performing 21 activities. Changes in VLA disability were assessed for 1 year from baseline. Affected VLAs were those with any level of difficulty or inability to perform. Mean age at baseline was 47.2 years, mean duration of SLE was 12.7 years, 91% were women, and 70% were white.

SLE Can Make the Demands of Everyday Life More Challenging

- Multiple symptoms can make simple tasks seem impossible
  - Fatigue
  - Skin manifestations
  - Joint stiffness
  - Pain
  - Depression
  - Cognitive dysfunction

Fatigue Is One of the Most Prevalent Clinical Manifestations of SLE

- Fatigue is prevalent across caucasians, African Americans, and Hispanics
- Severity may be related to psychosocial factors and/or disease activity

Prevalence of Fatigue Across Ethnic Groups (N=223)

- Caucasian (n=71): 88.7%
- African American (n=83): 85.5%
- Hispanic (n=69): 82.6%

A subanalysis of 223 patients participating in LUMINA, a prospective, multiethnic study of the outcome of SLE patients diagnosed ≤5 years prior to study entry, conducted jointly by the University of Alabama at Birmingham, the University of Texas-Houston Health Science Center, and the University of Texas Medical Branch at Galveston.
Skin Manifestations and Photosensitivity Limit Activities of Daily Life

• Cutaneous lupus with photosensitivity is associated with significant impairments related to symptoms, emotions, daily functioning, and overall quality of life¹
  – Photosensitivity was self-reported in 68% of patients with cutaneous lupus¹
  – Disease activity may be triggered by fluorescent lights as well as sunlight²
  – May cause patients to avoid outdoor activities¹,³

Survey: Work Loss Is a Common Consequence of SLE

Results from the National Burden of Lupus Survey, conducted by Gfk Roper Public Affairs and Communications from July through September 2011. Survey was designed to evaluate the daily and long-term impact of lupus on health, family relationships, career, and quality of life, and to identify potential gaps in communication. Includes feedback from 957 people in the lupus community (502 people with SLE [75% female], 204 supporters, 251 rheumatologists who treat SLE). Funded and developed by GlaxoSmithKline.

*To some extent.

SLE Increases Pregnancy Risks

- SLE increases several risks to mother and child\(^1,2\)

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<th>Fetal Risks</th>
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<td>Preeclampsia(^1)</td>
<td>Intrauterine growth restriction(^1)</td>
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<td>Thrombosis(^1)</td>
<td>Preterm delivery(^2)</td>
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<td>Maternal mortality(^1)</td>
<td>Neonatal/fetal death(^2)</td>
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- Risk of neonatal death is 7x greater than for the general population; risk of fetal death is 5x greater\(^2\)
- Yet the majority of women with SLE can have successful pregnancies\(^1\)
  - Conceiving when lupus has been in remission ≥6 months significantly reduces risks\(^3\)
  - Pregnancy loss has dropped from 43% (1960-1965) to 17% (2000-2003)\(^4\)

Pregnancy Risks May Lead Some Women to Avoid Having Children

• Concerns include¹
  – Maternal/fetal risks
  – Medication teratogenicity
  – Fear of genetic transmission of lupus to children*
  – Inability to care for child due to disability or premature death

*SLE has a complex pattern of inheritance, involving multiple susceptibility genes. Both genetic and environmental factors play a role in the development of SLE, and transmission cannot be predicted. Patient concerns about genetic transfer may be exaggerated.¹,²
88% reported that lupus negatively impacted their ability to fulfill various family roles²
- Mother/father
- Husband/wife
- "Breadwinner"
88% reported that poor mental health impaired their ability to participate in activities they found enjoyable²

Depression is common and some patients are suicidal¹

68% said lupus affects virtually every relationship they have³

Survey: Invisible Symptoms Create a Disconnect Between Patients and Those Around Them

87% Downplay Symptoms
87% of patients say they downplay symptoms to avoid upsetting their families*

Many Feel Unsupported
75% of patients say their family and friends think they can do more than they actually can*; think they can improve their condition by eating better or exercising more (80%)*; and believe they can identify with living with lupus (67%)*

Most Feel Misunderstood
Only 52% of patients say their family and friends are “very supportive”; 78% of supporters describe themselves as “very supportive”

Results from the National Burden of Lupus Survey, conducted by GfK Roper Public Affairs and Communications from July through September 2011. Survey was designed to evaluate the daily and long-term impact of lupus on health, family relationships, career, and quality of life, and to identify potential gaps in communication. Includes feedback from 957 people in the lupus community (502 people with SLE [75% female], 204 supporters, 251 rheumatologists who treat SLE). Funded and developed by GlaxoSmithKline.

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My coworkers don’t understand how it feels to be this tired. They resent that I’m less productive. I stopped making plans with friends because I never know what tomorrow will bring. They take it personally. They don’t realize how real my symptoms are. I’m starting to feel so alone.
Patient Support
Survey: Communication Gaps Exist Between Patients and Caregivers

52% of patients with lupus report they minimize their symptoms when they talk to their physicians*

72% of physicians are unaware that patients tend to under-report their symptoms*

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Survey: Patients May Feel Less Supported Than Their Doctors Realize

87% of patients wish there were more resources available to them*

54% of doctors are frustrated by the limited resources available to educate their patients*

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Patient Counseling May Improve Quality of Life for Those With SLE\(^1\)

• Unpredictable nature of SLE had the greatest impact on emotional distress and quality of life\(^2\)*
  – Frequency of flare was associated with depression and anxiety\(^3\)

• Increased education and perception of control over the illness were associated with reduced depression and anxiety regarding SLE challenges\(^3\)

• Environmental triggers, such as exposure to ultraviolet light, may be modified to limit onset and severity of flares\(^4\)

\(^*\)To some extent.

Patient Interactions Are Opportunities to Provide Support

• Foster open communication¹
  – Ask how patients are coping¹
    • Changes in physical appearance
    • Limitations on daily function
    • Emotional state
    • Socioeconomic challenges

• Emphasize participation in patient support groups and other resources¹

• Provide patient education¹

• Remind patients to schedule regular preventive care visits²
  – Primary care, gynecologist, dentist, optometrist

Empower Patients to Take Charge of the Factors They Can Control

✔ Diet¹
Eat a balanced diet to minimize cardiovascular risk and inflammation, maintain bone health, and prevent anemia

✔ Exercise¹
As tolerated, for physical/mental health and reduced fatigue

✔ Sunscreen¹
Protect against both UVA and UVB rays, fluorescent lights “Broad-spectrum protection” sunscreen with minimum SPF 15

✔ Sleep¹
8-10 hours a night to combat fatigue; naps whenever needed
Reinforce that need for rest is not laziness

✔ Stress¹-³
Practice stress management techniques

✔ Smoking¹
Emphasize the importance of not smoking

✔ Immunizations¹,⁴
Human papillomavirus; influenza and pneumococcal, with killed vaccines

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Focus on the Positive

56% Feel Hopeful

More than half (56%) of people with lupus reported feeling hopeful or optimistic, regardless of lupus*

87% Don’t Let Lupus Define Them

Living with lupus affects my life, but does not define me as a person: 87%*

82% Trust HCP With Care

My healthcare professional is the best there is when it comes to managing my lupus: 82%*

Positive Outlook

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*To some extent.
I was so achy today, but I pushed myself to put on sunblock and go for a 20-minute walk because I promised Nurse Samuels I would. I am so glad I did! It gave me energy. The fresh air really reminded me to take things one day at a time and appreciate everything I have. It’s strange, but in some ways, lupus has been a wake-up call. It’s caused me to slow down and realize what is truly important in life.

Patient perspective is for educational purposes only and represents hypothetical patient.
Key Takeaways
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• The pathogenesis of SLE involves immune dysfunction leading to autoantibody production, inflammation, and organ/tissue damage
• Immune dysfunction and subsequent organ/tissue damage leave patients with SLE at risk for serious chronic conditions and premature mortality
• SLE has a significant impact on daily function, work loss, interpersonal relationships, and emotional health
• Patient education and empowerment are valuable tools for improving quality of life
Thank You!