



Lupus Flare Activity from the Patient Perspective

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Disclosures

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Declaration of financial/other relationships

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WWN and ECS are employees of Mallinckrodt Pharmaceuticals; PD and LT are employees of the Lupus Foundation of America; MLR is employee of Vedanta Research.

References

Jolly M, Kosinski M, Garris CP, Oglesby AK. Prospective Validation of the Lupus Impact Tracker: A Patient-Completed Tool for Clinical Practice to Evaluate the Impact of Systemic Lupus Erythematosus. *Arthritis Rheumatol*. 2016 Jun;68(6):1422-31.

Ruperto N, Hanrahan LM, Alarcón GS, Belmont HM, Brey RL, Brunetta P, Buyon JP, Costner MI, Cronin ME, Dooley MA, Filocamo G, Fiorentino D, Fortin PR, Franks AG Jr, Gilkeson G, Ginzler E, Gordon C, Grossman J, Hahn B, Isenberg DA, Kalunian KC, Petri M, Sammaritano L, Sánchez-Guerrero J, Sontheimer RD, Strand V, Urowitz M, von Feldt JM, Werth VP, Merrill JT; Lupus Foundation of America, Inc. International Flare Consensus Initiative. International consensus for a definition of disease flare in lupus. *Lupus*. 2011 Apr;20(5):453-62.



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Study Goal and Background

- **Study Goal**: This study describes how individuals with lupus identify and manage their flares, and the burden of flare in their disease experience.
- The international clinician working group consensus definition of a lupus related flare is as follows¹:

“A flare is a measurable increase in disease activity and/or laboratory measurements. It must be considered clinically significant by the assessor and usually there would be at least consideration of a change or an increase in treatment”
- Persons with lupus may experience flares in disease activity that fall below this threshold, which may still impact disease course or require management.
- Self-reported flares or worsening of symptoms add insight into patient burden and may be important markers of disease control and healthcare resource use.

1. Ruperto M, Hanrahan LM, Alarcon GS, et al. Lupus. 2010;20(5):453-462.

Survey Methods

Two Sources for Respondent Recruitment

- Lupus Foundation of America constituents
- Research Now household panel members who self-reported a diagnosis of lupus

Survey Administration

- Respondents must consent to participate before they may proceed
- Respondents re-screened to confirm lupus diagnosis
- Web-based survey with average completion time of 30 minutes

Quality Control

- Conducted reliability checks
- Reviewed sample characteristics from the 2 sources to ensure comparability prior to combining the data

IRB approval provided by Ethical and Independent Review Services (Study ID# 16149-01)



Key Data in this Analysis

Sociodemographic characteristics: e.g. Age, sex, race/ethnicity, income

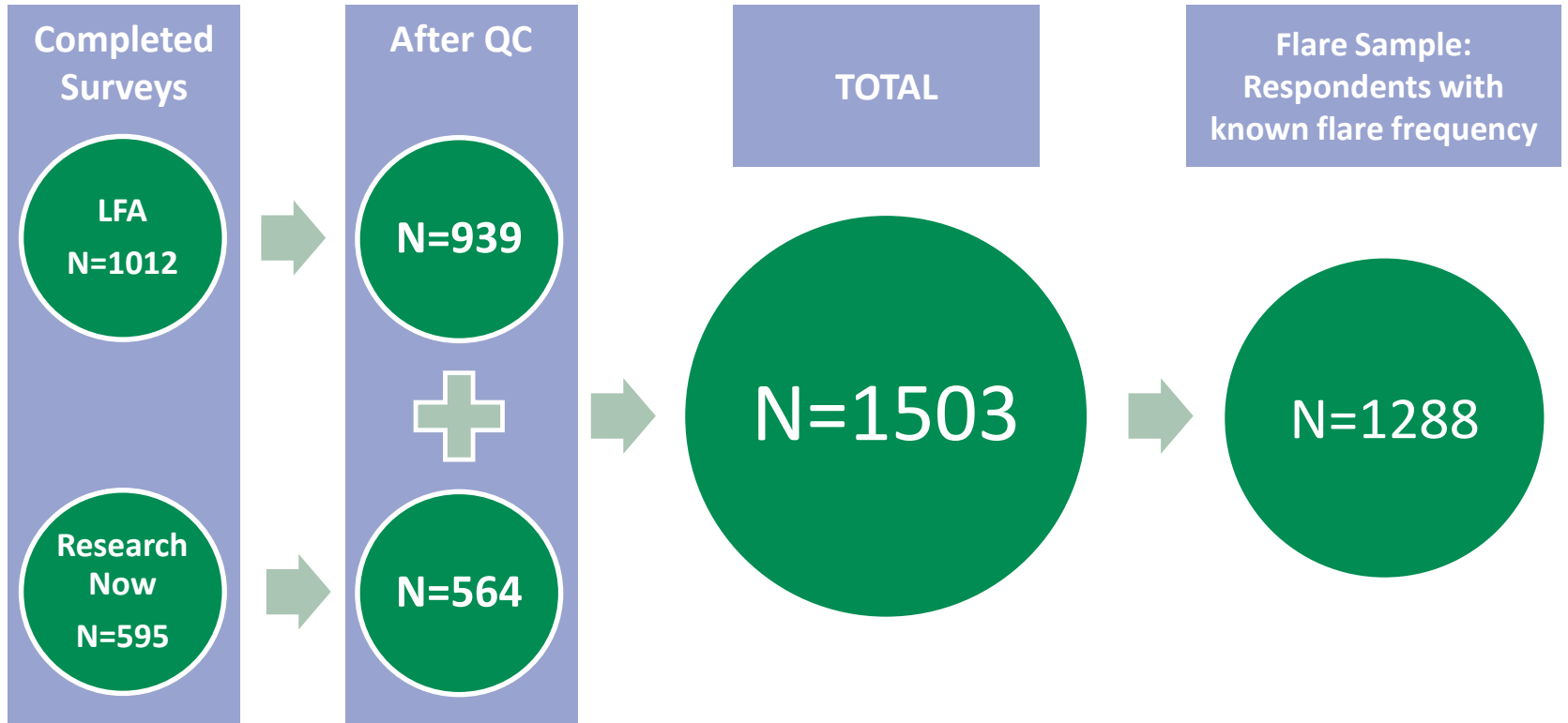
Flare profile: Severity, symptoms, frequency, management strategies

Lupus Impact Tracker (LIT): Validated instrument to assess impact of lupus on patients' daily functioning and well-being¹

Hospital admissions: Respondents were asked the number of times they were admitted to the hospital for lupus in the past 12 months

1. Jolly M, Kosinski M, Garris CP, et al. Arthritis Rheumatol. 2016;68(6):1422-31.

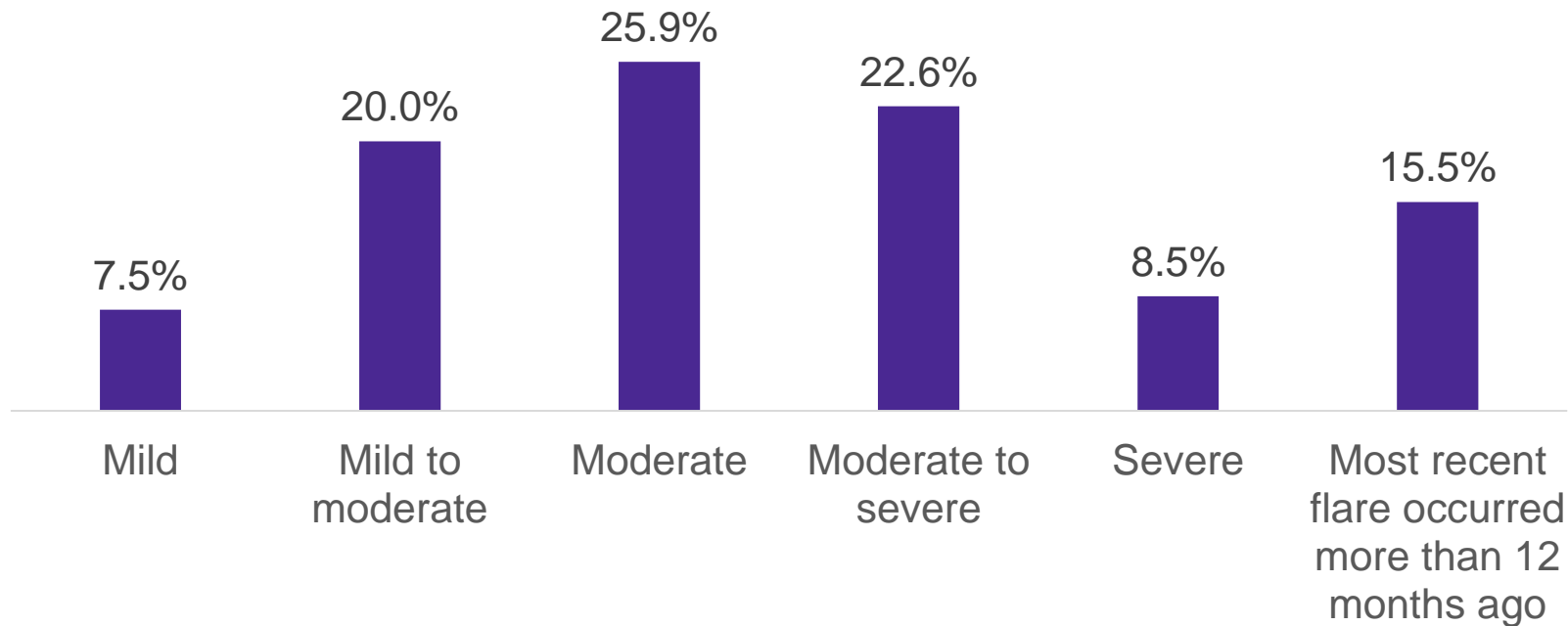
Sampling Results



Respondent Characteristics

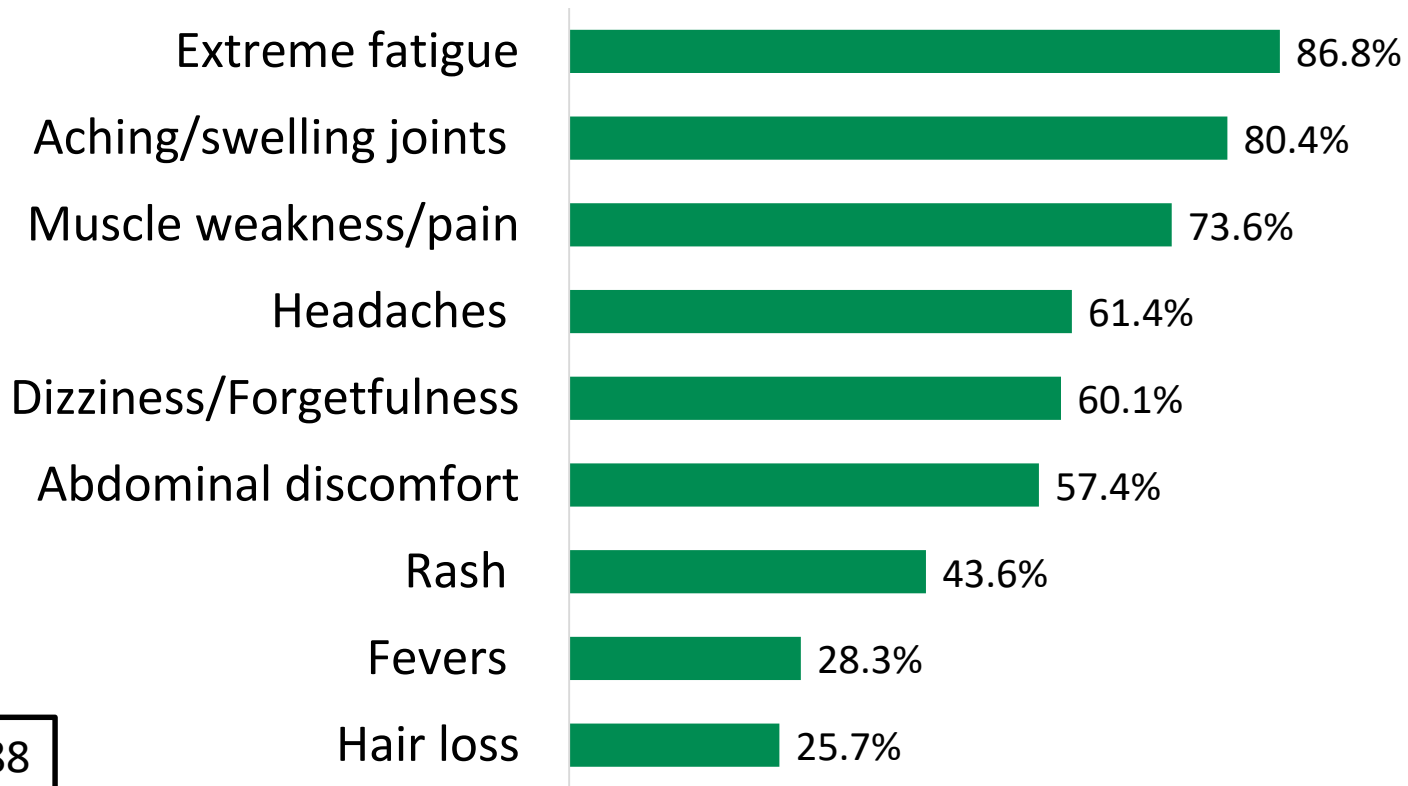
	Men (n=159)	Women (n=1344)	TOTAL (N=1503)
Age (mean, yr)	39.1	45.8	45.1
Caucasian	79.9%	76.9%	77.2%
Had flare activity in past yr	63.5%	79.8%	78.1%
Age at first Dx (mean, yr)	28.1	33.9	33.3
Duration of lupus (mean, yr)	10.9	11.8	11.7
Overweight (BMI 25-30 kg/m²)	33.3%	24.7%	25.6%
Obese (BMI >30 kg/m²)	25.2%	42.8%	40.9%
Urban	49.7%	31.5%	33.4%
Suburban	42.8%	48.3%	47.7%
Rural	7.5%	20.2%	18.9%

Flare Severity



N=1288

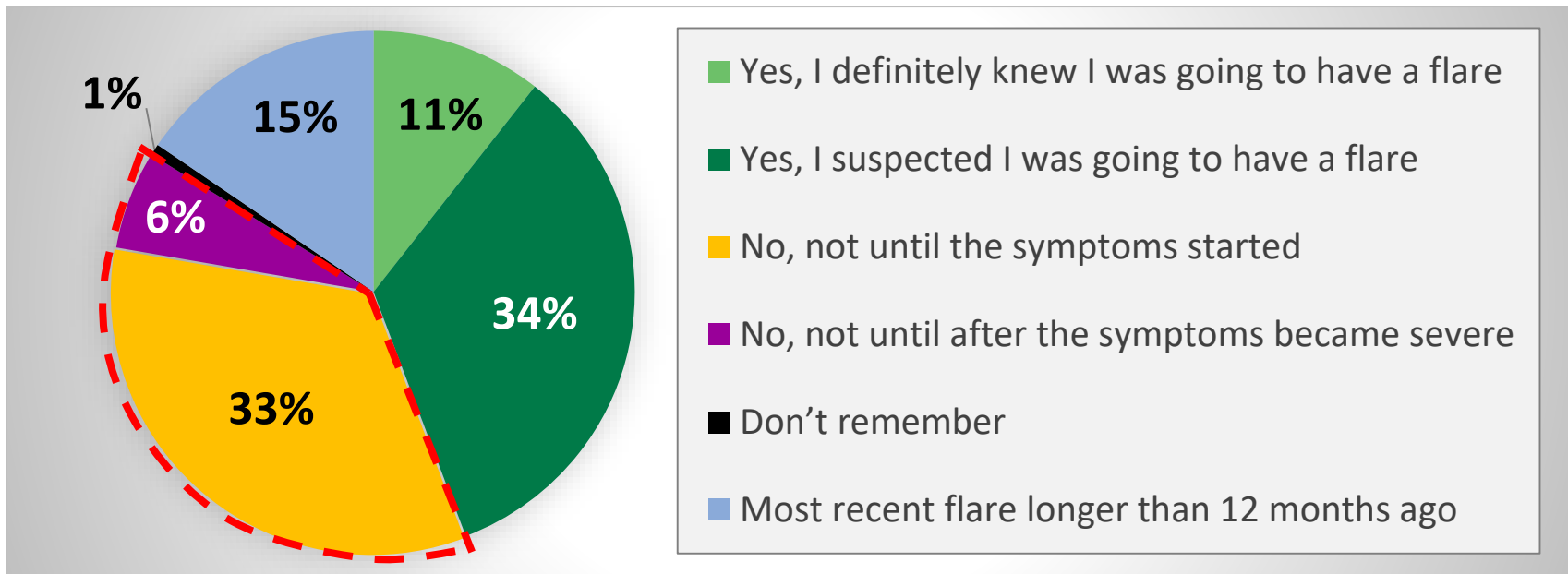
Symptoms Reported with Most Recent Flare



N=1288

Flare Prediction

39% of respondents could not predict when a flare would occur



N=1288

Strategies to Manage Flares

More than half of the patients would do this:

Take medication exactly as prescribed	68%
Avoid direct sunlight	65%
Wear sunscreen	63%
Get adequate rest	60%
Avoid strenuous physical activity	56%
Maintain cleanliness, e.g. extra hand-washing	54%

N=1288

Strategies to Manage Flares

More than a quarter of the patients would do this:

Maintain good nutrition	38%
Take vitamins or herbs	37%
Avoid places where exposed to illness	36%
Avoid certain foods	27%
Use relaxation techniques	27%

Lesser used strategies

Exercise, yoga, Tai Chi (24%); OTC meds (20%); Weight management (20%); Prescription meds (17%); Cognitive therapy (7%); Acupuncture (4%); Biofeedback (3%)

N=1288

Medical Care to Manage Flares

42% engaged the healthcare system, such as doctor, ER, or hospital, when suffering a flare

54% self-treated flares, most frequently with over-the-counter products and prescription drugs kept on hand

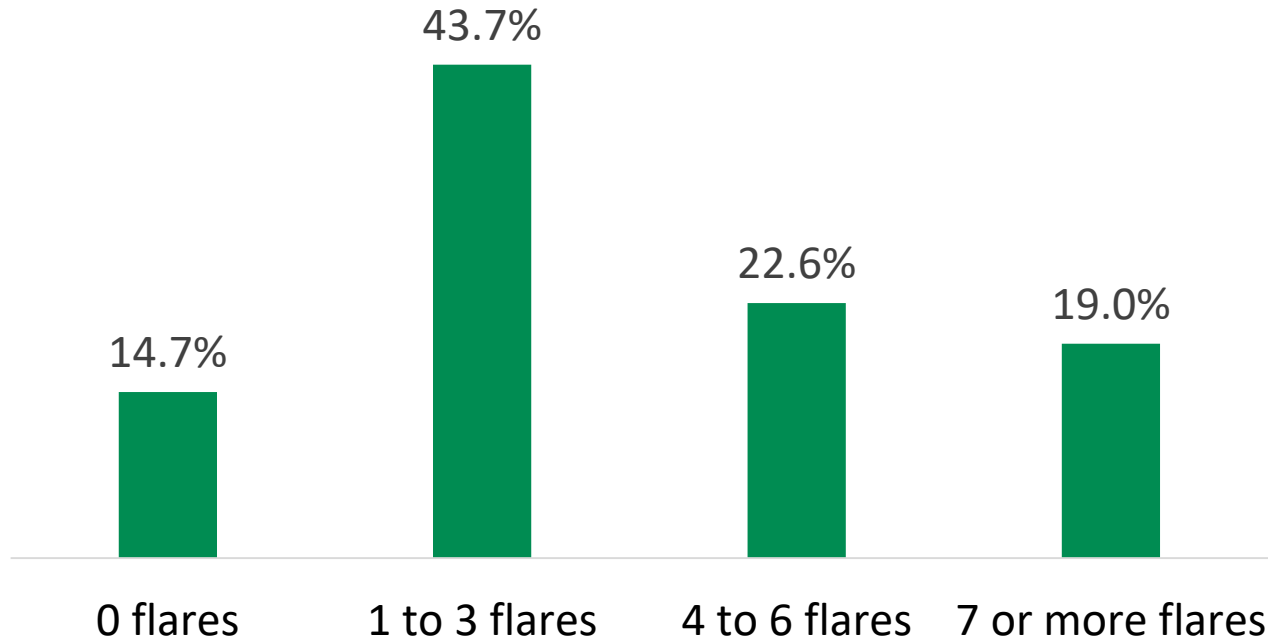
35% delayed seeking care for 3 days or longer

- Fewer Urban residents delayed care (24%)
- More Rural residents delayed care (42%)

53% had to wait longer than 24 hours before seen by HCP

- Fewer Urban residents had >24h wait time (46%)
- More Rural residents had >24h wait time (62%)

Flare Frequency and LIT Mean Score



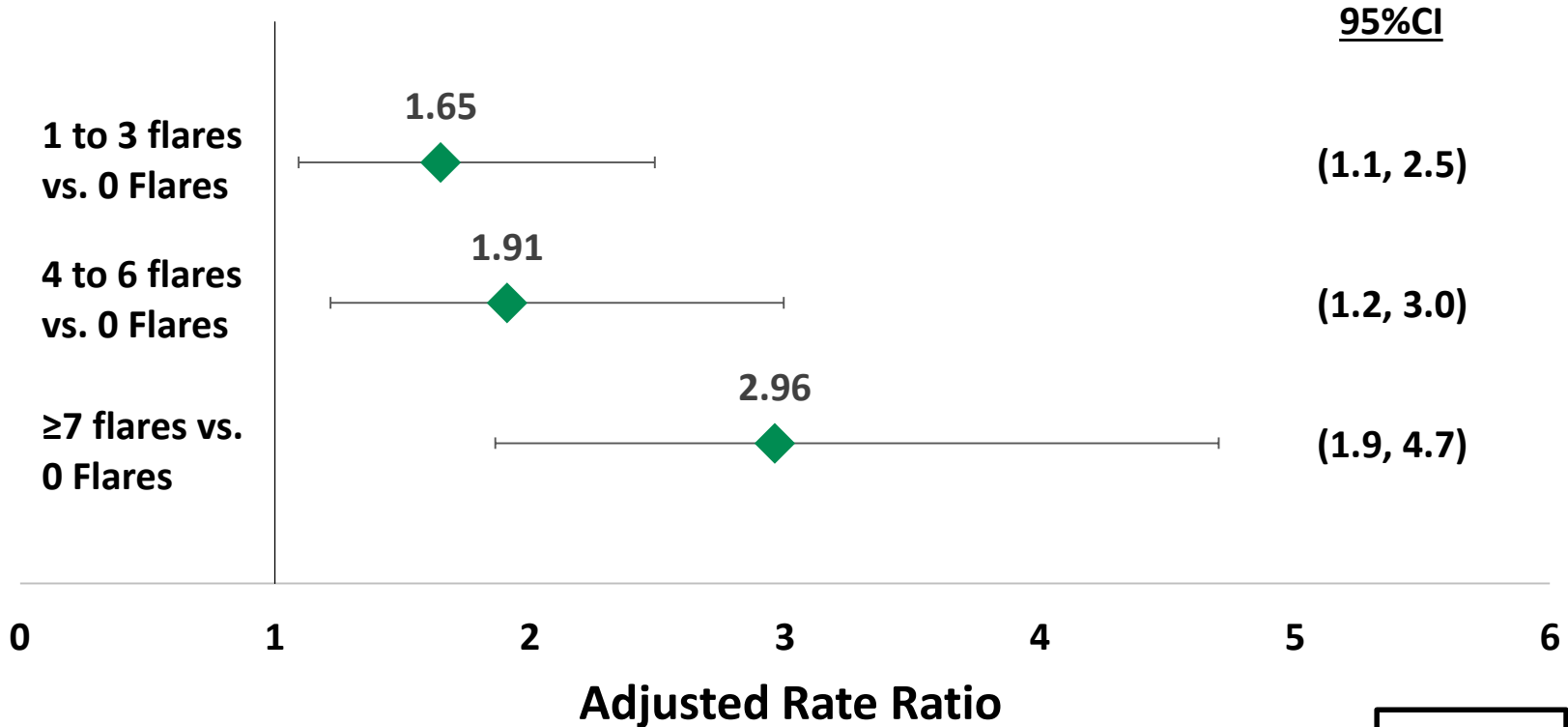
N=1288

LIT, mean (SD)	0 flares	1 to 3 flares	4 to 6 flares	7 or more flares
	27.2 (20.3)	47.0 (20.1)	55.8 (17.6)	64.9 (18.3)

(ANOVA F=150.3, p<0.001)

Adjusted Rate Ratios

Lupus-related Hospital Admissions



N=1288



Study Limitations

- Population based surveys may not capture the most severe cases
- Military, hospitalized, and upper and lower socio-economic status classes under-represented
- Flare frequency, severity and burden are subject to recall bias
- Hospital admissions are self-reported and not confirmed by medical records or claims
- Non-English speaking populations not represented

Key Findings

Challenge	The most common flare symptoms may not be congruent with how clinicians define flares, leading to communication challenges.
Opportunity	Improved patient-clinician communication can help patients better manage lupus flares.
Validation	Frequency of patient-reported flares is associated with the Lupus Impact Tracker score.
Burden	Frequency of patient-reported flares is associated with increased hospitalizations.



Conclusion

- This study described lupus flares from the patient perspective
- Lupus flare burden is high, and flares often resulted in healthcare encounters and medication use
- With better communication about what constitutes a flare, clinicians and patients can work together to manage flares more effectively