



# A Vision for Lupus

Calls to action to improve lupus care

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GSK conceived, developed and led this report in collaboration with a Global Multidisciplinary Steering Committee who received a fee for their services. GSK had editorial input into this document.

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# Executive summary

In March 2018, GSK convened a Global Multidisciplinary Steering Committee comprising a person with lupus, a patient advocacy expert, representation from international lupus patient organisations and clinicians specialising in the condition to discuss the future 'A Vision for Lupus'.

## **Their mission was to:**

- Consider current gaps and barriers to care for people with lupus
- Develop patient-centred calls to action to improve the quality of care
- Outline what difference putting these calls to action into practice could make to people with lupus.

## **The purpose of this 'A Vision for Lupus' report is to answer the following questions based on the Steering Committee's discussions:**

- **Where we are now?**  
What gaps and barriers are there to quality care?
- **Where do we want to be?**  
What do we want the future to look like?  
And what calls to action could help the lupus community to improve the provision of quality care to people with lupus?

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# Introduction to lupus

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Systemic Lupus Erythematosus (SLE) is a chronic, inflammatory, autoimmune disease.<sup>1</sup>

# Introduction to lupus

## What is lupus?

**Systemic Lupus Erythematosus (SLE) is a chronic, inflammatory, autoimmune disease.<sup>1</sup>**

This means that the body's immune system is 'out of balance' leading to the production of auto-antibodies, which target the body's own healthy tissue in addition to producing antibodies to protect against infection.<sup>2</sup> Over time, the disease can potentially affect many different organs and tissues of the body.<sup>2</sup>

The clinical manifestations of the disease are highly variable between patients and over the disease course. Some of the most common symptoms of lupus are painful and swollen joints (arthritis), extreme fatigue, skin rashes, anaemia and kidney problems.<sup>1</sup> There is no single diagnostic test that can determine whether a person has SLE; a diagnosis is the result of clinical reasoning, combining a patient's symptoms, physical signs and laboratory data.<sup>3</sup> In this respect, it may

take months or even years for a person to receive an accurate diagnosis.<sup>4</sup>

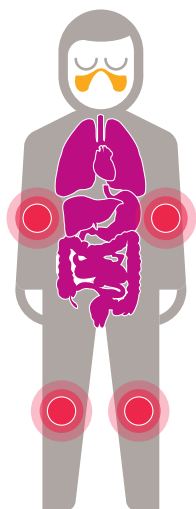
Typically, people with lupus alternate between periods of illness, called 'flares', and periods of relative wellness, or 'remission'.<sup>5</sup> While some environmental triggers of disease flares have been identified, in the majority of cases, causes of disease exacerbations cannot be clearly recognised. As a result of the unpredictable course of the disease, people with lupus may face uncertainty related to their condition. Severity of illness can vary; some are mildly affected and continue to lead normal lives, whilst others have frequent or life-threatening flares that require critical care.<sup>5</sup>

There is no cure for SLE,<sup>1</sup> so the goals of treatment are to achieve and maintain disease remission, prevent disease flares, prevent damage to the body's organs<sup>3</sup> and thus, improve quality of life for people with the disease.

## Who is affected by lupus?

Globally, five million people are thought to have lupus.<sup>6</sup> It is estimated that 70 to 90% of lupus cases are in females,<sup>7</sup> with the highest incidence during a woman's most productive childbearing and professional development years. Studies have also shown that non-Caucasian populations are more commonly affected by lupus.<sup>8</sup>

One study conducted in the UK between 1999 and 2012 showed an increasing prevalence of lupus, which may be due to the improved survival of people with lupus or the ageing population. This increase in prevalence supports the idea that "SLE is no longer a 'rare' disease, which has implications for healthcare planning.<sup>9</sup>



Some of the most common symptoms of lupus are painful and swollen joints (arthritis), extreme fatigue, skin rashes, anaemia and kidney problems<sup>1</sup>



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## What is the impact of lupus?

Lupus has a substantial impact on many aspects of people's lives, as well as the lives of their families and carers. A 2015 study conducted in the UK demonstrated that the burden of illness is considerable, with people experiencing physical, emotional, psychological, economic and social effects of the disease:<sup>10</sup>



of people with lupus experienced daily fatigue – the most common symptom<sup>10</sup>



of people with lupus reported a reduced ability to socialise<sup>10</sup>



had changed employment, while 52% had stopped working altogether<sup>10</sup>



of carers reported a worsened financial status, with more than half (52%) of carers in paid employment having missed work<sup>10</sup>



of carers also reported an interference with social activities<sup>10</sup>

SLE affects mainly women in the prime of their lives:<sup>8</sup> it can have an impact on their everyday plans, compromising their social life, and aspirations for a career and family that others take for granted, leading to a degree of fear and uncertainty about the future. On any given day, people with lupus may not be able to carry out daily activities or commit to plans, or may struggle to function as a parent, friend, partner or colleague.

Persistent SLE disease activity is associated with a higher risk of organ damage and mortality.<sup>11</sup> For people with lupus, the mortality risk is up to three times higher than the general population, and up to 10 times higher in people under 40.<sup>12</sup>

## What constitutes high quality care for people with lupus?

While researchers continue to pursue a cure for lupus, physicians focus on managing symptoms and preventing damage, with the aim of providing people with lupus the best possible quality of life, restoring their ability to participate in daily activities. High-quality care can result from shared decisions between informed people with lupus and their physicians, which have the potential to improve patient-physician communication, the quality of the decision-making process, adherence and subsequent outcomes. Survey results also suggest that the ability to address comorbid symptoms like depression, anxiety and fatigue may have an impact on patient-perceived disease burden and their satisfaction with treatment.<sup>13</sup>

"I felt very alone when I was first diagnosed with lupus and went through many phases to accept the disease and learn how to cope with it in everyday life. I also found myself searching for information on Google, which was scary and often misleading. It's important that people with lupus have access to credible sources of information and support, and a range of specialists with adequate tools to manage this multifaceted disease, including both its physical and psychological/emotional aspects."

Spanish lupus patient, former Secretary of FELUPUS and Vice-President of LUPUSMADRID

In some groups, mortality risk can be up to

**10** times higher compared with the general population<sup>12\*</sup>

\*Standard mortality ratio







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# Calls to action to improve lupus care

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- Awareness
- Service delivery
- Clinical research

# Calls to action to improve lupus care



## 1. Awareness

Raise awareness of lupus amongst key audiences, including the general public, people with lupus, their families, carers and primary care doctors in order to help achieve early diagnosis and help people with lupus feel more acknowledged, understood and supported



## 2. Service delivery

Improve access to specialist and multidisciplinary lupus clinics to ensure people with lupus are receiving quality care that addresses all aspects of this complex, multisystem disease; thereby helping to improve quality of life



## 3. Clinical research

- Raise awareness of ongoing clinical trials
- Encourage people with lupus to consider participating in clinical research
- Facilitate access to clinical trial research enabling people with lupus to make autonomous decisions in the management of their condition



## 1. Awareness

### The current situation

#### General awareness

Research has demonstrated a low public awareness of lupus. Over half (51%) of respondents to a recent global survey were unaware that lupus is a disease. Amongst those who were aware of lupus, 41% could not name any complications associated with the condition.<sup>14</sup> Public misconceptions about lupus may contribute to a lack of empathy for people with lupus, whose symptoms are often “invisible” to others, leading to them feeling frustrated, inadequately understood, isolated and alone. This is compounded by the fluctuating nature and relative invisibility of the condition; often there are no visible signs of lupus and, when people do look ill, they may stay at home.<sup>15</sup>

#### Patient and family awareness

Misinformation on unmoderated websites or social media may contribute to misunderstanding about the condition amongst people with lupus and their families. Inaccurate information can lead to unrealistic expectations about what can be achieved from treatment.<sup>16</sup>

A tendency for online sensationalism may cause unnecessary concern, creating anxiety and isolation from others and potentially decreasing quality of life for some people, for example those with mild skin lupus only.

A lack of understanding about what to expect in terms of symptoms might

lead to people with lupus being unsure when to seek medical help. People with lupus may think every ailment is a lupus flare (e.g.: a headache), even when this is not the case. Importantly, lack of education related to prescribed medicines, both pharmacological and non-pharmacological, can result in poor adherence, treatment failure and subsequent adverse events.

#### Awareness amongst primary care doctors / other specialists

While early diagnosis of lupus is important to improve some outcomes and reduce costs,<sup>17</sup> delayed diagnosis is common because primary care doctors see a small number of people with lupus each year and therefore may not immediately recognise the symptoms, which could otherwise prompt a specialist referral. Short consultation times, lack of continuity and often out-of-date information may also contribute to delays.

The time to diagnosis can vary, a UK study has shown that median time to diagnosis from appearance of the first clinical features is one year.<sup>4</sup> Moreover, 70% of people with lupus are initially misdiagnosed.<sup>10</sup> A US survey has identified that, on average, it takes an average of 3.5 years, and up to 5 years for some individuals from onset of symptoms to obtain a correct diagnosis of lupus, with people making multiple visits to different healthcare professionals during that time; 63% of people with lupus first receive a diagnosis other than lupus.<sup>18</sup> Other specialists could also benefit from improving their knowledge of the condition, so they are better equipped when providing consultations to people with lupus.



## The aim for the future

### To improve general awareness of lupus:

**Short-term: Build on the success of engagements with celebrities with lupus, cultivating a group of public figures who are willing to talk about the condition** – It is difficult to deny or invalidate a statement from a patient about what it is like to live with lupus, and the voice of celebrity is especially powerful. Therefore, the stories of public figures should be used to:

- Explain the impact of lupus to a variety of stakeholders, including employers, family and friends of people with lupus
- Show there can be a positive outcome for people with lupus who receive good treatment and care

### To improve patient and carer awareness of lupus:

**Short-term: Develop and implement a seal of approval for websites about lupus** – a standard seal should be collaboratively developed between patient organisations, supported by healthcare professionals, for websites that provide information and resources about lupus, with agreed criteria to ensure accuracy of information as certified by leading organisations (i.e.: EULAR, ACR, LFA, WLF and Lupus Europe).

**Short-term: Generate positive interaction between people with lupus** – create / support existing patient support groups or small national conferences to generate interaction between different people with lupus, generating a sense of empathy and shared experience.

**Long-term: Train advocates to provide accurate information on lupus, ensuring a shared message for maximum impact** – patient advocates and experts should be trained to use the internet, especially social media, as an effective platform to disseminate shared messages about lupus for maximum impact; as well as to identify fake and unverifiable information about lupus.

For example:

- The Lupus Foundation of America recently ran a campaign called 'Could I have lupus?'
- Research should be made available to patients (or patient advocates)

### To improve awareness of lupus amongst primary care doctors:

**Short-term: Find suitable ways to disseminate information to primary care doctors, with the aim of encouraging timely diagnosis and ongoing care for people with lupus** – recognising that primary care doctors have limited spare time, it is critical that lupus education is provided efficiently; i.e. through general journals (i.e.: Royal College of General Practitioners in the UK or similar organisations in Europe and the USA) or via targeted talks or informal small group discussions, which may elicit a higher level of engagement than less personalised approaches. This education should:

- Focus on enabling primary care doctors to consider lupus as a differential diagnosis and refer appropriately
- Make primary care doctors aware of referral sources in their own communities

**Long-term: Improve education around the psychological manifestations of lupus** – some experts believe there is under-diagnosis and under-treatment of depression in people with lupus; and understanding of psychological symptoms in lupus, such as depression, is still evolving. Critically, there are multiple causes of depression in lupus and physicians must consider these distinctly, as treatment approaches will differ for each.

- For example, the Steering Committee highlighted that reactive depression that results from the impact of lupus on the patient's life should be treated differently to depression caused by inflammation on the brain (directly caused by lupus) or depression induced by drugs (i.e.: as a side effect of prednisone)

Research has demonstrated a low public awareness of lupus. **Over half (51%)** of respondents to a recent global survey were unaware that lupus is a disease<sup>14</sup>





## 2. Service delivery

### The current situation

#### Access to specialist and multidisciplinary lupus care

Specialist lupus centres are available in some regions but not others. There are many excellent examples in the US and Europe. However, in the US and parts of Europe, there is a disparity between urban and rural areas in terms of access to specialist lupus centres, and there are insufficient numbers of lupus specialists to manage all patients, especially in more rural areas. People living in regions with no specialist centre or inadequate access to specialist physicians may have to travel a long distance for expert care. Alternatively, people with lupus may visit doctors who do not have specialist knowledge of the condition, which has the potential to delay diagnosis.

Lupus is a complex condition that affects every patient differently, so individualised care requires substantial one-on-one time and multidisciplinary teams of professionals working together.<sup>19</sup> However, structures to provide multidisciplinary care are not widespread across healthcare systems, so people with lupus may not have access to teams that include medical specialists working together (e.g.: a rheumatologist, renal specialists, obstetricians, etc), as well as allied healthcare professionals (e.g.: specialist lupus nurses, psychologists, physiotherapists, social workers, etc). Moreover, patient organisations are not equipped to provide individualised care or therapeutic education without support; and the relationship between the patient and physician does not always encourage optimal care.<sup>20</sup> The Vision for Lupus Steering Committee reported that initial consultations for lupus diagnosis, or consultations at the time of a lupus flare, take a substantial amount of time, and cannot be done within the timeframe allowed by national healthcare guidelines.

#### Access to emotional, psychological and social care

People with lupus want to be treated as a person rather than a set of medical symptoms,<sup>21</sup> however, a lack of multidisciplinary care structures may mean people miss out on elements of care beyond their immediate medical needs. Physicians are likely to focus on clinical aspects of care since that is their area of expertise, and consultation time is limited (as little as 20 to 30 minutes, or less with a senior specialist). This may lead to other concerns being insufficiently explored, such as emotional needs, body or self-image.<sup>22</sup>

It is important that people with lupus see their psychological needs as clinical issues that require expert help, for example, via therapies such as Cognitive Behavioural Therapy.<sup>23</sup> People must understand that, while rheumatologists or nephrologists may be empathetic, they are unlikely to be trained in psychological care; while payors and policy-makers must understand that psychology, behavioural therapy, nutrition, and exercise are all part of lupus treatment (i.e.: they should be covered benefits).

#### Tools for improving patient/physician communication

There are currently few patient-focused tools for assessing the burden of the condition on people with lupus and the impact of care on their quality of life. People with lupus can find it difficult to communicate their symptoms to doctors,<sup>21</sup> and may not report flares,<sup>10</sup> so new instruments are required that allow improved evaluation of lupus burden from the patient perspective. Tools like diaries and symptom checklists are often used to ascertain information from people with lupus to maximise consultation time, but these are not always popular:

- Questionnaires may not capture what really matters to people with lupus
- Manual tracking of symptoms can add to the perception of 'chronic burden'
- People with lupus may stop filling out diaries after a short time







Physicians are likely to focus on clinical aspects of care since that is their area of expertise, and consultation time is limited.

### Evidence to support patient self-management

More research is required to support the benefits of specific measures people with lupus can take to care for themselves, particularly the role non-medical

approaches may play in treatment. For example, although studies have shown that physical activity reduces fatigue in lupus,<sup>24,25</sup> there has been limited consideration as to how to support people with lupus to continue exercising beyond the clinical trial environment.

## The aim for the future

### Access to specialist and multidisciplinary lupus care

**Long-term: Improve access to multidisciplinary teams, including medical specialists and support services** – access to lupus specialists, as well as experts in psychology, physical therapy, nutrition, exercise and social work must be a priority for healthcare systems. Multidisciplinary working should be supported by connecting centres, for example, through the European Reference Network,<sup>26</sup> enabling sharing of experience. Advertising these clinics on local patient advocacy group websites would also be beneficial, as not all patients are aware of their existence. Improvements in digital technology may also facilitate virtual consultations for routine check-ups.

**Long-term: Utilise specialist lupus nurses** – multidisciplinary teams should include specialist lupus nurses who take a leading role in exploring what matters most to the patient, therapeutic education and linking to further services. This should be in addition to, rather than replacing, the clinical care provided by doctors.

**Long-term: Encourage more doctors to become rheumatologists** – ensure medical students are provided with sufficient information so they can pursue this rewarding speciality.

### Access to emotional, psychological and social care

**Short-term: Physicians/ people with lupus to co-create interactive tools to facilitate improved communication during consultations** – interactive tools such as diaries and questionnaires must be co-created with people with lupus, so they are user-friendly, they ask questions people want to be asked and to ensure transparency on the use of the information.

**Develop evaluation tools to assess the burden of lupus from the patient perspective** – more patient-focused evaluation tools are needed to improve evaluation of lupus burden from the patient perspective: to understand more about the daily lives of people with lupus, explore what symptoms matter most to them and direct them to the most appropriate care. Such tools should be co-created with people with lupus and physicians and should be consistent across all SLE centres to allow comparison. One example is the LFA-REAL™ (Rapid Evaluation of Activity in Lupus)<sup>27</sup> system. Studies to assess the burden of the illness as experienced by someone living with lupus and how to measure it are also important: one approach to gather further information may be to carry out an update of the 2013 Burden of Living with Lupus survey conducted by Lupus Europe.<sup>28</sup>

LFA-REAL is a registered trademark of Lupus Foundation of America, Inc

## Best practice examples of multidisciplinary lupus care

### Lupus Clinic in Pisa, Italy

The Rheumatology Unit in Pisa has a long tradition in SLE care dating back to the 70s, but the Lupus Clinic was formally established in 2011 to provide multidisciplinary care to people with lupus.

#### Multidisciplinary care

- The Lupus Clinic in Pisa is one of the best-recognised centres dedicated to SLE care in Italy. Its specialist team is comprised of rheumatologists, a dedicated lupus nurse, a pneumologist, nephrologist, obstetrician, nutritionist, dermatologist, a metabolic disease specialist and a psychiatrist. It also has a pregnancy clinic and a clinical trial centre
- Patients' reported outcomes are considered an important part of the assessment; thus, upon arrival, patients fill out self-administered questionnaires on their perception of disease activity, disease damage, quality of life, functioning and fatigue. Moreover, to ensure an accurate reporting of the symptoms over time, patients are asked to complete a diary between visits to the clinic.
- Clinical assessment is driven by the doctor, involving a

review of the patient's reported outcomes and a discussion about treatment. The patient also has an appointment with the specialist nurse to arrange their next consultation, book a hospital assessment / visit with other specialists or arrange an infusion at the hospital

#### Educational activity

- The Lupus Clinic in Pisa is part of a teaching hospital and is a tertiary referral centre for systemic autoimmune diseases; it regularly provides educational activities for undergraduate and post-graduate students
- Every two years, the Lupus Clinic hosts more than 70 young rheumatologists from EU and non-EU countries attending the European Congress of Rheumatology (EULAR) course on SLE, a residential course entirely dedicated to SLE
- The Lupus Clinic runs educational activities for

patients throughout the year to discuss symptoms and set goals for treatment. Brochures on pregnancy, diet and physical activity are also available in the waiting room

- Communication skills coaching sessions for nurses are organized by the clinic
- These educational platforms are aimed at improving patient-physician communication, sharing best practice and ultimately enhancing quality of care for patients

#### Constant evaluation

- The team is constantly evaluating their processes to identify areas for improvement. In the future, they aim to reduce waiting times for follow-up visits, optimise consultation time and improve nurse training to facilitate a triage system, which would maximise access to the clinic





## Louise Coote Unit, Guy's and St Thomas' Hospital, London, UK

The Louise Coote Unit is a centre of excellence dedicated to delivering high quality care for people with lupus

### Specialist lupus care

- This Louise Coote Unit is one of eight specialist lupus centres in the UK. It is vital to providing a high standard of care to people with lupus, thereby helping to improve quality of life for them and their carers
- The clinic has experts in dermatology, haematology, renal medicine, obstetrics and neurology, amongst other specialties. The clinic offers a programme for pregnant women, with ongoing monitoring and management of therapies before, during and after pregnancy

### Teaching and training

- Education is central to the unit, which offers undergraduate and postgraduate education and welcomes overseas visiting fellows. The clinic also conducts 'bench to bedside' translational research and numerous studies in its Lupus Clinical Trials Unit. With regards to patient support and education, the clinic has links to two major UK advocacy groups, Lupus UK and the Lupus Trust, which have a wealth of information on managing the disease

### Managing drug cost

- One of the key aims of the clinic is to manage high cost drugs, and it has a dedicated infusion suite to facilitate treatment on site





### 3. Research

#### The current situation

##### Access to clinical trial research in lupus

Pharmaceutical and biotechnology companies face many hurdles in developing potential new therapeutic options for managing lupus. Due to the heterogeneity of lupus, the variability and unpredictability of disease activity and the impact of background medications that patients must continue during the studies, clinical trials in lupus require a large pool of patients willing to participate. Consequently, clinical studies in lupus must be organised on an international scale, and have to overcome many barriers, including language, cultural

practices and health disparities that exist among people of different races and ethnicities.

There are various barriers that may limit clinical trial participation in lupus:<sup>29</sup>

*\*While this study is specific to cancer studies, it stands to reason that similar barriers would exist in lupus studies*

- Trials are often held at major lupus centres, so patients may live too far away to participate
- The patient's own doctor may not participate in research activities
- Primary care physicians may not encourage lupus patients to participate
- Taking part in a clinical trial can be logistically complex and time-consuming – patients may have

to arrange their lives around the clinical trial

- Patients may not want to be randomised and risk not receiving the study medication
- A high volume of complex information is provided to patients at the start of clinical trials, which may not be in a particularly patient-friendly format
- There is a lack of information, and therefore limited awareness of, the importance of participating in research.

A number of initiatives to address these barriers are underway in the US and Europe.\* However, we can do more.<sup>30,31,32</sup>



There are various barriers that may limit clinical trial participation<sup>29</sup>

Pharmaceutical and biotechnology companies face many hurdles in developing potential new therapeutic options for managing lupus.



## The aim for the future

**Provide education about clinical research opportunities for patients at specialist centres** – patient participation is key to furthering understanding of lupus and improving diagnosis and treatment, so education around the importance of clinical research is vital to encourage greater trial participation; for example, to relieve potential concerns around randomisation. Physicians should encourage patients to participate in registries / symptom libraries, so they become more comfortable with the concept of research and are more open to participating in clinical trials. Patient advocacy groups also play a role in advertising clinical trial research opportunities.

**Facilitate access for patients to take part in clinical trials** – where possible, recommend that patients receive treatment from physicians who participate in research, so they are more likely to be encouraged to participate in a clinical trial. Clinical trial centres must also work to identify individualised support mechanisms to help patients with their concerns, so trials are designed around patients rather than patients adapting to trials. For example, by providing transport to, or accommodation near the research centre, or broadening the base of investigators so more centres are running trials.

**Involve patients in the research agenda** – Involve patients in the study design of lupus clinical trials, to ensure they address the aspects of the disease which matter most to patients.

**Educate primary care physicians about the importance of clinical trial participation** – primary care physicians may not know how to approach conversations about clinical trial research with patients, so there is an opportunity to train them on the benefits of patient involvement.

**Explore other non-clinical trial research opportunities** – research is not just for new drug development, but also for other therapies, including cognitive behavioural therapy, for example. Patient advocacy organisations can play a role in supporting this non-clinical trial research.

**Help patients become accountable for their lupus care** – Patients demand more effective, tolerable treatments, and it is important that they contribute to achieving this through participation in clinical research. It is the role of healthcare professionals to encourage and empower patients to be a part of the solution.





# Conclusion

The increase in prevalence of lupus, as highlighted by a recent study, indicates that lupus is no longer classed as a rare disease.<sup>9</sup>

This observation puts greater emphasis on the need to tackle existing gaps in lupus management. Over the past few years, progress has been made in the management of lupus. However, there are still significant challenges and barriers in areas such as: awareness of the condition, access to quality care and participation in research/clinical trials, which are negatively impacting upon the quality of life for people with lupus.

The calls to action in this report are intended to stimulate conversations with a number of stakeholders, including the general public, people living with lupus, their families, healthcare professionals and policymakers. Their aim is to ensure steps are taken to address these barriers and ultimately improve quality of life for people with lupus.





## References

1. National Health Service. Lupus. Available at: <https://www.nhs.uk/conditions/lupus/>. Last accessed: January 2019.
2. NIH National Institute of Arthritis and Musculoskeletal Diseases. Handout on health: systemic lupus erythematosus. Available at: [http://www.niams.nih.gov/Health\\_Info/Lupus/](http://www.niams.nih.gov/Health_Info/Lupus/). Last accessed: January 2019
3. Cunha, JS. *Et al.* "Systemic lupus erythematosus: A review of the clinical approach to diagnosis and update on current targeted therapies." *Rhode Island Medical Journal* 99.12 (2016): 2
4. Rees, F., M. Doherty, P. Lanyon, G. Davenport, R. D. Riley, W. Zhang and M. J. Grainge. "Early clinical features in systemic lupus erythematosus: Can they be used to achieve earlier diagnosis? A risk prediction model." *Arthritis Care Res.* 2017;69(6): 833-841.
5. McElhone K, Abbott J, Gray J, *et al.* Patient perspective of systemic lupus erythematosus in relation to health-related quality of life concepts: a qualitative study. *Lupus*. 2010;19:1640-7.
6. Lupus Foundation of America. What is lupus? Available at: <https://resources.lupus.org/entry/what-is-lupus> Last accessed August 2018
7. Beeson PA. Age and Sex Association of 40 Autoimmune Diseases. *Am J Med* 1994; 96:457-462
8. Danchenko N, Satia JA, Anthony MS. Epidemiology of systemic lupus erythematosus: a comparison of worldwide disease burden. *Lupus* 2006;15: 308-18
9. Rees F, Doherty M, Grainge M, *et al.* The incidence and prevalence of systemic lupus erythematosus in the UK, 1999-2012 *Annals of the Rheumatic Diseases* 2016;75:136-141. Available at <http://ard.bmj.com/content/early/2014/09/29/annrheumdis-2014-206334>. Last accessed August 2018
10. Kent, T., A. Davidson, D. Newman, G. Buck and D. D'Cruz. "Burden of illness in systemic lupus erythematosus: results from a UK patient and carer online survey." *Lupus* 2017;26(10): 1095-1100.
11. Lopez R, Davidson JE, Beeby MD, Egger PJ, Isenberg DA. Lupus disease activity and the risk of subsequent organ damage and mortality in a large lupus cohort. *Rheumatology* 2012 Mar;51(3):491-8.
12. Bernatsky S, Boivin JF, Joseph L, *et al.* Mortality in systemic lupus erythematosus. *Arthritis Rheum* 2006;54:2550-7.
13. Mozaffarian N, Lobosco S. Satisfaction with control of systemic lupus erythematosus and lupus nephritis: physician and patient perspectives. *Patient Prefer Adherence*. 2016;10: 2051-2061.
14. World Lupus Federation, World Lupus Day International Survey (2018). <http://www.worldlupusday.org/filedownloads/Key-Survey-Findings-2018-05-09.pdf>
15. World Lupus Federation, Lupus Knows No Boundaries E-Report. (2017) Available at <http://www.worldlupusday.org/e-report.html>. Last accessed January 2019
16. Neville, C., D. Da Costa, C. Mill, M. Rochon, J. A. Avina-Zubieta, C. A. Pineau, D. Eng and P. R. Fortin. "The needs of persons with lupus and health care providers: a qualitative study aimed toward the development of the Lupus Interactive Navigator." *Lupus* 2014;23(2): 176-182
17. Oglesby, A., C. Korves, F. Laliberte, G. Dennis, S. Rao, E. D. Suthoff, R. Wei and M. S. Duh. "Impact of early versus late systemic lupus erythematosus diagnosis on clinical and economic outcomes." *Appl Health Econ Health Policy* 2014;12(2): 179-190.
18. Al Sawah S, Daly RP, Foster S, *et al.* Understanding Delay in Diagnosis, Access to Care, and Satisfaction with Care in Lupus: Findings from a Cross-Sectional Online Survey in the United States. Presented at the European League Against Rheumatism (EULAR) 2015 Annual Conference. June 2015. Rome, Italy.
19. Larsen, J. L., E. O. C. Hall, S. Jacobsen and R. Birkelund. "Being in a standstill-of-life: women's experience of being diagnosed with systemic lupus erythematosus: a hermeneutic-phenomenological study." *Scand J Caring Sci.* 2018;32: 654-662
20. GSK EnABLE Survey, Final report (2017). <https://www.gsk.com/media/4178/enable-survey-infographic.pdf>
21. Brennan, K. A. M. and A.-M. Creaven. "Living with invisible illness: social support experiences of individuals with systemic lupus erythematosus." *Qual Life Res.* 2016;25(5): 1227-1235.
22. Hale, E. D., D. C. Radvanski and A. L. Hassett, "The man-in-themoo face: a qualitative study of body image, self-image and medication use in systemic lupus erythematosus." *Rheumatology* 2015; 54(7): 1220-1225.
23. Navarrete-Navarrete N, Peralta-Ramírez M, I, Sabio-Sánchez J, M, Coin M, A, Robles-Ortega H, Hidalgo-Tenorio C, Ortego-Centeno N, Callejas-Rubio J, L, Jiménez-Alonso J. Efficacy of Cognitive Behavioural Therapy for the Treatment of Chronic Stress in Patients with Lupus Erythematosus: A Randomized Controlled Trial. *Psychother Psychosom.* 2010;79:107-115
24. Tench CM, McCarthy J, McCurdie I *et al.* Fatigue in systemic lupus erythematosus: a randomized controlled trial of exercise. *Rheumatology* 2003;42: 1050-1054
25. Avaux M, *et al.* Effects of two different exercise programs on chronic fatigue in lupus patients. *Acta Clin Belg.* 2016;71(6):403-406.
26. European Commission. European Reference Networks. Available at: [https://ec.europa.eu/health/ern\\_en](https://ec.europa.eu/health/ern_en) Last accessed April 2019
27. Lupus Foundation of America. LFA-REAL System. Available at: <https://www.lupus.org/improving-clinical-trials/lfareal-system>. Last accessed April 2019
28. Gordon C *et al.* The substantial burden of systemic lupus erythematosus on the productivity and careers of patients: a European patient-driven online survey. *Rheumatology (Oxford)*. 2013 Dec; 52(12): 2292-2301
29. English R, Lebovitz Y, Griffin R. Transforming clinical research in the United States. Institute of Medicine of the National Academies. Available at: [https://www.ncbi.nlm.nih.gov/books/NBK50892/pdf/Bookshelf\\_NBK50892.pdf](https://www.ncbi.nlm.nih.gov/books/NBK50892/pdf/Bookshelf_NBK50892.pdf). Last accessed January 2019
30. Lupus Research Alliance. Lupus Therapeutics Launches Peer Training Program to Help Patients Benefit from Clinical Trials. Available at: <https://www.lupusresearch.org/lupus-therapeuticslaunching-peer-training-program-help-patients-benefit-clinical-trials> Last accessed March 2019
31. The Lupus Initiative. Materials to Increase Minority Involvement in Clinical Trials (MIMICT). Available at: <https://thelupusinitiative.org/mimict> Last accessed March 2019
32. The Lupus and Allied Diseases Association, the Lupus Foundation of America, and the Lupus Research Alliance. Lupus: Patient Voices. Report on Externally-led Patient-Focused Drug Development Meeting: September 25, 2017. <http://www.lupuspdd.org/LupusPatientVoicesFINAL.pdf> Last accessed March 2019

