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Supplement Paper

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Supplement Paper

Improving access to SLE therapies in low and middle-income countries

Claudia Mendoza-Pinto[1,2], Ivet Etchegaray-Morales[2] and Manuel F. Ugarte-Gil[3,4,*]

[1]Systemic Autoimmune Disease Research Unit, Hospital de Especialidades, Centro Médico Nacional, MAV-Centro de Investigación Biomédica de Oriente (CIBIOR), Mexican Institute for Social Security, Puebla, Mexico
[2]Rheumatology and Immunology Department Medicine School Benemérita, Universidad Autónoma de Puebla, Puebla, Mexico
[3]Rheumatology Department. Hospital Guillermo Almenara Irigoyen, EsSalud, Lima, Peru
[4]Grupo Peruano de Estudio de Enfermedades Autoinmunes Sistémicas, Universidad Científica del Sur, Lima, Peru

*Correspondence to: Manuel F. Ugarte-Gil, Grupo Peruano de Estudio de Enfermedades Autoinmunes Sistémicas, Universidad Científica del Sur, Av Panamericana Sur Km 19. Villa El Salvador, Lima 15067, Peru.
E-mail: mugarte@cientifica.edu.pe

Abstract

SLE increases disease burden in those affected with it, and that is particularly the case in low- and middle-income countries. The 2019 Addressing Lupus Pillar of Health Advancement project is a multiphase initiative whose objective is to recognize, hierarchize and establish approaches for diligent SLE research, care and access to healthcare. Lack of access to high-cost medications that have been shown to be efficacious in the short term and that potentially reduce damage in SLE is a complex issue. In this review, we highlight opportunities and plans of action to diminish costs and improve access to therapies, which should be recognized and executed, preferably within regional strategies with multiple stakeholders (including supranational organizations, governments, the pharmaceutical industry, medical societies and the general population) connected with and grounded in structured and clear cost-effectiveness analysis.

Keywords: SLE, low- and middle-income countries, access to healthcare

Rheumatology key messages

- SLE can lead to a significant disease burden, especially in low- and middle-income countries (LMICs).
- Different strategies may be pertinent for improving the quality of therapy in LMICs.
- Suitable orientation of resources to limit harmful treatment delays and access to specialized referral centres is also a priority.

Introduction

SLE is a complex autoimmune disorder with a high impact, disparities in outcomes and increased mortality. The estimated prevalence, incidence and mortality of SLE vary substantially among geographic regions [1].

Earlier disease diagnosis and progress in treatment have led to improved outcomes in recent years. Nevertheless, mortality in patients with SLE remains excessive compared with that of the general population [1]. This high mortality rate can be due to disease severity, socioeconomic causes, reporting bias and access to therapy. It is possible that crucial inequalities in access to healthcare result not only in limitations in access to SLE therapies, but also in treatment heterogeneity; these may compromise patient outcomes [2]. In 2019, the Addressing Lupus Pillar of Health Advancement (ALPHA) project was launched with the objective of recognizing, hierarchizing and establishing action plans for advancing SLE research, care and access as a phase I study [3]. Three top barriers in access to the care pillar were identified as (i) less effective management of SLE, due to social health factors in mainly lower socioeconomic status regions, (ii) absence of patient access to clinical SLE experts, and (iii) limitation of access to medications due either to lack of coverage or to their high costs. Subsequently, phase II of the ALPHA study will deal with solutions applicable to the research obstacles detected in phase I of the analysis [4]. The ranked solutions for access to care included herein are presented in Table 1.

In this article, we review the state of the main obstacles to accessing therapies in patients with SLE in low- and middle-income countries (LMICs) and propose some potential solutions.

Health disparities and the burden of SLE in LMICs

Health disparities are inequalities in health status that are closely linked with economic, social and environmental

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Table 1. Impact of low socioeconomic status and/or non-White ethnicities on SLE-related outcomes

Outcome	Impact	Reference
Mortality	Increased	[10, 11, 13, 14, 20, 21]
Damage	Increased	[10, 17]
Disease activity	Increased	[10, 17]
Renal involvement and damage	Increased	[10, 15, 17, 18]
Work disability	Increased	[16]
Mental functioning	Decreased	[22]

disadvantages [5]. The incidence, prevalence and mortality of SLE vary substantially among patients from different geographic regions [1]. Estimates of the incidence and prevalence in patients of African or Asian backgrounds are around 2–3 times greater than those in Caucasian populations, and a higher risk of mortality has been reported among Black and Hispanic patients than among White populations [1]. For decades SLE has been reported as uncommon in the African continent [6]. Recent clinical research suggest that diagnostic delays caused by poor access to healthcare, limited knowledge about the disease, and a restricted number of rheumatologists might be the real causes of the previous apparent low prevalence of SLE in Africa [7]. With scarce resources for the surveillance of chronic diseases, epidemiological information on SLE remains unidentified in the majority of LMICs. More detailed epidemiological data on LMICs are described in this supplement [8]. Mortality rates were noticeably diverse among nations: in 2014, the highest age-standardized mortality rate (ASMR) was in Latin America, and the lowest was in Europe [9]. Health-outcome disparities have usually been linked with social factors, but genetic determinants may also influence disease severity [10]. As previously mentioned, multiple studies have shown that, compared with White patients with SLE, mortality is higher among Asian, Hispanic and Native patients and those of African ancestry. However, this difference was attenuated or even eliminated when mortality was adjusted for socioeconomic status in the majority of studies [1, 11–14]. The impact of low socioeconomic status and/or non-White ethnicity is depicted in Table 2 [10, 15–22].

Innovation in the pharmacological treatment of SLE

During the last few years, belimumab and anifrolumab have been approved for active SLE, and belimumab and voclosporin for lupus nephritis. This expansion of the therapeutic armamentarium is a welcome addition to the treatment of patients with SLE, demonstrating sustained improvements in disease activity, higher rates of long-term remission, reductions in glucocorticoid exposure, and minimization of the progression of organ damage [23]. Better lupus-activity control, requiring less glucocorticoid administration, may lead to a decrease in the risk of infections, which are the principal cause of mortality in both high-income countries (HICs) (15.1%) and LMICs (37.5%) [24]. In some LMICs, belimumab and rituximab (off-label use) are available (Mexico, Brazil and Argentina, among others); however, access to those SLE therapies is limited in some cases, in both private and public health systems. For instance, in Brazil, in the private health system, biologic therapy is not included on the list of procedures controlled by the National Regulatory Agency for Private Health Insurance and Plans (ANS), limiting its availability [25]. Although some barriers for access apply to both the private and the public health systems, patients in the private system may have better access to belimumab. Access to these new drugs for patients with SLE will be a decisive factor for the future clinical implementation of these study results, and the cost of these new treatments will presumably be a crucial factor in their access, especially in LMICs.

Table 2. Ranked solutions per pillar identified for access to care in lupus[a]

i) Build the case for the World Health Organization (WHO) prioritization of lupus
ii) Develop standardized and specialized, expert-driven care pathways
iii) Drive telehealth advances and reimbursement, and build on current infrastructures
iv) Explore broad partnering
v) Leverage social media
vi) Develop evidence base for interventions, including standardize endpoints/outcomes
vii) Provide prior education and establish alignment

[a] Proposed by the Global Advisory Committee, the ALPHA Project [4].

Specific challenges to LMIC healthcare systems

More than 85% of the world's population live in LMICs [26], where the majority of population growth also takes place; consequently, the burden of SLE will mainly impact individuals residing in these regions. The 2017 Global Burden of Disease Study, which evaluated musculoskeletal conditions (including SLE), provides regular estimates of burden, such as age-standardized Disability-Adjusted Life-Years (DALY) [27]. DALY equals the sum of years of life lost and years lived with disability: one DALY equals one lost year of healthy life, and therefore, DALY allow us to estimate the total number of years lost due to specific causes and risk factors at the country, regional and global levels [28]. In 2017, South Asia had the highest age-standardized DALY rate; however, in the majority of regions, DALY rates decreased between the years 1990 and 2017, except in a group of Latin American countries (Colombia, Costa Rica, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama and Venezuela) (+9.3%). Similarly, southern sub-Saharan Africa (10.5%) and the group of Latin American countries aforementioned (7.7%) showed increasing trends in age-standardized point/prevalence estimates between 1990 and 2017. A Colombian study found that patients with SLE who developed lupus nephritis had a 7-fold increase in mean annual direct costs per patient for the health system in that country compared with patients without it [29]. The overall average annual direct cost per patient has been calculated around 2355 US dollars (USD) in Colombia, while for HICs, the mean annual direct costs per patient ranged from 2214 to 16 875 USD [30]. These numbers emphasize the notable disparity in the investment in SLE care in LMICs compared with HICs.

Of the three newly approved drugs for SLE and/or lupus nephritis, only one, belimumab, is available in many LMICs. Nevertheless, even when additional new medications become accessible, they are generally only available to a favoured group of the population registered in private insurance plans. Generally, public health systems in LMICs exclude relevant new SLE therapies or limit their use to a few indications.

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Interestingly, in LMICs, several biologic drugs (including those used for autoimmune inflammatory diseases) often have prices similar to or even higher than in HICs [31]. In the majority of LMICs, access to health is identified as a legitimate right. On the basis of this legislative overview, and in many cases emboldened by the media, citizens who are unable to access medications via the habitual channels of health systems more frequently raise lawsuits against the government, adducing their legitimate right to healthcare [32]. The judicial system has had to arbitrate repeatably on the funding of a particular therapy for a selected patient. This tendency towards the judicialization of healthcare has exerted an influence on many LMICs. Those legal actions are gradually altering national financial policies, and may lead to a weakening of the viability of public health insurance by redirecting funding further away from a rational application for the community welfare of the general public [33].

Potential solutions

In light of this framework, we present various possible solutions to aid, contain and limit the increased cost of immunosuppressive medications in LMICs (Fig. 1).

Increasing and restructuring of resources for SLE care

SLE, as with other rheumatic diseases, should be a primary health concern in LMICs, and reasonable public financial support is required. After admitting the presence of disparities, an increase of public disbursement for SLE is advisable. However, even if there is a budget increase, fruitful distribution is crucial for rendering effective the acquired funding for high-cost therapies when they are needed. Implementing preventive health-care services for patients with SLE (such as cancer prevention or immunization), medical education programmes, early detection approaches, achieving low disease activity or remission, monitoring adverse events, and preventing damage are just a few examples of valuable actions to strategize these purposes.

Stimulating research that evaluates cost-effectiveness and health technology assessments

Over the past few years, the increased price of medical technologies, such as medications, together with restricted medical-care resources and conflictive policies has become an essential matter for society, and has driven public and private global organizations to explore approaches that permit health systems to accomplish their goals with considerable proficiency. Therefore, enormous efforts are required to identify these mechanisms.

In recent years, the 'value' of SLE treatments, in terms of taking into account assessments of their cost, efficacy and safety, has needed to be considered when balancing whether a new technology should be integrated into the preventive, diagnostic and therapeutic reserve of a health system. In addition, the leading specialist medical societies for rheumatology should use background information to explain the impact of SLE care in various clinical scenarios. Different approaches have been proposed by health economists to conduct cost-effectiveness analyses, including two central measures: quality-adjusted life years and incremental cost effectiveness ratios [34]. Generally, these cost-effectiveness measurements incorporate the health technology assessment (HTA) methodology, which is described as the 'systemic evaluation of medical technologies concerning their effectiveness, appropriateness and efficiency, as well as social and ethical issues and implications' [35]. Such appraisals are responsible for coordinated, evidence-based information for decision-making regarding health-care preferences, reimbursements and handling options in order to achieve maximal competence in the distribution of public budgets [35]. In view of these concerns, HTA is considered 'the bridge connecting evidence and policymaking' [36]. HTAs are executed by public and private institutions employing regulatory organizations and consultative boards. These bodies are constituted of a diverse mixture of stakeholders, such as physicians, academicians, pharmacists, medical economists, insurance and industry representatives, and patients [37]. HTA units are less advanced in LMICs than in HICs, and there can be considerations with respect to executing the findings of HTA analyses [38]. Recently, in order to generate evidence to inform HTAs of treatment for SLE, a systematic review of the decision-making model analysis of economic evaluations was carried out; it was found that, due to complexities in the diagnosis, management and progression of SLE, these evaluations are challenging and need to be improved [34].

Flexible patent laws for the use of generics and biosimilar drugs

Generics are chemical, small-molecule drugs that possess structural and therapeutic equivalents to a reference product, while biosimilars are non-original biologic medicines with active ingredients that mirror the biologic originator and that exhibit no clinically meaningful difference in safety, potency or efficacy. The use of generics and biosimilars provides significant cost-saving alternatives for patients and health-care systems that are comparable in efficacy and safety with novel products for certain indications in rheumatic diseases [39]. However, the successful use of biosimilars demands pharmacovigilance systems and adequate drug competitiveness to

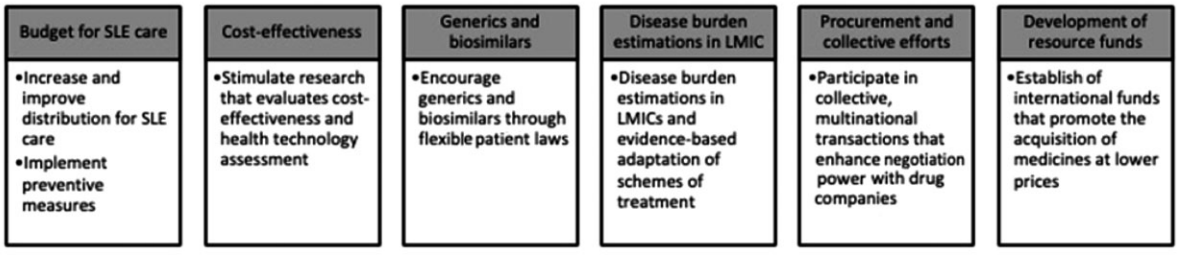


Figure 1. Some potential strategies to increase access to SLE therapies

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push costs lower; of note, the majority of LMICs, including the Latin-American countries, have been excluded from the issuing of regulatory directions and valid pharmacovigilance systems for these types of medications [40]. In terms of recent responsibilities determined by prevailing scientific innovations, the reform of patent laws to obtain equity between public and private commercial concerns is of importance. Lastly, as the Pan American Health Organisation has declared, Latin-American nations must guarantee that the flexibilities of Trade-Related Aspects of Intellectual Property Rights (TRIPR) are assimilated into their legal structures [32] and that, at the time of their adopting these procedures, it is better to execute them within regional or sub-regional resolutions, which is preferable to negotiating with extrinsic forces and evading mercantile penalties.

Improvements in disease-burden estimates in LMIC and evidence-based adaptation of treatment approaches

Better estimates of the disease burden by relying on lupus registries from the Centers for Disease Control and Prevention [41], either through national SLE surveillance schemes or via local epidemiological analyses, would support drug forecasting, streamline ordering and optimize the utilization of donations. This information would enable the evaluation of market tailoring for manufacturers in order for this to be developed and allow for competitive price negotiations. SLE guidelines should provide recommendations on new SLE therapies that are personalized for clinical settings and should offer counselling on how to minimize more adverse events and monitor SLE therapies, so that improved access does not cause more harm than good. These recommendations require translation into country-specific or region-specific management guidelines. Pharmaceutical corporations should incorporate new therapies into collective responsibility policies on SLE and contemplate favoured costing for LMICs.

Procurement and collective efforts

As mentioned, the value of high-cost medication frequently differs among nations. The purchasing of these in a region such as Latin America or Asia would provide specific nations with the prospect of engaging in unified, international agreements that strengthen their capacity for negotiation with pharmaceutical companies and would, presumably, diminish administrative expenses [42]. The Model List of Essential Medicines proposed by the World Health Organisation (WHO) [43] aids policymakers in decreasing costs by assisting them in the difficult duty of choosing the drugs that will have the greatest influence on public health and, consequently, on the adequate distribution of restricted funding. The introduction of novel medications into the WHO list embodies decisive progress in advancing their affordability, in that it satisfies the formidable mechanisms to be applied in the area of price discussion and procurement with drug companies, jointly with non-governmental institutions, professional organizations and patient associations, in order to influence governments and financiers.

Generation of resource funds is an approach connected with engaging in negotiation and procurement for the establishment of multinational resources that promote the obtention of drugs at less cost through mass acquisitions. This plan is particularly favourable for small LMICs that, in different circumstances, are required to pay higher prices for limited amounts.

Involvement in clinical research

LMICs are increasingly important in the performance of clinical trials. Many LMICs do have the regulatory structure, the clinical facilities and the number of patients needed to contribute to excellent research, and some LMICs have been ranked among the top 25 nations with highest involvement in clinical trials [44]. To a certain extent, participation in a clinical trial provides access to both standard and experimental therapies that are otherwise not accessible in LMICs. Nonetheless, this use is linked with ethical aspects, which are in turn associated with financial conflicts of interest and the suitability and affordability of the approved therapies [45]. Participation in clinical trials could be employed to reduce disparities between HICs and LMICs, which can be utilized to negotiate an affordable cost [43].

What can rheumatologists do?

Rheumatologists and experts in SLE who take care of underprivileged populations may be proactive rather than merely reactive as observers with respect to their circumstances. Rather than accepting what the industry proposes, a critical analysis of the evidence must be carried out for the existing clinical benefit of innovative agents to protect the reasonable utilization of therapy. In this regard, physicians are engaged in establishing national or regional recommendations for SLE management and verifying that SLE therapies with favourable cost–benefit balances are incorporated into national formularies [46].

For a critical analysis of evidence for interventions and to include cost awareness and the understanding of cost-effectiveness analyses, health education, especially in LMICs, should be expanded. With reliable instruments, experts are poised in an advantageous situation to collaborate in the discussion of economic priorities in healthcare and to persuade all possible stakeholders.

Conclusions

Novel drugs have notably improved SLE outcomes. Unfortunately, their high costs have proven excessive for the majority of LMICs, and even for wealthier countries. The prevalent rheumatology pricing framework is not sustainable and is risking the finances of health systems. Yet more disquieting is the reality that those expensive medicines must still be proven to have longer-term clinical benefits in individuals with SLE. This growing problem needs to be confronted. Some of the first steps required for the judicious distribution of restricted resources encompass the inclusion of methodological and transparent cost-effectiveness analyses completed via impartial, multidisciplinary panels or health-technology agencies. Based on these estimates, auxiliary recommendations can be designed, including debates and collective discussions, to address funding and the procurement thereof, contrasting pricing, expanding the application of evidence-based adapted management strategies and of the integrity of generics and biosimilars via TRIPR adaptabilities, and participation in clinical trials.

We consider that the potential solutions suggested across this review are likely to be more productive within a

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collaborative regional strategy. The obstacles and responsibilities of LMICs' health-care systems exceed nationwide administrative frontiers and have to be confronted collaboratively to improve national competences, to contrast outstanding procedures, and to relocate scientific and technical performance. Ultimately, all stakeholders, including the general public, must come to perceive that guaranteeing access to drugs amidst skyrocketing prices *per se* is implausible for implementing the amelioration of SLE deaths in these regions. SLE management is a prolonged spectrum with various areas for action, varying from early diagnosis with access to care to therapies and supportive care. Therefore, access to SLE therapies presents only a minuscule view of this challenge.

Data availability

No new data were generated or analysed in support of this research.

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