



# **A Survey of Barriers to Treatment Access in Rheumatoid Arthritis**

***Country Annex Report: Mexico***

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## 1 Interviews

A qualitative research based on in-depth interviews, was conducted in Mexico City. Participants were rheumatologists, internists, general practitioners and traumatologists. Their practice was governmental as well as private, at hospitals and office based, including specific physicians who attended insured patients. The sample of totally 15 respondents was formed with the distribution presented in Table 1.

**Table 1: Mexico - Affiliations & specialties of respondents**

Affiliation	Rheumatologists	Traumatologists	Internists	GPs
IMSS	4	1	1	1
ISSSTE	2	1		
MH	3		1	1
<b>TOTAL</b>	<b>9</b>	<b>2</b>	<b>2</b>	<b>2</b>

Note: The respondents are anonymous due to the ESOMAR code; IMSS= Mexican Social Security Institute; ISSSTE= Institute for Social Security and Services for State Workers; MH=Ministry of Health

## 2 Environment

### 2.1 Health care system

The Mexican health system is a plural system that includes different organization schemes, diverse services and financing, providing services for 105 million people. There are at least three schemes: private insurance, social security (health system for private employees (IMSS) and public employees (ISSSTE)) and the System for Social Protection in Health (SPSS, Sistema de Protección Social en Salud), also known as Seguro Popular (Popular Insurance). The first system is financed through individual contributions with direct payments and/or contributions to private insurance companies, made by employers or individuals; the second system is funded through a tripartite contribution, with contributions from the Federal Government, employers and employees; the third system is financed through Federal Government contributions, a recovery quote paid by affiliated families and a mixed contribution from the Federal Government and the State Government. Services are rendered in private institutions in the first instance, and in public hospitals in the second and third instances. Due to the existing pluralism, each has a different series of services, thus, private schemes cover the services that may be afforded; social security, with some exceptions, covers any disease; and the SPSS covers a package of interventions, although not covering all pathologies, As each institution in the different systems is autonomous, data reporting is usually heterogeneous and partial.

The program focused on people who are uninsured, the SPSS (or Seguro Popular), was implemented in a pilot phase in 2002, but not in all states of Mexico. Since the system manifestation in 2004, the pathologies covered by the system has marginally increased, although still only covering diseases classified as catastrophic. Nevertheless, the SPSS has facilitated an increase in the number of Mexicans eligible for enrolment into the Universal Health Insurance, where 45% of all inhabitants are covered by social security and 29% by

SPSS<sup>i</sup>, amounting to 74% of inhabitants enrolled in the Universal Health Insurance in 2009<sup>ii</sup>. Additionally, 5.7% of the inhabitants are privately insured<sup>iii</sup> whereas 20.3% of the inhabitants remain uninsured. The Mexican government has set a target of 2012 to cover those uninsured into the Universal Insurance. A premium based on income is paid by families, whilst those without an income are exempt from payment. In spite of the array of services, the inequality of service provision has been noted since such a system is characteristic of different levels of service provision based on funding received by different service providers.

In 2007, the official report of health expenditure in Mexico was 6.5% for 2005, where 56% corresponded to private expenditure and the remaining 44% to public expenditure. According to the Organization for Economic Cooperation and Development (OECD), Mexico is still below average compared to similar countries.

### 2.2 Market access and reimbursement

Access to drugs in Mexico depends on the financing scheme where individuals and/or their families are included. In the event of private financing at an individual level, it depends on the affordability of the individual, and on the coverage of the insurance contracted. In the instance of social security, there is a Basic Drug Formulary (CBM, Catálogo Básico de Medicamentos) for all the institutions involved: IMSS, Institute for Social Security and Services for State Workers (Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado – ISSSTE), Health Service Institute of Petróleos Mexicanos (PEMEX – a MH institution) and Armed Force Services. This CBM includes all the treatment possibilities that have been accepted as safe, efficient and, most of them, cost-effective (starting to be requested for the first inclusion step, although not clearly regulated). After their inclusion in the CBM, each institution decides individually the supplies that will be included for the population served. Prescription of medications depends, on the one hand, on the care level of practitioners, and on the specialty on the other. There are medications, such as some DMARDs that are only prescribed by specialists, e.g., a rheumatology specialist or a physician specialized in internal medicine, while others, such as NSAIDs, may be prescribed by a GP. Thus, in public practice, prescription is limited due to budget constraints, while in private practice, insurance drugs – and even others – may be prescribed.

The reimbursement concept, as known in other markets, is not applicable to the Mexican Health System. However, regarding price management, this depends on the instance under consideration. For the private level, prices defined by pharmaceutical companies for their drugs must be obtained through the Ministry of Economy that establishes a price cap. Then, market conditions provide the option to manage prices at the pharmacy and hospital level. Usually, private medical insurances cover partially or totally the cost of therapy, depending on the type of policy contracted by the insured person. Although insurance companies do not establish limits clearly, when the medication is included or the disease was diagnosed within the policy term, some are starting to establish a formulary for the drugs covered, which could limit future entry of new active substances. At the level of IMSS, Pemex, ISSTE and the Army, medications that are included in their formulary (Basic Formulary) are paid by

<sup>i</sup> Comisión Nacional de Protección Social en Salud (CNPSS)

<sup>ii</sup> Sistema Nacional de Información en Salud (SINAIS) & CNPSS

<sup>iii</sup> Asociación Mexicana de Instituciones de Seguros (AMIS) 2009

the institution and patients do not have to pay any cost for the medications. However, for expensive treatments, institutions establish limits regarding the seriousness of the disease, the specialty level they may prescribe or through internal budget controls. Some hospitals instruct their specialists that they may only address needs with high-specialty medications, as in this case, with biologics, for a limited number of patients, trying to achieve with this a selection of those patients who are and are not entitled to this therapy. Other health providers, such as Institutos Nacionales (high-specialty hospitals), only provide care to patients not covered. These patients usually have to pay parts of every medication prescribed, that will depend on their previously evaluated socio-economic level.

### 3 Features specific to RA

RA has been mentioned as one of the health problems in official documents of the Mexican government in the past years. It has been recognized just recently as a catastrophic disease due to the high costs it represents and the disability produced. However, it does not have an important specific weight as this disease is not considered in health actions, either through specific programs or research lines to fill information gaps.

A study carried out in one of the suburbs of Mexico City of 2500 subjects revealed that 25% had musculoskeletal pains not related to trauma (recent or in past). The study revealed a 0.3% prevalence of RA amongst adults [1], the majority of them treated by a GP. 75% of the RA patients took some medication for RA, out of which 75% received good efficacy. The study also showed a gender prevalence ratio of 1:3 representing males and females respectively for RA. Females had a higher frequency of reporting pain than males. Help seeking behavior was determined by three factors: age, severity of pain and associated disability. Still, registry data on RA patients in Mexico are scarce.

### 4 Guidelines

Although rheumatologists are familiar with the American and European guidelines, they all follow the guidelines provided by the American College of Rheumatology which the Mexican College of Rheumatology tends to imitate as its own guidelines [2]. It has been acknowledged by the respondents in the interviews that foreign guidelines are not appropriate for the country, in terms of medication choices and timelines for treatment milestones, due to the high cost of main drugs for RA and the low acquisition level of the population. In addition, respondents stated that the European guidelines are inappropriate in terms of the strict timings established for each of the steps of RA management, since each one represents an expenditure that Mexican patients cannot afford.

Mexican guidelines, unfortunately, are very superficial and not well adapted for the country's conditions, in terms of what are imperative tests and drugs. The guidelines for use of biologics have, according to some respondents, low credibility because the pharmaceutical industry is identified as their sponsor. Still, the guidelines reflect an international scientific consensus supported with evidence based medicine, increasing their credibility. The respondents of the interviews inform that there currently is a strategic plan for RA management, waiting for approval from governmental agencies. Their hope is that this plan

will result in improved Mexican guidelines for the management of RA and will have positive implications to finance a larger number of available treatments at government hospitals.

### 5 Provision of care

As stated earlier, the myriad of health care provision in Mexico has led to unequal service provision which is dependant on levels of funding for particular groups of people. Increased health provision is concentrated in the larger cities which have a high concentration of private and public sector workers who are able to boast their local health care system funding with employment contributions.

Official data on access to health care and treatment for any disease is variable. Regionalization of resources is a typical feature of the Mexican health system, with the highest concentration in the cities. Mexico City with population of 8.7 million has 71.4%<sup>iv</sup> of all rheumatologists, whereas the State of Quintana Roo with a population of 1.1 million has no rheumatologist (Association of Rheumatologists in Mexico). In areas where there are no rheumatologists available, patients get diagnosed and treated by their GP or internal medicine practitioner. According to the respondents, there is hence a risk that the physicians have little knowledge of biologics use and these patients may therefore miss out on the appropriate treatment unless they travel to a specialist.

In 2005, there were approximately 142,623 physicians working in the public sector. However, medical students and pre-graduate interns are also involved in the consultation process as an alternative to a qualified physician. An additional 55,173 physicians work in the private sector, resulting in 75–93 physicians per 50,000 inhabitants. However, some physicians work in both sectors (just adding them would make an over estimation) and some are restricted to certain services and therefore will not be available as initial contact for RA patients. The number of physicians attending RA patients is significantly less, an estimation from Instituto Nacional de Geografía y Estadística (INEGI) and Programa Nacional de Salud (PRONASA) 2007-2011, suggesting a total of approximately 25,000 GPs, students and pre-graduate interns within the public health care, the corresponding number for private sector unknown. There are 474 active specialist rheumatologists although it is not clear whether these are working in the public sector or private sector (Censo del Colegio Mexicano de Reumatología). This means that the number of specialist rheumatologists per 50,000 inhabitants is approximately 0.23. The Association of Rheumatologists in Mexico states that the figure is 0.95 per 50,000 inhabitants. Physicians (GPs) require first 4 years (previously 2 years) training to be an internal medicine specialist and thereafter another 2 years to become a specialist rheumatologists.

Timely treatment and diagnosis may also be dependent on equipment to establish RA diagnosis. Data from Observatorio del desempeño Hospitalario SSA 2006 suggest that the number of MRI scanners are low, amounting to 0.26 MRI per million inhabitants.

The limited number of rheumatologists and limited access to an unequally funded health care system leads to the conclusion that some RA patients will have restricted access to

<sup>iv</sup> Based on the number of affiliated members in the Association of Rheumatologists in Mexico.

treatment. Access to treatment is likely to vary between regions and social groups with those in cities and a stable income having easier access.

## 6 Diagnosis

In all government institutions, at a first level clinic, suspicion of diagnosis is made by the first contact physician, who is in most cases a GP. At IMSS, it takes 6 to 12 months for a patient to get to the rheumatologist because GPs attend at first level sites, where they are treated with NSAIDs and steroids, and very rarely with methotrexate. After several monthly visits, if the problem persists, the patient is forwarded to Internal Medicine at a second level clinic, where DMARDs and NSAIDs are the base of treatment. Patients are referred to a rheumatologist after 6-12 months to confirm or discard RA diagnosis. Treatment is recommended if required. ISSSTE and MH work very similarly but seem to be a little bit faster in referring the patient to the rheumatologist. Before the above situation can happen, a patient takes 6 to 12 months to reach the medical aid, from the moment he/she experiences the first symptoms at home. Private patients take around 1-4 months, but in both cases, this time is not only due to indecision and lack of health culture, but can be attributed to the tendency to ignore existence of pain and mistake this to be caused by strain, contusions, wrong position, or weather changes. Published studies state that it can take three years to receive a correct diagnosis from a specialist [2, 3], it is hence probably varying across the country.

Practitioners have confirmed that there are no restrictions for laboratory tests that are required at each step. This means that all are covered at IMSS, ISSSTE and PEMEX. Other MH hospitals, like Hospital General do not have a basic formulary to cover medicines nor tests. In this case, the patient pays for all the tests. However, it was highlighted that the anti-CCP test is unavailable at ISSSTE and MH hospitals. The perception is that this test is specific for differential diagnosis. The availability of imaging machines (MRIs 0.26/1 million inhabitants) is scarce and rarely used for diagnosis of RA.

The diagnosis is clinical in 80% of the cases whereas in 20%, diagnostic tests are required. However, in most of the patients already clinically diagnosed, tests are made to decide treatment and to differentiate from other similar illnesses such as osteoarthritis, arthropaty and parvovirus infection. The following observations are used to obtain clinical data for diagnosis:

- ◆ Symmetry in affected joints
- ◆ Tiredness
- ◆ Fever
- ◆ 25 - 60 years of age

After diagnosing RA, practitioners will in most cases classify patients according to the evolution and severity of the disease. A traumatologist (Orthopaedic) is not part of the treating panel at government institutions for RA management unless surgery is required.

The different stages of disease evolution can be classified as low, moderate and severe (has the worst prognosis).

## 7 Treatment

### 7.1 DMARDs

Rheumatologists as well as physicians in internal medicine are best trained to prescribe DMARDs. However, even though GPs acknowledge that rheumatologists or internal medicine are best placed for prescribing DMARDs, they are in some cases also involved in prescribing. GPs who prescribe DMARDs have stated that they have learnt to do this through experience based on reviewing and following other specialties prescriptions. Thus, they can manage patients when they return to their level (at governmental segment) or can initiate treatment in a few patients in their care. It was noted from the interviews that GPs are not familiar with the family name 'DMARDs' but are familiar with methotrexate or leflunomide.

In both the public and private care system, the following pattern is typical for DMARD treatment and management of RA patients up to the initiation of biologics. The only difference will be a longer waiting time under the public care system:

- ◆ Out of 102 patients with confirmed RA, 100 will receive methotrexate, 2 will not receive it due to drug intolerance
- ◆ 30 out of 100 will receive it as a monotherapy and will have positive results.
- ◆ 70 out of 100 will receive it in combination from start. This will most likely be in combination with leflunomide, but also with other DMARDs already mentioned.
- ◆ 40 of those 70 patients will have good results and continue with that treatment for a long period
- ◆ 30 out of 70 patients (42% of the patients treated with double or even triple DMARD scheme, but 30% of all patients that were started with a DMARD, which are almost 98% of patients with RA that contact a physician) will not have positive results, after monitoring for 4 to 6 months, and are candidates for a biologic.

Although methotrexate is defined as the most used drug, the Mexican Rheumatology Board on DMARD proposes leflunomide as first-line in the future.

All specialists are familiar with corticosteroids and are considered a bridge or rescue treatment. GPs can start low dosage treatment for 3 months in patients with severe pain and inflammation until the patient reaches the next level (internal medicine or rheumatologist). At this stage, it may be used in addition to NSAIDs, and at some point coexists also with DMARDs. It can continue to be used until the combination of drugs used for remission proves effective.

## 7.2 Biologics

PEMEX physicians stated that if the best results are not being achieved with the use of methotrexate alone and the patient had no financial restraints, biologics can be started immediately. However, this is not the common algorithm. Biologics are though the drug of choice almost one year after the combination of NSAIDS, DMARDS and even steroids have proved to be ineffective. The use of biologics is however not recommended in Mexico under the following conditions:

- ◆ History of cancer within the last 10 years
- ◆ Currently infected with tuberculosis

In the private care system, price consideration reduces the potential market since costs are around 15,000 pesos/month (\$1,100 USD), as an average of the three anti-TNFs available. Exception is rituximab, which has a reduced dosage scheme of only 2 consecutive applications with a cost of 80,000 pesos each (\$5,850 USD), meaning in addition an out of pocket cost of 160,000 pesos (\$11,700 USD) annually. These prices are affordable for only few patients at a private level. Patients prescribed rituximab will in most occasions have to pay up front because insurance companies do not always prepay the medication and therefore patients have to seek reimbursement later. Most patients are unable to pay up front, thus limiting access. The following factors also determine a patient's choice for a biologic:

- ◆ Preferring ambulatory application rather than infusion at the hospital or special center
- ◆ Preferring weekly rather than biweekly administration
- ◆ A medical practitioner may have a bias for a particular brand

According to the respondents of the survey, etanercept tends to be the first biological option because of longer experience and wider clinical evidence, illustrated in Table 2. Adalimumab tends to be the second option and for patients that do not want weekly administration (adalimumab has every two weeks whereas etanercept has every week). As third of fourth option, infliximab is often used and it is also used for patients who want to be monitored by a physician. Rituximab is mainly used after failure of anti-TNFs (high out of pocket expenses).

**Table 2: Biologics used for treatment of RA**

Treatment line of biological treatment	Biologic	Reasons for change
1 <sup>st</sup> Line	Etanercept	Patient preferences
2 <sup>nd</sup> Line	Adalimumab,	Patient preferences
3 <sup>rd</sup> Line	Infliximab , Rituximab	Monitoring in hospital

Infusion chairs or pulses rooms, used for chemotherapy administration as well as for inflixmab or rituximab use, are available at third level of all governmental hospitals. Rheumatologists are aware of 4 to 5 chairs sponsored by Schering Plough or Roche located in Mexico City at Hospital Español, Clínica Londres, Hospital Medica Sur, and somewhere in Ciudad Satélite (Mexico city suburbs). However, very little is known about the magnitude of use of these chairs for RA treatments.

### 7.3 Treatment consistency with EULAR recommendations

It should be noted that respondents in the interviews stated that the EULAR guidelines are not applicable in Mexico and therefore clinical practice may differ more than in other countries. Still, for the purposes of this study and for reasons of comparability between countries, an evaluation using EULAR guidelines is made (Table 3).

According to EULAR recommendations, a patient presenting with RA should be referred to a rheumatologist within 6 weeks after symptoms have been identified. Results of this study found a lack of adherence to this recommendation. The time to be attended by a specialist after disease onset is between 6-12 months in Mexico because of the health care system of three levels before having the possibility to attend a rheumatologist (in most cases). The time may be shorter when covered by a private health plan but longer if in a public health plan, specifically in rural areas. With regards to lab tests and imaging techniques, there seem to be a discrepancy between the guidelines and clinical practice, these are scarcely used in Mexico.

Some evidence suggests that Mexican clinical practice adhere to the guidelines with regards to DMARD therapy. Patients receive methotrexate as a first line treatment and initiation and switching cohere with the guidelines.

In addition to pharmaceutical treatment, non-pharmaceutical interventions such as physiotherapy, occupational therapy and psychotherapy are recommended.

**Table 3: Comparison of EULAR guidelines with practice**

EULAR Guidelines	Adherence to Guidelines
Reference to specialists within 6 weeks of disease onset	It takes 6 to 12 months for patients to be referred to a rheumatologist.
Ultrasound, Doppler & MRI for disease diagnosis	Scarcely used for diagnosis.
Lab tests required for diagnosis	Not all are used. Tests used include simple plaque, rheumatoid factor and acute phase reactants.
Recommended measurement factors for patients with early arthritis	All except CCP
Patients receiving DMARDs within recommended timeframe	There is compliance with this guideline.
Methotrexate considered as first line	Evidence of adherence to this guideline
Disease monitoring and events guides decision for switching of DMARDs	Evidence of adherence to this guideline
Non-pharmaceutical intervention recommended to complement pharmaceutical intervention	Physiotherapy, Occupational therapy and Psychotherapy recommended

Table 4 below lists the adherence of national practice to the EULAR guidelines by source of information (desk review or interviews). The results indicate that with regards to diagnosis, the Mexican clinical practice does not cohere with the guidelines. Some conflicting evidence was found with regards to treatment and monitoring, where the desk research found some breaching to the guidelines on information programs, DMARD initiation and monitoring of the treatment and disease.

## Barriers to RA treatment access across Latin America: Mexico

**Table 4: Consistency of Mexican RA practice with EULAR recommendations**

National practice consistent with EULAR recommendations				
	EULAR recommendation	Desk research	Interviews	Comments
<b>Diagnosis</b>	Patient presenting with arthritis is referred to and seen by a rheumatologist ideally within 6 weeks of symptomatic onset	No	No	Takes 6-12 months
	Clinical examination for detecting arthritis includes ultrasound, power Doppler and MRI	No	No	
	Diagnosis requires at least the following laboratory tests: complete blood cell count, urinary analysis, transaminases, and antinuclear antibodies	No	No	Diagnostic tests include simple plaque, rheumatoid factor and acute phase reactants
	Measurement of the following factors for patients presenting with early arthritis: number of swollen and tender joints, ESR or CRP, level of RF and anti-CCP antibodies, and radiographic erosions bodies	No	Yes	Except Anti-CCP
<b>Treatment</b>	Patients developing persistent/erosive arthritis should initiate DMARDs as early as possible	No	Yes	Gaps in proportion of patients receiving DMARDS
	Use of patient information and education programmes about coping with pain and disability and maintaining work	No	Yes	There are programmes sponsored by Roche, Mexican Rheumatology College and IMSS
	NSAIDs are considered in symptomatic patients	Yes	Yes	
	Among DMARDs, MTX is considered the anchor drug and should be used first in patients at risk of developing persistent disease	Yes	Yes	
	Systematic glucocorticoids to reduce pain and swelling are considered as a (mainly temporary) adjunct to DMARD treatment	Yes	Yes	
	The main goal of DMARD treatment is to achieve remission. Regular monitoring of disease activity and adverse events guide decisions on the choice or change of DMARDs and/or biologics used	No	Yes	Inconsistency in desk research as to the guidance of decisions
	Non-pharmaceutical interventions, such as dynamic exercises, occupational therapy and hydrotherapy, are applied as treatment adjuncts	Yes	Yes	
<b>Monitoring</b>	Disease monitoring includes tender and swollen joint counts, ESR and CRP assessment at 1 to 3 months	No	Yes	No follow-up recommendations of x-rays identified in desk research
	Structural damage is assessed by X-ray every 6 to 12 months. Functional assessment is used to complement disease activity and structural damage	No	Yes	First assessment 6-12 months from diagnosis. Afterwards, only if/when needed every 24 months

## 8 Conclusions

There are several barriers to RA treatment in Mexico, mainly due to a large proportion of people who are uninsured or with limited coverage and lack of specialists, especially in rural areas. The barriers can be summarized under the following points.

- ◆ Insurance gap

One of the major barriers to treatment for the Mexican population is the large proportion of inhabitants that are uninsured (20%) or only have limited health coverage (29%). These patients hence have limited access to innovative and high-quality health care, including biologic treatments for RA, unless they pay for it themselves which few can afford.

- ◆ Limitations for prescriptions and equipment

In Mexico, there are regulations restricting prescriptions which limit access to treatment for patients. First, only specialists (or GPs specialized in internal medicine) prescribes DMARDs or biologics. Second, institutions may have limits regarding who can receive therapy based on disease severity or through internal budget controls. There are also high out of pocket expenses needed for some treatments, limiting the selection even for those covered by insurance. Differences are also detected in available treatment budgets between urban and rural areas. Large cities tend to have more people employed with a stable income and thereby have better funds available within the insurance schemes. Evidence set forth in this study also suggests a shortage in available imaging techniques and lab tests to determine RA diagnosis.

- ◆ Access to rheumatologists

There is also a lack of rheumatologists, especially in rural areas. A large proportion is found in Mexico City. Also, it takes all together 6 years (4 previously) to become a specialist which probably further limits the number of rheumatologists. There is hence a regional difference in access to specialists, and because of the limitation for prescription, this further limits the access to treatment in rural areas. Rheumatologists are also situated in the third level of care, meaning that patients most often need to go through first and second level before attended by a specialist. This leads to long referral times.

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