

## **Hydroxychloroquine Access for People with Lupus During the COVID-19 Pandemic**

People with lupus are immunocompromised, meaning at greater risk for infection both from the disease and certain treatments. Hydroxychloroquine (Plaquenil) is one of the most frequently prescribed medications for lupus. It helps to mitigate symptoms with much fewer side effects than other commonly used medications.

As the novel coronavirus began making its way across the globe, fear and panic set in. The global medical and scientific community quickly began testing medications that might treat COVID-19. Hydroxychloroquine was one of the first to be tested. Although the preliminary study results were mixed, members of the medical community began writing prescriptions for hydroxychloroquine for people who did not have any of the FDA-approved indications.

As the US began to shut down in early March due to the coronavirus pandemic, it was recommended that the public secure supplies for a two-week home isolation period including enough medications to treat any chronic conditions.

In mid-March, hydroxychloroquine was mentioned at a nationally televised Coronavirus Task Force briefing and became a hot topic as its effectiveness in treating COVID-19 was debated. Shortly afterwards, people who take hydroxychloroquine for its approved uses including lupus and RA began reporting difficulties refilling their prescriptions. In late March, state governments got involved and began passing executive orders prohibiting dispensing of hydroxychloroquine for conditions not FDA approved.

On March 28, the FDA issued an Emergency Use Authorization (EUA) for Chloroquine Phosphate and Hydroxychloroquine Sulfate for Certain Hospitalized COVID-19 Patients, but shortages continued.

Advocacy groups moved quickly to ensure that people who depend on hydroxychloroquine to control their symptoms can get their medication.

- On March 31, a letter organized by the American College of Rheumatology and signed by over 50 advocacy organizations, was sent to Governors of all 50 states.
- On April 3, the LRA sent a letter from President and CEO Ken Farber to Congressional leadership.
- On April 12, the LRA sent a letter led by SAB chair Dr. Gary Koretzky and signed by leading scientists, to the heads of HHS, FDA and NIAID.

The hydroxychloroquine shortage continued to be a major topic on the news. Manufacturers of hydroxychloroquine ramped up production, and hundreds of thousands of doses were sent to the national stockpile for use in hospitals and in clinical trials to treat COVID-19.

In light of emerging data, the FDA issued on April 24 a Drug Safety Communication that cautioned against use of hydroxychloroquine outside of the hospital setting or a clinical trial due to risk of heart rhythm problems.

The utility of hydroxychloroquine for COVID-19 continues to be debated. However, as production increased, millions of doses were donated, and state regulations on dispensing prescriptions took effect, people with lupus began to report being able to refill prescriptions. But it has not been without a cost.

## Results From the Hydroxychloroquine/Plaquenil Access Survey for People with Lupus

In order to better understand the impact of the COVID-19 pandemic on the ability of people with lupus to continue treatment with hydroxychloroquine, the LRA created an online survey that was made available from May 6 to May 18. The survey was announced through multiple channels including the tens of thousands of people who receive LRA's emails and follow our social media channels.

The survey asked respondents to share their experiences in refilling hydroxychloroquine beginning March 1, 2020.

### Summary

Responses were received from across the United States and ranged from not needing a refill in the indicated time frame to being unable to refill their prescription with many different experiences in between.

- 334 people with lupus completed the survey with responses representing residents of 42 states and the District of Columbia and Puerto Rico
  - 31% had issues getting refills
  - 5% were not able to refill in this time frame
  - 4% did not need refill in this time frame
  
- Of the 36% who were not able to or had issues with refills
  - 66% had enough to take full dose
  - 33% split doses
  - 9% were completely out
  
- 72 people reported difficulty, but eventually being able to get their refill
  - 36% could not get it from their regular pharmacy
  - 58% reported it taking two or more weeks to get their refill

Some people reported being prepared in response to the pandemic in general, ensuring they had enough medication on hand to get through the uncertainty. Others quickly worked to get refills upon first hearing about the potential for hydroxychloroquine as a treatment for COVID-19. Several people indicated they were informed by their pharmacy that there might be a shortage coming and were able to get their refills.

Others needed to call multiple pharmacies to find one that could fill their prescription. Many could not get their normal supply and had to accept 14- or 30-day supplies. This resulted in concerns about possible exposure to the novel coronavirus due to necessitating additional trips to the pharmacy.

One common theme from respondents was the stress and anxiety this caused them.

## Respondent Characteristics

- Nearly half of respondents (49%) were diagnosed with lupus for 10 years or less with the average being 13.6 years.

| Number of Years Diagnosed with Lupus |             |             |
|--------------------------------------|-------------|-------------|
| Age Range                            | # Responses | Percent (%) |
| < = 5                                | 113         | 34          |
| 6 - 10                               | 50          | 15          |
| 11 - 15                              | 48          | 14          |
| 16 - 20                              | 34          | 10          |
| 21 - 25                              | 36          | 11          |
| 26 - 30                              | 24          | 7           |
| 31 - 35                              | 17          | 5           |
| > 35                                 | 12          | 4           |
| Total                                | 334         | 100         |

- 63% have been taking HCQ for over 5 years with the average being 11.4 years.

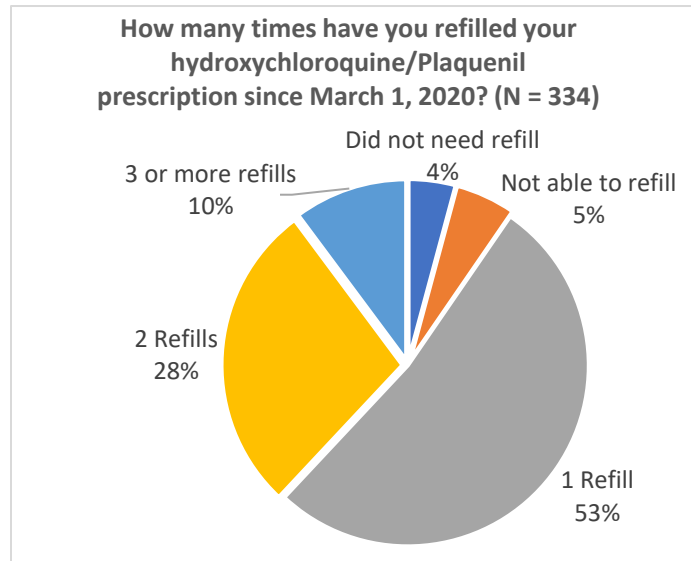
| Number of Years Taking Hydroxychloroquine/Plaquenil |             |             |
|---|-------------|-------------|
| # Years   | # Responses | Percent (%) |
| < = 5   | 123         | 37          |
| 6 - 10  | 68          | 20          |
| 11 - 15   | 46          | 14          |
| 16 - 20   | 32          | 10          |
| 21 - 25   | 35          | 10          |
| 26 - 30   | 18          | 5           |
| > 30  | 12          | 4           |
| Total   | 334         | 100         |

- Responses were received from residents of 42 states and DC and Puerto Rico
  - 10 or more responses from 11 states represented 63% of total responses

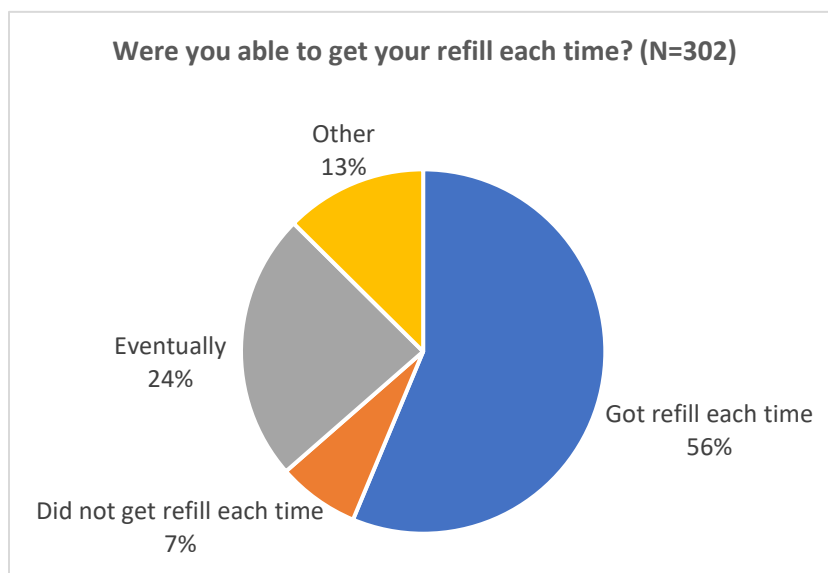
| States with >= 10 Respondents<br>(# Respondents) |                   |
|--|-------------------|
| California (49)                                  | Illinois (12)     |
| New York (45)                                    | Ohio (12)         |
| New Jersey (21)                                  | Georgia (11)      |
| Texas (15)                                       | Colorado (10)     |
| Maryland (13)                                    | Pennsylvania (10) |
| Florida (12)                                     |                   |

### Ability to Refill Prescriptions

- Five percent (5%) reported not being able to refill their prescription at all, and 4% had enough on hand and did not need a refill during this time period.



- Of the 18 people (5%) who were unable to refill their prescription, half consulted with their physician and
  - 7 had enough to continue taking a full dose
  - 8 split doses
  - 3 were completely out of medication
- Of the 302 respondents who reported having a prescription filled during this time period, about one-third had issues getting their refill but eventually were able to.



- Thirty (30) of the 94 respondents who reported not getting their refill each time or eventually getting their refill reported they split doses to make it last longer and 7 were completely out of their medication.
- Of the 72 respondents who reported eventually getting their refill:
  - 36% had to use a different pharmacy
  - 58% had to wait two weeks or longer to get their refill



- Some of the 170 respondents who reported getting their refill each time they needed it did encounter some issues as well:
  - 28 were not able to get their usual quantity
  - 12 had to use a different pharmacy
  - 15 had to pay more than usual

One hundred and seventy three (173) respondents provided additional information to the open-ended question at the end of the survey asking if they would like share any other information about their ability to access hydroxychloroquine/Plaquenil. Responses were grouped into categories and a sample is included here.

Some people had no issues getting their medication and others were prepared in response to the pandemic in general, ensuring they had enough medication on hand to get through the uncertainty:

*I got my refill prior to the news about Plaquenil. I also get a 3-month supply at a time but I did call my pharmacy for a refill and he said there was none but I'm good with my current supply until June.*

Others quickly worked to get refills upon first hearing about the potential for hydroxychloroquine as a treatment for COVID-19:

*I refilled as soon as I heard about the possibility of COVID-19 usage to avoid any issues.*

*I was able to get the last prescription as I called in as soon as I heard the news of hydroxychloroquine being tested for Covid-19. Thankful my prescription is a 3-month supply.*

Several people indicated they were informed by their pharmacy that there might be a shortage coming and were able to get their refills:

*I was lucky to be able to get my refill on time. It was a stressful week or two in between hearing that my usual pharmacy could not refill my prescription and having to find somewhere that could. I'm grateful my pharmacy told me far enough in advance that I could make other accommodations.*

*In April my pharmacist offered to refill 3 months instead of 1, since he had the supply at the time.*

*My pharmacy was able to get me 3 month's supply a week before the shortage occurred. They knew it could be a problem and reached out to me to get the refill early.*

Others struggled to get their prescriptions filled and had to call multiple pharmacies in order find one that could fill their prescription, or their prescription was filled by different or multiple manufacturers:

*I had difficulty finding a pharmacy within a 20-mile radius of my home that had any Plaquenil. Some pharmacies had enough for a week or 2, but nobody had a month supply. The Walgreens pharmacy I use located a 3-month supply for me just in time. I am extremely nervous and anxious about being able to get another refill when I run out.*

*I noticed the pill changed, the first one I had said Plaquenil on it this one doesn't.*

*This prescription was filled with 3 different manufacturers, my next refill will be in June - hope there will be no shortage.*

Many could not get their normal supply and had to accept 14- or 30-day supplies. The need to revisit the pharmacy caused concerns about additional possible exposure to the novel coronavirus:

*Could not get a 90-day supply. So I will need to expose myself again at the pharmacy.*

*At the beginning of April I was told I could only get a 14-day supply. This week I received a new letter from Kaiser that 30-day supplies were now available. My usual is 90 days.*

Others had insurance and cost issues:

*My difficulties in refilling hydroxychloroquine has been due to my insurance. They are only covering 40 pills over a 90-day period. This doesn't work for me as I take it twice daily.*

*The Insurance price for my 90-day supply Tripled!*

*I have to pay a copay for a 30-day supply. With a 90 day supply I don't have a copay. Very unfair.*

Having to supply proof of diagnosis was likely in response to state executive orders:

*My pharmacy stated that even though I have been on Plaquenil for a long time, my doctor had to write a letter saying I had lupus and had to be on Plaquenil?*

*The pharmacist questioned my prescription despite the lengthy amount of time that I've been on it.*

*Access was not extremely difficult, but I had to call the pharmacy to notify them of my condition and length of time taking it. There was a priority list for when supplies resumed.*

One common theme from respondents was the stress and anxiety this caused them:

*It was stressful worrying about being able to get my medication that for 25 years has helped me.*

*It was stressful every day for months as there are not many meds that work for lupus.*

The hydroxychloroquine shortage came on quickly, and fortunately for those with lupus who rely on this medication, the response to ensure access was swift. However, it was not without impact. The stress this created for people with lupus on top of dealing with the uncertainties of the pandemic as well as their everyday struggle with the disease was tremendous. Since stress can lead to flares for people with lupus, the situation was of particular concern for our community -- the thought of having to go the doctor's office or ending up in the ER due to a flare is something we can't really quantify. This one respondent sums it up:

*It was very draining having the extra stress of worrying about the potential of not getting my needed medication at the same time as dealing with the new realities of a global pandemic.*

For more information please contact:

Diane Gross

National Director of Advocacy and Programs

[dgross@lupusresearch.org](mailto:dgross@lupusresearch.org)