

## Hepatitis C treatment in Guatemala: the struggle for access

In Guatemala, where access to a new hepatitis C treatment is very limited, a court case has pushed the government towards its duty of care. Paul Webster reports from Guatemala City.



When Carlos Poncino, a soft-spoken 63-year-old salesman living in Guatemala City, did not overcome hepatitis C virus infection after 8 years of treatment with interferon-based drugs paid for by Guatemala's national social security scheme, he gave up. "I had to try to accept that the infection was going to kill me", he says.

But the introduction of a new category of direct-acting antiviral drugs that replaced the interferon-based drugs after 2014 in Guatemala gave him new hope. The new drugs reliably cure almost all patients within 12 weeks. Although they were first marketed in the USA in 2013 for about \$100 000 per patient, the costs have since been cut dramatically due to market competition, the introduction of Indian-made generic versions of the new drugs, and concessionary price agreements negotiated with drug-makers by numerous countries including Egypt, where treatment costs are now as low as \$100 per patient.

To Poncino's surprise, the Guatemalan social security scheme refused to pay for his treatment with the new drugs. "The new drugs are expensive and highly effective, and the social security officials know that thousands and thousands of infected patients are entitled to treatment", he explains. "They don't want to trigger a massive flood of new patients." He filed a lawsuit against the social security plan in Guatemala's Constitutional Court. The social security plan did not contest the case. The Court quickly ruled that he was entitled to treatment. "Even after I won the Court's decision, the social security officials remained reluctant to treat me. So I warned them they could go to jail. After that, they paid for my treatment."

Poncino, who sees his case as precedent setting, while acknowledging that the legal terrain around the

Guatemalan Government's duty to provide hepatitis C treatment remains highly ambiguous, says he expects to be fully cured by the end of the summer.

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Patricia Vélez-Möller, medical professor at the University of San Carlo in Guatemala City and president of the Guatemalan Liver Association, helped Poncino to fight for treatment. She consulted officials in the office of Guatemala's federal human rights investigator, who suggested Poncino sue the social security plan. So she wrote Poncino a medical certificate in support of his lawsuit. "I want my hepatitis patients to have the same legal right to treatment as HIV/AIDS patients do", she says.

Poncino's case is one of the first of its type in Guatemala, and Vélez-Möller says it will probably spur other patients to follow Poncino's lead and generate momentum for increased treatment in the country.

Vélez-Möller says that although no national surveillance data are currently available for hepatitis C virus in Guatemala, based on a population prevalence extrapolation, an estimated 88 000 Guatemalans require treatment. "Likely the problem is bigger than that, but it is an invisible killer and there is very limited public awareness and a great deal of stigma", she explains. "Plus, the government is reluctant to act on a problem that largely stems from its own neglect for the integrity of our bloodbanks and our blood supply."

Vélez-Möller has long urged the Guatemalan Government to adopt a multipronged approach to hepatitis including health-worker training, public

awareness campaigns, and negotiations for low-cost diagnostics and drug treatment. But "basic baseline research is still not being conducted", she says. Even the 750 people rejected as blood donors last year after preliminary tests showed possible HCV infection were not followed up for formal diagnostic testing, she notes. Newborn vaccination for hepatitis and other diseases is disastrously inadequate, she adds.

"We've never had any sustained high-level leadership", Vélez-Möller laments while noting that the government has missed numerous opportunities. Vélez-Möller characterises the government's attitude as "indifferent"; she also says that at one point in the past government officials told her they did not support raising public awareness because they would not offer mass diagnosis and treatment. "I can only hope. For now, the only people who get treated are those who pay for it privately, at a cost of around US\$1500 for generic drugs from India, or those who sue the Social Security Institute." In a country where per-capita income was \$3700 in 2016, hepatitis C treatment costs remains prohibitive for all but a few.

Lucrecia Mack, a physician and health economist who served as health minis-



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ter for a year before resigning in protest against government efforts to suppress transparency last year, describes Guatemala's public health system as severely underfunded, disorganised, and confounded by patronage appointments, embezzlement, and mismanagement. "Everything that the ministry purchases is overpriced. Someone always takes a cut", she charges. Many primary health-care programmes were suspended by the national Congress due to financial irregularities in 2015, she adds. "They still haven't been reformed or replaced." Including herself, there have been eight health ministers in 5 years, she notes.

Guatemala's public health-care system currently provides little more than rudimentary child survival and maternal health programmes, Mack explains. "We're at the bottom of the pack in the Americas. In 2015, for example, vaccination programmes were suspended for the entire year", she says. "Our health system is just too weak to address hepatitis as a national health problem. It's left to the hospitals to deal with it in a very piecemeal, limited way."

Jordán Rodas Andrade, Guatemala's federal human rights investigator, says the lack of hepatitis treatment "is a clear violation of the human rights of infected patients. And if this is happening in the cities, one can only imagine how dire the situation is in rural settings".

Juan Geraldo Argueta, a gastroenterologist at the San Juan de Dios Hospital in Guatemala City who serves as president of the Guatemalan Association of Gastroenterology and Hepatology, describes government leadership on hepatitis as almost non-existent.

Work towards a national hepatitis plan led by Carlos Mejia, an internist at the Roosevelt Hospital, was terminated when Mejia was murdered in a random attack last year, Argueta explains. "After he was murdered, the national policy initiative was stalled", he adds. "We are just beginning to recover. We need to start with a national prevalence study. This should be staged from the city's two referral hospitals. But the

government has not been in touch with us. We've heard nothing."

Meanwhile, Argueta says, many patients who are diagnosed with hepatitis C are not treated. "Frankly, the drug prices are simply abusive. Our strategy will have to be to try to make noise, so that the drug companies will offer lower prices in Guatemala."

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The Guatemalan Ministry of Health declined an interview request from *The Lancet*. Oscar Barreneche, director of the Pan American Health Organization's (PAHO) Guatemala office, said although "there is no coordinated approach", the Ministry participates in a recently formed hepatitis working group that also includes a representative from the National Social Security Institute, as well as PAHO. "It is difficult to develop a coherent approach when leadership has been undercut by the rapid succession of ministers", he explains.

In Washington, Nick Walsh, PAHO's Latin American regional adviser for viral hepatitis, says Guatemala's predicament is not unique. A recent PAHO survey concluded that access to HCV treatment with direct-acting antivirals is very limited in the region. Only ten of 22 reporting countries have these medicines available and recommended as the first-line therapy for chronic hepatitis C following WHO guidelines, Walsh notes.

Various options exist for countries struggling to pay for the drugs, Walsh says. One is through voluntary licensing agreements with drug manufacturers willing to reduce prices in return for bulk sales guarantees. This can reduce prices to around US\$4500 for treatment.

Another, far more affordable, cost-cutting option is the PAHO Strategic Fund, which offers 31 countries in the region pooled procurement opportunities to purchase diagnostics and medicines at reduced prices. So far, however, uptake has been lacking,

Walsh says, because prices are still relatively high compared with other regions. Regional political commitment is pending, with the exception of Brazil, which has negotiated reduced prices and could pursue generic drug production while quickly scaling-up diagnosis and treatment for an estimated 656 000 people infected with hepatitis C virus.

"Brazil is the only country in the region that is on track to achieve elimination by 2030", Walsh says. "They are far and away ahead." Chile and Colombia are also developing comprehensive plans, he adds. "There's no reason they cannot go for it."

Another option promising to deliver affordable drugs for hepatitis C treatment in Latin America comes from the Drugs for Neglected Diseases Initiative (DNDi), a Geneva-based organisation that licensed a once-abandoned direct-acting hepatitis C virus drug, that it aims to begin registering as a pan-genotypic therapy, starting in Malaysia.

"Most countries in Latin America are stuck due to the intellectual property regime", explains Graciela Diap, reference medical doctor for the DNDi. "The generic manufacturers cannot get in due to patent barriers."

While Diap is sympathetic to countries such as Guatemala that are intimidated by diagnostic and treatment costs, along with Fernando Contreras, president of the Latin American Liver Association, she says that hepatitis C diagnosis is now available for as little as \$17 per test, and that increased public awareness and mass diagnosis will lead to higher demand and lower treatment prices.

"Of course, it is easier not to acknowledge the disease", Diap reflects. "But many countries, including Egypt, Pakistan, and Georgia, have demonstrated that very low-cost mass treatment is possible. The Latin American Governments should look closely at these countries, and dramatically expand hepatitis diagnosis and treatment."

Paul Webster