

## HEPATITIS C VIRUS MICROELIMINATION PROGRAM IN HEMODIALYSIS PATIENTS: SUCCESS OF A MULTI-STAKEHOLDER PARTNERSHIP BASED ON A NATIONAL ERADICATION STRATEGY

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### Abstract

**Introduction:** Direct-acting antivirals (DAA) are highly effective in patients in hemodialysis and chronic hepatitis C and brings multiple benefits to this population. Our aim was to evaluate the effectiveness of DAA treatment in routine clinical practice in Argentina using a multidisciplinary network.

**Materials and methods:** In this prospective multi-center cohort study, all patients on dialysis at Fresenius Medical Care, were screened for anti-HCV. All HCV RNA-positive patients were offered treatment with sofosbuvir/velpatasvir and glecaprevir/pibrentasvir. FIB-4 and APRI scores, and liver stiffness, were performed in all HCV RNA-positive patients. A network was developed where nephrologists, after an HCV management training program and under the supervision of hepatologists by telemedicine, initiated treatment in each dialysis unit; and DAAs therapy was provided by the patients' insurance or by the national Ministry of Health.

**Results:** A total of 10 144 patients were evaluated between January 2018 and December 2023. A total of 323 (3.2 %) were anti-HCV positive, of which 149/323 (46.1%) had detectable HCV RNA. Genotype 1 was the more prevalent (69%) and most patients had mild fibrosis

(26% had F3-F4). By May 2024, 82 patients were evaluated 12 weeks after the end of treatment: 76 (92.7%) achieved sustained virological response, three died, one stopped treatment due to intolerance, and two were lost to follow-up.

**Discussion:** A multi-stakeholder partnership model (Fresenius Medical Care, physicians, insurance companies and Ministry of Health), implemented as a national microelimination strategy, has demonstrated increased treatment rates for HCV in dialysis units, exhibiting acceptable effectiveness.

**Key words:** hepatitis C virus, direct-acting antiviral agents, dialysis, microelimination

### Resumen

**Programa de microeliminación del virus de hepatitis C en pacientes en hemodiálisis: éxito de una alianza multi-sector basada en una estrategia nacional de erradicación**

**Introducción:** Los antivirales de acción directa (AAD) son altamente eficaces en pacientes en hemodiálisis con hepatitis C crónica (VHC) y aportan múltiples beneficios

en esta población. Nuestro objetivo fue evaluar la efectividad del tratamiento con AAD en la práctica clínica rutinaria en Argentina.

**Materiales y métodos:** En este reporte de cohorte prospectivo y multicéntrico, se realizó tamizaje de antiVHC en todos los pacientes en *Fresenius Medical Care*. A los pacientes con ARN detectable se les ofreció tratamiento con AAD. Se les determinó los índices FIB-4 y APRI, así como la rigidez hepática. Se desarrolló una red donde los nefrólogos, bajo la supervisión de un hepatólogo mediante telemedicina, empezaron el tratamiento; y los AAD fueron provistos por la cobertura médica o por el Ministerio de Salud de la Nación.

**Resultados:** Entre enero de 2018 y diciembre de 2023, se evaluaron 10 144 pacientes; 323 (3.18%) fueron positivos para antiVHC, y 149/323 (46.1 %) tenían ARN detectable. El genotipo 1 fue el más prevalente (69%) y la mayoría presentaba fibrosis leve (26% F3-F4). Para mayo de 2024, 82 pacientes fueron evaluados 12 semanas después de finalizar el tratamiento: 76 (92.6%) lograron respuesta virológica sostenida, tres fallecieron, uno interrumpió el tratamiento por intolerancia y dos se perdieron en el seguimiento.

**Discusión:** Un modelo de alianza multi-actor (*Fresenius Medical Care*, médicos, cobertura de salud y Ministerio de Salud), implementado como estrategia nacional de microeliminación, ha demostrado un aumento en las tasas de tratamiento del VHC en unidades de diálisis, con una efectividad aceptable.

**Palabras clave:** virus de la hepatitis C, antivirales de acción directa, diálisis, microeliminación

## KEY POINTS

### Current knowledge

- Patients on chronic dialysis are at increased risk for HCV infection. Direct-acting antivirals are effective and safe in this population, and global guidelines recommend treating all HCV-infected individuals, including those with end-stage renal disease, to reduce morbidity, mortality, and transmission.

### Contribution of this article to current knowledge

- This study demonstrates the feasibility and effectiveness of a national HCV microelimination strategy in dialysis

patients. A multidisciplinary network, with nephrologist delivering treatment with DAAs with an hepatologist as a consultant, achieving a 92.6% sustained virological response, supporting the implementation of integrated care models to eradicate HCV in high-risk populations.

Hepatitis C virus (HCV) infection remains a significant public health challenge worldwide, with an estimated global prevalence of 0.77% in 2020, accounting for approximately 58 million people who are viremic<sup>1</sup>. Despite substantial advances in direct-acting antiviral (DAA) therapies and reductions in the number of viremic patients in the last years, HCV continues to be a leading cause of chronic liver disease, cirrhosis, and hepatocellular carcinoma<sup>1,2</sup>.

One population at increased risk of HCV infection is patients undergoing dialysis because of factors such as frequent blood transfusions, prolonged vascular access, and the potential for nosocomial transmission in dialysis units. HCV prevalence among patients receiving dialysis is higher than in the general population, varying widely across regions, from 1% to over 48%, with a pooled prevalence of 21%. This variation may reflect differences in infection control practices and regional epidemiology<sup>3</sup>. In South America, the pooled prevalence is 19.4%<sup>3</sup>. In Argentina, the Argentine Registry of Chronic Dialysis indicate that HCV prevalence among patients beginning dialysis has exhibited a declining trend from 20.1% in 2004 to 8.3% in 2021, attributable to enhanced screening and infection control measures. However, this remains a significant concern, highlighting the need for targeted interventions in this vulnerable group<sup>4</sup>.

In 2016, the World Health Organization (WHO) endorsed the Global Health Sector Strategy to eliminate hepatitis infection by 2030 and established global targets for the management of HCV, including a 90% reduction in new cases of chronic hepatitis C, a 65% reduction in hepatitis C-related deaths, and the treatment of 80% of eligible individuals with chronic hepatitis C infections<sup>5</sup>. Unfortunately, only a small number of countries are keeping the pace of the WHO's elimination program, and most countries, especially in South America, are far beyond this ob-

jective<sup>6</sup>. Micro-elimination may be a viable strategy to achieve these objectives. It is defined as the targeted elimination or cure of HCV in specific high-risk populations or settings and represents a feasible approach to reduce the burden of HCV in dialysis units<sup>7</sup>.

Guidelines from the European Association for the Study of the Liver (EASL), American Association for the Study of Liver Diseases (AASLD), and Argentine Society of Hepatology (SAHE) emphasize the importance of treating HCV in patients on dialysis, citing the safety and efficacy of DAAs, even in those with end-stage renal disease<sup>8-10</sup>. They recommend that all patients with HCV, including those undergoing dialysis, should be considered for antiviral therapy with pangenotypic DAAs because of the benefits of viral eradication, which include reduced hepatic and extrahepatic complications, improved quality of life, and decreased transmission risk within dialysis units<sup>8-10</sup>.

This study aimed to analyze the implementation of a micro-elimination strategy for HCV in dialysis centers in Argentina, examining the challenges and opportunities to achieve this objective. Through an assessment of the epidemiological context and therapeutic recommendations, we sought to elucidate the potential impact of such strategies on reducing HCV burden among patients undergoing dialysis.

## Materials and methods

### Patients

In this prospective multicenter cohort study, we conducted comprehensive screening of all patients undergoing dialysis treatment at Fresenius Medical Care (FME) facilities in Argentina between January 2018 and December 2023, within the HCV Microelimination Project in Hemodialysis Patients of the National Program of Viral Hepatitis from the National Ministry of Health. All participating FME facilities are listed in the Supplementary material. All HCV RNA-positive patients were included in the study. They were treated in routine clinical practice with the standard of care according to national guidelines: the combination of a NS5B polymerase inhibitor sofosbuvir plus a NS5A inhibitor velpatasvir for 12 weeks (SOF/VEL), and the combination of a NS3/4A protease inhibitor glecaprevir plus a NS5A inhibitor pibrentasvir for 8 weeks (GP). The primary outcome was sustained virological re-

sponse (SVR) rate, defined as an HCV RNA level of less than 15 IU/mL, 12 weeks after the end of DAA therapy. The secondary outcomes included liver function and adverse events.

The inclusion criteria were: 1) patients who were at least 18 years of age and infected with HCV; 2) patients with all genotypes, compensated cirrhosis (Child-Pugh score  $\leq 6$ ), and/or extrahepatic manifestations of HCV infection; and 3) CKD Stage 5 (eGFR  $< 15$  mL/min/1.73 m<sup>2</sup>) requiring dialysis. Exclusion criteria were: 1) co-infection with chronic hepatitis B virus; 2) Child-Pugh B or C cirrhosis or history of hepatic decompensation (e.g., bleeding varices, encephalopathy, refractory ascites); 3) prior treatment with an NS5A or protease inhibitor; 4) life expectancy of less than 1 year; 5) patients with neoplasms other than HCC that required chemotherapy during DAA treatment; 6) patients with newly diagnosed HCC or recurrent HCC within the past 12 months; 7) patients who required treatment with any medication during DAA therapy and could not be changed to an alternative one; and 8) patients who were pregnant.

Initially, all patients underwent ultrasonography and transient elastography for liver stiffness measurement (LSM) (Fibroscan®; Echosens France, Paris, France) to document evidence of liver cirrhosis ( $> 12$  kPa, F4 by Fibroscan®) and portal hypertension on ultrasonography. Cirrhosis can also be determined by a combination of clinical signs of portal hypertension (i.e., presence of gastroesophageal varices on endoscopy) and/or biochemical parameters (i.e., presence of a platelet count less than 100 000/mm<sup>3</sup>). After the introduction of simplified treatment criteria in the national and international treatment guidelines<sup>8-10</sup>, patients were evaluated with non-invasive serological tests: FIB-4 score [= (Age [yr] x AST [U/L]) / ((PLT [10(9)/L]) x (ALT [U/L])<sup>(1/2)</sup>)] and APRI [= (AST / Upper Limit of Normal) \* 100 / Platelet] were performed. Advanced fibrosis was ruled out in those with a FIB-4 score  $< 3.25$ , and/or an APRI score  $< 1.5$ , and no further evaluation was required. Those with an FIB-4 score  $> 3.25$ , and/or an APRI score  $> 1.5$  were offered LSM. Patients with clinical signs or symptoms of portal hypertension, F3-4 on LSM (8-12 kPa represents F3 and  $> 12$  kPa represents F4), FIB-4  $> 3.25$  and/or APRI  $> 1.5$  were evaluated by a hepatologist. All other patients were evaluated by a nephrologist under the supervision of a hepatologist.

Plasma HCV RNA levels were quantified using the cobas® HCV test on the cobas® 6800 system (Roche Molecular Systems, Pleasanton, CA, USA), with a lower limit of quantification of 15 IU/mL, and HCV genotyping was con-

ducted using the cobas® HCV GT assay (Roche Molecular Systems, Pleasanton, CA, USA) in a centralized laboratory where FME routinely performed all virologic tests.

This study was approved by the Institutional Review Board of FME Argentina. The study protocol adhered to the Strengthening the Reporting of Observation Studies in Epidemiology guidelines<sup>11</sup>. All patient data were anonymous and codified, and handled in strict compliance with the Argentine Personal Data Protection Law (Law 25.326, Habeas Data Law). The study followed institutional, national, and international ethical standards, including those mandated by the Helsinki Declaration of 1975, as revised in 2008. All authors had access to the study data, reviewed the findings, and approved the final version of the manuscript.

### **Direct-acting antiviral treatment and follow-up schedule**

Patient demographics, complete blood counts, liver and renal biochemistry, HCV genotype (when available; genotype determination was not necessary for treatment initiation according to simplified treatment criteria), and RNA and serum alpha-fetoprotein (AFP) levels were measured before DAA treatment initiation. GP was initiated at 300 mg/120 mg daily for eight weeks, and SOF/VEL was initiated at 400 mg/100 mg daily for 12 weeks. DAA therapy was initiated at each dialysis unit under the supervision of hepatologists using telemedicine. Nephrologists involved in HCV treatment received training about patients and treatment management. The DDAs were provided by the medical coverage of each patient; in cases where this was not possible, they were provided by the National Program of Viral Hepatitis from the National Ministry of Health.

Patients were followed up at every dialysis session after initiation of DAA. Patients were monitored for complete blood counts and liver and renal biochemistry as required in routine clinical practice. Clinically significant events and side effects have also been documented. Complete blood counts, liver and renal biochemistry, and HCV RNA levels were determined 12 weeks after DAA treatment completion for SVR assessment.

Categorical variables are reported with frequencies and percentages. Numerical variables are reported according to their distribution as

means and standard deviation (SD) or medians. Since this is a descriptive study, no statistical analysis was performed.

### **Results**

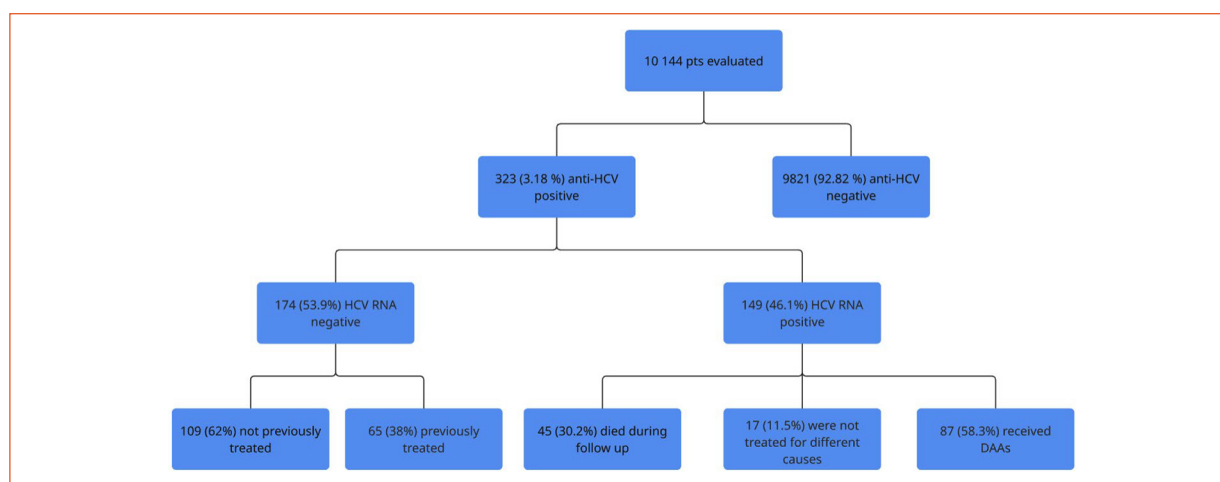
A total of 10 144 patients from all FME hemodialysis units (85 dialysis centers) in Argentina were evaluated between January 2018 and December 2023. A total of 323 (3.2 %) were anti-HCV positive, of whom 149 (46.1%) had detectable HCV RNA. A subset of 65 (20.1%) patients had been previously treated, whereas the remaining 109 (34%) patients were HCV RNA-negative and had not received prior treatment (Fig. 1). By May 2024, 87 patients had begun treatment, of whom 82 were evaluated 12 weeks after the end of treatment and were included in the analysis. Of the remaining 62 HCV RNA-positive patients, 45 died during follow-up without treatment and 17 were not treated based on treating physician decision. Most of the patients did not receive DDAs therapy mainly due to severe non liver comorbidities with low life expectancy compromising the potential benefit of HCV treatment (Fig. 1).

Baseline patient characteristics are presented in Table 1. Genotype 1 was the more prevalent (68.5%), followed by genotype 2 (22.5%) and 3 (8.1%); the remaining patient was genotype 4 (0.9%). Fibrosis was evaluated using LSM in 63 patients. Most patients demonstrated mild fibrosis: F0-1 44.4%, F1 7.9%, F2 19%, F3 14.3%, and only 14.4% presented with F4.

DAA therapy included GP in 67 patients (82%) and SOF/VEL in 15 (18%). Treatment was provided by the patients' insurance in 55% of the cases. In the remaining 45% of patients without insurance coverage, treatment was provided by the National Hepatitis Program of the Ministry of Health.

At the end of the study, 76 patients completed treatment, 3 died of liver unrelated causes (at home sudden death, heart failure, ischemic stroke), 1 stopped treatment due to intolerance (he received GP, stopped treatment because of intractable pruritus at week 4), and 2 were lost to follow-up. Overall, the SVR rate was 92.6%. All 76 patients who completed DAA therapy achieved SVR (100%). SOF/VEL and GP treatment was well tolerated in other patients, with minor adverse events considered not treatment related.



**Figure 1** | Patients' flowchart

HCV: hepatitis C virus; DAAs: direct acting antivirals

**Table 1** | Baseline patients' characteristics

Characteristics	N = 82
Age (years, mean $\pm$ SD)	54 $\pm$ 14
Male, n (%)	46 (54)
AST (IU/mL, mean $\pm$ SD)	29 $\pm$ 15
ALT (IU/mL, mean $\pm$ SD)	25 $\pm$ 19
Platelets (/mm <sup>3</sup> $\pm$ SD)	181 304 $\pm$ 63 891
HCV RNA (IU/mL $\pm$ SD)	1 718 826 $\pm$ 2 971 439
FIB-4 (mean $\pm$ SD)	2.08 $\pm$ 1.87
FIB-4 >3.25 n (%)	10 (11.8)
APRI (mean $\pm$ SD)	0.44 $\pm$ 0.29
APRI >1.5 n (%)	1 (1.3)
Diabetes n (%)	12 (14.3)
Time in dialysis up to DAA treatment (years, mean $\pm$ SD)	14.8 $\pm$ 11.4

AST: aspartate aminotransferase; ALT: alanine aminotransferase; FIB-4: fibrosis-4 score; APRI: aspartate aminotransferase/platelet ratio index; DAA: direct acting antiviral

## Discussion

This study demonstrated the effectiveness of a microelimination strategy for HCV among patients undergoing dialysis in Argentina, achieved through a multidisciplinary network involving nephrologists, hepatologists, patients' insurance providers, dialysis companies, and the National Hepatitis Management Program<sup>12</sup>. With a high SVR rate of 92.6% and 100% among patients who completed the treatment regimen, our findings corroborate previous research highlighting the efficacy and safety of DAAs in CKD patients.

The SVR rate observed in this study is consistent with the rates reported globally, where pan-genotypic DAAs such as SOF/VEL and GP have demonstrated excellent efficacy across diverse patient populations, including those with advanced CKD. Even though SOF, an NS5B polymerase inhibitor, was initially contraindicated in patients with CKD stages 4 and 5, numerous studies have subsequently demonstrated its safety and efficacy in this patient population<sup>13,14</sup>. The reported SVR rates range from approximately 92% to 98%, and a recent meta-analysis

demonstrated a pooled SVR rate of 100% (95% CI: 98–100 %) in non-cirrhotic patients and 98% (91–100 %) in cirrhotic patients when combining SOF with VEL, an NS5A polymerase inhibitor<sup>15</sup>. A protease inhibitor/NS5A inhibitor combination has been used in this population since the beginning of the DAAs era. The first approved combination was ombitasvir, paritaprevir, and ritonavir, but it was limited to patients infected with genotypes 1 and 4<sup>16</sup>. The new pangenotypic protease inhibitor/NS5A inhibitor combination, GP, replaced the previous combination and achieved a 98% SVR rate (95% CI: 95–100 %)<sup>17</sup>. A high SVR rate of clinical trials was also obtained in many real-world studies and summarized in a recent meta-analysis<sup>12,18</sup>.

The high SVR achieved in this study not only supports the recommendations of the European Association for the Study of the Liver (EASL) and the American Association for the Study of Liver Diseases (AASLD) to treat all HCV-infected patients, including those on dialysis with DAAs<sup>8,9</sup>, but also punctuate the vital importance of complementing clinical evidence with robust programs and public policies. This study reinforces the feasibility of eradicating HCV in dialysis units through a structured, multidisciplinary model, demonstrating that such an approach can be successfully replicated in similar settings. By integrating clinical excellence with coordinated policy efforts, we highlight the critical role of comprehensive strategies in translating medical advancements into tangible health outcomes.

One challenge in achieving comprehensive HCV microelimination is ensuring patient retention and treatment completion. In our study, treatment interruptions occurred for various reasons, including adverse events and patient mortality unrelated to HCV or its treatment. These findings suggest that while DAA therapies are generally well tolerated, individualized patient management remains crucial, especially in populations with high comorbidities and inherent dialysis-related risk factors. This underscores the importance of complementing clinical interventions with robust support programs aimed at enhancing patient adherence and addressing unique challenges faced by this vulnerable group. Additionally, the low rate of treat-

ment discontinuation (1.2%) observed in our cohort underline the effectiveness of patient selection and monitoring, consistent with recent studies that reported similar tolerability and safety profiles of DAA regimens in dialysis patients. In a meta-analysis, the estimated pooled incidence of treatment discontinuation was 0.8% (95% CI: 0.3–1.3 %), and death rates were 0.4% (95% CI: 0–0.8 %)<sup>12</sup>. These findings further highlight the safety of DAA therapy in the dialysis population and reinforce the feasibility of achieving HCV eradication through structured multidisciplinary approaches complemented by supportive programs and public health policies.

Another critical aspect of this study was the collaborative framework between nephrologists and hepatologists, which facilitates patient management through telemedicine. This model not only optimized resource utilization but also aligned with the WHO's hepatitis elimination goals, which advocates integrated healthcare models to overcome logistical barriers in treating at-risk populations<sup>5</sup>. The success of this partnership highlights the potential of telemedicine to support chronic disease management in resource-limited settings, which is a significant advantage for improving access to antiviral therapy in regions where healthcare resources may be limited<sup>19,20</sup>. These microelimination programs have been reported in other countries, achieving similar results<sup>21–23</sup>.

The main strengths of this study are its multifaceted nature. First, the large number of patients screened and evaluated for HCV infection enhanced the robustness and generalizability of our findings, making it one of the most extensive cohorts studied in this special population within the region. Second, the study shows the effective synergy of a multidisciplinary network involving nephrologists, hepatologists, patients' insurance providers, dialysis companies, and the National Program of Viral Hepatitis. This collaborative approach underscores the importance of multidisciplinary efforts to achieve successful health outcomes. Third, by implementing a unified program that guarantees universal coverage of HCV treatment based on simplified evaluation and treatment strategies, we demonstrated a feasible and effective model for microelimination. This is particularly significant in

Latin America, where comprehensive programs are scarce, highlighting the potential for replication in similar healthcare settings.

Despite these promising results, some limitations must be considered. The study was conducted in a single healthcare network, which may limit the generalizability of our findings to other settings with different patient demographics or healthcare infrastructure. In addition, the number of patients included was relatively small, potentially affecting the statistical power and causing some percentages, such as discontinuation rates, to be overestimated. To address these limitations, we are currently incorporating additional centers and increasing the number of patients treated with DAAs, which will enhance the robustness and applicability of our results.

In conclusion, this study provides valuable evidence for the efficacy of a microelimination

strategy for HCV among dialysis patients, demonstrating high SVR rates with minimal treatment discontinuation. The success of this initiative stresses the efficacy of a synergistic, multidisciplinary approach involving nephrologists, hepatologists, insurance providers, dialysis companies, and the National Program of Viral Hepatitis. By consolidating efforts and ensuring the comprehensive coverage of HCV treatment through streamlined evaluation and treatment strategies, we present a viable and effective model for HCV eradication. This approach not only proves successful in our context but also holds potential for replication in comparable healthcare environments, emphasizing the significance of integrating clinical excellence with coordinated public health policies.

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**Conflicts of interest:** None to declare

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## Supplementary material

### *List of Fresenius Medical Care (FME) participating Centers*

FME AVELLANEDA (Provincia de Buenos Aires)	FME MERLO 1 (Provincia de Buenos Aires)
FME BAHÍA BLANCA 1 (Provincia de Buenos Aires)	FME MERLO 2 (Provincia de Buenos Aires)
FME PRINGLES (Provincia de Buenos Aires)	FME MONTE GRANDE (Provincia de Buenos Aires)
FME BAHÍA BLANCA 2 (Provincia de Buenos Aires)	FME MORENO (Provincia de Buenos Aires)
FME BERAZATEGUI (Provincia de Buenos Aires)	FME MORÓN (Provincia de Buenos Aires)
FME BURZACO (Provincia de Buenos Aires)	FME NECOCHEA (Provincia de Buenos Aires)
FME CABALLITO (Ciudad Autónoma de Buenos Aires)	FME NEUQUÉN 1 (Provincia de Neuquén)
FME CEMIC SAAVEDRA (Ciudad Autónoma de Buenos Aires)	FME NEUQUÉN 2 (Provincia de Neuquén)
FME SÁENZ PEÑA (Provincia de Chaco)	FME NEUQUÉN DP (Provincia de Neuquén)
FME CHOELE CHOEL (Provincia de Río Negro)	FME NEUQUÉN ZAPALA (Provincia de Neuquén)
FME CIUDAD EVITA (Provincia de Buenos Aires)	FME NORFE RECONQUISTA (Provincia de Santa Fe)
FME CIUDELA (Provincia de Buenos Aires)	FME OBERÁ (Provincia de Misiones)
FME CLORINDA (Provincia de Formosa)	FME PILAR (Provincia de Buenos Aires)
FME CONCEPCIÓN DE TUCUMÁN (Provincia de Tucumán)	FME POSADAS (Provincia de Misiones)
FME CONCEPCIÓN DEL URUGUAY (Provincia de Entre Ríos)	FME QUILMES (Provincia de Buenos Aires)
FME CONCORDIA (Provincia de Entre Ríos)	FME RESISTENCIA (Provincia de Chaco)
FME CÓRDOBA (Provincia de Córdoba)	FME ROSARIO (Provincia de Santa Fe)
FME CORRIENTES (Provincia de Corrientes)	FME ROSARIO 1 (Provincia de Santa Fe)
FME CORRIENTES BELLA VISTA (Provincia de Corrientes)	FME ROSARIO DE LA FRONTERA (Provincia de Salta)