



IPOPI
LATIN AMERICAN
PID PATIENTS'
MEETING

OCTOBER 19-20, 2023
MEXICO CITY, MEXICO

an **IPOPI** event

SESIÓN 4

COLLABORATION



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¿Cómo abogar por el acceso al tratamiento? How to advocate for access to treatment?

Moderadora: Leire Solis

Moderator: Leire Solis

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IPOPI PID Life Index: análisis de los tratamientos disponibles

IPOPI PID Life Index: analysis of the treatments available

Martine Pergent

Introducción



- Mi charla de hoy repasará los principios de la atención de las IDPs:
 - ¿Qué son?
 - ¿Cómo podemos verlos en los diferentes países?
 - ¿Cómo podemos usarlo?



¿Cómo empezó esto?

- IPOPI ha trabajado con un equipo internacional de especialistas en IDPs, líderes de pacientes y médicos de los 5 continentes:
 - Definir lo que es importante para los pacientes con IDPs a nivel nacional.
 - Establecer una lista de principios de atención desde la perspectiva de los diferentes actores.



Primary immune deficiencies – principles of care

Helen Chapel^{1*}, Johan Prevot², Hubert Bobby Gaspar³, Teresa Español⁴, Francisco A. Bonilla⁵, Leire Solis², Josina Drabwell² and The Editorial Board for Working Party on Principles of Care at IPOPI¹

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Primary immune deficiencies (PIDs) are a growing group of over 230 different disorders caused by ineffective, absent or an increasing number of gain of function mutations in immune components, mainly cells and proteins. Once recognized, these rare disorders are treatable and in some cases curable. Otherwise untreated PIDs are often chronic, are treatable and in some cases curable. The diagnosis of PIDs can be difficult due to lack of awareness or serious, or even fatal. The diagnosis of PIDs is complex. This document was prepared by a worldwide multi-disciplinary team of specialists; it aims to set out comprehensive principles of care for PIDs. These include the role of specialized centers, the importance of registries, the need for multinational research, the role of patient organizations, management and treatment options, the requirement for sustained access to all treatments including immunoglobulin therapies and hematopoietic stem cell transplantation, important considerations for developing countries and suggestions for implementation. A range of healthcare policies and services have to be put into place by government agencies and healthcare providers, to ensure that PID patients worldwide have access to appropriate and sustainable medical and support services.

Keywords: primary immunodeficiencies, awareness, diagnosis, management, treatments, worldwide

INTRODUCTION

WHY A PRINCIPLES OF CARE DOCUMENT/CALL TO ACTION

Primary immune deficiencies (PIDs) are a large and growing group of over 230 different disorders, caused when some components of the immune system (mainly cells and proteins) are defective. While PIDs are generally recognized as rare disorders, some are more common than others. Taken as a whole, they represent an important group of conditions that, if not treated, can be chronic,

life-long, serious, and even fatal. The lives of patients with PIDs are profoundly impacted by their condition. The immune system normally helps the body to fight infections caused by germs (or "micro-organisms") such as bacteria, viruses, fungi, and protozoa. Owing to defective immune systems, people with PIDs are more prone to infections. In addition, a poorly regulated immune system may start to attack tissues, leading to inflammation, and autoimmunity (1, 2). When PIDs are left undiagnosed or are misdiagnosed, chronic illness and disability take a heavy toll on healthcare resources (3, 4).

The immune system is divided into two parts, each of which contains two components: on the one hand, soluble proteins may be particular for one germ (antibodies) or non-specific (complement). The other components are cellular – those that are specific for one germ only (lymphocytes) and innate cells that are involved in clearing all types of infections (such as phagocytes including macrophages and neutrophils).

Primary immune deficiencies are currently classified into groups, depending on the part(s) of the immune system affected. Over half the affected patients have antibody deficiencies and their treatment consists of replacing the missing antibodies (5). Cellular defects of lymphocytes are more severe and require replacement of stem cells that can mature to effective immune blood cells [hematopoietic stem cell transplantation (HSCT)] (6, 7) or replacement of the faulty gene.

While it is considered that many PIDs can be diagnosed easily with two simple blood tests (8), unfortunately many PIDs remain undiagnosed due to failure to consider this diagnosis. In addition,

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6 principios de atención para las IDPs

Diagnóstico

Tratamiento

Cobertura sanitaria universal

Centros especializados

Organizaciones nacionales de
pacientes

Registros

¿De qué trata cada principio?

Diagnóstico	Tratamiento	Cobertura sanitaria universal	Centros especializados	Organizaciones nacionales de pacientes	Registros
<ul style="list-style-type: none">• Tasa de diagnóstico• Disponibilidad del diagnóstico biológico• Disponibilidad del diagnóstico genético• Disponibilidad del diagnóstico prenatal• Cribado neonatal SCID	<ul style="list-style-type: none">• Antiinfeccioso• Inmunoglobulinas• Vacunas• Tratamientos curativos• Otras terapias	<ul style="list-style-type: none">• Reembolso por diagnóstico• Reemb. de terapias antiinfecciosas• Reemb. de Ig• Reemb. de vacunas• Reemb. de tratamientos curativos• Reemb. de otras terapias	<ul style="list-style-type: none">• Centro/red nacional especializado en inmunodeficiencia primaria• Servicios de inmunodeficiencia primaria para adultos• Atención de transición	<ul style="list-style-type: none">• Established national patient group• Professional paid staff• Main working areas	<ul style="list-style-type: none">• National PID registry• BMT donor registry

>Esto conduce a un gran conjunto de datos, que agregamos en un PID Life Index

>Los datos provienen de:

- nuestros miembros (organizaciones nacionales de pacientes), con el apoyo de sus asesores médicos,
- Los médicos también en países donde no tenemos organizaciones de pacientes. Todavía.

El PID Life Index de IPOPI

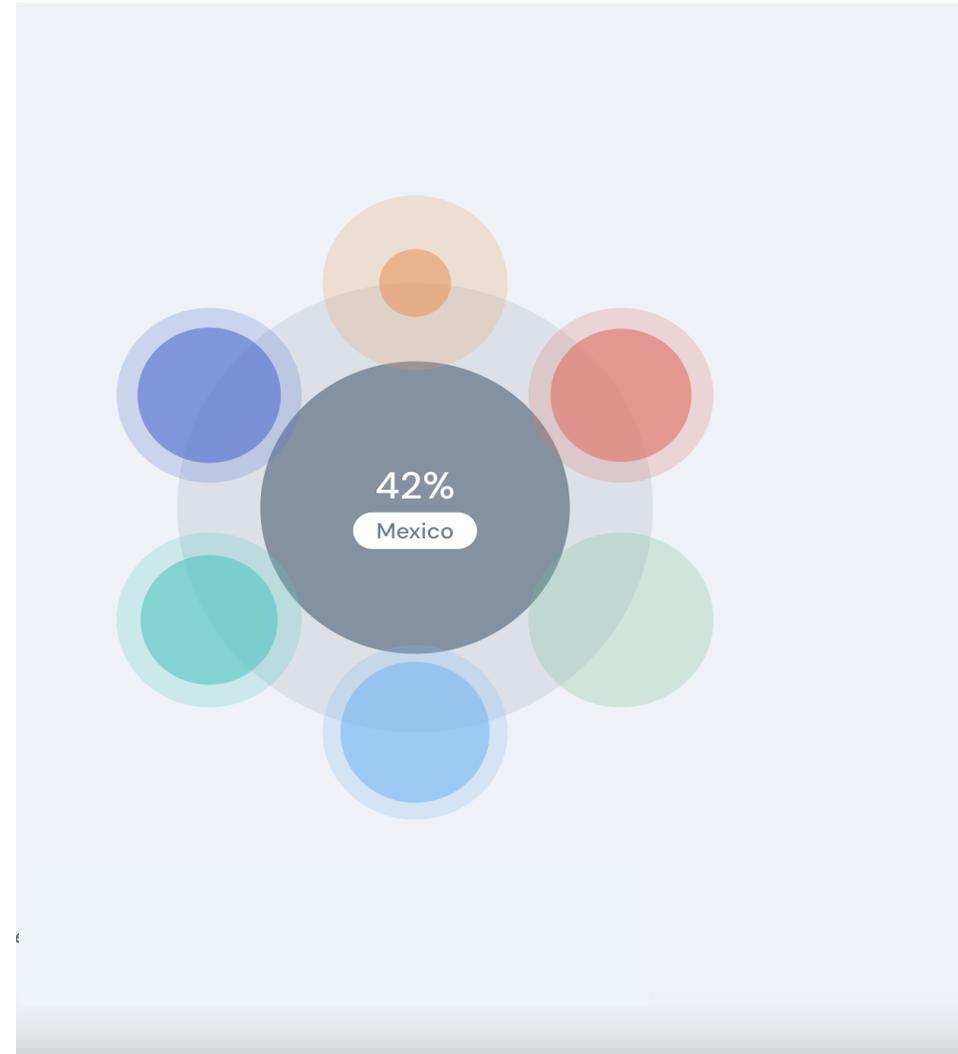
- Este índice se visualiza a través de una plataforma de VISUALIZACIÓN DE DATOS y un MAPA global

<https://pidlifeindex.ipopi.org>

Principios de atención de PID

Para cada país, la plataforma de visualización de datos presenta los 6 principios

>El ejemplo de México



Mexico

[See country page](#)

CONTINENT	America
SUB-REGION	Latin America, Central America, APEC member
LAST UPDATE	09/01/2020

POPULATION	128,932,753 (World Bank data)
NUMBER OF KNOWN PATIENTS	1,238
POPULATION BASED ON THEORETICAL PREVALENCE	64,466

42%
GLOBAL SCORE

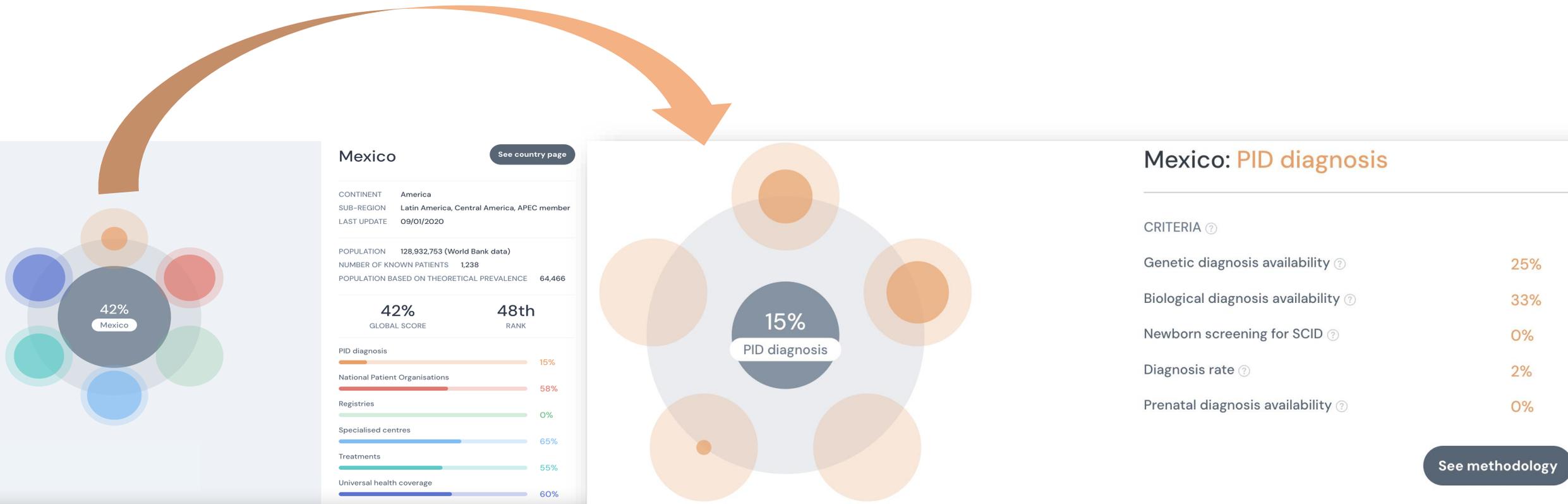
48th
RANK

PID diagnosis	<div style="width: 15%;"></div>	15%
National Patient Organisations	<div style="width: 58%;"></div>	58%
Registries	<div style="width: 0%;"></div>	0%
Specialised centres	<div style="width: 65%;"></div>	65%
Treatments	<div style="width: 55%;"></div>	55%
Universal health coverage	<div style="width: 60%;"></div>	60%

Criteria for each principle

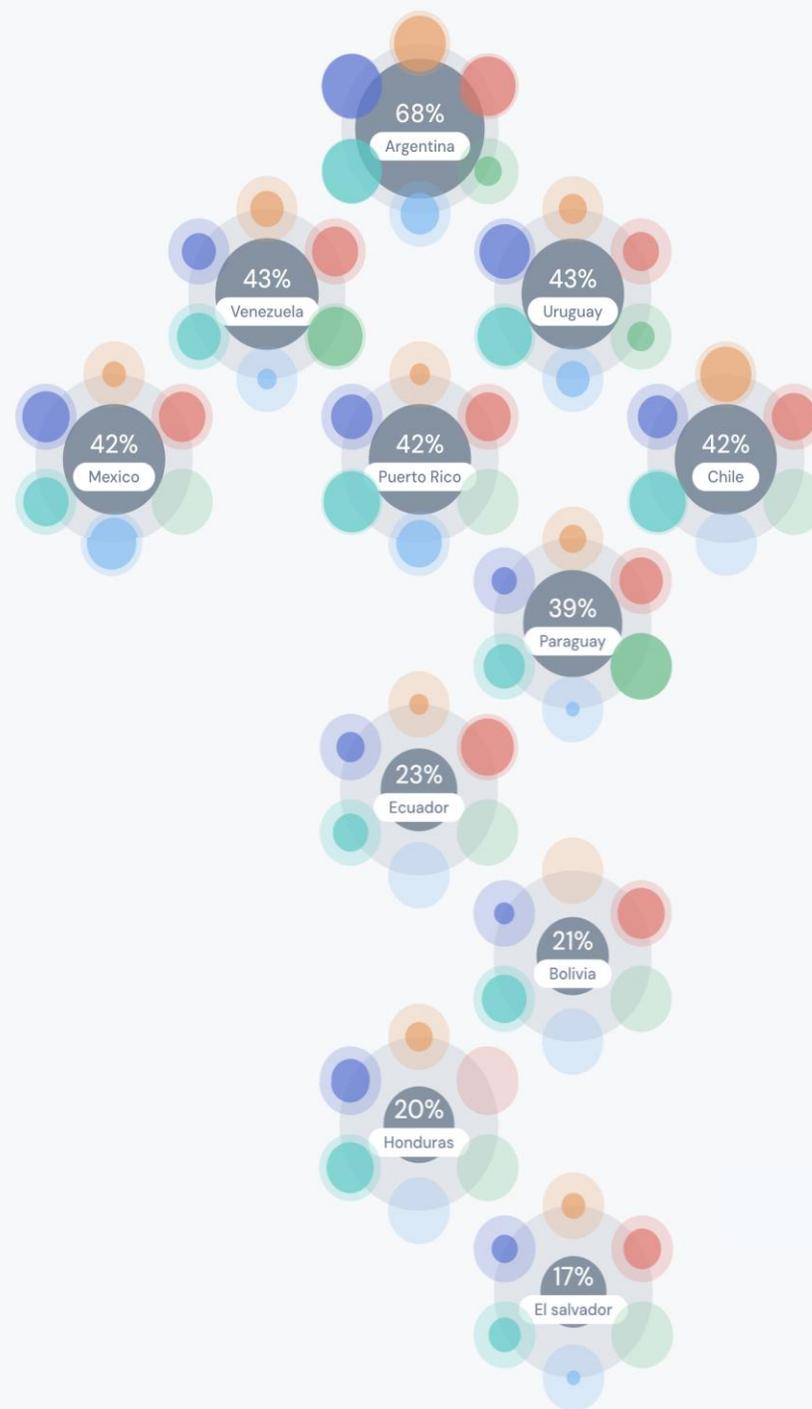


Each principle is constructed with different criteria

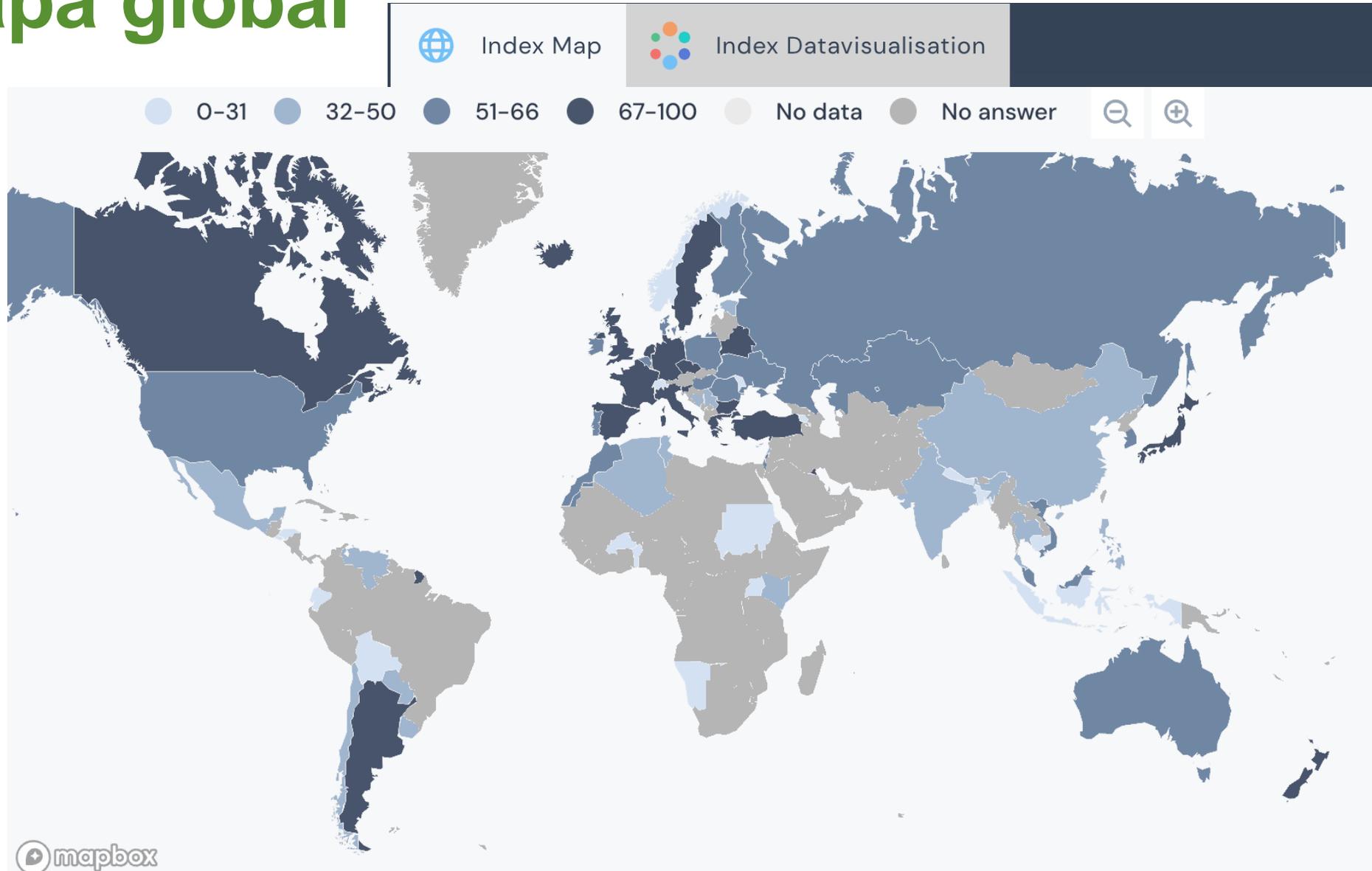


Visualización de datos regionales

Los países puntúan entre el 68% y el 17%
>Datos para la advocacy!



Un mapa global



Mapa regional

Por el momento, tenemos 10 países (y 2 territorios) representados:

Argentina
Bolivia
Chile
Ecuador
El Salvador
Honduras
Mexico
Paraguay
Uruguay
Venezuela

Guyana francesa
Puerto Rico



Principio: diagnostico de las IDPs



Criterios

- Genetic diagnosis availability
- Biological diagnosis availability
- Newborn screening for SCID
- Diagnosis rate
- Prenatal diagnosis availability

Comentarios

Tasa de diagnostico varia entre el 10% y el 72%

Principio: Organizaciones Nacionales de Pacientes



Criteria

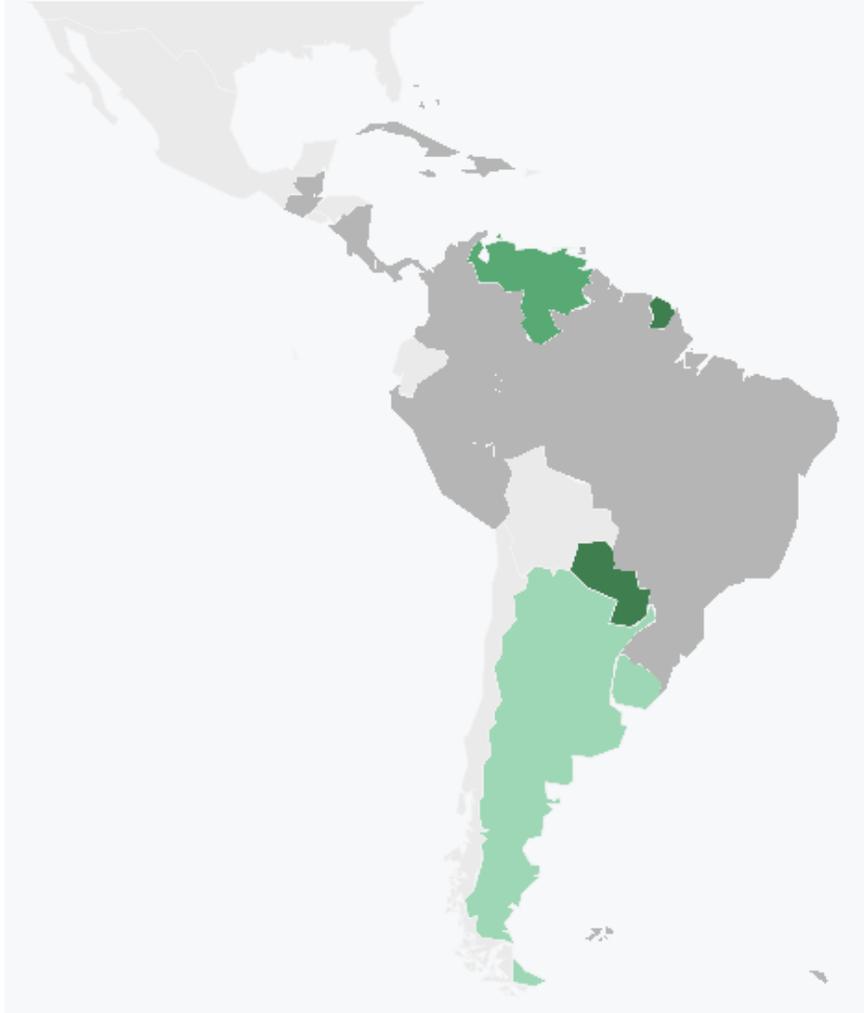
- Established national group in country
- Main working areas
- Professional paid staff

Comentarios

10/11 países tienen organizaciones nacionales de pacientes

Nota: otros 3 países son miembros nacionales de IPOPI (de pleno derecho o asociados): Brasil, Colombia, Nicaragua

Principio: Registros



Criteria

- Bone marrow donor registry
- National PID registry

Comentarios

Sólo un país declara tener un registro nacional

Principio: Centros especializados



Crterios

- Adult PID services
- National PID specialised centre/network
- Transition care

Comentarios

México (65%) y Argentina (40%) obtienen puntuaciones más altas que los demás países.

Principio: Cobertura Sanitaria Universal



Crterios

- Ig reimbursement
- Curative treatment reimbursement
- Anti-infectious Reimbursement
- Diagnosis Reimbursement
- Biological and targeted therapies (including biosimilars and generics) reimbursement
- Vaccines reimbursement

Comentarios

También hay discrepancias en la cobertura sanitaria universal, lo que significa dificultades financieras para los pacientes a la hora de acceder al diagnóstico, tratamiento y a la atención.

Muchos más datos disponibles

- Información detallada de cada país.
- Lista de centros especializados por país
- Lista de inmunoglobulinas registradas / por compañía farmacéutica / por país
- un glosario

Conclusión

- Datos primordiales para describir la situación vivida por los pacientes y por los médicos.
- Son fundamentales para crear conciencia y liderar iniciativas de promoción sobre los principales desafíos.
- **¿Aún no estás en el mapa? Por favor, habla con Leire y estara encantada de enviarte el cuestionario y comentarlo contigo.**

EI PID Life Index de IPOPI



> [Front Immunol.](#) 2023 Mar 30;14:1151335. doi: 10.3389/fimmu.2023.1151335. eCollection 2023.

Primary immunodeficiencies (PID) Life Index in Southeast Asia: A comparative analysis of PID Principles of Care (PoC)

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Affiliations + expand

PMID: 37063889 PMID: [PMC10097921](#) DOI: [10.3389/fimmu.2023.1151335](#)

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[Cite](#)

Abstract

Objective: To analyze the implementation of the Principles of Care (PoC) in primary immunodeficiencies (PID) in Southeast Asia (SEA) countries - six years after its call of action.

Methodology: Using the newly developed PID Life Index software, the index of implementation of principles of care in the management of PIDs patients involving the six participating SEA countries (Cambodia, Indonesia, Malaysia, Vietnam, Thailand, and Philippines) were extracted. For each of

¡Gracias
por su
atención!



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IPOPI.ORG

Taller: Explorar el panorama del acceso al tratamiento: disponibilidad, cobertura y personalización

**Workshop: Exploring the landscape of access to
treatment: availability, coverage and personalisation**

PAUSA
PAUSE
5 min

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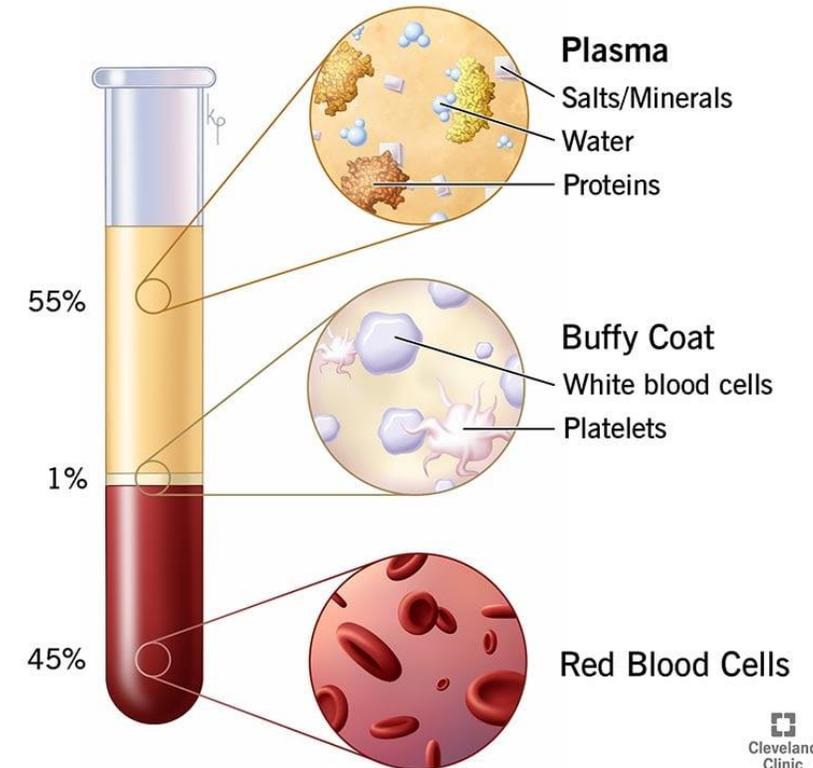
Proceso de colecta del plasma hasta el fraccionamiento

Process of plasma collection to fractionation

Roberta Anido de Pena

What is plasma?

- Plasma is the clear, straw-colored liquid portion of blood that remains after red blood cells, white blood cells, platelets and other cellular components are removed. It is the single largest component of human blood, comprising about 55 percent, and contains water, salts, enzymes, antibodies and other proteins.
- Composed of 90% water, plasma is a transporting medium for cells and a variety of substances vital to the human body.
- Plasma carries out a variety of functions in the body, including clotting blood, fighting diseases and other critical functions.



Source & Recovered Plasma

- Source plasma is plasma that is collected from healthy, voluntary donors through a process called plasmapheresis and is used exclusively for further manufacturing into final therapies (fractionation). Source plasma donors may be compensated for their time and effort.

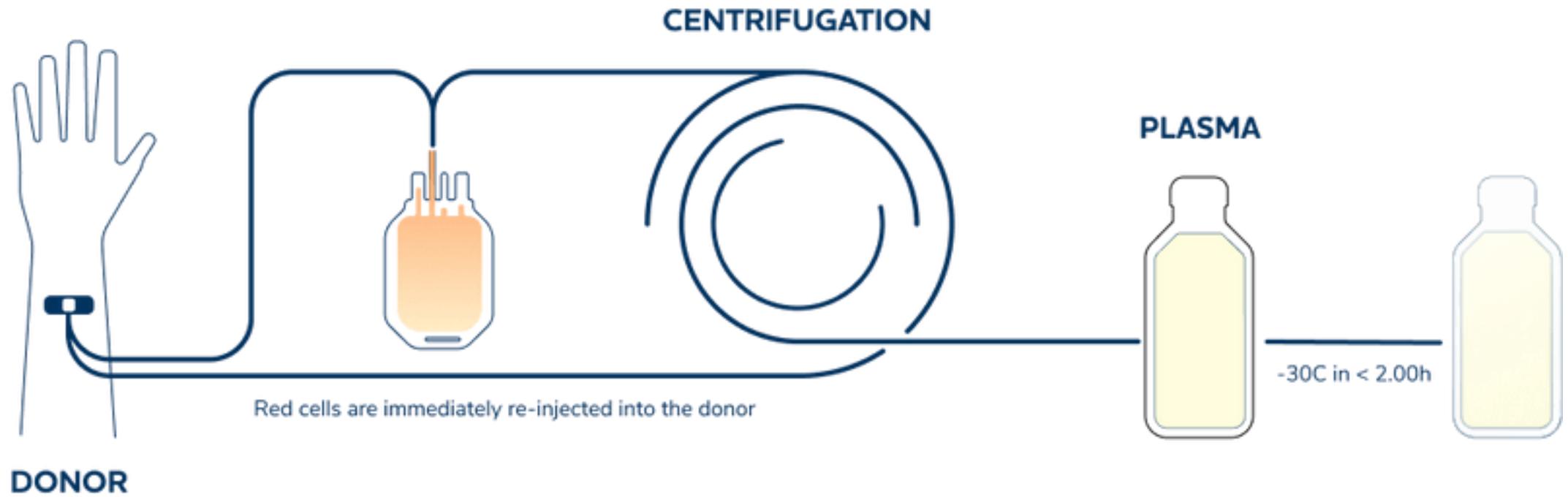


- Recovered plasma is collected through whole blood donation in which plasma is separated from its cellular components. Recovered plasma may be used for fractionation.



Source plasma collection in the U.S. is regulated by the U.S. Food and Drug Administration (FDA) and, in Europe, by the European Medicines Agency (EMA) and national regulatory authorities.

Plasma Collection



Plasma Manufacturing

Source and recovered plasma is the starting material used to manufacture lifesaving therapies.

The manufacturing process is known as fractionation.

Proteins are separated through this process to create a number of plasma protein therapies.

This process is carried out using well-established purification methods such as precipitation, centrifugation, separation, and filtration.



Plasma Fractionation

Plasma is pooled and processed through a process called "fractionation" that employs time, temperature, pH, and alcohol concentrations to extract specific therapeutic proteins. These are then subjected to various purification methods and viral inactivation and removal processes to further ensure their safety and efficacy.

Preparing a therapy often takes from **7-12 months** between donation and final product release. This sets the production of plasma protein therapies apart from chemical pharmaceuticals and other biologics whose manufacturing processes are much more condensed and whose direct manufacturing costs are a significantly smaller portion of the overall cost.

General considerations in the conservation, preparation and administration of blood products



- Be sterile
- Present homogeneity
- Be free of pyrethogens
- Be physicochemically stable (pH, oxidation, heat, light, etc.)
- Be painless (neutrality, isotony)
- Be clean and free of foreign particles
- Have an exact dosage

General considerations in the conservation, preparation and administration of blood products



Improper conservation or maintenance of medications or their administration devices can lead to problems related to effectiveness, loss of drug activity, or safety problems with the consequent appearance of side effects.

The appropriate conditions for each item mentioned are described in the Technical Data Sheet or leaflet of each pharmaceutical specialty and have been approved by the health authority of the country where the itself has been registered.

This information is the main source of consultation because it establishes the conditions verified and established by the manufacturer. In some cases it may be convenient to complement with information published in specialized bibliography.

General considerations in the conservation, preparation and administration of blood products



The appropriate conditions of temperature, humidity and lighting indicated of the products must be guaranteed at all stages of the distribution, transportation and storage chain, whether:

in the pharmaceutical industry, in drugstores or distributors, in office pharmacies, in pharmacy or nursing services of health institutions, at the home of each patient, if applicable, and during transportation from one place to another.

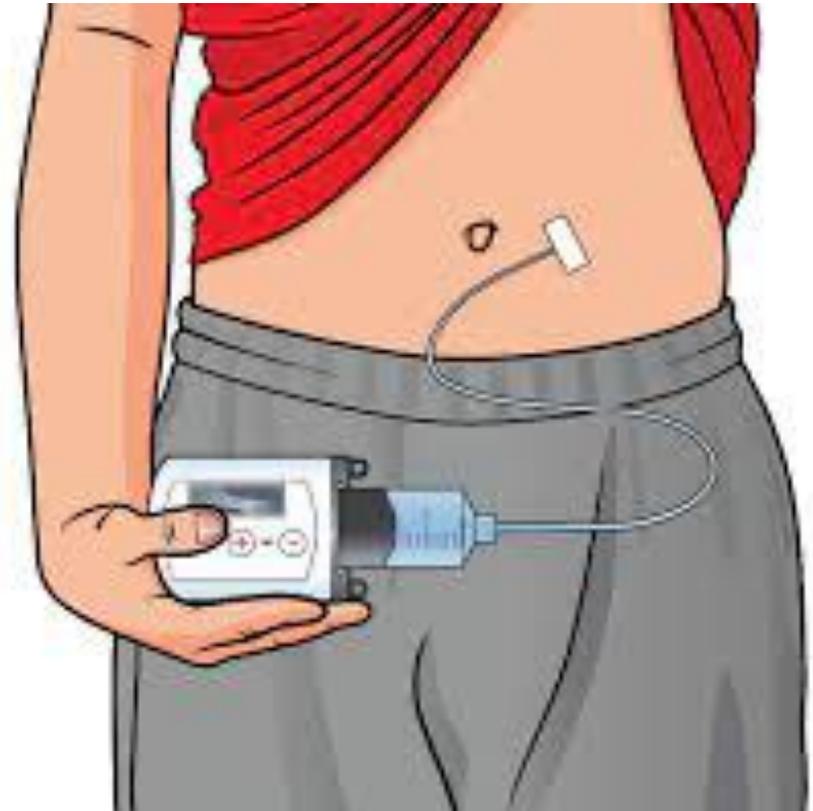
Conservation summary of hemoderivates products.

- Bring to room temperature before administration.
- Use the solution as soon as possible to avoid microbial contamination, since these preparations do not contain preservatives.
- Visually inspect the preparation, before administration, to detect any change in color or appearance of particles that could indicate that the preparation is not suitable for administration.
- Administer slowly.

Final journey of plasma



intravenous infusion



subcutaneous infusion

Thanks
Muchas gracias!

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Case study on plasma collection from Argentina patient organization for PIDs

Presentar estudios de caso de NMOs sobre colecta de plasma: Argentina

Roberta Anido de Pena: Argentina

WHO WE ARE



The Technical Expert Group is a peer-to-peer network of policymakers, government officials, doctors, academics and patients organization's.

- Dra. María Susana Pisarello - MINSAL
- Dr. Daniel Fontana - MINSAL
- Dr. Richard Malan - INCUCAI
- Dr. Oscar Torres - AAHITC
- Dra. Silvina Kuperman - HTAL. GARRAHAN
- Mgter. Andrea Corina Zucchi - HEMODERIVADOS UNC
- Roberta Anido de Pena - IPOPI/ AAPIDP/FADEPOF
- Dr. Carlos Safadi Márquez - HEMOFILIA FOUNDATION
- Lic. Luciana Escati Peñaloza - FADEPOF
- Dr. Marcelo Cases - TAKEDA



WORKING GROUP



independent from relevant stakeholders for the purpose of discussing and developing recommendations on possible solutions related to improving plasma supply, accessibility and standards with the aim of meeting patients' plasma needs. therapies derived, aligned and adapted to the Argentine context.

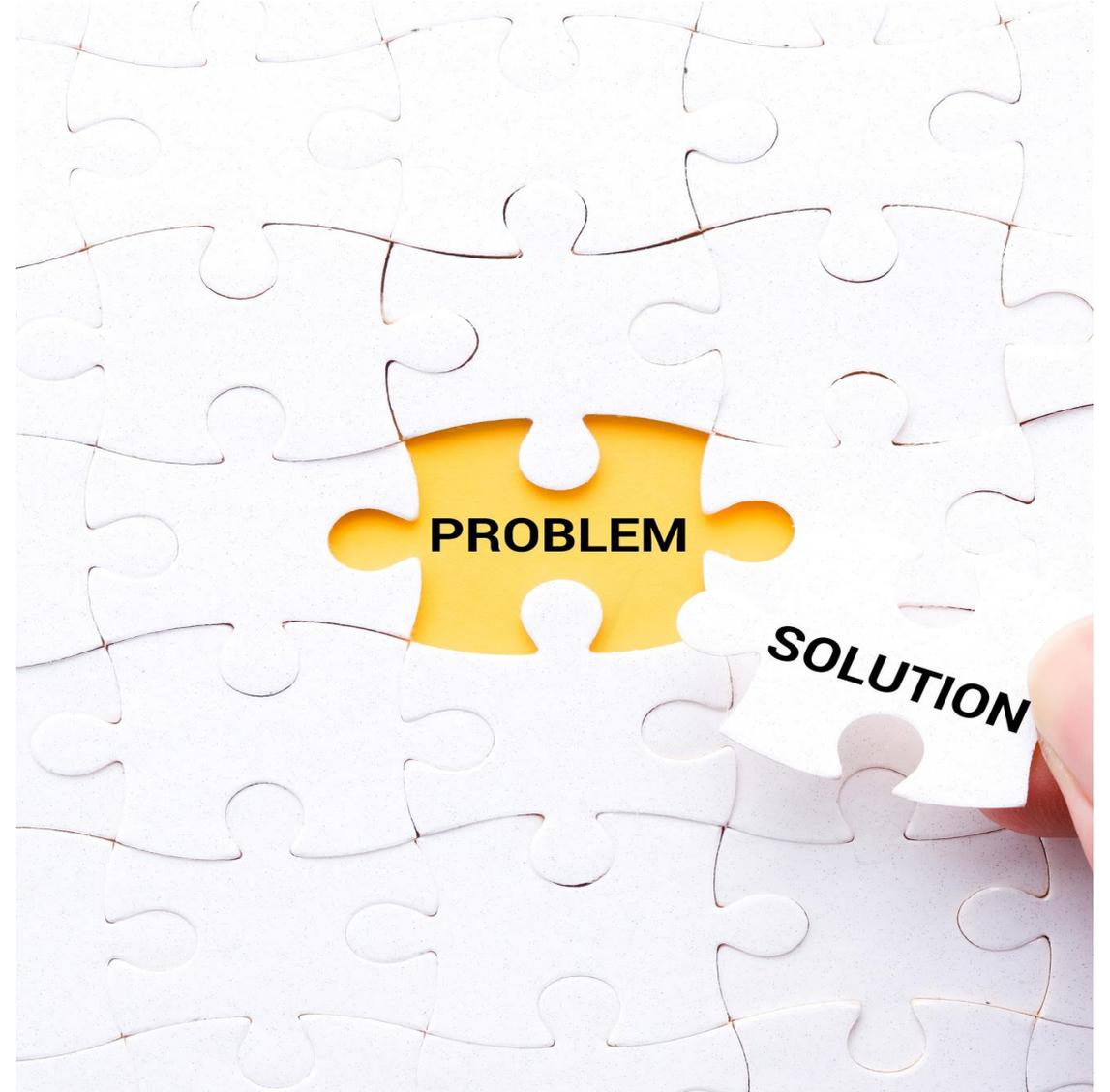


Improving plasma supply, accessibility and standards in Argentina

OBJECTIVES

The working group was established as part of the project implemented in collaboration between UNITAR and Takeda, with UNITAR acting as project leader and coordinator.

- ✔ Identify key issues/challenges related to the delivery of plasma and plasma-derived therapies.
- ✔ Develop recommendations and/or a framework plan to address these key issues/challenges (as specified by the working group).
- ✔ Comment and contribute to the knowledge resource platform developed by UNITAR, as well as other educational content and events.



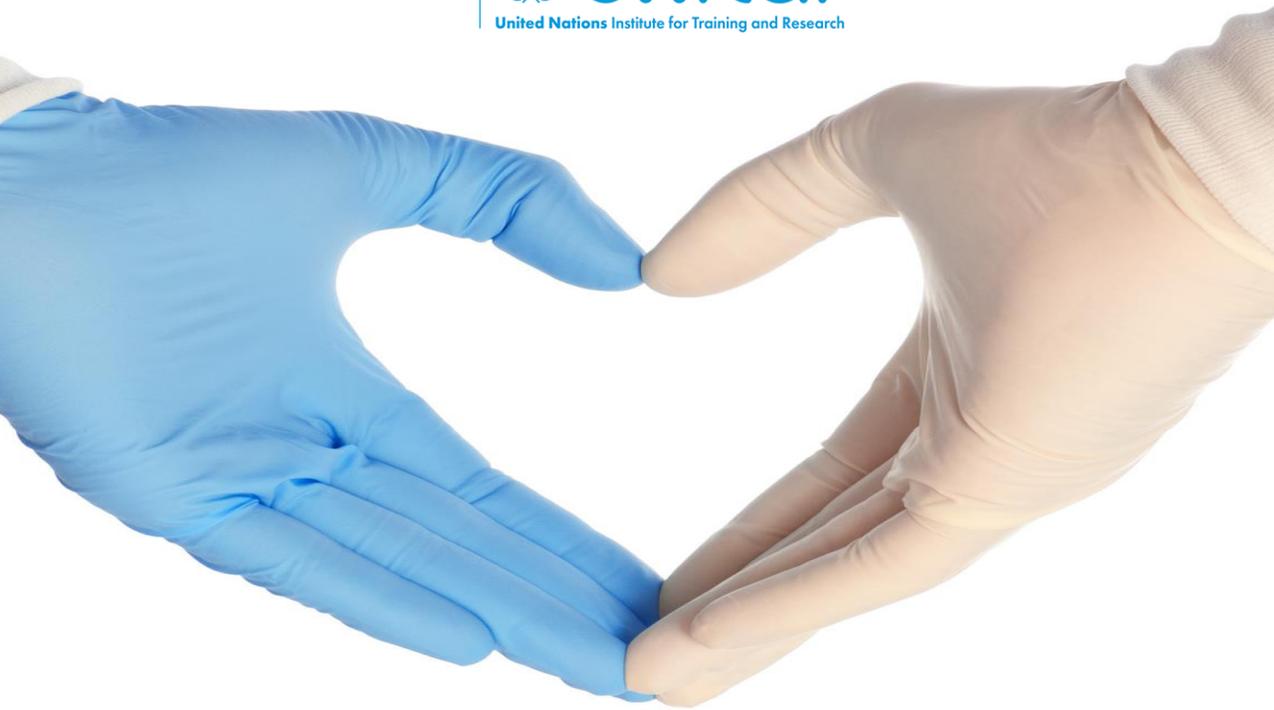
What strategies should we think about to achieve self-sufficiency in blood-derived medicines in Argentina and the region?



- Robust data on the status of blood banks in Argentina.
- Review of current regulations and policies.
- Exchange of scientific knowledge and best practices.
- In compliance with internationally recognized quality standards on the subject.

<https://plasma4.life/>





Plasma-derived therapies are life-saving treatments used to treat rare and life-threatening diseases resulting from trauma, congenital deficiencies, immune disorders, and infections.

PLASMA SURVEY IN ARGENTINA



Ministerio de Salud
Argentina



ACTIONS DONE



Gestión en Medicina Transfusional: Autosuficiencia en Medicamentos Hemoderivados en nuestro país.
Dirección de Medicina Transfusional
AGOSTO, SEPTIEMBRE Y OCTUBRE DE 2023



Visión de la Comunidad sobre la disponibilidad de Medicamentos Hemoderivados

Roberta Anido
Miembro de Junta Directiva IPOPI
Presidente AAPIDP
Presidente FADEPOF



Management Course in Transfunctional Medicine. Autosufficiency in Blood Derivative Medications in Argentina



Lecture about the “Community view on the availability of blood-derived medications”



XIX Argentine Congress of Transfusion Medicine

2023 CONVERSATORIO
¿QUÉ ESTRATEGIAS DEBERÍAMOS PENSAR PARA ALCANZAR LA AUTOSUFICIENCIA DE MEDICAMENTOS HEMODERIVADOS EN ARGENTINA Y LA REGIÓN?

Dirigido a todas las partes que participan en la prescripción, administración, gestión y consumo de productos medicinales derivados del plasma

JUEVES 5 OCT 18.30 A 19.30 HORA ARG

VIRTUAL

REQUIERE INSCRIPCIÓN

Logos: Ministerio de Salud Argentina, HEMODERIVADOS LABORATORIO FARMACÉUTICO UNC, Asociación Argentina de Hemoterapia y Transfusión Clínica, IPOPI, WFH, FUNDACIÓN DE LA HEMOFILIA Desde 1944, ASDEP, FADEPOF, Takeda.

WEBINAR

Panelists:

-  Dra. María Susana Pisarello Directora de Medicina Transfusional del Ministerio de Salud de la Nación
-  Mgter. Andrea Corina Zucchi Directora CMPB en Laboratorio de Hemoderivados - UNC
-  Dr. Carlos Safadi Márquez Presidente de Fundación de la Hemofilia y Vicepresidente de Federación Mundial de Hemofilia
-  Dra. Silvina Kuperman Jefa del Centro Regional de Hemoterapia, Directora del Banco Público de Sangre de Cordón Umbilical Hospital Garrahan
-  Dr. Oscar Torres Secretario General de la Asociación Argentina de Hemoterapia, Inmunohematología y Terapia Celular
-  Marcelo Cases Public Affairs Manager de Takeda.

Moderator: Roberta Anido - IPOPI/ FADEPOF/ AAPIDP

Thanks
Muchas gracias!

COLLABORATION

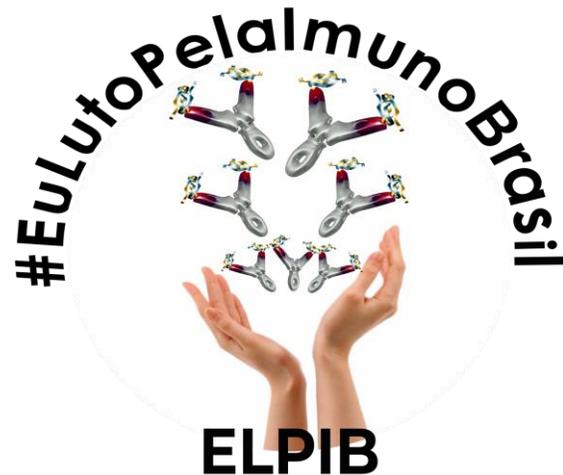


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Plasma Collection in Brasil: Insights from a patient organisation experience

Colecta de plasma en Brasil: la experiencia de una organizacion de pacientes



Juçaíra Giusti: Brasil

¿Cómo es la legislación sobre sangre vigente en Brasil?

Desde 1988, la Constitución brasileña prohíbe la comercialización de la sangre. Toda la sangre debe donarse voluntariamente, sin ningún tipo de remuneración, y sólo la empresa estatal Hemobras tiene derecho a procesar plasma.

Hemobras, creada por el gobierno federal en 2004, aún no produce inmunoglobulina en Brasil. Actualmente se considera un activo estratégico para la seguridad nacional, con una capacidad máxima de producción de 5 toneladas al año (cuando está en funcionamiento). En la actualidad, no hay recogida de plasma en Brasil, y Hemobras depende del plasma sobrante de las donaciones de sangre.

Visita a Hemobras en agosto de 2021.

Propuesta de enmienda constitucional - PEC 10/2022.

La ley establecerá las condiciones y requisitos para la obtención, procesamiento y comercialización de plasma humano por entidades públicas y privadas, para uso en laboratorios, desarrollo de nuevas tecnologías y producción de medicamentos derivados de la sangre, principalmente en beneficio del Sistema Único de Salud (SUS).

Situación de la inmunoglobulina en Brasil

El consumo de inmunoglobulina en Brasil es de 16,7 g/1.000 habitantes (3,34 toneladas al año).

La mejora de la atención sanitaria tiene como objetivo alcanzar los 50 gramos/1.000 habitantes (10 toneladas al año).

Hay escasez de medicamentos para los pacientes ya diagnosticados, y un número significativo de pacientes aún está en fase de diagnóstico.

El ELPIB presentó una denuncia ante la Fiscalía en 2020, que se convirtió en una demanda civil en septiembre de 2021. El fiscal federal insta a la Unión a cumplir con sus obligaciones constitucionales y encontrar una solución definitiva para regularizar el suministro de medicamentos de inmunoglobulina humana en todo el territorio nacional, con un medicamento seguro y eficaz debidamente registrado ante las autoridades brasileñas. El problema sigue sin resolverse, lo que lleva al gobierno a realizar compras de emergencia de medicamentos sin licitación y sin los registros necesarios ante la ANVISA. Se han dado incluso casos de incautación de medicamentos falsificados por parte de las fuerzas de seguridad.

¿Cuál es el mejor enfoque para resolver el problema de la recogida de plasma en Brasil?

¿Aprobación del PEC?

¿Corremos el riesgo de convertirnos en proveedores de plasma y seguir dependiendo de la compra de inmunoglobulinas?

¿No aprobar el PEC?

¿Crear que el gobierno será capaz de lograr en dos años lo que no ha hecho en 20? Mientras el resto del mundo explora la colaboración público-privada.

Muchas dudas y una sola certeza: hay mucha desinformación entre la población en general, incluidos los donantes de sangre, respecto a la donación de plasma para la producción de medicamentos hemoderivados.

Thanks! Gracias!
Obrigada!

jsmgiusti@gmail.com

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Taller: Convirtiendo los desafíos de la colecta de plasma en oportunidades

Workshop: Turning challenges on plasma collection into opportunities

CONCLUSIÓN CONCLUSION

Leire Solis

GRACIAS! THANKS!

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