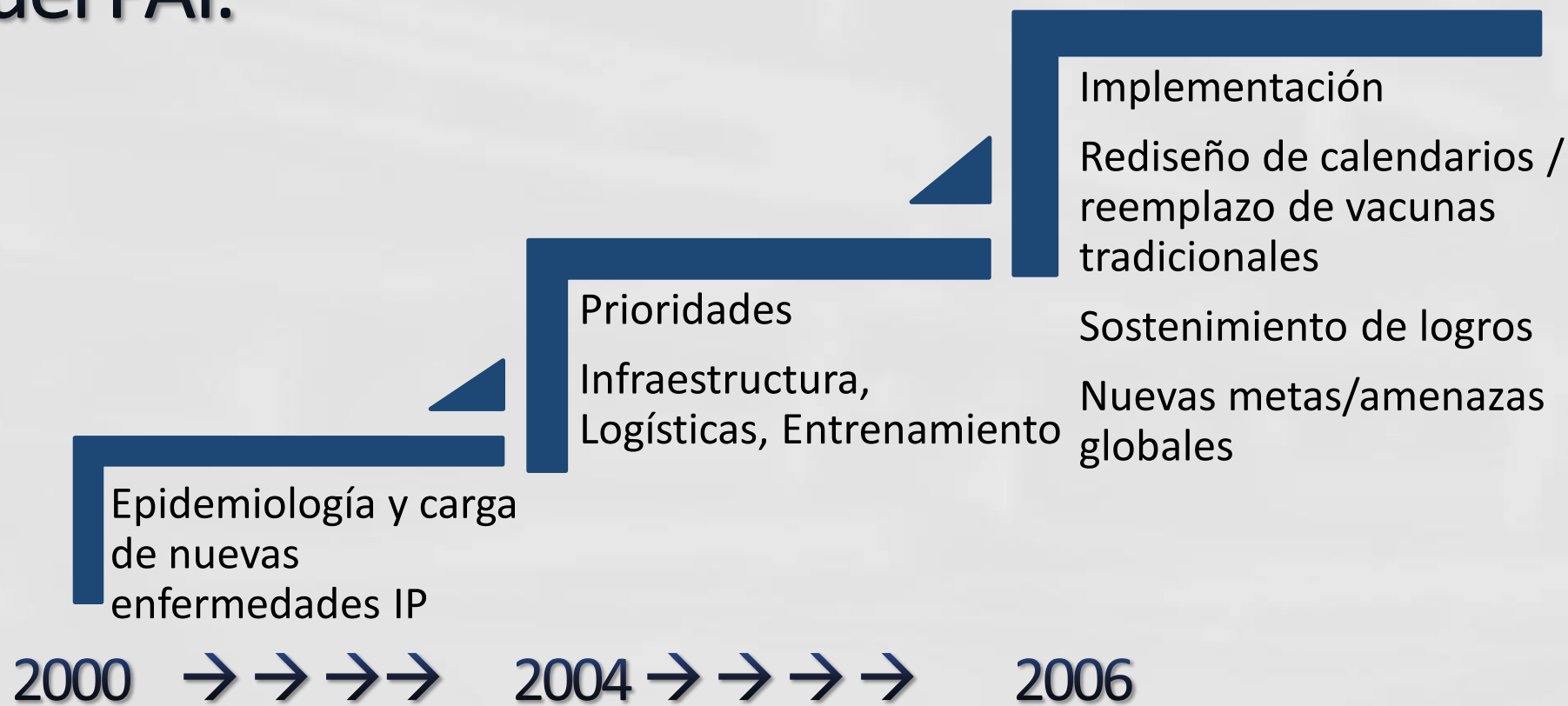


Monitoreo de los Riesgos y Beneficios de las nuevas vacunas programáticas *¿Qué tienen el común?*

Vaccinology-2018
XI International Symposium for Latin American Experts

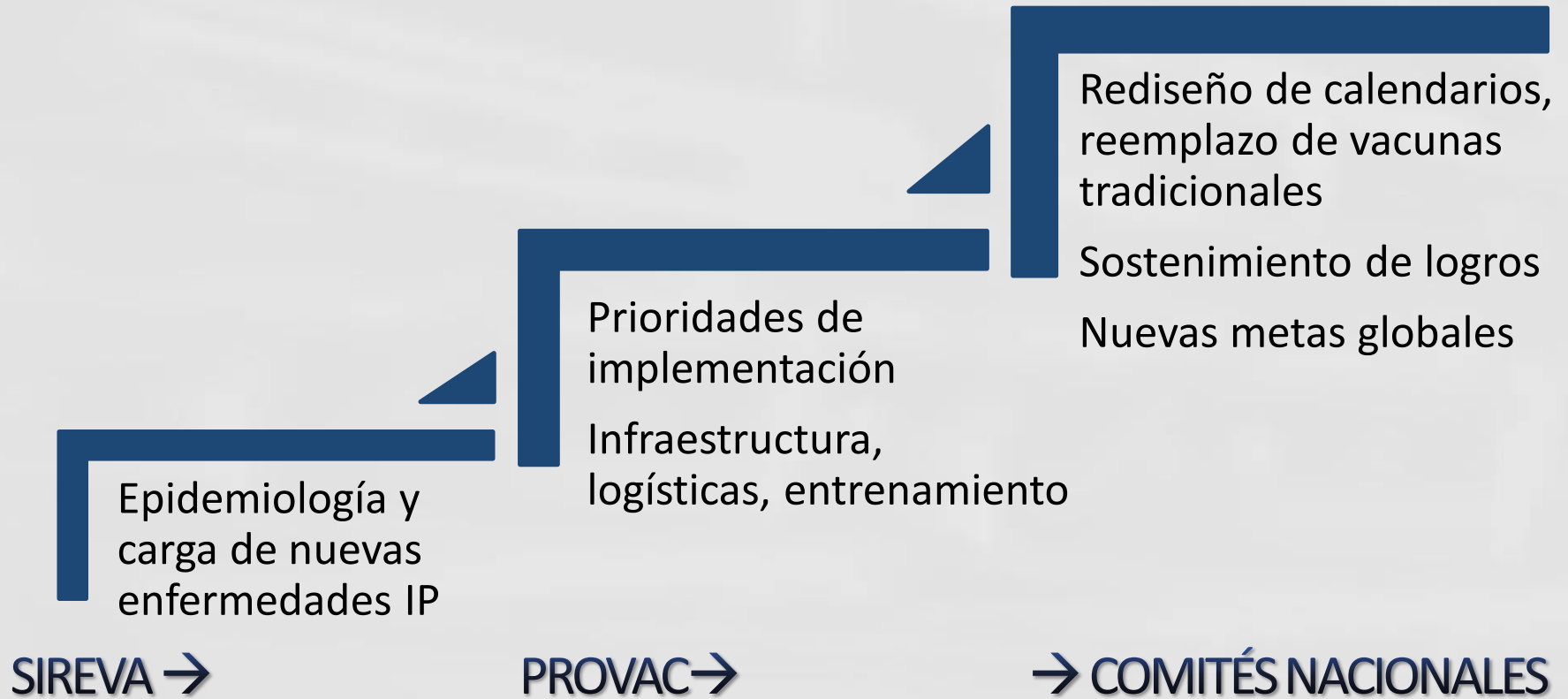
Cuidad de Panamá; Panamá
17-18 de Octubre de 2018

En países de AL, la “Alianza GAVI” trajo consigo exigencias técnicas crecientes para los gerentes del PAI.



PAI →

Apoyo internacional para el desarrollo de las competencias necesarias



PAI → Programas Nacionales de Inmunización

La incorporación de VPn-C se completó en menos de 5 años, tras la llegada de las vacunas de 2ª generación.

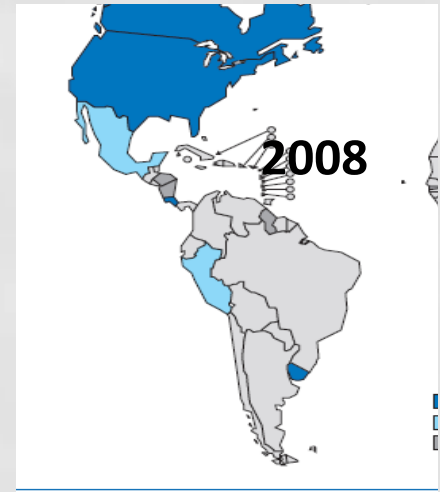
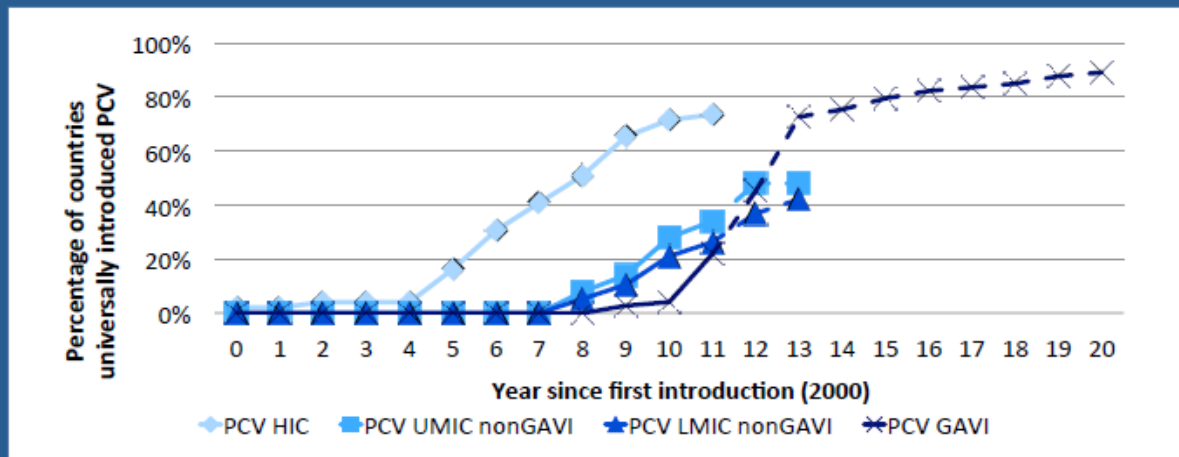


FIGURE 4

Rate of PCV Introduction: Middle income countries are being left behind



Note: Limited projections are available for PCV introduction in HIC, and non-GAVI UMIC, LMIC



The Accelerated Rollout of Pneumococcal Conjugate Vaccine: Its Impact on Health and Global Equity

Meghan L Stack¹ & Orin S Levine¹

¹ International Vaccine Access Center, Johns Hopkins Bloomberg School of Public Health

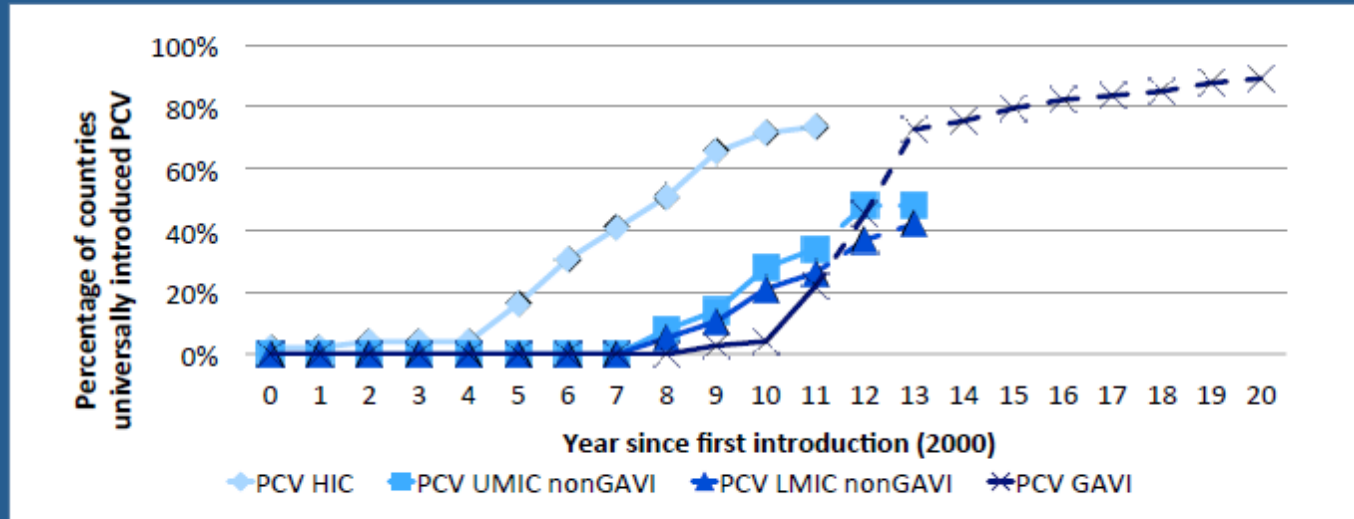


WHO/IVB Database, Sep/2015.
Immunization Vaccines and
Biologicals (IVB)

El avance hacia la igualdad de oportunidades vino de la mano con nuevas exigencias

FIGURE 4

Rate of PCV Introduction: Middle income countries are being left behind



Note: Limited projections are available for PCV introduction in HIC, and non-GAVI UMIC, LMIC



La implementación de vacunas recién llegadas al mercado implica asumir mayor nivel de incertidumbre en torno a sus posibles riesgos y beneficios en los distintos escenarios programáticos → Obliga a monitorear estrechamente los efectos esperados y no esperados

The Accelerated Rollout of Pneumococcal Conjugate Vaccine:
Its Impact on Health and Global Equity

Meghan L Stack¹ & Orin S Levine¹

¹ International Vaccine Access Center, Johns Hopkins Bloomberg School of Public Health



WHO/IVB Database, Sep/2015.
Immunization Vaccines and
Biologicals (IVB)

Objetivos Generales para el Decenio de Vacunas 2011-2020

Epidemiología y Carga

Prioridades de implementación
Infraestructura, logísticas, entrenamiento

Rediseño de calendarios
Sostenimiento de logros
Nuevas metas y amenazas globales

Conseguir un mundo libre de poliomielitis



Cumplir con los objetivos mundiales y regionales de eliminación



Cumplir con los objetivos de cobertura de vacunación en todos los países, regiones y comunidades



Desarrollar e introducir vacunas y tecnologías nuevas y mejoradas



Superar el Objetivo de Desarrollo del Milenio número 4 de reducir la mortalidad infantil

MDG4



Plan de Acción Mundial sobre Vacunas
2011-2020



2006

2008

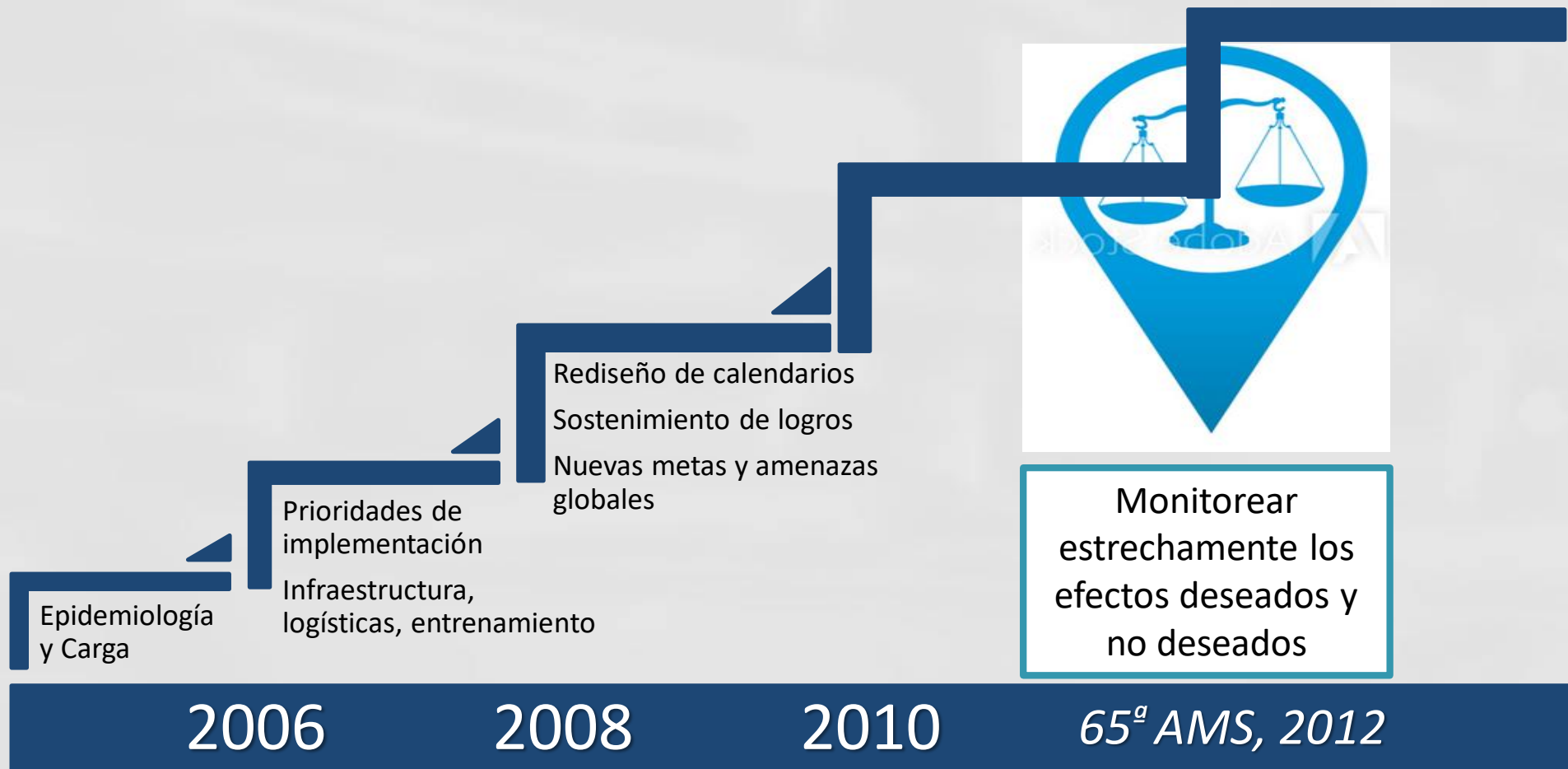
2010

65ª AMS, 2012

Objetivo Estratégico # 2



Individuos y Comunidades Comprenden el Valor de las Vacunas...



Sucesivos estudios han documentado que los sistemas de farmacovigilancia en países de ingresos medios y bajos son precarios

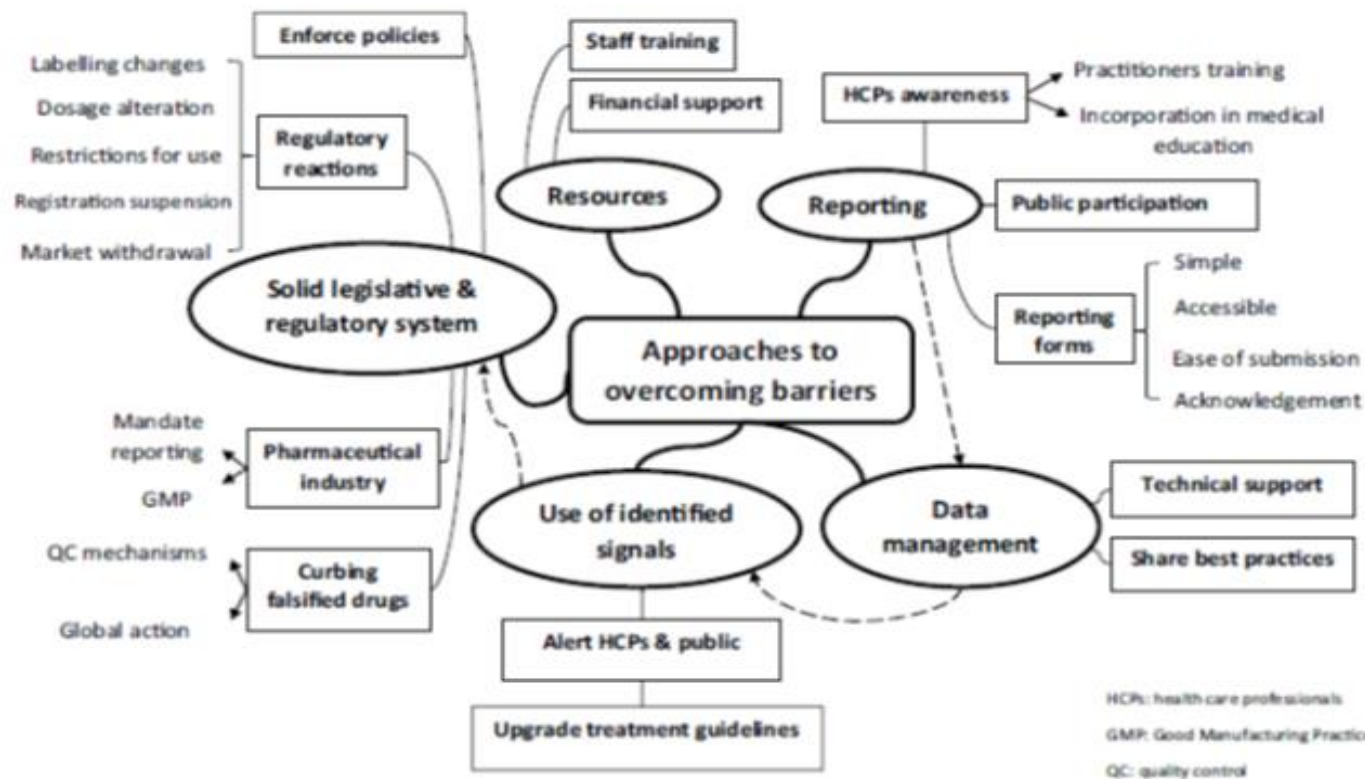
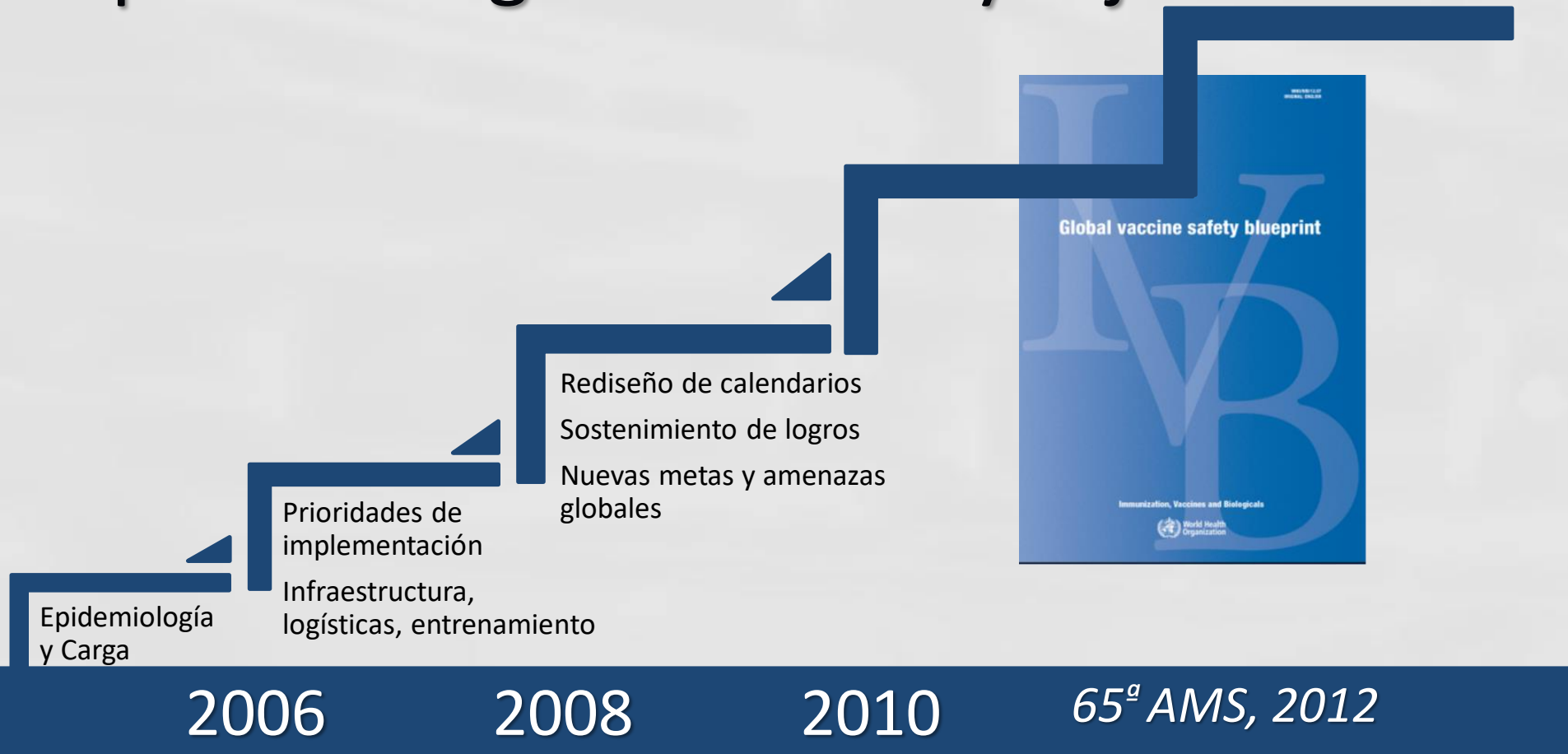


Fig. 1 Diagram illustrating strategies and approaches to promoting pharmacovigilance practice in developing countries

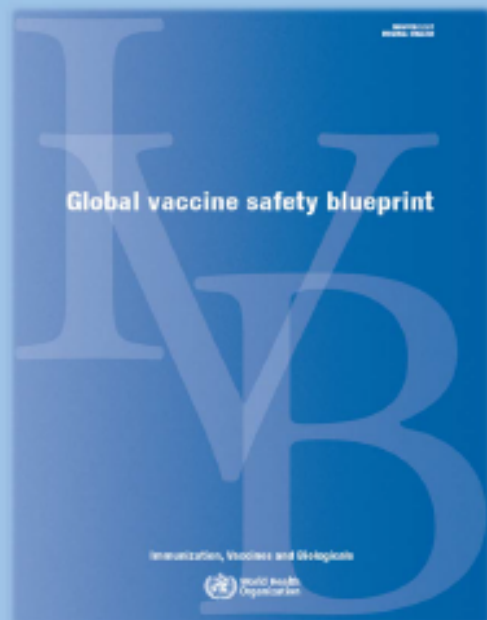
Plan estratégico para desarrollar/fortalecer las competencias de farmacovigilancia de vacunas en países de ingresos medios y bajos



Global Vaccine Safety Blueprint

VISION

Effective vaccine pharmacovigilance systems are established in all countries (by 2020...)



A capacity-building model towards, at least, a minimal capacity for vaccine pharmacovigilance.

Access to technical support from institutions with adequate expertise, cultural and geographical proximity through an integrated network.

Solutions for enhanced vaccine pharmacovigilance capacity to adequately monitor newly available vaccine products.

Pharmacovigilance business models aligned with those for drugs and other medicinal products.

http://extranet.who.int/iris/restricted/bitstream/10665/70919/1/WHO_IVB_12.07_eng.pdf

Edwin J. Asturias, MD
Associate Professor of Pediatrics and Epidemiology
Center for Global Health

GVSI
2018

SEVENTH MEETING OF THE
GLOBAL VACCINE SAFETY INITIATIVE
8-9 October 2018
Santiago, Chile

Capacidad Mínima: Indicadores de frecuencia, calidad y oportunidad de notificación espontánea de AEIFI

AEFI reporting ID number:

REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

<p>*Patient Name: *Patient's full Address: Telephone: Sex: <input type="checkbox"/> M <input type="checkbox"/> F</p> <p>*Date of birth: _ / _ / _ _ OR Age at onset: <input type="checkbox"/> <1 Year <input type="checkbox"/> 1 to 5 Years <input type="checkbox"/> >5 Years OR Age Group at onset: <input type="checkbox"/> <1 Year <input type="checkbox"/> 1 to 5 Years <input type="checkbox"/> >5 Years</p>	<p>*Reporter's Name: Institution: Designation & Department: Address:</p> <p>Telephone and E-mail: Date patient notified event to health system: _ / _ / _ _ Today's date: _ / _ / _ _</p>
---	---

Health facility (place or vaccination centre) name & address:							
Vaccine				Diluent (if applicable)			
*Name of vaccine	*Date of vaccination	*Time of vaccination	Dose (1 st , 2 nd , etc.)	*Batch /Lot number	Expiry date	Name of diluent	*Batch /Lot number

<p>*Adverse event(s):</p> <p><input type="checkbox"/> Severe local reaction <input type="checkbox"/> >3 days <input type="checkbox"/> beyond nearest joint</p> <p><input type="checkbox"/> Seizures <input type="checkbox"/> febrile <input type="checkbox"/> afebrile</p> <p><input type="checkbox"/> Abscess <input type="checkbox"/> Sepsis <input type="checkbox"/> Encephalopathy <input type="checkbox"/> Toxic shock syndrome <input type="checkbox"/> Thrombocytopenia <input type="checkbox"/> Anaphylaxis <input type="checkbox"/> Fever >38°C <input type="checkbox"/> Other (specify): _____</p> <p>*Serious: Yes / No → If Yes: <input type="checkbox"/> Death <input type="checkbox"/> Life threatening <input type="checkbox"/> Persistent or significant disability <input type="checkbox"/> Hospitalization <input type="checkbox"/> Congenital anomaly <input type="checkbox"/> Other important medical event (specify): _____</p> <p>*Outcome: <input type="checkbox"/> Recovering <input type="checkbox"/> Recovered <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Not Recovered <input type="checkbox"/> Unknown</p> <p><input type="checkbox"/> Died If Died, date of death: _ / _ / _ _ Autopsy done: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown</p> <p>Past medical history (including history of similar reaction or other allergies), concomitant medication and other relevant information (e.g. other cases). Use additional sheets if needed.</p>	<p>Date AEFI started: _ / _ / _ _</p> <p>Time: _ : _</p> <p>Describe AEFI (Signs & Symptoms):</p>
--	---

First Decision making level to complete:	
Investigation needed: <input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, date investigation planned: _ / _ / _ _
National level to complete:	
Date report received at National level: _ / _ / _ _	AEFI worldwide unique ID:
Comments:	

***Compulsory field**

Page 1 of 2 January 2016

Description of elements in the AEFI reporting form (revised Jan 2016)

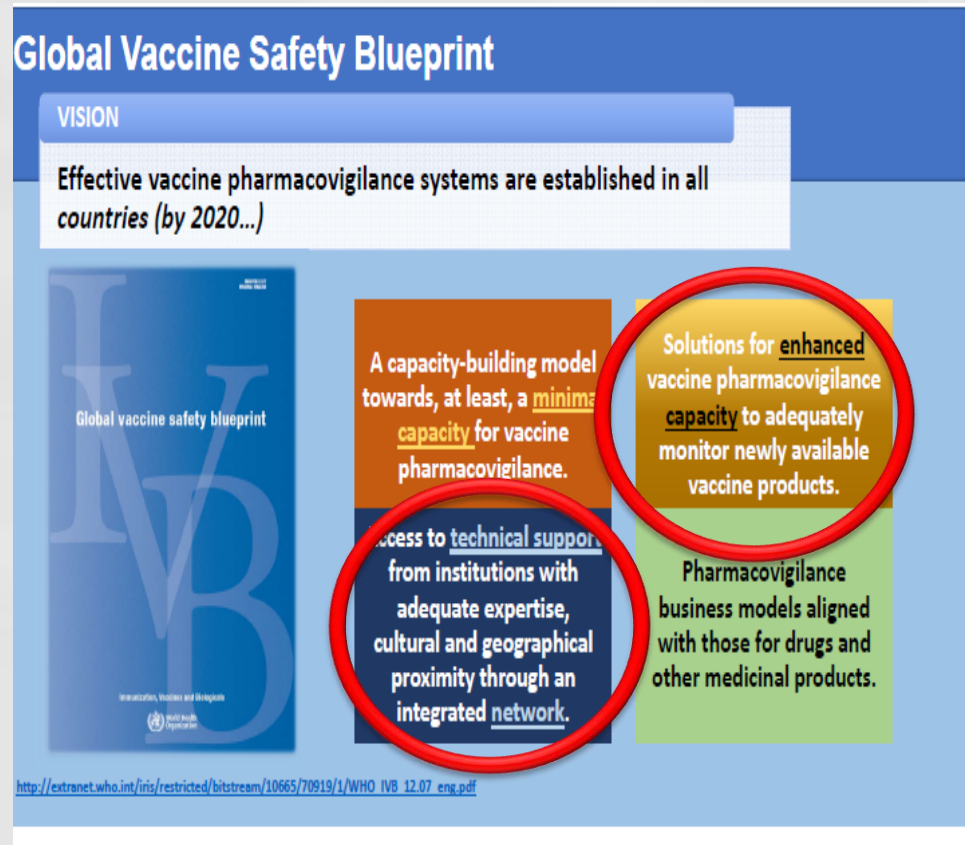
Reporting element	Description
AEFI reporting ID number	Unique number assigned to the AEFI case as per the national guidelines
*Patient's Name	The name of the patient or initials as decided by the country
*Patient's full Address	Geographic location of the case (address), please try to provide landmarks
Telephone	Number to contact to provide or receive additional information
Sex	Male or Female
*Date of birth	Date** patient was born
Age at onset	If date of birth is not known, this may be considered as first alternative
Age Group at onset	If date of birth and age at onset is not known, this may be considered as second alternative
*Reporter's Name	Name of person who has reported this AEFI to the healthcare system and also completed this form
Institution	The place where the reporter is working or is affiliated to
Designation & Department	Reporter's designation and his/her section of work
Address	Reporter's full address - Please add the name of the country here as well
Telephone	Reporter's phone number
E-mail	Reporter's e-mail address
Date patient notified event to health system	The date** when the event was first brought to the notice of the healthcare system
Today's date	Date** when the report was compiled by the reporter (this can be different from the date of notification [above])
Vaccination centre or place of vaccination - name & address	Name and address of the place where the child received the vaccine - provide details (e.g. mobile clinic, home etc.)
*Name of vaccine	The vaccine that is suspected to have caused the AEFI (provide brand name, if possible)
Name (of other vaccines)	Other vaccines that were administered at the same time (provide brand name, if possible)
*Date of vaccination	Date** when the vaccine was administered
*Time of vaccination	Time** when vaccine was administered - try to be as accurate as possible
*Batch/Lot number (of vaccine)	Batch number/lot number of each of the vaccines mentioned above
Dose (1st, 2nd, etc.)	Dose number of the vaccine for the vaccinee e.g. 2nd dose of DTP or 5th Dose of OPV etc.
Expiry date	The date** of expiry for each vaccine
*Batch/Lot number (of diluent)	The batch/lot number of diluent (if applicable)
Expiry date (of diluent)	The date** of expiry of the diluent
Time of reconstitution	Time when the vaccine was reconstituted with the diluent
*Adverse event(s)	The details of the events suspected to be caused by immunization. Multiple events can occur in a single patient. They need to be documented here.
Date & Time AEFI started	Date** and time** the event was first noticed
Describe AEFI (Signs & Symptoms)	Description of the events in chronological order
*Serious: Yes / No	If the case is serious, mark "Yes" and indicate one or several options: Death, Life threatening, Persistent or significant disability, Hospitalization, Congenital anomaly or Other important medical event that may jeopardize the patient or may require intervention to prevent one of the outcomes mentioned here
*Outcome	Outcome of the reaction(s). Indicate status of the patient at the time of reporting: Recovering, Recovered, Recovered with sequelae, Not Recovered, Unknown or Died
Died	Provide date of death and details of autopsy, if available
Past medical history	Please include history of similar reaction or other allergies, concomitant medication and other relevant information (e.g. other cases in the locality or among those vaccinated)
First Decision making level to complete	This section has to be completed by the decision maker for a detailed field AEFI investigation.
Investigation needed	Investigation needed.
Date investigation planned	Date** when detailed investigation (including field investigation) is planned to start.
National level to complete	This section has to be completed by the National level to decide on the next steps.
Date report received at National level	Date** this report was received at the National level
AEFI worldwide unique ID	Unique ID number (e.g. regulatory authority's case report number) for the AEFI case automatically generated for electronic transmission from National level to International level
Comments	Please add additional details that will help with processing this report. Please include other documents as attachments, if necessary

*** Compulsory field** **Items marked with an asterisk (*) have to be completed**

** Please use the local convention for the format e.g. DD/MM/YY or MM/DD/YY or YY/MM/DD, for time use a 12 or 24 hours format

Un estudio reciente examinó la factibilidad de detectar y verificar señales de alerta de alerta de seguridad a través de una red global compuesta por 26 hospitales, con participación balanceada de Regiones y países en desarrollo (65%)

(Prueba de Concepto)



The infographic is titled "Global Vaccine Safety Blueprint" and features a blue header. Below the header, a white box contains the "VISION" statement: "Effective vaccine pharmacovigilance systems are established in all countries (by 2020...)". To the left is a large blue graphic with the letters "IVB" and the text "Global vaccine safety blueprint". To the right are three colored boxes: an orange box with text about a capacity-building model, a dark blue box with text about technical support, and a yellow box with text about enhanced capacity. A red circle highlights the yellow box, and another red circle highlights the dark blue box. At the bottom, a URL is provided: http://extranet.who.int/iris/restricted/bitstream/10665/70919/1/WHO_IVB_12.07_eng.pdf

Global Vaccine Safety Blueprint

VISION

Effective vaccine pharmacovigilance systems are established in all countries (by 2020...)

Global vaccine safety blueprint

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http://extranet.who.int/iris/restricted/bitstream/10665/70919/1/WHO_IVB_12.07_eng.pdf

El estudio demostró factibilidad

Vaccine. 2018 Jan 8;36(3):347-354. doi: 10.1016/j.vaccine.2017.05.012. Epub 2017 May 17.

ELSEVIER
FULL-TEXT ARTICLE

PMC
Full text
FREE

Enhancing global vaccine pharmacovigilance: Proof-of-concept study on aseptic meningitis and immune thrombocytopenic purpura following measles-mumps containing vaccination.

Perez-Vilar S¹, Weibel D², Sturkenboom M², Black S³, Maure C⁴, Castro JL⁵, Bravo-Alcántara P⁶, Dodd CN⁷, Romio SA⁸, de Ridder M⁷, Nakato S⁷, Molina-León HF⁹, Elango V¹⁰, Zuber PLF⁴; WHO Global Vaccine Safety-Multi Country Collaboration.

Vaccine. 2018 Jan 8;36(3):363-370. doi: 10.1016/j.vaccine.2017.04.069. Epub 2017 Aug 10.

Building capacity for active surveillance of vaccine adverse events in the Americas: A hospital-based multi-country network.

Bravo-Alcántara P¹, Pérez-Vilar S², Molina-León HF³, Sturkenboom M⁴, Black S⁵, Zuber PLF⁶, Maure C⁶, Castro JL⁷; L.A.N.V.A.P. (Latin American Network for VAccine Pharmacovigilance).

La red reprodujo dos asociación previamente conocidas, entre vacunas y efectos adversos serios-raros.

Principales Obstáculos

- Errores de registro de las causas primarias de hospitalización (producto de imprecisiones del diagnóstico médico de egreso)
- Imprecisiones o falta información médica necesaria para la categorización de eventos en las historias clínicas de los pacientes
- Inconsistencias o falta de datos de identidad suficientes para vincular los eventos a la historia de vacunación de los pacientes.
- Registros de vacunación incompletos o no disponibles
- Limitaciones de recurso humano (investigadores “voluntarios”, con otras responsabilidades)



Lecciones → Recomendaciones

- Los sitios que deseen participar en futuros estudios similares deberán mejorar sus sistemas de registro y codificación de las causas de hospitalización, historias clínicas, acceso y documentación de las historias de vacunación.

Vaccine

Volume 36, Issue 3, 8 January 2018, Pages 355-362

Operational lessons learned in conducting a multi-country collaboration for vaccine safety signal verification and hypothesis testing: The global vaccine safety multi country collaboration initiative

Christine Guillard-Maure ^a  , Varalakshmi Elango ^b, Steven Black ^{c, d}, Silvia Perez-Vilar ^{e, f}, Jose Luis Castro ^g, Pamela Bravo-Alcántara ^h, Helvert Felipe Molina-León ⁱ, Daniel Weibel ^{d, e}, Miriam Sturkenboom ^{d, e, j}, Patrick L.F. Zuber ^a

the WHO Global Vaccine Safety-Multi Country Collaboration¹

Observaciones y Conclusiones personales.

- Las dificultades reportadas en este estudio son **exactamente las mismas** que hemos encontrado (en Chile) cada vez que intentamos utilizar paquetes de datos asistenciales de rutina para examinar el impacto /efectividad de las nuevas vacunas.
 - Las dificultades representan fallas de calidad de los registros asistenciales
- Los registros de los procesos asistenciales son la base del historial de salud de las personas
 - La obligación de calidad es inherente al propósito primario, e independiente de su potencial utilidad para efectos posteriores.