Global NITAG webinar 6 May, 15:00 CET

Time	Торіс	Speaker / Moderator
15:00-15:10	Welcome / Introductions Housekeeping (10 min)	Mario Melgar, Chair GNN
15:10-15:20	Update on Rabies elimination (10 min)	Bernadette Abela, WHO HQ
15.20 - 14:35	SAGE recommendations on rabies immunization from a country perspective (15 min)	Naseem Salahuddin,(Pakistan)
15:35 - 15:50	Gavi investment in human rabies vaccine (15 min)	Simbarashe Mabaya, GAVI
15:50-16:30	Q&A (mins) Discussion	

GNN webinar, 6 May 2024 Reaching zero human deaths from dog-mediated rabies by 2030

Dr Bernadette Abela, Global Programme for Neglected Tropical Diseases, abelab@who.int



Rabies is a neglected, vaccine-preventable disease

An indicator for impact on inequity and One Health

Presence of dog-transmitted human rabies, by country, 2022



- Rabies burden is highest in Asia (63%) and Africa (36%).
- Children are often victims.
- Surveillance is often inadequate, capturing insufficient data.
- Human rabies deaths are often underreported, particularly in Africa.



Rabies is transmitted via infectious saliva

Inoculation of infectious **saliva** via a bite (most common), scratch, or direct contact with mucosa (e. g. eyes, mouth, or open wound)

- Local **muscle** infection and uptake into peripheral nerves
- Spread to central nervous system

Replication in the **brain**

5

Spread to salivary glands and excretion in **saliva**



Rarely documented transmission:

- Human-to-human transmission via tissue and organ transplantation or mucosal route
- Inhalation of aerosolised virus (e.g. in labs)
- Handling of raw meat

Never documented transmission:

- Consumption of raw milk
- Rodent bites

"Zero by 30" is a coordinated strategy to act using a threepronged approach

Timely care



Dog vaccination & dog population management



Awareness & community engagement





Improving the availability and affordability of human vaccines is crucial

Status quo > Increased access to human vaccine > Increased access to human and dog vaccine





WHO guidelines for Post-exposure Prophylaxis (PEP) and Pre-exposure Prophylaxis (PrEP) recommendations

Expert Report on Rabies 2018

WHO Expert Consultation on Rabies: WHO TRS <u>N°1012 Third report</u>



World Health Organization

Rabies PEP administration decision tree

PrEP and PEP can be given intra-dermally or intra-muscularly

Intra-dermal (ID) = in the skin 1 dose = 0.1 mL of vaccine

Intra-muscular (IM) = in the muscle 1 dose = 1 entire vial (which is 0.5 mL or 1.0 mL of vaccine, depending on the product)

- All WHO pre-qualified vaccines can be administered by either route
- The injection sites for ID and IM are the same
- For ID, opened vials can be used up to 8 hours (WHO policy on the use of opened multi-dose vaccine vials)
- ID administration is simple to perform, if health care providers are adequately trained

! Do not inject vaccine in the gluteal region !

One-week Institut Pasteur Cambodia (IPC) Regimen -2-sites ID recommended for PEP

! Start PEP as soon as possible after exposure, but it is never too late to do it !

WHO position paper

Rabies immunoglobulin stops the virus at the wound site

Rabies immunoglobulin (RIG) is:

- recommended for **severe** exposure (Category III)
- not recommended if you have ever received rabies vaccine
- not recommended if you have received your first PEP dose >7 days ago

RIG:

- provides **fast protection** while the immune system responds to the vaccine
- must be administered **deep in and around all wounds**
- can be diluted for large and multiple wounds when requirement exceeds the maximum recommended dose
- consists of human (hRIG) or equine (eRIG) rabies antibodies both effective
- is administered, not exceeding the maximum dose, **calculated by body weight**: (*hRIG: 20 IU/kg and eRIG: 40 IU/kg*)
- Monoclonal antibody products are also available

RIG is often in short supply because of insufficient demand and supply forecasting, so its prioritization is essential

Pre-exposure prophlaxsis (PrEP) shortens, but does not replace, the post-exposure vaccine

PrEP is recommended for at **high-risk individuals**:

communities in remote, highly endemic settings with limited access to proper PEP

travellers to remote, highly endemic settings with limited access to proper PEP

individuals at occupational risk e.g., laboratory staff, veterinarians,

Guidance is available for countries to roll out rabies vaccination programmes

To highlight considerations specific to rabies PEP that can be integrated into existing systems

To inform policy discussions and operational planning

to introduce or expand rabies PEP into a national immunization programme:

Thank you!

Dr Bernadette Abela, Global Programme for Neglected Tropical Diseases, abelab@who.int

SAGE RECOMMENDATIONS ON RABIES

IMMUNIZATION FROM PAKISTAN'S PERSPECTIVE

Naseem Salahuddin Indus Hospital and Health Network, Karachi Pakistan

Population 240m

Pakistan, a low and middle-income country (LMIC), faces challenges in providing sustainable health care to its population due to inadequate financing, weak healthcare infrastructure, and insufficient human health resources

There are more than 190,200 registered dogs in Pakistan, in addition to at least another 3 million stray dogs. According to a study, more than one million dogbite cases are reported across Pakistan annually, and around 2,000- 5,000 people die of rabies every year.

Sindh Govt. reported 200,000 bites Jan-Oct 2023

Dawn 13-May-2023

ANIMAL BITE VICTIMS AT THE INDUS HOSPITAL Karachi

Animal bite victim annualy

RABIES DEATHS AT IHHN, JPMC 2009-202					<u>Totals</u> JPMC 88 TIH 60 Total 148			
No.	Estimated bite date	Date of arrival to TIH / JPMC	Gender	Age	Wound Category	Exact bite site	Incubation Period (days)	Vaccinated
99	1-Mar-2017	30-May-2017	М	28	III	Rt. Foot	90	No
100	7-Apr-2017	7-May-2017	М	30	III	Face	30	No
101	23-Feb-2017	9-May-2017	М	32	III	Rt. Foot	75	No
102	8-Jan-2017	11-Jan-2017	М	30	III	Rt. Aram (Fox Bite)	3	No
103	13-Mar-2017	11-Jun-2017	М	3	III	Face	90	No
104	13-Nov-2017	27-Jan-2018	М	38	III	Rt. Leg & Rt. Aram	75	No
105	2-Jan-2018	1-Feb-2018	М	75	III	Both Leg	30	No
106	5-Mar-2018	3-Ju1-2018	М	40	III	Lt. Hand	120	No
107	5-Jan-2018	6-Mar-2018	М	20	III	Rt. Foot Big Toc	60	No
108	22-Aug-2018	6-Sep-2018	М	62	III	Face & Rt. Lip	15	Yes
109	17-Sep-2018	7-Oct-2018	М	26	III	Lt. Hand	20	Yes
110	19-Mar-2018	8-Apr-2018	М	33	III	Muiltiple Bites	20	No
111	10-Jun-2018	9-Aug-2018	М	14	III	Chest on Latal Side	60	No
112	17-Aug-2018	15-Nov-2018	М	60	III	Lt. Hand	90	Yes

INDUS HOSPITAL HEALTH NETWORK

Challenges for PEP in LMICs

Lack of community awareness Poor knowledge, attitudes and practices amongst doctors and paramedics Inadequate understanding of cell culture vaccines and RIG applications

te Freque ling CCEEV ure

Frequent outages of CCEEV and RIG

PEP considered to be unaffordable

PLAN OF ACTION

ENABLEMENT ZONE

ENGAGEMENT ZONE

Rabies Vaccine

- Brands
- Volume 0.5/1 ml
- Prequalified/not
- Evolving IM/ID schedules
- Package insert: "for IM use"
- Storage of reconstituted vax
- Interchangeable brand/route
- Re-exposure
- Borderline Category 11/111
- PrEP/PEP
- FAQs

Rabies Immunoglobulin

RIG is unaffordable eRIG unsafe

Pre-2018: infiltrate wound, inject remaining into distant muscle

Post-2018: into wound only

- eRIG is safe; skin test not required;
- eRIG is noninferior to hRIG
- Victim received vaccine 8 days prior after rabid bite..... what to do?
- Saliva in eye

.

Regimen	Visits	Schedule	Vials	Route	Approval
NTV	14	Daily	Multodos e	S/c abd wall	1980 declared obsolete
Zagreb	3	0,7,21	4	IM	WHO 1992
Essen	4 (5)	0,3,7,14 (28)	4 (5)	IM	ACIP 2009
TRC ID	5	0,3,7,28,90	1	ID	TRC 1984
TRC updated	4	0,3,7,28	0.8	ID	WHO 2006
IPC 1 - week	<mark>3</mark>	<mark>0,3,7</mark>	<mark>0.6</mark>	ID	WHO 2018

Strategic Advisory Group of Experts (SAGE) Working Group on rabies vaccines and rabies immunoglobulins established July 2016 - June 2017

2018, 93, 201-220

World Health Organization Weekly epidemiological record Relevé épidémiologique hebdomadaire

Organisation mondiale de la Santé 20 APRIL 2018, 93th YEAR / 20 AVRIL 2018, 93* ANNÉE No 16, 2018, 93, 201-220 http://www.who.int/wei

Contents

201 Rabies vaccines: WHO position paper – April 2018 220 WHO Strategic Advisor Group of Experts (SAGE on immunization: request for nominations

Sommaire 201 Vaccins antirabiques: Note de synthèse de l'OMS - avril

2018 220 Le Groupe Stratégique Consultatif d'Experts (SAGE) de l'OMS sur la vaccination:

appel à candidatures

Rabies vaccines: WHO position paper – April 2018

Introduction In accordance with its mandate to provide

guidance to Member States on health policy matters, WHO issues a series of regularly updated position papers on vaccines and combinations of vaccines against diseases that have an international public health impact. They summarize essential background information on diseases and vaccines and conclude with the current WHO position on the use of vaccines worldwide.

The papers are reviewed by external experts and WHO staff, and reviewed and endorsed by the WHO Strategic Advisory Group of Experts (SAGE) on immunization (http://www.who.int/immunization/ sage/en). The GRADE methodology is used to systematically assess the quality of the available evidence. The SAGE decisionmaking process is reflected in the evidence-to-recommendation tables. A description of the processes followed for the development of vaccine position papers is available at http://www.who.int/ immunization/position_papers/position_ paper_process.pdf:

The position papers are intended for use mainly by national public health officials. They may also be of interest to internaVaccins antirabiques: Note de synthèse de l'OMS – avril 2018

No 16

Introduction

Conformément à son mandat qui est de donner aux États Membres des conseils sur les questions de politique de santé, l'OMS publie une série de notes de synthèse régulièrement actualisées sur les vaccins et les associations vaccinales contre les maladies ayant un impact sur la santé publique au niveau international. Elles résument les informations essentielles sur les maladies et les vaccins et présentent en conclusion la position actuelle de l'OMS concernant l'utilisation des vaccins dans le contexte mondial.

Ces notes sont examinées par des experts externes et des membres du personnel de l'OMS, puis évaluées et approuvées par le Groupe stratégique consultatif d'experts sur la vaccination (SAGE) de l'OMS (http://www. who.int/immunization/sage/fr). La méthodologie GRADE est utilisée pour évaluer de manière systématique la qualité des données disponibles. Le processus de décision du SAGE est reflété dans les tableaux de données à l'appui des recommandations. Une description du processus suivi pour l'élaboration de ces notes est disponible à l'adresse: http://www. who.int/immunization/position_papers/position_paper_process.pdf.

Les notes de synthèse de l'OMS s'adressent avant tout aux responsables nationaux de la santé publique. Toutefois, elles peuvent égale

WHO position paper on human PEP in 2018 suggested a shorter 2 – site,1– week ID regimen.

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The RIG infiltration into wounds only is a further step toward administering more bite victims effective rabies PEP.

A shorter post-exposure prophylaxis regimen for rabies, Pakistan

Naseem Salahuddin,^a Nadia Ansari^a & Muhammad Aftab Gohar^a

Bull World Health Organ 2021;99:506– 51http://dx.doi.org/10.2471/BLT.20.275453

Objective To assess the cost and effectiveness of the two-site, 1-week, intradermal rabies post-exposure prophylaxis regimen recommended by the World Health Organization (WHO) in 2018.

Methods We compared the number of rabies vaccine and rabies immunoglobulin ampoules consumed at The Indus Hospital in Karachi, Pakistan and their cost before and after implementing WHO's 2018 recommendations. In 2017, patients with suspected rabies-infected bites were treated using the two-site, 4-week, Thai Red Cross regimen, which involved administering four rabies vaccine doses intradermally over 4 weeks and infiltrating immunoglobulin into serious wounds, with the remainder injected into a distant muscle. In 2018, patients received three vaccine doses intradermally over 1 week, with a calculated amount of immunoglobulin infiltrated into wounds only. Remaining immunoglobulin was saved for other patients. The survival of patients bitten by apparently rabid dogs was used as a surrogate for effectiveness. **Findings** Despite treating 8.5% more patients in 2018 (5370 patients) than 2017 (4948 patients), 140 fewer ampoules of rabies vaccine and 436 fewer ampoules of rabies immunoglobulin were used, at a cost saving of 4202 United States dollars. Of 56 patients bitten by apparently rabid dogs, 50 were alive at 6-month follow-up. The remaining six patients could not be contacted but did not present to any hospital with rabies.

Conclusion The new regimen was more economical than the two-site, 4-week regimen and was equally effective. This regimen is recommended for preventing rabies in countries where the disease is endemic and rabies vaccine and immunoglobulin are in short supply.

	2017	2018	
# of patients injected vaccine	4,948 (99%)	5,370 (98.3%)	
# of ampoules consumed	7,174.6	7,034.7	
# of ampules saved in 2018	<mark>139.9</mark>		
Cost of each ampoules	5.65		
Total cost ampoules	40,536.5	39,746	
Cost of vaccine saved in 2018	790.5		
# of patients received RIG	2,249 (45%)	2,365 (43.3%)	
# of ampoules consumed	2,431	1,995	
Cost per victim	8.45	6.57	
Cost per ampoules	7.825		
<pre># of RIG ampoules saved</pre>	<mark>436</mark>		
Total cost of RIG	19,022.6	15,610.9	
Total cost of RIG saved	3,411.7		
Total Saving RIG + Vaccine	<mark>4,202.2</mark>		

Study Conclusion

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1 week 2-site ID regimen **saves vaccine and cost** without compromising patient safety Deleting D28 dose saves patient anxiety, cost of travel, accommodation and daily wages Frees space in Center's waiting area

Plans for 2024

Updated standard SOPs through National Guidelines

More PEP centers for hard-to-reach populations

1- week ID in high throughput clinics

Ensure accessibility to free vaccine and RIG through government

3 day Hands-on Pep Training For Health Care Providers

HCWs trained to.....

Wash

Intradermal injection of vaccine

Infiltrate RIG in severe or multiple wounds

Rabies PEP Centers through Indus Hospital and Health Network 2021-22

 29 health facilities identified in Sindh

Signing of MoU Sindh Health Ministry with IHHN

- Doctors & Nurses from 34 hospitals across sindh given PEP training
- Pre requisites: proper wash area, ARV, RIG, refrigerator
- 3 Day PEP training workshop includes pre-and post-evaluation tests, theoretical background of rabies, PEP, interactive sessions, and hands-on training
- 14 Hospitals have established proper PEP clinic and functioning effectively
- All using 1 week ID

EPI and NITAG in Pakistan

- EPI was launched in 1978 and Coordinated at the National level via the Federal Directorate of Immunization, Ministry of National Health Services, Regulation and Coordination NHSR&C).
- NITAG launched in 2014

Public Awarenss/education

RABIES FREE PAKISTAN 2017-2022 MASS DOG VACCINATION AND POPULATION CONTROL

What Pakistan needs to improve PEP

- Devolve from EMRO –WR MoH provinces divisions districts
- Organize/augment PEP centers
- Capacity building
- Enhance training of 1 week ID
- Provision of quality rabies vaccine

Remaining Challenges

Improving availability and affordability of **QUALITY** human vaccines is crucial

vaccine A Deaths B People vaccinated C Vaccine vials All countries 4000 -6000 100 -3000 -75 -Values (x1000) 4000 2000 50 -2000 -1000 -25 -0 0 0 2020 2025 2030 2035 2020 2025 2030 2035 2020 2025 2030 2035 Year Year Year

World Health

rganization

Status quo > Increased access to human vaccine > Increased access to human and dog

The potential effect of improved provision of rabies post-exposure prophylaxis in Gavi-eligible countries

Combined with renewed **public health education**, thorough risk assessments and mass dog vaccinations, such **updated human PEP regimens** can help to realize the global vision of **zero human deaths** caused via rabid dogs by **2030**.

Gavi human rabies PEP vaccine programme

Dr Simbarashe Mabaya MD, MPH

Senior Technical Advisor Primary Health Care, Vaccine Programmes

GNN webinar on rabies 6 May 2024

gavi.org

Objectives

- Introduce Gavi, The Vaccine Alliance
- Introduce Gavi application processes & key guidelines
- Gavi human rabies PEP vaccine programme

Background to Gavi

Vaccine Alliance partners

Gavi's portfolio: significant growth over time

1 Diphtheria, tetanus, pertussis (DTP) boosters, hepatitis B, *Haemophilus influenzae* type b (Hib), 27 GNN webinar on rables 6 May 2024 2 Emergency stockpiles

How Gavi supports countries: three key financing levers

*2021-2025 forecast expenditure excluding COVAX support

Gavi's eligibility, transition, co-financing policy and MICS approach

Eligibility for Gavi support

Initial self-financing

- Afghanistan
- Burkina Faso
- Burundi
- Central African Republic
- Chad
- Democratic Republic of the Congo
- Democratic People's Republic of Korea
- Eritrea
- Ethiopia
- Gambia
- Guinea
- Guinea-Bissau
- Liberia
- Madagascar
- Malawi
- Mali
- Mozambique
- Niger
- Rwanda
- Sierra Leone
- Somalia
- South Sudan
- Sudan
- Syrian Arab Republic
- Togo
- Uganda
- Yemen
- 50 **Zambia** 50 GNN webinar on rabies 6 May 2024

Preparatory transition phase

- Benin
- Cambodia
- Cameroon
- Comoros
- Congo
- Haiti
- Kyrgyzstan
- Lesotho
- Mauritania
- Myanmar
- Nepal
- Pakistan
- Senegal
- Tajikistan
- UR Tanzania
- Zimbabwe

Accelerated transition phase

- Bangladesh
- Côte d'Ivoire
- Djibouti
- Ghana
- Kenya
- Lao People's Democratic Republic
- Nigeria
- Papua New Guinea
- Sao Tome and Principe
- Solomon Islands

https://www.gavi.org/types-support/sustainability/eligibility

Application process overview & key Gavi guidelines

Gavi guidelines

Gavi.org \rightarrow Programmes & Impact \rightarrow How our support works \rightarrow <u>Gavi Support Guidelines</u>

Gavi Support Guidelines

Eligible countries can access detailed guidelines to manage the support they receive from Gavi.

Application Process Guidelines

Programme Funding Guidelines

Directives de financement du programme Gavi

Directives de Gavi pour le financement du soutien aux vaccins

Vaccine Funding

Guidelines

Budget Eligibility Guide

<u>Guide d'éligibilité</u> <u>budgétaire de Gavi</u>

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Directives pour le

processus de

demande de Gavi

Application Submission Process

approval usually contain 'issues to be addressed' which need to be clarified before the grant can move forward. This process is called Issue Resolution.

Independent Review Committee (IRC) Overview

- The IRC is established by the Board to serve as an independent, impartial group of experts seeking to guarantee the integrity and consistency of an open and transparent funding process.
- The IRC reviews all requests for new funding
- Composed of a wide range of experts in public health, epidemiology, relevant vaccines and diseases, finance and economics, supply chain, equity, fragile settings, etc.
- The IRC pool of experts currently consists of 99 members from across the globe: 38% from Africa, 31% from Europe, 21% from North America, and 3% from Asia; 38% of members are from Gavieligible countries.

2024 IRC Review Rounds

ROUND OPENING (ON THE PORTAL)	2024 DEADLINE FOR SUBMISSION	2024 IRC MEETING (INDICATIVE DATES)
~2mths prior	25 January	11–22 March
~2mths prior	15 July*	9–13 September
~2mths prior	18 April	3–14 June
~2mths prior	23 September	4–15 November
* Ad-hoc Application window for V	/IS2018 vaccines	

Gavi Rabies Vaccine programme support

2

Table of contents

Use these guidelines to understand how Gavi, the Vaccine Alliance supports the introduction and scaling up of vaccines; key considerations for applying for new vaccine support and Gavi-supported campaigns; and requirements for each Gavi-supported vaccine.

These guidelines complement other guidance, such as the Gavi <u>Programme Funding Guidelines</u> and <u>Budget Eligibility Guide</u>.

O Vaccine programme guidelines (chapter 3)

1 Introd	luction	3
2 Gavi s	upport to introduce and scale up vaccines	4
2.1	Comprehensive planning of Gavi support to reach immunisation goals	4
2.2	Equity and prioritisation of routine immunisation	5
2.3	Gavi support for new vaccine introductions, campaigns and optimisation	8
2.4	Required considerations for countries requesting campaign support	10
2.5	Gavi support for vaccines optimisation and switches	12
2.6	Support to middle-income countries	19
3 Vacci	ne programme guidelines	20
3.1	Oral cholera vaccine	23
	3.1.1 Cholera diagnostics support	29
3.2	COVID-19 vaccine	32
3.3	Diphtheria, tetanus and pertussis (DTP)-containing vaccine boosters	34
3.4	Ebola vaccine	38
3.5	Hepatitis B birth dose vaccine	42
3.6	Hexavalent vaccine	46
3.7	Human papillomavirus vaccine	49
3.8	Human rabies post-exposure prophylaxis vaccine	62
3.9	Inactivated polity vaccine	67
3.10	Japanese encephalitis vaccine	70
3.11	Malaria vaccine	73
3.12	Measles vaccine and measles-rubella vaccine	79
3.13	Meningococcal vaccine	89
3.14	Pneumococcal conjugate vaccine	95
3.15	Rotavirus vaccine	101
3.16	Typhoid conjugate vaccine	105
3.17	Yellow fever vaccine	109
	3.17.1 Yellow fever diagnostics support	112

Vaccine Funding Guidelines

GNN webinar on rabies 6 May 2024

Programme overview

- **Incremental support** (in addition to existing domestic funding) to help reinforce and strengthen countries' existing rabies programmes.
- Vaccine procurement and associated supplies (e.g., injection safety devices); No support for Prep or rabies immune globulin (RIG)
- Vaccine Introduction Grants (VIGs): Financial support for activities to facilitate the introduction of the rabies PEP vaccine
- Other Gavi support The rabies PEP vaccine will be introduced with a non-traditional schedule across all age groups. Countries are encouraged to utilise the full range of Gavi support including HSS grants (within the existing ceiling after accounting for other programmatic priorities), TCA and, where applicable, EAF to support the establishment and strengthening of platforms for delivery of these vaccines.

Available support

Key programmatic considerations

- Country decision for vaccine introduction: applications must provide a confirmation of the country's decision to introduce the rabies PEP vaccine Minister of Health or delegated authority signoff, minutes of the National Immunization Technical Advisory Group (NITAG) & immunisation Inter-agency Coordination Committee (ICC) meeting, or any other policy body in the country that made the recommendation for rabies vaccine introduction
- Target population and dose estimation: vaccine targets all age groups and is given post-exposure (after dog bite) – potential challenges with defining targets and dose estimation
- Vaccine delivery schedules: Countries are strongly encouraged to transition from IM to ID schedules and use Gavi VIGs support for this including for relevant training of healthcare workers (HCWs). Countries are required to submit their detailed training plans as part of their HRVIP.

Key programmatic considerations

- Comprehensive rabies control: vaccination plan should be based on the national rabies control strategic plan, which demonstrates complementary multi-sectoral rabies control activities, including collaboration with dog rabies control services
- Service integration: Need for stronger integration with primary health care services (PHC).
- Strengthened surveillance: It is strongly encouraged that countries implement IBCM to enhance quality data collection of <u>minimum data elements</u> for monitoring and evaluation of national rabies control programmes
- **Current rabies PEP vaccination programme:** Countries are required to provide a description of their current human rabies vaccination programme that includes the domestic funding committed towards the programme. Gavi support being incremental will not displace existing domestic funding.
- Equity considerations: Country applications are required to describe how equitable access, including for example gender-responsive programme design, to the rabies vaccine will be addressed.

Program will be launched on 12th June 2024

1st opportunity for countries to apply by **15th July** then by **23rd September**

In subsequent years 3 times through IRC windows

Gavi will provide TA (consultants) to support the development of the applications if needed

Thank you

Gavi Funding & Processes Briefing Series - https://www.dropbox.com/sh/8n1582v3h87shsn/AADpxANn8uM2IYKjBVAaMzuna?dl=0