Selection of suitable ORV strains and baits as potential candidates

WOAH Information Session on Oral Rabies Vaccines

Friday, 28 October 2022, 3 PM – 6 PM Japan Time (GMT+9)

Dr Gowri Yale

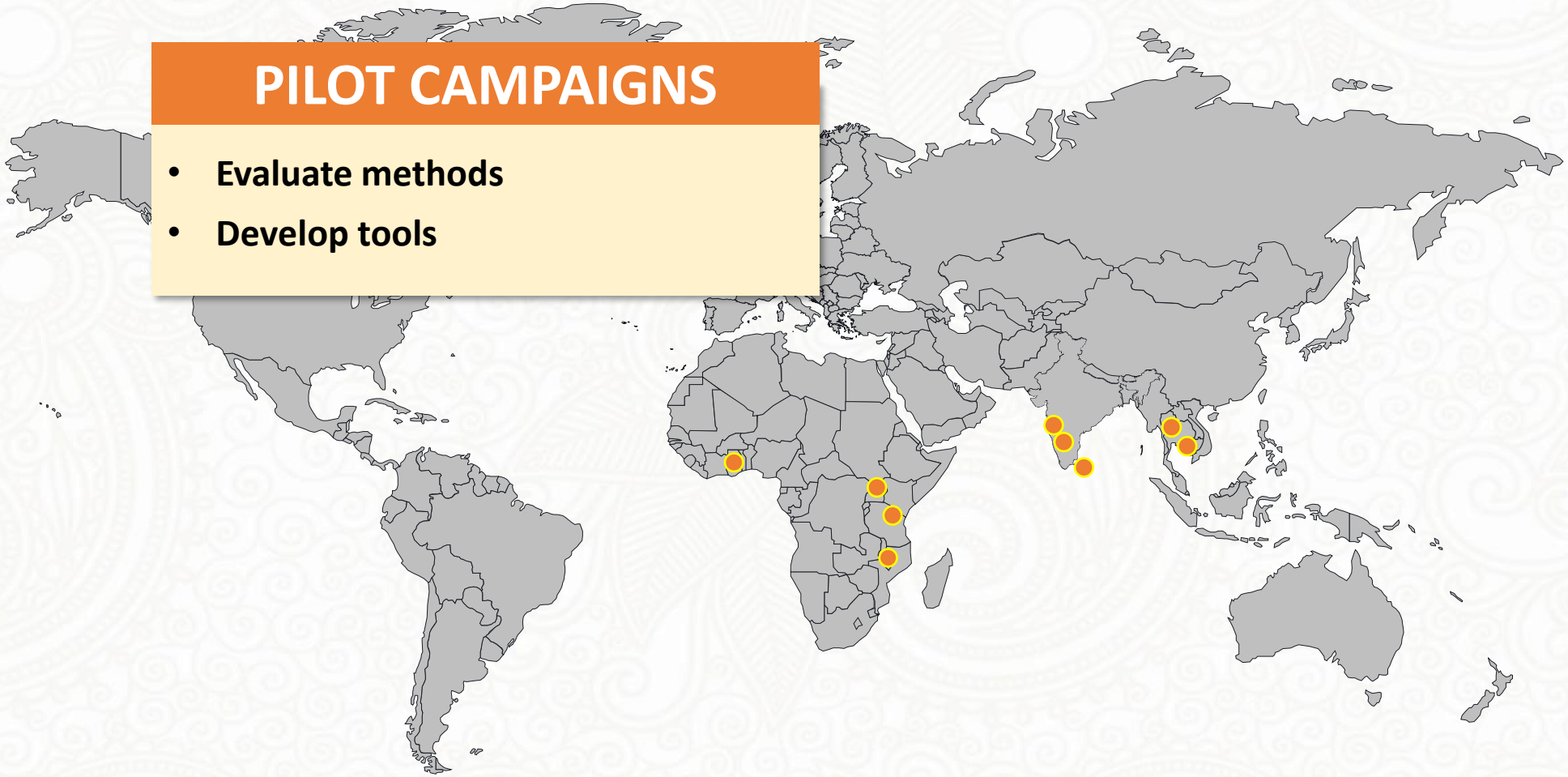
Technical Manager

Mission Rabies

MISSION RABIES

PILOT CAMPAIGNS

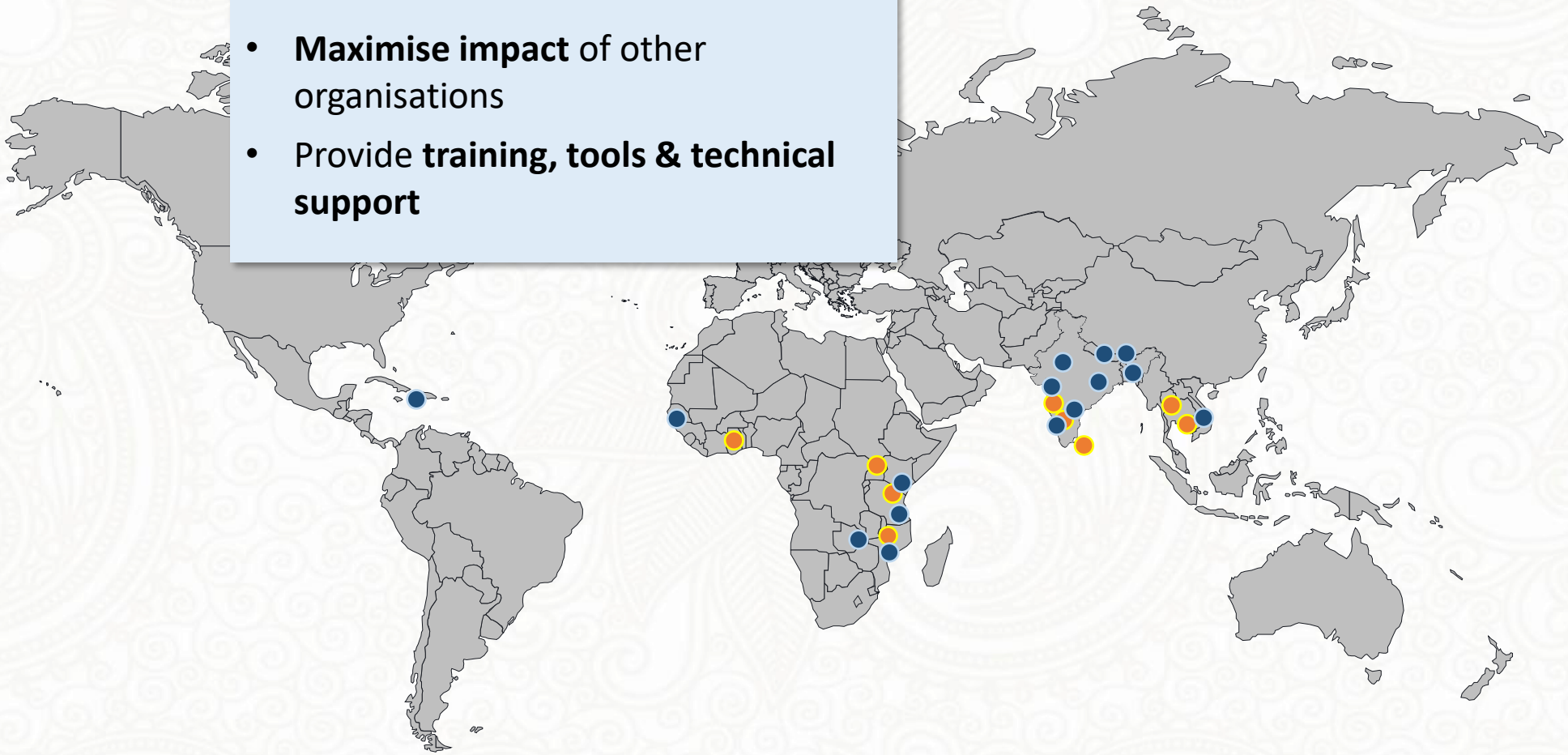
- **Evaluate methods**
- **Develop tools**



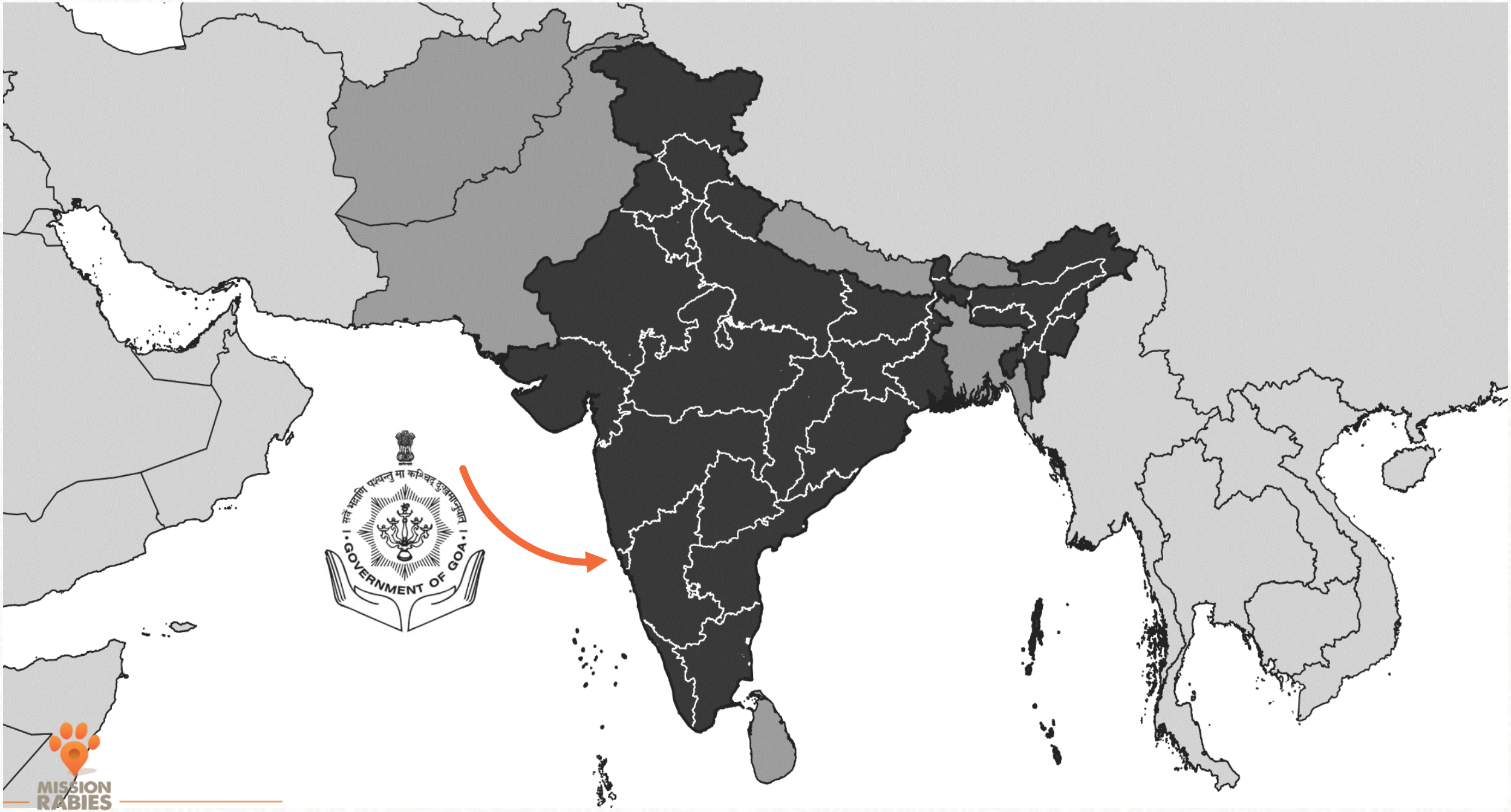
MISSION RABIES

TECHNICAL SUPPORT

- **Maximise impact** of other organisations
- Provide **training, tools & technical support**



MISSION RABIES


सर्वे भद्राणि पश्यन्तु मा कश्चिद् दुःखमाप्नुयात्
GOVERNMENT OF GOA
MISSION RABIES

2013

- September: Inauguration
- October: Pilot vaccination – 5000 dogs

2014

- Education program developed
- 24/7 Hotline established
- Mission Rabies App developed
- Vaccinated: 24,306 dogs

2015

- September: MoU with AH&VS
- Vaccinated: 56,681 dogs
- Rabies added to State curriculum

2016

- Established FAT at DIU
- Vaccinated: 51,294 dogs

2017

- Human rabies testing initiated
- AH&VS Necropsy Room built
- Vaccinated: 96, 033 dogs

2018

- Vaccinated: 97,368 dogs
- Started Hand catching method
- ORV bait trial studies
- Rabies virus genetic sequencing
- MoU with AH&VS renewed

2019

- State wide IBCM with DHS
- Vaccinated: 96,178 dogs

2020

- MH-Goa Border Dog movement Evaluation
- Vaccinated: 82,012 dogs
- Rabies chapter in std 6th text book

2021

- Rabies Controlled Area
- Static point vaccination pilot
- Vaccinated: 75,917 dogs
- Landfill for canine carcass disposal
- MoU renewed with exit strategy

2022

- Progress with ORV pilot plan
- No human rabies from Sept 2017 > 5 years
- One canine rabies case for > 1 year

GOVERNMENT OF GOA

MISSION RABIES

nature COMMUNICATIONS

ARTICLE

https://doi.org/10.1038/s41467-022-30371-y OPEN

Elimination of human rabies in Goa, India through an integrated One Health approach

A. D. Gibson[1,2,13✉], G. Yale[3,13], J. Corfmat[3,13], M. Appupillai[3,13], C. M. Gigante[4], M. Lopes[5], U. Betodkar[6], N. C. Costa[5], K. A. Fernandes[7], P. Mathapati[3], P. M. Suryawanshi[6], N. Otter[3,7], G. Thomas[1], P. Ohal[3], I. Airikkala-Otter[7], F. Lohr[1], C. E. Rupprecht[8], A. King[9], D. Sutton[10], I. Deuzeman[9], Y. Li[4], R. M. Wallace[4], R. S. Mani[11], G. Gongal[12], I. G. Handel[2], M. Bronsvoort[2], V. Naik[5,14], S. Desai[5,14], S. Mazeri[1,2,14], L. Gamble[1,14] & R. J. Mellanby[2,14]

Dog-mediated rabies kills tens of thousands of people each year in India, representing one third of the estimated global rabies burden. Whilst the World Health Organization (WHO), World Organization for Animal Health (OIE) and the Food and Agriculture Organization of the United Nations (FAO) have set a target for global dog-mediated human rabies elimination by 2030, examples of large-scale dog vaccination programs demonstrating elimination remain limited in Africa and Asia. We describe the development of a data-driven rabies elimination program from 2013 to 2019 in Goa State, India, culminating in human rabies elimination and a 92% reduction in monthly canine rabies cases. Smartphone technology enabled systematic spatial direction of remote teams to vaccinate over 95,000 dogs at 70% vaccination coverage, and rabies education teams to reach 150,000 children annually. An estimated 2249 disability-adjusted life years (DALYs) were averted over the program period at 526 USD per DALY, making the intervention 'very cost-effective' by WHO definitions. This One Health program demonstrates that human rabies elimination is achievable at the state level in India.

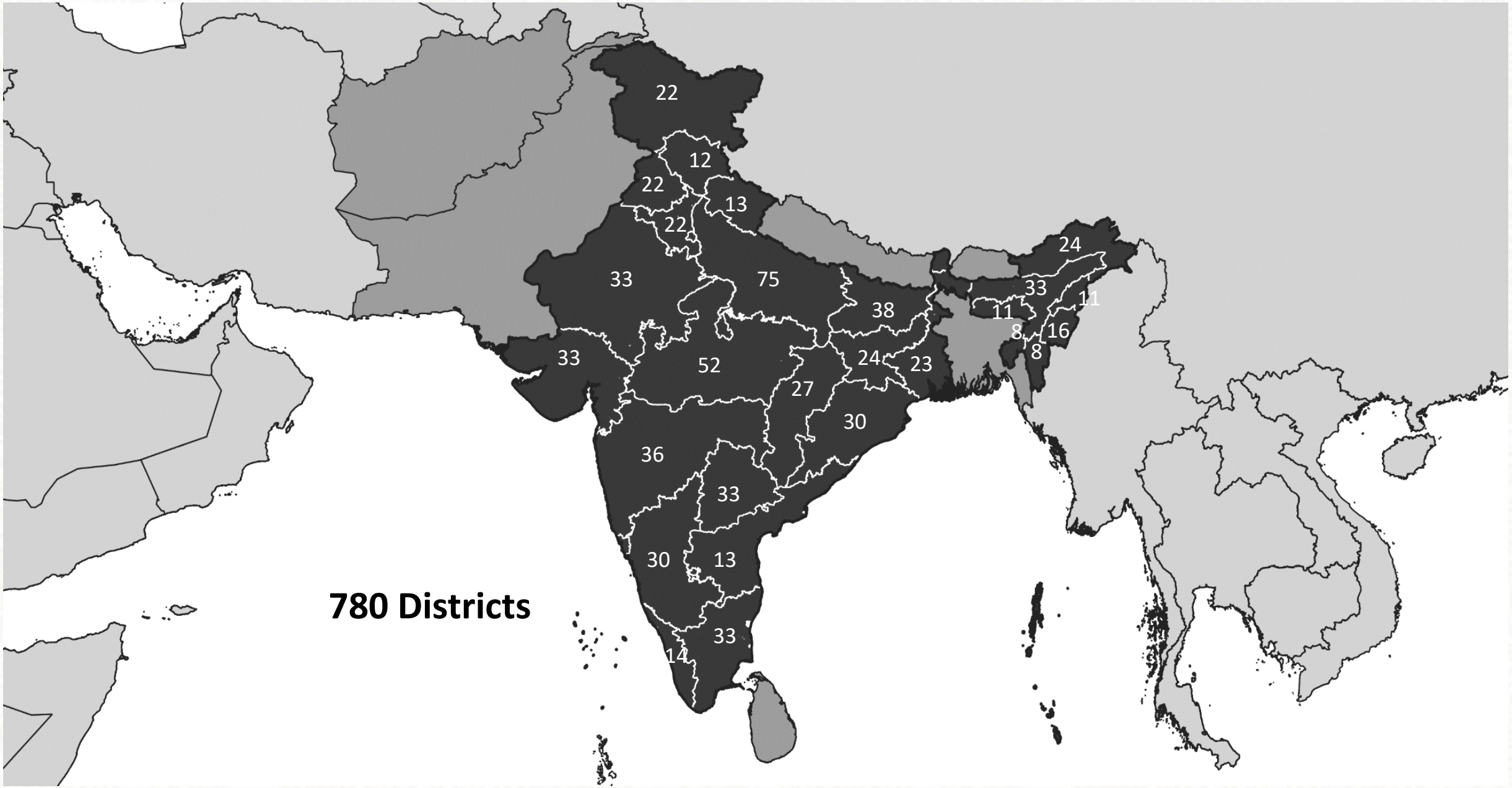
DAH&VS

DHS

MISSION RABIES

MISSION RABIES

GOVERNMENT OF GOA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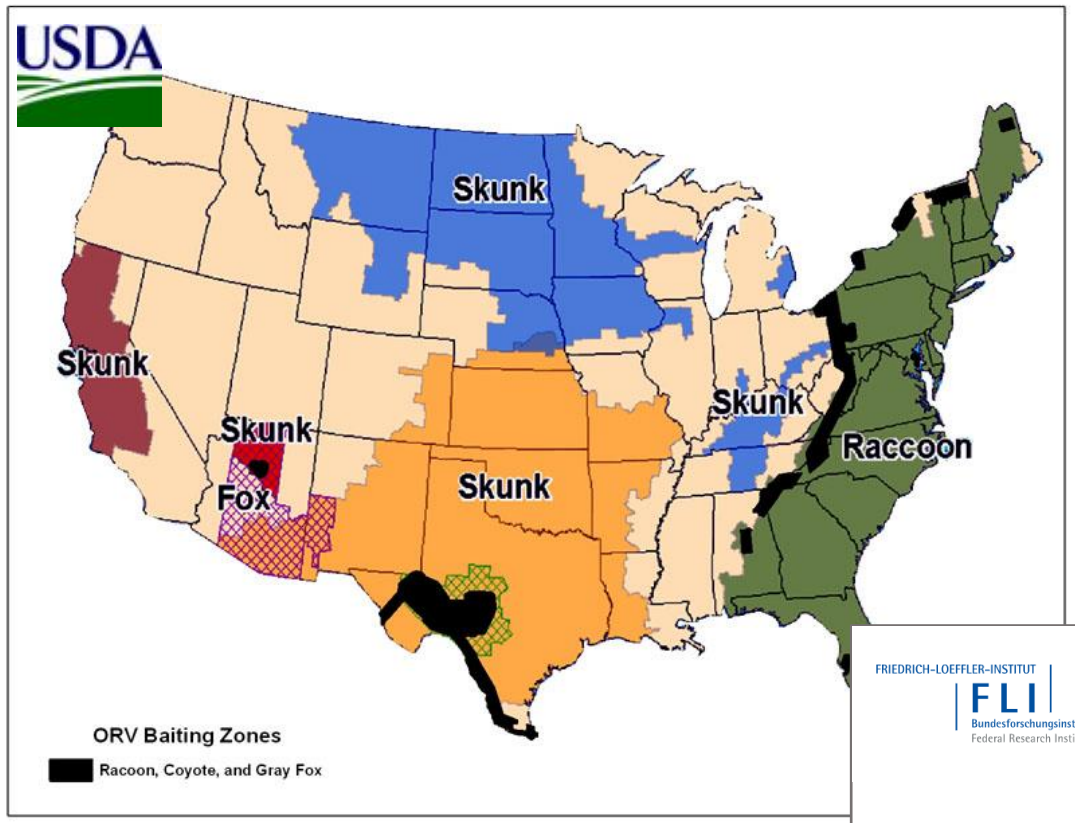
780 Districts


MISSION RABIES


USDA
Skunk
Skunk
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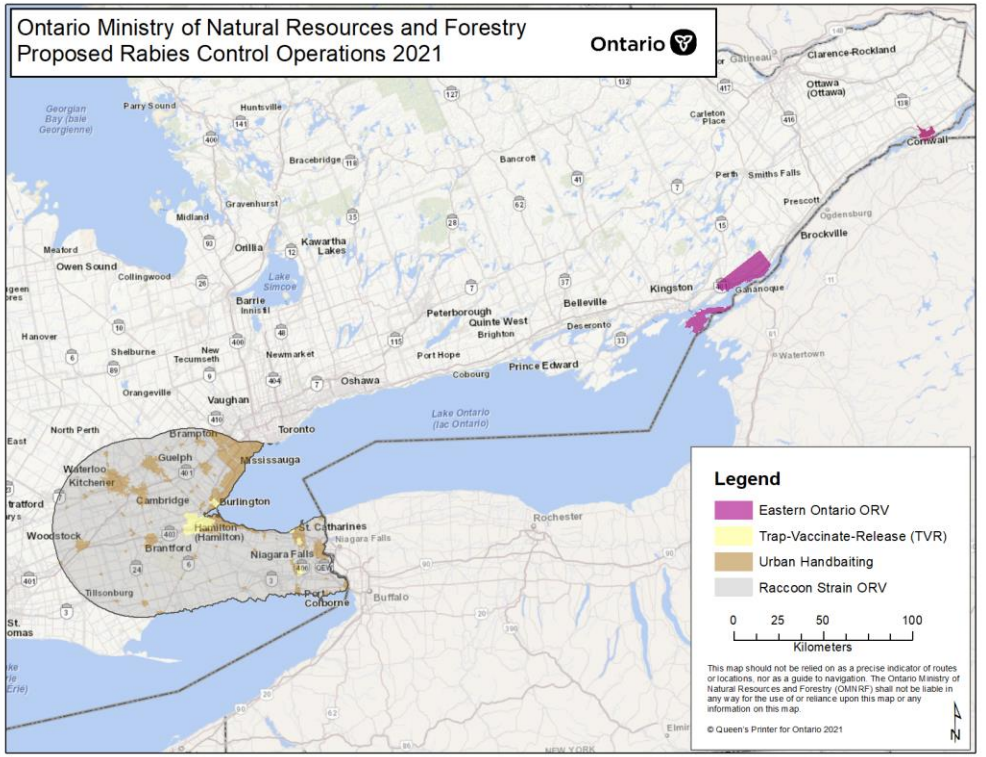
Fox
Skunk
Skunk
Raccoon
ORV Baiting Zones
Racoon, Coyote, and Gray Fox


Ontario Ministry of Natural Resources and Forestry
Proposed Rabies Control Operations 2021
Ontario
Legend
Eastern Ontario ORV
Trap-Vaccinate-Release (TVR)
Urban Handbaiting
Raccoon Strain ORV
0 25 50 100
Kilometers
This map should not be relied on as a precise indicator of routes or locations, nor as a guide to navigation. The Ontario Ministry of Natural Resources and Forestry (OMNRF) shall not be liable in any way for the use of or reliance upon this map or any information on this map.
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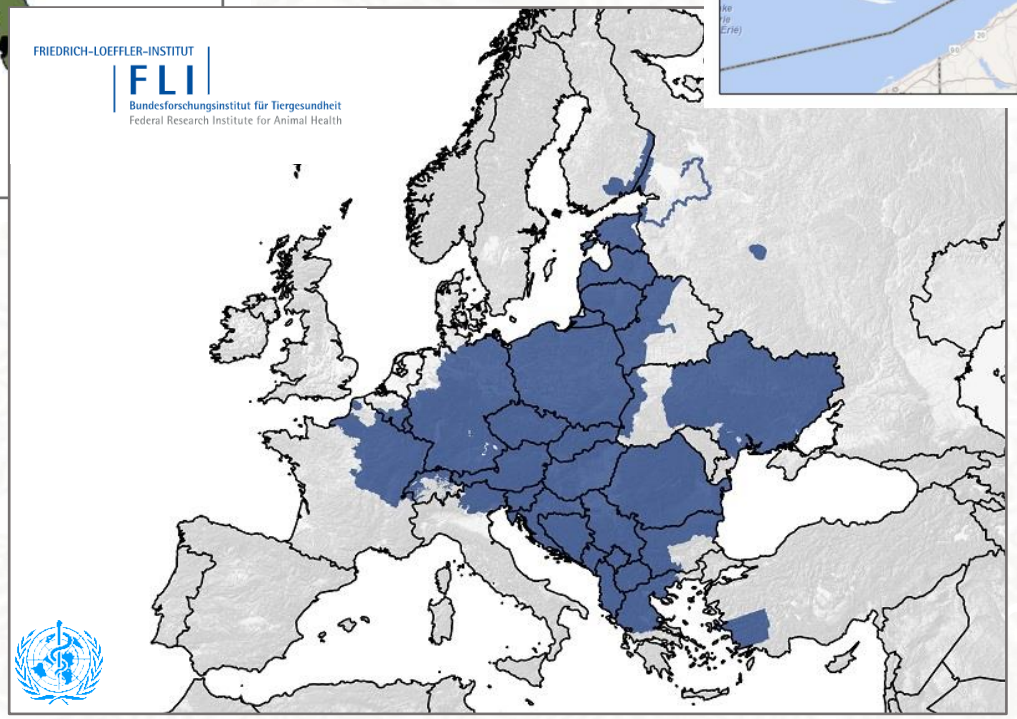

FRIEDRICH-LOEFFLER-INSTITUT
FLI
Bundesforschungsinstitut für Tiergesundheit
Federal Research Institute for Animal Health

Questions about ORV

Which vaccine?

Which bait?

Cost effective?

Which vaccine?

List of currently available ORVs.

Vaccine strain	Product name or brand name	Formula-tion	Vial size	Company	Country
SPBN-GASGAS	IDT Biologika	RABV	3rd	Reverse genetics with site-directed mutagenesis	Licensed for wildlife
ERA G333	Prokov	RABV	3rd	Reverse genetics with site-directed mutagenesis	Licensed for wildlife
SAG2*	Virbac	RABV	2nd	Monoclonal selection mutant	Licensed for wildlife
SAD B19	IDT Biologika	RABV	1st	Serial (passaged in vivo/in vitro)	Licensed for wildlife
SAD Bern	Bioveta	RABV	1st	Serial (passaged in vivo/ in vitro)	Licensed for wildlife
RB-97	FGBI "ARRAIH"	RABV	1st	Serial (passaged in vivo/ in vitro)	Licensed for wildlife
VRC-RZ2	No information	RABV	1st	Serial (passaged in vivo/ in vitro)	No information
KMIEV-94	No information	RABV	1st	Serial (passaged in vivo/ in vitro)	No information
V-RG*	Merial	Vaccinia virus		Recombinant, expressing rabies glycoprotein	Licensed for wildlife
AdRG1.3	Artemis Technologies	Adenovirus		Recombinant, expressing rabies glycoprotein	Licensed for wildlife

Source: WHO 2018 Technical Series

WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

WORKSHOP MATERIALS

Presentations and other materials related to this workshop are available at the OIE Regional Representation website, https://rr-asia.oie.int/en/events/oie-virtual-workshop-on-oral-rabies-vaccines/

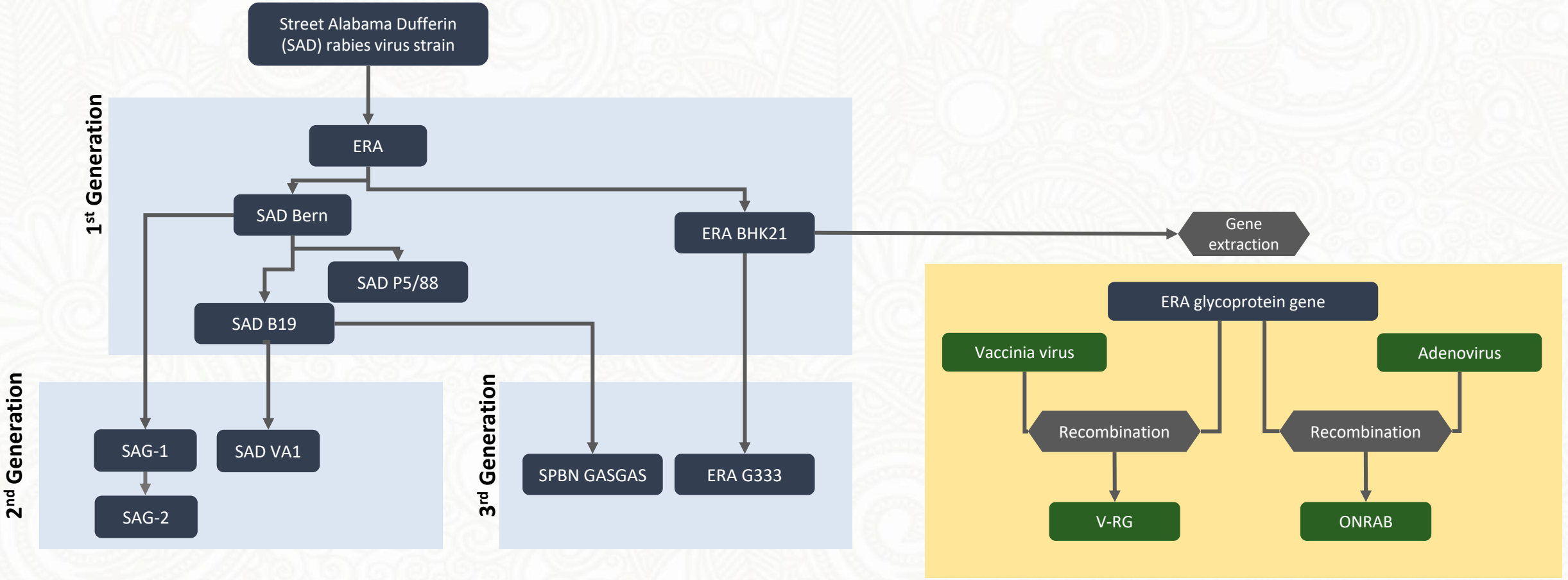
Table 1: List of ORVs piloted in dogs in Asia

Type	Vaccine Strain	Vaccine Name and Manufacturer	Species	Year In Use	Countries in which trial conducted	Reference
Modified Live (1st generation)	SAD B19	Fuchsoral, Ceva, France	Dog	2001	Philippines	Estrada et al., 2001
Modified Live (2nd generation)	SAG 2	RABIGEN® Virbac, France	Dog	2007	India	Cliquet et al., 2007
Modified Live (3rd generation)	SPBN GASGAS	Rabitec® Ceva, France	Dog	2020	Thailand	Leelahapongsathon et al., 2020
Vector–based (Vaccinia virus)	V-RG	Raboral V-RG® Boehringer Ingelheim, Germany	Dog	2000	Sri Lanka	Perera et al., 2000
Modified Live (3rd generation)	SPBN GASGAS	Rabitec® Ceva, France	Dog	2022	Indonesia	Trial is ongoing

Table 1. List of ORV used in wildlife and trialed in dogs.

Type	Vaccine Strain	Vaccine Name and Manufacturer	WILDLIFE					DOG		
			Species	Years In Use	Doses Distributed	Countries In Which Distribution Took Place	References	Year	Countries in Which Trials Have Taken Place	References
Modified Live (1st generation)	**SAD Bern**	Lysvulpen, Bioveta, Czech Republic	Red Fox, racoon dog	1979–1980	211,000,000	Europe	[29]	1994	Tunisia	[75]
	SAD B19	Fuchsoral, Ceva, France	Red fox	1978–2014	268,000,000	Europe	[29]	2001	Philippines	[72]
								1998	Turkey	[76]
	RV-97	Sinrab, FGBI ARRIAH, Russia	Racoon dogs	2002–current	4200,000	Kazakhstan, Ukraine, Belarus, Russia	[29,77]	-	-	-
	VRC-RZ2	Kazakhstan laboratory	Corsac fox, steppe wolf	2017	Laboratory	Kazakhstan	[78]	2017	Kazakhstan (laboratory)	[78]
	KMIEV-94	Institute of Experimental Veterinary, Belarus	Red fox	2009	10,300,000	Belarus	[29,79]	-	-	-
Modified Live (2nd generation)	SAG 2	RABIGEN® Virbac, France	Red fox, raccoon dog	199–2012	28,000,000	France, Switzerland, Finland, Estonia, Italy, Germany, Belgium	[29,80]	2007	India	[81]
								1998	Tunisia	[82]
								2012	Morocco	[68]
Modified Live (3rd generation)	SPBN GASGAS	Rabitec® Ceva, France	Red fox, raccoon dog	201–2019	Laboratory	Germany	[83]	2017	Haiti	[67]
								2020	Thailand	[84]
	ERA G333	Prokov, Russia	Red fox, raccoon dog	2017	Laboratory	Russia	[85]	-	-	-
Vector–based (Vaccinia virus)	V-RG	Raboral V-RG® Boehringer Ingelheim, Germany	Raccoon, coyote, grey fox, red fox, golden jackal, raccoon dog	1987–2017	250,000,000	USA, Canada, France, Belgium, Luxembourg, Ukraine, Israel, South Korea	[35]	2000	Sri Lanka	[86]
								2005	USA (laboratory)	[47]
Vector-based (Adenovirus)	AdRG1.3	ONRAB® Artemis Technologies Inc., Canada	Striped skunk, red fox, raccoon	2007–2017	28,500,000	Canada, USA	[28,44]	2016	USA (laboratory)	[61]
								2007	China (laboratory)	[87]

Yale, Gowri, Marwin Lopes, Shrikrishna Isloor, Jennifer R. Head, Stella Mazeri, Luke Gamble, Kinzang Dukpa, Gyanendra Gongal, and Andrew D. Gibson. "Review of Oral Rabies Vaccination of Dogs and Its Application in India." *Viruses* 14, no. 1 (2022): 155.



Müller et al. Rabies Vaccines for Wildlife. In Rabies and Rabies Vaccines; Springer International Publishing, 2020, pp. 45–70.
Yale et al. Review of Oral Rabies Vaccination of Dogs and Its Application in India. *Viruses* 14, no. 1 (2022): 155.

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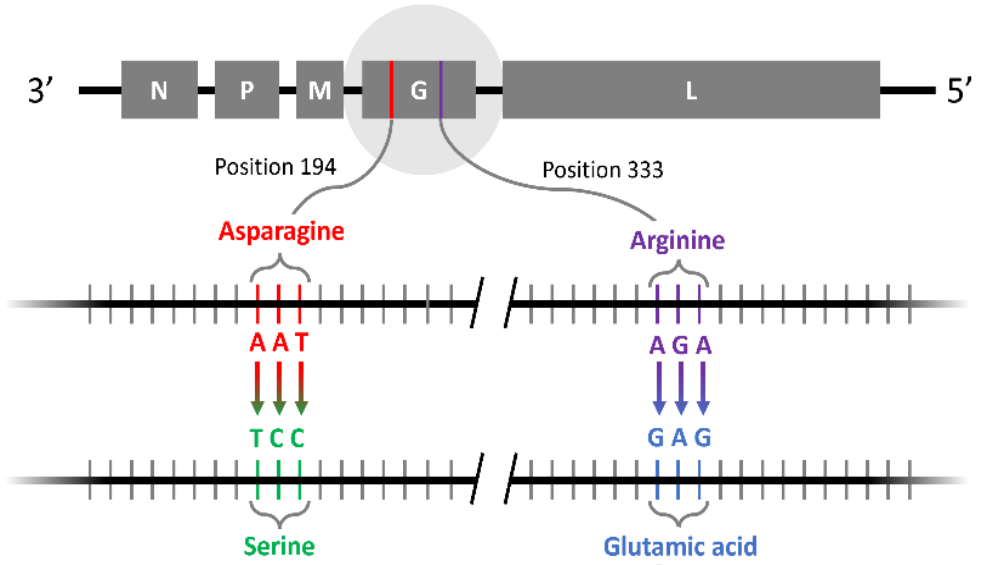
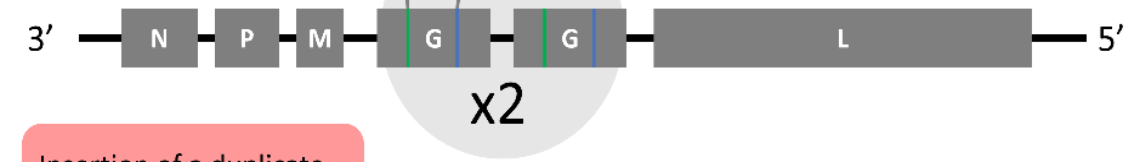
SAD B19
vaccine virus genome



All three nucleotides at two amino acid positions (194 and 333) changed minimising the risk of reversion.

SPBN GASGAS
vaccine virus genome



Insertion of a duplicate second G-protein gene

GENETIC MODIFICATION	CONSEQUENCE
Amino acid codon Arginine → Glutamic acid at position 333	Abolish residual pathogenicity
Amino acid codon Asparagine → Serine at position 194	Eliminate potential reversion to virulence
All 3 nucleotides changed at each amino acid position	Reduce potential back-mutation to the original amino acid
Insertion of a second G-gene	Enhance safety measure

No.	Major Categories for Assessment of an Oral Rabies Vaccine Candidate	Modified Live Vaccines								Vector-Based Vaccines	
		SAD Berne	SAD B19	RV-97	VRC-RZ2	KMIEV-94	SAG 2	SPBN GASGAS	ERA G333	V-RG	AdRG1.3
1	Description of the manufacturer	[91]	[92]	[93]	-	-	[94]	[92]	-	[95]	-
2	Description of the vaccine construct	[96,97]	[98]	[77]	-	[79]	[99]	[100]	-	-	[101,102]
3	Is the vaccine safe for the target animal?	[75]	[103]	-	[78]	-	[82,104]	[67,105]	-	[47]	[106]
4	Has safety been assessed for potential non-target animals?	Jackals [107]	[103]	-	-	-	[108]	[83,109,110]	[85]	[35]	[106,111]
5	Has safety been assessed in nonhuman primates?	[112]	[113]	-	-	-	[114]	Conducted in parent vaccine SAD-B19 [113]	-	[115]	-
6	Does the vaccine elicit an immune response in target animals (dogs)?	[75]	[76]	-	[78]	-	[81,116]	[67,84,105]	-	[47]	[60,61,106]
7	Have virulent challenge studies been conducted to assess duration of immunity?	[117,118]	Foxes [119]	-	[78]	-	[116,120]	Foxes [121]	Foxes and raccoon dogs [85]	[35,122]	[106]
8	Does the vaccine replicate in host tissues and is replicating virus excreted from animals?	-	[103]	-	-	-	[104]	[36]	-	[123]	[106,124]
9	Is the bait composition attractive to the target animal, and does it convey delivery of the vaccine to the target host-anatomy?	-	-	-	-	-	[68]	[63,105]	-	-	-
10	Have bait contact rates been described for the bait distribution method you are considering?	-	-	-	-	-	-	[20,67,105]	-	-	-
11	Has the vaccine been evaluated under field conditions and are storage requirements known?	[125]	[126]	-	-	[127]	[128]	[67,105]	-	[129,130]	[131]
12	Has an economic cost-benefit assessment been conducted?	-	–	-	-	-	-	[20]	-	-	-
13	Is the product currently acknowledged by an international public health agency for field use?	[132]	–	–	–	–	–	[67,105]	–	[133]	–
14	Is the product currently licensed in any countries for field use? *	Europe	Europe	Russia	Kazakhstan	Belarus	[99] Europe	[134] Europe	Russia	Europe, USA	[102] Canada

* Licensure refers to wildlife only.

Table 2. Recommendations outlined by WHO and World Organisation for Animal Health expert committee on the suitability for field trials in dogs, and reference supporting fulfilment of that recommendation for each of the oral rabies vaccines currently used in wildlife. In addition to these criteria are five further considerations which are not listed as they are not specific to a vaccine. These are as follows: "Is the community supportive of oral rabies vaccination of dogs?", "Can the responsible authority conduct postvaccination monitoring for persons potentially exposed to the vaccine?", "Can the responsible authority conduct postvaccination monitoring for vaccine exposures from contact with recently vaccinated dogs?", "Is there an effective postexposure prophylaxis for humans exposed to the oral rabies vaccine?", "Can the responsible health authority provide postexposure prophylaxis for persons potentially exposed to the vaccine?".

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viruses

MDPI

Review

Review of Oral Rabies Vaccination of Dogs and Its Application in India

Gowri Yale [1,*], Marwin Lopes [2], Shrikrishna Isloor [3], Jennifer R. Head [4], Stella Mazeri [5,6], Luke Gamble [6], Kinzang Dukpa [7], Gyanendra Gongal [8] and Andrew D. Gibson [5,6]

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[5] The Roslin Institute, The Royal (Dick) School of Veterinary Studies, The University of Edinburgh, Easter Bush Veterinary Centre, Midlothian, Roslin EH25 9RG, UK; stella.mazeri@roslin.ed.ac.uk (S.M.); andy@missionrabies.com (A.D.G.)
[6] Mission Rabies, Dorset, Cranborne BH21 5PZ, UK; Luke@missionrabies.com
[7] World Organisation for Animal Health (OIE), Regional Representation for Asia and the Pacific, Tokyo 113-8657, Japan; k.dukpa@oie.int
[8] World Health Organization (WHO), Regional Office for South East Asia, New Delhi 110002, India; gongalg@who.int
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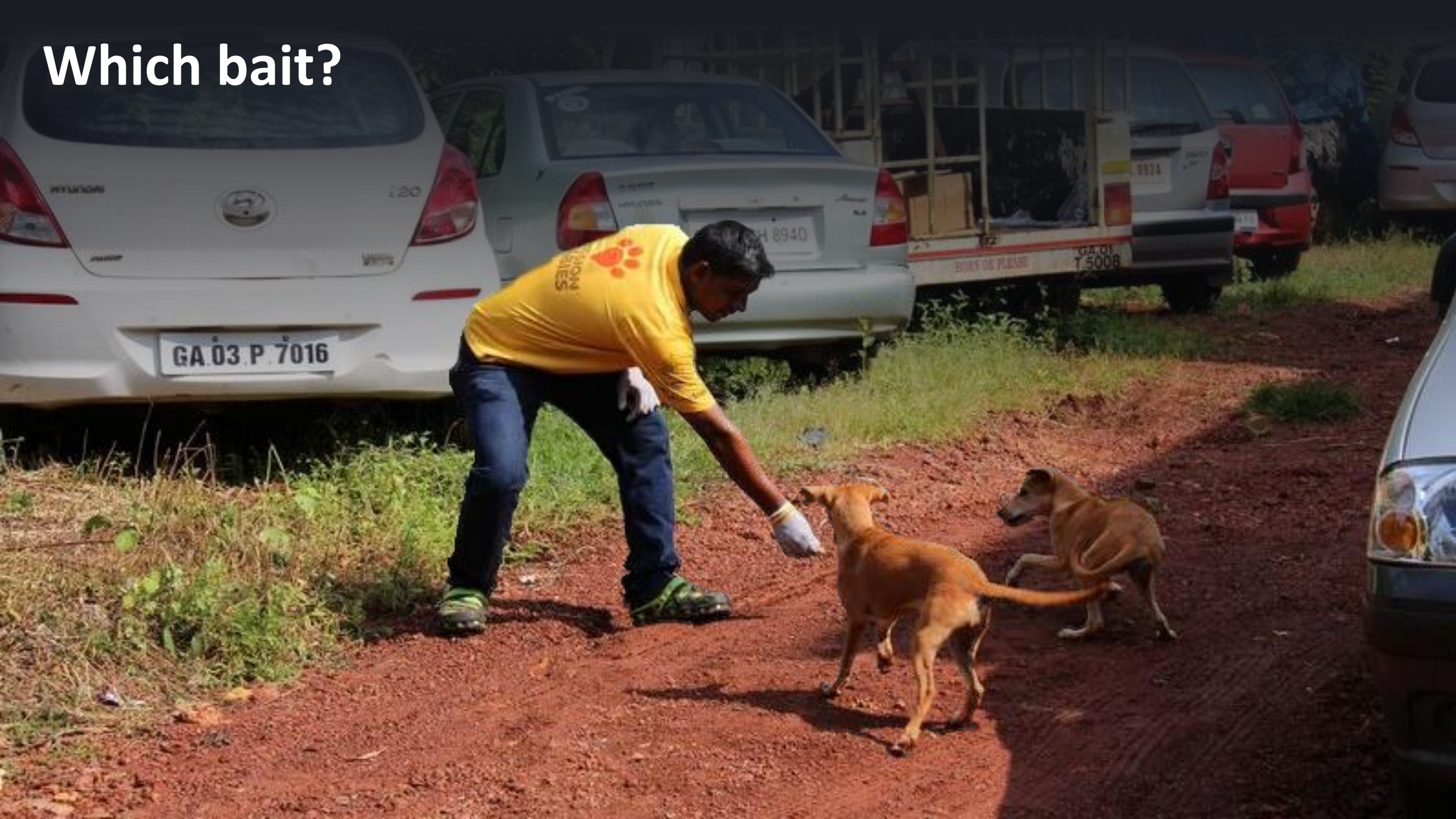
Accepted: 3 January 2022
Published: 14 January 2022

Abstract: Oral rabies vaccines (ORVs) have been in use to successfully control rabies in wildlife since 1978 across Europe and the USA. This review focuses on the potential and need for the use of ORVs in free-roaming dogs to control dog-transmitted rabies in India. Iterative work to improve ORVs over the past four decades has resulted in vaccines that have high safety profiles whilst generating a consistent protective immune response to the rabies virus. The available evidence for safety and efficacy of modern ORVs in dogs and the broad and outspoken support from prominent global public health institutions for their use provides confidence to national authorities considering their use in rabies-endemic regions. India is estimated to have the largest rabies burden of any country and, whilst considerable progress has been made to increase access to human rabies prophylaxis, examples of high-output mass dog vaccination campaigns to eliminate the virus at the source remain limited. Efficiently accessing a large proportion of the dog population through parenteral methods is a considerable challenge due to the large, evasive stray dog population in many settings. Existing parenteral approaches require large skilled dog-catching teams to reach these dogs, which present financial, operational and logistical limitations to achieve 70% dog vaccination coverage in urban settings in a short duration. ORV presents the potential to accelerate the development of approaches to eliminate rabies across large areas of the South Asia region. Here we review the use of ORVs in wildlife and dogs, with specific consideration of the India setting. We also present the results of a risk analysis for a hypothetical campaign using ORV for the vaccination of dogs in an Indian state.

Keywords: oral rabies vaccine; free roaming dogs; dog mediated human rabies; canine rabies control

Which bait?



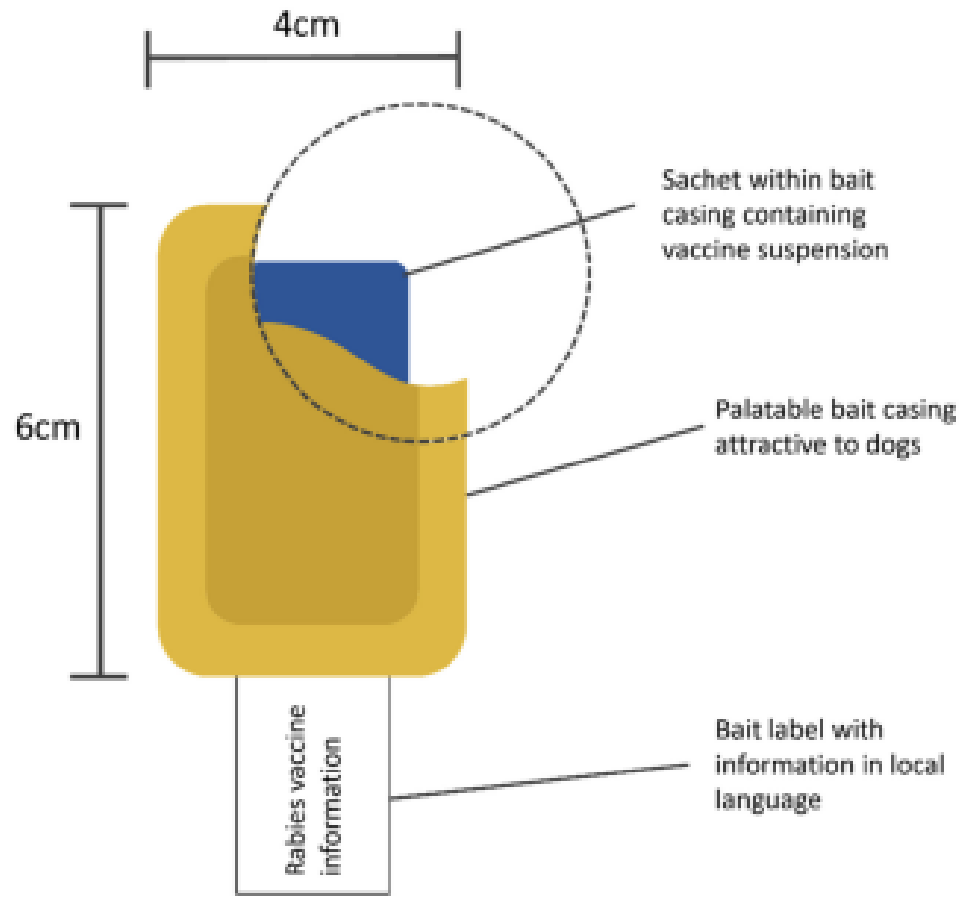
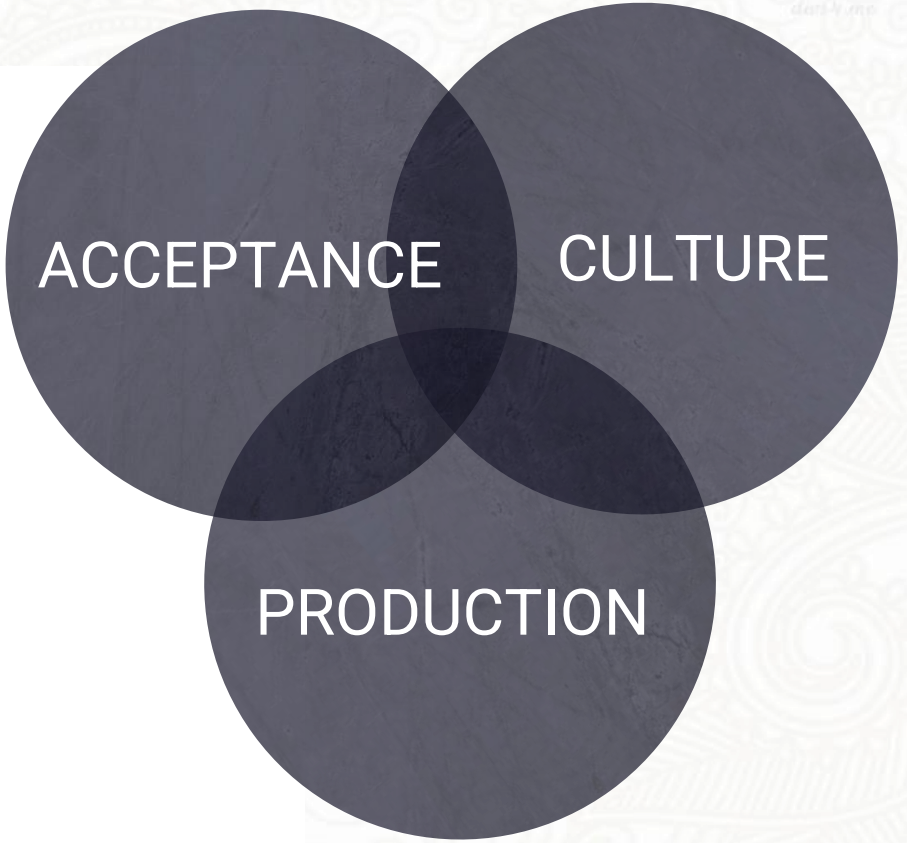


Figure 2. Illustration of components of an example ORV bait construct for use in dogs. The dotted circle shows a cut-away to reveal the impermeable sachet containing vaccine suspension within bait casing. Information is generally either printed directly on the bait casing or as a protruding label.

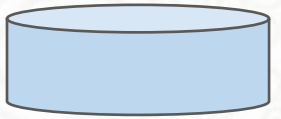


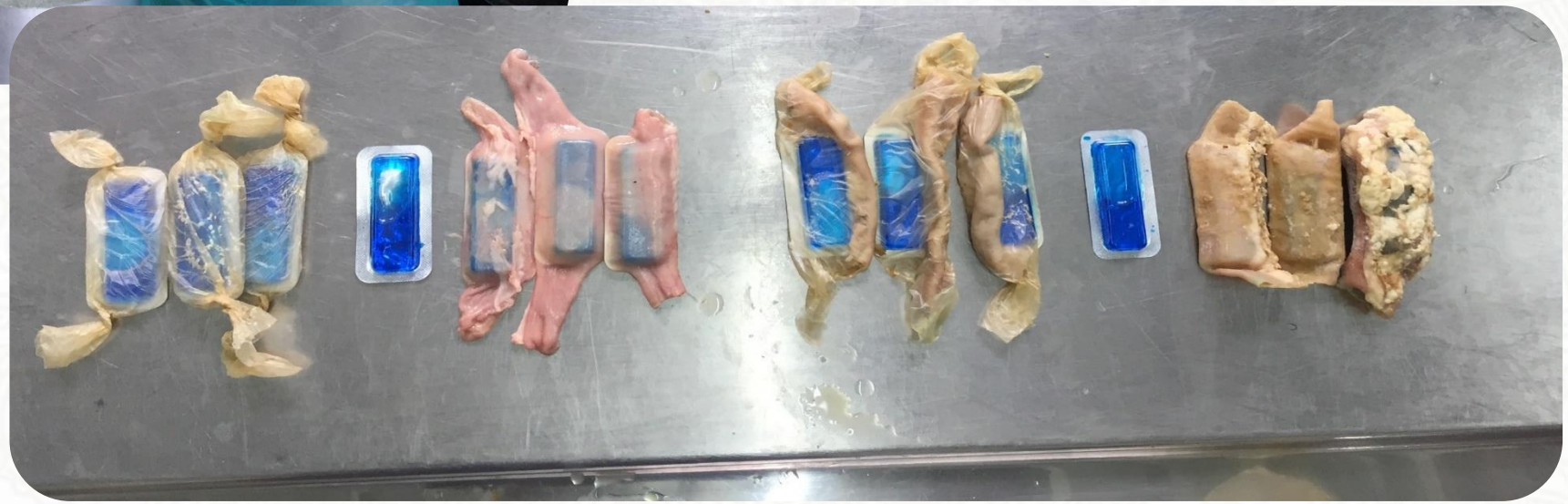
Intestine

Egg

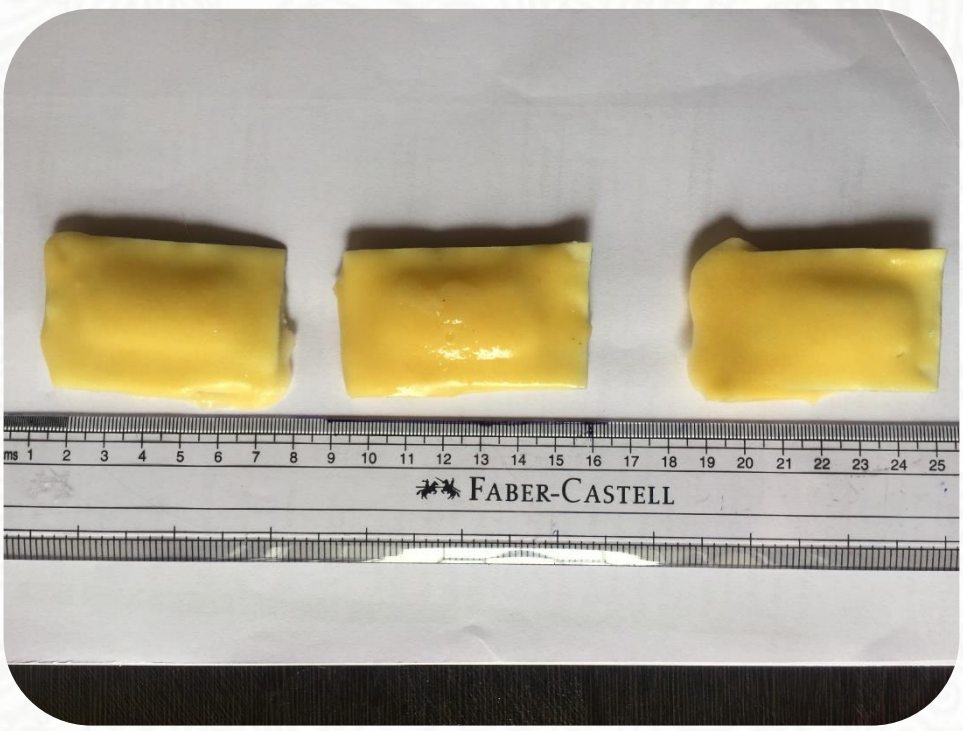
Fish

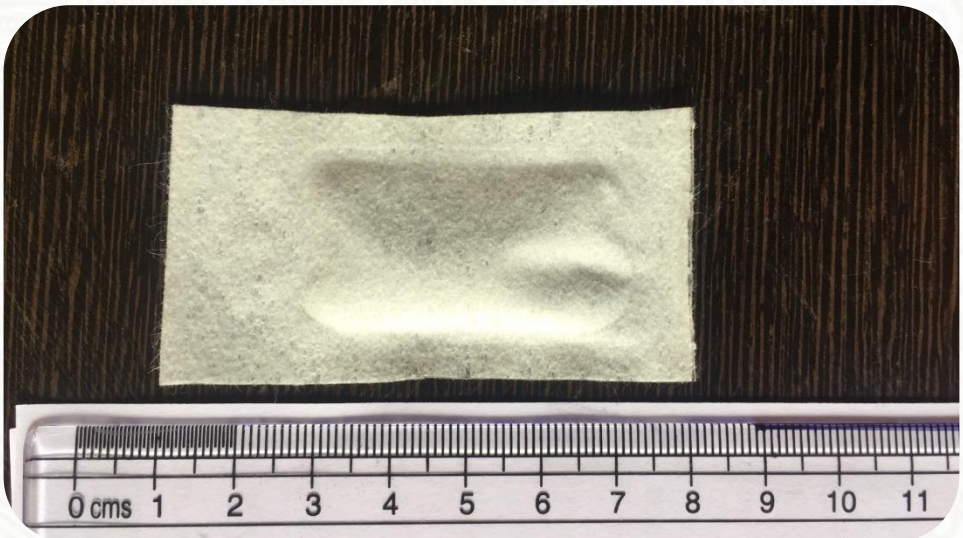
Pet food





MISSION RABIES





MISSION RABIES

MISSION RABIES

Tropical Medicine and Infectious Disease

MDPI

Article

Development of a Non-Meat-Based, Mass Producible and Effective Bait for Oral Vaccination of Dogs against Rabies in Goa State, India

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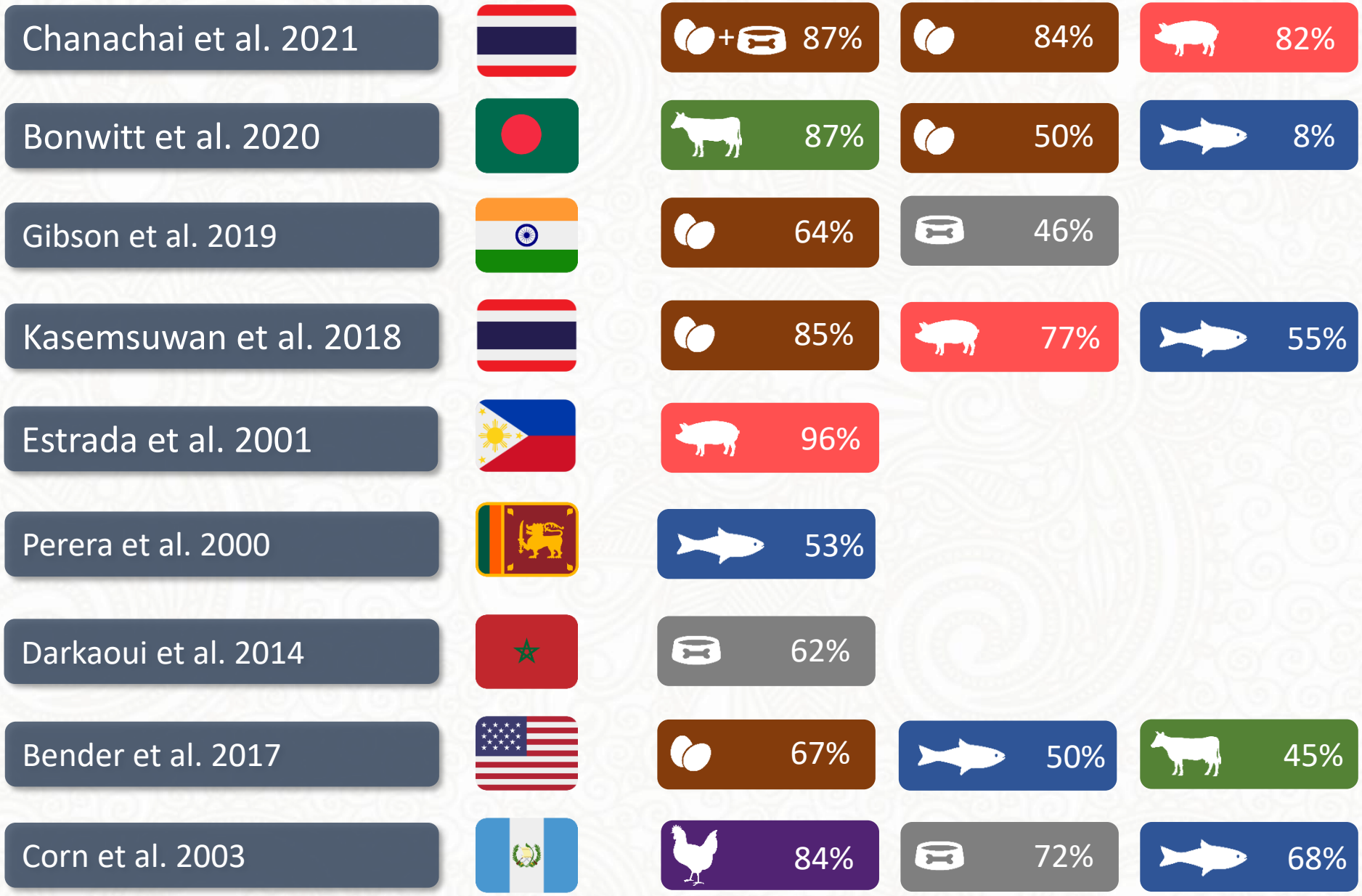
Abstract: *Introduction:* To achieve the global goal of canine-mediated human rabies elimination by 2030 there is an urgent need to scale-up mass dog vaccination activities in regions with large dog populations that are difficult to access; a common situation in much of India. Oral rabies vaccination may enable the vaccination of free-roaming dogs that are inaccessible to parenteral vaccination, and is considered a promising complementary measure to parenteral mass dog vaccination campaigns. WHO and OIE have published detailed minimum requirements for rabies vaccines and baits to be used for this purpose, requiring that baits must not only be well-accepted by the target population but must also efficiently release the vaccine in the oral cavity. For oral rabies vaccination approaches to be successful, it is necessary to develop baits which have a high uptake by the target population, are culturally accepted and amenable to mass production. The aim of this study was to compare the interest and uptake rates of meat-based and an egg-based prototype bait constructs by free roaming dogs in Goa, India. *Methods:* Three teams randomly distributed two prototype baits; an egg-flavoured bait and a commercial meat dog food (gravy) flavoured bait. The outcomes of consumption were recorded and compared between baits and dog variables. *Results*: A total of 209 egg-bait and 195 gravy-bait distributions were recorded and analysed. No difference ($p = 0.99$) was found in the percentage of dogs interested in the baits when offered. However, significantly more dogs consumed


Chanachai et al. 2021
87%
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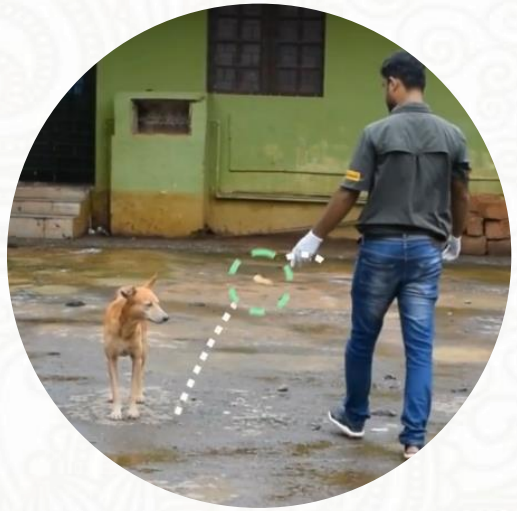
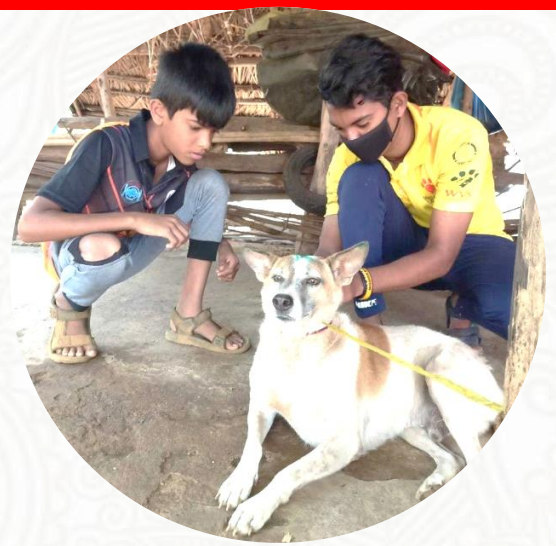
Cost effective?

Oral bait

Net catch





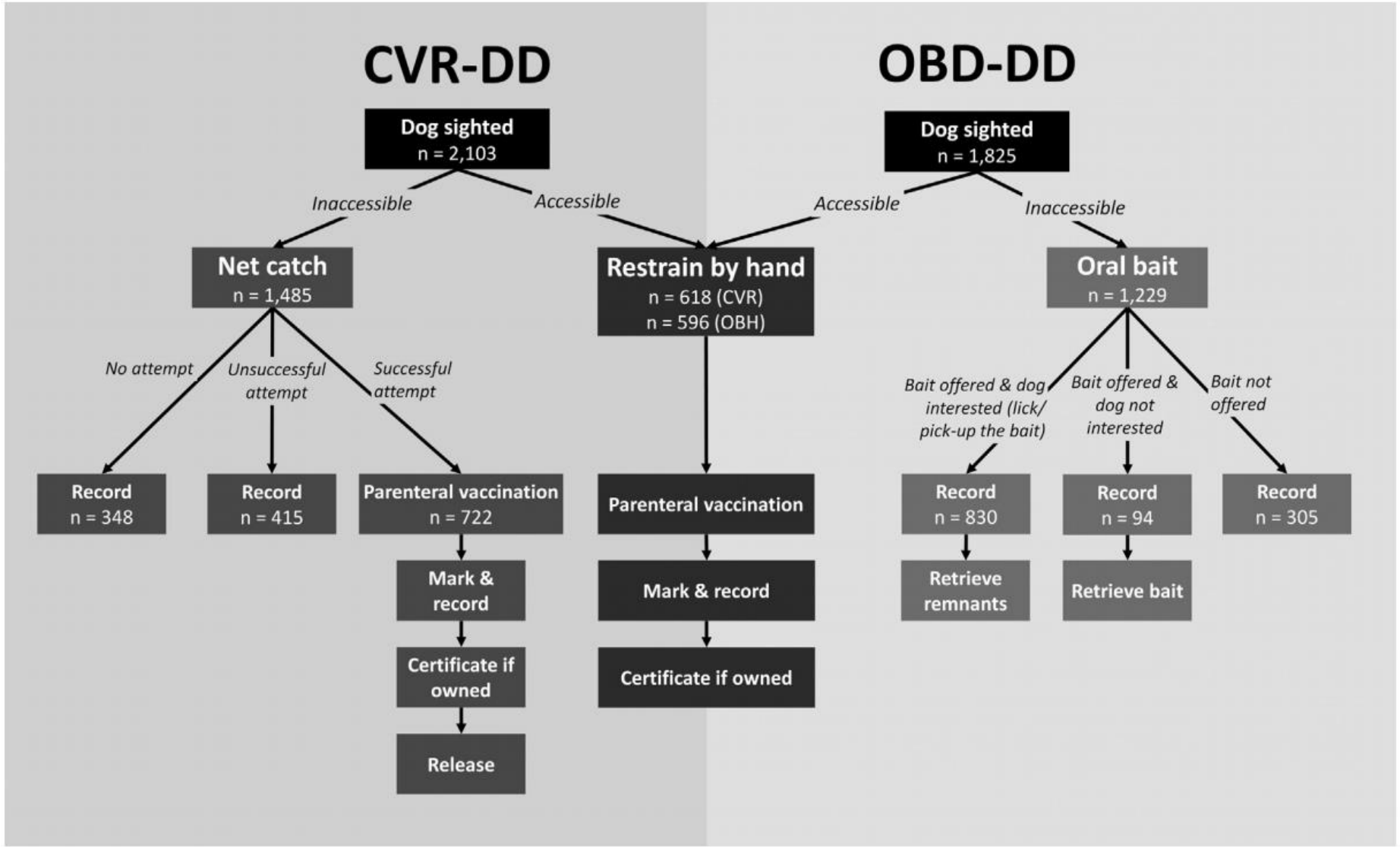


Fig. 2. Flow diagram for action taken for sighted dogs in each intervention arm. CVR = Catch-vaccinate-release, DD = Door-to-door, OBH = oral bait handout. Dogs which were reported by the owner as already vaccinated or refused vaccination were not included in the counts or analysis for either group.

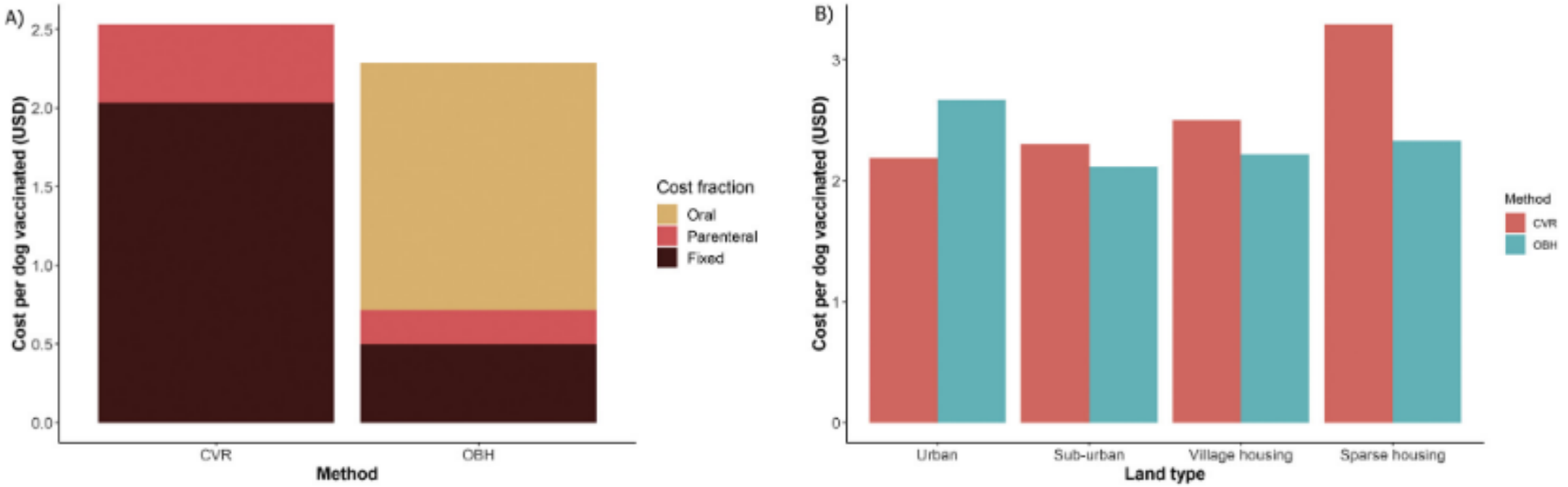


Fig. 4. (A) Graph showing a breakdown of mean Fixed and Variable (oral/parenteral) cost per dog vaccinated based on the mean number of dogs vaccinated per team per day in each method. (B) Bar graph of cost per dog vaccinated by land type and method in USD.

Cost Benefits of ORV:

1) Increased Operational Efficiency
2) Increased Vaccination Coverage

+ 20% coverage

50% coverage by parenteral vaccination

+

ORV?

Nets?

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Oral bait handout as a method to access roaming dogs for rabies vaccination in Goa, India: A proof of principle study

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ABSTRACT

Rabies has profound public health, social and economic impacts on developing countries, with an estimated 59,000 annual human rabies deaths globally. Mass dog vaccination is effective at eliminating the disease but remains challenging to achieve in India due to the high proportion of roaming dogs that cannot be readily handled for parenteral vaccination.

Two methods for the vaccination of dogs that could not be handled for injection were compared in Goa, India; the oral bait handout (OBH) method, where teams of two travelled by scooter offering dogs an empty oral bait construct, and the catch-vaccinate-release (CVR) method, where teams of seven travel by supply vehicle and use nets to catch dogs for parenteral vaccination. Both groups parenterally vaccinated any dogs that could be held for vaccination.

The OBH method was more efficient on human resources, accessing 35 dogs per person per day, compared to 9 dogs per person per day through CVR. OBH accessed 80% of sighted dogs, compared to 63% by CVR teams, with OBH accessing a significantly higher proportion of inaccessible dogs in all land types. All staff reported that they believed OBH would be more successful in accessing dogs for vaccination. Fixed operational team cost of CVR was four times higher than OBH, at 127 USD per day, compared to 34 USD per day. Mean per dog vaccination cost of CVR was 2.53 USD, whilst OBH was 2.29 USD. Extrapolation to a two week India national campaign estimated that 1.1 million staff would be required using CVR, but 293,000 staff would be needed for OBH.

OBH was operationally feasible, economical and effective at accessing the free roaming dog population. This study provides evidence for the continued expansion of research into the use of OBH as a supplementary activity to parenteral mass dog vaccination activities in India.

Answers:

Which vaccine? SPBN GASGAS

Which bait? Egg

Cost effective? Yes

The Team

Govt Goa

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- Dr Marwin Lopez
- Dr Utkash Betodkar
- Dr Vilas Naik
- Dr Niceta D'Costa







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- Gareth Thomas
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Thank you