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Progress Towards and Commonalities in Vaccine Development Against HIV, TB, and Malaria: **Commonalities across vaccine development efforts**

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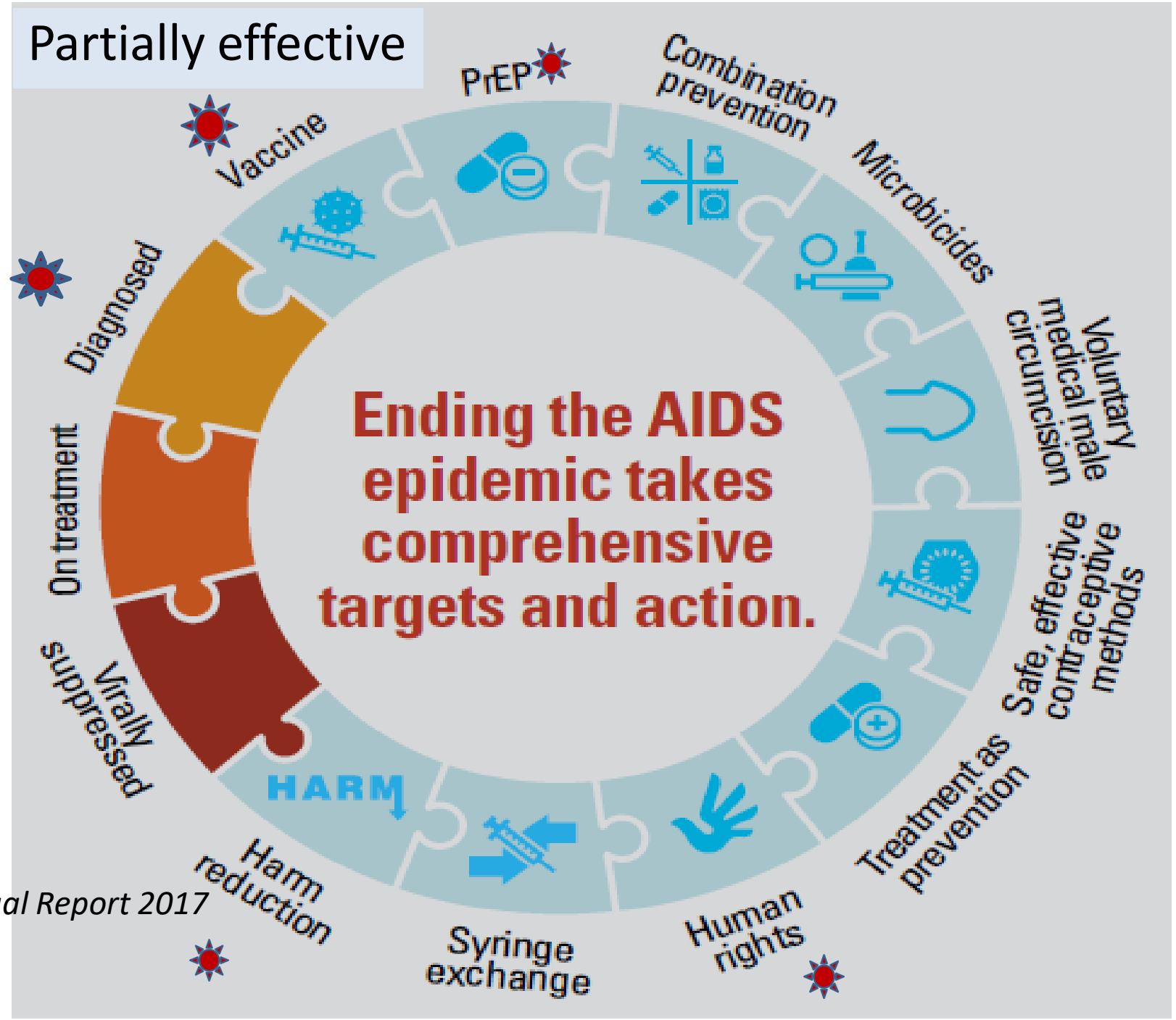
Commonalities of HIV ,TB , Malaria vaccines



Modified *Source: AVAC Annual Report 2017*

HIV Vaccine: Discussion Points

- Protocol design in the scenario if partially effective vaccine is licensed
- Implementation issues
- Funding issue

Protocol Design

Can the placebo be used?

Vaccine 32 (2014) 4708–4712

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

WHO report

Placebo use in vaccine trials: Recommendations of a WHO expert panel

[1,*], Abha Saxena[b], Abdhullah H. Baqui[c], Anant Bhan[d], Julie Bines[e],
otte Bouesseau[f], Arthur Caplan[g], James Colgrove[h], Ames Dhai[i],
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5.3. Testing a new vaccine when an existing vaccine is considered inappropriate for local use

A new vaccine is tested against a placebo because scientific experts or health officials in the trial country have determined that the existing vaccine should not be used in the national vaccination programme because it is not considered to be sufficiently efficacious due to local epidemiologic, demographic, environmental, or logistical factors. For example, the existing vaccine may provide inadequate levels of protection, the protection may not be durable, or it may require multiple vaccinations whose timely administration cannot be ensured under local circumstances. In this situation, a placebo arm is scientifically necessary in order to obtain sufficient information on the new vaccine's efficacy or effectiveness. An existing vaccine may also be considered inappropriate for local use when it is unacceptable to a population, including the potential study participants in the trial country, based on deeply held cultural or religious values (e.g. some religions do not approve of the use of

needs. The ultimate judgement about the acceptability of using a placebo control when an efficacious vaccine exists will depend on the specifics of the given trial. It is therefore critical that investigators and sponsors develop the design of vaccine trials in close collaboration with host country stakeholders, and that RECs and others thoroughly evaluate study protocols based on the available evidence and all relevant reasons. It is our hope that these recommendations will help to ensure that participants in vaccine trials are ted from unjustifiable risks, while facilitating the conduct of ble and urgently needed vaccine research.

May not be accepted especially In Africa as the burden is high.??

Protocol design & Conduct issues- Complex

- The design may involve many arms in the presence of PrEP

  in combination with other preventions –large sample size/then retention issue not only enrollment

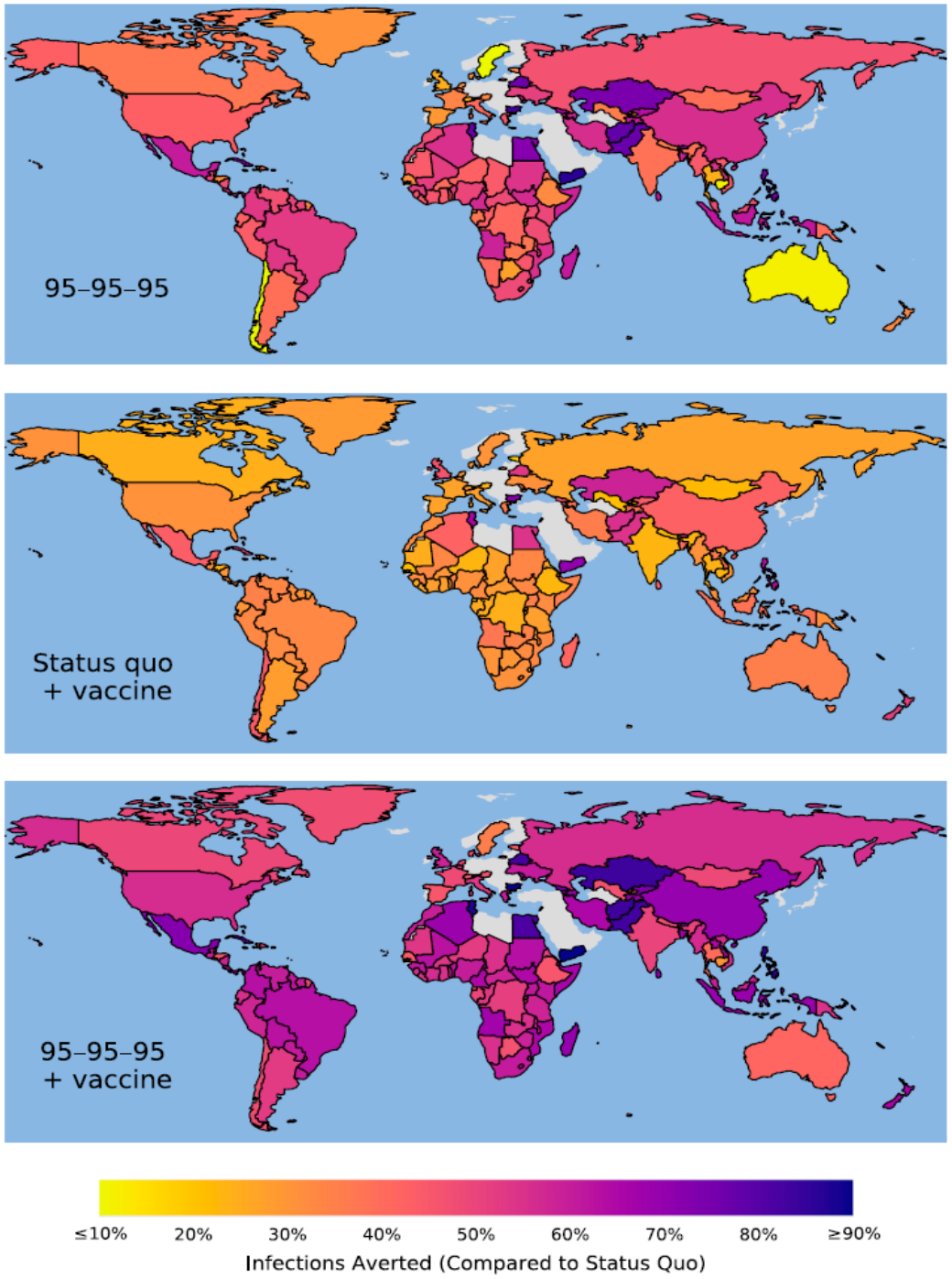
- Explore the adolescence group (15 years and above):

  not only because of the burden but the vaccine might work after primary series. So vaccines may have to be given as booster every 3-5 years to get the maximal effect

- Communication/education to participants, family, community
- How to make the trial close to the real scenario as many programs do not succeed much in implementation to the real world

Implementation

Use of partially effective vaccine in the presence of other Preventions seems to be the best option for now.



PNAS | April 11, 2017 | vol. 114 | no. 15 | 4019

Effectiveness of UNAIDS targets and HIV vaccination across 127 countries

Jan Medlock, Abhishek Pandey, Alyssa S. Parpia, Amber Tang, Laura A. Skrip, and Alison P. Galvani

Fig. 1. Infections averted between 2015 and 2035, compared with maintaining status quo diagnosis, treatment, and viral suppression, by the UNAIDS 95–95–95 target (*Top*); rollout of vaccination in 2020 while maintai… d viral suppression (*M*… ith 2020 vaccination ro… odel simulations in wh… distributions. See *SI*

49 m new infections projected between 2015-2035

Expanding current levels of Dx and Rx, predicting that 29 m new infection averted by 2035,

- With 50% efficacy vaccine introduction in 2020 additional 6.3 m will be averted

However, the regimens are complex

Improvements in future vaccine efficacy trials

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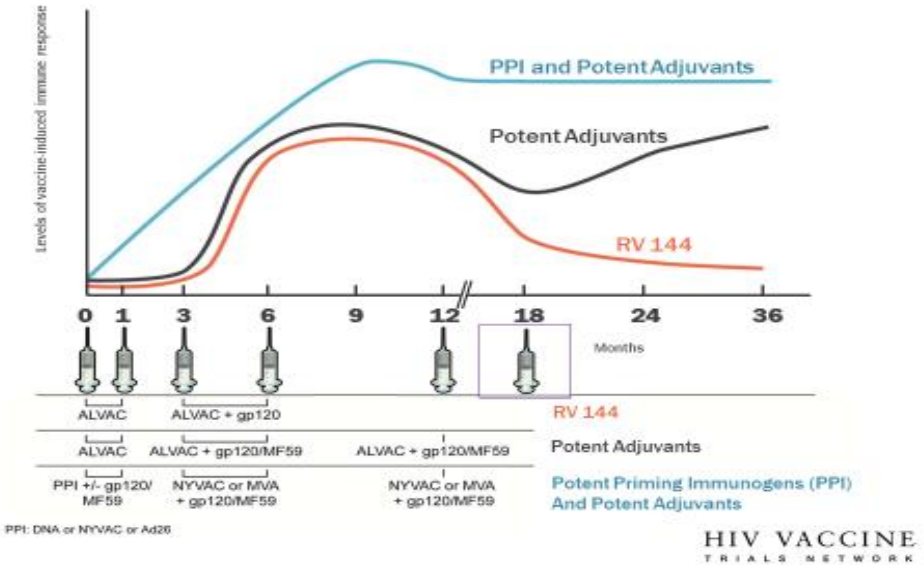


Mngadi K.

P5 LEAD Vaccine Products

AL,AD-MF59:P-B regimen up to 18 M

HVTN705/HPX2008

Vaccine composition and regimen

Double Prime

Ad26.Mos4.HIV

Ad26 vectors with Mosaic gag-pol or env inserts

Ad26.Mos1.Gag-Pol

Ad26.Mos2.Gag-Pol

Ad26.Mos1.Env (clade B-like)

Ad26.Mos2S.Env (clade C-like)

Co-formulated in 1:1:1:1 ratio

Double Boost

Ad26.Mos4.HIV

Ad26 vectors with Mosaic gag-pol or env inserts

Ad26.Mos1.Gag-Pol

Ad26.Mos2.Gag-Pol

Ad26.Mos1.Env (clade B-like)

Ad26.Mos2S.Env (clade C-like)

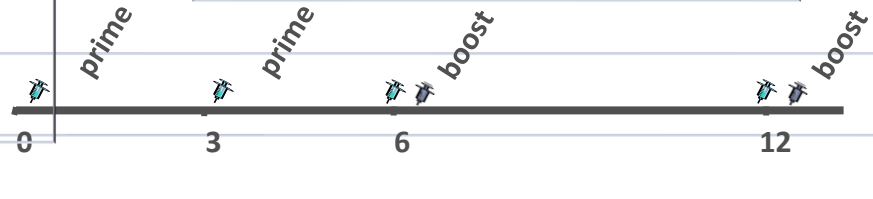
Co-formulated in 1:1:1:1 ratio

+

gp140 Clade C

Soluble trimeric gp140 Env protein

co-formulated with Alum



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How the VACCINE is going to implement if partially efficacious

- Combination with other existing preventions is expensive, any compliance issue may occur?
- Target group : all in high burden or only to special groups?
- How to make campaign? Acceptance?, stigma?- This may be more on the ASIA PACIFIC
- Acceptance of public/doctor/community/population

  (general or high risk-other regions)
- Education and communications- Public Campaign

Lesson learnt from other vaccines: Dengue-seropositive/seronegative

- Influenza : Missed match, low coverage, lost trust (few years ago)

Funding??? Not for Profit Organization or Global Funder Consortium, Host Countries???

Acknowledge with ThankS

- Dr. Kathy Mngadi
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- Dr. Mary Marovich-NIH
- Dr. Nelson Michael-MHRP

Thanks to your attention