

Public Health and Future Access Group

Recommendations

Public Health and Future Access Working Group

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Recommendations concerning presentation to the Ministry of Public Health

Start with a focus on the current context. Include these elements:

- Acknowledge that decisions are informed by scientific evidence, human rights principles, political/economic/social issues, and other considerations
- Present current epidemiology (e.g. incidence overall and by mode of transmission, dynamics, and geospatial aspects of the epidemic)
- Highlight the impending changes to the national treatment guidelines and their cost implications for modelling and cost-effectiveness work
- Present the current coverage of existing prevention services and identify gaps (UNGASS report due 31 March)
- Discuss the effectiveness of existing prevention methods and opportunities to improve strategies and combination prevention approaches to reduce HIV incidence in the absence of a vaccine
- Place the discussion in the context of Thailand's universal health care context; current adult vaccine delivery mechanisms; Thailand's commitment to biomedical HIV prevention trials; Thailand's National HIV Vaccine Plan

Recommendations concerning presentation to the Ministry of Public Health

Present data from the following work to inform decision-making:

- The RV144 results with an emphasis on the modified intent to treat analysis. Plans for the sieve analysis to improve vaccine immunogenicity
- Arguments against offering the RV144 prime-boost to the placebo group
- Arguments for and against involving the placebo group in further studies e.g. studies of risk behaviour enhancement post-vaccine
- Results of modeling impact on the epidemic of a 31% efficacious general population vaccine with 1 year duration of protection
 - standard parameters from RV 144 to apply to mathematical models should have been agreed to by modellers and RV144 researchers beforehand
 - several modelling teams should have been encouraged to model cost and impact; they should be convened to compare results and answer likely decision-maker questions before the May meeting if possible
- Cost-effectiveness data under 31% efficacy and varying cost and behavioural risk enhancement scenarios
- Acceptability studies

Recommendations concerning presentation to the Ministry of Public Health

Present arguments for:

- Target population for future vaccine trials and possibility of tailored prevention strategies, e.g. PrEP for MSM should IPREX report efficacy (likely becoming standard of prevention in this high incidence population which may preclude future vaccine trials)
- Funding of trials to determine post-vaccination risk behaviour enhancement /compensation (needs improved data collection methodologies/validation measures)
- Better estimate of what will happen in Thai population when vaccines are introduced e.g. assess information gathered post-PrEP trial results later this year and post-HPV vaccine introduction

Underscore the importance of:

- Strategies to manage the public's expectations

Recommendations concerning presentation to the Ministry of Public Health

Define the pathway to licensure:

- Determine regulatory processes and criteria for licensing in Thailand
- Refer to future trials that will be needed to support licensure
- Explore the potential for multiple licensing routes (Thai FDA, EMEA)

Present proposed timeline to assemble data for licensing:

- Depends on the number and duration of proposed future trials that are needed for licensure

Recommendations concerning presentation to the Ministry of Public Health

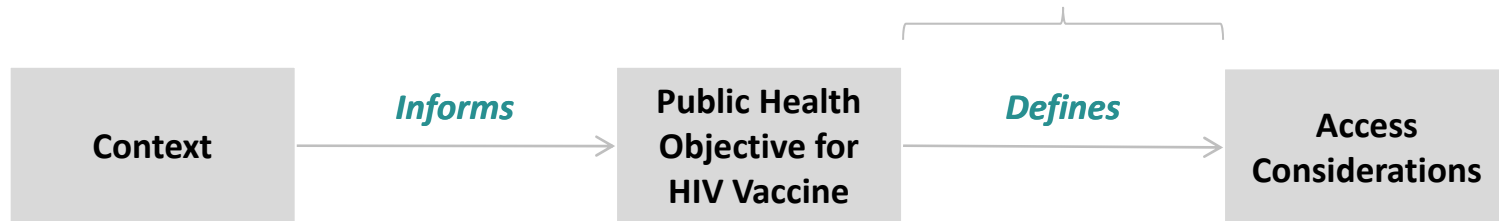
Discuss access considerations for the future when the vaccine or another is licensed (determine the level of detail that would be appropriate in May):

- Manufacturing, technology transfer
- Security of vaccine supply
- Demand forecasting and pricing strategy
- Equity of access (e.g. migrant populations, non-Thai groups)
- Importance of monitoring evolving epidemic dynamics to best target the vaccine
- Delivery strategies
- Budget implications and financing alternatives
- Impact on other public health services
- Post-marketing surveillance strategies

Communication Strategy: Manage Public Expectations

- Regulatory process and criteria
- Future trials needed to support licensure
- Potential for multiple licensing routes (Thai FDA, EMEA)

Pathway to Licensure



- Epidemiology (e.g. incidence, risk profile, geography of the epidemic)
- Change in treatment guidelines and cost implications
- Effectiveness of existing prevention methods: opportunities to improve strategies
- Coverage of existing prevention services: identification of gaps (UNGASS report due 31 March)
- Universal healthcare

- Modeling impact on the epidemic
- Cost-effectiveness under different efficacy, cost and behavioural risk enhancement scenarios
- Target population and product profile
- Acceptability

- Manufacturing, technology transfer
- Security of vaccine supply
- Demand forecasting and pricing strategy
- Equity of access
- Delivery strategies
- Budget implications and financing alternatives
- Impact on other public health services