

**How safe does a vaccine need to be
for a National Programme to take it on?**

or

‘How short is a piece of string?’

- ‘It depends what you want it for’

In what ways could a vaccine be *unsafe*?

- direct toxicity – immediate / later
- enhances target (or other) disease
 - ↑ severity, or deferred → more severe disease
- ↓ efficacy of other measures, eg vaccines
 - biological (esp immunological)
 - operational (eg makes EPI cumbersome or unpopular)
- behavioural
 - eg → belief* that other measures are now unnecessary
 - *(by population, Programmes, planners, donors)
 - if diverts resources/attention away from other problems
- **any of the above** in sub-groups – eg HIV+, malnourished

‘Acceptable’ safety level?

risk vs benefit

Considerations for country programmes

- Understand malaria disease burden – country-specific
- Know limits of likely malaria vaccine effectiveness
- Appreciate simplicity of vaccine
vs LLINs/IRS/ACTs
- Consistent reporting of safety from trials
- Likely sustainability of provision/funding
- Respected **international opinion** (= WHO)
- **Long-term M&E:**
 - but how to apportion blame among many new vaccines?
 - not every fever will = vaccine failure
 - optimise malaria diagnosis

(BEWARE lay impressions)

*'A vaccine is like a politician –
her reputation is easy to tarnish,
and hard to restore.'*

ANON