

Like any other drug?

As with any other drug, some vaccines are more useful than others. Some are useful when a large population is vaccinated; others should only be given to persons at particularly high risk. Some are pointless, perhaps because they offer protection against a benign condition; others have harms that are disproportionate to their minimal or uncertain efficacy.

Like any other drug, a vaccine's efficacy is best evaluated in comparative clinical trials. The design of these trials must take into account: the incidence of the infection; its natural history, to determine which endpoints to use, primarily clinical endpoints for a rapidly progressing disease; the existence of persons at increased risk of developing complications, to ensure they are enrolled in sufficient numbers; and the environments in which the populations most concerned live and where the trial is to be conducted.

As with any other drug, the data available for the analysis of a vaccine's adverse effects are often less robust than those available for analysis of its efficacy. It is also essential to look into a vaccine's foreseeable risks, based on its pharmacology: is it a type of vaccine that is well known and has already been used, e.g. based on an inactivated virus or a live attenuated virus? Does it contain adjuvants? Are these adjuvants well known and have they already been used? What long-term harms should be taken into consideration?

When all of these factors are taken into account, a vaccine sometimes clearly represents a therapeutic advance, as is the case for the Ebola vaccine rVSV-Zebov (Ervebo®) (see pp. 33-37 of this issue). The results of its evaluation, based on tangible outcomes for those most at risk, are convincing and justify the risks.

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