SARS vaccine development: caution versus urgency

Now that the urgency of developing a SARS* vaccine appears to have waned, some researchers are urging vaccine makers to take a more methodical approach as they initiate clinical trials, according to a recent report published in *Science*.

A number of candidate SARS vaccines are being developed. The leading such vaccine is being developed by researchers from Sinovac Biotech, China, and the Chinese Academy of Medical Sciences, who plan to initiate human safety trials as early as March. That may be too soon, comment some researchers, including many at the WHO meeting to review testing procedures that was held recently in Rotterdam, The Netherlands.

It is yet to be determined what the best animal is for testing the safety and efficacy of SARS vaccines, says the report. Without an appropriate animal model, human trials may be dangerous. Of particular concern is the possibility that a vaccine with a faulty design may actually exacerbate SARS. According to researchers at the WHO meeting, disease enhancement should be screened for using separate animal tests. Nevertheless, the meeting's attendees approved of the plan to initiate human safety trials of the Chinese vaccine candidate, reasoning that China is at the highest risk from SARS.

Another problem looms in the not-so-immediate future: if there is not another major outbreak of SARS, there may be no way of testing a vaccine for human efficacy. One possible way of testing efficacy without an outbreak is through utilisation of the US FDA's 'animal rule'. The rule allows the approval of certain drugs and vaccines against rare bioterrorism diseases based on animal data alone. However, it remains to be seen whether a SARS vaccine could meet the stringent conditions required by the animal rule, according to Dr Mark Abdy from the FDA. Nevertheless, vaccine developers are counting on flexibility from the FDA when it comes to fighting SARS.

* severe acute respiratory syndrome

Marshall E, et al. Caution urged on SARS vaccines. Science 303: 944-946, 13 Feb 2004

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