Why vaccine hard to develop

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KOTA KINABALU: The reason why vaccines are difficult to develop is because regulations make the procedure tedious and long winded, according to Universiti Malaysia Sabah's (UMS) Assoc Prof Dr Kenneth F Rodrigues (pic).

The academician from the university's Biotechnology Research Institute said there are three generations of vaccines which are currently available.

"The first generation vaccines, as the term suggests, represent the earliest vaccines, they consist of an attenuated virus or bacterium," he said.

He explained that attenuation is a process whereby biochemical procedures are applied to weaken or kill the virus or bacterium. This makes it impossible for the virus to replicate or reproduce inside the human or animal host, but is sufficient to elicit an immune response.

"Today, a vast majority of the vaccines available in the market are what are termed as second generation or "subunit vaccines".

"Subunit vaccines are developed by identifying a viral or bacterial cat protein, engineering this protein into bacteria such as Escherichia coli and producing it in large amounts in fermenters," he said.

He said the proteins are purified and dried using a special machine called a lyophilizer. These cost of production of second generation vaccines is very low, in fact the Serum Institute produces them at less than US dollars 3 (RM12.97)per dose.

He explained that subunit vaccines can be shipped without refrigeration into remote locations and all the doctor or nurse has to do is reconstitute them using sterile saline solution and inject them into the patient.

"Today, some of the subunit vaccines can also be delivered orally, thus reducing the fear of injection in children. Subunit vaccine are safe to produce as the technicians at the factory are not exposed to the complete bacterium or virus," he said.

He said the next generation of vaccines are termed as the third generation vaccines and these are in the form of Deoxyribonucleic Acid (DNA) and Ribonucleic Acid (RNA).

“These vaccines are injected into the human or animal host, following which the host produces the bacterial or viral protein in the host itself,” he said.
He explained that third generation vaccines represent the latest development in the vaccine industry as they are even cheaper to produce as compared to second generation vaccines.
“They can also be tailored to specific bacteria or viruses. For example, if a unique strain of virus begins to infect human hosts in Borneo, molecular biologists can rapidly sequence the genome, identify the unique regions and develop a synthetic DNA vaccine which targets the unique virus.
“The high degree of mutation in viruses has prompted a new interest in third generation vaccines as these are easy to design, develop and the production can be undertaken in a small certified laboratory,” he said.
The vaccines are injected in mice, and tested for their ability to elicit an immune response via antibodies. The results from mice trial must be reproducible and theantibodies must be proven to be specific to the pathogen being tested prior to release for further trials.
Finally, the vaccines can be tested on healthy human volunteers and these tests are conducted with placebos in order to ascertain whether the vaccine is actually effective. Trials must be repeated periodically over the life cycle of the vaccine which required additional periods of time. This is done in order to eliminate the possibility of long-term side effects and cross reactivity in diverse human hosts.

“All of this explains why a vaccine needs at least two to four years before it can be released by the respective nations Food and Drug Authority,” he said.
He said vaccines which produce side effects and have inconsistencies in response can face resistance among the public and this is the reason why stringent quality controls and procedures are essential.
“The current Covid 19 scenario has prompted many countries to proceed to rapid trials of vaccines and in many cases animal trials have been bypassed, which can have serious long term implications for public health and safety.
“Given the current scenario, it is imperative that every government prioritise vaccine development and production in their respective national strategies.
“The current shortage of personal protective equipment has proven that in pandemic situations, countries across the world restrict the export of critical equipment and this can have implications for public health in non-producer countries.
“The cost of developing adequate biosecurity measures which can be in the form of national vaccines and advanced surveillance is critical in a world where health care has now become a national priority,” he said.