

CAVEATS, COSTS AND COMPLEXITIES SHADOW FIRST MALARIA VACCINE

LONDON: It's a showpiece drug that has the potential to end a disease that kills half a million African children a year. Yet even before it wins a license, the world's first malaria vaccine has lost some of its sheen. Backed by billionaire philanthropist Bill Gates and developed by GlaxoSmithKline, the vaccine-called RTS or Mosquirix-is being assessed by regulators and global health authorities.

Granting it a licence and recommending it for rollout in sub-Saharan Africa, where malaria kills one child almost every minute, ought to be a no-brainer. But Mosquirix is hampered by caveats, complexities and cost implications that threaten to make its arrival on the global health stage more of a problem than a solution, possibly not just for malaria but for vaccines in general.

"There's a lot of excitement for a malaria vaccine. But it's a very complicated vaccine, so the recommendation is presumably going to be complicated too," says Seth Berkley, chief executive of the GAVI global vaccine group. Malaria is caused by a parasite carried in the saliva of mosquitoes. GSK's vaccine is designed to go to work at the point the parasite enters the human bloodstream after a mosquito bite.

Partial protection

By stimulating an immune response, it can prevent the parasite from multiplying in the liver. Without that response, the parasite re-enters the bloodstream and infects red blood cells, leading to fever, body aches and sometimes death. One big problem with Mosquirix is that

while it's the best malaria vaccine so far, it still doesn't work very well. Unlike polio or smallpox vaccines, which offer life-long high-level protection from the diseases they are designed to prevent, Mosquirix gives only partial protection against malaria, and even that dwindles within a few years.

Data from clinical trials which ran across seven countries in Africa show that at best, in children aged 5-17 months, it offers 50 percent protection. In babies aged around 3 months, that drops to 30 percent. Dosing is also a problem. Pedro Alonso, director of the World Health Organization's Global Malaria Program, explained in a briefing last week that even to get that efficacy, children would need for four doses over 18 months.

"In the absence of four doses, the efficacy disappears and no significant protection is documented," he said. "It's challenging in terms of understanding how it would best add value." The WHO has promised to make a decision on whether and how to recommend use of Mosquirix by the end of 2015. European Medicines Agency drugs regulators, who have been wading through a quarter of a million pages of evidence submitted by GSK, are expected to decide soon, likely later this month, on whether it should be licensed.

Costs and delivery

Sources close to the approval process suggest Mosquirix is likely to get both EMA and WHO backing, partly thanks to the weight of history pushing for the world's first malaria vaccine to get to market. But there will

be conditions attached, all of which carry cost implications that may make the reality of delivering Mosquirix prohibitively expensive.

GSK hasn't yet put a price on the vaccine, but the firm's charismatic chief executive Andrew Witty has promised it won't be expensive, with a profit margin of 5 percent over cost of manufacture which he promises to reinvest in research on malaria and other neglected diseases. Sources involved in planning for Mosquirix's potential future use told Reuters they have been advised to work with a price tag of around \$5 per dose.

That would make a dose of Mosquirix about the same as the cost of an insecticide-treated bednet. And while a bednet can protect two people for three years before it needs replacing, with Mosquirix, the likelihood is that one child would need four doses-around \$20 in medicine costs alone to get an extra 30 percent protection from malaria for a shorter time. Adrian Hill, a vaccine expert at Oxford University's Jenner Institute, notes the numbers look even less attractive if Mosquirix is recommended for slightly older babies. If the shot were to be licensed for babies of 3 months old, when it could be given as part of the routine so-called Expanded Program on Immunization, the cost of delivery could be relatively low. "The real problem arises if it's given at 6-12 months. The cost of delivery will be greatly increased and we just don't know how feasible extra immunization time points will be," Hill said. "Sadly, the data show the protection in younger infants, who we immunize routinely, is very modest, but it is better in older infants."

Reputational risk

As the world first human vaccine against a parasitic disease, Mosquirix is a historic milestone and close to the hearts of its key backers, the philanthropic Bill & Melinda Gates Foundation and GSK. If global health authorities push ahead despite the complexities, experts say there could be substantial reputational risks for Gates, Witty, the WHO and even for vaccines in general.

After all, if children vaccinated against malaria continue to get the disease, why should mothers trust other vaccines, developed by drugmakers, backed, promoted and recommended by the WHO, against diseases like pneumonia, measles and polio? The Gates Foundation is keen not to voice an opinion on Mosquirix at this sensitive time, when regulators and the WHO are assessing it, said foundation director Alan Magill. He stressed this is a first generation vaccine, "no silver bullet", and only one of a range of weapons against malaria. A GSK spokesperson also emphasized Mosquirix is designed for use alongside other malaria control measures such as bednets. "Given the huge burden of malaria in sub-Saharan Africa, we believe this could have a significant public health impact," she said.

Despite widespread acknowledgment of the complexities and costs surrounding Mosquirix, none of the experts Reuters spoke to believes regulators and the WHO will say no to the world's first malaria vaccine. "It's going to be a first time in history situation," said Alonso. "The challenges are around where this vaccine could provide additional benefits to the tools we already have." — Reuters

AFTER HALF A CENTURY HUNT, SCIENCE FINDS PENTAQUARKS

GENEVA: Data from the Large Hadron Collider (LHC) outside Geneva appears to have proved the existence of particles made of five quarks, solving a 50-year-old puzzle about the building blocks of matter, scientists said yesterday. Quarks are the tiny ingredients of sub-atomic particles such as protons and neutrons, which are made of three quarks. The less common and more unstable mesons, particles found in cosmic rays, have four.

A five-quark version, or "pentaquark", has been sought, but never found, ever since Murray Gell-Mann and George Zweig theorized the existence of such sub-atomic particles in 1964. Guy Wilkinson, spokesman for the LHC experiment based at CERN, the physics research centre that houses the LHC, said a telltale "bump" seen in a graph of billions of particle collisions could only be explained by a five-quark particle.

"From the point of view of our experiment, we think it has fulfilled all criteria of discovery. We have no other way of explaining what we have seen. But the scientific method is such that we have submitted a paper to a journal, the journal will consider it, then the community will judge," he told Reuters. The LHC, a circular 27 km underground particle accelerator, has provided reams of data since it started smashing protons together at close to the speed of light in 2010.

Analysis of the collisions has already proved the existence of the Higgs boson, a particle that gives mass to matter, and scientists are now looking for a "dark universe" that they believe exists beyond the visible one. The pentaquark discovery has opened even more new avenues.

"What we want to do now is to look for other five-quark particles and try and understand more about their nature, and this may tell us something about how even the matter inside our bodies is bound together," Wilkinson said. "It may also have cosmic consequences for ... understanding what happens to stars at the end of their life." He said it was still a mystery why it had taken 50 years to find pentaquarks. "There must be many, many pentaquarks out there. In fact in our analysis we found two. One is very evident, the other is a little harder to see. There should be many out there." —Reuters

AFGHAN RETURNEES FROM IRAN BRING DRUG PROBLEMS HOME

GRUELING CONDITIONS TURN WORKERS INTO HEROIN ADDICTS

ISLAM QALA: At Zero Point, the main border crossing between Afghanistan and Iran, hundreds of Afghan laborers return to their homeland each day. Some are exhausted by grueling working conditions, but many others bear the hallmarks of heroin addiction they acquired while in Iran. Under the watchful eyes of customs officials from both countries, the laborers cross the windy and arid plains at Islam Qala, the entry point to Herat province and western Afghanistan, after months or years spent working in Iran.

Every day, between 1,000 and 1,500 illegal Afghan migrants, mainly young men, return to their country, either voluntarily or in around a third of cases because they have been expelled. Iran, which shares a long border with Afghanistan, began taking in millions of Afghan refugees in the 1980s as they fled a war that began with the Soviet invasion and has continued to this day. The flow of people began to reverse following the fall of the Taleban regime at the end of 2001, with millions of Afghans choosing to return home. And the pace has picked up in the past few years due to an increasingly repressive environment for Afghan refugees in Iran, particularly the 1.7 million who are unregistered (a further 840,000 are legal).

Silent over criticism

Tehran has remained silent over criticism regarding the expulsion of illegal Afghans, earning it criticism from rights groups over the past few years. Situated 120 kilometers from the border, Herat, the main city in Afghanistan's west, welcomes the majority of those who have come back. But authorities have witnessed a disturbing trend: many of the returnees are addicted to drugs they first tried out while in Iran.

In an ironic twist, most of the drugs consumed are exported from Afghanistan, which produces 85 percent of the world's opium, later refined into heroin. Production has increased seven percent over the past year thanks in part to an evergreen Taleban insurgency and lack of government control in remote areas, according to the United Nations



HERAT: This photograph taken on May 27, 2015, shows migrants who have crossed into Afghanistan from Iran as they walk at Islam Qala on the outskirts of Herat near the border between Afghanistan and Iran. — AFP

Office on Drugs and Crime. A large portion of Afghanistan's drugs are transported to the rest of the world via Iran, where dealers and users find them easy to obtain.

At a drug treatment centre for in Herat, Mohammad Choghok, 50, tells AFP that up until two years ago he lived in the Iranian town of Mashhad, where he worked as a shepherd. And his employer, instead of paying him, gave him opium. "I have been addicted for almost 34 years," he murmurs. According to Mohammed Reza Stanikzai, a senior narcotics official at the

UNODC, initial research also backs the claim that "most (Afghan) drug users started their first drug use outside the country".

'Take drugs, work better'

"In many cases, their employers give them drugs and tell them: 'If you take these you will work better and be better paid,'" says doctor Safiullah Pardis, the head of a clinic for addicts in Herat. Akbar Anwari, 28, was born in Iran to Afghan parents. It was there that he became an addict, before his deportation. "My family lives

in Iran, I don't have any contact with him," he said, explaining he wants to rid himself of his drug habit before seeing them.

As night falls, dozens of heroin users roam the parks in the centre of Herat. Without a place to stay and money, some become delinquents and end up in prison. Of the 3,100 inmates in the city's lock-up 430 are addicts. Fewer than half of these detained addicts are treated in a tiny clinic within the prison. Crowded into a dormitory with bunk-beds, the shaven-headed detainees doze in the afternoon heat.—AFP

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