Are Covid-19 Boosters necessary?

The UK Government recently announced that Covid-19 booster vaccination will commence in September 2022. This follows the recommendation by the Joint Committee on Vaccination and Immunisation (JCVI) that a booster jab should be offered to everyone aged 50 and over as well as carers and those with underlying health conditions.

The Isle of Man Government will follow suit with the first appointments already booking for 5th September 2022.

However, the CEO of AstraZeneca, Mr Pascal Soriot, in an interview with the *Daily Telegraph* on 26th August 2022 surprisingly questioned whether such boosters were necessary and in fact may not be a good use of taxpayers money. The basis for his comments was the assertion that most of the population is vaccinated and will have a "foundation immunity" which will "last a long time (1 – 3 years)".

Some people may say that Mr Soriot's comments are just sour grapes given that the AstraZeneca vaccine will not be used as one of the autumn boosters. However, are there valid and sensible concerns about the booster programme?

According to a House of Commons *Public Accounts Committee* Report published in July 2022, there were **2.98 million** adults in the UK who had not received a single dose of any Covid-19 vaccine as at the end of May 2022.

Some of the reasons articulated for declining the offer of a Covid-19 vaccine have included the following:-

i) Cultural sensitivities in ethnic minority groups re historic medical colonialism.

ii) Concerns about the ingredients in Covid-19 vaccines e.g. the AstraZeneca vaccine has as its active ingredient a genetically modified *chimpanzee cold virus*. Moreover, the AstraZeneca Covid vaccine uses a host cell line called HEK (human embryonic kidney)-293 to produce this genetically modified chimpanzee cold virus. Such HEK-293 cells are clones of cells taken from the kidney of a legally aborted human foetus.

iii) The testing of Covid vaccines on animals e.g. the original Pfizer vaccine was tested on Macaque monkeys (and its new booster has been tested on mice – see further below).

iv) Prevention – knowledge that long term healthy lifestyles can provide satisfactory prevention.

v) Treatment – vaccination not necessary because illness can be treated adequately in a variety of different ways.

vi) Efficiency – uncertainty over how effective the vaccines are and how long protection lasts e.g. most persons in Isle of Man hospitalised with Covid have been vaccinated.

vii) Recovery – an appreciation that natural immunity gained from previous colds/flu/cleansing episodes may provide sufficient resilience.

viii) Overreaction – the understanding that for *most* persons the symptoms of Covid-19 will be relatively mild, no worse than flu.

According to UK Government official Covid statistics, as at 21st August 2022, 91% of individuals aged 12 and over have been vaccinated with one dose of Covid vaccine but only **72.5%** of individuals have accepted a booster.
Is this significant decline in uptake a result of greater awareness over time of the above factors? The offer of yet another booster provides renewed opportunity for people to carefully consider these factors and to make up their own minds on the available evidence.

Another reason frequently cited for declining a Covid-19 vaccine relates to safety concerns.

SAFETY

The original Moderna and Pfizer vaccines used relatively new MRNA technology. In addition all Covid-19 vaccines initially received only temporary or emergency use government authorisation valid for just 12 months. The testing pools were relatively small and the vaccines did not go through all of the usual human testing procedures.

Thalidomide was a medicine for morning sickness but tragically approximately 2,000 babies were born in the UK between 1958 and 1961 with severe defects after their mothers took the drug. Most regrettably, the drug had never been tested on pregnant women prior to official authorisation.

The UK Government's **Yellow Card** reporting scheme for adverse reactions to Covid-19 vaccines shows that there was a total of 456,718 adverse reactions reported in the UK up to 15th June 2022 in relation to AstraZeneca, Pfizer and

Moderna Covid vaccines (including 2,213 reported deaths within a short time of vaccination).

The concerns which were previously expressed about the dangers of the original Covid-19 vaccines used from December 2020 are now being raised again in relation to the new Covid boosters proposed for autumn 2022.

The autumn booster will either be a Pfizer or Moderna vaccine. Participants may be offered the new Moderna booster which has been designed to target the original strain of Covid-19 and the later Omicron variant. This booster is called a Bivalent vaccine.

The UK, on 15th August 2022, became the first country in the world to authorise use of this new Moderna booster, which is called **"Spikevax Bivalent Original/Omicron".**

Spikevax Bivalent Original/Omicron

This vaccine will be given to recipients in a 50 microgram shot (25 mg targeting the original Covid-19 and 25 mg targeting Omicron).

The UK Government's Medicines and Healthcare Products Regulatory Agency (*MHRA*) has published a document on this new vaccine titled *"Summary of Product Characteristics"* – see attached link below.

From this official government document the following should be noted:-

a) Duration of protection – "The duration of protection afforded by the vaccine is **unknown** as it is still being determined by ongoing clinical trials".

b) Safety – "the safety, reactogenicity and immunogenicity of a booster dose of Spikevax Bivalent Original/Omicron are evaluated in an on-going Phase 2/3 open-label study….In this study 437 participants received the Spikevax Bivalent Original/Omicron 50 mg booster dose".

c) Authorisation – "This medicinal product has been authorised under a so-called '*conditional approval'* scheme. This means that further evidence of this medicinal product is awaited".

d) Children – "The safety and efficiency of Spikevax Bivalent Original/Omicron in children less than 18 years of age has not yet been established*. No data are available".*

e) Interaction with other medicinal products – "No interaction studies have been performed. Concomitant administration of Spikevax (Original) or Spikevax Bivalent Original/Omicron with other vaccines has **not** been studied".

f) Pregnancy - The vaccine was tested on *female rats*, "by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. There were no vaccine related adverse effects on female fertility, pregnancy, embryo foetal or offspring development or post-natal development" (Spikevax Bivalent Original/Omicron has **not** therefore been tested on pregnant female humans).

New Pfizer Booster

Pfizer has recently submitted its next generation Covid-19 booster to the US Food and Drug Administration (FDA) for approval.

Astonishingly, this Pfizer booster has only been tested on mice.

In addition, because mice cannot normally contract Covid-19, they were *genetically modified* to carry a human specific receptor that is required for the virus to bind.

The mice were engineered at the embryonic level to pass the receptor onto their offspring.

Remarkably, therefore, the testing information submitted to the FDA by Pfizer about its new Covid booster is solely based on mice data (although human trials are due to commence in September 2022).

Conclusion

There is an alarming sense of *deja vu* about this issue.

The same concerns around very limited or non-existent testing arise. The Moderna booster has been tested on a tiny pool of participants, namely 437 people. Moreover, pregnancy testing was only conducted on rats, not female humans.

In effect the UK adult population will be the field trial for this Moderna booster.

Additionally, the new Pfizer booster has only currently been tested on mice.

The same concerns around limited authorisation arise, with the duration of protection afforded by the Moderna vaccine being stated as unknown and the product only granted conditional approval.

The same concerns around the interaction between Covid-19 vaccines and existing medical products such as the flu vaccine arise.

Significantly, in the UK the majority of persons were originally vaccinated with the **AstraZeneca** vaccine. The autumn booster campaign will offer the Pfizer and Moderna boosters. No research whatsoever has been undertaken in relation to the

interaction between the original AstraZeneca vaccine in a person's body and the introduction of the novel Pfizer or Moderna boosters.

The AstraZeneca vaccine is a viral vector vaccine, which uses as a vector the genetically modified chimpanzee cold virus whereas the Pfizer and Moderna vaccines use an entirely different model namely the MRNA technology. These two very different products within the same human body simultaneously represents unchartered water.

There is a clear and overwhelming international political will to be seen to be doing something in relation to Covid-19, which has led to expedited scientific process. The US Government announced on 29th July 2022 that it has ordered 66 million doses of the Moderna booster (Spikevax Bivalent Original/Omicron) at a cost of **$1.74 billion.** Given the extremely limited human safety and efficiency trials undertaken to date, this decision could justifiably be considered foolhardy and reckless.

Plainly, intended recipients of any new Covid-19 booster vaccines should properly be given by government clear and adequate information about the nature, risks and efficiency of a product about to be put into their bodies so that those persons can give **true and informed patient consent**. But will government be sufficiently candid and transparent?

Mr Soriot, the AstraZeneca CEO, raised timely concerns about whether Covid-19 boosters are necessary and appropriate this autumn. We agree, but for very different reasons.

Links

Spikexax_bivalent_
Original_Omicron_S

https://news.northeastern.edu/2022/08/24/genetically-modified-mice/