Covid-19 Vaccine Efficacy – Relative vs Absolute Risk

On November 18 2020 Pfizer and BioNTech issued a press release[1] stating that its Covid-19 vaccine candidate was "95% effective against Covid-19". Whilst this sounds good, it is actually based upon **relative risk** which is used to compare the risk in two different groups of people. In medical research different groups are compared to see if belonging to a particular group increases or decreases your risk of developing certain diseases. Typically, a treatment is performed in one group of people and the outcomes compared to a control group.

However, relative risk tells you nothing about actual risk. The size of the actual risk is what's really important. If the actual risk is very small, even a huge % effectiveness may not make much difference. But for a risk that is quite large already, a smaller % effectiveness can still have a big impact.

The 'risk' of something happening is its chance of taking place and there are different ways of describing a risk. The actual risk itself is often referred to as the **absolute risk.** Say you have a 1 in 10 risk of developing a certain disease in your life. This can also be said to be a 10% risk, or a 0.1 risk - depending on whether you use percentages or decimals.

Probability is about estimating or calculating how likely or probable something is to happen. The chance of an event happening could be 'certain', 'impossible' or 'likely'. Probabilities are usually written as fractions or decimals between 0 and 1, or percentages between 0% and 100%.

A worked example using the Pfizer and BioNTech Vaccine Study

We will work through an example using the Pfizer and BioNTech Covid-19 mRNA vaccine using information contained in the UK Medicines and Healthcare products Regulatory Agency (MHRA) Public Assessment Report[2]. **Appendix 1** provides further information about the study and outcomes.

A phase 3 clinical trial of the mRNA vaccine began in April 2020 and studied approximately 43,000 individuals. Participants were split into two even groups. One group received the vaccine and the other group received a placebo (the control group) and the outcomes were studied for a period up to two months after receiving the second dose of the vaccine.

Before we move on, it is useful to understand what is meant by **efficacy** and **effectiveness**:

Vaccine efficacy is the percentage reduction in disease incidence in a vaccinated group compared to an unvaccinated group under optimal conditions (e.g. randomised control trial)

Vaccine effectiveness relates to how well a vaccine works in the "real world" setting outside of clinical trials and when used in a wider variety of people.

[1] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine

[2] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/944544/COVID-19_mRNA_Vaccine_BNT162b2__UKPAR___PFIZER_BIONTECH__15Dec2020.pdf

The primary aim of the phase 3 study was to determine whether the vaccine reduces the risks of a person getting symptoms said to be associated with Covid-19.

Summarised below is an extract from the MHRA Public Assessment Report summarising efficacy outcomes of the phase 3 study.

Table 6: First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days)

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.3, 97.6)	>0.9999

There were 170 confirmed Covid-19 cases up to the cut-off date of 14 November 2020. In the vaccinated group, 8 people were reported to have confirmed Covid-19. In the control group, 162 people were reported to have confirmed Covid-19.

The **case definition** used in the phase 3 study for a confirmed COVID-19 case was:

- a positive SARS-CoV-2 PCR test; **and** the presence of **at least one** of the following defined list of symptoms:
- Fever;
- New or increased cough
- New or increased shortness of breath
- Chills
- New or increased muscle pain
- New loss of taste or smell
- Sore throat
- Diarrhoea
- Vomiting

We will use the actual numbers in the phase 3 study to now calculate the relevant risks.

Absolute Risk

The **absolute risk** of an event is the likelihood of occurrence of that event in the group at risk.

In the vaccine group, out of 17,411 people there were 8 cases of Covid-19, so the **absolute risk** of the disease would be 8 divided by 17,411, or **0.05%**.

In the placebo group, out of 17,511 people there were 162 cases of Covid-19, so the **absolute risk** of the disease would be 162 divided by 17,511, or **0.93%**.

We can see that the absolute risk **reduced** to 0.05% in the vaccine group compared to a risk of 0.93% in the placebo group.

The **absolute risk reduction (ARR)** is the difference in risk between the two groups. So 0.93% (placebo) less 0.05% (vaccinated) equals **0.88%**.

We can simplify and say that the overall actual risk has reduced by just under 1%.

The probability of an event not happening is 1 minus the probability of the event happening. So we can also say:

The probability of **not having the disease** for an individual picked randomly from the **vaccine** group is **99.95%** and for an individual picked randomly from the **placebo** group it is **99.07%**.

Relative Risk

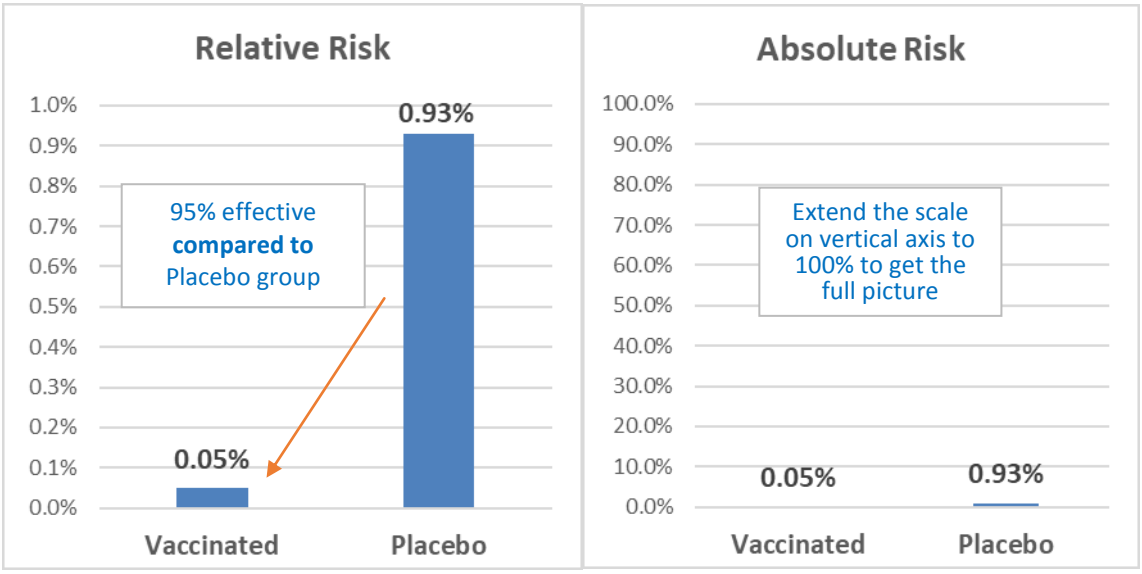
We have already calculated the difference in absolute risk between the two groups which is **0.88%.** We can now estimate the relative risk in the vaccine group compared to the placebo group by simply dividing the figure of 0.88% by the placebo control group risk of 0.93% which gives us a figure of **95%** - referred to as the **vaccine efficacy** (**VE)**.

So the efficacy or relative risk tells us how much more, or less, likely the disease is in one group, **compared to another**. This is an important point to understand. This metric can be used to conceal from view the actual absolute risk overall.

Many reports about the benefits of treatments present risk results as relative risk reductions rather than absolute risk reductions. This often makes the treatments seem better than they actually are.

When relative risks and benefits are stated it is important to also show the absolute risk to ensure a full picture is obtained.

The following chart demonstrates this point using the Pfizer and BionTech phase 3 study outcomes. **You can clearly see below how the benefits of a treatment can be exaggerated when not considered alongside the actual absolute risk**. The chart on the left only displays the vertical scale for risk to 1% level. The chart on the right displays the vertical scale to the 100% level.



Number needed to treat (NNT)

A figure which is often quoted in medical research is the Number Needed to Treat (NTT). This is the number of people who need to take the treatment for one person to benefit from the treatment. To estimate this figure, we simply use the following formula:

1 divided by absolute risk reduction (or 1 / ARR)

Using the Pfizer BionTech phase 3 study outcomes: 1 divided by 0.0088 (100% / 0.88%), gives a figure of **114**.

This means that in order for 1 person to benefit from the treatment, you would need to give it to 114 people.

Adverse Effects of Treatment

If a particular treatment was associated with benefits but it also came with a risk of side effects, then you would need to weight up whether the risk of reducing the disease occurrence is worth the risk of side effects you might experience.

No vaccine is completely risk-free and adverse events can occasionally result after an injection.

A vaccine reaction is an individual's response to the components of the vaccine. The Pfizer and BioNTech phase 3 study categorised these into a) local reactions and b) systemic events.

The study states that the commonest **local reaction** was pain, mostly mild or moderate. The commonest **systemic events** were fatigue, headache, chills and myalgia. Severity was mostly mild or moderate; antipyretic or pain medication was often needed.

Adverse events can range from minor side-effects to more severe reactions. Observing the rate of an adverse event in the vaccinated population and comparing it with the rate of this event among the unvaccinated population can help to distinguish genuine vaccine reactions

The study states that a higher proportion of vaccine recipients reported **adverse events** compared with placebo recipients. At least one adverse event was reported by 27% of participants after the mRNA vaccine compared to 12% of participants after placebo.

Further details of adverse events identified in the phase 3 study are provided in **Appendix 2**.

Weighing up the options

Taking the above into consideration, an individual can start to consider whether taking a particular treatment is appropriate or not considering the risks and benefits.

Questions such as the following should help:

- What is the absolute risk of getting the disease to start with and how much is the absolute risk reduced with treatment?
- How serious is the disease anyway and what are your chances of dying?
- What are the potential benefits of taking the treatment?
- What are the potential risks in taking the treatment?
- Are you satisfied that the potential benefit is valuable enough to take some risk connected with the treatment?

Risks and seriousness of the disease

Using the Pfizer BionTech phase 3 study outcomes, the absolute risk was **0.93%** in the control group. This was reduced by 0.88% to **0.05%** with treatment. The disease is rare in the first place and is made rarer with treatment.

Professor Chris Whitty, the UK Chief Medical Officer talked about the Covid-19 disease and associated risks in in a presentation he delivered on 30 April 2020[3] and stated that:

- *Over the whole epidemic, even if there is no vaccine, a high proportion will not get it.*
- *Of those who do, a significant proportion (exact number not yet clear) have no symptoms.*
- *Of the symptomatic cases, the great majority (around 80%) a mild moderate disease.*
- *A minority have to go to hospital, most need only oxygen. The great majority of these survive.*
- *A minority of those need ventilation.*
- *A minority of every age group sadly die with current treatment, but even of the oldest group most do not.*

Data so far suggest the following:

[3] https://www.youtube.com/watch?v=3BdPKpWbxTg Presentation on Covid-19 at Gresham College, City of London (12 min mark)

- 4 in 5 have no or mild moderate symptoms
- 1 in 5 have severe symptoms
- 1 in 100 require hospital treatment
- 1 in 750 intensive care

Global studies have estimated an overall Infection Fatality Rate (IFR) of 0.15% to 0.20%[4] - in other words, for every 1,000 people that have it (or are said to be infected), 2 will die.

The IFR for below 70 years of age is 0.03% to 0.04% - for every 10,000 people that have it, 3 to 4 will die

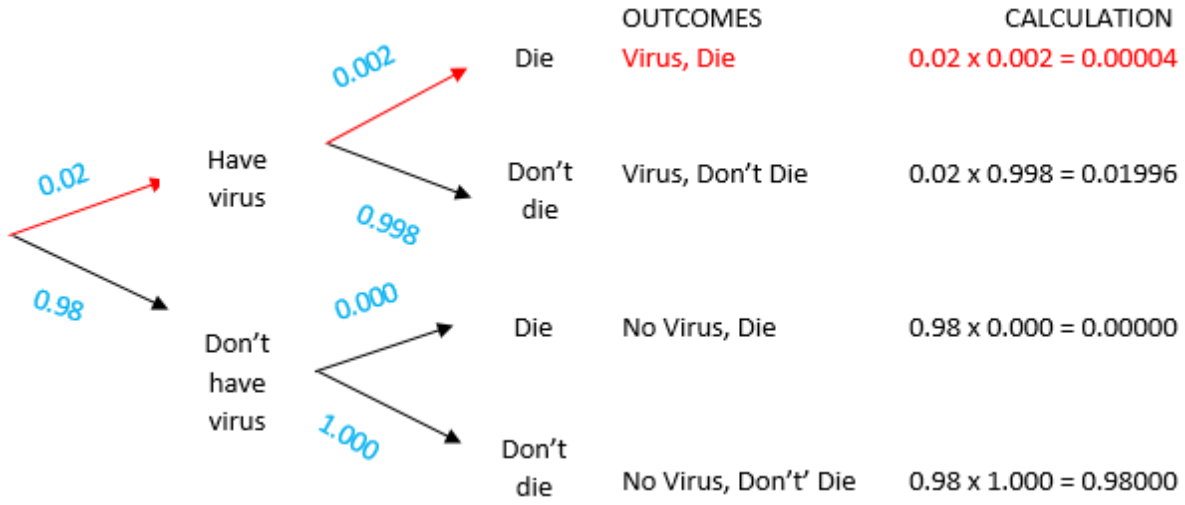
About 95% of fatalities will have had serious underlying health conditions. The average age of deaths is 82 - above average life expectancy - and deaths follow normal mortality profiles.

Risk of dying with Covid-19 – some basic maths

In England for the week ending 6 March 2021, it was estimated[5] that 200,600 people within the community population had Covid-19, equating to around 1 in 270 people or 0.37%. The highest estimate to date was for the week ending 2 January 2021 where it was estimated 1,122,000 people had Covid-19, equating to around 1 in 50 people or 2.06%.

Let's assume that 2% of the population currently has the virus and that the overall infection fatality rate is 0.2% across the whole population. We can use probability to estimate the risk of someone randomly picked from the population dying with Covid-19. The probability tree below exemplifies this.

The probabilities in blue font are in decimals and can be converted to % by multiplying by 100.



[4] Global perspective of COVID-19 epidemiology for a full-cycle pandemic, John P. A. Ioannidis https://onlinelibrary.wiley.com/doi/10.1111/eci.13423

[5] https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/coronaviruscovid19infectionsurveypilot/12march2021

The risk of someone randomly picked from the population dying with Covid-19 is 0.00004 or 0.004%. Now, compare this to morbidity and mortality risks associated with cancer, cardiovascular disease, diabetes and so on which are far higher.

Dr. Anthony Fauci, U.S. Director of National Institute of Allergies and Infectious Disease said in a briefing delivered on January 28, 2020[6] ''*Even if there is some asymptomatic transmission,* ***in all the history of respiratory-borne viruses of any type, asymptomatic transmission has NEVER been the driver of outbreaks****. The driver of outbreaks is always a symptomatic person. Even if there is a rare asymptomatic person who might transmit, an epidemic is not driven by asymptomatic carriers''.*

Benefits

Cases and Symptoms

In any medical research study, the **definition and accurate measurement of cases is important.**

According to the Pfizer and BioNTech study**, there was a 0.88% percent absolute risk reduction of disease** in the vaccine group.

So we can say that the benefit of the vaccine is that the **following symptoms are reduced**.

- fever
- new or increased cough
- new or increased shortness of breath
- chills
- new or increased muscle pain
- new loss of taste or smell
- sore throat
- diarrhoea
- vomiting

CAUTION – Covid-19 has NO UNIQUE SYMPTOMS of its own. The defined list of symptoms in the phase 3 study, now being described as ''Covid-19'', exist among the population generally and follow the spectrum of natural disease. No detailed examination was undertaken to discount other possible causes of these symptoms in the study.

The trials only compared the vaccine group to a placebo group (basically a do-nothing comparator). The outcomes and efficacy might have been very different if compared with other treatments. Many medical professionals across the world have used treatments that they say have proved extremely effective in reducing symptoms, when used at the right time and at the correct dosage, and have informed various regulatory and health committees about them – this includes the use of substances that have been proven to be safe for decades - in the pregnant, elderly and very young - and are also very cheap in comparison to a new vaccine. Such treatments include use of Vitamin C, Vitamin D, Zinc, Ivermectin, Clarithromycin, Hydroxychloroquine, Azythromycin and Doxicycline.

The point being that the benefit of a treatment can be greatly overstated when it is compared with a weak alternative or a do nothing option.

Nucleic acid amplification test or PCR

[6] https://www.youtube.com/watch?v=w6koHkBCoNQ&t=2642s

Another issue that needs to be highlighted is that the nucleic acid amplification test (or PCR test) used across the world and in the phase 3 study to confirm cases of Covid-19 **IS NOT**:

- a test for a particular disease, such as Covid-19;
- a test to determine the cause of any symptoms you may be having; or
- a test to determine if you are infectious.

PCR tests simply test for the presence of specific pieces of genetic material in a sample. They don't test for the presence of the whole genome of a virus, such as SARS-COV-2 which is claimed to be some 30,000 base pairs long and the cause of Covid-19.

The FDA states: "**Positive results are indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease**." And also: "**Detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms**." And also: "**This test cannot rule out diseases caused by other bacterial or viral pathogens**." Refer to the paper for many more statements of a similar nature. This shows that even the tests used in investigative procedures are not reliable and hence all claims made with respect to the virus, infection and disease amount to pure speculation.[7]

The virus that is said to cause Covid-19 has NOT been purified and isolated in the proper sense of these words, a crucial requirement. Instead what virologists have done is found small fragments of ribonucleic acid (RNA) of around 40 base pairs from **unpurified** samples. They then took these short segments and filled in the rest of the genetic code using a computer programme, proving an *in silico* (in the computer) sequence. Not one institution has confirmed possession of a **whole intact purified and isolated virus anywhere in the world**. This amounts to scientific fraud.

Infectiousness under the germ theory of disease

Conventional medical assumptions under the germ theory of disease about 'infectiousness' were not tested in the phase 3 study and answers to the following lines of enquiry could not be provided:

- Whether a vaccinated person can infect someone else;
- Whether a vaccinated person can be infected by someone else;
- Whether a vaccinated person obtains long term immunity from getting the disease or from ever being infected again.

Furthermore, the following crucial questions were not answered:

- Whether vaccination reduced hospitalisations;
- Whether vaccination reduced deaths.

Disappointingly, the study was not even designed to answer all or some of these questions, which are really important to know if a treatment is planned for mass roll-out across populations.

[7] https://www.fda.gov/media/134922/download pages 3, 41, 74, 79.

Most of the people reported to have died with Covid-19 were the elderly. This subset of the population comprised a very low proportion of the 43,000 participants in the phase 3 study (the over 75 age group were just 4% of the participants in the study). Ethical and health reasons could explain this.

Of the 170 confirmed Covid-19 cases reported in the phase 3 study, **it is not known just how many people in each group were actually tested**. If a higher proportion of people in the placebo group were tested, this could be one explanation for the higher reported case numbers in that group.

Risks

Reactions data was derived from participants that were followed up for at least 2 months after dose 2 of the vaccine or placebo. Reactions are summarised below, which also shows the increased risk of each event in the vaccine group compared to the placebo group.

Systemic events:

Fever	14-fold increase
Fatigue	2-fold increase
Headache	2-fold increase
Chills	5-fold increase
Vomiting	similar risk
Diarrhoea	similar risk
New or worsened muscle pain	3-fold increase
New or worsened joint pain	3-fold increase
Any systemic event	similar risk
Use of medication	2-fold increase

Local reactions:

Redness	5-fold increase
Swelling	10-fold increase
Pain at the injection site	5-fold increase
Any local reaction	5-fold increase

Adverse reactions:

Any event	2-fold increase
Blood / lymphatic disorders	4-fold increase
Gastrointestinal disorders	2-fold increase
General disorders	5-fold increase
Investigations	4-fold increase
Musculoskeletal/ tissue disorders	4-fold increase
Nervous system disorders	3-fold increase
Skin/ subcutaneous tissue disorders	2-fold increase

Systemic events highlighted in red are also symptoms said to be associated with Covid-19. Receiving the vaccine is associated with a higher risk of getting symptoms which it is supposed to protect against.

We earlier identified that 114 people needed to be treated to prevent 1 case of Covid-19. These 114 people will be exposed to adverse events from the vaccine but derive no benefit.

The US regulatory body[8] FDA in its consideration of the vaccine for emergency use authorisation makes mention of suspected cases of Covid-19 that were not PCR confirmed and not recorded as adverse events unless meeting various criteria for seriousness. ''*Among 3410 total cases of suspected but unconfirmed COVID-19 in the overall study population, 1594 occurred in the vaccine group vs. 1816 in the placebo group. Suspected COVID-19 cases that occurred within 7 days after any vaccination were 409 in the vaccine group vs. 287 in the placebo group*.'' **It would appear that there has been some subjectivity and judgement used in the trial which could have had some bearing on reported case numbers and study outcomes. It is unclear if suspected cases were tested or not.**

[8] https://www.fda.gov/media/144245/download page 42

If a proportion of these suspected cases were tested and cases were instead confirmed, then vaccine efficacy would be greatly reduced.

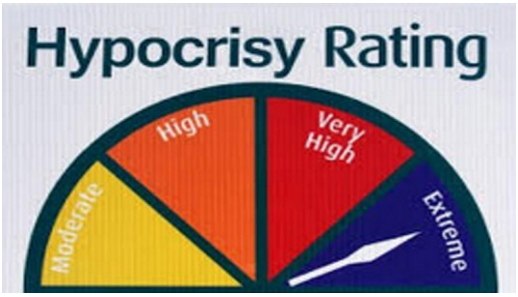
The phase 3 study identifies as Vaccine Associated Enhanced Disease (VAED) as an **important potential risk**. VAED occurs when a more severe presentation of disease develops in an individual who has previously been vaccinated, compared with when an infection occurs without prior vaccination. VAED has previously been associated with dengue fever infection; RSV, MERS and SARS-CoV-1 vaccine candidates; as well as a measles virus.[9] The phase 3 study states that this is a ''theoretical risk …and will be further investigated as part of the pharmacovigilance plan of this vaccine.''

Long-term impacts of the vaccine are not known. There could be a danger that after receiving a vaccine, the recipient might be more susceptible to illness in future.

Pfizer announced their trial results in press releases and there has been no scientific peer review for a vaccine candidate approved for mass rollout across the population. In the FDA briefing document on page 8, it is referred to as an 'investigational Covid-19 vaccine'. It is a new type of vaccine in humans which is like installing software (genetic material known as mRNA) to give instructions to the body.

Many false claims are being made that the roll-out of the vaccine is resulting in a drop in case numbers. This is unproven. On the contrary there have been reports of increased deaths of people, particularly the elderly following vaccination, which should require further investigation. In response to these reports the MHRA has said most of these reports were for ''**older people or people with underlying illness**, and a review of individual reports and patterns of reporting **did not indicate that the vaccine played a role in the death.''**

It appears that different standards are being used – a very loose definition of Covid-19 deaths attributed to a virus and for which the vast majority of deaths have been in older people and those with underlying conditions, yet when people have died shortly after a receiving a vaccine, and it is implicated, a dismissal and demand is made for more evidence of causal links.



Die within 28 days (or more) of a positive test:
''it's definitely, Covid … and you are a conspiracy theorist if you don't accept this''

Die within days of having the vaccine:
''just a coincidence – they were older people with underlying issues and would have died anyway''

Covid-19 deaths include people who died within 28 days (or more) of having a positive test FOR ANY REASON. This definition means that people who die from a car accident and who also happened to have a positive test result will be recorded as a Covid-19 death.

No scientific proof has demonstrated a **direct causal link** of the SARS-COV 2 virus to the symptoms attributed to the disease Covid-19. This is because a positive PCR test is not proof of causality and

[9] https://mvec.mcri.edu.au/references/vaccine-associated-enhanced-disease-vaed/

cannot discount other bacterial and viral causes. **Many people have tested positive for PCR – which simply indicates the presence of tiny fragments of genetic material in the body – but they have not displayed any of the symptoms which are being described as Covid-19**.

The presence of specific material in the body does not mean it is the cause of any symptoms you may be having. There are said to be trillions of viruses in the human body; if we tested for the presence of other viruses associated with the same broad symptoms through PCR, we would get positive test results for those viruses too – so would we also implicate them as being responsible for the broad symptoms described as ''Covid-19''?

Regulatory bodies

A report of the Independent Medicines and Medical Devices Safety Review was published on 8 July 2020 called **First Do no Harm**[10]. The review was led by Baroness Julia Cumberlege and its purpose was to examine how the healthcare system in England responds to reports about harmful side effects from medicines and medical devices and to consider how to respond to them more quickly and effectively in the future.

In a Letter to the Secretary of State from Baroness Cumberlege, she states ''We have found that the healthcare system – in which I include the NHS, private providers, the regulators and professional bodies, pharmaceutical and device manufacturers, and policymakers – is disjointed, siloed, unresponsive and defensive. It does not adequately recognise that patients are its raison d'etre**. It has failed to listen to their concerns** and when, belatedly, it has decided to act it has too often moved glacially. Indeed, over these two years we have found ourselves in the position of recommending, encouraging and urging the system to take action that should have been taken long ago''.

The Review heard concerns about the potential conflicts that arise as part of the financial links between drugs and medical device companies and consultants, hospitals or other organisations. The reported pointed at that this was not a new concern and that a paper by the Institute of Medicine in 2009 raised significant risks that individual and institutional conflicts of interests were unduly influencing professional judgements, and that such conflicts **'threaten the integrity of scientific investigations, the objectivity of medical education, the quality of patient care' and may also 'jeopardize public trust in medicine'.**

In a piece of written evidence to the Review, one respondent states 'MHRA has been too close to the industry… underpinned by common policy objectives, agreed processes, frequent contact, consultation and interchange of staff**…[we] have little faith in the ability of medical institutions that are responsible for patient safety to be open and transparent over patient safety failings.**'

The Review report made a specific recommendation in respect of the MHRA as follows:

Recommendation 6: The Medicines and Healthcare products Regulatory Agency (MHRA) needs substantial revision particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work.

[10] https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

The UK Parliament undertook a detailed review of pharmaceutical influence[11] raising huge concerns about the influence of the industry and highlightinf failings about the effectiveness of regulatory bodies such as the MHRA to protect the public. It would appear that some of the concerns raised have not been addressed.

Medical professionals across the world have used existing drugs and substances to successfully treat people with the broad symptoms described as Covid-19. Astonishingly, many regulatory bodies banned the use of such treatments. Had such treatments been used more widely, then authorisation for a new vaccine on an emergency use basis would be unlikely to be granted to pharmaceutical companies. The question that can be asked is whose interests are being served by the regulatory bodies – the public or pharmaceutical sector? For example, who determined that a vaccine is the only way out of this declared health crisis?

Vaccine damages and liability

The vaccine has been authorised on a temporary basis by the MHRA under regulation 174 of the Human Medicine regulations which allows an unlicensed medicine to be used in an emergency.

Vaccine manufacturers such as Pfizer have been granted civil immunity and are protected from being sued by recipients in the event of any complications.

In the UK, the national Vaccine Damages Payment Scheme (VDMS) can make payments up to a sum of £120,000 if individuals can prove they have been severely disabled as a result of a vaccine. The acceptance rate for such payments has been just 1.7% over the last ten years. Applicants must demonstrate a minimum disablement of 60% and a **direct causal link** to the vaccine.

The scheme has come under great criticism and legal experts have explained that claimants would be potentially entitled to millions if they won a civil trial against a vaccine manufacturer.

The pharmaceutical industry generated revenues of $1.25 trillion in 2019 and this is expected to grow over the coming years. They have paid over billions in damages and fines for a range of malpractices. Fraudulent and illegal conduct by this sector poses a great risk to public health. The payment huge fines and damages by some companies in this industry is just treated like a normal business ‘expense’.

It appears that much effort has been made to ensure governments, health professionals and companies are protected from claims of vaccine damages – while protections for people who might suffer vaccine damage are being reduced. If these vaccines are so safe, why is everyone ducking responsibility to pay compensation and damages to anyone harmed by them. If those people strongly advocating others to take the vaccine were prepared to take **personal liability** for any harms caused and to pay damages, perhaps they would not be so enthusiastic in encouraging take-up.

Figures released by the National Audit Office show that the UK has spent a total of £12bn on its vaccination campaign so far, with further funds to be allocated in future. It states ‘’The total cost to the taxpayer of government’s efforts to purchase and deploy vaccines is uncertain. The current estimate is up to £11.7 billion which includes the costs of purchasing and manufacturing vaccines for the UK, deploying them in England and investing in global efforts to purchase vaccines.’’[12]

[11] https://publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf House of Commons, The Influence of the Pharmaceutical Industry

[12] https://www.nao.org.uk/press-release/investigation-into-preparations-for-potential-covid-19-vaccines/

Informed consent

Claims about the effectiveness of vaccines in terms of relative risk should be given alongside information such as the actual absolute risk to allow a more informed understanding of the risks and benefits when individuals are deciding whether to take a treatment or not.

Coercing people into taking a vaccine is not informed consent. It is important that the public is presented with a balanced and unbiased presentation of facts to enable informed decisions to be made about whether to take any form of treatment or vaccine.[13] Taking peoples freedoms and rights away and only giving them back in return for taking a vaccine does not constitute free consent.[14]

Confidence and trust can only be achieved by being open and transparent. Health and regulatory bodies must demonstrate that the interest of the public is their foremost concern and that stringent due diligence has been undertaken in approving any medical treatment which must be proven to be absolutely necessary and appropriate to the health risks posed.

A Rafiq
March 2021

[13] https://www.nhs.uk/conditions/consent-to-treatment/

[14] https://pace.coe.int/en/files/29004/html Covid-19 vaccines: ethical, legal and practical considerations, section 7.3.1 and 7.3.2

Appendix 1: Pfizer and BionTech Covid-19 Study

- Phase 3 study enrolled 43,651 participants allocated evenly into a vaccine group, 21,823 and a placebo group 21,826.

- The primary aim of the study was to determine whether the vaccine reduces the risks of a person getting symptoms said to be associated with Covid-19.

- Study participants were subjects 12 years of age or older (with at least 40% more than 55 years of age); healthy or with pre-existing stable disease; at higher risk of acquiring COVID-19 (e.g. use of mass transportation, relevant demographics, frontline essential workers). The main causes for exclusion were a previous clinical or microbiological diagnosis of COVID-19, a known or suspected immunodeficiency, therapy with immunosuppressants, pregnancy or breastfeeding.

- Subjects with a history of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g. anaphylaxis) to any component of the study intervention(s) were also excluded from the study

- Participants received 2 doses of either mRNA vaccine BNT162b2 or placebo, 21 days apart.

- Overall, the phase 3 evaluable efficacy population included 49% females; 82% White, 10% African American, 4% Asian participants, and less than 3% from other racial groups; 26% of participants were Hispanic/Latino.

- Geographically, 77% of participants were from the US, 15% from Argentina, 6% from Brazil, and 2% from South Africa. The studies were conducted across 150 clinical sites.

- 21% of participants were 65 years of age or over; 4% were 75 years of age or over.

- The date for data cut-off for the final efficacy analysis was November 14, 2020, by which time a total of 170 confirmed COVID-19 cases were accrued. 8 in the vaccine group and 162 in the placebo group.

- Among 3,410 total cases of suspected but unconfirmed COVID-19 in the overall study population, 1,594 occurred in the vaccine group vs. 1,816 in the placebo group. Suspected COVID-19 cases that occurred within 7 days after any vaccination were 409 in the vaccine group vs. 287 in the placebo group.

- More than 19,000 had been followed up for at least 2 months after Dose 2 of BNT162b2 or placebo.

- As the interim and final analyses have a limited length of follow-up, it was not possible to assess sustained efficacy over a period longer than 2 months.

- Authorisation for the temporary supply of BNT162b2 was granted in the UK on 1 December 2020 by the MHRA on the grounds of an emergency.

Appendix 2: Adverse Events

Data obtained from MHRA Public Assessment Report Table 9 and Table 11

Vaccine Reactions	Vaccine		Placebo			
	Number studied 4108 (a)	Absolute Risk% % (b)	Number studied 4106 (c)	Absolute Risk% % (d)	Relative Risk % (b) / (d)	Relative to Placebo, Vaccine is associated with:
local reactions						
redness	389	9.5%	64	1.6%	594%	a 5.9-fold increase in risk
swelling	430	10.5%	42	1.0%	1050%	a 10.5-fold increase in risk
pain at the injection site	3455	84.1%	700	17.0%	495%	a 5-fold increase in risk
any local reaction	3481	84.7%	748	18.2%	465%	a 4.7-fold increase in risk
systemic actions						
fever	582	14.2%	38	0.9%	1578%	a 15.8-fold increase in risk
fatigue	2585	62.9%	1461	35.6%	177%	a 1.8-fold increase in risk
headache	2265	55.1%	1402	34.1%	162%	a 1.6-fold increase in risk
chills	1312	31.9%	289	7.0%	456%	a 4.6-fold increase in risk
vomiting	84	2.0%	62	1.5%	133%	a 1.3-fold increase in risk
diarrhoea	644	15.7%	576	14.0%	112%	a 1.1-fold increase in risk
new or worsened muscle pain	1573	38.3%	549	13.4%	286%	a 2.9-fold increase in risk
new or worsened joint pain	968	23.6%	360	8.8%	268%	a 2.7-fold increase in risk
any systemic event	**3181**	**77.4%**	**2255**	**54.9%**	141%	a 1.4-fold increase in risk
use of antipyretic or pain medication	1909	46.5%	810	19.7%	236%	a 2.4-fold increase in risk

Data obtained from MHRA Public Assessment Report Table 13

Adverse events	Vaccine		Placebo			
	Number studied 21621 (a)	Absolute Risk% % (b)	Number studied 21631 (c)	Absolute Risk% % (d)	Relative Risk % (b) / (d)	Relative to Placebo, Vaccine is associated with:
Any event	5770	26.7%	2638	12.2%	219%	a 2.2-fold increase in risk
Blood and lymphatic system disorders	90	0.4%	17	0.1%	400%	a 4-fold increase in risk
Cardiac disorders	52	0.2%	44	0.2%	100%	a similar risk
Congenital, familial and genetic disorders	2	0.0%	0	0.0%		
Ear and labyrinth disorders	61	0.3%	41	0.2%	150%	a 1.5-fold increase in risk
Endocrine disorders	12	0.1%	4	0.0%		
Eye disorders	54	0.2%	44	0.2%	100%	a similar risk
Gastrointestinal disorders	617	2.9%	403	1.9%	153%	a 1.5-fold increase in risk
General disorders/ site conditions	4007	18.5%	829	3.8%	487%	a 4.9-fold increase in risk
Hepatobiliary disorders	14	0.1%	5	0.0%		
Immune system disorders	26	0.1%	22	0.1%	100%	a similar risk
Infections and infestations	322	1.5%	320	1.5%	100%	a similar risk
Injury, poisoning and procedural complications	184	0.9%	220	1.0%	90%	a 0.9-fold increase in risk
Investigations	145	0.7%	40	0.2%	350%	a 3.5-fold increase in risk
Metabolism and nutrition disorders	86	0.4%	61	0.3%	133%	a 1.3-fold increase in risk
Musculoskeletal / connective tissue disorders	1511	7.0%	435	2.0%	350%	a 3.5-fold increase in risk
Neoplasms benign, malignant /unspecified	29	0.1%	31	0.1%	100%	a 1-fold increase in risk
Nervous system disorders	1277	5.9%	501	2.3%	257%	a 2.6-fold increase in risk
Pregnancy, puerperium ,perinatal conditions	0	0.0%	2	0.0%		
Product issues	1	0.0%	1	0.0%		
Psychiatric disorders	84	0.4%	58	0.3%	133%	a 1.3-fold increase in risk
Renal and urinary disorders	30	0.1%	24	0.1%	100%	a similar risk
Reproductive system and breast disorders	35	0.2%	36	0.2%	100%	a similar risk
Respiratory, thoracic and mediastinal disorders	187	0.9%	169	0.8%	113%	a 1.1-fold increase in risk
Skin and subcutaneous tissue disorders	196	0.9%	139	0.6%	150%	a 1.5-fold increase in risk
Social circumstances	3	0.0%	0	0.0%		
Surgical and medical procedures	29	0.1%	21	0.1%	100%	a similar risk
Uncoded term	38	0.2%	23	0.1%	200%	a 2-fold increase in risk
Vascular disorders	65	0.3%	69	0.3%	100%	a similar risk

In a mass roll out of vaccines across a population, people who derive no benefit from vaccines will be exposed to unnecessary risks. For example, if all of the UK population of 67 million received the vaccine, then 3.953 million people would be exposes to the risk of a nervous system disorder (67 million x absolute risk of 5.9% in vaccine group). This is an extra 2.412 million people when compared to the placebo group.