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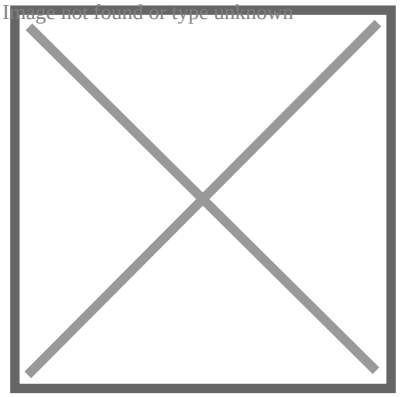


The Battle For Informed Consent

Description

UK : I first started researching vaccines for coronaviruses in spring and summer 2020 when it became obvious that lockdowns were not going to be “three weeks to flatten the curve”.

It became clear that it was intended that we should remain in lockdown until a vaccine was developed. I cannot convey how much that alarmed me. Everything that was happening at that time was in conflict with my core values and my response was visceral.

My first post on COVID-19, on March 20th 2020, reported that coronaviruses were first identified in the mid-1960s. We had thus known about coronaviruses for over 50 years. My research quickly revealed that we had developed no vaccines during that time.

This appeared to be because of something called antibody dependent enhancement, which showed up in animal testing. In brief, this meant that the animals developed antibodies following vaccination (which was good), but they then had a worse response than unvaccinated controls when exposed to the virus (which was bad).

Lockdown was announced in the U.K. on Monday March 23rd 2020. The U.K. Astra Zeneca COVID-19 vaccine trial was registered three days earlier on March 20th 2020. I didn’t know that at the time; it would have shocked me. The trial registration submitted full plans for 19 different arms or interventions.

These included the product to be injected (ChAdOx1 nCoV-19), the doses, the placebo (a meningitis vaccine), the timetable, the locations, the number of participants, inclusion and exclusion criteria etc. The speed at which products were moving from laboratories to arms was impressive to many and concerning to some (one could be both impressed and concerned).

I was aware that the Astra Zeneca (AZ) trial was already underway as early as spring 2020, as I knew one participant. When the first trial papers were published (December 2020), it was confirmed that recruitment for the AZ trial had started from April 23rd 2020 (Ref 3).

In October 2020, Dr. Peter Doshi’s important paper was published in the BMJ. This paper analysed seven vaccines in development and what they were designed to test. Doshi reported that none of the

vaccine trials were designed to test for either transmission or severity of outcome.

The two things that we most wanted to know – will vaccines stop spread and will they provide protection against bad outcomes – were not even being tested. The only outcome of interest was: did the trial participant test positive on a PCR test, which was a highly unreliable measure for, by itself, confirming active infection.

In December 2020, the outcome papers for the AZ and Pfizer trials were published in the Lancet and the NEJM respectively. I examined both here. Both vaccines were approved for use in the U.K. that month. Pfizer approval followed in more countries quickly. The AZ product was less readily adopted. On December 8th 2020 the first member of the public (as opposed to a trial volunteer) was given the Pfizer vaccine.

The trial protocols were disregarded from the outset. The December 2020 outcome paper for the AZ trial was a summary of four sub trials – two in the U.K. (COV001 and COV002), one in Brazil (COV003) and one in South Africa (COV005).

In COV001 alone there were four intervention groups and protocols (all versus the meningitis vaccine placebo): Group 1 single dose; Group 2 booster at eight weeks; Group 3 two doses 10 weeks apart; Group 4 single dose but with paracetamol.

The Pfizer protocol that was trialled was one jab followed by a second three weeks (21 days) later. The U.K. roll out started with a 12 week gap between the two injections. This was rationalised as ‘let’s give more people some protection’, but the 12 week protocol had never been tested before mass global rollout.

I didn’t give much thought to the injections over the winter of 2020-2021 as they weren’t intended for me. The message was 15 million jabs to freedom. The promise was that once the over-65s and younger people with comorbidities had been jabbed, we would all be released from house arrest. When that didn’t happen, my visceral fear reached a different level. The new message became “no one is safe until everyone is safe”.

But I knew that the injections didn’t stop someone getting Covid, they didn’t stop transmission of Covid and they didn’t reduce severity of outcome (the latter two not even having been tested). As 2021 progressed, the narrative became more and more sinister.

Soon pro-vaccine people who had had every vaccine throughout their lives were being called anti-vaxxer for having some doubts about this one. Soon after that, people were being refused entry to countries and venues and fired from jobs if they didn’t want this novel product.

Voluntary and informed consent

The U.K. National Health Service (NHS) principle of informed consent states:

> For consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision. The meaning of these terms are:
>
> - voluntary – the decision to either consent or not to consent to treatment must be

made by the person, and must not be influenced by pressure from medical staff, friends or family;
- informed – the person must be given all of the information about what the treatment involves, including the benefits and risks, whether there are reasonable alternative treatments, and what will happen if treatment does not go ahead;
- capacity – the person must be capable of giving consent, which means they understand the information given to them and can use it to make an informed decision."

Informed consent was abandoned during this period of medical history. Read those definitions of both "voluntary" and "informed" carefully. Regarding "voluntary", pressure was exerted from the Queen of England, the Prime Minister of New Zealand and the President of the U.S. and every world leader in between.

Medical staff, friends and family all exerted pressure, as did celebrities, neighbours, employers and social media 'influencers'. The denial of rights to travel, to enter venues and even to remain in employment were in stunning contravention of the voluntary aspect of informed consent.

Regarding "informed", the following is what happened when I tried to obtain information about the benefits and risks of the treatment.

My invitation

By spring 2021, Wales was rattling through the administration of injections. On March 11th, 2021, I received an invite from Aneurin Bevan University Health Board (ABUHB) to attend Cwmbran sports stadium to receive a Covid vaccine. I was given a date and time (March 24th 14.45pm). This was clever. A number of people I spoke to attended because they didn't want to miss an appointment and "let the NHS down" when the NHS was so busy.

I chose instead to write to the Chief Executive (Judith Paget CBE) and Chair (Ann Lloyd CBE) of Aneurin Bevan University Health Board as follows:

> Dear Ms Lloyd, Ms Paget (sent separately to each),
>
> Thank you for your kind invitation for me to receive a COVID-19 vaccine.
>
> Both the Pfizer BNT162b2 mRNA COVID-19 vaccine and the ChAdOx1 nCoV-19 Oxford/AstraZeneca vaccine are novel drugs. Both drugs have only been approved for emergency use. The trials are ongoing, with the Pfizer trial not due for completion until January 31st 2023 and the Oxford/AstraZeneca trial not due for completion until February 14th 2023.
>
> The NHS policy is "for consent to be valid, it must be voluntary and informed". Given the novelty, rapid development and incomplete trial history of these interventions, consent is vital. For my consent to be first informed, and second voluntary, please can you answer the following:

1) I have had COVID-19. Please can you explain why I need a vaccine for something to which I have immunity? In anticipation of an answer saying we don't know how long natural immunity will last a) how long does vaccine immunity last? and b) surely immunity to a virus is preferable to a message to try to replicate a spike protein?

2) The December 2020 publications reported 95% efficacy for BNT162b2 and 70% efficacy for ChAdOx1 nCoV-19. Please can you explain what efficacy means and the number of cases (positive PCR test and at least one symptom) that the 95% and 70% numbers were based on?

3) Please can you tell me (with sources) the Number Needed to Treat (NNT) and the Number Needed to Harm (NNH) for each vaccine?

4) Please can you tell me the safety profile for both vaccines after one, three and five years?

5) I understand that Antibody Dependent Enhancement (ADE) is a (or the) reason that we have had human coronaviruses for 55 years and no vaccine in that time. Please can you guarantee that ADE cannot happen with either of the vaccines you are offering me?

6) The vaccines try to introduce the SARS-CoV-2 spike protein into our body. Recent peer-reviewed literature reports that the SARS-CoV-2 spike protein "may affect the cells of systemic and coronary vasculatures, eliciting other cardiovascular diseases such as coronary artery disease, systemic hypertension and stroke". Please can you guarantee that this cannot and will not happen?

7) Given that the vaccine manufacturers have indemnity from providing compensation if something goes wrong, please can you confirm that I can sue the board and individual members directly, with unlimited liability, if I am harmed in any way?

I am one of the rare 1% of people who follow all five healthy behaviours associated with reduced mortality. I don't smoke. I don't drink alcohol. I exercise daily. I have maintained a BMI of 20 for many years. I eat an optimally nutritious diet. My health is of utmost importance to me. I will not risk the huge effort I dedicate to my health without fully understanding what risk I am taking. Especially when I can discern no benefit whatsoever in me taking that unknown risk.

Thank you

Yours sincerely,
Dr. Zoë Harcombe

The questions were a mix of ones to which I knew the answer, but I wanted to know if the Health Board did, and ones to which there was no answer and I wanted to know if the Health Board would admit this. Please note that I was questioning the cardiovascular impact of the Covid products as early as March 2021.

Cardiac issues are now acknowledged but dismissed as rare or mild (there is no such thing as mild myocarditis). Many people claim that we know more now than we did then. We do; but we knew

enough then. The concerns about mRNA technology were there from the outset.

My follow-up

On April 6th 2021, I needed to chase for a reply. I re-sent the two letters with a handwritten note at the top saying “Dear Ms Lloyd, Ms Paget (sent separately), I am being chased for my vaccine, so I need to chase you for my reply please. Thank you. Zoë.” I also submitted a Freedom of Information request (FOI) to the health board in parallel.

The first Health Board reply

On April 7th 2021, I received an email from ABUHB corporate services acknowledging receipt of the FOI request. I have no concerns about sharing this exchange, since FOI requests, by definition, are supposed to be freely available:

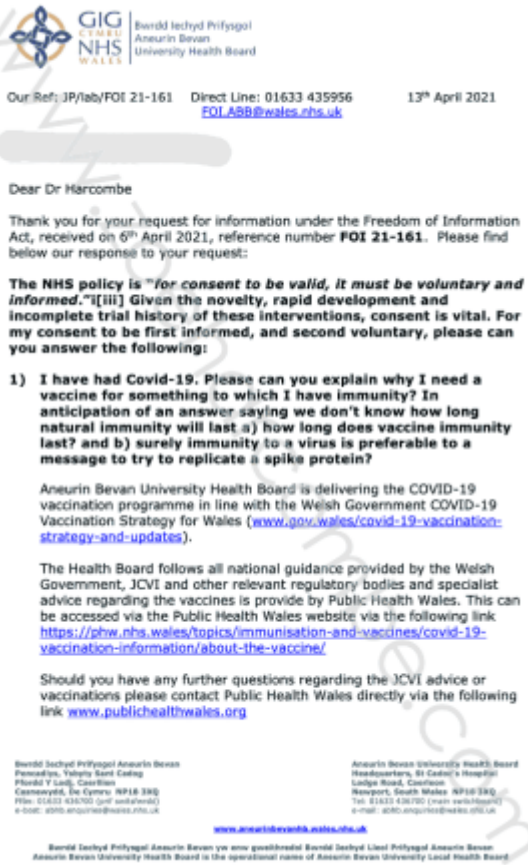
> Dear Dr. Harcombe
>
> Thank you for your request for information under the Freedom of Information Act received on April 6th 2021. We have allocated it the following reference number FOI 21-161 and will be in contact again shortly. We aim to respond to all Freedom of Information requests within 20 working days from the date of receipt.

The full Health Board reply

On 14th April 2021 I received an email with the response to the FOI request:

> Dear Dr. Harcombe
>
> Thank you for your request for information under the Freedom of Information Act, received on 6th April 2021.
>
> Please find attached the Health Board’s response to this request.

The attachment was as follows:



GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Aneurin Bevan University Health Board

Our Ref: JP/lab/FOI 21-161 Direct Line: 01633 435956 13th April 2021
FOI.ABB@wales.nhs.uk

Dear Dr Harcombe

Thank you for your request for information under the Freedom of Information Act, received on 6th April 2021, reference number **FOI 21-161**. Please find below our response to your request:

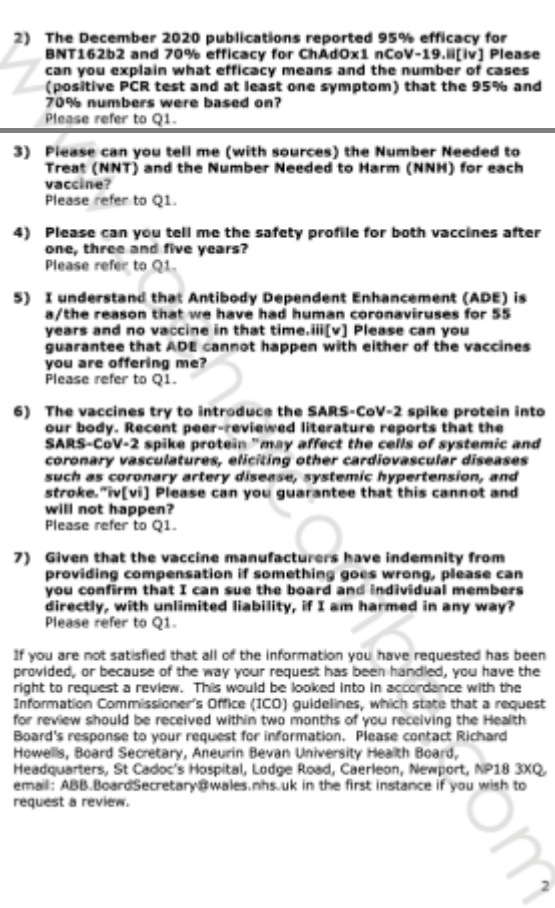
The NHS policy is "*for consent to be valid, it must be voluntary and informed*."i[iii] Given the novelty, rapid development and incomplete trial history of these interventions, consent is vital. For my consent to be first informed, and second voluntary, please can you answer the following:

1) **I have had Covid-19. Please can you explain why I need a vaccine for something to which I have immunity? In anticipation of an answer saying we don't know how long natural immunity will last a) how long does vaccine immunity last? and b) surely immunity to a virus is preferable to a message to try to replicate a spike protein?**

Aneurin Bevan University Health Board is delivering the COVID-19 vaccination programme in line with the Welsh Government COVID-19 Vaccination Strategy for Wales (www.gov.wales/covid-19-vaccination-strategy-and-updates).

The Health Board follows all national guidance provided by the Welsh Government, JCVI and other relevant regulatory bodies and specialist advice regarding the vaccines is provide by Public Health Wales. This can be accessed via the Public Health Wales website via the following link https://phw.nhs.wales/topics/immunisation-and-vaccines/covid-19-vaccination-information/about-the-vaccine/

Should you have any further questions regarding the JCVI advice or vaccinations please contact Public Health Wales directly via the following link www.publichealthwales.org



2) **The December 2020 publications reported 95% efficacy for BNT162b2 and 70% efficacy for ChAdOx1 nCoV-19.ii[iv] Please can you explain what efficacy means and the number of cases (positive PCR test and at least one symptom) that the 95% and 70% numbers were based on?**
Please refer to Q1.

3) **Please can you tell me (with sources) the Number Needed to Treat (NNT) and the Number Needed to Harm (NNH) for each vaccine?**
Please refer to Q1.

4) **Please can you tell me the safety profile for both vaccines after one, three and five years?**
Please refer to Q1.

5) **I understand that Antibody Dependent Enhancement (ADE) is a/the reason that we have had human coronaviruses for 55 years and no vaccine in that time.iii[v] Please can you guarantee that ADE cannot happen with either of the vaccines you are offering me?**
Please refer to Q1.

6) **The vaccines try to introduce the SARS-CoV-2 spike protein into our body. Recent peer-reviewed literature reports that the SARS-CoV-2 spike protein "*may affect the cells of systemic and coronary vasculatures, eliciting other cardiovascular diseases such as coronary artery disease, systemic hypertension, and stroke.*"iv[vi] Please can you guarantee that this cannot and will not happen?**
Please refer to Q1.

7) **Given that the vaccine manufacturers have indemnity from providing compensation if something goes wrong, please can you confirm that I can sue the board and individual members directly, with unlimited liability, if I am harmed in any way?**
Please refer to Q1.

If you are not satisfied that all of the information you have requested has been provided, or because of the way your request has been handled, you have the right to request a review. This would be looked into in accordance with the Information Commissioner's Office (ICO) guidelines, which state that a request for review should be received within two months of you receiving the Health Board's response to your request for information. Please contact Richard Howells, Board Secretary, Aneurin Bevan University Health Board, Headquarters, St Cadoc's Hospital, Lodge Road, Caerleon, Newport, NP18 3XQ, email: ABB.BoardSecretary@wales.nhs.uk in the first instance if you wish to request a review.

2

As you can see, the reply did not attempt to answer any of my questions. It said that ABUHB was delivering the Welsh Government strategy and following guidance from other public bodies. In essence, the ABUHB position was “Nothing to do with us”. The reply invited me to ask Public Health Wales if I had further questions. Further questions? I didn’t have answers to my opening questions.

Involving Public Health Wales

On April 19th 2021 I emailed Public Health Wales. The title of the email was “A request for a review of JP/lab/FOI 21-161.”

The email said:

> Dear Richard Howells, Board Secretary
>
> I would like to request a review of a recent FOI that I submitted.
>
> I was pleased with the speed of response, but not with the answers.

On March 16th, when I received an invitation for a COVID-19 vaccination, I sent the same letter to Judith Paget CBE, Chief Executive, and Ann Lloyd CBE, Chair. The letter asked seven questions, which I needed answering before I could accept the invitation. A copy is attached (the word file).

When I was chased for a jab, on April 6th I chased for replies. I submitted an FOI on April 6th in parallel. The FOI was the one responded to – although it wasn't. The FOI reply is also attached (PDF). None of my seven questions was answered. The only response given was that, in essence, "*Aneurin Bevan University Health Board is following Welsh government and Public Health Wales orders*".

That may be the case, but these questions need answering please. The clinical trials for these injections do not complete until 2023. The Pfizer trial completion date has slipped since my first (March 16th) letter. It is now April 6th 2023.

These are entirely reasonable questions to ask before taking part in a clinical trial with a novel drug with novel technology and known issues. Arguably you should not be vaccinating tens of thousands of people in ABUHB alone (two-three million across Wales) without knowing the answers to these questions.

If anything does go wrong (see Swine Flu), "*following orders*" would not be a defence.

I look forward to hearing from you.

Thank you.
Yours sincerely – Zoë

The attached letter said:

Dear Public Health Wales,

Following an invitation for a COVID-19 vaccination, I asked the following questions of my Health Board – Aneurin Bevan University Health Board. They have not answered them, but instead replied that "*The Health Board follows all national guidance provided by the Welsh Government, JCVI.*

And other relevant regulatory bodies and specialist advice regarding the vaccines is provide by Public Health Wales… Should you have any further questions regarding the JCVI advice or vaccinations please contact Public Health Wales directly."

And so I am. Please can you answer the following questions.
(The rest of the letter reiterated the seven questions).

Thank you.

Yours faithfully
Dr. Zoë Harcombe, PhD

The reply from Public Health Wales

I had to chase this too. The first response from Public Health Wales was an auto reply saying (paraphrased) "Is your request really necessary? We're dealing with a pandemic."

On April 25th 2021 I replied (verbatim) "I would like my FOI to be answered please. It is core to current issues and so cannot wait until the current issues are over."

On May 11th 2021 I received an email reply from Public Health Wales with an attached letter. The letter is copied below.

Freedom of Information request to Public Health Wales	
FOI Reference:	**FOI 730**
Date request received	**25 April 2021**
Date information is due to be sent	**24 May 2021**

Information Requested:

1) I have had Covid-19. Please can you explain why I need a vaccine for something to which I have immunity? In anticipation of an answer saying we don't know how long natural immunity will last a) how long does vaccine immunity last? and b) surely immunity to a virus is preferable to a message to try to replicate a spike protein?

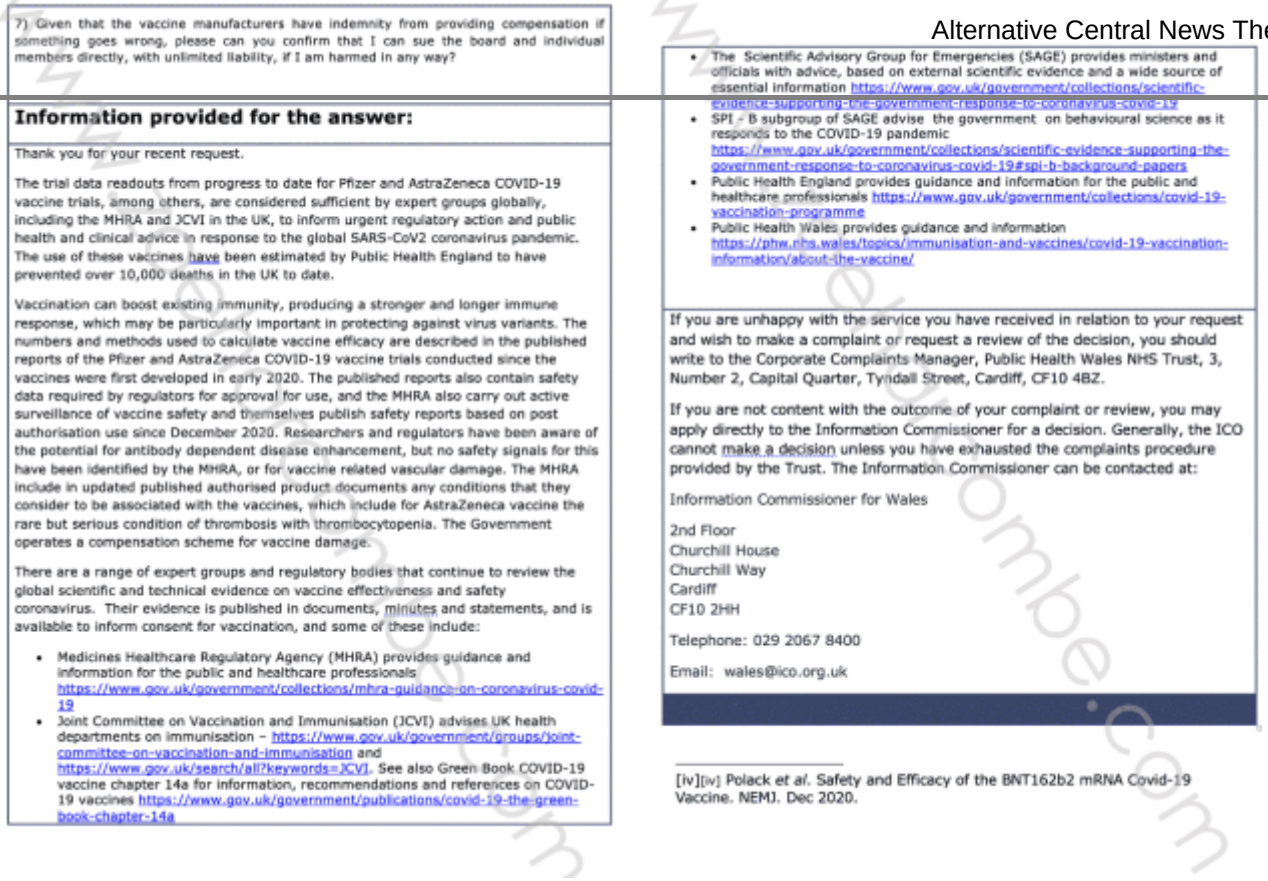
2) The December 2020 publications reported 95% efficacy for BNT162b2 and 70% efficacy for ChAdOx1 nCoV-19.[iv][iv] Please can you explain what efficacy means and the number of cases (positive PCR test and at least one symptom) that the 95% and 70% numbers were based on?

3) Please can you tell me (with sources) the Number Needed to Treat (NNT) and the Number Needed to Harm (NNH) for each vaccine?

4) Please can you tell me the safety profile for both vaccines after one, three and five years?

5) I understand that Antibody Dependent Enhancement (ADE) is a/the reason that we have had human coronaviruses for 55 years and no vaccine in that time.[v][v] Please can you guarantee that ADE cannot happen with either of the vaccines you are offering me?

6) The vaccines try to introduce the SARS-CoV-2 spike protein into our body. Recent peer-reviewed literature reports that the SARS-CoV-2 spike protein "*may affect the cells of systemic and coronary vasculatures, eliciting other cardiovascular diseases such as coronary artery disease, systemic hypertension, and stroke.*"[vi][vi] Please can you guarantee that this cannot and will not happen?



7) Given that the vaccine manufacturers have indemnity from providing compensation if something goes wrong, please can you confirm that I can sue the board and individual members directly, with unlimited liability, if I am harmed in any way?

Information provided for the answer:

Thank you for your recent request.

The trial data readouts from progress to date for Pfizer and AstraZeneca COVID-19 vaccine trials, among others, are considered sufficient by expert groups globally, including the MHRA and JCVI in the UK, to inform urgent regulatory action and public health and clinical advice in response to the global SARS-CoV2 coronavirus pandemic. The use of these vaccines have been estimated by Public Health England to have prevented over 10,000 deaths in the UK to date.

Vaccination can boost existing immunity, producing a stronger and longer immune response, which may be particularly important in protecting against virus variants. The numbers and methods used to calculate vaccine efficacy are described in the published reports of the Pfizer and AstraZeneca COVID-19 vaccine trials conducted since the vaccines were first developed in early 2020. The published reports also contain safety data required by regulators for approval for use, and the MHRA also carry out active surveillance of vaccine safety and themselves publish safety reports based on post authorisation use since December 2020. Researchers and regulators have been aware of the potential for antibody dependent disease enhancement, but no safety signals for this have been identified by the MHRA, or for vaccine related vascular damage. The MHRA include in updated published authorised product documents any conditions that they consider to be associated with the vaccines, which include for AstraZeneca vaccine the rare but serious condition of thrombosis with thrombocytopenia. The Government operates a compensation scheme for vaccine damage.

There are a range of expert groups and regulatory bodies that continue to review the global scientific and technical evidence on vaccine effectiveness and safety coronavirus. Their evidence is published in documents, minutes and statements, and is available to inform consent for vaccination, and some of these include:

- Medicines Healthcare Regulatory Agency (MHRA) provides guidance and information for the public and healthcare professionals https://www.gov.uk/government/collections/mhra-guidance-on-coronavirus-covid-19
- Joint Committee on Vaccination and Immunisation (JCVI) advises UK health departments on immunisation – https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation and https://www.gov.uk/search/all?keywords=JCVI. See also Green Book COVID-19 vaccine chapter 14a for information, recommendations and references on COVID-19 vaccines https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a
- The Scientific Advisory Group for Emergencies (SAGE) provides ministers and officials with advice, based on external scientific evidence and a wide source of essential information https://www.gov.uk/government/collections/scientific-evidence-supporting-the-government-response-to-coronavirus-covid-19
- SPI - B subgroup of SAGE advise the government on behavioural science as it responds to the COVID-19 pandemic https://www.gov.uk/government/collections/scientific-evidence-supporting-the-government-response-to-coronavirus-covid-19#spi-b-background-papers
- Public Health England provides guidance and information for the public and healthcare professionals https://www.gov.uk/government/collections/covid-19-vaccination-programme
- Public Health Wales provides guidance and information https://phw.nhs.wales/topics/immunisation-and-vaccines/covid-19-vaccination-information/about-the-vaccine/

If you are unhappy with the service you have received in relation to your request and wish to make a complaint or request a review of the decision, you should write to the Corporate Complaints Manager, Public Health Wales NHS Trust, 3, Number 2, Capital Quarter, Tyndall Street, Cardiff, CF10 4BZ.

If you are not content with the outcome of your complaint or review, you may apply directly to the Information Commissioner for a decision. Generally, the ICO cannot make a decision unless you have exhausted the complaints procedure provided by the Trust. The Information Commissioner can be contacted at:

Information Commissioner for Wales

2nd Floor
Churchill House
Churchill Way
Cardiff
CF10 2HH

Telephone: 029 2067 8400

Email: wales@ico.org.uk

[iv][iv] Polack *et al*. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. NEMJ. Dec 2020.

Again, none of my questions were answered. Again authority was deferred to. I had reached the end of the road to try to obtain the informed bit of informed consent, so I left it there.

I had asked reasonable and important questions and they had not been answered. I could not therefore give voluntary and informed consent to a novel intervention. What happened thereafter will forever horrify me.

Postscript

I happened to come across Judith Paget again in October 2023. Former Office for National Statistics (ONS) statistician James Freeman tweeted a letter that had been sent to him. The letter was from Paget, and it was to all Chief Executives of all NHS Wales organisations. You can see the letter in the tweet.

It was demanding to know what interventions would be made to overcome NHS staff “reluctance” to have more COVID-19 vaccines. This would be at least the fifth jab, if staff had accepted all invitations until then. I suspect, at the time of this demand, Paget still did not know the answers to my questions.

BY Dr. Zoë Harcombe

Category

1. Big Pharma Terror-Pandemic-Lockdowns
2. Crime-Justice-Terrorism-Corruption

3. Disasters-Crisis-Depopulation-Genocide
4. Main
5. NWO-Deep State-Dictatorship-Tyrrany

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