Dear colleague,

These are very special times for our profession. As doctors, we face a very important decision. Vaccination has recently started in Belgium with the new experimental Pfizer - BioNTech mRNA vaccine, which has gone through a fast-track procedure and has been on the market for less than a year. Meanwhile, the Moderna mRNA vaccine has also been approved **conditionally** by the EMA. These vaccines are presented by the government and our experts as highly effective and safe. As soon as the supply allows, they would like to vaccinate 70-80% of the population.

The primary questions that we as medical doctors need to ask in advance are:

- Has the safety of the covid-19 vaccines been demonstrated?

- Has the effectiveness of the covid-19 vaccines been sufficiently demonstrated?

- Who will take responsibility, or who can be held accountable, if these vaccines do not prove to be as safe as the media and the government portray? The government? Not the pharmaceutical companies, for they have been granted exemption from liability.[28] Or we as doctors, who participate in this large-scale medical experiment, to which the Nuremberg Code from 1947, Art. 6 § 1 of the Law on Experiments on the Human Person and Art. 23 of the Belgian Constitution is applicable (see further in this document)?

1. Has the safety of the covid-19 vaccines been demonstrated?

A. Do we have sufficient data to make this decision right now?

The EMA (European Medicines Agency) has recently approved the Pfizer-BioNTech vaccine (Comirnaty) and the Moderna vaccine for marketing. This does not mean that the full efficacy and safety (in the long term) has been demonstrated. Both vaccines are still **in phase 3 of clinical trials**.

Comirnaty has been granted a conditional marketing authorisation. This means that ***there is more evidence to come about the vaccine (see below), which the company is required to provide.*** *The Agency will review any new information that becomes available and this overview will be updated as necessary.* [1] [2]

As COVID-19 Vaccine Moderna is recommended for a conditional marketing authorisation, the company that markets COVID-19 Vaccine, ***Moderna, will continue to provide results from the main trial, which is ongoing, for 2 years.***[3]

De UK government states: *Whilst an acceptable level of information has been received to provide assurance that appropriate standards of quality, safety and efficacy have been met for authorisation of specific batches for temporary supply under Regulation 174 of the Regulations, it should be noted that* ***COVID-19 mRNA Vaccine BNT162b2 remains under review as MHRA continues to receive data***

from the company as it becomes available. This will include, for example, long-term follow-up efficacy and safety data.[4]

Pfizer says they release data "on request, and subject to review". But their study protocol says that Pfizer will only release data **after 24 months** when the study has ended.[5] Moderna's "data sharing statement" says that data "will be available upon request once the study is complete". This means sometime in mid to late 2022, since follow-up is planned for **2 years**.[5]

B. Side effects

B1. General consideration

Pfizer is conducting two studies at this moment [6]:

- BNT162-01: An on-going multi-site, Phase I/II, 2-part, dose-escalation trial investigating the safety and immunogenicity of four different prophylactic SARSCoV-2 RNA vaccines against COVID-19 using different dosing regimens in healthy adults.
- C4591001: An on-going phase 1/2/3, placebo-controlled, randomised, observer-blind, dose finding study to evaluate the safety, tolerability, immunogenicity and efficacy of SARS-CoV-2 RNA vaccine candidates against COVID-19 in healthy individuals.[7]

For the second study (phase 3), severe reactions were reported by 240 people (1.1%) who received the BNT162b2 vaccine, compared to 139 (0.6%) of the participants who received placebo.[6]

At least one adverse event was reported by 27% of participants who received the vaccine compared to 12% of participants who received placebo.[6]

Adverse reactions were more common in the younger study population (< 55 years).

The most common side effects are local symptoms, fever, headache, fatigue, chills, vomiting, diarrhoea and muscle and joint pain.[6]

In the *FDA briefing document* dated December 10, 2020 [8] and in *the MHRA public assessment report* [6], the following is reported about this phase 3 study:

Side effects:

- Local reactions: 84.1%
- Fatigue 62.9%
- Headache 55.1%
- Muscle pain 38.3%
- Chills 31.9%
- Joint pain 23.6%
- Fever >38° 14.2%

- Serious adverse reactions more frequent after the 2nd dose [8]
<55 years ≤ 4.6%
>55 years ≤ 2.8%

- Serious adverse events were observed in 1.1% of the vaccine group and in 0.6% of the placebo group [6]

- Bell's Palsy 4 in vaccine group - 0 in placebo group

- Appendicitis 8 in vaccine group - 4 in placebo group

- Very serious adverse events: 0.6 % in the vaccine group - 0.5 % in the placebo group [8]

Vaccine efficacy (follow-up less than 2 months)

- 18325 participants received placebo
    - o 162 experienced covid-19 from 7 days after the 2nd dose: 0.88%
    - o 3 with severe covid-19 from 7 days after the 2nd dose
- 18 198 participants received the vaccine
    - o 8 experienced covid-19 from 7 days after the 2nd dose: 0,04 %.
    - o 1 with severe covid-19 from 7 days after the 2nd dose

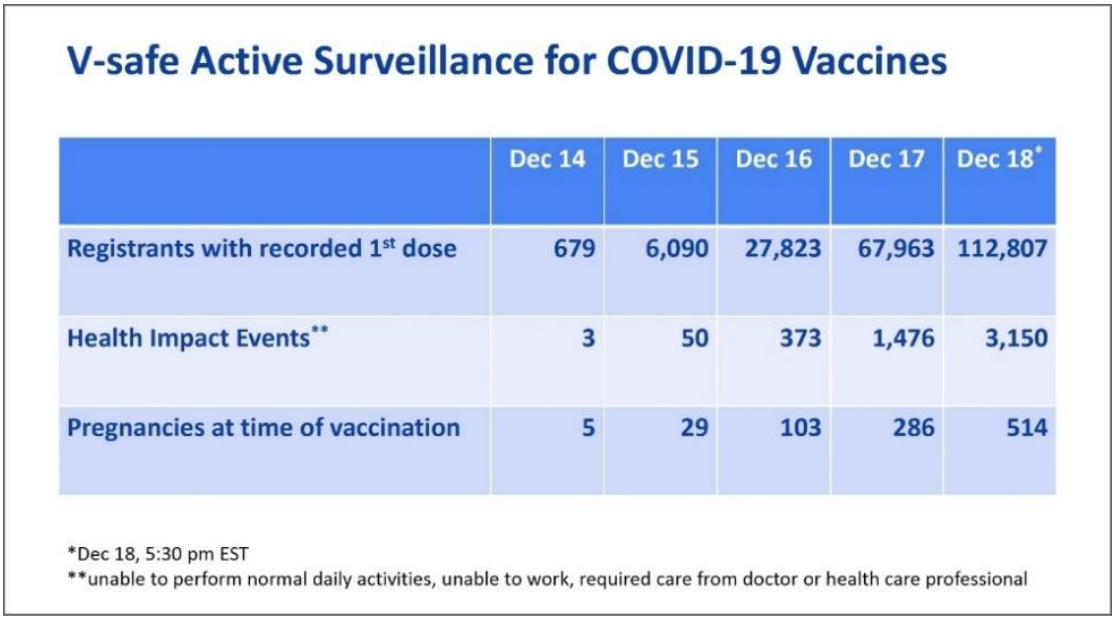
This means that for severe covid-19 infections the **gain** due to the vaccine is **0.01%** (3/18325 (placebo) minus 1/18198 (vaccine)) (**vaccine efficacy 66.4%**).
And that serious adverse events are observed in 0.5% of the people receiving the vaccine.
Or that we can expect **serious adverse reactions** in ≤ **4.6%** (if <55 years) *or* in ≤ **2.8%** (if >55 years) of the people receiving the vaccine.

Converted to 11 million Belgians, this means that through vaccination **we will protect 1100 people in Belgium from a serious covid-19 infection** and that through vaccination **55000 people in Belgium can have serious adverse events.**

Is this an acceptable safety profile? And we are only talking about the short term reactions ...

Looking at the "V-Safe Active Surveillance for covid-19 vaccines" reported by the CDC (Centre for Disease Control) in the US, early indications of observed "health impact events"

(HIE) show an alarming number of adverse reactions to the mRNA vaccine.



V-safe Active Surveillance for COVID-19 Vaccines

	Dec 14	Dec 15	Dec 16	Dec 17	Dec 18*
Registrants with recorded 1st dose	679	6,090	27,823	67,963	112,807
Health Impact Events**	3	50	373	1,476	3,150
Pregnancies at time of vaccination	5	29	103	286	514

*Dec 18, 5:30 pm EST
**unable to perform normal daily activities, unable to work, required care from doctor or health care professional

As of 18 December, 112807 people had been injected with the Pfizer/BioNTech vaccine in the US. Of these, 3150 were unable to carry out their daily activities, unable to work, needed care from a doctor or health professional. This is an **HIE of 2.8%**.

B2. Anafylactic reactions

Ingredients Pfizer/BioNTech vaccine

Highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced by cell-free in vitro transcription from the corresponding DNA templates

((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159), 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC), Cholesterol, Potassium chloride, Potassium dihydrogen phosphate, Sodium chloride, Disodium phosphate dihydrate, Sucrose, Water for injections [4].

Ingredients Moderna vaccine

Single-stranded, 5'-capped messenger RNA (mRNA) produced using cell-free in vitro transcription, encoding the pre-fusion stabilized Spike (S) glycoprotein of SARS-CoV-2.

Lipid SM-102, Cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000 DMG), Tromethamol (Tris), Tromethamol hydrochloride (Tris HCl), Acetic acid, Sodium acetate trihydrate, Sucrose, Water for injections [9].

Anaphylactic reactions have been reported following vaccination with the covid-19 vaccine.[9]

The CDC even created an additional page with "Interim Considerations: Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination". [10]

Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of an mRNA COVID-19 vaccine.

PEG *(polyethylene glycol)* has an immunising effect and gives rise to the production of anti-PEG antibodies. Since PEG is present in thousands of consumer products and medicines[11], we can assume that more and more people will develop anti-PEG antibodies. If high titres of anti-PEG antibodies are present in the blood, people without known allergies may develop severe hypersensitivity reactions to PEG.[12]

B3. Antibody Dependent Enhancement (ADE)

Vaccine associated enhanced disease (VAED) including Vaccine associated enhanced respiratory disease (VAERD) has been included as a potential risk. This is a theoretical risk which is relevant to all COVID-19 vaccines based on VAED having been seen in animal models for vaccines developed for SARS-CoV-1 (a similar but not identical virus to SARSCoV-2, the virus responsible for COVID-19) and also seen in association with use of another respiratory virus vaccine, the Respiratory syncytial virus (RSV) vaccine. [6, 13, 14, 15, 16]

ADE is a common problem with Dengue Virus, Ebola Virus, HIV, RSV, and the family of coronaviruses. In fact, this problem of ADE is a major reason why many previous vaccine trials for other coronaviruses failed. Major safety concerns were observed in animal models. If ADE occurs in an individual, their response to the virus can be worse than their response if they had never developed an antibody in the first place. This can cause a hyperinflammatory response, a cytokine storm, and a generally dysregulation of the immune system that allows the virus to cause more damage to our lungs and other organs of our body. In addition, new cell types throughout our body are now susceptible to viral infection due to the additional viral entry pathway. There are many studies that demonstrate that ADE is a persistent problem with coronaviruses in general, and in particular, with SARS-related viruses. ADE has proven to be a serious challenge with coronavirus vaccines, and this is the primary reason many of such vaccines have failed in early in-vitro or animal trials. [17]

In covid-19, every protein in the SARS-CoV-2 has at least one epitope that matches human proteins someplace in the human body. About one-third of the epitopes in SARS-CoV-2 virus that match human proteins match immune system proteins.[18]

These side effects can only be determined in the longer term.

B4 Some critical questions

Pregnancy and breastfeeding

*It is considered that sufficient reassurance of **safe use of the vaccine in pregnant women cannot be provided** at the present time.*[4]

However, use in women of childbearing potential can be supported, provided healthcare professionals are advised to rule out known or suspected pregnancy prior to vaccination. As a precautionary measure, women of childbearing potential are advised to ***avoid becoming pregnant until at least 2 months after vaccination****. It is unknown whether BNT162b2 is excreted in breast milk. Therefore, it is recommended that BNT162b2 should not be administered to women who are breastfeeding*.[6]

Administration of COVID-19 Vaccine Moderna in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.[9]

In a petition by Dr Wolfgang Wodarg, co-signed by Michael Yeadon, ex-CSO at Pfizer, the following concerns were raised:

Syncytin-1 is responsible for the development of a placenta in mammals and humans and is therefore an essential prerequisite for a successful pregnancy, is also found in homologous form in the spike proteins of SARS viruses. There is no indication whether antibodies against spike proteins of SARS viruses would also act like anti-Syncytin-1 antibodies. However, **if this were to be the case** this would then also prevent the formation of a placenta which would result **in vaccinated women essentially becoming infertile**.

According to the Pfizer/BioNTech trial protocol, a woman of childbearing potential is eligible to participate if she is not pregnant or breastfeeding, and is using an acceptable contraceptive method as described in the trial protocol during the intervention period (for a minimum of 28 days after the last dose of study intervention).

This means that it could take a relatively long time before a noticeable number of cases of postvaccination infertility could be observed. [17]

Possibility to develop auto-immune diseases?

When the mRNA instructs our body cells to make virus proteins, an expression of these proteins occurs on our cell surface. Is there a possibility that our immune system will attack these cells and thus develop autoimmune diseases?[19]

Incorporation of mRNA into our genetic material?

It has repeatedly been stated that mRNA cannot enter our genome. However, it is known that in HIV patients single-stranded RNA can be converted into DNA by reverse transcriptase and incorporated by integrase.

Apart from HIV, there is also a large number of other retroviruses that possess these enzymes.

Recent research has shown that this can also be done without the presence of a retrovirus, as remnants of ancient retroviral infections make up about 17% of the human genome. If

these sequences produce reverse transcriptase, it could happen that SARS-CoV-2 integrates into our DNA. As this can happen in people infected with both SARS-CoV-2 and HIV. [20] [21]

In the Pfizer study, 120 participants with HIV were included, but safety analyses are not yet available for this subgroup.[6]

If SARS-CoV-2 virus can integrate into our DNA, there is also a possibility that this can be done with the mRNA from the vaccine... If this happens, it is irreversible for all future generations. This avenue still needs to be explored further.

B5 Possible side effects of covid-19 vaccine presented by the FDA [22]

	Vaccines and Related Biological Products Advisory Committe October 22, 2020, Meeting Presentation	List of possible side effects of Covid-19 vaccine presented by FDA, US Drug Administration, October 22, 2020. Source: https://www.fda.gov/media/143557/
1	**Guillain-Barré syndrome**	**Nerve damage**. A condition in which the immune system attacks the nerves and damages the nerve sheath. The disease develops rapidly and spreads to all nerves in the body. It usually occurs after a viral infection. The mortality rate is up to 7%.
2	**Acute disseminated encephalomyelitis**	MS and other **injuries that affect nerves, brain, optic nerve, spinal cord**. The tissue (myelin) that protects the nerves gets damaged. Multiple sclerosis, MS, is such a disease.
3	**Transverse myelitis**	**Inflammation of the spinal cord** which damages the communication of the nerves and **causes pain, weak muscles, paralysis, brain damage** such as stroke, problems with the intestines and bladder.
4	**Encephalitis/myelitis/encephalomyelitis/ meningoencephalitis/meningitis/ encepholapathy**	**Inflammation in various parts of the brain, nerves and spinal cord** which is often caused by viral infection and causes tremors, confusion, vision and hearing problems, pain. Can be fatal.
5	**Convulsions/seizures**	**Convulsions** and seizures.
6	**Stroke**	**Stroke**. Often fatal and otherwise causing permanent brain damage such as aphasia, memory disorders and paralysis.
7	**Narcolepsy and cataplexy**	Sleep apnea, which occurred after recent years of flu vaccine. Cataplexy involves different types of **sleep disorders**.
8	**Anaphylaxis**	Life-threatening **severe allergic reactions** that can be very rapid and violent.
9	**Acute myocardial infarction**	Acute myocardial infarction. **Cardiac arrest**.
10	**Myocarditis/pericarditis**	**Inflammation of the heart muscle** which impairs the work of the heart. Often occurs from viral infections and medications and can cause blood clots. Causes chest pain, shortness of breath and arrhythmia.
11	**Autoimmune disease**	Autoimmune conditions. **The immune system attacks the body's tissues**.
12	**Deaths**	**Death...**
13	**Pregnancy and birth outcomes**	**Pregnancy and birth outcomes**
14	**Other acute demyelinating diseases**	Other **acute neurological** conditions.
15	**Non-anaphylactic allergic reactions**	Other severe **allergic reactions**.
16	**Thrombocytopenia**	Deficiency of platelets, which is a type of blood cell with the function of coagulation, i.e. to stop bleeding. If you have too few platelets, you risk getting **internal bleeding** and bleeding faster in case of injury and childbirth.
17	**Disseminated intravascular coagulation**	Scattered coagulation of blood in the blood vessels => **blood clots**.
18	**Venous thromboembolism**	**Blood clots** in veins.
19	**Arthritis and arthralgia/joint pain**	Arthritis; **inflammation** and other joint pain.
20	**Kawasaki disease**	**Acute inflammation** with red and swollen rash that more often **affects young children**. The skin on the tongue, lips, hands, feet and abdomen becomes red and swollen. Fever. Can be fatal if it affects the heart and coronary arteries.
21	**Multisystem Inflammatory Syndrome in Children**	**Fever, vomiting, diarrhea, rash, swollen feet, hands and tongue**. Occurs most often in children and adolescents a few weeks after infection with covid-19. Similar to Kawasaki.
22	**Vaccine enhanced disease**	**Other disease** exacerbated by vaccine.

2. Has the effectiveness of the covid-19 vaccines sufficiently been demonstrated?

With regard to the Pfizer-BioNTech vaccine:

- If we start from the figures reported in the FDA report of 10 December [8] (18 325 participants received a placebo, 162 experience covid-19 after 2°dose, 3 with severe covid-19 / 18 198 participants received the vaccine, 8 experienced covid-19 after 2°dose, 1 with severe covid-19) we see the following:

- The vaccine is 95% effective, i.e. the relative risk reduction (RRR) is 95%. 100% x (1 – (8/18198)/(162/18325)) = 95%
  However, if we look at the **absolute risk reduction (ARR),** we arrive at a completely different figure: 162/18325 - 8/18198 = 0.0084 = **0.84%.**

- If we repeat this with the **seriously ill people** in the study:
  RR: 100% x (1 - (1/18198)/(3/18325)) = **66.43%**
  ARR: 3/18325 - 1/18198 = 0.0001 = **0.01%**.
  Number needed to treat (NNT): 100%/0.01% = **10,000**

So we need to vaccinate 10,000 people to have 1 case of severe covid less! And this with a vaccine about which we still have insufficient safety data.

- The impact of vaccination on the spread of the SARS-CoV-2 virus is not yet known**. It is not yet known how much vaccinated people may still be able to carry and spread the virus.** [1]

- Data on **vaccine protection beyond 2-3 months are currently lacking**.[6]

- **Data in individuals above 75 years of age are limited** (about 1500 in total, half vaccinated). There is current uncertainty around vaccine efficacy in this age group. [6]

- There are **no data on concomitant immunisation**, in particular influenza vaccination, or concomitant **medications**.[6]

- There are **no data in pregnant women and immunosuppressed patients** as these subjects were excluded from the trial.[6]

- There are currently **no data in adolescents (12 to 15 years old)** as these have only been recently enrolled. [6]

- Clinical safety data are available from more than 43,000 participants aged over 16 years, of which more than 19,000 have been followed up for at least 2 months after Dose 2 of BNT162b2 or placebo. [6] **The other half will not be followed up anymore?**

- Peter Doshi, co-editor BMJ, asks the following questions[5]:

    - Pfizer reported 170 PCR confirmed covid-19 cases, split 8 to 162 between vaccine and placebo groups. But these numbers were dwarfed by a category of disease called “suspected covid-19”—those with symptomatic covid-19 that were not PCR confirmed. According to FDA’s report on Pfizer’s vaccine [8], there were “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."

With 20 times more suspected than confirmed cases, this category of disease cannot be ignored simply because there was no positive PCR test result. Indeed this makes it all the more urgent to understand. A rough estimate of vaccine efficacy against developing covid-19 symptoms, with or without a positive PCR test result, would be a relative risk reduction of 19% (see footnote)—far below the 50% effectiveness threshold for authorization set by regulators [23]. Even after removing cases occurring within 7 days of vaccination (409 on Pfizer's vaccine vs. 287 on placebo), which should include the majority of symptoms due to short-term vaccine reactogenicity, vaccine efficacy remains low: 29%

Pfizer's 92-page report didn't mention the 3410 "suspected covid-19" cases. Nor did its publication in the *New England Journal of Medicine*. Nor did any of the reports on Moderna's vaccine. The only source that appears to have reported it is FDA's review of Pfizer's vaccine.

- Another reason we need more data is to analyse an unexplained detail found in a table of FDA's review [8] of Pfizer's vaccine: 371 individuals excluded from the efficacy analysis for "important protocol deviations on or prior to 7 days after Dose 2." What is concerning is the imbalance between randomized groups in the number of these excluded individuals: 311 from the vaccine group vs 60 on placebo. (In contrast, in Moderna's trial [24], there were just 36 participants excluded from the efficacy analysis for "major protocol deviation"—12 vaccine group vs 24 placebo group.)

  What were these protocol deviations in Pfizer's study, and why were there five times more participants excluded in the vaccine group?

Too many questions remain unanswered and too many data are missing to conclude that the efficacy of the vaccine has been sufficiently and transparently demonstrated.

In summary, at this time (1 year after the SARS-CoV-2 outbreak) there is insufficient data, both on the safety and on the efficacy of the new vaccines, to administer them on a large scale to the population. Especially for a pandemic of which the median infection survival rate in case of infection is 99.77%, for people under the age of 70 even 99.95%, and the IFR (Infection Fatality Rate) is calculated at an average of 0.23%, as shown in the meta-analysis of Prof. Ioannidis, published on the WHO website.[25]

We can therefore conclude that this generalised vaccination campaign meets the definition of a medical experiment and that the Nuremberg Code applies to it.

3. Who will take responsibility, or who can be held accountable, if these vaccines do not turn out to be as safe as the media and the government portray?

As **doctors**, we are faced with the choice of providing our (in)direct cooperation and **can also be held liable for this**.

We have chosen a special and highly responsible profession. In doing so, we are primarily serving mankind and its well-being. We work according to the principle "Primum non nocere". It is precisely in this context that doctors take the Hippocratic Oath, in which, among other things, they swear the following to mankind:

"I will care for my patients above all else, promote their health and alleviate their suffering."

"I will inform my patients correctly."

*"**Even under pressure***, I will not use my medical knowledge for practices contrary to humanity."*

*Reference to the 1948 Declaration of Universal Human Rights and the 1947 Nuremberg Code. Its main purpose is to prevent the abuse of a doctor's medical knowledge, as happened during the Second World War, or to prevent the abuse of a doctor's medical knowledge through commercial pressure from the pharmaceutical industry.

What does the Law on Experiments on the Human Person 2004 say? [26]

Art. 6 § 1: With the exception of the persons referred to in articles 7, 8 and 9, a person may only participate in an experiment if he has **consented in a free and informed manner**, whereby the information referred to in § 2 was previously communicated to him. **The permission is given in writing.**

What does the Belgian constitution say? [27]

Art. 23 Everyone has the right to lead a life with dignity.

These rights include in particular:

2. the right to social security, **health protection** and social, medical and legal assistance;

What does the Nuremberg Code from 1947 say?

Art. 1. The voluntary consent of the human subject is absolutely essential. This means that the person involved **should have legal capacity to give consent**; should be so situated as to be able **to exercise free power of choice**, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and **should have sufficient knowledge and comprehension** of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. **The duty and responsibility for ascertaining the quality of the consent** rests upon each individual who initiates, directs, or engages in the experiment. **It is a personal duty and responsibility which may not be delegated to another with impunity.**

Art. 3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.

Art. 4. The experiment should be so conducted as **to avoid all unnecessary physical and mental suffering and injury.**

Art. 6. **The degree of risk to be taken** should never exceed that determined by the **humanitarian importance of the problem to be solved** by the experiment.

Art. 10. During the course of the experiment **the scientist in charge must be prepared to terminate the experiment at any stage**, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, **that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.**

We hope that physicians will act in accordance with the Hippocratic Oath, and in particular will respect and comply with the provisions of the Nuremberg Code from 1947 in all circumstances.

Kind regards,

Docs4opendebate

https://docs4opendebate.be/en/

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