SAFE AND EFFECTIVE?

A report on MHRA's Regulation of the Covid-19 vaccines

AUTHORS

This report has been co-authored by a multidisciplinary team of experts from various fields including medicine, safety management and pharmaceutical regulation. Its purpose is to bring to the attention of politicians and policy makers the serious shortcomings in the current regulatory system for drug approvals in general and the Covid-19 vaccines in particular, and the significant safety issues that result. In order to ensure the focus remains on the content of this work rather than on individual authors, the team have decided to remain anonymous at present.

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EXECUTIVE SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for ensuring the safety and efficacy of medicines used in the UK. It has become clear during the Covid-19 pandemic that the MHRA has failed to meet its responsibilities in multiple ways, despite prior warnings of inadequate regulation published in Government reports:

- no requirement for manufacturers to demonstrate sufficient safety, before or after approvals;
- approvals for younger age groups and children in the absence of long-term safety data, despite only negligible potential for benefit;
- failure to act promptly on evidence of adverse reactions, to rigorously assess safety evidence and to share it publicly to enable informed consent;
- failure to identify and address problems with manufacturing and quality control.

Bringing a new medicine to market typically takes around ten years but, under intense political pressure, MHRA gave Conditional Marketing Authorisation for the Covid-19 vaccines after less than one year of clinical trials. It would appear that lessons have not been learned from the rushed Pandemrix Swine-Flu vaccine (2009) or from the report of the Cumberlege report (2020). There were numerous published reports and warnings about the risks of MHRA approving the Covid-19 vaccines on such limited evidence. Indeed, even the manufacturers claim to have been expecting to provide more safety evidence for the new vaccines before approval.

Unforeseen serious side-effects emerged immediately. The AstraZeneca vaccine was suspended from use in young adults in many countries after only two months, but MHRA was still attesting to its safety until JCVI advised that alternatives should be offered for under 40s.

Evidence of numerous vaccine-related side-effects has grown since approval. Serious side-effects such as myocarditis, clotting problems, neurological problems and immunosuppression have all been extensively reported.

MHRA did not follow through on its promised 'Proactive Vigilance'. This was supposed to have included population-level NHS data, segmented by vaccination status to look for any link between the vaccines and reported serious side-effects.

MHRA falls short of best practice safety management and governance seen in other safety critical sectors such as nuclear, aviation, defence and oil/gas. Shortcomings include:

- no process for investigating fatal/serious Yellow Card reports;
- no independent safety audits of MHRA;
- lack of accountability and no predetermined safety thresholds in stark contrast to regulators of other industries;
- close funding arrangements involving the pharmaceutical industry, creating serious conflicts of interest.

The serious shortcomings identified raise grave concerns about the ability of MHRA to fulfil its statutory duty to protect the public from harm, by properly regulating the safety and effectiveness of medicines in the UK. Given the level of reported Covid-19 vaccine injuries and the excess deaths across all age groups, these products must be paused while they are properly investigated, and a full independent inquiry launched into MHRA's regulatory processes and performance.

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A. BACKGROUND

1. HOW ARE COVID-19 VACCINES DIFFERENT FROM OTHERS

1.1. It is important to recognize the difference between mRNA and viral-vector DNA technologies and standard established vaccine technology, especially with regard to the risks of the rapid approvals process. These new technologies have never been used in healthy populations before and their long-term safety has not been established. Yet the authorisation documentation used by the MHRA has followed that for standard vaccines rather than for a novel drug.

1.2. In a standard vaccine, a known amount of a killed or weakened virus or bacteria is injected into a subject whose immune system recognises that it is 'foreign' and so makes antibodies to it. The viral or bacterial protein is thus cleared and the antibody levels subsequently fall. The body's immune cells retain the memory so that fresh antibodies can be quickly produced if the person encounters the same infective agent in future.

1.3. For an mRNA product (Pfizer BioNTech and Moderna), a small sequence of synthesised genetic material (encoding part of the spike protein from the SARS-CoV-2 virus) is used. This mRNA is first 'modified' by replacing uridine, with a synthetic chemical (pseudouridine), which the body has never seen before, thus avoiding the body's normal ability to rapidly break it down.

1.4. This modified mRNA is then coated in tiny 'lipid nanoparticles' (LNPs) to allow it to enter cells. Once inside, the mRNA instructs the cell machinery to make the spike protein which is then pushed to the surface of the cell. The immune system then recognises the spike protein as foreign; antibodies are made against it, the cell is killed and the immune memory established.

1.5. Whereas traditional vaccination creates a stimulus in the injected muscle, the LNPs containing the mRNA can travel easily around the body into different organs and there is no information on how much spike protein is produced, or where, or for how long (days, weeks or even months?). This was confirmed by Pfizer's VP of vaccine clinical R&D, Dr Gruber, who admitted he had no information on these questions. Given the known toxicity of the spike protein, this lack of data on ongoing production following vaccination is very concerning.

1.6. From court-ordered release of the Pfizer clinical and non-clinical trial documents, the animal biodistribution studies showed that the LNPs travelled to the brain, spleen, adrenal glands, testes and ovaries. LNPs are known to be highly inflammatory. No biodistribution or pharmacokinetic studies were done on the finished product.

1.7. Viral-vector DNA products (such as AstraZeneca) work in a similar way using the spike genetic sequence (as DNA) carried by a harmless chimpanzee virus into the body's cells. As with mRNA vaccines, no work was done to show which organs would produce spike protein, in what quantity and for how long.

2. BALANCING THE RISKS AGAINST THE BENEFITS

When evaluating new drugs or preventive therapies, it is important to balance the potential benefits against the associated risks, and to carefully consider the risks posed by the disease being treated or prevented, in order to make an **informed decision**.

2.1. When evaluating new drugs or preventive therapies such as vaccines, it is crucial to weigh the potential benefits against the risks of harm associated with the product. To make an informed assessment, it is necessary to consider the risks posed by the disease being treated or prevented, as well as the likelihood of reducing that risk.

2.2. When treating an already ill patient, the potential benefits of a treatment may outweigh the associated risks, and higher risks may be deemed acceptable. However, when considering an otherwise healthy population, the acceptable levels of risk are lower, and the burden of proof is higher. This is particularly true for children, whose organ systems are still developing, and who may experience adverse events that affect them for decades over the remainder of their lives.

2.3. In the case of SARS-CoV-2 infections, the risks of severe disease or death are highly skewed to older age groups as shown in Figure 1. This is highly relevant when it comes to authorising vaccines for children. A review of all child deaths in England from March 2020 to March 2021, found that healthy children had a one in two million chance of dying with Covid-19. [1]

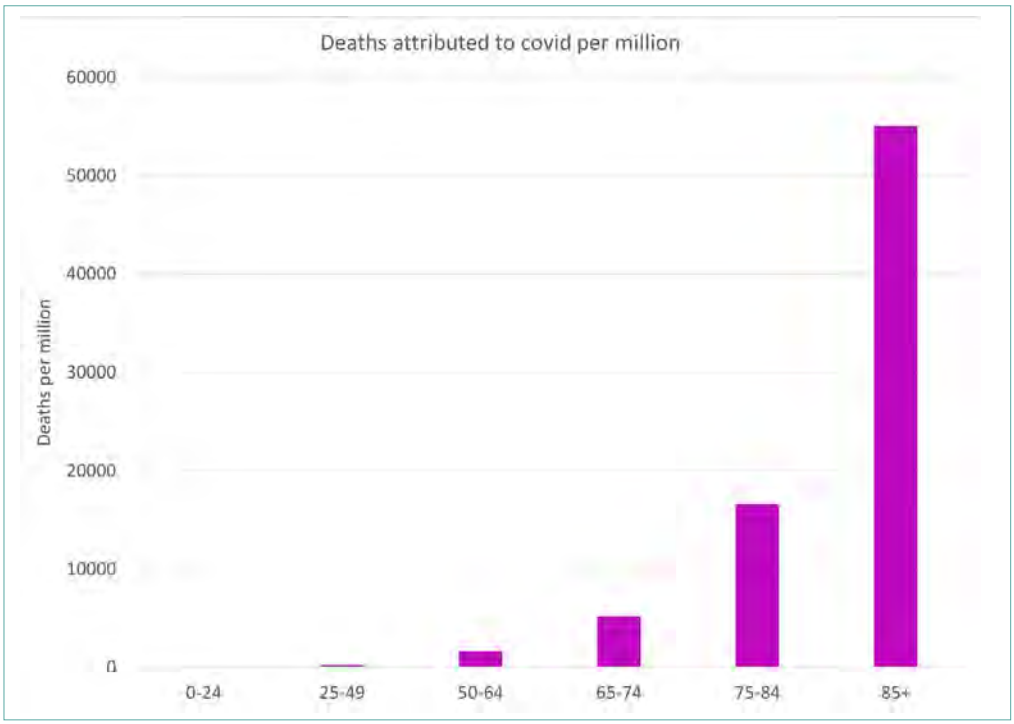


Figure 1. Deaths with Covid-19 by age per million population, 2020. ONS data [2]

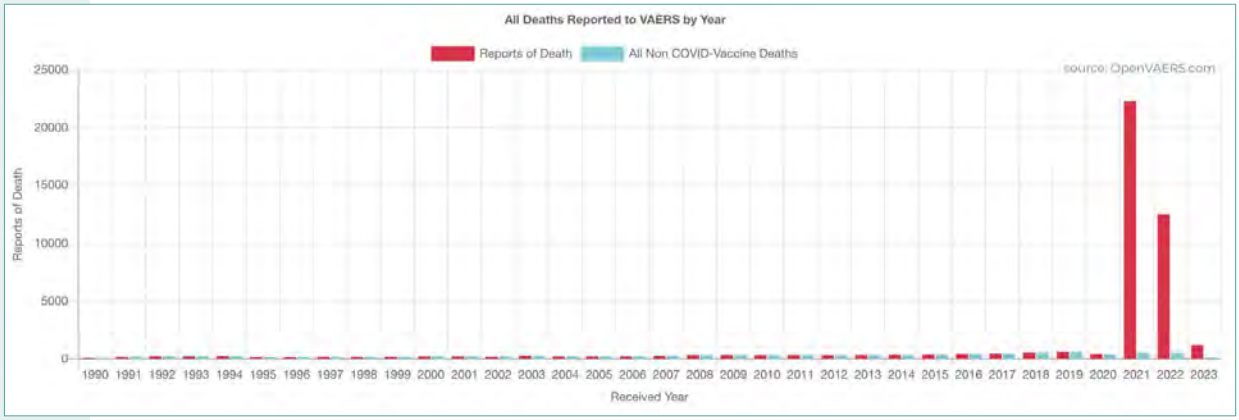
2.4. Many people have attempted to dismiss evidence of significant harm from Covid-19 vaccination on the basis that the benefits of lives saved outweigh the vaccine risks. A modelling paper [3] by Imperial College, which claimed that 20 million lives had been saved, had significant coverage in the mainstream media. To reach this figure, half a **million lives would need to have been saved in the UK alone**, which has been shown to be false. [4] The MHRA itself claimed that only tens of thousands of lives were saved, [5] and ONS [6] and NHS [7] have reduced this estimate further to only thousands being saved.

B. THE RISKS OF COVID-19 VACCINES

3. WHAT ADVERSE EVENTS HAVE COVID-19 VACCINES CAUSED?

Covid-19 vaccines have been associated with adverse events affecting **multiple organs**, including blood clotting, heart inflammation, and neurological conditions. Covid-19 vaccines have a higher rate of adverse events compared to common vaccines, including **more reported deaths**. The mRNA modification used in vaccines may have **unintended consequences**, including altering the immune response and potentially leading to increased rates of viral reactivation. Reported associations with other conditions are also concerning.

3.1. It is important to note that adverse events have been widely reported following Covid-19 vaccines and have affected multiple organs. In fact, as reported on the US Vaccine Adverse Events Reporting System (VAERS), there have been **more deaths** reported in 2021 and 2022 related to Covid-19 vaccines than all reported vaccine deaths in the past 30 years combined, even after accounting for increased awareness of VAERS in recent times. [8]



3.2. Adverse events have included **blood clotting, heart inflammation, neurological conditions, immune downgrading, and menstrual disorders,** at far higher rates compared to other vaccines. The following data [9] from Europe published in June 2022 also show a much higher rate of adverse events for the Covid-19 vaccines compared with common vaccines:

Vaccine	Approximate number who have been vaccinated	Total number of adverse events
All measles vaccines	673,200,000	48,913
All polio vaccines	673,200,000	8982
All influenza vaccines	unknown	44,618
Covid-19	341,628,772	1,800,000

Source: https://www.adrreports.eu/

Table 1: Total Number of Adverse Events on EudraVigilance - common vaccines

3.3. **Blood clotting:** On 10 March 2021, a fatal case of a rare type of stroke (cerebral venous sinus thrombosis) occurred in a person in Denmark, [10] shortly after their first AstraZeneca vaccine. Around 720,000 vaccines had been dispensed in Denmark at that time. The following day, the Danish Health Authority suspended the vaccine, pending a detailed analysis, and several other European countries followed suit. The patient was found to have a rare condition, Vaccine-Induced Thrombotic Thrombocytopaenia (VITT), which is an autoimmune condition. The Danish Ministry sent a letter to every person who had received AZ in the previous 14 days, telling them what symptoms to look out for and when to contact their doctor. By that date, **over 24 million vaccinations** had been given in the UK while the MHRA and JCVI still insisted it was safe. One month later, MHRA acknowledged the link between AZ vaccines and VITT, but described it as extremely rare and advised that benefits greatly outweighed risks, [11] stating, *"The MHRA is not recommending age restrictions in COVID-19 Vaccine AstraZeneca vaccine use"*

3.4. The UK paused doses for under 30s on the recommendation of the JCVI, and two months after Denmark's decision they withdrew it for under 40s, [12] by which time further needless deaths in the UK had occurred. Even then, **it was the JCVI rather than MHRA that recommended alternatives for this age group (note even JCVI did not recommend a full suspension)**. [13] The condition is now listed on the manufacturer's patient information leaflets, but no modification was made to the conditional marketing authorisation which is still in existence for age 16 upwards.

3.5. **Myocarditis:** Following the cessation of AZ, younger citizens in the UK were offered Pfizer instead, but this product proved to carry risks too. Reports of heart inflammation leading to chest pain, palpitations and breathlessness first began in April 2021, [14] particularly prevalent in teenage boys. Estimates of frequency among teenage boys range **from 1 in 9000** [15] **to as many as 1 in 43,** [16] this last number coming from a research team who gave diary cards to several hundred secondary school children and compared ECGs and blood tests before and after vaccination.

3.6. **Neurological conditions:** Transverse myelitis and Guillain-Barre syndrome, both conditions which cause paralysis, are listed side-effects. Seizures, pain, peripheral nerve injury, headaches, tremors and brain fog are all described by many, often young, people whose health has been severely damaged following vaccination. Worryingly, these conditions have not yet been recognised by the Vaccine Injuries Compensation scheme, despite numerous reports submitted. **Measurable damage** to the small vessels that supply the nerves has been demonstrated [17] and the spike protein itself has been shown to be **neurotoxic.** [18]

3.7. **Immune downgrading:** It has become evident that the vaccines' efficacy wanes within months. [19] During 2022, after multiple doses, the fully vaccinated had a **higher risk of catching SARS-COV-2** infection than the unvaccinated. [20] [21] This is not simply the return to baseline immunity, which might occur as the effect of a previous dose wore off, but suggests **deterioration of baseline immune function**. Indeed, there is much anecdotal evidence of multiple doses leading to increased infections, which cannot easily be disregarded.

3.8. The modification of the mRNA used in vaccines, as discussed in paragraph 1.3, may have the unintended consequence of camouflaging the mRNA from the immune system and **altering the body's innate immune response**. [22] This could potentially explain the increased rates of reactivation of herpes zoster, [23] pityriasis rosea, and Epstein-Barr virus following mRNA vaccination, as the innate immune response is the body's first line of defence against all infections. It has also been demonstrated that there is a change in the class of antibodies produced after the third dose. [24]

3.9. Of even greater concern are reports of **aggressive cancers** [25] developing shortly following booster shots. Precancerous cells are regularly produced in the body and cleared by the immune system (T-cells), so any downgrading of T-cell function could potentially allow cancers to develop unchecked.

3.10. **Menstrual disorders:** From as early as mid 2021, thousands of women suffering from menstrual abnormalities post mRNA vaccination were reported on various post-marketing vaccine surveillance programmes around the globe.

3.10.1. This was noted by the European Medicines Agency in their first ever Periodic Safety Update Report covering December 2020-June 2021 (obtained by FOI request). [26] An article published in September 2021 in the British Medical Journal stated, [27] *"Changes to periods and unexpected vaginal bleeding are not listed, but primary care clinicians and those working in reproductive health are increasingly approached by people who have* ***experienced these events shortly after vaccination****. More than 30,000 reports of these events had been made to MHRA's Yellow Card surveillance scheme for adverse drug reactions by 2 September 2021, across all Covid-19 vaccines currently offered." The author went on to state, "a link is plausible and should be investigated."*

3.10.2. It **took the MHRA until February 2023** [28] to update their summary of yellow card reporting information on coronavirus vaccines by adding Menstrual Disorders to their list of adverse reactions, their report stating, *"Evidence from the most recent review suggested a possible association between the Pfizer and Moderna Covid-19 vaccines and heavy menstrual bleeding."*

3.11. **Miscarriages (spontaneous abortions)**: Never before has the MHRA authorised the use of a medicinal product to the pregnant population with such a paucity of data, including no long-term safety data.

3.11.1. The NHS actively promoted mRNA vaccines to pregnant women as early as spring 2021, even when the MHRA product information on Pfizer-BioNTech Covid-19 vaccine stated, *"The* ***absence of reproductive toxicity data*** *is a reflection of the speed of development to first identify and select Covid-19 mRNA Vaccine BNT162b2 for clinical testing and its rapid development to meet the ongoing urgent health need…In the context of supply under Regulation 174, it is considered that* ***sufficient reassurance of safe use of the vaccine in pregnant women cannot be provided at the present time."***

3.11.2. The MHRA stood back, knowing that the NHS was promoting the vaccine to pregnant and lactating women. The MHRA appeared to side-step to quell a social media storm when attention was drawn to this. On or around Friday September 2, 2022, the MHRA added its first ever notice to its public assessment report of the Pfizer-BioNTech Covid-19 vaccine, stating that the assessment report *"summarises the initial assessment at the time of approval in December 2020".* [29]

3.11.3. Health authorities based their endorsement of the mRNA vaccine being safe in pregnant women on a **highly flawed study**.[30] Of 10,000 women vaccinated in pregnancy, over 60% were vaccinated during their third trimester, after the risk of miscarriage had passed, and only 1% vaccinated in the first trimester, which undeniably could have led to **bias in the results**. As late as December 2021, Pfizer had a consent form that stated, *"The effects of the Covid-19 vaccine on sperm, a pregnancy, a fetus or a nursing child are not known."*

3.12. A retrospective analysis by Thorp et al [31] studied the impact on pregnancy outcomes and menstrual function post Covid-19 mRNA vaccines compared to the influenza vaccine, which has been around for 25 years and is recommended annually for all adults in the USA and especially in pregnancy. They concluded: *"Pregnancy complications and menstrual abnormalities are significantly more frequent following Covid-19 vaccinations than Influenza vaccinations. A worldwide moratorium on the use of Covid-19 vaccines in pregnancy is advised until randomized prospective trials document safety in pregnancy and long-term follow-up in offspring."*

3.13. **Other potential harms:** There are still many unknowns for the mRNA technology. For example, a study in Sweden showed that the Pfizer-BioNTech (BNT162b2) mRNA is reverse transcribed intracellularly into human DNA in the laboratory within 6 hrs after exposure. [32] The possibility of genetic-based vaccines being integrated into cells has not been adequately studied.

3.14. All of the above concerns have come to light since the vaccine was rolled out, and many were also contained in **Pfizer's own postmarketing report**, obtained by FOI request. [33] Of note, **Pfizer originally refused to release any of its data, despite an FOI and requested a 75 year delay.** Following a court case in the US, they were forced to release all their original documents. [34] It is not clear whether MHRA had access to this material prior to the authorisation. An FOI request to the MHRA regarding the AstraZeneca data [35] was refused on the grounds that it is exempt under Section 12 & 14, i.e. that it would take too much time, effort and cost to produce the vast array of regulatory material encompassed by the request.

3.15. Another major deficiency in the regulatory approach was to allow Pfizer and other manufacturers to offer the vaccines to all the control group members in the trials. Where this may have been reasonable for those at high risk, the majority of the trial participants were in good health and the removal of the control group within less than 6 months was in contravention of advice from the International Coalition of Medicines Regulatory Authorities, of which the MHRA is a member. [36] This single decision, to eliminate the control group before the trials were completed, has made the ascertainment of mid- to long-term side effects almost impossible. In addition, all cause mortality is no longer used as the gold standard to assess harms.

4. MEASURING THE EXTENT OF HARM

Significant side-effects were not recognized in the original trials due to small sample sizes and **could only be measured** once the Covid-19 vaccines were rolled out to the general public. The MHRA has been **slow to detect and report safety problems.** There is growing concern among clinicians about the potential serious side-effects of Covid-19 vaccines, particularly as the rollout extended to younger age groups. Analysis suggests that **as many as 1 in 800 suffer a serious adverse event following vaccination**. Despite this, the MHRA appears to not be listening.

4.1. Significant side effects, not recognized in the original trials due to small sample sizes, could only be measured once the Covid-19 vaccines were rolled out to the general public.

4.2. In December 2020, MHRA issued its first alert, due to early reports of anaphylaxis associated with the Pfizer vaccine after **three of the first 400 people vaccinated had an anaphylactic reaction** and one had nearly died. [37]

4.3. At the beginning of March 2021, nine weeks after the AstraZeneca Covid-19 vaccine rollout began, national regulators in Austria, Denmark, Norway, Iceland and Germany, started to report a potential link between blood clots and the Covid-19 vaccines. Denmark suspended use of the AstraZeneca Covid-19 vaccine on 11 March 2021, after they had vaccinated 734,000 people. Other countries rapidly followed suit. [38] The MHRA said [39] on 11 March that it could see no evidence of the linkage, despite associated Yellow Card reports as early as 7 February, and did not publish safety advice until 7 April 2021. [40] By then**, 24 million people had been vaccinated in the UK without MHRA's pharmacovigilance system detecting a problem.**

4.4. As of December 2021, MHRA's weekly summary included approximately 10 serious conditions that were not listed at the beginning of the vaccine rollout. Some of these were new side-effects that were not observed during clinical trials, while others were known side-effects where the population-level rollout had exposed them as more frequent.

4.5. As the rollout of other Covid-19 vaccines continued, so did the number of peer-reviewed studies investigating serious adverse events worldwide. [41] Additionally, a growing number of highly qualified clinicians have publicly expressed concerns about the potential serious side-effects of Covid-19 vaccines, particularly when the rollout extended to younger age groups in the summer of 2021. The MHRA was warned directly [42] about these concerns, including the **potential risks to children of authorising a new drug without long-term safety data to prevent a disease that is typically mild in childhood.** [43]

4.6. The adverse events highlighted in worldwide studies [44] revolve around the following key issues: clotting, myocarditis and other heart issues, neurological conditions, and immunosuppression. Analysis of the original randomised controlled trials found that as many as 1 in 800 suffered a serious adverse event following vaccination. [45] This is in marked contrast to the very low risk of serious illness from Covid-19 for the majority of healthy adults.

4.7. In January 2023, the government released data that was originally provided to the JCVI in October 2022, indicating the estimated number of people in each risk and age group who needed to be vaccinated (NNV) in July 2022 to prevent a single hospitalisation or intensive care admission. For most age groups, the numbers were in the thousands or tens of thousands, but for healthy younger cohorts, the numbers were in the hundreds of thousands, as shown in Table 2. [46]

	Programme			
Age	Primary	Booster (2+1)	Autumn 22 boost	Spring 23 boost
5 to 11	112200			
12 to 15	162600			
16 to 19	106500	193500	185100	
20 to 29	166200	418100	275200	
30 to 39	87600	188500	217300	
40 to 49	53700	40600	175900	
50 to 59	18700	16200	48300	
60 to 69	5700	9200	27300	
70+	2500	10400	7500	
In a risk group	Primary	Booster (2+1)	Autumn 22 boost	Spring 23 boost
20 to 29	11400	43500	59500	59500
30 to 39	10700	28600	40500	40500
40 to 49	9400	10600	49800	49800
50 to 59	5600	6100	18600	18600
No risk group	Primary	Booster (2+1)	Autumn 22 boost	Spring 23 boost
20 to 29	no cases	no cases	706500	
30 to 39	318400	no cases	no cases	
40 to 49	186800	190400	932500	
0 to 59	51600	107000	256400	

Table 2: NNV for prevention of severe hospitalisation for different programmes

4.8. The MHRA replaced all of the full Yellow Card “Vaccine Analysis Print" reports with a report which condenses and omits most of the injuries associated with the Covid vaccines. This condensed and partial data is used by the Vaccine Damage Payment Scheme assessors, resulting in 94% of VDPS applications being declined. They now plan to stop the reports completely.

4.9. The MHRA shares data of injured people with vaccine manufacturers, therefore providing the pharmaceutical manufacturers with an advantage in any potential proceedings which may follow.

4.10. Despite the overwhelming evidence base of detailed studies on adverse reactions by researchers and anecdotal reports by clinicians, it appears that the MHRA is still not listening.

5. DEATHS

Relying solely on death certification as a measure of deaths caused by vaccination could lead to circular logic. Additional methods of surveillance should be employed to **accurately capture the true number of vaccine-related deaths.**
MHRA's safety surveillance process may be incomplete due to their **lack of proactive investigation and information gathering**, which could lead to missing important data on vaccine-related deaths.
Excess deaths not associated with Covid-19, particularly from **cardiovascular** causes have been noted **since spring 2021**.
Despite evidence from other countries reporting post-vaccination deaths, the MHRA has made **no attempt to obtain post-mortem information**.

5.1. Relying solely on death certification as a measure of deaths caused by vaccination could lead to circular logic. Until the MHRA announced in April 2021 that rare brain clots could be caused by vaccination, there were no death certificates with a mention of vaccination, [47] **Doctors wait for a connection to be reported** before including vaccination as a cause on death certificates. If the **MHRA also waits for individual doctors to certify deaths** before deducing a connection, then the link will never be made. Therefore, additional methods of surveillance should be employed to accurately capture the true number of vaccine-related deaths.

5.2. The MHRA has a process for handling Coroners Regulation 28 "Reports To Prevent Future Deaths" which it receives [48]. However, MHRA does not have a process for obtaining copies of Regulation 28 reports where a medicine was cited as the cause of death but where MHRA was not a primary or copy addressee. This lack of proactive investigation and information gathering suggests that MHRA's safety surveillance process may be incomplete.

5.3. The Chief Coroner collects Regulation 28 "Reports to Prevent Future Deaths (RPFDs)" that have included Covid-19 vaccination as the cause of death. However, it is the responsibility of individual Coroners to address RPFDs relating to medicines to MHRA, UKHSA or the Dept of Health. **The MHRA has not obtained any copies of Regulation 28 reports** citing the Covid-19 vaccines [49] despite at least two reports having been issued to date, [50] [51] even though the MHRA is, ultimately, responsible for licensing their use.

5.4. HM Passport Office is responsible for the General Register Office which collects Death Certificates, some of which have included Covid-19 vaccination as the cause of death. However, there is no system in place to alert the MHRA to death certificates citing a medicine as the cause of death.

5.5. There has been a significant number of excess deaths recorded in the UK, along with many other countries. [52] There was a **noteworthy rise in deaths in young males from spring 2021**. [53] Excess deaths not associated with Covid-19, particularly from **cardiovascular causes**, have been noted [54] since spring 2021, with a brief interlude in winter 2021/22 when there were fewer seasonal deaths than expected. Excess deaths across all age-groups have continued through most of 2022.

5.6. The only official statement regarding these excess deaths has come from the CMO, Dr Chris Whitty, in early December, who suggested that the excess deaths were due to heart disease and cancer cases being missed because of the prior Covid-19 lockdowns. This is **not supported by independent analysis**. [55] For example, there has been no reduction in prescriptions of heart drugs such as statins. [56]

5.7. There are fundamental problems in calculating vaccine effectiveness and safety, due to differences between ONS [57] and NIMS [58] datasets for the number of unvaccinated people. This has been highlighted repeatedly [59] but the MHRA has made no attempt to resolve this.

5.8. **Post-mortems**

5.8.1. The Royal College of Pathologists conducted a c**entralised audit of Covid-19 deaths** to better understand the pathology, despite the Coronavirus Act severely limiting the number of post-mortems. However, there has been **no similar work carried out for deaths following vaccination.**

5.8.2. In contrast, other countries have reported on **post-mortems after post-vaccination deaths.** In Germany, a study of 35 autopsies found 5 deaths caused by the vaccine, with a further 20 deaths where a contribution from vaccination could not be excluded. [60] Post-mortem studies have also shown inflammation of the coronary arteries after vaccination, causing death months later. [61] Furthermore, a separate post-mortem study found vaccine-derived spike protein in the heart muscle of a subject who had myocarditis before they died, in the absence of Covid-19 infection. [62] In addition, two US teenagers had died from myocarditis induced by vaccination. [63]

5.8.3. Despite this evidence, the MHRA appears to have made no attempt to obtain post-mortem information, and there are **few if any pathology laboratories in the UK that are performing the specialist stains for spike protein** used in Germany and the US.

6. LISTENING TO PATIENTS

6.1. In 2020, the Cumberlege Report [64] said that the healthcare system, including the MHRA, is "disjointed, siloed, unresponsive and defensive. It has failed to listen to (patients') concerns and when, belatedly, it has decided to act it has too often moved glacially.". Evidence below from Covid-19 vaccine injury support groups suggests nothing has changed.

6.2. UK CV Family [65] is the largest Covid-19 vaccine injury support group in the UK representing around 1000 members who have all been either injured or bereaved by the Covid-19 vaccinations and around 50 joining each month. They have strict membership criteria, those curious about vaccines or seeking information to use for their own agenda are not permitted to join.

6.3. So far, UK CV Family have contacted over 200 MPs that represent their vaccine-injured and bereaved constituents and the group has found over a third of those MPs to be supportive. This support ranges from help with applying for benefits through to raising questions and debating in Parliament.

6.4. UK CV Family have also contacted every NHS board director in the UK, offering to collaborate and help those suffering adverse reactions, but unfortunately none responded.

6.5. The MHRA has not been proactive in informing health professionals and the public of potential vaccine side-effects. Many doctors are not aware of the multiple symptoms and mechanisms behind Covid-19 vaccine adverse reactions, and this can lead to delayed diagnosis, treatment and many months of illness and suffering.

6.6. Members of UK CV Family have found that many doctors are not reporting their adverse reactions to the MHRA's Yellow Card system and therefore have had to file these reports themselves. They describe the Yellow Card system as difficult to navigate, for the following reasons:

a) The system consists of a complicated questionnaire that may be straightforward for medical professionals to use, but not for the general public.

b) There are multiple health conditions not listed in the drop-down menu.

c) Many patients have found that doctors have not completed a Yellow Card on their behalf, and some have been told to do this themselves. The Yellow Card system has never been marketed to the general public – many members were not aware of it until they joined the organisation.

d) The system is extremely challenging for anyone who is dealing with neurological issues.

e) Users have been unable to access their reports, and some have gone missing from the system.

f) After submitting Yellow Card reports, many members have not been given the opportunity to speak directly to an MHRA representative, and have only had access to inadequate and difficult email interactions with the MHRA.

6.7. UK CV Family wrote to Dame June Raine at the start of June 2022, [66] informing her of the group and offering to work with the MHRA going forward to help improve the system and the MHRA's response to those who have suffered adverse events. MHRA's reply was that members should all report via the Yellow Card system, that its Patient Involvement Strategy 2021-2025 [67] was being implemented and that the MHRA will "engage and involve the public and patients at every step of the regulatory journey". However, UK CV Family has not been contacted about any involvement and is not aware of any contact with its members.

6.8. UK CV Family also requested an urgent meeting with the new Patient Safety Commissioner (Dr Henrietta Hughes). The reply (13 December 2022) implicitly rejected a meeting, stating, "The Commissioner is resolutely focused on the issues which were raised in the First Do No Harm Review and a significant amount of time and resource from the Office is currently focused on the contents within the review, including the issues of Sodium Valproate and Mesh."

6.9. However, so far, UK CV Family are unaware of any members being contacted by the Patient Safety Commissioner, nor by anyone investigating the ongoing adverse reactions suffered by their members.

6.10. Vaccine Injured and Bereaved UK' (VIBUK) [68] is another Covid vaccine injury support group. It, too, has approached MHRA but has achieved no significant interaction.

6.11. The inexorable conclusion, made by groups representing the vaccine-injured and bereaved, is that the MHRA is still not listening.

C. REGULATION OF THE COVID-19 VACCINES

7. MHRA REGULATIONS BEFORE COVID-19

The Medicines and Healthcare products Regulatory Agency (MHRA) had already been criticised for its **lack of safety management and slow response to safety concerns**. Examples include the withdrawal of medications and devices that caused harm and the MHRA's failure to take action. It did not learn lessons from the rushed Swine Flu vaccine in 2009, and was heavily criticised in the Cumberlege Report in 2020. Funding cuts and staff shortages also undermined MHRA regulatory performance. Accountability and liability for drug harm stands in stark contrast to the finance industry.

7.1. Between 1971 and 2013, 55 prescription medicines were withdrawn on safety grounds in the UK. [69] The average time between licensing and withdrawal due to safety concerns was **approximately 10 years** (median 5 years), and it was not always the MHRA that took the first action. For instance, Pandemrix, a swine flu vaccine approved in 2009 after rushed clinical trials, was initially withdrawn on safety grounds by regulators in Sweden and Finland, as well as by the manufacturer, **but not by the MHRA**. [70] It is worth noting that the reporting rates of narcolepsy, a type of brain injury, were 10 times higher in these two countries than on the UK Yellow Cards. [71] There were **many lessons** [72] **for the MHRA to learn from this episode but it appears they were not learned**.

7.2. Another example is the contraceptive device Essure, which contains nickel. The manufacturer withdrew the product after a BBC program in 2017 reported multiple issues, some of which resulted in hysterectomies. [73] **However, the MHRA failed to take any action and continued to offer reassurance.**

7.3. The Cumberlege Inquiry investigated serious safety concerns with Primodos, sodium valproate, and pelvic mesh in 2018. The inquiry's report [74,75,76] in 2020 concluded that *"the healthcare system - which includes the NHS, private providers, the regulators and professional bodies, manufacturers, and policymakers - is disjointed, siloed, unresponsive and defensive"*. Theme 11 of the report highlighted **the need for improved regulation by the MHRA. While the MHRA** Delivery Plan 2021-23 [77] outlined the improvements it planned to make to its regulation of medicines to **address the identified problems**, it focuses primarily on "listening to patients" neglecting to address the basic safety governance issues outlined in Section 14.

7.4. On 13 December 2022, the Health Select Committee held a follow-up session to review progress with the implementation of the report's recommendations. [78] While the Committee noted that a start had been made, they also expressed concerns about the **slow progress.**

7.5. The MHRA faced additional challenges due to Brexit, which required them to regulate all UK medicines, a task previously covered by the European Medicines Agency. Unfortunately, in 2021, the MHRA had to make **300 redundancies** due to funding cuts, which further complicated matters. To make matters worse, as of August 2022, its vacancy rate was **20% below the new baseline**, [79] leading to major shortfalls in manpower, skills, and experience.

7.6. In contrast to the finance industry, where the senior management of banks can be held responsible for failures, pharmaceutical manufacturers do not hold their board of directors accountable for failures. Additionally, there is no capital requirements directive in the pharmaceutical industry, to ensure that manufacturers have enough credit to cover liabilities towards patients. Furthermore, unlike the finance industry, there are no outsourcing rules in the pharmaceutical industry to ensure that the primary risk of products remains within the manufacturer.

8. LICENSING OF COVID-19 VACCINES

8.1. In March 2022, Dame June Raine, Chief Executive of the MHRA, spoke proudly of the agency's transition **from "the watchdog to the enabler"** at a presentation at Somerville College, Oxford [80].

8.2. The Covid-19 vaccines have set new records for the speed of clinical trials and regulatory approval. Typically, the development and authorisation of a new medicine for public use **takes around 10 years**. The drug must pass through phases 1 to 3 of clinical trials and receive regulatory approval. Phase 1 trials involve a small number of healthy volunteers to assess dosage and side effects. Phase 2 trials test the drug on a small number of subjects to evaluate its safety and effectiveness. Phase 3 trials involve several thousand participants to determine the efficacy of the new drug compared to existing drugs or a placebo. However, the entire process of developing and authorising the Covid-19 vaccines was **compressed into less than a year** due to the urgent public health threat posed by the pandemic. [81]

Covid -19 Vaccine Development

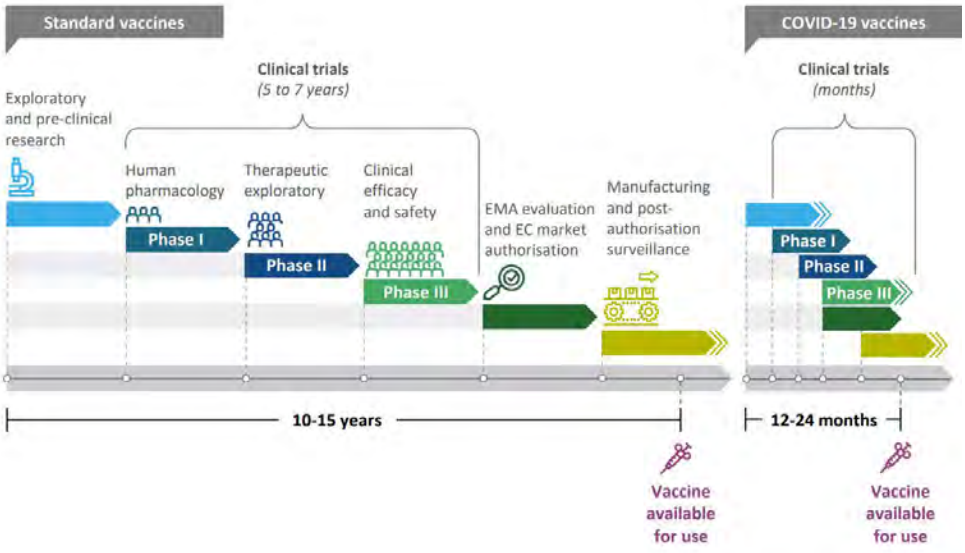


Figure 3. Standard vaccine development process and timeline vs Covid-19 vaccine development [82]

8.3. Regulation 174 of the Human Medicines Regulations was used to permit Temporary Authorisation while clinical trials were still only partially complete. **Huge political pressure** was brought to bear on a regulator with a poor recent record and serious resource problems as already described.

8.4. The risk from Covid-19 is **highly age dependent**, with a low risk for individuals under 60 without comorbidities. [83] The authorisation did not account for this. The accelerated timeline raised concerns about the adequacy of the risk/benefit analysis, particularly for use in children.

8.5. The WHO produced draft regulations for mRNA products in December 2020, [84] only weeks before temporary use authorisations were granted for Covid-19 vaccines. However, these **new regulations were quickly abandoned**, and the vaccines were approved using the same regulations as traditional vaccines.

8.6. The MHRA classified mRNA gene therapies as vaccines rather than medicines, which **lowered the regulatory requirements**, resulting in limited evaluation of pharmacodynamics, pharmacokinetics, and toxicology. The original Human Trial Information Sheet acknowledged this fact, [85] "Due to the urgent need for a vaccine against Covid-19, with agreement from the MHRA, some of the tests usually required for a newly manufactured vaccine have been modified, in order to make the vaccine available more quickly for assessment in this clinical trial."

8.7. At the time of the Temporary Authorisations in late 2020 and early 2021, Phase 3 trials for the vaccines were still ongoing, [86] with some trials not expected to complete until 2026. [87] The **manufacturers anticipated more thorough regulatory checks**, but the MHRA classified mRNA gene therapies as vaccines rather than medicines, resulting in lower regulatory requirements. Consequently, there was limited evaluation of pharmacodynamics, pharmacokinetics, and toxicology. For example, in March 2020, Pfizer [88] said, "*.... other jurisdictions may consider our mRNA-based product candidates to be new drugs, not biologics or gene therapy medicinal products, and require different marketing applications.*"

(cont)

In August 2020, Moderna said, [89] *"Currently, mRNA is considered a gene therapy product by the FDA. …. In addition, because no product in which mRNA is the primary active ingredient has been approved, the regulatory pathway for approval is uncertain. …. Moreover, the length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority …. may be difficult to predict."*

8.8. After the authorisation, it was discovered that no human studies had been conducted to determine the **distribution of the vaccine in the body, the organs that would produce spike protein, the quantity of spike protein produced, and for how long it would be produced**. Such measures are standard procedure for determining the amount of active substance in a drug before it is licensed. The MHRA did not require this research to be conducted prior to emergency approvals and full licensing, even though standard procedures mandate that manufacturers specify the amount of active substance in a drug.

8.9. The MHRA has not required these studies be conducted since authorisation either, but researchers have carried out this work. Human studies published more than a year after the vaccine rollout began showed mRNA was detectable in the bloodstream [90,91], for up to 28 days and both mRNA and spike protein were detectable in lymph nodes for up to 8 weeks post-vaccination. [92] In addition, **spike protein was found circulating in the blood for 4 months.** [93]

8.10. **Animal work was very limited.** Rat studies, [94] the results of which were only obtained by a Freedom of Information Request (FOIR), showed that lipid nanoparticles accumulate in organs including the spleen, heart, and ovaries, with levels still rising after 9 days. No distribution studies were done using the final mRNA product.

8.11. Pfizer's non-clinical overview document revealed that safety pharmacology, carcinogenicity, pharmacokinetic, and genotoxicity studies were not conducted as they were **"not deemed necessary".** [95] The MHRA's unprecedented rapid approvals meant that they did not appear to have identified (or discounted without investigation) that some of the ingredients were **novel and known to be toxic**.

8.12. For instance, Pfizer's lipid ingredients ALC-0159 and ALC-0315 had not been included in any licensed drug before and had undisclosed quality control standards. [96] ALC-0315 is a type of man-made molecule called a cationic lipid, which can be toxic because it can trigger a process that leads to inflammation and cell death. This has become a major challenge for using cationic lipids in different applications. [97] ALC-0159 contains PEG (Polyethylene glycol) which is known to **cause anaphylaxis**, [98] a life-threatening adverse effect.

8.13. The lipid nanoparticle technology used in the mRNA vaccines was previously **found to be toxic** when multiple doses were given, in attempts to make it work for conventional gene therapy. [99]

8.14. There were many reasons why the MHRA should have exercised **additional caution** for these products:

- There were **numerous warnings** that expediting the vaccines could increase the risk of downstream problems, including an article in Nature in October 2020, [100] warnings from UK Medical Freedom Alliance in November 2020, [101] and Dr. Sucharit Bhakdi's statements in December 2020; [102]

- there were 5 cases of **cardiac or respiratory arrest** in the group that received the Pfizer/BioNTech vaccine, compared to 2 in the placebo group; [103]

- the adenovirus vector used in the AstraZeneca vaccine has been known since 2007 to cause **platelet activation**, which can lead to blood clots;

- the mRNA in the vaccine is modified with synthetic nucleic acid to prevent it from degrading quickly in the body. It is **not known how the body handles this synthetic mRNA;**

- the spike protein, which is the **most toxic part of the virus**, can cause various medical problems. The protein code used in the vaccine was altered by folding away the area that allows the virus to enter cells (the receptor binding domain), but the lipid nanoparticles used in the vaccine undermined this by producing spike protein from inside cells;

- mRNA within cells can alter the cell's "signature," making it appear foreign to the immune system and increasing the **risk of autoimmune disorders;**

- spike protein has been shown to negatively affect the integrity of the human blood-brain barrier [104] and has been found in heart muscle cells and blood vessel walls. **Studies which could have identified these issues were not requested from the manufacturers before authorisation or since.**

8.15. The boosters and the children's vaccines were subjected to even less robust approvals than the original vaccines:

- Moderna bivalent booster was approved based solely on antibody levels in the blood, in a trial which included only 437 people.[105] Approval was given **despite a lower efficacy in preventing Covid-19 than the original vaccine;**

- Pfizer BA4/5 bivalent booster was approved [106] based largely on the data from testing the BA1 vaccine, which is a **different vaccine**. Even the BA1 trial itself involved only 610 participants; [107]

- a Pfizer representative admitted there was "no established immune correlate of protection" from their product. Yet boosters and the **children's vaccines** were authorised using antibody production as a proxy for clinical protection.

9. DEVELOPMENT AND MANUFACTURING

The MHRA should have been concerned about maintaining quality and safety when scaling up Covid-19 vaccine production. **Good Manufacturing Practice regulations were not followed** during the rollout of Covid-19 vaccines. **Batch problems** have occurred worldwide, resulting in withdrawals prior to release and after use. Vaccine preparation in vaccination centres increased the risk of **overdosing**.

9.1. The MHRA should have had **concerns about maintaining quality and safety when scaling up production** of the Covid-19 vaccines from small-scale trials to full-scale production - a common area of risk in many sectors, including medicines. In particular, larger quantities of ingredients are more difficult to mix, heat/cool, and package, [108] especially with fragile mRNA.

(cont) Additionally, the manufacturer must ensure that the manufacturing process is affordable, safe, and reliable/consistent. Another issue is that staff involved in full-scale production may be less skilled than those involved in lab manufacture of small quantities for research/trials.

9.2. It is not surprising that there have been **batch problems** with Covid-19 vaccines worldwide. Two batches were withdrawn prior to release, but there was no media coverage and sparse details obtained through Freedom of Information requests. [109, 110] One batch resulted in the hospitalisation of 120 children in Vietnam. [111] In Japan, 1.63 million doses of Moderna were recalled due to metallic contamination.[112]

9.3. The process of thawing, diluting and mixing Pfizer vaccines is carried out in vaccination centres, which poses a risk of **inadequate mixing leading to overdosing**. This risk is particularly significant when mixing is done by volunteer vaccinators instead of trained healthcare professionals. Good Manufacturing Practice, [113] the regulatory handbook covering drug manufacture, legally mandates "finishing" to be carried out in a facility licensed to manufacture pharmaceutical products, to minimise the risk of potentially dangerous errors. The vaccination centres, hastily constructed for the Covid-19 vaccine rollout, did not have the required licences and would not have been eligible for one.

10. QUALITY CONTROL

mRNA is responsible for protein production, and any alterations in its sequence can impact the protein's function. Leaked documents have revealed a significant **decrease in RNA integrity** in commercial batches of the Pfizer-BioNTech vaccine. The safety and efficacy implications of this drop in quality remain unclear, and contracts allowed for **exemptions from independent quality testing** of the vaccine vials. There has been limited investigation into the **potential unintended proteins** resulting from truncated or modified mRNA species; instead the **acceptance criteria were lowered** allowing for fragmented or truncated mRNA molecules. Evidence has emerged suggesting **possible fraudulent data** related to protein expression.

10.1. mRNA is a molecule that contains genetic instructions for making a protein. The sequence of the mRNA determines the sequence of amino acids that will make up the protein. The three-dimensional shape of the protein is critical for its function, and this shape is determined by the sequence of amino acids and the way they fold. If the mRNA sequence is altered, the resulting protein may have a different sequence of amino acids and/or a different folding pattern, leading to **changes in its function that are not well understood.**

10.2. Information has been released from leaked emails from the European Medicine Agency. [114] Assessment reports and Pfizer-related documents revealed an **alarming drop in the RNA integrity** of the Pfizer-BioNTech vaccine in commercial vaccine batches (around 55%) compared to clinical trial batches (around 78%). This was known by key regulators, including the MHRA, just a few weeks before emergency use authorisation was granted on 1st December 2020. [115] The EMA classified this drop in quality as a 'product related impurity,' and the solution was to lower the acceptance criteria of the commercial batches rolled out to the general public to 50%.

(cont)

Vaccine manufacturers have been allowed to produce lots/vials/doses where up to half of the mRNA molecules are fragmented or truncated. The safety and efficacy implications of this drop in quality of the vaccine were unknown, and **no tightening of acceptance criteria has occurred over the subsequent two years.**

10.3. The possibility of translated proteins other than the intended spike protein, resulting from truncated and/or modified mRNA species, was not properly investigated. BioNTech failed to characterise the protein expressed by the vaccine's modified mRNA and no sequencing of the expressed protein of the mRNA vaccine has been published. Recently, evidence has emerged suggesting that BioNTech and Pfizer **falsified key data**. [116] The size of proteins produced can be demonstrated using a process called Western blot tests. The results of such tests submitted to the regulator revealed *"highly unusual looking bands,"* indicating possible fraudulent data.

10.4. Visible particles were also observed in many of the commercial batches and classified as 'product-related impurities'. Canadian pharmacist, Maria Gutschi PharmD, who has over 30 years of experience in hospital, community, and government, discussed quality-related issues with the Pfizer vaccine in a highly informative presentation video. [117]

10.5. In the EU's PSUR, an important pharmacovigilance document, a section entitled "Most Frequently Reported Lot Numbers" revealed that from one lot, EL1484, a staggering 16,077 individuals reported adverse events. [118] Furthermore, an analysis of the contracts [119] signed by many countries to purchase the Pfizer/BioNTech vaccine, allowed for *"exemptions and waivers of country specific requirements for the Product or permitted by the Government authority (including but not limited to serialization*, **applicable laboratory or quality testing)."** This meant that **independent quality testing of the vials was prohibited by the purchasing contracts**. Many of these contracts have become available through the non-profit consumer advocacy organisation Public Citizen. [120]

10.6. In addition, a recent analysis of vaccines by an independent laboratory [121] has shown contamination with DNA in large quantities. This has potential risk of i**ntegration into the recipient's genome. The MHRA have published no details of quality control assessments.**

11. SAFETY MONITORING

The Covid-19 vaccines were granted **temporary** authorisation based on incomplete clinical trials. The MHRA promised "Proactive Vigilance" with four strands of monitoring, but an FOI request revealed that the latest report from one strand of monitoring was **15 months old**. MHRA's pharmacovigilance is also limited by several issues, including the use of disproportionality analysis and the voluntary nature of Yellow Card reporting. MHRA's **lack of proactive investigation** raises concerns about the completeness of its safety surveillance.

11.1. After drugs are approved, they are monitored by collecting and investigating **reports of adverse events**. However, this system has allowed unsafe drugs to remain on the market for years before being withdrawn (Section 7.1).

11.2. The Covid-19 vaccines were granted temporary authorisation based on incomplete clinical trials, so the MHRA promised **"Proactive Vigilance"** [122] "to quickly detect a potential safety signal" . This involved four strands of monitoring. In November 2022, an FOI request [123] asked for the latest report from one of these strands (Targeted Active Monitoring). However, the report provided was **15 months old** (from August 2021).

11.3. One of the strands of analysis at the MHRA was "Rapid Cycle Analysis and Ecological Analysis". The MHRA's Clinical Practice and Research Datalink division maintains a bibliography of peer-reviewed research and reports [124] that have used population-level data provided by the MHRA from NHS datasets for ICU, A&E, inpatients, outpatients, cancer registration, and pregnancy. However, it is apparent that the MHRA is either not conducting routine population-level data analysis or is not publishing the results because:

a) in January 2022, the MHRA confirmed that it **did not have any population-level hospitalisation analysis;** [125]

b) in August 2022, the UKHSA stated [126] that it only held population-level information on Thrombosis with Thrombocytopenia Syndrome (TTS); [127,128],

c) none of the datasets provided by the MHRA's CPRD division for analysis include any NHS data **after June 2021**;

d) as of February 2023, **only two population-level studies** relating to the Covid-19 vaccines were present in the MHRA/CPRD bibliography. Both studies focused on thrombocytopenia, **only one** of the Covid-19 vaccines' serious side-effects. [129]

11.4. There are further concerns, related to the MHRA's pharmacovigilance, based on statistical analysis of the accumulation of Yellow Card reports. These include:

a) the first filter used by the MHRA involves a weekly review of yellow card data on adverse events that are **more common than for other vaccines,** called "disproportionality analysis". [130] However, this 'relative' approach to safety surveillance is not used in other safety-critical sectors, and it risks being circular because **it does not account for the contribution to the background rate of adverse events from other vaccines or medicines;**

b) the disproportionality analysis is sensitive to the threshold settings, and **if set too high, potential signals of harm may be missed**, while if set too low, too many signals of interest may be generated. With the Covid-19 vaccines, the number of yellow card reports was unprecedented, so it seems likely that the thresholds were set high to avoid being overwhelmed by the volume of data;

c) in June 2022, the MHRA presented, to the Commission on Human Medicines Pharmacovigilance Expert Advisory Group, a report on the impact of the large proportion of Covid-19 vaccine reports in its Yellow Card database on disproportionality analysis and signal detection. However, an FOI request in December 2022 for a copy of the report is still outstanding;[131]

d) the way reporting has been set up means that adverse events are often distributed across many specific descriptors and categories, making it challenging to detect signals of harm based on individual event types;

e) Yellow Cards are a voluntary reporting system and there is known under-reporting. The system is estimated to capture only 10% of fatal or serious adverse events. [132] However, the MHRA has not provided its own estimate of the level of under-reporting but instead highlights that the voluntary nature of the system means that reported events could all be coincidences.

11.5. **MHRA does not have a process for investigating individual reports**, [133] even for reports involving serious side-effects, [134] deaths, or cases involving children and pregnant women. A proactive safety regulator would urgently and systematically follow up on the highest priority reports, but the MHRA does not seem to do so. When asked how many fatal Yellow Card reports it had followed up, the MHRA could not answer, stating, "Although we hold information on whether a Yellow Card report has been followed up, this information is not easily extractable...We consider that extracting the number of fatal reports that have been followed up will take longer than 24 working hours to complete". [135]

11.6. Finally, the MHRA has not published any commissioned prospective studies of vaccinations to proactively look for myocarditis, clotting disorders or other conditions. This **lack of proactive investigation** raises concerns about the completeness of the MHRA's safety surveillance process.

12. MHRA'S role in regulating advertising and false claims

The MHRA has **responsibilities for the monitoring of, and the enforcement of laws governing, the advertising of medicines in the UK**, which are outlined in its own guidelines to these laws "The Blue Guide". However, despite several complaints, they have proven unwilling to investigate any excessive promotional claims regarding covid vaccine safety and efficacy.

12.1. The MRHA in its own 'Blue Guide' [136] says ***"Advertising which states or implies that a product is "safe" is unacceptable. All medicines have the potential for side-effects and no medicine is completely risk- free..."***. However, the MHRA, the UKHSA and the NHS have all frequently used this term, along with numerous other breaches of advertising laws, when promoting use of Covid-19 vaccines. Despite several complaints about this specific matter the MHRA has continuously refused to take any enforcement action.

12.2. In another example, the vaccine manufacturers have focused on promoting the vaccines' Relative Risk Reduction (a large percentage), rather than the Absolute Risk Reduction (a small reduction of a very small risk). The Association of the British Pharmaceutical Industry (ABPI), the pharmaceutical industry's regulator, in its Code of Practice [137] **prohibits the use of relative risk reductions without discussing the absolute risk reduction** and the industry self-regulatory body the Prescription Medicines Code of Practice Authority (PMCPA) has upheld several complaints about this. However, government officials and agencies (including the MHRA themselves) are also guilty of this exaggeration and misrepresentation and the MHRA has again taken no action.

12.3. The MHRA is **responsible for monitoring the advertising of medicines**, as outlined in its 'Blue Guide,' but there is no evidence that it has investigated any of the excessive claims regarding vaccine safety. [138] Rather than take action, the MHRA have responded to complaints by asserting (without evidence) that advertisements forming part of government public health campaigns are **exempt** from the definitions and requirements of the Medicines Advertising Regulations.

12.4. A complaint filed by parents' action group UsForThem against Pfizer, was upheld by the ABPI, in relation to safety claims made by its CEO. [139] The MHRA is not known to have taken any enforcement action in this regard.

D. OTHER ISSUES

13. LACK OF TRANSPARENCY

The number of FOI requests to the UK's Medicines and Healthcare products Regulatory Agency (MHRA) has significantly increased, likely due to concerns about the regulation of Covid-19 vaccinations. However, the MHRA has been **slow to respond to these requests and often applies exemptions**, leading to complaints and **calls for greater transparency**, including the publication of the minutes of independent safety advice meetings.

13.1. The number of Freedom of Information (FOI) requests to the MHRA has increased substantially, from 609 in 2019, to 753 in 2020, and 1609 in 2021. A significant proportion are related to concerns about the regulation of Covid-19 vaccinations. However, **only 76% of these requests** were answered within the 20-day timeframe, with some receiving vague or evasive responses. For example, *"Regarding your request for information on the quantity of water in BNT162b2, MHRA neither confirms nor denies that it holds information falling within the description specified in your request."*

13.2. The MHRA also does not publish its FOI replies in a timely manner, with the **last disclosure being dated April 2022** , [140] and when it does publish, the original request is not included. Although the MHRA is required to have a "Publication Scheme" in line with ICO requirements, [141] there is none on its website.

13.3. The MHRA often applies FOI exemptions, including Section 12, *"Cost of compliance* exceeds appropriate limits," which seems **unreasonable when applied to questions that a proactive safety regulator should know already.** For example, in November 2021, an FOI [142] asked how many of the 1490 deaths reported by Yellow Card as potentially attributable to the Covid-19 vaccines had been investigated. The MHRA applied a Section 12 exemption – which implies that it did not know. Sometimes the MHRA has applied Section 22: *"Future publication"* and yet not gone on to publish the requested data. [143] Some FOI requesters have had to escalate their requests for Internal Review and raise complaints with the Information Commissioner. An independent audit in 2018 found that only 41% of FOI requests to the MHRA were successful compared to 77% for the US FDA. [144]

13.4. The MHRA uses the Commission on Human Medicines (CHM) to provide independent safety advice about all medicines. The minutes are published [145] **except those relating to the Covid-19 vaccines**, [146] despite mounting evidence that the claimed benefits were overstated and the risks understated. For transparency and to facilitate informed consent, these minutes should be publicly available.

14. SHORTCOMINGS AGAINST BEST PRACTICE SAFETY MANAGEMENT

MHRA's shortcomings against best practice include : **group decisions** rather than delegated safety responsibility to an individual, a **functionally-based organisation**, **lack of safety targets, use of relative risk assessment** and monitoring, and **lack of senior management safety governance.** These are considered to contribute to MHRA's **slow response to safety issues**. Furthermore, MHRA's safety management processes are not subject to **independent audit**.

14.1. **Responsibility & Accountability:** The Secretary of State for Health and Social Care retains personal accountability, as the Licensing Authority under the Human Medicine Regulations (Part 1, Section 6), for ensuring the safety of medicines in the UK. The Secretary of State delegates the responsibility for medicine safety to the MHRA for practical purposes. However, there is no process for delegating this safety responsibility within the MHRA. [147] Furthermore :

- medicines are assessed by groups of individuals [148] and **no single person within the MHRA is responsible for the decision to authorise;** [149]
- the MHRA is organised functionally, [150] with licensing and pharmacovigilance as two separate divisions, which further dilutes responsibility.

14.2. In contrast, in other safety-critical sectors there are clear, documented processes which define, among other things: the scope of the delegation of safety responsibility down and across the organisation, the requirements for the competences (qualifications, skills, experience, and training) of an individual to hold a safety delegation, any limitations on individuals' delegations, and the requirements for structured, routine safety reviews of products authorised by individuals in receipt of safety delegations.

14.3. Additionally, the lines of governance are not clear - the Joint Committee on Vaccinations and Immunisations (JCVI), NHS, Department of Health, MHRA and Secretary of State are all responsible for decision-making on who receives vaccinations.

14.4. **Authorisations:** Authorisation letters to companies are signed off by a person in the MHRA with the by-line "a person authorised to approve on behalf of the Secretary of State for Health." However, this is misleading because, as already noted, the MHRA has no delegation process for the signer to be "authorised to approve," nor are there any limitations on their "authority to approve" (such as type of medicine or level of safety risk).

(cont) The MHRA stated that *"Grant letters to companies do carry a signatory but this (is) most often provided by support staff and is simply an administrative formality."* [151] Yet, these authorisation letters are safety-critical because they contain safety-related conditions/limitations and **should be signed by delegated, competent individuals.**

14.5. **Safety Reviews:** There are no routine senior management safety reviews of individual medicines, even for high-risk products.[152] Compared with best practice, the lack of delegation of safety responsibility and governance of safety will have led to a weak safety culture.

14.6. **Risk assessment and monitoring** : In other safety-critical sectors, there is a clear, documented process for assessing the absolute risk and tolerability of products. In the defence sector, for example, this is done as part of the safety approval process (and monitoring usage) against absolute, quantified safety targets and risk assessments, as illustrated in figures 4 and 5. [153]

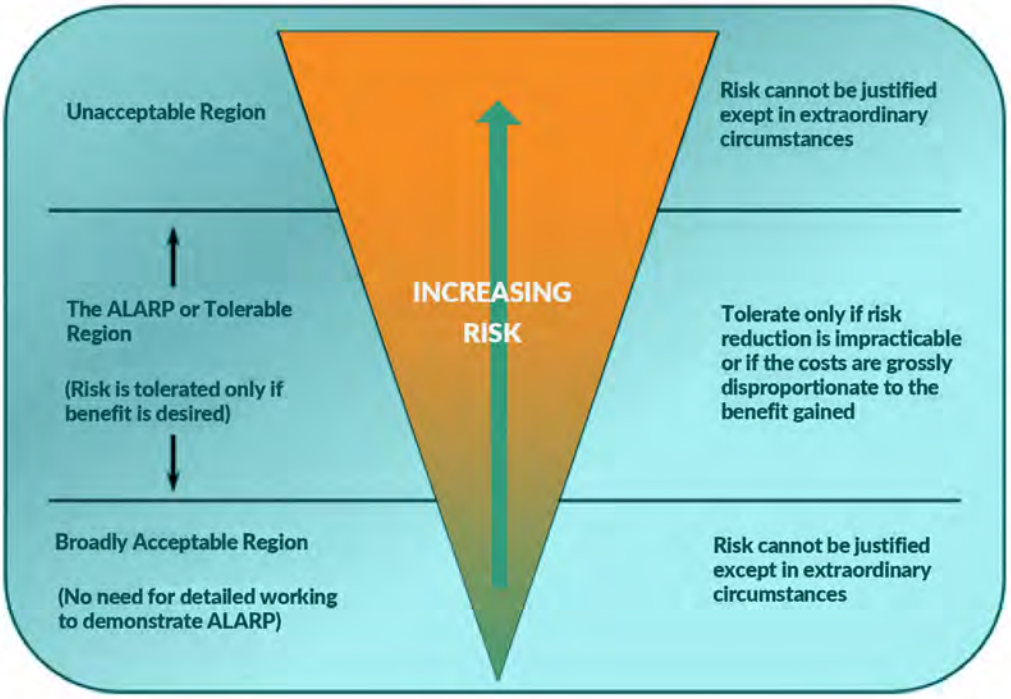


Figure 4: Risk Tolerability Framework Figure

		SEVERITY			
		Catastrophic	Critical	Marginal	Negligible
Frequency of Occurance	Frequent	A	A	A	B
	Probable	A	B	B	C
	Occational	B	C	C	C
	Remote	C	C	C	D
	Improbable	C	D	D	D
	Incredible	D	D	D	D

14.6. This underpins the governance of product safety. It helps to determine where to focus safety audit and assurance, the frequency and seniority of routine product safety reviews, the deployment of resources, and provides a clear threshold for action if subsequent evidence undermines the original safety risk assessment.

14.7. In contrast, **the MHRA defines "acceptably safe" in relative terms** : "For a medicine to be considered safe, the expected benefits of the medicine will be greater than the risk of suffering harmful reactions." [154, 155] Yet absolute risks will often turn out to be higher in practice due to the inherent limitations of clinical trials and lack of long term safety data.

14.8. Moreover, in monitoring usage, MHRA relies mainly on statistical analysis of Yellow Card reports to assess drug safety, comparing the frequency of side-effects for a new drug with those of other drugs. **No other safety-critical sector monitors safety on a relative basis.** It is like saying "his nuclear power station is safe because he gets fewer water leaks than yours".

In response to the first urgent report on 9th June 2021, which expressed serious concerns about the safety of the vaccine, Dr June Raine of the MHRA responded on July 22nd 2021 that **"reported events are not always proven side effects**. **Some events may have happened coincidentally."** Further to this, Dr Raine wrote: *"Overall, the number and nature of suspected ADRs reported so far is not unusual for an immunisation programme of this scale and the data we have analysed and published indicates that the safety of the COVID-19 vaccines is as expected based on the robust clinical trial data that supported the authorisations."*

14.9. Moreover, signal detection using statistical analysis is sensitive to the threshold levels used, and the MHRA is itself concerned about data bias caused by Covid-19 vaccine Yellow Card reports, which now dominate its database by about 20:1. [156]

14.10. Independent Audit & Assurance. Other safety-critical sectors are regularly subject to independent safety audits of both their products and internal safety management processes, as well as seeking regular independent assurance about their safety management systems. In contrast, it appears that the MHRA has never been subject to an independent safety audit. [157] The Commission on Human Medicines (CHM) provides independent assurance to the MHRA regarding the risks and benefits associated with individual medicines, but nobody provides independent assurance about the MHRA's internal safety management processes.

14.11. The MHRA conducts a biennial quality audit of its Pharmacovigilance system, as required by the Human Medicines Regulations. [158] However, there is a significant difference between a quality audit and a safety audit, and the biennial quality audit does not cover the MHRA's licensing process, which certifies medicines as "acceptably safe" in the first place. This lack of independent safety audit and assurance, for both products and internal safety management processes, leaves the MHRA vulnerable to failing to detect one-off and/or systemic errors and omissions. It also impedes wider improvement in its safety management.

15. COST RECOVERY & CONFLICTS OF INTEREST

The MHRA's regulation of medicines is mainly funded by fees from the pharmaceutical industry, while medical device regulation is primarily funded by taxpayers, prompting serious **concerns over transparency and the potential for conflicts of interest.**

15.1. The MHRA's regulation of medicines is primarily funded by fees from the pharmaceutical industry, [159] in line with Treasury guidance. [160] It is unclear why the MHRA's medical device regulation is funded differently, with a larger proportion of funding coming from taxpayers and only a small portion from fees. It is worth noting that all UK regulators have different cost recovery regimes.[161]

15.2. The MHRA is not unique in facing **concerns over industry funding**. Similar concerns have been raised regarding the funding of the FDA and EMA. [162]

15.3. In 2017, the MHRA **received over £980,000** from the Bill and Melinda Gates Foundation which is heavily invested in vaccines.

15.4. The key question is whether taxpayer funding of the MHRA's licensing and monitoring activities would improve safety management, particularly given the fundamental failings that have already been discussed.

15.5. The MHRA competes with the pharmaceutical industry for talented staff, and it is not uncommon for individuals to work in both sectors during their careers. To mitigate any potential conflicts of interest, stronger disclosure systems could be implemented to **reduce the risk of biased decision-making**.

E. CONCLUSIONS

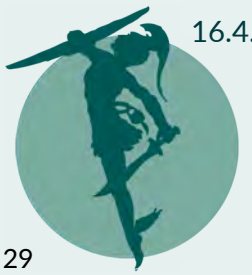
This detailed and comprehensive report has highlighted serious concerns regarding the MHRA's ability to regulate the safety and efficacy of medicines in the UK.

16.1. Despite previous warnings from the House of Commons Health Select Committee in 2004 [163] on the influence of the pharmaceutical industry, the late withdrawal of the Swine Flu vaccine in 2009, and the damning Cumberlege Report in 2020, it appears that **little has been learned and few actions have been taken to improve the situation.**

16.2. **The harm done to the vaccine-injured and bereaved family members, must be recognised.** Urgent measures are required to be put in place to ensure future victims are diagnosed, treated promptly and compassionately, and rapid action taken by the regulators to identify and reduce the risk of further injuries. In addition, we have a duty as a civilised society to recognise and make reparations for the huge price that many individuals and families have paid as a consequence of the failure of the MHRA to fulfil their duty of care to protect the public from dangerous products. Rapid implementation of easy access to much-needed financial and practical support and compensation must be made a priority, to alleviate significant hardship and suffering currently being endured by the vaccine-injured and bereaved.

16.3. Due to the **significant number of reported injuries** associated with Covid-19 vaccines **and increased deaths** across all age groups, it is imperative to **pause the use** of these products until a **thorough investigation** is conducted.

16.4. A comprehensive independent inquiry must be launched into the MHRA's regulatory processes and performance. The agency must **undergo an overhaul of its governance and accountability processes** to restore public trust.



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IMPORTANT QUESTIONS

What lessons from Pandremix influenced Covid vaccine Temporary Authorisation?
Why were mRNA products treated as vaccines, not gene therapies?
For how many other mRNA-based products has MHRA accepted fees relating to authorisation?
Why wasn't MHRA's manpower reduction or 20% vacancy rate in 2022 assessed for safety impact?

Would the government be concerned if other regulators shifted from "Watchdog to Enabler"?
Has advice been sought from other safety-critical sectors regarding MHRA's safety management?

What is MHRA's definition of the tolerable rate of fatal, serious and minor side-effects of medicines?
How does MHRA define 'safe'?
Why is safety monitored relative to other drugs, not in absolute terms?
What sensitivity analysis of signal detection levels was done in MHRA's Disproportionality Analysis?
What quality control information exists for Covid vaccine batches?

What risk assessments have been made for frequent mRNA boosters and their effects on the immune system, especially the potential for repeated antigen presentation inducing tolerance?
What risk management process was put in place for vaccination during a pandemic with a vaccine which did not prevent transmission?
What risk assessments exist for Covid vaccines in pregnancy, children, and reproductive-aged individuals?

What data has been gathered on death risk after vaccination?
What steps were taken to obtain post-mortem results?
Why isn't the government investigating links between Covid vaccines and excess deaths?

What was MHRA's assessment of the absolute risk reduction in December 2020 and now?
Other than trial data, what information was gathered to assess benefits?
What population-level hospitalisation analysis does MHRA hold?

Why were Covid vaccines licensed for younger age groups despite higher risk and lower benefit?
What was MHRA's assessment of the Number Needed to Vaccinate in December 2020 and now?

How did MHRA raise awareness of Yellow Card reporting and vaccine risks?
How many Yellow Card reports were investigated?
Does MHRA have a Vaccine Crisis Communication Manual?
Why haven't minutes from Covid vaccine expert working groups been published?
Why is Yellow Card data on the AZ vaccine no longer published?