

[informscotland.uk](https://www.informscotland.uk)

Date of letter: 20th May 2021

Dear Sir/Madam

The following is an open letter to the individuals, regulatory bodies, unions, healthcare authorities and professional institutions about a matter of very deep and urgent concern we have identified.

**Addressees:**

**Regulatory Bodies (members listed as permitted to administer vaccines under ScotGov protocol):**

- General Medical Council, Chair of the Council Dame Clare Marx
- Nursing and Midwifery Council, Chief Executive Andrea Sutcliffe
- General Dental Council, Chief Executive and Registrar Ian Brack
- General Pharmaceutical Council, Chief Executive and Registrar Duncan Rudkin
- Health and Care Professions Council, Chief Executive John Barwick
- General Optical Council, Chief Executive Officer Vicky McDermott

**Government bodies, individuals and Health Authorities:**

- Public Health Scotland, Chief Executive Officer Angela Leitch
- Scottish Government, Permanent Secretary Leslie Evans
- NHS Scotland Health Board Chief Executives (all 14 Boards)
- Prime Minister, Boris Johnson
- First Minister of Scotland, Nicola Sturgeon
- Deputy First Minister of Scotland, John Swinney
- Cabinet Secretary for Health and Social Care, Humza Yousaf
- National Clinical Director, Prof Jason Leitch
- Chief Medical Officer for Scotland, Dr Gregor Ian Smith
- Chief Nursing Officer, Professor Amanda Croft
- Chief Pharmaceutical Officer, Alison Strath

**Unions:**

- Unison Scotland, Scottish Secretary Mike Kirby
- Medical Defence Union, Chief Executive Christine Tomkins
- Medical and Dental Defence Union of Scotland, Chief Executive Chris Kenny
- Royal College of Nursing, Chief Executive Officer Donna Kinnair
- Royal College of General Practitioners, Chief Executive Officer Valerie Vaughan-Dick

**Also:**

- The Law Society of Scotland
- All MSPs
- All Scottish MPs
- All national and local newspapers and news channels

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**RE: The COVID-19 Vaccine Information Leaflets.**

We, Inform Scotland ([informscotland.uk](http://informscotland.uk)), are a group of professionals and conscientious Scottish citizens observing with concern the lack of informed consent in the rollout of the COVID-19 vaccines. We have been approached in recent weeks by professionals and members of the public, previously unknown to us, who also have grave concerns relating to this matter.

These concerns have been raised particularly in relation to circulating Scottish vaccine information leaflets. These are distributed to people in the 'Blue Envelopes' containing invitations to vaccination appointments. We have outlined our specific concerns about Version 5 in circulation in the attachment to this letter. We have access to other versions and have similar concerns about them all.

We share the view that neither the risks of COVID-19 nor the risks of the COVID-19 vaccines are being accurately communicated to people in these leaflets. We are concerned for the safety of the public. We are also concerned about the future legal problems **those giving vaccinations**, or **encouraging people to get vaccinated** may experience, in view of the fact that informed consent is hardly ever being obtained from participants in the vaccine programme.

We have tried to contact the three authorities named on the vaccine information leaflets using their indicated phone numbers. We have not been able to identify the authors of the leaflet, or any person who would take responsibility for the erroneous and incomplete contents.

The Supreme Court judgement of *Montgomery v Lanarkshire* (2015)<sup>1</sup> changed the standards of consent for medical procedures. We know you will be aware of this judgement. Patients must give informed consent for medical procedures, for the protection of the doctor (or other professional delivering a vaccine, for example) as well as the patient. The principles are very simple and we have outlined them below.

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In the context of the COVID-19 vaccines informed consent means:

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1. Participants in the vaccination programme must understand the risk from COVID-19. What is the risk that a person might become infected with SARS-CoV-2 without vaccination? What is the risk of a serious adverse outcome from infection with said virus and subsequent development of the disease COVID-19?
  2. Participants must accurately understand in a quantifiable way what the reduction in risk of suffering from COVID-19 is post-vaccination for them as an individual.
  3. Participants must understand the risk from the vaccine. They must understand what the known risks are and have those quantified to them as individuals. They must also understand what the limitations on the knowledge of the risks are and have those explained.
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In order to give informed consent in respect of the Covid-19 vaccines, there is a further, specific requirement that the patient is informed that safety trials have not been completed and that the

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<sup>1</sup> [Montgomery and informed consent - The MDU](#)

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vaccines remain currently only **authorised for emergency use**, and as such are **unlicensed** and not **approved** (see references in attachment). This is be a clear requirement for any person to be able to make a reasonable risk assessment.

In a vaccine safety trial, participants are followed up closely by research teams and monitored for side effects so that reactions to the trial vaccine can be recorded and studied. This process is incomplete for COVID-19 vaccines, the phase III clinical trials of which are not due to complete until 2023. Even so, people are being now vaccinated in their millions with no follow-up to ensure their safety, when expected reactions to these vaccines remain unknown.

None of these risk factors is being made clear to participants in the vaccine programme, and indeed, the vaccine information leaflet they receive **misinforms them on this and many other matters** and **fails to inform them** on several others. This means people are deciding to attend a vaccination appointment from a misinformed starting point and are therefore incapable of giving informed consent on the basis of the leaflet.

Regulated health professionals who are delivering vaccines without obtaining informed consent as required by *Montgomery vs Lanarkshire* are personally liable for subsequent vaccine damage **due to medical negligence**. The Government and Healthcare bodies delivering advice to the public about the vaccine have a responsibility to deliver that information in an accurate and comprehensive manner that informs, and does not mislead, both for their protection and the protection of healthcare professionals. Owing to the inaccurate and misleading nature of the information currently being provided, **Health Boards and GP practices may also find themselves liable for medical negligence**.

The information required to inform the public of the risks of infection with SARS-CoV-2 and the risks regarding vaccination is readily available to professionals and can be **reasonably expected** to be known by them. Professionals cannot rely on this patient information leaflet to inform a patient to give consent. We strongly urge that to ensure without any further delay that fully informed consent to Covid-19 vaccines is hereinafter obtained by each and every recipient of a Covid-19 vaccine, for the protection of the public and healthcare professionals.

Owing to the very serious concerns raised in this letter, we expect a response to this letter from the agencies listed by email to [admin@informscotland.uk](mailto:admin@informscotland.uk) by the end of May 2021, with each of the points addressed. This is an urgent matter of public safety. It is critically important the people of Scotland are able to trust their health authorities and have confidence in the advice they receive.

Yours Sincerely,

Inform Scotland

**Attachment:**

Re: The Covid-19 Vaccine “Important Information” Leaflet

Authored by: NHS Scotland, Healthier Scotland Scottish Government, Public Health Scotland

Version 5

Here we outline demonstrable and knowable items of misinformation in this leaflet relating to COVID-19 risks (exaggerated) and vaccine risks (minimised) and several major omissions of critically important information. This leaflet is the primary basis upon which people are giving consent for this vaccine, required to be **informed** under Human Rights legislation, Montgomery vs Lanarkshire and medical ethical codes.

Page 2 Section titled ‘What is COVID-19?’	
1.	‘[COVID-19] is <i>highly infectious and spreads through the air</i> when people cough or sneeze, or <i>when they touch surfaces where it has landed</i> then touch their eyes, nose or mouth.’
a.	The first part of this statement is misleading: although SARS-Cov-2 (not Covid-19) does spread through the air, the virus is only as infectious as susceptibility to it is high, and only infected people spread through coughing and sneezing. <sup>2</sup> Susceptibility to the virus is known to be continually falling from a recent large UK study. <sup>3</sup>
b.	The second part of this statement is also misleading: this virus has never been shown to spread through fomites. There have been many studies which have found the virus on surfaces, but culture has never been grown from these samples, nor is there any evidence that any person has contracted the virus through touching an infected surface. <sup>4</sup> In fact, recent scientific evidence clearly shows that fomite transmission is negligible. <sup>5</sup>
2.	‘It is possible to have COVID-19 without showing any symptoms’
	This is incorrect; COVID-19 is a disease and is a set of symptoms. It may be claimed, generally, that it is possible to be <i>infected</i> with SARS-CoV-2, or to <i>test positive</i> for that virus, when asymptomatic. But the <i>disease</i> of COVID-19 can only be experienced, identified and diagnosed by its symptoms.

<sup>2</sup> JAMA Network Open. 2020;3(12):e2031756. doi:10.1001/jamanetworkopen.2020.31756

<sup>3</sup> PHE Paper April 2021 “Impact of vaccination on household transmission of SARS-CoV-2 in England”

<sup>4</sup> [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30678-2/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30678-2/fulltext)

<sup>5</sup> <https://www.bmj.com/content/373/bmj.n913>

<p><b>Page 3 Section titled 'About the types of vaccine'</b></p> <p>This section, despite its title, gives no information about the types of vaccine. It does not reveal that Covid-19 vaccines are a new technology, nor how the different Covid-19 vaccines from different manufacturers vary. This is vitally important information to any person's attempt to give informed consent.</p>	
<p><b>3.</b> 'The vaccines will only be approved on the basis of <i>large studies of safety and effectiveness</i>'</p>	
	<p>This sentence is highly misleading in the way that it is drafted. The studies are in fact very small compared to the size of the population proposed to be vaccinated and therefore cannot determine likely outcomes in a much larger non-trial group. They are not approved in fact because the safety trials are not complete. They are authorised under emergency arrangements which, arguably, no longer apply, because the authorisation applies while a disease is in anticipation of being 'imminently in a pandemic' or 'a serious risk or potentially serious risk to human health'.<sup>6</sup> Currently, infection prevalence is 0.08% in Scotland, according to the ONS.</p> <p>Clinical studies carried out before the vaccine programme commenced in Scotland were all carried out on healthy individuals which are not representative of the general population. <b>Pregnant women were excluded from the trials.</b> On completion of those preliminary studies, we have very few data on safety or effectiveness in groups including elderly, children, pregnant women and those with pre-existing conditions and comorbidities. The risks to these groups therefore remain unknown.</p>
<p><b>4.</b> 'The UK vaccination programme has been very successful with tens of millions of people vaccinated and <i>many thousands of lives already saved.</i>'</p>	
	<p>This cannot be known. The decline in the cases and deaths in the UK as a whole have matched (or lagged) the decline at the end of the epidemic last year. This was clearly a seasonal effect then, since there was no vaccine in the spring of 2020, and there is no way to distinguish that it is not a seasonal effect now.<sup>7</sup> There is no clinical or statistical evidence to support the claim made in this leaflet. There is no control group to compare outcomes in the vaccinated to the unvaccinated. Finally, if this conclusion is being drawn on the basis of a comparison with autumn transmission and deaths, it is certainly invalid because it is not taking into account seasonal reductions in infections.</p>
<p><b>5.</b> 'The vaccine will reduce your risk of getting seriously ill from COVID-19.'</p>	
	<p>This statement must be quantified. The beneficial effect seen in the studies was minimal and infection rates have risen in almost every country where the vaccine has</p>

<sup>6</sup> <https://www.legislation.gov.uk/ukxi/2020/1125/regulation/14/made>

<sup>7</sup> See Graph at end of this document

	<p>been rolled out<sup>8</sup>, so it is in fact very difficult to calculate to what extent the reduction in risk of serious illness exists.<sup>9</sup> The studies were poorly designed to inform of the potential of the vaccines to save lives.<sup>10</sup> They also showed only a very low Absolute Reduction Ratio of around 1%.<sup>11</sup></p> <p>This statement also assumes that the risk is equal across the whole population regardless of age, good health etc. We know from official government statistics that the risk is not equal across the population. Those who are elderly, obese or have some well-defined pre-existing conditions have a higher risk of hospitalisation and death as a result of COVID-19 developing from SARS-CoV-2 infection.</p>
6.	<p>'Being healthy <i>does not reduce your risk of getting COVID-19 and passing it on.</i>'</p>
	<p>This is incorrect. Without comorbidities, or with minor comorbidities, you are much less likely to develop the <i>disease</i> COVID-19 following <i>infection</i> with SARS-CoV-2. If healthy, you are less likely to suffer severe symptoms and this reduces your risk of passing it on<sup>12</sup>. This is all very clear from the UK Government and Scottish Government data. Healthy people are not spreaders of this disease.<sup>13</sup></p>
7.	<p>'You can spread COVID-19 to family and those around you, even if you have very mild symptoms or <i>no symptoms at all.</i>'</p>
	<p>It is extraordinarily unlikely you will pass on the <i>disease</i> if you have no symptoms. Specifically, you cannot have a disease with no symptoms. But the proportion of cases attributed to spread of SARS-CoV-2 from an asymptomatic person is 0.7% in the home in the research, without correcting for false positives, so this is a tiny risk.<sup>14</sup> There was also a study of 10 million participants, published in Nature, which showed how negligible a problem asymptomatic transmission is.<sup>15</sup></p>
8.	<p>'Rates of COVID-19 infection remain high.'</p>
	<p>In the week 2nd to 8th May, the ONS prevalence survey showed that the infection rate in the Scottish population was 1 in 1250<sup>16</sup>. This is not 'high'. The percentage of positive tests being returned has been hovering around or below 1% for weeks in Scotland at the time of writing (15th May) and the false positive rate is unknown. This is a very low rate of infection and possibly, in fact, represents the false positive baseline. As with all epidemics, this epidemic has to end some time, and if it had ended now, the apparent infection rates we see now would be what we expect. <b>If the epidemic is over</b>, then the risk of the vaccine would become altogether unnecessary. There is no evidence of any</p>

<sup>8</sup> [ourworldindata.org/coronavirus](https://ourworldindata.org/coronavirus)

<sup>9</sup> Amit S, Beni SA, Biber A, Grinberg A, Leshem E, Regev-Yochay G. Post-vaccination COVID-19 among healthcare workers, Israel. *Emerg Infect Dis.* 2021 Apr [date cited]. <https://doi.org/10.3201/eid2704.210016>

<sup>10</sup> [www.bmj.com/company/newsroom/covid-19-vaccine-trials-cannot-tell-us-if-they-will-save-lives/](https://www.bmj.com/company/newsroom/covid-19-vaccine-trials-cannot-tell-us-if-they-will-save-lives/)

<sup>11</sup> [www.thelancet.com/journals/lanmic/article/PIIS2666-5247\(21\)00069-0/fulltext](https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00069-0/fulltext)

<sup>12</sup> [www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html)

<sup>13</sup> See reference 2

<sup>14</sup> See reference 2

<sup>15</sup> <https://www.nature.com/articles/s41467-020-19802-w>

<sup>16</sup> <https://www.gov.scot/publications/coronavirus-covid-19-daily-data-for-scotland/>

		widespread infection anywhere in Scotland now, nor any reason to believe there will be any widespread infection in the future with such a high proportion of the population vaccinated and many having acquired immunity from prior infection. This question needs to be addressed urgently: is the epidemic over?
<b>Page 5 Section titled 'What are the side effects?'</b>		
<b>9.</b>		'Even if you do have symptoms after the first dose, you still need to have the second dose.'
		There is a serious language error here. Symptoms and side effects are not interchangeable terms. Some <i>side effects</i> after the first dose are very serious adverse reactions and to encourage a participant in the vaccination programme to risk a second, potentially worse, reaction seems irresponsible. There is simply not enough known about the adverse events following second doses of these vaccines to make this recommendation as it appears in the leaflet.
<b>10.</b>		'... having the full recommended course will give you the best protection against the virus.'
		Referring to point 9, this seems unclear. It may give 'better' protection from COVID-19, but possibly at an unacceptable risk to the person receiving the vaccine.
<b>11.</b>		'These common side effects are much less serious than developing COVID-19 or complications associated with COVID-19.'
		This needs to be put in context of age. Looking at the yellow card reports (and even without correcting for under-reporting in them) there is reason to be concerned that the risks to most age groups from the vaccine are greater than the risks of COVID-19. <sup>17</sup> Most people in most age groups suffer no serious complications from COVID-19 and avoid developing the disease at all after infection, but the side effects seem rather more difficult to avoid for the vaccinated.
<b>Page 6 Section titled 'What should I do if I am concerned about my symptoms?'</b>		
This is inappropriate use of language because the leaflet seems to be referring to side effects. 'Symptoms' arise from infection/disease. 'Side effects' arise from treatment with medication. This is disappointing for a document written by health authorities. It should be mentioned here that it is very important and critical to the information being gathered about these vaccines, which have not concluded their safety trials, that all adverse events or <i>suspected adverse events</i> , should be reported through the Yellow Card Scheme. This can be done by the individual if a healthcare professional does not agree to it.		

<sup>17</sup> gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions

<b>Page 7 Section titled 'COVID-19 AstraZeneca vaccine and rare blood clots'</b>	
<b>12.</b>	'Because of the high risk of complications and death from COVID-19...'
	<p>For the vast majority, even the most at risk, the risk of complications and death from COVID-19 is low. The vaccine adverse reaction data have shown that those at higher risk of blood clots from the vaccines are in the younger age group. These people are at extremely low risk of a SARS-CoV-2 infection causing complications or death. Their risk of clots is increased as age reduces, and yet this is a group with a very low risk of hospitalisation or death from SARS-CoV-2 infection. This section does not take that into account and assumes again equal risks for all.</p> <p>This page also states "the risk factors for this condition are not yet clear", referring to blood clots and unusual bleeding. Blood clots and unusual bleeding arising in the young <b>as a result of vaccination</b> would seem to be a gravely alarming concern. However, despite this statement, the very next paragraph states "the balance is very much in favour of the vaccination". It is deeply irresponsible to write this before we have established the factors that predispose individuals to increased risk of blood clots. Until that assessment has been made it is impossible to calculate the risk-benefit ratio. If the Government has seen the evidence used to draw this conclusion, it must share it with the public to aid better understanding of this conclusion from the WHO, MHRA and EMA.</p>
<b>Page 10 Section titled 'Fertility'</b>	
<b>13.</b>	'There is no evidence to suggest that the COVID-19 vaccine will affect fertility.'
	<p>While this statement is correct, it needs context. There is no evidence for fertility being affected because there have been <b>no studies</b> into fertility changes with vaccination using these products, but early yellow card reports are alarming, referring to menstrual irregularities, spontaneous abortion and foetal death following vaccination.<sup>18</sup></p>
<b>Page 10 Section titled 'Pregnancy and breastfeeding'</b>	
<b>14.</b>	'For the latest advice on the COVID-19 vaccine during pregnancy or breastfeeding please speak to your midwife.'
	<p>Government Protocol clearly states that for both categories "women should be informed about the absence of safety data for the vaccine".<sup>19</sup> It would seem prudent to have stated this here. We should not be relying on good advice in every instance of advice being sought from individual midwives.</p>

<sup>18</sup> gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions

<sup>19</sup> COVID 19 – mRNA Vaccine BNT162b2 Pfizer/BioNtech Vaccine National Protocol from Scot Gov (advice applies to AstraZeneca vaccine as well).

<b>Page 11 Section titled 'Is the vaccine safe?'</b>	
<b>15.</b>	As part of the consent process, the individual/carer <b>must</b> be informed that this vaccine “does not have UK marketing authorisation but has been authorised for temporary supply in the UK by the MHRA and that it is being offered in accordance with national guidance”. <sup>20</sup> The advice is the same for the AstraZeneca vaccine.
<b>Page 11 Section titled 'How does the vaccine work?'</b>	
<b>16.</b>	'The vaccine is suitable for people with disorders of the immune system.'
	This cannot be known because the trials excluded people with immune system disorders. Those with immune system disorders or on medication to suppress antibody production are unlikely to be able to generate an antibody response and therefore would be unlikely to benefit from vaccination.  “As part of the consent process, inform the individual/carer that this vaccine does not have UK marketing authorisation but has been authorised for temporary supply in the UK by the MHRA and that it is being offered in accordance with national guidance.” <sup>21</sup> The advice is the same for the AstraZeneca vaccine. This should be included in the leaflet to facilitate informed consent <b>in advance of</b> attending.
<b>Page 13 Section titled 'I've had COVID-19 before, should I still get the vaccine?'</b>	
<b>17.</b>	'Yes. Even if you've already had COVID-19, you could still get it again.'
	There is no evidence for this statement. Re-infections were extraordinarily rare. <sup>22</sup> Those known to have had a prior infection were excluded in the trials, therefore it cannot be known what the risks to them from vaccination would be.  There is no mention that with previous infection/exposure to COVID-19 comes immunity and immune memory via the innate and acquired immune system consisting of antibodies, B Cells, T Cells and lymphocytes. Those who have already been infected, we know have robust immunity. Therefore, the risk taken on from vaccination in these people becomes entirely unnecessary and unjustified. Dr Noorchashm wrote about

<sup>20</sup> [gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions](https://gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions)

<sup>21</sup> [gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions](https://gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions)

<sup>22</sup> Assessment of protection against reinfection with SARS-CoV-2 among 4 million PCR-tested individuals in Denmark in 2020: a population-level observational study, *The Lancet*, Volume 397, Issue 10280, 27 March–2 April 2021, Pages 1204-1212

		<p>this.<sup>23</sup> It is widely seen in the research that immunity post-infection is long-lasting and robust.<sup>24</sup></p> <p>Evidence is emerging from the Yellow Card reporting system that there is a two- to three-fold increase in Adverse Events in those vaccinated who have previously had COVID. This must be addressed in this leaflet in order for those with a previous confirmed infection to give fully informed consent.</p>
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**Omissions**

**Page 3 Section titled ‘About the types of vaccine’**

This gives the patient no information about the vaccine, the novel nature of the technology or the differences in the technologies of the various manufacturers.

**Page 7 Section titled ‘Reporting side effects’**

This section does not explain to the patient the importance of reporting all side effects because these vaccines have not been fully trialled - **trials finish 2023**. This should have been stressed very strongly - and it is fairly mild advice in the way it is communicated in this leaflet.

**Page 8 Section titled ‘Are there any reasons you should not get the vaccine?’**

This section is woefully inadequate - the trials have not identified those who should not get the vaccine because they excluded any people who had health conditions. It only regards allergic reactions ‘confirmed’ to have been in response to ingredients of the vaccine, which this leaflet does not provide.

This section fails to mention specifically known contraindications, e.g. those with known allergic reaction/anaphylaxis to excipients within these vaccines e.g PEG (Polyethylene Glycol) with Pfizer and Polysorbate 80 with AstraZeneca. It refers to confirmed anaphylactic reaction to any of the ingredients of the vaccine but **does not list the ingredients**. In order to give informed consent, recipients of these vaccines need to know this information in advance and to be able to assess their own risk. They may need to check with their doctor any potential risks of any ingredients/excipients prior to appointment.

There is a link provided in the blue box at the bottom of this page of the leaflet to get further info on ingredients, however it is doubtful that many will actually access this. We called the helpline number twice and got no clarity from the call handler on either attempt. We found the ingredients hard to source.

**Page 9 Section titled ‘People with bleeding disorders or taking medication to thin their blood’**

Given the lack of trial data on people with these disorders, and the risks of blood clots seen due to the spike protein the vaccines instruct the cells to make, this is likely unwise advice. It is stated those with bleeding disorders should consult their specialist for vaccine advice, but this vaccine is novel so it is unclear how their specialist could advise them. It is not acceptable to rely on the good advice of every specialist in every instance under these circumstances.

<sup>23</sup>[noorchashm.medium.com/a-letter-of-warning-to-fda-and-pfizer-on-the-immunological-danger-of-covid-19-vaccination-in-the-7d17d037982d](https://noorchashm.medium.com/a-letter-of-warning-to-fda-and-pfizer-on-the-immunological-danger-of-covid-19-vaccination-in-the-7d17d037982d)

<sup>24</sup> <https://www.nature.com/articles/s41590-021-00923-3>

Warfarin, taken by many patients with bleeding disorders, is an unstable anticoagulant. Frequent international normalised ratio (INR) checks are necessary to ensure correct dosing/stable treatment. The Scottish Government protocol<sup>25</sup> states that those with bleeding disorders may be vaccinated, if in the opinion of a doctor familiar with the individual's bleeding risk, vaccination can be administered with reasonable safety. It also states patients being treated with warfarin must be stable and up to date with their scheduled INR testing with an INR below the upper level of the therapeutic range for vaccination to be safe.

This is critically important information to include in the vaccine information leaflet as it requires forward planning by patients to consult with any relevant specialists. At the very least, this leaflet should refer the reader to easily accessible advice and stress the importance of seeking it out.

**Page 14 Section titled 'After the vaccine'**

*'It is not yet known whether having the vaccine completely stops you spreading the virus to others'*  
This makes all the advice in this leaflet even more confusing, and it also makes a proper risk/benefit analysis impossible. But it is honest. We do not know to any extent at all how this vaccine prevents spread. In fact, it looks like there is reason to believe vaccinated people do spread the virus, since in almost every country where the vaccine is rolled out, there is a rise in COVID-19 infections immediately, and this phenomenon does not diminish as a larger proportion of the population is vaccinated.<sup>26</sup>

**Scottish Infections 20/4 - 7/7/20 (Scaled by factor 7) vs 7/1 - 26/3/21**

<https://www.gov.scot/publications/coronavirus-covid-19-trends-in-daily-data/>

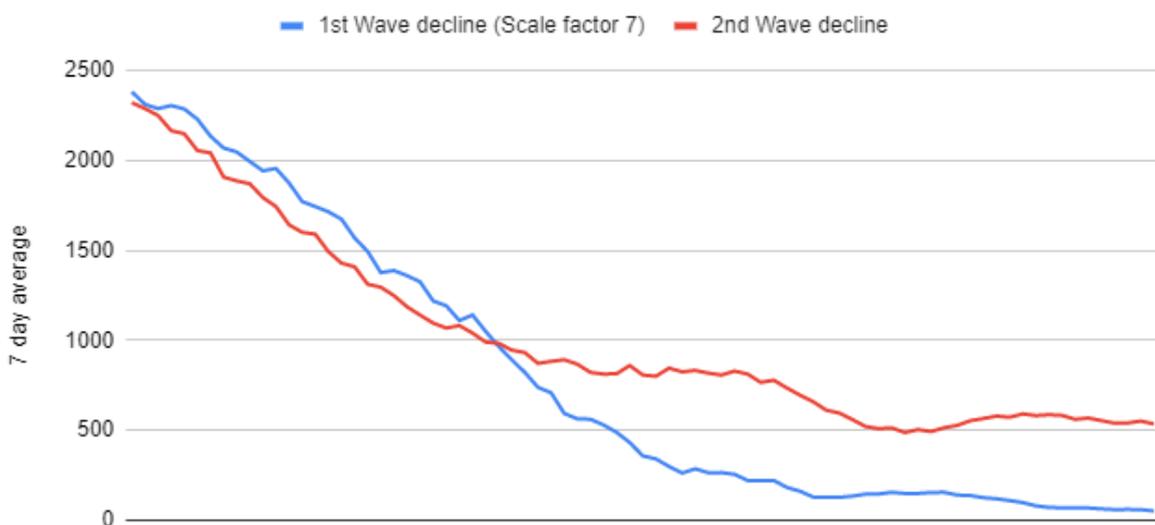


Figure - Due to testing differences, the infections for the first wave have been scaled up by a factor of 7 so they can be compared to the second wave. This shows there has been a slower rate of decline in the second wave, even with vaccinations.

<sup>25</sup> [gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions](https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions)

<sup>26</sup> [ourworldindata.org/coronavirus](https://ourworldindata.org/coronavirus)