MHRA issues new advice, concluding a possible link between COVID-19 Vaccine AstraZeneca and extremely rare, unlikely to occur blood clots

- The MHRA is not recommending age restrictions in COVID-19 Vaccine AstraZeneca vaccine use.
- The MHRA's scientific review of UK reports of extremely rare and unlikely to occur specific blood clots with lowered platelets has concluded that the evidence of a link with COVID-19 Vaccine AstraZeneca is stronger but more work is still needed.
- By 31 March 20.2 million doses of the COVID-19 Vaccine AstraZeneca had been given in the UK meaning the overall risk of these blood clots is approximately 4 people in a million who receive the vaccine.
- Anyone who did not have these side effects should come forward for their second dose when invited.
- The data suggest there is a slightly higher incidence reported in the younger adult age groups and the MHRA advises that this evolving evidence should be taken into account when considering the use of the vaccine.
- The MHRA is now issuing updated guidance for healthcare professionals on how to minimise risks, as well as further advice on symptoms for vaccine recipients to look out for 4 or more days after vaccination.
- Vaccines are the best way to protect people from COVID-19 and have already saved thousands of lives. Everyone should continue to get their vaccination when asked to do so unless specifically advised otherwise.

The Joint Committee on Vaccination and Immunisation (JCVI) have also published a statement following reports of an extremely rare adverse event after vaccination with the first dose of the AstraZeneca COVID-19 vaccine.

This includes information on the use of the vaccine in those under 30.

Updated information is being provided for people and healthcare professionals on the possible risk of extremely rare and unlikely to occur specific types of blood clots following vaccination with the COVID-19 Vaccine AstraZeneca, the Medicines and Healthcare products Regulatory Agency (MHRA) said today.

The MHRA has undertaken a thorough review into UK reports of a very rare and unlikely to occur specific type of blood clot in the brain, known as cerebral venous sinus thrombosis (CVST) occurring together with low levels of platelets (thrombocytopenia) following vaccination with the COVID-19 Vaccine AstraZeneca. It is also considering other blood clotting cases (thromboembolic events) alongside low platelet levels.

These reports have been analysed by the Government's independent advisory

body, the Commission on Human Medicines (CHM) and its COVID-19 Vaccines Benefit Risk Expert Working Group, which includes lay representatives and advice from leading haematologists.

Up to and including 31 March 2021, the MHRA had received 79 UK reports of blood clotting cases alongside low levels of platelets following the use of the COVID-19 Vaccine AstraZeneca:

- 44 of the 79 cases were of CVST with thrombocytopenia
- 35 of the 79 cases were of thrombosis in other major veins with thrombocytopenia
- 79 cases occurred in 51 women and 28 men, aged from 18 to 79 years. It should be noted that more women have been vaccinated with COVID-19 Vaccine AstraZeneca than men.
- Sadly, 19 people have died out of the 79 cases – 13 females and 6 males. 11 out of the 19 people who died were under the age of 50, 3 of whom were under 30. 14 of these 19 cases were of CVST with thrombocytopenia and 5 were of thrombosis with thrombocytopenia.
- All 79 cases occurred after a first dose of the vaccine.

This risk, based on reports up to and including 31 March, is slightly higher than the risk calculated from the reports published up to and including 24 March. However, likelihood of these blood clots occurring is still extremely rare.

As a precaution, administration of COVID-19 Vaccine AstraZeneca in people of any age who are at higher risk of blood clots because of their medical condition should be considered only if benefits from the protection from COVID-19 infection outweighs potential risks.

Anyone who experienced cerebral or other major blood clots occurring with low levels of platelets after their first vaccine dose of COVID-19 Vaccine AstraZeneca should not have their second dose. Anyone who did not have these side effects should come forward for their second dose when invited.

Pregnancy predisposes to thrombosis, therefore women should discuss with their healthcare professional whether the benefits of having the vaccine outweigh the risks for them.

The MHRA recently confirmed that the evidence to date does not suggest that the COVID-19 Vaccine AstraZeneca causes venous thromboembolism without a low platelet count.

It is important to note that this type of blood clot together with lowered platelets can rarely occur naturally in unvaccinated people as well as in people with COVID-19 disease.

While the MHRA continues to investigate these cases, as a precautionary measure, anyone who has symptoms four days or more after vaccination is advised to seek prompt medical advice, such as:

- a new onset of severe or persistent headache, blurred vision, confusion or seizures

- develop shortness of breath, chest pain, leg swelling or persistent abdominal pain,
- unusual skin bruising or pinpoint round spots beyond the injection site

Dr June Raine, MHRA Chief Executive, said:

> Over 37 million doses of vaccines against COVID-19 have now been administered in the UK, saving thousands of lives through the biggest vaccination programme that has ever taken place in the UK.
>
> No effective medicine or vaccine is without risk. We continually monitor safety during widespread use of any vaccine. This is to ensure vaccines are performing as expected, to identify any new side effects that may arise, and to ensure the benefits continue to outweigh the risks.
>
> The public's safety is always at the forefront of our minds and we take every report of a suspected side effect very seriously indeed. We thoroughly analyse each and every report as we receive it and although the number of reports of CVST and other thromboembolic events has increased over the last week, so has the overall number of vaccinations administered, therefore these blood clots remain extremely rare and unlikely to occur.
>
> We ask anyone who suspects they have experienced a side effect linked with their COVID-19 vaccine to report it to the Coronavirus Yellow Card website.
>
> It is still vitally important that people come forward for their vaccination when invited to do so.

Professor Sir Munir Pirmohamed, Chair of the Commission on Human Medicines, said:

> The independent Commission on Human Medicines (CHM) and its COVID-19 Expert Working Group, together with leading haematologists, has conducted a rigorous scientific analysis of all available evidence regarding reports of thromboembolic events occurring together with low platelets and COVID-19 Vaccine AstraZeneca and usage of the vaccine in different age groups.

We have a rich source of data – the best data there is – and the MHRA and CHM will continue to keep this under close observation. The public deserve nothing less.

Slides from press conference

Slides from 7 April 2021 press briefing – Communicating the potential benefits and harms of the Astra-Zeneca COVID-19 vaccine (PDF, 360KB, 5 pages)

Notes to editor

- Up to and including 31 March we have received 2 reports of blood clots (thromboembolism) reported with thrombocytopenia for the Pfizer/BioNTech vaccine. By this date, approximately 11 million first doses and 3.5 million second doses had been given.
- The Expert Haematology Panel has issued guidance on thrombosis and thrombocytopenia possibly occurring after vaccination with COVID-19 vaccines. This includes information on presentation and typical laboratory features, and treatment recommendations. The guidance also includes advice on recommended investigations for possible cases.
- The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
- The Medicines and Healthcare products Regulatory Agency ('the agency') has three centres. The MHRA, the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The agency is an executive agency of the Department of Health and Social Care.
- The Commission on Human Medicines is the UK Government's independent advisory body. It advises ministers on the safety, efficacy and quality of medicinal products.
- The COVID-19 Vaccines Benefit Risk Expert Working Group of the Commission on Human Medicines is formed from 27 experts from outside of the MHRA, including virologists, epidemiologists, immunologists and toxicologists.
- The MHRA encourages anyone to report any suspicion or concern they have beyond the known, mild side effects on the Coronavirus Yellow Card site. Reporters do not need to be sure of a link between a vaccine and a suspected side effect but are still encouraged to report.
- For more information on COVID-19 vaccine adverse reactions, see the MHRA's weekly report
- For more information on COVID-19 Vaccine AstraZeneca, see the MHRA's regulatory approval decision page

New Director General for Homeland Security announced

News story

New head of Homeland Security took up the role at the beginning of April.

Chloe Squires has been appointed as the new Director General for Homeland Security at the Home Office and Senior Responsible Officer for Counter Terrorism, replacing Tom Hurd who stepped down last month.

Chloe Squires, who took up the role on 1 April, has been with the Home Office since 2019 and has spent over a decade working across the national security community. Before joining the Home Office, she was Director of Strategy at the National Cyber Security Centre.

Home Secretary Priti Patel said:

> The number one priority of government is to keep people safe, and Chloe's wealth of experience working in national security will be invaluable to this mission.
>
> I look forward to continuing to work closely with her to tackle terrorism and safeguard our country from hostile threats and I want to thank Tom for his excellent work leading OSCT since 2016.

Permanent Secretary Matthew Rycroft said:

> Chloe is a fantastic addition to the top team and is absolutely the right person to lead on this critical part of the Home Office's work. I very much look forward to continuing to work with her.
>
> A huge thank you to Tom Hurd for being an excellent Director General for the Office for Security and Counter Terrorism since 2016. We wish him all the best for his new chapter.

Commenting on her appointment, Chloe Squires said:

> I’m thrilled to have been offered the role at this exciting time for the mission. I look forward to working with my brilliant colleagues across the Home Office and its partners to help deliver the government’s vital agenda in this area.

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ESFA Update: 7 April 2021

Condemning the use of chemical weapons

Thank you, Mr President. I’d like to start by thanking High Representative Nakamitsu for her briefing today. I would also like to thank the Director-General of the OPCW as always for his latest monthly report.

The recent anniversaries of the Ltamenah and Khan Shekyun chemical weapons attacks, and tomorrow’s anniversary of the Douma attack, remind us of why we are here.

We are here because of the repeated use of chemical weapons during the Syrian conflict. We are here because, by Syria’s own admission, its initial chemical weapons declaration was not accurate, and because of Syria’s failure, over a seven-year period, to resolve the outstanding issues in that declaration.

As the Director General noted in his 9 March statement to the OPCW Executive Council, the Declaration Assessment Team process has led to the subsequent declaration by Syria of one additional chemical weapons production facility, four additional research and development facilities, five previously undeclared chemical warfare agents and several thousand large calibre chemical munitions. Syria has now amended its declaration 17 times.

Nineteen issues with that declaration remain outstanding. As the Director General told the Executive Council, these relate to the fate of several hundred tonnes of chemical warfare agents and/or thousands of chemical munitions; indicators of three undeclared chemical warfare agents; and unknown, but potentially significant, quantities of chemical warfare agents.

While the detail on some of these issues is undoubtedly of a technical nature, their significance is unambiguous and squarely within the Security Council's mandate under resolution 2118 and its duty to maintain international peace and security.

Syria's failure to meet its obligations led to the Executive Council recommending a suspension of Syria's rights and privileges at the OPCW until it takes steps to redress the situation. We support the proportionate, measured action that will be considered by the Conference of States Parties this month, as do many other States Parties.

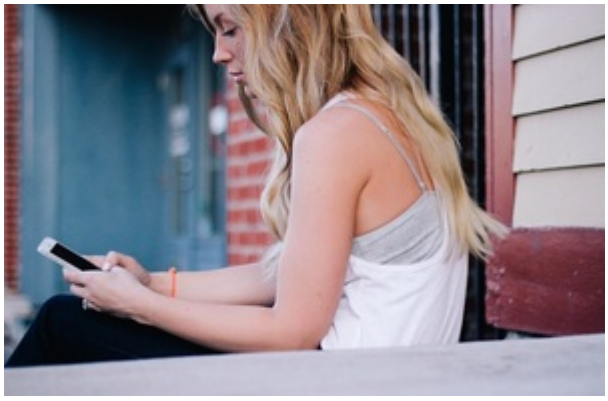
Finally, as we said last month, we support the investigation of any incidents of chemical weapons use by any party. This is fundamental to upholding the prohibition on their use. We are therefore reassured by a note from the OPCW Technical Secretariat dated 10 March indicating that the Technical Secretariat considered and analysed all 197 notes verbales submitted by Syria. While no links between the information provided and actual incidents under review could be found, we welcome that the OPCW will maintain a repository of the information for future comparison as necessary.

Thank you, Mr President.

Ofsted's review of sexual abuse in schools and colleges

Press release

Ofsted has today published plans for a review into safeguarding policies and practices relating to sexual abuse in state and independent schools and colleges.



The review was announced by government last week, after anonymous testimonials of sexual abuse were published on the website ‘Everyone’s Invited’. It will seek to find out whether schools and colleges have appropriate safeguarding processes in place. It will also consider whether current guidance is understood by schools and colleges, and whether it is sufficient to help them respond effectively to allegations.

We will visit a sample of schools and colleges where cases have been highlighted. As well as talking to school and college leaders, pupils and students, we will look at how well systems of support and response are working, and we’ll discuss the wider issues raised by the evidence.

The review will look at whether schools and colleges need further support in teaching about sex and relationships, and whether current inspection regimes in state and private schools are robust enough around the issue of sexual abuse. It will also consider how well schools and colleges are working with local multi-agency safeguarding partners.

We will work with representatives from social care, police and victim support groups, as well as school and college leaders. The review is aimed to conclude by the end of May 2021.

Amanda Spielman, Her Majesty’s Chief Inspector, said:

> Like so many others, I have been deeply troubled by the allegations of sexual abuse posted on the ‘Everyone’s Invited’ website. Many of the testimonies reveal that girls have not felt able to report incidents of sexual abuse to their schools. We hope that by listening to young people’s experiences first-hand, this review will provide much needed insight into what these barriers are and how they can be overcome.
>
> Schools play a vital part in promoting a culture of respect among young people – including between boys and girls. We will consider how schools can support and encourage appropriate behaviour, from the lessons in the classroom to the culture in the corridors. And when children do speak up about their experiences, it’s vital that schools have the support and structures in place to take them seriously and respond appropriately.

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