epidemiologists have investigated, reviewed, and evaluated thoroughly and scientifically all safety reports. And our safety rubric reviews are carried out in tandem with the vaccination program. We've gathered a large amount of data on the safety profile of the available vaccines, and we've done a rigorous scientific review of all the available data with regards to suspected blood clots with low platelet count. Professor Raine: (04:35) The Commission on Human Medicines Expert Working Group has also met frequently and critically assessed all the data alongside our regulatory review. And this has also included lay representatives and advice from leading hematologists. Based on the current evidence, the benefits of the COVID-19 vaccine AstraZeneca against COVID-19 and its associated risks, hospitalization and death continues to outweigh the risks for the vast majority of people. Professor Raine: (05:09) Our review has reinforced that the risk of this rare suspected side effect remains extremely small. By the 31st of March, over 20 million doses having been given, we have had 79 case reports up to and including that date, 31st of March. All 79 cases occurred after the first dose. Of these 79 cases, 19 people have sadly died. These cases occurred in 51 women and 28 men, age from 18 to 79 years. And from these reports, the risk of this type of rare blood clot is about four people in a million who received the vaccine. Three out of the 19 were under 30 years. 14 of the 19 were of the cerebral venous sinus thrombosis with low platelets and five were other kinds of thrombosis in major veins. Professor Raine: (06:07) The balance of benefits and risks is very favorable for older people, but it is more finely balanced for the younger people. And we at the MHRA are advising that this evolving evidence should be taken into account when considering how the vaccine is used. Today we'll be communicating information and advice to healthcare professionals on how to minimize risks. And this will provide a lot of guidance, including how to report any suspected cases. Professor Raine: (06:38) The information for healthcare professionals will be updated and there will also be information for the public. Things to look out for as we continue to monitor this issue. Anyone who has symptoms four days after vaccination or more should seek prompt medical advice. A new onset of a severe or persistent headache or blurred vision, shortness of breath, chest pain, leg swelling, persistent abdominal pain, or indeed unusual skin bruising or pinpoint spots beyond the injection site. Professor Raine: (07:10) So Professor Sir Munir will outline the Commission on Human Medicines further advice, but I'd like to reiterate again that this is extremely rare. And with the proven effectiveness against the disease that is still a huge risk to our population, the balance of benefits and known risks of the vaccine is still very favorable for the vast majority of people. So Professor Sir Munir, over to you. Prof. Munir Pirmohamed: (07:39) Thank you very much, June. So I've worked with the Commission on Human Medicines and the Expert Working Group separately to thoroughly review are all the cases coming in with the Oxford AstraZeneca vaccine in the UK. We've taken into account a wide range of data sources. We've looked at information about the usage of the vaccine on various age groups and updated incidents rates and benefit risk comparisons for different populations by age and gender. Prof. Munir Pirmohamed: (08:10) Over the last couple of weeks, the two committees have spent almost 24 hours in committee reviewing these reports. Each report has been carefully scrutinized by them MHRA and by the members of the Working Group and further information has been obtained where necessary. We've also had independent adjudication of these cases by an expert hematologist and we worked with another group of hematologists to develop a case definition of these events to make sure that the cases were identified throughout the UK and reported via the yellow card scheme. Prof. Munir Pirmohamed: (08:46) Based on the currently available data, the Commission on Human Medicines is advising the following. First, a pregnant woman should continue to discuss with the healthcare professional whether the benefits of having the vaccine outweigh the risks for them. Number two, people with a history of blood disorders that increase the risk of clotting should only have the COVID-19 vaccine AstraZeneca when the benefits outweigh any potential risks. Prof. Munir Pirmohamed: (09:14) Number three, anyone who experienced cerebral or other major blood clots occurring together with low levels of platelets after the first vaccine of COVID-19 AstraZeneca should not have the second dose. We will be continually monitoring further reports as they come in, continually monitoring other aspects to identify risk factors so that we can refine the advice that we give. At present, the data on people who've had two doses of the COVID-19 AstraZeneca vaccine are limited because these events are rare and comparatively small number of second doses have been given. Prof. Munir Pirmohamed: (09:56) Therefore, it is not possible to draw a conclusion about how frequently blood clots with a low platelet count happened following a second dose of the vaccine, but this will be monitored closely by the MHRA and by the CHM as part of the ongoing review. So just to put into context, these events are extremely rare as June has already mentioned. And I want to put it into context in relation to COVID-19 itself. Prof. Munir Pirmohamed: (10:22) It is important to remember the COVID 19 itself causes clotting and it causes lowered platelets. And I've got a few figures from a paper which was recently published. Pulmonary embolism, clots on the lungs occur in 7.8% of people who have COVID-19. DVT, deep venous thrombosis, clots in the legs occur in 11.2%. who've had COVID-19 and of those people who've been infected with SARS-COVID-2 getting COVID-19 and ending up in ITU, 23% will have some form of clot. Prof. Munir Pirmohamed: (10:59) COVID- 19 also causes strokes in about 1.6% and up to 30% of people who develop COVID-19 will get thrombocytopenia, which is lowering of the platelet count. And that puts into context that the risk of clots and load platelets is much higher with COVID-19 than these extremely rare events, which are occurring with the vaccine. So to finish off, the CHM has advised that the link between the vaccine and blood clots in the cerebral and other veins occurring together with lowered platelets is getting firmer, but absolute proof of the link between the vaccine adverse events will need extensive scientific work. Prof. Munir Pirmohamed: (11:41) Based on the currently available evidence the benefit-risks remains favorable for the vast majority of people, but as June said, is more finely balanced for the younger people. We are advising that this evolving evidence should be taken into account when considering the use of the vaccine. I'll hand back to Professor Van-Tam. Jonathan Van-Tam: (12:02) Thank you, Professor Sir Munir. Thank you, Professor