To: 5.1.2e [5.1.2e @astrazeneca.com]; 5.1.2e [5.1.2e @rivm.nl]; 5.1.2e 5.1.2e [5.1.2e @rivm.nl]
Cc: 5.1.2e [5.1.2e @rivm.nl]; 5.1.2e [5.1.2e @astrazeneca.com]
From: 5.1.2e
Sent: Sun 2/7/2021 3:42:55 PM
Subject: Antw: Follow-up Medisch Inhoudelijk overleg RIVM-AstraZeneca dd 01-02-2021
Received: Sun 2/7/2021 3:42:56 PM

Veel dank, waardevol voor ons deze antwoorden

5.1.2e

Van: 5.1.2e <5.1.2e @astrazeneca.com>
Datum: 7 februari 2021 om 16:33:57 CET
Aan: 5.1.2e <5.1.2e @rivm.nl>, 5.1.2e <5.1.2e @rivm.nl>, 5.1.2e <5.1.2e @rivm.nl>
CC: 5.1.2e <5.1.2e @rivm.nl>, 5.1.2e <5.1.2e @astrazeneca.com>
Onderwerp: Follow-up Medisch Inhoudelijk overleg RIVM-AstraZeneca dd 01-02-2021

Dag allemaal,

Onderstaand treffen jullie de antwoorden op de medisch inhoudelijke vragen die afgelopen maandag tijdens ons eerste medisch inhoudelijke overleg zijn besproken.

What is the experience in the UK with anaphylactic shock so far? Is it possible to share UK data already?
All vaccines (specially protein based ones) have a potential rare risk of anaphylaxis in some individuals with previous history. It is important to follow the guidelines of administration to observe time post vaccination of 15 to 30 min based on local guidelines. In the current clinical trials with a population well above 30k participants we did not see an increased risk of anaphylaxis, however it is an event we are following closely. The first set of data from the UK is being analyzed in these coming weeks and if anything is noted we will be sharing proactively as the question was now received and we will be happy to provide a response.

What is the experience in the UK in daily practice in getting more doses out of the vials? We know there is a certain "over-fill" in the vials, how does this work out in the UK? Can we learn from them?
From the UK SmPC: Each vaccine dose of 0.5 ml is withdrawn into a syringe for injection to be administered intramuscularly. Use a separate sterile needle and syringe for each individual. Each vial contains at least the number of doses stated. It is normal for liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for an additional dose. Care should be taken to ensure a full 0.5 ml dose is administered. Where a full 0.5 ml dose cannot be extracted, the remaining volume should be discarded.

What happens if the vaccine is given subcutaneously? For example if a person has a high BMI, the needle might not be long enough to inject intramuscularly.
We have no data on subcutaneous use. Sub cue vaccination or even monoclonal administration often leads to sub optimal distribution in the system. This is particularly important for vaccines where activation of cell mediated responses to activate both adaptive and memory responses required "calling" these specialized cells to the site of immunization and they are more readily available in the muscle that in the first layers of the epidemermis, making attempting subcue vaccination inefficient. Depending on age, BMI and skin condition size and length of needle should be adapted to reach the correct muscular tissue for vaccine immunization.

What if vaccine is wasted on hands of HCP, is cleaning with disinfectant enough?
From EMA SmPC: Spills should be disinfected using agents with activity against adenovirus. There is no additional information on disinfecting skin.

When do we expect more data on immunocompromised patients?
Patients with HIV have been included in several of our ongoing trials . These HIV patients had stable disease and were not severely immunocompromised. No data are currently available.
A study in an immunocompromised population is currently under design and will be available in the future.

Mochten er nog additionele vragen zijn dan horen we dat graag. Tot morgen!

Met vriendelijke groet,

5.1.2e
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