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Media Release

RUH pride in flu and COVID-19 vaccine research study

Research involving volunteers recruited at the Royal United Hospitals Bath NHS Foundation Trust has found that it is safe for people to receive a flu vaccine at the same time as a COVID-19 vaccine.

Reported side effects were mainly mild to moderate, and there were no negative impacts on the immune response produced by either vaccine when both were given on the same day, in opposite arms.

The study was led by researchers at the Bristol Trials Centre, University of Bristol and University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) and supported by the Clinical Research Network (CRN) West of England. It is funded by the National Institute for Health Research (NIHR), with the results due to be published in The Lancet.

Dr Kelly Spencer, RUH Head of Research Operations, said: "I am delighted that RUH was able to play a part in this crucial research study. We are extremely grateful to all of the volunteers who gave their time to enable this important question to be answered.

"We're really proud to be a research-active hospital and proud to have participated in this and a number of other national and international studies into COVID-19 since the pandemic began. It is vital that research like this into COVID vaccines and treatments continues to further improve the care and treatment we provide."

Earlier in the pandemic, it was not known whether further booster doses of COVID-19 vaccines would be required to give continued protection, and how giving boosters may fit in with the seasonal flu vaccine programme.



The Combining Influenza and COVID-19 Vaccination (ComFluCOV) study looked to establish the safety of co-administering the most widely used COVID-19 and influenza vaccines in the UK and describe the expected side effects and immune responses to the vaccines when they are given together. Two COVID-19 and three influenza vaccines were tested, meaning six combinations in all.

Participants recruited to the study were over the age of 18 and had already received one dose of either the Pfizer/BioNTech or the Oxford/AstraZeneca COVID-19 vaccine and were awaiting their second dose.

A total of 679 volunteers took part in the study across 12 NHS sites in England and Wales, and were randomly allocated into one of two groups:

- A group who received their second dose of the COVID-19 vaccine and the flu vaccine at their first study visit, then a saline injection (placebo) at their second visit
- A group who received their second dose of the COVID-19 vaccine and a saline injection (placebo) at their first visit and then the flu vaccine at their second visit.

Participants also attended a third study visit to discuss any side effects they experienced following their second appointment and to give a final blood sample.

The most common side effects were pain around the injection site and fatigue. With some combinations there was an increase in the number of people who reported at least one side effect when both COVID-19 and flu vaccine were given together, but the reactions were mostly mild or moderate.

The immune responses to both the influenza and COVID-19 vaccine were preserved when given together, and 97% of participants said they would be willing to have two vaccines at the same appointment in the future.

Dr Rajeka Lazarus, consultant in infectious diseases and microbiology at UHBW and Chief Investigator for the ComFluCOV study, said: "By conducting this study we have been able to establish that it is possible to protect people from both COVID-19 and flu at the same appointment.

"This is a really positive step which could mean fewer appointments for those who require both vaccines, reducing the burden on those who have underlying health conditions and would usually be offered the influenza vaccine.

"The results of this study have been presented to the Joint Committee on Vaccination and Immunisation (JCVI) for their consideration and will aid policy makers in planning the future of these important vaccination programmes."

<u>Chris Rogers</u>, Professor of Medical Statistics and Clinical Trials and Director of Bristol Trials Centre at the University of Bristol, said: "We are delighted to have worked with Dr



Lazarus to successfully deliver this important study and would like to thank all the volunteers who took part.

"The quality of the data provided by participants was excellent. It is reassuring that the results suggest that there are no safety concerns when giving the COVID-19 and flu vaccines together".

Professor Andrew Ustianowski, NIHR Clinical Lead for the COVID-19 Vaccination Programme and Joint National Infection Specialty Lead, said: "This research has quickly provided important and reassuring results that could make vaccination more efficient for both patients and the NHS. I'm proud of NIHR's role in funding this research that could help to control the COVID-19 pandemic through this upcoming winter."

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Notes to editors

Frequently asked questions about the ComFluCOV study and its results can be found on the UHBW website: https://www.uhbw.nhs.uk/assets/1/comflucov_results_faqs.pdf Please note that this information is also under embargo until 10pm 30 September.

The ComFluCOV study was led by the Bristol Trials Centre (CTEU) at the University of Bristol and University Hospitals Bristol and Weston NHS Foundation Trust, and participants were recruited across the following NHS sites:

- Cardiff and Vale University Health Board
- Gloucestershire Hospitals NHS Foundation Trust
- Great Western Hospitals NHS Foundation Trust
- Knowle House Surgery
- Newquay Health Centre
- North Bristol NHS Trust
- Royal Cornwall Hospitals NHS Trust
- Rotherham, Doncaster and South Humber NHS Foundation Trust
- Royal United Hospitals Bath NHS Foundation Trust
- The Alverton Practice
- University College London Hospitals NHS Foundation Trust
- University Hospitals Bristol and Weston NHS Foundation Trust

Ends

The Royal United Hospitals Bath NHS Foundation Trust provides acute treatment and care for a catchment population of around 500,000 people in Bath, and the surrounding towns and villages in North East Somerset and Western Wiltshire. The hospital provides healthcare to the population served by four Clinical Commissioning Groups: Bath & North East Somerset CCG, Wiltshire CCG, Somerset CCG and South Gloucestershire CCG.



The Trust provides 759 beds and a comprehensive range of acute services including medicine and surgery, services for women and children, accident and emergency services, and diagnostic and clinical support services.

In 2015 The Royal United Hospitals NHS Foundation Trust acquired the Royal National Hospital for Rheumatic Diseases (RNHRD) NHS Foundation Trust. The RNHRD treats patients from across the country offering services in rheumatology, chronic pain and chronic fatigue syndrome/ME, cancer related fatigue and fatigue linked to other long term conditions such as multiple sclerosis.

The RUH is changing - we have an exciting programme of redevelopment underway transforming our site and further improving the services we provide. The Trust has opened the purpose-built RNHRD and Brownsword Therapies Centre and is now working towards the new Dyson Cancer Centre. For more details visit: www.ruh.nhs.uk/about/fit_for_the_future

For more information about the Royal United Hospitals Bath NHS Foundation Trust visit: www.ruh.nhs.uk



