

The importance of *collaborative* working across the health board to effectively deliver an urgent public health study.



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The Trial overview.....



- ▶ A phase IV, participant blinded, UK multi-centre randomised controlled trial focused on evaluating the safety of *combining influenza and COVID-19 vaccination (COMFluCOV)*.
- ▶ Randomisation - Influenza vaccine vs saline (placebo) plus standard Covid vaccinations.
- ▶ Cardiff completed the AZ/Flublok under 65s cohort.
- ▶ Blood & saliva samples taken to look at the immune response to both vaccines when given together.
- ▶ Total study recruitment = **679** Cardiff recruitment target = **126**
- ▶ X3 study appointments; Cardiff & Vale UHB - Mass Vaccination Centre.

Principle Investigator (PI) Dr Andrew Carson-Stevens





Challenges



12
days

Delivering a study to run across both primary and secondary care.

Restricted time to set up the study.

Research naive Mass Vaccination Centre Staff (MVCS).

Different training requirements & skill sets impacting role allocation.

Conducting research at a non-hospital site - limited space within a busy environment.

Implementing research specific labs and pharmacy procedures including storage and blinding at a different location (non-hospital).

Lack of access to trial population due to pandemic.

Impact on research portfolios due to working on different sites.

Large recruitment numbers, small recruitment window.

6
days

col·lab·o·ra·tion

noun

Two or more people working together
towards shared goals



what are other
words for
collaborate?



cooperate, conspire,
join forces, get together,
team up, unite, participate,
work together, collude, combine



Team





Solutions



Forged relationships and managed expectations via early regular meetings with primary care staff.

Liaised with HCRW and utilised their booking team and text message system in order to offer the trial to patients attending the mass vaccination site.

Open communication between teams to problem solve.

Fast Track basic research training programme developed in order to allow research naïve primary care MVCS to assist with limited procedures involving administration of blinded medication.

Pooled resources between teams within the Clinical Research facility to ensure that usual studies could continue, as well as staffing an extra site.

Pharmacy and lab adaptations were assisted by liaising with Clinical Trials pharmacy, arranging site visits and creating new procedures for use in the study.

Outcomes



- Increased opportunities to develop working relationships across the Health Board. Interdisciplinary team working.
- Raised the profile of clinical research studies across sites within Cardiff and Vale and demonstrated that research is critical for improving healthcare.
- Cascade trained MVC members, inspiring them to become part of research.
- Demonstrated flexibility in the study set up process, ability to work under pressure effectively and in a different environment.
- Impact on the delivery and set up of future research studies. *"We've done it before we can do it again."*
- Increase feasibility of future similar studies (Multiple offers of vaccination studies since).
- Development of clinical skills which has helped to enhance delivery of future more complex trials.
- Public given opportunities to contribute to research.
- Impacted National policy regarding dual vaccinations.

Recruitment target

- Cardiff & Vale had a target of 126 but recruited 128 participants within a very limited timeframe.
- Cardiff & Vale: the team successfully set up, opened and completed the study meeting the Welsh Government's goal of recruiting to "time and target."
- Contributed to Welsh Government Key Performance Indicators (KPIs).

“...the whole process of taking part was really straight forward and easy...”
(participant feedback)



Cardiff and Vale **Research Delivery Team**
Tîm Cyflawni Ymchwil Caerdydd a'r Fro

Trial results

-"Concomitant vaccination with both COVID-19 and influenza vaccines over the next immunisation season should reduce the burden on health-care services for vaccine delivery, allowing for timely vaccine administration and protection from COVID-19 and influenza for those in need." (Lazarus *et al.*, 2021)
- Impact on standard practice. Study results used to inform the UK Immunisation Policy.
- The findings from the ComFluCOV trial featured in the Lancet Dec 2021 which included that concomitant administration of COVID-19 and influenza vaccines raised no safety concerns.
- Immune response not adversely affected (Lazarus *et al.*, 2021).

Flu and Covid jabs safe to be given at same time, study finds

Clinical trial on joint flu, Pfizer and AstraZeneca vaccinations reported only mild to moderate side-effects

- [Coronavirus - latest updates](#)
- [See all our coronavirus coverage](#)



📹 Researchers said the findings supported recent advice from the Joint Committee on Vaccination and Immunisation (JCVI) to offer Covid boosters alongside flu jabs this autumn and winter.



"...to get it up and running and have completed recruitment in such a timescale is a huge achievement!..."
(Dr Nicola Williams, Director of Support & Delivery)

"It's been an exemplary team effort. The commitment, enthusiasm and good will of so many has been really inspiring."
(Dr Andrew Carson-Stevens, Principle Investigator)

"The last few weeks have certainly been challenging but we achieved what seemed almost impossible at times and that is down to the professionalism, drive and commitment of you all."
(Sara Shankland, Senior Research Delivery Manager)

"I just wanted to say a huge thank you for your outstanding work to ensure this study completed in Wales. It is a fantastic achievement to complete recruitment today."
(Jayne Goodwin, Head of Research Delivery).

"I'm delighted that our research teams and staff at Bayside Mass Vaccination Centre played a key role in this study, once again making an important contribution to global research efforts to identify safe and effective treatments against COVID-19."
(Professor Stuart Walker, Interim Chief Executive of CVUHB 2021)

References

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Any Questions?

