

Right Under Your Nose. Pharmacy Support In The Implementation Of A Novel Randomised Controlled Trial.

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BACKGROUND

INHERIT, a randomised, placebo-controlled trial investigating efficacy of intranasal heparin in reducing transmission of COVID-19 amongst household contacts of COVID-19 positive adults and children, was implemented at Northern Health. Recent research suggests heparin binds to the SARS-CoV-2 virus in such a way it may reduce the virus' ability to enter cells. This may be an important way to tackle early stages of infection, which occur inside the nose. It is postulated that intranasal heparin could thus be used amongst people with early COVID-19 infection, and amongst their close household contacts to reduce the rate of virus transmission. Furthermore, recent studies suggesting that the risk of brain complications as a part of "long COVID", are directly related to the amount of virus in the nose. Reducing the viral load in the nose is thought to be effective in reducing these "long COVID" complications.

A large number of participants were anticipated to meet the eligibility criteria, with a significant portion of them being hospital employees. Northern Health was the first organisation taking part in the trial nationally, with pharmacy leading the sourcing, compounding and dispensing of investigational products in a blinded form.

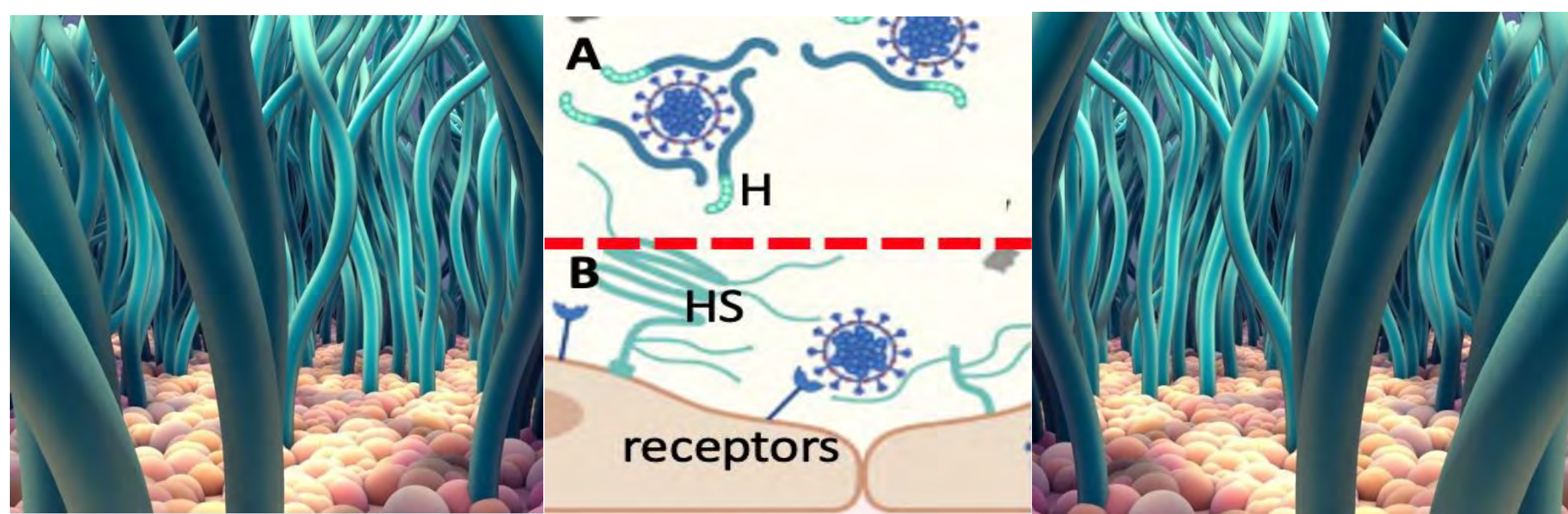


Figure 1. SARS-CoV-2 (Spiked blue circles) readily replicates in airway epithelial cells. (A) Heparin (H) avidly binds SAR-CoV-2 (B) preventing cellular infection via cell surface Ace 2 receptors thereby limiting viral replication and spread to close contacts.

OBJECTIVE

To implement a pharmacy workflow to securely access the randomisation codes, and manage compounding and dispensing of the investigational products, in a prompt and timely manner.

METHOD

A procedure was designed to ensure management of the trial and workflow. Sterile nasal spray bottles were sourced from an external supplier and thoroughly tested by the hospital's pathology service to ensure accurate heparin dosage delivery. A secure randomisation schedule was implemented, accessible only by pharmacy staff delegated to the trial. Finally, the required ingredients were entered into the pharmacy's dispensing software in a blinded form (Figure 2), ensuring general pharmacy staff were unable to access the code.

EVALUATION

With 74 households (>150 participants) randomised to the trial thus far, the trial was effectively executed; with the Northern Health pharmacy solely responsible for compounding and dispensing the investigational products. This process was established with no prior experience from other networks, given this was the first organisation to implement this trial nationally. The trial was open to many hospital staff to participate, further increasing the need to follow a strict blinding process at all times.

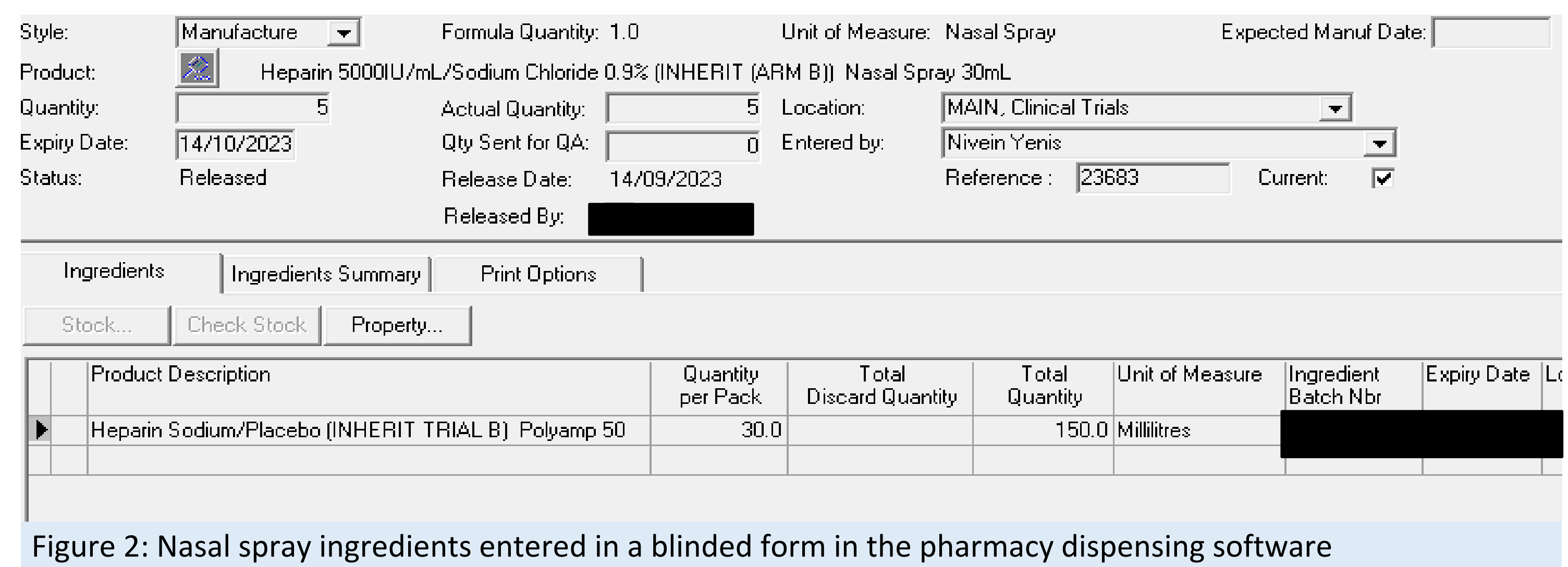


Figure 2: Nasal spray ingredients entered in a blinded form in the pharmacy dispensing software

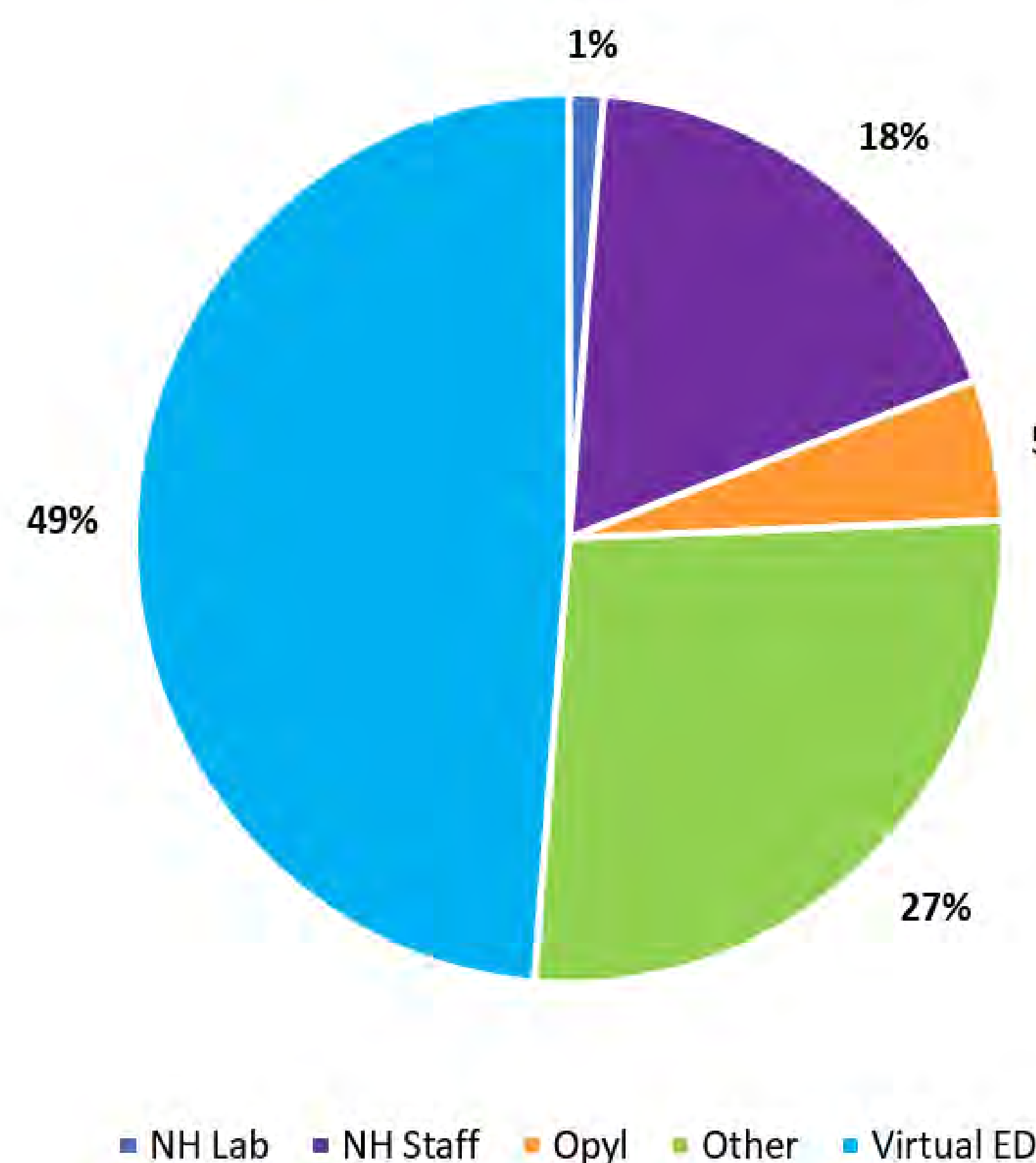


Figure 3: INHERIT trial enrolled households as of Oct 2023

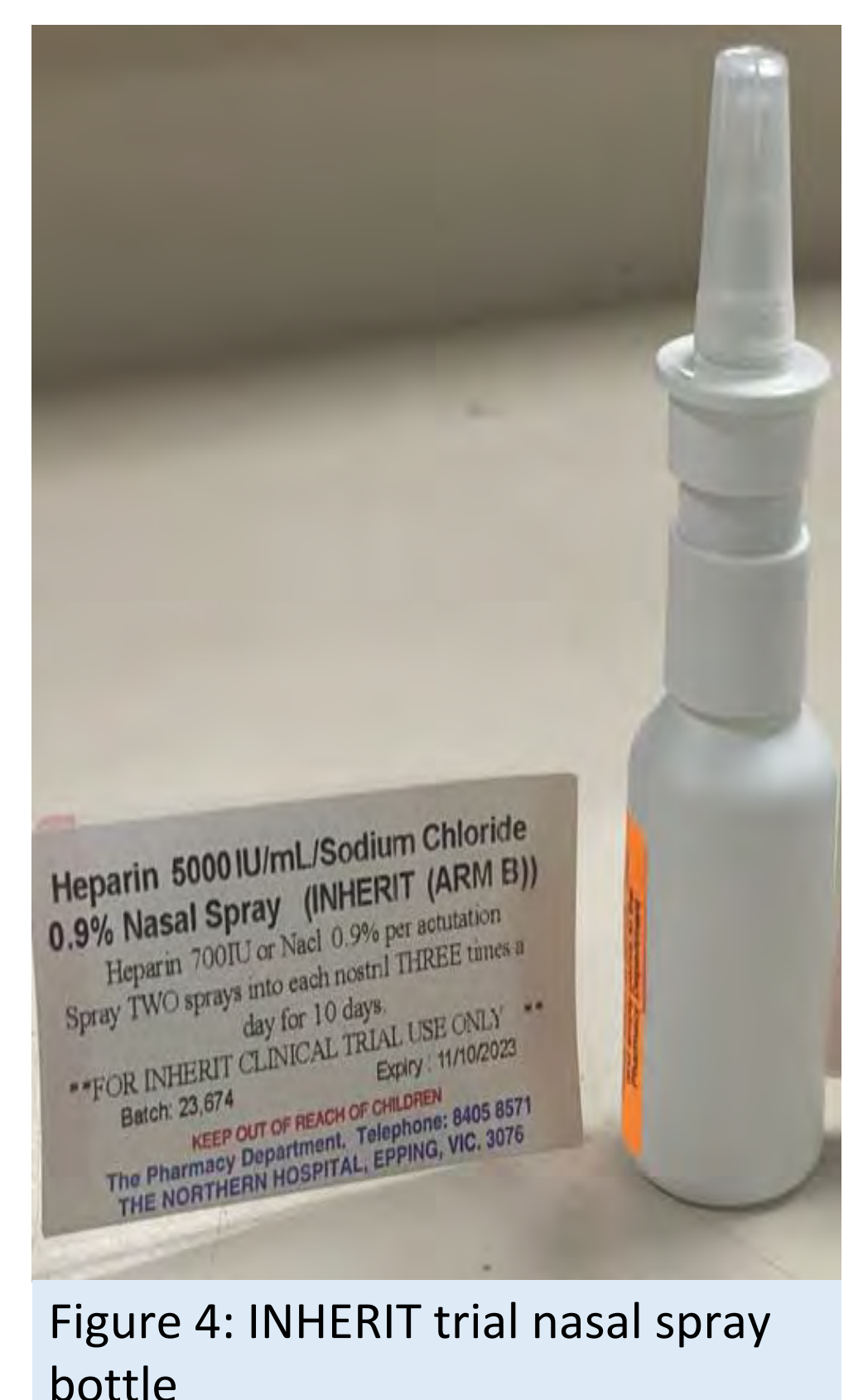


Figure 4: INHERIT trial nasal spray bottle

DISCUSSION

Pharmacy played a crucial role in supporting the successful implementation of the INHERIT trial by establishing a strict and blinded workflow, and further supporting the community in the management of COVID-19 infections.

If intranasal heparin is proven to be effective, there are many other potential uses, which could include primary prophylaxis for people working in high-risk environments and minimising illness in those undertaking travel. Heparin is safe, inexpensive and available worldwide, and if effective could be rapidly used across the world to slow progression of the COVID-19 infection.

THE INTRANASAL HEPARIN TRIAL (INHERIT)

