



St James's Hospital TB Service

Established in 2004, St. James's Hospital TB Service is the national centre for TB. The multi-disciplinary team comprises of Consultant Respiratory Physicians, Registrar, TB Clinical Nurse Specialist, Senior Pharmacist, Public Health Doctors and Nurses, and administration staff. Their aim is to ensure patients receive the appropriate TB investigations, treatment and support the patients to enable completion of treatment.

TB Clinical Nurse Specialist and study PI, Lorraine Dolan approached HIHI in January 2019 for support in securing a Video Observed Therapy (VOT) system at no cost to the health service for a pilot study. Lorraine had identified SureAdhere, a market leader in both UK and US VOT provision. The study was designed to test if VOTS is superior to DOTS in observing doses of TB treatment the patient receives.

Study objectives:

1. To test if levels of treatment observation are improved with VOT.
2. To measure patient satisfaction.
3. To assess cost effectiveness of VOT.

About Health Innovation Hub Ireland

Health Innovation Hub Ireland (HIHI) was established by the Department of Business, Enterprise and Innovation and the Department of Health, supported by Enterprise Ireland (EI) and the Health Service Executive (HSE) to drive collaboration between the health service and enterprise. We offer companies the opportunity for pilot and clinical validation studies and the health service access to innovative products, services and devices that they may not otherwise be exposed to.

HIHI is built on the recognition that collaboration with enterprise can benefit patient care, patient pathways

and outcomes. We assess all concepts for healthcare innovation from those on the frontline – from clinician to porter. We encourage healthcare professionals to get in touch with HIHI if they have an idea or solution to how something in your job might work better.



The Healthcare Challenge

Tuberculosis (TB) is the leading cause of death worldwide from an infectious agent, resulting in more deaths than HIV and malaria. Deaths from TB rose for the first time in more than a decade due to Covid 19 (WHO, 2022). Although TB is treatable, non-adherence to medication leads to ongoing transmission, disease progression and development of drug-resistant strains. Treatment is lengthy, ranging from six months to two years depending on the type and location of TB. St James's hospital, Ireland's national TB centre provides care for the majority of suspected and confirmed TB cases in Dublin area and manages all drug resistant cases in the country.

Compliance with TB medication is essential to prevent onward transmission, drug resistance and ensure treatment success. As per the 2010, Health Protection Surveillance Center (HPSC) guidelines those who are at risk of non-compliance require observed treatment. Directly observed treatment (DOT) has been the standard of care for tuberculosis since the early 1990s, but can be inconvenient and time consuming

for patients and service providers. Currently in Ireland, a public health nurse (PHN) physically visits a patient and observes each medication dose and records it manually on a hard copy – this is Direct Observed Therapy (DOT). Either a PHN visits a patients' home or the patient attends a local health centre once or twice a day, seven days per week.



The Healthcare Solution

Video Observed Therapy (VOT) uses a mobile smartphone application that allows patients to remotely record and send videos asynchronously of every medication dose ingested. A nurse views the date and time stamped videos on a secure web-based client management system that is password protected. Once a patient's videos upload to the web portal, they are automatically deleted from the smartphone.

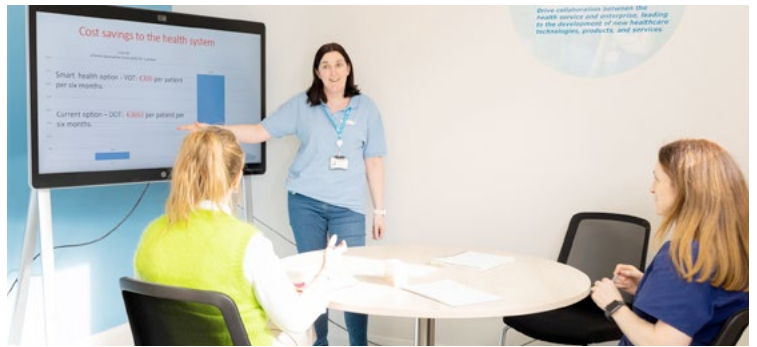
For the study VOTs ran through SureAdhere, an asynchronous system that includes a mobile smartphone application used by participant to record and send videos of every medication dose ingested. PI (Lorraine Dolan) viewed the date and time stamped videos

on SureAdhere's HIPAA compliant web-based Client Management System (CMS) that is password protected. Once participant videos are uploaded to the web portal they are automatically deleted from the smartphone. Observed doses was either one dose daily or twice daily doses.

In analysis for VOT, observations were classified as successfully completed if all doses were observed on video. Where patients forgot to record (but stated they did take dose) or where only partial doses occurred this was not classified as observed. In analysis for DOT observed doses were recorded by PHN in hard copy.

HIHI Role

HIHI led negotiations and secured the software for a two-year randomised study of VOT versus DOT at no cost to the national TB centre. HIHI supported study design, ethical and DPIA application.



Outcome Report

This study has shown that VOT had higher levels of treatment observation in the first two months of treatment and remained consistently high throughout treatment compared to DOT. VOT can facilitate twice daily dosing at no additional cost. For patients on twice daily dosing on DOT, typically the second afternoon dose in the PM could not be facilitated due to time constraints of PHN's. As a result, not all doses were observed which is a significant risk. In addition, this would double the cost of observation.

Financial Impact: Delivering DOT the system cost to the HSE is €3,362 extra per patient compared to VOT for same period. More patients can be observed via VOT and at considerably less cost compared to DOT.

Patient satisfaction: VOT empowered participants to continue normal work/life routines and took medications at a time convenient to them. Contrastingly, it was necessary for those on DOT to be available at set times suitable to the PHN's which disempowered and restricted the patients. Confirmed by the results of this pilot - participants transferred to VOT from DOT (n =7) was due to DOT caused time restrictions, interfering with employment.

Time Savings: The time for each individual PHN to carry out DOT for one patient was between 10 - 60 minutes. For VOT each patient video was on average one minute at the TB CNS computer. VOT can facilitate resource, time saving across staff teams, and support increased TB patient medication observation per day.

Testimonial

"This study would not have been possible without the support from HIHI. HIHI was instrumental in obtaining the use of the Sure Adhere platform at no cost for the two-year duration of the study. Their expertise in negotiating with the company and support with this study was invaluable. HIHI supported me in designing the study and throughout the ethics process. They offered advice and support throughout the study period and were always supportive. We worked together to review and present the findings of the study."

Lorraine Dolan,
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