CLINICAL EVALUATION STUDY





SymPhysis Medical are an Enterprise Ireland supported project based in the Lambe Institute in University College Hospital Galway. Their goal is to develop innovative technologies that treat a range of chronic diseases and to put the patient experience at the forefront of their solutions' design to improve patients' quality of life.

SymPhysis Medical's emergent technology, RelEase, is a catheter-based drainage technology to treat a common complication of late-stage cancers called malignant pleural effusion (MPE), also known as 'fluid on the lung'.

The driving force behind SymPhysis Medical is an unwavering commitment to provide independence and improved quality of life for patients with chronic conditions and those requiring palliative care.

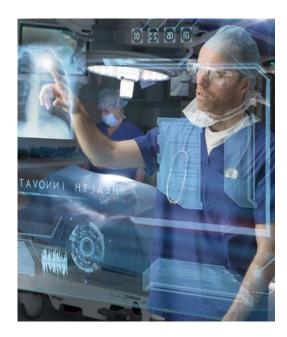
In 2019, SymPhysis Medical won the "Best New Idea" category in the county stage of Ireland's Best Young Entrepreneur competition. SymPhysis Medical are also finalists in the annual Futurescope One2Watch competition due to take place later in 2020.

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.



The Healthcare Challenge

A common complication of late stage cancers is malignant pleural effusions (MPEs) or 'fluid on the lung'. A pleural effusion is the accumulation of fluid around the lung, which causes shortness of breath and chest pain in patients and can significantly affect a patient's quality of life. Malignant or recurrent pleural effusions are those that persist despite first-line medical interventions and in cancers are often indicative of a patient approaching the end-of-life stage. MPE affects up to 15% of late-stage cancer, rising to 35% in patients with lung cancer. There are >200,000 new cases of MPE per year in the USA, and approximately 375,000 per year in Europe.

For patients to manage pleural effusions at home they have an indwelling pleural catheter (IPC) placed in the chest. The IPC is

designed to allow patients to relieve the breathlessness resulting from fluid build-up and must be drained 2-3 times a week. Often an IPC is in place for a significant portion of a patient's end-of-life stage as they are associated with very long (up to 12 months) and unpredictable treatment durations. Others issues with IPCs include the risk of acute hospital readmissions due to catheter-related complications and challenges with patient use and comfort.

The SymPhysis Medical team are collaborating with clinicians, public health nurses, patients and their carers in order to fully understand the limitations associated with the current IPC treatment for MPE so that an optimally designed catheter is designed that will improve clinical outcomes and better the patient experience.



The Healthcare Solution

The SymPhysis Medical team has identified an opportunity to provide an innovative technology that will be a more effective, better value, and a more user-friendly therapeutic option for managing MPE compared to the current standard of care. RelEase is a minimally invasive technology that incorporates a unique, active component designed to accelerate treatment, thus providing shorter and more predictable treatment durations, and allow the patient to be liberated from the catheter sooner. The technology will incorporate features that improve the functionality and the comfort/aesthetics of the device. A key aspect of the device's design is to enable most patients to manage their MPE unassisted. The device aims to improve clinical outcomes, reduce the clinical burden on clinicians, palliative resources and caregivers, shorten the treatment period for the patient, and improve patient independence.



HIHI Role

The main aim of the HIHI project was to gather end-user (i.e., nurses, doctors, and consultants) feedback on this clinical need and its core pain points. HIHI recruited specialist healthcare professionals with experience in the management of pleural effusions and the use of IPCs from hospitals across Ireland to engage in the project and facilitated feedback sessions where relevant information was gathered through detailed interviews and questionnaires. This information was presented in a report to SymPhysis Medical. This expert feedback is valuable to the company as they continue to develop and refine the design of their product. A secondary aim was to create a network of experienced clinicians in pleural effusion management that would engage in future feedback sessions to inform design and development.



Outcome Report

The report highlights the clinical need for an innovative minimally invasive solution for managing this condition at home that addresses issues associated with the current standard of care. The report identified that it should be possible for patients to independently service and manage their own IPC with the appropriate equipment and support. It advised that the next generation IPC should aim to address challenges currently associated with ease of use for patients and clinicians including patient access, product design, hygiene and sterility, dressing application, and the monitoring and tracking of use. Next generation devices should consider patient comfort in its design.

A minimally invasive, user-friendly solution would allow patients to manage their own IPC in the comfort of their own home. This would reduce the burden on healthcare resources and family members/caregivers, while enabling patient independence, and improving quality of life.

Testimonial

Through our engagement with the HIHI our team was able gain valuable insights from specialist healthcare professionals which will inform the design of a user-centric solution for an underserved population of patients.

Michelle Tierney, Founder

