Oxford AHSN Case Study

Date: Q3 2122

Theme/Patient pathway: Strategic and Industry Partnerships

Title: Oxford AHSN reaches first key milestone in major European partnership to improve outcomes for sepsis patients

Summary

IMPACCT (**IM**mune profiling of ICU **PA**tients to address **C**hronic **C**ritical illness and ensure heal**T**hy ageing) is a €4m study co-funded by EIT-Health and bioMérieux involving partners from France, Sweden and the UK.

Sepsis survivors often experience a weakened immune system. During the first days of sepsis, an overwhelming inflammation can take over. That initial over-activation phase is very often followed by a dramatic inhibition of the immune system (immunosuppression) which can lead to recurrent secondary infections, long-term disabilities and death.

Sepsis patients do not all face the same risks. By evaluating the immune status of sepsis patients while they are in intensive care (ICU) those at high risk of deterioration could benefit from improved care and personalised treatment.

The Oxford AHSN reached its first key milestone in the project at the end of December 2021 having carried out qualitative interviews and online surveys obtaining feedback from more than 100 healthcare professionals working in ICU and 50 payers from the UK, France and Sweden.

By June 2023 the study will enrol 600 sepsis patients hospitalised in ICU and their immune status will be monitored using a molecular platform. The first objective is to demonstrate if it is possible to identify a subgroup of sepsis patients at higher risk of poor outcomes and further infectious complications. The second objective is to validate prognosis biomarkers. Oxford AHSN will develop the value proposition and economic model to support future adoption.

The Immune Profiling Panel (IPP) is still in an early stage of clinical validation. The technology is being evaluated in clinical trials at Imperial College and University College Hospital, London, Karolinska Institute (Sweden), Paris and Lyon (France).

What is the challenge?

Sepsis is one of the most common causes of ICU admission in Europe, up to 37%. The clinical challenge is to identify patients in ICU whose immune responses have altered following a diagnosis of sepsis. A state of immune suppression induced by sepsis can leave some patients more susceptible to hospital acquired infections and at risk of deterioration, with long-lasting consequences that can affect the patient's quality of life after discharge from hospital and increase their need for other healthcare services. The main challenge however is that for adoption into routine clinical practice this innovative precision medicine approach will require significant pathway changes and stakeholder acceptance.

What did we do?

The Oxford AHSN supported bioMérieux and its clinical partners in their application for an EIT-Health grant. This partnership was instrumental in sourcing €4 million to cover the cost of the study.

The key objectives of our part of the study were to determine the differences in care pathways and stakeholders' opinions across the three countries to identify the value proposition of IPP and the potential barriers to adoption.

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EIT Health is supported by EIT, a body of the European Union.

What has been achieved?

The views and insights given by the clinicians and payers of the current clinical landscape and current practices in the management of these patients have helped to build an understanding of the barriers to implementation of IPP in the ICU care pathway for each country. This feedback is crucial in supporting bioMérieux to create an adoption plan for the IPP into the sepsis care pathway and a route to market strategy tailored for each country.

What have we learned?

Barriers and challenges to the adoption and spread of the product are:

- The technology and its utility in predicting which patients are at risk is still being tested in clinical trials
- The interviews with stakeholders demonstrated that processes in place for acquiring a new technology is different in each of the three countries and therefore implementation will require a country-specific approach.

Feedback

"We are highly satisfied by our collaboration with Oxford AHSN. They have already achieved key deliverables that will allow us to establish the clinical and economic benefits of IPP and to understand the barriers to implementation. Their input is key to the success of this project."

Karen Brengel-Pesce, Senior Director, Open Innovation & Partnerships, bioMérieux

"As a clinical academic, I have learnt that demonstrating the scientific proof behind innovation is only the first step. If we want to improve patient care, then we need effective knowledge mobilisation.

The team at Oxford AHSN are crucial to successful implementation of the novel technologies and techniques within different healthcare systems."

Anthony Gordon, Professor of Anaesthesia and Critical Care, NIHR Research Professor, Imperial College London

"As new immunotherapies come to market, IPP has the potential to ensure that those sepsis patients that would benefit from immunotherapies receive the treatment they need improving patient outcomes and quality of life for millions of sepsis patients."

Julie Hart, Director of Strategic and Industry Partnerships, Oxford Academic Health Science Network

Next steps

The EIT-Health project ends at the end of December 2022. However, patient recruitment will be extended to June 2023. A draft budget impact model will be created by Oxford AHSN in 2022 and in 2023 this model will be populated with trial data. The company will use the evidence generated from this project to apply for product registration (CE / UKCA marking). Once the product has acquired its regulatory status with proven clinical safety then there is the potential for hospitals to evaluate the product in a real world setting from 2024. Many hospital labs already use the BioFire molecular platform in the UK but there will be significant clinical education and awareness needed to promote the use of IPP. The technology is still going through clinical trials and the company is collecting the evidence needed for regulatory approval. Once approvals have been gained, there is the potential for real world service evaluations.

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