Oxford AHSN case study

Date: Q2 2020/2021

Programme / theme: Strategic and Industry Partnerships

Title: Consortium including Oxford AHSN and POCKiT Diagnostics secures over £700,000 in grant funding to improve diagnosis of stroke within the NHS in England

Overview Summary

Stroke affects 100,000 people in the UK each year[1]. 33% of patients will die and 90% of survivors will have a disability for the rest of their lives.[2]

POCKiT diagnostics is a Cambridge-based company created in 2017. In 2018, POCKiT Diagnostics performed a double-blind retrospective clinical study where they discovered a novel biomarker panel with high accuracy for stroke sub type differentiation.

Funded by an Innovate UK grant awarded in December 2018, POCKiT Diagnostics is working with the Oxford AHSN, Newcastle University, Newcastle Hospitals, Oxford start-up company Absolute Antibody and University of Reading start-up company Capillary Film Technologies Ltd, to develop their biomarker panel test for stroke diagnosis.

The Fplus1 test from POCKiT Diagnostics is a revolutionary innovation that combines ultra-rapid (<20 minutes) detection of blood biomarkers that are highly specific for stroke subtypes, within a point-of-care device. POCKiT Diagnostics partnered with Oxford AHSN as they wanted to understand the current stroke care pathway in the NHS and the cost consequences of introducing the use of Fplus1 for the rapid diagnosis and management of stroke patients in the NHS in England.

The Oxford AHSN team conducted an early economic evaluation and a feasibility study using its Lean Assessment Process (LAP) to assess the potential impact of Fplus1 test on the clinical pathway.

Challenge/ problem

The Fplus1 test from POCKiT Diagnostics is an automatic, cartridge-based portable device that can quantify blood-based biomarkers in 20 minutes. The hypothesis is that the Fplus1 test conducted at the Point of Care (PoC) will provide more accurate diagnosis of stroke sub-type, leading to the most appropriate and quicker treatment for the patient leading to better outcomes.

[1] https://www.stroke.org.uk/sites/default/files/state_of_the_nation_2018.pdf
[2] https://www.pockitdx.co.uk/

In stroke, the brain is damaged by restricted blood flow to the brain, which leads to death of brain cells. Two main types of stroke exist with patients having similar symptoms: ischemic stroke (IS) and intracerebral hemorrhage (ICH); whilst they have similar symptoms, treatment is opposite. IS is caused by a clot in the brain and treated with 'clot busting' drugs. If the clot busting drug is given fast enough (within 3-4 hours) the patient may recover with little or no damage to the brain. ICH is caused by bleeding in the brain. Clot busting drugs incorrectly given to ICH patient prevents clotting and healing, which is a disaster.

The problem is that currently, there are no point-of-care devices on the market for the accurate and rapid diagnosis of brain stroke subtype. In the virtual absence of competition, the innovation has the potential to disrupt and revolutionise current diagnosis of stroke and significantly reduce stroke-induced death and disabilities. The collaborative network brought together within this project aims at bringing forward the Fplus1 prototype towards full development of a product upon regulatory approval, Fplus1 will initially be introduced in the United Kingdom market, with the final goal of expansion to the European and global market. The challenge identified is that POCKiT Diagnostics wanted to understand the value proposition of the Flpus1 test in the NHS in England.

How is the AHSN involved?

Oxford AHSN facilitated bringing together the collaborative network for this project and assisted in developing the grant application. As a key partner in the grant, the Oxford AHSN team conducted an early economic evaluation and a feasibility study using its Lean Assessment Process (LAP) to evaluate the impact and potential cost effectiveness of Fplus1 in the NHS in order to develop the value proposition. The LAP methodology has most impact when conducted early in the process of healthcare technology development and its utility comes in making sure the product developed aligns with the needs of healthcare stakeholders.

The key objectives of the early economic evaluation were to assess cost impact of introducing Fplus1 in the stroke care pathway and identify the potential cost savings. The feasibility study looked at the potential impact of implementing the Fplus1 test within the NHS in England and understand the potential impact of the test in the initiation of faster and appropriate treatment.

Impacts and outcomes of the AHSN involvement to date

The early economic evaluation suggests that introducing the Fplus1 test into the care pathway may lead to significant savings when correctly identifying stroke mimics from a stroke before intravenous thrombolysis treatment. The cost analysis for implementing the Fplus1 test with an assumed population of 1,200 patient cohort suggests there are a possible savings of £1,996,886.28 annually (standard care cost of £2,689,946.76 versus cost with Fplus1 of £723,060.48), if all the stroke mimic patients are diagnosed by Fplus1 with a result time of less than 20 minutes and with high sensitivity and specificity before intravenous thrombolysis treatment.

This collaborative R&D project “Point-of-care stroke sub-type diagnose to enable rapid treatment” is funded by UK Research and Innovation (Innovate UK) from December 2018 to February 2021 with a funded value of £706,852.

One scenario is that the Fplus1 test from POCKiT Diagnostics may have the potential to help to differentiate stroke mimic patients from stroke (where stroke mimics are patients presenting with

acute stroke-like symptoms but turn out to have an alternative diagnosis). These patients are often incorrectly given intravenous thrombolysis treatment and therefore introducing the Fplus1 test could result in cost-savings in the stroke care pathway in the NHS in England. The collaborative network will continue working together as the project is extended into 2021 and have decided to apply for further grant funding to support similar work around the development of a complementary product.

Supporting quotes

Innovator

"The reports were very useful as it helped identify and quantify an alternative application of our technology. Based on the report, we decided to perform extra data analyses to confirm in our patient cohort whether the application suggested by the report was feasible. The data confirmed that we could have an application."

Edoardo Gaude PhD

Co-founder and CSO

AHSN

"Stroke is one of the prime causes of morbidity and mortality. Rapid identification of true stroke patients with point of care testing can result in increased patient prognosis and help in saving treatment cost."

Mamta Bajre

Lead Methodologist

Plans and timescales for spread and adoption

POCKiT Diagnostics needs to finish an extensive clinical study in order to achieve regulatory approval. This collaborative effort which started in December 2018 includes sample collection in partnership with Newcastle hospitals. The goal was to achieve market approval in 2020 but has been delayed due to Covid-19.

Start and end dates

June 2018 – ongoing

Contact

Mamta Bajre

Lead Methodologist

Mamta.bajre@oxfordahsn.org