NIHR | Newcastle In Vitro Diagnostics Co-operative

Impact Stories

The NIHR Newcastle MIC are experts in generating high quality evidence that demonstrates the potential value of a new in vitro diagnostic test

Our aim is to ensure that better diagnostics are delivered more quickly for the benefit of patients

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Supporting better diagnostics for patient benefit.

The NIHR Newcastle In Vitro Diagnostics Co-operative is a member of the National Institute for Health Research (NIHR) MedTech and In Vitro Diagnostics Co-operative (MIC) network.

We are experts in generating high quality evidence that demonstrates the potential value of a new in vitro diagnostic (IVD) test. (This is a diagnostic test carried out on patient samples).

Our work is focused on the analysis of the care pathway (a patient's journey through the healthcare system), economic modelling and clinical evaluations. This all helps to assess if a test is fit for use and if there is a currently unmet need for it within the NHS.

The focus of our work is mainly within three clinical areas:

- Ageing and long-term chronic conditions
- Infectious diseases
- Personalised and stratified medicine

This booklet provides examples of the work we have carried out and the different companies and organisations that we engage with in our work.

Since it has been regionally implemented, the two step testing strategy for FH has saved patient lives and the NHS money.

Problem

Familial Hypercholesterolaemia (FH) is a common inherited condition, affecting around 1 in 250 people. It is important to diagnose and treat the condition as early as possible as it can cause premature heart disease. However it can be difficult to identify individuals at risk and current genetic testing is expensive.

Action

We evaluated a two stage testing strategy:

- a low cost test is used to identify patients with common gene alterations.
- The current higher cost test is only used when gene changes are not detected in step 1.

£716k
NHS cost savings

12
deaths prevented

Outcome

- The two step testing strategy could save £65.91.
- We used Health Survey for England data to create a software tool to help identify individuals at high risk of having FH.

Impact

- This was a successful collaboration involving 10 Cardiovascular Clinics, 13 Clinical Commissioning Groups (CCGs), the Northern Genetics Service, NewGene Ltd, AHSN NENC, AstraZeneca and the British Heart Foundation.
- The study has prevented an estimated 12 deaths in the region.
- The study also led to a regional roll out of the strategy which has saved the NHS an estimated £716k since 2014, allowing resources to be used elsewhere for patient benefit.
- The age and gender specific reference ranges we developed have been incorporated into the recent version of the NICE guideline for FH identification and management.

Understanding patient value has helped Anasyst accelerate their test development.

Problem
Sepsis is a life-threatening condition caused when the body's usual responses to combat bacterial infection fail. It is challenging to identify sepsis as there is no laboratory test to quickly and reliably diagnose it. This can lead to delays in treatment and inappropriate use of antibiotics.

Action
We helped the UK SME Anasyst secure a NIHR Invention for Innovation (i4i) Connect award to develop a portable low cost test for quick detection of Sepsis.

Outcome
- We helped the company select the most appropriate molecules to be measured by the test.
- Through discussions with healthcare professionals and members of the public we identified that the test may add most value if it is used to "rule-out" sepsis when patients are admitted to hospital.

Impact
- We partnered with the UK Sepsis Trust to deliver a educational session around sepsis for the public.
- We also incorporated the views of the public regarding the clinical setting for the test.
- This is an example of a successful collaboration with the NIHR Innovation Observatory.
- This work was shortlisted for a 2018 Bright Ideas in Health Award.
- We aim to support the progress of this study into other NIHR funding streams through assessing the use of the test in different clinical settings and potential savings associated with the test.

MR-proADM alongside the NEWS helps to identify deteriorating patients with mild NEWS at hospital admission.

Problem
Patients admitted to hospital have their National Early Warning Score (NEWS) monitored to predict if they are getting worse. However we need to develop extra tests as the NEWS does not always accurately forecast declining health, especially in patients with an underlying medical condition.

Action
Thermo Fisher Scientific funded our study to examine whether their mid-regional fragment of pro-adrenomedullin (MR-proADM) test could improve the detection of worsening illness in patients with mild NEWS in an NHS setting.

Study publication
cited in NICE advice document

Outcome
- Measuring MR-proADM alongside NEWS score predicted deterioration in mildly and moderately ill patients more accurately than NEWS score alone (accuracy of 61% vs 55%).
- A potentially useful decision aid could be based on the NEWS, MR-proADM level and clinical features (accuracy around 69%).

Impact
- MR-proADM testing, when used alongside NEWS2, could help clinical decision making regarding care for patients with suspected infection and sepsis.
- This could potentially avoid unnecessary hospital admissions and ensure that patients with declining illness are transferred to high dependency and intensive care units and receive the most effective treatments quickly.
- Our publication of this study was cited in the Medtech innovation briefing for this test, an advice document produced by the National Institute for Health and Care Excellence (NICE) to support local decision making by NHS and social care commissioners and staff.

Speeding up and accurately diagnosing RSV at the bedside could reduce the spread of infection and produce cost savings for NHS hospitals.

Problem
It can take over 24 hours to get a test back from a laboratory to confirm if an infant has a respiratory syncytial virus (RSV) infection, the most common reason for a child to be admitted to hospital. The virus is highly contagious so there is a need for a fast and accurate diagnostic test for RSV to ensure appropriate use of isolation resources and prevent spread of the infection.

Action
Roche Diagnostics funded us to evaluate their cobas® Liat system for diagnosing RSV near the beside at the Newcastle Great North Children's Hospital and Sunderland Royal Hospital.

"I think as a parent it gives you piece of mind knowing actually what's wrong."

"You don't know what a child's immune system is like and you could be putting them in danger."

Outcome
- The cobas® Liat system was as good at detecting RSV infection as standard laboratory testing with a sensitivity of 98.9% and specificity of 94%.
- Waiting time for a test result was reduced, on average, to 36 minutes.
- A potential saving in isolation resource use of half a day per patient if the test was used.
- A predicted saving of £62/patient if the test was implemented.

Impact
- Use of the test could reduce the spread of infection, and potentially save the NHS time and money, through optimising the use of isolation resources.
- The new device could facilitate the development of targeted therapies.
- This was an example of patient and public involvement, engagement and participation as parent groups guided the study design and patient/parent information.
- The project has been presented at three international conferences and was selected as a finalist for a 2019 Bright Ideas In Health Award.

Faster diagnosis of C.diff using the Revogene test should ensure patients are treated and isolated more quickly, thereby reducing the spread of infection.

Problem
Clostridium difficile (C.diff) is a bacterium that can infect the bowel and cause severe life threatening infection. There is a need to develop a test that can rapidly diagnose C.diff as it can easily spread, especially within hospitals and care homes.

Action
A Canadian company, GenePOC, now acquired by Meridian Bioscience, funded us and health economists at Newcastle University to evaluate the potential benefits of their Revogene™ test for diagnosing C.diff at the bedside.

Outcome
- Interviews with clinical and scientific experts revealed that currently C.diff is diagnosed using multiple laboratory tests which are often conducted away from the hospital site. This can cause delays in the actions of the clinical team awaiting the test results.
- Economic modelling implied that Revogene™ would save £283,282 per 1000 hospitalised NHS patients with a suspected C.diff infection, primarily by reducing the length and cost of a stay in hospital.

Impact
- Faster diagnosis of C.diff, using Revogene™, should ensure that patients are treated and isolated more quickly.
- This would also reduce the spread of the infection.
- There could also be potential savings to NHS resources through a change in current practice for diagnosis and management of C.diff.
- The results of this research were presented at the 29th European Congress of Clinical Microbiology and Infectious Diseases.

Using BD OneFlow™ LST and B-CLPD T1, as an aid in the diagnosis of CLL, will enable patients to have earlier access to treatments and save NHS resources.

Problem

As the population ages, more people are developing chronic lymphocytic leukaemia (CLL) and there is increasing pressure to diagnose the condition. We need to find ways to increase the accuracy, speed and efficiency of diagnosis.

Action

Becton Dickinson (BD) funded our study to measure the performance of BD OneFlow™ LST and B-CLPD T1 as an aid in the diagnosing of CLL, and also to assess the economic value of adopting BD OneFlow™ LST and B-CLPD T1, in place of current practice.

Outcome

- NHS staff view the system as safe and effective.
- There was 100% agreement between BD OneFlow™ LST and B-CLPD T1 and the current NHS test.
- Using BD OneFlow™ saved 13 hours of staff time per 100 samples.

Impact

- Use of BD OneFlow™ LST and B-CLPD T1 could potentially produce NHS savings by allowing an increased workload to be handled more comfortably by the same workforce.
- This could also allow CLL patients, and individuals with other blood cancers, to receive a faster diagnosis and consequently earlier access to treatments.
- This project was an example of a successful collaboration with our colleagues at Newcastle University which has led to a publication.
- The technology is also available for potentially aiding the diagnosis of other blood cancers too.

Self-testing kidney function in the home gives accurate results, empowers patients and may save them and healthcare services time and money.

Problem

Kidney function needs to be frequently monitored in patients who have received a kidney transplant. Currently this occurs in a specialist kidney clinic, but this might be unnecessary since the patients are typically well.

Action

We explored the practicalities of patients testing their own kidney function at home by gathering their views and the opinions of clinicians. We also quantitatively compared home test results with standard laboratory test results.

Good agreement between home and laboratory testing results

Outcome

- There was a sufficiently high level of numerical agreement between the home and laboratory test results.
- Home monitoring could reduce the burden on the NHS and make routine examinations in the clinic more efficient, saving limited resources.

Impact

- Home monitoring of kidney function could improve the patient experience.
- This was an example of a successful collaboration with South Tees Hospitals NHS Foundation Trust and the Academic Health Science Network North East North Cumbria (AHSN NENC).
- The project team were finalists at the 2019 Bright Ideas in Health Awards.
- The results have been submitted to BMJ Open as a research paper, received mainstream media attention and have been summarised in a video case study: https://m.youtube.com/watch?feature=youtu.be&v=PqCnd5ASU9U

The work of the MIC has helped Mologic shape the design of their test and clinical study.

Problem
COPD is a group of lung conditions that cause breathing difficulties. A flare-up, when symptoms suddenly worsen, can significantly damage the lungs. Currently COPD patients monitor their health at home and seek medical advice when symptoms get worse, but this can be difficult to recognise.

Action
We helped the UK SME Mologic win an Innovate UK Small Business Research Initiative (SBRI)-Phase II award to further develop Headstart, a home-monitoring urine test for detecting early signs of a flare-up.

Outcome

- A steering group, containing healthcare professionals from hospitals and the community along with patients, contributed to the design of the test ensuring that it was user friendly for individuals with COPD.
- Working with Newcastle University and Nottingham Trent University, we delivered a complex statistical model to detect flare-ups.
- With Newcastle University health economists, we created a model to identify the optimal decision rules for early diagnosis.

Impact

- Home monitoring of COPD could improve the patient experience.
- This is an example of a successful collaboration with the NIHR Community and Healthcare MIC, Oxford AHSN and AHSN NENC.
- The project contributed to our shortlisting for an Antibiotic Guardian Award to decrease antibiotic usage.
- The models developed by the MIC will be validated in the next clinical study starting in November 2019.

"We would not have had the confidence

to continue with the challenges associated with introducing novel technologies without the help of the Newcastle MIC."

Ongoing projects

We are working with academic and industry partners on a number of early stage projects.

We are collaborating with the Newcastle University Stroke Research Group to clinically evaluate technologies which could be useful in an ambulance setting and ensure that patients with suspected stroke are transferred to the most appropriate treatment centres quickly:

- We will collaborate with Sarissa Biomedical Ltd on an Innovate UK SBRI phase 2 grant to develop a test to identify stroke "mimics" in a droplet of blood.
- We will work with Cerebrotech Ltd on a Medical Research Council (MRC) Confidence in Concept award to develop a non-invasive test to identify severe stroke patients.

We are collaborating with Queens University, Belfast on a NIHR HTA funded diagnostic accuracy study to assess the performance of three rapid tests for fungal (Candida) infection in 35 UK adult and paediatric intensive care units.

As part of a team, including Cardiff University, we will evaluate a "clinical decision support tool" to help GPs accurately diagnose the cause of male lower urinary tract symptoms through a NIHR Health Technology Assessment (HTA) award.

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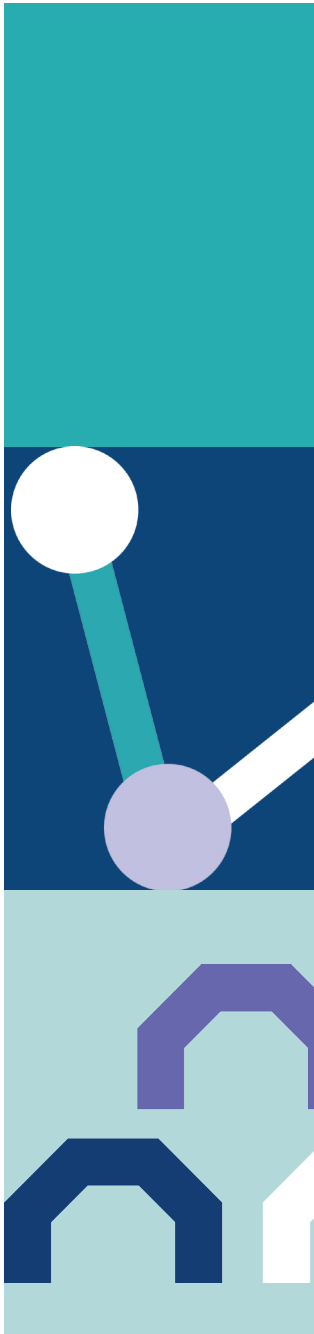

To find out more or submit a collaboration request visit:
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The information in this leaflet is correct at the time of printing.