Use of rapid genetic testing equipment – a human factors case study

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SUMMARY

A case study of the successful implementation of a rapid bedside genetic test in neonatal units, to reduce the likelihood of hearing loss in premature and sick babies.

KEYWORDS

Genetic test, hearing loss, implementation, healthcare

Introduction

Approximately 90,000 babies are admitted to neonatal units each year, the most common causes are premature birth or sickness. Many of these babies require antibiotic treatment on admission or soon after to treat and/or protect them against infections. The most common antibiotic used in neonatal units is gentamicin. However, around 1/500 babies have a small difference in their genetic make-up – a genetic variance (MT-RNR1 m.1555A>G) - which means that they can develop severe hearing loss or total deafness after only a single dose of gentamicin. Although there are established laboratory-based genetic tests which could be used to detect this genetic variance, these can take an extended amount of time, which is often too long when rapid treatment is required.

Manchester University and a technology company called Genedrive together created a medical device that performed a rapid point of care test (POCT) for this genetic variant that could provide a positive or negative result within 26 minutes. This rapid response meant that babies could be given the most appropriate antibiotic within the first hour of admission to a neonatal unit.

However, having the technology is only the beginning. The key is to make sure it can be used accurately and reliably, and to ensure that it can be integrated into the established, busy admission process for neonatal units. This was trialled in the NIHR-funded research study Pharmacogenetics to Avoid Loss of Hearing (PALOH) (McDermott 2020, 2021, 2022). Human factors good practice principles were reflected in this process. These are not restricted to good ergonomic device design, but also good project planning, organisation and engagement with key groups and specialists. These principles are described as a case study here.

Effective collaboration

The initial project team were awarded funding to bring together a broad team to trial the implementation of the genetic testing device over two busy neonatal intensive care units (NICUs) in the north-west of England. The team was made up of a wide range of disciplines including subject-matter experts, technologists, end-users and Public and Patient Involvement and Engagement (PPIE) contributors, one of whom was a Human Factors specialist. All members attended the monthly project meetings where project decisions were made, progress was summarised and crucially each member of the project team had an equal voice as the project developed.

In addition to this, additional project participants were involved as the project progressed, including experts in health economics to assess the impact that this device and test could prove to be cost-effective when compared against life-long costs associated with hearing loss.

Clarification of the project aims

It is important that the public can buy into the need for new medical devices and equipment. The diverse team and frequent engagement with patient representatives from an early stage helped to maintain the focus of the study. Engagement with the public also helped to raise the profile of the study, making people aware of the genetic variant and how this study had the potential to help reduce its impact by detecting it early.

Identification of the challenges

Early in the project it was acknowledged that the logistics of fitting a genetic test into the already busy first hour of a baby's admission to the neonatal unit (often referred to as the 'golden hour') was key. Exploring the potential to do this involved a task analysis-style approach to reviewing the admission process, the minimum number of people involved and their responsibilities, what was done when, in what order, and where administering the genetic test could be integrated without impeding this finely tuned process.

There are regularly a team of people involved in a baby's admission to the neonatal unit, carrying out a number of different tasks, from the immediate stabilisation of a baby's breathing, attaching the relevant monitoring devices, taking of blood gas measurements and swabs for MRSA. It was important to demonstrate that this new test could be carried out as part of this suite of tests, without compromising any of the existing, essential activities.

In order to not disrupt the usual admission routine, a task review was carried out to identify the best time for the test swab. This concluded that combining this with the routine skin swabs, such as those for covid and MRSA, felt intuitive as it was a single additional task added to an established and well-practiced process. The timing of these swabs, carried out early in the admission process, allowed time for the test result to be processed so that suitable antibiotics could be administered within the first hour of admission.

Identification of end-users and design of the medical testing device

The genetic test was carried out by performing a cheek swab on the baby, then transferring this sample to a handheld medical device for analysis. The end users of the device were identified (in this case 300 neonatal nurses were trained to perform the test) and a review carried out of the current skills and experiences of the neonatal nurses and how these could be drawn on to make the device as familiar and usable as possible to reduce the potential for error.

A task analysis approach was taken when reviewing the number of task steps needed to carry out the test, how this could be simplified and the process made as intuitive as possible. The design and usability of the genetic testing device was reviewed and revised in response to end-user and Human Factors specialist advice. Some of the initial feedback to the test equipment and process included:

- The need to simplify the information inputted into the testing device before the test, making the information input and layout more intuitive and allowing less opportunity for error
- Consideration of how to manage multiple tests being carried out concurrently
- Potential improvements to navigation within the testing device system
- Providing meaningful labels, from the name of the test equipment, to clear and unambiguous indication of the test results

This review also included the clarity of instructions and operator aids to guide the users as they became more familiar with the system and the training provided.

Teamwork was found to be important (Brown, 2024) in how the tasks were organised, e.g. one nurse would take the swabs and be 'hands-on' in carrying out admission tasks, the swabs would be handed to a second nurse who would run the tests and wait for results.

Engagement with the trial and understanding of the importance of the test was cited as a key issue in the success of the trial (Brown, 2024). Neonatal nurses reported that it was important to them that they were not harming the babies by giving them an antibiotic that would damage their hearing. Conversely this also meant that failure of a test could increase anxiety and frustration, increasing the importance of resolving any reported user frustrations during the testing. The majority of nurses interviewed at the end of the trial period reported that they felt that the test fitted well into the admissions process without any delays to administering antibiotics.

Errors encountered and how these were addressed

The study found that it had a failure rate of approximately 20.4%, 17.1% of which was attributed to equipment failure. The reasons for these failures were investigated during the trial period, along with initial operational feedback, and a number of improvements were made, which reduced the failure rate to 5.7%:

- A barcode scanner replaced manual input of patient data, which immediately associated a test with a specific baby and reduced potential for input errors at start of test.
- Five false positives were identified during testing. These babies were treated with an alternative antibiotic and underwent traditional genetic testing to investigate the accuracy of the test. The false positives were found to be a result of incomplete testing cartridge insertion – this was addressed by improving the design of the cartridge to ensure that it would be assembled and inserted correctly before the test could be performed.
- Test fails were found to be predominantly associated with low-signal intensity, which was resolved via modifications to the assay buffer following the initial testing period.
- There were instances of equipment not working as expected and the printer not working due to poor connectivity. The second generation of the testing device improved connectivity, improved the interface and reduced input errors.

Accessible information for patients (in this case, parents of patients)

The testing was carried out by medical staff, but for the purposes of the trial it was important that parents of neonatal babies had accessible information, delivered in a variety of different formats to help them understand what the testing involved. Focus groups were carried out with neonatal parents to develop appropriate information materials and provide the patient-parent perspective on other elements of the process, including the consent process (Dawes, 2024).

After care

Within the study, three babies were correctly identified as testing positive for the genetic variant. In addition to the requirement to an alternative antibiotic, it was recognised that the families with babies who tested positive would need support and advice. The project team included Health Psychologists and genetic counsellors who were able to develop appropriate processes and onward signposting to further support.

Reflection & identification of potential improvements

The project assessed 751 babies, three of whom tested positive for the genetic variant and were given an alternative antibiotic as a result. The test was fully integrated into the admissions process and did not delay antibiotics administration. Throughout the project equipment failure rates were improved through ongoing assessment and fine-tuning to reduce the potential for user-error.

Recognition

The results of the testing have been published and the genetic testing device was conditionally recommended by NICE for use in February 2023 (NICE, 2023). The impact of this testing on neonatal has been acknowledged through a number of awards, including the New Statesman Positive Impact in Healthcare award (2022), Manchester University Making a Difference award (2024) and the Times Higher Education STEM award (2024). Funding has been awarding for a follow-on project rolling out the testing across the UK.

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