12 NOV 2020

The role of routine data in the fight against COVID-19

Dr Marion Mafham leads the data linkage team for the UK's landmark Randomised Evaluation of COVid-19 thERapY (RECOVERY) trial. She describes the key role that routine patient data is playing in the world's largest clinical trial investigating effective treatments for COVID-19.

What is the RECOVERY trial?

When the coronavirus pandemic began, there were no specific treatments available for those severely affected by COVID-19. There was an urgent need for information about whether existing or new drug therapies were effective against the disease. Normally, a large clinical trial would take many months to set up but RECOVERY was launched in just nine days and recruited over 10,000 patients within two months. Patients hospitalised with COVID-19 who enter the trial receive either standard care alone or standard care with the addition of one of the treatments under investigation. So far, over 16,000 patients have now participated in the trial, from 176 hospital sites across the UK. This trial has already delivered important results, including the discovery that the steroid dexamethasone reduces death in ventilated patients by a third – a finding that may already have saved thousands of lives worldwide.

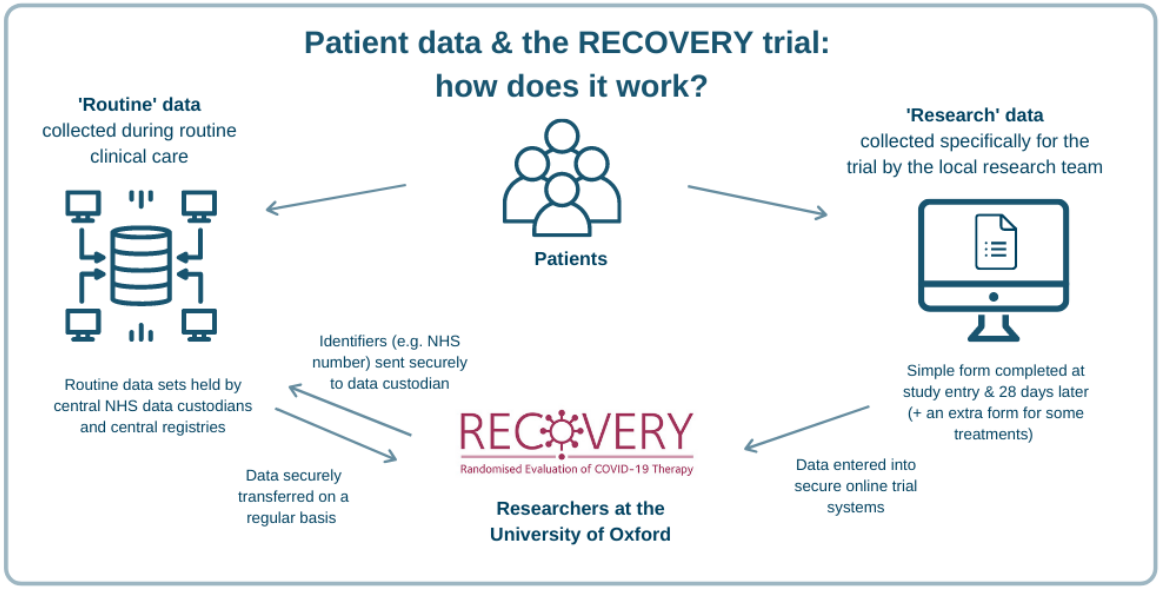
A recipe for success

RECOVERY's success has been driven by several key factors. First, the unified structure of the NHS and support for clinical research from the National Institute for Health Research (NIHR) allowed us to rapidly roll out the trial across England, Wales, Scotland and Northern Ireland. Secondly, the trial was designed to be easy to take part in for the staff in the local hospitals. The paperwork was short and simple to follow. Thirdly, having access to routine patient data stored in central databases has enabled us to make robust, evidence-based judgements without imposing additional burdens on the healthcare system.

The role of routine data

For any clinical trial, it is important that its conclusions are based on robust, complete, high-quality data. But during a global pandemic, it is simply not practical to ask frontline healthcare staff to obtain large volumes of information. Very sick patients are also unlikely to be in a position to fill out long forms to describe their full medical history. We focused on making the

process as simple as possible, so that staff only have to provide the essential information (such as the treatments the patient was receiving when they joined the trial e.g. oxygen). Our routine data team then links each recruited patient with their record in the databases held by the central NHS data custodian - NHS Digital for England, the SAIL Databank for Wales, Public Health Scotland and the National Records of Scotland. Linkage with data from other organisations like the UK Renal Registry and the Intensive Care National Audit and Research Centre adds additional information. This allows us to track the patient's progress over time, including whether they required ventilation or dialysis treatment, and ultimately if they made a recovery or not.



Better data = better knowledge

The ultimate advantage of using routine healthcare databases is that we can, with the patient's consent, instantly access the central health data, including previous hospital admissions and prescribed medication. This will help us to identify underlying health conditions, so that we can find out which groups of patients might benefit most from the treatments being tested. Most importantly, these records give complete information about patients' progress after they joined the study, even if they move to another hospital. Since information is continually added to their record, we can also analyse the effects of the treatments on health outcomes over the long term, such as later lung problems or kidney disease.

What about data security?

The University of Oxford has well-established systems and processes for keeping confidential data secure. Patient data is stored in secure servers in the University of Oxford and only a small number of University staff are permitted to access data that identifies the individual people taking part in the trial. Access to this data requires a secure username and password. The staff coordinating the trial have access to the 'research data' entered by the local site staff (see figure) so that they can check the data and ensure that the study is being run correctly. The 'routine' patient data is held in a separate secure database and this is accessed by the staff who receive the data and process it so that it can be analysed, and by the study doctors who need to work out how to analyse the data.

Going forward

RECOVERY has clearly demonstrated the value of routine data in supporting clinical trials. Wider adoption of this approach will help researchers have the most reliable evidence to judge potential treatments for any disease. This is the goal of the NHS DigiTrials Health Data Research hub, which was developed to enable more and better trials through effective use of routine health care data, while maintaining patient privacy. Initially, NHS DigiTrials focused on helping researchers to work out if a clinical trial is feasible, based on the number and location of potentially eligible patients. The hub is now supporting RECOVERY by providing comprehensive data held by NHS Digital to allow full evaluation of the treatment's effects and is working to make this service available to other researchers across the UK.

My hope is that the legacy of the coronavirus pandemic will see patient data put to use more effectively to help discover better, safer treatments that will benefit us all.

Find out more

https://www.recoverytrial.net

Acknowledgements

The RECOVERY trial is conducted by the registered clinical trials units in the Nuffield Department of Population Health in partnership with the Nuffield Department of Medicine. The core funding has been provided by UK Research and Innovation and the NIHR.