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FEATURE

DOCTORS AND RESEARCH

The lung study promising a breath of fresh air in research world

Could the Salford Lung Study be a "game changer" for the way clinical studies are conducted? **Matthew Limb** reports

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Researchers see it as a test bed for "real world" trials that could lead to the quicker introduction of drugs and medical devices. The Salford Lung Study is examining the safety and effectiveness of a new treatment for chronic obstructive pulmonary disease (COPD) in 80 general practices around Salford in north west England.[1] About 2500 patients are participating, half randomised to a new inhalation powder Relvar Ellipta (fluticasone furoate/vilanterol) and half to usual treatment.

Conventional randomised controlled trials are usually conducted in patients with selected characteristics, an arguably artificial setting. The Salford study differs in that it is a pragmatic trial of patients from everyday general practice, the first started before licensing.[2]

"In a real world study the question you're asking is, 'Will that medicine work in the general population … and in the health service setting in which it's provided?'" says David Leather, global medical affairs leader for sponsor GlaxoSmithKline (GSK).

"There is a lot about this that at the moment is unique to the UK and the NHS."

In 2011 GSK sought advice on the study from the Medicines and Healthcare Products Regulatory Agency and the National Institute for Health and Care Excellence via their joint scientific advice procedure. Leather says their positive attitude was "far sighted."

The study is a wide ranging collaboration and includes GSK, academics, GPs, hospitals, and pharmacists, underpinned by the ability to share patient data in real time.

It uses an integrated electronic health records system developed by North West EHealth, a not for profit partnership of clinicians and academics. The system originated from joining up information on diabetes across primary and secondary care, says its chief executive, Martin Gibson, a consultant diabetologist. To make the system regulatory compliant "we have built all the software and systems that allow you to do a late phase III trial," he says.

There are few exclusion criteria so the study enrols people who wouldn't normally be able to take part in a randomised trial, such as those also being treated for heart disease, cancer, diabetes, or depression. Patients see their GPs as they would usually and take their prescriptions to local pharmacies.

"That meant we had to have every pharmacy joined into the electronic health records system," says Gibson, who is also director of the National Institute for Health Research (NIHR) clinical research network for Greater Manchester.

Data tsunami

Susan Collier, GSK's head of medical operations for the study, says safety monitoring has been a huge challenge. Patients with comorbidities were expected to experience more serious adverse events, not necessarily related to the study. Collier suggests the safety alerting system and monitoring is "more robust than in a standard RCT" because it happens in real time with access to the "entire medical record."

She says, "We are seeing every event from beginning to end, from the moment patients enter the emergency department to the moment they're discharged home. We capture everything in our safety reporting—every blood test, every chest x ray, every ECG, every clinical note."

Hence the volume of data produced already—235 million "rows of it"—which Leather likens to a "tsunami."

Collier says, "The down side of that is we actually get too much information. But we're going to learn a great deal about what really happens to COPD patients in the real world and we're going to learn about safety in much more detail. The next big challenge is turning all these data into evidence that means something." A full report on the findings is expected next year.

Some 4200 patients with asthma are now being recruited for the next part of the study, which will report in 2017. The study is also examining patients' use of health services and the effect on costs.

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Leading and learning

Gibson says the UK is ideally placed to conduct such studies—the GP system and unique NHS patient number are "huge enablers" for bringing together and sharing data from different sources.

Ashley Woodcock, professor of respiratory medicine at University Hospital South Manchester, says a lot has been learnt already.

"The first thing is that it takes a lot of effort to set this up; it's hugely resource intensive. It's not a cheap way to do research.

"Secondly, you have to think differently, and, thirdly, you have to engage from top to bottom. So it's about team working, GPs, pharmacists, etc, all working to a common end."

The study architecture can now be used to test more drugs and devices. Shrinking the 15 year timeline for drug development to, say, 10 years should save companies money in the long run, reduce what the NHS has to pay, and bring benefits to patients sooner, says Gibson.

Woodcock says, "Honestly I've no clue whether the study's going to be showing a benefit for the new treatment. But I think it's game changing, really game changing. It's exactly the sort of research that should go on. And positive or negative there's going to be enormous learning from it."

Competing interests: I have read and understood BMJ policy on declaration of interests and have no relevant interests to declare.

Provenance and peer review: Commissioned; not externally peer reviewed.

1 GSK. Clinical trials meet the real world. www.gsk.com/en-gb/our-stories/everyday-health/clinical-trials-meet-the-real-world/.
2 New JP, Bakerly ND, Leather D, Woodcock A. Obtaining real-world evidence: the Salford Lung Study. *Thorax* 2014;69:1152-4.

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