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NHS National Institute for Health Research

Example 6: Design and optimisation of a saliva-based point-of-care biosensor for non-invasive monitoring of chronic obstructive pulmonary disease (COPD) exacerbations: COPD-SPOC sensor

About the research

Lead researcher: Professor Monica Spiteri, Directorate of Respiratory Medicine, University Hospital of North Staffordshire.

Funder: National Institute for Health Research (NIHR) Invention for Innovation (i4i) Programme.

Project aim: To develop and construct a simple analyser to measure biomarkers for COPD in saliva, to enable patients to monitor changes in their condition from home.

Type of research: Experimental and observational study to support the development of a new device.

Duration: Started April 2012, ending December 2014.

Who we spoke to

We interviewed the lead researcher Professor Monica Spiteri. Her comments are in blue below.

About the involvement

How patients influenced the research question

This project has been driven by patients' needs from the start. People with COPD need to monitor their condition to ensure they take their rescue medication, or increase their usual treatment as soon as their symptoms get worse, or if they develop a chest infection. This typically involves a visit to a GP, an out-of-hours clinic or A&E and often requires blood tests. This places a burden on COPD patients which could be avoided if better monitors were available for use at home.

> "The patients told us they would prefer not to have to give blood samples. They have very fragile skin because they often have to take steroids so they would prefer something non-invasive. Through earlier studies we found out that it's easier for patients to produce saliva at all times, and that saliva was much easier to use than sputum; importantly the biomarkers we're looking for in COPD could be detected in saliva." **Monica**

Patient / carer involvement prior to applying for funding

Patients and carers were consulted before and during the two previous studies that led up to this longitudinal research project. Both studies were funded by the NIHR - one by an i4i feasibility grant. Before putting in a second i4i funding application, patients and carers were again consulted about the overall approach and design. These patients / carers were found through a variety of routes - a local Patient Partnership Forum in Stoke-on-Trent, the researchers' database of previous research participants, the local Research Design Service (RDS) at Keele and personal contacts made through work on local groups and committees.

> "Some of the patients took part in informal discussion groups with tea and cake. But some of them didn't want to take part in a group meeting, so we met them one-to-one and captured their ideas. We funded this work through a patient and public involvement (PPI) grant from Keele University and from funds within our own department. We had to apply for this money.
>
> One of the patients was also a co-applicant. The patients had contributed a lot of good ideas and we thought it was important to acknowledge their input. It shows that they were genuinely part of the research team and they still are." **Monica**

Two people have become involved as PPI leads contributing ongoing advice to the research team. Their time is paid for through the project grants. They helped with writing the lay summary for the second grant application.

Impact of the early involvement

The involvement of patients and carers informed the approach used for **capturing patient data** which aimed to improve the communication between patients and the clinical team.

> "In the previous studies, participants kept paper diaries of their symptoms, which were collected weekly by the nurses. This was cumbersome for everybody. So we wanted to develop an electronic diary that could be completed in 10 minutes and sent to the clinic daily but we weren't sure whether this would be acceptable to the older patients. So we asked them whether they would be happy to use an electronic gadget if given training. Most of them already use mobile phones and were happy with this idea but they wanted something with a large screen interface. They helped us design the layout and the format." **Monica**

They also contributed to the **practical design** of the study to ensure it would be acceptable to people with COPD. This ensured that the participants were compliant with the requirements of the research.

> "We initially thought about asking participants to complete their diary and also give a saliva sample once a day but the patients we consulted thought daily saliva samples would be too much. They made us think about what information we really needed so in the end we agreed that saliva samples could be collected once a week when the patient was well, but that testing

would be brought forward if people began to feel unwell or the clinic noticed a decline in the scores. ” **Monica**

Continuation of involvement following funding

The PPI leads continue to provide advice to the project. They helped with drafting the participant information sheet prior to ethical review, and ensured it was accessible to patients / carers. One PPI lead regularly attends the Steering Committee meetings.

> “ He offers his very strong opinions on our findings – I mean that in a friendly way - he questions us and it contributes to our governance. ” **Monica**

As the work continues, patients and carers will be consulted at a number of stages along the way. For example, the electronic diary has been developed into an App, and patients will continue to be asked about its design and operability to ensure it meets the needs of the target audience. Similarly they will be involved in determining the final design of the saliva sampler.

Patients and carers will also be consulted about the final dissemination strategy to ensure the findings reach a broad audience.

Lessons learnt

> “ If you are trying to develop a device that patients use themselves then they have to be involved at every step of the way and remain engaged throughout. There are a number of redundant devices out there where the patient has been forgotten in the development process.
>
> It’s also very important to involve patients in the design of a clinical study – you can sit down and put together a very nice study without them, but your recruitment will be low if the design is not acceptable or practical for the people you want to take part.
>
> You need to think carefully about who is the best person to facilitate group discussions. You need someone who is independent of the research team so the patients can feel more relaxed and free to say what they think, not what they think you want to hear. ” **Monica**

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