Instructions for COVID-19 self-tests: what parts of the test are the most difficult to get right and how can information design help?

Article

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Keywords: COVID-19; information design; user instructions; self-test

ABSTRACT

This paper summarises a project funded as part of the UK COVID-19 rapid-response initiative. The cross-disciplinary project explored ways of making instructions for COVID-19 Lateral Flow Tests easy for lay people to use. Our method comprised rapid design decision making, where we used existing research, good practice in information design and consultation with diagnostic experts as part of the design process. Iterative review by a panel of users informed the development of prototype instructions: small studies investigated user preference for diagrams, and gathered feedback on the graphic articulation of the procedural steps involved in carrying out the test.

Short title: Designing instructions for COVID-19 self-tests

1. Introduction

This paper sets out an information design-led response to an urgent issue: communication in a pandemic. It addressed a need identified by manufacturers and distributors of lateral flow testing kits who wanted to produce a reliable product for people to use in their home or workplace without medical supervision. COVID-19 has seen an explosion of information about keeping safe, what citizens can and cannot do and, not least, how to carry out tests to check for the presence of virus or antibodies. For testing to be safe and effective, the quality of instructions and information available is as important as technical validation or accuracy.

Our United Kingdom Research and Innovation (UKRI)-funded project, 'Information Design for Diagnostics: Ensuring Confidence and Accuracy for Home Sampling and Home Testing', was part of a rapid-response initiative to consider the arts and humanities contribution to the COVID-19 pandemic. The project was funded for one year, and deliverables included a website, a 'toolkit' for producing guidelines for home testing, presentations and academic papers and industry engagement. The project's aim was to produce easy-to-follow instructions to ensure a reduction in the errors made when ordinary people carried out tests in home surroundings. Our method comprised rapid design decision making applying existing research and good practice in information design followed by iterative review of design variants by a user panel. The resulting design prototypes are intended for home-testing kits that require point-of-use instructions, not only those used for Covid-19 testing.

The cross-disciplinary project combined bioscience research in diagnostic testing with information design research and practice. The team included partners in the diagnostic testing industry, and in public health. The bioscientists brought understanding of the science, and the working of the tests and, importantly, had a vision for the future relevance of community-based diagnostic testing. The bioscience team also brought experience of making low-cost 3-D printed home-testing kits and had found that when they carried out tests with users to affirm ease of use, instructions for using the kit they provided needed improvement (Needs et al. 2020). They identified the parts of the test that needed to be carried out correctly to ensure accurate test results. For the purposes of this project we were therefore able to narrow down the variables we could realistically evaluate given our time constraints. Procedural steps that included actions such as 'squeeze' and 'rotate' that are difficult to describe in words and pictures; putting the correct number of drops in the test device, and interpreting the results were two other areas that appeared to cause problems. This work, led by the bioscience members of the team, informed the focus of the design work.

The paper describes how information design research and practice was applied to produce point-of-use instructions. It explains how point-of-use instructions differ from instructions for use and the design approach taken to the development of prototype point-of-use instructions including a research review, stakeholder engagement, and the application of information design research and practice. It concludes with an overview of how we are taking the work further to assist manufacturers of diagnostic tests and service users to produce point-of-use instructions based on information design principles.

2. Instructions for point-of-use home diagnostic testing kits

Home diagnostic testing kits are made to be operated independently by people without the supervision of or consultation with trained users. In settings where people are untrained or semi-trained, critical errors can occur if they do not follow instructions correctly (Wright 1981, and see for example Rennie et al. 2007, Peck et al. 2014, Wei et al. 2018, Weinhold et al. 2018). Common user errors with self-test kits include errors in positioning the sampling devices for the test, carrying out the steps in the right order, following the test times correctly, errors in interpreting the results (Seidahmed et al. 2008), and users failing to refer to the instructions altogether (Weinhold et al. 2018). Other common errors are errors in transferring a set volume of test sample (Incardona et al. 2018), and collecting insufficient sample volume, which results in blood spot samples being rejected (Govender et al. 2016, Chiku et al. 2019). The clarity of user instructions for self-administered tests becomes even more crucial when we consider that tests need to work across cultures and with patients of varying reading ability.

Specifically in relation to COVID-19, recent research (Atchison et al. 2020) has shown that diagrams with clear visual cueing and simple language helped lay users taking COVID-19 rapid tests. However, Kierkegaard et al. (2021), who reviewed the quality of information supporting lateral flow tests, suggested that more attention should be paid to the information needs of lay users and context of use. People carrying out tests at home need instructions at point-of-use (PoU). These are additional to and complement the 'Instructions for Use' (IfU) that manufacturers of tests are legally obliged to produce and include in test kits they sell or distribute. IfUs are produced in line with a regulatory framework of principles and general guidance about the structure of information and its visual organisation (IEEE 2019). However, while accurate and concise, most IfUs are not user friendly or produced with consideration of circumstances of use (fig 1).
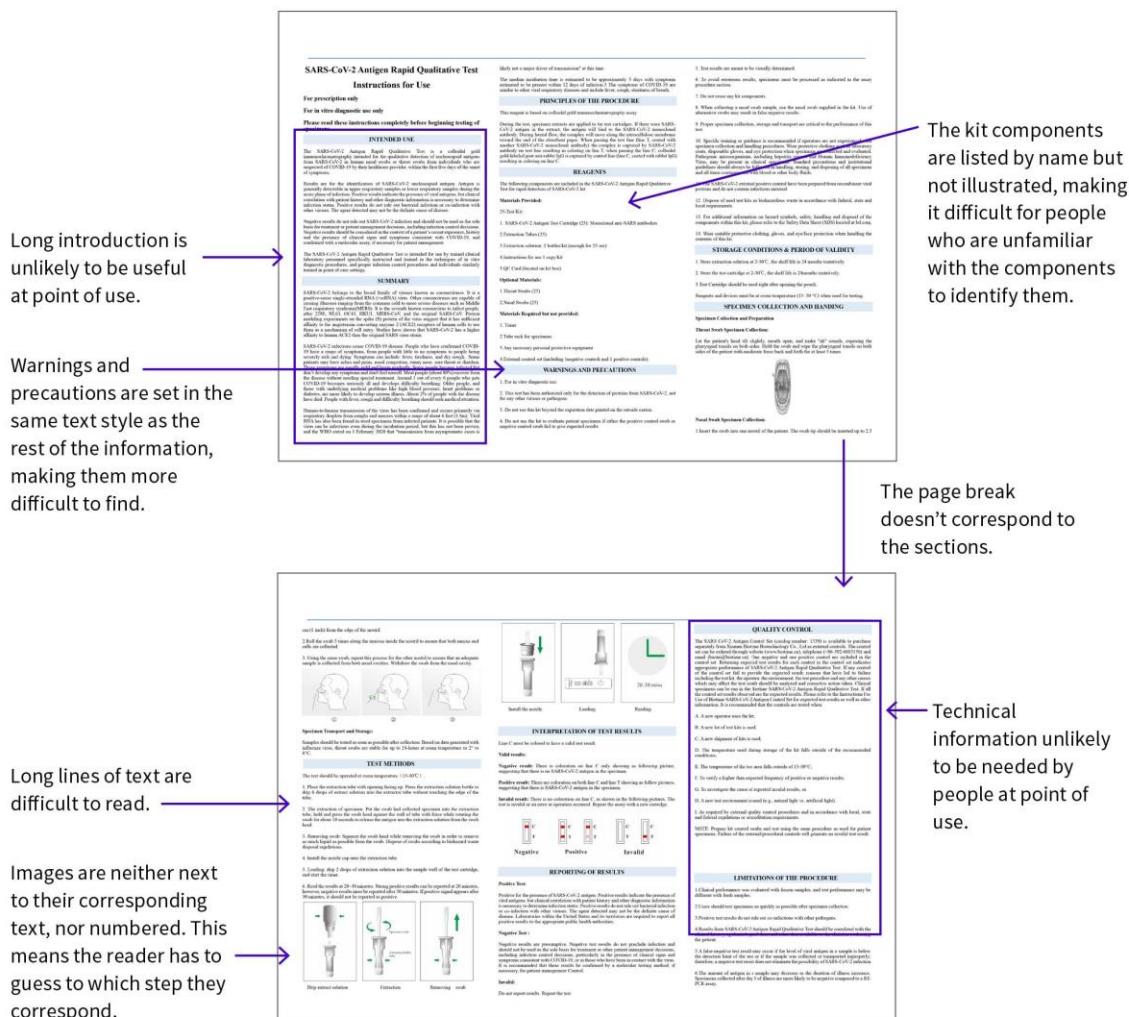
The kit components are listed by name but not illustrated, making it difficult for people who are unfamiliar with the components to identify them.

Long introduction is unlikely to be useful at point of use.

Warnings and precautions are set in the same text style as the rest of the information, making them more difficult to find.

The page break doesn't correspond to the sections.

Long lines of text are difficult to read.

Images are neither next to their corresponding text, nor numbered. This means the reader has to guess to which step they correspond.

Technical information unlikely to be needed by people at point of use.

Figure 1. Instructions for Use for COVID-19 lateral flow test. The annotation indicate the elements that may challenge the user.

3. Design approach

We used a range of techniques to enable rapid design decision making. This comprised review and distillation of existing research, stakeholder engagement and application of tacit information design knowledge (as two members of the research team were practitioners) (fig 2).
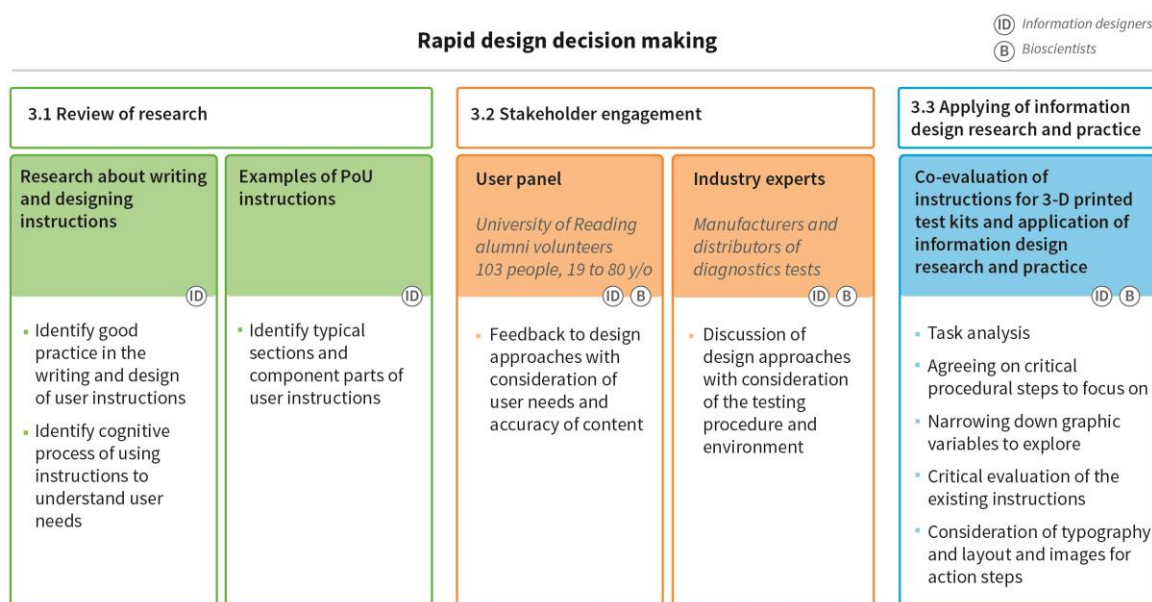
Rapid design decision making

Ⓘ *Information designers*
Ⓑ *Bioscientists*

3.1 Review of research		3.2 Stakeholder engagement		3.3 Applying of information design research and practice
Research about writing and designing instructions	**Examples of PoU instructions**	**User panel** *University of Reading alumni volunteers 103 people, 19 to 80 y/o*	**Industry experts** *Manufacturers and distributors of diagnostics tests*	**Co-evaluation of instructions for 3-D printed test kits and application of information design research and practice**
Ⓘ	Ⓘ	Ⓘ Ⓑ	Ⓘ Ⓑ	Ⓘ Ⓑ
▪ Identify good practice in the writing and design of user instructions ▪ Identify cognitive process of using instructions to understand user needs	▪ Identify typical sections and component parts of user instructions	▪ Feedback to design approaches with consideration of user needs and accuracy of content	▪ Discussion of design approaches with consideration of the testing procedure and environment	▪ Task analysis ▪ Agreeing on critical procedural steps to focus on ▪ Narrowing down graphic variables to explore ▪ Critical evaluation of the existing instructions ▪ Consideration of typography and layout and images for action steps

Figure 2. Overview of techniques to enable decision making in the design process.

3.1 Review of research about writing and designing instructions

The design members of the team were aware of the already considerable established knowledge about how people use and interpret instructions, the types of information they need and best practice for the visual organisation of text and image.[1] Our review of research concerned with helping people execute procedures successfully affirmed that instructions should:

- tell people to read all the instructions before starting the test
- start with an inventory of components that will be needed to carry out the task
- clearly set the goal of the procedure at the beginning
- provide step-by-step directives, focusing on actions around objects
- ensure each directive matches the order of the actions ('First do this... Then do this')
- divide complex instructions into steps, and set a clear subgoal for each step
- include warnings, caveats, prerequisite information and information on common problems and how to solve them

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[1] See our 'research briefings' at https://research.reading.ac.uk/design-research-for-testing-diagnostics/three-research-briefings-to-inform-the-design-of-instructions-for-covid-tests/
These briefings provide structured and annotated lists of key references.

- separate these from the action steps, but keep them together so that they appear when the reader needs them

And further, to help people locate, understand and apply information, instructions should:

- identify all the components that will be used in the procedure with an image and a label to identify them
- include numbered action steps, organised clearly on the page
- position text and image so they support each other
- use goals and subgoals to create clear sections
- position warnings and supportive information close to their relative action step
- use colour, arrows and numbers to highlight areas, cue motion, or indicate order
- use typography to denote hierarchy and emphasis

3.2 Stakeholder engagement

3.2.1 User panel

Input from stakeholders was key to the project. We recruited a user panel under terms of reference that complied with the research ethics requirements of the funded research. A group of University of Reading alumni volunteers agreed to be part of a user panel. The panel comprised 103 people (68 women and 34 men) between 19 and 80 years old. For each of the studies, we reached out to a different subset of panel members, taking care to get a mixed group of men and women of different ages each time. This panel agreed to be part of an iterative review process providing feedback or comments. For each iteration, panel members were asked to answer an online questionnaire, a Covid-necessary format. A questionnaire for each small study included questions about the meaning of a set of diagrams (for example '*Here are four ways to represent the action "rotate the swab". What does each one tell you about how to do this?*') and about their preference between alternative approaches (for example: '*Which of these options do you prefer for "rotate the swab against the tube wall"?*'). The questionnaire included preference questions (for example: '*Here are two ways to show how to check a test can be used. Which one do you prefer?*'), and open-ended questions provided the opportunity for users to give reasons for their preference.

3.2.2 Industry expertise and engagement

Manufacturers and distributors of diagnostic tests formed another stakeholder group. We were keen to find out whether or not manufacturers of tests considered or produced PoU instructions alongside the required IfUs. A team from a diagnostics company agreed to work

with us and expressed interest in the design of procedural instructions and information to support workplace testing.[2] We worked with them in on-line meetings to understand the testing procedure and environment from their point of view, as well as eliciting their views about aspects of the visual organisation of text and image. For example, they contributed to decision making about the illustration style that we used in the development of the prototype instructions (that was subsequently endorsed by our used panel). The industry team and our user panel had a clear preference for linear rather than a schematic form. Of the examples in Figure 3 the linear styles were described as 'clear' and providing an 'appropriate level of detail'. The 'sketchy' form was also described as 'humanised' and thought to be more approachable and possibly less daunting. This view aligned with the 'look and feel' we intended, so the project team decided to use this style in the development of the prototype instructions variants.
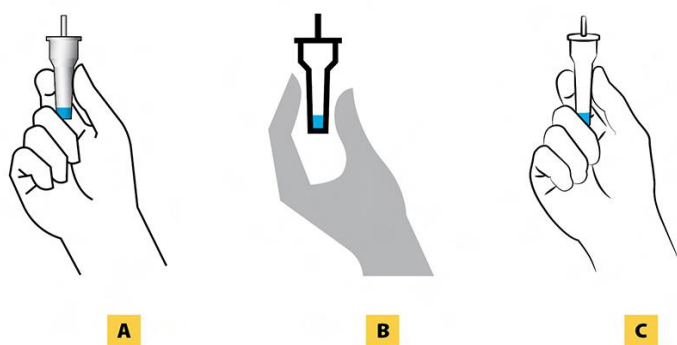
Figure 3. From left to right (A) 'clinical', (B) 'iconic' and (C) 'sketchy' styles.

3.3 Applying information design research and practice

3.3.1 Preliminary study: learning from designing instructions for 3-D printed test kits

We reviewed the initial instructions used by the bioscience members of the team (produced for 3-D printed testing kits using a lancet and fake blood). This review informed three new versions of instructions to explain procedural steps in carrying out a lateral flow test (LFT) with fake blood. Our review comprised:

- *Critical evaluation of the content.* We analysed the task, added text where there were gaps, and removed text that was not useful for the reader. We put the most important elements first and rewrote the text using simple and clear language.

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[2] We worked with a team of managers focused on partnering with clinicians, researchers, academics and industry to support the implementation of medical technologies.

- *Consideration of typography and layout.* The most important elements were made salient through type size, variant and colour. We associated text styles to each level of information and we kept the layout and presentation of action steps consistent throughout. We used prominent headings to chunk the instruction into manageable groups of actions, and reinforced the order of the steps with numbers. For each action step, we put the action first, followed by the modal information. Text styles distinguished the key action from the explanation of how to do it.
- *Thinking about images for action steps.* We created a consistent set of images (1 per action step). To reinforce modal information, we added arrows, pictograms and labels to the images. We used colour meaningfully and consistently: blue for movement, red for simulated blood.

Three versions were designed using the same structure, content and visual organisation: a static version with illustrations, a static version with photographs, and a video version (fig 4). Imagery and content from the instructions with photographs formed the basis of the video instructions, and the action steps were shown in the same way whenever possible (for example maintaining the frame and type of shot for showing the actions). We developed the video following perception and cognition principles for learning from multimedia (Tabbers 2002, van Merrienboer & Kester 2005) including:

- giving people the option to go at their own pace so that they have time to process information. Segmenting helps 'self-pacing' so we included boundaries to chunk the instruction into 3 parts.
- presenting mutually referring pictures and text (or animation and narration) as close in time as possible.
- using spoken text instead of captions.
- reducing unnecessary information.

Elements from the static version that did not translate successfully into video format were modified. The text from the static instructions formed the basis of a script for the spoken instructions in the video. The words were adjusted to achieve an informal and appropriate tone.[3]

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[3] The observations from people using the video version of our instructions are still under our consideration. They have not yet been taken forward to a prototype stage.
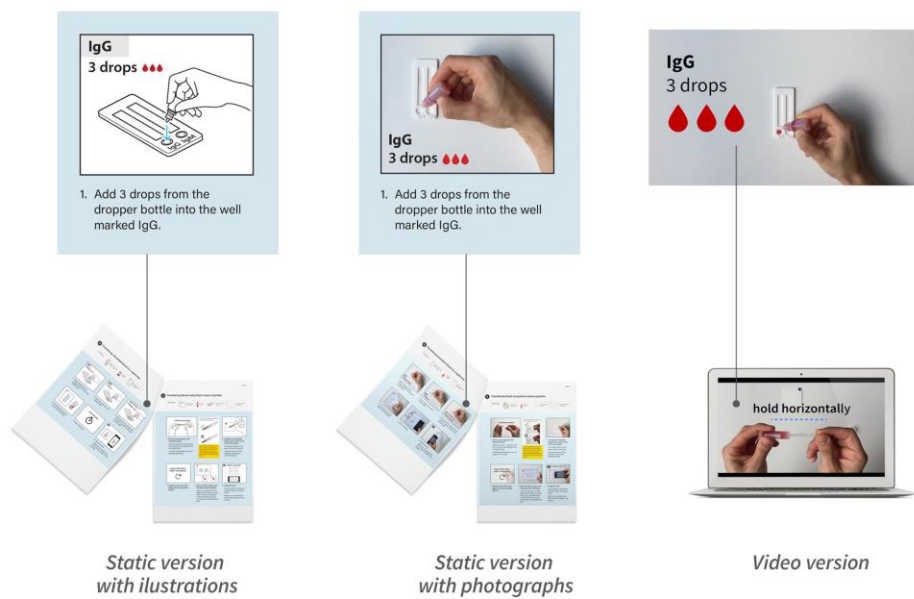
Figure 4. Top row from left to right, the static version with illustrations, the version with photographs, and the video on a screen. Static versions with illustrations and photographs were designed as multi-page documents and sent as PDFs to members of our panel. They were not asked to print and review them as hard copies, although some of them did. Bottom row from left to right: detailed views of each version show a comparison of the step 'Add 3 drops from the dropper bottle into the well marked IgG.'

Eight members of our user panel offered their views. In summary, participants thought that both photographs and simplified illustrations were both helpful in carrying out the test, but that illustrations depicted important details more precisely. Video instructions were thought to be helpful to provide an overview of what needed to be done to carry out the test, and print instructions for carrying out the steps of the procedure. A combination of video and print for a set of instructions may serve to fulfil different functions and be accessible to a wide group of people.[4] Comments from the participants included:

> *'Overall the procedure looks much less daunting in the video than in the printed versions.'*

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[4] See more detail about this preliminary study at https://research.reading.ac.uk/design-research-for-testing-diagnostics/covid-test-instructions-using-line-illustrations-photographs-or-video-a-pilot-study-to-find-out-about-preference/

'Being at home, it is easier to pick up the printed sheet, rather than having to set up YouTube … and to change pages and cross reference, it is much easier to do it on paper.'

'I would be happy to access the photo instructions online. But I am aware that my father, for example, would complain if they were provided online and would much prefer to have a hard copy.'

Other observations from this small study affirmed findings by Atchison et al. (2020) that some parts of the test were difficult to carry out, in particular, using the pipette to collect blood and putting the drops into the wells (the correct place) on the testing device.

This study also highlighted considerable variation in the preferences and needs of different kinds of use, something that is unlikely to be resolved by a single solution. The study reinforced that following instructions is a relatively cognitively complex activity, more so when people lack prior knowledge and when they are doing something for the first time (Ganier 2004, Van der Meij et al. 2004, de Koning et al. 2009). People are also more likely to make mistakes when they are nervous, anxious or uncertain (Vytal et al. 2012, Vytal et al. 2013).

3.3.2 Review of COVID-19 LFTs

The preliminary study informed our project work with COVID-19 LFTs. We began by reviewing some of the many kinds of COVID-19 instructions that were produced, as well as other kinds of instructions that had attracted the input of information designers (as eg Waller & Vandenberg 2017). While many of the instructions we reviewed contained similar procedural information, it was often not organised into clearly identified sections or discrete procedural steps with key actions that can reduce the cognitive load (Burnham 1992, Tversky et al. 2008). For COVID-19 LFTs, then, we identified confirmed the typical sections and component parts that contribute to the successful operation of self-administered tests by lay users:

- Set up information to explain good practice in getting ready to do the test
  - items contained in the test kit. This has an inventory function, prompting users to check they have a complete test kit, and helping them to identify each item in advance of using them
  - actions to be done before the starting the test
  - an overview of the procedure or a summary of the main goals
- Instructions for carrying out the test

      ○ a step-by-step explanation of actions necessary to complete the test. Includes feedback information so that users can monitor and check their progress

- Results and what to do next
  - a clear explanation of what the test results mean and actions to be taken

3.3.3 Eliciting feedback about representing actions

The parts of the COVID test that we focussed on were those actions that were critical to the success of the test and had been pointed out by our diagnostic colleagues in the research team. The studies described here were small in scale, and versions were produced to elicit feedback from users as part of an iterative process of designing.[5]

'Rotate the swab'. Four versions were designed to indicate rotate the swab in the liquid in the tube (fig 5). The feedback affirmed that all the options conveyed a 'rotation' action overall. However, some participants noted that A and B could be interpreted as 'up and down' or 'back and forth', and that D had an added focus on multiple rotations. The multidimensional arrows C and D were preferred over A and B to represent an action in a three-dimensional space. A further set of diagrams was produced showing the use of a ghosted shape to represent movement, in addition to an arrow (fig 6). 13/14 people preferred a diagram showing the swab in ghosted form.
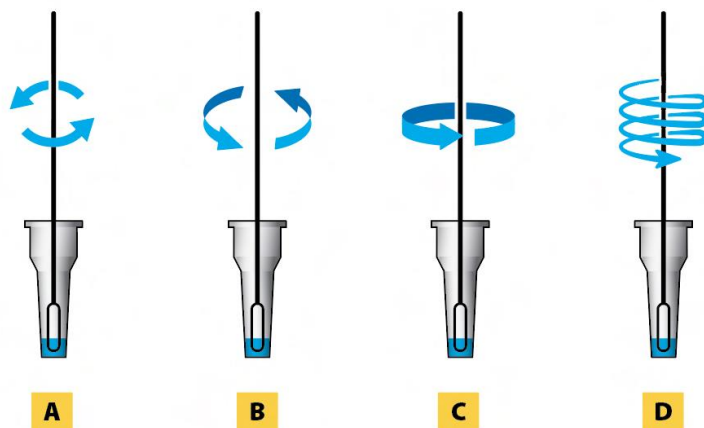

Figure 5. Different versions to indicate the action 'rotate the swab'.

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[5] See more detail about the studies at https://research.reading.ac.uk/design-research-for-testing-diagnostics/design-choices-in-diagrams-for-lft-instructions-results-from-user-feedback/
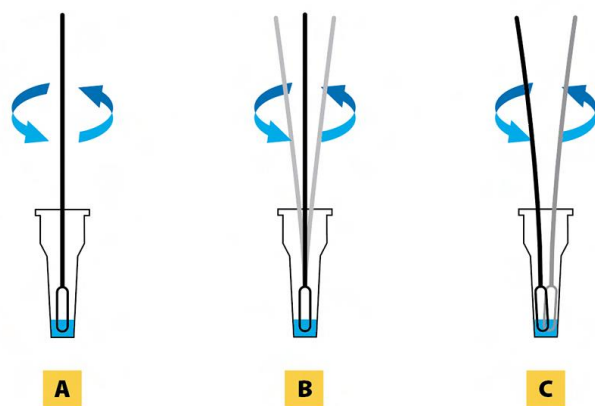
Fig 6. Examples B and C show versions of 'rotate the swab' using a ghosted shape.

'Squeeze the tube'. A further set of diagrams showed four versions of arrows to denote 'squeeze the tube': There was a clear preference for B, which seemed to be the best for indicating movement (fig 7). It suggests that 'squeeze' is best depicted by vertical gaps in the stem of the arrow rather than changing its shape.
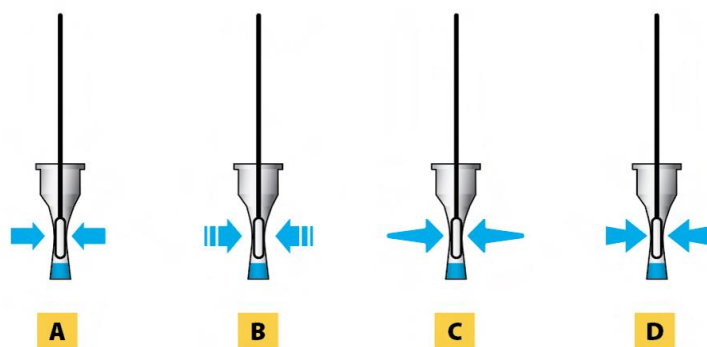

Fig 7. Different versions to indicate 'squeeze the tube'.

Further discussion relevant to the explanation of actions considered the representation of actions with no hands, one hand or two hands. Figure 8 illustrates the actions 'rotate the swab' and 'squeeze the tube' showing no hands, one hand or two hands. There was a clear preference among members of the user panel for the use of two hands, suggesting that this is an effective way to embody the action, and provide useful information for viewers. This aligns with existing research on the design of instructional diagrams (Szlichcinski 1984). As one participant commented: *'The use of hands combined with arrows leaves absolutely no doubt about the intended message'*. However, including one or two hands limits the scale at which the tube can be shown, which may make it less easy for users to interpret.
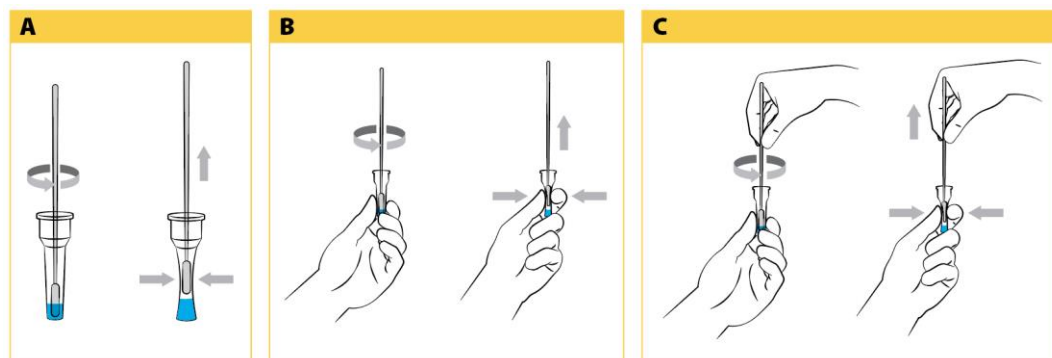
Fig 8. Different version of the actions 'rotate the swab' and 'remove the swab while squeezing the tube' showing the actions with no hand, one or two hands.

The findings from these small studies fed into a final prototype for instructions on paper as shown in Figure 9. The prototype included – to support the actions – the use of two hands and the user panel's preferred visual representations for the actions.
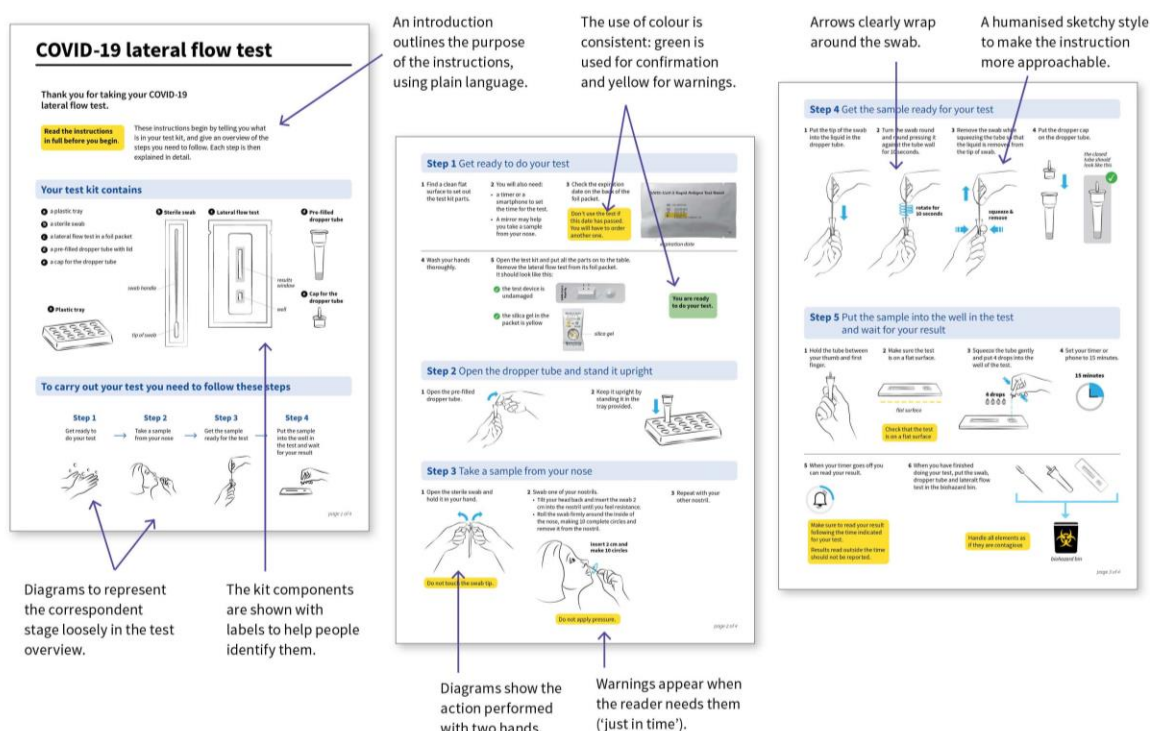

Fig 9. Prototype final instructions for a COVID-19 LFT.

3.3.4 Prototype and next steps

The prototype, produced by the design members of the team, took account of information design and practice as well as observations made by our user panel and industry experts

It emphasises the parts of the testing procedure the science members of the team agreed were important to ensure that the test was carried out correctly so that the results were accurate. For the bioscience and industry members of the team, the prototype was significant and useful in that it was driven by process and principles for ease of use that in turn had been informed by user involvement.

The prototype instructions have yet to be fully tested, but informal feedback to date is positive and we are currently working on applying these instructions to other kinds of LFTs and other kinds of health-related procedural instructions.

4. Overview and concluding remarks

While the need for instructions for COVID-19 LFTs is no longer paramount, the project has raised the profile of point-of-use instructions. Manufacturers and users of diagnostic tests that we have worked with agree that point-of-use instructions help to ensure efficient and effective use and that guidance for making these is needed. Our next steps involve producing a toolkit gathering the outcomes of our work for those who want to produce user-friendly instructions. The toolkit aims to provide guidance on how to engage lay users, and based on research evidence, to illustrate how to use clear language and graphic explanation can help users understand how to carry out a test correctly, resulting in fewer end-user errors.

In summary, our research indicated that:
- the application of information design research and practice enhances user access to instructional text
- particular care is needed for describing and illustrating action steps that may be perceived as challenging due to the dexterity needed
- while regulations strive to ensure in-vitro diagnostic test products are usable, in some cases there is a discrepancy between mandatory requirements and clear and simple instructions and guidance for use

The cross-disciplinary nature of this project has raised the profile of user-centred design to contribute to the reliability of LFTs for use at home. For the bioscientists in our team, being involved in the development and design of our prototype instructions and taking account of feedback from intended users, was a new and appreciated way of working. For the designers, being able to discuss and understand the relevance and significance of the procedural steps from the science perspective ensured the accuracy and relevance of images and text. Our intention is that the findings of our study are relevant to the growing number of home-testing kits for medical conditions.

It was a project with modest aims – can information design *help* people during what was a rapidly escalating pandemic. We applied existing research and practice and contributed to this by focusing on actions that were crucial to successful use of an LFT. The project drew attention to the importance of point-of use instructions to supplement the instructions for use that manufacturers are required to produce, and to the role of information design in enabling this. Our work affirmed that clear layout, typographic hierarchy, graphic cueing and meaningful use of colour contribute to the effectiveness of instructions (Harvey 2008, Kools et al. 2008, Waller & VandenBerg 2017).

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