1. ABOUT THE DATASET

Title: Data associated with the article 'Remote videolink observation of model home sampling and home testing devices to simplify usability studies for point-of-care diagnostics'

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Description: This dataset contains the video instruction resource used for remote testing of model home testing devices. The questionnaire given to participants along with a summary table of responses to the rating questions. This dataset contains images of model tests returned by participants during the study 'Remotely evaluating user experience of Covid-19 lateral flow devices'. A spreadsheet summary of the analysis of the returned images is also included.

Cite as: Sarah Needs (2020): Data associated with the article 'Remote videolink observation of model home sampling and home testing devices to simplify usability studies for point-of-care diagnostics'. University of Reading. Dataset. http://dx.doi.org/10.17864/1947.254.

Related publication: Needs, S., Bull, S., Bravo, J., Walker, S., Little, G., Hart, J., Edwards, A. (2020) Remote videolink observation of model home sampling and home testing devices to simplify usability studies for point-of-care diagnostics. Wellcome Open Research (In Preparation).

2. TERMS OF USE

3. PROJECT AND FUNDING INFORMATION

Title: Remotely evaluating user experience of Covid-19 lateral flow devices

Dates: April 2020

Funding organisation: EPSRC (EP/R022410/1 and EP/S010807/1), Wellcome Trust (204388/Z/16/Z.)

4. CONTENTS

File listing

1. README_NeedsEdwards_2020_Dataset.pdf

Contains information on what is contained in the data deposit.

2. Model_Test_Image_Returns.zip

Contains anonymised images of the model rapid test and model home sampling tests participants were required to perform in this study. Images are sorted in Pilot, Unsupervised, Video_Unsupervised and Video_Supervised.Participant number and instruction condition is summarised in the table below.

Condition	**Participant Number**
Pilot	01,02,03,04,05,06,07
Unsupervised	08,09,10,22,23
Video_Unsupervised	12,13,15,17,20
Video_Supervised	11,14,16,19,21

3. Video_Instruction.mp4

Video instructions of the study tests sent to participants prior to testing.

4. Model_Test_Results.xlsx

This spreadsheet contains the values used to calculate the calibration curves for the volume dispensed for the model rapid test and model blood sampling test. This file also contains the values of the participants' returned images.

5. Participant_Questionnaire.pdf

Contains the questions that participants were asked to fill out after the home testing and home sampling tasks were complete.

6. Questionnaire_Summary_Data.xlsx

Contains a table of responses to rating questions from the Participant Questionnaire.

5. METHODS

This pilot was designed to establish if remote observation was a suitable methodology for observation of usability and also quantification of accuracy of blood testing kits used in the home. The home testing packs used in this study included 3 components of home testing and sampling methods. These components were tested by observing lancet use, liquid handling for lateral flow rapid tests and liquid handling of blood sampling medical devices. Model lancets and rapid tests were 3D printed. The open source designs for these models in the form of OpenSCAD files and STL 3 dimensional geometry files can be downloaded and used or edited: https://gitlab.com/sneeds/model-home-testing-devices.

Participants had to complete a video call using Microsoft Teams whilst they followed the testing pack, and after completing the supervised task send images taken on their smartphone camera to the researcher via email. To avoid any risk of infection, these test kits were prepared in sterile

filtered air cabinet and 3D printed parts sanitised with 70% ethanol. After delivery, participants were instructed to leave the packs untouched for 48h prior to opening. In this pilot, participants also completed a screening questionnaire to identify and exclude any participants at greater risk of severe COVID-19 disease who were not recruited to this feasibility study.

Medical device blood collection devices were also included, that are designed to deliver a fixed volume of blood from a fingerstick to a POC test or onto a filter for home sampling. Microsafe (40 µL) and PTS Collect (40 µL) capillary blood collection tubes were used. Participants were given a tube containing 1 mL of simulated blood (2% PME red food colouring, 20% ethanol, 78% water). The test packs included a copy of the manufacturer's visual instructions for each collection device. Written instructions on capillary tube use were also provided on participant instructions and use of these devices presented in the video instructions.

Instructions for the rapid lateral flow test were adapted from the widely used SD BIOLINE Dengue Duo test product, to create a model lateral flow kit for evaluation. The model lateral flow test kit has two wells marked IgG and IgM. Filter paper inserts were designed to very simply permit remote measurement of the volume of simulated blood deposited by participants - the higher the volume, the further along the filter that the red dye travelled. Participants were provided with a Nalgene 4 mL capacity dropper bottle filled with simulated blood (2% PME red food colouring, 20% ethanol and 78% water)- these dropper bottles are routinely included in many lateral flow products to add buffer alongside sample. Participants were asked to follow the modified instructions, designed to represent the real test instructions and assess users ability to deposit different volumes into distinct parts of the device, but without requiring real blood.

Participants were asked to place the device on a template alongside representative images of a negative and positive lateral flow test. The participant were asked to photograph this with the digital camera on their own smartphone and return these images to the researcher. This acted as a baseline to identify if images sent to the researcher were of sufficient quality to identify test results of a known test. This also captured the volume of simulated blood deposited by each user.

An initial pilot study was performed using written instructions only (n = 7). Participants were randomly allocated into three groups: group 1 had written instructions alone and were not supervised (n = 5); group 2 were provided with both written and video instructions and encouraged to view the instructional video prior to starting the test (n = 5); and group 3

were given written and video instructions and were supervised by the researcher *(n = 5)* (Video 1). When they had completed the tasks, participants were asked to complete a questionnaire. At the end of the call participants were required to image and send images of the study consent form, questionnaire, blood sampling task and rapid home test task to the researcher.