Imperial College London

UNIVERSITY OF OXFORD

Study Title:

RECAP (Remote COVID Assessment in Primary Care): a learning system approach to develop an early warning score for use by primary care practitioners

Template-related:

1) How can I access the template?

For RCGP RSC practices (excluding practices in North West London): please go to Ardens portal https://www.ardens.org.uk/coronavirus-covid-19-resources/. There, you will find the COVID-19 templates:

- SystmOne Template (Figure 1) – For existing users
- SystmOne Templates – Open access – Free for practices who do not use Ardens
- EMIS Web Template (Figure 2) – For existing users + also free for practices who do not use Ardens

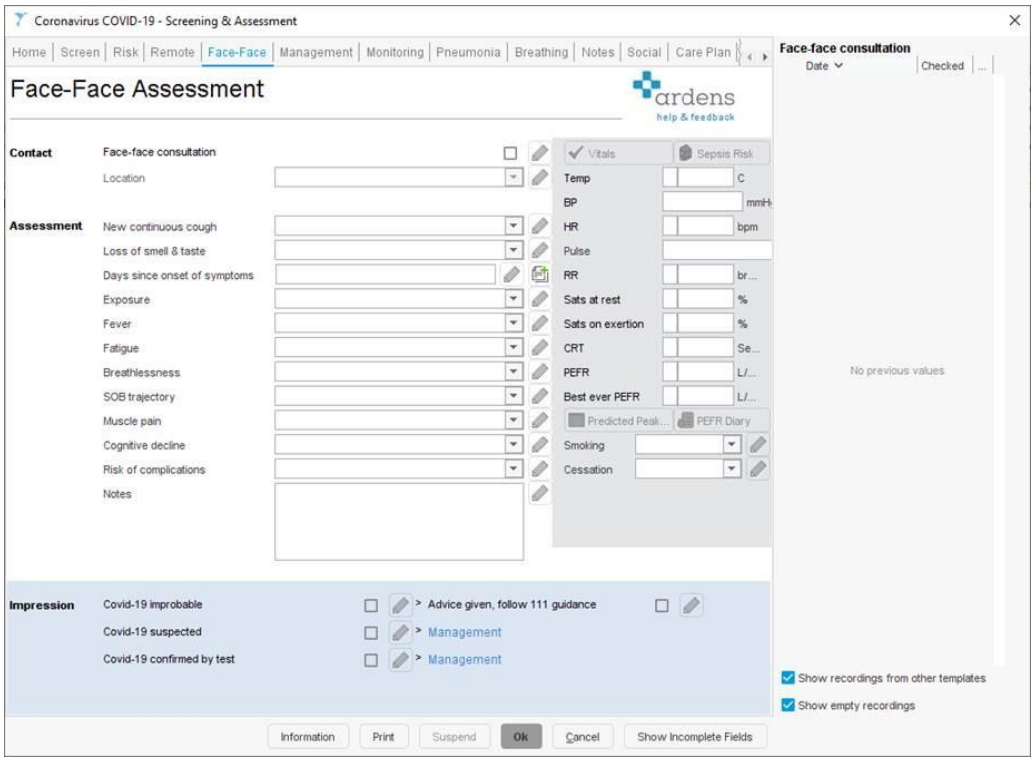

Figure 1 Screenshot of RECAP template in Ardens SystmOne

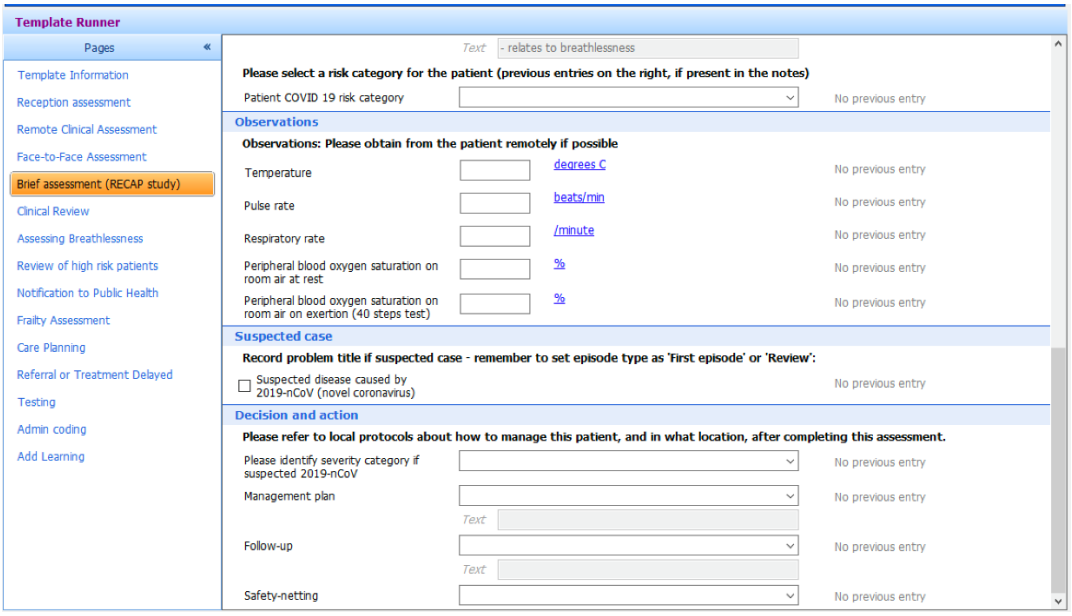

Figure 2 Screenshot of RECAP template in Ardens EMIS

Portal instructions here: https://support-ew.ardens.org.uk/support/solutions/articles/31000155232-practice-download-portal-downloading-and-importing-searches-templates-and-documents-to-emis-web

COVID-19 template instructions here: https://support-ew.ardens.org.uk/support/solutions/articles/31000154897-coronavirus-Covid-19-emis-web-template - this article confirms that the offering is free.

For North West London practices, the template can be accessed by:

- EMIS Templates: please, log a call with the NWL Service Desk by calling them on 020 3350 4050 or emailing them via nwlccg.servicedesk@nhs.net to request the template.
- SystmOne Templates: practices using SystmOne can find the template via the 00 COVID 19 Coronavirus folder in autoconsultations, it's called Coronavirus - COVID-19 - Clinical Assessment NWL.

2) Does the template link into the Ardens Covid-19 template?

The template is the current Ardens COVID-19 template v15.9 and can be downloaded from Ardens portal as explained in question 1.

If you already downloaded the template v15.8, this one´s codes are already aligned with RECAP project codes. However, EMIS template v15.9 is much more simplified and contains in just one tab all the information required to be filled for the study (Brief assessment (RECAP study) tab, Figure 2).

3) Are we able to see the EMIS template before we sign up?

Yes, the template is freely available for Ardens and non-Ardens subscribers can be downloaded from Ardens portal as an xml template and uploaded to EMIS. Practices should sign up (freely) and use the Ardens portal to download the template rather than sharing it by email etc as this allows the research team to keep track of who is using the template in case we ever need to send urgent updates.

Please note some local NHS IT organisations block the download of XML files, so you may have to get permission from your local IT organisation.

3) Are we able to leave bits blank if not carried out, e.g., oxygen saturation in remote assessment?

Yes, you can save the template despite any missing information. None of the fields on the template is mandatory, each item on the template is standalone so you fill whichever ones you want and save the data. It is up to the clinician to decide what you are recording.

Importantly, please, always remember to tick the participant consent box and type or add the study CPMS number (45890) when completing the template with a patient (e.g., at the bottom of home tab in SystmOne template in Ardens (Figure 3). If this information is not completed, we will not be able to retrieve this participant information and this will affect the reimbursement practices receive per each participant recruited.

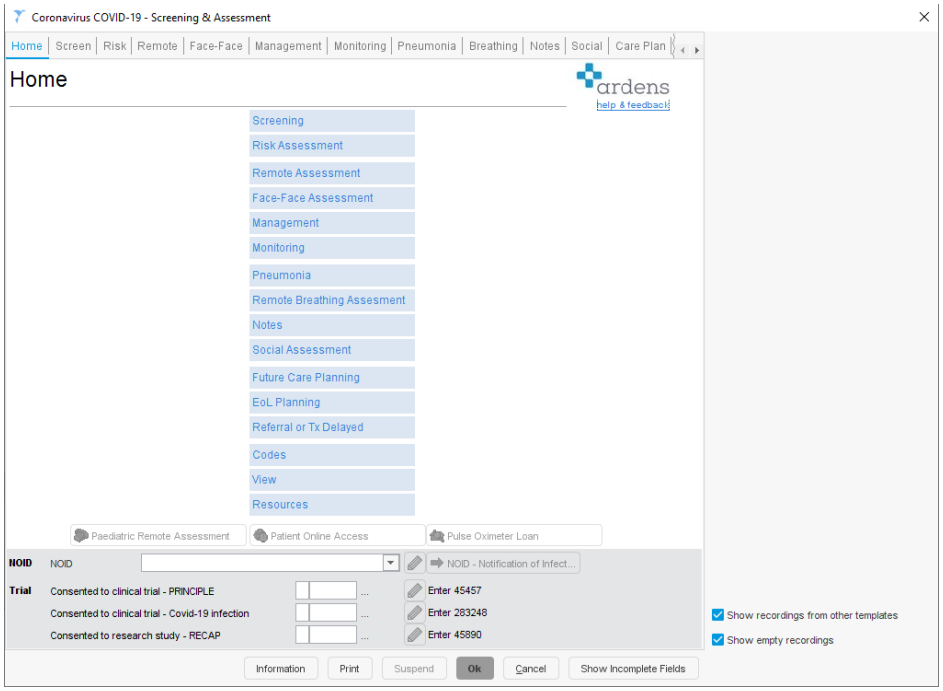

Figure 3 Screenshot of RECAP template in Ardens SystmOne

4) Which codes trigger the template?

You can add triggers to this clinical template so it will be prompted when you code patient's Covid-19 signs and symptoms. To do this, once you have uploaded the template in EMIS (here you can find instructions for this https://support-ew.ardens.org.uk/support/solutions/articles/31000154897-coronavirus-covid-19-emis-web-template), you can access Template Manager, search for the 'Novel Coronavirus (COVID-19) (Ardens) and then, on the ribbon Properties, click on the Triggers tab. You can Add Trigger, such as cough or fever there. If you already have triggers linked to the previous Covid-19 template, please, ensure you cancel those and add these triggers to the newly uploaded Covid-19 template (v15.9). This will guarantee you are using the correct template.

5) I have tried to access the Arden's portal to download the template but I do not have permission to access this page/ I need to log into the Ardens portal.

You can download the template freely from the Ardens portal:

http://ardens.live/portal or https://www.ardens.org.uk/coronavirus-COVID-19-resources/)

We asked practices to sign up (freely) with Ardents and download the template (COVID-19 v 15.8) from the portal since this makes it allows the research team to keep track of who is using the template in case we ever need to send urgent updates.

6) If practices download the templates (from here: https://www.ardens.org.uk/coronavirus-Covid-19-resources/), will they be RECAP-ready?

Once you download the template in xml format and upload it to EMIS (following the instructions you can find https://support-ew.ardens.org.uk/support/solutions/articles/31000154897-coronavirus-Covid-19-emis-web-template.), the practice will be then "RECAP-ready". After uploading, you will be able to find this template in the Templates & Protocols list, and you could run it by clicking Run Template option within a consultation and searching for 'Novel Coronavirus (COVID-19) (Ardens). If you would like to have the template triggered by signs and symptoms codes, please read question 4 and the template instruction in the Ardens portal.

7) My practice (xxxxx) has the Ardens template that pops up for COVID-19 – do I presume we are RECAP ready?

No. The template that pops up when entering signs and symptoms of potential COVID-19 infection is the old template and is not aligned with the RECAP codes. Please, follow the instructions in question 6 and 4 to ensure you are using the correct template, and add triggers to this template so you do not need to run the template manually in each consultation.

8) Is there a research code to be added to recall these patients?

The SNOMED code is embedded in the template, it is linked to the patient's consent box:

SNOMED - 873771000000107 | Consent given to participate in research study (finding) CPMS 45890.

As explained in question 3, it is very important to tick the consent box and add the study CPMS number (45890), otherwise, we will not have any way to retrieve number of participants recruited per practice.

9) Does the template take account of patient demographics? As it will affect the assessment and outcome.

Yes. Information related to patient demographics such as age, sex, relevant comorbidities and BMI are risk factors for COVID-19 outcomes. Demographic information is retrieved automatically from the patient record as part of the record linkage with the template. These are already coded and do not need to be coded separately.

10) Does the template give you a COVID-19 risk score?

There is no risk score at the moment as data collection will need to be carried out first. When the prospective code collection is completed, we will be then able to develop and validate the risk score.

11) Who can use the template?

The template is not locked to role profiles. Whilst any clinical staff can use the template (doctors, paramedics and nurses involved in the assessment of patients), practices are advised to make their own clinical judgements as there are sections on the template that require clinical assessments. There is a reception staff assessment page on the template mainly for triaging a patient effectively.

12) How often should the template be used?

We would encourage template use at every contact with a patient allowing data capture of patients who are in regular contact with their primary care service. This enables changes in the trajectory of specific signs, e.g. related to breathlessness, to be monitored that is important for data analysis.

Study participation-related

13) How much extra time will this add to the consultation and can doctors ignore template if they are very busy.

The use of the template is meant to support the systematic assessment of patients with signs and symptoms of COVID-19 (by phone, video or face-to-face). We really believe its use should not increase medical history taking or examination time. It should be used as a substitute for these rather than in addition.

The main aspect that may entail additional consultation time would be asking for patients' verbal consent to share their anonymised data for the study. A simple paragraph such as:

"Could I please ask your verbal consent to use your anonymised data for COVID-19 research? This would involve the linkage of your (anonymised) data with hospital data and you would be able to withdraw at any time if you wished so. More information on the COVID-19 study can be found in this website, I am sending you the link through accuRx or/and I am printing the patient information sheet for your information" may work.

Another example of accuRx message could be "*We are contributing data to a research study to look at the outcomes of Coronavirus. All personal details are removed, and the data is not directly linked to your records. The assessment information you just completed will be temporarily linked to your GP records and only medical staff will see it. For a detailed explanation about the research and how we look after your data, visit: https://imperialbrc.nihr.ac.uk/research/covid-19/covid-19-ongoing-studies/recap/"*

Patient's consent will be recorded by ticking a box in the template.

The template can be used by doctors, paramedics and nurses involved in the assessment of patients. Although the aim should be using template in every clinically relevant occasion, we do understand clinical schedule can be hectic sometimes. Therefore, they can ignore the template and assess their patients as they usually do if they are busy.

14) Most consultations are done by telephone so observations like pulse /saturation of oxygen etc will not be collected -how does this fit with the study?

The study aims to develop a risk prediction score to determine patients' severity by assessing objective and subjective signs and symptoms. Since remote consultations are the norm with COVID-19 patients, we are interested in collecting subjective symptoms (myalgias and breathlessness) and non-measurable objective signs (such as skin colour) and will identify their relationship with measurable signs (such as oxygen saturation) when available. Therefore, if the patient is at home and we cannot determine his oxygen saturation, please, keep using the template, the data collected will be invaluable as well.

15) Is data collected automatically from our system or manually by us?

Once you have filled the template, including the patient's consent box for data sharing, data will be collected automatically by the standard process of data extraction operating across the RSC (you can read more information on data collection and analysis in our website (https://imperialbrc.nihr.ac.uk/research/Covid-19/Covid-19-ongoing-studies/recap/).

16) Can you please advise exactly what reimbursement practices will receive?

For practices belonging to the RCGP RSC network, practices will receive financial support by the research team and LCRNs. This will cover time spent collecting patient's consent (we consider this will be about of five to ten minutes per patient/template) and assessing the patient, the total amount will depend on the number of patients recruited and the CRN/location of your practice. Additionally, practices will be also receiving a one-off set-up payment by LCRNs and research costs by the research team to cover for training time (there will be an optional training webinar) and template installation time. We would like to emphasise that the main study activity (filling the COVID-19 template when a patient has signs or symptoms of COVID-19) is standard clinical practice. We are conscious of the increase in practice workload the current circumstances have brought about and we would not ask primary care clinicians (GPs, nurses or paramedics) to dedicate any additional time to the assessment of these patients other than the time required to collect patient's consent (by ticking a box in the template and adding CPMS number 45890).

17.) Which activities are going to be reimbursed in addition to the set-up payment?

Practices will receive an extra-amount for any patient recruited, which also includes the time taken to ask for informed consent form.

18) How are patients made aware that their, anonymized, data is collected at a central level - what is the consenting process?

GPs or clinicians filling the template will be able to ask patients for their consent to use their (anonymised) data. We agreed with ethics committee that the GP can obtain verbal consent as this is a low-risk study and information collected will not be above what is standard practice. This verbal consent will be recorded by clicking a box in the template. The template contains a link to the study website and Patient's Information Sheet and patients are welcome to contact study research team for any queries on data management or study organisation they may have.

19) Is this just for GPs - a lot of our acute assessments are done by ANPs, particularly those that are COVID-19 related. By just focusing on GPs you may lose a cohort of interviews plus our nurses and paramedics are much more likely to use the template than the GPs are!

20) The local Hub-clinics use ARDENS templates - have they been contacted in order to upload and use the template

We are currently in communications with CRN leads who will help us approach local hot-hubs managers to invite them to take part as well. Rather than recruiting isolated practices across the country, our intention is to recruit clusters of practices, local network of practices collaborating with or working

on a local hot hub, so we can access the data from patients visited in these practices but also follow-up data when patients are sent to the hub for monitoring etc. CRNs can also help us reach local primary care networks and engage hubs. If you are working from a calm clinic or hot hub we can still extract data from you. Please contact Alexandra Deeks (alexandra.deeks@phc.ox.ac.uk), PLO at the RSC to set this up. Please note, data can only be linked from patients that are permanently registered at an RSC practice. Similarly, if you are also working in the hub and are in touch with other local practices collaborating in the hub, please feel free to let them know or give them our contact details, we would be pleased to explain them a bit more about the project and invite them to take part in it.

21) Can consent be taken by staff who do not have GCP?

Yes. There is no requirement of GCP as this is standard clinical practice. We will not be collecting any more data than would reasonably be collected by any clinician making any COVID-19 assessment in primary care. The study is not an intervention study that requires an appraisal for potential harm.

22) Does the consultation with the suspected/confirmed COVID 19 patient have to be first contact?

No, it does not.

23) Does the practice have to have more than one consultation with the patient (as it was suggested that they might be having daily calls, but one practice has suggested that this is not the case)?

One is sufficient, but it is recommended to have more than one.

24) Can a patient who has had a positive diagnosis, but still feeling unwell, say 3 months later be recruited?

No, because that is not acute Covid-19 which is nationally defined to be within first 2 weeks.

25) How can I claim the research costs to be paid by research institution?
Once you installed the template and start using it, your CRN lead will reimburse the set-up costs (amount depends on the CRNs). At the same time, you will be asked to generate an invoice for research costs (up to £98.70, which covers pre-recorded webinar time and template installation time). We are not providing a specific invoice template. Individual practices need to submit something on their stationery addressed as follows:

Finance Office, Nuffield Department of Primary Care Health Sciences, University of Oxford
Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG
Sent directly to post-award@phc.ox.ac.uk

For further queries, please, contact the study team (contact information can be found in the study website: https://imperialbrc.nihr.ac.uk/research/covid-19/covid-19-ongoing-studies/recap/healthcare-providers/)

- RCGP RSC practices: Laiba Husain (laiba.husain@phc.ox.ac.uk) and Alex Deeks (alexandra.deeks@phc.ox.ac.uk)

- North West London practices: Christian Ramtale (s.ramtale@imperial.ac.uk) and Ana Belen Espinosa (a.espinosa-gonzalez15@imperial.ac.uk)