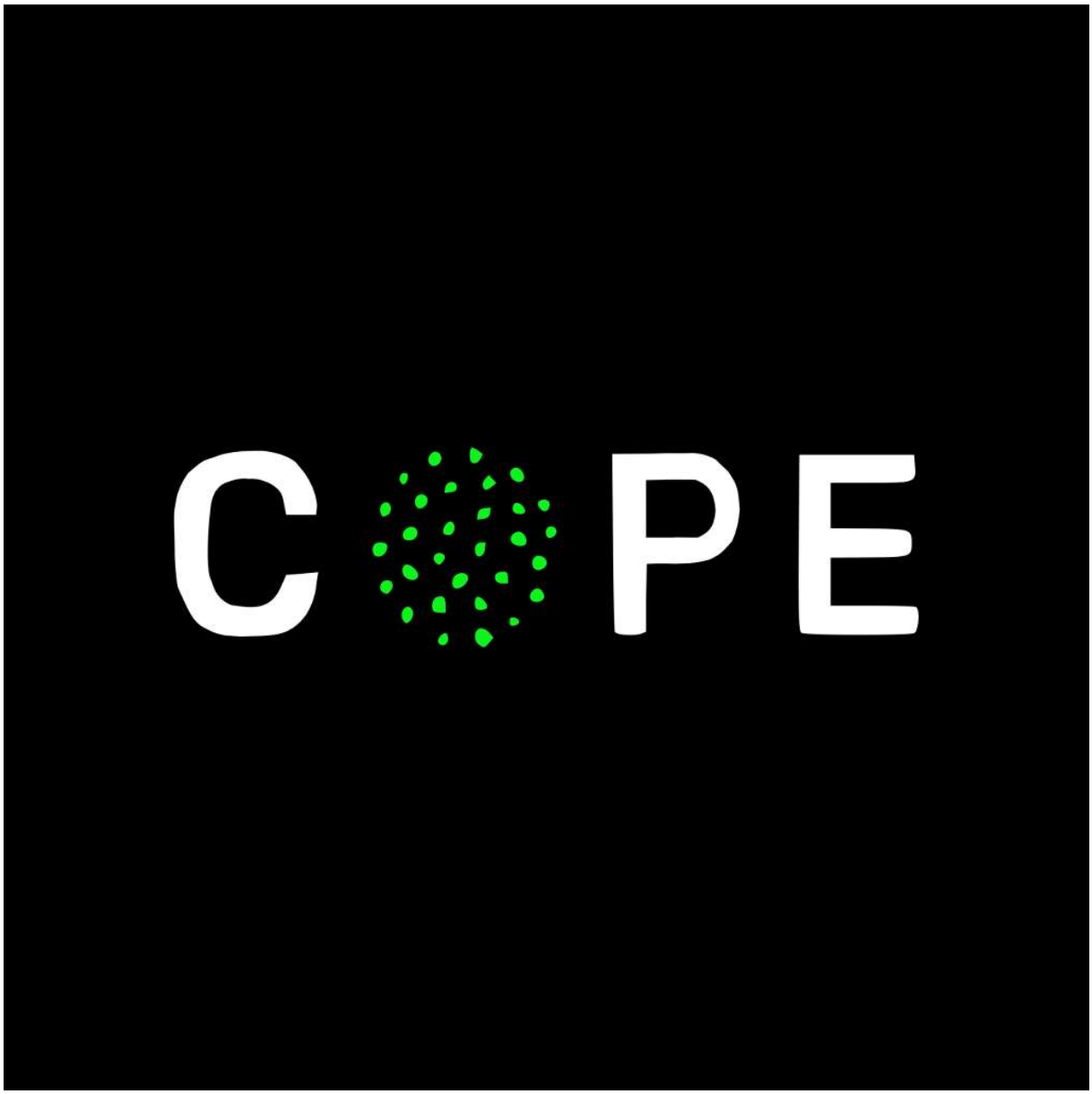
User manual



COVID Outcome Prediction in the Emergency department (COPE)

Version 2.1

Content

Information about the user manual

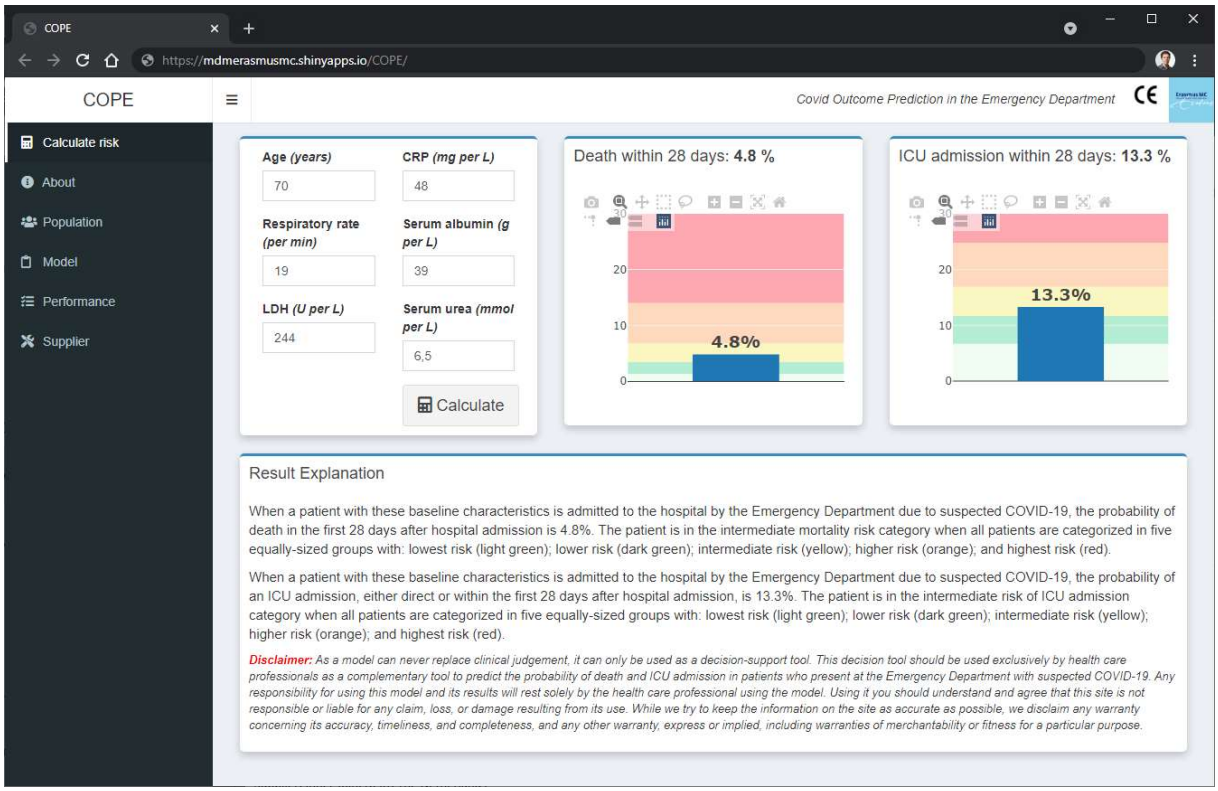
This user manual describes how to use "COVID Outcome Prediction in the Emergency Department (COPE)" and is intended for everyone who will work with the software.

Please read the operating instructions before using the COPE app.

If you have any questions, please contact Inner Join at erasmusmc@inner-join.nl.

1. Introduction

COPE (COVID Outcome Prediction in the Emergency department) is a simple tool based on 6 routinely measured predictors in the ED, that is well able to predict mortality and need for ICU admission for patients who present to the ED with suspected COVID-19. COPE may help to inform patients and doctors when deciding on hospital admission.



Cope should only be used by health care professionals.

Disclaimer: As a model can never replace clinical judgement, it can only be used as a decision-support tool. This decision tool should be used exclusively by health care professionals as a complementary tool to predict the probability of death and ICU admission in patients who present at the Emergency Department with suspected COVID-19. Any responsibility for using this model and its results will rest solely by the health care professional using the model. Using it you should understand and agree that this site is not responsible or liable for any claim, loss, or damage resulting from its use. While we try to keep the information on the site as accurate as possible, we disclaim any warranty concerning its accuracy, timeliness, and completeness, and any other warranty, express or implied, including warranties of merchantability or fitness for a particular purpose.

2. Intended application

2.1 Clinical benefit

COPE should provide accurate predictions of death and need for ICU admission within 28 days for patients who present to the emergency department with suspected COVID-19.

COPE may support emergency department physicians to identify high-risk patients – i.e. those at high risk of deterioration and/or death – requiring treatment in the ICU, intermediate-risk patients requiring admission to the clinical ward, and low-risk patients who can potentially be sent home.

2.2 The user

Emergency department physicians are end users of COPE.

2.3 The patient

All patients with suspected COVID-19 who present at the Emergency Department.

2.4 Contraindications

NA

3. Conformity

A Declaration of Conformity is in place for the COPE web app and the COPE native apps. Inner Join declares that the COPE apps meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

4. Description and operation

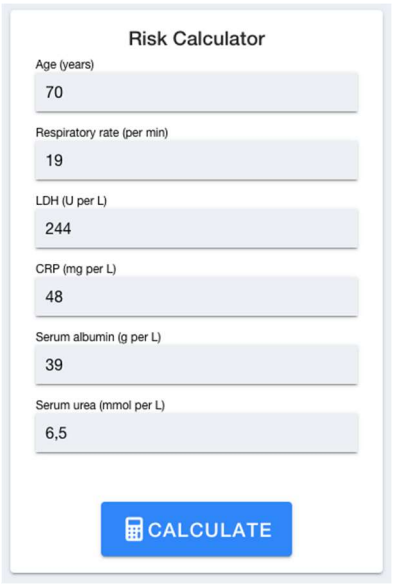
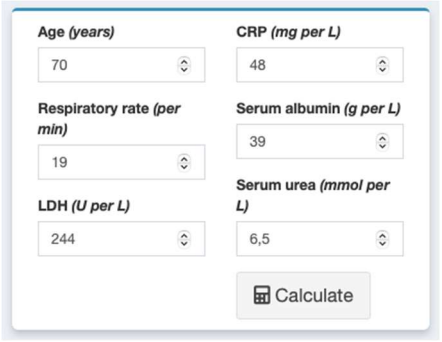
COPE (COVID Outcome Prediction in the Emergency department) is a simple tool based on 6 routinely measured predictors in the ED, that is well able to predict mortality and ICU admission for patients who present to the ED with suspected COVID-19. COPE may help to inform patients and doctors when deciding on hospital admission.

Here, we will distinguish the COPE webapp from the native COPE apps.

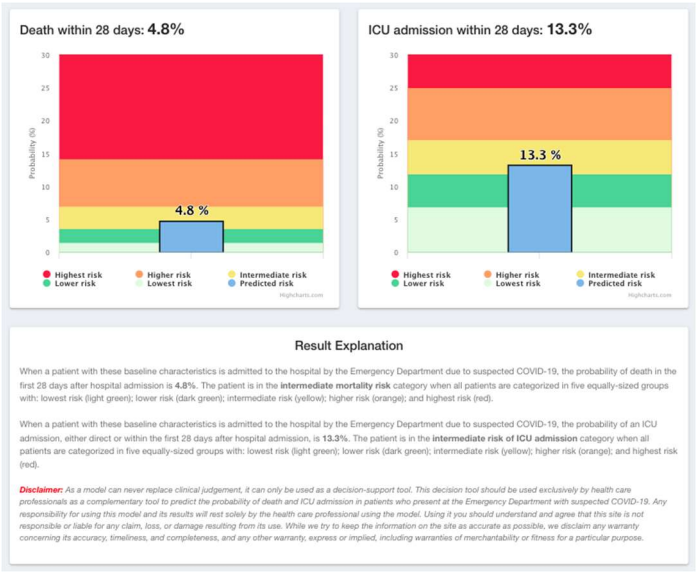
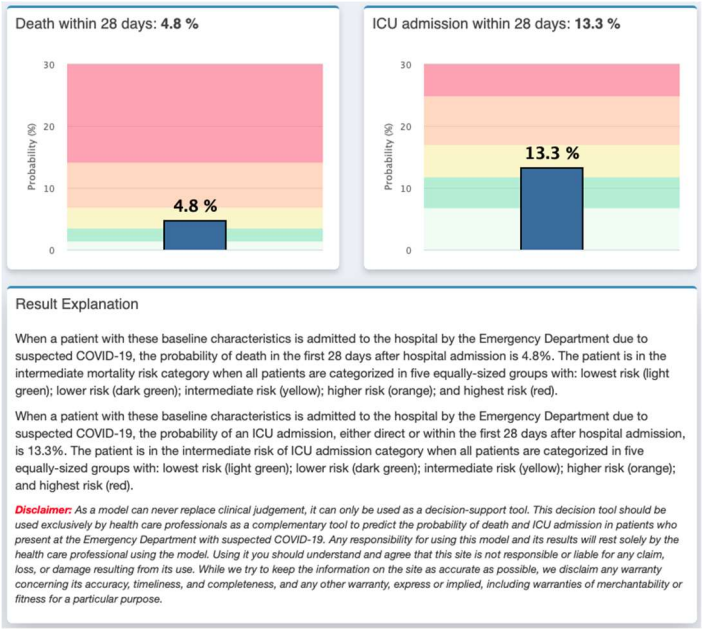
The native apps are developed in Ionic 5 and are compatible with iOS 11+ and Android 5+

The webapp is developed in R Shiny and is compatible with the latest 2 versions of Google Chrome, Mozilla Firefox, Safari and Internet Explorer.

This component of the app is used to input a patient's baseline characteristics required for the calculation of their mortality and ICU admission risk within 28 days of hospital admission:

Mobile Application	
Web Application	

COPE outputs the patient's mortality and ICU admission risk predictions based on the patient's input. The background colors are used to represent the patient's risk ranking compared to what was observed in the development population.

Mobile Application	
Web Application	

5. Security

CAREFUL!	Only specialist and trained staff are allowed to work with cope

Changes to the applications may only be implemented by Inner Join, or otherwise when written approval is gained.

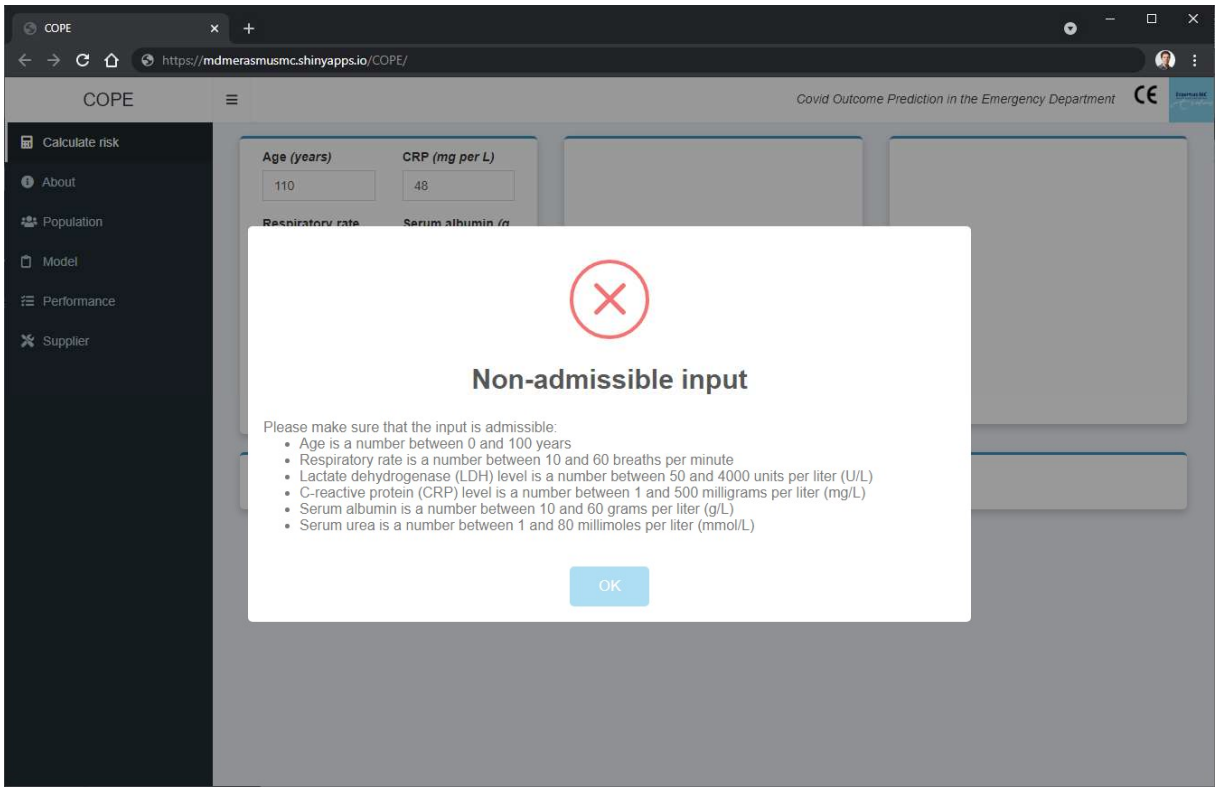
5.1 Built-in safety measures

- COPE is CE certified. A Declaration of Conformity is in place for the COPE web app and the COPE native apps. Inner Join declares that the COPE apps meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

- Cope should only be used by health care professionals. Therefore, each COPE calculation is accompanied by a disclaimer: “As a model can never replace clinical judgement, it can only be used as a decision-support tool. This decision tool should be used exclusively by health care professionals as a complementary tool to predict the probability of death and ICU admission in patients who present at the Emergency Department with suspected COVID-19. Any responsibility for using this model and its results will rest solely by the health care professional using the model. Using it you should understand and agree that this site is not responsible or liable for any claim, loss, or damage resulting from its use. While we try to keep the information on the site as accurate as possible, we disclaim any warranty concerning its accuracy, timeliness, and completeness, and any other warranty, express or implied, including warranties of merchantability or fitness for a particular purpose.”

- To prevent any coding errors in the COPE apps, a detailed test plan is in place for each new version of COPE. COPE 2.1 was successfully tested according to this test plan.

- COPE gives a warning and does not display any results when non-admissible input is entered:



5.2 Residual risks

The COPE apps meet the current safety requirements. However, even when used for the intended purposes and following all instructions, residual risks cannot be fully excluded.

- The web application may temporarily be unavailable when the server is down.

6. Storage

The source code of the webapp is saved on GitHub (USA).

The source code of the mobile apps is saved on GitLab (USA).

Inserted data is not being stored. When closing or refreshing the web browser all inserted data is deleted.

7. Installation

The webapp does not require installation and can be run in the latest 2 web browser versions of Google Chrome, Mozilla Firefox, Safari and Internet Explorer.

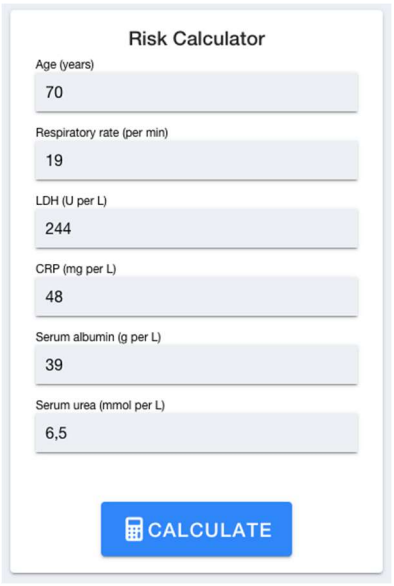
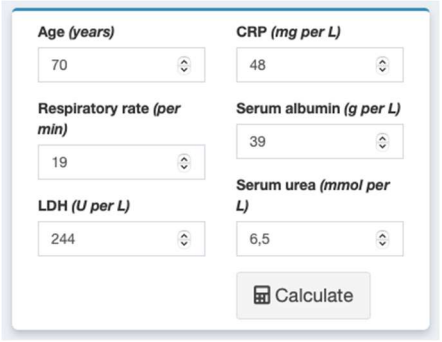
The mobile apps are installed through either the Google Play Store or the Apple Store.

8. Operation / instructions for use

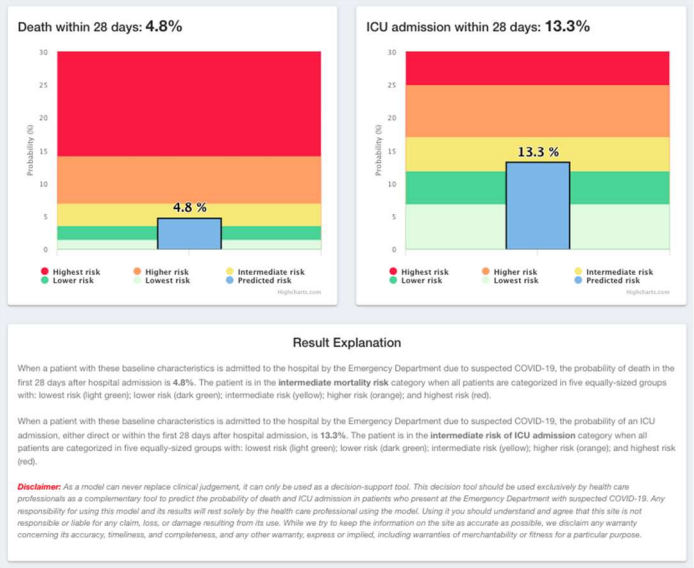
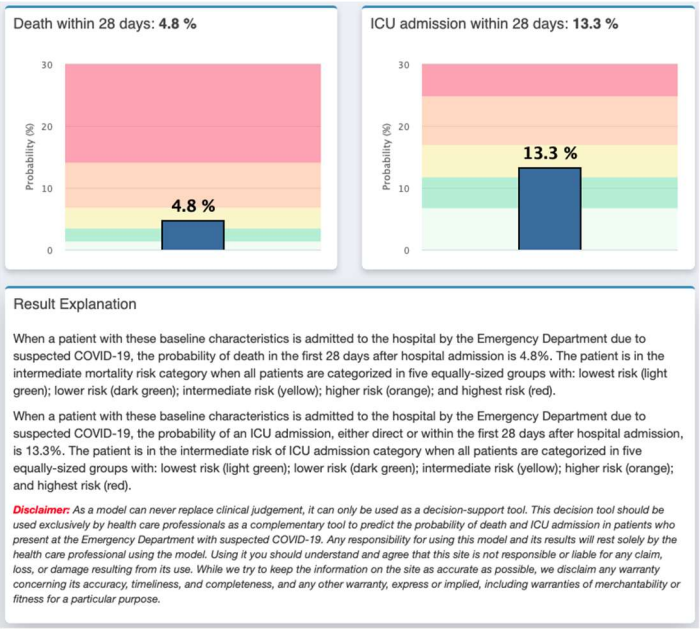
COPE starts in the “Calculate risk” tab. When a patient with suspected COVID-19 presents at the emergency department, enter the patient’s baseline characteristics. The necessary baseline characteristics together with their minimum and maximum values are:

Predictor	Minimum	Maximum
Age = Age (years)	0	100
RR = Respiratory rate (/min)	10	60
LDH = Lactatedehydrogenase (U/L)	50	4000
CRP = C-Reactive protein (mg/L)	1	500
Albumin = Serum Albumin (g/L)	10	60
Urea = Serum Urea (mmol/L)	1	80

After filling out the 6 values, press the button “Calculate”:

Mobile Application	
Web Application	

COPE returns the patient's mortality and ICU admission risk predictions based on the patient's input. The background colors are used to represent the patient's risk ranking compared to what was observed in the development population.

Mobile Application	
Web Application	

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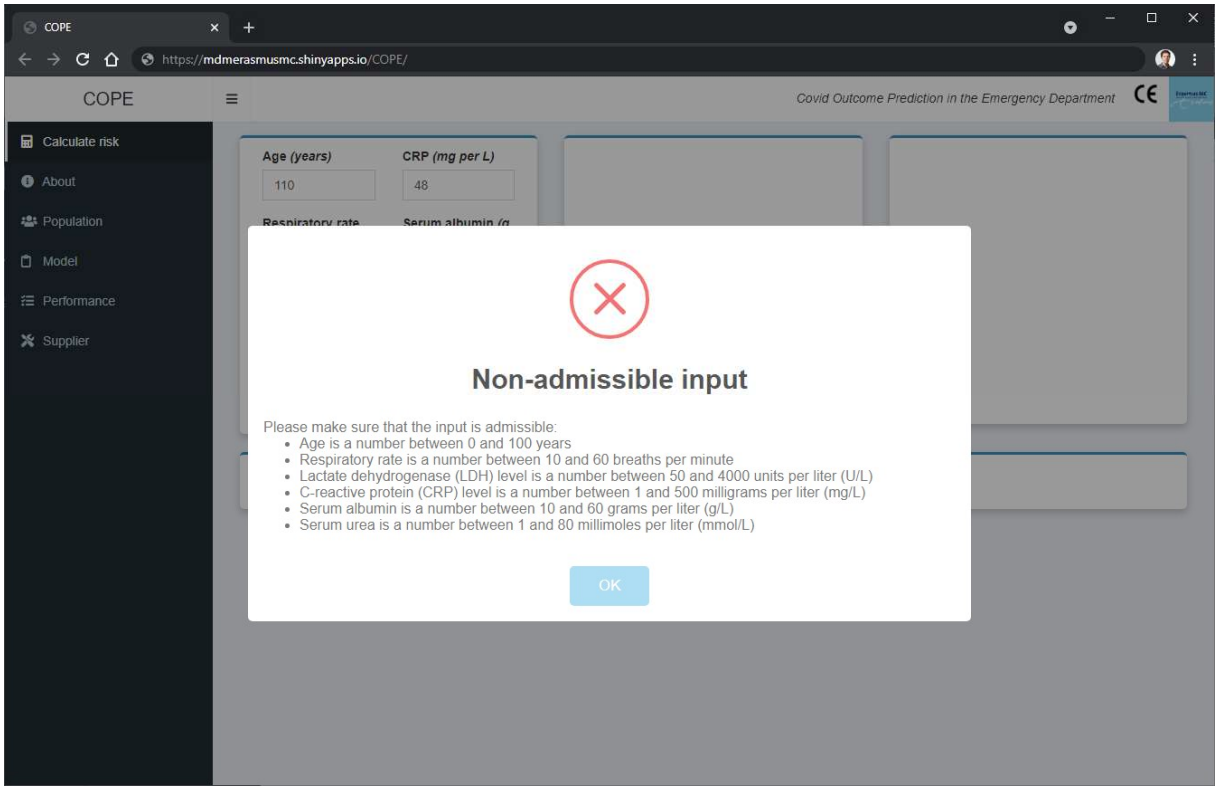
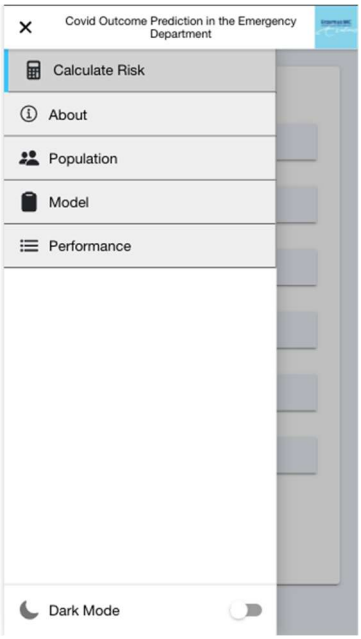
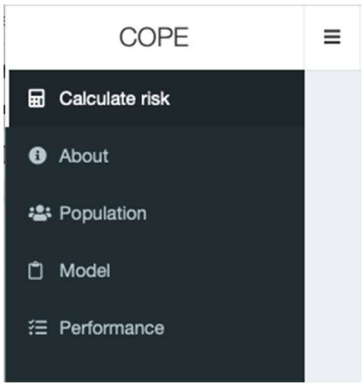
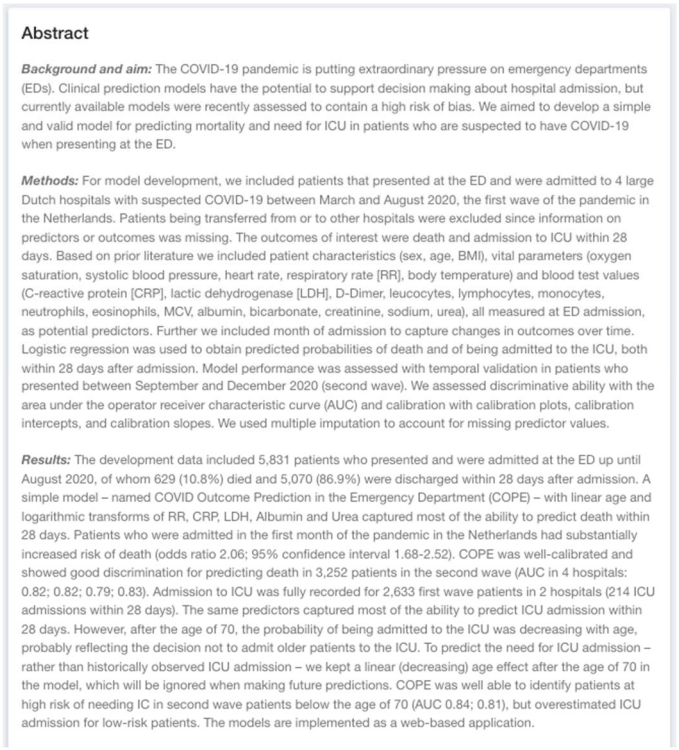
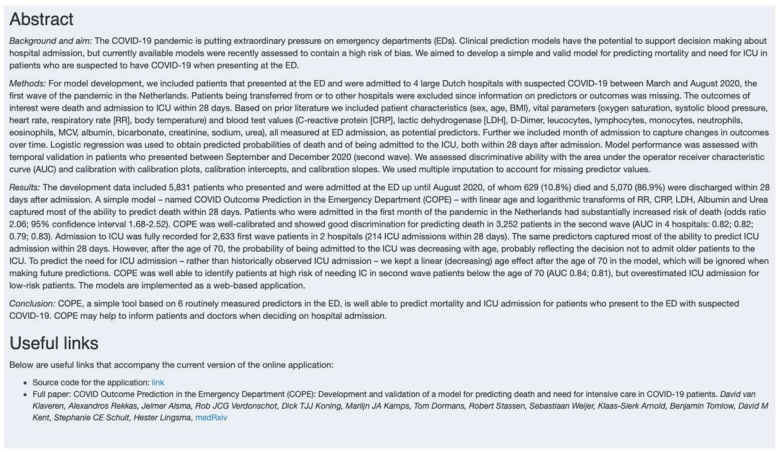


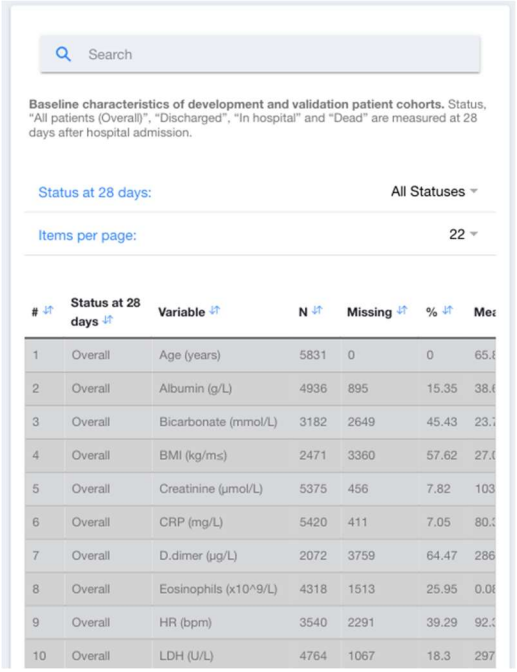
For transparency, COPE also provides information. This information can be viewed using the menu:

Mobile Application	
Web Application	

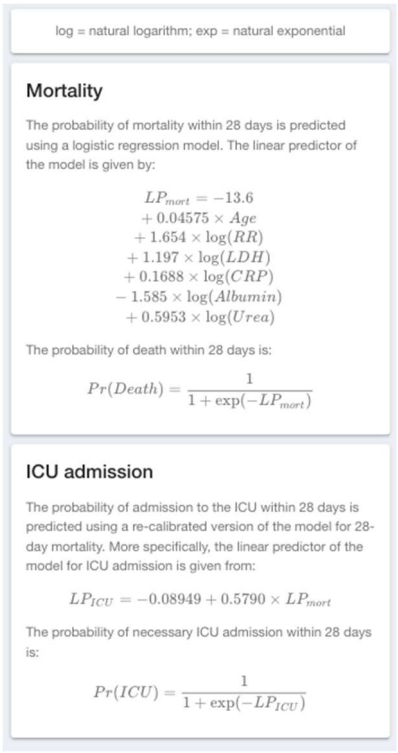
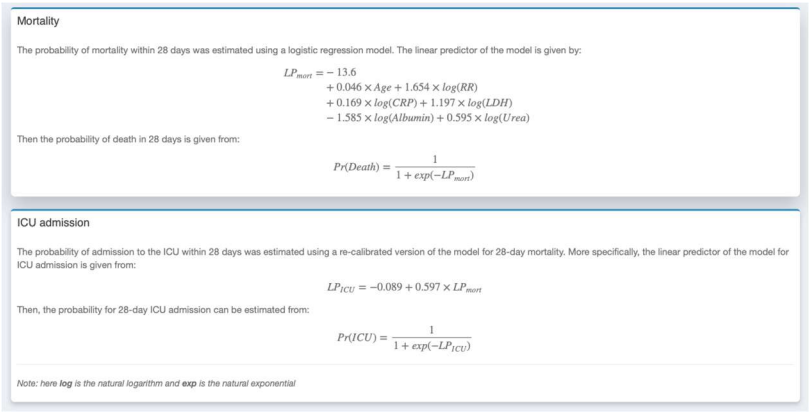
Under the “About” tab, COPE provides background information about the COPE app:

Mobile Application	
Web Application	

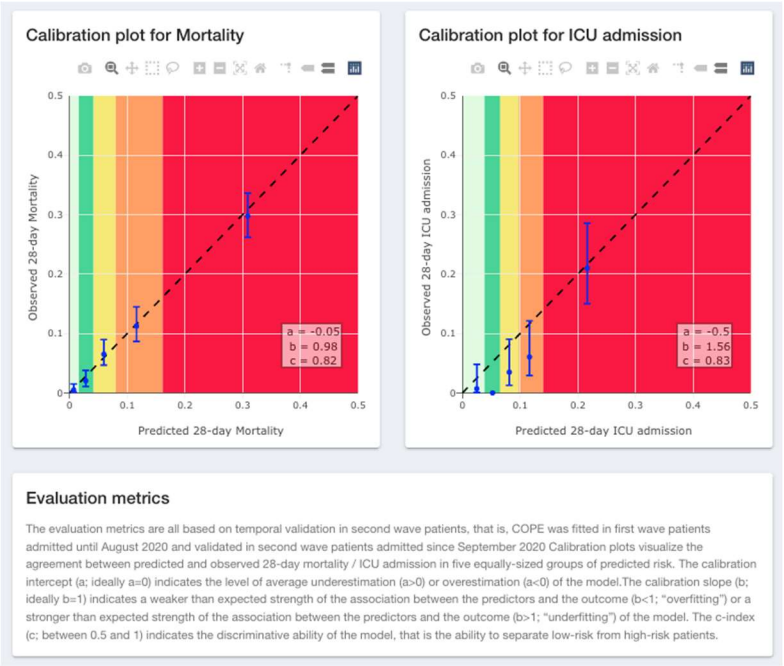
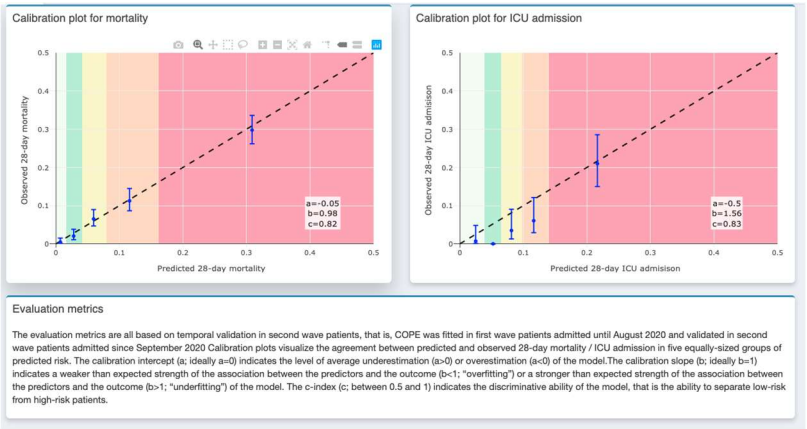
Under the “Population” tab, COPE provides aggregated information on the patients that were used to develop the COPE prediction models:

Name	Population Table
Description	Baseline patient characteristics measured at the Emergency Department.
View Mobile Application	
View Web Application	

Under the “Description” tab, COPE provides the exact mathematical formulas used for the prediction of risks:

Mobile Application	
Web Application	

Under the “Performance” tab, COPE provides commonly used performance evaluation metrics of the underlying risk prediction models:

Mobile Application	
Web Application	

9. Failures

Failure	Possible cause	Solution
Native app won't work in future OS versions	Incompatibility code with OS	Contact supplier and department about possible solutions (SLA)
Web app won't work in future web browser versions	Incompatibility code with new browser versions	Contact supplier and department about possible solutions (SLA)

If the fault has not been resolved using the table or if in doubt, please contact Inner Join at erasmusmc@inner-join.nl.

10. Maintenance

The current version is COPE 2.1. The version is visible under “About” tab.

11. Disposal / de-installation

The mobile app can be deinstalled using standard mobile phone functionality.