

QCovid® Online Risk Calculator R2 V2 - Instructions for Use

- [Introduction](#)
- [Product Details](#)
- [Intended Use](#)
- [Safety Information](#)
 - [Safety Instructions](#)
 - [Cautions](#)
 - [General Precautions](#)
- [Pre-Use Requirements and Dependencies](#)
- [Software Installation, Upgrade and Configuration](#)
- [Step by Step Instructions](#)
- [Troubleshooting](#)
- [Regulatory Information](#)

Introduction

The QCovid® Online Risk Calculator R2 provides a web user interface around the QCovid® Calculation Engine R2 software library. This library is a risk prediction algorithm to estimate hospitalisation and mortality outcomes from COVID-19 in adults. The website enables a user to enter a simple medical history for a patient and then uses the library to determine their risk of the aforementioned outcomes. The results are presented as absolute risks, risks relative to an individual with no risk factors, and also as a centile ranking within the general population.

It is a CE marked, Class I medical device (software as a medical device) under the Medical Devices Directive 93/42/EEC.

Product Details

	QCovid® Online Risk Calculator
	R2 (v2.0.0)

Intended Use

	<p>QCovid Online Risk Calculator R2 is a clinical decision support tool intended to facilitate individualised discussions between clinically trained professionals and patients about COVID-19 risk. Clinical conversations could include advice to shield to limit the risks of catching the virus, health promotion opportunities (such as losing weight) to reduce the risk of serious illness if infected, and COVID-19 risk mitigation in the workplace.</p> <p>The QCovid Online Risk Calculator has been developed for public health purposes rather than for individual therapeutic or health care decisions, except for interventions aimed at prevention of infection.</p> <p>Please read this instruction manual thoroughly before using the QCovid® Online Risk Calculator. Please keep these instructions for future reference.</p> <p>The website is not intended to support automated processes, but only manual use via a web browser application.</p>
---	--

Safety Information

Safety Instructions



Please follow the mandatory safety information supplied with the QCovid® Online Risk Calculator.

The QCovid® Online Risk Calculator cannot take the place of clinical assessment. No medical decision should be based solely on results provided by the risk calculator. This is a labelled misuse of the QCovid® Online Risk Calculator.

Users should take careful note of any disclaimers or warnings that appear on the calculation results page. In certain situations approximate results are shown with a warning, whilst all results carry a disclaimer relating to their inherent limitations. Before using the QCovid® Online Risk Calculator, users should review the published QCovid® research article (<https://www.bmj.com/content/374/bmj.n2244>) to ensure that its limitations are understood.

Cautions



Please follow the cautionary information when implementing the QCovid® Calculation Engine.

Clinicians are expected to apply their own clinical judgement to further risk stratify patients and are not expected to rely solely on the output from the QCovid® Online Risk Calculator in order to appropriately manage and advise their patients regarding COVID-19.

General Precautions

(Include general precautionary information here from the Clinical Evaluation Report, Clinical Safety Case Report and User Validation Report.)

The use of the QCovid® Online Risk Calculator is contraindicated as follows.

- People under the age of 19.
- It is not intended that this tool is used to make treatment decisions following admission to hospital.
- It is not intended to predict the expected outcomes of patients under different treatments.
- It is not intended to automatically remove people from a high risk group, or to deny anyone care, as QCovid is likely to underestimate risk in previously shielded groups.

Pre-Use Requirements and Dependencies

Use of the QCovid® Online Risk Calculator requires use of a web browser. The website has been verified on the following web browsers:

- Google Chrome 94.0

Software Installation, Upgrade and Configuration

There is no installation necessary to use the QCovid® Online Risk Calculator.

Step by Step Instructions

In the instructions below, please interpret the word “click” to denote either the act of using a mouse to click on an item, tapping on the item using a touch screen, or similar activation using a keyboard.

1. Upon visiting <https://qcovid.org/>, the user is presented with the home page.
 - a. If they have not previously visited the site in the chosen web browser, a cookie information side panel, will be displayed. The user should then click on either the “I Accept” or “I Do Not Accept” buttons to register their acceptance, or otherwise, of non-essential cookies. The side information panel will then close.
 - b. The cookie panel can be reactivated using the “C” button in the bottom right on the browser window.
 - c. Further information regarding cookies can be obtained using the Cookies link in the page footer.
2. The home page presents background information about the QCovid® Online Risk Calculator with a navigation bar at the top of the page. These include Frequently Asked Questions (FAQ), related Publications, the Licence and details of the Algorithm.

3. In the page footer, the user can find:
 - a. The version of the QCovid® Calculation Engine, which is provided for reference.
 - b. A link to the privacy notice.
4. Clicking on the Calculator link in the top navigation bar begins the process of a risk calculation.
5. If the user has not previously accepted the Licence, then they will be taken to the Licence page where they must first read and accept to the licence terms. Clicking on Accept Licence will then take them to the calculation. The licence acceptance is remembered for one day by their web browser, after which time the user must accept the licence again.
6. The user is then presented with a web form with asking if the user has had a Covid-19 vaccination. Click the appropriate answer and then click Continue.
 - a. If the user chooses yes, the calculator assumes the user has had two doses of vaccine.
7. Next the user is sent to with a longer web form via which they enter the personal and clinical information of the subject. The contents vary slightly depending on the answer to the above.
 - a. Age, height and weight are entered using text boxes, must be entered. Age is entered as a whole number of years. Only centimetres and kilograms are supported for height and weight respectively. The ranges are as follows, and are included in the validation messages which will display if an out-of-range value is entered.
 - i. Age: 19-100
 - ii. Height: 140-210cm
 - iii. Weight: 40-180kg
 - b. UK postcode is also entered using a text box but can be left blank. The postcode is only used to determine the appropriate Townsend deprivation score to use. Use of a blank postcode yields the UK-wide average score. If the entered postcode is unknown, then the UK-wide average score will be used and a warning will be displayed.
 - c. If "Yes" was selected for if the user has had a Covid-19 vaccination, a location can be chosen via a dropdown. The options are the United Kingdom, the nations within Great Britain, or the regions within England. No locations outside of these are supported.
 - d. Biological sex is entered via radio buttons, restricted to male or female. There are insufficient data to model alternatives or related hormone treatments.
 - e. Ethnicity is selected from a list of options, which includes "Ethnicity not stated".
 - f. Housing category is entered via a radio button list.
 - g. The clinical information is entered, mostly via check boxes, though some items are presented as radio button or drop-down lists.
 - i. Note that chemotherapy is specified via group options of Group A, Group B, or Group C. As noted on the FAQs page, these are detailed in the supplementary materials of the published QCovid® research article (<https://www.bmj.com/content/374/bmj.n2244>) or the table of Chemotherapy groups linked below the question.
 - h. The user should select if the subject was on the shielded patient list in 2020. This has no bearing on the calculation results, but controls a warning message that will be shown on the results page.
 - i. If "Yes" was selected for if the user has had a Covid-19 vaccination, a collapsed section labelled Advanced options will be present. Most users can ignore this section, but those using the tool for academic purposes may wish to change the values within.
 - i. The case rate (daily infections per 100,000 users as per PCR tests) can be overridden via a textbox. If left blank a recent figure from the government is used.
 - ii. The number of days over which Risk is calculated can be altered via a textbox. 90 days is the default, but it can be reduced to as low as 10 days.
8. The user clicks Calculate. If there are no validation issues with the form, then the user will be taken to the results page. Otherwise, they should review the validation messages and click Calculate again.
9. The risk assessment results are presented on the results page. The text on the results page explains the meaning of them as pertaining to a 90-day period similar to the first wave of COVID-19 in the UK.
10. The page also has a table laying out the various results. The rows of the table contain:
 - a. The risk of catching and being admitted to hospital with Covid-19.
 - b. If "No" was selected for if the user has had a Covid-19 vaccination, the risk of being admitted to hospital in the case that a person has a result on a PCR test indicating that they have Covid-19.
 - c. The risk of catching and dying from Covid-19.
 - d. The risk of dying in the case that a person has a result on a PCR test indicating that they have Covid-19.
11. The columns of the table contain:
 - a. Absolute risk (*a*), which is the percentage chance of a person either dying or being admitted to hospital. It is also indicated as a "1 in ..." format, e.g. 0.1% corresponds to "1 in 1000".
 - b. Absolute risk (*b*), which is the equivalent percentage for a person of the same age and sex, but without any risk factors. It is also indicated in the "1 in ..." format.
 - c. Relative risk (*a/b*), which is the ratio of the two and denotes how much more likely the subject is suffer death or hospitalisation than a person with no factors.
12. The value absolute risk of death is presented also in terms of the centile ranking, e.g. 68 of of 100, where 100 is most at risk.
13. If "Yes" was selected for if the user has had a Covid-19 vaccination, and the case rate was not altered under advanced options, the most recently published case rate for the chosen location, and the date it was published will be shown. Data is taken from <https://coronavirus.data.gov.uk/details/download>, though the total case rate and not PCR only case rate is used.
14. The BMI (body mass index) calculated from the supplied height and weight is shown. Note that if this value is to high or too low, then the closest in-range value will have been used and a warning will be displayed regarding this. The valid range is 15-47 kg/m².
15. Other warnings relating to the inputs are shown on the results page and should be noted.
16. To start another calculation, the user should click on Calculator again in the top navigation bar.

Troubleshooting

The FAQ link, available on the navigation bar at the top of each web page, provides answers to frequently asked questions.

Regulatory Information

	<p>Oxford University Innovation</p> <p>Buxton Court 3 West Way Oxford OX2 0JB</p>
	<p>This device fulfils the provisions of the UK Medical Devices Regulation (2002), as it exists in 2021, via the Medical Devices Directive 93/42/EEC.</p> <p>This software product has been designed according to:</p> <p>ISO 13485:2016 - Medical devices - Quality management systems for medical devices</p> <p>ISO 14971:2019 - Medical devices — Application of risk management to medical devices</p> <p>IEC 62304:2006 Amd 1:2015 - Medical device software – Software lifecycle processes</p> <p>DCB0129:2018 - Clinical risk management: its Application in the manufacture of health IT systems.</p> <p>This device has been developed under the strict quality management system of Oxford University Innovation</p>