



CITF Core Data Elements: COVID-19 and Vaccination

Version 4.1, April 4, 2022

Funding initiative: CITF-CIHR 2021, plus Omicron wave update

This document describes the 'COVID-19 and Vaccination' module of the CITF core data elements (CDE) conceived for COVID-19 history and outcomes in the vaccine era. The questions and responses were based on national surveys and the CDE for previous CITF-funded projects, and have been curated and reviewed by a large team of field researchers and epidemiologists.

Instructions for the investigator and questionnaire designer:

Please keep the wording of your questions as close as possible to the wording in this document to facilitate harmonization of your data with those from other CITF-funded projects. If there are questions you cannot ask of your participants, or if you must alter the wording, please discuss the changes with the CITF Data Management unit. If you add sub-questions or additional precision to the CDE questions, you do not need to share the additional detail.

These modules should be preceded by the concurrent version of the 'Background Questionnaire (demographics and general health)'. An optional Vaccine Safety module is also available.

The question numbers are only used for reference in this document and may change between versions.

Items in red are intended for the interviewer or study personnel.

Vaccination basics

Q #	CITF Adult General Vaccine CDE
00	Participant unique identifier (same across modules and visits)
01.a	Date of interview ___ / ___ / ___ DAY MO YR
40.	Have you been vaccinated against COVID-19? (Answer 'Yes' if you have received at least one dose of a COVID-19 vaccine) NO00 YES01 DON'T KNOW98



41.	How many doses have you received? ONE01 TWO02 MORE THAN TWO03 DON'T KNOW98
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Repeat the following section for each dose (make this a repeatable instrument within visit e.g., baseline, if needed)

Q #	CITF Adult General Vaccine CDE repeatable form
40.a.	<p><i>This question is a screen and placeholder for an e-questionnaire repeatable form [e.g., a REDCap repeated instrument]. It is optional if not needed for your questionnaire design.</i></p> <p>You answered [Q40 response, if = '00, 98'] to "Have you been vaccinated against COVID-19?"</p> <p>Do you have a COVID-19 vaccine scheduled?</p> <p>NO00 YES01 DON'T KNOW98 PREFER NOT TO ANSWER99</p>
41.a.	<p>You answered that you have had [Q41 response, if Q40 = '01'] doses.</p> <p>For which dose are you completing this form?</p> <p>FIRST01 SECOND02 LATEST OF 3 OR MORE03 DON'T KNOW98</p>
42.	<p>When did you receive this dose of the COVID-19 vaccine?</p> <p>___ / ___ / ___ DAY MO YR</p> <p>DON'T KNOW98</p>



Q #	CITF Adult General Vaccine CDE repeatable form
43.	Which vaccine did you receive? PFIZER AND BIONTECH mRNA01 MODERNA mRNA02 ASTRAZENECA OXFORD03 JOHNSON & JOHNSON (JANSSEN)04 OTHER09 (SPECIFY THE VACCINE) _____ DON'T KNOW98

COVID-19 history prior to latest vaccination dose

Q #	COVID-19 history Adult Survey
15.	Do you think you have had COVID-19? NO00 → q33 YES01 PREFER NOT TO ANSWER99
16.	Why do you think you have had COVID-19? [SELECT ALL THAT APPLY] SYMPTOM REVIEW ONLINE01 SYMPTOM PROFILE02 NASAL/THROAT SWAB TEST RESULT ...03 HEALTH CARE PROVIDER04 CONTACT WITH CASE05 OTHER06 SPECIFY: _____ PREFER NOT TO ANSWER99
17.	Were you hospitalized due to COVID-19? NO.....00 YES.....01 PREFER NOT TO ANSWER.....99
18.	Have you ever been tested for an active COVID-19 infection (using nasopharyngeal/throat swab, saliva or gargle test)? NO00 → next module YES01 DON'T KNOW98 PREFER NOT TO ANSWER99
19.	If yes, how many times have you been tested?



Q #	COVID-19 history Adult Survey
	<p>_____ NUMBER</p> <p>PREFER NOT TO ANSWER</p>
20.5	<p>a. Have you tested positive for COVID-19 on a test (nasopharyngeal, throat swab, saliva or gargle test)?</p> <p>NO00 YES01 DON'T KNOW98 PREFER NOT TO ANSWER99</p> <p>b. If yes, what was the date of the positive test (if more than one, the earliest)?</p> <p>____ / ____ MO YR</p>

* Q20.5 not a question in v2 but the same data can be derived from Q20, a 4-part question.

Optional detailed COVID-19 antigen test history

In lieu of question 20.5, if it benefits your research to collect a more detailed test history, please consider including the following questions. It has benefits for the CITF immunity modelling activities, as well. This was the format in version 2 and question 20.5 can be derived from this set of questions.

v2 #	Optional detailed COVID-19 antigen test history
20.1	<p>a. What was the date of the first test?</p> <p>____ / ____ MO YR</p> <p>b. What was the result of the first test?</p> <p>NEGATIVE00 POSITIVE01 DON'T KNOW98</p> <p>c. Did you have any symptoms of COVID when you had this test?</p>



v2 #	Optional detailed COVID-19 antigen test history
	<p>NO00 YES01 DON'T KNOW98</p> <p>d. If yes, what symptoms did you have? [SELECT ALL THAT APPLY]</p> <p>COUGH a FEVER b SHORTNESS OF BREATH c SORE MUSCLES d HEADACHE e SORE THROAT..... f DIARRHEA..... g DECREASED SENSE OF SMELL OR TASTE h OTHER i (SPECIFY) _____</p>
20.2	<p>If you took more than 1 test: a. What was the date of the second test?</p> <p>___ / ___ ___ MO YR</p> <p>b. What was the result of the second test?</p> <p>NEGATIVE00 POSITIVE01 DON'T KNOW98</p> <p>c. Did you have any symptoms of COVID when you had this test?</p> <p>NO00 YES01 DON'T KNOW98</p> <p>d. If yes, what symptoms did you have? [SELECT ALL THAT APPLY]</p> <p>COUGH a FEVER b SHORTNESS OF BREATH c SORE MUSCLES d HEADACHE e SORE THROAT..... f</p>



v2 #	Optional detailed COVID-19 antigen test history
	DIARRHEA..... g DECREASED SENSE OF SMELL OR TASTE h OTHER i (SPECIFY) _____
20.3	If you had more than 2 tests: a. What was the date of the third test? ___ / ___ MO YR b. What was the result of the third test? NEGATIVE00 POSITIVE01 DON'T KNOW98 c. Did you have any symptoms of COVID when you had this test? NO00 YES01 DON'T KNOW98 d. If yes, what symptoms did you have? [SELECT ALL THAT APPLY] COUGH a FEVER b SHORTNESS OF BREATH c SORE MUSCLES d HEADACHE e SORE THROAT..... f DIARRHEA..... g DECREASED SENSE OF SMELL OR TASTE h OTHER i (SPECIFY) _____
20.4	a. Have you tested positive for COVID-19 (using nasopharyngeal, throat swab, saliva or gargle test) on a test that was not included the questions above (that is, on the 4th or later test)? NO00 --> Q22 YES01 b. If yes, what was the date the first time you tested positive?



v2 #	Optional detailed COVID-19 antigen test history
	____ / ____ ____ MO YR

COVID-19 disease after latest vaccination dose (vaccine effectiveness)

We realize CITF-funded studies are using a range of study designs and may not have planned study visits. The questionnaire is designed for a typical cohort study, but we will work with studies on a case-by-case basis to find the best mapping between their design and the requested CDE. This section is also facilitates a 'test-negative' design.

Use this form at each study visit.

Q #	CITF Vaccine Effectiveness Adult Survey
60.	<p><i>Calculated field or enter manually (the objective is, over the study visits, to completely cover the time from first vaccination relevant to your study to present without overlap):</i></p> <p>Answer these questions for the time interval between your [most recent of: last study visit on [date] / last COVID-19 vaccine on [date]] and now.</p>
61.a.	<p>Were you tested for COVID-19 with a PCR test (nasopharyngeal, throat swab, saliva or gargle test)?</p> <p>NO 00 → Q61.b (next) YES 01 → Q62 DON'T KNOW 98 → Q61.b (next) PREFER NOT TO ANSWER ... 99 → Q61.b (next)</p>
61.b.	<p>Did you test yourself for COVID-19 with a SARS-CoV-2 antigen test (rapid antigen test, lateral flow test)?</p> <p>NO 00 → Q65 YES 01 → Q62 DON'T KNOW 98 → Q65 PREFER NOT TO ANSWER ... 99 → Q65</p>



Q #	CITF Vaccine Effectiveness Adult Survey
62.	<p>Did you have symptoms consistent with COVID-19 when you had your test (such as cough, fever, shortness of breath, sore muscles, headache, sore throat, diarrhea, decreased sense of smell or taste)?</p> <p>NO 00 YES 01 DON'T KNOW 98 PREFER NOT TO ANSWER ... 99</p>
63.	<p>Was the test positive? (If had both PCR and rapid test, answer for PCR test)</p> <p>NO 00 → Q65 YES 01 → Q64 DON'T KNOW 98 → Q65 PREFER NOT TO ANSWER ... 99 → Q65</p>
64.	<p>What was the date of the positive test? (If had both PCR and rapid test, answer for PCR test. If more than one, the first one in the time interval.)</p> <p>__ __ / __ __ / __ __ __ __ DD MM YYYY</p>
65.	<p>Did you visit a healthcare provider for a COVID-19 infection?</p> <p>NO 00 → Q65 YES 01 → Q64 PREFER NOT TO ANSWER 99 → Q65</p>
66	<p>What was the date of the visit (if more than one, the first one in the time interval)?</p> <p>__ __ / __ __ / __ __ __ __ DD MM YYYY</p>
67.a	<p>Were you hospitalized due to COVID-19?</p> <p>NO 00 YES 01 → Q66 PREFER NOT TO ANSWER 99</p>
67.b	<p>What was the date of hospitalization (if more than one, the first one in the time interval)?</p>



Q #	CITF Vaccine Effectiveness Adult Survey
	___ / ___ / ___ DD MM YYYY
67.c	What was the duration of your hospitalization? ___ ___ ___ DAYS DON'T KNOW 98 PREFER NOT TO ANSWER 99
67.e	[Were you / Was the participant] admitted to the ICU? NO 00 YES 01 DON'T KNOW 98

COVID-19 infection burden (pre- or post-vaccination)

80.	If you ever (pre- or post-vaccine) tested positive for COVID-19 or were diagnosed with a COVID-19 infection by a healthcare provider: What was the highest impact of your COVID-19 infection? (If more than one symptom or infection, the most serious.) NOT APPLICABLE (ASYMPTOMATIC COVID) 00 DID NOT INTERFERE WITH DAILY ACTIVITIES 01 INTERFERED WITH BUT DID NOT PREVENT DAILY ACTIVITIES 02 PREVENTED DAILY ACTIVITIES 03 DON'T KNOW 98 PREFER NOT TO ANSWER 99
81.	As of today, what is the outcome of your COVID-19 infection? [SELECT ALL THAT APPLY] FULLY RECOVERED 00 SYMPTOMS PERSISTING, INTERFERES WITH BUT DOES NOT PREVENT DAILY ACTIVITIES 01 SYMPTOMS PERSISTING, PREVENTS DAILY ACTIVITIES .. 02 ANTICIPATED PERMANENT DISABILITY 03 DON'T KNOW 98 PREFER NOT TO ANSWER 99

Commented [TM1]: If using questionnaire software, this can be automated.



70.	Did the participant die? NO 00 YES 01 DON'T KNOW 98
71.	Date of death: __ / __ / __ __ DD MM YYYY
72.	Was COVID-19 an underlying cause of death? NO 00 YES 01 DON'T KNOW 98