Maine DHHS

COVID-19 Vaccines
Information for Clinicians

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Welcome

- Introductions
- Session goals & format
- CME available (0.5 AMA PRA Cat 1 Credit/session)
  - **If CME desired, pls email your name & session attended to COVIDCME.DHHS@maine.gov**
- Future sessions
- Current context

Disclosures

The planners and faculty for this activity do not have any relevant financial relationships to disclose with any Commercial Interests and do not have any conflicts of interest to resolve

COVID-19 Vaccines – Info for Clinicians

- Context
- Science of vaccines
- Vaccine development & approval process
- **Viral variants**
- **New vaccines**
- Promoting vaccine equity
- Vaccine hesitancy
- Reporting & tracking adverse events

COVID-19 Viral Variants

- Variants are expected result of spontaneous mutations, accelerated by rapid spread
- Can be single letter “typos” in viral genetic code, or longer insertions or deletions
- Several mutations have affected spike (S) protein, increasing avidity of receptor binding
- Result is in marked increase in viral replication, resulting in substantial increase in transmissibility

COVID-19 Viral Variants

Variant Designation	Country	Date	Mutation Impact
B.1.177 (20.A.EU1)	Spain	May 2020	Changes to spike protein
B.1.1.7 (201/501 Y.V1)	UK	Sept 2020	50% more transmissible
B.1.351 (20H/501 Y.V2, E484K)	South Africa	Oct 2020	Changes to spike protein may help virus evade neutralizing antibodies
B.1.1.28, P.1 (20J/501Y.V3)	Brazil, Japan	Jan 2021	TBD

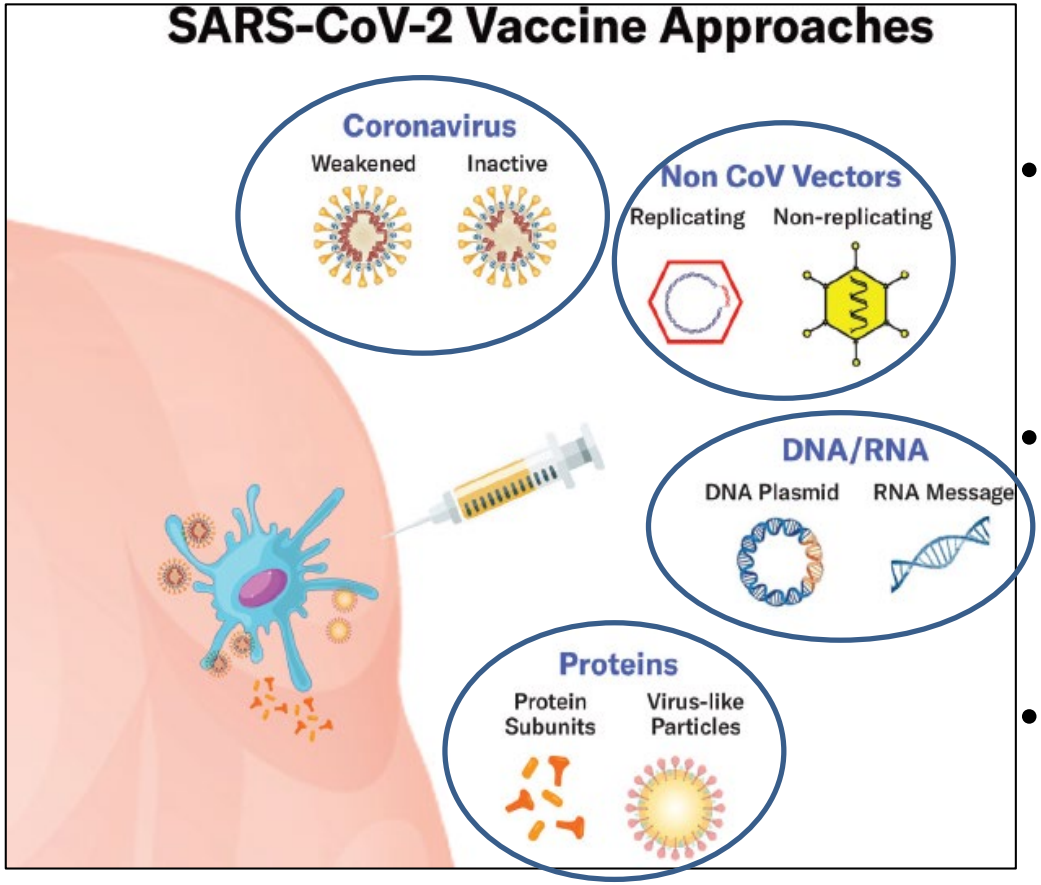
https://jamanetwork.com/journals/jama/fullarticle/2776039

Implications of Variants

- Variants emphasize the importance of:
  - COVID-19 mitigation basics, especially masking, physical distancing
  - Efficient vaccine rollout: Less transmission = less viral replication → fewer opportunities for mutation/viral evolution
  - Active molecular level surveillance
  - Ability to evaluate effectiveness of vaccines against variants, ability to adapt vaccines, potential role of "booster" doses

Major Types of COVID Vaccines

- Weakened or inactive virus vaccines



- Viral vector vaccines
- Nucleic acid (mRNA) vaccines
- Protein-based vaccines

[ASA Update-on-COVID-19-Vaccine-Development]

J&J Adenovirus Vector Vaccine

- Topline results reported in J&J press release Jan 29, 2021 – full clinical trial results pending; FDA review pending
- Single dose 72% effective in US, 66% effective across all sites at preventing moderate to severe COVID-19 at 28D post-vaccination
- 85% effective across all sites in preventing severe disease
- Offered complete protection against COVID-19 related hospitalization and death at D28
- Provided protection against severe disease across sites, ages, and across multiple virus variants, including South African/ B.1.351 lineage

www.jnj.com/johnson-johnson-announces-single-shot-janssen-covid-19-vaccine-candidate-met-primary-endpoints

Novavax Protein Subunit Vaccine

- Topline results reported in Novavax press release Jan 28, 2021 reporting results from UK & SA trials
- 89.3% efficacy in UK trial (approx 15K participants)
- UK variant present in 50% of confirmed cases
  - Vaccine 95.6% efficacy against original COVID-19 strain
  - 85.6% efficacy vs UK variant (B117)
- 60% efficacy in South Africa (small interim analysis)
- Phase 3 trials in US & Mexico still under way; expect to complete enrollment by mid-Feb

https://ir.novavax.com/news-releases/news-release-details/novavax-covid-19-vaccine-demonstrates-893-efficacy-uk-phase-3

COVID Vaccines & Efficacy

Company	Platform	Doses	Non-clinical results	Number of people who got vaccine	Protection from hospitalization/ death due to COVID-19	Protection from severe disease from COVID-19 (may not be hospital)	Efficacy against milder disease from COVID-19
moderna	mRNA-1273 mRNA in lipid nanoparticle	2	Neutralizing Abs; Strong Th1 response; protection from challenge	~15,000	100%	100% (30 cases in placebo arm; 0 in vaccine)	94.1%
Pfizer	BNT162b2 mRNA in lipid nanoparticle	2	Neutralizing Abs; Strong Th1 and Th2 response; protection from challenge	~18,600	100%	100% (9 cases in placebo arm; 0 in vaccine)	95%
AstraZeneca	AZD 1222 Non-replicating Chimp Adenovirus-DNA	2	Neutralizing Abs; Strong Th1 and Th2 response; protection from challenge	~5800	100%	100% (15 in placebo; 0 in vaccine)	90% half-full-dose; 70% overall; 76% with 1 dose
Johnson & Johnson	JNJ-78436725 Non-replicating human adenovirus/DNA	1	Neutralizing Abs; Strong Th1 and Th2 response; protection from challenge	~22,000	100%	85% (across South Africa, U.S., Latin America	72% US; 66% Latin America; 57% S. Africa
NOVAVAX Creating Tomorrow's Vaccines Today	NVX-CoV2373 Spike protein/RBD + Matrix M adjuvant	2	Neutralizing Abs; protection from challenge	~9700	100%		89.3% UK; 60% S. Africa
Sputnik V	Ad26 and Ad5 adenovirus/DNA	2	Neutralizing Abs; Strong Th1 and Th2	~14964	100%	100% (20 in placebo; 0 vaccine)	91.6%

Table courtesy of Monica Gandhi, MD, MPH, UCSF

Maine Phases for Vaccine Distribution*

Phase 1a

- Health Care Personnel
- Residents & staff of long-term care facilities
- Public safety
- State COVID response critical personnel

Phase 1b

- Older adults
  - **≥ 70 yo[1]**
  - 65-69 yo[2]
- Persons with high-risk medical conditions
- Front line essential workers

Phase 1c

- Other essential workers

Phase 2

- Persons aged 16-64 & not already eligible

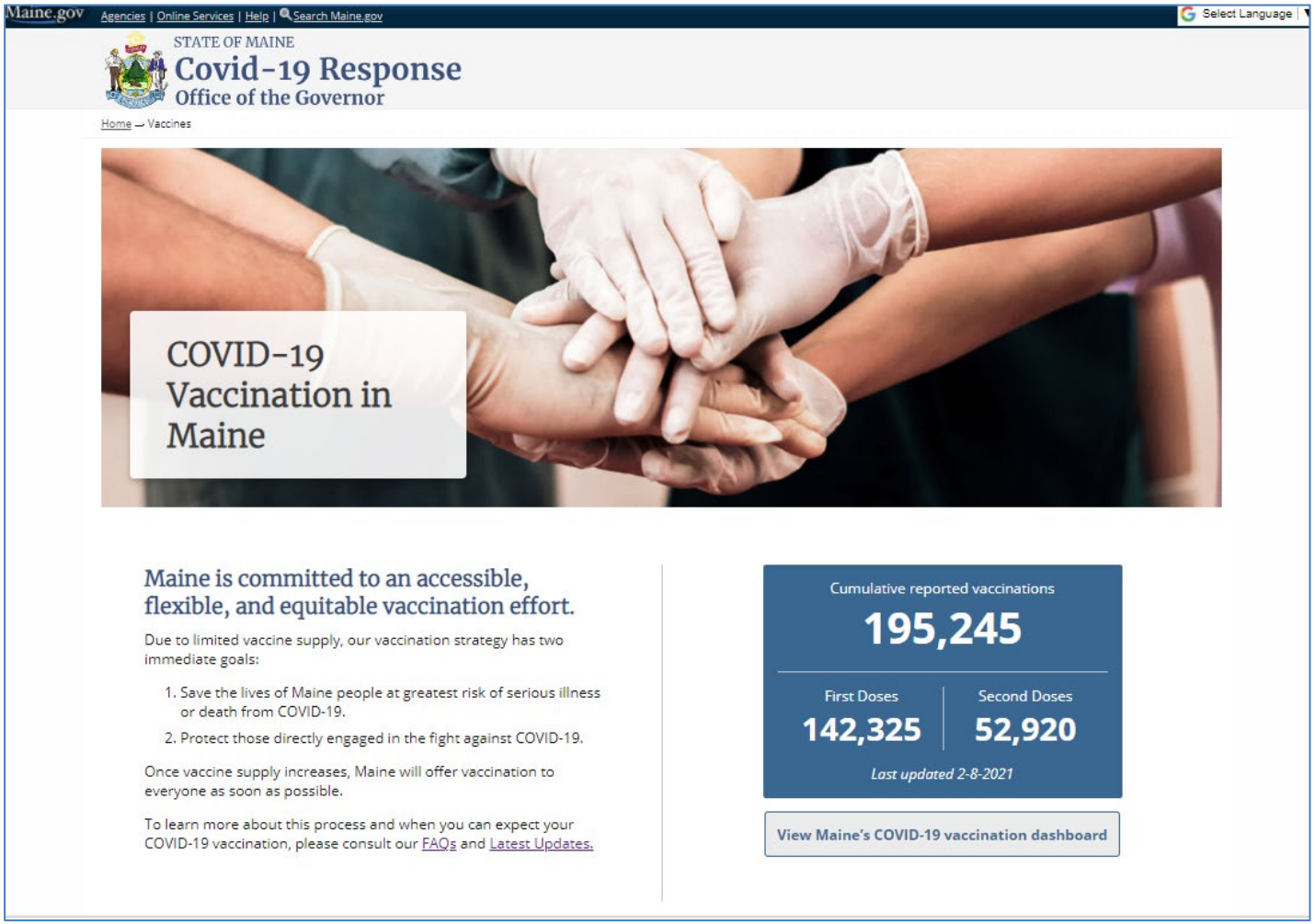
*Updates posted to Gov Mills COVID Vaccine website: www.maine.gov/covid19/vaccines

[1] 70+yo: Currently being vaccinated

[2] 65-69yo: Anticipate starting vaccination early March

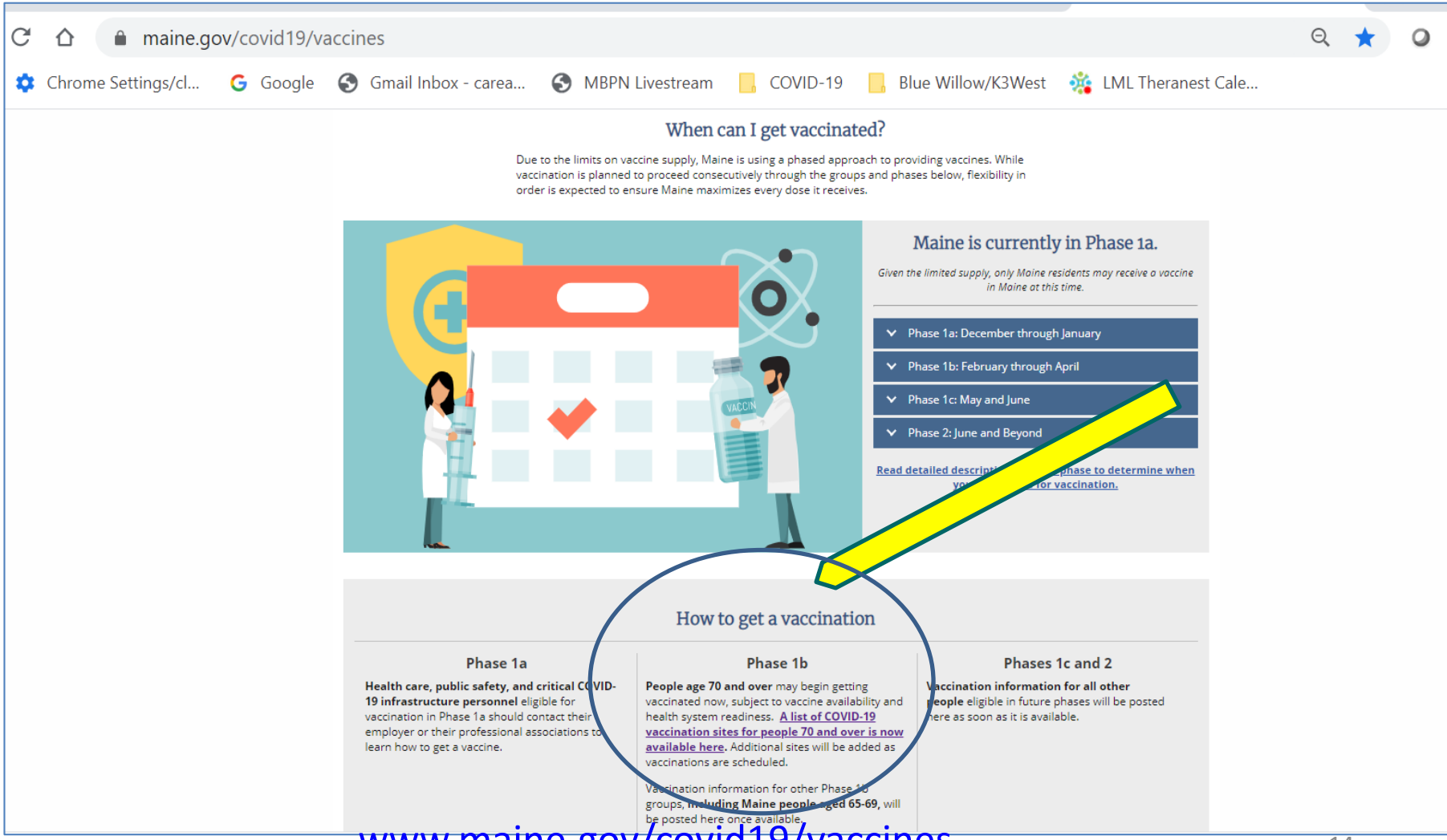
NOTE: Facilities booking appts listed at: www.maine.gov/covid19/vaccines/vaccination-sites

Gov Mills Info COVID Vaccine



www.maine.gov/covid19/vaccines

Gov Mills Info COVID Vaccine



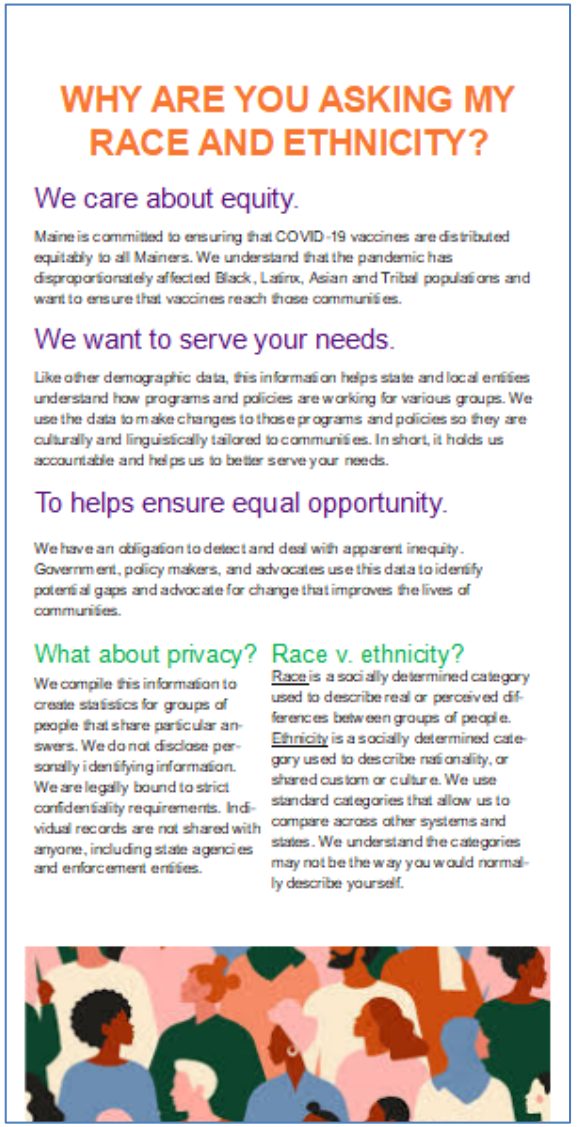
www.maine.gov/covid19/vaccines

Ensuring Racial/Ethnic Equity

ME DHHS Equity webinar Wed, Feb 17, 7:30A

- **Register in advance** for this and additional webinars in this monthly series: https://zoom.us/meeting/register/tJcsfuGvpj0jGdaRiW5Y15qnYa2AMVriHgaI , *OR*
- **Log on at the time of the webinar** with following link: https://zoom.us/j/93198786932
  - Meeting ID: 931 9878 6932
  - Passcode: 4FrT7H
  - One tap mobile: +13126266799,,93198786932#,,,0#,,416363#

***NOTE**: NO Clinician Info Session on Tues, Feb 16 at 7:30AM



WHY ARE YOU ASKING MY RACE AND ETHNICITY?

We care about equity.

Maine is committed to ensuring that COVID-19 vaccines are distributed equitably to all Mainers. We understand that the pandemic has disproportionately affected Black, Latinx, Asian and Tribal populations and want to ensure that vaccines reach those communities.

We want to serve your needs.

Like other demographic data, this information helps state and local entities understand how programs and policies are working for various groups. We use the data to make changes to those programs and policies so they are culturally and linguistically tailored to communities. In short, it holds us accountable and helps us to better serve your needs.

To helps ensure equal opportunity.

We have an obligation to detect and deal with apparent inequity. Government, policy makers, and advocates use this data to identify potential gaps and advocate for change that improves the lives of communities.

What about privacy?

We compile this information to create statistics for groups of people that share particular answers. We do not disclose personally identifying information. We are legally bound to strict confidentiality requirements. Individual records are not shared with anyone, including state agencies and enforcement entities.

Race v. ethnicity?

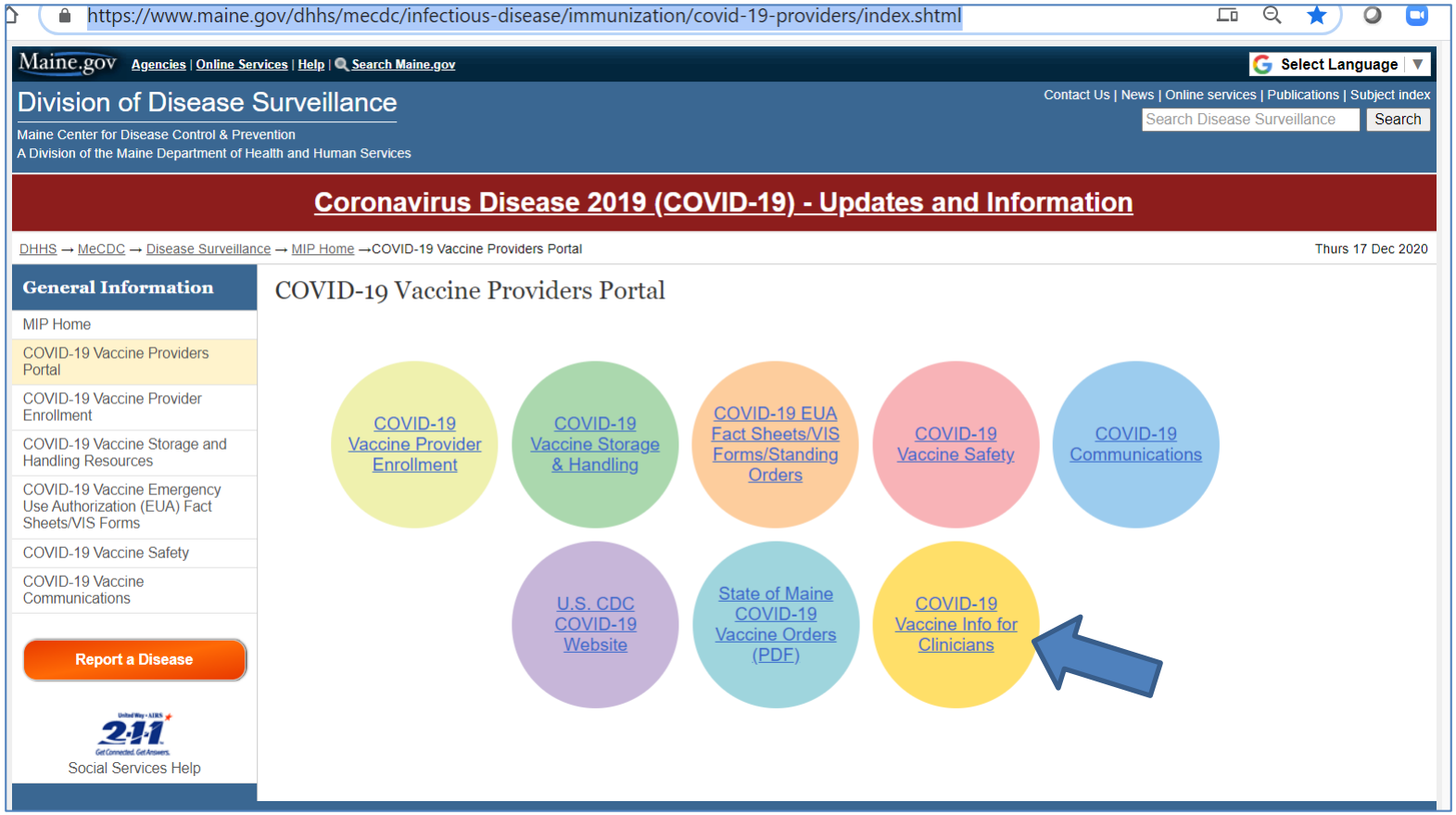
Race is a socially determined category used to describe real or perceived differences between groups of people. Ethnicity is a socially determined category used to describe nationality, or shared custom or culture. We use standard categories that allow us to compare across other systems and states. We understand the categories may not be the way you would normally describe yourself.

US CDC CISA Clinical Consultation

- Healthcare providers can request consultation from **CISA COVIDvax** for a complex COVID-19 vaccine safety question that is…
  (1) about an individual patient residing in US or vaccine safety issue and…
  (2) not readily addressed by CDC or ACIP guideline
- Request can be made by…
  – Calling 800-CDC-INFO (800-232-4636), or
  – Submitting a request via CDC-INFO webform
  – Contacting CISAeval@cdc.gov to request case evaluation

www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html

ME CDC COVID Vaccine Resources



[ME CDC COVID-19 Vaccine Resources](www.maine.gov/dhhs/mecdc/infectious-disease/immunization/covid-19-providers/index.shtml)
(www.maine.gov/dhhs/mecdc/infectious-disease/immunization/covid-19-providers/index.shtml)

Vaccine questions? Email:
C19vaccine.MECDC@maine.gov

Presenters

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COVID-19 Vaccines

Questions??