Addressing the COVID-19 Crisis: An Open Forum Webinar Series for Pharmacists

December 3, 2020

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Dean and Professor
Loma Linda University School of Pharmacy
President, APhA

Host and Moderator

Today's Focus:

Discuss breaking information about COVID-19 vaccines, including the latest in the development, approval, allocation, and distribution, as well as vaccine hesitancy.

Colonel (Ret.) John Grabenstein, RPh, PhD, FAPhA

Editor, Immunization Action Coalition

President, Vaccine Dynamics

Guest Speaker

Steve Foster, PharmD, FAPhA
APhA Liaison to ACIP
CAPT (Ret.), U.S.P.H.S.

Guest Speaker

Mitchel Rothholz, RPh, MBA
Chief of Governance & State Affiliates
American Pharmacists Association

Executive Director
American Pharmacists Association Foundation

Speaker

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President
Pharmacy Practice and Government Affairs
American Pharmacists Association

Subject Matter Expert: Q&A

Disclosures

Stephan Foster, PharmD, FAPhA, FNAP, has served as a speaker for Merck Vaccines, Pfizer and Seqirus. He has served on advisory boards for Pfizer and Seqirus.
John Grabenstein, RPh, PhD, FAPhA, serves an advisory board member for Janssen, VBI Vaccines and Bavarian Nordic. He is a consultant at Velneva. He has stock in Merck.
Mitchel C. Rothholz, RPh, MBA, declares that his spouse is an employee of Merck and that he has served on advisory boards for Merck and Pfizer.

All other individuals involved in the development of this material declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria. APhA's editorial staff declare no conflicts of interest or financial interests in any product or service mentioned in this activity, including grants, employment, gifts, stock holdings, and honoraria. For a complete list of APhA staff disclosures, please visit the APhA website at www.pharmacist.com/apha-disclosures.

CPE Information

Target Audience: Pharmacists

ACPE#: 0202-0000-20-389-L06-P

Activity Type: Knowledge-based

Note: CPE is only available live.

Learning Objectives

1. Discuss the latest updates on the various COVID-19 vaccines.
2. Describe emerging processes for approval, allocation, and distribution.
3. Review vaccine safety information and strategies to overcome vaccine hesitancy.

COVID-19 vaccines consisting of messenger ribonucleic acid (mRNA):

a. Contain protein subunits
b. Contain viruses that express spike protein
c. Direct host cells to express spike protein
d. Consist of inactivated whole viruses

Adverse events can be considered attributable to vaccination (cause-and-effect) if:

a. They occur soon after vaccination
b. They occur any time after vaccination
c. Many of them have been reported
d. They occur in vaccine recipients more often than among nonrecipients

The Advisory Committee on Immunization Practices met on December 1 and voted to make which of the following to be included in Phase 1a (top priority)?

a. Adults ≥65 years of age

b. Essential workers and anyone with high-risk medical condition

c. All healthcare personnel and essential workers

d. All healthcare personnel and residents of long-term care facilities

Format for Today's Webinar

1:00 pm: Introductions

1:05 pm: Interview with John Grabenstein, Steve Foster, and Mitch Rothholz

1:25 pm: Open Forum: A Minute for Your Thoughts

1:50 pm: Wrap Up: Review of APhA's Resources and Assessment Questions

Open Forum Ground Rules

- Use the **Questions** field on the GoToWebinar toolbar to submit comments and questions related to the topic discussion
- Individuals whose submissions are selected will be asked by the moderator to state the comment or question for the audience. The line for the individual will be unmuted to read their comment or question.
- To maximize the number of questions/comments addressed, **a 60-second time limit** will be in effect for everyone to state their question or comment.
- We will try to get to as many comments and questions as possible. We have created a new forum for COVID-19 discussions where further discussion post-webinar. Information on participating in this forum will be provided at the end of the open forum.

Discussion with John Grabenstein, Steve Foster, and Mitch Rothholz

Discuss breaking information about COVID-19 vaccines, including the latest in the development, approval, allocation, and distribution, as well as vaccine hesitancy.

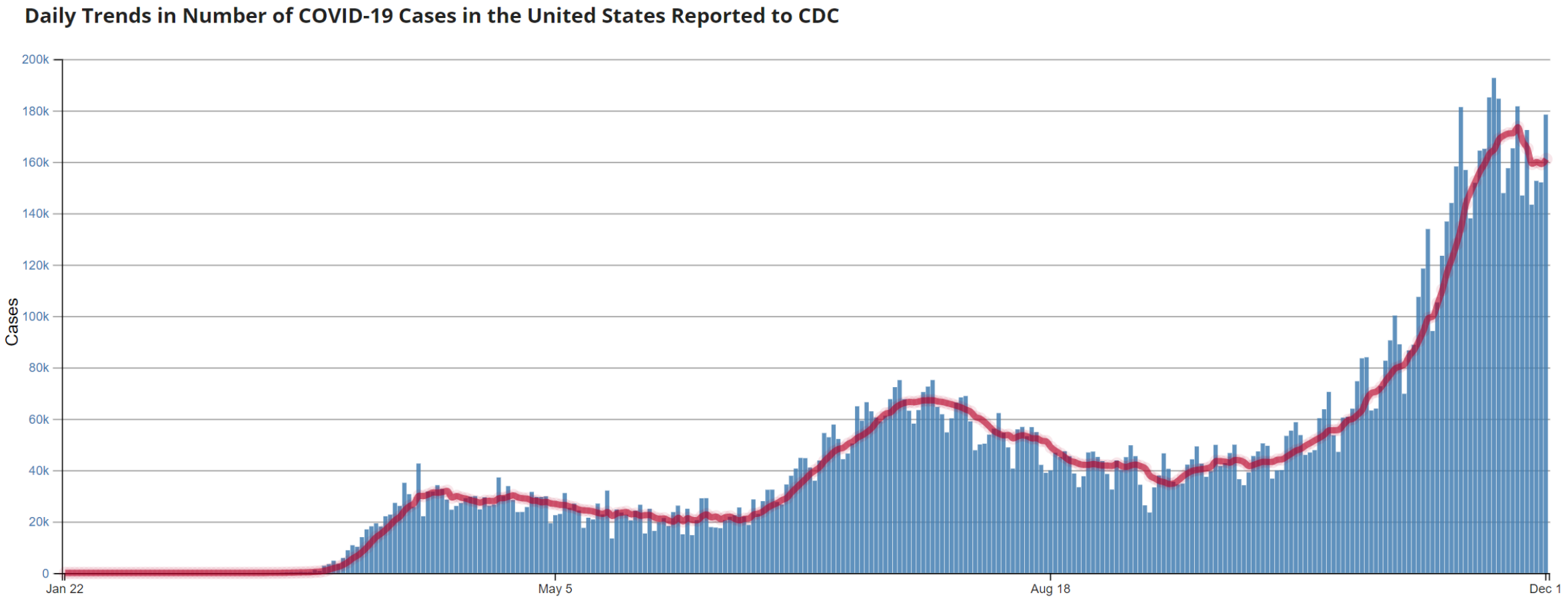
Evidence to Recommendation (EtR) Framework

EtR Domain	Question	Work Group Judgements
Public Health Problem	Is the problem of public health Importance?	
Benefits and Harms	Discuss after phase 3 trials	
Values	Does the target population feel the desirable effects are large relative to undesirable effects?	
Acceptability	Is intervention acceptable to key stakeholders?	
Feasibility	Is intervention feasible to implement?	
Resource Use	Is the intervention a reasonable and efficient allocation of resources?	
Equity	What would be impact of intervention on health equity?	

ACIP Presentation Slides: November 2020 Meeting

Trend in Number of COVID Cases, U.S. - 12/2/2020

Cases: 13,626,022 Deaths: 269,763



https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases

Evidence to Recommendation Framework (EtR)

Values

- Overall acceptability 42-86%
  - Changes based upon news of efficacy and safety
- Vaccination Intention
  - Varied by population, time, and vaccine characteristics
  - Many are open to vaccination but prefer not to be first
  - Fear that approval process too fast

Acceptability

- Surveys by CSC, Nurses
  - 63% healthcare providers would get vaccine
  - Nurses 34% would voluntarily receive vaccine
    - 57% comfortable discussing with patients
- All jurisdictions have submitted implementation plans
- Pharmacy committed to participate

ACIP Presentation Slides: November 2020 Meeting

Evidence to Recommendation Framework (EtR)

Feasibility

- Barriers
  - Financial – cost for implementation
  - Complexity of recommendations due to multiple vaccines
  - Access – may be limited in rural areas
  - Vaccine storage and handling – Ultra-cold, size of shipments, 1 or 2 dose schedules

Resource Use

- 20% population infected = $163 billion in Direct Medical Costs
- Health related costs estimated to be $8.5 trillion
- $10 billion to Warp Speed
- Vaccine provided at no cost to individual
- Cost-effectiveness not a primary driver for decision-making during a pandemic

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Evidence to Recommendation Framework (EtR)

Equity

- Implementation and confidence in vaccine pivotal to reducing health inequities
  - May depend upon which vaccine used
- Intervention in disadvantaged groups must be:
  - Accessible
  - Acceptable
  - Effective
  - Used by

ACIP Presentation Slides: November 2020 Meeting

Evidence to Recommendations (EtR) Framework

EtR Domain	Question	Work Group Judgements
Public Health Problem	Is the problem of public health Importance?	Yes
Benefits and Harms	Discuss after phase 3 trials	
Values	Does the target population feel the desirable effects are large relative to undesirable effects?	Probably yes; Varies
Acceptability	Is intervention acceptable to key stakeholders?	Probably yes; Varies
Feasibility	Is intervention feasible to implement?	Probably yes
Resource Use	Is the intervention a reasonable and efficient allocation of resources?	Yes
Equity	What would be impact of intervention on health equity?	Probably reduced/ probably increased depending upon vaccine

ACIP Presentation Slides: November 2020 Meeting

ACIP Vote – Interim Recommendation (12-1-2020)

When a COVID-19 vaccine is authorized by FDA and recommended by ACIP, vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a) should be offered to both 1) health care personnel[§] and 2) residents of long-term care facilities[¶]

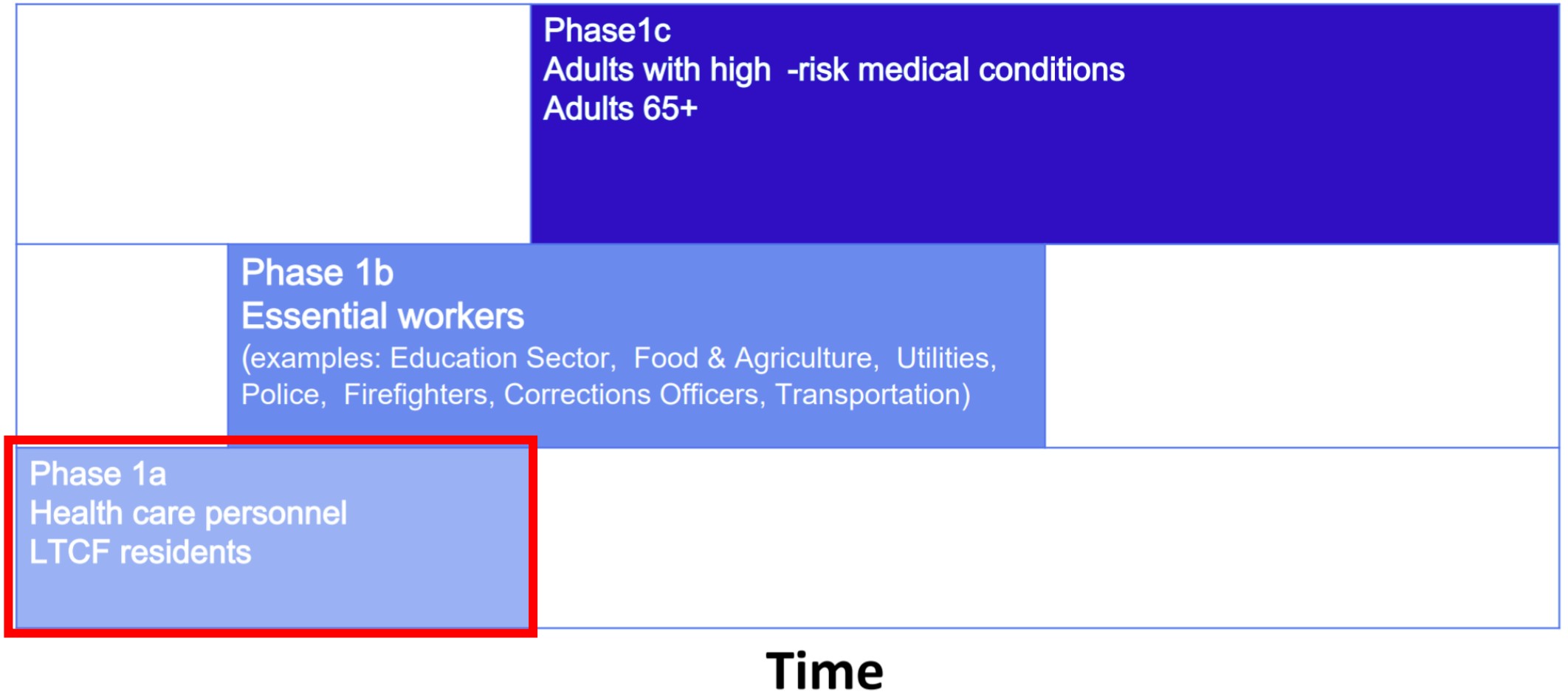
[§]Health care personnel are defined as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials

[¶] Long-term care facility residents are defined as adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently

https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm?s_cid=mm6949e1_w

Phased Allocation

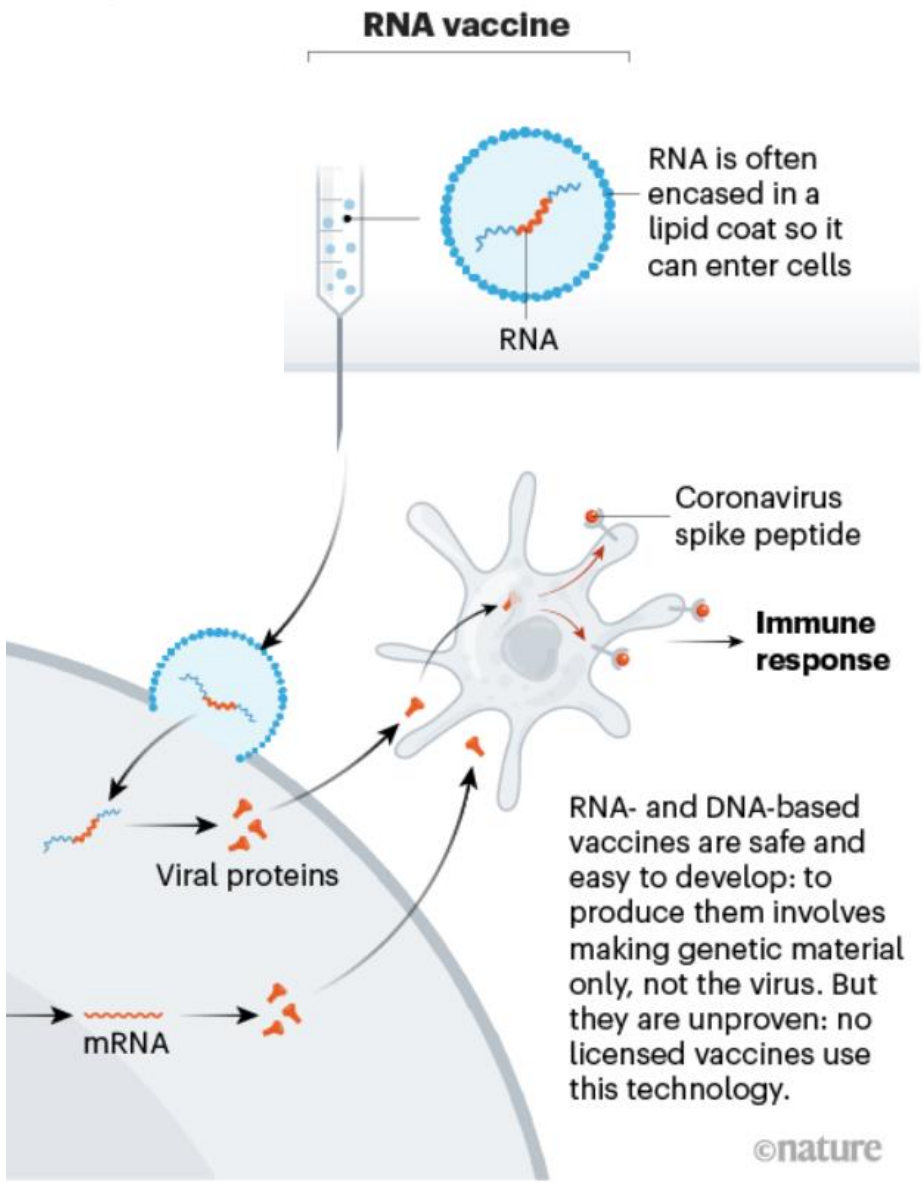
ACIP Vote – December 1, 2020



[ACIP Presentation Slides: December 2020 Meeting]

COVID-19 Vaccines Under FDA Review

NUCLEIC-ACID VACCINES



Callaway E. The race for coronavirus vaccines: A graphical guide. *Nature* 2020;580(Apr 28):576-577. https://www.nature.com/articles/d41586-020-01221-y

SARS-CoV-2 Vaccine Candidates

Vaccine Sponsor [w/ Major Partners]	ModernaTX USA	BioNTech with Pfizer
Product Designator	mRNA-1273	BNT162b2
Vaccine Type	mRNA	mRNA
Product Features	Lipid nanoparticle dispersion	Lipid nanoparticle dispersion
Production Medium (origin)	Cell free (synthetic)	Cell free (synthetic)
Route	IM	IM
Dosing Regimen	Days 0 + 28	Days 0 + 21
Human Data	94.1% (95% CI: _____)	95% (95% CI: _____)
Safety Summary	Most AEs mild or moderate. Grade 3: Fatigue 9.7%, muscle ache 9%, joint pain 5%, headache	Most AEs mild or moderate. Grade 3: Fatigue 3.8%, headache 2.0%.

Vaccines in phase-3 trials with USG contract (1 Dec 20)

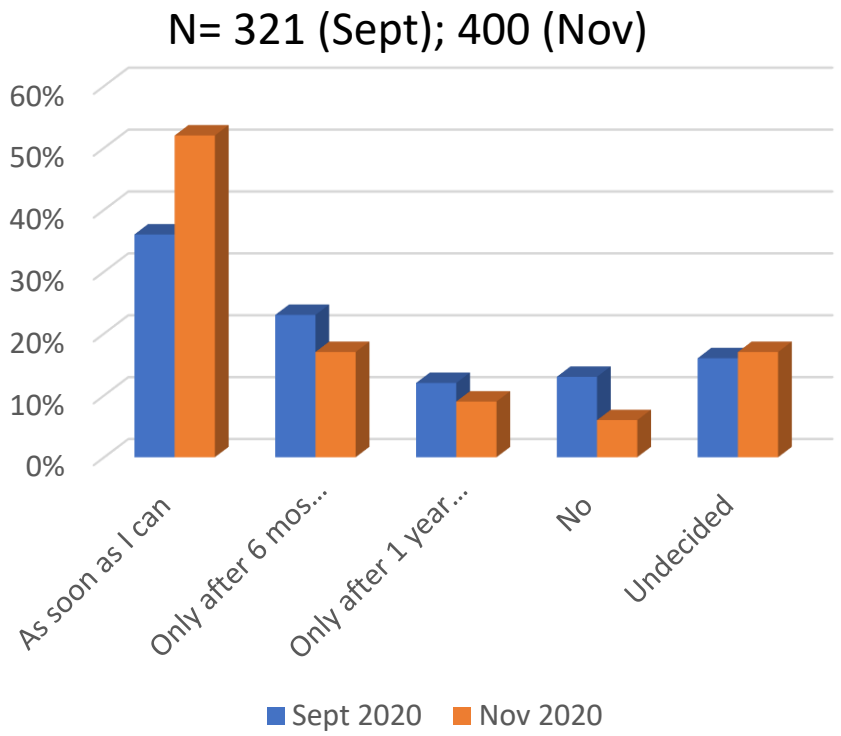
SARS-CoV-2 Vaccine Candidates

Vaccine Sponsor [w/ Major Partners]	ModernaTX USA	BioNTech with Pfizer
Expected Dose	100 mcg	30 mcg
Expected Packaging	Frozen liquid. 10-dose vial, no preservative	Frozen liquid. 5-dose vial, no preservative Dilute w/ NaCl 0.9%
Expected Storage & Handling Conditions	Ship @ -20°C. @ 2-8°C NMT 30 d. Rm temp NMT 12 h	Ship, store @ -70°C. @ 2-8°C NMT 5 d. Rm temp: Dilute, use in 6 h
Trial Status	IND, Phase 3	IND, Phase 3
Ages in phase 3 trial	18-64, 65+	12-56, 65-85
USG Contract '20-21	100 million	100 million

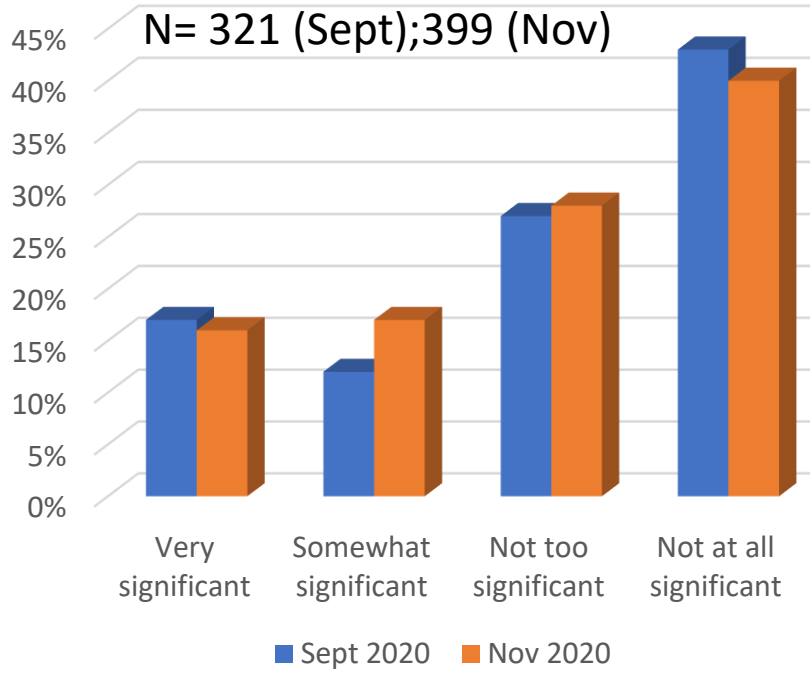
Vaccines in phase-3 trials with USG contract (1 Dec 20)

Pharmacists and COVID-19 Vaccine

Personally plan to be vaccinated with COVID-19 vaccine when it becomes available



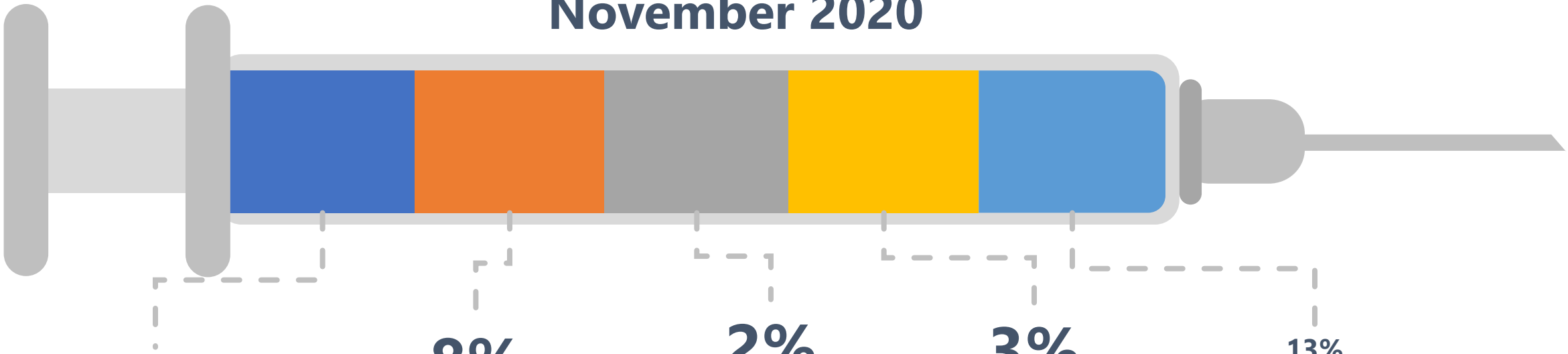
Significance of not having ability to be personally vaccinated against COVID-19 on pharmacist willingness to administer the vaccine to other individuals in high-risk populations



Significantly
Sept: 29%
Nov: 33%

Not Significantly
Sept: 70%
Nov: 68%

Pharmacists – Best Description of Personal Willingness to Order/Prescribe And Administer COVID-19 Vaccine November 2020



74%
Willing to order/prescribe And administer vaccine in practice and community (61% in Sept 2020)

8%
If force by employer but will not prescribe or order vaccine (9% in Sept 2020)

2%
Not willing to Order or administer COVID-19 vaccine (3% in Sept 2020)

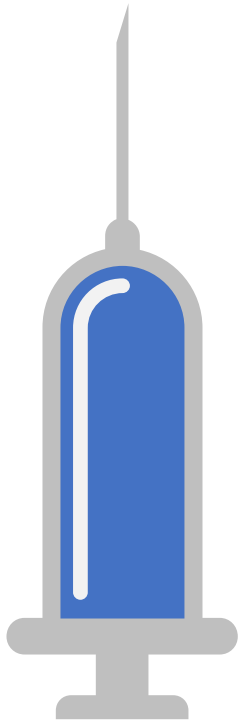
3%
Not yet decided (9% in Sept 2020)

13%
Not applicable (18% in Sept 2020)

N= 315 (Sept 2020); 386(Nov 2020)

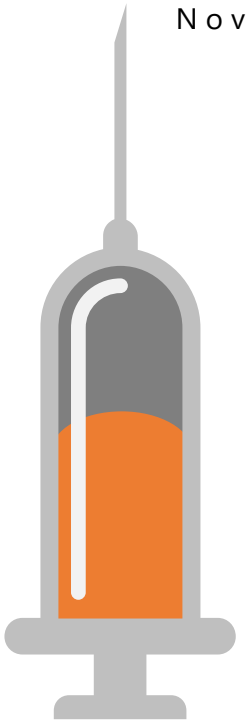
Pharmacist Readiness
In terms of logistics preparation to provide COVID-19 vaccine when it is released

November 2020 (N=359)



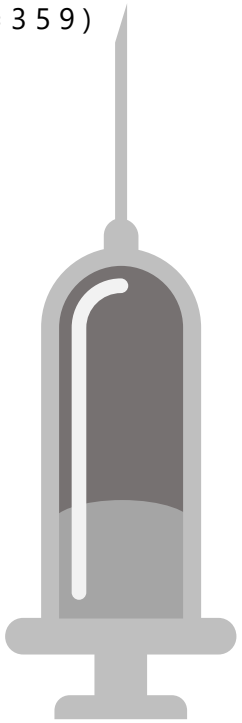
37%

Ready to receive vaccine and vaccinate as soon as vaccine available



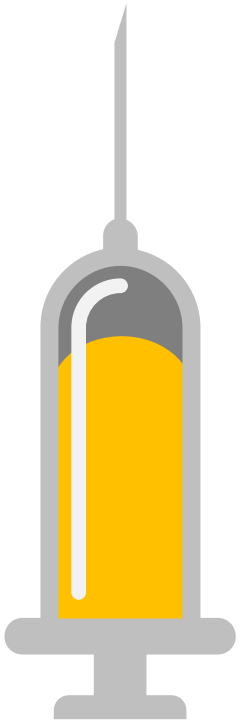
23%

In final prep stages & will be ready



34%

Not prepared to participate in first wave but plan to participate in future phases



6%

Logistics too difficult and thus will not participate

APhA

November 2020

Adequacy of support staff at your practice location to safely offer COVID-19 vaccine among other patient care services you provide

37% **Very adequate**
(Sept 2020: 34%)

33% **Somewhat adequate**
(Sept 2020: 36%)

17% **Not too adequate**
(Sept 2020: 15%)

13% **Not at all adequate**
(Sept 2020: 15%)

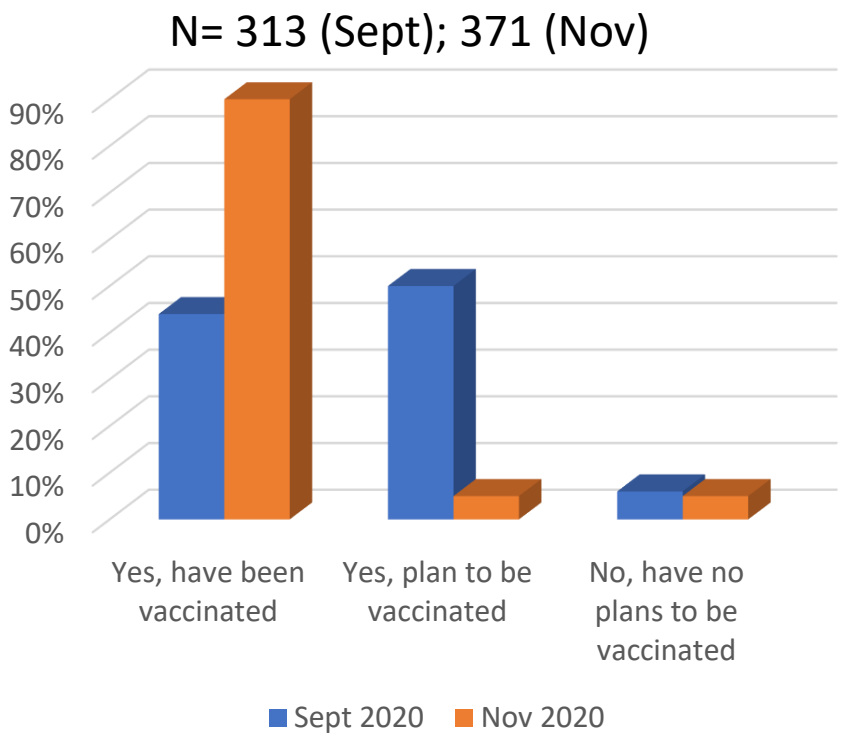
70%
Adequate

30%
Not Adequate

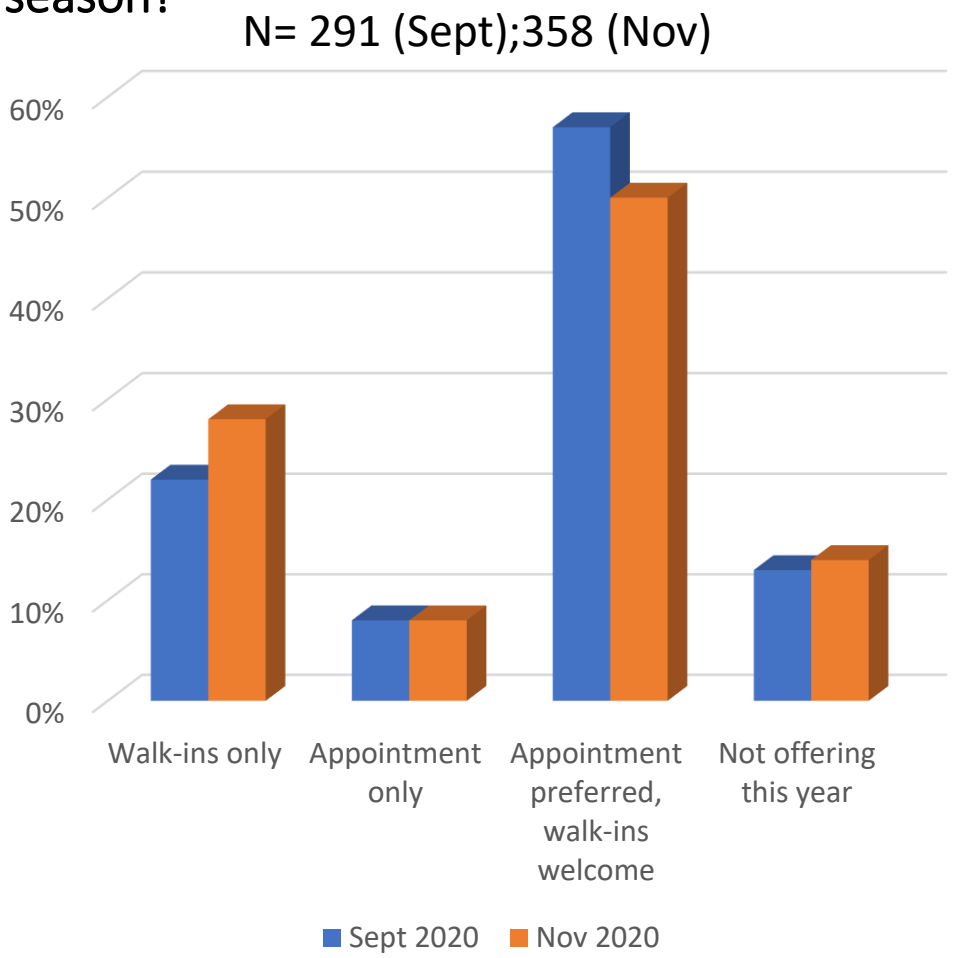
N= 292 (Sept); 354 (Nov); 55% / 59% Community pharmacy (chain & indep)

Pharmacists and Flu Vaccination

Personally plan to be vaccinated with influenza vaccine when it becomes available



How are you offering influenza vaccine this season?



Listen to Your Patients. Help Teach Them.

How do we know if these vaccines are safe?

- … large studies, > 30,000 volunteers, various ages—races—ethnicities—underlying diseases …
- … this is about same # of volunteers as in studies of Shingrix® …
- … no safety steps were skipped … thorough review by career scientists at FDA …

I heard COVID-19 vaccines cause a lot of side effects.

- … the most common side effects are ___ … About 1 in 10 or 20 people develop ___ …
- … most people do not have serious problems after being vaccinated …
- … your arm may be sore, red, warm to the touch … symptoms usually last a few days …
- … these reactions are a sign your immune system is doing what it is supposed to do …

Nobody knows whether these vaccines have long-term side effects.

- … it does take time to accumulate a lot of safety experience …
- … common side effects are pretty well understood …
- … FDA and CDC use multiple programs to monitor safety … independent experts review these data …

More information and resources available at: www.cdc.gov/vaccines/covid-19/index.html

Listen to Your Patients. Help Teach Them.

mRNA is brand new stuff – never used in a vaccine before – too risky – messes with your DNA (genes).

- … your cells use mRNA every day to make all kinds of proteins that enable you to live …
- … mRNA technology has been studied for more than a decade … rigorous clinical trials …
- … mRNA vaccines cannot cause COVID-19 …
- … mRNA vaccines do not enter the cell nucleus – cannot change your DNA (genes) …

Wouldn't surviving COVID give you better, more natural immunity?

- … COVID-19 is a lethal disease caused by a lethal virus …
- … you could infect others …
- … getting vaccinated is a safer choice … vaccines tap a body's natural abilities …

More information and resources available at: www.cdc.gov/vaccines/covid-19/index.html

Open Forum Discussion: A Minute for Your Thoughts *Comments, Questions, Feedback*

Review of APhA's Resources and What's Coming

APhA COVID-19 Resources: Know the Facts

Practical Information for Pharmacists to Know Now

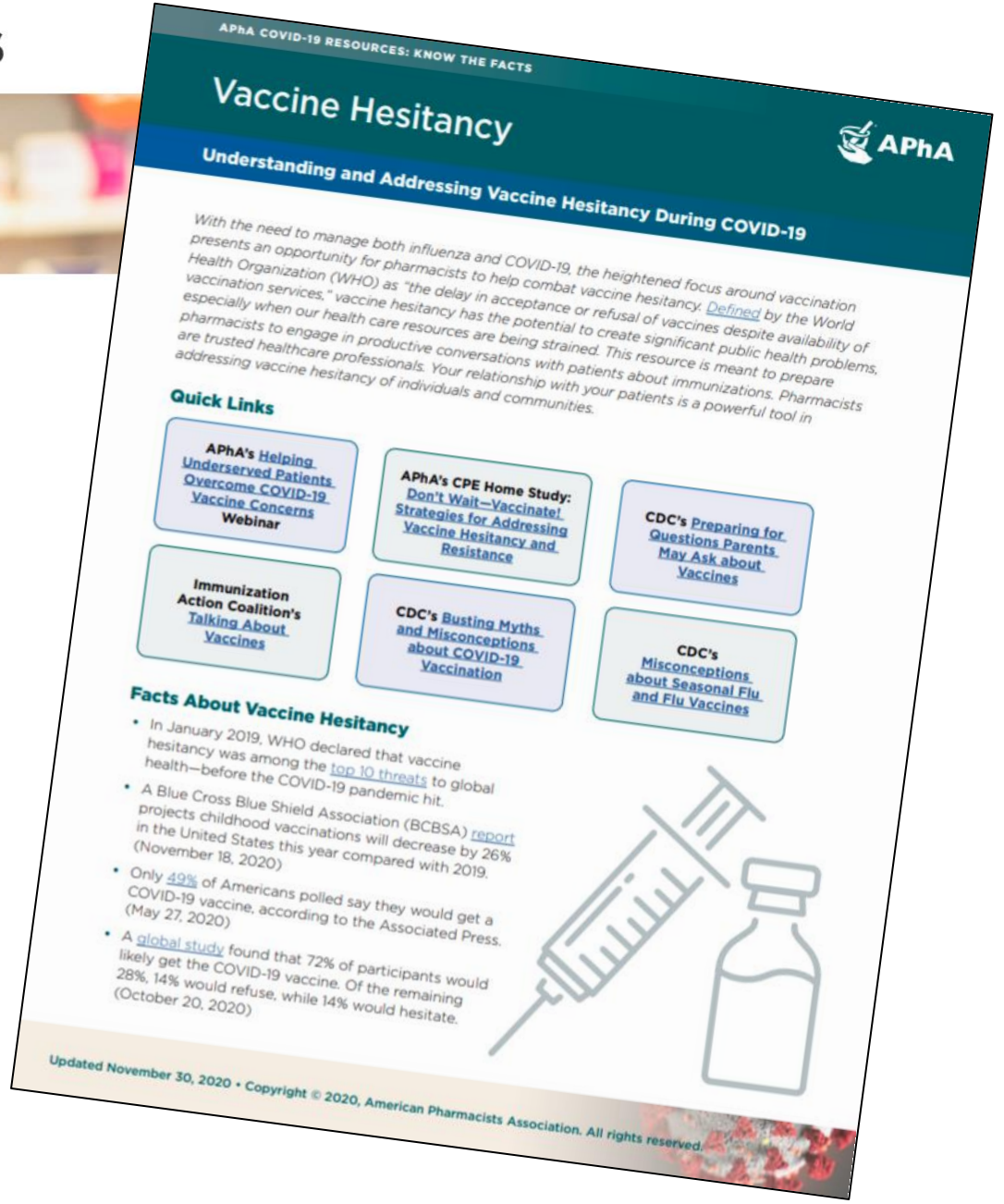
New Resource:

Vaccine Hesitancy: Understanding and Addressing Vaccine Hesitancy During COVID-19

Updated:

Reimbursement for Administration of COVID-19 Vaccine(s) – What We Know

Check out the library of practice resources here



APhA COVID-19 RESOURCES: KNOW THE FACTS

Vaccine Hesitancy

APhA

Understanding and Addressing Vaccine Hesitancy During COVID-19

With the need to manage both influenza and COVID-19, the heightened focus around vaccination presents an opportunity for pharmacists to help combat vaccine hesitancy. Defined by the World Health Organization (WHO) as "the delay in acceptance or refusal of vaccines despite availability of vaccination services," vaccine hesitancy has the potential to create significant public health problems, especially when our health care resources are being strained. This resource is meant to prepare pharmacists to engage in productive conversations with patients about immunizations. Pharmacists are trusted healthcare professionals. Your relationship with your patients is a powerful tool in addressing vaccine hesitancy of individuals and communities.

Quick Links

APhA's Helping Underserved Patients Overcome COVID-19 Vaccine Concerns Webinar

APhA's CPE Home Study: Don't Wait—Vaccinate! Strategies for Addressing Vaccine Hesitancy and Resistance

CDC's Preparing for Questions Parents May Ask about Vaccines

Immunization Action Coalition's Talking About Vaccines

CDC's Busting Myths and Misconceptions about COVID-19 Vaccination

CDC's Misconceptions about Seasonal Flu and Flu Vaccines

Facts About Vaccine Hesitancy

- In January 2019, WHO declared that vaccine hesitancy was among the top 10 threats to global health—before the COVID-19 pandemic hit.
- A Blue Cross Blue Shield Association (BCBSA) report projects childhood vaccinations will decrease by 26% in the United States this year compared with 2019. (November 18, 2020)
- Only 49% of Americans polled say they would get a COVID-19 vaccine, according to the Associated Press. (May 27, 2020)
- A global study found that 72% of participants would likely get the COVID-19 vaccine. Of the remaining 28%, 14% would refuse, while 14% would hesitate. (October 20, 2020)

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CE Available - Breaking News: COVID-19 Vaccines - Part 2

Register Today!

Today's webinar recording and slides will be available within 24hrs

https://www.pharmacist.com/coronavirus/weekly-webinars

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How to Claim CE Credit

1. After the webinar ends, return to the “My Training” page on pharmacist.com (http://elearning.pharmacist.com/my-training)
2. Log in using your pharmacist.com username and password
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4. Click on “Breaking News: COVID-19 Vaccines – Part 1” under the “Activities” heading
5. Enter the attendance code
6. Complete the evaluation
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