Barriers to Vaccination Sub- Work Group
VDH Advisory COVID -19 Workgroup
Co-chairs: Carolyn Moneymaker & Stuart Henochowicz

Goals Overview

- Identify strategies, needs, and obstacles, for public and private providers, in order to assist and administer the COVID vaccine
- Identify populations outside of the CDC critical populations that need to be considered within the Commonwealth of Virginia

Barriers Identification and Discussion

- From survey feedback, the storage of the vaccine may be problematic, should it require storage for a period of time on dry ice, etc.
    - Vaccines will be shipped and stored into containers and the ice will be replenished as needed (Judy Hackler)
- Receiving weigh-in from providers and their commitment to administering the vaccine
    - Concerns around the quick development of the vaccine
- The push to have a vaccine out faster than it may be ready for the public
- Anti-Science and massive PR (media presence to sway participation in receiving the vaccine)
- Reaching the under/uninsured population
- Transportation barrier
- Medicaid population
- Education surrounding the vaccine
    - Emphasis on the fear of the vaccine and how to explain the prioritization of specific groups/populations

Barriers Discussion: Questions, Suggestions, and Concerns

- **Question:** What are the age limitations of the vaccine?
    - 18 years and older
- **Question:** What information will be required in order to receive the vaccine?
    - This should be included in the educational portion of the vaccination guidance
- **Suggestion:** Placing a focus on the Flu vaccine first, and then moving to the COVID vaccine
- **Suggestion:** Direct support professionals, those in group homes, and the disabled population are not included until Phase 2.They should be moved to Phase 1 priority.
- **Suggestion:** Consider the homeless population to be included in prioritization
- **Suggestion:** Allow the first group to be those who are genuinely interested (voluntary) in receiving the vaccine, rather than targeting specific groups/populations (establishing trust within the communities)
- **Concern:** Mandating the vaccine in the workforce and the vulnerable populations could have an adverse overall impact

Next Steps

- Categorize vulnerable populations and essential workers in a more detailed manners
    - Helps with the education and transparency piece
- Additional brainstorming surrounding barriers
- Brainstorm setting up mobile units for administering the vaccine, in order to combat various access barriers (tents, mobile vans and pop-ups, etc.) while maintaining social distancing, mask wearing, and additional COVID-19 precautions
- Brainstorm beginning the educational portion of the vaccine, as well as additional communications and messaging
- Have an updated list of priority populations, while also looking at additional methods of prioritizations (i.e. healthcare workers and voluntary community members for Phase 1)

Action Item

- The Advisory Board will have the CDC Priority List screen-shared during the next meeting.

Next Meeting Date

- Wednesday, October 21st, @ 12:30pm

Communication & Messaging Sub- Work Group
VDH Advisory COVID -19 Workgroup
Co-chairs: Wendy Klein & Gaylene Kanoyton

Goals Overview

- Vet messaging of COVID-19 vaccine to the population
- Identify key audiences, effective communication activities, and messaging considerations such as risk/crisis response communication messaging and delivery.

Target Audience Brainstorming

- Low health literacy population
    - develop tools that are easily understandable
        - High emphasis on the inclusion of visuals
- Limited English Proficient (LEP)
    - websites are a great option, as they provide automatic translation
- Student population (technical, community college, universities)
    - this population can also assist with messaging
- Faith-based communities
- African American community
- Military spouses and their dependents, Veterans
- Essential workers
- Parents of school-aged children
- Pediatricians
- Native American population
    - Chiefs and ministers of their churches – list to be obtained
- Those with preexisting conditions
    - cancer patients
    - autistic population
    - asthma & heart disease
- Homeless
- Hard of Hearing
- Identify trusted messengers

Communications Discussion: Questions, Suggestions, and Concerns

- **Suggestion:** Format accessibility and plain English messaging for those who are within the LEP, deaf or hard of hearing, and the blind and vision impaired populations (screen readers, captioning, etc.)
- **Suggestion:** Utilize individuals who have received the COVID vaccine (when made available) to help relay the message to receive the vaccine
- **Suggestion:** A large education piece is needed to explain why certain target populations are a priority
- **Suggestion:** focus on individuals who are able to receive the vaccine first, rather than those who cannot
    - Children will not be in the first round of vaccines (18 and older age requirement)

- **Suggestion:** Touch base with the Partnerships Sup-Group to avoid duplication of work
- **Suggestion:** Ensure quality assurance
- **Suggestion:** Utilize influencers that can spread the message within communities with various languages and accessibility needs
- **Suggestion:** Utilize frontline nurses and nursing organizations
- **Suggestion:** Utilize Social Workers and SW orgganziations
- **Suggestion:** The State Association for Virginia Network of Private providers may be a reliable source
    - Jennifer Fidura - Executive Director (also sits on one of the sub-groups as well)

- **Question:** To Stephanie - VDH has done a great job with trying to address some of these barriers, can we learn what VDH has done when targeting their audience for COVID testing?
- **Question:** who decides when essential workers get the vaccine?
    - Centers for Disease Control and Prevention (CDC) decides this and will inform everyone (in terms of prioritization)

Next Steps

- Brainstorm strategies for approach when communicating with each target audience
- Brainstorm who the voices/individuals are (trusted messengers) that communities will listen to.
- Brainstorm influencers (Key Opinion Leaders)
    - Social media
    - Community leaders/members
    - Micro-influencers (barbers, hair stylists, DJs, etc.)
    - Culturally appropriate messengers
    - Foreign language radio stations

Action Item

- An article by the New York Times was shared to the group to read to provide perspective on approaching vaccine hesitancy and mistrust. See below:
    - Anthropologist and Director of the Vaccine Confidence Project, Professor Heidi Larson, suggests that vaccine hesitancy is not a byproduct of misinformation, but represents a problem with trust. Heidi's research focuses on what factors undermine vaccine acceptance and immunization uptake across the globe. She suggests that in order to build trust, health care providers need to focus communication strategies on answering the questions being asked and not just providing scientific information and public health recommendations. https://www.nytimes.com/2020/10/13/health/coronavirus-vaccine-hesitancy-larson.html
- A survey was sent members to ask a few questions below:
    - Beyond limited English proficiency and low literacy levels, what target groups need focused, specific messaging?
    - If you have specific names of proposed "trusted messengers" or community leaders for targeted populations please provide names and contact info.
    - How can we best identify specific concerns and misconceptions that need to be addressed within target groups?

Next Meeting Date

- Friday, October 30 @ 9am and meeting every 3 weeks

Partnerships Sub- Work Group
VDH Advisory COVID -19 Workgroup
Co-chairs: April Payne & Julie Dime

Discussion Topics:

- Critical contacts concerns
    - o Needs to be wide scale/state-wide basis to all registration process for vaccine providers to make attractive to onboard
        - ▪ Cumbersome process for private practice/time consuming
        - ▪ Possible streamlining/central data collection point for multiple locations within an organization
        - ▪ Standard CDC enrollment that has been proposed – could VDH have rights conferred to avoid duplicative entry of information
            - ▪ VIIS system alone is cumbersome and providers prefer not to use
                - • Use a spreadsheet format to submit information for data upload
        - ▪ CDC creating a system to track employees being vaccinated (provider agreement details still unclear?)
        - ▪ What providers are willing to provide vaccines – availability of proper storage, staff to administer
            - ▪ Where are the gaps for vaccine access – demographics, geographics
            - ▪ Virginia Board of Pharmacy –
                - • Possible to use the database to populate basic demographic information to reduce the amount of data entry for providers
    - o Minority populations/Underserved challenges
        - ▪ Lack of willingness to accept vaccine – need to have direct promotion to those populations ▪ Lack of trust as it relates to the Federal Government approving a vaccine through an EUA process
        - ▪ Concerns of cost associated with receiving the vaccine
            - • VDH stated vaccine will be provided free of charge
                - o Recommend making that message at the forefront of the state-wide Vaccine Champaign
    - o Development of a "playbook" for vaccine administration process for simplicity
        - ▪ Local Health Departments being leaned on heavily vs private practices or pharmacy providers

Next Steps:

- All participants to review stakeholder, community, and partner lists provided to offer edits and/or fill in gaps by COB October 15
- Next meeting set for October 22 @ 11am

Efficacy/Safety Sub- Work Group
VDH Advisory COVID -19 Workgroup
Co-chairs: Costi Sifri & Josh Crawford

Our group has held two meetings thus far. In our first meeting we described the normal approval process of medications and biologics (vaccines fall into the biologic regulatory category) as well as gave a brief overview of the leading vaccine candidates to date. COVID-19 vaccine candidates are undergoing the same level of review as any vaccine application. These vaccines may even be reviewed in more detail by more experts prior to approval than non-pandemic related vaccines.

Below are key takeaways discussed during our presentation and ensuing meeting:

- All vaccines must be approved for use by the Food and Drug Administration in the US. The decision to approve a vaccine is guided by the Vaccines and Related Products Advisory Committee (VRBPAC). This committee evaluates safety and effectiveness of vaccines prior to regulatory approval
- The Advisory Committee on Immunization Practices (ACIP) will also provide recommendations on the use of COVID-19 vaccines (ie: special populations, dosing schedules, etc).
    - For COVID-19, a separate safety group was assembled in June to support the full ACIP on the safety of COVID-19 vaccines pre and post-licensure: Vaccine Safety Technical Subgroup (VaST)
- Data and Safety Monitoring Boards (DSMBs) also provide an extra layer of scrutiny in evaluating COVID-19 vaccine candidates.
    - The primary responsibilities of the DSMB are to 1) periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy, and 2) make recommendations to sponsor concerning the continuation, modification, or termination of the trial.
- Vaccine safety assessment for essential works (V-SAFE)
    - Enhanced monitoring is planed following FDA-approval of any COVID-19 vaccine
    - Smartphone-based text, text-to-web survey, and email-to-web survey active surveillance program for early vaccine recipients
- NHSN sites will track weekly vaccine doses administered by dose number (i.e., denominator) in healthcare workers and LTCF residents. This will be matched to VAERS reports, which will serve as a numerator. Between these two databases calculation of crude overall reporting rates and adverse event-specific reporting rates should be possible
- Leading vaccine candidates:
    - Pfizer (BNT162b2)
        - Dosing schedule: 2 doses - 21 days apart
        - Storage: Frozen Storage: -70 C, Thawed but NOT reconstituted: Use in 24 – 48 Hours
        - Reconstituted: Use in 6 Hours
        - Shipment: Direct from Pfizer
    - Moderna (mRNA-1273)
        - Dosing schedule: 2 doses - 28 days apart
        - Storage: Frozen Storage: -20^{o}C, Refrigerated: Use in 7-14 days
        - Shipment: Via McKesson Wholesaler

We focused on the published safety data from Phase I/II clinical trials during our second subgroup meeting. The full summaries are available in Appendix B. The highlights from the review are summarized below:

- Pfizer Phase I/II trials
    - No grade 4 adverse events reported in any group
    - The only local AEs reported were pain at injection site
    - A small number of recipients from younger group reported severe systemic AEs, but no recipients from older group reported severe systemic AEs
- Moderna Phase I/II Trials
    - Systemic or local AEs occurring in more than half of participants
    - All systemic AEs were mild or moderate
    - Adverse effects were more common after second dose
    - Symptoms typically occurred on the day of vaccination or 1 day afterward and resolved quickly
- Astra Zeneca Phase I/II Trials
    - Severity and intensity of local and systemic reactions was highest on day 1 after vaccination
    - Transient neutropenia was observed in 46% of participants
    - Currently paused in the US due to report of transverse myelitis. Trial has resumed in most other countries in which it is being studied
- Johnson & Johnson Phase I/II Trials
    - Most common AEs were headache, fatigue, and myalgia
    - All fevers occurred within 2 days of immunization and resolved within 1-2 days
    - One patient hospitalized overnight with a fever related to vaccine
    - No participants discontinue the study due to an AE
    - No grade 4 adverse events in any group
- Novavax Phase I/II Trials
    - No grade 4 AEs were reported
    - 1 patient had severe joint pain and fatigue
    - No adverse event extended past 7 days after second vaccination
    - Mean duration of events for first and second doses was 2 days or less
    - Laboratory abnormalities
        - 10% had grade ≥2 laboratory abnormalities that showed no clinical manifestations
        - 5% had transient reductions in hemoglobin that resolved within 7-21 days
        - 3% had elevated liver enzymes that resolved within 7-14 days
- FDA published a briefing document on October 6th describing the approval requirements for a cOVID-19 vaccine
    - To get EUA issuance, sponsors must submit data from one well-designed Phase 3 clinical trial
        - Randomized, double-blinded, placebo-controlled
        - Known and potential benefits of product must outweigh known and potential risks (as determined by FDA)
        - Efficacy statistical considerations
        - Primary endpoint for efficacy trial should be at least 50% success (with lower bound of confidence interval >30%)
        - Non-inferiority comparison to COVID-19 vaccine that has already been proven effective should have lower bound >-10%
    - Safety assessments should include:
        - Solicited local and systemic AEs for at least 7 days
        - Unsolicited AEs for at least 21-28 days
        - Serious adverse events for at least 6 months

Appendix A Summary of Safety Results from COVID-19 Vaccine Phase I/II Clinical Trials

Summary of Safety Results from COVID-19 Vaccine Phase I/II Clinical Trials

Moderna (mRNA-1273 100 µg)

	First Dose (n=15), %	Second Dose (n=15), %
Local AEs	93	100
Erythema/Redness	13	13
Induration/Swelling	13	7
Pain	93	100
Systemic AEs	67	100
Fever	0	40
Arthralgia	13	13
Fatigue	27	80
Chills	7	80
Headache	27	60
Myalgia	7	43
Nausea	0	47

- Adverse events were solicited for 7 days following vaccination
- All systemic AEs were mild or moderate
- Systemic or local AEs occurring in more than half of participants
    - Fatigue
    - Chills
    - Headache
    - Myalgia
    - Pain at injection site
- There were 90 unsolicited AEs reported but none were serious
- One patient from lower dose group withdrew before second dose due to transient urticaria related to first dose

Pfizer (BNT162b2 30 µg)

First Dose				
	Age 18-55 (n=12), %	Age 18-55 Placebo (n=9), %	Age 65-85 (n=12), %	Age 65-85 Placebo (n=9), %
Pain at injection site	92	0	65	0
Redness	8	0	0	0
Swelling	0	0	0	0
Fever	17	0	0	0
Fatigue	42	33	25	22
Chills	33	0	0	0
Headache	50	33	0	11
Vomiting	8	0	0	0
Diarrhea	8	0	0	11
Muscle pain	33	0	0	22
Joint pain	17	0	0	11

Second Dose				
Pain at injection site	83	22	75	0
Redness	0	0	0	0
Swelling	0	0	0	0
Fever	17	0	8	0
Fatigue	75	56	42	0
Chills	58	11	17	0
Headache	67	11	25	0
Vomiting	0	11	0	0
Diarrhea	0	0	0	11
Muscle pain	58	0	25	0
Joint pain	17	0	8	0

- Adverse events were solicited for 7 days following vaccination
- No grade 4 adverse events reported in any group
- The only local AEs reported were pain at injection site
- A small number of recipients from younger group reported severe systemic AEs, but no recipients from older group reported severe systemic AEs
- Largest change in laboratory values was transient decreases in lymphocyte counts that resolved within a week

Johnson & Johnson (Ad26.COV2.S)

	Age 18-55 (n=402), %	Age ≥65 (n=394), %
Any AE	72	46
Local AEs	58	27
Systemic AEs	64	36
Fever	19	4
Grade 3 or higher AEs	11	1

- Adverse events were solicited for 7 days following vaccination
- Most common AEs were headache, fatigue, and myalgia
- All fevers occurred within 2 days of immunization and resolved within 1-2 days
- No participants discontinue the study due to an AE
- No grade 4 adverse events in any group
- 12 patients reported unsolicited AEs in the 28-day follow-up period that were considered by investigators to be related to the vaccine
    - All but 1 (worsening HTN) resolved during follow-up period
- One participant was hospitalized overnight with a fever due to suspicion of COVID-19 but recovered within 12 hours (fever judged to be vaccine-related)

AstraZeneca (ADZ1222/ChAdOx1 nCoV-19)

	N=487, %
Local AEs	
Pain after injection	67
Tenderness	83
Systemic AEs	
Fatigue	70
Headache	68
Muscle ache	60
Malaise	61
Chills	56
Feeling feverish	51
Temperature >38°C	18

- Adverse events were solicited for 7 days following vaccination
- Severity and intensity of local and systemic reactions was highest on day 1 after vaccination
- Pain after injection and tenderness were mostly mild to moderate
- All unsolicited adverse events considered to be potentially related to the vaccine occurring on days 0-28 were mild or moderate and resolved in the follow-up period
- Of unsolicited AEs days 0-28 post-vaccination, only headaches and oropharyngeal pain occurred in more than 2 patients
- Transient neutropenia was observed in 46% of participants

Novavax (NVX-CoV2373 5 µg + 50 µg Matrix-M1 adjuvant)

First Dose		
	5 µg + Adjuvant (n=26), %	Placebo (n=23), %
Local AEs	69	40
Pain	39	13
Erythema/Redness	0	0
Induration/Swelling	0	0
Tenderness	65	30
Systemic AEs	46	39
Fever	0	0
Joint pain/Arthralgia	4	4
Fatigue	31	17
Malaise	12	9
Headache	23	30
Muscle pain/Myalgia	23	9
Nausea/Vomiting	4	4

Second Dose		
Local AEs	92	19
Pain	58	10
Erythema/Redness	4	5
Induration/Swelling	4	0
Tenderness	81	10
Systemic AEs	65	33
Fever	0	0
Joint pain/Arthralgia	27	10
Fatigue	46	14
Malaise	35	14
Headache	46	29
Muscle pain/Myalgia	46	14
Nausea/Vomiting	8	0

- No grade 4 AEs were reported
- One participant in 25 μg + adjuvant first dose group had severe headache
- One participant in 25 μg + adjuvant second dose group had severe tenderness
- 1 patient in 5 μg + adjuvant and 2 patients in 25 μg + adjuvant second dose groups had severe joint pain and fatigue
- No adverse event extended past 7 days after second vaccination
- Mean duration of events for first and second doses was 2 days or less
- Unsolicited adverse events were predominantly mild and there were no reports of serious adverse events
- Laboratory abnormalities
    - 10% had grade ≥2 laboratory abnormalities that showed no clinical manifestations
    - 5% had transient reductions in hemoglobin that resolved within 7-21 days
    - 3% had elevated liver enzymes that resolved within 7-14 days

Appendix B: Systematic Grading of COVID-19 Vaccine Trials and Reports

Coming soon

Opportunities:

From: Trust for America's Health <tfah@healthyamericans.ccsend.com> on behalf of Trust for America's Health <info@tfah.org>
Sent: Thursday, October 15, 2020 9:04:15 AM
To: Shawn Metzner <metzner@vaems.org>
Subject: ONE WEEK AWAY: Building Vaccination Confidence in Communities of Color Webinar

Ensuring COVID-19 Vaccine Access, Safety, and Utilization: Building Vaccination Confidence in Communities of Color

October 21, 2020 | 1:00 PM EDT

Please join Trust for America's Health on October 21, 2020 at 1:00 pm ET for a 90-minute webinar titled, *Ensuring COVID-19 Vaccine Access, Safety, and Utilization: Building Vaccination Confidence in Communities of Color*.

This webinar comes at a critical juncture as COVID-19 vaccine development continues. As has been the case with previous public health emergencies, the COVID-19 pandemic is exposing racial inequities that have long existed in the U.S. Racial and ethnic disparities also continue in vaccine access, due to contributing factors such as lack of access to health coverage and care and issues of distrust.

The webinar will feature expert panelists to educate policymakers and stakeholders on the historical reasons for vaccine hesitancy in communities of color, highlight ongoing vaccination disparities and discuss policy recommendations to build vaccine confidence and access in communities of color. The webinar will include time for Q&A from the audience.

Moderator and Presenters

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