

# Efforts to Promote Diversity and Inclusion in Clinical Trials

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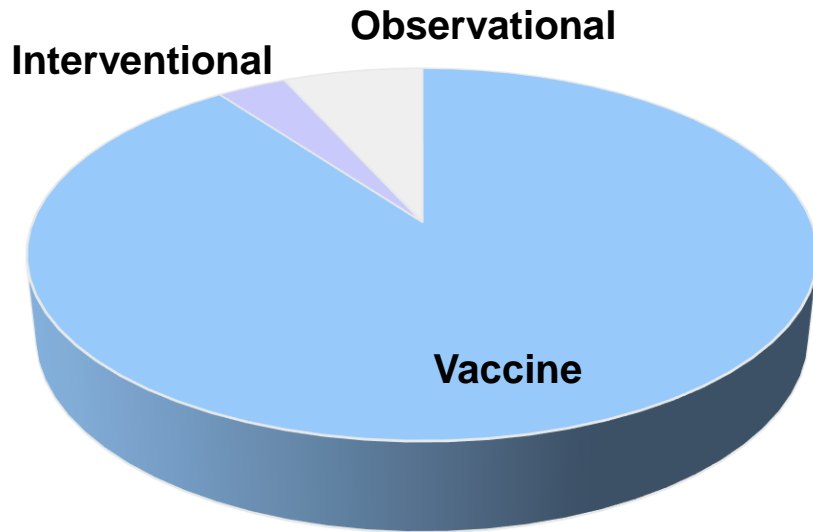
Division of Infectious Diseases



Lessons from the COVID 19  
Pandemic....



# URMC Infectious Diseases Division COVID-19 Studies



## 1. Natural History Studies:

- CEIRS COVID Surveillance and Immunity Study
- COVID Gene Expression

## 2. Therapeutic Trials:

- ACTT 1-4 Remdesivir
- ACTIV 2 Monoclonal Ab

## 3. CoVPN Vaccine Studies

- Pfizer
- Astrazeneca
- Moderna
- Sanofi



# Therapeutic Trials

## Adaptive COVID-19 Treatment Trial (ACTT)

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- **ACTT-1: Remdesivir vs. standard of care (SOC)**
  - Status: Completed, preliminary results published in *NEJM* May 22, 2020
- **ACTT-2: Remdesivir +/- Baricitinib**
  - Status: Closed enrollment 6/30 (1034 participants)
  - Full analysis late September
- **ACTT-3: Remdesivir +/- IFN beta-1a**
  - Enrollment began August 5



	<b>Study Description</b>	<b>Funding</b>	<b>N</b>	<b>Age</b>	<b>Sex</b>	<b>Race/Ethnicity</b>
<b>Acute COVID Natural History Study</b>	A descriptive study of the pathogenesis and immune response to SARS-CoV-2 during 2020 COVID-19 pandemic in adults, children, and the elderly	NIH	8	18-49 years = 5 50-64 years = 3	Male = 3 Female = 5	Black = 1 White = 7 NH = 8
<b>Whole Blood Transcriptomic Analysis of Acutely Infected COVID19</b>	Adults $\geq 18$ years of age either hospitalized or recruited from the community with symptoms compatible with COVID-19. Whole blood samples were collected to if assess gene expression in the blood of patients with mild to moderate vs severe COVID-19 might identify path clues to disease pathogenesis and discover new gene targets amenable to potential therapeutic interventions.	NIH	54	18-49 years = 16 50-64 years = 13 $\geq 65$ years = 24	Male = 28 Female = 26	Asian = 1 Black = 17 White = 32 Unknown = 3 Hispanic = 2 NH = 52
<b>ACTT1-4 (Adaptive COVID19 Therapeutic Trial)</b>	Placebo controlled Phase 3 therapeutic trials in COVID19 acutely infected hospitalized subjects.	NIH	70	18-59 years = 23 $\geq 60$ years = 47	Male = 38 Female = 32	Asian = 2 Black = 19 White = 49 1 Hispanic 69 NH





*The* NEW ENGLAND JOURNAL *of* MEDICINE

Perspective  
AUGUST 27, 2020

### **Racial Disproportionality in Covid Clinical Trials**

Daniel B. Chastain, Pharm.D., Sharmon P. Osae, Pharm.D., Andrés F. Henao-Martínez, M.D.,  
Carlos Franco-Paredes, M.D., M.P.H., Joanna S. Chastain, Pharm.D., and Henry N. Young, Ph.D.

- Black Americans accounted for only about 20% of the 1063 patients in the placebo-controlled Adaptive Covid-19 Treatment Trial (ACTT-1) funded by the National Institute of Allergy and Infectious Diseases (NIAID)
- The proportions of Latinx and Native American patients were provided only for ACTT-1 and were 23% and 0.7%, respectively

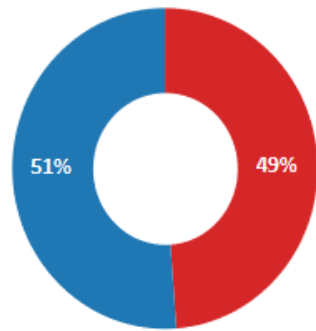


# Demographics of Trial Participation

## Demographic Categories

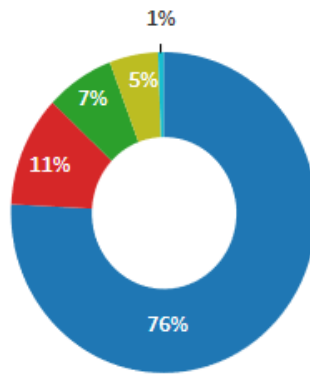
Clinical trial participation is broken down into four categories: sex, race, age, and ethnicity. \*

### Sex Distribution



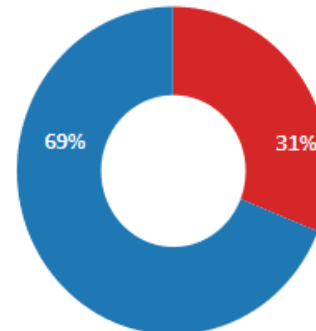
Female ■  
Male ■

### Race Distribution



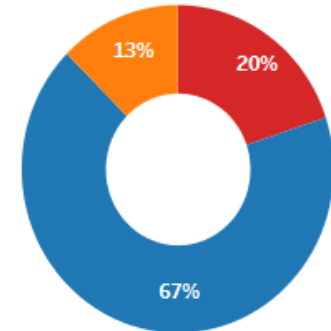
White ■  
Asian ■  
Black or African American ■  
Other ■  
American Indian or Alaska Native ■

### Age Distribution



< 65 Years ■  
>= 65 Years ■

### Ethnicity Distribution



Hispanic or Latino ■  
Not Hispanic or Latino ■  
Missing ■

<https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots>



## Sex, Race, and Age Participation by Therapeutic Area

Presented below is the cross-section of sex, race, and age categories in therapeutic areas with the highest numbers of participants.

		Cardiovascular Diseases		Endocrinology and Metabolism		Oncology and Hematology		Infectious Diseases		Neurology	
		< 65 Years	>= 65 Years	< 65 Years	>= 65 Years	< 65 Years	>= 65 Years	< 65 Years	>= 65 Years	< 65 Years	>= 65 Years
Male	White	79%	84%	72%	79%	71%	82%	67%	83%	75%	51%
	Asian	14%	11%	20%	15%	14%	9%	9%	7%	14%	47%
	Black or African American	3%	2%	5%	3%	5%	2%	17%	8%	5%	1%
	Other	4%	3%	3%	3%	10%	7%	6%	1%	5%	<1%
	American Indian	<1%	<1%	<1%	<1%	<1%	<1%	1%	1%	1%	<1%
Female	White	73%	84%	71%	78%	70%	85%	65%	83%	82%	56%
	Asian	16%	10%	17%	14%	16%	8%	9%	8%	6%	41%
	Black or African American	6%	2%	7%	5%	5%	2%	18%	6%	8%	2%
	Other	5%	4%	4%	3%	9%	5%	7%	2%	3%	1%
	American Indian	<1%	<1%	1%	<1%	<1%	<1%	1%	1%	1%	0%

<https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots>





# In Chicago, 70% of COVID-19 Deaths Are Black

By Elliott Ramos, Maria Inés Zamudio

April 5, 10:25 AM EDT

Politics

Covid-19 is ravaging black communities. A Milwaukee neighborhood is figuring out how to fight back.

## Black Communities Are Hit Hardest By COVID-19 In Louisiana And Elsewhere

WBTV ON YOUR SIDE

COVID-19

COVID-19 IMPACT ON MINORITY COMMUNITIES

MINORITY CORONAVIRUS DEATHS HIGH ACROSS U.S.

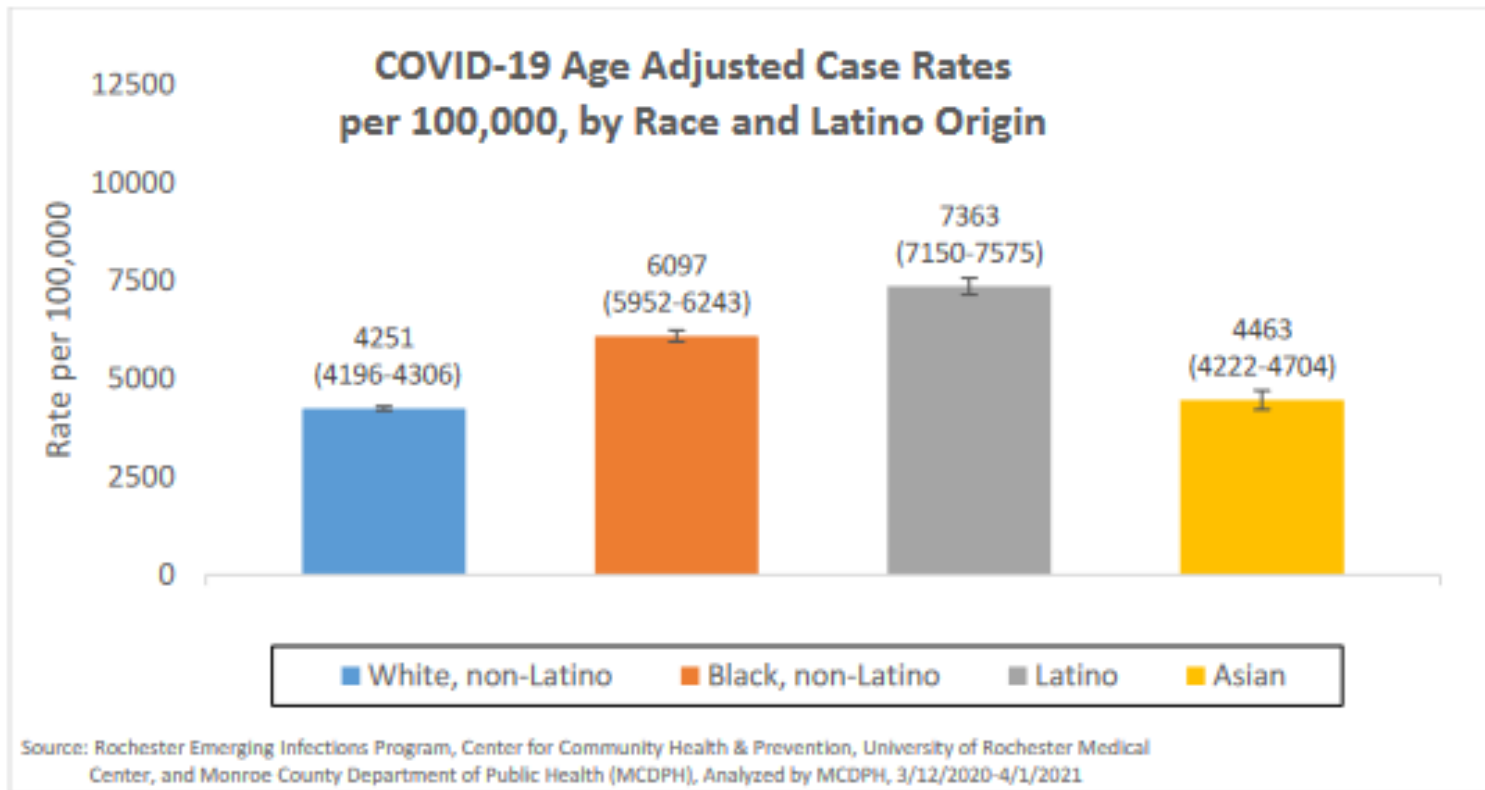
6:16 | 79°

3 WBTV  
ON YOUR SIDE



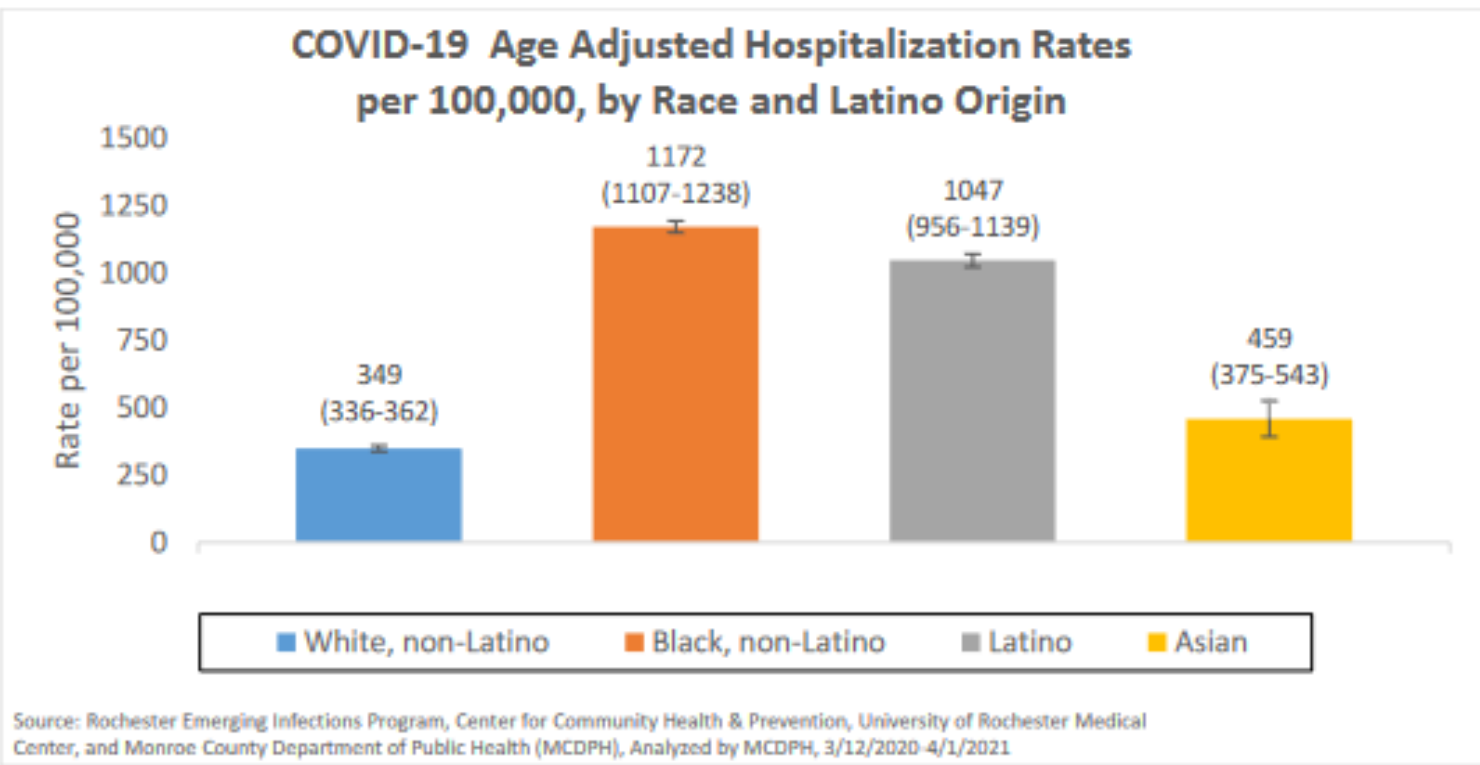
# Monroe County COVID-19 Surveillance, Preliminary Data as of April 1, 2021

Rochester Emerging Infections Program, Center for Community Health and Prevention



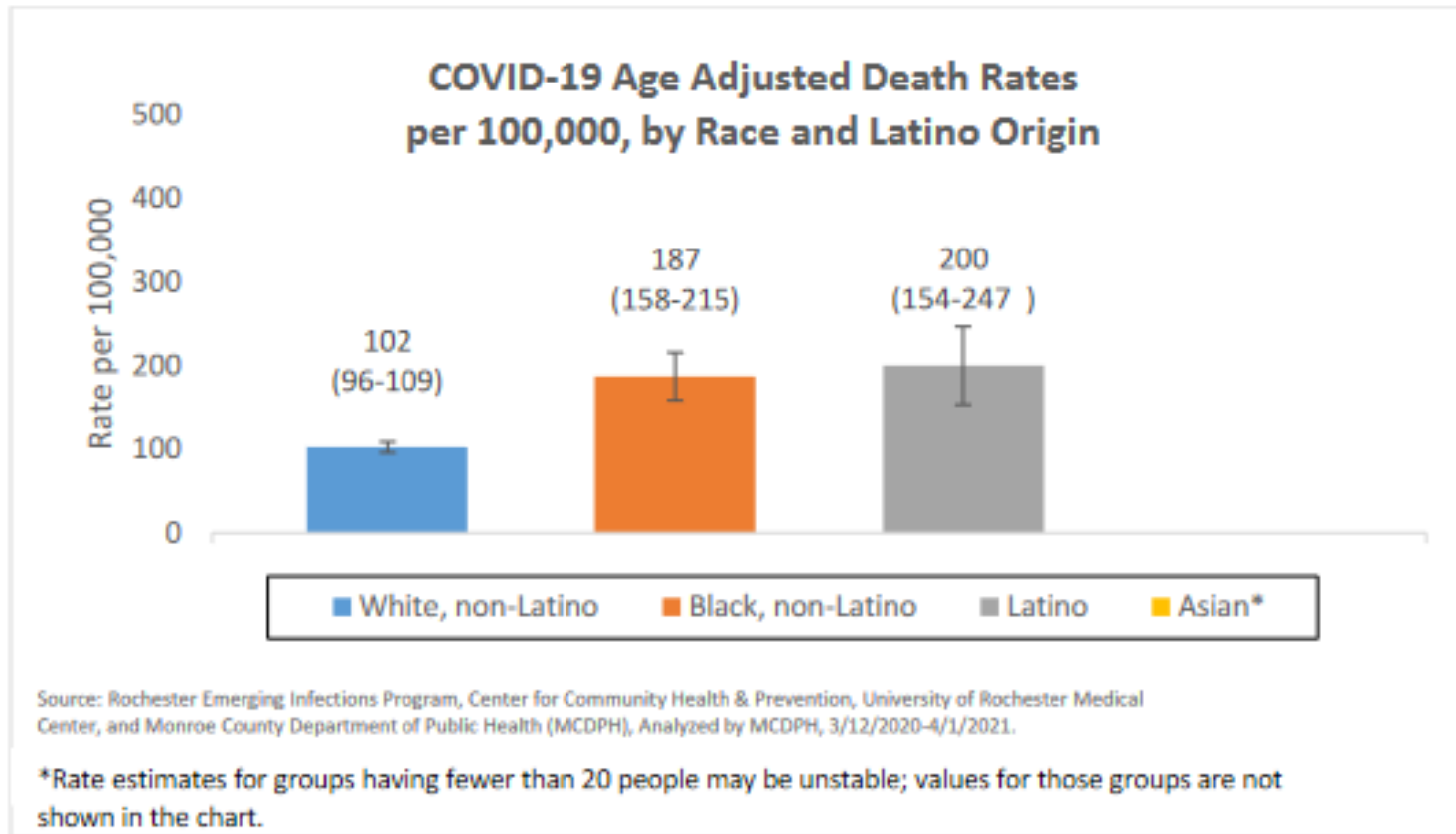
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# THE WALL STREET JOURNAL.

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BUSINESS | HEALTH CARE | HEALTH

## **Covid-19 Vaccine Trials Have a Problem: Minority Groups Don't Trust Them**

Drug companies, U.S. agencies work with churches and community activists to educate about benefits of vaccination



Why is it difficult to achieve  
diversity and inclusion in clinical  
research?



# Attitudes and Beliefs of African Americans Toward Participation in Medical Research

*Giselle Corbie-Smith, MD, Stephen B. Thomas, PhD, Mark V. Williams, MD,  
Sandra Moody-Ayers, MD*

- Thirty-three African-American adults presenting to an urban public hospital for outpatient medical care participated in one of five focus groups.
- The majority of focus group participants tended to be in favor of medical research, as long as they were not “guinea pigs.”
- Expressed concerns about participation in medical research included, but were not limited to:
  - (1) inconvenience—interfering with work schedules, restriction of normal behavior
  - (2) too much risk, particularly infection with unknown viral agents
  - (3) fear of injections and needle
  - (4) concerns about whether physicians would be fully honest with them about risks and procedures
  - (5) failure to see any need, given current good health
  - (6) concern that even if something good came out of the research, African Americans would not necessarily benefit because of racial discrimination and poverty



# Community Engagement Studio

*July 23, 2020*

1. *How can we reach individuals who are at higher risk for COVID19 infection and underrepresented in research (racially, ethnically, socioeconomically, etc), and who may have an interest in participating in our study?*
  - A. *Venues of engagement?*
  - B. *Methods of engagement?*
2. *What barriers to signing up can we address from individuals in underrepresented communities which may prevent participation?*





# Venues

- Collaboration with community organizations and faith-based organizations and groups
  - Black Physicians Network
  - Black Nurses Association
  - Common Ground Health
  - Latino Health Coalition
  - African American Health Coalition
  - Home health agencies
  - Promotores de Salud
  - Latinas Unidas
- Social media
- Historically Black fraternities and sororities (D9)
- Barber shops, beauty salons
- Mobile health unit
- Shelters and homes for homeless

VIA **zoom**

**SHOP TALK**  
WITH U.P.B.C.A

JOIN VIA ZOOM  
CALL IN BY PHONE OR  
WATCH LIVESTREAM ON YOUTUBE

TOPIC OF DISCUSSION  
***What About The Vaccination?***

Host: Willie Lightfoot  
Guest Speakers:  
Dr. Angela Branche, Infectious Disease Physician, UofR  
Jackie Dozier Common Ground Health, Program Manager  
Shani Wilson, PA-C, Internal Medicine Physician Assistant

MEETING ID: 986 1564 3994 OR CALL : 1.929.436.2866

**JANUARY 25TH, 2021 6PM**  
info@upbca.org / www.upbca.org

FIND LINK AT  
**WWW.UPBCA.ORG**

CLICK: JOIN THE  
CONVERSATION

Watch live on  
**UPBCA ASSOC**



# Methods

- 1) Presentations by researchers of color and ensure cultural competence and integrity
- 2) Vet messages in advance – offensive vs. attractive
- 3) Enter each interaction with willingness to understand peoples perceptions and speak to these
- 4) Be prepared for longer conversations
- 5) Ensure relevance and value to community

**“WIFM” – “What’s in it for me”**

- 6) Anticipate questions and come prepared with answers
- 7) Identify influencers within the community to work with on communication and outreach



Partic  
fo



**Participants Needed**  
for COVID-19 Research

**BRING  
ROC  
BACK**

Vaccine Study Facts



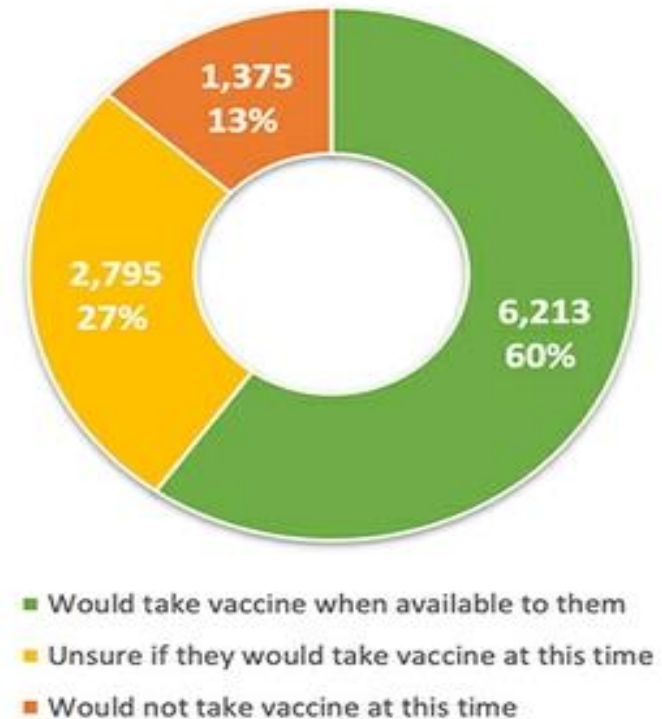
# URMC Employee Vaccination

## URMC Town Halls ( 12/11 and 12/14)

- Nursing
- Faculty and Staff
- Ancillary Services

*Result: (majority of URMC employees)*

UR Medicine	
Eligible for Phase 1a Vaccine	21,733
Received Vaccine	17,555 (81%)
Scheduled for Vaccine	826 (4%)
Declined Vaccine	3,352 (15%)



# Barriers

1. Trust is a big issue.
2. Researchers of color sharing their personal stories
3. Transparency is needed. Ensure concise, direct answers with important information, even if it's not the information the individual might want to hear.
4. Language and cultural deprivation. Communicating in their language will help to break down barriers.
5. Places where people gather, like health fairs, could be garnering only the same few people instead of reaching a wider, more diverse audience.









Community members gather by household in "bubbles" for a training session as part of an outreach program to the Black community to increase vaccine trial participation in Rochester, New York, U.S., November 14, 2020.

