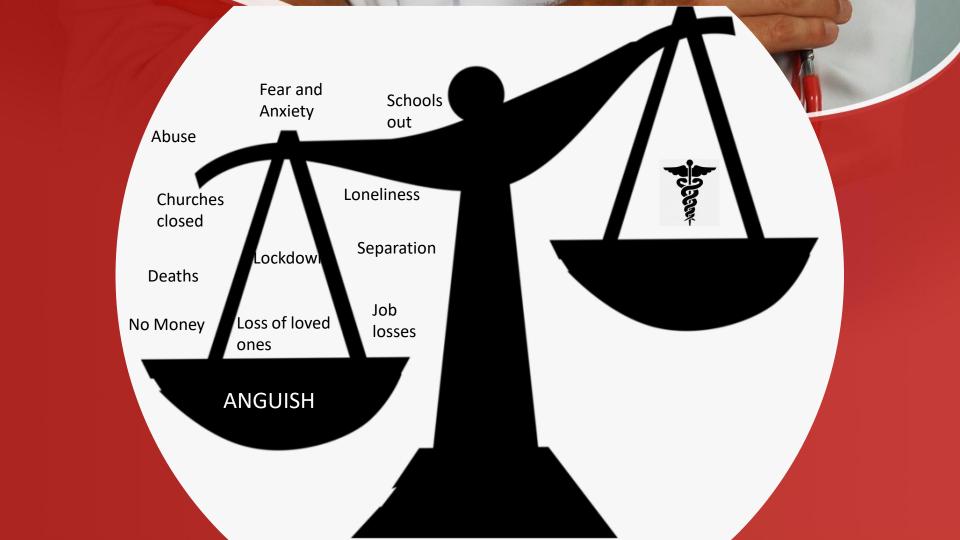


FEBRUARY 2021

THE BEGINNING OF.....

- Wuhan dozens treated for pneumonia? source
- China lockdown
- Japan, South Korea, Thailand and USA reports cases
- WHO declares global health emergency
- Deaths in Italy skyrockets
- Olympics postponed
- Jamaica gets first case
- Death toll climbs
- Global cases hits 1M





CRISIS - GLOBAL COLLABORATION

- Governments, health organizations, scientists, businesses, civil society, and philanthropists.....
 - Joined forces to speed up efforts to end the pandemic
 - Accelerate the development and manufacture of COVID-19 <u>vaccines</u>, <u>diagnostics</u> and <u>treatments</u>



TREAT, TREAT, TREAT

Tipped in favor of treatment

- Protect patient autonomy, privacy and liberty
 - Utilizing scientific methods to assess public health risks
 - Educating about the importance of their compliance with public health measures
 - Support mandatory quarantine and isolation for patients who fail to comply

TREAT, TREAT, TREAT CONT'D

- Do no harm
- Promote and secure the patients wellbeing
- Maximize possible benefits and minimize possible harms



TREAT, TREAT CONT'D

Fair

- Rights of one individual or group must be balanced against another
- Ensure
 - Impartiality
 - Equality
 - Reciprocity

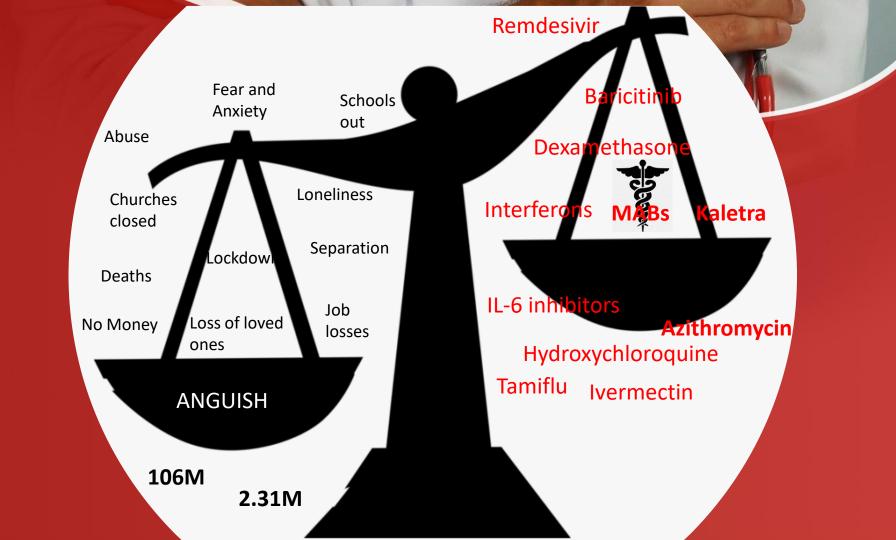
COVAX Facility

Guarantee rapid, fair and equitable access to all countries

EMERGENCY USE AUTHORIZATION (EUA)

• Facilitates the availability and use of medical countermeasures, including vaccines, during public health emergencies

• The use of <u>unapproved medical</u> products, or <u>unapproved uses of approved medical products to</u> diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are <u>no adequate</u>, <u>approved</u>, and available alternatives are allowed



COVID 19 VACCINES

Clinical trials

- Evaluation in tens of thousands of study participants to generate the scientific data and determine safety and effectiveness
- Rigorous standards

- Small number of generally healthy people
- Assess safety at increasing doses
- Information on how well the vaccine works to induce an immune response

COVID-19 VACCINES CONT'D

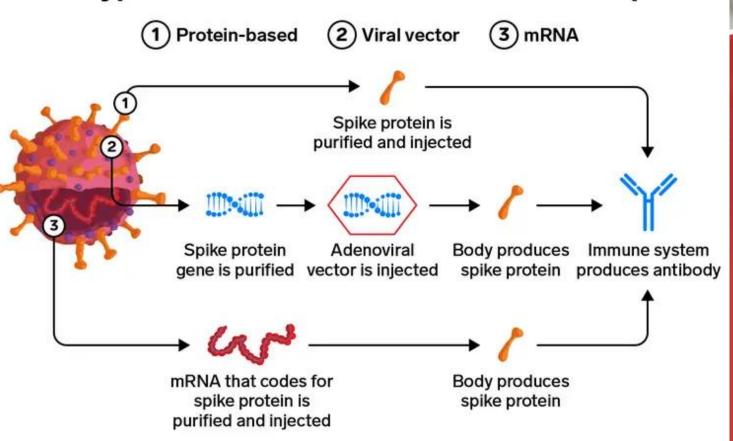
- Dosages are tested on hundreds of people with typically varying health statuses and from different demographic groups, in randomized-controlled studies
- Additional safety information on common shortterm side effects and risks
- Dose administered and the immune response
- Effectiveness of the vaccine



COVID-19 VACCINES CONT'D

- Thousands in randomized, controlled studies involving broad demographic groups (intended for use)
- Generates critical information on effectiveness and safety
- Additional information about the immune response in people who receive the vaccine compared to those who receive a placebo

Three types of coronavirus vaccines in development



SHORT CHANGED? CLINICAL TRIALS

PRECLINICAL TESTING (Monkeys and mice)

PHASE 1 SAFETY TRIAL

(Small # of people)

PHASE 2 EXPANDED TRIALS

(Hundreds of people split into groups)

PHASE 3
EFFICACY
TRIALS

(Thousands of people)

EUA

Approval

Phase 1

Phase 2

VACCINE TRIALS - CLINICAL

- Pfizer BioNTech Phase 3 clinical trial 43,500
- 95% effective against COVID-19 beginning 28 days after the first dose
- Efficacy was consistent across age, gender, race and ethnicity
 - Efficacy > 65 years of age > 94%
- Well tolerated across all populations
 - No serious safety concerns observed
 - Fatigue and headache

Pfizer-BioNTech COVID-19-vaccine

- Stored and shipped at -70°C
 - a GPS-enabled thermal sensor to track the location and temperature of each vaccine shipment 24/7
- Once thawed, the vaccine vial can be stored for up to <u>five days</u> at refrigerated (2-8°C) conditions
- Two doses required

PFIZER VACCINE COMPONENTS

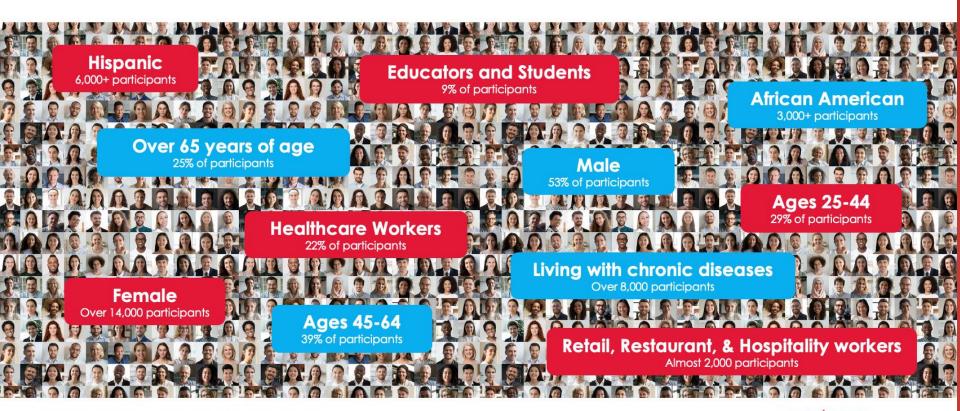
- Active Ingredient
 - nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2
- Lipids
 - (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis (ALC-3015)
 - (2- hexyldecanoate),2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
 - 1,2-distearoyl-snglycero-3-phosphocholine (DPSC)
 - cholesterol
- Salts
 - potassium chloride
 - monobasic potassium phosphate
 - sodium chloride
 - basic sodium phosphate dihydrate
- Other
 - sucrose

PFIZER SIDE EFFECTS

- Fatigue (3.8%)
- Headache (2%)
- Chills
- Tiredness



A vaccine for everyone...find yourself in the Cove study





MODERNA CLINICAL TRIALS

- 30,000
- Efficacy 95%
- Safety profile is encouraging
- Local reactions are limited, usually more with the second dose
- Very few serious adverse events
- Protection to the elderly

MODERNA

- mRNA-1273
- Stored at -20°C
- Stable for up to 30 days at temperatures between 2°C and 8°C
- Two doses required
- No reconstitution

Moderna nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol 1,2-distearoyl-sn-glycero-3-phosphocholine cholesterol SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate Tromethamine Tromethamine hydrochloride Acetic acid Sodium acetate sucrose

MODERNA SIDE EFFECTS

- Fatigue (9.7%)
- Muscle aches (8.9%)
- Joint pain (5.2%)
- Headache (4.5%)
- Pain (4.1%)
- Injection site pain (2.7%)
- Redness at the injection site (2%)



AstraZeneca - AZD12222

- Clinical trial 40,000
- 70% efficacy

AstraZeneca CONT'D

- Adenovirus-vector technology
 - Harmless, modified version of a common cold virus that does not infect humans
 - Altered virus can not make us sick, but carries a gene from the novel coronavirus' spike protein, this triggers an immune response
- Antibodies are then produced teaching your body how to respond should you become infected

AstraZeneca

- AZD1222
 - Stored between 2°C and 8°C for at least six months
 - Two doses required
 - The vaccine does not contain any preservative
 - After first opening the vial, it should be used within 6 hours
 - The vaccine may be stored between 2°C and 25°C during this period. After this time, the vial must be discarded



AstraZeneca COMPONENTS

- Recombinant, replication-deficient adenovirus vector
- Produced in genetically modified human embryonic kidney (HEK) 293 cells
- L-histidine
- L-histidine hydrochloride monohydrate
- Magnesium chloride hexahydrate
- Polysorbate 80
- Ethanol
- Sucrose
- Sodium chloride
- Disodium edetate dihydrate
- Water for injections

SIDE EFFECTS

VERY COMMON (>1 IN 10)

- Tenderness, pain, warmth, redness, itching, swelling or bruising where the injection is given
- Generally feeling unwell
- Fatigue
- Chills or feeling feverish
- Headache
- Nausea
- Joint pain or muscle ache

COMMON UP TO 1 IN 10

- Lump at the injection site
- Fever
- Vomiting
- Flu-like symptoms
 - high temperature, sore throat, runny nose, cough and chills

UNCOMMON SIDE EFFECTS (1 IN 100)

- Feeling dizzy
- Decreased appetite
- Abdominal pain
- Enlarged lymph nodes
- Excessive sweating, itchy skin or rash



VACCINE TRIALS - CLINICAL

Several continents, both sexes, diverse races & different ages

- China: Sinovac > 100,000 persons vaccinated
- Russia: Sputnick vaccine > 100,000 persons vaccinated
- Johnson & Johnson
- Novovac

WHO?

- Healthcare personnel
- Elderly > 60 years
- Non-Healthcare Frontline workers
- Infirmaries
- Residents and staff of Nursing Homes
- Institutionalized persons



Category	Estimated Number	# of doses needed	Total # of doses	Expected dose uptake (+10% wastage)
Healthcare personnel	16,000	2	32,000	21,120 (60%)
Parliamentarians, Senators and senior staff	250	2	500	495 (90%)
Elderly ≥ 60 years	379,355	2	758710	584,206 (70%)
JDF	5,000	2	10,000	6,600 (60%)
JCF	15,000	2	30,000	19,800 (60%)
JFB	4000	2	8000	8,800 (60%)
DCS	2,600	2	5,200	3,432 (60%)
PICA	1,000	2	2,000	1,320 (60%)
Infirmaries	1,377	2	2,754	2,726 (90%)
Residents and staff of Nursing Homes	3,242	2	6,484	4,279 (60%)
Institutionalized (persons in the penal institutions)	12,250	2	24,500	24,255 (90%)
TOTAL	440,074		880,148	677,033

COVID 19 VACCINES—TREAT OR NOT TO TREAT?

#	COVID 19 VACCINES	Pass	Fail
1.	Rigorously tested	✓	317
2.	Safe	✓	
3.	Maximize benefits and minimize possible harm	✓	
4.	Efficacy (70-95%)	✓	
5.	Secure the patients well-being	✓	
6.	Benefits Outweigh the Risks	✓	
7	Fairly Distributed	✓	







COVID-19 Let's Get Vaccinated

A Public Health Service Announcement







