

# Inside the Race to Develop a COVID-19 Vaccine

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21 October 2020



Department for  
Business, Energy  
& Industrial Strategy



**PERSPECTIVES**

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# Development of vaccines against COVID-19 is uncertain

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## **COVID-19 has traits which are not yet understood**

- People disproportionately affected
- Immune response variable
- No vaccine was approved for use against SARS1

## **Viruses mutate, e.g. flu**

- Herd immunity may never be possible

## **Poor immune responses in elderly**

## **Unknown durability of protection**

## **Demonstrating statistical clinical protection of a vaccine requires ongoing COVID-19 infection**

## **The most advanced clinical vaccine modalities have never been approved by regulators:**

- Adeno viral vaccines (e.g. Oxford) and mRNA vaccines (e.g. BioNtech, Moderna)
- No long term experience or safety data

# Goals of UK Vaccine Taskforce

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**Vaccinate the appropriate UK population against COVID19 as soon as practicable to restore UK's economic growth**

*Short term: to reduce mortality*

*Ultimately: to build sterilising population immunity*

**Goal 1:** Secure access to promising vaccine/s for the UK population

**Goal 2:** Make provision for international distribution of vaccines

**Goal 3:** Support industrial strategy by helping build a permanent team and vaccine and biotherapeutic capability to support a pandemic response

*Portfolio approach required as <15% likelihood of success for vaccines in the clinic*

**Workstream 1:** Vaccine Selection & Procurement

**Workstream 2:** Trials, Testing & Regulation

**Workstream 3:** Manufacturing & Supply

**Workstream 4:** Vaccine Deployment

**Workstream 5:** International

**Workstream 6:** Legacy

# UK Vaccine Taskforce: 2020 headline activities

## February



- BIA assembled manufacturing consortium for Oxford & Imperial

## June

- Core VTF leadership team in place
- Prioritised vaccine portfolio
- VTF Business case and budget
- LOI to acquire vaccine plant
- LOI to secure fill finish capacity
- *Deployment planning - DHSC*

## August

- Signed HoT for vaccines from:
  - Janssen
  - Novavax
- Approval for VTF budget and streamlined decision making
- *MHRA reg 174 consultation*

## October

- Phase 3 trials start for Novavax
- Human challenge model launch
- RFP for UK bulk antibody plant
- *First end-to-end vaccine deployment rehearsal*

## May

- Prime Minister confirmed VTF Chair appointment
- Oxford vaccine starts Phase 2/3 trial

## July

- Signed HoT for vaccines from:
  - Valneva
  - BioNTech
  - GSK/Sanofi
  - neutralising antibody cocktail (AZ)
- Launched NHS registry

## September

- £500m pledge to COVAX for international vaccine distribution
- Accredited assays for trials
- *Regeneron antibodies entered Recovery trial (DHSC)*
- *JCVI updated vaccination strategy*

# Building a portfolio of vaccines for the UK

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Strategy is to diversify modality, immunogenicity and delivery to build vaccine portfolio with clinically validated and unproven vaccine platforms – focusing on products which enter the clinic in 2020.

**Requires some risky bets.**

## Adenoviral vaccines

Oxford/AZ, UK  
Janssen (J&J), US/Belgium

## mRNA vaccines

BioNTech, Germany/Pfizer US

## Adjuvanted protein vaccines

GSK/Sanofi, UK/France  
Novavax, US

## Inactivated whole virus vaccines

Valneva, UK/France

## Neutralising antibodies

AZ antibodies, UK

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All so far above target the Spike Protein (except for Valneva – inactivated whole virus); this is a significant 'soft spot' but one we can't avoid right now.

# UK manufacturing and F&F capacity for vaccines



**Satellite VMIC** using Oxford Biomedica's clean rooms to manufacture before the **permanent VMIC** facility comes online. Rapid 70m surge dose capacity



**Acquisition of new animal vaccine plant** in Braintree, Essex for human GMP vaccine manufacture. Managed by Cell and Gene Therapy Catapult team



Expansion of BSL3 manufacturing facility at **Valneva**, Livingston Scotland



80m doses of **fill and finish capacity** (converting bulk drug substance into final drug product) with Wockhardt (Wrexham) and ThermoFisher (Swindon)



Exploring options for **bulk antibody manufacturing plant** for neutralising antibody production H2 2021 and long term pandemic preparedness

# JCVI vaccination prioritisation: Sept 25 2020

1. Older adults' resident in a care home and care home workers\*
2. All those 80 years of age and over and health and social care workers\*
3. All those 75 years of age and over
4. All those 70 years of age and over
5. All those 65 years of age and over
6. High-risk adults under 65 years of age
7. Moderate-risk adults under 65 years of age
8. All those 60 years of age and over
9. All those 55 years of age and over
10. All those 50 years of age and over
11. Rest of the population (priority to be determined) \*\*

## UK priority groups

<b>Elderly &gt;65</b>	<b>12m</b>
<b>NHS workers</b>	<b>1.5m</b>
<b>Social care/care homes</b>	<b>2m</b>
Co-morbidities <50	~3m
BAME	<4m
	<b>= 22m</b>

## **JVCI expert comments:**

- No long term safety data on novel formats (adeno, mRNA)
- Assume waste (10-15%) and uptake (60-75%)
- 28 day gap desirable between flu and COVID vaccine requirement
- May consider vaccinating younger people to stop asymptomatic transmission spread once safety established

## **US strategy**

- 78% of deaths are in >65yo, so focus on >65 yo intially

\* The final decision on the prioritisation for health and social care workers will be dependent on vaccine characteristics and the epidemiology at the start of any programme.

\*\* A risk-benefit assessment would likely be undertaken in advising on vaccination in group



# UK clinical trials, regulatory and testing capability

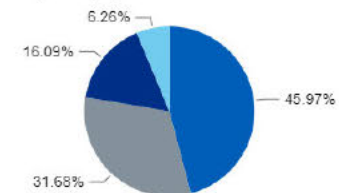
- National citizen registry >280k registered to date [NHS.UK/coronavirus](https://www.nhs.uk/coronavirus) to enable rapid recruitment
- Pre-existing clinical trial cohorts ready to enrich recruitment of target populations
- VTF funding for clinical testing
  - standardised accredited assays (neutralisation and elisa assays)
  - dedicated PCR testing capacity
- Real time COVID19 transmission data for rapid enrolment in hotspots
- MHRA: reg 174 conditional approval; Brexit plans
- Human challenge model for vaccine trials in 2021
- Post authorisation pharmacovigilance follow-up to build large real world evidence database

## SIGN UP TO BE CONTACTED FOR CORONAVIRUS VACCINE STUDIES

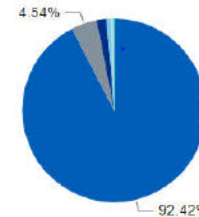


- Age Bracket
- 18-49
  - 50-64
  - 65+ no co-morbidities
  - 65+ with co-morbidities

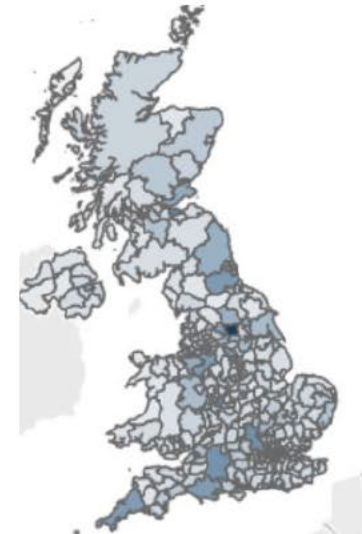
Subscriptions by Age Bracket



Subscriptions by Ethnicity



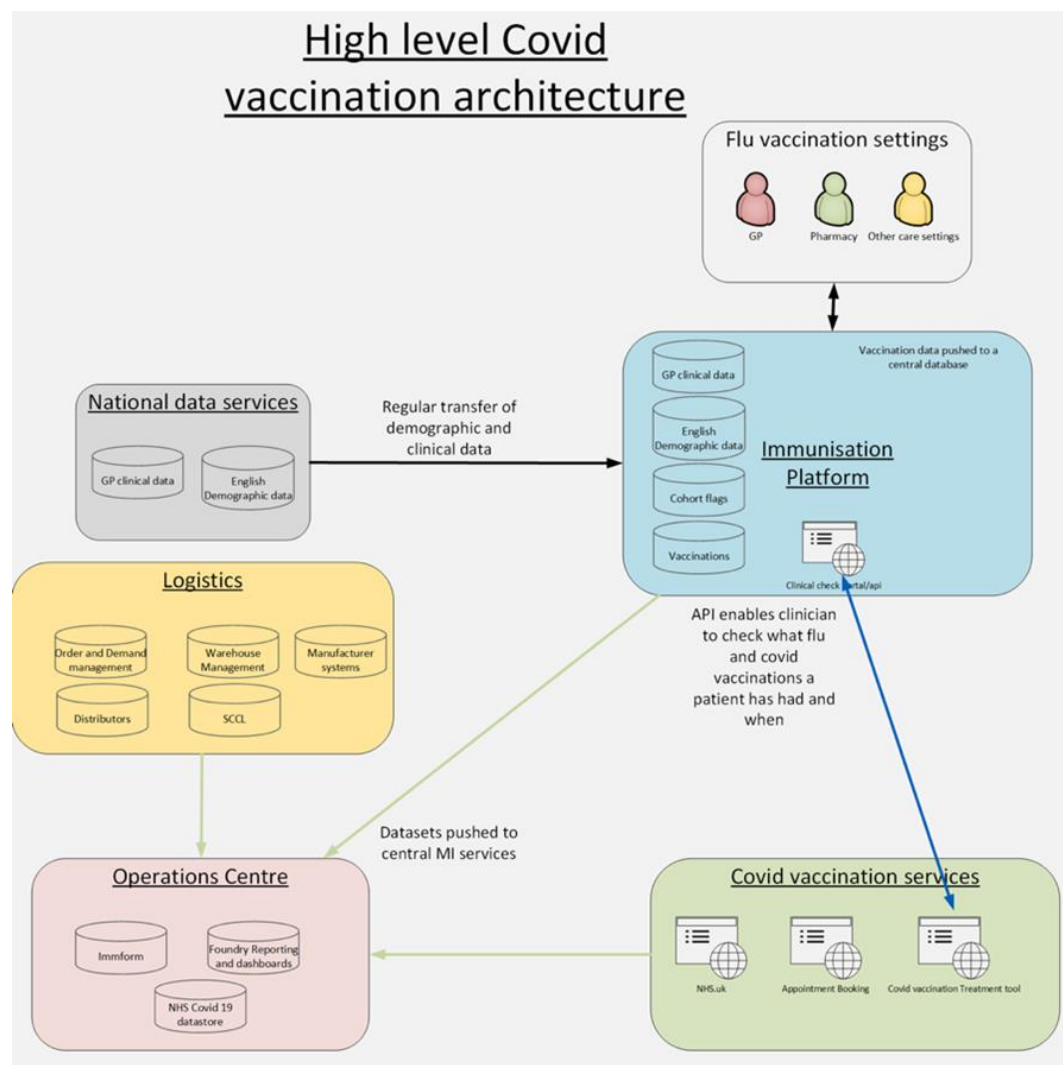
- Ethnicity
- White
  - Asian or Asian British
  - Mixed or multiple ethn...
  - Another ethnic group
  - Black, African, Black ...
  - Prefer not to say





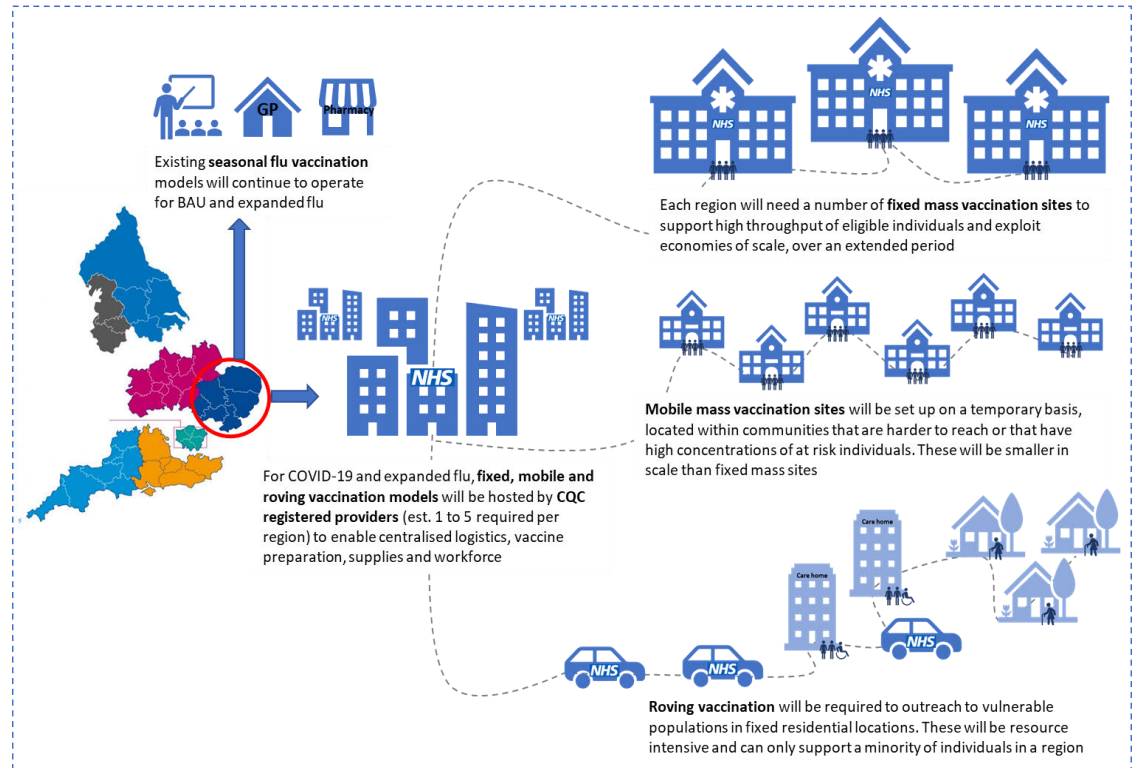
# Challenges of COVID19 vaccine deployment

- Cold chain
- Short stability
- On-site dilutions
- Tray size
- Multi-vials
- Flu vaccination schedule
- Workforce
- Legislation for vaccine administration
- EU exit impact



# UK deployment approach of COVID19 and flu vaccines

- **Fixed site/high volume:** e.g. sports venue, conference venues, airports
- **Mobile site:** Community site, mid-scale vaccination for a temporary period – e.g. polling station, COVID-19 test centre portacabin, container
- **Roving:** Vehicles that can deploy vaccinators, vaccine and supplies on an outreach basis, primarily to residential sites – e.g. St John's Ambulance, mobile units



# Antivax vs vaccine hesitancy; geopolitics

## Los Angeles Times

Anti-vax stupidity is spreading like measles



## Daily Mail

Russia spreads fake news claiming Oxford coronavirus vaccine will turn people into MONKEYS

- Antivaxers have taken advantage of the pandemic to multiply disinformation on social media
- Russian 'monkey' campaign against AZ

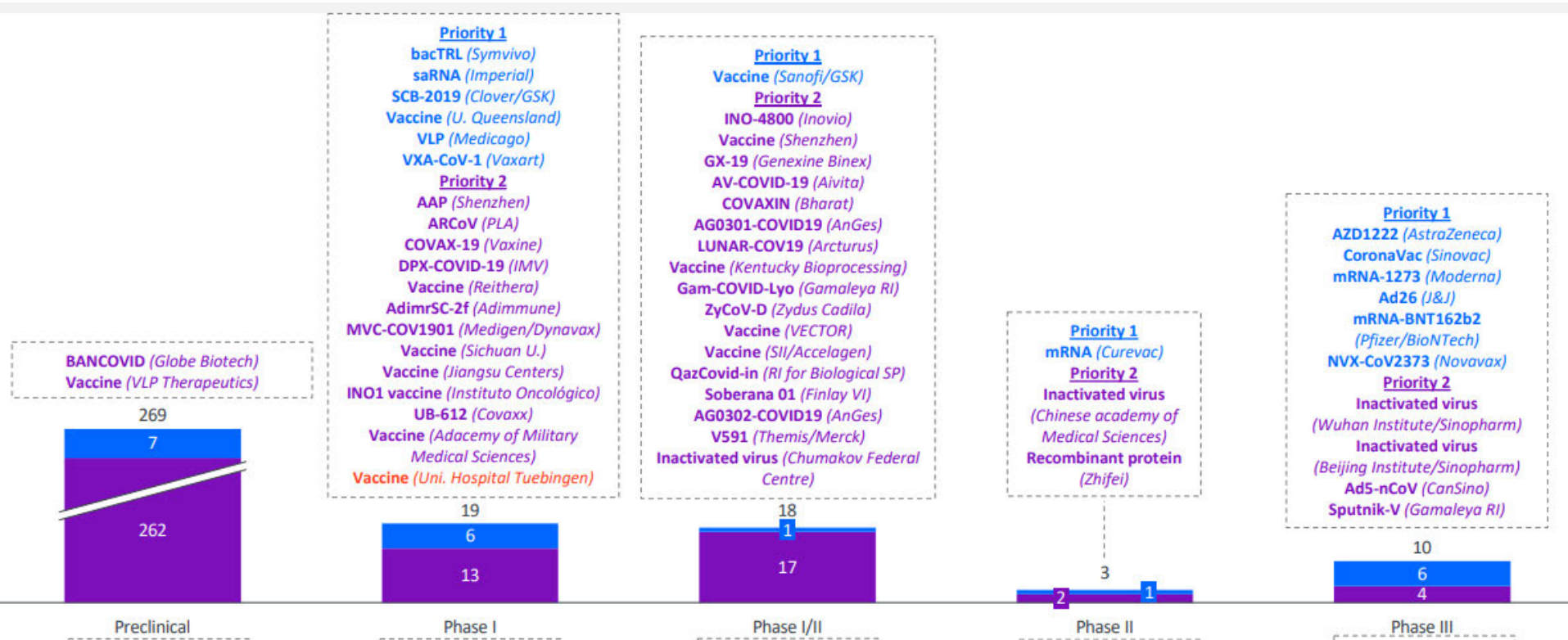


# UK contribution to international vaccine supply

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- **Global leadership to get vaccines to shared equitably**
  - *Up to £500m for COVAX: multilateral arrangement for vaccine procurement open to all countries*
  - *UK role in shaping the facility and encouraging countries to join*
  - *Support to COVAX team to share learnings*
- **Funding and delivery of professional vaccine trials**
  - *UK co-funding Janssen 2-dose vaccine trial to demonstrate long term immunity*
  - *UK funding of Recovery Trial delivering definitive results on efficacy, or lack of, COVID19 therapeutics inc neutralising antibodies*
- **Sharing UK manufacturing capacity**
- **Sharing benefits of UK funded R&D**
  - *HMG contracts require international distribution of UK publicly funded vaccines at non-profit prices inc AZ*

# Current global COVID19 vaccine landscape



Pfizer/BioNTech & Moderna likely to read out P3 data first in the US, and AZ/Oxford in EU

# Clinical trial endpoints driven by COVID19 infections

## Drivers of time to get results

- Attack rate of infections
- Recruitment rate and trial size
- Vaccine efficacy

## FDA criteria for emergency use authorisation (EUA)

- Vaccine efficacy >50%
- Lower bound confidence interval; >30%
- Median 2 months follow-up after 2<sup>nd</sup> dose/full vaccination regime
- >5 severe COVID19 cases
- Availability of vaccine for roll-out

Likely to have some contradictory regulatory opinions

- FDA, EMA, MHRA
- Russia, China

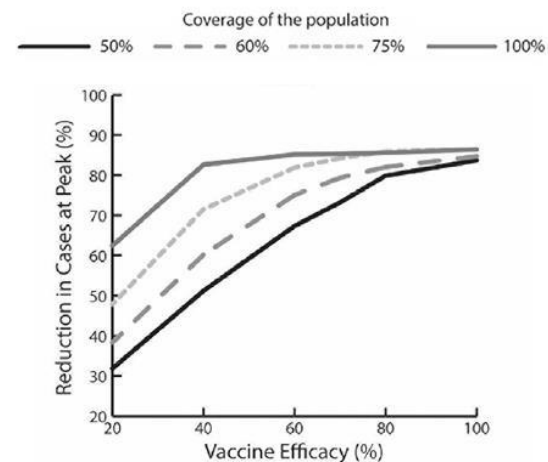


FDA In Brief: FDA Issues Guidance on  
Emergency Use Authorization for  
COVID-19 Vaccines



WHO R&D Blueprint  
novel Coronavirus  
WHO Working Group –  
Target Product Profiles for COVID-19 Vaccines

## Vaccine efficacy to reduce C19 infection at peak

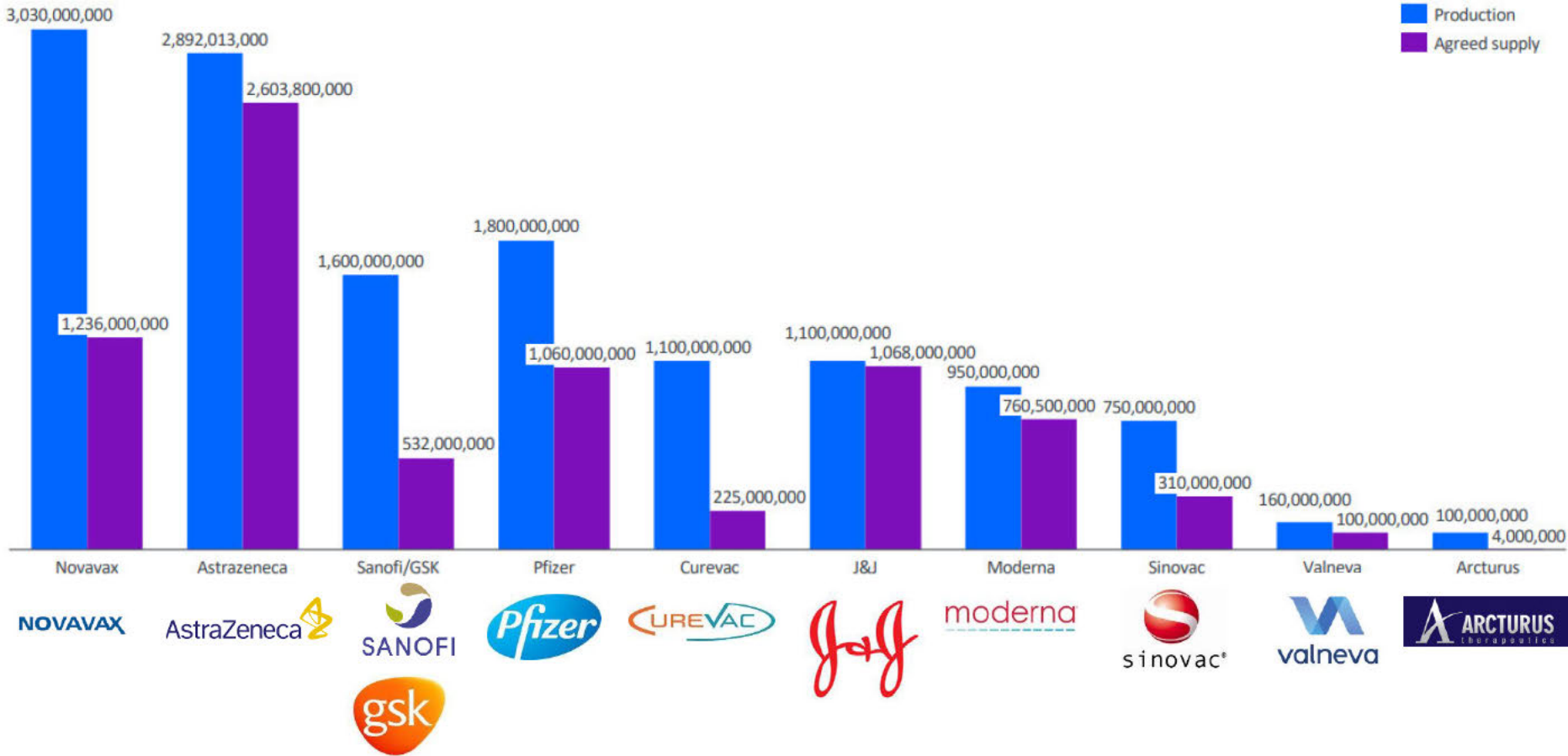


Source: Bartsch SM et al. American Journal of Preventive Medicine, 2020, July 15

## COVID-19 vaccine phase 3 trials underway

Vaccine	Vaccine type	Phase 3 trial locations	P3 size	# doses (time)	# cases for interim
AZ Oxford	Adeno (simian)	UK: & Brazil USA	20k 30k	2 (28)	
Pfizer BioNTech	mRNA	US, Argentina & Brazil	44k	2 (21)	32, 62, 92, 120
Moderna	mRNA	US	30k	2 (28)	53, 106
J&J	Adeno (ad26)	USA, Mexico, Brazil, Ukraine, Chile, Columbia, Peru, Philippines, South Africa	60k	1	20
Novavax	Protein + Matrix M adjuvant	UK	10k	2 (21)	
Sputnik V	Ad5 and ad26	Russia	40k	2 (21)	
Sinovac	Inactivated virus	Brazil, India, Turkey	11.7k	2 (14)	62
Cansino	Adeno (Ad5)	Pakistan	40k	1	
Sinopharm	Inactivated virus	Bahrain, UAE, Argentina	48k	2 (21)	

# Production vs supply of vaccines



J&J have allocated 500m doses to low income countries



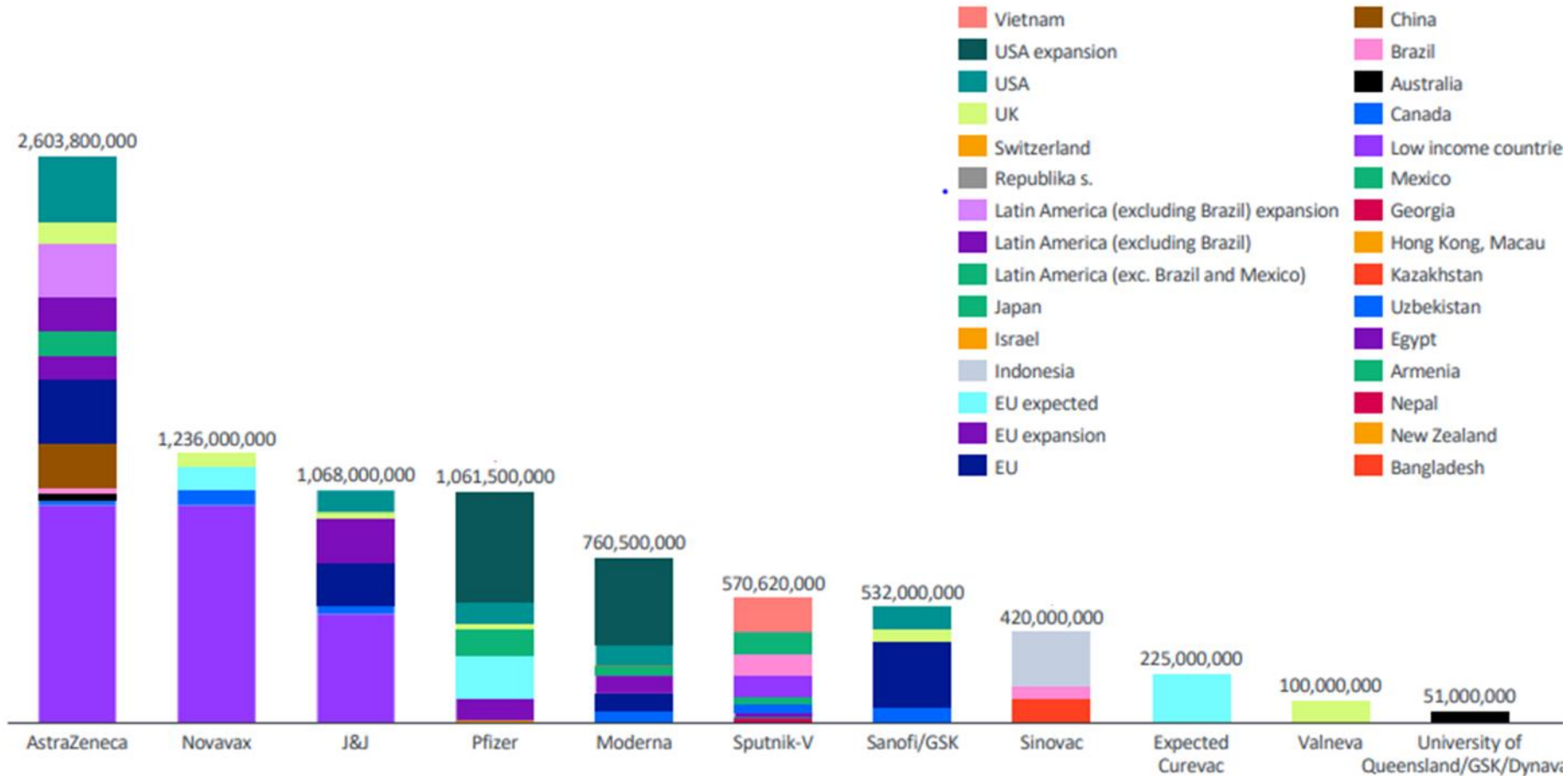
# Estimated price per dose

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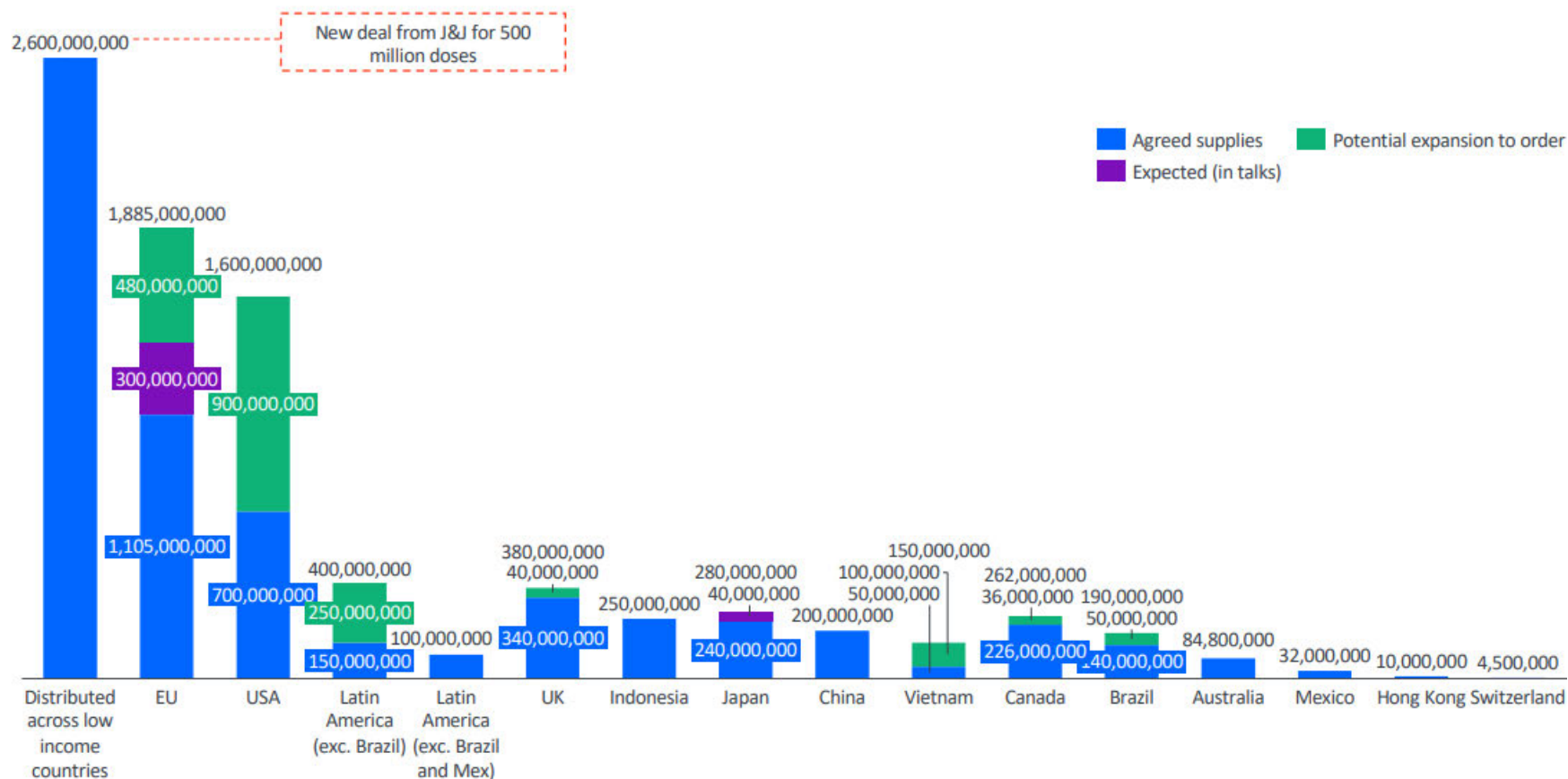
Vaccine (Company)	Estimated price per dose (\$)
BNT162b2 (BioNTech/Pfizer)	19.5
mRNA-1273 (Moderna)	32-37
AZD1222 (AstraZeneca)	4.0
VLA2001 (Valneva)	9.3
NVX-CoV2373 (Novavax)	16.0
Ad26.COV2.S (Johnson & Johnson)	10.0
CoronaVac (Sinovac)	72.5

Source: R<sub>x</sub> Securities

# Supply deals signed to date



## 2.6bn doses now confirmed for low income countries



Source: Airfinity 2020

## Vaccine roll out plans globally

	UK (interim)	US (ACIP/state prioritisation)	EU	Russia	Indonesia	China
Healthcare workers	✓	?	✓	✓	✓	✓
Public sector workers		?	✓ (education & transport)	✓		✓
Workers 18-59 yo		?			✓	
Elderly	✓ (>50)	?	✓			✓
Vulnerable	✓	?	✓			✓
Those working abroad in high risk countries		?				✓
Military		?				✓

# Issues to consider in building a pandemic vaccine portfolio



## Science and clinical :

- Strength, nature and durability of immune response
- Different vaccine formats for diverse vulnerable populations
- Speed, size, diversity and quality of execution of clinical trials



## Supply chain

- Manufacturing and scale up; fill finish; advanced purchasing of supplies
- Flexibility to manufacture different vaccine formats



## Regulatory

- Data requirements, alignment with other regulators; political influence

## Deployment



- Cold chain logistics, 2 doses, needle delivery, short stability
- Priority populations; hard to reach populations
- Antivax/vaccine hesitancy (inc religious sensitivities); impact on public trust



## Commercial

- Commercial terms: upfront vs options; indemnities



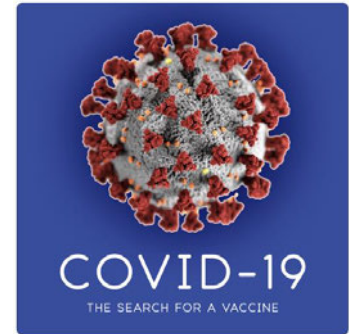
## International collaboration

- Permanent pandemic facility and leadership

# Issues for discussion

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- Safety (including trials being paused)
- Vaccine hesitancy
- Prioritisation of vaccination populations
- Next generation vaccines
- Future pandemic preparedness
  - Global manufacturing capacity and capability
  - Regulatory decision making: pandemic vaccine criteria, EUA
  - Permanent leadership and COVAX-type facility



## The UK Vaccine Taskforce - podcast series: The Search for a Vaccine

