COVID-19 VACCINATION

Safe. Effective. Free.

COVID-19 Vaccines

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Head, Infectious Diseases

Western Health

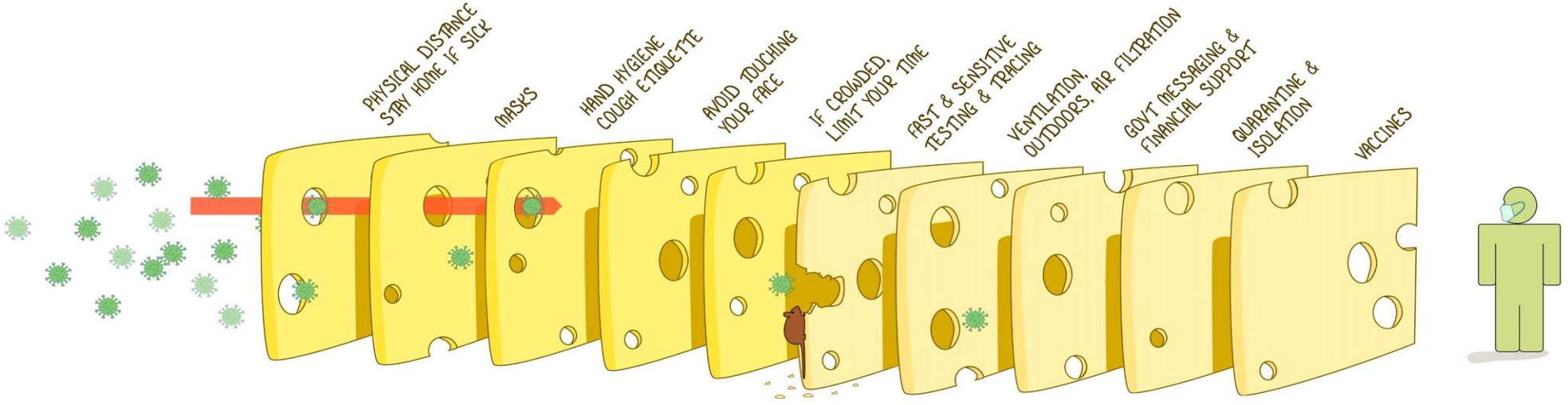
9 February, 2021

Disclaimer

This is a rapidly evolving situation– we are learning more about this virus and COVID vaccines on a daily basis.

The Swiss Cheese Respiratory Virus Pandemic Defence

Recognising that no single intervention is perfect at preventing spread



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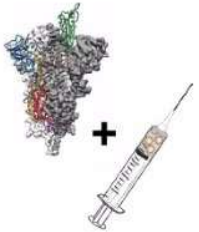
Multiple layers improve success.

Ian M Mackay
virologydownunder.com
With thanks to Jody Lanard, Katherine Arden & the Uni of Qld
Based on the Swiss cheese model of accident causation, by James T Reason, 1990
version 3.0
update: 24oct2020

Selected COVID-19 Vaccines

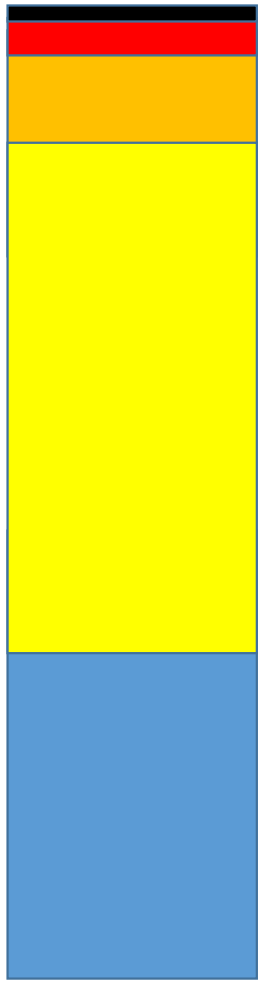
Platform	Developer	Status
Nucleic Acid (mRNA) -70 C	 moderna	94% efficacy vs. symptomatic disease → EUA
	BIONTECH Pfizer	95% efficacy vs. symptomatic disease → EUA
Adenovirus Vector 2-8 C	 Janssen Johnson & Johnson	72% efficacy in U.S. 85% efficacy overall vs. severe disease in U.S., South Africa → EUA TBD
	AstraZeneca	Phase 3 results → likely Feb./Mar. 2021 EUA TBD
Recombinant Protein and Adjuvant 2-8 C	 gsk SANOFI	Phase 2 starts → Feb. 2021
	NOVAVAX Creating Tomorrow's Vaccines Today	89% efficacy vs. symptomatic disease (U.K. Phase 3) → EUA TBD

Vaccine trial	Approximate # of people who received the vaccine	Of people vaccinated in the trial		
		# hospitalized for COVID	# who died from COVID	# who died from the vaccine
Moderna	15,000	0	0	0
Pfizer	18,600	0	0	0
Novavax*	13,000	0	0	0
Astra-Zeneca	5,800	0	0	0
J&J*	22,000	0	0	0

Death

ICU

Hospitalized



Mild-moderate symptoms

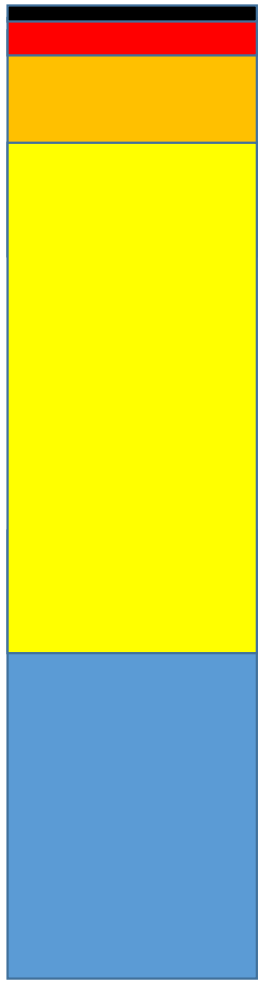
No symptoms but infectious

Severe disease

- Death
- ICU
- Hospitalized

Mild-moderate symptoms

No symptoms but infectious

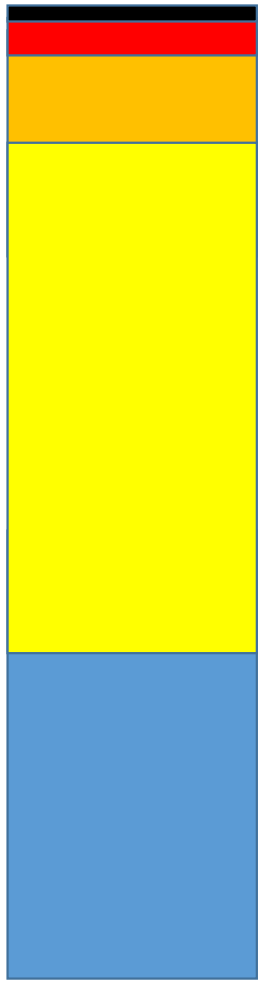


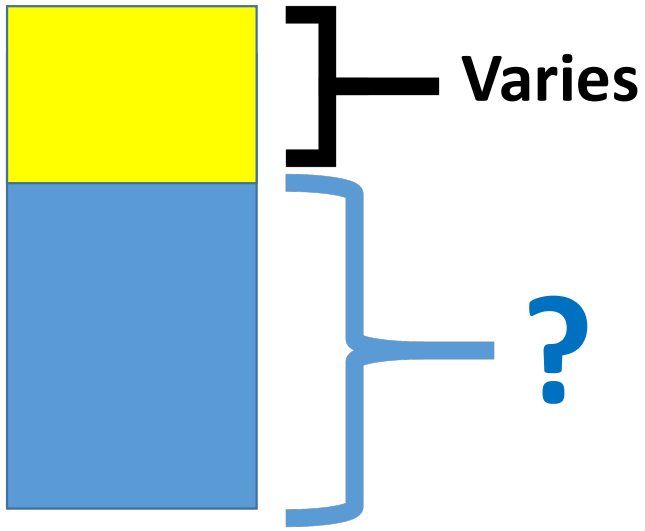
Vaccinated

Death
ICU
Hospitalized

Mild-moderate symptoms

No symptoms but infectious





Fast-tracking COVID-19 vaccines while ensuring safety

- **Researchers used existing vaccine clinical trial networks to conduct the COVID-19 vaccine trials.**
- **Manufacturing began while clinical trials were still underway. Normally, manufacturing doesn't begin until after completion of the trials.**
- **mRNA vaccines are faster to produce in large amounts than traditional vaccines.**
- **Regulators around the world, including TGA (Australia), EMA (Europe), FDA (US) are prioritizing review and authorization of COVID-19 vaccines.**

How COVID-19 mRNA vaccines work

- **mRNA vaccines teach our cells how to make a harmless piece of the "spike protein" for SARS-CoV-2.**
  - **After the protein piece is made, the cell breaks down the instructions (the mRNA) and gets rid of them.**
- **Cells display this piece of spike protein on their surface, and an immune response is triggered inside our bodies.**
- **This produces antibodies to protect us from getting infected if the SARS-CoV-2 virus enters our bodies.**

Source: Understanding and Explaining mRNA COVID-19 Vaccines | CDC

How COVID-19 mRNA vaccines work

- **mRNA vaccines do not use the live virus that causes COVID-19. They CANNOT give someone COVID-19.**
- **mRNA vaccines DO NOT affect or interact with our DNA in any way.**
- **mRNA vaccines are new, but the technology is not. mRNA vaccines have been studied for other infections.**

- **Two shots are needed to provide the best protection against COVID-19 .**
  - **First shot primes the immune system, helping it recognize the virus.**
  - **Second shot strengthens the immune response.**
- **Side effects are commonly seen in mRNA vaccines, especially after the 2nd dose.**
- **Side effects may include:**
  - **fever**
  - **headache**
  - **muscle aches**

Source: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html

About safety of COVID-19 mRNA vaccines

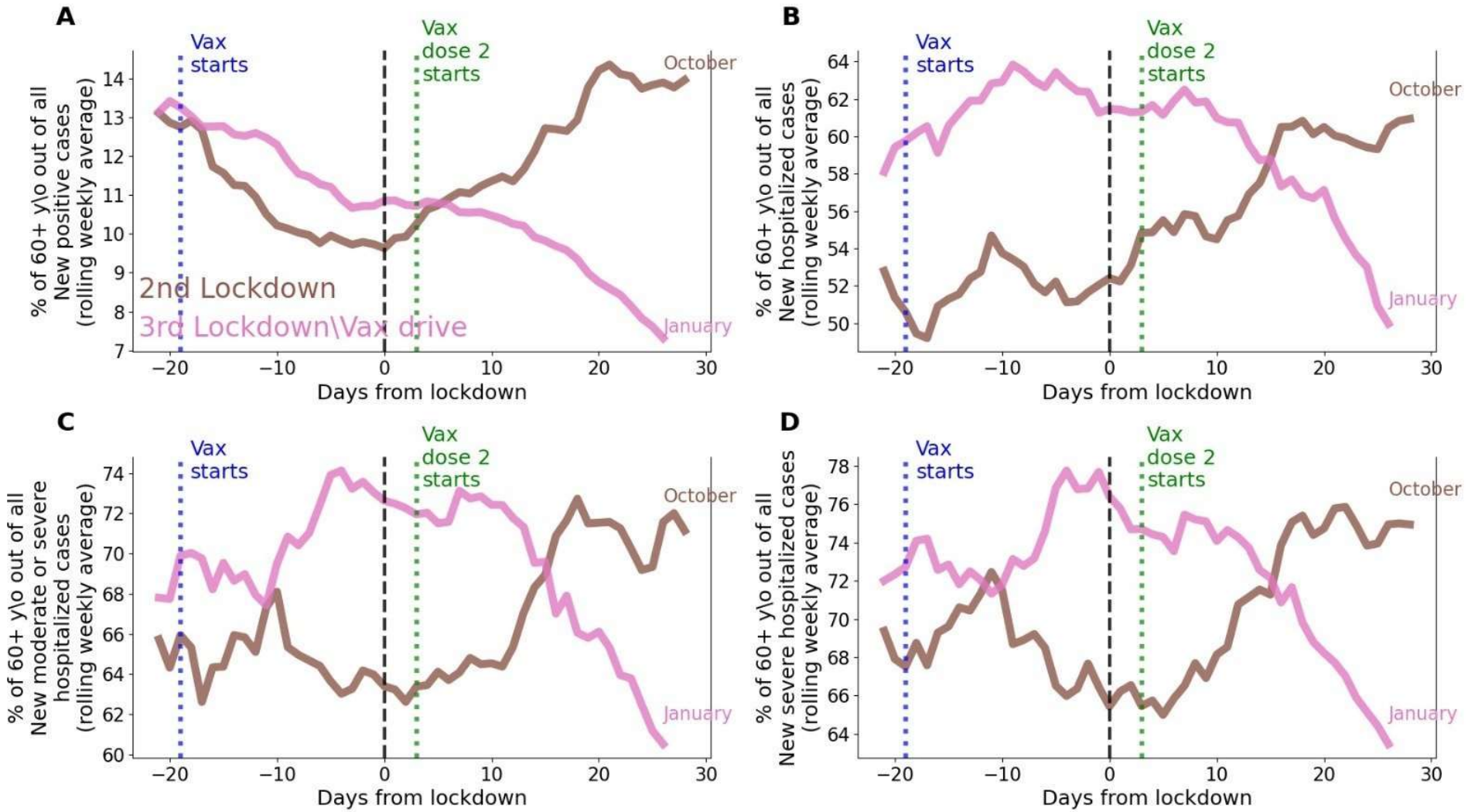
- **No significant safety concerns were identified in the clinical trials, although a small number of severe allergic reactions (anaphylaxis) have been reported**
  - **Pfizer COVID ~ 5 in 1,000,000**
  - **All vaccines ~ 1 in 1,000,000**
  - **Penicillin rate ~ 1 in 5,000**

  - **Recommendations for observation after vaccination include monitoring for 15 or 30 minutes.**

Reactogenicity reported to v-safe

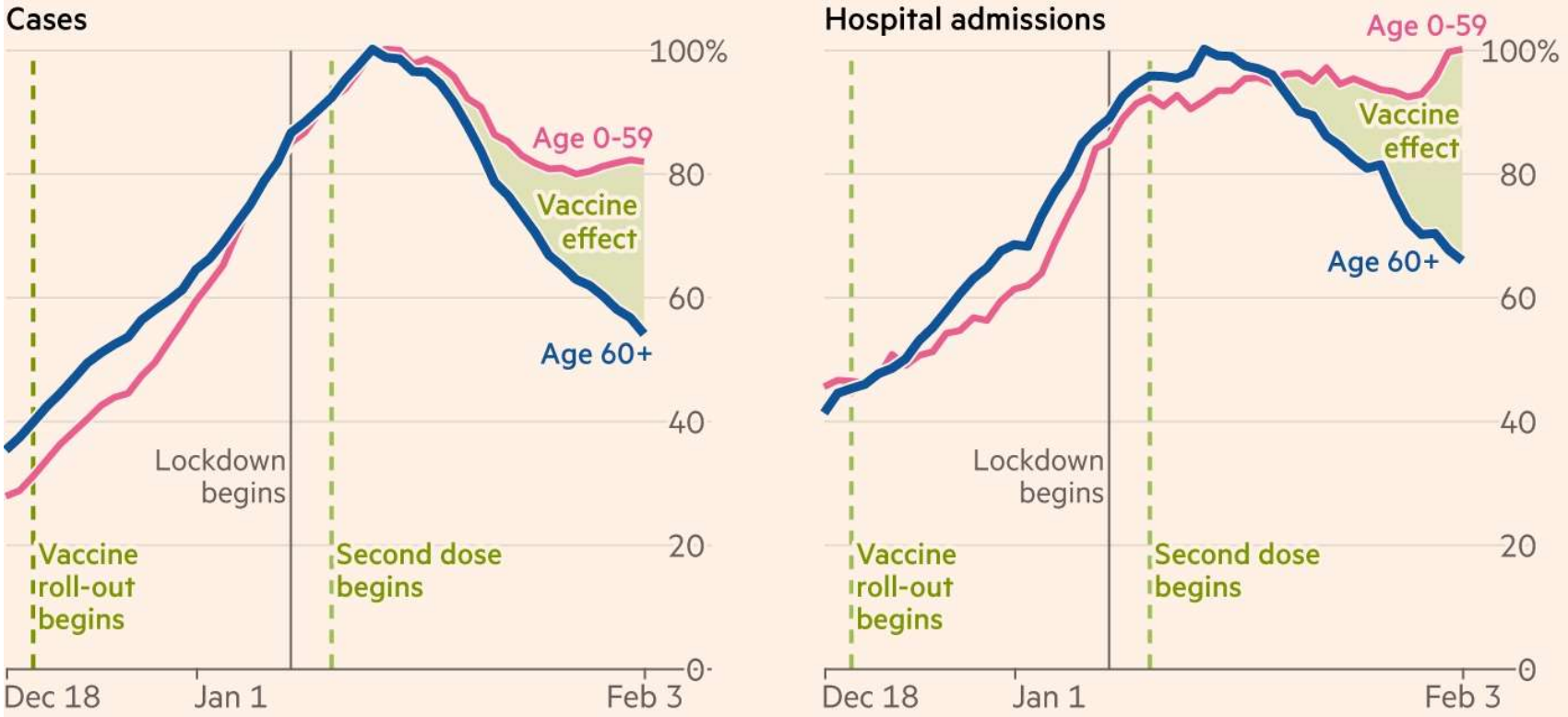
Local and systemic reactions, day 0-7*,†	All vaccines %	Pfizer-BioNTech dose 1 %	Pfizer-BioNtech dose 2 %	Moderna dose 1 %
Pain	70.7	67.7	74.8	70.1
Fatigue	33.4	28.6	50.0	29.7
Headache	29.4	25.6	41.9	26.0
Myalgia	22.8	17.2	41.6	19.6
Chills	11.5	7.0	26.7	9.3
Fever	11.4	7.4	25.2	9.1
Swelling	11.0	6.8	26.7	13.4
Joint pain	10.4	7.1	21.2	8.6
Nausea	8.9	7.0	13.9	7.7

Impact of Vaccination in Israel


A
Vax starts
Vax dose 2 starts
October
January
2nd Lockdown
3rd Lockdown\Vax drive
% of 60+ y\o out of all New positive cases (rolling weekly average)
Days from lockdown
B
Vax starts
Vax dose 2 starts
October
January
% of 60+ y\o out of all New hospitalized cases (rolling weekly average)
Days from lockdown
C
Vax starts
Vax dose 2 starts
October
January
% of 60+ y\o out of all New moderate or severe hospitalized cases (rolling weekly average)
Days from lockdown
D
Vax starts
Vax dose 2 starts
October
January
% of 60+ y\o out of all New severe hospitalized cases (rolling weekly average)
Days from lockdown

Cases and hospital admissions in Israel are falling much more steeply among vaccinated age groups than among younger groups

Cases and hospitalisations as a percentage of winter peak, by age group



Sources: Segal et al., Weizmann Institute, Tel-Aviv University

© FT

Variants of Concern

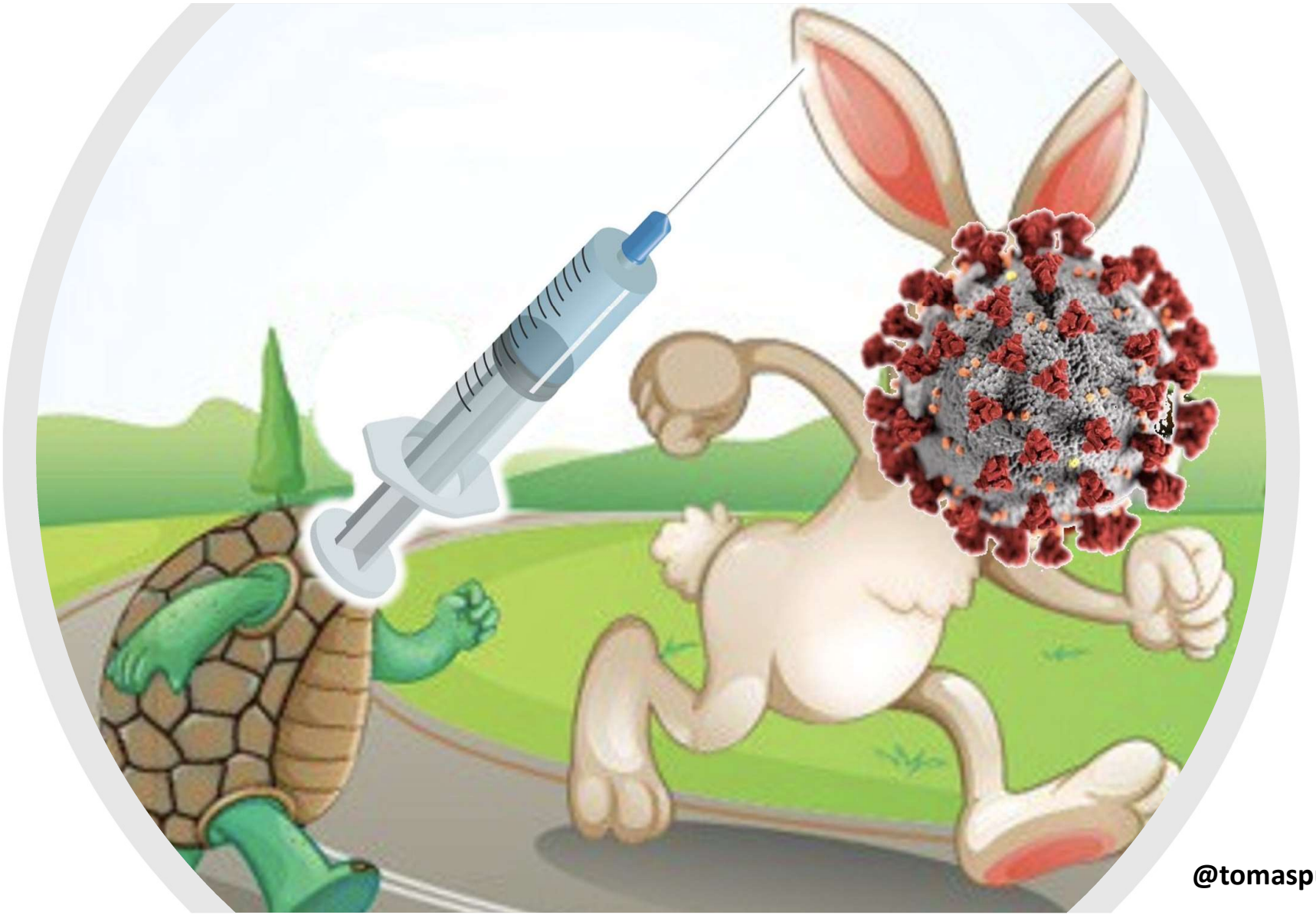
B.1.351 (Identified in South Africa)

Vaccine	N of Participants	Main Efficacy Findings
Novavax	4,422	60% efficacy HIV negative (89% in UK) 49% efficacy HIV positive No hospitalizations or deaths in SA
J&J	~10,900	57% efficacy (72% in US, D614G*) No hospitalizations or deaths in SA
Astra-Zeneca	~2,000	"minimal protection vs mild-moderate infections" details pending

B.1.1.7 (Identified in United Kingdom)

Vaccine	N of Participants	Main Efficacy Findings
Novavax	15,203	86% efficacy (vs 96% for D614G* in 56 symptomatic cases by sequencing)
Astra-Zeneca	4,236	75% efficacy (vs 84% for D614G* in 120 symptomatic cases by sequencing

D614G=ancestral strain or other variants not of concern for immune escape



@tomaspueyo

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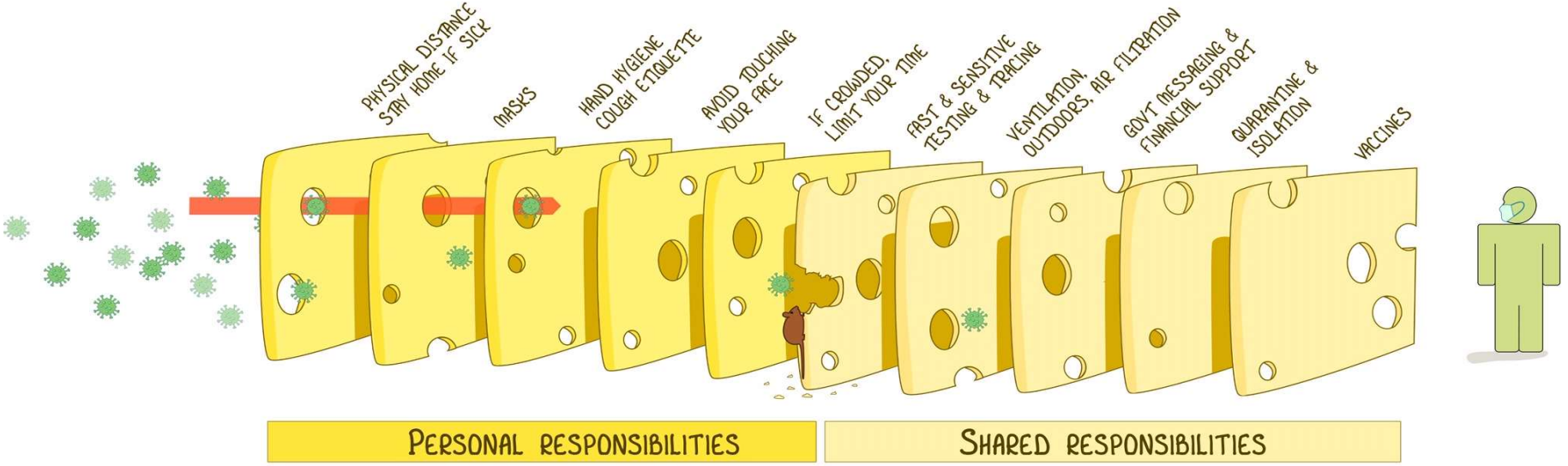

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update: 24oct2020

Longer Dose Interval Was Associated With Increased Spike-Binding Antibody Responses in Participants Seronegative At Baseline

SD/SD

Subgroup	Baseline GMT (95% CI)	28 days after dose 1 GMT (95% CI)	28 days after dose 2 GMT (95% CI)
Dose interval			
<6 weeks	(N=481) **60.51** (54.1, 67.7)	(N=479) **8734.08** (7883.1, 9676.9)	(N=443) **22222.73** (20360.5, 24255.3)
6–8 weeks	(N=137) **58.02** (46.3, 72.6)	(N=99) **7295.54** (5857.4, 9086.7)	(N=116) **24363.10** (20088.5, 29547.3)
9–11 weeks	(N=110) **48.79** (39.6, 60.1)	(N=87) **7492.98** (5885.1, 9540.2)	(N=106) **34754.10** (30287.2, 39879.8)
≥12 weeks	(N=154) **52.98** (44.4, 63.2)	(N=152) **8618.17** (7195.4, 10322.3)	(N=154) **63181.59** (55180.1, 72343.4)

LD/SD

Subgroup	Baseline GMT (95% CI)	28 days after dose 1 GMT (95% CI)	28 days after dose 2 GMT (95% CI)
Dose interval			
<6 weeks	(N=3) **50.92** (3.9, 669.2)	(N=3) **7496.44** (1461.4, 38454.7)	(N=3) **22121.36** (8547.7, 57250.2)
6–8 weeks	-	-	-
9–11 weeks	(N=30) **64.09** (40.4, 101.6)	(N=30) **4803.21** (3255.7, 7086.4)	(N=29) **36928.89** (24509.6, 55641.2)
≥12 weeks	(N=35) **52.42** (37.7, 72.9)	(N=35) **6750.27** (4184.6, 10889.0)	(N=35) **66274.91** (49546.6, 88651.1)

Similar results were seen with the nAb responses by pseudoneutralisation assay

nAb = neutralizing antibody.

COVID-19 Vaccine AstraZeneca, solution for injection in multidose container COVID-19 Vaccine (ChAdOx1-S [recombinant]). https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949772/UKPAR_COVID_19_Vaccine_AstraZeneca_05.01.2021.pdf. Accessed January 8, 2021.

Specific aims of the COVID-19 vaccination program

An Australian COVID-19 vaccination program should seek to achieve the following aims, noting they are interrelated

- Reduce COVID-19 related harm by preventing serious illness and death, and where possible, disease transmission
- Ensure equity of vaccine access and uptake, especially for groups likely to experience a disproportionate burden of disease
- Promote public and health professional trust in the utility of COVID-19 vaccines and their implementation to the Australian community
- Ensure COVID-19 Vaccines are listed within the national immunisation program
- Maintain functioning of health care and other essential services to preserve health, social and economic security

- **Reduce serious illness and death**
- **Disease transmission (if possible)**
- **Equity**
- **Maintain functioning of healthcare and essential services**

ATAGI – Preliminary advice on general principles to guide the prioritisation of target populations in a COVID-19 vaccination program in Australia (health.gov.au)

COVID-19 vaccine national roll-out strategy

First priority populations

COVIDSAFE

The Australian COVID-19 vaccination program will commence with priority populations including aged care and disability care residents and workers, frontline healthcare workers and quarantine and border workers.

Vaccine doses will be available through 30 - 50 hospital sites across Australia - in metro and regional areas (pending advice from states and territories) plus in residential aged care and disability care facilities.

Residential Disability and Aged Care Facilities

Doses quarantined in Hub based on readiness checklist information by facilities and picked up by contracted workforce on scheduled date(s) for vaccination day.

Vaccination Hubs

Aged care and disability care residents

1. Communications to facilities to advise of priority groups, locations and roll-out plans
2. Patient consent coordinated by contracted workforce in consultation with facility
3. Vaccination date(s) communicated
4. Vaccination doses received

Residential aged care and disability care workers

1. Communications to facility staff to advise of priority groups, locations and roll-out plans
2. Coordinate schedule of first and second doses by facility
3. Facilities to provide readiness checklist including staff numbers on vaccination date(s) to inform dose requirements
4. Vaccination date(s) communicated
5. Vaccination doses received

Priority frontline healthcare workers

1. Communications through states and territories and peak bodies to advise of priority groups, locations and roll-out plans
2. Vaccination date(s) scheduled and communicated to individual
3. Schedule and doses coordinated within State Governments to align with shifts and rosters
4. Vaccination doses received as per steps outlined below - proof of eligibility, consent and clinical screening conducted on check-in at vaccination Hub

Priority quarantine and border workers

1. Communications to advise of priority groups, locations and roll-out plans
2. Scheduling coordinated through State Government and communicated to individual
3. Individual attends Hub for vaccination at advised time by employer if applicable
4. Vaccination doses received as per steps outlined below- proof of eligibility, consent and clinical screening conducted on check-in at vaccination Hub

Day of vaccination - First dose

Patient screening → Vaccination dose given → Follow up information provided → Vaccination record entered into AIR (and relevant systems) → Post vaccination monitoring

Reminder of second dose - scheduled date(s) and location

Second dose

Repeat steps for first dose process

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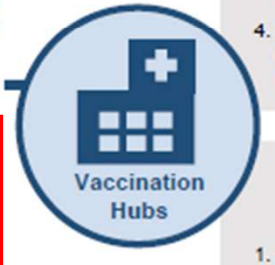

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Repeat steps for first dose process

Healthcare personnel are among the first in line for COVID-19 vaccine

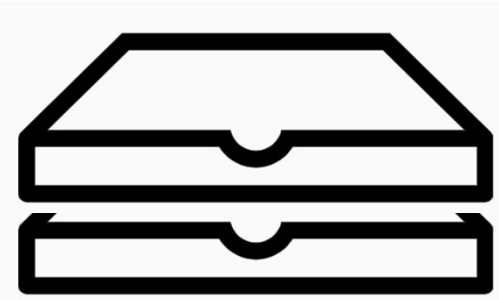
Why are you first in line?

- **On the front lines**
- **High risk of exposure**
- **Potential to transmit to others at higher risk**

We will learn a lot over the next weeks/months:

- If and to what extent each vaccine reduces transmission
- How well it performs among
  - Different populations eg:, age-groups, RACF residents
  - Different Variants of Concern
- Optimal dose (eg Low dose, Standard dose)
- Optimal dosing interval
- Impact of previous infection (need one dose only?)
- Data on safety in pregnancy

Flexible



ATAGI and Implementation

Associate Professor Michelle Giles

Disclosure: a member of ATAGI

I am presenting today in my professional capacity and not as a member of ATAGI

	Usual process for vaccines	COVID vaccines
Initiation	Sponsor applies to TGA and PBAC	Australian government, on advice from SITAG
Regulation: Is it safe and effective?	TGA, with advice from ACV	TGA, with advice from ACV
Purchasing: Is it value for money?	Australian Government, on advice from PBAC	Australian Government
Technical: How best to use and evaluate?	Statements from ATAGI and others eg NCIRS	Multiple providers: ATAGI, NCIRS fact sheets and training materials contracted by Commonwealth
Program: getting vaccines into arms	Australian Dept of Health and jurisdictions	COVID task force Australian Dept of Health and jurisdictions

ATAGI

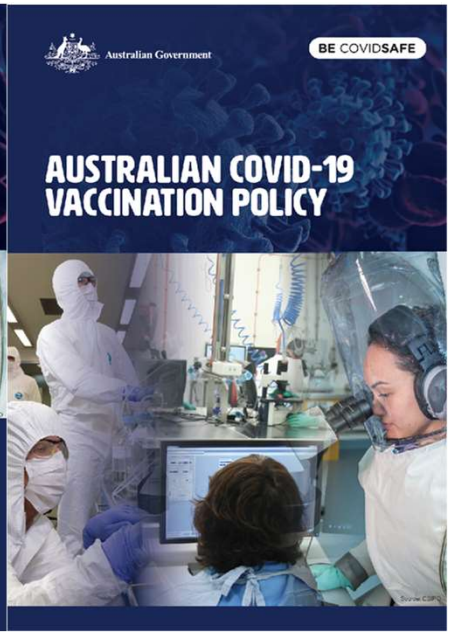
Voting members		Ex-officio members
Allen Cheng	Cheryl Jones	Darius Everett (DOH; AS, Immunisation)
Chris Blyth	Tony Korman	Kristine Macartney (NCIRS)
Karen Bellamy	Bette Liu	Robyn Gibbs (NIC)
Nigel Crawford	Debra Petrys (Consumer Rep)	Ting Liu / Megan Hickie (TGA)
Katie Flanagan	Nicholas Silberstein (GP)	Louise Flood (CDNA)
Katherine Gibney	Tom Snelling	**Technical and Administrative Support**
Michelle Giles	Diane Walsh (Consumer Rep)	NCIRS Policy Support Team
Madeline Hall	James Wood	Department of Health Secretariat

Australian Government
Department of Health

Aboriginal and Torres Strait Islander Member awaiting Ministerial approval

https://www.health.gov.au/committees-and-groups/australian-technical-advisory-group-on-immunisation-atagi#members

Towards a COVID-19 program



- **ATAGI was requested in August 2020 to establish an ATAGI COVID-19 working group to:**
- Provide technical advice to the Minister on the immunisation program for COVID-19 vaccines as they become available
- Identify and prioritise gaps in the immunisation landscape to improve impact, confidence and equity with the use of COVID-19 vaccines.
- Advise on the content of clinical and other communication materials, including updating the Australian Immunisation Handbook for any COVID-19 vaccines.
- Consult with key national committees on matters relating to the implementation of immunisation policies, procedures and vaccine safety related to COVID-19 vaccines.

Australian Government
Department of Health

Who is on the ATAGI COVID-19 WG?

Working party executive and NCIRS Policy Support Team meeting weekly with COVID-19 vaccine taskforce:
Lisa Schofield, Hope Peisley, Nick Henderson

WS1: Utilisation and prioritisation	
Katie Flanagan	Jodie McVernon
Chris Blyth	Vanessa Johnston
Kristine Macartney	Tom Snelling
Penny Burns	Kanta Sabbarao
Angus Dawson	James Ward
David Durrheim	James Wood
Kirsten Howard	Richard Kidd
Bette Liu	NCIRS Policy Support Team

WS2: Distribution & Program Implementation	
Robyn Gibbs	Chris Moy
Karen Bellamy	Lena Sanci
Scott Brown	Nicholas Silberstein
Katherine Gibney	Annaliese van Diemen
Michelle Giles	NCIRS Policy Support Team
Madeline Hall	

WS3: Safety, Evaluation, Monitoring ,Confidence	
Nigel Crawford	Tony Korman
Allen Cheng	Alan Leeb
Katie Attwell	Debra Petrys (consumer)
Margie Danchin	Diane Walsh (consumer)
Paul Effler	I-Hao Cheng (TGA)
Cheryl Jones	NCIRS Policy Support Team
John Kaldor	

https://www.health.gov.au/committees-and-groups/australian-technical-advisory-group-on-immunisation-atagi-covid-19-working-group#atagi-covid19-working-group-members

Priorities of the COVID-19 WG

WS1: Utilisation and prioritisation

October 2020:
Priority populations v1
Informed by WHO SAGE Roadmap

November 2020:
Vaccine modelling requirements:

December 2020:
Revised priority populations v2

January 2021:
Clinical guidance for COVID vaccines
Guidelines for vaccine co-administration

In-depth review of vaccine characteristics:
ongoing

Australian Government
Department of Health

WS2: Distribution & Program Implementation

October 20:
Frozen vaccine logistics
Workforce competencies

November 20:
Vaccination equipment and site checklist
AIR requirements
Multidose vial use and safety
H1N1 lessons learnt

December 20
Review of jurisdictional policies
Consent requirements

January 2021
Clinical guidance for COVID vaccines
Patient and provider information

WS3: Safety, Evaluation, Monitoring ,Confidence

October 2020:
Strategies to support uptake
(with COSSI)

November 2020:
COVID-19 vaccine communications strategies (with COVID-19 Taskforce)

December 2020:
COVID-19 vaccine pharmacovigilance plan
(with TGA)

January 2021
Clinical guidance for COVID vaccines
COVID-19 vaccine evaluation framework

Roles and Responsibilities

- Commonwealth
  - Secure and purchase vaccine
  - Approve vaccine (TGA)
  - Fund vaccine providers eg GP, pharmacy
  - Commission and oversee private RACF and disability staff and residents
- State
  - Commission and support establishment of vaccine clinics (Pfizer hubs)
  - Workforce and regulatory approval (allow nursing staff to administer without medical order- requires secretarial authorization)
  - Ensure safety, quality and manage AEFIs
  - Provision of Covid vaccine management system (CVMS)

Role and responsibility of vaccine centres

01

Manage vaccine product appropriately

02

Complete reporting requirements (AIR mandatory)

03

Report AEFIs

04

Establish Specialist Immunisation Services

Australian National Vaccine Safety Networks

- Immunisation Clinical Assessment Network [AEFI-CAN]
  - Currently meet 6-weekly
  - Discuss adverse events following immunisation (AEFI) cases
  - Paediatric and adult vaccine specialists
  - TGA and Commonwealth Immunisation representatives
  - Research projects and international collaborations

- Therapeutic Goods Administration (TGA)
  - Advisory committee of vaccines (ACV)
    - Vaccine causality
  - Jurisdictional-TGA meeting (monthly)- weekly for COVID19
  - Adverse Event Monitoring System (AEMS) database
  - Linking with other international regulators (FDA, EMA)- rolling review as data emerges, pharmacovigilance plans

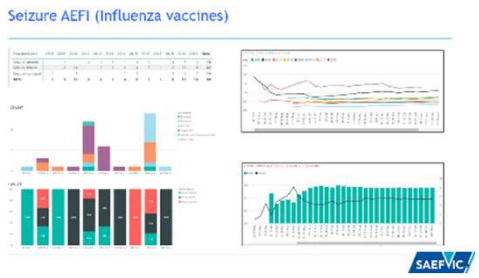
Slide acknowledgement Nigel Crawford

Immunisation workforce
Consumers
Aged care

Education & Comms

Spontaneous surveillance

Harmonised
Easier
Visualised



Collaboration

Active surveillance

National
Jurisdictional
International

Solicited
Syndromic
Data-linking

vaccine safety net

AusVaxSafety
An NCIRS led collaboration

SmartVax
Health
NSW GOVERNMENT
Hunter New England Local Health District

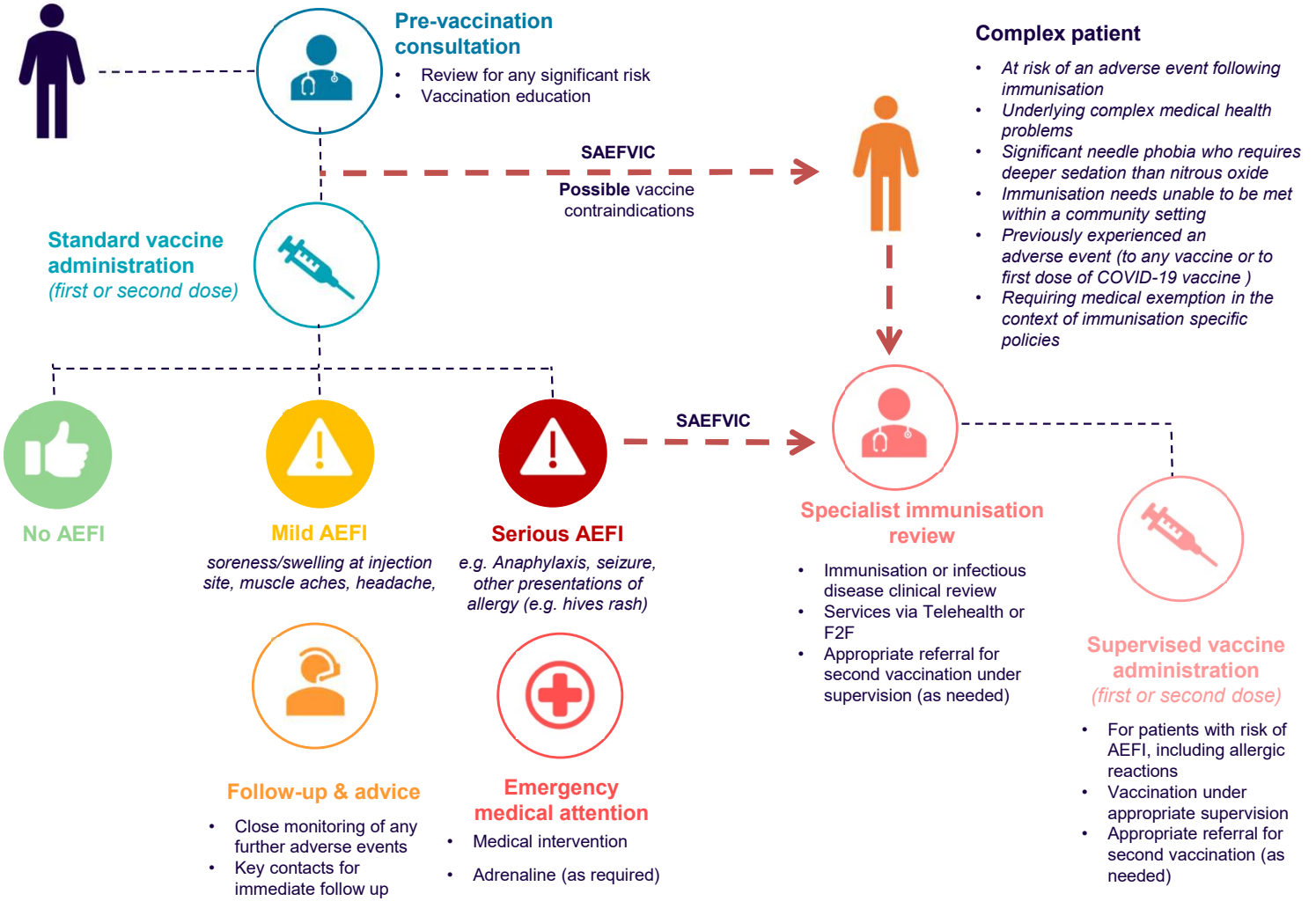
Vaxtracker Project

SAFESIG

https://www.who.int/vaccine_safety/initiative/communication/network/vaccine_safety_websites/en/

Slide acknowledgement Jim Buttery

Safety First – A Coordinated System



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OFFICIAL: Sensitive