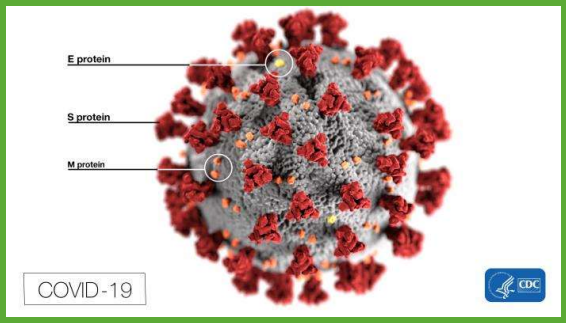
COVID-19 vaccines for NZ



Nikki Turner, Immunisation Advisory Centre

3 Feb 2021

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Major questions and concerns about the COVID vaccines

Survey of health professionals

19th – 26th January

- 788 respondents
  - 142 GP (Survey through E –pulse)
  - 187 Practice nurses (IMAC ImNuz survey)
  - 66 Pharmacists
- Variety of other health professionals (393) – community and secondary care

Authors: Prof Tony Dowell and the evaluation team to IMAC

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Main concerns

- Vaccine effectiveness/efficacy
- Vaccine safety
- Logistics and programme effectiveness
- Primary care capacity and workload

Significant commonality between health professions.

Some particular variations

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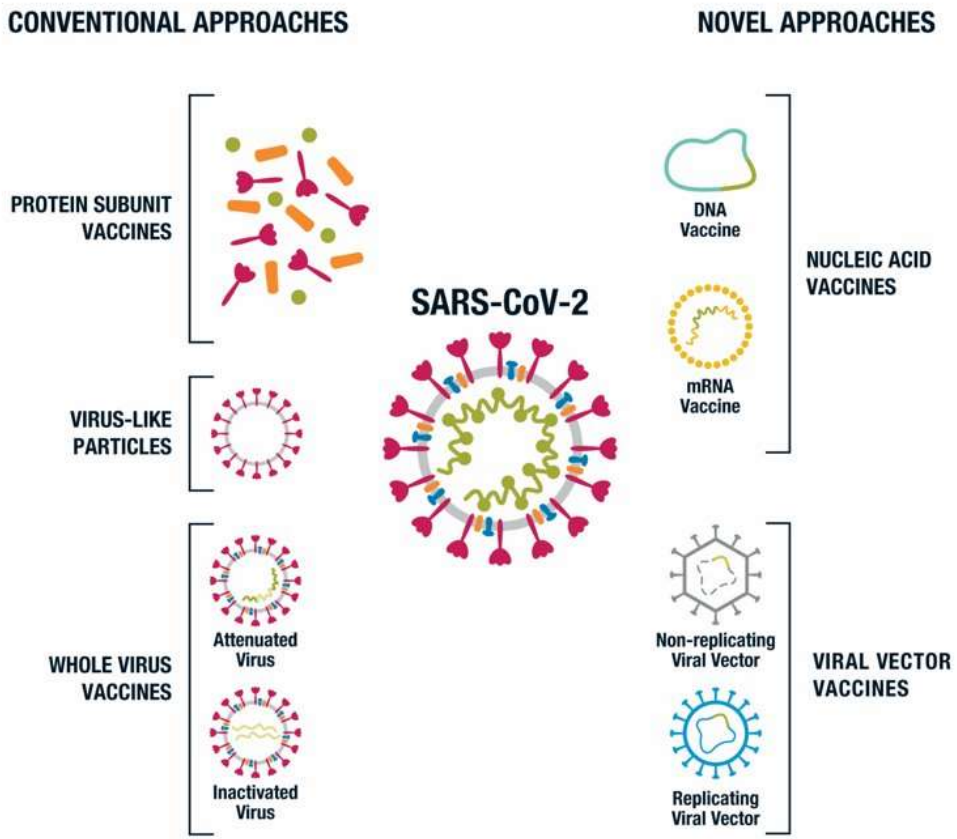

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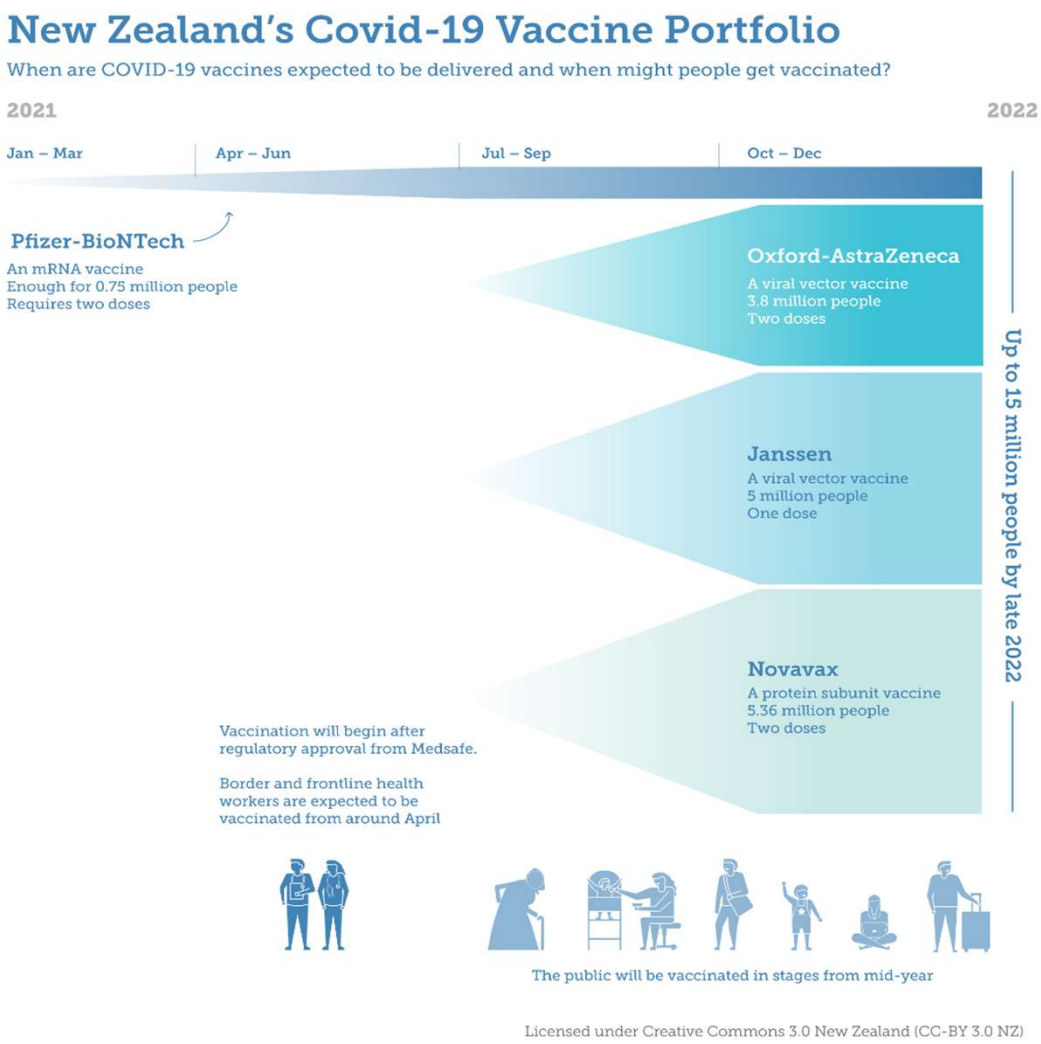

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Nucleic Acid Vaccines

- Nucleic acid vaccines (RNA or DNA) do not directly deliver an antigen to the body, instead they are designed to make the body produce antigenic material itself
  - An example of a nucleic acid vaccine is the **Pfizer/BioNTech** RNA COVID-19 vaccine.

Nucleic Acid Vaccines	
Pros	Cons
No risk of vaccine causing disease	No current nucleic acid vaccines are licensed for use in humans
Quickly designed and manufactured	Current stability data requires vaccine storage in very low temperatures. Difficult for delivering.

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Pfizer/BioNTech (Comirnaty, BNT162b2, Tozinameran)

A lipid bubble containing a fragment of RNA which gives instructions to cells to produce the full length S protein of SARS-CoV-2

Schedule: 2 doses, 21 days apart, IM,

Storage: -70 degrees Celsius, 5 days at 2-8^{0}C,

Multidose vials, reconstituted

Manufacturing scale up easier than others

Phase 3 studies underway since July 2020, continuing to Dec 2022,

- >40,000 participants, Healthy people 12 years plus
  - *No children, no pregnant women to date*
  - Not testing for asymptomatic infection
  - No data on new variants, lab based studies– neutralized UK variant, slightly less effective on Sth African variant,
- Vaccine efficacy 7 days after second dose 95% (90.3% - 97.3%), lab confirmed symptomatic
  - 1 severe case in vaccinated, 9 severe cases in placebo group
- Post licensure rollout Israel early data (phase 4):
  - 1 dose approximately 50% Vaccine effectiveness for PCR positive 13 - 24 days post vax, similar across all age, sex, ethnic groups, a bit lower in immunocompromised and diabetics

Pfizer/BioNTech (safety data

- Preclinical (animal) and early clinical studies
  - No signs of disease enhancement
- Clinical trials
  - Reactions quite common but well tolerated, more reactogenic in younger adults, more common after second dose
  - Subset of 8000 people in the phase 2/3 trial
    - 34%, 5% and 22% experiencing moderate fatigue, fever and muscle pain respectively (after 2 doses in 16-55yo),
    - 5%, 2% and 3% experiencing severe fatigue, fever and myalgia.
    - Antipyretics (e.g. paracetamol) were used by 45% of vaccinated subjects after vaccination.
  - Randomized clinical trials follow up average 2 months post vaccination
    - 4 events: shoulder injury related to admin, others not likely to be related (lymph node swelling, arrythmia, leg paresthesia)
    - 2 deaths in vaccinated, 4 in placebo – none considered linked
- Rollout to date….no surprises.
  - US (VAERS) data >12 Million doses: No unexpected events
    - Anaphylaxis: 5/million, 90% in < 30 min
    - No disproportionate events in conditions of interest
    - Deaths in frail elderly, no increase in deaths up to 30 days post vaccination

Viral Vectored Vaccines

Viral Vector Vaccines	
Pros	Cons
Potential for single doseschedule	Previous exposure to the vector could reduceeffectiveness/efficacy,because the immune system may raise an immune response to vector rather than antigen

- A genetic sequence which codes for a component of the pathogen is delivered into human cells by a modified virus (the vector)
- This technology utilises virus's innate ability to invade and replicate within cells
- The delivered code instructs cells to make a specific protein which will protect against disease
- The **AstraZeneca/Oxford** and **Janssen** COVID-19 vaccine candidates use this technology.

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Protein Subunit Vaccines

- Protein subunit vaccines contain only a specific component(s) of a pathogen which best stimulate the immune system
- An example of a COVID-19 protein subunit vaccine is the vaccine candidate from **Novavax**

Protein Subunit Vaccines	
Pros	Cons
Well established technology with ability for large scalemanufacturing	Booster shots and adjuvantsoften required
Able to be used ifimmunocompromised	Potentially slow to develop in an outbreak setting
No risk of vaccine causing disease	

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Examples of some early Qs and As on immune.org.nz

Am I able to privately purchase a COVID-19 vaccine before I travel?

COVID-19 vaccines will be allocated according to a prioritisation schedule and will be available free of charge. This means is will not be possible to purchase a vaccine to be given early.

Is the AstraZeneca COVID-19 vaccine inferior to other COVID-19 vaccine candidates?

There has been recent media coverage suggesting the AstraZeneca COVID-19 vaccine candidate is inferior when compared to other COVID-19 vaccines. Looking beyond media headlines, the evidence available thus far does not support this. This is because it is not straight forward to compare vaccine candidates due to differences in the way the clinical trials are conducted and analysed. For example, the number and severity of COVID-19 cases in the trials are different so making direct efficacy comparisons is problematic. Professor Peter McIntyre has written a great summary on this matter available here.

Can COVID-19 vaccines be given with other vaccines?

There will need to be a two week gap between the Pfizer COVID-19 vaccine and influenza vaccines. The Pfizer COVID-19 vaccine two dose schedule should take priority over flu vaccines (i.e. patients should receive the full two dose schedule and then wait two weeks before receiving a flu vaccine). There should be a four week gap between Pfizer's COVID-19 vaccine and all other vaccines.

Can you tell me more about genetically modified organisms and vaccines?

Genetically modified organisms (GMO) are defined in section 2 of the Hazardous Substances and New Organisms (HSNO) Act 1996. Under section 2A, genetically modified organisms are defined as new organisms. The Environmental Protection Authority (EPA), if requested, can formally determine if a vaccine is, or contains, a new organism. There is a medicines-specific rapid approval pathway for any vaccines that are - or that contain - new organisms, which includes genetically modified organisms. No formal applications have yet been lodged for consideration by the EPA. We already have a genetically modified vaccine available in New Zealand for Japanese encephalitis. For more details on the application process click here. Thanks to Dr Chris Hill, EPA general manager of Hazardous Substances and New Organisms for this answer.

Effectiveness and safety

New vaccines – short development time.

I am concerned that there has not been a lot of research into the vaccine as other vaccines have a lot of research done prior to roll out. Is it safe and what are the side effects? GP

Could mRNA vaccines have more serious side effects and in particular alter the human genome in anyway? (GP)

Special groups – Elderly, Pregnancy, Children, Immunocompromised.

Science questions: Aim of the vaccine – herd immunity

- *% of immunity, if any. Would the virus be eliminated? Does it prevent death? (PN)*

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Too Fast?

- COVID-19 vaccines have been manufactured so fast, they must be skipping steps. Is this true?
  - No. COVID-19 vaccines have been produced quickly but not at the expense of skipping key steps. The accelerated timeline has been made possible because:
    - Large amounts of funding have been made available, without the usual expectation of return
    - International collaboration not previously seen
    - Running steps in parallel rather than sequentially
      - A good example of this is developing manufacturing plants before approval has been received.
      - Authorisation / licensure processes accepting clinical data as it arises in a rolling process rather than all in a single full and final dossier

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Logistics and Programme delivery

Who , When and Where

- *A clear timeline for when people will be vaccinated - this is important as it will be one of the commonest questions that we will be asked in GP "When am i going to get my vaccine" (GP)*
- *Will primary care be giving the vaccines or will there be dedicated vaccination centres? (PN)*
- *is the vaccination able to be safely given outside eg such as the car park influenza clinics last year ? GP*

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Sequencing the Roll out of COVID-19 Vaccines

It is likely that vaccines will become available in stages, which means we will need to consider the best way to sequence their delivery to provide the best protection for those who are at a higher risk of poor outcomes from COVID-19. We are preparing for three different scenarios for rolling out the vaccine, based on on whether we are able to keep COVID-19 out of our borders or whether we are dealing with community transmission.

	Scenario One Low/no community transmission *Aim: Prevent transmission*	**Scenario Two** Clusters and controlled outbreaks *Aim: Reduce transmission and protect people in close contact*	**Scenario Three** Widespread community transmission *Aim: Protect those most vulnerable to prevent illness and mortality*
Group One First group of people to receive the vaccine in each scenario	Border and managed isolation & quarantine workforce Health workforce at highest risk of exposure to COVID-19 Household contacts of the above two groups	Border and managed isolation & quarantine workforce Health workforce at highest risk of exposure to COVID-19 Population affected by the outbreak	Older people (aged care residents, Māori and Pacific people, then others aged over 65 years) People under 65 with underlying conditions People living in long-term residential care settings
Group Two Second group of people to receive the vaccine in each scenario	High risk frontline health workforce High risk frontline public sector and emergency services	High risk frontline health workforce High risk frontline public sector and emergency services	High risk frontline health workforce High risk frontline public sector and emergency services Remaining frontline health workforce
Group Three Third group of people to receive the vaccine in each scenario	People in the community, including: • Older people • People with underlying conditions At risk health and social services workforce	People in the community, including: • Older people • People with underlying conditions At risk health and social services workforce	Remaining health and public sector workforce Other population groups

Ministry of Health STILL REFINING

Unite against COVID-19

17 December 2020 covid19.govt.nz

Logistics and Programme delivery

Cold Chain issues

- *Are we getting the vaccine in NZ that needs to be kept at very cold tempatures and how will this practicality happen? GP*
- *Vaccine storage. We have a standard size fridge with all our vaccines in.* (PN)

Vaccine delivery – practicalities

- *The logistics of using the multi-dose vial in different situations e.g. drive up vaccinations at pharmacies aren't as suitable in this situation (Pharm)*
- *Consider some flexibility for administration. (PN)*

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Logistics and Programme delivery

Vaccine Recording and administration. NIS/CIR/WTF

- *What IT platform is planned to capture immunisation status. NIR as it currently stands is not user-friendly or in real-time up to date status GP*
- *resources: please print a tear off sheet we can give to patients re side effects and whit to do/who to call PN*

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Eligibility and Equity

Equity

- *ensuring access to Maori and high needs groups isn't impacted by over complicated registration/location factors GP*

Eligibility and sequencing.

- Health professional eligibility
- *Why NZ does not follow other countries example of immunising health care workers in the first group and before the flu season? GP*
- *Frontline health workers should be done first (PN)*

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Communication / Vaccine hesitancy

To Primary Care

*Regular updates on vaccine testing and rollout from **ministry of health** on media and news would be appreciated. Communication during lock down was superb but has tailed off GP*

To the Public – not a great deal of concern about anti-vaxx etc

I understand it is an RNA vaccine. Can you please explore the implications in such a way as to convince the anti-vaxers on the internet that their concerns are unfounded PN.

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Primary Care capacity and workload

Significant concerns from all professional groups.

How are GPs going to cope with the extra work load in an already stretched primary care sector! We will need people to help us do this. (GP)

PHC nurses are fighting for pay parity with DHB nurses. Will we get paid the same as authorized vaccinators giving this vaccine in other areas like a covid vaccinator center? (PN)

Workload in specific areas – eg other immunisation programmes

How will we manage BAU plus flu /(non freezer)covid vaccines in our clinics - staff , waiting room space (knowing that 30 min direct observation is needed post vax), fitting in other care (GP)

Specific Lessons from 2020 Flu immunisation

Disorganised rollout and GPs being blamed like the flu issues in 2020 (GP)

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He Waka Eka Noa

Appreciative inquiry

- Listening to other voices (different to our own)
- There is often value in the past and the present
- Message to MoH
  - Appreciation of the work Primary Care in 2020 (2018/ 2019/ 2021…)
- Message to Primary Care
  - The MOH / DHBs / PHO are on our team too

Things are more complex than we think

- Predictably unpredictable shit happens
- Look for local innovation in change

Careful and common sense implementation leads to better results

H2F – Hindsight to Foresight

Dowell AC, Menning L, MacDonald N, Turner N. An evolution in thinking to support the post 2020 global vaccine strategy: The application of Complexity and Implementation Science. Vaccine (2019) Volume 37, Issue 31, 4236-4240 https://doi.org/10.1016/j.vaccine.2019.05.096

www.immune .org.nz

Currently adding Qs and As rapidly on our website as new issues arise

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