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COVID-19 UPDATE: EVERYTHING YOU NEED TO KNOW ABOUT VACCINES

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Recording and Presentation Slides: https://ubccpd.ca/covid-19-update-everything-you-need-know-about-vaccines

Disclaimer: Information on COVID-19 is changing rapidly and much of the research is preliminary. Assessment and management protocols are suggestions only; they do not take the place of clinical judgement. Please check with your own health authorities and local medical health officers as policies and support for the suggested approaches to patient care may vary between regions.

This summary was prepared by Dr. Birinder Narang and not by the speakers.

Webinar Summary

COVID-19 Vaccine Platforms

- **Vaccines in development**
  - Traditional
    - Weak virus - attenuated
    - Inactivated whole virus particle (ie flu vaccine)
    - Isolated piece of virus (subunit)
  - Genetic engineering
    - DNA – put into plasmid
    - mRNA – into lipid nanoparticle (ie Spike Protein Vaccine)
    - Embed DNA in adenovirus or other viral vector
- **Vaccine Development**
  - Traditional development (10-15 years)
    - Academic & pre-clinical research,
    - Phase 1 (safety)

        - Phase 2 trials (safety/immunogenicity)
        - Phase 3 trials (efficacy)
    - COVID 19 Vaccine
        - Lots of overlap in phases, including preclinical, phase 1-3 happening in overlap fashion
        - Willingness of regulatory bodies, ethics board to more rapidly approve covid related projects has helped
        - Able to deploy large scale manufacturing at same time as phase 2/phase
            - Taken on at risk – as if unsuccessful, may have product that will not be used
- **Canada Agreements (Company, vaccine type, Clinical Phase, # doses, reported efficacy)**
    - Pfizer/BioNTech – RNA, Phase 3, ≥20 million doses, 95% doses after 2 doses
    - Moderna – RNA, Phase 3, ≤ 56million doses, 95% doses after 2 doses (92% after 1)
    - Oxford/Astra Zeneca, Viral Vector, Phase 3 ≤ 20 million doses (70% after 2 doses)
    - Johnson & Johnson, Viral Vector, Phase 3, ≤ 38 million doses (66% after 1 dose)
        - Data from press release for moderate to severe disease
    - Novavax, Subunit, Phase 3, ≤ 76 million doses, 89% (2 doses)
        - Data from press release
- Outstanding Questions - We don't know the answers
    - Mechanism of protection
    - Duration of protection, including 1 vs 2 doses
    - Effectiveness against new variant strains
    - Safety, immunogenicity and effectiveness in populations outside trials
        - Extremes of age
        - Multiple/severe comorbidities
        - Immunocompromised
        - Pregnancy and breastfeeding

Question & Answers

Q: What is the ability to transmit, if fully vaccinated?

A: Wasn't looked at detail in Pfizer/Moderna trials. The primary endpoint was symptomatic COVID-19 disease, lab confirmed COVID + symptoms. In Moderna trial, there is some data that at time of 2nd dose, in participants with asymptomatic infection, those rates were lower compared to placebo (no formal statistical analysis). Some data from Oxford trial shows there may be some reduction in transmission (patients were swabbed weekly).

Q: US CDC is saying if vaccinated, don't have to quarantine, will this happen here?

A: No plan right now to change guidance for people who are vaccinated. Right now, even if you are vaccinated, if you come to Canada through international travel, you will be subject to quarantine. Even, if you are vaccinated, but are identified as a close contact of someone who tests positive for COVID19, you will still have to self-isolate. Until we have evidence vaccines prevent transmission, vaccination is only providing personal protection.

Q&A: Special Populations

Q: Are you eligible for vaccination if you are taking Prednisone? Biologics? If you have Diabetes?

A: People from immunocompromised states, breastfeeding and pregnant women, are rarely in initial clinical trials. This is not a live virus vaccine. We do give other non-live vaccines to pregnant patients/immunocompromised patients. Concern is usually with live virus vaccines. You cannot get COVID from this vaccine. Have to balance the risk of getting vaccinated vs getting infected by COVID19, as we are still in the midst of the pandemic, we are all still at risk of getting COVID19. You can tell these populations, that they can get vaccinated. On the ground in Vancouver, patients with immunocompromising conditions are being told that the risk is that the efficacy may be less but do believe that it is considered safe.

Q: How is it acceptable that the SOGC (Society of Obstetricians & Gynecologists of Canada) would offer the vaccine to pregnant women, if there is no research on them?

A: Another school of thought is that it is unethical to not offer pregnant vaccination, knowing they are at higher risk, knowing there is no evidence of harm, and may provide benefit. We know pregnant women are at higher risk of severe disease from COVID19, so there is not good justification to not offer vaccine to them.

Pregnant/Breastfeeding/Immunocompromised – when you consider theoretical and real risks, the risk from COVID19 is real in this population. For all other vaccines we have, we vaccinate using non-live vaccine.

New guidelines have come out to give live Varicella vaccine to pediatric solid organ transplant patients in the last year, that is the direction we are going.

Q: What about prenatal patients? NACI says to wait 28 days after 2nd dose before falling pregnant, UK says 2 months, US says no need to wait?

A: With MMR we ask patients to wait 4 weeks, prior to trying to conceive, as it is a live vaccine. NACI also did add that if you do fall pregnant in that time period, they do not recommend an abortion. Maybe the concern is around the 1st Trimester exposure, but an obvious risk/reason is not apparent to the panel. It does seem that there is data coming out of the ongoing vaccine trials, that participants did fall pregnant, and no safety signals have come out of it to date.

Q: Any special considerations for previous vaccine reaction, ie transient Guillain-Barre or transient oculomotor palsy from influenza vaccine?

A: Only absolute contraindication is anaphylaxis to previous dose of this vaccine or to a known constituent of this vaccine. Other reactions to different vaccines, is not applicable to this.

Q: Will children get the vaccine?

A: Vaccine are not licensed for children. Pfizer is for >= 16 years old, & Moderna >=18 years old. It is important to point out, children get infected less, transmit less, and likely get it from adults. This is why Public Health has had a lot of confidence in keeping schools open, not seeing transmission through schools. Clinical trials have started in children on these vaccines, so vaccines should be available soon for younger age groups.

Q&A: 2nd Dose

Q: What if I had previous Moderna Vaccine, but only Pfizer is only available for my 2nd dose? And vice-versa.

A: Theoretically, if it is the platform (ie mRNA vaccine), it should be okay. No evidence from trials about mixing doses yet to inform this. NACI does say if you don't know what their first shot is, then can give what you have available. Practically, in BC, every dose is being recorded and we are matching 1st dose and 2nd dose. If, for example, you come from another province, and don't know what you got, you will be offered what is available there.

Q: What to expect from 2nd dose?

A: Most common reaction is local reaction, mild flu-like symptoms, not a lot of systemic reactions. Patients are being advised to do COVID online assessment tool if symptoms persist. There is an adverse event reporting form which is reviewed by Medical Health Officer. Overall safety profile is good, some allergic reactions, but this is expected. We have seen patients who were vaccinated, but did contract COVID19 around the same time (ie were asymptomatic at time of vaccination, or contracted it prior to being able to generate immune response from vaccine).

For the Modernavaccine trials, supraclavicular lymphadenopathy has been seen as a side effect. We are seeing a sore red arm, up to 7-8 days later. Have also seen cases of patients being diagnosed with cellulitis (but this is very rare with vaccination). To differentiate cellulitis vs vaccine reaction, clinical context is important, cellulitis rare, and inflammatory reaction is common. Cellulitis may have fever, but a local reaction should not have a fever.

Q: Is it okay to delay 2nd dose?

A: Ethical decision was made to give more first doses, based on limited supply. Interval between doses has been extended to 42 days in BC now. Public Health feels very comfortable about this. The trial data does include participants who got their 2nd dose at 42 days. The analysis at 12-14 days after first dose

there is ~92% protection. Do not believe that protection will drop from that 21→28→42-day interval. Some data emerging that longer intervals lead to better booster immune response. Some jurisdictions are extending their 2nd dose to beyond 42 days (up to 12 weeks in Quebec). In the long term, for most vaccines, the longer interval, the better the longer-term response as well.

Practically speaking, 1 dose in Long Term Care settings in Vancouver has shown a dramatic decrease in spread of COVID19. Evidence from remote communities, quickly 1 dose of vaccine has decreased transmission in clusters of cases. People should not be concerned if the second dose is delayed, even if it is delayed beyond 42 days.

Q & A – Rollout, Ongoing & Future Considerations

Q: Once more vaccines are available, how will you approach the situation if multiple choices available?

A: Next likely licensed product will be Astra Zeneca, in Canada. In BC, at a vaccination clinic, you will be invited and offered a specific product, the decision will be made at higher level. We don't often have choices in our publicly funded vaccine programs. There may be preferences for special groups, but not known yet. If offered a vaccine, take it!

Q: How will patients > age 80 find out about their vaccine? What is the role of the Family Physician?

A: Phase 2, and population age > 80, that includes patients over age 65 in Indigenous populations. There will be planning for mass vaccination clinics, and this is still dependent on supply. Plans are dynamic and evolving right now. This is a provincial campaign, goal to avoid disparities throughout the province.

Family Physicians don't have vaccine in clinic right now due to storage requirements of available vaccines. Family Physicians will likely be invited to help in vaccination process, along with other vaccine providers at mass vaccination clinics.

Q: What is the efficacy of the Novovax Vaccine? When are we getting that in BC?

A: Press release in the last week, 89% efficacy with 2 doses of their vaccine, against symptomatic COVID disease. Awaiting peer-reviewed data but looks promising.

Q: Will vaccine efforts be rendered ineffective due to variants?

A: We have been expecting to see variants, it does seem to mutate slower than influenza. Will likely need to tweak existing vaccines in the future. Only time will tell how effective vaccines will be against these variants. Already seeing some emerging data, ie Johnson & Johnson looked to be good at protecting against moderate-severe disease against South African Variant, where Oxford wasn't, but it looked at all disease. So not a head-to-head comparison. Goal of vaccination program is to reduce severe disease, not necessarily get case count to 0.

Q: Will we see a new COVID vaccine annually, like influenza?

A: As variants emerge, companies are adapting. As they have the genetic sequence, and the platform needed, can use that to manufacture a new vaccine. We don't know whether we need a new vaccine every year yet, don't know if current vaccines will have an impact on the evolution of the virus.

Q: Dr. Bonnie Henry has been announcing BC is not getting the vaccine doses that we were promised. Why?

A: There has been a delayed roll-out. Canada has signed more contracts for per-capita doses than anywhere in the world, but we didn't know when they would be ready. We approved Pfizer, before USA did, but we have less per capita than the USA. All of our Pfizer supply is coming from Europe though, not USA. Pfizer European plant slowed down as they were renovating, to produce larger quantities. Federal Government says Pfizer is committed to fulfilling delivery target before end of March.

Q: Have we seen anaphylaxis? Is one vaccine safer than another?

A: Have seen a couple of anaphylactic reactions in dose #1 but have seen more in dose #2. If they have an anaphylaxis to an unknown source, or to Polyethylene Glycol, the immunizers take precaution, but have still been vaccinating. Have consulted with allergists, can't do allergic testing right now, as there are not enough extra doses. Advice that has been given is to try receiving it and monitor for up to an hour after. Still need more information needed in detail re: allergens. Risk of getting COVID is higher than risk for anaphylaxis.

Q: Vaccine Hesitancy? Any tips?

A: Timeline has been accelerated by prioritization, jumping the queue and cutting through red tape. No short cuts seen in robustness in detail of the studies. We don't know long term safety data, but we know from past vaccine knowledge, adverse effects happen shortly after vaccine. We are not seeing a lot of vaccine hesitancy right now. Number 1 reason that someone chooses to get vaccinated is because their health care provider that they trust, recommended it to them.

Thanks to the speakers on the video:

- Panelist: **Patty Daly**, VP, Public Health and Chief Medical Health Officer for VCH
- Panelist: **Manish Sadarangani**, Director, Vaccine Evaluation Center at BC Children's Hospital Research Institute
- Panelist: **Charmaine Enns**, Medical Health Officer, Island Health
- Panelist: **Julie Bettinger**, Associate Professor, Vaccine Evaluation Center, BC Children's Hospital Research Institute and UBC
- Panelist: **Nomi Mate**, Public Health Nurse
- Moderator: **Simon Moore**, Family Physician, UBC CPD Medical Lead