Health Canada and the Public Health Agency of Canada
Santé Canada et l'Agence de la santé publique du Canada
Canada

Preparing for pediatric COVID-19 immunization and adult booster doses

Webinar

November 17, 2021

Objective and Agenda

To inform and support planning and administration of COVID-19 vaccination for children 5 to 11 years of age as well as multi-product clinics

- Moderator
  - Ms. Katie Rutledge-Taylor, Nurse Manager/Epidemiologist, PHAC
- Overview of Pfizer-BioNTech vaccine for children 5 to 11 years of age and other upcoming vaccination campaigns
  - Dr. Bryna Warshawsky, Medical Advisor, PHAC
- Managing pain and needle phobia in children
  - Dr. Kathryn Birnie, Clinical Psychologist and Assistant Professor, University of Calgary
- Pediatric and multi-product vaccine administration models
  - Ms. Alexandra Nunn, Nurse Epidemiologist, PHAC

Conflict of interests

- Ms. Rutledge-Taylor has no conflicts of interest to declare.
- Dr. Warshawsky has no conflicts of interest to declare.
- Dr. Birnie has no conflicts of interest to declare.
- Ms. Nunn has no conflicts of interest to declare.

OVERVIEW OF:

PFIZER-BIONTECH VACCINE FOR 5-11 YEAR OLDS AND PEDIATRIC CLINICS

ADULT BOOSTER DOSES

Pediatric population

- There are 4.7 million children aged 0 to 11 years in Canada
  - 12.5% of population

- There are 2.9 million children in the 5 to 11 year age cohort
  - 62% of the population less than 12 years of age

Data source(s): Statistics Canada July 1st 2021 population estimates; https://health-infobase.canada.ca/covid-19/vaccination-coverage/

Children and COVID-19 – Data up to October 31, 2021

	Numbers and monthly rates in children less than 12 years of age		Percent of all events that are in children less than 12 years of age (12% of the population)		Percent of cases in children less than 12 years of age that result in severe outcomes	
	Course of the outbreak	**October 1 to 31, 2021**	**Course of the outbreak**	**October 1 to 31, 2021**	**Course of the outbreak**	**October 1 to 31, 2021**
Cases	**192,072** 212/100,000	18,824 395/100,000	11.3%	23.8%	N/A	N/A
Hospitalized	**1076** 1.2/100,000	98 2.1/100,000	1.2%	2.3%	**0.56%** 1/179	0.52% 1/192
ICU admissions	**129** 0.1/100,000	12 0.3/100,000	0.8%	1.5%	**0.067%** 1/1,489	0.064% 1/1,569
Deaths	**11** 0.01/100,000	1 0.02/100,000	0.04%	0.2%	**0.0057%** 1/17,461	0.005% 1/18,824

Total number of case of Multisystem Inflammatory Syndrome in Children (MIS-C) in children less than 12 years of age: **227** cases based on 7 provinces until October 30, 2021

Pediatric formulations

Pfizer-BioNTech Comirnaty

- Authorized in mid-November 2021
- 10 microgram dose (one third the adult/adolescent dose)
- A new formulation:
  - Easier to draw up the lower pediatric dose (0.2 ml)
  - Adult/adolescent formulation contains phosphate buffers; replaced with Tris/sucrose in the pediatric formulation to support longer time in the refrigerator (10 weeks, instead of the 31 days in adult/adolescent formulation)
- Submission for **6 months to less than 5 years** expected later in 2021 or early 2022 (3 micrograms)

Moderna Spikevax

- Submitted for authorization for **6 to 11 years of age** on November 16, 2021
  - Will use current formulation
  - Dose is expected to be 50 micrograms (0.25 ml), so half of the adult/adolescent dose
- Submission for **6 months to less than 6 years** expected in 2022

Pfizer-BioNTech Comirnaty

	Adult/adolescent formulation	Pediatric formulation
Age	12 years of age and over	5 to less than 12 years
Color	**Purple**	**Orange**
Diluent	**1.8 ml**	**1.3 ml**
Dose	**0.3 ml** (30 micrograms); 2 doses	**0.2 ml** (10 micrograms); 2 doses
Doses per vial	**6**	**10**
Potential allergens	Polyethylene glycol (PEG)	• Polyethylene glycol (PEG) • Tromethamine (Tris. Trometamol)
Post-dilution time Can be at room temperature	6 hours	• 12 hours
Ancillary supplies	Low dead volume needle/syringe	Low dead volume needle/syringe
Storage	• Ultra-frozen until expires (as written on label or with extension) • Frozen for 2 weeks • Refrigerator for 31 days • Room temperature: 2 hours pre-puncture; 6 hours post-puncture (post-dilution)	• Ultra-frozen until expires (manufactured date on the label, so add 6 months) • Do not store in the freezer at -25^{0}C to -15^{0}C • Refrigerator for 10 weeks • Room temperature: no more than 12 hours before dilution and no more than 12 hours post dilution
Transport	• Ultra-frozen or frozen • If thawed, 12 hours maximum of transport time	• Ultra-frozen • Thawed, as required and in keeping with other storage requirements

Pfizer-BioNTech Overview of Clinical Trial for 5-11 year of age

Component	Description	No. active vaccine	No. placebo
Safety – original phase 2/3 cohort	• Median follow-up 3.3 months from Dose 2	**1518**	**750**
Safety – additional cohort based on FDA request	• Median follow-up 2.4 weeks	**1591**	**788**
Immunogenicity	Immunobridging to 16 to 25 year olds (30 microgram dose) from the original adolescent/adult trial at one month after second dose	**264** 5-11 year olds (10 micrograms) **253** 16-25 year olds (30 micrograms)	**130** 5-11 year olds **45** 16-25 year olds
Immunogenicity against Delta	Supporting analysis in 5 to 11 year olds	**34**	**4**
Efficacy	Evaluable efficacy population after exclusions from phase 2/3 cohort; not previously infected	**1305**	**663**

Vaccines and Related Biological Products Advisory Committee October 26, 2021 Meeting Announcement - 10/26/2021 - 10/26/2021 | FDA

Pfizer-BioNTech, Comirnaty – Trial for 5 to 11 year olds - Results

Safety:

- ~3100 children with active vaccine
  - 3.3 months and 2.4 weeks of follow-up
  - Compared to 16 to 25 year olds (30 micrograms), slightly more local reactions (swelling and redness) and less systemic reactions
  - No serious adverse events; no myocarditis but small sample size not adequate to assess this

Immune response (immunobridging)

- **Antibody response similar to adolescents and adults 16 to 25 years of age**, where the vaccine is known to work very well. Geometric mean titres (neutralization assay) at one month after the second dose:
  - 5 to 11 year olds (10 microgram dose): **1,197**
  - 16 to 25 year olds (30 microgram dose): **1,147**

Efficacy:

- Preliminary information showed **90.7%** (95% CI: 67.7 to 98.3%) efficacy against symptomatic COVID-19 during the time when the Delta variant predominated

Vaccines and Related Biological Products Advisory Committee October 26, 2021 Meeting Announcement - 10/26/2021 - 10/26/2021 | FDA

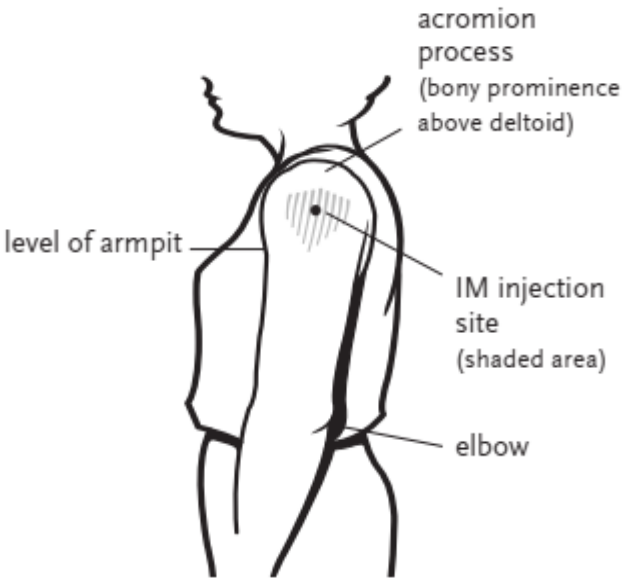
Specific recommendations of the National Advisory Committee on Immunization (NACI)

- The Pfizer-BioNTech vaccine **may be offered** to children 5 to 11 years of age
- The **interval** between the first and second doses should be at least 8 weeks
- As a precaution, should not routinely give the COVID-19 vaccine at the same time as, or within 14 days before or after, **a non-COVID-19 vaccine**
  - Would not apply to post-exposure prophylaxis with another vaccine if that was needed (e.g. vaccines for measles, hepatitis A, hepatitis B, chickenpox, rabies after an exposure)
- **Children with previous:**
  - COVID-19 may be vaccinated once no longer infectious and symptoms resolved;
    - may receive two doses with at least an 8 week interval; number of doses under review by NACI
  - Multisystem inflammatory syndrome in children (MIS-C) may be vaccinated once symptoms resolve or 90 or more days have passed since diagnosis, whichever is longest
- **Children with previous myocarditis/pericarditis:**
  - Unrelated to COVID-19 vaccine, should consult clinical care team and follow their advice. If no longer under care, may be vaccinated.
  - After a COVID-19 vaccine, should not receive another COVID-19 dose at this time
- No additional or booster dose recommendations

Vaccination in children 5 to 11 years of age

- Intramuscular vaccine in the deltoid
  - Alternative location is the anterolateral thigh
- Needle length
  - 1 inch (2.5 cm) will work for either site

Intramuscular (IM) injection site for children and adults



Give in the central and thickest portion of the deltoid muscle – above the level of the armpit and approximately 2–3 fingerbreadths (~2") below the acromion process. See the diagram. To avoid causing an injury, do not inject too high (near the acromion process) or too low.

Canadian Immunization Guide:
[Vaccine administration practices: Canadian Immunization Guide - Canada.ca]

Immunization Action Coalition:
https://www.immunize.org/catg.d/p2020.pdf

National Advisory Committee on immunization (NACI) recommendations for additional and booster doses for adults and adolescents

- Additional doses recommended for those with immunocompromising conditions at least 28 days from last dose (September 10, 2021)
- Booster doses for long-term care residents or seniors in living in other congregate settings (September 28, 2021)

- **Booster dose recommendations October 29, 2021**
- **At least 6 months from initial series**
- **Should be offered:**
  - Long-term care residents or seniors living in other congregate settings
  - Adults 80 years of age and older
- **May be offered:**
  - Adults 70 to 79 years of age;
  - Viral vector vaccines - people who received two doses of the AstraZeneca Vaxzevria/COVISHIELD vaccine or one dose of the Janssen vaccine;
  - Adults in or from First Nations, Inuit and Métis communities; and
  - Adults who are frontline healthcare workers who have direct in-person contact with patients and who were vaccinated with a very short interval.

Booster and Additional Doses for the General Population

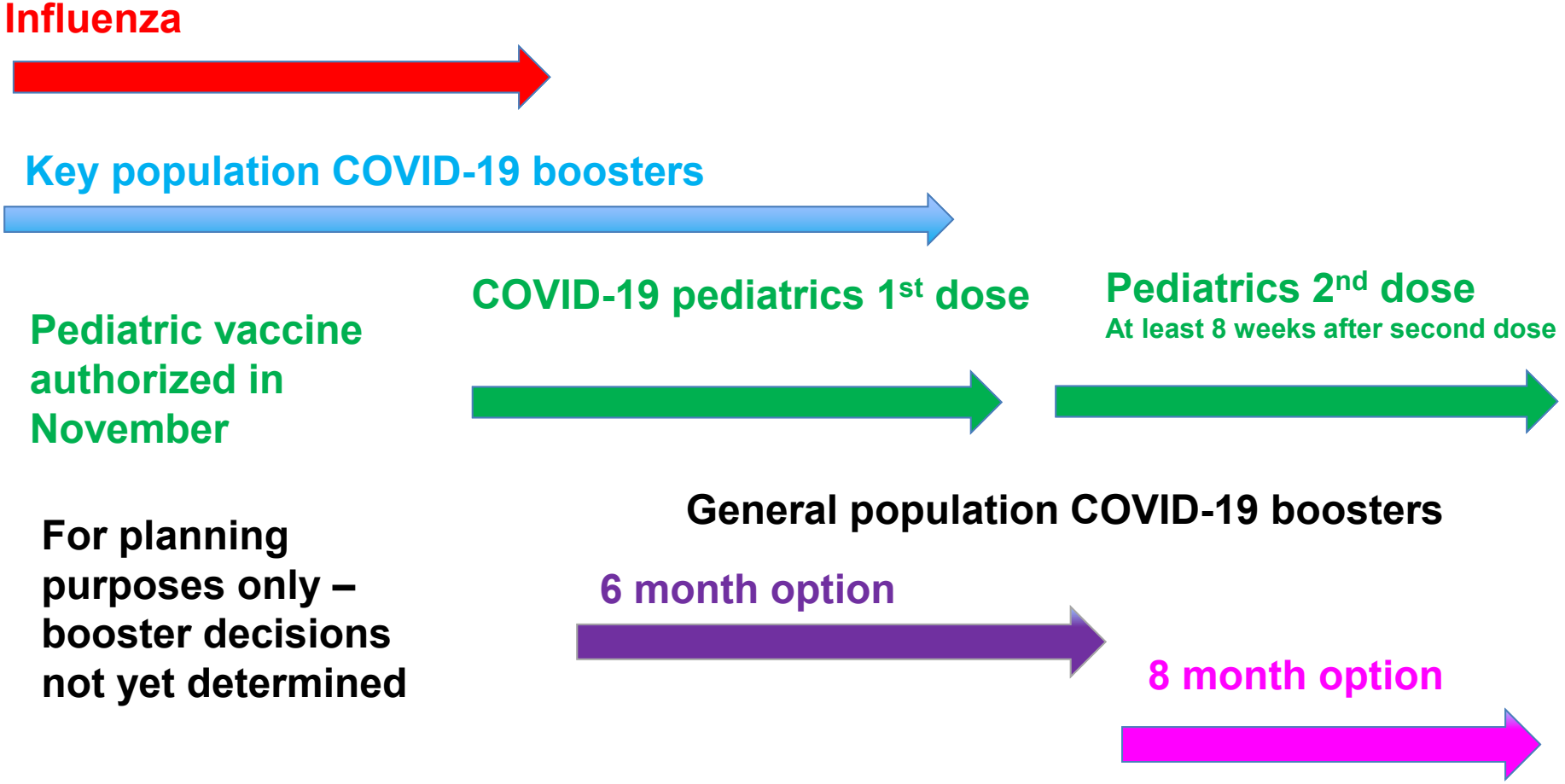
Timing of second dose and when adults and adolescents might receive boosters, depending on planning and NACI recommendations

Second dose	6 months from second dose	8 months from second dose	Numbers	Percent
January	July	September	105,716	<1%
February	August	October	371,555	2%
March	September	November	159,864	1%
April	October	December	242,664	1%
May	November	January 2022	977,184	5%
June	December	February 2022	8,898,132	41%
July	January 2022	March 2022	9,342,170	43%
August 1-14	February 2022	April 2022	1,550,910	7%

Source: Provincial/territorial data provided by special request as of August 14, 2021
Note: Excludes AB

Potential timing of immunization campaigns

For consideration and planning purpose only



Pfizer-BioNTech Comirnaty Summary of Use

November 19, 2021

Population	Formulation Diluent volume	Dose	Recommended Schedule
Initial series for 12 years of age and over *Not moderately to severely immunocompromised*	Adult/adolescent 1.8 ml of diluent	**0.3 ml** (30 mcg)	• **Two doses** • 8 week interval between first and second dose considered optimal
Initial series for 12 years of age and over for moderately or severely immunocompromised*	Adult/adolescent 1.8 ml of diluent	**0.3 ml** (30 mcg)	• **Three doses** • At least 21 days between doses 1 and 2, and 28 days between doses 2 and 3 • Longer intervals may result in a better immune response but may result in being susceptible for longer between doses
Booster dose for 18 years of age and over *If currently eligible for a booster dose*	Adult/adolescent 1.8 ml of diluent	**0.3 ml** (30 mcg)	• **One dose** • At least 6 months from completion of initial series
Initial series for children 5 to 11 years of age	Pediatric 1.3 ml of diluent	**0.2 ml** (10 mcg)	• **Two doses** • At least 8 weeks between first and second dose

Note: * For immunocompromised, booster (dose after third dose) schedule to be determined.

Moderna Spikevax Summary of Use

November 19, 2021

Population	Dose	Schedule
Initial series for 12 years of age and over *Not moderately to severely immunocompromised*	**0.5 ml** (100 mcg)	• **Two doses** • 8 week interval between first and second dose considered optimal
Initial series for 12 years of age and over for moderately or severely immunocompromised*	**0.5 ml** (100 mcg)	• **Three doses** • At least 28 days between doses 1 and 2, and 28 days between doses 2 and 3 • Longer intervals may result in a better immune response but may result in being susceptible for longer between doses
Booster dose for those 70 years of age and over, and for long term care residents and seniors living in other congregate settings	**0.5 ml** (100 mcg)	• **One dose** • At least 6 months from completion of initial series
Booster dose for 18 to less than 70 years of age *If not in row above and if currently eligible for a booster dose*	**0.25 ml** (50 mcg)	• **One dose** • At least 6 months from completion of initial series

Note: * For immunocompromised, booster (dose after third dose) schedule to be determined.

MANAGING PAIN AND NEEDLE PHOBIA IN CHILDREN

PEDIATRIC AND MULTI-PRODUCT IMMUNIZATION CLINIC PLANNING

Options for administration of pediatric vaccines

- School-based clinics
  - During school
  - After school or on weekends
- Large fixed community clinics
- Pop-up mobile clinics, mobile teams
- Drive-through clinics
- Health care providers' offices
- Pharmacies

Courtesy of Alberta Health Service, Edmonton Zone

Considerations: COVID-19 clinics for children

Environment

- Schedule appointments to avoid large crowds, long waits
- Minimize noise (avoid music)
- Budget for materials and supplies to adapt environment for children:
  - Decorations and signage
  - Privacy
  - Distractions at stations
- Consult with Child Life Specialists or other experts to advise on environmental considerations (e.g., private, relaxing space for children who are highly anxious or have developmental disabilities)
- Security

Immunization rate

- Lower rate expected
- Vaccinate siblings together if eligible, and offer to vaccinate the least fearful sibling first
- Encourage staff to take their time

Training

- How to manage pain and needle fears and make children comfortable
- Age-appropriate distraction techniques
- Supporting children with developmental and/or emotional needs
- How to respond:
  - Child attends with non-parent/guardian
  - Issues requiring child protection services have been identified
  - Adverse events in children

Considerations: School-based clinics

- ✓ Collaborate with school administrators and community
  - Expectations, roles and responsibilities
  - Maintain continuity / limit disruption of essential school functions
  - Clinic flow while maintaining public health measures
  - Determine whether parents can attend with child for vaccination in school
  - Available equipment
  - Security
- ✓ Communicate with parents and children about vaccination options
  - Educate parents and families about how to manage pain and fear related to vaccination
  - Considerations for children who may need extra support (parent attends school clinic, or family goes to another clinic location where they can attend)
- ✓ Getting informed consent
  - Mechanisms for parents to have questions answered
  - Consider reduce reliance on paper-based consent forms carried by children
  - Ensure written materials are available in languages appropriate to the school
  - On consent form, obtain multiple contact numbers for parents/guardians, consider collecting weight and date of weight and a question about child's past response to needles/vaccinations
- ✓ Logistics
  - Vaccine ordering, transportation of supplies, human resources
  - Processes to identifying students
  - Post-vaccination waiting period can be done in classroom
  - Debriefing

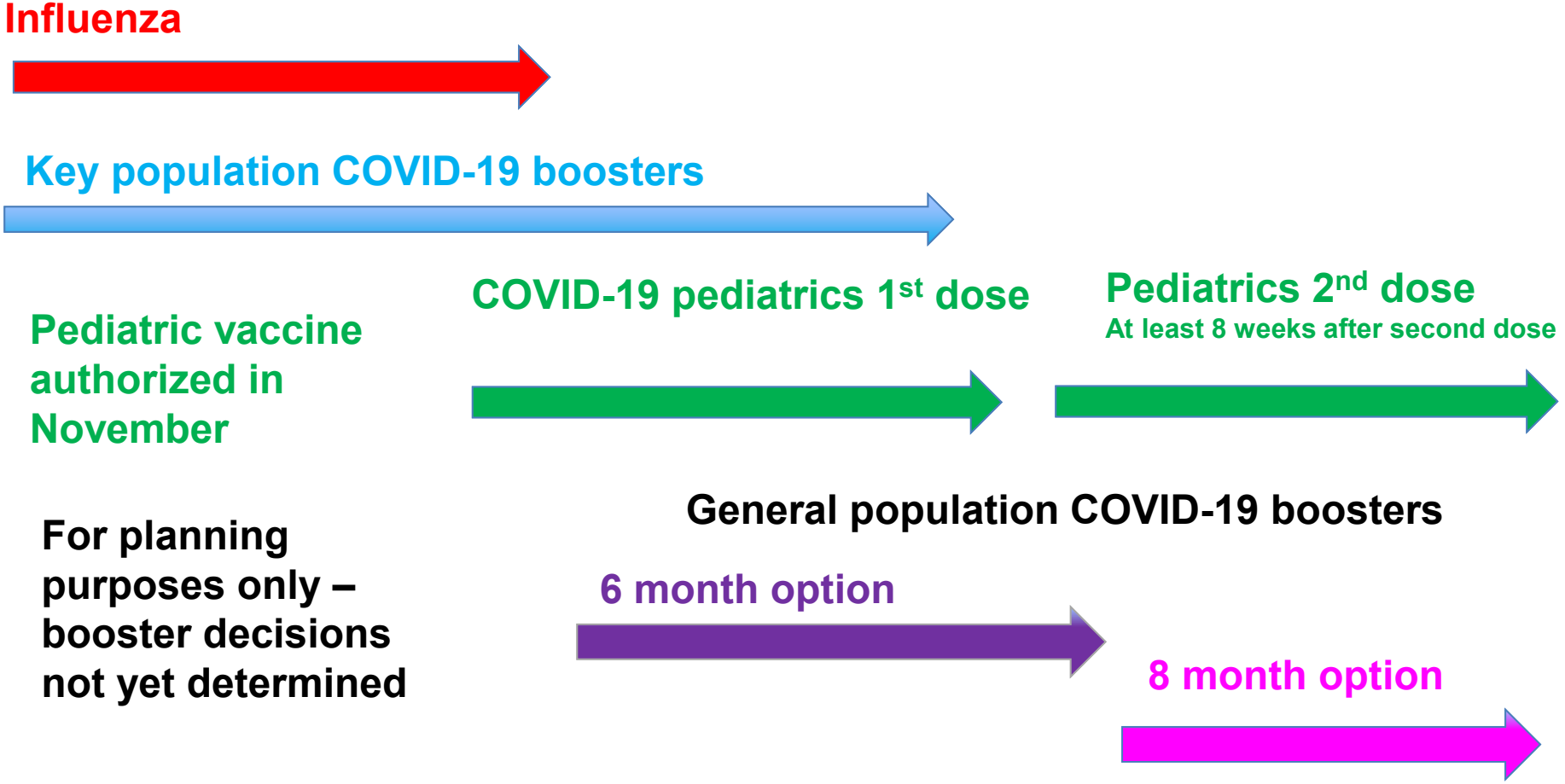
Immunization process for pediatric clinics

Pre-immunization	Immunization	Post-immunization
• Promote pre-registration to avoid large groups and long wait times • Inform parents in advance about pain management and comfort options	• Training and communication tools for immunizers • Pain management techniques (refers to Immunize.ca resources, CARD system, etc.) • Referrals to alternate clinic options if vaccination cannot be completed at this visit • Managing pediatric vaccine dosing errors	• Infection prevention and control considerations • Tokens of congratulation • After-care instructions • Instructions regarding second dose

MULTI-PRODUCT CLINICS

Potential timing of immunization campaigns

For consideration and planning purpose only



Advantages and challenges of multi-product clinics

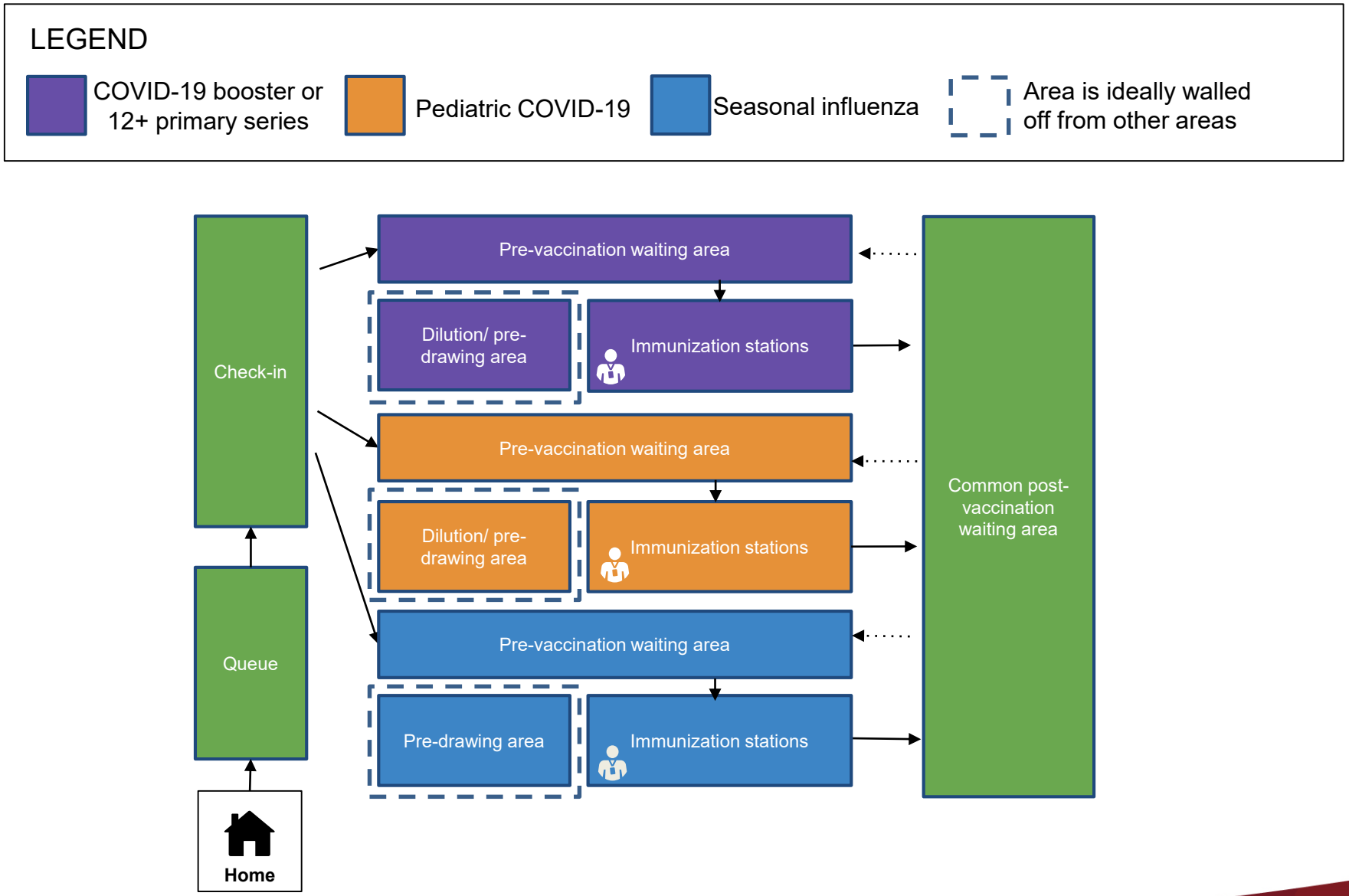
Advantages

- More convenient for the public
- May increase coverage for all vaccines being offered
- Requires fewer health human resources than separate clinics

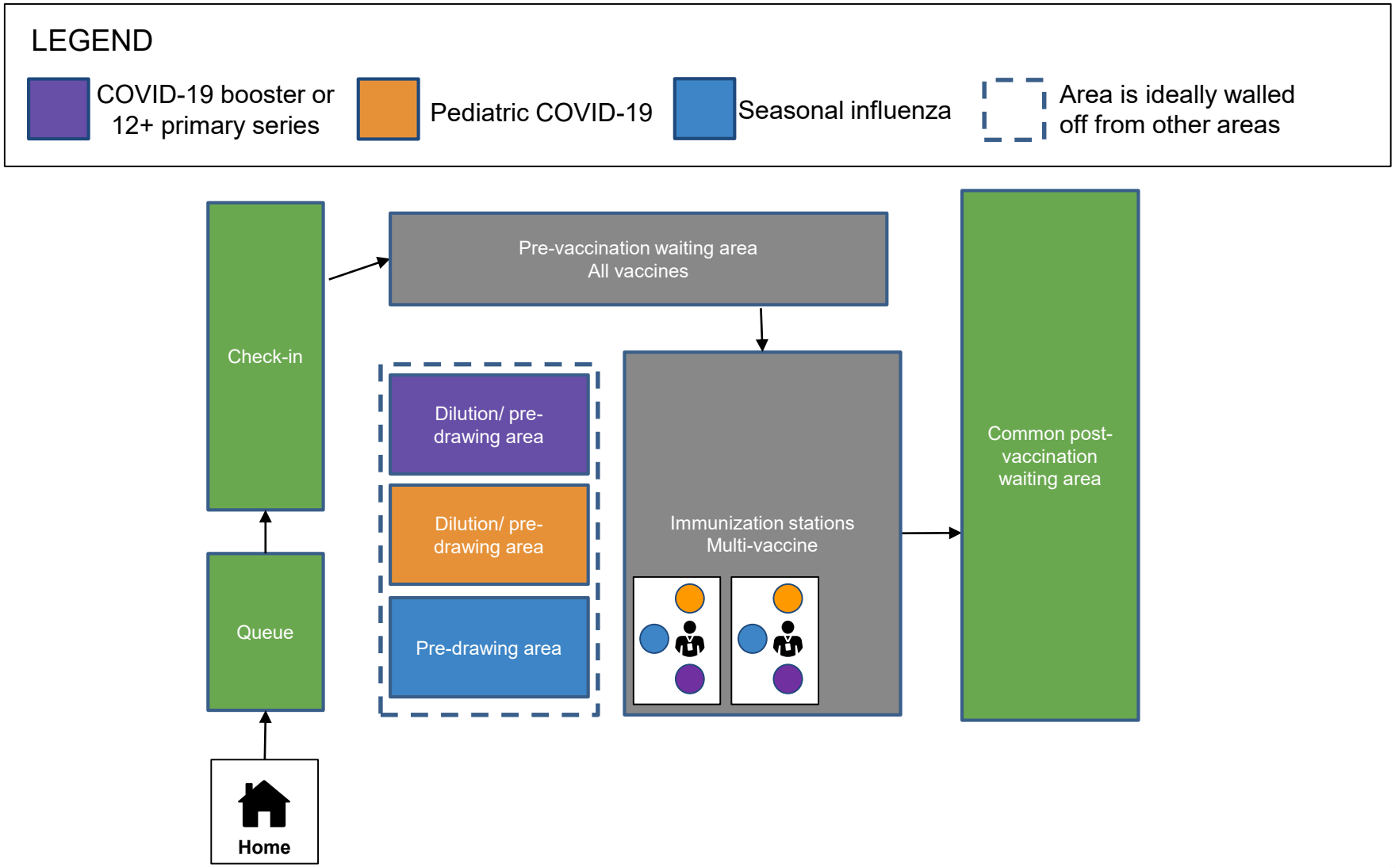
Challenges

- The operation of each clinic is more logistically complex
- Increased risk of administration errors, with potential health consequences for the individual and risk of reducing public confidence in mass vaccination campaigns and vaccination more broadly
- Multiple vaccination campaigns at the same site may lead to public confusion

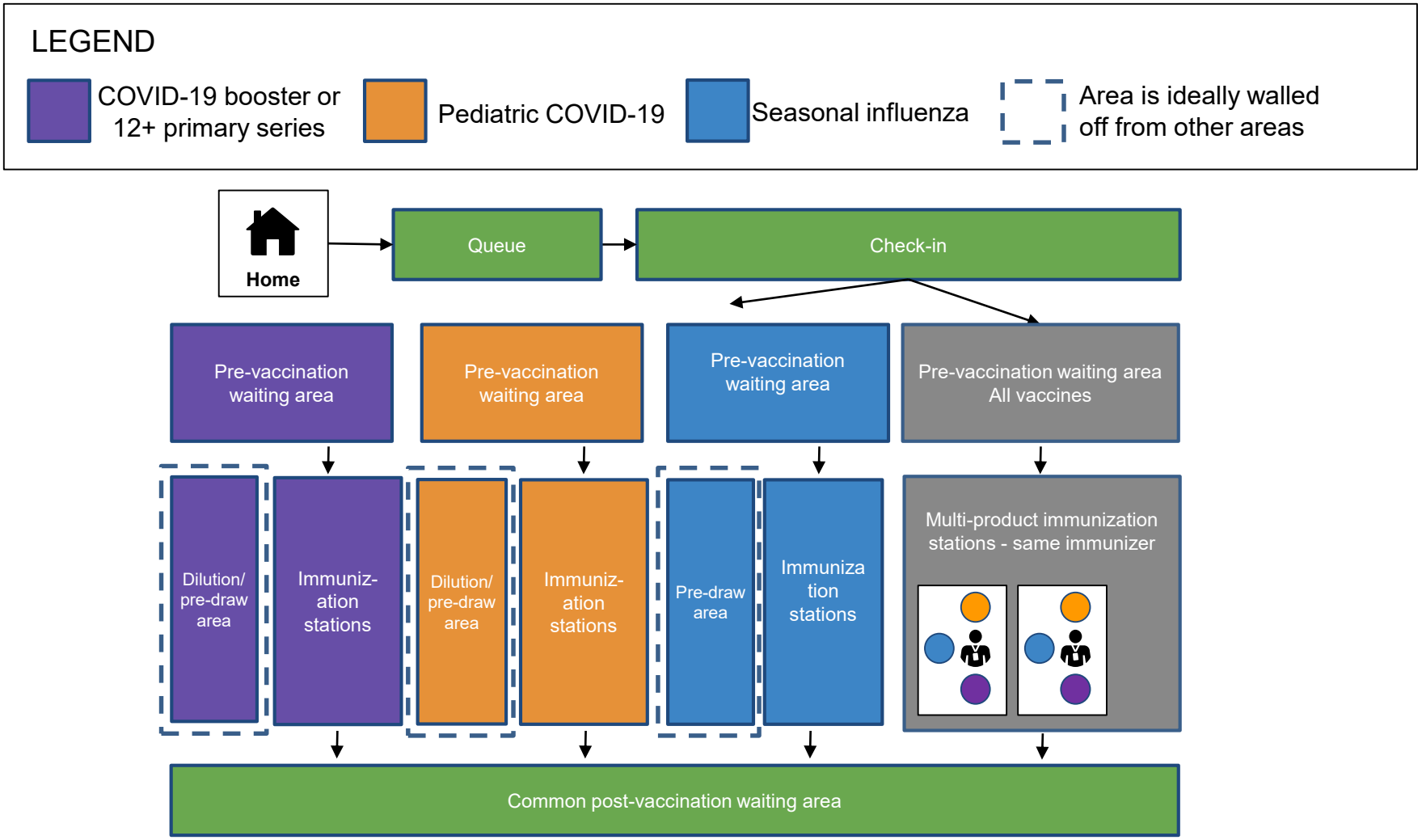
Model 1: Multi-product clinic with separate areas per product



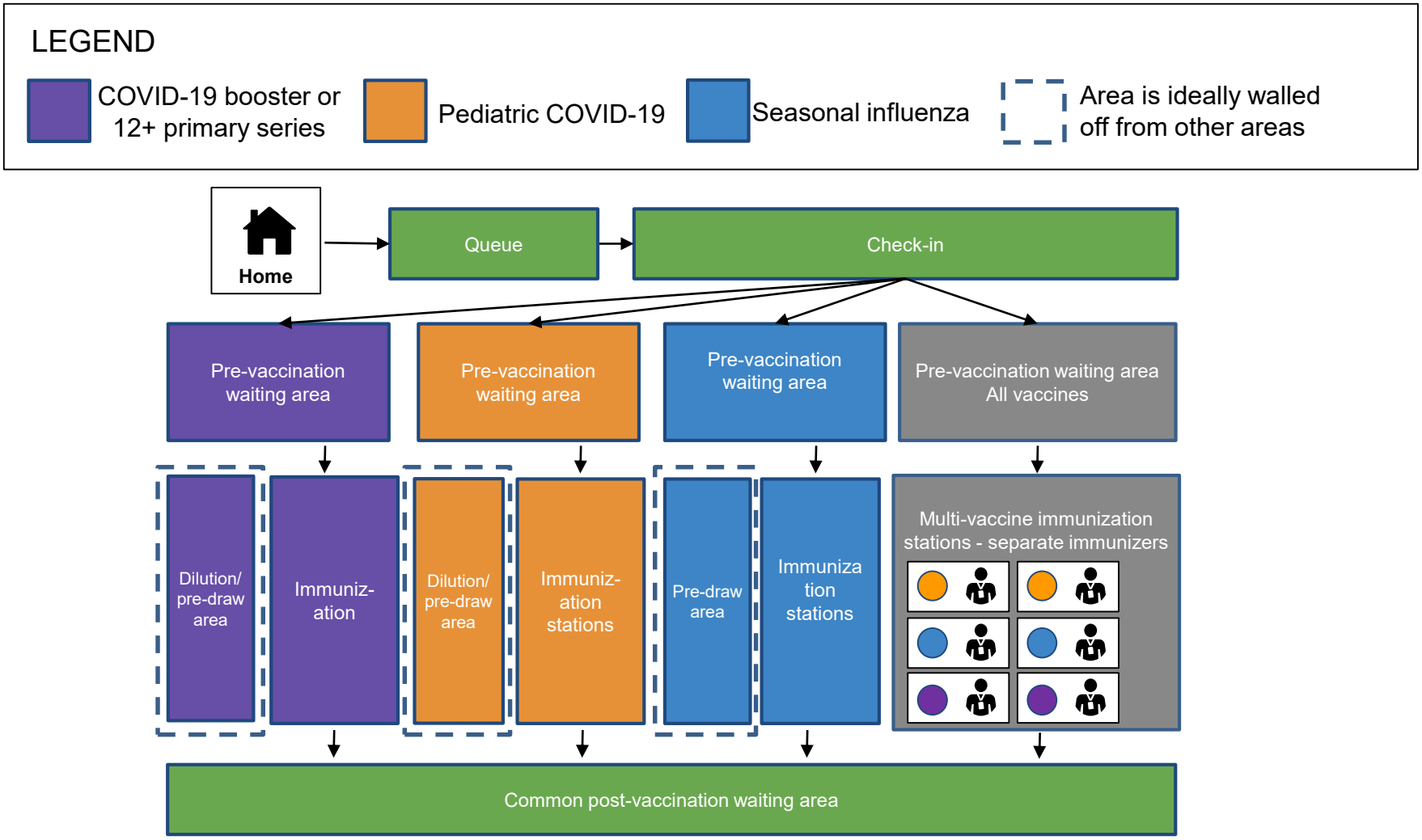
Model 2:
Multi-product clinic with vaccinators providing more than one vaccine



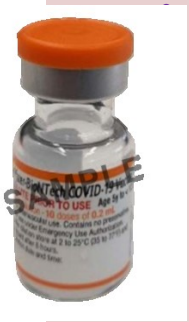
Model 3A:
Multi-product clinic with separate areas per product AND a multi-product area with vaccinators providing more than one vaccine



Model 3B:
Multi-product clinic with separate areas per product AND multi-product area with separate immunizers



Planning considerations – risk mitigation

Clinic design	Administrative controls
• Colour-code all items associated with each product  Pfizer-BioNTech adults/adolescent formulation: purple Pfizer-BioNTech 5 to 11 pediatric formulation: orange Moderna: brown Influenza standard quadrivalent vaccine: blue • Influenza older adult vaccine: grey • Separate dilution/drawing-up stations for each product or dosage	• Use of experienced staff if immunizer is giving more than one product or dose • Training • One product per shift for dilution/pre-drawing staff • Accountability checks • Provide job-aids corresponding to colour-coding • Policies and procedures to manage errors and actively encourage reporting **Do not** • Give through-put goals

For more information…

- **Canada.ca**
  - Coronavirus disease (COVID-19): Guidance documents
    - Health sector preparation
      - Planning guidance for immunization clinics for COVID-19 vaccines
        - Planning considerations for pediatric COVID-19 clinics
        - Planning considerations for multi-product immunization clinics

Thank you!