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**British Columbia's
Pandemic Influenza Response Plan (2012)
Pandemic Influenza Vaccine Storage, Transfer and
Security Plan**

September 2012

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EXECUTIVE SUMMARY

The emergence of a pandemic influenza virus will galvanize efforts of federal, provincial, local and supplier stakeholders. Coordinating and implementing action for the distribution and storage aspects of a pandemic influenza vaccine is the focus of this plan. The Province of B.C. works directly with the Public Health Agency of Canada (PHAC), Public Works and Government Services Canada (PWGSC), GlaxoSmithKline (GSK) and B.C. health authorities—all key participants—to achieve an optimal distribution and storage plan while safeguarding vaccine stability and security.

Pandemic influenza vaccine is manufactured by GSK in their Quebec facility, but its logistical services will hub through Burlington, Ontario. At the onset of a pandemic, the vaccine and its distribution is assessed nationally by PHAC, the Pandemic Vaccine Task Group, and PWGSC, and then communicated to the Canadian Immunization Committee via the Vaccine Supply Working Group for further action. This national plan supplies jurisdictions equitably among the provinces and territories on a per capita basis.

In devising a distribution and storage plan for the province, the BC Centre for Disease Control (BCCDC) held discussions, conducted surveys, and collected data from GSK and health authorities that focused on, but was not limited to, product formulation; product presentation; primary (components), secondary (SKUs) and shipping packages (cases); distribution from GSK to BCCDC and health authorities; intra-health authority distribution; storage capacities at BCCDC and health

authorities; handling unit size, resources and security. The plan is based on BCCDC vaccine distribution, which uses reefer delivery services to the health authorities. Ongoing product volume for each health authority was based on dividing BC's share among the per capita share of each respective health authority. Each designated site was then given a profile of the weekly volume for operational considerations.

Reefers, which are refrigerated transport—considered an optimal strategy—will be used to mitigate cold chain concerns, which could compromise product use within its limited supply. Reefers will traverse the province using scheduled runs and routes to designated sites within the province. These reefers will pick up inventory from GSK and drop ship to designated sites across the province. One of these drop sites will include the BCCDC, where inventory will get repackaged into unit doses. This repackaged inventory will be sent to health authorities once a week.

Because the inventory is much larger for a pandemic influenza vaccine than seasonal influenza vaccine, four of the five health authorities have a centralized depot to send the overflow amounts to; in other words, most of the inventory will not only go to health units/offices but will also go to a centralized site within the health authority from where they will further redistribute within a week. This process will take place on a weekly basis until all inventory has been allocated to B.C. to immunize up to everyone in the province who needs or want to be vaccinated.

1. INTRODUCTION

1.1 Pandemic Influenza Vaccine

Influenza pandemics represent global emergencies with potentially catastrophic impact. During a pandemic, worldwide epidemics of influenza due to a new viral subtype occur simultaneously. The emergence of pandemic H1N1 influenza virus demonstrated how quickly pandemics can spread, and the potential range of severity of pandemics. While the vast majority of people infected with pandemic H1N1 influenza experienced limited disease, a small percentage experienced severe disease. When the World Health Organization (WHO) recommended production of a vaccine, the need to quickly mobilize public health resources to provide vaccine to large numbers of people was necessary.

Influenza vaccination has long been considered the cornerstone of influenza prevention and control and also serves as the central preventive strategy during the next pandemic. The aim for an influenza pandemic is to offer the entire population vaccine over a period of four months, on a prioritized basis. The federal, provincial and territorial governments have made a commitment to secure enough pandemic vaccine for every person in Canada who will need or want the vaccine, in order to help prevent illness due to a pandemic virus. Health authorities and their partners, with the support of the BC Centre for Disease Control (BCCDC), are responsible for planning and implementing vaccination clinics in their respective geographical areas.

1.2 Manufacturing of the Pandemic Influenza Vaccine

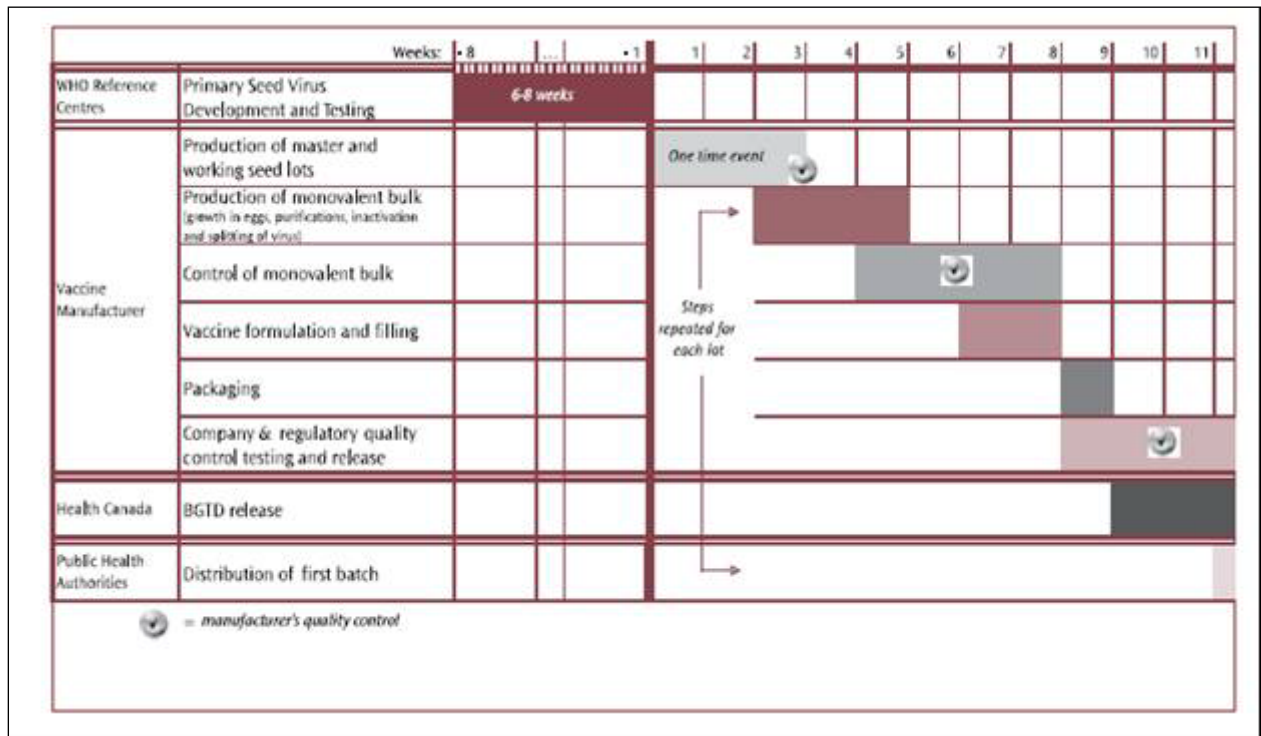
The manufacturing of the pandemic influenza (PI) vaccine will be carried out by GlaxoSmithKline (GSK) pharmaceutical company at their Saint Foy facility in Quebec. A great deal of effort is put into streamlining and shortening the timeline for production of a pandemic vaccine, compared to the seasonal influenza vaccine. In the Canadian Pandemic Plan, the following diagram (Figure 1) represents the current “best case” timeline for production of the first batch of a pandemic vaccine in Canada.

the virus in eggs, purification, inactivation and splitting of the virus to produce the monovalent bulk, followed by the formulation and filling into vials. There are quality control tests performed at a minimum on the seed lots, the monovalent bulk and the final product. The total timeline, from production of PI vaccine to first batch released, including clinical trials, and an expedited Biologics and Genetic Therapies Directorate (BGTD) review for lot approval will be 19 weeks inclusive.¹

Two types of vaccine are being manufactured. The majority of production will be the split virus adjuvanted vaccine manufactured in Canada using egg-based technology. A small amount of unadjuvanted vaccine will also be produced for Canadians. The timeline presented in Figure 1 is for the first lot of vaccine. After this, lots could be produced on a routine basis because the process is continuously repeated. The production process consists of growth of

¹ M. Naus, Personal email communication J. Seto, May 20, 2009.

Figure 1: Pandemic Vaccine Manufacturing Timelines



Note: For original figure, see *Canadian Pandemic Influenza Plan for the Health Sector* (Public Health Agency of Canada, 2006), Annex D, p. 13 (<http://www.phac-aspc.gc.ca/cpip-pclcpi/pdf-e/cpip-eng.pdf>).

1.3 Pandemic Influenza Vaccine Production Rate and Amount

In the current vaccine readiness contract the vaccine manufacturer is committed to a production rate target of 8 million monovalent doses of pandemic vaccine per month (i.e., approximately 2 million doses per week). This target was created when the contract was first developed in 2001, with the working assumption that each monovalent dose would contain 15 ug of antigen. In an effort to

accelerate the potential production rate, the domestic manufacturer developed and added a novel adjuvant to test batches of a new H5N1 vaccine. Clinical trials with a similar product in Europe have suggested that a dose containing 3.75 ug of antigen with the novel ASO3 adjuvant is sufficient to induce a significant immunological response to H5N1 in the vaccine recipient.

1.4 Provincial Distribution of Seasonal Influenza Vaccine

Provincially, BCCDC has the responsibility for immunization program planning, and the Division of Vaccine and Pharmacy Services serves as the provincial central depot for receipt, storage and distribution of vaccine products. There is a robust infrastructure to support regular immunization programs, such as the seasonal influenza immunization program. Storage and transfer of vaccine products in a pandemic will be modeled after this program; however, due to the unique challenges of a pandemic event, this system as it stands cannot be expected to handle the storage and transfer of a large immunization program. The volume of such a campaign will far exceed that of a typical immunization campaign, expanding beyond the standard target

populations to include potentially 75 per cent of the entire B.C. population. Safety and security are also vital considerations in large-scale emergency campaigns, particularly in the context where supplies may be limited and fear and anxiety may be widespread. All emergency immunization storage and transfer plans require security measures to address the safety of supplies and site security.

This plan provides detailed guidelines for the storage and distribution of the pandemic influenza vaccine from BCCDC to the health authorities, such that they are able to conduct influenza immunization clinics, while also delivering best routine programs concurrently, including the seasonal influenza vaccine.

2. GOAL STATEMENT AND OBJECTIVES

2.1 Goal

The purpose of this plan is to provide information to the regional health authorities and health care providers about the rapid

movement and transfer plans for a pandemic vaccine product.

2.2 Objective

This plan addresses the following issues:

- The conditions needed to maintain cold chain of a vaccine developed for pandemic influenza.
- How the vaccine will be distributed to the health authorities and out to providers.

- Package size information to ensure there is sufficient cold storage available for the housing of these products.
- Security considerations needed to safeguard the stockpile while vaccines are being administered in the population.

3. ASSUMPTIONS OR PLANNING SCENARIOS

For the purposes of provincial planning, we have made the following assumptions:

	Population in B.C.	75% uptake	2nd dose of 0.5 ml if needed	1 dose
Children 6 month to 9 years	416,726	312,545	312,545	312,545
Children and adults 10 years and up	4,010,280	3,007,710		3,007,710
Pregnant women	44,156	33,117		33,117
Pregnant women (second dose, if required)	22,078	16,559		16,559
Total Vaccine	4,493,240	3,369,930	312,545	3,369,931

- The population figures above for the province of British Columbia were used.²
- Pandemic Influenza vaccine will be manufactured by GlaxoSmithKline (GSK) from their Saint Foy facility and allocated per jurisdiction as determined by the Public Health Agency of Canada (PHAC).
- GSK anticipates the Biologics and Genetic Therapies Directorate (BGTD), Health Canada to approve the first lots of vaccine within 19 weeks from the start of production.
- Release of vaccine will be approximately 3 million doses each week for the entire nation, although the amounts released for the early lots may be less.³
- B.C. represents 13.25 per cent of the national population; therefore, B.C. may receive up to 397,500 doses per week, but the amount released during the early lots will range from 230,000 to 397,000 doses per week, and planning will need to accommodate unexpected changes in these numbers.
- Rate of use of the pandemic vaccine within the immunization clinics will match production rate; i.e., turnover of stock will be at steady state from receipt to clinic use.
- Non-health authority offices will access inventories from the regional health authorities, including First Nations communities who do not already access via provincial offices, physicians and pharmacists.
- Routine vaccines will continue to be provided by BCCDC for the infant and school-based programs.
- Seasonal influenza vaccine will have been delivered to the health units in order to begin a program after the Thanksgiving long weekend.
- Seasonal influenza vaccinations for eligible groups will be delivered concurrently with the pandemic vaccine where logistically feasible.

² Email communication with Ministry of Healthy Living and Sport, October.

³ M. Naus, Personal email communication J. Seto, May 20, 2009.

4. PANDEMIC INFLUENZA VACCINE DISTRIBUTION AND STORAGE

4.1 National Strategy for Distribution

The national strategy for distribution of pandemic influenza vaccine to all provinces and territories will be defined by PHAC and will be developed in partnership with GSK. The plan is that vaccine distribution will adopt the same guiding principle used for seasonal influenza; i.e., a per capita allocation of the designated users' requirements, and in the absence of epidemiological outbreaks that may deviate from this assumption.

4.2 Provincial Distribution

To help alleviate some of the logistical challenges involved with expediting inventories into public provider offices, including providing inventory in a timely fashion and under cold chain conditions to limit wastage, BCCDC will embrace a hybrid model of refrigerated trucks (reefers) as well as couriers (e.g., DHL or Dynamex) as the two main methods of delivery to health authorities. The majority of shipments, however, will take place through reefer deliveries in order to mitigate wastage of product.

Furthermore, in order to reduce the time it takes to deliver vaccines to health authorities, BCCDC will use the reefers already in provincial circulation (i.e., two trucks are used for day-to-day deliveries) and in total has contracted for the use of up to six reefer trucks. Trucks will deliver both the 500-dose shoebox and repackaged pandemic influenza vaccine, before directly dropping to the designated public health units. Note, this strategy was used in 2008/2009, outbound from the supplier's

The pandemic influenza vaccine is manufactured in a Quebec-based facility and then transferred to their logistics/distribution warehouses and as quarantined lots until approval has been granted by BGTD for their release to provinces and territories.

Ontario warehouse; reefer-delivered influenza vaccine shipments were dropped directly from the supplier, on multiple runs, to 71-designated public health offices across the province. However, approximately 75 per cent of the pandemic influenza vaccine will come to BCCDC directly from Ontario via reefer truck, to be repackaged into smaller units and then sent out to the health authorities.

As part of the current BCCDC reefer agreement, provisional language allows for enhanced services (e.g., pandemic influenza vaccine deliveries). These enhanced services include, but are not limited to, unmarked reefers, increased size and number of trucks, bonded drivers/human resources, scheduling of intra- and inter-provincial routes, liability issues, and temperature monitoring assurances. The cost for these services will be approximately \$1,000 each day per reefer run. Any unexpected increase in cost for these additional services must be weighed against the provider's ability to meet stability and security requirements.

4.3 Product Dimensions, Repackaging by BCCDC and Shipping Configurations

An adjuvanted vaccine will be manufactured in Canada by GSK. The product will be a two-component vaccine requiring reconstitution by adding an ASO3 adjuvant emulsion to the antigen liquid prior to use. Each reconstituted (antigen+adjuvant vial) unit will yield 10 x 3.75 ug doses. Stock keeping units (SKU) will be packaged by the supplier in a “shoebox” configuration assembling 50 x 10 mL vials of antigen in one sub-box and 50 x 3 mL vials of adjuvant, divided 25 each in two sub-boxes. It measures 260 x 113 x 97 mm and will contain 500 doses of the pandemic vaccine. GSK prefers to use reefer deliveries (i.e., skeleton truck) where possible to ensure cold chain maintenance but will ship, air-expedited, for smaller payloads. GSK’s standard of practice for determining if a delivery will be via reefer or by air in validated (RNC) containers is the number of cases for a payload. If the payload is less than 10 cases, UPS will use the RNC to ship via air. The risk of separation, or misdirected cases in isolation, increases with couriers; transit time is generally 24 to 48 hours, the latter applicable for more remote communities. If the payload is > 10, the shipment will be placed on a reefer. Each pallet measures 40” x 48” and has tie of 7, high of 5, equating to a 35-case payload.

In order to accommodate delivery of the pandemic influenza vaccine to the public in non-mass clinic settings, BCCDC will repackage the 500-dose shoebox into smaller units. Details are not finalized, but one option being considered is to have 100 doses packaged as 20 vial sets (10

adjuvant and 10 antigen) in a small corrugated cardboard box.

Each sub-box component is labelled with the content descriptor and corresponding lot number and expiry date. The outer shoebox label will detail the component lots but it will have a ‘master’ lot number which unifies the combination of the component lots. It is from the master lot that regulatory processes are referenced and approved for labelled use. Mixing of component lots from two different master shoe box lots is considered by Health Canada as off-labelled use.

The shoebox configuration was designed for mass immunization delivery where the 500-dose quantity was the equilibrium for meeting global and economical considerations. Immunizations in B.C. will be a hybrid of mostly public health but complemented by physician, pharmacist and other provider delivery. The distribution network will fan out to all corners of the province so positioning provider offices with inventories is especially critical at the onset of the campaign. However, given the small initial allocations, repackaging to 1 antigen to 1 adjuvant vial will be required to broaden distribution and reduce unnecessary wastage in smaller offices, while larger offices benefit from a compact shoebox occupying less fridge space. BCCDC Pharmacy will aim to repackage 75 per cent of the aggregate totals to facilitate this distribution plan, although this goal will be determined by the extent and severity of the pandemic.

4.4 Vaccine Volumes

To assess the impact the pandemic influenza weekly volumes, we created a chart for the health authorities that outlined the number of doses, cases, vials, and cubic feet required. They were also able to compare this to the seasonal influenza vaccine they normally receive.

Assuming a weekly delivery of 397,500 doses, it works out to approximately 2 times the amount the health units would receive for seasonal influenza. Note: the actual volume will depend on manufacturing variability.

4.5 Storage Requirements

Each shoebox SKU will contain 500 doses. There will be 20 SKUs per shipping case, similar to the seasonal ship as suggested by the supplier. Each case will contain 10,000 doses with the proposed shipping case.

Both components of the pandemic influenza vaccine need storage between 2°C and 8°C in their unreconstituted states. With reconstitution, chemical and physical in-use stability has demonstrated that the product is stable at room temperature (25°C) if used within 24 hours (with aseptic technique use).⁴ The time out of refrigeration allowance from

supplier to user is 48 hours at 25°C.⁵ Best practice includes maintaining storage between 2°C and 8°C at all times to avoid cold chain excursions that may render the product unstable. During a pandemic, like the seasonal influenza, the vaccine may only be produced in limited quantities, so opportunities to replenish cold chain broken vaccines may not afford poor cold chain maintenance practices. Extra measures should be taken to avoid freezing. Excursions $\leq 0^\circ\text{C}$ may freeze vaccine and will compromise stability, whereas brief excursions to warmer temperatures (i.e., $> 8^\circ\text{C}$) may be provisionally stable.

4.6 BCCDC Storage

Routine immunization programs require cold storage capacity at 2°C to 8°C for all vaccine inventories. BCCDC's cold storage capacity was doubled in 2008 in response to emerging public program needs. The maximum square foot capacity for BCCDC will be 5,200square feet. This translates into a maximum storage capacity of 81 of the 64 -square foot pallets. If each pallet contains 35 cases (each case = 10,000 doses), each pallet will hold a theoretical total of 350,000 doses. BCCDC anticipates that the maximum number of pallet spots required during a pandemic will not exceed 3 at any time. This translates into 1,050,000 doses.

An assumed 397,000 dose allocation to B.C. would constitute a 2-pallet delivery in the absence of direct drops. Therefore, with direct drops proceeding to public health and a buffer directed to BCCDC, the current fridge capacity can accommodate this weekly volume. If capacity is maximized at 48 pallets, the BCCDC fridge at its maximal occupancy can accommodate 24 weeks of incoming inventory. Since pandemic influenza vaccine releases may transpire over 20 weeks, and incoming inventories will be decremented by clinic demands, the BCCDC fridge can accommodate this requirement, or a portion thereof as buffer.

⁴ GSK. Personal email communication J. Seto, April 14, 2009.

⁵ GSK. Presentation to BCCDC, October 2, 2009.

4.7 Health Authority Assessment

To assess the operational and cold storage capacities at the health authority level, BCCDC conducted teleconferences and surveys with representatives from each of the health authorities. As discussions elapsed both collectively and individually with more health authority-directed focus, two pivotal end-point questions were addressed in helping guide this plan. A summary of the responses are noted in Table 2:

Question 1: Does each designated depot have capacity to store the volumes stated herein?

Question 2: Does the drop delivery to the designated offices, an adaptation to seasonal delivery, work for your health authority?

The summary of these health authority responses provides the foundation of a hybrid model of distribution: direct drop and centralized model deliveries—both via reefer deliveries.

Storage capacity at the health units for the routine immunization program is a health authority function and therefore capacity needed to be assessed at each local level. One of the key differences between routine immunization programs and a pandemic event is the quantity, cubic volume occupancy and range of vaccines that need to be managed through the storage and distribution systems. The current system is not likely sufficient to meet the extra demands.

As health authorities are considering expanded storage facilities to manage the increased

volume of vaccine, the following considerations should be reviewed:

- Proper conditions to maintain the safety and efficacy of the product (e.g., cold chain requirements); assessment of current cooling units/fridges (e.g., age, integrity, servicing, etc.).
- Inventory management (including monitoring of expiry dates where relevant) and restocking, use of electronic systems to standardize and increase accessibility of data; inventory—electronic and manual—systems may require upgrades to more robust, perpetual systems for end-to-end order fulfillment and supply chain sustainment. To assess ongoing inventories, BCCDC will schedule weekly communications (via teleconferences or emails) with the health authorities to discuss quantity on hand, reallocation, volume adjustments, etc.
- Security of supplies, particularly where shortages or potential tampering is an issue, including access controls to rooms/areas where the fridge is located (e.g., card access, cameras, security guards, etc.) and tiered local/regional requisition authority.
- Contingency planning for cases where the event takes place during a routine immunization campaign and existing refrigerated storage may already be at capacity. Given the need for rapid distribution, there must be measures in place to ensure the safe, secure transportation of the planned allocations.

Table 2: Summary of Responses from Health Authorities on Storage Capacity for the Pandemic Vaccine

Health Authority	Question 1 Does each designated depot have capacity to store the volumes stated herein?	Question 2 Does the drop delivery to the designated offices, an adaptation to seasonal delivery, work for your health authority?
Fraser Health Authority	Yes. Overflow volumes will be centralized at regional warehouse in Langley.	Yes. Overflow volumes will be directed to the Langley warehouse.
Interior Health Authority	Yes. Overflow volumes will go to Kelowna.	Yes. Overflow volumes will go to Kelowna.
Northern Health Authority	Yes. Prince George will be the hub.	Yes. Overflow will be in Prince George.
Vancouver Coastal Health Authority	Yes. Capacity for the urban centres (Vancouver, North Shore and Richmond) may be centralized. Smaller offices have capacity at the local level.	Yes, either to centralized depot where VCHA would then re-distribute. Designated drops for North Shore, Richmond and smaller communities will receive drop deliveries via BCCDC-commissioned reefers.
Vancouver Island Health Authority	No. At the onset, with fridges at near or full occupancy, capacity is limited.	No. BCCDC will need to deliver a certain amount of vaccine to VIHA every week due to their lack of fridge space.

4.8 Staffing

During a pandemic, the workforce absenteeism may be significant at times. The transport of pandemic influenza vaccine to the offices and repackaging from BCCDC will undoubtedly increase the demand for logistical and clinical support for evolving activities. Staffing considerations need to be addressed and built into the pre-pandemic plan. At the imminence

of vaccine rollout, new hires may need training opportunities for product handling. Temporary recruitment agencies may offer additional resources but recruitment of appropriate candidates, within a compressed window of time, as well as training and supervision of such candidates, will be necessary to safeguard vaccine-handling practices.

4.9 Security

During a pandemic, security will be assumed to be of no greater risk than the seasonal influenza vaccine distribution network. Should security be

compromised or the risk of criminal activity increased, provincial or municipal policing reinforcements will be required.

5. ROLES AND RESPONSIBILITIES

Pandemic influenza vaccine distribution will be a national and provincial network of collaborations between all stakeholders. BCCDC is an active member of the National Vaccine Supply Working Group (VSWG), who is tasked with pandemic influenza vaccine procurement and distribution issues. The VSWG meets regularly and ad hoc, as necessary, to address emerging vaccine issues, or issues tasked to it through the Canadian Immunization Committee to which it reports. BCCDC, Vaccine and Pharmacy Services, will work with the VSWG and other provinces and territories to ensure procurement of the pandemic influenza vaccine and its equitable distribution across Canada.

Provincially, BCCDC and public health providers partner in the management of inventory distribution, storage and handling of all vaccines including influenza. In this case,

BCCDC includes Vaccine and Pharmacy Services and Epidemiology/Immunization Departments, who co-manage the centralization of services for storage, inventory, processing orders, delivery of products, and immunization guidelines/priority groups for product use, coverage assessment, and program analysis and evaluation. BCCDC partners with health authorities through a designated Influenza Vaccine Coordinator. Each coordinator participates and messages, by sharing and exchanging their health authority requirements, to create local and provincial successes inclusive of all stakeholder issues. Decisions are generally reached by consensus. During a pandemic, the same stakeholders will be used to ensure appropriate storage, distribution and immunization guidelines around the pandemic influenza vaccine. Decision-making may need to become more directive.

Table 3: Roles and Responsibilities

Role	Responsibilities
Vaccine Procurement	<ul style="list-style-type: none"> BCCDC, Vaccine and Pharmacy Services, for national participation and provincial requirements Vaccine Supply Working Group (PHAC and jurisdictional members)
Vaccine Repackaging	<ul style="list-style-type: none"> BCCDC
Vaccine Distribution	<ul style="list-style-type: none"> BCCDC GSK
Vaccine Deliveries	<ul style="list-style-type: none"> BCCDC Public Health – PI Vaccine Coordinators Logistics Provider
Vaccine Storage (Overflow)	<ul style="list-style-type: none"> BCCDC
Efficient Inventory Management	<ul style="list-style-type: none"> Pharmacy
Vaccine Policy Guidelines	<ul style="list-style-type: none"> Epidemiology
Vaccine Uptake for Delivery	<ul style="list-style-type: none"> BCCDC Epidemiology

6. NEXT STEPS OR FUTURE RECOMMENDATIONS

As more information develops from the national strategy or the supplier, BCCDC will continue to communicate with health

authorities. These updates or plans may change the landscape from which this document was developed if it differs greatly from them.