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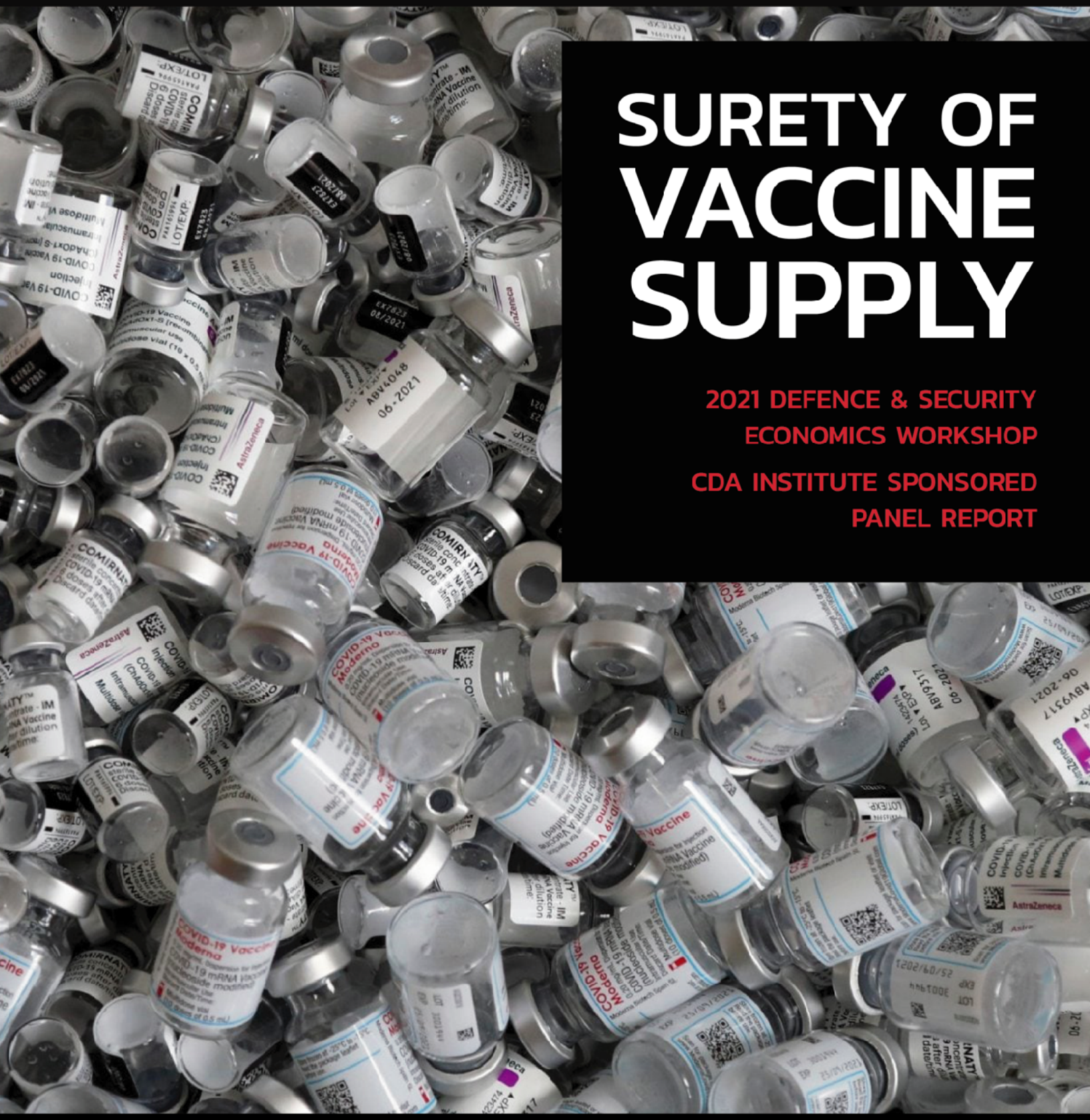

SURETY OF VACCINE SUPPLY

2021 DEFENCE & SECURITY ECONOMICS WORKSHOP

CDA INSTITUTE SPONSORED PANEL REPORT

VOLUME 27 | WINTER 2022

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ON TRACK is the official journal of the CDA Institute. Through its pages, the CDA Institute promotes informed public debate on security and defence issues and the vital role played by the Canadian Armed forces in society. ON TRACK facilitates this educational mandate by featuring a range of articles that explore security, defence, and strategic issues that may have an impact on the Canadian strategic interests and on the safety of its citizens. The views expressed in ON TRACK are those of the authors and do not necessarily represent those of the CDA Institute.

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2021 Defence and Security Economics Workshop 28-29 October 2021 | CDA Institute Sponsored Panel: Surety of Vaccine Supply

Context

Carleton University annually hosts the Defence and Security Economics Workshop, bringing together participants from universities, think tanks and research agencies across Canada and around the world. The Workshop, running since 2006, aims to provide a forum for the discussion of a broad range of theoretical and applied issues in defence and security from an economic analysis perspective. The 2021 Workshop was organized as a virtual event in recognition of the ongoing public health restrictions related to the COVID-19 pandemic.

The CDA Institute has been a Workshop partner for a number of years, sponsoring panel discussions on a range of topics aimed at encouraging a dialogue across a diverse range of disciplines to foster, encourage and support a wider national conversation about issues related to defence, security and the Canadian economy with a view to:

- Improving understanding of the scope, scale, and complexity of the symbiotic relationship between Canada's economy and its defence and security;
- Developing a clearer and more comprehensive understanding of the "as-is" condition of the defence and security industrial sector in Canada, including supporting and enabling government policies, programs, and plans; and
- Identifying and exploring issues that should influence and shape the future evolution of Canada's defence and security industries, both in terms of meeting the country's strategic defence and security needs and enhancing the sector's contribution to the wider economy.

The COVID 19 pandemic has highlighted the important reality that national security must be approached as a holistic concept extending well beyond traditional areas like defence, intelligence, diplomacy, and foreign aid. Non-traditional threats like disease and climate change can be no less damaging to the nation but require different kinds of responses from government and industry, and in recognition of this the 2021 panel focused on the issue of Vaccine supply.

2021 CDA Institute Sponsored Panel Discussion on Surety of Vaccine Supply

The Government of Canada responded to the COVID-19 pandemic by purchasing vaccines from many international suppliers and, while there was some disruption to early deliveries, this strategy has been successful – at least this time. However, the threat of pandemic disease will not disappear after COVID-19 and in support of the ongoing public discussion on whether Canada should establish a domestic capability to develop and produce its own vaccines, the 2021 panel was designed to undertake a broad exploration and scoping of relevant issues.

The panel was structured in two parts: Part 1 was the main session focusing on issues and challenges associated with creating a national program to assure vaccine supply; and Part 2 looked at potential lessons that could be drawn from existing government-industry assured supply programs in Canada and elsewhere.

The Part 1 speakers included:

- **Nathalie Nye,** Director-General Horizontal Integration, COVID-19 Vaccine Rollout Task Force, Public Health Agency of Canada. Her topic was: *Policy perspectives on assuring vaccine supply* and she provided an overview of the government's rapid development of policy responses and strategies to overcome the initial deficiencies in national readiness to deal with the pandemic, in particular describing in how the lessons learned in procuring Personal Protective Equipment (PPE) in the early days of the pandemic informed the federal strategy for vaccine acquisition.

- **Dr. Robert Van Exan,** President of consulting firm Immunization Policy and Knowledge Translation; and former Director, Immunization Policy at Sanofi Pasteur. He spoke on: *Industry perspectives on how to assure timely vaccine development and reliable supply*, comprehensively describing the very great complexity of both the problem set (comprising a wide range of pathogens we may need to defend against) and the solution set (with at least four vaccine technology platforms with varying levels of effectiveness against different pathogens) and continuing rapid evolution of the science.

- **Brigadier-General Krista Brodie**, Vice-President, Logistics and Operations, Public Health Agency of Canada. She addressed: *Logistics challenges of vaccine distribution*, providing a comprehensive picture of the complex effort to innovate and rapidly build from scratch a national logistics capability for efficiently delivering vaccines from point of manufacture to point of use.

- **Dr. Paul Grootendorst**, Associate Professor, Leslie Dan Faculty of Pharmacy and the School of Public Policy and Governance, University of Toronto. His topic was: *The economics and logistics of vaccine production*, looking at the complex "upstream logistics" of developing and producing vaccines. He identified three potential strategic options open to Canada for structuring a national vaccine capability, pointing out the pros and cons of each and suggesting that we may need to adopt more than one strategy given the diversity of technologies involved.

The Part 2 speakers were:

- **Dr. Ugurhan Berkok**, Professor of economics at Queen's University and the Royal Military College. His presentation provided an overview of the complexity of the challenges involved and summarized a number of international assured supply program models that could inform development of a Canadian vaccine capability.
- **Colonel Charles Davies (Retired)**, Retired CAF Logistics officer and Ammunition Technical Officer, and Fellow of the CDA Institute. He provided an overview of Canada's long-standing Munitions Supply Program and drew from it a number of potential lessons to consider in a vaccine supply program. He also moderated the panel.

This Special Edition of On Track

The panelists have summarized the information and insights provided in their presentations in the six articles presented in this special edition of On Track. The Panel discussions were also recorded and can be accessed for viewing through the CDA Institute's website https://cdainstitute.ca/.

The very clear message from Part 1 of the panel discussion and the first four articles presented here is that any national vaccine supply program must be designed for agile, flexible and adaptable response. As both Dr Van Exan and Professor Grootendorst warn in their articles, the science of vaccines and the production technologies are continuously evolving, and at a very high pace. Even in the short time between the panel discussion and publication of this edition, remarkable advances in both areas have been made both

in Canada and globally.[1] Ms Nye's article clearly shows the need for government to be able to set aside its traditional linear procurement processes when necessary, and adopt more rapidly responsive approaches – while still exercising reasonable prudence and probity in the expenditure of public funds. Brigadier-General Brodie paints a remarkable picture of "on-the-fly" innovation and rapid collaborative invention of a broadly integrated national vaccine delivery system that has been, by any measure, stunningly successful. Her caution not to let the valuable fruits of this great achievement go to waste is a sobering challenge for government and Parliament.

The Part 2 presentations and the last two articles here offer a range of insights drawn from existing assured supply programs in Canada and elsewhere. These tend to be defence-related and mostly focused on munitions, so the technologies and industrial capabilities involved are different from vaccines, but nevertheless provide potentially useful perspectives. Professor Berkok provides a broad overview of the challenges faced in designing an assured vaccine supply

program and outlines several different models that could be applied to it that have been adopted by different nations for particular defence requirements. Colonel Davies looks specifically at Canada's Munitions Supply Program to offer lessons from it that could apply to a vaccine program.

Given the complex and fluid nature of the threat posed by pandemic disease, development of a national program for assuring future vaccine supply will be difficult to say the least, so the problem requires much deep analysis and thought. We hope readers will find this collection of articles a useful contribution to the national discussion about how Canada should assure its national security in the face of future pandemics.

[1] To cite only one example see Ivan Semeniuk, "How an inhaled vaccine might breathe new life into the fight against COVID-19" *The Globe and Mail*, December 13, 2021.

(1/6) Lessons learned in procuring Personal Protective Equipment (PPE) in the early days of the pandemic directly informed the federal strategy for vaccine supply acquisition

Nathalie Nye, Jordan Owens, Nevena Askins

The Government of Canada's strategy of vaccinating as many people in Canada as quickly as possible has resulted in some of the highest vaccination rates in the world and prevented many cases of COVID-19. Earlier in the pandemic, however, the federal government faced initial challenges obtaining personal protective equipment (PPE). Flowing from the lessons learned in the early days of pandemic-related PPE supply shortages, the Government of Canada was able to take a unique approach to vaccine procurement that ultimately resulted in a timely access to a robust vaccine portfolio,

and more than 85% of the eligible population fully vaccinated as of November 13, 2021[2].

In the early days of the pandemic, supply chain disruption and increased global demand created unforeseen challenges in procuring PPE to support the healthcare sector. As detailed in the May 2021 Report 10 of the Auditor General of Canada,

> *As a result of long-standing unaddressed problems with the systems and practices in place to manage the National Emergency Strategic Stockpile, the Public Health Agency of Canada was not as prepared as it could have been to respond to the surge in provincial and territorial needs for PPE and medical devices brought on by the COVID19 pandemic. However, when faced with the pressures created by the pandemic, the agency took action.3*

In response, the federal government quickly pivoted its PPE strategy from *"reactive management to informed planning and allocation [including an] initial shift to a bulk purchasing strategy…fostered by strengthened collaboration and communication among the agency and other federal organizations, provinces, and territories."*[4] Effectively, this meant being less risk averse in procurement, growing its human resources and logistics capacity to support these efforts, working more collaboratively with partners, and investing in domestic manufacturing solutions.

By late 2020, Canada had revamped its PPE procurement efforts to focus on securing diversity in its supply to meet established pandemic stockpiling targets for key commodities. The federal government was able to mitigate many of the risks posed by intense global competition and constrained supply chains by developing its own domestic industry and working with multiple providers, some of whom were new to working with Canada. While not without its own set of challenges, doing so allowed Canada to procure significant quantities of PPE during this time of scarcity and also created spinoff domestic economic benefits. Efforts continue to build sustainable domestic quality and capacity, however, the lessons learned from PPE procurement – taking more risk in contracting, working with new suppliers, taking steps to mitigate the risk that some

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[2] "COVID-19 vaccination in Canada: Vaccine Coverage" Government of Canada https://health-infobase.canada.ca/covid-19/vaccination-coverage/.

[3] "2021 Reports of the Auditor General of Canada to the Parliament of Canada: Report 10—Securing Personal Protective Equipment and Medical Devices" https://www.oag-bvg.gc.ca/internet/English/parl_oag_202105_01_e_43839.html.

[4] Ibid

suppliers may not be able to deliver, and the importance of intense preplanning – is reflected in Canada's strategy for vaccine supply acquisition.

Informed by the advice of experts, Canada adopted a procurement strategy to supply everyone in Canada with the most promising COVID-19 vaccines.

Taking into account the lessons learned on PPE procurement, Canada adopted a procurement strategy that was built on ensuring a diversified roster of vaccine suppliers while completing its traditional responsibilities of providing regulatory review and approval, and distributing vaccines to provinces, territories and federal populations.

Canada prepositioned for procurement by creating emergency authorities to allow for more streamlined spending and vaccine authorization. To manage these efforts, the Government of Canada set up the COVID-19 Vaccine Rollout Task Force (VRTF), within the Public Health Agency of Canada (PHAC). The VRTF was established in October 2020 to provide surge support and manage the substantial task of making COVID-19 vaccines available to every eligible and willing person who falls within Canada's jurisdiction.

To build a diversified roster of vaccine suppliers, Canada signed agreements with multiple vaccine manufacturers identified as having promising vaccine candidates. This strategy – effectively the policy equivalent of "not putting all your eggs in one basket" – maximized the likelihood that even if multiple candidates were delayed or failed to make it to market, other vaccines would still be available to Canadians as soon as possible. By casting a wide net and identifying likely candidates for success, Canada was able to acquire a diverse portfolio of viral vector, mRNA, and protein subunit vaccines, signing seven contracts with manufacturers between July and October 2020. As of November 2021, four of the seven vaccine candidates have been approved and administered in Canada. Other manufacturers' technologies are under review or are expected to be ready for Health Canada review in the coming months, including most recently the Novavax vaccine. Thanks in part to this approach, over 65 million COVID-19 vaccines have been distributed to provinces and territories and

nearly 60 million doses of COVID-19 vaccine have been administered in Canada as of November 22, 2021.[5]

Our work is not done. Immunization efforts will continue into the fall and winter.

As of November 13, 2021, over 85% of the eligible Canadian population[6] is fully vaccinated and nearly 89% has received at least one dose.[7]

Despite these successes, there is still work to be done. The VRTF, working alongside colleagues at PHAC and Health Canada, is targeting gaps in vaccine confidence and uptake; working to meet Canada's need for additional doses, boosters, and pediatric doses; proactively managing supply; and ensuring Canada's excess vaccine supply is available to international partners who need them.

Canada has secured enough doses to meet the population's needs through 2023 and is prepositioning to deliver additional doses, booster doses, and pediatric doses to provinces and territories for administration. Canada's procurement and distribution efforts are largely informed by recommendations from the Vaccine Task Force, as well as the National Advisory Committee on Immunization (NACI).[8] Throughout fall 2021, NACI has continued to provide guidance on additional doses and booster doses for immunocompromised and at-risk populations who may be at increased risk of lowered protection over time since their initial vaccination series was administered. As of November 22, 2021, Health Canada has approved boosters from Pfizer and Moderna for those over the age of 18.

Children ages 12 and older are currently eligible for vaccination and Canada is experiencing high levels of uptake among young people. On October 18, 2021, Health Canada received its first submission for a pediatric vaccine from Pfizer-BioNTech, seeking regulatory authorization for its vaccine for children aged five to eleven (5-11), and received a similar submission from Moderna on November 16, 2021, for children aged six to eleven (6-11). Pfizer's pediatric vaccine was approved by the regulator on November 19, and ongoing

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[5] Public Health Agency of Canada, *Canadian report on COVID-19 vaccine doses administered* (Ottawa: Public Health Agency of Canada; November 22, 2021). https://health-infobase.canada.ca/covid-19/vaccine-administration/.
[6] Ages 12 and older.
[7] "COVID-19 vaccination in Canada: Vaccine Coverage."
[8] "National Advisory Committee on Immunization (NACI): Statements and publications" Government of Canada https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html.

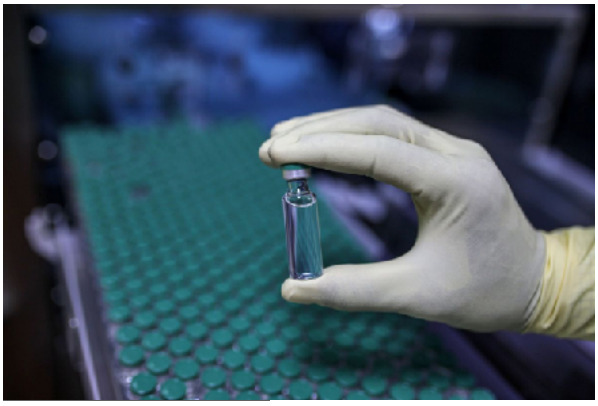
conversations continue to take place between federal, provincial, and territorial governments to ensure pediatric vaccination proceeds in a timely, ordered fashion.

Continuing to incorporate lessons learned in efforts to assure Canada's vaccine supply for 2022 and beyond.

As Canada continues to respond to the evolving nature of the pandemic, there is a deliberate effort to remain flexible to meet future demand and address emerging developments. To do so, Canada is engaging in a variety of strategies including long-term agreements, reprofiling, donations and domestic manufacturing.

Canada has a variety of policy tools at its disposal to manage vaccine supply in the months and years to come. The government has signed long-term agreements with existing vaccine suppliers, allowing for confidence in ongoing and longer-term supply, and has secured doses from Pfizer and Moderna for 2022 and 2023, with options to extend into 2024. Part of Canada's agreements with manufacturers allow Canada to re-profile deliveries, deferring receipt of vaccine doses to future years. This helps to alleviate supply abundance in the short-term while preventing scarcity in the long-term. Canada also participates in the COVID-19 Vaccine Global Access Facility (COVAX). In addition to Canada's commitment to COVAX's mission of increasing access to COVID-19 vaccines for low and middle income countries, COVAX acts as mechanism that can be used to manage supply, ensuring vaccines do not expire in Canada at a time of high global demand.

The Government of Canada is investing in domestic biomanufacturing to ensure Canada has the ability to manufacture vaccines in country. Notably, the government has signed a Memorandum of Understanding (MOU) with Novavax to develop the capacity to produce its COVID-19 vaccine at the National Research Council of Canada's Biologics Manufacturing Centre in Montreal[9], with Moderna to build a state-of-the-art



[9] "New support to produce COVID-19 vaccines and treatments in Canada" Government of Canada https://pm.gc.ca/en/news/news-releases/2021/02/02/new-support-produce-covid-19-vaccines-and-treatments-canada.

mRNA vaccine production facility in Canada[10], and has announced investments to support a variety of vaccine, therapeutic, and biomanufacturing projects in Canada. These efforts will not only contribute to efforts to protect Canadians from COVID-19, but they ensure we are able to fight future pandemics, while building Canada's biomanufacturing capacity as part of our economic recovery plan.

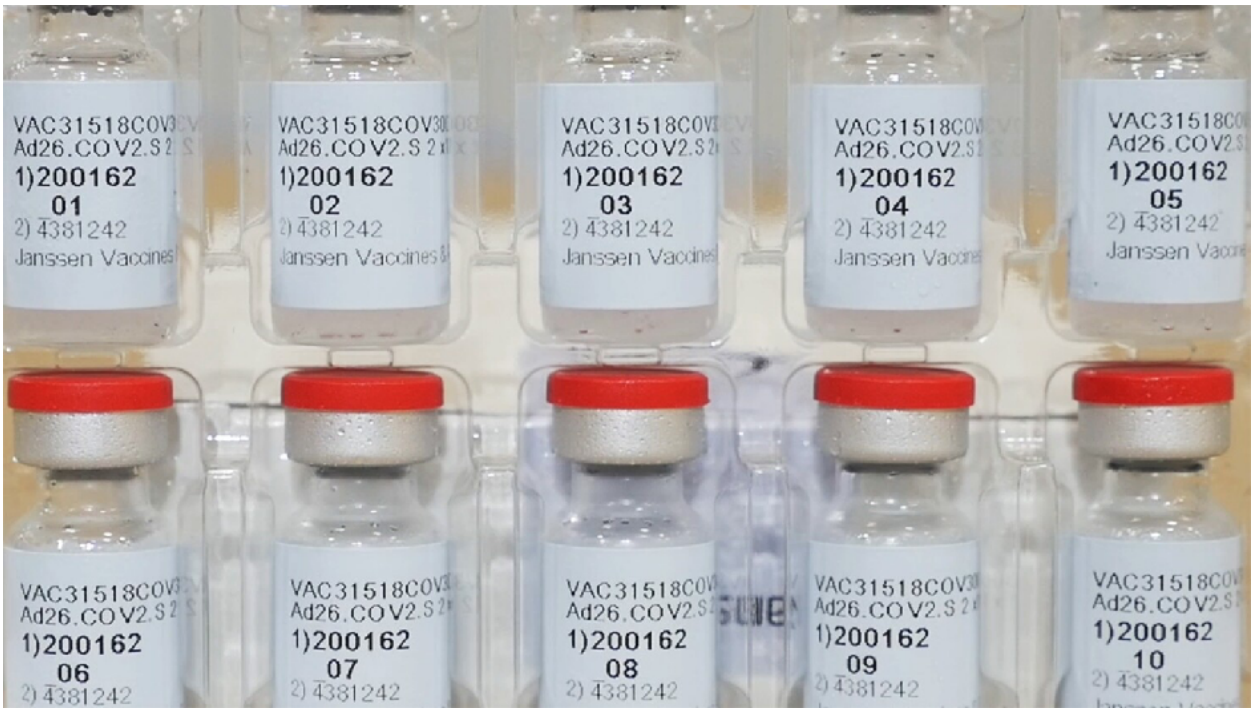
By learning from PPE procurement challenges in the early days of the pandemic, Canada was able to use a variety of policy mechanisms to procure enough doses of vaccine for everyone eligible. Canada is now focusing on refining its tactics to secure supply in the medium-to-long term, as pediatric, booster, and third doses are recommended. Concurrently, Canada is also focusing on ensuring it has enough vaccines to meet the needs of everyone in Canada, while not letting doses go to waste, and focusing on building capacity through investments in biomanufacturing to ensure Canada is on the road to economic recovery and well-positioned for challenges that the future may bring.

Natalie Nye is the Director General, Vaccine Roll-out Task Force; Jordan Owens, Senior Policy Analyst; and Nevena Askin, Policy Analyst, Public Health Agency of Canada

[10] "Government of Canada announces agreement with leading COVID-19 vaccine developer Moderna, Inc. to build mRNA vaccine facility in Canada" Government of Canada https://www.canada.ca/en/innovation-science-economic-development/news/2021/08/government-of-canada-announces-agreement-with-leading-covid-19-vaccine-developer-moderna-inc-to-build-mrna-vaccine-facility-in-canada.html.

(2/6) Timely Vaccine Development and Reliable Supply: An Industry Perspective

Dr. Robert Van Exan



National security of vaccine supply is not something that just happens – it has to be planned. Normal supply of routine vaccines in Canada is a challenge under the best of circumstances given that: 1) Eighty percent of vaccines currently licensed for use by Health Canada are manufactured by only five companies; and 2) fifty-seven percent of licensed vaccines are sole sourced.

Vaccines are a difficult business. The products are rooted in biological production technologies which are extremely complex, highly regulated and have high up-front costs with a very high risk of return on investment. The average vaccine development time is fifteen years with an average success rate of only sixteen percent.[11] The complex manufacturing processes can take two to five years to scale up and building a full-scale

[11] Douglas, R. G. and Sanabtm V. B. "The Vaccine Industry." In: Plotkin, S., Orenstein, W. A., Offit, P. A. and Edwards, K. M. *Plotkin's Vaccines (7th edition)*, (Philadelphia: Elsevier, 2018).

production facility for a new vaccine can take five years and cost up to a billion dollars. The cost of vaccine manufacturing space is five times that of normal manufacturing space.[12] This explains why most vaccine manufacturing facilities have capacities designed to meet global vaccine demands rather than supply individual countries. Only a handful of multinational companies or state-owned companies in China, Russia and India have the wherewithal and experience to develop and manufacture vaccines.

Vaccine supply should be an integral part of a national vaccine supply strategy and a national pandemic plan. If we have learned anything from the COVID-19 pandemic, it is that it is too late to start thinking about vaccine supply after the pandemic has started.

Pandemics are unpredictable. Pandemics can be caused by many different types of organisms. Influenza is a regular pandemic organism and corona viruses have been at the root of SARS, MERS and COVID-19. But there are many other potential pandemic viruses. The Global Alliance for Vaccines and Immunization (GAVI) top ten includes Ebola, Marburg, Lassa Fever, MERS, SARS, Zika, Nipa, Rift Valley Fever, Monkey Pox, and Crimean-Congo haemorrhagic fever.[13] Add to these a host of non-viral pathogens and any new or modified organisms resulting from natural mutation, species cross-over or resulting from human genetic manipulation and you have a rather large and unpredictable list of potential pandemic pathogens.[14] The planning for a pandemic is further complicated by the fact that the mode of transmission is unpredictable (vector, aerosol, droplet, water born, food born, terrorist or military activity). Finally, all of this can be complicated by exacerbating challenges such as climate change, antimicrobial resistance,[15] or other natural or man-made catastrophic events. The bottom line here is that the

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[12] David W. Thomas, Justin Burns, John Audette, Adam Carroll, Corey Dow-Hygelund, Michael Hay, *Clinical Development Success Rates 2006-2015* (Washington DC: Biotechnology Innovation Organization, 2016), https://www.bio.org/sites/default/files/legacy/bioorg/docs/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf

[13] "Ten infectious diseases that could be the next pandemic," GAVI, 2020. https://www.gavi.org/vaccineswork/10-infectious-diseases-could-be-next-pandemic

[14] Amesh A. Adalja, Matthew Watson, Eric S. Toner, Anita Cicero and Thomas V. Inglesby, "Characteristics of Microbes Most Likely to Cause Pandemics and Global Catastrophes" In: Thomas V. InglesbyAmesh A. Adalja Eds. "Global Catastrophic Biological Risks", Current Topics in Microbiology and Immunology, Vol 424. 2019. Springer, Cham. https://doi.org/10.1007/82_2019_176

[15] C. Raina MacIntyre and Chau Minh Bui, "Pandemics, public health emergencies and antimicrobial resistance - putting the threat in an epidemiologic and risk analysis context," Archives of Public Health (2017) 75:54

vaccine you need to respond to a pandemic, and therefore the vaccine platform most suitable to respond to a pandemic, will depend on the organism causing the pandemic.

Lessons learned from our response to the COVID-19 pandemic

The first and most positive observation is that an unprecedented global response and collaborative commitment from governments, the vaccine industry, small biotechnology

companies and academic institutions resulted in the development of several vaccines within two years.[16][17][18] Many factors were involved in this:[19]

- Vaccine development began as early as January, 2020[20] as soon as the genetic code for the virus was published. From that point onward, academic/medical research on the organism and its pathology and immunology were carried on in parallel to vaccine pre-clinical and clinical development. In fact, pre-clinical development was reduced or eliminated for many of the vaccine candidates.
- Clinical development phases are normally carried out sequentially to minimize financial losses should the vaccine candidate fail at an early stage. Clinical developments of COVID-19 vaccine candidates were conducted in parallel with expensive phase III studies starting before phase I or II studies were complete. This dramatically reduced the time needed to complete clinical development without jeopardizing safety but it greatly increased the financial risk to the developer.
- Manufacturing scale up was accelerated and began in parallel with clinical development to reduce the timeline for full scale manufacturing. Investing in expensive vaccine scale-

[16] Douglas and Sanabtm.
[17] Stuart A Thompson, "How Long Will a Vaccine Really Take?" *New York Times,* April 30, 2020.
[18] Anthony McDonnell, Robert Van Exan, Steve Lloyd et al. "COVID-19 Vaccine Predictions: Using Mathematical Modelling and Expert Opinions to Estimate Timelines and Probabilities of Success of COVID-19 Vaccines," Center for Global Development Policy Paper 183, October 2020.
[19] Thompson.
[20] Shrotri, Swinnen, Kampmann, Parker (2021), "An interactive website tracking COVID-19 vaccine development," Lancet Glob Health; 9(5):e590-e592. London School of Hygiene and Tropical Medicine Vaccine Centre https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/ Sept 8, 2021 update.

up before knowing whether the vaccine candidate was viable increased the financial risk to the developer. Some vaccine developers began building new manufacturing facilities or modifications to existing facilities before phase III trials were complete to shorten the time interval between completion of phase III trials and the production of first vaccine lots. This too was instrumental in shortening the time frame for access to COVID-19 vaccines but also increased financial risks if the candidate was unsuccessful in getting regulatory approval.

- Vaccine production began at risk before phase III trials were completed.

- Emergency Use Authorization (EUA) protocols and rolling submissions were put in place to shorten the regulatory approval time.

Government support for vaccine developers helped to reduce the elevated financial risks associated with parallel clinical development, process development, and manufacturing scale-up to substantially accelerate normal development time frames. This was accomplished through large, up-front investments to accelerate clinical development and pre-purchase agreements to accelerate vaccine production such as those made by the US through Operation Warp Speed[21] and many other countries each with their own contractual details. Government financing, then, was instrumental in managing the financial risk of the vaccine developers to enable the accelerated development.

Two other factors were critical in addition to large sources of government funding: 1) a strong and active vaccine pipeline in which numerous new vaccine technologies were already in development in the decade before the pandemic hit; and 2) luck that the pandemic organism was a relatively simple virus with one obvious antigenic target and with which we had previous experience in the vaccine pipeline (SARS and MERS). All of these lessons need to be captured in strategic vaccine supply plans and pandemic vaccine plans.

The second observation relates to the strength and magnitude of the response from the academic, biotechnology and vaccine industry communities.[22] By spring of 2020 there were 235 COVID-19 vaccine candidates from 35 countries in development. Canada ranked third in the number of candidates. Most of the candidates were from entities that had no prior vaccine experience but many had

[21] Moncef Slaoui, Ph.D., and Matthew Hepburn, M.D. "Developing Safe and Effective Covid Vaccines — Operation Warp Speed's Strategy and Approach," N Engl J Med. 2020 Oct 29;383(18):1701-1703.

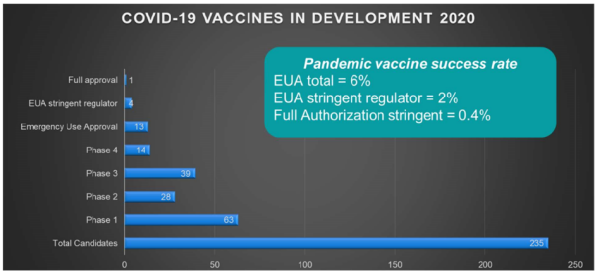
[22] McDonnell, Van Exan, Lloyd et al.

vaccines in the pipeline and twenty-one percent of the candidates were from manufacturers who had one or more licensed vaccine products. The vaccines were grounded in at least eight different platforms. Three of these were traditional platforms which have produced many of the vaccines used today for routine immunization programs. These technologies were based on mass production of antigens against the virus. Four of the platforms were new and as yet untested in routine vaccine programs for humans. These were based on the concept of producing genetic code for the COVID-19 spike protein rather than producing the antigen itself. The DNA, mRNA, non-replicating viral vector and the replicating viral vector platforms all work on the principle of delivering genetic code that would enable production of COVID-19 spike protein antigen in the cells and tissues of the vaccine recipient. A number of other candidates were based on new technologies recently introduced to the vaccine development pipeline which improved the safety and or effectiveness of traditional vaccine platforms.

The third observation relates to the success rate (Figure 1). Within the first two years after the initial signs of the pandemic, thirteen vaccines had received some form of EUA and were being used around the world to protect people from COVID-19.[23] While their

development was very quick compared to normal standards, the success rate was low, only six percent compared to the normal average of about sixteen percent.[24] If one looks at EUA from a "stringent regulator" as defined by the World Health Organization (WHO), the success rate is even lower – only two percent. The bottom line here is that it is very difficult to pick winners in the middle of a pandemic and you cannot pick winners in advance. Your vaccine supply plan must therefore be highly flexible in terms of the number of different vaccine technology platforms and the kinds of manufacturing capacity available.

Figure 1: Success Rate of COVID-19 Vaccines in the first two years



[23] Shrotri, Swinnen, Kampmann, Parker.
[24] David W. Thomas et al.

The fourth observation is derived from looking at the institutions that did produce

Figure 2: COVID-19 Vaccines with some form of Emergency Use Authorization.

Vaccine	Country of origin	Platform				No countires reporting use
		RNA	Viral Vector	Protein	Inactivated	
Janssen Ad26.COV2.S	USA		✓			54
Moderna	USA	✓				75
BioNTech-Pfizer	Germany/USA	✓				136
AstraZeneca	UK		✓			180
Beijing Sinopharm BBIBP CorV	China				✓	74
Cansino Ad5-nCorV	China		✓			7
Sinovac Corona Vac	China				✓	42
Wuhan Sinopharm vaccine	China				✓	3
Gamaleya Sputnik V	Russia		✓			53
Vector institute EpiVacCorona	Russia			✓		2
Bharat Covaxin BBV 152	India				✓	7
RIBSP Kazakhstan QazCovid-In	Kazakhstan				✓	1
CIGB CIGB-66 Abdals	Cuba			✓		1
Instituto Finlay de Vacunas Soberana 02	Cuba			✓		1
Total Number of vaccines (14)		2	4	3	5	

EUA vaccines within the first two years.[25] These can be divided into two types: those developed by vaccine manufacturers from OECD countries; and those developed by state owned or state supported manufacturers such as those from China, Russia or India (Figure 2). These two types have four things in common: 1) they all had vaccine development and manufacturing experience as validated by existing vaccine products; 2) they all had large scale vaccine production capacity; 3) they all worked in partnership with academic or small biotechnology companies/institutions; and 4) they all had a large injection of government money directed to COVID-19 vaccine development. The point here is that experience, collaborative partnerships and financing are critical success factors in responding to the need for pandemic vaccine production.

Vaccine Platforms have different advantages and disadvantages depending on the nature of the pandemic.[26] Vaccines derived from different platforms produce different kinds of immune response. They can produce different types of antibodies, different types of cellular immunity, and the duration of the immune response can be anywhere from a year to a life-time. They can produce single or multiple antigens and they can be used in different ways to target multiple strains, variants or serotypes of the pandemic organism. This will be related to how effective they are: prevent symptoms; prevent infection; prevent transmission; or eradication. This must be balanced with how fast the platform can be developed, and how fast it can be scaled up, the production capacity and the manufacturing cycle time which will determine how quickly and how much vaccine you can produce. This points

[25] Shrotri, Swinnen, Kampmann, Parker.

[26] Douglas and Sanabtm; and McDonnell, Van Exan, Lloyd et al.

to the fact that different platforms may be better suited to tackle different kinds of organism and that different vaccines may have a role in different stages of a pandemic. For COVID-19, the RNA vaccines were fast to develop and highly effective in preventing mild or severe disease but less effective in preventing infection and disease transmission. Other vaccines will be needed to consider eradication.

Vaccine manufacturing consists of three distinct processes supported by a complex, international supply chain.[27] Primary production results in a purified bulk vaccine concentrate which can be stored for relatively long periods of time under the right conditions. Formulation is the process whereby the bulk concentrate is diluted to its final dose strength and other ingredients such as stabilizers, preservatives, adjuvants or immune modulators are added. It is also the stage at which multiple antigens can be mixed together to form combination vaccines or multivalent vaccines. This process yields the final bulk vaccine. Sterile filling and packaging is the stage where the final bulk is filled into appropriate sized vials and where the vials are labelled and put in packages. Different labels and packages are required for distribution in different countries. All three process are usually done in one facility by one manufacturer but the intermediate products from these three fundamental stages of production can be shipped between different facilities without difficulty. An example (based on an actual product) would be a combination vaccine where two of the bulk components are produced in Europe and three are produced in North America. They are formulated into a combination vaccine at one site in Canada and the final bulk shipped to another site in the US for filling and packaging. This is routinely done within vaccine manufacturing companies but it is feasible that it could be done between experienced manufacturers as well, providing much greater flexibility to the pandemic vaccine plan. The point of this is that security of supply can be enhanced by contracting space in different types of facilities to do different parts of the overall vaccine production. This is the principle behind the NRC facility in Montreal which is a bulk vaccine facility, currently contracted to produce Novavax COVID-19 vaccine. This product will be formulated, filled and packaged in other facilities that have the expertise and capacity to complete the product, presumably within Canada.

Vaccine platforms may require different types of primary production. Influenza vaccine is usually produced using an inactivated vaccine platform in egg-based production facilities but it can also be produced in a cell-culture-based production facility. Influenza vaccine, which uses a protein subunit platform, can be produced in either an insect-cell or plant-based production facility. Genetic vaccines

[27] Douglas and Sanabtm.

rely on biological processes for plasmid production but the rest of the production process is largely biochemical in nature. Different types of production facilities are not readily interchangeable. Therefore, security of supply will require multiple types of vaccine primary production. The advent of modular production facilities and single use bioreactors show promise in solving this challenge but they are new, as yet untested in production of a licensed vaccine and production capacities are somewhat smaller than traditional vaccine production methods.

Canada has significant vaccine manufacturing infrastructure for a small country. Two of the five largest vaccine manufacturers in the world (GSK and Sanofi Pasteur) have manufacturing facilities in Canada producing vaccines on a global scale. These vaccine manufacturing sites have been producing vaccines in Canada for 80 and 110 years respectively and represent primary hubs of vaccine manufacturing expertise in Canada. Moderna, which so far has only one vaccine product, has recently committed to build an RNA vaccine facility in Canada. Medicago is a new entry into the vaccine manufacturing field. It has no licensed vaccines as yet but it has a large-scale plant-based manufacturing facility in the US and is building a small manufacturing facility in Canada. NRC is currently building a vaccine manufacturing facility which it hopes to use in partnership with Novavax to produce a COVID-19 vaccine. Finally, Vido-Intervac has a pilot scale facility in Saskatchewan. This provides Canada with significant manufacturing capacity for a number of different vaccine platform technologies, however, only two have the experience and global reach to bring a vaccine from concept to global scale production and none of them have surge capacity to be able to produce a new vaccine for a new pandemic, with the exception of the influenza facilities at GSK and under construction at Sanofi Pasteur. Canada, therefore, has significant infrastructure but is not in a self-sufficient situation with respect to pandemic vaccine security of supply.

There are a number of actions that Canada could take to improve its strategic vaccine supply capabilities. These would require engagement, collaboration and perhaps joint ventures or partnerships with the larger multinational vaccine players. A few constructive initiatives are identified as follows:

1. Create a comprehensive National Vaccine Security Strategy.

2. Establish a government vaccine agency with a mandate (like the US Biomedical Advanced Research and Development Authority (BARDA)) to engage the vaccine industry on vaccine development and manufacturing. This could be the NRC but it would have to focus less on its own vaccine research interests and more on partnering with large

companies to develop vaccines and vaccine infrastructure in Canada.

3. Invite global vaccine manufacturing expertise to the pandemic/vaccine supply planning table. Canada has expertise centred in the manufacturers already well-established here or planning to establish here (GSK, Sanofi Pasteur, Moderna, Medicago). This expertise should be tapped at the planning table.

4. Establish an attractive environment for investment in new vaccine manufacturing technologies in Canada. Of particular interest are the new modular facilities capable of producing multiple platforms in the same facility. Sanofi Pasteur has just committed to build such a facility in France.

5. Foster a collaborative environment between government, vaccine industry, and academia. Canada's academic and small biotechnology companies punch above their weight on the world stage in terms of vaccine development but they lack access to the multinational manufacturers who can bring their products through the clinical development, scale up and manufacturing phases.

6. Establish contractual agreements, funding and/or partnerships to build and maintain surge capacity for vaccine manufacturing platforms in Canada – especially modular facilities

7. Establish contractual trade agreements and funding to support importation of bulk concentrates or final bulks from off shore facilities to formulate and/or fill at facilities in Canada.

8. Initiate a government vaccine stock pile plan to open and access surge capacity.

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(3/6) Logistics Challenges of Vaccine Distribution

Brigadier-General Krista Brodie

Introduction

This article is a paraphrased transcript of comments delivered during the CDAI hosted 2021 Defence and Security Economics Workshop (29 October 2021). It provides a retrospective of the Canadian Armed Forces (CAF) mission to support the Public Health Agency of Canada (PHAC) in the distribution of COVID-19 vaccines across Canada. The military contribution to that task is now ended and PHAC is now resourcing and organizing to manage Strategic Vaccine Supply as a core business line.

I'll discuss three broad themes: the key logistical challenges of Canada's COVID-19 Vaccine Distribution Operation in the broader context of the national COVID-19 Immunization Campaign (as outlined by Nathalie Nye in her article) as revealed in the "logistics preparation of the battle space;" unprecedented partnerships; and supply chain resilience and the underpinnings of a national mobilization capacity.

Theme 1: COVID-19 Vaccine Logistics in Canada

There are two key elements that differentiate COVID-19 vaccines from the established vaccine program pre-COVID. First, procurement and initial distribution of COVID-19 vaccines is a federal (vice provincial/territorial) responsibility. Second, the early COVID-19 vaccines approved for use in Canada have unique cold chain requirements – for which there was no dedicated pre-existing supply chain infrastructure in Canada.

The Pfizer-BioTech and Moderna mRNA vaccines were the first through the regulatory and production gateways, Pfizer requiring an Ultra Low Temperature (ULT) cold chain, and Moderna requiring a -20°C cold chain. While there was some very limited storage capacity in a few discrete research and hospital settings, there was no warehousing or distribution capacity for ULT or -20°C products to speak of in Canada in the fall of 2020.

Over the years, Canada has cultivated a tremendous reservoir of vaccine expertise and talent, but at the start of the pandemic many of those people were working offshore in support of global immunization programs. Understanding the national need, many quickly migrated back to PHAC from other government departments and international

organizations to join a dedicated core of professionals that were very much in the "close fight" on Canada's pandemic response.

The technical experts quickly appreciated that it would take a Whole of Nation effort to operationalize vaccine distribution on a monumental scale in record time. It also became clear there was an operational gap that the CAF was ideally positioned to provide. The result was "Operation VECTOR", which wrapped up at the end of October 2021 and was Canada's longest domestic operation to date. (The CAF was no stranger to embedded operations with the PHAC however – a team of logistics experts had worked within the agency from March through August 2020 on the contracts to support the warehousing and distribution of Personal Protective Equipment.)

Following an operational needs assessment, an initial team arrived in October to begin planning the distribution operation. They were soon joined by a team to establish and run the National Operations Centre; and in November, a team of strategic and interagency enablers.

The military typically starts this kind of mission with what it calls "logistics preparation of the battle space." The assessment was alarming, but not unsurprising. There was no established supply chain and extremely limited cold chain capacity for the first COVID-19 vaccines. There were no systems in place to provide a common operating picture or to share information in a transparent and expedited fashion among the federal departments and agencies, the provinces and territories, and indigenous partners. There were deeply rooted jurisdictional divides in the health care domain that hindered the flow and aggregation of information.

Consequently, just about everything had to be assembled from scratch in a colossal collaborative effort: the vaccines themselves (procured through Advance Procurement Agreements tenaciously negotiated by Public Services and Procurement Canada (PSPC)), the ancillary equipment (syringes, needles), the freezers, thermal shipping containers, cold packs, dry ice, dry ice handling kits, temperature data loggers, and much more. Basic supply principles and systems like material accountability, inventory management, and in-transit visibility all had to be brought to life as materiel was assembling and flowing in real time from thousands of different sources.

The first order the team sent in for ULT freezers came back with a market availability assessment of 9…in the world. That

demonstrates the magnitude of the global mobilization effort that was occurring and the corresponding strain on supply chains everywhere.

The two parallel cold chains that were built for Pfizer and Moderna in Canada are almost elegant in both their simplicity and sophistication when you see them now, as a vast integrated web of 2-way logistic hubs and spokes connecting every community in this vast, diverse, and dispersed country – but the cumulative complexities of making it real were more than a little bit crazy. It was no small feat to land Pfizer at the first 14 Vaccine Delivery Sites on the 14th of December 2020, or to send Moderna into the North before the New Year – and that was only the beginning.

The National Operations Centre lived and died by the Allocation Tables – a tool designed by the planning team to manage the apportionment of available vaccines – updated every time a new shipment was confirmed by the manufacturers. Guided by the principles of Equity and Transparency, Canada's COVID-19 vaccines are allocated on a per capita basis with adjustments for vulnerable populations consulted and agreed upon at federal, provincial, territorial and Indigenous governance tables.

The inventory management system evolved from excel spreadsheets at the outset [no kidding – the team was tracking the delivery of millions of doses to thousands of vaccine delivery sites on Excel spreadsheets and managing analog aggregation of data from at least 3 incompatible systems] before migrating to an in-house designed Stock Management System platform, and later to an SAP "Intelligent Supply Model" that launched during the height of the "Big Lift" in June and that continues to evolve to manage a much more mature Strategic Vaccine Supply inventory management system.

In-transit visibility for sensitive biomedical products includes not just knowing where the shipments are, but what the temperature of each package is at every point on their journey to ensure safety and efficacy. The system was designed so effectively that incidents of temperature excursions and closed-vial wastage were extremely rare.

Theme 2: Unprecedented Partnerships

The team was driven throughout by a sense of common purpose and national imperative. From the early days and months of vaccine scarcity to sufficient supply, the tenet of service before self, of ownership and accomplishment, was a shared equity among all the military, civilian, public and private sector partners.

Just as there were unique logistical considerations, so too did unique working relationships emerge, not only across all levels of government from local to federal, but in our relationships with manufacturers,

with industry, with foreign governments and export authorities, and with supporting organizations like the Canadian Red Cross.

Vaccine acquisitions involved close collaboration among PSPC (the procurers of goods and services), Manufacturers (the providers of the vaccines), Health Canada (the Regulator), PHAC (charged with operationalizing pandemic response) and Global Affairs Canada (supporting international donations) among others.

The relationships with and among Logistics Service Providers (LSPs) were especially critical, in particular the federal government partnership with FedEx-Innomar and Pfizer's partnership with UPS. While the National Operations Centre served as the central command and control hub for the distribution operation, the execution was a partnered endeavor leveraging the LSPs. Their employees have many stories of working the assembly line in a -20°C freezer unit when millions of doses of Moderna were arriving every few days in July, needing to be broken down into smaller shipments, packed with reconditioned cold packs and temperature data loggers, and shipped out at a frantic pace – of what it felt like to be the person who handed off a thermal shipping container at a remote First Nations nursing station, having travelled by fixed wing aircraft, truck, helicopter, boat, and then by foot to the designated vaccine delivery site.

Concluding Theme – Modern Mobilization Mindset

To offer some concluding perspectives, we must guard against being cavalier in our discussion of Supply Chain Resilience, and of National Resilience. They are not a given and the devil is in the detail.

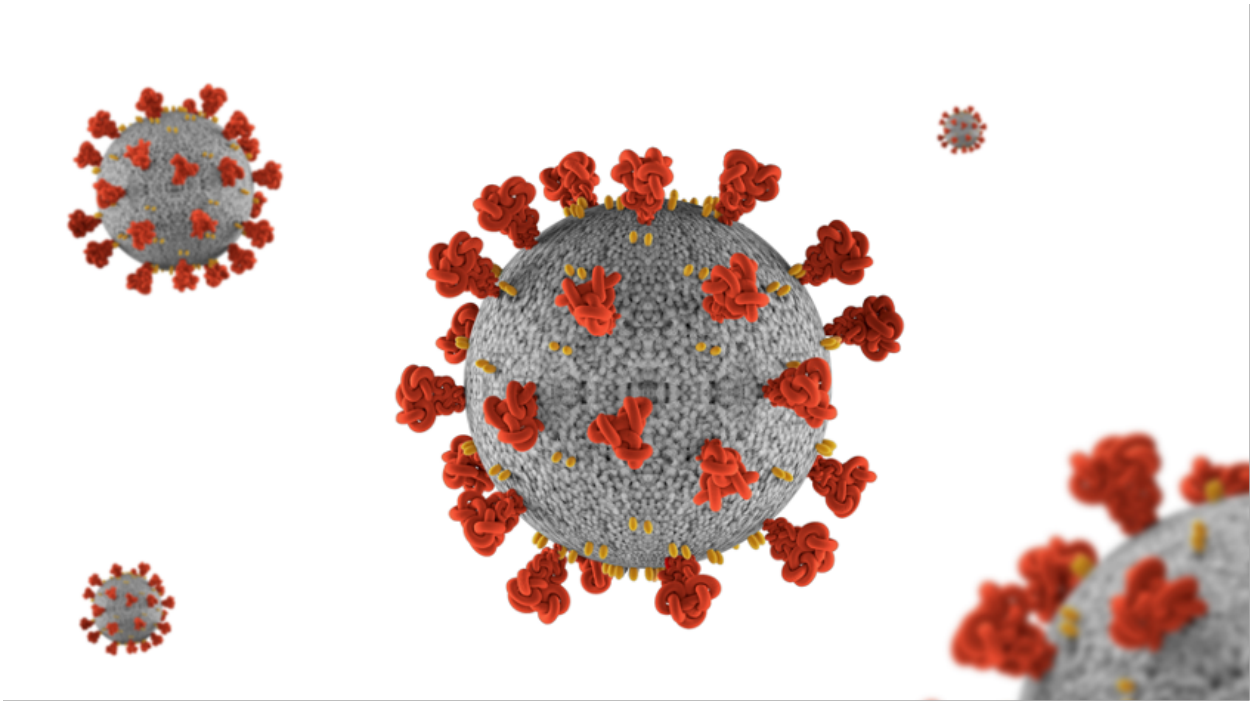
We have achieved a measure of resilience in our layered vaccine supply chains, in our "assured contracted supply" for COVID vaccines, in our nascent efforts to develop national manufacturing capacity, in our *de facto* National Strategic Reserves (that need continuous care and attention and careful lifecycle management – if you consider vaccines alone, each type, each lot number, has a different expiry date, and must be carefully managed), in our industry partnerships – with the public sector ensuring critical redundancies and gap fills (like the CAF transporting -20°C freezers into the North just ahead of the first vaccine deliveries).

We have collectively elevated the baseline of foundational pandemic response capacity in Canada – but the gains are fragile, and must be formally assessed and "locked in" to allow us to build from here going forward. Too much has been invested – a too high a human cost – to retreat from the ground we now hold.

Brigadier-General Krista Brodie served as Vice-President, Logistics and Operations for the Public Health Agency of Canada

(4/6) How should Canada ensure access to vaccines for the next pandemic?

Dr. Paul Grootendorst



Introduction

The policy objective for Canada is clear: ensuring access to the vaccine or vaccines developed for the next "big one." More specifically, it is to have expedited access to at least one safe and effective vaccine for the next pandemic virus, and for this we will need enough shots for about 40 million people plus the amounts we should donate to those living in lower income countries. (To this end, Canada should negotiate with its peer countries to determine what its donor obligations are.). Those donations will not be made for purely altruistic reasons – they are also in our own national interest because until a pandemic disease is brought under control everywhere it can mutate and strike anywhere.

The problem is that we do not know the characteristics of the next pandemic virus, and so we don't yet know what the vaccine will look like and we don't know which vaccine production platform is required. Certainly, some emerging platforms, such as the mRNA platform, look promising but there is no guarantee that this will be a suitable

platform to produce vaccines for the next big one. Given this uncertainty, we have three very different policy options which I will describe in turn.

Policy Options

The first option is to do nothing. (Canada has lots of experience with this option.) What this means in practical terms is that we enter into agreements with vaccine manufacturers, possibly domestic, but more likely foreign, when the need arises. This approach has both pros and cons.

The pro is that it defers costs into the future. It also will allow us to select what appear to be the most promising vaccines under development.

The cons are that we would need to pay premium vaccine prices to secure access at the time of the next pandemic, and even if we did so we may face the risks of vaccine nationalism and other causes of access delays. For instance, the US did block COVID vaccine exports to Canada for a period of time. On the other hand, I think that vaccine manufacturing capacity globally has and will continue to increase in the wake of the COVID pandemic so the global supply constraints may not be too big a problem in the future.

The second policy option is to achieve domestic self-sufficiency in both vaccine R&D and in manufacturing. In terms of R&D, this would require major, sustained public investments in both academic and commercial areas of the life sciences sector. The advantage is that we would build domestic expertise in vaccines development and this would have spin off benefits including expertise in biologic therapeutics development. The cost is that we would need many independent research projects on the go. If the probability that any one project successfully develops a pandemic vaccine is 15%, then (according to the binomial distribution) Canada would need at least 19 research projects to attain a 95% probability of at least one success. It would be very expensive to maintain this capacity. Moreover we would need the capacity to conduct large scale clinical trials in different countries to test the new vaccine.

Looking at manufacturing, in order to achieve self-sufficiency we would need to acquire technology licenses from foreign producers and ensure sufficient domestic reserve production capacity exists in each of the four vaccine platforms that Rob Van Exan described in his article. This approach would have the benefit of providing both better supply security and likely lower unit vaccine costs than doing nothing. However, it has three cons:

1. There would be considerable investment costs;
2. We would need to contract with domestic organizations who routinely use the platform and have requisite

expertise, and this means a commercial operator who can profitably make and sell vaccines. This is not like activating the local volunteer fire department to put out a fire – the producers need to be producing vaccines full time; and

3. Whole virus plants require very large scale to achieve the lowest possible unit costs.

The third policy option available to Canada is an agreement with international partners. It would specify which countries will maintain sufficient reserve capacity in each of the four vaccine production platforms such that there would be enough doses to share among all participants. Note that producers need not engage in the final two stages of vaccine production – formulation and fill and pack. These tasks could be shared among the signatories under an agreed formula defining the financial and in-kind contributions each would make.

This approach does have some things to recommend it. First, it allows for some redundant supply capacity – which is needed -- but it can avoid excessive duplication. Also, the whole virus plants can operate at optimal scale.

However, there are some cons:

1. Ensuring ongoing compliance of all participants with the agreement may be difficult as future events evolve. Vaccine nationalism or other domestic pressures may lead some participants to stray from their commitments; Canada's failed COVID vaccine development project with China serves as a good example.

2. Ensuring manufacturing plants of some of our international partners meet Canada's regulatory standards may be challenging; this is especially the case for plants located outside the United States and the European Union region.

3. It is unclear if the United States and European Union would participate because they are probably already self-sufficient and have their own large domestic markets. That leaves commonwealth nations like the United Kingdom, Australia, and New Zealand and possibly countries like Japan, Brazil, or Turkey as potential partners.

How to Proceed?

The three options outlined here are not necessarily mutually exclusive. For example, my sense is that we should start by focusing on ensuring domestic supply security in the mRNA/DNA platforms along the lines of the second option. The mRNA/DNA plants can be operated economically at relatively small scale and this seems to be a promising technology. This approach will also develop expertise in the federal government to engage

with producers. The first order of business would be to identify competent domestic suppliers and enter into supply contracts.

On the other hand, whole virus plants need larger production scales so in this case it would be best to enter into an international agreement as in the third option. A starting point might be asking Sanofi or GSK Canada if they could create sufficient capacity on demand to supply Canada and several other countries, and if so under what conditions and at what cost. Based on their responses, a framework for an assured supply agreement could be developed.

Conclusion

Preparing for vaccine responses to future pandemics is a tough challenge. As Rob Van Exan has noted in his article, the range of potential pathogens we may have to deal with is enormous. As we have seen here, the range of technologies in the available solution set is similarly very diverse, with major implications for the way effective and rapid R&D and production capabilities have to be built. On top of this, the science is rapidly evolving and any capability must be capable of adapting to new developments. Agility and adaptability have to be core watchwords in any assured vaccine supply solution Canada may adopt.

In this kind of environment, knowledge is key to charting a successful way forward. Industry, academia and government all need to bring expertise to the process. Further, a successful solution will not be a "perfect" solution because each pathogen we may face

at any given point in the future will require its own response with the then-current technologies. Rather, we need to put the foundations in place to be able to rapidly develop "good enough" solutions at need.

This is an enormous challenge, but one that Canada can take on successfully, and should.

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(5/6) Future Domestic Vaccine Manufacturing in Canada: Learning from Munitions Supply

Dr. Ugurhan G. Berkok

Canada's current vaccine acquisition mechanism of securing vaccines from three[28] foreign suppliers was an urgent national security response to the current pandemic. Yet, an industrial policy of building a domestic vaccine manufacturing industry may enable future acquisitions from a domestic manufacturing industry with surge capability. The future domestic vaccine landscape necessarily depends on the current domestic vaccine manufacturing capabilities[29] as well as vaccine development facilities.[30] Noting that this latter capability discovered 15 of the 235 vaccine candidates from 35 countries,[31] it may even supply one of the pandemic vaccines in the next pandemic. Against this background detailed in Dr Van Exan's article, several future market structures may emerge from the national security, industry and trade policies of today. This article concentrates on the spectrum of manufacturing options based on the current industry capabilities and by drawing on how countries acquire munitions[32] as there are similarities between munitions and pandemic vaccines markets in terms of the need for surge capacity and the purchaser being mostly the domestic government.

Future Vaccine Supply

The first option for Canada could well have been the status quo. The vaccine acquisition was successful as the federal government had signed several acquisition contracts early on and the vaccine rollout was nearly at par with similar countries. However, the future existence of a pandemic vaccine manufacturing capability will certainly provide better assurance. We thus concentrate on future options that require current industrial policy intervention with modest commitments already in place and taking into

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[28] AstraZeneca, Pfizer BionTech, Moderna and Johnson & Johnson. Plus, the never acquired CanSino vaccine produced by Tianjin-based CanSino Biologics (https://www.cbc.ca/news/canada/cansino-deal-canada-nrc-fifth-estate-1.6208241).

[29] Sanofi Pasteur, GlaxoSmithKline, Medicago/GlaxoSmithKline, Moderna, NRC/Novavax, Vido Intervac.

[30] Van Exan, R. [2022], "Timely Vaccine Development and Reliable Supply: An Industry Perspective", presentation at the 16th Defence & Security Economics Workshop 2021, forthcoming in On Track.

[31] Van Exan [2022].

[32] Davies, C. [2022], "Assuring Vaccine Supply: Lessons from the Munitions Supply Program", paper presented at the 16th Defence & Security Economics Workshop 2021, forthcoming in On Track.

account the fact that there exist technologically advanced vaccine R&D capabilities in the country as well as some vaccine manufacturing capacity.[33]

The National Security Perspective

SARS-CoV-2 virus and its variants demonstrated the national security threat a pandemic poses from overloaded hospitals, supply chain disruptions to key industries and, potentially, political instability from prolonged lockdowns and restrictions. A more infectious and more lethal virus would only exacerbate these threats. Although the timely domestic development of a vaccine must remain uncertain, building a domestic, surge-able and multi-platform vaccine manufacturing capability depends on our willingness to do so. The tradeoff between acceptable risks and the cost to the taxpayer will determine its fate. As the major future buyer of pandemic vaccine doses in the country, the federal government has the legal and financial power to shape the supply side of the market in tandem with the provinces.

Noting that that pandemic vaccine manufacturing differs from those for standard vaccines in terms of urgency as well as manufacturing processes invokes two questions.[34] First, can the R&D for vaccine development and manufacturing facilities switch easily and swiftly to brand new vaccines against a brand new virus? Second, will those facilities, even if they exist, have the surge-ability to respond to the spontaneous demand increase triggered by a new virus?

The Canadian federal and provincial governments have already made a few hard commitments to rebuild the country's vaccine manufacturing capability by investing in existing and new facilities. While this may be an acceptable step forward, it is a rush decision because there exist several routes forward from the existing pharmaceutical infrastructure towards a surge-able vaccine manufacturing capability of the future. Whereas, a well-functioning vaccine R&D market exists in Canada, a pandemic vaccine manufacturing capability does not. Assuming the federal and provincial governments will intervene to create that capability, they have to design the market,[35] together with its corresponding institutions, that will incorporate such a capability.

Industrial policy and domestic vaccine manufacturing capabilities

[33] Van Exan [2022].

[34] Van Exan [2022].

[35] The market design refers, first, to either the identification that a market does not exist, e.g. the case in hand, or that it does not function well, e.g. pollution. Moreover, then, an industrial policy is designed to either create the market or correct its functioning. (Agarwal, N. & E.B. Budish [2021], "Market Design, NBER Working Paper No. 29367, http://www.nber.org/papers/w29367).

Industrial policy towards building a future domestic vaccine manufacturing capability requires initiatives[36] in the vaccine development and manufacturing sectors.

1. Vaccine research and development

The current vaccine R&D sector with several biotech firms is alive and well in Canada. In fact, two Covid vaccine candidates, Medicago and Providence Therapeutics,[37] have made it to human trials and Medicago's may be approved by Health Canada early in 2022 alongside with the Novavax vaccine that will be manufactured in National Research Council's (NRC) Montréal facility. Despite this successful performance in vaccine development, two policy interventions may prove necessary vis-à-vis a future pandemic. First, individually, biotech firms may have little incentive to invest in emerging pathogen surveillance. Thus, a continuing pathogen surveillance capability, similar to that in the Obama Administration's "Playbook,"[38] can provide these biotech firms early notice of emerging pathogens. Moreover, this capability ought to coordinate better with international entities like World Health Organization (WHO) and countries that invest in such surveillance. Second, the riskiness of allocating resources to a potential pandemic vaccine R&D where the success corresponds to winner-takes-all reward.[39] Since this is pre-emptive activity with the high likelihood of no commercial reward, the industrial policy aiming to build the pandemic vaccine eco-

[36] See the most recent federal government announcement at https://www.canada.ca/en/innovation-science-economic-development/news/2021/07/the-government-of-canada-announces-biomanufacturing-and-life-sciences-strategy.html.

[37] Respectively, VLP (virus-like particles) and mRNA vaccines.

[38] National Security Council [2016], *Playbook For Early Response To High-Consequence Emerging Infectious Disease Threats And Biological Incidents*, https://stacks.stanford.edu.

[39] Azimi, T., M. Conway, J. Heller, A. Sabow & G. Tolub [2019], "Refueling the innovation engine in vaccines", McKinsey & Company, https://www.mckinsey.com/industries/life-sciences/our-insights/refueling-the-innovation-engine-in-vaccines.

system must include cost-sharing measures as biotech and pharmaceutical firms, government, academia and clinicians must be involved.[40] Since the aggregate potential benefit is disproportionately large though uncertain,[41] a case for public financing arises. In fact, several of the 15 Covid-19 vaccine candidates discovered in Canada,[42] of 235 in the world,[43] have been discovered in private[44] and public research institutions or jointly.[45] The federal government's Strategic Innovation Fund and the National Research Council (NRC), a crown corporation, must remain instrumental in maintaining and strengthening the existing competition within the domestic biotech eco-system not only for reasons of national security but also as an internationally competitive sector[46] at the frontiers of biotechnology.[47]

2. Vaccine platforms and a surge-able manufacturing capacity

A vaccine R&D sector is not, of course, necessary for the viability of a pandemic vaccine manufacturing capability that can manufacture licenced vaccines. A pandemic vaccine-manufacturing capability would require a platform matching the licenced vaccine and it must be surge-able to desired capacity. Both these needs may be unprofitable to maintain as demand for a pandemic vaccine is fundamentally uncertain. Moreover, large and platform-specific production facilities are not substitutable, thus adding to surge capacity costs.[48] The large

[40] Wyonch, R. & S. Makbool [2020], "Public Health and Emergency Measures Working Group, Summary Discussion", https://www.cdhowe.org/council-reports/%E2%80%8Blessons-first-wave-covid-19-public-health-and-emergency-measures-working-group

[41] We use the term uncertain in the sense that the probability of the next pandemic, both in terms of timing as well as the pathogen's infectivity and virulence, is insurmountably difficult to compute.

[42] For instance, IMV(NS), Entos Pharmaceuticals (AB), Providence Therapeutics (AB), Glycovax Pharma and Biodextris (QC) and Symvivo (BC) which were funded by the National Research Council and Variations Biotechnologies (ON), Medicago (QC), Precision Nanosystems (BC), Northern RNA (AB) funded by the Strategic Innovation Fund. Moreover, several therapeutics candidates were similarly funded (https://www.ic.gc.ca/eic/site/151.nsf/eng/00010.html).

[43] This places Canada 3rd in the world (Van Exan [2022]).

[44] Such as Edesa Biotech, IMV Inc., AbCellera, Medicago, Precision NanoSystems, VBI Vaccines, and VIDO InterVac.

[45] In countries where a full defence platform can be manufactured, small R&D firms are heavily subsidized simply because the outcome of R&D presents large risks to private sector while the resulting product mostly sells to governments (Rogerson, W.P. [1994], ''Economic Incentives and the Defense Procurement Process'', *Journal of Economic Perspectives* 8(4), 65-90).

[46] BIOTECanada Vaccine Industry Committee [2010], "Building on the legacy of vaccines in Canada: The future of vaccines in Canada", http://www.biotech.ca/policy-matters/health/canadas-vaccine-industry-committee/building-legacy-vaccines-canada/.

[47] Michael Houghton of the University of Alberta won the 2020 Nobel Prize due to his research in virology.

[48] Van Exan [2022].

cost of surge capacity, given that the pandemic inflicts costs on the whole population, must then be publicly subsidized as only the government can spread the risk so widely. Briefly, there exists a market failure just like in the case of terrorism insurance in the aftermath of 9/11 when the U.S. Federal Government introduced the re-insurance program Terrorism Risk Insurance Act (TRIA), passed in 2002, to cover very large losses from uncertain terrorist attacks when individual insurers could not. The pandemic equally being a public bad, the surge capacity is like an insurance like TRIA, except that it has to exist prior to a pandemic.

Given the upstream advanced vaccine R&D capabilities in Canada, building on the existing downstream vaccine manufacturing capability would appear sensible for three reasons. First, if a successful vaccine is developed, the manufacturing capacity would enhance national security by the public good reason discussed above and by reducing the burden on required efforts to import sufficient doses in a new pandemic when foreign supplies may be hard to come by. Second, in terms of vertical integration and the nascent possibility of exporting the new vaccine, the investment in capability creation may prove successful if indeed the vaccine can be exported. And, third, the existing spectrum of vaccine manufacturing platforms will be augmented by the mRNA platform of Emergent BioSolutions (Manitoba) to manufacture Providence Therapeutics' vaccine. Despite the fact that Canada has been relatively successful under the current pandemic by importing sufficient quantities of vaccine doses, distributing them domestically and vaccinating its residents, such a domestic capability would add to the epidemic management arsenal.[49]

There are three issues within the industrial policy discussion. First, the capability must be platform interoperable with effective vaccines, whether domestic or foreign. Thus, the platform choice, made well in advance of the appearance of the next pandemic virus, will determine whether licenced production may take place. Second, since the domestic manufacturing capability may include several facilities, whereas it would be more affordable to concentrate on a single platform but higher capacity to benefit from significant scale economies,[50] a less risky option might be to induce a multi-platform capability.

[49] The arsenal must include the "always on" epidemic management systems anyway. (M. Craven, A. Sabow, L. Van der Veken & M. Wilson [2020], "Not the last pandemic: Investing now to reimagine public-health systems", McKinsey Report, https://www.mckinsey.com/industries/public-and-social-sector/our-insights/not-the-last-pandemic-investing-now-to-reimagine-public-health-systems.

[50] Van Exan [2022].

Third, the capability must include a surge-able capacity, which is costly to maintain in normal times and hence may require careful planning to allow multi-use features in order to minimize its overall cost.[51]

Currently, the domestic vaccine-manufacturing capability[52] consists of facilities operated by GlaxoSmithKline (U.K.) and Sanofi Pasteur (France) and others such as Medicago (Québec), National Research Council and Novavax (U.S.) partnership, and Vido-Intervac (Saskatchewan) and Moderna (U.S.) either have existing facilities or are building new ones. The new Moderna facility will manufacture vaccines on the mRNA platform. The existing Canadian vaccine-manufacturing infrastructure is currently surge-able only to meet the demand for influenza vaccines.

Sanofi Pasteur is already active in Canada and recently signed an agreement with Ontario and the Federal Government to expand its footprint in Toronto. Sanofi is currently building a facility in Lyon (France) that will endow the company with "a platform of platforms" to respond to an emerging virus with more than a single platform with which to manufacture vaccines.[53] Clearly, such a capability reduces the pandemic risks in two ways. First, under an emerging pandemic, such a multi-platform facility may well be the only one ready to manufacture a vaccine urgently. Second, if not, it would be still critical by taking the pressure off the bottlenecks in the manufacturing of other vaccines, indirectly relieving pressure on hospitals. Recently, the Sanofi facility in New Jersey started manufacturing Moderna's Covid-19 vaccine. From a domestic industrial policy perspective, there may thus be a tradeoff between the variety of platforms and surge-ability over a given platform within a country. However, the need for costly domestic surge capacity may be moderated by contractually tying down redundancies elsewhere if advance contractual commitments are in place. Other avenues may include co-investment into further domestic and foreign facilities, the use of retainer fees and of guaranteed demand for sustaining surge-able capacities.

Munitions Supply Policy Examples from Similar Countries

The similarity between the pandemic vaccine and munitions surge capacities can be codified in three critical features. In both

[51] An example is the one a UK consortium is developing: https://www.businesswire.com/news/home/20210729006001/en/UK-Biomanufacturing-Team-to-Spearhead-Development-of-Advanced-Controls-to-Accelerate-Drug-and-Vaccine-Manufacturing.

[52] Van Exan [2022].

[53] Sanofi press release [2020], "Sanofi invests to make France its world class center of excellence in vaccine research and production", https://www.sanofi.com/en/media-room/press-releases/2020/2020-06-16-12-00-00.

cases, the need for a surge in production represents a low probability but high impact need. Moreover, for a surge capacity to exist, facilities must be built in advance. Finally, in both public health and national security, the government is directly responsible for supply.

The Canadian munitions industry, a franchise monopoly, mostly manufactures licenced products. The following munitions supply programs can serve as benchmarks and examples for Canada's impending industrial policy towards a future pandemic-vaccine manufacturing industry.[54]

- **Radical**: Recently, in 2015, Australia used a franchise bidding policy for its munitions supply. The franchisee assumes contractual responsibility for the surge. This design may well be a non-starter in Canada as the vaccine manufacturing industry already exists but must be expanded.

- **Prime contractor**: U.K. contracted BAE Systems for its munitions supply. In turn, BAE Systems contracts domestic and offshore contractors for the surge by diversifying the sources and hence managing the surge risk. This design resembles an augmented version of the Australian munitions supply program with BAE managing the program.

- **Crown Corporation**: U.K.'s Nuclear Warhead Factory recently transitioned from a GoCo to a government agency, thus becoming an ALB, Arm's-Length-Body, resembling a Canadian Crown Corporation like NRC.

- **Franchise monopoly**: Canada's munitions supply arrangement with General Dynamics is a franchise monopoly with built-in surge clauses in the contract. If the recent accord with Sanofi Pasteur remained exclusive the company would have become a franchise monopolist. However, the operational presence of other vaccine manufacturers in Canada with new entries rules out the franchise monopoly. In this regard, we note the tradeoff between scale economies from longer production runs with a monopolist and the supply security from an oligopoly.

- **Franchise oligopoly**: Perhaps a likelier scenario, based on the current active presence of several vaccine manufacturers, is similar to the full Munitions Supply Program (MSP) where

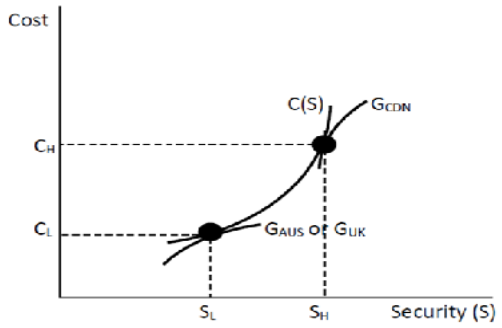
[54] This section draws on U.G. Berkok & C.E. Penney [2014], "The political economy of the Munitions Supply Program", CORA at Defence Research & Development Canada, https://apps.dtic.mil/sti/citations/AD1016983.

there are four franchise monopolies.[55] Under the MSP accords, such a market is not exactly an oligopoly because franchisees operate in their own silos where each manufactures a certain group of munitions. Such a compartmentalization would be restrictive and thus inefficient. However, public investment into certain facilities with different platforms in return for assured surge capacity may resemble a franchise oligopoly.

- **No structural change, just regulatory/ transactional structures**: This is the "do-nothing" policy.[56] The federal government is now experienced in remaining as the purchaser of vaccines on behalf of the whole population. This option retains a somewhat lower risk (with developing new domestic manufacturing capacity) and lower cost (than the peak-load prices paid early in the pandemic) with the recent progress towards an increase in domestic manufacturing capacity.

The Way Forward

Whereas the domestic vaccine development sector appears satisfactory, the domestic manufacturing capability may not yet possess surge capacity to supply vaccines to Canada upon a new pandemic despite recent entries by Sanofi Pasteur, NRC/Novavax, Madicago/ GSK and Providence Therapeutics/Emergent BioSolutions facilities that form an oligopolistic market structure with multiple manufacturing platforms. However, the federal government must so design the regulatory environment that it must not be contractually constrained to purchase developed-in-Canada or manufactured-in-Canada vaccines. If the surge capacity falls short of the short-run need of volume, such constraints may delay the rollout of vaccination. This may well be one of the major takeaways from the MSP.



Moreover, there exists an inevitable tradeoff (illustrated in diagram above) between domestic manufacturing that yields higher supply assurance versus its higher cost due to short runs of production. Larger volumes of

[55] Berkok & Penney [2014], Davies, C. [2021], "National Security and Domestic Vaccine Supply: Lessons from the Munitions Supply Program", https://cdainstitute.ca/national-security-and-domestic-vaccine-supply-lessons-from-the-munitions-supply-program/.

[56] Grootendorst [2022], "How should Canada prepare for the next pandemic?", presentation at the 16th Defence & Security Economics Workshop 2021, forthcoming in On Track.

production warranted by exports may mitigate this cost effect.

For example, the new multi-platform Sanofi facility being built in Lyon has enough surge capacity to supply vaccines to 67 million French and then more for Sanofi exports. Then, the manufacturing risk is eliminated provided the successful vaccine can be manufactured on one of its platforms. On the graph above, the curve C(S) represents the cost of security. If Canada were to pick a combination like (S_H, C_H) on the graph, it would establish a broad-based domestic industry. Of course, if a country is not endowed with all platforms at sufficient capacities, security decreases but so does the cost. Australia and the U.K., in their choice of munitions acquisition, accepted a higher risk by relying more on foreign production. They picked a combination like (S_L,C_L) in their munitions acquisition programs. The current industrial policy will determine whether the future pandemic vaccine market will resemble the MSP or the choice made by Australia and the U.K.

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(6/6) Assuring Vaccine Supply: Lessons from the Munitions Supply Program

Col Charles Davies (ret'd), Former CAF Logistics officer and Ammunition Technical Officer

Introduction

This article is intended to contribute to the ongoing national discussions about strengthening Canada's capacity to respond to future pandemic disease threats, in particular the potential establishment of a domestic capability to develop and produce vaccines and other relevant critical commodities. Specifically, it provides an overview of an existing government-industry program designed to assure supply of a key group of products, the Munitions Supply Program (MSP), drawing out a number of lessons from it that could apply to the design of a future vaccine supply program.[57]

Background

The MSP was established by the Government of Canada in 1978 under the authority of the Defence Production Act. Since its inception, its objectives have been to:

- Contribute to national security and defence by providing an assured domestic source of supply for high-volume-usage ammunition and small arms weapons for the Canadian Armed Forces (CAF); and
- Contribute to economic growth by maintaining and developing technologies and industrial capabilities that are globally competitive and sustain good jobs.

In pursuing these objectives, balance has been sought between sometimes higher costs of production in Canada and the benefits of increased surety of supply (including a production surge capacity), industrial development, and export success.[58]

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[57] This article substantially amplifies and extends comments initially offered by the author in an earlier CDA Institute blog post. See Charles Davies, "National Security and Domestic Vaccine Supply: Lessons from the Munitions Supply Program," CDA Institute, February 22, 2021, https://cdainstitute.ca/national-security-and-domestic-vaccine-supply-lessons-from-the-munitions-supply-program/

[58] Department of National Defence, Chief of Review Services, *Evaluation of the Munitions Supply Program 1258-101-4 (CRS)* (Ottawa, December 2007).

The MSP underwent a comprehensive policy review and update in 2016-2017, with Cabinet approving a continued mandate with minor modifications.[59] The Minister of Public Services and Procurement is lead authority for the program, although National Defence provides the associated funding.

How the Program Works

Under the MSP, roughly one hundred specified high-volume products are procured exclusively from designated Canadian-based suppliers. A much larger range of munitions products are sourced competitively in global markets, with MSP companies also able to bid on these requirements. The current MSP participants include:

- Colt Canada, based in Kitchener, Ontario. It manufactures small arms weapons and their associated spare parts.
- General Dynamics Ordnance and Tactical Systems Canada, with facilities in Valleyfield, Le Gardeur, Nicolet and Repentigny, Québec. It manufactures large, medium and small calibre ammunition as well as propellants, explosives and other energetic materials. It is the largest participant in the MSP.
- IMT Defence in Ingersoll, Ontario. It manufactures specialized metal components for ammunition and related products.
- Magellan Aerospace in Winnipeg, Manitoba. It specializes in the production of rocket motors and related systems at its plant in Rockwood, Manitoba.

In general, the MSP companies have complementing, not competing capabilities in recognition of the fact that the domestic market for their products is not large or stable enough to support successful competition between them. The government funds the ongoing maintenance of essential core production capabilities, including a surge capacity, through Strategic Source Agreements with the companies. Extraordinarily high levels of control and oversight over workplace safety, product safety, and product quality are typically required and many of the manufacturing processes involved need specialized facilities and equipment not normally found elsewhere in industry.

The Marketplace

The marketplace the MSP companies operate within is challenging. Governments are

[59] The author acted as a consultant for both DND and the MSP companies during this review, guiding broad stakeholder consultations and drafting a number of key input documents.

essentially their only customers and product demand can be highly variable depending on events. For example, the war in Afghanistan vastly increased CAF demand for munitions but levels quickly fell again after Canada withdrew its forces. In 2012, as the mission was ending, MSP companies had total sales of about $1.6 Billion (roughly 60% to Canada, the remainder to export customers, including partner nations in the mission)[60] whereas only four years later in 2016 the companies were reporting revenues of just $443 Million (about 46% of that from the Canadian government and the rest from export sales).[61]

These 2016 business levels are fairly representative of the "normal" market although there is still year-to-year variability. While for many industries this size of market could sustain a reasonable level of competition, for munitions the magnitude of the investments needed to establish and maintain the required production capabilities make a competitive domestic market not economically viable.[62] This reality applies not only to Canada but also most other nations with munitions industries.

Lessons for an Assured Vaccine Supply Program

While there are substantial differences between the munitions and vaccine industries in Canada, it is possible to derive a number of lessons from the MSP experience that may usefully inform the design of an assured vaccine supply program. The MSP's recent policy reset in particular provided an opportunity for government and industry to collaboratively crystallize important perspectives that are worth consideration. A number of these are discussed below.

Both surety of supply and economic benefits need to be sought in balance. There is an ongoing investment cost to assuring supply, and these expenditures need to continue to be supported by future decision-makers and taxpayers. If there is little economic benefit being obtained from a vaccine supply program, justifying its ongoing cost on national security or public

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[60] Ugurhan Berkok and Christopher Penney, *The Political Economy of the Munitions Supply Program* (Kingston: Defence R&D Canada contract report, 2014).

[61] OMX Data Analytics, *Munitions Supply Program Economic Impact Report* (Ottawa, 2017). The report is proprietary to the MSP companies and not publicly available, however the data cited here has been released by the MSP companies to the author for public use.

[62] A good proportion of the facilities operated today by the MSP companies are in fact legacy infrastructure originally built during World War II. They have been modernized as needed over the years but to replicate and sustain the capabilities they provide on a new-build site would be very costly. See, for example, Andrée Prévost et al, *Le 75e anniversaire de l'usine de Valleyfield*. (Valleyfield, Québec: General Dynamics Ordnance and Tactical Systems – Canada Valleyfield, 2016) internal company historical publication. Copy in the author's possession.

health grounds alone is likely to become increasingly difficult over time as the present pandemic becomes a distant memory. The fact that government expenditures on MSP products and services has been shown to be consistently generating considerably larger net contributions to Canada's GDP[63] through export success and other impacts has proven very helpful in justifying continuation of that program. In the case of vaccines, similar net benefit would need to be sought by, for example, having the assured supply program participants become the preferred suppliers of specified vaccines to all provinces and territories. This could enable them to maintain a development and production capacity base upon which to also build export markets.

Be clear about what "assured supply" is intended to mean. It can be taken to mean sourcing all materials and technologies domestically, but this is likely to be cost-prohibitive. Also, as Dr Van Exan and Professor Grootendorst have shown in their articles, it may be counterproductive in that it could lock Canada into a very limited a range of technology options in an area where science is moving quickly in multiple directions. The MSP uses a risk-managed approach in which materials and components may be sourced internationally where it makes sense, but the domestic technical expertise is maintained to acquire or develop appropriate substitutes if necessary. This may also be a suitable model for vaccine supply.

Assured supply programs need to be scaled for both normal and surge demand. Surge capability is expensive to maintain "just in case." For the MSP the cost is over $50 Million annually, but the Afghanistan mission showed the strategic value of that investment. During periods when all the nations involved were looking to urgently replenish ammunition inventories depleted in heavy fighting, MSP companies kept the CAF supplied with key natures by surging their production as much as five times normal levels while halving delivery lead times.[64] This was despite the fact that under their Strategic Source Agreements the suppliers were required only to be capable of doubling production. The COVID-19 pandemic has shown a similar need for the ability to source large volumes of vaccine in a short time.

Private sector solutions can work well. While there have been calls for a publicly owned vaccine capability, the MSP shows that the private sector can do the job well. The companies' product quality and pricing has been consistently superior to the levels the former Crown Corporation (Canadian Arsenals Ltd.) was able to maintain before being privatized in the 1980s.[65]

Establish a consistent process for defining what is in a vaccine supply program and what isn't. Unless the policy intent is to deliver all vaccines for Canada through the program, as medical science and vaccine technologies evolve decisions will need to be made as to which products will be sourced through it and which ones through the open market. Under the MSP, these decisions have not always been made based on clear and consistent policy criteria, which has been an ongoing problem for both government and industry.

The politics of a vaccine supply program may be more difficult than for the MSP. The prohibitive cost to enter the limited munitions market means that there is little political cost to maintaining the MSP's long-term preferred supplier relationships. Vaccine production is different, with a diverse

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[64] Gregory van Bavel, *The Munitions Supply Program during Canada's participation in the NATO lnternational Security Assistance Force in Afghanistan – A look at the effect of a surge in demand on selected calibres* (Ottawa: Defence R&D Canada Scientific Letter, 2015). The report is based on study of five ammunition natures over the period from 2000 to 2014.

[65] The author was personally involved in technical reviews of several ammunition accident reports in the 1980s where product quality was either the primary or a contributing cause. Conversely, in 2013 the annual report of DND's Director of Ammunition and Explosives Regulation specifically noted the remarkably good condition of ammunition backloaded from Kandahar to Canada during the CAF withdrawal despite it having been stored in very poor climatic and other conditions for an extended period. This was a testament to the quality of its production and design of its packaging. Director Ammunition and Explosives Regulation, *Annual Report* (Ottawa: Department of National Defence, 2013), 16.

domestic marketplace and more manageable investment costs for new products and facilities, so a different model will likely be required. Extensive consultations with industry, provinces and territories may be required to develop a politically sustainable model.

Conclusion

While the parallels are by no means exact, the MSP can offer some useful insights in considering how to structure a domestic assured source of supply for vaccines. Even the differences between the two cases can point to factors that need to be considered. We have highlighted six areas here in particular, and further deeper examination may be useful in driving more of the devils out of the detail in a vaccine program design effort.

Fundamentally, however, it needs to be remembered that assuring supply of munitions, vaccines or any other commodity is not by itself a complete national security solution. Similar to any other threat, pandemic disease readiness requires a comprehensive strategy encompassing strategic early warning; effective defence; resiliency in the face of attacks; countermeasures, in this case effective treatments and the ability to rapidly defeat diseases; post-pandemic recovery; and more. An assured domestic vaccine supply may be an important element of such a strategy, but will not by itself defend Canada against pandemic disease.

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