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Field Laboratory Upgrade for Canadian Forces Chemical, Biological, Radiological, and Nuclear Teams

Lieutenant-Commander Joseph Diclaro

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AIM

1. The result of a biological agent in 2020 decreased the CAF Operational Readiness to 40%.[1] In 2007, the Joint Doctrine for the Canadian Forces Chemical, Biological, Radiological, and Nuclear (CBRN) Defense Operations specifically highlighted an example of Severe Acute Respiratory Syndrome (SARS) as a biological hazard and the potential threat that an adversary could weaponize.[2] Whether the SARS-CoV-2 (COVID-19) pandemic of 2020 was a coincidence or manufactured, it identified the need to re-examine the CAF CBRN biological detection capabilities. This Service Paper will discuss the need for adding advanced field-deployable Polymerase Chain Reaction (PCR) laboratory capabilities to CAF CBRN teams for biological threat detection and assessment during military operations and agile enough to contribute to broader CAF Public Health efforts when needed.

INTRODUCTION

2. The primary function of CAF CBRN is to provide protection and mitigation strategies against Weapons of Mass Destruction (WMD) to operational forces and the citizens of Canada.[3] The most challenging WMD, the CBRN team, to encounter is a biological weapon. The limiting factor in an intentional or natural biological incident is detection. No matter how robust or sophisticated a sentinel surveillance system may be, the initial indicator of a biological weapon may be mass casualties from an unexplained illness. Once a biological threat has been considered, the rapid deployment of testing capabilities needs to be swiftly dispatched to assess the prevalence and impact of the pathogen. In addition, accurate detection and identification of the biological agent in both the casualties and the environment will be critical in containing and eliminating the threat.

3. Examining the current CAF doctrine assumes that CBRN teams respond to any CBRN agents' hostile, natural, or accidental release in the interest of force and population protection.[4] CAF CBRN team procedures establish field testing sites as close to the event source as possible as part of the effort to contain and mitigate the threat. CAF provides its CBRN team with a field-deployable PCR capability that is solely testing for specific targeted biological agents. Newer PCR platformers can and are flexible to use broader custom-made assays to process human, animal, and environmental samples. In addition, most require no cold chain and have advanced

[1] Canada. Military response to COVID-19. Accessed at: https://www.canada.ca/en/department-national-defence/campaigns/covid-19-military-response.html.
[2] Canada, DND. Canadian Forces Chemical, Biological, Radiological, and Nuclear Defence Operations. Joint Doctrine Manual. 2007. 1-2-1
[3] United States. Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans. Homeland Security. 2017. 116.
[4] Canada. DND. Canadian Forces Chemical, Biological, Radiological, and Nuclear Defence Tactics, Techniques and Procedures. Joint Doctrine Manual. 2013. iii.

real-time mapping software features.[5] Also, extremely compact to allow CAF CBRN response teams to detect potential biological hazards at the point of collection and provide real-time information to deploy appropriate countermeasures for Force Health Protection.

4. The COVID-19 pandemic highlighted the massive impact a biological agent can have on a population that is not prepared. Canada did its best to pool governmental resources for the testing and treatment of its citizens, including requesting assistance from CAF, but like other countries were very overwhelmed with COVID-19 cases.[6] Although the CAF was seen as a governmental resource to add to the national response, the CAF CBRN team was not. The CAF policy for defense against CBRN threats is rooted in Canada's Chemical, Biological, Radiological, Nuclear, and Explosive Resilience Strategy described in the Defense Administrative Orders and Directives.[7] The CAF doctrine developed from this policy directs how the CAF will organize to detect, respond, and mitigate CBRN threats domestically and internationally. The guidance in developing CAF CBRN policies is NATO-agreed and ratified with alliance doctrine from the United States, Britain, and Australia. [8] However, there are similarities in CBRN practices; the CAF policy framework includes the whole government response that assigns specific roles and responsibilities for each agency. Not including the CAF CBRN team in a biological agent response indicates either a significant gap in interagency communication or that the CBRN is not adequately trained and equipped.

DISCUSSION AND ANALYSIS

5. Military relevance of a CBRN team is centered on the possible release of a bioweapon by an adversary or terrorist organization.[9] Bioweapons are relatively inexpensive to produce and produce a high number of casualties. CBRN field response to a biological event requires vital practical skills in personal protection, detection, and decontamination. From the three skills listed, detecting the biological hazard has the most significant influence that will impact the overall response strategy.[10]

6. The biological threat detection concept in the current CAF CBRN biological doctrine is to deploy multiple stationary bio-sentry devices that are strategically placed. This passive collection network facilitates detecting harmful biological agents circulating in the environment and serves as an early warning system for mission-critical structures.[11] The bio-sentry surveillance network is supported by a self-contained field molecular laboratory capability called

[5] Franklin™ Real-Time PCR Thermocycler. Accessed January 21, 2022 at: https://shop.biomeme.com/products/franklin-real-time-pcr-thermocycler

[6] Canada. Coronavirus disease (COVID-19): Canada's response, 2020.

[7] Canada, DND. CFJP 3-8 Canadian Forces Chemical, Biological, Radiological, and Nuclear Defence. Joint Doctrine Manual. 2012. 1-5.

[8] United States. Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans. Homeland Security. 2017. 1-6.

[9] Hawley, R. J. and E.M. Eitzen Jr. "Biological Weapons A Primer for Microbiologist." Annual Review of Microbiology. 2001. 248-249

[10] Lee, B. Y. "The Role of Internists During Epidemics, Outbreaks, and Bioterrorist Attacks." Society of General Internal Medicine. 2007. 131

[11] Canada. DND. Canadian Forces Chemical, Biological, Radiological, and Nuclear Defence Tactics, Techniques and Procedures. Joint Doctrine Manual. 2013. P1-P18

RAZOR®. The RAZOR® is a field-portable PCR instrument that tests for selected species of biological agents in unknown samples from bio-sentry devices or collected swabs of possibly exposed equipment and the environmental sampling. The RAZOR® weighs 11 pounds and can test one sample for ten targets per run.[12] Its internal battery, fully charged, allows for five runs for a total of two and a half hours of operational time. The benefit of the RAZOR® is that it allows mobile laboratory testing for a set panel of harmful biological species with little processing time from room temperature prepackaged cartridges. The typical process is that the RAZOR® is set up in a central location, and CBRN teams will collect specimens to carry back to the instrument for processing and testing. The results are displayed on a built-in screen that can be transcribed for reporting. Results can then be communicated per protocol to the CBRN Incident Commander.

7. In comparison, field academic researchers and healthcare professionals use newer field-based PCR platforms such as the Franklin™ thermocycler in remote and austere environments to conduct PCR testing from multiple types of collected samples.[13] Uses for this PCR platform have included diagnostics for COVID-19, ecological surveillance, biosurveillance in wildlife, and environmental sampling. The Franklin™ instrument weighs less than three pounds and can test for twenty-seven targets in one sample or three targets in nine samples. Like the RAZOR® test, kits do not require refrigeration and are prepackaged. Depending on the desired assay total testing time is thirty minutes to one hour. A full battery charge allows twenty-four hours of operational time. The Franklin™ thermocycler connects to a dedicated smartphone via Bluetooth to display results from the test. The available software for this PCR platform can be used without cellular service but, if connected, can share results and collection coordinates as they are complete.[14] An example of the synergistic value of the benefits of the mapping software with the testing capabilities of this PCR platform has been demonstrated during a large-scale tick collection effort conducted in the State of Pennsylvania.[15] During the Pennsylvania study, researchers tested ticks collected from vegetation and animals and were able to test them for two disease-causing pathogens at the point of collection simultaneously, *Babesia microti* and *Anaplasma phagocytophilum*. The collected ticks' negative and positive results were transmitted and added to a map of collection points in real-time. This data could then be used to develop a prediction map and focus the public health team on where to apply their efforts.

8. As previously mentioned, the RAZOR® test kit contains a cartridge that performs ten assays for ten species of specific biological threats: Anthrax, Brucella, Botulism, Q fever, E. Coli O157, Tularemia, Ricin, Salmonella, Smallpox, and Plague.[16] Due to how this platform operates and is manufactured, there is no clear path to customize the cartridge to include pan-assays that may perform a broader set of tests for potential biological threats not covered in the ten species listed. Therefore, a consideration in adding a new CBRN PCR platform to the equipment is essential to consider the ability to rapidly develop and customize PCR assays that are both

[12]RAZOR® Mk II BioThreat Identification Information Sheet. Accessed January 20, 2022 at https://www.biofiredefense.com/wp-content/uploads/2019/09/RAZOR-MkII-BioThreat-Identification-InfoSheet-MRKT-PRT-0125.pdf

[13]Realtime PCR anywhere you need it. Accessed January 20, 2022 at https://biomeme.com/

[14]PCR Web API. Accessed January 21, 2022 at https://info.biomeme.com/web-api

[15]Tick Map Alpha. Accessed January 20, 2022 at https://maps.biomeme.com/

[16] RAZOR Detection Kit: RAZOR Pouch Instruction Booklet. 2020. page 22

military relevant and support general CBRN operations.[17] For example, the Franklin™ PCR platform "go-strips" can be ordered in customized packages for specific species or by pan-assays that do not limit the application of the device.[18]

9. The flexibility and agility of a CBRN team are critical to responding during and after CAF forces or the Canadian population is exposed to a natural or manufactured biological event. CAF CBRN team has the training and experience to serve as first responders to a bioweapon deployed on their bases, civilian facilities, and during operations.[19] A perimeter is established to contain the affected area in a bioweapon situation as the Incident Command Center is set up and the field laboratory teams begin their sweeps to sample the environment. People within the area are sampled utilizing specific rapid antigen tests and then processed through decontamination. Depending on the biological agent, an incubation period could create a secondary uncontained biological effect if the exposed population is not under observation, so there is also a focus on the isolation of patients.[20] Rapid PCR testing becomes critical to segregate the asymptomatic infected from the uninfected. Although a natural event is listed in CAF CBRN doctrine, there is no clear guidance on how the CAF CBRN would respond or assist, leaving the burden of effort solely on Health Services to test and treat patients. Although the CBRN team is not entirely staffed with medical professionals, it has containment and testing capabilities that can generate critical epidemiological data collected from human and environmental samples.[21] However, the current CBRN laboratory capability does not have the bandwidth to provide large-scale laboratory results but can deploy multiple sample collection teams to cover a large area.

[17] Cekovic, B. and D. Rothbacher. "A Fresh Approach: Review of the Production Development of the CBRN/HAZMAT Equipment," 2017. 96-98.

[18] Realtime PCR tests. Accessed January 20, 2022 at https://info.biomeme.com/real-time-pcr-tests

[19] Canada, DND. Canadian Forces Chemical, Biological, Radiological, and Nuclear Defence Operations. Joint Doctrine Manual. 2007. 301-314

[20] "Terrorism Incident Management," in Terrorism Incident Management," 2005. 5-6.

[21] "Government Guidelines ans Advisories," in PDR Guide to Biological and Chemical Warfare Response, 2002. 375-376.

CONCLUSION

10. Adding Franklin™ thermocyclers to the CAF CBRN equipment will allow field-deployable PCR testing capabilities to significantly increase the detection bandwidth for many biological threats. The Franklin™ thermocycler's rapid specimen processing time with its durability, portability, and 24-hour operational battery life expands the CAF CBRN's effectiveness in assessing the biological threat in contingent and domestic operations. The ability to rapidly customize species-specific or pan assays allows the CBRN team to provide a more extensive scope of information. The advanced mapping software linked to a secure smartphone assist in the biological event's epidemiological assessment to focus resources and countermeasures. Additional CAF CBRN field-based PCR laboratory capabilities will enhance CAF CBRN global operations and be a ready and equipped team to harmonize with Canadian Health Services for a future biological crisis.

RECOMMENDATIONS

11. This service paper's primary recommendation is to add multiple Franklin™ thermocyclers to the CAF CBRN equipment list. Each unit costs $10k and average approximately $10 to $20 per assay.[22] The relatively low cost and added capability make them a wise and beneficial purchase for CBRN biological responses domestically and internationally. In addition, the RAZOR® PCR platform requires a degree of advanced laboratory training that is not required for the Franklin™ platform that would allow multiple devices to be deployed simultaneously. However, this service paper does not recommend removing the RAZOR® from the CBRN inventory but enhancing capability and CAF CBRN relevance by adding the Franklin™ to the CRBN unit formation reconnaissance and survey functions.[23] Ideally, the RAZOR® platform would be used as a centralized confirmation testing capability, and several mobile teams would use the Franklin™ PCR instrument.

12. There is no current formal process to update biological agents of CAF concern. Recommend establishing a procedure to review the list of biological agents annually to guide the purchase of needed laboratory assays. The CAF CBRN has a list of thirty-six potential biological threats in its CBRN Operations doctrine.[24] Although all of these biological material occurs naturally, the concern is that any one of those agents can be weaponized or potentially create an international public health emergency like COVID-19. As part of the 2002 Bioterriosm Act in the United States, the U.S. Center for Disease Control (CDC) and the United States Department of Agriculture (USDA) developed a list of sixty-eight biological agents considered severe threats to humans, animal, and plant health.[25] The CDC and the USDA review and update this list of

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[22] PCR Devices and Software. Accessed January 21, 2022 at: https://shop.biomeme.com/collections/devices/products/franklin-real-time-pcr-thermocycler?hsCtaTracking=186b1b2c-a7c8-442b-b7ec-d976347d499b%7Ce8c62bb8-33f9-45ec-95d5-77b1374c6a67

[23] Canada. DND. Canadian Forces Chemical, Biological, Radiological, and Nuclear Defence Tactics, Techniques and Procedures. Joint Doctrine Manual. 2013. 2-1-1 – 2-1-4

[24] Canada, DND. Canadian Forces Chemical, Biological, Radiological, and Nuclear Defence Operations. Joint Doctrine Manual. 2007. 2B3-2B7

[25] United States. 2020 Annual Report of the Federal Select Agent Program: HHS and USDA Select Agents and Toxins 7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73.

select agents biannually to provide information to other organizations to regulate and monitor these potential biological threats. The U.S. Department of Defense (DoD) Defense Threat Reduction Agency (DTRA) Cooperative Biological Engagement Program (CBEP) utilizes the select agent list to develop research and mitigation strategies with international partners and allies to develop biosecurity protocols and improved disease surveillance.[26] CAF CBRN can utilize the CDC and USDA list to create a CAF biological agent priority list annually and then coordinate research and development efforts with CBEP to improve internal CBRN capabilities.

13. The CAF support during the COVID-19 response was mainly with the support of medical personnel in long-term care facilities and remote northern communities.[27] The current CBRN doctrine mentions supporting natural events but focuses on passive monitoring and immediate reaction posture for isolated events. It would be beneficial to incorporate the public health team adding mutually beneficial capability. Having Franklin™ thermocyclers embedded with the CAF CBRN teams enables them to contribute to bioterrorism, outbreaks, and pandemic responses.[28] Recommend updating the joint doctrine language to include expanded laboratory capability that can be integrated as a field surveillance asset and a mobile rapid diagnostic capability in remote areas. The compact PCR units can fit in a small backpack or cargo pocket and require little to no training, allowing multiple teams to rapidly sweep and conduct multiple tests in a large area of operation. The CAF CBRN teams equipped with the Franklin™ PCR platforms will provide realtime testing results to the Incident Commander to assist in directing containment and mitigation strategies or provide vital public health data for prevention efforts. CAF CBRN can harmonize with medical assets for a joint response to ease laboratory testing burden by providing initial screening, and its data will assist with better resource allocation.

[26] United States. The Cooperative Biological Engagement Program Research Strategic Plan: Addressing Biological Threat Reduction Through Research. Defense Threat Reduction Agency. 2015. 6.

[27] Canada. Military response to COVID-19. Accessed at: https://www.canada.ca/en/department-national-defence/campaigns/covid-19-military-response.html.

[28] Canada, DND. Canadian Forces Chemical, Biological, Radiological, and Nuclear Defence Operations. Joint Doctrine Manual. 2007. 1-12

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Cekovic, B. and D. Rothbacher. "A Fresh Approach: Review of the Production Development of the CBRN/HAZMAT Equipment," in Cyber and chemical, biological, radiological,

nuclear, explosives challenges: Threats and counter efforts, ed. M. Martellini and A. Malizia, 91-128. Springer International Publishing, 2017.

"Government Guidelines ans Advisories," in PDR Guide to Biological and Chemical Warfare Response, ed. B. Lagow, 373-404. Tomson PDR, 2002.

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