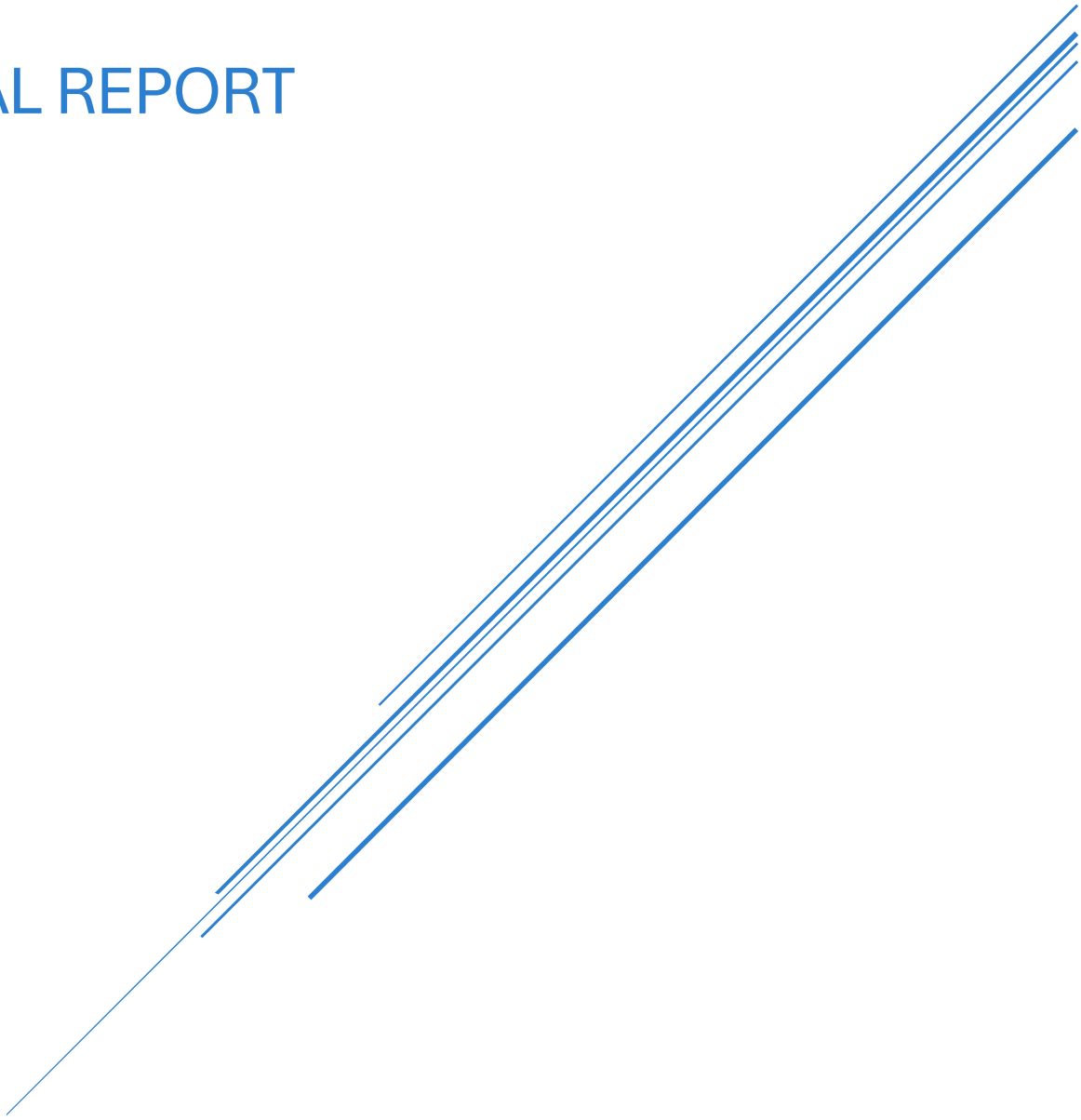
ALBERTA'S COVID-19 PANDEMIC RESPONSE

Alberta COVID-19 Pandemic Data Review Task Force

FINAL REPORT



January 2025

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Foreword

Dear Premier Smith,

On behalf of the Alberta Pandemic Data Review Task Force, I am pleased to present this report on the review of the response of the Alberta government to the 2020-2022 COVID-19 pandemic.

This review might be one of few being conducted by Canada's provinces. It examines the quality, use, interpretation, and flow of information and data that informed Alberta's pandemic response to COVID-19. Because of this very specific focus, we do not discuss economic issues, although we recognise that negative economic impacts will have down-stream negative effects on public health. We also do not engage in issues regarding media handling of the pandemic, nor pose any questions of how, when and why the SARS-CoV-2 virus originated. We have sought to produce a report that identifies apparent shortcomings of the evidence used during Alberta's response rather than absolve the decisions in the context of many uncertainties. However, the Task Force is very aware that decisions made throughout the pandemic did not have the benefit of hindsight, so we try to use it sparingly.

This document presents a blueprint around key public health questions for a formal COVID-19 inquiry. In separate chapters we summarize key background information on the governance of information and how it was passed to decision makers. We pose specific questions about failures to protect high-risk Albertans, non-pharmaceutical interventions – including their collateral harms, misleading risk communication, downplaying infection-acquired immunity, masks, testing, vaccine effectiveness and safety, therapeutics, and epidemiological modelling. While this report does not attempt to explicitly analyse "why?" decision makers were willing to accept the possibility of greater societal harm over the proclaimed benefits against COVID-19, the question will manifest throughout its text.

The report is the product of months of analysis of the documentation and the reported experience of some of those who were involved in the response and others who were close observers. Our quest for answers was impeded by barriers, including reluctance from key stakeholders to engage with the Task Force's mandate.

Throughout the interviews we conducted, it has become obvious that the situations in Italy and New York were given disproportionate importance amongst those in the Health Emergency Operations Centre. Whether, or not, these two international jurisdictions

applied to Alberta, they certainly set the reference point for many judgements moving forward from March 11, 2020. Faced with the uncertain situation of a pandemic, many respondents were simply happy to be doing what other jurisdictions were doing. Unfortunately, amongst many of the quick decisions made, there was little consideration of the delayed consequences of the actions taken — largely because they were not immediately quantifiable.

It must be acknowledged that the spread of SARS-CoV-2 and its effects were not uniform and was influenced geographically, temporally, and demographically. Despite this, the relatively few deaths that did occur in otherwise healthy people, were – as they would be under any circumstances – tragic and poignant.

The pandemic and the response it generated confirms how quickly routine methods to ensure timely and efficient action can be warped if a threat is perceived to be large enough. But pandemics are recurring events throughout history, and there will be others in the future. It is therefore critically important that we use this opportunity to strengthen evidence-based decision making and position the government to better manage pandemics. However, we leave any improvements that could be identified to more formal means of inquiry.

The Task Force wishes to express their gratitude to all who responded to the call for evidence, to all those who gave up their time to meet and discuss their experiences. Any errors or omissions in this report are solely ours.

Yours sincerely,

Dr. Gary Davidson

Biographies

Dr. Gary Davidson, MD

Task Force Role: Author / Review Lead / Chair

Dr. Davidson was an Emergency physician at the Red Deer Regional Hospital for over 16 years. Dr. Davidson was the clinical lead of Emergency Medicine for the central zone and Chief of the Emergency Department at Red Deer Regional Hospital from 2016-2020. He was also an Associate Clinical Professor at the University of Alberta when his position was terminated due to his stance against some public health measures.

Dr. Blaine Achen, MD

Task Force Role: Author / Review Co-Chair

Dr. Achen has been a leading Anesthesiologist in Alberta for 19 years and an Assistant Clinical Professor for Anesthesiology & Pain Medicine at the University of Alberta since 2008. Dr. Achen was the Chief of Cardiac Anesthesia at the Mazankowski Alberta Heart Institute however, he was terminated for choosing not to be vaccinated, after having contracted COVID. He like other healthcare workers was allowed back to work but was never reinstated in his former position.

Dr. David Vickers, PhD

Task Force Role: Author / Review Co-Chair

Dr. Vickers is currently a statistical associate at the University of Calgary. His applied research experience has included using surveillance systems to understand the spread of infection, health outcomes linked to chronic infection, and the public health interventions used in response to COVID-19. He has worked as a consultant for a GlaxoSmithKline Vaccines project, an epidemiologist for Alberta Health Services, and a theoretical immunologist at the Imperial College of London.

Dr. Justin Rashad Chin, MD

Task Force Role: Author / Contributor

Dr. Justin Rashad Chin is an Emergency Medicine Specialist working full-time at the University of Alberta Emergency Department since 2013. His background training includes a Master's Degree in Disaster Medicine. In addition, he supports the region in his role as a Trauma Team Leader. During the pandemic, he provided support coverage in the Covid ICU.

Dr. Chin had his academic appointment abruptly terminated for publicly raising concerns about the public health response measures. He was reinstated following a successful appeal of his termination.

Angela Wood

Task Force Role: Author / Contributor

Angela holds a Juris Doctorate and practices law in Alberta, focusing on civil litigation, medical malpractice, and health law, with a particular interest in health policy. Her professional experience also includes expertise in financial fraud investigations and risk management. Angela has a deep understanding of healthcare-related legal matters and provides strategic counsel in medical malpractice cases and health policy issues. Additionally, Angela's professional background includes considerable experience in financial fraud investigations and risk management in the financial and insurance sectors.

Frank Byl, BSc (Kinesiology, SFU)

Task Force Role: Technical support and assisting in compiling data and documentation

Frank taught school 13 years, concluding his teaching career in the Philippines in 1997. In 1998 he began PowerConcepts, bringing short term one- and two-day computer courses, designed for business staff. Frank has been a Microsoft Master Instructor since 2004 where he and his team have taught about 60,000 individuals in business, government, as well as those going through work transitions. He is an expert in the end user experience in Microsoft Office 365 and is proficient in Excel, MS Project, Teams, Outlook and OneNote.

Mark Bell

Task Force Role: Contributor / Report Writing and Project Skill Use and Alignment Focus

Mark Bell is an energy sector entrepreneurial manager at Kennedy Power Inc, experienced in reviewing and evaluating the current needs of an organization, then developing a strategic path forward that guides the organization in meeting its business objectives. He is also a project and asset manager, who is experienced in leading teams to develop physical assets and technical documentation.

Dr. David Speicher, PhD, DTM

Task Force Role: Author / Contributor

Dr. Speicher specialises in molecular virology and epidemiology, concentrating on infectious disease detection and monitoring. His expertise includes use of saliva for diagnostics, oral cancers, and sexually transmitted infections. Recently, he identified adulteration in Pfizer and Moderna COVID-19 modRNA vaccines, noting significant levels of plasmid DNA and SV40 components. His findings have been cited in U.S. Senate and European Parliamentary hearings and contributed to Florida's Surgeon General's call to pause COVID modRNA vaccines.

Dr. Byram Bridle, PhD

Task Force Role: Contributor / Provided Feedback on Report Draft

Dr. Bridle is an Associate Professor of Viral Immunology in the Department of Pathobiology at the University of Guelph. His research is dedicated to designing and optimising novel biotherapies for the treatment of cancers, as well as studying host responses to viruses and other inflammatory stimuli. The Bridle Lab specializes in developing effective cancer vaccines and applies this knowledge to create vaccines for infectious diseases, including those triggered by highly pathogenic coronaviruses.

Dr. Jay Bhattacharya, MD, PhD

Task Force Role: Contributor / Provided Input on Key Topics Covered in Final Report

Dr. Bhattacharya is a Professor of Medicine at Stanford University. He is a research associate at the National Bureau of Economics Research, a senior fellow at the Stanford Institute for Economic Policy Research, and at the Stanford Freeman Spogli Institute. He directs the Stanford Center on the Demography of Health and Aging. Dr. Bhattacharya's research focuses on economic, legal, and medical aspects of health care and health policy around the world with an emphasis on the health and well-being of vulnerable populations.

Dr. Kevin Bardosh, PhD

Task Force Role: Contributor / Provided Input on Key Topics Covered in Final Report

Dr. Bardosh is the former Director and Head of Research at Collateral Global, a research institute and educational charity based in the U.K. He has worked in more than 20 countries

around the world on infectious disease research and control programs, including in the response to Zika and Ebola.

Natasha Gonek B.Sc., NCIT Specialized

Task Force Role: Contributor on Key Topics

A professional investigator who has worked for regulatory healthcare colleges and the Office of the Chief Medical Examiner in Alberta. Natasha provided investigative research and compiled the publicly available data for the analysis of the regulatory bodies pandemic response.

Note: The name of Dr. John Conly was included as one of the Contributors in error and that the Pandemic Data Review Task Force regrets this error, and the name and bio has since been removed. The Task Force acknowledged that Dr. John Conly was interviewed on a singular item related to the interpretation of one of the quoted articles.

Contents

Abbreviations

Abbreviation	Description
AEMA	Alberta Emergency Management Agency
AH	Alberta Health
AHS	Alberta Health Services
BAL	Bronchoalveolar Lavage
BSE	Bovine Spongiform Encephalopathy
CDC	Centre for Disease Control and Prevention
CMOH	Chief Medical Officer of Health
COO	Chief Operating Officer
COVID-19	Coronavirus Disease 2019
COVID-END	The COVID-19 Evidence Network to support Decision-making
EMCC	Emergency Management Cabinet Committee
ECC	Emergency Coordination Centre
EWS	Early Warning System
FMD	Foot and Mouth Disease
HCoV	Human Coronavirus
HEOC	Health Emergency Operations Centre
HPA	Health Professions Act
ICU	Intensive Care Unit
MERS	Middle Eastern Respiratory Syndrome
mRNA	Messenger Ribonucleic Acid
NACI	National Advisory Committee on Immunization
NAAT	Nucleic Acid Amplification Test
NML	National Microbiology Laboratory
NP	Nasopharynx

NPIs	Non-pharmaceutical interventions
OECD	Organisation for Economic Co-operation and Development
OP	Oropharynx
OSI	Oxford Stringency Index
OxCGRT	Oxford COVID-19 Government Response Tracker
PCR	Polymerase Chain Reaction
PHAC	Public Health Agency of Canada
PICC	Priorities Implementation Cabinet Committee
PPE	Personal Protective Equipment
REP	Restriction Exemption Program
$\boldsymbol{R_E(t)}$	Effective Reproduction Number
SAG	Scientific Advisory Group
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
VOC	Variant of Concern
VP	Vice President
WHO	World Health Organisation
ZEOC	Zone Emergency Operation Centre

Introduction

Alberta's response to COVID-19 highlights the need and opportunity to scrutinize the provincial pandemic response decision-making process, including the actions of key individuals responsible for important decisions, and the evidence and data that informed those decisions.

On November 14, 2022, the Premier of Alberta issued a mandate requesting the establishment of a Task Force under the Health Quality Council of Alberta to conduct a data review of the last several years of health information with a view to offering recommendations on how to better manage a future pandemic.

The data review analyzed publicly available information relevant to the study's scope, guided by the following questions:

- Data supply: was the right data being collected?
- Data quality: was it accurate and consistent (i.e., was the data collection standardized using consistent data definitions and processes for collection across the province)?
- Data resources: was there sufficient and integrated infrastructure (data bases, equipment, people, etc.) to support efficient and effective data collection, collation, analytics, interpretation, and reporting?
- Data analytics: were the appropriate analytic methods and tools utilized to create reliable and valid information to inform decision-making?
- Data interpretation: were the data and evidence interpreted correctly from a clinical and non-clinical perspective, e.g., were the limitations of the data (importance, validity, reliability) clearly identified, articulated, and applied to how the data was assessed?
- Data triangulation: was the data validated or corroborated against other evidence, experiences, and sources?

- Data flow: was it effective in how it was shared with and interpreted by the end users to support timely and appropriate decision-making (i.e., were the end users skilled, sufficiently knowledgeable, and/or supported to use the information appropriately)?

The objective of this report is to analyze publicly available data to unravel the intricacies of Alberta's decision-making framework during the pandemic. By examining who made key decisions, what information those decisions were based upon, and how information was disseminated and utilized, the Task Force aims to provide a clearer understanding of Alberta's response strategies. This analysis is critical not only for evaluating past actions but also for enhancing future preparedness for public health emergencies.

In the initial stages of the COVID-19 pandemic, decision-making was characterized by urgency and uncertainty. Health officials, government leaders, and advisory bodies were required to interpret emerging scientific data, balance public health concerns with economic and social impacts, and assess appropriate public health and safety risk. The interplay between political leadership, health authorities, and expert advisors formed the backbone of Alberta's pandemic response.

This report also delves into the types of information that influenced COVID-19 response decisions. This information encompasses epidemiological data, scientific research, health system capacity metrics, and socio-economic considerations. By scrutinizing the sources and reliability of the data used, we can assess the extent to which evidence-based decision-making was employed and identify gaps or limitations in the information landscape.

In Chapter 1, the report reviews the governance and flow of information during Alberta's COVID-19 response, examining external data flowing into the province from national and international sources, as well as inter-provincial information exchanges. It also details how this information was shared and relied upon for decision-making and identifies the groups associated with and responsible for policy decisions.

Chapter 2 reviews the COVID-19 response recommendations of Alberta health system regulatory bodies and how this information shaped policy, processes, and guidelines within

each regulated profession. Chapter 3 analyzes the modeling used to guide decisions and public policy.

Chapters 4 and 5 evaluate non-pharmaceutical interventions, such as closures, restrictions, and masking, and examine the data supporting these initiatives to slow the spread of the SARS-CoV-2 virus. Chapter 6 examines the testing strategies employed in Alberta's response to COVID-19.

Chapter 7 investigates the data and research on COVID-19 infection-acquired immunity and its impact on decision-makers. Chapter 8 focuses on a data review of the COVID-19 vaccines, including the approval process, efficacy, and safety.

Lastly, chapter 9 examines the data used to determine the therapeutics employed and discontinued for treating a COVID-19 infection.

Methodology

The methodology outlines the systematic approach employed to gather, analyze and interpret data for this review. The goal is to provide a transparent and replicable framework that underpins the findings and recommendations presented in this report. This section details the steps taken for preparation, data collection, review, and analysis that guided our investigation.

A dedicated Task Force established and led by the Chair was comprised of a group of physicians and advisors. The collective expertise of the Task Force members was essential for the comprehensive execution of this review and allowed for the successful execution of a multidisciplinary perspective and approach.

Preparation and Gathering of Information

Publicly Available Pandemic Plans and Pandemic related reviews.

- Alberta Influenza Pandemic Response Plan
- Canadian Pandemic Influenza Preparedness documents
- Federal/Provincial/Territorial Public Health Response Plan for Biological Events
- Public Health Agency of Canada documents
- Pan-Canadian Public Health Network documents
- National Advisory Committee on Immunization
- KPMG Review of Alberta's COVID-19 Pandemic Response (March 1 to October 12, 2020)
- World Health Organization Pandemic Response Plans and related documents
- International Health Regulations and related documents

Surveillance Data

- Publicly available surveillance data on COVID-19 caused by the SARS-CoV-2 virus

Vaccine Information

- Publicly available documentation related to the approval, manufacturing, dissemination, and public health programs related to COVID-19 vaccines
- Medical journal articles, research, and studies conducted on the COVID-19 vaccine

Communication and Media

- Publicly available communications regarding the pandemic response
- Media excerpts

Professional Regulatory Bodies

- Publicly available information from relevant professional regulatory bodies

Alberta-Specific Data Collection

- Interviews and Surveys
    - Interviews with individuals in key decision-making roles within Alberta Health (AH) and Alberta Health Services (AHS)
    - Surveys of key decision-makers, managers, and department heads in AH and AHS

Review and Analysis

- Examination of information received and gathered
- Review and analysis of research

Report Development

- Development of interim briefing notes and preliminary findings for presentation to the Premier
- Creation of draft report for review by team members and the Chair
- Presentation of draft report to the Premier
- Revisions and final draft preparation
- Final report presentation to the Premier

Chapter 1: Governance and Flow of Information

Executive Summary

The Task Force conducted a comprehensive review of Alberta's response, focusing on governance, the flow of information and decision-making processes. The review revealed challenges in communication and coordination between different government bodies and stakeholders. Alberta relied on national and international sources of information and had close collaboration with federal partners. However, there were concerns about the transparency and timeliness of decision-making. The abandonment of the existing pandemic response plan and the lack of engagement with available evidence raised questions about the rationale behind decisions. Recommendations were made to establish a central command center, improve transparency, and ensure thorough review of evidence in future health crises. Further inquiry is needed to address information access challenges and gain a deeper understanding of Alberta's pandemic response.

- Alberta declared a public health state of emergency in March 2020 and had pandemic response plans in place.
- Decision-making structures involved Cabinet Committees and the Emergency Management Cabinet Committee (EMCC) and Priorities Implementation Cabinet Committee (PICC).
- The Health Emergency Operations Centre (HEOC) and the Chief Medical Officer of Health (CMOH) played crucial roles in coordinating the response.
- Alberta relied on national and international sources of information and had close coordination with federal partners and provincial colleagues.
- The Emergency Coordination Centre (ECC) and Zone Emergency Operation Centers (ZEOCs) were responsible for managing emergencies and disasters.
- The Scientific Advisory Group (SAG) played a significant role in Alberta's response to the COVID-19 pandemic. The SAG leveraged a wide range of resources, including non-published/non-peer reviewed literature, grey literature, international and

national information, messaging, and publications. The SAG's recommendations were considered privileged over other resources, particularly in the context of public health recommendations. However, there were concerns about the quality of their reviews, as the rapid turnaround times often prevented a full critical appraisal of the evidence. The SAG's use of evidence showed inconsistencies, raising questions about their approach.

- The Task Force identified biases in the process, source, and weight of evidence used in decision-making.
- Alberta did not utilize its existing pandemic response plan and lacked transparency in decision-making.
- Further inquiry is recommended due to challenges in accessing relevant information from key stakeholders.

Introduction

The Task Force's initiative to conduct this chapters' review is essential for comprehending the governance and information flow during a health crisis, a critical aspect for ensuring effective crisis management and response. A clear governance structure ensures that decision-making processes are well-defined, roles are understood, and responsibilities are appropriate. This clarity fosters efficient coordination and collaboration among various stakeholders, enabling swift and synchronized action. Moreover, a transparent flow of information enhances accountability and trust, as stakeholders can scrutinize decision-making processes and hold authorities accountable. Understanding how information is gathered, analyzed, and disseminated allows for the identification of gaps and inefficiencies and a thorough understanding of governance and information flow is essential for orchestrating a cohesive and effective response to a health crisis, ultimately safeguarding public health and safety.

What Was Done

COVID-19 Pandemic

As a result of the World Health Organization's ("WHO") declaration of a Global Pandemic in March 2020, Alberta with the rest of Canada – and the world - entered the battle against COVID-19.

On March 17, 2020, Jason Kenney, the Premier of Alberta and Provincial Cabinet declared a public health state of emergency pursuant to s. 52.1 of the Public Health Act *("PHA"). Once declared, s. 38 of the PHA allowed cabinet the authority to order the closure of any public place.*

Section 52.6(1) of the PHA outlines what the provincial government may do for the purpose of preventing, combating, or alleviating the effects of the public health emergency and protecting the public health which includes:

(a) acquire or use any real personal property;

(b) authorize or require any qualified person to render aid of a type of the person is qualified to provide;

(c) repealed;

(d) authorize the entry into any building or on any land, without warrant by any person;

(e) provide the distribution of essential health and medical supplies and provide, maintain and co-ordinate the delivery of health services.

Additionally, under Section 29 of the PHA, a medical officer of health – including the Chief Medical Officer of Health ("CMOH") – is afforded the authority to take whatever measures they deem necessary to: suppress the disease in those already infected, protect those not exposed, and break the chain of transmission.[1,2]

Beginning in March 2020, CMOH Dr. Deena Hinshaw took aggressive steps to prevent the virus from spreading and to "flatten the curve."[3]

Pandemic Planning: Provincial

The Government of Alberta has been preparing both the province and its healthcare system for an influenza pandemic since 1999. Upon formation in 2009, Alberta Health Services ("AHS") did not adopt or amalgamate nine pre-existing regional health authority pandemic strategies. Benefiting from the comparatively moderate initial phase of the 2009 H1N1 pandemic, AHS utilized this period to concentrate on formulating a strategic pandemic blueprint and an exhaustive operational framework.

The strategic pandemic blueprint was completed in November 2009 and fully developed by Alberta Health and Wellness ("AHW") and Alberta Emergency Management Agency ("AEMA").[4]

In February 2010, the Health Quality Council of Alberta (HQCA), responding to a directive from the Minister of Health and Wellness and in adherence to Section 13 of the *Regional*

Health Authorities Act, assessed Alberta's handling of the 2009 H1N1 influenza pandemic. The final report, published in December 2010, outlined commendable steps taken during Alberta's response while also pinpointing several recommended measures for subsequent implementation.[5]

A key focal point in crafting a comprehensive pandemic response strategy is "the imperative utilization of established incident command systems, coupled with suitable governmental oversight, and clearly delineated roles and responsibilities for Alberta Health and Wellness, Alberta Health Services, and the Alberta Emergency Management Agency." – HCQA Review of Alberta's Pandemic Response to the 2009 H1N1 Influenza Pandemic.[6]

Considering the recommendations contained in the 2009 HQCA report, an Alberta Pandemic Influenza Plan ("APIP") was developed jointly by AH, AHS and AEMA replacing all previous plans.[7] The APIP undergoes regular reviews to ensure alignment with guidelines from the Public Health Agency of Canada (PHAC). It serves as a conduit for support and coordination between the Government of Alberta and the pandemic operational plans of AHS.

Pandemic Planning: Federal

Drawing from the 2003 SARS outbreak and the 2009 H1N1 pandemic, Canada seized the opportunity to enhance its preparedness for future pandemics. Informed by these experiences, the Canadian government took steps to create and enact multiple recommendations aimed at bolstering its response to public health emergencies.

A significant outcome of these efforts was the establishment of PHAC, which was designed to strengthen the federal government's role in public health initiatives.

In response to COVID-19, Canada utilized a combination of existing pandemic response plans and adapted strategies to respond to the COVID-19 pandemic. The country's

response was guided by various documents, including *Canadian Pandemic Influenza Preparedness: Planning Guidance for the Health Sector*, which provided a framework for pandemic preparedness and response within the healthcare sector.[8] Additionally, the *Federal/Provincial/Territorial* ("FPT") *Public Health Response Plan for Biological Events* served as a broader framework for coordinating responses to biological emergencies, including pandemics like COVID-19.[9]

The FPT Public Health Response Plan for Biological Events was developed by the FPT Public Health Network Council (PHNC) to serve as a comprehensive governance framework guiding FPT public health responses to biological incidents.

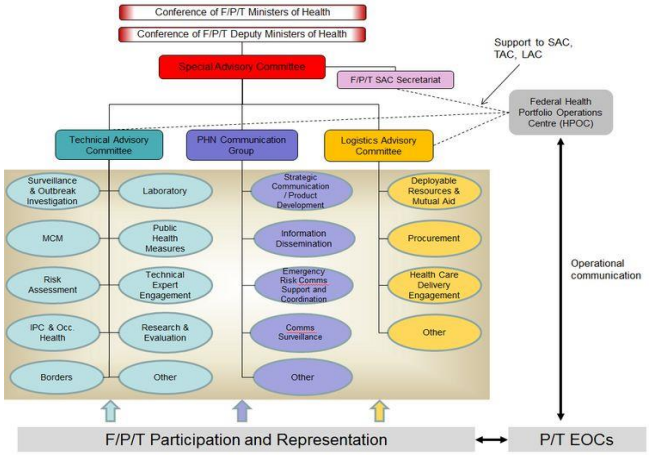
This plan was formulated by a task force comprising public health and emergency management experts identified by the Public Health Infrastructure Steering Committee (PHI-SC) and the Communicable and Infectious Disease Steering Committee (CID-SC). It received approval from the PHNC on October 17, 2012, and is maintained as a dynamic document by PHAC, specifically the Centre for Emergency Preparedness and Response (CEPR).[10] This flexible and modifiable document can be used in full or in part to coordinate response through PHAC dependent on the response level required. The plan incorporates a Technical, Logistics, and Communications stream. A coordinated response is determined by one of the four response levels described in the plan:

1. Routine
2. Heightened
3. Escalated
4. Emergency

Only an 'Escalated' or 'Emergency' level event requires a coordinated FPT response.

The plan provides for a Special Advisory Committee (SAC) to be the main decision-making body for the duration of FPT coordinated responses and with governance structure through the Conference of Deputy Ministers of Health ("CDMH") as needed. The determination of whether a coordinated FPT response is recommended is made through an initial assessment presented by PHAC to the co-chairs of the PHNC, the chair of the Council of Chief Medical Officers of Health (CCMOH) and the Deputy Minister Liaison who collectively make the decision. As outlined in Table 1 of the Plan, a level 4 or "Emergency" event requires a coordinated FPT response. COVID-19 was classified as an Emergency. Figure 1 outlines the governance structure for a coordinated FPT response.

Figure 1. Governance Structure for a Coordinated FPT Response.

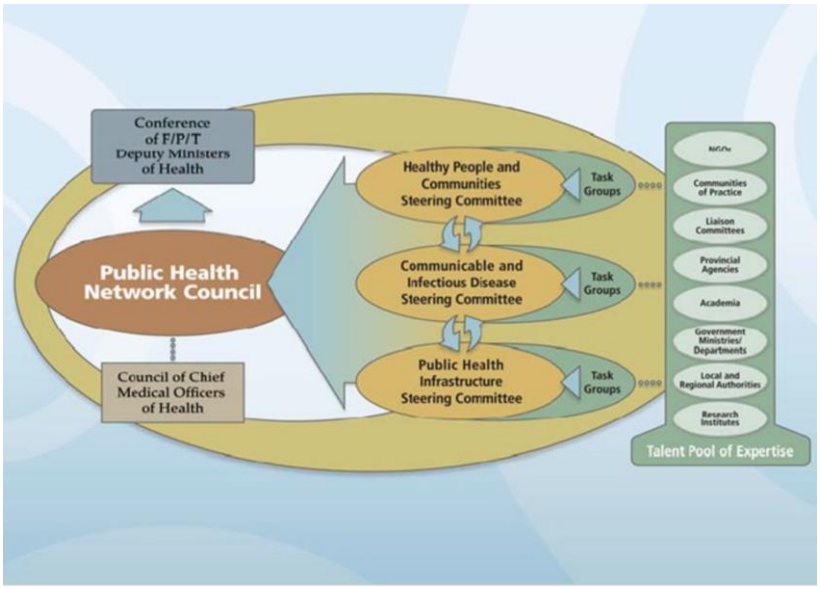


A detailed review of the various groups and committees active within the governance of a coordinated FPT response are beyond the scope of this report. However, this governance structure is highlighted to demonstrate the federal government's involvement when a level 4 Emergency such as COVID-19 is declared. This is further confirmed in the HQCA report under section 1.1.1.

It is important to note that the primary lead role for a level 4 Emergency response falls to the province or territory, leaving Canada with a coordinating or convening role while provinces and territories seek supports from the federal government when and as needed.

Another influential player in FPT COVID-19 response in Alberta was the Pan Canadian Public Health Network ("PCPHN"). Established in 2005, and following a governance transition in 2011, the PCPHN is now overseen by a 17-member Council consisting of FPT government officials, including the Chief Public Health Officer of Canada and senior public health officials from all jurisdictions. This Council reports to the Conference of FPT Deputy Ministers of Health, which provides direction and approves public health policy priorities for Canada.

Figure 2. Pan-Canadian Public Health Network structure as of April 1, 2011.[11]



The PCPHN is managed by three FPT steering committees, which report to the Pan-Canadian Public Health Network Council:

1. Healthy People and Communities Steering Committee
2. Communicable and Infectious Disease Steering Committee
3. Public Health Infrastructure Steering Committee

The PCPHN Council has representatives from each province, including Alberta's CMOH, Dr. Deena Hinshaw (at that time), and British Columbia's Provincial Health Officer, Dr. Bonnie Henry. The Council was chaired by Dr. Theresa Tam, the federal representative.

During the COVID-19 pandemic, a Special Advisory Committee was established according to the terms outlined in the *FPT Public Health Response Plan for Biological Events*. This committee was comprised of members from both the PHN Council and the CCMOH.

During the COVID-19 pandemic, Alberta's CMOH met regularly with the Special Advisory Committee to exchange information and receive guidance and updates from federal and provincial counterparts.

Alberta's Initial COVID-19 Response Review

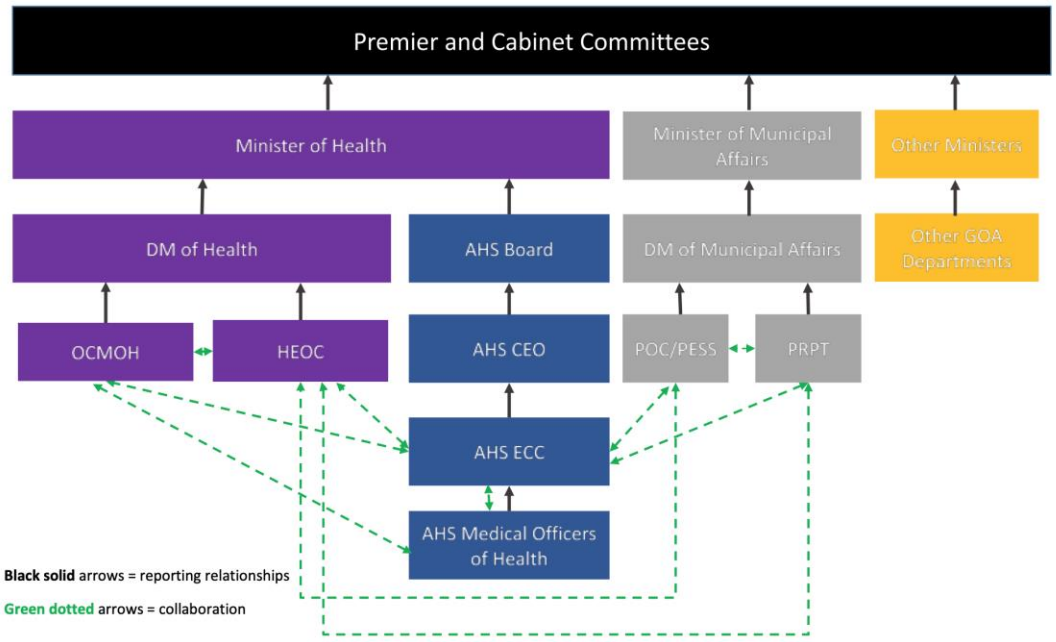
In January 2021, the Government of Alberta released the results of a review it commissioned KPMG to undertake into its initial response to COVID-19. The limitations of the KPMG report include: 1) a narrow period of time during which data was collected and used (up to November 27, 2020); 2) limited and targeted internal stakeholder engagement, focused only on provincial COVID-19 response, (i.e., the actions of the federal and municipal governments, as well as third-party stakeholders such as private continuing care facilities, were beyond the scope of the review); and 3) recommendations could not be advanced on all aspects of the report. Despite the narrow period reviewed, the KPMG report contains a significant amount of useful information for future pandemic planning. However, to maintain scope and perspective, and for the purposes of this report, the KPMG report serves as a snapshot of Alberta's pandemic response.[12]

This highlights Alberta's departure from its established emergency management procedures, despite significant development since the 2009 H1N1 pandemic, culminating in the 2014 Alberta Influenza Pandemic Plan. Notably, the 2014 Plan emphasized federal, provincial, and territorial (F/P/T) coordination during public health emergencies. This deviation underscores that Alberta had a well-thought-out pandemic response strategy, which recognized the need for a comprehensive approach to curb the virus's spread while also addressing secondary and tertiary impacts on its residents.

Key areas of focus in the KPMG report include virus reduction, minimal to no social disruption, minimization of economic impact and proper use and allocation of provincial resources.

Alberta's COVID-19's response as reviewed in the KPMG report shows the reporting relationships and coordination as demonstrated below:

Figure 3. KPMG of Alberta COVID-19 Response Reporting Structure



Further noted in the KPMG report was an outline of the decision-making structures.

Policy decisions concerning the pandemic response were deliberated and made by Cabinet Committees and Cabinet itself.

These committees were tasked with offering timely recommendations and decisions that struck a balance between public health imperatives and economic considerations, while also supervising the effective implementation necessary for managing the COVID-19 pandemic response. The Emergency Management Cabinet Committee (EMCC) was convened and met from March 2 to June 9. Following the conclusion of EMCC's operations, the Priorities Implementation Cabinet Committee (PICC) assumed its responsibilities starting June 12, 2021.

The Premier presided over both EMCC and PICC, with both the Deputy Minister of Health and the Chief Medical Officer of Health attending to provide expert advice and information. Additionally, other Deputy Ministers were invited to participate, aiming to facilitate responsiveness and promptness in translating plans and proposals into actionable measures.

The composition of EMCC encompassed Ministers from the following portfolios:

- Executive Council
- Municipal Affairs
- Justice and Solicitor General
- Treasury Board and Finance
- Environment and Parks
- Agriculture and Forestry
- Transportation
- Infrastructure
- Community and Social Services
- Health
- Indigenous Relations

PICC's membership consisted of Ministers from the following portfolios:

- Executive Council
- Environment and Parks
- Treasury Board and Finance
- Energy
- Jobs, Economy, and Innovation
- Health
- Justice and Solicitor General
- Children's Services[13]

> *Under the* Emergency Management Act *and* Government Emergency Management Regulation*, the Deputy Minister of Health is empowered to establish and execute crisis plans.*[14,15]

In response to the emerging COVID-19 crisis, the Deputy Minister of Health formed the Health Emergency Operations Centre (HEOC) in late January 2020 to oversee the department's pandemic response. The HEOC leverages the Incident Command System (ICS) for streamlined communication and decision-making, adjusting resources as needed. Operating within Alberta Health's Crisis Management Plan, HEOC coordinates public health interventions, clarifies health orders for the public and businesses, and collaborates on scenario planning and data interpretation to inform evidence-based decision-making, including epidemiological modeling in partnership with AHS and the University of Alberta.

> *The CMOH offers evidence-based guidance on public health matters, mandated by the Public Health Act and appointed by the Minister of Health, reporting to the Deputy Minister of Health.*[16]

Authorized under the PHA, the CMOH investigates and can enforce measures to safeguard public health during communicable disease outbreaks or emergencies, such as implementing isolation or quarantine protocols.

The CMOH's responsibilities include:

- Monitoring public health and advising the Minister and AHS on protective measures and disease prevention.
- Serving as a liaison between government bodies and health authorities, ensuring adherence to the PHA.
- Overseeing the activities of AHS and health officers under the PHA and providing directives when necessary.

The CMOH presents evidence and recommendations to relevant authorities, including the Minister, Premier or Cabinet, for decision-making. CMOH Orders are authorized under s. 29(2) or 29(2.1) of the Public Health Act, which outline enforceable directives.

On April 2, 2020, the Alberta legislature passed Bill 10, the *Public Health Emergency Powers Amendment Act*.[17] Under this Bill, a cabinet minister was empowered to make legislative changes by ministerial order without prior approval of the legislature. In response to criticism of this measure, Bill 66 was introduced and enacted in April 2021, reversing the expansive powers granted by Bill 10. Additionally, Bill 66 eliminated the provision for mandatory vaccinations under the *Public Health Act*. One of the primary reasons for scaling back executive authority under Bill 10 and removing government's ability to mandate vaccinations was public opposition to such measures.[18] Notwithstanding concerns about unchecked governmental authority, the Alberta government took no action to reduce the powers available to the CMOH under the PHA.

AHS stood up their Emergency Coordination Center ("ECC") which served as a conduit between the HEOC and AHS for the purposes of monitoring metrics for acute care, redeployment of staff across acute care sites and identifying operational needs. The ECC operated similarly to the HEOC model and met regularly with the HEOC.

Data Reviewed

The Task Force examined publicly available information and data for this review and conducted stakeholder interviews with individuals in key positions during the COVID-19 pandemic.

This investigation revealed that information relied upon in Alberta's response to COVID-19 originated from national and international sources, filtering through the federal government to various provincial working groups established during the crisis. This flow of information significantly influenced the decision-making process and the formulation of policies.

Health Emergency Operations Center

As discussed above, the Health Emergency Operations Center (HEOC) housed in Alberta Health was partially stood up by the provincial government in January 2020 and reported to the Deputy Minister of Health. Staffing of the HEOC was comprised of a variety of individuals occupying various roles within the Department of Health. In the execution of its mandate, the Task Force undertook to interview individuals in leadership positions within the HEOC.

Interviewees confirmed that the function of the HEOC was to provide planning and policy advice for public health perspectives, i.e., recommendations, restrictions, guidelines, and document development as well as isolation and quarantine measures (e.g. isolation hotels) and the development of the public health guidelines and protocols.[19]

Interviewees noted that throughout the initial wave, there was a consistent and evolving stream of information, with much of it comprising surveillance and epidemiological data from other nations.

Alberta placed significant reliance on international sources of information and collaborations with the federal government and select provincial counterparts.

Additionally, the interviewees highlighted Alberta's daily meetings with federal partners PHAC and provincial colleagues. Health Canada assumed substantial responsibility for tracking and gathering international data for subsequent dissemination. As information was relayed to Alberta, the province commenced the full establishment of the HEOC. Information was presented to the HEOC in packets from National groups, and further disseminated through HEOC.

The specific foundations of the established initiative remain uncertain; however, interviewees indicated that Alberta recognized the necessity for a

distinct approach to pandemic response, leading to the abandonment of its existing emergency pandemic response plan.

With the expansion of the HEOC team, members of the office of the CMOH assumed roles within federal groups, facilitating a national collaborative approach to engagement with FPT counterparts.

Additionally, the interviewees highlighted the substantial oversight and review provided by the Council of the Chief Medical Officer of Health (CCMOH) which included information from the Technical Advisory Committee (TAC) which occurred concurrently and was led by a specialist in population and public health and included members from both provincial and federal levels.

The interviewees further recalled that "when there was a [lack of] formal evidence and expertise, opinion [stood] in the place of robust evidence."

During the first wave of the pandemic, the absence of grey literature meant that all analyses and discussions were primarily conducted at federal forums and sourced from international channels. An interviewee clarified that the HEOC did not allocate resources to gather literature or conduct systematic reviews, as they deemed it unnecessary due to ongoing efforts by other organizations at national and international levels, including the Scientific Advisory Group (SAG) within AHS, which was established to conduct research, review data, and offer recommendations.

The interviewee confirmed the following groups as key sources of information:

- Public Health England
- Australian Clinical Evidence Task Force
- Center for Infectious Disease Research and Policy (University of Minnesota)
- Center for Disease Control ("CDC")
- World Health Organization ("WHO") – international perspective

- National Advisory Committee on Immunization
- Public Health Ontario
- Texas and Florida – used for contextual comparison at the local level.
- Technical Advisory Committee (TAC)

The interviewee further confirmed the existence of two epi-groups, the AHS surveillance group and AH surveillance group, noting that the information from each did not always align, and communication between the groups was not consistently maintained, leading to differing world views on the issues.

As the pandemic progressed into subsequent waves, maintaining close national coordination became increasingly challenging due to the rapidly evolving nature of COVID-19. Consequently, Alberta primarily sourced information from a global perspective through collaborative channels such as the TAC, Council of the Chief Medical Officers of Health, and the SAG.[20]

When questioned about controversial policies such as lockdowns and masking, an Interviewee stated that COVID-19 presented a concrete and measurable risk at the time, in contrast to the more abstract and difficult-to-quantify potential harms associated with these policies. The interviewee noted that the limited available research on these potential harms made it challenging to assess their existence or magnitude. The interviewee emphasized that recommendations were based on the quantifiable risks present, despite acknowledging that some impacts were foreseeable. The Task Force's assessment of the interviewee's response raised additional questions yet to be answered. For example, why did the interviewee not include community members representing economic and mental health issues in their discussions? Furthermore, why did the HEOC recommend policies with associated risks and harms in the absence of an appropriate public safety assessment?

Further information was gleaned from interviews with key individuals in decision-making roles which outlined the following points:

During the first wave, the precautionary principle guided decision-making, and the same approach was applied to Waves 2 and 3, as they were equally unanticipated.

The HEOC played a crucial role in providing information directly to the CMOH, serving as a major source of information flow.

All information funneled to the CMOH and Cabinet, with decisions tightly controlled and interventions closely guarded by Cabinet, leaving little room for additional information outside of established channels.

Cabinet decisions were made behind closed doors. Initially, decisions were informed by observations of other jurisdictions' COVID-19 responses, assuming that replicating these actions would yield favorable outcomes.

However, it became apparent after the first wave that there was a lack of scientific understanding concerning the virus, prompting a rush to gather data and insights. International rules and protocols provided a structural framework for the response, reflecting established international practices. AHS primarily relied on qualitative data, lacking sufficient quantitative data on operational or clinical processes. AH received a comprehensive plan from AHS only toward the end of the pandemic. Policy discussions between AH and AHS rarely addressed capacity considerations, with AH largely not engaging in AHS Zones. Lockdown interventions were implemented based on the precautionary principle, with limited scientific data supporting such measures during the initial wave.

Emergency Coordination Centre and Zone Emergency Operation Centers

The Emergency Coordination Center ("ECC") was the hub for AHS during the COVID-19 pandemic. It served as an integral component in the overall Incident Management System in AHS and worked in tandem with the five AHS Zone Emergency Operation Centers

("ZEOC"). These systems and more were supported by the Emergency/Disaster Management Division within Provincial Population and Public Health (PPPH) with a central purpose of managing emergencies and disasters. The ECC enables a consistent response and triggers the ability for rapid decision making when needed. The Task Force interviewed a senior leader in AHS during the pandemic.[21] This leader emphasized their thorough comprehension of the information flow from the perspective of AHS.[22] They confirmed the occurrence of routine meetings among Chief Medical Officers of Health nationwide, facilitated by an effective information-sharing group that incorporated input from PHAC.

The AHS senior leadership praised PHAC for its effectiveness in uniting national and provincial groups to ensure a cohesive message.

While acknowledging the constitutional constraints on federal jurisdiction over provincial health matters, the AHS senior leader argued that the Federal government should take a leading role in coordinating emergencies like COVID-19 to ensure consistent messaging.[23] Information from the ECC underwent regular consultation with the ZEOCs for operational and clinical data, public health insights, and guidance from the Scientific Advisory Group (SAG), before being relayed to the executive leadership of AHS and ultimately the CMOH. As the senior leadership elaborated on the initiatives undertaken by AHS and the communication disseminated to the CMOH, they underscored persistent obstacles hindering seamless communication between AHS and Alberta Health.

Additionally, the AHS leader highlighted uncertainties surrounding the research conducted by AH.[24]

The AHS senior leader also delineated the ECC's engagement with public health, highlighting distinct channels through which public health input was solicited: one via the ECC and another through the zone structure and ZEOCs. The ECC heavily relied on the Scientific Advisory Group (SAG) and information sourced from the zones. The AHS senior

leader confirmed that AHS messaging evolved from a clinical approach to that of public messaging.[25] Further clarification was provided to the Task Force in the interview regarding ZEOC operations. ZEOCs continuously monitored clinical and operational data which included capacity. The monitoring would occur multiple times a day with information being shared with the ECC and AH.

According to the AHS senior leader, it was evident that "there was diminished trust" between AHS and AH, which further complicated matters specific to data collected and shared, and that both groups did not share in one "world view" of the pandemic.[26]

Within the ECC, diverse groups offered guidance, with specific teams tasked with research and recommendation formulation. All recommendations were vetted through the AHS executive leadership team. There was a close collaboration between the CEO of AHS, the Deputy Minister of AH and the Minister of Health. Ultimately, the CEO, Deputy Minister and Minister would make the final decisions. This process was followed for all major decisions, such as implementing visitor restrictions in long-term care facilities.

While ultimately Alberta Health is "responsible for the delivery of health care in Alberta, AHS was established as the delivery arm for a substantial part (but not all) of health care."[27] As part of AHS's mandate, the scope of AHS's responsibilities are subject to the direction of the Minister of Health. Given this understanding established under the *Alberta Public Agencies Governance Act*, and *the Regional Health Authorities Act*, furthered by our review, the question remains: why did AHS enact an in-house pandemic response structure independent from Alberta Health's guidance and direction?

Scientific Advisory Group

The Scientific Advisory Group (SAG) commenced its operations in April 2020 to address inquiries regarding COVID-19 and concluded its activities on December 31, 2020. Although not the sole method for information and resource review, the SAG was tasked with leveraging evidence and assessing resource availability to furnish recommendations

supporting policy and operational decisions for the AHS Emergency Coordination Center during the COVID-19 incident response.

Employing a swift recommendation protocol, the SAG committed to providing responses within one week to any queries posed, a notable deviation from the typical turnaround time of several weeks to months.

The SAG was instrumental in providing research and recommendations in response to questions advanced to it.[28] The Task Force reviewed the SAG's recommendations in response to various questions throughout COVID-19 and ascertained a variety of resources were used to form their recommendations, including non-published/non-peer reviewed literature, grey literature, international and national information, messaging and publications.

HEOC leadership noted that the SAG was considered a source of information but privileged over other resources, especially as it pertained to public health recommendations. In contrast, senior leadership in AHS confirmed the SAG was heavily relied on for information.[29]

EMCC

Led by the Premier, EMCC was tasked with making decisions regarding the COVID-19 pandemic and its response, including determinations on public health measures, as well as recovery and support programs. This committee was stood up specifically in response to the COVID-19 pandemic.

Priorities Implementation Cabinet Committee

Under the leadership of the Premier, the Priorities Implementation Cabinet Committee ("PICC") oversaw decisions concerning the COVID-19 pandemic, including public health measures and recovery initiatives. However, PICC's scope was not limited solely to COVID-19 matters and was not solely stood up due to the pandemic.

As mentioned earlier, decision-making authority was granted to the CMOH through section 29 of the *Public Health Act*. Throughout the pandemic, various groups provided reports and recommendations to the EMCC for evaluation and review. However, the case of *Ingram v Alberta (Chief Medical Officer of Health)*, 2023 ABKB 453 revealed that Cabinet overstepped the CMOH's legislative authority, becoming the ultimate decision-makers. Justice Romaine stated in para 520:

> "In summary, I find that the impugned Orders are *ultra vires* section 29 of the *Public Health Act* in that the final decision makers were the cabinet and committees of cabinet, rather than the CMOH or one of her statutorily authorized representatives."[30]

Discussions within the EMCC are classified under Cabinet confidence, meaning they are not intended for public disclosure. However, the information presented to the EMCC through presentations, reports, and slide decks would be considered reviewable by the Task Force. Despite repeated requests, the Task Force was unable to access these records. Consequently, the Task Force was unable to review the information provided to the EMCC upon which decisions were made, despite these decisions exceeding their decision-making authority.

Conclusion and Recommendations

Task Force Observations on COVID-19 Recommendations

Containment of the virus was paramount in many of the recommendations and policy directives implemented in Alberta to minimize transmission. Measures included, but were not limited to, testing, isolation, workplace policy recommendations, school and business closures, and work-from-home recommendations. Despite the controversial history of such approaches in containing publicly transmissible viruses like influenza, Alberta's strategy contradicted known information at the time. Alberta's *Public Health Disease Management Guidelines* emphasized actions aimed at "containment."[31] This stance was based on the Government of Canada's *Public Health Management of Cases and Contacts Associated with COVID-19*, which acknowledged that "epidemiological evidence suggests that the majority of people with COVID-19 do not require care in a hospital," as supported by daily updates from the Government of Canada.[32] Given the data and information available, the

Task Force is unclear as to why Alberta continued to implement containment measures through policy and mandates when the information at the time did not justify such aggressive actions.[33] Additionally, it is not clear why Alberta's researchers and decision-makers overlooked crucial data when forming their recommendations and policies.

As noted above, the SAG was a highly influential group providing recommendations based on their review and research in response to COVID-19 questions advanced to them. Tight turnarounds and deadlines of mere days to a week increased the likelihood of errors, insufficiently comprehensive research, and the potential for bias and borrowed conclusions to shape their recommendations. We provide a few examples below.

The SAG's recommendations exhibit three main areas where biases can infiltrate their reports:

1. **Process Biases**
    - Due to short timelines and specific questions about COVID-19, the SAG often relied on librarians to gather a wide range of documents from various sources. However, the rapid turnaround times often prevented a full critical appraisal of the evidence, raising concerns about the quality of the reviews.
2. **Source Biases**
    - The SAG sometimes repeated recommendations from external bodies (COVID-END, NACI, PHAC, WHO) without conducting an independent review, particularly for significant topics.
3. **Evidence Weight Biases**
    - The SAG showed inconsistency in their use of evidence. For example, they used product monographs to recommend against Ivermectin for COVID-19 treatment but did not apply the same scrutiny to vaccines regarding transmission. Although COVID-19 vaccine monographs do not address viral transmission, the SAG claimed that widespread vaccination was most likely to reduce community transmission compared to NPIs.

Pandemic Response Plans

Pursuant to the federal *Emergency Management Act*, Public Safety Canada has the mandate to ensure we have a safe and resilient country by providing leadership in emergency management.[34,35] Within the emergency management are four major functions:

1. Mitigation,
2. Preparedness,
3. Response and
4. Recovery.

Emergency management takes an all-hazards approach and resources can be used interchangeably between functions. The process for each of the four functions is identical. Each province has an emergency management operations system. In Alberta it is the AEMA.

According to Lieutenant-Colonel David Redman (retired), former head of the Alberta Emergency Management Agency, every province and territory in Canada had a written pandemic response plan in place prior to COVID-19, as did the federal government. However, none of these plans were utilized during the COVID-19 pandemic.[36]

In Alberta, the pandemic response plan was created and refined over many years of government response to emergencies, with Lt. Col. Redman being instrumental in the development of the 2005 plan. The latest 2014 pandemic response plan was based on the following approach:

1. Controlling the spread of influenza disease and reducing illness (morbidity) and death (mortality) by providing access to appropriate prevention measures, care, and treatment.
2. Mitigating societal disruption in Alberta through ensuring the continuity and recovery of critical services.
3. Minimizing adverse economic impact.
4. Supporting an efficient and effective use of resources during response and recovery

Lt. Col. Redman understood that pandemics happen on a continual basis and are not just public health emergencies that affect only the health of the general population but are rather public emergencies that affect all areas of society. This prior understanding in Alberta of how to address pandemics prioritizes an immediate and effective response that protects the most vulnerable while minimizing social disruption, including impacts to the economy, education, mental health, and social services. In response to COVID-19, however, Alberta opted to reinvent the wheel, creating a hastily assembled operational system without a clear mandate and relying heavily on direction and guidance from national and international groups.

Canada's emergency response approach took a further turn with the revision of *An Emergency Management Framework for Canada*, which was approved by FPT leaders in 2017. This revised plan established the framework for a common and collaborative emergency response. At a 2019 FPT meeting, the *Emergency Management Strategy for Canada: Toward a Resilient 2030* was approved. By March 2022, the first in the series of action plans for 2030 was released entitled *2021-22 Federal, Provincial, and Territorial Emergency Management Strategy Interim Action Plan*, which defined concrete steps for a collaborative FPT response to future emergencies.[37] This shift suggests a strong and persuasive federal government influence on Alberta's COVID-19 response.

The Task Force has not found evidence in support of the rationale behind the decision to deviate from Alberta's established pandemic response planning. Our review of Alberta's COVID-19 response shows that at the onset of a novel pandemic, with many uncertainties, Alberta had a plan designed to respond to such a situation. Why did AHS and Alberta Health abandon this plan and adopt an ad hoc and reactive approach instead?

According to Lt. Col. Redman, a robust pandemic response plan was in place at the onset of the COVID-19 pandemic yet was not utilized, leaving Alberta with no plan or strategy to follow.

Closing Remarks and Future Action

The goal of this chapter was to comprehensively explore the governance structure and information flow that impacted decision-makers and policy development. While our review was thorough, it has unearthed additional inquiries that demand attention. The research revealed a pressing need to address unanswered questions. Despite the unprecedented scale of the COVID-19 pandemic impacts to Alberta, it remains unclear why there was such a significant level of disconnect, confusion and uncertain decision-making in response to the pandemic. Specifically, why did Alberta not leverage previous emergency plans rooted in past emergency response experiences? Why did the policy responses implemented lack thorough engagement with existing literature and best practices?

Why did Alberta resort to the precautionary principle despite awareness of potential harms associated with such stringent measures?

The Task Force's search for answers to these questions was hindered by informational barriers, including reluctance of key stakeholders to acknowledge and engage with our mandate.

Throughout our review, it became evident that Alberta's response to COVID-19 was heavily influenced by national and international interests, with less consideration given to the local context.

In addition to the above, our data review yielded several points which require further examination to surface questions and develop recommendations for actions to improve pandemic response in the future:

1. There appears to be a fundamental lack of transparency and willingness to reveal information and discuss decisions and actions taken by AHS during the pandemic.

During our data review, there has been a lack of willingness on the part of AHS officials to cooperate with the Task Force in our requests for data and information.

2. Why did Alberta seek direction and ultimately form decisions based on federal and international recommendations as opposed to Alberta's pre-existing pandemic response plan? Alberta's pandemic response plan took into consideration urban/rural differences, the economy, and mental health challenges, among other factors.
3. Canada's decision to sign on to the WHO's 2005 *International Health Regulations* ("IHR"), which require a coordinated response by provinces and territories to pandemics, paved the way for federal government's protagonism in pandemic response, replacing the previous leadership of provinces and territories. However, the burden of responsibility to meet the requirements of the IHR solely rests with the federal government, not the provinces.
4. Alberta tasked an independent company, KPMG, to review Alberta's pandemic response between March and October 2020. The report recommendations recognized the need for Alberta to review its pandemic response plan and engage in a robust review of non-COVID-19 related health impacts, including mental health and deferred medical procedures as well as industry-specific economic impacts. Given this information was made available early in the pandemic, why did Alberta not begin a thorough review into these secondary and tertiary impacts of its pandemic response?
5. The information provided to the EMCC/PICC flowed through various working groups to the Deputy Minister of Health. By their own admission, the DMOH lacked the necessary medical or scientific expertise to review information advanced to them, and ultimately to the EMCC. Given this lack of expertise, why did Alberta not involve the AEMA?

Recommendations

1. To prepare for future public health emergencies, ensure:
    (a) a central command center such as the AEMA is mobilized to direct the appropriate response;
    (b) the Alberta Pandemic Influenza Response Plan is reviewed, maintained and utilized; and
    (c) all data and research are collected, gathered and reviewed at a provincial level to ensure the most effective and appropriate response for Alberta.
2. Ensure transparency at all levels of decision-making.
3. All decisions regarding Alberta's response to any public health emergency shall be made by the AEMA or appointed person.

The content of this chapter relies primarily on publicly accessible information due to difficulties obtaining relevant information from key stakeholders and individuals of interest. Due to these information access challenges the Task Force recommends further inquiry.

Chapter 2: Regulatory Bodies

Executive Summary

The Task Force conducted an in-depth review of the regulatory framework governing the Colleges in Alberta during the COVID-19 pandemic. The actions taken by Alberta regulatory bodies and the Minister of Health were examined, focusing on communication, decision-making processes, and the impact on healthcare professionals and patient care. The Task Force found several shortcomings and failures in regulatory governance during the pandemic, including over-centralization, lack of transparency, limited consideration of alternative perspectives, and potential regulatory capture. They made preliminary recommendations to address these shortcomings, including decentralizing decision-making, strengthening appeal mechanisms, codifying the process for developing guidelines, respecting physicians' clinical judgment, creating platforms for open dialogue, and implementing accountability measures. The Task Force also called for further inquiry into areas such as funding sources, potential regulatory capture, transparency measures, impact on professional autonomy, and the "substantially equivalent" directive. The Task Force emphasized the need for lessons to be learned and improvements to be made to Alberta's public health emergency response system. Overall, the Task Force's review and findings highlight the importance of transparency, accountability, and a balanced approach to decision-making in regulatory governance. The Task Force's recommendations aim to strengthen the regulatory framework and ensure fair, evidence-based, and patient-centered care during public health emergencies.

- The Chapter examines the processes and data used by regulatory bodies in Alberta during the COVID-19 pandemic.
- It emphasizes the importance of reliable data, integrity in the review process, and transparency in decision-making to maintain trust in the healthcare system.
- Health regulatory bodies in Alberta play a critical role in ensuring high standards of practice and ethics among healthcare providers.

- The Chapter discusses the challenges faced by regulatory bodies in accessing and maintaining up-to-date COVID-19 data sources and the importance of involving relevant stakeholders and considering diverse viewpoints in policy development.
- It highlights the pre-existing policy development processes outlined in the *Health Professions Act* ("HPA"), which require review, comment, and approval of standards of practice.
- Healthcare providers had a reasonable expectation that regulatory policy developments made during the pandemic would be handled with diligence and thoroughness.
- Recommendations are made to enhance oversight, improve transparency measures, and ensure a fair and evidence-based disciplinary process including:
    - examining the mechanisms of oversight and accountability for the Chief Medical Officer of Health (CMOH) during public health emergencies;
    - balancing necessary public health measures with individual rights and engaging frontline healthcare professionals in guideline development; and,
    - the need for widely accepted clinical practice guidelines, accurate data, and a comprehensive strategy.
- The Chapter concludes by advocating for a decentralized approach to decision-making and further inquiry into transparency measures and accountability mechanisms.

Introduction

Regulatory Oversight and Pandemic Data Sources

Background

The COVID-19 public health emergency presented an unprecedented challenge to healthcare systems globally, resulting in rapid policy responses and regulatory adjustments. This section of the report outlines an examination of the processes and data that Alberta regulatory bodies (Colleges) relied upon to make or modify policies during the response, the connections of these new policies to well-established standards, and the potential effects on the trajectory of the emergency response. It is expected that health regulatory bodies conduct rigorous data analysis and review before implementing significant regulatory changes as clearly outlined in the *Health Professions Act* ("HPA").[38]

The reliability of the data, the integrity of the review process, and the transparency of decision-making are critical to maintaining trust in the healthcare system and ensuring that the measures enacted are both effective and justifiable.

Health regulatory bodies in Alberta play a critical role in ensuring that healthcare providers adhere to high standards of practice and ethics to safeguard the health of Albertans. These bodies are governed under the HPA, which establishes the framework for regulation and accountability of healthcare professionals. The Act outlines the responsibilities of the Colleges, including registration, continuing competence, complaints handling, and disciplinary procedures.

This report serves as a critical examination of how these regulatory bodies managed their pivotal roles during the pandemic, particularly focusing on the self-reported sources that informed their policy decisions and the extent to which these decisions aligned with or contradicted their pre-existing standards of practice.

What Was Done

Challenges with COVID-19 Data Sources

The Task Force sought to review the data sources used by the Colleges to gain a better understanding of their role in the trajectory of the public health emergency response. A high degree of vigilance was necessary to ensure data reliability and validity. A thorough review of the Colleges' actions and the data used to support them is critical so that we learn lessons in the event of any potential future public health emergency. Decisions should be underpinned by accurate data, properly analyzed and interpreted, to meet the necessary standards of diligence and integrity expected in health governance.

Pre-Existing Policy Development Processes Across Regulatory Bodies

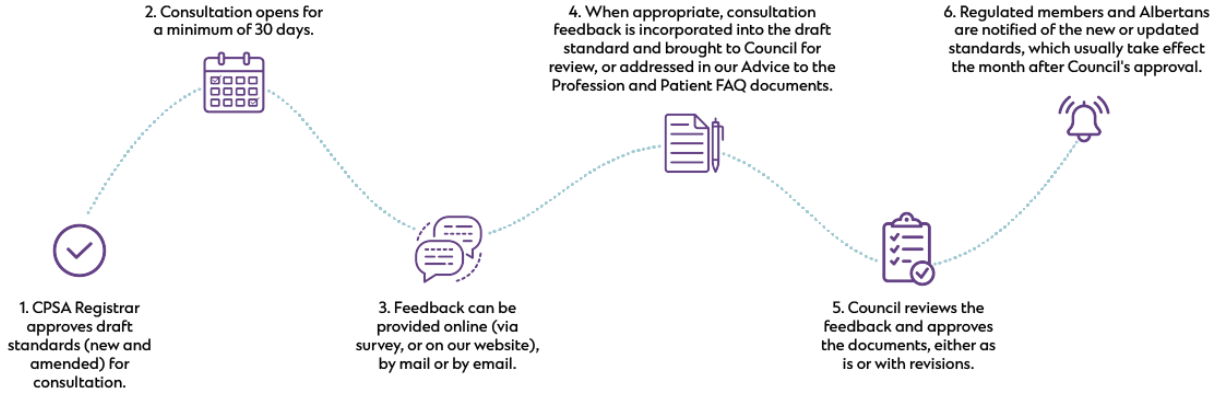
The *HPA* stipulates how the Colleges are to adopt or amend their Codes of Ethics and Standards of Practice. This is an established, comprehensive, and rigorous policy development process, which includes providing a copy of proposed standards to various stakeholders, particularly its regulated members, for review and comments before final approval by the Minister of Health.

Case example: College of Physicians and Surgeons of Alberta Bylaws regarding Standards and Codes Development.

Using the College of Physicians and Surgeons of Alberta ("CPSA") as a specific example, section 8 of their Bylaws,[39] and their website detail the robust process for developing the Code of Ethics and Standards of Practice. This includes solicitation of written feedback for consideration prior to a vote of members of the Council. Additional details from the CPSA website expanding on how they implement the above consultation process:[40]

The CPSA summarized with the following infographic:

Figure 1. CPSA Consultation Process.



The Task Force found that a variety of provincial and federal stakeholders influence the CPSA's regulatory standards and policies. These include the Alberta Medical Association, Alberta Health Services ("AHS"), Alberta Health, the Public Health Agency of Canada ("PHAC"), Health Canada, and the National Advisory Committee on Immunization ("NACI"). Not-for-profit organizations like the Canadian Medical Protective Association ("CMPA"), as well as hospitals and clinics, medical professionals, including pharmacy and nursing professionals, educational institutions such as medical schools and residency programs, legal and ethical experts also provide input on CPSA standards and policies. In addition to the above, during the COVID-19 pandemic, the CPSA also received practice recommendations from the AHS COVID-19 Scientific Advisory Group ("SAG").[41]

Expectations of Healthcare Providers Regarding Regulatory Policies

The previous section outlines the commitment that is required of the Colleges to extensively involve relevant stakeholders in their policy development processes. Ideally this should allow for diverse viewpoints and important feedback to be considered.

The aim is to reflect the needs and expectations of all parties involved and maintain transparency in the outcomes to uphold public trust and accountability.

Given the history of robust methodologies, healthcare providers had a reasonable expectation that any policy developments during the COVID-19 public health emergency would be handled with the same level of diligence and thoroughness. Providers would thus be justified in expecting that changes would be thoroughly vetted through solid evidence, comprehensive stakeholder engagement, and a transparent decision-making process that adhered to the fundamental principles of healthcare.

This approach is expected to be a standard practice across all health regulatory bodies in Alberta given that it is outlined explicitly in the HPA ensuring that healthcare providers can rely on the regulatory frameworks to guide their professional responsibilities effectively and ethically.

Data Reviewed

Data Review and Analysis of Actions taken by The Minister of Health

Ministerial Order 645/2020 signed October 29, 2020, by Minister Shandro.[42]

This order authorized the following regulated members under the HPA:

- Clinical Pharmacists under the Alberta College of Pharmacy;
- Dental Hygienists under the College of Registered Dental Hygienists of Alberta;
- Dental Assistants under the College of Alberta Dental Assistants; and
- Dieticians under the College of Dieticians of Alberta.

to perform the following restricted activity:

> "To insert or remove instruments, devices, fingers or hands beyond the point in the nasal passages where they normally narrow for the purposes of nasopharyngeal swabbing"

With detailed terms and conditions. The provisions for the above Ministerial Order are outlined in section 1.4 of the HPA:

The loosening of the restrictions as outlined above allowed for a significant expansion in the ability to perform PCR testing via nasopharyngeal swab sampling. The expansion of testing in itself can be a positive action as it relates to a public health emergency response. It is, however, dependent on testing being applied to appropriate populations. For example, indiscriminate testing, particularly among asymptomatic individuals, may lead to a high incidence of false positives, thereby complicating the accuracy and effectiveness of the public health response. Specific questions do arise regarding the extension of this restricted activity:

1. **Training Adequacy:** Given the rapid expansion, could the training provided to newly authorized personnel, such as clinical pharmacists and dental hygienists, be sufficiently comprehensive to ensure competent performance in nasopharyngeal swabbing?
2. **Error Rates Among New Testers:** Might there be an increased likelihood of procedural errors by newly trained testers, potentially leading to incorrect swabbing techniques or improper handling of samples?
3. **Selection of Test Subjects:** Could the expansion of testing responsibilities to a broader range of professionals result in a less discerning selection of individuals for testing, particularly including asymptomatic individuals or others who may not meet specific epidemiological criteria?
4. **Impact on Public Health Data:** How might increased testing of asymptomatic individuals by professionals new to this task affect the reliability of public health data, potentially leading to an overestimation of case numbers due to false positives?
5. **Resource Allocation:** With the expanded scope of practice, is there a risk of resource misallocation, where critical testing supply and human resources might be used sub-optimally?
6. **Professional Competence:** Given the diverse backgrounds of the professionals authorized to perform swabbing, how consistent is the skill level across different groups, and what impact might this have on the quality of the testing process?

7. **Impact on Professional Workload:** What are the implications for the workload of these professionals, and how might their primary responsibilities be affected by the additional duties?

The Task Force recognizes the significance of the above questions and concerns regarding the expansion of nasopharyngeal swabbing capabilities to additional healthcare professionals. Given the potential risks and implications associated with such an expansion—ranging from training adequacy and procedural errors to resource allocation—the Task Force strongly recommends that these issues be thoroughly explored through a further formal inquiry.

This inquiry should aim to assess the efficacy and safety of the expanded practices, ensuring that they align with the highest standards of public health and professional integrity.

Data Review and Analysis of Actions Taken by Regulatory Bodies

Background on Colleges and their Roles

The Task Force performed a review of the actions taken by the regulatory bodies (i.e., Colleges). While the review included all the Colleges, the Task Force focused discussion on the Colleges that played the most significant role in shaping the trajectory of the public health emergency response.

Resource Management

There were multiple changes enacted by the CPSA to manage human resources, including expanding the workforce available to respond to the public health emergency.[43] These temporary measures were found across multiple Colleges, e.g., "Temporary Conditional Registration" by the Alberta College of Pharmacists.[44]

Emergency Register

Emergency Registration details:

> As per clause 9(2) of the Physicians, Surgeons, and Osteopaths Profession Regulation, CPSA Registrar, Dr. Scott McLeod, activated an Emergency Register on

> March 19, 2020, allowing physicians currently registered in another province or territory to temporarily work in Alberta during emergency circumstances, such as the current COVID-19 pandemic.

Scope of Practice Flexibility

Scope of Practice flexibility details:

> CPSA recognizes that during the COVID-19 pandemic, physicians may be required to work outside of their normal scope of practice and training. We are working hard to ensure you have all the resources you need to be able to focus on providing front-line care to Albertans during these are extraordinary times.
>
> During this time, any physician who has privileges and is working in an Alberta Health Services (AHS) or Covenant Health facility can be deployed in any way they see fit.

CPSA Assessments

CPSA Assessments details:

> In light of the COVID-19 pandemic, CPSA is postponing most non-urgent assessments and committee meetings until further notice. We are still prioritizing some registration assessments to help put physician resources into Alberta's health system.

Conclusion and Recommendations

In the view of the Task Force, the above actions by the CPSA appeared reasonable. Similar resource management actions should be taken in the event of a future public health emergency provided there is proper decision-making, including accountability, a well-defined process, and transparency.

Public Health Emergency Communications

During the Health Emergency Response, the Colleges communicated with their regulated members via different methods and labels. These included e-mail, website postings, and printed materials, with examples of the communication's labels being Guidance, Statement, Message, FAQs, Advice, and Policies. Of note, these communications were not new or amended "Standards" or "Codes of Ethics."[45] The HPA defines the clear process

required to adopt or amend a standard, including that changes to standards require the comment and feedback from members and approval by the Council prior to implementation.[46]

There was no requirement for communications to be supported by policy-grade evidence.

Had the Colleges followed a similar process when drafting their communications during the pandemic, regulated members could have contributed and provided valuable feedback on many areas of COVID-19 response. For example, physicians could have expressed concerns that emerging evidence supported certain off-label medications that had an extremely low risk of harm or that certain non-pharmaceutical interventions were contributing to various short- and long-term harms and were doing so without policy-grade evidence of benefit.

A major concern is that without proper correcting processes, a false sense of consensus is created, which can result in solidifying the trajectory of a public health emergency response in a direction which can be fundamentally flawed.

The idea that a given scientific assessment of any aspect of the COVID-19 response could represent a 'settled' state appears to be contrary to the scientific method, especially in a situation where data was constantly evolving. Put another way, the Colleges appeared to perpetuate as definitive an inappropriately narrow range of health care delivery options to combat the pandemic.

An in-depth discussion of every COVID-19 communication across thirty Colleges would not be practical. In our review, the Task Force identified the key themes below to highlight. Further, we provided a summary discussion from the perspective of physicians and their regulatory body, the CPSA, as the impact from this College was significant.

The key themes relate to:

1. Regulations pertaining to facility and/or provider operations, i.e. Infection Prevention and Control (IPAC).[47]
2. Regulations pertaining to individualized provision of care:
    (a) Prescribing medications (including off-label medications) in opposition to prior established Standards of Practice, Standards of Informed Consent, and Standards of Practice Outside of Established Conventional Medicine.[48]
    (b) Provider assessment and determination of qualifications for "exemptions to pharmaceutical or non-pharmaceutical interventions."
3. Actions pertaining to consequences or disciplinary measures undertaken.

Concerns regarding the above are outlined in the sections below.

Examples of College Communications

An email communication jointly issued by the CPSA and the Alberta College of Pharmacy to the profession was issued on March 31, 2021, providing guidance for the immediate cessation of prescribing hydroxychloroquine, chloroquine, remdesivir, lopinavir/ritonavir, colchicine, and azithromycin, among others, as treatments for COVID-19, as these medications had not been approved for this use. (Another "Joint statement from CPSA and ACP regarding inappropriate prescribing and dispensing of ivermectin to treat or prevent COVID-19.")[49]

It is important to convey that these communications were not subject to rigorous scrutiny and a due diligence process according to College standards, yet they played a critical role in the trajectory of Alberta's COVID-19 response. The content was also unprecedented as the Task Force was unable to identify any previous occurrence when the CPSA specifically directed the cessation of prescriptions.

CMOH Order 16-2020[50]

Previously outlined were the flaws in the regulatory bodies' communication development process which may have contributed to an inappropriately narrow range of responses and

solutions during the public health emergency. However, fault cannot be fully attributed to the Colleges as they were required to conform to an extremely restrictive mandate from the CMOH.

CMOH Order 16-2020 was signed May 3, 2020, and effective until rescinded June 12, 2020, by Deena Hinshaw.

"[E]ach college established under the Health Professions Act must, as soon as possible, publish COVID-19 guidelines applicable to the regulated members of the college that are substantially equivalent to the guidance set out in the Workplace Guidance For Community Health Care Settings developed by Alberta Health, along with any additional guidelines specific to the usual practice of the regulated profession."[51]

The CMOH required that the Guidelines be 'substantially equivalent' to the "Workplace Guidance for Community Health Care Settings" developed by Alberta Health, given that Section 4 ordered that each College provide the CMOH with a copy of any guidelines published and that, per Section 5, the CMOH may amend any COVID-19 guidelines created by a College if the CMOH determined that the guidelines were insufficient to reduce the risk of transmission of COVID-19 in the practice of the regulated profession.

The mandating of COVID-19 guidelines with a level of restrictiveness that exceeds practical necessity, underscores a troubling overreach of authority.

While the intent to safeguard public health is understandable, the rigidity imposed by these mandates not only stifled the flexibility and professional discretion that healthcare practitioners needed during an unprecedented crisis but also obscured potential harms caused by such restrictive measures.

> *By compelling compliance to "substantially equivalent" standards developed without sufficient consultation with the actual caregivers on the front lines, this approach not only undermined the autonomy of healthcare professionals but also likely hampered innovative responses that could have been tailored to more effectively address specific local conditions and mitigate unintended consequences.*

Such excessive centralization of decision-making, especially in the dynamic context of a public health emergency, is not only inefficient but also unjustifiably authoritarian, reflecting a misplaced overprotection rather than a principled and pragmatic public health strategy.

Questions – Next Steps

Considering the concerns, it is imperative to critically examine the mechanisms of oversight and accountability that govern the actions of the CMOH, especially during a public health emergency. This examination should aim to ensure that while public health safety is prioritized, the measures imposed do not unjustifiably infringe upon the autonomy and professional discretion necessary for effective healthcare practice. The following questions are recommended for exploration:

1. When does it become unreasonable for the CMOH to invoke specific clauses of the HPA in the name of public health to override other sections of the same Act?
2. How can a balance be maintained between necessary public health measures and the preservation of professional autonomy and judgment?
3. What legal frameworks and ethical principles should guide the CMOH's decision-making during public health emergencies?
4. How can these guidelines ensure a balance between individual rights and public safety?
5. What criteria should be used to assess the proportionality and necessity of directives issued by the CMOH during a public health emergency?
6. How can these criteria ensure directives are effective and minimally intrusive?

7. How can the CMOH enhance transparency and improve communication with healthcare professionals and the public during the drafting and implementation of health directives?
8. What mechanisms can facilitate effective feedback and dialogue?
9. How can the process of developing health guidelines during emergencies be made more inclusive, engaging frontline healthcare professionals to ensure that the guidelines are practical, context-sensitive, and adaptable to evolving circumstances?
10. How should the impact of health directives be assessed in terms of healthcare delivery and outcomes?
11. What processes can be implemented to continuously evaluate and adjust these directives to maximize positive impacts and mitigate negatives?
12. To which individuals and bodies should the oversight of the CMOH's emergency powers be assigned?
13. What robust checks and balances should be established to scrutinize the actions of the CMOH and ensure accountability?
14. What framework should be implemented for conducting comprehensive after-action reviews of the CMOH's decisions and actions?
15. How can the findings from these reviews inform future preparedness and response strategies?

This set of questions is designed to initiate a thorough examination and improvement of the regulatory frameworks governing public health emergencies. By focusing on establishing clear principles and criteria, enhancing transparency, and fostering inclusive consultations, this approach aims to ensure the frameworks are robust enough to address unique challenges while preserving professional autonomy and ensuring effective healthcare delivery.

Public Health policies, including in Emergency situations, affect many areas of society.

Therefore, an initial recommendation of the Task Force is that for a Public Health Emergency, the CMOH and Public Health division comprise one part of the Emergency Response Team, rather than be the major authority.

Any structure should ensure a multi-disciplinary approach, leveraging expertise from various fields to enhance decision-making and response effectiveness, as well as to identify and mitigate harms. This integration would allow for balanced perspectives and more comprehensive strategies.

Communications – In-Depth Data Review

The Task Force reviewed College communications to the public and their members, noting CMOH Order 16-2020, both before and after this order was rescinded on June 12, 2020. We considered the possibility that the Colleges were under the impression that they must follow the CMOH Order 16-2020 even after it was rescinded.

Forcing the College's direction to be "substantially equivalent" is fundamentally flawed as it prevents the Colleges from being able to perform independent analysis and decision-making.

Regarding College communications, the HPA outlines that if a college chooses to publish any information in addition to the information set out in section 135.92 (2), the Council must make a bylaw describing the additional information that may be published on the college's website. We reviewed some of the Colleges' Bylaws, and COVID-19 communications do not appear to be explicitly outlined in those Bylaws. However, taking the CPSA as a specific example, the publication of communications, e.g., "Advice to the Profession," has been utilized prior to the COVID-19 public health emergency, with the disclosure on their website that "[u]nlike standards, advice documents don't require approval from Council and can be updated at any time."[52]

While it is reasonable that Colleges provide some level of guidance to their members regarding new or emerging issues, members should not be disciplined based on Communications which do not meet the same meticulous review as the 'Standards of the Profession' outlined by the HPA.

Data Review – Communications Review Methodology

The Task Force searched the websites of the Colleges for public health emergency communications (i.e. Guidance, Statement, Message, FAQs, Advice, Policies, and/or any publications with relevance to COVID-19). Some of the communications were found on internet archives as they have been removed from active websites. Of note, we were unable to access information behind password-protected member portals. We made formal requests of the Colleges to disclose COVID-19-related information. We reviewed the communications and noted the sources which were referenced by the Colleges. We made direct requests to each College for information regarding methodology or other due diligence to support their health communications.

The Task Force reviewed the communications and noted all the sources, resources, or references which were stated by the Colleges for analysis. We noted the references cited from endnotes and footnotes, as well as from the body of the text for each communication. Some communications made statements relevant to the COVID-19 public health emergency response but did not contain any references. For these, the Task Force assessed this as "no reference." Some communications on pandemic-related topics clearly did not constitute statements requiring references. These were not counted as "no-reference" and were not included in the denominator for the total count. Despite that, these statements may still have influenced regulated members' understanding, perceptions, or responses to the pandemic. We maintained these communications and their sources for future reference. Frequently, a College referenced one of their pre-existing communications or standards. These were classified as "self-reference." When a College referenced another College, the reference was classified as "inter-college." For communications which referenced primary sources, a classification of "communication with multiple primary sources referenced" was assigned.

When a College Communication stated a reference, the Task Force made efforts to clarify the citation. For example, we considered 'Dr. Hinshaw' as equivalent to 'CMOH.' Other references were not as clear, e.g., 'Canadian Health Authorities.' When these could not be categorized, the references were maintained as originally cited.

The purpose of the above analysis was not to critically evaluate each individual source (where cited) but rather to evaluate to what extent primary reference sources were cited by the Colleges for their communications as opposed to simply deferring to another entity. Furthermore, the purpose of this analysis was not to assess the extent to which any of the referenced entities themselves may have utilized unbiased primary sources.

For our analysis, we did not utilize a simple count, as the Task Force recognized that the number of communications and the number of citations per communication would bias the results toward those with higher numbers of either of the above. This was corrected by normalizing the count for each College. That is, when calculating the overall contribution of the references, each College was given equal weighting to ensure consistent relative strength.

As well, when a communication cited multiple primary sources, it was classified as 'communication with multiple primary sources referenced.' For example, if a College published 10 communications with each citing multiple primary sources, these would be considered '100% primary source cited.' Whereas, if a College published 30 communications with 3 citing primary sources, these would be considered '10% primary source cited.' The number of primary sources within the 3 communications would not disproportionately influence the Colleges' overall classification, even if those 3 Communications referenced dozens of sources. This approach was taken to ensure a balanced assessment of how frequently primary sources are utilized across all communications. Thus, even if a few communications are heavily sourced, the overall evaluation remains fair and reflects the general trend rather than isolated instances of thorough referencing. This method prevents any skewing of data and provides a clearer

picture of the Colleges' commitment to basing their communications on multiple primary sources.

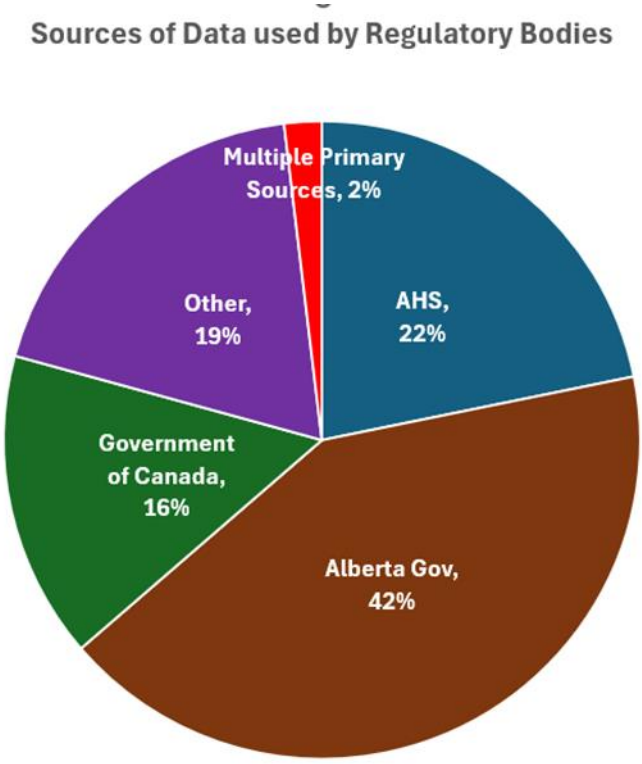
Corrections were made for the more detailed results ("corrected analysis") highlighted in the section of this report. References which were unlikely to be pointing to source information regarding COVID-19 or public health emergency response measures were excluded from the calculations. For instance, references to the HPA, the *Government Organizations Act*, the *Health Information Act*, municipal bylaws, the *Alberta Fire Code*, and the *Human Rights Act* by the Colleges did not appear intended for supporting specific information related to the COVID-19 disease, interventions, or emergency response measures. Similarly, references within the same College (self-reference) and between Colleges (inter-college reference) were removed, as well as removing the category "no-reference."

Data Review – Communications Review Results

A total of 341 communications across 30 Colleges were included. While there were additional communications published during the COVID-19 public health emergency (2020-2023), and although the policies may have affected aspects of members' practice during the pandemic, they were not included if there was no specific mention of the COVID-19 pandemic. The total reference count was 786.

- There were 11 (1.4%) College Communications which referenced primary sources.
- The corrected/normalized analysis showed:
- Primary sources constituted 2% of the references.
- Government of Alberta (42%), AHS (22%) and Government of Canada (16%) sources comprised the majority (74%) of references cited by the Colleges.
- 47 entities comprised the Other category (19%)

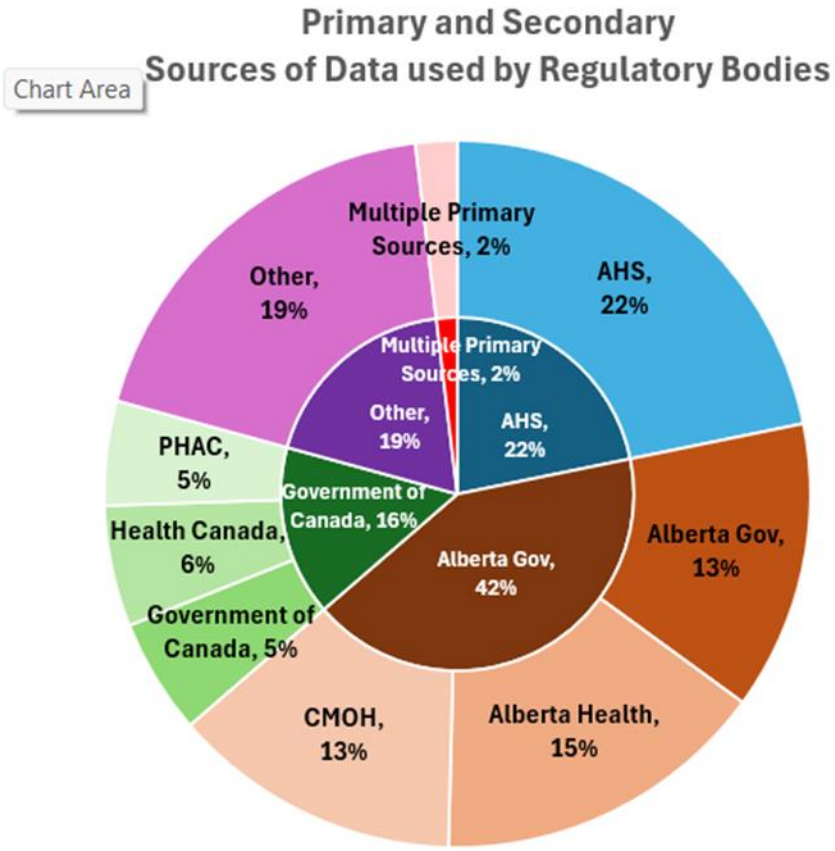
Figure 2. Sources of Data Used by Regulatory Bodies.



This second more detailed chart shows how closely related entities were combined.

These charts highlight that when the Colleges presented references to support their position on COVID-19-related matters, it was predominantly from a few entities. More importantly, the proportion of Communications which referenced primary sources, an indicator of due diligence by the Colleges, was exceedingly low.

Figure 3. Primary and Secondary Sources of Data Used by Regulatory Bodies.



The "Other" reference category accounted for a corrected 19% of the references cited by the Colleges. This category was comprised of 47 entities, varying from international bodies (e.g., WHO, CDC, European Medicines Agency), provincial and national associations (e.g. Alberta Medical Association, Canadian Psychologists Association, Alberta Pharmacists Association), pharmaceutical sources (e.g. COVID-19 Vaccine Product Monograph), and other entities (e.g. '19 to Zero').

The Task Force recommends further analysis to assess the extent of overlapping sources, and the due diligence performed among the non-primary references cited by the Colleges, i.e. AHS, Alberta Health, Government of Canada, and the 47 entities that comprised the 'Other' source category.

Data Review – Communications Review Limitations

There were limitations in the review and analysis of the data review of communication sources and references.

1. If a communication mentioned a reference, such as from the CMOH, it was counted as a source even if the document was largely unreferenced otherwise. This method may misrepresent or overstate the degree to which some documents were referenced.
2. Some references were vague or unclear, such as simply stating "government" without specifying whether it referred to the Government of Alberta or the Government of Canada. Despite efforts to clarify, these ambiguities remained a challenge to categorize.
3. The study did not evaluate the rigor of the due diligence performed by the referenced entities. References to organizations like AHS or Canada Health were taken at face value without assessing the quality of their methodologies.
4. Some communications were included in the analysis because they mentioned COVID-19 but were only minimally relevant to the pandemic response. These could include procedural or administrative content. This may have affected the final analysis despite attempts in the correction process described above to filter these communications out.
5. There was no independent validation of the accuracy or relevance of the references cited. Some references may have been outdated or superseded by new information, impacting the reliability of the communications.
6. Determining which references were relevant, as well as grouping similar entities, involved a degree of subjectivity.
7. Many communications pointed the reader to other locations or posted links. It is not known to what extent that the Colleges reviewed or verified the content within the links.

8. Any informal or non-published communications (e.g., verbal instructions or internal memos) were not included in the review. These could have played a significant role in shaping the actions and policies of the regulatory bodies.

Despite these limitations, the data review and analyses appear sufficient to show the primary objective of assessing the extent to which Colleges performed due diligence and cited primary sources for their communications compared to relying on other bodies.

Communications Review Commentary-Overlap of References / Sources

In the Task Force's data review of the communications, there was a significant overlap in the references and sources cited.

While referencing the same overlapping sources does not inherently lead to an error, as the entities could have converged on the same positions, it could potentially contribute to a higher likelihood of the following two categories of errors. On one hand, a high degree of overlap might lead to overlooking alternative perspectives or nuances. On the other hand, relying heavily on common sources could result in overemphasizing approaches.

Overall, it suggests a limited window of scientific inquiry and may indicate a lack of diverse perspectives. This reliance on a narrow set of references could lead to a reduced ability to thoughtfully and critically evaluate alternative viewpoints or emerging evidence.

Commentary on References / Sources

In general, the Colleges primarily relied on centralized bodies for their communications, citing primary literature only rarely, 1.4% by simple count and 2% corrected in the analysis.

It does not appear that the Colleges conducted independent in-depth evaluations of the data or sources.

The Task Force could not identify any strong methodology or due diligence processes independently performed by the Colleges, including in response to direct requests for disclosure.

In fact, this was directly admitted. In a specific example regarding mandatory vaccination, the Alberta College of Paramedics disclosed that they were not a "subject matter expert" and that the "College defers the decision of what is in the best interest of Albertans on the matter of mandatory vaccination to Alberta Health and the healthcare professionals who are experts."[53] While deferring when matters do not fall within their expertise or jurisdiction is obviously reasonable, it should be accompanied by abstaining from endorsing any particular position and applied consistently in all relevant contexts. Where Colleges' positions contravened existing Standards or Codes of Ethics, they may have been expected to defend these standards or codes instead, especially if they were pertinent to defending members who were subject to disciplinary actions. This is discussed in further sections of this report.

Moreover, it seems that the Colleges did not consider potential conflicts of interest within the bodies whose data they cited. This omission is particularly concerning, as it's crucial to recognize and manage such conflicts to ensure the integrity and validity of the information being presented. In the context of the Colleges' communications, overlooking potential conflicts of interest could have led to an imbalance in the representation of information.

The above instances may constitute a failure in governance. The Colleges have a well-defined due diligence process, as outlined in the HPA for "Standards of Practice" but no such process applied to the communications during the response to COVID-19. Instead, they passively accepted and followed other bodies without critically examining the information, thereby perpetuating a false consensus. Assessing the extent to which the CMOH Order 16-2020 contributed to this false consensus is a complex task, as it likely played a significant role in shaping the Colleges' decisions and actions.

Requests for Disclosure

The Task Force requested disclosure of pandemic-related data from the Colleges. Specifically, we requested disclosure of the following classes of information:

- All actions (policies, adapted policies, etc.) from January 2020 to present, related to the COVID-19 pandemic;
- Meeting notes minutes for the above actions;
- Supporting documents, i.e. such as studies/data evaluated, which informed the College of Acupuncturists of Alberta's position on prevention options (including masking and vaccinations); and
- Methodology used to monitor developments in COVID-19 prevention and assess the validity of those options.

As of the June 30, 2024, draft of this report, only 5 of the 29 Colleges provided a response to the above request.

One College disclosed information implying that the office of the CMOH did exert significant influence on COVID-19 response guidelines. From that College's redacted meeting minutes "the College developed Guidelines for re-opening which were posted online and have been forwarded for review by the Chief Medical Officer of Health's office. The College has received feedback and has re-submitted a revised document." Their briefing outlined that "The College will continue to follow guidance from the Chief Medical Officer of Health."

Overall, the disclosures matched what the Task Force identified from our review of publicly available information; The Colleges reported to the Task Force that their Health Emergency Response Communications were adapted for the most part from the same overlapping sources.

Also consistent with our findings from publicly available communications, the Colleges did not report to the Task Force any in-depth internal independent review of data or sources.

Communication Framing

The communications contained content which was framed in ways to suggest consensus on various aspects of the COVID-19 response. For example, communications made definitive statements such as, "masking is effective", without considering factors such as types of masks, use considerations, settings applicable, or other nuances. Others framed their communications to denigrate alternative therapeutics without citing evidence for their claims. When framing statements in such a way to assume consensus or scientific conclusion, many of the assertions were not referenced. In a FAQ from the College of Registered Nurses of Alberta, there were numerous assumptions which were presented in such a way to imply a consensus, leading the reader to believe that the statements were conclusive.[54]

Recommendations and Questions for Further Inquiry

To mitigate the risk of perpetuating narrow and potentially flawed health strategies, it is crucial to integrate the following recommendations into the communication frameworks of healthcare regulatory bodies.

1. Establish clear guidelines and procedures for evaluating the quality, relevance, and credibility of data sources and references used in public communications. This should include independent review and assessment by the Colleges, rather than simply relying on external sources.
2. Require Colleges to disclose their methodology, data sources, and decision-making processes related to public communications. This will help to promote transparency and accountability, as well as enable stakeholders to better understand the basis for regulatory decisions.
3. Encourage and support the consideration of multiple perspectives and sources of information, rather than relying on a narrow range of references. This will help to ensure that a broad range of ideas and approaches are considered, and that potential harms and limitations are not overlooked.

4. Regularly evaluate and improve the Colleges' communication processes and materials, including ongoing assessments of the accuracy, efficacy, and relevance of the information provided.
5. Establish clear guidelines for public communications, including the need for accuracy, transparency, and the provision of sufficient context and information. This should include guidance on the use of language and framing that avoids misleading or overly simplistic statements.
6. Establish a tiered review system for Colleges communications that distinguishes between low, medium, and high-impact or sensitive communications. Low-impact communications would be reviewed internally by the College, while medium-impact communications would be reviewed by a designated committee appointed by the College. High-impact or sensitive communications would be reviewed by a 3-person committee appointed by the Minister of Health to assess the nature and implications of the proposed communication. The Minister should have the final authority to approve or reject the proposed communication before its publication.
7. Establish clear guidelines and procedures for evaluating the quality, relevance, and credibility of data sources and references used in public communications. This should include independent review and assessment by the Colleges, rather than simply relying on external sources.
8. Strengthen the regulatory framework to ensure that Colleges maintain their independence and are not unduly influenced by external entities or directives. This should include regular evaluations of the Colleges' decision-making processes and the provision of adequate resources to support independent thinking and analysis.
9. Avoid using threats and disciplinary actions against regulated professionals who challenge or question the direction set by the Colleges. This will help to foster a culture of open communication and critical thinking to ensure that diverse perspectives are considered.
10. Encourage and facilitate the inclusion of a dissenting or critical voice in the decision-making process of regulatory bodies and professional associations. This can be

achieved by setting aside a designated time and space for alternative perspectives to be presented and debated, ensuring that all members are aware of the importance of considering opposing views.

By integrating these recommendations into the communication frameworks of healthcare regulatory bodies, Alberta can enhance the adaptability and effectiveness of healthcare delivery during emergencies, thus maintaining the integrity of public health responses.

External Influence on Regulatory Bodies

During the course of the data review, the Task Force identified potential sources of external influence on the College, with a few being particularly notable. As it is naïve to believe that human and corporate incentives do not affect outcomes both intentionally and unintentionally, a more pertinent question is to what extent incentives affected outcomes. Although the effects of incentives may be complicated and impractical to delineate in detail, the concerning questions that arise are noteworthy. For this reason, the section below outlines examples of external entity connection.

Membership with Non-Regulated Federations

The Colleges are members of the Alberta Federation of Regulated Health Professionals ("AFRHP"), an external organization which is not governed by the HPA, with multiple potential conflicts of interest.[55] The following points and questions highlight concerns.

- The AFRHP is not governed under the HPA, therefore not accountable under the relevant legislation.
- The AFRHP does not have a mandate from Albertans to consult as experts (a title they self-declare) to the Colleges.
- The AFRHP has connections to external private corporations with financial incentives.
- AFRHP annual reports are no longer posted online and archived websites do not allow access to the information.
- Information regarding funding is unavailable and not transparent.

Alberta's Medical Regulatory Body, the CPSA, is a member of FMRAC, the Federation of Medical Regulatory Authorities of Canada.[56] Similar to the AFRHP, FMRAC is another entity which is not governed by the HPA. Many of the concerns listed above are relevant to the connection between the CPSA and FMRAC. Further inquiry is needed to assess this body's degree of influence on the CPSA, and whether it affects the CPSA's ability to fulfill its mandate independently.

External Entity Connection

Web archives reveal that AFRHP is closely connected to "19 to Zero", a private entity that appears to receive funding from many corporations, including pharmaceutical companies, with concerning conflicts of interest.[57] This organization was launched in August of 2020 by Dr. Jia Hu, Public Health Physician and Clinical Assistant Professor at University of Calgary and Chair of 19 To Zero. This organization declares that its core team is made up of physicians, public health researchers, behavioural economists, and creative professionals, supported by a wide partner network. In addition, 19 to Zero was directly referenced in College communications.

Discussion and Recommendations Regarding External Influence

The Task Force's analysis has revealed significant concerns regarding the influence of external entities on the Colleges. Notably, the involvement of the AFRHP, an organization external to the mandate of the HPA, raises critical questions about the potential influence of it and its partners on Colleges. AFRHP's connections with private corporations and other entities that potentially have financial interests further complicate the landscape, suggesting a multi-tiered network of influence that could affect the impartiality and effectiveness of healthcare regulation in Alberta. Given the lack of transparency in the AFRHP's operations and its apparent influence on the Colleges, there is a compelling need to address these concerns to preserve the integrity of healthcare governance under the HPA. It is essential to ensure that regulatory decisions are made based on unbiased and rigorously vetted data, free from undue external influence.

Recommendations for College Associations to Enhance Transparency and Accountability

The Task Force suggest further inquiry into the following:

1. To whom is the AFRHP accountable?
2. What authority does the AFRHP hold over its members?
3. To what extent does this reflect a complex network of influence that obfuscates the primary data sources and allows for indirect multi-tiered influence propagation?
4. Should the Colleges be connected to external organizations which can exert influence without transparency of relationships, incentives, funding, biases, or conflicts of interest?

Initial Task Force Recommendations:

1. The Colleges should develop and implement clear guidelines regarding their associations with external organizations like the AFRHP. These guidelines should outline the criteria for membership in external entities, the nature of permissible interactions, and the mechanisms for transparency and accountability in these relationships.
2. There should be mandatory transparency regarding the nature of relationships and financial transactions between the Colleges and any external bodies. This includes a requirement for annual disclosures of conflicts of interest and financial audits that are publicly accessible.
3. Establish an independent oversight committee tasked with monitoring and reviewing the interactions between the Colleges and external entities. This committee should have the authority to investigate potential conflicts of interest and influence, ensuring compliance with the HPA.
4. Increase public involvement in the regulatory process by establishing forums and consultation processes that allow stakeholders, including the public and healthcare professionals, to provide input on the governance and oversight of the Colleges.
5. Initiate a comprehensive review of the AFRHP's role and its impact on the Colleges' governance during COVID-19. Consider legislative or regulatory changes to ensure that entities like the AFRHP and FMRAC, which exert influence over healthcare regulatory bodies, are also bound by standards of transparency and accountability consistent with those required under the HPA.

6. Implement ongoing education and training programs for members of the Colleges on governance, ethical considerations, and management of external influences. This will help ensure that all members are equipped to recognize and mitigate undue influences on their professional and regulatory responsibilities.

By pursuing these questions and implementing these recommendations, the regulatory framework can be strengthened to guard against external influences that could undermine the ethical and professional standards mandated by the HPA.

Disciplinary Actions

Healthcare providers are required to follow the standards and codes set by their respective Colleges. These Colleges hold the authority to both investigate and impose penalties. Thus, they ultimately hold the authority over whether a provider can practice their profession. Throughout the Task Force's data review of communications, Colleges indicated to members that disciplinary actions might be initiated for various actions by regulated members. Many of these investigations remain open; therefore, the complete impact on health professionals is yet to be known. These disciplinary actions shaped the trajectory of the COVID-19 public health emergency response, both for those investigated and those who changed their practice out of fear that they might be targeted by their College. The following is a summary of the Complaint Investigation Process and the Consequences to a regulated member.

Complaint Investigation Process

Section 40.1(1) of the *HPA* outlines that a "complaints director" of a College can "[impose] conditions on a regulated member's practice permit [...]"[58]

Formally, as a part of the Professional Conduct Complaint Process the complaints director "...may conduct, or appoint an investigator to conduct, an investigation."[59] The complaints director holds various powers including the power to "require any person to answer any relevant questions and direct the person to answer the questions under oath, and require any person to give to the investigator any document, substance or thing relevant to the investigation that the person possesses or that is under the control of the person" and "...at

any reasonable time enter and inspect any building where a regulated member provides professional services."[60] Further actions could be taken per Section 63 (3) by applying to "the Court of King's Bench."

A regulated member is subject to the various consequences including imposing conditions on an investigated person's practice permit, or suspension.[61,62]

Potential Consequences to the Health Professional

Consequences that a regulated member may face range from cautions, to permit conditions, to re-education, to permanent suspension or cancellation of their practice permit.[63] Significant monetary penalties may also be incurred.

Disciplinary actions, including warnings and complaint investigations, and the effects of disciplinary actions by Colleges on the pandemic health response trajectory are discussed below with relevant background information and context.

Pre-Existing Health Regulatory Standards and Codes

The relevance of pre-existing health regulatory body professional standards and codes of ethics, as stipulated by the HPA, cannot be overstated. The adoption of these standards and codes requires specific due process as prescribed by the Act.[64]

While each health profession has its own specific standards of practice and code of ethics, there are large areas of overlap resulting in similar, if not identical, standards and codes. The Task Force opted to focus on specific sections relevant to new or amended standards and codes implemented during the COVID-19 public health emergency.

1. CPSA Standard on Ethics and Professionalism
2. CPSA Standard on Informed Consent
3. CPSA Standard on Practicing Outside of Established Conventional Medicine

CPSA Standard on Ethics and Professionalism[65]

CPSA has a standard on Ethics and Professionalism, whereby "A regulated member must comply with the CMA Code of Ethics & Professionalism adopted by the College in accordance with section 133 of the *Health Professions Act* and the College bylaws."[66]

The Code of Ethics declares that physicians enhance trustworthiness in the profession by striving to uphold the following interdependent virtues, including:

Virtues exemplified by the ethical physician

1. **Honesty**: An honest physician is forthright, respects the truth, and does their best to seek, preserve, and communicate that truth sensitively and respectfully.

Contradiction/Inconsistency

During the Public Health Emergency Response, the CPSA threatened and initiated disciplinary actions towards physicians for various reasons, including communicating peer-reviewed scientific evidence which contradicted the prevailing public health narrative.

This created an environment where physicians were forced to comply, thereby interfering with their ability to be honest with their patients. This may have damaged the relationship between physicians and patients and may have endangered the health of Albertans.

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2. **Humility**: A humble physician acknowledges and is cautious not to overstep the limits of their knowledge and skills or the limits of medicine, seeks advice and support from colleagues in challenging circumstances, and recognizes the patient's knowledge of their own circumstances.

Contradiction/Inconsistency

The CPSA failed to exercise humility in acknowledging that pharmaceutical and non-pharmaceutical interventions could cause harm to patients, and inappropriately restricted physicians from exercising individual clinical assessments for mask and vaccine exemptions.

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3. **Prudence**: A prudent physician uses clinical and moral reasoning and judgement, considers all relevant knowledge and circumstances, and makes decisions carefully, in good conscience, and with due regard for principles of exemplary medical care.

Contradiction/Inconsistency

The CPSA implemented policies (e.g., restrictions on prescriptions of off-label pharmaceuticals, restrictions on granting exemptions for masks and vaccines after thorough medical assessment, and mandating within their own organization a novel pharmaceutical product without appropriate long-term safety data) that prevented physicians from exercising the actions defined above for a prudent physician.

Fundamental Commitments of the Medical Profession

1. **Commitment to the well-being of the patient**:

   "Consider first the well-being of the patient; always act to benefit the patient and promote the good of the patient. Provide appropriate care and management across the care continuum. Take all reasonable steps to prevent or minimize harm to the patient; Disclose to the patient if there is a risk of harm or if harm has occurred. Recognize the balance of potential benefits and harms associated with any medical act; act to bring about a positive balance of benefits over harms."

Contradiction/Inconsistency

Fulfilling the commitment to the well-being of patients requires physicians to perform clinical assessments and determine individualized care plans. Overarching guidelines, except in rare circumstances, should not be imposed with such specific detail as to interfere with or restrict individual care plans. This includes treatments and exemptions to treatments or interventions.

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2. **Commitment to respect for persons**:

   "Always treat the patient with dignity and respect the equal and intrinsic worth of all persons. Always respect the autonomy of the patient. Never exploit the patient for personal advantage. Never participate in or support practices that violate basic human rights."

Contradiction/Inconsistency

In requesting exemptions from mandated pharmaceutical therapies (e.g., novel injections), patients explicitly express their medical autonomy. The CPSA interfered with physicians' ability to abide by this commitment.

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3. **Commitment to professional integrity and competence**:

   "Practice medicine competently, safely, and with integrity; avoid any influence that could undermine your professional integrity. Develop and advance your professional knowledge, skills, and competencies through lifelong learning."

Contradiction/Inconsistency

Pursuant to the commitment to professional integrity and competence, physicians sought to advance their knowledge and competencies by considering emerging data and global publications on COVID-19. The CPSA discouraged this development of knowledge, skills and competencies when they admonished physicians for considering data and evidence the College deemed unacceptable.

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4. **Commitment to professional excellence**:

   "Contribute to the development and innovation in medicine through clinical practice, research, teaching, mentorship, leadership, quality improvement, administration, or advocacy on behalf of the profession or the public. Participate in establishing and maintaining professional standards and engage in processes that support the institutions involved in the regulation of the profession. Cultivate collaborative and respectful relationships with physicians and learners in all areas of medicine and with other colleagues and partners in health care."

Contradiction/Inconsistency

The CPSA prevented physicians from developing innovation in medicine through clinical practice when physicians were prevented from implementing individualized care plans including the use of off-label medications. Of note, many of these medications have since been shown to have favorable risk- benefit profiles.

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5. **Commitment to inquiry and reflection**:

   "Value and foster individual and collective inquiry and reflection to further medical science and to facilitate ethical decision-making. Foster curiosity and exploration to further your personal and professional development and insight; be open to new knowledge, technologies, ways of practicing, and learning from others."

Contradiction/Inconsistency

Physicians who asked questions and welcomed scientific debate were threatened with complaint investigations, suspensions, and license removals. This is a clear contradiction to the above expected commitment.

Professional Responsibilities

The CMA Code of Ethics and Professionalism further provides a list of 44 Professional Responsibilities. The Task Force considers many of these relevant to the practice of medicine during the Covid-19 public health emergency.

The following selected excerpts are reproduced below:

- "The physician owes a duty of loyalty to protect and further the patient's best interests and goals of care by using the physician's expertise, knowledge, and prudent clinical judgment."

- "Act according to your conscience and respect differences of conscience among your colleagues; however, meet your duty of non-abandonment to the patient by always acknowledging and responding to the patient's medical concerns and requests whatever your moral commitments may be."
- "Inform the patient when your moral commitments may influence your recommendation concerning provision of, or practice of any medical procedure or intervention as it pertains to the patient's needs or requests."
- "Recommend evidence-informed treatment options; recognize that inappropriate use or overuse of treatments or resources can lead to ineffective, and at times harmful, patient care and seek to avoid or mitigate this."
- "Medical Decision making is ideally a deliberative process that engages the patient in shared decision-making and is informed by the patient's experience and values and the physician's clinical judgment. This deliberation involves discussion with the patient and, with consent, others central to the patient's care (families, caregivers, other health professionals) to support patient-centered care."
- "In the process of shared decision-making: Empower the patient to make informed decisions regarding their health by communicating with and helping the patient (or, where appropriate, their substitute decision-maker) navigate reasonable therapeutic options to determine the best course of action consistent with their goals of care; communicate with and help the patient assess material risks and benefits before consenting to any treatment or intervention."
- "Respect the decisions of the competent patient to accept or reject any recommended assessment, treatment, or plan of care."
- "Fulfill your duty of confidentiality to the patient by keeping identifiable patient information confidential; collecting, using, and disclosing only as much health information as necessary to benefit the patient; and sharing information only to benefit the patient and within the patient's circle of care."
- "Recognize that conflicts of interest may arise as a result of competing roles (such as financial, clinical, research, organizational, administrative, or leadership)."

- "Contribute, individually and in collaboration with others, to improving health care services and delivery to address systemic issues that affect the health of the patient and of populations, with particular attention to disadvantaged, vulnerable, or underserved communities."

Task Force Commentary

There is universal consensus that the COVID-19 public health emergency was complex and multi-faceted, from both a health professions and regulatory body perspective. The above 'Professional Responsibilities' are longstanding, well-established, and universally accepted. These responsibilities should not be ignored in a future pandemic or health emergency event. Elaborating on every aspect of how the College's actions contradicted physicians' professional responsibilities is beyond the scope of this Task Force. However, we did conclude these contradictions deserve mention given how they affected the trajectory of Alberta's COVID-19 response.

1. How is a physician to exercise their duty of loyalty to protect and further their patient's best interests and goals of care when restrictions are placed on individualized care, with threats of disciplinary action for exercising sincere clinical judgment?
2. If a physician has differing beliefs regarding moral commitments to a pharmaceutical or non-pharmaceutical intervention, to what extent is there abandonment of patients and their medical concerns?
3. Did physicians consider emerging evidence of harm regarding pharmaceutical and non-pharmaceutical interventions, and did they seek to avoid or mitigate that harm?
4. Given that medical decision-making is an ideally deliberative process that engages the patient in shared decision-making, and is informed by the patient's experience and values and the physician's clinical judgment, what rationale do Colleges have for interfering with this process?
5. As it pertains to shared decision-making, actions consistent with goals of care, and risk-benefit assessment, what basis did the Colleges have for interfering with the following principle: "In the process of shared decision-making: Empower the patient

to make informed decisions regarding their health by communicating with and helping the patient (or, where appropriate, their substitute decision-maker) navigate reasonable therapeutic options to determine the best course of action consistent with their goals of care; communicate with and help the patient assess material risks and benefits before consenting to any treatment or intervention."?

6. Given the restrictions are placed on individualized care, and issues related to disciplinary action, how do the Colleges justify interfering with the principle which emphasizes to "Respect the decisions of the competent patient to accept or reject any recommended assessment, treatment, or plan of care"?
7. By limiting vaccine and mask exemptions, did the College force physicians to violate their duty of confidentiality, as stated here: "Fulfill your duty of confidentiality to the patient by keeping identifiable patient information confidential; collecting, using, and disclosing only as much health information as necessary to benefit the patient; and sharing information only to benefit the patient and within the patient's circle of care"?
8. Given the connection of the AFRHP to entities with corporate sponsors, including pharmaceutical corporations, how did the Colleges fail to "Recognize that conflicts of interest may arise as a result of competing roles (such as financial, clinical, research, organizational, administrative, or leadership)"?
9. With the clear age-stratification regarding the risk of COVID-19, and children being vulnerable to harms from pharmaceutical and non-pharmaceutical interventions, did the Colleges prevent physicians from upholding their professional responsibility to "contribute, individually and in collaboration with others, to improving health care services and delivery to address systemic issues that affect the health of the patient and of populations, with particular attention to disadvantaged, vulnerable, or underserved communities"?

CPSA Standard on Informed Consent[67]

CPSA has a standard on Informed Consent whereby:

1. A regulated member must obtain a patient's informed consent prior to an examination, assessment, treatment or procedure.

2. A regulated member obtaining informed consent from a patient, or the patient's legal guardian or substitute decision maker must ensure the decision maker:
    (a) is aware of his/her right to withdraw consent at any time;
    (b) is free of undue influence, duress or coercion in making the consent decision;
    (c) receives a proper explanation that includes but is not limited to:

        diagnosis reached; advised interventions and treatments; exact nature and anticipated benefits of the proposed examination, assessment, treatment or procedure; common risks and significant risks; reasonable alternative treatments available, and the associated common risks and significant risks; and natural history of the condition and the consequences of forgoing treatment.

Additional supplemental 'ADVICE TO THE PROFESSION Informed Consent for Adults' outlines:

1. **Voluntary consent**: Patients must be free of compulsion, duress or coercion when consenting to or refusing treatment.
2. **Explicit consent**: While the patient's consent may be implied, explicit consent is necessary, e.g. when injecting vaccines or other drugs.[68]

The CPSA additionally points to the Canadian Medical Protection Agency's 'Consent: A guide for Canadian Physicians', affirming that:

> "it has become a basic accepted principle that "every human being of adult years and of sound mind has the right to determine what shall be done with his or her own body." Clearly physicians may do nothing to or for a patient without valid consent. This principle is applicable not only to surgical operations but also to all forms of medical treatment and to diagnostic procedures that involve intentional interference with the person.
>
> For consent to serve as a defence to allegations of either negligence or assault and battery, it must meet certain requirements. The consent must have been voluntary, the patient must have had the capacity to consent, and the patient must have been

> properly informed. Patients must always be free to consent to or refuse treatment and be free of any suggestion of duress or coercion. Consent obtained under any suggestion of compulsion either by the actions or words of the physician or others may be no consent at all and therefore may be successfully repudiated."[69]

During the COVID-19 public health emergency, regulatory bodies, including the CPSA, exhibited significant failures in supporting physicians' ability to adhere to the standard of informed consent.

This failure is evident in the coercive measures employed to ensure the uptake of novel pharmaceuticals, including vaccines, which undermined the principles of voluntary and explicit consent. Physicians were pressured to conform with mandates that did not allow for individualized patient assessments or the honouring of patient autonomy in medical decision-making. This coercion directly contravenes the ethical requirement that consent be free of undue influence, duress, or coercion, as stipulated in the CPSA standards and the Canadian Medical Protection Agency's guidelines.

The Colleges placed physicians in a position where they were unable to fully inform patients of the risks, benefits, and alternatives to novel medical interventions, thus compromising the integrity of informed consent.

If physicians were to deviate from the imposed guidelines, they were threatened with disciplinary action, including investigations, suspensions, and license removals. This not only hindered physicians' ability to respect patients' rights to accept or reject treatments but also imposed the will of regulatory bodies over the professional judgment and clinical expertise of individual practitioners. Consequently, the CPSA's policies during this period represented a clear contradiction to the established professional and ethical standards, ultimately compromising the trust and efficacy of the physician-patient relationship. It could even be argued that the Colleges interfered in the patient-physician relationship to the point of the College inappropriately influencing patient treatment.

CPSA Standard on Practicing Outside of Established Conventional Medicine[70]

The CPSA Standard outlines that a regulated member who offers a therapy that is outside of conventional medicine to a patient must practice in a manner that is informed by current best-available medical evidence and upholds their professional, ethical, and legal obligations; always act within the scope of their practice based on their qualifications, skill, knowledge, and level of competence; and respect the autonomy of the patient in making decisions about their health care, including choosing a therapy that is outside of conventional medicine instead of, or in addition to, conventional medicine.

All patient assessments and diagnoses must be consistent with the standards of conventional medicine and be informed by current best-available evidence. A regulated member must: offer a conventional medical approach before offering any therapy outside of conventional medicine; conduct a clinical assessment of the patient that includes taking an appropriate patient history and performing/ordering any necessary diagnostic tests, investigations or procedures that are required to establish a conventional diagnosis; offer therapeutic options that are informed by current best-available evidence prior to offering therapies outside of established conventional medicine; and counsel the patient, to the best of their ability and knowledge, about the risks and benefits of any diagnostic testing/investigation or therapeutic procedure so the patient can give informed consent.

“Complementary and alternative medicine” (hereafter referred to as “CAM”) refers to healthcare approaches developed outside of mainstream or conventional medicine that are used for specific conditions or overall well-being."

- “Complementary” refers to a non-conventional practice used in conjunction with mainstream conventional medicine.
- “Alternative” refers to a non-conventional complementary therapy used in the absence of mainstream conventional medicine.
- “Emerging therapies” refers to therapies developed within mainstream medicine with support from clinical research but currently lacking in rigorous, peer-reviewed evidence to support their use.

Contradiction/Inconsistency

The CPSA cited this standard when inappropriately interfering with individualized patient care and intruding into the sanctity of the physician-patient relationship during the response to COVID-19. The standard outlines that "Practicing outside of established conventional medicine includes practices that are not included in widely accepted clinical practice guidelines and can include complementary and alternative medicine and emerging therapies."

The Task Force considers the premise that there existed "widely accepted clinical practice guidelines" for the treatment of COVID-19 viral infection to be unreasonable given that both the pathogen was novel, and the viral evolutionary process resulted in variants. Therefore, it was not possible for there to have been any "established conventional medicine practice."

Even if it were to be accepted that guidelines for or against COVID-19 treatments were "established" and "widely accepted", there remain several additional concerns.

Off-label use is a common practice in medicine, as many medications are shown to have beneficial effects for conditions that are not initially identified at the time of initial approval for use.[71] Thus, it does not appear reasonable to describe the off-label use of a well-established pharmaceutical as an example of "healthcare approaches developed outside of mainstream or conventional medicine" nor an "alternative" referring to a "non-conventional complementary therapy."

The closest description might be to consider Ivermectin therapy as "emerging therapies" given the clinical research, which was ongoing worldwide during the COVID-19 pandemic, as highlighted in other sections of this report. The CPSA's "ADVICE TO THE PROFESSION - Practicing Outside Established Conventional Medicine" states that the therapy being considered for use should be within the physician's usual field of expertise, and there are peers and evidence to support its use for a clinical indication.[72] If this is the case, physicians should not have been prevented from providing personal and individualized care to their patients, as the practice can fall within the confines of the pre-existing standard and CPSA

advice. The CPSA directing physicians not to prescribe a specific medication is unprecedented. There are few "scientific conclusions", thus it is not possible to reach one regarding an emerging therapy. Furthermore, all therapies should be considered at the individual level, based on a patient's personal health history and the intricacies of their condition, such that a benefit-risk calculation can be explored within the sanctity of the physician-patient relationship. Moreover, even if that risk-benefit calculation result ranged from uncertain to harmful, there remains the requirement to "respect the autonomy of the patient in making decisions about their health care, including choosing a therapy that is outside of conventional medicine instead of, or in addition to, conventional medicine."

Warnings and Complaint Investigations

The Task Force reviewed data surrounding 'Warnings, Complaints, and Discipline Reports', which shed light on how regulatory standards were enforced during the pandemic, noting that many cases remain in progress as the complaint investigations are not yet resolved. As before, the Task Force highlights issues relating to the physicians and the CPSA given their impact on the trajectory of Alberta's COVID-19 response. The CPSA frequently references both the HPA and the *Canadian Medical Association Code of Ethics and Professionalism* (which the CPSA has adopted).[73]

Below are excerpts from a September 21, 2021, online CBC News article, including quotes from the CPSA Registrar and Council Members, with clear negative framing towards Alberta physicians who were exercising caution regarding novel therapeutics, respecting the principles of medical autonomy and informed consent, and raising concerns over the risks and harms of non-pharmaceutical interventions.[74]

Physicians and their actions were negatively framed in this article as:

- "undermining" the response to the pandemic.
- "…a source of incredible frustration…"
- "intransigent doctors."

An expert medical determination of a valid vaccine exemption, it was reported, might be considered “absolutely inappropriate” as physicians were “handing out vaccine exemptions” in such a way to “skirt the rules”, or were “practicing inappropriately.”

The “college registrar Dr. Scott McLeod said the CPSA has already told doctors spreading misinformation that their behaviour is considered unprofessional.”

Physicians exercising their own right to medical autonomy and informed consent were “defiant” and that “complaints against them will be prioritized” with the false assertion that they “are putting patients in harm’s way by refusing to get vaccinated or wear protective equipment.”

The article suggested forthcoming threatening actions by the CPSA:

- “Regulators to get tough with doctors…”
- “College of Physicians and Surgeons of Alberta to crack down on anti-vax doctors.”
- “I think we should take people to task for it.”
- “Another Councilor, Dr. Ian Walker, pushed strongly for a warning to intransigent doctors that they will face sanctions.”
- “"Nobody wants to wind up on that sanction list," Walker said. "That is permanent and stays with you for your entire career. "But has there even been anything that would warrant that more than some of this behaviour that we're seeing right now?”. He said, "You think about some of the other things that have landed people up on that list, and they're actually quite a lot less significant in my humble opinion than what we are talking about here."
- “Even though we do take action, we need to make it incredibly clear, and councillors wanted it to be very clear, they were in support of much stronger actions in this area," McLeod said.”
- “Complaints against doctors who actively undermine efforts to combat the COVID-19 pandemic will be prioritized, says the College of Physicians and Surgeons of Alberta”

- "The College of Physicians and Surgeons of Alberta has lost patience with doctors who have actively undermined the province's response…"
- "…council members unanimously supported issuing a strongly worded warning letter…"
- ""I think that person can expect to have a complaint filed against them and I think it is likely that complaint would be followed by formal hearing," McLeod said, adding that is now happening in other provinces, which eventually will make it easier to sanction doctors through the college's hearing process in Alberta."
- Unsubstantiated claims that physicians were "potentially putting the public at risk" which should result in complaint reports. "The province's doctors, and the public, will be encouraged to report other doctors whose practices or social media posts are potentially putting the public at risk."
- ""I would also recommend that if any member of the public sees this type of practice behaviour going on, report that to us as well so that we can take action."
- "McLeod said the college has to get tough now…"

Furthermore, The CPSA Registrar implied that "unvaccinated people" "caused the crisis in Alberta's health-care system."

CPSA Communication Example

On October 14, 2021, the CPSA issued a communication on their website titled: "Further actions to address the spread of COVID-19 misinformation by physicians" which outlined their guidance and expectations surrounding spreading COVID-19 misinformation and inappropriate prescribing and issuance of vaccine and mask exemptions by physicians.[75] The CPSA refers to the Canadian Medical Association, the CPSA, and provincial public health as guidance for practice. The communication in full is reproduced below.

> "CPSA is very concerned by the increase in physicians reportedly violating CPSA's Standards of Practice, the Canadian Medical Association's Code of Ethics and Professionalism, and provincial public health measures in their handling of COVID-

19. Because we have seen a significant increase in the number of concerns submitted, CPSA will be taking further action to address the spread of COVID-19 misinformation, inappropriate prescribing and inappropriate issuance of vaccine and mask exemptions by physicians.

CPSA recognizes that most physicians are practicing safe, evidence-based medicine, following public health measures and doing right by their patients. For this, we thank you and are grateful for your efforts.

While these situations are expected to be rare, Part 3.1 of the *Health Professions Act* provides CPSA the authority to conduct unannounced on-site clinic inspections to confirm adherence to CPSA's Standards of Practice when certain thresholds are reportedly breached. An on-site inspection may occur when—but is not limited to—allegations arise of inappropriate issuance of COVID-19 vaccine and/or mask exemption letters, prescribing inappropriate interventions, such as ivermectin, for the prevention and treatment of COVID-19 and spreading of misinformation related to COVID-19.

Inspection reports will determine next steps, which may include referral to CPSA's Continuing Competence team, or to the Professional Conduct department in cases where allegations of unprofessional conduct are supported. Should a physician refuse an on-site inspection, CPSA has the authority to apply to the Court of Queen's Bench for a court order to move forward with the inspection.

In situations where blatant evidence is present—such as video recordings or screen shots of social media messages where physicians publicly attack other physicians and health professionals or egregiously spread misinformation—physicians will be directly referred to Professional Conduct.

We understand this further action may be a cause for concern for some physicians who are practicing good, safe and evidence-based medicine. This notice is not to be interpreted a moratorium on the issuance of vaccine and mask exemptions, rather, it is a reminder there must be a justifiable clinical reason for mask and/or vaccine

> exemptions, which should be well and clearly document in the patient chart. Physicians know their patients best and we trust in your clinical judgment to make the right, evidence-based decisions for your patients.
>
> If you have questions or are looking for guidance, or if you wish to raise a concern regarding COVID-19, please contact covid19@cpsa.ab.ca."

The publication further noted:

> "Physicians are not permitted to prescribe ivermectin as a preventive measure against COVID-19. Health Canada has not approved ivermectin for use in preventing or treating COVID-19, and CPSA supports this position."

Based on the CPSA website reporting, there were 22 complaints related to COVID-19 in 2021, and 29 complaints, in 2022.[76]

Deputy Registrar Susan Ulan published the following in the February Messenger 2022, Medical Matters:

> "CPSA has conducted nine unannounced inspections of physician practices in the Edmonton, Calgary, Central and South Zones. Inspections primarily involve a review of patient charts and are conducted by two CPSA inspectors: the Infection Prevention & Control Program Manager and a physician.
>
> To date, five physicians have signed voluntary agreements to no longer offer exemptions from COVID-19 vaccination or masking requirements, or to prescribe or recommend off-label use of drugs such as ivermectin to treat or prevent COVID-19. Physicians who do not voluntarily agree to these conditions are referred by the Deputy Registrar (me) to CPSA's Complaints Director to determine whether there is evidence to support unprofessional conduct."[77]

There are examples of threats of unannounced inspections from the other Colleges as well. For example, the Alberta College of Denturists:

> "OHS officers conduct inspections to determine if Alberta work sites comply with provincial legislation and enforces compliance with provincial laws through these inspections as well as orders, penalties, violation tickets and other measures."[78]

Effects of College Disciplinary Actions on Alberta's COVID-19 Response

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Disciplinary actions undertaken by various Colleges during COVID-19 profoundly influenced the trajectory of the healthcare response, impacting not only those directly under investigation but also the broader community of healthcare providers.

These actions, while purportedly intended to uphold professional standards, often obstructed healthcare providers from performing their duties in good faith.

College actions led to an environment where health professionals were either directly restricted in their practices or chose to alter their approaches due to potential disciplinary scrutiny.

The chilling effect was pervasive, instilling a climate of fear and caution that deterred providers from utilizing their full expertise during critical times, and seeking the optimal path forward.

The optimal path forward requires open scientific questioning and debate. Other Colleges published messaging which appears to have had the intention of instilling fear in their members. (E.g., ACCLXT Guidance with FAQ's: "a chiropractor in Nova Scotia lost her license to practice and was assessed $100,000 in fines due to her posting on social media about disproved and unfounded views on vaccination.")[79]

Moreover, the data underpinning the communications that informed these disciplinary actions was notably one-sided and lacked the rigorous due

> *diligence that should accompany measures with such significant implications.*

The Task Force's review indicated that College communications often framed emerging public health measures as having the imprimatur of scientific consensus when, in fact, they were not universally endorsed within the scientific community. Many statements were presented without adequate referencing, and where references were provided, there was a noticeable overlap, suggesting a narrow scope of scientific inquiry, as previously outlined our data review of communications. This reliance on a limited set of references and sources, potentially introduced biases and diminished the capacity to critically assess important viewpoints or evolving evidence.

Communications, formed by way of a foundationally flawed developmental process, were then the basis of disciplinary actions. These communications (i.e., “guidances”) were neither codified as "standards" nor "codes of ethics" as per the HPA, nor were they reflective of established norms. Furthermore, it appears that the Colleges deemed any information that differed from what they determined to be scientific consensus as “misinformation”, even if the information was or could be accurate. One such ‘Advice to the Profession – Professionalism in Public Forums’ communication provides some defense of diversity of opinion, but nevertheless contains various internal inconsistencies.[80]

> *Notably, the CPSA suggested that COVID-19 public health orders were infallible, and that “providing advice or behaving in such a manner that encourages the public to act contrary to public health orders or recommendations is not acceptable, as it puts all members of the public at risk.”*

Such actions not only stifled the professional autonomy necessary for an adaptive response during the health crisis but also led to the adoption of practices that may not have been in the best interests of public health or patient care.

Furthermore, having become aware that many qualified expert physicians, the vast majority without prior College complaints, had concerns with the scientific rigor of the communications, for what reasons did the Colleges choose to take disciplinary actions against physicians rather than independently assess the criticisms and concerns raised?

These actions by Colleges may indicate a systemic issue with the regulatory framework, where compliance with emerging guidance, irrespective of its evidential basis, was prioritized over collaborative review and dialogue.

This approach may have compromised the principles of professional independence and evidence-based practice, essential for maintaining trust and efficacy in the healthcare system during a public health crisis.

The above approach was not limited to the CPSA and included many other health profession Colleges. The Alberta College of Speech Language Pathologists and Audiologists ("ACSLPA"), for instance, published a message that their "Members are expected to comply with ACSLPA advisory statements. If you choose not to follow ACSLPA's requirements, a complaint could be filed against you. Further to this, there may be implications for your professional liability insurance coverage and/or outcomes of a hearing."[81]

It is crucial to explore how these "guidances", while presented as authoritative directives, contradicted the established standards and codes of conduct discussed earlier in this report, further complicating the regulatory landscape during a time when clarity and flexibility were paramount.

This examination underscores the need for a more decentralized, evidence-based approach to formulating public health directives, ensuring they are grounded in robust multidisciplinary scientific rather than constrained by rigid interpretation of emerging data.

This becomes especially relevant if Colleges attempt to position themselves as arbiters of truth, issue directive communications and proceed with disciplinary actions.

Overall, it appears that disciplinary actions threatened and undertaken in relation to COVID-19 were predicated on communications with 1) concerning source overlap; and 2) subjective, contradictory, and inconsistent interpretations of pre-exiting standards. A notable example of this is an April 23, 2020, statement made by CPSA Registrar Dr. Scott McLeod:

> "Physicians should not be reluctant to provide care, even when it may be extremely difficult to follow some components of CPSA's Standards of Practice. CPSA will always consider the individual circumstances and context if a complaint arises during the COVID-19 pandemic. In an emergency situation, failure to meet standards is not considered unprofessional conduct if a physician can demonstrate they took all reasonable actions in their service to patients."[82]

The Registrar claimed that the "CPSA will always consider the individual circumstances and context." However, the CPSA's actions regarding communications and disciplinary measures on mask and vaccine exemptions, and off-label therapeutic restrictions, contradicted this statement. Their communications attempted to make it impossible for physicians to consider individual circumstances and context.

In another leading statement, the CPSA Registrar sought to emphasize that 'there are almost no medical conditions that would universally warrant a complete exemption from initial COVID-19 vaccination, implicitly discouraging physicians from exercising nuanced clinical judgement by performing an individual risk and benefit analysis.[83]

Regulators actively sought to intimidate, threaten, and discipline medical professionals during and after the COVID-19 public health emergency

> *response, despite their efforts to provide the best care within the accepted pre-existing standards of their respective professions.*

Examples of these actions include issuing warnings, conducting complaint investigations, and performing unannounced inspections.

> *The Colleges directed members to report colleagues to regulators and actively pursued disciplinary actions against professionals for actions completely within their scope of practice. Most actions for which professionals were pursued by regulators during COVID-19 have now been shown to be defensible.*

Colleges not only failed to ensure the public was protected but negatively affected the trajectory of Alberta's COVID-19 response by actively discouraging, preventing, and weaponizing the decision-making process to account for emerging data, including the identification of harms to Albertans. This environment impacted the trust between healthcare providers and regulatory bodies, with potential long-term consequences for professional autonomy and patient care.

Non-Traditional Therapy

A specific note on disciplinary actions related to non-traditional therapy was identified in Schedule 21:5 of the *Health Professions Act*.

> *"Despite anything in this Act, a regulated member is not guilty of unprofessional conduct or of a lack of competence solely because the regulated member employs a therapy that is non-traditional or departs from the prevailing practices of physicians, surgeons or osteopaths unless it can be demonstrated that the therapy has a safety risk for that patient that is unreasonably greater than that of the traditional or prevailing practices."*

There has been notable discouragement and threats by the Colleges against the use of off-label treatments. This was facilitated through the issuance of "guidance," "advice," and

"statements" which were directed to physicians without undergoing the standard amendment processes such as public comment, feedback, or Council approval.

It may be that a considerable number of physicians were unaware of the protective stipulations outlined in Schedule 21 of the HPA. Consequently, many physicians ceased prescribing out of apprehension of potential disciplinary actions. Those who persisted in such prescriptions faced formal investigations or the looming threat thereof, sometimes amplified by media involvement. This climate of scrutiny likely deterred other physicians from prescribing, even those who were persuaded by emerging evidence that supported such treatments. For physicians entangled in these complaints and investigations, the process itself often served as a punitive measure. It is likely that physicians, overwhelmed by the ordeal, chose to resign and relinquish their practice permits.

It is imperative for physicians still under investigation to be made aware of the provisions in Schedule 21, which crucially shifts the burden of proof to the accuser to demonstrate that a therapy like Ivermectin presents a greater safety risk than the traditional or prevailing practices — a significant challenge given the novel nature of the pathogen and its variants.

COVID-19-Related Disciplinary Decisions

The Task Force takes note that COVID-19 complaint investigations against medical professionals may be ongoing or have been resolved without publication. The following examples of denote disciplinary decisions related to COVID-19:

- CARNA. January 4, 2022. DISCIPLINARY COMPLAINT RESOLUTION AGREEMENT.[84]
- CNDA, October 17, 2022. DECISION OF THE HEARING TRIBUNAL OF THE COLLEGE OF NATUROPATHIC DOCTORS OF ALBERTA.[85]
- CNDA, May 26, 2021. DECISION OF THE HEARING TRIBUNAL OF THE COLLEGE OF NATUROPATHIC DOCTORS OF ALBERTA.[86]
- ACO, undated. DECISION SUMMARY.[87]
- CCA, July 4, 2022. AGREEMENT AND UNDERTAKING.[88]

Recommendations for Protection against Weaponization of Disciplinary Processes

It is imperative to develop strategies to protect healthcare professionals from the weaponization of disciplinary processes. This section outlines recommendations aimed at ensuring disciplinary actions are fair, evidence-based, and conducive to a healthy professional environment that encourages scientific discourse and patient-centered care.

1. **Establish Clear, Evidence-Based Standards**

   ***Codification and Transparency*.** Ensure that all guidelines, advisories, and communications from regulatory bodies are codified following a transparent process that includes public consultation. This will prevent ad-hoc directives that may lack rigorous evidence and clarity.

   ***Periodic Review*.** Implement a system for the periodic review of standards and guidelines to incorporate the latest scientific evidence and address any emerging concerns from the healthcare community.

2. **Decentralize Decision-Making**

   ***Local Committees*.** Form local committees comprising practicing physicians, ethicists, and patient representatives to review complaints and disciplinary actions. This decentralization will ensure decisions are made by those with direct understanding and experience of clinical realities.

   ***Appeal Mechanisms*.** Strengthen appeal mechanisms to allow healthcare professionals to challenge decisions made by regulatory bodies. These mechanisms should be independent and have the authority to overturn or amend decisions based on comprehensive reviews.

3. **Protect Professional Autonomy**

   ***Support for Non-Traditional Therapies*.** Reinforce the protections provided under Schedule 21 of the Health Professions Act. Physicians should be informed and assured that employing non-traditional therapies, when evidence suggests they are safe and potentially beneficial, will not be deemed unprofessional conduct without substantial proof of higher risk of those therapies.

Respect Clinical Judgment. Encourage regulatory bodies to respect physicians' clinical judgment, especially in unprecedented situations like a public health emergency. Guidance should allow flexibility for individualized patient care.

4. **Enhance Scientific Rigor and Diversity**

   Diverse Sources. Regulatory bodies should consider a diverse range of scientific sources and viewpoints when formulating communications to avoid bias and ensure a comprehensive understanding of evolving evidence.

   Independent Reviews. Prior to issuing any disciplinary actions related to emerging therapies or practices, conduct independent reviews by panels of experts not involved in the initial complaint. This will add an additional layer of scrutiny and fairness.

5. **Foster Open Scientific Debate**

   Encourage Dialogue. Create forums and platforms where healthcare professionals can discuss and debate emerging evidence without fear of retribution. Such dialogue is crucial for advancing medical knowledge and improving patient care.

   Whistleblower Protections. Strengthen protections for physicians who raise legitimate concerns about public health measures or emerging therapies. These protections should ensure that whistleblowers are not subjected to retaliatory disciplinary actions

6. **Improve Communication and Education**

   Training Programs. Develop and mandate training programs for regulatory body members on the ethical and professional standards related to disciplinary processes. This training should emphasize the importance of evidence-based practice and the need for due process.

   Transparent Reporting. Ensure that the rationale behind disciplinary actions is transparently reported and communicated to the public and healthcare professionals. This transparency will build trust and accountability.

7. **Safeguards Against Biased or Politically Motivated Disciplinary Actions**

Identification and Consequences. Establish clear criteria for identifying disciplinary actions that are driven by mal-incentives, vexatious intent, bias, or political motivations. Once identified, such actions should be subject to stringent review and possible annulment.

Accountability Measures. Implement accountability measures for individuals or entities that are found to misuse the complaint process. This could include sanctions, fines, or other disciplinary actions against those who initiate complaints with malicious intent.

Protective Legislation. Advocate for protective legislation that shields healthcare professionals from disciplinary actions that are not based on solid evidence or are motivated by external pressures. These reforms should include clear definitions of what constitutes unprofessional conduct and ensure that disciplinary actions are proportionate and justified.

Support Systems. Provide support systems for healthcare professionals who are targeted by such disciplinary actions. This could include legal assistance, counseling, and advocacy services to help them navigate the process and protect their professional integrity.

Training for Reviewers. Develop comprehensive training programs for those involved in the review and adjudication of complaints to recognize and mitigate biases, ensuring a fair and objective process.

The recommendations outlined above aim to create a balanced and fair disciplinary process that protects healthcare professionals and encourages a practice environment rooted in scientific inquiry and patient-centered care. By implementing these strategies, regulatory bodies can maintain high professional standards while fostering a culture of trust, autonomy, and continuous improvement in healthcare.

The Task Force takes note of a recent positive development related to professional discipline where the Alberta Court of Appeal has significantly changed the approach to costs orders in professional discipline cases. In *Jinnah v Alberta Dental Association and College*, 2022 ABCA 336, the Court set aside an order for a dentist to pay $37,500 in investigation and

hearing costs and referred the issue back to be reconsidered using a new framework. The Court described a new "presumption" that "[t]he College should bear the costs associated with the privilege and responsibility of self-regulation unless a registrant has committed serious unprofessional conduct, is a serial offender, has failed to cooperate with investigators, or has engaged in hearing misconduct."[89]

Conclusion and Recommendations

Alberta's health professions regulatory framework is designed to maintain an arm's-length distance from government and stakeholders, while ensuring the public's protection and preventing undue influence over health professionals.

Did regulatory bodies meet the high standards expected of them, to uphold professional integrity and protect public health during a crisis, and ensure the longevity of Alberta's health care system?

For the many reasons outlined in this chapter, regulatory governance failed during the COVID-19 pandemic.

While Alberta's Colleges ostensibly provided regulatory oversight, it was not independent as it followed external directives from the CMOH and did not appear to undergo internal review or due diligence. There is a notable lack of transparency in how Colleges reviewed and validated external data they used, if at all. Merely using recommendations from bodies such as AHS, AH, or Health Canada does not demonstrate that Colleges conducted independent and thorough reviews of the underlying studies and data these recommendations were based on.

This led to a centralizing force that constrained Alberta's COVID-19 response within a narrow range. As a result, measures implemented were inaccurately represented, not as efficacious as claimed, and lacked proper consideration of potential harms. Moreover, the Colleges' inability to consider alternatives outside the 'acceptable' Overton window further limited the scope of the response.

The lack of transparency in how or if the Colleges reviewed and validated the external data they used is concerning.

The absence of detailed descriptions of the methodologies used for data analysis and decision-making in the documents reviewed makes it challenging to assess whether due diligence was adequately performed. For regulatory changes that have significant impacts on public health and professional practices, it is critical that each step of data review and policy formulation be well-documented and publicly accessible to uphold the standards of transparency and accountability.

Threats and disciplinary action further constrained health professionals into a narrow band of COVID-19 responses acceptable to health regulators. This stifled critical thinking and limited the ability of professionals to consider alternative perspectives and approaches. As a result, the potential range of effective solutions was curtailed, and harms not given due consideration.

It appears that Alberta Colleges were not sufficiently independent from the CMOH or provincial government. The Alberta College of Combined Laboratory and X-ray Technologists explicitly admitted this in their communication regarding vaccine hesitancy.[90]

"As vaccinations are established public health practices in preventing infectious disease, we received clear direction from the government regarding the College's role in vaccination promotion and vaccination hesitancy. As our mandate is to protect the public interest, it is the College's responsibility to support public health recommendations and prevent anti-vaccination messaging from being promoted by our Registrants."

This position fails to recognize that novel vaccine technologies may not have the same characteristics as previous "established" practices. It also fails to recognize the possibility that public health recommendations may not be infallible.

The failure to critically assess or openly discuss the limitations and counterpoints within the scientific debate surrounding COVID-19, points to a shortfall in the regulatory standards expected. Without thorough internal review and rigorous analysis of data, these regulatory bodies risked making policies that were too rigid or not adequately tailored to the unique circumstances of individual healthcare providers and their patients.

Overall, the direction provided by many of the Colleges led to a reduction in the proposed range of solutions, without due consideration of harms, and likely resulted in various harms to patients and the public as outlined in this report.

The Task Force found the way COVID-19 emergency response data, information, and messaging were developed and propagated was a critical failure of Alberta's health system and is an ongoing concern.

When a few centralized entities are at risk of capture by special interests, it can result in the implementation of biased policies and measures in response to public health emergencies like COVID-19. The immediate and long-term effects of this institutional capture may go unrecognized and underappreciated.

In review of the COVID-19 Health Emergency Response, it has become increasingly evident that a decentralized approach to decision-making and information dissemination, along with increased transparency and independent review of data, would have been beneficial in preventing the centralization of power and ensuring that diverse perspectives and evidence were considered in shaping public health policies and guidelines.

The over-centralization issue appears to be particularly relevant to Alberta Colleges' COVID-19 communications.

The Task Force recognizes that human progress requires that we learn from our mistakes, and with humility take the necessary steps to improve. This is report is incomplete in that

1. looking back, there remain many areas that require formal inquiry; and
2. looking forward, there are many preliminary recommendations with critical need for exploration.

Many, like the COVID-19 Assembly, were among those early to suggest areas for improvement.[91] Excerpts from their recommendations are applicable to various aspects of the Global Health Emergency Response, including to our own local regulatory body actions. Like their broad assessment, Alberta's Colleges, by stifling scientific debate on the potential harms of non-pharmaceutical interventions, were complicit with "curbing the liberty and essential freedoms of large swaths of the population, many of whom will suffer long term consequences." This should serve as a strong reminder to always "behave with humanity" and that "fear and isolation are killers in themselves." "No one should be barred from a dying parent's bedside," the authors stressed. They asked the "Government to pledge that it will always act with humanity." The Task Force agrees with those who "advocated for a comprehensive public inquiry and balanced public debate. We need to examine every aspect of the response to COVID-19," including the failures of our own regulatory bodies. Their actions affected the trajectory of Alberta's COVID-19 response, impacting various sectors of society, from health to the economy. The Task Force concurs that "we need to hold those responsible for mistakes to account and ensure that they do not happen again, as this will not be the last time we face a threat from an infectious disease. Experts need the freedom to challenge bad policies."

Regulatory bodies should not have the power to stifle scientific inquiry and debate.

Sweden's approach to Covid-19 resulted in better outcomes across many areas. Healthcare provision in Sweden follows a decentralized model, where the primary responsibility rests with the regional councils and, in some instances, local councils or municipal governments. Sweden is geographically divided into 290 municipalities and 21 regional councils. The decentralization of healthcare services is governed by the Swedish *Health and Medical Service Act*.[92] The central government's role is to establish overarching principles, guidelines, and set the political agenda for health and medical care. The National Board of Health and Welfare (Socialstyrelsen) operates as a government agency under the Ministry of Health and Social Affairs. It is tasked with compiling information and developing standards aimed at ensuring optimal health, social welfare, and the delivery of high-quality health and social care services across the entire population. The National Board also regulates licensure and registration.

Sweden's crisis management system is founded on three core principles: Responsibility, Similarity, and Proximity.[93]

1. Responsibility stipulates that the entity or authority accountable during normal circumstances maintains that responsibility during a crisis.
2. Similarity refers to activities during a crisis should ideally mirror those under normal circumstances.
3. Proximity underscores that crises should be managed where they occur, primarily by the most affected and responsible entities, such as municipalities or regions. State intervention occurs only if local resources prove inadequate.

Sweden's constitutional framework prohibits the declaration of a state of emergency, and fundamental civil liberties can only be suspended during times of war. Public health emergencies are governed by ordinary law, rendering it legally impossible to enforce general quarantine or lockdown measures. Politicians in Sweden are unable to usurp the authority of the PHA.[94]

From a broad perspective, the Task Force recommends that to correct the failures of over-centralization, Alberta should closely examine the three core principles of Responsibility, Similarity and Proximity for crisis management.

Preliminary Recommendations

The Task Force's in-depth review of the regulatory framework governing the Colleges in Alberta has led to identification of several areas for improvement. These preliminary recommendations aim to address the shortcomings and failures observed during the COVID-19 public health emergency response.

1. **Decentralize Decision-Making and Information Dissemination:** Empower local committees comprising practicing physicians, ethicists, and patient representatives to review complaints and disciplinary actions. This decentralization will ensure decisions are made by those with direct understanding and experience of clinical realities.
    - Strengthen appeal mechanisms to allow healthcare professionals to challenge decisions made by regulatory bodies. These mechanisms should be independent and have the authority to overturn or amend decisions based on comprehensive reviews.
2. **Enhance Transparency and Accountability:** Codify and make publicly available the process for developing guidelines, advisories, and communications by regulatory bodies. This transparency will prevent ad-hoc directives and ensure that regulatory bodies are accountable for their actions.
    - Implement a system for the periodic review of standards and guidelines to incorporate the latest scientific evidence and address emerging concerns from the healthcare community.
3. **Protect Professional Autonomy and Patient-Centered Care:** Reinforce the protections in the Health Professions Act, allowing physicians to employ non-traditional therapies, especially when evidence suggests they are safe and potentially beneficial.

- Encourage regulatory bodies to respect physicians' clinical judgment especially in unprecedented situations like a public health emergency. Guidance should allow flexibility for individualized patient care.

4. **Foster Open Scientific Debate and Whistleblower Protections:** Create forums and platforms where healthcare professionals can discuss and debate emerging evidence without fear of retribution. Such dialogue is crucial for advancing medical knowledge and improving patient care.
    - Strengthen protections for physicians who raise legitimate concerns about public health measures or emerging therapies. These protections should ensure that whistleblowers are not subjected to retaliatory disciplinary actions.
5. **Enhance Scientific Rigor and Diversity:** Encourage Regulatory Bodies to consider a diverse range of scientific sources and viewpoints for communication development to avoid bias and ensure a comprehensive understanding of evolving evidence.
6. **Improve Communication and Education:** Develop and mandate training programs for regulatory body members on the ethical and professional standards related to disciplinary processes. This training should emphasize the importance of evidence-based practice and the need for due process.
    - Ensure the rationale for disciplinary decisions is transparently reported and communicated to the public and healthcare professionals. This transparency will build trust and accountability.
7. **Safeguard Against Biased or Politically Motivated Disciplinary Actions:** Establish clear criteria for identifying disciplinary actions that are driven by mal-incentives, vexatious intent, bias, or political motivations. Once identified, such actions should be subject to stringent review and possible annulment.
    - Implement accountability measures for individuals or entities that are found to misuse the complaint process. This could include sanctions, fines, or other disciplinary actions against those who initiate complaints with malicious intent.

- Conduct independent reviews by panels of experts not involved in the initial complaint process. This will add an additional layer of scrutiny and fairness.

By implementing these preliminary recommendations as well others detailed throughout this report, the regulatory framework governing the Colleges in Alberta can be strengthened to ensure that College processes are fair, evidence-based, and conducive to a healthy professional environment that encourages scientific discourse and patient-centered care.

Call for Further Inquiry

Comprehensive review of the regulatory framework governing the Colleges in Alberta has identified several areas requiring further inquiry to ensure lessons are learned and improvements made to Alberta's public health emergency response system. These areas include:

1. **External Influences on Regulatory Bodies:**
   Initiate an inquiry into the sources of external influence on regulatory bodies, including funding sources, partnerships, and collaborations, to assess their impact on decision-making processes and policy development. This should include the role of external stakeholders, such as pharmaceutical companies, in shaping public health policies and guidelines.
2. **Regulatory Capture and Conflicts of Interest:**
   Perform a detailed analysis of the mechanisms that can lead to regulatory capture, including the appointment processes for regulatory body members, to identify potential vulnerabilities and areas for improvement. An assessment of the current policies and procedures in place to manage conflicts of interest among regulatory body members, including their effectiveness and potential gaps is needed.
3. **Transparency and Accountability:**
   Review the current transparency measures in place for regulatory body decision-making processes, including the disclosure of meeting minutes, agendas, and conflict of interest declarations. Conduct an examination of the effectiveness of

current accountability mechanisms, including complaint procedures and appeal processes, to identify areas for improvement.

4. **Professional Autonomy and Patient-Centered Care:**
   Initiate an investigation into the impact of regulatory body actions on professional autonomy and patient-centered care, including the effects of disciplinary actions on healthcare professionals' ability to provide individualized care.
5. **Open Scientific Debate and Whistleblower Protections:**
   Examine the current mechanisms in place to facilitate open scientific debate and discussion among healthcare professionals, including the role of regulatory bodies in promoting or hindering these discussions. Strong protections should be implemented to protect whistleblowers.
6. **Scientific Rigor and Diversity:**
   Study of the current processes in place to ensure the scientific rigor and diversity of regulatory body decision-making, including the use of independent review panels and the consideration of diverse scientific perspectives. This should include the policies surrounding novel therapies and interventions.
7. **Review of the "Substantially Equivalent" Directive:**
   A critical examination of the "substantially equivalent" directive and the potential consequences of this directive on the provision of high-quality healthcare services in Alberta.

The Task Force recommends a formal inquiry and analysis be conducted in these and other areas outlined in this report to ensure that lessons are learned, and improvements made for any future public health emergency response.

Chapter 3: Modelling

Executive Summary

The Task Force conducted a comprehensive analysis of COVID-19 modelling and decision-making processes in Alberta. The models used during different periods of the pandemic were reviewed and their strengths and limitations identified. The Task Force emphasized the importance of conducting sensitivity analyses, validating models with real-world data, and continuously updating models and assumptions based on evolving evidence. The Task Force recommends using models as tools to inform decision-making rather than relying solely on their outputs. Alberta used mathematical modelling to guide decision-making, considering worst-case scenarios and real-time forecasts for infections and acute care admissions. The Task Force found that early COVID-19 modeling scenarios were not accurate but saw improvements in late-2020. Modelling data gaps were also identified, highlighting the need for more accurate forecasting and planning. Overall, the Task Force's findings underscore the challenges of developing models in real-time and the importance of using these tools as one source of information among others in decision-making.

- The Task Force conducted a comprehensive analysis of COVID-19 modelling and decision-making processes in Alberta.
- The strengths and limitations of the models used during different periods of the pandemic were reviewed.
- The Task force emphasizes the importance of conducting sensitivity analyses and validating models with real-world data.
- Continuously updating models and assumptions based on evolving evidence is recommended.
- Alberta used mathematical modelling to guide decision-making, considering worst-case scenarios and real-time forecasts for infections and acute care admissions.
- Collaboration with universities and transparency in model communication were emphasized.

- Early modeling scenarios were found to be inaccurate, but improvements were seen in late-2020.
- Data gaps and the need for more accurate forecasting and planning were identified.
- The Task Force recognizes the challenges of developing models in real-time and stressed the importance of using them as one source of information in decision-making.

Introduction

The Purpose of Modelling COVID-19

Throughout the pandemic, policy makers from provincial and federal levels, including organizations such as PHAC, used modelling to help guide decisions. Public health has a long history of using epidemiological (i.e., mathematical/simulation) models for a variety of purposes, including:

1. To gain an understanding of infectious disease dynamics,
2. To predict future health care needs to ensure sufficient capacity, and
3. To fill in for missing real-world data.

For COVID-19, well-known modelling applications have been used to generate possible worst-case scenarios,[95] shape decisions around major interventions such as mixing in public,[96] testing,[97] planning for the deployment of public health resources,[98] and to infer key epidemiological parameters describing how the epidemic might manifest in different settings.[99] These different purposes shape decisions about model complexity and approach, the level of precision required of model results, and the extent to which modelling conclusions will generalize to different situations or questions.[100]

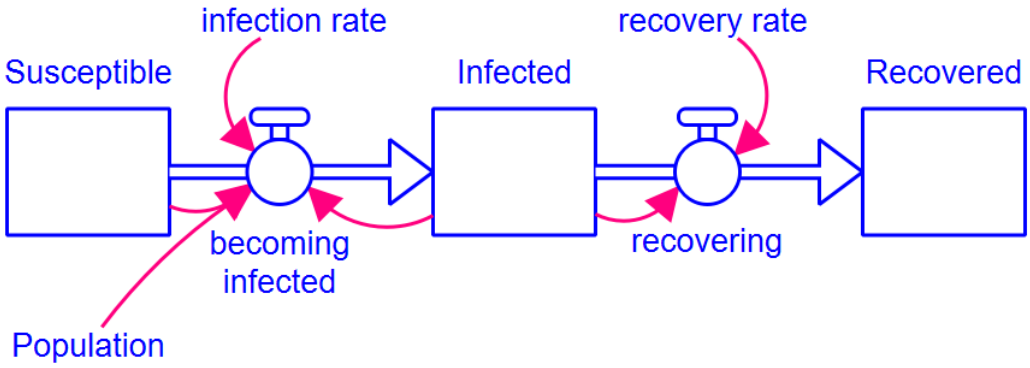
In April 2020, Alberta's decision-making body called the PICC/EMCC made use of mathematical modelling to help guide decisions around the use of NPIs.

In general, mathematical models are used to try and understand how people move between three main states, and how quickly. Individuals are either classified as:

- susceptible to infection (S);
- have become infected and are infectious (I);
- and then either recover (R) or die.

Those who have recovered are presumed to be immune to a certain pathogen and can no longer pass on the infection, if re-infected.

Figure 1. Schematic (non-mathematical) diagram of a simple "SIR" model.[101]



The simplest models (such as the "SIR" model in Figure 1) make basic assumptions about population dynamics. One example is that everyone has the same chance of catching the virus from an infected person because the population is perfectly and evenly mixed. This assumption implies that, on a provincial scale, someone in Fort McMurray is equally likely to encounter someone else from Calgary, Oyen, or Lethbridge.

However, these models can vary widely in complexity depending on the circumstances surrounding a particular pathogen (e.g., whether there's a long latent period, or if infection confers long-lasting immunity) or the characteristics of a particular population (e.g., the immunosuppressed, aged cohorts). More-advanced models might subdivide people into smaller groups — by age, sex, health status, and so on — to represent who meets whom, when, and in which places.

Each of these descriptive states represents a conduit by which one might attempt to affect the course of an epidemic. For example, providing those in the "Infected" category with medical treatment is designed to move "Infected" people into the "Removed" category, at a rate faster than "natural" recovery. Fewer infected people remaining lead to fewer new infections generated.

The COVID-19 pandemic saw a significant increase in the use of epidemic modelling and simulation, with some key differences compared to previous potentially large-scale infectious disease events:

1. **Increased scale and speed of model development:** the imperative to urgently slow the spread of SARS-CoV-2 resulted in rapid, large-scale model development world-wide. Researchers scrambled to incorporate new data from other countries and interventions.
2. **Primary focus placed on NPIs:** models heavily focused on simulating the impact of public health measures like closing businesses and schools and contact tracing.
3. **Increased scrutiny and public awareness:** due to the widespread focus on COVID-19, the results of these models were highly scrutinized by scientists outside of the province's decision-making and the public. This led to a greater emphasis on model transparency and communication of limitations.

The failure in epidemic forecasting is an old problem.[102]

Previous Poorly Predicted Health Events

The reliability of simulation models to produce accurate forecasts, in previous health events, has varied across different locations and over time. For some experts, the "failure in epidemic forecasting is an old problem" has not retained a lot of credibility among decision-makers.[103]

Three prominent examples from the United Kingdom are:

1. Modelling for swine flu predicted between 3,000 to 65,000 deaths in the U.K.[104] Only 457 deaths occurred.[105]
2. Inaccurate models developed in 2001 by epidemiologist Neil Ferguson and associates to predict the spread and impact of foot-and-mouth disease in the U.K. were subsequently questioned in 2006, challenging why nearly 10 million animals had to be slaughtered.[106]
3. Predictions for bovine spongiform encephalopathy ("BSE") (popularly known as "mad cow" disease) expected U.K. deaths counts to be as high as 150,000 people.[107]

The minimum estimate for these predictions was 50 deaths – a number more aligned with the final count of fatalities.

Obtaining a glimpse of the future may work in idealized, isolated communities with uniform populations, not the complex current global world.[108]

The variability in the accuracy of forecasting, in different geographical locations, can be affected by:

1. Local transmission trends;
2. The size and density of the population;
3. The quality and availability of data used to inform the models. Imperfections in surveillance data, delays in reporting, and limited availability of high-resolution data can all affect the performance of a model; and
4. The assumptions and methodologies used in the models, be they mechanistic or statistical.

What Was Done

How Modelling Was Used by Alberta for COVID-19

As confirmed by the Department of Health to the Task Force, there were many different sources of information put forth to the PICC/EMCC for consideration in responding to COVID-19, epidemiological models were just one source of information. Many PICC/EMCC decisions, particularly in early 2020, used mathematical models to look into the future. Several were developed for different purposes:

1. The infectious disease models provided projections 4-6 weeks into the future under a variety of transmission (which included the use of NPIs), SARS-CoV-2 variant, and vaccination scenarios. When needed, the models were developed in collaboration with the University of Alberta and York University.

2. Models developed by Treasury Board and Finance produced real-time, two-week forecasts for daily infections and acute care admissions using econometric methods based on previously observed values of acute care admissions and its covariates; as well as
3. An early warning system ("EWS") used internally by AHS for short-term forecasts of non-ICU and ICU bed requirements. The EWS projections were created using a combination of statistical models and public health factors, which were automatically adjusted over time to reflect current information regarding the COVID-19 pandemic.

Data Reviewed

Modelling Alberta's Unfolding Epidemic

Infectious Disease Modelling

In March 2020, the Province's modelling efforts saw Alberta Health generate three scenarios based on a combination of empirical data from Italy, France, the United Kingdom, China, and preliminary data from Alberta.

At the time, Alberta data sources included confirmed cases, probable cases, deaths, current hospitalizations, number of patients in the ICU, tests performed, and people tested.

Each scenario contained slight differences in the assumptions concerning the infectivity of SARS-CoV-2, the degree to which Albertans mixed with one another, and the frequency of a severe outcome (i.e., hospitalization or death) once a person was infected.

The three Alberta scenarios were outlined as follows:

1. **Probable Scenario:** For every case, 1-2 more people are infected. This scenario was deemed comparable to the growth of SARS-CoV-2 seen in the UK based on the interventions they had implemented. The belief at the time was that because of early and aggressive interventions to limit spread, this was the most likely scenario for Alberta.[109]

2. **Elevated Scenario:** For every case, 2 more people are infected. This scenario is comparable to the more rapid growth of SARS-CoV-2 cases initially seen in China's Hubei Province. Planning for this scenario was thought to be "prudent and responsible given the catastrophic impacts should the health system become overwhelmed."
3. **Extreme Scenario:** For every case, 3 more people are infected. This scenario assumed limited and late interventions to show what would have happened if Alberta did not undertake early and aggressive interventions to limit spread.

These analyses also estimated that Alberta was likely to experience a peak in the number of infections around early- to mid-May, followed by a decline into late summer 2020 (see Figure 2 below). Ultimately, the output from these scenarios over-estimated the extent of SARS-CoV-2 infections, and COVID-19 hospitalizations and deaths (see Table 1). In almost all circumstances, relative differences between observed Alberta data and model estimates were orders of magnitude apart.

Peak (non-ICU) hospitalizations from initial epidemic models were 1068% to 1329% higher than what was observed.

Figure 2. Modelling scenarios presented on April 8, 2020. Each of the three scenarios displayed are outlined in more detail above.[110]

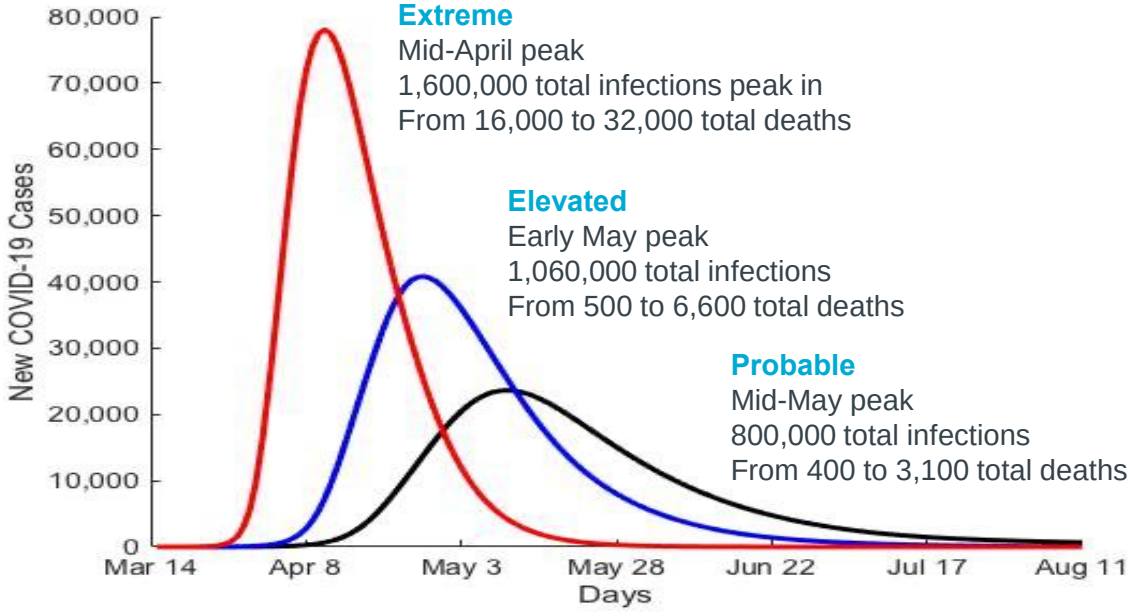


Table 1. Modelling scenarios presented on April 8, 2020.[111] Each of the three scenarios displayed are outlined in more detail above.

Outcome	Probable	Elevated	Extreme	Observed	Absolute Diff. (vs. Probable)
Total Infections*	800,000	1,060,000	1,600,000	197,453†	602,547
Peak Hosp.‡	736 – 900	1,491 – 1,649	N/A§	63	673 – 837
Peak ICU	220 – 244	372 – 412	N/A	20	200 – 224
Total Deaths	400 – 3,100	500 – 6,600	16,000 – 32,000	240	160 – 2,860

* Point estimate copied from Alberta Health for period March 14 to August 11, 2020.

† "Observed" infections were calculated by multiplying cumulative adjusted seroprevalence estimates ending August 7, 2020, to cumulative case counts in Alberta (ending August 11, 2020); cumulative seroprevalence was linearly interpolated to align with the case counts between March 14 to August 11, 2020. (Charlton, C. L., Nguyen, L. T., Bailey, A., Fenton, J., Plitt, S. S., Marohn, C., . . . Tipples, G. (2021). Pre-Vaccine Positivity of SARS-CoV-2 Antibodies in Alberta, Canada during the First Two Waves of the COVID-19 Pandemic. Microbiology Spectrum, 9(1)).

‡ Interval estimates for peak in early-May (Elevated) and May-June (Probable) 2020.

§ N/A = Hospitalization scenarios were not produced for the Extreme scenario.

One reason used to explain why forecasts often do not transpire is – counterintuitively – the forecasts, themselves.[112] The argument suggests that if new policies that increase control of the epidemic are introduced, then the trajectory of an epidemic will be altered, rendering any previous forecast obsolete.

It is very likely that the baseline parameter values used in the above three scenarios – simply – did not apply to the Alberta context. Unrealistic baselines would conflate imprecise modelling assumptions and approximations – because of inappropriate use of data – with an estimate of the effect of the public health measures introduced.[113]

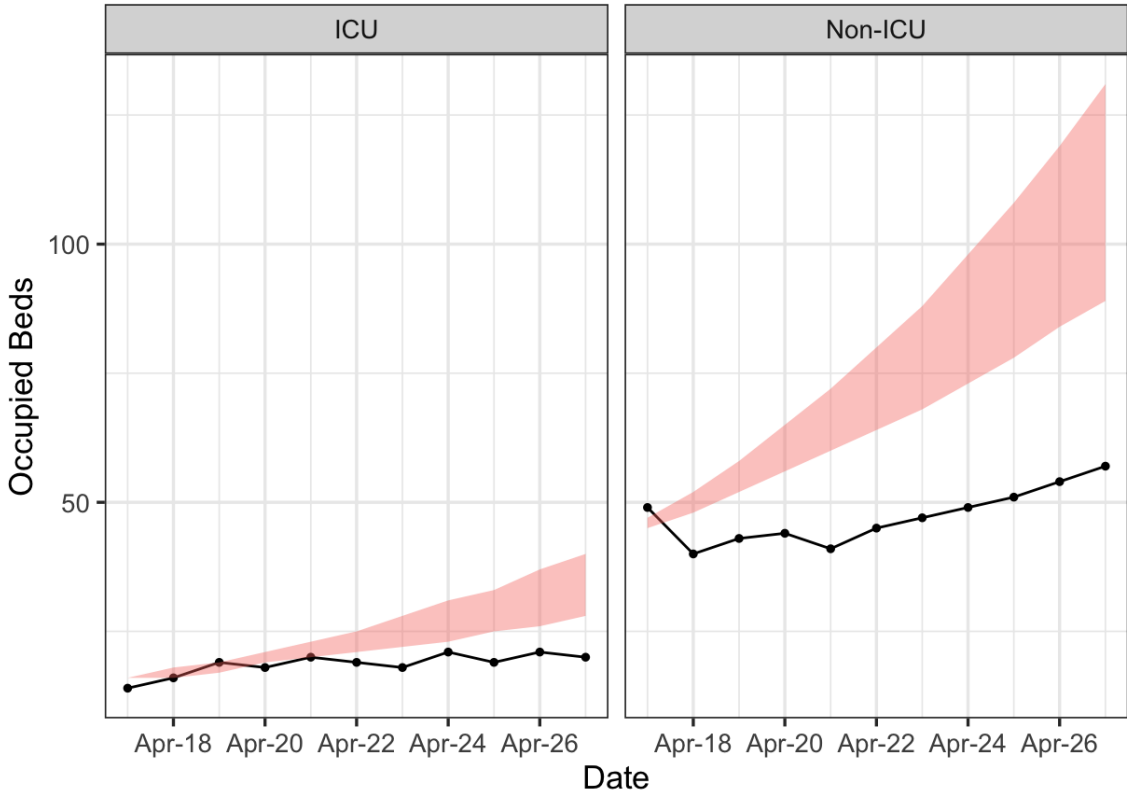
Planning for Acute Care Bed Use

In the first and subsequent waves in Alberta, acute care planning decisions were grounded in part in an EWS. The EWS used information on current numbers of inpatient (non-ICU) and ICU beds occupied by COVID-19 patients to create short term projections of beds that could possibly be occupied by COVID-19 patients, detailed by Zone and facility across Alberta.

Forecasted bed use over the first wave, either by Zone or facility, were not released to the Task Force. However, we were able to obtain an early example of the EWS output from a publicly available affidavit of the former Vice President and Chief Operating Officer of AHS.[114] If what has been stated by the former VP-COO is correct, then it appears that at times during the first wave, the forecasted hospital occupancy of COVID-19 patients over-estimated bed use for both ICU and non-ICU admissions (Figure 3).

***Substantive data gaps**: The small amounts of modelling output provided by AHS or obtained by the Task Force demarcate only the bookends of the pandemic period (see Figures 3-5, below). Neither offer any evidence of accurate forecasting for acute care bed use, particularly ICU beds. It is unknown if there are any extant examples demonstrating the usefulness of the EWS.*

Figure 3. EWS-forecasted COVID-19 occupied inpatient beds (shaded light-red bands) compared to the observed number (black line with dots) for Alberta between April 17 and April 27, 2020.



Did the Predictive Ability of the Models Improve with Time?

Infectious Disease Modelling

Because the modelling scenarios generated in April 2020 were based on non-Alberta data, they were not well positioned to offer any useable insight into the spread of SARS-CoV-2 and its implications for COVID-19 cases. However, modelling projections were reported to have improved as time progressed into late-2020, though documentation of any modelling improvements were not provided directly to the Task Force.

One example independently obtained by the Task Force outlined short-term forecasting of both the timing and magnitude of the peaks in (non-ICU) hospitalizations and ICU admissions do demonstrate improvement over the modelling released in early-April 2020 (Table 2):

Table 2. Example of revised projections for the peak number of COVID-19 cases and hospitalisations (both non-ICU and ICU) in Alberta for the period November 1, 2020, to January 14, 2021. The revised estimates were based on simulations forward in time beyond data ending on October 31, 2020.

Outcome	Predicted*	Actual†	Absolute Difference	Predicted Peak	Actual Peak	Difference
Peak Cases	2,023	1,867	-156	Dec. 15, 2020	Dec. 13, 2020	2 days early
Peak Hosp.	648	715	67	Dec. 27, 2020	Jan. 5, 2021	9 days late
Peak ICU	168	181	13	Dec. 29, 2020	Dec. 21, 2020	8 days early

Acute Care Bed Planning

Acute care forecasting results that were released to the Task Force by AHS were neither stratified by zone or facility, but were instead aggregated for all of Alberta, and only for a small window of time between December 14, 2021, to January 17, 2022. These forecasts demonstrate an expected improvement from the first wave (see Figures 4-5). Despite some improvement, however, they do retain a tendency to over-estimate acute care bed use, particularly in Alberta's ICUs, although it appears that some over-estimation was expected during late 2021 with the Omicron variant.

Because modelling scenarios provide easily understandable figures, and because of their mathematical underpinnings, models can appear to be scientifically robust. Thus, it is understandable if decision makers, either at the PICC/EMCC or AHS, set a great deal of store in the modelling they were presented with. However, across all 18 forecasts provided by AHS, only 28% of ICU forecasts ended up containing the observed beds used (Figure 4). This

* Point estimates of predicted outcomes are taken from an affidavit of the former Head of Analytics at AH (Rebecca Marie Ingram, Heights Baptist Church, Northside Baptist Church, Erin Blacklaws and Torry Tanner vs. The Province of Alberta and The Chief Medical Officer of Health, 2021).

† Actual outcomes, including the timing of the peak outcomes, were taken from the AH's Interactive Aggregate Data on COVID-19, last accessed April 11, 2022.

was less of an issue for non-ICU beds, where 44% of the forecasts contained the observed beds used (Figure 5).

The inaccuracy of forecasts released to the Task Force raises the concern that many hospital services may have been unnecessarily reduced.

Figure 4. EWS ICU bed forecasts (light-red bands) versus observed bed counts (black line) between December 14, 2021, and January 17, 2022. Each panel represents a moving 14-day window, beginning on December 14, that advanced daily, and ending on January 13, 2022.

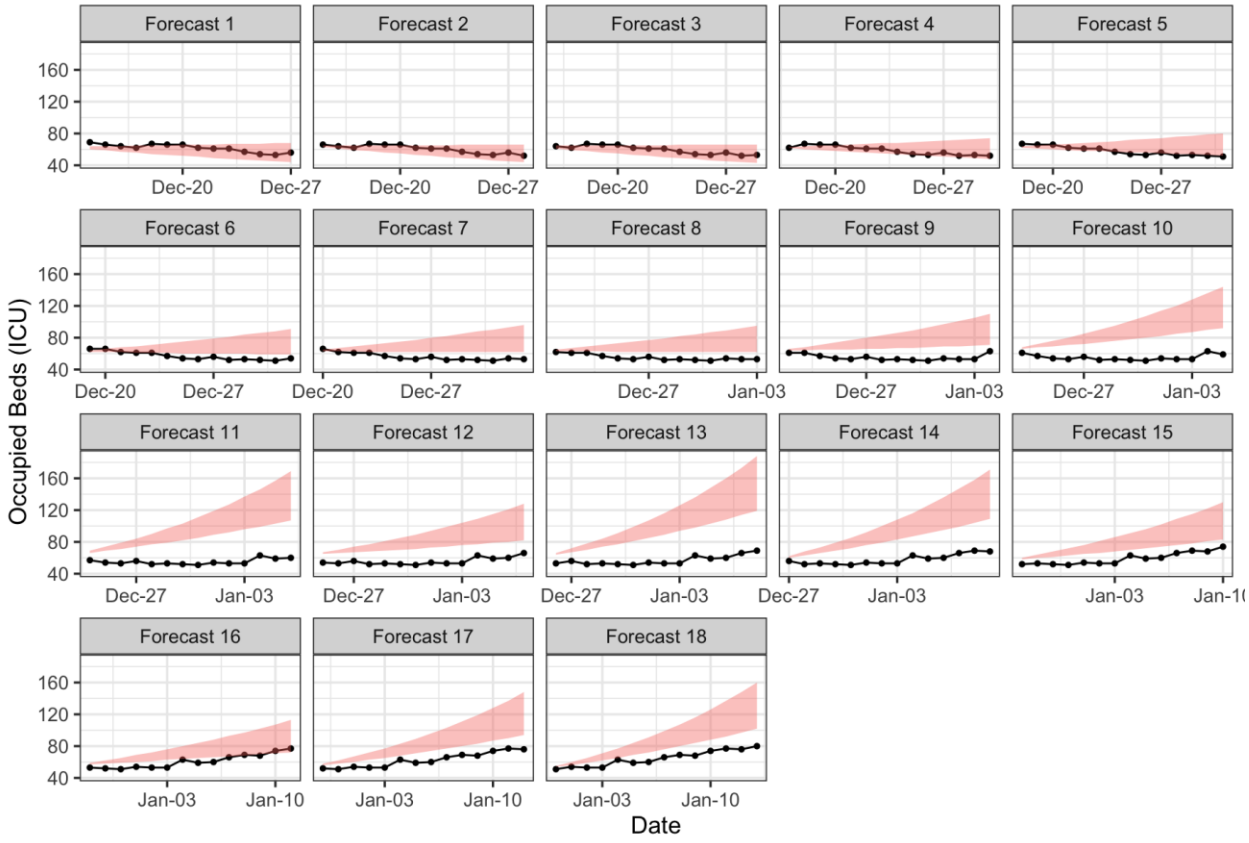
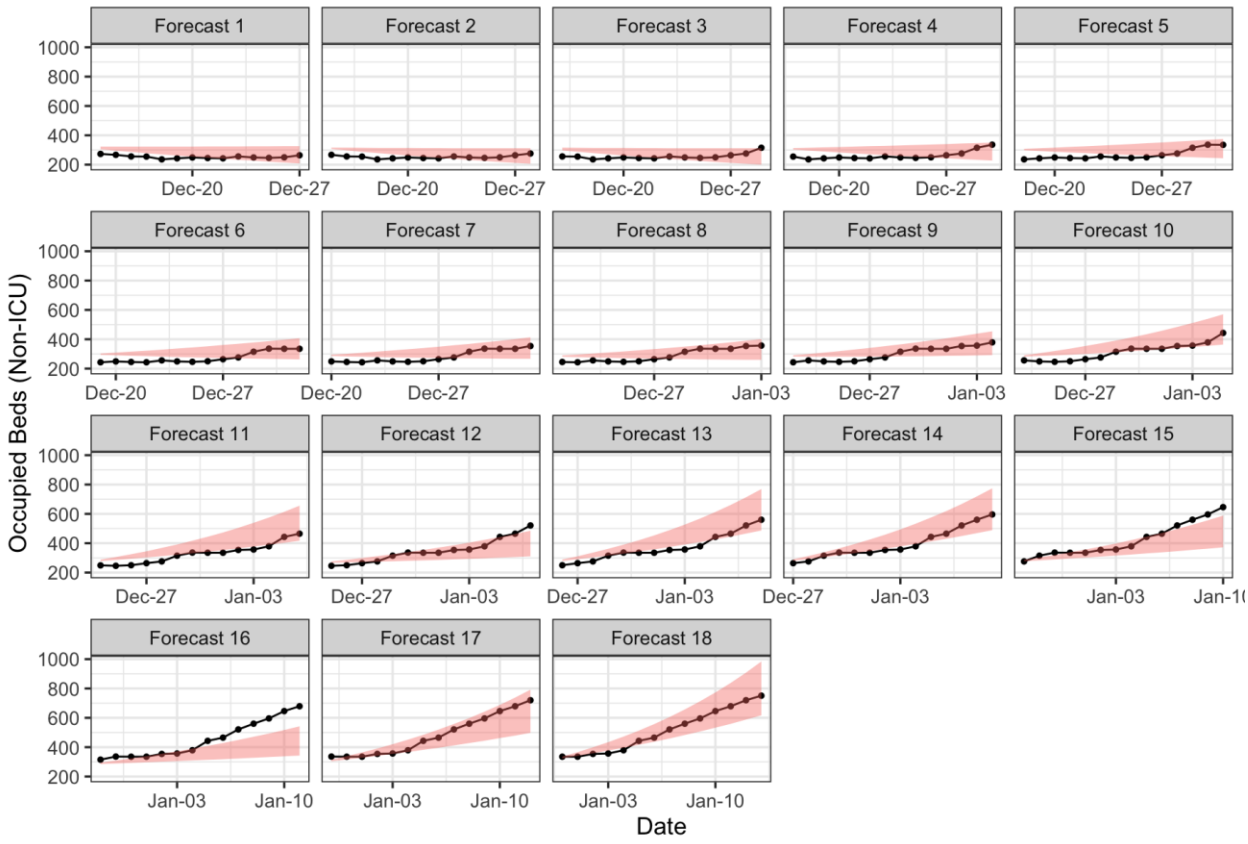


Figure 5. EWS non-ICU bed forecasts (light-red bands) versus observed bed counts (black line) between December 14, 2021, and January 17, 2022. Each panel represents a moving 14-day window, beginning December 14, that advanced daily, and ending January 13, 2022.



Modelling the Effects of Interventions to Slow the Spread

Models of Spring-Summer 2020

Despite the initial inaccuracies in the results on April 8, 2020, they were later reviewed after 20 days with new Alberta-specific data. The province introduced revised "probable" and "elevated" scenarios, as well as a new **Low Scenario**, to compare against COVID-19 hospitalisations (Figure 6, top panel) and ICU admissions (bottom panel) in Alberta. During a press conference on April 28, 2020, the former Premier of Alberta stated that he was:

> *"...[P]leased to now say that our updated COVID-19 data and modelling shows that our efforts to reduce the peak of the virus are working [because] the number of Albertans hospitalised and admitted to intensive care is well below what modelling originally projected..."*[115]

It is unknown if COVID-19 modelling limitations were not understood or incrementally simplified as information was passed from the EOC's Data Analytics Team, to the CMOH and Minister of Health, and onto PICC/EMCC.

Figure 6. Revised modelling output for hospitalisations (top panel) and ICU (bottom panel) in Alberta. The discrepancy between the modelled scenarios (solid lines) and actual data (grey bars) represents the perceived effect of Alberta's efforts to slow the spread of SARS-CoV-2.

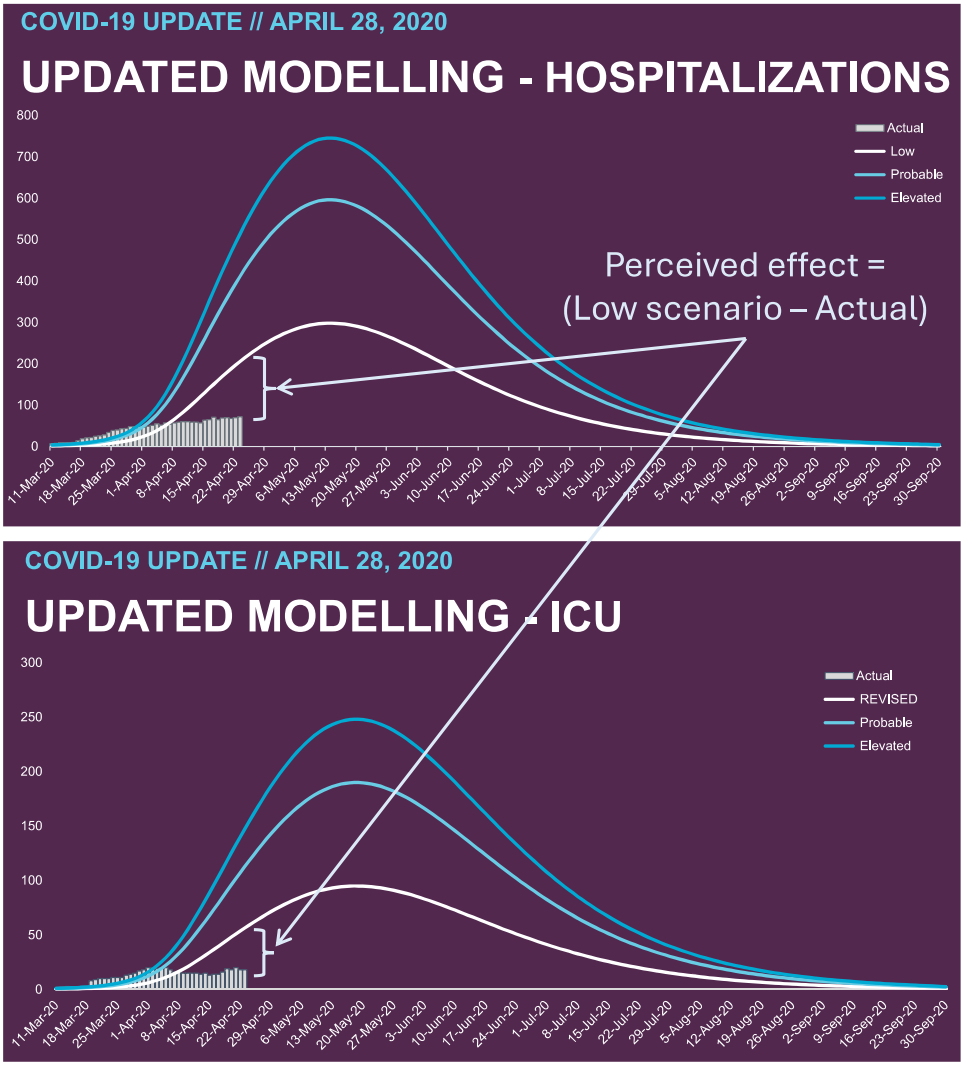


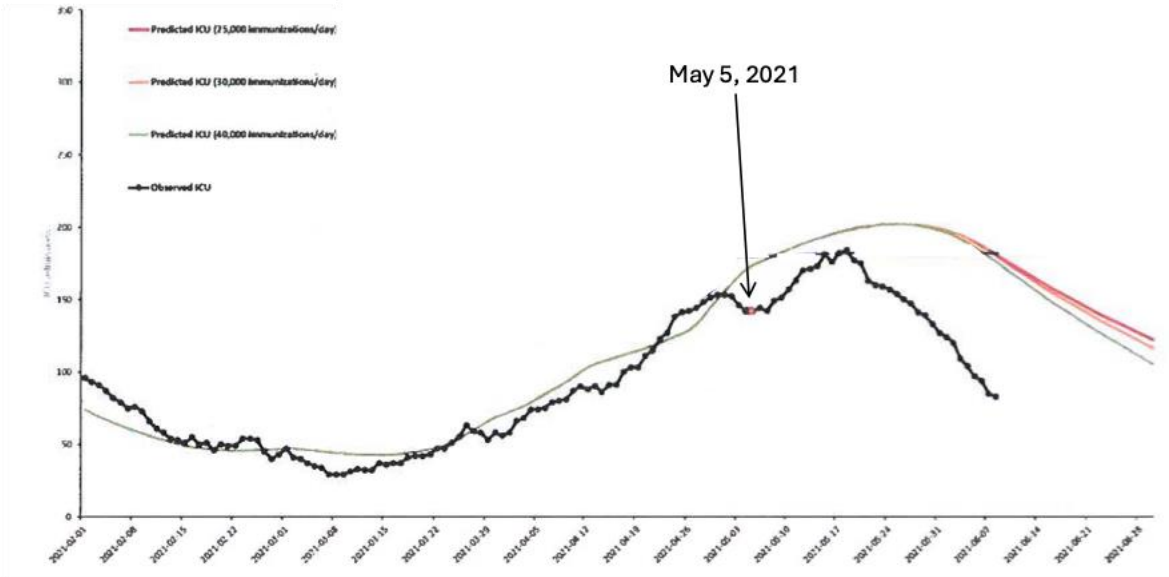
Table 1 and Figures 4-6 demonstrate that none of these modelled scenarios reflected the actual state of COVID-19 in Alberta during the period forecasted.

Models of Late 2020 and early 2021

According to the testimony of the CMOH, one benefit of the province's modelling was to provide counterfactual (or "alternate reality") evidence that the mandatory measures in late 2020 were effective at slowing the spread of SARS-CoV-2.[116] When coupled with jurisdictional scans, counterfactual reasoning repeatedly served as a reference point that the decisions made successfully slowed the spread of SARS-CoV-2.

The head of Data Analytics at AH discussed in an affidavit a simulation model calibrated (or "fit" to data) to reproduce historical COVID-19 patients in the ICU, up to May 5, 2021, on which date additional mandatory measures were introduced across the province.[117] As an approximation of "what could have happened", the model was then simulated forward in time to the end of June 2021, and the number of simulated COVID-19 patients in ICU were compared to the number of observed COVID-19 patients in ICU (Figure 7).

Figure 7. Predicted impact of the third "wave" of COVID-19 cases in Alberta's ICUs without restrictions implemented on May 5, 2021 (red, orange, and green lines) compared to the actual number of COVID-19 cases in ICU (black line with dots). Figure is "Exhibit F" in *Ingram et al vs. The Province of Alberta*.[118]



If what has been stated by both the former head of Data Analytics and former CMOH is correct, then it appears that the CMOH was distracted by modelling artefacts, not actual events. Inherent delay structures in the model (such as those that control the time from infection to hospitalization) could be different than their actual values. If the model were sensitive to these structural assumptions, then the "what if?" scenarios from May 5 onward (Figure 5) can produce inconsistencies with observed data that can be easily mis-interpreted.[119]

For example, the peak number of COVID-19 patients in the ICU during the third wave was observed on May 18, 2021, while the model's predicted peak was around May 27, showing a difference of 9 days which was nearly identical to the disparity listed in Table 2. These similar discrepancies between predicted and actual peak ICU admissions are a signature of systematic errors in the model's structure rather than an effect of public health measures.

Models that are sensitive to critical assumptions may generate misleading intervention outcomes that are easily to misinterpreted.

External Collaboration, Model Checking and Amendments

It is important to conduct sensitivity analyses to mitigate against model parameters becoming overly reliant on specific inputs. Not doing so greatly limits their usefulness and predictive ability using real-world data, which tend to be messy and variable.

According to interviewees from the Analytics team in the Department of Health, this type of "model validating" was done continually throughout 2020 and 2021. They defined a well-performing model as one whose projections stayed within uncertainty intervals and followed general trajectories observed in the data. Based on these qualitative criteria, the epidemiological models used throughout the pandemic were deemed to have performed well in forecasting COVID-19 outcomes for the immediate future. Additional validation made use of existing collaborations with colleagues at the University of Alberta and York University.

Were non-COVID-19 Outcomes Considered?

The modelling used by the EMCC/PICC during the pandemic primarily analyzed the future trends of COVID-19 cases, hospitalizations, and deaths, which were considered as direct health outcomes. However, a senior policy advisor told the Task Force that other significant outcomes not related to COVID-19 were neglected due to their lack of quantifiable attributes. As discussed in the chapter on NPIs, the public health measures used between 2020 and 2022 have already elicited a broad range of collateral consequences, including:

- Learning loss from closed schools,
- Worsening mental health from fewer social contacts,
- Cancelled cultural events and religious services, and
- Increased substance abuse due to isolation.

Conclusion and Recommendations

The Task Force acknowledges that it is easier to criticize a model than to build one. Developing a model in real-time, with small numbers of qualified staff, while under immense time constraints, and frequently amended data is a formidable task.[120]

The Task Force anticipates a resurgence of model use with the potential arrival of a new pandemic. A major concern of ours is whether model-makers and decision-makers can avoid past errors by handling, interpreting, and communicating model findings with greater care to avoid compromising the effectiveness of public health strategies.[121] Releasing to the public simulation model results, which inherently involve nuances, should be avoided at all costs.

Previous research provides evidence to suggest that even meaningless mathematics can give the illusion of high-quality analyses,[122] generating a false sense of control over complex, dynamical phenomena.[123] Undue acceptance of modelling results is a common consequence of an "interpretation pitfall" whereby the model's users – the decision makers in the PICC/EMCC – lacked critical distance from its shortcomings.[124]

Minimising the effect of this type of pitfall requires involving experts from different disciplines to provide a necessary "red team" perspective to decision making; replacing speculative assumptions with real, empirical data as quickly as possible; and modifying – or even reversing, if necessary – decisions considering the evolving evidence in its entirety, not just a selective subset.[125]

Chapter 4: Non-Pharmaceutical Interventions: Closures & Restrictions

Executive Summary

The Task Force conducted a thorough assessment of the impact of non-pharmaceutical interventions (NPIs), like closures and social restrictions, on COVID-19 transmission. We observed that while these measures had a limited effect on reducing infection growth, they also incurred significant social and economic costs, emphasizing the importance of a balanced approach considering both health and economic implications. Our review of NPIs in Alberta provides valuable insights into the effectiveness and consequences of such measures in response to COVID-19 pandemic. The Task Force conducted a comprehensive review of NPIs in Alberta's response to COVID-19.

- Closures and social restrictions were implemented throughout 2020 and 2022, including banning gatherings, cancelling public events, restricting business hours, and closing schools.
- The stringency of NPIs had a small relative effect on the growth of infections.
- These measures aimed to limit interactions, protect vulnerable populations, reallocate resources, and promote hygiene practices through information campaigns.
- There were high costs, both socially and economically, to closures and restrictions, with limited relative benefit.
- Timely measures are recognized as important in preventing health services from being overwhelmed.
- Public information campaigns and changes in mobility have an impact on contact rates.
- Task Force findings highlight the need for a balanced approach considering both health and economic impacts of NPIs.
- NPIs as a tool to manage the COVID-19 pandemic were less effective and had more collateral consequences on Albertans and the economy than anticipated.

Introduction

Starting in March 2020, Alberta applied a series of health restrictions which banned gatherings, cancelled public events, restricted business hours, and closed schools. Collectively, these measures are often referred to as "lockdowns", and they were applied because they purportedly slow the spread of infection and protect the vulnerable, thus preserving healthcare resources. Advocates of these strict measures cited the benefit using national-level data collected overseas, that may or may not have applied to Canada's provinces or territories. Until we look at data from sub-national jurisdictions, we may – as many have done – prematurely infer that lockdowns slow the spread of respiratory pathogens. This chapter outlines research evidence, highlighting Alberta's data, demonstrating that the closures and restrictions used against COVID-19 lacked effectiveness and have likely incurred high costs, both socially and economically.

Setting the Context: Follow-up to a Previous Report

The KPMG review of Alberta's response to COVID-19 commissioned by the provincial government in late 2020 acknowledges that because scientific understanding of COVID-19 was changing rapidly, so too would the information driving public health policies.[126] A review of the Province's response needs to be informed by a clear understanding of the context for that response – including the different actions taken that have impacted Albertans – but also through an understanding of the evolving epidemiological and therapeutics literature.

The timeline for public health decisions made in 2020 is summarized in Figures 1-3, while an evidence review between 2020 and 2023 is displayed in Table A1 at the end of this chapter. It is important to note that Figures1-3 and Table A1 represent a selection of significant actions, events, and publications during the period of review and not an attempt to exhaustively catalogue all actions taken.

What Was Done

Closures and Social Restrictions

Throughout 2020, non-pharmaceutical interventions (NPIs) were the primary tools employed by governments and public health agencies to slow the spread of SARS-CoV-2 and protect healthcare capacity.[127] Amongst Canada's provinces, just as in many other countries, common NPIs included border closures, bans on non-essential travel, mandatory physical distancing measures and limits on mass gatherings.[128]

NPIs are meant to:

1. **Reduce Spread of Infection:** limit people from interacting, ultimately alleviating the burden of respiratory illness on healthcare systems, such as excess admissions to hospital.
2. **Protect Vulnerable Populations:** because frail and immunocompromised people are at higher risk of severe disease, NPIs were used to shield these populations from exposure.
3. **Allow Resources to be Re-Distributed:** if the spread of infection is slowed, healthcare resources can be more efficiently allocated to treat severe cases.
4. **Create Public Awareness:** information campaigns provide a reminder of the existence of COVID-19 which will promote many individuals to modify their hygiene practices.

As a nation, Canada's pandemic response, in terms of health and economic impacts, has been assessed as more effective than some peer countries, averting significant numbers of deaths and economic losses.[129] The results of these evaluations give the impression that Canada compares favourably to its peers. However, since the assessments are based solely on counterfactuals – "if Canada was like Australia" – or on rankings, they likely over-emphasize the link between Canada's top-ranked pandemic responses and its low burden of disease outcomes.[130]

Decisions Involving the Use of NPIs in 2020-2022

In March of 2020, PHAC began recommending closures and restrictions across various sectors, including borders, Parliament, social gatherings, schools, restaurants, playgrounds, salons, spas, fitness centres, and care facilities. These lockdown measures remained in place, in one form or another, until the late spring of 2022. According to the "Stringency Index" from the OxCGRT,

* Canada had more stringent lockdown measures than nine other OECD nations (Figure 4).[131]

With a lack of available evidence to ground decision-making, Alberta's actions in response to COVID-19 wereideologically and culturally based. This is neither good nor bad, but it needs to be acknowledged.

As the first COVID-19 cases and hospitalizations were confirmed in Alberta, like many other regions, a state of public health emergency was declared, and public health orders were issued to limit the spread of SARS-CoV-2 infection (see timeline depicted in Figures 1-2). Despite little contemporary evidence, Alberta applied a series of health restrictions which banned gatherings, cancelled public events, restricted business hours, and closed schools (CMOH Order 01-2020).[132] Alberta's CMOH issued the following Orders in relation to further public health measures:

1. Closing public recreational and private facilities, bars and nightclubs, and gatherings of more than 50 people (CMOH Order 02-2020);
2. Limiting visitors at health care facilities, which included auxiliary hospitals, nursing homes, designated and licensed supportive living and lodge accommodations (CMOH Order 03-2020);

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* The OSI is a composite measure that combines a set of pandemic responses into an index to help abstract away from the subtleties of different "packages" of responses across jurisdictions. It also permits quantitative comparisons between the "intensity" of government responses and spread of infection. We will frequently make use of the OSI throughout this report.

3. Prohibiting gatherings of 15 or more people and prohibiting close-contact businesses (CMOH Order – 07-2020); and
4. Prohibiting visitors in health care facilities, including residential addiction treatment services (CMOH Order – 09-2020).

Figure 1. Timeline of SARS-CoV-2 between January to April 2020, when COVID-19 cases were detected in Wuhan, up until cases first appeared in Alberta. Figure from KPMG Report, 2021.

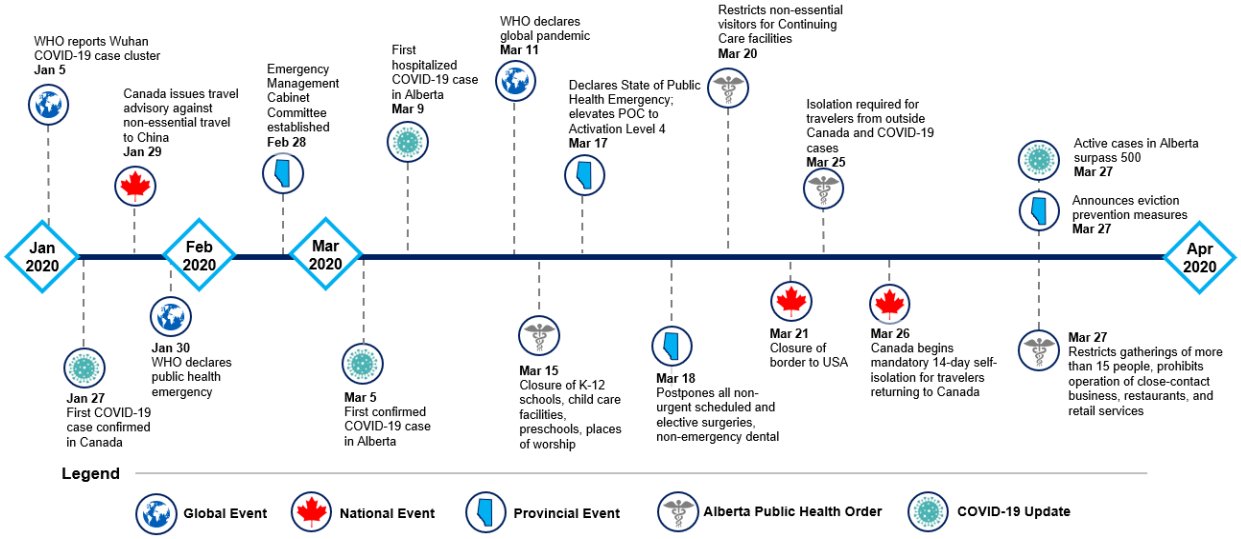
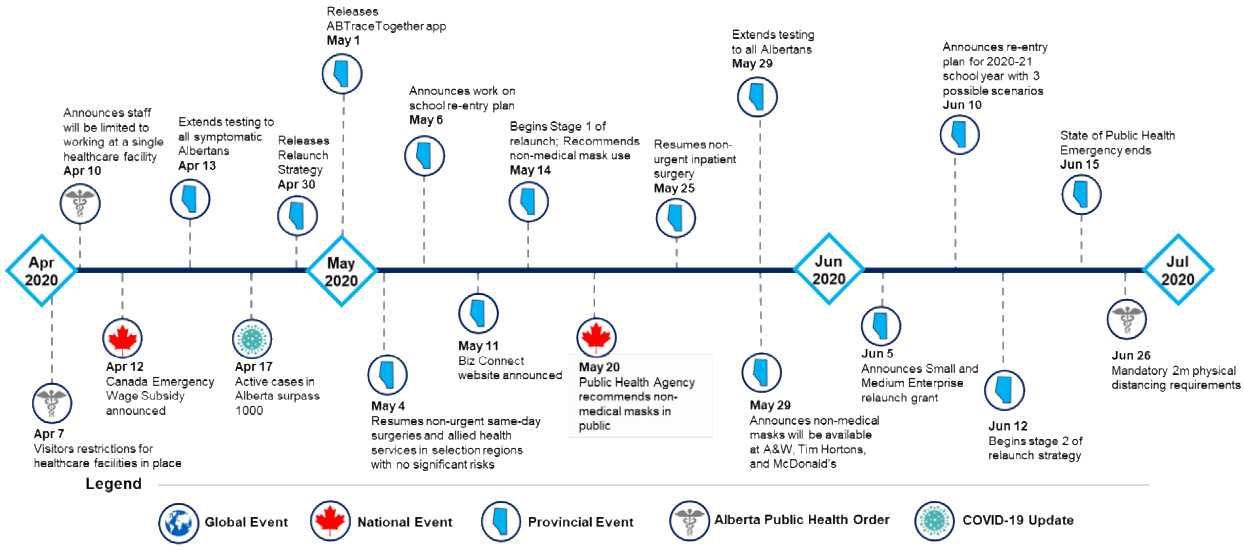


Figure 2. Timeline of activity tied to the "first wave" (spring 2020) and into Alberta's summer relaunch. Figure from KPMG Report, 2021.



Public health restrictions eased over the summer of 2020, and were re-introduced in October (where the timeline in Figure 3 ends) with the addition of the following Orders:

1. Prohibiting indoor and outdoor gatherings, both private and public, effective immediately and for a minimum of four weeks, province wide (CMOH Order 41-2020);
2. Ordering new province-wide business closures and restrictions on other services, retail businesses and attendance at places of worship (CMOH Order 42-2020);
3. Implementing new restrictions for retail, fitness, and performance activities (CMOH Order 08-2021);
4. Announcing stricter measures including new restrictions for municipalities or areas with more than 50 new cases per 100,000 people, and with 30 or more active cases (CMOH Order 19-2021);
5. Reinstating mandatory physical distancing, reduced capacity for gatherings (CMOH Order 42-2021); and
6. Reducing private outdoor social gatherings from 200 to 20 people, as well as requiring physical distancing between households (CMOH Order 47-2021).

Figure 3. Timeline of evolving response efforts into October 2020, when the timeline of KPMG's report ends. Figure from KPMG Report, 2021.

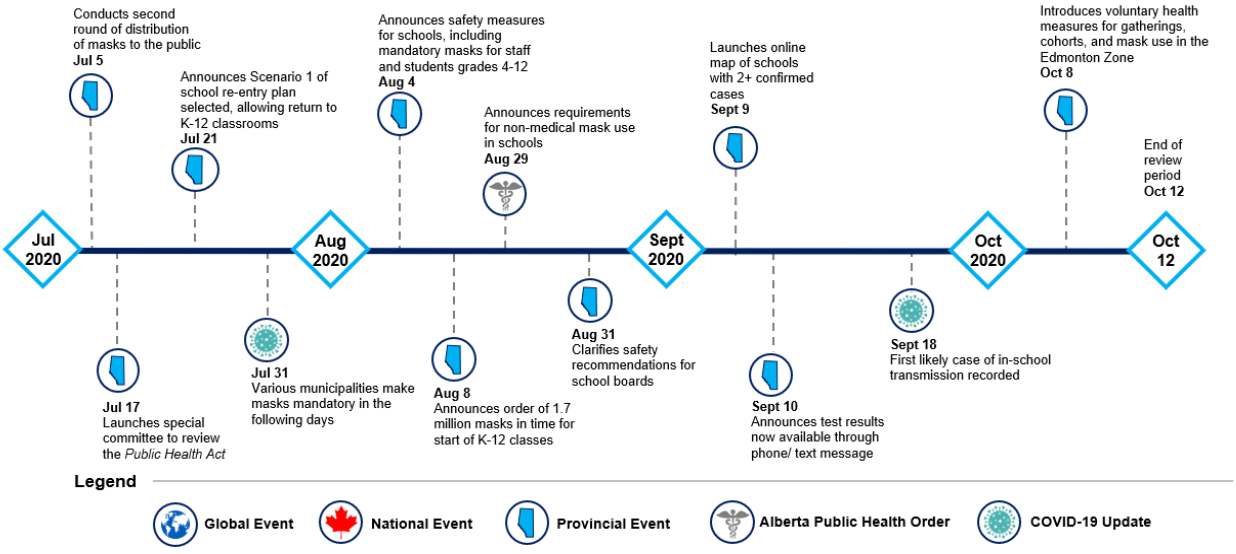
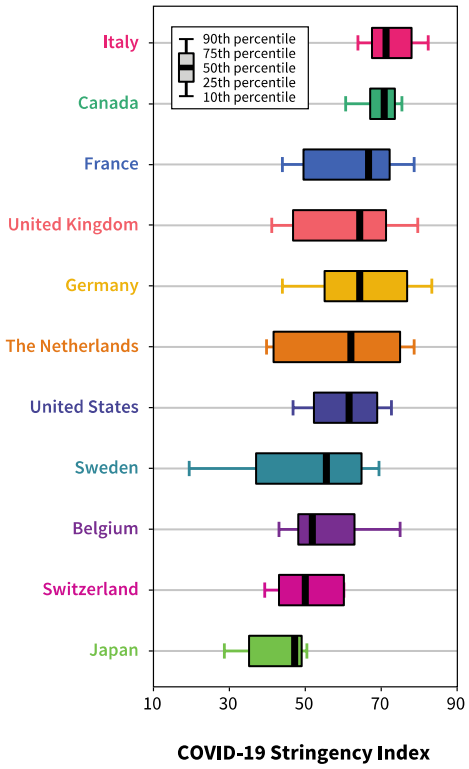


Figure 4. Box-and-whisker plot of the OSI from 11 OECD countries since March 11, 2020, to February 8, 2022.[133]



Expanding beyond the CMOH's orders listed above reveals that social restrictions, closures (including closing health services), and travel measures changed 90 times between March and December 2020 (see Table 1). Often, once one set of measures had been introduced, others followed within days to weeks.

Table 1. The number of changes to pandemic interventions in Alberta between 2020 and 2022 stratified by broad category.[134]

Intervention Category	2020 Changes = 135	2021 Changes = 171	2022 Changes = 31
Case management	7 (5%)[†]	20 (12%)	6 (19%)
Closures/openings	42 (31%)	45 (26%)	7 (23%)
Distancing	14 (10%)	15 (9%)	2 (6%)
Health services	18 (13%)	4 (2%)	1 (3%)
Health workforce	32 (24%)	8 (5%)	5 (16%)
Public information	11 (8%)	16 (9%)	4 (13%)
Travel	5 (4%)	4 (2%)	0 (0%)
Vaccine	6 (4%)	59 (35%)	6 (19%)

Data Reviewed

Sources of Information Used in Alberta's Decisions

The traditional approach to generating and analyzing evidence about the effectiveness of any intervention that is intended to alter health outcomes, is to conduct carefully designed controlled trials.[135] In these trials, two or more closely matched groups of people are randomized to receive interventions that differ in strictly defined and limited ways.

Other approaches used throughout 2020-2022 were:

1. **Jurisdictional scans:** comparing the outcomes elsewhere, be it a neighbouring province or country, that received the intervention with those in a population not receiving the intervention in a different region of a country or another country.

[†] Number (%) of total changes.

2. **Evidence reviews:** have the aim of establishing the quality and strength of the deductive evidence about the effectiveness of individual NPIs.
3. **Simulation modelling:** comparing an outcome (or outcomes) in a simulated population after receiving an intervention against the same outcomes, in the same modelled population, where history is "re-run" in the absence of the intervention. The difference between the two modelling scenarios is considered the intervention's "impact". The simulation modelling approach is presented in a separate chapter.

Jurisdictional Scans

Personnel in the Department of Health informed the Task Force that jurisdictional scans of COVID-19 responses were undertaken for British Columbia, Ontario, and Quebec, as well as international jurisdictions, such as Italy and New York. Alberta's process to determine broadly focused closures as a reasonable response to COVID-19 was to avoid the experience in other jurisdictions by following the impact that COVID-19 was having in terms of overwhelming their hospitals and fatality rates. Any perceived impact in comparable jurisdictions was used as evidence in terms of what measures might be needed in Alberta.

Evidence Reviews by the AHS Scientific Advisory Group

Recommendations that drove Alberta's initial COVID-19 response decisions were later coupled with information provided by the AHS Scientific Advisory Group ("SAG"). As mentioned elsewhere in this report, the SAG became operational for review of questions related to COVID-19 in April 2020 and ended its operations on December 31, 2020.

While the SAG was not the only method of informational/resource review, their purpose was to use evidence and consider resource availability to provide recommendations to support policy and operational decision-making to the AHS ECC for COVID-19 incident response.

The SAG used a rapid recommendation response which allowed for up to 1 week to provide a response to any question posed to the SAG – a marked departure from their usual turnaround of several weeks to months. All requests to the SAG came from:

1. AHS ECC, physician leads, or ZEOC;
2. PPE Task Force (a subcommittee of Operations section of the ECC); and

3. Alberta's CMOH.

Working and networking diligently with colleagues and appropriately communicating ideas and information across provincial lines are the key to the success of any epidemiological activity.[136] However, these types of jurisdictional activities can quickly become unwieldy, especially when Alberta's PICC/EMCC/HEOCs were constantly trying to navigate massive amounts of information at the expense of determining, which NPIs for Alberta, were "working" and which were not.

Outstanding questions: *Was there an analytic strategy outlined in advance as part of an evaluation of the province's interventions aimed at COVID-19? If there was, what did the results of that evaluation indicate?*

What effect did NPIs have on Alberta's experience with SARS-CoV-2?

SAG Rapid Review on NPIs

With respect to the use of various NPIs in Alberta, the AHS SAG reviewed the effectiveness of several NPIs in reducing the transmission of SARS-CoV-2. In their final revised report (AHS Scientific Advisory Group, 2021), from the references they had collected, they concluded that:

1. Effects of reducing transmission should not be considered precise. The data on NPI's effectiveness is largely inferential based on retrospective, observational data of control measures implemented during the first wave of COVID-19 across many countries, with a variety of definitions, measures and methods used to try to isolate the effects of specific interventions when applied in simultaneous and stepwise combinations.
2. The effects may vary from small to large depending on whether assessed as a single measure or in addition to other NPIs which may be effective on a community rather than a national basis. After initial measures, the effectiveness of prolonged or repeated restrictions may lessen which is related to population adherence.

3. Restrictions applied for a long period, or reintroduced late in the pandemic (for example, in the event of a resurgence of cases) may exert a weaker, attenuated effect on the circulation of the virus and the number of casualties related to population "lockdown fatigue".[137]

Independent Assessments of NPIs on Growth Rate of SARS-CoV-2 in Alberta

The former CMOH has stated that comparing Alberta's first and second waves of COVID-19 demonstrated that early application of mandatory measures significantly reduced cases and hospitalizations. For the CMOH, this highlighted the importance of timely measures in preventing overwhelming health services.[138]

If what the former CMOH had stated is correct, it appears that there was failure to recognize a fundamentally important issue in monitoring the effects of NPIs over time. NPIs are intended to reduce contact rates between individuals in a population. Their primary impact, if effective, is on transmission rates, and the appropriate outcome to consider are growth rates with appropriate lags – not total cases, hospitalizations, or deaths as indicated.[139]

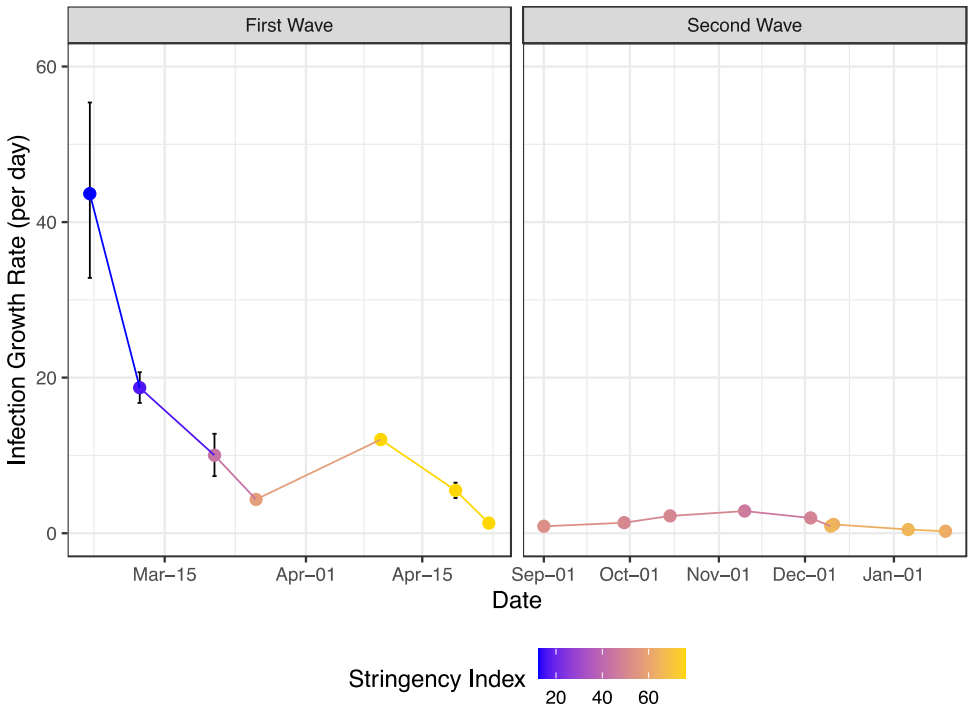
However, other peer-reviewed research which focused on several of Canada's provinces suggests that:

1. The overall stringency of Alberta's NPIs had a small relative decrease on $R_E(t)$ of 0.4% per one-unit increase in the stringency index when compared to the transmission rates of the previous two weeks.[140] In other words, historical values of $R_E(t)$ have a larger relative impact on current its values than "how hard" Alberta responded.
2. Higher values of the OSI demonstrated a law-of-diminishing-returns with the growth rate of SARS-CoV-2 infections.[141] However, the observed early dose-response effect was small and began plateauing before May 2020 – long before any "lockdown fatigue" could have emerged (Figure 5).

Both papers demonstrate similar qualitative results, despite discussion by others as being contradictory.[142]

If stricter measures do not correlate with lower infection growth rates, then they are unlikely to have had a large effect on COVID-19 hospitalizations and mortality.[143]

Figure 5. Growth rates (per day) of cases in Alberta for both first and second waves. The left panel below shows a rapid decline in the growth rate occurred with corresponding values of the OSI < 20 out of 100 in the first wave.[144]



Observation from 2020: Public Information Campaigns & Large Changes in the Mobility of Albertans

Interpreting the lack of association between greater NPI stringency and reduced case growth could be bolstered through de novo data collection exploring voluntary behaviour changes and the network structure of human interactions, rather than the use of routinely collected surveillance data.

For example, information campaigns provide a reminder of the existence of COVID-19 which will promote many individuals to modify their behaviour. Google's Community Mobility Reports provided insights into how people's movements changed in response to Alberta's public health policies aimed at SARS-CoV-2 (and COVID-19).[145] Broadly, these data

represent the percent change, from pre-pandemic movement, of where Albertans were going based on a proportion of cell phone "pings" across 6 different categories: residential, workplace, transit stations, parks, groceries and pharmacies, and retail and recreation.

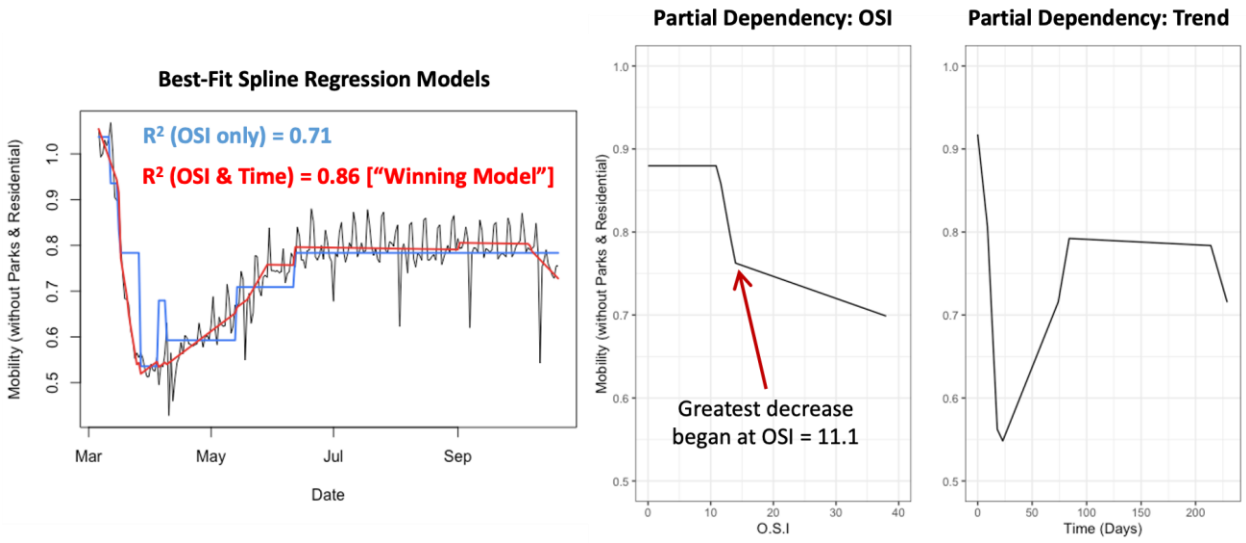
If changes in Albertan's movement outside the home are any indication of changes in contact rates, then the largest decline in contact coincides when Alberta's OSI was 11.1 out of 100 (see Figure 6, middle panel).

The individual NPIs linked to this value of the stringency index included:

- Asking international travellers to quarantine, and;
- Coordinated information campaigns (either through traditional or social media).

It is doubtful that returning international travellers had the largest effect on the mobility of the entire province of Alberta.

Figure 6. Alberta's Mobility Data between March and October 2020 as a function of the best-fit values of two multivariate adaptive regression splines (left panel) that included data of the OSI and a time trend (in days) as covariates.‡ The middle and right panels display partial dependence plots of the "winning model" which shows how people's mobility changes, on average, as the OSI (middle panel), and time trend (right panel) vary.



‡ During the pandemic OxCGRT published their data in several formats that may be different to the final dataset. The values of the stringency index in the middle panel are derived from the version available in December 2020.

Conclusion and Recommendations

What trade-offs from pandemic responses are emerging across Canada?

The degree to which NPI measures will be effective in slowing the transmission of respiratory pathogens is uncertain and will largely depend on the context, timing, and epidemiology of the outbreak.[146] The range of NPIs that might be used in response to a respiratory pathogen will differ significantly in terms of their feasibility, costs, consequences, and evidence. Public health authorities should have the capacity to provide risk/benefit analyses to decision makers, driven by scientific evidence, where it exists, before NPIs are initiated in a crisis.[147]

Despite repeated statements of the existence of trade-offs by the former CMOH,[148] both Alberta and other provinces yielded significant gaps in their research when implementing stringent public health measures, including only minimal consideration of any wide-reaching negative impacts. Often, a version of the precautionary principle was the modus operandi to recommend and implement stricter, mandatory measures, despite concerns raised that overly restrictive NPIs would cause significant multi-dimensional harm to society.[149]

Internationally, two systematic reviews demonstrate that the collateral damage of the pandemic response was substantial and is likely to leave behind a legacy of harm to be felt for decades by millions of people.[150]

Across Canada, some recent research highlights a range of unintended consequences stemming from pandemic responses affecting various aspects of society and individual well-being:

- In long-term care homes, pandemic management strategies restricted visitation which adversely impacted the perceived health and well-being of residents and their families, revealing a pre-existing care gap in public long-term care facilities;[151]

- School closures and shutdowns have raised concerns about long-term academic achievement and learning gaps among students, with the need for research to understand and mitigate these effects;[152]
- Responses to the pandemic have exacerbated socioeconomic and health challenges for transgender and non-binary populations, as well as with the broader social determinants of health in Canada, reflecting intensified pre-existing inequities;[153]
- Deteriorating mental as well as negative physical and social effects amongst Canadians, as evidenced by responses on social media;[154]
- Five-year historical highs in deaths from substance use;[155] according to the Alberta substance use surveillance system, acute substance deaths have, on average, doubled between March 2020 and June 2022 vs. a pre-pandemic period January 2016 to December 2019 (see Figure A1 at the end of this chapter);[156]
- An over-policed public aimed at deterring normal social behaviour;[157] and
- Soaring government spending.[§]

These findings underscore the multifaceted and nuanced impacts of pandemic responses. Required going forward is a balanced approach that considers both intended outcomes and potential unintended consequences.

Conclusions and Recommendations

As our coexistence with COVID-19 continues, people's focus on the time between 2020 and 2022 has dwindled. For government and public health institutions in Alberta, this is a chance to demonstrate a willingness to endure the painful contemplation required to learn from past mistakes and avoid the desire to simply "move on".

Restrictive NPIs were attractive because they offered a simple message: staying home protects the vulnerable. However, our review demonstrates that "lockdowns" did not

[§] Data from the OxCGRT state that Alberta spent in-excess of $540M on emergency investments in healthcare (Oxford COVID-19 Government Response Tracker, 2023). However, monetary indicators are incomplete and should be used with caution.

substantively reduce transmission or off-set the use of healthcare resources and have come at considerable social and economic costs.

Recommendation 1: *Return to pre-2020 pandemic guidance where communities faced with contagion respond best when the normal social functioning of the community is minimally disrupted.*[158] *This means safeguarding people's autonomy to ensure that every adult Albertan has the individual right to make informed decisions about their risk behaviour — even in the face of a pandemic.*

Importantly, the findings of Canada-specific research suggest that the minimal benefit and diminished returns associated with stricter NPIs should be a signal for a better understanding of what "works" and "for whom" when it comes to mitigating the spread of infection.

Recommendation 2: *Create oversight for future declared public health emergencies. NPI public health restrictions, like their pharmaceutical counterparts, require balanced scientific evidence showing they are safe and effective before being implemented. Ensure that all "countermeasures" undergo real-time evaluation, including risk-benefit analyses. Evaluation should be overseen by a panel of peers, representing different faith, societal, and socio-economic groups.*

By fall of 2020 some analysts realized that policies around containment and closures had little effect on the spread of the virus and that the economic costs of these policies could be enormous.[159] Yet, almost 2-years after the pandemic was declared, PHAC's CMOH suggested Canada adopt "a more sustainable approach to managing COVID-19", an approach that countries like Sweden recognized at the outset.[160]

Alberta, and the rest of Canada, need to better analyze the potential value and impact of NPIs. Specifically, it needs to be determined in which future contexts – if any – NPIs would be effective, and conclude in which contexts they are likely do more harm than good.

Recommendation 3: *Use a "Red Team" approach within health emergency operations centers. For making policy decisions, red teams overcome groupthink, confirmation bias, and anchoring behaviour which impairs the critical thinking ability of individuals and organizations.*[161]

Recommendation 4: *Alberta's well-being before, during, and after the pandemic requires that other important metrics – besides public health indicators – need to be examined.*

When categorized by the aspects of life these metrics should represent:

Social Well-being

- Life expectancy at birth: This reflects the average number of years a newborn can expect to live. It's influenced by healthcare access, nutrition, and overall living standards.
- Education levels: Literacy rates and standardized test scores for students in Grades 6 and 9. These will provide insights into the knowledge and skills.
- Poverty rates: The percentage of people living below a certain income threshold indicates the level of material deprivation within a society.
- Gini coefficient: This measures income inequality, with a higher number indicating a larger gap between rich and poor.

Economic Well-being (in addition to GDP)

- Income distribution: How income is spread across the population is more important than just the overall provincial income.
- Employment rates: Employment figures indicate the health of the labor market and economic opportunities for individuals.

Overall Well-Being

- Human Development Index: This UN index combines life expectancy, education, and income into a single score, providing a good overview of a country's (or other region's) development level.

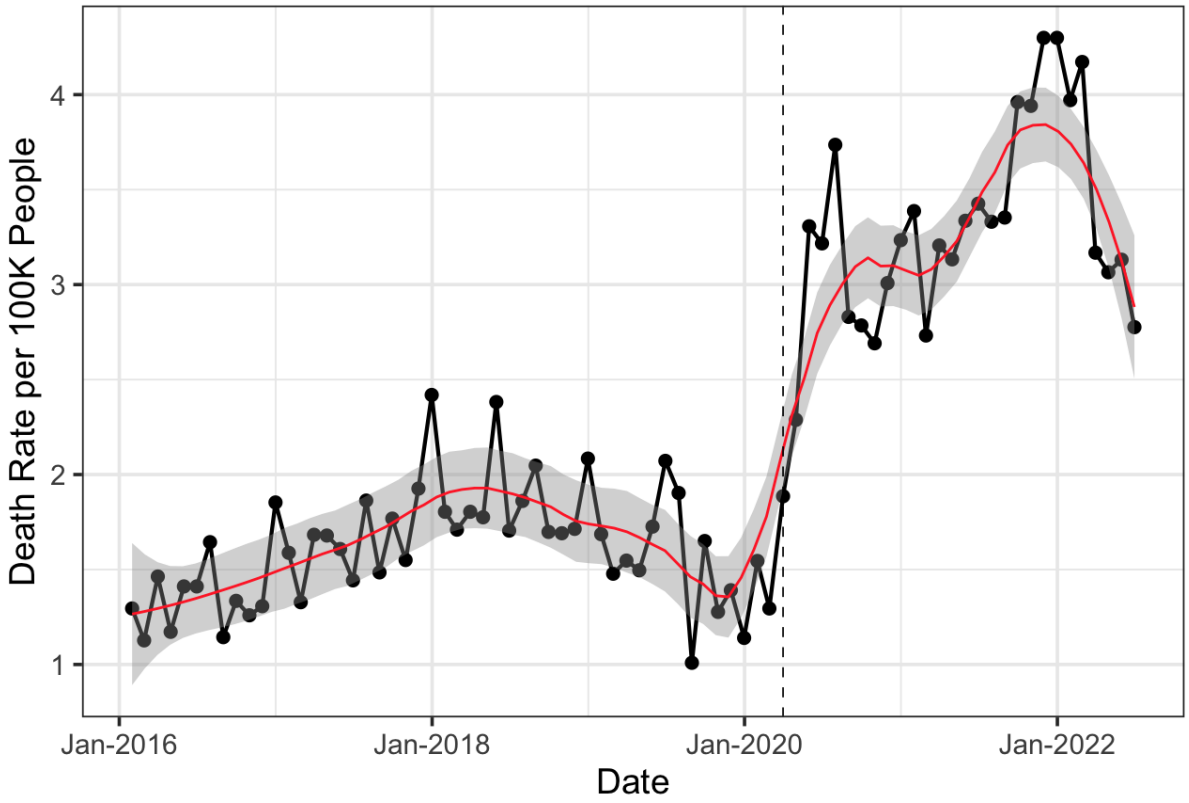
Table A1. Evidence reviews of NPIs used during COVID-19 pandemic.

Business Closure and/or Restrictions	
Mendez-Brito et al (2021)	Literature on different levels of business closure was assessed in a systematic review with one preprint analysis showing no additional value to closing all non-essential services in comparison to initial mandatory closure of selected businesses, which in most countries included "non-essential" businesses such as restaurants, malls, stores, and theatres.
Brauner et al (2021)	Found that targeted closures of face-to-face businesses with a high risk of infection, such as restaurants, bars, and nightclubs, had a small-to-moderate effect (31% decrease in R). Closing most non-essential businesses delivering personal services was somewhat more effective (40%, moderate effect). When these interventions were already in place, issuing a stay-at-home Order had only a small additional effect.
Chang et al. (2021)	In terms of relative risk of COVID-19 transmission at various public locations, a very detailed mobility network analysis of 98 million people in the US informed a well performing model which suggested that 'superspreader' points of interest may account for a large majority of infections, and that restricting the maximum occupancy at each point of interest is potentially more effective than uniformly reducing mobility This study did not examine workplace closure and pertains to an unimmunized population. Highest risk points of interest (>100 extra infections per 100,000) included full-service restaurants, fitness centres, cafes and snack bars, hotels and motels, limited-service restaurants, and religious gatherings, with full-service restaurants significantly higher risk even across income strata (associated with >500 to >1500 additional infections per 100,000). Upon reopening, reducing maximum occupancy is predicted to limit infections (example, in this model, capping at 20% of the maximum occupancy in the Chicago metro area reduced the predicted number of new infections by more than 80% with only a 42% reduction in overall customer throughout).
Event Size Restrictions	
Mendez-Brito et al (2021)	A systematic review notes that definitions in these studies vary (the definition of social gathering restrictions ranged from mass gathering bans to banning gatherings of less than ten people.) While mass gathering bans were associated with a reduction of incidence-related outcomes in 7 out of 14 studies (50%), social gathering bans were associated with a reduction in 11 out of 15 (73%).
Liu et al, 2021	In higher and intermediate quality studies, restrictions of smaller social gatherings were consistently found to be more effective than restrictions of very large gatherings, with one source suggesting restrictions on gatherings of more than 1000 people were not effective.
Brauner et al (2021)	In an analysis of the effectiveness of NPIs across 41 countries in the first wave banning gatherings was effective with a large effect for

	limiting gatherings to 10 people or less, a moderate-to-large effect for 100 people or less, and a small-to-moderate effect for 1000 people or less: they estimated a 36% and 21% reduction in the reproduction number when limiting gatherings to 10 people or less, and to 100 people or less, respectively.
Brauner et al (2021	Noted that recommended workplace closures or staying at home had been effective, implying that voluntary physical distancing has played an important role with differences in the assessment of whether there are improved outcomes, when all–but essential workplaces were closed. Work from home is also sometimes defined as "small gathering cancellation".
Ebrahim et al (2020)	Analysis of a novel crowdsourced US data set at the level of US counties showed a strong positive correlation between non-essential workplace closures and shelter-in-place Orders at the county level, with increased rates 2-6 weeks after the end of workplace closure. There was variability between policies in adjacent counties and across states, but the correlation between periods of work closure and reduced transmission was consistent suggesting smaller regional area policies can reduce local transmission. Thus, workplace closure (with the practical implication that remote-work or income support for affected workers is maintained) appears to be evidence based.
Lockdown – Stay-at-Home Orders	
Pan et al, 2020	In the first wave, "lockdown", or stay-at-home Orders were the most stringent measure to stop community transmission. In the initial Wuhan outbreak, a stringent lockdown dropped the R value from over 3 prior to January 6, 2020, to below 1.0 on February 6, and below 0.3 on March 1, 2020.
Haug et al (2020)	Looking across countries with varying degrees of stringency, lockdown was ranked as a consensus NPI with an R reduction of 0.14, found effective in 3 analyses. Brauner found lockdown /stay-at-home Orders as a measure had a small effect size when other NPIs were already in place (approximately 12% additional R reduction) but analyses by Flaxman and Hsiang included these measures in their assessment of lockdown and showed a large effect size.
Goldstein et al (2021)	An economic lens on lockdown effectiveness analysis suggested that restrictions applied for a long period, or reintroduced late in the pandemic (for example, in the event of a resurgence of cases), may exert a weaker attenuated effect on the circulation of the virus and the number of casualties related to population lockdown fatigue.
Li et al, (2020)	A preprint study assessed the effectiveness of community level, local lockdowns in Chile, with the effectiveness of local lockdowns highly affected by the duration of the local lockdown, and the level of spillover from neighboring municipalities under different control measures. In three municipalities a local lockdown lasting 3-weeks longer would have reduced cases by 33-62% in that time period. Better results of municipal level lockdowns would be expected from geographically isolated municipalities without shared transmission

	networks, or if neighboring municipalities also extend their local lockdowns.
World Health Organization (WHO) (Guidance on selection of optimal policy measures for national and subnational governments).	In this document, a rubric that evaluates effectiveness, socioeconomic cost, and public acceptance is presented, where benefit outweighs risk but higher costs to measures supports their use in higher transmission settings (see Table 3 below): • Lowest socioeconomic costs: teleworking, cohorting, limiting LTC visitation (this would be less relevant post vaccine); • Intermediate socioeconomic costs: social gathering limits, altering school contacts, minimizing workplace exposures, limiting non-essential travel; • Higher socioeconomic costs – beneficial in high transmission: close high-risk businesses, schools, travel restrictions; and • Highest socioeconomic costs: lockdown (prohibit all movement, only essential services open)
Amuedo-Dorantes, Kaushal, & Muchow, 2021	Earlier implementation makes a significant difference during the early growth phase of the pandemic, with one modelling study showing that adopting non-essential business closures 1-day earlier lowers COVID-19 deaths by 0.7%. Responding early slowed spread and prevented overburdening of the health care system.
CDC	The CDC has a ranking system for community transmission risk; however, specific epidemiologic thresholds and actions are not delineated.
PHAC	PHAC has some guidance for community settings to allow a risk assessment by operators which might be shared within local communities
Public Health England	Public Health England has issued guidance that includes examples of local and regional level actions. This includes contingency plans for reimposing economic and social restrictions at a local, regional, or national level if evidence suggests they are necessary to suppress or manage a dangerous variant. Such measures would only be re-introduced as a “last resort to prevent unsustainable pressure on the National Health Service.” Regulations which enable local authorities to impose restrictions, requirements, or prohibitions on individual premises, events, and public outdoor places have been maintained.

Figure A1. Monthly per-capita acute substance deaths in Alberta between January 2016 and June 2022. The red curve and shaded areas are a local polynomial regression model and its 95% confidence region, respectively. The vertical dashed line indicates the beginning of the pandemic period in March 2020.[162]



Chapter 5: Masking

Executive Summary

The Task Force conducted an in-depth review of the available evidence and resource considerations which shaped Alberta's masking recommendations. This chapter highlights the weak evidence base concerning the effectiveness of continuous masking in preventing respiratory illnesses, including COVID-19. Masking studies showed limited or mixed results, particularly in community settings. The Task Force also observed potential harms of masking, such as self-contamination, discomfort, and a false sense of security. Despite the limited evidence and potential harms, Alberta implemented mask mandates in various settings, including schools, public gatherings, and businesses. The number of COVID-19 infections did not decrease despite these mandates and the widespread vaccination. Based on these findings, the Task Force makes recommendations for a more balanced approach to masking to improve future pandemic response.

- The Task Force review indicated a weak evidence base for the effectiveness of continuous masking in preventing respiratory illnesses, including COVID-19.
- Studies showed limited or mixed results regarding the effectiveness of masks in community settings.
- The Task Force observed potential harms of masking, such as self-contamination, discomfort, and a false sense of security.
- Despite the limited evidence and potential harms, mask mandates were implemented in various settings in Alberta.
- The number of COVID-19 infections did not decrease despite the implementation of mask mandates and widespread vaccination.
- Alberta should acknowledge the absence of evidence showing continuous masking provides protection against respiratory illnesses, including COVID-19, and highlight the potential harms associated with masking.
- The choice to wear a mask should be a personal medical decision, guided by informed consent.

- Proper education on mask usage and the selection of appropriate masks should be provided to the public.

Introduction

Facemasks have a history dating back to ancient times, where they were used for protection against dust and other particles. In the medical field, the 17th century saw the use of masks with beak-like structures by doctors to protect against the plague, often filling them with herbs believed to prevent disease. By the late 1800s, face masks became common in surgical settings to protect patients from potential bacterial transmission through exhalation by physicians. These early masks were made of a single layer of gauze, reflecting the emerging understanding of germ theory, which linked microbes to disease transmission.[163] This early understanding was the launch pad into a long-standing controversial history on the effectiveness of masking both in healthcare settings and the broader community in the prevention of respiratory infection transmission.

The SARS outbreak in 2003 and MERS outbreak in 2012 renewed interest in the use of masks. Studies from these periods indicated that masks could reduce the transmission of respiratory viruses, but the evidence was still limited and primarily focused on healthcare settings.[164] Further review was conducted for the effectiveness of community masking both during and after the 2009 H1N1 outbreak resulting in the similar findings for the use of facemasks by healthy individuals in community settings.[165]

What Was Done

International and National Guidance on Masking

At the beginning of the outbreak, the World Health Organization ("WHO") and health authorities across Canada, including Alberta's, advised against the public use of face masks by healthy individuals, emphasizing that the need for masks was low in settings where exposure to COVID-19 was minimal.[166] Maintaining this position, Dr. Theresa Tam, the Canadian Chief Public Health Officer, told Canadians that face masks should be reserved for healthcare workers, largely as a result of shortages of personal protective equipment at the beginning of the pandemic as well as the uncertainty surrounding the efficacy in preventing transmission in public settings.[167] Dr. Tam further warned against the use of face masks by untrained individuals, noting that the incorrect donning and doffing of a mask may

actually increase face-touching, and possibly increase the risk of self-contamination.[168] The WHO maintained the same message, informing the public that the use of masks by healthy individuals could induce a false sense of security that might erode adherence to other more effective preventative measures. Further, the WHO also advised against community masking as "no evidence is available on its usefulness to protect non-sick persons." [169]

In a reversal of earlier guidance, the masking recommendations of both the United States Centers for Disease Control and Prevention ("CDC") and the WHO shifted to suggest that cloth face coverings are most effective at reducing the spread of COVID-19 when widely used by the general public.[170] This marked departure from previous messaging recommended that facemasks be worn by healthy people in community settings and was the guiding force behind mask mandates throughout Canada.[171] In lockstep with international messaging, federal and provincial health authorities in Canada swiftly updated their recommendations as evidenced by the Council of Chief Medical Officers of Health of Canada ("CCMOH") which advised the public to use non-medical face coverings when in public.[172]

Masking in Alberta

Our review revealed that Alberta quickly aligned its masking policies with recommendations from the WHO and the CCMOH. The first mask mandates were introduced on August 1, 2020, in Edmonton and Calgary. Orders from the Chief Medical Officer of Health (CMOH) included school mask mandates (August 29, 2020), mask mandates for public gatherings (November 24, 2020), and business mask mandates (November 27, 2020).[173] Further, on December 8, 2020, new province-wide mandatory health measures were implemented which included mandatory indoor masking in the community.[174]

Data Reviewed

Alberta's assessment of the efficacy of masking was led by the Scientific Advisory Group ("SAG"), which commenced its work in April 2020 and concluded on December 31, 2022, following a decrease in information requests. The SAG played a pivotal role in addressing COVID-19-related inquiries, although it was not the only source of information review. The

primary objective of the SAG was to use available evidence and resource considerations to offer recommendations that would guide policy and operational decisions for the AHS Emergency Coordination Center's response to the pandemic. As noted in other chapters of this report, during COVID-19 the SAG provided recommendations on the various questions received with a response of days opposed to a usual response time of months. The SAG undertook an initial review on community masking's efficacy, including surgical and homemade cloth masks. As per the rapid response report, the SAG's review into the efficacy of community masking was based on the potential for pre-symptomatic and asymptomatic transmission, with the goal of shaping Alberta's masking recommendations.

The inquiry into the efficacy of community masking was based on the potential for pre-symptomatic and asymptomatic transmission, with the goal of shaping Alberta's masking recommendations. The SAG's review indicated that, despite a weak evidence base, the use of masks in the community is likely effective in reducing transmission, especially from symptomatic individuals. The only clinical study on cloth mask efficacy, conducted in a healthcare setting, showed higher respiratory infection rates among healthcare workers using 2-ply cotton cloth masks compared to standard practices. The SAG also observed that the extent of pre-symptomatic and asymptomatic transmission to community spread remains unclear and that there is no direct evidence that mask use significantly reduces this risk. Harms were also identified as well as risks associated with community masking which included self-contamination, discomfort, a false sense of security, and challenges for vulnerable populations and in hot and humid environments.

Masking recommendations transitioned into mandates starting in mid-2020 and persisted throughout most of the pandemic. Our review of the available information revealed that, despite these strong recommendations and mandates, the number of COVID-19 infections did not decrease. Instead, infections continued to rise, even after the COVID-19 vaccine became available.

Figure 1. COVID-19 Cases in Alberta, 2019-2020 to 2023-2024.[175]

COVID-19

Summary of laboratory-confirmed COVID-19 cases in Alberta, 2019-2020 to 2023-2024

Season	Cases (n)	Hospitalizations (n)	ICU admissions (n)	Deaths (n)
2023-2024	21,079	5,297	328	628
2022-2023	32,822	5,918	462	973
2021-2022	350,230	15,536	2,006	2,410
2020-2021	238,963	9,941	1,952	2,215
2019-2020	13,144	679	134	243

Note: A hospital or ICU admission in a laboratory-confirmed COVID-19 case is counted when the reason for admission is either directly resulting from the disease, or when the disease is a contributing factor for the admission. Information on reason for hospitalization was unavailable prior to 2022-02-01. **Data before and after that reporting change date are not directly comparable.**

When Alberta implemented mask mandates, public messaging emphasized that masking was effective in reducing community transmission among both symptomatic and asymptomatic individuals. However, the data did not support this claim and criticism of the effectiveness of masking in the community focused on the lack of proper education on correct mask usage, including how to put on and remove masks, ensuring proper fit, and choosing the right type of mask. Alberta did not have quality control measures in place to ensure strict adherence to these protocols, which further reduced any possible protection afforded by wearing a mask.

Further review of the available research and data appeared to support the previously understood limitations of masking. As outlined in a March 4, 2020, *JAMA* publication by Angel N. Desai and Preeti Mehrotra:

> "Face masks should not be worn by healthy individuals to protect themselves from acquiring respiratory infection because there is no evidence to suggest that face masks worn by healthy individuals are effective in preventing people from becoming ill."[176]

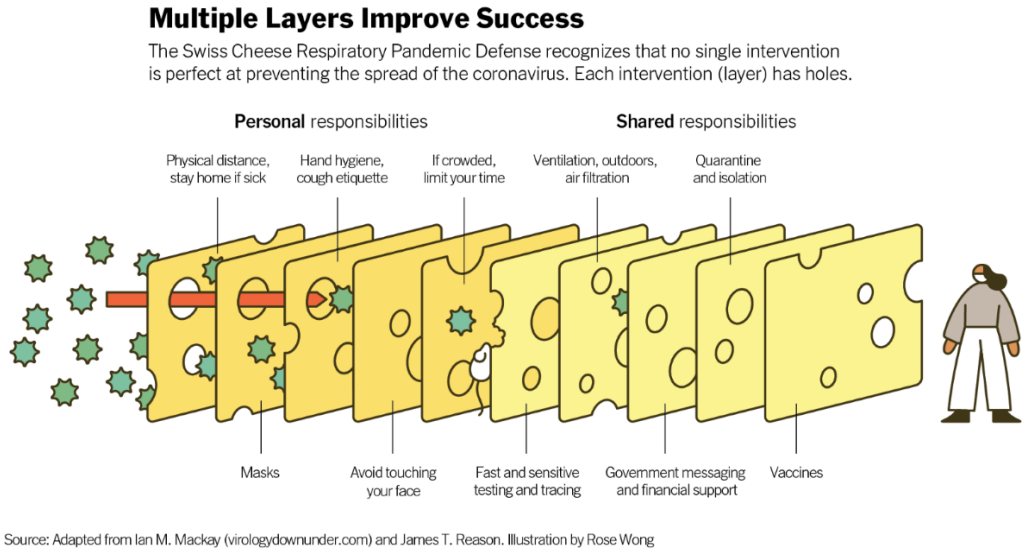
Scientific reviews assessing the use of facemasks and respirators during an influenza pandemic have found limited evidence of their benefits in healthcare settings for protecting against influenza infection, with only marginal benefits observed.

> "Given the potential loss of effectiveness with incorrect usage, general advice should be to only use masks/ respirators under very particular, specified circumstances, and in combination with other personal protective practices."[177]

Masks have been shown to decrease disease transmission in healthcare settings. However, research on their effectiveness in community environments has yielded varying outcomes. While masks can provide some benefit in reducing the spread of respiratory viruses, the evidence is mixed, particularly for community settings. Many studies show limited or inconsistent results regarding the effectiveness of masks in preventing the transmission of COVID-19 among the public. The benefits of masks are more pronounced in healthcare settings but the extent of their effectiveness in broader community use is not well established.[178]

Supporters of community masking suggest that wearing a mask – any mask – helps lower the risk of spreading infections unknowingly or inhaling enough virus to become infected. However, a mask's effectiveness diminishes if it fits poorly, is worn below the nose, is made of a single layer of cloth, has a loose weave, includes an unfiltered valve, is not disposed of properly, isn't washed, or if hands aren't sanitized after touching it. Each of these instances represents a vulnerability, even within a single layer. The Swiss Cheese analogy appropriately depicts the issues and controversy surrounding the efficacy of community masking, and further raises the question of the appropriateness to implement a mask mandate that not only has significant data to support its lack of efficacy but has the potential to provide the opposite desired effect.

Figure 2. Swiss Cheese Respiratory Pandemic Defence Model.



Before the COVID-19 pandemic, consensus held that masks offered little, if any, benefit in curbing the spread of respiratory viruses. A meta-analysis of 14 randomized controlled trials concluded that surgical masks did not effectively reduce laboratory-confirmed influenza transmission, whether worn by infected individuals or by the general community.[179] Similarly, a Cochrane analysis of nine trials found no clear reduction in respiratory viral infections with medical/surgical masks during seasonal influenza.[180] Studies involving healthcare workers suggested uncertain benefits against respiratory pathogens, including the common cold.[181] Even a 2020 study on mask use as source control found no difference in infection rates among household contacts between masked and unmasked groups.[182]

The harms of masking especially on children during the pandemic have been a significant concern for parents and healthcare professionals. Prolonged mask-wearing can impact children's social and emotional development by hindering their ability to read facial expressions and non-verbal cues, which are essential for communication and social interactions. The psychological stress associated with mask-wearing, combined with disruptions to usual human interactions have raised worries about the long-term effects on children's development and educational progress during the pandemic. In a 2023 report by Komodo Healthcare, speech disturbances and delays in children aged 0-12 increased 110% in 2022 compared to pre-pandemic times.[183] Similar data was seen

through a poll of audiologists and speech-language pathologists conducted by the American Speech-Language-Hearing Association ("ASHA") where an increase in referrals were seen for children aged birth to 5 years concerning hearing, speech, and language delays.[184]

Conclusion and Recommendations

Due to the lack of evidence to support community masking as an effective means in preventing COVID-19 transmission, questions have been raised regarding the collection and review of data, and ultimate decisions to mandate masking in Alberta throughout the pandemic. Given mask mandates were also implemented in Alberta schools, with significant impacts to students' physical and mental health, learning capabilities, and social and language development, gaining a good understanding of what decision-makers based this policy on is critical to understanding how Alberta can appropriately respond to any future health crisis.

It is inaccurate to suggest that masking is entirely safe and provides effective protection against SARS-CoV-2 infection. Our data review found that there is an absence of evidence show protection from continuous masking against respiratory illnesses, including COVID-19, using medical/surgical masks, or even N95 respirators. The efficacy of masking to prevent viral transmission remains a contested area of study, however an overwhelming amount of research has determined that masking outside of healthcare settings does not provide statistically significant protection against transmission, and in fact can have an undesired affect through incorrect usage, contamination, and a false sense of security as well as long term negative impacts on the developing child.

Recommendations

1. **Public mask messaging to Albertans should be updated.** Specifically, there is no evidence to indicate Alberta should shift away from pre-COVID-19 masking policies. The policy-grade data indicates a lack of masking effectiveness at protecting against SARS-CoV-2 infection. This includes continuous masking in the community and

universal masking within the healthcare setting. The potential harms from masking need to be highlighted, especially among children.

2. **Alberta should refrain from future mask mandates for respiratory illnesses.** The choice to wear a mask is a personal medical decision, guided by informed consent and patient autonomy. As such, the maxim that "Where there is risk, there must be choice" should guide any future policies.
3. **Children should not participate in continuous or universal masking.** Children have very low-risk from COVID-19, and do not readily spread SARS-CoV-2.[185] This dispels the myth that children posed a transmission risk to adults.
4. **There is no benefit for masking asymptomatic individuals**. Asymptomatic SARS-CoV-2 transmission occurs in < 5% of cases.[186] Symptomatic Albertans should avoid being in public and consider isolation at home. For some symptomatic individuals, there remains a false sense of security that they cannot transmit SARS-CoV-2 if wearing a mask. Publicly acknowledging this will help to lower SARS-CoV-2 transmission.
5. **Alberta should adhere to the Canadian Biosafety Handbook which categorizes SARS-CoV-2 as a biosafety level 3 pathogen.** This requires stringent engineering controls for containment, including the need to dilute, filter and destroy SARS-CoV-2 with ventilation technologies.[187] Such approaches have already been successfully implemented by the airline industry, schools, and assisted-living facilities.[188]

Questions

1. Given the available research, why did Alberta public health officials, government, and agencies advocate for masks as effective against SARS-CoV-2 and begin enforcing surgical mask recommendations and mandates?
2. Why were harms associated with masking, especially in children, not considered when mandating masks in Alberta schools and communities?
3. Why was masking allowed to be mandated in schools given that children were at low risk of severe COVID-19 outcomes?

4. Given the lack of evidence to support the efficacy of masking, why were most individuals denied mask exemptions?

Chapter 6: Testing

Executive Summary

The Task Force conducted a comprehensive review of testing strategies employed in Alberta's COVID-19 response. The primary focus was on PCR-based testing, serological testing, and rapid antigen tests (RATs). The findings of the review shed light on several important aspects of testing and provided valuable recommendations for optimizing testing strategies.

Regarding PCR-based testing for COVID-19, the Task Force acknowledged the significant increase in testing capacity but found the accuracy of the tests and potential for false-positive and false-negative results to be concerning. The Task Force also found the proportionality of PCR-based screening for asymptomatic individuals to be questionable and suggested that testing should be based on established risk factors instead.

In terms of serological testing, it is important to use assays that assess a spectrum of antibodies and epitopes to accurately measure immunity. Antibody tests need to be appropriately selected and professionally administered to ensure reliable results. Serological tests are not suitable for diagnosing current infections but can provide valuable information about previous exposure.

COVID-19 rapid antigen test (RAT) performance varied, raising concerns about accuracy as a screening tool. The Task Force advises against using RATs to guide containment measures and underscores the importance of obtaining reliable surveillance data. There are also still concerns about COVID-19 testing bias and the possible wrong interpretation of vaccine performance. Because of these issues, the use of RATs and surveillance data needs to be reevaluated, taking into account the limitations of test performance and policy concerns.

Overall, the Task Force highlights the need for further evaluation and validation of testing methods. It is important to tailor testing decisions based on local context, including testing capacity, the stage of the pandemic, and individual needs. The Task Force recommends

optimizing testing strategies to improve accuracy and ensure the effective use of testing resources in future pandemic responses.

- The Task Force conducted a review of PCR-based testing, serological testing, and rapid antigen tests (RATs) in Alberta's COVID-19 response.
- Concerns were raised about the accuracy of PCR tests and the potential for false-positive and false-negative results.
- The Task Force questioned the proportionality of PCR-based screening for asymptomatic individuals and suggested testing based on established risk factors instead.
- Serological testing was highlighted as a valuable tool for measuring immunity, with a recommendation to use assays that assess a spectrum of antibodies and epitopes for accurate results.
- Professional administration of diagnostic testing and appropriate selection of antibody tests is important to ensure reliable results.
- The performance of RATs varied, and concerns were raised about their accuracy as a screening tool.
- The Task Force recommends RATs not be used to direct containment measures.
- Testing bias and the potential misinterpretation of vaccine performance are concerning; RATs and surveillance data should be re-evaluated considering test performance limitations and policy considerations.
- Further evaluation and validation of testing methods is necessary.
- Testing decisions should be tailored based on local context and individual needs.
- The recommendations provided by the Task Force aim to optimize testing strategies, improve accuracy, and ensure the effective use of testing resources in future pandemic responses.

Introduction

The COVID-19 pandemic presented unprecedented challenges for public health systems worldwide, prompting swift and dynamic responses across different jurisdictions. This chapter explores the development of COVID-19 testing regimes by health system regulators in Canada and their implementation by public health authorities in Alberta during the pandemic.

COVID-19 testing falls broadly into two categories: 1) diagnosis and screening for active infections and 2) detection of previous infections. The practical implications of national regulator-based schemes for the approval of COVID-19 tests during the pandemic were that they allowed local authorities to determine whether to use certain tests for specific purposes, such as screening, policy development, or diagnosis.

The following topics outline the challenges in diagnosing, screening, and detecting COVID-19 across various testing methods used during the pandemic. Our review shows the flaws in polymerase chain reaction (PCR) testing, which involves amplifying samples over and over in the lab to find viral genetic material remnants, with the risk of getting false positives or negatives. Additionally, we found that rapid antigen tests have low sensitivity, often necessitating repeated or serial testing to identify SARS-CoV-2. Our review demonstrates that the efficacy and accuracy of COVID-19 testing evolved rapidly and provisionally throughout the pandemic, as reflected in scientific literature and clinical results.

What Was Done

COVID-19 Testing in Canada and Globally

There are two main categories of testing for COVID-19 infections, for which both Health Canada and global regulatory bodies have developed approved testing regimes. The first category consists of diagnosing and screening for active infections. The second comprises tests that detect previous infections. It is important to note that regulators have provided guidance regarding each type of COVID-19 test approved for use and noted limitations arising in each testing category and method.

Diagnosing and Screening for Active Infections

Throughout the pandemic, the main NAATs used were polymerase chain reaction (PCR) tests and loop-mediated isothermal amplification (LAMP) tests. These tests detect the genetic material of SARS-CoV-2 through amplification of a known genomic target. PCR tests are highly sensitive and specific, while LAMP tests are highly specific but less sensitive than PCR. These two tests formed the basis for diagnosing people infected with SARS-CoV-2.

Limitations – Nucleic Acid-Based Testing[189]

Most PCR tests that look for the ribonucleic acid (RNA) or genetic fingerprint of the SARS-CoV-2 virus use a method where certain parts of the virus's genetic fingerprint are made much stronger by repeating biochemical and enzymatic reactions up to 45 times. These are called amplification cycles. The number of amplification cycles required to create enough copies is inversely proportional to the viral load in infected individuals.[190]

The more RNA present in a patient sample, the fewer cycles are required for a COVID-19 infection signal to reach the detection threshold (i.e., have a low cycle threshold, or Ct). The less RNA present in a clinical sample, the more cycles are required to detect it. Therefore, a low Ct value corresponds to a high viral load, while a high Ct value corresponds to a low viral load.[191]

As a result, the greater the Ct value, the more likely the test will find a positive COVID-19 infection. It is not possible to directly translate a Ct value into degree or duration of infectiousness. A person is deemed infectious if they shed virus particles that are intact and able to be transmitted to infect others.[192] PCR tests only measure levels of a known viral RNA sequence that may or may not be actual replication-competent viral particles, and that a person who has recovered from COVID-19 may test positive with a viral load Ct > 30 for up to 90 days. As a result, it is not recommended that Ct values be routinely clinically reported with SARS-CoV-2 RT-PCR results.

While it was simpler to categorize all PCR positive samples as patients with SARS-CoV-2 it can only be determined if a patient has COVID-19 if they are

symptomatic. Reporting COVID-19 cases as all those people who were PCR+ created a (possibly unreliable) "casedemic".

Limitations – Rapid Antigen Detection Tests

Rapid antigen detection tests (RATs), sometimes called COVID-19 rapid tests, are used to detect virus proteins. While the technology is advancing, antigen tests are generally less sensitive than molecular tests for diagnosing COVID-19 in people who have no symptoms of illness (i.e., asymptomatic). Antigen tests are, however, useful because they are easily deployed, can save on costs (vs. NAATs), and can be used to screen asymptomatic people – especially when tested at regular intervals (i.e., serial testing).

Serial testing is usually done two to three times over a period of 36 hours. This increases the overall sensitivity of the RATs by allowing detection of the virus when levels begin to increase in infected individuals.

A commercial PCR test roughly costs $100 per sample, whereas a RAT is roughly $16 per sample. ***An outstanding question is:*** *how much public money was spent on PCR reagents and RATs that went unused and expired?*

To help ensure the most accurate test result can be obtained, Health Canada recommends that manufacturers of COVID-19 antigen self-tests add a serial testing claim to instruct people who are suspected of being infected with SARS-CoV-2 virus:

- After the first negative test, test again 48 hours later, if you have symptoms.
- After the first negative test, test again 48 hours later and then another 48 hours after the second negative test if you do not have symptoms.[193]

As vaccination levels increased, Alberta implemented "back to normal policies" in the fall of 2021 based on vaccination status. First, in the summer of 2021, screening requirements for fully vaccinated close contacts, healthcare workers, and residents being admitted to or returning to congregate living facilities were lifted. Second, in the fall of 2021, AH

encouraged public sector organizations to adopt vaccination policies that often required frequent RAT testing of only unvaccinated employees to return to work. For those employees working in high-risk areas, RAT results would need to be confirmed with a PCR test, which, if positive, would then be recorded as a COVID-19 case.

Detection of Previous Infection Through Antibody Tests

The second category of COVID-19 testing encompasses serology or antibody tests. These tests do not detect the virus itself. Rather, they detect antibodies in the blood that are produced in response to a previous infection by the SARS-CoV-2 virus vaccination. Most serology tests are not able to distinguish the source that is the cause of the antibodies (for example, from vaccination or a previous infection). They also cannot confirm that an individual has adequate antibodies in their blood to protect them from future infection.

Limitations – Understanding Serological Testing Results

Antibody production reflects only one component of the overall immune response to infection, and care is required when interpreting serological test results. However, infection produces different types of antibodies at different stages of an infection:

- Early antibodies, called IgM antibodies, provide the first indication of the body's response to an infection;
    - these antibodies are not as specific and generally are not as long-lasting, so interpreting their significance requires clinical experience.
- IgG antibodies are specific to a virus, such as the SARS-CoV-2 virus;
    - early research results suggest these antibodies can be reliably detected 14 days after a person is infected with COVID-19.[194]

Antibody tests for respiratory infections measure antibodies produced either in the blood or mucosa. The accuracy of an antibody test depends on the quality of the specimen collected, test performance, and the timing of the test, among other factors. The relationship between antibodies in response to infection and immunity to infection with SARS-CoV-2 is still unknown. It is unclear whether people with antibodies from previous infection are immune to re-infection, or if they are still infectious to others when reinfected.

The sensitivity of serological testing in elderly or immuno-compromised people is also unknown. This is because their age or condition can have an impact on their body's immune response. Also, antibodies are present for an undetermined period after an infection has ended. For the above reasons, serological test results should be interpreted with caution.

Regardless of the category of the COVID-19 testing regime, Health Canada and other global regulators are responsible for approving tests deployed for use in their respective jurisdictions. The practical implications of a regulator-based approval scheme for COVID-19 tests are to allow local authorities to determine whether to use certain tests for specific purposes such as screening, policy development, or diagnosis. This brings an inherently local analysis to the efficacy of a given test chosen for a specific purpose.

Data Reviewed

COVID-19 Testing in Alberta

The Alberta Health Services Scientific Advisory Group ("SAG") conducted three rapid response reviews on the utilization of various COVID-19 testing practices in Alberta.

1. 2020-04-17 – Rapid Review: Comparison of testing characteristics for RT-PCR using different swab methods;[195]
2. 2020-04-22 – Rapid Review: The role of serologic testing for COVID-19 and potential indications;[196] and
3. 2020-11-17 – Rapid Review: Performance and feasibility of rapid COVID-19 tests.[197]

The 2020-04-17 – Rapid Review: Comparison of testing characteristics for RT-PCR using different swab methods

In conducting this rapid review, the SAG was tasked with assessing the negative predictive value of COVID-19 testing when using PCR tests. The SAG focused on the collection of the COVID-19 sample to see if any collection methods differentiated to produce negative predictive values or invalid tests. The SAG focus was based on concerns raised by clinicians about variability in testing characteristics (e.g., sensitivity, specificity, and negative predictive value) depending on the anatomical site from which the sample was taken.

The SAG found, *inter alia*:

- Problems with swab collection have been noted, and it is unknown how the anatomical site of sampling and the timing of the sample relative to the disease progression affect the likelihood of RNA detection in a person who is infected with SARS-CoV-2.
- There is very limited data regarding the negative predictive values and clinical sensitivity and specificity of commercially developed molecular tests for SARS-CoV-2. What data that exists publicly is a different assay from what is used in Alberta, and comparisons should be made with caution.
- Studies comparing RNA detection from different sites used samples collected from any of the following sites: nasopharynx (NP), nose, throat, sputum, or bronchoalveolar lavage (BAL) fluid. The evidence was mixed with respect to the superiority (or inferiority) of nasal swabs compared to throat swabs. A small study (n = 30) that is ongoing in Alberta indicates that NP and throat swabs may be equivalent while nasal swabs may have lower sensitivity. It is suspected that this is related to a lack of familiarity with deep nasal swab collection and poor collection technique, though this is based on anecdotal evidence.
- Based on the evidence, false negative samples are infrequent but do occur and would appear to result from insufficient sample collection, emphasizing the importance of proper sampling.
- The current lack of a gold standard for confirming positive cases is a significant challenge.
- Nasopharyngeal swabs are preferred for COVID-19 sample collection. When this is not possible, for instance due to potential shortages in NP swabs, throat swabs can be used, but more evidence is needed to ensure that throat swabs are equivalent in quality to NP swabs for the purposes of COVID-19 testing.
- Information should be distributed to remind clinicians that a negative PCR can occur, and a negative result does not mean that the case is a true negative, especially when there is a high probability of disease. Clinical judgment and multiple lines of evidence (such as clinical signs and symptoms, medical imaging results, and contact with lab-

confirmed cases) should be considered when making decisions for patient care and staff protection.

Further Research on Different Swab Methods

A review of best practices for respiratory virus testing published in 2011 found that the detection of 12 respiratory viruses using a nucleic acid amplification test (NAAT) panel was significantly less sensitive with oropharyngeal (OP) swab specimens (54.2%) than with either NP swabs (73.3%) or NP wash specimens (84.9%).[198] Both nasal and oropharyngeal swab samples are not recommended because of concerns about sensitivity.[199] A systematic review of specimen collection methods for influenza found that combining nasal and OP swabs resulted in a test with approximately the same sensitivity as an NP swab in both children and adults.[200] A review by the Centre for Evidence-Base Medicine (CEBM) compared the accuracy of OP swabs to NP swabs for COVID-19 and found two low-quality studies that suggested NP swabs yielded a higher detection rate than OP swabs.[201]

The infection dynamics of COVID-19 and how they relate to detecting the virus are also unclear, as it has been shown that both OP and NP swabs can yield negative results in positive cases (confirmed by BAL) or can test positive after long periods of negative results.[202] Viral load between sample sites has also been compared, and the evidence is inconclusive with respect to whether the nose or the throat is a better sample site.[203] Zou et al. (2020) suggest that nasal swabs are better during days 1-6 post-symptom onset, while Yuan et al. (2020) suggest that throat swabs are superior to nasal swabs.[204] Another report comparing viral loads in NP and throat swabs found no difference in nine confirmed COVID-19 positive patients.[205] The observed differences may be due to sample collection method and variability between collectors, which is not often controlled in these studies. Different swab methods will likely have a significant influence on a test's results, potentially playing a crucial role in policy decisions.

The 2020-04-22 – Rapid Review: The role of serologic testing for COVID-19 and potential indications

In conducting this rapid review, the SAG examined the highest priority indications for the use of serologic testing for COVID-19 clinical purposes and to inform public health efforts in Alberta.

The SAG found, *inter alia*:

- No evidence was identified to inform the clinical or public health implications of serological testing in special populations such as immunocompromised people, critical care patients, or the organ transplantation community.
- There was no direct evidence for using serology to inform 'return-to-work' ("RTW") policies. However, findings from the immunological and infection dynamics during infection suggest that a combination of RNA testing, IgG testing, and IgM testing may help inform RTW decisions for healthcare personnel once a better understanding of the antibody response to infection is gained.
- It is not recommended that serological testing be used to inform decisions around healthcare worker RTW policies or for acute care diagnostics.

2020-11-17 – Rapid Review: Performance and Feasibility of Rapid COVID-19 Tests

In conducting this rapid review, the SAG was tasked with assessing the performance characteristics of the rapid COVID-19 tests that have been approved for commercial (diagnostic) use in Canada as well as advising on the optimal strategies for deployment of rapid testing to improve either clinical care or outbreak control in health care and community settings.

The SAG found, inter alia:

- The body of evidence for rapid testing platforms is poor – many of the studies are at high risk of bias. It is important to note that the evidence on this topic is rapidly evolving, and meta-analytic findings should be considered carefully rather than accepted as truth. No high-quality evidence was identified regarding the deployment of rapid tests.

- Studies validating rapid test platforms are generally at high risk of bias and often do not report the sensitivity and specificity of the platform. Instead, the reported results are framed as concordance with the reference standard (usually an NP swab tested on an RT-PCR platform). The applicability of these results may be limited in the Alberta context.
- The manufacturers' specifications for testing kits are often higher than the characteristics seen under real-world conditions.
- Guidelines from the WHO, Health Canada, and the United States Centres
- for Disease Control and Prevention suggest that rapid testing should be deployed in settings where repeat testing and/or rapid turnaround times are important. Situations where rapid tests could provide benefit include outbreak control, proactive monitoring in populations with high community prevalence, monitoring high-risk congregate living settings (e.g., homeless shelters), or in communities where standard testing is not available, such as remote Indigenous communities.
- Beyond the clinical sensitivity and deployment strategy, there are practical implementation considerations to be made. The availability of the test kits is a major driver of which assays are implemented. The Public Health Agency of Canada distributed many Abbott ID NOW and Panbio kits and instruments at no cost to the province, while the technically superior Cepheid kit has relatively low availability and would have had to be purchased by APL for implementation.
- Expert opinion on the deployment of rapid test platforms suggests that these tests can be used as a surveillance tool for lower-risk populations to conserve diagnostic testing capacity for populations where accuracy is paramount.

Further research of Rapid Antigen Tests

Meta-analyses show that for rapid nucleic acid testing systems, the Abbott ID NOW system has notably lower sensitivity than the Cepheid Xpert Xpress system.[206] Pooled estimates of testing characteristics suggest that the sensitivity of Abbott ID NOW is 77- 80%, although the specificity is 99-100%.[207] The Cepheid Xpert Xpress platform is approximately 99% sensitive and 97-100% specific.

Systemic bias against Abbott systems is suggested by Mina et al. (2020), who rebuts the findings of Basu et al. (2020), included in the meta-analyses.[208] Mina et al. (2020) comment that some factors that may have resulted in reports of lower sensitivities for the Abbott ID NOW are the type of sample handling procedures, populations skewed towards very low RNA concentrations, and different specimen collection. However, the Mina study itself is heavily biased towards Abbott and should be considered with a critical eye.

Two sets of guidelines were identified describing a model for rapid test distribution and implementation.[209] Health Canada and the WHO both suggest using rapid testing to monitor high-risk situations. These might include outbreak control, proactive monitoring in populations with high community prevalence, or use in remote/closed communities where standard testing is not available. The guidance also suggests using rapid testing platforms to supplement capacity for asymptomatic testing (if there is sufficient sensitivity) or as a screening tool for symptomatic individuals, followed by confirmatory RT-PCR.

Both Health Canada and WHO note that antigen tests (such as BD Veritor and Panbio) should be used with caution where the decrease in sensitivity may result in missed cases, such as in areas with low prevalence, where critical actions rest on the results (such as treatment decisions or individuals in high-risk settings), or where the lower sensitivity can't be mitigated by repeated testing protocols.

The U.S. CDC w more specific with their guidance on rapid antigen tests.[210] They suggest that the antigen tests should be used for screening in high-risk congregate settings where repeat testing may quickly identify SARS-CoV-2 positive individuals, and that RT-PCR be used to confirm the screening test when the antigen test result is inconsistent with the clinical context. The test results from an antigen test should be considered presumptive; however, they may not need confirmation if there is a correlated pretest probability of disease (e.g., high pretest probability prior to a positive test result).

In 2020, the United States Department of Health and Human Services purchased 150 million Abbott BinaxNOW lateral flow colourimetric antigen tests and published an overview of their

distribution plan.[211] The distribution pattern appears to balance clinical need with equity. The plan can be summarized as follows:

- States: 100 million tests to be distributed at their discretion.
- Nursing homes and assisted living: number based on degree of positivity in the county. Areas with >10% positivity get tests for all staff twice per week; areas with 5-10% positivity get tests for 50% of staff once per week.
- Home Health and Hospice: Largest 100+ agencies receive tests to allow for staff testing once per week.
- Historically Black Colleges and Universities: Allocation based on number of staff and students. May be used at HBCU leaders' discretion.
- Indian Health Service: 300K tests distributed for eligible health programs; allocation at IHS discretion.

Briefly, diagnostic testing by RT-PCR should be designated for high-risk populations (to themselves or the public) or for confirming the results of screening tests.[212] Rapid tests with reasonable precision can be used to screen the proportion of the population that exceeds diagnostic capacity (e.g., lower risk, asymptomatic, contacts, etc.), with diagnostic testing as a confirmatory step.

Conclusion and Recommendations

Test Strategies

Our review of the data regarding the testing implemented during COVID-19 shows that conflicting studies and information regarding test types, administration methods, cycle thresholds, and testing of symptomatic and asymptomatic individuals may have resulted in inconsistent determinations regarding the actual infection rate in Alberta. As a result, these inconsistencies could have influenced subsequent decisions and policies, which include secondary and tertiary impacts such as the unnecessary costs associated with the tests, broader economic impacts on both the province and Albertans, and lockdown measures including isolation, masking, and business closures. Consequently, the task force has identified the following recommendations:

1. RT-PCR represents an excellent high-sensitivity test to aid in accurate diagnoses of symptomatic people – if they are used for the intended purpose and at optimal Ct values (vs. Ct values at "high positive" cut-offs).
2. Rapid tests with reasonable accuracy should not be used for screening the general population but could be used as an additional diagnostic tool, where clinically indicated.
3. We recommend that future pandemic responses prioritize minimizing severe disease and mortality over extensive case detection. Specifically, Alberta should focus on developing a screening tool to help estimate individual risk. This approach will optimize resource use by directing testing capacity, which can be appropriately directed by evidence-based practices, such as testing symptomatic individuals, those whose management may be influenced by test results, and for specific surveillance scenarios.
4. We recommend that levels of immunity be gauged using a multi-antibody serological and/or mucosal assay that accounts for both pre-existing immunity as well as the presence of immune cells with the potential for cross-protection.
5. All tests should also be professionally administered and sufficiently sensitive to detect low antibody levels while sufficiently specific to distinguish between target and non-target antibodies. This also applies to laboratory tests used to identify specific respiratory viruses. Individual risk estimates can then be used to inform individual needs for protection either through the use of personal protective measures and/or vaccination.
6. Without being linked to a set of standardized clinical criteria, we recommend against the use of PCR tests as the sole criteria for a case definition. A confirmed case should include a pre-determined profile of signs and/or symptoms AND a positive test for the infection of concern PLUS any relevant patient history and confirmed epidemiological information.
7. Ensure that local surveillance data are used and interpreted when determining strategy and policy.

Chapter 7: Infection Acquired Immunity

The Task Force reviewed infection-acquired immunity in the context of COVID-19, comparing it to vaccine-acquired immunity based on scientific data. The findings emphasized the durability and effectiveness of infection-acquired immunity as a protective measure. We conclude that a comprehensive approach considering both types of immunity is crucial for transparent and effective public health messaging and policies during pandemics.

- The Task Force reviewed the concept of infection-acquired immunity and its implications for public health policy and messaging in Alberta during the COVID-19 pandemic.
- Infection-acquired immunity, obtained through prior infection with SARS-CoV-2, can provide durable and protective immune responses.
- Infection-acquired immunity should not be overlooked or downplayed in public health messaging and policies.
- Both vaccination and prior infection contribute to immunological memory.
- The Task Force reviewed evidence suggesting the presence of pre-existing immune responses to SARS-CoV-2 and cross-reactive immunity from previous exposure to related coronaviruses.
- Studies demonstrated similar levels of immune response between vaccinated individuals and those who have recovered from COVID-19, indicating the non-superiority of vaccine-acquired immunity compared to infection-acquired immunity.
- Alberta messaging and policies focused primarily on vaccine-acquired immunity and failed to adequately consider infection-acquired immunity.
- A balanced approach to communicating about immunity, avoiding coerced vaccination in populations with either high levels of infection-acquired immunity or low baseline susceptibility to severe disease, should be pursued to promote truth and transparency in public health messaging.

- The Task Force's findings highlight the importance of considering infection-acquired immunity in public health decision-making and emphasize the need for a comprehensive and nuanced approach to immunization strategies during the pandemic potentiating herd immunity during the pandemic.

Introduction

Public health messaging in Alberta continually emphasized the novelty of SARS-CoV-2 and the urgent need for vaccination. Downplaying infection-acquired immunity resulted in COVID-19 policies based on the belief that vaccines offer superior immunity to infection acquired immunity. The decisions made provincially led to policies based on extensive vaccination requirements, even for those with prior SARS-CoV-2 infection, despite both forms of immunity having benefits for individuals and communities.

Immunological Memory

It has been known since the Athenian plague of 430 BCE that recovered individuals "were never attacked the same way twice – never at least fatally."[213] Remarkably, these observations were made more than 2,000 years before we knew about the immune system or how "germs" play an important role in disease.[214] Today, it is accepted that immunological memory is an integral part of long-lasting protection against previously encountered pathogens when someone is re-exposed, at least for some amount of time. We refer to this as "infection-acquired immunity" and, throughout the chapter discuss it in contrast to "vaccine-acquired immunity".

Protection stemming from immunological memory may be absolute or partial; it may result in sterilizing immunity – that which prevents infection – or non-sterilizing immunity – that which decreases severity of disease if reinfected. With few individuals becoming reinfected early in the pandemic, it was obvious in mid- to late-2020 that most recovered individuals mounted robust and protective immune responses.[215] Although sterilizing immunity may wane over time, protection from severe disease post-COVID-19 is long-lasting as it is with other coronaviruses that cause common colds.[216]

Infection-Acquired Immunity & COVID-19

The issue of infection-acquired immunity was at the core of many disputed pandemic policies. Without durable immunological memory, herd immunity cannot be reached, there would be no effective vaccines, and high-risk individuals would have to be sheltered

indefinitely, unless the virus was eradicated. However, evidence existed early on that prior infection with SARS-CoV-2,[217] as well as other seasonal human coronaviruses,[218] conferred durable protective immunity in the case of SARS-CoV2, meaning that efforts should have been aimed at protecting high-risk individuals until sufficient immunity could be reached in the population through a combination of infection and vaccination.

Despite this early evidence suggesting a degree of pre-existing immunity in the population, public health messaging in Alberta between 2021 and 2022 predominantly emphasized vaccine-acquired immunity, often downplaying the role of infection-acquired immunity. Emphasis on the uncertainties behind "natural" immunity led to misguided COVID-19 policies that vaccines were assumed to have superior immunity compared to the immunity generated by infection, an assumption that led to widespread vaccine mandates even in previously infected people.* Both prior infection and vaccination provide a form of immunological memory, and acknowledging infection-acquired immunity is not an argument against vaccines. For example, the purpose of the measles vaccine is to prevent the clinical symptoms of measles, and any untoward, down-stream outcomes. However, those who have already had measles do not need the vaccine.

What Was Done

Alberta's Use of Infection-Acquired Immunity in Policy & Messaging

Infection- vs. Vaccine-Acquired Immunity

Vaccines are designed to mimic the immune response from an infection while avoiding the risks involved with being infected, such as severe disease. Albertans are capable of understanding risks when given accurate information.

Acknowledging that infection-acquired immunity is superior to vaccine-acquired immunity is not equivalent to promoting infection over vaccination.

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* Here, "natural" immunity is synonymous with infection-acquired immunity (i.e., immunity is acquired after natural infection); it contrasts with the immunity acquired after an "artificial" exposure like vaccination.

From March 2020 onward, AH and the CMOH operated their messaging on the premise that because "[SARS-CoV-2] is a new virus no one has existing immunity", and that "when the young and healthy are [vaccinated] it keeps everyone in the community safer." In several pamphlets distributed publicly, AH wrote that "early evidence suggests that immunity after infection with [SARS-CoV-2] may not last very long, and isn't as strong as vaccine protection, so you should get vaccinated even if you've had the virus." Beginning in mid-2020, many of these statements were already incorrect, but still managed to be at the forefront of AH and AHS policies and public messaging.

Data Reviewed

A Not-So-Novel Coronavirus?

As early as May 2020, several studies from the U.S., Netherlands, Germany, Singapore, the U.K., and Sweden reported finding T-cell reactivity to SARS-CoV-2 antigens amongst individuals with no known exposure to the virus, with rates ranging from 20% to 50%.[219] While these findings did not yet offer precise figures on pre-existing immune responses to the virus, they were compelling and were published in reputable scientific journals such as *Cell*, *Nature*, and *Science*. The observations, despite being small-scale at the time, were indicative of a strong foundation of evidence suggesting pre-existing immune responses to SARS-CoV-2 in populations worldwide.[220]

SARS-CoV-2 also shares 80% homology with SARS-CoV-1 and 50% homology with MERS meaning that individuals previously exposed to circulating HCoVs would most likely have developed antibodies that shared HCoV epitopes providing some degree of cross-reactive immunity.[221]

The presence of pre-existing immunity was later bolstered in March 2021 and July 2022 when two key studies provided evidence to suggest that SARS-CoV-2 may have been circulating in Canada and Italy much earlier than January 2020.[222]

A Valuable Lesson from 2009 Overlooked

Following the 2009 declaration of the H1N1 "swine flu" as a global pandemic, some research demonstrated that pre-existing immunological responses in adults, such as B- and

T-cells, were responsible for mitigating the severity of that "novel" virus.[223] One study from the U.S. CDC found that 33% of individuals aged older than 60 years possessed cross-reactive antibodies to the 2009 H1N1 virus, indicating the presence of pre-existing immunity,[224] while two other studies also showed that individuals with pre-existing reactive T-cells experienced milder H1N1 symptoms.[225] These data ultimately led to a shift in perspective at the WHO away from most people "will have no immunity to the pandemic virus" to one that acknowledged a role of pre-existing immunity in population vulnerability to pandemics.[226]

The Task Force was unable to find any evidence amongst publicly available documents that either AH or the AHS SAG considered these insights from past pandemics. Instead, we learned that, despite evidence to the contrary, policy decisions demonstrated a tendency to "stay the course":

1. AH maintained that "susceptibility used to be universal, [but] COVID-19 vaccines are now available in Canada, and they [are effective] at preventing infection, symptomatic disease and severe outcomes such as hospitalization and death related to COVID-19" and that "[p]revious infection should not be considered a substitute for immunization to meet vaccine requirements such as workplace vaccine mandates";[227] and
2. The recommendations of the AHS SAG emphasized the importance of vaccinating the 300,000 Albertans who had recovered from a documented SARS-CoV-2 infection, despite recognizing the strong infection-acquired immunity that reduces re-infection risk by over 80% for at least 6 months.[228] If AH or SAG would have re-visited this estimate 3 months later, they would have seen that estimate of 6 months triple.[229]

The Non-Superiority of Vaccine-Acquired Immunity

It is important to know if the vaccines can provide the same or similar level of immunity as infection-acquired immunity. Published results from phase I/II trials evaluating the immune response and effectiveness of COVID-19 mRNA vaccines demonstrated that 21-day plasma IgG levels post-second dose shared considerable overlap with convalescent plasma levels

from individuals who had recovered from COVID-19.[230] Although authors interpreted the study results as evidence of the activity of the two dose regimens, the study also demonstrated the equivalency of two doses to a single natural exposure in terms of plasma IgG levels (see Figures 1-2), not the reverse.

Figure 1. Immunogenicity of Pfizer mRNA Vaccine compared to >14 days convalescent plasma.[231]

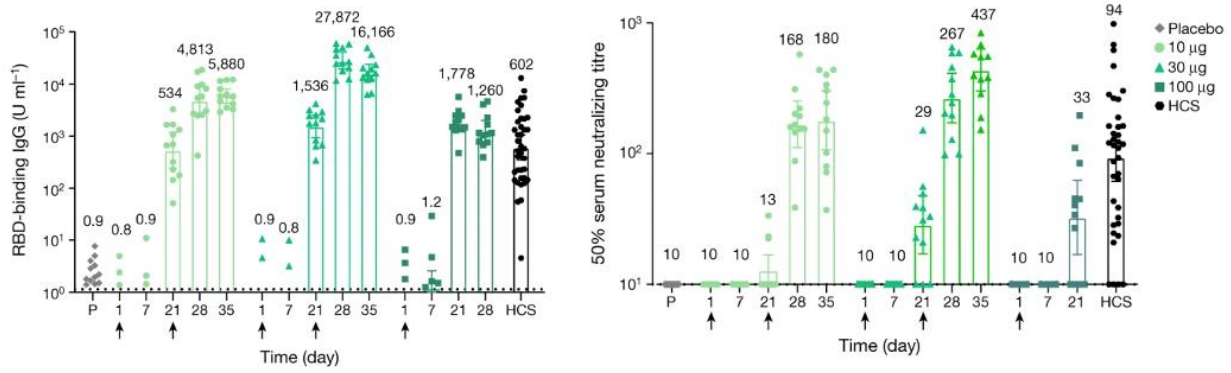
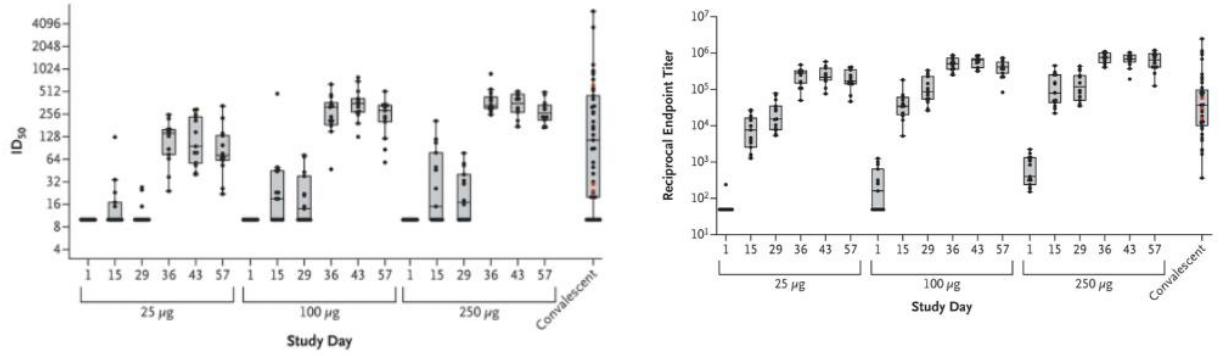


Figure 2. Immunogenicity of Moderna vaccine compared to <30 days convalescent plasma.[232]



Early important population-level studies on that topic were conducted in Israel,[233] Sweden,[234] and Qatar.[235] Of these, the most-significant finding was in August 2021 – before Alberta's REP took effect – in Israel.

This study demonstrated that SARS-CoV-2-naïve vaccinees had a 13.1-fold (95% CI: 8.08 to 21.11) increased risk for breakthrough infection with the Delta variant compared to unvaccinated-previously-infected individuals. The increased risk was much more substantial for symptomatic disease with SARS-CoV-2-naïve vaccinees being at a 27-times

higher (95% CI: 12.7 to 57.7) than the previously infected group. A later study from Qatar confirmed the findings of the Israel study demonstrating that natural infection cohort was 2-4 times less likely to be infected or experience severe, critical, or fatal COVID-19, respectively (Table 1). However, the SAG's rapid review did not place any emphasis on these findings. Why?

The narrow focus on maximizing vaccine coverage is evidence that Alberta's readiness to roll-out of vaccines for future pandemics needs revision.

Table 1. Hazard ratios for the incidence of SARS-CoV-2 infection as well as severe, critical, and fatal COVID-19 outcomes.[236]

	Natural infection versus BNT162b2 vaccination study		Natural infection versus mRNA-1273 vaccination study	
	Natural infection cohort	BNT162b2-vaccinated cohort	Natural infection cohort	mRNA-1273-vaccinated cohort
Total follow-up, person-weeks	1985243	1921539	1374220	1338649
Incidence rate of infection, per 10000 person-weeks	18·1 (17·5–18·7)	37·1 (36·2–37·9)	16·7 (16·1–17·4)	32·0 (31·0–33·0)
Unadjusted HR for SARS-CoV-2 infection	0·48 (0·46–0·50)	1 (ref)	0·51 (0·49–0·54)	1 (ref)
Adjusted HR for SARS-CoV-2 infection*	0·47 (0·45–0·48)	1 (ref)	0·51 (0·49–0·54)	1 (ref)
Unadjusted HR for severe, critical, or fatal COVID-19†	0·25 (0·08–0·77)	1 (ref)	0·27 (0·06–1·32)	1 (ref)
Adjusted HR for severe, critical, or fatal COVID-19*†	0·24 (0·08–0·72)	1 (ref)	0·24 (0·05–1·19)	1 (ref)

95% CIs for HRs and incidence rate are shown in parentheses. HR=hazard ratio. *Cox regression analysis adjusted for sex, 10-year age group, ten nationality groups, comorbidity count (table 1), and timing of primary infection or first-dose vaccination. †Severe, critical, and fatal COVID-19 cases were defined according to WHO guidelines.[37,38]

***Table 2*: HRs for the incidence of SARS-CoV-2 infection and severe, critical, and fatal COVID-19**

Herd Immunity: Misunderstood?

In theory, outbreaks of contagious disease follow a certain trajectory. In a population that lacks immunity new infections grow rapidly. However, as the number of susceptible people decreases, an inflection in this growth occurs and the incidence of infection will begin to fall.

The term "herd immunity" refers to a threshold where a sufficient proportion of people in a population have acquired immunological memory against a specific infectious agent, either through recovery from infection or vaccination, so that the agent can no longer circulate at epidemic levels. It is not an all-or-none phenomenon, nor is it maintained at a fixed threshold, and it does not necessarily refer to infection being eradicated.

On the contrary, once herd immunity is achieved, an endemic equilibrium stage is reached in which the infection rate shifts to a dependency on the rate of waning immunity and the growth in the number susceptible individuals. With seasonal effects, it is possible to reach herd immunity during summer months with the epidemic reemerging when seasonality raises the reproductive number during the fall or winter.

For some infectious diseases such as measles, vaccination results in immunological memory that can last for at least 14-15 years – and may require booster vaccination – while immunity from infection is discussed as lifelong as long as re-exposure occurs over time.[237] For SARS-CoV-2 and other related HCoVs, immune protection against reinfection ranges between 18 months and 2-11+ years, depending on the immune cells measured.[238] However, these shorter periods of immunological memory do not mean that herd immunity cannot be achieved. Rather, periodic reinfections that lead to mild (if any) disease or vaccination will restore community protection while protection from severe disease is maintained.

Public statements from AH and the former CMOH have demonstrated that this concept was poorly understood at the highest levels. In an article posted on October 28, 2020, entitled "Herd Immunity and the Great Barrington Declaration" (no longer available online), the former CMOH questioned whether the phenomenon of herd immunity applies to SARS-CoV-2. The conclusion reached by the former CMOH was that herd immunity cannot be maintained if immunological memory is lost. But this is incorrect.

The emergence of herd immunity does not require life-long sterilizing immunity, an effective vaccine, or universal vaccination. It only requires the weaker condition that $R_E(t)$ remain below 1 so that new infections arise at a slower rate than old infections are removed. This

means that herd immunity is also driven by the infectivity of the pathogen, the rate of recovery, the rates of births, migration, and deaths in the population – not just the loss of immune people. While herd immunity may not entirely limit transmission, it will protect against severe disease. This is the very same premise that vaccination is based, and yet when discussed in the context of infection-acquired immunity, was conveniently absent from any AH or AHS messaging.

Conclusion and Recommendations

In April 2022, Omicron likely appeared when exposure to other SARS-CoV-2 variants was already high, and people were being infected a second time – thus giving the appearance of reduced virulence. In response, Alberta, and other jurisdictions across Canada relaxed most restrictions and gave people free access to rapid tests, relying on people to decide for themselves what measures to take to protect themselves. In this final phase of the pandemic, exposure to circulating variants would continue to maintain high levels of population-wide immunity. Despite this, AH continues to promote boosters as a means of maintaining immunity.

We were unable to identify any quality data supporting the AH's ongoing assumption that waning antibody levels are proof of population-wide susceptibility to severe disease. We were also unable to identify any well-conducted comparative studies demonstrating that vaccines provided better protection from severe disease than natural exposure to circulating variants. For the Task Force, this raises concerns regarding the ability of both AH and AHS to collect useful data and reliably use those data to inform booster policy moving forward.

Recommendations

To improve public health policy and messaging in the future, several key changes are required by the Alberta Government:

Recommendation 1: *A balanced and nuanced approach to communicating about immunity is essential – for example, vaccination is*

> *not the sole conduit to being "immunized", and it sometimes fails to achieve this goal.*

AH needs to acknowledge the individual roles of vaccine-acquired and infection-acquired immunity, explaining their similarities and differences, and their synergy to achieving herd immunity. This should also include recognizing those people who might benefit from a combination of both.

> ***Recommendation 2**: Avoid coerced vaccination of any population, especially when there are high levels of infection-acquired immunity and/or low baseline susceptibility to severe disease.*

Acknowledge the limitations of current knowledge, avoid sensationalism, and engage in open dialogue with the public. Overall, being transparent and truthful in public health messaging is crucial.

> ***Recommendation 3:** Public health policy that incorporates immunological concepts needs to be grounded in sound fundamental principles and to avoid ideological bias geared towards maximizing vaccine coverage.*

This involves recognizing the complexity of the immune response and the diversity of individual experiences, and tailoring policies to reflect this reality.

Chapter 8: Vaccines

Executive Summary

The Task Force conducted a comprehensive review of the data and decisions related to the approval and use of COVID-19 vaccines in Alberta. The Task Force analyzed various aspects, including the risk of COVID-19 to the public, the safety of the vaccines, their effectiveness in preventing transmission, hospitalization, and death, and the specific impact on minors.

The Task Force found that the risk of severe COVID-19 infection or death is primarily associated with age, with the elderly being most at risk. Children and teenagers have a very low risk of serious illness from COVID-19. COVID-19 vaccines were not designed to halt transmission and there is a lack of reliable data showing that the vaccines protect children from severe COVID-19.

In terms of safety, the Task Force identified reports of deaths and injuries attributed to the vaccines, as well as a known risk of myocarditis, particularly in young males. The long-term safety of the vaccines is undetermined due to their rapid deployment and limited follow-up.

Task Force recommends halting the use of COVID-19 vaccines without full disclosure of their potential risks, ending their use in healthy children and teenagers, conducting further research into their effectiveness, establishing support for vaccine-injured individuals, and providing an opt-out mechanism from federal public health policy.

Overall, the Task Force's review highlights the need for a careful assessment of the risks and benefits associated with COVID-19 vaccination, particularly in specific populations such as minors. Further research, transparency, and individual choice in decision-making will be important for any future pandemic response vaccination initiative.

- The Task Force conducted a review of COVID-19 vaccines in Alberta.
- They found that severe COVID-19 primarily affects the elderly with comorbidities.
- Children and teenagers have a low risk of serious illness from COVID-19.

- The COVID-19 vaccines were not designed to halt transmission of the virus and there is limited data on their effectiveness in preventing severe illness in children.
- Reports of deaths and injuries attributed to the vaccines were identified, as well as a known risk of myocarditis, particularly in young males.
- The Task Force recommends halting the use of vaccines without full disclosure of their potential risks, ending their use in healthy children and teenagers, and providing support for vaccine-injured individuals.
- The Task Force recommends additional research and an opt-out mechanism from federal public health policy.
- Careful assessment of risks and benefits, transparency, and individual choice in decision-making are vital for any future pandemic response vaccination initiative.

Introduction

This chapter examines the data surrounding the COVID-19 vaccines mandated to much of the Alberta workforce and public. Amidst a global pandemic that posed a significant threat to a substantial portion of the population in Alberta, Canada, and worldwide (refer to the Modelling Chapter), our healthcare system faced the constant strain and risk of being overwhelmed. This crisis and threat dominated the daily narrative everywhere. This fear was leveraged internationally to push several novel vaccine platforms through development, delivery, and implementation in record time through Emergency Use Authorization (EUA). The expedited process incurred profound consequences. The EUA approval pathway left large holes in the efficacy and safety data that is now being questioned by academic and clinical specialists internationally. This chapter will focus on the data and decisions surrounding the approval and continued use of the COVID-19 vaccines in Alberta.

Summary of Key Findings

- Health Canada was solely responsible for approving COVID-19 Vaccines.
- Health Canada's definition of an "ideal vaccine" is a vaccine that is safe with minimal adverse effects and effective in providing lifelong protection against disease after a single dose.
- NACI identified significant gaps in the COVID-19 vaccines during the approval process. The Task Force did not find discussion of these gaps anywhere in the Alberta data.
- NACI recommends the COVID-19 vaccines despite the concerning gaps in safety and efficacy data provided.
- Results of a risk assessment for the Alberta population performed by the Chief Medical Officer of Health (CMOH) or the Scientific Advisory Group (SAG) are unknown.
- The highest risk of severe infection was in people 75 years old and older, with two or more comorbidities. It is unknown why vaccines were aggressively pushed for people under 60 with much lower risk profiles.

- Pfizer vaccine safety data from the three-month post-authorization trial was alarming.
    - 1,223 deaths attributed to the vaccine.
    - 42,086 people injured within 4 days of vaccination.
    - 45% of these were between the ages of 18-50 (who were at negligible risk from COVID-19 infection).
- Lipid nanoparticles have a well described toxicity in scientific literature after multiple injections.
- Pregnant women in the Pfizer randomized controlled trial did not fare well. It is unknown why vaccines were recommended in Alberta to pregnant women and those of childbearing age.
- Healthy minors were at low risk of serious COVID-19 infection and yet were recommended vaccination despite known and unknown safety risks inherent in the vaccines.
- COVID-19 vaccination carries a well-documented risk for developing myocarditis and pericarditis. These heart conditions have lifelong and potentially fatal consequences.
- It is relatively easy to authorize novel therapies under Emergency Use Authorization but very difficult to halt or discontinue them if concerns are warranted.
- It is very difficult to access relevant vaccine safety and efficacy data in Alberta's publicly funded health system.

What Was Done

Background

Heath Canada was responsible for approving COVID-19 vaccines in Canada.

The process Health Canada employed when approving the vaccines was to review product monographs, as well as, phased clinical trials for each vaccine submitted for approval. The

following represents information known or available to Health Canada when assessing COVID-19 vaccine approval and recommendation for continued use.

Health Canada's definition for an ideal vaccine states the following:

> "Vaccines are complex biologic products designed to induce a protective immune response effectively and safely. **An ideal vaccine is: safe with minimal adverse effects; effective in providing lifelong protection against disease after a single dose**[239].

National Advisory Committee on Immunization

The National Advisory Committee on Immunization ("NACI") is an external advisory body that provides PHAC with independent, ongoing medical, scientific, and public health advice in response to questions relating to immunization. The Alberta recommendations largely mirrored the NACI findings, and the Alberta SAG relied heavily on NACI review (Recommendations on the use of COVID-19 Vaccinations 2021-10-22).[240]

Key Gaps Identified from NACI Review of the COVID-19 Vaccinations

1. Due to the availability of only short-term clinical trial data, the duration of protection provided by COVID-19 vaccination is currently unknown.
2. The clinical trials of the authorized and available COVID-19 vaccines assessed efficacy against severe COVID-19 disease, but not all provided sufficient data to be able to assess the efficacy against severe COVID-19 disease, and not all provide sufficient data to be able to assess the efficacy against hospitalizations or deaths.
3. Due to limitations in the number of participants, and duration of follow up from COVID-19 clinical trial data, long-term evidence on immunogenicity is unknown.
4. Due to limitations in the number of participants and duration of follow-up from COVID-19 clinical trials, medium and long-term evidence on vaccine safety is limited.
5. Clinical trials of the authorized COVID-19 vaccines excluded individuals with a history of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

Notable Statements in the NACI Review

1. Anyone receiving any authorized mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) should be informed of the risks associated with mRNA COVID-19 vaccines (myocarditis and anaphylaxis) and be advised to seek medical attention if they develop signs and symptoms suggestive of these conditions.
2. Anyone receiving any authorized viral vector COVID-19 vaccine (AstraZeneca/COVISHIELD or Janssen) should be informed of the risks associated with viral vector vaccines (GBS, VITT/TTS, CLS) and be advised to seek medical attention if they develop signs and symptoms suggestive of these conditions.

None of the COVID-19 vaccine data reviewed in Alberta, including government communications or SAG reviews of vaccination, included the NACI cautions above.

Alberta Health and Government of Canada Messaging on COVID-19 Vaccine Approval

The Alberta Health COVID-19 website states the following:

> "All vaccines approved in Canada undergo a rigorous review and approval process to ensure they are safe and effective."[241]

The Alberta website links to a Government of Canada site discussing the approval process for COVID-19 vaccines:

> "On September 16, 2020, the Interim Order Respecting the Importation, Sale, and Advertising of Drugs for Use in Relation to COVID-19 (ISAD IO) introduced a temporary regulatory pathway. This helped expedite authorizations for COVID-19-related drugs and vaccines without compromising patient safety.
>
> The ISAD IO created a more agile pathway to facilitate the availability of COVID-19-related drugs and vaccines for Canadians in 4 ways:
>
> 1. Authorizing a brand-new drug based on available evidence with more agile administrative and application requirements;

2. Authorizing a new drug based on the approval of a trusted foreign regulatory authority;
3. Allowing expanded use of an already approved drug to include COVID-19-related indications based on known evidence with or without an application from the market authorization holder; and
4. Permitting the Public Health Agency of Canada to import promising COVID-19 drugs for placement (pre-positioning) in Canadian facilities before they are authorized in Canada[242].

NACI Recommendations

NACI made the following recommendations about COVID-19 vaccination:[243]

1. NACI preferentially recommends that a complete series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group without contraindications to the vaccine (Strong NACI Recommendation); and
2. NACI recommends that a viral vector COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine, to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, as well as the need to seek immediate medical care should symptoms develop (Discretionary NACI Recommendation).

Based on the key gaps concerning vaccine safety and efficacy noted above, **NACI must have believed the risk to the public was high enough to warrant endorsing COVID–19 vaccines despite the deficits in safety and efficacy knowledge noted above.**

Vaccines are given to healthy people, those without the malady they are being immunized against. In contrast, most therapeutics are offered to patients who are already afflicted with a specific illness for which they are being treated. The risk-benefit analysis is generally more favorable in this case as side effects or complications from a therapy are tolerated for the benefit of recovering from the illness. This is assuming the therapy has a well-documented side effect profile and reasonable chance of relieving the illness or symptom(s) being

treated. The risk-benefit ratio must be favorable for a therapeutic to be recommended to a patient. For vaccines, the risk-benefit ratio must greatly favor benefits over risks to recommend to an entire healthy population.

Did SAG and the CMOH of Alberta perform their own risk assessment of the Alberta population?

It is significant that only 5% of study patients in the original randomized control trials of the Pfizer, Moderna and Johnson & Johnson vaccines were over 75 years old.[244]

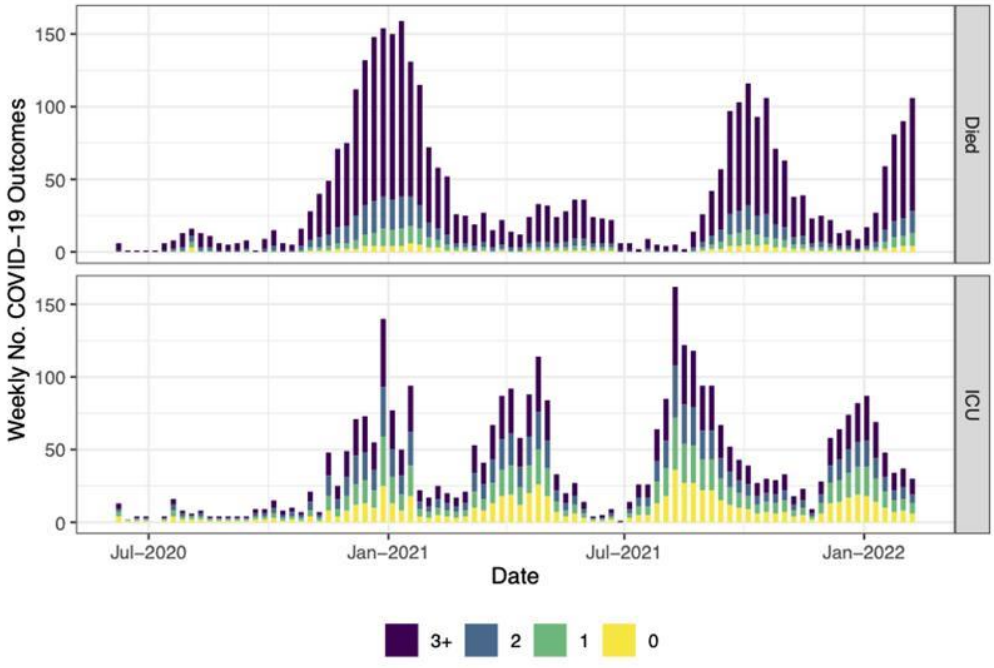
What was the risk to the healthy population of severe COVID-19 infection (e.g., hospitalization or death)?

Data Reviewed

Risk of COVID-19 to the Public

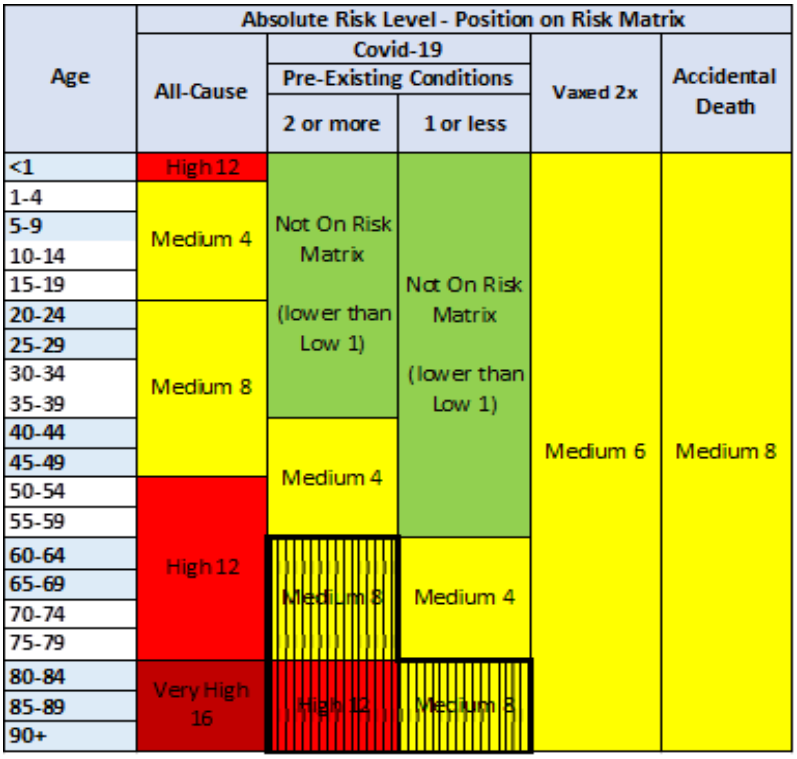
Figure 1. Weekly No. Of COVID-19 Outcomes based on a set of 10 comorbidities.

The graph below illustrates the outsized impact that two or more comorbidities had on the severity of outcomes for those admitted to hospital.



Based on data from the CDC, as of January 27, 2021, those 85 and older were 119 times more likely to die of COVID-19 than those aged 25-34, while those under 15 were 73 times less likely to die of COVID-19 than those 25-34. Therefore, age and comorbidities played the dominant role in severe outcomes.[245]

Figure 2. COVID-19 Absolute Risk Levels.



Outcome: everyone was treated as equally at risk, vaccinations were aggressively promoted to everyone, including infants and minors (despite their negligible risk from serious COVID-19 infection).

Improvement: perform a risk-benefit analysis to protect the at-risk demographic. Decrease or halt mitigation resources on populations with a positive risk benefit analysis.

Safety of COVID-19 Vaccines for the Public

A forensic analysis of the 38 subject deaths in the 6-month interim report of the Pfizer/BioNTech BNT162b2 mRNA vaccine clinical trial was published in September 2023.[246] It found that:

1. The C4591001 placebo-controlled randomized clinical trial of 22,030 vaccinated and 22,030 placebo subjects was the world's only opportunity for an unbiased evaluation of the Pfizer/BioNTech BNT162b2 vaccine.
2. Unblinding of placebo subjects starting in Week 20 terminated the placebo-controlled clinical trial, thereby ending all unbiased evaluation of possible adverse event signals.
3. The mRNA-LNP platform is novel, not previously phase 2/3 tested in humans, and the toxicity of PP-Spike protein was unknown. Taken together, a 20-week placebo-controlled clinical trial is NOT sufficient to identify any except for the most common safety concerns.
4. The number of all-cause deaths is NOT decreased by BNT162b2 vaccination.
5. Of the 38 deaths reported in the 6-Month Interim Report of Adverse Events, 21 BNT162b2 vaccinated subjects died compared to 17 placebo subjects.
6. Delayed reporting of the subject deaths into the Case Report Form, which was in violation of the trial protocol, allowed the EUA to proceed unchallenged.
7. The number of subject deaths was 17% of the expected number, based on age-adjusted US mortality. One possible explanation could lie in the 395 subjects that were "Lost to Follow-up".
8. There was a 3.7-fold increase in cardiac events in subjects who received the BNT162b2 vaccine versus the placebo.
9. Of the 15 subjects who were Sudden Adult Deaths (SAD) or Found Dead (FD), 12 died of a cardiac event, 9 of whom were vaccinated.
10. The cardiac adverse event signal was obscured by delays in reporting the accurate date of subject death that was known to Pfizer/BioNTech in the subject's Narrative Report.

A group of concerned medical practitioners forced the release of this information from the US FDA via two court orders. This is now part of the material used by our health authority to determine that the vaccine was safe and effective.

Table 1. Pfizer / BioNTech Post-Authorization Trial – Approved by the US FDA April 2, 2021.

Notes:

1. In the first 3 months post authorization, the vaccine caused the death of 1,223 and injured 42,086, most of these occurred within 4 days of vaccination.
2. 45% of the injured were between 18-50 - the people at negligible risk of covid-19 death (see chart 8 – page 13 this document), 71% of the relevant cases are female.
3. Within the same document this table came from there is a List of Adverse Events of Special Interest; 9 pages long – 1,236 different diseases caused by the vaccine.
4. There are various expert opinions about the completeness of adverse event reporting; estimates range from 1 to 10% of all events are recorded.[247]

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

Pregnant Women in the Pfizer Randomized Control Trial

In August 2022, Dr. Pierre Kory MD, MPA, published his analysis of the Pfizer trial data concerning pregnant women.[248] Dr. Kory found that:

> "According to the Pfizer "Cumulative Analysis of Post-Authorization Adverse Events Report" section 5.3.6 on page 12, two hundred and seventy pregnancies were reported during the trial. Of these two hundred and thirty-eight had no outcome

attached to them. No explanation in the document for the lack of reporting. Did they lose the chart? The remaining thirty-two had the following results:

- Twenty-three spontaneous abortions
- Two spontaneous abortions with intra-uterine death
- Two premature births with neonatal death
- One spontaneous abortion with neonatal death
- One normal outcome

This means there was an 87.5% fetal/neonatal mortality for the thirty-two pregnancies they had reported an outcome for in their post authorization follow-up period. These are devastating results. Can anyone say, with a clear conscience, the Pfizer Covid -19 vaccine is safe in pregnant women based on this original Pfizer data?"

History and Safety of the Lipid Nano Particle (LNP)

In May 2024, Dr. Byram Bridle provided an expert statement on the lipid nano particle used as the delivery vehicle for mRNA in COVID-19 vaccines.[249] The following is an excerpt:

"LNPs were originally designed with the goal of delivering drugs throughout the body, including into the brain to treat things like Alzheimer's disease, brain cancers, and Parkinson's disease.[250] The plan for a delivery vehicle for therapeutic agents including gene therapy products was largely abandoned by many pharmaceutical companies over the toxicity that occurred with multiple uses of the LNP in treatment regimens. It was known in 2006 that LNP's had toxic effects likely involving inflammatory activation of the immune system.[251]

In demonstration of this, consider the following quotation from a journalist that interviewed the Chief Executive Officer of Moderna in 2016: *"Delivery – actually getting RNA into cells – has long bedeviled the whole field. On their own, RNA molecules have a hard time reaching their targets. They work better if they're wrapped up in a delivery mechanism, such as nanoparticles made of lipids.* ***But those nanoparticles can lead to dangerous side effects, especially if a patient***

has to take repeated doses over months or years. Novartis abandoned the related realm of RNA interference over concerns about toxicity, as did Merck and Roche."[252]

Then consider this quotation in the article from Dr. Katalin Karikó who recently received the Nobel prize for developing the synthetic modified RNA technology: *"I would say that* ***mRNA is better suited for*** *diseases where* ***treatment for short duration*** *is sufficiently curative,* ***so the toxicities caused by delivery materials are less likely to occur."*** Of concern, it was discovered after awarding the Nobel prize that modRNA gets mis-read by the protein manufacturing machinery in cells, causing the unanticipated production of unpredicted foreign proteins that represent a "high level of impurity."[253]

Finally, please note this quotation: *"Moderna's most advanced competitors, CureVac and BioNTech, have acknowledged the* ***same challenge with mRNA. Each is principally focused on vaccines for infectious disease*** *and cancer,* ***which the companies believe can be attacked with just a few doses of mRNA."***[254]

The decision to approve the vaccines was made by Health Canada. Once this decision was rendered, it is unknown whether there was a mechanism available to the CMOH of Alberta to challenge it based on:

1. The low risk to the population under age 60 with one risk factor or less for serious COVID-19 infection (i.e., obesity, hypertension and/or diabetes); and
2. Questions surrounding the safety of the vaccines.

Outcome: significant harm to population which has not been tracked.

Improvement: insist on higher standards before approving novel vaccines.

Efficacy of COVID-19 Vaccines

The Role of Product Monographs

Viral transmission is NOT an approved indication for any of the approved COVID-19 vaccines.

A Product Monograph is a "factual, scientific document on a drug product that, devoid of promotional material, describes the properties, claims, indications, and conditions of use for the drug, and that contains any other information that may be required for optimal, safe, and effective use of the drug".[255]

The product monographs of each approved COVID-19 vaccine do not include any information related to the transmission of SARS-CoV-2. Viral transmission is NOT an approved indication for any of the approved COVID-19 vaccines. The word 'transmission' or any of its correlating terms indicating viral conveyance to another person, does not appear in these documents and therefore the manufacturers cannot claim the vaccines prevent viral transmission to other people.

This fact begs the following questions:

1. Why were COVID-19 vaccines put forth as the way to stop the spread of the pandemic and return to normal?
2. Why was the Restrictions Exemption Program (REP) based on COVID-19 vaccination when the original Pfizer randomized control trial never tested the vaccine's efficacy for halting transmission of the virus?
3. Why did the CMOH of Alberta not disclose the serious shortcomings of the original Pfizer trial regarding efficacy against transmission of the virus?

All three of the originally approved vaccines, Pfizer, Moderna and Johnson and Johnson, were not powered for nor tested the efficacy against hospitalization, death or stopping transmission. The end point was efficacy against symptomatic COVID-19 infection.

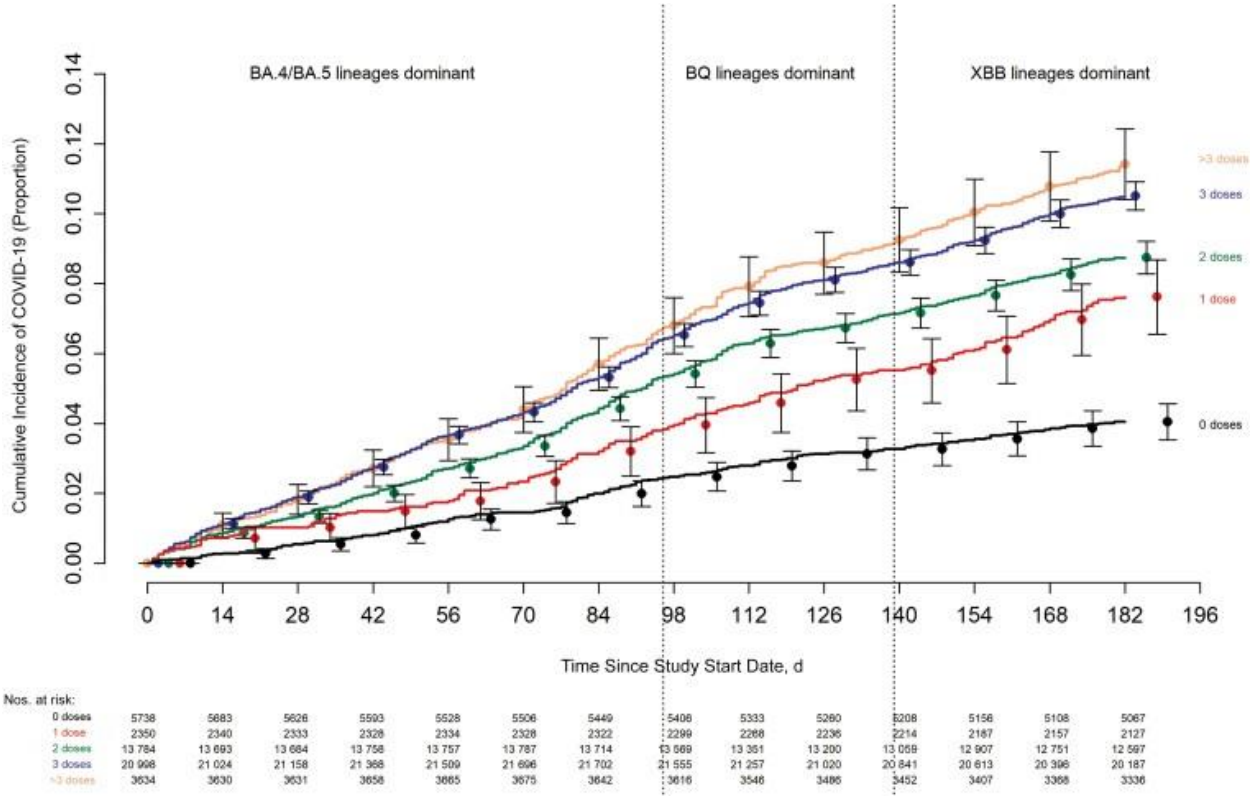
The tag line "Safe and Effective" was repeatedly used to assure the population and encourage vaccination against COVID-19. Based on the evidence that has emerged to date, it cannot be concluded that these COVID-19 vaccines are safe. Were they at least effective?

The COVID-19 Vaccines Were Not Effective in Stopping Transmission

The CDC site states that:

> COVID-19 vaccines are highly protective against severe illness and death and provide a lesser degree of protection against asymptomatic and mild infection (6). Receipt of a primary series alone, in the absence of being up to date with vaccination through receipt of all recommended booster doses, provides minimal protection against infection and transmission (3,6). Being up to date with vaccination provides a transient period of increased protection against infection and transmission after the most recent dose, although protection can wane over time.
>
> The graph below was from a large study undertaken by Cleveland Clinic involving 51,017 employees. The study demonstrated waning efficacy against the dominant lineages especially XBB. This underscores the problem of trying to keep up to a rapidly mutating virus.

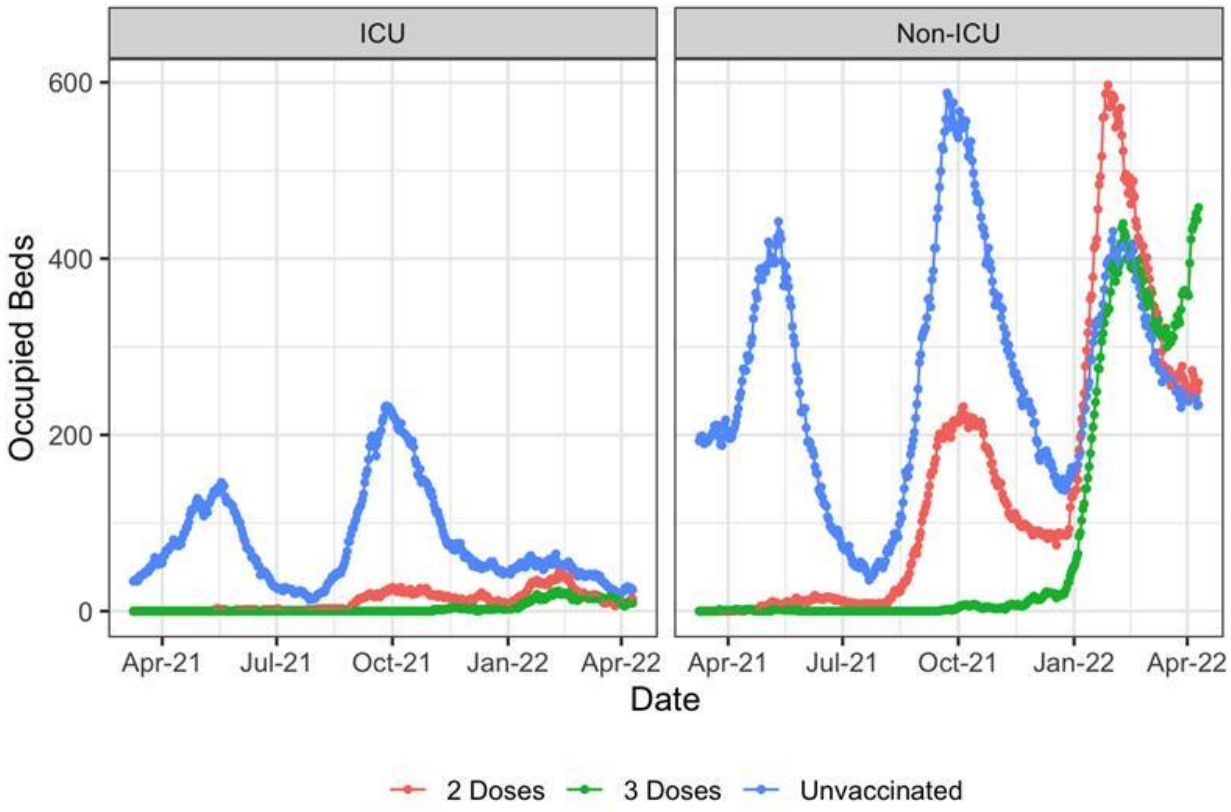
Figure 4. COVID-19 Vaccine Efficacy.



The estimated vaccine effectiveness was 29% (95% confidence interval, 21%-37%), 20% (6%-31%), and 4% (-12% to 18%), during the BA.4/5-, BQ-, and XBB-dominant phases, respectively. The risk of COVID-19 also increased with time since the most recent prior COVID-19 episode and with the number of vaccine doses previously received. (Open Forum Infect Dis. 2023 Apr 19;10(6):ofad209.)

How Effective Were the Vaccines in Preventing Hospitalization?

Figure 5. Number of Occupied Alberta Hospital Beds by Vaccine Status.[256]



The data to produce the graph above was taken from the AHS dashboard. The dashboard was taken down after the number vaccinated far exceeded the unvaccinated in hospitalizations. If the vaccine was effective in preventing serious infection, you would expect very few vaccinated individuals to be hospitalized. Remember Health Canada's definition of an ideal vaccine!

How Efficacious Were the Vaccines in Preventing Death?

The original Pfizer RCT had 21 all cause deaths in the vaccinated arm and 17 in the unvaccinated arm (See Forensic Analysis of the 38 subject deaths, above). You would expect the vaccinated arm to have fewer all-cause deaths than the unvaccinated arm.

It is therefore not accurate to say the original Pfizer Vaccines prevented death compared to placebo in their own RCT.

COVID-19 Vaccines in Minors

It is necessary to review decisions that were made at the height of the COVID-19 pandemic to ensure the best care is offered to Alberta's children and teenagers in the future. This careful review will focus on a risk benefit analysis for children aged six months up to seventeen years.

Key Messages

What is the risk of severe COVID-19 infection in children and teenagers? (Appendix 1)

The most significant risk factor associated with severe COVID-19 infection is age.[257] Early in the pandemic it became clear that the elderly (75 years+) were most at risk of hospitalization and death due to COVID-19 infection.

It was equally clear that children and teenagers had a very low risk of serious illness (150 pediatric admissions compared to 34,000 adult admissions during the same period, representing 0.4% of all admissions from COVID-19).[258] The CDC (Centers for Disease Control and Prevention) states, "studies have found that compared with adults, children may have similar or higher incidence rates of SARS-CoV-2 infection but more frequently experience asymptomatic infection or less severe symptoms."[259]

This very low risk necessitates a highly efficacious vaccine with a favorable and well-documented safety profile to justify use in young Albertans.

What is the efficacy of COVD-19 vaccines in children and teenagers against transmission, infection, and severe COVD-19?

The COVID-19 vaccines were not designed to halt transmission (Appendix 2).

Among all the COVID-19 vaccine trials conducted in children, the greatest net reduction in symptomatic COVID-19 infection for the vaccines compared to placebo was a mere 4.6% (Appendix 3).

According to the FDA briefing package provided by Pfizer (pg. 52) two or three doses of the Pfizer vaccine demonstrated extremely low efficacy against the Delta variant and even lower against the Omicron variant in children ages six months to five years.[260] In children aged five

to eleven years, there was a similar rapid decline in Pfizer vaccine effectiveness during Omicron.[261]

The continued emergence of variants challenged vaccine efficacy further. Estimated vaccine efficacy (VE) was 70.2% for Delta but plummeted to 21.8% for Omicron requiring regular boosters with upgraded vaccines to maintain efficacy.262

In addition, there is a lack of reliable data showing that COVID-19 vaccines protect children from severe COVID-19 as none of the COVID-19 vaccine trials were designed to assess this outcome (Appendix 4).

If low and short-lived efficacy necessitates ongoing COVID-19 boosters, are they at least safe?

Is the COVID-19 vaccine safe in children and teenagers?

The COVID-19 vaccines for children and teenagers were approved based on small trials and short follow-up periods.[263]

These trials reported large increases in rates of any (up to a 40%) and severe (up to 12%) systemic adverse events compared to placebo following vaccination. The sample sizes were too small and study length too short to detect rare but serious adverse long-term events (Appendix 5).

There is a well-documented link between mRNA COVID-19 vaccines and myocarditis in males (12 to 29 yrs. old).[264] A follow-up surveillance paper published in the Lancet on myocarditis in vaccinated 12-29 yr. olds, demonstrated an abnormality on Cardiac MRI in 81 of 151 patients.[265] This same study revealed 32% of patients were not cleared for physical activity and 26% were still on daily medications at least 90 days post diagnosis. In another paper Krug, et al showed cases of myo/pericarditis (n = 253) included 129 after dose 1 and 124 after dose 2; 86.9% were hospitalized.[266] Incidence per million after dose two in male patients aged 12–15 and 16–17 was 162.2 and 93.0, respectively. The Relative Risk (RR) of the first dose may be more than 6 times the risk of COVID-19 hospitalization in healthy boys with prior COVID-19 infection. Myocarditis can be a very serious long term health issue.

According to Alexander and co-workers' 20-year study of 175 children with myocarditis, survival free from death or transplantation was 74% at one year, 65% at five years, 62% at 10 years, and 56% at 20 years (Appendix 6).

The long-term safety of the COVID-19 vaccines is undetermined as the vaccines were rapidly deployed with just two months of safety data in minors. This was enabled via the Emergency Use Authorization pathway despite FDA guidelines which call for an observation period of up to 15 years for gene therapy (Appendix 7).

Conclusions Regarding Risk Benefit Analysis

The overall risk of severe COVID-19 in our children and teenagers is exceptionally low (Appendix 1).

There is a lack of reliable data showing that COVID-19 vaccines protect children from severe COVID-19 (Appendices 2, 3, 4).

There is reliable evidence of harm following vaccination and the COVID-19 vaccine trials were not designed to detect rare or long-term adverse effects (Appendix 5).

There is a known risk for myocarditis, especially in young males (Appendix 6).

There is no long-term safety data for these novel mRNA vaccines (Appendix 7).

Conclusions and Recommendations

1. Immediately halt the use of all COVID-19 vaccines without full disclosure to patients regarding both the safety and efficacy issues by their physician.
2. End use of the COVID-19 vaccines for healthy children and teenagers as other jurisdictions have done. See Denmark, Sweden, Norway, Finland, and the UK.
3. Further research to establish the safety and efficacy of COVID-19 vaccines is necessary before widespread use in adults and children.
4. Establish a website and/or call-in center for the vaccine injured in Alberta.
5. Establish a mechanism for opting out of federal health policy until provincial due process has been satisfied.

Appendix 1

Minors are at an extremely low risk of severe COVID-19.

- Early in the COVID crisis, Alberta public health and the Canadian pediatric society recognized that children are not at risk of severe COVID-19.[267]
- Their diminished risk of severe COVID-19 is likely due to their strong innate immunity16 and low levels of viral receptors in their airways.[268]
- Most Albertans now have naturally acquired immunity (Figure A1.1) which provides long-lasting protection against re-infection (Table A1.1) and severe COVID-19 which is superior to vaccination (Table A1.2).[269]
- Delta and Omicron variants are associated with an even lower risk of severe outcomes in children.[270]

Figure A1.1. Weekly number of COVID-19 cases, vaccination coverage and seroprevalence of antibodies induced by vaccination and infection or infection alone in Alberta since the start of the pandemic.

Weekly number of COVID-19 cases (black line), vaccination coverage (dotted, red line) data were obtained from the Government of Canada COVID-19 epidemiology update and vaccination webpages (respectively) on October 15, 2023. Data on seroprevalence of antibodies induced by vaccination and infection (anti-S; "naturally- and vaccine-acquired immunity" - orange line) or infection alone (anti-N; "naturally acquired immunity" - blue line) were obtained from the COVID-19 Immunity Task Force, SARS-CoV-2 seroprevalence in Canada webpage.

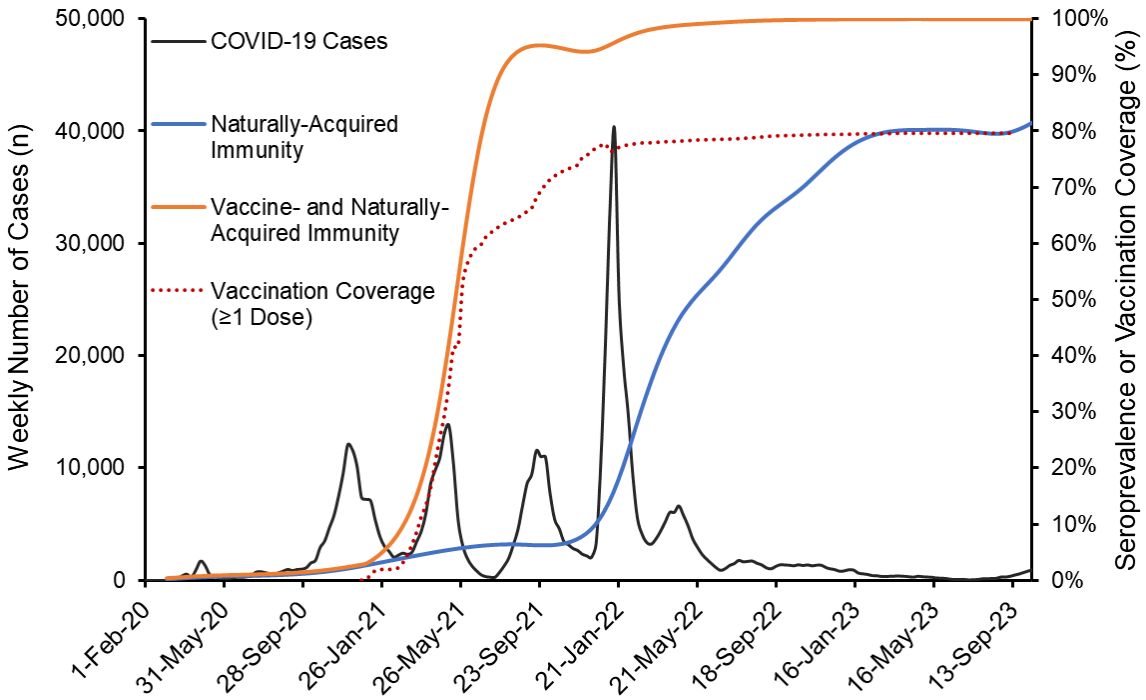


Table A1.1. Testing results at different times since infection and effectiveness of naturally acquired immunity against SARS-CoV-2 symptomatic infection using case-control test negative design.[271]

	Outcome: SARS-CoV-2 symptomatic infection				
	Cases (symptomatic and PCR-positive)		Controls (PCR-negative)		
Months after infection	Previously infected	SARS-CoV-2 naïve	Previously infected	SARS-CoV-2 naïve	Effectiveness of naturally acquired immunity against COVID-19, % (95% CI)
3-6	3	6537	46	6494	93.6 (79.3-98.0)
6-9	35	6555	229	6361	85.5 (79.2-89.9)
9-12	26	6540	114	6452	78.3 (66.5-86.0)
12-15	33	6543	125	6451	76.3 (64.5-84.2)
15-18	22	6535	70	6487	69.8 (50.7-81.5)
18-21	3	6537	46	6494	93.6 (79.3-98.0)

Lasts almost 2 years

Table A1.2. Hazard ratios for the incidence of SARS-CoV-2 infection and severe, critical, and fatal COVID-19 in the national, matched, retrospective cohort study in Qatar.[272]

	Natural infection versus BNT162b2 vaccination study		Natural infection versus mRNA-1273 vaccination study	
	Natural infection cohort	BNT162b2-vaccinated cohort	Natural infection cohort	mRNA-1273-vaccinated cohort
Total follow-up, person-weeks	1 985 243	1 921 539	1 374 220	1 338 649
Incidence rate of infection, per 10 000 person-weeks	18·1 (17·5–18·7)	37·1 (36·2–37·9)	16·7 (16·1–17·4)	32·0 (31·0–33·0)
Unadjusted HR for SARS-CoV-2 infection	0·48 (0·46–0·50)	1 (ref)	0·51 (0·49–0·54)	1 (ref)
Adjusted HR for SARS-CoV-2 infection*	0·47 (0·45–0·48)	1 (ref)	0·51 (0·49–0·54)	1 (ref)
Unadjusted HR for severe, critical, or fatal COVID-19†	0·25 (0·08–0·77)	1 (ref)	0·27 (0·06–1·32)	1 (ref)
Adjusted HR for severe, critical, or fatal COVID-19*†	0·24 (0·08–0·72)	1 (ref)	0·24 (0·05–1·19)	1 (ref)

~75% reduction in risk of severe COVID-19

95% CIs for HRs and incidence rate are shown in parentheses. HR=hazard ratio. *Cox regression analysis adjusted for sex, 10-year age group, ten nationality groups, comorbidity count (table 1), and timing of primary infection or first-dose vaccination. †Severe, critical, and fatal COVID-19 cases were defined according to WHO guidelines.[37,38]

Table 2: **HRs for the incidence of SARS-CoV-2 infection and severe, critical, and fatal COVID-19**

Appendix 2

COVID-19 vaccines were not designed to stop the transmission of the virus.

- Elimination of a virus or sustained reduction of local transmission is possible, if there is an accumulation of immune individuals with immunity that is highly effective at preventing (re)infection ('sterilizing' immunity).[273]
- Elimination of a virus is more difficult to achieve for coronaviruses like SARS-CoV-2 as immunity from infection or vaccination is relatively ineffective at preventing subsequent (re)infection (Table A2.1).[274]
- The registration trials for the COVID-19 vaccines did not assess transmission and none of the vaccines studied were able to completely prevent infection and were associated with high rates of breakthrough infection.[275]
- As the COVID-19 vaccines are unable to prevent transmission and (re)infection they are not an effective tool for eliminating the virus.

Table A2.1. Comparison between features of vaccines for measles and COVID-19.[276]

	Measles	COVID-19
Vaccine prevents severe disease.	Yes	Yes*
Vaccine prevents transmission.	Yes	No†
Indirect protection of non-immune individuals ('herd effect').	Yes	No†
Mass vaccination results in elimination via herd immunity.	Yes	No
Immunity after infection prevents reinfection/transmission.	Yes	No
Vaccine available for higher risk groups.	No (eg, infants)	Yes (eg, older adults)

*Severe disease is nevertheless more common after COVID-19 vaccination than after measles vaccination.

Appendix 3

COVID-19 vaccines are associated with modest reductions in infection and considerable increase in harm.

- According to the FDA briefing package provided by Pfizer (pg. 52) two or three doses of the Pfizer vaccine demonstrated extremely low efficacy against the Delta variant and even lower against the Omicron variant in children ages six months to five years. Vaccine efficacy (VE) was 70.2% for Delta but plummeted to 21.8% for Omicron (Table A3.1).[277]
- Among all the COVID-19 vaccine trials conducted in children, the greatest net reduction in COVID-19 cases for vaccines compared to placebo was 4.6% in infants 2 to 4/5 years (Table A3.2; Figure A3.1)
- There were no reported episodes of severe COVID-19 in the vaccination or placebo arms of the registration trials.[278]
- Increases in rates of severe systemic adverse events, meaning a child is so unwell that they cannot carry out their daily activities, were 5x and 7x greater than reductions in rates of COVID-19 cases for children and adolescents, respectively.

Table A3.1. Vaccine Efficacy – First COVID-19 Occurrence from 7 Days After Dose 2 to Before Dose 3 – Blinded Follow-Up Period – Phase 2/3 – Dose 2 Evaluable Efficacy Population.[279]

From Pfizer Briefing Materials for June 14 - 15, 2022 - Vaccines and Related Biological Products Advisory Committee Meeting.

	6 Months to <5 Years of Age		2 to <5 Years of Age		6 Months to <2 Years of Age	
Participants Without Prior Evidence of SARS-CoV-2 Infection						
	Case Split (BNT162b2:Placebo)	**VE (2-sided 95% CI)**	**Case Split (BNT162b2:Placebo)**	**VE (2-sided 95% CI)**	**Case Split (BNT162b2:Placebo)**	**VE (2-sided 95% CI)**
Overall VE	163:113	28.3% (8.0%, 43.9%)	90:69	35.9% (11.0%, 53.7%)	73:44	16.1% (-24.9%, 43.1%)
VE against Delta	9:15	70.2% (27.2%, 88.5%)	8:9	56.3% (-27.5%, 85.3%)	1:6	91.6% (30.6%, 99.8%)
VE against Omicron	154:98	21.8% (-1.7%, 39.7%)	82:60	32.9% (4.7%, 52.5%)	72:38	4.2% (-45.9%, 36.2%)
Participants With or Without Prior Evidence of SARS-CoV-2 Infection						
Overall VE	173:120	27.0% (7.1%, 42.5%)	97:73	34.3% (9.7%, 52.0%)	76:47	15.6% (-24.2%, 42.1%)
VE against Delta	10:15	66.3% (19.7%, 86.4%)	8:9	56.0% (-28.4%, 85.2%)	2:6	82.6% (2.7%, 98.3%)
VE against Omicron	163:105	21.4% (-1.4%, 38.9%)	89:64	31.2% (3.6%, 50.7%)	74:41	5.7% (-41.6%, 36.5%)

Table A3.2. Benefits and risks associated with mRNA vaccination of children based on Moderna and Pfizer's pivotal trials.[280]

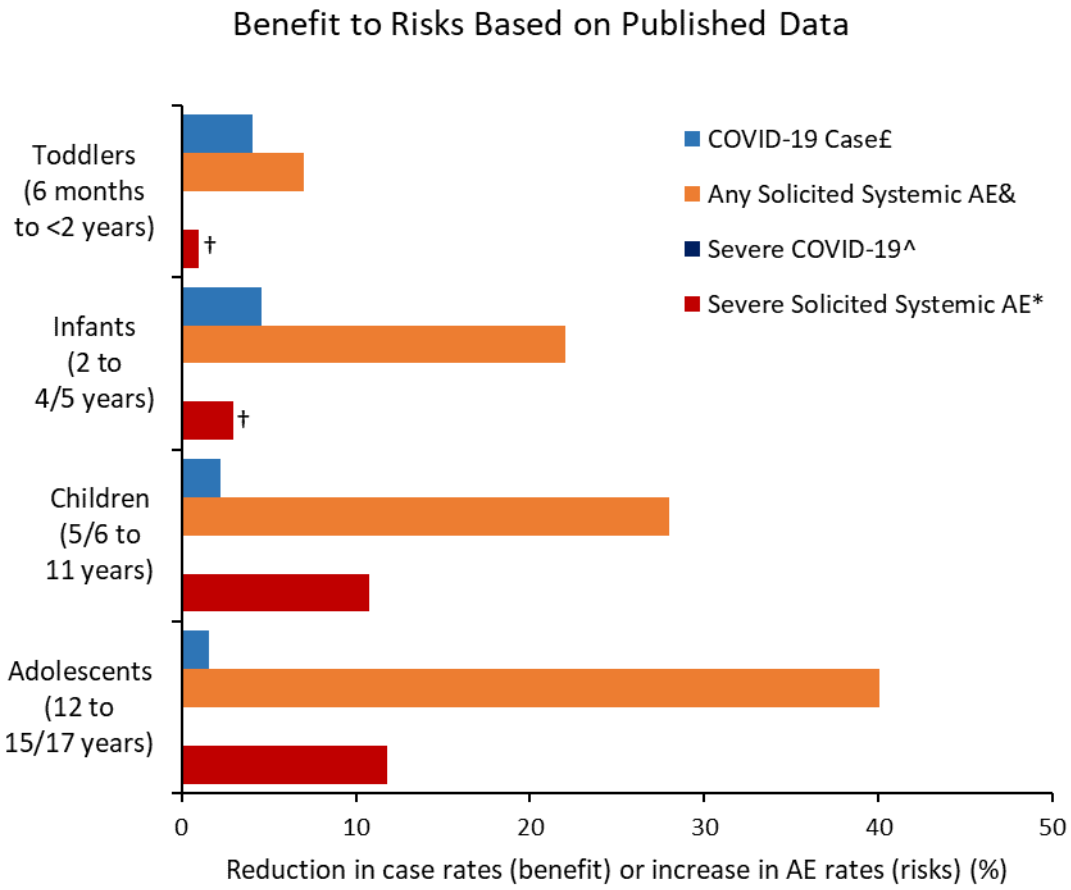
Note: Summarizes maximum differences in symptomatic case or adverse event rates (highest reported absolute benefit and highest reported absolute risk, respectively) across Pfizer and Moderna trials of COVID-19 vaccines in different age groups of children and adolescents 6 months to 15/17 years.

Maximum benefits versus Risks of Pfizer and Moderna vaccines compared to placebo.

	Any Event		Severe Event	
	Any COVID-19 Cases£	**Any Solicited Systemic Adverse Event**	**Severe COVID-19^ Cases**	**Severe Solicited Systemic Adverse Event ***
Adolescents (12 to 15/17 years)	↓ 1.6%	↑ 40.1%	0%	↑ 11.8%
Children (5/6 to 11 years)	↓ 2.2%	↑ 28%	0%	↑ 10.8%
Infants (2 to 4/5 years)	↓ 4.6%	↑ 22%	0%¥	↑ 3%†
Toddlers 6 months to <2 years	↓ 4.1%	↑ 7%	0%¥	↑ 1%†

AE, adverse event; COVID-19, symptomatic COVID-19 case.
£ Used per-protocol case definitions; analyses of vaccine efficacy based on CDC case definition may also be available.
& For this analysis, solicited local events were not considered. Given the large increases in frequency of local events (namely pain at injection site) with the vaccine, this will substantially underestimate overall frequency of solicited AEs. When rates of participants with AEs were not reported, the estimate provided is the maximum difference in rate of a single systemic AE between vaccine and placebo arms. Note that values do not reflect cumulative toxicity across multiple doses or multiple AEs in the same participant, i.e. they likely underestimate total burden associated with the intervention.
^ According to definition for adults; Pfizer trial analysis for younger age groups (6 months to 4 years) used a modified definition of severe COVID-19. Severe cases only meeting the modified definition were not considered.
* Solicited systemic AEs that prevented daily activity or worse. When rates of participants with severe solicited systemic AEs were not reported, the estimate provided is the maximum difference in rate of a single solicited systemic severe AE between vaccine and placebo arms. Note that values do not reflect cumulative rate of events across multiple doses or multiple AEs in the same participant, i.e. they likely underestimate total burden associated with the intervention.
¥ Number of severe COVID-19 cases was not reported. Since this is a clinically relevant endpoint for which occurrences should be mentioned, number of events was assumed to be zero in both arms.
† Calculated based on rates per arm estimated from a bar plot.

Figure A3.3: Plot of maximum differences in event rates across Pfizer and Moderna trials of COVID-19 vaccines in different age groups of children and adolescents 6 months to 15/17 years. Data was extracted from the published reports of pivotal studies for the respective age group.[281]



£ Used per-protocol case definitions; analyses of vaccine efficacy based on CDC case definition may also be available.
& For this analysis, solicited local events were not considered. Given the large increases in frequency of local events (namely pain at injection site) with the vaccine, this will substantially underestimate overall frequency of solicited AEs. When rates of participants with AEs were not reported, the estimate provided is the maximum difference in rate of a single systemic AE between vaccine and placebo arms. Note that values do not reflect cumulative toxicity across multiple doses or multiple AEs in the same participant, i.e. they likely underestimate total burden associated with the intervention.
^ According to definition for adults; Pfizer trial analysis for younger age groups (6 months to 4 years) used a modified definition of severe COVID-19. Severe cases only meeting the modified definition were not considered.
* Solicited systemic AEs that prevented daily activity or worse. When rates of participants with severe solicited systemic AEs were not reported, the estimate provided is the maximum difference in rate of a single solicited systemic severe AE between vaccine and placebo arms. Note that values do not reflect cumulative rate of events across multiple doses or multiple AEs in the same participant, i.e. they likely underestimate total burden associated with the intervention.
† Calculated based on rates per arm estimated from a bar plot.

See Appendix 8 for source documents.

Appendix 4

There is a lack of reliable data showing that COVID-19 vaccines protect children from severe COVID-19.

- Naturally acquired immunity is the gold standard for immunity and was the benchmark used to demonstrate COVID-19 vaccine activity.[282]
- None of the registration trials in children comparing the COVID-19 vaccines to placebo were designed to assess protection from severe COVID-19.[283]
- Although several real-world analyses have reported reductions in the risk of hospitalization in adolescents and children following vaccination, absolute benefits are small.[284]
- Results from real-world analyses should be interpreted with caution as reported hospitalizations are not always due to COVID-19, and it is difficult to control for bias arising from the increased testing of the unvaccinated (Figure A4.1).[285]
- Numerous studies have shown that naturally acquired immunity provides sustained protection against infection and superior protection against severe COVID-19 compared to vaccination (Figure A4.2).[286]

Figure A4.1. Alberta Public Health Guidance Required More Testing of Vaccinated Compared to Unvaccinated.[287]

Public Health Disease Management Guidance (PHDMG) June 28, 2021

Table 7a: Management of Immunized Close Contacts

Immunization Status on First Day of Exposure	Symptoms*	COVID-19 Testing Recommendations	COVID-19 Test Results	Management
Fully Immunized -more than 14 days after receiving the second dose of a two-dose vaccine series OR one dose in a one-dose vaccine series	No	No	If NO test done OR if tested & result is negative	NO quarantine required
			If tested & result is positive	Manage as a confirmed case of COVID-19
	Yes Begin to isolate*	Yes Test immediately after symptom onset	If NO test done	Manage as a probable case, Continue to isolate**
			Result is negative	Strongly recommended to stay at home and limit contact with others until symptoms resolve. NO quarantine required
			Result is positive	Manage as a confirmed case of COVID-19
Partially Immunized -more than 14 days after receiving one dose in a two-dose vaccine series	No Begin to quarantine	Yes Test on day 7 or later after exposure	If NO test done	Complete quarantine for 10 days from last day of exposure
			If tested BEFORE day 7 & result is negative	
			If tested on day 7 or later & result is negative	Quarantine lifted after negative test result received
			If tested at any time and result is positive	Manage as a confirmed case of COVID-19
	Yes Begin to isolate*	Yes Test immediately after symptom onset	NO test done	Manage as a probable case, Continue to isolate**
			If tested BEFORE day 7 & result is negative	Complete quarantine for 10 days from last day of exposure***
			If tested on day 7 or later & result is negative	Quarantine lifted after negative test result received AND Strongly recommended to stay at home and limit contact with others until symptoms resolve.
			If tested at any time & result is positive	Manage as a confirmed case of COVID-19

*This includes symptoms outlined in Table 2a: Symptom List for COVID-19 Testing
**Isolate for 10 days from onset of symptoms or until symptoms have improved AND afebrile for 24 hours, without the use of fever-reducing medications, whichever is longer
*** If tested again on day 7 or later, quarantine can be lifted after receipt of negative result.

PHDMG June 2021 The following individuals are eligible for testing: 1) any person exhibiting symptoms listed in Table 2a: Symptom List for COVID-19 Testing. 2) close contacts of confirmed and probable COVID-19 cases. NOTE: Testing is not recommended for close contacts who are fully immunized and are asymptomatic. For more information refer to Section 7: Management of Close Contacts Immunized Against COVID-19

PHDMG September 2021 1) Testing upon admission to a congregate living facility e.g., licensed supportive living (including lodges and group homes), long-term care (nursing homes and auxiliary hospital) and hospices is NOT required for all new residents who are asymptomatic and fully immunized unless they have been identified as a close contact. 2) Residents who are asymptomatic and fully immunized and have not been identified as a close contact also do NOT require testing upon return to these settings post-hospitalization for non-COVID-19 illnesses. 3) Testing upon admission or return from hospitalization is recommended for any resident who is symptomatic, not fully immunized or has had a known exposure.

PHDMG February 2022 – 6) Asymptomatic HCWs working in an auxiliary hospital, nursing home, designated supportive living or hospice setting, who are identified as a close contact may have additional screening requirements, such as rapid testing prior to each shift, based on their immunization status. Refer to the COVID-19 Licensed Supportive Living Daily Checklist and see applicable CMOH order.

Appendix 5

There is now considerable evidence that the COVID-19 mRNA-based vaccines are associated with short-term harm.

- COVID-19 vaccines are associated with up to a 40% increase in adverse events and up to a 12% increase in severe systemic adverse events in children following vaccination (Appendix 1).
- Long-term trial follow-up in children is unavailable, the best available safety data comes from the CDC V-safe program which showed that 33% of those enrolled had adverse health impacts;12% were unable to perform daily activities, 13% missed work or school, and 8% required medical care (Figure A5.1).[288]
- A CDC V-safe analysis assessing the safety of boosters following vaccination found that 20% of adolescents were unable to perform daily activities following vaccination and 1% required medical care (Figure A5.2).[289]

Figure A5.1. I-CAN dashboard for CDC's V-Safe data on COVID-19 vaccine adverse health impacts (accessed April 5, 2024).[290]

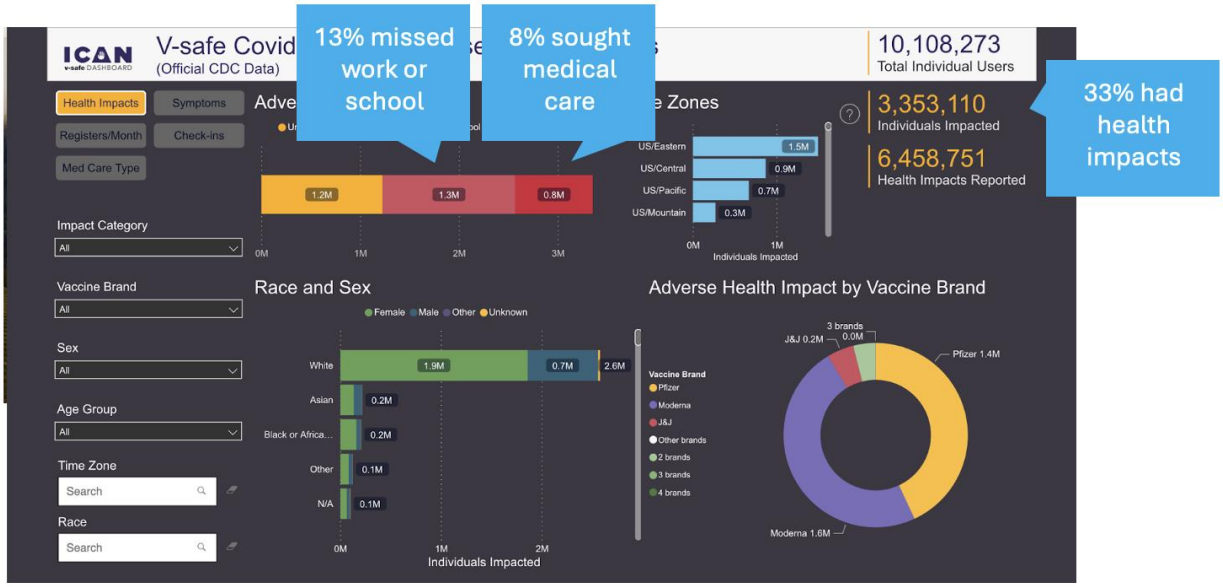
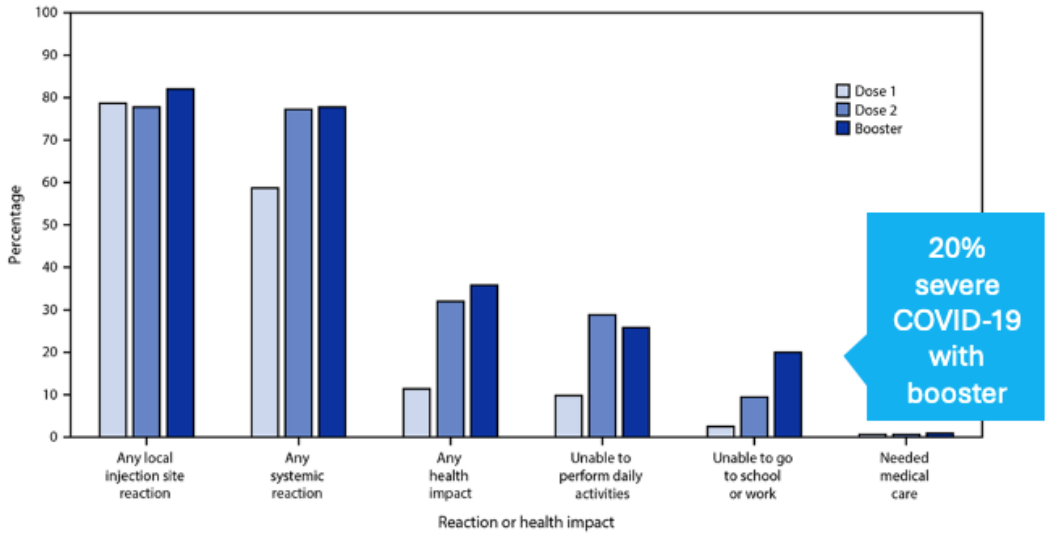


Figure A5.2. Adverse reactions and health impacts reported* among persons aged 12–17 years (N = 3,274) who received a homologous Pfizer-BioNTech COVID-19 vaccine booster, by vaccine dose — United States, December 9, 2021–February 20, 2022.[291]



* Registrants aged ≤15 years must be enrolled by a parent or guardian. The odds of reporting an event after dose 2 and booster dose were compared for registrants who completed at least one v-safe health check-in survey on days 0–7 after each vaccination using a multivariable generalized estimating equations model. This model adjusted for demographic variables and accounted for repeated measures among doses reported by each registrant (needed medical care was not adjusted due to small numbers); $p < 0.05$ was considered statistically significant. All dose 2 and booster dose comparisons were statistically significant, except any systemic reaction and needed medical care.

Appendix 6

There is a well-documented link between mRNA Covid vaccines and myocarditis in males (12 to 24 years old).

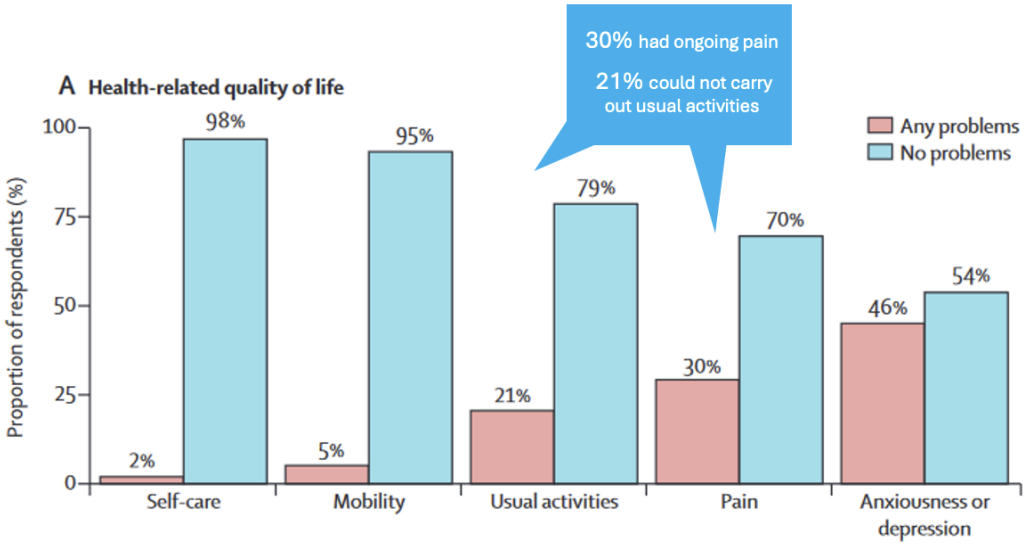
- Nordic countries have restricted use of vaccines in children, referencing a large Nordic population-based study which showed that the 28-day risk of in-patient myocarditis was higher in the vaccinated compared with the unvaccinated. For males 16 to 24 years the risk of myocarditis was 5x higher following 2 doses of Pfizer, 14x higher following 2 doses of Moderna and 36x higher with a Pfizer followed by a Moderna vaccine (Table A6.1).[292]
- An Ontario study found that 1 in 5,139 male adolescents will get myocarditis following a primary series.[293]
- A Thai study of 301 students carefully monitored for heart damage, found that 214 students (71.4%) had elevated troponin-T levels, a sign of cardiac damage, following full vaccination.[294]
- A US, Lancet-published study8 assessing the long-term health quality of life effects of adolescents and young adults diagnosed with myocarditis following vaccination found that they were unable to complete their usual activities (21%), had pain (20%), and had anxiety or depression (46%) in the 90 days following their diagnosis (Figure A6.1).[295]
- Norway, Finland, Denmark, Sweden, and UK have limited use of COVID-19 vaccines in children.[296]

Table A6.1. Myocarditis Within 28 Days After a Dose of SARS-CoV-2 Vaccine in males 16 to 24 years.[297]

Subgroup, exposure[b]	No. of events[c]	Follow-up, 1000 person-years	Crude incidence rate per 1000 person-years of follow-up[d]	IRR (95% CI)	No. of excess events in 28 d per 100 000 vaccinees (95% CI)
Males, ages 16-24 y					
Unvaccinated	149	794.6	0.188	1 [Reference]	0 [Reference]
AZD1222	0	0.70	ND	ND	ND
AZD1222/AZD1222	0	0.10	ND	ND	ND
BNT162b2	24	63.9	0.376	2.16 (1.40 to 3.33)	1.55 (0.70 to 2.39)
BNT162b2/BNT162b2	37	41.5	0.891	5.31 (3.68 to 7.68)	5.55 (3.70 to 7.39)
BNT162b2/mRNA-1273	17	4.6	3.687	35.62 (18.87 to 67.25)	27.49 (14.41 to 40.56)
mRNA-1273	≤5	11.5	ND	2.90 (1.05 to 7.97)	1.75 (−0.20 to 3.71)
mRNA-1273/mRNA-1273	15	5.8	2.584	13.83 (8.08 to 23.68)	18.39 (9.05 to 27.72)

36x greater risk of myocar ditis

Figure A6.1. Self-assessment of health-related quality of life among patients with myocarditis after mRNA COVID-19 vaccination.[298]



Appendix 7

The long-term safety of COVID-19 vaccines is undetermined in minors.

- The precautionary principle requires that an intervention be resisted if there is uncertainty regarding safety.[299]
- According to FDA guidance for industry, mRNA vaccines are human gene therapy products, which should undergo up to 15 years of safety monitoring prior to widespread use (Figure A7.1).[300]
- Development of COVID-19 vaccines began in 2020, therefore safety data for all age groups is limited to less than 4 years.
- Registration trials in children25-30 were small and provided approximately 2 months of safety data for the COVID-19 vaccines compared to placebo.[301]

Figure A7.1. FDA Guidance for Industry - Long Term Follow-Up After Administration of Human Gene Therapy Products.[302]

Human gene therapy product: FDA generally considers human gene therapy products to include all products that mediate their effects by transcription or translation of transferred genetic material or by specifically altering host (human) genetic sequences. Some examples of gene therapy products include nucleic acids (e.g., plasmids, in vitro transcribed ribonucleic acid (RNA)), genetically modified microorganisms (e.g., viruses, bacteria, fungi), engineered site-specific nucleases used for human genome editing,[10] and ex vivo genetically modified human cells. Gene therapy products meet the definition of "biological product" in section 351(i) of the Public Health Service (PHS) Act (42 U.S.C. 262(i)) when such products are applicable to the prevention, treatment, or cure of a disease or condition of human beings.[11]

Taking these discussions into consideration, we provided detailed recommendations in the 2006 Delayed Adverse Events guidance document on the duration and design of LTFU observations (Ref. 1). The Agency advised sponsors to observe subjects for delayed adverse events for as long as 15 years following exposure to the investigational GT product, specifying that the LTFU observation should include a minimum of five years of annual examinations, followed by ten years of annual queries of study subjects, either in person or by questionnaire.

Appendix 8

Source documents from Tables and Figures in Appendix 1

Adolescents (12 to 15/17 years)

COVID-19 Cases, ↓ 1.6%; Severe COVID-19^, 0%

Source: Frenck NEJM 2021

ble S3). No cases of severe Covid-19 were observed in this age cohort.

Any Solicited Systemic AE&, ↑ 40.1%; Severe Solicited Systemic AE; ↑ 11.8%*

Source: Ali NEJM 2021 (Supplementary Appendix)

Table S8: Frequency of Solicited Local and Systemic Adverse Reactions Within 7 Days After First and Second Injections by Grade – Participants 12 to <18 Years of Age and Participants 18 to 25 Years of Age

Event	Injection 1`				Injection 2`			
	Study P203 12 to <18 Years	Study P301 18 to ≤25 Years	Study P203 12 to <18 Years	Study P301 18 to ≤25 Years	Study P203 12 to <18 Years	Study P301 18 to ≤25 Years	Study P203 12 to <18 Years	Study P301 18 to ≤25 Years
	mRNA-1273 N = 2482 (%)	mRNA-1273 N = 878 n (%)	Placebo N = 1238 n (%)	Placebo N = 900 n (%)	mRNA-1273 N = 2478 n (%)	mRNA-1273 N = 819 n (%)	Placebo N = 1220 n (%)	Placebo N = 839 n (%)
Any systemic AR, n	2,482	878	1,238	900	2,478	819	1,220	839
Any, n (%)	1,701 (68.5)	578 (65.8)	687 (55.5)	486 (54.0)	2,134 (86.1)	702 (85.7)	561 (46.0)	343 (40.9)
Grade 3, n (%)	108 (4.4)	46 (5.2)	36 (2.9)	26 (2.9)	340 (13.7)	177 (21.6)	25 (2.0)	23 (2.7)
Grade 4, n (%)	0	0	0	0	3 (0.1)	0	1 (<0.1)	0

Children (5/6 to 11 years)

COVID-19 Cases, ↓ 2.2%; Severe COVID-19^, 0%

Source: Walter NEJM 2022

90.7% (95% CI, 67.4 to 98.3) (Fig. 3). No cases of severe Covid-19 or MIS-C were reported.

Any Solicited Systemic AE[&], ↑ 28%; Severe Solicited Systemic AE, ↑ 10.8%*

Source: Creech NEJM 2022 (Supplementary Appendix)

Table S18. Solicited Systemic Adverse Reactions Within 7 Days After First and Second Injection by Grade: Participants 6-≤12 Years and 18-≤25 Years of Age (Part 2, Solicited Safety Set)

	Injection 1*				Injection 2*			
	mRNA-1273		Placebo		mRNA-1273		Placebo	
	50 µg	100 µg			50 µg	100 µg		
Event n (%)	Children 6-<12 Years N = 3004	Young Adult ≥18-≤25 Years N = 878	Children 6-<12 Years N = 993	Young Adult ≥18-≤25 Years N = 900	Children 6-<12 Years N = 2988	Young Adult ≥18-≤25 Years N = 819	Children 6-<12 Years N = 969	Young Adult ≥18-≤25 Years N = 839
Systemic AR, N1	3004	878	993	900	2988	819	969	839
Any	1740 (57.9)	578 (65.8)	518 (52.2)	486 (54.0)	2335 (78.1)	702 (85.7)	485 (50.1)	343 (40.9)
Grade 3	53 (1.8)	46 (5.2)	12 (1.2)	26 (2.9)	364 (12.2)	177 (21.6)	14 (1.4)	23 (2.7)
Grade 4	0	0	1 (0.1)[TT]	0	0	0	0	0

Infants (2 to 4/5 years)

COVID-19 Cases, ↓ 4.6%; Severe COVID-19^, 0%[¥]

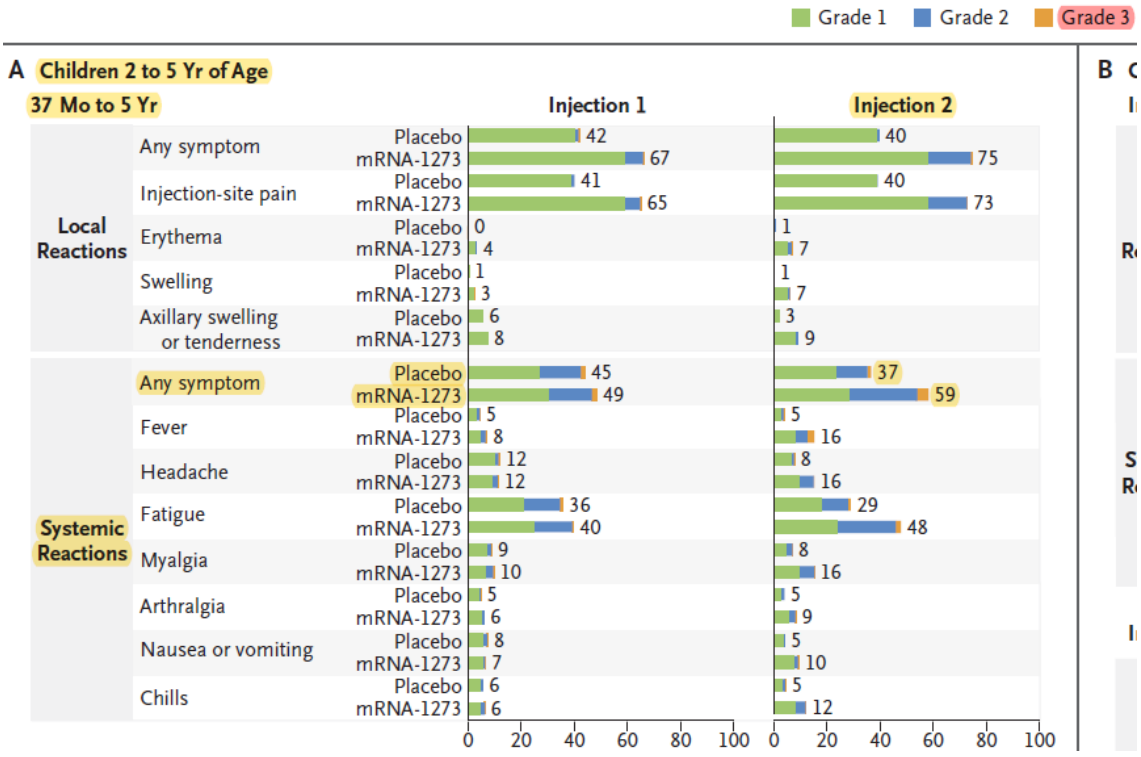
Source: Anderson NEJM 2022; Muñoz NEJM 2023

Severe cases not reported for either trial.

Any Solicited Systemic AE[&], ↑ 22%; Severe Solicited Systemic AE, ↑ 3%†*

Source: Anderson NEJM 2022

Moderna divides 2-5 years in 2 sub cohorts: 3-5 years and 2-3 years. Used the largest value from the larger cohort (3-5 years) for simplicity. Alternatively, could do a weighted average across sub cohorts (or other approach) to take into account both sub cohorts.



Toddlers 6 months to <2 years

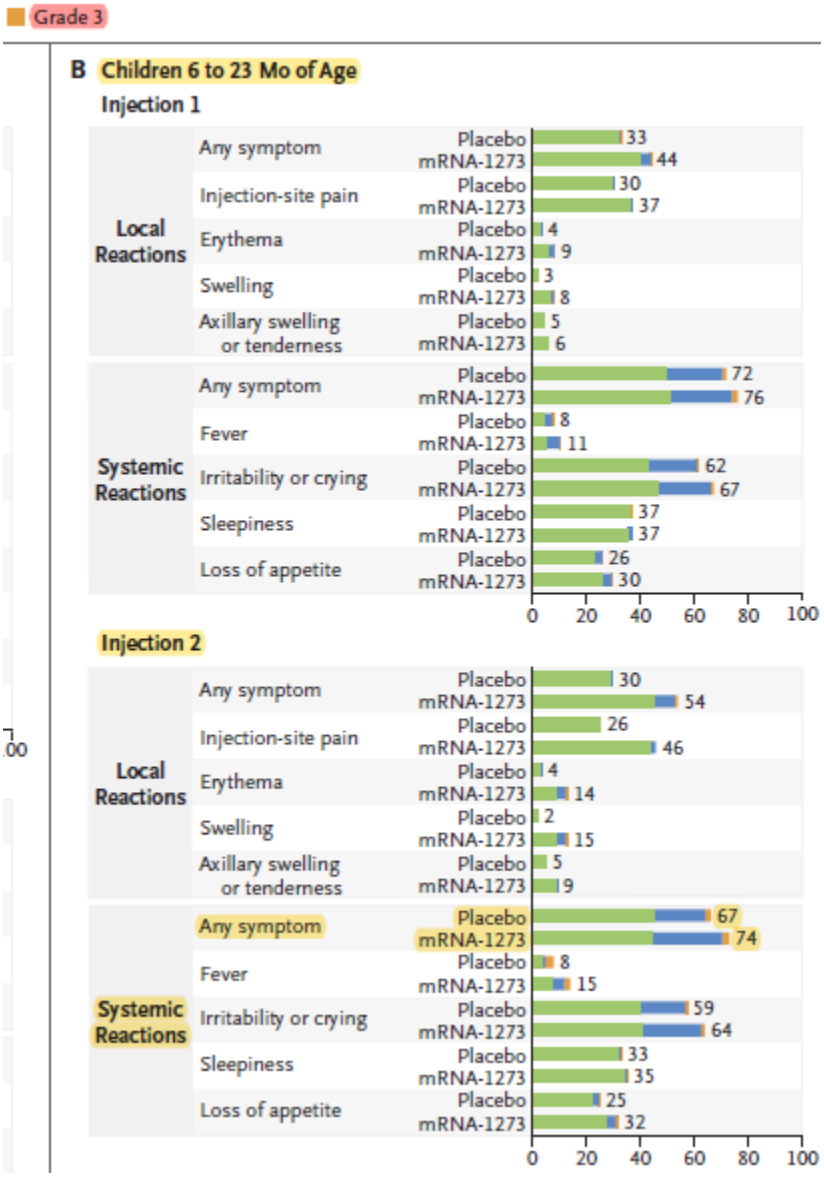
COVID-19 Cases, ↓ 4.1%; Severe COVID-19^, 0%¥

Source: Anderson NEJM 2022; Muñoz NEJM 2023

Severe cases not reported for either trial.

Any Solicited Systemic AE&, ↑ 7%; Severe Solicited Systemic AE, ↑ 1%†*

Source: Anderson NEJM 2022



Chapter 9: Therapeutics

Executive Summary

The Task Force conducted an in-depth review of various treatments for COVID-19, and the evidence used to make decisions about their use. This chapter highlights the restrictive approach taken by federal and provincial health authorities toward certain treatments, such as repurposed drugs and supplements, despite their potential benefits. The chapter specifically discusses the drugs ivermectin, hydroxychloroquine, fluvoxamine, and colchicine, as well as monoclonal antibodies and vitamin D3.

Initial studies showed promising results for ivermectin in terms of viral clearance and reduced hospitalization and death rates. Hydroxychloroquine showed promise in observational studies and meta-analyses, but poorly conducted trials and a retracted study raised doubts about its effectiveness. Fluvoxamine and monoclonal antibodies were also mentioned during the pandemic as potential COVID-19 treatments, with fluvoxamine showing promise in a small randomized controlled trial and monoclonal antibodies receiving approval for mild to moderate COVID-19. Colchicine was studied extensively and showed a decrease in poor outcomes, but the Alberta Scientific Advisory Group (SAG) recommended against its use due to the risk of dehydration. Vitamin D3 was discussed, with a study showing a correlation between low levels and poor COVID-19 outcomes, but the SAG did not include this study in their review and recommended not using vitamin D3 for treatment.

The chapter also notes the potential benefits of zinc supplementation and the use of hydroxychloroquine as a zinc ionophore. The chapter concludes with recommendations to protect the rights of healthcare professionals to provide treatments in the best interest of patients and to ensure rigorous safety standards.

Overall, the chapter highlights the need for further research and consideration of alternative treatment options for COVID-19. It raises questions about the restrictive approach taken by

health authorities in Alberta and encourages the exploration of treatments that may offer potential benefits.

- The Task Force examined various treatments for COVID-19, including repurposed drugs and supplements such as ivermectin, hydroxychloroquine, fluvoxamine, colchicine, monoclonal antibodies, and vitamin D3.
- Federal and provincial health authorities took a restrictive approach toward these treatments.
- Studies show promising results for ivermectin in terms of viral clearance and reduced hospitalization and death rates.
- Fluvoxamine and monoclonal antibodies were noted as potential treatments, with fluvoxamine showing promise in a small randomized controlled trial.
- The Alberta SAG recommended against the use of colchicine due to the risk of dehydration.
- A study showed a correlation between low vitamin D3 levels and poor COVID-19 outcomes, but the Alberta SAG recommended against using vitamin D3 for treatment.
- Zinc is an essential mineral for the immune system and inhibits coronavirus RNA-dependent RNA polymerase activity.
- Remdesivir is the only antiviral included in the COVID-19 Adult Admission Order Set for hospitalized patients in Alberta.
- Health Canada approved Remdesivir for treatment of COVID-19 in adults and adolescents with pneumonia requiring supplemental oxygen.
- Corticosteroids, such as prednisolone and dexamethasone, were considered for COVID-19 treatment.
- Alberta should allow healthcare professionals to prescribe treatments in their patients' best interest and ensure access to therapies with established safety records.

- The restrictive approach taken by Alberta health authorities toward alternate COVID-19 therapeutics is concerning and further investigation is required into the restriction of treatment options for COVID-19.

Introduction

From the outset of the pandemic, it was evident that a safe and effective treatment for COVID-19 was urgently needed. Typically, Canadian physicians have the discretion to prescribe off-label treatments in the best interest of their patients, provided they inform patients about the potential side-effects. However, during the COVID-19 pandemic, federal agencies, health service providers and regulators discouraged the use of potentially lifesaving off label treatments. This approach compromised the well-being of Albertans and violated their right to informed consent.

This restrictive, anti-discretionary approach raises several questions and concerns. Why were drugs with a long safety record restricted? Why were safe drugs prohibited from being used to treat COVID-19 based on population studies that showed poor efficacy? Additionally, why were physicians who questioned this approach vilified and sanctioned? Many of these maligned treatments, repurposed drugs, and supplements have since been shown to be helpful, which raises the question: why these treatments made unavailable when our seniors were dying alone in their rooms?

As stated by the standing Senate Committee on Social Affairs report of 2014, Canadian physicians are at liberty to prescribe in a manner that is in their patient's best interest.[303]

Off-label or re-purposed drug use is a common practice, especially for conditions for which there are areas of clinical need. A Canadian study found that that 11% of drugs are not prescribed for their listed indications and in the pediatric population up to 75% of drugs are used off-label.[304]

Repurposed drugs with extensive safety records are particularly attractive in situations of high clinical need as they allow physicians to prescribe these drugs for new indications with little risk to patients, even in the absence of high levels of supporting evidence.

What Was Done

In this chapter, we examine both the COVID-19 treatments that were utilized and those that were prohibited, along with the evidence used to justify these decisions. The optimal strategy to overcome a health crisis is to treat the affected and provide prophylaxis to those who are still healthy. However, the approach taken was quite the opposite.

A year after COVID-19 vaccines became publicly available, overwhelming evidence indicated that they did not prevent virus transmission. Metanalyses of mask mandates showed weak evidence of altering community spread of the virus. Additionally, social distancing rules, as revealed in Dr. Anthony Fauci's testimony, were not science-based.

Given this context, a pertinent question arises: would it not have been prudent to allow, or even encourage, medical practitioners to try any evidence-based COVID-19 treatment, with health authorities closely observing the impact on populations? Instead, public health authorities restricted the use of most alternative treatments for COVID-19.

Data Reviewed

We reviewed the publicly available data and scientific research used to support the treatment approaches endorsed and discouraged by health authorities in Alberta's COVID-19 response.

Outpatient Treatment

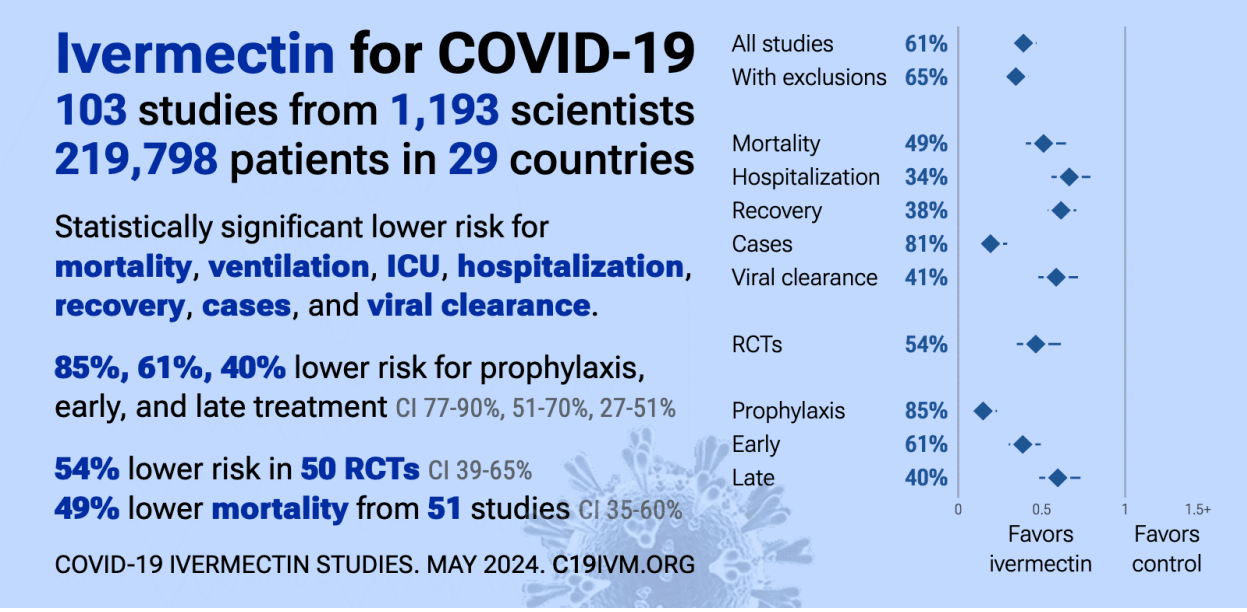
Within days of declaring the COVID-19 pandemic, most jurisdictions around the world implemented non-pharmaceutical interventions, such as, social distancing and masking policies with low levels of supporting evidence for efficacy, and with a high likelihood of harm.[305] "Watchful Waiting," or sitting at home in fear until becoming critically ill, proved fatal for many Albertans and was often the only care option offered. Residents of long-term care facilities often received less care. For many, care levels were arbitrarily changed to "comfort care" by health care teams. This designation meant residents experiencing severe episodes of any disease, whether COVID-19-related or not, were denied access to acute care services and instead made "comfortable" as they died in place.[306] In 2020, most

COVID-19 deaths (~83%) occurred among residents of long-term care facilities, potentially due to a withdrawal of care.

During this time of acute clinical need, there were many promising repurposed drugs available. Drugs such as, hydroxychloroquine, ivermectin and fluvoxamine, colchicine, cortico-steroids and even vitamins, were widely available, safe, inexpensive, and listed on the World Health Organization's list of essential medicines.[307]

Ivermectin

Figure 1. Ivermectin for COVID-19



Ivermectin came into the spotlight a few months into the pandemic when a systematic review published in June 2020 showed that it was effective against several viruses. In vitro and small human trials showed faster SARS-CoV-2 clearance in patients taking ivermectin compared to placebo.[308] By late 2020, a meta-analysis of RCTs assessing ivermectin mostly as an early treatment showed that it improved viral clearance, delayed symptom progression and reduced the risk of hospitalization and death.[309] Surprisingly, despite these promising findings, the author recommended against ivermectin's use outside of clinical trial, a position that was adopted by the World Health Organization in March 2021.[310] That article was retracted and revised following multiple notes of concern.[311] Two other meta-

analyses were published in early 2021, by Bryant, et al., and Kory, et al., confirming an ivermectin benefit.[312] By mid-July 2021, a Cochrane Review, which included a very limited number of eligible RCTs, concluded that evidence of ivermectin safety and efficacy was uncertain, meaning that there was insufficient evidence to confidently claim either a benefit or lack of benefit from ivermectin.[313]

In September 2021, the College of Physicians and Surgeons of Alberta, and the Alberta College of Pharmacy, released a joint statement stating that "[t]here is no evidence that prescribing and dispensing ivermectin is beneficial but there is certainly significant risk of patient harm."[314] The two Colleges advised that going against public health guidance and prescribing or dispensing ivermectin would be indicative of a lack of professionalism and would be subject to discipline.

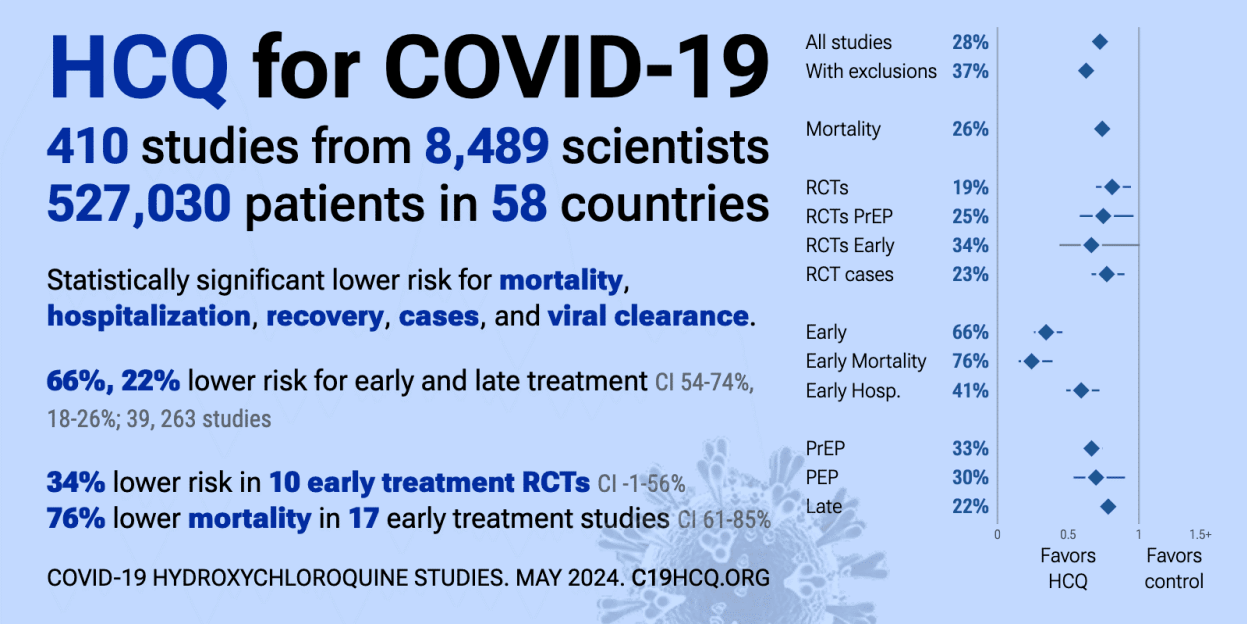
The Alberta Colleges, which are charged with ensuring practitioners provide safe care, did not provide any evidence of harm from ivermectin use and did not express similar concern over other COVID-19 interventions or treatments with more concerning risk profiles. An analysis of the WHO/Uppsala VigiAccess pharmacovigilance database on March 22, 2021, showed that the number of adverse events associated with ivermectin after decades of use was lower than Remdesivir, tocilizumab, and COVID-19 vaccines (Figure 1).[315]

It is noteworthy that ongoing, more comprehensive living meta-analyses of ivermectin use continue to show high confidence for reductions in mortality, ventilation, ICU admission, hospitalization, progression cases and viral clearance (Figure 1).[316] Physicians who sought to treat patients with alternative methods during Alberta's response to COVID-19, however, were subject to disciplinary review and reputation-damaging criticism from some media outlets.[317] On October 5, 2021, AHS published an evidence review recommending against use of ivermectin outside of clinical trials in alignment with recommendations by the WHO, the United States National Institutes of Health, Health Canada, and the U.S. Food and Drug Administration ("FDA").[318]

The FDA recommendation against ivermectin has since been rescinded following a U.S. court order that mandated the removal of social media posts claiming that ivermectin was unsuitable for COVID-19 treatment.[319] It subsequently clarified that the concerns from by Health Canada and the FDA were mainly around the use of veterinary grade ivermectin in humans. This issue could have been averted if physicians and pharmacists had been allowed to prescribe or dispense human grade ivermectin.

Hydroxychloroquine

Figure 2. Hydroxychloroquine for COVID-19.



As of July 2020, observational data showed that hydroxychloroquine, an antimalarial drug with a strong safety record, reduced the risk of death for patients hospitalized with COVID-19 when used in combination with azithromycin.[320] Additional observational studies, real-world evidence and meta-analysis of these studies also demonstrated promise when hydroxychloroquine was given as an early treatment followed by prednisone.[321] These findings are consistent with hydroxychloroquine's antiviral properties and non-immunosuppressive immunomodulatory and anti-inflammatory activities, which enhance its effectiveness when administered early in the disease course (Figure 2).[322]

> *However, a series of poorly conceived trials assessing hydroxychloroquine alone for later stage disease called its efficacy as a treatment into question. The first study was a multinational hospital registry study published in the Lancet in May 2020 which showed that hydroxychloroquine failed to reduce the mortality risk for hospitalized COVID-19 patients. This study was later shown to be fraudulent and retracted.*[323]

The results of the randomized WHO Solidarity trial followed in February 2021, showing that hydroxychloroquine did not significantly lower the mortality risk of hospitalized patients.[324] Results of the TOGETHER trial published in April 2021, showed a numerical non-significant decrease in hospitalization even with later hydroxychloroquine use, administered 5 days after symptom onset.[325]

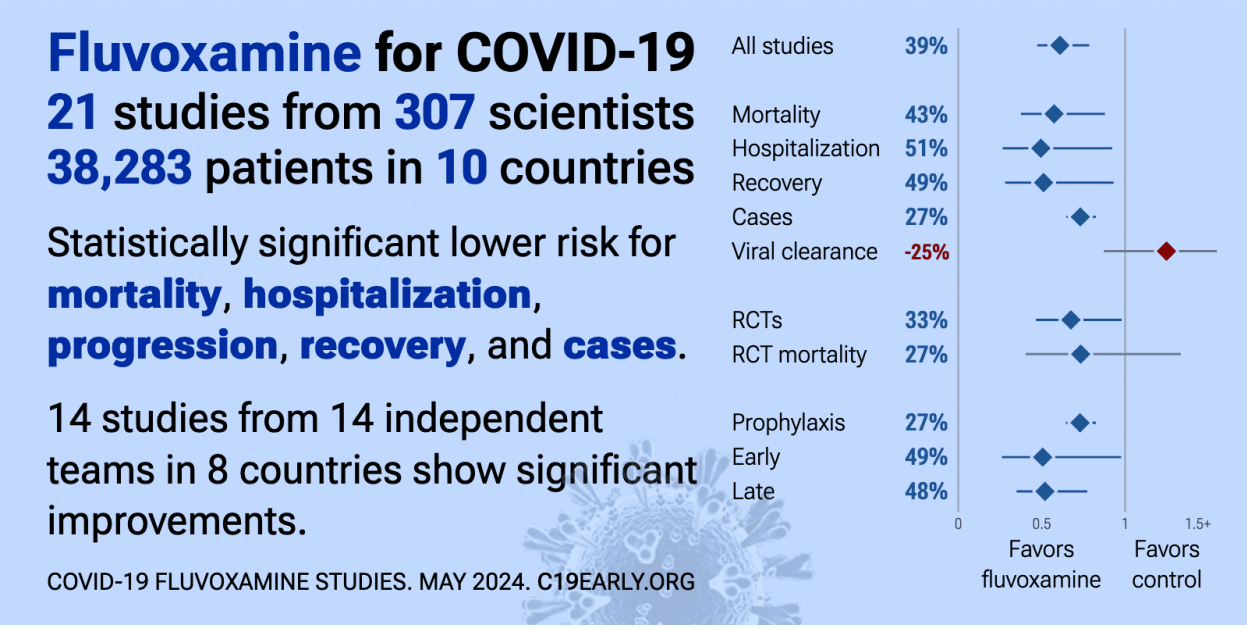
> *The study was prematurely terminated despite trends toward benefit, with several trial conduct issues bringing the integrity of the trial into question.*[326]

An early retrospective case series study showed the clear benefit when hydroxychloroquine was used in conjunction with zinc and azithromycin, which should have prompted the health authorities to investigate it further in Alberta.[327]

> *Despite the best available evidence continuing to show hydroxychloroquine was safe, and with no compelling evidence showing it was an ineffective early treatment, by the end of 2021 the medical community had thoroughly dismissed hydroxychloroquine as a viable early treatment option*

Fluvoxamine

Figure 3. Fluvoxamine for COVID-19.



Fluvoxamine, a selective serotonin reuptake inhibitor ("SSRI") used for the treatment of depression and known to reduce inflammation and cytokine production, was another repurposed drug that showed promise in early COVID-19 treatment.[328] A small RCT published in November 2020 assessing fluvoxamine as an early outpatient treatment demonstrated a statistically significant difference in clinical deterioration compared to placebo.[329] As of October of 2021, the Brazilian TOGETHER study showed a reduced need for hospitalization compared to placebo when fluvoxamine was administered to high-risk symptomatic outpatients.[330]

In contrast with the hydroxychloroquine cohort from the same platform trial, a large proportion (41%-44%) of patients treated with fluvoxamine received the drug 0-3 days after symptom onset and the study was allowed to run its full course.

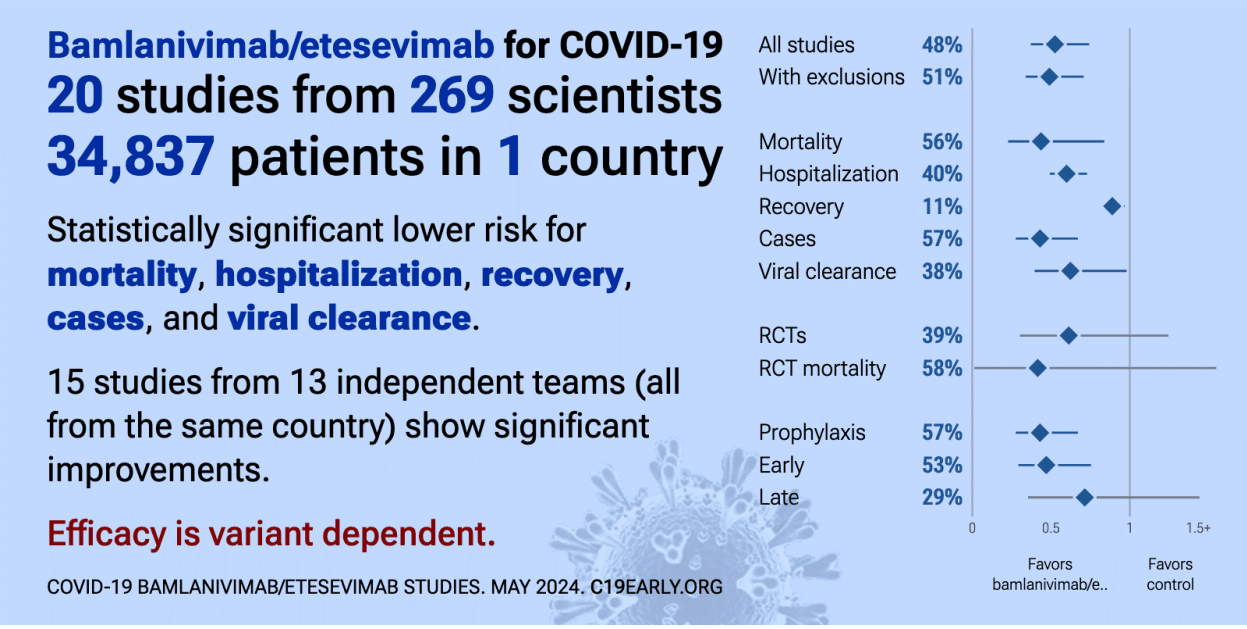
Fluvoxamine was subsequently conditionally approved in Ontario for COVID-19 treatment, but as of May 13, 2022, AHS continued to state that there was insufficient evidence to support its use for COVID-19.[331]

Optimally, front-line doctors would have been encouraged to work with these agents to find ways to improve efficacy through combinations or sequences designed to address the various stages of disease progression.[332] Instead, we seemed to see a quelling of scientific discourse, and some Albertan physicians were punished for finding innovative ways to care for their patients.

American front-line doctors developed two multi-drug protocols, the McCullough Protocol and the FLCCC protocol, to help slow COVID-19 progression.[333] The people of Alberta would have benefitted from a trial of these protocols rather than having them obstructed and maligned without consideration. The protocols relied on approved medications with extensive safety track records in patient care.

Monoclonal Antibodies

Figure 4. Monoclonal Antibodies for COVID-19.

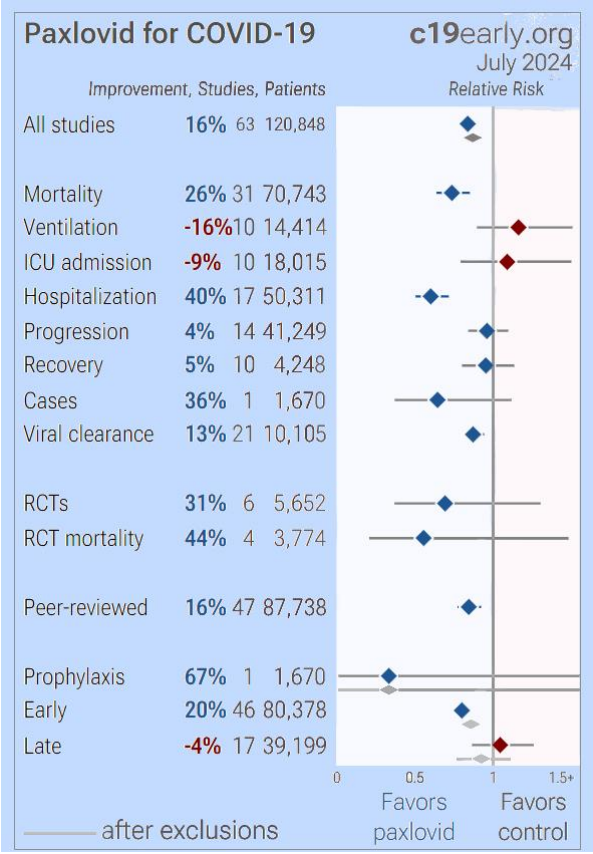


In late 2020 and into 2021, Health Canada approved multiple anti-SARS-CoV-2 spike protein monoclonal antibodies with neutralizing activity for treatment of mild to moderate COVID-19 (non-hospitalized outpatients) based on comparable or poorer evidence. The first approval of Bamlanivimab, was based on a "numerical" (i.e., not statistically significant) reduction in proportion of hospitalized patients in a study that failed to meet its primary endpoint of viral load reduction at day 11.[334] The second approval of casirivimab/imdevimab was supported by descriptive results of a single small phase I-III RCT with serious trial conduct issues.[335]

Despite major gaps in the data supporting efficacy and safety of these medications, their approved indications were expanded to include adolescents without any directly supporting clinical evidence.

Paxlovid

Figure 5. Paxlovid for COVID-19.



Pfizer has denied access to Paxlovid for independent RCTs.[336] Pfizer's own RCTs report very good results, while non-Pfizer RCTs show less favorable outcomes, finding that over 50% of patients who died had conditions that made Paxlovid unsuitable for them.[337] Retrospective studies that include patients with these conditions may overestimate the drug's efficacy.

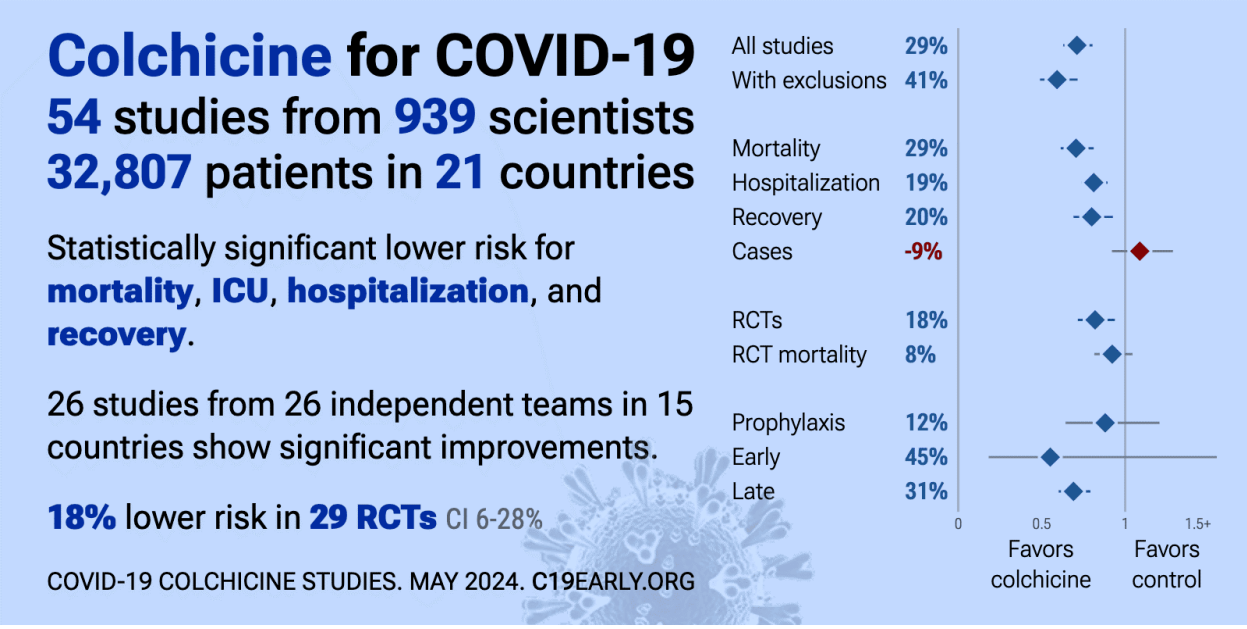
The FDA black box warning for Paxlovid notes that "severe, life-threatening, and/or fatal adverse reactions due to drug interactions have been reported in patients treated with Paxlovid."

Population studies often do not account for different expected outcomes for the class of patients that seek out and receive early treatment. Paxlovid is a combination of nirmatrelvir and ritonavir. Nirmatrelvir is a first-generation SARS-CoV-2 3CL protease inhibitor.[338] Ritonavir is an HIV drug used to boost the levels of nirmatrelvir in the body by inhibiting its metabolism.[339]

Why was Paxlovid readily available in Alberta while drugs that had many years of safe use were prohibited?

Colchicine

Figure 6. Colchicine for COVID-19.



Colchicine is a drug with a long history of strong anti-inflammatory effects.[340] For centuries, acute gout was treated with extracts from autumn crocus (*Colchicum autumnale*) until the active pharmaceutical ingredient (the lipophilic alkaloid, colchicine) was identified in the 18th century.[341] Colchicine blocks cell division, specifically mitosis, by binding to tubulin and preventing the elongation of microtubules. At lower concentrations it leads to microtubule arrest, and at higher concentrations it leads to microtubule depolymerization.[342] Although the exact mechanisms by which colchicine acts on the immune system are not fully understood, it appears to exert anti-inflammatory effects through multiple modes of action, which, together, result in altered leukocyte adhesion and migration, as well as cytokine production and secretion.[343] In addition to gout, colchicine is used to treat numerous systemic inflammatory diseases, including familial Mediterranean fever, Behçet's disease, primary biliary cirrhosis, and pericarditis.[344] In clinical practice it is important to note that the therapeutic window of colchicine is relatively narrow and inter-individual pharmacokinetic variability is high.[345]

Colchicine, first approved by the FDA for gout in 1961, was later studied in various trials, including the COLCOT, LoDoCo, and LoDoCo2 trials, which evaluated the anti-

inflammatory effects of colchicine on reducing cardiovascular events in patients with established atherosclerotic cardiovascular disease ("ASCVD") or patients at risk of developing ASCVD.

Colchicine is a non-steroidal anti-inflammatory ("NSAID") that does not cause renal injury that other NSAIDs can cause with prolonged use. It has been studied and used extensively in the treatment of gout and pericarditis. It blocks the immune response by inhibiting white blood cells and Interleukin 1β and 18. Because an over reactive immune response appears to be one cause of severe disease in viral pneumonia, it was looked at as a treatment for COVID-19. A review of 51 papers with 199,932 patients showed a 32% decrease in poor outcomes from COVID-19 when treated with colchicine (Figure 6).[346] In a SAG recommendation, colchicine was recommended against due to the risk of diarrhea causing death from dehydration in Alberta patients with COVID-19. The SAG concluded that any perceived risk tipped the balance toward not recommending the drug.

The recommendation against Colchicine was based on possible dehydration, even though it had been used for years in Alberta and there were no known deaths from dehydration caused by the drug. There appeared to offer significant benefit. This should have led to a recommendation of caution and an Alberta-based study on the use of the medication as a treatment for COVID-19.

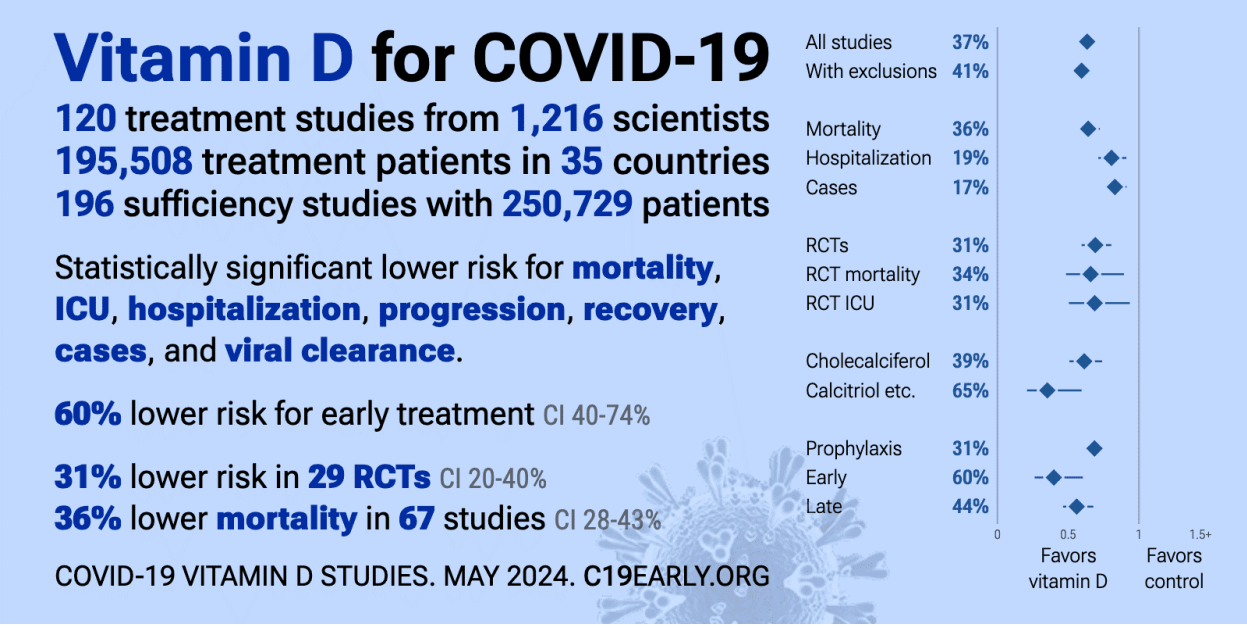
The SAG further advised against the use of colchicine in Alberta largely based on the study by Tardiff et al., "Colchicine for community-treated patients with COVID-19 (COLCORONA)," a phase 3, randomized, double-blinded, adaptive, placebo-controlled, multicentre trial,[347] which was funded by the Bill and Melinda Gates foundation which appears to be involved in the WHO's worldwide vaccine program.

Yet the conclusion of the study still supports the use of colchicine for COVID-19. From that study paper: "Interpretation: In community-treated patients including those without a mandatory diagnostic test, the effect of

colchicine on COVID-19-related clinical events was not statistically significant. Among patients with PCR-confirmed COVID-19, colchicine led to a lower rate of the composite of death or hospital admission than placebo. ***Given the absence of orally administered therapies to prevent COVID-19 complications in community-treated patients and the benefit of colchicine in patients with PCR-proven COVID-19, this safe and inexpensive anti-inflammatory agent could be considered for use in those at risk of complications.*** *Notwithstanding these considerations, replication in other studies of PCR-positive community-treated patients is recommended." The Alberta SAG, however, focused on a possible self-limiting diarrhea side effect as being dangerous to COVID-19 patients and advised against its use.*

Vitamin D3

Figure 7. Vitamin D for COVID-19.

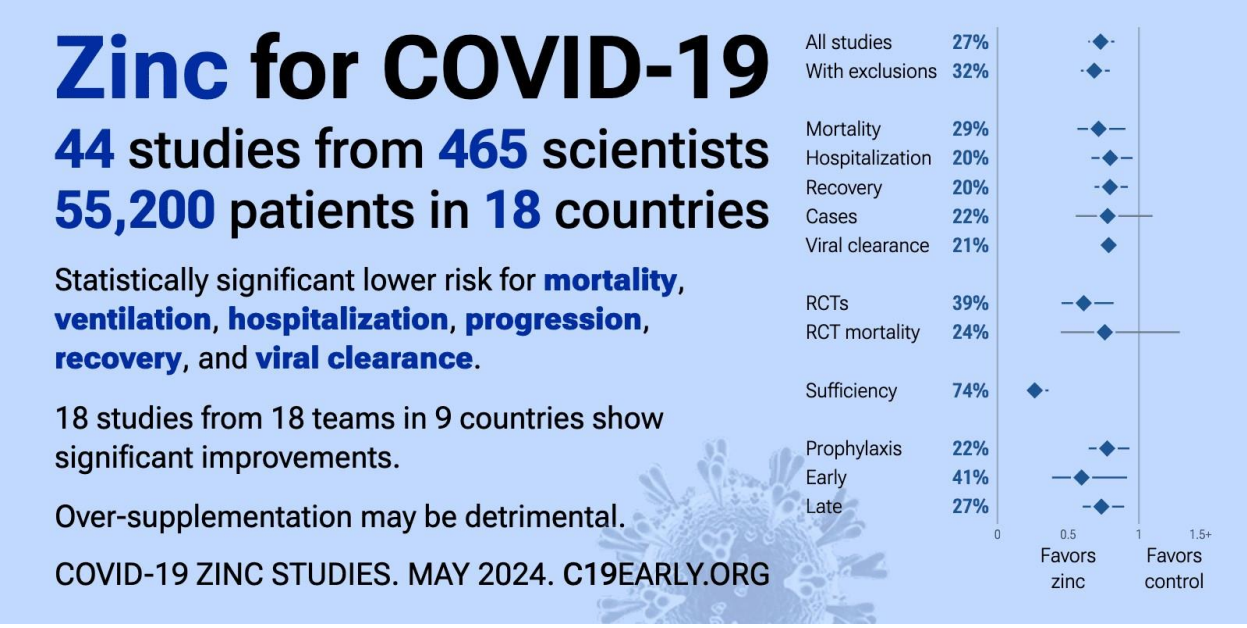


Vitamin D3 is a cofactor in the function of the immune system in the human body. It is essential for good health and is converted from the necessary precursors in the skin from the actions of sunlight. Vitamin D3 is often deficient in populations residing in northern climates due to long winters and short summers. It is available as a supplement and is recommended for those who live in northern latitudes. Because of its key role in the regulation of the immune system, it was reasonable to wonder if supplementation could aid

in the treatment and prevention of COVID-19. There were many studies done and reviews of these studies by various health authorities.[348] In 2021 the Mayo Clinic did a well-designed study on the correlation of serum Vitamin D3 blood levels and COVID-19 outcomes.[349] It showed a direct correlation to low Vitamin D3 levels and poor outcomes. The AHS SAG reviewed Vitamin D3 literature but did not include this study in their review and recommended against using Vitamin D3 in the treatment of COVID-19.

Zinc

Figure 8. Zinc for COVID-19.

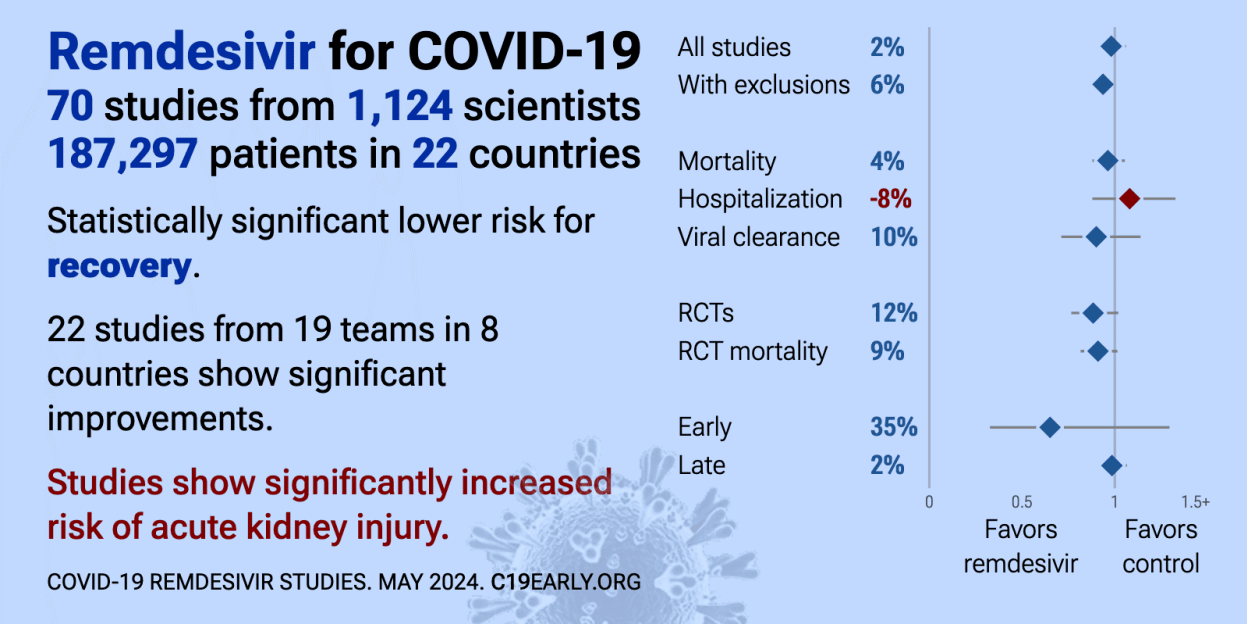


Zinc is an essential mineral for the human immune system and inhibits coronavirus RNA-dependent RNA polymerase (RdRp) activity.[350] Therefore, it would have made sense to see if Zinc supplements could have helped in the fight against COVID-19 virus. In conjunction with hydroxychloroquine, which is a zinc ionophore (carries the zinc into the cell), there appeared to be grounds to investigate its use in Alberta. While there was no official recommendation for or against the use of zinc in treating COVID-19 in Alberta, it was not encouraged. Zinc supplementation should have been studied in Alberta for possible benefit.

Inpatient Treatment

Remdesivir

Figure 9. Remdesivir for COVID-19.



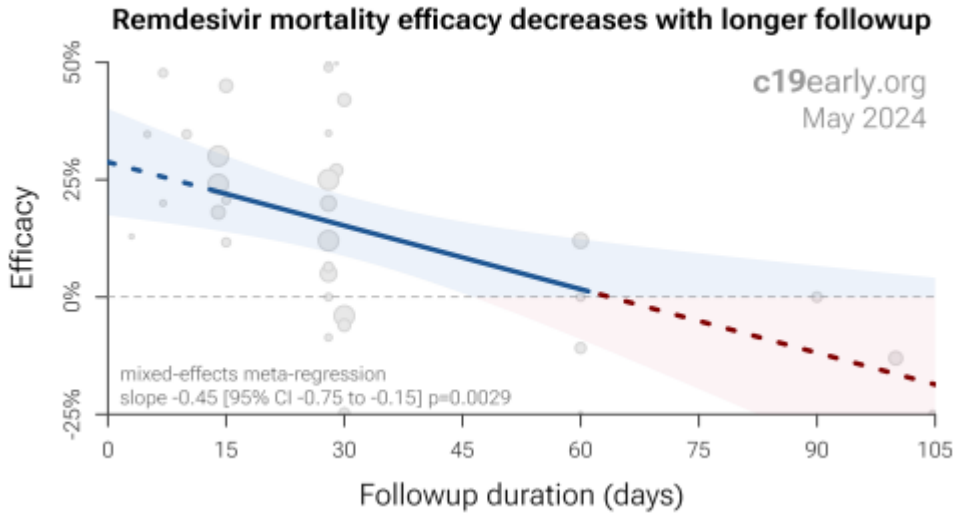
Remdesivir was the only antiviral included in AHS's COVID-19 Adult Admission Order Set for management of hospitalized patients with COVID-19 during 2020 to 2021.[351] Health Canada approved Remdesivir on July 27, 2020, for treatment of COVID-19 in adults and adolescents with pneumonia requiring supplemental oxygen based on interim data from a single phase III trial showing improvement in time to recovery within 28 days.[352] As stated in the docket, the decision summary indicated the absence of an established "clinical proof-of-concept for its antiviral activity." Patient follow-up for this primary outcome was incomplete and no benefit was found in the subset patients on mechanical ventilation or extracorporeal membrane oxygenation on day 1. Importantly, data on the key secondary endpoint of mortality at 28 days was not available.

Data from another phase III placebo-controlled RCT in hospitalized patients with COVID-19 published in the Lancet was available at the time of the review and showed no significant reduction in time to clinical improvement and mortality.[353]

Safety follow-up in all these studies was limited and therefore Remdesivir's safety profile remains ill-characterized. The data however was sufficient to show increases in markers of hepatoxicity, and Remdesivir use COVID-19 treatment has since been associated with cases of liver failure.[354] Despite the uncertain benefits, and known and unknown risks, Remdesivir was not only approved but also its use in COVID-19 treatment was expanded beyond the scope of available clinical data to include adolescents (12-17 years-old) based solely on a modelling study. On October 15, 2020, data from the large Phase III SOLIDARITY trial was publicly available showing no benefit in mortality reduction for Remdesivir in hospitalized patients with COVID-19.[355] Although representing the best available evidence at that time, the data was withheld by the sponsor from the European Commission during contract negotiations.[356] This was insufficient to trigger regulatory review of Remdesivir's conditional approval in Canada and to stop the FDA's approval on October 22, 2020.[357] On November 20, 2020, WHO recommended against use of Remdesivir in COVID-19 patients.[358] Additionally, anecdotal evidence reviewed indicated that patients who survived severe COVID-19 and received Remdesivir during their hospital treatment were monitored for at least one year after treatment.

When Remdesivir patients were followed past 60 days, the efficacy of the drug dropped to 0 and at 100 days post treatment it reaches nearly –20% efficacy. Despite this performance, Alberta's SAG advised its use for treatment of COVID-19 without evidence from its own formal analysis.

Figure 10. Remdesivir Mortality Efficacy Over Time.[359]



Corticosteroids

Corticosteroids are routinely used as an anti-inflammatory in lower respiratory tract infections (LRTIs). Therefore, it made sense to determine whether there was a place for them in COVID-19 treatment. Prednisolone is used to treat children with RSV pneumonia, while prednisone is used to treat the exacerbation of chronic obstructive pulmonary disease ("COPD"). Dexamethasone (Decadron), another corticosteroid, is used in a variety of acute pulmonary conditions. Inhaled cortico-steroids like Pulmicort and Fluticasone are used routinely to treat asthma and COPD.

The Recovery trial showed some benefit from dexamethasone in COVID-19 inpatients, but none was seen in conjunction with Remdesivir.[360] Pulmicort was also studied in the Recovery trial, and it showed some benefit for unvaccinated patients but none for the vaccinated.[361]

Dexamethasone was used extensively in the treatment of inpatients in Alberta. We found no studies in Alberta examining what effect this drug had on patient outcomes. Pulmicort was used often in the outpatient setting as it is a commonly used medication for many LRTIs and has a long safety record in the community. We could not find an Alberta study looking at the effects of pulmicort use in the outpatient setting.

Conclusions and Recommendations

In order to ensure that residents of Alberta have the best available treatment in any future potential future health emergencies, we need to guard Albertan's right to care and informed consent and the right of their health care professional to provide treatments that are in their best interest.

Recommendations

1. Amend the *Health Professions Act* ("HPA") to prevent regulatory bodies from using "professionalism" or "codes of conduct" to obstruct the administration of approved medications for off-label uses.
2. Instruct regulatory bodies to halt all prosecution or disciplinary actions against healthcare workers or pharmacists for using, promoting, or publicly discussing the benefits of approved medications for off-label treatment of illnesses.
3. Amend current law or prepare new legislation that makes the public discussion of alternative medical treatments a matter protected under the *Alberta Human Rights Act*.
4. Amend the HPA to protect a physician's right to prescribe and a pharmacist's ability dispense drugs that, in their professional judgement, are in a patient's best interest. This includes personalizing established guidelines and prescribing off-label drugs.
5. Amend the *Alberta Human Rights Act* to protect Albertans' right to access to therapies in their best interest including off-label drugs and natural health products.
6. Ensure rigorous standards of safety are upheld for all treatments, even during a public health emergency, and allow for greater flexibility in the use of therapies with established safety records.
7. When reporting on health-related matters, require media to cite levels of supporting evidence and publicly disclose any political or financial competing interests that may influence their reporting, including publicly disclosing the dollar value and conditions of their public health and pharmaceutical contracts.

8. Enact whistleblower legislation to protect a physician's right to publicly voice concerns regarding potentially harmful or ill-conceived policies enacted by public health, regulatory bodies, or medical facility management organizations.
9. Create an avenue to expediate creation of clinical trials of off label or other treatments.

Appendix 1

Figure 11. Adverse Events by COVID-19 Treatments and Other.

Data retrieved from WHO/Uppsala VigiAccess pharmacovigilance database (22.03.2021)				
Medicine	**Year reporting started**	**Deaths**	**Deaths per year**	**Adverse events**
Ivermectin	1992	16	< 1	4702
Aspirin	1968	1432	8	177606
Remdesivir	2020	467	467	5733
Tocilizumab	2005	769	48	47545
COVID-19 vaccines	2020	2402	9612	309403
Tetanus vaccine	1968	32	< 1	14725

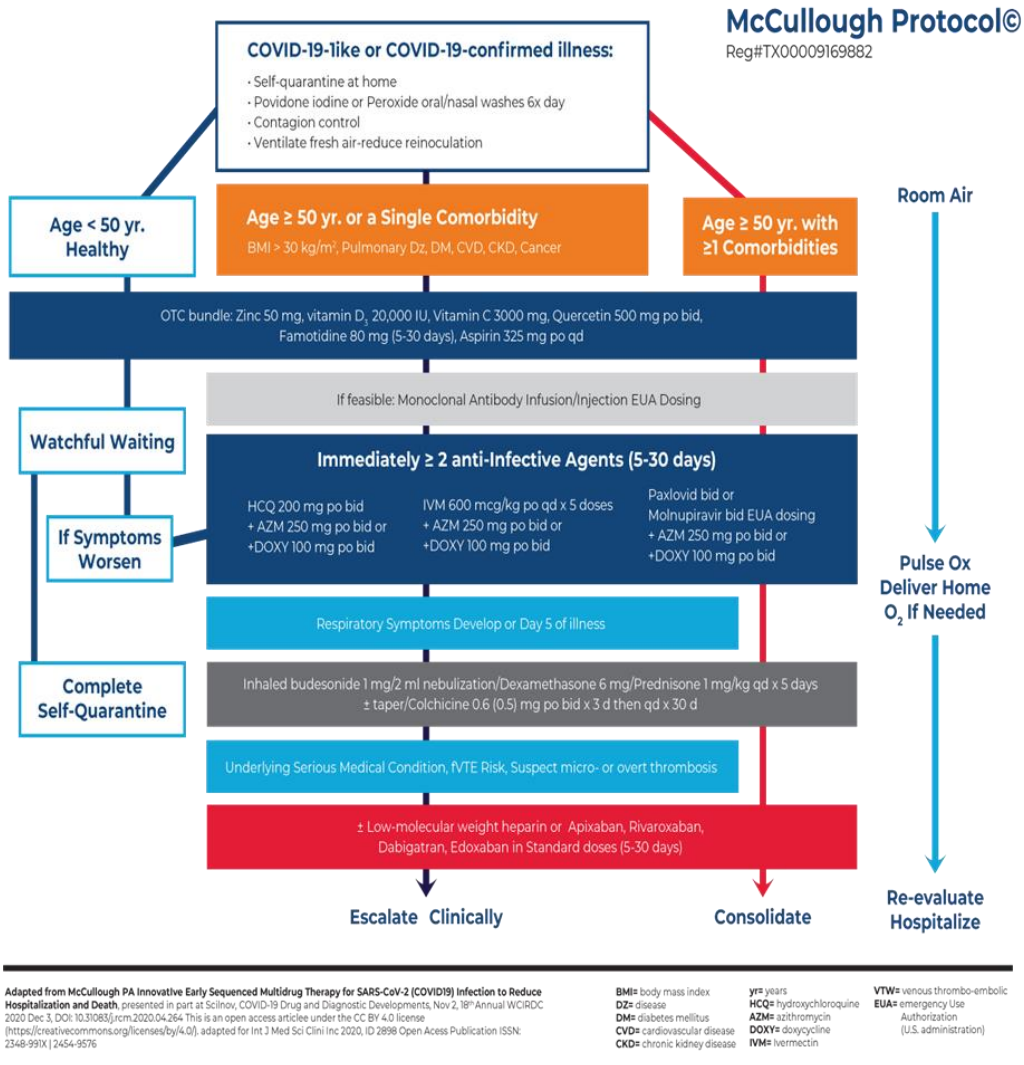
Adverse events in the VigiAccess pharmacovigilance database associated with ivermectin, aspirin, a tetanus vaccine, and different COVID-19 pharmaceutical interventions with regulatory approval.[362]

Appendix 2

Outpatient Treatment Protocols Used for COVID-19

There were many outpatient protocols used in the fight against COVID-19. The most well-known is the McCullough protocol developed by cardio-renal specialist, Dr. Peter McCullough, in Texas. He presented a staged treatment protocol that was physiologically relevant to the mechanism he observed with COVID-19. It was dependent on early and targeted treatment. Dr. McCullough is one of the most published specialists in his field and followed up on tens of thousands of COVID-19 patients that were treated with his protocol to determine its efficacy.[363]

Figure 12. McCullough COVID-19 Treatment Protocol.



Adapted from McCullough PA Innovative Early Sequenced Multidrug Therapy for SARS-CoV-2 (COVID19) Infection to Reduce Hospitalization and Death, presented in part at Scilnov, COVID-19 Drug and Diagnostic Developments, Nov 2, 18th Annual WCIRDC 2020 Dec 3, DOI: 10.31083/j.rcm.2020.04.264 This is an open access articlee under the CC BY 4.0 license (https://creativecommons.org/licenses/by/4.0/). adapted for Int J Med Sci Clini Inc 2020, ID 2898 Open Acess Publication ISSN: 2348-991X | 2454-9576

BMI= body mass index
DZ= disease
DM= diabetes mellitus
CVD= cardiovascular disease
CKD= chronic kidney disease
yr= years
HCQ= hydroxychloroquine
AZM= azithromycin
DOXY= doxycycline
IVM= Ivermectin
VTW= venous thrombo-embolic
EUA= emergency Use Authorization (U.S. administration)

The McCullough protocol was used with many COVID-19 patients in Alberta with very positive results, yet healthcare providers were strongly discouraged by medical authorities from using any part of it. Why was this? In 2020, when there were no other treatments for COVID-19 and 82%-83% of all deaths were in seniors, why was use of this protocol not encouraged, and the results compiled into an Alberta-based study? There was no vaccine and no other safe treatments available at the time. This appears to be at odds with how science ought to be conducted and needs to be investigated.

Disclaimer

The members of the Task Force hold a wide range of opinions and are not united by any political viewpoints or ideologies. Many Task Force members have voiced criticisms of how Alberta's experience with COVID-19 was handled by government agencies and the individuals appointed as public figures. This is a document reviewing both clinical and public-health data, as well as the decisions that resulted, and we write it as scientists, physicians, and lawyers with different specific areas of expertise, but sharing similar views of the basic principles of public health. Aside from the request from the Offices of the Premier and the Minister of Health, our work on this document was not on behalf of any institution, public or private. Furthermore, the statements written in each chapter represent the personal interpretations of Task Force members and do not necessarily represent those of their employers. Finally, as new studies emerge, parts of this report may become out of date or less accurate. However, the contents of this report are based on current information as of April 2024.

Endnotes

Chapter 1: Governance and Flow of Information

[1] *Public Health Act*, RSA 2000, c P-37, s 1(bb), https://www.canlii.org/en/ab/laws/stat/rsa-2000-c-p-37/latest/rsa-2000-c-p-37.html.
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Chapter 9: Therapeutics

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