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The Role of Vaccine Safety in Health Services Research

Current practice and future directions

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Disclosure

- Primary employer, Institute of Health Economics, not-for-profit research organization.
- Secondary affiliation, University of Alberta
- Voting member, National Advisory Committee on Immunization (Volunteer position)

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Health services research

> Health services research focuses on improving health care for everyone. By studying how health care services are organized, supported, and delivered across Canada, we can make the overall system better.
>
> **– Canadian Institute for Health Research**

Examples of vaccine safety in health services research

Vaccine safety in health services research

Impact of vaccine safety outcomes of health services use

- Health care use for adverse events following immunizations (AEFIs)

Vaccine safety in health services research

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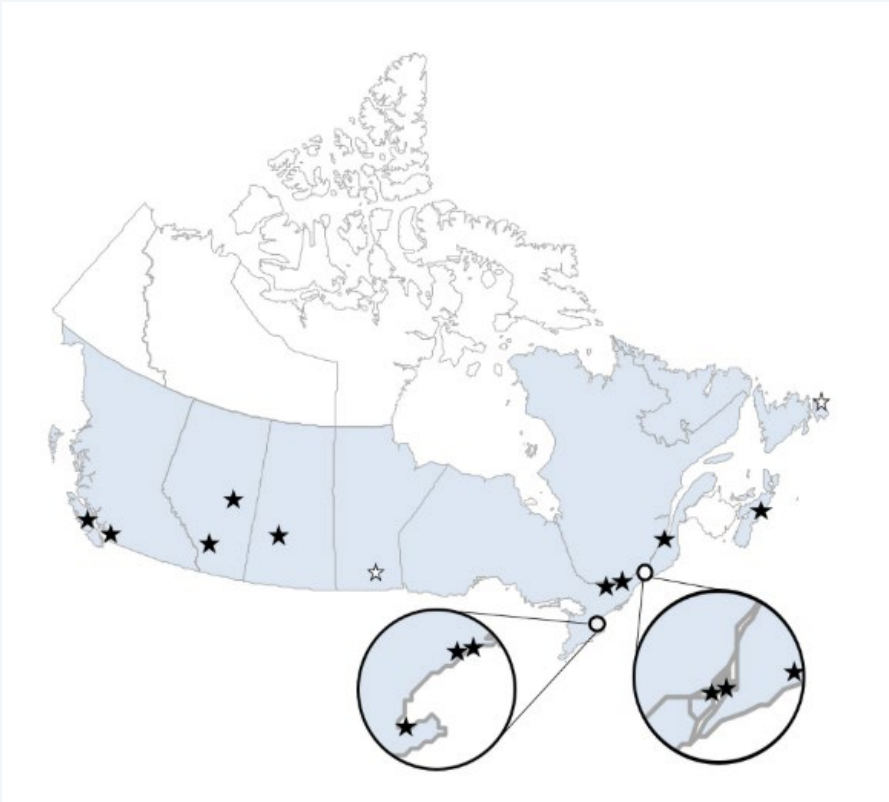
Vaccine provider and safety outcomes

- Do AEFIs or vaccine errors differ by vaccine provider
- Impact of dedicated vaccine safety clinics



Special Immunization Clinic (SIC) Network

WHAT IS SIC?

The Special Immunization Clinic (SIC) Network aims to improve the assessment and management of patients with medically challenging adverse events following immunization (AEFIs) and underlying medical conditions that may complicate immunization.

SIC conducts standardized assessments of patients with previous AEFIs and underlying medical conditions, and assesses the risk of AEFI recurrence following revaccination.

SIC evaluates vaccine safety, immunogenicity and coverage in immunocompromised patients

SIC has built a national registry of patients assessed in the clinics and their outcomes after

Vaccine safety in health services research

Impact of vaccine safety outcomes of health services use

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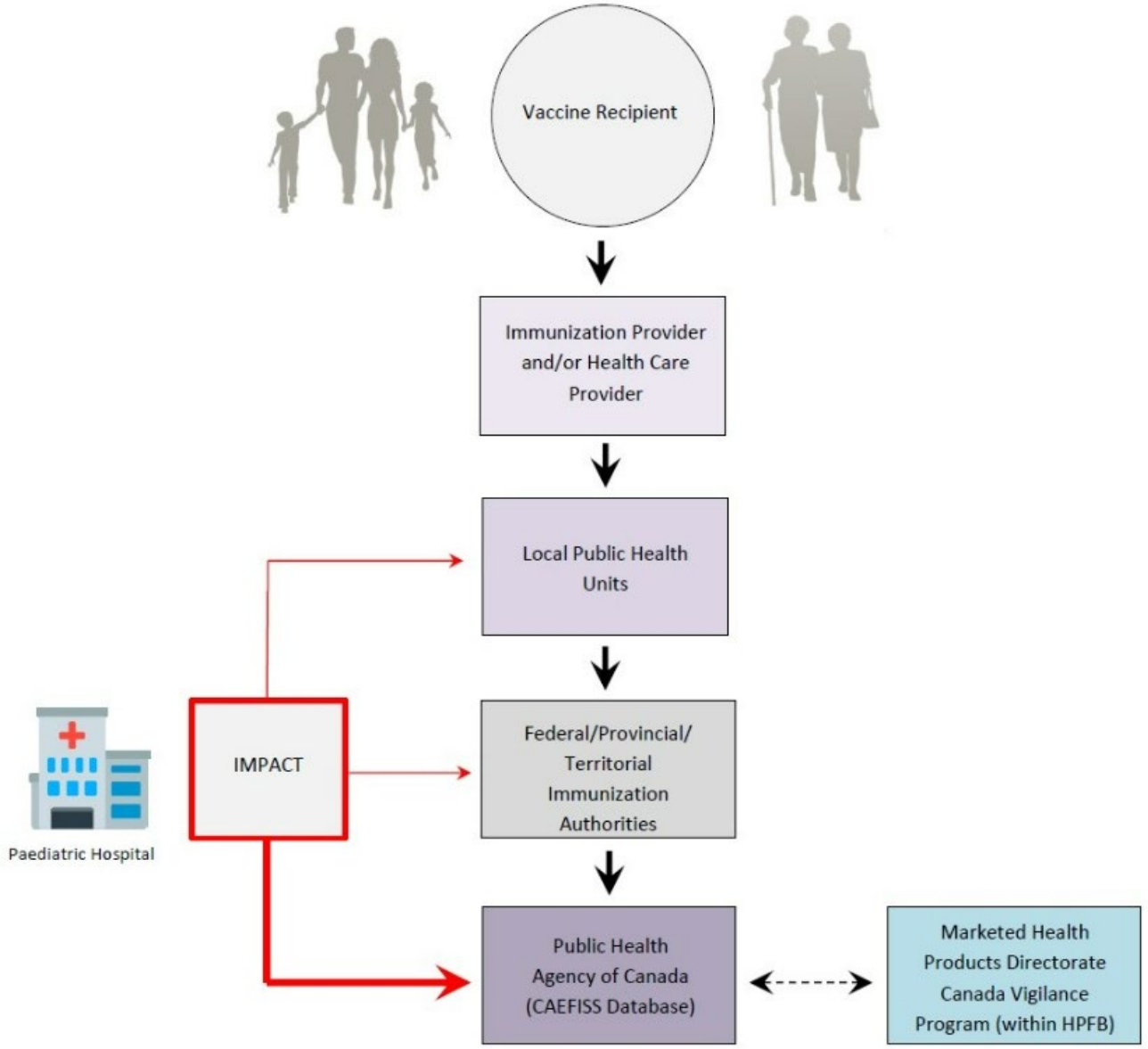
Post-marketing vaccine safety surveillance

- Limited number of people included in clinical trials
- Often vaccine safety signals are only captured when distributed to larger populations

Post-marketing vaccine safety surveillance

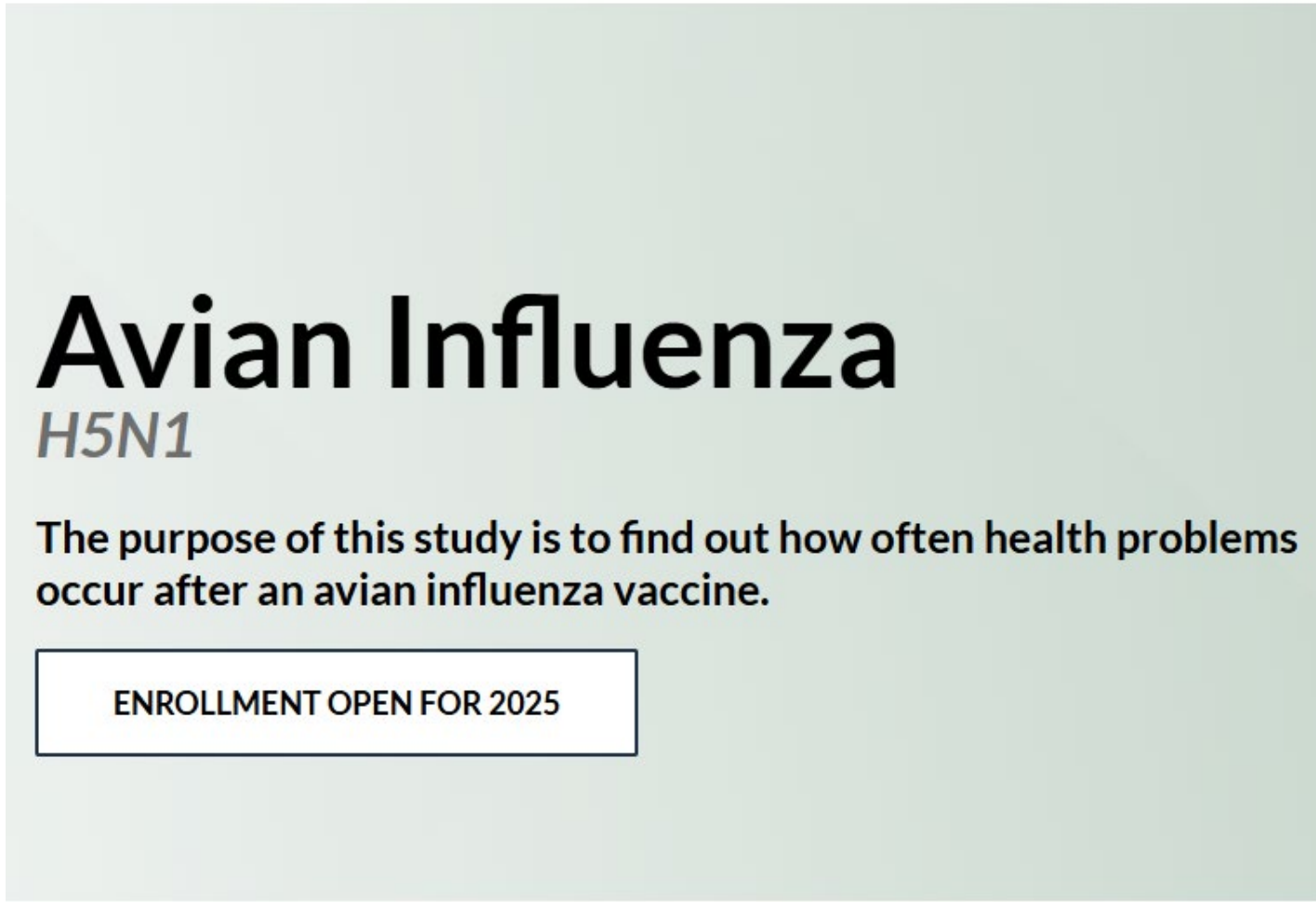
- Canadian Adverse Events Following Immunization Surveillance System
- Passive surveillance
  - Spontaneous reports to local public health units or primary care, then onward from FPTs
- Active surveillance
  - IMPACT (Immunization Monitoring Program ACTive)



Active surveillance

Canadian National Vaccine Safety (CANVAS) network.

- Run multiple active vaccine safety studies



Why is post-marketing surveillance and health services research important?

- Increases in frequence or severity of previously identified AEFIs
- Previously unknown adverse events potentially related to a specific vaccine
  - New at-risk populations
- Areas for future investigation or research
- Provide timely information on AEFIs profiles
  - Help inform future immunization decisions
- Increase confidence in vaccines and their safety
- Better communication of risks to vaccine providers and receivers

Vaccine safety in health services research

Integration into routine care

- How we can integrate vaccine safety monitoring into primary care and hospital systems.

Vaccine safety in health services research

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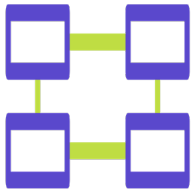


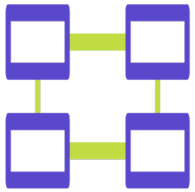
Vaccine safety monitoring systems

- Setting up appropriate systems to capture AEFIs
- Evaluating the impact of these systems

Vaccine safety in health services research

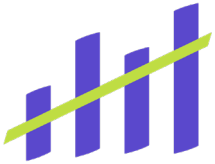
Integration into routine care

- How we can integrate vaccine safety monitoring into primary care and hospital systems.



Vaccine safety monitoring systems

- Setting up appropriate systems to capture AEFIs
- Evaluating the impact of these programs



Health Economics

- Better estimates of cost-effectiveness of vaccines
- Better vaccine decision-making
- Appropriate pricing

Overview economic evaluation of vaccines

What is an economic evaluation?

- Economic evaluation is the comparative analysis of alternative courses of action in terms of their costs and consequence
    - Elements needed in an economic evaluation
        1. Comparison of alternatives (e.g., current practices vs. new vaccine)
        2. Cost of alternatives
        3. Consequences or effects of the alternatives

Purpose of economic evaluations

- In a world with limited resources
  - Estimate cost-effectiveness
  - Determine value for money and resource allocation
  - Optimize limited funds

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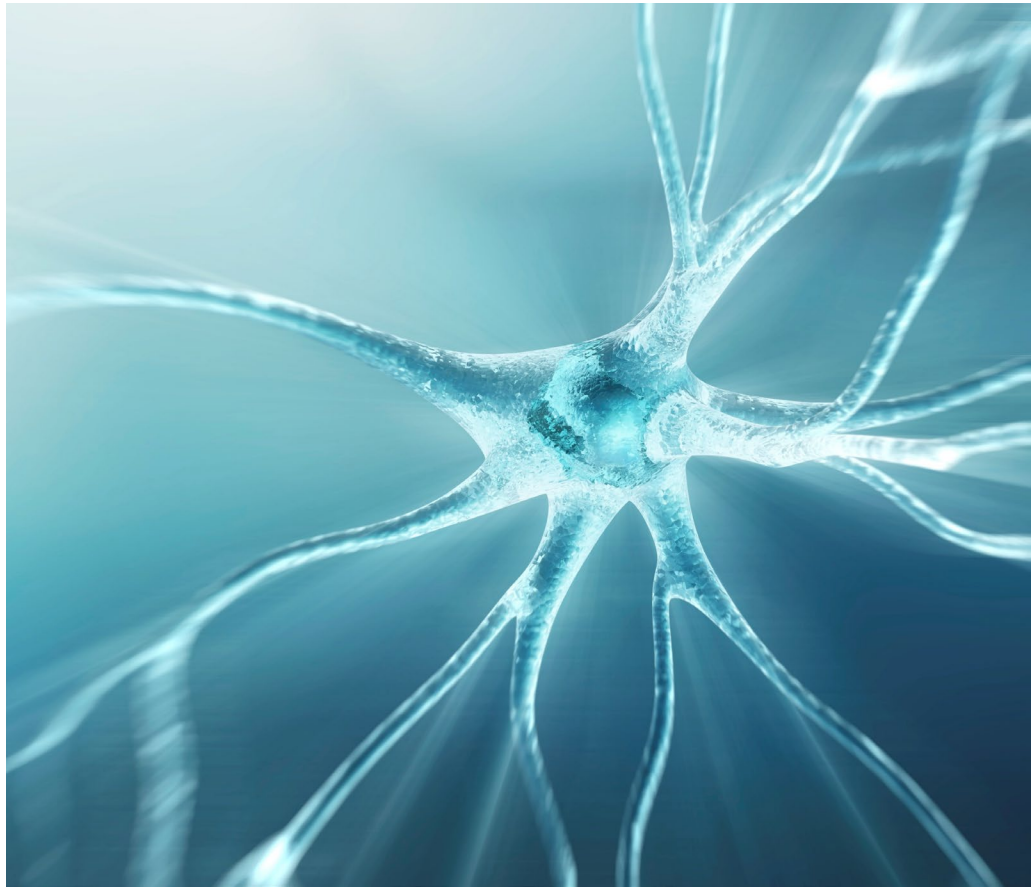
Parts of an economic evaluation



1. Disease/intervention model
2. Economic analysis
   - Data inputs
     - Relevant outcomes
     - Relevant costs

ScienceDirect

Contents lists available at **sciencedirect.com**
Journal homepage: **www.elsevier.com/locate/jval**

Themed Section: Vaccines

What We Know Now: An Economic Evaluation of Chickenpox Vaccination and Dose Timing Using an Agent-Based Model

Ellen R.S. Rafferty, PhD, Wade McDonald, BSc, Nathaniel D. Osgood, PhD, Alexander Doroshenko, MD, Marwa Farag, PhD

Vaccine safety in economic evaluations: Current practice

- AEFIs
  - **Health outcomes associated with immunization**
- Chickenpox example
  - Febrile seizures

Vaccine safety in economic evaluations: current practice

- AEFIs
  - Health outcomes associated with immunization
  - **Healthcare service use**
- Chickenpox example
  - Emergency room visits for febrile seizures

Vaccine safety in economic evaluations – current practice

- AEFIs
  - Health outcomes associated with immunization
  - Healthcare service use
  - **Healthcare and productivity loss costs**
- Chickenpox example
  - Health care costs associated with febrile seizure
  - Time spent going to and from care
  - Parking

Vaccine safety in economic evaluations – current practice

- AEFIs
  - Health outcomes associated with immunization
  - Healthcare service use
  - Healthcare costs
- **Coverage**
- Chickenpox example
  - How will safety concerns impact overall vaccine uptake?

Future directions

Areas of future direction

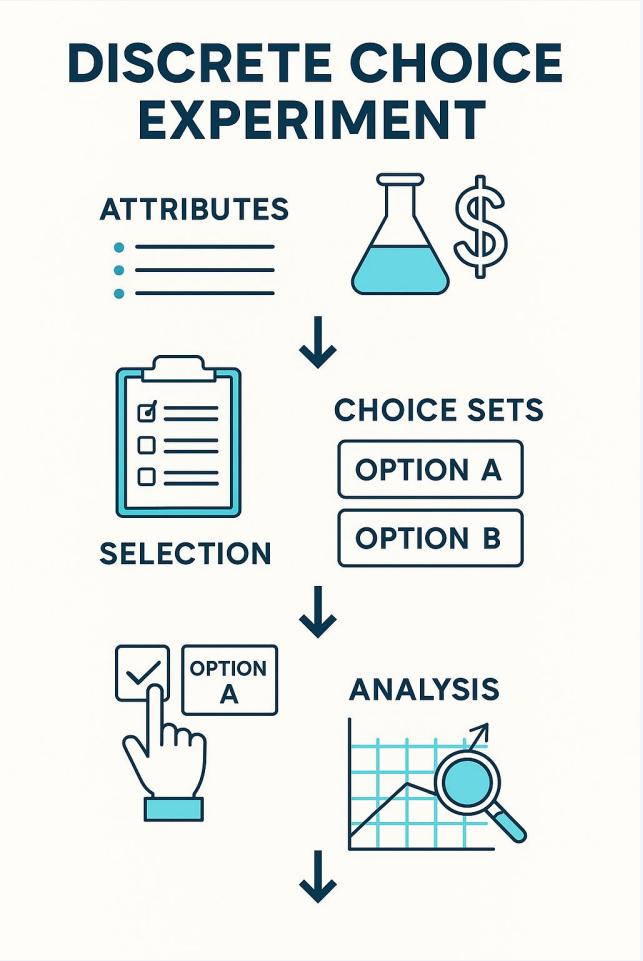
1. Capturing immunization preference and choice

Product (Vaccine or mAb)	Type / Platform	Indication / Population
Abrysvo (Pfizer)	Protein subunit vaccine	Adults 60+
Arexvy (GSK)	Protein subunit vaccine	Adults 60+
mRESVIA (Moderna)	mRNA vaccine	Adults 60+
Nirsevimab (Beyfortus, Sanofi/AstraZeneca)	Monoclonal antibody	Infants during first RSV season
Clesrovimab (Enflonsia, AstraZeneca)	Monoclonal antibody	Neonates/infants entering first RSV season

Product (Vaccine or mAb)	Type / Platform	Indication / Population
Comirnaty (Pfizer/BioNTech)	mRNA vaccine	Broad use (children & adults)
Spikevax (Moderna)	mRNA vaccine	Broad use
Vaxzevria (AstraZeneca)	Viral vector vaccine	Adults (some countries)
Nuvaxovid (Novavax)	Protein subunit vaccine	Adults & adolescents

Discrete choice experiment

- Participants shown series of hypothetical examples
  - "Which vaccine would you choose?"
    Option A: 95% effective, mild side effects in 1/100, two doses, $20
    Option B: 85% effective, no severe side effects, one dose, free
  - They pick the option they prefer in each scenario
- These can then be incorporated into decision tree models and economic evaluations
- Also allows for estimations of willingness to pay
  - Which can help set prices for vaccines, especially for the private market.



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Of studies looking at what vaccine preferences are driving vaccine-decision making found vaccine risk was a significant factor.

Research | Open access | Published: 28 August 2021

Vaccine preferences driving vaccine-decision making of different target groups: a systematic review of choice-based experiments

Marilyn Emma Diks, Mickael Hiligsmann & Ingeborg Maria van der Putten

BMC Infectious Diseases **21**, Article number: 879 (2021) | Cite this article

Areas of future direction

1. Capturing vaccine choice

2. Risk-based pricing

The risk-based price: incorporating uncertainty and risk attitudes in health technology pricing

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Areas of future direction

1. Capturing vaccine choice

2. Risk-based pricing

3. Earlier integration of vaccine safety considerations into economic evaluations

When to integrate vaccine safety?

Viral Vector Vaccine Platforms for Rapid Response to Future Pandemics

Director: Peter Pelka **Co-Director:** Maya Shmulevitz

CBRF: $18.9M **BRIF**: $38.1M

This proposal is the largest federal research investment ever received by the University of Manitoba. It is led by Dr. Peter Pelka at the University of Manitoba and Dr. Maya Shmulevitz at the University of Alberta, with team members also at the University of Calgary and University of Saskatchewan/VIDO. This team brings expertise in virology, immunology, infectious disease, biomedical engineering, health economics, artificial intelligence, and bioprocessing.

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Thank you! Questions?

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