



# Building on the Legacy of Vaccines in Canada: Value, Opportunities, and Challenges

## 9

### Ensuring Vaccine Safety and Effectiveness for Canadians



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Vaccine Industry Committee

# **Ensuring Vaccine Safety and Effectiveness for Canadians**

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**Assurer l'innocuité et l'efficacité des vaccins au profit des Canadiens**

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Ce document forme une partie de la série, *Les vaccins au Canada, un héritage à faire fructifier : Valeur, possibilités et défis*. Pour lire la série entière, veuillez visiter [www.biotech.ca/vaccines](http://www.biotech.ca/vaccines). (Document disponible en anglais seulement.)

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## 9.1 Executive Summary / Sommaire

### 9.1.1 Executive Summary

Immunization is currently considered a cornerstone of public health practice in Canada. Fortunately, given the tremendous potential for immunization in terms of contributing to “public good”, currently available vaccines have a favourable safety record; most side effects are minor and serious complications are rare. Yet the continued success of immunization programs in Canada requires a comprehensive, effective and efficient vaccine safety system, including ongoing pre- and post-licensure testing and regulatory controls, as described in Paper 4, as well as vigilant post-market assessment of adverse events following immunization (AEFI), described herein. While manufacturers typically conduct Phase IV studies to evaluate vaccine safety and/or efficacy – and are also required by law to report serious AEFI – the majority of post-market vaccine safety reporting is conducted by health providers and public health authorities, as part of the extensive Public Health Agency of Canada (PHAC) surveillance framework.

The term “surveillance” is defined as the systematic ongoing collection, collation and analysis of data, with timely dissemination of information to those who require it in order to take action, i.e. to improve prevention or control of relevant conditions. Within the context of immunization, effective surveillance systems permit monitoring of: i) the epidemiology and burden of vaccine-preventable diseases (VPD); ii) vaccine coverage; and iii) post-market vaccine safety, including AEFI. Hence, it should be emphasized that post-licensure safety initiatives represent but one arm of an even broader set of surveillance systems to support immunization programs in Canada. Operating in concert, these surveillance networks have the potential to provide critical intelligence, not only to support the rationale for introducing new vaccination programs, but also to gauge their subsequent impact on disease incidence and burden, and to evaluate vaccine safety in the post-marketing phase. Such information ultimately guides vaccine policy – to help optimize the safety, effectiveness, value and success of immunization program planning and delivery.

Since disease surveillance falls within Canada’s federal mandate, most VPD are under surveillance by one or more national systems, including the Notifiable Diseases Reporting System (NDRS) coordinated by the PHAC. The NDRS is a passive (voluntary) surveillance system used to monitor more than 40 notifiable infectious diseases, encompassing numerous VPD. At present, disease surveillance in Canada is very complex, since multiple programs exist at the national, provincial/territorial (P/T), and regional/municipal levels; this system is characterized by substantial gaps, delays, and inconsistencies in data reporting. Significant improvement will be required in the existing disease surveillance infrastructure, i.e. to help generate accurate, timely data regarding VPD occurrence – as a basis for public health decision-making.

With regard to surveillance of vaccine coverage rates in Canada, information is currently derived from a variety of sources, including immunization surveys (typically conducted every second year), as well as through vaccine registries, which are used to manually record data from patient records. At present, roughly half of Canada’s P/T jurisdictions have fully functional vaccine registries; the remaining jurisdictions are in the process of implementing or evaluating potential options – including consideration of data standards to ensure compliance with the pan-Canadian public health surveillance system known as Panorama (part of Canada Health’s INFOWAY). Overall, considerable variation currently exists in the frequency and type of data collected across P/T vaccine registries, and it remains extremely challenging to determine uptake rates for childhood or adult vaccines. Substantial future resources will be needed to develop a nationwide system of registries that can accurately track vaccination status across the country.

As one major avenue for advancing vaccine registries in Canada, the development of a standardized vaccine bar coding system is anticipated to facilitate future data entry, i.e. by dramatically increasing the speed, accuracy and completeness of recording vital immunization information. More broadly, vaccine bar coding would also permit real-time inventory management, thus helping to reduce supply shortages, and could also improve patient compliance and safety, e.g. by facilitating scheduling for multi-dose immunizations and/or accelerating appropriate follow-up for patients who experience AEFI. Building on previous work initiated by the PHAC, the Automated Identification of Vaccine Products Advisory Task Group (AIVP ATG) – as co-chaired by BIOTECCanada's Vaccine Industry Committee (VIC) – has recently conducted a cost-benefit analysis to assess potential bar coding options. The ATG has proposed a step-wise implementation strategy, beginning with the introduction of a bar code to provide *non-variable* data (specifying the manufacturer and product tradename) on the primary vaccine package; manufacturers could work towards implementing such a standard, on a voluntary basis, within 18-24 months.

In addition to surveillance activities conducted to monitor disease incidence and vaccine coverage (e.g. through registries), significant efforts are undertaken in Canada to ensure the safety of approved vaccines, and to rapidly detect any safety signals of concern. Such post-market safety surveillance of preventive vaccines is overseen primarily by the PHAC, with input from the Biologics and Genetic Therapies Directorate (BGTD). Specifically, two distinct systems are in place to support voluntary and mandatory surveillance of approved vaccines; these networks are known as the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS), and IMPACT (Immunization Monitoring Program ACTive), respectively. Notably, the IMPACT system documents AEFI through 12 pediatric hospitals across the country. Recent findings from these surveillance programs clearly document the rarity of harm from immunization, and overwhelmingly support the argument that the vast, vast majority of those immunized do not suffer any negative effects. In general however, since Canada's current surveillance systems are limited by a lack of timely, standardized, and complete reporting methods (across local, P/T and national levels), analysis of case-specific AEFI rates requires extremely cautious interpretation.

While serious AEFI are rare and far outweighed by the benefits of immunization, Canada currently has no national program in place to compensate those injured by vaccines. Many calls have been made for a no-fault compensation (NFC) system, which could rapidly provide financial support to individuals who have experienced documented vaccine-related harm (i.e. while undergoing an intervention that contributes to the greater public good), without having to go through the expensive traditional litigation process. Such calls for a national NFC scheme are driven by the need for patient access to fair compensation within an ethical, just, and socially responsible system. In tailoring a unique national program, Canada should draw upon best practices in other jurisdictions, including Germany, the United States, the United Kingdom, and Québec – which introduced a provincial NFC program in the mid-1980s.

Overall, as the number of available vaccines and the complexity of P/T immunization schedules continues to grow, Canada needs to strengthen its capacity to collect, investigate, share, and respond to information in a timely fashion (e.g. across local/regional/national levels and among distinct surveillance networks) – through the continued development of a comprehensive, standardized, and robust vaccine-related surveillance infrastructure. To achieve this ambitious goal, and to ensure vaccine safety and effectiveness for all Canadians, close cooperation will be required among many partners, including front-line health providers, manufacturers, regulators, and public health officials at all levels of government. In the spirit of such collaboration, and for the sake of fairness to individuals and the health of the broader population, the VIC has put forward the following recommendations for consideration by F/P/T governments.

### Federal/Provincial/Territorial (F/P/T) Recommendations

1. To enhance Canada's capacity to evaluate the (baseline) health and socio-economic burden of vaccine-preventable diseases, and to permit accurate, timely assessment of the public health benefits of subsequent vaccination, F/P/T governments should allocate significant additional funds/resources to strengthen Canada's multi-faceted (but currently fragmented) disease surveillance infrastructure.
  - Given that the National Advisory Committee on Immunization (NACI) review process for new vaccines relies heavily on epidemiology data for vaccine-preventable diseases, the availability of current, standardized, comprehensive (national) disease surveillance information will also facilitate (and minimize delays in) evidence-based decision-making and recommendations for emerging vaccine technologies in Canada.
2. To compel jurisdictions to rapidly share epidemiologic and other disease surveillance information, both routinely and during disease outbreaks/threats, more formal data-sharing agreements (i.e. to establish clear, formal legal obligations) should be implemented across F/P/T governments – following the example of an agreement signed between the federal government and Ontario in 2008.
3. To improve Canada's ability to track immunization coverage in a timely, accurate manner, federal leadership and additional investment by F/P/T governments will be required to further develop vaccination registries, including the finalization of data standards to ensure compliance with the immunization registry module of the pan-Canadian Panorama surveillance system.
4. To facilitate future data entry into vaccine registries (i.e. via electronic scanning), the development of a standardized bar coding system for vaccines will be required in Canada. The VIC, in collaboration with the AIVP ATG, recommends a step-wise implementation strategy for such a system, beginning with the early adoption of a bar code on the primary vaccine package with *non-variable* data only. In this case, a linear bar code, using reduced space symbology (RSS), would encode the Global Trade Item Number (GTIN), which identifies the manufacturer and product tradename. Vaccine manufacturers could work towards implementing such a bar code on a voluntary basis within a reasonable timeframe, e.g. 18-24 months.
5. To ensure the successful implementation of vaccine bar coding standards in Canada, the PHAC/AVIP should continue to work collaboratively (e.g. through the AIVP ATG) with manufacturers, BGTD, GS1 Canada, P/Ts, and end-users (health practitioners, hospitals, and patient associations) to address the requirements of all relevant stakeholders across a wide range of immunization settings.
6. To support timely, accurate, systematic, and comprehensive reporting of AEFI – and thus to permit rapid detection of any safety signals of concern – additional F/P/T government funds/resources should be deployed to strengthen Canada's post-marketing safety surveillance infrastructure, including enhancement of the current CAEFISS and IMPACT networks.
  - Improvements should be made in information sharing and communication speed (from local to P/T and national levels) to permit timely, efficient analysis of aggregate data.
7. To protect individuals who have suffered vaccine-related injuries (as well as to provide a more secure legal environment for vaccine innovation, and to help protect the vaccine supply), Canada should establish a national no-fault compensation (NFC) program similar to those that exist in other jurisdictions worldwide.
  - In tailoring a compensation scheme uniquely for Canada, the current U.S. and Québec NFC systems could serve as useful comparative models, from which to draw lessons regarding the optimal national legal structure – including consideration of appropriate financing schemes, claim criteria, adjudication procedures and litigation rights.

## 9.1.2 Sommaire

*L'immunisation est considérée comme l'une des pierres angulaires de la pratique en santé publique au Canada. Heureusement, compte tenu des possibilités énormes qu'offre l'immunisation en contribuant au « bien commun », les vaccins actuellement disponibles ont une excellente feuille de route en matière d'innocuité; la majorité des effets secondaires sont minimes et rares sont les complications graves. Néanmoins, la réussite continue des programmes d'immunisation au Canada exige la mise en place d'un système complet et efficace de surveillance de l'innocuité des vaccins, y compris des mécanismes d'évaluation et de réglementation avant et après leur homologation, comme il est question dans le document 4, ainsi que d'un système rigoureux d'évaluation des effets secondaires suivant l'immunisation (ESSI), comme l'explique le présent document. Bien que les fabricants réalisent habituellement des études de phase IV afin d'évaluer l'innocuité et(ou) l'efficacité des vaccins – et qu'ils soient également tenus par la loi de déclarer les ESSI graves – ce sont les professionnels de la santé et les autorités en matière de santé publique qui établissent la majorité des rapports post-commercialisation sur l'innocuité des vaccins dans le cadre du vaste programme de surveillance de l'Agence de la santé publique du Canada (ASPC).*

*On entend par « surveillance » la collecte, la compilation et l'analyse systématiques et continues de données, et la diffusion en temps utile de ces données aux personnes qui ont besoin de les connaître pour prendre les mesures qui s'imposent, c'est-à-dire améliorer la prévention et le contrôle des maladies connexes. Dans le contexte de l'immunisation, la mise en place de systèmes de surveillance efficaces permet d'évaluer : i) l'épidémiologie et le fardeau des maladies évitables par la vaccination (MEV), ii) la couverture vaccinale et iii) l'innocuité des vaccins après leur commercialisation, y compris les ESSI. Il importe, par conséquent, de souligner que les efforts visant à assurer l'innocuité des vaccins après leur homologation ne sont qu'une partie d'un ensemble encore plus vaste de systèmes de surveillance destinés à appuyer les programmes d'immunisation au Canada. Conjointement, ces réseaux de surveillance ont la capacité de fournir des renseignements indispensables, qui non seulement contribuent à justifier la mise en place de nouveaux programmes de vaccination, mais aussi à en mesurer l'impact ultérieur sur l'incidence et le fardeau de la maladie, et à évaluer l'innocuité des vaccins après leur commercialisation. Ces renseignements servent en bout de ligne à orienter les politiques sur les vaccins afin d'optimiser la sécurité, l'efficacité, la valeur et la réussite de la planification et de la prestation des programmes d'immunisation.*

*La surveillance des maladies étant du ressort du gouvernement fédéral, la majorité des MEV font l'objet d'une surveillance de la part de plusieurs systèmes nationaux, dont le Registre national des maladies à déclaration obligatoire (RNMDO), coordonné par l'ASPC. Le RNMDO est un système de surveillance passive qui suit de près plus de 40 maladies infectieuses à déclaration obligatoire, dont beaucoup de MEV. La surveillance des maladies au Canada est actuellement très complexe compte tenu de l'existence de nombreux programmes à l'échelle nationale, provinciale et territoriale, mais aussi régionale et municipale. Le système présente des lacunes, des retards et des incohérences substantiels sur le plan de la communication des données. D'importantes améliorations devront être apportées à l'infrastructure actuelle de surveillance des maladies, notamment pour recueillir des données précises et opportunes sur la prévalence des MEV – fondement des décisions qui sont prises en santé publique.*

*En ce qui concerne la surveillance des taux de couverture vaccinale au Canada, les renseignements proviennent actuellement de sources diverses, notamment des enquêtes sur la vaccination (réalisées habituellement tous les deux ans) et des registres de vaccination, dans lesquels sont inscrites manuellement des données tirées des dossiers des patients. Actuellement, près de la moitié des provinces et territoires du Canada possèdent des registres entièrement fonctionnels; les autres sont en train de mettre en place ou d'évaluer des options possibles, dont celle d'élaborer des normes de données afin de se conformer au système pancanadien de surveillance de la santé publique, appelé Panorama (élaboré par Inforoute Santé du Canada). En général, des écarts considérables sont observés actuellement dans la fréquence et la nature des données recueillies d'un registre à l'autre, et il demeure très difficile de déterminer les taux de vaccination chez les enfants et les adultes. On devra pouvoir compter sur des ressources importantes dans l'avenir afin d'élaborer un système pancanadien de registres renfermant des données précises sur l'état vaccinal de la population d'une province et d'un territoire à l'autre du pays.*

On prévoit que l'élaboration d'un système normalisé de codage à barres des vaccins, considéré comme l'un des principaux moyens d'améliorer les registres de vaccination au Canada, facilitera l'entrée des données futures, notamment parce qu'il augmentera la vitesse, la précision et l'intégralité de l'enregistrement de données essentielles sur l'immunisation. D'une manière plus générale, le codage à barres des vaccins permettrait également la gestion en temps réel des stocks, ce qui contribuerait à réduire les pénuries et pourrait améliorer la conformité et la sécurité des patients, notamment en facilitant l'établissement des calendriers pour l'administration de vaccins à doses multiples et/ou en exerçant un suivi rapide et adéquat des patients victimes d'ESSI. Misant sur les travaux amorcés antérieurement par l'ASPC, le Groupe de travail consultatif sur l'identification automatisée des vaccins (IAV) – coprésidé par le Comité de l'industrie des vaccins (CIV) de BIOTECCanada – a réalisé dernièrement une analyse coûts-avantages visant à évaluer les options possibles relatives au codage à barres. Le groupe de travail a proposé une stratégie de mise en œuvre par étape, à commencer par l'apposition d'un code à barres contenant des données non variables (indiquant le nom du fabricant et l'appellation commerciale du produit) sur l'emballage des vaccins primaires; les fabricants pourraient travailler à la mise en œuvre d'une norme du genre, à titre facultatif, dans un délai de 18 à 24 mois.

Outre la surveillance de l'incidence des maladies et de la couverture vaccinale (notamment par l'entremise de registres), d'importants efforts sont faits au Canada pour assurer l'innocuité des vaccins approuvés et détecter rapidement tout problème pouvant susciter des inquiétudes quant à leur innocuité. La surveillance post-commercialisation de l'innocuité des vaccins préventifs est supervisée principalement par l'ASPC, en collaboration avec la Direction des produits biologiques et des thérapies génétiques (DPBTG). Deux systèmes distincts ont été mis en place notamment afin d'appuyer les activités facultatives et obligatoires de surveillance des vaccins approuvés; il s'agit respectivement du Système canadien de surveillance des effets secondaires suivant l'immunisation (SCSESSI) et du Programme de surveillance active des effets secondaires associés aux vaccins, appelé aussi IMPACT, qui, instauré dans 12 hôpitaux pédiatriques au pays, dépiste notamment les ESSI. Les résultats obtenus récemment par ces réseaux indiquent clairement que l'immunisation entraîne rarement des complications et appuie fortement la thèse selon laquelle la très grande majorité des personnes immunisées ne souffrent pas d'effets secondaires. En général, toutefois, étant donné que les systèmes de surveillance actuellement en place au Canada sont limités par l'absence de modes opportuns, normalisés et complets de déclaration (à l'échelle régionale, provinciale, territoriale et nationale), les analyses des taux des ESSI se rapportant à des cas particuliers doivent être interprétées avec beaucoup de prudence.

Bien que les ESSI graves soient rares et largement éclipsés par les avantages de l'immunisation, le Canada ne dispose d'aucun programme national visant à indemniser les personnes ayant subi des blessures liées aux vaccins. On a maintes fois demandé la mise en place d'un régime d'indemnisation hors faute, qui, sur présentation de documents à l'appui, allouerait rapidement une aide financière aux personnes ayant subi des blessures liées aux vaccins (c'est-à-dire pendant qu'elles se prêtaient à une intervention contribuant au bien commun), sans qu'elles aient à recourir au processus traditionnel – et coûteux – de litige. Ces demandes relatives à la mise en place d'un régime national d'indemnisation hors faute sont alimentées par la nécessité d'améliorer l'accès des patients à une indemnisation équitable au sein d'un système éthique, juste et socialement responsable. Afin de concevoir un programme national qui lui est unique, le Canada devra s'inspirer des pratiques exemplaires utilisées dans d'autres pays, dont l'Allemagne, les États-Unis et le Royaume-Uni, ainsi qu'au Québec – qui s'est doté d'un programme provincial d'indemnisation hors faute au milieu des années 1980.

En général, alors que le nombre de vaccins disponibles et la complexité des calendriers de vaccination provinciaux et territoriaux continuent de croître, le Canada doit renforcer sa capacité de recueillir des données (notamment à l'échelle régionale, provinciale et nationale, et au sein des différents réseaux de surveillance), de les étudier, de les communiquer et d'y réagir de façon opportune, dans le cadre de l'élaboration continue d'un système complet, normalisé et rigoureux de surveillance des vaccins. Pour réaliser cet objectif ambitieux et assurer l'innocuité et l'efficacité des vaccins au profit de tous les Canadiens, de nombreux partenaires, y compris les professionnels de la santé qui travaillent aux premières lignes, les fabricants, les organismes de réglementation et les responsables de la santé publique à tous les échelons de gouvernement, devront travailler en étroite collaboration. Dans cet esprit de collaboration, dans un souci d'équité envers les personnes et pour protéger la santé de l'ensemble de la population, le CIV a formulé les recommandations suivantes à l'intention des gouvernements fédéral, provinciaux et territoriaux.

### Recommandations à l'intention des gouvernements fédéral, provinciaux et territoriaux

1. Afin d'accroître la capacité du Canada d'évaluer le fardeau (initial) des MEV pour la santé et sur le plan socio-économique, et de permettre la réalisation d'une évaluation précise et opportune des avantages de la vaccination subséquente pour la santé publique, les gouvernements fédéral, provinciaux et territoriaux doivent allouer des sommes et des ressources supplémentaires importantes en vue de renforcer l'infrastructure canadienne de surveillance des maladies, qui, bien que polyvalente, est actuellement fragmentée.
  - Étant donné que le Comité consultatif national de l'immunisation (CCNI) se sert beaucoup des données épidémiologiques relatives aux MEV pour évaluer les nouveaux vaccins, la disponibilité de données (nationales) actuelles, normalisées et exhaustives sur la surveillance des maladies facilitera également la prise de décisions et la formulation de recommandations fondées sur des données probantes concernant les nouvelles technologies vaccinales au Canada (et en réduira les délais).
2. Afin d'obliger les gouvernements à communiquer rapidement les données épidémiologiques et autres données sur la surveillance des maladies, tant systématiquement que dans le cas d'épidémies ou de dangers de maladies, les gouvernements fédéral, provinciaux et territoriaux doivent établir entre eux des ententes plus officielles concernant la communication des données (c'est-à-dire établir des obligations légales claires et explicites) – à l'image, par exemple, de l'accord signé entre le gouvernement fédéral et l'Ontario en 2008.
3. Afin d'améliorer la capacité du Canada d'exercer un suivi rapide et opportun de la couverture vaccinale, un leadership fédéral et des investissements supplémentaires des gouvernements fédéral, provinciaux et territoriaux seront nécessaires pour élaborer davantage les registres de vaccination et mettre au point des normes de données conformément au module du système de surveillance pancanadien Panorama sur le registre d'immunisation.
4. Afin de faciliter l'entrée des données futures dans les registres de vaccination (notamment par balayage électronique), un système normalisé de codage à barres des vaccins devra être élaboré au Canada. Le CIV, en collaboration avec le Groupe de travail consultatif sur l'IAV, recommande la mise en œuvre par étape de ce système, à commencer par l'adoption précoce d'un code à barres ne contenant que des données non variables, qu'on apposera sur l'emballage des vaccins primaires. Dans ce cas, le code à barres, utilisant la symbologie d'espace réduit (RSS), comprendrait un code-article international (GTIN) servant à identifier le produit (nom du fabricant et appellation commerciale du produit). Les fabricants pourraient travailler à la mise en œuvre de ce code, à titre facultatif, dans un délai raisonnable de 18 à 24 mois, par exemple.
5. Pour que les normes relatives au codage à barres des vaccins soient mises en œuvre avec succès au Canada, l'ASPC (notamment par l'entremise du Groupe de travail consultatif sur l'IAV) doit continuer de travailler en collaboration avec les fabricants, la DPBTG, GS1 Canada, les gouvernements provinciaux et territoriaux, et les utilisateurs finals (professionnels de la santé, hôpitaux et associations de patients) afin de répondre aux exigences de tous les intervenants concernés dans les nombreux établissements où l'on administre des vaccins.

6. *Afin de favoriser la déclaration opportune, précise, systématique et complète des ESSI – pour ainsi détecter rapidement tout problème pouvant susciter des inquiétudes quant à l’innocuité des vaccins – les gouvernements fédéral, provinciaux et territoriaux doivent allouer des sommes et des ressources supplémentaires en vue de renforcer l’infrastructure canadienne de surveillance post-commercialisation de l’innocuité des vaccins et améliorer les réseaux actuellement en place, soit le SCSESSI et IMPACT.*
  - *La communication des données doit être améliorée, de même que la vitesse avec laquelle on communique les données (à l’échelle régionale, provinciale, territoriale et nationale), afin de permettre l’analyse opportune et efficace des données agrégées.*
7. *Afin de protéger les personnes ayant subi des blessures liées aux vaccins (et d’établir un cadre juridique plus sûr pour l’innovation en matière de vaccins et protéger les approvisionnements en vaccins), le Canada doit se doter d’un programme national d’indemnisation hors faute semblable à ceux qui existent dans d’autres pays.*
  - *Afin de concevoir un système d’indemnisation qui lui est unique, le Canada pourrait se servir des systèmes actuellement en place aux États-Unis et au Québec comme modèles de comparaison, et s’en inspirer pour adopter une structure juridique optimale – et envisager l’établissement de systèmes de financement, de critères de recevabilité des demandes d’indemnisation, d’un processus de règlement des demandes et de droits de poursuite qui soient adéquats.*

## 9.2 Introduction

As we enter the second decade of the 21st century, immunization remains one of the most powerful and cost-effective of all health interventions. Vaccines continue to prevent debilitating illness and disability, and to save millions of lives annually worldwide. Indeed, with the exception of safe water, no other modality, not even antibiotics, has had such major effect on mortality reduction.<sup>1</sup> Fortunately, in view of the tremendous potential for immunization in terms of contributing to “public good”, currently available vaccines have a favourable safety record; most side effects are minor and serious complications are rare.

As described in Paper 3, one fundamental difference between developing preventive vaccines and most other therapeutic medicines is that vaccines are typically administered not only to large populations, but also to otherwise healthy individuals, to protect against potential future disease. When viewed through the lens of the fundamental medical principle that stipulates, “first, do no harm”, this shifts the balance of benefits versus risks, such that greater value is placed on patient safety.<sup>2</sup> Thus vaccines are held to exacting safety standards, with lower tolerance for adverse events, in today’s risk-averse society.<sup>3</sup> Furthermore, as summarized Paper 8, the very success of immunization programs has proven to be one of their “weaknesses”, since generations have grown up without witnessing the devastating consequences of vaccine-preventable diseases such as polio or measles<sup>4</sup> – and this lack of direct experience has resulted in increased complacency towards immunization. While these factors have raised public expectations for vaccine safety, and increasingly vocal “anti-vaccination” groups have emerged, these trends underscore the need to address potential vaccines safety concerns in a highly coordinated, effective manner.<sup>5</sup>

In general, ensuring that vaccines are safe, effective, and of high quality, is a pivotal element of overall vaccine development and deployment.<sup>6</sup> This process normally begins in the laboratory, where vaccine components are tested for key criteria such as purity, potency, and immunogenicity (Paper 3), and continues with clinical testing for safety and efficacy in humans, followed by regulatory approval (Paper 4). Subsequent to vaccine licensure, post-market testing of vaccine batches (lots) is conducted to verify consistency of the production process. While these stringent testing procedures play a critical role in ensuring that vaccines are as safe as possible – and thus reduce the likelihood of a vaccine-related adverse event – additional monitoring is also undertaken by manufacturers through sizeable post-licensure (e.g. Phase IV) studies. Such trials are often performed to assess long-term vaccine safety and effectiveness, as well as the health, social and economic effects of the vaccine (e.g. under “real world” conditions).<sup>7</sup>

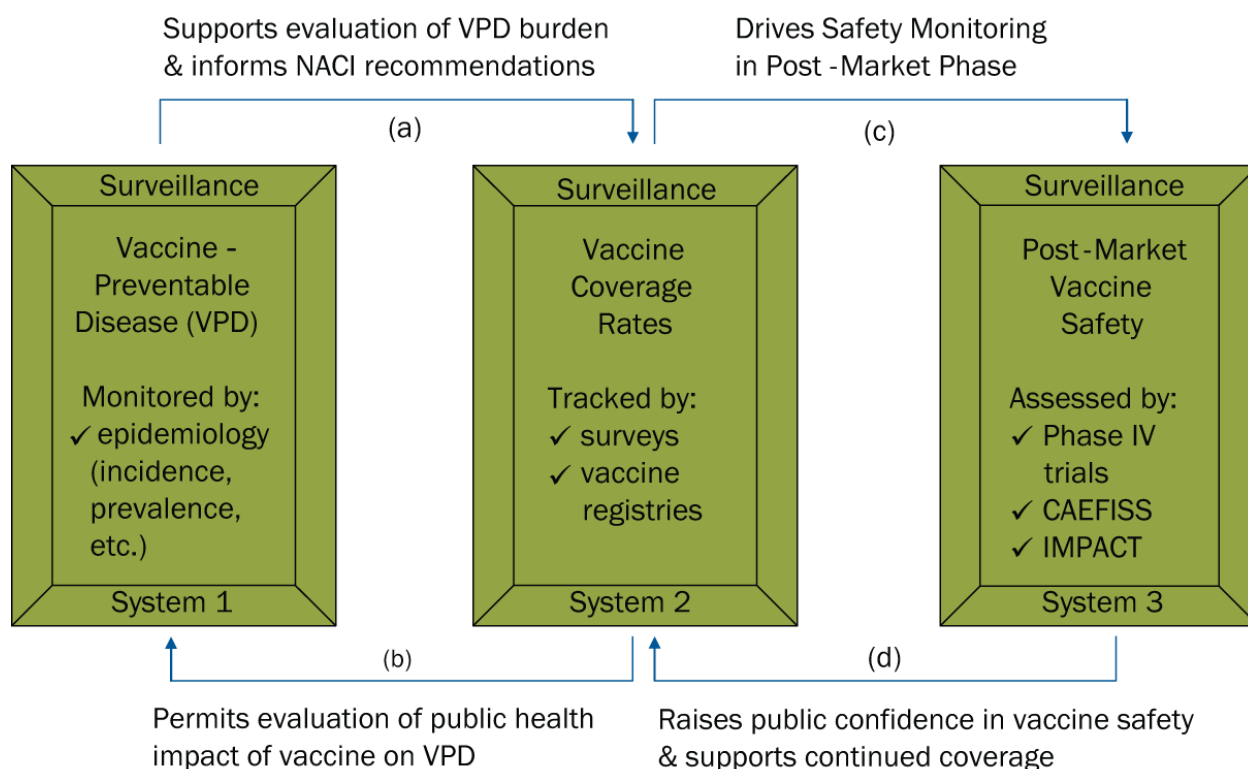
Against the backdrop of myriad issues pertaining to vaccine safety and effectiveness, this paper will focus more narrowly on monitoring vaccine safety in Canada in the post-market period. In this context, post-licensure vaccine safety is currently evaluated through multiple means, as part of a series of significant post-market surveillance efforts. As alluded to above, manufacturers usually conduct Phase IV studies in relatively large patient populations, i.e. to monitor for rare or delayed adverse reactions that might not have been apparent in smaller clinical trials prior to licensure,<sup>8</sup> and/or to examine potential side effects or contraindications with other medications already in use by vaccinees.<sup>9</sup> Apart from this type of active surveillance, vaccine manufacturers are also required by law to report to Health Canada any serious adverse events related to immunization within 15 days of notification of their occurrence,<sup>10</sup> and manufacturers must also provide periodic safety update reports (PSURs) – which summarize adverse reactions – as requested by Health Canada.<sup>11</sup> In addition to surveillance activities initiated by manufacturers, other investigation systems (which fall primarily under the responsibility of the Public Health Agency of Canada, PHAC) are also in place to support both voluntary (passive) and mandatory (active) post-market surveillance of all approved vaccines, including rapid detection of any safety signals of concern (see Sections 9.3.5 and 9.3.6 below).

## 9.3 Surveillance Systems Supporting Immunization Programs in Canada

### 9.3.1 Vaccine-Related Surveillance Systems

The term “surveillance” is defined as the systematic ongoing collection, collation and analysis of data, with timely dissemination of information to those who require it in order to take action, i.e. to improve prevention or control of relevant conditions.<sup>12</sup> Within the context of immunization, effective surveillance systems permit monitoring and assessment of: i) vaccine-preventable diseases; ii) vaccine coverage; and iii) post-market vaccine safety, including adverse events (see conceptual schematic in Figure 9.1). Hence, prior to presenting further details of vaccine safety surveillance systems (Sections 9.3.4 - 9.3.6), it should be emphasized that such post-licensure monitoring initiatives represent but one arm of an even broader set of surveillance systems to support immunization programs in Canada. Operating together, these three main types of surveillance systems are indispensable in guiding the decision-making process for the introduction of new vaccines, monitoring the impact of these new vaccines on disease patterns and burden, and conducting post-market surveillance to ensure the safety of all approved vaccines.<sup>13</sup>

Figure 9.1 – Surveillance Systems to Support Immunization Programs in Canada



Source: Author’s synthesis, Nora Cutcliffe BioPharma Consulting, 2010

NACI = National Advisory Committee on Immunization  
 CAEFISS = Canadian Adverse Events Following Immunization Surveillance System  
 IMPACT = Immunization Monitoring Program ACTIVE

Specifically, the left side of the Figure 9.1 indicates that information gleaned from surveillance of vaccine-preventable diseases – including epidemiological data (regarding disease incidence, prevalence, morbidity and mortality) as well as assessment of microbial strain distribution, population susceptibility and risk factors related to the infectious agent – supports evaluation of the overall health and social-economic burden of a given vaccine-preventable disease, see Figure 9.1 (a) and Section 9.3.2. In Canada, such disease surveillance data also supports evidence-based decision-making and recommendations by the National Advisory Committee on Immunization (NACI) and/or provincial/territorial (P/T) advisory committees, i.e. when a new vaccine is being considered for introduction into national or P/T immunization programs.<sup>14</sup> Subsequently, following the adoption of a new immunization program, surveillance data regarding vaccine coverage rates – as tracked by survey data and/or vaccine registries (Section 9.3.3) – provides essential information in evaluating the public health impact of a specific vaccine, and thus in determining the effectiveness, value and success of a new immunization program, see Figure 9.1 (b). In addition, the right half of Figure 9.1 shows that vaccine coverage rates also drive the need for post-market safety surveillance of all approved vaccines (c). Finally, aggregate data pertaining to vaccine-related adverse events (as compiled within safety surveillance databases) helps to reassure the public regarding the favourable risk-benefit ratio of vaccines, and more broadly, provides direct evidence to support continued coverage under a given immunization program (d).

Collectively, vaccine-related surveillance systems play a key role in providing critical intelligence to support immunization program planning, priority setting, and allocation of resources, as well as to monitor trends, and assess the impact of disease control programs and progress towards goals. Hence the information gathered and evaluated under each of the inter-related surveillance systems has the potential to influence future vaccine development as well as to guide vaccine policy.<sup>15</sup> Since vaccine-related surveillance systems represent essential, foundational components of a successful immunization program, efforts to strengthen immunization surveillance, monitoring and evaluation can ultimately help to provide more accurate, timely data to improve overall health system management and performance.

### 9.3.2 Disease Surveillance

Although disease surveillance is not the focus of the current paper, it is pertinent to provide a brief overview of the current status of disease surveillance systems in Canada – particularly because such systems are essential in determining the scope and severity of vaccine-preventable infections, and assessing the benefits of new immunization programs. Since disease surveillance falls within the federal mandate in Canada, most vaccine-preventable diseases are under surveillance by one or more national systems, including the Notifiable Diseases Reporting System (NDRS) coordinated by the PHAC, and other enhanced disease-specific systems coordinated by Centre for Immunization and Respiratory Infectious Diseases (CIRID) – such as FluWatch, the national influenza surveillance network.<sup>16</sup>

The NDRS is the passive (voluntary) surveillance system used to monitor more than 40 national notifiable infectious diseases, including numerous vaccine-preventable diseases (e.g. diphtheria, pertussis, tetanus, polio, varicella, and invasive meningococcal and pneumococcal disease).<sup>17</sup> In general, disease surveillance in Canada is very complex, since multiple surveillance programs exist at the national, P/T, regional/municipal and hospital levels. Overall, disease surveillance activities require close cooperation and rapid information-sharing among many partners – from front-line health care workers to public health officials at all levels of government – to coordinate an effective national response (and support global disease prevention/control plans) during potential disease outbreaks.<sup>18</sup>

Limited incremental progress in improving Canada's national disease surveillance capacity has recently been reported by the PHAC, particularly in terms of accomplishments achieved under Canada's National Immunization Strategy (NIS) – including preliminary activities of the Vaccine-Preventable and Respiratory Infections Surveillance (VPRIS) working group, initially established in December 2005.<sup>19,20</sup> However, the PHAC has been severely criticized by several groups for its failure to develop an integrated, reliable national surveillance system; for example, a recent (3rd) review by the Auditor General, Sheila Fraser, has deemed the agency's surveillance capabilities as (still) largely ad hoc and piecemeal.

The May 2008 report states, “To obtain routine surveillance information, the PHAC relies on the goodwill of the provinces and territories. However, due to gaps in its information-sharing agreements with them, it is not assured of receiving timely, accurate and complete information. A data-sharing agreement recently signed with Ontario re-established the regular flow of information about individual cases after two years when this flow was limited. However, the Agency has not reached similar data-sharing agreements with the remaining provinces and territories”.<sup>21</sup> The PHAC has also been chastised by other policy experts for relying too heavily on informal “working relationships” and thus failing to establish clear, firm legal obligations that compel federal and P/T governments to share epidemiologic information, both routinely, and during disease outbreaks.<sup>22</sup> As stated by these researchers, time lost is tantamount to lives lost. Other weaknesses identified in Canada's current surveillance framework include the lack of standardization across key governing factors such as: i) specific diseases reported; ii) disease case definitions; and iii) diagnostic methods for disease-causing agents, e.g. real-time polymerase chain reaction (RT-PCR), versus less sensitive cell culture or rapid antigen testing, as used for influenza surveillance.<sup>23, 24, 25</sup> In the absence of appropriate standards, it remains a significant challenge to interpret surveillance data and/or to account for discrepancies in data collection methods – let alone implement a cohesive, accurate surveillance framework nationwide.

Unfortunately, the current flaws in Canada's disease surveillance structure limit the ability of the PHAC to provide Canadians with a complete, consistent snapshot of the status of infectious disease as a basis for public health decision-making. In turn, by lacking the ability to generate timely, accurate status updates, the PHAC is currently viewed as unable to meet Canadian obligations for notifying the World Health Organization (WHO) of outbreaks within the deadlines specified by the recently established International Health Regulations (IHR).<sup>26</sup> Moreover, existing disease surveillance systems are not robust enough to assess progress towards national immunization goals.<sup>27</sup> For example, as described in Paper 5, it is presently difficult, if not impossible, to evaluate the full public health and economic impact of the four vaccines introduced under the NIS during the period 2004 to 2007,<sup>i</sup> i.e. due to substantial gaps, delays (in the range of two to four years) and discrepancies in data reporting. Finally, these limitations also result in delays in the time required for epidemiological review as part of the NACI evaluation and recommendation process, thus leading to delays in patient access to emerging vaccine technologies.

Overall, Canada's capacity to detect, monitor and control infectious diseases in a timely fashion is clearly inadequate. To protect Canada from epidemic crises, significant improvement is required in surveillance infrastructure and systems for tracking vaccine-preventable diseases, including mechanisms to ensure timely domestic reporting of infectious disease threats. In addition, Canada requires enhanced surveillance systems to facilitate the planning of new immunization programs, and to help evaluate whether recommended (and publicly-funded) vaccines are having the desired impact on disease burden.

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<sup>i</sup> The four vaccines that were introduced under NIS funding included acellular pertussis, meningococcal C conjugate, pneumococcal conjugate and varicella.

### 9.3.3 Immunization Coverage Rates and Vaccine Registries

In Canada, information regarding immunization coverage rates is currently derived from a variety of sources, including frequent use of regional or national immunization surveys, as well as increasing use of vaccine registries, which record available data from individual patient records. While immunization surveys rely heavily on public opinion survey methods – and hence can only estimate true coverage rates – such surveys are also unable to assess specific subpopulations, and may be limited by non-participation bias.<sup>28</sup> Furthermore, the largest national survey, known as the Adult and Childhood National Immunization Coverage Survey, is conducted only every second year, and results may not be made public for up to two more years following data collection (see Paper 8, Section 8.4.2).

With regard to immunization registries, each province and territory maintains its own system for tracking vaccine coverage rates, and a lack of communication is generally observed across jurisdictions. Significant inter-jurisdictional variation also exists with respect to the frequency and type of data being collected. The latter variations, due in part to inconsistencies in P/T immunization schedules, may include: i) target populations for assessing immunization status, such as routine childhood immunization coverage in one-year-olds, or two-year-olds, or school entry children; and ii) the vaccine antigen or vaccine agent reported for coverage, i.e. some P/Ts may report immunization status by individual antigens (e.g. diphtheria; tetanus; pertussis), whereas others may report by vaccine agent (including combination vaccines such as Pentacel; or diphtheria, tetanus, and pertussis, inactivated polio vaccine, known as dTap-IPV).<sup>29,30</sup>

The PHAC has reported that, as of 2006, five jurisdictions have fully functional vaccine registries,<sup>ii</sup> which they plan to continue to use (Manitoba, New Brunswick, Saskatchewan, Prince Edward Island and British Columbia); four are in the process of implementing a registry (Alberta, Ontario, Newfoundland and Labrador, and the First Nations and Inuit Health Branch, FNIHB, of Health Canada); two are evaluating options for a new registry (Québec and Northwest Territories); and three have no registry (Nova Scotia, Yukon and Nunavut).<sup>31</sup> Several P/Ts without a current registry are either planning or evaluating the immunization module within Canada Health INFOWAY's Panorama, a pan-Canadian public health surveillance system that includes a registry module to support immunization management.<sup>32,33</sup>

As a key component of the NIS, and the basis for the Electronic Health Record,<sup>34</sup> the Canadian Immunization Registry Network (CIRN) has developed draft functional and data standards for immunization registries. These standards, published in 2005, include recommendations for reporting on national immunization coverage, and provide guidelines for reporting on frequency (and time of year) of assessment, age cohorts and populations, agent/antigen specific coverage, and up-to-date immunization.<sup>35</sup> The CIRN continues to monitor the status of immunization registry development across the country, and, in conjunction with the CIRID, is currently participating in the development of Panorama, i.e. to ensure that the immunization registry module will be compliant with existing national standards for immunization registries in Canada. It should be noted that the implementation of a standardized vaccine bar coding system in Canada is also anticipated to facilitate future data entry into vaccine registries (Section 9.4).

Although recent (slow, incremental) progress has been made through CIRN and NIS initiatives in setting and communicating standards to support best practices for immunization registries, Canada's current tracking system for immunization coverage is still deemed to be “woefully inadequate”.<sup>36</sup> As just one example, in the context of initial allegations regarding a potential link between autism and thimerosal, e.g. as previously used in the measles, mumps, and rubella (MMR) vaccine – a concern now refuted by a large body of scientific evidence<sup>37</sup> (see Paper 8, Section 8.3) – it has not been possible to accurately ascertain whether this controversy has had any impact on MMR immunization rates in Canada. Essentially, the current registration system is insufficient to state unequivocally whether the national MMR vaccination rate has recently increased or decreased. More broadly, in the absence of a high-quality national registry, it is impossible to determine (with absolute certainty) current uptake rates for major childhood or adult vaccines. There is also a lack of data on national rates of immunization refusal, although almost all family physicians and pediatricians can anecdotally reference families that decline certain vaccines.<sup>38</sup>

<sup>ii</sup> While a subsequent update in 2008 indicates that six P/Ts have fully functioning registries, the sixth jurisdiction is not specifically named. Source: Interim Evaluation of the National Immunization Strategy, PHAC, October 2008.

Significant leadership and further resources are clearly needed in Canada to achieve the ambitious goal of developing a nationwide system of population-based immunization registries that can systematically and comprehensively track vaccination status across the country. While such a broad-based system would permit timely, accurate surveillance of national immunization coverage rates, it could also act in synergy with other disease surveillance and safety surveillance networks in Canada (see Figure 9.1). Collectively, these interdependent surveillance systems have the potential to act as powerful, integrated tools to guide future decision-making on the control of vaccine-preventable disease. As one component of such surveillance infrastructure in Canada, Table 9.1 summarizes the advantages of implementing a fully functional national vaccine registry – including benefits to both individuals and the broader population.

**Table 9.1 – Potential Benefits of a National Vaccine Registry**

<p><b>Benefits to individuals</b></p> <p>A fully functioning, nationwide, integrated immunization registry would provide robust database capabilities to:</p> <ul style="list-style-type: none"> <li>determine immunization needs of individuals, e.g. identify specific children/adults due or overdue for vaccinations</li> <li>generate individualized recall/reminder notifications to patients or parents, and actively schedule appointments for follow-up immunization, e.g. to enhance physician/patient compliance with recommended immunizations</li> <li>facilitate transfer of (and access to) unique immunization records, e.g. to help ensure continuity of immunization when an individual moves to another jurisdiction</li> </ul>
<p><b>Benefits to the Canadian population through improved health system management</b></p> <p>A fully functioning, nationwide, integrated immunization registry would provide robust database capabilities to:</p> <ul style="list-style-type: none"> <li>record immunizations administered to all Canadians by all providers (within the public and private health systems)</li> <li>generate annual (or more frequent) reports to monitor routine or new/specific immunization programs, thereby reducing the need for vaccination coverage surveys</li> <li>enhance timely, pan-Canadian surveillance of immunization coverage rates (percentages of the recommended population who received the vaccine), i.e. to improve immunization program planning, evaluation and research</li> <li>benchmark progress towards national immunization goals, and provide accurate data to demonstrate and promote program effectiveness/success – thus enhancing broader public support (and government funding) for current/future immunization programs</li> <li>identify subpopulations at risk for delayed or under immunization, i.e. to enable health authorities to target interventions appropriately</li> <li>facilitate linkages across disease surveillance and vaccine safety surveillance networks (see Figure 9.1), e.g. by providing critical data on vaccine uptake to evaluate public health impact, as well as accurate denominator data (number of individuals immunized) to support safety assessment of adverse events following immunization (AEFI)</li> <li>permit new linkages among vaccine registries and other disease-specific or screening registries, e.g. to monitor the impact of human papillomavirus (HPV) vaccination on Canadian cervical cancer incidence and screening practices</li> </ul>
<p>Source: Author’s synthesis, <i>Nora Cutcliffe BioPharma Consulting</i>, 2010</p>

### 9.3.4 Post-Market Vaccine Safety Surveillance

Over the past several decades, immunization coverage rates have generally increased in developed countries, and the incidence of vaccine-preventable disease has concomitantly fallen. Simultaneously however, as highlighted in Section 9.2, there has been increasing concern regarding the potential side effects of vaccines. In Canada, significant efforts are undertaken to ensure vaccine safety through continued monitoring of approved vaccines. Such post-market safety surveillance of preventive vaccines is overseen primarily by the PHAC, in conjunction with the Biologics and Genetic Therapies Directorate (BGTD), which provides input on post-market risk assessment of adverse events following immunization (AEFI).<sup>39</sup> In contrast, adverse events for therapeutic vaccines – although none have been licensed in Canada to date (see Paper 4, Section 4.5.1) – are to be monitored by Health Canada’s Marketed Health Products Directorate (MHPD), as for most other drugs.<sup>40</sup>

The key goals of Canada's national vaccine safety surveillance activities are to monitor all approved vaccines, and to rapidly detect (and appropriately investigate and respond to) any evidence of concern regarding safety, including all AEFI.<sup>41</sup> The broader objective of such safety surveillance is to minimize any negative effects on the health of individuals and to reduce the potential negative impact of immunization on the population.<sup>42</sup> Although vaccine manufacturers typically conduct Phase IV studies (which may evaluate both safety and efficacy) – and market authorization holders are also required by law to report serious adverse events (as described in Section 9.2) – the majority of post-market vaccine safety reporting is conducted by health care providers (including public health nurses and physicians) as part of the extensive PHAC surveillance framework (Figure 9.1).

Vaccine safety has been identified as one of the five integral components<sup>iii</sup> of the NIS (along with national goals and objectives, immunization program planning, vaccine procurement, and immunization registry networks).<sup>43</sup> Thus initial NIS funding over five years (since 2004) has been provided to strengthen federal infrastructure and programs to optimize the Canadian vaccine safety system, with the specific objectives of maintaining professional and public confidence in vaccine safety, and addressing growing anti-immunization concerns. Key elements of these stated objectives include improving: i) the vaccine safety monitoring system (i.e. the passive surveillance system, the active surveillance system, and the ability to flag potential threats to safety), and ii) the public health response (i.e. the review and follow-up of potential vaccine-associated adverse events, and the ability to mobilize adequate human resources (expertise) to respond to urgent “surge capacity” situations. To date, limited tangible progress towards these goals has been reported by the PHAC; such documented advances include establishment of the federal/provincial/territorial (F/P/T) Vaccine Safety Network to develop an action plan for identified gaps, and initial attempts to improve the timeliness of producing reports from the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) database (Section 9.3.5 below).<sup>44</sup>

Despite the slow progress towards achieving NIS goals, the PHAC remains committed to ensuring vaccine safety in Canada within the context of available resources. Unquestionably, aggregate data compiled to date from the current voluntary and active surveillance systems (described below) help to reassure the public that vaccines are safe, and that the benefits of immunization for both parents and children far outweigh the potential risks of serious reactions. Specifically, as reported in the PHAC’s Canadian National Report on Immunization 2006, the total number of adverse events reported annually through the national surveillance systems is extremely low; from 1992 to 2004, the annual rate has not exceeded 40 AEFI per 100,000 doses of distributed<sup>iv</sup> vaccines.<sup>45</sup> The report also indicates that, for 2004, hospital admission was required for only 5% of AEFI cases, with emergency department assessment required for 7%, and non-urgent outpatient visits associated with 31% of reported cases.

<sup>iii</sup> In contrast to vaccine safety surveillance, disease surveillance corresponds to a cross-cutting theme under the NIS, rather than a “main component” (see Section 9.3.2).

<sup>iv</sup> In this analysis, “distributed vaccines” excludes any doses returned to manufacturers.

Even more convincingly, it has also been estimated that roughly 33% of all AEFI reports in Canada are deemed unrelated to vaccination, with approximately only 25% of serious cases likely to be causally related to immunization (note that data for proper assessments is lacking in approximately another 25% of cases).<sup>46</sup> Overall, recent findings from Canada’s safety surveillance programs clearly document the rarity of harm from immunization, and overwhelmingly support the argument that, “the vast, vast majority of people who are vaccinated do not suffer any negative effects.”<sup>47,48</sup> Taking a cautious approach, however, the PHAC has expressed the opinion that, while the aggregate safety surveillance data do not reveal any worrying trends regarding adverse events following recently introduced vaccines, it is much too early to draw any firm conclusions, other than the need for continued surveillance.

### 9.3.5 CAEFISS – Voluntary Surveillance System

Spontaneous adverse event reporting (known as passive, or voluntary, surveillance) is currently the cornerstone of Canadian post-market surveillance of vaccine safety. In this context, the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) is largely a voluntary reporting system, although four provinces (Saskatchewan, Ontario, Québec, Nova Scotia) currently have mandatory reporting requirements.<sup>49</sup> Within the CAEFISS framework – previously called the Vaccine Associated Adverse Events Surveillance System, VAAESS – most adverse events reports are submitted (after removal of any identifying personal information) by health care providers (or parents) to local health units or P/T jurisdictions for public health action and follow-up. The reports are then transferred to the national level, where all reports are aggregated by CIRID’s Vaccine Safety Unit (VSU) and stored in a computerized, Web-enabled database.<sup>50</sup> While reports are submitted for events that health care providers feel are temporally associated with immunization, it should be emphasized that such *temporal* reporting does not necessarily imply that the vaccine is *causal* in triggering the adverse event. In other words, the adverse event may be unrelated to vaccination, and may have occurred coincidentally, after inoculation.<sup>51,52</sup>

Specific adverse events of public health interest are included on the national version of the AEFI Reporting Form that is used (with modifications) by all provinces and territories. This form can be retrieved online at [www.phac-aspc.gc.ca/im/pdf/hc4229e.pdf](http://www.phac-aspc.gc.ca/im/pdf/hc4229e.pdf). Reports of other severe or unusual events are also solicited and should be submitted if the health care provider feels the event may have been due to vaccine administration. An expert Advisory Committee on Causality Assessment (ACCA) – in operation since 1994, and comprised of specialists in pediatrics, public health, epidemiology, infectious diseases, immunology, neurology and adverse event surveillance – systematically reviews selected reports on a case-by-case basis to evaluate the likelihood that an adverse event is causally related to a vaccine.<sup>53</sup>

A significant drawback of the current CAEFISS system is that the vast majority of reports is still submitted on a voluntary basis, with marked variability in both the quantity and quality of information provided, and a lack of standardization of underlying case definitions. In addition, the total number of reports can fluctuate dramatically from year to year, due to several factors, including: changes in the type and number of vaccines provided through publicly-funded programs; implementation of mass immunization programs in response to an outbreak (e.g. H1N1 influenza), or catch-up programs; changes in computer systems and/or data entry practices; and changes in personnel capacity at the local, P/T, or federal levels.<sup>54</sup>

Furthermore, increased reporting rates may be due to intense media focus (e.g. pertaining to previously alleged links between thimerosal and autism), or enhanced awareness pertaining to clusters of specific adverse events, such as oculo-respiratory syndrome (ORS) following influenza vaccination.<sup>55</sup> This type of “reporting bias” may give the false appearance of a higher frequency of adverse events. Current reporting methods can also be limited by a lack of appropriate “denominators” in calculating adverse event rates (due to uncertainties in the number of doses of vaccine distributed, versus vaccine actually administered), or by incomplete detail to support an accurate medical diagnosis (and/or to consider other possible etiologies that may have caused the AEFI, such as intercurrent infection or concomitant drugs). Moreover, the increasing number of new vaccines added to immunization schedules in recent years, and the fact that many are given in combination, adds to the challenge of monitoring vaccine safety. In general, analyses of calculated adverse event rates require extremely cautious interpretation.

Finally, and perhaps most importantly, another significant limiting factor of the current CAEFISS framework is its lack of ability to support timely adverse event reporting, analyses and rapid response planning. In general, for the rapid detection of any safety signals of concern, the availability of aggregate, national data increases the likelihood of early detection of a rare or unusual event, i.e. by permitting evaluation of trends across multiple jurisdictions, rather than just within a single region. In turn, the speed and validity of national data analyses clearly depends on the timely compilation of reports by all jurisdictions. However, since AEFI reports are voluntarily sent first to the local health unit, then to the central P/T health departments, and then transferred to the PHAC for entry into the national CAEFISS database, there are many stages at which gaps and delays in reporting can occur. Overall, timely and complete reporting of AEFI is crucial, thus the PHAC has recently elected to examine year-to-year trends in reporting timeliness as a key measure of the quality and utility of vaccine safety surveillance in Canada. The PHAC has also expressed its intent to actively improve the timeliness of national reporting of vaccine-related adverse events in collaboration with P/T partners as well as with participants and administrators of Canada's active vaccine safety surveillance networks.<sup>56</sup>

### 9.3.6 IMPACT – Active Surveillance System

In addition to the voluntary CAEFISS reporting system, Canada also has a complementary, active surveillance system known as IMPACT (Immunization Monitoring Program ACTive). IMPACT is a national pediatric hospital-based active surveillance network for adverse events following immunization, including the more serious hospitalized cases, and selected outpatient visits, particularly those affecting children. In addition to its safety surveillance initiatives, the IMPACT network also actively monitors the epidemiology of selected vaccine-preventable infections, i.e. by conducting disease surveillance activities pertaining to *Haemophilus influenzae* type b, varicella, pertussis, meningococcal and pneumococcal diseases, influenza and rotavirus infection. Established in the early 1990s, IMPACT is administered by the Canadian Paediatric Society (CPS) and is funded primarily by the PHAC/CIRID, with some additional industry funding.<sup>57</sup>

The IMPACT network currently encompasses 12 (of 16) Canadian pediatric tertiary care centres, located across eight provinces that receive referrals from all jurisdictions (Table 9.2).<sup>58</sup> IMPACT centres account for approximately 90,000 admissions every year and represent roughly 90% (2,000) of all tertiary care pediatric beds in Canada. At each IMPACT site, nurse monitors and clinical investigators perform active case-finding, based on regular reviews of admission and discharge records, as well as laboratory reports; these detailed reviews are assisted by infection control nurses, emergency and unit nurses, physicians, laboratory personnel, and medical records technicians.<sup>59</sup>

Each IMPACT centre communicates with the local public health department and the provincial epidemiologist, i.e. to forward detailed case report forms and collect relevant immunization histories. Information on each case reported is sent to the IMPACT data centre at the Vaccine Evaluation Centre in Vancouver, B.C., where data are entered, cleaned and analyzed. All reports from both the IMPACT and CAEFISS surveillance systems are forwarded to CIRID's VSU, where they are aggregated and stored in the PHAC's national AEFI database. In a similar fashion to those cases reported through the CAEFISS, case examples of AEFI reported through the IMPACT network reflect temporal associations with immunization (which are not to be confused with events deemed to be caused by the vaccine), and the ACCA reviews all IMPACT case reports that meet specific criteria for severity or "unexpectedness". In the event that any unexpected or increased side effects due to vaccines are indeed observed, CIRID – in conjunction with the BGTD – decide upon the best course of action for resolution.<sup>60</sup>

Table 9.2 – IMPACT Pediatric Tertiary Care Centres in Canada

IMPACT Centres
• Alberta Children's Hospital, Calgary, Alta.
• BC Children's Hospital, Vancouver, B.C.
• Centre Mère-Enfant de Québec (CHUQ), Québec, Que.
• Children's Hospital of Eastern Ontario, Ottawa, Ont.
• CHU-Sainte-Justine, Montreal, Que.
• IWK Health Centre, Halifax, N.S.
• Eastern Health Janeway Child Health and Rehabilitation Centre, St. John's, Nfld.
• Montreal Children's Hospital, Montreal, Que.
• Royal University Hospital, Saskatoon, Sask.
• Stollery Children's Hospital, Edmonton, Alta.
• The Hospital for Sick Children, Toronto, Ont.
• Winnipeg Children's Hospital, Winnipeg, Man.
Source: Canadian Immunization Monitoring Program Active (IMPACT), Canadian Paediatric Society; <a href="http://www.cps.ca/english/surveillance/IMPACT/IMPACT.htm">www.cps.ca/english/surveillance/IMPACT/IMPACT.htm</a>

As an excellent example of recent research within the IMPACT network – which also demonstrates the compelling advantages of linking vaccine-related disease surveillance and safety surveillance systems – investigation of rotavirus (RV) infection has been underway since 2007 (with case documentation extending retrospectively from 2005 to the present).<sup>61, 62</sup> This research is intended to provide valuable baseline information that will contribute to understanding the epidemiology and burden of RV disease, i.e. by measuring the rate of RV infection in those children hospitalized for gastroenteritis.<sup>63</sup> Such data will help to gauge the economic impact of treating RV infection in Canada, and will enable physicians, public health officials, and parents to make informed decisions regarding the potential benefits of newly licensed rotavirus vaccines. Furthermore, this research should also provide unique insight regarding the early impact of vaccine use on the disease burden, as well as on rotavirus vaccine safety. Apart from RV-related hospital admissions (as the newest IMPACT surveillance target), other selected targets for evaluating potential post-immunization adverse events within the current IMPACT system include: i) neurological events (e.g. seizures, encephalopathy); ii) hypotonic-hypo-responsive episodes (HHE); and iii) other events such as anaphylaxis, thrombocytopenia, and arthritis.<sup>64</sup>

Although research conducted through the IMPACT network benefits significantly from a careful balance of both disease surveillance and safety surveillance activities, and the active network is considered an invaluable adjunct to the CAEFISS, the IMPACT system is not without limitations.<sup>65</sup> For example, the IMPACT network is presently limited by data delays, as inherent in paper-based systems. Although the use of a Web-based reporting platform (e.g. for influenza cases) has been recently introduced, to enable analysis to begin several months earlier than in previous years, further transition to digital formats will be required in the near-term future to accelerate data collation and reporting in other disease area. Another major drawback is that the IMPACT network is not entirely comprehensive; while it accounts for the majority (90%) of Canada's tertiary care pediatric beds and hospital admissions, it does not include secondary care centres. In addition, the current IMPACT system has limited capabilities to screen for emergency department visits potentially related to immunization. Moreover, the system focuses exclusively on children, and while an equivalent network for adult hospitals would be desirable, the logistical challenges to implement such a system in Canada are daunting.<sup>66</sup>

With respect to surveillance initiatives targeting Canadian adults, it is noteworthy that in mid-2009, the PHAC and the Canadian Institutes of Health Research (CIHR) announced a partnership to fund the PHAC/CIHR Influenza Research Network (PCIRN) as a pan-Canadian network of key influenza vaccine researchers, with a specific focus on pandemic influenza. As one of its many initiatives, the PCIRN will initiate a new "Adult SOS Network" across seven adult hospitals to collect data pertaining to: i) influenza vaccine effectiveness in the prevention of influenza-related hospitalization and death, and ii) possible adverse events following influenza immunization.<sup>67,68</sup> Under the direction of Dr. Shelly McNeil at the Canadian Center for Vaccinology in Halifax, this new network will aim to replicate and expand upon the current IMPACT model described above.

## 9.4 Bar Coding Initiatives

As alluded to in Section 9.3.3, the development of a standardized bar coding system in Canada is anticipated to play a critical role in efficiently, accurately populating vaccine registries (e.g. via electronic scanning) in the near-term future. At present, each time a dose of vaccine is administered, the health care practitioner manually records relevant details<sup>v</sup> into the patient's health record (ideally including vaccine agent, tradename, manufacturer, lot number, expiry date, dose volume, route and date of administration).<sup>69</sup> However, transcription error is common, and may become increasingly problematic, especially given the growing complexity of immunization schedules and vaccine technologies.<sup>70</sup> Notably, recent audits in British Columbia and Manitoba have indicated that: i) 15% of immunization records are incomplete (e.g. with insufficient detail regarding the vaccine agent); ii) 24% contain inaccurate information; and iii) lot numbers are missing from 20% of vaccine associated adverse event reports.<sup>71,72</sup> Theoretically, albeit a challenging goal, the use of bar coding could dramatically increase the speed, accuracy and completeness of recording immunization information; it could also facilitate documentation of vital information into vaccine registries (see related benefits in Table 9.1) – assuming mechanisms are available to read electronic vaccine bar codes.

More broadly, bar coding of vaccines would also permit real-time inventory management, which could in turn help minimize product expiries and waste, thus reducing undesirable supply shortages (see Paper 7). Other advantages include the ability to effectively manage the vaccine supply chain during disease outbreaks, and to generate timely, robust data for demand forecasting models. Furthermore, enhanced vaccine traceability could improve regional/national system capabilities in terms of responding to product recalls. Finally, automated identification of vaccines is also expected to play an important role in improving patient safety – not only by preventing medical errors at the point of inoculation – but also by facilitating appropriate follow-up for patients who experience adverse events following immunization.<sup>73</sup>

Motivated by the multi-faceted, convincing benefits of a bar coding system – and a recommendation by NACI in 1999 to include bar codes as part of vaccine product labeling<sup>74</sup> – significant efforts have been made by key stakeholders over the past decade toward the development of standards for implementing such a system in Canada. While this collaborative process has taken into account end-user needs, it has also considered manufacturers' concerns, including production constraints (such as bar code size, print requirements, potential reduction in line speed, and overall production capacity); regulatory hurdles (e.g. re-validation of labeling process and subsequent regulatory review); and additional capital investment requirements (e.g. for new or upgraded equipment).<sup>75</sup>

Specifically, since 2002, the PHAC and the CIRN have been working with stakeholders to develop bar coding standards in Canada through the Automated Identification of Vaccine Products (AIVP) project. The AIVP standards proposed in November 2005 included recommendations for bar code content, specifications, symbologies, and the use of peel-off (detachable) labels for affixing to patient records.<sup>76</sup> These AIVP recommendations proposed the use of bar codes with *variable* data (e.g. lot number and expiry date) on both the primary (inner) and secondary (outer) vaccine packages.<sup>77</sup> Subsequently, in March 2007, the AIVP Advisory Task Group (ATG) was created as a collaborative effort among all stakeholders in immunization, and is currently co-chaired by representatives from the PHAC and BIOTECanada's Vaccine Industry Committee (VIC).<sup>78</sup> The mandate of the AIVP ATG is to provide further leadership and overall guidance in the development and implementation of vaccine bar codes in Canada, and to assist in developing global standards, e.g. through collaboration with GS1 Canada – the Canadian Healthcare User Group (HUG) that designs and implements global standards for use in supply chain management.<sup>79,80</sup>

<sup>v</sup> Currently, this information (excluding volume and date of administration) is provided in human-readable format on the primary package (e.g. vaccine vial or syringe) in Canada.

To continue to refine the proposed AIVP recommendations, two major initiatives were completed in 2008. First, in January 2008, a stakeholder roundtable meeting was hosted by the Canadian Patient Safety Institute (CPSI); this meeting included participation by both the PHAC/AIVP and the VIC to present issues surrounding the feasibility (and potential solutions for) vaccine bar code standards.<sup>81</sup> Second, the AIVP ATG conducted an in-depth cost-benefit analysis to assess the relative benefits of five potential bar coding options (Options B, C, D, E and F) versus the current status quo for vaccine labeling in Canada (Option A).<sup>82</sup> It should be emphasized that vaccine manufacturers in Canada presently use only human-readable data on primary packages, whereas secondary packages include linear bar codes (with *non-variable* data); these bar codes include the Global Trade Item Number (GTIN),<sup>83</sup> which identifies the manufacturer and product tradename. Overall, the cost-benefit analysis<sup>vi</sup> included evaluation of 11 cost categories (e.g. scanner purchase, reconfiguration of plant layout, practitioner training, etc.) and five benefit categories (such as improved data entry speed and supply chain efficiency).

Through this detailed analysis – and within the context of model assumptions and limitations – a consensus was reached that Option B was the most cost-effective (with highest cost-benefit ratio), thus suggesting this option for an early adoption scenario, which vaccine manufacturers could work towards implementing (on a voluntary basis) within a reasonable timeframe, e.g. 18-24 months.<sup>84</sup> Option B would provide *non-variable* data on the primary package (e.g. with GTIN data encoded in a linear, reduced space symbology, RSS, bar code, also known as GS1 bar code). In general, the AIVP ATG has proposed a step-wise bar code implementation strategy, with progression towards increasingly complex options over time, eventually including the use of *variable* data on secondary, and subsequently, primary vaccine packages. It should be noted that Health Canada's BGTD has no plans to mandate bar coding for vaccines under the *Food and Drug Regulations*; the BGTD position is that bar coding requirements will remain under the lead of the PHAC, and are indeed likely to be implemented by manufacturers on a voluntary basis.<sup>85</sup>

Moving forward to 2010, the AIVP has established three working groups to continue to work towards implementing standards for bar coding on vaccine products; these working groups will focus on: i) Communications; ii) State of Readiness; and iii) and an Implementation Roadmap.<sup>86</sup> Since partnership across all stakeholders is critical to the success of a vaccine bar coding system in Canada, the VIC will continue to work in close collaboration with the PHAC, AIVP, BGTD, GS1 Canada, P/T jurisdictions, and relevant end-users (including health practitioners, hospitals, and patient associations) – with the broad goal of addressing the requirements of Canadian stakeholders in a wide range of immunization settings. In addition, the VIC will also work with these stakeholders to help find funding solutions to support future advances in vaccine bar coding, including progress with identified research priorities.<sup>87</sup>

In summary, the VIC supports any initiative that will help improve the safety of patients, including bar coding technology that will promote disease prevention through physician/patient compliance. However, the VIC holds the position that implementation of future bar code requirements – particularly for *variable* data – should be harmonized with global standards that are currently being developed.<sup>88</sup> Furthermore, the Canadian bar code standard must not jeopardize production capacity or access to vaccine supply. The VIC remains committed to working jointly with all stakeholders to enable domestic adoption of global bar coding standards, and to securing an affordable supply of current and future vaccines for all Canadians.

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<sup>vi</sup> While the details of the cost-benefit analysis fall outside the scope of this discussion, the five progressively complex options can be summarized as follows: Option B includes a bar code (with *non-variable* data) on the primary package; Options C and D include bar codes with *variable* data on the secondary package (and both packages) respectively; and Options E and F are similar to C and D, with 1 (or 2) peel-off labels added, respectively.

## 9.5 Vaccine Injury Compensation

Despite the best efforts of medical science, manufacturers, regulators, health authorities and medical practitioners to ensure vaccine safety (as described in preceding sections), it is well acknowledged that there are inherent risks associated with the operation of immunization programs – namely, that serious adverse events following vaccination may nonetheless occur.<sup>89</sup> While such adverse events are rare and far outweighed by the benefits of immunization, Canada currently has no national program in place to compensate those injured by vaccines. Over the past two decades, many calls have been made for a no-fault compensation (NFC) program; such a program would rapidly provide financial support to those individuals who have experienced documented vaccine-related harm, regardless of who is at fault, and without having to go through the expensive traditional legal (civil litigation) process.<sup>90</sup> In this type of alternative compensation scheme, the federal court would essentially protect manufacturers from civil lawsuits filed by patients or guardians – using special funds set aside for this purpose.

The basic premise underlying a NFC system is that individuals typically receive immunization not only for their own benefit, but also for the benefit of other members of society, e.g. through the phenomenon of herd immunity (see Paper 1).<sup>91,92</sup> Thus, if an individual is harmed while undergoing an intervention that contributes to the greater public good, there is a strong ethical argument that such an individual should be compensated.<sup>93</sup> This concept is also termed “redistributive justice”, which stipulates that compensation should be provided to victims whose injuries, on the balance of probabilities, have occurred through compliance with recommended immunization schedules.<sup>94</sup> Although mandatory vaccination is not *directly* legally enforced in Canada,<sup>95</sup> those who refuse vaccination can face severe restrictions such as exclusion from daycare, school, or work. Therefore, as Canada moves towards more “coercive-type” vaccination policies,<sup>96</sup> there is a growing need to establish a national NFC program to support those who suffer from vaccine-related injuries, particularly given that immunization is urged (and indirectly enforced) by government, public health, or other “state” officials.

First introduced in Germany in 1961, NFC systems have now been implemented in the United States, the United Kingdom, Québec, and at least eight other jurisdictions worldwide. In the U.S. specifically, a key impetus for introducing such a program was the alarming rise in the number of vaccine-related lawsuits during the 1970s and early 1980s, many of which were unsupported by scientific evidence. Significant payouts of lawsuit claims had increased operational costs for manufacturers, which in turn stifled investment for new innovation, and manufacturers began to exit the vaccine segment – ultimately decreasing vaccine supply.<sup>97</sup> Thus in 1986, the U.S. government established a national Vaccine Injury Compensation Program (VICP), not only to compensate those who had been injured, but also to provide a more secure legal environment for technology innovation and to protect the vaccine supply.<sup>98</sup>

The U.S. VICP program is funded through an excise tax collected on each dose of vaccine sold (i.e. for “covered” vaccines, including those for routine children immunization, and certain other vaccines, e.g. for influenza and HPV).<sup>99,100</sup> Claimants are required to seek compensation first through the VICP program, under which claims are based on predetermined amounts, depending on the type and extent of the injury. If a VICP award is accepted, the claimant cannot also file a lawsuit against the manufacturer. However, if a VICP claim is rejected, claimants can pursue subsequent legal action through the traditional tort (litigation) system. Overall, the VICP program has been regarded as a success, notwithstanding documented loopholes, and liability against manufacturers has been markedly reduced since 1986 – thus encouraging manufacturers to remain in (or enter) the vaccine business.<sup>101</sup> The VICP system is also perceived as efficient; the program paid out approximately \$US 600 million for vaccines administered between 1988 and 2004, with more than 98% of funds awarded to claimants and only 2% to cover legal fees. Apart from the VICP, other U.S. models of liability protection relevant to vaccines have also been described in the literature (including tort reform approaches, as embodied in the swine flu compensation program in 1976);<sup>102,103</sup> these models fall outside the scope of the current discussion.

In Canada, Québec is the only jurisdiction that has implemented a NFC program to date.<sup>104</sup> This program, entitled, “Programme d’indemnisation des victimes d’immunisation au Québec”, was introduced in the mid-1980s, after the Supreme Court of Canada rejected the tragic case of a girl who suffered severe brain damage after measles vaccination.<sup>105</sup> In an unusual move, and despite the unfavourable outcome of the case, the federal court had advocated for government consideration of alternative compensation schemes for individuals injured by vaccination in the absence of fault. Moreover, it was recognized by the Québec government that such individuals were entitled to compensation within the broader context of the victim’s human dignity and worth in relation to the rest of society. Currently, the Programme is run by the Bureau de la santé publique, and provides compensation for those injured directly/indirectly from voluntary immunization (including serious mental or physical injury/death); claims must be filed within a three-year deadline, and physician support is required.<sup>106</sup> During the first two decades of Programme operation, approximately 100 claims have been made, with several dozen awards. It should be noted, however, that the current Programme is not without pitfalls, and existing programs in both Québec and the U.S. have been criticized both by those in favour of (and those against) vaccination.<sup>107</sup>

With the exception of Québec, in the remainder of Canada, individuals injured through vaccination currently have no effective recourse to obtain compensation. The traditional litigation system and other possible routes of compensation (such as first party private insurance and government social programs) are not specific or effective enough to deal with the unique nature of vaccine-related injuries. Yet the federal government, represented by the PHAC, has no concrete plans to implement a NFC system; rather, as late as September 2009 (in the midst of the H1N1 influenza pandemic), the federal government has only stated it will, “provide additional details around this issue in due course, following appropriate discussions and deliberations”.<sup>108</sup> In Canada, the call for a national NFC program is driven primarily by the need for patient access to fair compensation within an ethical, just, and socially responsible system – particularly given the increasing number of recommended vaccines, and the recurring threat of future flu pandemics – and less by concerns regarding lawsuits against vaccine manufacturers, as seen in the U.S..

There are multiple mechanisms by which a national NFC concept could be implemented in Canada, with suitable tailoring required to emphasize the unique Canadian context in which it will operate. Drawing upon the lessons of existing NFC systems, research will be needed to determine the most favourable legal model, including litigation rights; appropriate financing schemes (e.g. excise tax versus other options such as manufacturers’ premiums, etc.); claim criteria (e.g. for which types of vaccines and injuries); and procedures for adjudication (e.g. involving review bodies, award categories/ceilings, retroactive claims, appeal procedures, etc.).<sup>109</sup> The over-arching goals of establishing an optimal medico-legal NFC structure in Canada are to offer fair compensation, while promoting open communication regarding unexpected vaccine-related injuries – thus helping to reduce the likelihood of inflicting future harm. A national NFC program should also help (indirectly) encourage early reporting of AEFI in Canada, thereby supporting more accurate, comprehensive vaccine safety surveillance, including “early signal detection” capabilities.

Overall, Canada has a social responsibility and a moral obligation to implement a national no-fault vaccine-related injury compensation scheme similar to those that exist in other jurisdictions worldwide. Indeed, in a statement made by Madam Justice Mary Anne Sanderson of the Ontario Superior Court, a NFC program is deemed a necessity, “for the sake of the health of citizens and fairness to individuals”.<sup>110</sup> The development of such a scheme should also serve to increase the confidence of Canadians in essential immunization systems, and to rebuild their trust in public health’s commitment to vaccine recipients. Until a national NFC system is in place to protect those who have suffered rare but serious vaccine-related consequences, Canada cannot claim its immunization programs are complete. Ultimately, since the risks of vaccination are not nil, this reality must be incorporated into broader Canadian public policy.

## 9.6 Recommendations

Immunization is currently considered a cornerstone of public health practice in Canada. Although it is widely acknowledged that the benefits of vaccination far outweigh the potential risks, a small number of vaccine recipients will indeed experience side effects, and an extremely small percent of those inoculated may suffer more serious adverse events. Therefore, the continued success of immunization programs in Canada requires a comprehensive, effective and efficient vaccine safety system, including ongoing pre- and post-licensure testing and regulatory controls, as well as vigilant post-market assessment of vaccine-related adverse events. At present, the PHAC plays the lead role in monitoring the safety of all approved vaccines, i.e. as part of the broader (three-pronged) surveillance infrastructure that supports immunization programs in Canada – an infrastructure that forms the crucial backbone of public health planning in controlling vaccine-preventable diseases.

As described in this paper, three inter-dependent surveillance systems monitor the epidemiology and burden of vaccine-preventable diseases, track vaccination coverage, and assess adverse events following immunization, respectively. Operating in concert, these surveillance networks have the potential to provide critical intelligence, not only to support the rationale for new vaccination programs, but also to gauge their subsequent impact on disease occurrence, and to evaluate vaccine safety in the post-marketing phase. Such information ultimately supports public health decision-making to optimize the safety, effectiveness, value and success of immunization program delivery. In general, as the number of available vaccines (and the complexity of P/T immunization schedules) continues to grow, Canada needs to strengthen its capacity to collect, record, investigate, share, and respond to information in a timely fashion (e.g. via enhanced linkages across local/regional/national levels, and among distinct surveillance networks) through the continued development of a coordinated, standardized, and robust vaccine-related surveillance infrastructure. To achieve this ambitious goal – and to ensure vaccine safety and effectiveness for all Canadians – close cooperation will be required among many partners, including front-line health providers, manufacturers, regulators, and public health officials at all levels of government. In the spirit of such collaboration, and for the benefit of the health of individuals as well as the broader population, the VIC has put forward the following recommendations for consideration by F/P/T governments.

### Federal/Provincial/Territorial (F/P/T) Recommendations

1. To enhance Canada's capacity to evaluate the (baseline) health and socio-economic burden of vaccine-preventable diseases, and to permit accurate, timely assessment of the public health benefits of subsequent vaccination, F/P/T governments should allocate significant additional funds/resources to strengthen Canada's multi-faceted (but currently fragmented) disease surveillance infrastructure.
  - Given that the NACI review process for new vaccines relies heavily on epidemiology data for vaccine-preventable diseases, the availability of current, standardized, comprehensive (national) disease surveillance information will also facilitate (and minimize delays in) evidence-based decision-making and recommendations for emerging vaccine technologies in Canada.
2. To compel jurisdictions to rapidly share epidemiologic and other disease surveillance information, both routinely and during disease outbreaks/threats, more formal data-sharing agreements (i.e. to establish clear, formal legal obligations) should be implemented across F/P/T governments – following the example of an agreement signed between the federal government and Ontario in 2008.

3. To improve Canada's ability to track vaccination status (immunization coverage rates) in a timely, accurate manner, federal leadership and additional investment by F/P/T governments will be required to further develop jurisdictional/national vaccination registries, including the finalization of data standards to ensure compliance with the immunization registry module of the pan-Canadian Panorama surveillance system.
  - While F/P/T immunization registries remain under development, it is recommended that the Adult and Childhood National Immunization Coverage Survey continue to be conducted every two years.
  - Once a national registry is fully functioning, it is recommended that national immunization coverage data be reported from registry records on an annual basis.
4. To facilitate future data entry into vaccine registries (i.e. via electronic scanning), the development of a standardized bar coding system for vaccines will be required in Canada. The VIC, in collaboration with the AIVP ATG, recommends a step-wise implementation strategy for such a system, beginning with the early adoption of a bar code on the primary vaccine package with *non-variable* data only. In this case, a linear bar code, using reduced space symbology (RSS), would encode the Global Trade Item Number (GTIN), which identifies the manufacturer and product tradename. Vaccine manufacturers could work towards implementing such a bar code on a voluntary basis within a reasonable timeframe, e.g. 18-24 months.
  - The AIVP ATG proposes that progression could be made towards increasingly complex bar coding options over time, eventually including the use of *variable* data (e.g. lot number and expiry date), first on the secondary vaccine package, and subsequently on both the primary and secondary vaccine packages.
5. To ensure the successful development and implementation of vaccine bar coding standards in Canada, the PHAC/AVIP should continue to work collaboratively (e.g. through the AIVP ATG) with manufacturers, BGTD, GS1 Canada, P/Ts, and end-users (health practitioners, hospitals, and patient associations) to address the requirements of all relevant stakeholders across a wide range of immunization settings.
6. To support timely, accurate, systematic, and comprehensive reporting of adverse events following immunization (AEFI) – and thus to permit rapid detection of any safety signals of concern – additional F/P/T government funds/resources should be deployed to strengthen Canada's post-marketing safety surveillance infrastructure, including enhancement of the current CAEFISS and IMPACT networks.
  - Improvements should be made in information sharing and communication speed (from local to P/T and national levels) to permit timely, efficient analysis of aggregate data.
  - Standardization of reporting methods and underlying case definitions should be enhanced to decrease P/T variability in the quantity and quality of information provided (e.g. CAEFISS).
  - Further transition towards digital/Web-based reporting platforms (for a broader range of target diseases) will be required to accelerate AEFI data collection and reporting (e.g. IMPACT).

7. To protect individuals who have suffered vaccine-related injuries (as well as to provide a more secure legal environment for vaccine innovation, and to help protect the vaccine supply), Canada should establish a national no-fault compensation (NFC) program similar to those that exist in other jurisdictions worldwide.
  - In tailoring a compensation scheme uniquely for Canada, the current U.S. and Québec NFC systems could serve as useful comparative models, from which to draw lessons regarding the optimal national legal structure – including consideration of appropriate financing schemes, claim criteria, adjudication procedures and litigation rights.



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