

Approaches to Immunization Data Collection Employed Across Canada During the Pandemic (H1N1) 2009 Influenza Vaccination Campaign

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ABSTRACT

Objectives: A critical component of the 2009 H1N1 vaccination campaign was the collection of immunization data at the point of care. To meet reporting requirements and to ensure timely availability of coverage information, many jurisdictions across Canada employed new or modified approaches to vaccine data collection. The objective of this study was to observe and characterize the range of influenza immunization data collection approaches used across Canada.

Methods: As part of a multi-stage observational study, the research team visited immunization clinics at which tasks related to data collection and management were observed. Tasks included registration, medical history collection and review, vaccine record-keeping, proof of vaccination preparation, and data entry. Field notes were analyzed in order to understand the data collection mechanisms that comprised each information system as a whole.

Results: Data collection mechanisms were grouped into two categories: electronic systems (9/38), in which all data were captured on computer; and hybrid systems (29/38), comprised of computerized and paper-based data collection tasks. Observed systems included stand-alone databases, immunization registries, and electronic health records. Organizations incorporated magnetic card reader technology, telephone registration, and pre-populated fields into data collection approaches. Electronic systems captured a greater number of data elements.

Conclusion: Canadian jurisdictions employed a range of data collection approaches during the H1N1 vaccination campaign. System characteristics can have important implications for on-site efficiency and organization as well as program planning and evaluation. The systems observed have been described in detail to allow vaccine providers and planners to learn from what has been done elsewhere.

Key words: Influenza; human; immunization; information systems

La traduction du résumé se trouve à la fin de l'article.

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As part of the public health response to the 2009 influenza A (H1N1) pandemic, and in accordance with federal and international pandemic plans, Canadian health jurisdictions carried out a universal immunization campaign between October 2009 and January 2010. A critical component of this campaign was the collection of immunization data at the point of care. To meet reporting requirements, ensure timely availability of coverage information for assessment of the response, and to monitor adverse event rates, a wide range of data collection approaches were used across Canada, including many new or modified information systems.

To explore these approaches from a systems perspective, an observational study was carried out during the immunization campaign. Study sites included public health mass immunization clinics and occupational health clinics operating in hospitals. We describe and categorize the data collection approaches that were observed at immunization clinics across Canada.

In addition to an awareness of the capabilities that various types of data repositories possess, an understanding of how data are obtained and processed at the point of care is critical for vaccine providers and/or policy-makers who are considering alternative approaches to immunization data collection. Many information systems and registries that capture immunization data are described in the literature, imparting valuable information about systems' capacity, performance and validity. Examples of these include childhood registries,¹⁻³ health provider records,⁴ and population health

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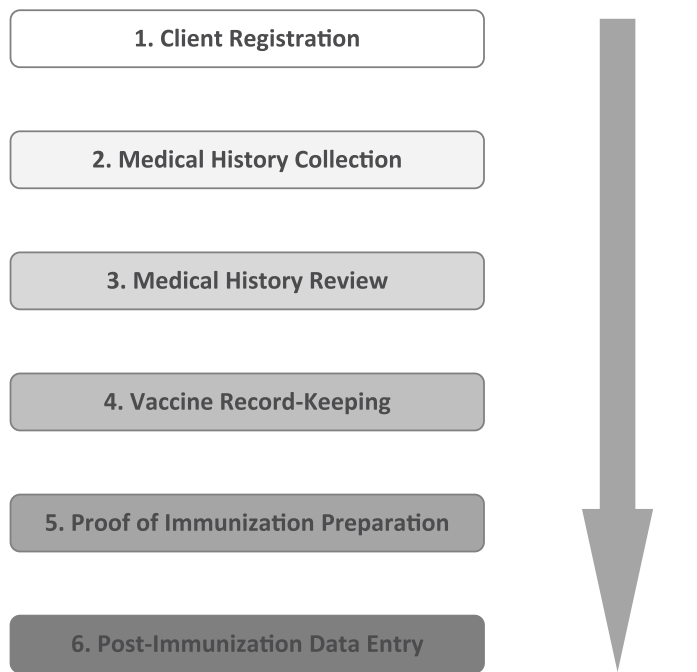
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Conflict of Interest: Maryse Guay received a research grant from Hoffman-Laroche in 2006, and honoraria from Merck Frosst Canada for lectures delivered between 2007-2009. Jennifer Pereira is engaged in consultancy work for GlaxoSmithKline in areas unrelated to influenza vaccine. No other authors have conflicts of interest.

Figure 1. Data collection tasks



information systems or immunization databases.⁵⁻⁹ There is a paucity of in-depth information available regarding how data collection is incorporated into clinic processes, however, and this is the first study to examine and illustrate the range of data collection practices employed in Canadian mass influenza vaccination settings.

METHODS

This study was conducted in the context of a three-stage evaluation, integrating time and motion methodology, user perception surveys, and passive observation. The present paper describes the passive observation evaluation. Full study methods have been described previously.¹⁰

To ensure that participant sites reflected variation in data collection methods, geographic diversity and a range of clinic settings across Canada, this study’s sampling frame included public health organizations in every province and territory. Participant sites were recruited through email; invitations were sent to all public health organizations across the country, as well as a convenience sample of acute care hospitals. A maximum number of study sites was not set. Ethics approval was obtained from the University of Toronto’s Health Sciences Research Ethics Board, as well as from the ethics review boards of participating jurisdictions, as required.

Three clinic days were spent at each participating site, during which one member of the research team spent several hours collecting data. To supplement time observations and survey data, this team member observed clinic processes, focusing particularly on tasks related to data collection. These tasks included client registration, collection and review of medical history, vaccine record-keeping (lot number, date of administration, etc.), proof of vaccination preparation, and post-vaccination data entry (Figure 1). An observation guide* outlining questions regarding the clinic environment, equipment and overall clinic processes, as well as a checklist of data elements, directed the documentation of this

* This unpublished guide was developed by colleagues within our research network and is available upon request.

Table 1. Site Characteristics

	Number of Sites (%)
Province/Territory	
Alberta	8 (10.1)
British Columbia	5 (6.3)
Manitoba	14 (17.7)
Newfoundland and Labrador	6 (7.6)
Nova Scotia	15 (19.0)
Nunavut	2 (2.5)
Ontario	15 (19.0)
Quebec	6 (7.6)
Saskatchewan	8 (10.1)
Organization Type	
Public Health	74 (93.7)
Hospital	5 (6.3)
Data Collection Approach	
Electronic	14 (17.7)
Hybrid	65 (82.3)
Clinic Location*	
Rural	27 (34.2)
Urban	52 (65.8)

* Classified according to postal code; the number in the second position of the postal code indicates whether the forward sortation area is urban or rural.¹³

information in detailed field notes. Client information forms obtained from each organization identified the data elements that were recorded on paper and captured electronically. Field notes were analyzed in order to understand the data collection mechanisms that comprised each information system as a whole; our interpretations of these system characteristics were summarized and sent to each organization for validation.

RESULTS

Seventy-nine clinic sites in thirty-eight organizations were observed across nine provinces and territories between October 27th and December 17th, 2009, representing 23% of the 165 organizations invited to participate. Due to logistical constraints, we were unable to visit a small number (n=5) of interested organizations. The characteristics of participating sites are described in Table 1.

Data collection approaches varied extensively among and often within provinces and territories, but could be grouped into two broad categories. *Electronic* systems captured all data electronically on a computer prior to or at the point of immunization; *hybrid* systems comprised both electronic and manual data collection components. Within these classifications, we have described systems according to the nature of the infostructure (information infrastructure) in which the data were ultimately housed. Table 2 illustrates the processes followed within each of the systems described below.

Electronic systems

Two fully electronic systems were observed in this study.

In one organization, client immunization data were captured in a regional electronic health record (EHR) that incorporated a telephone booking system (System A). Appointments were made over the phone and directly entered into each individual’s electronic record by a clerk; if no file existed for a caller, a new client record was created when the appointment was made. On arrival at an immunization clinic, each client was directed to an immunizing nurse who selected his/her electronic record from a list of registered individuals. Medical history and vaccine details (dose, site, lot number) were entered electronically into the client’s record through a series of check-boxes and drop-down menus. All of these data were retained within each individual’s health record in the regional reg-

Table 2. Data Collection Tasks by System

	Electronic Systems (# of organizations)		Hybrid Systems (# of organizations)						
	A (1)	B (8)	C (5)	D (1)	E (1)	F (10)	G (3)	H (2)	I (7)
Registration									
Clerk calls up client record in pre-populated registry			•						
Card swiped to populate demographics in a new client record		•			•				
Prior to clinic visit, over the phone; entered into electronic patient record	•								
Client or clerk completes paper immunization form						•	•	•	•
Clerk manually creates new client record within database				•					
Medical History									
Reviewed and entered into electronic system by nurse	•								
Entered into electronic system by clerk; reviewed by nurse		•	•	•					
Completed on paper by client or clerk; reviewed by nurse			•		•	•	•	•	•
Vaccine Record-keeping									
Entered into electronic system by nurse	•	•							
Completed on paper by nurse			•	•	•	•	•	•	•
Proof of Vaccination									
Immunization card or form; handwritten, pre-printed, carbonless copy, or no proof*	•		•	•	•	•	•	•	•
Printed from client record		•							
Immunization Data Entry									
All immunization data are captured electronically at the point of care	•	•							
Manually entered into influenza immunization database			•	•					•
Immunization information not captured electronically					•				
Manually entered into provincial immunization registry						•			
Majority retained as aggregate counts; remaining in immunization registry							•		
Entered into influenza immunization database using specialized interface								•	

* This varied by clinic and organization, not necessarily by system.

istry, and transferred daily to a secondary server to facilitate reporting. Immunized clients were provided with a handwritten proof of vaccination card for their records.

The second electronic system, employed in eight observed organizations, was a system developed specifically to capture influenza immunization data (System B). Upon arrival at a clinic, clients were registered by clerks equipped with laptops connected to a networked database. Demographic information was retrieved by swiping a health insurance card or driver's licence,* or captured through manual data entry when necessary. Responses to medical history questions posed by the registration clerk were also entered into the client's record. Clients then proceeded to an immunization nurse, also equipped with a laptop, who retrieved each individual's electronic record and reviewed the client's medical history before administering the vaccine. Following immunization, vaccine details were entered into the client's record through check-boxes and by selecting pre-populated vaccine information. Printed directly from the system, a proof of vaccination record was provided to each client. The individual vaccine records created at each immunization clinic were uploaded daily into a centralized, regional database.

Hybrid systems: Electronic client registration

Hybrid systems integrated both electronic and paper elements into their data collection approaches. In several hybrid systems, electronic immunization records were created for each client at registration, and in six organizations the following process was observed: upon arrival at the clinic, clients provided their name, health card number, and, if necessary, demographic information to a registration clerk for entry into an electronic database. This was either a) pre-populated with residents' individual-level data from regional or provincial records (System C), or b) a stand-alone

* In some Canadian provinces and territories, demographic information is embedded within health insurance cards and/or driver's licences and is automatically scanned and uploaded when the card is swiped through a magnetic reader.

database into which all information was manually entered as new records at the time of registration (System D). Following registration, a paper immunization form was printed and taken to an immunization nurse for medical history review and immunization documentation. The additional information recorded on these forms was later manually entered into each client's electronic immunization record. Varying by clinic, clients' proof of vaccination documentation consisted of pre-filled cards printed at registration or a form signed and dated by the immunizer; in some cases, no proof was provided.

In another organization, software and swipe technology similar to those described as System B were incorporated into a hybrid data collection process (System E). Upon clinic arrival, clients completed a paper immunization form and presented it to a clerk at the time of registration. Together with demographic information from a health card or driver's licence, the information on this form was used to create an electronic immunization record in a new stand-alone influenza database. The paper form was returned to the client and used by the nurse as a reference for medical history review and, once updated with immunization documentation, was retained by the organization operating the clinic. No additional information was entered into the electronic system after registration. Nurses completed a proof of vaccination form for each client.

Hybrid systems: Manual data collection at the point of care

Twenty-two organizations shared a common data collection approach, in which all data collection tasks at the point of care were performed manually using paper forms; the primary differences lay in the mechanisms used to transfer data from paper records into an electronic form. Demographic and medical history fields were completed on paper consent forms by either clients or registration staff. These forms were brought to the immunizing nurse who reviewed the medical information and completed all required vaccine administration details (in some jurisdictions, date

Table 3. Data Elements Captured at the Time of H1N1 Immunization*

	Element collected in electronic organizations (%) n=9	Element collected in hybrid organizations (%) n=29	Total organizations retaining element electronically†,‡ (%) n=38
Personal and Demographic Information			
Name	9 (100)	29 (100)	38 (100)
Unique identifier (health insurance or employee number)	9 (100)	29 (100)	38 (100)
Sex	9 (100)	29 (100)	38 (100)
Date of birth	9 (100)	29 (100)	38 (100)
Ethnicity	8 (88.9)	2 (6.9)	10 (26.3)
Aboriginal status	9 (100)	20 (69.0)	27 (71.1)
Full address	9 (100)	19 (65.5)	27 (71.1)
Postal code	9 (100)	28 (96.6)	37 (97.4)
Priority Status and Medical Information§			
Chronic medical conditions	9 (100)	29 (100)	36 (94.7)
Details of chronic conditions (type and/or meds)	9 (100)	12 (41.4)	9 (23.7)
Pregnancy status	9 (100)	28 (96.6)	34 (89.5)
Health care worker	9 (100)	29 (100)	35 (92.1)
Care provider or household contact of high-risk individual	9 (100)	12 (41.4)	20 (52.6)
From remote community	9 (100)	2 (6.9)	11 (28.9)
Allergies	9 (100)	18 (62.1)	13 (34.2)
Overall health status on the day of immunization – feeling well, fever, etc.	9 (100)	19 (65.5)	10 (26.3)
Vaccination Details			
Vaccination date	9 (100)	29 (100)	38 (100)
Prior receipt of 08/09 or 09/10 seasonal vaccine¶	9 (100)	15 (51.7)	22 (57.9)
Vaccinator name/initials/identification	9 (100)	29 (100)	21 (55.3)
Lot number	9 (100)	29 (100)	30 (78.9)

* In some settings, depending on organizational discretion, not all of the fields on the client information form or computer interface were completed for all clients.

† In three organizations, data were only captured electronically for children 9 years of age and younger.

‡ Some of these elements were already contained in client records and thus were not collected at the time of immunization but were retained and accessible electronically.

§ In some organizations, only one risk category was recorded as the reason for immunization, although an individual may fall into two or more of these groups.

|| Not applicable for three organizations in which information was only captured electronically for children 9 years of age and younger.

¶ In one organization, information regarding prior immunizations was only captured for some individuals.

stamps and/or lot number stickers were used to expedite record-keeping). Proof of vaccination consisted of either a carbonless copy of the immunization form or an immunization card – pre-printed in some organizations and requiring handwritten documentation in others.

In some jurisdictions, data were transferred from paper forms into provincial immunization registries (System F). In one province, in which seven organizations were observed, this registry contained client-level records for all individuals registered for health coverage, reflecting most immunizations administered over the past several years. Data were transferred from paper forms into the registry by data entry clerks. In another province in which three organizations were observed, the provincial registry previously used exclusively to capture childhood immunizations was expanded to incorporate adult immunizations in advance of the pandemic H1N1 immunization campaign. Using paper forms, data entry staff updated existing client records in the internet-based registry and created new records for all individuals (adults and children) who did not have a previous record in this registry.

In three other organizations, the individual-level data entered into provincial or regional registries were limited to certain subgroups. Immunization data for children nine years of age and younger were entered into childhood immunization registries (system G), in order to track immunization doses received at the individual level, as initially it was expected that all children under the age of ten years would require two doses of the pandemic H1N1 vaccine (this directive was later modified). Data for the remaining population were retained electronically as aggregate counts of vaccines by age- and risk-group.

Specialized influenza interfaces were developed by some organizations to expedite data entry (System H). In one organization, an

influenza immunization registry created from health insurance data was pre-populated with individual-level demographic information for all residents of the jurisdiction. Data entry involved retrieving each client's profile using a unique identifier and completing fields from the paper form. Another organization used an immunization interface to enter vaccine data into each employee's human resources record. Again, individual records were retrieved during the data entry process and vaccine data were entered into a series of prompted fields.

Seven organizations observed in one province created new influenza databases into which individual-level data from immunization forms were entered by data entry staff (System I). Since these databases were not integrated with previously-established registries, as was done in other organizations, new records were required for all clients.

Data elements

We observed substantial variability in the data elements captured by or entered into electronic information systems. Certain core demographic and clinical elements were collected by all organizations, while supplementary data retained electronically in individual immunization records varied extensively across participating jurisdictions. Table 3 describes the key data elements collected, the proportion by information system type, and the proportion of observed organizations that retained these elements within individual electronic records.

DISCUSSION

The observed approaches used to capture and store pandemic H1N1 immunization data varied considerably across Canada. In some instances, the use of pre-existing health records, pre-populated

databases, pre-entered lot and expiry information, or magnetic card reader technology reduced manual data entry, improving data collection efficiency,¹¹ and potentially data quality (although this was not assessed in the present study). Further, systems that allowed electronic immunization records to be created or accessed at the point of registration/immunization and updated electronically made information readily available for evaluation and analysis.

The nature of an information storage system and the data collection methods employed, as well as the data elements retained in the system, have important implications for when, how, and which data can be analyzed and used. Fully electronic systems and individual electronic records that are updated shortly after each clinic day allow a range of functions to be performed during the immunization campaign in a highly automated and consistent fashion. These include dose and date monitoring for individuals who require multiple doses, and lot number tracking in the case of adverse events. Through the collection of a comprehensive set of medical and demographic data, and provided that these data are rapidly available for analysis, vaccine uptake among vulnerable populations can be assessed throughout the immunization campaign and addressed through public health outreach initiatives as necessary. Though check-boxes make these data straightforward to collect either on paper or in electronic form, our observations indicate that organizations employing electronic systems captured a greater number of data elements. We were not able to ascertain the reasons for this in the context of the current study but the fact that a greater number of elements can be collected without lengthening paper consent forms, coupled with the potential to use the data immediately rather than relying on data entry, are likely significant factors. Electronic immunization data collected over a number of influenza seasons can enhance longer-term policy-making, program planning and evaluations by allowing trends in uptake across a range of client and clinic characteristics to be observed. From a clinical perspective, electronic registries allow rapid access to vaccine information for both care providers and clients, who may require vaccination confirmation for employee or personal records. Further, robust research and evaluation regarding the safety and impact of a vaccine are dependent on system characteristics and data elements collected. The inclusion of unique identifiers in immunization records allows these data to be linked with other health information for program evaluation and research purposes, including safety and effectiveness assessments, and also minimizes possible duplication of client records in the system. Capturing clinic data directly in an EHR, within which a range of other individual personal and medical information is stored, ensures that immunization history is part of a client's comprehensive clinical profile.

The specific approach to data collection that is most appropriate for an organization is highly dependent on several factors. In addition to the information needs and size of the population being served, the financial and technical resources available are also critical considerations.¹² While electronic components may hasten data collection tasks, their implementation requires the purchase of hardware and software and requires staff with appropriate expertise to install and maintain these elements. The capacity of an organization to preserve data security, in order to ensure that privacy and confidentiality legislation is upheld, is another important factor to consider when personal health information is collected

and stored electronically. In addition to database architecture that is suitable from an operational perspective, jurisdictions employing electronic systems must have the appropriate infrastructure and standards in place to maintain the integrity of any identifiable information that is collected.

Collecting and electronically maintaining a broad range of immunization data is a considerable yet worthwhile investment if these systems are used to their full capacity, but if they are not, time and resources could be more appropriately spent elsewhere. Recognition of the value of fully electronic systems is essential for these investments to be made. This exploration was not within the scope of this study; an important next step is to understand how immunization data are being applied, at which organizational levels, and by whom.

A key limitation of this study is its emphasis primarily on mass immunization clinics managed by public health organizations. Hospital settings were included in our sampling frame but because recruitment coincided with the beginning of the pandemic's second wave and health care workers were identified as a priority group and quickly vaccinated, it was only possible to obtain consent to observe a small number of hospitals while their immunization campaigns were still operating. Physician offices and other settings were excluded from this study due to complexities related to recruitment within a very short time period. Further, because it was not possible to recruit sites in all public health jurisdictions, nor all provinces and territories, there may have been other approaches to data collection used within Canada that are not described in this paper.

Public health organizations and hospitals across Canada employed a wide range of immunization data collection approaches during the pandemic (H1N1) 2009 influenza vaccination campaign, several of which were newly developed or modified. System characteristics can have important implications for on-site efficiency and organization of vaccine services as well as longer-term planning and program evaluation. The systems observed have been described in detail with the intention that vaccine providers and program planners will be able to learn from what has been done elsewhere. Further studies examining systems' data quality, user acceptability and ease of integration with clinic operations will be valuable in moving toward provincial/territorial, if not national, consensus on optimal approaches for collecting immunization information. It is hoped that an in-depth understanding of the system features and characteristics that facilitate the collection of high-quality data with greater usability will be incorporated into Panorama, the proposed pan-Canadian public health surveillance system, as well as other information systems as they continue to be developed and implemented across Canada.

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RÉSUMÉ

Objectifs : L'un des éléments clés de la campagne de vaccination de 2009 contre la grippe H1N1 était la collecte de données d'immunisation au point d'intervention. Pour respecter les exigences de déclaration et assurer la disponibilité en temps utile des données sur la couverture vaccinale, de nombreuses administrations au Canada ont employé des approches nouvelles ou modifiées pour cette collecte de données vaccinales. Nous avons voulu observer et caractériser l'éventail d'approches utilisées au Canada pour la collecte de données sur le vaccin contre la grippe.

Méthode : Dans le cadre d'une étude observationnelle multistade, l'équipe de recherche a visité des cliniques de vaccination pour y observer les tâches de collecte et de gestion des données : inscription, prise et examen des antécédents médicaux, tenue des registres de vaccination, préparation des preuves de vaccination et saisie des données. Les notes de terrain ont été analysées afin de comprendre les mécanismes de collecte de données de chaque système d'information.

Résultats : Les mécanismes de collecte ont été regroupés en deux catégories : les systèmes électroniques (9/38), où toutes les données sont saisies par ordinateur; et les systèmes hybrides (29/38), où la collecte des données se fait par ordinateur et sur papier. Les systèmes observés comprenaient des bases de données autonomes, des registres d'immunisation et des dossiers médicaux électroniques. Les établissements ont utilisé des lecteurs de cartes magnétiques, l'inscription téléphonique et des champs préremplis comme méthodes de collecte de données. Les systèmes électroniques ont saisi un plus grand nombre d'éléments d'information.

Conclusion : Les administrations canadiennes ont employé diverses méthodes de collecte de données durant la campagne de vaccination contre la grippe H1N1. Les caractéristiques de ces systèmes peuvent avoir d'importantes conséquences sur l'efficacité et l'organisation de la clinique, ainsi que sur la planification et l'évaluation du programme. Les systèmes observés sont décrits en détail pour permettre aux vaccinateurs et aux planificateurs d'apprendre de ce qui se fait ailleurs.

Mots clés : grippe humaine; immunisation; systèmes d'information



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