Canada's Response to Pandemic H1N1 Influenza: The Collection of Individual-Level Data at the Point of Vaccination

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The collection of individual-level immunization data at the point of vaccination is ideal for immunization clinic operations, rapid and precise monitoring of vaccine coverage and the evaluation of vaccine safety and effectiveness. While this practice has been adopted for routine childhood and seasonal influenza immunization in selected Canadian jurisdictions, most settings do not have this capability. However, with the emergence of pandemic (H1N1) 2009 influenza and the subsequent planning of vaccination clinics across Canada, decision-makers at the provincial/ territorial level decided to begin collection of individual-level pandemic immunization data.

Why Was Individual-Level Data Collected during Canada's Pandemic Vaccination Campaign?

Collecting individual-level pandemic immunization data was considered to be valuable for numerous reasons. First, assessing pandemic vaccine coverage for priority groups was a vital aspect of program evaluation to ensure that the vaccines were getting to the appropriate people in a timely manner. Individual-level data permitted more flexible and accurate assessments of vaccine coverage at finer levels of geography (e.g., regional as opposed to provincial). Second, as the pandemic vaccine was new, its safety and effectiveness across both a large heterogeneous population and within smaller age- and risk-based subsets had not been established definitively when the vaccination campaign began. Therefore, it was desirable to collect data that would facilitate studies to more clearly determine the risk-benefit ratio of the vaccine in different populations, such as those with chronic conditions or those who had been vaccinated previously against seasonal influenza. Third, if vaccine safety or efficacy issues were identified for specific vaccine lots, notifying recipients of those lots was possible only if contact information was accessible for each person; this was especially important for the pandemic

vaccine because as a new combination of antigen and adjuvant, there were less safety data available for it compared with more established vaccines ("Supply and Safety Issues" 2009). Finally, collecting individual-level data made it possible for reminders to be sent to caregivers when children were due to receive their second pandemic vaccine dose (and when guidelines were revised during the campaign to state that not all children required a second dose, this information could be communicated in a targeted manner to caregivers whose children had already received one dose).

Most provinces and territories instituted individual-level pandemic immunization data reporting requirements to ensure consistent data collection within their jurisdictions. In response, many public health authorities adapted existing systems or implemented new systems to better facilitate this data collection at the point of vaccination.

How Are Individual-Level Data Collected?

Individual-level immunization data may be collected using manual paper-based approaches, electronic methods or hybrid systems that use a combination of the two.

Paper-Based Systems

Paper-based recording of vaccination information in a patient's chart or via a consent form is common practice in some jurisdictions and meets professional practice documentation standards (College of Nurses of Ontario 2009). This approach requires the data collector to record the patient, provider and immunization data on a paper form to be stored in a physical file location. This is the simplest and least costly approach for data collection but greatly limits what can be done with the data and how quickly data can be used. Obtaining useful information such as vaccine coverage based on geographical region, age or high-risk group becomes very resource intensive as trained abstractors must manually audit all the forms and extract these data. Collecting

large numbers of individual vaccinations, as was the case for pandemic influenza, is highly time intensive and potentially increases the risk for human error in data extraction.

Electronic Systems

Electronic data collection methods require providers to access an information system or software application, usually via a computer, through which data are entered directly into a database. All aspects of registration, medical history collection, vaccine administration record keeping and proof of vaccine administration are completed within these systems. Approaches have been developed to increase user efficiency and reduce errors during the entry of patient data. These include drop-down menus and point-and-click applications, as well as card-swiping technologies that automatically read data from a health card or a driver's license. If the information system is linked to a patient registry, it can be programmed to automatically populate certain fields once a name or unique identifier such as a health insurance number has been entered.

The primary benefit of collecting data electronically is that the data are available in a format that permits the rapid generation of reports for decision-making purposes. Having pre-existing data (e.g., date of previous doses, presence of medical conditions) available to providers at the point of care is also useful for improving patient care.

Despite these benefits, there are key barriers associated with information systems. First, there are significant financial and human resources required to implement, support and maintain these systems. While these may not be insurmountable obstacles in all jurisdictions, they may hinder the rapid implementation of electronic systems in certain settings.

Second, barriers related to the accessibility and use of electronic individual-level immunization data can be challenging to overcome, particularly in jurisdictions where vaccinations are delivered by public health staff, institutional occupational health staff and physicians. Combining data from a range of providers into a centralized registry requires considerable coordination.

Acquiring legal authority to collect individual-level data is a third potential barrier due to the challenges of ensuring the privacy and security of this personal health information in electronic systems. Safeguards such as encryption of personal identifiers, password protection and the audit of data access can readily address such concerns.

Inaccuracies in the collected immunization data pose a fourth barrier to their optimal use for operational planning and research. However, modern databases can validate entered data at the time of entry when it is possible to correct errors quickly. Accuracy could also be increased through data linkages that permit real-time verification with existing electronic health records. Such linkages would also increase the usefulness of the data for certain research purposes.

Finally, human barriers could affect the willingness of jurisdictions to adopt an electronic system to collect individual-level immunization data. Front-line immunization staff may not be comfortable with computer technology, perhaps perceiving that this would increase their workload. However, studies testing the use of electronic data entry have demonstrated that after an initial - and often brief - training period, user input time decreases and overall efficiency is improved (Bosman et al. 2003). Rapid data entry approaches, including swipecard technology for patient demographic data and the use of pre-populated registries, can save time.

Hybrid Systems

Hybrid data collection systems allow the provider to collect data using paper-based methods but also include a process for making these data available electronically. The most common practice is to record immunization data on paper at the point of care and commit additional resources to manually enter all paper records data into an electronic repository; however, this time-intensive approach does not facilitate immediate availability of data. An alternative approach is to use scanning technologies in which patient data are recorded by pen or pencil on customized forms. As these forms are scanned, software applications "read" the data and export the records into a database.

While hybrid systems may retain a few of the barriers associated with electronic systems, this approach preserves the simplicity of capturing data on paper without losing the ability to have these data available electronically in a timely fashion. Even as a hybrid solution, the considerable benefits of an electronic system include the rapid retrieval of patient data for operational and program-related elements of vaccine delivery, as well as the potential for data linkage to public health and health administrative databases to assess vaccine safety and effectiveness efficiently. These functionalities could prove tremendously important to Canada's future national surveillance efforts.

The collection of individual-level pandemic immunization data has been incorporated as an important component of mass vaccination campaigns across Canada.

Future Research

The collection of individual-level pandemic immunization data has been incorporated as an important component of mass vaccination campaigns across Canada. We have been documenting the specific methods used to collect pandemic immunization data in a pan-Canadian study involving on-site assessments of public health and hospital settings. Analyses of the collected

data are under way, with comparisons being made across the range of data collection methods with respect to specific clinic processes, time required to collect immunization data (for registration, medical history collection and review, vaccine record keeping and proof of vaccine administration), number of individual-level data elements collected and clinic staff perceptions of the usability of the method employed at their immunization site. Such research is critical to provide immunization decision-makers with the information they require for optimal vaccine delivery and to facilitate a fully coordinated national effort for collecting and sharing patient data during future influenza seasons. HQ

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