Data Specification for Information Systems for the Immunization Cold Chain

Fahad Pervaiz and Richard Anderson
Computer Science & Engineering, University of Washington
Email: fahadp@cs.washington.edu, anderson@cs.washington.edu
Sophie Newland
PATH
Email: snewland@path.org

Abstract: In this paper, we present work on developing information systems for immunization logistics in developing countries. We developed multiple systems for managing Cold Chain Equipment Inventories (CCEI) that facilitate a country’s management and planning of their immunization programs. In addition, we led an effort to create a data standard for CCEI to facilitate the process of moving between different implementations, and to allow for visualization and analysis tools that are independent of the platform for inventory.

A broader contribution of this work is as a case study of how the information needs of a vertical program fit into an overall Health Information System (HIS). It is not unusual for health data to exist simultaneously in spreadsheet applications, standalone PC applications, and database applications. There are situations where each one of these is the appropriate architectural choice. We argue for the development of data standards as a mechanism for migration between these different approaches.

Keywords: Cold Chain Inventory, Immunization, Vaccine Supply, Health Information Systems, Developing Countries, and Data Standards.

1. INTRODUCTION

Health information systems are critical for strengthening public health in developing countries (Ammenwerth 2003)(Panir 2011). Accurate and up-to-date information supports management and decision-making, and allows resources to be directed to where they may have the most impact. The health information system collects data through the health hierarchy and the data is maintained centrally. Reports and analysis from the data can be generated either at the national level or in a distributed manner. The health information system often supports multiple health domains, where each health domain is a programmatic area around a disease, intervention or service.

However, countries face many challenges in deploying effective health information systems. Many reports are still submitted on paper forms, with the resulting information stored in standalone databases or spreadsheets. Network infrastructure, although improving rapidly, still can be unreliable, especially at the periphery. The software environment for a health system is often complex. In addition, organizational issues may make change difficult since some groups

may lose control over data and new working relationships need to be established. IT resources are also often limited, making it difficult to maintain and support systems. Finally, decisions on the adoption of health systems software can be highly political (Sahay 2009).

Recognizing the complexity of existing information systems and organizations, how does a country successfully implement a modern health information system? To explore how information system needs for a health vertical tie into the overall health information system, we look at one particular domain, immunization and the vaccine cold chain. We want to understand how addressing programmatic needs for use of data can align with centralizing information services. In this paper we describe work that we have done to support over a dozen countries in building information systems for their vaccine cold chains, and then draw some general lessons to inform work in other program areas. One of our main findings is that data standards are needed to provide a bridge between the multiple implementation options, as well as providing a link between the software applications and practitioners.

Literature in standardization argues that standards emerge through use rather than consensus (David 1986). Given the rapidly growing complexity around the standards makes achieving a consensus very difficult. This is mainly because of the bureaucratic processes of standardization bodies are too slow (David and Shurmer 1996). Informal bodies can contribute tremendously in shaping the standards in today's complex space (Shapiro et al. 2001). Shared standards can be successful and largely adopted if enough actors are convinced (Kossi 2009). If the standards are simple and flexible to changes then it can be adopted in complex health information systems (Braa et al. 2007).

We argue that a standard can emerge through consensus if the community is specific. In cold chain domain, the consensus is achievable since the programs are fairly uniform. The standard need to define backbone of the cold chain space and have flexibility to extend for specific implementations. This is not only to incorporate future expansions but also to reach an agreement within the community of cold chain experts.

2. IMMUNIZATION

Immunization is recognized as one of the most successful public health interventions in history. Vaccines save millions of lives every year from preventable diseases. An example of the success of immunization is the near eradication of polio. The number of cases per year has declined from an estimated 400,000 in 1980 to just 413 reported cases in 2013 (Polio 2014). There are robust global organizations supporting immunization, both in terms of donor funding, as well as in global governance and coordination. In almost all developing countries, routine immunization is part of the public health system and is administered centrally by a separate department inside the Ministry of Health. Vaccines are distributed nationally and are available for free or at low cost in public health facilities. Vaccines are imported into the country to the national vaccine store, and are then distributed through a hierarchy of vaccine stores until they reach health facilities. At health facilities, vaccines are stored for immunization use or are sent on to secondary facilities. To ensure that the vaccines remain viable, it is critical that they are kept at appropriate temperatures during transit, storage and use. This is done with refrigerators and freezers at storage locations, and refrigerated trucks and cold boxes for transit, which are collectively referred to as the “vaccine cold chain” (Maurice 2009).

Immunization logistics is concerned with the distribution of vaccines. Essential problems include maintaining adequate stock levels and ensuring that vaccines maintain safe temperatures. A logistics information system manages information about vaccine shipments, vaccine use, and the fixed assets in the system. In this work, we focus just on the information systems associated with the physical cold chain, which consists of an inventory of the cold chain storage equipment along with associated information about the health and storage facilities. Even though this basic equipment and facility information is fundamental, it is often unavailable or out of date.
Perhaps the most basic question about a country’s vaccine cold chain is whether or not it has sufficient capacity to store the required vaccines. However, in many countries, the answer to this question is not known, as the Ministry of Health does not know how much cold storage equipment is available for vaccines. This question becomes especially important with the introduction of new vaccines such as the rotavirus and pneumococcal vaccines. These new vaccines take up more space, and are more expensive and more sensitive to heat than older vaccines, which increase the importance of having sufficient capacity in the cold chain. It is also important to understand the quality of the cold chain, including the working condition and age of equipment. Since many health facilities do not have access to regular grid electricity, there are vaccine refrigerators with other power sources including gas, kerosene, and solar power. Knowing the distribution of power sources of equipment is critical for estimating overall costs (for example, gas and kerosene can be ten times as expensive as grid electricity) and planning for upgrades. Information about the cold chain is also important for management of existing equipment, and acquisition and allocation of new equipment, which often takes place at an intermediate level, such as at the district level.

3. COLD CHAIN INFORMATION SYSTEMS

A cold chain equipment inventory (CCEI) is a data set consisting of information about vaccine storage devices (refrigerators, freezers, cold rooms, freezer rooms, cold boxes and vaccine carriers) along with information about the health facilities. Basic information about the cold chain equipment includes age, model, working condition, and the health facility it is located in. We discuss the data fields in more detail below. When we talk about a cold chain equipment inventory we generally are referring to a national inventory, although in some large countries, such as India, inventories might be done by state. The inventory generally focuses on facilities in the public health system as in most low and middle-income countries vaccines are distributed through the public system.

We now present a number of use cases for the cold chain equipment inventory. In this discussion, it is important to consider the stakeholders, which we divide into three broad categories: Global: donors and intergovernmental organizations such as UNICEF and WHO; Implementers: NGO’s, consultants, and academics; and Country Staff: Ministry of Health (MOH), National Immunization Program (NIP), and logisticians. Although all of these stakeholders are aligned on the goal of strengthening immunization systems, they have differences in priorities and emphasis.

Cold chain equipment inventories are used to support all of the following activities:

- **Assessment**: Evaluation of the vaccine cold chain to determine if there is sufficient working storage capacity to ensure that vaccines are kept safe until they are used. One of the important areas for assessment is when new vaccines, such as pneumococcal and rotavirus vaccines. New vaccines often have large packaging requirements, which can overwhelm existing storage capacity.

- **Quantification of need**: Determine how many new refrigerators are needed to meet storage demands for vaccines. This quantification can be based on scenarios such are addition of new vaccines and retirement of different types of refrigerators. This may be expressed as a multi year plan that identifies needs over several years.

- **Re-engineering supply chains**: There is interest reorganizing how vaccines are distributed within countries by doing things such as removing intermediate levels of storage and changing delivery timings. Estimating the cost requires having the underlying cold chain inventory data, and possibly applying sophisticated computer modeling with systems such as Hermes (Lee 2011).

- **Market shaping**: Cold chain inventory data provides important information to estimate the global demand for different classes of vaccine refrigerators, such as solar powered
refrigerators. One application of this is to demonstrate sufficient demand so that manufacturers will be able produce and market certain models.

- Cold chain management: The cold chain inventory support many tasks on managing equipment from allocation of refrigerators to health facilities, to planning equipment upgrades, and tracking maintenance.
- Immunization information systems: The cold chain inventory can be a component of other information systems for immunization to support other activities such as managing vaccines in a logistics management information system.

These use cases impose different requirements on a cold chain equipment inventory, and are motivated by the different stakeholders. For example, assessment is a use case that is driven at the global level, and may be a requirement before funding is released to support vaccine introduction. Management on the other hand is activity at the country level, where information is used to make decisions about individual pieces of equipment, and is not a direct concern to the external stakeholders.

4. SOFTWARE CONTEXT AND CHALLENGES

Wide ranges of systems are used to manage cold chain inventories. The context differs between countries, so it is natural to see a range of approaches taken. Inventories are sometimes managed by a standalone, local application without web support, and other times are part of a larger database or a component of an application for another purpose. In this section we give an overview of various approaches for maintaining cold chain inventories. One thing to note is that the cold chain inventories fall into a common pattern of health domain software systems where there are simultaneously spreadsheet tools, single machine database tools, and web-based database tools.

4.1. Spreadsheet Solutions

The most common and basic approach to representing a cold chain inventory is to track the information using spreadsheets. There are advantages to this approach: spreadsheets are simple to use and software is widely available. However, spreadsheets are generally single-user documents and there are challenges in maintaining multiple versions. Further, the functionality of spreadsheets is limited with respect to analysis of the data. A prime concern about spreadsheets, raised to us by a World Health Organization (WHO) official, is the difficulty in linking information across spreadsheets (e.g. associating refrigerators with health facilities).

There is a range of spreadsheet approaches used for cold chain inventories that can be modeled using a hierarchy:

1. Simple spreadsheets. The most basic approach is to maintain the information as lists. We have seen many different ways this information is stored. For example, in Laos, separate spreadsheets existed (in different formats) for each manufacturer of equipment, in addition to extra sheets for facility information and populations.

2. Inventory spreadsheets. The next level up the hierarchy is spreadsheets that are designed specifically for a cold chain equipment inventory. An example we have worked with is an inventory for three states in India that consists of seven separate spreadsheets for equipment from different types of facilities, along with another two spreadsheets for vaccine logistics for these facilities. The ID numbers from the original inventory forms are used to link equipment to facilities. Due to the complexity of the survey forms, the spreadsheets were quite large, with some having over 300 columns.

3. Excel-based cold chain tools. At the top of the list are a group of cold chain analysis tools built in Excel. WHO maintains a group of tools for national and regional immunization managers that support activities such as tracking immunization coverage and managing stock levels. Some of these tools, such as District Vaccine Data Management Tool (DVD-
MT) provide sheets for an inventory of cold chain equipment. The DVD-MT tool provides a well-structured inventory that includes many of the fields we recommend in our own data model (discussed further below).

4.2. Single Machine Applications

Moving up from spreadsheets are applications using local storage, frequently implemented using Microsoft Access. The most widely used cold chain equipment inventory application is CCEM (Anderson 2012), which was developed by PATH in collaboration with UNICEF, WHO, and USAID. CCEM is a Microsoft Access application with the following functionality:

1. Equipment Inventory. As an Access application, the database is represented with a set of interlinked tables. The main tables are for health facilities, refrigerators, the administrative hierarchy and refrigerator types.

2. Report Generation. This is the key functionality for users, with domain specific reports and charts.

3. Modeling. CCEM was designed to support the development of multi year equipment acquisition plans. CCEM has a simple modeling engine that determines an equipment allocation to satisfy requirements, and allow schedules for adding or removing equipment over several years.

4. Inventory process support. By presenting a clearly defined data model, CCEM has provided an entry point for countries to begin monitoring their cold chain inventories. This schema in turn makes it easy to generate forms from the data model to facilitate the collection of useful inventory information. Together these features have made creating and maintaining a cold chain inventory a more tractable problem, which has been one of the contributions of CCEM.

4.3. Web Based Applications

The basic requirements for an inventory tool are to allow updates and generation of reports from multiple sites. This suggests a web-accessible database. There are many possible ways to implement this. Generally speaking, the sizes of the databases involved are modest, so this is not an inherently difficult problem. The only web-based cold chain inventory tool of which we are aware was developed by UNICEF for use in India. It is currently undergoing pilot use in several states of India. The system tracks cold chain equipment at the facility level, and also maintains information about human resources and training.

Multiple other applications support logistics and the immunization system. These systems frequently maintain information about the cold chain, even though this is not the main purpose of the application. Pakistan’s Vaccines Logistic Management Information System (vLMIS) is a web-based national system designed to give latest data on key vaccine logistics and cold chain indicators essential for better decision-making. The system is designed with access to users from federal, provincial, and district levels with responsibilities varying from data entry to analysis and decision-making. This project is designed and developed by USAID Deliver project and John Snow, Inc. (JSI). Currently, it is running in 54 polio endemic and adjacent districts, with multi-year expansion plan to reach reporting from all districts. Other examples are the logistics management system OpenLMIS (VillageReach 2012) and the vaccine stock management system VSSM (PAHO 2010). Both of these applications track limited information about the vaccine cold chain. Currently, the cold chain inventory applications are completely separate from these logistics management systems, but there are obvious synergies when interoperability issues are addressed.

An alternative to building a custom inventory system is to build on top of a more general platform. DHIS2 is an open source health indicator reporting system developed by the Health Information Systems Program (HISP) and used in roughly 30 countries. HISP has been active since 1994 in developing health information systems with the goal of making health data useful at all levels of
the health system (Braa 2012)(Braa 2004). The motivation behind developing DHIS2 was to improve the quality of health data and use information for action based on different tools (Miscione 2007). DHIS2 is a three-tier application that uses Hibernate to manage the data layer, allowing multiple database implementations to be used, including PostgreSQL and MySQL. The service layer uses the Spring framework, and the web presentation layer uses Struts 2, which includes Jasper Reports, a GIS module, and JQuery.

DHIS2 allows system administrators to design the reporting units, indicators, validation rules, and data entry forms. This is significant since it makes DHIS2 a generic tool that can be easily adopted for countries implementing their health information system. The core data model for DHIS2 is designed around abstract data sets, data values and date elements associated with organizational units. The organizational units are then organized into an organizational unit hierarchy.

The facility model for CCEM matched the organizational units for DHIS2, so the facility data could be handled by the existing mechanisms. The extension that was necessary was for assets, where a collection of assets was associated with each organizational unit and had their individual properties. Instead of directly implementing the cold chain assets types such as refrigerators or cold rooms, generic equipment types and equipment attributes were used. The asset model also relies on catalogs so that fixed properties of a type of equipment could be represented separately from the instance. To handle this generically, catalog types and catalog type attributes were included. This level of indirection allows new types of assets to be added by the system administrator without updating the DHIS2 code. For example, diagnostic equipment could be added to an instance of the inventory module just by adding appropriate equipment and catalog items.

With the completion of the asset module for DHIS2, we have a version of the cold chain tool running on a web-based system. We used one of our existing country data sets for the test version, and implemented reporting for 30-day temperature alarms and recorded equipment maintenance. The base module can be used for cold chain inventories for other countries and it is possible to extend the system to handle other data associated with the cold chain such as automatically collected temperature data (Chaudhri 2010).

4.4. Challenges

There are several challenges with cold chain equipment inventories. The logistical challenge to build an initial cold chain inventory can be enormous, since this is often done by having trained teams of workers visit all the health facilities in the country to collect information. Since countries typically have about one health facility for every 10,000 people, the number of health facilities is large, for example, Kenya has over 5,000 health facilities for a population of 44 million. Travel to all facilities is expensive and time consuming due to difficult roads.

After an inventory is constructed, the main challenge is keeping it up to date. This is, in fact, the major criticism of cold chain inventories: they are generally not kept up to date, and so the investment is squandered. We know of several countries (for example, Malawi, Nicaragua, and Uganda) that have kept inventories updated by maintaining a standalone database and having updates done centrally. However, in many other countries that we are familiar with, the inventory remains static after it has been collected. One of the arguments for a web-based implementation of a cold chain inventory system is that it should be easier to maintain the latest state by allowing distributed updates. Some PC based implementations of inventories approach the update problem with a “feed forward files” to allow the merging of updates from multiples versions of the database for different regions.

The challenges surrounding implementation of an inventory model include maintaining data quality and allowing the system to be easily updated. Ensuring that the data is accurate can be extremely difficult, especially if the data is recorded passively and is not being used to provide feedback to people involved in the immunization system. Finding some means to keep the
Information up-to-date is the biggest challenge around inventory implementation. This relates both to the technology and the procedures that are in place for updates to be received and processed. The updating process is further complicated if the inventory is not managed centrally and is instead represented by disconnected data sources.

Inconsistent data models introduce a huge barrier in merging the inventories for better analysis. These issues start from a basic problem of merging separately maintained datasets on health facility logistic details and cold chain details. This makes a simple query of looking up available refrigerators with vaccines required a daunting and challenging task. Inconsistent data models also makes it challenging to feed the data to generic modeling and planning tools for better decision making.

Several organizations, including PATH, CHAI, Village Reach, JSI and local governments, are working on improving the data reporting for immunization. These efforts occur at regional or country level in various parts of the world. Most of these projects are running independently, which makes it harder to expand them at later stages and merge with other efforts. Major difficulties arise from mismatch in data being collected or the data format being used in various technologies supporting these projects.

We propose that with the appropriate technology, the opportunity exists to have cold chain inventory data promptly updated to reflect changes, as well as to incorporate additional information gained through routine reporting. Analysis and visualization tools at all levels could support planning and management tasks to ensure that appropriate equipment is acquired and that the cold chain is of sufficient quality and capacity for immunization programs. Further, the cold chain inventory system could be tied to other information systems, such as those used for stock management, and could also serve as a backend for new applications that support features such as automatic temperature monitoring.

5. DATA STANDARDS

Through our work on multiple tools and country deployments, we became convinced that a major gap was a lack of common data standards for Cold Chain Equipment Inventories (or CCEI). This was reflected by difficulties in building country inventories based on available data, the fragmented tools used to work with inventories, and the confusion that people had between the inventory and the tool used to store it. Our hope was that the existence of a data standard would:

1. Regularize the process of data collection for cold chain equipment inventories, including making it easier to generate data collection tools,
2. Provide a mechanism for cold chain data to be shared between applications and allow applications to interoperate,
3. Give a basis for common analysis tools to be used across cold chain data sets
4. Support the structured representation of inventory data, thus increasing quality of the data.

The CCEI data model was developed in a collaborative manner. The initial model and data definitions were based upon those inside CCEM. Since the CCEM tool had been developed through a series of stakeholder workshops in Uganda and Panama, and in consultation with UNICEF and WHO, its definitions were already in close agreement with the data reporting supported by WHO. The model was refined over a period of 18 months through multiple rounds of review. An initial review was conducted by members of UNICEF Cold Chain Logistics group. Based on that effort, a more formal set of definitions was developed that was then circulated individually to about 15 immunization cold chain experts from UNICEF, WHO, and NGOs including PATH (PATH 2014) and CHAI (CHAI 2014), who provided very detailed feedback that was incorporated into a final version. The project built upon existing standards where possible, such as using the WHO Performance, Quality and Safety (PQS)/Product Information Sheets (PIS) catalogs and defining several of the fields with respect to ISO standards.
The CCEI standard was established with a core to represent information about health facilities and refrigeration equipment. It is expected that the standard will be extended to include additional modules. Examples of modules that are under consideration, and are of interest to different stakeholders are transportation, equipment maintenance, and temperature monitoring.

One of the requirements for CCEI was to include sufficient information to assess the quality and capacity of a national cold chain, and to be a basis for estimates of the equipment that would be necessary to upgrade the cold chain for introduction of new vaccines. This requirement influenced the selection of indicators associated with the health facilities, such as recording the population associated with a health facility, and identifying the energy sources available for refrigerators. Since many of the assets in the cold chain are standard equipment, the inventory also includes an official catalog of models of equipment available. This means that a refrigerator can be represented by just a model name, and information for the refrigerator (such as capacity) can be pulled from the model database.

The data model is a set of facilities and a set of assets. Assets come from a group of predefined types (such as refrigerators and cold rooms) and there is a reference catalog that gives the properties of specific models of equipment. The most detailed information is associated with facilities, where location information, including position in the country’s administrative hierarchy, is stored along with information on the population served by the facility, the power infrastructure, and process of vaccine distribution. In addition to specifying the basic inventory models, the CCEI data model includes standards for the administrative hierarchy and country localization.

Although we consider the outcome to have been a success, there were multiple challenges faced in constructing the standard. As with any standards efforts, there were disagreements over details of data elements and a balance between completeness and not complicating the standard. One of the challenges throughout the process was conveying to the stakeholders what a data standard was and distinguishing between the process of specifying the data definitions, and their use in various applications. Scoping the data definition was also problematic, as there were many suggestions of other components of the immunization system that could potentially be included. One solution to this was to state that in the future, extensions to the standard could be consider with the inclusion of additional modules. Finally, there is potential overlap of aspects of this standard, with other efforts, such as work on facility registries.

6. DISCUSSION

We now present a number of observations from our experience with cold chain equipment inventories.

We believe that there is a need for multiple architectural approaches in the implementation of cold chain equipment inventories based on different contexts in countries. We consider a web based system utilizing a database for the cold chain inventory as the “obvious” architectural choice for many reasons, including reliability and the ability to support distributed updates. However, we has seen a continual demand for our stand alone Microsoft access tool, where it has been used in countries including Philippines, Indonesia, Pakistan, and Georgia for inventories. We came to understand that the autonomy that a PC application allows, so that it can be used without needing to engage a larger organization, is an important feature in some situations. Tasks such as creating a cold chain inventory can be managed by a small group of health officials, so being able to use laptops, without engaging IT staff removes an institutional obstacle.

It is important to be able to support the migration between inventory systems. This was one of the motivations for the development of the data standard – so that applications could import from / export to a specific format to migrate data. We used an excel representation of the CCEI model for this. We have used this to move data from multiple CCEM inventories, including Malawi, Kenya, and Ghana to DHIS2 systems, with other countries, such as Uganda, also interested in moving from CCEM to their national DHIS2 system. One of the successes in developing the data
standard is that it has allowed other organizations to build tools with cold chain inventories and include the data from existing CCEM deployments.

Pakistan Cold Chain Equipment Inventory maintenance effort was started by UNICEF at small scale by targeting 55 polio high-risk districts in the country. They initiated the project by using CCEM as their primary tool that provided them the convenience to run it on their local PC or laptop. They collected data on paper forms from 2083 health facilities and then entered the data on local machines without the need of Internet. This database was then incorporated in a web-based national Vaccine Logistic Management Information System (vLMIS), developed by John Snow Inc at a later stage. vLMIS has scripts to extract data from CCEM files and add it to this online system.

The starting point for building a cold chain equipment inventory is almost always an existing dataset represented in excel - so there is a migration from an excel based inventory to one of the other tools - which again is accomplished by representing a standard form in a sheet. There are multiple challenges to doing this with difficulties around the structure of data (such as the choice of fields) as well as the quality of data, including issues such as having to deal with a wide range of spellings of the same terms. The representation of names of facilities can be a particular challenge.

Cold chain equipment inventory is a small yet critical dataset in immunization and health domains that is easily ignored. We expect any data collection system in this space will eventually be consumed by wide scoped national health information systems. Hence it is important that an agreed upon data standard exist so that data can be prepackaged and moved into popular information systems. Given that all the small scale and intermediate tools in this domain also support this standard, the interoperability of these individual systems and scaling-up will be a much easier and smooth task.

7. CONCLUSION
The underlying goal of this effort is to make cold chain equipment inventories more useful to the management of country immunization programs. A major gap was the lack of a common model for inventories, leading to ad hoc representations, difficulties in moving between inventory tools, and the confusion between the actual inventory and the software that was used to represent it. We developed a data model, which has been shared with the relevant technical communities, and has been used to align a collection of existing software tools. We have the aspiration to see this evolve into an 'open data standard', but recognize that it is not at that level yet. The validation of the standard will be through its use in multiple tools and if it becomes a common representation used for by countries when storing and sharing their inventory data - in other words, if it becomes a de facto standard. Formalization of the model into a true open standard will require an organization that hosts the standard and a structure for community agreement in updates to the standard.

We have discussed multiple use cases that we encountered while working in this space where a data standard could play a critical role. These use-cases include spreadsheet to database data migration and coexistence of single machine and web-server applications. We also discussed some future work in standardizing analysis tools that can be achieved given the data standards are deployed in information systems.

8. REFERENCES AND CITATIONS


CCEI (2014). *Cold Chain Equipment Inventory data definition* - https://github.com/fahadp/CCEI


