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- The 30 nurses in Shkoder, Albania who adopted the system so enthusiastically, for their patience and feedback.
ACRONYMS

The following acronyms are used in this document.

AEFI  adverse events following immunization
BCG  Bacillus Calmette-Guérin
DPH  Directorate of Public Health
DTP  a combination vaccine containing diphtheria, tetanus toxoid, and pertussis vaccines
DTP-3  third dose of DTP
EPI  Expanded Programme on Immunization
EVM  Effective Vaccine Management
HII  Health Insurance Institute
IIS  Immunization Information System
IPH  Institute of Public Health
IT  information technology
MOH  Ministry of Health
MMR  a combination vaccine containing measles, mumps, and rubella vaccines
MMR-1  first dose of MMR
NIP  National Immunization Program
Penta-1  Pentavalent vaccine containing DTP, hepatitis B, and Haemophilus influenzae type b vaccines (first dose)
Penta-3  Pentavalent vaccine containing DTP, hepatitis B, and Haemophilus influenzae type b vaccines (third dose)
PATH  Program for Appropriate Technology in Health
SFAT  Stock Flow Assessment Tool
SMS  short message service
UNICEF  United Nations Children’s Fund
USB  universal serial bus
WHO  World Health Organization
1. INTRODUCTION

1.1. Overview
This report presents the results of demonstration projects and other activities undertaken in Albania as part of a partnership between project Optimize and the Albanian Institute of Public Health (IPH).

Between 2010 and 2012, Optimize collaborated with the IPH to demonstrate innovations in the supply chain that can help to meet the demands of an increasingly large and costly portfolio of vaccines. This report describes the two demonstration projects undertaken in Albania as part of the collaboration:

1. Immunization Information System (IIS).
   The project developed and implemented an online Immunization Information System that can record immunization data and manage vaccine stock. The new system—named IIS—can schedule and record child immunizations, as well as manage vaccine stock and storage. The aim of the project was to measure the impact of accurate and timely immunization data on immunization and vaccine stock management.

2. Remote temperature monitoring.
   The project tested a short message service (SMS, or text-message)-based system to monitor and log temperature conditions in peripheral cold chain equipment. The aim was to assess whether these remote alarm systems facilitate better vaccine and cold chain management than non-connected temperature loggers.

1.2. About project Optimize
Project Optimize is a five-year partnership between the World Health Organization (WHO) and PATH to identify ways in which supply chains can be optimized to meet the demands of an increasingly large and costly portfolio of vaccines.

Optimize works directly with national governments and other institutions to identify problems in the supply chain and test innovative solutions. It also works with vaccine manufacturers and policymakers to help ensure that new products and policies enable supply chain systems to function effectively. The goal is to help define an ideal vaccine supply chain that can be used to develop stronger, more adaptable, and more efficient logistics systems, extending the reach of lifesaving health technologies to people around the world.

For more information, please visit the Optimize website:
PATH: www.path.org/projects/project-optimize
WHO: www.who.int/immunization_delivery/optimize
1.3. Finding more information

In 2013, Optimize will publish comprehensive information on the demonstration projects and other initiatives it has been involved in. To view a full list of the resources that Optimize has published to document its work in Albania, please refer to the Albania resources page of the Optimize website. This is available on both PATH and WHO’s website.

PATH: www.path.org/projects/project-optimize-resources-country.php#albania
WHO: www.who.int/immunization_delivery/optimize/albania

You can also find these documents, as well as detailed information on other innovations relating to vaccine supply and logistics systems, on the TechNet21.org website.

www.technet21.org
2. ALBANIA IN CONTEXT

2.1. The immunization system

Albania has experienced rapid social and economic change as a result of moving to a free-market economy and becoming a more open, liberal society. This has led to economic growth but also to mass emigration both within and outside the country. Migration, urbanization, and reforms within the health care system itself have put pressure on the country’s immunization system. A polio epidemic in 1996 and further outbreaks of measles and rubella revealed its limitations and encouraged reforms beyond mass campaigns. However, despite the challenges, Albania has maintained a relatively well-performing immunization system that has maintained high coverage. WHO best estimates indicate 99 percent coverage for all childhood vaccination programs in 2010. A demographic health survey conducted in 2008 validated this estimate, with 97 percent DTP-3 (diphtheria, tetanus, pertussis third dose) coverage and 97 percent MMR-1 (measles, mumps, rubella dose-1) coverage.\(^1\)


Important organizations in the Albanian immunization system are:

- The National Immunization Program (NIP), part of the IPH Department of Epidemiology and Control of Infectious Diseases. The NIP manages the implementation of the nationwide immunization program and is responsible for the forecasting, planning, and distributing of vaccines and supplies.

- The Institute of Public Health (IPH) is responsible for purchasing vaccines and maintaining most of the cold chain. The Technical Group of Experts within the IPH provides important guidance on the introduction of new vaccines, their effectiveness, impact, and safety based on the best evidence and current good practice and expert opinion.

- The Directorate of Public Health (DPH) at the Ministry of Health (MOH), which oversees public health district administration and the implementation of all public health programs in the country.

- The Albanian Health Insurance Institute (HII) is responsible for health care facilities and employs health care workers, including vaccinators.


\(^2\) The pentavalent vaccine is a combination of five vaccines in one: diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenzae type b.
• District public health directorates with their epidemiologic services are responsible for planning, distributing, and overseeing the immunization program within their district.

• Primary health care centers offer immunization services at the point of care. Vaccination is provided through a wide network of 2,282 child consultation services in urban health centers (including maternity hospitals) and in health posts in rural areas. Nurses in urban areas are often dedicated to vaccination, but those in village health posts generally have a broader set of tasks. Patronage nurses provide door-to-door visits for newborns and infants and follow up on vaccination schedules.

An ongoing health-sector reform process in Albania has led to the consolidation of 36 district health administrations into 12 prefecture (regional) administrations. It has also led to the stricter application of health worker performance (encounter) targets, which may eventually lead to the consolidation of health posts into larger units. The ongoing primary health care reforms have acknowledged immunization services as one of the most important, and vaccination coverage has been included as a key performance indicator for primary care services. Dedicated vaccination staff exist at the district level (each district has a group of chief vaccinators, who supervise health center vaccinators) and in the health centers.

The administrative structure of the immunization system in Albania is described in Figure 1. Dotted lines indicate oversight responsibility, whereas solid lines represent the formal hierarchy in the health system. Over time, the district function may be absorbed entirely by the prefecture level.
2.2. The supply chain

Vaccines are procured through the United Nations Children’s Fund (UNICEF) by the IPH. The funds are approved by the MOH and the Ministry of Finance (who delegate the purchase authority to the IPH).

Vaccines are received twice each year and stored in central cold rooms at the IPH. From there, vaccines are distributed according to a quarterly delivery schedule to the 36 districts, where they are stored in one or two chest refrigerators, depending on the size of the district. Districts receive sufficient vaccine to serve their population for three months and are expected to maintain one month of buffer stock at all times.

The vaccines are collected by health center nurses on a monthly basis and stored in small refrigerators until they are administered in the health center or taken in vaccine carriers by nurses to more remote village health posts for immunization days. Nurses are supposed to collect only
enough vaccine for the children they plan to vaccinate in a given month, based on a recount of due or overdue children in their immunization registries.

### 2.3. Baseline assessment

A rapid baseline assessment in Shkoder district conducted in December 2009, and a feasibility assessment conducted in July 2009, highlighted the following strengths (Table 1) and weaknesses (Table 2) of vaccine management in Albania.

#### Table 1. Strengths of the vaccine supply chain and immunization information systems in Albania

<table>
<thead>
<tr>
<th>Strength</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low levels of buffer stock</td>
<td>The supply of vaccines from district store to health center depends on a detailed monthly planning process, through which only the minimum required quantities are released to immunize all due and overdue children in a health center. The low level of buffer stock in the health centers reduces the risks to which vaccines are exposed.</td>
</tr>
<tr>
<td>Stock management</td>
<td>In the central store, stock management is well organized and supported by an adequate digital information system. District stores mostly use paper-based systems.</td>
</tr>
<tr>
<td>Temperature monitoring</td>
<td>Temperatures in refrigerators are well monitored. In the baseline study, recording sheets were used in 22 out of 24 health centers with refrigerators. Fridge-tag® temperature monitoring devices are also widely used to monitor temperatures in the refrigerators.</td>
</tr>
<tr>
<td>Cohort control</td>
<td>Albania has a strong registration culture and vaccinators have good information about the children in their catchment area. They are also informed about births in their area by the maternity hospital. “Patronage nurses” are available to perform door-to-door visits to ensure that children are included in vaccination schedules.</td>
</tr>
<tr>
<td>Reporting discipline</td>
<td>Staff at health centers and district stores report on vaccine coverage in a complete and timely fashion.</td>
</tr>
</tbody>
</table>
Table 2. Weaknesses of vaccine management in Shkoder district

<table>
<thead>
<tr>
<th>Weakness</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stock management at district level</td>
<td>Even though a stock ledger was available at the time of the baseline assessment, it showed a major difference from the physical inventory of vaccines in refrigerators: the stock ledger overestimated the physical stock by 10 to 20 percent. Furthermore, an analysis of two vaccines (pentavalent and MMR) showed that the district kept on average about five months of pentavalent vaccine in stock, while just more than one month of MMR was kept in stock. Since stock is replenished every three months, and the aim is to maintain a safety stock of one month, stock levels would ideally be maintained between one and four months. That corresponds to an average stock of 2.5 months. This implies that there was too much buffer stock of pentavalent vaccine and not enough MMR. (There were indeed two stockouts of MMR in 2009.) Only one district was included in the baseline assessment, so these results may not be representative of all districts.</td>
</tr>
<tr>
<td>Lack of stock data at the health center level</td>
<td>No functional stock ledger system was in place in the health centers, so no historical information was available to assess the efficiency of stock management at that level.</td>
</tr>
<tr>
<td>High administrative workload for health workers</td>
<td>In a timed test, nurses spent on average 153 minutes per month preparing quarterly coverage reports, and 7 to 30 minutes to register each immunization encounter in the various official and unofficial forms and registers. At the district level, consolidation of health center coverage reports and preparation of the quarterly report to the IPH took roughly three working days.</td>
</tr>
<tr>
<td>Lack of relevant coverage data</td>
<td>The coverage monitoring system provides very little information for policy development, as coverage is extremely high in almost all districts and health centers.</td>
</tr>
<tr>
<td>Data accuracy concerns</td>
<td>Denominators (the demographic targets) are collected through the same system that collects immunization activity (administered doses). This raises questions about their validity, as there is no guarantee that the system is able to register all children. System failures (overreporting and underreporting) are not exposed, as denominators would be under- or overreported to the same extent as the numerators. Refer to “Quality of immunization data” on page 20 for more information.</td>
</tr>
</tbody>
</table>

Abbreviations: IPH = Institute of Public Health; MMR = measles, mumps, and rubella vaccine.
2.4. Challenges and opportunities

Like other economies that have made a transition to a free-market model, the public health sector in Albania faces increasing constraints, especially with available human resources. Moving to a model with larger health centers and higher target populations, for example, may jeopardize past achievements in monitoring the immunization status of individual children. Urbanization and increased internal and external migration has put further stress on existing systems.

At the same time, as Albania introduces new and more expensive vaccines, there is a need to create systems that ensure better oversight and chain-of-custody over these resources, and avoid unnecessary wastage. Together with project Optimize, IPH officials identified two ways to achieve this:

- Develop and implement an electronic information system that supports the current registration process and reinforces stock management practices.
- Test a system to remotely monitor temperatures in vaccine refrigerators in a timely way.

In the context of ongoing health-sector reform and administrative reorganization, there is also an opportunity to design the vaccine supply chain in Albania based on objective criteria such as cost and availability considerations, rather than basing supply chain design on current administrative boundaries. Optimize, therefore, conducted a study to allow officials to analyze cost and performance tradeoffs of different supply chain scenarios (status quo scenario versus the new one).
3. IMMUNIZATION INFORMATION SYSTEM

3.1. Goal
The goal of this intervention was to develop and implement an online IIS that can provide health staff at all levels with timely access to immunization records and vaccine stock data. The objectives of the system are to:

- Help ensure timely and equal access to immunization by all children.
- Generate accurate and useful data that can be used to improve the management of the vaccination program.
- Improve vaccine stock management by providing better control of wastage and buffer stocks, and by enabling vaccine supply to be more closely matched with demand.
- Reduce the administrative burden of health workers by automating time-consuming tasks.

3.2. Rationale

3.2.1. The problem
Currently, nurses and the district head of vaccinators work together using a paper-based system to ensure that all children receive the vaccinations they require. Each month, the nurse makes a list of the children due to be vaccinated that month in her health center, based on a review of the health center’s immunization and cohort registries. She uses this list to schedule the vaccinations, notify parents, and determine how much vaccine to order. She then records every vaccination administered on up to six forms and registers. At the end of each quarterly period, she reviews the registers to produce a vaccination coverage report, which compares the number of children due for vaccination with the actual number of children vaccinated. The nurse then sends this report to the district head of vaccinators, where the figures are reviewed, aggregated, and then sent to the NIP at the end of each quarter.

Despite the hard work of health staff, errors in data collection and reporting are inevitable. There is also no easy way to keep track of children who move to another area of the country. In addition, officers at the national level only receive summarized data that are not helpful to manage and improve the program. For example, they only receive coverage estimates by district, when what they need to know is the vaccination coverage by community, who the unvaccinated children are, where they live, and why they have not been vaccinated. Monitoring aggregate coverage estimates may not be enough to improve already high immunization coverage—achieving this requires a system that can track individual children in real time.

Further, as Albania is introducing newer and more expensive vaccines, the limitations of using a paper-based system to track vaccine stock are becoming increasingly apparent. Supervisors have currently no visibility about stock or wastage at lower levels, and cannot therefore effectively manage vaccine supply chains.
**3.2.2. A possible solution**

An online system that manages information about the immunization status of children, vaccine stock, adverse events following immunization (AEFI), and cold chain conditions at every location has the potential to:

- Improve the ability of health staff at operational levels to track the immunization status of children in their area, identify defaulters, and provide more timely vaccination.
- Identify the reasons for missed opportunities and eliminate unnecessary duplicate immunizations.
- Improve reporting of AEFI, identify clusters on time, and take appropriate actions.
- Improve the quality of monitoring data by providing access to more accurate, more relevant disaggregated data at all levels in a more timely fashion.
- Enable “just-in-time” distribution of vaccines for the immunization needs of individual children, thus better matching supply and demand and reducing the need for buffer stocks and the risk of wastage.
- Improve stock management through better visibility about available stock.
- Enable regular monitoring of vaccine cold chain conditions.
- Reduce the overall administrative burden for health workers.

**3.3. System overview**

This section provides an overview of IIS. It describes how nurses can:

- Access IIS.
- Register children and schedule appointments.
- Plan vaccinations.
- Order new vaccine stock.

This section also describes how staff at the district and national levels can use IIS to:

- View detailed information on immunization coverage rates.
- View detailed information on vaccine stock levels.
- Configure the system.

**3.3.1. Accessing IIS**

IIS is composed of a centrally hosted database and a web-based software application that can be securely accessed through a web browser. Staff at all levels (national, district, maternity hospital, and health center) can access IIS in this way, although their access rights are determined by their role and by their level. For example, a nurse can only access stock information for her own health center level, while officers at the district level can access that information for their own district store as well as for all health centers in their district.
Nurses at smaller health posts that lack a computer with an Internet connection use printed monthly plans to organize their sessions. They then report to the commune health center on the immunizations they have administered, and this information is entered into IIS.

The IIS database and software are currently hosted by Agjencia Kombëtare e Shoqërisë së Informacionit (AKSHI), an Albanian state agency that was set up to host data and software for public institutions. The application also runs web services that allow mobile phone applications to exchange information (upload/download) with the database. An app for Android phones is under development but has not yet been deployed. Due to potential data synchronization issues between unconnected devices, no offline version of IIS is planned.

### 3.3.2. Registering children and scheduling appointments

When a child is born at a maternity hospital, the maternity nurse enters the child’s details into IIS (see Figure 2). This includes identification and contact details, as well as information about the child’s caretaker (the person responsible for the child, typically a parent).

As soon as the child’s details are entered, a set of immunization appointments is automatically generated and scheduled at a health center specified by the caretaker. In this way, the nurse at that health center can be made aware of a new child in the community two months ahead of the child’s first scheduled visit. (If the child is not born in the maternity hospital or recently moved in from outside Albania, the nurse at the health center needs to register the child at the first encounter.)

**Figure 2. A child’s record: IIS automatically generates the future immunization appointments for a newborn**

When an appointment is due, the child is automatically included in the monthly plan of the health center responsible for the child (see Figure 3). This means that nurses no longer need to go
through their immunization registries to find the children who need to be vaccinated. Instead, they can use the monthly plan itself to organize their vaccination schedules. And because the contact details of the child’s caretaker are recorded in IIS, nurses can phone caretakers or send them text messages to confirm their appointments. The monthly plan can be accessed online, but it is also printed at district stores and dispatched to health centers with the vaccines required each month.

Figure 3. The monthly plan for a health center (some personal data have been blurred)

3.3.3. Ordering new vaccine stock

When a vaccine is recorded as having been administered, IIS automatically updates the relevant vaccine stock balance. At the end of each month, nurses perform physical stock counts and update this stock balance where necessary.

A nurse’s monthly plan automatically calculates the total number of vaccine doses required for the following month. This is useful for nurses, as it helps them to determine the right vaccine quantities to order. By comparing the vaccine stock requirements listed in the monthly plan with current stock levels in IIS, nurses can order the correct amount of new vaccine from the district level. This process helps to ensure that health centers always have enough vaccines without needing to keep large quantities of buffer stock (see Figure 4).
3.3.4. Recording vaccinations

When a child visits a health center to attend a vaccination appointment, the nurse will update the child’s records directly in IIS. Alternatively, if there is no Internet connection available, the nurse can use the printed monthly plan she received from the district store and mark in separate columns the date and vaccine lot used for each vaccination. This information can then be recorded in IIS at a later date.

If the vaccine cannot be administered because of permanent contraindication to vaccination or parental refusal, the nurse can indicate this and close the appointment without the vaccination taking place. In all other cases, the appointment will be rescheduled in the following monthly plan, where it will be marked as an overdue appointment.

Not every vaccination encounter can be planned. For example, a child may move and need to be vaccinated in a different health center than the one it was originally assigned to. To handle this, IIS enables nurses to retrieve and update the vaccination records of any child in the system. This is particularly useful for changing the health center where the child is registered. Children who move within Albania can thus be easily reassigned to a health center in their new location.

3.3.5. Viewing immunization coverage rates

IIS provides a set of reports that enable IIS users to view detailed information on immunization coverage. These reports allow service-level staff to identify unimmunized children, and their supervisors to monitor program performance. The most important of these reports are described in Table 3.
Table 3. Coverage reports in IIS

<table>
<thead>
<tr>
<th>Report</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohort coverage</td>
<td>Calculates the immunization status of all registered children born between specific dates, in a specific district or health center, by antigen. The report can also list the unvaccinated children included in the cohort.</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Table" /></td>
</tr>
<tr>
<td>Fully immunized children</td>
<td>Shows the percentage of fully immunized children as well as dropout rates between certain antigens, as a table for all health centers in a district or for all districts in the country.</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Table" /></td>
</tr>
<tr>
<td>Coverage compared to plan</td>
<td>Compares the number of children scheduled for vaccination between specific dates with the number actually vaccinated during this time. The report can also list all unvaccinated children during this time.</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Table" /></td>
</tr>
</tbody>
</table>
### Report | Description
--- | ---
Unimmunized children | Lists unimmunized children born between particular dates, or in a specific district or health center, by antigen.

<table>
<thead>
<tr>
<th>Vaccine: MMR - 1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LastName</strong></td>
</tr>
<tr>
<td>Kejai</td>
</tr>
<tr>
<td>Silvi</td>
</tr>
<tr>
<td>MIR EMELA</td>
</tr>
<tr>
<td>Gjergj</td>
</tr>
<tr>
<td>Asli</td>
</tr>
<tr>
<td>Klevisa</td>
</tr>
<tr>
<td>Francesca</td>
</tr>
<tr>
<td>Ensan</td>
</tr>
<tr>
<td>Samuel</td>
</tr>
<tr>
<td>Samuel</td>
</tr>
<tr>
<td>Onjejs</td>
</tr>
</tbody>
</table>

Vaccination activities | Displays all the vaccinations administered by a specific health center or district during a particular year, by month.

<table>
<thead>
<tr>
<th>DSMP Shkoder</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vaccine</strong></td>
</tr>
<tr>
<td>BCG</td>
</tr>
<tr>
<td>HepB - 0</td>
</tr>
<tr>
<td>HepB-Hib-DTP - 1</td>
</tr>
<tr>
<td>HepB-Hib-DTP - 2</td>
</tr>
</tbody>
</table>

### 3.3.6. Viewing vaccine stock information
IIS provides a set of reports that enable IIS users to view detailed information on vaccine stock in real time. These reports are most useful for district- and national-level supervisors to make sure that appropriate stock balances are maintained, and to find out how much of each vaccine is being wasted. This information can potentially be used to reorganize the vaccine supply chain or even change vaccine presentations. The most important of these reports are described in Table 4.
### Table 4. Stock reports in IIS

<table>
<thead>
<tr>
<th>Report</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stock balances</strong></td>
<td>Calculates the stock balance in each store by vaccine, compared to preset minimum and maximum levels. Stock balances can also be seen by health center or district, for the level just below. A similar report can be used to show the available stock by lot.</td>
</tr>
<tr>
<td></td>
<td><strong>Note:</strong> Preset minimum and maximum levels are not yet in use.</td>
</tr>
<tr>
<td></td>
<td><img src="image1" alt="Vaccine Quantity in Stock" /></td>
</tr>
<tr>
<td><strong>Vaccine wastage by health center or district</strong></td>
<td>Shows for a certain time frame how many doses of each vaccine were used, administered, and wasted by health center or district.</td>
</tr>
<tr>
<td></td>
<td><strong>Note:</strong> Problems with the system and the way it is used have not yet allowed for a meaningful analysis of wastage (open-vial wastage and physical stock are not yet systematically reported, and nurses sometimes fail to link the correct lot used for each vaccination).</td>
</tr>
<tr>
<td></td>
<td><img src="image2" alt="DSHP Shikoder" /></td>
</tr>
<tr>
<td><strong>Wastage by reason</strong></td>
<td>Classifies the wasted doses of unopened vials that were reported as wasted by reason code (for example, whether the doses were damaged, frozen, wet, etc.).</td>
</tr>
<tr>
<td></td>
<td><img src="image3" alt="Wastage by reason" /></td>
</tr>
</tbody>
</table>
### Report

| Lot tracing | Shows the locations where a particular vaccine lot is being stored and to which children it has been administered. That is potentially valuable in case a lot needs to be recalled because of quality concerns. |

The number of children vaccinated with this lot from this H. center is: 1069

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | ...

<table>
<thead>
<tr>
<th>LastName</th>
<th>FirstName</th>
<th>H. Center</th>
<th>District</th>
<th>Caretaker</th>
<th>Mother</th>
<th>Father</th>
<th>BirthDate</th>
<th>NationalId</th>
</tr>
</thead>
<tbody>
<tr>
<td>Golem</td>
<td></td>
<td>Shkoder</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shilak</td>
<td></td>
<td>Shkoder</td>
<td>Marta</td>
<td>Ninoja</td>
<td></td>
<td></td>
<td>15/04/2012</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Shkoder</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>16/04/2012</td>
<td></td>
</tr>
<tr>
<td>Vinoteke</td>
<td></td>
<td>Shkoder</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15/04/2012</td>
<td></td>
</tr>
</tbody>
</table>

#### 3.3.7. Configuring IIS

IIS administrators at the national level have the ability to change the way that vaccination schedules are created by IIS. They can also choose to add new vaccines to the system and include them in vaccination schedules. Should they do so, all report drop-down lists will be automatically updated to reflect these changes. By configuring the system in this way, IIS can accommodate changes to the country’s immunization program without software development support.

Other configuration tasks are delegated to immediate supervisors. For example, users at the district level can add new nurses, health centers, and health posts to the system.

#### 3.4. Implementation

This section describes how IIS was developed and then implemented in Albania. Table 5 describes the project timeline and major milestones.

### Table 5. IIS timeline

<table>
<thead>
<tr>
<th>Year</th>
<th>Month</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>November</td>
<td>First exploratory meeting between the IPH and WHO on potential collaboration.</td>
</tr>
<tr>
<td>2009</td>
<td>April-October</td>
<td>Work plan agreed, following joint assessments conducted by the IPH, MOH, and Optimize to define areas of collaboration.</td>
</tr>
<tr>
<td>2010</td>
<td>January</td>
<td>First meeting with stakeholders to agree to high-level design of IIS.</td>
</tr>
<tr>
<td>2011</td>
<td>March</td>
<td>Alpha testing of IIS; system functionality accepted by the IPH.</td>
</tr>
<tr>
<td></td>
<td>May</td>
<td>IIS presented to vaccinators and doctors.</td>
</tr>
<tr>
<td></td>
<td>June</td>
<td>Training of nurses and beta testing.</td>
</tr>
<tr>
<td>Year</td>
<td>Month</td>
<td>Milestone</td>
</tr>
<tr>
<td>------</td>
<td>-------</td>
<td>-----------</td>
</tr>
<tr>
<td>2012</td>
<td>May</td>
<td>South-eastern Europe Health Network meeting.</td>
</tr>
<tr>
<td>2013</td>
<td>January</td>
<td>Project report published.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>Month</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>May</td>
<td>South-eastern Europe Health Network meeting.</td>
</tr>
<tr>
<td>2013</td>
<td>January</td>
<td>Project report published.</td>
</tr>
</tbody>
</table>

Abbreviations: HII = Health Insurance Institute; IPH = Institute of Public Health; IIS = Immunization Information System; MMR = measles, mumps, and rubella; MOH = Ministry of Health.

### 3.4.1. Exploratory meetings

From the first exploratory meetings between the IPH and WHO in November 2008, it became clear that information systems represented a good area of common interest and collaboration. The IPH was looking for ways to collect more complex data and had already attempted to implement an electronic child immunization registry system. For that project, the IPH had adopted a software system in use by a neighboring country’s public health directory.

This system was abandoned after an initial pilot phase, as the IPH was unable to sustain the system without the knowledge required to adapt and maintain the software, extract the data, or analyze it systematically. Furthermore, as this was a PC-based system, local data had to be aggregated and shared on universal serial bus (USB) memory sticks and information was easily lost when computers crashed or memory sticks were lost. The experience reinforced the need to build local capacity and to design the system in a way that was easy to run and maintain.

Even though the Optimize mandate focuses on strengthening vaccine supply chains, the project decided that an investment in information systems should not be limited to stock management and cold chain functionality only. Albania already had a system in which vaccine supply was linked to immunization activities: nurses only order vaccines for the children they plan to vaccinate in a certain month. Furthermore, initial assessments found that a vaccine management system would only thrive within a broader information system in which the different parts reinforce each other.

It also became clear from the start that Albanian officials wanted to take full ownership of the project. Therefore, the IPH took the role of overseeing and assisting the project, considering it as its own important immunization activity. The staff overseeing and guiding district immunization services were also closely involved with the project. The role of Optimize and the local WHO office was limited to providing administrative support, high-level guidance, and liaising with other organizations.

Optimize evaluated the system used by HII to record medical encounters and considered the option to build IIS on the HII platform. However, since both systems serve very different purposes and since the HII system architecture did not allow for online access to a national database of immunization records, this option was rejected. Instead, a decision was taken to develop a web-based immunization system, and to plan to build appropriate interfaces so that both systems could become interoperable.
3.4.2. System definition

In October 2009, a work plan was agreed upon that captured the project’s guiding principles and laid out a common vision. This vision was further developed at a meeting in January 2010 between key Albanian stakeholders and project Optimize to discuss the kind of information system that was needed and the kind of benefits that were expected. Since it became apparent that available systems in use in other countries could not easily be adapted for the Albanian context, a core team was formed to develop such a system:

- The head of the Department of Epidemiology and Control of Infectious Diseases at the IPH championed the project within the IPH and the MOH, and made key decisions when necessary.
- The Albanian Expanded Programme on Immunization (EPI) manager assumed the role of project coordinator, and was responsible for the definition of user requirements and functional design in coordination with other users of the system.
- Two staff at Shkoder district, the chief epidemiologist and the head of vaccinators, assumed responsibility for the implementation, monitoring, and evaluation of the pilot system in Shkoder. They were also instrumental in defining system design and needs.
- A local information technology (IT) company, INET Albania, was hired through a competitive process to develop the application and database based on local requirements and needs.
- Project Optimize (WHO/PATH) provided technical and financial assistance to facilitate the project.

The project setup, in which people from local institutions worked together with local IT providers, was meant to ensure that the system would closely match local needs while facilitating long-term sustainability. Involving users from the start also would help to ensure the system’s acceptability once implemented.

3.4.3. Development and release

The development of IIS started in January 2010 with a stakeholder meeting in Tirana, in which a sample of nurses and district staff provided input about the kind of system that would be useful to them. After this, a small core team documented the business processes that IIS was going to support, as well as the user requirements for each process. At first, INET interacted mainly with the core team as they developed the software. The core team also discussed the system with potential users and specialists outside the immunization system.

Once the core team was happy that the agreed system requirements had been successfully implemented in the system, IIS was formally tested by a select group of users at the IPH in March 2011. After this “alpha testing,” where the testers played certain roles to make sure that the system was functionally sound, feedback was received and incorporated.

The system was ready for training and user testing (“beta testing”) in June 2011. It finally went live on September 1, 2011 in the pilot district. At this point, nurses started entering real data into IIS for the first time. Since then, IIS has been shown to other district staff to start scale-up planning, and also showcased at a subregional meeting to the countries of Southeast Europe.
3.4.4. Current status

Since IIS went live in the pilot district one year ago, the progress and status can be summarized as follows:

1. IIS is fully functional for child and caretaker registration, vaccination planning, and monitoring. Nurses have now entered more than 13,000 children (or roughly seven birth cohorts on average) into the system over a ten-month period. This progress is not evenly spread and some health centers have experienced more problems than others, but this is still a huge achievement by the vaccinators. Having relatively complete datasets means the system can already be used to monitor vaccination coverage, even for previous years.

2. The stock management module is fully functional at the district level but is not yet being fully used at the health center level. The main reasons are that until September 2012, nurses did not report actual stock systematically and they often did not select the proper vaccine lot when they recorded vaccinations. The available data will be useful for monitoring and evaluating stock monitoring practices at the district level, but not yet at the health center level.

3. The reporting tools in IIS were released in early 2012. As a result, managers are only starting to explore their benefits. The impact of having better analytical data will be felt in years to come but will not yet have made a discernible impact on management practices.

3.5. Results

IIS has made several important changes to the way both vaccination coverage and vaccine stock are managed in Albania. It has also affected the workload of health care staff at all levels. This chapter describes the results of the IIS demonstration project in these three areas.

3.5.1. Vaccination coverage

IIS has affected the following aspects of vaccination coverage in the pilot district:

- Quality of immunization data.
- Coverage rates.
- Timeliness of immunization.
- Ability to monitor equal access to immunization.
- How immunization data are used.

Quality of immunization data

To assess immunization data quality, we compared the 2011 coverage and cohort reports from Shkoder district to the information that was entered into IIS for the same year. We looked at:

- Completeness— the extent to which indicators are based on a full dataset (districts, health centers, children, etc.).
- Accuracy— the extent to which data reflect reality.
- Timeliness—up-to-date information is more valuable than outdated information.
- Relevance—the usefulness of data to produce insights that can be translated into action.

**Completeness:** By comparing the number of children entered into IIS (1,791) with the birth cohorts reported by nurses in the paper-based system (1,833), we can see that IIS has an almost complete dataset for the 2011 birth cohort (Table 6). Children from previous birth cohorts are still being entered and will soon be completed.

**Table 6. Birth cohort data entered into IIS compared to the paper-based registry**

<table>
<thead>
<tr>
<th>Birth cohorts</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper based</td>
<td>1,959</td>
<td>1,837</td>
<td>1,862</td>
<td>1,866</td>
<td>1,833</td>
</tr>
<tr>
<td>IIS</td>
<td>1,1417</td>
<td>1,479</td>
<td>1,670</td>
<td>1,787</td>
<td>1,791</td>
</tr>
<tr>
<td>Difference</td>
<td>-542</td>
<td>-358</td>
<td>-156</td>
<td>-79</td>
<td>-42</td>
</tr>
</tbody>
</table>

Abbreviation: IIS = Immunization Information System.

The analysis shows that IIS has already caught up with the existing paper-based system. (This does not prove that all children in Shkoder are registered in IIS. It is possible that there is a significant number of children whose existence is not being recorded at all. A systematic comparison between the data in IIS and the civil registry database may confirm the completeness of data in IIS, but has not been undertaken.)

**Accuracy:** This indicator represents the percentage of children in a certain age group who were vaccinated with a certain antigen. In the previous paper-based system, coverage was estimated by comparing the vaccinations administered during a year or quarter to the number of children that were planned for vaccination in the same period. So if a nurse planned to vaccinate 100 children in a quarter, but only managed to vaccinate 97, coverage was estimated at 97 percent. Vaccinations administered to overdue children (planned in a previous period) were then added to this number. For example, if the same nurse would have vaccinated five children that were actually planned in a previous period, her coverage would now be calculated as 102 of 105, or slightly more than 97 percent. This system was complicated and vulnerable to mistakes and inconsistencies.

The 2011 coverage report for Shkoder district illustrates some of these inconsistencies. One would expect the BCG (Bacillus Calmette-Guérin) denominator for 2011 (1,725; Table 7) to be identical to the 2011 birth cohort (1,833; Table 6). In other words, the total number of people planned to receive the BCG vaccine ought to be the same as the total number of recorded births that year. Similarly, one would also expect the MMR-1 denominator for 2011 (1,905) to be identical to the 2010 cohort (1,866). But the MMR-1 denominator for 2011 adds 39 children to the 2010 birth cohort.

The 2011 report also states that coverage rates among children younger than one year are between 99 and 100 percent, which is implausible (Table 7). It is probable that the issues with this report arise from double-counting doses and numerator-denominator inconsistencies.

To assess whether IIS does a better job of estimating coverage, we compared the data in IIS with the results from the paper reports. IIS can report the coverage among children of a certain birth
cohort directly, but additionally a report was built to closely match the previous reporting system, in which planned vaccinations are compared to actual vaccinations. Table 7 summarizes the coverage numbers for 2011 and compares them to the coverage data obtained from the paper reports.

**Table 7. Comparison of 2011 vaccination coverage data**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Coverage data (paper based)</th>
<th>Coverage data (IIS)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Plan</td>
<td>On time</td>
</tr>
<tr>
<td>BCG</td>
<td>1,725</td>
<td>1,725</td>
</tr>
<tr>
<td>Penta-1</td>
<td>1,829</td>
<td>1,812</td>
</tr>
<tr>
<td>Penta-3</td>
<td>1,853</td>
<td>1,844</td>
</tr>
<tr>
<td>MMR-1</td>
<td>1,905</td>
<td>1,893</td>
</tr>
</tbody>
</table>

Abbreviations: BCG = Bacillus Calmette-Guérin; IIS = Immunization Information System; MMR-1 = measles, mumps, and rubella (dose 1); Penta = pentavalent (doses 1 and 3).

The on-time coverage column shows the number of doses planned for 2011 and administered before February 15, 2011 (the cutoff date for coverage reporting). In contrast to the numbers from the paper-based system, IIS data are internally consistent: coverage for later doses is not higher than earlier doses, and there is a slight dropout between earlier and later doses.

With data from IIS for comparison, we can also be confident that the high coverage rates from the paper-based system slightly overestimate the actual coverage. With IIS, for example, we can identify more unimmunized children than should exist if the 99 percent coverage rate from the paper-based system were correct.

**Timeliness:** Before IIS was implemented, coverage data were reported on a quarterly basis and would thus become available a few weeks after every quarter. The data in IIS are now available in a timelier manner because they are entered in close to real time.

**Relevance:** The greatest benefit in terms of data quality may be its increased relevance. IIS has changed the way in which vaccination coverage is monitored in the pilot district. Previously, this monitoring came down to making sure that everybody achieved very high coverage rates. Now, the system allows managers and vaccinators to identify unvaccinated children and focus on them. Can they be found and vaccinated? If not, what are the reasons for non-vaccination? This offers the possibility to monitor equal access to immunization in a more effective and targeted way.

**Coverage rates**

Obtaining higher coverage using IIS was never a project goal, especially since baseline coverage in Albania is already so high. In fact, IIS shows consistently lower coverage rates than those assumed before (see Table 7). These lower numbers are believed to be more accurate. For more information on why this is the case, refer to Quality of immunization data on page 20.
**Timeliness of immunization**

With a computerized registry, it is now feasible to monitor the timeliness of immunization. To assess the impact of IIS in this respect, we compared the timeliness of immunization in Shkoder cohorts before IIS was implemented with timeliness after. Timeliness is in this case expressed as the proportion of children who have received an overdue vaccination, one month or more after the due date. One month is used as a cutoff date because many nurses provide vaccination on a monthly basis: they may not vaccinate a child on the exact date it is due to be vaccinated, but will always aim to do so within a month of this date.

There are two reasons why the implementation of IIS may lead to immunizations being administered in a more timely matter. First, since nurses receive information about newborns from the maternity hospital through IIS, they can contact the parents if required and do not need to wait until parents visit the health center. Second, because the monthly plans are automatically generated and distributed systematically, it is less likely that some children will be missed by the immunization program.

Table 8 shows the timeliness of 18,696 vaccinations administered in Shkoder district between 2009 and 2012, expressed as the percentage of vaccinations that were administered at least one month late. There is a slight decrease in 2012, which may be attributable to the implementation of IIS. The results are largely inconclusive, however, and it will be useful to reassess these findings once the system has been used for a few more years.

**Table 8. Percentage of children who were vaccinated more than one month late (IIS data)**

<table>
<thead>
<tr>
<th></th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penta-1</td>
<td>5%</td>
<td>7%</td>
<td>6%</td>
<td>4%</td>
</tr>
<tr>
<td>Penta-3</td>
<td>15%</td>
<td>16%</td>
<td>17%</td>
<td>15%</td>
</tr>
<tr>
<td>MMR-1</td>
<td>18%</td>
<td>14%</td>
<td>13%</td>
<td>11%</td>
</tr>
</tbody>
</table>

Abbreviations: Penta = pentavalent (doses 1 and 3); MMR-1 = measles, mumps, and rubella (dose 1).

**3.5.2. Stock management**

IIS has affected the following aspects of stock management in the pilot district:

- Maintenance of buffer stock at the district level.
- Maintenance of buffer stock at health centers.
- Monitoring of vaccine wastage.
- Lot tracing.

**Maintenance of buffer stock at the district level**

Vaccine stores at all levels need to maintain an appropriate level of buffer stock. If they do not keep enough vaccine, they risk stockouts, but if they store too much vaccine, they risk wasting perishable stock. Stock managers and vaccinators alike can maintain an appropriate level of stock
by ordering the right quantities based on their knowledge of how much they have and how much they estimate they will need during the time the order is supposed to cover.

Since districts receive vaccines on a quarterly basis, they need at least three months of stock at the beginning of a quarter, plus some buffer stock, to avoid stockouts at the end of the quarter. For districts, one month of buffer stock is usually considered to be an adequate level. That way, districts will not run out of vaccines if the next shipment arrives a few weeks late or if for some reason, they need more stock. Rational levels of stock are thus maintained between a minimum of one month and a maximum of four months.

By providing real-time visibility on stock balances, as well as the data necessary to estimate demand (including average monthly consumption for each vaccine), IIS enables users to make better-informed decisions on the quantities of vaccine stock to order.iii

To assess whether IIS may have made a difference in stock management, we compared the stock balances in Shkoder for pentavalent and MMR vaccines between the baseline year (2009) and the first year the stock management module in IIS was functional (January to September 2012). The difference in stock balance for pentavalent vaccine is shown in Figure 5.

**Figure 5. Stock balance for pentavalent vaccine in Shkoder in 2009 and 2012**

The difference in stock balance for MMR vaccine is shown in Figure 6.

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iii There are broadly two ways to estimate demand: the method that is recommended by WHO is to estimate vaccine needs based on population estimates and assumptions about wastage and coverage. An alternative method is to estimate future needs based on past consumption.
In 2009, pentavalent was consistently overstocked: more vaccine was delivered to the district than its health centers could use. On average, the district maintained almost five months of stock. At the same time, MMR vaccine twice ran out of stock, for a total duration of 67 days. The district only maintained 1.3 months in stock on average, which was not enough to avoid stockouts.

In 2012, the stock balances for pentavalent and MMR show comparable patterns. Stock never quite runs out, even if the buffer stock is all but depleted at the end of the first quarter and again at the end of the third quarter. The average months of consumption in stock are 1.7 months for pentavalent and 2.5 months for MMR.

Whether this improvement can be attributed to IIS is too early to tell, and would need to be confirmed with a bigger sample of districts. However, there is no doubt that having this information available to the district managers and their supervisors is theoretically useful.

Maintenance of buffer stock at health centers

IIS helps health center nurses to determine the right quantity of vaccine to order, based on their available stock and the amount of vaccine needed to vaccinate every child in their monthly plan. (Refer to Ordering new vaccine stock on page 12 for details.) Furthermore, as IIS provides real-time visibility of vaccine stock at every level, the district supervisor will soon be able to monitor available stock balances in his health center and compare them to preset minimum and maximum levels. These levels have yet to be determined, as the district supervisor is still determining the average consumption rates for each health center.

There is anecdotal evidence that stock is being managed more tightly in health centers and that there is less overstocking due to IIS. However, the absence of baseline data for stock at health centers (health centers did not keep stock records before the implementation of IIS) and the current low quality of stock data in IIS at this point does not allow for quantitative analysis into changes that IIS may have caused.

Monitoring vaccine wastage

Prior to IIS, vaccine wastage was not recorded or reported by health centers or district stores. For planning purposes, wastage rates were simply assumed to be around 10 to 20 percent. This made it impossible to monitor vaccine wastage in the country, quantify the problem, or do anything about it.
With IIS, all vaccine that is distributed must be accounted for. Any quantity that is used but not administered can be identified as wasted and categorized according to wastage type. The stock reporting features of IIS (described on page 15) enable users to monitor wastage of each type and at all levels. These data enable vaccinators and supervisors to take corrective measures to resolve stock management problems.

IIS provides two reports to identify vaccine wastage. These reports provide stock managers with access to detailed and reliable data on vaccine wastage for the first time. The first report (Vaccine wastage by health center or district) lists all vaccine wastage by health center or district during a certain time frame, such as a month, quarter, or year. It shows the number of doses of each vaccine that were used, administered, and wasted.

Open-vial wastage is only captured through stock corrections (differences between theoretical and physical stock) when vaccinators report actual stock at the end of every month. Closed-vial wastage is reported explicitly by vaccinators and district managers, with the reason the vaccine was wasted. This information is summarized in the second IIS report (Vaccine wastage by reason). It classifies the wasted doses of unopened vials that were reported as wasted by reason (for example, whether the doses were damaged, frozen, wet, etc.).

These stock reporting features were only released in October 2012. Wastage data has begun to be added to the system, but it is not yet comprehensive enough for stock managers to use. In time, this functionality has the potential to become a powerful tool for managing and reducing vaccine wastage.

**Lot tracing**

Before IIS, it was not possible to trace vaccine lots. In the case of a lot withdrawal, it was not possible to locate vaccine stock from the withdrawn lot, or identify people immunized with vaccines from that lot. With IIS, staff can use the Lot tracing report to locate vaccine stock from any given lot, as well as the children vaccinated with that lot. This is an extremely useful tool to manage AEFI and vaccine quality in general.

**3.5.3. Workload**

During the baseline assessment in January 2010, vaccinators and district staff were interviewed about the administrative workload of recordkeeping and reporting. Overall, nurses needed time to draft monthly vaccination plans (based on a review of immunization registries), enter each child’s data into various registries and cards, and report back on coverage to the district. They reported spending on average 2.5 hours per nurse per month on planning and reporting, and between 7 and 30 minutes per child to complete the primary vaccination records. The district head of vaccinators, who received and aggregated all health center reports, needed 12 hours per month to complete this task.

Nurses are expected to update the vaccination status of children in the system, while also keeping a paper immunization registry and completing health cards. Therefore, the registration of vaccination after sessions takes slightly more time than it did before. However, they save themselves the time to prepare monthly plans and monthly reports. District staff do not need to
aggregate reports anymore but may assume new duties, as the system will produce new and more detailed information.

During the first year of operation, nurses also entered child records for previous years’ cohorts, which increased their workload substantially. This was a one-off exercise that impacted the workload perception but that will not be required going forward.

### 3.5.4. Indicator framework

To monitor and evaluate the progress of work in Albania, Optimize used a pre-established indicator framework. Table 9 shows selected indicators that were used to measure success and how they were affected by the implementation of IIS. These focus on the stock management aspect rather than on medical record aspects of IIS.

**Table 9. Indicators used to measure success and how they were affected by IIS**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>2009</th>
<th>2012</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>District stock turnover— M M R vaccine</td>
<td>9.4 times per year</td>
<td>4.8 times per year</td>
<td>Turnover of M M R vaccine came down from a very high level. In 2009, the district did not keep enough stock of M M R to avoid stockouts. This turnover corresponds to an average stock level of about 2.5 months, which can be considered optimal in a system that aims to keep stock between 1 and 4 months.</td>
</tr>
<tr>
<td>District stock turnover—pentavalent vaccine</td>
<td>2.5 times per year</td>
<td>7.1 times per year</td>
<td>Turnover of pentavalent vaccine accelerated considerably, to a level that may be a bit too high. This turnover corresponds to an average stock level of about 1.5 months, and while there were no stockouts, the minimum level was breached systematically.</td>
</tr>
<tr>
<td>Stockouts at district— M M R vaccine</td>
<td>67 days</td>
<td>0 days</td>
<td>There have been no district-level stockouts in 2012. It is not certain that this can be attributed to IIS.</td>
</tr>
<tr>
<td>Stockouts at district—pentavalent vaccine</td>
<td>0 days</td>
<td>0 days</td>
<td>There have been no district-level stockouts in 2012. It is not certain that this can be attributed to IIS.</td>
</tr>
<tr>
<td>Availability of wastage rates at health centers</td>
<td>No</td>
<td>Partial</td>
<td>For some health centers, IIS produces reliable wastage rates, but in general, the data in the system need to become more reliable.</td>
</tr>
<tr>
<td>Availability of consumption rates at health centers</td>
<td>No</td>
<td>Yes</td>
<td>Consumption rates by district and health center can now be analyzed through the system.</td>
</tr>
<tr>
<td>Indicator</td>
<td>2009</td>
<td>2012</td>
<td>Comments</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>------</td>
<td>------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Availability of stock balance data at health centers</td>
<td>No</td>
<td>Yes</td>
<td>Stock balances by district and health center can now be analyzed through the system.</td>
</tr>
</tbody>
</table>

Abbreviations: IIS = Immunization Information System; MMR = measles, mumps, and rubella.

3.6. Acceptability and feasibility

An assessmentiv of the acceptability and feasibility of the IIS intervention was conducted to explore the perceptions of the stakeholders engaged in its development and implementation. The assessment took place September to October 2012 in Tirana, Albania, and used qualitative methods including focus group discussions and interviews.

The findings presented in this section reflect opinions gathered from 18 semi-structured interviews with implementers/designers (9) and key decision-makers (9), as well as 4 focus group discussions with participation of 15 implementers (vaccinators) from urban and rural health centers (as seen in Table 10).

Table 10. Total number of respondents

<table>
<thead>
<tr>
<th>Respondent</th>
<th>Semi-structured interview</th>
<th>Focus-group discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designers/implementers</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Decision-makers/stakeholders</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>Implementers (vaccinators)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.6.1. Factors of acceptability

All interviewed designers/implementers (9) perceived IIS as generally appropriate for their job and health centers. They considered IIS as a system that is user friendly, facilitates vaccinators’ jobs, and reduces paperwork/time. Another important view expressed by implementers was the fact that IIS has consolidated immunization-related information and generated high-quality data. It automatically calculates vaccine uptake, usage, and stock management and generates timely monthly plans and vaccine coverage reports. One respondent implied larger-scale consequences from IIS:

Through IIS, we have a better stock management which in fact reduces vaccination cost budget as well.

Pediatrician, rural health center

iv This assessment was deemed “non-research” per PATH’s Research Determination Committee policies.
The focus-group participants reiterated the messages of acceptability from the interviews. The majority of participants highlighted that IIS is comfortable to work with and fast and accurate in compiling statistics and generating reports. It also reduces paperwork and the time staff spend obtaining records and responding to record requests, as this respondent illustrates:

Now to provide child’s information on immunization records we can do this with a click, while before this procedure required two to three days.

Focus-group discussion participant, rural area

Respondents reported that all IIS menus facilitate their work, reduce paperwork and time, and produce accurate information on immunization records. In addition, the registration, vaccination, and reports menus were the ones frequently mentioned as improving the system, as this respondent explained:

IIS reduces paperwork as vaccination and reporting menu automatically calculates vaccination progress, and we just click and print it out.

Focus-group discussion participant, urban area

3.6.2. Factors of unacceptability

There were very few factors of unacceptability listed by respondents. One issue referred to was that when children move to Albania there is no way to integrate the immunizations they have received from their home country into the list in the system, which then shows the child as unvaccinated, lowering the numbers of vaccinated children in reporting. As one respondent explained:

There is a difference between vaccination list in Albania and other countries. There are a group of vaccines that are not applied in Albania, and when these children who have lived abroad come to Albania and continues vaccination calendar there is a gap in the vaccination list. We have to contact with our centre (DPH Unit) and ask them how to report such cases, because as I said there are a group of vaccines that we do not apply here.

Head of department, urban area

In focus groups and interviews, the respondents mentioned two other factors of unacceptability, system/page blockage and the low speed of operating IIS. Respondents reported these are due to low Internet speed and the IIS system itself. One respondent expressed the effects of these problems on the workload:

When the system is blocked this creates problems as we miss information and we have to reboot the system [...] and we get bored because of our work we are obliged to process things quickly.

Focus-group discussion participant, rural area

3.6.3. Factors of feasibility

In order to evaluate the perceptions of designers/implementers regarding IIS feasibility, respondents were asked: “How easy or difficult has it been to implement the intervention?” And on the ease of some important parts of IIS they had to choose a response on how easy or how
difficult it has been for them to work with or use IIS and its submenus. The four categories included:

1. Easy—No problems.
2. Sometimes have problems.
3. Often have problems.
4. Difficult—Always have problems.

For three of the menus (child registration, preparing monthly reports, and preparing monthly plans) 8/9 participants responded that IIS was easy to use, while the remaining three menus (immunization registration, stock management, preparing immunization cards) resulted in more varied responses.

In the focus groups, 10/15 of the respondents reported that IIS was easy to use and presented no problems. The registration and vaccination menus were ranked by all participants as easy to use, and the reporting menu was ranked easy to use by most respondents (14/15). However, the stock management menu was reported to “sometimes have problems” by most respondents (9/15), and 5/15 thought it was “easy to use” (1 thought it was “difficult; always had problems”). Explaining the lower feasibility of the stock menu, respondents explained that it required more attention when entering data, as one vaccinator explained:

With stock management we have started a bit later and myself I am not skillful to use it as the others.

Focus-group discussion participant, rural area

The set of feasibility questions asked of decision-makers aimed to explore what the unexpected requirements and positive/negative consequences were or other issues that arose during the IIS implementation. The following pre-identified issues were presented: workload, worker incentives, policy or protocol, planning, budget, training, management practices and capacity, infrastructure and capital, regulatory requirements, synergies with existing systems, and working environment/relationship. In all categories, more respondents listed positive consequences versus negative consequences and no unexpected issues. There were some mixed results for budget, mainly due to respondents reporting their inability to answer because they were not involved in budget decisions. Some decision-makers interviewed identified unexpected requirements including problems with Internet coverage, staff turnover, and a need for more training. When asked to identify the main positive consequence of the IIS, decision-makers noted that it made vaccinators’ jobs much easier and improved the quality of data, as this respondent explained:

IIS is like a mirror. It gives a clear picture of vaccinated children from 0 to 14 years old. The IIS records are established within the first days of birth (maternity) and vaccinators are aware of every newborn.

Decision-maker, regional level

Notably, workload also elicited a mixed response, with 4/9 respondents reporting that IIS caused unexpected requirements to workload, and 5/9 also reporting that these resulted in negative consequences. When prompted, the implementers attributed the workload issues to the double data entry from previous cohorts and the anticipation of staff turnover. One respondent explained:
The unnecessary double data-entry process and pushing vaccinators to enter immunization data from previous years increased vaccinators’ workload.

### 3.6.4. Decision-maker national-level factors of continuation

All the respondents in both the implementers/designers interviews and focus groups thought the IIS should be continued. Those interviewed were asked how long they thought it should continue; the most common response was permanently (6/9). One respondent noted the effects of the intervention:

- Children and vaccination performance are better monitored via IIS. Two years ago we had to meet weekly and report to Directory of Public Health, but now we don’t do this anymore.

  Focus-group participant, urban health center

Another respondent, a director of a rural health center reported that:

- IIS facilitates vaccinators’ job, reduces paperwork and save time... It is an accurate system, it automatically calculates vaccines needed and stock management.

  Implementer, rural area

The decision-makers were asked whether the IIS had any influence on or resulted in any changes to the district’s broader health system, beyond the immunization program. All mentioned that IIS resulted in changes, as a novelty intervention for the health system in Albania. Foremost, it had an influence on the mother and child program, as IIS is directly linked and is an integral part of this service. As one respondent reported:

- The IIS has changed the image of health system as has showed the advantages of implementing new vaccination system and technology.

  Decision-maker, national level

### 3.6.5. Improving IIS

Designers and implementers also shared ideas on how to improve IIS. These consisted of improving the server/Internet connectivity issues, enabling SMS options, improving some menu functions, and improving the ability to collect the geographic movement of children in the system. As this respondent explained:

- The IIS is working quite well, but I suggest improving the data analysis part, which would help not only vaccinators but the work at higher levels as well.

Q: And how specifically can this menu be improved?

A: By creating other subcomponents of the reporting menu in order to better respond to vaccinators and other health worker’s needs.

Designer, urban area
3.7. Cost

3.7.1. Demonstration project costs

The direct financial investment of project Optimize in this demonstration project amounted to about US$306,000. This included costs related to software development ($164,000—54%), training, supervision and in-country staff ($105,000—34%), the purchase of equipment ($23,000—8%), and wireless communication for a number of health centers over two years ($14,000—5%). Development costs included a $40,000 investment in mobile technology that was discontinued during the project.

Project Optimize spent an additional $190,000 on categories that did not directly contribute to the implementation of IIS, such as advocacy, international travel and meetings ($90,000), local office administrative and technical support ($75,000), and evaluation and documentation ($25,000).

This investment did not include:

- Project Optimize staff and travel costs.
- Albania MOH staff costs (at all levels).
- The cost of hosting the application and database, which were absorbed by a government agency.
- Voluntary investments by health centers and Shkoder district in Internet connections and equipment such as surge protectors and printers.

3.7.2. Total cost of ownership

The costs presented above are not necessarily comprehensive enough to reflect the total cost of ownership of IIS over multiple years for Albania. The $307,000 reflects the costs of development and piloting of the system. In this phase, most money was spent on software development, which was a fixed cost that did not cover the final scale of the system.

After the pilot phase, the system will first need to be scaled up and then sustained over a number of years. During scale-up, most money will be spent on deployment—training people, acquiring and installing computers—rather than on software development. After that, sustaining the system will require ongoing expenditure for operating costs like refresher training, communication activities, and maintenance of the current system.

The cost to scale and sustain the system will be driven by the number of users and the cost for each user. As an illustration, we made some high-level assumptions that:

- The final number of users, or places where the system will be implemented over the next three years, will be 500.
- The cost per user to deploy the system will be $1,000 for a PC, installation, and training.
- The cost per user to run the system will be $200 per year for communication, refresher training, and servicing of the computer equipment.
Under these assumptions, the spending profile up to 2017 is shown in Figure 7. This illustrates that pilot costs ($307,000 over three years) were relatively small compared to the projected scale-up costs ($716,000 over 2013 to 2015). The operating costs to sustain the system going forward will also be substantial, at $110,000 per year after the system has been scaled up. This does not mean that any one partner or institution will pay that amount; many of the costs may be locally absorbed. As Albania will be deploying more health information systems within the same time frame (like the HII system), synergies can also be found.

3.8. Challenges

3.8.1. Delays in development
Development took longer than initially expected. From the point of view of the Optimize coordinator, the main cause for this was that the company developing IIS was uncomfortable with end-users—rather than developers—defining the software’s functionality and how it should be implemented. This mostly occurred in the initial phase of development. After it became clear that acceptance of deliverables and related payments would depend on adherence to documented and agreed upon requirements, this dynamic changed somewhat. Eventually, the success of custom development depends greatly on good communication between business and IT people (for more information, see Lessons learned on page 35).

3.8.2. Reliability of the system
Technical challenges with the way the system was set up meant that it crashed frequently in the first few weeks it was deployed. This was not noticed before because it had not been properly tested under stress, with many concurrent users. The root of the problem was eventually detected
and solved. Had it not, this would have derailed the entire pilot. The main implication is that the required quality controls need to be in place at the end of each development phase.

### 3.8.3. The need for interoperability

IIS is set up as a specific immunization system, but depends on support from institutions beyond the IPH for integration into the broader health system. Determining ways to make IIS interoperable with other systems (such as the HII system) should ensure that it becomes valuable enough to gather broader support.

### 3.8.4. Distribution of workload

Even with sufficient training, not all users have acquired the same skills. Furthermore, some users in the largest health centers are faced with a disproportionate workload as they try to load several years of birth cohorts and vaccination history into the system. There is a need for ways in which vaccinators can help each other to balance the workload and get each other up to speed. Another possibility would be to hire data entry staff to help with the initial loading of the system.

### 3.8.5. Connectivity issues

Connectivity issues persist in some health centers. Workarounds exist: some vaccinators access the system at the district when they come to pick up their vaccines for the month. Others work from home or at Internet cafes, but in the end, the scale-up and sustainable use of the system depends on a minimum level of connectivity in large health centers. A mobile phone component is being developed to help fill some of the connectivity gaps.

### 3.8.6. Ongoing funding requirements

Reliable funding for the scale-up and ongoing operation and maintenance of the system may be the biggest challenge (for more information, see Cost on page 32).

### 3.9. Scale-up

The IPH has started discussions with HII and the Department of Public Health at the MOH to plan for the institutionalization and scale-up of IIS. First, a memorandum of understanding between these three institutions will be drafted. This will potentially lead to a ministerial decree about the use of IIS as part of the system. Scale-up will then be achieved in step with the expansion of IT infrastructure and the insurance system that is already envisaged. Officials estimate that three to five years will be required to achieve national scale.

After a first meeting with epidemiologists and chief vaccinators from other districts, in which IIS and the Shkoder project results were shown, districts are now evaluating their readiness to implement IIS based on the requirement set by the IPH. A meeting with districts and stakeholders is planned for January 2013 to plan this scale-up process in more detail.
3.10. Conclusions

3.10.1. Most valuable changes

IIS showed how an information system can change the way people work together. It has produced more accurate and timely data, and has also demonstrated that these data can be effectively used by health care workers. The most valuable change the system has brought about in the pilot district is that it has changed the way people work and collaborate to improve the immunization program:

- Managers can now base strategic decisions on the data the system provides them. They can find answers, discuss issues, and make decisions in a timely manner. For example, is vaccine refusal a common issue in Albania, and should we communicate better with the population about vaccine safety? Are there any communities that are underserved by the system? Is the birth dose of hepatitis B administered in a timely matter?

- Supervisors now have new tools to better understand the challenges faced by health workers, to assess their performance, and to help them improve. Supervisors can now answer questions such as: how many unimmunized children does each center have, and what are the resources required to find and vaccinate them? What is the wastage for each center, and how much buffer stock do they keep?

- Vaccinators can collaborate more effectively between each other. They can now discuss specific cases of children that are registered in their health center but actually visit another one, for example. Overall, IIS empowers vaccinators to improve the quality of their work as it provides them with concrete tasks (unvaccinated children) to focus on, instead of a rather abstract coverage indicator.

From that point of view, the demonstration was a success, even though its long-term scalability and sustainability still needs to be proven.

3.10.2. Lessons learned

While the project stakeholders are happy with the outcomes of the project, there is also a realization that some activities could have gone faster and better. The following are some lessons learned from the development and implementation of IIS in Albania.

1. It is not necessary to reinvent the wheel—many other countries have implemented immunization information systems or are planning to do so. At the start of the IIS project in Albania, not enough time was spent exploring what could be learned from similar projects elsewhere.

2. Public health officials often lack the tools and the guidance to undertake complex information systems projects. Without collaboration within the context of Optimize, it would have been much harder for the Albanian IPH to successfully develop and implement a software system like IIS.

3. There is a need for close collaboration between IT and health staff. This is not always easy, but in the Albania project, the formal documentation of user requirements helped to develop a common understanding from the start. When the system was tested and did not
meet expectations, the NIP manager was able to point to these requirements. They helped her to take control of the project.

4. System development is a highly iterative process, requiring both formal and informal testing. In all phases of development, valuable feedback from users and managers needs to be captured and incorporated.

5. Conversations with partners and stakeholders must begin early, so that everybody feels they are stakeholders in the project and want to make it work. Equally important is the need to involve future users of the system early in the project.

6. Computerizing processes that are well understood is easier than implementing a system that introduces a new process or activity. In the case of Albania, the stock management process was relatively informal, and health center staff did not typically keep a stock ledger or register stock transactions in any other way. This meant that new stock management processes required by the IIS system were less well understood by the system users.

7. New abilities mean new challenges— before the system was available, district staff had little information about stock management and only knew that overall coverage was high. New information about unimmunized children, wastage, and stock levels now leads to more work for them, but better overall performance of the immunization program.

3.10.3. Potential applicability outside Albania

Immunization managers in many low- and middle-income countries are looking for ways to improve their immunization information systems. Some are exploring or have started development of a registry-based system like the one in Albania. Based on the Albania experience, countries embarking on a similar effort should have the following conditions in place:

- A registry culture, in which health workers already register children in a paper book or card system. As we discovered in Albania, supporting existing processes with a system is much easier than implementing new processes through an information system.

- A method of identifying children or their parents. This can be through formal national identification cards, names, dates and places of birth, telephone number, etc. It can also leverage the existing health or immunization cards on which a number or a barcode could be added.

- A minimal level of Internet access, either through computers or cell phones, at least down to the district level. Remote health centers can be served through appropriate paper systems.

- Access to the knowledge and tools to acquire or develop, scale, and maintain a computerized information system. Based on the Albania experience, we realize that not many countries will have the resources to develop a system from scratch.
4. REMOTE TEMPERATURE MONITORING

4.1. Goal
The goal of the project was to assess the value of remotely connected temperature monitoring devices, compared to conventional non-connected temperature monitoring devices.

Please note: This chapter summarizes the methodology and results of the remotely connected temperature monitoring demonstration. For a comprehensive analysis, please refer to the PATH publication “Assessment of a Remote Alarm System for Vaccine Storage in Albania.”

4.2. Rationale

4.2.1. The problem
Proper monitoring of temperatures is crucial to ensuring the quality of vaccines. As vaccine efficacy can be affected by exposure to excessive heat and cold, it is important that vaccines are correctly transported and stored from the point of manufacture to the point of use. Temperature monitoring helps ensure vaccine handling quality, detect malfunctioning equipment, and prevent temperature fluctuations that can negatively impact vaccine potency and safety.

Temperature monitoring has traditionally been performed by health workers, who are required—twice a day—to review and record the temperatures displayed on standard or minimum/maximum thermometers installed in vaccine refrigerators.

Recently, technology for temperature monitoring in vaccine refrigerators evolved from standard thermometers to 30-day recording devices with visual alarms. These alarms are typically triggered after 10 consecutive hours of temperatures greater than 8°C or 60 consecutive minutes of temperatures less than -0.5°C, as per WHO standards. In Albania, 30-day recording devices are used in most health centers where vaccines are stored. However, when an alarm is activated, health workers cannot respond during nonworking hours when they cannot see the alarm, and without supervisor assistance, they cannot always provide necessary follow-up.

4.2.2. A possible solution
To help address the problem, Optimize designed and implemented a study in Albania to evaluate the potential benefits of remotely connected temperature monitoring devices. These devices use mobile phone technology to log temperatures on remote servers and immediately issue an alert whenever temperature limits are exceeded. The alert is then sent by SMS to the mobile phones of managers and health workers.

This report is available on the PATH and WHO Optimize websites:
The potential benefits of this system include:

- Reduction in the delay between an alarm being raised and a health worker becoming aware of it. The SMS message containing the alarm can be sent to the health worker’s mobile phone even on holidays or during nonworking hours.
- Improved support for corrective action. Health workers or storekeepers can be immediately contacted on their mobile phones by supervisors to discuss appropriate follow-up.
- Increased compliance by health workers with the temperature monitoring procedure, based on the knowledge that supervisors are automatically informed of all temperature excursions.
- Greater visibility of temperature excursions. The creation of a permanent, detailed record of refrigerator performance, available at supervisory levels of the system, can accelerate and reinforce corrective actions, such as the swift replacement of faulty equipment.

4.3. Implementation

The following table describes the major milestones in the project.

Table 11. Remote temperature monitoring timeline

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2009</td>
<td>Meeting to present and finalize study protocol.</td>
</tr>
<tr>
<td>January 2010</td>
<td>Training for technicians and supervisors on installing remote temperature monitoring devices.</td>
</tr>
<tr>
<td>March 2010</td>
<td>Training of nurses.              Installation and testing of monitoring equipment.</td>
</tr>
<tr>
<td>March to December 2010</td>
<td>Data collection, monitoring, supervision, and focus group discussions.</td>
</tr>
<tr>
<td>January 2011</td>
<td>Meeting to present results and discuss with health workers.</td>
</tr>
</tbody>
</table>

In collaboration with the NIP and Berlinger, the company that manufacturers the Fridge-tag® temperature monitor, Optimize installed an SMS-based system that monitors and logs temperature conditions in peripheral cold chain equipment.

A total of 24 storage locations (health centers) in Albania’s Shkoder district were equipped with remote temperature monitoring devices (sensors, monitors, and SMS gateways). When an alarm was activated, an SMS text message was sent to a central server that logged the issue and sent a notification to health workers and supervisors in charge of the storage location. Once the problem was addressed, its status was reset on the central server. Over 10 months, 136 alarm incidents
were detected, including 22 low and 114 high temperature alarms. This was in line with a previous study into the use of Fridge-tag® monitors in Albania.\textsuperscript{vi}

In focus group discussions with district- and national-level supervisors, it became clear that to judge the working status of refrigeration equipment, supervisors rely not only on an analysis of the frequency of alarms, causes, and responses, but also on an analysis of temperature curves in that piece of equipment. These graphs can be downloaded from the temperature recorders to a computer for analysis, but apart from sending alarms, mobile phones can also be used to transmit frequent temperature measurements in refrigerators to a central server.

Optimize tested one such system, FoneAstra, to assess whether this capability would allow program management to manage cold chain equipment in a more informed and systematic way. To test the technology, FoneAstra devices were installed at six sites in Albania. Temperature probes were placed inside equipment, with the accessory and mobile phone mounted externally. The accessory sampled the connected temperature sensors every few minutes and aggregated these data. Detailed temperature logs are periodically sent to a central server via SMS. For instance, the system could be configured to query sensors every 15 minutes and send detailed temperature reports every 12 hours. All the data received on the server, including temperature reports and alarm notifications, are stored in a database and can be easily viewed using a standard web browser.

4.4. Results

The main findings of the study were that the text message alarms alerted health workers to cooling failures at all times, even when the health centers were closed, enabling them to respond promptly. Secondly, the awareness and involvement of supervisors reinforced the process of seeking solutions and, in particular, replacing inadequate equipment. Finally, temperature plots and performance data were collected on refrigerator models, enabling better procurement choices.

The question is now whether the fact that the alarms were transmitted via text messages made a difference in the management response and whether any quantifiable benefits were realized. It was established that the management response was faster and better organized when alarm data were transmitted automatically. However, in terms of impact, the study could not establish that vaccine wastage was avoided because of the system. As a matter of fact, none of the alarm conditions led to any damage to vaccines.

4.5. Acceptability and feasibility

In informal focus group discussions, the system was judged acceptable and useful by both the vaccinators and their supervisors. These discussions were not structured and were not part of the formal study that was conducted around acceptability and feasibility of IIS.

\textsuperscript{vi} Karto\textsuperscript{li} U, Nelaj E, Maire D. Improving temperature monitoring in the vaccine cold chain at the periphery: an intervention study using a 30-day electronic refrigerator temperature logger (Fridge-tag®). Vaccine. 2010;28(24):4065–4072. Available at: http://dx.doi.org/10.1016/j.vaccine.2010.03.076.
Staff felt that the following factors made the technology acceptable:

- The study increased awareness of the importance of temperature monitoring.
- The study improved collaboration between vaccinators and supervisors to resolve alarm events and cold chain problems.
- There was a sense that this technology provided a “best-in-class” level of quality control.
- The study served to improve the entire cold chain system in Shkoder district.

If there were factors that made the technology unacceptable, they were not voiced in the focus group discussions. Potential concerns would be that staff may feel micromanaged or even spied upon.

There were also no concerns around feasibility from a usability or technology point of view. Cost feasibility is discussed below.

### 4.6. Cost

As the study tried to establish potential benefits of a concept, rather than to implement a sustainable and scalable system, there was no attempt to produce the remote temperature devices at low cost. The component cost of the initial Fridge-tag®-based system amounted to $1,000 per monitoring device. At this price level, the system is clearly not affordable. Experience with the FoneAstra project suggests that this cost may come down to about $100 per device. Communication costs amounted to $5 per device per month, or $1,440 per year for the pilot.

Assessing affordability is rather subjective since the benefits are qualitative and cannot be easily quantified, so no business case can be made in which costs are weighted against savings. In Table 12, ballpark investment and running costs are shown, based on assumptions of a $100 price point per device and a $5 per month service charge, and a server cost of $1,000 plus a $50 per month charge.

<table>
<thead>
<tr>
<th>Usage</th>
<th>Investment cost</th>
<th>Running cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central level 36 district stores</td>
<td>$4,700</td>
<td>$2,820 per year</td>
</tr>
<tr>
<td>Central level 36 district stores 500 health centers</td>
<td>$54,700</td>
<td>$32,820 per year</td>
</tr>
</tbody>
</table>

Under these assumptions, national and district supervisors consider that use at the district level would be affordable and costs would justify the qualitative benefits that are gained. Even so, it is hard for any institution to guarantee continued payment of any kind of service fee (in this case, telephone connections).
4.7. Challenges
No major challenges were encountered during the implementation. The lack of availability of baseline data (how many alarms would be needed under normal conditions, outside of a study like this? how would people manage them?) makes an evaluation of the impact more difficult.

4.8. Scale-up
From the outset, IPH and DPH staff regarded this intervention as a study and were aware that the technology for potential scale-up might not be available by the end of the demonstration.

Berlinger will launch a new version of the Fridge-tag® in the first quarter of 2013, and its features were partly driven by the experience gained in this project. The new Fridge-tag® device will be more expensive, at around $25 per unit, up from $15, but it will allow data to be downloaded through a USB connection. These data could then be transmitted through a general packet radio service or SMS gateway, as in the study in Albania. Remote temperature monitoring could thus become feasible at scale.

The barrier to adoption, however, may lay in the need to fund communication costs on an ongoing basis. Regardless of the actual amount that is needed for this, it will always be a challenge to make sure that recurring costs are included in health budgets in a sustainable way.

4.9. Conclusions
The adoption of non-connected recording devices such as Fridge-tag® and LogTag has already proven the willingness to invest in temperature monitoring equipment to safeguard expensive vaccines. The prospect for adoption of remote monitoring systems will likely be driven by cost. The experience in Albania suggests it may become a niche product, mostly suitable for places where high vaccine stock values are at stake or for remote storage points with unreliable storage conditions.

The demonstration was a partial success. We gained better insight into the potential value of remote temperature monitoring technology from a qualitative point of view. There is also ongoing work and research in this area, both in other countries collaborating with Optimize (Senegal) and by other entities such as the UNICEF-led Cold Chain and Logistics Task Force. The fact that we were not able to quantify potential benefits, in terms of vaccine saved, weakens the case a bit. Further research would be needed.
A. Monitoring activity performance

Method

The monitoring and evaluation approach adopted by Optimize consisted of:

1. Monitoring relevant indicators in three categories—quality, availability, and efficiency.
2. Observing, documenting, and measuring changes in similar/dissimilar demonstrations.
3. Conducting research around acceptability and feasibility, as well as cost analyses.

This approach enabled us to present our findings in ways that will attribute changes we observed from demonstrations; make simple comparisons of before and after data; and contribute data that supports descriptive research on cost, acceptability, and feasibility.

The analysis plan consisted of simple baseline-endline indicator comparisons. These comparisons described the changes observed at multiple levels of the vaccine supply chain during the intervention. The comparisons do not exclude (or measure) the contribution of confounding factors to observed changes in the performance indicators.

The evaluation approach is a descriptive comparison based on observation, primary data collection, and available secondary data. We triangulated among the three sources to understand the attribution of performance to the interventions. This attribution was established through a rationale that logically describes why and how the interventions contributed to changes in performance. The strength of attribution depended upon the strength of the logical rationale.

Data sources and tools

All data collection was structured around visiting health facilities in the demonstration countries. During these visits, data were collected from the following sources (Table 13).

Table 13. Sources for data collection

<table>
<thead>
<tr>
<th>Source</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-person interviews</td>
<td>Data were collected from interviews with health care workers, such as cold chain managers, medical personnel, and facility managers. During the collection of baseline data, interviews were sought with appropriate personnel. Data-collaborators followed structured questionnaires in these interviews.</td>
</tr>
<tr>
<td>Temperature-monitoring devices</td>
<td>Data were collected from existing or Optimize-installed temperature-monitoring devices in cold chain equipment. Several forms of data-collection tools or devices that monitor temperature were used to collect these data, including LogTag, TRID7-30F, LIBERO, Tiny Tag, FoneAstra, and FridgeTag®. These data were aggregated from spreadsheet outputs that show temperature readings.</td>
</tr>
</tbody>
</table>
Data were collected throughout 2009 to 2011. Some of the baseline data include vaccine stock data from 2008 and 2009 because these data were based on reports from previous years (see Table 14).

**Table 14. Baseline data collection dates**

<table>
<thead>
<tr>
<th>Country</th>
<th>Baseline data collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albania</td>
<td>December 2009 to February 2010</td>
</tr>
<tr>
<td>Senegal</td>
<td>May 5 to 18, 2011</td>
</tr>
<tr>
<td>Tunisia</td>
<td>May 2010</td>
</tr>
<tr>
<td>Vietnam</td>
<td>2010 to 2011</td>
</tr>
</tbody>
</table>

**Indicator definitions and descriptions**

The three outcome categories were availability, efficiency, and quality. Each category included detailed sets of indicators, described in Table 15. These indicators were selected to demonstrate that the country-level interventions had been designed and validated. The process included finding common measurement tools and indicators for the distinct interventions and differing country contexts.

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vii SFAT was previously called the Vaccine Stock Tool.

viii Optimize Strategic Objectives 2.1 and 2.2.
<table>
<thead>
<tr>
<th>Category</th>
<th>Indicator</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Availability</td>
<td>Data accuracy</td>
<td>A measure of the accuracy of the registry information, measured with a physical count of vaccines versus system records (inventory).</td>
</tr>
<tr>
<td></td>
<td>Data use</td>
<td>Whether the correct data had been used to make the calculations for the amount of vaccine to be issued. Data were (1) current stock of the health facility and (2) consumption during the last period or demand based on schedule.</td>
</tr>
<tr>
<td></td>
<td>Stockout rate</td>
<td>Number of days with stockout for any vaccine. The measure was aggregated by intermediate district or province level (i.e., proportion of facilities with stockout).</td>
</tr>
<tr>
<td>Efficiency</td>
<td>Cost per cm³</td>
<td>Cost per cm³.</td>
</tr>
<tr>
<td></td>
<td>Cost per $1,000 of vaccines</td>
<td>Cost per $1,000 of vaccines.</td>
</tr>
<tr>
<td></td>
<td>Logistics costs as percentage of vaccine value</td>
<td>Logistics costs as percentage of vaccine value.</td>
</tr>
<tr>
<td></td>
<td>Delivery time</td>
<td>The mean time between orders and receipt of vaccines from the order, measured in days.</td>
</tr>
<tr>
<td>Quality</td>
<td>Wastage— closed vial</td>
<td>Number of doses discarded, including unopened vials due to expiry, vaccine vial monitor indication, heat exposure, breakage, freezing, missing inventory, and theft.</td>
</tr>
<tr>
<td></td>
<td>Temperature (for handling vaccines, assessing performance of equipment during storage and transport)</td>
<td>Number of high and low alarms, continuous temperature record, and actual temperature on inspection. Cumulative time at temperatures greater than 8°C and less than -0.5°C, number of times temperature dropped to less than 0°C, and continuous temperature record.</td>
</tr>
</tbody>
</table>
B. Acceptability and feasibility assessment

This component provided for external assessment of the factors that made the interventions acceptable or unacceptable and also feasibility and how the interventions affected the health system. The overall purpose of this assessment\textsuperscript{ix} was to identify key advantages and challenges associated with the project Optimize in Albania intervention within the global project Optimize monitoring and evaluation framework. To accomplish this, the assessment explored the perceptions of stakeholders engaged in the development and implementation of the project Optimize in Albania intervention. (As required by PATH’s Research Ethics Committee for the protection of human research subjects, PATH employees were not included as stakeholders in this research.)

This study sought to measure stakeholder perceptions of the acceptability and feasibility of the IIS intervention in Albania (as well as its main components). The terms, “acceptability” and “feasibility” can often overlap. For the purpose of this research, the two terms were defined as follows to help keep them as distinct as possible.

- **Acceptability**: Acceptability refers to what the stakeholder likes and dislikes about an intervention. An acceptable intervention is desirable and satisfactory.

  Examples: An intervention might be considered acceptable because of benefits to mothers and infants with better access to immunization or because of benefits to MOH immunization staff through reduced workload. An intervention might be considered unacceptable if it has a small benefit for mothers and infants or low benefits to MOH immunization staff through added workload or resources.

- **Feasibility**: Feasibility refers to the difficulty, or ease, with which the stakeholder can implement required intervention activities. If an intervention is feasible, it is practical and easy to carry out and achieve.

  Examples: A feasible intervention is practical to achieve with the available time, staff, and resources. Think about the introduction of a new vaccine. A feasible scenario would be the introduction of a new vaccine that comes in vials similar to existing vaccines and that is handled in the same cold chain conditions as existing vaccines. An unfeasible intervention is not practical to achieve with the available time, staff, and resources. An unfeasible scenario would be the introduction of a new vaccine with packaging so large that you cannot fit enough doses in the district refrigerator, it requires dry ice to be transported, and the shelf life is only a few weeks long.

Regarding general study design and overview of methods, this was an observational study to provide descriptive results from qualitative methods. An Albanian research team used a variety of locally adapted methods to collect and analyze qualitative data obtained from intervention stakeholders. The methods used in completing this evaluation included, semi-structured interviews, focus group discussions, site visits, and stakeholder meetings. The data collection phase took place September to October 2012.

The team conducted interviews with implementers, designers, and decision-makers/stakeholders from key intervention partners including the pertinent national government ministries and other

\textsuperscript{ix} This assessment was deemed “non-research” in accordance with PATH’s Research Determination Committee’s policies.
implementing partners. Each respondent gave verbal consent and was asked to be recorded. Responses were analyzed using Atlas.ti software, and results were triangulated with monitoring data.

In addition to the semi-structured interviews, this study conducted four focus group discussions with implementers in order to explore acceptability and feasibility issues from a different perspective in greater detail. Each focus group discussion consisted of three to four participants, with an average of four, and lasted approximately two hours. The final analysis triangulated the interview and focus group data. The findings from the acceptability and feasibility assessment contributed to the five components of the global project Optimize monitoring and evaluation framework.