AIM
ASSOCIATION OF IMMUNIZATION MANAGERS

Lessons from the Field:
Digital Data Loggers

immunizationmanagers.org/DDL

About

This document examines the experience of immunization programs (IPs) that were early adopters of Digital Data Loggers (DDLs). The document highlights key decisions made by the early adopters in six different areas and provides information about different approaches to DDL implementation; the benefits and considerations of each approach; implementation tips; and lessons learned. Comments from DDL vendors are also included to provide additional perspectives.

AIM created this resource to share experiences from those in the field. It is not an implementation guide, and does not address federal requirements or recommendations. Please refer to the most current Centers for Disease Control and Prevention (CDC) Vaccines for Children (VFC) Guide and VFC Compliance Site Visit Reviewer Guide for more information on federal requirements and recommendations. In addition to federal requirements, state/territorial/local IPs authorized to administer the VFC program in their respective localities, referred to as "awardees" in this document, may have additional requirements and recommendations for participating providers.

PROUD SPONSOR

AIM
ASSOCIATION OF IMMUNIZATION MANAGERS

Lessons from the Field:
Digital Data Loggers

immunizationmanagers.org/DDL

AIM appreciates the support from the following sponsors:

berlinger
feel safe

Stephen Fields
General Manager
stephen.fields@berlinger.com
973-214-8744
www.berlinger.com/temperature-monitoring/products-hardware/data-loggers

DeltaTrak

Michelle Gonzalez
Inside Sales Representative - USA Vaccines for Children and Canada Life Science
mgonzalez@deltatrak.com
1-800-962-6776 ext. 4123
www.deltatrak.com/product/381-flashlink-certified-vaccine-usb-pdf-data-logger-model-40527

CONTROL COMPANY
TRACEABLE® PRODUCTS | TraceableLIVE
Vaccine Temperature Monitoring. Embrace Technology.

Clark Doherty
Key Account Manager
cd@control3.com
281-400-2107
vfc.traceable.com/resource

LASCAR electronics

Brian Law
Executive Vice President
info@lascarelectronics.com
814-835-0621
www.lascarelectronics.com

LogTag Recorders

Stephen Rader
Vice President
srader@logtagrecorders.com
908-209-7477
logtagrecorders.com

ONSET
InTemp® Monitoring Solutions

Sean Kelly
Strategic Sales Representative
sean_kelly@onsetcomp.com
508-743-3155
www.onsetcomp.com/intemp

DIGI SmartTemps®

Josh Griggs
Director of Healthcare Sales
josh.griggs@digi.com
574-347-6166
www3.smart-temps.com

TEMPARMOUR REFRIGERATION
WORRY FREE VACCINE REFRIGERATION

Laura Griffin
Manager
laura.griffin@tempstable.com
1- 866-485-4199
www.TempStable.com

SECTION I.

Introduction

AIM
ASSOCIATION OF IMMUNIZATION MANAGERS

Lessons from the Field:
Digital Data Loggers

Maintaining recommended temperatures for vaccine storage is vital to preserving the potency of vaccines. Providers must track the storage temperatures with a device that is precise, reliable and able to record temperature history over time. Without monitoring, providers may not notice if vaccines are stored in temperatures that are too warm or too cold, and may administer ineffective vaccines.

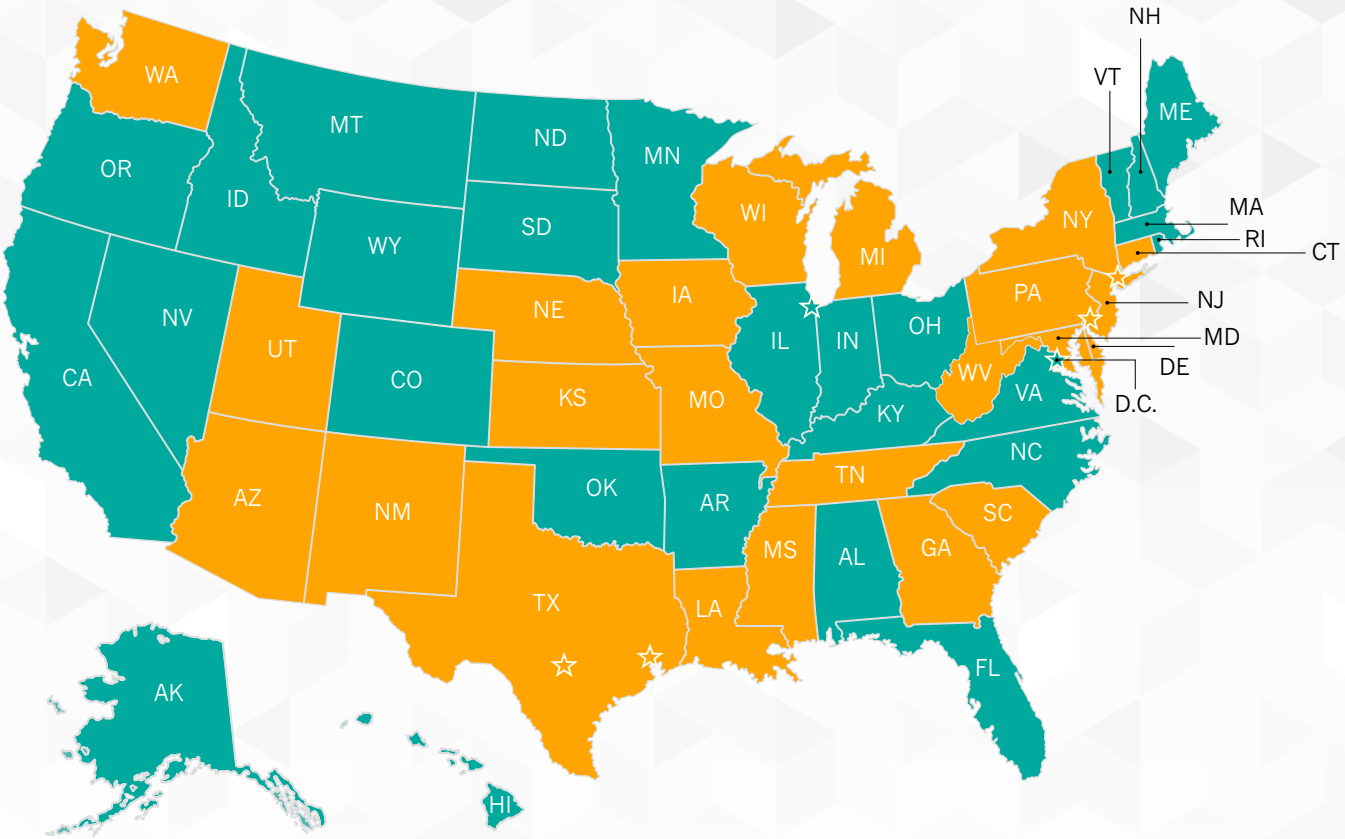
DDLs continuously monitor temperatures and provide information on when and how long a storage unit has operated outside the acceptable temperature range. DDLs are usually battery operated and set to record at defined time intervals, making it possible to store and record thousands of discrete temperature readings. All data loggers are digital and most have specialized software allowing the user to download temperature readings, with the option of determining the maximum and minimum readings and the time they occurred.

On January 1, 2018, more than 44,000 providers nationwide participating in the Vaccines for Children (VFC) program will be required to use DDL in all vaccine storage units that hold VFC. Awardees administering the VFC program will provide oversight, support, and enforcement of this new requirement.

As of June 1, 2017, 35 awardee immunization programs required DDLs in VFC provider offices. Figure 1 displays the immunization programs that required DDLs as of June 2017 and Figure 2 shows immunization program plans to support DDL use in provider offices as of January 1, 2018.

FIGURE 1

As of June 1, 2017, IPs that required VFC-enrolled providers use a DDL



54% **YES** (N=35)

44% **NO** (N=28)

2% **Did not provide an answer** (N=1)

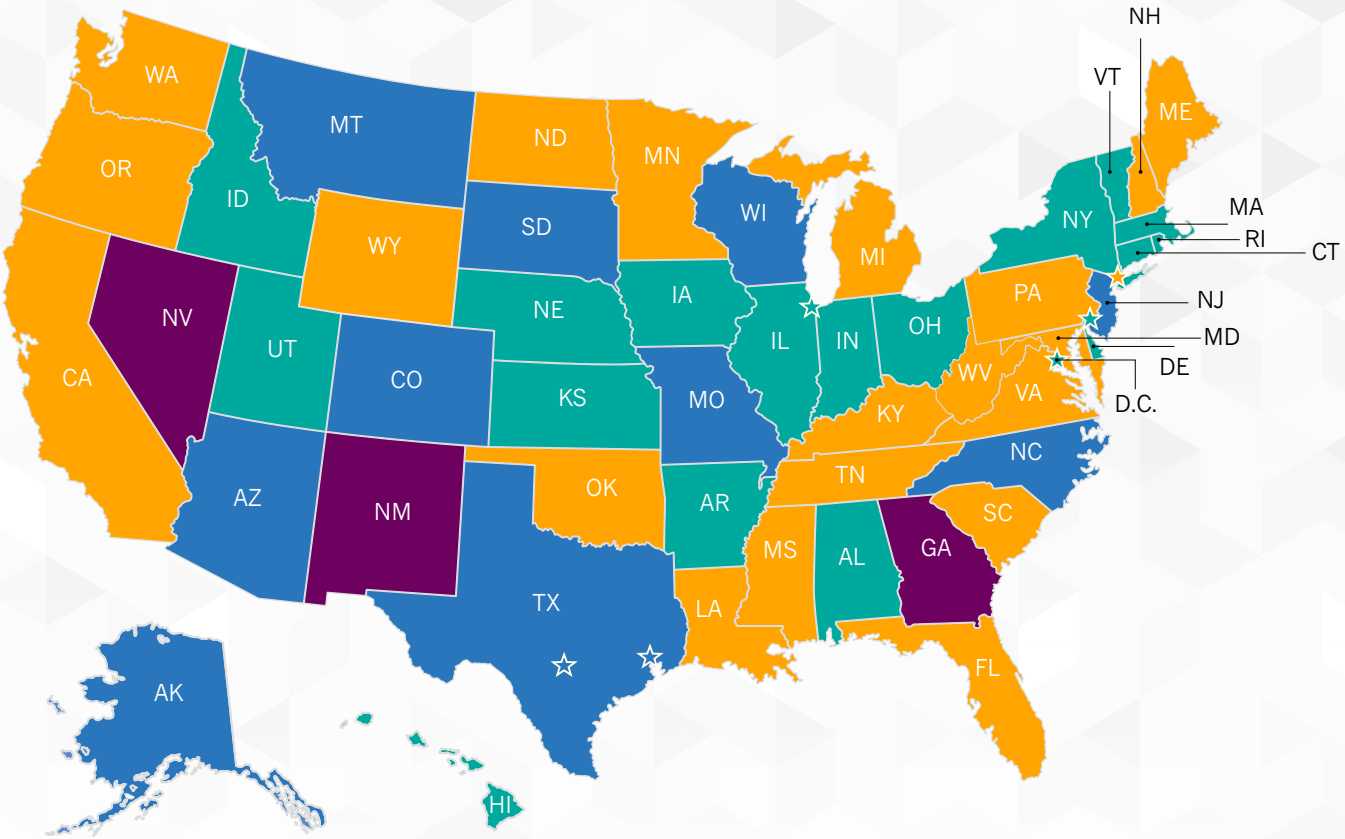
☆ U.S. Cities/Metro Areas
Chicago
District of Columbia
Houston
New York City
Philadelphia
San Antonio

U.S. Territories
American Samoa
Guam
Republic of Marshall Islands
Federated States of Micronesia
Northern Mariana Islands
Palau
Puerto Rico
Virgin Islands

Information collected from the 64 state, local and territorial IPs via an online survey that was administered July-August, 2017

FIGURE 2

As of January 1, 2018, IP plans to support DDL use in VFC providers offices



42%	**Program will purchase DDL for providers** (N=27)
33%	**Program will require providers to purchase a DDL of their choice that meets CDC requirement** (N=21)
4%	**Program will require providers to purchase a specific brand/vendor of DDL or choose from a list of recommended brands/vendors** (N=3)
19%	**Other – Combination of approaches** (N=12)
2%	**No answer (did not complete survey)** (N=1)

☆ U.S. Cities/Metro Areas
Chicago
District of Columbia
Houston
New York City
Philadelphia
San Antonio

U.S. Territories
American Samoa
Guam
Republic of Marshall Islands
Federated States of Micronesia
Northern Mariana Islands
Palau
Puerto Rico
Virgin Islands

Information collected from the 64 state, local and territorial IPs via an online survey that was administered July-August, 2017

Map depicts IP plans as of July-August, 2017. Actual support of DDL use in VFC providers offices may change by the January 1, 2018 requirement.

Eliminate Paper Logs. **Save** Time. **Save** Money. **Exceed** Compliance.

DIGI SmartTemps®

The Digi SmartTemps system of temperature monitoring devices saves you time and money, eliminates hand written paper logs, all while ensuring you exceed compliance standards. Our easy to use system works for any size operation, and fits perfectly into all budgets. Visit us online, or call today to see how Digi SmartTemps can help.

1-866-806-2653 | www3.smart-temps.com | josh.griggs@digi.com

SECTION II.
Implementation Approach

AIM
ASSOCIATION OF IMMUNIZATION MANAGERS

Lessons from the Field:
Digital Data Loggers

To help simplify and share common experiences, AIM categorized the implementation of the DDL requirement into three general approaches (the numbers do not reflect a preference for one approach over another):

APPROACH #1	Select and purchase DDL for providers
APPROACH #2	Require providers to purchase specific DDL brands/models
APPROACH #3	Allow provider choice of DDL

Information gathered from early adopters of vaccine storage DDLs points to various benefits and considerations for each approach and other considerations related to staffing, financing, and sustainability.

IP selecting and purchasing DDL for providers (Approach #1)

Benefits:

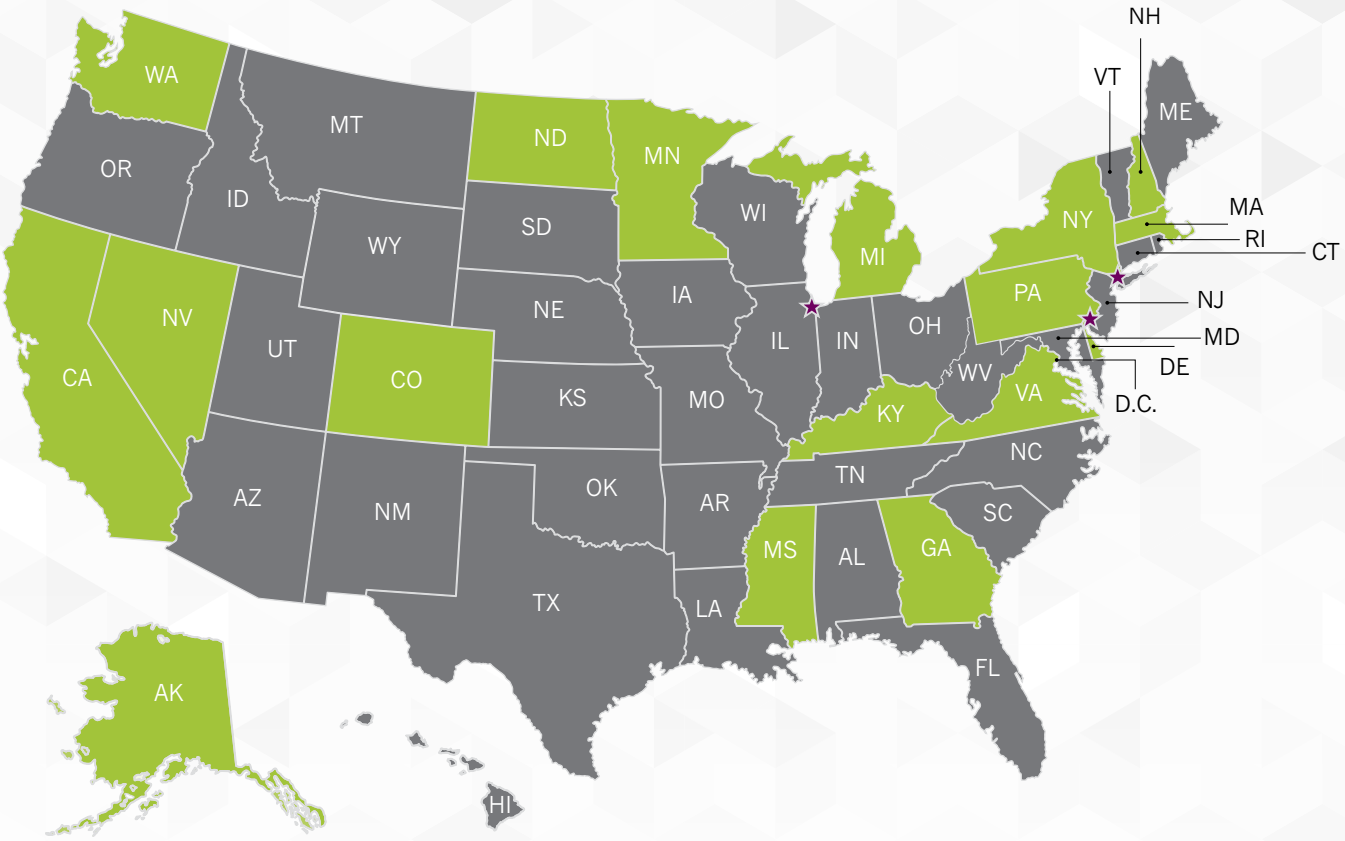
+ No cost to provider: eases the burden on provider, increases provider compliance, and reduces likelihood of provider dropout in VFC program
+ Volume purchasing power: increases ability to negotiate for better pricing, features, vendor training and vendor customer service
+ Assurance of conformity to VFC requirements
+ Control and consistency of DDL features: simplifies training for both IP staff and providers
+ Greater assurance that new provider staff who are responsible for vaccines will know how to use DDLs
+ Ability to manage calibration testing
+ Greater ability to help providers with technical support

Considerations:

+ Cost
+ Implementation burden: state/local/territorial purchasing mechanisms, regulations, and average time to complete
+ Choice of DDL brand and model
+ Assistance to providers with set up, maintenance, calibration testing, training, back-up thermometers, customer support and technical issues
+ Staffing: May require dedicated IP staff, increased staff time and training
+ Sustainability

FIGURE 3

2012 Prevention and Public Health Funds (PPHF) awarded to pilot test DDLs

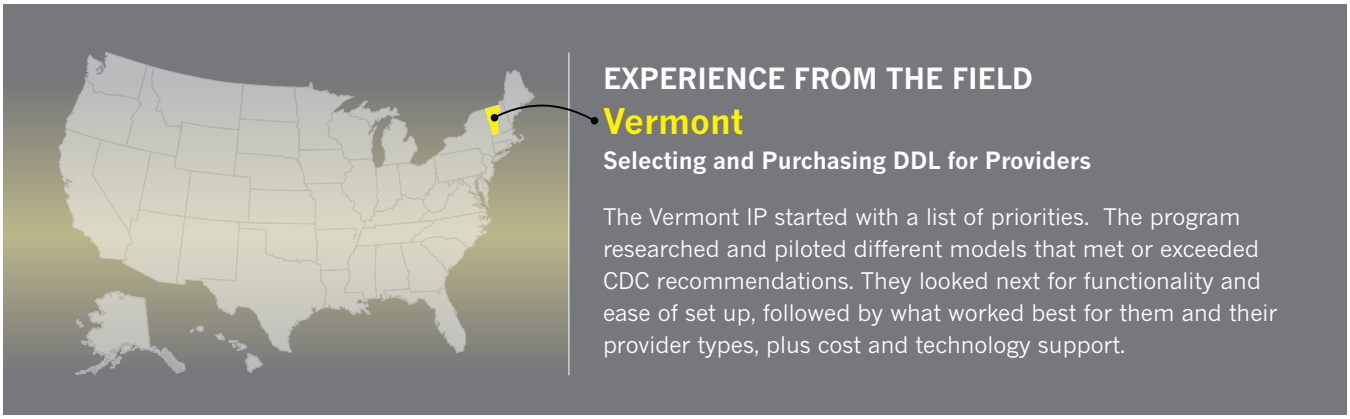


Awarded States

Awarded U.S. Cities and Territories

U.S. Cities/Metro Areas
Chicago
New York City
Philadelphia

U.S. Territories
Republic of Marshall Islands
Palau



EXPERIENCE FROM THE FIELD

Vermont

Selecting and Purchasing DDL for Providers

The Vermont IP started with a list of priorities. The program researched and piloted different models that met or exceeded CDC recommendations. They looked next for functionality and ease of set up, followed by what worked best for them and their provider types, plus cost and technology support.

Cost

Resources must be identified to support the purchase of DDLs for providers, including financing for increased IP staffing, funding to support initial purchase, and funding to sustain the DDL program. Resources are also needed to cover fees related to calibration testing and monthly maintenance of cloud-based systems.

Common funding mechanisms to purchase and sustain DDL:

- 2012 Prevention and Public Health Funding (PPHF) *(see Figure 3 [Map of historical PPHF funding])*
- State/territorial/local general funds
- State/territorial/local special funds earmarked for vaccine storage and handling improvements
- State funding from Medicaid Administrative Claims
- IP CDC cooperative agreement

Sustainability

Without additional and continuous funding, IPs may be forced to forgo purchase of DDLs and should be prepared to shift their approach strategy from select and purchase (Approach #1) to either select or recommend/require (Approach #2) or provider choice (Approach #3).

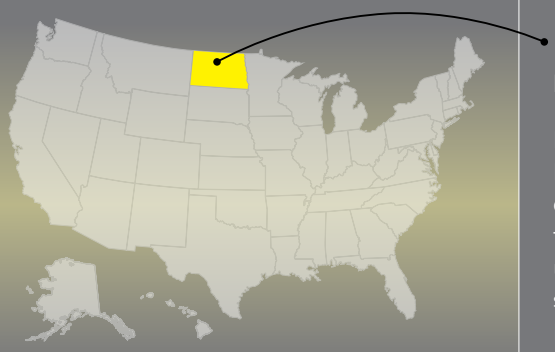
Shift in Purchase Strategy

Several IPs that previously purchased DDLs for providers have transitioned from purchasing to recommending or allowing provider choice. Other IPs plan to purchase the first DDL for providers but will require providers to purchase the subsequent devices.

The following suggestions may allow for a smooth transition when changing purchase policies:

- Focus on early and frequent provider communication for policy change and provide rationale
- Emphasize the value and continued benefit of DDLs
- Recommend providers look carefully at vendor/manufacturer support as part of purchasing agreement for new DDLs
- Encourage providers to use vendor/manufacturer support for technical questions

- Continue to work with vendors/manufacturers to update IP staff on variety of DDLs, including features, software requirements and provider training resources
- Plan to assign specialized staff (usually enables reduced staffing needs) for provider DDL support



EXPERIENCE FROM THE FIELD

North Dakota

Method for Shifting Support Strategy

North Dakota's IP purchased a round of DDLs for providers with PPHF funding, but told providers they would need to pay for calibration testing and future DDL purchases. The communication to providers provided rationale on the continued benefit of DDL use and informed providers of the dollar value of their existing stock of VFC vaccine. To assist providers in choosing their next DDL, the North Dakota IP developed a list of potential devices meeting CDC requirements.

Immunization Program Resources

- Rhode Island provider DDL request form: https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Logger_Request_Form.pdf
- Rhode Island vendor bid form for DDL: https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/RFQ_For_Data_Loggers_Final_Draft.doc

IP requiring providers to purchase specific DDL brand or model (Approach #2):

Benefits:

+ Assurance of conformity to requirements
+ Consistency of DDL features – easier training, technical support and data collection
+ Cost savings – IP not responsible for purchase of DDL
+ Ability to add requirements or enhancements as technology improves

Considerations:

+ Brand selection may cause conflict of interest and/or ethical considerations
+ Provider resistance to limitations on choice of DDL
+ Provider expectation of IP responsibility for selected DDL
+ Provider challenges with cost and sustainability of selected DDL

IPs allowing provider choice of DDL (Approach #3):

Benefits:

+ Less IP time spent on researching, pilot testing and selecting DDL
+ Elimination of DDL purchase funding issues
+ No involvement of IP finance or other purchasing agent
+ No potential conflict of interest issues
+ No DDL purchase sustainability issues
+ Less provider expectations of IP involvement in technical support

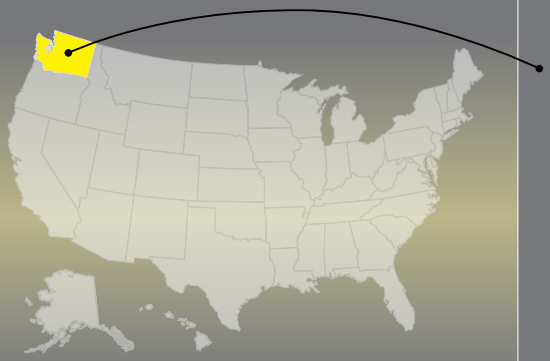
Considerations:

+ Less control over assuring that DDL meets requirements
+ Increased need for technical support for providers
+ Lack of consistency in DDL may require more IP staff training, resources and time
+ Lack of ability to add enhancements later, such as cloud-based access or data download
+ Slower acceptance of DDL by providers
+ More complicated software and technology needs for IP in order to read data files from multiple types of devices

Immunization Program Resources

- North Dakota guide for providers selecting DDL
  http://www.ndhealth.gov/Immunize/Documents/Providers/Forms/Thermometer_Guide2017.pdf
- Oregon guide for providers selecting DDL (see page 7-8)
  https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/vfc/Documents/VFCthermguide.pdf
- Tennessee guide for providers selecting DDL
  http://www.tn.gov/assets/entities/health/attachments/DATA_LOGGER_Info_Sheet.pdf
- Washington guide for providers selecting DDL
  https://c.ymcdn.com/sites/aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/348-538_Thermometer_Guide_for_2018.pdf

Regardless of implementation approach, adding the DDL requirement to provider vaccine storage and handling protocols is a major undertaking. IPs should expect and plan for increased staffing during the implementation phase to handle a variety of issues.



EXPERIENCE FROM THE FIELD

Washington

Allowing Provider Choice of DDL

The Washington IP prefers to be inclusive when selecting digital data loggers. They ran a pilot asking volunteer providers to test various loggers that would meet 2018 CDC requirements for DDLs. This enabled the IP to collect information, such as affordability, ease of use, vendor customer service, and overall functionality.

Staffing Needs

Below are common staffing demands reported during the implementation and maintenance phases.

IMPLEMENTATION PHASE:

- Communicate and enforce local and national requirements
- Respond to questions related to device set up and IT limitations (eg, firewall issues)
- Train providers on DDL use
- Answer questions related to increased number of DDL alarm notifications
- Provide guidance related to the increased awareness of temperature excursions:
  - Replacement of household combination refrigerators/freezers because they invariably have problems holding correct storage temperatures
  - Vaccine Wastage
  - Revaccination

MAINTENANCE PHASE:

- Continue to communicate and enforce local and national requirements
- Continue to provide guidance related to temperature excursions
- Identify and train new provider staff members
- Communicate and enforce policies related to DDL calibration testing

IP Words of Wisdom

> "At first we had only health educators taking calls, with many inquiries needing escalation to our medical director. We now have a centralized help desk with staff trained in handling excursions and setup questions. It is working well – we have multiple levels of expertise available."
>
> **— Oregon Immunization Program**

Early adopters of DDL technology have suggested that IP staff should be thoroughly and continuously trained and updated as to what to expect during DDL implementation and maintenance phases. With all three implementation approaches, IPs should prepare for a significant influx of demands on staff as DDLs are first implemented in provider offices. In time, staff may be reduced or roles/responsibilities can be changed to meet the lesser demands typically related to the maintenance phase.

There are common IP staffing strategies to consider regardless of the approach:

- Hire new full-time employees dedicated to DDLs
- Hire temporary staff for additional help during implementation phase
- Dedicate and train existing staff to assist without necessarily changing job descriptions
- Cross train all or some staff for support, particularly during implementation phase
- Utilize specialized IT support staff for data management and provider IT support
- Utilize DDL vendor customer support lines to assist with technical difficulties and issues with set up
- Ensure VFC site visit staff can provide DDL support, such as assisting with correction of DDL set up and assuring temperature excursion reporting
- Establish or incorporate DDL management support in a central help desk

Immunization Program Resources

- **Rhode Island quality assurance specialist job description**
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/QA_DDL.docx
- **North Dakota immunization quality assurance coordinator job description**
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/ImmunizationQA_Coordinator_TEMP__10-12.doc

Lessons Learned from Early Adopters | Choosing an Approach

1. Formulate policies early
As part of planning, develop clearly defined policies for temperature excursions, acceptable devices, provider monitoring and reporting, calibration testing, failure to comply with DDL requirements, etc.

2. Consider key factors when planning
Determine the best DDL approach based on budgetary considerations, staffing, IP management capacity for DDL set up/monitoring/calibration testing, and conflict of interest considerations.

3. Define staff protocols to manage DDL use in provider offices
During the planning phase, develop internal protocols for managing temperature excursions, technical questions, calibration testing, site visit training, and corrective actions.

4. Plan for adequate staff support
Plan for increased staff time and program resources during the first year of implementation and keep in mind that staffing demands will decrease with time.

5. Identify staff experts
Plan on at least some one-to-one assistance and support to providers during implementation. This assistance may include immunization program staff support for set up and troubleshooting of DDL, temperature excursion management and ongoing technical support.

FlashLink®

Certified Vaccine USB PDF Data Logger with Glycol Bottle

Designed for monitoring temperature conditions inside refrigerator and freezer storage units where vaccines and other temperature sensitive liquid medicines are kept.

Meets all updated CDC recommendations for January 2018, and guidelines in states where lowest temperature required for freezer monitoring is -50°C (-58°F)

Supplied preconfigured for either refrigerator or freezer. User programmable with FlashPDF Program Manager software (included).

Each unit comes with an ISO 17025 Calibration Certificate from in-house A2LA Accredited Lab

Model 40527

- Compatible with CDC guidelines
- 21 CFR Part 11 compliant
- Single channel, external sensor in glycol bottle
- Automatically generates encrypted PDF, CSV and Daily Log reports
- Glycol buffered sensor emulates products and prevents false alarms
- Ideal for monitoring vaccines and liquid medicines during storage
- Audible and/or visual alarms
- Low battery indicator on LCD
- Quick disconnect cable to download logger
- User programmable: manual or auto start, logging intervals, hi/low alarms
- Scroll through recorded data on LCD

Michelle Gonzalez
Inside Sales Representative - USA Vaccines for Children and Canada Life Science
mgonzalez@deltatrak.com
1-800-962-6776 ext. 4123

DeltaTrak®
www.deltatrak.com

SECTION III.

Brand and Model Choice

AIM
ASSOCIATION OF IMMUNIZATION MANAGERS

Lessons from the Field:
Digital Data Loggers

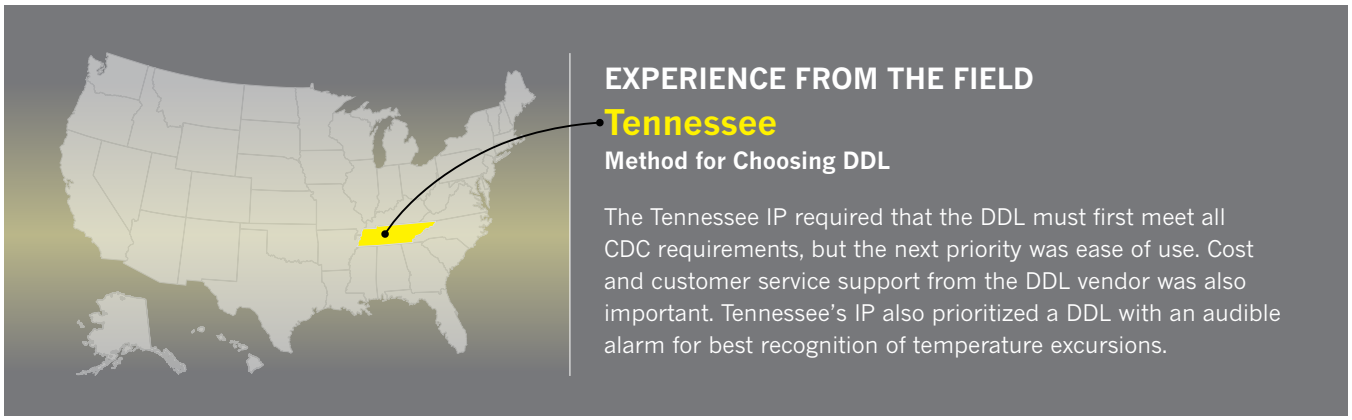
DDLs are available with varying features and functionalities. Some can be as basic as devices displaying min/max/current temperatures, while others have capabilities to send the temperature data to a central location, provide smart phone alarms and have calibration testing performed onsite without disconnecting the DDL.

Choosing a DDL

Based on suggestions from early adopters of DDL technology, IPs should have a clear understanding of CDC requirements (as outlined in the CDC VFC Operations Guide) as well as their own program goals. IPs should consider additional features, such as Wi-Fi, SMS, bluetooth, cloud-based technologies and DDL integrated storage units regardless of which implementation approach selected.

Some of the major considerations for choosing a DDL among the early adopters included:

- Ability to meet CDC requirements
- Cost
- Specific feature, such as ability to transmit data to their Immunization Information System (IIS)
- Type of system: simple and basic, or a DDL with extensive features



EXPERIENCE FROM THE FIELD

Tennessee

Method for Choosing DDL

The Tennessee IP required that the DDL must first meet all CDC requirements, but the next priority was ease of use. Cost and customer service support from the DDL vendor was also important. Tennessee's IP also prioritized a DDL with an audible alarm for best recognition of temperature excursions.

Vendor Insight

"Providers ranging from pediatricians to school nurses expressed interest in a DDL that can send a real-time alert if there is an excursion and can reach recipients remotely."

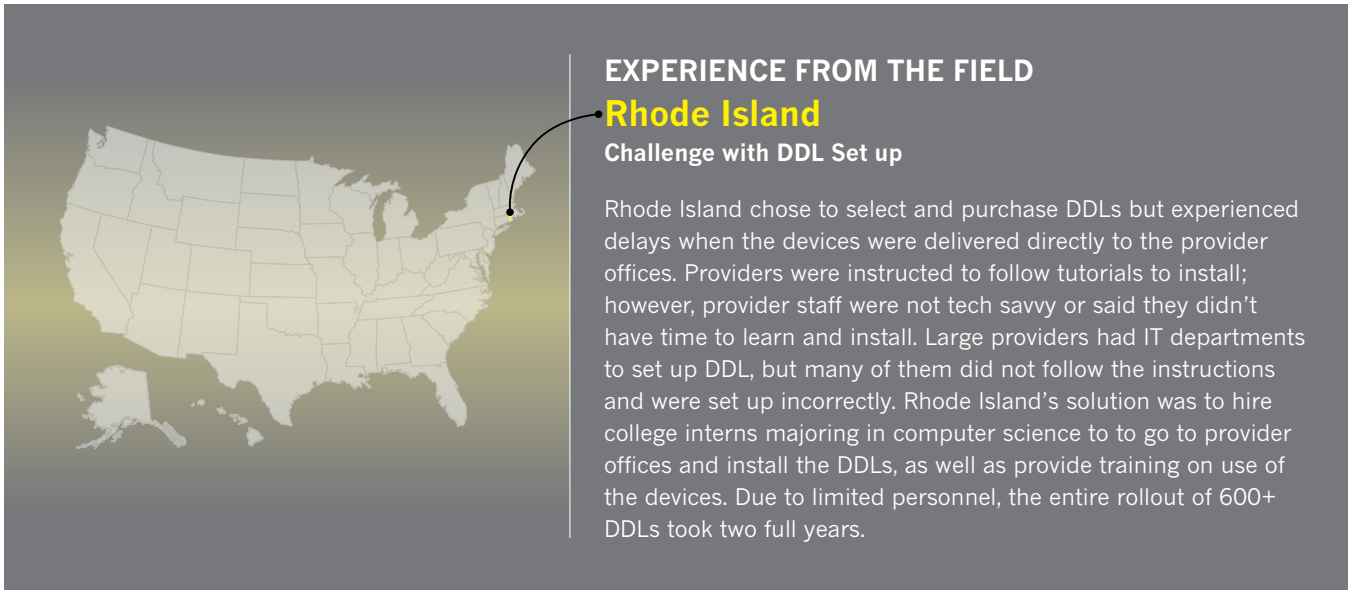
— **Berlinger (DDL Vendor)**

Assessing Program Needs

Assessing IP goals and expectations is important when evaluating DDL choices. The following are examples of questions that an IP should consider when determining the desired features.

Does the IP:

- Currently require providers to report temperature monitoring data?
- Analyze vaccine storage and handling and/or temperature data?
- Have tech-savvy providers?
- Have desire and capacity to monitor vaccine temperatures in provider offices?
- Have an IIS or other capacity to receive temperature data?
- Have a high percentage of providers using combination refrigerator units?
- Have sufficient staff to support goals and sufficient resources for provider education and training?
- Have state/local security or other requirements for cloud-based systems?



EXPERIENCE FROM THE FIELD

Rhode Island

Challenge with DDL Set up

Rhode Island chose to select and purchase DDLs but experienced delays when the devices were delivered directly to the provider offices. Providers were instructed to follow tutorials to install; however, provider staff were not tech savvy or said they didn't have time to learn and install. Large providers had IT departments to set up DDL, but many of them did not follow the instructions and were set up incorrectly. Rhode Island's solution was to hire college interns majoring in computer science to to go to provider offices and install the DDLs, as well as provide training on use of the devices. Due to limited personnel, the entire rollout of 600+ DDLs took two full years.

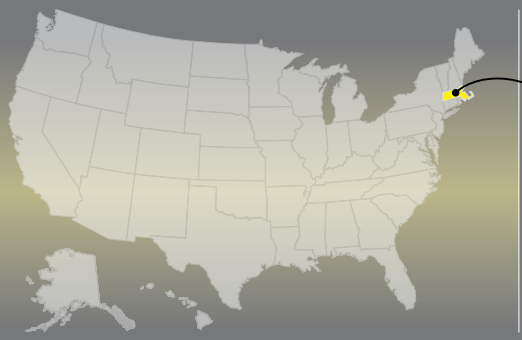
Assessing Provider Needs

It may be helpful to survey providers to determine their needs and preferences prior to choosing a DDL to purchase or requiring providers to purchase. The following are examples of questions to ask regarding desired features:

- Is the provider currently using a DDL and what is the brand?
- If currently using a DDL, what features do they like/dislike?
- Is the provider's office linked to a central temperature monitoring system?
- What kind of vaccine storage unit does the provider currently use?
- Does the provider need to connect multiple storage units via Wi-Fi/cloud?
- What staff will receive training for DDL set up and use?

Vendor Insight

"The simpler the DDL is to use, the better."
— **TempArmour Refrigeration (Vaccine Refrigerator Vendor)**



EXPERIENCE FROM THE FIELD

Massachusetts

Survey Provider Needs

The Massachusetts IP surveyed providers during the DDL planning stage and learned that one-third of them were not able to download or install software without IT support. This led the IP to choose a DDL that did not require software.

Immunization Program Resources

- Massachusetts surveys to providers
  Version1: https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Data_Logger_Initial.pdf
  Version2: https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Data_Logger_Survey.pdf
- Rhode Island survey to providers
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Logger_Survey.pdf

Piloting DDLs

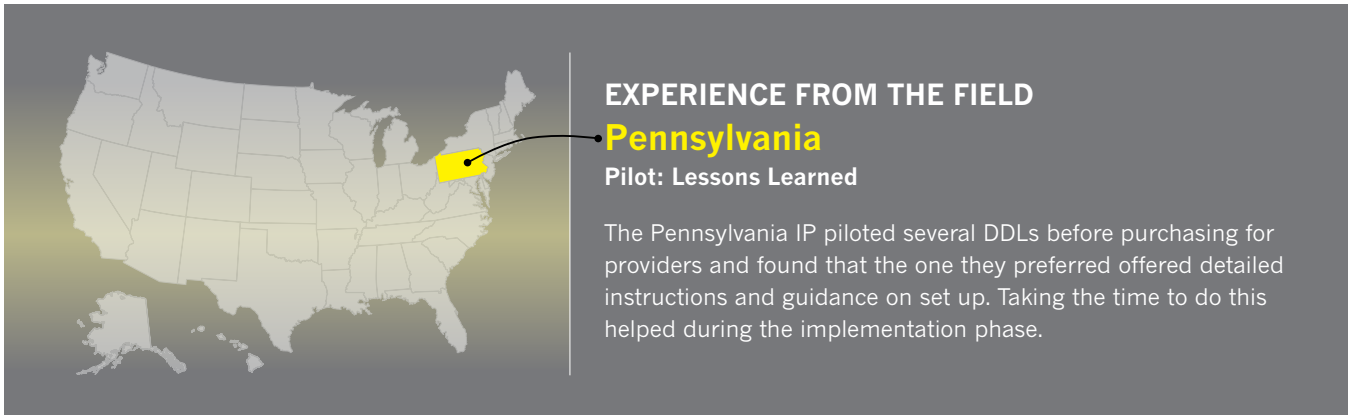
Piloting several DDLs may help both providers and IPs learn more about the various types of DDLs, desired features and functions, training needs, and policy planning.

Consider the following when planning a DDL pilot:

- Meet with a select group of vendors/manufacturers
  - ask about customer service and resources provided
  - inquire about existence of pilot program service
- Ensure that any DDL to be piloted meets VFC requirements at minimum
- Survey providers to determine devices currently in use and collect feedback on DDL experience
- Decide on additional features or capabilities desirable for providers
- Review AFIX listserve for comments from other IPs that have piloted the same DDL
- Develop a list of questions or criteria for DDL vendors/manufacturers to assist in pilot selection process
- Pilot in provider offices to collect real-life experience directly applicable to device function
- Develop a chart of provider experiences with piloted DDLs, including ease of set up, use, data management, features and customer service

Immunization Program Resources

- **North Dakota pilot results webinar & report**
  Webinar: https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Data_Loggers_ND_August_2015.pptx
  Report: https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Guidance_Final_Progress_and_Performance_Report_ND_MH_MB_AB.docx



Vendor Insight

"Before making a DDL purchase, talk with other owners of that brand. Get references from non-sales people. Talk with other people like yourselves. Peer references seem to be extremely valuable.."

— LogTag Recorders (DDL Vendor)

Learn More About the Various Brands of DDLs

The AIM Virtual Exhibit Hall (VEH) is a series of informational presentations showcasing vaccine-related products. Each VEH webinar features a company sharing its product in a 20-minute presentation followed by a question-and-answer period. All companies participating in the VEH also supply a fact sheet answering Frequently Asked Questions (FAQs). Both the webinar recording and the FAQs are available for future viewing.

Go to www.immunizationmanagers.org/VirtualExhibitHall to access the VEH webinar recording and FAQ sheet for the following DDL vendors:

---

berlinger
feel safe

CONTROL COMPANY
TRACEABLE PRODUCTS | SpaceableLIVE
Vaccine Temperature Monitoring. Embrace Technology.

DeltaTrak

ONSET
InTemp® Monitoring Solutions

LogTag Recorders

Lessons Learned from Early Adopters | Brand and Model Choice

1. Choose a DDLs
Consider more than meeting minimal requirements when choosing DDL device. Any DDL must minimally meet CDC requirements. Other considerations include ease of use, cost, technical and training support by vendor, provider needs including provider staff knowledge, and ability to enhance or upgrade.

2. Consider a Method to Approve DDL Units After Set-up
Consider a site visit to providers. Site assessment is the most common way to assure that DDL are set up and used properly, as well as for temperature excursion identification and follow up.

ONSET

VFC-Compliant Vaccine Storage Monitoring

InTemp CX402-VFC data loggers monitor temperatures in refrigerators, freezers, and other temperature-controlled environments. Designed to streamline data collection and reporting, InTemp meets all of the requirements for the CDC Vaccines for Children program as well as hospitals, clinics, and WHO sites.

NEW!
Get real-time alerts and automatic data downloads with CX Gateway!

- Get remote notifications of temperature excursions with new CX Gateway device
- Automatically download data from one or more loggers within range of the new gateway
- Easily transfer logger data to the free InTempConnect cloud storage
- Wireless set up and download via Bluetooth Low Energy to mobile devices

Visit on.onsetcomp.com/aim
Call 1-866-244-3197
Email sales@onsetcomp.com

SECTION IV.

Data Oversight and Management of Temperature Excursions

AIM
ASSOCIATION OF IMMUNIZATION MANAGERS

Lessons from the Field:
Digital Data Loggers

immunizationmanagers.org/DDL

The CDC VFC Operations Guide requires providers to record temperatures daily and IP staff members to review temperature records during site visits (See CDC VFC Operations Guide and CDC VFC Compliance Site Visit Reviewer Guide for specific requirements). However, IPs can choose to provide additional DDL data oversight to ensure vaccine is kept at correct storage temperatures.

There are three methods to provide additional DDL data oversight:

METHOD #1	IP assumes responsibility for data oversight via cloud-based system
METHOD #2	IP requires regular reports of DDL data from provider, such as before vaccine orders
METHOD #3	IP reviews DDL data only in certain situations, such as an alarm notification or during VFC compliance site visit

Data Oversight

The following are the benefits and considerations related to each method of DDL data oversight.

IP assumes responsibility for data oversight via cloud-based system. (Method #1)

A cloud-based system utilizes the Internet to transport data from DDLs in provider offices to an offsite location such as the health department. The provider office staff may not be responsible for monitoring the temperature. Instead, the temperature it is monitored by staff located at an offsite location. For example, large health care facilities have centralized their temperature monitoring via the cloud in the pharmacy. Pharmacists are responsible for checking temperatures, responding to alarms and following up on potential temperature excursions. An IP can also use this system by centralizing all provider temperature data collection in the IP.

Benefits:

+ Ability to identify and address out-of-range temperature conditions in real time
+ Assurance that temperature excursions are not going unnoticed
+ Ability to identify and replace storage units incapable of maintaining proper vaccine storage temperatures
+ Ability to collect and analyze universal provider data

Considerations:

- Provider reliance on IP staff to monitor temperature changes may result in provider complacency about DDLs and vaccine-temperature oversight
- Additional staff and resources may be needed to review data, especially during the implementation phase
- Cloud-based systems require additional resources and may require added data security

Vendor Insight

"The greatest challenge for providers in properly maintaining DDL is remembering to check the display for out-of-range temperatures. Continuous monitoring systems remove this challenge and alert site-level contacts for temperature excursions and power outages."

— DIGI SmarTemps (DDL Vendor)

IP requires regular reports of DDL data from provider, such as before vaccine orders. (Method #2)

Benefits:

- Assurance that temperatures are monitored on a regular basis
- Establishes temperature monitoring culture promotes accountability and awareness of providers

Considerations:

- Potential burden on IP staffing to review large amount of temperature data
- Greater provider training needs to assure data collection and analysis

IP Words of Wisdom

"We found that providers were overlooking temperature excursions, and the only time they were identified was when the VFC coordinator reviewed them during site visits. In some cases, we found that nonviable vaccine (discovered during our review) had already been administered, thus leading to revaccination. We review DDL data weekly, preferably first thing Monday morning."

— Oregon Immunization Program

IP reviews DDL data only in certain situations, such as an alarm notification or during VFC compliance site visit. (Method #3)

Benefit:

+ Low burden on IP staff
+ Increased provider responsibility for temperature monitoring leads to greater accountability and understanding of temperature fluctuations

Considerations:

+ Increased chance that excursions will not be caught or may only be identified during a site visit
+ Lack of required provider reporting may lead to provider complacency
+ Loss of information that may be needed in the event of a temperature excursion
+ Increased provider education and training may be needed

IP Words of Wisdom

"Using a DDL was a big eye opener because of the increase in recognized excursions. Since most clinics were new to this technology, every out-of-range reading (no matter how slight) generated a call to our office."

— Oregon Immunization Program

DDL Data Oversight: Implementation Tips

- Develop IP protocols on how to handle various implementation issues.
- Consider requiring providers send temperature data with every vaccine order. Data should include all temperature logs since the last order.
- Consider reviewing temperature data before filling any provider order.
- Include in provider DDL training, information on temperature excursion recognition and response.
- Alert providers to the possibility of temperature excursion alarms, especially if a provider is using a household combination refrigerator/freezer.
- Discourage providers from using more than one temperature monitoring device in a storage unit. This only confuses providers as to which device is correct.
- Routinely communicate with providers to review DDL data and investigate excursions according to IP protocols.

Common Policy and Procedures for DDL Data Monitoring

There are policies and procedures to develop based on each method for DDL data oversight. Below are factors to consider when developing IP and provider policies and procedures:

IP ASSUMES RESPONSIBILITY FOR DATA OVERSIGHT VIA CLOUD BASED SYSTEM (METHOD #1)

- Frequency of IP staff data review (eg, daily, weekly)
- Prioritization of response to alarm notifications, especially during the implementation phase, when influx of alarm notifications can be expected
- Length of time for out-of-range temperature to trigger alarm
- Protocols for action following an alarm notification or out-of-range temperatures for various lengths of time, ie, when to contact the provider, when to contact the manufacturer, etc.
- Managing providers who do not respond to alarm (see section VII Provider Compliance)
- Communication with providers to review DDL data and investigate excursions according to IP protocols

IP REQUIRES REGULAR DDL REPORTS AND REVIEWS ON A REGULAR BASIS, SUCH AS BEFORE VACCINE ORDERS (METHOD #2)

- Frequency of provider DDL data submission (eg, weekly, monthly, before orders)
- Format for data submission (eg, IIS, email, fax, etc.)
- Length of time for out-of-range temperature to trigger alarm
- Protocols for action following an alarm notification or out-of-range temperatures for various lengths of time, who contacts the manufacturer, etc.
- Managing providers who do not respond to alarm (see section VII Provider Compliance)

IP REVIEWS DDL DATA ONLY IN CERTAIN SITUATIONS, SUCH AS AN ALARM NOTIFICATION OR DURING VFC COMPLIANCE SITE VISIT (METHOD #3)

- Frequency of staff review of DDL data
  (eg, alarm notification, annual enrollment period, randomly, during site visits, etc.)
- Length of time for out-of-range temperature to trigger alarm
- Format for DDL data submission (eg, IIS, email, fax, etc.)
- Type of file formats to be sent from provider to IP
- Managing providers who do not respond to alarm (see section VII Provider Compliance)

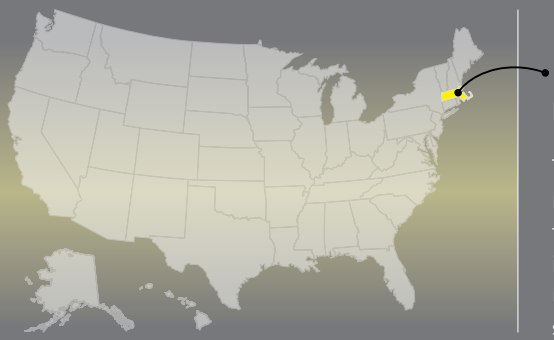
Vendor Insight

"Providers need to know how to correctly set up alarms. The alarm can go off 10 times per day and then providers stop caring about it. Providers can become desensitized to alarms."

— Onset (DDL Vendor)

Immunization Program Resources

- **Rhode Island cloud-based temperature monitoring lessons learned: NIC Presentation**
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Cloud_Based_Logging.pptx



EXPERIENCE FROM THE FIELD

Massachusetts

Massachusetts' Approach to Monitoring DDL Data

The Massachusetts IP requires all providers to report out-of-range temperatures. The IP evaluates temperature data before filling orders. They have found that, especially early in DDL implementation, out-of-range temperatures are not discovered until ordering. Massachusetts is working to build a system to support provider download of temperature data to the IIS.

IMPORTANT NOTICE

As of Jan. 1, 2018, nine IPs* will require or allow providers to report DDL data through the IIS.

* Arizona, Florida, Kansas, New York City, New York State, Maine, Massachusetts, New Mexico and Philadelphia
— Data from AIM DDL Survey
53 of 64 IPs responded to survey

Managing Excursions

With the implementation of DDLs, IPs should expect an increase in recognition, reporting, and follow-up to temperature excursions. A temperature excursion occurs when the refrigeration/freezer unit is operating outside of the recommended temperature range. IPs need to have policies in place in response to temperature excursions to define and manage vaccine waste, revaccination and restitution (see CDC VFC Operations Guide and CDC VFC Compliance Site Visit Reviewer Guide for requirements and recommendations). Early adopters of DDLs have suggested that IPs prepare for excursions by considering specific DDL staff demands and common situations that can lead to excursions.

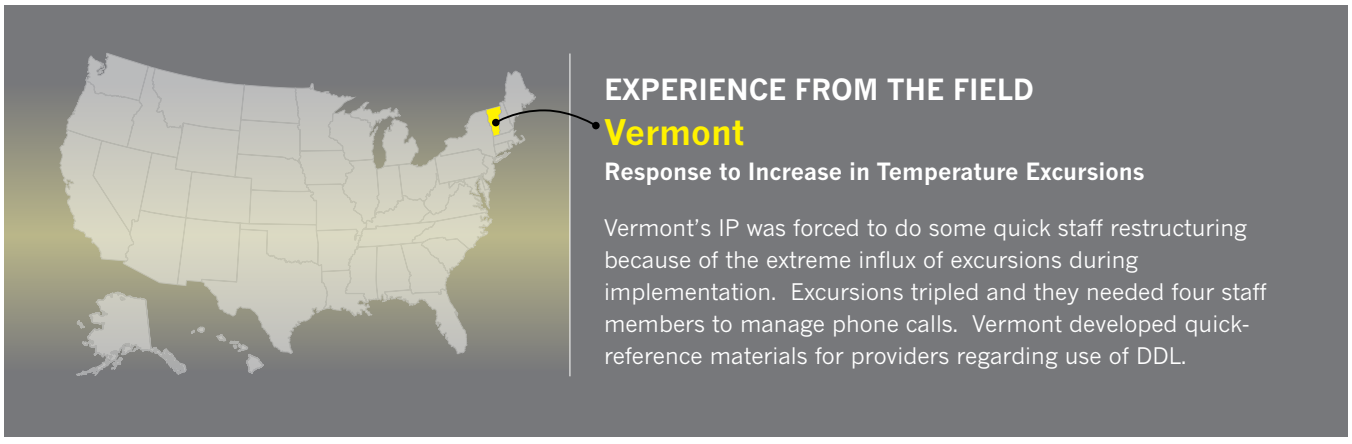
IP Staff Demands

There are increased staffing demands that should be expected with DDL implementation.
Staff time will be needed:

- To answer provider questions about temperature excursions that were not previously identified when only checking temperatures twice daily.
- To manage the recognition and replacement of storage units that demonstrate the inability to maintain correct temperatures.
- To problem solve with provider and DDL vendor if the excursion was caused by an improperly installed or faulty DDL.
- To follow-up with providers to ensure that the original problem causing the temperature excursion is corrected.
- During site visits to identify provider DDL practices that can reduce temperature excursions.

Immunization Program Resources

- North Dakota staff protocol for managing excursions
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Managing_out_of_range_temperature.docx
- Tennessee staff temperature excursion procedures & tracking form
  Procedures: https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Temperature_Excursion_Procedures_Final.pdf
  Tracking Form: https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/TempExcursionIntakeSheet_updated_5-24-17_LW.docx



Provider DDL Practices that Lead to Excursions

There are many common provider DDL practices that can lead to temperature excursions, and IPs should plan accordingly to identify and respond appropriately. These include but are not limited to:

- Improper DDL set up or placement of the probe
- Improper set up of DDL alarm interval
- Turning off/ignoring DDL alarms
- Inadequate training of provider staff on DDL operation
- Continued use of DDL devices with expired calibration dates
- Lack of back-up calibrated DDL device
- Lack of back-up battery on site or not replacing DDL battery
- Incorrect download of DDL data or not downloading at regular intervals

Immunization Program Resources

GUIDANCE DOCUMENTS FOR PROVIDERS

- **Tennessee VFC provider handbook - reporting a temperature excursion** (see page 28)
  http://www.tn.gov/assets/entities/health/attachments/VFC_Provider_Handbook.pdf
- **Tennessee temperature monitoring and excursion guidance: public health department & non-health department**
  http://www.tn.gov/assets/entities/health/attachments/Temp_Monitoring_Excursion_Guidance_-_HD.pdf
  http://www.tn.gov/assets/entities/health/attachments/Temp_Monitoring_Excursion_Guidance_-_Non_HD.pdf
- **North Dakota vaccine storage troubleshooting guide**
  http://www.ndhealth.gov/Immunize/Documents/Providers/Forms/Vaccinetroubleshootingguide10-27-2016.pdf
- **Vermont temperature excursions protocol**
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Temperature_Excursions_Protocol_2017.pdf

COMMUNICATION TO PROVIDERS

- **Tennessee memo to providers informing how to report temperature excursions**
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/TE_memo_7-26-16_klm7-28-16.docx
- **North Dakota memo to providers to replace storage unit**
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Replace_unit_Final_Sample.doc

Lessons Learned from Early Adopters | Managing Excursions

Plan for increased temperature excursions. Be prepared for initial large increases in recognized temperature excursions, especially with combination household units for vaccine storage. Providers may need to replace storage units and you may receive push back on additional expense.

Meet the industry's new star player.

Built-in audible alarm

(Optional) Glycol Buffer to mirror the temperature environment inside a vaccine vial.

New, easy to read LCD display with 30 day summary.

Interchangeable External Probe with high quality gold plated connector.

Up to 15,900 recordings. Enough memory for 66 days at 6 minute logging.

Introducing the new: LogTag TRED30-16R

-40°C to +99°C (-40°F to +210°F) measurement range via an External Probe.
The display is designed to show 'at a glance' if temperature excursions have occurred and a built-in audible alarm will sound when an alarm is active.

LogTag Recorders

www.logtagrecorders.com

SECTION V.

Maintenance: Calibration Testing

AIM
ASSOCIATION OF IMMUNIZATION MANAGERS

Lessons from the Field:
Digital Data Loggers

DDLs must undergo calibration testing after a certain timeframe of use ***(see CDC VFC Operations Guide)*** according to DDL brand specifications. Calibration testing proves the accuracy of a data logger by testing the instrument according to an internationally recognized standard for calibration and traceability. All temperature monitoring equipment will drift over time and frequency of use. In addition, sensors and probes become inaccurate if misused, mishandled or damaged. Calibration testing should be done through a nationally or internationally recognized testing laboratory with proven accuracy standards and appropriate equipment.

IPs can either choose to manage or require providers to manage DDL calibration testing. With each method, there are benefits and considerations, as well as practices that can be employed to ensure successful calibration testing.

IP assumes responsibility for calibration testing. (Method #1)

Benefits:

+ Enables IP to monitor testing dates and notify providers
+ Helps ensure that DDL are current and accurate
+ Can be easily checked and documented during site visits

Considerations:

+ Requires staff time to manage data on calibration testing and coordinate with providers
+ Requires additional planning, provider coordination, and coordination with testing facility
+ Requires assurance of additional DDL so that provider storage units are not without DDL during calibration testing
+ Requires resources to pay for calibration testing
+ May require additional funding for purchase of DDL for use by providers during calibration testing
+ May require VFC site visit staff to carry additional DDL for provider use

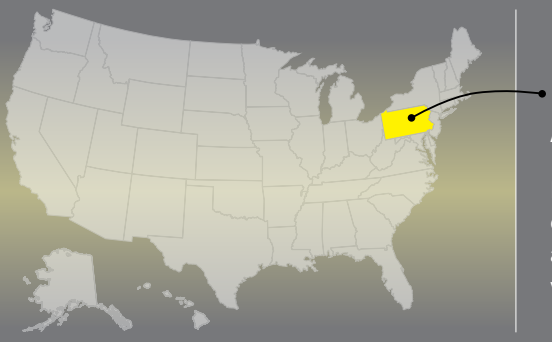
Provider assumes responsibility for calibration testing. (Method #2)

Benefits

+ Provider can choose to pay for calibration testing or purchase new DDL
+ Certificate of calibration can be checked during site visit
+ No additional IP staff time needed to track calibration dates and notify providers
+ Encourages providers to be accountable for DDLs with current calibration
+ No additional IP funding required for testing or purchase of additional DDL
+ Calibration testing date can be added as part of provider enrollment agreement

Considerations

- If calibration certificate is expired and discovered during site visit, provider cannot continue to use storage unit without another calibrated DDL
- Different vendors and different DDLs have different dates for calibration testing, making it difficult to track
- Providers forget about calibration testing dates, lose certificates of calibration testing and don't understand need for calibration testing
- Provider may dislike having to check and pay for calibration testing
- Calibration testing becomes part of compliance and can lead to consequences of noncompliance including delay in orders, suspension and termination



EXPERIENCE FROM THE FIELD

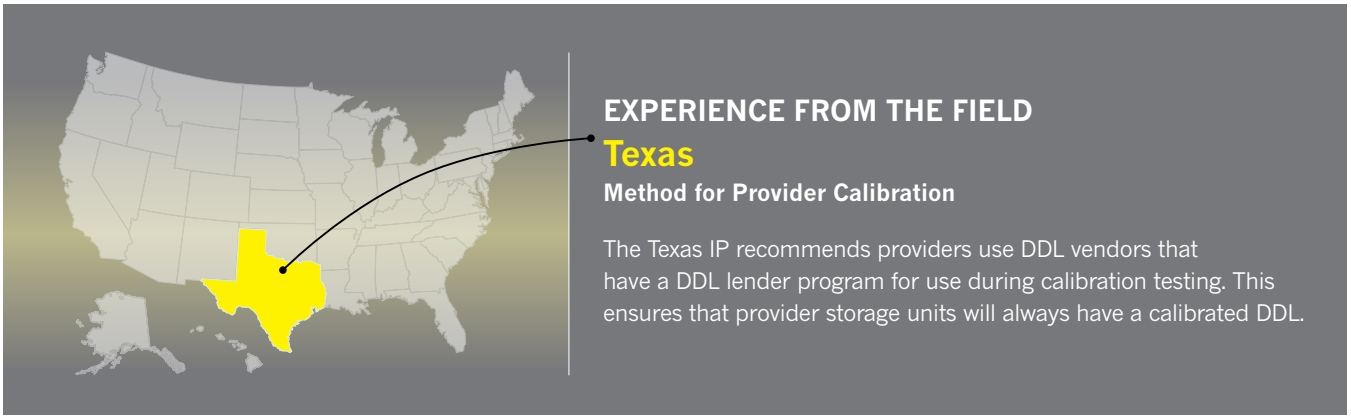
Pennsylvania

Approach to Expired DDL Calibration

Pennsylvania's IP suspends providers from ordering if DDL calibration is not up to date. The medical director is informed and he/she determines when the provider may return to routine vaccine ordering.

Calibration Testing: Implementation Tips

- The IP can track expiration dates of calibration for providers on a master spread sheet and notify providers when it is time to retest.
- If the IP purchases the DDL and funds are available, the IP can purchase additional units to lend to providers who need temporary replacement DDL while their units are out for calibration testing.
- If the IP purchases all DDLs, the IP can request all units have the same calibration testing date, so there is no need to track dates.
- IP can request providers include calibration testing dates on their annual provider enrollment.
- IP can request the vendor provide calibration testing dates to the IP if providers are required to use the same DDL.
- IPs can educate providers on the advantage of staggering primary and back-up DDL calibration testing due dates.



EXPERIENCE FROM THE FIELD

Texas

Method for Provider Calibration

The Texas IP recommends providers use DDL vendors that have a DDL lender program for use during calibration testing. This ensures that provider storage units will always have a calibrated DDL.

Common Practices and Considerations for Calibration Testing

IP ASSUMES RESPONSIBILITY FOR CALIBRATION TESTING (METHOD #1)

- Plan on additional IP staff time for coordination of DDL calibration testing
- Obtain database of DDL calibration testing dates, either through device manufacturers or develop one with information directly from providers
- Communicate early with providers regarding plans for DDL recalibration

If the IP selects and purchases DDL for providers:

  - Decide whether the IP will simply replace the DDL when calibration testing is due
  - Purchasing new DDL may be more costly than calibration testing; therefore, this may be a consideration if the IP is providing the DDL
  - When purchasing DDLs, stagger calibration testing dates so as to lessen the workload on staff
  - Inquire if vendors have a DDL lending program while provider unit is being recalibrated
  - Purchase additional DDLs to give to providers while their devices are out for calibration testing

PROVIDER ASSUMES RESPONSIBILITY FOR CALIBRATION TESTING (METHOD #2)

- Educate providers on the rationale for DDL calibration testing
- Enact policies outlining timeframes for DDL calibration testing and consequences of noncompliance
- Encourage providers to maintain primary and back-up DDL units with staggered calibration testing dates
- Encourage providers to ask DDL vendors if notification of calibration testing is part of customer service and if they have a DDL lending program while their unit is being calibration tested
- Obtain DDL calibration testing dates on provider VFC annual enrollment forms to help manage compliance

Vendor Insight

"Knowing when to recalibrate is a big challenge for providers. We get countless calls from providers when expired DDL calibration is discovered at site assessment. If no system is in place to notify providers when to recalibrate, many struggle. Not just when, but how to calibrate. Many don't know until the auditor is there and it is too late. It's helpful or IPs to maintain a spreadsheet with serial numbers and expiration dates – then do monthly checks. Providers can use outlook calendar or some kind of reminder for calibration."

— Control Company (DDL Vendor)

Lessons Learned from Early Adopters | Managing DDL Calibration Testing

Plan ahead for recalibration: Considerations for managing and assuring calibration testing need to be thought through as part of early planning.

LASCAR electronics

VACCINATION MONITORING

The Lascar EasyLog family of vaccination data loggers is an inexpensive series of standalone USB and WiFi-enabled sensors allowing discrete and continuous temperature monitoring of vaccines. Exceeding Center for Disease Control guidelines on data loggers used in vaccination storage, these sensors are supplied with glycol bottles and a calibration certificate.

Center for Disease Control Guideline on Minimum Data Logger Features

High/low alarms to alert out of range temperatures	✓	At least 4,000 readings stored	✓
Display of current, min and max temperature readings	✓	Data loops when memory is full	✓
Reset button for min and max readings	✓	Detachable temperature buffered probe	✓
Low battery indicator	✓	User programmable logging rates are available	✓
Accuracy ±0.1° C / ±0.2° F	✓	Integral magnet to affix logger to outside of storage unit	✓

USB Stand Alone Monitoring

EL-USB-TP-LCD-PROBE-G

The EL-USB-TP-LCD-PROBE-G is a handheld, battery powered data logger that measures and stores temperature readings on-board until data is downloaded from it via USB. Simple to set-up, the user just plugs this device into the computer's USB port and, using Lascar's FREE configuration software, names the device, chooses a sampling rate, selects high and low alarms and a logging start time. Place the glycol bottle into the area of vaccine storage and secure the logger on the outside of the fridge or freezer using the magnet included in the pack.

An alarm breach is indicated by a flashing red LED. In the event of a breach, plug the unit into the computer USB port and download data using Lascar's free software. Data can be viewed in graphical or tabular form.

WiFi Remote Monitoring

EL-WiFi

Remove the need for physical data retrieval and logger set up with the EL-WiFi. The EL-WiFi-TP+-PROBE-G allows remote data collection over a WiFi network to either a single host PC or the Cloud. Using Lascar's FilesThruTheAir™ Cloud Service, users can remotely view multiple EL-WiFi data loggers in multiple locations from any internet-enabled device or using the Apple or Android FilesThruTheAir App, change settings, access 'Event Logs' for a record of any past triggered alarm events and graph sensor data online or set up e-mail alerts which will notify them as soon as an alarm event happens.

21 CFR Compliance

Lascar's latest software offering allows users to store data in compliance with the regulations of 21CFR Part 11. As well as the core offerings of Lascar's existing EasyLog software, individual users can now be assigned specific permissions. The readings collected from the data logger are stored in an encrypted format which cannot be edited. EasyLog21CFR software provides a full audit trail of activities, with users able to add comments to specific readings before being approved by an authorized user. Electronic signatures are added to all of the reports to show who has started, stopped and approved the session data. The software is compatible with data loggers monitoring temperature, relative humidity and dew point.

SECTION VI.

Provider Education and Training

AIM
ASSOCIATION OF IMMUNIZATION MANAGERS

Lessons from the Field:
Digital Data Loggers

Experience has shown that provider education is necessary to ensure compliance, according to early adopters of DDLs. The CDC has specific vaccine management training requirements that should be the basis of an educational approach ***(see CDC VFC Operations Guide Training for requirements)***. IPs can choose to facilitate DDL specific training and/or depend on vendor/manufacturer training resources.

There are advantages and challenges related to program- versus vendor-facilitated DDL training, and suggestions for refresher training.

Choosing an Educational Approach

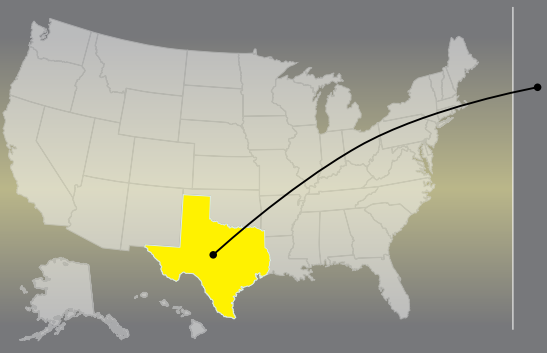
IP-Facilitated DDL Training and Education (Approach #1)

Benefits

+ IP can coordinate multiple training tools
+ IP can develop personalized training tools that include IP-specific requirements, recommendations and expectations
+ IP can benefit from tools developed by other IPs
+ IP can assure the provider has been trained by tracking attendance at training events, participation in webinars, completion of learning modules, etc.

Considerations

+ Requires more staff time and resources for development of training tools and support
+ Providers may see IP as first option for problems and rely on IP for support to resolve any issues, including technical support



EXPERIENCE FROM THE FIELD

Texas

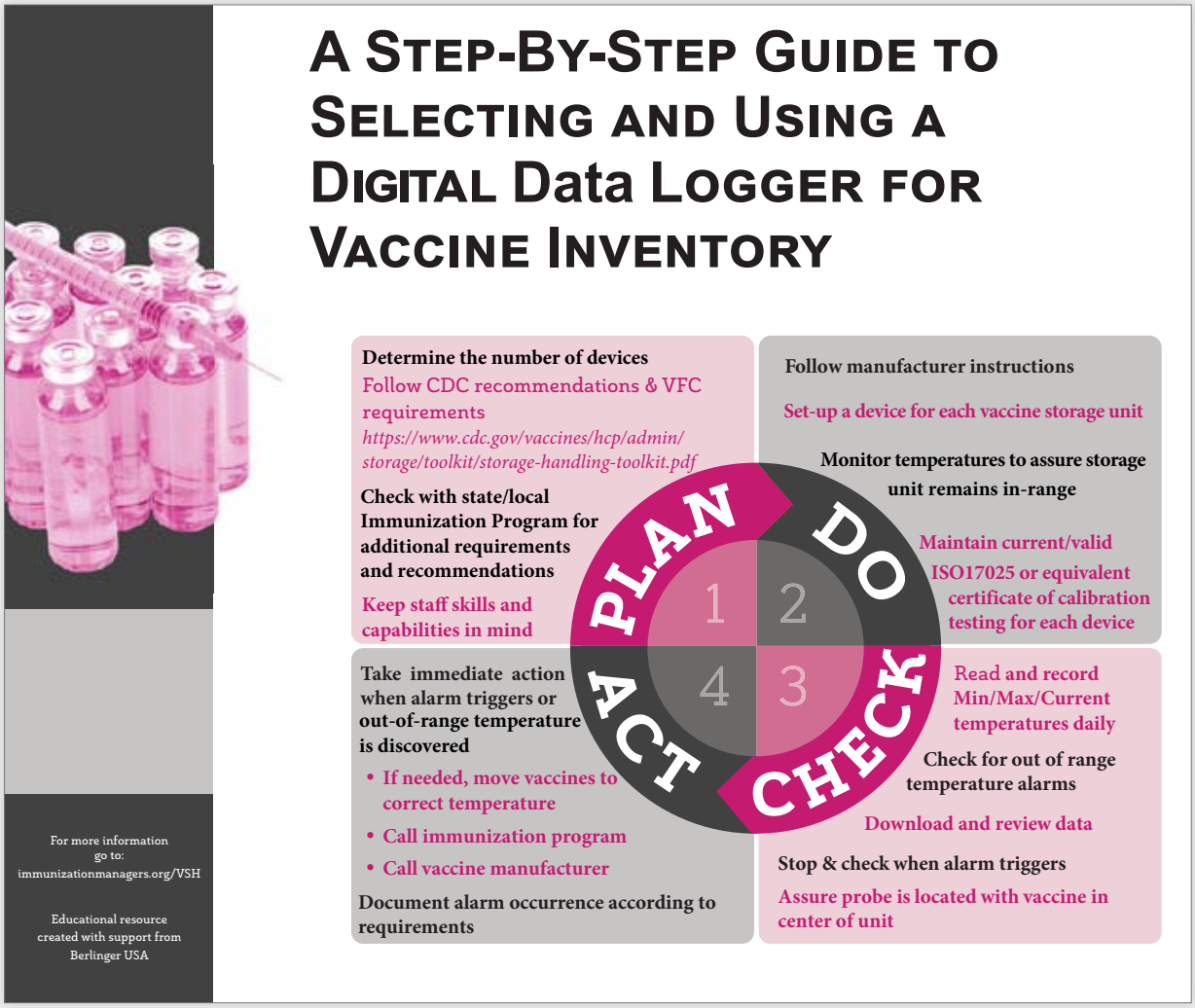
Mixed Approach to Education

The Texas IP is set up in regions, and LHDs are responsible for provider training. Vendors were asked to create informational packets and webinars to address various types of DDLs, and additional resource guides were developed by the LHDs and regions.

Provider Guide For Using DDLs

AIM and Berlinger USA collaborated to develop a provider step-by-step guide for selecting and using DDLs. The one-page resource includes reminders about planning for DDL use, routine checks and responding to alarm notifications. Visit http://www.immunizationmanagers.org/resource/resmgr/virt_exhibt_hall/Fridge-tag_Data_Logger_Flyer.pdf for the updated guide.

Contact AIM staff, kwells@immunizationmanagers.org, for a version that can be edited with your immunization program logo and contact information.



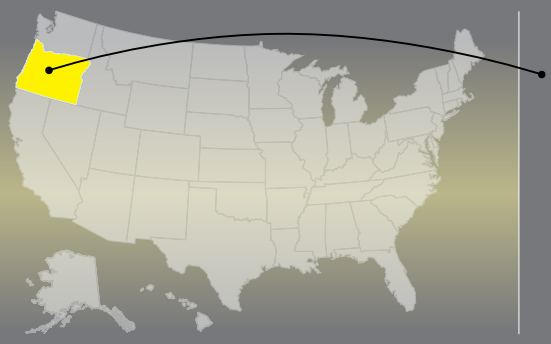
DDL Vendor-facilitated education (Approach #2)

Benefits

+ Saves IP staff time and resources as vendor pays for development of training and supporting tools
+ Vendors may have more resources for individual provider training needs
+ Vendors frequently have webinars and training videos already developed and accessible that would be costly or impossible for the IP to develop
+ Vendor training tools may already be tested to ensure successful provider training

Considerations

+ Little or no control over content of vendor-developed training tools
+ Training tools are specific to individual DDL vendor/manufacturer
+ Tools may contain incorrect interpretation of VFC policy requirements
+ Training may include unwanted marketing of specific devices



EXPERIENCE FROM THE FIELD

Oregon

Use of Vendor Support for Education

Although providers choose their own DDL in Oregon, the bulk of providers seem to purchase from one vendor. As part of customer service, the vendor has team members familiar with Oregon VFC requirements who assist their providers with setup and troubleshooting. The vendor has also developed a robust training guide for DDL use with online step-by-step tutorials.

Refresher Training

Refresher DDL training will be needed as provider staff turnover frequently, and additional training may be required as part of follow-up actions to temperature excursion or vaccine mismanagement.

When developing refresher training policies and procedures, keep the following in mind:

- Develop a process to identify new provider staff who need training
- Consider inclusion of expectations and requirements for refresher training in provider annual agreement
- Include refresher training as part of follow-up actions for noncompliance
- Well-developed online training tools, such as webinars, quick guides and DDL manuals, can be used to provide refresher training
- Annual conferences and provider site visits provide the optimal opportunity for face-to-face interaction for refresher training

IPs should also keep in mind that vendors can support refresher training needs with existing tools on set up and use of specific DDL.

Common DDL Training Formats and Venues

- One-on-one training with provider
- VFC site visits for one-on-one training and additional education
- Webinars and on-line learning modules
- One-page DDL basic use guides
- Step-by-step tutorials
- Training sessions at IP and regional conferences
- Vendor online tutorials (eg, YouTube videos)

Vendor Insight

"The best way to teach providers is through instructional videos and tutorials that can be paused, allowing providers to set up their DDL at their own pace."

— Lascar Electronics (DDL Vendor)

Immunization Program Resources

PROVIDER FAQS SHEETS

- **North Dakota DDL FAQ**
  http://www.ndhealth.gov/Immunize/Documents/Providers/Forms/Dataloggerfactsheet.pdf
- **Vermont DDL FAQ**
  http://www.healthvermont.gov/sites/default/files/documents/pdf/ID_IZ_INFOHCP_S%26H_DataLoggerFAQs.pdf

TRAINING WEBINARS

- **North Dakota DDL webinar slides for implementing DDL Training 1 & Training 2**
  Training 1: http://www.ndhealth.gov/Immunize/Documents/Providers/Forms/3_FT2_Start_Read_Report_Training_color.pdf
  Training 2: http://www.ndhealth.gov/Immunize/Documents/Providers/Forms/VFC5000color.pdf
- **Tennessee temperature monitoring and excursions webinar slides**
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/TE_&_DDL__PPT__4-11-17_LW.pptx
- **Tennessee VFC requirement webinar slides – DDL starting on slide 31**
  https://c.ymcdn.com/sites/aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Spring_Review-CC_CH3-23-17_klm.pdf
- **Texas Data logger training webinar slides**
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/VFC400.pptx

PROVIDER USER GUIDES

- **Oregon VFC Thermometer Guide**
  http://www.oregon.gov/oha/PH/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/vfc/Documents/VFCthermguide.pdf
- **Rhode Island DDL step-by-step user guide**
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Data_Logger_User's_Guide.pdf

PROVIDER QUICK REFERENCE DOCUMENTS

- **Massachusetts quick reference guide for monitoring temperatures daily**
  http://www.mass.gov/eohhs/docs/dph/cdc/immunization/fridge-tag-2-infographic.pdf
- **Tennessee quick reference guide for monitoring temperatures daily**
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/TEMPERATURE_MONITORING_QRG.pdf
- **Vermont DDL quick reference guide tips**
  http://www.healthvermont.gov/sites/default/files/documents/pdf/ID_IZ_INFOHCP_S%26H_DataLoggerTips.pdf

WEBPAGES

- **Vermont vaccine storage and handing webpage for providers (see DDL section II)**
  http://www.healthvermont.gov/immunizations-infectious-disease/immunization-health-care-professionals/vaccine-storage-and-handling

Lessons Learned from Early Adopters | Choosing an Educational Approach

Prepare multifaceted education for providers: Providers have various technical capabilities and learning preferences. Training should be a multifaceted approach that includes webinars, quick reference guides, and one-on-one support.

The Temp Stable Vaccine Refrigerator

Virtually Eliminates Temperature Excursions

Large Capacity - Holds over 2000 doses*, comparable to a 21ft³ upright model

38"W x 28"L x 35"H

No "Cold Spots"

- Store vaccines anywhere in fridge with confidence
- Spacing between vaccines not required

No More Temperature Spikes or Freezing

- Consistent daily temperature readings

Maintains temperature within range for up to 6 days in the event of:

- Power outage
- Unplugged cord
- etc.

Comprehensive Vaccine Organization System

- 5 baskets (3 top & 2 Bottom)
- Dividers / labels / trays

Significant Cost Savings due to:

- Remote monitoring and on-call staff not required
- Backup power not required
- Very low power consumption

Accurate Temp. Monitoring

- Min max thermometer and data logger included (meet all CDC & VFC requirements)

*over 200 boxes of 10x0.5ml vials or 700 single dose syringes. Based on typical manufacturer box sizes.

TEMPARMOUR REFRIGERATION
WORRY FREE VACCINE REFRIGERATION

1.866.485.4199 | info@temparmour.com
www.TempArmour.com

Know Your Vaccines are SAFE without the Hassle

Download Data and Recieve Alerts without Software.

Excursion-Trac™ & Memory-Loc™ Traceable® Datalogging Thermometers or TraceableLIVE® cloud-based connected system

Easily Download Data Readings with a USB Flash Drive

Excursion-Trac™ & Memory-Loc™ Traceable® Dataloggers Download CRITICAL data from device via USB, then upload to a PC.

Remotely Download and Recieve Alerts from Anywhere

TraceableLIVE® for VACCINE TEMPERATURE MONITORING lets you know if anything goes wrong by sending you a text, E-mail, or Push notification.

Learn more at vfc.traceable.com/resource

SECTION VII.
Provider Compliance

AIM
ASSOCIATION OF IMMUNIZATION MANAGERS

Lessons from the Field:
Digital Data Loggers

No matter the approach taken to implement DDL requirements, IPs need to determine policies and procedures for providers to assure compliance with the CDC VFC Operations Guide and CDC VFC Compliance Site Visit Reviewer Guide.

Below are suggested actions for IPs to promote DDL compliance.

IP Practices to Promote Provider Compliance:

- Provide early and frequent clear communication to providers outlining expectations and consequences of noncompliance
- Calculate and communicate the cost of vaccine supplied through the VFC program and cost of waste and revaccination generated by the individual provider
- Recommend that providers choose computer savvy staff to manage the DDL
- Consider adding DDL requirements as part of the annual VFC provider enrollment form
- Utilize site visits as an opportunity to assure compliance with DDL use
- Develop for providers quick-reference guides for interpretation and use of DDL temperature data and response to temperature excursions
- Require DDL temperature data submission as part of vaccine ordering process
- Review temperature data at periodic intervals
- Plan for adequate provider training so providers are equipped to manage DDL initial set up, data reporting, alarm notification and response to temperature excursions
- Consider requiring annual DDL provider training

For IPs that select and purchase DDLs for providers, advice from early adopters suggests that providers should require providers to sign an agreement that outlines care and use of program-provided DDLs and replacement.

IP Words of Wisdom

"Identify providers in need of additional training, such as those with temperature excursions or alarms, those with new administrative staff, those previously requesting technical support and those who present challenges during site visits. Time spent identifying providers early on will be recouped in the long run."

— Tennessee Immunization Program

Immunization Program Resources

COMMUNICATION TO PROVIDERS

- North Dakota provider memo on DDL use and expectations
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/memo_-_data_logger.doc
- Tennessee memos to providers outline expectations and consequences of non-compliance
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/TE_memo_7-26-16_klm7-28-16.docx
- Tennessee memo to providers announcing required training
  https://c.ymcdn.com/sites/aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/VFC_Provider_Memo_-_Temperature_Monitoring_Webinar_CH_Corrected.pdf
- Massachusetts replacement digital DDL provider memo
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Replacement_Data_Logger_Memo_2-16.doc

STAFF TOOLS

- Tennessee Staff VFC Provider Site-Visit Check List
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/PH4086_-_Revised_2017_05-22_CC_Editable_PDF.pdf

PROVIDER TOOLS

- Tennessee vaccine storage unit/DDL sign-off sheet
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Vaccine_Storage_Unit_Digital_Data_Logger_Sign-off_Sheet.pdf

PROVIDER POLICY AND REQUIREMENTS

- Massachusetts 2017 Guidelines for Compliance with Federal and State Vaccine Administration Requirements (see page 6 for DDL)
  http://www.mass.gov/eohhs/docs/dph/cdc/immunization/guidelines-vaccine-compliance.pdf
- Pennsylvania VFC DDL Policy
  http://www.health.pa.gov/My%20Health/Immunizations/Vaccines-for-Children/Documents/Approved%20Section%206-J%20Pa.%20VFC%20Digital%20Data%20Logger%20Policy.pdf
- Oregon Vaccine Management Guide – (see page 13 – 15)
  http://www.oregon.gov/oha/PH/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/vfc/Documents/VFCthermguide.pdf
- North Dakota Provider Policy for Temperature Recording Devises (see page 23 -26)
  http://www.ndhealth.gov/Immunize/Documents/Providers/Forms/VaccinePolicy17.pdf
- Tennessee VFC Provider Handbook - Thermometer (see page 23-31)
  http://www.tn.gov/assets/entities/health/attachments/VFC_Provider_Handbook.pdf

Vendor Insight

"One suggestion overrides all – have one regulation that all providers can comply with. Everyone will know what they need to do to be compliant."

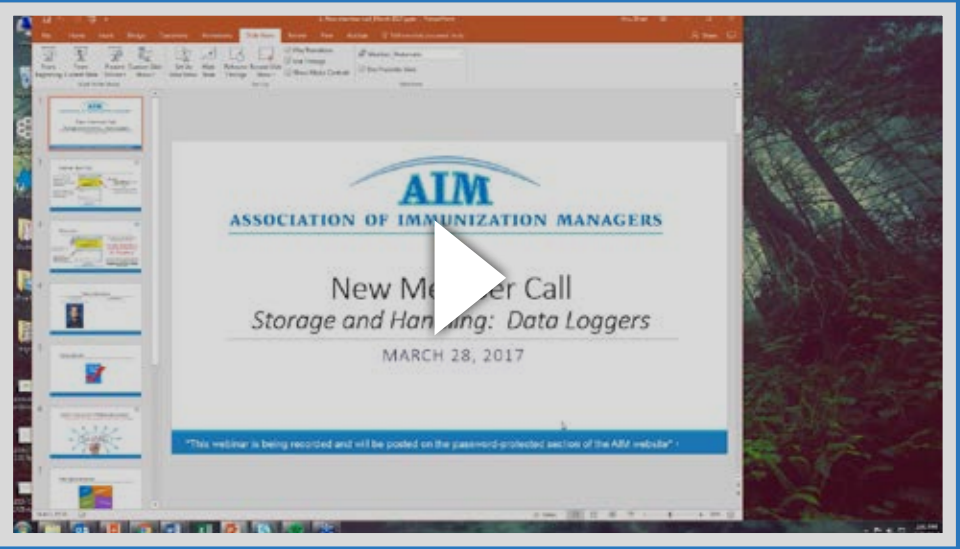
— DeltaTrak (DDL Vendor)

Learn More From Other Immunization Programs

AIM hosted a webinar that featured hot topics related to storage and handling, specifically focusing on data logger experiences and provider education.

Presentations were made by the Massachusetts Immunization Program and the Montana Immunization Program.

https://aim.site-ym.com/general/custom.asp?page=NewMemCallDDL328



Common Practices for DDL approval after set up

Once a provider has installed a DDL, the IP may choose to approve the device after initial set up. For all approaches to DDL implementation, this ensures the DDL has been set up and is functioning appropriately.

These are the common methods to consider when deciding if and how to approve DDL units after set up:

- No approval needed
- Review temperature reports for a set-period of time (eg, 2 weeks) – request providers send reports or view data via cloud
- Provide a DDL set up visit to each provider office
- Ensure set up during routine and unannounced VFC/AFIX site visits

Immunization Program Resources

- **Rhode Island site visit staff DDL rollout check list**
  https://aim.site-ym.com/resource/collection/96E4F3F3-3B8E-461D-9D67-1525760CF3D5/Rollout_Site_Checklist_WiFi_Ver__1_Rev_4.docx

Unique DDL situations

The CDC requires that the temperature must be displayed outside the unit. IP staff should also be prepared to address systems functioning outside of VFC requirements. This can include health systems already on a centralized temperature monitoring system or providers that have a pharmaceutical-grade refrigerator that does not display the temperature outside the unit.

IP Words of Wisdom

"To encourage provider buy-in, consider creating a document that shows the amount of vaccine in each provider refrigerator, cost of the DDL and cost savings for providers if they have storage failures."

— North Dakota Immunization Program

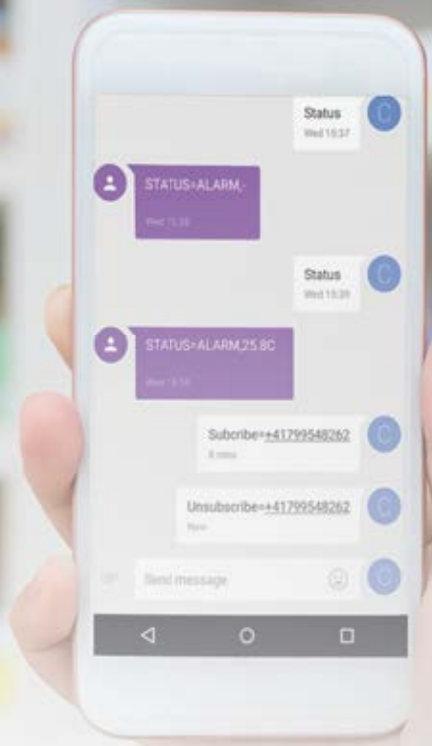
Lessons Learned from Early Adopters | Promoting Provider Compliance

Detail expectations: To promote provider compliance, as early as possible establish and notify providers of changes in policy requirements and incorporate into provider annual agreements.

SWISS Quality

Temperature monitoring when it matters most.

Precision monitoring of refrigerators, freezers and cold rooms.



- ✓ Audible alarm
- ✓ User settable
- ✓ 56 days on a PDF report and 30 day history on display
- ✓ No software needed

Fridge-tag® 2 L

- ✓ Real-time alerting
- ✓ SMS / Email notification
- ✓ Up to 5 recipients
- ✓ Audible alarm
- ✓ Back up battery

Fridge-tag® 3

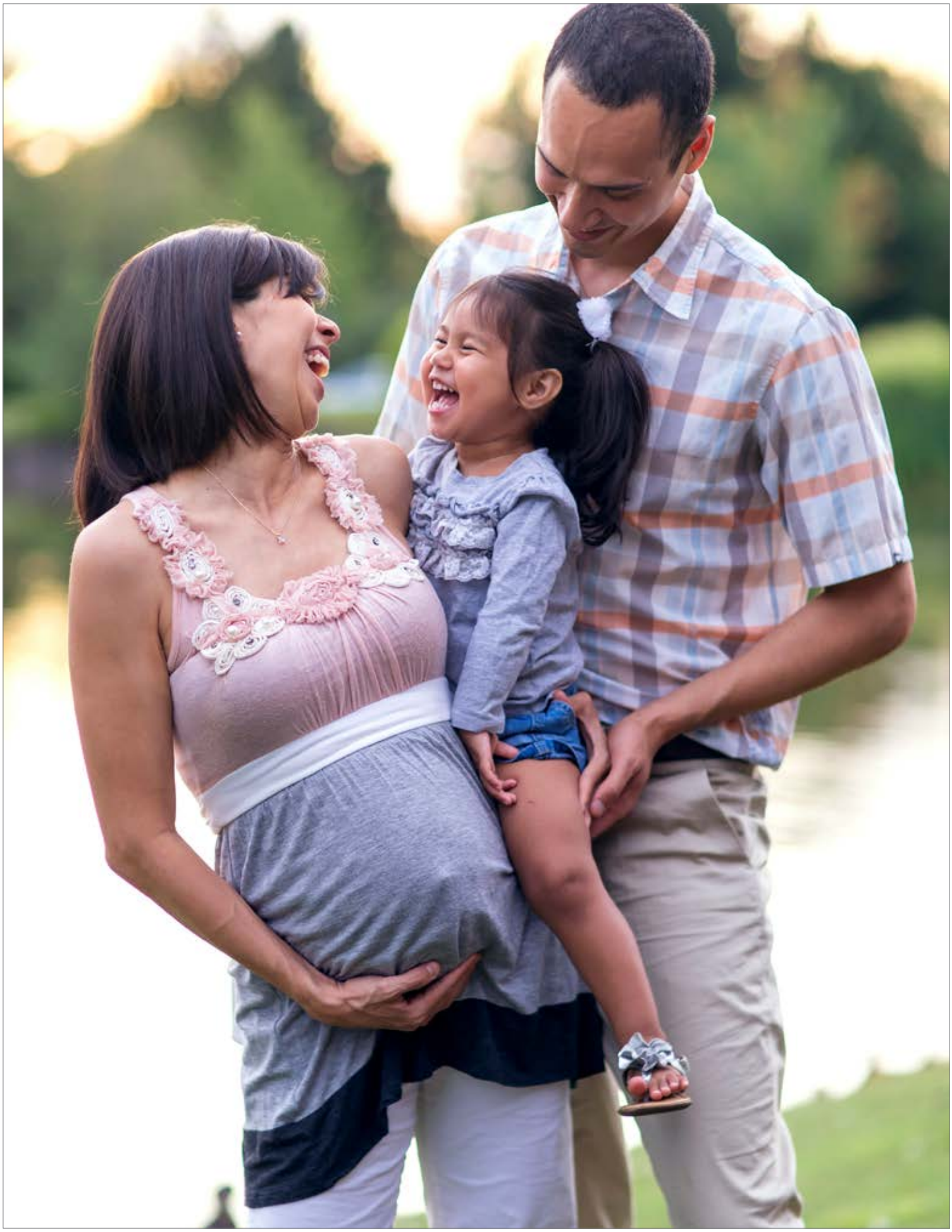
SIM card

Learn more: www.berlinger.com/health

Check out: Configuration videos

berlinger
feel safe

Berlinger & Co. AG Switzerland +41 71 982 88 11
Berlinger USA LLC +1 508 366 0084
info@berlinger.com | www.berlinger.com



AIM
ASSOCIATION OF IMMUNIZATION MANAGERS

620 Hungerford Drive, Suite 29
Rockville, MD 20850
Tel: (301) 424-6080 | Fax: (301) 424-6081
info@immunizationmanagers.org

www.immunizationmanagers.org