In 2011–12, in accordance with a nationwide, standardized approach, Kaiser Permanente replaced approximately 17,000 large-volume pumps with smart infusion pumps, which offered more robust safety features, the promise of wireless connectivity, and the ability to gather continuous quality improvement data.

This case study outlines our implementation efforts and describes the challenges and rewards of converting to a smart infusion pump, including wireless issues, support-related challenges, and leveraging quality data to improve the safety and usefulness of the pump. This article describes the interdisciplinary approach used to address challenges, the steps followed to meet those challenges, and the benefits realized through the adoption of smart pumps.

History
Kaiser Permanente has implemented a national standard for infusion pumps nationwide for a number of years. In 2011, our existing standard pump suffered a recall and prompted the organization to reevaluate the pump marketplace. This evaluation led to a transformation in the approach to infusion pumps. The scope of the work transitioned to determining the value of a smart pump device to replace our current basic infusion device. This analysis resulted in the selection of a new vendor that offered smart pumps promising the following advantages:

- More robust and sophisticated drug libraries that could offer user guidance and support programming in order to prevent errors
- Collection of comprehensive data on usage to support quality initiatives and drive performance improvement
- Wireless connectivity to the enterprise network, allowing for hands-free management of the drug libraries and data collection
- A software package of reporting tools to leverage the raw data for analysis

The New Approach
The goal of replacing, implementing, and training clinical and support staff for the replacement of 17,000 pumps was a large task. Very early on, we discovered the importance of cross-discipline collaboration for this conversion. Although infusion pumps are a clinical tool, elements of smart pump technology require the insight of information technology (IT) and healthcare technology management (HTM), in conjunction with the clinical team. A partnership approach was necessary to fully implement and optimize the smart pump device.

The clinical team was tasked with 1) developing and maintaining a standardized set of profiles, 2) coordinating the review and sharing of data to provide a best practice approach to safe use of the technology, and 3) developing a comprehensive interdisciplinary governance structure to maintain consistent standards and manage change across all regions. A standardized set of profiles was developed for these pumps, in order to develop drug library content that was meaningful and could be measured.
consistently across regions. Both drug library content and pump use could be monitored and measured. Our standardization approach involved sharing and learning from regional practices in order to arrive at enterprise standards. Achieving agreement on this new standard among all regions from across the country was a challenge. The team consisted of nursing leaders, pharmacists, and clinical leads, along with facilitation from IT and clinical informatics. We met weekly over several months and worked through each of the profiles to determine a commonly accepted set of standards. This was possible because of the strong leadership support and direction. Through high-level leadership engagement and resource availability, the organizational commitment was evident. After the standards were established, we proceeded with developing a governance structure in order to keep the regions aligned with these standards.

The purpose of the governance structure was to ensure that enterprise standards continued after the project was complete. This required developing consensus from the regions that incorporated the following standards and processes: 1) identifying national and regional accountable decision makers, 2) agreeing on enterprise standard profiles, 3) developing enterprise and regional change control processes, 4) developing enterprise and regional communication plans, 5) establishing criteria for validation of change success, and 6) developing exception processes for missed updates.

Through high-level leadership engagement and resource availability, the organizational commitment was evident. After the standards were established, we proceeded with developing a governance structure in order to keep the regions aligned with these standards.

The governance structure was developed in the same fashion, through ongoing discussions between the national team and representatives from IT, HTM, pharmacy, and nursing from each region. One challenge with establishing this governance structure was that initially, the

All AAMI Sterilization standards for hospitals in one place!

AAMI’s most popular sterilization collection—now with 14 key guidance documents for healthcare facilities, including:

► ST79, Steam Sterilization
► ST58, Chemical Sterilization
► TIR34, Water for reprocessing
► ST91, Endoscope processing
► TIR63, Loaned devices requiring sterilization
► PB70, Liquid barrier performance of protective apparel

Order Code: STBK15-1 or STBK15-1-CD
List $625 / AAMI member $435

Order Today!
Visit www.aami.org/store

Not an AAMI member?
Join us today!
Case Study

The smart pump solution involved three interacting components: smart pumps, central servers, and a suite of applications for maintaining pumps, maintaining drug libraries, and providing quality reports.

The smart pump software allowed pumps to be identified as belonging to a particular facility. Unfortunately, the vendor implementation of this feature created challenges because the pump could only be associated with a single facility and the association was implied from the pump's network address. This limitation created several challenges with our enterprise needs. First, if the pump traveled to another facility, all of the data on the pump became identified as having originated at the new facility, regardless of where the care actually took place. Second, because certain regions had multiple servers for scalability, if the pump traveled to a facility not associated with its server, the facility wouldn’t be recognized, so the pump data would be ignored. In addition, if the server didn’t recognize the facility ID as valid, it would no longer update the pump with drug library changes. Finally, the vendor software could only push drug library updates to one facility at a time, even though standard libraries were used across the organization. The more facilities there were, the more work it took to update the devices with a new drug library.

Because of these limitations, the technical and clinical teams worked together to determine appropriate compromises. Most regions chose to use some variation on service area or geographic clusters, which provided enough fine-grained detail for reports without causing the pharmacists to have to repeatedly release the same drug library to many different facilities. Standard operating procedures were developed for migratory pumps to minimize the risks of data loss or misattribution, as well as missed drug library updates.

The data available in smart pump technology was a key factor in the decision to move forward with this tool. However, reporting turned out to be a surprisingly large challenge. The data generated by smart pumps allows us to analyze the use and administration of infusion medications by leveraging data gathered from the pumps automatically via the wireless network. This is critical both from a patient safety and regulatory perspective, especially for programs such as the Medication Error Reduction Plan program. The data allow us to review elements and make clinical determinations on actions to improve use of the safety software, ultimately leading to improvement in safe administration of infusion medications and an overall reduction in administration errors.

We were faced with challenges related to these data resulting from information being housed in multiple servers across multiple regions. Regions with larger numbers of pumps needed to implement more than one server to handle the load. This meant that in order to generate an enterprise and, in some cases, a regional report, the data had to be exported and manually aggregated. To resolve this issue, a central server was developed and the data were transferred to a single location, where we are able to benchmark the data from all levels of the organization.

To address this software limitation, we recruited students working to attain their master’s degree in computer science from a local university to develop a central reporting server and reports. This partnership benefited the students by providing them with a real-world challenge to solve (and class credit). It provided us with reports at all levels of the enterprise and varieties beyond the limited number provided by the vendor reporting tool. Because of the initial success of this partnership, it continues to this day.

The smart pump solution involved three interacting components: smart pumps, central servers, and a suite of applications for main-
taining pumps, maintaining drug libraries, and providing quality reports. As with any critical application, we subjected the components to a series of tests as part of a risk assessment. Our security consultants found that the pumps suffered from security flaws ranging from unsecured network credentials to susceptibility to packet attacks: Issues included:

- Network credentials were displayed in clear text on the pump screen.
- Access to pump settings could be controlled only with a lock/unlock toggle button.
- Configuration tools came without authentication or authorization controls.
- No network resiliency had been built in; the pump could be crashed by a corrupted packet with no malicious intent.
- Wireless connectivity had been added without adequate controls to protect patient data.
- Unusual handling of network timeouts limited the number of pumps that could be on the network before they created an unintentional distributed denial of service attack on our network.
- Supporting applications allowed elevated access without even rudimentary security.
- The web-based administrative console allowed cross-site scripting, which allows hackers access to any website the user has access to without logging in.

In addition, other odd features were observed, such as servers requiring virtual machine (VM) environments but not supporting VM features and not possessing the ability to be used in a clustered, shared VM infrastructure.

Maintaining clear roles and responsibilities for addressing issues was important. The vendor was responsible for the integrity of the systems and software it developed. Therefore, the vendor was required to address the product flaws. The vendor addressed software issues through upgrades of its pump and server software. The vendor also upgraded its network cards to support WPA2-Enterprise (a business-level security protocol) and modified them to ensure that the pumps did not flood the network with authentication requests as a result of occasional server timeouts.

On the Kaiser Permanente side, teams from application security, wireless infrastructure, IT, HTM, network capacity management, and data center design collaborated to ensure a safe and stable environment in which the solution could operate. In addition to vendor fixes, we layered further security around the pump credentials by implementing network access control rules that allowed the pump credentials to connect only to designated servers. Similarly, the applications were installed on locked-down workstations with authorization restrictions to help control access. Finally, stand-alone VM environments were established that complied with vendor limitations.

After all foundational elements were developed and finalized, implementation and training were addressed. In addition to clinical users requiring training, support disciplines needed to be trained to maintain, support, and update the smart pumps. The training took place at each site as the smart pump initiative was rolled out, and a waterfall schedule, showing which site was next on the calendar, was created to prepare each facility for the training and implementation.

Achievements
The planning and testing of the pump for implementation took approximately 10 months. The process was carried out through regular weekly meetings with key stakeholders and an interdisciplinary team. After the planning phase was completed, the implementation phase was started and more than 17,000 pumps were implemented across eight regions in 11 months. The implementation phase included staff training for users and the support teams from IT and HTM.

A support structure was put into place to ensure that the pumps were monitored and supported at an enterprise level, allowing practices and issues to be shared. The support structure also focused on collection of data within pumps and training for staff to run reports and interpret data. During the initial phase, while wireless connectivity issues were still being resolved, the pumps were scheduled for manual drug library updates and manual data extraction in a manner the caused the least disruption to patient care. Implementation of a medical device with network connectivity and servers hosted in IT data centers required a close partnership and high degree of collaboration among the HTM, clinical user, and IT teams.
is largely transparent to the clinical end user and will be the basis for support in future integration efforts.

**Lessons Learned**
Several lessons were learned from this project. First, we recognized the importance of establishing a consistent change control process. Without a governance process firmly in place, the ability to maintain a collaborative build can break down. The governance process should be carried over for all phases of pump implementation and transitioned to the ongoing governance group at the end of the implementation project. Smart tool technology has changed the process for ongoing operational support and has required continuous maintenance, monitoring, and support.

Another key to success was establishing an interdisciplinary planning team that included key stakeholder groups (e.g., nursing, pharmacy, HTM, supply chain, clinical education, IT). In addition, communication is fundamental at all phases of a smart pump implementation. Communication should occur early and often, and key agreements should be documented. The communication needs to be transparent and archived so that if key stakeholders’ roles change during the project, the historical information is housed in an easily accessible location.

The roles/responsibilities of the implementation team and key stakeholders were not always clearly defined, leading to delays in the planning process. We recommend clearly defining, reviewing, and approving roles/responsibilities of the implementation team and key stakeholders early in the process. We created three tracks of work (clinical applications, technical infrastructure, and HTM) to help organize this challenge.

Key stakeholders should be involved early in the planning process. IT could have been engaged earlier in the project to allow sufficient time for testing and project planning. Unfortunately, many vendors are still learning how to provide a secure, stable network connection for their devices. During our testing process, we learned that standard controls were missing from the pumps. For example, the wireless component of the solution had to be delayed until networking issues had been resolved. This resulted in higher-than-expected HTM resource needs to manage updates manually until the wireless capability could be safely enabled.

The availability of a testing environment for all disciplines helps to facilitate workflow issues, training tools, and support needs. Having a central location for representatives from different geographic locations and disciplines to come together for a productive planning session provides the ability to capture issues.

Finally, leadership support and direction are pivotal in the any cross-discipline technology implementation. The involvement and visibility of leadership encouraged successful implementation, from planning, to training, and to launch. The presence of leadership at multiple levels helped staff to understand the importance of the new technology.

**Conclusion and Next Steps**
The current work describes one process used to implement a complex technology—smart infusion pumps—across a multiregion, multisite organization. Careful planning, testing, and collaboration are essential for ensuring that smart technology is enabled in the best way to promote improved patient safety. The project’s next phase is integration with our electronic medical record system, which will require another closely collaborative approach to achieve success.