Medical Device Integration with an Ambulatory Electronic Health Record System

Alliance of Chicago Community Health Services
Welch Allyn

INTRODUCTION
A fully functional electronic health record (EHR) system that is integrated with other automated medical devices has significant potential to improve the quality, safety, and efficiency of care delivered. These improvements are made possible with the overarching objectives of medical device integration: 1) reduction in errors, 2) access to data, and 3) improved workflows. Most of documented progress to date with the integration of medical devices with EHRs has occurred in the inpatient environment. In this paper, we describe a demonstration study in which a commercially-available, ambulatory EHR was successfully integrated with a vital signs device in an urban community health center (CHC).

BACKGROUND
Despite the promise that integrating medical devices with EHRs hold, little has been studied and published on this topic. The Health Information Management Systems Society (HIMSS) Analytics team collected data from 825 US hospitals for a white paper published in December 2010 (Medical Devices Landscape: Current and Future Adoption, Integration with EMRs and Connectivity, 2010). Findings revealed that 96% of the hospitals surveyed stated that their primary reason for integrating medical devices with the EHR was efficiency – the ability to automatically chart the clinical data from the device directly to the EHR. Only one-third of hospitals reported that an interface was present at their organization between devices and their electronic medical records.

One of the main reasons for scarce pilot studies in this area is likely the number of significant challenges that exist around successful integration.

Current Challenges to Successful Integration
Below is a list of known challenges to integrating medical devices with ambulatory EHRs:

1. **Devices are developed in isolation:** Individual manufacturers historically have developed devices in isolation, and may not adhere to emerging cross-vendor standards.

2. **Need for custom interfaces:** In the absence of interoperability, custom interfaces need to be built, linking the medical device to the EHR. This build requires a highly technical, dedicated resource skilled in the complexity of interface construction. Many health care organizations, particularly those in safety net settings, do not have an individual with this specialized knowledge base to manage such an effort.

3. **Lack of published lessons learned:** To date, there has been a scarcity of well-defined use cases that describe successes and challenges in integrating devices. Without such cases, each institution attempting this has to essentially start from scratch in obtaining information and determining best practices for project management and implementation of device integration.

4. **Ambulatory setting:** Primary experience with integrating medical devices with EHRs has been in hospital settings, for which the nuances of ambulatory care may not be identified and recognized.

5. **Staff compliance:** Ensuring that staff adhere to one standardized workflow of entering clinical data the same way, into the proper EHR data fields, with every patient encounter is challenging. In many settings, especially safety net centers, staff turnover is common, so knowledge transfer on optimal use of EHRs and medical devices is a challenge.

6. **Complexity of data elements:**
   - For many data elements, such as diastolic and systolic blood pressure values, multiple entries are possible. Deciding which value to choose as the most appropriate value for this workflow needs to be clarified when integrating a device with an information system. Clinical staff, who are responsible for choosing and entering such data, may find difficulty in this concept, because they see all clinical values as relevant and needing to be included in the documentation of the patient encounter.
   - Clinical values that are similar but from disparate data sources need to be differentiated, which is challenging from a device integration standpoint. For example, a clinician would want to know explicitly when a heart rate is gathered
from an ECG reading versus a heart rate obtained by listening to the patient’s heart via stethoscope. Ensuring that these values are stored into the EHR with such a differentiation can be difficult to program.

**National Initiatives to Address Interoperability**

There is a rise of multi-stakeholder groups dedicated to promote evaluation, adoption of integrated technologies, such as the “Medical Device Plug n’ Play” (MDPNP) initiative. The founding health care organizations of this initiative include: Massachusetts General Hospital Partners HealthCare System, Inc. Kaiser Permanente, and Johns Hopkins Medicine. MDPNP promotes standards-based interoperability of medical devices to:

- Create error-resistant medical systems;
- Support the widespread use of data obtained from medical devices;
- Improve clinical workflow to enhance patient safety and reduce healthcare costs;
- Produce complete and accurate EHRs for clinical care and research; and
- Enable the development of a medical grade network for high-acuity health care.

**METHODS**

**Setting**

Near North Health Service Corporation (Near North) is a Federally Qualified Health Center (FQHC) and one of largest providers of community-based primary care in Chicago, Illinois. Near North provides health care, social services, and nutrition education to the medically indigent and uninsured residents of Chicago. In fiscal year 2008, Near North served 47,506 clinical and non-clinical patients through more than 98,508 visits. Almost half (51%) of Near North users are uninsured; 42% have Medicaid coverage, and 7% are covered through Medicare. Females account for 67% of patients, 70% of Near North users live at or below 100% of the Federal Poverty Index (FPI), and another 25% is between 100% to 200% of FPI.

Near North is one of the founding health centers of a Health Center Controlled Network called the Alliance of Chicago Community Health Services (Alliance). In 2006, the Alliance implemented a robust, fully functional, commercially-available EHR in all of its health centers.
The Alliance-wide EHR incorporates an approach to data collection and analysis at both patient and population levels to improve quality of care and patient health outcomes. This approach includes evidence-based, point-of-care clinical decision support, integrated performance measures, and a data warehouse and infrastructure for data analysis and research. All of these capabilities support the member health centers’ involvement in chronic disease prevention and management. One of the benefits to a health center controlled network like the Alliance is the ability to disseminate best practices, such as medical device integration, to all CHCs hosted by the Alliance following a pilot test at one health center. That dissemination is the immediate next step upon completion of the pilot at Near North.

*Description of Medical Device*

The medical device of focus for this implementation was the Welch-Allyn Vital Signs machine. This device contained equipment to gather a patient’s blood pressure, pulse rate, oxygen saturation via pulse oximeter, and temperature, with additional capabilities to enter a height and weight directly into the device. This device can be easily integrated into the workflow of the ambulatory care environment, due to the routine nature of a patient’s vital signs being gathered at most clinician office visits and the device’s mobile capability to be wheeled to multiple exam rooms. Three devices were implemented into Near North’s health center, to accommodate the primary departments that see patients and collect vital signs: Internal Medicine, Pediatrics, and Women’s Health.

*Programming the EHR and Initial Testing*

Evaluation of the device’s capabilities and functions required an in-depth analysis of where information from the Welch-Allyn Vital Signs machine could be communicated and documented within the EHR. This involved an examination of the data capabilities of the specific EHR product used as the Alliance-wide EHR solution, GE Centricity Practice Solution™. This also included an analysis of the EHR’s clinical content – the interactive displays where clinicians enter patient documentation during the visit that feed into the EHR. This clinical content is wholly created and managed separately by the Alliance Clinical Informatics team. In addition, investigation was performed into how this information can be communicated through the Citrix server network in which the Alliance EHR is housed.
Upon this detailed analysis, it was determined that this device integration project would necessitate a multi-pronged approach to ensuring that the data from the device would communicate efficiently, accurately, and safely throughout this complex health information environment. Tasks included the following:

- Hardware evaluations to ensure that the device plugged into the correct port of entry in the computer terminals in the patient exam rooms.
- Network setup changes and communication path determinations for creating a safe, secure route for communicating the device data; and
- Programming design changes to the EHR clinical content for receiving the Vital Signs information into a screen where it is easily interpreted and validated by the clinician.

Prior to testing the devices in the community health center, Alliance technical staff ran simulations of the equipment with the EHR in a demo environment, to make sure all technical issues were resolved.

Workflow Assessment
The overall patient care workflow was analyzed to ensure a seamless process for collection and review of vital signs, without adding additional steps or significant slow-downs. Workflow consideration is key to obtaining clinician buy-in and sustainability of the overall project. Medical assistants and nurses who commonly collected vital sign information during the patient care visit were active participants in the evaluation of the new workflow. They helped determine changes in the intake process necessary to incorporate use of the Welch-Allyn Vital Signs machine. These changes included:

- New location for taking vitals – an intake room where the device was connected to a desktop computer – rather than taking vitals in the exam room;
- How to physically use the new device with the computer; and
- How they would interact with both the patient and the EHR simultaneously to ensure data accuracy while providing attentive care to the patient.
Training Staff

Once the device integration solution was tested and the new workflow was established and agreed to by all users, training of the clinical staff occurred to ensure proper knowledge transfer and standardization of the workflow. Near North health center identified the specific clinical staff members that needed to know this new process. An FAQ document was developed and communicated to these staff members, complete with screenshots and detailed steps on what to do during the patient visit. In-person training was provided by Alliance staff prior to clinic opening on the first day.

Go-Live and Health Center Support

A scheduled date for “go-live” was identified and communicated to staff when they would start using device integration. On this go-live date, Alliance staff was onsite to emphasize the previous training they had received, provide support through this transition, and serve as a resource for health center staff as questions and concerns arose. In addition, Near North staff who serves as the first-line of Help Desk support at the health center were educated on the device integration workflows and were instructed on how to troubleshoot and communicate issues to the Alliance Help Desk if any problems arose. Since the date of go-live, Alliance staff has also returned to the health center to monitor usage and reinforce training information. More importantly, these onsite, post-go-live assessments have also been useful to obtain significant feedback from the Near North on workflow nuances not initially identified during the design and implementation process, managing such nuances, and evaluation of how consistent the devices have been used in patient visits by the staff across all departments.

Measuring the Impact of Vital Signs Device Integration

The overall evaluation plan for this integration pilot study encompasses both quantitative and qualitative methods to gather information.

Measures:

- Data on number of practitioners/clinical staff and patients utilizing the device
- Patient Satisfaction – assessed twice annually
- Provider Satisfaction – assessed annually
• Time/flow studies demonstrating time saved – trained Alliance staff user stop watches to
time how long vital sign collection lasted pre and post device integration
• Reduction in errors – as a proxy measure for inaccurate data, we analyzed the number of
pre and post device integration. Further, we compared the vital sign values that were
taken by the traditional, manual device and the newly integrated, automated device, to
understand the rate of agreement between what was measured, and what was actually
entered into the EHR.

RESULTS

Efficiency Results
According to the observational data on the duration of vital signs collection, we found a
measurement difference in time pre and post device integration. On average, the amount of time
the blood pressure cuff was on the patient’s arm (typically left on for all vitals) was 58 seconds
before the device was integrated, and 38 seconds after. Further there was a significant reduction
in overall time spent by the medical assistant in the intake room from 326 seconds pre device
integration and 204 seconds after integration (see Table 1 below). The range from highest to
lowest scores were large for both the pre and post measurements.

Table 1. Time spent taking vitals, pre and post device assessment

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<thead>
<tr>
<th></th>
<th>BP Cuff Time</th>
<th>Total Time Spent in Room</th>
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<tbody>
<tr>
<td></td>
<td>PRE</td>
<td>POST</td>
</tr>
<tr>
<td>Average (in seconds)</td>
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<td></td>
</tr>
<tr>
<td>Average (in seconds)</td>
<td>58</td>
<td>38</td>
</tr>
<tr>
<td>Median (in seconds)</td>
<td>41</td>
<td>36</td>
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<tr>
<td>Range (in seconds)</td>
<td>18–120</td>
<td>12-93</td>
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Accuracy Results
There was agreement between the manually obtained blood pressure values and what was in the
EHR 88.5% of the time before the device was integrated with the EHR.
PRE-IMPLEMENTATION: % of the BP values in EHRS matched what MA reported: 
88.5%

Following integration, there was agreement between measured values and stored values 96.3% of the time.

POST IMPLEMENTATION: % of the BP values in EHRS matched what MA reported: 96.3%

CONCLUSIONS
The integration of a commercially-developed medical device and an ambulatory EHR system is possible, despite these technologies being developed in isolation. Clinical staff acceptance continues to be high after an initial period of adjustment, and now staff say that they much prefer to practice in their clinic setting compared to those still collecting vital signs in traditional manners.

Preliminary findings suggest that there is a positive impact both on time for vital sign collection and rooming a patient; as well as in accuracy of the data being stored in the EHR system. In this demonstration project, sample sizes were small, so further study is needed to see if our results are replicable on a larger scale.

Medical device integration in the outpatient setting, and eventually home setting, has tremendous potential toward improving care. Given the rapid adoption of technology and the corresponding financial incentives, it is critical for safe, efficient, and effective care to be enhanced, not threatened by systems integrating together.