A Randomized Trial of Standardized Nursing Patient Assessment Using Wireless Devices
Patricia C. Dykes DNSc, RN\textsuperscript{a}, Diane L. Carroll RN, PhD, APRN, BC, FAHA\textsuperscript{b}, Angela Benoit BComm\textsuperscript{a}, Amanda Coakley, RN, PhD\textsuperscript{b}, Frank Chang\textsuperscript{a}, Joanne Empoliti, RN MSN\textsuperscript{b}, Joan Gallagher RN\textsuperscript{a}, Cynthia Lasala RN, MSN\textsuperscript{b}, Rosemary O’Malley RN, MSN\textsuperscript{b}, Greg Rath\textsuperscript{a}, Judy Silva RN, MSN\textsuperscript{b}, Qi Li MD, MBA\textsuperscript{a}
\textsuperscript{a}Partners Healthcare System, Boston, MA, USA
\textsuperscript{b}Massachusetts General Hospital, Boston, MA, USA

Abstract
A complete and accurate patient assessment database is essential for effective communication, problem identification, planning and evaluation of patient status. When employed consistently for point-of-care documentation, information systems are associated with completeness and quality of documentation. The purpose of this paper is to report on the findings of a randomized, cross-over study conducted to evaluate the adequacy of a standard patient assessment module to support problem identification, care planning and tracking of nursing sensitive patient outcomes. The feasibility of wireless devices to support patient assessment data collection at the point-of-care was evaluated using wireless PDAs and tablet PCs. Seventy-nine (79) nurses from two patient care units at Massachusetts General Hospital (Boston, MA) were recruited into the study and randomized to complete patient assessment using wireless or paper devices. At the end of six weeks, nurses who where randomized to the paper assessment module were assigned to a device and those who used a device were assigned to paper for an additional six weeks. Impact was evaluated with regard to data capture, workflow implications and nurse satisfaction. Findings suggest that a standard patient assessment set promotes patient sensitive and quality data capture, which is augmented by the use of wireless devices.

Keywords: assessment, electronic medical record, nursing sensitive patient outcomes, acute care, nurses.

Background and Significance
In acute care settings, the registered nurse is at the hub of patient and interdisciplinary communication and serves in the roles of communicator and integrator of care.\textsuperscript{[1]} The primary purpose of the nursing patient assessment is to gather data and information necessary to support identification of patient problems and symptoms that are sensitive to nursing care and to provide an evidence base from which communication and referrals to other disciplines are made.\textsuperscript{[2-3]} The patient assessment database (e.g., all patient assessment data entered into the medical record) provides the foundation of care planning and represents the basis on which patient status is evaluated. A complete database is essential for effective communication, problem identification, planning of efficacious interventions and evaluation of patient progress towards the goals of hospitalization.\textsuperscript{[2]} In recognition of the role that accurate, complete and ubiquitous patient assessment data and information play in delivery of effective care, automation of these data in non-acute settings has received significant support at the federal level and is now mandated in long-term care facilities and home health agencies for Medicare reimbursement.\textsuperscript{[4-5]}

While the federal government has not yet mandated automation of assessment in acute care settings, accreditation bodies (JCAHO), patient advocacy groups (Leapfrog), payers (CMS) and quality groups (ANCC/NQF) are driving standardization of patient assessment documentation to support tracking of the impact of nursing care on patient outcomes.\textsuperscript{*} Integration of standard assessment scales such as the Braden Scale (skin risk inventory) and the Morse Fall Scale provide a means of standardizing data collection across sites, establishing a baseline and providing comparative data for benchmarking. In 2005, a group of nurses from across Partners HealthCare (Partners) sites collaborated to define a core set of patient assessment data and information necessary for providing quality care and tracking nursing sensitive patient outcomes across the healthcare system. While many disparate documentation systems exist currently, the vision of this group was to lay the groundwork for ubiquitous access to patient assessment data and information within and across sites providing nursing care. Under the direction of the Partners Chief Nurse Council, nurse leaders from each site brought the recommended “core set” of assessment content (assessment module) back to local documentation committees to begin the work of integration and testing in existing electronic and paper systems.

\textsuperscript{*} JCAHO: Joint Commission on Accreditation of Healthcare Organizations; CMS: Centers for Medicare & Medicaid Services; ANCC: American Nurses Credentialing Center; NQF: National Quality Forum
documentation systems. This paper describes the findings of a follow-up study conducted at Massachusetts General Hospital (MGH) to evaluate the adequacy of this standard assessment module to support problem identification, care planning and tracking of nursing sensitive patient outcomes. In addition, the feasibility of wireless devices to support patient assessment data collection at the point-of-care was evaluated using personal digital assistants (PDA) and tablet personal computers (TPC).

Site
The study was conducted on two clinical units at MGH (interventional cardiology/general medicine). MGH has a robust outpatient electronic medical record (EMR) in place, but is currently in a transition phase from paper to electronic documentation system on inpatient units. Provider order entry, a discharge module and results are available electronically. All other clinical documentation is completed in a paper record. In addition, MGH is in the planning phase for implementation of an electronic medication administration record (EMAR) and is undergoing vendor selection for an acute care documentation system. Nurses at all levels at MGH are involved in standardizing documentation and workflow processes to facilitate the transition from paper to electronic documentation systems. Therefore, this site provided an ideal lab for testing the standard assessment module and how wireless devices might be used to facilitate patient assessment data capture.

Research Methods
The goals for the study and corresponding hypotheses were as follows:

Goal 1: To evaluate the Partners standard patient assessment module at the point of care.

Hypothesis 1: The standard patient assessment module will be associated with completeness of documentation needed to identify problems and track nursing sensitive patient outcomes.

Goal 2: To evaluate feasibility of the use of wireless devices for point-of-care collection of patient assessment data and information from multiple perspectives including ease of use, completeness and quality of data capture, impact on workflow and nurse satisfaction.

Hypothesis 2: Patient assessment data/information documented in wireless devices will be more complete than the patient assessment documented on the paper module.

Hypothesis 3: Nurses will be more satisfied with the wireless devices than with the paper documentation module.

Hypothesis 4: Wireless devices will support busy and complex acute care workflows associated with the patient assessment data collection process.

The Partners standard patient assessment module was integrated into three patient assessment tools; 1) the existing MGH paper documentation form, 2) Partners-built web-based application for use on TPC and 3) Partners-built PDA application. Structured responses were employed on all tools to provide decision support for identifying patient risks, generating referrals to other disciplines, for discharge planning, and to determine whether or not required items had been answered. While the content (question sets) was identical across devices, electronic modules used branching logic to tailor follow-up questions to patient responses. All content was visible on the paper forms. Risk scores and identification of recommended referrals were automated in the electronic applications and computed manually on the paper forms. Patient assessment data and information entered into the PDA was reviewed and edited on a desktop application. While edits could be made on the PDA, review of the completed patient assessment on a desktop application made it possible for the user to view a “print preview” copy of the assessment, make changes and add annotations quickly, as all assessment items displayed in a single table, rather than in the series of screens available on the PDA. Once completed, the patient assessment module documented using the wireless devices was printed and stored in the manual record in accordance with hospital documentation policy. The wireless devices used Partners web-based services to provide the patient lists (PCIS), enterprise allergies (PEAR) and the preadmission medication list (PAML).

The study was reviewed and approved by the Partners HealthCare Institutional Review Board. A prospective randomized crossover trial was conducted for 12 weeks on two clinical units at MGH. Inclusion criteria included all registered nurses employed 16 hours per week or more on the selected units and willing to participate. Previous experience with wireless devices was not necessary. Nurses in orientation period (first three months of employment) were not included in the study.
Pre-implementation education was provided for nurses on all shifts. Nurses participated in a 30-minute hands on training session on the new paper form and on the wireless device (Hewlett Packard 2790 IPAQ PDA or Fujitsu ST4000 TPC) that they were assigned to use during the study. “Just-in-time” training was provided the week prior to go-live and “unit champions” received additional training to provide on-going device support on all shifts. Unit champions, while study participants were not paid, “unit champions” were paid a stipend to attend a one-hour training session with the device vendor. Tutorial and study information sheets were distributed to all staff to supplement one-on-one instruction. Where possible, the assessment devices were integrated into the existing workflow (e.g. existing paper forms were removed and replaced with the new form. The electronic devices were stored in a locked room with other devices routinely used by nursing staff such as cell phones, blood glucose machines). Due to the high acuity and rapid turnover of patients on the study units, nurses were instructed that if they encountered a problem with the device or if the device was interfering with patient care, they should notify the research team and revert to the paper assessment module until device-related issues were resolved.

Study Design
The study was reviewed and approved by the Partners HealthCare Institutional Review Board. A prospective randomized crossover trial was conducted for 12 weeks on two clinical units at MGH. Consenting registered nurses employed 16 hours per week or more were randomized to use either a device (n=40) or paper (n=39) for the first six weeks. Nurses assigned to a device were randomized to use either a wireless PDA (n=20) or TPC (n=20). After six weeks, nurses who were assigned to a device used the paper form and nurses who used the paper form for the first six weeks of the study were randomized to use a PDA (n=19) or TPC (n=20) for the final six weeks.

Ease of Use. To evaluate ease of use, actual use of each device (paper/PDA/TPC) was compared to expected use (based on randomization pattern).

<table>
<thead>
<tr>
<th></th>
<th>Expected</th>
<th>Actual</th>
<th>% of Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper</td>
<td>635</td>
<td>867</td>
<td>136.5%</td>
</tr>
<tr>
<td>PDA</td>
<td>317.5</td>
<td>179</td>
<td>56.4%</td>
</tr>
<tr>
<td>Tablet</td>
<td>317.5</td>
<td>224</td>
<td>70.6%</td>
</tr>
</tbody>
</table>

Table 1: Device Use (*expected use based on randomization pattern).

Documentation Completeness and Quality. A record review was conducted to evaluate the degree to which the standardized patient assessment module was associated with documentation completeness and to assess for differences in completeness across device types with regard to “nursing sensitive” assessment sets (e.g., patient falls, pressure ulcers, pain management) and quality and regulatory assessment sets (e.g., aspiration prevention, malnutrition prevention, DVT/VTE prevention, substance abuse, tobacco prevention, suicide prevention). When problems or risks were documented in the assessment module, the care plan was reviewed to evaluate whether a problem and associated goals and interventions were added. Based on an apriori power analysis, the sample size needed to detect a projected 30% improvement in completeness of documentation using electronic devices with 80% power is 88 records. Chi square analysis (Wilcoxon Signed-Rank test) was employed to evaluate differences in completeness of documentation, problem/risk identification and care planning across device types.

Web Survey. A web-based survey was developed to assess nurse satisfaction with the devices (paper/PDA/TPC) and impact on workflow. The survey included 15 questions (plus demographics) and was based on information collected during acute care documentation focus group discussions at MGH and the work of Davis, (1989) on perceived usefulness and ease of use.[6] Responses were on a seven-point Likert scale with one representing “strongly disagree”, six representing “strongly agree” and seven representing “not applicable”. A link was sent out via email to all nurses during the final week of each study arm (week 6 and week 12). Therefore, nurses responded to the survey twice; once in relation to use of the paper assessment module and once in relation to the assessment module integrated into a wireless device. The Kruskal-Wallis test was employed to evaluate median differences in nurse satisfaction across assessment tools with regard to impact on workflow, ease of use and usefulness.

Results
The study was conducted at MGH from June 1 – August 24, 2006. There were a total of 1270 admissions during study period across both acute care units.

Ease of Use. The wireless devices were used 63.5% of the time expected based on randomization pattern. Actual and expected usage patterns for each device are included in Table1.
PDA (29), and TPC (36). Assessment modules were reviewed to evaluate the completeness of patient assessment documentation across the standard question sets to support tracking of nursing sensitive and quality patient outcomes and follow-through. Results are displayed by device type in Table 2. Differences in completion between electronic and paper tools were very significant for the following measures (p<.001): fall prevention, pressure ulcer prevention, pain management, aspiration prevention, malnutrition prevention, and DVT/VTE prevention. Differences were significant (p<.05) for completion of suicide prevention assessment. No significant differences were found across device types with regard to problem identification, referrals and interventions documented on the plan of care.

Patient Assessment Set % Completion

<table>
<thead>
<tr>
<th>Nursing Sensitive Assessment Set</th>
<th>Paper</th>
<th>PDA</th>
<th>Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fall Prevention</strong></td>
<td>60%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Pressure Ulcer Prevention</strong></td>
<td>51.9%</td>
<td>100%</td>
<td>97.2%</td>
</tr>
<tr>
<td><strong>Pain Management</strong></td>
<td>93.1%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality Assessment Set</th>
<th>Paper</th>
<th>PDA</th>
<th>Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aspiration Prevention</strong></td>
<td>55%</td>
<td>96.6%</td>
<td>91.7%</td>
</tr>
<tr>
<td><strong>Malnutrition Prevention</strong></td>
<td>58.6%</td>
<td>96.6%</td>
<td>91.7%</td>
</tr>
<tr>
<td><strong>DVT/VTE Prevention</strong></td>
<td>76%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><em>Suicide Prevention</em></td>
<td>86.2%</td>
<td>100%</td>
<td>97.2%</td>
</tr>
<tr>
<td>Tobacco Prevention</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Alcohol Abuse</td>
<td>96.6%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Violence Prevention</td>
<td>96.6%</td>
<td>96.6%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 2: Completion of Nursing Sensitive and Quality Assessment Sets by Device Type; **p<.001; *p=<.05.

Web Survey. Seventy-nine (79) respondents answered the web-based survey 57% from the first arm and 33% from the second arm of the study. The majority of nurse respondents were female (98.4%), age 21-30 (58.1%), with a BSN degree (81.3%), employed in their profession for 0-5 years (59.7%). The Kruskal-Wallis test was employed to test for differences in mean rank satisfaction scores across the three devices. Overall satisfaction was significantly greater with the electronic devices (mean rank: PDA-33.19, tablet PC-33.08, paper-32.74; p<.008). The Wilcoxon Signed-Rank test was performed and mean rank scores for perceived usefulness, ease of use and workflow implications were compared for paper and electronic devices. Differences in responses across devices were not significant, indicating that the wireless devices were not perceived to be significantly different than paper with regard to workflow implications of point-of-care assessment data collection, ease of use and usability. There were no significant differences in survey responses by study arm.

Discussion

Research studies on the benefits of point of care nursing information systems are limited in scope and number, and have yielded mixed results. However, studies to date suggest that integrated, point-of-care information systems, are associated with decreased documentation time, increased time with patients, and improved documentation completeness and quality.[8-9] These studies suggest that information systems hold promise for large-scale evaluation of the link between nursing care and patient outcomes. However, automation of data collection alone is not sufficient to support evidence based nursing practice. Standardization of the patient assessment data collection content is needed to compare results across institutions and geographical areas and to facilitate pooling of data collected at disparate sites.

At the time of this report, the authors were unable to locate any published reports of randomized trials conducted to evaluate the effectiveness of handheld devices by nurses for documentation of patient assessment on inpatient units. In a recent systematic review of the evidence assessing the effects of handheld electronic medical records on clinical care, only two randomized trials were identified and both evaluated the use of handheld electronic devices by physicians caring for orthopedic patients [10]. In these studies, while documentation completed with electronic devices was more complete, it was not found to be more accurate when compared to documentation completed on paper. Additional studies are needed to evaluate effectiveness of hand held devices with regard to other outcomes and for use in different clinical settings and specifically for use by nurses performing patient assessment at the point-of-care. [10]

Our findings related to device use suggest that continued work is needed to integrate devices into routine processes of care to support consistent use while nurses are caring for patients at the bedside. Only then will patients potentially benefit from evidence-based assessment content and decision support features. As noted above, the paper module was used about 33% more frequently than expected based on the randomization pattern. While the survey results suggest that the nurses were satisfied with the devices, we believe that the frequency with which the paper modules was used, suggests that further work is needed to integrate the devices into the workflow. In the context of this study, the research team was responsible for “24-7 tech support” and had requested that the nurses revert to the paper assessment module when device issues were impeding good patient care. It is possible that this issue may have resolved if the study was conducted over a longer period of time.

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One important barrier to use of the devices noted in this study was the secure sign-on process. Each time a device was used, the nurses were required to sign on to the device and then login to the Partners network. This process was time consuming and identified in the comments section of the survey as a major dissatisfier. In addition, lack of integration of electronic assessment modules with the paper-based plan of care was also identified as a dissatisfier and may have been a contributing factor to the findings that there were no differences in problems identified on care plan based on electronic versus paper assessment, even when the electronic assessment database was more complete. While more complete assessment data was available in the record, we found that the nurse did not transfer identified problems or risks from the printed assessment module to the paper plan of care document.

Our findings suggest that standardizing the patient assessment content by integrating reliable and valid question sets or modules does facilitate capture of data and information necessary to track nursing sensitive and quality outcomes. While all devices (paper/PDA/TPC) integrated with the standard assessment question set content supported data capture, the electronic devices significantly improved data capture for all of the nursing sensitive patient outcomes assessment sets and for several of the quality assessment sets.

There are several limitations to this study. The study was performed at one academic medical center in the Northeastern United States. However, we believe that the work described and associated processes are generalizable to other health care systems and will become more meaningful as more systems engage in similar work. MGH is currently using a paper-based system for clinical documentation. Therefore, the electronic nursing assessment modules examined in this study existed in silos. While evidence-based content and branching logic assisted nurses with documenting a complete patient assessment and decision support features identified potential problems and areas of risk, the patient assessment module and associated recommendations were printed and required additional paper-based documentation for integration into the plan of care or for initiation of referrals. We also believe that the “siloded” assessment contributed to the lack of perceived differences between the electronic devices and paper with regard to workflow implications of point-of-care assessment data collection, ease of use and usability. Qualitative comments from the survey indicate that providing information and recommendations alone is not sufficient. Information and recommendations must be actionable and integrated into current documentation and patient care workflows.

**Conclusion**

This paper describes one healthcare system’s attempt to integrate standard, reliable and valid patient assessment sets into routine nursing documentation processes to establish the infrastructure for tracking the impact of nursing care on patient outcomes. Access to reliable and valid assessment content in devices that are integrated into busy acute care workflows, will facilitate populating an accurate and complete nursing assessment database and holds potential for supporting evidence-based practice and nursing research.

**Acknowledgments**

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**References**