Clinical Evaluation of the Sorbaview SHIELD Securement Device Used on Peripheral Intravenous Catheters in the Acute Care Setting

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Abstract

Peripheral intravenous therapy (PIV) is probably the most common acute care invasive procedure, estimated at 90 percent for all inpatients. Current standards of practice recommend the use of a manufactured catheter stabilization device to secure PIVs. At FirstHealth Moore Regional Hospital (MRH), the PIV policy requires the use of a stabilization device to achieve a 96 hour dwell time for the PIV. The hospital does not utilize an intravenous therapy team; all nurses can insert PIVs and apply the dressing. In 2009, as a cost reduction measure, MRH changed securement devices from a two piece dressing and securement device to the Sorbaview SHIELD (SHIELD). A clinical evaluation of the SHIELD was conducted in January 2010, with 109 medical-surgical patients with PIVs, to demonstrate the expected cost savings associated with the SHIELD by maintaining the PIV for 96 hours and meeting patient and staff expectations. In 91.5% of the patients, the PIV stayed in for their length of stay (if less than 96 hours) or for 96 hours, only eight patients had unscheduled restarts. Eighty-six percent of nurses surveyed rated the device as excellent to good. Ninety-one percent of patients reported no discomfort of their PIV site. Changing to this device in 2009 has resulted in an average annual cost savings of $120,000 over the two piece device and has improved compliance by nursing.

Background

Major forces affecting health care today include cost containment, patient safety, and customer satisfaction. These forces impact not only major strategic decisions but also those decisions which may appear at first glance less significant, such as product selection for delivering patient care. Evidence based practice (EBP) is an approach that gives clinicians the ability to provide a high quality of care to meet the needs of their patients and often leads to cost savings (Melnyk & Fineout-Overholt, 2005).

Intravenous therapy is probably the most common acute care invasive procedure. It is estimated that at least 90 percent of inpatients have a peripheral intravenous catheter (PIV) at some point in their stay (Hanchett, 2007). The Infusion Nurses Society (INS) Standards of Practice recommend the use of a manufactured catheter stabilization device (INS Standards, 2006). Studies have indicated that the use of a stabilization device increases catheter dwell time, and decreases the incidence of phlebitis, infiltration, and infection which are the most common complications of PIV therapy and are reported by patients to cause significant discomfort and pain. A number of companies including BARD, Baxter, and Centurion all manufacture stabilization devices.

A study of the BARD StatLock (StatLock) stabilizing device on 10,164 patients conducted by Dr. Gregory Shears indicated that in a 300 bed hospital, annual cost savings of $277,000 could be realized by using a stabilizing device on peripheral intravenous catheters (Shears, 2006). Studies conducted using Centurion's SorbaView devices have shown similar results in terms of potential cost savings due to increased dwell time and decreased rates of complications (McNeill et al 2009; Penney-Timmons, 2005). FirstHealth Moore Regional Hospital's (MRH) policy on peripheral PIV therapy states that if a stabilization device is used, the PIV catheter must be changed every 96 hours. If a stabilization device in not used, the PIV catheter must be changed every 72 hours. MRH does not use an intravenous therapy team; all nurses can insert PIVs and apply the dressing. Nurses who work on inpatient units are required to use a securement device when starting PIVs.

In 2009, MRH changed securement devices from the StatLock device and a dressing to the integrated securement device, the Sorbaview SHIELD (SHIELD) as a part of cost reduction measures that were put into place. As with any change, some

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Figure 1. Sorbaview SHIELD SV254

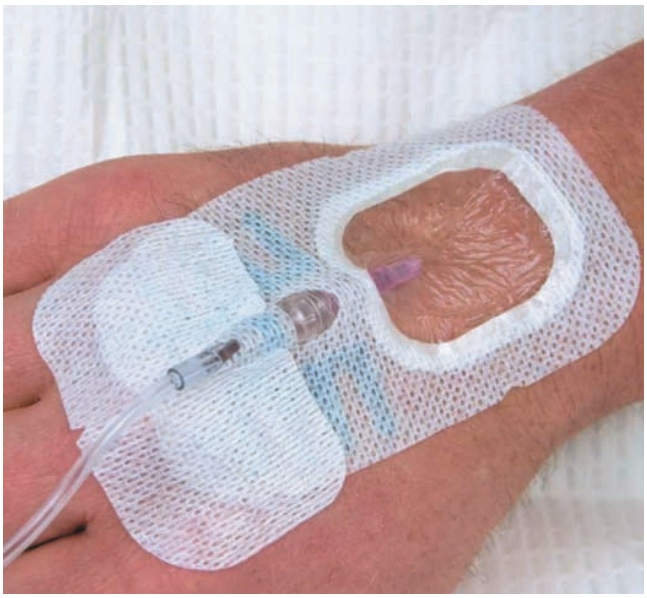
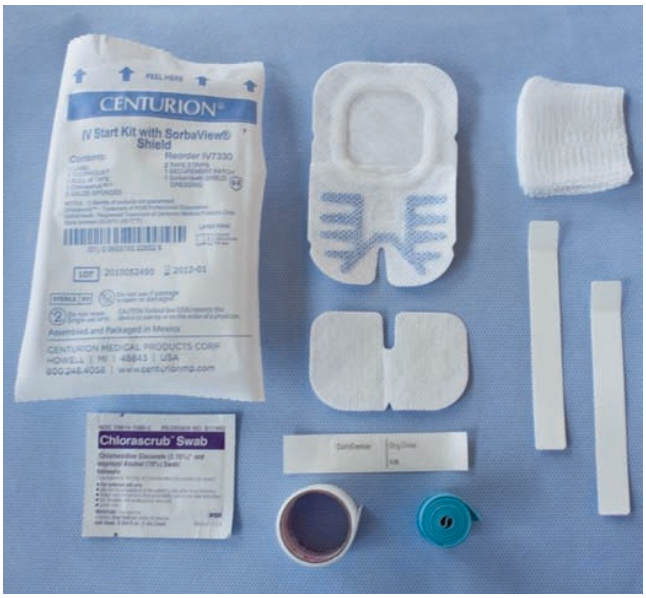


Figure 2. Custom IV Start Kit



nurses liked the "old" StatLock and some preferred the "new" SHIELD devices. Nurses began to ask, is one device better than the other in terms of length of dwell time? If the SHIELD costs less but doesn't result in a dwell time of 96 hours, is it really saving MRH money? To improve compliance with the SHIELD device by all nurses, we decided to evaluate the performance of the SHIELD and observe a minimum of 50 PIV sites to determine if in fact it was securing the PIV for 96 hours.

The purpose of this project was to determine if PIVs secured with the SHIELD stayed in place for 96 hours and to collect information on patients' perception of comfort of the PIV site, and nurses' rating of the SorbaView SHIELD in terms of ease of application, ability to view the PIV site, and reliability. The evaluation was conducted in January 2009 in three phases that included 85 nurses on three medical/neurological acute care units and 109 patients.

Methods

Materials

The securement device we evaluated was the Sorbaview SHIELD SV254 (Centurion Medical Products Corporation), which is shown in Figures 1 and 2. The SHIELD combines the dressing and securement system in one-piece, which provides for a one step application process.

Design and Procedures

This project was designed to be a clinical evaluation of the SHIELD. Data was collected on a convenience sample of inpatients with PIV catheters on three medical/neurological acute care units at MRH, a 385-bed, non-profit acute care hospital in central North Carolina. The units, 2 Neurology, 3 Medical and 4 Medical, were chosen based on their high use of peripheral intravenous catheters and patients' length of stay.

Phase I

This phase consisted of reeducation and training of all nurses who worked on the participating units on the proper application of the SHIELD by Centurion educators prior to the start of data collection to assure all nurses were using the product correctly. The SHIELD had been in use for approximately six months prior to Phase I. During this phase, 85 nurses on the participating units also completed a short anonymous survey rating the SHIELD. The survey was based on a tool used by McNeill et al (2009) on the Sorbaview 2000 dressing and simply asked nurses to rate the SHIELD based on four performance characteristics (Table 1).

Table 1. Nurses Rating of SHIELD

Based on your current experience, please rate the Sorbaview SHIELD based on the following criteria:

	Excellent	Good	Average	Fair	Poor
Easy to apply					
Kept IV sterile and secure					
Ability to visualize IV site					
Reliability					

Comments:

Table 2. **Data Collection Tool**

				Day 1			Day 2			Day 3			Day 4			
Participant ID #	Room # /Last Name	Date/Time IV Started	IV Site Location/Gauge	Day 1: Date & Time of Observation/	Description of Site	Patients rating of discomfort (0-5); 0= no discomfort 5=lots of discomfort	Day 2: Date & Time of Observation/	Description of Site	Patients rating of discomfort (0-5); 0= no discomfort 5=lots of discomfort	Day 3: Date & Time of Observation/	Description of Site	Patients rating of discomfort (0-5); 0= no discomfort 5=lots of discomfort	Day 4: Date & Time of Observation/	Description of Site	Patients rating of discomfort (0-5); 0=no discomfort 5=lots of discomfort	TOTAL DWELL TIME

IV SITE OBSERVATIONS

WNL dry/intact/ no redness/ no pain

D/C'd scheduled D/C

USR _____ unscheduled restart (indicate reason) **

a. Dislodgement b. Catheter leaking c. Infiltration d. Infection

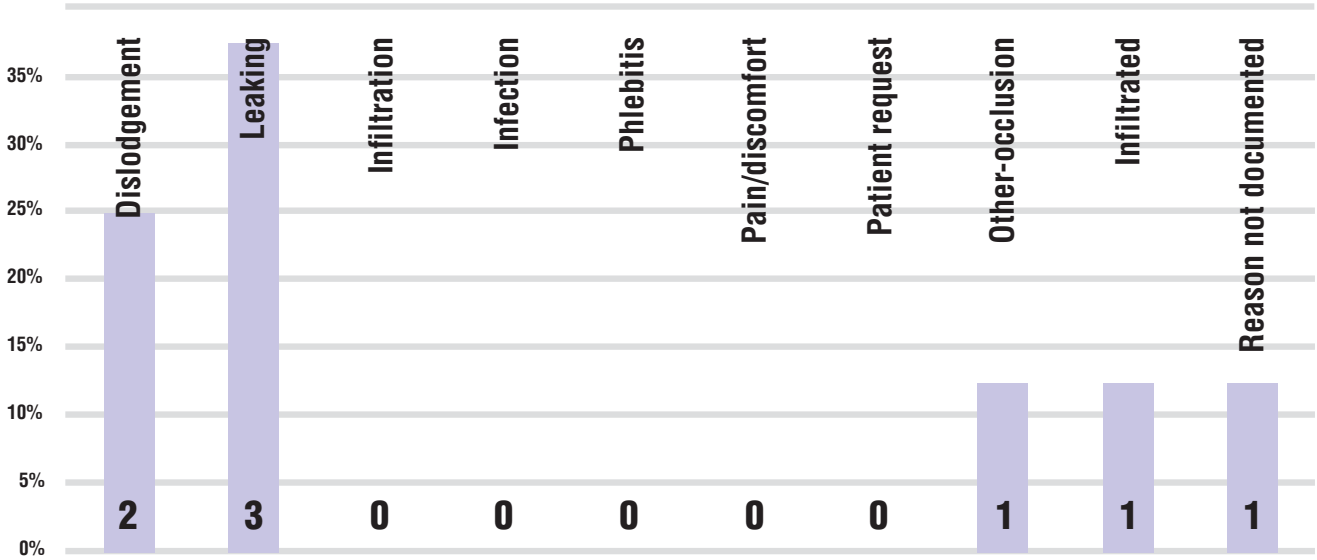
e. Phlebitis f. Pain/discomfort g. Pt request h. Other (list on back of form)

ID#	Reason for USR

** When IV restarted either a scheduled restart or USR, start a new entry for the patient

Abbreviation Key: ID – identification, WNL – within normal limits D/C'd – discontinued, USR – unscheduled restarts

Figure 3. Reasons for Unscheduled Starts



Phase II

At the completion of Phase I, data was collected on the three units using a self developed tool to evaluate dwell time, unscheduled restarts, PIV anatomical site, and patients' rating of comfort of the PIV site (Table 2). Data on the location of the PIV and gauge of needle were collected to determine if location and size made a difference in the dwell time of the PIV. (Tables 5 and 6)

To minimize bias and increase reliability of the data collected, IVECON Training, Inc., a company which provides education and training to nurses on infusion therapy, was contracted by Centurion to provide a registered nurse (RN) to collect data, observe patients' PIV sites and record the information on the data collection tool. (Hereafter known as the project support nurse). The project support nurse was trained by the authors to complete the data collection tool and was vetted and granted appropriate privileges to collect data per current MRH and FirstHealth policies.

Patients were followed for 96 hours or until the end of PIV therapy if less than 96 hours. Patients who were admitted whose PIVs were started in another department had to have the SHIELD applied to their PIV site by their primary nurse on admission to the unit to be included in the evaluation. During the evaluation period, the project support nurse completed the data collection tools, and the primary nurse of the patients documented their assessments of the sites in the patients' medical record per their usual practice. If there were any sites assessed with possible complications by the project support nurse, she verified her assessment of the PIV site with the patient's primary nurse.

Table 3. Dwell Time

Dwell Time	IV Count	%
Total IV's Started on study units	94	100%
Stayed in until IV D/C'd (LOS/TX < 96 hrs)	58	61.7%
Stayed in for 96 hrs.	28	29.8%
Stayed in for LOS/TX or 96 hrs	86	91.5%
Unscheduled restarts	8	8.5%

Abbreviation Key: IV – intravenous sites, D/C'd – discontinued, Hrs – hours, LOS/TX – length of stay or PIV therapy

Phase III

At the conclusion of data collection, a final survey of nurses on the participating units was conducted on their rating of the SHIELD based on the same performance characteristics used in Phase I to determine if their rating of the product would improve with more intense training (Table 1).

Subjects Consent and Protection of Patients' Rights

The project was presented to the Sandhills Multi-Institutional Review Board (SMIRB). Upon review, the SMIRB determined that because the use of the SHIELD was not a new intervention (and therefore classified the clinical evaluation as a quality improvement project of an existing product in use) and because the risk to privacy and confidentiality was considered minimal, the proposal was exempt from full review by the SMIRB.

The following precautions were taken to maintain privacy and confidentiality: as part of the vetting process, the project support nurse was asked to sign a patient confidentiality agreement; patients who participated were de-identified by being assigned a participant number by the authors and no identifying information such as name was kept on file that could link data collected to specific patients; the project support nurse did not have access to patients' medical records; data was reported in aggregate form only and could not be traced back to individual patients. The evaluation took only 5-10 minutes of patients' time and involved a brief visual inspection of the PIV site and required patients to verbally rate the comfort level of their PIV site.

Table 4. Nurses' Rating of the SHIELD Pre- and Post-Evaluation

	Excellent Pre-Eval	Excellent Post-Eval	Good Pre-Eval	Good Post-Eval	Avg Pre-Eval	Avg Post-Eval	Fair Pre-Eval	Fair Post-Eval	Poor Pre-Eval	Poor Post-Eval
Easy to apply	61%	56%	25%	37%	13%	7%	0%	0%	1%	0%
Kept IV sterile	58%	52%	24%	26%	8%	15%	7%	7%	3%	0%
Able to visualize site	71%	59%	20%	37%	6%	4%	3%	0%	0%	0%
Reliable	56%	45%	24%	33%	11%	11%	6%	11%	3%	0%
Overall rating	62%	53%	23%	33%	10%	9%	4%	5%	2%	0%

Abbreviation Key: Eval=Evaluation

Verbal consent was obtained by the project support nurse upon the first contact with the patient. Obtaining written informed consent would have identified the patients who participated in the evaluation of the SHIELD. The project support nurse read a brief script and obtained the verbal consent of patients to observe their PIV site and answer the question about comfort of the PIV site. All patients on the participating units received the same standard PIV care per MRH policy and there was no change in treatment or standard of care as a result of the study.

Data Analysis

Dwell time, restart rate, complication rates, patients' rating of comfort of site, and nurses rating of the SHIELD were tabulated using descriptive statistics.

Results

Dwell Time

A total of 109 patients with PIVs were available for observation on the participating units during Phase II, which exceeded the minimum goal to observe 50 patients with PIVs. Dwell time, unscheduled restarts, patients' rating of comfort of site, and nurses' rating of the SHIELD were evaluated. Of the 109 patients followed, 15 were eliminated from the evaluation because their PIV's were started by nurses on non -participating units and were not changed on arrival to the units participating in the evaluation. Eighty-six of the remaining 94 PIVs (91.5%) stayed in for the patient's length of stay or for 96 hours. There were eight unscheduled restarts. (Table 3)

A breakdown of unscheduled restarts is detailed in Figure 3. The data on this table is notable for what is not included as a reason for an unscheduled restarts, namely phlebitis and infection. No phlebitis was observed in the 94 patients in this study. Phlebitis rates of 3.6% with tape dressings and 0.7% with a stabilization device were previously reported by Shears in his study of 10,164 patients (Shears, 2006).

Patient Rating of Discomfort of PIV Site

During each observation of their PIV site, patients were asked to rate the comfort of their site on a scale of 0 –5 (0= no discomfort; 5= lots of discomfort). The majority of patients (91%) responded that they experience no discomfort (0), only 1% of patients experienced lots of discomfort (5), and 8% of patients were non-verbal and unable to respond (Figure 4).

Nurses' Rating of the SHIELD

Nurses were asked to rate the SHIELD pre- and post-evaluation regarding its ease of application, ability to keep the PIV sterile, reliability, and the ability to visualize the PIV site with the SHIELD in place. Table 4 describes nurses' rating of the SHIELD pre and post evaluation. When rating the overall performance of the Shield, 86% of nurses rated it as good to excellent.

Discussion

Following our clinical evaluation an analysis of data suggests that the SHIELD is a very reliable and effective device in that these results were obtained as nurses used a variety of sites for the location of the PIV, from the most vulnerable securement locations to the typically least troublesome and with both small and large gauge catheters. (Tables 5 & 6) Even though we did not compare the SHIELD to any other securement devices and do not know how patients would have rated those devices, it was an additional positive that the majority of patients rated the discomfort of their PIV site when secured with the SHIELD as "0=no discomfort".

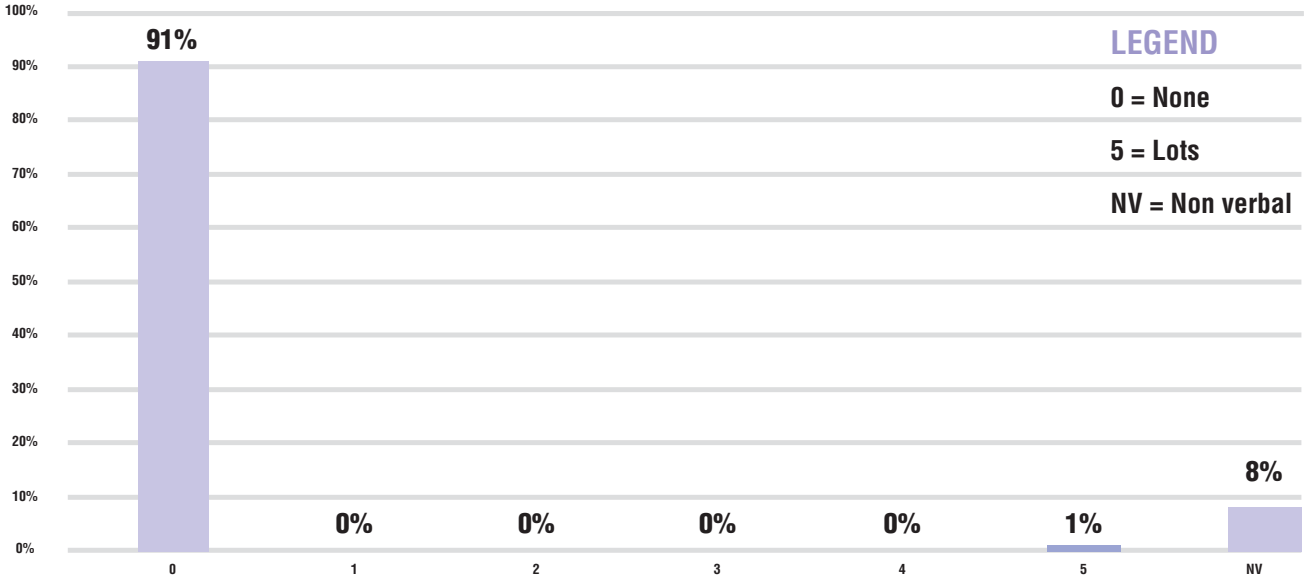
Table 5. Location of IV Sites

Location of IV Sites	
Forearm	31%
Wrist	23%
Antecubital	20%
Hand	19%
Other	4%
Shoulder	2%
Foot	1%

Table 6. Breakdown of Catheter Gauge Used

Catheter Gauge Used	
20	47%
22	33%
18	13%
24	5%
Not Documented	2%

Figure 4. **Patients' Rating of Discomfort of PIV Site**



Although there was not a considerable difference in nurses' rating of the SHIELD pre and post study, the data was still very valuable. First and foremost it illustrated the importance of having nurses perform a return demonstration of correct application of the SHIELD. Prior to changing to the SHIELD, Centurion provided "walking rounds" where sales staff visited each unit and demonstrated how to apply the SHIELD, a return demonstration was not part of the "walking rounds." As the Centurion educator was conducting the pre-evaluation training, it became apparent that not all nurses were applying the SHIELD properly. MRH's clinical educators have collaborated with Centurion and developed a timetable to reeducate nurses who were not on the participating units on the correct application of the Shield, which will include a return demonstration. The survey of nurses also served to validate and quantify their level of satisfaction with the SHIELD rather than relying on anecdotal reports.

This evaluation also identified a need to improve documentation of PIV therapy throughout the hospital. Nurses on units routinely document the PIV site, gauge, and if the PIV is intact, however when a PIV is discontinued or restarted, the reason is seldom documented. In the emergency department (ED), nurses rarely document that a PIV has been started. When reviewing ED documentation, it was not unusual to find a physician's order for a PIV and nursing documentation that the patient had received "X" amount of IV fluid, but there was hardly ever documentation that the PIV was actually started, let alone documentation of the site and gauge.

The use of the Sorbaview SHIELD, can improve patient safety by reducing unscheduled restarts as evidenced by only eight patients requiring unscheduled restarts and the fact that none of the restarts were due to phlebitis or infection. Safety for nurses is likely improved as well by reducing the exposure they have to PIV restart needles. Statistics on needle sticks indicate that on average discontinuing and starting PIVs accounts for 3% -9 % of needle sticks in institutions (NIOSH, 1999).

Initially the change to the SHIELD at MRH was initiated to reduce the cost of the PIV dressings and securement devices. One of our goals was to determine if changing to the Sorbaview SHIELD as a cost savings measure was indeed saving MRH money. If PIVs were lasting for 96 hours with the SHIELD then fewer restarts and materials were needed. According to our Materials Management Department, for fiscal year 2009, the estimated annual materials savings in terms of the direct cost of the SHIELD has been $120,000. A very high percentage (91%) of PIVs secured with the SHIELD had a dwell time of out to 96 hours and the restart rate was only 9%. This is consistent with results of other studies on other securement devices (McMahon, 2002 and Royer, 2003). Not calculated into the estimated costs savings is the money being saved by not having to restart PIVs as frequently which includes those intangible costs such as decreased complication rates for patients and nursing time savings by reducing restarts. Based on average salary and benefits for an RN, the average time of 36 minutes for a nurse to trouble shoot and restart a PIV translates to a labor cost of an estimated $22.79 per incident (Rosenthal, 2005).

This evaluation had several limitations. First, there was no baseline data collected on dwell time and restart rates before use of the SHIELD, therefore it was not possible to quantify the improvement in dwell time and reduction in restart rates with the use of the SHIELD. A second limitation is that data was not collected on whether the PIV catheter was connected to a saline lock or a continuous infusion. Even though the restart rate was only 9%, the type of PIV (saline lock or continuous) may have an effect on dwell time. Finally, a third limitation is the scope of the project. The purpose was to evaluate performance of the SHIELD and staff's satisfaction with it. It was not powered or designed for statistical comparisons which limit the conclusions that can be made.

Conclusion

The purpose of this clinical evaluation was to determine if PIVs secured with the SHIELD stayed in place for 96 hours and to determine patients' perceptions of the comfort of the SHIELD, and nurse satisfaction with the product. The SHIELD product was found in this evaluation to last out to 96 hours or until the PIV was discontinued in 91% of patients followed. There were eight patients that required restarts none of which were related to phlebitis or infection. The SHIELD is less expensive than other securement devices on the market and 86% of nurses are satisfied with its performance. The majority of patients had no discomfort at the PIV site. MRH has determined to continue the use of the SHIELD. Opportunities for reeducation of nurses on the proper application of the SHIELD and evaluation of nurses' documentation of IV therapy were identified.

Acknowledgements

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